

# Health LifeSciences in Ireland - An Enterprise Outlook

October 2009

## Foreword

The Government's framework document, *Building Ireland's Smart Economy*, recognises the importance of the export sector to Ireland's future. Today, the LifeSciences sector generates almost one third of total exports and employs in excess of 52,000 people. Companies' activities extend from R&D to manufacturing, customer support and headquarter and/or shared services functions.

To fully realise the potential of LifeSciences for Ireland in terms of economic and health benefits and given the complexity of the sector, it is critical that we achieve enhanced and effective collaboration across a broad range of stakeholders (including businesses, research institutes, healthcare professionals, regulators and Government). All countries are grappling with the challenge of stimulating genuine collaborative effort, however, Ireland's small size and flexibility is a definite advantage in this regard.

The LifeSciences sector globally is undergoing significant change. Developments in science and increased technology convergence are enabling a shift toward personalised healthcare. Competition from other locations to attract investment in LifeSciences and to stimulate the emergence and growth of new innovative companies has intensified significantly. In this context, Ireland must continue to build on its existing strengths in manufacturing excellence and make the changes necessary to enable firms based here to take advantage of future opportunities, specifically in the areas of translational medicine, convergent products, remote healthcare and functional foods.

We have a strong base on which to build - but we must continue to work together to enhance the business environment to support a sector that itself is evolving at a remarkable pace. Actions need to be taken now so that we realise the opportunities for growth, achieve the optimum impact from investments already made, and focus investments from within existing resources to enhance the environment in Ireland for LifeSciences enterprises.

We welcome this Forfás report and we will do our part to make it a reality.



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## Executive Summary: Health LifeSciences in Ireland - An Enterprise Outlook

The health LifeSciences sector has experienced rapid growth over the past decade and is currently estimated to be worth approximately US\$1.2 trillion globally with predicted overall compound annual growth rates (CAGR) of 7% per annum - although certain segments, such as biopharma, convergent products and remote healthcare are forecast to grow at even higher rates<sup>1</sup>.

The LifeSciences sector has contributed significantly to Ireland's economic development over the past decades and will continue to be vital in driving export led growth in the future. Today the sector employs in excess of 52,000 people in over 350 enterprises and at €44.4 billion (2008) accounts for almost 30% of total exports. Exports have grown year on year by approximately 6.3% since 2000.

Although much is already happening to develop and support the sector in Ireland, given the pace and extent of change it is timely to take stock and to ensure that we gain optimum impact from investments to date.

This report takes an industry perspective, acknowledging at the same time, that the aims of business and of healthcare are not mutually exclusive and that developments in the LifeSciences sector have the potential to deliver both health and economic benefits. It outlines the key drivers impacting the sector globally, presents Ireland's strengths in this context, and highlights ongoing developments within companies, research institutes and supporting infrastructures.

This report identifies ways in which the sector in Ireland can evolve to take advantage of global trends, and continue to deliver high value-added products and services based on technology, scientific expertise and clinical research excellence. It identifies the actions needed to develop the 'right' environment, leveraging and enhancing what is already in place, as well as (but not only) addressing current barriers to growth that have been articulated by industry and LifeSciences stakeholders.

### Drivers of Change

Today, the sector is facing unprecedented global challenges. Aging demographics and increases in chronic illness, more informed consumers, and a focus on wellness provide high growth opportunities. Pressures on healthcare systems have resulted in a greater focus on enhanced efficacy of treatments and cost reduction. At the same time technological advances and convergence across the sub-sectors are enabling a shift toward personalised healthcare.

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<sup>1</sup> This report is concerned with the health sciences sectors of pharmaceuticals, red (health) biotechnology, medical technologies and includes functional foods/nutraceuticals. It also takes into account the increasing convergence across these formerly discrete sub-sectors, and the convergence with ICT together with the supporting industry specific research, technology and services. The scope of the study does not include blue (marine), white (industrial) or green (agricultural) biotechnology

## Global Trends - Macro Level



At the firm level companies are facing growing pressures to reduce costs and maximise returns on investment in the context of stringent regulation, loss of patent protection and increasing research and development (R&D) costs, while maintaining high quality standards and managing risk.

## Firm Level Drivers of Change



The drivers at the global and firm level have prompted a number of developments in how the LifeSciences sector operates. There has been a marked shift towards greater collaboration, networking and mergers & acquisitions (M&A) activity between stakeholders in the sector to gain access to new ideas and products and to share the cost and risk associated with bringing medicines and medical technologies to the market. There has also been an increase in the disaggregation of value chain activities - similar to the model that was embraced by sectors such as ICT a decade ago. These trends create opportunities for smaller LifeSciences companies to position themselves within the global supply chain with innovative, technology intensive solutions, with options for partnering, licensing, shared revenue deals and M&A.

## The Global Shift toward Personalised Healthcare

The global trends in LifeSciences indicate a shift toward personalised healthcare. Personalised healthcare incorporates individual genetic, behavioural and environmental information to define individual prescriptions for health maintenance, disease prediction, prevention, and tailored therapy. It is effectively enabling a shift from 'illness' to the concept of 'wellness.'

*Personalised healthcare embraces research, diagnostics and testing, delivery mechanisms and devices and the concept of ‘the appropriate treatment, in the appropriate way, to the appropriate patient, at the appropriate time.’*

We are still some way from personalised healthcare in its purest form - i.e. where drugs and treatments are tailored to treat a ‘population of one’ enabled by advances in diagnostics; but there is no doubt that advances in science and technology have facilitated a shift from the traditional ‘one size fits all’ approach to one where treatments can be targeted at sub-populations of patients based on their genetic makeup and lifestyle.

Translational medicine is a critical underpinning process to enable personalised healthcare that involves the translation of health research *‘from bench to bedside.’*

Personalised healthcare has implications for the manufacture of medical solutions (medicines, devices and convergent products) as the production processes are more complex and require multi-disciplinary capabilities.

Technology advances have also enabled a shift in the point of care, so that some elements of patients’ healthcare management can now be undertaken remotely.

In addition, nutraceuticals and functional foods have a key role to play in responding to the increased focus on ‘wellness.’

**Personalised healthcare could:**

- Predict which patients will most likely benefit from a treatment
- Aid in the development of safer and more effective treatments by reducing the risk of side effects
- Save patients’ lives and improve their quality of life.

By increasing efficacy and safety, personalised healthcare could make therapies more cost effective through:

- Development of diagnostic products that can save costs by targeting therapies to the patients who are most likely to respond
- Development of diagnostics that reduce and/or avoid serious side effects of treatments.

## Ireland’s LifeSciences Sector

Ireland has a strong international reputation and track record in LifeSciences - specifically for the manufacture of pharmaceuticals and medical devices, its positive regulatory environment, and supportive fiscal regime. The sector has been, and will continue to be, of critical importance to Ireland’s economic growth and development.

Today the sector employs in excess of 52,000 people in over 350 enterprises and contributes almost 30% toward total exports, valued at €44.4 billion in 2008<sup>2</sup>. For every 100 jobs created in LifeSciences manufacturing, an additional 137 supporting services jobs are created in the pharmaceuticals sector and an estimated 62 jobs in the medical devices sector<sup>3</sup>.

<sup>2</sup> Central Statistics Office, 2009, Forfás, 2009, Annual Business Survey of Economic Impact

<sup>3</sup> Forfás, 2007, Secondary Employment created by Manufacturing (unpublished)

Nutraceuticals represent a small but increasingly important area of LifeSciences activity in Ireland. Ireland's strong ICT and engineering base is also a significant resource for the sector, particularly with the increased focus on technological convergence and informatics and their potential for LifeSciences.

Over recent years, Ireland's strengths in manufacturing and in supporting services have been complemented through considerable investment in underpinning R&D by Science Foundation Ireland (SFI), Enterprise Ireland (EI), the Programme for Research in Third Level Institutions (PRTL), the Health Research Board (HRB), Teagasc and the Department of Agriculture, Fisheries & Food (DAFF). Supported by the development agencies, EI and IDA Ireland, in-firm R&D investments have also increased over recent years and many successful innovative indigenous companies have been established. In Ireland research activity is centred on age related therapeutic areas and chronic conditions.

Ireland has gained international recognition in a number of therapeutic areas, most notably:

- Immunology<sup>4</sup>
- Oncology
- Neuroscience
- Gastroenterology.

## A Complex Environment

Because of the nature of the industry, the LifeSciences business environment is particularly complex - and has become increasingly so as the sector evolves. The stakeholder community is diverse and includes industry, research institutes, the hospital system - clinicians and patients - government departments and agencies and regulatory bodies. Each has a different overarching focus and each has potentially conflicting demands within their own mandates. However, their aims need not be mutually exclusive, and each has a critical role to play in achieving economic and health benefits through the development of a robust LifeSciences sector in Ireland.

The LifeSciences ecosystem incorporates research and development capability and capacity in academia, hospitals and firms, technology transfer and commercialisation infrastructures, education and skills, the regulatory and fiscal regime, international markets and physical infrastructures (Appendix II). An effective business ecosystem is not only about the individual elements, but also about how they interact and complement each other to create a dynamic, innovative and supportive environment for the growth and development of a sector.

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<sup>4</sup> According to Lab Times, publications in immunology by Trinity College researchers for the period 2000-2006 have led to Ireland being ranked second in the world in terms of citations per paper. Lab Times, 2007, Publication Analysis 2000-2006, Immunology, Issue 4

LifeSciences Enterprise Sector - Stakeholders

| Stakeholder                                  | Interest/Benefit  | Contribution   |
|--|---|--|
| <b>Health Practitioners &amp; Clinicians</b> | <ul style="list-style-type: none"> <li>Improved clinical practices and patient care with the ability to monitor, diagnose and treat patients in the most appropriate setting</li> <li>Increased efficacy of treatments</li> <li>Early identification and diagnosis and improved patient outcomes</li> </ul>   | <ul style="list-style-type: none"> <li>Knowledge and understanding of patient community</li> <li>Expertise in diagnosis, treatment and care</li> <li>Ability to identify potential ‘gaps’ in the marketplace and/or product enhancement opportunities (particularly in relation to medical devices)</li> </ul> |
| <b>Industry</b>                              | <ul style="list-style-type: none"> <li>New opportunities to develop innovative products that deliver effective and tailored healthcare</li> <li>Access to multi-disciplinary teams and research that is core to achieving industry aims</li> <li>Access to clinical trial expertise</li> <li>Increased efficiencies in product development, testing, validation and commercialisation and faster time to market</li> <li>Reduced costs</li> </ul> | <ul style="list-style-type: none"> <li>Market knowledge and access</li> <li>Ability to commercialise and market products</li> <li>Commercially oriented R&amp;D capability</li> <li>R&amp;D project and risk management</li> <li>Funds</li> </ul>  |
| <b>Academic Researchers</b>                  | <ul style="list-style-type: none"> <li>Engagement in leading-edge research</li> <li>Publications and international reputation</li> <li>Intellectual property (IP) development (with potential to license)</li> <li>Direct access to patients &amp; trial data</li> </ul>  | <ul style="list-style-type: none"> <li>International reputation for scientific excellence</li> <li>Leading edge, core, in-depth expertise</li> <li>Multi-disciplinary teams (increasingly)</li> </ul>  |
| <b>Patients</b>                              | <ul style="list-style-type: none"> <li>Opportunity to become involved in clinical trials</li> <li>Higher possibility of success through tailored treatments</li> <li>Increased potential for ‘self-management’ (remote healthcare)</li> </ul>   | <ul style="list-style-type: none"> <li>Feedback on efficacy which can inform product and treatment enhancement opportunities</li> </ul>  |
| <b>Regulators/ Ethics (facilitators)</b>     | <ul style="list-style-type: none"> <li>Improved efficiencies and early identification of potential bottlenecks</li> <li>Access to market intelligence and ‘new’ combination processes/projects</li> </ul>   | <ul style="list-style-type: none"> <li>Streamlined processes</li> <li>Early engagement improves overall issue resolution</li> <li>Expertise</li> </ul>   |

This report is focused on harnessing the engagement of the above key stakeholders; with the proactive and cohesive support of:

- Government departments & bodies
- Enterprise development & research support agencies
- Industry associations
- Private funding institutions & investors
- Infrastructure providers.

High levels of collaboration are fundamental to the success of the LifeSciences sector. Other countries are grappling with this issue and, as a small country that has demonstrated its flexibility and adaptability in the past, Ireland can develop a compelling proposition through genuine collaborative action. The current economic uncertainties could serve to inhibit action - on the other hand - the timing is ideal if we wish to 'steal a march' on others.

## LifeSciences Clusters - Characteristics for Success

Other locations are putting in place aggressive strategies with strong commitment and resources from Government to build a reputation in LifeSciences and an attractive location to stimulate indigenous company start-up and growth and to encourage Foreign Direct Investment (FDI).

A comprehensive analysis of a small number of successful LifeSciences clusters (Medicon Valley, Singapore and North Carolina) revealed different approaches to supporting the sector<sup>5</sup>. At the same time the analysis highlighted a number of common overarching characteristics that informed the recommended actions in this report.

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<sup>5</sup> The LifeSciences Cluster Analysis report is available on [www.forfas.ie](http://www.forfas.ie) and was undertaken by Ernst & Young Consultants

| Characteristics for Success             |  |
|---|--|
| <b>Strong Leadership</b>                | Provided by industry preferably with the commitment of university and hospital leaders and of the state as appropriate |
| <b>Strategy</b>                         | Well defined and understood, with regular review and refresh mechanisms in place                                       |
| <b>Visibility</b>                       | Both nationally and internationally is essential for the success of the sector   |
| <b>Connection across Sectors</b>        | To take advantage of opportunities arising from increased convergence of technologies                                  |
| <b>Commercialisation</b>                | Continuous, focused and concerted effort with a supportive business environment is essential                           |
| <b>Risk Capital</b>                     | Ability to attract venture capital funds   |
| <b>Physical Infrastructures</b>         | Science & technology parks, laboratories, incubation centres and enabling broadband infrastructures etc.               |
| <b>Centralised Information Resource</b> | To serve and inform a diverse stakeholder group  |

Although Ireland is relatively well positioned within the global LifeSciences sector today, the increased focus and investment by other countries reinforces the imperative to communicate a strategic direction for Ireland’s LifeSciences sector internationally, and to demonstrate leadership and collaborative effort in delivering on actions required to support its evolution over the next decade.

## Ireland's Future in LifeSciences - Realising the Potential

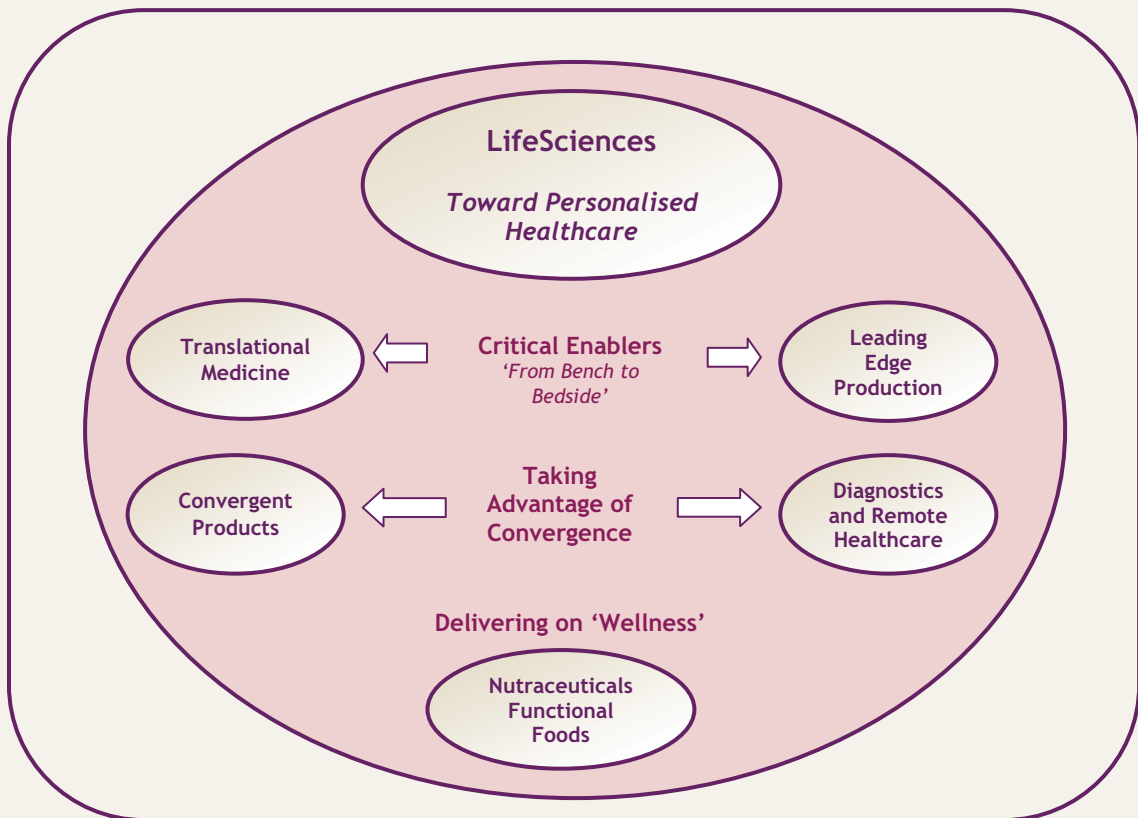
Ireland is well placed to take advantage of emerging global trends. By taking action now we will effectively prepare the ground for the sector's evolution in Ireland as globally the industry shifts increasingly toward personalised healthcare.

By 2015 Ireland will be renowned for providing:

**A Highly Collaborative, Innovative and Internationally Networked Environment for LifeSciences**

**Achieved by Harnessing Technologies and Multi-disciplinary Skills to Provide Creative Solutions for Next Generation Products and Services**

### Harnessing Opportunities and Building on Strengths



## LifeSciences - Toward Personalised Healthcare

### Critical Enablers

#### Translational Medicine

Translational medicine has been increasing in importance as a process for bridging research from the laboratory, through clinical trial processes and commercialisation to delivery in the marketplace - effectively translating research '*from bench to bedside.*' It is characterised by a number of well aligned elements working together, including scientific excellence in research, a functioning clinical research system, a supporting regulatory and ethics system and engagement by technology intensive firms in R&D and commercialisation.

It facilitates the more effective development and delivery of diagnostics and treatments that are tailored to individuals' needs, enabled in part by the genomics and bioinformatics revolution. It is a highly iterative process involving a continuous feedback loop between researchers, clinicians, industry and patients and requires their proactive collaboration. It increases cost efficiencies as it reduces the probability of failures at a late stage in the clinical trials process based on the concept of '*fail early, fail cheaply.*'

Ireland already has a number of the building blocks in place to make the realisation of excellence in translational medicine a genuine possibility (although some aspects are less mature than others).

#### Leading Edge Production

Ireland is internationally renowned for its track record for quality and reliability in manufacturing for LifeSciences. Many companies in Ireland are now investing in process R&D and demonstrating the capabilities to streamline processes, reduce costs and time to market and increase productivity. New products (whether based on biologics, chemicals, electronics or convergent technologies) also require new processes and Ireland's ability to adapt and to play a key role in the future for LifeSciences is well recognised. Wyeth, based in Dublin, being one of the largest biopharma plants in the world, is an excellent demonstration of this capability.

### Taking Advantage of Convergence

#### Convergent Products

Convergent medical products are based on more than one technology platform and integrate, for example, biologics, devices and/or drugs into a combined therapy, treatment or surgery and are marketed as a single unit. They can be as simple as antibiotic-coated plasters or as complex as a drug-coated stent. Ireland has expertise and skills in many of the relevant technologies and sectors, including pharma, biopharma, medical technologies, engineering, information and communications technologies (ICT), both within companies and in research activities. This leaves us well placed to take the necessary actions to develop a differentiated proposition for companies grappling with the challenges presented by increasing technology and sectoral convergence.

### **Remote Healthcare and Diagnostics**

Remote healthcare refers to the ability to diagnose and/or treat a symptom, issue or problem from a distance. It is enabled by technology developments such as sensors, wireless, and photonics. In the medical devices sector, advances in technologies such as orthobiologics, neurostimulation and robotic surgery enable the development of new techniques and solutions, including for example simpler medical kits for the home, enhanced imaging and minimally invasive and restorative treatments. These developments facilitate treatments in less expensive outpatient settings.

The existing company and research base in ICT and medical technologies positions us to take advantage of the potential this growth area offers. The Technology Research for Independent Living (TRIL) initiative is an excellent demonstration of Ireland's capability to bring together world class industrial and academic experts and multi-disciplinary skills, clinicians and patients to research and develop new technologies.

Since the mapping of the human genome was completed more than seven years ago, innovative technologies and tests have emerged, based on a better understanding of the role that genes play in disease and therapy. Molecular diagnostics is now the fastest growing field in diagnostics and, coupled with advances in laboratory equipment, will play an increasing role in early diagnosis, monitoring and targeted pharmaceutical intervention. This has particular relevance in the context of diminishing product pipelines in pharmaceuticals. Diagnostics can be used to 'rescue' existing compounds that failed to achieve regulatory approval for use in the general population but which could be more effective if targeted to specific sub-populations.

### **Delivering on Wellness**

#### **Functional Foods and Nutraceuticals**

The increased focus on health and wellness, developments in enabling technologies and increased knowledge about the pharmacologic effects of certain nutrients has led the development of functional foods and nutraceuticals. These products include any food substance that provides medical or health benefits, over and above its basic nutritional functions, such as cholesterol reducing products, and those that improve bone health or aid digestion. A number of Irish based food companies are engaged in development and production of functional foods and this, together with recent investments such as the Food for Health Ireland (FHI) initiative based at University College Cork (UCC) and Ireland's international reputation for quality food, puts Ireland in a good position to take advantage of this growth opportunity.

### **Actions for Success**

There is evidence of a depth of expertise in some areas, emerging research capability in others, and nascent developments directly relevant to the opportunities identified. The recommended actions are intended not only to address current barriers to accelerated growth, but are also about taking the necessary steps now to enable Ireland's LifeSciences sector to capture future opportunities as the sector evolves globally. Additional resources will

not necessarily be required - but rather existing resources can be refocused strategically to achieve optimum benefit, both now and over the next decade<sup>6</sup>.

**The actions focus on five key areas**

|  |  |
|--|--|
| <b>Enhanced Collaboration</b>            | harnessing the proactive engagement of a wide range of contributors      |
| <b>Translational Medicine</b>            | putting in place the necessary infrastructures and supports              |
| <b>Manufacturing and Process R&amp;D</b> | building on our international reputation for excellence in manufacturing |
| <b>Skills</b>                            | creating, developing and attracting Talent                               |
| <b>Physical Infrastructures</b>          | underpinning the opportunity areas identified                            |

This report is focused on the medium to longer term opportunity. Immediate action needs to be taken to address the area of cost competitiveness to enable the industry to continue to operate effectively from Ireland during this particularly challenging global downturn. The Annual Competitiveness Challenge, 2008, published by the National Competitiveness Council highlights the areas of concern for business and the necessary actions<sup>7</sup> (Appendix V).

## 1. Ireland’s Future in Health LifeSciences - Maximising Potential through Enhanced Collaboration

The increased blurring across the formerly discrete sub-sectors, including ICT, has heightened the complexity within the LifeSciences as well as the need for a cohesive approach to developing the sector in Ireland.

Ireland has many of the elements in place to address the range of opportunities and issues faced by the sector. However, there is a need for a mechanism to drive an overarching agenda and to enhance coordination and collaboration across LifeSciences stakeholders to realise the potential of the sector for Ireland.

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<sup>6</sup> Assuming a continued commitment to the Strategy for Science, Technology & Innovation, 2006 - 2013

<sup>7</sup> National Competitiveness Council, 2009, Annual Competitiveness Report 2008, Volume Two: Ireland’s Competitiveness Challenge, January

## Recommended Actions

### 1.1 Maximising Potential through Enhanced Collaboration

This report highlights the complexity of the business environment for the LifeSciences sector, the significant pace of change and the increased need for proactive collaborative action across a wide range of stakeholders.

- The realisation of Ireland's potential in LifeSciences, as articulated by this report, should be driven by an industry led LifeSciences Alliance made up of industry representatives, the enterprise development agencies, and representatives of the health sector in Ireland. (IBEC, Forfás)
- The LifeSciences Alliance should work to:
  - Harness stakeholder commitment to and engagement with the implementation process
  - Leverage existing resources and capacity from across the industry associations, the enterprise agencies, academia and health representative bodies to best effect to realise the potential of the overarching LifeSciences sector for Ireland
  - Complement and build on existing sub-sectoral activities and initiatives
  - Develop and implement a comprehensive marketing and communications programme, both nationally and internationally, ensuring a cohesive and coordinated approach to developing the sector across multinationals, indigenous firms and research institutes.

## Knowledge Sharing

Although there is already a high degree of collaboration between the enterprise development agencies, the degree of activity and the pace of change is such that it is almost impossible to achieve full benefit from information flows without the introduction of a more systematic approach to capturing, managing and sharing information in the LifeSciences sector. There are a number of options that could be considered and/or delivered in a phased approach.

### 1.2 Knowledge Sharing

- Based on specific information needs or target audience(s) develop and disseminate a strategic intelligence bulletin on a quarterly basis. (Forfás, Industry Associations)
- Having defined specific needs, and if demand for more real time information justifies, establish a knowledge sharing portal between all of the state bodies connected to the LifeSciences ecosystem to facilitate collaborative effort and cohesion, and an enhanced service to the industry. (To be determined)

## 2. Translational Medicine

Ireland already has a number of the building blocks in place to support translational medicine but there are a number of issues that must be addressed if Ireland is to harness its full potential through proactive and effective engagement.

### Translational Medicine

Progress has been made in developing Ireland's translational research infrastructures and supporting systems and there are a number of successful projects in place, such as the GlaxoSmithKline/Trinity translational medicine project and the SFI funded Strategic Research Cluster on Molecular Therapeutics for Cancer. However, there is still work to be done to overcome a number of well documented challenges outlined below. A holistic approach is required to ensure that *all* elements relevant to a cohesive, robust and fully functional translational medicine environment become pervasive across therapeutic, diagnostic and research domains where Ireland can further enhance its international reputation.

