PRIORITY AREA F
DIAGNOSTICS ACTION PLAN
JULY 2013

Diagnostics (Priority Area F)

Context

Diagnostic products are designed to provide information on health status, disease propensity and progression or therapeutic impact. They can broadly be segmented into categories:

- Imaging & In-Vivo Diagnostics: products used to conduct tests directly on a patient: e.g. X-rays, MRI and associated contrast agents and newer biological targeting techniques.
- In-Vitro and molecular Diagnostics: products used to test patient samples e.g. blood, urine and tissue. These include clinical chemistry assays; immuno-assays; and DNA or molecular diagnostics.

Enterprise capacity in Ireland is currently stronger in the *in-vitro* and molecular diagnostics segment. There are approximately 25 companies in Ireland developing *in-vitro* and molecular diagnostics. Of these, 9 are based on technologies from Irish HE institutions and 10 are units of MNCs including Abbott, & Beckman Coulter. Some MNC activity in imaging exists in Ireland (in particular in manufacturing of contrast agents), but activity from SMEs and HE research in Ireland is relatively small compared to other locations and is spread across diverse fields. New technology uptake is important, but product development is mainly conducted within companies as many have a specific platform (sometimes proprietary) on which their products are delivered. Most of R&D activity in imaging in Ireland is in developing applications rather than novel technologies.

The global market for *in-vitro* diagnostics was valued at $44b in 2010 (anticipated CAGR of 5 per cent) and imaging market was valued at $5.7b. The diagnostics market is continually expanding, and also dramatically changing. Priority areas include: new markers of disease or health status arising from basic biomedical research; new formats of diagnostic products e.g. point of care testing; companion diagnostics; and home diagnostics. Companion diagnostics is a growing area, which may provide a basis for pharma-diagnostic collaborations. Medical imaging represents a further major area of growth globally and advances in imaging technology and in image analysis software are driving this sector. Nevertheless, R&D activity in Ireland is limited to a few centres.

Ireland has built significant research strengths and capacity in diagnostics and other research fields of relevance to diagnostics and the Research Prioritisation Steering group recommended that state funding should be maintained at current levels. There are at least three major dedicated nationally funded research centres operating in the area of in vitro diagnostics. There are also 15 other centres with relevant activities which contribute to Ireland's capacity in this area and investigators are not typically exclusively involved in diagnostic development. Diagnostic products are based on diverse technologies (biological, physical and engineering) and require widely different research expertise and enterprise capacity. Basic biomedical research underpins and acts as a critical driver in the diagnostic space particularly in biomarker identification and development.

Technologies of relevance to in vitro diagnostics may emerge from chemistry/biochemistry (new reagents and signal detection systems) and from materials and nanotechnology enabling miniaturisation and physical/engineering research (analytical and reader equipment).

The *in-vitro* diagnostics market is attractive in that there are relatively low entry barriers for new products and companies. 17 projects, representing €2.4m investment, have been supported by EI in the diagnostics area and it is anticipated that this will grow considerably. There is some research capacity in the Irish system in imaging and in vivo technology, but little enterprise activity beyond manufacturing of contrast agents by MNCs.

There is now an opportunity to harness these existing strengths and identify and exploit commercialisation opportunities in the *in-vitro* diagnostics market, particularly in emerging growth areas including for example, nutrition related diagnostics, veterinary diagnostics, industrial diagnostics, personalised medicine/companion diagnostics, point-of-care devices and applications in connected health. However, there are an enormous number of sources of new technology that could be applied in diagnostics and a key challenge is in identifying and suitably resourcing the development of those technologies that are most likely to find application in the marketplace. This will require focussed, coordinated investment in research underpinning development of diagnostics products and services and mechanisms to ensure that emerging technologies can be developed and commercialised effectively. Commercialisation opportunities should be prioritised on the basis of a strong analysis of market pull and having the greatest chance of success and state support for commercialisation should be confined to these identified priority opportunities.

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 Diagnostics 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.

