PRIORITY AREA E
MEDICAL DEVICES ACTION PLAN
JULY 2013

Medical Devices (Priority Area E)

Context

The global medical device market was reported as $296 billion in 2010. Growth varies from 3-9 per cent per annum depending on sub-segment, with higher growth forecast for technology intensive segments. The sector is diverse and produces over 500,000 individual products, in 10,000 generic groups ranging from simple tongue depressors to highly complex artificial hearts. Structural factors within the medical device industry create a pivotal role for the sub-supply and contract manufacturing segment, with outsourcing in the region of 40 per cent of output. Major drivers of growth in the medical device sector are demographics (the ageing population) and technology innovation and convergence, particularly between medical devices and therapeutics, where devices are becoming an integral part of therapeutic treatments in ever more sophisticated ways.

Ireland is one of the leading global hubs for the medical devices industry, generating €6.7 billion (2009) in exports and employing more than 22,700 people (90 per cent in foreign multinational companies). Ireland is now the second largest exporter of medical products in Europe, behind Germany. Eight of the world's 10 largest medical device companies are located in Ireland. Of the 120 companies in the sector, 50 are foreign owned (mainly US) MNCs, 40 are Irish companies engaged in sub-supply and contract manufacturing and there are approximately 30 indigenous companies involved in developing and marketing finished products (some innovative). While the R&D base is small, most foreign MNC do carry out R&D in Ireland; mainly process, but some product R&D. Of the key FDI companies in the sector, Abbott, Boston Scientific, Medtronic, Stryker, De Puy, Vistakon, Covidien and Nypro are engaged in significant product development. Creganna –Tactx Medical also has a significant product development activity. Most of the Irish sector is focused on the development and manufacture of medical and surgical instruments, and on surgical appliances and supplies. There is a strong reliance on interventional cardiology, with 80 per cent of global stent products manufactured in Ireland. Medical devices based on electronics and information technology form a major part of the device sector globally, but only a small part of the sector in Ireland. As sector of employment and export in Ireland, support for new product development within the medical device sector has clear economic and societal benefits.

There has been a significant Irish investment in medical device research in the last 10 years; from 2003 to 2010, SFI has invested approximately €160 million in Bio-engineering, Diagnostics, Devices and Imaging. In addition, over €150 million has been invested in applied and industry partnered research. Key areas of research include: Minimally-Invasive Surgical innovations; Cardiovascular and vascular disease, particularly stents; Biomaterials and scaffolds, particularly in orthopaedics.

The medical device sector is constantly driven by research and development and continues to demonstrate strong growth prospects. Ireland has built strength and critical mass in a number of research areas that underpin the sector including materials, nanotechnology, biomedical research etc. Building on basic research capacity, a number of clusters and centres (including SFI funded CSETs and several SFI-funded Strategic Research Clusters) are currently engaging with and supporting the activities of the medical device industry. An important enabler of innovation is

engagement by the healthcare sector with industry, and with academic and clinical researchers, to facilitate testing, validation and adoption of new medical devices and to support clinician-led innovation and the generation of start-up companies.

Acknowledging that research in health can benefit both the economic and societal/health agendas, it is clear that the realisation of the full potential of Medical Devices research and commercialisation requires the engagement of the health system. While continued investment in research in population health sciences, health services research, integrating clinical infrastructure and translational research will be required, it is important to recognise that this investment has a dual purpose. On the one hand, these research areas enable the generation of evidence to inform policy, improve clinical practice and create opportunities for improved healthcare delivery and better health outcomes. At the same time, research in these areas can benefit the wider economic agenda which aims to further develop the healthcare industry in Ireland for the domestic and potentially international markets. It can do so by strengthening the infrastructure, capability and capacity that will enable, inter alia, the identification, development, validation and potentially the adoption of enterprise outputs within the health system.

Medical Devices

Vision/opportunity: To further develop Ireland's position as a global hub for Medical Devices, through integrating existing enterprise and research strengths to meet strategic research needs of the sector, drive diversification and ensure development and manufacture of next generation Medical Devices here.