An overview of the optimum environment for translational medicine has been provided on page 45, informed by the success of the Cleveland Clinic.

#### 2.1. Demonstration Projects

- Building on progress to date, implement a competitive funding initiative (from within existing resources based on a continued commitment to the SSTI) to support translational medicine projects that would serve as demonstration models, in areas where Ireland has the potential to gain international recognition. (SFI, HRB, EI)

The call for proposals should explicitly require a multi-disciplinary collaboration between industry, academia and medical practitioners and harness the commitment from technology transfer offices, ethics, and regulatory bodies to accelerate approval processes to support the projects.

### Developing a Functioning Clinical Research System

The development of a functioning clinical research system is fundamental to the evolution of LifeSciences in Ireland. Healthcare practitioners play a vital role in identifying unmet medical needs and giving direction and support to LifeSciences research. The Strategy for Science, Technology & Innovation, 2006 - 2013 (SSTI), highlighted the relatively low levels of translational and/or clinical research underway in Ireland and stated that “the introduction of an R&D culture within mainstream health service has been relatively slow (and) there is a need to strengthen considerably the health services research and policy research capacity nationally”<sup>8</sup>. Research, development and innovation in healthcare involves a broad range of activities and disciplines, including product and service development and enhancement, population health sciences and health services systems across hospitals, community and in-home care.

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<sup>8</sup> Department of Enterprise, Trade & Employment, 2005, Strategy for Science, Technology & Innovation, 2006 - 2013

The reality today is that the resource pressures faced by the hospital system means that research has tended to take 'second place.' This report contends that it should not be seen as an either/or situation and that dedicating resources to research and its translation to products and enhanced clinical practice ultimately leads to improved healthcare for all and a more efficient healthcare system.

Currently no comprehensive information resource exists regarding the nature and extent of research being undertaken within the research hospitals and mechanisms to facilitate commercialisation are particularly weak in this area<sup>9</sup>.

Enabling protected time for clinicians to undertake research has been under discussion for some time, and although there have been some recent developments, this issue has not been satisfactorily resolved. The necessary research administrative supports are insufficient and there are also a limited number of available positions for academic clinicians in the higher education system.

## 2.2. Developing a Functioning Clinical Research System

Stimulate increased participation by clinicians in translational medicine:

- Dedicate a senior executive to oversee and promote clinical research within each hospital. (HSE)
- Introduce Technology Transfer Officers, linked to and supported by the university TTO attached to the hospital. (HSE, EI)
- Establish clinical training posts in translational medicine. Senior House Officers (SHOs) should have the option to choose a translational medicine rotation during their 2 year training rotation. (Funded by HRB, HSE, SFI)
- Establish a professorship in translational medicine in each of the university training hospitals. This professor should be supported by two (medicine and surgery) registrar posts. These registrar posts should be both clinical and research focused<sup>10</sup>.
- Regularise research nurse grading with regard to: competence, level of experience and pay grade so as to ensure availability of appropriately skilled nursing professionals to support translational research projects and to provide a transparent career track for research nurses. (HSE)

### Technology Transfer: Industry/Higher Education Institutes

It is apparent from interviews that Ireland is still in the process of building a world-class Technology Transfer Office (TTO) environment. Concerns were raised regarding time-lags and lack of depth of expertise and multi-disciplinary skills, particularly as there is an increasing shift toward convergent products.

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<sup>9</sup> Research is underway within Forfás to document all research activity in Ireland - which will also include research in hospitals and all activity relevant to LifeSciences

<sup>10</sup> UCD has appointed a Professor of Translational Medicine and NUI Galway has initiated a recruitment process to appoint a Professor of Translational Medicine

Under the Technology Transfer Strengthening Initiative which started in 2007, EI has provided resources to higher education institutes (HEIs) to build up their TTOs and to access central resources in EI<sup>11</sup>. New resources include dedicated technology transfer professionals with specific domain knowledge and industry experience including LifeSciences and biomedical expertise. As this programme has a funding life-time of 5 years, clarity regarding its future will be important.

Not all relevant research needs to be (or even could be) undertaken in Ireland, but the ability to identify and license international research is vital. In this context the work of TechSearch<sup>12</sup> through EI, and appropriate IP and fiscal environments are important.

### 2.3. Technology Transfer

- Review TTO infrastructures and supports in a timely way to ensure improvements have been introduced through EI's strengthening initiative and in time for a possible second phase. This review should focus on the specific needs of the LifeSciences sector given the complexity of the sector and particular expertise required to manage technology transfer and commercialisation of LifeSciences products and services.

As part of the review, consider the volume and range of contract negotiations and licensing arrangements and the rationale for building in-depth expertise through the establishment of a centralised support office. (TI)

### Enabling Processes: Ethics Committees, Regulation and the IP Environment

Improvements are needed to address the significant delays being experienced by companies, clinicians and researchers in establishing clinical trials in Ireland in areas of medical technologies and clinical research that are not governed by the Clinical Trials on Medicinal Products for Human Use Regulations. The delays primarily arise from the need for to obtain ethics approval from each participating centre for multi-centre clinical investigations and the sequential review process whereby Irish Medicines Board (IMB) approval can only be sought after approval is obtained from the relevant ethics committee/s rather than in parallel.

The current problems are compounded when convergent products are being considered as, by definition, they straddle existing statutory classifications of regulated products thereby complicating the selection of the appropriate review and approval pathway. Industry has expressed its concern that members of ethics committees do not have the depth of expertise and regulatory experience required. Over recent months the IMB has set up a specific unit to oversee and manage the regulation of convergent products. However it is now critical that the issue pertaining to ethics committees be resolved.

The supplementary budget introduced a scheme of tax relief for the acquisition of intangible assets, including IP, as a measure of supporting the Smart Economy and which is welcomed in the context of this report.

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<sup>11</sup> Launched in 2007 the €30 million Technology Transfer Strengthening Initiative is being implemented over a five year period

<sup>12</sup> [www.enterprise-ireland.com/TechSearch](http://www.enterprise-ireland.com/TechSearch)

## 2.4. Ethics Committees, Regulation and the IP Environment

- Consolidate the existing ethics approval committees for clinical research through the Health Information Bill. The ethics approval committees should be linked to the core research hospitals and have standard operating procedures. This consolidation allows for skills and expertise to develop based on volume of activities. (DOHC)
- Streamline the ethics approvals process, and enable electronic submissions, so that the principles of single opinion and parallel review apply to the approval of all clinical research carried out in Ireland and not only to ethics approval for pharmaceutical clinical trials. (DOHC)
- Develop a comprehensive and clear guide on the conduct of investigator and industry led clinical research in Ireland in accordance with regulations and best practice. (IMB, NSAI<sup>13</sup>, HRB, HSE)
- Review the National Code of Practice for Managing and Commercialising Intellectual Property from Public-Private Collaborative Research (2005)<sup>14</sup> to ensure that how it operates in practice remains appropriate to the needs of industry and academia and supports the development of effective IP agreements in a timely manner. (TI)

## 3. Manufacturing & Process R&D

Ireland has a significant opportunity to leverage its strengths in manufacturing. The future of manufacturing will see the introduction of smaller batches, more complex processes and the emergence of multi-product facilities over time. It is also important that existing companies are supported as they transition to the next generation of production.

*(The development of the appropriate multi-disciplinary skills and industry placements during undergraduate and post-graduate training are particularly important and are included in the section on skills).*

### Recommended Actions

#### 3.1 Manufacturing and Process R&D

- Direct a higher proportion of enterprise development agency supports toward process development in LifeSciences. (IDA, EI)
- Actively support indigenous and foreign owned companies to carry out pilot manufacturing in Ireland to leverage the process development and manufacturing expertise in Ireland. (EI, IDA)
- Increase supports for specific training in the areas of PAT, QbD, Lean Manufacturing and Six-Sigma. (IDA, EI, SkillNets, FÁS)

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<sup>13</sup> National Standards Authority of Ireland (NSAI)

<sup>14</sup> Advisory Science Council, 2005, National Code of Practice for Managing and Commercialising Intellectual Property from Public-Private Collaborative Research, November

## 4. Skills - Supporting the Evolving LifeSciences Sector

Skills for the evolving LifeSciences sector, which includes a focus on translational medicine, excellence in leading edge production, convergent products and remote healthcare, require not only a depth and expertise in core disciplines, but also the ability to work in multi-disciplinary environments and/or to complement core scientific skills with other disciplines.

There are growing calls from industry for highly skilled PhDs that have industry experience and capacity in the area of applied research. Skills in the areas of IP (valuations, negotiations), regulation (and increasingly relevant to convergent products and personalised healthcare), and informatics and analytics are critical for the sector.

### Recommended Actions

#### 4.1 Converging Technologies

- Develop a programme to provide for up-skilling of relevant personnel in the area of converging technologies and the implications for regulation, IP, valuations and negotiations. (SkillsNet - facilitated by the IMDA, PharmaChemical Ireland, IBIA<sup>15</sup>)
- Include a module in the Licensing Executives Society (LES)/Forfás facilitated IP Lecture Series specific to the LifeSciences sector to highlight considerations relating to valuations and M&A negotiations specific to converging technologies. (LES)

#### 4.2 Research Expertise

- Complement existing research capability through a call for proposals to build expertise in the areas of systems biology, biomarker validation and biomedical imaging.

#### 4.3 Industry Experience and Relevance

- The HEIs, working with the HEA, should establish an Industrial PhD programme to complement existing academic PhD programmes available in Ireland. The Advisory Science Council (ASC) has carried out research in relation to increasing the relevance of PhD programmes for industry which should inform the establishment of the Industrial PhD programme. (Appendix VI provides an overview of an Industrial PhD programme)
- Encourage the development of an MBA-type qualification in conjunction with industry and a leading academic institution - the Master of Business in Innovation for the LifeSciences - which will equip students on the programme with the skills to manage the process of taking LifeSciences products and services from initial conception through to successful commercialisation. (HEA)

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<sup>15</sup> Irish Medical Devices Association (IMDA), Irish BioIndustry Association (IBIA)

## **Maths and Physical Sciences - A Fundamental Building Block for the Future**

We also highlight the vital importance of stimulating interest in the core areas of maths and science and support the recommendations arising from the Task Force on Physical Sciences (2002), the Expert Group on Future Skills Needs (EGFSN) Statement on Raising National Mathematical Achievement (2008) and the NCC Statement on Education and Training (2009).

Although some advances have been made on the implementation of a number of these recommendations it is critical to accelerate progress to:

- Incentivise students to take Leaving Certificate mathematics at a Higher-Level
- Provide Professional Development of teachers at Primary-level and Second-level in the teaching of mathematics
- Develop an ongoing research programme to benchmark and evaluate Ireland's mathematical performance in an international context. Work already undertaken by the National Council for Curriculum and Assessment, the State Examination Commission and the Educational Research Centre could be built upon in this regard
- Promote recruitment to science, engineering and technology programmes at third level. Measures to increase the amount of time dedicated to studying science and mathematics in schools should be considered and implemented in this regard.

The Medical Devices Skills report published in 2008 outlines the supply and demand of specific skills over the next 3-5 years for this segment of LifeSciences<sup>16</sup>. A complementary study could be undertaken to assess the specific skills needed within the context of the strategic direction outlined in this study for the entire LifeSciences sector.

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<sup>16</sup> Expert Group on Future Skills Needs, 2008, Future Skills Needs of the Irish Medical Devices Sector, February

## 5. Other Infrastructures

### Recommended Actions

#### 5.1 Infrastructures to underpin the shift toward Personalised Healthcare

- A national biobanking resource underpinned by a national policy for biobanking has been identified by stakeholders as a fundamental requirement within the Irish LifeSciences infrastructure.
  - Develop a national biobanking policy setting out standards for biobanking protocols and procedures as a matter of priority. The recommendations from the reports of the Expert Group on a National Cancer Biobank and MMI's design phase for the Gene Library Ireland initiative provide a framework for defining and developing a governance structure for biobanking and should inform the development of the national biobanking policy.

The policy should also give full consideration to Ireland's involvement in European biobanking initiatives<sup>17</sup>. (DOHC, HRG)

- Undertake a comprehensive analysis of the requirements for biobanking (to include imaging) infrastructures and develop a cohesive implementation plan to deliver on required biobank facilities and supports.

Given the value to the health system, industry and academia, of both Gene Library Ireland and the National Cancer Biobank as critical elements of the overall infrastructures, implementation should be progressed in tandem with development of the national biobanking policy. (HRG)

- Invest in the delivery of wet laboratory infrastructures over the next 3-5 years which are critical to support the sector, particularly SMEs and start-up high technology companies. (An EI commissioned study identified a potential shortfall in supply over the period to 2012 that is unlikely to be provided by the market). (EI)
- Actively promote the use of ICHEC's supercomputing facility and analytical capabilities in support of LifeSciences R&D projects, in particular those dealing with personalised healthcare<sup>18</sup>. (HEA, SFI, IDA, EI)

#### 5.2 Specific to Convergent products

- Establish an industry led convergent technologies network to facilitate networking and collaboration between companies, academics and medical practitioners, across the formerly discrete sectors of medical technologies, pharma, biopharma, ICT and engineering.

The network should have a defined objective(s) to stimulate action (e.g. in marketing, applied research, process development and/or skills and training), and could be supported through existing initiatives provided by EI such as the Industry Led Research Platforms. The imperative is upon companies themselves to formulate and submit proposals to the development agencies in response to calls for proposals. (EI, IDA)

<sup>17</sup> Such as the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)

<sup>18</sup> The Irish Centre for High-End Computing (ICHEC)

## Next Generation Broadband

The implementation of Next Generation Networks (NGNs) is relevant to all aspects of the LifeSciences sector. As the sector shifts toward personalised healthcare the volume of data and images will increase exponentially. The ability to manage, store, analyse and securely transfer this data and management information between stakeholders, across hospitals, research institutes, patient homes and companies both nationally and internationally will become paramount. The lack of high speed, resilient and secure broadband at a competitive price is a barrier to realising the potential outlined in this study. In fact, high quality broadband is as necessary as electricity for the sector to function successfully in the future.

### 5.3 Specific to Remote Healthcare

- Develop next generation broadband infrastructures and services to ensure that there is capacity to facilitate fast, reliable and secure transfer of patient and analytical data nationally and internationally. Specific targets which have been outlined by the development agencies in this regard are:
  - Access to next generation infrastructure and services in all the regional Gateways of at least 12Mbps uncontended, symmetric service for premises and homes by 2012
  - Access to next generation infrastructure and services in all the NSS Hubs and county towns of at least 12Mbps uncontended, symmetric service for premises and homes by 2015.

## Chapter 1: Introduction

The LifeSciences sector has contributed significantly to Ireland's economic development over the past decades, and will continue to be vital to our future growth. Today, the sector is facing unprecedented global challenges<sup>19</sup>.

This report outlines the key drivers impacting the sector globally, together with industry and country policy responses, and presents Ireland's strengths in this context. It aims to identify ways in which the sector in Ireland can take advantage of global trends and outlines the business environment required to enable the sector to continue to deliver high value-added products and services based on technology and scientific expertise.

The LifeSciences sector in Ireland is dynamic. It has a strong reputation for manufacturing, new companies are being formed, both public and private investment in LifeSciences research and development (R&D) has increased significantly over recent years, and many foreign companies have expanded their activities to include corporate services.

However, given the extent and pace of change, the current uncertain economic environment and the fact that resources are not unlimited, it is time to take stock, and to ensure that we gain the optimum economic impact from our investments.

The actions identified in this report are focused on taking a strategic, coordinated and proactive approach to developing the 'right' environment, leveraging and enhancing what is already in place, as well as (but not only) addressing current barriers to growth that have been articulated by industry and LifeSciences stakeholders.

This report starts from an industry perspective. Companies have an overriding commitment to increasing shareholder value - and in the LifeSciences such aims need to be managed in the context of individuals' health and risks relating to treatments. Government has the dual aim of providing efficient and effective healthcare and fostering a healthy population, as well as that of providing a business environment that supports the enterprise sector. These aims are not mutually exclusive, and the development of a reinforcing business environment should benefit all.

A Steering Committee guided the production of this report, bringing valuable industry and academic expertise and insights to the process (Appendix I). The report has been produced by Forfás, in conjunction with the development agencies, IDA Ireland, Enterprise Ireland (EI), and Science Foundation Ireland (SFI), and Ernst & Young was commissioned to bring international expertise and to undertake independent stakeholder interviews.

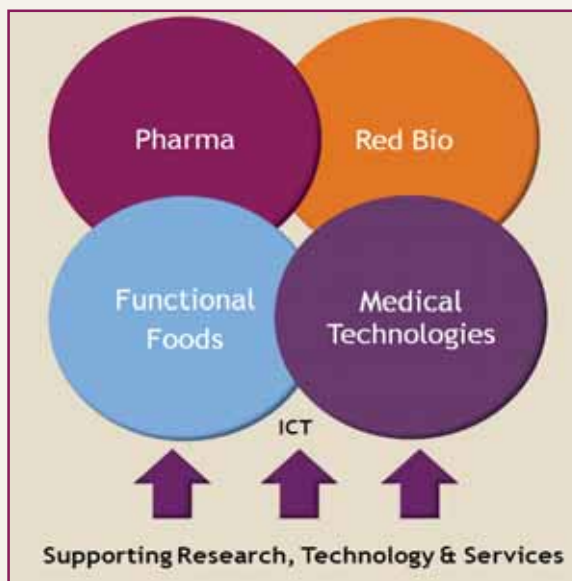
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<sup>19</sup> This report is concerned with the health sciences sectors of pharmaceuticals, red (health) biotechnology, medical technologies and includes functional foods/nutraceuticals. It also takes into account the increasing convergence across these formerly discrete sub-sectors, and the convergence with ICT together with the supporting industry specific research, technology and services. The scope of the study does not include blue (marine), white (industrial) or green (agricultural) biotechnology

## Health LifeSciences - A Definition

The LifeSciences sector is a collective term used to describe the pharmaceutical, biotechnology and medical devices and diagnostics sectors.

This report is concerned with the health sciences sectors of pharmaceuticals, red (health) biotechnology, medical technologies<sup>20</sup>, and includes functional foods/nutraceuticals. It also takes into account the increasing convergence across these formerly discrete sub-sectors, and the convergence with ICT together with the supporting industry specific research, technology and services.



*These sectors have experienced rapid growth over the past decade and are currently estimated to have a combined value of over US\$1.4 trillion globally by 2011.*

**Table 1: Global Market Projections**

|   | 2006  | 2011                     | CAGR |
|---|---|--------------------------|------|
| <b>Pharmaceuticals</b>                  | US\$643 Billion   | US\$811.5 Billion (2010) | 8.7% |
| <b>Biopharma</b>                        | US\$78 Billion  | US\$118.2 Billion        | 8.7% |
| <b>Medical Technologies</b>             | US\$211.9 Billion   | US\$336.5 Billion        | 9.7% |
| <b>Nutraceuticals</b>                   | US\$62.2 Billion (est.)   | US\$96 Billion           | 9.0% |
| <b>Convergent Products<sup>21</sup></b> | The market for convergent products is currently estimated to be US\$40-50 billion and growing at 14% annually |                          |      |

Source: Mintel, IMS Health Inc., Euromonitor, PRTM Management Consultants

The medical technologies sector (devices & diagnostics) is particularly diverse and many sub-sectors including convergent products (combining more than one technology platform) forecast higher growth rates ranging from 14% to 20%.

<sup>20</sup> The medical technologies sector is highly diverse and encompasses medical devices, diagnostics and drug delivery tools

<sup>21</sup> Also described as combination products

## Chapter 2: Drivers of Change

There are a number of global drivers, many of which are interrelated, that present both challenges and opportunities for the LifeSciences sector at the macro level. Aging demographics, lifestyle patterns, the intensified pace of technological advances and increased convergence across the sub-sectors have impacts on the nature of healthcare products and delivery.

At the level of the firm, companies are facing growing pressures on reducing costs and maximising returns on investment in the context of stringent regulation, loss of patent protection and increasing R&D costs, while maintaining high quality standards and managing risk.

### Global Drivers of Change

Figure 1: Global Trends - Macro Level



### Demographics and Lifestyle

Global demographic, socio-economic and consumption trends are having a major impact on the markets for LifeSciences products and services. The United Nations projects that the world's population will increase from 6.6 billion in 2005 to 7.7 billion by 2020. Aging populations in developed economies will drive demand for a wide range of treatments to address age related ailments. At the same time, aging populations and the growth of chronic and lifestyle related conditions are putting significant pressures on healthcare systems globally.

The rise of emerging economies as locations of production and markets will also alter the LifeSciences landscape over the coming decade.

Enterprises now invest in emerging economies to undertake a range of activities, including R&D and clinical trials. That said, for now, many senior executives cite infrastructural deficiencies, shortages of relevant PhDs and regulatory bureaucracy, as potential risks to such investments.

*A survey of LifeSciences senior executives revealed that the majority expect more than 25% of their company's revenues to be derived from the emerging markets of Africa, Asia, Eastern Europe and South America.*

## A Growing Market for ‘Wellness’

For many people, increased wealth and free time has resulted in a focus on a healthier lifestyle. This increased focus on overall ‘wellness’<sup>22</sup> has led to a growing demand for lifestyle related treatments and products such as vitamins and health enhancing functional foods and nutraceuticals. These products include any food substance that provides medical or health benefits, over and above its basic nutritional functions. Such products range from isolated nutrients, dietary supplements through to products that reduce cholesterol, improve bone health or aid the digestive system.

### Advances in Science & Technology

**Genomics** is the study of an organism’s genome and deals with the systematic use of genome information, associated with other data, to provide answers in biology, medicine and industry.

**Pharmacogenomics** combines traditional pharmaceutical sciences such as biochemistry with an understanding of common DNA variations in the human genome. It examines the inherited variations in genes that dictate drug response and explores the ways these variations can be used to predict patient responses to a drug.

**Biomarkers** are molecular, biological, or physical measures that can be used to measure a person’s risk for disease, to diagnose disease and assess a person’s prognosis and to guide treatment.

**Orthobiologics** involves the inclusion of biology and biochemistry in the development of bone replacement materials for muscular-skeletal healing and includes any product that is primarily intended to act as a scaffold and/or actively stimulate bone growth.

**Neurostimulation** is a medical treatment to address chronic pain. A small device, much like a pacemaker, delivers low voltage electrical stimulation to the spinal cord or targeted peripheral nerve to block the sensation of pain.

### Well Informed Consumers

Patients are increasingly well-informed, both because of the fact that health issues are reported on in the media to a greater extent and the fact that the Internet has played a significant role in expanding health awareness and providing extensive information on health related issues<sup>23</sup>. This trend has seen consumers taking a more active role in managing their health; demanding choices for treatment options and alternatives.

### Advances in Science & Technology

The pace and degree of technological advances have unfolded a series of new, predictive sciences which are opening the possibility of new approaches to drug development, more effective diagnosis, therapeutics, and patient care.

These predictive sciences include genomics, pharmacogenomics, and proteomics, which effectively enable the development of drugs and treatments that are tailored to an individuals’ genetic makeup, and enable early ‘signalling’ of an individuals’ propensity to a specific disease. In this context, molecular

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<sup>22</sup> Wellness is generally used to mean a healthy balance of the mind, body and spirit that results in an overall feeling of well-being i.e. wellness means being much more than just being disease free

<sup>23</sup> However, recent surveys indicate areas of concerns including quality and accuracy of information and trustworthiness/credibility.

Health on the Net Foundation, 2006, 9th HON Survey of Health and Medical Internet Users 2004-2005, available from <http://www.hon.ch/Survey/Survey2005/res.html> (accessed May 28th 2009)

diagnostics is now the fastest growing field in diagnostics and coupled with advances in laboratory equipment will play an increasing role in early diagnosis, monitoring and targeted pharmaceutical intervention. This takes on particular relevance given the reduced product pipelines in pharmaceuticals, such that existing compounds can be modified and/or targeted for sub-populations to increase overall efficacy.

Developments in biotechnology are enabling the creation of new biopharmaceuticals, improvements in manufacturing processes and in the greater application of the predictive sciences<sup>24</sup>.

A recent OECD report envisages that biotechnological knowledge will play a role in the development of all therapies by 2015, both small molecule pharmaceuticals and large molecule biopharmaceuticals, and that advances in biotechnologies will be instrumental for realising the potential for personalised healthcare<sup>25</sup>.

#### Biotechnologies with a High Probability of Reaching the Market by 2030

- Many new pharmaceuticals and vaccines, based in part on biotechnological knowledge, receiving marketing approval each year
- Greater use of pharmacogenetics in clinical trials and in prescribing practice
- Improved safety and efficacy of therapeutic treatments due to linking pharmacogenetic data, prescribing data, and long-term health outcomes
- Extensive screening for multiple genetic risk factors for common diseases such as arthritis where genetics is a contributing cause
- Improved drug delivery systems from convergence between biotechnology and nanotechnology
- Low-cost genetic testing of risk factors for chronic diseases such as arthritis, Type II diabetes, heart disease, and some cancers
- Regenerative medicine providing better management of diabetes and replacement or repair of some types of damaged tissue
- New nutraceuticals, some of which will be produced by genetically modified micro-organisms and others from plant or marine extracts.

Source: OECD, 2009, The Bioeconomy to 2030, Designing a Policy Agenda

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<sup>24</sup> Biotechnology can be defined as the application of biological knowledge relating to living cells and genetic material in order to develop products, processes or services for commercial or medical purposes. Biotechnology has a wide range of applications across healthcare, agriculture, food processing and industrial processing. This report is focused specifically on red bio which refers to biotechnology as it relates to medical processes

<sup>25</sup> OECD, 2009, The Bioeconomy to 2030, Designing a Policy Agenda

There are considerable challenges if the potential is to be fully realised, however, not least the enormity of the logistical demands in undertaking large-scale population genotyping and the design of the genotyping diagnostics tests, intellectual property (IP) considerations, computing infrastructures and ethical issues.

In the medical devices sector, for example, advances in technologies such as orthobiologics, neurostimulation and robotic surgery enable the development of new techniques and solutions, including simpler medical kits for the home, enhanced imaging and minimally invasive and restorative treatments. These developments facilitate treatments in less expensive outpatient settings. Advances in computer algorithms and software hold promise for new applications in diagnostic imaging and in-vitro diagnostics.