Diagnostics

Vision/opportunity: Seek to create a mechanism to effectively leverage the research base and identify and exploit commercialisation opportunities with strong market pull in medical, nutritional, veterinary, industrial and in vitro diagnostics. Further investigate potential in imaging and in vivo diagnostics.

Objective 1	To further develop and refine national mechanisms to identify areas of strength in the research base and opportunity in the marketplace, where appropriate mechanisms and focused investment could increase the rate of commercialisation of diagnostic technologies.
Objective 2	To deliver a functioning wider innovation ecosystem for development of in vitro diagnostics in the nutritional, veterinary, industrial and medical fields of use in Ireland including mechanisms to effectively commercialise emerging diagnostic technologies.
Objective 3	To further develop national expertise in regulation and reimbursement of next generation diagnostics with a view to supporting companies in using Ireland as a base for diagnostics development, approval, manufacture and commercialisation in multiple jurisdictions.
Objective 4	To ensure availability of appropriate skills to support development and commercialisation of diagnostic products in Ireland.

No	Action	Deliverable	Benefit	Lead	Support	Timeline
Objective 1	To further develop and refine national mechanisms to identify areas of strength in the research base and opportunity in the marketplace, where appropriate mechanisms and focused investment could increase the rate of commercialisation of diagnostic technologies.					
F 1.1	Update and maintain intelligence on research strengths, activity and investments in diagnostics across funding agencies building the information generated during the NRPE for each priority area and other relevant available sources of	Current intelligence in the relevant funding agencies on research strengths relevant to	Understanding of research strengths, commercialisation opportunities and stage of development.	SFI, EI	IDA, HRB, DAFM	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	information.	diagnostics.				
F 1.2	With representatives from industry and the health system, periodically: ▪ identify immediate and long term market opportunities; ▪ internal industry research capability; and ▪ the need for research from the public sector to realise these opportunities (including infrastructural requirements and skills)	Market snapshot and (with 1.1) a gap analysis of industry immediate and long term research 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 technology product trends and requirements industry research needs. A resource for research performers and funders. A regularly updated statement of research needs of the diagnostics industry	EI, IDA On-going by Diagnostics Development Centre if created	IMDA, HRB, SFI, DAFM	Q3, 2013
F 1.3	Based on the outcome of 1.1 and 1.2, if found to be required, identify the most appropriate funding instruments and initiate calls focused on maximising exploitation of opportunities identified.	Optimal funding instrument(s) to facilitate maximal exploitation of opportunities identified e.g. thematic	Increased collaboration, development, and start-up and licensing activity.	SFI, EI, IDA	DAFM	Q1, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
		Diagnostics call				
F 1.4	In addition to potential targeted call(s), continue to fund excellent research underpinning the development of diagnostics through bottom-up calls	Existing bottom up approach to funding research of relevance to Diagnostics continued.	Continued development of a vibrant research base in platform technologies and other research underpinning diagnostics development to ensure Ireland remains competitive and well positioned to drive future innovative diagnostic products and solutions and respond to short, medium and long term research demands from industry.	SFI	HRB, DAFM	Q1, 2013
F 1.5	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	DAFM	Q2, 2015
F 1.6	Devise appropriate stage gate	Evaluation	On-going industry relevance	All funding		Q2, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	approach to assessment of funding proposals where relevant	processes consistent with the objectives of calls	of the public research base to diagnostics priority area.	agencies		
F 1.7	Increase capacity for, and investment in, high-quality Health Services Research that examines how social factors, behaviours (patient and/or clinician), organisational structures, business 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.	Knowledge base around usability and barriers to uptake of new technologies in healthcare and evidence around quality, cost and implementation.	Uptake and implementation considerations built into product development and evaluation.	HRB	HSE, DOH, other relevant funders & stakeholders	Q4, 2016
F 1.8	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 populations groups (e.g. older people, people with disabilities)	Generation of and evidence base for prevention and health promotion strategies Opportunity for better input into product development for targeted groups.	HRB	DOH/HSE All other relevant funders & stakeholders	Q4, 2016
Objective 2	To deliver a functioning wider innovation ecosystem for development of in vitro diagnostics in the nutritional, veterinary, industrial and medical fields of use in Ireland including mechanisms to effectively commercialise emerging diagnostic technologies.					
F 2.1	Based on the outcome of 1.1 and	An assessment of	If established One stop shop	EI, IDA	SFI, HRB,	Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	1.2, explore the rationale for creation of a Diagnostics Development Centre to support development of in vitro diagnostic assays/platforms/products/services (veterinary, nutritional, industrial and clinical applications).	the requirement for or against development or a Diagnostics Development Centre	for enterprise and the health system to engage with diverse elements of research relevant to diagnostics. Mechanism for effective communication of market pull for new technology to research community. National mechanism to ensure effective coordination and prioritisation of diagnostics research as it progresses from basic (biomarker discovery) through applied (assay development) to commercialisation.		DOH, HSE, DAFM, Veterinary and Nutritional CoE's, Clinical researchers	
F 2.2	Undertake a cross agency review of the branding and marketing message of the various research PIs/groups/centres and deliver a national diagnostics 'brand' to establish a framework within	A marketing tool to help industry understand what research capability is available in Ireland and how it	Create a sense of critical mass in research in this area through consolidation of brands without requirement for radical increase in spend or	DJEI through TI	IDA, SFI, EI	Q1,2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	which funders and researchers act cohesively to deliver on identified opportunities¶	can meet their needs An influencing tool to encourage existing and new research centres/individuals to collaborate and co-market their capability	immediate consolidation of centres. Unified and coherent marketing message around Ireland's research strengths in this area. Facilitate easier and faster access by industry to knowledge & expertise to meet specific research challenges.			
F 2.3	Establish a funding incentivisation mechanism to encourage greater collaboration across various diagnostics R&D groups. For example, subject to go/no go decision on diagnostics development centre, incentivise "feed in" of findings in basic research to the Centre. Implement effective prioritisation mechanisms to identify and support development of potential	Coordinated funding approach to promote greater synergies in diagnostics R&D spend	Critical mass in research in this area through consolidation of brands without requirement for radical increase in spend or immediate consolidation of centres.	SFI, EI	DJEI, DAFM	Q1, 2014

