

Submission to the Interdepartmental Committee on Science, Technology and Innovation

Molecular Medicine Ireland (MMI) welcomes the IDC consultation exercise to inform the successor to SSTI 2006-2013. Areas of focus in the consultation paper coincide with areas of strategic importance to MMI.

MMI is a not for profit research partnership established by NUI Galway, Royal College of Surgeons in Ireland, Trinity College, University College Cork and University College Dublin to give expression to their shared vision of improved healthcare through the development of diagnostics, therapies and devices from concept to realisation. The mission of MMI is to mobilise the strengths of the five partner institutions to coordinate, support and promote translational and clinical research to achieve the shared vision. Information about MMI is available on our website at www.MolecularMedicineIreland.ie

The Economic Return on Investment in Health Research

In 2008, the Wellcome Trust, the Medical Research Council and the Academy of Medical Sciences published a study of the economic benefits from medical research in the UK. Undertaken by Brunel University and Rand Europe, the research identifies the key economic benefits of medical research as 1) health gains – net of the costs to the health services of delivering them – and 2) the gains to GDP that result directly and indirectly from medical research. They found that a £1 investment of public or charitable funds in cardiovascular disease research yielded a stream of benefits to the UK thereafter equivalent in value to earning £0.39 per year in perpetuity. One message from the research is that the impact of investment in medical research takes time to emerge - in cardiovascular disease, for example, the lag between investment and impact is between 10 and 25 years.

Clinical trials are a necessary step in demonstrating the effectiveness of new medicines, vaccines and devices or new applications for established products before they are used in the clinical care of patients. The economic return on investment in clinical trials is substantial. A comprehensive review of all phase 3 clinical trials supported by the US National Institute of Neurological Disorders and Strokes found that, on a conservative estimate, the economic benefit in the United States from just eight of the trials reviewed, exceeded \$15 billion over the course of 10 years. The investment in most of the trials was returned through health benefits within 1.2 years after the trial funding ended.

University Funding and Irelands Global Reputation

Ireland does not feature in the latest list of the world's 100 most prestigious universities. Trinity is the highest-rated Irish university, falling somewhere between 150th-200th place, while University College Dublin (UCD) is outside the top 200.

A university's global academic reputation is vital and was a key driver of success, helping institutions to attract the top student and academic talent as well as investment and research partners. Universities that benefit from sustained public and private funding generally dominate the rankings.

The presence of highly ranked universities in Ireland would enhance the country's reputation in attracting international students, researchers and foreign direct investment. For Ireland to have world - class universities requires adequate investment and resourcing at internationally competitive levels.

Business Model of the Life Science Industry

The business model of the life sciences works because health services, patients and taxpayers are willing to pay for more effective ways of preventing disease, diagnosing and treating illness and organising more effective delivery of health services. The future success of the life science industry depends on a pipeline of ideas from research that can be licensed and developed as new products for purchase in the health sector. Increasingly, the life science industry is looking to academia for research ideas to commercialise and to health systems to test the effectiveness of the new products before their release on the market. Within the life science sector, SMEs and start-ups need the support of academia to spin out (or spin in) their ideas and of the health service to conduct the clinical trials to pass regulatory and product standards. Countries

that make academic-industry interaction in the life sciences easy and whose health systems are organised to support clinical studies and facilitate innovation, will reap the rewards in terms of investment by the multi-national life science sector, the growth of SMEs and start ups and the creation of jobs in this knowledge intensive sector. Ireland, with its track record in biomedical research, its reputation for quality in manufacturing in the life science industry, its cadre of highly trained and committed clinicians, a patient population that is well disposed to participating in clinical studies and a health system that aspires to provide world class care to the population, is particularly well placed to benefit from the new paradigm of the life science industry, if certain steps are taken quickly.

Translational and Clinical Research as a bridge to the Life Science Industry

MMI considers that translational and clinical research, because it provides a bridge between biomedical and other basic research and the life science industry, has demonstrated its capacity, both nationally and internationally, to generate new companies and products and to create jobs.

The aim of translational and clinical research is to apply the advances in biomedical and related sciences to the challenge of preventing disease, curing illness and increasing the health of the population. The prevention, diagnosis and treatment of illness has been transformed in the past two decades by the application of research advances in molecular biology, genomics, proteomics, physics and information sciences. The outcome of these advances are new vaccines to prevent illness, new ways of diagnosing disease and more effective treatments for illnesses that were previously poorly controlled. This transformation is still in its early stages – there are many more scientific advances to be translated into better care of patients, a healthier population and more effective health services. Translational and clinical research can provide an economic dividend in Ireland in those disease areas where we have established international research leadership, where we have clinicians engaged in research and sufficient patient numbers for studies and where the outcomes of research provide a commercial return.

