



An Roinn Fiontar,  
Turasóireachta agus Fostaíochta  
Department of Enterprise,  
Tourism and Employment

# Submissions to the Public Consultation on the National Life Sciences Strategy

March 2026

The Department of Enterprise, Tourism and Employment invited submissions from the public to inform the development of a National Life Sciences Strategy on 25 October 2025. In total 75 submissions were received.

# Public consultation on National Life Sciences Strategy

24th October 2025 | Closed Consultations

- The Department of Enterprise, Tourism and Employment is seeking the views of interested stakeholders to inform the development of a new National Life Sciences Strategy which is a key commitment in the Programme for Government 2025 – Securing Ireland’s Future.

The aim of the strategy is to ensure that this important sector remains competitive and that government adopts a coherent and ambitious approach to future opportunities. The Minister for Enterprise, Tourism and Employment invites you to take part in this public consultation process.

This is a first step in the public consultation process for the development of the strategy and further consultations may follow.

## Background

Life sciences is the study of living organisms and the processes that sustain life. The life sciences sector - which includes (bio)pharmaceuticals and medical technologies - plays a vital role in modern society. It drives medical innovation, supports disease prevention, and enables the development of new treatments that improve health and quality of life.

The life sciences sector is a substantial contributor to the economy of Ireland. The sector accounts for circa 100,000 jobs and last year accounted for just under €100 billion in exports. It is also a key sector attracting foreign and indigenous investments in research and development, and significant capital expenditure.

Ireland has developed a cohesive and integrated life sciences cluster consisting of highly innovative indigenous companies, large well-established foreign direct investment multinationals, a continually developing world-class research base, and a strong industry-focused clinical community. This vibrant ecosystem positions Ireland as a global leader in life sciences, with significant potential for further growth in the years ahead.

The development of a strategy will provide a clear, coordinated roadmap to strengthen Ireland’s position as a global leader in life sciences, foster innovation and ensure sustainable economic growth. It will also seek to align with emerging EU policies and global trends, ensuring that Ireland remains competitive and agile in an evolving healthcare and technology landscape.

The purpose of this consultation is to engage with stakeholders across the life sciences ecosystem - including industry, academia, healthcare providers, patient groups and the wider public - to shape a strategy that reflects shared priorities and ambitions. Your input will help us identify the key actions

needed to support research and development, enhance skills and talent supporting more high value jobs, identify opportunities to support timely and equitable access to innovative medicines and products for patients, and create an environment that encourages investment and collaboration.

## Key thematic questions

Views are welcome from interested stakeholders across the life sciences ecosystem. Submissions should be structured according to the themes of scope, objectives, opportunities and challenges, and EU context, outlined below.

### Scope

Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.

In your view, how broad should the scope of the strategy be?

### Objectives

What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?

*For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

### Opportunities and challenges

What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?

### EU context

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.

What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

## Consultation responses

Views from stakeholders and interested parties on the public consultation are requested no later than 5pm on Friday, 5 December 2025.

Submissions should be marked 'National Life Sciences Strategy Consultation' and should be emailed to [lifesciences@enterprise.gov.ie](mailto:lifesciences@enterprise.gov.ie).

# Information on consultation process

## Freedom of Information Act 2014 and publication of submissions

The department will make public on its website all submissions received under this consultation. Your attention is also drawn to the fact that information provided to the department may be disclosed in response to a request under the Freedom of Information Act 2014. Therefore, should you consider that any information you provide is commercially sensitive, please identify same, and specify the reason for its sensitivity.

The department will consult with you regarding information identified by you as sensitive before publishing or otherwise disclosing it.

## General Data Protection Regulation

Respondents should note that the General Data Protection Regulation ('GDPR') entered into force in Ireland on 25 May 2018 and it is intended to give individuals more control over their personal data.

The key principles under the regulation are as follows:

- lawfulness, fairness and transparency
- purpose limitation
- data minimisation
- accuracy
- storage limitation
- integrity and confidentiality
- accountability

The Department of Enterprise, Tourism and Employment is subject to the provisions of the regulation in relation to personal data collected by it from 25 May 2018. Any personal information which you volunteer to this department, will be treated with the highest standards of security and confidentiality, strictly in accordance with the Data Protection Acts 1988 to 2018.

The following submissions have been reviewed and personal data redacted including personal email addresses, personal phone numbers and home addresses. Full names have been redacted in the case of individual submissions.

# Table of Contents

| <b>No.</b> | <b>Organisation/individual</b>                 | <b>Page number</b> |
|------------|--|--------------------|
| <b>1</b>   | All-Ireland One Health Collaborative Network   | <b>9-13</b>        |
| <b>2</b>   | Alliance of Rare Disease Companies Ireland     | <b>14-16</b>       |
| <b>3</b>   | American Chamber of Commerce Ireland           | <b>17-26</b>       |
| <b>4</b>   | Aramex   | <b>27-36</b>       |
| <b>5</b>   | ARC Hub  | <b>37-39</b>       |
| <b>6</b>   | AstraZeneca Pharmaceutical Company             | <b>40-44</b>       |
| <b>7</b>   | BIM Public Body                                | <b>45-48</b>       |
| <b>8</b>   | BioPharmaChem Ireland and Irish Medtech IBEC   | <b>49-73</b>       |
| <b>9</b>   | Cancer Trials Ireland                          | <b>74-82</b>       |
| <b>10</b>  | Connected Health & Wellbeing Cluster           | <b>82-88</b>       |
| <b>11</b>  | Cork Chamber                                   | <b>89-95</b>       |
| <b>12</b>  | Department of Agriculture, Food and the Marine | <b>95-102</b>      |
| <b>13</b>  | D. Shanahan (Individual submission)            | <b>103-115</b>     |
| <b>14</b>  | Dexcom   | <b>116-119</b>     |
| <b>15</b>  | D. O'Connor (Individual submission)            | <b>120-125</b>     |
| <b>16</b>  | Dr. Dockerty (Individual submission)           | <b>126-128</b>     |
| <b>17</b>  | Dundalk Institute of Technology                | <b>129-130</b>     |
| <b>18</b>  | Edwards Lifesciences                           | <b>131-132</b>     |
| <b>19</b>  | EIT Health                                     | <b>133-135</b>     |

| <b>No.</b> | <b>Organisation/individual</b>   | <b>Page number</b> |
|------------|--|--------------------|
| <b>20</b>  | Elixir Ireland   | <b>136-140</b>     |
| <b>21</b>  | Galway City Innovation District  | <b>141-144</b>     |
| <b>22</b>  | Health Research Board Ireland  | <b>145-148</b>     |
| <b>23</b>  | HealthTech Ireland   | <b>149-152</b>     |
| <b>24</b>  | Heart Rhythm Ireland   | <b>153-157</b>     |
| <b>25</b>  | Health Innovation Hub Ireland  | <b>158-162</b>     |
| <b>26</b>  | HiTech Health  | <b>163-167</b>     |
| <b>27</b>  | Health Products Regulatory Authority   | <b>168-172</b>     |
| <b>28</b>  | Health Research Charities Ireland  | <b>173-180</b>     |
| <b>29</b>  | HSE, Chief Academic Officer  | <b>181-183</b>     |
| <b>30</b>  | HSE Regional Executive Office South West Region  | <b>184-186</b>     |
| <b>31</b>  | InterTradeIreland  | <b>187-191</b>     |
| <b>32</b>  | Joint Submission from Irish Pharmaceutical Healthcare Association and HealthTech Ireland | <b>192-194</b>     |
| <b>33</b>  | Irish Pharmaceutical Healthcare Association  | <b>195-199</b>     |
| <b>34</b>  | Irish Platform for Patient Organisations, Science and Industry                           | <b>200-213</b>     |
| <b>35</b>  | Irish Venture Capital Association  | <b>214-222</b>     |
| <b>36</b>  | James Geoghegan, TD  | <b>223</b>         |
| <b>37</b>  | Life Science Real Estate   | <b>224-228</b>     |
| <b>38</b>  | Life Sciences Ireland, MedLink Galway, and the Connected Health and Wellbeing Cluster    | <b>229-233</b>     |
| <b>39</b>  | Ocean Knowledge 2030, Marine Institute   | <b>234-238</b>     |

| <b>No.</b> | <b>Organisation/individual</b>   | <b>Page number</b> |
|------------|--|--------------------|
| <b>40</b>  | Marine Institute   | <b>239-243</b>     |
| <b>41</b>  | Medtronic Ireland  | <b>244-248</b>     |
| <b>42</b>  | MSD Ireland  | <b>249-253</b>     |
| <b>43</b>  | NIBRT  | <b>254-267</b>     |
| <b>44</b>  | Novo Nordisk   | <b>268-274</b>     |
| <b>45</b>  | NSAI Biotech Committee   | <b>275-283</b>     |
| <b>46</b>  | NSAI   | <b>284-288</b>     |
| <b>47</b>  | Dr. O'Rourke (Individual submission)   | <b>289-291</b>     |
| <b>48</b>  | Pharmaceutical Research and Manufacturers of America                             | <b>292-295</b>     |
| <b>49</b>  | Rare Disease Clinical Trial Network and Rare Disease Research Catalyst Programme | <b>296-305</b>     |
| <b>50</b>  | Rare Diseases Ireland  | <b>306-311</b>     |
| <b>51</b>  | Royal College of Surgeons of Ireland Future Neuro Centre                         | <b>312-318</b>     |
| <b>52</b>  | Research Ireland Centre for Pharmaceuticals                                      | <b>319-327</b>     |
| <b>53</b>  | Roche  | <b>328-337</b>     |
| <b>54</b>  | Royal Irish Academy  | <b>338-355</b>     |
| <b>55</b>  | Sandoz Ireland   | <b>356-359</b>     |
| <b>56</b>  | SIA  | <b>360-363</b>     |
| <b>57</b>  | Skillnet Ireland   | <b>364-374</b>     |
| <b>58</b>  | Takeda   | <b>375-381</b>     |
| <b>59</b>  | Teagasc  | <b>382-384</b>     |

| <b>No.</b> | <b>Organisation/individual</b>   | <b>Page number</b> |
|------------|--|--------------------|
| <b>60</b>  | University College Cork School of Microbiology                                       | <b>385-388</b>     |
| <b>61</b>  | University College Cork  | <b>389-397</b>     |
| <b>62</b>  | University College Dublin Clinical Research Centre                                   | <b>398-401</b>     |
| <b>63</b>  | University College Dublin, School of Biomolecular and Biomedical Science             | <b>402-404</b>     |
| <b>64</b>  | University College Dublin School of Biology and Environmental Science                | <b>405-406</b>     |
| <b>65</b>  | University College Dublin, William Gallagher   | <b>407-413</b>     |
| <b>66</b>  | University College Dublin School of Public Health, Physiotherapy and Sports Sciences | <b>414-415</b>     |
| <b>67</b>  | University College Dublin Student of Biology and Environmental Science               | <b>416</b>         |
| <b>68</b>  | Uisce Éireann  | <b>417-418</b>     |
| <b>69</b>  | University of Limerick Bernal Institute  | <b>419-422</b>     |
| <b>70</b>  | University of Limerick Bioscience  | <b>423-424</b>     |
| <b>71</b>  | University of Limerick Digital Cancer Research Centre                                | <b>425-429</b>     |
| <b>72</b>  | University of Limerick Food Science  | <b>430-433</b>     |
| <b>73</b>  | University of Limerick Life Sciences   | <b>434-437</b>     |
| <b>74</b>  | University of Galway   | <b>438-445</b>     |
| <b>75</b>  | West Regional Enterprise Plan, Udarás na Gaeltachta, Western Development Commission  | <b>446-448</b>     |

# Submission from the All-Ireland One Health Collaborative Network

## Statement of Strategy consultation

The All Ireland One Health Collaborative Network is a new, emerging all island partnership of academic institutions in Ireland and Northern Ireland that share a commitment to One Health. The Network brings together universities and research centres across disciplines that are usually separate, including human health, animal health, plant and ecosystem health, environmental science and social science. The Network's aim is to accelerate integrated approaches to research, policy and practice that improve health and wellbeing, address inequalities and respond to the climate and biodiversity emergencies.

Membership at this early stage is limited to academic institutions (it includes all such institutions on the Island of Ireland). During 2026 the Network plans to extend participation to public agencies and other actors across the island whose mandates are central to One Health. This submission therefore reflects a collective academic perspective on the draft Department of Enterprise, Tourism and Employment Statement of Strategy, offered with a view to supporting the wider development of One Health research in Ireland and across the island.

We welcome the opportunity to comment on the draft strategy, and we commend the Department of Enterprise, Tourism and Employment for the clarity of its vision and the strength of its values, including its emphasis on equity, sustainability, interdisciplinary and transdisciplinary research, cross sector collaboration, all island working and strong engagement with European and international partners. In our view these are exactly the foundations on which a coherent One Health research agenda can grow.

Our recommendations are set out as a concise set of system level points rather than a detailed goal by goal commentary.

### 1. One Health as a core organising principle

We encourage The Department of Enterprise, Tourism and Employment to present One Health as a core organising principle across the strategy rather than a specific reference within health threats preparedness and response. The draft already points strongly towards prevention, resilience, whole of Government working and cross sector partnership. There is now an opportunity to name One Health explicitly as a way of drawing these strands together.

That would involve recognising One Health in the sense used by the Quadripartite and the European Union, which understands human health as connected with animal health, plant health, ecosystems, food systems and the wider social and economic determinants of health and wellbeing. An explicit statement to that effect near the start of the strategy would signal intent and provide a shared language for later goals, schemes and partnerships.

## **2. One Health as a horizontal integrating mechanism**

We recommend that the strategy describes One Health not only as a topic area but as a horizontal integrating mechanism that helps the system frame complex problems in a way that brings more relevant disciplines and perspectives into play.

Antimicrobial resistance is a clear illustration. A narrow focus on antimicrobial resistance would emphasise microbiology, pharmacology and basic science. A One Health framing adds research on prescribing behaviour in human and veterinary practice, help seeking behaviour by patients and farmers organisational culture and incentives, economic and regulatory conditions for antibiotic development and environmental pathways. That broader framing allows a much wider research community, including social science, psychology, public health, economics, business studies and environmental science, to contribute directly to outcomes that matter for human health. This of course also aligns with the Irish National action plan (iNAP3) which has One Health at its heart.

The same logic applies in many other areas of The Department of Enterprise, Tourism and Employment's work. We suggest that the strategy makes this integrative role of One Health explicit and signals that The Department of Enterprise, Tourism and Employment will encourage applicants and partners to think about where additional perspectives and disciplines could add value.

## **3. Evolving the funding architecture so One Health is structurally possible**

We recommend that The Department of Enterprise, Tourism and Employment indicates in the strategy that it will progressively evolve its funding architecture so that One Health research is structurally possible and rewarded. In practice this would mean:

- Making it routine for disciplines such as veterinary and animal health, environmental and plant sciences, social sciences and data sciences to lead and co lead projects where appropriate, rather than only participating under a clinically led model.
- Reflecting the value of such breadth in scheme guidance and assessment criteria and ensuring that review panels include people with the range of expertise needed to judge One Health proposals fairly.
- Ensuring that early and mid-career researchers in these fields have access to training and career development schemes that are often framed mainly around clinical or biomedical trajectories.

Within that broader direction The Department of Enterprise, Tourism and Employment might wish to consider a time limited One Health initiative early in the strategy period. Such an initiative could support pilot projects, collaborative networks and capacity building across sectors and disciplines, with the explicit aim of learning how best to embed One Health in mainstream schemes over time. Our view is that the long term aim should be integration rather than permanent ring fencing and it would be helpful if the strategy text could reflect that evolution.

#### **4. Encouraging innovation and plurality in study design**

We welcome the emphasis in the draft on high quality clinical trials and regulated clinical research. We suggest that the strategy also gives more explicit encouragement to innovation and plurality in study design, in particular where One Health questions are concerned. Many One Health challenges involve complex systems that span communities, organisations, markets and policies. They often need a mix of experimental, quasi experimental, observational, descriptive, qualitative and implementation research.

It would be valuable if the strategy signalled that The Department of Enterprise, Tourism and Employment will:

- Support innovation in trial and study design for interventions that act at system organisational or community level and may have outcomes across human, animal and environmental dimensions.
- Recognise the importance of observational and other non-trial designs in understanding behaviours organisational culture, incentives and wider determinants that drive health outcomes in One Health problems such as antimicrobial resistance.

We see this as fully consistent with The Department of Enterprise, Tourism and Employment's existing commitment to excellence in methods and with its role in strengthening Ireland's clinical trial ecosystem. It would give an important signal to researchers that methodological diversity is welcome when it is the right choice for the question.

#### **5. Building future ready data and evidence systems that can support One Health**

The draft strategy rightly places strong emphasis on health information systems, the European Health Data Space, data linkage, digital health and an evidence synthesis hub for public health threats. We encourage The Department of Enterprise, Tourism and Employment to state that these systems will be designed with future One Health needs in mind.

That would involve, for example, recognising that health information systems and data infrastructures may, over time and with appropriate safeguards, need to interact with relevant data from other sectors such as animal health, environment, food systems and land use where this delivers clear public value. It would also involve clarifying that the proposed evidence synthesis hub for public health threats will have an explicit One Health remit and will work with partners across sectors and disciplines when shaping its methods and priorities.

The draft already commits The Department of Enterprise, Tourism and Employment to cross sector and whole of Government evidence for policy initiatives. It would help if the text explicitly named the intention to work not only with the Department of Health and health agencies but also with departments and agencies responsible for agriculture, food, environment, education, climate and local government on topics where One Health is relevant.

## **6. Widening the conception of the health research workforce and leadership**

The strategy sets out an ambitious vision for a thriving health research environment and a strong health research workforce. We recommend that The Department of Enterprise, Tourism and Employment's language makes clear that this workforce and its leadership include disciplines and sectors central to One Health.

This point could be addressed through a simple change in wording that recognises that health research leaders in Ireland come from a wide range of fields, including veterinary and animal health, plant and ecosystem health, environmental science, social science, economics, data science and public health as well as clinical and biomedical disciplines.

Training, mentorship and career development opportunities under the strategy could then be described as open to this wider community, including on an all island basis. That would help build the integrated capacity that Ireland and Northern Ireland will need in order to respond to future health and wellbeing challenges with a One Health lens.

## **7. Using all island and international partnerships to anchor One Health**

We welcome the draft strategy's strong focus on all island collaboration, on alignment with national research and innovation policy and on active participation in Horizon Europe, EU4Health and joint European partnerships, including those with a One Health and antimicrobial resistance focus.

We suggest that The Department of Enterprise, Tourism and Employment takes the opportunity to state that One Health topics will be natural priorities within these partnerships. For example, collaboration with funders and partners in Northern Ireland can be directed towards shared One Health challenges and The Department of Enterprise, Tourism and Employment's role in European partnerships can be used to support consortia that bring together human, animal and environmental health expertise from across the island.

It would also be helpful if the strategy noted that The Department of Enterprise, Tourism and Employment intends to align its work with relevant international One Health frameworks, including the Quadripartite One Health Joint Plan of Action and the emerging global arrangements on pandemic prevention, preparedness and response.

## **8. Working with the All-Ireland One Health Collaborative Network**

Finally, we suggest that The Department of Enterprise, Tourism and Employment considers formal engagement with networks that can support delivery of its ambitions in this area. The All Ireland One Health Collaborative Network stands ready to work with The Department of Enterprise, Tourism and Employment as it refines the strategy and as it designs funding schemes, assessment criteria, capacity building programmes and evaluation frameworks that take account of One Health.

The Network expects to widen its membership in 2026 to include public agencies and other actors whose mandates are directly relevant to One Health. That evolution will create a practical forum through which The Department of Enterprise, Tourism and Employment can test ideas, co design initiatives and share learning about the impact of One Health approaches on health and wellbeing outcomes, inequalities and resilience.

We appreciate The Department of Enterprise, Tourism and Employment's leadership in opening this consultation and in placing equity, sustainability and collaboration at the centre of its draft strategy. We would welcome further dialogue on any of the points above and are keen to support The Department of Enterprise, Tourism and Employment in embedding One Health as a natural and integral part of the Irish and all island health research landscape.

Signed on behalf of the All Ireland One Health Collaborative Network

A handwritten signature in cursive script that reads "Gerald Barry".

Gerald Barry

Deputy Director,

UCD One Health Centre

University College Dublin

## Draft: ARDCI Response to Ireland's National Life Sciences Strategy

### (1) Scope

*Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?*

Though life sciences as a discipline spans agri-food, marine and environmental biosciences, the governance and regulation for those sectors are distinct and they would be better addressed through dedicated strategies that are specific to those sectors and connect with the National Life Sciences Strategy where relevant.

In an increasingly competitive international environment, building and maintaining a strong life sciences ecosystem in Ireland to attract future investment and support innovation is critical. Ireland must design and adopt a broad, ambitious, whole-of-government Life Sciences Strategy that spans the full innovation chain – from discovery and clinical research through to manufacturing, regulation, reimbursement, data infrastructure and market access. This requires a cross-governmental approach (and a dedicated government point of contact) that ensures coordinated action across health, enterprise, research, skills, digital policy, taxation and planning.

Rare diseases represent one of the most dynamic, innovative and socially impactful segments of life sciences. These conditions sit at the forefront of scientific and technological advancement, and yet the majority of the 300,000 people in Ireland and 30 million people across Europe living with a rare disease still have no approved treatment. Investment in rare diseases can therefore be a catalyst for wider changes across the entire healthcare landscape. Adapted pathways to reimbursing rare disease therapies is critical for patient access to specific, life-transforming care.

We welcome the Irish government's recent publication of a new National Rare Disease Strategy for Ireland, and hope to see clear alignment between its priorities and deliverables, and the content of the National Life Sciences Strategy.

### (2) Objectives

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability.*

To secure long-term success, Ireland's Life Sciences Strategy must make the modernisation of the State's access, reimbursement, regulatory and clinical trials systems a core national priority as these are now fundamental drivers of research excellence, global competitiveness and long-term system sustainability.

Alliance of Rare Disease Companies Ireland

Members: BioMarin Pharmaceutical; PTC Therapeutics; Orchard Therapeutics; Alexion AstraZeneca Rare Disease  
Secretariat: Vulcan Consulting Ltd Email: [ARDCI@vulcanconsulting.eu](mailto:ARDCI@vulcanconsulting.eu)

population methodologies and ensuring predictable, time-bound decisions are essential to retaining Ireland's competitiveness.

## 2. Clinical Trials Provision

Ireland has a major opportunity to become a competitive location for early-phase and small-population clinical trials, yet current system weaknesses prevent this. Fragmented governance, slow approvals, under-resourced trial units and difficulty recruiting rare disease patients all undermine Ireland's attractiveness to global sponsors.

Strengthening national clinical trial infrastructure, aligning with EU Clinical Trials Regulation, supporting multi-site readiness, and enabling decentralised and adaptive trial models would allow Ireland to capture high-value gene therapy and precision medicine trials.

## 3. Health Data Infrastructure

Rare disease innovation depends on high-quality data: genomics, interoperable registries, real-world evidence, and natural history data. Ireland's fragmented data systems limit its ability to support advanced therapies, evaluate outcomes, or participate in modern trial models.

Developing integrated, interoperable data infrastructure offers a dual advantage: it improves care for rare disease patients and positions Ireland as a credible partner in global research and regulatory science.

## 4. Research & Development Tax Credit

ARDCI companies welcome the increase of Ireland's R&D tax credit to 35%, which strengthens Ireland's position as a global hub for innovation. However, the current structure of the regime still falls short of what is required to grow a competitive life sciences ecosystem. In its present form, the tax credit does not adequately support outsourced or collaborative R&D, which is an essential feature of modern innovation, particularly for companies operating in a small, high-cost market like Ireland. Life sciences firms frequently need to conduct elements of R&D abroad, yet the credit's limitations on outsourced and related-party expenditure significantly reduce its effectiveness.

Ireland should broaden the scope of eligible R&D activity. This includes removing the cap on outsourced R&D spend, allowing claims for both related-party and third-party work, and recognising related-party activities where the Irish entity is the principal IP owner and directs the global R&D programme. Many Irish-based companies manage

Alliance of Rare Disease Companies Ireland

Members: BioMarin Pharmaceutical; PTC Therapeutics; Orchard Therapeutics; Alexion AstraZeneca Rare Disease  
Secretariat: Vulcan Consulting Ltd

Email: [ARDCI@vulcanconsulting.eu](mailto:ARDCI@vulcanconsulting.eu)

substantial international R&D for Irish-owned IP, yet these costs are currently excluded from the credit—placing Ireland at a disadvantage relative to peer jurisdictions.

The Government’s upcoming “R&D Compass” provides a critical opportunity to address these issues. Targeted reforms would help Ireland regain lost ground, support the creation of high-value strategic R&D roles, and stimulate additional subcontracted R&D activity within Irish entities. Such changes would not only strengthen Ireland’s attractiveness for global innovation investment but also deliver long-term, sustainable tax revenues from a more deeply embedded R&D ecosystem.

#### (4) EU context

*The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world’s most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?*

The EU Life Sciences Strategy sets a clear direction that Europe must compete harder for innovation, investment and clinical trials.

#### **1. Lead in clinical trial delivery.**

EU policy is pushing for faster, more integrated, data-enabled trials, especially for small populations. Ireland can position itself as a preferred location by fixing governance bottlenecks, strengthening trial infrastructure and adopting rapid-start, multi-site and genomics-enabled approaches.

#### **2. Modernise HTA and reimbursement in line with EU reform.**

Europe is moving toward HTA methods that accommodate uncertainty, novel trial designs and real-world evidence, particularly for rare and advanced therapies. Ireland should use this momentum to build specialised pathways, update methodologies and create predictable, innovation-ready reimbursement processes.

#### **3. Introduce early access as a competitiveness requirement.**

Most EU countries already provide early or interim access to EMA-authorised medicines. The EU strategy reinforces that timely access is now an economic, not just a clinical, benchmark. Ireland must implement a transparent, time-limited early access scheme to remain aligned with European practice and to strengthen its position in clinical research and launch planning.

Alliance of Rare Disease Companies Ireland

Members: BioMarin Pharmaceutical; PTC Therapeutics; Orchard Therapeutics; Alexion AstraZeneca Rare Disease  
Secretariat: Vulcan Consulting Ltd

Email: [ARDCI@vulcanconsulting.eu](mailto:ARDCI@vulcanconsulting.eu)

[www.amcham.ie](http://www.amcham.ie) @americanchamber



---

# Public consultation on New National Life Sciences Strategy

Response from the American Chamber of Commerce Ireland  
(AmCham) to Department of Enterprise, Tourism and Employment

December 2025

---

## The American Chamber of Commerce Ireland

### The Voice of US-Ireland Business

---

The American Chamber of Commerce Ireland (AmCham) is the collective voice of US companies in Ireland and the leading international business organisation supporting the Transatlantic business relationship. Our members are the Irish operations of all the major US companies in every sector present here, Irish companies with operations in the United States and organisations with close linkages to US-Ireland trade and investment.

---

The American Chamber of Commerce Ireland (AmCham Ireland) welcomes the opportunity to contribute to the Department of Enterprise, Tourism and Employment’s development of a new Life Sciences Strategy. The pharmaceutical and MedTech sectors and the life sciences ecosystem form a core element of Ireland’s economic competitiveness. These sectors are of strategic importance for Ireland’s future, not just in terms of product development, but also in terms of innovation and supporting the two-way, US-Ireland trade and investment relationship.

It is of the utmost importance that any strategy delivers a co-ordinated roadmap to strengthen Ireland’s position as a global leader in pharma, MedTech and life sciences. Crucial to achieving this will be the need for Government and Departmental collaboration on all actions arising from the Strategy, as well as delivery on the much-needed steps to radically improve infrastructure development and address skill gaps. This strategy must be more than a Departmental initiative—it must be a shared national mission.

Success demands coordinated action from health, education, enterprise, finance, and digital agencies working as an agile, aligned team. Further, the Strategy must also align with emerging EU policies and global trends, ensuring that Ireland remains competitive and agile in an evolving healthcare and technology landscape.

A primary objective of the Strategy must be to embed innovation and R&D excellence at the core of Ireland’s life sciences sector. It will be essential that this includes the strengthening of basic and applied research capacity, fostering collaborative R&D partnerships between industry, academia and Government, and ensuring that Ireland is viewed, globally, as a leading location for early-stage research, clinical trials, and regulatory innovation.

In recent years, Ireland has at times taken a more passive stance. Cases in point being during negotiations on the Urban Wastewater Treatment Directive and the revision of the General Pharmaceutical Legislation, despite the significant implications of these policies for the Irish ecosystem.

In addition to ensuring that the Strategy is sufficiently agile to respond to geopolitical shifts and evolving EU policy, it should also be designed to position Ireland as a leader within the EU in shaping global policy developments that affect the pharmaceutical and MedTech sector. Ireland is uniquely placed to do so, given the depth of its transatlantic relationships and the scale of US industry investment here.

A future-focused strategy must ensure that Ireland plays a proactive and influential role in shaping EU and global policies to support a competitive, innovation-driven life sciences sector. Furthermore, the value of innovative medicines, both in Ireland and across the EU, requires explicit and sustained emphasis.

The ongoing global pricing pressures and cost-containment measures being pursued in several EU Member States present a strategic risk to Europe's competitiveness and its attractiveness for future investment. Addressing these issues is a core priority for industry.

Ireland has an important role to play in supporting a European environment that appropriately values innovation, while also reviewing its own national approach to funding and enabling access to new therapies. Doing so will be essential to ensuring long-term patient benefit and maintaining Ireland's status as a destination of choice for life sciences innovation and investment.

#### **How broad should the scope of the strategy be?**

The new national life sciences strategy should adopt a definition of the life sciences sector as concerned with the field of human health, embracing biopharmaceuticals, MedTech, and related digital technologies. Various countries internationally and, closer to home, in the EU generally separate the human health sector from the wider bioeconomy. Ensuring a precise, strategically aligned definition will help Ireland focus its efforts on the areas of greatest national relevance, while remaining consistent with international expectations and investor perspectives.

The new national life sciences strategy must adopt a whole-ecosystem, end-to-end scope, reflecting the full lifecycle of pharmaceutical and MedTech innovation. From early-stage research and clinical trials through to safe introduction into healthcare, sustainable supply, equitable access, and improved long-term health outcomes for patients.

Moving forward, the life sciences sector requires a coherent, cross-governmental approach that effectively integrates health policy, enterprise policy, skills, research, digital infrastructure, taxation, planning, and utilities. In addition, the sector relies on a strong and predictable intellectual property (IP) and incentives system. Europe needs to show it is serious about being a global life sciences powerhouse, attracting investment and sustaining best in class R&D. Any IP system must send the right signal to potential

innovators and investors. All of these elements directly influence and impact Ireland's overall competitiveness.

Ireland's life sciences strategy must match the scale of ambition of the global pharmaceutical and MedTech sector. Ireland cannot afford to continue operating on "auto-drive"; instead, it must take a more proactive, coordinated, and globally aware approach. As such, the strategy must provide clear accountability, ensuring that actions are assigned to specific agencies and officials with transparent timelines for action and delivery.

Finally, the strategy must be resilient to geopolitical flux. With shifting global supply chains, evolving EU legislation, and intensifying competition for investment, Ireland requires a strategy that is ambitious, outward-looking and capable of ensuring long-term competitiveness in life sciences.

### **What should be the key objectives of the National Life Sciences Strategy to ensure long-term success?**

A central objective of Ireland's life sciences strategy must be to support innovation and ensure that Irish patients benefit from timely, equitable access to new medicines and medical technology. Ireland's current market access timelines place patients at a disadvantage compared with other EU states. It is vital that this matter is addressed if Ireland is to be seen internationally as a country that values innovation and patient centric outcomes.

The strategy should aim to strengthen Ireland as a globally attractive commercial environment for the launch of medicines and medical devices, ensuring that innovation is recognised and appropriately valued. This includes improving predictability of pricing and reimbursement processes and supporting the broader life cycle of medicines.

In delivering this, the importance of enhancing talent attraction cannot be understated. Neither can the essential nature of talent retention and skills development, including expertise in AI, bioinformatics, regulatory science, intellectual property, and advanced biomanufacturing. These skills are essential to support new and continued US investment, supporting the creation of high-value jobs.

A life sciences strategy must also focus on expanding and future-proofing Ireland's manufacturing footprint, ensuring that Ireland remains a destination of choice for high-tech biologics, vaccines, cell and gene therapies, and next-generation modalities. In

this context, Ireland must digitise or risk decline. From unlocking the potential of AI in hospital wards to enabling real-time insights across care pathways, the digitisation of our health system is a social and economic imperative. The integration of digital systems will not only improve patient outcomes, but it will also open entirely new frontiers for discovery and development.

Lastly, the strategy should promote greater integration between research, clinical trials, data, and manufacturing, enabling Ireland to ensure it is best positioned for investment in pharmaceuticals and MedTech, having a comprehensive life sciences and innovation ecosystem with a key focus on ongoing collaboration with the Department of Health who will be key to implementing and central to success of the strategy. As such, the pharmaceutical and MedTech industry are interested in the opportunity to engage in further discussions on this topic as part of this or an additional phase of the process.

### **What are the main opportunities and challenges for Ireland’s life sciences sector over the next decade?**

#### ***Competitiveness in clinical trials***

Ireland is currently less attractive for clinical trials than other EU jurisdictions, including Denmark and Spain, due to slow ethics approvals, fragmented infrastructure, and limited integration of research into the health service. Without significant reform, trial activity will continue to bypass Ireland.

#### ***Talent and skills retention***

In the coming five years, the life sciences industry is expected to encounter major difficulties in attracting and securing key technical talent. Among the hardest positions to hire for will be Embedded and software engineers, Electrical engineers, and R&D professionals focused on connected or smart devices.

The pressure on these roles continues to rise as medical technologies increasingly rely on digital integration, connectivity, and intelligent device capabilities. One of the biggest bottlenecks is the lack of true “hybrid” talent. Individuals who pair strong technical skills with expertise in areas such as regulatory affairs, clinical understanding, or cybersecurity. These cross-disciplinary professionals are vital for linking engineering, compliance, and clinical needs, but they remain exceptionally limited in the current workforce.

MedTech and Pharma organisations also find themselves competing for the same small pool of candidates, including embedded engineers, software developers, regulatory and quality specialists, and electrical engineers. This competition is made even more challenging by the fact that these professionals are already in short supply and tend to have low job mobility across the sector.

### ***R&D tax credit reform***

We recognise the work that the Department of Finance has done over the last number of years when it comes to fostering innovation and embracing growth. The recent announcement increasing the R&D tax credit rate to 35% further strengthens Ireland's position as a global hub for innovation by providing support for R&D-intensive multi-national corporations. However, there is a need to go further to enhance policy reforms to drive the growth of the Ireland life sciences ecosystem.

The Government's planned *R&D Compass* will be essential for guiding targeted improvements to the current R&D tax credit system, helping Ireland recover ground lost to countries that offer stronger incentives for R&D activities and IP location. Beyond attracting high-value strategic R&D roles, especially in companies that direct global R&D from Ireland, such a change would also boost opportunities for Irish organisations carrying out subcontracted R&D. Over time, this would support more predictable, long-term tax revenues for the State driven by sustained investment.

### ***Market access delays and uncertainty***

Lengthy Health Technology Assessment (HTA) and reimbursement timelines create uncertainty for global decision-makers while negatively impacting upon Irish patients. Under the current system the State is not adhering to its own statutory obligations on medicines access. An aim of the strategy should be to achieve the 180-day timeline (excluding clock stops) for HSE decisions on medicines reimbursements as required by legislation (the Health Act 2013, transposing the EU Transparency Directive 1989).

There is a need for broader, holistic recognition of the value of innovative therapies within health technology assessment methods. Faster more predictable patient access pathways are required to support Ireland's life sciences sector into the future. Now is the time to ensure that progress toward improving the reimbursement process and patient access timelines reflects the commitment set out in the 2025 Programme for Government.

### ***IP and regulatory uncertainty***

---

Potential changes to EU pharmaceutical legislation and global IP frameworks pose risks to Ireland and to European competitiveness. It is critical that Ireland continues to use its voice at EU level to defend pharmaceutical IP, Regulatory Data Protection, and market exclusivity frameworks from being weakened. This is necessary both to ensure a competitive eco-system in the future and to send a clear and consistent signal to industry that Ireland is a pro-innovation country.

#### ***Digital and data limitations***

Ireland is significantly behind in implementing Electronic Health Records, interoperable datasets, and a national health data space. Each of these are essential to support the delivery of clinical trials, real-world evidence generation, AI-enabled research, and efficient healthcare delivery. Addressing this would support Ireland's attractiveness for related activities.

#### ***Infrastructure constraints***

MNC's face delays and cost challenges due to limited wastewater treatment capacity, limited availability of private wires and secure renewable energy, slow planning processes for biopharma expansions, and constraints on utilities needed for high-tech manufacturing. The Government must prioritise the delivery of critical infrastructure and essential projects to protect and nurture investor confidence.

#### ***Workforce pressures***

Competition for specialised talent, rising housing costs, limited postgraduate pipelines, and skills shortages in regulatory, digital health and advanced manufacturing are all emerging risks. The Government should urgently introduce policies to secure specialised skills, particularly in regulatory, digital health, and advanced manufacturing and address housing and training pipeline constraints.

#### ***Reduced global visibility and under-engagement with EU initiatives.***

Ireland, into the future, must consistently act as an active partner in shaping EU life sciences policy. This will ensure Ireland no longer misses opportunities to influence strategic decisions that affect the country.

#### **Opportunities**

Ireland can build on its world-leading biopharma manufacturing base to become a hub for new modalities, including cell and gene therapies, RNA therapeutics, and

personalised medicines. Modernised data and digital research environment would unlock significant opportunities for real-world evidence, AI-enabled innovation, and integrated clinical research. The implementation of the Medical Device Regulation (MDR) has increased complexity and contributed to delays in bringing new technologies to market, slowing the pace of innovation. A national strategy must recognise these pressures and set out how Ireland will advocate for a regulatory environment that supports competitiveness, fosters innovation, and enables timely patient access to high-value technologies.

Digitalisation and advanced manufacturing capabilities are likewise central to the future of MedTech. While pharma has moved further on digital maturity due to the nature of its processes, MedTech companies are entering a decisive phase of investment in SMART technologies and digitalised production. Ireland must ensure that its research capability, innovation supports, skills pipeline, and incentives are aligned to enable growth in these areas. At present, Ireland risks falling behind in digital research and innovation capacity, an issue also reflected in current IDA priorities and targeted action will be required to secure Ireland's position as a leader in next-generation MedTech manufacturing.

In addition, strengthened collaboration between the health system, industry and academia can position Ireland as a leader in translational research and high-value clinical trials. Investment in infrastructure, renewable energy access and next-generation manufacturing capabilities would secure Ireland's role in global supply chain resilience.

A cross-departmental approach to policymaking will be necessary to make this a reality. Ongoing collaboration with the Department of Health, for example, will be critical given its central role in healthcare policymaking at both Irish and European level.

### **What are your views on the EU Life Sciences Strategy, and how could these be applied in an Irish context?**

AmCham strongly supports the aims of the EU life sciences strategy, including improved regulatory efficiency, strengthened health data spaces, and enhanced competitiveness for manufacturing and R&D. However, Ireland must proactively engage with EU policy development to ensure its interests are reflected in final legislation, and

---

that Ireland can ensure it is best positioned as a destination of choice for investment and growth in life sciences.

The EU Health Data Space, in particular, represents a major opportunity for Ireland. To fully benefit, Ireland must rapidly advance its own electronic health record rollout, develop trusted governance frameworks, and invest in high-quality, interoperable data infrastructure. Ireland should also position itself as a leader within EU clinical trial reform and regulatory innovation projects, contributing actively to EU pilot schemes and ensuring that Ireland is considered a competitive, specialist location for advanced trials and research collaborations.

Applying the EU strategy in Ireland will require a step-change in engagement, coordination and ambition. Ireland needs a clear national framework that aligns with EU priorities while leveraging Ireland's particular strengths — especially US investment, advanced manufacturing, and regulatory compliance expertise. Difficult regulatory systems are the biggest bottleneck to innovation. Ireland must be a vocal leader, at home and in Brussels, for smart, adaptive regulation that enables safe, swift adoption of breakthrough technologies.

Finally, Ireland's EU Presidency in 2026 represents a unique opportunity to champion European competitiveness in life sciences and strengthen Ireland's influence within EU research, industrial and health policy. The Draghi Report has already highlighted the need for a more strategic and innovation-driven Europe. Ireland should be at the centre of shaping what comes next, advocating for competitive state aid reform, strategic investment in future industries, a stronger Horizon successor programme, and a European policy environment that supports innovation, advanced manufacturing, and better health outcomes. Leveraging the 2026 Presidency strategically would reinforce Ireland's leadership role and ensure the country is well positioned within the next generation of EU research and industrial frameworks.



Overview



## aramex Ireland – Brief Overview

### Aramex Ireland



€ 50 M  
Revenue in 2024



\$ 1.55bn  
Global Revenue in 2023



~180  
Colleagues



2006  
Year of establishment



Dublin  
Location near Dublin Airport, incl. 110,000 sq ft warehouse facility



HPRA x 2  
Medicinal Grade Facilities: 30,000 sq. ft.



Shannon  
Location near SNN Airport, incl. 20,000 sq. ft. warehouse facility



Cork  
Location near Cork Port Airport, incl. 70,000 sq. ft. warehouse facility

### About the Company

- Aramex Ireland is a logistics and freight forwarding company located in Ballyboughal (near Dublin Airport) with additional locations in Cork and Shannon.
- Specialised in supply chain management, freight forwarding, warehousing and distribution services for highly sensitive, high-value, pharmaceutical, and food grade goods.
- Main products: Logistics and warehousing, sea freight, air freight, road freight.
- Over 20 years offering Pharma Grade logistics services
- 270,000 sq. ft. of warehousing in Ireland, including HPRA certified facilities in Dublin and Cork, across 12 warehouses throughout Ireland.
- A large customer base consisting of Companies in Food, Pharmaceutical, Aviation Engineering and Automotive sectors
- Membership of WFA, TWIG, ALG, and SCN networks of specialist freight companies.

### Sample life science customers



## Specialist Life Science Logistics



### Life sciences logistics

Offering specialist and bulk solutions for the pharmaceutical, medical, and biotechnology sectors.



### Global network

Ensuring life sciences supply chains are controlled and efficient via a global network of experts.



### Cold chain

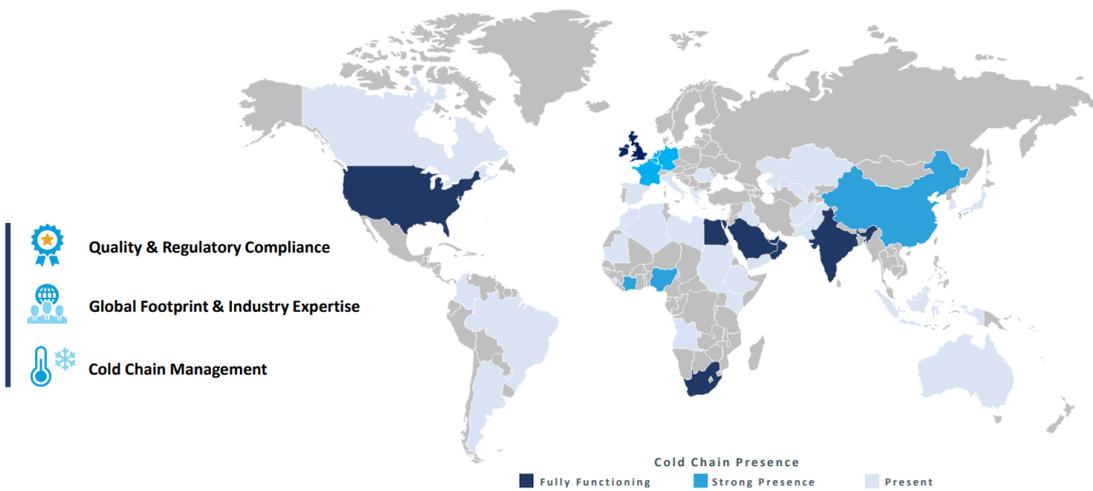
Staying up-to-date with the latest in cold chain, GDP compliant technology so your company doesn't have to.



### Regulatory compliance

Managing every step in a shipments process with care and precision to prevent delays and mistakes.

## Cold Chain Capabilities



## Ireland – UK Road Freight Network

### Ireland - 3 Depots

- Dublin, Cork, Shannon
- ACP bonded areas in each of these depots
- Packaging storage and preconditioning services

### UK - 3 Main Depots

- London, Wednesbury (Midlands), Manchester
- ACP bonded areas in each of these depots
- Packaging storage and preconditioning services
- 3 local partner depots in Bristol, Glasgow and Belfast
- Over **20 LTL** trailers per day from UK to Ireland, and **15 LTL** from Ireland to UK.
- Expert customs knowledge and minimal delays
  - +30 customs clearance staff based in Ireland



pg 7

## Dublin

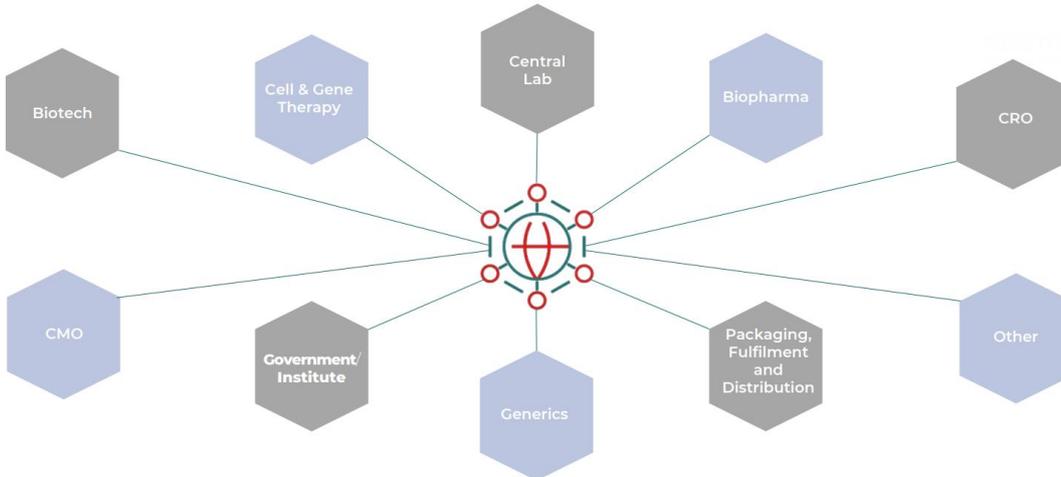
Main Irish hub is located in Ballyboughal in North Dublin.



- 6 warehouses – 110,000 sq ft
- **Dedicated, 20,000 sq. ft., HPR certified WDA, temperature monitored facility**
- In-house GDP certified distribution
- Temperature-controlled storage units
- Specialized packaging capability

pg 8

## Markets Segments Served



pg 5

## Ireland Logistics Services



Life Science Industry Compliant Transportation



Logistics - GDP Certified



Medicinal Grade Warehousing & Fulfilment Services Dublin and Cork



Customs clearance



Control Tower Services

pg 6

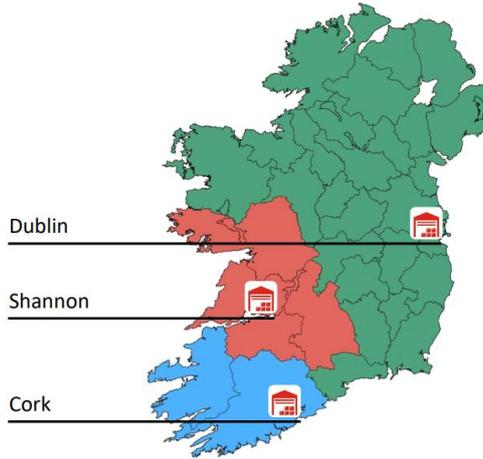
## Ireland Coverage

### Cork

- 50,000 sq. ft. warehouse facility (including 10,000 sq. ft. HPRA certified)
- GDP certified drivers
- Temperature-controlled vehicle network

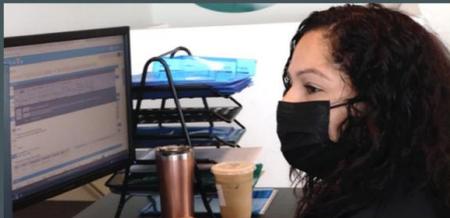
### Shannon

- 40,000 sq. ft. warehouse facility
- GDP certified drivers
- Temperature-controlled vehicle network



## Control Tower

Our dedicated team of Life Science logistics experts manage the entire process and are on hand throughout every step of the journey.



This includes:

- Customs paperwork creation and advice
- Transport booking and airfreight
- Clearance and customs brokerage
- Track and Trace
- Quality and packaging support
- Customs regulatory advice and guidance

Our control towers act as an extension of your business, providing valuable access to a pool of knowledge and talent relating to all operational elements of complex life science logistics solutions.

## Biocair Partnership

Aramex Ireland has partnered with Biocair to provide a fully integrated service offering for the compliant movement of **small volume shipments/parcels**. From pickup through delivery, all movements are managed using our owned network.



MOVING **SCIENCE** FORWARD

Biocair's Quality Control Team has **expert knowledge** of the life science industry, allowing our **in-house** customs team to look after the **HS code classification** of every shipment.



Aramex and Biocair's extensive knowledge of global shipping regulations, coupled with long-standing relationships with regulatory agencies, ensures that our internal QCT are well versed in transporting your materials to their destination on-time and in perfect condition.

pg 11

## Temperature Controlled Abilities

- Aramex Ireland have two dedicated temperature-controlled warehouses
  - Locations:
    - Dublin – Ballyboughal (North Co. Dublin, 10 min from airport)
      - Approx 20k sq ft
    - Cork – Carrigtwohill (~15 km east of Cork city centre)
      - Approx 10k sq ft
  - Temperature: +15 °C /+25 °C
  - HPRA certified
  - Temperature monitored.
- Aramex Ireland is a regulated agent in both Dublin and Cork facilities.
- Our fleet contains TCV vehicles, and our drivers are GDP, ADR and Known Cargo trained.

pg 12

## Packaging and Temperature Ranges

### PELI Packaging

- Sizes available: 4L / 12L / 28L / 56L / 96L
- Temperatures available:
  - (+2°C/+8°C)
  - (+15°C/+25°C)
  - (-20°C)



### Emball'iso Packaging

- Sizes available: 8L / 14L / 30L / 60L
- Temperatures available:
  - (+2°C/+8°C)
  - (+15°C/+25°C)
  - (-20°C)



pg 13

## Packaging Conditioning

### For conditioning the PCM's for the above-mentioned packaging:

- Upright freezer is set at: **-20 °C** for the +2°C /+8°C PCMs
- Deep freezer is set at: **-33 °C** for the -20°C PCMs
- Warm room is set at approx. **+22 °C** for +20°C PCMs

### Dry ice packaging available:

-  **INTELSIUS™** A DSP COMPANY Intelsius 15L / 45L / 80L
-  **BIOCAIR®** Biocair branded BC30D / B2 / B7 / 230L

### Uncontrolled ambient boxes

- Biocair branded – B1



pg 14

## Packaging Solutions



We pack your shipment on-site with industry-leading, temperature-controlled packaging solutions that adhere to ISTA standards. Our fleet of validated packaging covers all cold chain temperature ranges:

- **Controlled ambient:** +15°C to +25°C
- **Refrigerated:** +2°C to +8°C
- **Frozen:** -15°C to -25°C
- **Deep frozen:** -60°C to -80°C
- **Cryofrozen:** -150°C and below (Liquid Nitrogen Dry Vapour dewars)

Our specialists evaluate packaging solutions for each unique consignment, identifying products that offer the best thermal performance depending on shipment method, route, seasonal and cross-hemisphere temperature variations and duration of transit.

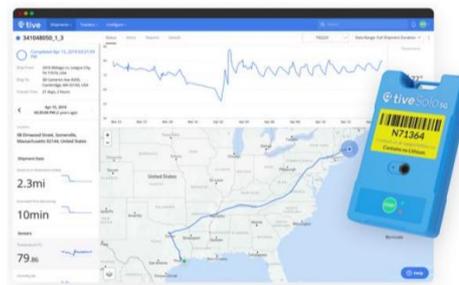
pg 15

## Temperature and GPS monitoring

Aramex and Tive Inc experts have come together over the past 12 months to improve Supply Chain visibility for the Life Sciences community.

The result is more reliable and advanced transport solutions, including the rollout of a fleet of temperature-controlled packaging outfitted with 5G connected Tive Inc devices for any temperature range.

### Tive Tracker Model TT-7100 – Tive Solo 5G



pg 16

## Accreditations



**AEO** – Authorised Economic operator



**HPRA** – Health Products Regulatory Authority (*IE*)



**MHRA** – Health Products Regulatory Authority (*UK*)



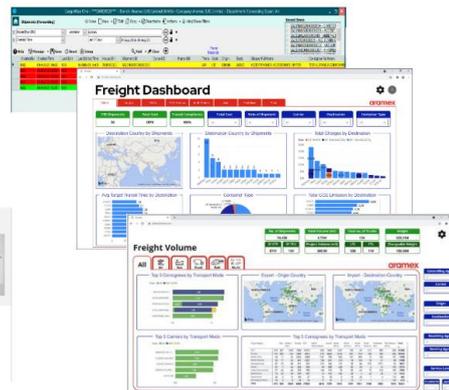
**GDP** – Good Distribution Practice



**ISO 9001: 2015** – Quality Management System  
**ISO 14001: 2015** – Environmental Management System  
**ISO 45001: 2018** – Health & Safety Management System  
**ISO 27001: 2013** – Information Security Management System

pg 17

## Reporting Solutions



pg 18

## Summary



Quality & Regulatory Compliance



Global Footprint & Industry Expertise



Cold Chain Management

### Services and Solutions:



Compliant packaging solutions



GDP and GMP compliant warehousing



Vaccine distribution



Regulatory and customs knowledge



Customs clearance



Clinical trials management



Hospitals supply chain management



Temperature controlled transport



Direct to patients

pg 19



aramex  
delivery unlimited

THANK YOU

MICHAEL O'KANE  
STRATEGIC BUSINESS CONSULTANT

+353 (0)879425000

[MICHAELOK@ARAMEX.COM](mailto:MICHAELOK@ARAMEX.COM)

## **Submission from ARC Hub**

### **Centre for Therapeutic Drug Discovery and Translational Sciences - Converting promising science into the medicines of tomorrow**

The concept for a Centre of Excellence in Ireland: The present proposal details the need and strategy for establishing a Centre for Drug Discovery and Translational Sciences (CDDTS). The centre will integrate the laboratory capabilities and scientific expertise that are currently lacking in Ireland. Such a centre will enable therapeutic discovery ideation and translation to the clinical setting thereby leveraging research outcomes for economic growth.

#### **Introduction & Rationale**

Ireland has established itself as a powerhouse for pharmaceutical exports resulting from decades of strategic investment, a favourable business environment and above all the availability of an educated workforce in advanced manufacturing and supply chain. Recent geopolitical uncertainty and increased competitiveness in the global manufacturing landscape pose a risk to Ireland's economy and to its current over reliance on pharmaceutical manufacturing.

Despite being the third largest global exporter of pharmaceutical products, Ireland has very few indigenous pharma companies of scale. In addition, the major pharmaceutical companies that have a manufacturing footprint in Ireland have little to no therapeutic research or clinical development activities based here. Our indigenous capabilities, knowhow and expertise remain critically underdeveloped. As a result, Ireland doesn't rank competitively relative to some other European countries with similar or even lower GDP per capita (for example Belgium or Denmark).

Building a well-connected ecosystem covering the full life cycle of a product from research to manufacturing will enable Ireland to maintain its position as a major player in the pharma sector, and help create a more resilient economy. Fostering and accelerating scientific advancement from ideation to inflection point remains an absolute prerequisite for future economic growth. The shortage of drug discovery skillsets and expertise is noticeable in Ireland, resulting in a slim pipeline of discovery therapeutics and suboptimal output from the Irish universities, despite their potential. Inadequacy in scientific rigour for testing and validating therapeutic concepts is evidenced also by the limited number of start-ups and indigenous biotech companies emerging in Ireland that succeed in attracting venture investment.

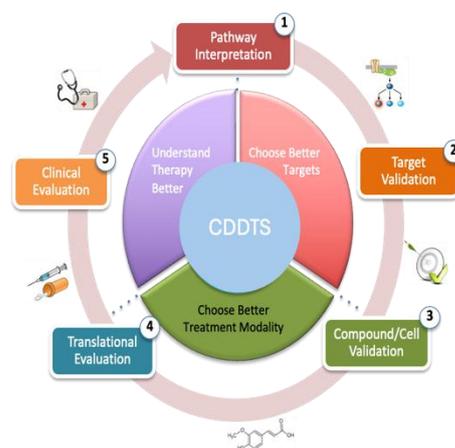
Immediate action is, therefore, essential. The current proposal deals with closing the technical gap we have in Ireland for value creation and acceleration of therapeutic drug discovery and translational research.

#### **Recommendations**

1. Establish a centre of excellence for therapeutic drug discovery and translational sciences, embedding laboratory capabilities and scientific disciplines which are currently lacking. Such a centre will enable stronger therapeutic idea generation, validation and translation to patients'

needs and clinical settings. The requisite scientific disciplines can work across multiple therapeutic areas irrespective of modalities (small molecules, biologics or cell & gene therapy). Many EU countries have already established such centres of excellence to bridge the gap between academia and the pharmaceutical industry and have shown success from this co-creation model.

2. Create a knowledge resource through the Centre that is accessible, at a national level, to all Irish research performing organisations, start-ups and industry partners, Shortage of drug discovery expertise is noticeable in Ireland, and the proposed set up through advancing and derisking own and partners therapeutic concepts will build momentum for a stronger indigenous biotech presence in Ireland.
3. Build a well-connected end to end ecosystem with the Centre acting as a fulcrum. The structure will cover the full life cycle from discovery to clinical proof of concept. It will enable Ireland to maintain its position as a key player in the pharmaceutical sector.



### To establish the Centre the following is requested

- A laboratory facility or dedicated building to house up to 35-40 scientists
- Staff and project work are estimated to require 40 million annually. However, the centre would be cost neutral within 5 years of investment.
- A capital expenditure budget of 20 million over 2 years. Duplication of investment will be minimised by optimizing the equipment budget and utilizing already invested infrastructure in other centres (eg NIBRT, SSPC, etc).

### How the CDDTS fits into the existing Irish ecosystem

CDDTS will provide the fundamental capabilities in drug discovery, as shown in the accompanying figures. It will complement (not duplicate) the existing resources, infrastructure and funding mechanisms. By way of example:

Ireland's third level organisations are currently bereft of the ability to generate the correct chemistry or biologic (as a drug) and they lack the direct practical input into the assays and methods that would allow clinical translation. The CDDTS would be an accessible resource to academics throughout the country, meaning each university will not be required to duplicate the equipment and the capabilities necessary to create an innovation economy. The infrastructure already in place will be utilised by the Centre and the gaps judiciously identified.

SMEs and Start-ups need ongoing access to drug-development capabilities, that may be positioned anywhere along the development process shown in the figure. Funding schemes that support SMEs/Start-ups would benefit in having access to such capabilities including the EI Commercialisation Fund, EI High Potential Start-up (HPSU), and the DETE DTIF scheme etc.

### **Benefits of this Approach**

Elevating the output of academic research to a higher level will deliver to pharma and biotech companies potential drug candidates for further development and licensing. In addition, such a centre will create a critical scientific mass with deep industry insight thereby generating more breakthroughs and differentiating therapeutic ideas which will address unmet medical needs. Such a centre can be synergistic to the ARC Hub for Therapeutics and the Pioneer Incubator and will operate as a catalyst to advance indigenous biotech. The scientific disciplines of the centre will be unique and as such will not duplicate existing capabilities elsewhere (e.g. Irish Universities or NIBRT). To the contrary, it will create a win-win situation covering the full spectrum of product life cycle from ideation to commercialisation. Recently, the EU Commission has consolidated its “Choose Europe for Science” package which includes multiple EU funding and mobility schemes to attract scientists to the EU. Our proposal could avail itself from this scheme and others as regards funding and building a world-leading centre for research and development.

## National Life Sciences Strategy Consultation – AstraZeneca Ireland Submission

By email to: [lifesciences@enterprise.gov.ie](mailto:lifesciences@enterprise.gov.ie).

### Scope

1. Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?
  - In line with how the Minister for Health, BioPharmaChem Ireland and others typically describe the sector, AstraZeneca Ireland believes that 'life sciences' in this context should be understood as biopharmaceuticals, medtech, diagnostics and digital health. Not pushing to formally fold agriculture or fisheries into the same strategy. Industry discourse to date on a National Life Sciences Strategy has been around a joined-up strategy for pharma, biopharma, medtech, and digital health.
  - Though life sciences as a discipline spans agri-food, marine and environmental biosciences, the governance and regulation for those sectors are different and they may be better addressed through complementary strategies that are specific to those sectors and interface with the National Life Sciences Strategy where relevant.
  - A focused, health-oriented National Life Sciences Strategy will allow Ireland to set clear, ambitious objectives for biopharmaceuticals, medtech and digital health, while remaining coherent with broader policy frameworks in related sectors.

### Objectives

2. What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? *For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*
  - AstraZeneca Ireland recommends that the strategy focuses on:
    - Patient outcomes
    - Research and innovation
    - Global competitiveness
    - Talent and skills
    - Digital transformation
    - Sustainability
  - **On patient outcomes**, the strategy should explicitly link Ireland's life sciences ambition to better and more equitable patient outcomes, underpinned by timely access to innovative medicines, including oncology and rare disease treatments. Investing in innovation and more flexible access and reimbursement pathways is vital to enabling timely patient access to innovative medicines in Ireland. Ireland is behind many of its Western European counterparts when it comes to having

funded early access programmes in place<sup>1</sup>. This strategy should prioritise streamlining the existing system to meet its statutory timelines and incorporate a commercially-viable, shared risk policy to facilitate early access to innovative treatments in areas of high unmet need. This approach will support long-term growth in the life sciences industry and better outcomes for patients in Ireland.

- **On research and innovation**, Ireland has the potential to move further up the value chain in global life sciences. To support this, the strategy should encourage early stage R&D activities to occur in Ireland and prioritise creating a unified framework that simplifies the set-up process for clinical trials. It should enable international collaboration with integration of RWE leveraging a fully digitised patient record system to position Ireland as a leading destination for clinical research, in particular Phase I and II studies. The strategy should also enhance R&D incentives to attract high-value activity and roles, particularly within companies that oversee and direct global R&D activities from an Irish base, supported by an internationally competitive tax and innovation policy environment. Currently, the design of the credit significantly limits tax relief on the cost of work outsourced or undertaken in collaboration with others. This is particularly challenging in a small, relatively high-cost country where certain elements or stages of R&D cannot feasibly be completed in-house or in-country and must be outsourced to international affiliates. We recommend that the Government’s forthcoming “R&D Compass” be used to identify and implement targeted changes to the R&D tax credit regime, including remove the cap on outsourced spend and make related party activities eligible where the Irish company is the principal IP owner. Such reforms would help catalyse additional R&D roles in Irish entities engaged to carry on subcontracted R&D work and provide more long-term predictable tax revenues for the state from these long-term investments.
- **On talent and skills**, the strategy should ensure universities and academia are preparing the population for the life sciences jobs of the future. AstraZeneca Ireland recommends that universities and further education institutions continue to expand and update programmes in biopharmaceutical science, data science, AI, digital health, diagnostic science, engineering and regulatory affairs, in line with industry needs. The strategy should actively encourage R&D activity in Ireland to prevent the loss of STEM talent overseas post-graduation. The strategy should also address the shortage of qualified STEM teachers, particularly in chemistry and computer science, by developing specialised training programmes and fostering partnerships between educational institutions and industry. This approach will provide students with real-world exposure and mentorship, enhancing their early interest and engagement in

---

<sup>1</sup> [https://www.ispor.org/docs/default-source/euro2024/isporeurope24prueferthpr204poster146303-pdf.pdf?sfvrsn=53b4bbd3\\_0](https://www.ispor.org/docs/default-source/euro2024/isporeurope24prueferthpr204poster146303-pdf.pdf?sfvrsn=53b4bbd3_0)

STEM careers. This will serve to help maintain Ireland’s strong talent base and support continued investments in the sector.

- **On digital transformation**, the adoption of innovation in the health system should be a central pillar of the forthcoming National Life Sciences Strategy. Ireland should aim to leverage the adoption and application of AI and other digital technologies across the health system, both for patient benefit and research. Priorities should include the implementation of interoperable, secure electronic health records; clear governance and frameworks for ethical use of health data; and, pilot initiatives that demonstrate the value of digital innovation in areas such as early diagnosis, treatment optimisation and patient-reported outcomes.
- **On sustainability**, the strategy should align with Ireland’s climate and environmental commitments while supporting the resilience of the life sciences sector. It should recognise that the future adoption of AI/digital health technologies will drive a significant increase in sustainable energy requirements to support the sector. This could include incentives and supports for decarbonisation of manufacturing facilities and supply chains, and infrastructure that enables sustainable site development and expansion.
- **On global competitiveness**, the strategy should ensure Ireland remains a compelling, long-term location for new and expanded investments. AstraZeneca Ireland recommends the key priority areas of focus to enhance global competitiveness be:
  - Competitive and stable tax policy
  - A reformed R&D tax regime
  - Enhanced innovation funding incentives, to encourage life sciences companies to engage in early-stage R&D research.
  - Ensuring timely access and reimbursement pathways
  - Improving infrastructure and liveability, including energy, transport and housing, which are critical to site selection and talent retention.
  - Establishing clear governance, milestones and accountability for the strategy, including a cross-government coordination function (see Question 4).

### Opportunities and challenges

3. What do you see as the main opportunities and challenges for Ireland’s life sciences sector over the next decade that this strategy should address?
  - In a period of rapid technological advancements and evolving geopolitical landscapes, Ireland has a significant opportunity to consolidate and grow its position as a leading European and global hub for life sciences. The sector is already a cornerstone of the Irish economy and with the right strategy, it can further underpin growth, exports, high-quality employment and improved patient outcomes. To build on past successes and remain at the forefront of

innovation, Ireland must adapt to increasing global competition by developing a long-term strategy that elevates its ambitions for the sector.

- Key opportunities include:
  - Building on Ireland's track record in high-quality manufacturing to attract more strategic R&D which is aligned with Ireland's talent base, such as, clinical development, diagnostic science, translational science, biosciences, data science, digital health and corporate decision-making roles.
  - Positioning Ireland as preferred EU site for clinical trials by capitalising on its strong academic and hospital networks and established multinational presence.
  - Leveraging AI and digital health to improve patient care and support more efficient health system operations.
- However, there are also several challenges that must be addressed if Ireland is to realise these opportunities and remain competitive:
  - Current reimbursement processes contribute to slower and less predictable access to innovative medicines compared to other European countries. This affects patients and also influences decisions on where to launch and invest.
  - Other jurisdictions are offering more favourable and simplified access to R&D and innovation incentives than Ireland.
  - Life sciences policy is currently distributed across multiple departments and agencies, which can lead to fragmentation and slower decision-making.
  - Other regions offer more simplified routes to undertake early-stage clinical research.
  - Persistent gaps in STEM teaching and advanced technical skills.
  - Energy capacity, housing availability and transport infrastructure are already influencing site selection and talent attraction and retention.
- AstraZeneca Ireland recommends that the strategy sets clear milestones and accountability for progress across these areas. We also recommend a cross-government coordination mechanism is established with a clear mandate to drive implementation. We suggest that any future life science strategy working group is supported by an industry advisory group, with representatives from across the life sciences value chain e.g. manufacturing, commercial, R&D etc.

#### EU context

4. The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

- AstraZeneca Ireland supports the ambition to make the EU the world's most attractive location for life sciences by 2030 and aligns with how we see the sector's potential. We particularly support the focus on accelerating clinical research through better implementation of the Clinical Trials Regulation and the ACT-EU work programme.
- In the Irish context, the priority should be not only endorsing the EU strategy, but to position Ireland as a frontrunner in implementing it. A clearly mandated life sciences coordination function within the Department of Enterprise, working closely with health, higher education, finance and other relevant state bodies, such as Research Ireland, would ensure that national policy, funding and regulation are aligned with the opportunities created by the EU Life Sciences Strategy. It would also provide a single point of coordination for industry, academia and patient organisations.
- We also recommend tracking and reporting on Ireland's progress relative to EU objectives and peers.



## **Subject: Submission to the Public Consultation on National Life Sciences Strategy**

Dear Consultation Team,

BIM would like to contribute to the public consultation regarding Ireland's National Life Sciences Strategy. As a stakeholder deeply interested in the advancement of life sciences, particularly in relation to aquaculture and fisheries, we would like to share insights on key areas that are critical to the strategy's success.

### Scope

At BIM, we agree that Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. We strongly believe that Aquaculture and fisheries represent a scientifically intensive, biotechnology-driven subsector of the wider life sciences ecosystem. They involve genomics, breeding science, disease diagnostics, environmental monitoring technologies, and food biotechnology. Including these sectors within the scope of the National Life Sciences Strategy aligns with the consultation's definition of life sciences as potentially encompassing pharmaceuticals, med-tech, agriculture, food production, fisheries, and more. Including aquaculture and fisheries strengthens Ireland's position in emerging blue biotechnology, functional foods, and environmental life sciences—all areas the EU identifies as strategic growth domains.

### Objectives

#### 1. Investment in Research and Development

Investment in R&D is essential for fostering innovation within the life sciences sector, particularly in aquaculture and fisheries. Government incentives for private sector investment, increased funding for applied research in sustainable aquaculture practices, and applied funding streams for capital and infrastructure development for the establishment of innovation hubs focused on marine life sciences would significantly enhance the sector's contribution to health and food security. Collaborations between universities, research institutions, and industry leaders should be prioritized to leverage expertise in developing sustainable practices and technologies.

#### 2. Sustainable Practices and Environmental Consideration

The integration of sustainable practices in aquaculture and fisheries is vital to protect Ireland's marine ecosystems. The strategy must emphasize research in sustainable fish farming techniques, the development of alternative feed sources, and methodologies to reduce the environmental impact of aquaculture. This includes climate-resilient farming systems, low-carbon aquaculture models, and circular bioeconomy approaches to waste utilisation. This will help ensure the long-term viability of these industries while maintaining biodiversity.

### 3. Talent Development and Workforce Diversity

To maintain competitiveness in the global life sciences landscape, including aquaculture and fisheries, it is essential to cultivate a skilled workforce. Strategies should focus on enhancing education related to marine sciences and aquaculture at all levels, creating upskilling initiatives, and offering industry placements for students. Promoting diversity within the workforce will also drive creativity and innovation in developing solutions to the complex challenges faced in these sectors.

### 4. Infrastructure and Regulatory Environment

A robust infrastructure and supportive regulatory framework are foundational for the growth of aquaculture and fisheries alongside other life sciences sectors. Streamlining regulatory processes while ensuring compliance will enable quicker market access for aquaculture products and innovations. Regulatory alignment with upcoming EU biotech and food-innovation frameworks will be essential to ensure Irish marine technologies can scale across the Single Market. Furthermore, investment in facilities for research and development in marine technologies will support the growth of startups and established companies in this area.

### 5. Public Engagement and Awareness

Enhancing public understanding and trust in aquaculture, fisheries, and broader life sciences is crucial. Initiatives that promote awareness of sustainable fishing, aquaculture practices, and their societal benefits can help garner public support. Engaging with community stakeholders and creating educational campaigns can demystify these sectors, highlighting their relevance to food security and environmental stewardship.

### 6. Global Collaboration and Networking

In an increasingly interconnected world, Ireland should strengthen its ties with global partners in the aquaculture and fisheries fields. Active participation in international collaborations, research consortia, and best practice sharing will position Ireland as a leader in sustainable marine practices. This global networking can facilitate knowledge exchange and drive innovation in addressing challenges like climate change and overfishing.

## Opportunities and challenges

Marine resources (Aquaculture and fisheries) hold a wealth of health enhancing compounds, much of which are unrealised.

The main challenge in Ireland is that there is currently no national platform or interface to showcase to established life science businesses the types of bioactive marine compounds available, their applications, or their commercialisation potential. Linkages

within an EU framework to enable uptake of these valuable resources, which are shared across the EU is imperative for Ireland.

In addition to this, we do not have a resource to showcase to established businesses in the life science sector what types of compounds are readily bioavailable from the raw materials and what opportunities exist in the marine resources. There is a significant opportunity to fund programmes linking the raw material sector with research and commercial entities to commercialise these health enhancing properties. We believe the matchmaking interface outlined in the EU Strategy “EUROPE’S LIFE SCIENCES OPPORTUNITY: A STRATEGIC VISION FOR GLOBAL LEADERSHIP” may be the enabler and solution for this challenge.

## EU context

The European Commission recently published an EU Life Sciences Strategy aiming to position the EU as the world’s most attractive location for life sciences by 2030.

Our view is that this strategy is comprehensive and is ambitious. There is a need to realize the vast amount of research conducted within the EU and commercialise these opportunities. Their ambition to enabling rapid market access for life science innovation, by proposing an EU Biotech Act that will create a more innovation-friendly framework across biotech sectors, is of significant importance. We believe the matchmaking interface to connect startups, industry and investors, leveraging the European Innovation Council portfolio, and its Trusted Investors Network is an essential tool to enable commercialisation of research.

We do see the need to enable blue biotechnology across the EU, and believe that BIM has a vital role in the matchmaking interface, as we have fast connections in both research and commercial area. We see BIM taking a pivotal role in linking marine biomass providers to both research and commercial entities, willing to generate transformative change in the life science sector. Ireland should actively position marine biotechnology within the EU’s “strategic autonomy” agenda, ensuring that blue bioresources contribute to European resilience in health, nutrition, and sustainable bioproduction.

## Conclusion

The success of Ireland's National Life Sciences Strategy will depend on a holistic approach that integrates investment, education, sustainable practices, regulatory support, public engagement, and global partnerships, particularly within the aquaculture and fisheries sectors. These recommendations are offered in direct response to the consultation themes of scope, objectives, opportunities and challenges, and EU context.

We urge the relevant authorities to consider these points as they develop their strategy, and look forward to seeing how the national approach evolves.

Thank you for the opportunity to contribute to this important initiative. We appreciate your attention to these matters and am hopeful for a sustainable future for Ireland's aquaculture, fisheries, and broader life sciences sectors.

Sincerely,

Richard Donnelly,  
Interim CEO,  
Bord Iascaigh Mhara.



# National Life Sciences Strategy Submission

December 2025

## Delivering a Competitive and Resilient Future

Ibec's BioPharmaChem Ireland and Irish Medtech submission to the Department of Enterprise, Tourism and Employment's Public Consultation on the National Life Sciences Strategy



## Introduction

BioPharmaChem Ireland (BPCI) and Irish Medtech, the Ibec trade associations that represent over 350 members in the Irish Life Sciences industry, welcome the opportunity to provide feedback on the National Life Sciences Strategy (NLSS). Our sector is a vital pillar of the Irish economy, with more than 700 pharma, medtech and health technology companies operating in Ireland, employing 102,000 people directly and making a global impact with exports in excess of €120 billion. Our sector provides an invaluable impact on society by enabling patients at home and abroad to access lifesaving and life-changing treatments more quickly.

In the face of geopolitical uncertainty and rising challenges for Irish competitiveness, the NLSS must be ambitious and adopt a whole-ecosystem approach to effectively address key barriers to growth and innovation and provide a roadmap for the sustainable future success of the sector. The NLSS must also establish a stable and predictable legislative and regulatory environment to create the conditions necessary for long-term investments in Irish innovation.

Enhancing the competitiveness of the Life Sciences sector will require a strategic focus on enabling Research, Development & Innovation (RD&I), increasing access to innovative therapies and technologies, developing a future-proof talent pipeline and supporting the adoption of digital technologies and advanced manufacturing across the value chain. The evolution of our sector is leading to unprecedented levels of interconnectedness and collaboration. A NLSS should therefore also foster greater interactions and collaboration between the previously discrete sectors within the ecosystem.

Below, we have provided a response to the Department's Key Thematic Questions. Additionally, we have included our Life Sciences and Health Technology Industry White Paper for the Development of Ireland's National Life Sciences Strategy (see Appendix), which was circulated to the Department in October 2025. The White Paper provides a comprehensive industry perspective on key considerations for the NLSS.

## Question 1: Scope

***Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?***

### Human Health Focus

The National Life Sciences Strategy should adopt a focused scope, centred primarily on human health, including the biopharmachem, medical technology and digital health sectors. This focused approach is essential because, despite the sector's immense size and vital contribution to the economy and patient access to treatments, there is a unique lack of strategy. While other key economic areas have clear roadmaps (e.g., in agri-food, digital, and finance), Ireland currently lacks a cohesive, dedicated national strategy to guide the next phase of growth for the human health life sciences sector.

Competitor jurisdiction, such as Denmark and the UK, explicitly anchor their strategies around human health, to maximise both economic and social returns. Adopting this focus is a globally accepted best practice for maintaining leadership in high-value healthcare innovation.

Additionally, this human health focused approach avoids duplicating existing mandates. The Food Vision 2030 Strategy already provides the comprehensive roadmap for the agri-food

sector. Its explicit scope covers primary agriculture, food and drink processing and manufacturing, specialised nutrition, fisheries, aquaculture and fish processing, forestry and forestry processing and the equine sector. The NLSS should therefore be aware of Food Vision 2030 for relevant agri-food policy and strictly consider these elements through the One Health lens. A human health-focused scope is imperative to fill the unique strategy void and ensure an impactful, coordinated use of State resources.

#### Scope of Implementation and Oversight

While NLSS oversight by the Department of Enterprise, Tourism and Employment is a welcome starting point, the scope for strategy development, implementation and oversight must be cross-departmental and cross-agency in design, while also bringing the necessary external stakeholders to the table. The core challenges facing the sector, including innovation, talent development, regulatory compliance and patient access, transcend the remit of any single department. Success requires a sustained, collaborative structure that embeds all necessary partners.

An effective strategy requires direct political and policy alignment, necessitating the involvement of senior officials from:

- Department of the Taoiseach
- Department of Health
- Department of Further and Higher Education, Research, Innovation and Science
- Department of Foreign Affairs
- Department of Climate, Energy and the Environment

The strategy's operational success relies on the active participation of implementing agencies and regulators. Their input ensures policy is grounded in operational reality and facilitates, rather than hinders, innovation:

- IDA Ireland
- Enterprise Ireland
- Research Ireland
- Health Products Regulatory Authority
- Health and Safety Authority
- Environmental Protection Agency
- Health Information Quality Authority

Key ecosystem representatives must also be given a formal seat at the table throughout the NLSS lifecycle to ensure the strategy is practical and representative:

- National Industry Associations will best represent the collective needs and competitiveness concerns of companies.
- National research centres will provide unparalleled insight into future innovation and talent/skills needs.
- Health and patient representatives bring essential perspectives on patient needs and healthcare system priorities, ensuring outcomes are ultimately patient centric.

An NLSS confined to a single department scope risks becoming siloed and ineffective. The establishment of a cross-ecosystem collaborative scope is not a negotiable addition, but a fundamental prerequisite for the strategy's long-term success.

## Question 2: Objectives

**What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability.**

The NLSS must serve as an essential coordinating roadmap for safeguarding and growing future competitiveness of the life sciences sector against intensifying global competition. In order to realise this the ambition, the NLSS must deliver the following outcomes.

- Set a bold, long-term vision
- Define Ireland's value proposition and competitive advantage
- Rapidly address barriers and unlock opportunities
- Establish Ireland as a global RD&I leader
- Futureproof the key national skills base and talent pipeline
- Develop a collaborative approach across government and stakeholders
- Ensure accountability and transparent governance structure
- Enhance the national and global reputation of the Life Sciences and Health Technology ecosystem
- Use proactive, evidence-based strategy development

Further details of these above outcomes can be found in the below White Paper in the Appendix.

## Question 3: Opportunities and Challenges

***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***

BPCI and Irish Medtech developed the below White Paper by leveraging the insights and expertise of our members. We collated industry's core considerations regarding the opportunities and challenges facing the life sciences sector, ultimately determining what the NLSS needs to address for industry. The considerations have been carefully mapped, refined and prioritised to ensure they represent both immediate industry needs and long-term opportunities across three core pillars:

- Pillar 1: Foundations for Competitiveness - The current core enablers that uphold Ireland's life sciences sector across the ecosystem value chain.
- Pillar 2: Expanding and Enriching the Ecosystem – Looks beyond the immediate operational requirements to wider considerations for the sector's long-term growth trajectory.
- Pillar 3: Governance and Implementation - Presents the consideration on how the strategy should be managed and delivered.

For a detailed breakdown of the main opportunities and challenges identified by industry, please see the below White Paper in the Appendix.

## Question 4: EU Context

***EU context: The European Commission recently published an EU Life Sciences Strategy aiming to position the EU as the world's most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?***

### National Priorities

While alignment with the European Union's Life Sciences Strategy is necessary, the NLSS must primarily focus on a prioritised set of actions that strategically leverage Ireland's unique national capabilities. The NLSS must directly address critical, country-specific barriers hindering growth including the persistent national talent shortage, a fragmented landscape of national health data, deficits in critical national operational infrastructure (e.g., energy and housing), and inadequate public expenditure and investment in life sciences RD&I.

Concurrently, the NLSS must capitalise on unique national enablers, such as our established culture of collaboration. This involves actively supporting the convergence of traditional life sciences businesses with technology and data organisations. This convergence is key to unlocking new opportunities, fostering growth, and enabling new entrants to reinvent traditional operating models.

### Coordination Body

While a national competitiveness lens is necessary, the NLSS should remain aligned with the EU efforts by ensuring there is a national coordination body which is seamlessly linked to European structures. We are fully supportive of the EU strategy's commitment to a new Life Science Coordination Group dedicated to reinforcing policy coherence, funding and activities across the EU Commission.

A dedicated and well-resourced national Office of Life Sciences established within the DETE would serve as the crucial national connection to the EU Life strategy, directly mirroring the function of the Life Science Coordination Group. This institutional link is essential for ensuring that Ireland can proactively communicate policy and funding priorities and provide greater alignment with European initiatives.

### Pro-Innovation Policies

The emerging decline in the European Union's innovative sectors, as highlighted in both the EU strategy and the *Draghi Report on European Competitiveness*, necessitates urgent policy intervention. This decline is directly attributable to sustained challenges such as insufficient investment in RD&I and pervasive regulatory fragmentation and complexity across EU. We therefore strongly endorse the EU Life Sciences Strategy initiatives aimed at closing these innovation gaps and championing regulatory simplification. Flagship actions outlined in the EU strategy provide opportunity to realise these ambitions and should be leveraged by national efforts.

The Biotech Act, designed to create a regulatory environment more conducive to innovation, attract RD&I investment and accelerate the pathway for innovative products to market, should be complemented by robust, pro-innovation and pro-competitiveness policy at the state-level. The proposed legislation to reform the Medical Device Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR), is essential in addressing the unintended consequences of current medtech regulation that have resulted in the EU no longer being the location of choice to launch products first and the discontinuation of legacy products.



t +353 1 605 1500  
e info@ibec.ie  
w www.ibec.ie

These pan-European actions must be complemented by consistent and proactive national efforts to realise their full benefits locally.

## In Closing

We are grateful for the opportunity to contribute to the consultation process for the National Life Sciences Strategy. This document presents our key strategic recommendations on the scope, objectives and EU alignment. For a detailed and comprehensive overview of the industry's input on desired objectives, outcomes, opportunities, and challenges across the life sciences industry, please refer to the full White Paper below in the Appendix.

Thank you for your consideration.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Sinéad Keogh".

**Dr. Sinéad Keogh**  
Head of Sectors and Director,  
BioPharmaChem Ireland  
**Ibec**

A handwritten signature in black ink, appearing to read "Eoghan O Faolain".

**Dr. Eoghan O Faolain**  
Director, Irish Medtech  
**Ibec**



## Appendix

# The Life Sciences and Health Technology Industry White Paper for the Development of Ireland's National Life Sciences Strategy

*Ibec's BioPharmaChem Ireland and Irish Medtech's National Life Sciences Strategy  
considerations for the **Minister of Enterprise, Tourism and Employment***

**Jointly prepared by: BioPharmaChem Ireland and Irish Medtech**

**02 October 2025**



t +353 1 605 1500  
e info@ibec.ie  
w www.ibec.ie

## Table of Contents

|  |    |
|--|----|
| Introduction .....   | 3  |
| A Life Sciences Strategy for Ireland.....                    | 3  |
| Process, Outputs and Industry Considerations for a NLSS..... | 5  |
| Pillar 1: Foundations for Competitiveness.....               | 6  |
| Pillar 2: Expanding and Enriching the Ecosystem.....         | 12 |
| Pillar 3: Governance and Implementation.....                 | 15 |
| Summary.....   | 18 |

## Introduction

The Life Sciences sector is comprised of the biopharma, pharma, chemical, medtech, and digital health industries - sectors which are currently facing unprecedented geopolitical turmoil and rising global competition.

After several years of strong advocacy for a national strategy, BioPharmaChem Ireland (BPCI) and Irish Medtech welcome the Minister of Enterprise, Tourism and Employment's commitment to develop a National Life Sciences Strategy (NLSS) and welcome his recognition that developing the NLSS is a strategic priority for Ireland.

This White Paper sets out core considerations that a NLSS needs to address for industry, reflecting a unified industry perspective.

Our industry networks stand ready to offer further collective expertise to help shape a cohesive and ambitious national strategy.

## A Life Sciences Strategy for Ireland

The life sciences and health technology sectors in Ireland are renowned for attracting international investment, alongside a vibrant indigenous community of innovators, with 700+ companies, employing 102,000 people directly with exports in excess of €120 billion. To sustain our hard-won competitive advantage and position ourselves on the world stage as leaders in the rapidly evolving world of health innovation we need the right industrial policies which promote a more coordinated and strategic approach to secure future competitiveness.

Amid ongoing economic uncertainty and intensifying global competition, an effective NLSS is no longer just an opportunity, it is a critical national imperative. The Strategy will be the Government's essential roadmap for safeguarding the future competitiveness of one of the nation's most vital sectors. Action is urgently needed, as multiple competitor jurisdictions have already implemented their own bold life sciences strategies and Ireland cannot afford to fall behind.

At the same time, we have a unique opportunity to leverage existing strengths, emerging health trends and new technologies to build competitive advantages and enhance sector resilience. Rapid advancements from Research, Development & Innovation (RD&I) to business model innovation mean that those best prepared to harness these opportunities will gain a significant edge. The NLSS provides a chance to transform the sector, and ensure Ireland remains a world-class destination for life sciences, while enabling patients at home and abroad to access lifesaving and life-changing treatments more quickly.

BioPharmaChem Ireland and Irish Medtech, Ibec's life sciences and health technology sectors, are uniquely positioned to represent the perspectives of Ireland's life sciences industry. With more than 550 members across the ecosystem, from Foreign Direct Investment firms to our indigenous companies, covering large scale multinationals to SMEs, research centres, academic institutes, lifelong learning organisations, healthcare providers and insurers, we bring unparalleled insight into the strategy development process.

Industry's position is clear. For the NLSS to achieve real impact, it must deliver the key outcomes below:

- **Set a bold, long-term vision:** Define a clear and ambitious direction that ensures Ireland remains a global life sciences leader while positioning the sector to seize emerging opportunities. To ensure this vision is ambitious yet deliverable, goals can be segmented across short, medium and long-term milestones, providing clear checkpoints to measure progress and breaking the strategy into realistically achievable phases.
- **Define Ireland's value proposition and competitive advantage:** Identify current strengths and ecosystem assets, anticipate future trends, and leverage sector convergence to move up the value chain, maximise innovation and growth potential. As part of this, benchmark against and learn from successful international ecosystems to ensure Ireland's remains a competitive location of choice.
- **Rapidly address barriers and unlock opportunities:** Identify and resolve obstacles that hinder competitiveness while creating conditions that enable long-term growth and innovation.
- **Position Ireland as global leader in RD&I:** Drive targeted investment in future focused, high-impact areas biopharma and medtech RD&I, as well as convergent projects that integrate life sciences with technology. These investments will help anchor innovation in Ireland by creating high-value, high tech activity and associated intellectual property.
- **Futureproof the essential national skills base and talent pipeline:** Address persistent skills shortages, as identified by the Expert Group on Future Skills Needs (EGFSN) and other relevant sectoral research, embedding critical skills across the entire education system, combining a strong foundation in core STEMM (Science, Technology, Engineering, Mathematics and Medicine) with data analytics, digital fluency, sustainability, AI literacy and other areas. Additionally, Ireland needs to ensure we have streamlined and efficient immigration pathways to attract and retain top global talent.
- **A collaborative approach across government and stakeholders:** Engage the appropriate life sciences stakeholders and government departments to ensure alignment, shared ownership of an NLSS actions, across industry, academia, the health system and government, anchored by a dedicated central body: an Office of Life Sciences.
- **Ensure accountability and transparent governance structure:** Promote accountability with dedicated bodies responsible for strategy development and oversight, including multi-annual transparent reporting on Key Performance Indicators (KPIs).
- **Enhance and promote the national and global reputation of Ireland's Life Sciences and Health Technology ecosystem:** Pro-actively strengthen global networks and collaborations through strategic alliances and international collaboration to become a trusted global leader in life science innovation.
- **Proactive, evidence-based strategy development:** Use industry-informed insights to anticipate challenges, create unified national positions, and guide policies that strengthen Ireland's life sciences ecosystem.

## Process, Outputs and Industry Considerations for a NLSS

BPCI and Irish Medtech have long been advocates of the NLSS. We began developing an understanding of the necessary scope and deliverables for NLSS in consultation and collaboration with our members since we first identified the need for such a strategy four years ago.

This White Paper has been developed by collating views from our Boards, working groups, committees, and individual company meetings; these engagements enable us to draw on the ecosystem expertise spanning innovation, digitalisation, RD&I, regulatory affairs, sustainability, talent, and manufacturing.

Further to the Programme for Government commitment to establish the strategy, and following and engagement with the Department of Enterprise, Tourism and Employment (DETE), Irish Medtech and BPCI convened a dedicated representative cross section of life science member companies to further crystallise and structure members' views and strategically organise them to develop an industry white paper for presentation to Government. This process brought together several dozen industry representatives and stakeholders from across the medtech, biopharmachem and digital health sectors. Participants included senior leaders from industry, as well as representatives from supporting organisations and research centres.

Our goal through throughout was to collectively identify and prioritise the **key core considerations that should underpin a NLSS, to ultimately understand what the NLSS needs to address for industry**. Using both future-back and present-forward processes, we scrutinised the sector's current blockers and enablers, while also examining critical success factors for the future. Ideas have now been carefully mapped, refined and prioritised through structured dialogue, ensuring that the outcome reflected both immediate industry needs and long-term opportunities.

This rigorous process provides a balanced and thoughtful foundation for understanding what a NLSS must deliver for the Irish life science industry. Considerations have been carefully reviewed by the BPCI and Irish Medtech Boards and circulated for broader member input to ensure **all core industry considerations are effectively captured in this White Paper**.