Bioinformatics advances the understanding of disease states and optimal treatments<sup>26</sup>. The application of bioinformatics in drug discovery and development is expected to reduce the annual cost of developing a new drug by 33%, and the time taken for drug discovery by 30%. It is expected that the global bioinformatics market will be worth nearly US\$3 billion in 2010; more than triple what it was in 2000<sup>27</sup>. Major players include Accelrys, Compugen, Celera Genomics, IBM Life Sciences and Structural Bioinformatics among others.

*These scientific advances underpin the trend toward personalised healthcare.*

*This concept relates to managing a patient's health based on the individual's specific characteristics, including age, gender, height/weight, diet, environment, etc.*

*In its broadest definition, personalised healthcare embraces research, diagnostics and testing, delivery mechanisms and devices and the concept of 'the appropriate treatment, in the appropriate way, to the appropriate patient, at the appropriate time.'*

Other technological advances, such as those in wireless, sensors, nanotechnologies, microelectronics and 'wearable' technologies that collect and transmit data from patient to clinician will have an impact on future healthcare diagnostics and delivery.

Optoelectronic or photonic technologies have enabled advances particularly in relation to the evolution of 'labs-on-a-chip,' which are devices that integrate one or several laboratory functions on a single chip of only millimetres to a few square centimetres in size.

#### **Technological Advances: Lab-on-a-Chip**

The revolutionising potential of lab-on-a-chip systems is widely recognised in biotechnology and related application areas such as genomics, biochemical analysis, pharmacy, medical diagnostics and drug delivery.

Benefits of micro technology-based systems are reduced costs, better performance and higher throughput.

Today, only parts of the process chain are miniaturised but leading equipment innovators expect that processes like cell lysis, sample amplification and dilution, sample cleaning, fluorescent labelling, process monitoring and optical detection will all be integrated in lab-on-a-chip systems in the next couple of years.

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<sup>26</sup> The science of developing computer databases and algorithms to enhance biological research

<sup>27</sup> BCC Research, 2005, Bioinformatics: Technical Status and Market Prospects, August

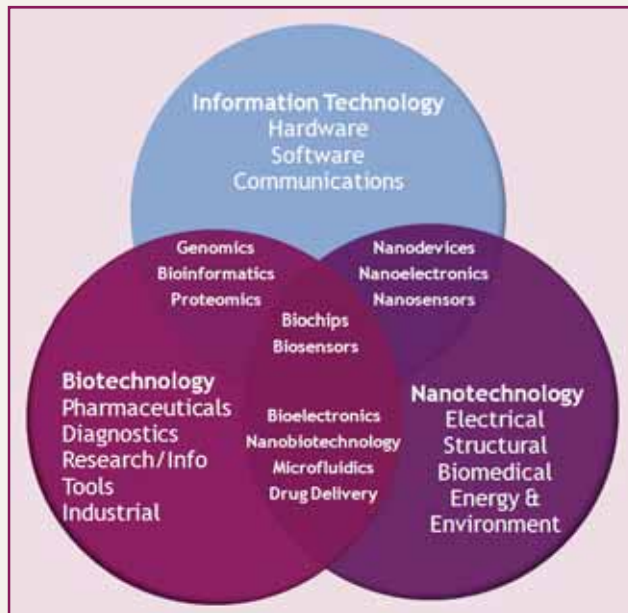
Labs-on-a-chip and the ability to communicate and analyse the data captured are key enablers for remote medicine. Ultimately advances in the area of photonics will enable microscopy techniques that can detect biomarkers at the single molecule level and the development of medical devices that will allow surgery at the single cell level of precision.

Over the past 20 years the growing body of knowledge about the pharmacologic effects of certain nutrients at the cellular level, coupled with increased focus on health and wellness, has led toward the development of nutraceuticals (also frequently called functional foods). The term nutraceuticals refers to foods which have a medicinal effect on human health. The underpinning sciences, regulatory controls, food processing technologies and the need for scientific evidence to underpin medical claims are very similar to those within other LifeSciences domains.

*The global market for functional foods is estimated to be US\$74 billion and growing rapidly at between 8-10% each year<sup>28</sup>. In Ireland, the sector is growing annually at approximately 10% and is valued in excess of €100 million a year<sup>29</sup>.*

### Convergence

Convergence is defined as the intersection and combination of more than one technology platform, for example, nanotechnology, biotechnology, ICT, & cognitive sciences<sup>30</sup>. Although the concept of convergence is not new, the pace at which it is enabling the development of



leading-edge innovative new products and solutions has accelerated.

Convergence stretches across devices, pharma, biotech and diagnostics, and has already resulted in the creation of many convergent products.

The impact on industry has resulted in a blurring of the lines between formerly discrete sectors and product development and marketing now more often than not involves alliances or M&As between companies from different sectors and the development of new revenue sharing and business models.

<sup>28</sup> [www.marine.ie/home/aboutus/newsroom/pressreleases/MarineFunctionalFoodLaunch.htm](http://www.marine.ie/home/aboutus/newsroom/pressreleases/MarineFunctionalFoodLaunch.htm)

<sup>29</sup> Bord Bia, 2007, Anticipating Tomorrow

<sup>30</sup> The National Science Foundation understands the phrase ‘convergent technologies’ to mean “the synergistic combination of four major ‘NBIC’ (nano-bio-info-cogno) provinces of science and technology.” National Science Foundation, 2003, Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science, Roco, M.C. and Bainbridge, W.S.(Eds.), Kluwer Academic Publishers

*Traditionally, the medical devices and pharmaceutical sectors have represented two different facets of the LifeSciences industry.*

*However, the introduction of drug eluting stents (DESs) - the most successful combination product so far with a market size of US\$5.5 billion worldwide - stimulated both of the sectors to collaborate and create a whole new line of products.*

According to PRTM Management Consultants, the market for convergent products is currently estimated to be around US\$40-50 billion and growing at 14% annually. However, this area is still in its early stages, and several challenges need to be addressed. These include risks associated with the technological components and interfaces needed for integration, the challenges of partnering with other firms, often from other industry sectors, and uncertainties about the size and receptiveness of prospective markets.

From an investor perspective, convergent technologies combine the risks of drug development with the quite different risks of device development, without decreasing overall risk. There is also a matter of regulatory issues - as products get smaller in size and are implanted in the patient's body to reach the targeted area, their safety will be of utmost importance. That said, there are many successful convergent products already in the market.

*The number of applications for convergent products with the US Food & Drug Administration (FDA) increased from less than 100 in 2003 to 275 by 2005.*

Although these advances in science and technologies are enabling the realisation of personalised healthcare, there are many different views as to when and to what extent it will become a reality.

Factors such as the economic viability of production, costs and infrastructures, individual risk and insurance and data protection need to be taken into consideration. Having said that, evidence points to products and solutions being developed that are tailored for groupings of patients with similar genetic dispositions (as opposed to being tailored specifically to the individual).

#### **Convergent Products in the Market Today**

- Drug-eluting stent that opens and inhibits restenosis in coronary and peripheral arteries
- Bone grafting scaffold/sponge coated with a growth protein that promotes bone regeneration
- Implantable, programmable pump that delivers a drug or biologic in small, timely doses
- Implantable polymer wafer that releases a chemotherapy agent to a specific site
- Implantable neuromodulator that enables the targeted, regulated delivery of a drug or electrical stimulation
- Transdermal patch that transports drugs locally and systematically through the skin
- Pre-filled, metered dose syringe, injector pen, or inhaler
- Screening test for the presence of a specific gene or protein coupled with targeted drug therapy
- Use of passive pharmaceuticals and radiopharmaceutical tracers as contrast agents for positron emission tomography (PET) scanner.

## Firm Level Drivers of Change

### Increasing Pressures from Public and Private Payers

A 2006 OECD report found that public spending on health and long-term care amounted to an average of 6.7% of GDP in 2005<sup>31</sup>; in the US healthcare expenditure came to 16% of GDP in 2005<sup>32</sup>. Total healthcare expenditure in OECD countries could rise to as much as 13% of GDP by 2050. Set against this trend of rising healthcare costs governments and other payers are looking to contain the costs of drug and diagnostic spending. These cost containment strategies generally take the form of price cuts on pharmaceutical, biopharmaceutical and medical device products, reductions in public investment in R&D, and greater efforts to tie medical decision making to scientific evidence of successful impacts on patients.

Figure 2: Firm Level Drivers of Change



### Increasing Costs of R&D and Declining R&D Pipelines

The costs of drug development are increasing while at the same time the drug pipeline, particularly in the pharmaceuticals sector, is thinning. The typical net cost of bringing a drug to market is US\$800 million<sup>33</sup>. R&D makes up a major portion of this cost with approximately 25% of all R&D expenditure going on clinical trials. The average time to market for a new pharmaceutical product can be anywhere between 5 to 15 years depending on the type of drug and its status and between 3 and 5 years for a medical device<sup>34</sup>.

*“R&D investment by the pharmaceutical industry mushroomed from US\$2 billion in 1980 to US\$43 billion in 2006<sup>35</sup>.”*

<sup>31</sup> OECD, 2006, Projecting OECD health and long-term care expenditures: what are the main drivers?

<sup>32</sup> CBS News, 2007, Health Care Costs Approach \$2 Trillion, January

<sup>33</sup> Tufts Centre for the Study of Drug Development

<sup>34</sup> Datamonitor, 2008, Current & Future Trends and Strategic Issues facing Pharma, March and consultation process

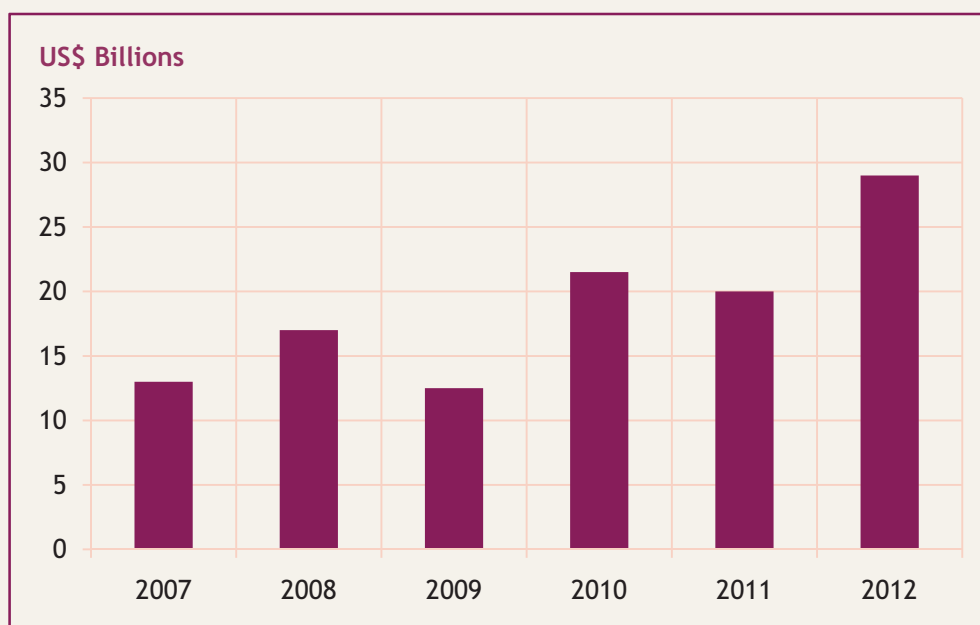
<sup>35</sup> Garnier, J.P., 2008, Rebuilding the R&D Engine in Big Pharma, Harvard Business Review, May

Only one in twenty drugs entering clinical testing successfully completes the clinical trial process and the FDA approved only 19 new drugs in 2007, the fewest in 24 years<sup>36</sup>. In many cases the failure of a drug to gain approval does not happen until late in the process at which time major investment has been committed to large scale clinical trials.

### Loss of Patent Protection and Increased Product Commoditisation

It is estimated that US\$115 billion of branded drugs from the top 50 pharmaceutical companies will lose patent protection by 2012 and will be open to competition from generics<sup>37</sup>. This presents a real challenge for manufacturing companies based in Ireland to reposition themselves within the context of their parent company strategies, and for Ireland to provide the supportive business environment to enable them to do so effectively. Generic drug production now comprises over half of all prescriptions currently written<sup>38</sup>.

Figure 3: Value of Drugs Going Off Patent, 2007 - 2012



Source: Datamonitor, 2008, Current & Future Trends and Strategic Issues facing Pharma

For medical technologies products, the lifecycle is much shorter. The main challenge facing companies is the fact that products become commoditised at a relatively early stage which demands ongoing investment in innovation and successful delivery of new higher value products to market within a relatively short time frame.

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<sup>36</sup> Datamonitor, 2008, Current & Future Trends and Strategic Issues facing Pharma, March

<sup>37</sup> Ibid.

<sup>38</sup> Ibid.

## Regulation

In an environment where LifeSciences companies are facing pressures to reduce costs and time to market, they must also comply with regulatory processes and requirements for sufficient clinical data to illustrate a product's safety and effectiveness for approval.

The blurring of the distinction between medical devices and medicinal products creates a challenge for regulators (and industry) to identify an appropriate regulatory approach to handling products based on convergent technologies. Regulation is being coordinated across the globe by the International Conference for Harmonisation (ICH). Ireland is represented in the negotiations at the ICH through the European Commission (DG Enterprise) and through the European Federation of Pharmaceutical Industries and Associations (EFPIA). Key guidance notes have been prepared by the Irish Medicines Board (IMB) to assist industry on the use of relevant Directives and Regulations.

*“Part of the consequence of this failure of the R&D and successful regulatory approvals process has been a decline in the value of companies within the pharmaceutical industry.*

*From December 2000 to February 2008 the top 15 companies in the industry lost roughly US\$850 billion in shareholder value and the price of their shares fell from 32 times earnings on average to 13 times earnings.”*

Source: Garnier, J.P., 2008, Rebuilding the R&D Engine in Big pharma, Harvard Business Review, May

## Changing Business Models

### Eli Lilly - FiPNET Model

Lilly has established itself as a fully integrated pharmaceutical network (FiPNet), which involves entering into risk-sharing relationships. In its 2007 agreement with Nicholas Piramal India Ltd. (NPIL), NPIL will develop one of Lilly's molecules at its own expense, from preclinical work to early clinical trials. If NPIL is successful and the compound reaches the second stage of human testing, Lilly can reacquire it in exchange for certain milestone payments and royalties.

These collaborative business models offer several benefits: reducing costs, increasing development capacity, accelerating the drug development process and better leveraging not only of Lilly's assets, but also those of its external partners. This model has been very successful for Lilly with sales increasing at a compound annual growth rate of 11% from 2002 to 2007.

Source: IBM, 2008, Global CEO Study, Enterprise of the Future

### Value Chain Disaggregation

Traditionally, LifeSciences companies have sought to maintain full control and ownership of the product development process from R&D to market launch. This required companies to have strengths across the entire cycle including research, testing, manufacturing, marketing, logistics, etc.

There is an emerging trend in the industry for enterprises to focus on those activities where they have strengths and to outsource non-core activities in order to reduce costs (*following the model embraced by ICT sector for many years*). In particular, late stage development, manufacturing and clinical trials processes tend to be increasingly outsourced.

This shift from being fully integrated companies with all functions held internally to fully networked models (FiPNET) provides both opportunities and threats for companies based in Ireland.

Larger firms based in Ireland may experience less reluctance from parent companies to conduct R&D outside of the immediate corporate headquarters; smaller technology intensive companies will find opportunities to licence technologies to the larger players that have ready access and infrastructures in place to market end products; disaggregated support and centralised corporate services are likely to become more prevalent; as is the engagement of contract research organisations (CROs) and contract manufacturing organisations (CMOs).

#### Increased M&A Activity - Innovation through Collaboration

In 2001 Roche had only one potential blockbuster drug (Xenical). Over the next five years Roche had 25 new registrations ready to file, largely developed through its collaborations with Genentech, a US biotechnology company, in which Roche held a majority stake.

Roche took a hands-off approach and gave its smaller partner the freedom to pursue innovative R&D. The close collaboration with Genentech has been key to Roche's success in recent years, with all of the Swiss company's best-selling cancer drugs emerging from the California based biotechnology company's laboratory. These products include Herceptin, Rituxan and Avastin which are all blockbuster oncology products.

In March 2009 Roche bought out the remaining stake in Genentech to take 100% ownership of the company.

#### Increased M&A Activity

Large LifeSciences companies are increasingly looking to start-ups and biotechnology companies as a source of new IP acquired through licensing, collaboration or M&A to bolster their product pipeline and future revenue growth. 15-20% of sales revenue of the top 20 pharmaceutical companies now comes from licensed products and about 40% of their pipelines are composed of externally sourced compounds.

#### Eli Lilly - Collaboration & Open Innovation

To bring new medicines to market faster Eli Lilly integrates an extensive network of external partners through its collaborative business models.

In 2001 Lilly launched InnoCentive, an open web-based marketplace for innovation. On this website, 'seeker' organisations anonymously submit scientific challenges to a diverse crowd of more than 140,000 'solvers' from 175 countries. The best solutions can earn financial awards of up to US\$1 million. Lilly has since spun off InnoCentive, and still retains partial ownership in the venture.

Source: IBM, 2008, Global CEO Survey, Enterprise of the Future

#### Open Innovation & Increased Collaboration

It has long been recognised that the 'go it alone' approach to innovation and development is no longer viable. Today the complexity of problems and the need for multidisciplinary approaches requires the flow of ideas and knowledge exchange. Collaborating and partnering enables innovation and new industry creation<sup>39</sup>.

Universities and independent research groups are focused to a greater extent

<sup>39</sup> Burnside, B. and Witkins, L., 2008, Forging successful university-industry collaborations, Industrial Research Institute, March/April

on collaborating with industry in order to improve R&D outputs and commercialisation, e.g. GlaxoSmithKline's and Harvard University's collaboration on stem cell research and others such as AstraZeneca and Pfizer<sup>40</sup>.

### Conclusion

The pace and extent of change facing the LifeSciences sector is unprecedented, stimulated by advances in science and technology, patient demands and increased knowledge, and the desire by the healthcare system to improve efficacy of treatments. Companies need to adapt to capture the opportunities presented, while at the same time manage costs and adhere to stringent standards and regulations.

The drivers of change point toward an increased possibility of personalised healthcare. The wider definition of personalised healthcare embraces research, diagnostics and testing, delivery mechanisms and devices and the concept of *'the appropriate treatment, in the appropriate way, to the appropriate patient, at the appropriate time.'*

There are many different views as to when and to what extent personalised healthcare in its purest form will become a reality. Having said that, evidence points to products and solutions being developed that are tailored for groupings of patients with similar genetic dispositions. Given the importance of the sector to Ireland's future, it is a trend that cannot be ignored.

Chapter 3 considers the LifeSciences sector in Ireland today, and Chapter 4 outlines the globally competitive landscape for LifeSciences against which we need to develop Ireland's compelling proposition.

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<sup>40</sup> GlaxoSmithKline, 2008, GSK and the Harvard Stem Cell Institute announce a unique collaboration to enable the discovery of new medicines, July



## Chapter 3: Health LifeSciences in Ireland - Taking Stock

### Overview

Ireland has a strong international reputation and track record in LifeSciences - specifically for the manufacture of pharmaceuticals and medical devices, its positive regulatory environment, and supportive fiscal regime. The sector has been, and will continue to be, of critical importance to Ireland's economic growth and development.

Today the sector employs in excess of 52,000 people in over 350 enterprises and contributes almost 30% toward total exports, valued at €44.4 billion in 2008<sup>41</sup>. For every 100 jobs created in manufacturing, an additional 137 supporting services jobs are created in the pharmaceuticals sector and an estimated 62 jobs in the medical devices sector<sup>42</sup> (Table 2).

**Table 2: Contribution of LifeSciences Sector to Ireland's Economy, 2008**

| Exports €m | Employment | %    | GVA €m        | %   | IEE <sup>43</sup> €m |
|------------|------------|------|---------------|-----|----------------------|
| 44,364     | 52,149     | 2.5% | 17,962 (2007) | 41% | 5,710 (2007)         |

Source: CSO, Forfás ABSEI

The sector has experienced strong compound annual growth rates (CAGR) over the period since 2000, with higher increases in exports and GVA<sup>44</sup> being evidence of greater productivity (Table 3).

**Table 3: LifeSciences Growth in Ireland, 2000 - 2008**

|                     | 2000   | 2008        | CAGR |
|---------------------|--------|-------------|------|
| Exports (€ Billion) | 28.0   | 44.4        | 5.9% |
| GVA (€ Billion)     | 11.7   | 18.0 (2007) | 6.4% |
| Employment          | 41,395 | 52,149      | 2.9% |

Source: CSO, Forfás ABSEI

<sup>41</sup> Central Statistics Office, 2009, Forfás, 2009, Annual Business Survey of Economic Impact, October, Forfás, 2009, Annual Employment Survey, March

<sup>42</sup> Forfás, 2007, Secondary Employment created by Manufacturing (unpublished)

<sup>43</sup> Irish Economic Expenditure (IEE): Expenditure on Irish sourced goods, services and payroll

<sup>44</sup> GVA is defined as output, less intermediate materials and services used in its production - it effectively equates to profits and wages

Ireland's success in the sector stems initially from the country's ability to attract and maintain foreign direct investment (FDI) from multinationals, including Wyeth, Abbott, Boston Scientific, Baxter Healthcare, and J&J to name a few. This has been enhanced by a progressive indigenous LifeSciences sector made up of medium sized Irish owned multinationals and a number of technology intensive small and medium sized enterprises (SMEs). Ireland has a cohort of indigenous companies that have gained leadership positions in a variety of areas including medical devices, chemicals, drug delivery and in the provision of specialist support services including contract research, contract manufacturing, regulatory specialists and project/construction expertise.

Nutraceuticals represent a small but increasingly important area of LifeSciences activity in Ireland. As well as large established food and biopharmaceuticals companies, a growing number of SMEs such as Alimentary Health, Deoxy, Euroflavour, Marigot and Cybercolloids operate in the functional foods sector.

Ireland's strong ICT and engineering base is also a significant resource for the sector, particularly with the increased focus on technological convergence and informatics and their potential for LifeSciences.

Over recent years, Ireland's strengths in manufacturing and in supporting services have been complemented through considerable investment in underpinning R&D by Science Foundation Ireland (SFI), Enterprise Ireland (EI), the Programme for Research in Third Level Institutions (PRTLII), the Health Research Board (HRB), Teagasc and the Department of Agriculture, Fisheries & Food (DAFF). Supported by the development agencies EI and IDA, in-firm R&D investments have also increased over recent years and many successful innovative indigenous companies have been established. The sector also has active industry organisations in the Irish Medical Devices Association (IMDA), the Irish BioIndustry Association (IBIA), the Irish Pharmaceutical & Healthcare Association (IPHA), PharmaChemical Ireland and the Food & Drink Industry Ireland association (FDII) (Appendix IV).

## The Health LifeSciences Ecosystem - A Complex Environment

The LifeSciences ecosystem includes a broad range of business environment factors. It incorporates research and development capability and capacity in academia, hospitals and firms, commercialisation infrastructures, education and skills, the regulatory and fiscal regime, international markets and physical infrastructures (including laboratories, high-spec properties, waste, broadband etc.).

It also includes a broad range of actors including individuals and relevant associations - researchers, academics, clinicians, business representatives, industry associations, government departments and bodies (Appendix II).

An effective business ecosystem is not only about the individual elements, but also about how they interact and complement each other to create a dynamic and innovative environment for the growth and development of a sector.

The LifeSciences sector itself has unique characteristics given the broad range of stakeholders. This report is focused on harnessing the engagement of these critical primary stakeholders:

- Industry
- Researchers based in research institutes
- Clinicians and researchers based within hospitals
- Patients
- Regulatory bodies & ethics committees as critical facilitators<sup>45</sup>

With the proactive and cohesive support of:

- Government departments & bodies<sup>46</sup>
- Enterprise development & research support agencies<sup>47</sup>
- Industry associations
- Private funding institutions & investors
- Infrastructure providers.

**LifeSciences Stakeholders - Working to Develop the Health Research Infrastructure in Ireland**

A cross-departmental/agency Health Research Group (HRG) was established in 2007 under the auspices of the Interdepartmental Committee for Science and Technology with a mandate to advise on the improving the health research infrastructure in Ireland.

Published in December 2008 “Building Ireland’s Smart Economy: A Framework for Sustainable Economic Renewal” sets out the Government’s direction for economic recovery and growth. The document recognised the importance of health research as a key plank of Ireland’s innovation framework. Health research is important, not only in terms of enhancing individual health and developing better quality healthcare services, but also in terms of future economic prosperity by generating high-technology employment opportunities.

The HRG is due to publish an Action Plan for health research in the last quarter of 2009 and will be complementary to this more industry focused report.

The overarching global trends highlight the need for a significant step up in collaboration across disciplines and stakeholders.

Other countries are grappling with this issue - and, as a small country that has demonstrated its flexibility and adaptability in the past - Ireland can develop a compelling proposition through genuine collaborative action. The current economic uncertainties could serve to inhibit action - on the other hand - the timing is ideal if we wish to ‘steal a march’ on others.

We are aware that each stakeholder has a different overarching focus, and that each has potentially conflicting demands within their own mandates. However, their aims need not be mutually exclusive, and each has a critical role to play in achieving economic and health benefits through the development of a robust LifeSciences enterprise sector in Ireland.