Objective 1	To fund research that meets the immediate and strategic needs of the medical device sector.
Objective 2	To deliver a functioning innovation ecosystem for medical device development in Ireland, agree and develop a coherent, integrated system of effective mechanisms for industry to engage with research and translational infrastructure (both clinical and non clinical).
Objective 3	To ensure a leading regulatory environment for medical device development, approval and manufacture in Ireland.
Objective 4	To ensure availability of appropriate skills to support development of the Medical Device sector in Ireland.
Objective 5	Recognising the multi-disciplinary nature of medical device technologies, to ensure appropriate connections are in place between universities, hospitals and industry in order to drive efficient technology transfer and enable access to expertise.

No	Action	Deliverable	Benefit	Lead	Support	Timeline
Objective 1	To fund research that meets the immediate and strategic needs of the medical device sector					
E 1.1	Update and maintain intelligence on national research strengths, activity and investments relevant to medical devices building on analysis of investments and strengths for the Research Prioritisation Exercise.	Current intelligence in the relevant funding agencies on research strengths relevant to Medical Devices	Understanding of research strengths, commercialisation opportunities and stage of development.	SFI, EI	IMDA, HRB, IDA	Q3, 2013
E 1.2	Develop a list of current and strategic research needs of the medical device sector drawing on the recently published IMDA research strategy. Validate findings with key industry executives (local and corporate HQ) in a small number of selected companies to validate initial analysis and further define strategic research needs. Compare national research strengths and platform technology capability with industry research needs.	Gap analysis of industry (immediate and strategic) needs versus academic strengths. Assessment of need for targeted calls to address gaps or if existing bottom up approach is sufficient.	Mechanism for alignment of the public research base with industry needs. A resource for research performers and funders. A regularly updated statement of research needs of the medical device industry.	EI, IDA,	SFI, IMDA, HRB	Gap analysis Q3, 2013 Validation of strategy, Q2, 2014.
E 1.3	If gaps or a requirement for a change in focus are identified	Medical Devices Thematic calls	Increased collaboration and development.	SFI, EI	IDA	Q1, 2014