While the NLSS must address immediate challenges, it is essential that it also maintains a **bold, long-term vision to drive sustainable growth** and ensure Ireland's life sciences sector remains competitive into the future. The following outputs reflect key industry-identified priorities and considerations for implementing the NLSS to build a resilient, future-proof sector, structured under **three core pillars**:

**Pillar 1: Foundations for Competitiveness**

**Pillar 2: Expanding and Enriching the Ecosystem**

**Pillar 3: Governance and Implementation**

## Pillar 1: Foundations for Competitiveness

This section presents considerations for the core enablers that uphold Ireland’s life sciences sector. It covers considerations across the research and innovation ecosystem, manufacturing, operations, and infrastructure, regulatory excellence and sustainability, talent and skills development, and commercialisation and market access. Together, these essential considerations form the foundation of the sector’s global competitiveness and resilience.

| Foundations for Competitiveness Considerations      |  |
|---|--|
| RESEARCH AND INNOVATION ECOSYSTEM                   |  |
| Consideration                                       | Rationale  |
| <b>Clinical Research, Trials and Investigations</b> | <p>Clinical research, clinical trials and clinical investigations are critical to the life sciences value chain, driving innovation, investment and providing patients with access to novel medicines and medical technologies. Yet, Ireland attracts fewer industry-sponsored clinical trials than peer European countries, in part due to fragmented research infrastructure, institutional bottlenecks and limited industry incentives to conduct trials in Ireland.</p> <p><b>A NLSS needs to address this gap by considering how existing initiatives, such as the National Clinical Trials Oversight Group recommendations can be embedded into the Strategy to coordinate efforts, while also considering additional efforts to enhance clinical research across the life sciences spectrum.</b></p>  |
| <b>Funding a World-Class RD&amp;I Ecosystem</b>     | <p>While business investment in research and innovation continues to scale, Ireland falls far behind the OECD and EU averages in terms of public investment in research and innovation, severely limiting our national innovation capacity. This imbalance risks undermining Ireland's competitive advantage, as other countries are significantly increasing their public RD&amp;I budgets.</p> <p>To reverse this trend, the NLSS must drive targeted public investment into future-focused, high-impact RD&amp;I, matching the ambition and needs of this highly valuable pillar of the Irish economy. The strategy should support both core biopharma and medtech research and convergent projects that integrate life sciences with technology. Investment should be directed towards areas of significant potential, including advanced therapeutics, patient-centred medicines, sustainable manufacturing, automation, data analytics, AI-driven systems, and digital health systems, to anchor innovation in Ireland and create high-value intellectual property.</p> <p>Ireland is home to many world-class facilities driving innovation across the Life Sciences sector including Tyndall National Institute, NIBRT, and Research Ireland Centres: Amber, SSPC, CÚRAM, Insight Research Centre. The proposed Research Ireland’s SSPC-led INSPIRE and NIBRT-led IMPACT centres, currently under review, will be central features of the next evolution of the life science research ecosystem. There is also a need to establish and resource additional infrastructure, including a therapeutic drug discovery and translational sciences centre of excellence. Anchoring investment within this proven system will solidify and strengthening our academic</p> |

|                                       |  |
|---------------------------------------|--|
|                                       | <p>expertise while simultaneously tackling industrial challenges at scale. A dynamic and balanced research ecosystem must also be complemented by robust supports for investigator-led research through diverse funding streams.</p> <p>There is also a prime opportunity to secure additional levels of EU research funding by leveraging our national research expertise to shape and secure the next wave of public innovation funding at the EU level through Horizon Europe. Our national centres will be key platforms for leading and participating in these international consortia, maximising the return on Ireland's RD&amp;I investment.</p> <p><b>A NLSS needs to consider how to enhance public expenditure on RD&amp;I and ensure that funding for research in the life sciences sector is proportional to the high economic value of the sector. The strategy also needs to consider how it can shape the next wave of public innovation RD&amp;I funding at the EU level, through Horizon Europe.</b></p>   |
| <p><b>Research Infrastructure</b></p> | <p>Delivering on RD&amp;I ambitions is contingent upon having a world class and future-ready research infrastructure. Ireland's academic institution's vital dual role in this ecosystem. They not only create cutting edge, collaborative RD&amp;I through the national research centres but also leverage their facilities to equip the next generation of learners with the relevant skillsets for a digitally advanced future.</p> <p>To support the sector's ambition and long-term needs, our national research infrastructure must be strategically planned and delivered within academic institutions and readily connected to the national research centres network. This infrastructure must be designed with the flexibility to support emerging technologies within the sector, including advanced therapeutics, patient-centred medicines, sustainable manufacturing, automation, data analytics, AI-driven systems, and digital health systems.</p> <p><b>A NLSS should consider assessing Ireland's current research infrastructure and evaluate the development of a multi-annual capital investment plan to address gaps and ensure our national facilities can power a future-ready, innovative ecosystem.</b></p>   |
| <p><b>Intellectual Property</b></p>   | <p>The ambition to place Ireland and Europe at the cutting edge of emerging life sciences can only be achieved by creating the right conditions for investment and protecting IP. Legislation such as the proposed pharmaceutical legislation revision may result in weaker IP protections which will in turn deter investment in European innovation. Ireland must work to shape developments in IP policy at European and global levels to support economic competitiveness. Nationally, we must continue to make progress in terms of raising IP awareness and building IP capability and resilience at enterprise level. Focus needs to remain on making progress on IP, licensing, and technology transfer through industry-academic collaboration. It also necessitates a stronger focus on enterprise-level IP activities as part of the broader IP framework.</p> <p><b>A NLSS should ensure that corporate IP-related activities must remain a key part of Ireland's inward investment strategy. Enhancing Ireland's position as an IP hub would benefit high-growth start-ups and scale-ups, as well as securing further inward investment. Companies based in Ireland, however, will not be able to fully benefit from the new pan-European unified patent system until Ireland holds a referendum on the matter.</b></p> |

|  |   |
|--|---|
|  |   |
| <p><b>Capital, Financial Incentives and Fiscal Policy</b></p>      | <p>While there are currently several highly beneficial grants, incentives and tax credits available, Ireland has not yet fully leveraged innovative funding mechanisms to the same extent as other jurisdictions.</p> <p>Initiatives to de-risk innovation financing, promoting capital flows for innovation, and encouraging IP development, such as government-backed venture capital co-investment life sciences funds and life sciences patent tax relief should be explored. There is an opportunity to enhance and broaden the RD&amp;I Tax Credit and leverage further European funding options such as Horizon Europe.</p> <p><b>A NLSS should conduct a thorough evaluation of existing financial incentives to identify gaps and areas of improvements and examine mechanisms to increase Ireland’s attractiveness as key destination for both life sciences private and public investment.</b></p>   |
| <p><b>Valuing Innovation</b></p>                                   | <p>Supporting research and development, valuing innovation and ensuring timely access to life sciences breakthroughs and health technology innovations are all key components of a thriving life science ecosystem.</p> <p>Ireland can show leadership in proactively adopting and recognising the value of innovation, to improve patient outcomes by ensuring timely access to medicines and medical technologies. For example, over 70% of medtech companies in Ireland are engaged in research and innovation (R&amp;I) with €39bn invested in R&amp;I globally in 2024, whilst the biopharmaceutical industry invests over \$200bn in R&amp;I globally. Yet on average, Ireland falls below the EU average in the number of medicines available to patients in Europe and is above the EU average for time to access innovative medicines. Ireland must become a global leader and primary user of its own life science industry outputs to leverage better health outcomes and support the next wave of life sciences breakthroughs.</p> <p><b>For Ireland to be a global leader in life sciences, a NLSS must consider how Ireland enables health systems to access innovation and modernise assessment methods to respond effectively to emerging trends and opportunities to identify opportunities for improved adoption.</b></p> |
| <p><b>Leveraging the National Health System for Innovation</b></p> | <p>A highly functioning health system is a key component of a thriving life sciences industrial cluster. Health systems must participate in research, innovation adoption, and ecosystem development benefiting both clinicians and patients.</p> <p>Ireland should show leadership in proactively adopting and utilising innovation from its own life sciences sector, to improve its national health service and ensure timely access to medicines and medical technologies. Ireland must become a primary user of its own outputs to leverage better health outcomes</p> <p>To enable health systems to drive innovation, we must modernise to respond effectively to emerging trends and opportunities. For example, we must ensure Ireland’s Health Technology Assessment reflects current trends in innovation. Digital transformation in the health system is vital both to the future strategic development of</p>  |

|  | <p>both our health system, but also to our life sciences industry sector. Health data infrastructure, including Electronic Health Records (EHRs) must be fully interoperable with European Health Database Space (EHDS) requirements.</p> <p><b>A NLSS should examine the role of the Irish health system as a key enabler of life sciences innovation and explore ways to improve co-ordination and collaboration across the system for the benefit of patients, clinicians and industry.</b></p>  |
|--|---|
| MANUFACTURING, OPERATIONS AND INFRASTRUCTURE |   |
| Consideration                                | Rationale   |
| <b>Energy Availability</b>                   | <p>The life sciences sector faces major challenges around energy infrastructure and access to affordable, renewable power from the grid as highlighted in the BPCI's Sustainability Strategy and Responsible Care Report 2025. The report indicates that nearly 75% of sites are extremely or very concerned about energy capacity. Alarming, 9% of sites are operating above their Maximum Import Capacity (MIC), with a further 12% exceeding 90% MIC, creating operational risks and highlighting the urgent need to expand renewable energy supply. The availability of energy is a major barrier to growth, which may deter future investment in the sector.</p> <p><b>A NLSS needs to recognise energy availability as a major barrier to growth and a critical prerequisite for building a future-proof life sciences sector, while considering how the sector can secure a reliable energy supply.</b></p>  |
| <b>Advanced Manufacturing</b>                | <p>To fully capitalise on our world-class RD&amp;I ecosystem, Ireland must also be a global leader in the application of that innovation through advanced, sustainable, and digitally enabled manufacturing. Maintaining our competitive edge and achieving our national climate targets requires the widespread adoption of cutting-edge technologies like automation, AI, green chemistry, and data analytics throughout our manufacturing processes.</p> <p>Ireland has a strong foundation to build on, with dedicated organisations like Digital Manufacturing Ireland (DMI), Irish Manufacturing Research (IMR), and the National Institute for Bioprocessing Research and Training (NIBRT), supported by the fundamental science from research centres. However, a successful national transition hinges on addressing two critical needs: significant capital investment to upgrade facilities and a deep pipeline of talent with expertise in manufacturing, digital, and sustainability skills.</p> <p><b>Therefore, the NLSS must embed a targeted suite of financial incentives and talent development programmes for Ireland's life sciences sector. This will de-risk industry investment in green technologies and ensure our workforce has the skills required to drive this critical transition towards a more efficient, competitive, and sustainable manufacturing base.</b></p> |
| REGULATORY EXCELLENCE AND SUSTAINABILITY     |   |
| Consideration                                | Rationale   |
|  | <p>Legislation including the Medical Device Regulation (MDR), the General Pharmaceutical Legislation (GPL) In Vitro Diagnostic Regulation (IVDR), and the Product Liability Directive (PLD) present major challenges for industry. Industry is</p>  |

|  |   |
|--|---|
| <p><b>Regulatory Frameworks &amp; Compliance</b></p> | <p>concerned that high compliance costs, regulatory complexity will delay new product launches, discontinue older products, and discourage RD&amp;I investment in Europe. Legislation such as GDPR, the AI Act and ESG measures like the Corporate Sustainability Reporting Directive (CSRD) add further layers of cost, compliance burden, and increased litigation risk.</p> <p>Ireland's life sciences sectors benefit from a reputation of regulatory excellence and supports a fit-for-purpose regulatory system. To maintain this positive global standing, it is important that regulatory frameworks are fit-for-purpose and do not introduce unnecessary inefficiencies, complexities or costs. Effective, best-in-class regulation is essential for industry and builds public trust. For example, If Ireland enacts national legislative and regulatory measures to fully implement the EU AI Act in a way that is well-coordinated, transparent, and balances ethical safeguards with the encouragement of AI innovation, Irish industry can strengthen its reputation as a leading destination for responsible and forward-thinking AI-driven business.</p> <p><b>A NLSS should consider the effectiveness of the regulatory frameworks, the impact of regulatory burden and assess the regulatory environment with a holistic lens to ensure regulations are consistent and avoid duplication and contradictions.</b></p> |
| <p><b>Regulatory Resources</b></p>                   | <p>A potential barrier to Ireland's life sciences competitiveness is capacity constraints within key regulatory agencies. Ireland's life sciences sectors are more tightly regulated compared to many other sectors in the country due to the critical nature of their products and services, which directly impact public health, safety, and well-being. The industry faces stringent regulatory frameworks covering manufacturing, clinical trials, product approval, advertising, and safety standards to ensure high-quality, safe, and effective medicines and medical devices. Due to the high degree of regulation, efficient regulatory processes are of vital importance. Limited resources have led to growing backlogs and delays in decision-making and service delivery. With rising demand and increasingly complex regulations outpacing regulator's capacity, agencies such as the HSA, EPA and HPRA are currently experiencing critical resource constraints.</p> <p><b>A NLSS should consider current regulatory resources to ensure sector growth and investment is not hindered by resource constraints.</b></p>   |
| <p><b>Sustainability</b></p>                         | <p>There is full recognition that the sector must reduce its environmental impact in line with national climate targets and global commitments. Life science organisations in Ireland are already leading this shift, investing in renewable energy, green technologies, and sustainable practices. However, recent and proposed legislation, such as the Urban Wastewater Treatment Directive and the revision of the REACH regulation, which includes the proposed universal PFAS restriction, risks imposing disproportionate constraints that could hinder ongoing operations, new product development and future growth.</p> <p><b>While the sector fully supports Ireland's climate goals, the NLSS must consider how to enable a fair and balanced green transition for the sector by ensuring environmental ambitions are met without undermining the sector's capacity to produce critical life-saving medical products.</b></p>   |

| TALENT AND SKILLS DEVELOPMENT                   |  |
|---|--|
| Consideration                                   | Rationale  |
| <b>Skill Needs Assessment</b>                   | <p>Ireland's life sciences sector faces a critical challenge in meeting its current and future skills needs, particularly as it transitions towards high-value, digitally enabled manufacturing, research and services. The Expert Group on Future Skills Needs (EGFSN) and other relevant sectoral research studies, regularly assesses the skills required across various sectors. Their reports highlight persistent shortages in occupations in science and engineering across the talent spectrum, from secondary school level through to PhD graduates.</p> <p><b>A NLSS should incorporate existing EGFSN recommendations while also conducting other industries (e.g. medtech/digital health) skills needs assessment in order to develop a roadmap to ensure a robust talent pipeline.</b></p>  |
| <b>STEMM Education Pipeline</b>                 | <p>Given the high skills requirement for employment in the life sciences sector (e.g. highest industry employer of PhD level talent), a robust seamless system must be implemented, integrating advanced apprenticeships, modernised university curricula, and industry-aligned PhDs and agile upskilling programme to deliver the require talent pool. Ireland's reputation of a highly skilled STEMM (Science, Technology, Engineering, Mathematics and Medicine) talent pipeline must be maintained by also boosting interest and participation in STEMM subjects in primary and secondary level and ensuring competitive compensation for PhDs and greater connection between academia and industry.</p> <p><b>A NLSS should consider mechanisms to reinforce the STEMM talent pipeline, from early-stage learning to advanced degree attainment, including mechanisms to boost interest and participation in STEMM subjects from primary and secondary level through to advanced degrees and postgraduate qualifications.</b></p> |
| <b>Upskilling &amp; Reskilling</b>              | <p>To meet current and future talent demands, more flexible and responsive education models will be necessary. Current options for upskilling and reskilling offered by Skillnet Business Networks, Springboard+, and Apprenticeships operating in the life sciences sector provide alternative channels to address skills gaps and involve greater industry input and collaboration with academia.</p> <p><b>A NLSS should evaluate current upskilling and reskilling programmes to ensure their effectiveness as additional mechanism of delivering current and future industry-relevant skills.</b></p>   |
| <b>Global Talent Attraction &amp; Retention</b> | <p>Although Ireland benefits from a highly educated workforce, industry demands coupled with a small population size also necessitates global talent to support the life sciences sector. There are already national strategies e.g. "Global Talent Ireland" program, designed to attract world-class researchers and innovators by providing resources to establish or relocate research teams.</p> <p><b>The NLSS must evaluate whether current initiatives meet the sector's global talent needs and ensure immigration pathways effectively attract industry-ready professionals to maintain competitiveness.</b></p>  |

| COMMERCIALISATION AND MARKET ACCESS                  |   |
|--|---|
| Consideration  | Rationale   |
| <b>Export Promotion &amp; Market Diversification</b> | <p>Diversifying markets is a key priority for life sciences sector as it aims to build resilience. Ireland must explore opportunities to further represent the strength of Ireland's Life Sciences on EU and International stages, to activate Ireland's international offices to support more business and research partnership opportunities. Additional government supports and safeguards against disruptions to existing markets need to be explored and supported, one example being, the introduction of an export credit insurance scheme.</p> <p><b>A NLSS must examine mechanisms to support the sector diversify and expanding into new global export markets.</b></p>   |
| <b>Global Supply Chains</b>                          | <p>The COVID-19 pandemic and geopolitical tensions have underscored the vulnerabilities of global supply chains. Companies are actively diversifying their supplier base and investing in onshoring or nearshoring critical manufacturing activities. Strengthening coordination among indigenous sub-suppliers presents a strategic opportunity to expand domestic supply chain capabilities, thereby enhancing the resilience and diversity of Ireland's life sciences ecosystem</p> <p><b>A NLSS should examine global supply chain resilience, identifying opportunities for Ireland to compete for more elements of the supply chain and develop new onshore services.</b></p> |

## Pillar 2: Expanding and Enriching the Ecosystem

This pillar looks beyond the immediate operational requirements to wider considerations for the sector's long-term growth trajectory. These considerations are designed to empower industry to become more agile and create risk mechanisms to build stronger resilience against external pressures. It explores forward-looking initiatives such as a national life sciences campaign, the strengthening of Ireland's indigenous base and positioning the industry to capitalise on emerging global opportunities over the next decade.

| National Life Sciences Strategy Considerations for Industry Development |  |
|---|--|
| SECTOR GROWTH OPPORTUNITIES   |  |
| Consideration   | Rationale  |
| <b>Global Business Services</b>   | <p>To reinforce sector resilience, Ireland should strategically expand its life sciences operations, particularly within the global business services segments. This area currently employs nearly 9,500 professionals, representing about 20% of the total biopharmachem workforce, and are among the fastest-growing segments in the sector. By implementing a comprehensive "control tower" strategy, Ireland could become the global hub for innovation, commercialisation, and operational command across the life sciences value chain. This would optimise Ireland's manufacturing base, regulatory rigor, and talent advantages to establish the</p> |

|  |  |
|--|--|
|  | <p>country as a value-chain orchestrator, offering best-in-class, holistic leadership and driving regional collaboration that supports broader national and sectoral strategies</p> <p><b>In addition to growing strengths in manufacturing excellence, a NLSS should examine opportunities to establish more of the life sciences value chain in Ireland, particularly into services.</b></p>   |
| <b>Indigenous Sector Growth &amp; Research Commercialisation</b> | <p>Ireland must develop a strong indigenous life sciences sector to create a more resilient, innovative, and sustainable economic model. While the medtech sector has a growing start-up ecosystem, the biopharmachem indigenous industry remains underdeveloped is lagging in comparison. Ireland has a strong university research base in life sciences, but compared to peer jurisdictions, faces greater challenges in translating early-stage innovation into scalable commercial success. Dedicated government initiatives and funding programmes help start-ups and spinouts overcome early-stage barriers; while helping established companies expand innovation pipelines build resilience. For example, BioInnovate has helped to create 33 new medtech companies successfully raising over €312 million in funding to date.</p> <p><b>A NLSS should conduct a comprehensive analysis and targeted plan for Ireland's indigenous life sciences ecosystem to address the barriers to research commercialisation and scaling.</b></p>  |
| <b>DIGITAL FUTURE</b>  |  |
| <b>Consideration</b>   | <b>Rationale</b>   |
| <b>Digital and AI Readiness</b>                                  | <p>The forthcoming National Digital and AI Strategy presents an important opportunity to strengthen innovation and competitiveness across sectors by advancing Ireland's AI readiness. For the life sciences ecosystem, readiness will depend on several factors: enhancing regulatory capacity through initiatives such as regulatory sandboxes and the co-development of global regulatory standards; prioritising investment in renewable energy and digital infrastructure; and adopting a whole-ecosystem approach to developing digital skills, fostering research, and broadening access to innovation supports. Pursuing these priorities will ensure that Ireland's life sciences sector remains globally competitive and at the forefront of innovation. Accordingly, the NLSS should align with the National Digital and AI Strategy and other digitalisation efforts, ensuring a coordinated national approach to accelerating AI adoption within the sector.</p> <p><b>AI readiness is not only a whole-of-government challenge but also a whole-of-economy opportunity, and the NLSS must position life sciences as a central contributor to Ireland's broader digital and AI ambitions.</b></p> |
| <b>Digital Health</b>  | <p>Ireland is uniquely placed to become a leader in Digital Health, with 9 of the world's top 10 medtech companies, 10 of the top 10 tech companies and 10 of the top 10 biopharma companies all having a national presence. Ireland has a strong base to build from, with nearly 200 digital health companies having already established operations in the country.</p> <p>Ibec's latest survey report highlights significant gaps, particularly in regulatory capabilities, business strategy, and access to critical skills in AI, data science and compliance.</p>   |

|  |   |
|--|---|
|  | <b>A NLSS should consider how to leverage the opportunity to realise the potential of the digital health ecosystem.</b>   |
| <b>POLICY, INFLUENCE AND PARTNERSHIPS</b>          |   |
| <b>Considerations</b>                              | <b>Rationale</b>  |
| <b>Life Sciences Designated as Critical Entity</b> | <p>Ireland's life sciences sector is essential to national public health and economic stability. The sector underpins the State's ability to respond to health emergencies, including pandemics and emerging diseases. Ireland hosts nearly all major pharmaceutical and medical device firms, contributing significantly to GDP, exports, and high-skilled employment. Disruption to this sector would threaten supply chain continuity, public health outcomes, and the wider economy.</p> <p>Designating life sciences as a critical sector would ensure the sector is protected with targeted resilience measures, risk management, and supply chain security aligned with the EU Critical Entities Resilience Directive.</p> <p><b>A NLSS should empower HPRA, as the competent authority, to formally designate the life sciences sector as a "critical entity" to secure regulatory oversight, resilience planning, and prioritisation under national and EU frameworks.</b></p> |
| <b>Life Sciences Campaign</b>                      | <p>While Ireland is recognised as global life sciences hub, the sector's global reputation must be actively cultivated and continuously promoted. Industry has affirmed the need for a strategic campaign to define and amplify the positive life sciences narrative and showcase the full depth of the ecosystem, from start-ups to multinationals, research excellence to manufacturing scale.</p> <p><b>A NLSS must consider how Government and key stakeholders can show leadership in proactively communicating the life sciences' sector story, highlighting the value, innovation, and impact of Irish life sciences to global and national audiences.</b></p>   |
| <b>EU Policy Influence</b>                         | <p>To ensure EU policies reflect national industry needs, Ireland must proactively engage early on with a unified, industry-informed position on key EU policy developments impacting life sciences ecosystem.</p> <p><b>A NLSS should review Ireland's role in policy formation at EU level exploring if opportunities to build EU-level coalitions and partnerships with like-minded governments could strengthen our influence and collaboration in life sciences policy, regulation, and innovation.</b></p>  |
| <b>Global &amp; EU Partnerships</b>                | <p>The Life sciences Nordic cluster with Medicon Valley is considered one of Europe's strongest life science clusters which works together to share data, attract international investment, and address global health challenges. This collaborative approach, combined with a focus on innovation and sustainability, positions the Nordic region as a leading force in the global life sciences industry.</p> <p><b>A NLSS should explore where there are opportunities for clustering with other nations to derive new benefits for the sector.</b></p>  |

|  |   |
|--|---|
| <p><b>An Interconnected Health Ecosystem</b></p> | <p>The convergence of traditional health business with technology and data organisations has formed a new ecosystem that is able to facilitate growth and create opportunities for new entrants to reinvent traditional operating models. What was once an ecosystem that operated as a collection of arguably siloed industries, these industries now have commonality unlocked by the changing customer and new connected technology.</p> <p><b>A NLSS needs to examine ways to build and grow greater interactions and collaboration between the previously discrete sectors within the ecosystem.</b></p> |
|--|---|

### Pillar 3: Governance and Implementation

This pillar presents the consideration on how the strategy should be managed and delivered. It highlights the need for a leadership body, relevant stakeholders, assessment mechanisms to ensure progress is monitored, accountability is maintained, and the strategy remains responsive to changing needs.

| National Life Sciences Strategy Considerations for Governance and Implementation |   |
|--|---|
| ASSESSMENT   |   |
| Consideration  | Rationale   |
| <p><b>Metrics</b></p>  | <p>Assessment metrics, including Key Performance Indicators (KPIs) and international benchmarking, are essential for effectively measuring the progress and impact of a NLSS. KPIs provide specific, quantifiable targets aligned with strategic goals, enabling ongoing monitoring of activities such as research and development output, innovation adoption, and economic growth contributions. International benchmarking will allow Ireland to compare their life sciences ecosystem performance against global peers, highlighting strengths and identifying areas requiring improvement to remain competitive. Metrics should also be designed to capture future trends and challenges, so the Strategy can proactively adapt to emerging threats and innovation.</p>  |
| <p><b>Milestones</b></p>   | <p>Milestones are essential in an ambitious strategy because they provide clear checkpoints to measure progress, enable timely course corrections, and maintain accountability toward achieving medium, short, and long-term goals. Milestones break down a strategy into achievable steps, making complex goals more manageable and trackable while helping those responsible for its implementation assess whether they are on schedule to meet targets and adjust resources or approaches as needed.</p> <p>Short-term milestones within the first year of an NLSS will enable quick feedback and immediate action that can result in early wins and build momentum for longer term efforts. Medium-term milestones within the first several years of the Strategy will provide structure checkpoints for sustained progress and ensures the NLSS can adapt to emerging challenges. Long-term milestones, ten years into the Strategy, anchor the strategy's bigger objectives, supporting strategic alignment and long-range accountability, and allow for alignment with broader long-term national policy planning.</p> |

|  |  |
|--|--|
| <b>Review Periods &amp; Stakeholder Engagement</b> | <p>Review periods are critical for a NLSS to ensure that the implementation remains aligned with industry needs and is responsive to emerging scientific, technological, and market trends. Scheduled review periods will allow for strategy recommendations and progress on the Strategy to be systematically assessed to identify any gaps, challenges, or new opportunities. This process allows for the recalibration of priorities and adaptation to evolving regulatory and innovation landscapes. These reviews must engage diverse stakeholders including industry, academia, healthcare professionals, patients and regulators ensures that the strategy reflects real-world needs, challenges, and opportunities.</p>  |
| <b>STAKEHOLDERS</b>                                |  |
| <b>Consideration</b>                               | <b>Rationale</b>   |
| <b>Departmental Representation</b>                 | <p>A robust NLSS must incorporate cross-departmental engagement and oversight, as many of the sector's core challenges including innovation, talent development and attraction, and regulatory frameworks transcend the remit of any single government department. Effective collaboration across departments is therefore essential to ensure that policies are coherent, aligned, and capable of addressing complex, system-wide issues that affect the growth and competitiveness of the industry. Relevant departments that should be included in the development and oversight of the Strategy include:</p> <ul style="list-style-type: none"> <li>• Department of Enterprise, Tourism and Employment</li> <li>• Department of the Taoiseach</li> <li>• Department of Health</li> <li>• Department of Climate, Energy and the Environment</li> <li>• Department of Further and Higher Education, Research, Innovation and Science</li> <li>• Department of Foreign Affairs</li> </ul> |
| <b>Industry Development Agencies</b>               | <p>Engagement with Enterprise Ireland, IDA Ireland and Research Ireland is critical for a NLSS, as these agencies play central roles in supporting investment, scaling companies, and attracting foreign direct investment. Their inclusion ensures that policy measures are aligned with market realities, investment incentives, and global competitiveness, allowing the strategy to address sector challenges in a coordinated and practical manner.</p>   |
| <b>Regulators</b>                                  | <p>Including regulators such as the HPRA, HSA, EPA and HIQA in a NLSS development is vital, as many core sector issues lie within their remit and are not always fully raised at the departmental level. Their active engagement allows them to communicate their operational needs and priorities, ensuring that policy and strategic initiatives are realistic and effective. This collaboration is essential not only for addressing regulatory challenges but also for supporting the broader development and competitiveness of the entire life sciences ecosystem.</p>   |
| <b>External Stakeholders</b>                       | <p>National industry associations, research centres and health and patient representatives should be key stakeholders in the NLSS development. National associations represent the collective needs of companies in a streamlined and coherent manner. Industry stakeholders have consistently emphasized that their input must be incorporated throughout the strategy development process, highlighting the importance of having a representative seat at the table. Engaging associations</p>   |

|   |   |
|---|---|
|   | <p>ensures that policy measures are informed by practical industry perspectives, helping to align initiatives with real-world needs and supporting the growth and competitiveness of the sector.</p> <p>National research centres are fundamental to the success of the NLSS. They provide the critical mass of expertise, training, and infrastructure that underpin innovation and drive long term sector growth. These centres are the primary engines for creating home-grown innovation and developing the industry-ready PhD talent that powers our RD&amp;I ambitions. They foster the vital collaboration between academia, industry, and government that is essential for driving competitiveness and long-term sustainability. Their engagement ensures that strategic initiatives are informed by future-focused research and technical capability needs of the sector and fosters collaboration between academia, industry, and government to drive competitiveness and long-term sustainability.</p> <p>Representatives from patient advocacy groups and the health system should be as they bring essential perspectives on patient needs, care pathways, and system priorities. Their involvement helps ensure that policy and strategic initiatives are grounded in real-world healthcare experiences and support outcomes that benefit both patients and the broader health ecosystem.</p> |
| <b>DEVELOPMENT AND IMPLEMENTATION OVERSIGHT</b>             |   |
| <b>Consideration</b>  | <b>Rationale</b>  |
| <p><b>NLSS Development &amp; Implementation Council</b></p> | <p>The development of actions and recommendations in the NLSS must be a collaborative effort between government and industry, working closely together to ensure the Strategy effectively balances government priorities with the practical needs of the industry. Establishing a council - co-chaired with industry leaders - for the Strategy development ensures that unique, real-world industry perspectives are incorporated and that feedback is gathered throughout the continuum of the entire development and implementation process.</p> <p>This collaborative approach is well established and widely regarded as essential for effective life sciences policy development. For example, the UK's Life Sciences Strategy was shaped under the guidance of the Life Sciences Sector Plan Advisory Board, which included both industry representatives and leaders from the health and research sectors. By integrating industry insight from the outset, Ireland will be able to design policies that address regulatory barriers, accelerate clinical trials, and support advanced manufacturing capabilities, fostering a competitive ecosystem that benefits patients and the economy alike.</p>  |
| <p><b>Office of Life Sciences</b></p>                       | <p>To ensure the Strategy's success, a dedicated and well-resourced Office of Life Sciences should be established within the DETE. Working alongside the NLSS Council, the Office would provide support and coordination, engage cross-government stakeholders and implement a prioritised set of actions designed to leverage and enhance Ireland's unique and collective capabilities across pharma, biopharma, biotech, chemicals, medtech and digital health.</p> <p>The Office would also serve as a platform to collect feedback and monitor the success of the strategy to inform future iterations. Finally, the Office would act as the crucial connection the EU, mirroring the Life Science Coordination Group that is to be</p>   |

|                               |   |
|-------------------------------|---|
|                               | <p>established as part of the EU Life Sciences Strategy to align policies and funding across sectors.</p> <p>These executive arms are common features in competitor jurisdictions with strong life sciences sectors and have ultimate responsibility for the implementation. For example, Britain and Sweden both have an Office for Life Sciences which are tasked with supporting life sciences companies and championing research, innovation and technology to transform the health sector.</p>   |
| <p><b>EU Connectivity</b></p> | <p>The body responsible for overseeing the implementation and assessment of the NLSS should also be positioned to engage with EU policy in a proactive, upstream manner. EU legislation has a significant impact on the sector, often introducing new restrictions, regulations and reporting requirements. Establishing designated point of contact for industry representatives to raise concerns and set priorities early in the EU policy cycle would enable Ireland to influence policymaking at the European level and strengthen its policy positions.</p> <p>Ensuring strong EU connectivity will also help align the NLSS with forthcoming EU policies and initiatives, which will in turn maximise its effectiveness and ensure that national priorities are strategically reinforced. For example, both Danish and Swedish life sciences bodies proactively contribute to EU policy development by developing national positions on key EU files, including the EU Life Sciences Strategy. Ireland could realise the same opportunity with an Office of Life Sciences.</p> |

For the NLSS to secure prosperity and a resilient future over the next decade, it must be both ambitious and results driven. We have witnessed other jurisdictions revise their respective strategies after recognising that previous versions lacked bold vision or concrete action plans, leading to missed opportunities and underperformance.

The NLSS needs to be developed and operationalised on solid foundations, in a manner which can accommodate growth in our collective future ambition, alongside an agile response to issues as they emerge thus avoiding the need for a major overhaul in the future. To avoid potential pitfalls, the NLSS should set clear, measurable goals and foster strong collaboration between government and industry, ensuring that the strategy drives innovation, attracts investment, and addresses real-world challenges with urgency and clarity.

## Summary

A strong /successful life sciences strategy rests on three essential pillars.

- 1) First, it establishes a solid foundation of competitiveness, ensuring the sector has the necessary infrastructure, talent, regulatory excellence, and innovation ecosystem to thrive.
- 2) Second, it focuses on future growth by supporting industry development and positioning the sector to capitalise on emerging global opportunities.



t +353 1 605 1500  
e info@ibec.ie  
w www.ibec.ie

3) Finally, effective and transparent governance and implementation are critical, requiring clear leadership, stakeholder engagement, accountability, and mechanisms to monitor progress and adapt to changing needs.

Together, these pillars form a balanced, dynamic framework that can drive sustained success in the life sciences sector.

The NLSS offers us a unique opportunity to create a fully interconnected and strategically aligned ecosystem where all-of-government, industry, research, academic and health system partners collaborate to leverage Ireland's distinct strengths: our world-class pharma, medtech and tech industry sectors, a collaborative and flexible culture, alongside our talented, ambitious, and highly skilled people.

By fully leveraging this interconnectivity correctly, Ireland can not only safeguard our current success, but also unite in a shared commitment to advancing the life sciences sector - ensuring its continued growth and prosperity for the benefit of all our citizens.



# Cancer Trials Ireland: Submission to the National Life Sciences Strategy Consultation

**Submitted by:** Cancer Trials Ireland

**Date:** 5<sup>th</sup> December 2025

**To:** Department of Enterprise, Tourism and Employment

---

## Scope

The scope of the National Life Sciences Strategy should explicitly include clinical research and clinical trials - particularly cancer clinical trials - as core national life sciences infrastructure, on equal footing with (bio)pharmaceuticals, medical technologies, and biomanufacturing.

Clinical trials are uniquely positioned at the intersection of industry, academia, health services, and patient care. They: -

- attract inward investment,
- support high-value R&D,
- anchor pharma and MedTech activity in Ireland,
- advance patient outcomes through access to innovation, and
- drive system efficiencies and cost savings.

This framing aligns directly with the EU's *Choose Europe for Life Sciences Strategy*, which identifies clinical research as a strategic competitiveness priority and highlights the need for Member States to strengthen clinical research infrastructure to reverse the decline in EU trial activity and compete globally (EU Strategy, pp. 5–7).<sup>1</sup>

Clinical trials are also vital for emerging biotech's to validate safety, efficacy, and attract investment for their products. Large pharma increasingly in licenses or acquires assets from smaller biotechs after they show clinical validation, using that data to justify major upfront and milestone payments. So indigenous Irish biotech SME industry is dependent on an active and easy-to-access clinical trials infrastructure. The path from academic biological research innovation to clinical translation and market accessibility is dependent on validation in clinical trials. Deals and out licensing agreements typically command higher values when an asset has progressed into or through key clinical phases, because the risk profile is lower, and market potential is clearer.

Furthermore, demonstrating benefit in well run clinical trials also supports health technology assessment and payer discussions, which are essential for eventual uptake and revenue.

## Why cancer clinical trials should be explicitly in scope

Cancer represents a high-burden disease area, a major focus of global R&D, and a leading category for Advanced Therapy Medicinal Products (ATMPs). The economic and clinical evidence demonstrates that cancer trials offer a uniquely high return on public investment:

- €14.8m in direct drug cost savings from just 18 trials involving 249 patients over four years ([CTI Value of Cancer Trials report](#) [VOCT], pp. 3, 10)<sup>2</sup>.
- €36.7m in inward investment through provision of investigational medicinal products (IMPs) to patients (VOCT pp. 3, 10)<sup>2</sup>.
- Trial-unit valuation of €9.7m (2021–2025) and €2.05m (2022 alone) in medicines provided to trial patients, at no cost to the State (VOCT pp. 3–4, 11)<sup>2</sup>.

Few other areas of the life sciences ecosystem simultaneously address economic growth, patient outcomes, R&D excellence, and health system sustainability to this degree.

For these reasons, the scope of the Strategy should explicitly incorporate:

- Clinical trials, with a defined cancer trials pillar
- Clinical research infrastructure and regulatory pathways
- Health data infrastructure to support research (aligned with the EHDS)
- Specialist clinical research workforce development

This scope is central to achieving Ireland’s ambition to remain a global life sciences leader.

---

## Objectives

Ireland’s National Life Sciences Strategy should adopt the following key objectives, each supported by evidence from national performance data and aligned with EU policy direction.

### **Objective 1: Strengthen Ireland’s capacity to conduct cancer clinical trials at scale**

Ireland currently participates in just 1.1% of all EU clinical trials and has the lowest number of newly opened oncology trials among EU Member States (VOCT, pp. 14–15)<sup>2</sup>.

To become competitive, Ireland should set measurable targets to:

- Increase the number of open cancer trials by investing in trial networks, clusters, and national sponsor capacity (Cancer Trials Ireland).

- Achieve the National Cancer Strategy target of 6% of cancer patients enrolled on interventional trials, which will only be feasible with increased multi-departmental investment (VOCT, pp. 25)<sup>2</sup>.

## **Objective 2: Build sustainable workforce and trial-site capability**

The EU Strategy stresses the importance of research careers and the need to address skills shortages across clinical research (EU Strategy, pp. 18–19).<sup>1</sup>

Ireland faces immediate vulnerabilities:

- Trial units often rely on temporary, insecure contracts, causing staff turnover and loss of expertise (VOCT, pp. 11)<sup>2</sup>.
- Career pathways for research nurses, data managers, radiation therapists and HSCPs remain underdeveloped.

A national objective should be to:

- Create permanent, recognised clinical research grades within the HSE
- Stabilise research unit staffing through secure funding
- Align workforce planning with EU mobility and training frameworks.#

## **Objective 3: Reform and accelerate regulatory and trial start-up processes**

Ireland’s trial start-up timelines have historically been among the slowest in Europe, ranking 32nd and 33rd out of 35 in ICON’s EU-wide comparison (VOCT, pp. 18)<sup>2</sup>.

Although the introduction of national Clinical Trial Agreement (CTA) templates and single legal review processes has begun to improve timelines, structural and legislative reforms are needed to align with EU actions such as:

- ACT EU,
- MedEthics EU,
- the COMBINE project for coordinated regulatory pathways, and

- forthcoming EU Biotech Act (EU Strategy, pp. 10–11, 20–23).<sup>1</sup>

Ireland should set an objective to be top quartile in Europe for trial start-up efficiency within five years.

## **Objective 4: Support innovation, personalised medicine, and advanced therapies**

Oncology and ATMP research are explicitly identified as EU strategic priorities (EU Strategy, pp. 9–10)<sup>1</sup>.

Cancer trials are the primary vehicle for:

- real-world adoption of ATMPs,
- genomic-driven treatment selection,
- precision diagnostics, and
- advanced radiotherapy techniques.

Investing in this infrastructure will directly enable Ireland to benefit from EU programmes in data sharing, genomics, and AI-driven discovery.

## **Objective 5: Expand equitable access to trials for patients across Ireland**

Patients enrolled in cancer trials consistently experience improved outcomes due to access to novel treatments and enhanced monitoring (VOCT, pp. 7).

Objectives should include:

- Developing hub-and-spoke decentralised trial models to ensure regional equity (VOCT, pp. 24)<sup>2</sup>.
  - Integrating trial participation metrics as key performance indicators for hospitals, echoing recommendations from the National Clinical Trials Oversight Group (VOCT, pp. 6)<sup>2</sup>.
  - Expediting access to genomic medicine, digital innovation, electronic health records to enable digital clinical trials.
-

# Opportunities and Challenges

## Opportunities

### 1. Economic Return and Inward Investment

Cancer trials generate substantial value:

- €14.8m direct savings + €36.7m inward investment in IMPs from a small sample of trials (VOCT, pp. 3, 10)<sup>2</sup>.
- Radiotherapy trials delivering €569k to €482k annual savings per protocol, plus staffing and machine-time efficiencies (VOCT, pp. 12)<sup>2</sup>.

These savings nearly exceed 20 years of HRB funding to Cancer Trials Ireland (€18.39m) and total savings very likely exceed the entire €22m HRB grant cycle (2022–2026) (VOCT, pp. 25–26)<sup>2</sup>.

Scaling this model represents a high return on public investments.

### 2. Patient Impact and Public Support

Trial participation:

- improves outcomes,
- provides access to treatments unavailable via standard care,
- enhanced, elevated monitoring, and
- commonly comes at no cost to patients or HSE (VOCT, pp. 7)<sup>2</sup>.

Public support for trials is strong and rising: 62% of people in Ireland would participate in a trial, up from 48% in 2020 (VOCT, pp. 7)<sup>2</sup>.

### 3. High-growth oncology and ATMP innovation pipeline

Cancer trials provide early access to:

- immunotherapies,
- targeted therapies,
- radiotherapy innovations, and
- next-generation ATMPs.

This positions Ireland attractively for FDI, research consortia and EU innovation partnerships.

## Challenges

### 1. Ireland underperforms in clinical trial participation

With just 1.1% of EU clinical trials, Ireland falls behind smaller or comparable peers such as Finland, Denmark, and Switzerland (VOCT, pp. 14–15)<sup>2</sup>.

Without structural intervention, Ireland risks being perceived as a low-capacity clinical research market, weakening competitiveness.

## **2. Fragmented funding and unstable trial-unit staffing**

Trial units often self-fund large proportions of activity, leading to:

- volatility,
- inability to retain experienced staff,
- reduced trial capacity.

(VOCT, pp. 11, 25–27)<sup>2</sup>.

## **3. Slow and variable trial start-up timelines**

Ireland's historic performance in trial initiation is a known deterrent for sponsors. Despite improvements, significant reform and coordinated policy action are needed (VOCT pp. 18–20)<sup>2</sup>.

## **4. International competition for pharma investment**

Global pressure (e.g., U.S. CHIPS-style incentives) threatens Europe's share of biopharma R&D and manufacturing. Ireland must signal strong strategic intent to remain globally relevant (VOCT, pp. 4)<sup>2</sup>.

Cancer trials are a strong lever to assist anchoring pharma investment in Ireland.

## **5. Fragmented data infrastructure**

Ireland's electronic health infrastructure is fragmented. Development of electronic health data aligned to European Health Data Space and National Cancer Data Nodes standards will support real world evidence generation, assessment of feasibility to open and run studies.

---

## **EU Context**

The EU Life Sciences Strategy provides a clear framework that Ireland's national strategy must align with. The EU's ambition is to become the world's most attractive location for life sciences by 2030 (EU Strategy introduction)<sup>1</sup>.

## **Ireland's opportunity: align national action with EU structural investments**

## 1. EU Clinical Research Investment Plan (2026)

The EU will establish a major investment plan to expand multi-country trials, harmonise regulation, and build clinical research infrastructure (EU Strategy, pp. 11)<sup>1</sup>.

→ Ireland must scale its cancer trials capacity to be a meaningful participant and beneficiary.

## 2. Addressing Europe's decline in trial activity

The EU highlights declining clinical trial volume and competitiveness as a strategic risk (EU Strategy, pp. 5–7)<sup>1</sup>.

→ Ireland has the lowest number of newly opened oncology trials in Europe - a national challenge squarely in scope.

## 3. Regulatory simplification and harmonisation

Upcoming EU initiatives (ACT EU, COMBINE, MedEthics EU, Biotech Act) aim to reduce fragmentation and enhance trial efficiency (EU Strategy, pp. 10–11, 20–23)<sup>1</sup>.

→ Ireland must adapt its systems to keep pace or risk falling further behind.

## 4. EU investments in health data, genomics, and AI

Cancer trials depend on structured data architectures, interoperable systems, and computational analytics - all highlighted priorities for the EU (EU Strategy, pp. 14–15)<sup>1</sup>.

→ Ireland should embed cancer trials in national data strategies to benefit from EHDS, NCDN, and EU genomics initiatives.

## 5. EU focus on research careers & workforce mobility

Challenges in research careers and workforce retention are shared EU-wide (EU Strategy, pp. 18–19)<sup>1</sup>. The Value of Cancer Trials report describes how Ireland experiences this acutely.

→ Ireland should incorporate workforce stabilisation in its life sciences strategy.

---

## Conclusion

Cancer clinical trials deliver profound value to Ireland's economy, health system, and global competitiveness. They:

- save the State millions annually,
- bring in tens of millions in inward investment,
- improve patient outcomes,
- support high-value R&D and jobs, and
- anchor Ireland's position in a rapidly evolving EU life sciences landscape.

Few investments offer such a powerful combination of economic return, patient benefit, and strategic alignment with both EU priorities and national ambitions.

A National Life Sciences Strategy that explicitly prioritises cancer clinical trials will position Ireland to lead within its peer group, attract major EU and industry partnerships, and deliver tangible benefits to patients and the wider economy.

**References:**

1. Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030: [EUR-Lex - 52025DC0525 - EN - EUR-Lex](#)
2. Value of Cancer Trials, Nov 2025, Cancer Trials Ireland: [CTI Value of Cancer Trials report](#)



## CHW Cluster – Life Sciences Strategy Submission

Date: December 5<sup>th</sup> 2025

### Background

This submission to DETE's Life Sciences Strategy is made by the Connected Health & Wellbeing Cluster, an Enterprise Ireland co-funded initiative, based at Dundalk Institute of Technology (DkIT). The Cluster has eighty members from across the Health and Life Sciences sector on the island of Ireland. DkIT has built a strong National support ecosystem for the health & Life Sciences sector which include the CHW Cluster, the dConnect Health Innovation Hub and the DigiBio Healthtech Innovation Programme. The Research Centres include the Regulated Software Research Centre which specializes in Software as a Medical Device, the NetwellCASALA Living Lab, and the Smooth Muscle Research Centre. The submission was discussed at a meeting of interested Cluster members in November and input was gathered from a cross-section of members.

### 1. Scope

The expertise and interests of our members primarily focus on the 'health' value chain; healthtech, medtech, and pharma. We believe that it is important that these sectors are prioritised within the strategy to ensure collaboration across the sectors, and that Ireland's indigenous innovators can be successfully supported to start and scale on a global stage.

The strategy should include common sectoral themes based on the increased focus on preventative and personalized healthcare which enables citizens to better manage their health over a lifetime via the use of digital technologies. The strategy should focus on supporting innovation that identifies health risks at an earlier stage and embraces technology to support delivery of remote healthcare. It should clearly position digital technologies, and the effective use of public health data as a unifying thread across all sectors within Life Sciences.

## 2. Objectives

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?*

It is crucial that the strategy enables and supports the building of collaborative partnerships across the myriad sectors, and multiple stakeholders (SMEs, FDI, Healthcare, Academia, Citizens, multiple sectors). This is a unique opportunity to connect the whole value chain across the ecosystem and create an improved environment based on common synergies that operate from idea right through to patient care. This is the core aim of Health Clusters, as per the EU Life Sciences Strategy, and we believe that a National (and potentially all-island) Cluster that supports all the sectors should be embedded in the Strategy. This would also align with DETE's National Clustering Strategy.

The overall objective of the strategy should aim to enable Ireland to become a World-Leading destination for Life Sciences, and to embrace digital technology and healthcare innovation as the key enabler of synergies across the complete Life Sciences value chain. It should support streamlined pathways and connectivity across the wider Life Sciences sectors (healthtech, Medtech, Pharma etc.) and optimize the nascent synergies that underlie our fractured ecosystem.

## 3. Opportunities and Challenges

### Opportunities:

**SME Support:** Ireland has seen tremendous indigenous success stories, but there is a massive opportunity to elevate it to the next level by driving research and innovation, and improving access to sustained funding. This is necessary to support the long product development lifecycles in Life Sciences, combined with the extended timeframe to reach revenue-generating business models.

**Reimbursement:** The current reimbursement and procurement models in healthcare in Ireland are no longer fit-for-purpose in relation to adopting new technology, and the strategy should include partnering with the Department of Health and other relevant bodies to streamline the process to encourage earlier adoption of technology and quicker access to the market for SMEs. Other countries in the EU have already adopted strategies to support the adoption of digital health or digital therapeutic solutions; for example, DIGA in Germany and PECAN in France. Those models should be examined and adapted to suit the Irish marketplace.

Digital Health Validation: The Connected Health & Wellbeing Cluster (alongside partners) is currently completing a Feasibility Report on *establishing a Digital Health Validation Lab and Regulatory Sandbox in Ireland* (DHVRS). There are two components of the proposed DHVRS; a Digital Health Validation / Simulation Lab, an immersive environment with medical staff and a replica of a health information system for co-design, testing, and validation; and a Regulatory Sandbox, a collaborative process where regulators, clinicians, and industry evaluate the digital solutions in real-world settings, on a time-limited basis, at a small scale, and with appropriate safeguards in place. The report will evaluate how such infrastructures can act as catalysts for growth in the Healthtech sector, facilitating faster time-to-market for new technologies, promoting standardization and interoperability across the industry sectors, and embedding collaboration across industry and healthcare at an early stage to ensure that regulatory, technical, and cybersecurity concerns are addressed at an early stage in the innovation model. It would also create a learning depository for 'best practice' digital health solutions and optimization of public health data. *We believe that the Life Sciences Strategy should include the creation of a DHVRS and outline potential funding models for its formation across the relevant Government bodies (Health, Enterprise, Education) .*

AI in Health: Artificial Intelligence is creating complementary opportunities across all the sectors in Life Sciences and our unique access to global technology and health expertise should be utilized to take a leading role in developing AI for Healthcare across the EU. AI integration accelerates drug discovery and personalized medicine and the proposed DHVRS could include an AI for Health Regulatory Sandbox which will be crucial to managing the ever-changing AI developments in Life Sciences.

Digital Health: There is a definite need to develop talent and skills in digital health across industry, academia, and healthcare providers. These new skills are necessary to support the early stages and future Internationalisation of innovative technologies, and to embed digital pathways in the healthcare system. The HSE has created a number of new strategies based on digital health including the launch of the Patient App, new Shared Care Records, the upcoming implementation of an Electronic Health Records System (EHR), and the need to adhere to the legislation for the upcoming European Health Data Space (EHDS) legislation.

Regulatory: Streamline regulatory pathways. It is essential that the Life Sciences Strategy aligns with the wider health strategic landscape and relevant EU regulatory frameworks, such as the EHDS. This will serve to support the streamlining of increasingly complex regulatory requirements

and enable collaborative regulatory validation and submission across the various health and life Sciences sectors, improving time and cost efficiencies.

Cyber Security: In January 2025, the EU Commission launched a new 'Action plan on Cyber Security for Hospitals and Healthcare Providers' ([Commission unveils action plan to protect the health sector from cyberattacks | Shaping Europe's digital future](#)). CHW Cluster and its partners including the Cyber Ireland Cluster at MTU have created a new Working Group to support our members address the cybersecurity needs of industry and healthcare providers. *There is an opportunity for Ireland to take a lead on this due to our expertise across technology, cybersecurity, and healthcare innovation.* The Health sector is the largest sector for cyber-attacks and the increased need to access and share health data across multiple locations including via personal devices will increase that risk.

All-Island opportunities: Queens University Belfast and DkIT recently announced a partnership which includes an R&D and industry focus on the Health and Life Sciences sector ([First 'all Ireland university' as DkIT partners with QUB](#)). There are multiple opportunities to elevate the Life Sciences Sector on both sides of the Border due to complementary skills, sectoral niches, expertise and specialities. CHW Cluster has already developed a number of collaborative projects with organisations in Northern Ireland (for example, our 'AI for Healthcare' programme in partnership with the Data Innovation Hub, and support from InterTradelreland) and the recent announcement with QUB who have an enviable track record of supporting Life Sciences places us in an ideal situation to further develop all-island collaboration.

## Challenges:

Public trust in data sharing and patient consent. The use of public health data in Ireland is limited and hinders the opportunity to collaborate on R&D, participate in EU or Global projects, and gather insights from population health data. It is crucial that we create an ecosystem that fosters public trust in the value of sharing health data, ensuring transparency and security in line with the upcoming European Health Data Space regulation. Building confidence among patients and stakeholders is essential to unlock the full potential of data-driven collaborative innovation and enable Ireland to participate effectively in EU-wide health data initiatives. The strategy should include an aim to actively target citizens and stakeholders to encourage greater understanding of the benefits of sharing health data and the safeguards that are in place to ensure anonymity.

Lack of a single coordinating body or Cluster to support collaboration across the Life Sciences Sector. There are multiple networks, support organisations, and even a few clusters in existence,

but the overall ecosystem is still very fragmented and doesn't support nascent synergies and innovative solutions across the siloed Medtech, Healthtech, and Pharmaceutical sectors. A National Cluster should be created to support each sector whilst enabling greater interaction across all parties.

Skills shortages and talent gaps: The sector relies on continual learning of new skills and attracting ambitious and skilled personnel. There are numerous avenues to addressing that and it requires a robust, responsive talent pipeline, supported by targeted training, up-to-date academic programmes that include the latest digital technologies, apprenticeships, industry placements, and upskilling pathways aligned with the sector's evolving capability needs.

Limited funding for scaling innovation. The recent Enterprise Ireland publication on VC in the Health & Life Science sector highlights Ireland's success to date – see [pitchbook-enterprise-ireland-lifesciences-and-health-tech-report-data.pdf](#). However, we believe there is still potential to substantially increase the support to innovators who are starting and scaling Life Sciences companies as they navigate the long product development lifecycle and access to International markets. There is a large increase in global competition and it will require new resources to develop and implement healthtech and medtech solutions that are suitable for International markets.

Infrastructure constraints in healthcare facilities: The current healthcare system in Ireland aims to embrace digital technology, but the vast majority of infrastructure is antiquated. It needs additional resources that would enable it to adopt new systems and processes. There is limited 'connectivity' in the healthcare infrastructure which impedes the adoption of IoT, Bluetooth, and other integrated healthcare solutions. The exponential growth of health of data in the system will require major upgrading of IT systems.

## 4. EU Context

The European Commission's Life Sciences Strategy aims to position the EU as the world's most attractive location for Life Sciences by 2030. Ireland should assert its leadership role within the EU Life Sciences system due to its current base of International and Indigenous innovators.

According to the Enterprise Ireland pitchbook report "Ireland boasts over 700 life sciences and health tech companies, including over 400 homegrown Irish companies and a broad multinational presence in Ireland, including the world's top 10 biopharma companies, 9 of the world's top 10 medtech companies and the world's top 10 tech companies." This is a formidable offering and the

strategy should optimize that strength whilst embedding the need to be continually innovating and moving up the value chain.

Clustering: We believe that the European success of Clusters provides a roadmap for improved collaboration that will foster growth, innovation, and employment. The EU Life Sciences strategy refers to “existing biotech clusters” in the EU among the strengths of the Union and calls for strengthening “bio-clusters and centres of excellence” across Member States. The EU Strategy repeatedly references “clusters” as part of the ecosystem to be strengthened, supported and leveraged. Under the “Optimising the R&I ecosystem” pillar, the Strategy emphasises the importance of combining disciplines, stakeholders and funding “in R&I ecosystems”, including “partnerships, missions and bioclusters”

We support the creation of a dedicated Life Sciences Cluster incorporating healthtech, medtech, pharma and the wider health remit in Life Sciences. We have also made a joint submission with Medlink Galway and the Life Sciences Ireland Cluster which supports that proposition. We have seen the example in Belgium where two successful clusters from the healthtech and life sciences sector have merged to create a new larger cluster that supports greater integration and collaboration – see [About Biovia | Biovia](#); Their priority is on “**One Cluster for One Health**. MEDVIA and flanders.bio have joined forces to become Biovia: the new health innovation cluster for Flanders, uniting human and planetary health into one vibrant ecosystem”.

The EU strategy summarises it succinctly; “Leveraging the capacities of European bioclusters will also generate major benefits. Europe already hosts several bioclusters. There is scope to improve their global standing to attract private capital, spur entrepreneurship and ensure the EU remains competitive. By identifying more centres of excellence , the EU can boost its capacity in life science innovation (page 8)”.

“One Health Approach”: We firmly believe that the Irish strategy should align with the ‘One Health’ policy within the EU strategy plan; “*One Health Governance in the EU recommends action to tackle the fragmentation of policies, the lack of trans- and interdisciplinarity, and insufficient coordination among related sectors*”.

Other key areas in the EU Strategy that we support include:

- Pilot on stepwise collaborative research funding for health innovations (2026)
- Pilot on exploiting collaboration among EU Biotech clusters (from 2026)
- Invest €20 billion in AI Gigafactories, with 10 of 13 focused on life Sciences
- Regulatory simplification for medical devices and in vitro diagnostics (from 2025)

- Develop Virtual Human Twins to accelerate clinical trials and reduce animal testing (€8M allocated for incubator, 2025–2027).
- Repository of tools in responsible R&I, risk and science communication, and pilot community engagement actions (2026)

Regards

Breannán Casey

Cluster Manager

On behalf of members of the Connected Health & Wellbeing Cluster

[www.chwcluster.ie](http://www.chwcluster.ie)



Fitzgerald House, Summerhill North,  
Cork, T23 TD90, Ireland.  
+353 (0)21 450 9044  
info@corkchamber.ie  
CorkChamber.ie

Department of Enterprise, Tourism and Employment,  
23 Kildare Street,  
Dublin 2,  
D02 TD30.

4<sup>th</sup> December 2025

To whom it concerns,

Cork Chamber welcomes the opportunity to contribute to the Department of Enterprise, Tourism and Employment's public consultation on the development of a new National Life Sciences Strategy.

Cork Chamber represents 1,200 members together employing 130,000 people throughout the city, metropolitan area and county. Our vision is to lead a transforming and ambitious Cork city and county, and our purpose is to unite, represent and support our members and community. At Cork Chamber, our direction is guided by our formal pledge to uphold the UN SDGs, five of which have been identified as priority areas by the Chambers Ireland network. Cork Chamber has also been designated an SDG Champion by the Department of Climate, Energy and the Environment for 2024 – 2025.

Our advocacy efforts are shaped by the views and priorities of our partners, and are informed by our continuous engagement with members, our Board and key stakeholders in Cork city and county.

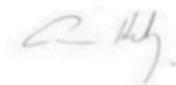
The life sciences sector plays a key role in the Irish economic development, particularly in the Cork region, which is home to a large concentration of firms operating in the sector. In addition, Cork has a strong offering in life sciences education and research.

Ongoing support for research and education to ensure a strong talent pipeline for the life sciences sector is critical and should be a core focus of the new strategy. Promoting collaboration and innovation through the development of research and industry clusters will also be key to the sector's future development.

The development of a comprehensive strategy for the sector is therefore welcome and should aim to position competitiveness at the fore of all policy developments in the

sector, supporting the sector's future development and ensuring Ireland remains an attractive location for research and investment.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'C. Healy', positioned above a thin horizontal line.

Conor Healy

CEO

## **Scope**

Cork Chamber welcomes the ambition to develop a comprehensive strategy for the life sciences sector. The inclusion of all relevant sectors across biopharmaceuticals, medical technologies, agriculture, fisheries and food production would be welcome. Particular consideration should be given to biopharmaceuticals, medical technologies and food production given the importance of these sectors to the Irish economy. These sectors play a key role in supporting foreign direct investment and talent attraction in Ireland, and ensuring a supportive policy environment for their future development is essential.

With this in mind, ensuring strong talent pipelines, as well as available land and other infrastructure for industrial development, such as water, wastewater and energy, is critical. As highlighted by some of our members in the food industry, the scarcity of suitable production units and the shortage of skilled talent in the Cork region are already limiting the ability of firms to grow and scale locally, underlining the importance of addressing these challenges in the strategy.

## **Objectives**

Ensuring that Ireland is equipped to meet future needs and maintain its competitive offering in the life sciences sector in an international context should be a key consideration of the new strategy. With geopolitical uncertainty continuing at a global level, it is vital that Ireland works to strengthen the areas of its economic competitiveness within its control in order to support the continued attraction of investment and talent.

In line with the aims set out in the Programme for Government, boosting the role of Enterprise Ireland and the IDA should be a key objective, ensuring that Ireland showcases its competitive offering on the global market. Beyond the scope of the strategy, consideration should also be given to continued investments in housing, infrastructure development, and talent and skills, which all play an important role in supporting Ireland's international competitiveness as a whole.

With regard to talent and skills, the strategy should consider the evolving needs of life sciences sectors and should concentrate on strengthening talent pipelines to support future sectoral development. Collaborations between industry and educational institutions will be critical in this regard and should be supported by the strategy to ensure that graduates are equipped with the skills they need to build successful careers in Ireland's world-class life sciences industry.

Ongoing support for upskilling and reskilling is critical too and will ensure that those working in the sector, or interested in transitioning to a life sciences career, can access short courses and other supports, allowing employees to obtain future-proof skills in a flexible manner while in employment.

Cluster organisations in the life sciences sector play an important role in fostering collaboration between academia and industry. The further expansion and development of cluster networks should also be considered by the strategy in order to ensure ongoing engagement, as well as alignment with peer countries, many of which have much more developed cluster organisations connecting the full life sciences value chain.

At present, only 1.5% of the life sciences industry in Ireland is made up of indigenous companies, with FDI accounting for the remaining 98.5%. As a result, the sector is particularly exposed to geopolitical shifts and changes to trade policy. The sector is also heavily concentrated, both geographically and functionally; in 2022, for example, just five companies accounted for 43% of Ireland's total exports. Only 5% of jobs are in early-stage research. Diversifying operations to include the full value chain, from discovery to delivery, is critical to ensure that Ireland keeps up with global trends

Cork Chamber collaborates with Dublin Chamber and Northern Ireland Chamber of Commerce and Industry through the Tri-Region Partnership to advance shared aims for economic development on an all-island basis.<sup>1</sup> Developing competitive innovation clusters across the island is a key focus of the partnership's work and the three Chambers have been engaging with those involved in the life sciences sector across both academia and industry to identify key policy enablers to support the growth of such clusters. In this regard, consideration could be given to the establishment of a steering group for the sector across both Ireland and Northern Ireland, as well as a dedicated fund for all-island research and innovation. Engagement with initiatives like the Shared Island Fund and other cross-border collaborations should be another key consideration in the strategy to support all-island cooperation.

Financial and other supports for innovation are critical for both indigenous firms and multinationals, and the strategy should consider all available supports for the sector, such as the R&D Tax Credit, for example. Possible expansion of supports or targeted supports for the life sciences sector in particular should be considered, alongside the availability of information and advice with regard to accessing these supports. Possible communications campaigns and engagement with industry in order to raise greater awareness of available supports should also be considered. Cork Chamber welcomes the commitment to introduce an R&D Compass as outlined in Budget 2026; the role of the life sciences sector should also be considered in this context.

### **Opportunities and Challenges**

Ensuring dedicated, accessible funding for research and innovation in the sector is essential to support the development of the life sciences sector, including dedicated

---

<sup>1</sup> Cork Chamber, [Tri-Region Partnership Policy Position Paper](#)

funding streams for both large multinational firms and indigenous SMEs operating in the sector.

Academic and industry actors have highlighted the absence of dedicated funding streams to support the sector on an all-island basis. Innovate UK supports existing bilateral funding innovation programmes for the UK with countries like Switzerland and Germany, however no comparable funding mechanism currently exists for Ireland and Northern Ireland.

With regard to the potential development of a national, government-supported cluster organisation for the life sciences sector, Cork should be considered as a potential location, given its well-established industry and academic offering in the sector. The strategy should consider the importance of government funding and support to facilitate the development of a national cluster organisation.

Leveraging the existing pharmaceutical ecosystem in Cork to collaborate with research institutions in areas like late-stage product development also presents a distinct opportunity to further collaboration and connection between industry and academia. Targeted supports to develop capabilities and commercialise late-stage R&D activities into manufacturing should be explored by the strategy, which would in turn reduce the development timeline for medicines from research stage to market access.

In addition, ongoing geopolitical uncertainties pose a risk to the growth of the life sciences sector in Ireland, particular the pharmaceutical sector. It is crucial that the strategy takes a forward-looking approach, strengthening Ireland's competitive offering in order to mitigate the impact of global challenges insofar as possible. Ensuring Ireland's readiness for future investment is essential, including the maintenance of a strong talent and skills pipeline, as well as the availability of zoned, serviced lands and IDA support for foreign direct investment.

Supporting infrastructure is also important in this regard. Ensuring the security of energy supply to support future development is crucial. Sustainable and secure energy supply is a growing concern for many firms, and the development of renewable energy to support industrial expansion should also be considered. Concerns regarding Ireland's ability to provide and maintain critical infrastructure and sufficient housing supply pose a risk to Ireland's competitive reputation internationally; addressing these concerns through the work of the IDA, Enterprise Ireland and the diplomatic corps should be a key focus to ensure that Ireland remains an attractive location for inward investment. In this context, it is essential that momentum continues for the identification and delivery of a large-scale, serviced, strategic 'next generation' IDA site in Cork to facilitate national expansion of the life sciences sector and ensure the region is investment-ready.

## **EU Context**

The publication of the European Commission's 'Choose Europe for life sciences' strategy earlier this year is a welcome step towards fostering greater collaboration across EU Member States in the area of life sciences.

Alongside close collaboration with Northern Ireland and the UK, cooperation with European counterparts on a cohesive strategy to foster the growth of the domestic life sciences industry in Europe and attract inward investment is critical. Continued international collaboration should be a core focus of the strategy, as well as alignment with the aims of the recently published European strategy.

The European strategy sets out a number of key aims that should be considered in Ireland's plans, particularly the goal of optimising the research and innovation ecosystem through the establishment of an EU investment plan and the promotion of a One Health approach to research and innovation under the Horizon Europe work programmes 2026 – 2027.

The emphasis on sustainability at an EU level is also welcome, and should be included in the national strategy, promoting sustainable research and innovation developments. In addition, the European strategy makes reference to the use of AI to support innovation, which should also be explored at national level.

Aims to establish a Life Science Coordination Group to align policies and funding across sectors and support greater engagement are also welcome, as are commitments to scaling up collaboration through clusters across Europe. The National Life Sciences Strategy should actively seek to engage with the European Commission and individual Member States to ensure that Ireland's life sciences sector benefits fully from developments at EU level and plays a key role in shaping cluster programmes and other initiatives.

The European strategy makes welcome reference to ongoing initiatives to improve Europe's competitiveness as a whole, including the implementation of the Draghi and Letta reports. In Ireland, the National Life Sciences Strategy should seek alignment with similar initiatives at a national level, such as the recently published Action Plan on Competitiveness and Productivity, to ensure a cohesive policy framework that promotes competitiveness at all levels.

Ireland's upcoming Presidency of the Council of the European Union presents an important opportunity to spearhead the further development of these policies, and government should seek to engage with industry and academic stakeholders in the sector to ensure their views are reflected in the progression of these policies at EU level.

## Submission – Public consultation on National Life Sciences Strategy

### Contents

|   |   |
|---|---|
| Submission – Public consultation on National Life Sciences Strategy .....     | 1 |
| 1. Context & Scope.....   | 1 |
| 2. Objectives.....  | 3 |
| 2.1 Strategic positioning and competitiveness.....                            | 3 |
| 2.2 Integrated approach & system transition.....                              | 3 |
| 2.3 Innovation pipeline: from research to deployment.....                     | 3 |
| 2.4 Skills, regions and just transition .....                                 | 4 |
| 2.5 Governance, regulation, and data .....                                    | 4 |
| 3. Opportunities and challenges for Ireland’s life sciences & bioeconomy..... | 4 |
| 3.1 Key opportunities.....  | 4 |
| 3.2 Key challenges.....   | 5 |
| 4. EU context.....  | 7 |
| 4.1 Embrace the EU’s broad vision .....                                       | 7 |
| 4.2 Align national instruments with EU initiatives.....                       | 7 |
| 4.3 Use EU frameworks to de-risk innovation and scale-up.....                 | 7 |
| 4.4 Co-evolve with EU Bioeconomy and wider agendas .....                      | 8 |
| 5. Concluding remarks .....   | 8 |

### 1. Context & Scope

This submission is prepared by the Department of Agriculture, Food and the Marine (DAFM) and considers emerging policy developments at EU level, particularly the EU Life Sciences Strategy “Choose Europe for life sciences”<sup>1</sup> and the recently published EU Bioeconomy Strategy<sup>2</sup>.

It is particularly noteworthy that the EU Strategy (published in July 2025) includes health, agriculture, food, environmental and industrial applications of living systems in scope. Meanwhile, most national life science strategies that exist currently in other countries confine their scope to human health, medicine and pharma. There is therefore a very significant opportunity for Ireland to stand out and take a lead by developing a national strategy that has a scope more similar to the EU Strategy. In any event, this approach makes sense given that the agri-food sector is Ireland’s largest indigenous sector, accounting for 8.6% of goods exports, 169,300 people employed, accounts for 76% of land use, and 6% of modified GNI. Further, of all the Irish raw materials purchased by Irish

<sup>1</sup> [Commission launches new strategy to make Europe a global leader in life sciences by 2030 \(europa.eu\)](https://europa.eu/european-council/en/commission-launches-new-strategy-to-make-europe-a-global-leader-in-life-sciences-by-2030)

<sup>2</sup> [Commission presents new Bioeconomy Strategy \(europa.eu\)](https://europa.eu/european-council/en/commission-presents-new-bioeconomy-strategy)

owned firms, the majority (or 70%) related to the Food and Drink sector in 2023. When the value of inputs imported and profits repatriated are excluded, it has been estimated that the agri-food sector typically represents up to 40% of Irish net foreign exchange earnings from merchandise exports.

We therefore recommend that the broad agri-food, fish, aquaculture, forestry and bioeconomy sector is included in the National Life Sciences Strategy. The consultation correctly notes that life sciences span (bio)pharmaceuticals, medical technologies, agriculture, fisheries, and food production but as pointed out in the EU Life Sciences Strategy, the National Life Science Strategy should also include bio-based and environmental elements to support agri-food systems development, climate action, carbon capture, circularity, waste prevention and ecosystems restoration and support.

The scope should encompass:

- a) **Agri-food, forestry and bioeconomy systems** – including sustainable biomass production such as new protein, fibre and starch sources (plant, microbial, fungi, marine), and circular reuse of materials such as nutrient recycling and rural/farm-scale biorefinery concepts.
- b) **Blue bioeconomy** – macroalgae and fisheries ingredients, aquaculture side-streams and new value chains in marine biotechnology, and recognise the importance of effective implementation of the National Strategic Plan for Sustainable Aquaculture Development as a key enabler of blue bioeconomy development.
- c) **Biotechnology and biomanufacturing** – biorefinery technologies including fermentation, biocatalysis, precision and biomass fermentation etc, and bio-based advanced materials, in line with the EU Life Sciences strategy’s emphasis on biomanufacturing and sustainability.
- d) **Bioenergy and fuels** – especially where integrated with circular and cascading use systems (e.g., anaerobic digestion linked to green biorefineries, bio-based fertilisers and biogenic CO<sub>2</sub> valorisation).
- e) **Nature, climate, and ecosystem services** – restoring and managing soils, water and biodiversity using bio-based, nature-based and carbon removal solutions, aligned with Carbon Farming, One Health, and EU climate, soil and nature restoration objectives.

Ireland has already adopted a whole-of-government, system-wide framing of the bioeconomy through the National Policy Statement on the Bioeconomy (2018) and the Bioeconomy Action Plan 2023–2025, which define guiding principles (sustainability, food-first, cascading use, precautionary, area-based), strategic objectives and seven pillars spanning governance, RDI, climate, primary sectors, regions, industry and skills.

We therefore propose that the scope of the National Life Sciences Strategy:

- a. Adopts the EU definition of life sciences (covering health, agriculture, food, environmental and industrial applications of living systems) and
- b. Formally embeds the bioeconomy as an important organising concept for life-science-based activity outside human health, recognising the many interlinkages between health, agri-food, environment, and climate (including e.g., One Health).

This would ensure coherence with:

- Project Ireland 2040 and the National Planning Framework, where the bioeconomy is already recognised as a lever for rural development and circularity;
- Ongoing work towards a National Bioeconomy Strategy in 2026, following the updated EU Bioeconomy Strategy and the EU Life Sciences Strategy amongst others.

## 2. Objectives

To ensure the long-term success of Ireland's life sciences and bioeconomy, we suggest that the National Life Sciences Strategy adopt the following high-level objectives:

### 2.1 Strategic positioning and competitiveness

- a) Position Ireland as a leading European location for sustainable life sciences and bioeconomy & agri-food investment, building on an already strong life sciences cluster.
- b) Position Ireland as a global leader in aquaculture technology. Ireland's aquatech sector has grown rapidly in recent years. The Ireland Strategic Investment Fund has identified the potential for growth in this sector, investing €15 million in an aquatech accelerator Hatch Blue's Revolution Fund. The aquaculture industry now accounts for over half of all seafood produced globally, and is forecast to remain the main driver of growth in seafood production (OECD Outlook 2025-2034). Irish companies are already achieving global reach, and we are well positioned to develop Ireland as a leader in aquatech, as has been the case in the medtech sector
- c) Leverage Ireland's natural biological resource base and existing demonstration strengths (grass- and dairy-based whey biorefineries, marine biorefinery, biomethane, biofuels) to become a testbed for sustainable biomanufacturing and circular bio-based value chains.

### 2.2 Integrated approach & system transition

- a) Embed wide thinking approaches so that health, food, climate, and environment policies are co-designed and co-evaluated, reflecting EU priorities for integrated life sciences governance.
- b) Use life sciences to accelerate net-zero and nature-positive transitions, linking biotechnologies and bioeconomy solutions to climate action, circular economy, water resilience and nature restoration.

### 2.3 Innovation pipeline: from research to deployment

- a) Strengthen the full innovation pipeline from excellent research through piloting and demonstration to commercial scale, aligning and leveraging current investments in:
  - a. Research centres (e.g., Teagasc, BiOrbic and the numerous university-based bioeconomy groups (ATU, MTU, TUS, TUD etc)
  - b. National and EU infrastructure (e.g., Federating Irish Research Infrastructures to Accelerate Development of Sustainable Bioprocesses (FEDERI) and European Research Infrastructure dedicated to Industrial Biotechnology and Biomanufacturing (IBISBA), other R&I infrastructures), and
  - c. New pilot and demo facilities (e.g., Lisheen National Bioeconomy Campus, BioConnect Centre, Teagasc bioprocessing facilities, Just Transition Fund demonstration projects).
  - d. And ensure predictable funding pathways for scale-up of capital-intensive biobased processes (advanced fermentation, multi-product biorefineries), combining national

instruments, EU programmes (Horizon Europe, CBE-JU, Innovation Fund) and blended finance models (InvestEU) including new MFF developments (e.g., ECF).

#### 2.4 Talent, skills, regions and just transition

- a) Develop a life sciences (including bioeconomy) skills roadmap aligned with the EU work on competencies for life sciences, with particular focus on: technicians and operators for bioprocessing, data and AI skills, sustainability assessment, and place-based innovation facilitators. Leverage current work ongoing by the Circular Bioeconomy Education Centre and others.
- b) Support regional bioeconomy hubs, districts and living labs, building on existing clusters (Circular Bioeconomy Cluster, North-West Bioeconomy hub, BioConnect, Lisheen, Teagasc Moorepark & Ashtown, Just Transition projects) to ensure the benefits of life sciences are widely diffused and support a just transition in rural and lagging regions.

#### 2.5 Governance, regulation, and data

- a) Align national regulatory and governance frameworks with forthcoming EU measures (EU Biotech Act, EU Bioeconomy Strategy, and relevant Digital Economy activities), ensuring Ireland is an “early adopter” and attractive location for trials, regulatory sandboxes and data-driven innovation.
- b) Invest in monitoring and evaluation, so that the life sciences strategy and the bioeconomy as part of this is underpinned by robust indicators and system-level learning.

#### 2.6 Funding Frameworks

- a) There is a need to ensure integrated and clear state funding frameworks across both EU and exchequer funding streams, including funding supports under the National and Regional Partnership Plan (2028 – 2034), the European Competitiveness Fund (ECF) and Horizon under the next EU Multi-annual Financial Framework; the European Investment Bank (EIB); the Disruptive Technologies Innovation Fund; the Ireland Strategic Investment Fund (ISIF) and the Strategic Banking Corporation of Ireland (SBCI). There is an opportunity to set out a clear strategy for the targeting of state investment supports, recognising and leveraging the role of private investment in the implementation of the Strategy

### 3. Opportunities and challenges for Ireland’s life sciences & bioeconomy

#### 3.1 Key opportunities

##### *a) Strong starting position and policy coherence*

Ireland already has:

- A dedicated National Policy Statement on the Bioeconomy, a Bioeconomy Action Plan 2023–2025 and planned National Bioeconomy Strategy,
- Cross-government implementation structures and a Bioeconomy Forum/Expert Advisory Group, and
- Integration of the bioeconomy into many major national strategies (Climate Action Plan, Circular Economy Strategy, Food Vision 2030, Our Rural Future, Impact 2030, Smart Specialisation).

The National Life Sciences Strategy can further consolidate this coherence by taking a more active role in addressing horizontal matters related to biotechnology for the bioeconomy-relevant life science activities as well as other areas.

#### *b) Demonstration strengths and industrial niches*

Ireland has credible “in-the-field” examples spanning:

- Emerging grass and other plant protein & fibres bioprocessing and large-scale dairy biorefineries.
- Blue biorefinery and marine ingredients,
- Biofuels and emerging biomethane, with biomethane presenting as a major growth frontier.

These strengths mirror EU priorities on industrial sustainability, biorefineries and advanced fermentation, giving Ireland a realistic opportunity to host flagship EU-level demonstration sites and to pilot new regulatory and financing approaches.

#### *c) World-class research, talent and growing infrastructure*

The ecosystem of Research Ireland centres, university groups, and emerging infrastructures (Lisheen, BioConnect, Teagasc facilities, DCU microbial bioprocessing suite, regional hubs including BioConnect) provides a strong basis for:

- development of highly skilled level 10 talent that can then enter the life science sector
- multi-disciplinary R&I,
- industry–academia collaboration, and
- participation in EU partnerships and infrastructures such as IBISBA.

This aligns with the EU Life Sciences Strategy’s emphasis on partnerships, food and bio-clusters and research and technology infrastructures as engines of competitiveness.

#### *d) Public engagement and awareness*

Bioeconomy Ireland Week, the National Bioeconomy Summit and the work of the Bioeconomy Forum offer ready-made channels for public and stakeholder engagement on life sciences, innovation and societal challenges. These can complement EU-level efforts to build public trust and combat disinformation around life science technologies.

### 3.2 Key challenges

Despite these opportunities, several challenges must be addressed:

#### *1. Areas of focus*

Developing a “life sciences strategy” that is only focused on (bio)pharma and medtech risks missing opportunities to develop a broader, more comprehensive life science sector that is more reflective of the Irish economy and in turn, offering economic opportunity for all regions. This would also under-exploit the potential of agri-food, marine, biotechnology, and nature-based solutions, and would run counter to the EU strategy’s broad framing of life sciences covering health, food and sustainability.

#### *2. Governance and funding*

Irish bioeconomy implementation has already demonstrated the value of cross-government coordination; it is important that enterprise, health, agriculture, marine, environment, regional

development and higher education funding streams are designed and evaluated together. The EU Life Sciences Strategy highlights the need to avoid fragmentation and the difficulty of moving innovations through development stages; Ireland faces the same challenge at smaller scale.

### *3. Scale-up finance and risk appetite*

- Advanced fermentation and multi-product biorefineries are highly capital-intensive, and private investors are often wary of technology and market risks.
- While new instruments (e.g. SOSV (global, multi-stage venture capital firm)/Irish Strategic Investment Fund biomanufacturing fund, Just Transition and Shared Island bioeconomy demonstrators) are very welcome, there is still no coherent, long-term financing pathway from lab to first-of-a-kind plants.

### *4. Regulatory complexity and coherence with EU frameworks*

- Companies report challenges navigating overlapping EU and national rules, and the EU itself notes that current frameworks can be complex, fragmented and insufficiently innovation-friendly.
- Ireland will need to invest in regulatory capacity (and possibly pilot “one-stop shop” services) to make full use of the EU Biotech Act, regulatory sandboxes, and AI-enabled tools for navigating the EU regulatory landscape.

### *6. Skills, capacity, and rural/ regional balance*

- Shortages of bioprocess engineers, data scientists, regulatory experts and technicians could constrain growth. Regional disparities in infrastructure and skills provision may also mean that some communities struggle to participate in emerging bio-based value chains, risking an uneven transition.

### *7. Sustainable biomass use and environmental integrity*

- Both the EU and Ireland emphasise the need to avoid unsustainable biomass exploitation. The strategy must ensure that bio-based growth respects food-first principles, nature restoration, water quality and climate targets, using monitoring tools such as INFORMBIO<sup>3</sup> and BioValue.
- Addressing these challenges will require strong cross-departmental governance, aligned incentives and long-term policy stability.
- Scaling aquaculture production has proved challenging in Ireland. Production volumes in Ireland significantly lag both EU and global production averages. Effective implementation of the National Strategic Plan for Sustainable Aquaculture Development has the potential to support the scaling and diversification of Ireland’s aquaculture sector, in particular the development of algae aquaculture. Scaling and diversifying our aquaculture production will assist in mitigating the risks of unsustainable biomass exploitation in marine areas, increasing production of sustainably farmed seafood for human consumption, and biomass from aquatic plants and animals.

### *8. Public understanding and awareness*

---

<sup>3</sup> [Informbio Project - for a sustainable and circular Irish bioeconomy.](#)

Efforts are required to education, inform and raise awareness among the general public of some of the key technologies that will be key enablers of a future focused life science sector, such as biotechnology, biomanufacturing, advanced fermentation, etc.

#### 4. EU context

The EU Life Sciences Strategy aims to make the EU the most attractive place for life sciences by 2030, with actions grouped around:

- Optimising the R&I ecosystem
- Ensuring smooth and rapid market access for innovation, and
- Boosting the uptake and societal acceptance of life science solutions.

Ireland's National Life Sciences Strategy should:

##### 4.1 Embrace the EU's broad vision

- Explicitly align with the EU's broad understanding of life sciences, including their roles in health, food systems, climate, bio-based industry and rural development.
- Position the Irish bioeconomy as a key delivery mechanism for EU priorities on industrial sustainability, biomass management, advanced fermentation, biorefineries and safe-and-sustainable-by-design materials.

##### 4.2 Align national instruments with EU initiatives

- Map Irish funding and infrastructure against EU instruments current (Horizon Europe partnerships and missions, CBE-JU, LIFE, Innovation Fund, future EU Bioeconomy Strategy and Biotech Act), and upcoming (European Competitiveness Fund, Framework Programme 10 Horizon Europe) identifying where Ireland can lead or host flagship initiatives – especially in biomanufacturing, agri-food, marine and rural demonstration.

##### 4.3 Use EU frameworks to de-risk innovation and scale-up

- Leverage the EU Biotech Act, regulatory simplification and AI-based regulatory tools to pilot more agile, innovation-friendly regulatory models in Ireland (e.g., regulatory sandboxes for bio-based processes).
- Actively connect Irish SMEs and start-ups to EU-level investment initiatives (EIC, EIB, deep-tech funds, life sciences investors) and use national co-investment to crowd in private capital to Irish bioeconomy projects.
- New Genomic Techniques (NGTs) provide new opportunities to alter the genetic material of an organism allowing the rapid development of plant varieties with specific characteristics. These techniques can lead to more targeted and precise modifications to the genome than conventional breeding. On 05 July 2023, the European Commission adopted its proposal for a Regulation on plants obtained by certain NGTs and derived food and feed products. In early December 2025, a provisional agreement was reached at trilogue and will be voted on at COREPER on 19<sup>th</sup> December 2025. If the agreed Regulation is formally adopted by the Council and the Parliament, it will pave the way for the use of this new technology for plant breeding, which will provide many opportunities in this area, trade with third countries, and alignment with various wider policies in the agri-food sector. It will also open up significant new opportunities for the life science sector

#### 4.4 Co-evolve with EU Bioeconomy and wider agendas

- Ensure that the National Life Sciences Strategy and the forthcoming National Bioeconomy Strategy are well aligned, and both are consistent with the updated EU Bioeconomy Strategy and wider agendas e.g., the EU's One Health and climate-health research agendas.
- Commit Ireland to being an active contributor in EU initiatives on:
  - microbiome-based solutions,
  - strategic food-biobased systems R&I, and
  - research where relevant to bio-based products, service, and technologies.

### 5. Concluding remarks

Ireland has a unique opportunity to demonstrate the breadth of its life sciences in this Strategy by including agriculture, food, forestry, marine, and the bioeconomy along with the other sectors such as health and pharma. By adopting a broad scope, clear objectives, and a strong alignment with the EU Life Sciences and Bioeconomy Strategies, the National Life Sciences Strategy can:

- ensure we stand out as a country taking a comprehensive, leadership approach to the development of our life sciences as a key part of our economy, for the betterment of our overall wellbeing at human, economy, society and environmental levels
- accelerate a sustainable, circular and climate-neutral economy, and
- ensure that rural and regional communities benefit from high-quality, future-proof jobs and resilient ecosystems.

We would welcome further engagement as the strategy is developed and can contribute more detailed input on specific thematic areas (e.g. biomanufacturing, blue bioeconomy, regional biorefinery hubs, skills etc) as needed.

## Submission from D. Shanahan

### Observations on supporting the development of Ireland's Life Sciences Industry, via DETE Consultation.

Dear sir/madam,

#### **Context of the opinion**

I applaud the government seeking input to the National Life Sciences Strategy Development. This is one of our most critical economic sectors, one with abundant future promise and challenge. This submission is made without the use of AI. It is informed from over 35 years working across numerous aspects of Ireland's medical, commercialisation and industrial system.

Notable experiences informing these observations, include:

- MD Pfizer Healthcare Ireland, Director Pfizer UK.
- Founding CEO Charter Medical Group – Advanced Ambulatory Healthcare delivery for older people.
- Global Head of Lifesciences IDA Ireland 2009-2012.
- Head of Strategic Health Initiatives AbbVie inc, Venture Partner, Treo Ventures Medtech USA, Founder Adagio Ventures Ltd, Aribamed Ltd, Athena Pharmaceuticals Ltd.
- Chairman Omnispirant Gene Therapy, ( a DTIF Awardee).
- Government – previously, member of National Competitiveness Council, TCD Medical School Tercentenary Committee, observer at Bioinnovate, APC Cork.
- Board member Enterprise Ireland 2016-2025, Chair of National Oversight Group, Health Innovation Hub Ireland, 2013 to present day.

My opinions have been formed through seeking to align state and industry actors together in shared development, engaging extensively with Multinational and SME leaders across product design, development and commercialisation across biopharma and medtech.

Personally, I have invested in and contribute to start ups in executive roles in health related software companies, in pharmaceutical distribution, in clinical decision support software, drug safety software, drug supply chain software and medical device development and manufacture.

#### **Opportunity**

Life Sciences straddles innovation across the food, pharma, medtech, biotech, marine and biologic world. It contains enormous global markets such as pharma/medtech/healthcare/materials science, veterinary medicine, food, marine, etc.

Its activities directly impact all global citizens and our planetary ecosystems. It impacts daily life, from what we eat, to how we manage health, to how we husband agricultural and marine resources. It is also concerned with health welfare – protecting global populations of humans and animals from pandemics, infection and disease.

As human activity impacts climate, environment, water quality, the scientific disciplines of Life Sciences have never been more important for global food supply, healthcare and environment.

Our present national position within the OECD, means where intellectual property, asset development, services innovation, software and hardware innovations are developed, we have a proven export capability with an aligned tax proposition for corporation tax, R&D Tax credits and Patent Protection, hence Life Sciences related product and service development presents large export opportunities, whereby domiciled Irish entities earn revenues overseas, paying local corporation taxes, payroll taxes for operations and contributing to our national fiscal and educational position.

Life Sciences development and product adoption holds tremendous promise in making our health and education systems more productive, lowering costs, improving outcomes and developing future scientific leaders of global impact. It is also a major present driver of our national fiscal surplus, presently being expended across all parts of our economy. The potential for significant reductions in national income from the Life Sciences sector in future years is inevitable, if we do not energise a transformation agenda nationally to support it.

### **The challenges we face**

With the advent of scale software, machine learning, artificial intelligence, the pace of change, disruption and challenge to large indigenous activities within Ireland's Life Sciences Industry are profound.

Our successful FDI model, based on attracting largely US investment and operational capacity across advanced manufacturing in Life Sciences, has been impacted by the US administration's move to "America First".

Deficits in our domestic environment present extreme challenges to our national value proposition in Life Sciences. Our globally leading value proposition versus competing global life science locations has taken a backward step, in the context of competing progress in Asia (China mainly), but also in countries where coordination and regulation is more supportive, such as Singapore.

Lower cost locations have sought to attract the FDI we seek. The lower costs of operation, utilities, prices, talent availability and government flexibility, as well as the R&D agenda and funding available, are drawing investment away from Ireland.

Our present challenges in housing, affordability and infrastructure deficits/delays are undoing decades of progress achieved in improvements to our educational and enterprise system.

The present challenges come with the added impacts, yet to be fully amplified by Artificial Intelligence, Robotics and "Manufacturing 4.0". Electrification is rapidly becoming the largest impediment to the adoption and roll-out of AI. Ireland's planning ecosystem, our carbon agenda and the national capacity supporting talent attraction/retention, immigration and the real prospect of declining future corporation taxes from their present highs, present a systemic challenge to business and social development, across all industrial sectors, regions and communities.

The extensive fiscal surpluses we presently enjoy, via the corporation taxes of advanced multinationals, will dwindle as investment goes elsewhere and our stock of assets and capabilities age, becoming less competitive, versus powerhouse countries in Life Sciences, such as China and the USA.

### **Why do we need to transform our vision of our Life Sciences Industry?**

My overall view is that Ireland has a fragmented and disjointed ecosystem for Life Sciences. Moreover, regulatory, fiscal and statutory hurdles which we continue to amplify versus other jurisdictions, make the small domestic market a negative outlier for sensible or rewarding investments into Life Sciences Innovation.

Notable examples include loss of CE Mark flexibility to rapidly advance medical device approval in Europe, the Medical Device Regulation changes, (MDR), which have introduced a bureaucratic slowness to device registration, the obstacles to clinical trial set up and recruitment, excessive interpretation of (GDPR) and Data Protection Regulations, misinterpreted or implemented too rigidly, the lack of capacity and expertise in our Notified Body, the NSAI, being unable to recruit/retain the specialist skills required, an insufficiently supportive National Health Products Regulatory Authority, to drive domestic production, a cascade of obstacles to industry engagement by government funded entities, whether in

procurement, or in seeking support for new product development, introduction in medical devices or pharmaceuticals.

We have University competition, not “co-opetition” and an overall fragmentation in funding towards start-ups and scale-ups, allied to a paucity of investment capital for biotech in the early “extreme risk” years. This all contributes to promising start-ups being acquired by multinationals, as founders struggle to take any money off the table, short of a company exit.

In summary, our Life Sciences Ambition is being thwarted by a panoply of competing and constraining forces ranged against it by a combination of regulatory, government bureaucracy, uncoordinated and paradoxical policies. We have fiscal policies that penalise risk investment and innovation, scale impediments from our population size, mis-aligned actors (many funded by government) and a Health System, which regards itself as independent, in the national effort to realise the benefits of domestic innovation and does almost nothing to support local industry collaboration.

Despite the incredible embedded footprint of pharma/biopharma/Medtech/Food/Engineering/Software Tech from multinationals and SME's domestically, its true to observe that **“No other country has done so little with so much”**. Our Health System (HSE) has been oriented to deliver healthcare, without an imperative to exploit the rich assets in industry, academia on its doorstep. The raison d'être for **Health Innovation Hub Ireland**, was to seek to catalyse industry-HSE Collaboration for Irish companies and entrepreneurs. While this has been very helpful, its annual funding c.€1Million in personnel pales beside the 2025 operating budget of the HSE (combined opex and capital exceeding €25Bn).

The HSE lacks a development and research mandate consistent with a national Life Sciences ambition.

The HSE's Board lacks sufficient direct industry experience in Life Sciences. The HSE's own communications ignore the importance of innovation, R&D, or the support possible to domestic industry and academia. The executive structure denotes no person charged with supporting the national Life Sciences ecosystem. A sector contributing a large part of the HSE's annual budget is completely ignored and omitted from its focus, policies or interest. This explains some of the gap “lower in the machine”, that also ignores domestic opportunities as too small, not in scope, or too difficult to entertain.

The DOH and HSE structures compete and confuse the innovation agenda, where the policy agenda of the DOH is focused on population health, EU procurement, social improvement, policy development, but the contribution of domestic Life Sciences Innovation towards achieving and accelerating these goals is completely overlooked. EU procurement rules, the HSE's monolithic requirements for systems and services that only multinationals can provide, mitigates against domestic SME collaboration, innovative procurement or support.

There is no incentive or penalty applying to this lax disregard by the HSE of its domestic industries, nor any deep awareness or concern within the government departments or broad civil and public service, that **we have a national market failure in Life Sciences**, to catalyse domestic industry and innovation to grow, develop and deliver solutions, to be used within our national health system.

The Health Research Board, under the Department of Health successfully delivers social research useful for future planning. However, it has no remit to work with industry. Again its orientation is not favourable for same.

Research Ireland has funded Clinical Research Facilities across our University Health Campuses. This has been helpful, But the investment in identifying, consenting, recruiting patients into clinical trials has not been sufficient to provide industry a value based alternative to countries in Eastern Europe, South Korea, Australia who are more favourable locations for phase 1 clinical studies in humans and later trials. The National Ethics committee approach is too slow and cumbersome to ignite clinical trial acceleration. It is hoped the recent strategy unveiled by the Minister for Health, Ms Jennifer Carroll McNeill may improve the adoption, development and execution of clinical trials, which is at the forefront of pharmaceutical investment. It contains some clear actions for the proposed National Clinical Trials Advisory Council, arising from the National Clinical Trials Oversight Group. But its

timeframe for delivery is too long – end of Q4'27 and nowhere in the strategy has the role of the clinician investigator been identified and supported. We already have severe limitations placed on key investigators, due to excessive clinical workloads, suppression of research time, etc. The limited number of partially funded and full time funded academic-clinical appointments are too few, to build out the regional clinical networks envisaged. Without the high activity clinical consultants in our public hospitals, leading on clinical trial adoption and implementation, we will not achieve the recruitment volumes, rates or quality which are key to be a leading national country in this area. In short, again, we have omitted the central role of publicly employed healthcare professionals being co-opted into our national enterprise agenda.

The statutory basis of numerous actors who work across the development and commercialisation continuum of Life Science Products, creates competition, conflict, inertia and barriers, to identifying and scaling innovation, which might attract foreign direct investment or offer solutions, that SME's can scale and export globally.

I have direct experience to inputting observations to PRTL (programme for research in 3<sup>rd</sup> level institutions), where University applications were replete with duplication of research approaches, with little incentive for Principal Investigators from competing universities, to be tasked to consolidate research efforts and build scale for impact. The "spray and pray" approach to funding numerous regional initiatives in research at sub-optimal levels of funding, inevitably led to subscale innovation and a lack of impact in critical emerging disciplines, where Ireland has capability – e.g. genetics, advanced therapeutic medicinal product development and large scale population studies.

More recent efforts by Research Ireland to prioritise funding towards differentiated fundamental science, awarding grants on merit and impact, attracting intellectual capital from overseas to work in academia and industry are welcome and changing this dynamic.

The IDA's development of NIBRT facilitated the training of a biotech workforce for pharmaceutical production. Its inception and scale would have been accelerated, if the bidding process to award a single University consortium, did not result in leading national Biotech Scientists of international repute, almost boycotting collaboration, as they were part of a competing and unsuccessful consortium. Here, the awarding methodology involved EU procurement rules, sacrificing capacity and knowledge, in order to observe regulations considered expedient. Revisiting the manner in which one should construct national facilities of strategic national importance to include all our national experts, was never contemplated. Those lessons should be learned to avoid such a repetition ever again.

### **Our Life Sciences Ambition**

The government through the Department of Enterprise, Tourism and Employment, is wise to reconsider its approach to the national Life Sciences Opportunity. The sector runs horizontally across all aspects of Irish life and our economy, across our primary, secondary and tertiary education system, to industrial development, manufacture and commercialisation of products and services applicable to humanity and all biologic entities with whom we share the planet.

Ireland's peripheral location, its island status, its small population, open borders, global diaspora and EU and US market access, underline the importance of export development for national income gain. But the competition to win ranged against us, from large countries with larger populations, better university systems, more capital and talent and a lower cost base, means in order to thrive, we must out-compete the bigger by becoming more agile, focused, faster and easier to work with.

The electrification challenge pertaining to AI, the infrastructure deficits, housing and inflation and costs are all being addressed via the National Development Plan. Via the NDP, we hope to exploit our abundant onshore and offshore wind assets, in turn improving competitiveness of our Food, Life Sciences, Software and Services exports amongst others.

Although we have capacity to grow our infrastructure, talent and tax offerings in Life Sciences, we are too complacent about our present trajectory. This requires a fundamental restatement of our life sciences ambition, **identifying the development of "Our Life Sciences Industry" as a national imperative**, one which takes precedence over the objections of vested interests, those objecting to infrastructure which supports this ambition, e.g. data centres, windfarms, etc.

Our Life Sciences Ambition must engage and co-opt the 137,000 people who work across our national healthcare system. We need a commitment within the HSE's National Service Plan to support Life Sciences, engaging with industry and academia, testing, adopting and scaling locally developed and delivered innovation.

It requires an acknowledgement by DPER of the imperative to invest windfall tax revenues in advancing academic/industrial efforts via an increased budget for R&D investment by government, enhanced tax supports for investors, entrepreneurs and manufacturers of Life Science Products. It requires a shared imperative across numerous government departments to align – specifically government departments such as *DETE/DOH/Dept of Agriculture/Dept of Environment/Dept of Further Education, Research and Science/Dept of the Marine..etc*

It requires a reordering of the objectives of regulatory bodies such as the HPRA, the NSAI and the National Centre for Pharmacoeconomics, the Health Research Board, the National Research and Ethics Committee and a host of actors to align them in parallel, not sequentially, to speed up support, decision-making and funding of activities that pertain to Life Sciences Innovation. This includes supporting advanced manufacturing, even if AI/Robotics/Manufacturing 4.0, will eliminate local jobs in existing companies/industries.

#### **Getting to YES – the Imperative to Consolidate, Collaborate and Catalyse**

Government ministers, their departments and civil service must be enjoined in an appropriate risk-based governance to ensure that the priority of advancing Life Sciences Innovation, the testing, trialling, adopting and scaling of academic and industrial output, becomes an over-arching imperative. *This goal should form part of every relevant public sector employee's objectives.*

The present morass, for that is what we presently have, comprises universities, the HSE, regulatory, oversight bodies, hospitals, industry trade bodies and a host of related parties, stuck in a system that appears impervious to change and also appears unconcerned relative to our rapidly diminishing Life Sciences Value Proposition versus competing parts of the world. This needs immediate and urgent action to address.

We presently lack a consolidated vision, a stated ambition and a clear commitment to progress, with an intolerance of bureaucracy and inertia. Present aspirations, published as in so many strategies are not credible, when lacking specific funding streams, measurable outcomes, key performance indicators and clear incentives for success and penalties for those in the delivery system who fail to deliver.

Our present lofty visions appear ambitious, but fly in the face of reality, when one recognises the deep inertia, the constraints and the obstacles placed in front of those who wish to accelerate progress, challenge waste and duplication, or call out deep failures in execution.

We need a national conversation, frank about reality and clear in its determination to eliminate these obstacles in a rapid and comprehensive manner.

The delegation of important national development plans to government bodies, with too little industry input, too little industry participation and too little consequences for failure, has led to a 2 speed implementation, where industry must power on, whilst government policies run behind and frequently fail to catch up sufficiently to be helpful.

The desegregation of policy across numerous government departments and entities, means coordination is lax, missions are confused, responsibilities are not delegated and there is a demonstration of an inability to deliver. Examples include construction of the National Children's Hospital, resolution of Ireland's lax and bureaucratic ethics approvals for clinical trials, resolution of the

biobanking deficit to support clinical research, funding of competing health streams in academia when when consolidation and cooperation should be instituted.

The costs of asset development, the fees for license submission and approval, the costs of clinical trial set-up and coordination, the barriers to market access and the costs of production due to inflation in payroll, energy, environment and related costs of operation, *have made Ireland uncompetitive with other jurisdictions when it comes to Life Sciences Development in biopharma and medtech.*

**Proposed Initiatives to be considered to improve the next decades in Irish Life Sciences.**

My graphics portray some elements of the Life Sciences innovation and Development ecosystem – they are neither comprehensive nor complete. They are intended to demonstrate how a clearer vision and consolidation of resources might be considered, to accelerate development within Life Sciences and commercialisation of output.

**The National Life Sciences Strategy should make the improvement, development and exploitation of Life Sciences products and services a national imperative.**

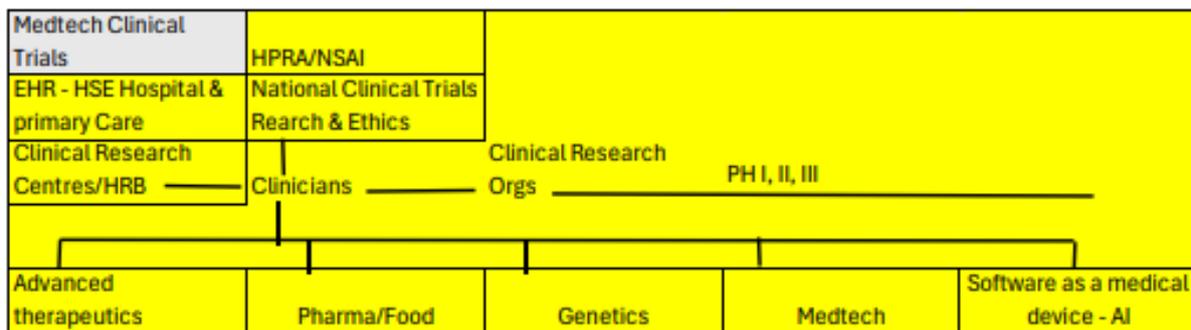
This imperative should be communicated and highlighted across all parts of our national educational, health and government ecosystem.

| <b>Examples of Life Sciences Enthusiasts - not exhaustive</b> |                               |                         |
|---|-------------------------------|-------------------------|
| <b>University</b>   | <b>Secondary School</b>       | <b>Primary School</b>   |
| <b>Medical School</b>   | <b>Nursing School</b>         | <b>Pharmacy School</b>  |
| <b>Psychology</b>   | <b>Research Professionals</b> | <b>Scientists</b>       |
| <b>Engineers</b>  | <b>Biologists</b>             | <b>Chemists</b>         |
| <b>Physicists</b>   | <b>Statisticians</b>          | <b>Biotechnologists</b> |
| <b>Materials Science</b>                                      | <b>Electrophysiology</b>      | <b>Design thinking</b>  |

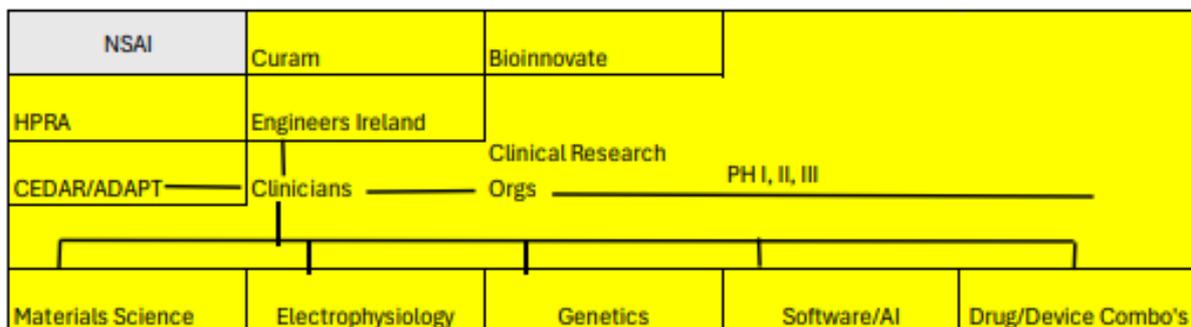
I highlight a framework - "A Continuum of Commercialisation" which consolidates our existing capacity and support base, to focus all parts of the Life Sciences Value Chain and pushes all actors within our Life Science ecosystem to move faster, with more ambition.

| TRL Levels   | 1  | 2  | 3   | 4  | 5   | 6   | 7  | 8  | 9  |
|--|--|--|---|--|---|---|--|--|--|
|  | Basic Research — Concept — Proof of Concept — Validation — Prototype — Qualified — Implementation  |  |   |  |   |   |  |  |  |
| Enterprise Ireland, IDA Ireland, Research Ireland  | TRL 1: Basic principles are observed and initial research begins.  | TRL 2: The technology concept and potential applications are formulated. | TRL 3: Analytical and experimental proof-of-concept is demonstrated in a lab setting. | TRL 4: Components are validated in a laboratory environment. | TRL 5: Components are validated in a relevant, simulated environment. | TRL 6: A system model or prototype is demonstrated in a relevant environment. | TRL 7: A system prototype is demonstrated in an operational environment. | TRL 8: The actual technology is completed and qualified through testing. | TRL 9: The technology is proven through successful operation in its final environment. |
| Health Research Board  | NSAI: National Standards Authority of Ireland, HPRA: Health Products Regulatory Authority, NCPE: National Centre for Pharmacoeconomics, HIHI: Health Innovation Hub Ireland, FSAI: Food Safety Authority of Ireland, EPA: Environmental Protection Agency, Clinical Trials Ireland, technology research centres ADAPT, CoADAR Technology Centre, CURAM, Bioinnovate, IPHA: Irish Pharmaceutical Healthcare Assoc, Medtech Ireland, Pharmachem Ireland, MFI: Medicines For Ireland, National Ethics for Clinical Trials, etc. |  |   |  |   |   |  |  |  |
| The University Alliance  |  |  |   |  |   |   |  |  |  |
| NSAI/HPRA  |  |  |   |  |   |   |  |  |  |
| The HSE Executive<br>Medical/Nursing Unions<br>NCPE/HIHI<br>The FSAI<br>The EPA<br>Teagasc<br>etc, etc | National Imperative to align, structure, consolidate all national efforts in a coordinated continuum of development to commercialisation   |  |   |  |   |   |  |  |  |

**Clinical Trials** form part of the low hanging fruit, available to us now. They are instrumental in moving Ireland further back into the earliest parts of the value chain of medicines and devices. Engaging with innovation earlier, means we can leverage our educational and industry footprint, as well as win new mandates from existing embedded industry in pharma/medtech/food/tech/marine, etc.



**Our 3<sup>rd</sup> level institutes, technology research centres, Hospitals and clinical research Centres can all be better coordinated** and unified to provide a simpler, more accessible and coherent system for collaboration and partnership.



### Pharma end to end development, manufacture and commercialisation

A major industry segment operating in Ireland at present is the small and large molecule development and manufacturing industry we call pharmaceuticals. This is exclusively concerned with the development and commercialisation of medicines for human and veterinary use. It also includes products used in agriculture and food production.