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<sup>45</sup> Health Information Quality Authority (HIQA), Irish Medicines Board (IMB), Food Safety Authority of Ireland (FSAI), National Standards Authority of Ireland (NSAI)

<sup>46</sup> Department of Health & Children (DOHC), Department of Enterprise, Trade & Employment (DETE), Department of Agriculture, Fisheries & Food (DAFF), Department of Education & Science (DES), Health Service Executive (HSE)

<sup>47</sup> EI, IDA Ireland, SFI, HEA, HRB, Teagasc, FÁS, the Irish Research Council for Science, Engineering and Technology (IRCSET), the Irish Research Council for the Humanities and Social Sciences (IRCHSS)

**Table 4: LifeSciences Enterprise Sector - Stakeholders**

| Stakeholder                                  | Interest/Benefit  | Contribution  |
|--|---|---|
| <b>Health Practitioners &amp; Clinicians</b> | <ul style="list-style-type: none"> <li>▪ Improved clinical practices and patient care with the ability to monitor, diagnose and treat patients in the most appropriate setting</li> <li>▪ Increased efficacy of treatments</li> <li>▪ Early identification and diagnosis and improved patient outcomes</li> </ul>   | <ul style="list-style-type: none"> <li>▪ Knowledge and understanding of patient community</li> <li>▪ Expertise in diagnosis, treatment and care</li> <li>▪ Ability to identify potential 'gaps' in the marketplace and/or product enhancement opportunities (particularly relating to medical devices)</li> </ul> |
| <b>Industry</b>                              | <ul style="list-style-type: none"> <li>▪ New opportunities to develop innovative products that deliver effective and tailored healthcare</li> <li>▪ Access to multi-disciplinary teams and research that is core to achieving industry aims</li> <li>▪ Access to clinical trial expertise</li> <li>▪ Increased efficiencies in product development, testing, validation and commercialisation and faster time to market</li> <li>▪ Reduced costs</li> </ul> | <ul style="list-style-type: none"> <li>▪ Market knowledge and access</li> <li>▪ Ability to commercialise and market products</li> <li>▪ Commercially oriented R&amp;D capability</li> <li>▪ R&amp;D project and risk management</li> <li>▪ Funds</li> </ul>   |
| <b>Academic Researchers</b>                  | <ul style="list-style-type: none"> <li>▪ Engagement in leading-edge research</li> <li>▪ Publications and international reputation</li> <li>▪ IP development (with potential to license)</li> <li>▪ Direct access to patients &amp; trial data</li> </ul>  | <ul style="list-style-type: none"> <li>▪ International reputation for scientific excellence</li> <li>▪ Leading edge, core, in-depth expertise</li> <li>▪ Multi-disciplinary teams (increasingly)</li> </ul>   |
| <b>Patients</b>                              | <ul style="list-style-type: none"> <li>▪ Opportunity to become involved in clinical trials</li> <li>▪ Higher possibility of success through tailored treatments</li> <li>▪ Increased potential for 'self-management' (remote healthcare)</li> </ul>   | <ul style="list-style-type: none"> <li>▪ Feedback on efficacy which can inform product and treatment enhancement opportunities</li> </ul>   |
| <b>Regulators/Ethics (facilitators)</b>      | <ul style="list-style-type: none"> <li>▪ Improved efficiencies and early identification of potential bottlenecks</li> <li>▪ Access to market intelligence and 'new' combination processes/projects</li> </ul>   | <ul style="list-style-type: none"> <li>▪ Streamlined processes</li> <li>▪ Early engagement improves overall issue resolution</li> <li>▪ Expertise</li> </ul>  |

## The LifeSciences Value Chain - Where Ireland Sits

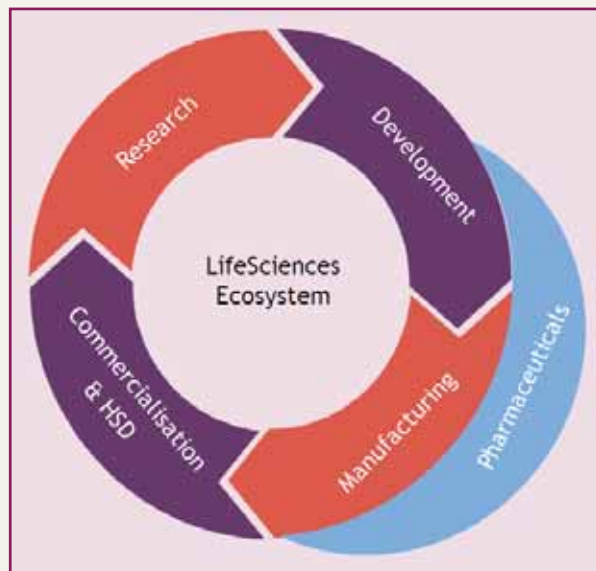
In order to get a clear picture of Ireland’s relative strengths and weaknesses it is useful to map Ireland’s capacity in the subsectors against the value chain. While there are sub-sectoral differences today, over time, the distinctions will blur to an even greater extent than is currently evident.

In its simplest form, the LifeSciences value chain encompasses the four phases of research, development, manufacturing and commercialisation & health service delivery (HSD) (Figure 4 below). In reality, there are continuous feedback loops between each and every element of the value chain. Patients are involved in clinical trials; on-site clinicians evaluate patients’ needs and efficacy of medical devices and inform R&D; and pilot production and process R&D is tightly aligned with understanding delivery mechanisms and a breadth of complex technologies.

### Pharmaceuticals

Today 9 of the top 10 global pharmaceutical companies are located in Ireland, with 7 out of 10 pharmaceutical blockbusters produced here. Although the pharmaceuticals sector is primarily made up of foreign companies there are a number of Irish owned pharmaceutical manufacturers such as Ovelle and Chanelle. The sub-sector employs 24,800, and accounts for 24.5% of Ireland’s total exports<sup>48</sup>. Support services to the sector employ a further 24,000 people according to IPHA.

**Figure 4: Mapping Ireland’s Pharmaceutical Industry to the Value Chain**



#### Increased in-firm Investment in Development

- Merrion Pharmaceuticals, an indigenous company, reformulated Fosamax (Alendronate Sodium), one of its most clinically advanced products, which is marketed by Merck Sharp & Dohme.
- Merrion Pharmaceuticals acquired some of its molecules from Ireland’s internationally recognised pharmaceutical company - Élan.
- Élan which started out as a drug delivery company in the pharmaceutical sector has in recent years moved into the biotechnology sector.

<sup>48</sup> Central Statistics Office, 2009, Forfás, 2009, Annual Business Survey of Economic Impact, October, Forfás, 2009, Annual Employment Survey, March

In the main, foreign owned companies are involved in production of Active Pharmaceutical Ingredients (API) and/or formulation, and in more recent years a number of companies have extended their mandates to include additional activities such as supply chain management, international financial management, shared services and headquarter activities. Supported by the development agencies, there has been increased investment in in-firm R&D, and in process R&D in particular. A number of firms are also linked into R&D initiatives being undertaken by research institutes supported by SFI.

The past five years have seen the emergence of an indigenous drug development segment from a nascent base. It is principally comprised of early stage start-up and growth stage enterprises focused on developing therapies in niche areas such as the treatment of autoimmune disorders. The presence and success of Élan has encouraged former employees to establish many of the LifeSciences start-ups within the ecosystem. Examples of these include speciality pharma companies Azur Pharma, Circ Pharma, and AGI Therapeutics. The concentration of pharmaceutical companies, their length of experience (typically 20-30 years) and the successful regulatory track record within Ireland combine to create a highly reputable and trusted global supply centre for the industry.

There is a view that the emerging drug development indigenous companies are unlikely to become large scale entities, mainly because of the current industry dynamic and extent of M&A activity within the sector, and across pharma and biopharma. Many are likely to develop high value IP licensing and/or partnering models, whereby they license technologies to larger pharmaceutical or biopharma enterprises or partner with them to bring products to market. In these cases Ireland's IP, fiscal and legislative structures are particularly important. Indigenous LifeSciences companies could also be encouraged to undertake pilot manufacturing in Ireland particularly in the context of expanded capabilities in the area of process R&D.

## Biopharmaceuticals

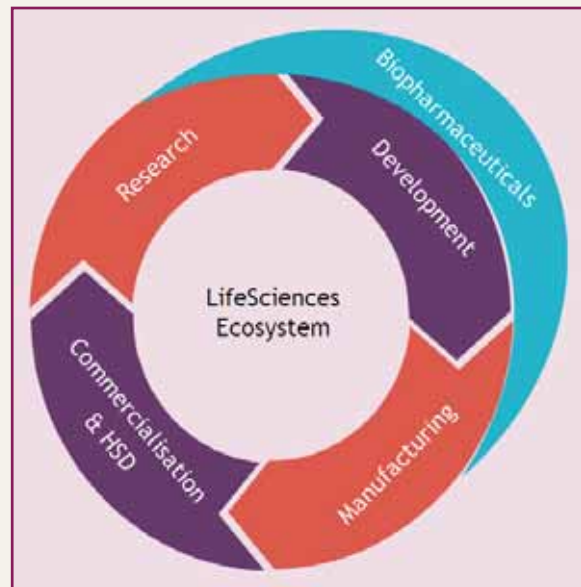
Due to its relative youth, the biopharma industry is more diverse than the pharmaceutical industry. In Ireland there is a mix of start-ups, high growth SMEs and large multinationals such as Genzyme, Schering Plough and Gilead. It is estimated that there are 60 biotechnology companies in Ireland employing approximately 4,000 people<sup>49</sup>.

### Driving the Development of Biotechnology in Ireland

In 1983 biotechnology was identified as a key area for development by the then National Board for Sciences and Technology. In 1987 BioResearch Ireland was established as a partnership between five Irish universities and the Irish Government to develop an R&D infrastructure in biotechnology.

Today, the sector is positioned to take advantage of more recent scientific developments, production processes and commercialisation. It is supported by SFI, EI and IDA investments, through industry & networking associations such as the IBIA, BioLink USA and BIOConnect, and the investment in the National Institute for Bioprocessing Research and Technology (NIBRT) which focuses specifically on process R&D and the skills and training needs of the sector.

**Figure 5: Mapping Ireland's Biopharmaceutical Industry to the Value Chain**



Today the industry has a strong presence in manufacturing and development with companies such as Wyeth establishing globally strategic plants and Lilly building from their pharmaceutical heritage to establish a biopharmaceutical plant in Ireland. There is also a growing cohort of established indigenous biopharmaceutical companies including Sigmoid Pharma and Opsona.

<sup>49</sup> Based on data from the Forfás Annual Business Survey of Economic Impact (ABSEI), the Central Statistics Office (CSO) and the Irish Business and Employers Confederation (IBEC). It is difficult to determine the exact number of companies and employees within the biopharmaceutical industry. The sector has not been assigned an individual NACE (European Classification of Economic Activity) code but is captured under pharmaceuticals and medical devices

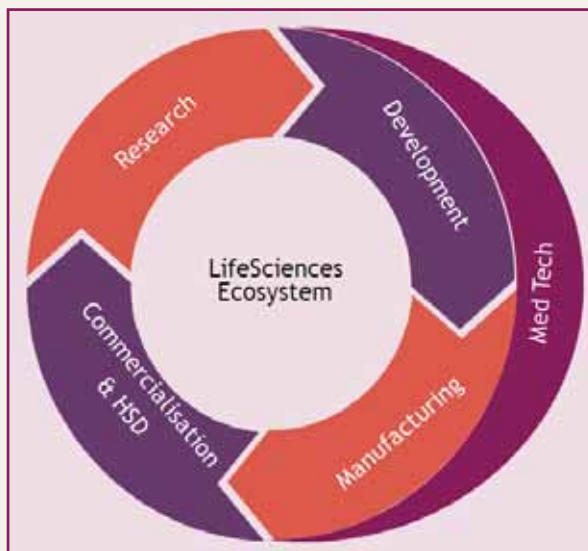
## Medical Technologies

The medical technologies sector generates €6.3 billion in exports and employs more than 24,500 people today; both exports and employment in the sector have grown substantially over the past decade. Fifteen of the world's top 20 medical technologies (devices and diagnostics) companies are located in Ireland, including Abbott, Hospira, Medtronic, J&J, Baxter, Boston Scientific and Stryker. More than 60 of the 140 medical technologies companies in Ireland are Irish owned. Internationally recognised Irish multinationals in the sector include Creganna, Trulife and Steripack. Products manufactured in Ireland include interventional products, diagnostics, medical equipment, dental, vision and hearing products and orthopaedic implants.

Many companies are now engaged in R&D and business service operations, and foreign entities hold strategic roles in product development within their global organisations. The indigenous proprietary medical device segment is relatively small, but has demonstrated growth potential in recent years, as illustrated by companies such as Proxy Biomedical, Clearstream, Zerusa and Brivant. It is true to say that there is a broader range of companies within the medical technologies sector involved in R&D than is the case for pharma or biotechnology. This may be explained to some extent by the lower levels of investment, shorter time required to get to market and lower risk profile relative to drug discovery.

The medical device sub-supply segment comprises manufacturers of components and contract manufacturing service providers. This segment is almost wholly made up of indigenous companies and has grown significantly in recent years, as engineering enterprises have entered the sector. Many of these companies are heavily reliant on the foreign owned enterprises located in Ireland, and face increasing competition from low cost competitors and challenges in expanding into international markets.

**Figure 6: Mapping Ireland's Medical Technologies Industry to the Value Chain**



### Medical Technologies - a High Growth Sector in Ireland

The sector is growing strongly with both employment and exports increasing significantly since 2000.

Exports from the sector have more than doubled since 2000 and employment in the sector has grown by close to 50% over the same period employing over 24,500 people in 2008.

## Nutraceuticals and Functional Foods

The food sector has been a steady source of employment and contributor to Irish Gross Domestic Product (GDP) and exports for the past number of decades. Scientific advances, changes in EU funding regimes and consumer lifestyles have resulted in a shift toward market-led (as opposed to production-led) strategies within the industry. It is an intensely competitive sector, although with emerging higher value activities based on IP, branding and differentiation.

Nutraceuticals and functional foods represent a small but increasingly important area of LifeSciences activity in Ireland. As well as large established food groups such as Kerry and Glanbia, a growing number of SMEs, such as Alimentary Health, Deoxy, EuroFlavour, Marigot, and Cybercolloids operate in the functional foods sector, principally in the development of active ingredients for consumer foods.

### Nutraceuticals - Investing in Wellness

In recent years there has been significant investment to support fundamental and applied research in the areas of functional and marine health foods in Ireland including:

**Food for Health Ireland (FHI):** FHI is a functional foods research initiative headquartered in University College Cork (UCC). The FHI research centre will carry out research into how natural components of milk can be extracted and used as food ingredients to deliver health benefits for consumers. The initiative involves a unique partnership between four of Ireland's leading dairy companies; Dairygold Food Ingredients, Glanbia Nutritionals, Carbery and Kerry Ingredients Ireland. The research consortium is led by UCC and includes University College Dublin (UCD), the University of Limerick (UL) and Teagasc. The objectives of FHI are to facilitate the development of the functional food industry in Ireland by creating a new, internationally competitive, interdisciplinary, industry-focused research centre and by developing skills and technologies that will lead to new products, processes and services.

**Nutramara: The Marine Functional Foods Research Initiative (Nutramara)** was launched in 2007 to develop a research consortium focused on marine functional foods and food ingredients research. The marine environment is potentially a rich source of other nutritional materials as yet undiscovered and which may have applications in the area of functional foods. This €5.2 million initiative is being funded through the Department of Agriculture, Fisheries & Food (DAFF) and the specific objectives of Nutramara are to:

- Create a strong, interdisciplinary research capability, capable of exploiting marine biodiversity as a source of materials for use in functional foods
- Develop capabilities to process marine-based materials for use by the functional ingredients sector
- Support the creation of new research capacity in areas that underpin research in marine functional ingredients and foods.

Research activities carried out through the Nutramara initiative will combine expertise from a number of national institutes including Teagasc's Food Research Centres, UCC, UCD, UL, NUI Galway, and the University of Ulster, Coleraine.

**ELDERMET:** The ELDERMET project involves scientists from UCC, the Alimentary Pharmabiotic Centre, Teagasc Moorepark and Cork hospitals. It is supported by the Department of Health & Children, DAFF and the HRB. It examines how diet and lifestyle influence, and are influenced by, the bacteria in the gut, and how this knowledge can be used to promote health in people over 65 years. ELDERMET's outcome will be the production of functional foods designed specifically for older populations.

## Life Sciences Services and Support Companies

Ireland has been successful in building up a strong base of ninety plus companies which support the LifeSciences sector especially those based around ICT and software, including enterprise resource planning (ERP), regulatory compliance systems and electronic patients' record management, with companies such as Qumas, GXP Systems, Brentech, Data Systems and Zenith Technologies.

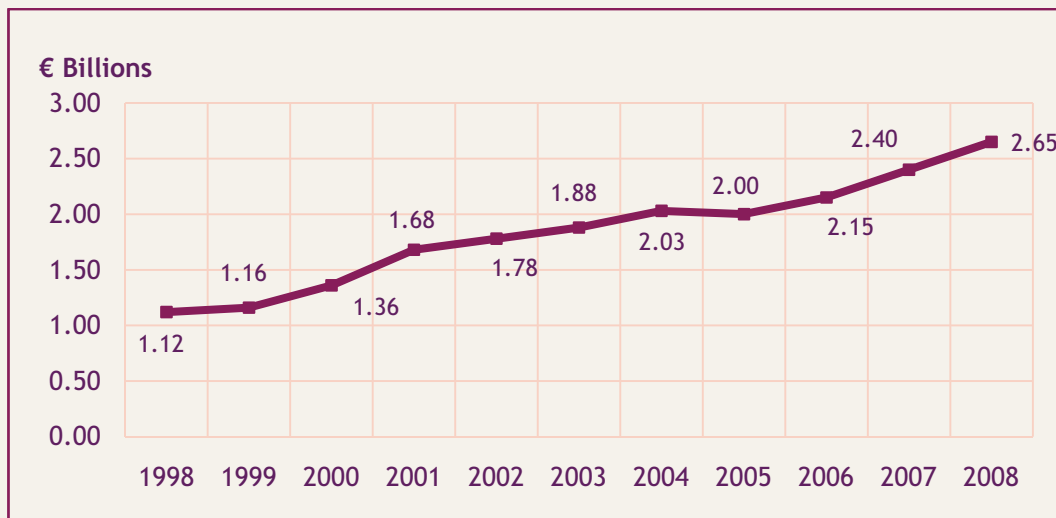
Contract research organisations (CROs) and contract manufacturing organisations (CMOs) include companies such as Icon, Shandon, Life Scientific, Sigma Aldridge and Cordon Pharma. Although limited to a small number of companies, Ireland has a recognised world class expertise in designing and constructing state-of-the-art manufacturing facilities<sup>50</sup>.

A growing number of foreign owned ICT companies (many of which have subsidiaries based in Ireland) are focusing on the LifeSciences sector including HP, IBM, Siemens and Philips to provide services, products and solutions. In Ireland, Intel has announced a €25 million health research and innovation programme through the Technology Research for Independent Living (TRIL) Centre as part of its Digital Health programme.

## Life Sciences Research in Ireland

A total of €8.2 billion was committed to research, technological development and innovation under the current National Development Plan (NDP) 2007-2013 and state commitment to building Ireland's research base has increased almost two and a half fold between 1998 and 2008 (Figure 7 below).

Figure 7: State Expenditure on Science & Technology, 1998-2008 (current prices)



Source: The Science Budget 2007/2008, Forfás, December 2008

<sup>50</sup> Project Management Group (PMG), an Irish engineering company, is recognised as a world leader in the construction of life science manufacturing plants

Ireland has developed globally recognised academic and/or clinical expertise in a number of therapeutic areas, predominantly in age related ailments and chronic diseases. There is also evidence of emerging capabilities in the areas of cardiovascular and regenerative medicine. At the same time the increased investment in research infrastructures in terms of people, facilities and networks in Ireland has fostered the development of capabilities in a number of the underpinning sciences and enabling technologies.

**Table 5: LifeSciences - Research & Clinical Expertise in Ireland**

| Therapeutic Expertise     | Underpinning Sciences        | Enabling Technologies        |
|---------------------------|------------------------------|------------------------------|
| Immunology <sup>51</sup>  | Molecular biology            | Sensor technology            |
| Oncology                  | Molecular diagnostics        | Photonics & optics           |
| Gastro-intestinal health  | Pharmacology/biopharmacology | Bioengineering               |
| Neuroscience/therapeutics | Genomics                     | Analytics & bioinformatics   |
|                           |                              | Nanotechnology <sup>52</sup> |

### Enterprise R&D

In tandem with increased state investment in basic research, the development agencies and the HRB provide direct supports for in-firm and clinical R&D. Business expenditure on R&D is relatively small, although has increased substantially in recent years and is targeted to grow to about €3.8 billion per annum by 2013. The indigenous sector tends to be relatively R&D intensive due to its SME and start-up population. A number of foreign firms have recently invested in in-firm process R&D, and others are engaged in collaborative product R&D in SFI/IDA supported programmes. It is estimated that 800 people are currently employed in pharma or biopharma process R&D in Ireland<sup>53</sup>.

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<sup>51</sup> Publications in immunology by TCD researchers for the period 2000-2006 have led to Ireland being ranked second in the world in terms of citations per paper. Lab Times, 2007, Publication Analysis 2000-2006, Immunology, Issue 4

<sup>52</sup> Forfás is undertaking a feasibility study for the potential development of a nanotechnology facility to support industry and academia in Ireland

<sup>53</sup> Van Egeraat, C., Barry, F., 2008. The Irish pharmaceutical industry over the boom period and beyond, National Institute for Regional and Spatial Analysis, No. 39

**Table 6: Examples of R&D Activity in Ireland**

| <b>Company</b>              | <b>Activity</b>   |
|-----------------------------|---|
| <b>Genzyme</b>              | <p>Pilot plant R&amp;D facility involved in the development of tablet manufacturing and processes and further product line extensions.</p> <p>Liquid and capsule development with the capability to manufacture Phase I and II clinical materials.</p>  |
| <b>Wyeth</b>                | <p>A drug development facility focused on moving products from the research pipeline to commercial manufacturing.</p>   |
| <b>Medtronic</b>            | <p>The Galway based R&amp;D team designs and develops catheters and stents delivery systems for worldwide markets. Medtronic is also collaborating with the Regenerative Medicine Institute (REMEDI) at NUI Galway.</p>   |
| <b>Creganna</b>             | <p>Creganna creates, designs and builds products and technologies for medical device &amp; LifeSciences companies. They specialise in technologies for minimally and less invasive device solutions that enable the delivery of a therapy or access to the anatomy. They are ranked among the top 10 providers of medical device outsourcing solutions worldwide.</p>   |
| <b>Cellix</b>               | <p>Established in 2004 Cellix is a Dublin based instrumentation company that has developed and commercialised the first semi-automated continuous flow cell-based assay system.</p> <p>To date Cellix's platform has been approved for a wide range of therapeutic areas and indications including cardiovascular, oncology, respiratory conditions, immunology and bacteriology. Cellix's client base includes AstraZeneca, Amgen, Pfizer, Sanofi Aventis, Servier and the National Institutes of Health in the US.</p>  |
| <b>Trinity Biotech</b>      | <p>Founded in 1992, Trinity Biotech specialises in the development, manufacture and marketing of clinical diagnostic products. The company has grown through a combination of organic growth and acquisitions and now has a portfolio of more than 500 products.</p>  |
| <b>Glanbia Nutritionals</b> | <p>Glanbia has established a significant presence in the nutraceuticals/functional foods space. To enhance their capacity to provide science based solutions in this area the company established the Glanbia Group Innovation Centre (GIC) in Kilkenny. The GIC is equipped with specialist laboratories, a pilot plant, sensory analysis facilities, and is staffed with a team of nutritionists, microbiologists, immunologists, food scientists and applications experts.</p> <p>The GIC is responsible for developing and testing nutritional solutions for a broad range of industries, such as functional foods, dietary supplements, clinical, infant and sports nutrition.</p> |

### Enterprise - Academic R&D Collaboration

In more recent years, the emphasis is on leveraging these R&D capabilities to best effect by stimulating increased collaborative initiatives between industry and academia, and to stimulate technology transfer and commercialisation<sup>54</sup>.

Science Foundation Ireland (SFI) plays a key role in promoting enterprise-academic R&D collaboration with the support of the development agencies, industry associations and the higher education sector<sup>55</sup>. Two of the major programmes run by SFI to promote innovative and collaborative research in Ireland are the Centres for Science Engineering and Technology (CSET) and Strategic Research Clusters (SRC) programmes. These programmes help to link scientists and engineers in partnerships across academia and industry to:

- Address crucial research questions
- Foster the development of new and existing Irish technology companies
- Expand educational and career opportunities in science and engineering
- Grow partnerships with industry that could make an important contribution to Ireland and its economy

A number of the research activities funded through the SRC and CSET programmes, including the Irish Drug Delivery Network, the Regenerative Medicine Institute (REMEDI) and the Biomedical Diagnostics Institute are directly relevant to the health LifeSciences. As well as Ireland's leading academic institutions, a number of LifeSciences companies in Ireland are actively involved in these initiatives including GlaxoSmithKline, Procter & Gamble, Medtronic, Boston Scientific, Oplona, Alimentary Health, Sigmoid Biotechnologies, Intel and HP. Examples of CSETS and SRCs are presented throughout the document.

*Although investments by firms in R&D and collaborations with research institutes are relatively recent - they demonstrate the ability to build on Ireland's global reputation in manufacturing. The emerging pockets of excellence in research provide a strong basis for the evolution and growth of the sector in Ireland.*

This focus on building up the national research, innovation and knowledge transfer infrastructures in Ireland is beginning to show dividends. A recent 2008 report found that scientific output in Ireland (publications per capita) was just above the OECD average<sup>56</sup>. Although some research institutes in Ireland have built an international reputation, many are small in scale. In the context of increased demand for multi-disciplinary teams and global competition, collaboration between research groups and between research centres and industry is particularly important over the next decade.

<sup>54</sup> Including initiatives such as Centres for Science Engineering and Technology (CSETs) supported by SFI, and the Innovation Partnerships and Applied Research Enhancement Centres supported by EI

<sup>55</sup> Set up in 2000 SFI is responsible for promoting investment in basic research, particularly in the science and engineering that underpin the fields of biotechnology, information and communications technologies, and energy efficient technologies.

<sup>56</sup> OECD, 2008, OECD Science, Technology and Industry Outlook 2008, October

### HEAnet: Linking Research through Technology

HEAnet is Ireland's National Education and Research Network. The network was established in 1984 and today provides high quality internet services to Irish Universities, Institutes of Technology and the research and educational community, including all primary and secondary schools.

HEAnet also provides a high-speed national network with direct connectivity for its community to other networks in Ireland, Europe, the USA and the rest of the world.