SSTI - Investment in Translational and Clinical Research

1. Funding

Maintain/ increase levels of investment in biomedical research: MMI believes that it is vital to maintain/increase investment in biomedical research in those fields in which Irish based researchers are strong - such as immunology, infection, neurosciences, aspects of cancer, systems biology and information sciences - to ensure a pipeline of ideas of interest to the life science industry. Present research capacity in biomedical research has been built up on the back of support from the HRB over many decades and more recently by funding from the PRTL and SFI. Funding for high quality biomedical research needs to continue as otherwise the life science industry will look elsewhere for new ideas and academic partnerships. Investment should be across the research continuum, basic through applied.

Provide more incentives to translate research into applications: MMI recommends that there should be greater incentives to translate the advances in biomedical and related sciences into the development of diagnostics, therapies, devices and vaccines that demonstrate a benefit to patients and which can be developed as commercial products.

Invest in clinical trials: MMI supports investment in building national capacity to undertake scientifically relevant clinical trials, both industry sponsored and investigator-led. A capacity to undertake clinical trials is necessary to improve the quality of care for patients and the population, to facilitate innovation by indigenous companies and to attract R&D investment by international pharma and medical device companies. Clinical trials create employment in the conduct of trials, in the companies that use trials to test their products and through the foreign direct investment that may result.

The HRB is investing significantly in the infrastructure to support multi-centre clinical trials, including (with the Wellcome Trust) the Dublin Centre for Clinical Research and new clinical research facilities in Cork and Galway. The HRB has committed to further investment to support the formation of disease groups to undertake high quality clinical studies that will lead to significant improvements in outcomes for patients and a more effective health service. They have also committed to invest in a national Clinical Research Coordinating 'centre' that will provide the services needed to support multi-centre clinical trials, both industry and investigator-led, to the highest regulatory and ethical standards.

Invest in our Universities: The decline in the position of Irish universities in global rankings must be addressed. There is no one reason for this decline. However, improved funding for research through a successor to PRTL15 would be a critical step in addressing this deficit and support continued investment in our human capital which is a critical part of our national research and innovation eco system.

2. Leadership, strategy and legislation

While continued funding for clinical and translational research is essential, this investment will not yield its maximum return for the Irish taxpayer without simultaneous movement on three key issues: the active engagement of the Health Service Executive, the passage of the Health Information Bill and a national strategy on biobanking.

Active engagement of the HSE: MMI is of the view that clinical and translational research will only achieve its potential in Ireland if the HSE as the main funder of health services, actively engages in supporting the research activities of clinicians, the recruitment of patients to clinical studies and the fostering of innovation in all aspects of health care. The health services needs to engage with research in a manner similar to the way in which the universities reorganised around research a decade ago. Legislative change is required to make support for research and innovation a core responsibility of the HSE or its successor and the appointment within the HSE of a leader with responsibility to implement national policy on research and innovation is urgently required.

Health Information Bill: The long promised Health Information Bill is necessary to streamline the process for ethical approval of clinical trials, to provide for a unique patient identifier and to permit the sharing of patient information, subject to strict safeguards. MMI calls for its introduction and implementation as soon as possible.

National Strategy on Biobanking: MMI believes that the adoption of a national approach to biobanking is a key element of overall initiatives to develop an effective translational and clinical research infrastructure in Ireland linked to the life science industry. Biobanks are collections of biological samples, such as blood, tissues or DNA, with associated epidemiological, clinical and research data which are used to identify genetic influences on disease and to personalise new therapies. High quality biobanking is essential for biomarker development and validation. The national approach to biobanking should encompass:

- A national policy, underpinned by legislation, on the storage of samples and the use of biological data and associated patient information for the purposes of research;
- The networking of existing and new biobanking resources – with required ICT supports and in association with European partners. MMI calls for a coordinated approach by the research funding agencies to implement the national approach when agreed.

Conclusion

MMI recommends that investment in translational and clinical research be prioritised because of the proven economic return on such investment. Funding in those areas of biomedical research in which Ireland is strong should be maintained to generate a pipeline of ideas for translation and application in clinical settings. There should be greater financial incentives for translational research and support should be available further back on the translational chain. Commitments by the HRB to invest in clinical research capacity should continue there should be a dedicated stream of competitive funding for investigator-driven clinical trials. Invest in our Universities through a successor to PRTL15. To maximise the return on investment in clinical and translational research, the HSE should play a leadership role in implementing national research and innovation policy, the Health Information Bill should be introduced without further delay and a national strategy on biobanking agreed and implemented.