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	following analysis described in 1.1, thematic call(s) to be run. Most appropriate instrument to be identified, e.g. a technology centre or directed SFI call.	(Technology centre, SFI investigator call or SFI centre call).				
E1.4	In addition to targeted call(s), continue to fund research underpinning the development of Medical Devices through bottom-up calls, with strong emphasis on potential impact.	Existing bottom up approach to funding research of relevance to Medical Devices continued.	Continued development of platform technologies and other research underpinning medical device development.	SFI	HRB	Q1, 2013 and Ongoing
E1.5	Where appropriate, centres with engagement with companies to implement a hub and spoke model for industry engagement (which includes mechanisms for interdisciplinary research)	Where appropriate, Hub and spoke model in research centres engaging with industry.	Mechanism for Industry to engage with academic groups on a bilateral basis to facilitate technology flow without being hindered by competition and IP factors. Increased industry academic collaboration and tech transfer.	SFI, EI, IDA		Q2, 2015
E1.6	Increase capacity for, and investment in, high-quality Health Services Research that examines how social factors, behaviours (patient and/or clinician), organisational structures, business	Knowledge base around usability and barriers to uptake of new technologies in healthcare and evidence around	Uptake and implementation considerations built into product development and evaluation. Opportunity for improved healthcare delivery and better	HRB	DOH/HSE, other relevant funders and stakeholders	Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	processes and/or financing systems impact on access, uptake, use, quality and cost of healthcare (e.g. HTAs and services provision costs) and healthcare interventions.	quality, cost and implementation.	health outcomes.			
E1.7	Continue investment in Population Health Research that focuses on behaviours and lifestyle factors, and on prevention and health promotion strategies for specific populations or groups.	Knowledge base around the needs, behaviours and lifestyle of specific population groups (e.g. older people, people with disabilities)	Generation of an evidence base for prevention and health promotion strategies. Opportunity for better input into product development for targeted groups.	HRB	DOH/HSE, other relevant funders and stakeholders	Q4, 2016
E1.8	Devise appropriate stage gate approach to assessment of funding proposals where relevant.	Evaluation processes consistent with the objectives of calls.	On-going industry relevance of the public research base to medical device priority area.	All funding agencies		Q2, 2014
Objective 2	To deliver a functioning innovation ecosystem for medical device development in Ireland, agree and develop a coherent, integrated system of effective mechanisms for industry to engage with research and translational infrastructure (both clinical and non clinical).					
E2.1	Establish (T1) and implement (T2) HRB funded CRF activities at Galway (not including building), Cork and St. James Hospital.	CRFs in academic teaching hospitals.	Research infrastructure in health care settings supporting health research, and including medical devices, therapeutics, food for health, diagnostics and connected health.	HRB	DOH, HSE, funding agencies, industry and other non-exchequer funding	T1 = Q4, 2014 T2 = Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			Access to research for patients.		sources	
E2.2	Establish a collaborative network between HRB-funded and other existing CRFs.	Provide a national point of access to, and coordinated support for, multi-site health research projects for investigator-led and industry-led studies	Efficient support for multi-site studies delivered through the CRFs. Access to research for patients.	HRB	EI, IDA, SFI, HSE, academic medical schools, DAFM	Q4, 2016
E 2.3	Establish health research networks to increase capacity for collaborative working within and between health specialisms	Health research networks established. Access to large-scale and multi-site patient cohorts for health research	Increased capacity to generate research evidence to clinical practice. Access to research for patients.	HRB	HSE, EI, IDA, SFI, other relevant stakeholders	Q2, 2014
E 2.4	Establish the Health Innovation Hub	Deliver demonstrator project to assess feasibility in the first instance.	Vehicle to a) facilitate industry and healthcare system engagement to develop and validate products and services informed by health needs and b) support adoption and commercialisation, as appropriate of new innovations.	Innovation Hub Project Team	EI, IDA, SFI, DJEI, DOH, HSE	Q4, 2014.
E 2.5	Deliver Medical Devices Technology Centre	Medical Device Technology Centre	Vehicle for applied research in Medical Devices.	EI	IDA,SFI	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
		that can provide efficient access for medical device companies to research expertise				
E 2.6	Take steps to establish a national biobanking system and support infrastructure	Governance Board established. National Biobanking core support infrastructure established. Nationally agreed processes and standards to assure quality of biobanks and associated datasets developed.	National Biobanking System will enable: research activity across the entire spectrum of health research (basic, applied, translational, clinical, population health) seamless access to national biosamples/ associated datasets the quality of biosamples/associated datasets in Ireland are to the highest international standards improved efficiencies, effective cost management and reduced fragmentation of biosample collections/ associated datasets Ireland to be more competitive for industry and international research endeavours	HRB, SFI, EI	IDA/DAFM, Academic medical schools, CRFs, industry	Q4, 2016