What is also important is that we acknowledge that Ireland need not always 'create our own' and that fostering effective linkages with international research and expertise is a critical element of overall success. As we build our own capabilities and relevant skills base, it is important that firms are enabled to acquire technologies (whether nationally or internationally developed) and to adapt them to produce differentiated innovative products and services. In this context the recent changes to the tax treatment of intangible assets is welcomed.

## Health and Clinical Research Infrastructure in Ireland

The Advisory Science Council's (ASC) "Review of Health Research in Ireland" in 2006 and the SSTI both highlighted the need to enhance the health research infrastructures in Ireland as part of ongoing efforts to improve patient care and also to support the development of the LifeSciences sector in Ireland.

In recent years, progress has been made and the report by the Cross Sectoral Clinical Trials Taskforce, found that the level of interest from patients, academics, manufacturers and clinicians in conducting clinical research in Ireland was on the increase<sup>57</sup>. Having said that, a number of barriers remain that inhibit the development of a robust, fully functioning clinical research system to stimulate the level of engagement by industry that is desirable<sup>58</sup>. An overview of key recent developments to build Ireland's health and clinical research infrastructures is provided below.

### Developing the Research Infrastructure: National Nutrition Phenotype Database

The Joint Irish Nutrigenomics Organisation (JINGO) a research consortium, made up of UCD, UCC, Trinity College Dublin (TCD) and the University of Ulster, is developing a National Nutrition Phenotype Database with joint funding from DAFF and the HRB and with support from 4 hospitals.

The National Nutrition Phenotype Database will be used to study the interaction between genes and nutrients. Information on nearly 8,000 Irish adults will be collected to furnish the database and will combine dietary, physical activity, body measurement and lifestyle data with nutrigenomics technology data. Researchers will be able to use the database to examine genes for variations in the genetic sequence thereby explaining the different effects that food has on people.

Findings from this project will be utilised in the area of 'personalised nutrition' and in the development of functional foods.

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<sup>57</sup> Cross Sectoral Clinical Trials Taskforce, 2006, Enhanced Clinical Trials Infrastructure Required to Benefit Public Health, October

<sup>58</sup> Biobanking and its importance for clinical research is discussed in detail in Chapter 5

### Clinical Research Facilities

There has been considerable progress in recent years in the expansion of Clinical Research Centres (CRCs)/Clinical Research Facilities (CRFs) on or near hospital grounds in Ireland. CRCs provide dedicated access for health researchers to laboratories, medical staff and research personnel, procedure and examination rooms and inpatient/outpatient beds, etc. as required.

There are three CRCs in Dublin with a fourth centre currently being built at St. James. Together the four CRCs will make up the Dublin Centre for Clinical Research (DCCR), which encompasses the CRCs associated with the three Dublin Medical Schools (Trinity College Dublin, TCD, University College Dublin, UCD, and the Royal College of Surgeons in Ireland, RCSI) located at the Mater Hospital, St. Vincent's University Hospital and Beaumont Hospital. CRCs are also scheduled to open on the grounds of Cork and Galway University College Hospitals in 2010/2011.

### Translational Medicine Networks

The All Ireland Cooperative Oncology Research Group (ICORG) is a clinical research organisation set up in 1997 by a group of cancer consultants. The aim was to put a formal structure in place to make Ireland more attractive as a location to international cancer research groups and the pharmaceutical industry and to facilitate access for Irish patients as early as possible to the latest cancer treatments through research. ICORG has been very successful and has been instrumental in attracting a number of pharmaceutical companies including GSK and Pfizer to carry out trials in Ireland.

In its first ten years ICORG opened 71 research protocols and allowed access to research treatments to more than 3,000 Irish cancer patients at thirteen separate hospitals nationally. Today it has 349 members and counts more than 95% of the Islands cancer treating consultants among its membership.

ICORG has developed strong links with many leading international cancer research groups such as Cancer Research UK, the Cancer Research International Research Group (BCIRG) and those in industry developing the most promising new cancer treatments. It is a not-for-profit entity funded by the Irish Cancer Society and through a HRB administered grant awarded to it by the All Ireland cancer consortium.

### Molecular Medicine Ireland

Molecular Medicine Ireland (MMI) is a non-profit company set up by UCD, TCD, RCSI, NUI Galway and University College Cork (UCC) which allows the separate institutions to act as one coordinated group working to improve Ireland's clinical and medical research capacity.

The aim of MMI is to speed up the translation of advances in science into new drugs, devices and diagnostics that will improve the health of people in Ireland.

One major outcome has been the establishment of a CRC at St. James supported by the HRB and the Wellcome Trust<sup>59</sup>, which will connect with the new and emerging CRCs at other Dublin teaching hospitals through the Dublin Centre for Clinical Research.

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<sup>59</sup> The project is part of an Ireland/UK Clinical Research Collaboration. This initiative has brought together the HRB in Ireland with the Wellcome Trust, the British Heart Foundation (BHF), Cancer Research UK, the Wolfson Foundation, the Medical Research Council (MRC) and Health Departments in England, Northern Ireland, Scotland and Wales

### Harnessing Systems Biology in LifeSciences Research

Systems biology is a powerful new way of converging the power of computers and mathematics to understand biology. It seeks to unravel the complexities of cells, biological systems and disease through the use of models that predict biological behaviour.

The recent establishment of the SFI funded institute, **Systems Biology Ireland (SBI)**, at UCD will build significantly on the strengths of Ireland in this area and enable quicker and better therapies to be delivered more effectively to patients.

The research programme at the institute will be carried out in collaboration with NUI Galway. SBI is also being supported through the significant contributions of industry partners and will also enable new and innovative collaborations across academic and clinical environments.

### The Irish Clinical Research Infrastructure Network (ICRIN)

MMI is funded by the HRB and the Health Service Executive (HSE) to host the Irish Clinical Research Infrastructure Network (ICRIN)<sup>60</sup>. Established in 2006, ICRIN's role is to harness investment in clinical research facilities and personnel across Ireland in a single national network that supports multi-site clinical studies across a wide range of diseases. ICRIN also represents Ireland in the EU funded European Clinical Research Infrastructures Network (ECRIN)<sup>61</sup>.

ICRIN considers the effectiveness of the totality of the clinical research infrastructure for medical technologies, medicines and clinical health research including ethics, regulation, and data management, and has taken a number of initiatives to address current deficits. A Roadmap for Clinical Research in Ireland which recommends steps to overcome obstacles to undertaking clinical research will be published later in 2009.

EI has funded the appointment of an Industrial Liaison Officer with ICRIN to provide support to companies to carry out clinical research in Ireland.

### Health Research Training & Development

The HRB has initiated a programme for funding fellowships for senior clinician scientists which provides consultants with protected time for research. The HRB also provides PhD training fellowship for health professionals, as well as a new scheme, co-funded with the HSE, which allows the integration of specialist clinical training with research training for registrars. Similarly, MMI is coordinating the award of up to 27 fellowships for clinician scientists funded through the Programme for Research in Third Level Institutions (PRTL). These initiatives will add to the stock of trained clinician scientists and focus particularly on the area of translational medicine.

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<sup>60</sup> Including representatives from UCD, TCD, RSCI, UCC, NUI Galway and the MMI

<sup>61</sup> ECRIN is funded under Framework Programmes 6 and 7 to develop an infrastructure of support, training and expertise, for clinical research in the participating EU member states. A major objective of ECRIN is to stimulate the creation of coordinating centres and national networks for their subsequent connection to the European network

The HRB has also recently funded a Research Methodology Support Centre which is due to open over the coming months. It will provide support to health and social care practitioners and academics. Its objectives are to strengthen quality in health services, primary care and clinical research, and to provide training and education in research methodologies. This will enhance the quality of investigator-led clinical trials and of clinical trial applications which, in turn, should shorten the time to approval by a research ethics committee.

#### From 'Bench to Bedside': Investing in Translational Research

Established in 2009, the SFI funded Strategic Research Cluster in Molecular Therapeutics for Cancer will assemble and build a fully integrated national translational cancer drug discovery and development programme that will significantly benefit cancer patients in Ireland. In a focused partnership of industry, science and medicine, the group aims to move away from the classical direct toxicological onslaught on tumours, to identify new rational diagnostics and treatments based on molecular knowledge of the tumour. The consortium will use advanced proteomic, transcriptomic, imaging, modelling and analytical technologies coupled with translational studies and trials to identify new diagnostic targets for advanced cancer treatment and increase the efficacy of the emerging raft of molecularly-targeted cancer therapeutics.

This Research Cluster will:

- Focus on breast cancer initially, making use of an existing translational laboratory infrastructure with advanced cellular, gene expression and proteomic platform technologies
- Combine advanced in-vitro mechanistic pharmaceutical modelling of resistance with molecular profiling of patient cancers
- Make maximum utility of a continually emerging clinical pipeline of proprietary targeted therapies to identify new/better treatment schedules for these cancers
- Couple this with novel treatment combinations which exploit biochemical weakness in each tumour type
- Develop technology to monitor the individual course of treatment with minimally invasive diagnostics which will generate sufficient information to guide the use of appropriate new treatment combinations and provide data on their response long before the patient suffers recurrence of their disease
- Conduct early stage clinical trials to evaluate emergent hypotheses.

### Commercialisation

EI in particular, plays a strong role in promoting commercialisation of state funded R&D. EI has invested in the provision of physical infrastructures such as incubator facilities (co-located with higher education institutes (HEIs)) which combine laboratory and business space with access to financial, legal and marketing advice<sup>62</sup>. EI also supports the Technology Transfer Offices (TTOs) in HEIs, industry liaison officers and technology acquisition. Over the past two years EI has initiated a Technology Transfer Strengthening Initiative<sup>63</sup> with the

<sup>62</sup> EI invested €4 million between 2004 and 2006 to establish 6 bioincubators located in Dublin, Cork and Galway and in doing so has doubled on-campus bioincubation space

<sup>63</sup> Launched in 2007 the €30 million initiative is being implemented over a five year period

objectives of increasing the level of IP transferred to industry from research in HEIs and to facilitate the development of high quality and effective systems and policies to ensure that the IP is identified, protected and transferred, where possible, into companies in Ireland.

#### **Integrated Solutions to Support LifeSciences and Health Innovation/Commercialisation in Ireland**

The Colles Institute was established in 2008 with the primary objective of enhancing patient care through supporting the development of optimal therapeutic strategies and technologies and by providing education and training to ensure the rapid transfer of these standards into practice.

The Institute was established by the Royal College of Surgeons in Ireland (RCSI) and brings together the expertise of three existing RCSI centres across the areas of surgical practice, training, clinical research and the development and commercialisation of new medical technologies:

- The Centre for Innovation in Surgical Technology (CIST) which provides services to assess, develop and commercialise surgical technology ideas from surgeons, researchers and industry
- The Centre for Clinical Research & Development (CCR&D) which provides clinical research services and facilitates clinical research through its network of RCSI affiliated surgeons in Ireland as well as internationally
- The National Surgical Training Centre (NSTC), a leader in the development and delivery of procedural based education, training and assessment.

The amalgamation of these centres enables the provision of integrated services and solutions to clinicians, academics and industry to support bringing a treatment from the initial ideas phase to clinical research and commercialisation right through to clinical practice.

The Colles Institute is the first of its kind in Ireland and brings together the relevant expertise to support innovation, technology transfer and translational research in Ireland. The Colles Institute is also leveraging its international network to provide world class supports and advice to clients - for instance, Colles has developed linkages with the Lerner Institute for clinical research & development at the Cleveland Clinic which is one of the top three hospitals in the US and a world leader in cardiology.

Developments are underway on a new state-of-the-art facility to house the Colles Institute which will be operational from 2011 and will be equipped with leading edge training and research facilities. The Colles Institute has been set up with the support of Enterprise Ireland.

#### **Venture Capital**

Access to finance is of critical importance to support early stage company investment and commercialisation. LifeSciences enterprises are highly research and capital intensive, requiring significant investment in equipment and on highly skilled human resources. At the same time, the time to commercialisation and profitability is long relative to other sectors.

Seven venture capitals (VC) funds have been established to date under the EI Seed and Venture Capital Scheme 2007-2012. Two of these funds are dedicated to the LifeSciences to ensure access to venture funding for the sector in Ireland. These are being run through Fountain Healthcare Partners and Seroba Kernel.

## Conclusion

From a predominately manufacturing base twenty years ago, Ireland's LifeSciences sector has continuously evolved, and is increasingly investing in new product and process development. Many multinationals have expanded their activities to include a wide range of business functions. Indigenous firms are strongly based in technological capability and are embracing new business and licensing models. The state's investment in R&D ensures that there is a strong underpinning for the next evolution of the sector in Ireland. Continuous investment in, and enhancement of, the clinical research infrastructures is a critical foundation, not only for increased efficacy of clinical practice and healthcare, but also as an attractor of investment by firms in Ireland for economic benefit.

The next chapter outlines the global competitive environment for LifeSciences in which we operate. Taking into consideration the global trends, Ireland's strengths and the global context, Chapter 5 develops a strategic vision for the evolution and future growth of the LifeSciences sector in Ireland.



## Chapter 4: Intensified Global Competition

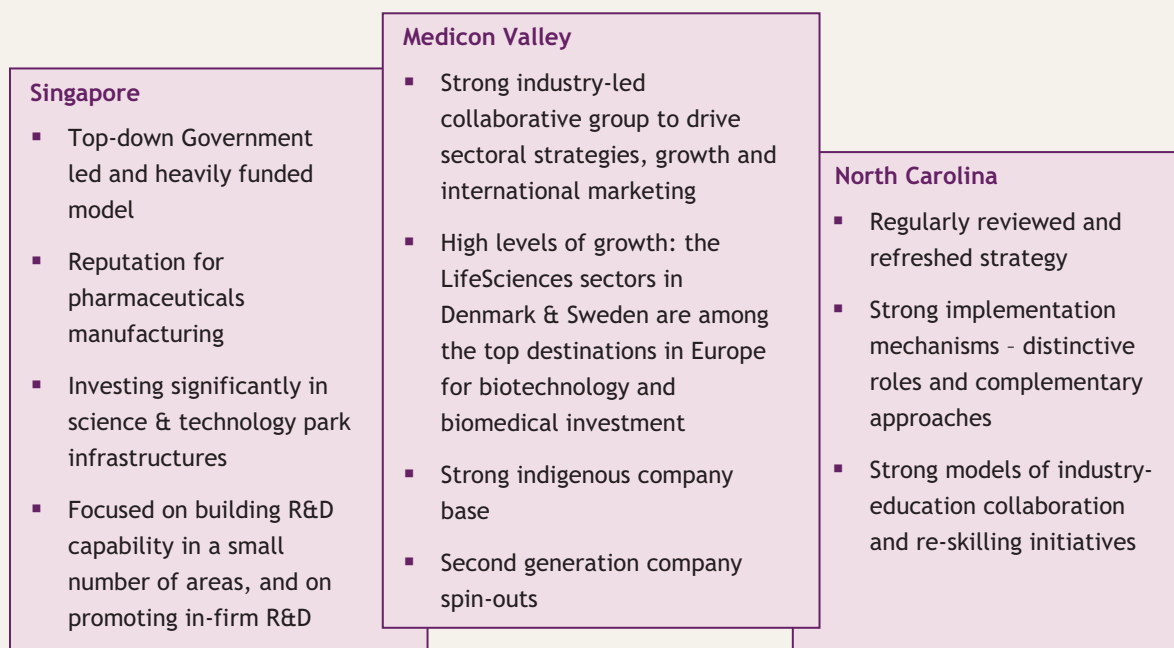
We have highlighted the extent and pace of global change that is having a transformational impact on the LifeSciences sector. Many countries are taking advantage of opportunities through the development of appropriate policies that will inform investment priorities and that are robust enough to allow for timely responses to ongoing change.

Forfás undertook a comprehensive analysis of a small number of LifeSciences clusters<sup>64</sup>, together with a desk-based review of over 15 country/region strategies. By understanding what other countries are doing, and analysing Ireland’s strengths relative to them, we are in a more informed position to develop and implement a comprehensive and differentiated strategy.

### Cluster Analysis at a Glance: North Carolina, Singapore & Medicon Valley

This chapter presents a brief synopsis of three successful clusters, North Carolina, Singapore & Medicon Valley, and outlines the proactive strategies that each has pursued.

**Figure 8: LifeSciences Clusters - A Snapshot**



<sup>64</sup> The LifeSciences Cluster Analysis is available on [www.forfas.ie](http://www.forfas.ie). The in-depth review was undertaken by Ernst & Young consultants, and included a combination of desk based research and interviews with key stakeholders (nationally and internationally)

**Table 7: LifeSciences Ecosystem - Cluster Analysis at a Glance**

|                   | Medicon Valley   | Singapore  | North Carolina   | Ireland  |
|-------------------|--|--|--|--|
| Maturity/<br>Size | Created 1997<br>“Middle-aged”<br>About 10 large companies and more than 200 start-ups and SMEs   | Created 2003<br>Emerging, getting big very fast<br>About 10 large and 100 smaller players  | Emerged in the late 80s/early 90s<br>Third largest LifeSciences cluster in the US<br>450+ companies  | Emerged 1960s<br>Manufacturing<br>Predominantly foreign owned<br>Increasing emergence of indigenous companies<br>350+ companies  |
| Main Activities   | Personalised medicine<br>Medical technologies<br>Biotechnology<br>Enzymes & food sciences<br>IT for LifeSciences<br>Therapeutic areas: <ul style="list-style-type: none"> <li>▪ obesity &amp; diabetes</li> <li>▪ cancer</li> <li>▪ inflammation/immunology</li> <li>▪ neuroscience</li> </ul> High level research | Drug manufacturing<br>Drug R&D<br>Strong bio focus<br>Genomics<br>Cell and molecular biology<br>Bioengineering & nanotechnology<br>Bioinformatics<br>Bioprocessing | Most aspects of LifeSciences<br>Drug/agri manufacturing<br>Health & nutrition research<br>IT for LifeSciences<br>Very strong research institutions (Duke)<br>Heavy industry investment | Pharmaceutical manufacturing - API & formulation<br>Combination products<br>Diagnostics<br>Bioprocessing & formulation<br>Complemented by increasing R&D activity<br>Emerging research strengths in: <ul style="list-style-type: none"> <li>▪ oncology</li> <li>▪ immunology</li> <li>▪ gastrointestinal health</li> <li>▪ neurosciences/therapeutics</li> </ul> |
| Governance        | Strong leadership centralised through Medicon Valley Alliance - multi-stakeholder group  | Strong leadership<br>Government-led ‘top-down’ initiative<br>Shared through EDB and A*Star <sup>65</sup>   | Regularly refreshed strategy<br>State Government highly active in stakeholder groups   | Sub-sectorally arranged industry organisations: IMDA, PharmaChem<br>Ireland, IPHA, IBIA<br>Enterprise development agencies: EI, IDA, SFI   |

<sup>65</sup> Agency for Science, Technology and Research (A\*Star), Singapore; Economic Development Board (EDB), Singapore

## FORFÁS HEALTH LIFESCIENCES IN IRELAND - AN ENTERPRISE OUTLOOK

|                                   | Medicon Valley   | Singapore  | North Carolina  | Ireland  |
|-----------------------------------|--|--|---|--|
| <b>Investment Environment</b>     | Good public support<br>Good VC and private equity environment                                | Mostly public<br>Limited LifeSciences VC access  | Good public support<br>Good industry investments  | Funding supports via development agencies<br>Somewhat limited VC access                            |
| <b>Human Resources</b>            | Highly educated & efficient workforce - (in limited numbers)<br>Focus on training/visibility | Strong incentives to attract foreign workforce<br>Focus on improving curricula to meet needs                                 | Intensive training initiatives in manufacturing<br>Intense industry/ university collaboration | Educated workforce<br>Increased emphasis on training initiatives and multi-disciplinary approaches |
| <b>Other Specifics</b>            | Strong local CROs and CMOs   | Focus on clinical trial facilities and Proof of Concept (specific grants)  | Biotechnology Centre (since 1985)<br>Heavy investments in workforce education                 | Investment in supporting research and competence centres   |
| <b>IP and Technology Transfer</b> | University curricula are beginning to focus on IP<br>Numerous science parks and incubators   | Safe IP environment<br>High spec science parks for manufacturing activities<br>Few incubator facilities to support spin-outs | Safe IP environment<br>Managed by universities<br>Strong tech transfer focus (BATON)          | Safe IP environment<br>Limited high spec incubation space  |

## Characteristics for Success

The overall review and analysis has highlighted a number of overarching characteristics that are apparent in the more successful LifeSciences clusters, outlined below.

| Characteristics for Success             |  |
|---|--|
| <b>Strong Leadership</b>                | <p>Provided by industry preferably with the commitment of university and hospital leaders and of the state as appropriate.</p> <p>A strong leadership group builds consensus for wider intervention based on a firm understanding of the sector's importance to economic growth.</p> |
| <b>Strategy</b>                         | Well defined and understood, with regular review and refresh mechanisms in place.  |
| <b>Visibility</b>                       | Both nationally and internationally is essential for the success of the sector. High profile research initiatives play a key role in attracting world-class researchers, talent and investment.  |
| <b>Connection across Sectors</b>        | To take advantage of opportunities arising from increased convergence of technologies. It requires engaging a wider set of stakeholders - including those that do not appear to be immediately relevant.   |
| <b>Commercialisation</b>                | Continuous, focused and concerted effort with a supportive business environment is essential - with strong leadership that can work across 'silos' and overcome the difficulties presented when working on activities outside an institution's core mission.                         |
| <b>Risk Capital</b>                     | Ability to attract VC funds with different approaches depending on the stage of development of the cluster. Less established locations generally focus on establishing regional angel investment networks and promoting the region to VC firms.                                      |
| <b>Physical Infrastructures</b>         | Science & technology parks, laboratories, incubation centres and enabling broadband infrastructures etc.   |
| <b>Centralised Information Resource</b> | To serve and inform a diverse stakeholder group regarding regulation, access to supports and relevant facilities etc.  |

## Conclusion

The increased focus and investment by other countries to drive the sector within their own economies reinforces the imperative to articulate and communicate a strategic direction for Ireland's LifeSciences sector, both internationally and nationally.

It is critical to demonstrate leadership and collaborative effort in delivering on the actions required to support its evolution over the next decade.

## Chapter 5: Ireland's Future in Health LifeSciences - Realising the Potential

This chapter sets out the areas where Ireland has the potential to capture new opportunities. It provides a 'pen picture' of what the overarching global trends can mean for Ireland based on our existing strengths in the sector, and outlines the optimal environment to facilitate companies to undertake activities that are high value, future oriented and differentiated.

### A Vision for Success - LifeSciences 2015

Building on core strengths and harnessing future opportunities, Ireland will become internationally renowned as:

**A Highly Collaborative, Innovative and Internationally Networked Location for LifeSciences**

**Achieved by Harnessing Technologies and Multi-disciplinary Skills to Provide Creative Solutions for Next Generation Products and Services**

By taking the actions outlined later in this report, by 2015, the LifeSciences sector in Ireland will have:

- A dynamic and connected LifeSciences sector, encompassing a range of innovative foreign and indigenous firms, internationally and nationally connected, engaged in collaborative activities across the value chain
- A strong cohort of companies and research institutes engaged in activities underpinning the shift toward personalised healthcare, harnessing the potential of converging technologies and capable of translating research (whether nationally or internationally sourced) into products and services to deliver tailored healthcare solutions
- A greater number of food companies embracing R&D and the potential for functional foods and nutraceuticals
- Higher numbers of firms engaging in process R&D to deliver solutions embracing more complex manufacturing requirements, delivering to superior quality while reducing time to market
- Higher levels of commercialisation of research in Ireland, supported by a fully functioning clinical research system, resulting in a greater number of technology licenses and third-level spin-outs
- A strong entrepreneurial economy, with an increased number of start ups serving international markets, whether directly or by partnering with larger global companies

- A reputation for risk management capability and for embracing regulation to facilitate the shift toward personalised healthcare and convergent products in an effective way to provide efficacy, safety and confidence
- An attractive environment that enables the commercialisation of IP and its global management and exploitation from Ireland and that is supportive of new and emerging business models resulting from increased industry and technology convergence.

## Health LifeSciences - Toward Personalised Healthcare

The global trends in LifeSciences all point toward personalised healthcare becoming a reality over time. Personalised healthcare involves capturing individual genetic, behavioural and environmental information to define individual prescriptions for health maintenance, disease prediction, prevention, and tailored therapy. It is effectively enabling a shift from ‘illness’ to the concept of ‘wellness’ and disease prevention.

*The wider definition of personalised healthcare embraces research, diagnostics and testing, delivery mechanisms and devices and the concept of ‘the appropriate treatment, in the appropriate way, to the appropriate patient, at the appropriate time.’*

This report considers the implications of this global shift for Ireland and the steps that need to be taken now to enable companies to take advantage of the many opportunities presented. Personalised healthcare is underpinned by developments in the process that involves the effective translation of research ‘*from bench to bedside.*’ It has implications for the production of medical solutions (medicines, devices, diagnostics and convergent products) such that the processes are increasingly complex and require multi-disciplinary skills-sets. Technology advances have also enabled a shift in the point of care, so that some elements of patients’ healthcare management can now be undertaken remotely. Nutraceuticals and functional foods have a key role to play in responding to the increased focus on ‘wellness.’

By evaluating the individual characteristics of patients and their diseases personalised healthcare could:

- Predict which patients will most likely benefit (or not) from a treatment
- Aid in the development of safer and more effective treatments by reducing the risk of side effects
- Save patients’ lives and improve their quality of life.

By increasing efficacy and safety, personalised healthcare, could make therapies more cost effective through:

- Development of diagnostic products that can save costs by targeting therapies to the patients who are most likely to respond
- Development of diagnostics may also help avoid serious side effects.

### Scientific Advances underpinning the Shift toward Personalised Healthcare

**Systems biology** is the study of an organism, viewed as an integrated and interacting network of genes, proteins and biochemical reactions. Instead of analysing individual aspects of the organism, systems biologists focus on all the components and the interactions among them, all as part of one system. Systems biology is still in its infancy but is crucial to developing a ‘systems’ understanding of an organism that will ultimately transform our understanding of human health and disease.