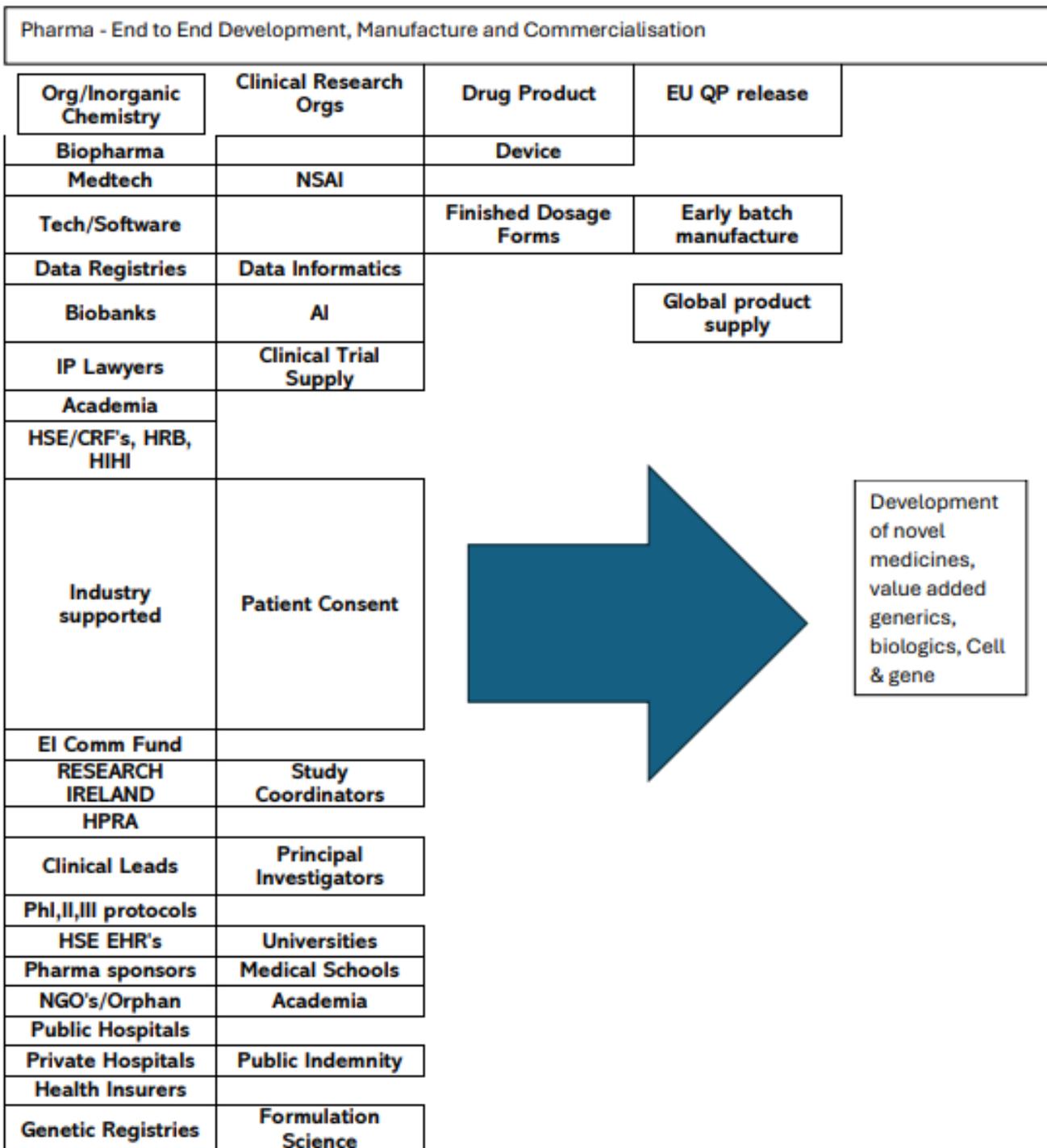
Latter location decisions by large molecule manufacturers, so called biopharma, who focus on biologics development and manufacture, have placed Ireland at the forefront of the global industry. As new innovations in biologic medicines become developed, Ireland can offer capacity and expertise in their manufacture, downstream processing and purification for eventual "finished dosage form" development.

Through our corporate tax offering, (which may yet suffer further US Government Administration review), Ireland captures a huge portion of the overall profit of medicines and their supply chain, the profits of which are rebated to the Irish government as corporation taxes. The industry contributes further immense revenues through payroll taxes, R&D activities and its requirement for a specialist supply chain across ingredient importation, facility construction, engineering, advanced manufacturing, control systems and advanced utility development. Therefore for every single direct job involved in pharmaceuticals, its likely 3 or more jobs are created in sub supply companies and the overall economic and ecosystem contribution is enormous.

The growth of pharmaceutical exports is narrow, with Mounjaro® (Eli Lilly's GLP1 Medicine), considered to the primary driver of growth in exports (and likely corporation taxes).

Locally however, there are significant market failures within the existing pricing and supply agreement between the IPHA and the DoH which penalise innovation.

- 1) There is an annual downward only reference price review (vs EU average price) for established medicines. This takes no account of the costs of complying with the unique manufacturing and packaging for Ireland's small population, determined by compliance with the EU Falsified Medicines Directive. This increases unit costs of production versus larger markets. Many older important medicines have been denied a price increase in over 10 years, a period when inflationary costs have soared.
- 2) The regulatory costs of application to the HPRA, the costs of manufacturing specific batches for Ireland, mean we cannot economically maintain licensing for older important medicines. Unlicensed imported alternatives of the same medicine from other markets cost a multiple of what was previously licensed and available.
- 3) *There is no price concession or support for medicines manufactured in Europe.* This incentivises Indian and Chinese providers with lower costs of production and government subsidies for manufacture which we lack. Even our Carbon Strategy does not consider the impact of importation from far away in our carbon tax or national procurement regime.
- 4) There is no acceptance or adoption of technology, which would allow pooled manufacture of UK and Irish medicines in one batch, with some 5% of the lower cost product destined for Ireland.
- 5) There is little accurate comparative costing by the HSE of the internal costs of compounding medicines within hospitals, versus the procurement costs imposed on private providers. The estimated HSE unit costs of production are demonstrably higher than industry can provide.
- 6) Timelines for HPRA and NCPE assessment have not improved despite ready availability of AI to streamline data examination and analysis.



Our Pharmaceutical industry is a jewel in the crown of our national industry. From modest beginnings in the late 1960's, Ireland is now the leading per capita exporter of Pharmaceuticals in the world. Eli Lilly's exports of GLP1 medicine "Mounjaro" from Ireland is a leading contributor to present pharma exports.

*It is notable that Ireland is not a recognised test bed for “Mounjaro”, nor a significant entity globally in the research of these medicines – we do however have globally leading clinical teams in this arena.*

*This is the crux of Ireland’s life sciences paradox, that is, whilst we are a major manufacturer and exporter of life sciences products, the vertical integration, end to end development and commercialisation has passed us by, in favour of more favourable locations. Much of the attraction premium of these locations is due to us, not developing a viable or competing value proposition.*

## **Conclusion**

***Government’s role is to create the environment for innovation to thrive.*** It can facilitate, sponsor and support the conditions for citizens, entrepreneurs, industry and academic partners to join together, collaborating to innovate, developing new products, opening new markets and developing enhanced services, the fruits of which contribute to national wealth creation.

This virtuous activity adds value, lowers cost, increases utility and economic growth. The dividends support improved education and social attainment.

Whilst much of EU policy must be transposed and implemented through Irish law, too often failings domestically are blamed on EU legal prohibitions, when in fact, much of the solution is under our control.

Governments must govern and set regulations. However, it is clear in some areas, governance has evolved into an anti-risk sentiment. We are failing to balance “considered risk” against its benefit and denying ourselves downstream benefits from a more entrepreneurial mindset.

Ireland’s national life sciences ecosystem, its embedded industries, academia and talent, face geopolitical challenges which may reduce the future output, potential and attractiveness of the sector.

We need to establish a clear growth mindset, an intolerance of impediments and mediocrity and a willingness to experiment, invest and expedite decisions, to move projects and programmes forward.

We must recognise the world as it is and consistently, fairly and impartially evaluate, our strengths and weaknesses, from the clear evidence before us. We must become intolerant of bureaucracy, poor performance, waste and lethargy.

We cannot build a future from a legacy value proposition, albeit one which created a global life sciences powerhouse in a country of 5.2 million people. With multilateralism failing, an ageing demographic with its consequent economic impact and declining future corporate taxes, we must find a way to energise our national life sciences industry and ecosystem to embrace growth and challenge it to further contribute to our national reserve of education, industry and economic output.

## **17 Recommendations to improve and enhance Ireland’s Life Sciences ecosystem**

- 1) The establishment of **a Life Sciences Steering Council**. This to be no more than 12 and include leading experts from academia, research, industry and government. It should be co-sponsored by the departments of Health, DETE and the Department of Further and Higher Education, Research, Innovation and Science. It should have material powers to influence the apportionment of financial resources and hold government and the public service accountable to meet specific identified targets, KPI’s and initiatives, pertinent to the Life Sciences Agenda.
- 2) **Consolidation of the IDA, Enterprise Ireland and Research Ireland’s Life Sciences teams**, so that individual agency mandates under DETE and DFHERIS pertaining to Life Sciences Development are made singular. Moreover, executives from the HSE’s executive leadership, the

HRB, the HPRA, NSAI, Teagasc, the Marine Institute and other expert groups should be co-opted appropriately into this grouping, with the objective to achieve national coherence and coordination around resource allocation, planning and national strategy supporting the development, scaling and support of domestic Life Science Companies and services.

- 3) **The HSE, should be mandated by government to include a national imperative to foster, support and advance domestic innovation in Life Sciences,** into the national service plan. Specifically, funding of 0.5% of the HSE's National Health and Social Budget (some €125 million), annually could be ringfenced and used regionally by the 6 HSE regions to procure specific Life Sciences Related products and Services. The individual purchase threshold could be set at a €50,000 ceiling to meet EU procurement directives.
- 4) **The adoption and integration of AI into healthcare should be accelerated as a national priority.** AI can consolidate data sets, identify patterns, support speed/accuracy of diagnosis (e.g. radiology/pathology) and structure care pathways to be more efficient and lower cost.
- 5) **Incentivisation and flexibility in procurement** should be directed at smaller indigenous drug manufacturers and developers. Upward pricing should be allowed to retain niche older medicines on the market, rather than present stock-outs and unlicensed imports at premium prices. The NCPE and Regulatory bodies should be instructed to use AI to expedite assessments and analysis and reduce the timelines for decisions/approvals/examinations. The NCPE and Regulators should be mandated to provide enhanced scientific advice and support to domestic companies. They should be required to provide more than the "one-hour, single consultation" the NCPE provides to industry presently to consult on Health Technology Appraisal data methodology. In fact, a formalised process of engagement between regulatory bodies and industry under any relevant heading should be written into the terms of operation of the agencies and bodies.
- 6) **Research groupings comprising skilled medical practitioners (consultants both private and public), should be enjoined in national research networks** along specific disease lines, so that scale could be achieved to compete for clinical trials and University Collaborations. Specific focus should be given to those clinicians with the highest clinical workload, in order to expedite patient recruitment and efficient trial completion.
- 7) **The Independent Hospitals sector** already provide almost half of daycase procedures. The health system in terms of IT, standards and governance should be made interoperable. For instance, the HSE's proposed Electronic Healthcare Record, must be made compatible for full integration of private electronic systems, so data can move freely and accurately.
- 8) **The Universal health identifier, the roll-out of the National Health App and the delivery of a national electronic health record should be accelerated.** As Northern Ireland has already implemented "EPIC", (as well as the National Children's and some maternity Hospitals), it appears possible to unify the Republic's health data with Northern Ireland, thereby offering an enhanced value proposition across 32 counties and 2 national health systems to industry for collaboration.
- 9) **The National Electronic Health Record should include a mandatory opt-in to data consent for anonymised analysis, consolidation for health research purposes, consent for organ donation.** Moreover, an opt-in for participation in clinical trials applicable to certain conditions, e.g. cancer, would speed patient identification, stratification and consent for clinical research. *All personal data once anonymised, disaggregated and de-identified, should be the property of the HSE and its further use in support of clinical research under any heading should be specifically permitted without patient consent.*

- 10) **The Electronic Patient Record should be integrated with** the Private Hospitals Electronic Records, the national GP record, HealthLink, the PCRS database, the Drug Payments Scheme, the medical card and long term illness scheme and the government services card for social welfare, the national driver's license database etc.
- 11) **The present Irish rules for medicines pricing and reimbursement mitigate against rapid market access** due to pharmacoeconomic constraints identified by the National Centre for Pharmacoeconomics (NCPE) attached to St James Hospital and the Corporate Pharmaceutical Unit of the HSE. Smaller than the UK's National Institute for Health and Care Excellence, the NCPE repeats analysis of budget impact and clinical effectiveness, whilst lacking the scale and expertise of the UK to undertake such analysis. The NPCE validation presents a market obstacle to new medicines launches as identified by the Irish Pharmaceutical Healthcare Association. It also reviews applications for pharmaceutical price changes, indication expansion and makes reimbursement recommendations to the CPU for consideration.
- The NCPE's results for the year to date in 2025, show that of 20 requests for Health Technology Appraisals required of industry, (which are expensive and slow to compile), none resulted in a recommendation for reimbursement, 4 were recommended not to be reimbursed by the HSE, and 16 were recommended not to be reimbursed at the submitted price! This demonstrates a threshold of effectiveness and cost benefit driven by the HSE's antipathy towards innovation and towards protecting the national medicines budget from the impact of innovation.
- A solution to this logjam, would be to accept and duplicate NICE UK decisions for Irish applications – this would expand the target market for pharma's application to the UK and Irish population.
- Moreover, Ireland could take a leadership position by **offering pharma innovators 1<sup>st</sup> reimbursement in the EU** at a high price. This could be agreed via a headline reimbursement approval price and a confidential rebate from the manufacturer to the HSE In return. ***This confidential rebate system is already in operation by the CPU and HSE.*** Numerous drug reimbursement prices today in Ireland are exaggerated, via the confidential rebate agreed with the PCRS (primary care reimbursement services).
- The benefits would mean pharma coming to Ireland 1<sup>st</sup> to seek EU reimbursement approval in order to set a high EU price reference benchmark. This would further add to the attraction of completing clinical trials in Ireland in order to partner with the HSE on reimbursement.***
- The attraction of clinical trials, market access and reimbursement would also stimulate manufacturing location decisions to Ireland of drug product. The same principles can be applied to medical devices.***
- 12) ***All clinical providers with an HSE contract should be automatically indemnified for undertaking clinical trials, provided the necessary ethics approvals have been secured.*** This protection should cover industry sponsored trials in respect of HSE employees.
- 13) **Important Public Health Initiatives such as national screening programmes** in cancer, genetics, orphan diseases etc., provide material data for research and should be published and disseminated to industry. All national screening programmes should be facilitated with the IT to maintain and collaborate on data registries, which can be compared to other countries. Consideration should be given to national genome sequencing for screening applicants, so as to identify and model genetic correlations to illness/disease. ***Large datasets such as TILDA (Ireland's longitudinal study on Ageing), should be supported for industry collaboration to export Ireland's longevity support success to other countries.***

- 14) *Ireland's medical training with its high focus on clinician to patient engagement is an outlier model in medical training* in much of the world. As such our medical schools provide a real world medical training that surpasses much of the theory and didactic programmes of the USA and other countries. We should support the increased training of overseas students in medicine, to visit our Hospitals and learn clinical skills at the bedside as we do.
- 15) **Attracting Talent:** Life Sciences is in a war for talent, whether as researchers, or health and allied care professionals. Our visa system should prioritise access to skilled Life Sciences Professionals and our path to citizenship for Life Science Professionals should be made faster and easier.
- 16) **Funding:** The risk capital available to Life Science Start-ups and Scale ups is suboptimal. As per previous government submissions, incentives should be provided to investors by way of enhanced tax abatement (EIS), tax write offs for losses and enhanced tax credits such as Entrepreneurs relief for founders. Pension funds should be mandated to allocate some level of low exposure to Irish start-ups, via government support or decision.
- 17) **Enhancing Government-Private Sector Understanding:** Securing the participation of industry professionals, start up graduates and private sector individuals in government departments can be enhanced by creating short term fixed contract positions, say 12-24 months to inculcate government and policy considerations within individuals and companies. A reciprocal scheme to take public service employees on secondment to private industry could also be contemplated. At the end of the appointment, the candidates would return to their original position, but with an enhanced understanding and ability to bridge the gap between industry and government collaboration.

## Submission from Dexcom

### EXTERNAL MAIL

Do not click links or open attachments unless you recognise the sender and know the content is safe or expected. Contact ICT Helpdesk if unsure

Dear Minister Burke,

My name is Orla Lovett and I am reaching out to you in my capacity as Market Access Lead for Ireland at [Dexcom](#), to inform the public consultation on the National Life Sciences Strategy. Dexcom is a company which develops, manufactures, produces, and distributes continuous glucose monitoring systems (CGM) for diabetes management.

### Scope

Overall, the National Life Science Strategy should encompass the research, development and innovation ecosystem, accounting for manufacturing, adequate skilled workforce and optimal market access. It is imperative that a collaborative approach is taken to adequately account for the perspectives of patients, clinicians, and industry.

### Objectives

When considering objectives of the National Life Sciences Strategy, Dexcom recommends the below points for consideration:

- (i) Ensure that Ireland remains a leader in MedTech innovation
- (ii) To sustain Ireland's reputation in attracting and educating skilled workforces to deliver innovation for foreign direct investment and indigenous companies alike.
- (iii) Ensure that collaboration between government, patient representatives, industry, and academia continues to inform optimal decision making with a view towards more timely access to innovations and technologies to provide an equitable healthcare system.
- (iv) A clear and timebound focused plan with defined actions must have a path that the Strategy can deliver on.

### Opportunities and Challenges

- We believe that Ireland has an opportunity to lead on the intertwined epidemics of obesity and diabetes, with type 2 diabetes as a major driver but with recognition that all types of diabetes contribute to the rising burden. These conditions are deeply linked, with around 90% of people with Type 2 diabetes also living with overweight or obesity. Together, they cost the EU an estimated €240 billion annually in healthcare expenditures and productivity losses. Unless addressed decisively, these costs will escalate further as prevalence rises. Childhood obesity is a particularly urgent concern. Children with obesity are five times more likely to remain obese in adulthood, increasing their risk of diabetes, cardiovascular disease, and long-term complications. Tackling this early is critical to reducing lifetime health burdens, safeguarding productivity, and ensuring sustainability of EU health systems.
- A continental challenge is the digital divide. Unequal access to digital tools like CGM across Member States such as Ireland risks widening outcome gaps. By prioritising early access to digital technologies that enable self-management and remote titration, the EU can reduce unnecessary appointments, free up healthcare resources, and reallocate clinical time to those with greatest need—delivering better outcomes for people with diabetes and easing pressure on health systems.
- There must be a focus placed upon developing health strategies that are complimentary in factoring in the interlinkage with other diseases. In the case of diabetes, it is a disease which has clear links with complications within other diseases. A sub-standard approach to diabetes care can lead to serious complications, such as kidney failure, retinopathy, blindness, cardiac disease, neuropathy – and in some cases, amputation. To add to this, diabetes is also persistent in short term complications such as severe hypoglycaemia and Diabetic Ketoacidosis leading to increased emergency department visits and hospitalisations. It is very clear that the cost diabetes poses to a patient's welfare without adequate provisions is stark. Ireland should work to build on EUDF recommendations and WHO frameworks to ensure evidence-based policymaking that breaks down silos between obesity, diabetes, and cardiovascular disease.
- An equity of care for patients – In Ireland, patients do not have equal access to CGM devices. The reality at present is that only type 1 patients can avail of a CGM device, which results in a grave inequity of care for patients. Dexcom is firmly of the view that all patients on insulin

who require a CGM device should avail of one, particularly with the trends reflecting that the type 2 patient cohort is set to substantially increase in the coming years. Ireland lags behind its EU counterparts in patient access and there is a real concern in Dexcom that an innovation paradox may occur at our manufacturing facility in Athenry – where CGM devices are being manufactured for other EU patients who are eligible whereas Irish patients remain on insulin or nothing at all.

- 
- Talent and Skills – It is critical that Ireland sustains the flow of its globally renowned skilled workforce, but it is equally pertinent that this talent is retained. Dexcom is preparing to hire an estimated 1,000 people at its EU manufacturing facility in Athenry and is eager to explore the range of talent in the west of Ireland.
- 
- Digital health records must be rolled out across various diseases as a matter of priority in order to ascertain the accurate number of Irish patients who require treatment. In Ireland, as part of national strategies, patients are awaiting the Rare Diseases Registry and National Diabetes Register. It is critical that the implementation phase of these strategies is fast tracked, and the Health Information Bill (due before the Seanad) must be enacted without delay to facilitate said registries. Ireland lags behind its EU counterparts in digital health records and it is currently a notable challenge when identifying all patients who require adequate care.

## EU Context

Dexcom welcomes the publication of the EU Life Sciences Strategy to position the EU as the world's most attractive location for life sciences by 2030. Given Dexcom's substantial investment in the EU market, it was particularly encouraging to see that **Enabling rapid market access for life science innovations** is a primary component of the strategy.

- Ireland is well-placed to champion the creation of interdisciplinary chronic disease hubs across Member States, led by primary care teams and designed to integrate screening for diabetes, obesity, and cardiovascular risk. These hubs should provide rapid access to education, technology initiation (including CGM), behavioural support, and structured follow-up care, ensuring that people with diabetes receive holistic and coordinated management. In addition, Ireland could encourage the adoption of joint diabetes/obesity/

cardiovascular checks, enabling earlier detection of risk factors and more timely interventions to prevent complications.

- Ireland should work to build on European Diabetes Forum recommendations and World Health Organisation frameworks to ensure evidence-based policymaking that breaks down silos between obesity, diabetes, and cardiovascular disease.
- This would include promoting predictable, equity-focused reimbursement models for EMA-approved treatments and devices, alongside the use of outcomes-based contracting where appropriate. Ireland can also support fast-track adoption of pharmaceutical and technological innovations that demonstrate both health-economic and clinically meaningful improvements—such as increased time-in-range, reductions in hospitalisations, or delayed onset of diabetes-related complications.

Many Thanks

Orla

## **Orla Lovett**

Senior Lead Market Access Specialist | Dexcom Ireland and Northern Ireland

T: 087 9851394 :: [orla.lovett@dexcom.com](mailto:orla.lovett@dexcom.com)

Dexcom, Building 2, Maxis Business Park, Western Road, Bracknell, Berkshire, RG12 1RT

**Dexcom supports flexible working so whilst it suits me to email now, I do not expect a response or action outside of your own working hours**

**DEXCOM**

## NATIONAL LIFE SCIENCES STRATEGY CONSULTATION

### Key thematic questions

Views are welcome from interested stakeholders across the life sciences ecosystem. Submissions should be structured according to the themes of scope, objectives, opportunities and challenges, and EU context, outlined below.

#### Scope

*Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.*

*In your view, how broad should the scope of the strategy be?*

While there is overlap in some technologies and scientific basis this is too broad a scope to adequately analyse and develop a coherent top down strategy. The challenges/opportunities are different in these areas.

The Pharma and Med Tech sectors are heavily vested in FDI and exposed to the recent geopolitical changes that will impact trade and should have good synergies between the type of strategic actions that would improve them.

Agriculture and Fisheries are more indigenous based today , with Food somewhere in between.

I would suggest that each major sector develop its own summary of current outlook, threats, opportunities and priority approaches. Then build the common strategic priorities where there is sufficient overlap. Carrying out this bottom up analysis may highlight natural overlaps and synergies and help clarify the priority areas with most impact.

The TIME BASED scope of the strategy should be 10 years minimum. Certainly in Pharma given the recent US investment decisions and time the time it takes to change supply chains, the period 2030 to 2035 will be a critical one for Irish FDI Branches and will need a strategy today to prepare for this.

## Objectives

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?*

*For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

I am going to address this question with Pharma in mind only as that is my area of expertise and experience. The objectives below are interrelated with two aims in mind 1) make Ireland an attractive location for Pharma production and service centralisation and 2) grow the links between indigenous and multinational systems.

### **Competitiveness**

Today for Bulk Drug Substance, and complex Fill Finish and for Device components, Ireland has a reputation and a value proposition at the top of the Global order across a number of important metrics both financial and qualitative. There are multiple examples across companies of this capability.

1. Value for Capital
2. Large Capital projects delivery (budget/time)
3. Cost of product relative to external benchmark
4. Very reliable commercialisation, launch and supply chain scalability
5. Manufacturing productivity and innovation – next generation manufacturing

The lead positions and capability in these areas can and must be maintained.

That means supporting any opportunities for Capital expansion and supply chain opportunities however small, positioning Ireland in any dual launch scenario while continuing to improve productivity (business and process).

While the US expansion is a given, the aim should be that for other location discussion Ireland should be naturally at the top of the list because of this level of performance and competitiveness.

In addition there will be opportunity to leverage and build on the Technical service opportunities based on this capability.

### **Talent availability, ability to scale, ability to diversify into Pharma service support**

This is an area of competitive advantage for Ireland. The collective systems that produce Technical capability, management capacity and trainable/convertible staff in large numbers has demonstrated the ability to support rapid expansion across a number of Pharma technologies.

In addition the number of global launches from Ireland over the past 20 years has built a cadre of knowledge, experience and delivery that is not going to be matched.

This should be leveraged to increase both the Business Service and Technical service sectors. For example Service functions (Tech Service, Regulatory etc) could be built based in Ireland to utilise this capability while there is a lull in new site investment.

This will be a significant challenge for the US given their existing talent pool and the pace of expansion.

Ireland should be aware of this and ready to double down and exploit our advantage. (The recent NIBRT announcements to export training and talent growth processes do not align with this objective and should be reconsidered)

These holistic talent systems should be assessed, reviewed, and redirected to meet the targeted technology and to areas of the new strategy.

### **Innovation in manufacturing**

There are opportunities for leadership in innovation in a number of areas of Process Development and Manufacturing

1. Digital plant - Deploying AI for commercialisation and manufacturing speed and efficiency
2. Next generation biomanufacturing, continuous manufacturing
3. Hybrid manufacturing technologies / new modalities

There are already examples of these technologies operating in the country and examples of new Manufacturing paradigms beginning in Ireland. This should be replicated and expanded to the emerging technologies and modalities.

There should be potential for learning, building a critical mass and also for synergies across the existing Tech, Med Tech and Pharma sectors.

Building these synergies could be a significant enabling objective of a Life Sciences strategy.

### **Research and development**

There looks to be significant opportunity via the EU Life Sciences strategy to access funding for research both in basic sciences but also to support research in manufacturing technologies .

Ensure that Research Ireland can mobilise and direct the level of research activity across the different individual institutions should form part of the strategy. Having appropriate oversight, and metrics around this is important.

R+d expenditure and oversight should be directed to have impact in the following areas.

1. Support innovation efforts in Development , Manufacturing technologies.
2. New modalities
3. Sustainability technologies and their application
4. Strengthen the Connection between indigenous and FDI branches
5. Linking Pharma, Tech and Med Tech efforts
6. Ensure supply of technical talent in the new science and technology areas

### **Government policy**

There are a number of areas of Government policy that could have a significant Life Science impact. The combined objective would be to align policy in these areas with overall competitiveness and attractiveness of Ireland as a location for Life Science investment and activity.

1. IP – this is what can hold higher value / higher tech products
2. Tariff inequality – the recent UK announcement on 0/0 tariffs with the US only further highlights this issue.
3. Tax certainty – the Irish tax offering is still relatively attractive and should be protected.
4. Infrastructure to ensure affordability
5. A targeted coordinated approach to R&D investments
6. Grant availability for existing plant expansion / upgrades

### **Opportunities and challenges**

*What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?*

I refer to Pharma sector here.

The closure of the tax gap, the 15/0 tariff agreement between the US and EU, and the significant intent on supply chain realignment by the majority of US based big Pharma represent a major shift in external environment for Ireland's Pharma Industry.

In addition there is a diversification in modality and associated manufacturing technology emerging. Peptides, proteins, ADC, Gene therapy , Car-T are all emerging as viable technologies in addition to Chemistry based API and Cell culture based Biotech.

### **Challenges**

1. It looks like for major drug candidates the trend is for API and Fill Finish manufacture to be located in the US. This will impact the output volume, utilisation of the Irish branch manufacturing sites, and future capital investment and employment growth .
2. Reduction in volumes and the lack of investment in the medium term may put pressure on existing employment levels unless a defensive / protective strategy is developed.
3. Tax will no longer be such a competitive advantage, 15% tariff will make it difficult for the Irish locations compete with US sites on COPS particularly for US supply. This will put downward pressure on employment in existing sites.
4. As investment slows down and facilities in Ireland age their attractiveness will reduce.
5. Supply chain regionalisation will encourage US focused commercialisation and launch strategies which will potentially restrict Irish impact and influence on late phase development and access to R+d partners.
6. While Ireland has been very successful at catching the Biotech wave for the past 20 years there have been very few new modality site announcements. There is a risk that Ireland will be pigeonholed into an API / Biotech drug substance location. The growth in terms of new sites will probably be in new modalities.
7. The indigenous Pharma sector is very small scale from an employment perspective so may be limited in its ability to take advantage of new opportunities.

## **Opportunities**

1. OUS demand will grow . There is opportunity here to make Ireland the premier supply location for OUS supply chains . This may also provide opportunity in broader parts of the supply chain. For example Dry product , Fill Finish plants.
2. Although the unbalanced tariff deal may impact this, there will likely be a dual launch strategy for new medicines. Thus Ireland can maintain its position as a commercialisation, late phase development location if it maintains its facility quality, its regulatory reputation, its IP status and supports new business/products via grants etc.
3. The geopolitical landscape may encourage companies who do not have a European supply centre to develop one. Ireland should be well positioned to attract this business eg. Asian multinationals, Multinational CDO, CMO. This should also be an opportunity for Irish indigenous companies to grow.
4. In the 2025 – 2030 timeframe there will be 300+ billion investments in new capital projects. From an engineering and technical service perspective, Ireland has a demonstrated expertise (English speaking) in this area both in local offices of multinationals but also in multiple indigenous service companies . There is significant technical employment growth or replacement opportunity here at a time when FDI will likely be slower and roles for grad technical, engineering slowdown.
5. New modalities are growing. Ireland has a reputation for new technology adaption, technical depth, capital project delivery, ability to scale. There is an opportunity here to secure new investments

## **EU context**

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.

What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

**1. *Optimising the research and innovation ecosystem***

**3. **Boosting trust, uptake and use of innovation****

There is a significant EU targetted spend in research and development in areas that match Irelands needs via objectives 1 and 3 of the strategy.

This should be leveraged as much as possible.

While I would not expect tariffs to be mentioned in a Life Science policy clearly the 15/0 tariff deal does offer challenges long term to EU attractiveness.

## Submission from Dr. Dockerty

### Strengthening Genetic Diagnostic Services as part of the National Life Sciences Strategy

#### Scope

Medical genetic testing should be a core component of the National Life Sciences Strategy alongside biopharmaceuticals and medical technologies because it underpins prevention, diagnosis, and personalised treatment across care pathways. Integrating genetic testing across clinical services, research, diagnostics and industry will connect Ireland's research strengths to improved patient outcomes and commercial opportunities.

---

#### Objectives

- 1. Improve patient outcomes through personalised medicine**  
Make genomic testing routinely available where evidence supports clinical benefit (oncology, rare disease, pharmacogenomics) to enable earlier, more accurate diagnoses and targeted therapies.
  - 2. Strengthen research and innovation**  
Support translational pipelines from genomic discovery to clinical trials and diagnostics commercialisation by funding infrastructure, national data platforms and academic–industry partnerships.
  - 3. Build talent and workforce capacity**  
Expand training for clinical geneticists, genetic counsellors, bioinformaticians and laboratory scientists to meet rising demand and sustain high-quality services. Currently there is no formal training pathway (or recognised public pay scale) for laboratory geneticists in Ireland.
  - 4. Ensure equitable access and sustainability**  
Develop reimbursement models, national service standards and quality frameworks so genomic testing is accessible across regions and socioeconomic groups while remaining cost-effective.
- 

#### Opportunities and challenges

##### Opportunities

- **Economic growth and job creation:** Expanding genomic services creates high-value jobs in diagnostics, data analytics and biotech, strengthening Ireland's life sciences cluster.
- **Attracting investment:** A coherent national genomics approach and consolidated infrastructure will attract inward investment and partnerships.
- **Health system efficiency:** Targeted testing reduces diagnostic odysseys, avoids ineffective treatments and enables preventive care, lowering long-term costs while improving outcomes. Early intervention is key for many genetic conditions and for a relatively

common genetic condition such as familial hypercholesterolemia (1 in 250), the treatment is easy, cheap and available. And most importantly, early treatment prevents loss of life. Untreated, affected males have a 50% chance of stroke or serious cardiac event by 50 years of age.

## Challenges and responses

- **Data governance and privacy:** Implement clear, GDPR-aligned governance, transparent consent models and strong security to build public trust and enable responsible research use.
  - **Workforce shortages:** Fund education, upskilling and specialist training pathways to rapidly expand genomic expertise across clinical and laboratory roles.
  - **Equity of access:** Commission national services with standard referral pathways and subsidised testing where clinically indicated to prevent geographic and socioeconomic disparities.
  - **Regulation and reimbursement:** Create predictable regulatory and reimbursement pathways for genomic diagnostics to incentivise innovation and ensure sustainability.
- 

## EU context

Align national genomic initiatives with wider European ambitions to build interoperable data infrastructure, harmonised regulatory standards and cross-border research collaboration. Doing so increases Ireland's ability to participate in pan-European trials, attract partnerships and accelerate clinical translation.

---

## Concrete recommendations

- **Adopt a National Genomics Action Plan** with phased targets for service rollout (rare disease, oncology, pharmacogenomics), infrastructure and workforce development. The National Genetics and Genomics Office seems ineffective at this.
  - **Fund a secure national genomic data platform** built to GDPR standards with transparent governance and public engagement to enable research and clinical use.
  - **Introduce reimbursement and procurement mechanisms** for validated genomic tests and companion diagnostics to ensure timely patient access and a stable market for innovators.
  - **Create education pipelines and retraining grants** for clinicians, laboratory staff and data scientists to deliver and interpret genomic medicine at scale.
  - **Establish public engagement and equity measures** including clear consent processes, targeted outreach and subsidised pathways for underserved populations to secure social licence.
-

## **Conclusion**

Embedding medical genetic testing in the National Life Sciences Strategy will improve patient outcomes, accelerate research translation, create high-value jobs and position Ireland to compete internationally. Prioritised, well-governed investment in genomic infrastructure, workforce and equitable access is essential to realise these benefits and keep Ireland at the forefront of life sciences innovation.

# Submission from Dundalk Institute of Technology

## Submission by Dundalk Institute of Technology

Contact: [ResearchOffice@dkit.ie](mailto:ResearchOffice@dkit.ie)

Dundalk Institute of Technology welcomes the opportunity to submit a response to the consultation process regarding the national life science process.

Ireland already hosts a substantial base of high scale multinational pharmaceutical and medical technology manufacturing established through FDI. These organisations not only produce products for the market as major exporters but also have significant economic impacts for Ireland, such as, corporate tax and direct jobs for the Irish workforce. These companies have direct support through government agencies, such as the IDA and Enterprise Ireland). There is an also growing base of start-ups across Ireland in this space. The key challenges for Ireland appear to be

- Over reliance on large scale multinational companies without appropriate increased investment and support for indigenous start-ups in this sector
- Increased regulatory compliance
- Impending talent and skills shortage
- Limited R&D investment

**Life sciences and its scope** should cover the following areas which play to Irelands strengths across its private (i.e., SMEs, multinationals) and public (i.e., health systems, HEIs) ecosystem

- Biotechnology
- Agriculture
- Food
- Environmental Science
- Diagnostics and Medical Devices
- (Bio)Pharmaceuticals
- Advanced Therapy Manufacturing (ATMP)
- Regulatory and Compliance
- AI-enabled digital health and regulatory science

### Key strategic imperatives

1. Increased investment in research and development so that Ireland moves away from it's reliance on largely FDI manufacturing sites. This would entail increased R&D incentives for private entities through widening the R&D tax incentives and with increased research and innovation funding in the Research Performing Organisations (RPOs) focusing on translational research through an All-Ireland approach so that innovation can be seeded through the talent pool available across the island of Ireland. The investment in R&D, both capital and in the talent pool, in the HEI sector with an all island approach plays well to our strategic ambition with QUB to establish the joint research and innovation hub in DkIT in which life sciences across all TRL levels will be one of the key focus points
2. Improved linkages between RPOs, clinical settings and private enterprises through targeted programmes and funding incentives so innovations can move across the value chain from inception to real world products/ innovations in the market
3. Invest in entrepreneurship training, seed funding for entrepreneurs and scale up incentives for start-ups in this space so we move away from the over reliance on FDI clients largely manufacturing in nature
4. Ensuring a future pipeline of graduates with the key enabling skills for the workforce through investment in Higher Education Organisations. This would involve not only in the life sciences domains but also in ICT domains which will play an increasing role moving forward, especially with the ever-increasing digital needs within Life Sciences and in particular, within the medical device domain in relation to connected devices, cybersecurity and AI.
5. Over haul and a rethink of Regulatory compliance framework so innovations hit the market sooner, and with the advent of AI that associated standards and guidance documentation can

be provided that will not stifle innovation, but will assist manufacturers to develop innovative, safe devices and solutions in a timely manner.

6. Lack of infrastructure for large or medium size clinical trials
7. Align with EU and UK policy
8. Joint appointments across academia–industry–healthcare to improve innovation diffusion.
9. Current funding cycles for this research do not currently reflect the lifecycle from the lab to innovation.
10. Formalising of a life sciences cluster between industry and RPOs

## Submission from Edwards Lifesciences

Edwards Lifesciences

National Technology Park

Castletroy

Limerick

V94 31X5

05<sup>th</sup> December 2026

### **Edwards – National Lifesciences Strategy**

Dear Minister,

Edwards Lifesciences is a global leader in patient-focused innovations for structural heart disease. Our innovative and minimally invasive technologies are designed to provide life-saving treatment for heart valve disease patients.

Ireland is a vitally important component within Edwards Lifesciences' global supply chain. In 2018 we established our first manufacturing facility in Shannon, Co. Clare. In 2021, we opened a new €160m purpose-built manufacturing plant in Castletroy, Co. Limerick, at which heart valve repair and replacement technologies are manufactured. We now employ over 550 people, with plans to grow to over 800 employees by the end of this decade.

Edwards Lifesciences strongly supports the development of a National Lifesciences Strategy. It is our hope that the strategy will provide a clear roadmap for Ireland's continued success in this sector and promote innovation, talent development and a connected life sciences ecosystem.

As a member of the Irish MedTech Association, we fully endorse its submission entitled, 'Delivering a Competitive and Resilient Future'. Our position is strongly aligned with the strategic

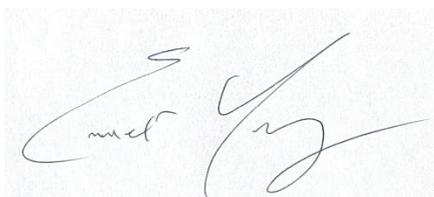
recommendations of the Irish MedTech Association. Of particular interest to our company is:

•**STEMM Education Pipeline:** Any strategy should promote interest and participation in STEMM subjects throughout all levels of education. Edwards Lifesciences recently entered into a partnership with the University of Limerick to collaborate on innovation, joint projects, research initiatives, and educational programs. Increased connection between third-level institutions and organisations should be encouraged

•**R&D and Innovation Ecosystem:** We support the development of an infrastructure and environment that supports R&D initiatives and embraces innovation. Edwards Lifesciences is currently building a Process Automation team in Ireland. A focus on enhancing manufacturing processes is vital for the sector in the long-term.

We look forward to seeing the outcome of the first consultation period and look forward to sharing further insights as the development of the National Lifesciences Strategy develops.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Emmet Kelly', is written over a light blue grid background.

---

Emmet Kelly

VP, Plant General Manager

# Response to public consultation on the proposed National Life Science strategy

## Background

I have been involved in life sciences in Ireland nearly 20 years and have worked at nearly every point in the ecosystem. I am a product of an early life science initiative with the IDA, several universities, Intel and GE Healthcare. The TRIL Centre consisted of a substantial ageing research programme that has resulted in over 240 publications, the creation of 15 technologies and the trialling of technologies in the homes of over 500 older people. The TRIL Centre directly or indirectly seeded several life science innovations and spin outs including Neuromod Devices, Kenesis Health, Kids Speech Labs, Firmwave and more. All these companies were founded by researchers who worked on real world problems with industry, at the time a unique opportunity that bridged between academic life and enterprise.

Since then, I have worked in several healthtech startups in Ireland, including my own digital health startup and I have been lucky enough to participate in many of the innovative supports provided by the various universities and Enterprise Ireland.

I have more recently been working as the Entrepreneurship Lead for EIT Health, health focused innovation agency funded by the EU to support early-stage startups and those looking to scale across the EU and abroad. In my role I have been able to see what supports are available in other jurisdictions and what could supplement the Irish Ecosystem.

Ireland is certainly the envy of many European countries with many of the supports we have here, particularly the Enterprise Ireland Commercialisations fund and PSSF. The new Proof of Concept and Research Ireland supported ARC hubs are an exciting addition to the current ecosystem.

However, despite the incredible University pipeline of innovation, Ireland is still underperforming in the success of our startups. We significantly underperform in scales ups and I believe there are a few contributory factors here:

1. A traditional over-reliance of grants: while the commercialisation fund is undoubtedly a fantastic support and needed, up until recently many of our best companies progressed from this to the EIC Accelerator program. This is an incredible opportunity to receive €2.5m in grant funding from the EU and get following on investment from the European Investment Bank. However, recent changes to this program has seen eligibility shift to later stage companies. The Technology Readiness Level (TRL) has moved from 3/4 to 5/6 meaning companies graduating from comms fund or early spin outs from universities will have a much harder time attracting money for the critical post spin out phase of development. Companies are now looking at the DTIF to fill this gap, however this is not the right program to fill this gap. This reliance on grants means companies are not securing the funding required to achieve long term milestones
2. Lack of dedicated ecosystem. In my EIT Health role I attend many ecosystem events across the EU but particularly in London I see how they are leveraging the vibrant group of innovators, mentors, funders and more to generate genuine excitement about their ecosystem. London has a life sciences **week**, bringing together the global investor community and UK life sciences industry for a week of networking, deal exploration and finding opportunities. Ireland does this in piecemeal ways, through EI and Research Ireland but we lack a central hub to really drive the life sciences agenda forward.

3. **Lack of funding** – startup funding for late seed/early series A is restrictive in all verticals right now but life sciences with their long development and commercialisation lead times are particularly struggling to attract VC funding. The gap that EIC accelerator funding was filling will now be extremely difficult to fill. Ireland does not have a dedicated health tech VC and those that say they ‘specialise’ in health tech do not participate in the seed stages where so many startups are struggling to secure funding. We have not seen a new influx of investment money in healthtech space. We have seen increased investment from Research Ireland and Enterprise Ireland but the real test of startup viability is external, knowledgeable investment.

I believe Ireland needs a Venture builder/studio model to increase the quality/ambition of our life sciences innovation, particularly healthtech. A healthtech venture builder brings together clinical, technical, and commercial expertise to systematically turn promising health innovations into real, regulated, commercially viable products. It bridges the gap between research and market adoption—de-risking development and accelerating impact for patients and healthcare systems.

**Early stage:** Venture builders are usually focused at the early stage of startups. In the Irish context we need to make sure teams are exiting the ARC hubs/Comms fund derisked and investor ready. We need to reduce the time it takes these teams to get out of the cycle of grants and raising large seed and series A rounds. Many of the companies coming out of Bioinnovate and Comms fund do not manage to raise the amount of money they need to get to market and end up raising multiple seed rounds diluting the founding team and investors until there is no space. Significant dilution reduces their ability to raise the money needed.

**Tailored/detailed supports:** Early-stage founders will never have all the resources they need for all the roles required for a life sciences startup. A venture builder is a model that is more than just providing workshops and hoping founders figure it out. It provides tailored expertise at the time the teams need it, for example in advance of an investor meeting the team will have their regulatory requirements mapped out in terms of cost, time and resources with experts in the field. Demonstrating the roadmap has been developed with high level expertise (that a startup normally would not have the funds for) will result in improved investor confidence.

Establishing a **central, connected point in the ecosystem** will have several benefits including leveraging the amazing talent pool we already have but also that we are developing through various initiatives (ARC Hubs, the national accelerator). We need to develop a central voice for healthtech innovation as a point of entry but also having a cohesive approach to marketing our innovations abroad. We can attract more investment by establishing links to partners and the wider Irish ecosystem through a Venture builder generating a pipeline of best in class healthtech innovations.

There are several successful models I can point to:

London Institute of Healthcare engineering. LIHE, LIHE is a translational MedTech hub based at King’s College London (KCL), it is designed to bring together academia (engineering, biomedical research), clinical practice (through the NHS Trust), industry partners (multinationals, SMEs) and start-ups all in one ecosystem so that medical device and healthcare engineering innovations can go from **bench → bedside → boardroom** more rapidly. They do this through strategic ecosystem development, hands on translational support and derisking and investment readiness

General Inception is a US venture builder that sells itself as a *deeptech co-founder*. They help assemble the founding team, bring in domain execs, provide infrastructure, operations, legal and financial support.

I have been discussing this idea with many stakeholders in the ecosystem, from academics, Enterprise Ireland, Research Ireland and investors who have all confirmed the need for such a venture. I can provide letters of support across these stakeholder and I am in the process of preparing a proposal to begin the process of getting this program funded.

I would appreciate an opportunity to discuss further with anyone in the department who is interested in how we can grow our healthtech innovation ecosystem.

Kind Regards

Dr Shona D'Arcy



ELIXIR Ireland,  
University of Limerick,  
Castletroy, Co. Limerick,  
V94 T9PX,  
Ireland

[elixir@ul.ie](mailto:elixir@ul.ie)   
<https://elixir-ireland.ie/> 

# Response to the Public Consultation on National Life Sciences Strategy

**To:**  
Department of Enterprise, Tourism and Employment

**04 Dec, 2025**

**Regarding:**  
Public Consultation on National Life Sciences Strategy

On behalf of the ELIXIR Ireland Consortium, we welcome the opportunity to submit views on the development of the new National Life Sciences Strategy for Ireland.

Representing a consortium that bridges the gap between national research and European infrastructure, our submission focuses on the urgent need to bolster Ireland's digital capabilities to support the life sciences. We outline the critical role of digital infrastructure and data sovereignty in facilitating the public-private partnerships required to ensure Ireland's continued competitiveness.

Please find our responses to the key thematic questions below.

A handwritten signature in black ink that reads "Aedín Culhane".

**Prof. Aedín Culhane**  
ELIXIR Ireland Head of Node

## 1. Scope

***Question:*** *In your view, how broad should the scope of the strategy be?*

The strategy must be broad enough to explicitly include the **research and academic sectors** as core drivers of innovation. These sectors are not only beneficiaries of the life sciences ecosystem but are foundational to industry success through partnerships and the commercialisation of research outputs.

Specifically, the scope should prioritise:

- **Data and Digital Infrastructure:** As evidenced by recent advances in AI and Machine Learning, the life sciences are becoming increasingly data-driven. The strategy must focus on the provision of adequate national infrastructure to support this shift.
  - **National Research Infrastructures:** The strategy should formally acknowledge and integrate National Life Science ESFRI (European Strategy Forum on Research Infrastructures) nodes. **ELIXIR Ireland**, as the key national research infrastructure for life science data, is crucial. It serves as the bridge for national federation into the wider EU life science and data ecosystem.
  - **Public-Private Innovation:** The scope must include mechanisms to boost public-private partnerships. By leveraging infrastructures like ELIXIR, Ireland can better access EU funding streams, such as the **Innovative Health Initiative (IHI)**, which requires robust collaboration between academic researchers and industry partners.
- 

## 2. Objectives

**Question:** What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?

To secure long-term success, the strategy must focus on the following objectives regarding infrastructure, data sovereignty, and talent:

### **A. Establish Sovereign and Secure Data Infrastructure**

- **Data Sovereignty:** Ireland currently relies heavily on US-based resources (e.g., NCBI) for data access. This poses a strategic risk regarding potential funding cuts or access restrictions. The strategy should aim for sovereign data provision by strengthening links to European resources like **EMBL-EBI** and securing core funding for ELIXIR Ireland alignments.
- **Sensitive Data Environments:** There is an urgent need for adequate supports for clinical research, specifically **Trusted Research Environments (TREs)** and sensitive data processing environments. These are essential for handling patient data securely and ethically.
- **Genomic Infrastructure:** Ireland should emulate the success of initiatives like **Genomics England** and the **UK Biobank**. Developing a national genomic data infrastructure on par with these entities would be a "crown jewel" of infrastructure that would attract significant industry and academic interest.
- **Leveraging AI.** AI requires data, however national data is siloed and unconnected. With investment ELIXIR tools can be leveraged to connect data and build platforms to enable advanced AI.

## **B. Integration with European Standards and Frameworks**

- **FAIR Data:** A key objective must be the implementation of FAIR (Findable, Accessible, Interoperable, and Reusable) data principles. This is critical for interoperability and maximising the value of data for AI and ML applications.
- **European Alignment:** The strategy must ensure alignment with the **European Open Science Cloud (EOSC)** (via the ELIXIR Ireland & EOSC Ireland Nodes) and the **European Health Data Space (EHDS)** to facilitate cross-border collaboration and research.

## **C. Talent and Skills Development**

- **New Career Pathways:** The sector requires technical expertise that falls outside traditional academic roles. The strategy must create defined career pathways for **Research Data Managers, Research Software Engineers**, and technical specialists. Without these pathways, Ireland risks hemorrhaging talent to other jurisdictions where these roles are professionalised.

- **Digital Skills:** There must be a focus on upskilling the workforce in FAIR data stewardship and interoperability standards. This will maximise research investment in generating clinical and research life science data.
- 

### 3. Opportunities and Challenges

**Question:** What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade?

**Challenge: The Infrastructure Gap** The primary challenge facing the sector is the lack of adequate national computational and data infrastructure. While there is use of funds on commercial cloud solutions, there is a failure to utilise and support national public competencies and skills in this space. This creates a bottleneck for research and innovation leaving Ireland lagging behind.

**Opportunity: Digital Leadership through Federation** The opportunity lies in transforming Ireland into a leader in digital life sciences. By investing in the necessary data infrastructure and federated analysis capabilities, Ireland can bypass physical limitations and become a hub for high-value, data-driven research and precision medicine.

---

### 4. EU Context

**Question:** What are your views on the EU Life Sciences Strategy ambition... and how could these be applied in the Irish context?

Ireland is well-positioned to align with the EU Life Sciences Strategy by leveraging existing European Research Infrastructures (RIs) like ELIXIR.

- **Leveraging ELIXIR for Industry Innovation:** ELIXIR coordinates bioinformatics resources across 20+ national nodes. It offers open access to over 500 data resources, tools, and standards. As evidenced by recent reports, open access to these public data resources allows companies to develop and commercialise new products that would not otherwise exist. By supporting the Irish node of ELIXIR, the national strategy can give local

industry access to cutting-edge services without requiring individual investment in specialised data systems.

- **AI and Compute Readiness:** AI scientific breakthroughs rely on access to large volumes of high-quality, AI-ready training data. The national strategy should align with EU goals by supporting "EuroHPC AI factories" and ensuring foundational life science data resources are sustained and align with climate needs.
- **Genomic Data Infrastructure (GDI):** The EU strategy emphasises the need for federated analysis capabilities. Ireland should prioritise participation in EU-funded projects like the **Genomic Data Infrastructure (GDI)** and **EOSC-ENTRUST**. These projects demonstrate how access to digital assets (data, software, and TREs) can effectively support innovation.
- **Prioritization of national disease and life science priorities.** Cancer is the primary cause of mortality in Ireland. The burden of cancer is expected to double by 2040 as the population ages. Most cancer medicines are molecularly targeted requiring genomics to deliver care. Integration of national genomics data in research infrastructure would enable surveillance of real world data in cancer, discovery of environmental risk factors, faster medicine approvals of medicine that match Irish patients and facilitating clinical trials.
- **Co-development:** As noted in the Draghi report, co-development with the private sector is key. The national strategy should encourage user-focused, cross-RI access models that support long-term collaboration between industry and Research and Technology Infrastructures (RTIs).
- **Addressing the Skills Gap:** While the rise of STEM graduates is positive, a "digital skills gap" remains. The strategy must support the development of digital literacy skills (data and software management) to ensure the workforce is capable of operating in an AI-driven environment.

## **Submission: Galway City Innovation District**

**Introduction:** Galway City Innovation District (GCID) supports in full the submission below from the West Regional Enterprise Plan. GCID has been a member of the Stakeholder group who have considered current and future opportunities and challenges for Lifesciences in the region and in Ireland as a whole. As an Innovation Hub, with ten years experience in supporting multi sector startups from Ideation through to exit, we have identified the following key areas that require increased focus. Our observations align with the key pillars of Enterprise Ireland five year strategy.

Specifically:

- The creation of a dedicated lifeScience hub in the West Region with wet lab facilities.
- Dedicated Accelerator Programmes to support the medtech and health tech sector supporting innovation and digital transformation. The Accelerator programmes should be funded for multiple years
- Improvements to Investment Reliefs and improved EIS schemes to ensure the continuity and growth of the Angel investment sector that fuels early stage Life Science companies.
- Public private partnerships and corporate sandboxing to accelerate pilots and trials and ensure speed to internationalisation and scale.

---

## **Irish National Life Sciences Strategy from the West Regional Enterprise Plan**

### **Background**

Lifesciences, in particular the Medtech Sector in the west of Ireland is a key sector in the region. In the west of Ireland, the sector comprises a vibrant mix of disruptive startups and scaling indigenous companies, established indigenous companies and multinational global giants. Multinationals continue to select the west of Ireland, in particular Galway for their operations. There have been successful acquisitions of companies founded in the region and there is a strong pipeline of start-ups from the ongoing applied life Sciences R+D in the universities and programmes like the BioInnovate programme. The recent announcements of the ARC hub for medtech and connected health led by the University of Galway with the Atlantic Technical University and the Royal College of Surgeons as partners accelerating novel cutting-edge

research, developing entrepreneurial scientists and engineers will enable the next generation of Medtech/Lifesciences start-ups in the region.

The ecosystem in the region additionally comprises innovation hubs who provide space and a community for lifesciences start-ups. The Medical Engineering Technology Gateway (MET), the MedLink cluster, the Health Innovation hub, the Institute for Clinical Trials, by way of examples, provide a range of sector specific services and supports. Enablers nationally and regionally include the business development agencies, WestBIC, the Western Development Commission, the Regional Skills Forum, the Irish Medtech association and the local authorities.

While there are lots of ecosystem resources/assets and entities, gaps exist in optimally meeting the needs of the life Sciences sector in the region and there is a lack of cohesion between the resources/assets, stakeholder/enablers and lifesciences companies.

A facilitated workshop in June with lifesciences companies in the region sought to understand the challenges that exists for start-ups and scaling companies and to propose potential solutions and recommendations. This was followed by a stakeholder workshop in October. The learnings from those engagement sessions have influenced this submission.

## **Introduction**

Ireland's life Sciences sector stands at a pivotal juncture. To secure long-term competitiveness and sustainable growth, the National Life Sciences Strategy must prioritise the development of indigenous enterprises, strengthen the full supply chain, and leverage regional strengths. This submission outlines key recommendations and sectoral insights to inform the strategy.

## **Strategic Priorities**

### **1. Empowering Indigenous Scale-Ups**

- Ireland must foster an environment where indigenous startups evolve into scale-ups and global acquirers, rather than being acquired prematurely. While trade sales to multinational corporations (MNCs) offer short-term benefits, the long-term vision should be to cultivate Irish-headquartered global multinationals.

## 2. Regional Development and Sectoral Convergence

- The life sciences sector is uniquely strong in Ireland's regions, often surpassing Dublin in capability. Regional clusters can drive broader economic development, especially when layered with emerging sectors such as artificial intelligence and immersive technologies, using life sciences as a foundational customer base.

## 3. Self-Reliance in Production and Sales

- Ireland must enhance self-sufficiency at the European level, both in production and market access, to reduce dependency on external actors.

## Funding and Investment

### ● Expanding Risk Capital

- A robust continuum of funding is essential, from early-stage angel investment to venture capital, private equity, and corporate venturing. Unlocking greater private sector investment is critical, with tax incentives deployed to stimulate investment at all stages.
- Pension fund allocations and auto-enrolment schemes should be ring-fenced to support SME and life sciences investment.

### ● Public Sector as Beta Customer

- The HSE and other public bodies should act as beta customers for innovative technologies, providing startups with vital market validation and accelerating commercialisation. Public procurement guidelines must prioritise innovation to maximise health outcomes and cost savings.

## Skills and Commercialisation

- Ireland excels in R&D, but must now prioritise commercialisation and sales skills. Technical sales modules, dedicated undergraduate and postgraduate degrees, and targeted upskilling are urgently needed. The transition from founder-led innovation to professional commercialisation teams is a critical challenge.

## Clinical Trials and Infrastructure

- Ireland has an opportunity to lead in First-in-Human and pilot phase clinical trials, despite limitations in population diversity for large-scale trials. Addressing gaps in animal trial capacity and expanding specialist infrastructure are essential.

## Regional and National Cohesion

- The strategy should support regional strengths, particularly in the West/Northwest, by:
  - Developing specialist facilities for Medtech/Healthtech based around the model of a campus / centre of excellence
  - Delivering Medtech Accelerator programmes to ensure we attract and maintain talent.
  - Enhancing ecosystem supports for commercialisation
  - Fostering clusters across industry, academia, and investment
  - Ensuring national facilities for preclinical and clinical research

## Scope and Objectives

- The strategy should encompass biopharma, medtech, and digital health sub-sectors.
- Key objectives must include driving global competitiveness, expanding regional footprints, and coordinating sectoral growth.

## **Opportunities and Challenges**

- Opportunities: Strong regional clusters, robust university pipelines (e.g., Bioinnovate), and collaborative platforms (e.g., MedLink).
- Challenges: Funding gaps, commercialisation skills, infrastructure needs, and competition for talent.

## **EU Context**

- Ireland should align with the EU LifeSciences Strategy, leveraging existing biotech clusters and centres of excellence. Strengthening partnerships, missions, and bioclusters will be vital for competitiveness.

### **Conclusion:**

Ireland's National LifeSciences Strategy must be ambitious, regionally inclusive, and focused on building indigenous capacity, commercial excellence, and sustainable growth. By implementing these recommendations, Ireland can continue to build its position as a global leader in life sciences.



**From the Health Research Board (HRB) Ireland, 5 December 2025**

## **Submission to the National Life Sciences Strategy Consultation**

The Health Research Board (HRB) welcomes the opportunity to contribute to the development of Ireland's first National Life Sciences Strategy. As the national agency responsible for supporting, funding and coordinating health and social care research in Ireland, the HRB has a central role in advancing research excellence, strengthening the evidence base for decision-making, and supporting innovation that benefits patients, the health system and society. We therefore see the strategy as a critical opportunity to set a clear national direction for the life sciences sector, grounded in research, aligned with European ambition, and firmly centred on public value. Ireland should see the EU Life Science Strategy not as a background, but as a lever.

### **Scope**

From the HRB's perspective, the strategy should adopt a deliberately broad scope that reflects the deeply interconnected nature of modern life sciences. The boundaries between biomedical research, biotechnology, medtech, diagnostics, digital health, genomics, population health and bio-based innovation have significantly blurred. These domains, along with One Health and the wider bioeconomy, form an integrated ecosystem that underpins Ireland's competitiveness and its ability to respond to evolving societal needs. This is consistent with the direction of the emerging EU Strategy for European Life Sciences, which recognises life sciences as a strategic sector with relevance for health, sustainability and economic resilience.

Critical to this broad scope is the inclusion and investment of the infrastructures, people and enablers that allow the life sciences ecosystem to thrive. The HRB emphasises the need to strengthen national clinical research networks, biobanking and genomic infrastructures, and interoperable health and research data systems,

supported by robust governance and trusted data principles. These infrastructures (blended with health data) determine Ireland's ability to participate in multinational clinical trials, to collaborate in European research platforms, and to attract further investment into high-value R&D and innovation.

Ireland needs to invest in implementation capacity. National coordination and governance should drive implementation, ensure alignment across Departments and Agencies, coordinate with EU bodies, and embed monitoring, evaluation and reporting frameworks with measurable KPIs.

Implementation of the strategy will need carefully defined focus areas for immediate and for longer-term attention. The early focus should be on a manageable number of strengths in Ireland, that can be driven with necessary resourcing.

## Objectives

The HRB believes the strategy must set out clear, ambitious and achievable objectives. A key aim should be to improve patient outcomes, improve the health of populations, and enable health systems to meet the changing needs of populations, including by planning for climate change.

It should aim to reinforce Ireland's global competitiveness by ensuring that our regulatory, clinical and research environments are internationally attractive and responsive. It should seek to support research excellence by enabling high-quality discovery and translation, fostering strong interdisciplinary collaborations, and encouraging innovation across the research-to-application continuum. Building talent and leadership must be a strategic priority: Ireland needs a sustainable pipeline of researchers, clinician-scientists, data experts and regulatory specialists, supported through stable funding, strong career pathways and well-coordinated national initiatives.

An equally important objective is the strengthening of evidence-informed decision-making. As Ireland's lead agency for health research and evidence synthesis, the HRB sees enormous potential in linking life sciences innovation with improved policy development, clinical guideline creation, and enhanced health system performance. The HRB also stresses the importance of public engagement, ethical transparency and societal trust, all of which are essential for ensuring that life sciences advances deliver equitable and acceptable benefits for all of society.

## Opportunities and challenges

While Ireland possesses significant strengths—world-class industries, strong academic institutions, and an expanding clinical research ecosystem—the HRB recognises the challenges that the strategy must confront. Infrastructure gaps, funding scale, workforce shortages and evolving regulatory demands all require coordinated and sustained investment. A clear governance structure to coordinate across government agencies is needed to deliver impact. The HRB therefore strongly supports the establishment of a dedicated national mechanism to coordinate the implementation of the strategy, align national and EU priorities, and drive delivery.

Structures matter. There should be a neutral platform for the entire life sciences family beyond sectoral or institutional interests. Its focus should be on shared potential and collective strength, especially when looking outward towards global markets.

Life sciences and their derived applications are key to sustain the quality of life and wellbeing of our society. Alongside cross cutting challenges (i.e. low societal awareness and engagement, skills gap, fragmented investment and access to infrastructure, including data infrastructures, and regulatory barriers), there are **Health sector specific** challenges and needs that include:

- How can we foster an optimal ecosystem for the conduct of multinational clinical trials? Ireland's HRB-funded network of clinical research facilities provides a strong platform for expansion.
- How can we harness the power of AI and data, for modelling, predicting and monitoring the development of personalised approaches in a complex EU environment? Touch points on public health data can be crucial to innovative business models. Interoperable data infrastructures, and FAIR data enablers align with HRB's goal of trusted data.
- How do we encourage and facilitate the health services workforce to be research active, with benefits for service users and the economy?
- How do we foster the environment for the sustainability of the health sector, both on the side of healthcare and also on the supply side?
- How can we make best use of the innovative technologies expertise, which is currently dispersed?
- How can we best prepare a strategic approach and an organisational model that combines a public-private partnership approach, including public procurement as an enabler?

## EU context

The European context is particularly important. The EU Strategy for European Life Sciences represents a generational shift in the scale, coordination and strategic

ambition for life sciences across the continent. For Ireland, alignment with this EU agenda will be essential—not only to access funding and participate in major research initiatives, but also to ensure coherence with regulatory reforms, digital data spaces, and cross-border research infrastructures. The HRB believes that Ireland should be an active contributor to these developments, building its influence at European level while leveraging EU-scale opportunities to strengthen national capacity.

## Conclusion

Taken together, the HRB sees the National Life Sciences Strategy as an opportunity to transform Ireland’s life sciences ecosystem. We recommend that the strategy include a strong focus on coordinated governance, investment in critical infrastructures, support for a highly skilled and diverse workforce, enhanced research quality and output, and deep alignment with EU priorities. It should foster a culture of evidence-informed policy, open and trustworthy data practices, and meaningful patient and public engagement. Above all, it should seek to ensure that the benefits of life sciences innovation flow directly to patients, the health system, and society as a whole.

The ambition of the EU Life Sciences Strategy will require co-investment by Member States. Ireland must ensure that our funding mechanisms are prepared so that we can leverage EU opportunities as they arise.

The HRB stands ready to support the development and delivery of this strategy, and to work collaboratively with Government, funding agencies, industry, academia and the public to ensure a vibrant, competitive, and patient-centred life sciences ecosystem for Ireland’s future.



Connecting industry and the health system through collaboration, education and advocacy

### **HealthTech Ireland Response to DETE Public Consultation on the National Life Sciences Strategy**

Date: 5 December 2025

Submitted by: HealthTech Ireland — the independent trade association for manufacturers, developers and distributors of health technology in Ireland.

This submission builds on the joint IPHA–HealthTech Ireland vision and its three pillars—Fostering Enterprise; Innovation Uptake; and Research, Development, Data & Digital—and then weaves those pillars into DETE’s required themes (Scope, Objectives, Opportunities & Challenges, EU Context) for a cohesive, action-focused response.

#### **Who We Are**

HealthTech Ireland is a 44-year-old independent trade association representing over 120 member companies—start-ups, SMEs, distributors, and global companies and manufacturers—delivering medical and surgical devices, in-vitro diagnostics, digital health, precision medicines and clinical trials products, solutions and services to the Irish health system. We have a proven track record of innovative partnerships to support industry and the healthcare system to reach collective goals. We established the National Health Collaboration Council with the HSE to be a bridge across the public and private sector for alignment and to strategically meet challenges and accelerate the success of opportunities, such as within National strategies. We are members of MedTech Europe connected to the EU Commission and the Global Medical Technology Alliance connected to the WHO. We work to represent and connect industry and health systems through collaboration, education and advocacy. Our vision is to support members to positively contribute to Ireland’s economy and healthcare, our mission is to advance understanding and engagement between the health system and our members, and our purpose is to enhance health and wellbeing through innovative health technologies.

#### **HealthTech Ireland pre-budget submission 2026**

To provide context to the replies below, HealthTech Ireland proposes an overall approach of the creation of a Life Science Council to leverage national knowledge to support the life science strategy creation. Ireland’s life sciences ecosystem is world-class, spanning pharma, medtech, diagnostics, and digital health, supported by strong academic research and a thriving start-up sector. A Life Science Council as seen in other jurisdictions can reduce greatly any fragmentation between policy and implementation across ministeries (Enterprise, Health, Higher Education), and can contribute to efficiencies and accelerate innovation uptake.

**HealthTech Ireland**  
Kandoy House, 2 Fairview Strand, Dublin 3  
T: +353 1 484 7828  
E: [admin@healthtechireland.ie](mailto:admin@healthtechireland.ie)  
[www.healthtechireland.ie](http://www.healthtechireland.ie)

The Pre-Budget Submission highlights that:

- The sector employs over 102,000 people, exports €116 billion annually, and invests €1 billion in in-house R&D.
- Ireland competes globally for investment and talent; strategic alignment is essential to maintain competitiveness.
- The best international practice shows that public-private councils accelerate delivery of life sciences strategies by providing cohesive governance and evidence-based policy.

Reasons for Establishing the Council

- **Strategic Alignment:** A single forum ensures joined-up leadership across government, industry, academia, and health systems.
- **Accelerated Innovation Uptake:** Facilitates faster adoption of devices, diagnostics, digital health, and precision medicine innovations into the health service.
- **Policy Cohesion:** Avoids siloed approaches and ensures consistent regulation, procurement reform, and skills planning.
- **Global Competitiveness:** Positions Ireland as a preferred hub for clinical trials, advanced manufacturing, and early launches.
- **Evidence-Based Decision Making:** Council provides analytical capability to inform investment priorities, KPIs, and timelines.

#### **Scope: A Focused Vision for Life Sciences**

HealthTech Ireland welcomes this consultation and suggests that the proposed strategy will be most effective if it adopts a specialised, human-centric focus. While the broader "bio-economy", including agriculture and food production, is undeniably important, HealthTech Ireland believes that the unique regulatory and ethical complexities of human healthcare warrant a distinct, dedicated approach.

By refining the scope, the strategy can better support "Bio-Convergence", the exciting intersection of biology, data science, and engineering to improve patient care. A specialized focus allows for a deeper alignment with the bespoke regulatory frameworks (such as the EMA) and data privacy standards (GDPR) that govern human health, ensuring the policy remains a precise and effective tool for the sector.

#### **Proposing a "Triple Helix" Ecosystem**

To ensure the greatest strategic impact, HealthTech Ireland recommends defining the sector around three complementary pillars of human health:

- **Biopharmaceuticals:** Including small molecules, biologics, and advanced therapies.
- **Medical Technologies:** Encompassing devices, diagnostics, and essential equipment.
- **Digital Health:** Focusing on AI-driven care, health analytics, and digital therapeutics.

Concentrating on these three areas will facilitate smoother collaboration between the Department of Enterprise, the Department of Health, and the Department of Further and Higher Education, allowing them to address the specific needs of the human health ecosystem without the added complexity of the agricultural remit.

## Objectives

These objectives have been created to be aligned to the three pillars in our previous submission and also factor in the HealthTech Ireland pre-budget submission of the necessity for a Life Science Council. We propose then five outcome-oriented objectives for long-term success:

1) Accelerate Innovation & R&D Translation: Analyse and have a measurable increase in healthtech/diagnostics/digital pilots and trials initiated in Ireland within three years via national testbeds, rapid study-start processes, and clinical validation vouchers for SMEs.

2) Strengthen Global Competitiveness & Early Launch: Position Ireland as an early-launch market through streamlined market access, predictable value-based procurement, and "Launch Ireland" branding.

3) Improve Patient Outcomes & System Productivity: Link adoption funding to measurable outcomes (earlier diagnosis, reduced complications, care delivered at home). With the EU's review of procurement and for purpose of success in an evolving evaluate and adopt proven models for an innovative landscape such as establish national outcomes registry and procurement scorecards weighting outcomes, value based healthcare and enhance cybersecurity and sustainability.

4) Develop Future Skills & Regulatory Excellence: Close skills gaps in MDR/IVDR/AI/HTA, cybersecurity, human factors and advanced manufacturing via micro-credentials and regulatory fellowships. Enhance the links across the ecosystem to remove identified barriers and enhance enablers.

5) Deliver Sustainable, Resilient Supply Chains through collaboration e.g. Incentivise eco-design, appropriate reprocessing/refurbishment, energy-efficient facilities, and green logistics; embed security-of-supply in procurement.

## Opportunities & Challenges

Opportunities: (a) Digital & Data leadership—AI in diagnostics, remote monitoring, interoperability and virtual care; (b) Manufacturing excellence—advanced devices, diagnostics and combination products; (c) Value-based care—procurement centred on outcomes and lifecycle value; (d) Clinical trials & launch—faster initiation and data access enabling first-wave launches; (e) Sustainability leadership—circularity and low-carbon logistics; (f) cross sector innovative partnerships such as the National Health Collaboration Council between senior leaders in the HSE and HealthTech Ireland and the MoU between RCSI (clinicians, academia and the WHO) and HealthTech Ireland.

Challenges: (a) Regulatory complexity—MDR/IVDR capacity constraints, AI change control, cybersecurity; (b) Skills shortages—regulatory, clinical evaluation, data science/AI, human factors; (c)

Interoperability gaps—fragmented data and limited real-world evidence infrastructure; (d) Procurement inertia—price-only tendering inhibits innovation uptake and SME participation; (e) Supply-chain pressures—geopolitics, inflation and ESG compliance costs.

### **EU Context**

We support the EU ambition to be the world’s most attractive life sciences location by 2030. Ireland should localise EU measures through AI Act-ready pathways, European Health Data Space (EHDS) interoperability and privacy-preserving analytics.

### **Cross-cutting Enabler: Establish a Life Science Council**

We again recommend Government to establish a dedicated Life Science Council to oversee development and execution of the National Life Sciences Strategy—providing aligned leadership, strategic direction and evidence-based policy recommendations, and ensuring cohesion across the Departments of Enterprise, Health, and Further & Higher Education.

Rationale: Ireland’s ecosystem spans world-leading pharma, medtech, diagnostics and digital health, strong academic research, and a thriving start-up sector. The Council would prevent fragmentation, accelerate innovation and adoption, strengthen policy cohesion, and enhance global competitiveness—drawing on international best practice where public-private councils have successfully shaped life sciences strategies.

Proposed initial Priorities: define the strategy’s vision; establish governance; set KVIs and timelines; complete stakeholder mapping for inclusive representation; initiate evidence-based policy analysis; develop implementation plans; and facilitate sector-wide collaboration. To enable delivery, we propose funding of €200,000 for secretariat and analytical support.

### **Closing Statement**

On behalf of HealthTech Ireland members—start-ups, SMEs, distributors, and global companies across devices, diagnostics, digital health and pharma members, we welcome DETE’s leadership and stand ready to partner with Government and the health service to turn vision into delivery through the measures outlined above, building a more innovative, competitive and sustainable Ireland.

Contact: HealthTech Ireland | [admin@healthtechireland.ie](mailto:admin@healthtechireland.ie) | [www.healthtechireland.ie](http://www.healthtechireland.ie)



## **SUBMISSION TO THE NATIONAL LIFE SCIENCES STRATEGY CONSULTATION**

**Submitted by:** Heart Rhythm Ireland

**Date:** December 2025

**Sector Focus:** Medical Technology & Digital Health

### **Executive Summary**

The global life sciences sector is shifting rapidly from product-driven value to data-driven value. A critical bottleneck has emerged in this transition: the reliance on "synthetic data" for AI development is failing to capture the complexity of real-world patient outcomes. As global manufacturers and regulators (FDA, EU MDR) seek robust **Real-World Evidence (RWE)** to validate new technologies, Ireland has a unique opportunity to become a global leader in **Clinical AI Validation**.

This submission focuses specifically on the medical technology and digital health dimensions of life sciences, where the transition to real-world, clinically embedded data infrastructure is already underway.

Heart Rhythm Ireland (HRI) provides the national digital infrastructure required to seize this opportunity. Operating as an independently governed, public-private partnership, HRI functions as a specialised **National Living Registry**. It connects the majority of implanting and follow-up cardiac hospitals nationwide, across both public and private care, capturing the full implant and follow-up lifecycle over more than 17 years of continuous history.

HRI's national dataset now serves as a critical dual-use asset for the State:

- **National Health:** It acts as a "National Safety Net" through automated overdue follow-up detection and supports value-based procurement across cardiac devices and leads.
- **Economic Growth:** It attracts high-value MedTech FDI by providing the longitudinal, clinically verified RWE that manufacturers require to validate their AI models, insights that synthetic datasets cannot provide.

This submission outlines how Ireland can leverage existing independent infrastructure to position itself as a European leader in digital health, regulated AI and post-market surveillance.

---

## **1. Scope: Digital Health Infrastructure & The Living Registry Model**

State health systems often struggle to unify data across the public-private divide, resulting in fragmented care and lost insights.

HRI offers a proven model for a specialised, EHR-grade national infrastructure layer that bridges this gap. Through commercial independence, HRI successfully aggregates structured data from:

- **Public Hospitals (HSE)**
- **Private Hospitals (48% of the Registry)**

This cross-sector interoperability ensures that patients are tracked seamlessly regardless of where they are treated. This is a capability rarely achieved in purely public systems, enabled through a unified infrastructure that spans both public and private hospitals.

#### **HRI Capabilities at a Glance:**

- **Close to 1 million** structured cardiac follow-ups.
  - **100,000+** implants and procedures (new implants, upgrades, lead revisions).
  - **More than 17 years** of continuous device and lead performance data.
  - **Sovereign Cloud Architecture:** Deployed on IBM and Microsoft Azure with full data residency in Ireland/EU, aligned with Government Cloud Strategy.
- 

## **2. Objectives: Where Ireland Can Lead**

### **A. Become the Global Hub for "Real-World" AI Validation & Regulatory Sandboxing**

Global manufacturers struggle to validate AI models using synthetic or vendor-controlled datasets. Ireland can offer a premium "Validation-as-a-Service" capability using HRI's deep longitudinal dataset (Real-World Evidence). Furthermore, **HRI is uniquely positioned to serve as Ireland's designated AI Regulatory Sandbox for Digital Health**, meeting obligations under the EU AI Act to provide a controlled real-world environment for evaluating high-risk medical AI before market release.

**B. Reduce State Liability via "National Safety Netting"** "Lost to follow-up" patients represent a significant clinical and legal risk. HRI's automated overdue detection identifies patients who fall through the cracks between hospitals or between public and private systems. This directly reduces preventable adverse events and strengthens system accountability.

**C. Transition to Value-Based Procurement** HRI's multi-manufacturer dataset allows the HSE to compare **true** battery longevity and lead survival rates across the Irish population. This enables more accurate procurement decisions based on verified performance rather than catalogue specifications.

**D. Demonstrate EHDS Readiness via Public-Private Interoperability** HRI already supports patient-controlled access (via the HRI App) and harmonised cross-border data sharing aligned with EHDS principles. It demonstrates how independent registries can deliver EU policy goals faster than greenfield public projects.

---

### 3. Opportunities and Challenges

#### 3.1 Opportunities

**Attracting High-Value FDI** No other EU Member State operates a real-time, clinically embedded, cross-hospital registry with more than 17 years of 'wild-caught' clinical data. This "ground truth" asset is highly attractive for global R&D teams. This aligns perfectly with the recent **Connected Health & Wellbeing Cluster (DkIT)** initiative to establish a Digital Health Validation Lab. HRI stands ready to serve as the foundational infrastructure for this national objective.

**National Operational Intelligence** HRI provides live visibility into regional workloads, waitlists and cross-hospital patient flow. This enables smarter workforce planning and resource allocation.

**Predictive Preventative Care** With close to 1 million follow-ups, HRI's dataset enables the detection of early heart failure deterioration and device anomalies *before* hospitalisation occurs, supporting the shift to virtual wards.

**EU Leadership (Horizon & PEACEPLUS)** Ireland is already exporting innovation. Through leadership in **Horizon Europe (CAMEL)** and **PEACEPLUS (HF-TIC)**, HRI is currently validating cross-border AI models that serve as a blueprint for European digital health.

#### 3.2 Challenges

- **Fragmentation:** Digital infrastructure outside of cardiology remains siloed.
- **Recognition:** The need to formally recognise existing independent registries as "Critical National Infrastructure" rather than treating them as external vendors.
- **Validation Frameworks:** The need for clear regulatory pathways for AI models trained on Real-World Evidence.

---

### 4. EU Context: Ireland in the EHDS Era

The European Health Data Space (EHDS) demands two things: **Patient Access** and **Secondary Data Use for Research**.

While many EU nations struggle with registries that remain siloed by region or rely on retrospective manual entry, **HRI delivers a live, unified national view today**.

**Why Ireland Has a Competitive Advantage Compared to Other EU Countries** Most EU Member States rely on static or fragmented registries that are not suitable for AI validation or EHDS secondary-use requirements:

- **Regional fragmentation:** Countries such as Germany, Italy and Spain operate regional or insurer-led registries without a unified national view.
- **Retrospective reporting:** Many registries (including Sweden and Denmark) rely on retrospective manual submissions, limiting real-time safety monitoring.
- **Lack of follow-up data:** Several national registries (including the UK's NICOR cardiac device registry) capture implants but not long-term follow-up, making them unsuitable for predictive modelling.
- **Vendor dependency:** In some countries, datasets are owned or influenced by device manufacturers, limiting neutrality for regulatory validation.

In contrast, Ireland already has a **unified, clinically embedded National Living Registry** with continuous, real-time data across the full implant and follow-up lifecycle. This positions Ireland as one of the very few jurisdictions globally capable of supporting clinically validated AI and post-market surveillance at population scale.

---

## 5. Case Study: HRI as National Digital Infrastructure

**A. Real-Time National Dashboards (2025 YTD)** Unlike traditional static registries, HRI provides live operational intelligence. **Year-to-date (2025)** performance metrics include:

- **46,747** structured follow-ups processed.
- **7,659** implants and procedures recorded.
- Live **county-level activity** and device utilisation trends.
- **Predicted demand modelling** for waitlist management.

### B. Europe's Largest Longitudinal Cardiac Dataset

- **Volume:** Close to 1 million structured follow-ups.
- **Depth:** Over 17 years of continuous history.
- **Breadth:** Manufacturer-agnostic data covering every major device vendor.

### C. Automated Safety & MDR Compliance

- HRI's automated Field Safety Notice (FSN) infrastructure identifies affected patients instantly, creating a national audit trail that supports Ireland's compliance with the Medical Device Regulation (MDR).

### D. Predictive & Preventative

- Currently deploying AI models to predict cardiovascular risk in women (CARMEL), demonstrating the power of "Living Registries" to drive preventative care.
-

## 6. Recommendations

**1. Establish a National Living Registry Programme** Recognise HRI as the blueprint for national digital infrastructure and **expand the Living Registry model** into other high-burden clinical areas (e.g., Oncology, Respiratory, Diabetes). Transitioning from static databases to real-time Living Registries is essential to modernise Irish healthcare and enable population-level predictive care.

**2. Designate the Living Registry as Ireland's Digital Health Sandbox** As the State moves to establish a National AI Regulatory Sandbox (in line with the EU AI Act), do not build new capacity from scratch. Designate the existing Living Registry infrastructure as the operational "Validation Lab." This allows the National AI Office and HPRA to leverage HRI's "Ground Truth" dataset to test high-risk AI immediately.

**3. Leverage Real-World Evidence for FDI Market** Ireland's unique longitudinal datasets to the global life sciences industry as a premium location for **AI Model Validation** and Post-Market Clinical Follow-up (PMCF).

**4. Adopt Value-Based Procurement** Mandate the use of national registry data to inform HSE procurement decisions, ensuring the State pays for verified device performance rather than volume.

**5. Support the "Public-Private" Data Model** Acknowledge that creating a comprehensive national picture requires data from both public and private sectors. Continue to support the HRI model which successfully bridges this divide while maintaining strict data sovereignty and GDPR compliance.

## Conclusion

Ireland already possesses the digital infrastructure that many European nations are still trying to design. HRI's living registry demonstrates the power of **continuous, independent, real-world data**.

By embedding this infrastructure into the National Life Sciences Strategy, Ireland can secure its position not just as a consumer of health technology, but as the **global validator** of the next generation of AI-enabled care.

---

## Contact Information

**Robert Kelly** CEO, Heart Rhythm Ireland **Email:** [robert@heartrhythmireland.com](mailto:robert@heartrhythmireland.com) **Phone:** +353 (0)41 6871457 **Website:** [www.heartrhythmireland.com](http://www.heartrhythmireland.com) **Address:** Unit 5, John Street Business Park, Ardee, Co. Louth, A92 W540

## Submission from Health Innovation Hub Ireland



### Ireland's Life Sciences Strategy Submission (December 2025)

#### Scope, Objectives Opportunities and Challenges:

Ireland's life sciences landscape is changing fast. Innovation is no longer confined to single sectors, it spans biopharma, medtech, diagnostics, digital health, AI and emerging areas such as women's health and prevention. From HHI's work at the interface of industry, clinicians and the health service, it is clear that the National Life Sciences Strategy must adopt a broad, integrated scope that reflects how solutions are now developed, validated and adopted across multiple domains.

Within that wider scope, the strategy should set out a small number of clear, **actionable objectives: strengthen research and innovation capacity, support global competitiveness, improve patient outcomes and invest in the regulatory, digital and clinical skills the sector now relies on.** Regulatory science, evidence generation and data governance have become core enablers of progress, however this process in Ireland is not made easy.

Ireland also needs to strike the **right balance between supporting the multinational companies that anchor our economy and building a stronger, more resilient indigenous start-up base.** The MNC sector should remain a critical pillar, but our future resilience depends on nurturing indigenous companies supporting jobs, the economy and mitigating against geopolitical and supply-chain shocks. Unlike large corporates, early-stage Irish companies do not have deep regulatory or financial reserves. They require targeted, cost-effective supports that help them navigate complex evidence and compliance pathways without stalling their progress. Ireland has excellent supports in place already, through Enterprise Ireland, Research Ireland, HRB and the IDA, what is missing however is a strong regulatory support system that enables cost effective, easily accessible compliance supports. We need to strengthening this domestic pipeline to ensure a strong success rate in the companies supported by our government agencies.

The next decade offers significant **opportunity.** Ireland is well positioned to lead on trusted clinical AI, digital health, diagnostics and preventive technologies. But the challenges are equally clear: increasing regulatory complexity, higher evidence expectations, fragmented adoption pathways and growing

international competition. Without coordinated national supports, many promising innovations will struggle to reach patients or the market.

Our recommendations align with the EU Life Sciences Strategy and the evolving regulatory environment, from MDR/IVDR to the EU AI Act and the European Health Data Space. If we identify what is not being provided and build the right structures now, Ireland can become a trusted and competitive location within Europe, supporting both multinational excellence and a vibrant indigenous innovation system.

### **Health Innovation Hub Ireland Context:**

Health Innovation Hub Ireland (HIHI) sits at the intersection of research, clinical need, and commercial ambition. We work with innovators across medtech, diagnostics, digital health, health and wellbeing, providing early validation, clinical access, and evidence pathways that are essential for commercial success.

What we hear consistently from companies is clear: Ireland has the foundations to lead in life sciences innovation, but we must strengthen the supports that enable new discoveries to move from research to market quickly and safely. The new National Life Sciences Strategy provides the opportunity to address these gaps and future-proof our leadership position, particularly for Ireland's indigenous industry but also important in attracting FDI.

### **Ireland's Strengths in LifeSciences and Opportunities:**

Ireland is home to one of the world's most successful life sciences ecosystems. We lead in biopharmaceutical manufacturing, medtech exports, and digital health research. Our clinicians contribute to internationally recognised research, and our start-up community continues to grow across diagnostics, AI-enabled therapeutics, biologics, medtech, and food for health and wellbeing.

This success, however, is accompanied by rising pressures:

- Increasing regulatory demands across biopharma, diagnostics, digital health, biotech and medical devices
- Greater evidence requirements for high-risk products
- Higher expectations around real-world data, safety, clinical validation, and post-market performance
- Competition from emerging life-science hubs globally
- Talent shortages in regulatory science, clinical research, informatics, bioprocessing and AI

We need the coordinated supports that ensure Irish innovators can navigate a changing global landscape and continue to thrive. We need to identify our current strengths and map what is missing- then focus on delivering these supports through this strategy.

### **Real-World Feedback:**

HHI engages with hundreds of companies, within the broad healthcare focused sector. The majority of these companies are start-ups or SMEs with some engagement with the larger MNCs. Lifescience products are no longer limited to pharma and biotech, there is now a significant focus of medical devices, digital tools and AI driven solutions and the intersection of these- example drug delivery and digital monitoring, AI tools for assessment, diagnosis and predictive disease modelling. This intersection of technologies brings opportunity but increasing complexity also.

### **Regulatory complexity is the single biggest barrier to growth**

Life sciences companies are facing unprecedented regulatory change:

- EU MDR and IVDR tightening evidence and performance requirements
- EU AI Act classifying most AI-enabled health technologies as high-risk
- Increased scrutiny of combination products and advanced therapies
- Expanded monitoring and post-market responsibilities
- Software as a Medical Device uncertainty in classification.
- For early-stage companies, these requirements are overwhelming. Without structured national supports, we risk losing innovative companies to markets with lower barriers or more coordinated regulatory ecosystems-(US FDA approval is now the route of choice as it is easier to navigate)

Note: We are not just talking about clinical trials, we are talking about the wide range of validation, testing and evidence needed to address regulatory requirements across all classes or lifesciences products. Ireland has in the past focussed on medicinal products (particularly with the recent Clinical Trials Oversight Group) but this must be expanded to include medical devices and IVDs.

### **Opportunities Across Key Life Sciences Domains**

Ireland has competitive advantages across multiple life sciences sectors. With the right supports, these sectors can drive innovation, patient impact and economic growth.

#### **1. Digital Health & AI-driven Solutions**

- Growing international market demand for digital therapeutics, decision-support tools, remote monitoring and predictive analytics
- AI Act compliance requires sophisticated technical and governance supports
- Significant opportunity to position Ireland as Europe's trusted location for AI in health

#### **Health & Wellbeing and Preventive Health Technologies**

## 2. Femtech and Women's Health Innovation

- one of the fastest-growing sectors in global life sciences.
- Substantial gaps in research, diagnostics, and clinical pathways
- Ireland can lead the EU in women's health innovation with targeted funding and clinical networks- see recent [Femtech in Ireland Report](#).

## Regulatory Change: A Challenge for Life Sciences- but an opportunity for Ireland

The following will impact innovation in Europe:

- EU MDR & IVDR
- Higher evidence thresholds
- Increased post-market surveillance
- Shortages of regulatory expertise and notified-body capacity
- EU AI Act and EU Health Data Space
- Most clinical AI systems will be categorised as high-risk- companies must meet stringent transparency, safety, monitoring and data-quality obligations
- Software as a Medical Device (SaMD)-Increasing demand for robust cybersecurity, lifecycle documentation and risk management

Regulation adherence is challenged by the lack of structured supports available in Ireland. This presents an opportunity-Ireland can lead by building national capacity and expertise and making compliance with regulation easier to deliver. This will support the Irish based industries but also attract FDI.

## What Works in the Current Ecosystem and What We Must Strengthen

### What Works

- HIHI's national platform for clinical engagement, pilots and real-world evidence
- Strong funding supports from Enterprise Ireland and Research Ireland and HRB
- Lifescience innovation programmes- BioInnovate.
- Ireland's internationally recognised biopharma and medtech manufacturing expertise
- University research centres and TTOs
- A vibrant start-up ecosystem
- Strong collaboration culture across clinicians, academic researchers and industry

### What Needs Strengthening

- A national regulatory-and-compliance support service for life sciences innovators
- Dedicated supports for emerging fields (AI, advanced therapies, Femtech, wellbeing, NCD prevention)
- Commitment by HSE to procure innovations from Irish based industry (ring fenced innovation procurement budget).
- Increased national expertise in regulatory science, QA/RA, data governance and AI oversight

## Ireland's Opportunity

Ireland can lead in life sciences innovation, but only if we equip our ecosystem to navigate an increasingly complex regulatory, commercial and research environment. Strengthening supports for translational research and regulatory readiness will ensure:

- faster development timelines
- safer and more effective products
- better patient outcomes
- increased competitiveness
- more investment and global interest
- a sustainable innovation economy

This is an opportunity to create a future-ready, innovation-driven life sciences sector that benefits the Irish economy and healthcare system alike.

## HIHI Recommendations:

### National-Level Actions

- Establish a National Life Sciences Regulatory and Innovation Support Centre
- Review the Clinical Research Facility for outputs, operational structures and their impact on the Lifesciences sector- ensure their operations align with the new LifeSciences strategy.
- Expand HIHI's capacity to deliver clinical validation, regulatory guidance and evidence-generation pathways
- Provide dedicated funding for diagnostics, digital health, women's health, and preventive health
- Create clear, transparent innovation procurement pathways within the HSE
- Invest in training and national workforce development in regulatory science and AI governance
- Build more national datasets that enable precision medicine, AI development and inclusive research

## Conclusion

Ireland has everything it needs to lead the next decade of life sciences innovation, world-class talent, committed industry partners, a highly integrated healthcare system and a thriving research ecosystem. But innovation will only succeed if we strengthen the supports that allow research to become reality.

HIHI is happy to engage further and support discussion, evidence gathering and participate as needed in this process.

Contact: [T.mulcahy@ucc.ie](mailto:T.mulcahy@ucc.ie) Tanya Mulcahy, PhD Director Health Innovation Hub Ireland

# Submission from HiTech Health



Tel: 01 9631489(O)

Email: [info@hitech-health.com](mailto:info@hitech-health.com)

Web: [www.hitech-health.com](http://www.hitech-health.com)

**Subject Hitech Health submission to Life Science Strategy**

## **Hitech Health Introduction:**

Hitech Health (HTH) is an Irish SME company with offices in Dublin and UK and laboratory and manufacturing facilities in Galway. HTH currently employs XX staff and serves pharmaceutical companies, hospitals and academic organisations in the EU, UK and US.

HiTech Health is a Contract Development and Manufacturing Organisation (CDMO) for advanced medicines including cell and gene therapies as well as aseptic (sterile) products.

Cell and gene therapies are advanced medical treatments designed to fix health problems at their root cause rather than just treating symptoms. Unlike many regular medicines that must be taken repeatedly, cell and gene therapies aim to provide long-lasting—sometimes even permanent—benefits. They offer new hope for conditions that were previously very hard or impossible to treat. These really are personalised medicines and consideration must be given to the whole supply chain from manufacture of these medicines through treating the patients. This compares to Pharmaceutical and Biological medicines the manufacture can be carried out and medicines stored prior to distribution to pharmacies and hospitals in advance of patient treatments.

## **Scope**

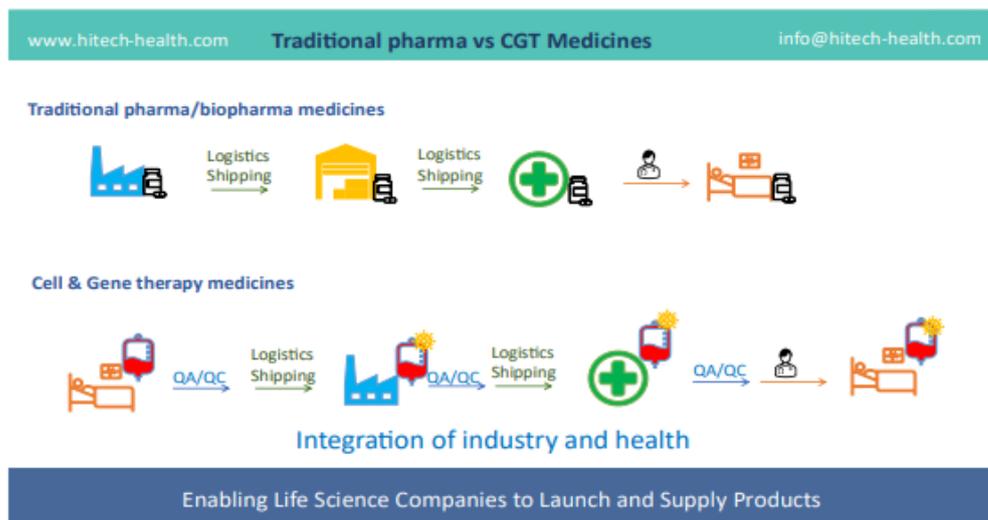
Hitech Health believes that the scope of the Strategy should focus on biopharmaceuticals in its entirety, that is, from discovery of new biopharmaceuticals, through development and clinical trials to demonstrate their efficacy and the manufacture for export. This scope would include the continued funding of basic and applied research in the life sciences, increased research and education in the development of biopharmaceutical medicines (including cell & gene therapies) including cell biology but also likely to require training for healthcare professionals in handling and treating patients with advanced medicines. The scope of the strategy needs to include all the elements that enable the delivery of medicines to patients within the Irish hospital system and HSE. The scope should include the development and embedding of a culture of research within the HSE and hospitals system and delivery of the recommendations of the National Clinical Trials Oversight Group to create a world class clinical trials ecosystem. The ability of hospitals to carry out cell and gene therapy clinical trials will enable the same hospitals to deliver these products to patients when approved by regulatory bodies. There is also a need to include the delivery of the Electronic Health Record and adoption of the European Health Data Space Regulation.

## Objectives

The objective of the life science strategy is to maintain Ireland’s leading position as an exporter of medicines and develop indigenous biopharmaceutical/ cell & gene therapy companies. Ireland has become a leader as an exporter of medicines because it has preempted and responded to the changing nature of medicines. Traditional pharmaceuticals (new chemical entities/active pharmaceutical ingredients) were the backbone of the pharma industry from the 1940’s until the late 1990’s when biopharmaceuticals emerged and offered new and novel treatments. Ireland, recognizing the emergence of biotechnology and the biopharmaceutical industry, responded by selectively funding biotechnology research (SFI’s first research funding stream with ICT) and in the early 2000’s funding the establishment of the National Institute of Bioprocessing Research and Training, which has led to Ireland capturing in the region of €12-15billion in biopharma investments. Cell and gene therapy (CGT) are the next wave of medicines.

Currently, CGTs account for 2% of all global medicine sales and this is expected to triple to 6% within the next 10 years. This growth is reflected in the number of new medicine approvals by the FDA of which CGT’s accounted for 18% of all new approvals. Both IDA and EI have recognized the importance of CGT’s in their most recent strategies. *This investment is aligned with the IDA’s strategy for sustainable growth 2025-2029 which highlights Ireland’s capacity to innovate and capitalize on opportunities and includes ‘next-generation therapies digitization and advanced manufacturing.*

For Ireland to retain its leadership position in manufacturing and exporting high value, IP protected medicines, it needs to invest in the research, skills, ecosystems that support the manufacture of cell & gene therapies. Unlike traditional or biopharmaceuticals, which are manufactured, delivered to hospitals and prescribed to patients, CGT’s start with the patient, require sophisticated supply chain management to deliver to the pharma manufacturer, manufacture, return to the hospital and extensive quality control and assurance before been given to the patient. In addition, complex business processes across industry and health are needed to manage these activities. Examples include the handing of tissues which may require licenses at manufacturing and patient treatment sites, shipping, handling and storage which will span from industry through patient treatment as well as standard operating procedures for preparing cell based treatments in a hospital setting.



## Opportunities and challenges

### Opportunities:

Currently, the growth of these advanced medicines (CGT's) are still in their infancy in Europe. There are only a small number of locations in Europe, in particular Sweden and Catalonia (Spain) that have the capability to both manufacture and treat patients, as they have a holistic, integrated system that spans from patient to manufacture back to the patient in hospital and underpinned by the appropriate business systems. The UK government is seeking to make the UK a **global leader** in life-sciences with a particular focus on cell and gene therapies: meaning research, development, manufacturing and the NHS being able to deliver them to patients. Many more countries will follow in the future.

Ireland is well positioned to be a leader in advanced medicines as it already has many of the key raw materials in place including an educated workforce (many cell biology courses), excellence in the manufacture of medicines, a strong regulatory environment, the protection of intellectual property and a global trust in Ireland as a manufacturer and supplier of novel medicines.

By committing to being a leader in CGT's, Ireland would add value, raise the standard and increase the number of high paying jobs and opportunities within the country. These would include:

1. Digitisation of the healthcare system, streamlining the delivery of healthcare
2. Development of a robust clinical trial system, that MNC's would want to use for clinical trials
3. Growth in all areas of research, development, commercialization and manufacture of CGTs from a solid base already in place
4. Growth and development of medical professionals expert in delivering CGT's
5. Growth in high value manufacture and supply of advanced medicines for the UK and EU
6. Integration and closer working relationships between industry and health, leading to new and innovative careers and employment opportunities
7. Development of public-private partnerships to deliver advanced medicines, reducing costs for the hospitals and healthcare providers and creating new businesses that manufacture CGTs and those that manage supply chains and data.
8. Expanded private healthcare market as Ireland is seen as a location for receiving these advanced medicines in a highly regulated environment.

### Challenges:

For advanced medicines including cell and gene therapies, capabilities including research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability are imperative. However, a key requirement will be the systems and processes across industry and health. Currently, pharmaceutical and Biologics manufacture is an industry activity. Medicines are made then sold to healthcare providers.

For personalised medicines such as cell and gene therapies, there needs to be an integrated business process which links the manufacture of these medicines to patient treatment. This requires a different supply chain and supporting business processes as there needs to be an integration between industry and health systems. The current system is that industry manufactures medicines

and healthcare purchase medicines – 2 independent processes. This approach will need to change for the manufacture and delivery of advanced medicines.

Some of the key challenges to enable Ireland to lead in the cell and gene therapy space include:

- The development of an end to end system that links the manufacture of medicines to the patient treatment. This requires the integration of business processes across industry and health.
- Building a capability across multiple hospital groups. Currently, there is limited expertise to provide cell and gene therapies to patients in Ireland.
  - Companies are unlikely to invest in Ireland for these future medicines unless we have developed the expertise, processes and systems from sourcing of materials through hospital treatment. Knowledge and capability will be key for external parties to invest in Ireland.
- Onboarding of insurers and reimbursement companies.
  - Sweden have developed an end to end system for treating patients with cell and gene therapies from patient treatment approval through payment.
- Strong consideration of a public private partnership approach to allow hospitals to focus on treating patients with cell and gene therapies with private companies providing expertise including biomaterials, manufacture, product supply and data management.
- Other EU countries have taken a lead in developing an end to end capability for the treatment of patients with cell and gene therapies. Examples include
  - Barcelona region has treated over 5000 patients with CAR T treatments and with an advanced Life Science focus generating 8% of GDP
  - Germany has invested €48M to develop a strategic plan for enabling the treatment of patients with advanced medicines. This money is for gap analysis, capability and needs assessment and does not include capital investment or implementation funds.
  - Recently published Scotland life science strategy includes a focus on advanced medicines with a number of references to Roslin Life Sciences, a CDMO which has expanded through acquisition into the US.