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E2.7	Develop a national database and policy for maintenance and support of existing research and innovation infrastructure including appropriate access policy/systems.	National equipment database and policy on maintenance, support and access to existing research and innovation infrastructure	Avoidance of duplication or underutilisation of exchequer funded infrastructure	HEA	IDA, EI, SFI	Q4, 2013
E2.8	Complete an inventory of research infrastructure/facilities (in particular in Europe) which could be enabling for future medical device design, prototyping and pilot production to be updated by funding agencies.	Inventory of research infrastructure not available in Ireland.	Facilitated access to enabling design, prototyping and pilot production infrastructure and expertise for the medical device industry	HEA and FP7 project MERILL	IDA, EI, SFI, Forfás	Q4, 2013.
Objective 3	To ensure a leading regulatory environment for medical device development, approval and manufacture in Ireland					
E3.1	Publish Health Information Bill.	Publication of Health Information Bill.	A legal framework for the introduction of an individual patient identifier. Provision for identifiers for provider organisations. Supporting a conducive environment for health research in Ireland by streamlining the ethics approval process for health research not governed by statutory regulation and EU Law.	DOH		Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
E 3.2	Ensure regulatory bodies are resourced to respond to next generation medical device requirements.	Strong supportive responsive regulatory environment for Medical Device sector.	Increased attractiveness of Ireland as a location for development and manufacture of next generation Medical Devices.	NSAI, IMB	EI, IDA, NDA	Q4, 2012
E 3.3	Leverage existing investment in regulated software to develop national competence to support software development for medical devices applications in compliance with regulatory requirements.	Briefing of industry when new regulations are finalised. Ensure alignment and awareness amongst relevant research centres around this.	Industry operating to new standards.	EI, IDA	NSAI, IMB, NDA	Q4, 2012
E 3.4	Broaden stakeholder participation in eHealth Standards Advisory Group (eSAG) to include representative from PAG as an observer.	Membership of eSAG extended to include PAG representative	Standards prioritisation work of eSAG reflects priorities for Medical Devices thereby enabling the market particularly for SMEs.	HIQA	PAG	Q1, 2013
Objective 4	To ensure availability of appropriate skills to support development of the Medical Device sector in Ireland.					
E 4.1	Launch the employment based postgraduate programme.	Critical mass of graduates with skills required by industry.	Skills to drive innovation and development and manufacture of next generation medical devices in Ireland	Irish Research Council		Q2, 2013
E 4.2	Continue funding for Bioinnovate Ireland pilot programme.	Medtech professionals with innovation and	Increased levels of Medtech start-ups	EI		Q4, 2012

No	Action	Deliverable	Benefit	Lead	Support	Timeline
		entrepreneurial skills.	Increased capacity for new product development in the Medtech sector.			
E 4.3	To support the development of relevant skillsets in graduates, postgraduates and researchers to achieve the critical mass to meet the strategic needs of industry and the research community, including the development of structured training programmes at postgraduate level, to address relevant skills gaps as identified and validated by the EGFSN.	Critical mass of masters graduates with skills required by industry.	Skills to drive innovation and development and manufacture of next generation medical devices in Ireland.	HEA	EI/IDA/SFI	Q2, 2013
E 4.4	Build capacity within the health research system to address specific skills deficits in population health sciences and health services research	National structured PhD programme investment in relevant disciplines Investment in post-doctoral research capability at trainee, fellow and senior fellow levels Investment in new senior research	Timely and relevant research evidence to address cost, quality, effectiveness and implementation issues Increased capacity in the health research system from current very low base Development of multi- and inter-disciplinary approaches to health challenges Health system partnerships	HRB	HSE, DOH, HEIs, HEA, Medical charities	Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
		leadership capability Investment in projects, programmes and centres	provide greater opportunities for evaluation and commercial exploitation of a range of health care interventions			
Objective 5	Recognising the multi-disciplinary nature of medical device technologies, to ensure appropriate connections are in place between universities, hospitals and industry in order to drive efficient technology transfer and enable access to expertise.					
E 5.1	Develop initiatives to facilitate knowledge transfer and exchange between academia and the health services / Government Departments / State Agencies / industry	Relevant and appropriate knowledge transfer and exchange initiatives developed	Better understanding of health care and services needs by industry Better understanding of health industry needs and processes by academia and health system	HRB	All funders; HEIs, DoH, Industry	Q4, 2016
E 5.2	Investigate potential approaches to developing appropriate IP management, technology transfer and commercialisation capability in the healthcare system to ensure that innovations emerging from the healthcare system can be captured, developed and exploited.	Options for implementation of technology transfer in the health system consistent with 2012 IP Protocol	Increased technology transfer, commercialisation and implementation of research findings in the health research system. Increase level of health innovation in terms of products, processes and services Improved competitiveness Opportunity for improved healthcare delivery and better	National Healthcare Innovation Hub	cTTO, HSE, DOH, HRB, EI, All funders; HEIs; Industry	Q4, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			health			

Forfás

An Roinn Post, Fiontar agus Nuálaíochta
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