**Biomarkers** include all diagnostic tests, imaging technologies and any other objective measure of a person’s health status and all pharmacodiagnostic tests. Genetics, genomics, proteomics, modern imaging techniques and other technologies enable the detection and quantification of many more markers than ever before which facilitates prediction of the response to therapies; can expand the molecular definition of disease; and can recognise the stage of diseases. Discovering, developing and validating diagnostic markers (biomarkers) is a highly complex and time-intensive undertaking.

**Ribonucleic Acid Interference (RNAi)** involves switching particular genes on or off and opens up new fields of research and approaches to drug development. RNAi is believed to have significant potential for research on cancer and infectious diseases.

The availability of digitised patient information and a sustainable national biobanking resource (including imaging and biological data) have been identified by stakeholders as essential requirements within the Irish LifeSciences infrastructure. They are critical enablers of the shift toward personalised healthcare allowing the integration of bio-specimens (blood, DNA, tissue) and medical imaging data with corresponding patient data such as genetic profiles, medical histories and lifestyle information.

- **Biobanking**

Biobanks are characterised by a collection of biological samples, such as blood, tissues or DNA, plus associated epidemiological, clinical and research data<sup>66</sup>. Biobanks are an integral component of a growing knowledge-based economy. For example, completion of the human genome sequence has enabled rapid advances in the genomic analyses of human diseases. Such advances in the genetic and molecular understanding of human diseases have been dependent on the availability of high quality, standardised collections of patient samples and clinical data.

As medicine and information technologies continue to converge, biobanking offers new abilities to study the complex interaction between genes, the environment and social factors and are a fundamental underpinning infrastructure for the translation of LifeSciences research into improvements in human health through the development of new diagnostics and/or treatments.

It is essential that Ireland develops a national approach to biobanking and that all Irish research centres and hospitals adopt standardised biobanking practices as a matter of priority. Consideration should be given to Ireland’s involvement in European biobanking initiatives, such as the Biobanking and Biomolecular Resources Research Infrastructure

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<sup>66</sup> For further information on biobanks please see [www.hrb.ie](http://www.hrb.ie) and [www.biobankcentral.org](http://www.biobankcentral.org)

(BBMRI), which aims to network biobanks across the EU. However, Ireland's involvement in such initiatives is hindered by the absence of a national biobanking policy.

As a first step towards developing a national biobank physical infrastructure, the HRB and Northern Ireland Research and Development Office co-funded the design phase of an all Ireland control DNA biobank, Gene Library Ireland (GLI), conducted by Molecular Medicine Ireland. The proposed GLI biobank will contain detailed medical information, blood and DNA samples for 10,000 individuals and, as a control group, would represent an extremely valuable resource for researchers in both academia and industry<sup>67</sup>.

- Clinical Data

The availability of digitised patient information and a networked ICT environment across the healthcare system is a necessary enabler. This report does not focus specifically on this aspect as initiatives are ongoing under the direct auspices of the HSE through the iSOFT patient record management project and the National Health Data Centre initiative<sup>68</sup>. The Department of Health & Children (DOHC) is finalising the proposed Health Information Bill which will be published early in 2010. The main purpose of the Bill is to establish a legislative framework to enable patient related data and information to be used to best effect to enhance medical care and patient safety. The proposed development of Unique Patient Identifiers would allow for up-to-date clinical data on a patient to be collated, stored and accessed as appropriate. This aim needs to be complemented with procedures for safeguarding patient confidentiality and for enabling the research community to access information on an aggregated basis.

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<sup>67</sup> For further information on Gene Library Ireland (GLI) please see [www.molecularmedicineireland.ie](http://www.molecularmedicineireland.ie)

<sup>68</sup> The iSOFT initiative involves a ten year €56 million investment in healthcare record administration and management across the Irish hospital system - this system will ultimately extend to the entire national healthcare system. It is presently live in 26 hospitals across the country and will be rolled out to the rest of the hospitals by 2015. Ryan, H.J.F., 2007, eHealth strategy and implementation activities in Ireland, Report on the framework of the eHealth ERA project, September

**Toward Personalised Healthcare: Harnessing Opportunities and Building on Strengths**

Based on our analysis of Ireland’s strengths and potential for growth, this report highlights a number of specific opportunity areas, outlined below, that Ireland is well placed to take advantage of in light of emerging global trends and the shift toward personalised healthcare.

| The Critical Enablers               |   |
|-------------------------------------|---|
| Translational Medicine              | Bringing research from bench to bedside, and critical to personalised healthcare, including pharmaceuticals, biopharmaceuticals, nutraceuticals and medical devices |
| Leading Edge Production             | A key element in the ‘manufacturability’ of new products (drugs and devices) requiring innovative approaches to process design and development                      |
| Taking Advantage of Convergence     |   |
| Convergent Products                 | Enabled by converging technologies and resulting in a blurring across the formerly discrete bio, medical devices & diagnostics, pharma and ICT sectors              |
| Diagnostics & Remote Healthcare     | Enabled by advances in science and technologies, including genomics, proteomics, imaging, wireless, sensors and nanotechnologies                                    |
| Delivering on ‘Wellness’            |   |
| Nutraceuticals and Functional Foods | Capturing the increased consumer focus on ‘wellness’ and healthier lifestyles   |

**The Critical Enablers**

**Translational Medicine**

Translational medicine has been increasing in importance for translating research from the laboratory, through clinical trial processes, commercialisation and to delivery in the marketplace.

Our research highlighted the fact that there are various definitions and interpretations of what is meant by translational medicine (with the word often being used interchangeably with personalised medicine and/or clinical trials). It is important that there is a common understanding of its characteristics so that all stakeholders fully understand their role in making it a reality for Ireland.

Translational medicine is characterised by a number of elements working together.

- Tailored

Translational medicine allows for new drugs, treatments and delivery mechanisms to be more effectively and swiftly developed, enabled in part by the genomics and bioinformatics revolution and the development and use of biomarkers. These and other technologies facilitate stronger linkages between basic researchers and clinicians to develop treatments tailored for the genetic makeup of a particular sub-set of patients. In principle, this allows for smaller more targeted clinical trials.

- Patient Oriented & Iterative

Translational medicine is more consumer/patient oriented than traditional medicine has been up to very recently. It is a more iterative process involving a continuous feedback loop between researchers, clinicians and patients and facilitates not only the development and commercialisation of new products and treatments but also systemised enhancements in clinical practice and patient care.

- Cross Disciplinary & Collaborative

Traditionally, research, drug development, and clinical medicine were three virtually separate endeavours; bench scientists, drug developers, biomedical engineers and clinical researchers rarely, if ever, met together to share ideas through the research, development and commercialisation phases. Proactive collaboration between all parties, harnessing the relevant research systems and infrastructures, is fundamental to the success of translational medicine.

- More Efficient

Well designed translational medicine studies which incorporate effective patient monitoring, such as imaging and diagnostics for the stratification of patient sub-populations based on common, but unique, characteristics enable companies to:

- Reduce the probability of failures at a late stage in the clinical trials process, saving both time and money
- Develop and market ‘nichebuster’ drugs; based on their effectiveness in specific patient populations in tandem with validated biomarkers and companion diagnostics<sup>69</sup>.

Allied to the concept of translational medicine is the linkage with production and developing appropriate processes and testing ‘manufacturability.’ The optimal environment to support translational medicine is outlined overleaf.

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<sup>69</sup> Nichebusters are drugs with global sales of US\$250,000 annually

**The Optimal Environment for Translational Medicine requires:**

- **A research culture and processes within the healthcare delivery management system** including dedicated time and resources for clinicians to carry out research and collaborate on research-driven initiatives
- **Dedicated research and commercialisation funding** that supports translational research and collaboration and linkages with national, international and/or European-wide initiatives
- **Technology transfer initiatives** and supports, advice and expertise in the valuation and commercialisation of intellectual property from higher education institutes and hospital sources both nationally and internationally
- **Direct industry engagement** bringing market intelligence, issue identification, expertise and capabilities to bear
- **Enabling research disciplines** that support translational research, including for example, bioinformatics, genomics, systems biology and molecular medicine
- **Fundamental skills** in mathematics, sciences and engineering complemented with **multi-disciplinary** capabilities and strong international project management
- **Specific research and clinical infrastructures** including biobanks, wet labs, supercomputing facilities etc., together with an appropriate data protection environment
- **A conducive regulatory environment and ethics process.**

The Cleveland Clinic, based in Ohio, is recognised worldwide for its progressive approach to healthcare research and services<sup>70</sup>. Although unrealistic to assume that Ireland could duplicate infrastructures of such scale, EI has engaged proactively with the clinic to see what Ireland can learn from its processes, networks and approach.

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<sup>70</sup> Translational Medicine in Cleveland Clinic, [www.lerner.ccf.org](http://www.lerner.ccf.org)

## Why Ireland

- Established research strengths and clinical capabilities in a number of therapeutic areas including immunology, gastroenterology, oncology and neurology. Emerging research and clinical capacity in cardiovascular and regenerative medicine
- Increasing capacity in underpinning sciences and platform technologies to support translational medicine such as genomics, proteomics and bioinformatics
- Emerging capacity in the area of RNAi through a research collaboration between the Alimentary Pharmabiotic Centre in UCC and GSK with support from IDA Ireland
- Demonstrated capabilities in clinical trials in the area of oncology in particular
- A supportive and highly regarded regulatory system and a reputation for bringing a problem solving attitude to bear in research, development and production
- Supercomputing infrastructures and analytical capabilities.

## State Investment in R&D - Building Capacity in Translational Medicine

Funded through the PRTL, the **Conway Institute of Biomolecular and Biomedical Research** is a multidisciplinary research centre based in UCD. The Institute brings together over 550 research staff from all over the university and its associated teaching hospitals. UCD Conway also has formalised collaborations with TCD and RCSI. The close collaboration of scientists and clinicians underpins the translational nature of this research from the 'bench to the bedside.'

The research focus of the UCD Conway Institute is on the identification of molecular mechanisms underlying human and animal diseases primarily in the areas of infection, immunity & repair, diabetes & vascular biology and neuroscience. The Institute places particular emphasis on fostering entrepreneurship and creating strong partnerships with industry and works closely with NovaUCD and EI Bio.

Wyeth Research Ireland has established a bio-therapeutic drug discovery research facility there with the support of IDA Ireland. The €13 million facility currently employs twelve top class research scientists focusing on product discovery, pre-clinical research and drug discovery technology development.

The longer term objectives of the Institute are focused on the integration of the biological sciences with those sciences not traditionally associated with biology including computer science, applied mathematics, engineering and economics.

## Gaps and/or Areas to be Enhanced

- The culture for R&D is underdeveloped within the healthcare system, and a fully functioning health and clinical research system is necessary to stimulate enterprise engagement in translational research
- Today, Ireland continues to build capacity and capability in the areas of biomarker validation and systems biology
- Although there are initiatives in place that support collaboration and networking between industry and academia, there is the potential to focus supports on translational research in specific therapeutic areas where Ireland can gain international recognition

- Ireland’s IP environment is reasonably developed, and its corporation tax and patent exemption regimes are supportive for IP creation and exploitation. However, there is a need to further develop the depth of expertise required to ensure timely and effective IP licensing agreements
- The efficiencies of ethics committees need to be improved as a matter of urgency so that the process for clinical trials can be streamlined and expedited (this should not be interpreted to mean a reduction in attention to quality, standards and safety issues)
- The existing skills base can be further developed to build capacity in multi-disciplinary skills and approaches to problem solving.

### Leading Edge Production

It is important that we do not interpret a shift toward more innovative and research intensive activities as meaning that manufacturing no longer matters. It does - and Ireland has the opportunity to build on its reputation to forge tighter links with R&D activities, and to provide the environment for pilot and early stage production.

We consider two elements of the future of manufacturing processes for the LifeSciences sector (although they are not necessarily mutually exclusive):

- Cost Optimisation

Firms are focused on reducing costs and time to market and minimising waste, while at the same time the need to ensure compliance with regulation and quality guidelines set out by the FDA and the ICH is paramount<sup>71</sup>. The FDA launched its Critical Path Initiative in 2004 to stimulate firms to modernise processes and to develop innovative methods to transform initial concepts into physical products in a shorter time frame.

*“The greatest benefit of optimising a product design for manufacturability is reducing or eliminating costly engineering changes<sup>72</sup>.”*

Continuous improvement within manufacturing is fundamental to future success, cost optimisation and increased productivity and involves:

- Integration of technical innovation and product quality indicators
- Process understanding and control
- Variability reduction
- Quality planning
- Risk and change management

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<sup>71</sup> International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - the guidelines are not compulsory today

<sup>72</sup> Randy Hagler of the Tech Group cited in Ford, C., 2008, Seven Steps to Successful Combination Product Design, Medical Product Outsourcing, March

There are a number of concepts that underpin continuous improvement, including Quality by Design (QbD), Process Analytical Technology (PAT) and Quality Risk Management (QRM).

|            |  |
|------------|--|
| <b>QbD</b> | A systematic approach to development that begins with predefined objectives and emphasises product and process understanding and process control, based on sound science and quality risk management   |
| <b>PAT</b> | An uninterrupted process of adding, processing, and removing material (to reduce downtime of manufacturing processes)  |
| <b>QRM</b> | A system for designing, analysing, and controlling manufacturing through timely measurements (e.g. during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality |

- The Future of Manufacturing - Innovative Solutions

In the future manufacturing will become increasingly complex and will require knowledge and expertise across a range of disciplines. It will require inter-disciplinary approaches to problem solving and will require flexible approaches that deliver on smaller batch sizes and product variations in multi-product manufacturing facilities.

Process design and development for new and innovative products requires a greater understanding of the range of potential delivery mechanisms and package design, interactions between different materials under different environments, testing and quality control and validation processes. For example, some of the sterilisation programmes that are unique to a physical device will be less familiar to scientists used to working in pharmaceutical labs that specialise in testing fluids in small volumes and in small containers.

As a new product is developed and brought to market ‘manufacturability’ is an important consideration. If we link our manufacturing and process development capabilities to the translational medicine and commercialisation elements of the value chain, Ireland can deliver a compelling proposition to firms operating across the world.

### The Future of LifeSciences: A Challenge for Manufacturers

The **design phase** for convergent products includes material selection, toleration analysis, human factors, tooling, moulding and assembly characteristics to improve device performance and feasibility prior to investing in small- and large-scale manufacturing solutions. Upon completion of this device design prototyping phase, the developer and manufacturer focus on prototyping the manufacturing processes.

**Material selection** is a critical part of product design, and not only includes the mechanical and physical performance needs of applications, but also considerations such as advanced material surfaces and biocompatibility. Material considerations affect device durability, protection, resiliency and consistency of use.

**Process development** is the practice of defining and developing a manufacturing process to accommodate the specific requirements of a given product while meeting process quality and cost objectives.

**Sterilisation:** Not only must the manufacturer be certain that all components within a combination product reach a sterile state, but also that all materials are compatible with the sterilisation process. In many cases, the package design is expected to facilitate sterilisation. In general, sterilisation methods are determined early in the design process as materials of construction are being selected.

Source: adapted from *Medical Product Outsourcing*, March, 2008

### Why Ireland

- An in-depth expertise in manufacturing across pharmaceuticals, medical technologies (including convergent products), and ingredients and Ireland has successfully engaged in the more recent biopharma domain
- The necessary core skills in chemistry, biologics, medical technologies, electronics and engineering
- An increasing proportion of companies that have invested in process R&D, and some that have gained international/global control of specific product lines
- The emergence of contract manufacturing organisations (CMOs) that provide flexibility and core competences (although only a small number to date)
- A valuable asset in NIBRT<sup>73</sup> that provides training and R&D services for companies involved in biopharmaceuticals. Their main research focus areas include bio-reaction engineering, downstream processing and process & product analytics
- A strong and internationally renowned regulatory track record
- A growing research expertise and capacity in the area of process R&D through a number of research centres and academic-industry collaborations.

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<sup>73</sup> The National Institute for Bioprocessing Research and Technology (NIBRT) focuses specifically on process R&D and the skills and training needs of the biopharmaceutical sector

## Gaps and/or Areas to be Enhanced

Although Ireland has a strong track record in production, many of the facilities are foreign owned, and many of the first and second generation facilities have been built with little flexibility to accommodate processes with different design or at different scale. Over time, although large scale single-product sites will still exist, there will be an increasing emphasis within the industry globally on manufacturing facilities and processes that can be adapted and/or retooled to facilitate the production of new products.

In this context, investment in process R&D and in building multi-disciplinary teams is particularly important for firms based in Ireland. Not only does such investment respond to demands from healthcare payers for increased efficiencies and addresses issues of cost and time to market but it also builds on our core strengths and facilitates backward integration to product development and commercialisation and offers an attractive career path for highly qualified scientists and engineers.

Indigenous firms (where it makes business sense) should be actively encouraged to undertake pilot production (or outsource to CMOs) in Ireland.

## Manufacturing Process Research in Ireland

Based in UL the **Solid State Pharmaceuticals Cluster's** research programme focuses on investigating how the process of producing the active ingredients for tablets in powder form can best be done and improved. Academic research partners include TCD, UCD, NUI Galway and UCC.

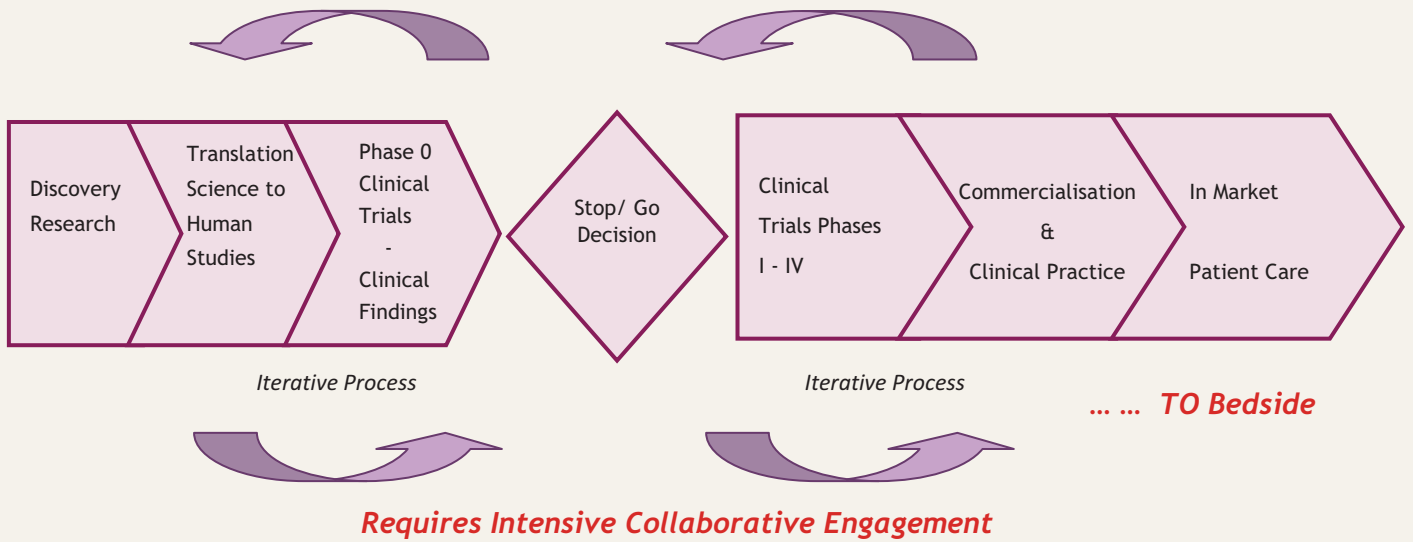
The work of the cluster is highly relevant to industry needs in the pharmaceutical sector, which is looking to develop more efficient methods of producing small molecule drugs. There are a large number of companies actively involved in the SFI funded cluster including Janssen, GSK, Schering Plough, Eli Lilly, Merck Sharp & Dohme, Roche, Pfizer, Covidien and Helsinn.

The **Biopharmaceutical Process Analytical Technology Network (BioPAT)** was launched in 2009 and is funded through the EI Applied Research Enhancement programme. BioPAT's research focus is on the delivery of more efficient, reliable and cheaper processes for manufacturing biopharmaceutical medicines. Based in UCD the research activities are being carried out in collaboration with Dublin City University (DCU), NIBRT and the Tyndall Institute based in UCC. There are 15 indigenous and multinational companies involved in the project including Stokes Bio, Luxcel Biosciences, Technopath, ABB, Genzyme and Wyeth.

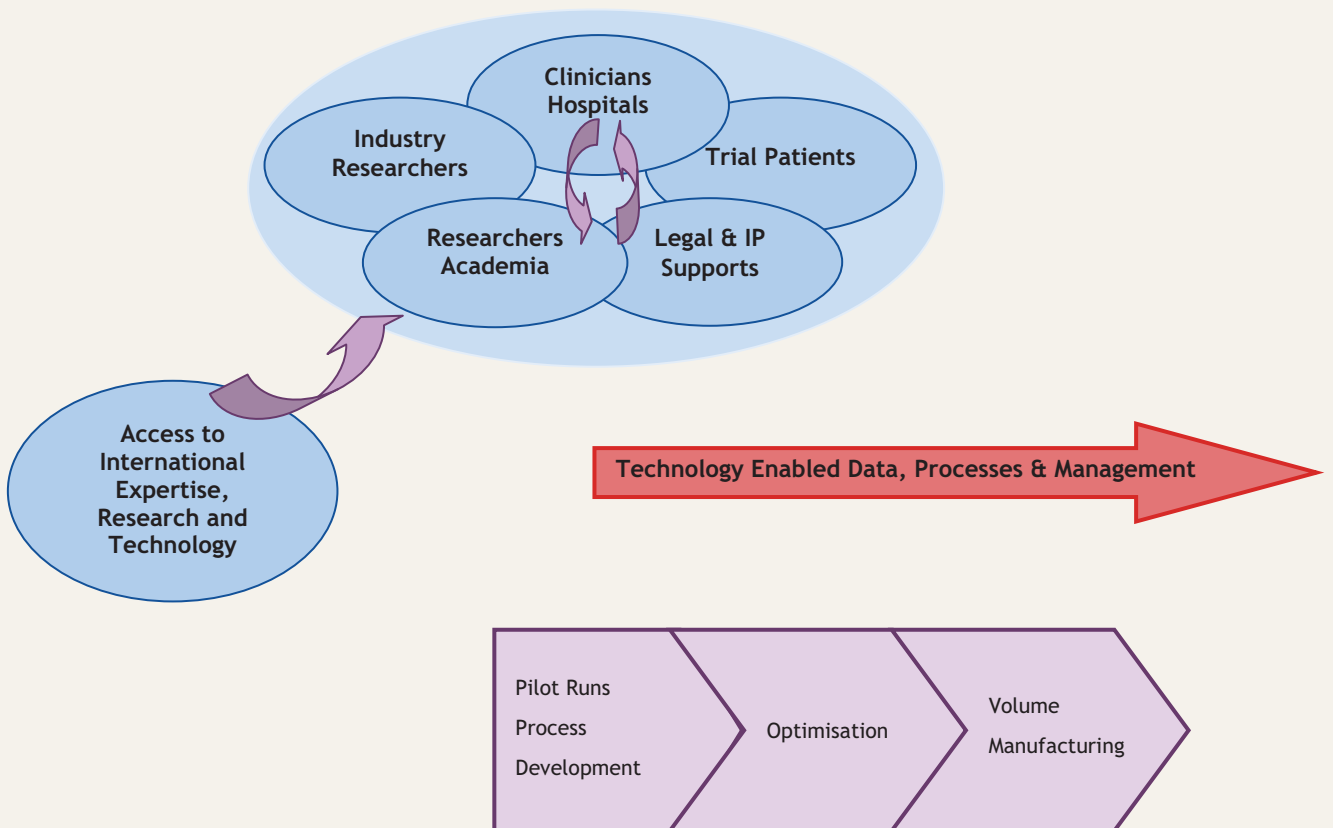
The **Alimentary Glycoscience Research Cluster (AGRC)** is based in NUI Galway in partnership with NIBRT, UCC, UCD and Teagasc. The cluster is exploring the role of gut glycosylation in host-microbe interactions. The research being undertaken by AGRC will have research and commercial applications for the biopharmaceutical, dairy and food sectors. The cluster is funded through SFI's Strategic Research Cluster programme. Industry partners include Agilent Technologies, Alimentary Health, Biomining, and Bristol Myers Squibb.

Figure 9: Translational Medicine & Leading Edge Production - Taking Research from 'Bench to Bedside'

... .. FROM Bench



... .. TO Bedside



## Taking Advantage of Convergence

### Convergent Medical Products

As outlined in Chapter 2, convergent products have been in the market for some time. It is estimated that the worldwide market for drug delivery technologies alone in 2008 was more than US\$70 billion<sup>74</sup>. Advances in science and technologies coupled with new applications of existing technologies are now driving increased activities in the development of new convergent products which are at the cutting edge of biomedical science and health service delivery.

As well as capabilities in production a number of factors provide the optimum environment for convergent products, including cross-sectoral industry networks and regulatory and IP expertise well versed in the complexities of multi-technology based products.

### Why Ireland

- Ireland has demonstrated capabilities in the regulation and production of convergent products, particularly in the area of drug eluting stents. Abbott, Medtronic, Clearstream, Cook Medical and Boston Scientific manufacture advanced drug eluting stents out of their Irish based facilities; merging the formerly discrete sub-sectors of medical technologies and pharmaceuticals
- The ‘made in Ireland’ brand has a strong global reputation in relation to the quality and reliability of medical technology products
- Ireland has recognised capabilities in materials, including research institutes such as the Materials Ireland Research Centre and the Centre for Nanotechnology and Materials Research, which are directly relevant to convergent products
- Ireland has a number of research groups/institutes that have expertise directly relevant to convergent products
- Ireland has significant capacity in many of the engineering disciplines which underpin convergent products, including software, electronic and biomedical engineering.