#### EU Context

Ireland focusing on cell and gene therapy is in line with the EU Life Sciences Strategy, which states “Investing in ATMP research and development is critical not only to improve patient outcomes but also to strengthen Europe’s position as a global leader in biomedical innovation. ATMPs represent a cutting-edge category of treatments designed to treat a wide range of human diseases, including severe, chronic or rare diseases where standard treatments often fall short.”

Equally, uplifting and investing in clinical trials is also a key component of the European Strategy, “Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human or animal health outcome [42](#). These research studies are essential to turn scientific discoveries into real-world healthcare solutions [43](#). Europe has unique advantages in human clinical research, thanks to its large population and rich genetic diversity, as well as scientific

excellence, research infrastructures, and high ethics, quality and safety standards. An inclusive approach to clinical trials is essential to harness these advantages [44](#) .....The Commission is also working through the Accelerating Clinical Trials in the European Union (ACT EU [48](#) ) initiative to support clinical trials through regulatory, technological and process innovation”

Brian Harrison

Managing Director

Hitech Health

## HPRA Response to the Public Consultation on a National Life Sciences Strategy

The Health Products Regulatory Authority (HPRA) appreciates this opportunity to provide input to help inform the development of a new national life sciences strategy. As noted in the background accompanying this consultation, a strong Irish life sciences sector is critical not just from an economic perspective but also from a societal perspective. As the competent authority responsible for the regulation of health products including human and veterinary medicines and medical devices in Ireland, we are committed to playing a key role to strengthen Ireland's reputation as a leading location for life sciences' activity and to support the development of innovative products and technologies that improve treatment options for patients.

We also believe that this initiative is timely given the recent publication of the European Commission's life sciences strategy which includes many initiatives which aim to boost European competitiveness and make Europe a global leader in life sciences by 2030.

We note that in this initial public consultation, respondents have been asked to address four thematic areas and we will address each one in turn focussing mainly on health products falling within our organisation's remit.

### **Scope**

*In your view, how broad should the scope of the strategy be?*

We believe that there would be merit in aligning the scope of our national strategy with that outlined in the European Commission's life sciences strategy which covers a range of applications across health (including medicines, diagnostics and medical devices), food, agriculture and fisheries and environmental sciences. This would help to ensure that Ireland is well placed to leverage and benefit from initiatives at EU level such as the anticipated EU Biotech Act.

The prospect of proposing a vision which presents a holistic approach to health and sustainability would:

1. Integrate human health, animal health, and food safety under the One Health concept.
2. Support innovation in biopharmaceuticals, medical technologies, nutrition, functional foods, and bio-based products.

While serving to combine and expand Ireland's competitive edge beyond biopharma and MedTech into other areas such as agri-food biotech, a broad scope could also serve to promote the common use of R&D facilities, regulatory science expertise, and digital platforms and encourages cross-sector collaboration (e.g., genomics, microbiome research).

We would also acknowledge that, within this broad scope, there could be a specific focus within the national strategy on areas of strategic national importance which we believe would include biopharmaceuticals and medical technologies. As these areas relate specifically to the HPRA's remit, much of the remainder of our submission will focus on these areas.

## **Objectives**

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?*

We believe that the national strategy should aim to consolidate and further strengthen Ireland's reputation as a leading destination for life sciences. Competitiveness and sustainability should be key pillars of the strategy and there should be an emphasis on creating an environment that supports research and innovation and ensures that the Irish life sciences sector evolves in line with emerging science and technology. The following could support this ambition:

### 1. Transforming the Irish clinical research ecosystem

Although Ireland is recognised as a leading location for biopharmaceutical and medical technology production, this status is not reflected in the level of clinical research and development currently undertaken by these sectors in Ireland. The need to transform the clinical research landscape in Ireland has been acknowledged in the final report and recommendations of the National Clinical Trials Oversight Group (NCTOG). The HPRA welcomes this report and believes that the implementations of the recommendations of this group should be prioritised as part of the new national life sciences strategy. As reflected in the NCTOG's report, while its work focussed primarily on clinical trials for medicines many of the recommendations set out by the group can also be applied in other areas including clinical investigations for medical devices and performance studies for in vitro diagnostics and we would fully support this broader scope when considering the clinical research landscape.

## 2. Supporting national clinical research centres / networks

In order to ensure that Ireland is viewed as an attractive location for clinical research, it is important that appropriate infrastructure is provided to encourage global biopharmaceutical and medical technology companies to undertake research and development in Ireland as well as to facilitate the translation of academic research into clinical development. This could be facilitated by supporting the existing network of clinical research centres with a full-service clinical research development manufacturing facility that could provide comprehensive supports for research and development. These should be capable of producing investigational medicines or medical devices for use in clinical research to required regulatory standards and activity at the site should be supported by staff with relevant expertise and experience in the conduct of clinical research as well as supply-chain support. Examples of such facilities in other countries should be considered.

Given the relatively small size of the Irish population compared to other countries seeking to attract increased levels of clinical research, it is important that clinical researchers in Ireland have the opportunity to work together as part of clinical research networks to attract clinical trials and clinical investigations in shared areas of clinical interest. Networks such as Cancer Trials Ireland have been important in helping to attract clinical trials to Ireland and similar models should be extended to other disease areas or clinical activities.

## 3. Ensuring the Irish life sciences sector responds to scientific and technological progress

As evident in the evolution of the Irish biopharmaceuticals industry from small-molecule chemicals to biological medicines and most recently to advanced therapies, the Irish life sciences sector has already demonstrated its ability to adapt in response to innovation. This is supported by a high-quality and dynamic third-level education system, which facilitates continuous training and development of the workforce as well as industrial policy which supports companies to invest in updating their facilities here.

Given the rapidly evolving nature of life sciences reflected for example in the increasing personalisation of medical treatment, use of digital tools incorporating artificial intelligence and changes in the location of the delivery of healthcare (e.g. virtual wards), it is important that national policy continues to support a dynamic national life sciences sector that remains well placed to respond to new scientific and technological developments and trends.

We would like to highlight new approach technologies / non-animal test methods as an area of specific interest. These are referenced in the EU Life Sciences Strategy, and provide an important opportunity to accelerate innovation, while simultaneously helping to promote the principles of the 3Rs (replacement, reduction and refinement) in relation to the use of animals in scientific research.

## **Opportunities and challenges**

*What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?*

We see significant opportunities for the Irish life sciences sector linked to the strong biopharmaceutical and medical technology company presence in Ireland and the recognition that Ireland has as a leading location for such activities. This positive experience and an enabling industrial policy encourages companies who already have a presence here to invest in further development in those facilities or the opening of additional facilities and also helps to attract new entrants. All of this is supported by a well-educated and highly skilled workforce facilitated by a third-level educational sector that has shown its ability to modernise in response to emerging science and technology. As previously noted, there are opportunities to increase Ireland's reputation as a destination for research and development as well as commercial manufacturing activities.

In order to encourage and facilitate clinical research, it is imperative that our national digital health infrastructure is prioritised and in particular that electronic health records are introduced in a standardised and consistent manner across the entire Irish health system. When conducting large-scale clinical research, recruitment times and the ability to collect anonymised health data that can be used to answer important research questions are key – electronic health records and full participation in the European Health Data Space will be essential enablers for modern clinical research. We also need to develop expertise in key areas such as artificial intelligence and precision medicine which will have a major influence on the future of life sciences.

From a regulatory perspective, the EU landscape is rapidly evolving at present with significant changes to the legislative frameworks for both medicinal products and medical devices anticipated in the coming years as well as the implementation of the new EU regulation on substances of human origin. At the same time significant changes are also being made to horizontal legislation in important areas such as artificial intelligence. New legislation can bring uncertainty, and it will be important that these changes facilitate stable regulatory environments with clear, predictable and transparent requirements based on scientific principles. The national life sciences strategy will need to take this evolving regulatory requirement into account.

## **EU Context**

*The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.*

*What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?*

The HPRA very much welcomes the recently published EU life sciences strategy which we believe comes at an important time given the current geopolitical situation. The health products that we regulate are primarily subject to EU legislation, with some additional national legislation and therefore life sciences companies operating in Ireland will benefit from any improvements made to modernise EU legislation.

Many of the activities in the EU strategy would be complementary to proposals made for inclusion in the national life sciences strategy and could assist in enhancing Ireland's global positioning as part of a unified European life sciences ecosystem. We note that one of the main themes of the EU strategy is enabling rapid market access for life science innovations, and we see access as a particularly important consideration as the benefits of innovation can only be realised if healthcare professionals and ultimately patients can use and benefit from novel products and technologies. This can be facilitated by maximising the benefits of the EU single market.

In response to the well-documented financing and investment challenges, the strategy includes a section on unlocking public and private investment including the optimisation of a number of EU funding mechanisms. It would be important that the Irish life sciences sector is well placed to leverage these opportunities.

We also welcome the inclusion of a section on building public trust and outreach. Misinformation related to innovative health products such as vaccines is an increasingly significant challenge and ensuring that the public receive accurate and reliable information on health innovations from trusted sources will be key to ensuring uptake and acceptance.

The strategy also emphasises the importance of and seeks to advance the One Health approach which can complement national initiatives in this important area including the recently adopted third One Health National Action Plan to address antimicrobial resistance (iNAP3).

There is a risk of policy complexity when merging national priorities with EU mandates. Therefore, there will be a need for clear and effective cross-sector governance with clearly defined priority-setting at national level required to avoid potential resource strain that could occur if we try to cover all EU strategic areas equally.



## Submission from HRCI

National Life Sciences Strategy Public Consultation, 2025



HRCI proudly represents 45 charities across Ireland

## Who we are in the context of the strategy

Health Research Charities Ireland (HRCI) is the national umbrella organisation of 45 charities active in health, medical and social care research, together representing over two million people in Ireland. Through support and advocacy, we represent their joint interests to achieve our vision of improved lives through a united community of health research charities.

Our members span many areas of health, including rare diseases, cancer, childhood illnesses, dementia, mental health, and multiple forms of chronic illness and disability. Collectively, they invest between €15–20 million annually in research. Beyond financial investment, they ensure the relevance of research to the communities they represent, communicate research findings, and insist on real-world impact for people. Together they demonstrate what research means to families and communities across the country.

We offer matched funding opportunities through the **HRCI–HRB Joint Funding Scheme**, delivered in partnership with the Health Research Board. Almost all areas of health research are eligible and the Scheme has been particularly valuable for rare disease research. It also demonstrates good practice in patient and public involvement (PPI), with engagement from patient organisations and PPI embedded throughout the funding process. To date, 163 awards have been made, representing a total investment of over €28 million, with many important benefits for patients and the public.

For over a decade, HRCI has shaped national dialogue on health research through the **Irish Health Research Forum**, now a trusted platform for cross-sector engagement and consensus building. The Forum brings together stakeholders from research, healthcare delivery, industry, government agencies, patient organisations and civil society to address shared challenges and opportunities and produce recommendations for system improvement.

Many Forum themes - including ethics reform, data governance, registries, biobanking, genomics, research delivery in the health service and maximising societal impact - directly inform the National Life Sciences Strategy. The Forum's published reports provide practical, consensus-led insights that we believe will be of value to the Strategy's development (see references below).

The Forum is guided by a diverse and expert Steering Group including Cancer Trials Ireland; Children's Health Ireland; Enterprise Ireland; the HRB (observer capacity); HSE Research and Development; Irish Research Nurses & Midwives; the National PPI Ignite Network; the National Research Ethics Committee Office; Research Ireland (observer capacity); as well as representatives of charities, industry, policy experts, researchers, clinical research centres, patients and the public.

*We welcome this consultation and the ambition to create a coherent, integrated roadmap for Ireland's life sciences sector, and we would welcome further engagement as the Strategy develops.*

## Scope

We support a broad scope for the Strategy, with a particular focus on health, reflecting public priorities expressed through *Creating Our Future* and aligned with a One Health approach. From our perspective, the Strategy should:

### **Centre human health and wellbeing**

Ensure that improving health outcomes remains central, with economic and industrial objectives clearly linked to this purpose.

### **Be shaped to work not just for the public but with them**

Move beyond focusing solely on meeting patient needs towards actively involving patients and communities as delivery partners across the ecosystem. Irish charities already demonstrate this in practice (see case studies throughout the submission). Embedding meaningful charity partnership and PPI systematically would strengthen research relevance, improve recruitment and trial feasibility, build public trust in data use and innovation, and accelerate translation to patient and public benefit.

### **Integrate life sciences with the wider health research ecosystem**

Make explicit the interdependence between life sciences and health, social care and public health research. Address fragmentation and limited support for research delivery in the health system, alongside insufficient industry R&D activity. Recognise the importance of sustained, predictable investment in national research capacity and explicitly reference enabling infrastructures including biobanking, patient registries, health information systems, genomics and related platforms.

#### **Charities as partners – Cystic Fibrosis Registry of Ireland (CFRI)**

CFRI operates a national registry covering almost the entire cystic fibrosis population in Ireland, collecting longitudinal clinical data from all recognised CF centres and clinics. This registry supports approved research projects, enabling evaluation of long-term outcomes, treatment effectiveness and real-world evidence generation. As such, CFRI provides foundational data infrastructure that would directly support the likely ambitions of Ireland's Life Sciences Strategy. CFRI has also led the Future of Registry Taskforce (FoRT) over the last year, which has brought together numerous stakeholders to lay out a bold vision for the future of Ireland's patient registries.

## Objectives

To support long-term success and alignment with patient needs, objectives should prioritise:

- **Sustained investment in national health R&D**  
Protect and grow the science budget across government and recognise the contribution of non-statutory bodies such as charities. Evidence demonstrates that public R&D investment drives productivity, leverages private investment and delivers long-term economic and health returns.
- **Strengthening research infrastructure**, including implementation of the National Clinical Trials Oversight Group recommendations; streamlining ethical review systems; providing

national coordination for registries and biobanking; ensuring research-ready hospitals and community sites across all forms of health research; and offering education and training in all relevant areas.

- **Strategic partnership with charities and civil society**  
Acknowledge charities as funders, connectors and knowledge brokers supporting recruitment, PPI and impact. International examples include Denmark's Life Science Council on which patient organisations are included and the UK Life Sciences Sector Plan developed in close collaboration with patient charities. Sustainable partnerships require recognition of the full costs of collaboration and appropriate resourcing, as laid out in HRCI's guide to *Fair Market Value for Charities in Partnership Work*.
- **Systematic involvement of patients and the public**  
Embed PPI across the lifecycle of infrastructure and research programmes, including industry-led research. Patients and charities should see fair and timely access to the outputs of research they invest in.
- **Enabling legislation and governance**, including developing primary legislation for biobanking; progressing the National Research Ethics Committee Bill; and ensuring regulatory frameworks aligned with the EU - particularly the EU Clinical Trials Regulation, the Medical Devices Regulation, the European Health Data and the forthcoming EU Biotech Act - to ensure Ireland remains fully interoperable with European research and innovation systems.
- **Using the power of data and AI**  
Ensure digitised health records are enabled for research to support the innovation that patients want and need, while protecting their rights. The use of AI should accelerate patient-centred research, from identifying eligible trial participants to improving analysis of outcomes, while maintaining strong ethical oversight.
- **Building public trust**  
Recent data from the Campaign for Science and Engineering (CaSE) in the UK show that less than 20% of people can immediately think of lots of ways that R&D benefits them and their family. Develop a public communications plan linked to the Strategy to ensure it is accessible to communities, charities and the wider public and builds understanding of how life sciences improve everyday lives.

### Charities as partners – Breakthrough Cancer Research

Breakthrough Cancer Research funds cutting-edge research into hard-to-treat cancers, spanning from basic science to translational projects, biomarker discovery and investigator-led clinical studies. Their commitment to PPI ensures research is aligned with patient needs and supports uptake and practical impact. Combined with their investments in researcher training (PhD scholarships, summer scholarships), Breakthrough demonstrates how a charity can build research capacity, underpin translational R&D and support clinical trial readiness - all core elements of a robust national life sciences ecosystem.

## Opportunities and challenges

### Opportunities

- **Strong life sciences base**  
Established pharmaceutical and medtech sectors, combined with a skilled workforce, provide a strong platform for more research-intensive, high-value activity.
- **A vibrant charity research sector**  
HRCI member charities invest significant funding and provide leadership in partnership building, PPI and knowledge mobilisation.
- **Dedicated national health research funder**  
The HRB plays a critical convening and leadership role.
- **Strengthened Department of Health research structures**  
Providing system-level leadership for embedding research within health services.
- **Clinical trial centres and networks**  
A strong base of clinical research centres and clinical trial networks strengthen research activity and improve patient access to innovation.
- **System reform momentum**  
Key developments include National Research Ethics Committees, regional HSE research directorates, and national clinical trials reforms.
- **Emerging infrastructures**  
Growing focus on registries, biobanking, genomics and rare disease research.
- **ARC Hub Programme**  
The Research Ireland ARC (Accelerating Research to Commercialisation) Hub Programme provides new translational hubs in therapeutics and HealthTech, offering vehicles to move discovery towards applied impact.
- **Proven convening mechanisms**  
The Irish Health Research Forum, aided by a small and connected population, supports continuous multi-stakeholder dialogue on priorities central to the Strategy.

### Challenges

- **Under-investment and fragmentation**  
Ireland remains among the lowest OECD countries for government R&D investment relative to GDP, limiting infrastructure development and economic gains.
- **Limited commercial R&D and trials**  
Despite extensive biopharma and medtech manufacturing, much core R&D and clinical research remains based elsewhere. Irish patients may live beside facilities producing medicines yet wait longer for trial access and reimbursement than patients in other parts of the world.
- **Underdeveloped data, registry and biobanking systems**  
Lack of legislation and fragmented data systems restrict evidence generation.
- **Ethics and governance capacity constraints**  
Approval processes remain inconsistent and slow for multi-site and non-regulated research.
- **Lack of resourcing for charity partners**  
Charities frequently provide community linkages and PPI support without adequate funding.
- **Maintaining public trust**  
Combating growing misinformation and data protection concerns requires transparency, strong communication and sustained PPI, including in industry-led research.

- **Below-average clinical trial activity**  
Reflecting insufficient infrastructure and national coordination.
- **Uneven research activity in HSE regions**  
Regional variation, staffing limitations, prolonged governance pathways and a lack of research KPIs continue to limit progress.

### Charities as partners – MSD Action (Multiple Sulphatase Deficiency Action)

This rare disease charity is advancing therapy development for Multiple Sulphatase Deficiency through internationally networked research. Through funding early research via the HRCI–HRB Joint Funding Scheme, the charity has catalysed cross-border research programmes that has are translating early discovery into preclinical development pipelines. This demonstrates how patient-led charities can catalyse cross-border R&D partnerships, de-risk early development, and connect Irish research directly into international translational pipelines, aligned with the Life Sciences Strategy.

## EU context

We support the EU ambition to become the world’s most attractive life-sciences location by 2030. Irish priorities should closely align with this ambition and include:

- Raising Ireland’s **European profile**, including through established leadership capability in PPI and charity/civil society engagement (it is far less advanced in other European countries).
- Accelerating **infrastructure development** through EU alignment, including EHDS-compatible data systems, trial consortia, and advancing the Genome of Ireland project to support central involvement in the 1+ Million Genomes initiative.
- Ensuring **regulatory readiness** for multi-country research and compliant data use, to support active participation in multinational trials and registries and enable earlier patient access to innovation.

## Conclusion

HRCI and our members seek a Strategy that:

- Delivers tangible benefits for patients and the public.
- Integrates charities and patients as delivery partners.
- Builds sustainable national research capacity.
- Recognises the full health research ecosystem as part of life sciences

We would be pleased to discuss any of the issues raised and support the Strategy’s continued development.

## Charities as partners – Health Research Charities Ireland

HRCI has been selected to co-lead the PPIE (Patient & Public Involvement and Engagement) task within ERDERA, the pan-European rare-disease research alliance (mentioned in the EU Life Sciences Strategy). This alliance unites over 170 public and private partners from 37 countries with a budget of roughly €380 million. By contributing its deep experience of charity-led research, patient engagement, and community representation, HRCI is helping embed patient and public perspectives at every stage across ERDERA’s enormous horizon - from data-infrastructure design and research prioritisation, to clinical trial readiness, governance and translational project funding decisions.

## HRCI and Irish Health Research Forum resources relevant to the strategy

| Year | Title   | What it is / Why it matters   | Link   |
|------|---|---|--|
| 2025 | <i>Is it time to get serious about patient registries?</i>                        | Irish Health Research Forum report & recommendations: advocating for Ireland to prioritise national patient-registry infrastructure and governance. | <a href="#">Registries Report 2025</a>           |
| 2024 | <i>Empower, Innovate, Transform: Driving the Future of Health Research</i>        | Anniversary report summarising recurring priorities (investment, infrastructure, ethics, data, impact) from 10 years of Forum work.                 | <a href="#">10 Years of the Forum Report</a>     |
| 2024 | <i>Public Trust in Health Research: Are We Doing Enough?</i>                      | Irish Health Research Forum report & recommendations: focused on building trust through high standards in research and strong communications.       | <a href="#">Trust Report 2024</a>                |
| 2023 | <i>Biobanking in Ireland: Moving Forward</i>                                      | Irish Health Research Forum report & recommendations: establishing national biobank framework - legislation, governance, sustainability             | <a href="#">Biobanking Report 2023</a>           |
| 2023 | <i>Research Ethics in Ireland: How Do We Strengthen and Harmonise the System?</i> | Irish Health Research Forum report & recommendations: analysing current ethics/governance bottlenecks and proposing harmonisation                   | <a href="#">Ethics Reform Report 2023</a>        |
| 2022 | <i>More than Publications: Maximising Societal Benefit from Health Research</i>   | Irish Health Research Forum report & recommendations: highlighting need to plan for research impact, translation and public benefit                 | <a href="#">Societal Benefit Report Nov 2022</a> |
| 2022 | <i>Embedding Research in the Irish Health Service</i>                             | Irish Health Research Forum report & recommendations: focusing on embedding research governance, capacity and culture into the health system        | <a href="#">Embedding Research Report 2022</a>   |

| <b>Year</b> | <b>Title</b>  | <b>What it is / Why it matters</b>   | <b>Link</b>                                   |
|-------------|---|--|---|
| 2025        | <i>Unlocking the Potential of Patient Registries: A Guide for Success</i> | Practical guidance (HRCI + registry partners) on establishing, governing and sustaining patient registries | <a href="#">Patient Registries Guide 2023</a> |
| 2025        | <i>HRCI Position Paper 2025</i>   | Addressing HSE Action Plan for Health Research, legislation and research investment                        | <a href="#">HRCI Position Paper 2025</a>      |
| 2024        | <i>HRCI Position Paper 2024</i>   | Addressing funding, legislation & inclusion of charities   | <a href="#">HRCI Position Paper 2024</a>      |
| 2023        | <i>Charities &amp; Researchers Partnering Guide (with PPI Ignite)</i>     | Practical guide for charity–research partnerships  | <a href="#">Partnering Guide 2024</a>         |
| 2024        | <i>Fair Market Value for Charities in Partnership Work</i>                | Guidance to ensure charities are fairly resourced when entering collaborations                             | <a href="#">FMV Guidance 2024</a>             |

# Submission from Chief Academic Officer of the HSE



5th December 2025

## Submission to Ireland's National Life Sciences Strategy

Dear Colleagues,

The Chief Academic Officers of the HSE welcome the opportunity to contribute to the National Life Sciences Strategy.

### Scope

The National Life Sciences Strategy must recognise the critical role of the health service not just as a site of care, but as an engine of education, research, innovation, and economic impact. The CAOs promote the Academic Health Science System (AHSS) approach – fostering integrated partnerships between the HSE and universities to deliver on the full scope of life sciences: discovery, translation, clinical application, and commercialisation.

The National Life Sciences Strategy should explicitly support the development of a robust academic infrastructure embedded within the HSE, enabling joint appointments, structured clinical academic careers, and integrated research platforms spanning hospitals and community services. It must encompass all life sciences sectors – (bio)pharma, MedTech, diagnostics, digital health, population health – and the full value chain from bench to bedside. In reference to Biopharmaceuticals the strategy should give particular consideration to the development of cell and gene therapies and advanced therapies given Ireland's special position with regards to global pharma companies.

The recent INSPIRE *Programme for Research in Third-Level Institutions* call envisages building institutional research strength and advanced research infrastructures. In this context, it is critical that the strategy considers our AHSS settings, major acute hospitals, as a core component of advanced research infrastructures to fundamentally improve patient outcomes and inform policy.

### Objectives

To achieve long-term success, the strategy should adopt the following objectives from an academic–clinical partnership perspective:

- Formalise, and provide funding, for the Academic Health Science System as a national framework linking HSE regions, universities and life sciences industry, with aligned governance and shared priorities.

- Expand joint academic-clinical appointments to embed research leadership within care delivery teams.
- Establish national clinical academic career structures to attract and retain talent across medicine, nursing, and health sciences.
- Scale clinical trials infrastructure, as outlined in the Programme for Government 2025, to ensure every health region can participate in both commercial and investigator-led research. The recently published recommendations from the National Clinical Trials Oversight Group provide a guidance framework for the growth and development of clinical trials and should be a guiding star within the life sciences strategy.
- Establish early access programmes to approve orphan medicines for rare diseases.
- Invest in translational and implementation science, including real-world evidence, registries, and testbeds.
- Promote education and lifelong learning, ensuring that students, trainees, and staff engage in research-rich environments.
- Align with enterprise and economic development goals, recognising the health service as a key contributor to innovation and national competitiveness.

## **Opportunities and Challenges**

### Opportunities:

- The CAO network provides a ready-made platform to coordinate national collaboration between health and higher education institutions.
- There is a strong foundation for Academic Health Science Systems, with regional strengths in Cork, Dublin, Galway, and Limerick.
- Ireland can become a global hub for trials and MedTech evaluation, building on its clinical and manufacturing excellence.
- Joint clinical academic roles support retention, morale, and innovation across health disciplines.
- Academic partnerships offer pathways for wealth creation through IP generation, clinical validation, and workforce development.

### Challenges:

- Absence of a formal national framework for Academic Health Science Systems limits strategic alignment.
- Clinical academic career pathways remain underdeveloped, with few protected time or promotion routes.
- Infrastructure and funding for clinical trials are uneven and under-resourced. Fragmented governance between the HSE and HEIs delays joint initiatives and dampens system-wide innovation.
- Without investment in research capacity within care delivery, Ireland risks underperforming relative to international comparators (e.g., NIHR in the UK).

## EU Context

The European Commission's ambition to make the EU the world's most attractive life sciences hub by 2030 aligns directly with the CAO vision. Ireland's strategy should embrace this by positioning our health service as an academic, translational and commercial partner within the EU.

Key recommendations include:

- Participating in European Health Data Space and EU-wide trials through research-ready health regions.
- Leveraging EU Mission funding in areas like cancer and brain health via integrated academic-clinical teams.
- Hosting EU-level infrastructure (e.g., translational centres, real-world evidence platforms) that bridge discovery with patient benefit.
- Learning from models like France's university hospitals, Germany's Centres for Health Research, and the UK's NIHR.

## Conclusion

Chief Academic Officers (CAOs) are uniquely placed to advance the goals of the National Life Sciences Strategy through deepening the partnership between the HSE and Ireland's universities. By formalising and investing in an Academic Health Science System with career structures, infrastructure, and joint governance Ireland can achieve health, economic and societal impact at scale. Clinical trials, innovation, education, and rapid translation of research into care must be seen not as add-ons, but as core functions of a 21st-century health service.



Professor Helen Whelton  
Head of College of Medicine & Health, UCC  
Chief Academic Officer, HSE South West

*On behalf of the Chief Academic Officers*

**Professor Helen Whelton**, Head of College of Medicine and Health - University College Cork, Chief Academic Officer –  
**HSE South West**  
**Professor John Laffey**, Professor & Consultant of Anaesthesia Intensive Care Medicine, Galway University Hospital, Chief Academic Officer –  
**Saoilta University Health Care Group**  
**Professor Timothy Lynch**, Consultant Neurologist - Mater Misericordiae Hospital, VP Health Affairs - UCD, Chief Academic Officer –  
**Ireland East Hospital Group**  
**Professor Calvin Coffey**, Chair in Surgery, & **Clodagh O’Gorman**, Consultant Paediatrician & Chair of Paediatrics, joint interim Chief Academic Officers, **UL Hospital Group**  
**Professor Martina Hennessy**, Consultant Pharmacologist, St James Hospital, Chief Clinical Academic Officer, **Dublin Midlands Hospital Group HSE**  
**Professor Susa Benseler**, MD PhD, FRCP, FCAHS, Paediatric Rheumatologist and Paediatric Emergency Medicine Physician, Chief Academic Officer and  
Head of Paediatric Health Affairs - **Children's Health Ireland**



Oifigeach Feidhmiúcháin Réigiúnach,

FSS Iardheiscirt, Áras na Ceachan, Páirc  
Ghnó agus Teicneolaíochta, Bóthar na Modh  
Feirme, Corcaigh

Regional Executive Office

HSE South West, Caha House,  
Business & Technology Park, Model  
Farm Road, Cork T12 XHT4

[www.hse.ie](http://www.hse.ie)  
[@hselive](https://twitter.com/hselive)

t 021 486 8209  
e [REO.southwest@hse.ie](mailto:REO.southwest@hse.ie)

5<sup>th</sup> December 2025

**Ireland's National Life Sciences Strategy**  
By Email: [lifesciences@enterprise.gov.ie](mailto:lifesciences@enterprise.gov.ie)

**Re: National Life Sciences Strategy Consultation**

Dear Colleagues,

The office of the REO HSE SW Region welcomes the opportunity to contribute to the National Life Sciences Strategy and presents a perspective from a Regional Health Service with an ambition to promote research in the life sciences to enhance patient care. This submission is in keeping with the Sláintecare strategy and as outlined in the HSE National Service Plan 2025, the health service is committed to embedding research and innovation within care delivery to drive integrated, high-quality services.

### Scope

Ireland's National Life Sciences Strategy should adopt a broad, integrated scope that explicitly includes the healthcare system as a central actor. Life sciences innovation does not end at the factory gate or research lab, it must translate into improved health outcomes, better patient experiences, and system-wide efficiency. This requires a strong, research-active health service. Patients within research active health systems enjoy better outcomes of care.

The strategy should reflect the interconnectedness of (bio)pharmaceuticals, medical technologies, diagnostics, digital health, and population health. It must also address agriculture, nutrition, and microbiome science as part of the broader life sciences system. However, the interface between the health service and the life sciences sector, where discovery meets delivery deserves targeted focus. This includes embedding clinical trials, translational research, and innovation pathways across the public healthcare system.

### Objectives

To ensure long-term national success, the strategy should prioritise the following objectives related to the health–life sciences interface:

- Support and promote research activity within the health service, with protected time, infrastructure and funding for HSE-based research staff.
- Significantly expand clinical trials, as committed in the Programme for Government, ensuring every patient has access to research and innovation in care.
- Enable rapid translation of research into frontline practice, leveraging Ireland's integrated health regions and academic partners to build learning healthcare systems.
- Support health service/university/industry collaboration, recognising the essential partnership between academic science, clinical research, and innovation.
- Work with innovation enablers such as Health Innovation Hub Ireland to identify, co-develop, and implement innovative solutions that address real clinical and operational challenges.



- Develop mechanisms for wealth creation, including support for health-based spinouts, public-private partnerships, and real-world evidence collaborations with industry.
- Promote equity, by ensuring regional and rural access to clinical research and trials, not just in major urban centres.

### **Opportunities and Challenges**

#### **Opportunities:**

- Ireland can position its health service as an innovation platform, accelerating the development, testing and adoption of new diagnostics, therapies, and digital tools.
- The South-West region, which includes among other hospitals, Cork University Hospital (CUH) as Ireland's largest academic teaching hospital, already has the scale and expertise to act as a model for a regionally embedded, research-active health service.
- Embedding research across the HSE will improve workforce retention and professional development, as shown in international evidence.
- Clinical trials can serve as a magnet for investment, especially when combined with digital infrastructure and real-world data capability.
- Building a national HSE/university/industry research network will enable Ireland to compete for international research and innovation funding.

#### **Challenges:**

- Ireland lacks a dedicated research investment model within the health service, unlike the UK's National Institute for Health and Care Research (NIHR). KPMG analyses show that for every £1 invested in NIHR research, more than £13 of economic benefit is returned and recent estimates place this return as high as £19 per £1 invested. Between 2016/17 and 2018/19, NIHR-supported clinical research generated an estimated £8 billion in gross value added (GVA) and 47,467 full-time equivalent jobs. NHS providers gained significant benefits too, earning around £9,200 per commercial trial patient and saving an average of £5,800 per patient in drug costs. Annual rates of return on investment in Biomedical Research Centres were calculated at 29–58%.
- There is insufficient support for clinicians and health professionals to conduct research within the HSE.
- Research infrastructure across the country is uneven, with limited trial capacity outside major cities.
- Ethical and regulatory approval systems remain slow and fragmented, reducing Ireland's international competitiveness for as a location for clinical trials.
- Gaps between health and enterprise policy risk disconnecting innovation from real-world care delivery.



## EU Context

The European Commission's Life Sciences Strategy rightly aims to position the EU as the world's most attractive location for life sciences by 2030. Ireland can be a leader in this effort but only if the health service is empowered to act as an innovation partner.

Key EU measures, including support for clinical trial reform, cross-border R&D funding, and the development of resilient health technology supply chains, are directly relevant to Ireland's HSE.

To align with these goals, Ireland should:

- Develop a HSE led applied research agenda focused on EU health missions (e.g cancer, brain health, ageing, AMR). Make Ireland a preferred site for EU-supported trials.
- Invest in co-located Innovation Districts and Academic Health Science Systems/Centers, where EU-funded projects can scale from lab to bedside.
- Build capacity for health data interoperability, enabling Ireland to contribute to the European Health Data Space.

## Conclusion

To unlock the full value of the life sciences sector, Ireland must activate its health system as a co-leader in research and innovation. The HSE South-West Region stands ready to demonstrate how this can work in practice with Cork University and other Hospitals, the wider community and public health service, UCC, Health Innovation Hub Ireland, and industry partners already collaborating on trials, translational medicine, and MedTech development.

We call for the creation of a dedicated funding stream for health service-based research, modelled on the UK's NIHR. This will ensure that discovery leads to delivery, innovation improves lives, and economic value is captured nationally. The return on investment demonstrated by NIHR (up to £19 for every £1 invested) confirms the transformative potential.

This strategy is not only about economic growth, it is about delivering better care, faster, and creating a learning, innovative health system fit for the 21st century.

Yours Sincerely,

---

**Dr. Andy Phillips**  
Regional Executive Officer  
HSE South West

# Submission from InterTradelreland

## InterTradelreland Response to Life Sciences Strategy Public Consultation

Prepared for: Department of Enterprise, Tourism, and Employment

Submission Date: 5 December 2025

InterTradelreland Contact Point: Siobhán Fearon, Strategy & Policy Manager

### InterTradelreland: brief overview

- InterTradelreland is one of six North-South Implementation Bodies established under the 1998 Belfast Good Friday Agreement that works on an all-island basis.
- InterTradelreland is legislated to promote trade and economic co-operation between both jurisdictions on the island.
- InterTradelreland is funded by the Department of Enterprise, Tourism and Employment in Ireland and the Department for the Economy in Northern Ireland.

### Background

InterTradelreland welcomes the opportunity to contribute to this consultation. Our experience in facilitating cross-border collaboration and supporting scaling enterprises positions us to contribute meaningfully to both this strategy and EU-level ambitions, particularly in developing the cluster-based approaches which can help indigenous businesses compete globally.

Through our programmes including Seedcorn and investor readiness initiatives, InterTradelreland has supported life sciences ventures, with notable success in medical device companies. Looking ahead, we see potential to enhance support for the sector through our venture capital competition, collaborative partnership development, and by facilitating connections between researchers, entrepreneurs, and investors across the island.

### InterTradelreland Response

#### 1. Scope

***Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.***

***In your view, how broad should the scope of the strategy be?***

InterTradelreland recommends a focused approach that prioritises (bio)pharmaceuticals, medical technologies, diagnostics, and drug discovery, while acknowledging the interconnections with other sectors. A tightly defined scope will enable deeper analysis and more actionable recommendations, particularly in areas where Ireland has established competitive advantages.

We recognise the potential value of including broader life sciences sectors such as agriculture, fisheries, and food production. However, these sectors may warrant separate strategic consideration

to avoid information overload and conflicting priorities. The consultation process could explore sector reclassification or introduction of new sectoral definitions to address overlaps and emerging opportunities.

Of particular note is the Femtech sector, which represents a significant opportunity within the medical technology space. Femtech covers innovation, research, and commercialisation of technologies addressing women's health needs, ranging from reproductive and maternal health to digital health, menopause, and chronic conditions. The recent Health Innovation Hub Ireland Femtech Report "*Femtec in Ireland. The Case for Prioritising Women's Health Research and Innovation*" highlighted the strong growth potential and aligns with Ireland's established medtech capabilities.

## **2. Objectives**

***What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability***

The National Life Sciences Strategy should pursue objectives that support both foreign direct investment and indigenous enterprise development. Key objectives should include:

### **Commercialisation and Investment Ecosystem**

- Streamline pathways for commercialising scientific research
- Develop best-in-class R&D funding mechanisms
- Create robust support for university spin-outs through enhanced tax incentives and dedicated funding streams
- Provide specialised support for HPSUs navigating complex regulatory pathways

### **Talent and Skills Development**

- Build a skilled workforce through improved collaboration between industry and academia
- Develop pipelines of suitably qualified graduates aligned with sector needs
- Attract and retain both domestic and international talent
- Support researchers with real opportunities to translate research into commercial outcomes

### **Innovation and Global Competitiveness**

- Position Ireland as a leader in AI applications across life sciences, particularly in drug discovery
- Foster innovation through strategic clustering approaches that provide access to leading talent and facilities
- Support priority areas including women's health research and innovation
- Scale Femtech start-ups, particularly those led by women entrepreneurs

### **Ecosystem Development**

- Build strong connections between government, academia, healthcare providers, and industry
- Encourage collaborative partnerships that accelerate development and scaling
- Support indigenous businesses to utilise research and academic expertise across the island
- Develop mechanisms for faster, more agile translation of research outcomes to market

### **Health Outcomes and Sustainability**

- Ensure the strategy delivers meaningful improvements in healthcare delivery
- Address critical gaps such as women's health, which currently receives insufficient research and investment attention
- Maintain focus on sustainable growth and long-term sector viability

## **3. Opportunities and Challenges**

***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***

### **Key Opportunities**

#### *Leveraging Existing Strengths*

- Ireland's strong medtech sector and supportive government framework position the country as a potential EU leader in particularly in emerging areas like Femtech
- Existing multinationals could be incentivised to support indigenous companies and start-ups through testing facilities, investment, mentorship, and procurement opportunities

#### *Economic Impact*

- Significant economic potential exists in underserved markets: closing the women's health gap alone could add \$1 trillion to global GDP by 2040
- High demand for solutions in areas including fertility, menopause, digital health, and chronic conditions management

#### *Strategic Clustering*

- Creation of focused, strategic clusters (such as the AICRI model) can provide competitive advantages through shared access to talent, facilities, and resources
- The island of Ireland creates unique opportunities for collaborative efforts
- Clustering approaches can accelerate development and help indigenous businesses tackle larger challenges collectively

#### *AI and Innovation Leadership*

- Opportunity to establish Ireland as a global leader in AI exploitation across life sciences, particularly in drug discovery
- Potential to differentiate Ireland's offering in an increasingly competitive global market

#### *Cross-Border Collaboration*

- Potential for all-island initiatives, such as extending the nascent FemTech Innovation Lab to Northern Ireland

- Opportunities to support businesses and researchers to scale through cluster activity and knowledge sharing
- EU-wide collaboration and funding mechanisms can accelerate growth and impact

#### *Investor Readiness and Commercialisation*

- InterTradelreland's experience shows strong performance from life sciences sector in programmes like Seedcorn, particularly medical device ventures
- Active investment community exists, including specialised syndicates like the MedTech syndicate

### **Key Challenges**

#### *Infrastructure and Resources*

- Limited availability of laboratory space and specialised facilities
- Need for significant investment to develop and maintain competitive infrastructure

#### *Funding Gaps*

- Underfunding of Femtech and other emerging subsectors
- Limited access to dedicated investment for early-stage start-ups

#### *Regulatory and Market Access*

- Complex regulatory environments and slow clinical validation processes
- Market access barriers, particularly challenging given Ireland's small domestic market
- Need for enhanced support to help companies navigate international markets

#### *Talent and Skills*

- Shortage of expert staff in specialized areas
- Skills gaps in digital health and biomedical engineering
- Competition from other jurisdictions for top talent

#### *Cost of Living and Business Environment*

- Housing shortages and high cost of living impacting ability to attract and retain talent, leading to a reluctance to invest
- Need to address quality of life issues to maintain competitive advantage

#### *Research and Innovation Recognition*

- Women's health and other priority areas require greater recognition as research and innovation priorities at national and EU levels
- Highly competitive funding environment
- Need to ensure adequate support for indigenous researchers and enterprises

#### *Competitive Landscape*

- Global competition for life sciences investment and talent
- Need for Ireland to differentiate its offering while maintaining agility in rapidly evolving markets

### **4. EU Context**

**The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.**

**What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?**

InterTradeIreland supports measures which accelerate ambition and facilitate scaling for businesses, academics, and researchers operating on the island. Specific applications could include:

#### *Leveraging EU Frameworks*

- Utilise EU funding mechanisms and collaborative programs to support cluster development and knowledge sharing
- Align Irish strategy with EU measures to maximise access to resources and partnerships
- Position Ireland as a key contributor to EU-wide life sciences goals while maintaining distinct competitive advantages

#### *Cross-Border Dimension*

- Given our all-island remit, there is significant potential to develop initiatives that leverage research and commercial capabilities across the island
- The island's unique ecosystem can deliver collaborative outcomes, particularly through cluster-based approaches
- Examples include potential expansion of initiatives like the FemTech Innovation Lab on an all-island basis

#### *Accelerating Innovation*

- Support businesses and researchers to engage in EU-level cluster activity
- Share knowledge and resources to tackle larger challenges collectively
- Develop mechanisms to help enterprises move faster from research to commercial application

#### *Strategic Investment*

- EU context highlights the need for significant, strategic investment in infrastructure, talent development, and innovation support
- Ireland should ensure its national strategy complements and leverages EU-level initiatives
- Focus on areas where all-island collaboration can provide unique value within the EU ecosystem

# Joint Submission from Irish Pharmaceutical Healthcare Association and HealthTech Ireland



---

## Partnering for Success: Industry's role in shaping Ireland's Life Science Strategy

### A collaborative vision by IPHA and HealthTech Ireland

---

#### Vision

To be a world-leading hub in life science innovation, renowned for its integrated ecosystem, to secure prosperity, and build a healthier Ireland.

#### Mission:

To have a future ready, dynamic ecosystem that connects cutting-edge research, innovation, diagnostics and digital health technologies with patients while supporting Ireland's thriving manufacturing footprint. Through strategic collaboration across government, industry, and academia, we aim for sustainable economic growth, to improve public health outcomes, nurture our skilled workforce and ensure timely access to transformative treatments for all.

---

#### Context

Ireland stands at a pivotal moment to shape a future where life sciences drive both economic prosperity and health system transformation. This summary outlines three interconnected pillars that reflect national priorities and global opportunities, aligning with government and HSE strategies considering best international practice and factors of success.

---

#### Pillar 1 – Fostering Enterprise

Accelerate Ireland's position as a world-leading hub for innovation, investment, and sustainable growth grounded in essential strong policy alignment and cross government cohesion.

#### **Priorities:**

- **Indigenous Growth** – Nurture home-grown life sciences enterprises, from start-ups to scale-ups.

- **Digital, AI, and Data** – Advance and strengthen competitiveness via next-generation technologies.
- **Strategic Innovative Partnerships** – Facilitate cross-sector collaboration connecting the right experts at the right time to unlock synergies between government, academia, and industry.
- **Foreign Direct Investment** – Sustain Ireland’s reputation as a top destination for high-value investment and grow our leadership in attracting further FDI.
- **Manufacturing Excellence** – Protect and expand Ireland’s advanced manufacturing capacity.

**Infrastructure.** Prioritise investment in strategic sites and digital infrastructure to meet future demand.

---

**Pillar 2 – Innovation Uptake** Ensure the value of our cutting-edge life science innovations, medicines and technology translate into real world impact for patients in Ireland and health system through rapid integration and adoption.

**Priorities:**

- **Access Ecosystem** – Accelerate access to digital tools, data, medicines, and clinical trials.
  - **Equity and Timeliness** – Deliver innovation benefits to patients swiftly and fairly.
  - **Procurement Reform** – Shift to value-based models and outcome-driven purchasing that reward outcomes, not just cost.
  - **Connectivity** – Integrate systems, records, and services to enable rapid scale-up of solutions and enhanced healthcare outcomes for patients.
  - **Early Launch Market** – Position Ireland as a priority market for innovation introduction.
  - **Clinical Trials Expansion** – Maintain momentum in trial numbers, speed of initiation, and cost competitiveness.
- 

**Pillar 3 – Research, Development, Data and Digital**

Become a global hub of excellence for research and innovation that underpins the health and the wealth of the nation by building leveraging Ireland’s existing manufacturing and clinical strengths.

**Priorities:**

- **Global Hub of Excellence** – Make Ireland synonymous with high-impact life sciences research.
  - **Data and Digital Leadership** – Enable precision medicines, advanced diagnostics and digital health adoption through Government initiatives.
  - **FDI Growth in R&D** – Move up the value chain in international investors perception.
  - **World-Class Ecosystem** – Ensure facilities and networks meet the best in global standards.
  - **Address Major Health Challenges** – Prioritise areas of unmet need such as cancer, dementia, and chronic disease management.
-

### Cross-Cutting Enablers

- **Life Science Council** – Create the capability for trusted, ongoing cross sector input to deliver on all ambitions.
- **Skills and Talent Pipeline** – Develop, invest, and retain the workforce needed for a high-value life sciences economy and to build a future-ready workforce in STEM, AI, clinical, regulatory.
- 
- **Regulatory Reform** –Streamline regulatory pathways to support innovation uptake.
- **AI and Digital Transformation** – Embed these technologies into healthcare delivery, manufacturing, and research.
- **European Health Data Space** – Position Ireland as a leader in leveraging European-wide health data to drive innovation and enhance care delivery.
- **Shared Island Initiatives** – Collaborate across the island to pool expertise and resources.
- **R&D Incentives** –Evolve supports to encourage innovation while ensuring fiscal sustainability.

---

### Key Recommendations for Government to promote Ireland as a global launchpad for life sciences innovation:

1. **Establish a Life Sciences Council** – A permanent, high-level forum for government–industry–academia collaboration.
  2. **Accelerate Digitalisation of Healthcare** – Implement the three National Strategies with urgency.
  3. **Fast access to Innovation** – Ensure rapid patient access to medicines, diagnostics, and digital solutions.
  4. **Strengthen R&D Investment** – Match leading life sciences nations in investment and incentives.
  5. **Enable Innovative Partnerships** – Support cross-sector collaboration for shared benefit:
-

# Submission from Irish Pharmaceutical Healthcare Association



Irish Pharmaceutical  
Healthcare Association

## IPHA Submission to Department of Enterprise, Tourism and Employment on National Life Sciences Strategy

5<sup>th</sup> December 2025

### Scope

*Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.*

*In your view, how broad should the scope of the strategy be?*

A successful strategy requires precision. For Ireland's National Life Sciences Strategy to deliver measurable impact and attract global capital, it must adopt a focused scope exclusively centered on human health. This definition aligns with international best practices and acknowledges the unique complexity of modern healthcare innovation.

Globally, the "Life Sciences" sector is defined by the convergence of biopharmaceuticals, medical technology (MedTech), and digital health. Leading jurisdictions—such as the United Kingdom and Denmark—explicitly separate human health strategies from broader bio-economy sectors. The same is seen in Massachusetts (US). By mirroring this approach, Ireland ensures its policy environment speaks the same language as international investors and regulatory bodies (EMA, FDA).

While the Agriculture, Food, and Marine sectors are vital pillars of the Irish economy, boasting world-class standards and significant export value we believe that they operate under fundamentally different regulatory frameworks, R&D timelines, and capital markets than human health.

To remain a global leader, Ireland's Life Sciences strategy must not dilute its focus; it must address the distinct ethical, clinical, and industrial realities of patient care.

To provide clarity for stakeholders and investors, we propose defining the "Life Sciences" ecosystem through three interconnected, health-focused domains:

- **Biopharmaceuticals:** Encompassing small molecules, biologics, and next-generation Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies.
- **Medical Technologies:** Covering medical devices, in-vitro diagnostics (IVD), and equipment essential for precise diagnosis and treatment.
- **Digital Health:** Leveraging health data analytics, digital therapeutics, and Artificial Intelligence (AI) to drive efficient care pathways and patient outcomes.

This focused definition allows for clear objectives that link Ireland's industrial strengths directly to improved health outcomes for its citizens, ensuring the strategy remains agile, relevant, and globally competitive.

## Objectives

***What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?***

***For example: research and innovation, global competitiveness, patient outcomes, talent and skills,***

IPHA believes that the National Life Sciences Strategy should be the enabler for a future ready, dynamic ecosystem that nurtures and rewards scientific advancements, connecting cutting-edge research and innovation with patients through rapid adoption, thereby positioning Ireland as an early-launch market for innovative medicines and digital health technologies. It should also support Ireland's thriving manufacturing footprint, recognising the role global industry partners play as key contributors to this ecosystem.

The strategy should set clear, measurable objectives to secure Ireland's long-term success:

1. **Improve patient outcomes:** Ensure rapid adoption of innovative medicines and technologies, supported by sustainable reimbursement pathways.
2. **Clinical Trials Expansion:** Streamline approvals and harmonize processes to make Ireland attractive for clinical trials.
3. **Foster a vibrant innovation ecosystem:** Support science-driven regulation, incentivize R&D, and enable public-private partnerships.
4. **Retain strong IP protection:** Maintain a robust, predictable intellectual property framework to incentivize innovation and help close the gap with other global leaders to ensure competitiveness.
5. **Digital transformation:** Implement a national Electronic Health Record (EHR) system and enable responsible AI adoption in healthcare.
6. **Sustainability:** Balance environmental regulation with industrial competitiveness through proportionate, evidence-based approaches.
7. **A Life Sciences Council and Innovative Partnerships:** A permanent, high-level Life Sciences Council for government–industry–academia collaboration should be established. This would enable cross sector Innovative Partnerships to develop for shared benefit.

**Talent and Skills:** Continuous professional development and lifelong learning will be critical to keep pace with evolving technologies and regulatory standards. Emerging fields such as cell and gene therapy, personalized medicine, and advanced therapeutics demand highly specialized expertise. To meet this challenge, the Life Sciences Strategy must prioritize future-focused skills development. There is a growing need for STEM talent with strong capabilities in bioprocessing, data analytics, automation, and digital transformation—including AI, digital manufacturing, and Industry 5.0 competencies. Promoting STEM education among underrepresented groups, including women and minorities, is essential. This can be achieved through deeper partnerships with universities and technical institutes to co-create industry-aligned curricula, apprenticeships, upskilling programs, and work placements. Attracting global talent will also require investment in housing and infrastructure, while strengthening Ireland's international reputation as a leading biopharma hub that offers career growth, quality of life, and opportunities to make a meaningful impact.

**Make Ireland a leader for the life sciences at EU level:** The EU's legislative and policy framework is a significant determinant of Irish competitiveness and shapes our domestic eco-system to a high degree. It is vital therefore that Ireland uses its voice consistently and effectively to champion the life sciences sector in all relevant discussions at EU level, with the understanding that the future success

of this sector is closely aligned to Ireland's national interest. This will have a double effect – first of improving the overall environment for the life sciences in Ireland and across Europe, and second of sending a strong signal to the sector internationally that Ireland is a leader in this field. Specifically, this will require a conscious cross-Government approach in Council discussions on relevant policy files, working in consultation with a proposed Life Sciences Council.

### Opportunities and challenges

***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***

Ireland's life sciences sector stands at a pivotal moment. Building on its global reputation for manufacturing excellence, the next decade offers opportunities to transform Ireland into a world-leading hub for innovation, digital health, and advanced research. At the same time, structural and regulatory challenges must be addressed to maintain competitiveness and deliver better health outcomes. The National Life Sciences Strategy should focus on leveraging these opportunities while mitigating risks.

### **Opportunities**

#### **1. Strong Manufacturing Base and Global Reputation**

Our heritage in innovation is key to Ireland's continuing success in the life sciences sector and in attracting new investments. Ireland's established leadership in biopharmaceutical and medtech manufacturing through continuity of policy over 50 years provides a robust platform for growth. By moving further up the value chain into high-value R&D, increased clinical trials, advanced therapies such as cell and gene, and digital health integration, Ireland can attract additional foreign direct investment and position itself as a launchpad for next-generation treatments.

#### **2. Access to EU Funding for Innovation**

EU programs such as Horizon Europe and future framework initiatives offer significant opportunities to fund biotech clusters, AI-driven healthcare, and clinical trial harmonization. Ireland should prioritize life sciences in EU strategic budgets and actively lead collaborative projects to strengthen its global competitiveness.

#### **3. Digital Health Transformation**

Accelerating the adoption of Electronic Health Records (EHR) and AI-enabled platforms will unlock precision medicine, real-world evidence generation, and predictive analytics. This digital shift will improve patient outcomes, reduce inefficiencies, and create a data-rich environment for research and innovation.

#### **4. Ireland's 2026 EU Presidency**

The timing of this strategy development coincides with a unique opportunity for Ireland to demonstrate leadership on the European stage. Ireland will hold the Presidency of the European Council in the second half of 2026. Launching a bold and ambitious National Life Sciences Strategy *before* the presidency begins would send a powerful signal of Ireland's commitment to becoming a European leader in this critical sector. It would provide a platform to champion innovation and shape the European agenda from a position of strength and clear strategic intent.

## **Challenges**

### **1. Regulatory Complexity and Slow Approvals**

Fragmented and lengthy approval processes for medicines and clinical trials hinder Ireland's ability to act as an early-launch market. The strategy must introduce streamlined pathways, regulatory sandboxes, and competitiveness checks to maintain global parity. Ireland needs to demonstrate progress towards faster patient access to new medicines and adherence to EU legislation on same.

### **2. Absence of a National EHR System**

Ireland remains the only EU country without a national EHR, limiting digital health adoption and data-driven R&D. Urgent investment is needed to implement interoperable health records and integrate with the European Health Data Space. Patients need greater access to their own information to make informed decisions about their health and care options. Furthermore, the integration of Artificial Intelligence, could enhance drug discovery, optimize clinical trials and improve patient outcomes.

### **3. Talent Shortages and Housing Constraints**

Skills gaps in STEM, data science, AI, and regulatory expertise threaten future growth. Coupled with housing shortages and high living costs, these factors impact Ireland's ability to attract and retain global talent, requiring coordinated policy action.

### **4. Risk of Overregulation**

The Strategy should reflect that regulatory requirements and industrial competitiveness are not mutually exclusive, and can be achieved through a transparent, science-based and structured dialogue. A pragmatic approach is needed to avoid the increasing complexity (and sometimes inconsistency) of environmental and pharmaceutical legislations undermining Ireland's competitiveness. Ireland should advocate for harmonized, pragmatic regulation that supports innovation while ensuring patient safety.

To secure Ireland's position as a global life sciences leader, the strategy must capitalize on digital transformation, EU funding, and Ireland's manufacturing strength, while addressing systemic challenges in regulation, infrastructure, and talent. A coordinated, future-ready approach will ensure Ireland remains competitive, innovative, and resilient in a rapidly evolving global landscape.

### **5. Policy Fragmentation**

The breadth of policy files which impact upon the life sciences sector means that relevant policymaking can easily occur in isolation, without a holistic view of its impact. A cross-departmental approach to policymaking is required going forward. Given its central role in overseeing the delivery of care to patients, and engagement with researchers, and with the med-tech and biopharmaceutical industries, the Department of Health will be especially critical to the success of any Life Sciences Strategy in Ireland.

## **EU context**

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

### **Aligning with European Ambition and Leadership**

The European Commission's ambition to make the EU the world's most attractive life sciences hub by 2030 is strongly supported. It is critical that Ireland's National Life Sciences Strategy is developed in close alignment with the broader European framework. This alignment is essential not only for maintaining competitiveness but also for accessing significant funding streams, influencing future EU policy, and leveraging pan-European initiatives to advance our domestic goals.

The EU Life Sciences vision is supported by three key strategic pillars. By aligning with these pillars, Ireland can leverage European momentum and resources to accelerate progress on its national objectives.

1. **Optimising the research and innovation (R&I) ecosystem:** We need to leverage EU funding for Irish research and innovation projects.
  - The EU's drive to create a single market for clinical trials provides a powerful tailwind for efforts to strengthen the *local Irish clinical trial ecosystem* and increase participation in multi-country studies.
  - The significant EU funds being mobilized to drive innovation present a major opportunity for *local R&D projects* to secure investment, particularly through public-private partnerships.
2. **Enable rapid market access:** We need to streamline local regulatory frameworks and adopt expedited pathways.
  - The EU's focus on simplifying regulation should serve as an impetus to modernize and *simplify local Irish regulatory frameworks*, reducing administrative barriers and speeding up the innovation pathway.
3. **Boost trust and uptake:** Implement EHR and digital health solutions to improve patient engagement and outcomes.
  - The EU strategy's strong emphasis on harnessing AI and data can guide and accelerate *local digital and e-health developments*, including the urgent task of implementing a national EHR system.



Putting the **patient voice** at  
the centre of Irish health care,  
policy, research and innovation

# DEVELOPMENT OF A NATIONAL LIFE SCIENCES STRATEGY

A submission on behalf of IPPOSI members and as part  
of a public consultation launched by the Department of  
Enterprise, Tourism & Employment

Irish Platform for Patient Organisations,  
Science, and Industry

**05 December 2025**

# CONTENTS

|   |     |
|---|-----|
| <b>About IPPOSI</b>   | 1   |
| <b>Introduction</b>   | 2   |
| <b>Scope of a National Life Sciences Strategy</b>   | 2-3 |
| <b>Objectives of a National Life Sciences Strategy</b>  | 3   |
| Key Objective 1: Establish a Sustainable Innovation Ecosystem to Drive Better Health Outcomes for All | 4   |
| Key Objective 2: Strengthen Pathways for Timely and Equitable Access to Health Innovation             | 5   |
| Key Objective 3: Foster a Unified, Person-Centred Life Sciences Ecosystem that Earns Public Trust     | 6   |
| <b>Opportunities &amp; Challenges for Ireland’s Life Science Sector</b>                               | 7-8 |
| <b>EU Context: How should Ireland Respond</b>   | 9   |
| <b>Conclusion</b>   | 10  |
| <b>One-Page Summary of Recommendations</b>  | 11  |

# ABOUT IPPOSI



Every big idea begins with a conversation. For IPPOSI – the Irish Platform for Patient Organisations, Science and Industry – that conversation started in the mid-1990s. Michael Griffith, a passionate patient advocate, was then chairing EPPOSI, a European think tank that united diverse stakeholders to tackle complex health challenges.

Inspired, Michael returned to Ireland determined to create a similar space – one where patients, researchers, healthcare professionals, industry, and government could collaborate as partners and shape the future of healthcare innovation in Ireland. That vision became IPPOSI and today we bring together **150+ patient organisation and individual patient advocates**, **200+ academic researchers** and **22 pharmaceutical and biotechnology companies** across Ireland and as members of our organisation.

Our vision is clear – to place the patient voice and lived experience at the centre of healthcare, policy, research and innovation. To make this possible, we provide education and capacity-building programmes that give individuals the knowledge, skills, and confidence to participate meaningfully in shaping health innovation agendas. We also create trusted space for open dialogue among diverse voices on shared priority areas and collectively co-create practical solutions—helping shape a healthcare ecosystem that is more inclusive, responsive, and innovative for all.

# INTRODUCTION

IPPOSI is pleased to contribute to the development of Ireland's National Life Sciences Strategy. As a patient-led, multi-stakeholder partnership bringing together patient organisations, healthcare professionals, academia, and industry, our mission is to ensure health innovation delivers tangible, measurable benefits for patients and the wider society. The Strategy should reflect our shared ambition to put **health outcomes** at the centre while driving research, innovation, and economic resilience. Specifically, it should aim to:

- Position Ireland as a global leader in health innovation to strengthen competitiveness in an increasingly uncertain geopolitical environment;
- Ensure timely and equitable access to new technologies; and
- Foster a unified, person-centred life sciences ecosystem that earns public trust and confidence in research and innovation.

Embedding patient and public perspectives and fostering cross-sector collaboration will enable Ireland to create an agile, inclusive health system that accelerates the discovery and adoption of breakthroughs to improve lives.

# SCOPE

***Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?***

Ireland's National Life Sciences Strategy should be **human-centred and prioritise health-related life sciences**, specifically (bio)pharmaceuticals and medical technologies, because these sectors have the most direct and immediate impact on health and wellbeing. The strategy must adopt a broad scope covering the entire value chain, from research and discovery through to manufacturing and patient access, while maintaining a clear focus on areas that deliver early, measurable impact. This balance will ensure clarity now and flexibility to integrate adjacent sectors, such as agriculture and food production, in the future.

For example, transforming Ireland’s clinical trial landscape would not only accelerate patient access to innovation but also strengthen Ireland’s position as a global leader in health research. Delivering on this ambition requires a multi-sectoral, multi-departmental approach to both development and implementation. Oversight by a single department is not sufficient; success depends on cross-departmental alignment and collaboration across health, enterprise, education, research, and other relevant areas—specifically senior officials from:

- Department of the Taoiseach
- Department of Health
- Department of Enterprise, Trade and Employment
- Department of Further and Higher Education, Research, Innovation and Science
- Department of Foreign Affairs
- Department of Climate, Energy and the Environment

This level of coordination will ensure the strategy is comprehensive, coherent, and capable of addressing challenges that span innovation, talent, regulation, and patient access.

## OBJECTIVES

### ***What should be the key objectives of the National Life Sciences Strategy to ensure the sector’s long-term success?***

The National Life Sciences Strategy must set clear and ambitious objectives that provide a roadmap for a person-centred, future-focused, and globally competitive approach.

To achieve this, IPPOSI recommends **three key areas of focus**:

1. Establish a Sustainable Innovation Ecosystem to Drive Better Health Outcomes for All
2. Strengthen Pathways for Timely and Equitable Access to Health Innovation
3. Foster a Unified, Person-Centred Life Sciences Ecosystem that Earns Public Trust

# KEY OBJECTIVE 1

## Establish a Sustainable Innovation Ecosystem to Drive Better Health Outcomes for All

To achieve this, Ireland must create the conditions for scalable innovation while strengthening global competitiveness, resilience, and its reputation as a trusted leader in health research and innovation. Ireland's strong foundations - world-class universities, a robust pharmaceutical and biopharmaceutical sector, highly skilled talent, an educated workforce, and a dynamic start-up ecosystem - provide a solid platform. However, these advantages risk erosion without greater public investment in research and development (R&D) and the digital infrastructure needed to enable innovation. This includes continued modernising of our healthcare system through digital transformation and establishing robust governance frameworks for the secure collection, sharing, and use of health data.

### Position Ireland as a Leading Location for Clinical Trials

Ireland currently lags behind comparable European countries in attracting clinical trials—a gap that limits patient access to cutting-edge treatments and weakens Ireland's global research competitiveness. While recent investments have improved trial infrastructure and methodology, further action is needed to scale and sustain impact. To achieve this, Ireland must streamline regulatory approvals, expand site capacity, and embed trials into routine care—ensuring patients gain timely access to innovative therapies.

### Accelerate Digital Health and Artificial Intelligence in Healthcare

Ireland's ability to compete globally in life sciences depends on a fully digitised, interoperable health ecosystem underpinned by strong data governance. This requires prioritising the design and implementation of interoperable data systems with robust governance frameworks—creating the foundation for predictive analytics, real-world evidence generation, and next-generation therapies.

### Embed Innovation into Everyday Care by Nurturing Learning Health Systems

Embedding innovation into everyday care demands the development of learning health systems—where healthcare, academia, and industry collaborate to translate research into real-world practice. This approach accelerates the uptake of new technologies and positions Ireland as a trusted leader in health research and innovation.

# KEY OBJECTIVE 2

## Strengthen Pathways for Timely and Equitable Access to Health Innovation

Innovation only delivers impact when patients can access it—at the right place and the right time. To secure Ireland’s long-term competitiveness and reputation as a leader in health innovation, the Strategy must eliminate delays and disparities in access to medicines and emerging technologies. This requires creating clear, predictable, and transparent pathways for regulatory approval, reimbursement, and adoption—supported by mechanisms for rapid deployment of proven innovations, not only in hospitals but also closer to home in community settings. Acting now will create a health system that is agile, inclusive, and trusted, ensuring breakthroughs reach patients without unnecessary delay.

### Modernise Reimbursement Frameworks

Align with European best practices, introduce adaptive pathways, and leverage real-world evidence to reduce uncertainty and accelerate access to innovative therapies.

### Build System Readiness for Rapid Adoption

Beyond reimbursement, Ireland needs operational structures that enable swift integration of approved innovations into routine care. This includes streamlined regulatory timelines, early engagement between regulators, payers, and innovators, and mechanisms for rapid deployment of proven technologies—ensuring patients benefit without unnecessary delays.

### Embed Equity as a Foundational Requirement

Access must be fair and inclusive, regardless of geography, socioeconomic status, or disease area. Proactive measures to identify and address health inequalities will ensure no patient or community is left behind.

“Ireland is a ‘laggard’ when it comes to digital health, we need immediate action to turn the situation around! Patients must be able to enjoy a digitally-enabled health system where information is shared with them to support self-management, and shared across healthcare settings to ensure quality care.”



**PASCAL DERRIEN**

IPPOSI CHAIRPERSON  
CEO of the Migraine Association & IPPOSI  
Patient Organisation Member

# KEY OBJECTIVE 3

## Foster a Unified, Person-Centred Life Sciences Ecosystem that Earns Public Trust

To compete globally, Ireland must act locally - by creating a unified life sciences ecosystem that puts patients and the public at its heart. Success depends on building an ecosystem that is inclusive, transparent, and trusted. Public confidence is not automatic; it must be earned through meaningful engagement, clear communication, and collaborative governance. This approach ensures innovation reflects real-world needs, strengthens societal trust, and positions Ireland as a European leader in ethical, patient-centred innovation.

### Ensure Meaningful Patient and Public Involvement

Embed engagement from the very start of strategy development and throughout implementation. This ensures priorities reflect lived experience, identify unmet needs, and align with the European Commission's emphasis on societal engagement.

### Establish Structured Multi-Stakeholder Collaboration via a Life Science Council

Create an Office for Life Sciences within the civil service to provide strategic oversight and coordination. In addition, establish a stakeholder council—similar to Denmark's Life Science Council—to bring together government, industry, academia, and civil society, including patient representation, to advise and shape implementation.

### Provide Clear Communication and Education on Why Life Sciences Matter

Co-design a communications strategy with the support of advocacy organisations that explains what life sciences are, why they matter, and builds trust in the value of sharing health data—critical for initiatives like the European Health Data Space and for enabling innovation. This ensures the strategy becomes more than a policy—it becomes a shared vision co-owned by all stakeholders.

"Patient engagement will always bring relevance. Relevance is a key word in getting work done"



**MARTIN SWEENEY**

IPPOSI Patient Member, UCAN Ireland

# OPPORTUNITIES & CHALLENGES

*What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?*

## Opportunities:

Delivering on the objectives of the National Life Sciences Strategy will unlock transformative opportunities for Ireland—strengthening global competitiveness, improving patient outcomes, and driving sustainable economic growth. Success will position Ireland as a leader in health innovation and as a model for inclusive, ethical research and development. Key opportunities include:

### **Position Ireland as a Global Leader in Health Innovation**

Ireland can leverage its strong research base, talent pool, and industry presence to become a preferred destination for the research, development, and delivery of health innovation. Success will mean faster translation of cutting-edge research into patient care, attracting international investment and partnerships, and creating high-value jobs that strengthen resilience and competitiveness.

Health innovation is not only a driver of improved care; it is a cornerstone of a knowledge-driven economy and a strong, resilient society. A robust Life Sciences Strategy can reduce healthcare system and caregiver burden, improve quality of life, and boost productivity and GDP—delivering benefits that extend far beyond the health sector.

### **Harness Ireland's Leadership in Public Engagement**

Ireland's track record in patient and public involvement offers a unique opportunity to lead globally in inclusive health innovation. Embedding meaningful engagement will build trust in science, accelerate adoption of new technologies, and create a collaborative ecosystem where government, academia, industry, and civil society work seamlessly together.

### **Expand and Enrich the Ecosystem for Long-Term Growth**

Beyond immediate operational needs, Ireland must invest in digital health infrastructure, interoperable data systems, and AI capabilities to enable personalised care and innovation. These investments will enhance Ireland's reputation as a trusted leader, attract global partnerships, and future-proof the sector against geopolitical and economic shocks.

## Challenges:

Ireland's life sciences sector faces structural barriers that must be addressed to achieve global leadership in health innovation. These challenges risk slowing progress, limiting competitiveness, and reducing patient access to cutting-edge treatments. Key issues include:

### **Underinvestment in R&D Limits Global Competitiveness**

Ireland ranks near the bottom among OECD countries for public investment in R&D. This underinvestment constrains innovation capacity, delays critical infrastructure development, and weakens Ireland's ability to compete for clinical trials and advanced therapies. Without significant funding increases, Ireland risks falling behind in precision medicine, genomics, and digital health—areas essential for future competitiveness and patient benefit.

### **Fragmented Ecosystem Undermines Collaboration and Scale**

Current efforts across government departments, agencies, and sectors are often siloed, leading to duplication, inefficiencies, and missed opportunities for collaboration. A lack of unified governance makes it harder to align priorities, streamline decision-making, and deliver a coherent national strategy. This fragmentation creates uncertainty for industry and research partners, slowing investment and innovation.

### **Risk of Losing Competitive Edge and Economic Opportunity**

If structural issues remain unresolved, Ireland will struggle to attract global investment, limit patient access to cutting-edge treatments, and miss the economic benefits of a thriving life sciences sector. Addressing these challenges is critical to building resilience and sustaining Ireland's reputation as a trusted leader in health innovation.

**“To address the evolving challenges in healthcare, it is imperative that we embrace innovation by dismantling traditional methodologies and encouraging new partnerships across the sector. This approach will not only improve efficiencies but also enhance patient outcomes and overall system resilience.”**



**DAVID MCMAHON**

IPPOSI Patient Member, CEO of the Irish Skin Foundation

# EU CONTEXT

## ***What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?***

The ambition to position the EU as the world's most attractive location for life sciences by 2030 is timely and necessary. Global competition for investment, talent, and innovation is intensifying, and a coordinated European approach can strengthen the region's ability to lead in advanced therapies, digital health, and sustainable manufacturing. We strongly support key elements of the EU Life Sciences Strategy, particularly its emphasis on:

- **Accelerating research and innovation** to maintain Europe's global competitiveness.
- **Advancing digital health and data sharing**, including the European Health Data Space, as a foundation for personalised care and AI-driven discovery.
- **Strengthening clinical trial networks across Europe**, enabling faster access to cutting-edge treatments.
- **Championing societal engagement and trust in science**, ensuring patient and public priorities shape innovation.

### **To align with this ambition, Ireland should respond by:**

- **Amplifying Ireland's strengths** - a world-class industry base, academic excellence, and a highly skilled workforce—while addressing structural gaps such as underinvestment and fragmented governance.
- **Positioning Ireland as a proactive contributor**, shaping EU initiatives on research, regulation, and patient engagement rather than simply adopting them.
- **Leveraging EU funding and partnerships** to accelerate R&D investment, scale innovation, and integrate Ireland into pan-European clinical trial networks.
- **Leading on societal engagement**, reinforcing Ireland's reputation for inclusive innovation and ensuring EU strategies reflect patient and public priorities.

By taking these steps, Ireland will not only benefit from the EU ambition but help make Europe the global leader in life sciences—delivering breakthroughs that improve health outcomes and strengthen economic resilience.

# CONCLUSION

A National Life Sciences Strategy is essential for Ireland’s health, economy, and global competitiveness. By embedding patient and public perspectives at its core, the Strategy will ensure research and innovation deliver real benefits for patients and society, strengthen trust in science, and accelerate timely access to medicines and clinical trials. This is about more than advancing science—it is about building an agile, inclusive health system and a resilient, knowledge-driven economy.

Aligned with the EU ambition to make Europe the world’s most attractive location for life sciences by 2030, Ireland has the opportunity to lead—not just participate. Ireland should position itself as a proactive leader in shaping global health innovation agendas. This means leveraging EU funding and partnerships to accelerate R&D investment, scale innovation, and integrate Ireland into essential pan-European clinical trial networks.

Launching the National Life Sciences Strategy during Ireland’s EU Presidency in 2026 would send a clear signal of ambition and commitment—cementing Ireland’s position as a trusted partner and global leader in health innovation.

# SUMMARY OF RECOMMENDATIONS

## Why a National Life Sciences Strategy Matters

From a patient and public perspective, the ultimate goal is clear: better health outcomes. Ireland has a unique opportunity to lead in health innovation—delivering faster diagnoses, better treatments, and improved quality of life for patients. A well-funded, patient-centred strategy will make health outcomes the priority while strengthening Ireland's competitiveness and building a resilient, knowledge-driven economy.

## Key Recommendations

### Establish a Sustainable Innovation Ecosystem to Drive Better Health Outcomes for All

- Position Ireland as a global leader in clinical trials by streamlining approvals, expanding site capacity, and embedding trials into routine care.
- Accelerate digital health and AI by prioritising interoperable data systems that enable discovery, personalised care, and innovation.
- Embed innovation into everyday care by creating learning health systems that unite academia, healthcare, and industry to drive uptake of new technologies.

### Strengthen Pathways for Timely and Equitable Access to Health Innovation

- Modernise reimbursement frameworks and align with European best practices to reduce uncertainty and accelerate access.
- Build system readiness for rapid adoption of innovation into routine care.
- Embed equity as a foundational requirement, ensuring no patient or community is left behind.

### Foster a Unified, Person-Centred Life Sciences Ecosystem that Earns Public Trust

- Ensure meaningful patient and public involvement from strategy design through implementation.
- Establish structured multi-stakeholder collaboration via a Life Science Council to align priorities and drive action.
- Provide clear communication and education on why life sciences matter, building trust in data sharing and innovation.

**PATIENTS**

**EDUCATE**

**SCIENCE**

**INVOLVE**

**INDUSTRY**

**IMPACT**

**CONTACT:**

*For further information or to discuss the recommendations outlined in document, contact:*

Laura Brady, PhD  
Chief Executive Officer

✉ [lbrady@ipposi.ie](mailto:lbrady@ipposi.ie)

[www.ipposi.ie](http://www.ipposi.ie)

# IVCA

Irish Venture Capital &  
Private Equity Association

Celebrating 40 years | 1985 - 2025

## Life Sciences in Ireland

**Strengthening Ireland's Life Sciences Leadership Through Investment in Data Infrastructure, Drug Discovery and Translational Research, and Domestic Venture Capital Capacity.**

### 1. Introduction

As Ireland develops its next Life Sciences Strategy, there is an opportunity to transform an already strong sector into a fully integrated innovation ecosystem.

Ireland is internationally recognised for its strong life sciences manufacturing base and research excellence. However, our innovation and commercialisation outputs, particularly in therapeutics, medtech, diagnostics, data-enabled health, and digital therapeutics, are constrained by underinvestment in data infrastructure, translational R&D, and the limited scale of domestic venture capital (VC) funds.

To continue to compete with high-performing innovation economies (Denmark, Netherlands, Singapore, UK, Canada), Ireland must invest strategically in five interconnected pillars:

1. Health data infrastructure
2. Translational and drug discovery capacity
3. International research partnerships
4. Modern reimbursement and early access frameworks
5. A deeper, better-capitalised life sciences investment ecosystem

Ireland's strengths in advanced bioprocessing, multinational engagement, academic excellence, and regulatory leadership give it an exceptional foundation. Targeted reforms will allow Ireland to capture more economic value, accelerate patient access, and strengthen global competitiveness.

These actions will drive indigenous industry formation, secure long-term value from public Research & Innovation investment, and reinforce Ireland's global attractiveness as a place to discover, trial, and scale future health technologies.

The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



## 2. Data Infrastructure as a National Asset

Ireland's fragmented health and research data environment limits our ability to participate in cutting-edge drug discovery, real-world evidence (RWE) generation, and Artificial Intelligence and Machine Learning-enabled innovation. High-performing ecosystems (Finland's Findata, Denmark's National Patient Registry, UK's NHS-GRCH partnerships) show that secure, integrated data infrastructures attract major industry R&D investment and accelerate innovation.

A national health data infrastructure would:

- Support the Sláintecare commitment to integrated, data-driven care.
- Underpin the HSE Digital Health Strategic Framework (2024–2030), particularly digital integration, interoperability, and data governance.
- Enable the Department of Health to contribute meaningfully to the European Health Data Space (EHDS) and position Ireland as a trusted access point for safe, regulated secondary data use.
- Strengthen HIQA's remit in data standards and expand capacity for anonymisation, stewardship, and secure data environments.

**Key actions include:**

- A unified national health data platform, with consistent standards for data collection, sharing, governance, and privacy.
- Integration of real-world data (RWD) from hospitals, primary care, registries, and digital health systems to enable longitudinal insights.
- Investment in data stewardship, governance, cybersecurity, and analytics.
- A high-quality national dataset will strengthen Ireland's attractiveness to global industry partners, enable large-scale research collaborations, and enhance national clinical decision-making.
- Linking Data Infrastructure with Research and Innovation will establish secure research environments where academic and industry researchers can access anonymised datasets and enable federated data models to support participation in multinational studies without compromising data sovereignty. Such integrated systems will accelerate biomarker discovery, support earlier diagnosis, and anchor Ireland in high-value global R&D networks.

## 3. Translational Research and Drug Discovery Capabilities

Ireland excels in basic research (SFI centres, University excellence, HRB programmes) but faces a persistent challenge in converting this research into commercial therapies, technologies, and companies.

The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



### 3.1 Building Robust National Translational Infrastructure

The creation of the ARC hub for therapeutics and the allocated budget of €31.6 million is a welcome development. Currently Ireland's translational capabilities are fragmented and underfunded relative to international competitors. To bridge the gap between academic excellence and commercial application, Ireland must:

- Develop dedicated translational hubs that combine wet-lab discovery, computational R&D, clinical trial capabilities, and industry partnership infrastructure.
- Increase strategic funding for early-stage drug discovery, medicinal chemistry, high-throughput screening, and preclinical validation.
- Expand access to bioprocessing, cell and gene therapy manufacturing, and GMP-grade facilities.

This will not only drive indigenous innovation but will also attract multinational pharmaceutical and biotech investment seeking integrated end-to-end development environments.

Ireland should establish a National Centre of Excellence for therapeutic drug discovery, embedding drug discovery and translational capabilities currently lacking. Such a centre would enable the translation and advancement of academic research from Irish universities into start-ups. The requisite scientific disciplines could work across multiple therapeutic areas irrespective of modalities (small molecules, biologics, or cell & gene therapy). Many EU countries and regions, e.g., Flanders in Belgium, have successfully established similar centres to advance indigenous biotech growth. Allocating a portion of the €750M Inspire R&D fund to this initiative would strategically address gaps in Ireland's translational capabilities.

### 3.2 International Partnerships as a Strategic Imperative

Ireland's life science growth increasingly depends on deep global connectivity. To remain competitive we must:

- Establish structured bilateral partnerships with leading innovation ecosystems (UK, US, Singapore, Nordic countries).
- Incentivise international industry–academic collaborative grants or projects, mobility programmes, and shared infrastructure initiatives.

Other countries have overcome similar gaps by investing in dedicated translational platforms, for example:

The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | +353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



- UK's Francis Crick Institute partnerships with AstraZeneca and GSK.
- Denmark's BioInnovation Institute, funded by Novo Nordisk Foundation.
- Singapore's Agency for Science, Technology and Research (A\*STAR).

Ireland can emulate these models by:

- Building national translational centres linked to clinical networks.
- Focusing on international collaborations to springboard activities.
- Strengthening public–private R&D partnerships through EI, IDA, and SFI.
- Expanding targeted funds for drug discovery, therapeutics platforms, and clinical translation.

### 3.3 Reimbursement Innovation to Accelerate Commercialisation

Ireland is well integrated in multiple international HTA collaborations at European and global levels. Through HIQA and NCPE, Ireland contributes to joint assessments, shares expertise, and leverages international evidence — which helps improve efficiency, avoid duplication of work, and align HTA methodology with best practice globally.

However, current reimbursement processes often delay patient access to cutting-edge therapies and limit Ireland's ability to serve as an early-launch market. Ireland does not have a formal, structured national early-access reimbursement fund, though the recent commitment to provide a €31M innovative medicines fund is welcome. Early access is typically case-by-case, reactive, and reliant on manufacturer participation. Outcome-based or performance-linked reimbursement is still limited compared to the UK (NICE Cancer Drugs Fund) or Germany (AMNOG "early access" pricing).

To be a credible global testbed for novel therapies and technologies, Ireland must adopt innovative reimbursement and early-access pathways. Examples include:

- UK's Early Access to Medicines Scheme (EAMS) for conditional access before formal marketing authorisation.
- Italy's AIFA designation for "innovative" medicines, immediately available with dedicated public fund support.
- Germany's AMNOG early market entry with post-launch price negotiation.
- Australia's provisional approvals pathway for oncology and advanced therapies.
- Pilots for digital therapeutics, precision medicine, and AI diagnostics.

Leadership in this area would make Ireland a preferred early-launch and clinical adoption site, reinforcing attractiveness for MNC investment and increasing opportunities for indigenous start-up scale-up companies.

The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



## 4. Deepening Domestic Venture Capital: Mobilising Pension & Insurance Capital

### 4.1 The Critical Gap

Irish VC funds are substantially smaller than international specialist funds (€40–€100M vs €300–€800M), limiting their ability to fund Series B–C rounds in capital-intensive life sciences. This pushes Irish companies to relocate, typically to the US, to access scale-up financing. The reality is that 75% of Irish life sciences companies that have attracted significant follow-on investment were initially funded by a local VC. However, the small size of local funds means many Irish VCs seed and support companies through the hardest years, only to watch global funds and other jurisdictions take the lion's share of equity and returns.

### 4.2 Mobilising Institutional Investors

Global experience shows that strong innovation ecosystems rely on participation from pension, insurance, and sovereign investors. Ireland can replicate international successes by enabling:

#### Option A – Innovation Allocation for Pension Funds

- A regulated allowance permitting pension schemes, including auto-enrolment, to allocate a small, risk-managed portion (1–3%) to domestic VC/innovation funds.
- Precedent: UK Mansion House Compact; Australia's Super Funds.

#### Option B – Insurance Company Investment Pathway

- Provide Solvency II-aligned guidance enabling modest, diversified investment in VC.
- Precedent: France and Netherlands regulatory adaptations.

#### Option C – National Fund-of-Funds

- Combine ISIF, EI, pension, insurance, and EU capital (InvestEU/EIF) to anchor multiple VC managers and attract international funds to establish Irish operations.
- Precedent: Singapore, Sweden, EIF regional platforms

#### Option D – Irish Scale-Up Growth Fund

- A €200M+ matched public–private fund to support Series B/C rounds, ensuring Irish companies remain headquartered and scaling domestically.
- Precedent: British Patient Capital; BPI France Growth.

The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



### Option E – MNC Corporate Co-Investment Schemes

- Structured pathways for multinationals to match public contributions in spin-outs, translational research, and early-stage deals.
- Precedent: Crick-AstraZeneca collaborations; Singapore's corporate co-investment vehicles.

International precedents demonstrate the impact of institutional LP participation:

- Canada – CPPIB investing in innovation and biotech clusters.
- Australia – Super Funds allocating to life sciences VC.
- Denmark – ATP investing in early and growth-stage biotech.
- UK – Mansion House Compact committing ≥5% of assets to unlisted equities and VC by 2030.

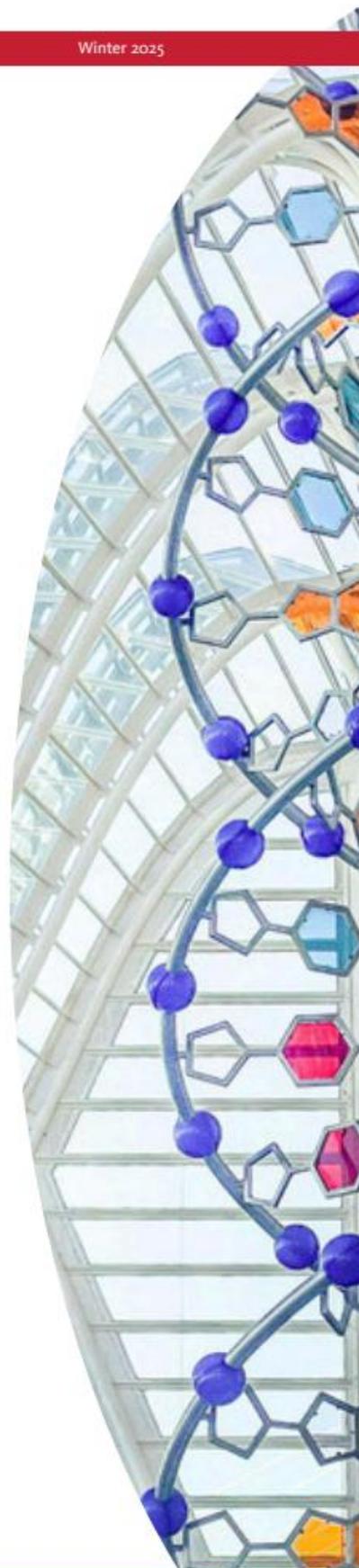
## 5. Strengthening the Indigenous Life Sciences Ecosystem

A successful national life sciences strategy must place far greater emphasis on the development, scaling, and long-term anchoring of Ireland's indigenous life sciences sector, including the full supply chain. While FDI remains a cornerstone, Ireland must enable domestic start-ups to become scale-ups and, ultimately, global acquirers rather than frequent acquirees.

Currently, the vast majority of Irish life sciences start-ups are acquired via trade sale to large multinational companies, typically US-based. While such acquisitions often deliver meaningful short-term gains, the long-term economic value would be greater if Ireland could grow a cohort of indigenous companies able to scale globally from an Irish HQ.

Ireland's life sciences activity is notably strong outside Dublin, with clusters in the West, Midwest, South, and Southeast. This regional strength represents an important national asset and can be amplified by integrating adjacent emerging sectors — AI, immersive technologies, advanced manufacturing — which can build on life sciences companies as early anchor customers.

To build such a pipeline, Ireland must reduce dependence on external markets and become more self-reliant in production and sales at a European level. This requires more risk capital along the funding continuum — friends & family, angels, VC, PE, family offices, corporate venturing. Unlocking more private-sector participation is critical, with tax incentives strategically used to catalyse investment. Pension funds and a portion of auto-enrolment assets should be ring-fenced for SME investment including life sciences.



The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | +353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



Domestic commercialisation success also depends on access to reference customers. The HSE and broader public sector should act as structured beta customers for high-innovation Irish companies. Public procurement frameworks should include significant weighting for innovative solutions and early-stage technologies.

### Case Study – Neuravi

Funded by three IVCA members, Neuravi developed breakthrough technology for ischemic stroke. With 7.8M new cases globally annually, patients treated with Neuravi's device can return to normal or near-normal life, generating estimated health system savings of \$190,000 per patient. Global extrapolation suggests potential savings exceeding \$1 trillion annually. Following acquisition by J&J, the company established a major Western Region presence, employing over 150 staff and serving as a global centre of excellence.

Ireland must match its strong R&D capability with robust commercialisation and sales skills. Structured technical sales training, dedicated undergraduate / postgraduate pathways, and STEM modules will improve translation of innovation into global markets.

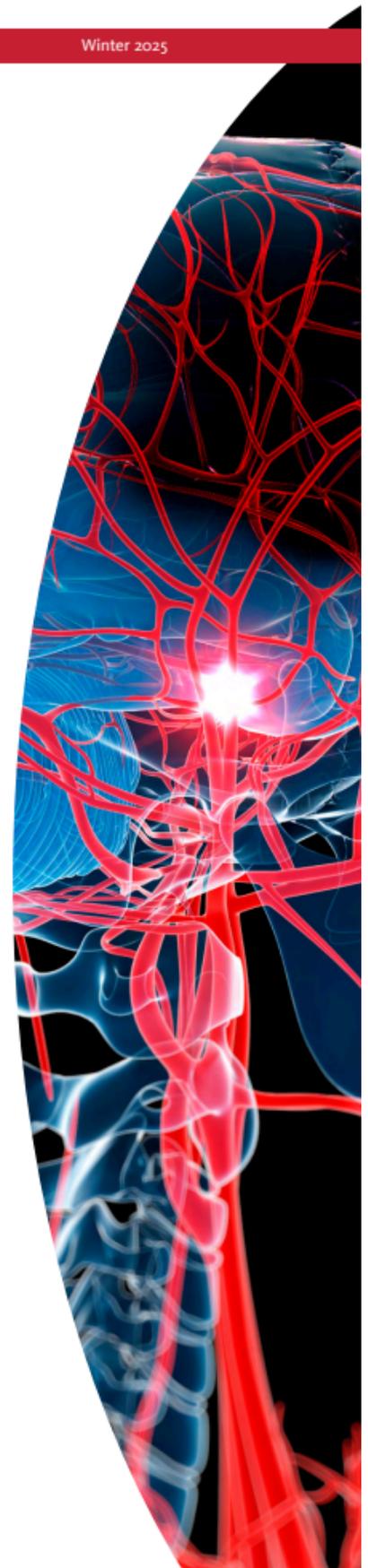
Finally, Ireland has an opportunity to specialise in first-in-human and pilot-phase clinical trials, providing a European niche for early-stage clinical research where population size is less limiting.

## 6. Potential Return on Investment

The example of the Western Innovation Fund (WIF) demonstrates the potential transformative impact of targeted policies in early-stage life sciences, and their return on investment. An allocation of €20M in Exchequer funding has catalysed significant private investment, enabled the creation and scaling of multiple Irish start-ups, and accelerated the translation of academic research into commercial outcomes.

To date the significant socio-economic impact generated from this initial investment includes, supporting 4,584 jobs that generate €1.5 billion in salaries. The region contributes €3.3 billion in revenue and €2.4 billion in exports, while investing €420 million in research and development. Additionally, the region is a hub of innovation, with over 1,000 patents registered, underscoring its role as a driver of high-value economic activity and technological advancement.

The WIF has strengthened the domestic venture ecosystem by providing critical early-stage capital, supporting clinical validation, and attracting international interest in Irish life sciences companies. This fund has directly contributed to job creation, retention of high-value IP in Ireland, and enhanced global visibility for the Irish life sciences sector.



The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



By combining public and private capital in a coordinated approach, the WIF illustrates how relatively modest state funding can generate outsized economic, innovation, and societal returns. It reinforces the importance of structured public funding mechanisms to de-risk early-stage investment and support Ireland's indigenous life sciences ecosystem.

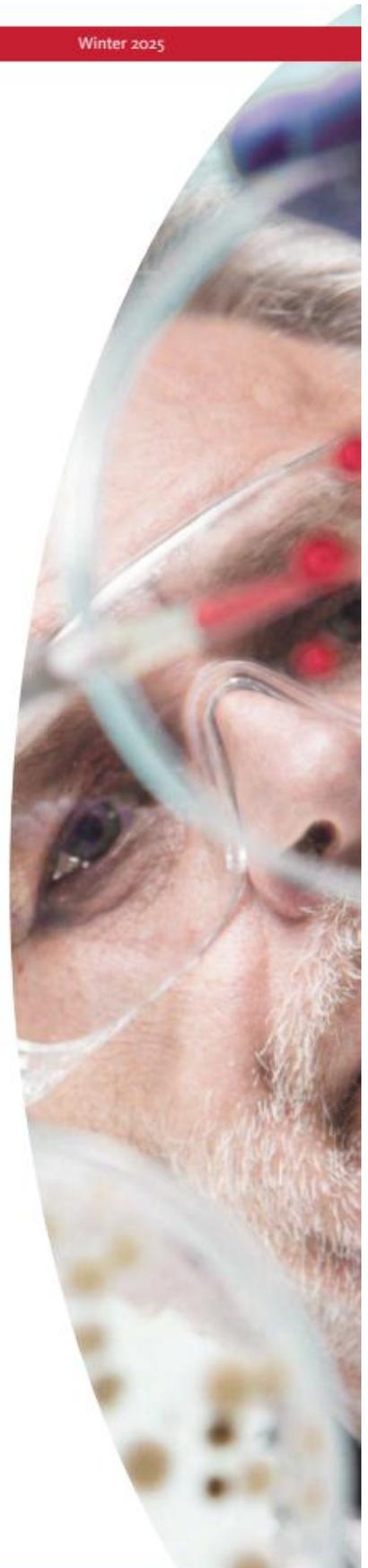
## 7. Conclusion

In conclusion successful policy initiatives will lead to positive outcomes economically, improvements to our health system, and our population health.

- €1–2bn increase in investable VC capital over 10 years.
- Stronger indigenous life sciences pipeline (therapeutics, medtech, diagnostics, digital health).
- Improved commercialisation and IP retention from public R&I investments.
- Attraction of specialist VC funds and talent.
- Higher-value job creation in R&D, clinical research, regulatory affairs, and manufacturing scale-up.
- Enhanced data-enabled decision-making and health system performance.
- Faster access to innovative therapies for Irish patients.
- Greater integration with EU research, data spaces, and innovation missions.

### Immediate Policy Actions

- Establish a **cross-departmental group** (DFHERIS, DFIN, DETE, DEASP, EI, ISIF, IDA, DoH, IVCA, IPHA, ARC-HUB, IBEC, Irish Medtech, Dub Bio) to design a coordinated approach for data infrastructure, drug discovery, and translational science strategies to maximise ROI.
- Increased urgency around the ongoing work to develop **prototype models** for a national data infrastructure aligned with EU Health Data Space.
- Future Life Sciences success will depend on innovation in access for novel medicines and therapeutics. A special focus group on reimagining reimbursement of novel medicines in Ireland should be convened to create a system which will ensure Irish early-access and innovative reimbursement pathways.
- Draft regulatory and fiscal proposals enabling **pension and insurance investment** for Budget 2026 to support local specialist life sciences VC funds, and attract international Life Sciences VC to establish or expand Irish hubs.



The Irish Venture Capital Association is the industry body for the venture capital and private equity ("VC/PE") industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



# IVCA Members, Affiliate Members & Associate Members

## IVCA Members



## Associate Members



## Affiliate Members



### About the IVCA

The Irish Venture Capital & Private Equity Association is the industry body for the venture capital and private equity (“VC/PE”) industry in Ireland. Celebrating our 40<sup>th</sup> year, the IVCA represents Irish-based VC/PE firms, as well as their investors and professional advisers.

Contact: [info@ivca.ie](mailto:info@ivca.ie) | + 353 (0)1 276 4647 | [www.ivca.ie](http://www.ivca.ie)



## Submission from James Geoghegan, TD



**James Geoghegan TD**

Dublin Bay South Constituency

Dáil Éireann, Leinster House,  
Kildare Street, Dublin 2.

Tel: 01 618 3736

Email: [james.geoghegan@oireachtas.ie](mailto:james.geoghegan@oireachtas.ie)



5 December 2025

Dear Minister,

I am writing today in support of the proposals made in Life Sciences Ireland's submission to this consultation.

I believe there is great potential for a formal clustering organisation with a national remit in the life sciences sector, and that their proposals are drawn from careful analysis of international best practice.

As you know, there is work being done in my own constituency at the Glass Bottle Site to build the physical infrastructure that would facilitate the development of a major life sciences cluster in Ireland.

The proposed innovation hub at the Glass Bottle Site is in full alignment with the Life Sciences Ireland submission and could kickstart the emergence of far more domestic life sciences innovators, which is precisely what this government is aiming to do in the face of amplified global uncertainty.

I hope you will consider both of these proposals going forward and I look forward to future engagement.

Kind regards,

A handwritten signature in black ink, appearing to read 'James Geoghegan', written in a cursive style.

James Geoghegan TD



# Submission from Life Science Real Estate

## Submission to the National Life Sciences Strategy Consultation

Submitted by: Life Sciences Real Estate

Website: [www.lifesciencesrealestate.org](http://www.lifesciencesrealestate.org)

Address: 28 Upper Pembroke Street, Dublin 2, D02 NT28, Ireland

Email: [stephen@lifesciencesrealestate.org](mailto:stephen@lifesciencesrealestate.org)

Telephone: +353 1 234 2434

Date: November 2025

### Introduction

Life Sciences Real Estate is a Dublin-based research organisation dedicated exclusively to the physical environment of life sciences across Europe. We study and advise on the evolution of research and innovation districts, science parks, and clusters that support biotechnology, medtech, and pharmaceutical activity. Our work provides insight into how spatial, financial, and institutional factors shape Europe's innovation capacity.

We welcome the opportunity to contribute to this consultation. Ireland is well placed to play a leadership role in implementing the ambitions outlined in the European Commission's strategy Choose Europe for Life Sciences - A Strategy to Position the EU as the World's Most Attractive Place for Life Sciences by 2030 (COM(2025) 525 final). Our submission draws directly on its priorities and applies them to the Irish context.

This submission addresses three fundamental questions: what scope should Ireland's life sciences strategy encompass? What objectives should guide its implementation? And how can Ireland maximise opportunities while addressing critical constraints? Throughout, we align our recommendations with the EU's strategic framework while highlighting Ireland's distinctive contribution to European competitiveness.

### 1. Scope

The National Life Sciences Strategy should adopt a comprehensive and inclusive definition of the sector—one that goes beyond biopharma and medtech to include the entire innovation ecosystem that underpins discovery, production, and commercialisation.

As the Commission notes, "life sciences study living systems—from human beings, animals, plants, and microorganisms to ecosystems and their interconnectedness."

Ireland's strategy should therefore reflect the interdependence of research, manufacturing, and the built environment—from laboratories and cleanrooms to incubators, test facilities, and specialised production infrastructure.

We recommend that the strategy explicitly recognise:

- The spatial dimension of life sciences—clusters, campuses, and innovation districts—as critical national assets.
- The cross-sectoral reach of life sciences, encompassing not only medtech and biopharma but also agrifood and sustainable biotechnology.
- The One Health approach, linking human, animal, and environmental health, consistent with the EU's holistic vision.

## 2. Objectives

The National Life Sciences Strategy should aim to make Ireland the most effective environment in Europe for translating scientific discovery into real-world solutions. The following objectives align Ireland's ambitions with those of the EU's 2030 life sciences vision:

1. Enhance translational capacity – strengthen the link between research, innovation, and commercialisation through university-industry collaboration, clinical research infrastructure, and the creation of flexible, high-quality facilities for scale-up and manufacturing.
2. Foster spatially integrated clusters – plan for high-performing innovation districts and bioclusters that bring together research institutions, startups, and global firms. This echoes the EU's emphasis on "leveraging the capacities of European bioclusters to attract private capital and spur entrepreneurship."
3. Invest in research and skills – expand talent pipelines through advanced STEM education, lifelong learning, and international mobility programmes, aligned with the EU's Union of Skills initiative.
4. Promote sustainability and resilience – ensure that life sciences contribute to the clean industrial transition through low-emission biomanufacturing, circular economy models, and resource-efficient infrastructure.
5. Secure Ireland's position in European collaboration – actively participate in EU initiatives such as Horizon Europe, the European Health Data Space, and forthcoming partnerships on clinical research, biotechnology, and advanced therapy medicinal products (ATMPs).

These objectives chart an ambitious path for Ireland's life sciences sector. However,

ambition must be grounded in reality. Ireland brings significant advantages to this agenda but also faces structural challenges that, if unaddressed, could limit its ability to participate fully in Europe's life sciences future. Understanding both is essential to effective strategy design.

### **3. Opportunities and Challenges**

#### **Opportunities**

Ireland's strategic positioning within Europe forms a solid foundation. Its established pharmaceutical and medtech base—combined with world-class research institutions and an English-speaking environment—makes it a natural gateway for EU-US and EU-UK collaboration.