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	opportunities with the greatest chance of commercial success based on strong analysis of market pull.					
F 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
F 2.5	Ensure alignment of missions and synergies between the proposed Diagnostics Development Centre and other infrastructures including for example the Health Innovation Hub etc.	Synergistic relationship between diagnostics innovation ecosystem components	Streamlined effective translation of diagnostics research	EI, IDA, SFI	DJEI, HRB, DOH, HSE, DAFM	Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
F 2.6	Ensure an efficient business development and marketing function, coordinated with EI and IDA, within the proposed Diagnostics Development Centre if/when established.	Effective business development and marketing functions in place in Diagnostics Development Centre	Efficient technology transfer and commercialisation of diagnostics technologies from universities and hospitals	EI, IDA	SFI, HRB, HSE, TTOs, cTTO, DAFM	Q1, 2014
F 2.7	Ensure strong coordination between the Diagnostics Development Centre, institutional TTOs and the cTTO particularly in scenarios where IP from multiple universities is being bundled.	Effective IP management and coordination across Diagnostics Development Centre and TTOs with responsibility for the IP.	Efficient technology transfer and commercialisation of diagnostics technologies from universities and hospitals	EI, TTOs, cTTO	SFI, IDA, HRB, HSE, DAFM	Q1, 2014
F 2.8	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	DOH		Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			research not governed by statutory regulation and EU Law.			
F 2.9	Develop a national database and policy for maintenance and support of existing research and innovation infrastructure including a national policy on and sharing of resources with all relevant stakeholders.	National equipment database and policy on maintenance, support and access to existing research and innovation infrastructure	Avoidance of duplication/underutilisation of exchequer funded infrastructure	HEA	IDA, EI, SFI, DAFM	Q4, 2013
F 2.10	Complete an inventory of research infrastructure/facilities (in particular in Europe) which could be enabling for future diagnostics 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 diagnostics industry	HEA and FP7 project MERILL	IDA, EI, SFI, Forfás, DAFM	Q4, 2013
F 2.11	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	HRB	DOH, HSE, funding agencies, industry and other non-	T1 = Q4, 2014 T2 = Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
			for health, diagnostics and connected health. Access to research for patients.		exchequer funding sources	
F 2.12	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 supports for multi-site studies delivered through the CRFs. Access to research for patients.	HRB	EI, IDA, SFI, HSE, academic medical schools, DAFM	Q4, 2016
F 2.13	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, DAFM and others	Q2,2014
F 2.14	Take steps to establish a national biobanking system and support infrastructure	Governance Board established National Biobanking core	National Biobanking System will enable: research activity across the entire spectrum of health	HRB, SFI, EI	IDA, DAFM, Academic medical schools,	Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
		support infrastructure established Nationally agreed processes and standards to assure quality of biobanks and associated datasets developed	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		CRFs, industry	
Objective 3	To further develop national expertise in regulation and reimbursement of next generation diagnostics with a view to supporting companies in using Ireland as a base for diagnostics development, approval, manufacture and commercialisation in multiple jurisdictions.					
F 3.1	Ensure strong communication and cooperation between companies,	Strong supportive responsive	More efficient dialogue between companies,	NSAI, IMB, EI, IDA	NDA	Q4, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	development agencies, academics, Clinicians and regulatory bodies to ensure mutual understanding of regulatory challenges in development of next generation diagnostics.	regulatory environment for diagnostics sector	development agencies and regulators hence increasing Ireland's attractiveness as a location for development and manufacture of next generation diagnostics.			
F 3.2	Ensure strong communication and cooperation between companies, development agencies and payors in the Irish system to ensure mutual understanding of reimbursement challenges associated with development of next generation diagnostics.	Strong supportive environment for identifying and addressing reimbursement considerations in the diagnostics sector	More efficient dialogue between companies, development agencies and payors hence increasing Ireland's attractiveness as a location for development and manufacture of next generation diagnostics.	HSE, Health insurance companies, EI, IDA		Q4, 2013
F 3.3	Leverage existing investment in regulated software to develop national competence to support software development for diagnostics 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, 2013
F 3.4	Broaden stakeholder participation in eHealth Standards Advisory	Membership of	Standards prioritisation work of eSAG reflects	HIQA	EI, IDA	Q3, 2013