#### Industry and Research Institutes working together on Convergent products

Led out of NUI Galway the SFI funded **Network of Excellence for Functional Biomaterials (NFB)** has academic partners from national and international institutions including UCD, the AO Research Institute in Switzerland, the University of Toronto, the Georgia Institute of Technology and the Mayo Clinic in the US. The research focus of the NFB is on developing and manipulating a new generation of biomaterials which will allow the delivery of therapeutic genes and other agents to specific targeted treatment areas. Industry partners include a mix of leading global and indigenous medical technologies companies including Abbott Vascular, Medtronic, Boston Scientific, Zerusa and Proxy Biomedical.

The **Tyndall National Institute** in UCC has a programme on novel micro-nanotechnology for biological and medical applications. Research in this area includes: bioanalytical microsystems, bionics, biophotonics, microfluidics, chemical micro analytics, electronic instrumentation systems, and nanobiotechnology.

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<sup>74</sup> Episcom Business Intelligence, 2007, Drug Delivery Technologies: Players, products & prospects to 2015, November

### Gaps and/or Areas to be Enhanced

- There is significant potential to build on existing activities in convergent technologies and to stimulate increased networking by firms across formerly discrete sectors, particularly between medical devices, ICT, pharma, biopharma and engineering
- The amount of in-firm R&D being undertaken by firms based in Ireland is relatively low (for process or product R&D)
- The clinical trials infrastructure is relatively under-developed and is currently acting as a disincentive for company investment in R&D
- Engagement by clinicians, which is critical not only terms of problem identification enabled by their close interaction with patients but also for R&D, is not optimised
- A depth in regulatory expertise specific to innovative convergent products needs to be further developed.

### Remote Healthcare and Diagnostics

Advances in science and technology have created an environment that facilitates remote diagnostics and delivery of healthcare services over considerable distances. Remote healthcare is enabled by technology developments in areas such as sensors, wireless technologies and transmitters, photonics, imaging and process simulators. It is estimated that the global telemedicine market was worth US\$1.25 billion in 2007 and is predicted to grow at a five year CAGR of 44%<sup>75</sup>.

Key infrastructures that support companies, medical practitioners and researchers to take advantage of the growing market for remote healthcare and diagnostics include high capacity communications networks, high performance computing capacity and data banks. Networks that facilitate the open and collaborative interaction of companies, academic researchers and clinicians with relevant expertise in the areas of medical devices, diagnostics and ICT are extremely valuable.

#### Remote Diagnostics: Demonstrating Ireland's Capability

Irish owned firm, **Silicon & Software Systems Ltd. (S3)**, designs integrated circuits and embedded software solutions for the world's leading technology companies, such as Philips Medical, Intel and Nokia. One of their key areas of focus is on the integration of wireless and mobile technology into medical applications and home environments for remote medicine solutions.

The SFI funded **Biomedical Diagnostics Institute (BDI)** is based in DCU. BDI's primary research focus is on sensors and the development of next-generation biomedical diagnostic devices especially for Point of Care (POC) and self-testing applications. Industry partners include Becton Dickinson, J&J Enfer Scientific, Analog Devices and Hospira.

**ICHEC - the Irish Centre of High-End Computing**, provides high-end computer resources principally for researchers in third-level institutes. A skills team supports the development of internationally competitive computational modelling for leading edge researchers across all main disciplines and institutions. ICHEC also engages with organisations and consortia such as PRACE and DEISA to ensure the Irish research community is linked to Europe's most advanced high performance computing facilities.

<sup>75</sup> Datamonitor, 2007, Moving towards the Integration of Telehealth into Healthcare, July

## Why Ireland

- A strong base of companies and a growing R&D expertise in areas that are central to remote healthcare and diagnostics including sensors, high power computing, photonics, nanotechnologies, mobile communications, biomedical engineering and semiconductors
- Proven expertise in R&D and advanced manufacturing in medical technologies, embedded software systems and wireless communications
- An advantage as an island when it comes to ‘isolating’ wireless spectrum and radio frequencies for testing remote diagnostic products and services to assess their efficacy and scalability<sup>76</sup>
- Supporting infrastructures and skills in place, including for example, data centres and the ICHEC facilities at NUI Galway and the Trinity Technology & Enterprise Campus, coupled with analytical and computational capabilities.

## Gaps and/or Areas to be Enhanced

It is essential that next generation broadband infrastructures and services with sufficient capacity are put in place to enable fast, reliable and secure transfer of patient and analytical data to facilitate R&D and piloting of remote healthcare products and services in Ireland.

### ICT Underpinning Remote Healthcare

The Technology Research for Independent Living (TRIL) Centre is a coordinated collection of research projects, based in TCD and involving collaborations with UCD, NUI Galway, and Intel.

The TRIL Centre focuses on the research of new technologies to enable people to live independent lives in the environment of their choice. The Centre created dedicated laboratories at Intel and in each of the universities involved. The TRIL Centre is one of the largest research centres of its kind, bringing together a multi-disciplinary team of world-class industrial and academic experts.

The TRIL Centre has also created the fully operational TRIL Clinic at St. James’s Hospital in Dublin. Since opening, the Clinic has evaluated more than 100 patients with full ethical approval, and expects to have assessed in excess of 600 by end 2009. The data that the TRIL researchers will gather will help them understand the impact of falls and find ways of predicting and reducing them.

## Delivering on Wellness

### Functional Foods and Nutraceuticals

The food sector is core to Ireland’s economic growth, and there is significant potential to leverage our capabilities, strengths and international image to take advantage of global market trends. Today, a number of firms in Ireland are involved in the area of functional foods and nutraceuticals, from both the food and LifeSciences sectors. IBEC provides industry support, information and networking through its business association, Food & Drinks Industry Ireland (FDII). Ireland also recently invested to support fundamental and applied research in

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<sup>76</sup> [www.comreg.ie](http://www.comreg.ie)

the areas of functional and marine health foods in line with the SSTI, 2006-2013 and the AgriVision 2015 Action Plan (a number of these investments are described in Chapter 3). This investment builds on existing research carried out through the SFI funded Alimentary Pharmabiotic Centre in UCC, the Teagasc Dairy Products Research Centre, the Irish Phytochemical Network and through the Food Institutional Research Measure (FIRM)<sup>77</sup>.

### Why Ireland

- The presence of a leading cohort of food, marine and biopharmaceutical companies
- A growing research expertise and international recognition in gastroenterology and immunology. Much of the underlying scientific research, skills and expertise highlighted as relevant to pharmaceuticals and biologics is also relevant to nutraceuticals
- Extensive access to a rich marine natural resource that has been relatively untapped to date.

#### *Gastroenterology and Immunology - Ireland's depth of expertise*

Ireland has a core competence in the areas of gastroenterology (GI) and immunology. It is home to some of the world's leading researchers and clinicians in the GI and immunology areas. TCD is ranked second in the world in immunology research.

There are a number of innovative Irish companies whose products, technology and research are making breakthroughs within the GI market - gastroesophageal reflux disease (GERD), irritable bowel syndrome (IBS), and irritable bowel disease (IBD).

- AGI Therapeutics has a drug in Phase III for the treatment of a type of IBS. This drug has 'blockbuster' potential if it successfully progresses through the regulatory approvals process
- A technology developed by Alimentary Health in Cork is the basis of a new probiotic product that has recently been launched on the market by one of the top 10 GI companies in the world, Proctor & Gamble
- Opsona Therapeutics, a spin-out from TCD, is developing a number of products to modulate the human immune system using a platform of small molecules, monoclonal antibodies and biologics. The company successfully raised €18 million in venture capital (VC) funding in February 2009 and will be starting clinical trials on its lead candidate OPN-305 in 2010
- A number of indigenous medical devices companies such as Vysera Biomedical and Creganna are developing products in the area of interventional endoscopy
- 8 of the top 10 companies in the GI market have facilities in Ireland (1 of which manufactures their leading GI drugs here)
- There are a number of internationally renowned researchers and clinicians actively involved in the areas of gastroenterology and immunology.

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<sup>77</sup> Administered through the Department of Agriculture & Food (DAFF)

## Gaps and/or Areas to be Enhanced

Many of the gaps and areas identified for enhancement in earlier parts of this document are relevant for this opportunity.

Functional foods/nutraceuticals also present a significant challenge for many existing food companies that have been more directly involved in dairy processing to date - those companies that are already facing cost competitiveness issues, low margins and pricing pressures. It brings to bear the added complexities similar to those facing LifeSciences firms whose manufacturing processes involve biological components and the need for clinical trials and testing to substantiate health claims for their products.

There is further potential to raise awareness amongst food/marine companies of the potential in the area of nutraceuticals/functional foods, and to provide mechanisms for knowledge sharing with pharmaceuticals companies.

## Skills: of Critical Importance

International research indicates that the attraction of talent - i.e. the best person available for the job - is one of the most crucial factors facing firms today. With increased mobility, people can now choose where to work, and firms undertake searches for talent on a global basis.

This section specifically considers the skills and expertise required of the LifeSciences sector as it evolves, and in particular, those required in the context of the opportunity areas identified.

Superior capability in the core skills of mathematics and analytics, physical sciences, electronics and engineering are critical to the sector. This needs to be complemented with multi-disciplinary skills and at the very minimum, the ability of an individual schooled in one discipline to work effectively and proactively in multi-disciplinary teams.

Although the permutations of production and R&D processes vary for pharmaceuticals, medical devices, biopharmaceuticals and nutraceuticals sub-sectors, the requirements relating to quality and continuous improvement do not. Expertise in the areas of Quality by Design (QbD), Process Analytical Technology (PAT), Quality Risk Management (QRM) and Continuous Process Improvement is fundamental if Ireland is to build on its track record in production.

### Talent Attraction - An Area of Concern for Firms Globally

Recruiting and retaining the right talent is source of concern for LifeSciences CEOs. This is probably because biopharmaceutical R&D is a highly specialised activity - and one that will become still more complex over the next few years, with the shift to targeted treatments combining diagnostics, drugs and medical services, and the gradual convergence of the pharmaceutical and healthcare industries.

*“The number of people capable of understanding all these sciences and working across more than one sector is likely to be even smaller than the number who can perform conventional R&D”*

Source: IBM, 2008, Global CEO Survey: The Enterprise of the Future, Life Sciences Industry Edition, August

For translational medicine, success is premised on bringing together a range of core skills to:

- Analyse phenomenal amounts of genotypic information about patients and their responses to specific treatments
- Develop diagnostic tools to identify which patients will respond best to which treatments and at what dosage
- Devise and manage sophisticated clinical trials to scientifically validate the effectiveness of treatments.

**Skills for Translational Medicine include:**

|                                    |                                   |
|------------------------------------|-----------------------------------|
| Clinicians                         | Research nurses                   |
| Pharmacologists                    | Pathologists                      |
| Molecular biologists               | Data managers & bioinformaticians |
| Biostatisticians & epidemiologists | Regulatory & quality specialists  |
| Biomedical engineers               | Legal & IP specialists            |

There are specific needs for each of the sub-sectors that were identified by industry representatives during interview and which are outlined below. The consultation process highlighted a clear demand for more graduates and trainees at all levels that have gained industry experience as part of their education and training.

**Pharmaceutical Skills**

- An adequate supply of highly trained chemists at PhD level in the areas of organic, analytical and pharmaceuticals, and chemical engineers (usually at graduate level)
- Expertise in solid state/crystallography (API/formulation interface), which is key to reducing time to market and exposure to industry practices as part of the education programme
- Graduates with exposure to fundamental research and chemistry, as this develops the skills necessary to carry out advanced process development work in companies upon graduation.

**Biopharmaceutical Skills**

- Graduates and postgraduates in bioprocessing, biochemistry, and bioengineering (NIBRT has a direct role in meeting this industry need)
- Graduates and post graduates with capabilities in systems biology and glycosciences.

## Medical Technologies Skills

The Expert Group on Future Skills Needs (EGFSN) issued its report on The Future Skills Needs of the Medical Devices sector in Ireland in February 2008<sup>78</sup>. A number of the recommendations centred on the need to ensure the availability of appropriately skilled people to:

- Work in the area of convergent products through the introduction of programmes which bring together mechanical, electronic and bioscience technologies
- Design, manage and conduct clinical trials
- Develop and commercialise medical technology products
- Manage regulatory affairs and IP processes particularly in the context of convergence.

The consultation process also highlighted the need for:

- Graduates and postgraduates in biomedical engineering, process design, sensors and materials
- Graduates with product management and commercialisation skills.

## Functional Foods<sup>79</sup>

- Graduates and postgraduates with training in microbiology, immunology, food science, formulation science and food business
- Graduates with exposure to fundamental research in biology and chemistry, as this develops the skills necessary to carry out advanced formulation and development work in companies upon graduation
- The availability of appropriately skilled people to design and manage clinical trials that meet (and ideally exceed) the requirements of national and international legislation for verification of health claims on food.

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<sup>78</sup> Expert Group on Future Skills Needs, 2008, Future Skills Needs of the Medical Devices Sector, February

<sup>79</sup> The Expert Group on Future Skills Needs (EGFSN) is preparing a study on skills needs in the food sector, Future Skills Requirements of the Food and Beverages Sector, to be published in the final quarter of 2009

## Chapter 6: Actions for Success

A depth of expertise already exists in some of the opportunity areas identified and there are emerging pockets of research capability and/or nascent developments directly relevant to others.

The actions outlined below are focused on a number of areas specific to the sector. Additional resources will not necessarily be required - but rather existing resources can be refocused in a strategic way to reinforce and leverage the areas where we have demonstrated strengths, and to forge the linkages and expand the networks needed to optimise the impact of investments to date. The proposed actions are not only intended to address current barriers, but are also about taking the necessary steps now to enable Ireland's LifeSciences sector to make the transformation required to take advantage of future trends and to ensure that LifeSciences continue to be a large contributor to export-led growth.

### The recommended actions focus on five key areas

|  |  |
|--|--|
| <b>Enhanced Collaboration</b>            | harnessing the proactive engagement of a wide range of contributors      |
| <b>Translational Medicine</b>            | putting in place the necessary infrastructures and supports              |
| <b>Manufacturing and Process R&amp;D</b> | building on our international reputation for excellence in manufacturing |
| <b>Skills</b>                            | creating, developing and attracting Talent                               |
| <b>Physical Infrastructures</b>          | underpinning the opportunity areas identified                            |

In the short term action needs to be taken as a matter of urgency to address the area of cost competitiveness to enable the industry to continue to operate effectively from Ireland, specifically in relation to energy, waste and labour costs (Appendix V).

### 1. Ireland's Future in Health LifeSciences - Maximising Potential through Enhanced Collaboration

The increased blurring across the formerly discrete sub-sectors, including ICT, has heightened the complexity within the LifeSciences as well as the need for a cohesive approach to developing the sector in Ireland.

Ireland has many of the elements in place to address the range of opportunities and issues faced by the sector. However, there is a need for a mechanism to drive an overarching agenda and to enhance coordination and collaboration across LifeSciences stakeholders to realise the potential of the sector for Ireland.

## Recommended Actions

### 1.1 Maximising Potential through Enhanced Collaboration

This report highlights the complexity of the business environment for the LifeSciences sector, the significant pace of change and the increased need for proactive collaborative action across a wide range of stakeholders.

- The realisation of Ireland's potential in LifeSciences, as articulated by this report, should be driven by an industry led LifeSciences Alliance made up of industry representatives, the enterprise development agencies, and representatives of the health sector in Ireland. (IBEC, Forfás)
- The LifeSciences Alliance should work to:
  - Harness stakeholder commitment to and engagement with the implementation process
  - Leverage existing resources and capacity from across the industry associations, the enterprise agencies, academia and health representative bodies to best effect to realise the potential of the overarching LifeSciences sector for Ireland
  - Complement and build on existing sub-sectoral activities and initiatives
  - Develop and implement a comprehensive marketing and communications programme, both nationally and internationally, ensuring a cohesive and coordinated approach to developing the sector across multinationals, indigenous firms and research institutes.

## Knowledge Sharing

Although there is already a high degree of collaboration between the enterprise development agencies, the degree of activity and the pace of change is such that it is almost impossible to achieve full benefit from information flows without the introduction of a more systematic approach to capturing, managing and sharing information in the LifeSciences sector. There are a number of options that could be considered and/or delivered in a phased approach.

### 1.2 Knowledge Sharing

- Based on specific information needs or target audience(s) develop and disseminate a strategic intelligence bulletin on a quarterly basis. (Forfás, Industry Associations)
- Having defined specific needs, and if demand for more real time information justifies, establish a knowledge sharing portal between all of the state bodies connected to the LifeSciences ecosystem to facilitate collaborative effort and cohesion, and an enhanced service to the industry. (To be determined)

## 2. Translational Medicine

Ireland already has a number of the building blocks in place to support translational medicine but there are a number of issues that must be addressed if Ireland is to harness its full potential through proactive and effective engagement.

### Translational Medicine

Progress has been made in developing Ireland's translational research infrastructures and supporting systems and there are a number of successful projects in place, such as the GlaxoSmithKline/Trinity translational medicine project and the SFI funded Strategic Research Cluster on Molecular Therapeutics for Cancer. However, there is still work to be done to overcome a number of well documented challenges outlined below. A holistic approach is required to ensure that *all* elements relevant to a cohesive, robust and fully functional translational medicine environment become pervasive across therapeutic, diagnostic and research domains where Ireland can further enhance its international reputation.

An overview of the optimum environment for translational medicine has been provided on page 45, informed by the success of the Cleveland Clinic.

#### 2.1 Demonstration Projects

- Building on progress to date, implement a competitive funding initiative (from within existing resources based on a continued commitment to the SSTI) to support translational medicine projects that would serve as demonstration models, in areas where Ireland has the potential to gain international recognition. (SFI, HRB, EI)

The call for proposals should explicitly require a multi-disciplinary collaboration between industry, academia and medical practitioners and harness the commitment from technology transfer offices, ethics, and regulatory bodies to accelerate approval processes to support the projects.

### Developing a Functioning Clinical Research System

The development of a functioning clinical research system is fundamental to the evolution of LifeSciences in Ireland. Healthcare practitioners play a vital role in identifying unmet medical needs and giving direction and support to LifeSciences research. The Strategy for Science, Technology & Innovation, 2006 - 2013 (SSTI), highlighted the relatively low levels of translational and/or clinical research underway in Ireland and stated that “the introduction of an R&D culture within mainstream health service has been relatively slow (and) there is a need to strengthen considerably the health services research and policy research capacity nationally”<sup>80</sup>. Research, development and innovation in healthcare involves a broad range of activities and disciplines, including product and service development and enhancement, population health sciences and health services systems across hospitals, community and in-home care.

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<sup>80</sup> Department of Enterprise, Trade & Employment, 2005, Strategy for Science, Technology & Innovation, 2006 - 2013

The reality today is that the resource pressures faced by the hospital system means that research has tended to take 'second place.' This report contends that it should not be seen as an either/or situation and that dedicating resources to research and its translation to products and enhanced clinical practice ultimately leads to improved healthcare for all and a more efficient healthcare system.

Currently no comprehensive information resource exists regarding the nature and extent of research being undertaken within the research hospitals and mechanisms to facilitate commercialisation are particularly weak in this area<sup>81</sup>.

Enabling protected time for clinicians to undertake research has been under discussion for some time, and although there have been some recent developments, this issue has not been satisfactorily resolved. The necessary research administrative supports are insufficient and there are also a limited number of available positions for academic clinicians in the higher education system.

## 2.2 Developing a Functioning Clinical Research System

Stimulate increased participation by clinicians in translational medicine:

- Dedicate a senior executive to oversee and promote clinical research within each hospital. (HSE)
- Introduce Technology Transfer Officers, linked to and supported by the university TTO attached to the hospital. (HSE, EI)
- Establish clinical training posts in translational medicine. Senior House Officers (SHOs) should have the option to choose a translational medicine rotation during their 2 year training rotation. (Funded by HRB, HSE, SFI)
- Establish a professorship in translational medicine in each of the university training hospitals. This professor should be supported by two (medicine and surgery) registrar posts. These registrar posts should be both clinical and research focused<sup>82</sup>.
- Regularise research nurse grading with regard to: competence, level of experience and pay grade so as to ensure availability of appropriately skilled nursing professionals to support translational research projects and to provide a transparent career track for research nurses. (HSE)

### Technology Transfer: Industry/Higher Education Institutes

It is apparent from interviews that Ireland is still in the process of building a world-class Technology Transfer Office (TTO) environment. Concerns were raised regarding time-lags and lack of depth of expertise and multi-disciplinary skills, particularly as there is an increasing shift toward convergent products.

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<sup>81</sup> Research is underway within Forfás to document all research activity in Ireland - which will also include research in hospitals and all activity relevant to LifeSciences

<sup>82</sup> UCD has appointed a Professor of Translational Medicine and NUI Galway has initiated a recruitment process to appoint a Professor of Translational Medicine

Under the Technology Transfer Strengthening Initiative which started in 2007, EI has provided resources to higher education institutes (HEIs) to build up their TTOs and to access central resources in EI<sup>83</sup>. New resources include dedicated technology transfer professionals with specific domain knowledge and industry experience including LifeSciences and biomedical expertise. As this programme has a funding life-time of 5 years, clarity regarding its future will be important.

Not all relevant research needs to be (or even could be) undertaken in Ireland, but the ability to identify and license international research is vital. In this context the work of TechSearch<sup>84</sup> through EI, and appropriate IP and fiscal environments are important.

### 2.3 Technology Transfer

- Review TTO infrastructures and supports in a timely way to ensure improvements have been introduced through EI's strengthening initiative and in time for a possible second phase. This review should focus on the specific needs of the LifeSciences sector given the complexity of the sector and particular expertise required to manage technology transfer and commercialisation of LifeSciences products and services.

As part of the review, consider the volume and range of contract negotiations and licensing arrangements and the rationale for building in-depth expertise through the establishment of a centralised support office. (TI)

#### Enabling Processes: Ethics Committees, Regulation and the IP Environment

Improvements are needed to address the significant delays being experienced by companies, clinicians and researchers in establishing clinical trials in Ireland in areas of medical technologies and clinical research that are not governed by the Clinical Trials on Medicinal Products for Human Use Regulations. The delays primarily arise from the need for to obtain ethics approval from each participating centre for multi-centre clinical investigations and the sequential review process whereby Irish Medicines Board (IMB) approval can only be sought after approval is obtained from the relevant ethics committee/s rather than in parallel.

The current problems are compounded when convergent products are being considered as, by definition, they straddle existing statutory classifications of regulated products thereby complicating the selection of the appropriate review and approval pathway. Industry has expressed its concern that members of ethics committees do not have the depth of expertise and regulatory experience required. Over recent months the IMB has set up a specific unit to oversee and manage the regulation of convergent products. However it is now critical that the issue pertaining to ethics committees be resolved.

The supplementary budget introduced a scheme of tax relief for the acquisition of intangible assets, including IP, as a measure of supporting the Smart Economy and which is welcomed in the context of this report.

<sup>83</sup> Launched in 2007 the €30 million Technology Transfer Strengthening Initiative is being implemented over a five year period

<sup>84</sup> [www.enterprise-ireland.com/TechSearch](http://www.enterprise-ireland.com/TechSearch)

## 2.4 Ethics Committees, Regulation and the IP Environment

- Consolidate the existing ethics approval committees for clinical research through the Health Information Bill. The ethics approval committees should be linked to the core research hospitals and have standard operating procedures. This consolidation allows for skills and expertise to develop based on volume of activities. (DOHC)
- Streamline the ethics approvals process, and enable electronic submissions, so that the principles of single opinion and parallel review apply to the approval of all clinical research carried out in Ireland and not only to ethics approval for pharmaceutical clinical trials. (DOHC)
- Develop a comprehensive and clear guide on the conduct of investigator and industry led clinical research in Ireland in accordance with regulations and best practice. (IMB, NSAI<sup>85</sup>, HRB, HSE)
- Review the National Code of Practice for Managing and Commercialising Intellectual Property from Public-Private Collaborative Research (2005)<sup>86</sup> to ensure that how it operates in practice remains appropriate to the needs of industry and academia and supports the development of effective IP agreements in a timely manner. (TI)

## 3. Manufacturing & Process R&D

Ireland has a significant opportunity to leverage its strengths in manufacturing. The future of manufacturing will see the introduction of smaller batches, more complex processes and the emergence of multi-product facilities over time. It is also important that existing companies are supported as they transition to the next generation of production.

*(The development of the appropriate multi-disciplinary skills and industry placements during undergraduate and post-graduate training are particularly important and are included in the section on skills).*

### Recommended Actions

#### 3.1 Manufacturing and Process R&D

- Direct a higher proportion of enterprise development agency supports toward process development in LifeSciences. (IDA, EI)
- Actively support indigenous and foreign owned companies to carry out pilot manufacturing in Ireland to leverage the process development and manufacturing expertise in Ireland. (EI, IDA)
- Increase supports for specific training in the areas of PAT, QbD, Lean Manufacturing and Six-Sigma. (IDA, EI, SkillNets, FÁS)

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<sup>85</sup> National Standards Authority of Ireland (NSAI)

<sup>86</sup> Advisory Science Council, 2005, National Code of Practice for Managing and Commercialising Intellectual Property from Public-Private Collaborative Research, November

## 4. Skills - Supporting the Evolving LifeSciences Sector

Skills for the evolving LifeSciences sector, which includes a focus on translational medicine, excellence in leading edge production, convergent products and remote healthcare, require not only a depth and expertise in core disciplines, but also the ability to work in multi-disciplinary environments and/or to complement core scientific skills with other disciplines.

There are growing calls from industry for highly skilled PhDs that have industry experience and capacity in the area of applied research. Skills in the areas of IP (valuations, negotiations), regulation (and increasingly relevant to convergent products and personalised healthcare), and informatics and analytics are critical for the sector.

### Recommended Actions

#### 4.1 Converging Technologies

- Develop a programme to provide for up-skilling of relevant personnel in the area of converging technologies and the implications for regulation, IP, valuations and negotiations. (SkillsNet - facilitated by the IMDA, PharmaChemical Ireland, IBIA<sup>87</sup>)
- Include a module in the Licensing Executives Society (LES)/Forfás facilitated IP Lecture Series specific to the LifeSciences sector to highlight considerations relating to valuations and M&A negotiations specific to converging technologies. (LES)

#### 4.2 Research Expertise

- Complement existing research capability through a call for proposals to build expertise in the areas of systems biology, biomarker validation and biomedical imaging.