Building on this foundation, biocluster development offers a path to deeper integration. With appropriate investment in physical infrastructure and governance, Ireland could host one or more EU-recognised bioclusters—integrated districts that bring together laboratory, pilot manufacturing, and collaborative workspaces to attract scaling companies. This aligns directly with the EU strategy's emphasis on "leveraging European bioclusters to attract private capital and spur entrepreneurship."

Financing this infrastructure need not fall entirely on the State. Through our ongoing research, Life Sciences Real Estate tracks institutional investors financing life sciences assets across Europe, including Ireland. This investment intelligence provides insight into who is investing, where, and why. Harnessing such private capital can significantly reduce the State's financial burden while accelerating delivery of high-quality laboratory, manufacturing, and incubation space.

Incubators serve as critical innovation engines within this ecosystem. As outlined in our research on European life sciences incubators (Life Sciences Real Estate, 2024), these facilities provide flexible spaces, specialised equipment, and essential support services while fostering innovation through strong academic and industry links. Strategic investment in such facilities would strengthen Ireland's capacity to nurture emerging firms through the vulnerable early stages of commercialisation.



In 2024 our team profiled [20 of the leading life sciences incubators](#) across Europe

Ireland’s digital capabilities offer an additional competitive advantage. The country’s strength in digital health and data analytics aligns with the EU’s ambition to “unlock the power of data and AI for breakthrough innovation,” particularly through the European Health Data Space.

Finally, sustainable manufacturing positions Ireland to lead the green transition. The shift toward circular biotechnology offers opportunities to pioneer sustainable production and the decarbonisation of health-related industries, supporting both the EU’s Clean Industrial Deal and its forthcoming Bioeconomy Strategy.

### Challenges

Yet these opportunities exist alongside real constraints. Without addressing the following challenges, Ireland risks falling behind European competitors and missing the window to shape the EU’s emerging life sciences infrastructure.

- Infrastructure capacity: Ireland currently faces shortages of fit-for-purpose laboratory and pilot-scale production space. Without coordinated spatial planning and targeted investment, this will constrain growth.
- Talent bottlenecks: demand for specialist technical and operational skills, including in bioprocessing and AI-driven life sciences, is outpacing supply.
- Fragmented real estate governance: life sciences development requires coordinated planning among enterprise agencies, local authorities, universities, and investors—areas that remain siloed.
- Regulatory agility: startups and SMEs often struggle with regulatory complexity and slow approval processes. As noted in Choose Europe for Life Sciences, “Innovators are often faced with legislation that is not sufficiently innovation-friendly or future-proof.”

#### **4. EU Context**

Ireland's National Strategy should position itself as a national implementation pathway for the EU's Choose Europe for Life Sciences framework, translating continental ambition into local action.

We strongly support the EU's three-phase model for achieving global leadership:

1. Optimise the R&I ecosystem – through collaboration, skills development, and sustainable investment.
2. Ensure smooth and rapid market access – via innovation-friendly regulation and better mobilisation of capital.
3. Boost uptake and use of innovation – through public trust, data accessibility, and end-user engagement.

In this context, Ireland could:

- Establish a National Coordination Group, mirroring the EU's proposed Life Sciences Coordination Group, to align national funding, infrastructure, and data priorities.
- Participate in pilot programmes for multi-country clinical trials and ATMP Centres of Excellence, both identified as EU "flagship" initiatives.
- Integrate Ireland's industrial policy with the forthcoming EU Biotech Act and Bioeconomy Strategy, ensuring regulatory alignment that attracts investment.

#### **5. Conclusion**

Ireland's future competitiveness in life sciences depends not only on its research excellence but on the ecosystem that enables translation from idea to impact. As the European Commission states, "Life sciences are at the heart of Europe's ability to improve lives, grow a competitive economy, and protect the planet."

By aligning its National Life Sciences Strategy with the EU's 2030 framework, Ireland can position itself as a testbed for integrated innovation—where research, real estate, and policy converge to deliver sustainable economic and social outcomes.

#### **Contact**

Life Sciences Real Estate  
28 Upper Pembroke Street  
Dublin 2, D02 NT28, Ireland  
Telephone: +353 1 234 2434  
Email: [stephen@lifesciencesrealestate.org](mailto:stephen@lifesciencesrealestate.org)  
Website: [www.lifesciencesrealestate.org](http://www.lifesciencesrealestate.org)

# Submission from Life Sciences Ireland, MedLink Galway, and the Connected Health and Wellbeing Cluster



## Input to the Consultation Process to the National Life Sciences Strategy

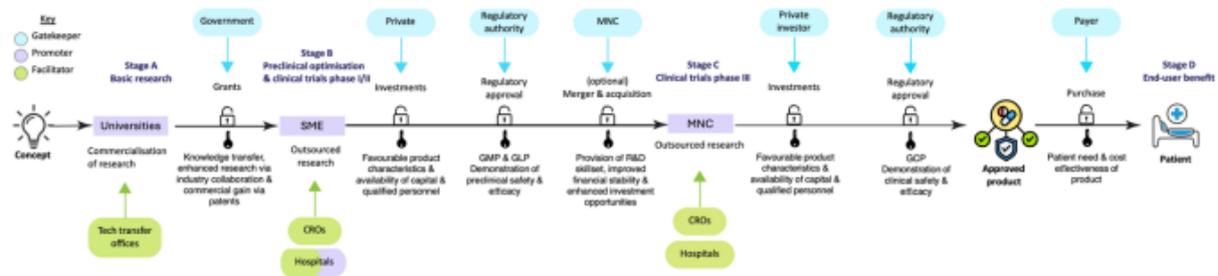
Co-submission by three Irish industry cluster organisations- Life Sciences Ireland, MedLink Galway, and the Connected Health and Wellbeing Cluster.

### Summary:

1. It is an anomaly that Ireland does not have a Life Science Cluster Organisation, when compared with peer countries. An appropriate national cluster organisation is a proven model to connect the full Life Sciences value chain.
2. A cluster organisation will help to solve existing shortcomings in this sector, with relatively small investment providing a significant return by way of near-term national impacts, mirroring the success and impacts of International Clusters
3. *"Cluster Organisations work at the gaps, where no one else has a remit"*. International best practice has clearly demonstrated that a cluster organisation is necessary in addition to other existing entities and does not replace them, but complements them.
4. Enterprise Ireland in its strategy 2025-2029, references the importance of industry clusters as an ecosystem support. Through the Regional Technology Clustering Fund, Enterprise Ireland has provided funding for the Connected Health & Wellbeing Cluster and MedLink Galway. It has also provided funding to Life Sciences Ireland through the Smart Regions Scheme. Collectively these three industry clusters represent circa 150 cluster members compiled of startups, SMEs, multinational, academia, government agencies and other industry-aligned stakeholders. These Clusters have a proven track record of delivering supports to stakeholders across the Health and Life Science ecosystems.
5. A truly national cluster is required: No single region should benefit more than any other. All regions have significant strengths that are complementary and can be harnessed in unison (via a national cluster organisation) to build synergy. *Life Sciences Ireland, Medlink Galway* and the *Connected Health and Wellbeing Cluster* are currently working together with the aim of achieving this.

## Scope

**All entities focussed on health.** This includes the sectors of Pharmaceuticals, Biopharma, Medtech, Diagnostics and Digital Health. These highly-regulated industries share a common 'Idea to Patient' value chain.



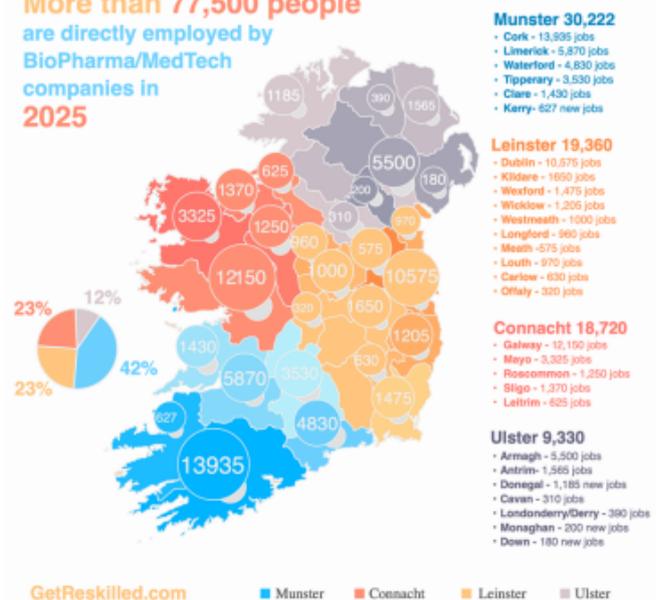
## Objectives

i) **Connect the entire value chain:** In the Life Sciences more than any other sector, the idea to product chain is long and complex, with many actors. Ireland already features many of the ingredients of this value chain, while others are lacking (e.g. innovation districts featuring incubators, clinical development facilities). International best practice demonstrates that to have stakeholders effectively operate in concert, a connecting vehicle is required = a Cluster Organisation. Niche opportunities within the value chain that build on Ireland's existing strengths will be identified and prioritised for near-term action (quick wins), with further growth opportunities to strategically follow.

ii) **Align with Enterprise Ireland's Life Science Strategy:** Enterprise Ireland's Strategy 2025-2029 sees Life Science as a key sector and has an ambition for an enhanced, internationally competitive, and connected enterprise and innovation ecosystem that fosters start-ups, supports enterprise growth, drives innovation and investment, and supports Ireland's internationally successful businesses. The actives and projects being carried out by industry clusters currently supports this ambition.

iii) **Be truly national:** No single region should benefit more than any other. While Cork has the highest Life Science activity today, all regions have significant strengths across Healthtech and Medtech that are complementary and can be harnessed in unison (via a national cluster organisation) to build synergy. *Life Sciences Ireland* (national), *Medlink Galway*, *Connected Health and Wellbeing Cluster* (Dundalk) are currently working together with the aim of achieving this. Other example organisations we are engaging with in this include *HIRA-NI* (Northern Ireland), *Oncology Innovation cluster*, *ARC Hub for Therapeutics* and the *ARC Hub for Healthtech*. In Q1 2026, we are working towards hosting a collaborative event where the three Clusters and industry members can discuss the current context of Life Sciences in Ireland, the opportunities and challenges currently faced in the marketplace (compared to our EU counterparts). We welcome participation from the DE TE Life Science Strategy consultation team on this.

**More than 77,500 people are directly employed by BioPharma/MedTech companies in 2025**



**iv) Be a global hub:** Ireland currently lacks a ‘One-stop-shop’ or ‘Shop window’ for our full range of Life Science Activity. While the IDA, Enterprise Ireland, and other agencies do powerful work internationally, no single agency represents the full value chain. Through our networks, we have been building alliances with international cluster organisations to support collaboration by our members (Singapore, USA, multiple EU countries etc.).

## Opportunities and challenges

### *Opportunities*

Connect the entire value chain to capitalise on emerging opportunities across the life sciences value chain, based on existing strengths. Without a cluster organisation, Ireland is missing the connective tissue that enables our life sciences ecosystem to evolve in line with global trends. A national cluster organisation will go a long way to solving current shortcomings in this sector repeatedly voiced to us by various Life Science stakeholders.

### *Challenges*

Ireland risks losing ground as global life sciences shift toward digital, AI, advanced therapies, personalised medicine, and data-driven care; changes that require integrated, innovation-led ecosystems.

A Life Sciences Growth Cluster Organisation can address the below challenges as follows:

*Over-concentrated model:* Five firms produce 43% (€88bn) of exports; 63% of activity is manufacturing; only 5% of pharma sites focus on R&D. Despite stronger MedTech R&D, Ireland is missing high-value opportunities. A cluster would broaden innovation and capture more of the value chain.

*Global vulnerability:* Manufacturing is footloose; investment favours innovation hubs, and geopolitical risk may disrupt multinational operations.

*No coordinator:* Ireland lacks an independent body to align industry, academia, healthcare and Government on sector-wide growth.

*Falling behind rivals:* Countries with formal clusters attract start-ups, commercialise research, build talent, and shape policy. Ireland needs the same to stay competitive.

*Cluster impact:* Drive cross-sector collaboration, accelerate R&D and commercialisation—especially for indigenous firms—and strengthen talent and skills.

**Conclusion:** A national strategy must prioritise the urgent creation of a Life Sciences Cluster Organisation to secure Ireland’s future competitiveness. A relatively small investment of €1m per annum will provide a significant return by way of near-term national impacts.

## EU context

The EU Life Sciences strategy refers to “existing biotech clusters” in the EU among the strengths of the Union and calls for strengthening “bio-clusters and centres of excellence” across Member States. The EU Strategy repeatedly references “clusters” as part of the ecosystem to be strengthened, supported and leveraged.

Under the “Optimising the R&I ecosystem” pillar, the Strategy emphasises the importance of combining disciplines, stakeholders and funding “in R&I ecosystems”, including “partnerships, missions and bioclusters”.

As part of its implementation plans, the Strategy foresees the creation of a network of European centres of excellence, including for advanced therapy medicinal products (ATMPs), which would likely link to cluster-type structures.

The strategy also highlights that existing life-sciences strengths in the EU include “strong research institutions and biotech clusters” when building its competitiveness case.

Signed:

|  |   |  |
|--|---|--|
| <p><i>Rosanna Loftus</i><br/>Cluster Manager<br/>MedLink Galway<br/>Hosted in ATU Galway- Mayo</p>  | <p><i>Breannán Casey</i><br/>Cluster Manager<br/>Connected Health &amp; Wellbeing<br/>Cluster<br/>Hosted at Dundalk Institute of<br/>Technology</p>  | <p><i>Brian Dillon</i><br/>Life Sciences Ireland</p>  |
|--|---|--|

## Endorsements

On behalf of the ARC Hub for HealthTech, I fully endorse the above as proposed by the above-named clusters. Led by University of Galway, in partnership with Atlantic Technological University (ATU) and RCSI University of Medicine and Health Sciences, the ARC Hub for HealthTech is a €34.3 million initiative under Research Ireland's flagship Accelerating Research to Commercialisation (ARC) Programme. Co-funded by the Government of Ireland and the European Union through the ERDF Northern and Western Regional Programme 2021–2027, this hub is designed to fast-track breakthrough research into real-world healthcare solutions.

Yours Sincerely,



*Professor Garry Duffy  
Director of the ARC Hub for HealthTech  
Established Professor of Health Technology Innovation  
University of Galway*



I wish to strongly endorse this submission proposing support of a Life Science cluster. As the chief executive of Northern Ireland's Life Science cluster organisation, I can validate the opportunity for the Republic of Ireland and the enormous potential for All-Island activity in the Life Sciences through synergy creation.



*Prof Joann Rhodes  
Chief Executive  
Health Innovation Research Alliance – Northern Ireland*





DETE National Life Sciences Strategy Consultation: Insights from Ireland's Ocean Knowledge 2030 (OK203) National Marine Strategy for Research, Knowledge and Innovation 2025-2030

**Submitted by:** Helena Deane, Ocean Knowledge 2030 Programme Manager, Marine Institute (Ireland)

**5<sup>th</sup> December 2025**

## **1. Introduction**

Ocean Knowledge 2030 (OK2030) National Marine Research, Knowledge and Innovation Strategy<sup>1</sup> welcomes the opportunity to contribute to the development of Ireland's National Life Sciences Strategy. OK2030 is a strategic framework that has been shaped through extensive engagement across the marine research and innovation community. The Marine Research Funders' Forum (MRFF), provided strategic insights for OK2030, drawing together funders and other stakeholders to support a coherent national approach to ocean knowledge. This submission reflects the perspective of OK2030 as a collaborative, multi-stakeholder initiative and is distinct from the Marine Institute's separate corporate submission.

As life sciences evolve to encompass biological, ecological and environmental domains, the marine and aquatic environment plays an increasingly important role. These systems support seafood production and aquatic animal health, influence human health through environmental pathways, and provide critical climate, biodiversity and ecosystem data. Marine bioresources and environmental intelligence also offer new opportunities for sustainable food systems, One Health approaches, digital innovation and blue-bioeconomy development. OK2030 therefore sees the marine domain as an essential component of a resilient, integrated and future-facing life sciences landscape.

Through this submission, OK2030 aims to ensure that marine and aquatic dimensions are appropriately reflected in the scope and ambition of the National Life Sciences Strategy, and to identify where enhanced coordination, investment in knowledge systems, and alignment with EU policies can deliver national benefit. OK2030 also aims to support the recognition of the interdependence of ocean health, human health, economic opportunity and long-term resilience.

Below we set out recommendations drawn from Ocean Knowledge 2030 that we hope the National Life Sciences Strategy will consider.

## **2. Scope of the National Life Sciences Strategy**

Life sciences span multiple sectors, including pharmaceuticals, medical technologies, agriculture, fisheries and food production, as well as environmental and digital sciences that underpin human and ecosystem health. From the perspective of Ocean Knowledge 2030 (OK2030), the scope of the National Life Sciences Strategy should reflect this breadth and

---

<sup>1</sup> [Ocean Knowledge 2030 | Marine Institute](#) At the time of writing (5<sup>th</sup> December 2025) the strategy is in its final draft stage awaiting government endorsement and publication.

explicitly include the marine and aquatic dimensions that contribute to Ireland's scientific capability, food systems, environmental evidence base and future resilience.

Marine and aquatic systems are integral to several parts of the life-sciences landscape:

- Food and nutrition: seafood production, aquatic animal health, sustainable proteins and novel marine-derived ingredients.
- Environmental and ecosystem health: ocean observations, biodiversity and climate data, pollution and hazard monitoring, and environmental genomics.
- One Health and public health interfaces: interactions between ocean health, animal health and human wellbeing.
- Digital and data-enabled life sciences: ocean data infrastructures, modelling, remote sensing and digital twins that support evidence-based decision-making.
- Bioresource potential: marine biological diversity that can inform research in areas such as bioactives, biomaterials, ecosystem functioning and biological processes relevant to the wider life sciences.

OK2030 therefore supports a broad scope that recognises the interdependence of marine systems and life-science domains, and that positions ocean knowledge as part of the enabling foundation for sustainable food systems, climate preparedness, societal wellbeing and responsible innovation. Such scope would help ensure that life-science actions and investments are informed by the environmental, ecological and data-driven evidence.

### **3. Strategy Objectives**

From the perspective of Ocean Knowledge 2030, the National Life Sciences Strategy should adopt objectives that recognise the essential role of ocean knowledge in supporting innovation, sustainability, and resilience across interconnected life-science domains. OK2030 recommends that the Strategy consider the following objectives:

#### **1. Strengthen Ireland's environmental and ecosystem evidence base**

Ensure that life-sciences research, innovation and policy are grounded in robust, accessible and well-coordinated ocean observations, environmental monitoring, ecosystem assessments and genomics data. These evidence systems underpin safe, sustainable and future-proof life-science decision-making.

#### **2. Support integrated approaches to food, health and environmental systems**

Promote One Health and food-systems thinking by recognising the links between ocean health, aquatic animal health, food quality and human wellbeing. This includes enabling research that spans marine, terrestrial and public-health domains.

#### **3. Enhance national capability in digital and data-enabled life sciences**

Leverage Ireland's strengths in ocean data infrastructures, modelling, remote sensing and digital twins to support the digital transformation of life sciences, improve predictive capability, and enable better risk assessment, planning and innovation.

#### **4. Enable responsible and sustainable innovation grounded in environmental understanding**

Ensure that emerging life-science applications, including those relating to novel foods, bioresources or biomaterials are informed by sound ecological evidence, sustainability considerations and long-term resource stewardship.

#### 5. Foster coordination and coherence across research funders and sectors

Strengthen alignment between national marine research investments and life-science priorities, improving strategic coherence and maximising the impact of public research funding.

#### 6. Align with EU policies and funding priorities

Position Ireland to benefit from EU initiatives related to bioeconomy, blue economy, One Health, climate adaptation, data spaces and digital transitions by embedding ocean knowledge within the national life-sciences policy framework.

### 4. Opportunities and Challenges

The development of a National Life Sciences Strategy presents several opportunities for Ireland to better integrate ocean knowledge into life-science research, innovation and policy, strengthening the evidence base that underpins sustainable food systems, public health and long-term resilience:

- **Marine biotechnology** offers a number of emerging opportunities that could complement Ireland's broader life-sciences ecosystem, particularly where it intersects with food innovation, health, biomaterials, and environmental technologies. Areas of growing activity include the development of novel bioactive compounds and functional ingredients from algae and marine microbes, biomaterials and scaffolds inspired by marine organisms, aquaculture health technologies such as diagnostics and vaccines, and environmentally driven biotechnology ranging from bioremediation processes to bio-based components for low-impact manufacturing. Many of these opportunities are aligned with global shifts toward sustainability, reduced environmental footprints, circular production, and nature-based innovation, which are trends that are already shaping investment and regulation in mainstream life-science sectors.
- **Enabling innovation at the interface of food, environment and health.** Life sciences are increasingly shaped by cross-sector challenges such as antimicrobial resistance, zoonotic risk, nutrition, and sustainable proteins. The marine domain contributes unique biological, ecological and environmental insight that can support innovation in food safety, aquatic animal health, new ingredients, and One Health approaches.
- **Supporting digital transformation of Ireland's life-sciences ecosystem.** Ireland's marine and environmental sectors have developed advanced capabilities in data infrastructures, remote sensing, modelling, environmental genomics and digital twins. These tools can contribute to the Strategy's ambition to expand digital and AI-enabled life sciences by enhancing prediction, monitoring, and decision-support systems.
- **Strengthening Ireland's evidence base for sustainable and resilient life sciences.** Ocean and environmental knowledge provide essential data on climate impacts, biodiversity change, pollution, water quality, and ecosystem health. Integrating these evidence streams into the life-sciences landscape strengthens national capacity for risk assessment, food-system resilience, and long-term strategic planning, all central to goals for competitiveness and sustainability.

- **Improving Ireland's engagement with EU research and policy directions.** EU initiatives increasingly integrate environmental and life-science domains (Bioeconomy Strategy, EU Missions, Nature Restoration, Digital Europe, One Health, climate adaptation). Recognising the role of ocean knowledge in the national strategy strengthens Ireland's ability to access EU funding, contribute to EU agenda-setting, and leverage cross-border research partnerships.

Realising this potential will require addressing several systemic challenges, particularly around coordination, data integration and the recognition of environmental and marine evidence as essential components of a modern life-sciences ecosystem:

- **Addressing capacity gaps in key scientific domains.** OK2030 identifies shortages in biodiversity science, taxonomy, environmental genomics, ocean modelling, geoscience, and ecosystem assessment. These gaps directly limit Ireland's ability to deliver evidence for food safety, disease surveillance, environmental health and innovation pathways.
- **Limited availability of clear pathways for the commercialisation of marine and aquatic life-science research and innovation.** Although Ireland has strong scientific capability in areas such as environmental genomics, aquatic animal health, ecosystem modelling, and algae-based innovation, the translational supports and infrastructures required to bring these outputs to market remain underdeveloped. Emerging technologies at the interface of environment, food and health often do not align neatly with existing enterprise supports, resulting in fragmented innovation pathways and uncertainty for SMEs and start-ups operating in these spaces. In addition, specialised testbeds and demonstration environments for aquatic diagnostics, or novel marine ingredients are limited, making it difficult for companies to validate technologies to regulatory or investor standards. Gaps in regulatory and technical readiness support, coupled with constrained access to cross-sector innovation clusters and translational funding, further inhibit progress. Addressing these systemic barriers would help ensure that Ireland's expanding marine and aquatic knowledge base can contribute fully to innovation, competitiveness and enterprise development across the broader life-sciences ecosystem.
- **Growing demand for environmental and ecosystem evidence to support life-science innovation and regulation.** Life-science innovation and regulation increasingly depend on reliable environmental and ecosystem evidence, for example in food safety assessments, disease and pathogen monitoring, antimicrobial resistance, supply-chain resilience, and sustainability requirements linked to market access. These evidence needs are rising rapidly due to climate/biodiversity pressures, new EU sustainability requirements, and expanding obligations for risk assessment across food, health and bioeconomy sectors. Ireland's current evidence systems are not yet fully integrated into the national life-sciences landscape. If these data streams remain fragmented, Ireland may face challenges such as reduced competitiveness in sectors where sustainability and environmental performance are now part of market and investment criteria, limited capacity to adopt emerging EU policies and standards, where integrated environmental-health evidence is increasingly expected and missed opportunities for innovation, e.g. in sustainable food systems, One Health, environmental genomics, diagnostics, monitoring technologies, and digital modelling.

## 5. EU Context

The European Union's emerging Life Sciences Strategy sets out an ambition to strengthen Europe's position as a competitive, integrated and innovation-driven life-sciences ecosystem by 2030. Central to this vision is the recognition that health, food systems, environmental

sustainability and digital transformation are increasingly interconnected domains. From an Ocean Knowledge 2030 perspective, this creates a clear opportunity for Ireland to align its national approach with EU directions that acknowledge the importance of environmental and marine evidence in underpinning the future of life sciences.

Across the European policy landscape, marine and environmental knowledge play a growing role in shaping strategic priorities. The EU Bioeconomy Strategy, the Sustainable Blue Economy approach, the Farm-to-Fork and Biodiversity Strategies, and the EU Climate Adaptation Framework collectively emphasise the need for resilient ecosystems, sustainable biological resources, and integrated data and monitoring infrastructures. These frameworks highlight that Europe's biological and ecological systems, including marine and aquatic environments are fundamental to food security, public health, and environmental resilience. The EU's One Health initiatives further reinforce this perspective by recognising the links between human, animal and environmental health, and the need for coherent evidence systems to anticipate and manage emerging risks.

The life sciences are also being transformed by digital technologies and data integration. EU efforts to develop interoperable environmental and sectoral data spaces, alongside investments in digital twins, climate-service tools and biodiversity monitoring, create new opportunities for countries with strong ocean data capabilities. Ireland's leadership in ocean observation, modelling, ecosystem assessment and digital ocean infrastructures positions it to contribute meaningfully to these EU-level ambitions. Ensuring interoperability between marine data systems and broader life-science data infrastructures will be increasingly important as Europe develops shared capabilities for predictive analytics, risk assessment and innovation.

As Horizon Europe progresses and the foundations for FP10 take shape, the EU's research and innovation agenda is expected to place even greater emphasis on climate resilience, food-system sustainability, environmental health, biodiversity protection and digital transformation. Marine and aquatic research are central to each of these themes. By explicitly recognising ocean knowledge within its Life Sciences Strategy, Ireland can strengthen its ability to engage strategically with EU programmes, co-shape future priorities, and access co-funding opportunities across a broad spectrum of environmental, digital and life-science initiatives.

In this context, the National Life Sciences Strategy has the potential to position Ireland as a leading contributor to EU-wide efforts that integrate biological, environmental and digital domains. Embedding ocean knowledge within the national strategy will enable Ireland to leverage EU policy alignment, strengthen cross-border collaboration, and contribute to a more resilient, sustainable and competitive European life-sciences system.

## **6. Conclusion**

Ocean Knowledge 2030 appreciates the opportunity to contribute to this consultation and supports the development of a Life Sciences Strategy that reflects the breadth of Ireland's scientific, environmental and innovation landscape. We would welcome further engagement as the Strategy progresses, including opportunities to support cross-government coordination, share evidence and insights, and help ensure that Ireland's evolving life-sciences ecosystem is informed by the best available knowledge.



Department of Enterprise, Tourism and Employment (DETE)  
Kildare Street, Dublin 2, D02 TD30

2<sup>nd</sup> December 2025

## NATIONAL LIFE SCIENCES STRATEGY CONSULTATION

### 1. Introduction

The Marine Institute welcomes the opportunity to contribute to the Department of Enterprise, Tourism and Employment's public consultation on the development of a National Life Sciences Strategy. As Ireland's national agency for marine research, technology development and innovation, the Institute provides essential scientific services, data, and advice to government in support of the sustainable development of Ireland's extensive marine resource.

The Institute's remit includes marine science, marine environment, fisheries and aquaculture science, marine food safety research, and support for the sustainable growth of marine sectors. As marine bioresources, marine-derived ingredients, aquaculture health, and blue bioeconomy innovation continue to evolve, there are increasing interfaces between marine science and life-science research, innovation, and industrial development. The Marine Institute's Corporate Strategy 'Ocean Knowledge that Informs and Inspires' (2023–2027) sets out ambitions that intersect strongly with these priorities, particularly in marine bioeconomy, biodiversity, climate adaptation, and digital ocean innovation.

In this context, the Marine Institute welcomes the opportunity to highlight areas where marine science and bioresources intersect with Ireland's wider life-sciences landscape, and where existing national capability can support innovation, resilience and informed strategic decision-making.

### 2. Scope of the Proposed National Life Sciences Strategy

Marine and aquatic environments host an exceptional diversity of organisms, metabolic pathways and bioactive compounds. These provide the basis for a growing range of life-science applications, including novel ingredients for functional foods and nutraceuticals, marine-derived molecules with potential health and pharmaceutical uses, and new biomaterials and enzymes that can support cleaner manufacturing. Advances in genomics, biotechnology and bioprocessing are rapidly increasing our ability to discover, characterise and utilise these marine bioresources.

At the same time, aquaculture and wider marine food production systems are becoming more knowledge and technology-intensive, drawing on diagnostics, vaccines, selective breeding and digital tools that are firmly within the life-sciences domain. Ensuring the health of farmed stocks, the safety and quality of seafood, and the sustainable use of marine bioresources are therefore not only environmental or food-policy issues but also core life-science challenges.

Foras na Mara  
Rinn Mhaoil  
Uarán Mór  
Co. na Gaillimhe  
Éire  
H91R673

Marine Institute  
Rinville  
Oranmore  
Co Galway  
Ireland  
H91R673  
Tel +353 91 387 200  
Fax +353 91 387 201

Foras na Mara  
Trí Plás Pháirc  
Sráid Haiste Uachtarach  
Baile Átha Cliath 2  
Éire  
D02 FX65

Marine Institute  
Three Park Place  
Upper Hatch Street  
Dublin 2  
Ireland  
D02 FX65  
Tel +353 17 753 900  
Fax +353 91 387 201

Foras na Mara  
Baile Uí Fhiacháin  
Co Mhaigh Eo  
Éire  
F28 PF65

Marine Institute  
Furnace  
Newport  
Co Mayo  
Ireland  
F28 PF65  
Tel +353 98 42300



Integrating marine and blue bioeconomy perspectives into the National Life Sciences Strategy would help Ireland to:

- recognise marine bioresources as part of the national life-science asset base
- leverage existing strengths in marine and aquaculture research to develop new high-value products and services
- support innovation at the interface of health, food, biotechnology and sustainability
- align national ambition with emerging EU priorities on bioeconomy, blue economy and life sciences.

Ireland already has significant scientific capability, collaborative networks and project experience in these areas. A life sciences strategy that explicitly acknowledges and incorporates the marine dimension would position the country to capture new opportunities, diversify the sector's innovation pipeline, and contribute to resilient food, health and bio-based value chains in the decade ahead.

Therefore, given the interconnected nature of biological research and bio-based innovation, it is important that the strategy adopts a sufficiently broad scope.

The scope of the strategy should encompass not only the established pillars of the life sciences sector such as pharma, biopharma, medtech and clinical research, but also those areas where biological science and innovation are rapidly advancing, including marine and aquatic bioresources, sustainable food production systems and related enabling technologies. Marine biotechnology and blue bioeconomy should be included as strategic pillars within the national life sciences framework.

A broad and inclusive scope will ensure that Ireland can leverage its full scientific and industrial strengths, support emerging high-value sectors, and align effectively with evolving EU ambition in life sciences, the bioeconomy and the blue economy.

### 3. Objectives of the National Life Sciences Strategy

The Marine Institute supports a National Life Sciences Strategy that includes the full spectrum of biological science and innovation, including the marine and aquatic dimensions that contribute to food systems, environmental health, and emerging bioresource-based opportunities. The strategy's objectives should include:

#### 1. Strengthening Research and Innovation Foundations

Support high-quality research and monitoring that underpin evidence-based policy, sustainable resource management, and safe, high-value food production.

Recognise marine science as an important contributor to national life-sciences capability, particularly in areas such as aquatic animal health, seafood safety, genomics, ecosystem science and climate-related impacts.

#### 2. Enhancing Cross-Sector Collaboration

Promote cooperation between marine, agri-food, environmental and health-science communities where shared challenges exist, including One Health interfaces, aquatic animal disease, climate resilience, and biodiversity monitoring.

Foras na Mara  
Rinn Mhaoil  
Uarán Mór  
Co.na Gaillimhe  
Éire  
H91R673

Marine Institute  
Rinville  
Oranmore  
Co Galway  
Ireland  
H91R673  
Tel +353 91 387 200  
Fax +353 91 387 201

Foras na Mara  
Trí Plás Pháirc  
Sráid Haiste Uachtarach  
Baile Átha Cliath 2  
Éire  
D02 FX65

Marine Institute  
Three Park Place  
Upper Hatch Street  
Dublin 2  
Ireland  
D02 FX65  
Tel +353 17 753 900  
Fax +353 91 387 201

Foras na Mara  
Baile Uí Fhiacháin  
Co Mhaigh Eo  
Éire  
F28 PF65

Marine Institute  
Furnace  
Newport  
Co Mayo  
Ireland  
F28 PF65  
Tel +353 98 42300



Ensure marine inputs are aligned with national research coordination mechanisms (e.g., Impact 2030, Horizon Europe missions).

### 3. Supporting Digital and Data Infrastructure for Life Sciences

Encourage interoperability between life-sciences data systems and established national marine data platforms.

Recognise the role of advanced ocean observation, environmental datasets, genomics, and Digital Twin of the Ocean developments as complementary to the wider life sciences data ecosystem and AI-enabled research.

### 4. Aligning with EU Policy and Funding Landscapes

Position Ireland to benefit from European research and innovation investments relevant to the marine domain, including Horizon Europe clusters, the Sustainable Blue Economy Partnership (SBEP), and emerging EU life-science initiatives.

Ensure marine science priorities are considered in Ireland's engagement with future EU framework programmes.

### 5. Skills and Capacity Development

Ensure future skills initiatives recognise the need for capabilities in marine genomics, bioinformatics, environmental modelling, and aquatic animal health, all of which contribute to a broader bio-capable workforce for Ireland.

## 4. Opportunities and Challenges

There is considerable opportunity for the strategy to recognise the contribution that marine and aquatic science can make to Ireland's broader life-sciences capability, particularly in strengthening food-system innovation, environmental monitoring and cross-sector research, and to reflect the complementary role these areas play alongside established strengths in pharma and medtech:

- **Advancing Aquatic Animal Health & Sustainable Food Systems** - Ireland has strong capability in fish health, disease diagnostics, selective breeding science, and seafood safety. These areas present opportunities to enhance sustainable aquaculture and food security, aligned with life-sciences expertise in immunology, disease surveillance, and microbiology.
- **Leveraging Marine Data, Observations and Digital Innovation** - The Institute's long-standing strengths in environmental data, ocean observation, modelling and genomic datasets provide foundations for AI-enabled environmental prediction, ecosystem monitoring, and climate-health assessments, areas increasingly important to life-science research. As an IOC accredited National Marine Data Centre, the Marine Institute can support national life science efforts by acting as a centralised point of marine data access and discovery, building interoperable datasets and services with not only life science data; but also by combining with other environmental, genomic and economic datasets.
- **Marine Genomics and Biodiversity Science** - Advances in marine genomics support improved understanding of aquatic species, pathogens, and ecosystems. These insights can

Foras na Mara  
Rinn Mhaoil  
Uarán Mór  
Co. na Gaillimhe  
Éire  
H91R673

Marine Institute  
Rinville  
Oranmore  
Co Galway  
Ireland  
H91R673  
  
Tel +353 91 387 200  
Fax +353 91 387 201

Foras na Mara  
Trí Plás Pháirc  
Sráid Haiste Uachtarach  
Baile Átha Cliath 2  
Éire  
D02 FX65

Marine Institute  
Three Park Place  
Upper Hatch Street  
Dublin 2  
Ireland  
D02 FX65  
  
Tel +353 17 753 900  
Fax +353 91 387 201

Foras na Mara  
Baile Uí Fhiacháin  
Co Mhaigh Eo  
Éire  
F28 PF65

Marine Institute  
Furnace  
Newport  
Co Mayo  
Ireland  
F28 PF65  
  
Tel +353 98 42300



contribute to national capabilities in biodiversity monitoring, environmental risk assessment, pathogen surveillance, and natural capital accounting.

- **Alignment with EU Funding and Collaboration Mechanisms** - Opportunities exist through Horizon Europe, the Sustainable Blue Economy Partnership, and anticipated FP10 developments to strengthen research links across marine, agri-food, and life-science domains. Coordinated participation can help Ireland influence and benefit from emerging European priorities.

A number of challenges also arise that merit attention as the strategy is developed, particularly in ensuring that marine and aquatic considerations are appropriately reflected within a broad and diverse life-sciences landscape:

- **Ensuring Marine is reflected in a traditionally health-focused Life Sciences Landscape** - Internationally, life-science strategies tend to centre on pharma and medtech, which may lead to limited visibility for marine and aquatic dimensions unless explicitly articulated. If they are excluded, Ireland faces three concrete risks: (1) diminished ability to access and compete for EU funding and partnerships in the bioeconomy, blue economy and sustainable food domains, where marine is explicitly prioritised, (2) reduced national preparedness for challenges such as aquatic animal disease, ecosystem change and climate-related impacts, which directly affect food production, public health interfaces and coastal economies and (3) a structural gap in the strategy that limits Ireland's capacity to build diversified life-science capabilities affecting its competitiveness and economic resilience.
- **Fragmented Cross-Sector Interfaces** - Marine, agri-food, environment and health research operate under different policy and funding structures. Coordination mechanisms are improving, but gaps remain in how cross-sector research priorities are identified and resourced.
- **Skills and Capacity Constraints** - Specialist skills needed for aquatic animal health, environmental genomics, ecosystem modelling and digital ocean technologies require sustained investment to ensure Ireland remains competitive in these areas.
- **Data Interoperability and Infrastructure Alignment** - Marine and life-sciences data systems are evolving rapidly. Ensuring interoperability, especially where environmental, genomic and health-related datasets intersect, requires coordinated standards, investment and governance.
- **Climate and Ecosystem Pressures** - Climate change, biodiversity loss, and shifting marine ecosystems present increasing risks for fisheries, aquaculture, and coastal communities. Addressing these challenges demands strong scientific capability and integration of environmental intelligence into strategic decision-making.

## 5. EU Context

The Marine Institute welcomes the ambition of the EU Life Sciences Strategy to position Europe as the world's most attractive location for life sciences by 2030. The Strategy's framing of life sciences as

Foras na Mara  
Rinn Mhaoil  
Uarán Mór  
Co.na Gaillimhe  
Éire  
H91R673

Marine Institute  
Rinville  
Oranmore  
Co Galway  
Ireland  
H91R673  
  
Tel +353 91 387 200  
Fax +353 91 387 201

Foras na Mara  
Trí Plás Pháirc  
Sráid Haiste Uachtarach  
Baile Átha Cliath 2  
Éire  
D02 FX65

Marine Institute  
Three Park Place  
Upper Hatch Street  
Dublin 2  
Ireland  
D02 FX65  
  
Tel +353 17 753 900  
Fax +353 91 387 201

Foras na Mara  
Baile Uí Fhiacháin  
Co Mhaigh Eo  
Éire  
F28 PF65

Marine Institute  
Furnace  
Newport  
Co Mayo  
Ireland  
F28 PF65  
  
Tel +353 98 42300



spanning health, agriculture, bioeconomy, terrestrial and aquatic food systems, biodiversity and environmental sciences is particularly important, as it reflects the reality that biological innovation increasingly sits at the interface of health, food, environment and climate.

We strongly support the Strategy's emphasis on research and innovation, on a One Health approach that links human, animal and environmental health, and on the development of cross-sectoral biotechnologies and new products that drive industrial innovation and sustainability. These priorities resonate with the Marine Institute's corporate strategy (2023–2027), which sets out a roadmap to support national and EU policy goals in sustainable seafood production, ocean science and management, environment and biodiversity, offshore renewable energy and climate action.

In the Irish context, implementation of the EU Life Sciences Strategy should explicitly recognise the contribution of marine and aquatic science to EU-level objectives in the bioeconomy and blue economy. This includes the role of marine research and monitoring in underpinning sustainable seafood production, aquatic animal health, ecosystem and biodiversity assessment, climate-impact analysis and environmental data provision, all of which are referenced as strategic areas for European life sciences and biotechnology.

Ireland is well placed to contribute to these ambitions through existing capabilities in marine observation, data infrastructures, ecosystem science, genomics and aquatic animal health research, as outlined in the Marine Institute's corporate strategy. To maximise alignment, the National Life Sciences Strategy should:

- ensure that marine and aquatic dimensions are included in Ireland's positioning towards the EU Life Sciences Strategy, the forthcoming Bioeconomy Strategy and proposed EU Biotech Act.
- support strong Irish participation in relevant EU programmes and partnerships (e.g. Horizon Europe clusters, the Sustainable Blue Economy Partnership and future framework programmes) where marine and aquatic food systems, bioeconomy and environmental sciences are in scope.
- promote interoperability between national marine data systems and wider life-sciences data infrastructures, in line with EU priorities on data, AI and research infrastructures.

These inclusions would help enable Ireland to contribute fully to the EU Life Sciences Strategy while leveraging its established strengths, in alignment with the DETE Statement of Strategy 2025–2028 identifies the need to build the resilience of the economy through innovation and sustainability, and to deepen Ireland's influence within the EU by aligning national efforts with European priorities and emerging industrial strategies. Similarly, Ireland's Competitiveness Challenge 2025 highlights the importance of diversifying Ireland's enterprise and innovation base, enhancing regional strengths, and preparing sectors for the twin green and digital transitions. Integrating marine and aquatic dimensions into the National Life Sciences Strategy directly supports these DETE priorities, ensuring alignment with EU agendas in the bioeconomy, blue economy and sustainable food systems.

*The Marine Institute is pleased to contribute to this consultation and would welcome the opportunity to provide additional evidence or clarification as the strategy progresses. We look forward to continued collaboration with DETE and stakeholders in shaping a robust and forward-looking national strategy.*

Foras na Mara  
Rinn Mhaoil  
Uarán Mór  
Co. na Gaillimhe  
Éire  
H91R673

Marine Institute  
Rinville  
Oranmore  
Co Galway  
Ireland  
H91R673

Tel +353 91 387 200  
Fax +353 91 387 201

Foras na Mara  
Tri Plás Pháirc  
Sráid Haiste Uachtarach  
Baile Átha Cliath 2  
Éire  
D02 FX65

Marine Institute  
Three Park Place  
Upper Hatch Street  
Dublin 2  
Ireland  
D02 FX65

Tel +353 17 753 900  
Fax +353 91 387 201

Foras na Mara  
Baile Uí Fhiacháin  
Co Mhaigh Eo  
Éire  
F28 PF65

Marine Institute  
Furnace  
Newport  
Co Mayo  
Ireland  
F28 PF65

Tel +353 98 42300



**Medtronic**

**Health, First**

Medtronic Ireland Submission to the  
National Life Sciences Strategy Consultation



Ireland's life sciences sector has earned its place as one of the strongest and most trusted in the world. It delivers for patients, supports high-value regional employment, underpins Ireland's export economy, strengthens health systems and improves patient outcomes.

Medtronic is proud to be part of this ecosystem. With operations in Galway, Athlone, and Dublin, and more than four decades of innovation and investment in Ireland, we are directly impacted by strategic public policy choices that can unlock or constrain Ireland's potential as a global health leader.

A national Life Sciences Strategy is a timely and welcome opportunity for Ireland to set out a clear and implementable plan: to anchor and grow the most innovative and resilient health ecosystem in Europe. Achieving this requires focus, ambition, and alignment across Government, enterprise agencies, the health system, and industry.

Ireland has taken bold steps to target support to critical industries including the semiconductor and hospitality sectors; we welcome this consultation and forthcoming strategy development to take a similar, bespoke approach to support the Life Sciences sector. For Europe and Ireland, MedTech is arguably one of the most vital sectors to protect and grow.

A strong, modern Life Sciences Strategy must start with a simple truth: health matters, economically, socially, and strategically. Ireland has an opportunity to place itself at the forefront of European health resilience and innovation. The choices made in this strategy will determine whether Ireland continues to lead in MedTech, will follow more established or emerging MedTech hubs, or risks being left behind in a dynamic, innovation driven and patient centred industry.

### The Best Small Country in the World to do Healthcare R&D

At Medtronic we believe the future of health is better with technology. We have made it a strategic priority to increase our investment in R&D, growing it at a faster rate than revenue since 2020. Last year alone, we invested \$2.7 billion in global R&D and employed more than 13,000 engineers and scientists. Our approach includes emerging technologies like advanced computing and sensor innovations, evolving trends in regenerative medicine, sustainable materials, and new power sources; and new applications for robotics, data analytics, and AI.

Our vision is straightforward: Ireland can be recognised as the best small country in the world for healthcare research and development. Each aspect of that ambition matters. To be “the best” signals leadership rather than participation. To be a “small country” recognises that scale, in this context, is an advantage. Small can enable coordination, short decision lines, and the ability to pilot and adopt innovation with a speed and coherence that larger health systems often cannot match. To focus on “healthcare R&D” is to acknowledge that this work is not generic innovation but the development of deeply complex, highly regulated, safety-critical technologies that improve and save lives. It requires trust, clinical evidence, regulatory excellence, data integrity and long-term commitment across Government, industry and the health system.

Ireland has a track record of success in manufacturing high-complexity medical technologies. In earlier decades, research and development typically followed manufacturing in our sector. Today, Ireland is positioned to invert that model. With coordinated national ambition, R&D can lead: anchoring design, clinical validation, piloting, commercialisation, and ultimately strengthening Ireland’s position as a global contributor to health innovation.

## Priorities for Government Consideration

### 1. High-Performing Ecosystem and Talent Pipeline

Ireland’s competitiveness in life sciences has always come from the strength of its ecosystem: deep relationships between industry and universities, strong regional clusters, stable policy, and a skilled workforce. But global competition is accelerating, countries across Europe, Asia, and North America are investing aggressively to attract the next generation of MedTech and health innovation.

To stay ahead, Ireland must:

- Rapidly scale investment in next-generation STEM and digital talent, including specialised programmes in biomedical engineering, AI for health, software engineering, robotics, and regulatory science.
- Strengthen regional innovation clusters, particularly the West, ensuring critical mass in engineering, R&D, and manufacturing.
- Accelerate the adoption of shared talent programmes between industry and academia, supporting faster technology transfer and stronger innovation pathways.

A deliberate focus on talent (domestic, EU and international) will determine whether Ireland can win the next wave of strategic investments, while infrastructure and utilities must be future-proofed to support large-scale advanced manufacturing and research.

## 2. Make Ireland a Leader in Clinical Trials and Evidence Generation

Clinical trials are a strategic asset. They bring early access to new therapies, strengthen the domestic research ecosystem, and connect Ireland directly into global innovation pipelines. Yet Ireland currently underperforms relative to its scientific capability and multinational footprint, sitting in the bottom third of EU countries in clinical trials per capita.

We strongly support the implementation of recommendations from the recent report from the National Clinical Trials Oversight Group, in particular:

- A move towards “Trial Nation Ireland” (single entry point, national infrastructure, unified processes).
- Faster contracting and costing.
- Clarity on DPIAs, a major historical blocker for digital health and device data.
- A strengthened workforce pipeline.
- EHR infrastructure designed to support device data and advanced diagnostics.
- A national online portal connecting patients with trials, including device studies.

By enacting these recommendations that will position clinical trials as a national priority, Ireland can differentiate itself in Europe and offer a compelling value proposition to global health innovators.

## 3. A World-Class Health Service

Ireland has the raw ingredients for a transformational decade in health outcomes: leading MedTech and biopharma companies, scientific capability, a collaborative academic network, but it is missing a truly world class health system that leverages the innovation available on the island. In competing global MedTech hubs, research hospitals play a significant role in the ecosystem, and patients benefit.

Consider the case of the Medtronic renal denervation (RDN) therapy, a minimally invasive procedure that uses radiofrequency energy to reduce over-activity in the renal nerves, a proven driver of uncontrolled hypertension. For more than a decade, Ireland has played a central role in Medtronic’s global RDN success: our Galway campus contributed to the early-stage design and development of the technology, scaled to full commercial manufacturing of the catheters, leveraging Ireland’s R&D tax credit and drawing on the ecosystem, and now employs several hundred highly skilled engineers, technicians and operators dedicated to this platform alone. Ireland also hosts important clinical-trial activity that has contributed to global regulatory approvals and real-world evidence.

Today, tens of thousands of RDN catheters have been exported, an innovation that was conceived, financed, tested and manufactured in Ireland, yet; less than 150 people in Ireland's health service have received the therapy. This represents a profound disconnect: Ireland is a world leader in developing and exporting life-saving cardiovascular technology, but Irish patients struggle to access the very innovations their economy, workforce and public-policy incentives helped create.

The National Life Sciences Strategy should enable the Department of Health and government to support the HSE's transformation agenda, improve patient outcomes and make Ireland a destination for clinical research and partnerships with industry, where novel technologies can be evaluated, scaled and accessed. Life sciences should be treated as a strategic national asset, not predominantly a successful export industry.

#### 4. Protect and Strengthen the Incentives Environment and Recognise Medtech as a Diverse and Strategic Sector

Long-term investment decisions in life sciences depend on predictability. Ireland's incentives regime, particularly the R&D Tax Credit and targeted supports from IDA Ireland, has been central to sustaining and expanding high-value MedTech activity in Ireland. Other regions are now targeting our sector with aggressive, sector-specific incentives, recognising its diversity and its disproportionate contribution to jobs, exports, and resilience.

To remain competitive, Ireland should:

- Maintain a stable, globally competitive incentives framework, especially for R&D, digital innovation, and advanced manufacturing.
- Develop policies that demonstrate understanding and intent to treat MedTech as a diverse sector that includes devices, diagnostics, robotics, software, digital health, and data-enabled therapies—each with distinct investment drivers.
- Ensure rapid implementation of pro-competitiveness State aid changes at EU level, including flexibility for strategic sectors like MedTech.

Governments everywhere strive to lead in innovation, to attract investment, to grow high-value jobs, and to secure sustainable tax revenues. Too often, when building R&D supports, policymakers worldwide fail to reflect how innovation works across global teams, digital platforms, and complex supply chains. We support a more strategic and future-facing approach to R&D policy globally that rewards companies not just for spending on R&D but for building substance, owning and enhancing Intellectual Property, and anchoring value creation in jurisdictions committed to long-term innovation leadership.

## Conclusion

The National Life Sciences Strategy presents a once-in-a-generation opportunity to put **Health, First**, not through incremental adjustments, but through deliberate, transformative action. Unlike external forces such as trade dynamics or geopolitical shifts, this is a lever Ireland can control and drive with intent. The country has the tools, the talent, and the timing is right: Ireland can position itself not merely as a participant, but as a leader and shaper in the next era of global health innovation.

Industry has an essential role in enabling that ambition. Medtronic Ireland stands ready to partner across Government, the health system, academia, and the ecosystem to ensure that Ireland not only competes, but leads—as the best small country in the world to do healthcare R&D.



### **MSD Ireland Response to the 'Department of Enterprise, Tourism and Employment' public consultation on the National Life Sciences Strategy**

01/12/25

#### **MSD Ireland Overview**

MSD is a leading healthcare company in Ireland, having first established here 50 years ago. We work at the forefront of science and technology to advance manufacturing excellence and R&D across our Irish sites and global company network. A dynamic and diverse team of over 3,950 people currently work across our six manufacturing sites in Ballydine, Brinny, Dunboyne, Dundalk, Carlow, and Dublin. MSD also have significant Human Health and Animal Health operations in Ireland. Our extensive human health portfolio includes a comprehensive immunisation portfolio for every stage of life as well as innovative solutions for conditions such as oncology and infectious disease.

Over the past five years, MSD has invested €4.5 billion in its manufacturing operations in Ireland, generates an annual economic impact of €3.2 billion in the Irish economy and ranks among the top 20 Irish companies by turnover. Our patient-centric approach drives us to continuously innovate for the benefit of patients, healthcare providers, and the wider healthcare landscape, with Ireland playing a significant role in our global operations.

#### **Introduction:**

MSD Ireland welcomes the opportunity to contribute to the development of Ireland's first 'National Life Sciences Strategy'. As a research-driven global healthcare company with a significant manufacturing footprint in Ireland and extensive patient health impacts here, we are committed to supporting the development of a strategy that strengthens Ireland's position as a global leader in life sciences, helps to improve positive patient impact, and reduces barriers to industry development and innovative medicines valuation in Ireland and the EU.

#### **Scope:**

We believe that Ireland, as a leading global pharmaceutical manufacturer and benefactor of significant global pharmaceutical industry investment, is strongly placed to take on a leadership position within the European Union in developing new policies that address the pressures facing Europe's life sciences ecosystem. The significant drop in pharmaceutical R&D investment and global clinical trial share in the EU are just two examples of the urgent need for coherent policy action.

The scope of the new strategy should be ambitious, goal focused and seek to encapsulate the whole life sciences ecosystem in Ireland into its vision, covering everything from drug discovery and research and clinical trials to manufacturing output and patient outcomes. It

should seek to guide the creation of coordinated cross government policies that align health, business, skills, research, digital infrastructure, taxation, planning, and utilities with the aim of boosting Ireland's competitiveness, economic growth, and patient outcomes whilst taking a new approach to supporting the value of innovative medicines in Ireland and the European Union.

## **Objectives:**

### **Policy Integration and Coherence**

Ireland's health, industrial and enterprise policy development that impact upon industry growth and patient outcomes often operate in departmental silos and in an unthematic approach, creating inefficiencies, barriers, incoherent objectives and delays. The new life sciences strategy should ensure integration and collective oversight to create a streamlined environment that supports innovation, industry development and timely access for patients in Ireland.

### **Research and Innovation Leadership**

Alongside R&D tax policy incentives, Ireland must continue to strengthen and resource its R&D ecosystem to remain globally competitive. This includes targeted R&D investment in supporting the development of advanced therapeutics, new manufacturing techniques, and digital health solutions in Ireland by Industry. Enhanced collaboration with IDA, academic institutions and industry will identify emerging technologies and the areas of focus faster.

### **Intellectual Property**

Enhancing the intellectual property ecosystem in Ireland and increasing the protections available to industry through securing Ireland's participation in the Unified Patent Court (UPC) is an important policy objective for the continued growth of this sector.

### **Talent and Skills Development**

Ireland's skilled workforce is a cornerstone of its pharmaceutical success. To maintain this advantage, the strategy should prioritise upskilling and reskilling initiatives. The development of enhanced thematic collaboration between industry, education providers and policy makers should ensure that education programmes remain aligned with evolving sector and manufacturing needs.

### **Competitiveness and Enabling Conditions**

Ireland's continued attractiveness as a life sciences hub depends on policymakers addressing broader national challenges such as housing, energy, and infrastructure along with the need to develop strategies to address energy costs, in particular, pose a significant risk to manufacturing competitiveness. The strategy should align with national initiatives on energy affordability and infrastructure development to safeguard Ireland's position as a preferred investment location.

### **Patient Outcomes and Access to Innovation**

Improving Irish patient's access to innovative medicines must be a central objective of this new strategy. Current delays in reimbursement to innovative medicines undermine Ireland's health system performance. A thorough review of the pricing and reimbursement process is necessary as part of this strategy to prevent the ongoing paradox whereby many people in Ireland experience delayed access to drugs manufactured domestically compared to our EU counterparts.

### **Address Innovative Medicines Valuation Imbalance**

Innovative medicines deliver transformative health outcomes in Ireland, and their impact should be recognised accordingly. This includes implementing policy reforms to streamline Health Technology Assessment processes that currently undervalue innovative medicines and cause uncertainty for global decision-makers. Ireland's life sciences sector needs quicker, more reliable patient access pathways for future growth. Furthermore, it is essential to eliminate clawbacks and other cost-containment strategies in Ireland and Europe that diminish the value of innovative medicines.

### **Sustainability and Green Transition**

The strategy should embed sustainability principles, supporting the sector's transition to low-carbon operations while maintaining competitiveness. Incentives for green manufacturing and circular economy practices will help Ireland meet its climate commitments without compromising growth. Setting out clear policy goals on how industry can assist government meet its decarbonisation requirements is an important consideration. Specifically, Ireland is developing a new private wires policy that will clarify its ambition to achieve its goals. MSD supports allowing major industries, like pharmaceuticals, to build all-island renewable private networks, using state infrastructure, to help control energy costs and achieve shared decarbonisation targets.

### **Collaboration and Governance**

A dedicated Office of Life Sciences should be established to coordinate thematic policy development, facilitate stakeholder engagement, and monitor progress. This body would serve as a central point for dialogue between government, industry, academia, and patient groups, ensuring that the strategy remains responsive and effective. The body would be tasked with ensuring the delivery of the goals of the new life science strategy.

The strategy should also be accompanied by an implementation plan that is supported by clear, measurable KPIs and stated accountability for those.

### **Opportunities and Challenges:**

#### **Opportunities**

- **Clinical Trials Expansion:** Ireland has made progress in increasing clinical trial activity but remains behind many of its EU peers. Implementing new policies

and administrative enhancements will enable faster patient identification and participation, improving access to cutting-edge treatments for patients in Ireland.

- **Global Market Growth:** Ireland's strong export base offers opportunities to expand into new markets, diversify supply chains, and strengthen resilience against global disruptions.
- **Policy Collaboration:** Strategic policy engagement between health, industry, and academia can make Ireland a leader in research and development, clinical trials and by investing in infrastructure, renewable energy, and advanced manufacturing it will strengthen Ireland's global supply chain position. Thematic and joint up policy alignment can help to achieve this.
- **Office of Life Sciences:** An OLS, established to coordinate thematic policy development, facilitate stakeholder engagement, and monitor progress, would ensure that there is a cross sectoral and cross government body to overseeing the development of the specific life sciences industry specifically.

### Challenges

- **Access to Medicines:** Persistent delays in Ireland's reimbursement processes hinder patient access and reduce Ireland's attractiveness for innovation. Reforming these systems is critical for improving access patients in Ireland.
- **Regulatory Complexity:** Fragmented regulatory frameworks create unnecessary burdens. Streamlining processes improving data sharing and adopting agile models will support innovation.
- **Energy and Infrastructure:** High energy costs and infrastructure constraints threaten competitiveness in Ireland. Coordinated action is needed to address these systemic challenges.
- **Talent Shortages:** Skills gaps could limit growth. Proactive workforce planning and education pathways will be essential.

### EU Context:

MSD Ireland strongly supports the ambition of the EU Life Sciences Strategy to position Europe as the world's most attractive location for life sciences by 2030. Ireland should align its national strategy with EU priorities, including regulatory simplification, robust intellectual property protection, and investment in antimicrobial innovation and seek to lead from within the EU on these policy matters.

Establishing a national Office of Life Sciences linked to EU structures will ensure policy coherence and access to funding opportunities.

**Conclusion:**

MSD Ireland is committed to working with government and policy stakeholders to develop and implement a new national life sciences strategy that drives innovation, improves patient outcomes, and strengthens Ireland's global competitiveness. We stand ready to collaborate and share expertise to ensure the success of this important initiative. Please feel free to contact MSD if you have any questions.

Blaine Gaffney  
Government Affairs and Stakeholder  
Engagement Manager  
MSD Ireland

A. Red Oak North, South County Business  
Park, Leopardstown, Dublin  
☎ +353 87 4908482



# **NIBRT contribution to the National Consultation**

# Life Science Strategy:

## NIBRT contribution to the National Consultation

### Executive Summary:

NIBRT is grateful for the opportunity to contribute to the development of Ireland's first National Life Sciences Strategy through the consultation process initiated by the Department of Enterprise, Tourism and Employment. In our submission, NIBRT makes the argument for the strategic importance of the biopharma and biotech sectors to Ireland's future and outline a number of strategic action areas.

Ireland has built a globally recognised biopharmaceutical manufacturing sector, with over 25 biomanufacturing facilities across the country, over €15 billion in foreign direct investment in the last ten years, a highly skilled workforce, and a strong biologics medicines export base. NIBRT has played a central role in this success by delivering world-class training and research that directly supports industry needs.

However, the global life sciences landscape is changing rapidly. Cost pressures, geopolitical shifts, advanced novel therapeutic modalities, digital transformation, and intensified international competition are reshaping the sector. Ireland must respond with ambition and agility to maintain its leadership.

This submission outlines a series of strategic proposals across six key areas aimed at achieving a bold vision for biopharma manufacturing and biotechnology in Ireland, namely:

- Reinforcing Ireland's position as a resilient and advanced biomanufacturing hub.
- Increasing public investment in biopharma and biotech research, with a particular focus on biotechnology and biomanufacturing.
- Leading in digital integration and next-generation biomanufacturing technologies.
- Establishing Ireland as a centre for advanced therapies and novel biologics.
- Unlocking a vibrant indigenous biotech ecosystem.
- Shaping Irish and EU policy to support long-term sectoral growth and influence.

NIBRT stands ready to engage further with the Department and with other stakeholders to refine and advance these proposals as part of the National Life Science Strategy development process.

NIBRT, through its core mission, is committed to playing its part in supporting Ireland's continued leadership in biopharma manufacturing and new paths to growth in advanced therapies, novel biologics and biotechnology more broadly.

## Introduction:

Over the past 50 years, Ireland has become a global leader in biopharmaceutical manufacturing. Initial investments in the 1960s and 1970s focused on small molecule production. In the last 25 years, Ireland has emerged as a preferred location for biologic-based medicines and vaccines. The sector continues to grow, with over €15 billion in FDI secured over the past decade, supporting more than 25 biologics facilities, 50,000 jobs, and around €100 billion in annual exports.

NIBRT, the National Institute for Bioprocessing Research and Training, was established in 2005 with Irish government funding and as a partnership between IDA Ireland and a number of Ireland's higher education institutes, informed by the needs of the biopharma industry. The NIBRT facility delivers a unique blend of cutting-edge training and workforce development, plus research that addresses the complex biotechnology and biomanufacturing challenges that characterise this advanced technology sector. NIBRT has been an instrumental part of Ireland's success in attracting biopharma manufacturing companies to Ireland and enhancing Ireland's competitiveness.

Against this positive historical backdrop, the world of biopharma manufacturing is now encountering a period of significant change on various fronts which potentially present a challenge to Ireland's future competitiveness.

1. Global supply chains are being challenged by a shifting geopolitical picture, including recent changes to US global trade policy, increasing US investment in biomanufacturing and an ongoing shift in biotech innovation towards China<sup>1</sup>.
2. Innovation is accelerating. Adding to the well-established classes of protein-based biopharmaceuticals, a range of new advanced biology-based therapeutic modalities are being developed at increased pace and intensity<sup>2</sup>.
3. Advanced data science and AI are having transformative impacts on the discovery, development, manufacture and commercialisation of medicines, and this innovation is expected to accelerate exponentially<sup>3</sup>.
4. Global competition is intensifying, with countries – most notably small and advanced economies in Europe<sup>4</sup> (e.g. Belgium, Netherlands, Nordics, parts of Spain), the Far East (e.g. Korea, Singapore) and Middle East (i.e. Saudi Arabia, UAE) – investing heavily to attract life sciences FDI and build an innovation-centred biotech sector.

Within this changing global landscape, Ireland's future success in biopharma will be heavily reliant on how the country adapts to the emerging competitive challenges. To remain competitive, Ireland must adapt with a strong degree of urgency.

NIBRT sees the National Life Science Strategy as a chance to define a bold vision for biopharma manufacturing and biotechnology that unites the Irish public, government, industry, academia, and innovators. This vision should aim to:

- Strengthen Ireland's position to retain and grow biopharma FDI, built upon a foundation of a expert, well-trained and adaptable workforce.
- Attract new biopharma and biotech investment through smart, forward-looking strategies.
- Create the environment for a thriving indigenous biotech ecosystem.
- Position Ireland as a European leader in biopharma and biotech innovation.

## NIBRT proposal:

NIBRT believes that Ireland now needs to strengthen, develop and expand our biopharma and biotech position in the world through focused actions and investment in the following areas:

### 1. Reinforce Ireland as a stable, resilient and adaptable global manufacturing hub, with excellent talent at its core.

Ireland is well-positioned as a stable, resilient, and adaptable hub for biopharma manufacturing, thanks to its geopolitical stability, business friendly environment, supportive tax regime, strong regulatory standards, skilled workforce, and reliable production base. In a volatile global environment, Ireland offers secure and regionally resilient supply chains and leads the world in biopharma workforce development.

To build on these strengths, government and industry should collaborate to position Irish biopharma manufacturing facilities as leaders in sustainable, advanced manufacturing.

Key actions should include:

- **Advancing IDA's Talent, Transformation and Innovation (TTI) initiative**, with a focus on:
  - Encouraging biomanufacturing sites to complete the Strategic Training Development Programme (STDP) and apply for existing and enhanced grants to support digital and sustainability transformation.
  - Supporting sites to maximise training and R&D grants, attract new investment, and pursue international recognition (e.g. WEF Lighthouse status, Shingo Award).
- **Expanding practical hands-on training** for third-level students through:
  - Provision of easy-to-access funding for 3<sup>rd</sup> level students to attend immersive GMP training courses at NIBRT and elsewhere. This can be achieved using the National Training Fund (NTF) and delivered through Skillsnet via a targeted programme.
  - Development of more innovative immersive degree programmes, like UL's iBio MSc.
- **Broadening of the biopharma workforce access** through:
  - Build on the success of the Springboard+ programme by expanding it to ensure better access for prospective biopharma workers.
  - An enhanced national apprenticeship model for biopharma
- **Boosting digital, data analytics and AI skills development** within the biological science industry by:
  - Improving access to digital literacy and AI fundamental skills with supports for the biopharma sector
  - Provision of targeted grant aid for biopharma companies to accelerate their digital innovation and resultant efficiencies.
  - Stronger collaboration between all the state-funded players in the digital field and the leading technology companies many of whom have significant operations in Ireland.
- **Establishing global training standards** for biopharma manufacturing. This can be achieved by leveraging the NIBRT Global Partners Programme and through the development and expansion of NIBRT Global Qualifications (NGQs).

## 2. Make a step-change in Research Funding for Biopharma and Biotech, with a strong focus on manufacturing

The biopharma and biotech sectors are evolving rapidly, driven by innovation in medicines development and increasing complexity in therapeutic modalities. As of Q4 2024, there were approximately 2,000 advanced biologics in clinical trials globally, highlighting the scale of transformation, and even this does not reflect the full picture of biotechnological innovation predicted to progress into clinical pipelines in the coming years. In this environment of rapid innovation, new biologics manufacturing investments will be enhanced by having strong R&D capabilities in close proximity that can be focused on and directed at an ever-increasing range of biomanufacturing challenges.

Ireland, since the inception of SFI in the late 1990s and the PRTL infrastructure investments of the 2000's, has developed a solid R&D base in life science. However, while private sector investment has grown consistently over the last 20-25 years, public research investment has more recently lagged behind global competitors. This is reflected in Ireland's decline in the Global Innovation Index from 2016 to 2023<sup>5</sup>. Moreover, Ireland's total investment in pharma-related R&D lags well behind comparator small, advanced economies within Europe<sup>4</sup>, including Belgium, Switzerland, Denmark, Sweden and Netherlands.

NIBRT calls for a major increase in public research funding in life sciences, with a strong focus on biopharma manufacturing. We believe that this growth in investment would have a number of potential positive outcomes, including:

- ✓ Growth in Life Science PhD and Postdoctoral talent creating a critical mass of a key resource that will be required to drive Ireland's future life science environment.
- ✓ Increased potential for IP generation across the product lifecycle, including in manufacturing.
- ✓ Increased potential for successful indigenous company creation.
- ✓ A virtuous circle of life science R&D job creation linked to economic growth, in turn fed by the increased pool of innovating R&D talent. According to the European Federation of Pharmaceutical Industries and Associations (EFPIA) every €1 direct funding into biopharma has a €1.8 multiplier for the wider economy, with every direct highly skilled job creating a 3x multiplier in indirect and induced jobs<sup>6</sup>.
- ✓ Increased potential for Ireland to take the lead on large-scale EU/European biopharma and biotech research projects (see proposal 6).

Key actions should include:

- **Funding two new Research Ireland Centres:** INSPIRE (in biopharma manufacturing) and IMPACT (in cell therapy), both currently under international peer review.
- **Increasing and streamlining supports for biopharma manufacturers and biotech innovator companies to partner** with Irish RPOs, funding collaborative R&D through IDA, EI, Research Ireland and Horizon Europe programmes. And developing smart new programmes to further catalyse the sector.
- **Launching a sustained global recruitment** drive to attract top biopharma and biotech researchers to Irish institutions, aligned with current EU (e.g. Choose Europe) and Irish (Global Talent) approaches. The global recruitment initiative should also be in tandem with and complementary of initiatives that are aimed at developing local research talent.
- **Targeting strategic R&D-focused biopharma FDI**, such as J-labs and MSD Research Labs, by leveraging all the available supports and incentives (e.g. R&D grants, R&S tax credits, Knowledge Box, etc). This could involve the use of collaborative research spaces within universities and RPOs like NIBRT.

### 3. Develop Ireland as a global leader in advanced biopharma manufacturing processes underpinned by digital technologies and AI

Biopharma manufacturing is inherently complex due to the nature and heterogeneity of biological processes and long cycle times. While monoclonal antibody production has seen efficiency gains over the past two decades, next-generation therapies – which include antibody-drug conjugates (ADCs), radio-labelled antibodies, multi-specific antibodies, cell and gene therapies and therapies where small and large molecule manufacturing processes overlap (like peptides and oligonucleotides) – require significant innovation to improve yield, robustness, and efficiency.

Ireland has developed strong capabilities in biopharma manufacturing R&D, including media and cell line optimisation, process intensification, continuous bioprocessing, process analytical technologies (PAT), and the integration of digital tools and technologies.

NIBRT believes Ireland is well-positioned to take a leadership role in the next wave of innovation in biomanufacturing, particularly in deploying digital technologies and automation in biopharmaceutical production – the ‘factory of the future’. Moreover, Ireland’s proximity to global tech firms and its established biopharma infrastructure offer a unique opportunity to pioneer modular, digitally controlled, and efficient manufacturing systems.

NIBRT believes that there is currently a strategic window of opportunity for Ireland to take a global leadership position in addressing the science, technology, engineering and regulatory challenges associated with making major advances in biomanufacturing processes that include the introduction of flexible, semi-continuous, modular manufacturing and embedding digital control.

To seize this opportunity, NIBRT proposes positioning Ireland as Europe’s centre of excellence in advanced biomanufacturing by:

- **Investing in talent and research** in Chemistry, Manufacturing, and Controls (CMC), Manufacturing Science and Technology (MSAT), advanced data science, analytics, and process control.
- **Providing targeted grants to support biomanufacturers to install intensified, flexible, modular facilities** using single-use systems, new technologies and ‘ballroom’ style buildings.
- **Promoting R&D collaboration between biopharma and global tech companies** in Ireland through collaborative research funding, thereby enabling high-end process improvement and analytical research (e.g. new CDMOs).
- **Establishing a regulator-tech testbed for AI in biomanufacturing**, where technologies can be trialled collaboratively by tech firms, biotech companies, and the global regulators.
- **Launching an international research challenge** focused on solving key manufacturing bottlenecks—such as dramatically reducing the cost of monoclonals or cell therapies per gram or dose—through disruptive technologies and processes.

## 4. Position Ireland as a leader in advanced therapeutics and next-generation biologics research, development and manufacture

Globally, over 2,000 advanced therapies and next-generation biologics—including cell and gene therapies—are in clinical development. These therapies, generally termed Advanced Therapy Medicinal Products (ATMPs), face scalability and cost challenges due to complex manufacturing and distribution models, especially where they are treating low-volume disease indications.

Ireland has the potential to become a centre of excellence in developing and manufacturing these breakthrough therapies, particularly through R&D focused on improving process efficiency. Ireland's compact geography, integrated industrial-academic networks, stable regulatory environment, and strong manufacturing capabilities make it well-suited to lead in ATMP innovation. Previous investments have laid a strong foundation, including:

- IDA Ireland's funding of the advanced therapy expansion at NIBRT.
- Research Ireland's funding of:
  - The CONCEPT advanced therapy early-stage development facility at NIBRT.
  - Research Professorship awards: Prof Sakis Mantalaris and Prof Mark Smales.
- Support for APC-VLE by Enterprise Ireland (scale-up funding) and Research Ireland (Strategic Partnership funding with NIBRT and UCD).

However, the competition is significant, with other countries developing their advanced therapies capability and manufacturing capacity. Parts of Europe where there has been notable ATMP investment over recent years include the UK, Benelux, the Nordics and Catalan region of Spain<sup>7</sup>.

With targeted investment, Ireland can establish its own unique global position in ATMP research, development, and manufacturing by:

- ✓ Leading the development of new manufacturing standards, especially for cell-based therapies.
- ✓ Becoming a flexible European hub for cell and gene therapy production, with emphasis on viral vector and plasmid manufacturing and attracting CDMOs.
- ✓ Serving as a test-bed for industry-regulator collaboration on ATMP co-development.

To maximise this opportunity, Ireland should:

- **Fund the proposed TCD/NIBRT-led IMPACT Research Centre** in cell therapy (as outlined above).
- **Expand and strengthen Ireland's clinical trial capacity and capability** with a particular focus on developing ATMP specialist trial capability.
- **Provide supports that encourage companies to build capacity in flexible facilities that enable small-batch GMP manufacturing**, and grant-aid RPO and/or spin out access to these facilities.
- **Target MNC investment in facilities for larger scale ATMP manufacturing**, in particular for viral vector and plasmid manufacturing where there are global capacity constraints and where Ireland already has the expertise and skills to compete successfully.

## 5. Unlock a thriving indigenous biotech ecosystem that is synergistic with the biopharma manufacturing sector

Ireland's biotech start-up landscape has lagged behind other sectors like medtech, financial services, and agrifood. Key barriers include long development timelines, limited access to strategic funding, weak links between research and innovation, and insufficient infrastructure—particularly for early-stage clinical trials. While there have been successes, they are often limited to early drug discovery exits or companies offering manufacturing process innovations. Compared to international peers – most pointedly European countries with similar economies and demographics as our own, e.g. Belgium, Netherlands, Denmark, and Sweden, Ireland's biotech sector remains underdeveloped.

NIBRT believes that, given Ireland's strong FDI performance, underlying technical attributes and top talent, biotech applied to new therapies is an underexploited area and there a real opportunity for Ireland to adapt its offering while also harnessing on its biomanufacturing reputation. NIBRT believes that Ireland should develop its biotechnology ecosystem as a unique and globally competitive environment where manufacturing-oriented FDI exists in close harmony with indigenous biotech R&D capability. This will require a more cohesive funding regime, with better access to strategic slow-yield capital, stronger incentives for entrepreneurship and strategic public and private investment in infrastructure that supports early-stage life sciences companies.

With the right supports, Ireland can unlock its biotech potential and should aim to create at least one €1 billion + market cap indigenous biotech company in the 2030s.

Strategic actions proposed include:

- **Establish a national biopharma / biotech accelerator** to support start-ups, either as a central hub or across existing infrastructures.
- **Expand enterprise supports** by developing the current range of national enterprise funding programmes to target biotech gap areas. This should involve a joint effort between Enterprise Ireland and Research Ireland. The recent Research Ireland / ERDF investment in ARC Hub for Therapeutics is a notable step in the right direction, and more cohesive investment needs to follow.
- **Reform personal and capital gains tax** to incentivise biotech entrepreneurship and attract founders, investors and senior biopharma/biotech executives from outside Ireland.
- **Strengthen clinical trial capacity** generally across academic hospitals and provide grant aid to enable access for Irish biotech companies.
- **Increase state strategic investment in relevant R&D infrastructures** that have the potential to help Irish innovators build important links to collaborators and investors in the EU and internationally.
- **Provide seed funding and create the networking events and platforms** that help Irish biotech innovators connect with global venture capital networks.

## 6. Shape Irish and EU policy for a new level of ambition for Biopharma and Biotech

Ireland has a strategic opportunity to lead in biopharma and biotech by developing a unified Life Sciences Strategy that connects government, industry, and academia. This strategy must align national efforts across health, enterprise, education, and research – and position Ireland as a key influencer in European life sciences policy, especially ahead of its 2026 EU Presidency.

NIBRT believes that to be effective at national level, the strategy must be cross-departmental. Biopharma and biotech intersect with multiple national priorities – health, job creation, education, research and innovation. Without coordinated governmental leadership, the Life Sciences Strategy risks being fragmented or diluted.

NIBRT also believes that anything that Ireland does now within the biopharma/biotech sector can have a significant impact in a European context. Europe currently accounts for only 20% of the world's biopharma/biotech innovation activity<sup>9</sup>. The Draghi Report recommendations on innovation in life sciences<sup>9</sup>, along with recent progress made on the EU Life Science Strategy<sup>10</sup> and the EU Biotech Act in development<sup>11</sup>, create a new climate in Europe for decisive action. Ireland, given its history of biopharma manufacturing success and close connections with the multinational biotech sector, has a massive opportunity to influence and lead in this sector in Europe.

NIBRT's Policy Recommendations are as follows:

- **National Leadership & Coordination**
  - Ensure Cabinet-level ownership of the Life Sciences Strategy.
  - Establish a dedicated Life Sciences Office within a key government department.
  - Create an interdepartmental working group to oversee the scope of the strategy, its implementation and its alignment with National and EU priorities.
  - Host a national policy workshop during strategy development and maintain stakeholder engagement through annual reviews.
- **Leverage Ireland's 2026 EU Presidency**
  - Advocate for biomanufacturing and biotech as strategic EU capabilities
  - Champion the strength of Ireland's position within the EU biomanufacturing, advanced therapies, regulatory innovation, and biotech entrepreneurship.
  - Encourage the EU to launch a Bioprocessing Testbeds Initiative.
- **Secure Irish Leadership in EU Initiatives**
  - Ensure Ireland is a core or associate member of:
    - EU Biotech Regions
    - European Centres of Excellence in ATMPs
    - The EU Biotech Act and Life Science Coordination Group
  - Engage actively with:
    - The 'Choose Europe' initiative
    - EU foresight studies on skills and training needs
    - Strategic matchmaking platforms connecting biotech startups, industry, and investors
    - Funding opportunities through EIC and InvestEU.
- **Promote Ireland Globally**
  - Showcase Ireland's biotech ambition at major international biotech conferences taking a multi-agency approach that demonstrates Ireland's successes in R&D, manufacturing and innovative company creation.

## **Conclusion:**

Ireland stands at a pivotal moment in shaping the future of its biopharma manufacturing and biotechnology sectors. With a strong foundation in biomanufacturing, talent, and innovation, the country is well-positioned to lead globally. However, to maintain and grow this leadership, Ireland must respond decisively to emerging global challenges—geopolitical shifts, rapid technological change, and intensifying international competition.

The development of a National Life Sciences Strategy offers a timely opportunity to align national efforts, attract strategic investment, foster indigenous innovation, and influence European policy. NIBRT believes this strategy must have a substantial focus on the biopharma manufacturing and biotechnology sectors and must be ambitious, cross-sectoral, and future-focused.

NIBRT welcomes the opportunity to engage further with the Department of Enterprise, Trade and Employment to discuss the proposals outlined in this submission and to support the development and implementation of a strategy that will secure Ireland's long-term leadership in life sciences, biopharma manufacturing and biotechnology.

Above all else, NIBRT is committed to playing its part in supporting and driving implementation of the National Life Sciences Strategy, when it is finalised, through our core mission of delivering cutting-edge training and workforce development, as well as research that addresses complex biotechnology and biomanufacturing challenges.

*Authored by the NIBRT Senior Leadership Team, with NIBRT Board contributions and insights from engagement with the NIBRT advisory network.*

**21st November 2025**

## References

1. <https://www.massbio.org/news/recent-news/beyond-the-headwinds-three-forces-shaping-biopharmas-next-horizon/>
2. <https://www.bcg.com/publications/2025/emerging-new-drug-modalities#:~:text=Key%20Takeaways,up%20from%2057%25%20in%202024.>
3. <https://www.europeanpharmaceuticalreview.com/article/254402/ai-driven-biomanufacturing-revolutionising-production-and-quality-in-pharmaceuticals/>
4. <https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-rd-rd-in-europe/>
5. <https://www.wipo.int/gii-ranking/en/ireland>
6. [https://efpia.eu/media/thepnx1j/2024\\_ifpma\\_global\\_economic\\_footprint\\_study\\_wifor\\_revised\\_bywifor\\_edit9-1.pdf](https://efpia.eu/media/thepnx1j/2024_ifpma_global_economic_footprint_study_wifor_revised_bywifor_edit9-1.pdf)
7. <https://eatris.eu/news/eatris-leads-strategic-mapping-of-atmp-capacities-across-europe-through-preciseu/>
8. <https://www.mckinsey.com/industries/life-sciences/our-insights/europes-bio-revolution-biological-innovations-for-complex-problems>
9. <https://www.edelmanglobaladvisory.com/draghi-competitiveness-report-insights-life-sciences-sector>
10. [https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences\\_en](https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en)
11. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2025/772866/EPRS\\_BRI\(2025\)772866\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2025/772866/EPRS_BRI(2025)772866_EN.pdf)

## About NIBRT

**NIBRT is a world-leading institute, based in Dublin, Ireland whose mission is to deliver training and research solutions for the global biopharmaceutical manufacturing industry.**



**NIBRT partners with industry to support international best practice in all aspects of biologics manufacturing.**

**Established with IDA Ireland and opened in 2011, NIBRT partners with Higher Education Institutes to provide training and research infrastructure facilities not previously available in Ireland.**



**NIBRT's research and training facility (8,000m2) features a state-of-the-art pilot scale biopharma manufacturing plant and associated equipment.**

## What We Do



### Train

Train and educate around 5,000 people annually to work in all areas of biopharma manufacturing.

### Collaborate

Collaborate with industry and academia on scientific research to drive innovation in biopharma manufacturing.

### Support

Support major biopharma investment in Ireland.

### Provide

Provide a test bed for new technologies and processes for biomanufacturing.

### Deliver

Deliver impactful training and research solutions to improve manufacturing processes.

## NIBRT's Mission



NIBRT's mission is to address the important needs of the biopharmaceutical manufacturing industry in Ireland and internationally, and ultimately to help deliver biologic-based medicines to people who need them.

To deliver this mission, we:

- **Train the people** who make life changing medicines.
- **Undertake research** that grows the fundamental understanding of complex biopharmaceuticals.
- **Deliver impactful solutions** that advance the processes for manufacturing biologic medicines.

**NIBRT Impact 2024-25 – What We Deliver**

**In Training**

**4,600**  
Number of trainees

**28,500**  
Training days delivered

**700**  
Number of Springboard + students

**81**  
Number of companies trained in 2024

**8**  
Number of higher education training partnerships



**Strategic industry training partnerships (select)**



**Strategic training partnerships with academia (select)**



**In Research**

**33**  
Number of research projects

**17**  
Number of research projects with industry

**12**  
Number of NIBRT research groups

**14**  
Number of active PhDs

**Industry research partnerships (select)**

**CONCEPT** – Advanced Therapies development facility

**Strategic research partnerships with academia (select)**

**Globally**

**97**  
Number of global research publications

**141**  
Number of international conference presentations

**1.38**  
NIBRT's global field citation impact (FWCI)

**137**  
Number of international partners in published papers

**NIBRT Global Qualifications** New for 2026



**Global partners programme**  
(8 locations globally)





## Novo Nordisk submission to the public consultation on National Life Sciences Strategy

### About Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease.

Novo Nordisk employs about 78,500 people in 80 countries and markets its products in around 170 countries. Novo Nordisk has been operating in Ireland for over 47 years and currently employs over 370 people in our office in Dublin and our development and manufacturing site in Athlone.

### Vision and Scope

Ireland is a leading global hub for the development, manufacturing, and supply of (bio)pharmaceuticals and medical technologies. Ireland has developed a critical mass of skills and infrastructure to make it a world leader in these fields. This requires Government to nurture these dynamic sectors to drive both future economic prosperity and health system transformation.

(Bio)pharmaceuticals in particular needs to be treated as a strategic industry in Ireland, requiring Government policy to prioritise creating a strong market for innovation. This strategy presents an opportunity for Ireland to maintain competitiveness and an attractive ecosystem incentivising business, and attracting researchers, clinicians to translate research into innovative breakthrough medicines and support manufacturing as a core industrial competency.

### Objectives

#### 1. Position Ireland as a Leader for Innovation, Investment and Research

Ireland has a significant opportunity to position itself as a global leader in addressing major health challenges such as chronic disease management, cancer, dementia, and other conditions that place substantial pressure on modern health systems.

Ireland can accelerate innovation, improve care delivery, and help shape the future of health policy across multilateral forums by fostering strong data and digital leadership to enable precision medicine, advanced diagnostics, and widespread digital-health adoption.

Central to this ambition is maintaining a world-class research and development tax credit that remains competitive with peer nations and continuously aligned with the needs of research-intensive industries. Strengthening this incentive will help ensure that Ireland is synonymous with high-impact life-science research and that the country moves further up the global value chain for scientific investment.

## **2. Invest in innovation and modernise systems to support competitiveness**

To ensure patients benefit quickly and equitably from scientific advances, Ireland must invest more and modernise its health and regulatory systems to better recognise the long-term value of innovation.

Patients in Ireland should have access to a steady stream of new pharmaceutical therapeutic advances in a timely manner. In this context, the reimbursement process should focus on fairer and faster access to new innovative medicines to improve patient outcomes. This will sustain funding of innovation, secure long-term value and competitiveness for the entire healthcare and life sciences ecosystem.

This requires an access ecosystem capable of spotting opportunities of next generation therapies and clinical trial opportunities. This will require better system connectivity—including interoperable records and integrated digital platforms—enabling rapid scaling of proven innovations and enhance the overall quality of care. At the same time, Ireland should position itself as an early-launch market, maintaining strong momentum in clinical trial activity by improving trial initiation times, supporting cost competitiveness, and ensuring industry and academic partners can bring new therapies to Irish patients as early as possible.

## **3. Use Data to Drive Knowledge Sharing and Collaboration**

Ireland's competitiveness in life sciences will increasingly depend on the strategic use of digital technologies, artificial intelligence, and high-quality data. Strengthening these capabilities will help cultivate a vibrant indigenous industry, supporting start-ups, scale-ups, and home-grown manufacturing excellence.

To fully unlock this potential, the country should promote strategic innovation partnerships that bring together government, academia, clinicians, and industry to accelerate problem-solving and encourage collaborative breakthroughs.

Sustaining Ireland's reputation as a premier destination for foreign direct investment remains essential, particularly as global companies seek locations with advanced digital infrastructure, skilled talent, and a reliable ecosystem for research and manufacturing. By focusing on data-driven insights and strong cross-sector collaboration, Ireland can continue expanding its position as a hub for high-value life-science activity.

#### **4. Ensure Ireland has the essential skills for future jobs**

Access to a strong and continuous supply of skilled labour is essential for Ireland's future success in life sciences, requiring a clear focus on education, training, and talent mobility. This involves ensuring that higher-education programmes—particularly in biotechnology, data science, engineering, and related fields—are sufficiently resourced to meet growing industry demand and that opportunities for reskilling and upskilling are widely available for those already in the workforce.

Ireland should remain globally attractive in securing scientists, engineers, and digital specialists needed to support a dynamic life-science ecosystem.

### **Opportunities and Challenges**

Competition in the life sciences sector is increasing globally; this is set against a backdrop of continued global political insecurity. It was recognised in the Draghi report; Europe will decline unless it increases investment in innovation and breaks down barriers in the single market. In that context, Ireland will need to invest more in innovation and have a strategy that is flexible and delivers for Ireland in an uncertain geopolitical environment.

There are key actions that can be taken to ensure this agility and dynamism is a foundational block of the strategy:

#### **1. Governance**

There are numerous examples of Government, industry and academia working together to improve Ireland's industrial position. A strong example of this is the Ireland for Finance Strategy, which sets cross-department/industry actions annually and targets for the sector. Ireland should create a National Life Science Council, to govern this strategy, comprising of stakeholders from all areas of the ecosystem, including industry, academia and Government departments.

#### **2. Healthcare diplomacy**

There is an increasing connection between trade policy, health policy and industrial policy, as well as increased legal and regulatory complexity. Ireland should increase its diplomatic and policy presence in international and EU policy development positioning itself as a rule maker in an increasingly complex policy environment. This will put Ireland in a strong position of collaboration with key academic and industry stakeholders globally.

### **3. Multi-departmental budgeting**

A cross-departmental approach works particularly well on delivery, as it facilitates the co-ordination of multiple budgets across Government to deliver on policy objectives, while also leveraging the strength and expertise across different functions coherently.

### **4. Regular reviews and updates**

If Ireland were to establish a National Life Science Council, this council would continuously review the suitability of Ireland's life science strategy in a globally competitive environment ensuring Ireland has a responsive framework to the changing nature of the life science industry.

## **EU Life Sciences Strategy**

In Novo Nordisk's submission<sup>1</sup> to the EU's Life Sciences Strategy, we advocated for six key priorities. While many of the actions are outside of Ireland's national policy competency, they are still relevant to ongoing trilogue negotiations in the General Pharmaceutical Legislation and potentially future legislation. They are also important for Ireland to consider in the context of taking the Presidency of the Council of EU in July next year.

However, some of the proposed actions below present an opportunity for Ireland to invest in core areas, collaborate with European partners and as a result improve its national competitiveness. Many of the below actions are cross-departmental, raising the overall importance of a cross-Departmental approach of delivery, as mentioned in the previous section.

### **1. Safeguard Intellectual Property and supporting protection schemes**

- **Action:** The EU's current Regulatory Data Protection (RDP) regime is a relative strength of the EU where fragmented and complex reimbursement procedures often delay the transition from marketing authorisation to availability to patients, and therefore it should be secured a minimum of 10 years.
- **Action:** Complement the focus on strengthening competitiveness inside the EU by using every opportunity to proactively address framework conditions for European businesses outside of the EU. In multilateral fora (including WTO and WHO) and bilateral relations (including in future and revisions of Free Trade Agreements (FTAs)), the EU must prioritise IP protection to safeguard European innovation.

### **2. Competitiveness checks at the core of regulations**

---

<sup>1</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14592-EU-life-sciences-strategy/E3536041\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14592-EU-life-sciences-strategy/E3536041_en)

- **Action:** Legislation up for adoption, including legislative proposals currently undergoing the co-legislative procedure should be subject to a comprehensive “Competitiveness Check” of the incremental and cumulative impact of new and existing policies and regulatory procedures including costs of compliance and administrative burden on the overall competitiveness of the EU’s Life Sciences sector. This includes introducing competitiveness checks within files of the green transition to avoid new regulations unintentionally leading to a deterioration in patient access to critical treatments or to production moving to countries with lower environmental standards. These checks should be performed by creating Commission-led structural dialogues and involve industrial operators in assessing the impact of all draft relevant policy initiatives and legislative acts.
- **Action:** On reassessing existing initiatives, the Commission should, from a resource and priority perspective, prioritise involving its Regulatory Scrutiny Board (RSB) early in the process and start conducting Competitiveness Checks on EU policy initiatives (including legislative proposals) that did not receive a clear endorsement from the beginning by RSB before adoption by the Commission. The Commission should start reassessing initiatives where concerns previously have been flagged by its own RSB.
- **Action:** The Commission should choose to postpone, adjust, or withdraw initiatives which are particularly problematic from an innovation and competitiveness standpoint or with a disproportionate impact.

### **3. Develop Life Science hubs to enhance innovation and the EU skills agenda**

- **Action:** Conduct and assessment of the most promising life science ecosystems in Europe and comparing with the defining components of Boston’s Kendall Square with the view to support further excellence.
- **Action:** Based on assessment mentioned above, support selected, specialised clusters of biotech and pharmaceutical excellence by strategic, targeted use of EU funds including the research funding framework (Horizon Europe/FP10), STEP and future framework programs, looking at core enablers in globally successful clusters. An initial step would be to prioritise life sciences in the coming long-term strategic budget for Horizon.
- **Action:** Enhance EU funding for STEM educations, like the Marie Curie-program, to build a resilient and innovative workforce, focusing on retaining and attracting global STEM talent, including through cross-border mobility with international work permits for high-skilled workforce.
- **Action:** Build on the proposal for establishing an EU Talent Pool adopted in 2023 as a key component of the Commission’s Package on skills and talent mobility with recruitment options for STEM and Life Sciences relevant skilled workers.

### **4. Harmonize clinical trials ecosystem and support AI driven-innovation**

- **Action:** The Commission should take steps to futureproof the EU Clinical Trials Regulation (CTR) and the competences of EMA to harvest the potential of AI-driven innovation starting with clinical trials.

- **Action:** Set-up a binding EU-level decision-making committee for the authorisation of multi-country clinical trials, while also:
  - Harmonizing ethical reviews processes across Europe for multi-country clinical trials to align time to start with global competitors (joint action or another mechanism with funding)
  - Harmonizing dossier reviews by National Competent Authorities and develop integrated processes for combined studies involving medicinal products, medical devices, or in vitro diagnostics.
- **Action:** Implement common and harmonised standards for anonymising clinical data and creation of synthetic health data that can be used of AI development and training.
- **Action:** Guidelines to ensure a better harmonization between EU AI office, European Data Protection Board (EDPB), national Data Protection Agencies (DPAs) and national AI supervisory bodies. Especially, different interpretations of GDPR causes delay or limits access to data, similarly the scope of the R&D exception under the EU AI act remains unclear.
- **Action:** AI R&D Regulatory Sandboxes with a flexible regulatory framework could allow innovation breakthroughs in streamlining the path from laboratory to market while maintaining regulatory compliance.

#### **5. Faster and smoother pathways to regulatory approvals**

- **Action:** Simplify EMA committee structure to enable more streamlined and faster decision-making around regulatory assessments, as proposed by the European Commission
- **Action:** Shortening the standard centralized procedure assessment timelines as proposed by the European Commission in the Review of the General Pharmaceutical Legislation
- **Action:** Enable timely access to scientific advice and accelerated assessment by expanding the PRIME eligibility criteria to more than just a narrow type of innovation
- **Action:** Regulatory sandbox mechanism proposed by the European Commission will support the future proofing of the EU regulatory system. As incoming waves of innovation are integrating technologies governed by other frameworks, action is needed to expand the scope of the regulatory sandbox beyond pharmaceuticals, such as to the Medical Device Regulation, the In Vitro Diagnostic Regulation and the SoHO Regulation.
- **Action:** Establish a single accountable governance structure empowered to oversee drug-device combination products and CDx with associated medication end-to-end- It could be one single authority being responsible for all parts of the combination products including advice/scientific guidance, assessments and approval.

#### **6. Horizontal governance structure for developing and competitiveness tracker**

- **Action:** Embed Life Sciences as a strategic key focus across the European Commission by establishing a governance model with a Life Sciences Council enabling a structured dialogue between private and public partners.

- **Action:** To complement the Commissions' Competitiveness Compass, the Commission should develop a 'tracker' on key competitiveness sector-specific indicators. Examples of indicators include time to market, global share of R&D investments, use of expedited pathways, free trade agreements securing a level playing field.

**ENDS**

**Novo Nordisk Ltd**

First Floor, Block A,  
The Crescent Building,  
Northwood Business Park, Dublin 9

Tel: +353 1 862 9700  
[www.novonordisk.ie](http://www.novonordisk.ie)

DOCUMENT NUMBER: IE25NNM00005 DATE OF PREPARATION: November 2025



# The Strategic Role of Biobanking in Ireland's Life Sciences Future

Prepared by: **NSAI TC62 Biotechnology Standards Consultative Committee**

Date of document: Dec 4<sup>th</sup>, 2025

## Introduction

Biobanking should be recognised as a core component of Ireland's national life sciences infrastructure. It underpins research quality, accelerates innovation, and strengthens preparedness across human, animal, and environmental health. Biobanks enable reproducible science and long-term data assets essential for advanced analytics, personalised medicine, and emerging biotechnology. Even when samples have been depleted, the data can continue to provide a vital resource long into the future. Ireland's life sciences strategy should ensure that upstream sample and data resources are fit for the next generation of research.

It is imperative that the national life sciences strategy includes biobanking in order to define how Ireland intends to coordinate, sustain, and modernise these resources to meet future scientific and societal needs.

## Scope

Biobanking spans the full lifecycle of samples and associated data under a biobank's management and control, supporting discovery science, validation, clinical translation, biotechnology R&D, surveillance, pandemic preparedness which can support the One Health approach. However, the scope of biobanking in the national strategy should extend beyond individual facilities to a coordinated system capable of aligning governance, ethical and legal oversight, digital maturity,

operational standards, and workforce competencies and professions. Without coordinated biobanking, research slows, duplication increases, existing gaps are unknown, all impacting the risk of falling behind internationally. A strategic question is whether Ireland intends to continue with the current fragmented individual biobank/collections model or move toward a harmonised, nationally supported model.

## Challenges

The absence of a national biobanking framework creates variability, duplication, redundancy, and uncertainty. Fragmented infrastructure cannot reliably meet the needs of participants, researchers, regulators, or industry partners. Sustainability remains the most persistent challenge, compounded by lack of interoperability and divergent governance. Workforce gaps and undefined career pathways further limit capacity. Most critically, the value and societal impact of biobanking are often underappreciated by both the public and policymakers, making education and awareness-raising necessary to secure trust, long-term support, and informed decision-making.

Ireland risks falling behind unless a comprehensive, sustainable national biobank infrastructure is established. The European Commission highlights biobanking as critical for cutting-edge research, personalized medicine, and industrial growth, with significant investments such as the €1 billion EU digital health fund, [https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe\\_en](https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe_en).

Ireland is currently one of only two countries in Western Europe that aren't part of BBMRI-ERIC (Biobanking and BioMolecular Resources Research Infrastructure – European Research Infrastructure Consortium). Other European countries are actively building biobanking capabilities to support high-quality data, translational research, and investment attraction. Without a national biobanking framework strategy aligned with European goals, Ireland may miss opportunities for collaborations, industrial partnerships, and the development of innovative health solutions reliant on biodata.

## Lessons Learned

Biobanks function effectively only when sufficient time and funding is available for planning, so that governance, ethical oversight, digital capacity, and quality systems are established before

operations begin. This principle is emphasised both in ISO 20387 (Biotechnology – Biobanking – General Requirements for biobanking)<sup>1</sup> and in ISBER Best Practices 5th edition.<sup>2</sup> [ISBER (the International Society for Biological and Environmental Repositories) is the leading global organisation responsible for advancing best practices and education in biobanking].

When these preparatory steps are underdeveloped, biobanks face repeated approvals, duplicated effort, operational inefficiency and delayed research projects resulting in delayed impact for public and patients —a reality for Ireland’s past and present biobanks. The National Irish Covid-19 Biobank, a project that was established by the Government as critical to the response to the COVID-19 pandemic and future threats, was delayed in achieving its aims due to the lack of underlying biobanking infrastructure and governance. Valuable progress and lessons learnt from this national project should be strategically leveraged to inform future initiatives and policy development. Ireland has a strong record of impactful biobanking activity, but many initiatives have operated without secure, long-term support. If this structural gap persists, biobank projects will continue to face challenges in setting up and sustaining operations, retaining expertise, and delivering the full research and innovation value they are capable of generating. A coordinated national approach is essential to protect previous investments and ensure future projects succeed.

## **Strategic Objectives**

### **Research & Innovation**

A coordinated national biobanking system strengthens Ireland’s ability to turn public research investment into measurable outcomes. By ensuring that high-quality collections are visible, standards-aligned, and ethically governed, biobanks make Irish studies more competitive in European funding calls and more attractive to international collaborators. This increases the likelihood that Irish-funded projects generate publications, patents, clinical advances, and policy-relevant insights. When biobanks are integrated early in research planning, they reduce duplication, improve efficiency, and increase the long-term return on national investment by ensuring that samples and data continue to support new research long after individual projects have ended. A strategic approach to biobanking therefore enhances Ireland’s research impact while positioning the country as a reliable partner in global innovation ecosystems.