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	Group (eSAG) to include representative from PAG as an observer	eSAG extended	priorities for Diagnostics thereby enabling the market particularly for SMEs			
Objective 4	To ensure availability of appropriate skills to support development and commercialisation of diagnostic products in Ireland					
F 4.1	Consider developing a new training programme akin to the Bioinnovate Ireland programme for diagnostics	Diagnostics professionals with innovation and entrepreneurial skills	Increased levels of diagnostics start-ups Increased capacity for new product development in the diagnostics sector	EI	Diagnostics Development Centre, BDI	Q4, 2013
F 4.2	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 diagnostics in Ireland	HEA	EI, IDA, SFI, EGFSN, DAFM	Q2, 2013
F 4.3	Build capacity within the health research system to address specific skills deficits in population health	National structured PhD programme	Timely and relevant research evidence to address cost, quality,	HRB	HSE, DOH, HEIs, HEA, Medical	Q4, 2016

No	Action	Deliverable	Benefit	Lead	Support	Timeline
	sciences and health services research	investment in relevant disciplines Investment in post-doctoral research capability at trainee, fellow and senior fellow levels Investment in new senior research leadership capability Investment in projects, programmes and centres	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 provide greater opportunities for evaluation and commercial exploitation of a range of health care interventions		charities	

Forfás

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