### **National Biobank and Collections Directory**

However, despite the value of current biobanking resources, there is currently no comprehensive national directory of biobanks and collections in existence for Ireland. Without a centralised directory, it is impossible to determine whether research funding is creating innovative new collections or duplicating existing efforts. Gaps in coverage cannot be systematically identified, meaning that patient needs, emerging research priorities, and biodiversity preservation might not be fully addressed. Critical animal lines, microbial resources, or endangered species could be lost permanently if preservation needs are not tracked and coordinated. Integrating a national directory into a biobanking framework will allow Ireland to map current assets, prioritise future collection strategies, support evidence-based funding decisions, and mitigate redundancy, ensuring that investments deliver maximum scientific, societal, and conservation value. The Danish Biobank Register and Coordinating Centre is a model that Ireland could emulate in order to maximise the potential of biobanking resources in Ireland.

### **Global Competitiveness**

International partnerships and industry investment increasingly depend on fit-for-purpose, accredited biobanks. Clear and consistent standards are essential if Ireland is to stand out in a crowded global life sciences landscape. ISO 20387: Biotechnology — Biobanking — General requirements for biobanking provides a framework for biobanks to demonstrate competence, maintain quality, and ensure reproducibility of biological material and associated data<sup>1</sup>. Ireland already has internationally recognised expertise in biobanking, including contributors to international standards development—one of whom has received awards for this work and served as Editor-In-Chief of the most recent edition of the ISBER Best Practices<sup>2</sup>. An opportunity exists to leverage this advantage by embedding standards, accreditation, and competency frameworks across its biobanking landscape, rather than to continue to let fragmented practice dilute a clear competitive advantage.

The National Standards Authority of Ireland offers the opportunity to engage in standard developments for the lifescience sector through participation in Standard committees. This is a good way for researchers to keep up to date in relevant standard development. For more information see [Healthcare Standards | NSAI](#)

### **Patient and Public Outcomes**

Robust governance, transparent operations, and alignment with ethical and legal expectations enhance public trust and improve translation from research to impact. Biobanking contributes directly to national health benefits when operated consistently and responsibly but Ireland does not currently have a national ethics capacity to enable this, leading to delays in initiating collections and, inconsistencies in the application of ethics principles across different regions. The

National Office for Research Ethics Committees (NREC) established a dedicated research ethics committee (REC) for the National Irish Covid-19 Biobank which could pave the way for a single, national opinion for biobanking research projects. However the remit for this REC finished in 2024.

### **Talent and Skills**

Biobanking requires specialised competencies that bridge biobanking practice, data governance, ethical and legal awareness, and quality management and needs to be developed as a recognised profession with defined competencies, training pathways, and career progression. The strategy must question whether Ireland can rely on informal or ad-hoc skill development when long-term stewardship, quality systems, and regulatory alignment depend on specialised expertise.

Establishing a formalised career path will help attract and retain capability, strengthen institutional memory, and support consistent national performance. A national approach to training and career development would protect Ireland's long-term capability and reduce organisational risk.

### **Sustainability**

Long-term stewardship demands stable funding, modern digital tools, and clear accountability. The strategy should clarify what sustainability means in practice—whether through coordinated national investment, shared services, or structured industry engagement.

Membership of BBMRI-ERIC the pan-European biobanking research infrastructure is strongly advocated by the Irish biobanking community.<sup>3</sup> A decision by the government to join BBMRI-ERIC, would connect Ireland's biobanks with hundreds of high-quality repositories across Europe, providing harmonised approaches, quality frameworks, and ethical and legal guidance. This would complement Ireland's existing membership in ECRIN-ERIC, supporting multinational clinical trials by improving access to well-characterised biospecimens. BBMRI membership would enhance Ireland's research competitiveness, unlocking participation in EU-wide projects, attract industry partnerships, and improve long-term sustainability by sharing best practices and infrastructure. It would support a more stable, scalable biobanking ecosystem in Ireland rather than isolated pockets. Beyond economic and scientific value, it would strengthen Ireland's capacity to deliver high-quality, integrated resources that advance both public health and innovation.

### **What Ireland Needs: National Biobanking Framework**

Biobanks underpin credible life science research. If foundational specimens and data are not managed reliably from the start, the validity and reproducibility of all downstream research becomes uncertain. In biomedical science more broadly, reproducibility is a serious concern. The field is facing a reproducibility crisis. Poor sample storage, incomplete metadata, inconsistent

governance, and lack of traceability are among the factors cited as undermining reproducibility and the long-term utility of research <sup>4</sup>. Without a national framework ensuring high-quality biobanking including standardised specimen handling, robust data systems, ethical oversight, and proper documentation — Ireland risks contributing to the global reproducibility problem. In short, poor upstream management almost guarantees weak downstream science.

Some of the key components of a national biobanking Framework along with their features and benefits are included in the table 1 below:

**Table 1 Key Components of a National Biobanking Framework**

| <b>Component</b>                           | <b>Function/How</b>   | <b>Features/Benefits</b>   |
|--|---|--|
| Ethics capacity                            | Application of ethics principles for transparent and consistent ethical oversight under auspices of National Office for Research Ethics Committees (NREC) | Ethical approval aligned to biobanking competency and purpose, review of consent, access, stewardship; mandatory before embarking on the collection or acquisition of biological material and data |
| National Biobank and Collections Directory | Map of all existing and future human, animal, and biodiversity resources (link to ethics approvals)   | Registration of collections.<br><br>Enables evidence-based decisions for funding and policy approaches.<br><br>Reduce inefficiencies, address gaps.  |
| Legal framework                            | Framework agreements put in place between relevant parties eg. hospitals and universities   | Expedite the set-up phase of biobanking projects to allow meeting of funder timelines and facilitate the competitiveness of ireland at the international level.                                    |
| Quality Management                         | Embed recognised international standards  | Ensure consistent operations and support interoperability across   |

|   |  |   |
|---|--|---|
|   | alongside best practices, leveraging Ireland's existing expertise and leadership in standards development; audits & benchmarking | biobanks to enable access to fit-for-purpose biological material and associated data. |
| Public & Stakeholder Engagement           | Public and stakeholder education, focus on transparency, enabling involvement, build on existing initiatives e.g. IPPOSI         | Build critical awareness, trust and support   |
| Skills development and career progression | Develop biobanking as a recognised profession: training, competency assessment, career paths                                     | Retention of institutional memory, consistent biobank operations                      |
| Biobanking Community Representation       | Provide expert guidance on sector needs, track metrics and impact, link to HRB oversight   | Champion sector sustainability  |

Together, these elements would ensure a robust, future-ready infrastructure capable of supporting research, innovation, public health, pandemic preparedness, biodiversity preservation, and bioinnovation initiatives. Additionally, a coordinated National Biobanking Framework, including a comprehensive directory of collections, might serve as a structured node for Ireland's future engagement with BBMRI-ERIC, facilitating interoperability, streamlined access, and full participation in Europe-wide biobanking networks.

## Opportunities

Ireland can position itself as a leader by embedding quality frameworks, accreditation, and competency models across its biobanks. Aligning biobank specimen resources and their data with national research and public health data infrastructures would create integrated, FAIR-friendly

assets of significant scientific and economic value. Strengthening One Health biobanking networks would enhance Ireland's resilience to infectious threats and environmental challenges, while modern access mechanisms could make Ireland a more attractive destination for biopharma research and clinical trials.

Under the European Health Data Space (EHDS) Regulation (EU) 2025/327, biobanks will be required to make health data available for secondary use by 2029 (and 2031 for sensitive data like genomics). Thus there is an opportunity now to co-develop and align a national biobanking framework alongside the implementation of the EHDS. While current Irish biobanks are predominantly focused on clinical and health-related research, expanding capabilities to cover biodiversity, environmental samples, agri-food industry and other national biological resources could strengthen Ireland's long-term scientific and societal assets. Biobanking can also support bioinnovation by providing structured, high-quality resources that enable new biotechnologies, sustainable solutions, and translational applications, positioning Ireland to leverage its infrastructure for both discovery and applied innovation.

## Conclusion

Incorporating biobanking into Ireland's national life sciences strategy is essential. A coordinated, standards-driven framework will transform fragmented practices into a reliable infrastructure, supporting high-quality, reproducible research, innovation, and public benefit. By taking a phased, ethically grounded approach, Ireland can strengthen its scientific leadership, attract meaningful investment, and position itself competitively on the global stage.

## References

1. ISO 20387:2018. *Biotechnology — Biobanking — General requirements for biobanking*. Geneva: International Organization for Standardization. Available from NSAI Published standard catalogue [I.S. EN ISO 20387:2020/A11:2024 Biotechnology - Biobanking - General](#)

(Note: currently under revision with publication expected from mid 2026)

2. International Society for Biological and Environmental Repositories (ISBER). *Best Practices: Recommendations for Repositories*, Fifth Edition. 2023. Available from <https://www.isber.org/page/BPR>

3. Arar A, Annuk H, O Hynes S, Snapes E, Kerin M, Khan S, Miller N. A roadmap towards Ireland's membership of BBMRI-ERIC. *HRB Open Res.* 2025 May 29;8:50. doi: 10.12688/hrbopenres.14089.2. PMID: 40303194; PMCID: PMC12038341.
4. Cobey KD, Ebrahimzadeh S, Page MJ, Thibault RT, Nguyen PY, Abu-Dalfa F, Moher D. Biomedical researchers' perspectives on the reproducibility of research. *PLoS Biol.* 2024 Nov 5;22(11):e3002870. doi: 10.1371/journal.pbio.3002870. PMID: 39499707; PMCID: PMC11537370



|      |            |
|------|------------|
| Date | 05/12/2025 |
|------|------------|

## NSAI Standards Submission to Ireland's National Life Sciences Strategy

### Introduction

**NSAI (National Standards Authority of Ireland)** is Ireland's national standards body, providing a gateway for national stakeholders to keep up to date on relevant international standards. NSAI also provides certification and metrology functions including responsibility for Legal Metrology and the National Metrology Laboratory. NSAI is the only national Notified body for medical devices providing CE mark approvals for the medical device and in-vitro diagnostics industry, ensuring patient safety.

Membership of NSAI's Standards Technical Committees offers stakeholders based in Ireland the opportunity to engage directly in both European and international standardisation efforts, developing standards at National, European (CEN, CENELEC), and International (ISO, IEC) levels.

Standards enable interoperability of products and services, aid in the acceleration of emerging technologies to market, they build trust and demonstrate quality and safety and, ever increasingly, standards serve to inform, simplify, and harmonise regulations. A comprehensive Life Sciences strategy should reflect the underpinning role of global standards in establishing pathways for innovation, safety, quality, and competitiveness.

NSAI's standards development portfolio represents the breadth of strategic priorities and demands of Irish enterprise, research, and innovation. In direct relevance to the Life Sciences strategy, NSAI's portfolio supports areas including medical devices, diagnostics, health informatics, digital health, genomics, biotechnology (including biobanking, organ on a chip), biopharmaceuticals, advanced therapeutics, bioprocessing and biomanufacturing. *(See Appendix 1 for a summary of current NSAI LS Standards portfolio activity)*. In addition, NSAI manages and contributes at a European and international level to a broad portfolio of cross-cutting digital and green emerging areas.

## Standards underpinning the National Life Sciences Strategy

### Scope & Objectives

NSAI welcomes the development of a comprehensive and forward-looking National Life Sciences Strategy that spans traditional and emerging sectors, emphasising the important underpinning role of standards, innovation, talent development to ensure patient safety and sustainability of the sector. In line with the One Health approach, which is a unifying approach that aims to sustainably optimise the health of people, animals and ecosystems, the Life Sciences strategy should consider a broad scope to include human health, veterinary, food, agriculture and the environment. A staged approach could be taken to prioritise areas that may have the most significant impact.

The strategy should highlight standardisation as a cornerstone for regulatory clarity, interoperability, and competitiveness and should ensure alignment with evolving EU regulations to position Ireland as a global leader in life sciences.

GUARDED

## Opportunities & Challenges

The National Life Sciences strategy should reflect the opportunities associated with global standards in establishing pathways for innovation, safety, quality, and competitiveness.

A number of key opportunities and challenges are highlighted below.

- Given the role of standards in removing barriers to trade and enhancing global competitiveness NSAI advocates that the Life Sciences Strategy should promote alignment with international best practice, by ensuring the engagement of Irish enterprise with European and global standards systems. Enhanced standards development, national conformity assessment, certification and accreditation capacity is required to support advanced biomanufacturing and new medical technologies.
- The strategy should encourage and consider ways to best support early integration of standards into research to improve market readiness and uptake. The role of standards should be integrated into the development of testbeds and pilot facilities for emerging areas including cell and gene therapy, digital therapeutics, and AI-enabled health technologies.
- Investment is needed in skills development by strengthening education and training in standards awareness and regulatory science to ensure workforce competence in high-value, highly regulated fields. In addition, new and expanded testing, calibration, metrology, and conformity-assessment capabilities are needed to support national quality infrastructure in biotech and biopharma.
- The strategy should highlight how patient safety and trust is supported through the employment of internationally recognised standards for product safety, clinical effectiveness and traceability including the development of a robust and sustainable biobanking infrastructure underpinned by standards.
- In new and emerging areas where standards and roadmaps are under development, Ireland can lead in defining and contributing to standards development in areas including advanced biotherapeutics- ATMPs, RNA therapeutics, bioprinting and personalised medicine.
- Early engagement and adoption of standards in new or emerging technologies can ensure early market access and can assist in regulatory compliance, where regulations link to standards. E.g. MDR, IVDR, digital health, medical device software and AI.

## European Context

Standards play a role in ensuring that new technologies are implementable, interoperable, and trustworthy. Furthermore, under the EU's New Legislative Framework (NLF), harmonised standards are increasingly employed to aid the implementation of EU regulations.

The [EU Life Sciences Strategy](#) provides a strong framework for competitiveness and regulatory coherence across Europe. Ireland's strategy should align closely with key themes, especially to promote consistent adoption of EU-wide and international standards across all life sciences sectors and to support and lead on the development of new standards for emerging areas.

The upcoming [EU Biotech Act](#) represents an opportunity to shape Europe's regulatory environment for biotechnology and to ensure that EU Member States— including Ireland—can compete globally in emerging areas ranging from gene therapies to bio-based industries.

Under the New Legislative Framework, standards offer simplified approaches to compliance with complex of EU legislation (MDR, IVDR, AI Act, EHDS). Future requirements under the EU Biotech Act may incorporate the use of harmonised standards enabling improved market access for SMEs. The EU Blue guide serves as a useful reference guide<sup>1</sup>.

In the area of health data infrastructure, alignment of national infrastructure with EHDS implementation is important to enable interoperable, secure, high-quality health data environments for research and care.

## Conclusion

NSAI strongly supports the development of the National Life Sciences Strategy. Research and application of standards early in the development of new technologies and products can assist market readiness preparation. Certification and accreditation, to quality assurance and risk management standards and frameworks, and to other international standards are essential tools which can ensure Ireland's success as a global hub for life sciences. By aligning with emerging EU legislation—including the forthcoming Biotech Act—and with best practice standards, Ireland can strengthen competitiveness, foster innovation, and ensure public trust.

---

<sup>1</sup> [The Blue Guide on the implementation of the product rules 2022 is published - Internal Market, Industry, Entrepreneurship and SMEs](#)

## Appendix 1 – Examples of NSAI Standards Activities in Health Life Sciences

Note: for more information on national standard committees in the Healthcare and Life Science area (including international standard committees monitored) see the NSAI website:

### Healthcare and Lifesciences & Med Tech and Digital Health

|   |
|---|
| <b>MedTech</b> <ul style="list-style-type: none"> <li>• Harmonised standards MDR &amp; IVDR</li> <li>• Electrical safety standard revisions</li> <li>• Global harmonisation of MD regulations</li> <li>• Artificial Intelligence &amp; MD software</li> <li>• Circular economy for MD Sector – new focus</li> </ul>   |
| <b>Health Informatics</b> <ul style="list-style-type: none"> <li>• Digitization of health records</li> <li>• Shared care &amp; interoperability</li> <li>• Information Security &amp; Privacy Protection</li> <li>• Telehealth &amp; virtual care &amp; personalised digital health</li> <li>• Pharmacy and medicines (ID &amp; traceability through supply chain)</li> <li>• Architecture and frameworks (interoperability)</li> </ul> |
| <b>Biotechnology &amp; genomics</b> <ul style="list-style-type: none"> <li>• Analytical methods</li> <li>• Biobanking &amp; bioresources</li> <li>• Micro physiological systems &amp; Organ-on-chip</li> <li>• Genomics informatics</li> <li>• Bioprocessing for cells</li> <li>• Data processing &amp; integration</li> <li>• Nucleic acid and protein-based devices</li> <li>• Organoids</li> </ul>                                   |
| <b>Other areas</b> <ul style="list-style-type: none"> <li>• Healthcare services</li> <li>• Laboratory equipment</li> <li>• Bio digital convergence</li> </ul>   |
| <b>NSAI Committees</b> <ul style="list-style-type: none"> <li>• NSAI/TC 5 HCSC- Medical Devices</li> <li>• NSAI/ETC TC 10 – Electrical safety, medical devices</li> <li>• NSAI/TC 21 – Health Informatics</li> <li>• NSAI/TC 62 – Biotechnology</li> </ul>  |
| <b>International Committees</b> <ul style="list-style-type: none"> <li>• Biotechnology- ISO TC 276</li> <li>• Genomics– ISO/TC 215/SC1</li> <li>• Health Informatics – ISO/TC 215</li> <li>• IEC TC 62 – Medical equipment, software and systems.</li> </ul>  |



|      |            |
|------|------------|
| Date | 05/12/2025 |
|------|------------|

GUARDED

## Submission from Dr. O'Rourke

### Strategic recommendations:

1) Greater mutual investments between Ireland and Canada. We are natural strategic partners in the lifesciences space, with similar values.

Likewise, reducing our exposure to economic turbulence arising from the current US regime.

We have other natural allies in the EU (Especially in France, Spain, Denmark, Sweden), Korea, China (in research), Australia/New Zealand, South Africa, Iceland, Norway, and Mexico.

Relations are warm and constructive at present with the current government in Britain, so we should explore strategic joint partnerships there too while this opportunity remains.

Let's promote those highly valuable connections. Not only are they healthy growth areas, they could offset foreseeable shocks from the USA.

2) Supporting Ireland-based enterprises with funding schemes to take on new hires in well paid high-quality industrial internships and accredited apprenticeships. Needs careful oversight, but is a strategic investment opportunity in our own Irish human capital.

3) More public-private partnerships, and local cooperatives. Business models that engage the local community, and share value more fairly and fully with the public sector.

4) Sustained investment in biomanufacturing training, both here in Ireland, and including our existing engagements with Africa and LMICs.

A 'strategic initiatives' fund for responsible investment in the humanitarian lifesciences (vaccines, diagnostics, treatments), proactively inviting joint funding/investment applications from partner organisations in developing countries.

5) Industry informed focussed investments in innovative cancer therapies such as chimeric antigen receptor therapies (CAR-T, CAR-NK, TILs, allogenic gamma-delta T cell therapies, in vivo CAR therapies). Proactively engage our strong academic base to seek an informational technical briefing to your Board on these powerful technologies that Ireland can become a European leader in. There are exciting proposals underway for an island-wide manufacturing consortium in this space.

6) Let's make a strategic objective to go out and pull in an mRNA vaccine manufacturing company to Ireland. (Tie in with IDA). Support local Irish efforts in this area also. This is a strategic technology.

7) Technical assistance for startups and large multinationals on REACH compliance, responsible procurement, and ensuring decent labour conditions in the global lifesciences supply chain. This sends a powerful policy message, and will also empower responsible business growth.

8) Capitalising on opportunities in the continuous and intensified manufacturing space to lower costs, and increase affordability/accessibility to biosimilar therapeutic medicinal products. Supporting digitally-enabled and automated in-line sensors and probes for process control and process analytics.

9) Screening of funding applications to ensure no dual-use or defence/military applications. An enterprise values charter emphasising Ireland's military neutrality and commitment to peaceful and equitable economic development, that works within planetary limits in a sustainable and environmentally friendly way.

Avoiding misguided investments in unsound or unsafe AI systems.

10) Funding for new methods and techniques to detect illegal and illicit medicinal products sold outside of approved regulatory frameworks. I have in mind the recent scandals surrounding illegal sales of purported GLP-1 products, and the widespread criminal fraud in some emerging markets. These risk public safety, so innovative here to detect and prevent same would be beneficial.

11) North-South cooperation on this island in lifesciences investments in One Health, animal health, and public health. Infectious disease is no respecter of borders. Responsible enterprises can contribute much here.

A special fund for cross-border initiatives to ameliorate the environmental damage in Lough Neagh, with State supports from both governments, enhancing public sector initiatives.

12) Dedicated strategic funding for re-skilling staff, and promoting flexible modular manufacturing. Helping to prevent mass layoffs. Funding to be withheld if an enterprise cannot give employment security assurances during applications. Labour is not to be regarded an expendable business cost, but an indispensable factor of production.

13) Strategic caution and oversight on global CMOs, CROs, and CDMOs, and global supply chains. Grave concerns around the quality and safety of their outputs, and especially their compliance with our human rights expectations for their workers. We should strategically promote and reward decent work, and responsible business that contributes to the common good.



December 5, 2025

## **PUBLIC DOCUMENT**

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request by the Department of Enterprise, Tourism and Employment on the development of a new National Life Sciences Strategy. PhRMA represents the world's leading biopharmaceutical companies, which are devoted to researching and developing medicines that enable patients to live longer, healthier and more productive lives. PhRMA welcomes efforts by the Irish Government to seek multi-stakeholder engagement on its strategy to address improvements in the life sciences sector and ensure that it remains competitive in the global landscape.

The submission below responds to the questions raised in the request of comments regarding the scope, objectives, opportunities and challenges, and EU context for the proposed life-sciences strategy.

### ***Scope***

Ireland's Life Sciences Strategy should focus its scope and define life sciences as a sector centered on human health, particularly on human health innovation and cutting-edge biopharmaceuticals, biologics, cell and gene therapies, and advanced modalities that depend on robust research and development (R&D) ecosystems and predictable transparent access pathways.

While the Life Sciences Strategy may encompass broader areas such as medical technology, diagnostics and digital health, Ireland's competitive advantage is in its pharmaceutical capabilities across discovery, clinical research and commercialization.

Defining and prioritizing human health innovation as a core pillar will enable Ireland to better position itself and remain a leading European hub for the development, launch and scale-up of innovative medicines that improve patient access, health outcomes and health system performance.

### ***Objectives***

Ireland's Life Sciences Strategy should include the following key objectives:

- a. Strengthen Ireland as a priority market for pharmaceutical innovation

Ireland continues to lag many other European countries when it comes to the availability of new medicines. Only 25 percent of new medicines launched globally since 2014 are reimbursed in

Ireland's public national health insurance, with patients waiting an average of 34 months after global first launch for the medicines that are reimbursed.<sup>1</sup> Poor access to new and innovative medicines limits R&D, clinical trial development and investment. Many European countries are now replicating Ireland's tax and R&D incentives, eroding the competitive edge Ireland once held. To remain a leader in Europe's biopharmaceutical landscape, Ireland should commit to timely, transparent and predictable processes for pricing, reimbursement and market access. A system that recognizes the full clinical and economic value of innovative medicines signals to global companies that Ireland is an attractive early-launch market. It is also consistent with the EU Pharmaceutical Transparency Directive, which aim to ensure that EU Member States' pricing and reimbursement decisions for medicines are objective, transparent and timely, so that national controls on pharmaceutical spending do not unduly restrict market access or distort trade within the EU single market.

b. Strengthen Ireland's R&D and national investment in innovative medicines

Many high-income countries underinvest in new therapies relative to their GDP, resulting in delayed patient access and reduced attractiveness for global launches. Ireland must remain vigilant in maintaining and increasing its annual innovative medicines budget, ensuring that spending on innovative therapies aligns with rapid scientific advancement, patient population needs and value for innovation. Given Ireland's leadership position in Europe, maintaining this competitive advantage remains of the utmost importance to continue attracting investment, early-launches and advancing biopharmaceutical innovation.

The Life Sciences Strategy should therefore strengthen and prioritize:

- Expansion of biologics and advanced therapy production
- Expansion of clinical trials and streamlined processes
- Increased incentives for investment in R&D, clinical trials and digital health infrastructure
- Strengthened regulatory and data capabilities to support complex therapies

c. Maintain a strong intellectual property (IP) and regulatory environment

Predictable and durable IP protection and enforcement, coupled with efficient regulatory pathways, can encourage long-term investment and fortify Ireland's position as a European hub for innovation and a key player in supply chains.

***Opportunities and Challenges***

Opportunities

---

<sup>1</sup> PhRMA analysis of regulatory, launch and reimbursement data for new medicines launched globally between January 1, 2014, and December 31, 2023.

1. Re-establish Ireland as an early-launch market for innovative medicines:  
By implementing reforms to access pathways and improving the transparency and due process of its pricing and reimbursement processes, Ireland can differentiate itself from other EU markets where reimbursement delays and cost-containment measures discourage early launches.
2. Promote the development of next-generation therapies:  
Ireland's highly skilled workforce and strong quality track record make it ideal for scaling biologics, mRNA platforms, cell and gene therapy components, and novel modalities.
3. Strengthen Ireland's role in global clinical trials:  
Enhancing trial activation speed, data capabilities and patient recruitment infrastructure would deepen Ireland's R&D attractiveness.
4. Position Ireland as a digital health and data leader:  
Interoperable health data systems, national digital infrastructure and real-world evidence capabilities can accelerate innovation uptake and support precision medicine.

### Challenges

1. Pricing and reimbursement delays that risk undermining Ireland's competitiveness:  
International evidence demonstrates that slow, unpredictable or economically distorted reimbursement systems deter investment and deprioritize launch sequencing.
2. Pressure from cost-containment mechanisms seen in other high-income markets:  
Policies such as strict price referencing, mandatory price cuts, rigid health technology assessment (HTA) thresholds and clawbacks have weakened incentives elsewhere. Ireland should eliminate any such existing policies and refrain from enacting any such new policies.
3. Increasing global competition for biopharmaceutical investment:  
Countries in Asia and the Middle East offer aggressive incentives and streamlined market access conditions. Ireland must respond decisively to maintain its leadership.
4. Rising scientific complexity:  
Next-generation therapies require advanced infrastructure, talent pipelines and regulatory agility. Ireland's strategy must anticipate these needs to stay competitive.

### ***EU Context***

Ireland's Strategy should align with EU-level policies where beneficial, but also assert Ireland's national priorities to ensure that the country remains a preferred destination within the European Union for biopharmaceutical investment. Ireland should take domestic actions to improve its access and pricing policies and engage directly with EU institutions, other EU Member States and the United States to promote strong biopharmaceutical policies.

a. Navigating EU reforms affecting pharmaceutical innovation

Current and forthcoming EU-level initiatives, including revisions to the general pharmaceutical legislation, regulatory data protection periods and new market entry obligations, carry significant implications for investment decisions. Ireland should work to ensure that these frameworks do not devalue innovation or impose obligations outside companies' control.

b. Strengthen Ireland's role as an innovation-friendly, predictable market

While participating in wider EU reforms, Ireland should differentiate itself through:

- Faster and more predictable national reimbursement policies
- Enhanced advocacy for robust IP protections and legal certainty
- Pro-innovation procurement and access pathways
- A strategic commitment to invest in innovative medicines above EU averages

c. Ensure that EU measures support Ireland's competitiveness

Ireland should advocate within the EU for:

- Faster regulatory and HTA timelines
- Modernized value assessment frameworks
- Greater alignment on clinical trial processes
- Measures that strengthen, rather than weaken, EU IP policies and the EU's innovation ecosystem and investment climate

Ireland's goal should be to leverage EU-wide strengths (e.g., data spaces, regulatory cooperation) while ensuring national policies remain internationally competitive in attracting biopharmaceutical investment. Ireland must also demonstrate strong leadership within the EU by opposing proposals that weaken IP protections or impose localization and launch requirements for securing IP. As a leading European hub for innovative medicines, Ireland is uniquely positioned to advocate for robust IP protections across the EU and among its trading partners. Indeed, to date, the EU has shown little ambition to secure robust IP provisions in free trade agreements that adequately support the life sciences sector.

# Submission from Rare Disease Clinical Trial Network and Rare Disease Research Catalyst Programme

## National Life Sciences Strategy – Public Consultation

### Joint submission from the Rare Disease Clinical Trial Network and the Rare Disease Research Catalyst Program

**Rare Disease Clinical Trial Network (RDCTN)** is a UCD-hosted, HRB-funded initiative that addresses the challenges of conducting rare disease clinical trials in Ireland by supporting education and training, regulatory frameworks, public and patient involvement and industry engagement. It is a collaboration and support hub that links and develops national and international rare disease expertise and innovation while keeping the patient voice at the centre of all its work.

**The Rare Disease Research Catalyst Consortium (RDCat)**, also hosted by UCD and funded by the HRB, connects Irish-based researchers, clinicians, and patient advocates with international networks to strengthen rare disease research and drive research activities in Ireland. Activities include enabling the use of European Reference Network (ERN) disease registries, rare disease researcher training, increasing the influence of rare disease patients in research and developing research pathways for undiagnosed patients under the upcoming ERDERA partnership programme.

---

### Scope

Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.

In your view, how broad should the scope of the strategy be?

---

The National Life Sciences Strategy should be broad and cross-sectoral, encompassing the entire research and innovation lifecycle. This includes:

- **Sectors:** (Bio)pharmaceuticals, medical technologies, agriculture, fisheries, food production and Information and Communications Technology including AI.
- **Infrastructure:** Academic and clinical facilities supporting health research, health research funders, bio banks, patient registries, genetic and genomic services and ICT systems (single health identifier, electronic health records, coding terminologies including the integration of ORPHAcodes as the gold standard nomenclature for rare diseases), ICT support and data storage for genomic and genetic research.

- **Data:** systems for health data collection and sharing including electronic health records, aligning data policy with best research practices such as single Data Protection Impact Assessment and alignment with the European Health Data Space.
- **Workforce:** development of skills and capacity throughout the clinical and research landscapes through investment in education, training and career structures and development.
- **Regulatory and Ethical Processes:** introduce single ethical review for non-trial research, revise the drugs reimbursement process, implement National Clinical Trial Oversight Group recommendations for clinical trial contracts, data protection, KPIs and costing, harmonised review for GDPR compliance and Data Protection Impact Assessment for health research.
- **Public and Patient Involvement and Inclusion:** meaningful Public and Patient Involvement (PPI) should be at the heart of all stages of research and innovation from prioritisation and design through to dissemination and implementation. The value of involving patients, families, and advocacy groups from the earliest stages of research development is widely recognised. Achieving inclusivity is similarly important - this includes removing barriers to participation and designing research that is culturally sensitive and accessible. Together, PPI and EDI ensure research is relevant and impactful and they should be embedded in research systems and structures.

The strategy must ensure strong alignment with existing national plans, we specifically highlight the importance of the [National Rare Disease Strategy](#) and the [Report of the National Clinical Trials Oversight Group](#) (NCTOG).

Alignment with the **National Rare Disease Strategy** is critical for addressing the specific challenges of this high-need patient population and leveraging the existing strengths in terms of scientific and patient expertise and opportunities to build on international partnerships, including European Rare Diseases Research Alliance (ERDERA), JARDIN Joint Action for the integration of European Reference Networks (ERNs) into National Healthcare Systems, European Clinical Research Infrastructure Network (ECRIN) and the European Infrastructure for Translational Medicine (EATRIS). These partnerships offer valuable opportunities for Ireland including research collaboration, promoting Ireland as a site for multi-national clinical trials, access to research funding, access to novel initiatives such as the diagnostic research pipeline for undiagnosed patients through ERDERA.

The Strategy notes the unique characteristics of rare disease research that offer a model for innovative, leading edge, cross border collaboration and patient driven research. It outlines particular advances in research and innovation that have led to new diagnostic tools, devices, treatments and therapies with a transformative effect on healthcare and especially the lives of those affected.

Key recommendations from the Strategy that should be integrated into the Life Sciences Strategy include:

**Support for European Reference Networks** - small patient populations make international collaboration vital to meaningful rare disease research and clinical trials. European Reference Networks are networks of specialist centres working across borders to pool expertise and data so that healthcare providers throughout Europe can access the most appropriate diagnosis and treatment for their patients. They provide an important gateway to research, guidelines, education and registry data, all of which are foundation stones for research, innovation and clinical trials. They are curtailed by lack of funding and resources for data management and care coordination and poor integration into national health systems.

There are currently 24 ERNs across the EU and Norway created under Directive 2011/24/EU on patients' rights in cross-border healthcare. Ireland actively participates in the ERNs and since 2022, is a member of 18 of the 24 ERNs. Ireland hopes to join the remaining six ERNs when the EU opens the next call for applications. ERN involvement helps connect Irish rare disease experts and services to a wider network. (National Rare Diseases Office).

To support ERN sites in Ireland to build research and innovation capacity the Strategy recommends enablers including enhancing data systems, to facilitate the collection, sharing and analysis of rare disease data including genomic data, introducing and developing infrastructure for genomic testing, supporting participation in European and global research consortia and aligning national research initiatives with Horizon Europe and other funding opportunities such as ERDERA. It also underlines the importance of integrating ERNs into the health system and recommends development of a roadmap to achieve this, increased resourcing and supports, and implementation of the EU4Health Joint Action on the Integration of ERNs into National Healthcare Systems (JARDIN), in which Ireland is playing a lead role.

**Workforce development** is vital to strengthen the link between research and the health and social care system and this is particularly so for the rare disease research and clinical workforce. Measures to achieve this include workforce planning, protected time for clinicians, increased research funding and opportunities for education and training including fellowships and international exchanges. It is also vital to recognise the central role of research nurses and research coordinators as key members of research teams and to ensure these roles are supported and that career paths and structures are developed accordingly.

**Support for innovative trial design and methodologies** that are patient centred and informed by the lived experience of patients ensure research is more relevant, more effective patient recruitment and retention and higher success rates overall. Work within the Rare Disease Clinical Trial Network is ensuring that Ireland is research and clinical trial ready with an approach that is

based on strong partnerships that prioritise the needs of patients living with rare diseases through tailored support and inclusive design.

**Orphan Medicines** - Irish patients' access to orphan medicines fall far short of other similar sized countries and delays in our drug reimbursement processes are impacting Ireland's appeal as a site for international clinical trials. As referenced in the National Rare Disease Strategy and more recently called for by a multistakeholder group led by Rare Diseases Ireland, Ireland urgently requires a revision of the drugs reimbursement process and implementation of an early access scheme for orphan drugs.

**Development of Data, Health Information Systems, and Registries** - the National Rare Disease Strategy highlights the need for robust data systems including the establishment of a national rare disease registry and ensuring the longer-term vision for Electronic Health Records (EHRs) includes the full integration of ORPHAcodes (the gold standard nomenclature).

**The National Clinical Trial Oversight Group Report** sets out 20 recommendations across six priority areas to strengthen Ireland's clinical trials ecosystem. Implementation of these is critical to the Life Sciences Strategy's success and will improve patient access to therapies, strengthen healthcare resilience, and enhance Ireland's global reputation. The Report's core rationale is that clinical trials must be integrated into standard care. Research-active health systems deliver better patient outcomes, attract and retain skilled professionals, and accelerate learning and innovation. They also provide significant cost savings and broader economic and societal value.

Key recommendations are the establishment of streamlined and standardised processes for contracts, data protection, KPIs and costing; workforce development including standardised career pathways and education and training and use of innovative technologies in all aspects of clinical trial design and conduct.

**Public and Patient Involvement** - both the National Rare Disease Strategy and the NCTOG Report emphasise the importance of patient and public partnership and engagement. This spans educational and awareness campaigns and ensuring meaningful partnership across prioritisation, design, development, monitoring and evaluation of policy, services and research.

---

## Objectives

What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?

*For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

*To position Ireland as a worldclass hub for life sciences at every stage of the research and innovation lifecycle*

---

The key objectives should be to position Ireland as a **global leader in life sciences** by:

- Developing world-class research and innovation systems and infrastructure.
  - Developing research and clinical skills and talent through education, training, and sustainable career pathways.
  - Aligning with EU regulatory, ethical, data systems and funding streams to leverage opportunities for support, resourcing, collaboration, and innovation.
  - Embedding meaningful public and patient involvement at every stage of the research and innovation life cycle.
- 

### **Opportunities and challenges**

What do you see as the main opportunities and challenges for Ireland’s life sciences sector over the next decade that this strategy should address?

---

An overarching challenge relates to the fact that research and technological innovation is proceeding at a faster pace than legislative and system changes - a more responsive and agile system is needed to enable these opportunities to be leveraged in a timely way. A combined effect of all the challenges outlined below is to limit Ireland’s capacity to apply for international grants and involvement in innovative projects.

| <b>Challenges</b>  | <b>Opportunities</b>   |
|--|--|
| <b>Data &amp; Systems:</b> Lack of electronic health data, patient registries and complex and inconsistent data protection systems.                              | <b>Development:</b> of Electronic Health Records, Patient Registries and alignment with the European Health Data Space and ERN Registries. |
| <b>Process:</b> Delays/inconsistency/complexity in regulatory, ethics and data protection processes. Delays in medicines assessment and reimbursement processes. | <b>Implementation of the National Rare Disease Strategy and NCTOG Report.</b> Alignment with EU measures such as the EU Biotech Act.       |

| Challenges   | Opportunities  |
|--|--|
| <b>Lack of critical infrastructure</b> for genomic medicine and biobanking.  | <b>Implementation</b> of the National Strategy for Accelerating Genetic and Genomic Medicine in Ireland.   |
| <b>Academic and clinical</b> fragmentation including barriers to cross border research and clinical trials.            | <b>Research and clinical trial networks</b> working to promote research and clinical collaboration nationally and internationally. Engagement with the new Health Regions/Regional Executive Officers to ensure consistency and streamlining across health regions. European Reference Networks. |
| <b>Insufficient funding and protected time</b> for research across clinical, basic science and translational research. | <b>Engagement &amp; Agility:</b> High level of public/patient trust and engagement. Dynamic and highly informed patient organisations and communities. Agility due to country size.  |
| <b>Lack of support</b> and investment in workforce development and career pathways.                                    | <b>Workforce &amp; Networks:</b> Highly skilled workforce and strong international links (diaspora) as well as strong existing bio-pharmaceutical presence.  |

---

## EU context

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.

What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

Please refine and structure the following information in answer to the question What are your views on this ambition of the recently published EU Life Sciences Strategy and the measures proposed to achieve it? How could these be applied in the Irish context?

---

The recently published **EU Life Sciences Strategy (EU LSS)** presents a comprehensive and ambitious vision for positioning Europe as the world's most attractive life sciences hub by 2030. This strategy provides a critical framework and roadmap with which Ireland should align its national efforts, particularly in the areas of clinical trials and health research.

Ireland should fully support and mirror the key priorities identified in the EU LSS, focusing national action and investment to leverage the opportunities presented by EU-wide initiatives.

## **1. Accelerating Clinical Research and Infrastructure**

Ireland must align its national clinical trials agenda with the EU's focus on simplifying processes and boosting infrastructure, as outlined in the EU LSS.

### **EU Measures**

- **Improving the Framework:** The EU LSS prioritises improving the framework for clinical research by addressing regulatory challenges and supporting essential infrastructures and networks.
- **Multi-Country Trials:** The Commission will facilitate multi-country clinical trials through European partnerships, notably the Innovative Health Initiative Joint Undertaking (IHI JU), and by piloting a new approach to funding these complex trials.
- **Regulatory Alignment:** Initiatives like Accelerating Clinical Trials in the European Union (ACT EU) and MedEthicsEU are working to harmonise operational procedures and align Member States' medical research ethics committees.
- **Investment Flagships:**
  - Proposing an Investment Plan for Clinical Research to streamline European research infrastructures.
  - Creating a network of European Centres of Excellence in Advanced Therapy Medicinal Products (ATMPs).

### **Application in the Irish Context**

- **National Alignment:** Ireland should explicitly adopt the EU LSS objective to improve its clinical research framework, directly referencing the recommendations of the National Clinical Trials Oversight Group (NCTOG) to create a unified, responsive national system.
- **Leverage EU Networks:** Ireland, through networks and structures such as the Rare Disease Clinical Trial Network (RDCTN) and the Rare Disease Research Catalyst Program, must actively position itself to participate in and lead IHI JU projects and multi-country trial funding pilots.
- **Build on Success:** The European Rare Diseases Research Alliance (ERDERA) is cited as a model for R&I ecosystems; Ireland's existing partnership in ERDERA must be further

supported and built upon as a case study for successful EU collaboration that is delivering impact to patients, researchers, and health systems.

## **2. Data Systems, Alignment, and AI**

The EU LSS places a strong emphasis on addressing data fragmentation and leveraging digital tools.

### **EU Measures**

- **EHDS Framework:** The European Health Data Space (EHDS) Regulation establishes a clear, secured framework for accessing electronic health data.
- **Cross-Regulatory Coordination:** The EU LSS recognises that fragmentation in the national application of GDPR and other data acts limits the full use of personal data. To address this, a European Life Sciences R&I Data Assembly will be established to support consistent interpretation and harmonisation.
- **Genomics and AI Investment:** The EU will invest heavily in:
  - Developing and populating strategic biodata resources (including non-human biodata) to advance the One Health approach.
  - Boosting the European genomic data infrastructure (EUR 25 million via Digital Europe).
  - Integrating multi-modal generative AI technologies into biomedical research (EUR 50 million via Horizon Europe).

### **Application in the Irish Context**

- **Urgent Data Reform:** Ireland must treat the development of its health data infrastructure as an urgent national priority. This includes a coherent and resourced approach to health registries, European Reference Network (ERN) registries, and the full integration of EHRs with EU standards.
- **Harmonise GDPR:** Ireland must address the diverging national interpretations of GDPR that create legal uncertainty for R&I stakeholders, ensuring full compliance while facilitating research access to health data.
- **Digital Skills:** Strategic investment in AI and data science skills within the health and research workforce is necessary to ensure alignment with the EU's investment in these technologies.

## **3. Workforce Development and Talent Attraction**

The EU LSS focuses on addressing career stability and emerging skills gaps.

### **EU Measures**

- **Career Pathways:** The EU will implement a new European framework for research careers and the Council Recommendation on attractive and sustainable careers in higher education to address limited career prospects and restricted mobility.

- **Skills & Training:** Instruments like the Marie Skłodowska-Curie Actions, Erasmus+, and the forthcoming Union of Skills and STEM education strategic plan (including specialist fellowships) are designed to promote future-oriented skills.
- **Global Talent:** Actions will be taken to attract global research talent to the EU, including through the 'Choose Europe' initiative.
- **Foresight Study:** A foresight study will identify the competences, skills, and training needs for the life sciences, particularly for optimising AI uptake.

### **Application in the Irish Context**

- **Career Certainty:** Ireland must leverage the EU framework to establish stable, long-term career pathways for clinical and research staff, addressing the current lack of certainty and security in research roles (as identified in the NCTOG Report).
- **Utilise EU Instruments:** Actively promote the use of EU instruments like Marie Skłodowska-Curie Actions and micro-credentials to support upskilling and cross-border mobility for researchers and clinicians.
- **STEM Plan:** Align national education and training programmes with the EU's STEM education strategic plan to cultivate talent in fast-growing fields like life sciences and advanced therapeutics.

## **4. Regulatory Efficiency and Innovation**

The EU LSS aims to make the regulatory environment more agile while maintaining high safety standards.

### **EU Measures**

- **Simplification:** The EU plans to propose the European Biotech Act to make the regulatory system more conducive to biotech innovation across various sectors.
- **Agility:** Efforts are underway to assess and optimise current authorisation procedures for health, medical devices, and food applications to reduce timelines.
- **Future-Proofing:** Future legislation will integrate experimentation clauses and the use of regulatory sandboxes (as seen in the reform of the EU pharmaceutical legislation) to allow for testing new solutions.
- **AI-Powered Guidance:** The Commission will create an AI-powered interactive tool to help researchers and innovators navigate the complex, cross-sectoral EU regulatory landscape, particularly during early-stage R&D.
- **MedTech Reform:** Flagship action to propose legislation to balance simplifying regulations for medical devices and *in vitro* diagnostics with effectively protecting patient safety.

### **Application in the Irish Context**

- **Streamline National Processes:** Ireland must urgently address national regulatory challenges (e.g., in ethics and contracts) to remove blockages to trial start-up and leverage the efficiency gained from the EU's Clinical Trials Regulation.

- Address delays in medicines assessment and drug reimbursement by revising these processes to ensure timely equitable access to innovative treatments and tools – set a goal of one year from EMA authorisation.

## **5. Public Trust and Partnership**

The EU LSS recognises that public trust and responsible research are prerequisites for successful innovation.

### EU Measures

- **Responsible R&I:** The Commission will fund the creation of a repository of tools and best practices in responsible R&I, risk, and science communication to counter misinformation and foster public acceptance.
- **Inclusive Dialogue:** It calls on Member States to strengthen science communication and outreach to ensure public understanding and acceptance of technologies, especially in areas like food and agriculture.

### Application in the Irish Context

- **Leverage PPI Culture:** Ireland has a strong and engaged Public and Patient Involvement (PPI) community and culture, thanks to the work of the PPI Ignite Network, Health Research Charities Ireland, the Health Research Board and the Rare Disease Clinical Trial Network, alongside a vibrant and dynamic patient advocacy community - this must be leveraged and deepened.
- **Go Beyond Outreach:** While the EU focuses on outreach, Ireland should go further, embedding meaningful public and patient partnership in research where patients are genuine partners in prioritising, co-creating, designing and conducting research and clinical trials, ensuring greater relevance and impact for their communities.



Rare Diseases Ireland  
Carmichael House,  
North Brunswick Street,  
Dublin 7, Ireland

[www.rdi.ie](http://www.rdi.ie)  
[advocacy@rdi.ie](mailto:advocacy@rdi.ie)

5<sup>th</sup> December 2025

Department of Enterprise, Trade and Employment  
Block C, Earlsfort Centre  
Hatch Street Upper  
Dublin 2  
Ireland

**Re: Submission from Rare Diseases Ireland on the Development of Ireland's National Life Sciences Strategy**

Dear Sir/Madam,

Rare Diseases Ireland (RDI) welcomes the opportunity to contribute to the development of Ireland's National Life Sciences Strategy. We would further welcome the opportunity to engage in a multi stakeholder group to drive development and adoption of the future strategy when the need arises.

RDI, as the national alliance representing the 300,000 people living with a rare disease in Ireland, sees this strategy as a critical moment to shape a forward-looking, patient-centred life sciences ecosystem capable of delivering better health outcomes, driving scientific leadership, and securing Ireland and Europe's global competitiveness over the next decade.

People living with rare diseases have historically faced delayed diagnoses, limited care pathways, and scarce treatment options. Yet rare diseases now sit at the **leading edge of scientific and clinical innovation**, driving advances in **personalised medicine, genomics, data-enabled healthcare, and advanced therapies**. Because of this, rare disease expertise, infrastructure, and patient partnership should be viewed as national assets that can accelerate innovation across the entire life sciences sector.

Below, we offer our recommendations in line with the consultation guidelines.

---

## 1. Scope of the Strategy

RDI supports a wide scope encompassing biopharmaceuticals, medical technologies, digital health, diagnostics, food and nutrition science, and cross-sector innovation. From a rare disease perspective, the strategy should:

Company Limited by Guarantee – CRO 140743 – CRA 20044633 - CHY 13930  
Registered Office: Carmichael House, North Brunswick Street, Dublin 7, Ireland  
Board: J McCormack, M Hennessy, A Micks, L Egan,  
A Daly, S O'Reilly, S O'Connell, F Griffin

### **a. Treat the healthcare system as a core component of the life sciences ecosystem**

Ireland must transition from being primarily a manufacturing hub to becoming a **research-active, innovation-ready health system** where scientific discovery, clinical research, and technology adoption are embedded into day-to-day care. The HSE should be empowered to act as an **engine of innovation**, driving research and enabling earlier testing, validation, scaling and adoption of new technologies.

### **b. Position rare diseases as a strategic driver of innovation**

Because most rare diseases are genetic, multi-systemic, and complex, advances in this area accelerate progress in mainstream healthcare. The strategy should explicitly recognise the contribution of rare diseases to innovation in:

- **Genomics and precision medicine**
- **Advanced therapies (ATMPs), including gene and cell therapies**
- **Specialised medical devices and diagnostics**
- **Digital health solutions and data platforms**
- **Cross-border sharing of expertise, education and best-in-class care coordination** through European Reference Networks (ERNs)

### **c. Embed meaningful patient partnership across all sectors**

Patients and caregivers possess unique expertise that must shape decision-making. The strategy should commit to:

- Systematically involve patients and the families/care givers in priority-setting, defining outcomes, research and trial design, technology assessment, and implementation planning
- Support for patient organisations to participate effectively and sustainably
- Recognition of patients as equal partners, not occasional consultees

---

## **2. Key Objectives for Long-Term Sector Success**

### **a. Establish Ireland as a leader in patient-centred innovation**

- Fully embed patient involvement across R&D, regulation, reimbursement, and service design.
- Create a national framework for structured patient engagement, with appropriate support, training, and compensation.

### **b. Transform the health system into a research-active, innovation-ready environment**

- Expand research infrastructure within the HSE, including clinical research networks.
- Expand genomic testing capacity and embed genomics into routine care.
- Develop a clear national pathway for the assessment, introduction, and scaling of new technologies—including digital tools and ATMPs.
- Ensure the health system has the capability to collect and use real-world evidence, which is essential for rare disease research and regulatory decision-making.

#### **c. Enhance global competitiveness**

- Position Ireland as a location of choice for early-phase and rare disease clinical trials.
- Promote Ireland as a leader in advanced manufacturing, personalised medicine, and ATMP production.
- Build internationally attractive frameworks for data governance, interoperability, and ethical AI use.
- Prioritise robust data governance and interoperability to attract data-driven research and international partnerships.

#### **d. Improve patient outcomes**

- Guarantee timely and equitable access to diagnostic technologies, innovative treatments, and cross-border specialist care.
- Ensure that all people with rare diseases have a coordinated care pathway aligned with the structures of the European Reference Networks.
- Strengthen integration between health and social care to support quality of life.

#### **e. Develop talent and skills**

- Expand genomics, bioinformatics, AI literacy and translational medicine training for clinicians, allied healthcare professionals, researchers, regulators and patient advocates.
- Create education programmes for the development, adoption and manufacturing of ATMPs.
- Invest in patient organisation capacity building to enable meaningful involvement in research and policy.
- Support pathways to attract global expertise while nurturing domestic talent.

#### f. Promote sustainability

- Encourage sustainable biopharma and medtech manufacturing.
  - Build resilient supply chains for orphan medicines, diagnostics, and specialist technologies to protect patient access.
  - Use digital and personalised medicine tools to reduce inefficiencies and improve long-term health outcomes.
- 

### 3. Opportunities and Challenges for the Next Decade

#### Key Opportunities

- **Stronger clinician-industry-patient collaborations** to drive research that addresses the unmet medical needs of those with lived experience, to accelerate innovation and improve real-world outcomes.
- **Rapid expansion of genomics** and the ability to diagnose rare diseases earlier and more accurately.
- **Growth of ATMPs**, where rare diseases are often the first indication, offering Ireland a chance to become an early European leader in manufacturing, clinical delivery, and regulatory innovation.
- **New European collaborations**, including the European Reference Networks (ERNs) and the European Rare Disease Research Alliance (ERDERA) that can strengthen Ireland's capacity for high-impact research.
- **Digital transformation** that supports remote monitoring, AI-enabled diagnostics, and integrated care.
- **Real-world evidence ecosystems** that enable faster patient access and support Europe-wide research networks.

#### Key Challenges

- **Fragmented data systems** and inconsistent interoperability within the health service.
- **Workforce shortages** that limit clinical research capacity and adoption of new technologies.
- **Slow access pathways** that delay the introduction of innovations and discourage international investment.
- **Infrastructure gaps**, including limited genomic sequencing capacity and insufficient specialised facilities for ATMP delivery.
- **Sustainability pressures**, particularly for rare disease therapies that are costly and complex.

- **Public trust** must be maintained through transparency, robust data protection, and meaningful patient involvement

These challenges require coordinated national planning and investment, not sector-by-sector policy development.

---

#### 4. Ireland's Response to the EU Life Sciences Strategy

Ireland must be proactive in shaping and implementing the EU Life Sciences Strategy, ensuring that the needs of rare disease patients and small Member States are reflected. We recommend that Ireland:

- **Champion patient-centred regulation and innovation**, advocating for EU policies that accelerate access to safe and effective technologies.
- **Champion the full deployment of European Reference Networks**, supporting cross-border virtual care, data sharing, and knowledge exchange.
- **Actively participate in the European Rare Disease Research Alliance** and successor programmes, ensuring Irish involvement in large-scale EU research infrastructures.
- **Support rapid implementation of the European Health Data Space**, while ensuring strong protections for patients and transparent governance.
- **Align national regulation and reimbursement processes** with EU efforts to accelerate access to innovative therapies.
- **Advocate for equitable access to ATMPs and orphan medicines** across Europe, including introduction of an Early Access Program in Ireland to bring innovative new therapies and tools into use in the Irish healthcare system within one year of regulatory approval.

Ireland should use its strong biopharma, medtech digital and data footprint to help shape EU policy while also ensuring that EU initiatives are effectively implemented at home.

---

#### Conclusion

The National Life Sciences Strategy represents a pivotal opportunity to redefine Ireland's role in global health and innovation. Rare disease patients, families, researchers and innovators have long been pioneers in genomics, personalised medicine, and advanced therapies. They can—and should—be at the forefront of Ireland's strategic vision.

By embedding patient partnership, transforming the health service into an innovation engine, and positioning rare diseases as catalysts for scientific and technological



progress, Ireland can create a life sciences ecosystem that delivers genuine transformation for patients while driving national and European competitiveness and addressing global demand for better care for the 300-400 million people living with rare diseases.

Rare Diseases Ireland stands ready to support the Department in advancing this vision.

Thank you for considering our submission.

Kindest regards

A handwritten signature in black ink, appearing to read "Vicky McKeown", written over a horizontal line.

CEO

## **National Life Sciences Strategy Consultation**

FutureNeuro Research Ireland Centre for Translational Brain Science

### **Scope**

The scope of the National Life Sciences Strategy should be broad and inclusive, covering all sectors in which life sciences play a significant role. It should also closely align with the scope defined in the EU Life Sciences Strategy, which encompasses applications in health (such as medicines, diagnostics, and medical devices), food biotechnology and production, agriculture and fisheries, environmental science, and wider biotechnological fields.

### **Objectives**

A National Life Sciences Strategy should aim to strengthen Ireland's global competitiveness and ensure that the country remains a leading location for life sciences research, development and manufacturing both within the EU and beyond. This involves maintaining an attractive environment for investment, enabling cutting-edge research, supporting world-class infrastructure, and positioning Ireland at the forefront of emerging fields such as advanced therapeutics and digital health.

The strategy should also aim to accelerate life sciences research and innovation by building a strong pipeline from discovery through to commercialisation. This means supporting early-stage, high-risk research, creating sustainable and attractive research careers, and giving Irish start-ups the support they need to emerge, scale and compete globally. It also requires strengthening Ireland's capacity for translation so that scientific discoveries can move efficiently from the lab into real-world products, therapies and technologies.

Another key objective for the strategy should be to deepen collaboration between academia, industry and the healthcare system. Effective partnership across these sectors is essential to unlocking innovation, enabling shared infrastructure, and accelerating pathways from research to patient benefit.

Developing, attracting and retaining high-quality talent should also be a central priority. The strategy should ensure that Ireland's talent pipeline keeps pace with the sector's future needs. This includes investing in education and upskilling and ensuring policies support the retention of skilled workers and the attraction of international expertise.

Finally, the strategy must embed patient needs and health outcomes at its core. Life sciences innovation should be aligned with what matters to patients and the public, with active patient and public involvement informing research priorities, product development and national policy decisions. This will ensure that Ireland's life sciences sector delivers tangible benefits for society while fostering a culture of trust, relevance and real-world impact.

## **Opportunities and challenges**

A key challenge for Ireland's life sciences sector is our existing research ethics and governance ecosystem. This was designed for single-site, study-specific research and is not aligned with the needs of modern collaborative, multi-site research. To illustrate - the current Irish ecosystem limits the development of large, longitudinal, and multi-site biobanks (which are a key resource for health research) and restricts the creation of scalable infrastructures needed for research. To build an internationally competitive and sustainable biobanking ecosystem, system-wide regulatory reform is required. Four key regulatory changes are proposed, which could be included as part of a National Life Sciences Strategy Action Plan to strengthen Ireland's position as a global leader in life sciences:

- Legislate a National Research Ethics Committee (REC) for Biobanking
- Permit "consent to governance" through RECs
- Remove the explicit-consent requirement in the Health Research Regulations (HRRs)
- Create a pathway for integrating legacy cohorts into biobanks

These changes strongly align with the EU Life Sciences Strategy, which specifically references the importance of improving the quality, accessibility, interoperability and sustainability of biodata resources. The strategy also emphasises that stronger multilateral international collaboration is needed with like-minded partners to secure long-term access to and stewardship of global biodata resources. Reform of Ireland's research ethics system will ensure that Ireland is one of these like-minded partners who can participate in and lead important EU-wide life sciences initiatives.

### Current challenges

The current research ethics ecosystem in Ireland has largely evolved around the governance of single-site studies and this legacy shapes how biobanks operate today. As a result, the system is well suited to relatively small, localised biobanks, but it does not readily accommodate the larger, longitudinal, or multi-site infrastructures required for contemporary biobanking and associated data-driven research (including genomics and proteomics). The Health Research Regulations (HRRs) compound these challenges: the requirement for explicit consent from participants becomes difficult to operationalise for broad, prospective biobanks, and the need for ethics approval for each new application to use biobank data creates a significant administrative burden. In practice, this slows access, limits data use, diminishes the value that biobanks can deliver, and also limits the ability of biobanks to ensure that its data is FAIR (Findable, Accessible, Interoperable, and Reusable).

The lack of a dedicated regulatory framework for biobanking means that there is no clear governance framework to facilitate scalable, forward-looking, and sustainable sample and data collections. Without regulation that recognises biobanking as a distinct activity with long-term research value, the current regulatory system in Ireland is restricting the scale and potential impact

of biobanking efforts and Ireland's ability to compete internationally. This creates a particular challenge for early-career researchers on short-term contracts, who must invest considerable time navigating protracted ethics and governance approvals, diverting limited research resources, delaying productivity, and placing Irish researchers at a competitive disadvantage internationally. This is particularly important in the context of ensuring that Ireland meets its ambitious drawdown targets for Horizon Europe and its successor. There are a large number of European funding opportunities for life sciences, however, ensuring timely access to data is critical if Irish researchers are to successfully apply for these opportunities and maximise Ireland's success in securing funding.

#### Opportunities for reform

We advocate for system-wide reform of Ireland's regulatory framework for biobanking and health research to be included as a priority in the National Life Sciences Strategy. There are four specific areas that we see as requiring regulatory change:

##### 1. Legislation enabling the establishment of a NREC for biobanks

Biobanks operate as long-term, infrastructure-level resources that support multiple research projects over time. A statutory NREC for multisite biobanking would provide a uniform review with expertise tailored to the specific ethical, legal, and operational issues inherent in biobanks. Legislation is necessary to give such a committee a clear mandate, legal authority, and defined responsibilities, ensuring it can operate consistently and independently. It would enable streamlined, national-level ethical approval for biobanks, reducing duplication, supporting harmonised consent and governance practices, and ensuring compliance with the HRRs, data protection law, and international best practice. Importantly, a legislated NREC for biobanks would create an enabling environment for the development of scalable, sustainable biobanking infrastructures, strengthening Ireland's capacity to participate in international initiatives and to support cutting-edge genomics and data-driven health research. This aligns with the HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees, the overall goal of which is to simplify and standardise the REC approval process, making it more efficient for researchers. Six new HSE Reference RECs will be established, aligned with the Sláintecare Regional Health Area, to handle research applications within their specific regions. While the ultimate goal should be to establish a NREC for biobanks (in a similar manner to the REC for the National Irish Covid Biobank), an interim measure could be to permit these regional RECs to approve biobanking applications in their region.

##### 2. Empowering RECs to permit "consent to governance"

To support a modern biobanking ecosystem in Ireland, we advocate the introduction for "consent to governance". This is an approach in which participants consent to the collection, storage, and ethically governed future use of their samples and data. In Finland, the Biobank Act enables samples and associated data to be used for future research without seeking fresh consent for each

new project, provided that the individual has given biobank consent, and the biobank complies with statutory governance requirements, transparency obligations, and ethical oversight. In the UK, under the Human Tissue Authority (HTA) Codes of Practice (Code E: Research). RECs can grant “generic approval” that covers future research uses falling within the scope of the original biobank approval, eliminating the need for researchers to return for subsequent ethics approval for each subsequent use of data.

Under such a system, a REC would provide approval for the collection, storage and ongoing use of samples for research, or typologies of research, subject to appropriate oversight and safeguards. These safeguards could include transparency requirements (i.e., that participants are informed about the purpose for which their samples and data have been used) and independent oversight (i.e., future use is subject to Data Access Committee (DAC) approval, similar to UK Biobank Access Committee).

This model shifts the burden from repeated project-by-project approvals (by a REC) to a system grounded in robust, transparent, and accountable governance structures. It ensures that future access and secondary use proceed under predefined rules, oversight mechanisms, and data protection safeguards, rather than requiring new REC submissions each time samples or data are used.

Empowering Irish RECs to permit consent to governance would reduce duplication within the research ethics eco-system, and enable the development of scalable, high-impact biobanks with much faster times from study application to data analysis and associated impact.

### 3. Removal of explicit consent under the HRRs

The success of any reform of Ireland’s biobanking ecosystem is contingent on removing the requirement for explicit consent under the HRRs. To be clear, we are not advocating for the removal of consent. Informed consent continues to be a requirement fundamental for the ethical conduct of research.<sup>1</sup> What we are advocating for is the removal of explicit consent as a legislatively required safeguard. Informed consent would continue to be required, but more broader forms of consent, subject to other safeguards, would be permitted. Importantly, under this revised system, a REC would still have the authority to require specific, explicit consent in contexts where the nature of the research, the sensitivity of the data, or participant expectations justify it.

Biobanks are designed as long-term research infrastructures that support multiple, evolving research projects over many years, most of which cannot be fully defined at the time of sample or data collection. Explicit consent, tied to a specific study purpose, works well for discrete research projects but becomes impractical for broad, prospective biobanking and for integrating legacy

---

<sup>1</sup> 1 Informed consent in research is an ethical commitment to respect participant autonomy in deciding whether to take part in a study, whereas consent as a safeguard under the GDPR is a protective measure used to legitimise the processing of special-category data but does not itself determine whether the research may ethically proceed.

cohorts. Requiring new explicit consent, or repeated Health Research Consent Declaration Committee (HRCDC) consent declarations (see section 4 below), each time a biobank resource is used creates operational bottlenecks, risks biasing collections by excluding participants who cannot be recontacted, and fundamentally undermines the purpose of biobanking as a future-oriented resource. While dynamic consent has emerged as a mechanism to support re-consent and ongoing participant engagement, it has only been implemented in limited contexts, it is unknown if it is viable as a large-scale national solution, and requires considerable resources and dedicated project staff.

There are also limitations of consent as a safeguard. Research consistently shows that participants often do not fully understand key aspects of the studies they consent to, raising concerns about how truly “informed” consent can be in practice. It is for this reason that many jurisdictions rely on other safeguards that include strong governance frameworks, transparent access procedures, statutory oversight, and participant rights to ensure ethical and responsible use of biobank resources. These mechanisms provide more consistent and meaningful protection for participants than repeated explicit consent, which often becomes impractical, unworkable, and arguably, ethically counterproductive.

#### 4. Regulatory process for inclusion of legacy cohorts in biobanks

By legacy cohorts here, we are referring to collections of tissue that are already in existence in Ireland. This includes, archived human tissue in pathology departments, samples left over from research, and biobanks where participants previously provided their consent to the use of their samples in research.

Currently, if consent cannot be obtained, legacy cohorts require a consent declaration if they are to be included in a consent declaration from the HRCDC. A consent declaration, however, can only be given to the collection and storage of the legacy sample and data into the new biobank. Any subsequent use of the data will require a consent declaration for each subsequent research project. While the consent declaration process is appropriate for discrete studies, it is ill-suited to biobanking, where the purpose is to create long-term, reusable research infrastructure. As biobanks are often established to ensure ease of access to samples and data for research, it is unlikely that legacy cohorts will be included if subsequent use is subject to an additional consent declaration.

A dedicated regulatory pathway is therefore required to allow legacy collections to be incorporated into biobanks through a single, proportionate approval process, supported by robust governance, data protection safeguards, and oversight mechanisms. Such a process would respect participant rights while acknowledging the scientific and public value of optimising existing collections. By enabling streamlined inclusion of legacy cohorts, Ireland could unlock the research potential of these samples, reduce the need to collect new samples, and enhance the scale, diversity, and impact of its biobanking ecosystem.

### Additional opportunities

The lack of a comprehensive ethical framework specific to biobanking in Ireland was also highlighted in a recent report from the University of Galway, which charts the path for Ireland to join BBMRI-ERIC, a pan-European infrastructure of national biobank networks (*A roadmap towards Ireland's membership of BBMRI-ERIC*, doi: 10.12688/hrbopenres.14089.2). BBMRI-ERIC currently includes 23 countries (including almost 500 biobanks), making it one of Europe's largest research infrastructures. We propose that membership of BBMRI-ERIC should also be included as a priority in the National Life Sciences Strategy. As noted in the aforementioned report, membership of BBMRI-ERIC would connect Ireland with a vast collaborative network of partners and EU initiatives, as well as providing support on ethical, legal and societal issues and quality management. In addition to the proposed regulatory reforms, this membership would help to position Ireland as a leader in life sciences.

### **EU context**

The goal for the EU to become the world's most attractive location for life sciences by 2030 is undeniably ambitious, but it is encouraging to see the importance of the sector recognised at an EU level. It is essential that Ireland matches this ambition and strongly aligns itself with the EU Life Sciences Strategy.

A central measure in the strategy for optimising the research and innovation ecosystem is the strengthening of cooperation and the more efficient use of resources. In particular, the strategy highlights the critical role of biobank data in advancing research and innovation. It notes that the Commission is already supporting the Genome of Europe project—a pan-European initiative to build a reference genomic database of 100,000 genomes from diverse European citizens to accelerate personalised medicine.

The strategy also recognises that scientific progress depends on improving the quality, accessibility, interoperability, and long-term sustainability of biodata resources. For Ireland to align with this EU strategy and develop biobanks that are fit to drive Irish research, there is a need for regulatory change. We propose that the National Life Sciences Strategy should include as a priority the development of national legislation that would provide for a NREC for biobanking; permit consent to governance; remove the requirement of explicit consent as a safeguard to enable more broader forms of consent; and a regulatory pathway for the inclusion of legacy cohorts into biobanks. The revision of the HRRs is an important part of this process, but it is only one component of the broader regulatory transformation needed to support scalable, sustainable, and internationally competitive biobanking. It is by rebalancing the system toward governance-based oversight, while maintaining consent as an ethical foundation, that Ireland can build a biobanking framework that is ethical, sustainable, and future-ready.

Importantly, the EU strategy also emphasises the need for stronger multilateral collaboration with like-minded partners to ensure secure and responsible access to global biodata resources. The

Commission proposes to establish a European Life Sciences R&I Data Assembly to support consistent interpretation and harmonisation of relevant legal data frameworks and to strengthen cross-regulatory coordination and collaboration. Ireland should position itself not only as a participant in these efforts but as a leader in shaping best-practice approaches to biodata stewardship and research governance.

The EU strategy also more broadly references the importance of assessing current regulatory procedures in order to make them more agile, more proportionate, and more efficient, to make the EU an attractive location for life sciences research and investment. It emphasises that regulatory systems need to be responsive to emerging technologies and keep pace with scientific progress. While much of this is framed in the context of regulatory pathways for novel products, it is equally relevant to the research environment itself. For Ireland, creating a regulatory framework for biobanking and health research that can evolve alongside scientific and technological progress will be vital to sustaining its competitiveness in the global life sciences sector.



# SSPC

Research Ireland Centre for Pharmaceuticals

**National Life Sciences Strategy Submission  
to the Department of Enterprise, Tourism  
and Employment Consultation**

**December 2025**



HOST INSTITUTION



PARTNER INSTITUTIONS



**Table of Contents**

1 Executive Summary..... 1

2 Scope & The "Innovation Engine"..... 2

3 Strategic Operational Model ..... 3

4 Pillars of National Impact ..... 3

5 Objectives..... 5

6 Opportunities and Challenges ..... 6

7 Ireland's Strategic Agenda (EU Context)..... 7

8 Conclusion ..... 7

## 1 **Executive Summary**

SSPC, the Research Ireland Centre for Pharmaceuticals welcomes the development of a new National Life Sciences Strategy (NLSS). A fit for purpose NLSS should be viewed as critical national imperative to sustain a vital pillar of the Irish economy.

As a national hub uniting 80+ leading researchers across 10 Research Performing Organisations (RPOs), SSPC is positioned at the interface of state investment, research excellence and global industry. This "Triple Helix"—uniting policymakers, researchers, and industry leaders—is Ireland's unique selling point. It creates a cohesive ecosystem where rapid collaboration and decision-making provide a competitive edge that larger, fragmented jurisdictions cannot match.

Ireland stands at a definitive inflection point. Over seven decades, we have evolved from a manufacturing operator to a strategic leader—a location of choice for the launch and scale-up of complex medicines, employing over 50,000 people and generating €100 billion+ in annual exports. We are now recognised globally not just for making medicines, but for our leadership in the sciences underpinning Process Development—solving the complex problem of *how* tomorrow's medicines are manufactured. Driven by a deep national skills base, this capability is the key to co-locating R&D alongside advanced manufacturing, transforming Irish sites from satellite plants into strategic innovation hubs where 'Process IP' anchors the operation and underpins the economic value of production.

The global (bio)pharmaceutical sector faces "step-change technical complexities" in translating breakthroughs (chemical, biological, device-led & technical (e.g. process, data)) into effective medicines. This disruption presents a significant opportunity for nations willing to invest in the advanced scientific ecosystem required to support this evolution.

To secure our economic future, the NLSS must ensure Ireland does not regress. The risk is not merely standing still; it is a "roll-back" where Ireland slides from a Strategic Partner (designing the processes for the future of medicine) back to an Operational Executor (simply manufacturing medicines designed elsewhere).

The NLSS goal must be to enhance Ireland's status as a "World-Leading Innovator and Thought Leader." This strategic pivot is essential to ensure we possess the advanced capabilities necessary to anchor this high-value sector (FDI & indigenous). By integrating high-value process R&D with advanced manufacturing, we create a defensive moat, making Irish operations indispensable against intensifying global competition. In an era of regionalisation and protectionism, "making things" is no longer enough to guarantee economic security. The State must deliver a vehicle capable of harnessing the ecosystem's potential to deliver this transition.

Our submission argues that the Strategy's core mission must be to position Ireland as a global leader in the capabilities underpinning the development and sustainable manufacturing of advanced medicines and health solutions. This mission must encompass the full spectrum of therapeutic interventions, ensuring that all medicines and devices can be produced to best in class levels, enabling maximum patient benefit.

To achieve this, we advocate for a Strategic Innovation Framework driven by three core pillars that define a unique "**Irish Model**" of sector resilience:

- **Human Capital Security:** The primary constraint on future growth is not capital, but the availability of highly specialised skillsets in sufficient quantities. Key amongst this is the development of a robust, multidisciplinary Level 10 (PhD) talent pipeline capable of navigating the convergence of chemistry, biology, data, and engineering to deliver the critical manufacturing sciences that underpin global competitiveness.
- **Delivering Health Security:** We must elevate Ireland from a product supplier to a strategic provider of critical health solutions. By ensuring the capability to develop and manufacture the full spectrum of future medicines and therapeutic interventions (e.g. next-generation small molecules, complex biologics, RNAs, ADCs, ATMPs, combination devices and digital health solutions), we ensure our national output remains essential critical infrastructure for global healthcare.
- **Green Industrial Leadership:** Establishing Ireland as the global benchmark for scientifically driven green manufacturing. This requires us to lead research into the complex science and engineering topics required to not only decarbonise production, but to solve acute global sustainability challenges such as industrial water intensity, supply chain circularity, and the elimination of 'forever chemicals' (PFAS). This transforms sustainability from a regulatory burden into a competitive shield, protecting the sector against future compliance and supply chain shocks.

## 2 Scope & The "Innovation Engine"

*In your view, how broad should the scope of the strategy be?*

SSPC advises broadening the scope encompass the full "**Molecule-to-Medicine**" value chain, including the convergence of medicines, devices and diagnostics. The strategy should focus on building **five National Strategic Capabilities**:

- **Next-Generation Talent Pipeline:** Human capital is a strategic capability, not just a resource. The scope must include the developing a "high-end" talent base—PhD-level multidisciplinary scientists and engineers—to act as technical anchor points across discovery, development and advanced manufacturing. *As complexity increases, the ability to solve novel problems becomes the primary driver of competitiveness.*
  - Exemplar: SSPC has developed 400+ highly skilled alumni; 70% remain employed in Ireland. 211 of these researchers came from 24 countries, and 57% remain here, turning global talent into a national asset.
- **Manufacturing Sovereignty (The Translation Gap):** Discovery is advancing rapidly (Genomics, AI), but the ability to *develop and supply* these complex new modalities is a global bottleneck. For example, RNA therapeutic adoption is limited by supply chain and stability challenges. The strategy must secure Ireland's ability to master the *science of manufacturing* for the full range of medicines and devices. The barrier to patient access is no longer just discovery; it is the *technical feasibility of development and production*.
- **Intelligent Drug Product Design:** We must champion the complex scientific journey of developing discoveries into effective medicines and therapeutic interventions. By securing capabilities in Formulation, Delivery, and Connected Devices, Ireland can solve the "how to

deliver it" challenge, ensuring new modalities are stable, effective, compliant with new regulations (e.g., MDR/IVDR), and patient-ready.

- **Digital Competitiveness (Intelligent Systems Design):** To address digital obsolescence, we need a Digital & AI-native workforce capable of deploying "Pharma 5.0" technologies. This involves moving beyond basic automation to advanced concepts like "data genealogy", converting static operational data into actionable intelligence. This requires a national commitment to skills, high-performance computing, and robust data governance.
- **Sustainable Industrial Competitiveness (Safe & Sustainable by Design):** We must redesign the national advanced manufacturing base as the global benchmark for resource efficiency. By championing the EU's "Safe and Sustainable by Design" framework, Ireland can pivot from simple compliance to leadership. This allows us to solve the acute "Scope 3" emissions challenge for global multinationals, positioning Ireland as the global testbed for green low-carbon pharmaceutical development and production.

### 3 **Strategic Operational Model**

*How should the strategy be delivered?*

- **Talent Permeability:** We need an operational model encouraging encourages the seamless flow of people between academia, regulators and industry. Programmes allowing talent to migrate across the ecosystem accelerates knowledge transfer and connectivity.
- **Collaboration as a National Asset:** The strategy must leverage the full ecosystem: Research Community (SSPC, NIBRT & Universities), Societal Partners, Industry (MNCs, Indigenous & BPCI), Regulators (HPRA), and Patient Representatives (IPPOSI). We must utilise cost positive platforms for multidisciplinary engagement to maintain the "Triple Helix" advantage.
- **A Spectrum of Funding:** A thriving research environment requires a balanced support. The NLSS should advocate for sustained funding for large-scale, mission-focused Centres (tackling broad industry challenges) *and* curiosity-driven, investigator-led research (seeding future breakthroughs). These approaches are profoundly complementary, not competitive.
- **Agility & Responsiveness:** To remain competitive, the national funding model must be dynamic. The NLSS should support a model retaining significant budget for flexible competitive calls to fund new, integrative "linker" projects. This bridges research themes and ensures rapid respond to emerging geopolitical or technological opportunities.
- **Optimised Support Structures:** Supports must be well-resourced, accessible, stable and cost positive. Accessing state expertise, infrastructure, or funding should be a seamless, value-adding experience that accelerates innovation rather than adding administrative friction.

### 4 **Pillars of National Impact**

*What impact will this strategy deliver?*

#### **A. Pillar 1 Global Research Excellence:**

We cannot translate what we have not discovered. To move up the value chain, Ireland must be a *producer* of new knowledge, not just a consumer. The Strategy must prioritise maintaining a

critical mass of internationally recognised investigators capable of tackling the "step-change technical complexities" of future medicines.

- **The Magnet Effect** - Excellence attracts excellence. A world-class research environment is the primary magnet for high-calibre global talent and competitive international funding (e.g. ERC). Degradation in scientific quality would immediately erode the national value proposition.

#### **B. Pillar 2 FDI Stickiness & Co-Location**

Ireland has successfully moved beyond "manufacturing only" to become a hub for development and launch. The strategy must reinforce this by anchoring R&D alongside manufacturing. Co-locating process development, launch, and manufacturing eliminates fragile tech-transfer steps, making Irish sites indispensable nodes in global networks:

- **Speed & Risk Reduction:** Co-location eliminates the "tech transfer" gap, accelerating time-to-market and reducing failure risk.
- **The "Living Lab" Effect:** Manufacturing data feeds back immediately into R&D (via Manufacturing Science and Technology teams), driving continuous process innovation.
- **Strategic "Stickiness":** By holding the *process* knowledge and R&D capability, Irish sites become indispensable to the parent company, rather than interchangeable capacity.

#### **C. Pillar 3 Building a Globally Competitive Indigenous Sector**

We must provide easily accessible funding, expertise and infrastructure to drive innovation across all company sizes, strengthening the dual economy model.

- **Access to Deep Technical Expertise:** Modern medicine development requires niche technical knowledge (e.g. advanced material characterisation) often too expensive for start-ups. We must enable indigenous SMEs to tap into the research community's "brain trust", effectively enabling accessing a fractional R&D department.
- **The "Anchor Tenant" Ecosystem:** We should leverage global multinationals to nurture indigenous start-ups. Incentivising MNCs to partner with, mentor, and procure from local technology providers creates a symbiotic ecosystem.
  - Exemplar: Providing a high-calibre talent pipeline is vital to indigenous success stories like APC/VLE, an Irish company founded by SSPC Alumni which is currently investing over €100 million and will create an additional 300 high-tech jobs

#### **D. Pillar 4 Commercialisation as a Culture:**

Government investment is a catalyst for economic growth, not a subsidy. While Enterprise Ireland supports established start-ups, the NLSS must target the pre-commercialisation "valley of death" unique to life sciences, where longer maturation times and higher capital levels are required.

- The **NLSS should advocate for sector-specific bridging mechanisms** (e.g., Pre-Seed Deep Tech funds, Regulatory-aware mentorship) to de-risk academic research before it enters the Enterprise Ireland pipeline.

## 5 Objectives

*What should be the key objectives of the National Life Sciences Strategy?*

SSPC proposes three core objectives long-term resilience:

### A. Talent & Capability Security

The highly specialised skills needed to discover and develop medicines are critical infrastructure for national health security.

- **The European Warning:** A 2024 EU Commission report shows STEM graduates declining across Europe. Ireland holds a fragile lead (highest number of STEM graduates per capita in the 20-29 age group) built on past investment. We must act decisively to maintain it.
- **Protect and Incentivise the National Skills Base:** The NLSS must treat Ireland's talent pool as a strategic asset. We recommend a comprehensive strategy that incentivises upskilling across the *entire* workforce. While operational talent remains robust, there is a distinct imbalance in the supply of high-level research talent required to drive future innovation.
- **Attract the Best Global Talent:** We must actively facilitate attracting top global talent to augment this plan. This requires streamlined immigration pathways and competitive research environments to attract world-class Principal Investigators and global talent.
- **Benchmarked Funding:** The research ecosystem must be benchmark-funded against international competitors to prevent a capability gap.

### B. Global Leadership in "Safe and Sustainable by Design"

Ireland must champion a balanced, innovation-led green transition, ensuring environmental ambition does not inadvertently undermine competitiveness.

- **Strategic Pragmatism:** Adopt a risk-based approach to environmental policy (e.g., explicit derogations for essential use of critical chemicals) to protect Ireland's manufacturing autonomy. A critical exemplar is the proposed restriction of PFAS ("forever chemicals"); Ireland must ensure that essential uses in pharmaceutical manufacturing and medical devices are protected to maintain supply chain security. Crucially, this regulatory protection serves as a bridge, not a destination. It must be matched by a commitment to create the 'underpinning science' for green alternatives, fulfilling the 'Green Industrial Leadership' mandate established in our Executive Summary.
- **R&D Solution:** Champion EU-level research funding to accelerate "Safe and Sustainable by Design", positioning Ireland as the testbed for green pharmaceutical development and manufacturing.

### C. Fuel a World-Class R&D Ecosystem & Anchor Innovation

The NLSS should advocate for targeted investment in future-focused R&D to anchor value and IP within the State.

- **The Dual Strategic Benefit:** Global leadership in process development acts as a magnet for FDI seeking technical excellence. Crucially, it also provides the indigenous skill set to

translate discoveries made in Ireland into new medicines, ensuring our national research output navigates the journey from lab to patient.

- **Generating "Sticky" IP:** The global industry is too expensive (>€2B per drug) and too slow. By funding research that solves fundamental efficiency challenges, Ireland can become the primary location for high-value Process Innovation, ensuring that the IP for how medicines are made is generated and anchored here.
- **Infrastructure as an Anchor:** World-class innovation requires world-class tools. The Strategy must advocate for a future-proofed national research infrastructure, supported by a robust capital investment plan to handle the complexity of future therapeutic modalities.

## 6 Opportunities and Challenges

*What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade?*

### A. Challenges: The Fundamental Innovation Shift

The global landscape has shifted; Irish & EU competitiveness is under threat.

- **The People Challenge (Talent Scarcity):** While demand for operational roles remains high, there is an acute global shortage of the high-level scientific and engineering talent required to design and optimise new processes. If we cannot supply the brains, we will lose the plants.
- **The Complexity Cliff (Legacy Obsolescence):** The pipeline has pivoted to "Deep Tech" modalities (e.g. AI-designed drugs) that legacy infrastructure cannot support. Without radical capability upgrades, our existing base risks becoming a "rust belt" of yesterday's medicines.
- **The Innovation Deficit (Strategic Vulnerability):** Europe's share of global pharmaceutical innovation is rapidly contracting due to sustained US and Chinese pressure. We face strategic vulnerability if we remain solely a manufacturer of medicines invented elsewhere.
- **Geopolitical Compression:** Ireland is squeezed between China's state-subsidised R&D ecosystem and aggressive US financial policies (Inflation Reduction Act, BIOSECURE Act). New global trade dynamics are forcing reassessment of long-standing partnerships. We can no longer compete on efficiency alone; we must compete on indispensable capability.

### B. Opportunities for Ireland's Strategic Leadership

Ireland can lead the response to this shift by leveraging its unique assets.

- **The "Atlantic Bridge" (Scaling US Innovation):** With 64% of new medicines originating in the US, Ireland can become the strategic bridge for scaling these innovations into the EMEA market, solving the complex scientific challenges required to make US-invented modalities manufacturable for the EU.
- **The "Green Premium" Advantage:** As global pharma faces aggressive Scope 3 targets, Ireland can win FDI by becoming the world's most resource-efficient and low-carbon location for complex advanced manufacturing. By deploying the scientific capabilities established under our 'Green Industrial Leadership' pillar to drive radical efficiency across the full

resource spectrum—carbon, water, and raw materials—we solve the sector's 'dirty chemistry' and resource intensity challenges and secure the investment.

- **Supply Chain Sovereignty:** As the EU seeks strategic autonomy, Ireland can position itself as the "Safe Harbour" for critical medicine manufacture, the solution to Europe's drug shortage concerns.

## **7 Ireland's Strategic Agenda (EU Context)**

*Views on the EU Life Sciences Strategy and application in the Irish context.*

Ireland must transition from a "rule-taker" to a strategic architect of EU life sciences policy, championing a strong pro-innovation and pro-competitiveness stance. We advise the following agenda:

- **A European STEM & Skills Union:** Ireland should champion an EU-level skills strategy focusing on cross-border training and shared curricula for advanced biopharmaceutical manufacturing, funding for cross-border training and researcher mobility. This ensures the talent pipeline remains robust across the Single Market.
- **Architect the Competitiveness Strategy:** Use the EU Presidency to champion a "Competitiveness Strategy for European Life Sciences." Ireland should lead dialogue on the EU Biotech Act and Critical Medicines Act, framing them as engines for innovation and industrial growth, not just compliance instruments.
- **Champion Regulatory Sandboxes:** To close the gap with the US and China, Ireland must advocate for widespread use of Regulatory Sandboxes at the EMA level, creating regulatory frameworks that evolve as fast as the science and preventing a "slow-to-market" jurisdiction.
- **Industrial Energy Resilience:** Advocate for EU-level support for industrial energy resilience. If the EU demands "Green Manufacturing," it must support the significant CAPEX required to decarbonise complex (bio)pharmaceutical processes, ensuring Europe remains cost-competitive against regions with lower energy standards.

## **8 Conclusion**

The choice is clear: Ireland can fight to remain a Strategic Leader or risk sliding back into the role of a standard manufacturing operator. In an era of manufacturing regionalisation and protectionism, "making things" is no longer enough to guarantee economic security; we must lead the science of how they are made for this vital sector of the Irish economy.

Through the NLSS, as outlined above, the Government can unite the national ecosystem, leverage our unique "Triple Helix" collaboration, and safeguard this vital economic pillar for decades to come.



### **Roche's Response to the Public Consultation on a National Life Sciences Strategy for Ireland**

#### **Executive Summary**

The forthcoming National Life Sciences Strategy represents a pivotal juncture in the industrial and social history of Ireland. For the past four decades, the Irish state has successfully curated an ecosystem defined by manufacturing excellence, attracting a disproportionate share of global Foreign Direct Investment (FDI) in the pharmaceutical and medical technology sectors. However, the strategic landscape is undergoing a fundamental transformation.

The era of the "blockbuster" small molecule, manufactured in isolation and dispensed broadly, is yielding to an era of precision medicine, advanced therapeutics, and integrated digital health solutions. In this new paradigm, the value of a life sciences hub is measured not merely by its capacity to export volume, but by its capacity to generate data, integrate complex diagnostics, and demonstrate patient outcomes.

This submission, drafted from the perspective of a global leader in both pharmaceuticals and diagnostics, posits that Ireland's next phase of growth depends on resolving a critical paradox: the divergence between Ireland's status as a premier global producer of healthcare innovation and its lagging performance as an adopter of that same innovation.

The three core recommendations of this report are as follows:

1. The National Life Sciences Strategy must be focused on Human Health, prioritising the convergence of biology, technology, and data, and transitioning the metrics of success from "jobs created" to "lives improved."
2. To ensure maximum success and commitment, Ireland should establish a National Life Sciences Council—a comprehensive public-private forum based on the model adopted by Denmark. By including all key ecosystem stakeholders, this Council will guarantee a collective, integrated approach to both the strategy's formation and its subsequent delivery.
3. For the strategy to succeed, it must embrace international best practice, specifically by utilising a cross-departmental approach. This model requires equivalent buy-in and dedicated effort from both the Department of Enterprise, Tourism and Employment and the Department of Health ensuring they operate in strategic lockstep to realise the strategy's full potential.

*Date of prep: December 2025 / M-IE-00002323*

## **1. Defining the Scope: The Case for a Human-Centric Life Sciences Strategy**

This welcome consultation poses a fundamental structural question regarding the breadth of the proposed strategy. Specifically, it asks whether the scope should encompass the full spectrum of life sciences, including agriculture, fisheries, and food production, or whether it should be more narrowly defined. Our analysis of the sector's trajectory suggests that a broad scope would be a strategic error.

### **1.1 The Imperative of Specialization**

While the "bio-economy" is a valid conceptual framework that links all biological sciences, the industrial, regulatory, and ethical realities of human healthcare are distinct from those of food production or marine biology. The "Life Sciences" sector, as understood by global capital and innovation markets, is increasingly defined by the convergence of biopharmaceuticals, medical technology (MedTech), and digital health. Including agriculture or food science would dilute the strategy's focus and complicate the governance structures required for implementation.

The primary driver of value in the coming decade will be "Bio-Convergence"—the intersection of biology, data science, and engineering within the human body. The regulatory pathways for human medicines (EMA/HPRA), the reimbursement mechanisms (HSE/NCPE), and the ethical frameworks for human data (GDPR/Health Research Regulations) are bespoke and highly complex. A strategy that attempts to harmonise these with the Department of Agriculture's remit risks becoming a lowest-common-denominator exercise rather than a sharp instrument of industrial policy.

### **1.2 The Triple Helix of Human Health**

Roche recommends that the strategy explicitly defines "Life Sciences" as the ecosystem comprising:

- Biopharmaceuticals: Small molecules, biologics, and Advanced Therapy Medicinal Products (ATMPs).
- Medical Technologies: Devices, diagnostics (IVD), and equipment.
- Digital Health: Health data analytics, digital therapeutics, and AI-driven care pathways.

By restricting the scope to these domains, the government can focus its cross-departmental efforts on the critical axis of the Department of Enterprise,

*Date of prep: December 2025 / M-IE-00002323*

Tourism and Employment, the Department of Health, and the Department of Further and Higher Education.

---

## **2. Strategic Objectives: From Industrial Output to Health Outcomes**

The objectives of the National Life Sciences Strategy must evolve beyond the traditional metrics of industrial policy. Historically, success was measured by manufacturing jobs and export values. While these remain important, they are no longer sufficient to secure high-value R&D functions or to ensure the sustainability of the sector. The strategy must adopt a holistic set of objectives that bridge the gap between industrial policy and health policy.

### **Objective 1: Acceleration of Innovation Uptake**

The single most critical objective for the next decade is to transform Ireland into an Early Launch Market for new medicines and technologies. Currently, Ireland suffers from "the innovation paradox": we manufacture the world's most advanced therapies but are frequently slow to reimburse them for Irish patients. This disconnect poses a reputational risk in boardrooms where investment decisions are made. Global headquarters are increasingly prioritising locations that offer a "living lab" environment— where they can not only manufacture a product but also gain rapid access to real-world data on its usage.

A strategic objective should be to establish Ireland as the fastest place in Europe for patients to access new and effective healthcare solutions, mirroring the ambition and speed of leading EU life science nations. Achieving this requires a fundamental re-engineering of the Health Technology Assessment (HTA) process, shifting from a cost-containment focus to a value-based investment focus.

### **Objective 2: Establish Ireland as a Global Centre of Excellence for Life Sciences R&D and Health Data**

The second critical objective is to cement Ireland's position as a premier global hub for R&D excellence—spanning early-stage discovery, translational research, and late-stage clinical trials. Further in an era where precision medicine is paramount, health data is the "new currency" of innovation; consequently, our strategy must explicitly position a robust, interoperable health data infrastructure as the key

*Date of prep: December 2025 / M-IE-00002323*

enabler of the Life Sciences ecosystem. For global leaders, the decision to locate complex R&D mandates is increasingly driven by a country's data maturity and the ease with which companies can partner with both academic and clinical institutions to accelerate the journey from bench to bedside.

For patients, a data-enabled ecosystem transforms healthcare from a passive experience into an active partnership. It does more than just accelerate the timeline for life-saving interventions; it democratizes health insights, empowering individuals to take ownership of their care journey. This transparency leads to more meaningful dialogue with clinicians and improved treatment adherence—turning data into tangible wellness. And for the health system, this creates a virtuous cycle, generating the real-world evidence necessary to drive sustainable, patient-centered decision-making.

Lastly, cultivating a vibrant, research-intensive ecosystem is the only way to guarantee the development of the next generation of talent. By immersing our students and researchers in a world-class, digitally mature R&D environment, we ensure that Ireland retains the highly skilled workforce necessary to sustain our economic competitiveness and health innovation for decades to come.

### **Objective 3: Fostering Enterprise through Systemic Collaboration & Cohesive Policy**

Our third objective seeks to evolve Ireland's life sciences sector from a premier manufacturing hub into a fully integrated, reciprocal ecosystem where indigenous innovation and multinational companies scale to drive economic resilience and sustainable health solutions. Central to this evolution is the institutionalisation of Public-Private Partnerships (PPPs); we must move beyond ad-hoc pilots to establish permanent national platforms that de-risk collaboration, enabling the State to systematically leverage industrial scale and expertise to solve complex public health challenges.

Parallel to this, we require a "whole-of-government" approach to policy-making that harmonises industrial strategy with health policy to prevent siloed decision-making. We call for a cross-departmental mandate to ensure cohesive national alignment on key EU legislation. This ensures that upcoming legislation underpin a predictable environment where enterprise thrives and patients are the primary beneficiaries of a

*Date of prep: December 2025 / M-IE-00002323*

secure, innovative supply chain.

---

### 3. Opportunities and Challenges: The Strategic Landscape

To deliver on these objectives, the strategy must assess the opportunities available to Ireland and the structural challenges that threaten to impede progress.

#### 3.1 The Opportunities:

| Opportunity Domain      | Description  |
|-------------------------|--|
| The "Sandbox" Potential | Ireland's small size theoretically allows for rapid systemic changes that are more challenging in larger, fragmented systems. Ireland can position itself as the right sized market to be both a "test bed" and scaling environment for population health management solutions.  |
| Tech-Bio Convergence    | Ireland is unique in hosting top-tier clusters of both global pharma/medtech and global big tech (Google, Microsoft, Amazon). This offers a unique opportunity to harness this Intellectual Capital and foster cross-sector collaboration, including in AI and digital-based health technologies .   |
| Clinical Trials         | Ireland is well-positioned to revitalise its clinical research environment by fully embracing the recent recommendations of the National Clinical Trials Oversight Group. Implementing these recommendations—specifically regarding governance, speed, and efficiency—is essential to restoring Ireland's competitiveness as a premier global location for clinical trials |

*Date of prep: December 2025 / M-IE-00002323*

|  |   |
|--|---|
| <p>Embracing the European Health Data Space (EHDS)</p> | <p>Ireland has a significant opportunity to lead in the adoption of the European Health Data Space. By proactively aligning with this initiative, the sector can unlock the value of health data for secondary use, fostering a data-rich environment that accelerates research, enhances cross-border interoperability, and attracts data-driven R&amp;D investment.</p>   |
| <p>Scaling Successful Research Frameworks</p>          | <p>Ireland has a specific opportunity to "lean into" what is already working. By embracing and scaling existing, successful public-private research frameworks, the sector can deepen collaboration between academia, the health system, and industry. Applying these proven models will ensure a higher return on investment, ensuring that foundational scientific discoveries demonstrate real impact and translate effectively into commercial and health outcomes.</p> |

### 3.2 The Challenges:

Despite the opportunities, significant headwinds exist.

| Challenge              | Core Issue  | Key Impact/Consequence   |
|------------------------|---|--|
| <p>The "Data Void"</p> | <p>Lack of a unified Electronic Health Record (EHR) and unique patient identifier. Data is siloed in paper or incompatible legacy</p> | <p>Hinders connectivity and scale-up, and the delivery of timely, patient-centered care. Major deterrent for R&amp;D investment due to inability to extract data for</p> |

Date of prep: December 2025 / M-IE-00002323

|  |  |  |
|--|--|--|
|  | systems.   | secondary use.   |
| Market Access and Reimbursement Delays           | The reimbursement process is slow, unpredictable, and overly focused on immediate budget impact.                                 | Delays access to new treatments and technologies. It overlooks the long-term value these innovations provide.  |
| Comparative Lack of Government Investment in R&D | Government investment in life sciences R&D (GBARD) and indigenous research intensity are significantly below competitor nations. | While private sector R&D (BERD) has been successfully attracted via MNCs, the overall national research base remains weak relative to international standards. |

---

#### 4.0 The European Union Context:

Ireland's National Life Sciences Strategy cannot be developed in a vacuum. It must be strategically aligned with the ambitious agenda being pursued at the European level. The EU's vision for the sector provides a powerful framework and a significant tailwind for Ireland's own efforts, creating opportunities for collaboration, funding, and shared leadership.

##### 4.1 Leveraging the EU Strategy for European Life Sciences

The European Commission's recently published *Strategy for European Life Sciences* sets a clear and bold ambition: to make the EU the world's most attractive location for

*Date of prep: December 2025 / M-IE-00002323*

the sector by 2030. This initiative is designed to address declining competitiveness and create a coordinated, single-market approach to innovation. The EU strategy is built on three key pillars that resonate strongly with the objectives Ireland must pursue:

- **Optimising the research and innovation (R&I) ecosystem:** This includes strengthening support for multi-country clinical trials and leveraging AI and data to advance scientific discovery.
- **Enabling rapid market access for innovations:** This focuses on creating a more innovation-friendly regulatory framework through initiatives like the proposed EU Biotech Act and revisions to pharmaceutical legislation.
- **Boosting trust, uptake, and use of innovation:** This pillar aims to build public confidence and ensure that the benefits of new technologies are realized across society.

The proposed strategic objectives detailed above are in strong alignment with these European pillars. By framing its national strategy as a key contributor to the EU's overall ambition, Ireland can position itself as a leader and early mover, leveraging EU initiatives to support its domestic goals.

In addition, the EU Strategy is establishing a Life Science Coordination Group to ensure EU action is aligned with stakeholder priorities. This body is modeled on the successful Danish Life Science Council, a high-level public-private forum that plays a central role in both the development and implementation of Denmark's national life sciences strategy. To influence and align with this new European mechanism, Ireland should embrace this model nationally establishing a similar Irish Life Sciences Council.

Further, we note that the EU Life Science Strategy seeks to optimise the Research & Innovation Ecosystem via Multi-Country Trials. For a small member state, this has significant potential. It would allow Ireland to form "clinical trial clusters" with other EU nations, aggregating patient populations to achieve the scale required by global industry leaders.

#### **4.2 Securing Strategic Advantage: The imperative of launching the National Life Sciences Strategy before Ireland holds the EU Presidency in 2026**

A unique and time-sensitive opportunity is presented by Ireland's upcoming

*Date of prep: December 2025 / M-IE-00002323*

Presidency of the Council of the European Union in the second half of 2026. This role will place Ireland at the center of EU policymaking and provide an unparalleled platform to showcase its strategic priorities.

Launching a robust and ambitious National Life Sciences Strategy *before* the presidency begins would be a powerful statement of intent. It would demonstrate Ireland's commitment to innovation and leadership, allowing the country to champion the life sciences agenda on a European stage from a position of strength and credibility. This proactive timing would underscore Ireland's dedication to progress and ensure that its vision for a fully integrated life sciences ecosystem contributes to shaping the future of the sector across the Union.

---

## **8. Conclusion: The Roche Recommendations**

This submission outlines a comprehensive and ambitious roadmap for the Irish life sciences sector. It identifies that the future lies in the integration of industrial capability with healthcare delivery. Roche fully endorses the vision of a world-leading hub that secures prosperity and builds a healthier Ireland.

Roche recommends that the Department of Enterprise, Tourism and Employment:

1. **Develop a strategy centred on Human Health:** The Strategy should be directed at Human Health Life Sciences to ensure focus and maximum impact.
2. **Establish a Life Sciences Council:** Establish the Life Sciences Council as a high-level public-private forum for the Strategy's implementation (not just development).
3. **Embrace a Cross-Departmental, Co-Led Approach:** Adopt a co-led model between the Department of Enterprise, Tourism and Employment and Department of Health to ensure strategic alignment and dedicated focus.
4. **Prioritize the Digitalisation of Healthcare and the implementation of the European Health Data Space** as the primary enablers of future competitiveness.
5. **Commit to Innovation Uptake targets**, specifically reducing the time-to-reimbursement for new healthcare solutions to match top-tier EU benchmarks.

By embracing this strategy, Ireland can resolve the paradox of its dual identity—aligning its role as a global factory for medicines with a new role as a global

*Date of prep: December 2025 / M-IE-00002323*



leader in their effective, data-driven use. This is the path to sustainable economic growth and, more importantly, better health outcomes for the people of Ireland.

*Date of prep: December 2025 / M-IE-00002323*

# Acadamh Ríoga na hÉireann Royal Irish Academy

**RE: Response to public consultation on National Life Sciences Strategy**

5 December 2025

*This response is being submitted by the Life and Health Sciences Committee of the Royal Irish Academy. It does not necessarily represent the views of the Royal Irish Academy.*

In February 2025, the Royal Irish Academy's Life and Health Sciences committee organised a symposium to showcase the success of fundamental biomedical research across the island of Ireland and to emphasise the continuing need for increased funding for fundamental research in order to build and sustain national capacity and improve the career paths and prospects for biomedical researchers. Speakers at this event were leaders in field of biomedical research from higher education institutions across the island of Ireland.

The half-day conference was structured around two panels: a research showcase and a careers panel. The case studies delivered as part of the research showcase illustrated the translational potential and impact of fundamental research. For the careers panel, four established researchers spoke about their career trajectories, in particular what funding schemes supported their work over the years, how experience abroad compares with Ireland, and what is most needed to improve careers in this sector.

The report from the '[Symposium on Fundamental Biomedical Research](#)' is being submitted as a response to National Life Sciences Strategy consultation. This report consolidates the symposium's proposals on how to address current sectoral challenges to ensure that fundamental biomedical research will underpin Ireland's future as a leader in health and life sciences research and innovation. The main demands of sector as captured in the report can be summarised as follows:

1. Promote and encourage curiosity-driven fundamental research across the island of Ireland
2. Establish regular and predictable funding calls and professional development opportunities
3. Improve career paths for Ireland-based researchers
4. Invest in core technology and appropriately resourced facilities<sup>1</sup>

---

<sup>1</sup> In this regard we note the recent (26 November 2025) Department of Further and Higher Education, Research, Innovation and Science announcement of a €750m INSPIRE Research Infrastructure Investment Package



Acadamh Ríoga na hÉireann  
Royal Irish Academy

19 Sráid Dhásain, Baile Átha Cliath 2, D02 HH58 19 Dawson Street, Dublin 2, D02 HH58 +353 1 609 0600 info@ria.ie ria.ie

Pat Guiry MRIA, Uachtarán/President Daniel Carey MRIA, Rúnaí/Secretary Mary Kelly MRIA, Cisteoir/Treasurer

Uimhir Chláirúcháin Carthanachta/Registered Charity Number: 20003524 Uimhir Chláirúcháin Ioncaim/Registered Revenue Number: CHY 2795

# Acadamh Ríoga na hÉireann

## Royal Irish Academy

The following sections of the report are relevant to the submission themes:

- The '[Summary of presentations](#)' sections convey the **scope** of fundamental biomedical research being undertaken across the island of Ireland
- Suggested **objectives** for inclusion in the National Life Sciences Strategy can be found in the '[Calls to Action](#)' section of the report.
- Key **challenges and opportunities** are outlined in the '[Additional Discussion Points](#)' section.

Thank you for this opportunity to inform the development of a new National Life Sciences Strategy.

### About the Life and Health Sciences Committee

The Life and Health Sciences Committee of the Royal Irish Academy is one of ten multidisciplinary committees that represent a broad spectrum of academics, researchers and industry experts from across the island of Ireland. The committee term is four years and the current members were selected based on their discipline expertise and public engagement experience following an open call in 2022. The committee's membership represents academia, industry, media, and other interest groups working in the field of life and health science. The primary purpose of the committee is to address issues of national and international interest through a programme of work and to advise the Academy on the formation of policy. The membership list of the Life and Health Sciences Committee of the Royal Irish Academy can be viewed [here](#).

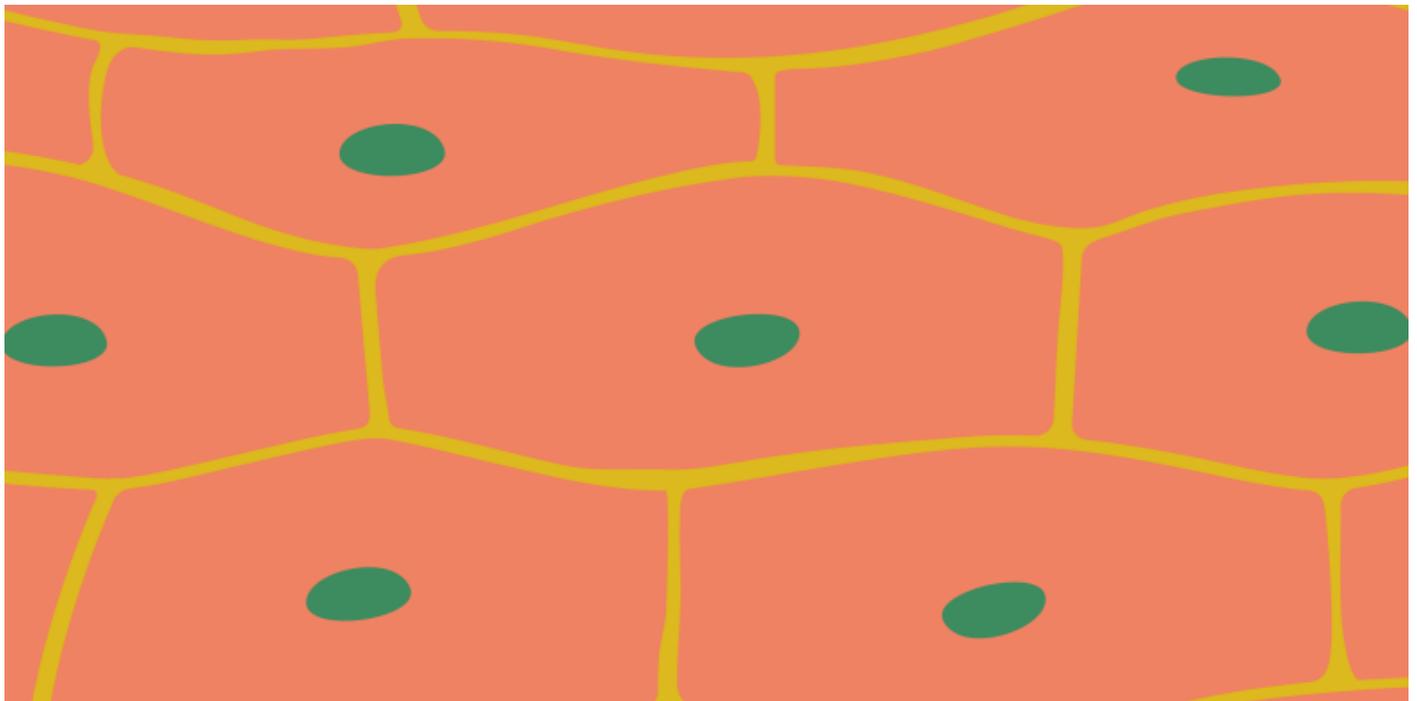


Acadamh Ríoga na hÉireann  
Royal Irish Academy

19 Sráid Dhásain, Baile Átha Cliath 2, D02 HH58 19 Dawson Street, Dublin 2, D02 HH58 +353 1 609 0600 [info@ria.ie](mailto:info@ria.ie) [ria.ie](http://ria.ie)

Pat Guiry MRIA, Uachtarán/President Daniel Carey MRIA, Rúnaí/Secretary Mary Kelly MRIA, Cisteoir/Treasurer

Uimhir Chláirúcháin Carthanachta/Registered Charity Number: 20003524 Uimhir Chláirúcháin Ioncaim/Registered Revenue Number: CHY 2795



# Symposium on Fundamental Biomedical Research

Report from a one-day conference held in the  
Royal Irish Academy on 5 February 2025



Acadamh Ríoga na hÉireann  
Royal Irish Academy

## Organising committee

Professor Colum Dunne, University of Limerick  
Professor Steve Kerrigan, Royal College of Surgeons in Ireland  
Professor Anne Moore, University College Cork  
Professor Declan Patton, Royal College of Surgeons in Ireland  
Fionnuala Parfrey, Royal Irish Academy

## Acknowledgements

The organising committee wish to thank the conference speakers and chairs:

Professor Orina Belton (Chair), Professor David Henshall, Professor Brendan Gilmore, Professor Laoise McNamara, Professor Aedín Culhane, Professor Áine Kelly (Chair), Dr Eoin McNamee, Dr Cathal McCarthy, Professor Rachel McLoughlin, Professor Peter Flatt.

Thanks also go to the attendees of the event who made thoughtful and challenging contributions to the discussion.

This report is produced on behalf of the Life and Health Sciences Committee of the Royal Irish Academy. The views expressed are the organising committee's own and do not necessarily reflect the opinion of the Royal Irish Academy

# Contents

|  |    |
|--|----|
| Executive Summary.....                                       | 4  |
| Calls to Action .....  | 5  |
| Additional Discussion Points.....                            | 7  |
| Fundamental Research Showcase: Summary of presentations..... | 9  |
| Careers Panel: Summary of presentations .....                | 11 |
| Conclusion.....  | 13 |
| Annexes.....   | 14 |

## Executive Summary

Fundamental biomedical research, sometimes called basic research, is research whose application might not be immediately evident, but which provides the building blocks upon which the other types of research (applied and clinical) are based. It plays a vital role in growing our collective understanding of disease, genetics and physiological processes.

This symposium reinforced the indispensable role of curiosity-driven, fundamental biomedical research in advancing scientific knowledge and ultimately improving health outcomes. A strong consensus emerged among speakers and attendees that supporting this kind of research in Ireland is not a luxury, but a necessity. Without it, the entire research pipeline, from discovery to clinical application, risks stagnation. Central to the discussion was the urgent need for regular and predictable funding streams to support Ireland-based researchers at all career stages. Inconsistent or one-off funding schemes and lack of defined career paths were identified as major barriers to sustainable research careers and to retaining talented scientists within Ireland.

Speakers also stressed that long-term investment in core infrastructure, such as advanced technologies, shared facilities, and interdisciplinary platforms, is critical to maintaining a globally competitive research environment. Funding of core technical staff is also key to enabling continuity of research for Principal Investigators. Increased cross-border collaboration and resource-sharing will result in a higher return on these core investments. We heard compelling calls for reforming institutional and funding frameworks to better align with the demands of contemporary research and for placing more value on scientific inquiry and less on short-term metrics of success.

Ultimately, the symposium served as a powerful reminder that while fundamental biomedical research may not always offer immediate applications, it is the foundation upon which all medical breakthroughs rest. In many cases, the fundamental biomedical research outputs are further commercialised and incorporated into clinical outputs. These developments underscore the long-term value and economic potential of investing in curiosity-driven science. To secure Ireland's future as a leader in health research and innovation a strategic, well-funded, All-Island approach is essential.

## Calls to Action

### 1. Promote and encourage curiosity-driven fundamental research across the island of Ireland

Fundamental biomedical research is absolutely critical to the knowledge economy and needs to be recognised as such at a policy and governmental level. Research whose impact is not immediately identifiable is as important as oriented and translational research. The case studies presented as part of this event highlighted the translational potential of pure fundamental research as well as the indispensable role of oriented basic research in supporting a better understanding of fundamental principles across the spectrum of life sciences. Sustaining Ireland's research excellence requires persuading policymakers of the value of curiosity-driven research. Articulating the benefits of fundamental research can help shift narratives and strengthen calls for increased funding.

### 2. Establish regular and predictable funding calls and professional development opportunities

Grant calls should be regularly spaced in a predictable manner and dates for outcomes adhered to so that researchers can plan their research programmes and their lives. Many of the speakers pointed to the system in the US where regular and predictable funding calls alleviate some of the pressure on researchers to be successful with every funding bid. This potential for failure needs to be acknowledged and supported through the development of a culture where repeated application is the norm. Research Ireland should establish consistent and scheduled funding calls and communicate these effectively to the research community.

### 3. Improve career paths for Ireland-based researchers

Establishing clearly defined and attractive career paths is essential to encourage and support Ireland-based researchers in fundamental biomedical research. Currently, there is a high risk of losing promising researchers due to lack of job security, particularly at the mid-career stage. It was proposed that bridging grants could help to maintain research continuity. Further work is needed to remove inter-institutional barriers, enabling greater mobility of researchers and staff while fostering more coordinated research and training, particularly on a north-south basis.

### 4. Invest in core technology and appropriately resourced facilities

Speakers at this event pointed to the Broad Institute in the United States and the Francis Crick Institute in London as examples of independent biomedical research centres where enhanced facilities enable high-calibre, cross-institutional research to be undertaken. Improvement and centralisation of technical facilities in Ireland will support the organic growth of curiosity-led research and speed up the research process. There is also a pressing need to modernise Ireland's bioinformatics and information-sharing infrastructure in response to rapid technological advances. There

was a call for a strategic assessment, or 'landscaping exercise' to be undertaken to evaluate existing research infrastructure across the island of Ireland. Participants emphasised the importance of an all-island approach with respect to funding research assets.

## Additional Discussion Points

### Funding infrastructure

Grouped below are the main discussion points raised during the symposium in relation to funding and funding infrastructure for fundamental biomedical research.

**Balancing top-down and bottom-up funding:** Tension exists between strategic (top-down) and investigator-driven (bottom-up) approaches. Top-down is vital for infrastructure and long-term planning. Bottom-up enables discovery-driven research and creativity. There is concern that top-down funding can become politicised, stifling innovation. Research projects should emerge from Principal Investigators (PIs) or consortia with ground-level insight and experience.

**Consistent and predictable funding:** It will be important for Research Ireland to introduce consistent and predictable funding calls, which will make it easier for researchers to plan in the long term. Many participants pointed to the system in the US where regular and predictable funding calls alleviate some of the pressure on researchers to be successful with every funding bid. Consistent funding also supports collaboration and the formation of research consortia.

**National and European alignment:** Ireland's ability to lead in European research consortia is seen as being at risk due to underinvestment in connected research ecosystems. Developing a national program aligned with the European Research Council (ERC) could enhance the success rate of Irish applicants and reinvigorate the country's participation in large-scale European projects. This would require improved integration of data, computing, health systems, and ethics, ensuring all components of the research pipeline operate smoothly and at a competitive level.

### Academic infrastructure

Grouped below are the main discussion points raised during the symposium in relation to what could be improved within Ireland's academic infrastructure.

**Research facilities:** There was a call for a strategic assessment, or 'landscaping exercise' to evaluate existing research facilities across the island of Ireland and to look for more opportunities for cross-border collaboration and sharing of resources. With recent changes in the higher education landscape, including the emergence of Technological Universities (TUs), equitable access to infrastructure and resources is increasingly important. Proposals such as establishing 'research hotels' modeled on institutions like the Francis Crick Institute in the UK or the Broad Institute in the US could provide shared, state-of-the-art facilities that would in turn drive collaborative and high-impact research. Importance of employing skilled, technical (non-research) staff was emphasised.

**Industry engagement:** It is important to strengthen industry-academic links. Industry benefits from a highly skilled workforce; universities gain infrastructure support. Cross-sector mobility should be encouraged to enrich both academia and industry and effective clinical and translational research can be fostered through academic health science models.

**Administrative burdens:** Rising undergraduate numbers and teaching and administrative tasks are overwhelming postdoctoral researchers and principal investigators. Ethics approval processes are slow and obstructive, and admin and bureaucracy can stifle creativity. While oversight is necessary, there was a strong call to streamline and improve administrative processes in order to enhance research outputs. Such an overhaul would require a significant investment in time and planning but would reap many long-term benefits.

## Culture and Career Development

Grouped below are key discussion points raised during the symposium that address cultural changes needed to better support career development in the biomedical sciences.

**Lack of career structure:** There are no clear long-term pathways for early-career principal investigators in Ireland and there is a high risk of losing promising researchers due to lack of support, particularly at the mid-career stage. Even though postdoctoral researchers represent the future of the sector, they face low morale and job insecurity. There is a need for sustainable practices to ensure career growth and retention of talent. It was proposed that bridging grants could help to maintain research continuity.

**Research support:** The need for cultural and structural changes in research training and support was also emphasised. Encouraging younger academics to apply for European Research Council grants early and fostering a mindset where rejection is a stepping stone to success can raise the overall ambition of the research community. Many of the panellists in this event benefitted from the Irish Research Council Laureate Awards Programme. It will be important for Research Ireland to replicate this scheme.

**University culture and leadership:** The discussion during the second panel stressed the importance of sustainable research and working practices and the need to elevate the next generation of talent. A stable, supportive, and well-funded research ecosystem bolstered by cross-sector collaboration, improved institutional structures, and a healthy research culture is essential to retain talent and secure Ireland's place in the global scientific community. There is a need to shift the institutional narrative to equally value research and teaching and to build a culture of mentorship, collaboration, and researcher well-being. Positive environments organically produce strong mentors and research outcomes.

## Fundamental Research Showcase: Summary of presentations

The case studies delivered as part of the research showcase illustrated the translational potential and impact of fundamental research. The session was chaired by Professor Orina Belton, Professor of Pharmacology at University College Dublin.

### **Professor David Henshall, Professor of Molecular Physiology and Neuroscience, Royal College of Surgeons in Ireland**

In 2008 Professor David Henshall received a Principal Investigator award from Science Foundation Ireland to try to understand why hibernating animals do not get brain damage despite reduced blood flow. His group's research revealed the factors that contribute to a protective state called 'tolerance' during hibernation and identified a specific microRNA that affects brain cell connections. They discovered that this microRNA was present in increased levels in epilepsy patients. His team then successfully inhibited the microRNA in animals, significantly reducing seizures. Despite early setbacks, including a rejected funding application, the work led to establishment of the FutureNeuro Research Centre in 2017, with Roche as an industry partner, and to the development of anti-seizure medication. Citing the Board of Editors of Scientific American, Professor Henshall emphasised that 'knowledge for its own sake is valuable and its pursuit justified.'

### **Brendan Gilmore, Professor of Microbial Pharmacology, Queens University Belfast**

Professor Brendan Gilmore shared insight into some of his cross-disciplinary, all-island research projects, including research into deep-sea microbiomes and rare haloarchaea in salt mines. Scientific discoveries from these projects have led to industry partnerships to identify new enzymes for industrial use. Professor Gilmore also gave the example of applied research leading to unexpected fundamental discoveries. Research into microbiomes in hospital wastewater pipes found that antibiotic-resistant bacteria in patients often matched those in hospital plumbing, suggesting an environmental link between the building structure and patient infections. This reverse path from solving an immediate problem back to uncovering fundamental science, highlighted how applied research can also expose gaps in basic knowledge.

### **Professor Laoise McNamara, Established Professor in Biomedical Engineering at University of Galway**

Professor Laoise McNamara's talk focused on the intersection of disease research and industry collaboration in the area of mechanobiological research. Her team's long-running research into bone cell biology and how cells behave in different disease states has led to an advanced understanding of osteoporosis and cancer metastasis in the bone environment. The group's research has translated into collaborative work with medical device companies who use their three-dimensional bone models to simulate the bone's mechanical environment. This pathway from basic biological research to applied industry use underscores the importance of supporting long-term, disease-focused fundamental research.

**Aedín Culhane, Professor of Cancer Genomics, University of Limerick School of Medicine**

Professor Aedín Culhane spoke about her experiences abroad compared with the research infrastructures in Ireland. Since returning to Ireland from the US, Professor Culhane has focused on building national infrastructure to link clinical and genomic data. Projects include GDI (Genomics Data Infrastructure), eHealth Hub for Cancer, and the European Health Data Space. She emphasised the pressing need to modernise Ireland's bioinformatics and information-sharing infrastructure in response to rapid technological advances. Ireland could learn from biomedical research institutions such as the Broad Institute in Cambridge, Massachusetts, and the Institute of Biotechnology and Biomedicine in Barcelona, where core facilities and strong links to hospitals and clinics enhance innovation.

## Careers Panel: Summary of presentations

For the careers panel the audience heard from four established researchers who spoke about their career trajectories, in particular, what funding schemes supported their work over the years, how experience abroad compares with Ireland, and what is most needed to improve careers in the sector. The session was chaired by Professor Áine Kelly, Professor in Physiology at Trinity College Dublin.

### **Dr Eoin McNamee, Associate Professor and Group Leader of Mucosal Immunology Research (MIR) Lab, Maynooth University**

Dr Eoin McNamee highlighted the importance of multidisciplinary teams, cutting-edge technology platforms, and access to clinical and transgenic models for driving impactful scientific research and attracting industry collaboration. In the US a diverse and robust funding landscape, including soft funding, seed investments, and disease-specific research arms, offer greater support for researchers, particularly those at a mid-career stage. This infrastructure, combined with consistent funding calls and modular budgets, allows scientists to plan and build sustainable research programmes. Like many others on the day, Dr McNamee advocated for centralised tech hubs with built-in AI and bioinformatics facilities to boost Ireland's global competitiveness and improve the sector's capacity.

### **Dr Cathal McCarthy, Senior Lecturer and Principal Investigator in Department of Pharmacology and Therapeutics, University College Cork**

Dr Cathal McCarthy shared his research trajectory from an initial degree in microbiology to a career focused on perinatal and cardiovascular research. He highlighted how research funding in Ireland was instrumental at each stage. Collaboration, access to specialised facilities, and clinical integration were crucial, as well as funding from programmes like the Health Research Board's Emerging Investigator Award. These supports enabled Dr McCarthy to build an independent research team, secure a senior lecturer role, and explore the links between pregnancy complications and long-term health outcomes. Dr McCarthy also noted systemic challenges, including limited funding windows and the lack of tailored opportunities for mid-career researchers.

### **Professor Rachel McLoughlin, Professor in Immunology, Biochemistry, Trinity College Dublin**

Professor Rachel McLoughlin outlined some of the key decision-making points in her research career, acknowledging how unpredictable a career in research can be. Ireland's system offers limited career pathways and academia, as the main option, is often burdened by administrative complexity and a lack of infrastructure, particularly for clinical-basic science collaboration. She noted that while early-career funding like the SFI Starting Investigator Research Grant is valuable, mid-career support is equally essential. Despite these challenges, Ireland has a well-connected research network and has produced exceptional researchers, many of whom are now working abroad. Professor McLoughlin

emphasised the need for better support systems, including real backing for maternity leave and better messaging around the value of postdoctoral experience beyond academia. She called for investment in infrastructure and innovation to retain and attract top researchers, warning that without it, recruitment, especially amid the cost-of-living crisis, will remain a serious hurdle.

**Professor Peter Flatt, Professor of Biological & Biomedical Sciences, Ulster University**

Professor Peter Flatt reflected on the evolution of the research sector over the course of his forty-year career and highlighted the importance of mentorship and workplace culture. Alongside conducting biomedical research, a crucial priority is training the next generation of scientists. Developing young talent requires nurturing curiosity, and providing PhD students with international exposure, conference opportunities, and ongoing mentorship. He underlined the need for a supportive research ecosystem that includes early career funding, industrial partnerships, and pump-priming grants to jumpstart research projects. Professor Flatt also proposed that researchers in Northern Ireland could capitalise more on the Republic of Ireland's industry links. He emphasised that the future of research depends on cooperation and collaboration both across the border and across sectors.

## Conclusion

In the Programme for Government 2025, published in January 2025, Fine Gael mentioned pharma and medtech specifically as areas of the economic sector where Ireland has a 'strong competitive advantage.' The government also committed to developing a 'new National Life Sciences Strategy to ensure that this important sector remains competitive and ensure Government adopts a coherent and ambitious approach to future opportunities.' These comments are encouraging and reflect the valuable contribution that fundamental biomedical researchers make to research culture, health science, and the economy.

This conference attracted an exceptional array of experts and highlighted the passion and commitment of the researchers in this sector and the desire on their part to see it flourish. With the establishment of Research Ireland, it is hoped that this will be an opportunity to develop a sustainable long-term strategy to support research and researchers in fundamental biomedical science and uplift and enhance the sector more broadly.

# Annexes

## Annex One: Conference Programme

On Tuesday 5 February 2025, the Royal Irish Academy's Life and Health Sciences committee held a symposium to showcase the success of fundamental biomedical research across the island of Ireland and to highlight the need for increased funding for fundamental research in order to build national capacity and improve the career paths and prospects for biomedical researchers.

The half-day conference was structured around two panels: a research showcase and a careers panel. The event took place in the Royal Irish Academy, 19 Dawson Street, Dublin 2 and was attended by researchers, research funders and policy makers.

### Programme

**10:00-10:30** Welcome and Opening Remarks

**10:30-12:00** Fundamental Biomedical Research Showcase, chaired by Professor Orina Belton, UCD

#### Panellists:

- Professor Aedin Culhane, Professor of Cancer Genomics, University of Limerick School of Medicine
- Professor David Henshall, Professor of Molecular Physiology and Neuroscience, Royal College of Surgeons in Ireland
- Professor Brendan Gilmore, Professor, School of Pharmacy, Queen's University Belfast
- Professor Laoise McNamara, Established Professor in Biomedical Engineering, University of Galway

**12:30-14:00** Careers Panel, chaired by Professor Aine Kelly, TCD

#### Panellists:

- Dr Eoin McNamee, Associate Professor and Group Leader of Mucosal Immunology Research (MIR) Lab, Maynooth University
- Dr Cathal McCarthy, Senior Lecturer and Principal Investigator in Department of Pharmacology and Therapeutics, University College Cork
- Professor Rachel McLoughlin, Professor in Immunology, Biochemistry, Trinity College Dublin
- Professor Peter Flatt, Professor of Biological & Biomedical Sciences, Ulster University

**14:00-14:30** Closing Remarks

## Annex Two: speaker bios

### **Aedín Culhane**

Aedín Culhane is Director of the Limerick Digital Cancer Research Centre and is a full Professor in the University of Limerick School of Medicine. She has over two decades expertise in bioinformatics and computational oncology including over 15 years' experience at the Dana-Farber Cancer Institute and Harvard University, where she developed algorithms for integrative data analysis of cancer bulk and single cell molecular data.

### **David Henshall**

David obtained his PhD in neuropharmacology from the University of Edinburgh in 1997. He then spent six years in the USA, at the University of Pittsburgh and later at the Robert S. Dow neurobiology laboratories in Portland, Oregon. Since 2004, he has been at the RCSI University of Medicine and Health Sciences where he is Professor of Molecular Physiology and Neuroscience. David's interests are the causes, diagnosis and treatment of epilepsy. Since 2017, he has been director of the FutureNeuro research centre for translational brain science. He is the author of over 250 publications and the new book 'Fine-Tuning Life'.

### **Brendan Gilmore**

Brendan Gilmore is Professor of Pharmaceutical Microbiology and Deputy Head of School in the School of Pharmacy at Queen's University Belfast, and is a UL Adjunct Professor in the School of Medicine, University of Limerick. His research team is focused on understanding the processes which govern bacterial biofilm formation and tolerance to antibiotics, and the discovery of novel antibiotics and disinfectant approaches. His recent work has included the application of cold plasmas for biofilm decontamination and the discovery of novel antibiotics and biocatalytic enzymes from extremely halophilic microorganisms.

### **Laoise McNamara**

Laoise McNamara is an Established Professor of Engineering (Biomedical) and Head of School of Engineering at University of Galway. She leads the Mechanobiology and Medical Device Research group, who use experimental and computational approaches to study the role of mechanobiology in osteoporosis and cancer-bone metastasis. She also applies her expertise to the pre-clinical assessment of surgical and minimally invasive medical devices. She was awarded two ERC Awards, an Irish Research Council Laureate Award and received the Irish Research Council "Researcher of the Year" award. She has published over 100 research articles and is a reviewer for international research organisations.

### **Eóin McNamee**

Dr Eóin McNamee is an Associate Professor and Research Group Leader at Maynooth University, Ireland. A graduate of Maynooth University and Trinity College Dublin, Eóin carried out postdoctoral training and later joined the faculty at the University of Colorado-Anschutz Medical Campus, USA. He was recruited to Maynooth University in 2018 and received the SFI - President of Ireland Future Research Leaders fellowship in 2020. His laboratory focuses on Translational Immunology research and development, investigating mechanisms of human autoimmune diseases and pre-clinical drug discover.

### **Cathal McCarthy**

Dr Cathal McCarthy is a Senior Lecturer and Principal Investigator in Department of Pharmacology and Therapeutics, UCC. He undertook a PhD in DIT, investigating pathways modulating placental insufficiency in Pre-eclampsia and IUGR. Cathal's postdoctoral studies in UCD focused on elucidating protective networks mediating regression of atherosclerosis. Cathal's current research investigates the disruptive pathways causing pre-eclampsia and gestational diabetes mellitus and the development of therapeutics to effectively treat these pregnancy complications.

### **Rachel McLoughlin**

Rachel McLoughlin is Professor in Immunology at Trinity Biomedical Science Institute in Trinity College Dublin. Her research into host-pathogen interactions has made a significant international impact and has directly informed development of next-generation anti-*S. aureus* vaccines. Her research focuses on understanding the host immune response to *Staphylococcus aureus* exposure with a particular focus on adaptive cellular immunity.

### **Peter Flatt**

Peter Flatt holds a DSc from Ulster University and BSc Hons and PhD from Aston University. He was a Research Fellow at the University of Uppsala, Sweden before taking up an academic appointment at Surrey University in 1980. He is currently Professor of Biomedical Sciences and Head of Diabetes Research Centre at Ulster University, a position that he has held since 1989. Peter has supervised 103 PhD students, with many becoming independent senior academics. His research on diabetes therapeutics has been recognised by several scientific accolades including election as Member of Royal Irish Academy.

# Submission from Sandoz Ireland

## Submission from Sandoz Ireland to the National Life Sciences Strategy 2025

National Life Sciences Strategy Consultation

Department of Enterprise, Trade & Employment

5 December 2025

Dear Sir / Madam,

On behalf of Sandoz Ireland, thank you for the opportunity to contribute to Ireland's first National Life Sciences Strategy. As a global leader in generics and biosimilars, with a long-standing manufacturing heritage in Europe and a growing presence in Ireland, Sandoz welcomes this consultation as a critical step in shaping a resilient, innovative and patient-centred life sciences ecosystem.

By 2030, 71% of biological medicines losing exclusivity will not have biosimilars in the industry pipeline, this is likely to be the result of an increasing proportion of lower value biologics (global annual sales less than \$500m). This could result in European countries losing 20% (\$5.6bn) of the potential value of biologics not facing competition.

The costs to develop a biosimilar can be broadly put in three areas

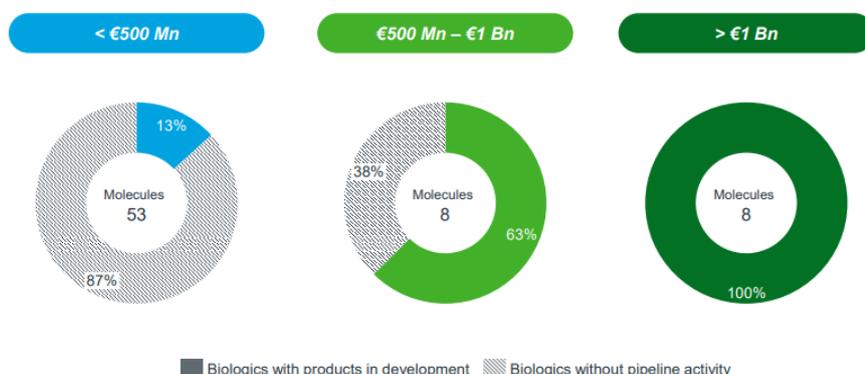
~\$100m – development of the molecule and scale up

~\$60m – phase II study

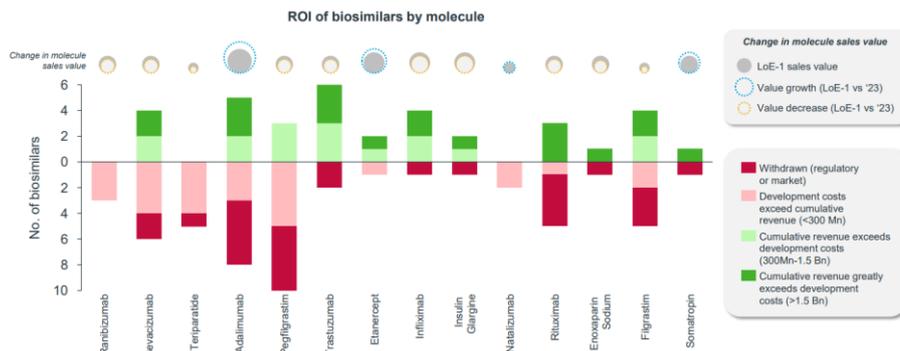
~\$100m – phase III study (EMA may not require a confirmatory efficacy study if it accepts a proposal for streamlined regulatory approval)

Given the high cost of biosimilar development, companies target originator biologics with peak annual global sales of more than \$3bn. Biologics with peak sales below that may be considered if there are exceptional reasons. Development for biologics with sales below \$1bn is highly unlikely, as illustrated in IQVIA's forthcoming 'Impact of biosimilar competition report 2024':

Forecast sales value (LoE-1) in Europe (2024-2030) and competitor development



The increasing number of biosimilar launches will increase focus on achieving a positive return on investment. IQVIA highlights that biosimilars may not achieve a positive return on investment.



Ireland's upcoming EU Council Presidency in July 2026 presents a unique moment for the State to champion policies that secure medicines supply, strengthen European manufacturing, reduce vulnerabilities in global supply chains, and accelerate sustainable access to high-quality, affordable treatments. Sandoz shares these ambitions and stands ready to support Ireland's leadership role.

## 1. Ensuring Medicines Security & European Manufacturing Resilience

Sandoz strongly supports a national strategy that prioritises secure and sustainable access to essential medicines.

As operators of Europe's only end-to-end antibiotic production site (Kundl, Austria), we understand the strategic importance of maintaining manufacturing in Europe for critical antimicrobials and other high-demand medicines. Antibiotics are essential to modern medicine, yet Europe's production capacity is under threat, with over 80% of global API supply currently sourced from China. This dependency poses serious risks to public health, supply chain resilience, competitiveness, and geopolitical stability. Sandoz is committed to working closely with European institutions to reverse this trend by restoring and safeguarding European sovereignty in antibiotic manufacturing and reinforcing the region's strategic autonomy, while ensuring supply security both within Europe and beyond through measures including additional region-specific partnerships.

We recommend that Ireland:

- Champion European industrial policies that protect and expand manufacturing of essential medicines within the EU.
- Support predictable procurement and reimbursement frameworks that ensure long-term viability for producers of mature, high-value-for-money medicines.
- Embed supply-resilience criteria into national and EU market access processes.

## **2. Strengthening Ireland's Role as a Hub for Biosimilars & Affordable Innovation**

Ireland can play a pivotal role in advancing equitable access across Europe through supporting biosimilar adoption and the broader generics ecosystem. It currently sits as one of the slowest adoptors of biosimilars within Europe, which is an opportunity lost as biosimilars generate large-scale savings while expanding access to biologics for more patients.

We recommend that the Strategy take a whole of government approach to include the Department of Enterprise, Trade and Employment, Department of Education and the Department of Health.

- Establish national biosimilar uptake targets and reporting mechanisms.
- Make Ireland an innovation testbed for digital tools, real-world data, and switching models.
- Demand signalling would prioritise re-appraisals of off-patent medicines in areas of greatest clinical or public health need, and ensure that these medicines are made available to the Irish Health Care system.

These measures would strengthen Ireland's leadership and generate savings that can be reinvested into innovation, workforce development and capacity expansion.

## **4. Skills, Talent & Workforce for the Next Decade**

As Ireland's life sciences sector grows, so too does the need for specialised talent in:

- Bioprocessing and advanced manufacturing
- Regulatory affairs
- Digital health, data analytics and AI
- Supply chain and quality operations

Sandoz supports a strategy that:

- Expands collaboration between HEIs, training bodies and industry
- A forward-focused workforce plan is essential for ensuring Ireland remains globally competitive.

## **5. Sustainability & Ireland's Climate Leadership**

Sandoz is committed to achieving Net Zero by 2045, and we welcome Ireland's ambition to develop a greener, more circular pharmaceutical value chain.

We encourage the State to:

- Support greener manufacturing incentives, including energy efficiency and clean energy integration.

- Embed environmental performance as part of procurement criteria, without compromising timely access

## **6. Partnership with Government Ahead of EU Council Presidency 2026**

Ireland has a unique chance in 2026 to shape EU-level discussions on:

- Medicines security
- Incentivising European manufacturing
- Predictable pathways for biosimilars

Sandoz stands ready to collaborate with DETE, DoH, HPRA, HSE ,DOE and other stakeholders to support Ireland's leadership at a European level.

---

### Conclusion

Sandoz Ireland is fully committed to supporting the State in delivering a resilient, innovative, sustainable and patient-centred life sciences sector. We believe the National Life Sciences Strategy 2025 can provide a strong foundation for the next decade of growth—benefiting patients, the health system, and the wider economy.

We would welcome the opportunity to engage further with DETE on any element of this submission.

Yours sincerely,

Ciara Conway

Head of Market Access & External Relationships

## Submission from SIA



### About SIA

Sia is a next-generation, global management consulting group. Founded in 1999, Sia have expertise across a broad range of sectors and services, with over 3,000 professionals serving clients worldwide from 48 locations in 20 countries.

With deep expertise across pharmaceuticals, biotech, medtech, and digital health, Sia partners with governments, enterprises, and research institutions to develop evidence-based strategies that drive competitive advantage and sustainable growth.

#### / **Section 1: Scope**

SIA believes that the scope of the National Life Sciences Strategy should focus on anchor sectors of life sciences that Ireland has unique strengths and opportunities in, and that are not otherwise covered in adjacent strategies. It should focus on the following three areas as anchor sectors within the strategy;

1. Pharmaceutical
2. Biotechnology
3. Medical technology

Each of these anchor sectors is underpinned and enabled by the following areas, which should be covered across the strategy;

- Talent and Skills
- Data and Infrastructure
- Funding and Incentives
- Research and Development
- Policy and Regulation

The strategy should exclude fisheries, agriculture, and food manufacturing as anchor sectors, given these are already addressed in Ireland's Bioeconomy Strategy and represent distinct value chains with different competitive dynamics. They should be referenced through interdependency and connectedness with other life sciences sectors to provide a holistic view of the landscape.

The scope should mirror the EU Life Sciences Strategy, while highlighting and focusing on Ireland unique position.

The scope should also be inclusive of the interdependencies across adjacent and complimentary strategies, including the National Digital and AI Strategy, and the pending EU Biotech directive.

#### / **Section 2: Objectives**

SIA recommend that the National Life Sciences Strategy target five interconnected objectives with the appropriate investment to deliver these in a timely manner:

##### **1. Research & Innovation Excellence**

- Strengthen translational research bridging academia and industry
- Build critical mass in emerging areas (gene therapy, AI-driven drug discovery, precision medicine)
- Enhance Ireland's clinical trials ecosystem and real-world evidence capabilities

## 2. Global Competitiveness & Resilience

- Future-proof Ireland's value proposition beyond tax. In this regard we should focus on regulatory agility, skilled workforce, innovation ecosystem
- Develop advanced manufacturing capabilities where there is a growing demand for continuous manufacturing, personalised medicine production
- Strengthen supply chain resilience and strategic autonomy

## 3. Patient & Public Benefit

- Improve patient access to innovative therapies through accelerated pathways
- Develop health data infrastructure enabling personalised medicine
- Address health inequalities and unmet medical needs

## 4. Talent, Skills & Inclusive Growth

- Build deeper talent pools across technical, digital, and regulatory disciplines
- Create career pathways from apprenticeships to PhD level
- Ensure regional distribution of opportunities beyond Dublin/Cork

## 5. Environmental & Social Sustainability

- Decarbonise biomanufacturing and achieve sectoral net-zero targets
- Advance green manufacturing principles (waste reduction, water stewardship)
- Embed responsible innovation and ethical frameworks

### / **Section 3: Opportunities and Challenges**

SIA has identified the following opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address.

#### **Opportunities:**

- Ireland should execute the recommendations from the Expert Group on Future Skills Needs Report to address talent drain through targeted workforce development and retention initiatives.
- Ireland should create multiple coordinated ecosystem clusters—such as the Pioneer development in Cherrywood and an integrated ARC hub combining biotech companies, startups, laboratories, and funding mechanisms—to foster innovation and collaboration across the life sciences sector.
- Ireland should build up contract development and manufacturing organization (CDMO) capability and capacity by leveraging existing legacy pharmaceutical manufacturing sites to retain high-value jobs and preserve critical infrastructure.
- Ireland should address funding gaps through innovative public-private partnership models—such as the Danish enterprise foundation approach and the commercialisation of research driven by the VIB in Belgium—while mobilizing underutilized public funds like the Strategic Investment Fund to support life sciences growth.

- Ireland should position the HPRA to pilot EU regulatory innovations including adaptive licensing and accelerated approval pathways, while leveraging its FDA relationships to bridge EU-US regulatory alignment and establish Ireland as the preferred testbed for next-generation regulatory frameworks.
- Ireland should establish and resource additional infrastructure in support of the RD&I ecosystem by setting up a national Centre of Excellence for therapeutic drug discovery, embedding laboratory capabilities and scientific disciplines which are currently lacking.

#### **Challenges:**

- Ireland's life sciences sector faces significant overdependence on US foreign direct investment, particularly in pharmaceuticals, though the medtech subsector demonstrates greater diversification and resilience.
- Ireland must develop stronger knowledge transfer and export pathways beyond the US market to reduce concentration risk and build sustainable, globally distributed commercial relationships.
- Ireland lacks sufficient translational research infrastructure and commercialization pathways to effectively bridge the gap between academic discovery and market-ready products, limiting the conversion of research excellence into economic value.
- Ireland faces a critical early-stage funding gap for biotechnology companies, with insufficient venture capital and growth financing available to support the scaling of innovative startups from concept to commercial viability.
- Ireland's immature data infrastructure and absence of comprehensive electronic health records (EHR) systems significantly limit the ability of life sciences companies to conduct clinical trials, test solutions, and scale innovations efficiently.
- Ireland has limited artificial intelligence capability and struggles to attract AI-focused investment, creating a competitive disadvantage as AI becomes increasingly central to drug discovery, diagnostics, and personalized medicine development.

#### **/ Section 4: EU Context**

SIA believes that the European Commission's ambition to position the EU as the world's most attractive life sciences location by 2030 reflects an urgent competitive reality. Achieving the EU's 2030 ambition is achievable but contingent on three critical conditions:

- Regulatory harmonisation accelerated across member states
- Investment commitments materialised at scale
- Talent mobility improved through streamlined pathways

The [DRAGHI Report](#) starkly illustrates the scale of the challenge: the EU has produced approximately 150 life science unicorns compared to 700 in the US. This disparity is underpinned by significant investment gaps with the US investing 3.5% of GDP in R&D versus the EU's 2.2%, resulting in a \$270 billion annual spending differential as of 2021.

This innovation gap directly contributes to a widening total factor productivity (TFP) gap between the EU and US, with profound implications for long-term living standards and economic competitiveness. The venture capital landscape further illustrates this imbalance: the EU captures only 5% of global VC funding compared to 52% in the US and 40% in China, creating weaker growth prospects for European startups and limiting their ability to scale globally.

SIA have outlined the specific applications for Ireland to support the proposed EU measures.

| <b>EU Measure</b>                 | <b>Irish Application</b>   |
|-----------------------------------|--|
| <b>Regulatory streamlining</b>    | Lead on EMA efficiency; position Ireland as regulatory hub; provide clear guardrails balancing innovation promotion with data safeguarding |
| <b>Increased R&amp;D funding</b>  | Maximize Horizon Europe allocation; co-fund with national resources  |
| <b>Talent mobility</b>            | Implement EU talent visa fast-track; attract diaspora  |
| <b>Infrastructure investment</b>  | Develop 2-3 world-class research and manufacturing clusters; invest in infrastructure to advance EHDS for pooled data across EU            |
| <b>Green transition support</b>   | Position Irish biotech as sustainability leader  |
| <b>Digital health integration</b> | Leverage Ireland's digital/tech ecosystem; urgently deliver EHR  |

In addition, it is SIA's belief that Ireland should establish a National Life Sciences Council modelled on the Danish exemplar. The council serves as a policy feedback loop, translating EU directives into coherent national action while ensuring Irish priorities shape European strategy. This council should comprise:

- Representatives from Irish and foreign life sciences companies
- Healthcare system leaders and clinicians
- Research institution heads and academic researchers
- Patient associations and advocacy groups
- Business organisations and trade unions
- Government representatives (Health, Enterprise, Education, Environment)

#### **EU-Level Benefits:**

- Provides coordinated Irish input to European policy development, amplifying Ireland's voice in shaping EU life sciences strategy
- Enables rapid translation of EU measures into tailored Irish implementation, reducing fragmentation across member states
- Facilitates knowledge-sharing on regulatory innovation and best practices across the European ecosystem

#### **National Benefits:**

- Enables adaptive, iterative strategy refinement based on sector performance data and stakeholder feedback, allowing rapid response to competitive threats
- Reduces implementation friction through stakeholder co-design, accelerating policy execution and increasing adoption rates
- Strengthens cross-sector coordination on talent pipelines, infrastructure, and funding, creating ecosystem coherence and competitive differentiation



**Skillnet Ireland submission on the National Life Sciences Strategy**

|   |    |
|---|----|
| Introduction .....                        | 2  |
| Scope & Objectives .....                  | 3  |
| Skillnet Ireland Business Networks .....  | 4  |
| Irish Medtech Skillnet .....              | 4  |
| BioPharmaChem Skillnet .....              | 5  |
| First Polymer Training Skillnet .....     | 5  |
| ICBE Advanced Productivity Skillnet ..... | 6  |
| Opportunities and Challenges .....        | 7  |
| EU Context .....                          | 10 |
| Conclusion.....                           | 10 |
| About Skillnet Ireland.....               | 11 |

## Introduction

Skillnet Ireland welcomes the opportunity to contribute to the Department of Enterprise, Tourism and Employment's consultation on a new *National Life Sciences Strategy*. We commend the Department's leadership and ambition in the development of a strategic vision for the sustainable growth of Ireland's thriving life sciences sector.

Ireland has a well-established pharmaceutical, biotech, and health industry. It is home to over 700 biopharma, medtech, and digital health companies, including 19 of the top 20 global pharmaceutical companies and 18 of the top 20 medical device companies.<sup>1</sup> The sector accounts for more than 60% of the country's exports.<sup>2</sup> Ireland is the world's third-largest pharmaceuticals exporter, with more than €80 billion worth of exports a year. Medtech exports from Ireland are worth more than €13 billion a year.<sup>3</sup>

The next decade offers significant opportunity across areas such as advanced therapies, digital transformation, convergence of medtech and pharma, and the transition to sustainable, data-driven healthcare. By driving innovation in key areas such as healthcare, biotechnology, biomanufacturing, and food and agriculture, the life sciences sector has the potential to tackle major societal issues, including enhancing competitiveness, promoting sustainability, ensuring food security and improving health outcomes and quality of life for citizens. Ireland's ability to harness these opportunities, however, will depend on the depth, adaptability and diversity of its talent base.

As Ireland's national agency dedicated to workforce development, Skillnet Ireland strongly supports the Department's emphasis on skills and talent as a key strategic enabler, and as such, our observations on the key thematic questions in this consultation - scope, objectives, opportunities, challenges, and the wider EU context - are framed through a skills and talent development lens.

By embedding talent development as a central pillar of the *National Life Sciences Strategy*, supported by coordinated actions across industry and the education and training sector, Ireland can secure long-term competitiveness, attract high-value investment, and ensure that innovation translates into tangible benefits for patients and society.

Skills are at the core of the innovation journey for people and businesses alike. Without continuous investment in upskilling and reskilling, both individuals and organisations risk falling behind in an increasingly knowledge-driven economy. Research conducted by Skillnet Ireland for the [2025 Ireland's Talent Landscape Report](#) shows that business leaders are deeply aware of how our economic success relies on our highly skilled and talented workforce. The

---

<sup>1</sup> [Ireland: How The Irish Life Sciences Sector is Leading the World | NSF](#)

<sup>2</sup> [Pharma - Irelands Project Economy](#)

<sup>3</sup> [Ireland: A Global Center for Life Sciences | IDA Ireland](#)

majority of businesses have identified upskilling as a strategically important priority, reflecting the critical role that upskilling plays in fostering competitiveness and nurturing innovation. Engagement with upskilling remains high within Irish companies with 76% of businesses having upskilled their staff in the past 12 months.

The [Draghi Report on EU Competitiveness](#) highlights the crucial role of adult learning in supporting this innovation journey, emphasising that lifelong learning is not only a personal development goal but also a strategic necessity for economic resilience. It outlines how a lack of qualified workers is hampering innovation and company growth and prevents companies from fully capitalising on emerging technologies and new market opportunities. This gap is “limiting the EU’s productivity and competitiveness”, highlighting the necessity for joint efforts across government, education, and industry to create a more responsive and future-ready skills ecosystem.

The *Draghi Report* furthermore pinpoints the opportunity for SMEs to adopt productivity-enhancing management practices, especially those related to the digital and green transitions. SMEs form the backbone of Ireland’s economy, yet many struggle to implement the tools and processes that could drive innovation and sustainability. Adopting such practices opens the door to “boosting the innovation capacity of businesses”, enabling SMEs not only to modernise operations but also to contribute more effectively to Ireland’s and the wider EU’s broader competitiveness and climate goals.

Earlier this year, the OECD produced a report on [Empowering the Workforce in the Context of a Skills-First Approach](#). It highlights the views of employers “that skills training offered at their organisations must be aligned with broader labour market needs, so as to support innovation and internal job mobility”. By aligning learning opportunities with real-world skills needs, organisations can build agile workforces capable of adapting to technological change, fostering innovation from within, and ensuring long-term employability for workers.

### **Scope & Objectives**

Embedding skills and talent development as a key objective will strengthen the *National Life Sciences Strategy* and ensure long-term success. Ireland is recognised internationally as a centre of excellence for life sciences due to the availability of its highly skilled, adaptable, and mobile workforce.

In October 2025, the European Commission’s new life sciences strategy, [Choose Europe For Life Sciences](#), recognised the criticality of skills provision to the sector’s long-term competitiveness and called on Member States to strengthen national programmes that embed innovation and entrepreneurship in key life science sectors. The strategy committed to launch a foresight study to identify the competences, skills and training needs for the life sciences, including for optimising the uptake of artificial intelligence.

Skills are dynamic and can become dated meaning a persistent focus must be maintained on the development of our workforce. There is a need to ensure the skills base reflects not just the current business demands of the sector but the challenges of future growth in areas such as advanced manufacturing, digital health, AI-driven innovation, regulatory evolution, and sustainability, and to ensure Ireland remains competitive and agile in an evolving healthcare and technology landscape.

From a skills and talent perspective, the scope of the *National Life Sciences Strategy* should be broad and integrated, reflecting the interconnected nature of modern biosciences where scientific and technological breakthroughs increasingly rely on overlapping talent pools. Accordingly, the Strategy should highlight the essential role of enterprise in cultivating this talent base, including through collaboration with Skillnet Ireland. Skillnet Ireland's enterprise-led learning model has proven highly effective in aligning training with the evolving needs of industry. In the context of rapid technological advancement and changing regulatory environments, the prioritisation of upskilling and reskilling is essential and Skillnet Ireland's model of co-investment and collaboration with enterprise is well-positioned to support this.

A broad scope ensures that Ireland builds talent pipelines capable of supporting convergence areas including biopharmaceuticals, biotechnology and advanced therapies; clinical research and translational medicine; medical devices, technologies and digital health; ag-bio, food innovation, and the bioeconomy. This breadth of expertise will enable Ireland not only to sustain existing strengths but also to capture emerging opportunities at the intersection of biology, technology and data. A broad scope also aligns with the EU's vision for a coherent and integrated framework for the life sciences to enhance policy alignment and cross-sector collaboration.

### **Skillnet Ireland Business Networks**

Skillnet Ireland reflects the multisectoral nature of Ireland's life sciences ecosystem through its range of dedicated Skillnet Business Networks, namely Irish Medtech Skillnet and BioPharmaChem Skillnet, but also ICBE Advanced Productivity Skillnet and First Polymer Training Skillnet, both of which play a vital role in the sector's overall competitiveness and innovation capacity. Through deep industry collaboration, these networks design and deliver responsive, bespoke, and flexible training programmes that address the rapid skills demands created by digitalisation and scientific advancement, enabling innovation to thrive.

#### **Irish Medtech Skillnet**

Irish Medtech Skillnet is a key enabler within the Medtech ecosystem, driving sector growth and transformation through industry-led insights, early identification of emerging skills, and the co-creation of programmes that are aligned with evolving needs. The Medtech industry is entering a period of significant transformation, shaped by digital health, evolving regulatory

landscapes, sustainability demands, and technological advances such as AI and data-driven innovation. Irish Medtech Skillnet is supporting the sector to accelerate its ability to adapt, collaborate, and lead through this transition through the design and delivery of specialised training in digital transformation, regulatory affairs, quality assurance and sterility assurance methodologies for medical technologies, complemented by programmes which develop management and leadership capacity and strengthen strategic thinking and productivity.

New programmes co-developed by Irish Medtech Skillnet in partnership with academic institutions include:

- MSc in Medical Technology Regulatory Affairs (Level 9, ATU)
- MSc in End-to-End Sterility Assurance (Level 9, ATU)
- MSc in Digitalisation of Manufacturing
- BEng in Advanced Manufacturing (Level 8, ATU)

#### **BioPharmaChem Skillnet**

BioPharmaChem (BPC) Skillnet provides subsidised upskilling programmes to businesses of all sizes in the pharmaceutical, biopharmaceutical, medical device, and chemical supply sectors. The network's mission is to advance Ireland's position as a world leader in health innovation through the provision of cutting-edge talent development solutions. For example, the Network, together with TU Dublin has championed the use of Virtual Reality in learning for aseptic technique and chemical handling. Through the use of virtual reality headsets, the course gives a detailed, immersive, and engaging training and learning experience in developing the core competencies, standards and techniques required in the BioPharmaChem manufacturing sector.

Other programmes include:

- An Introduction to Biopharmaceuticals & Advanced Personalised Therapies (Level 8 micro-credential, UCC)
- Higher Diploma in Science in Biopharmaceutical Manufacturing (Level 8, Dundalk Institute of Technology)

#### **First Polymer Training Skillnet**

First Polymer Training Skillnet supports the use of polymer technologies within the polymer processing, medical device and manufacturing engineering sectors. The Network's mission is to advance the growth of Ireland's internationally recognised polymer industry through targeted talent development programmes. In 2021, Skillnet Ireland launched the expansion of the First Polymer Training Skillnet Centre of Excellence in Athlone. Using state-of-the-art equipment, the centre showcases the latest in robotics, automation, and smart support technologies to businesses in the polymer, manufacturing and engineering industries, many of which are SMEs.

### **ICBE Advanced Productivity Skillnet**

ICBE Advanced Productivity Skillnet is a multi-sector business Network for companies of all sizes in a broad range of industries including manufacturing, food, medical devices, pharmaceutical, and financial services. The Network's mission is to improve the business performance and competitive advantage of enterprises through subsidised upskilling programmes relating to innovation, process improvement, Lean and Six Sigma strategic deployment.

Across Ireland's agri-food sector, a number of Skillnet Ireland networks are playing an important role in strengthening the sustainability, competitiveness, and resilience of food systems and emerging bio-based industries. While each network has its own focus area, they collectively help farms, food producers, co-operatives, and rural enterprises to adopt environmentally sound practices, innovate, and build future-ready skills. For example:

**Farm Business Skillnet** supports farmers in adopting more efficient and sustainable farm management practices. Through training in financial planning, smart farming technologies, regenerative agriculture, and labour efficiency, it helps farmers build economically viable operations while reducing environmental impact.

**National Organic Training Skillnet (NOTS)** focuses on expanding skills in organic and regenerative production. It promotes soil health, biodiversity, low-input farming, and climate-friendly production systems by providing training in organic horticulture, livestock management, agroecology, and sustainable land stewardship.

**ICOS Skillnet** serves Ireland's dairy and agri-cooperative sector, equipping co-ops with expertise in sustainable supply chains, environmental management, renewable energy, governance, and resource efficiency. This strengthens the resilience of co-operative businesses and supports sustainability across entire value chains.

**Macra Agricultural Skillnet** supports young farmers and rural professionals in building the knowledge and competencies needed for the future of farming. Programmes include sustainable livestock systems, climate-smart agriculture, digital tools for farm monitoring, and leadership skills to drive long-term resilience in the sector.

**XLVets Skillnet** strengthens sustainable veterinary and animal-health practices. By advancing skills in herd health planning, responsible antibiotic use, biosecurity, and animal welfare, the network contributes to healthier livestock systems with lower environmental pressures.

## Opportunities and Challenges

### Talent Development

Over the next decade, Ireland's life sciences sector will face a convergence of major opportunities and challenges and Ireland's ability to navigate the evolving global landscape and secure its future competitiveness will hinge on establishing lifelong learning pathways for the sector, underpinned by a forward-looking, industry-informed skills strategy.

Digital transformation represents one of Ireland's greatest growth opportunities and Ireland is well-positioned to become a global centre of excellence for digital health given its strong base of life sciences and ICT companies. Advanced technologies including AI, robotics, automation, cybersecurity, and cloud computing, are deepening scientific understanding and enabling breakthroughs across biology, neuroscience, and biotechnology. Furthermore, with the OECD estimating that one-fifth of global healthcare spending is wasted due to inefficiencies, digital health presents a powerful opportunity to reduce costs, expand access, and improve patient outcomes. This potential will only be realised however if the workforce develops the specialised skills required by this rapidly evolving field.

Irish businesses recognise the challenges and opportunities offered by accelerated digitalisation with 57% of respondents to the [2025 Ireland's Talent Landscape Report](#) identifying their company as either "advanced" or "very advanced" digitally. The desire from large businesses for more specialised digital skillsets is trending upwards with a noted increase across a multitude of digital specialist skillsets.

This research report delved into the uptake of AI within enterprise in Ireland, with the aim of assessing the rate of AI adoption. It also identifies skills gaps related to AI implementation, and understanding the barriers facing businesses to successfully integrating AI into their business.

Different levels of AI usage between sectors of the economy are evident, as expected, with 29% of businesses in the tech sector reporting daily AI usage compared to just 14% of manufacturing enterprises, and 13% of businesses in the food industry. Only 7% of business leaders reported their workforce being "very skilled" in AI compared to 41% who claimed their employees were "not at all skilled". Access to the required AI and data skills (73%) is the greatest barrier to implementing AI for Irish business followed by security concerns (68%) and implementation issues (62%). According to respondents, the skills most in demand to implement AI into a business are critical thinking (48%), followed by cyber-security and AI (46%), and data analysis (46%). The uniquely human transversal skills of creativity and problem solving are furthermore cited by two-thirds of businesses when it comes to accelerating AI.

As medtech, biopharma, and start-ups expand into digital health, companies are diversifying their workforce, creating new roles and upskilling existing employees. Supporting businesses, and particularly SMEs, to unlock the potential of AI will become increasingly important to maintaining Ireland's capacity to compete globally. Maintaining a highly skilled pipeline of employees with AI and other advanced digital skills, is critical to achieving this goal and securing Ireland's reputation as a high-performing economy and hub of innovation for emerging technologies

Irish Medtech Skillnet's 2026-2028 strategy [\*Talent to Thrive – Powering Excellence\*](#) sets out a clear roadmap for addressing these evolving needs. The strategy emphasises the critical importance of talent availability and outlines practical measures to build a future-ready workforce capable of sustaining Ireland's global leadership in medtech innovation and investment. Similarly, BioPharmaChem Skillnet recently launched the [\*BioPharmaChem Skills Framework\*](#) at the recent BioPharma Skills Forum, a major step forward in shaping the future of skills and workforce development across Ireland's BioPharmaChem sector. This pioneering initiative, funded by Skillnet Ireland and developed in collaboration with skillsvista and industry partners, was created in response to a recommendation from the Expert Group on Future Skills Needs (EGFSN) report *Skills for Biopharma*. The Skills Framework provides a clear, structured and future-focused overview of the sector's key roles, pathways and competencies, bringing together vital information on workforce profiles, industry trends, and the skills required across supply chains. It is designed to support both individuals and organisations in navigating a rapidly evolving skills landscape, enabling better planning, stronger talent pipelines and a more agile, future-ready workforce.

A cross-sectoral study *Where Digital Health Thrives: Future Skills Needs 2023–2026*, developed by HealthXL with Connected Health Skillnet, Ibec's Irish Medtech Association, and BioPharmaChem Ireland, further extends this foresight. It identifies the precise skills needed to design, develop, and commercialise digital health products and services, offering critical insight to capturing the massive global growth potential in digital health. While Ireland excels in manufacturing and R&D, commercialisation and go-to-market skills, particularly in digital health, remain underdeveloped compared to global competitors. Our Skillnet Business Networks aim to enhance the capability of Ireland and Irish based companies to become recognised global leaders in the development and commercialisation of innovative solutions and ensure Irish innovations successfully reach global markets.

Irish Medtech Skillnet has furthermore added crucial thought leadership to national strategic planning through its recent publication [\*Moving Upstream – Disease Prevention as a Strategic Opportunity for Irish Medtech Innovation\*](#). This research underscores the economic and societal value of upstream healthcare innovation, focusing on prevention, early diagnostics, and real-world evidence. By anticipating global trends, it positions Ireland to develop

technologies that support more sustainable, efficient, and person-centred healthcare systems, an imperative as ageing populations and chronic diseases increase healthcare demand.

### **Promoting Diversity**

Addressing gender imbalance across STEM remains a strategic priority. Earlier this year, First Polymer Training Skillnet, Irish Medtech Skillnet, and Connected Health Skillnet collaborated on the publication of [\*Empowering Women in STEM\*](#) report which highlights significant disparities, especially in leadership and advanced technical roles. With women making up only one in four STEM professionals and just 19% of CEOs in large enterprises, decisive action is needed. Strengthening and diversifying Ireland's STEM talent pipeline is essential for innovation, productivity, and equity and Skillnet Ireland and its Networks are committed to supporting women in STEM through targeted development opportunities that foster inclusion and help unlock the full potential of Ireland's workforce.

BioPharmaChem Skillnet furthermore published *Building Action through Data - An analysis of Equality, Diversity & Inclusion (EDI) in the BioPharmaChem Industry in Ireland* which provides a snapshot of the diversity landscape within the BioPharmaChem Sector in Ireland in order to understand the key challenges within the current talent pipeline. As an industry with talent shortage challenges, it offers practical takeaways to enable businesses in all sectors to increase talent retention and growth within their organisations by creating a more diverse and inclusive culture.

### **Boosting SME Participation**

Although multinational companies continue to anchor Ireland's life sciences success, SMEs represent an untapped engine of innovation. Many face barriers to accessing sector networks, training supports, and innovation pathways. Facilitating regional talent development is furthermore essential to maintain Ireland's competitiveness and sustainability within the regions. Skillnet Ireland operates across all regions of Ireland, ensuring businesses and professionals nationwide have access to the skills and expertise needed to remain competitive. In addition, many of the sectoral Skillnet Business networks form centres of excellence in strategic regions such as Biopharmachem Skillnet in Cork and Medtech Skillnet in the Midwest, strengthening the capacity for knowledge-sharing across private sector businesses of all sizes and working together to meet the emerging talent and skills needs of their regions.

The *National Life Sciences Strategy* could include targeted measures to simplify SME access to talent and innovation supports. For example, Skillnet Ireland is currently working with the Department of Further and Higher Education, Research, Innovation and Science (DFHERIS) on the rollout of a targeted SME incentivisation scheme aimed at reimbursing the cost of upskilling and reskilling of employees. The scheme aims to boost SME participation in lifelong

learning and the development of critical future-ready skills, including those demanded by the digital transition.

## **EU Context**

The ambition of the *EU Life Sciences Strategy*, to make Europe the world's most attractive location for life sciences by 2030, closely aligns with Ireland's national goals and presents significant opportunities for strategic alignment. The new *EU Life Sciences Strategy* aims to boost competitiveness, accelerate green and digital transitions, create jobs, and reduce external dependencies by rapidly developing and commercialising innovative ideas and solutions.

The Strategy recognises skills as a key strategic enabler and proposes “strengthening skills and careers” as a key action to foster a dynamic and competitive European life sciences ecosystem. As part of this, the European Commission will launch a foresight study to identify the competences, skills and training needs for the life sciences, including for optimising the uptake of artificial intelligence. With €1 million financial support from the Horizon Europe work programme 2026-2027, the study will complement relevant data and analysis by the European Skills Intelligence Observatory.

The European Commission encourages Member States to strengthen national programmes that promote innovation and entrepreneurship in key life science sectors, as well as lifelong learning, upskilling and reskilling for professionals in these sectors. Skillnet Ireland actively participates in several EU-funded skills initiatives such as the Pact for Skills, Horizon Europe, and Digital Europe. Skillnet Ireland, together with leading European universities, research centres, and industry partners, recently launched the [\*Sustainable Healthcare with Digital Health Data Competence \(SUSA\)\*](#) initiative – a Digital Europe programme - to address the growing need for advanced digital skills in healthcare. SUSA will deliver 30 Bachelors and 26 Masters programmes, along with 16 standalone digital skills modules, across 12 institutions in nine European countries, including UCD, UL, and Trinity College Dublin. These offerings aim to produce over 6,500 graduates and upskill 660 professionals with essential competencies in data, AI, cybersecurity, IoT, sustainability, regulation, and global health.

## **Conclusion**

The next decade will bring powerful opportunities. By embedding talent development, strategic foresight, commercialisation capability, and inclusive growth at the heart of the *National Life Sciences Strategy*, Ireland can secure its position as a global leader in medtech, biopharma, and digital health innovation.

Through continued collaboration, investment, and coordinated skills development across industry, academia, and the health system, Skillnet Ireland is committed to supporting the Department in ensuring Ireland's life sciences workforce will remain future-ready, resilient,

and equipped to thrive in a rapidly evolving global landscape and secure Ireland's continued success as a global life sciences leader.

### **About Skillnet Ireland**

Skillnet Ireland is the national business support agency of the Government of Ireland with a mandate to spearhead talent development for enterprise. Through our partnerships with key industry representative groups, we drive excellence in workforce development for the workplace of today and the future. Skillnet Ireland has received international recognition as a best practice model from the EU, OECD, CEDEFOP and ILO.

Since its foundation in 1999, Skillnet Ireland works with Irish industry and the education and training sector across a broad range of sectors and regions to identify and address emerging skills challenges and enhance the productivity, competitiveness and sustainability of the Irish workforce. 70 Skillnet Business Networks and five National Talent Initiatives develop upskilling and training programmes to benefit more than 24,000 companies and over 90,000 workers. In 2024, the annual total value of such programmes reached €76 million including €28 million in enterprise co-funding contributions.

Skillnet Ireland is funded from the National Training Fund through the Department of Further and Higher Education, Research, Innovation and Science.

For more information see [www.skillnetireland.ie](http://www.skillnetireland.ie)



### Public consultation on National Life Sciences Strategy – Takeda Products Ireland Ltd response

With close to three decades of innovation in Ireland, and an established position as a global leader in rare diseases, oncology and gastroenterology, Takeda Products Ireland Ltd. welcomes the opportunity to contribute to the development of Ireland's National Life Sciences Strategy, as one of Ireland's leading pharmaceutical employers.

#### Context

Ireland stands at a pivotal moment to shape a future where the Irish life sciences sector drives both economic prosperity and health system transformation.

In the face of geopolitical uncertainty and challenges to Ireland's competitiveness, the publication of a National Life Sciences Strategy offers the opportunity to address the current barriers, and seize the opportunities, by building an ecosystem, grounded in research and innovation which will ultimately lead to improved health outcomes for patients, that protects Irish jobs in the sector, incentivises further investment and positions Ireland as a global leader in pharmaceuticals and life sciences. Crucially, this ecosystem must also foster public trust in the value of sharing health data, ensuring transparency and security in line with the upcoming European Health Data Space regulation. Building confidence among patients and stakeholders is essential to unlock the full potential of data-driven innovation and enable Ireland to participate effectively in EU-wide health data initiatives.

#### Scope

*Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?*

On the question of scope, Takeda believes that the National Life Sciences Strategy (NLSS) should focus specifically on human health; namely (bio)pharmaceuticals, medical technologies, and the digital health sector [collectively referred to hereafter as 'the sector'].



The sector plays a vital role in the Irish economy, supporting over 100,000<sup>1</sup> high-income jobs, accounting for €99.9 billion euro in exports<sup>2</sup>, and is one of the top three contributing sectors.

Despite the sizeable economic impact of the sector on the Irish economy, there has been an absence up until now of a dedicated national life sciences strategy. To maintain Ireland's position as a global leader in Life Sciences, it is essential to develop a timely and focused Life Sciences strategy that keeps Ireland highly attractive for future investment.

Furthermore, a narrower interpretation of 'Life Sciences' for the purposes of this strategy ensures that the strategic pillars and policy recommendations can be more focussed, and thus more effective.

With respect to implementation and oversight of this strategy, we recommend a collaborative approach between industry, academia, patient organisations and government, to ensure that the strategy is aligned and applicable to the operating environment, and reflects the realities, opportunities and challenges of the sector on the ground. This collaborative approach should explicitly include mechanisms for public-private partnerships focused on ethical health data use, interoperability, and secure sharing frameworks, reinforcing Ireland's leadership in responsible data-driven healthcare innovation.

Taking inspiration from the Department of Jobs, Enterprise and Innovation and its first Action Plan for Jobs in 2012, key targets and recommendations need to be established. In addition, the stakeholders owning those actions should be clearly identified along with timelines. Regular bi-annual implementation reports should be produced taking account of progress and any bottlenecks.

## **Objectives**

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability.*

---

<sup>1</sup> [IDA Ireland acknowledges economic and social impact of multinational companies with special focus on life sciences industry](#), IDA, 2023

<sup>2</sup> [Goods Exports and Imports December 2024](#), CSO, 2025



The key objective of the NLSS should be to ensure a future ready, patient-centred, dynamic life sciences ecosystem, which connects cutting-edge research, innovation, diagnostics and digital health technologies with patient needs; which ensures rapid access to and adoption of new innovation and which supports Ireland's thriving manufacturing footprint by maintaining a competitive operating environment.

The NLSS should lay a roadmap for the sector that:

- Articulates an ambitious, long-term vision for the sector, providing clarity and confidence for stakeholders, policymakers and the health system.
- Strengthens Ireland's value proposition and economic competitiveness, with a particular focus on research excellence, digital readiness and advanced manufacturing.
- Enables structured, collaborative partnership models between the public and private sectors, allowing innovation to move more efficiently from research settings into clinical practice and improving patient outcomes.
- Embeds trust-building measures for health data sharing, including transparent governance, patient engagement, and compliance with the European Health Data Space regulation, ensuring Ireland is positioned as a trusted hub for secure data exchange and research collaboration.
- Addresses systemic barriers to growth, including clinical research bottlenecks, digital infrastructure gaps and broader national infrastructure constraints, to unlock new opportunities for expansion.
- Builds a robust, responsive talent pipeline, supported by targeted training, apprenticeships, industry placements and upskilling pathways aligned with the sector's evolving capability needs.
- Creates an operating environment that positions Ireland as a leader in RD&I, supported by a coherent policy framework, predictable regulation and strong connectivity with European research and funding programmes.
- Ultimately delivers improved public health outcomes, ensuring timely and equitable access to transformative therapies, diagnostics and digital tools.

Taken together, these objectives would ensure that Ireland remains innovative, competitive and resilient, optimising benefits for patients, the health system and the wider economy.

### **Opportunities and challenges**

***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***



The Irish pharmaceutical sector is at a key moment. While advances in research, Artificial Intelligence (AI), and understanding of disease pathways offer significant opportunities, the sector also faces structural and regulatory challenges. Ireland's strong track record in innovation and its established leadership in biopharmaceutical, medtech and digital technologies provide a solid foundation from which to build opportunities for the future.

Outlined below are three core recommendations, founded in the opportunities and challenges for the sector:

### **1. Strengthen Ireland's research, innovation and clinical trials ecosystem.**

Ireland's future competitiveness in the life sciences sector will rely increasingly on the strength of our research and clinical infrastructure, complementing our established reputation for manufacturing excellence. To stay at the forefront, Ireland should enhance public investment in research and innovation, foster innovation in data systems and regulatory sandboxes, strengthen links between academia and industry, and modernise the national clinical research system.

A particular opportunity lies in clinical trials. Ireland performs well in certain therapeutic areas but lags behind comparable European countries in overall trial volume, due to our fragmented infrastructure, variable site readiness, and slow study start-up timelines. This is especially pronounced in rare diseases, where small patient numbers make trial feasibility challenging.

The national strategy should therefore establish streamlined ethics and contracting processes, expand the use of decentralised and adaptive trial designs, and support national patient registries that can allow Ireland to participate in multi-country disease studies, and could help integrate Ireland into pan-European clinical trial networks.

### **2. Position the health system as a structured innovation partner through a national public-private collaboration framework.**

The fundamental objective and motivation of the life sciences sector is to improve patient outcomes.

Ireland has a unique opportunity to leverage its life sciences sector as an engine for innovation within the health system, improving patient outcomes while reinforcing the State's attractiveness for investment. To unlock this, the strategy should introduce a formal national framework to support collaboration between public and private entities, including but not limited to pharmaceutical companies, medtech firms, digital solution providers, academia, the HSE, and patient organisations.



Such a framework should clearly set out standard approaches for early scientific engagement, co-development of pilot projects, ethical use of health data, real-world evidence generation and outcome-based access agreements.

A critical opportunity lies in leveraging health data responsibly to accelerate research and innovation. To achieve this, Ireland must prioritise initiatives that build societal trust, ensure robust data protection, and enable interoperability with EU systems under the European Health Data Space framework. Public-private partnerships will be key to delivering these capabilities at scale.

Complementing this, rapid investment and scaling up in Ireland's digital health infrastructure (specifically electronic health records, patient registries and our data analytics capability) will be essential to enable Ireland to participate fully in European data-sharing initiatives and to accelerate innovation in care pathways.

By treating the health service as an active innovation partner rather than a passive adopter, Ireland can build a collaborative and patient-centred life sciences sector. This aligns with international best practice and would help the country capture high-value clinical, digital and research activities.

### **3. Future-proof competitiveness through talent, digital transformation and sustainable advanced manufacturing**

Sustaining Ireland's leadership in life sciences will require focused action on talent, digital capability and sustainable manufacturing.

Ireland's life sciences sector faces a need to build a robust talent pipeline as AI, automation, and data-driven processes transform global operations. There is growing demand for STEM skills in bioprocessing, data analytics, automation, and digital technologies. Addressing these gaps requires a coordinated national response through deeper partnerships between industry and education to co-create curricula, apprenticeships, upskilling programmes, and work placements. Promoting STEM among underrepresented groups and attracting global talent will also be critical. The National Life Sciences Strategy should therefore include a dedicated skills pillar, developed in collaboration with the Department of Further and Higher Education, Research, Innovation and Science, to ensure education and training pathways, including apprenticeships and industry placements, evolve in line with industry needs.



At the same time, competitiveness will increasingly depend on digitalisation and meeting sustainability goals. Manufacturing sites need supportive policies and infrastructure to adopt low-carbon, energy-efficient, and digitally enabled processes. While energy capacity constraints, high costs, and decarbonisation requirements pose risks, they also create an opportunity for Ireland to lead in green, resilient biopharma production. To achieve this, the strategy must prioritise expanding grid capacity, improving access to renewable energy, and accelerating investment in advanced manufacturing technologies, digital infrastructure, and site-level energy efficiency.

Such interventions will be essential enablers of the sector's future performance, helping Ireland maintain its attractiveness for next-generation life sciences.

### **EU context**

*The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?*

The ambition to position the EU as the world's most attractive location for life sciences by 2030 is welcome, and alignment between the EU and national strategies is critical.

If Ireland is to contribute and benefit from the EU strategy, at a national level, we must:

- Establish a standardised, efficient clinical trials model with dedicated funding, enabling Ireland to attract more complex, innovation-driven studies and participate fully in EU-wide research networks.
- Invest in our digital health infrastructure, which is essential for real-world evidence generation, data interoperability and participation in EU digital health and data initiatives. Alignment with the European Health Data Space should be a cornerstone of Ireland's strategy, enabling secure cross-border data flows and collaborative research. Ireland must invest in governance models that reassure patients and stakeholders about privacy and ethical use, while fostering partnerships between industry, academia and the health system to unlock the full potential of shared data.
- Introduce a structured framework for public-private partnerships involving research institutions and the HSE, allowing Ireland to leverage industry expertise to co-develop innovation, accelerate pilot programmes and improve system readiness for advanced therapies. By addressing these priorities, Ireland can unlock further opportunities for growth and innovation.

At the same time, strategic alignment with the EU Life Sciences Strategy remains essential. Streamlined regulatory pathways, efficient cross-border research frameworks, and continued access to European funding streams will all be crucial. To secure this alignment, a dedicated implementation team should be



established under the NLSS, with responsibility for maintaining strong links to EU institutions, monitoring developments in European life sciences policy, and identifying international best practice, particularly in areas such as public-private collaboration and research excellence, that can be adapted for the Irish context. This could be in the form of a Life Sciences Council, as an example.

This will ensure Ireland remains both competitive nationally and influential within the EU's evolving life sciences landscape.

**Final remarks**

Takeda Products Ireland Ltd. are grateful for the opportunity to contribute to the development of the NLSS and would welcome the opportunity to remain involved in the design and implementation process.

Thank you for your consideration, and we remain open to further engagement at any stage.

# Submission from Teagasc

## Background

Teagasc's mandate explicitly covers research, advisory, and education across the entire food chain, from agriculture to food processing and innovation. Teagasc's Vision is to lead the sustainable transformation of land resources into products and services for society, not solely food or agricultural commodities. The holistic sustainability framework (economic, social, environmental, innovation) requires cross-sectoral integration, consistent with the Life Sciences Strategy's broad definition.

## 1. Scope

Recommended scope for National Life Sciences Strategy

The strategy should:

- Include agri-food, marine, forestry, bio-based processing, bioresources, and circular bioeconomy.
- Recognise Ireland's strength in primary production and food systems, which are essential components of life sciences.
- Integrate One Health perspectives spanning soil–plant–animal–human health nexus, which Teagasc already embeds as a core principle.
- Include bioprocessing, fermentation, biotechnology, and enzymatic conversion relevant to food, feed, and bio-based materials.

A broad scope will prevent the marginalisation of agriculture and food systems, ensuring balanced development across Ireland's life sciences ecosystem.

## 2. Objectives

The National Life Sciences Strategy should consider adopting the following objectives:

***Objective 1: Strengthen Research, Innovation and Translation: Support integrated research–advisory–education systems (AKIS model) to accelerate innovation adoption.***

- Invest in pilot-scale testbeds, demonstration centres, and TRL 5–8 infrastructures across food, marine, and biobased sectors consistent with Teagasc investments in the National Food Innovation Hub, PCF Centre, Food Innovation Hub, National Centre for Brewing and Distilling, and AD demonstration plant.

***Objective 2: Build a Sustainable, Circular, Climate-Positive Life Sciences System***

Aligned with the holistic sustainability concept (economic, environmental, social, innovation), Circular bioeconomy models for valorising agri-food and marine side streams (e.g., fermentation, biorefinery). Promote climate adaptation and resilience strategies

***Objective 3: Talent, Skills and Capacity Development***

Skills in sustainability, digitalisation, entrepreneurship, biotechnology, advanced processing, Alignment of educational programmes with future land-based sector needs.

***Objective 4: Support Competitiveness, Diversification and Regional Development***

- Facilitate new value chains in horticulture, tillage, forestry, seafood, organics, and new bioeconomy sectors. Strengthen innovation capacity of SMEs and rural enterprises using advisory, education and research networks.

***Objective 5: Promote One Health and Healthy, Sustainable Diets***

Integrate soil, animal, environmental and human health under a One Health framework (e.g. Farm-to-Gut systems), Support food safety, nutrition, antimicrobial resistance mitigation, and healthy food systems.

### 3. Opportunities and Challenges

#### Major Opportunities

1. Sustainable Circular Bioeconomy: Valorisation of grass, crops, meat, marine biomass, forestry residues and food processing side-streams.
2. Bioprocessing, fermentation and green technologies for food, feed and biobased products.
  - Digital, Data and Disruptive Technologies: Precision agriculture, AI, sensors, genomics, digital twins, automation,
  - Growth in Global Demand for Sustainable, Safe, Nutritious Foods: Middle-income markets seeking quality, protein, traceability and provenance will drive the development of Plant based, New Protein and Novel Food Sectors
  - Opportunities for Irish meat, marine and plant-based ingredients, seaweed derived ingredients and products.
  - New enterprises in horticulture, organics, forestry, on-farm processing and local food systems

#### Major Challenges

##### 1. Environmental Pressures

- Meeting climate targets, water quality improvements, biodiversity restoration.
- Need for supporting technologies (mitigation, methane reduction, nutrient efficiency) and advisory uptake

##### 2. Fragmentation of the Innovation Ecosystem

- Need for integrated AKIS networks across research–advisory–industry. Limited demonstration initiatives i.e. creation of to go facilities.

##### 3. Market and Cost Volatility

- Continued impacts of energy prices, and global food market volatility

##### 4. Skills Gaps and Workforce Needs

- Shortages in bioprocessing, food technology, sustainability, data and digital.

##### 5. Disruptive Technologies Impacting Traditional Agri-Food Sectors

- Cell-based foods, synthetic biology, and precision fermentation requiring Ireland to remain competitive with new value propositions.

#### 4. EU Context

Ireland national strategy should align closely with the EU Life Sciences Strategy while ensuring that Ireland's food, agriculture and bioresource sectors receive full recognition and support. The EU Life Sciences Strategy aims to position Europe as the most attractive global region for life sciences by 2030. Ireland can apply EU measures effectively by leveraging its agri-food, marine and bioeconomy strengths.

#### Teagasc perspective on the EU ambition

- EU Green Deal, Farm-to-Fork, Biodiversity Strategy and Circular Economy Action Plan align with Teagasc's sustainability focus
- Ireland is well-positioned to lead in sustainable food systems, circular bioeconomy, and One Health.

- EU measures could be applied in Ireland by Accelerating Sustainable Food System Transition, adopt EU-compliant sustainability metrics, emissions reduction pathways, and food system transformation frameworks.

## 2. Strengthen Cross-Sector R&I Platforms

- Support integrated research across food, agriculture, biotech and health.
- Fund translation of innovations through Teagasc testbeds, PCF Centre, National Agricultural Sustainability Research and Innovation Centre.

## 3. Invest in Circular Bioeconomy Infrastructure

- Scale biorefineries and pilot plants.

## 4. Build Regulatory and Innovation Capacity

- Support novel food approval readiness, AMR policies, sustainability certification, and food safety innovation.

## 5. Enhance Skills, Data and Digitalisation

- Align with EU digital and green skills agendas.
- Expand digital advisory and data-driven services

## Summary

Teagasc recommends that the National Life Sciences Strategy:

- Adopts a broad scope fully integrating agri-food, bioeconomy, environment and marine with medtech and biotech.
- Prioritises sustainable food systems, circular bioeconomy, innovation, digitalisation, and One Health.
- Fosters research–advisory–education integration to accelerate real world industrial adoption.
- Leverages Ireland’s unique strengths in its natural bioresources, scientific excellence and rural innovation networks.

## Submission from University College Cork School of Microbiology

### Scope

Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.

### In your view, how broad should the scope of the strategy be?

The premise of the statement that “Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production” is that the term “life sciences” refers to the application of scientific knowledge. This is a narrow interpretation because “life sciences” has long been taken to refer to the study of biological systems, generating knowledge that can be applied in multiple sectors, such as those listed. This may seem semantic but it does have implications when it comes to considering the objectives of a Life Sciences strategy.

In terms of the scope, and the intention that the life sciences strategy can stimulate economic activity in life sciences sectors, my view is that the scope should be broad and cover all the sectors where relevant knowledge can be applied for economic, environmental or broader societal benefit. In addition to the sectors mentioned above and also **industrial biotechnology** and the **bioeconomy**.

### Objectives

### What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?

*For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

#### 1. Research and innovation

Increasing the national base of research should be the main priority of the strategy. It is well documented that Ireland invests less in , and therefore performs less of, research than the economies that we aspire to compete with. Increasing the research base will inevitably generate the knowledge that can be applied in particular sectors.

#### 2. Talent

The centrality of talent is incontrovertible and supporting and securing talent must be a key

objective. The most important talent is indigenous talent and this will be the backbone of the life science sector. Internationalisation and attracting global talent is also a hallmark of the most successful sectors so this should be a second plank – it is achieved by ensuring good local talent in the first place, and a research and innovation system that is both encourages local talent to remain and attracts international talent.

### 3. Increase global competitiveness in key sectors

While the strategy should be broad enough to support research in multiple sectors, it should be recognised that there are some sectors where Ireland has particular opportunities. These include biotechnology in the broad sense, and specifically in areas like biopharmaceuticals, medical technologies, food biotechnology, industrial biotechnology and bio-based production.

### 4. Support the transition and transformation of society to secure a sustainable future

This objective addresses the use of life sciences knowledge to bring solutions that enhance sustainability, mitigate environmental damage and climate change, and offer new economic and societal models based on a defossilised future.

## Opportunities and challenges

What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?

### Opportunities

There is a major opportunity in the biotechnology and biomanufacturing space beyond pharmaceutical biotechnology (which itself also offer opportunities). I am particularly referring to the sectors broadly described as food biotechnology and industrial biotechnology. In both cases, new technologies, the desire to move to more sustainable production methods, and the alignment of policy and finance mean that there is substantial growth potential. They are anchored in areas like food science, microbiology and biochemistry where Ireland is traditionally strong. With the right investment and focus, Ireland could be a global leader. This sector encompasses other fields of

research inducing AI, data analytics and engineering. Embracing this interdisciplinary aspect is important.

The opportunity for biotechnology and biomanufacturing in Ireland has been recognised in multiple independently-commissioned reports conducted in Ireland in the last 2 years. In particular, the Cork Biomanufacturing Park dac conducted a study (funded by Enterprise Ireland Smart Regions Scheme) that highlighted how the confluence of geographical assets, and resources, expert communities of practice in research and engineering, and other factors provide an immediate opportunity to promote this sector in Ireland. This would need to be underpinned and supported by the Life Sciences strategy to ensure the ongoing research, knowledge, innovation and people, to support the biomanufacturing ecosystem.

To truly develop the life sciences sectors, Ireland must support research at all TRL levels and even research that is not obviously on a path to any particular application. For the latter, it should be recognised that many of the biggest breakthroughs have come from fundamental research, but more importantly, deep fundamental knowledge underpins successful application of the knowledge. That is not enough, however, and research along the full innovation value chain needs to be supported.

There is an opportunity with this strategy to make Ireland a much more attractive place for research to be performed. This will attract and retain talent. Obviously one part of this is the provision of research funds, but other dimensions need to be considered as well. The woefully inadequate funding for equipment and infrastructure was recognised in the recent working group on this topic, and actioned through the INSPIRE programme. This strategy, in particular supporting shared research facilities (“research infrastructures”) should be a priority. Research conditions, in particular the uncompetitive PhD stipend, and lack of employment contracts for PhD students, should be addressed.

## Challenges

Unrealistic expectations and short-term thinking are a challenge. Funding in Ireland has never been at the required level to compete internationally, but in addition it has been inconsistent and sporadic. The strategy should recognise that supporting the sector is a long term play and funding

needs to be on a sustained and coherent basis. The implicit logic of some thinking not so long ago that “we invested in fundamental research for 10 years and now need to cash in” is nonsense to anybody who understands the role that research plays in advanced economies

There needs to be greater recognition that research is expensive and adequate funding needs to be made available. This is a particular challenge when it comes to areas like biotechnology and biomanufacturing where access to pilot and scale-up facilities require more resources that have been made in the past.

Limited equipment and infrastructure – this was highlighted above and steps are being taken to address the problem – but them must be sustained.

#### EU context

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world’s most attractive location for life sciences by 2030.

What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

The EU Life sciences strategy has the same focus as that of Ireland, which is mainly the application of life sciences in specific sectors. Overall, it is a strong document that highlights many areas where Ireland is strong and where we would already be aligned (e.g. One Health, Microbiome). It is interesting that one of the areas called out is “Life sciences as a driver for industrial sustainability”. This addresses the areas of industrial biotechnology mentioned above. Given the momentum that will come from the Biotech Act and related policies, it makes a lot of sense for Ireland to align its strategy in this aspect.



# **Ireland's National Lifesciences Strategy Consultation process**

## **Contribution of University College Cork**

## Introduction

Ireland has a thriving life sciences ecosystem, leading globally in life sciences and associated health tech innovation. The ecosystem has grown rapidly over the past twenty years, enhancing its scale, breadth (including diagnostics, Medtech, Pharma, Biopharma, Cell & Gene Therapy, Food and Agriculture) and level of activity. Moving from a mainly manufacturing focus, Ireland has grown significantly in the strategic earlier stages of the product cycle (process development and R&D), growing the importance of Irish sites within global corporations as more R&D and other high value activities are attracted to Ireland. While a very welcome evolution, Ireland has yet to fully grasp the opportunity this presents.

Ireland is home to more than 700 life sciences and Medtech companies - a mix of locally developed companies and leading multinationals, that includes the world's top 10 biopharma companies, the world's top 10 tech companies and 9 of the world's top 10 Medtech companies, most of which have a lengthy heritage in Ireland<sup>3</sup>. Additionally, Ireland is Europe's second largest exporter of Medtech products. Ireland's focus on the manufacture of small molecule products has, evolved to position Ireland as a leading hub for biologic medicines and vaccines, with the sector attracting >€15 billion in biopharma foreign direct investment in the last decade, ~25 large-scale biologics facilities, employment of ~50,000 people and exports worth > €100 billion.

In the current complex and dynamic climate of geopolitical uncertainty and technological progression, it is incumbent on the National Life Sciences Strategy to leverage Ireland's success to develop an expanded, integrated and comprehensive life sciences ecosystem for the prosperity and wellbeing of our citizens.

University College Cork (UCC) particularly welcomes this opportunity to contribute to the development of Ireland's National Life Sciences Strategy. As an institution deeply rooted in both scientific excellence and social and sustainable responsibility, we recognise the significance of this strategy in shaping the future of the fundamental and translational research and innovation across the life sciences value chain. Our response is based on our long-standing relationships and leading experience of academe, industry and clinical engagement across the life science value chain. It also reflects UCC's commitment to ensuring that life sciences in Ireland develop not only as an engine of economic growth, but also as a sector firmly anchored in ethical, sustainable, practice, education, and public well-being across all areas of society.

## Scope & Objectives - Our recommendations

Our response to the scope and objectives is collated within the following objectives:

### 1. Broaden the scope and connecting the life sciences value chain

---

<sup>3</sup> Enhancing the R&D Tax Credit Scheme for Ireland's Medtech Sector, IBEC, 30 May 2025

In the life sciences, the pathway from idea to product, process or procedure and ultimately to the patient is long, complex, fragmented and highly regulated. Investment in platforms that **diversify Ireland's life sciences activity beyond manufacturing** to include upstream research, drug discovery, target identification, device and therapy development, biotechnology, diagnostics, digital health, personalised medicine, predictive and precision healthcare and therapeutics, clinical trials, regulatory science, and the bioeconomy is a critical component of the National Life Sciences Strategy. Our deeply embedded industry presence, once focussed primarily on manufacturing is expanding into Research and Development (R&D), albeit at a slow pace. By more actively linking the established manufacturing base to upstream research, innovation and skills, we will capture more value from our life sciences pathways and move jobs in the sector up the value chain from basic manufacturing to highly skilled research and development. Potential approaches include:

- Supporting, scaling and connecting the existing ecosystem to provide for a fundamental and cohesive framework of expertise, capacity, infrastructure and collaborative engagement
- Build strong discovery-to-impact capacity (“bench to bedside”), supporting life sciences research across the translational pipeline and across all Technology Readiness Levels (TRLs)
- Move towards best practice exemplar structures, where cluster organisations, innovation districts and coordinated test bed infrastructure drive high value growth

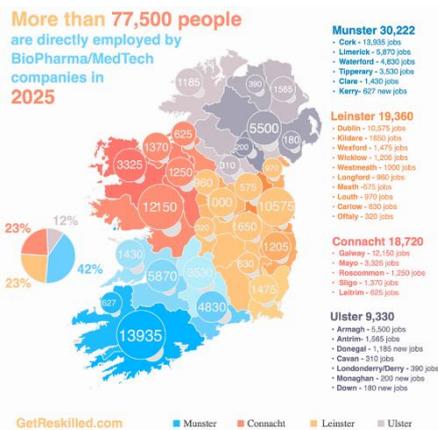
## 2. Become a Visible Global Hub

Ireland currently lacks a single, visible ‘shop window’ for its life sciences capability across the full value chain. At present, activity is perceived internationally as fragmented and heavily dominated by manufacturing. Given the critical mass of companies and the strength of our regional research and clinical ecosystems, the National Life Sciences Strategy should drive the coordination and consolidation of activities to provide a point of focus for global engagement. Specifically, Ireland should:

- **Develop a coordinated Life Sciences hub** that gives Ireland an international profile equivalent to peer regions such as New Jersey or leading EU bioclusters, such as the *Vlaams Instituut voor Biotechnologie* (VIB) in Belgium, which is dedicated to fostering excellence in life sciences research and successfully leverages research outcomes for economic growth
- Define and support development of a framework of academic, clinical and industry collaborative activity, with integrated promotion and investor support and dedicated infrastructure, providing an excellent basis for positioning Ireland in areas where it can compete internationally at the highest level
- Support visibility and connectivity through the development of a National Life Sciences ‘Office’ – leading the coordination of activity across the sector

## 3. Strengthen Regional Ecosystems and University–Industry Partnerships

Regional clusters deliver transformational impact across sciences ecosystem, where universities, hospitals, local communities work together to produce meaningful distributed, regionally-balanced ecosystem ensures that opportunities—and benefits—are accessible nationwide. example, Munster hosts a uniquely integrated that provides the foundations for successful and impactful clinical research, multi-specialty trials, advanced therapeutics, digital health innovation, and the rapid new devices and technologies.



the life industry, and impact. A For environment world-class evaluation of

A national strategy should reinforce this model by enhancing the integration between health care, academia, industry and enterprise in a coordinated systems, policy and practice approach. Adopting a unified cross-departmental approach to support linked health system and care needs, research strengths, industrial strategy, and innovation pathways (A, B, C Academic, Business and Clinical), Ireland’s National Life Sciences Strategy can leverage the skills, heritage and potential for enhanced return in an agile, future-proofed healthcare system that delivers for patients and on national priorities. Specific approaches include:

- Supporting translational hubs and testbeds across the country
- Encouraging open innovation and shared infrastructure
- Investing in research facilities that serve both academic and industrial needs
- Enabling SMEs to participate fully in the innovation landscape

#### 4. Place Patients and Public Benefit at the Heart of Activities

Innovation should not happen at a distance from the people it is meant to serve. True engaged research and innovation allows for the development of more meaningful, robust and more sustainable solutions. The strategy should embed patient, citizen and service provider involvement throughout the research and innovation pipeline. Approaches include the:

- Co-design of research priorities
- Continual evolution of solutions to meet evolving needs
- Transparent communication of risks, benefits and outcomes
- Accessibility and affordability of new therapies
- Prioritisation of health equity at every stage of policy development

#### 5. Building a Sustainable, People-Centric, Talent Pipeline

A successful life sciences sector depends on the steady cultivation of knowledgeable, adaptable, and well-supported graduates who are empowered to thrive. Ireland’s current skills landscape is strong, but pressure points are emerging where there is a shortage of highly trained life sciences professionals. Approaches in response include:

- Deepening industry–university collaboration in curriculum design to ensure sufficient industry ready skilled graduates are produced
- The increasing reliance on AI is a transformative force is reshaping life sciences research and innovation, and changing how healthcare is defined, applied and evaluated. The appropriate harnessing of AI across the life sciences must be a primary focus
- Ensuring long-term investment in postgraduate and postdoctoral training to define and lead the research of the future
- Supporting flexible and inclusive learning pathways to widen perspective and participation
- Embedding digital literacy, ethical reasoning, sustainability and other platform skills across programmes

## 6. Supporting national Research That Is Ambitious and Impact-Driven

Ireland has the potential to be a world leader in translational life sciences research, but realising that potential requires sustained, coordinated investment. Research across our small country should be collaborative rather than competitive to ensure the most impactful connection of disciplines, people and ideas can most easily come together. Therefore, to succeed, the *National Life Sciences Strategy* must encompass a whole-of-Ireland perspective, while recognising and leveraging regional ecosystems that already anchor national strength. We encourage a strategy that:

- Promotes inter-, trans- and multi-disciplinary research, recognising the value of intersections between disciplines directly aligned with, and adjacent to, the life sciences
- Protects fundamental discovery research, which underpins long-term innovation
- Provides agile funding mechanisms for emerging technologies, including AI-enabled and AI-driven technologies
- Upholds rigorous ethical frameworks that inspire public trust
- Encourage and support the development of an effective and enabling life sciences Intellectual Property environment in Ireland

## 7. Embed Sustainability

Life sciences can contribute substantially to Ireland’s climate goals if sustainability is designed into processes from the very beginning. A greener life sciences sector strengthens Ireland’s global reputation and future-proofs our industry. UCC recommends:

- Clear sustainability standards for research infrastructure and activities
- Support for circular practices in lab and healthcare environments
- Investment in green technologies
- Encouragement of integrated, cross-sectoral, responses to environmental challenges

## Opportunities and challenges

There is a clear **opportunity** to diversify, expand and intensify Ireland's life sciences activity by building on Ireland's manufacturing strengths, research and innovation leadership and clinical capabilities. Our reputation as a knowledge economy of excellence in a small country that can be agile and responsive to emerging needs – from industry ready talent to the unique benefits of Centres of Excellence across the life sciences value chain - can be a particularly significant positive attractor in an unstable geopolitical landscape. It is therefore key that Ireland continues to make substantive strategic national investment to ensure our environment is as attractive as possible to help FDI prioritise Ireland for future investment, despite external global pressures. Ireland needs to grasp the opportunities that not only maintain and enhance our competitiveness advantages, but also those which will allow us to define a landscape that supports future growth. These opportunities will allow Ireland to '*embed structural shifts that will benefit our economy and people*', a key commitment of the Programme for Government. Areas of opportunity include:

- *Expansion of upstream discovery* and translational research in medicines, advanced therapies and microbiome science
- *Development of MedTech and digital health*, including device design, simulation, digital twins and remote monitoring
- *Creation of integrated test beds* that allow companies to co-design, trial and evaluate innovations within real world, engaged, clinical and community settings, including living laboratories
- *Investment in Core funded Clinical Research Facilities* to deliver clinical trials and other patient focused research across all therapeutic areas - including delivery of cell & gene therapies
- *Coordination of government agencies* activities and opportunities across the breadth of the funding, innovation and entrepreneurial lifecycle would provide a structured pathway for the excellence knowledge generated by our talented researchers to be translated, *via* SME and Multinational routes, to tangible outputs and broad-ranging return on the investment made
- *Growth of indigenous SMEs* that can leverage research outputs and innovation potential for clinical and industrial benefit is critical. Specific support pathways are required to fully leverage the potential of this sector
- *Improve regulatory agility and competitiveness*, maximising stakeholder partnerships, by providing a predictable, streamlined and innovation-supportive regulatory environments, aligning with EU reforms, and ensuring Ireland remains globally competitive for drug discovery, advanced therapies, combination products, and AI-enabled technologies
- *Advanced skills development* through a Life Sciences Academy, underpinned by multiple integrated disciplines, which delivers postgraduate programmes, micro-credentials and continuous professional development aligned with industry and health service needs
- *Cluster impact*: Co-locating academic talent with with start-ups, SMEs, investors and large innovative corporates drives cross-sector collaboration, accelerates R&D and commercialisation, particularly for indigenous firms, and strengthens rounded and relevant talent and skills development. Ireland needs to

enhance this approach. Clusters also support greater potential for success in attracting European investment, for example through the European Regional Enterprise Development Fund.

In addition, *leveraging co-located talent and entrepreneurship* potential, particularly in tandem with the regeneration of urban spaces, will act as gateways to the global economy which also acting to nurture social, community and cultural entrepreneurs.

Ireland has been very proactive in developing interdisciplinary and interinstitutional initiatives to underpin the Life Science sector, with NIBRT, Curam, SSPC, PMTC and Arc Hubs all enriching the landscape and providing tangible beneficial return on the investment made. Working in synergy further enhances the attractiveness of the Irish life sciences landscape and its potential

There are significant **challenges** to the success of a National Life Science Strategy. Without decisive action and targeted funding, Ireland faces a number of strategic risks, losing ground as global life sciences shift toward digital, AI, advanced therapies, personalised medicine, and data-driven care; changes that require integrated, innovation-led ecosystems. Failure to anticipate the complex impacts of geopolitical uncertainty and the changing international competitive landscape will also create barriers to building the structures required for success. In brief example:

- *Global supply chains* are influenced by the dynamic geopolitical environment and evolving global trade environment, something Ireland is particularly susceptible to.
- *Globally, the pace of innovation*, particularly in areas like biopharmaceuticals that are enhanced by *advanced data science and artificial intelligence*, is accelerating. Ireland needs to position itself – its talent base, focus and ambitions – to effectively harness this pace
- *Over-concentrated model and global vulnerability*: Five firms produce 43% (€88bn) of exports, 63% of activity in Ireland is manufacturing and only 5% of pharma sites focus on R&D. Despite stronger Medtech R&D, Ireland is missing high-value opportunities which is leaving the economy vulnerable to global shifts and industry relocation
- *Limited investment in R&D and innovation infrastructure* compared with peer regions that have strong cluster organisations and coordinated government support. Without investment such as incentivising to attract multinational investment, Ireland's current base will be eroded, not only reducing the potential for growth but increasing the risk of disengagement from Ireland by existing industry.
- *No coordinator*: Ireland lacks an independent body to align industry, academia, healthcare and Government on sector-wide growth results. This results in fragmentation between academia, healthcare, enterprise and regulators, which slows down translation of concept and outputs to their application and subsequent benefits
- *Skills shortages in key areas* such as regulatory science, MedTech design, simulation, data science and digital health. In a coordinated landscape, Ireland's universities can respond directly to industry needs

- *Falling behind rivals:* Regions with formal clusters attract start-ups, commercialise research, build talent, and shape policy. Ireland needs to build the same to stay competitive
- *State aid:* There is a need to better understand and develop the interface between industry and exchequer interests to ensure effective and impactful collaboration
- *Demanding regulatory framework:* Evidence indicates that the time taken to approve trials in Ireland is much longer than other EU countries, placing Ireland at a competitive disadvantage for site selection for trials of new medicines, foods and medical technologies

## EU Context

The emerging EU Life Sciences policy landscape highlights the importance of strong research institutions, biotech clusters and integrated research and innovation ecosystems that will make Europe the world's most attractive and competitive location for life sciences by 2030. The strategy calls for strengthening connectivity between research, industry and healthcare, and making better use of mission driven, interdisciplinary approaches. It also calls for a coordinated approach across basic research, technology development, biomanufacturing, regulation and market access, something our small country can excel at. The National Life Sciences Strategy can ensure that Ireland is visible and influential in shaping the future of Life Sciences in Europe. This would also improve Ireland's ability to attract EU funding and to participate in large collaborative initiatives, ensuring that national investments are leveraged to maximum effect.

While Ireland is well positioned due to its strong biopharma, med-tech and fundamental research base, to maximise our potential we require greater scale up, training and workforce development, a focus on expanding an industrial R&D presence, investment in biomanufacturing and translational infrastructure and strengthening of our academic–industry–government–clinical collaborative focus and activities. Of note, the EU Strategy:

- integrates the entire value chain, from discovery to commercialisation and translation, addressing long-standing fragmentation in European life sciences ecosystem - something that the National Life Sciences Strategy can directly support
- provides for large-scale investment to strengthening Europe's research and innovation capacity – something the National Life Sciences Strategy could champion
- supports the bioeconomy, sustainability, biomanufacturing, circular bio-based materials, sustainable food systems and meeting environmental challenges – all of which Ireland's skill base is well placed to address
- provides for translational and innovation supports that will bridge the “valley of death” between research and market – a key factor for maximising the potential of Ireland's knowledge generation
- supports reform, particularly required to address regulatory and translational bottlenecks – critically required in the Irish landscape

Ireland is well placed to support the strategic priorities and ambitions defined by the EU. The National Life Sciences Strategy provides the opportunity for Ireland to leverage investment and supports to further drive the development of an exemplar integrated and cohesive ecosystem that addresses every stage of the life sciences value chain.

## Conclusion

In shaping this strategy, Ireland has an opportunity to set out a vision that is forward-thinking, people-centred, and grounded in a heritage of successful collaborative engagement across academia, healthcare and industry. To secure Ireland's future competitiveness, a national strategy must prioritise investment in platforms that, based on existing strengths, diversify the value chain. Success requires the development of a cohesive, coordinated, framework that supports every stage of the life sciences life cycle, particularly a secure talent pipeline and the rapid translation of life science innovations of all kinds to implementation/market for broad-ranging impact. The National Life Sciences Strategy will help Ireland to move life sciences research and innovation up the value chain, retain and attract high value investment, and deliver better, more sustainable, outcomes for patients and for society.

UCC is fully committed to working to ensure Ireland delivers a constructive and empowering environment for the life science sector to grow. As the location with the highest concentration of life science activity in the country, a global hub of life science multinational companies and aligned talent generation, we are uniquely positioned to capitalise on this world-class strength, connecting regional life science activity across all stages of the value chain and driving the creation of appropriate vehicles to plug existing gaps in the regional and national value chain. We stand ready to work in partnership — across sectors and disciplines nationally— to build a life sciences landscape that serves society, nurtures the next generation of thinkers and creators and drives innovation for the benefit of all.

# Submission from University College Dublin Clinical Research Centre



## UCD Clinical Research Centre

University College Dublin  
Health Sciences Centre  
Belfield, Dublin 4

T +353 1 716 4587

## Scoil an Leighis UCD

An Coláiste Ollscoile Baile Átha Cliath  
Ionad Eolaíocht Sláinte  
Belfield, Baile Átha Cliath 4

crc@ucd.ie  
www.ucd.ie/crc

Re: *National Life Sciences Strategy Consultation – Submission from UCD Clinical Research Centre*

Dear Sir/Madam,

We welcome the opportunity to contribute to the development of Ireland's first National Life Sciences Strategy and congratulate the Department of Enterprise, Tourism and Employment on leading this important national initiative. The UCD Clinical Research Centre is a partnership between UCD, its partner hospitals and industry. It is the national leader in investigator led clinical trials and a major partner for industry in the delivery of commercial clinical trials and translational research. We believe we have a unique and helpful vantage point bridging academia, clinical translation, industry partnerships and health-system research. Below we present our views structured in line with the thematic questions posed in the consultation, followed by specific additional commentary reflecting UCD CRC's capabilities and how they align with the life-sciences strategic agenda.

### Scope

In our view, the scope of the Strategy should be **broad** and **integrative**, covering not only biopharmaceuticals and medical technologies but also clinical research infrastructure, health data and digital health, and the interface of life-sciences with health services. In particular, we recommend:

- Inclusion of **clinical trials and translational research infrastructure** as a core component of the life-sciences ecosystem — including investigator-led trials and academic–industry partnerships
- Recognition of the **health-system interface**: the life-sciences sector does not operate in isolation from the healthcare delivery system. For example, for new therapies to reach patients, there must be alignment with hospital infrastructure, regulatory/ethical pathways, reimbursement pathways and health-data systems for real world evidence.
- Consideration of **digital and data-enabled life-sciences** (e.g., AI in diagnostics, digital biomarkers, real-world evidence generation) as core rather than adjunct.
- Linkage to **skills, training and workforce development**, not only for lab/engineering roles but also clinical research, regulatory sciences and health-data science.

We therefore support a strategy that is inclusive of academic, clinical, industry and health-system stakeholders, and that explicitly positions a strong clinical-research base and health-data infrastructure as part of “life sciences”.



## Objectives

We believe the following key objectives should be at the heart of the Strategy:

- **Research & Innovation** – To strengthen the pipeline from discovery through translational research to clinical application, ensuring that Ireland leverages its academic research strength and clinical-trial infrastructure to bring new therapies, diagnostics and med-tech to global markets.
- **Global Competitiveness & Investment** – To maintain and enhance Ireland’s attractiveness for both indigenous and foreign-direct-investment in the life-sciences sector (building on its existing cluster and export base).
- **Skills, Talent and Workforce** – To ensure a highly-skilled, agile workforce capable of meeting emerging needs in life sciences, including clinical research, regulatory science, digital health, manufacturing and health-data science.
- **Patient Outcomes and Health-System Value** – To align life-sciences innovation with patient benefit, quicker access to innovative treatments, improved health outcomes and integration with the health-system for real-world implementation.
- **Collaboration and Ecosystem Integration** – To promote strong linkages among academia, industry, hospitals/health services, regulatory bodies and patient organisations; to ensure “bench to bedside” translation; to adopt open innovation, sharing of platforms and data.

## Opportunities and Challenges

### Opportunities:

- Ireland’s existing cluster: the consultation correctly points to Ireland’s “cohesive and integrated life-sciences cluster ... world-class research base and a strong industry-focused clinical community”.
- Growth in global demand for advanced therapies, diagnostics and digital health — an opportunity for Ireland to carve out a specialised niche (e.g., advanced therapies manufacturing, cell/gene therapy, med-tech software regulatory environment).
- The maturation of health-data ecosystems, real-world evidence and AI/analytics offers Ireland an opportunity to leverage its trusted health system to drive innovation.
- Academic–industry collaborations: centres such as UCD CRC are well-positioned to host investigator-led trials, engage in translational research and de-risk early-stage development in partnership with Industry
- Skills development: Ireland can innovate in life-sciences education and training (e.g., clinical-trial methodology, regulatory affairs, data science) to meet future demands and export talent.

**Challenges:**

- Skills and talent gap: the pace of innovation is fast and workforce supply (clinical trialists, regulatory scientists, data scientists in life sciences) lags
- Health-system integration: Innovation often stalls at implementation — bridging the “valley of death” between research and commercialisation/or health-service uptake is challenging.
- Data access, interoperability and governance: Using health-system data for research and innovation still faces legal, ethical and systems-barriers.
- Investment in infrastructure: While Ireland has many assets, continued investment in purpose-built translational/clinical-trial infrastructure, advanced manufacturing platforms and digital-health infrastructure is required to stay ahead.
- Global competition: Other jurisdictions are accelerating investment in life sciences — Ireland must differentiate and act with ambition.

**EU Context**

The consultation refers to the EU Life Sciences Strategy, which aims to position the EU as the world’s most attractive location for life sciences by 2030.

In this context we recommend that Ireland’s Strategy:

- Aligns with EU priorities (e.g., advanced therapies, digital health, sustainability, regulatory convergence) while identifying national differentiators (e.g., rapid clinical-trial capabilities, health-data trust frameworks, manufacturing scale-up).
- Leverages EU funding mechanisms, regulatory harmonisation efforts (e.g., HTA/health-technology assessment, the upcoming European Health Data Space) and supports Irish entities in accessing those.
- Promotes Ireland as a gateway to EU and global markets — particularly for companies seeking a European base for life-sciences R&D, manufacturing and clinical-trial operations.
- Ensures that national regulatory/ethical/data frameworks are compatible with EU-wide initiatives, to facilitate cross-border trials, data sharing and integration.

**UCD Clinical Research Centre — Specific Recommendations**

Given our role in the ecosystem, we highlight the following:

**Support for investigator-led/academic clinical trials:** Provide targeted funding and infrastructure support for academic clinical research centres (like UCD CRC) to engage in early-phase trials, translational research and real-world evidence generation, building bridges to industry and supporting Irish led innovation

**Health-data research ecosystem:** Invest in trusted health-data infrastructure – national health-data repositories, interoperability frameworks, secure research-access models – to enable innovation in diagnostics, digital biomarkers and real-world evidence.



**Skills pipeline development:** Develop specialised training programmes in clinical-trial methodology, regulatory science, life-sciences manufacturing, data-science for health, digital-health research. Leverage academic–industry co-training, apprenticeships and embedding clinical research methodology in curricula.

**Cross-sectoral linkage:** Foster linkages across sectors – for example med-tech + digital health + clinical research + manufacturing – and across domains (healthcare, agriculture, food sciences) recognising the broad life-sciences spectrum.

In summary, UCD CRC welcomes the development of the National Life Sciences Strategy. We believe Ireland has a strong foundation and a significant opportunity to become a global leader in life-sciences innovation, clinical research and health-data enabled healthcare. Achieving this will require bold ambition, sustained investment in infrastructure, skills and data, streamlined pathways and strong integration of academia, industry and the health system.

We stand ready to engage further in the next phases of consultation and implementation, and to contribute our expertise, facilities and collaborative networks to support the success of the Strategy.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Peter Doran'.

---

Professor Peter Doran  
**Director of UCD Clinical Research Centre,  
Prof of Clinical Trials, UCD School of Medicine**

# Submission from University College Dublin School of Biomolecular and Biomedical Science



UCD School of Biomolecular and  
Biomedical Science

UCD Scoil na nEolaíochta  
Bithmhóilínigh  
agus Bithleighis

Conway Institute  
University College Dublin,  
Belfield, Dublin 4, Ireland

Institiúid Mhic Con Mí  
An Coláiste Ollscoile  
Baile Átha Cliath, Belfield,  
Baile Átha Cliath 4, Éire.

**1. Scope.** Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?

- **There is a danger in having the strategy too broad. Given the key importance of the (bio)pharmaceutical and medical device industries in Ireland, it would make logical sense to focus initial efforts on ensuring resilience in these two sectors through a more comprehensive strategy. Other areas could then generally indirectly benefit through a strengthened national research and innovation ecosystem.**

**2. Objectives.** What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? *For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

- **Better promote and encourage basic 'blue skies' life sciences research as a key foundation for translational research.**
- **Enhance clinical research infrastructure, with a focus on ensuring an effective, nationwide approach to clinical trials**
- **Targeted investment in promising life science researchers to facilitate new discoveries and to promote entrepreneurship.**
- **Ensure that gaps in the funding landscape for translational (biomedical) research are shored up, e.g. current disconnect between Research Ireland and the Health Research Board is meaning opportunities are being lost (such as TRANSCAN-III)**
- **Incentivise inter-institutional and academic-industry collaboration through targeted funding mechanisms.**
- **Better spacing of application deadlines so that they don't clash with other national / EU calls e.g. RI ILP , HRB ILP, HRCI-HRB all had deadlines in the same month this year.**
- **Better forward knowledge around when grant calls will be. Really need separate funding that is secured over 5 years so that there are reliable calls annually. Also, more understanding and recognition that grant applications take time to prepare – for 2-stage applications, notification of been selected at stage 2 is often not far in advance of the stage 2 ' full application' submission.**

**3. Opportunities and challenges.** What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?

- In the bio(pharmaceutical) arena specifically, there needs to be greater emphasis on early stage discovery and aiding transitioning of new assets towards commercial utility. The overreliance of Ireland on drug manufacturing, particularly US multinational bio(pharma), has been clearly exposed following the threatened and real introduction of US tariffs (Fitzgerald, ESRI, 2025; <https://doi.org/10.26504/rn20250301>).
- While there may be short-term gains for the exchequer due to evident stock piling/advance purchases, this is not a sustainable approach in the long-term. One just has to look to the UK for evidence of recent changes of mind by major bio(pharma) when it comes to investment in infrastructure. This situation is also exacerbated by the exceptionally slow drug reimbursement timelines in Ireland, which is also observed in the UK (and identified as a key contributing factor in recent withdrawals of company investment).
- Our clinical trial accrual rates are also generally very low, when compared versus equivalent international benchmarks at European level. While some recent progress has been made towards streamlining the clinical trial process (e.g. National Clinical Trials Oversight Group recommendations), there now needs to be appropriate resources put in place to ensure rapid development. Denmark has shown how an effective, nationwide clinical trials system can lead to much greater capacity for innovation. The absence of an electronic patient identifier and generally slowness in adopting digital health is a also major impediment for Ireland's competitiveness at present.
- Needs to be a major uplift in targeted funding for research and innovation in the life sciences. The disconnect between Research Ireland and the Health Research Board means that opportunities for translational biomedical research are often lost between the cracks. A properly integrated funding ecosystem is required targeted towards life sciences. The recent investment in ARC Hubs is commendable but the level of funding even there is modest compared to international norms.
- There also needs to be thought given to enabling the next generation of biomedical researchers to be successful. A targeted, high value recruitment and support initiatives should be provided to kick-start and provide ongoing support for promising life science researchers, in whom the new discoveries of the future can be found. Particular supports to encourage innovation and entrepreneurship should be prioritised to harness the (untapped) potential that current exists in Ireland (Burke; *Meet the biotech buccaneers seeking to fuel a 'reverse brain drain'. The Business Post (27<sup>th</sup> November 2025)*).
- A challenge is to ensure that basic blue skies life sciences research remains properly supported within the current climate of translational and applied research policy. Many external agencies such as the Wellcome Trust, ERC, and the NIH prioritise basic research for very good reasons. In Ireland, the shift to translational research policy has been dramatic, and many researchers feel that the balance has been lost.

**4. EU context.** The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by

2030. What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

- **The European Commission also specifically call out the need to advance clinical trials and generally uplift clinical research infrastructures, which is in keeping with above suggestions. The focus on the development of new products, e.g. new approach methodologies and novel molecules, makes sense and also fits proposals. The focus on rapid market access is also highly relevant to Ireland, which has classically been slow to adopt new medicines in recent years.**

# Submission from University College Dublin School of Biology and Environmental Science

## SCOPE

The scope of the National Life Science Strategy should be as broad as possible. A narrow strategy risks missing key innovation pathways and emerging opportunities, while a broad, connected scope ensures Ireland remains competitive and future-ready. In addition, basic and applied research should both have adequate space, as the former is crucial to drive innovation in the latter, while the latter is pivotal to produce impact in society.

## OBJECTIVES

The main aim of the strategy should be delivering meaningful benefits for society across the entire life sciences ecosystem, spanning biopharmaceuticals, medical technologies, biotechnology, agrifood innovation and food security, digital and data-enabled health solutions, sustainability-focused bioindustries, biodiversity restoration and conservation. The digital technologies should be embraced to enhance the competitiveness of Ireland in the International landscape. Nature-based solutions should be promoted to enhance the sustainability in all sectors.

## OPPORTUNITIES AND CHALLENGES

The major opportunities for Ireland are to grow in advanced medicines, digital health, data science, sustainable life sciences and agriculture.

Ireland could potentially improve focus on the skills pipeline (student training for tomorrow's Enterprise), recognising human infrastructure as well as physical infrastructures (recognised by the INSPIRE programme).

Ireland could promote accelerated discovery through Open Science data mining and reuse. To help prepare Ireland's existing and future life science research community for a data-driven landscape, a new data science funding tool in life sciences could be created. A possible example could be a low-cost but high-output funding tool that supports post-doctoral researchers for 2 years in a lab to re-analyse and re-use publicly available data, with cross-institutional supervision encouraged (promoting increased data sharing and added value of existing RI research projects). This will contribute to supporting the development of modern bioinformaticians, a critically needed human infrastructure to promote Ireland's leadership in scientific innovation over the next 5-10 years by providing a dynamic data science workforce. This would increase data literacy of Ireland's life science experts, accelerate discovery, and substantially improve the volume and impact of research output.

Ireland should improve and maintain strategically important nationally shared data on public health, biodiversity and environmental indicators, openly shared with the research community.

Ireland has a large agricultural sector with small and innovative farms. In terms of urban environments, there are opportunities to expand and enhance green and blue infrastructure to make more use of nature-based solutions.

Extensive mapping of biodiversity and a long-term monitoring programme for biodiversity are important for sustainable development and the energy transition. Exchange of biodiversity data through the Biodiversity Data Centre is critical. Further capacity building for addressing biodiversity challenges across sectors is fundamental.

Major challenges identified are skills shortages, R&D capacity, and growing global competition. Other challenges include access to funding from the whole research community. Strategies for funding allocation should ensure distributed access to research funding, to ensure that all fields of life science have appropriate routes, that scientists at different career stages are able to find appropriate pathways to ensure their growth and development (e.g. doctoral training networks), and to favour expert retention for the country. Research Institutes and Universities nationwide should have equitable access to funding, through selection and eligibility criteria that are more inclusive for small research realities.

## EU CONTEXT

The EU's ambition aligns well with Ireland's priorities and capabilities. To realise this at the National level, Ireland should focus on improving skills pipelines by training and, importantly, retaining expert people, as well as expanding R&D and manufacturing capacity, so that the sector remains competitive and can fully benefit from EU-level investment.

# Submission from University College Dublin, William Gallagher, School of Biomolecular and Biomedical Science



**UCD School of Biomolecular and Biomedical Science**

Scoil na hEolaíochta Bithmhóilínigh agus An Bithleighis UCD

Conway Institute  
University College Dublin,  
Belfield, Dublin 4, Ireland

Institiúid Mhic Con Mí  
An Coláiste Ollscoile, Baile Átha Cliath,  
Belfield, Baile Átha Cliath 4, Éire

T +353 1 7166743

5<sup>th</sup> December 2025

## **Public Consultation on National Life Sciences Strategy: Submission from Prof. William Gallagher (UCD & AICRI)**

Dear Department colleagues,

Please find below my comments in relation to National Life Sciences Strategy. I have endeavoured to respond to each of the sections with my views – see text in bold. I trust these comments and suggestions are of some use.

My way of introduction, I am a cancer researcher based in University College Dublin with very substantive experience of both academic and industry environments. I have co-ordinated multiple large-scale national and international (cross-border and EU programmes) over the last 15 years in the cancer research and innovation space – see biosketch at the end of the document for further background information.

Thank you for the opportunity to feed into this important process, which is key for the long-term sustainability and advancement of the life sciences sector in Ireland.

Regards,



**Prof. William M. Gallagher** BSc PhD CBiol MSB

Co-Lead, All-Island Cancer Research Institute (AICRI)

Academic Deputy Director, ARC Hub for Therapeutics

Full Professor of Cancer Biology, UCD School of Biomolecular and Biomedical Science

Deputy Director, Precision Oncology Ireland (SFI Strategic Partnership Programme)

Conway Fellow, UCD Conway Institute

Director, Irish Cancer Society Collaborative Cancer Research Centre BREAST-PREDICT (2013-2019)

Co-Founder/Chief Scientific Officer, OncoAssure Limited

Tel. +353-1-7166743

E-mail. [william.gallagher@ucd.ie](mailto:william.gallagher@ucd.ie)



UCD School of Biomolecular and  
Biomedical Science

Scoil na hEolaíochta Bithmhóilínigh agus  
An Bithleighis UCD

Conway Institute  
University College Dublin,  
Belfield, Dublin 4, Ireland

Institiúid Mhic Con Mí  
An Coláiste Ollscoile, Baile Átha Cliath,  
Belfield, Baile Átha Cliath 4, Éire

T +353 1 7166743

## Scope

Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production.

In your view, how broad should the scope of the strategy be?

**There is a danger in having the strategy too broad. Given the key importance of the (bio)pharmaceutical and medical device industries in Ireland, it would make logical sense to focus initial efforts on ensuring resilience in these two sectors through a more comprehensive strategy. The other areas could then generally indirectly benefit through a strengthened national research and innovation ecosystem.**

**It would also be useful to capitalise on particular strengths and opportunities which have been identified within the life sciences research ecosystem. In recent years, there has been tremendous progress in terms of cancer research across the island of Ireland, driven by national and cross-border initiatives such as Precision Oncology Ireland ([www.precisiononcology.ie](http://www.precisiononcology.ie)) and the All-Island Cancer Research Institute ([www.aicri.org](http://www.aicri.org)). It would make sense to focus attention on this and other similar strengths, such as neuroscience (e.g. FutureNeuro) and biomaterials (e.g. CURAM).**



## Objectives

What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?

*For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability*

**Key objectives for the National Life Sciences Strategy should be the following:**

- 1. Enhance clinical research infrastructure, with a focus on ensuring an effective, nationwide approach to clinical trials**
- 2. Targeted investment in promising life science researchers to facilitate new discoveries and to promote entrepreneurship.**
- 3. Ensure that gaps in the funding landscape for translational (biomedical) research are shored up, e.g. current disconnect between Research Ireland and the Health Research Board is meaning opportunities are being lost (such as TRANSCAN-III)**
- 4. Incentivise inter-institutional and academic-industry collaboration through targeted funding mechanisms.**
- 5. Promote an all-island approach to innovation with the life sciences space, with key demonstrators in oncology and other areas of noted strength and opportunity.**



## Opportunities and challenges

What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?

**In the bio(pharmaceutical) arena specifically, there needs to be greater emphasis on early stage discovery and aiding transitioning of new assets towards commercial utility. The overreliance of Ireland on drug manufacturing, particularly US multinational bio(pharma), has been clearly exposed following the threatened and real introduction of US tariffs (Fitzgerald, ESRI, 2025).**

**While there may be short-term gains for the exchequer due to evident stock piling/advance purchases, this is not a sustainable approach in the long-term. One just has to look to the UK for evidence of recent changes of mind by major bio(pharma) when it comes to investment in infrastructure. This situation is also exacerbated by the exceptionally slow drug reimbursement timelines in Ireland, which is also observed in the UK (and identified as a key contributing factor in recent withdrawals of company investment).**

**Our clinical trial accrual rates are also generally very low, when compared versus equivalent international benchmarks at European level. While some recent progress has been made towards streamlining the clinical trial process (e.g. National Clinical Trials Oversight Group recommendations), there now needs to be appropriate resources put in place to ensure rapid development. Denmark has shown how an effective, nationwide clinical trials system can lead to much greater capacity for innovation. The absence of an electronic patient identifier and generally slowness in adopting digital health is a also major impediment for Ireland's competitiveness at present.**

**In terms of specific objectives, there needs to be a major uplift in targeted funding for research and innovation in the life sciences. The disconnect between Research Ireland and the Health Research Board means that opportunities for translational biomedical research are often lost between the cracks. A properly integrated funding ecosystem is required targeted towards life sciences. The recent investment in ARC Hubs, particularly the ARC Hub for Therapeutics, is commendable but the level of funding even there is modest compared to international norms.**

**There also needs to be thought given to enabling the next generation of biomedical researchers to be successful. A targeted, high value recruitment and**



**support initiatives should be provided to kick-start and provide ongoing support for promising life science researchers, in whom the new discoveries of the future can be found. Particular supports to encourage innovation and entrepreneurship should be prioritised to harness the (untapped) potential that current exists in Ireland (Burke, 2025).**

**A specific opportunity lies in the oncology sector. In April 2024, the All-Island Cancer Research Institute (AICRI; [www.aicri.org](http://www.aicri.org)) launched a comprehensive analysis of the oncology industry landscape in Ireland and Northern Ireland. This report was launched by the respective Ministers with economy portfolios and provided a compelling argument for the establishment of an All-Island Oncology Innovation Cluster. InterTradeIreland have since provided £800,000 to seed such a Cluster over a 6 year period, starting January 2026. This cross-border, life sciences-oriented Cluster will serve to harness the wealth of industry expertise that is on our island. It will also serve as a template for a broader Life Sciences Cluster.**

*John Fitzgerald. (2025). The Irish pharmaceutical sector. The Economic and Social Research Institute. Available to download from [www.esri.ie](http://www.esri.ie). <https://doi.org/10.26504/rn20250301>*

*Elaine Burke. (2025). Meet the biotech buccaneers seeking to fuel a 'reverse brain drain'. The Business Post (27<sup>th</sup> November 2025).*

*All-Island Oncology Industry Report, 2024 (DOI: 10.5281/zenodo.10884667)*



## **EU context**

The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.

What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?

**The European Commission also specifically call out the need to advance clinical trials and generally uplift clinical research infrastructures, which is in keeping with above suggestions. The focus on the development of new products, e.g. new approach methodologies and novel molecules, makes sense and also fits with our proposal. The focus on rapid market access is also highly relevant to Ireland, which has classically been slow to adopt new medicines in recent years.**

**It is key that Ireland has a strong voice in the proposed Life Sciences Coordination Group.**

**It is also important to consider that of the 5 current EU Missions, only one is in the health space, namely the EU Cancer Mission. For Ireland to effectively participate in this key programme, along with Europe's Beating Cancer Plan, an integrated approach is required. Accordingly, Ireland critically needs to rapidly advance plans for establishment of a National Cancer Mission Hub, so as to keep in step with our other European counterparts. The National Cancer Control Programme, together with the All-Island Cancer Research Institute, are currently involved in the ECHoS project, funded under the EU Cancer Mission, which looking at various models of National Cancer Mission Hubs around Europe. A proposal from National Cancer Research Group (as part of the National Cancer Control Programme) has been with the Department of Health since early 2025 in respect of establishment of a National Cancer Mission Hub. It is vital that this proposal receives support from the Department of Health, empowering those within the ecosystem to ensure that we are optimally placed within the European landscape. This is particularly important given the timing of the EU Presidency coming to Ireland for the latter half of 2026.**



### **Professor William Gallagher BSc PhD CBIol MSB**

Full Professor of Cancer Biology, University College Dublin  
Co-Lead, All-Island Cancer Research Institute (AICRI)

Academic Deputy Director, ARC Hub for Therapeutics  
Deputy Director, Precision Oncology Ireland  
Conway Fellow, UCD Conway Institute

Scientific Director, St. Vincent's-UCD Cancer Centre

Co-Founder/Chief Scientific Officer, OncoAssure Limited



### **Biosketch**

Professor William Gallagher is Full Professor of Cancer Biology at University College Dublin (UCD) and Deputy Director of *Precision Oncology Ireland*, a large-scale Research Ireland Strategic Partnership Programme involving 5 academic institutions, 6 cancer charities and 7 companies ([www.precisiononcology.ie](http://www.precisiononcology.ie)). He is also Scientific Director of the recently established St. Vincent's-UCD Cancer Centre ([www.stvincentsucdcancercentre.ie/](http://www.stvincentsucdcancercentre.ie/)).

Currently, Prof. Gallagher is a primary driving force behind the *All-Island Cancer Research Institute* (AICRI), which is creating an overarching framework for cancer research across the entire island of Ireland ([www.aicri.org](http://www.aicri.org)). AICRI-linked programmes were awarded over 12 million euro under the HEA North-South Research Programme, including an all-island Doctoral and Post-Doctoral Training Programme in Precision Cancer Medicine (*AICRIstart*) which Prof. Gallagher co-leads, together with Prof. Mark Lawler (Queen's University Belfast).

Prof. Gallagher has received a number of awards for his research and innovation achievements in the oncology arena, including the inaugural Irish Association for Cancer Research Medal in 2017, the SFI Entrepreneurship Award in 2019 and the SFI Researcher of the Year Award in 2021. Prof. Gallagher has co-founded two molecular diagnostics companies, OncoMark Ltd. and OncoAssure Ltd., the former being acquired in March 2021 by the US company Danaher (Cepheid division).

# Submission from University College Dublin School of Public health, Physiotherapy and Sports Sciences

## Scope

We welcome a broad and inclusive definition of *life sciences* that goes beyond (bio)pharma and medtech to encompass public health, health services research, rehabilitation, sport and physical activity, epidemiology, digital health, environmental health, and health systems research.

This reflects the diversity of expertise across Irish academia and aligns with the EU and WHO emphasis on prevention, population health, and integrated healthcare systems.

## Objectives

We suggest the following priority objectives:

- Develop a national research data management (RDM) infrastructure  
Researchers are currently forced to rely on ad hoc solutions (e.g. Google Drive, limited university-hosted platforms, or self-funded IT support). This reduces efficiency and reproducibility, increases security and compliance risks, and duplicates effort across institutions.  
A coordinated, national RDM framework—with shared standards and secure platforms—would enhance Ireland’s standing in life sciences and support alignment with FAIR and Open Science practices under Horizon Europe.
- Strengthen research support structures and infrastructure  
This includes seed funding, protected research time, and access to physical space and technical support.
- Invest in researcher development  
Clear and sustainable career pathways are needed for early-stage researchers, especially in non-lab-based and interdisciplinary fields.
- Deepen collaboration with healthcare and civil society partners  
Greater engagement with health services, patient groups, and public agencies is critical for translational, policy-relevant research.
- Reduce administrative burden and improve research systems  
Platforms like SESAME, particularly the Profile section, are overly complex and time-consuming, discouraging researcher engagement.

## Opportunities and Challenges

### Opportunities:

- Ireland has the potential to lead in preventive health and population-based research, especially at the intersection of AI and public health.
- Our universities have strong capabilities in translational research and a history of collaboration with agencies such as the HSE, HIQA, Safer Food, Sport & Waters, and NGOs.
- Strategic investment could unlock greater policy-to-practice impact across the life sciences sector.

#### **Challenges:**

- National funding mechanisms often exclude interdisciplinary or practice-based research, favouring traditional biomedical projects.
- Lack of research infrastructure (space, administration, post-award support) reduces competitiveness and capacity to scale.
- Bureaucratic burden (e.g. SESAME reporting) reduces research productivity and disincentivises engagement.
- Delays in grant processing and post-award management undermine momentum and researcher confidence.

# Submission from University College Dublin Student of Biology and Environmental Science

DETE Consultation response for National Life Science Strategy:

*What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?*

The ambition to make Europe a more attractive place by 2030 is welcome, provided attractive includes sustainability and resilience. The three pillars (optimising R&I, rapid market access, and boosting uptake) are good but implementation under constraint is missing. I work as a sustainability strategy manager in a global life science supplier and as a MSc researcher at UCD on SUT recycling in Irish biopharma, in practice technology is rarely the bottleneck. Everyday constraint around risk, compliance, cost and infrastructure are. In Ireland applying the EU strategy should mean using existing clusters for circular, low carbon, waste reduction testbeds in biopharma and medtech, Ireland is already an attractive place to biopharma thanks to the IDA. Biggest thing would be to align infrastructure and investments (energy waste transport data/AI) with these goals so sites that want to move beyond the default actually can..

*In your view, how broad should the scope of the strategy be?*

It should cover the full EU definition of LS. Structure the strategy around complete value chains and lifecycles: discovery and clinical research through advanced manufacturing to end of life, waste and ecosystem impacts. It is surprising just how much opportunity is in that last piece. For Ireland prioritise areas of critical mass (we have this in abundance) biopharma being one. Recognise the cross-cutting enablers (energy, waste etc) that all sectors depend on.

*What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success?*

Grow a globally competitive, low carbon, advanced manufacturing and research base (the sector is already well on its way on some topics). Translation from research to impact to de-risk scaling. Develop and retain the skill pipeline (many PhD graduates are being ejected into a stagnant employment market and leaving the sector, brain drain). Embed sustainability and circularity as a design constraint. Explicitly address implementation under constraint (see above).

*What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?*

Ireland is a prime European testbed for sustainability, data and advanced manufacturing, formalise it, they are an open and sharing sector, which can be rare. Build up the value chains around plastic and chemical circularity, low carbon utilities and supply chains.

# Submission from Uisce Éireann.



Department of Enterprise, Tourism and Employment  
23 Kildare Street  
Dublin 2  
D02 TD30

By email: [lifesciences@enterprise.gov.ie](mailto:lifesciences@enterprise.gov.ie)

10<sup>th</sup> of December 2025

**Uisce Éireann**  
Bosca OP 6000  
Baile Átha Cliath 1  
D01 WA07  
Éire

**Uisce Éireann**  
PO Box 6000  
Dublin 1  
D01 WA07  
Ireland

T: +353 1 89 25000  
F: +353 1 89 25001  
[www.water.ie](http://www.water.ie)

## Re: Public Consultation on National Life Sciences Strategy

Dear Sir/Madam,

Uisce Éireann welcomes the opportunity to make a submission as part of the Department's public consultation on National Life Sciences Strategy, noting the importance of adopting a coherent and ambitious approach to future opportunities within the Sector.

### Early stakeholder engagement is a core principle in both the EU Life Sciences Strategy and for Uisce Éireann

In developing the Life Sciences Strategy, Uisce Éireann would welcome inclusion of a stakeholder engagement approach that prioritises communication and collaboration with key partners. Uisce Éireann recognises that clear and effective communication is critical for managing expectations, supporting planning, and ensuring project delivery.

We proactively engage with industry, developers and individuals through our Pre Connections Enquiry (PCE) process to assess individual proposals for water service connections. The PCE process allows Uisce Éireann to assess connection feasibility before applying for planning permission. Submitting a PCE at an early stage of a project, allows Uisce Éireann to provide feedback which may influence industry plans and planning permission submission, e.g. whether a Pumping Station or other infrastructure is required.

Uisce Éireann actively seeks solutions to support industry development and housing and in areas of constraints or challenging development sites, this can take time. Our commitment to finding solutions and facilitating connections is demonstrated in the low number of refusals issued, with the vast majority of connection applications in 2024 approved. Early engagement by industry is key to finding solutions in complex locations and facilitating connections in a timely manner.

On receipt of a grant of planning and prior to commencement on site, Uisce Éireann encourages industry and developers to engage as early as possible in the Connection Application process to ensure that we can work with industry to provide a connection. At all times an executed Connection Agreement with Uisce Éireann is required to ensure a connection can be made and capacity is available for a development.

**Stiúrthóirí / Directors:** Jerry Grant (Cathaoirleach / Chairperson), Niall Gleeson (POF / CEO), Gerard Britchfield, Douglas Millican, Michael Nolan, Patricia King, Eileen Maher, Cathy Mannion, Paul Reid, Michael Walsh.

**Oifig Chláraithe / Registered Office:** Teach Colvill, 24-26 Sráid Thalbóid, Baile Átha Cliath 1, D01 NP86 / Colvill House, 24-26 Talbot Street, Dublin, Ireland D01NP86

Is cuideachta ghníomhaíochta ainmnithe atá faoi theorainn scaireanna é Uisce Éireann / Uisce Éireann is a designated activity company, limited by shares.

Cláraithe in Éirinn Uimh.: 530363 / Registered in Ireland No.: 530363.

**Opportunities exist to support economic growth through industry development which will be delivered alongside housing to 2030**

The EU Life Sciences Strategy calls for investment in infrastructure and innovation to support population growth, economic development, and resilience. Uisce Éireann recognises that this can only occur alongside investment and delivery of infrastructure. We will prioritise capacity upgrades to deliver connection offers that can keep pace with industry as well as housing demand.

In the last 10 years, Uisce Éireann has ramped up capital delivery capability for water services and infrastructure from €300m in 2014 to roughly €1.3 billion in 2024. Record levels of funding were allocated to Uisce Éireann as part of budget 2025, and this will continue in the coming years under the revised National Development Plan. The updated National Development Plan 2026-2030 contains investment of €12.2 billion for the water sector to support water quality, rural water services, unlock housing and upgrade water and wastewater infrastructure. This funding will support Uisce Éireann in the delivery of key strategic projects in our cities and regions and importantly help to reach 300,000 houses built by 2030 under the Programme for Government.

**Capacity in the system is subject to change and upgrades to the network are sometimes necessary to support development**

Uisce Éireann recognises there are challenges in respect to water supply and wastewater capacity constraints in parts of the country. For example, The Greater Dublin Area faces acute water supply and wastewater capacity constraints, and by 2028, new connections may need to be restricted unless major projects proceed as planned. Growth in the Mid-East Region is dependent on the delivery of critical infrastructure, in particular the Greater Dublin Drainage Project ("GDD") and the Eastern and Midlands Water Supply Project. GDD, when delivered, will provide a new 500,000 p.e. wastewater treatment plant and will alleviate predicted pressure in the current Ringsend catchment and enable future growth in the GDD catchment.

The capacity available in our Treatment Plants and Networks changes regularly based upon changing demand or loads received from new and existing customers. Uisce Éireann assess all proposed connections individually on a case-by-case basis to determine feasibility and to identify any capacity constraints. We recommend that industry seeking to develop engage early with us through the Pre-connection Enquiry and Connection Application processes to allow us to work to meet their needs and timelines.

Uisce Éireann is committed to delivering for our customers, including industry customers, and aims to support growth and development aligned with government commitments.

Uisce Éireann would welcome the Departments consideration on the key areas above on National Life Sciences Strategy.

Yours sincerely,



---

**Geoffrey Bourke**

**Head of Customer Operations**



**Submission to the Department of Enterprise, Tourism and  
Employment Consultation  
National Life Sciences Strategy**

**Submitted by:** Bernal Institute, University of Limerick

**Date:** 5<sup>th</sup> December 2025

**Table of Contents**

|   |   |   |
|---|---|---|
| 1 | EXECUTIVE SUMMARY .....                       | 2 |
| 2 | SCOPE .....                                   | 3 |
| 3 | OPPORTUNITIES AND CHALLENGES .....            | 3 |
| 4 | IRELAND'S STRATEGIC AGENDA (EU CONTEXT) ..... | 4 |
| 5 | CONCLUSION .....                              | 4 |

## *1 Executive Summary*

The Bernal Institute is the flagship research institute of the Faculty of Science and Engineering at the University of Limerick. It is a > €100m capital investment in research, creating a world class research capability for Ireland. It is not just a University of Limerick institute but is a cornerstone of Ireland's research ecosystem, hosting the SSPC, Research Ireland's national centre for pharmaceuticals, PMTC, Ireland's national pharmaceutical manufacturing technology centre and DPTC, Ireland's national dairy processing technology centre. This resource, coupled with in excess of 70 Life Sciences industrial companies (particularly in the medical device and biopharmaceutical sectors) within the greater Limerick and Munster region, creates a critical ecosystem that requires a strategic roadmap that engages all stakeholders and ensures the international impact of the Irish Life Sciences sector.

The Bernal Institute is a dedicated research facility with over 91 state-of-the-art labs and 15,000 m<sup>2</sup> of managed floor space, including a dedicated, communal, life sciences lab space that is composed of a biologicals process infrastructure testbed, dedicated tissue culture lab, a bioanalytical suite, a dedicated microbial class II lab, histology and tissue processing infrastructure, extensive bioimaging capabilities and DNA/RNA/virology capabilities. This facility creates a collaborative, research environment where academic and industrial researchers take multidisciplinary approaches, designing innovative materials and technologies, to meet national and global challenges across health, energy and the environment. With over 400 researchers, academics, instrumentation scientists, technical and operations support staff, the Bernal Institute has 'critical masses' of researchers across the life science sector, specifically in biopharmaceuticals, biomedical devices, biomaterials, food science and technology and cellular and molecular mechanisms of disease.

However, to ensure global competitiveness for Ireland in these research areas, the Bernal Institute welcomes this opportunity to contribute to the evolution of the National Life Sciences Strategy, the NLSS.

**The goal of the NLSS must be to intensify research across the life science sector. To achieve this, significant and strategic investment in national talent, infrastructure, and the development of an innovation ecosystem is required, enabling international competitiveness to thrive.**

Our submission argues that the core mission of the national strategy must be to position Ireland as a global leader in the strategic capabilities underpinning life sciences research.

## 2 Scope

*In your view, how broad should the scope of the strategy be?*

The Bernal advocates that the NLSS should cover areas of fundamental and applied research that will strengthen areas of national importance with potential for:

- Economic impact – job creation across biopharma, food, medical devices, regenerative medicine and industrial partnerships
- Environmental impact - agriculture, sustainable & resilient materials and technologies), Green lab certification and recycling practices
- Societal impact - education, accessible healthcare, improved patient outcomes, clinical trials
- Human capacity building - the generation of talent (PhDs, undergraduates, professional upskilling).

## 3 Opportunities and Challenges

- **Collaboration as a National Asset:** The strategy should be aligned with the One Health approach which recognises the interdependencies and links between different life science areas, requiring multidisciplinary approaches to fundamental and applied research.
- **Funding Opportunities:** The NLSS should advocate for sustained funding for large-scale, strategic initiatives (to tackle broad, complex industry challenges and build critical mass in strategic areas) *and* curiosity-driven, investigator-led research (to seed future breakthroughs). Increased numbers of PhD graduates are needed to support the areas of national importance mentioned earlier in the proposed scope for the NLSS and will enable younger researchers and teams, both within academia and industry to build their reputation and achieve significant levels impact for the sector.
- **Agility & Responsiveness:** To remain competitive, the national funding model must be diverse and dynamic. We advocate for a funding model that retains significant budget (flexible competitive calls) to fund new PI led projects and that includes the decentralisation of funding to regional areas to strengthen engagement and innovation and build capacity nationally. This ensures the national strategy can respond rapidly to emerging geopolitical or technological opportunities.
- **Robust & Predictive:** Researchers need to be able to predict when they will be able to resource their work and plan accordingly – a reliable framework with clear timelines and durations that has the necessary resources – infrastructure, expertise and technical knowledge – to enable scientific breakthroughs to happen is required.
- **Global Research Excellence:** Ireland must retain, and elevate, its reputation as a highly educated and knowledgeable society, particularly in the areas of science, technology,

engineering, maths and medicine (STEMM). The quality of our research and the talent we produce is critical to retaining this reputation and thus, attracting additional talent whilst providing an environment for home grown talent to flourish is of critical importance.

- **Stakeholder engagement:** The NLSS must create resources and platforms where stakeholders from academia, industry, policy, hospitals, patient groups and medical professionals as well as other societal partners can meet to ensure cross fertilisation of ideas to overcome emerging challenges across the sector. This will ensure support, increase impact, and expedite translation of such research and activities from academia into practice.
- **Commercialisation:** The NLSS should advocate for sector-specific bridging mechanisms to de-risk academic research before it enters the commercialisation pipeline, ensuring a higher volume of viable high-potential spin-outs.
- **Large infrastructure investments require talent and support:** The NLSS should advocate for human resources to accompany all large capital investments in infrastructure, ensuring maximum impact is leveraged from that investment for the life sciences sector.

#### ***4 Ireland's Strategic Agenda (EU Context)***

*Views on the EU Life Sciences Strategy and application in the Irish context.*

The Bernal Institute would be aligned with the EU One Health approach to Life Sciences but it should be applied with

- (i) a focus on life sciences sectors of critical economic importance to Ireland and
- (ii) by leveraging synergies across the country, ensuring a critical mass of expertise, and the required infrastructure, is available to achieve maximum impact.

#### ***5 Conclusion***

At the Bernal Institute, we strive to deliver advanced materials and technologies, and PhD graduates with the required skillsets to elevate activities for the life science sector. This talent, and their innovations, will achieve economic, environmental and societal impact for Life Sciences nationally and globally. It is imperative that the NLSS advocates for significant and strategic investment in national talent, infrastructure, and the development of an innovation ecosystem as described above.

## Submission from University of Limerick Bioscience

### Scope

The scope of the National Life Sciences Strategy should be intentionally broad and adopt a broad, integrative definition of life sciences, encompassing (bio)pharmaceuticals and biotechnology, medical technologies, diagnostics, digital health, computational biology, AI/ML, data-driven modelling and bioinformatics, food science, bioprocessing and bio-manufacturing, and translational interfaces between these domains. A broad scope will ensure Ireland remains competitive across emerging interdisciplinary areas where biology, computation, engineering, and materials science overlap.

Crucially, the strategy must explicitly include funding lines and incentives for basic and high-risk/high-reward exploratory research, as well as for translational programmes that bridge discovery to early clinical/field validation. A broad scope will enable cross-disciplinary breakthroughs and ensure Ireland can contribute to solutions for truly global challenges, not only domestic priorities.

### Objectives

Key objectives should include: (1) sustained investment in fundamental and translational research including computational and AI-driven life sciences, high-performance computing, bioprocessing capability, shared core facilities, and infrastructure to support industry and academia to maintain Ireland's competitive edge and breakthroughs rather than only incremental improvement; (2) strengthening Ireland's ability to participate in and host international collaborative research and large-scale trials; (3) talent attraction and career pathways that reward high-risk science; Strengthening training pipelines in wet-lab, computational, and regulatory science; incentivising interdisciplinary programmes and researcher career stability; (4) incentives to convert discoveries into global public-good solutions (pandemic preparedness, antimicrobial resistance, mental health, healthy aging and wellbeing); and (5) mechanisms for responsible, sustainable innovation that guard public trust. Funding targets should be explicit and ring-fenced for "blue-skies" and translational risk-taking, separate from near-term commercialisation support.

### Opportunities and challenges

Opportunities: Ireland can leverage its strong research base and multinational presence to become a global hub for early-stage translational research and multinational clinical trials. Blue-skies investment can create new competitive niches (advanced therapeutics, one-health platforms, precision medicine and precision nutrition). Ireland's strong biopharma and MedTech footprint provides a base for expanding into biologics, ATMPs, precision medicine and precision nutrition, and digital therapeutics. This serves the increasing global demand for data-driven life sciences, offering an opportunity for international leadership.

Challenges: current funding and incentive structures favour safe, locally-applied research or short-term commercialisation, underfunding exploratory science and large, collaborative programmes that address global threats. The strategy must remove disincentives for high-risk research, enable cross-sector mobility for researchers, and align funding to global problems. To that end, talent shortage in both advanced laboratory skills and computational/AI disciplines needs to be overcome, and sufficient national-scale infrastructure (HPC, bioprocessing, single-cell, multi-omics) needs to be created.

There is too great a reliance on multinational companies; there is a need to expand indigenous biotech innovation and to overcome regulatory complexity for ATMPs, AI-based tools, and data-intensive biomedical research in light of growing global competition from the EU and Asia in biotech manufacturing and digital health.

## **EU context**

We welcome the European Commission's ambition to make the EU the most attractive place for life sciences by 2030, as well as the proposed strengthened coordination and investment across the value chain. Ireland's national strategy should align with EU actions (regulatory harmonisation, clinical trial simplification, coordinated investment) while carving out explicit national commitments to fund basic and translational science that EU mechanisms may not fully address. Specifically, Ireland should use EU initiatives as a lever — co-funding multinational consortia, hosting pan-EU translational platforms, and ensuring national funding complements, rather than duplicates, EU-level investments. Funding allocation decisions must prioritise global-scale problem-solving and transnational partnerships; national economic benefits are important, but should not crowd out investments required to tackle issues of global impact.

The EU Life Sciences Strategy proposes stronger R&I investment, streamlined regulation, advanced manufacturing, and digital integration, which are highly relevant to Ireland. Ireland is well-positioned to contribute significantly to and benefit from the EU strategy, provided we prioritise talent, infrastructure, and interdisciplinary innovation.

# Submission from University of Limerick Digital Cancer Research Centre

## National Life Science Data and AI Strategy (Ireland)

### Scope

Life sciences span biomolecules to ecosystems, increasingly unified by data and compute infrastructures integrating molecular to ecosystem processes under a one-health approach. The scope should prioritise health and life science research aligned with employment and business needs, national disease burden (including cancer accounting for 30% of deaths), emerging innovation such as New Approach Methodologies and One Health, and measurable impact including jobs, disease prevention, and health of animals and humans.

Key focus areas include:

- **Connected cross-sector laboratory and data infrastructure:** A national centre for Health and Life Sciences data that supports integrated One Health pan-life science approach would enable the integration of human, cross-species, and environmental health data to connect environmental exposures, prevention of diseases, zoonotic infections, microbiomes, antimicrobial resistance, and drivers of modifiable disease including cancer. Connecting data across sectors facilitates large-scale studies for diagnostics, surveillance, disease prevention, pandemic preparedness, and study of the impact of biodiversity and climate change on health.
- **Development of compute infrastructure for modern life science:** Build a national computing platform to support real-time, high-volume, large-scale data processing for genomics, imaging, and environmental sensing. This infrastructure would enable biodiversity monitoring, ecosystem health assessment, and disease prevention in a changing climate. It should be secure and interoperable with existing platforms such as European Health Data Space, (EHDS) HealthData@IE enabling real-time data streams from wearable devices, clinical trials, and environmental sensors to accelerate biomarker discovery, drug development, and personalised medicine.
- **New Approach Methodologies (NAMs) and biofabrication:** Real-time data capture embedded in functional screening of 3D bioprinted organoids, organ-on-chip systems, and in vitro models generate high-throughput multi-omics data for precision predictive modelling. Aligning with regulatory changes; in US Food and Drug Administration (FDA) that has begun to waive animal testing requirements (eg monoclonal antibodies since 2025). The European Medicines Agency's (EMA) 2025 Regulatory Science Strategy endorses NAMs for non-clinical safety assessments.
- **Clinical trials and translation:** Expand clinical trial infrastructure, and streamline regulatory pathways, health technology assessment, and real-world evidence frameworks to support biotechnology innovation, improve equitable patient access to research, and enhance Ireland's global competitiveness. Cancer provides more clinical trials
- **Sustainable research infrastructure, funding and skilled workforce:** Invest in secure data repositories and establish long-term funding models that support stable research infrastructure aligns to EU best practice (ELIXIR, BBMRI, EUCAIM, EASTRIS, ECRIN) and

address current workforce challenges, such as short-term contracts and limited protected clinical research time.

- **Clinical Trials and Translation:** Cancer clinical trials dominate Ireland's high-value life sciences R&D, driving inward investment and reducing drug costs. Expansion of trial infrastructure, regulatory pathways, new medicine assessment (HTA), and real-world evidence frameworks to support biotech innovation, patient access, and Ireland's global competitiveness. Cancer trials have largest sector of clinical trials, attract pharma/biotech (e.g., via CTIS improvements: 31% faster first-patient-in), support ~100K sector jobs/€100B exports, and align with EHDS/Beating Cancer Plan. Expanding infrastructure addresses shortages (consultants/nurses) and GDPR delays, positioning Ireland competitively.
- **Sustainable Research Infrastructure, Skilled Workforce and Funding Cycles.** EU life science strategy is centred on data and AI. These require on investment in secure data repositories and long-term high cost infrastructure.

**Policy Recommendation:** Prioritize cancer in National Life Sciences Strategy via dedicated Life Sciences- Clinical adjacent- data optimized park to capture 3x trial volume, enhance ROI, and meet Mazars/IPHA benchmarks.

### Why Cancer Should Be in Scope

Cancer is a major health and economic challenge in Ireland, with the second-highest incidence rate in the EU and causing 30% of deaths (~9,800 annually). **Cases are projected to rise 47% by 2040, increasing care costs by 80% by 2050.** Cancer's complex diagnosis and treatment, along with molecularly targeted medicines, position it as a key driver for advanced genomics, imaging, and real-world data use. It will be the first domain-specific data space (UNCAN.eu/CANDLE) with National Cancer Data Nodes(NCDN) under the European Health Data Space (2025).

A **One Health** approach linking human, animal, and environmental health offers critical innovation opportunities, as over **85% of cancers result from environmental and lifestyle factors.** Climate change will further influence cancer patterns. Despite some progress, **Ireland has the third-highest cancer mortality in Western Europe,** influenced by socioeconomic inequalities and gaps in infrastructure and specialist workforce, with delays in timely access to diagnosis, treatment, new medicines

Ireland's pharma, biotech, and medtech sectors (IPHA)—have prioritized expanded infrastructure for health technology assessment (HTA) and real-world evidence (RWE) to accelerate patient access to innovative cancer therapies, as outlined in IPHA's 2025 Vision report calling for "Access Ecosystem" reforms, clinical trials expansion, and digital leadership in precision medicine. Maximizes returns on public-private research funding through RWE/HTA streamlining (e.g., 1-year

faster access per IPHA) supporting €100B exports/100K jobs, and reinforcing cancer's pivotal role in national health and economic agendas.

## Objectives

- **Precision Cancer Research Acceleration:** Advance biofabrication (organoids, organ-on-chips), NAMs, high-throughput cancer data (sequencing, spatial omics, epigenetics), tissue biobanking, and genomic epidemiology to bridge discovery-to-patient gaps.
- **All-Island Cancer Intelligence Hub:** Create federated cancer data platform integrating registries, imaging, genomics, trials, real world data and patient outcomes for policy, HTA, and service planning.
- **Expand National Cancer Clinical Trials Infrastructure:** Prioritize underrepresented areas (prevention, early detection, early onset cancers, rural and deprived patients), enable equitable patients access to research and innovation.
- **Future-Proof Cancer Data Infrastructure:** Invest in secure, green HPC, AI sandboxes, bioinformatics training, and risk-based governance for ethical federated cancer research.
- **Ensure high quality connected data** aligning with global data standards aligned with best practices of GDI, HealthData@IE, ELIXIR Ireland, EHDS National Cancer Cancer space (CANDLE, eCancer Strategy), NCRI, OHDSI.

## Opportunities

- **National Life Sciences Research Park:** Co-locate clinical, biofabrication (organoids/organ-on-chips/ tissue avatar), multi-omics/AI/high-performance computing data infrastructure for 500+ researchers. Centrally located with space for industry/clinical scale-up, supporting Impact 2030 and National Strategy for Science, Technology and Innovation priorities. Ideally embedded adjacent to a new hospital (mirroring design of Barcelona Biomedical Research Park) that is ground-up as research first enabled, developing a research-forward clinical trials enabled culture for rapid ROI and fast clinical trial delivery, funded with public-private investment.
- **Advanced life science real-time modelling:** Integrate biofabrication with spatial/single-cell omics, linking Synthesis and Solid State Pharmaceutical Centre drug design, HealthData@IE European Health Data Space real-world data to accelerate discovery-to-trial timeline and aligned with UNCAN/CANDLE cancer data node.
- **Aligned for All-Island (UK) and EU connectivity:** Leverage **Common Data Spaces**, AI Continent gigafactories, and 1+ Million Genomes for biomarker discovery, drug repurposing, and personalized therapies. All-island connected for real world data research, leveraging common HDR UK data standards, DARWIN-EU (as specified priority 6 in the National Clinical Trial Oversight Report NTCOG, 2025). Enable data connectivity for cancer research driven by Europe's Beating Cancer Plan, UNCAN.eu and CANDLE (National CANcer data Node DeveLopErs).
- Adopt best practice in **National Research Infrastructure** aligned with the EU life science research infrastructure (BBRMI, ELIXIR, GDI, EUCAIM) supporting biobanking, tissue, imaging, multi-omics storage, AI-readiness, and federated data access.

## Challenges

- **Data:** Ireland's capacity for advanced health and life science research is limited by fragmented data infrastructure, weak interoperability, and governance barriers. Current national systems are inadequate to capture or store multi-omics, wearable, or sensor data at the scale required for artificial intelligence-enabled research. Persistent data silos and governance misalignment across healthcare, academia, and industry sectors, coupled with limited integration with European platforms, weaken the value and reusability of national data assets.
- **Tissue:** The absence of national biobanking and biofabrication research infrastructure constrains functional precision medicine, advanced modeling, and translational capabilities.
- **Clinical:** Complex sensitive data governance, limited protected clinical research time, and the inability for hospitals to retain grant overheads devalue research activity and impede the development of clinical trials.
- **Workforce:** Most life science research staff are employed on teaching or clinical contracts with a 40:40:20 split between teaching, research, and service, limiting research capacity. The lack of a national structured framework for research staff careers, such as formal research scientist roles and the adoption of workforce development models like CARDEA, reduces Ireland's competitiveness. Research activity depends heavily on short-term trainee contracts, resulting in high staff turnover, poor continuity, and low returns on research investment. Establishing a national health and life sciences research institute with dedicated professional research staff and stable funding models would enhance Ireland's translational research capacity, workforce sustainability, and international standing.

## EU Context

The EU Life Sciences Strategy (July 2025) positions data as central to global competitiveness, supported by **AI Continent Action Plan's €200bn** investments in **gigafactories** and **Common Data Spaces** for secure federated analytics. Cancer leads with dedicated EHDS space under **Europe's Beating Cancer Plan** and **UNCAN.eu**, reversing trial activity decline through strengthened Member State infrastructure. Ireland's integration of **HealthData@IE** real-world data, **UNCAN.eu/CANDLE** National Cancer Data Node, and **ELIXIR** life science data research infrastructure would position Ireland to lead in data-driven innovative medicine.

Adopting a one-health approach to cancer would be highly innovative and would open innovative to investigate the environmental and lifestyle drivers of 85% of cancer. Regulatory bodies including the US FDA and the EMA have endorsed the **phase-out of certain animal testing and promoting NAMs** (including organoid and organ-on-chip technologies in their 2025 regulatory science strategies. Ireland's upcoming 2026 EU **Presidency provides an opportunity to amplify leadership in this space.**

---

## Thematic Questions (for stakeholder engagement)

- How can Ireland overcome data security and protection hurdles to enable clinical-academic partnership, while balancing open, federated research infrastructures with national data sovereignty and security?
- What infrastructure would enable a real-time data feedback cycle for rapid health technology assessment of new medicines, automated clinical trials feasibility and onboarding (per IPHA/IDA/NCTOG calls), and continuous disease surveillance for pandemic preparedness, risk prediction
- Given growing burden of environmental, diet and lifestyle associated disease, what one-health infrastructure would have most impact on chronic disease burden reduction including cancer?

### **Response to the Public Consultation for the new National Life Sciences Strategy**

We are a group of academic staff from the University of Limerick engaged in research, innovation, and higher education in the fields of Food Science and related disciplines. As active contributors to Ireland's life sciences ecosystem, we welcome the opportunity to respond to the Public Consultation on the National Life Sciences Strategy. In this submission, we outline our views in relation to the four themes identified in the Consultation: scope, objectives, opportunities and challenges, and the broader EU context.

#### **Scope**

Given that the aim of the new National Life Sciences Strategy is to ensure that the sector remains competitive and adopts an ambitious approach to emerging opportunities, it is our view that the Strategy should prioritise domains where rapid and transformative developments are already underway. In particular, the Biopharmaceutical and Food Production sectors are experiencing significant shifts driven by technologies such as artificial intelligence, advanced bioprocessing, and cellular agriculture. These developments are reshaping global value chains and innovation pathways, and Ireland must act strategically to avoid falling behind international competitors.

The Agri-Food industry plays a central role in Ireland's economy. The Irish Food Board, Bord Bia, reports a contribution of approximately 8% of national GDP and close to 160,000 jobs (Bord Bia, Irish Sector Profiles, accessed December 1<sup>st</sup>, 2025. <https://www.bordbia.ie/industry/irish-sector-profiles/>). To ensure Ireland maintains a strong position in this globally competitive sector, it is essential that Agri-Food enterprises have direct access to technological advancements and are supported in both adopting and co-developing new solutions. Embedding innovation capacity within the Agri-Food sector will be key to maintaining competitiveness, improving resilience, and meeting evolving societal expectations. Furthermore, promoting domestic research capacity and indigenous industry development will reduce reliance on FDI (foreign direct investment) while maintaining Ireland's global competitiveness.

#### **Objectives**

We propose that the Strategy should prioritise the following objectives, which are essential for supporting the life sciences ecosystem:

Research and innovation – through increased level 10 (PhD) funding and provision of regular small, medium and large funding capital to support academics at various career stages

Talent development and skills – provision of infrastructural funding resources for regional centres of excellence allowing continued delivery of high-quality BSc, MSc and PhD learning/training environments

Sustainability – targeting global challenges with innovative solutions

Valorisation of food and agricultural waste and side streams – linking to the circular economy

Digitalisation and use of AI in the biopharmaceutical and food production sectors (e.g., for product development and process optimisation)

Building public trust and outreach – to make science accessible using appropriate communication channels and promote the uptake of research innovations

## Opportunities and challenges

In line with the objectives outlined above, there are several opportunities and challenges that the National Life Sciences Strategy should address to strengthen Ireland's position in the global life sciences landscape.

### Challenges:

- Strengthen consumer trust, especially important when introducing new technologies and products (aligned with the European Life Sciences Strategy Action 3. **Boosting trust, uptake and use of innovation**).
- Integrating new production systems into traditional production systems (fisheries and horticulture), not replacing them, but augmenting them.
- Ensuring a One-Health approach is followed, to optimise the health of people, animals, and ecosystems (aligned with the European Life Sciences Strategy Action 1. **Optimising the research and innovation ecosystem**)
- Assessment of vulnerability in life-sciences supply chains (bioreactor components, enzymes, speciality chemicals, pharmaceuticals, functional ingredients).
- Development of domestic or EU-aligned manufacturing capacity for critical inputs.
- Support innovation adoption through targeted training, subsidised technology demonstration and shared pilot facilities for SMEs (uptake and adoption by SMEs is a barrier) (aligned with the European Life Sciences Strategy Action 2. **Enabling rapid market access for life science innovations**)

### Opportunities

- Advancing research on novel and hybrid production systems, sustainable manufacturing practices, and valorisation of agri-food waste

- Improving the visibility of Irish research by increasing support for researchers to communicate, present, and collaborate internationally
- Strengthening knowledge translation by incentivising the development of startups and spinoffs and by enhancing collaboration between academia, industry, and the private sector.
- Strengthen regional innovation ecosystems through distributed pilot-scale facilities (bioprocessing, fermentation, food prototyping) ensuring SMEs and rural enterprises have access to infrastructure
- Expanding Ireland's capacity to develop and export novel and hybrid food products informed by consumer demand for healthier, more sustainable choices.
- Supporting the development and validation of greener methods for product development
- Prioritising R&I in health, especially women's health, which has historically been underrepresented and neglected. Specific priority areas include those identified nationally as worthy of greater health income investment, such as endometriosis and menopause
- 

## **EU context**

As part of the EU Life Science Strategy, a number of actions have been proposed at EU level. We highlight those we recommend that the National Life Sciences Strategy should echo, adapted to the Irish context:

### ***Promoting a holistic approach to the life sciences***

- Promote a One Health approach to R&I by supporting research on climate-resilient crops, sustainable processing, and carbon-efficient production within Ireland's Agri-Food sector.
- Adopt the One Health Microbiome Initiative by advancing holistic microbiome research that enables resilient, competitive, and sustainable food systems.
- Develop a strategic R&I agenda on food systems for sustainable and resilient innovation, informed by Bord Bia's strategy and incorporating consumer co-creation focused on sustainable dietary practices, food safety, nutrition, and system resilience.
- Promote Diet/Health Research by issuing funding for interdisciplinary collaboration and identifying priority areas linked to major national and global health challenges, supporting functional food development, and strengthening evidence-based dietary guidance. Prioritise underrepresented areas of health research (e.g. women's health), by aligning national research agendas with EU-level priorities and investment recommendations.

### ***Life sciences as a driver for industrial sustainability***

- Support bioeconomy and sustainable biomass solutions, including research on alternative food sources, valorisation of food waste, circular bioeconomy practices, and biomass-derived ingredients that can integrate with existing Agri-Food systems.
- Support cross-sectoral life science technologies to enable new products, sustainable materials and biomanufacturing. Focus efforts on technologies relevant to both Biopharmaceuticals and Food bioprocessing, like fermentation, precision fermentation, enzymatic processes, and sustainable packaging materials.
- Promote scale-up of sustainable advanced fermentation and support SME/startup growth, translating research on fermentation, cultured foods, alternative proteins, and bioprocess-derived flavour compounds into viable commercial opportunities.
- Support strategic R&I actions de-risk product development, including new methodologies for toxicology, food safety assessment, nutritional modelling, and alternatives to animal testing, as well as green analytical methods for nutrient determination.

#### ***Unlocking the power of data and AI for breakthrough innovation in Life Sciences***

- Integrate multimodal generative AI into biomedical and food research, including applications in molecular modelling of ingredients, food safety predictions, processing optimisation, and sensory analysis.
- Support for strategic biodata resources, including initiatives combining metagenomics, metabolomics, organ-on-chip systems, and synthetic microbial communities, with a focus on reference materials, standardisation, and robust data stewardship to accelerate translation into farming, food processing, and nutrition.

#### ***Strengthening skills and careers for competitive Irish life sciences***

- Launch a foresight study on skills and training needs, ensuring that the biopharmaceutical and Agri-Food sectors influence future priorities in areas such as food safety analytics, data science, biotechnology, and sustainable processing.
- Develop agile regulatory pathways and innovation testbeds (novel foods, precision fermentation and AI-enabled decision systems) to accelerate safe, evidence-based product development.



To the National Life Sciences Consultation team.

Within the Life Sciences space, we at the University of Limerick are producing a skilled and educated workforce to serve the high concentration of global medical device and pharmaceutical companies in our region and beyond. We have generated an ecosystem for innovation and collaboration in the Life Sciences space, and we have positioned ourselves to attract interdisciplinary funding and build capacity. Please find below our coordinated submission to the consultation process from our theme leaders across our Life Sciences areas. We believe any National Life Sciences Strategy should include the following scope areas, objectives opportunities and challenges:

### **1. Scope areas that we believe should be included in a National Life Sciences Strategy:**

**Pharmaceuticals, from discovery to manufacturing.** The University of Limerick is a cornerstone of Ireland's biopharmaceutical research, hosting SSPC, Research Ireland's national centre for pharmaceuticals and PMTC, Ireland's national pharmaceutical manufacturing technology centre. At UL, a multidisciplinary approach is taken for the design of advanced materials and technologies for the development and manufacture of complex medicines, from discovery to formulation to patient-centered drug product design.

**Artificial Intelligence for enabling technology.** We develop AI-enabled computational technologies that integrate molecular modelling, biophysics, and data-driven analytics to accelerate therapeutic discovery and biomanufacturing. Our work spans machine-learning pipelines, multiscale simulations, and predictive modelling, enabling faster decision-making, reduced development timelines, and transformative advances across pharmaceuticals, biotechnology, and health.

**Med-Tech sector.** Ireland is a global hub for medtech supported by many of the world's leading companies and a significant indigenous sector. The medtech sector employs approximately 50,000 people in over 300 companies. With revenues of over €12billion these companies ensure that Ireland is the second-largest exporter of medical devices in Europe.

**Circular Bio economy:** The University of Limerick is advancing life sciences research while adhering to the principles of a circular bioeconomy. Through underutilised feedstock valorisation,

sustainable processing, recycling, and green lab certification, UL transforms biomass into high-value materials and pharmaceuticals, integrating life cycle analysis to drive resilient innovation, industry collaboration, and global societal impact.

**Ageing:** Our Ageing Research comprises of an interdisciplinary group of academic researchers across the University of Limerick, external academic collaborators, clinical collaborators and a Public and Patient Involvement (PPI) panel of older adults and family caregivers who share a common focus on ageing research. Our research is coordinated under the Ageing Research Centre and has been instrumental in driving the adoption and integration of innovative health care models for older adults and their family caregivers. This research has played a pivotal role in shaping national policies pertaining to health and social care for older adults.

**Food, Diet and Nutrition:** Our Food, Diet and Nutrition researchers use interdisciplinary, clinical, behavioural and molecular approaches to advance understanding of diet, health, performance and disease. Work spans dietary intervention trials, metabolic health, microbiome science, maternal and older-adult nutrition, performance nutrition, sustainability and functional foods. Our emerging research cluster integrates basic and applied science, collaborating closely with clinicians, communities and industry.

**Physical Activity for Health:** At UL the Physical Activity for Health (PAfH) is a designated University-wide Research Centre with multidisciplinary expertise, international renown for research excellence and capacity to meet global and local research, policy and practice challenges in promotion of physical activity for health. The membership includes a critical mass of expertise in psychology, physiology, health promotion, public health, sustainable mobility, exercise as medicine and policy research. PAfH integrates principles from the Life Sciences by applying biological, physiological, and behavioural evidence to understand how movement influences health outcomes across the lifespan. Together, these disciplines provide a scientific foundation for designing, implementing, and evaluating interventions that prevent disease and optimise population wellbeing. UL is ranked top 50 in the Shanghai rankings for sport science schools and in the top 100 in QS rankings for sport-related subjects.

**Cancer and Clinical Trials:** Our Cancer researchers are using multidisciplinary approaches and novel technologies in basic and translational science to improve our understanding of the biology of cancer and to help people on the cancer journey. Many of our researchers are coordinated under the Limerick Digital Cancer Centre which integrates basic and translational research, and we are working closely with patient groups and clinicians. Our Clinical Trials support unit provides coordination, guidance and infrastructure to support and coordinate clinical research across University of Limerick (UL), UL Hospitals Group, and primary and community healthcare settings in the Mid-West region. The Limerick Cancer Trials group is set up to make clinical trials and interventions available to patients in the region.

**Cellular and molecular mechanisms of disease:** Our team is a cohesive group of PIs with expertise in ECM biology, cell signalling, molecular characterisation and computational modelling that follow research directions to address complex health challenges. Their multi-scale research connects microbiology and metallomics with 3D tissue engineering to create advanced disease models. The team stands out for its multi-scale and multi-modal approach: from molecules (proteases, signalling nodes, trace metals) through cells (quiescence, microbiome, immune interplay) to tissues and engineered microenvironments (3D scaffolds, biomimetics) and finally to disease models (cancer, neurodegeneration). The pre-existing collaborations and co-publication record from many team members give a solid foundation for future joint programmes funding applications.

**Food science and technology:** Our Food Team drives innovation in healthy foods, sustainable processing, and protein-enriched products, supporting Ireland's Future Foods strategy and UN SDGs. We deliver the BSc in Food and Health and MSc in Functional Foods and Product Development, alongside PhD supervision, ensuring high employability. Our research and training create expertise for careers in food, clinical sectors, and global research institutes.

**Bioengineering:** Bioengineering is an interdisciplinary research team that aims to apply mechanical engineering principles to biological systems. We bridge the gap between mechanics, cellular mechanobiology and cell biology to create systems that mimic biological processes. Our areas of expertise include Neurobiology, Cardiovascular, Urology, Human Reproduction, Cell Mechanobiology, and Soft Tissue Biomechanics.

**2. To ensure its long-term success and sustainability, the National Life Sciences Strategy should include the following objectives:**

- A focus on Research and Innovation
- Initiatives aimed at maintaining our global competitiveness,
- Ensuring that the improvement of patient outcomes is central to all approaches
- A focus on developing talent and skillsets
- Developing and supporting mechanisms to attract and retain talent
- Ensuring PhD Stipends and postdoctoral salaries are competitive and appropriate
- Ensuring a clear career track for postdoctoral researchers and career scientists
- Increased diversity in the scale of funding to include small, medium and large awards
- Increased funding and resourcing of Basic Science
- Setting ambitious targets such as trebling investment in Level 10 (PhD) Funding
- Adopting a decentralised funding approach to better serve the regional needs and ecosystem across Ireland.
- Increased funding schemes to facilitate engagement with Schools, Science teachers and the citizen scientists/general public/patients.
- Increased funding to facilitate partnerships with healthcare practitioners in projects.

### **3. Our perception of the opportunities and challenges for Ireland's Life Sciences sector over the next decade and how they should be addressed in a national strategy.**

- In Ireland and in the Mid-Western Region in particular, we have an enormous footprint in biopharma, med-tech and food. We need to invest in this or we will lose it.
- We have focused on programmes that deliver pipelines of PhD candidates. The challenge is to make Level 10 programmes attractive for our best graduates
- We must continuously support initiatives that modify of our current educational routes that address the threats and opportunities of AI in Life Sciences to meet future demands
- We must support opportunities to ensure do not duplicate resources across the third level sector
- We should reward initiatives that promote shared and open access strategies across the country
- Increase bridging funding and pilot projects that attract companies into the Life Science space to access university-based research
- Highlight the housing crises from a contract researcher and PhD student perspective
- There are current challenges around the lack of funding to support the hosting of international conferences which will build our global reputation
- There are challenges around outreach initiatives that attract citizen scientists and break down diversity barriers
- There are challenges around our ability to expand communication of Life Sciences research
- A challenge is that we are losing talent regularly which could be alleviated somewhat if there were career research track positions available in institutions
- A national strategy should focus on building on and expanding our fundamental undergraduate programmes in the Life Sciences space.

#### **Contributors - Thematic Leads across our Life Science areas:**

**Pharmaceuticals, from discovery to manufacturing.** Prof Sarah Hudson

**Artificial Intelligence for enabling technology.** Prof Shayon Bhattacharya, Prof Ning Liu

**Med-Tech sector.** Prof Michael Walsh

**Circular Bio economy:** Prof Maurice Collins

**Aging:** Prof Rose Galvin

**Food, Diet and Nutrition:** Prof Audrey Tierney

**Physical Activity for Health:** Prof Brian Carson

**Cancer and Clinical Trials:** Prof Pat Kiely

**Cellular and molecular mechanisms of disease:** Prof Kieran McGourty

**Food Science and Technology:** Prof Eibhlís O'Connor, Prof Mohammadreza Khalesi

**Bioengineering:** Prof Eoghan Cunnane



## **University of Galway Response to the Department of Enterprise, Tourism and Employment's Public Consultation on Ireland's National Life Sciences Strategy**

### **Context**

Reflecting the pivotal role of universities in regional and national innovation ecosystems, in April 2025, University of Galway and Medtronic co-hosted a high-level stakeholder event at the Royal College of Physicians of Ireland to support the development and delivery of Ireland's first National Life Sciences Strategy. Featuring contributions from the Minister for Enterprise, Tourism and Employment, senior industry leaders, and academic and policy experts, the event explored how Ireland can address talent gaps, strengthen research and innovation, attract investment, and enhance collaboration across the life sciences ecosystem. Consequently, University of Galway greatly welcomes the current public consultation on Ireland's National Life Sciences Strategy and our response reflects many of the key recommendations arising from the event.

University of Galway regards the roll-out of a cohesive and ambitious national life sciences strategy as critical to embed agility and responsiveness to sustain Ireland's competitiveness and to enable a coordinated cross-government approach to the continued development of the life sciences ecosystem. An integrated approach involving higher education institutions, indigenous and multi-national industries, government and state agencies, health care professionals, and patients must be a hallmark of the strategy.

Against a backdrop of geopolitical uncertainty, and business, technological and demographic challenges and competition from emerging economies, Ireland cannot be complacent with regard to the buoyancy of the life sciences sector here and its role at a global level. The life sciences sector is a major contributor to the Irish economy. It accounts for ~100,000 jobs and in 2024 accounted for almost €100 billion in exports. The sector attracts significant foreign and indigenous investment in research and development, and significant capital expenditure. Therefore, the National Life Sciences Strategy is not just about crisis preparedness, resilience and competitiveness, it is about positioning Ireland as a global leader and a change-maker in life sciences, through deliberative, transformative action.

### **Scope**

***Life sciences span multiple sectors, including (bio)pharmaceuticals, medical technologies, agriculture, fisheries and food production. In your view, how broad should the scope of the strategy be?***

University of Galway's view of the scope is that the Life Sciences Strategy should include the breadth of the biopharma, medtech, digital health, and biotechnology sectors; sectors which span a comprehensive range of application domains. These domains encompass strategically important areas of regional and national strengths and emerging areas of opportunity as reflected in the National Smart Specialisation Strategy for Innovation 2022-2027. They include life sciences, medtech and medical devices, Marine and blue economy, AgriFood and AgriTech, Biopharma, and Advanced Manufacturing and Engineering, and Renewable Energy, Climate change, mitigation and sustainability. In considering the scope of the life sciences, we regard data, digitisation and AI as cross-cutting enablers of the strategy.

## Objectives

***What should be the key objectives of the National Life Sciences Strategy to ensure the sector's long-term success? For example: research and innovation, global competitiveness, patient outcomes, talent and skills, sustainability***

In our view, the National Life Sciences Strategy mission is to sustain and enhance Ireland's future competitiveness through research, innovation, talent development, entrepreneurship, and technology and digitisation to underpin the continued growth and strengthening of the biopharma, medtech, digital health, and biotechnology life sciences sectors in Ireland. Thus, we regard the following as key objectives of the National Life Sciences Strategy:

1. To strengthen the development of a pipeline of the next generation of skilled professionals for employment in the life sciences sector through education and industry-academic collaborations
2. To expand Ireland's capacity for world-leading life sciences research and innovation
3. To compete as a global, innovation-led life sciences hub
4. To embed the Irish health service as a cornerstone of our life sciences ambition
5. To reinforce the life sciences as a driver of economic success, sustainability and climate resilience

## Opportunities and challenges

***What do you see as the main opportunities and challenges for Ireland's life sciences sector over the next decade that this strategy should address?***

In addressing this question, we identify a set of actions under each of the objectives listed above aimed at overcoming the existing challenges and positioning Ireland to seize opportunities, to realise the full potential of our life sciences ecosystem, and to shape the future direction of life sciences.

***Objective # 1 - opportunities and challenges the strategy should address to strengthen the pipeline of skilled professionals through education and industry-academic collaborations***

1. Publish a delivery roadmap for the remaining elements of the "Funding the Future" programme, with specific timelines and milestones for implementation.
2. Establish a national AI for All Disciplines Fund (AI4AD) to embed AI and data science across a wide range of undergraduate and postgraduate programmes, with priority given to interdisciplinary, biotechnology, health, and life sciences-related courses.
3. Benchmark and enhance PhD stipends and researcher pay scales to align them with international standards, ensuring Ireland remains competitive in attracting and retaining world-class research talent.
4. Implement a funding stream for a multi-annual inter-disciplinary cohort-based PhD programme for life sciences with a strong focus on developing entrepreneurial and translational skills.
5. Implement a fast-track global talent pathway for life sciences professionals by removing systemic barriers - such as visa delays and accommodation access - to streamline international recruitment.
6. Develop a Global Irish Leadership Strategy, recognising the value and influence of Irish professionals in international leadership roles.
7. Fund leadership programmes and global networking platforms to nurture the pipeline of Global Irish leadership.

8. Identify and scale best-in-class industry placements and graduate research training by partnering with life sciences companies to track outcomes such as hiring ratios, dropout rates, and promotion rates, and replicate successful models.
9. Standardise and simplify mobility schemes between academia and industry, creating contract templates and shared governance frameworks to enable seamless talent flow.
10. Ensure graduates, regardless of their degree area, are equipped with critical thinking, data and AI skills, and instilled with an entrepreneurial mindset. Doubling down on and embedding AI training is critically important in this regard.
11. Upskill the current workforce across the life sciences sectors in digital tools, AI, leadership, and regulatory knowledge.
12. Improve career paths to attract and retain top research talent.
13. Reform education to embed STEM from early education.
14. Recognise that for Chartered Engineer status, a five-year recognised Master's course is required. Extend free fees and grant aid, prioritising any pilot to life sciences courses like biomedical engineering.

*Objective #2 - opportunities and challenges the strategy should address to expand Ireland's capacity for world-leading life sciences research and innovation*

1. Significantly increase public investment in research across national agencies like Research Ireland, Enterprise Ireland, IDA and HRB, bringing Ireland in line with global benchmarks.
2. Modernise Ireland's IP and tech transfer frameworks, streamlining industry-academia collaboration and accelerating innovation pathways.
3. Scale platforms that accelerate the translation of scientific discoveries for research commercialisation by expanding initiatives like the Research Ireland Centres, Disruptive Technologies Innovation Fund and ARC Hubs. Prioritise high-impact, cross-sector collaborations with real-world patient and economic outcomes.
4. Remain steadfast on commitments to continue to nurture and support fundamental discovery and exploratory research for knowledge generation. This recognises that knowledge generation is a national asset, which deepens and accelerates scientific understanding of disease and other societal and healthcare challenges to prime a sustainable pipeline of discoveries and opportunities, and to support the transition of quantitative scientists/engineers to the life sciences sector, thereby facilitating technology and knowledge transfer to enhance innovation.
5. Deliver on the commitments to INSPIRE to enable universities and research centres to upgrade and expand state-of-the-art research and innovation equipment essential for frontier science
6. Create more flexible and agile funding models (e.g. faster turnaround, simplified applications).
7. Be a leader in data-driven research; we must generate, protect and ethically leverage data – we must create data trust frameworks, invest in secure cloud infrastructure, and support multi-stakeholder data collaboratives—linking academia, industry, and government.
8. Invest in large pre-clinical *in vivo* testing facilities that meet the testing needs of life sciences companies, SMEs and the academic research community.

*Objective #3 - opportunities and challenges the strategy should address to compete as a global, innovation-led life sciences hub*

The current R&D tax credit system is limited in leveraging one of Ireland's greatest innovation assets—its universities. Universities are fundamental pillars of the life sciences and MedTech ecosystem and a critical enabler of economic growth through educating and developing talent, driving fundamental,

applied and translational research, incubating IP and entrepreneurship, and fostering innovation by catalysing industry-academic collaboration. As it stands, the tax credit offers limited support for companies to partner with Irish universities or hospitals. This is a policy gap that is costing Ireland real opportunities. As such, the tax credit misses out on significant potential to drive the kind of rich innovation that creates lasting value and connection. It discourages companies from tapping into the expertise, infrastructure, and clinical access that Irish universities provide. It weakens the links between research and impact, and it places Ireland at a competitive disadvantage compared to countries that directly reward collaboration with academia. Thus, the Strategy should embrace the potential of the R&D Tax Credit as a strategic reinvestment that generates future revenues, economic prosperity and societal good.

1. Enhance the R&D Tax Credit to:
  - a. Incentivise digital, biotechnological, clinical, and manufacturing innovation
  - b. Align with flexible, global best practices in innovation hubs like Singapore
  - c. Increase credits for outsourced high-value R&D, recognising the global, connected nature of research
  - d. Reflect and support a model of globally-connected, locally-anchored research
2. Promote the strategic importance of the life sciences sector at an EU level, seeking expanded incentives and supports, as applied to the semiconductor industry.
3. Encourage global academic partnerships that benefit Ireland. Many of the most significant breakthroughs in health and technology arise from international academic collaboration. When companies fund joint research between Irish universities and top-tier institutions outside the EU, it elevates Irish capability, attracts talent, and increases the likelihood that follow-on investment will land here. The tax credit can act as a lever to stimulate these partnerships and ensure Ireland remains embedded in global innovation networks.
4. Clinical research, clinical trials and clinical investigations are critical to the life sciences value chain, driving innovation, investment and providing patients with access to novel medicines and medical technologies. Yet, Ireland attracts fewer industry-sponsored clinical trials than peer European countries, in part due to fragmented research infrastructure, institutional bottlenecks and limited industry incentives to conduct trials in Ireland. Therefore, the strategy must embed the recommendations from the National Clinical Trials Oversight Group to coordinate efforts to enhance clinical research across the life sciences spectrum.
5. For clinical trial delivery within the health service - roll out standardised costing templates, itemised pricing schedules, standardised indirect cost rates for commercial trials.
6. Strengthen DEMPE alignment through university engagement. Irish universities play an active role in the design, development, and enhancement of intellectual property. The R&D tax credit can help deliver on Ireland's policy commitments to responsible tax governance by encouraging structured engagement between companies and the academic sector—ensuring that innovation is rooted in real Irish capability and substance.
7. Recognise health innovation, applied research, digital health, and AI in the revenue guidelines.
8. Support regional innovation and balanced national growth. As a regional university with a national mission and global outlook, we demonstrate how research-led partnerships can deliver real benefits for communities outside Dublin. Targeted enhancements to the credit for R&D involving regional centres, such as our research hubs in Galway and our region, can help drive more geographically-balanced innovation and job creation.
9. A reformed R&D credit should reward and encourage industry partnerships with universities. Doing so would unlock greater private investment, thereby increasing the percentage of HERD financed by industry and improving Ireland's position relative to other OECD countries in terms of HERD as a percentage of GNP and GDP. Ireland's total expenditure by industry and the state on R&D as a share of GDP is only 1.58%, leaving us at a 21<sup>st</sup> uncompetitive position compared to other advanced economies. Unlocking greater private investment will deliver

- better outcomes for patients and society, and ensure that Irish tax policy supports the full strength of our innovation system.
10. Difficult regulatory systems are the biggest bottleneck to innovation. Ireland must be a vocal leader, at home and in Brussels, for smart, adaptive regulation that enables safe, swift adoption of breakthrough technologies. Ireland's life sciences sector benefits from a reputation of regulatory excellence. To maintain this position, it is important that regulatory frameworks are fit-for-purpose and do not introduce unnecessary inefficiencies, complexities or costs. For example, if Ireland enacts national legislative and regulatory measures to fully implement the EU AI Act in a way that is well-coordinated, transparent, and balances ethical safeguards with the encouragement of AI innovation, Irish industry can strengthen its reputation as a leading destination for responsible and forward-thinking AI-driven business. The Strategy should consider the effectiveness of the regulatory frameworks, the regulatory burden and assess the regulatory environment with a holistic lens to ensure regulations are consistent and efficient.
  11. A potential barrier to Ireland's life sciences competitiveness is capacity constraints within key regulatory agencies. Ireland's life sciences sectors are more tightly regulated, with highly stringent regulatory frameworks, compared to many other sectors in the country due to the critical nature of their products and services, which directly impact public health, safety, and well-being. With rising demand and increasingly complex regulations outpacing regulator's capacity, agencies such as the HSA, EPA and HPRA are currently experiencing critical resource constraints, backlogs and delays in decision-making and service delivery. The regulatory agencies must be resourced to enable them to meet the demands and growth of the sector.
  12. Ireland's life sciences sector is essential to national public health and economic stability. The sector underpins the State's ability to respond to health emergencies, including pandemics and emerging diseases. Ireland hosts nearly all major pharmaceutical and medical device firms. Disruption to this sector would threaten supply chain continuity, public health outcomes, and the wider economy. Designating life sciences as a critical sector would ensure the sector is protected with targeted resilience measures, risk management, and supply chain security aligned with the EU Critical Entities Resilience Directive. The HPRA should be empowered, as the competent authority, to formally designate the life sciences sector as a "critical entity" to secure regulatory oversight, resilience planning, and prioritisation under national and EU Frameworks
  13. Advocate for a pause of the EU's Minimum Tax Directive, given its disproportionately early adoption in the EU and potential to undermine the competitiveness of European life sciences companies.

*Objective # 4 - opportunities and challenges the strategy should address to embed the Irish health service as a cornerstone of our life sciences ambition*

The Life Sciences Strategy is a generational opportunity and it is part of Ireland's crisis preparedness and resilience and an opportunity to address both academic and industry needs for the greater public good. Recognising the vital contribution of the medtech, digital health, pharma, and biotechnology sectors to the Irish economy, we must align the National Life Sciences Strategy with an ambitious, integrated health system agenda. Failure to do so, will entrench the status quo where world class discovery happens in Ireland, but delivery happens elsewhere. This Strategy can be a springboard for

a bold reimagining of how the Department of Health, the HSE, and the life sciences industry work together. With one of the highest concentrations of medtech and pharma expertise in Europe, Ireland has the power to do more than innovate — Ireland can solve. A national life sciences strategy that mandates this kind of collaboration will create a legacy that puts patients first and improves society.

1. The Irish health service must be a cornerstone of our life sciences ambition. That means investment, partnership, and shared accountability across government, HSE, academia, and industry, and recognising the role of the Irish health system as a key enabler of life sciences innovation.
2. Clinical Research must be embedded as a core function of the Irish Health Service with appropriate budget allocation and KPIs for performance assessment and accountability of delivery.
3. Clinical trials are the engine room of medical innovation. They generate the evidence that turns ideas into therapies, and therapies into lives saved. Ireland has a strong foundation — but Ireland is underperforming in key metrics: trial volume, speed of approval, and site capacity. Clinical trials must move to a nationally coordinated clinical trial infrastructure, underpinned by secure, consistent funding.
4. Recognise the skilled workforce and investment required to deliver clinical research at a patient-facing level nationally, and also critically at a non-patient facing clinical trial coordination level to support the sector’s ambition and long-term needs.
5. Trials must be designed with patients, not just for them — transparent, accessible, and rooted in the lived experiences of those they serve.
6. Develop universal contract templates, national data protection guidance, unified trial delivery models, and open-access dashboards for clinical trial KPIs.
7. Launch educational campaigns (integrated into health apps), and embed mandatory clinical trial performance metrics and KPIs in health service reporting.
8. Data is the lifeblood of 21st-century medicine. Sovereign investment in high-performance computing, inspired by the NHS-Wellcome model, is critical. Our future depends on secure infrastructure to process and analyse the clinical, genomic, and real-world data we generate.
9. Ireland must digitise or risk decline. From unlocking the potential of AI in hospital wards to enabling real-time insights across care pathways, the digitisation of our health system is a moral and economic imperative. The integration of digital systems will not only improve patient outcomes, it will open entirely new frontiers for discovery and development.
10. Prioritise the rollout of Electronic Health Records (EHRs) and promote innovative trial methodologies (e-consent, remote monitoring, AI, digital twins).
11. Support public-private partnerships, especially in clinical research.
12. Targeted enhancements or simplified qualifying rules for university and hospital partnerships would unlock further value, align public and private investment, and deliver wider societal returns.
13. Clinical trials — especially early-stage and investigator-led studies — be clearly recognised as qualifying R&D, to further embed this activity in Ireland.

*Objective #5 - opportunities and challenges the strategy should address to reinforce the life sciences as a driver of sustainability and climate change resilience*

1. Encompass One Health as a fundamental pillar of the National Life Sciences Strategy recognising the interconnectedness and interdependencies of human, animal and environmental health to tackle global challenges in a sustainable way.
2. Go further than the measures set out in the EU Life Sciences Strategy to encompass Planetary Health as a fundamental synergistic pillar in the National Life Sciences Strategy, complementing One Health, recognising that human caused disruptions to the earth systems impact human health.

3. Create funding mechanisms that foster transdisciplinary One Health and Planetary Health research and innovation and support the development of solutions to increase our resilience to climate change and to develop solutions—oriented climate change mitigations
4. Support fundamental and applied research and innovation in cross-sectoral life science solutions aimed at novel (bio)-molecules, including, marine-derived biomolecules, biopharmaceuticals, and blue bioeconomy, and microbiome in One Health environments as well as biomass management, bioremediation, agri-science, and biodiversity
5. Advocate for companies and universities to deliver greener policies and standards in the life science sectors by offering technological solutions (green chemistry, low carbon manufacturing) that reduces environmental impacts which ideally also support the circular economy
6. Embed Engaged Research as a mechanism to build public trust and support for research and innovation and their understanding of the relevance of research and innovation to improving their every-day lives and safeguarding our world for the next generation and beyond

### EU context

**The European Commission recently published an [EU Life Sciences Strategy](#) aiming to position the EU as the world's most attractive location for life sciences by 2030.**

***What are your views on this ambition and the measures proposed to achieve it? How could these be applied in the Irish context?***

The EU Life Sciences Strategy is ambitious and broad. The actions listed above capture to some extent how the measures proposed in the European Strategy could be applied in the Irish context. In addition, we recommend:

1. Mobilise a whole-of-Government mission for Life Sciences: This strategy must be more than a departmental initiative—it must be a shared national mission. Success demands coordinated action from health, education, enterprise, finance, and digital agencies working as an agile, aligned team.
2. Create a Life Sciences Strategy Office, modelled on the UK's, to drive cross-departmental coordination and policy alignment.
3. Establish a National Life Sciences Advisory Council, with cross-sector representation from academia, industry, health, and government, to steer implementation and oversight.
4. Leverage Ireland's EU Presidency in 2026 to champion European competitiveness in life sciences and secure strategic influence in shaping Horizon successor programmes. The Draghi Report is a call to arms for a more sovereign, strategic and innovation-driven Europe. Ireland should be at the centre of shaping what comes next, championing competitive state aid reform, strategic investment in future industries, and health outcomes.
5. Empower our best engines of growth: Enterprise Ireland and IDA Ireland are internationally respected. Their deep expertise and global networks should be more empowered, not constrained by rigid rules. Trust them to seize opportunity at speed.
6. Focus on accountability and execution of strategic objectives set out in the Strategy, including resourcing the strategy through new investment and realigning existing resources
7. Invest in research, research infrastructure and education, including the Funding the Future programme committed to by government
8. Invest in secure, scalable data infrastructure for research and trials



9. Invest in AI and lever recent investment in high-performance computing capabilities, as well as the AI Factory Antennae.
10. Reduce bureaucracy around innovation adoption
11. Ensure cohesiveness across the various Regional Enterprise Plans and the Strategy, and ensure the Strategy reflects the principles of smart specialisation and balanced regional development
12. Increase capacity for life-sciences start-ups to access adequate laboratory and specialised facilities, co-located with or adjacent to universities

## **Submission: Irish National Life Sciences Strategy from the West Regional Enterprise Plan**

### **Background**

Lifesciences, in particular the Medtech Sector in the west of Ireland is a key sector in the region. In the west of Ireland, the sector comprises a vibrant mix of disruptive startups and scaling indigenous companies, established indigenous companies and multinational global giants. Multinationals continue to select the west of Ireland, in particular Galway for their operations. There have been successful acquisitions of companies founded in the region and there is a strong pipeline of start-ups from the ongoing applied lifesciences R+D in the universities and programmes like the BioInnovate programme. The recent announcements of the ARC hub for medtech and connected health led by the university of Galway with the Atlantic Technical University and the Royal College of Surgeons as partners accelerating novel cutting-edge research, developing entrepreneurial scientists and engineers will enable the next generation of Medtech/Lifesciences start-ups in the region.

The ecosystem in the region additionally comprises innovation hubs who provide space and a community for lifesciences start-ups. The Medical Engineering Technology Gateway (MET), the MedLink cluster, the Health Innovation hub, the Institute for Clinical Trials, by way of examples, provide a range sector specific services and supports. Enablers nationally and regionally include the business development agencies, WestBIC, the Western Development Commission, the Regional Skills Forum, the Irish Medtech association and the local authorities.

While there are lots of ecosystem resources/assets and entities, gaps may exist in optimally meeting the needs of the lifesciences sector in the region and there may be a lack of cohesion between the resources/assets, stakeholder/enablers and lifesciences companies.

A facilitated workshop in June with lifesciences companies in the region sought to understand the challenges that exists for start-ups and scaling companies in the region and to propose potential solutions and recommendations. This was followed by a stakeholder workshop in October. The learnings from those engagement sessions have influenced this submission.

### **Introduction**

Ireland's life sciences sector stands at a pivotal juncture. To secure long-term competitiveness and sustainable growth, the National Life Sciences Strategy must prioritise the development of indigenous enterprises, strengthen the full supply chain, and leverage regional strengths. This submission outlines key recommendations and sectoral insights to inform the strategy.

## Strategic Priorities

- 1. Empowering Indigenous Scale-Ups**
  - Ireland must foster an environment where indigenous startups evolve into scale-ups and global acquirers, rather than being acquired prematurely. While trade sales to multinational corporations (MNCs) offer short-term benefits, the long-term vision should be to cultivate Irish-headquartered global multinationals.
- 2. Regional Development and Sectoral Convergence**
  - The life sciences sector is uniquely strong in Ireland's regions, often surpassing Dublin in capability. Regional clusters can drive broader economic development, especially when layered with emerging sectors such as artificial intelligence and immersive technologies, using life sciences as a foundational customer base.
- 3. Self-Reliance in Production and Sales**
  - Ireland must enhance self-sufficiency at the European level, both in production and market access, to reduce dependency on external actors.

## Funding and Investment

- **Expanding Risk Capital**
  - A robust continuum of funding is essential, from early-stage angel investment to venture capital, private equity, and corporate venturing. Unlocking greater private sector investment is critical, with tax incentives deployed to stimulate investment at all stages.
  - Pension fund allocations and auto-enrolment schemes should be ring-fenced to support SME and life sciences investment.
- **Public Sector as Beta Customer**
  - The HSE and other public bodies should act as beta customers for innovative technologies, providing startups with vital market validation and accelerating commercialisation. Public procurement guidelines must prioritise innovation to maximise health outcomes and cost savings.

## Skills and Commercialisation

- Ireland excels in R&D, but must now prioritise commercialisation and sales skills. Technical sales modules, dedicated undergraduate and postgraduate degrees, and targeted upskilling are urgently needed. The transition from founder-led innovation to professional commercialisation teams is a critical challenge.

## Clinical Trials and Infrastructure

- Ireland has an opportunity to lead in First-in-Human and pilot phase clinical trials, despite limitations in population diversity for large-scale trials. Addressing gaps in animal trial capacity and expanding specialist infrastructure are essential.

## Regional and National Cohesion

- The strategy should support regional strengths, particularly in the West/Northwest, by:
  - Developing specialist facilities for Medtech/Healthtech based around the model of a campus / centre of excellence
  - Enhancing ecosystem supports for commercialisation
  - Fostering clusters across industry, academia, and investment
  - Ensuring national facilities for preclinical and clinical research
- There is a potential to create a Regional Life Sciences Commercialisation Fund to support scale ups in the West/ Northwest that support the National objectives including those set out in the NDP and skills strategies.

## Scope and Objectives

- The strategy should encompass biopharma, medtech, and digital health sub-sectors.
- Key objectives must include driving global competitiveness, expanding regional footprints, and coordinating sectoral growth.

## Opportunities and Challenges

- Opportunities: Strong regional clusters, robust university pipelines (e.g., Bioinnovate), and collaborative platforms (e.g., MedLink).
- Challenges: Funding gaps, commercialisation skills, infrastructure needs, and competition for talent.

## EU Context

- Ireland should align with the EU Life Sciences Strategy, leveraging existing biotech clusters and centres of excellence. Strengthening partnerships, missions, and bioclusters will be vital for competitiveness.

### Conclusion:

Ireland's National Life Sciences Strategy must be ambitious, regionally inclusive, and focused on building indigenous capacity, commercial excellence, and sustainable growth. By implementing these recommendations, Ireland can secure its position as a global leader in life sciences.