#### 4.3 Industry Experience and Relevance

- The HEIs, working with the HEA, should establish an Industrial PhD programme to complement existing academic PhD programmes available in Ireland. The Advisory Science Council (ASC) has carried out research in relation to increasing the relevance of PhD programmes for industry which should inform the establishment of the Industrial PhD programme. (Appendix VI provides an overview of an Industrial PhD programme)
- Encourage the development of an MBA-type qualification in conjunction with industry and a leading academic institution - the Master of Business in Innovation for the LifeSciences - which will equip students on the programme with the skills to manage the process of taking LifeSciences products and services from initial conception through to successful commercialisation. (HEA)

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<sup>87</sup> Irish Medical Devices Association (IMDA), Irish BioIndustry Association (IBIA)

## **Maths and Physical Sciences - A Fundamental Building Block for the Future**

We also highlight the vital importance of stimulating interest in the core areas of maths and science and support the recommendations arising from the Task Force on Physical Sciences (2002), the Expert Group on Future Skills Needs (EGFSN) Statement on Raising National Mathematical Achievement (2008) and the NCC Statement on Education and Training (2009).

Although some advances have been made on the implementation of a number of these recommendations it is critical to accelerate progress to:

- Incentivise students to take Leaving Certificate mathematics at a Higher-Level
- Provide Professional Development of teachers at Primary-level and Second-level in the teaching of mathematics
- Develop an ongoing research programme to benchmark and evaluate Ireland's mathematical performance in an international context. Work already undertaken by the National Council for Curriculum and Assessment, the State Examination Commission and the Educational Research Centre could be built upon in this regard
- Promote recruitment to science, engineering and technology programmes at third level. Measures to increase the amount of time dedicated to studying science and mathematics in schools should be considered and implemented in this regard.

The Medical Devices Skills report published in 2008 outlines the supply and demand of specific skills over the next 3-5 years for this segment of LifeSciences<sup>88</sup>. A complementary study could be undertaken to assess the specific skills needed within the context of the strategic direction outlined in this study for the entire LifeSciences sector.

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<sup>88</sup> Expert Group on Future Skills Needs, 2008, Future Skills Needs of the Irish Medical Devices Sector, February

## 5. Other Infrastructures

### Recommended Actions

#### 5.1 Infrastructures to underpin the shift toward Personalised Healthcare

- A national biobanking resource underpinned by a national policy for biobanking has been identified by stakeholders as a fundamental requirement within the Irish LifeSciences infrastructure.
  - Develop a national biobanking policy setting out standards for biobanking protocols and procedures as a matter of priority. The recommendations from the reports of the Expert Group on a National Cancer Biobank and MMI's design phase for the Gene Library Ireland initiative provide a framework for defining and developing a governance structure for biobanking and should inform the development of the national biobanking policy.
 

The policy should also give full consideration to Ireland's involvement in European biobanking initiatives<sup>89</sup>. (DOHC, HRG)
  - Undertake a comprehensive analysis of the requirements for biobanking (to include imaging) infrastructures and develop a cohesive implementation plan to deliver on required biobank facilities and supports.
 

Given the value to the health system, industry and academia, of both Gene Library Ireland and the National Cancer Biobank as critical elements of the overall infrastructures, implementation should be progressed in tandem with development of the national biobanking policy. (HRG)
- Invest in the delivery of wet laboratory infrastructures over the next 3-5 years which are critical to support the sector, particularly SMEs and start-up high technology companies. (An EI commissioned study identified a potential shortfall in supply over the period to 2012 that is unlikely to be provided by the market). (EI)
- Actively promote the use of ICHEC's supercomputing facility and analytical capabilities in support of LifeSciences R&D projects, in particular those dealing with personalised healthcare<sup>90</sup>. (HEA, SFI, IDA, EI)

#### 5.2 Specific to Convergent products

- Establish an industry led convergent technologies network to facilitate networking and collaboration between companies, academics and medical practitioners, across the formerly discrete sectors of medical technologies, pharma, biopharma, ICT and engineering.

The network should have a defined objective(s) to stimulate action (e.g. in marketing, applied research, process development and/or skills and training), and could be supported through existing initiatives provided by EI such as the Industry Led Research Platforms. The imperative is upon companies themselves to formulate and submit proposals to the development agencies in response to calls for proposals. (EI, IDA)

<sup>89</sup> Such as the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)

<sup>90</sup> The Irish Centre for High-End Computing (ICHEC)

## Next Generation Broadband

The implementation of Next Generation Networks (NGNs) is relevant to all aspects of the LifeSciences sector. As the sector shifts toward personalised healthcare the volume of data and images will increase exponentially. The ability to manage, store, analyse and securely transfer this data and management information between stakeholders, across hospitals, research institutes, patient homes and companies both nationally and internationally will become paramount. The lack of high speed, resilient and secure broadband at a competitive price is a barrier to realising the potential outlined in this study. In fact, high quality broadband is as necessary as electricity for the sector to function successfully in the future.

### 5.3 Specific to Remote Healthcare

- Develop next generation broadband infrastructures and services to ensure that there is capacity to facilitate fast, reliable and secure transfer of patient and analytical data nationally and internationally. Specific targets which have been outlined by the development agencies in this regard are:
  - Access to next generation infrastructure and services in all the Regional Gateways of at least 12Mbps uncontended, symmetric service for premises and homes by 2012
  - Access to next generation infrastructure and services in all the NSS Hubs and county towns of at least 12Mbps uncontended, symmetric service for premises and homes by 2015.

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## Appendix I: Steering Group

|                       |   |
|-----------------------|---|
| Helena Acheson        | Forfás  |
| Seamus Chamberlain    | Department of Enterprise, Trade & Employment (DETE)   |
| Margaret Cooney       | Élan Pharma International Ltd.<br>(Formerly Irish Clinical Research Infrastructure Network (ICRIN)) |
| Dr. Finbar Dolan      | Georgia Tech Ireland  |
| Dr. Declan Farrell    | Cork Cancer Research Centre (CCRC)  |
| Dr. David Fitzpatrick | University College Dublin (UCD)   |
| Peter Gingras         | Proxy Biomedical  |
| Maria Ginnity         | Forfás  |
| Sharon Higgins        | Irish Medical Devices Association (IMDA)  |
| Michael Howe          | Creganna  |
| Eddie Hughes          | Enterprise Ireland  |
| Hugh McGuire          | Glanbia   |
| Barry O'Dowd          | IDA Ireland   |
| Dr. Brian O'Neill     | Enterprise Ireland  |
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| Niamh Scannell        | Digital Health Group, Intel   |
| Dr. Stephen Simpson   | Science Foundation Ireland  |

### Cross Agency Working Group

|                     |                            |
|---------------------|----------------------------|
| Maria Ginnity       | Forfás                     |
| Barry O'Dowd        | IDA Ireland                |
| Dr. Brian O'Neill   | Enterprise Ireland         |
| Dr. Stephen Simpson | Science Foundation Ireland |
| Kate Flinter        | Forfás                     |



## Appendix III: Glossary of Terms

**Bioinformatics** is the science of developing computer databases and algorithms to enhance biological research.

**Biomarkers** are molecular, biological, or physical measures that can be used to measure a person's risk for disease, to diagnose disease, and assess a person's prognosis and to guide treatment.

**Biotechnology** can be defined as the application of biological knowledge relating to living cells and genetic material in order to develop products, processes or services for commercial or medical purposes. Biotechnology has a wide range of applications across healthcare, agriculture, food processing and industrial processing.

**Clinical trials** are research studies that involve patients or healthy people and are designed to test new treatments to ensure the treatment does not pose excessive risk to the patient<sup>91</sup>. Clinical trials are a critical tool for determining which preventive, diagnostic, and/or therapeutic interventions have value and to compare alternative treatments.

**Genomics** is the study of an organism's genome and deals with the systematic use of genome information, associated with other data, to provide answers in biology, medicine and industry. Genomics has the potential of offering new therapeutic methods for the treatment of some diseases, as well as new diagnostic methods. Other applications are in the food and agriculture sectors.

**Manufacturing process development** is the practice of defining and developing a manufacturing process to accommodate the specific requirements of a given product while meeting process quality and cost objectives.

**Medical Technologies:** The medical technologies sector is a highly diverse industry and encompasses medical devices, diagnostics and drug delivery tools. The medical technologies sector covers thousands of products, ranging from simple bandages and spectacles, through implantable devices, equipment for screening and diagnosing diseases and health conditions, to the most sophisticated diagnostic imaging and minimally invasive surgery equipment.

**Nanotechnology** refers broadly to a field of applied science and technology whose unifying theme is the control of matter on the molecular level in scales smaller than 1 micrometre, normally 1 to 100 nanometres, and the fabrication of devices within that size range. It is a highly multidisciplinary field, drawing from fields such as applied physics, materials science, colloidal science, device physics, supramolecular chemistry, and even mechanical and electrical engineering. It has particular relevance to the LifeSciences sector, most significantly in terms of drug delivery mechanisms. Nanobiotechnology offers a solution to solubility problems, intracellular delivery and improvements in skin penetration.

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<sup>91</sup> In this context 'treatments' are taken to cover a wide range of healthcare approaches that can be tested in a clinical trial including drugs, vaccines, other approaches to disease prevention, surgery, radiotherapy, physical and psychological therapies, educational programmes and methods of diagnosing disease

The **National Spatial Strategy (NSS)** (2002) is a coherent national planning framework for Ireland for the next 20 years. The NSS aims to achieve a better balance of social, economic and physical development across Ireland, supported by more effective planning. In order to drive development in the regions, the NSS proposes that areas of sufficient scale and critical mass will be built up through a network of gateways and hubs.

**Neurostimulation** is a medical treatment to address chronic pain. A small device, much like a pacemaker, delivers low voltage electrical stimulation to the spinal cord or targeted peripheral nerve to block the sensation of pain.

**Nutraceuticals/functional foods** include any food substance that provides medical or health benefits, over and above its basic nutritional functions, such as cholesterol reducing products, and those that improve bone health or aid digestion.

**Orthobiologics** involves the inclusion of biology and biochemistry in the development of bone replacement materials for muscular-skeletal healing and includes any product that is primarily intended to act as a scaffold and/or actively stimulate bone growth.

The **pharmaceutical** industry involves the development and marketing of both branded and generic prescription and over the counter drugs. Traditional pharmaceuticals are derived from chemical synthesis processes and are often referred to as 'small molecule' drugs.

**Pharmacogenomics** combines traditional pharmaceutical sciences such as biochemistry with an understanding of common DNA variations in the human genome. It examines the inherited variations in genes that dictate drug response and explores the ways these variations can be used to predict patient responses to a drug.

**Process Analytical Technology (PAT)** relates to the manufacturing process and is the uninterrupted process of adding, processing, and removing material to reduce downtime of the manufacturing process.

**Proteomics** is the large scale study of proteins, particularly their structures and functions. Proteomics has the potential to reduce drug development time and drug attrition rates in that it enables the assessment of how an individual's holistic protein and genetic make-up affects their response to drugs.

**Quality by Design (QbD)** relates to manufacturing process design. It is a systematic approach to development that begins with predefined objectives and emphasises product and process understanding and process control, based on sound science and quality risk management.

**Quality Risk Management (QRM)** relates to manufacturing process design. It is a system for designing, analysing, and controlling manufacturing through timely measurements (e.g. during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality.

**Ribonucleic Acid Interference (RNAi)** involves switching particular genes on or off and opens up new fields of research and approaches to drug development. RNAi is believed to have significant potential for research on cancer and infectious diseases.

**Systems biology** is the study of an organism, viewed as an integrated and interacting network of genes, proteins and biochemical reactions. Instead of analysing individual aspects of the organism, systems biologists focus on all the components and the interactions among them, all as part of one system. Systems biology is still in its infancy but is crucial to developing a 'systems' understanding of an organism that will ultimately transform our understanding of human health and disease.

## Appendix IV: LifeSciences Business Networks & Associations

There are a number of national and European level business networks and associations that represent the specific interests of businesses operating in the LifeSciences sector in Ireland.

### Medicines, Medical Devices and Healthcare Products

- **The Irish Medical Devices Association (IMDA)**

The IMDA represents the medical devices and diagnostics sector in Ireland and has a membership of over 80 multinational and indigenous companies based throughout the country. The IMDA's broad focus is to promote and support an environment that encourages the sustainable development and profitable growth of medical device and diagnostic companies operating in Ireland.

The IMDA aims to make Ireland the location of choice for research and development, manufacture and marketing of innovative products in the medical device and diagnostic sector. The IMDA has a number of working groups which look at specific areas of importance to the sector such as supply chain management and human resource development.

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- **PharmaChemical Ireland**

PharmaChemical Ireland has a membership of approximately 55 pharmaceutical and chemical companies and works to provide an environment which is conducive to the success and further growth of the pharmaceutical industry in Ireland. It works to achieve this through lobbying Government, state agencies and other relevant stakeholders on behalf of its membership.

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- **The Irish BioIndustry Association (IBIA)**

The IBIA has a membership of over 50 companies and works to promote, support and encourage the further development of the multinational and indigenous biotechnology sector in Ireland. The IBIA is active in a range of activities relating to the biotechnology industry in Ireland including biotech patents, regulations on plant biotechnology, formulating a national biotechnology strategy and promoting research to industry.

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- **The Irish Pharmaceutical Healthcare Association Limited (IPHA)**

The IPHA represents the international research-based pharmaceutical industry in Ireland. Its membership is made up of manufacturers of prescription medicines and non-prescription or consumer health care medicines. IPHA's core aim is to promote and support an environment which enables research-based pharmaceutical companies in Ireland to meet the healthcare needs and expectations of patients.

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- **The European Federation of Pharmaceutical Industries and Associations (EFPIA)**

The EFPIA represents the manufacturers of prescription medicines at European level. Its members include national pharmaceutical industry associations throughout Europe and 45 companies undertaking research, development and manufacture of medicinal products for human use in Europe. The mission of EFPIA is to improve the competitiveness of the research-based pharmaceutical industry in Europe in a regulatory and political environment, which stimulates R&D and innovation.

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- **The International Federation of Pharmaceutical Manufacturers (IFPMA)**

Based in Switzerland, the IFPMA represents the international research-based pharmaceutical industry and other manufacturers of medicines which are intended for sale as prescription items or under the supervision of healthcare professionals. IFPMA is a non-governmental organisation which is officially recognised by the World Health Organisation (WHO). Its members include pharmaceutical industry associations in over 50 countries worldwide.

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- **CEFIC**

CEFIC, the European Chemical Industry Council, represents the European chemical industry. It represents, directly or indirectly, about 40,000 large, medium and small chemical companies which employ about two million people and account for more than 30% of world chemical production.

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- **EuropaBio**

EuropaBio represents the biotechnology industry in Europe. The organisation represents 85 corporate and 7 associate members operating worldwide, 5 Bioregions and 25 national biotechnology associations, as well as representing over 1,800 small and medium sized biotech companies in Europe.

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## Nutraceuticals & Functional Foods

- **Teagasc**

As the national Agriculture and Food Development Authority Teagasc has responsibility for the provision of coordinated research, advisory and training services to the agriculture and food industry and rural communities.

The Food Directorate of Teagasc undertakes a comprehensive range of activities, including training, consultancy and technical services. In addition the Food Directorate runs a food research programme carried out at its two food research facilities in Ashtown, Dublin and Moorepark, Cork. The food research programme aims to support the development of a high quality, market oriented, competitive and innovative food sector in Ireland. The food research programme covers the full spectrum of the innovation process, ranging from market studies through strategic research to technology development services and training programmes. Nutraceuticals and foods with a health benefit are a particular area of focus for the programme.

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- **Food & Drink Industry Ireland (FDII)**

FDII is an umbrella organisation for 26 federations and associations representing the interests of food, drink and non-food grocery manufacturers. It is the main trade association for the food and drink industry in Ireland and the work of the FDII focuses primarily on the areas of meat, dairy, retail suppliers and alcoholic beverages. It works to promote the common interests of the sector by providing an organised forum for the exchange of ideas, promotion of industry goals and influencing public policy at national and European level. The member federations/associations of the FDII most closely involved with nutraceuticals and functional foods include the Irish Dairy Industries Association, the Food Processors and Suppliers Group and the Infant Nutrition Committee.

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- **IDACE: Association of the Food Industries for Particular Uses of the European Union**

IDACE is a European association which represents the views of its members, the dietetic food industry associations of the EU member states, at the European level. IDACE carries out a range of activities in this regard including:

- Developing and communicating a common industry position on European issues
- Working with academics and scientists involved in food for particular nutritional uses
- Consulting with stakeholder groups etc.
- Working with the European institutions on the development of relevant food legislation.

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- **Confederation of the Food & Drinks Industries of Europe (CIAA)**

CIAA is the main representative organisation of the food and drinks industry at the level of both European and international institutions. It works to promote an environment where all European food and drinks companies can compete effectively both within the EU and on global markets. It works across a range of areas including competitiveness, food safety and quality, consumer information and the environment as they relate to the food and drinks industry.

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## Health Research & Clinical Trials

- **Irish Clinical Research Infrastructure Network (ICRIN)**

Established in mid 2006 through a Memorandum of Understanding between a number of the major universities and research institutes in Ireland (UCD, TCD, RSCI, UCC, NUI Galway and MMI) ICRIN aims to support the development of a world class clinical research capacity in Ireland. The work of ICRIN is supported by both the HRB and the HSE.

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- **European Clinical Research Infrastructures Network (ECRIN)**

ECRIN is a not-for-profit consortium of 12 networks of clinical research centres (CRC) and clinical trial units (CTU) from across 9 EU member states and Canada. The aim of ECRIN is to support trans-European clinical research projects. ECRIN does not focus on any one specific speciality or disease category; rather it works to foster transfer of best research practice from speciality to speciality all over Europe. ICRIN is the Irish representative on the consortium.

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## Appendix V: Cost Competitiveness

### The critical barrier to future development

The recommendations in this report have focused specifically on those required to stimulate the evolution of the LifeSciences sector in Ireland. However, the Steering Committee has identified Ireland's cost competitiveness relative to other countries as *the* barrier to growth - specifically in the following areas:

#### 1. Energy

The availability of a reliable, competitively priced and sustainable supply of energy is essential for the competitiveness of the LifeSciences sector. The 2009 NCC Statement on Energy highlights the policy priorities that need to be addressed to improve energy competitiveness in Ireland and the Steering Committee calls for the implementation of the recommendations in this statement as a matter of urgency.

In the second half of 2008, Irish industrial electricity costs were the fourth highest in the EU-27 and were 35.5% above the Eurozone average (based on latest data available). Although prices are currently moderating somewhat as international fuel prices fall, recent reductions in electricity and gas prices are welcome but are not sufficient to improve Ireland's comparative position.

A number of initiatives have been announced recently to reduce electricity prices for Irish businesses, particularly large energy users in sectors such as food, pharmaceuticals and ICT. These include continuing the temporary rebate introduced in 2008 to reduce prices for large energy users and the proposed introduction of legislation to recover the carbon windfall gains to 2012. These are important steps on the path to more competitive electricity prices for businesses in Ireland. However, further policy action is required to bring the cost of electricity for Irish businesses into line with their European counterparts.

It is critical that restoring energy cost competitiveness is prioritised and that practical steps are taken in the immediate term that bring energy costs back in line with the EU. The Steering Group welcomes the recent commitment from the Energy Regulator to work with energy companies to reduce energy costs in this regard.

Energy efficiency is one of the most effective tools to jointly address cost competitiveness, security of supply and environmental sustainability objectives. Enhanced financial supports should be made available to companies to assist them in the drive towards increased energy efficiency. A specific measure in this regard should be the expansion of the scheme of accelerated capital allowances for energy efficient equipment.

#### 2. Waste

The Forfás report, *Waste Management in Ireland: Benchmarking Analysis and Policy Priorities*, 2009, highlights the significant progress Ireland has made in developing its waste management infrastructures over the past decade. However, the availability of waste management services and facilities and the associated costs continue to be a key competitiveness issue for enterprise in Ireland.

The benchmarking report sets out the policy actions that need to be prioritised to ensure that Ireland meets the waste management needs of enterprise now and in the future. It is of critical importance to the LifeSciences sector that progress is made on the first priority area identified in the report:

- A range of infrastructures are required along the waste hierarchy to meet Ireland's waste management requirements. Specific infrastructures that need to be developed include:
  - thermal treatment capacity to recover energy from municipal and industrial waste
  - thermal treatment or landfill capacity for hazardous waste
  - biological treatment (composting, anaerobic digestion) throughout Ireland
  - reprocessing capacity for recovered materials.

### 3. Labour

The cluster analysis carried out as part of this study clearly illustrates the high level of international competition that exists in the LifeSciences sector. A key driver of this level of international competition is that positions in the LifeSciences sector are typically highly skilled, knowledge intensive and comparatively well paid.

The sector provides in excess of 52,000 jobs in over 350 companies in Ireland. This report outlines the significant potential that exists to further build and sustain the sector in Ireland both for indigenous and foreign owned companies. In order to fully capitalise on these opportunities it is essential that total employment costs in Ireland are competitive vis á vis international counterparts so that we can continue to attract and maintain the sector in Ireland over the long term.

In broad terms wage growth in Ireland over the past decade has been faster than in Ireland's main trading partners, notwithstanding the slowdown in real wage growth in Ireland since 2006. Unit labour costs<sup>92</sup> increased in 2007 by approximately 5.4%. The robust increase in unit labour costs in Ireland reflects the combination of higher wages coupled with modest productivity growth, which is a reversal of the trends of the previous decade, when unit labour costs increased by 2% on average per annum<sup>93</sup>.

Moderation in wage growth combined with a continued focus on increasing productivity is central to restoring unit labour cost competitiveness in Ireland. Data for 2008 indicates considerable moderation in wage growth; wages grew by an average of 3.9% in 2008 down from 5.9% in 2007.

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<sup>92</sup> The measure 'unit labour costs in common currency terms' incorporates the effects of both wage and productivity growth in Ireland relative to Ireland's trading partners as well as exchange rate movements

<sup>93</sup> Central Bank & Financial Services Authority of Ireland, 2008, Quarterly Bulletin, No. 4, October, 2008. Dublin: Central Bank

## Appendix VI: Industrial PhD Programmes

Industrial PhD programmes have relevance for all business sectors but have particular advantages in the LifeSciences area where there are growing calls from industry for highly skilled PhDs that have industry experience and capacity in the area of applied research.

Similarly such a programme would offer PhD students the opportunity to conduct world class research in an industry environment and to develop a core set of skills which are highly transferable to industry. Further benefits include the:

- Build up of know-how, knowledge dissemination and interaction between academic and research institutions and enterprises
- Greater opportunities to ensure commercialisation of new know-how and research, including development of knowledge and technology based enterprises.

The experience of Denmark in relation to its industrial PhD programme which has been in place since 1970 may serve as a model for developing such a system in Ireland. Typically the Danish model works in the following way:

- The research project stems from a research issue identified by the participating enterprise
- The PhD student works in the enterprise and works full-time on the project but their time is split equally between the enterprise and the academic institution.

The costs associated with the research programme are split between the host enterprise and the Danish Agency for Science, Technology and Innovation (DASTI).

This programme involves high levels of ongoing collaboration between the enterprise, the PhD student and the academic institution to ensure that the project is progressing and that it meets the requirements for the award of a PhD in the given area.

## Appendix VII: Stakeholder Consultations

- Allergan
- AstraZenca
- BAK Basel Economics
- Baxter
- BioM Biotech Cluster Development GmbH
- Boston Scientific
- Centocor Biologics (J&J)
- Cook Ireland
- Cordlife
- BioSingapore
- Delta Partners
- Economic Development Board (EDB)
- Eirgen
- Elan
- Enterprise Ireland (EI)
- Ernst & Young
- Fighting Blindness
- Food and Drink Industry Ireland (FDII)
- Fountain Healthcare
- Genentech
- Gilead Sciences Ireland
- Glanbia Nutritionals
- GlaxoSmithKline
- H. Lundbeck A/S
- Health Research Board (HRB)
- Health Research Group (HRG)
- Higher Education Authority (HEA)
- ICT Ireland
- IDA Ireland
- Intel
- Irish BioIndustry Association (IBIA)
- Irish Medical Devices Association (IMDA)
- Irish Medicines Board (IMB)
- Kernel Capital Partners
- Medicon Valley Alliance (MVA)
- Medtronic Vascular
- Molecular Medicine Ireland (MMI)
- National University of Singapore
- NC Bio
- North Carolina Biotechnology Center (NCBC)
- NUI Galway
- Opsona
- Oxford University
- Pfizer
- Roche Pharmacogenetics
- Royal College of Surgeons of Ireland (RCSI)
- Science Foundation Ireland (SFI)
- Takeda
- Teagasc
- Trial Form Support
- Trinity Biotech
- Trinity College Dublin (TCD)
- UNC Greensboro
- University College Cork (UCC)
- University College Dublin (UCD)
- University of Copenhagen
- University of Pennsylvania
- Windhover
- Wyeth (Wyeth Biopharma Campus)

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| <b>A Quantitative Tool for Workforce Planning in Healthcare: Example Simulations</b><br>Expert Group on Future Skills Needs | June 2009      |
| <b>The Expert Group on Future Skills Needs Statement of Activity 2008</b><br>Expert Group on Future Skills Needs            | June 2009      |
| <b>The Global Entrepreneurship Monitor 2008: The Irish Report</b><br>Global Entrepreneurship Monitor supported by Forfás    | May 2009       |
| <b>An Evaluation of Discover Science and Engineering, A Review by an International Panel</b><br>International Review Panel  | May 2009       |

|   |               |
|---|---------------|
| <b>Our Cities: Drivers of National Competitiveness</b><br>National Competitiveness Council  | April 2009    |
| <b>NCC Statement on Education and Training</b><br>National Competitiveness Council  | March 2009    |
| <b>Annual Employment Survey 2008</b><br>Forfás  | March 2009    |
| <b>Business Expenditure on Research and Development 2007/2008</b><br>Forfás / CSO   | March 2009    |
| <b>Assessment of Port Services Issues for Enterprise</b><br>Forfás  | January 2009  |
| <b>Annual Competitiveness Report 2008, Volume One: Benchmarking Ireland's Performance</b><br>National Competitiveness Council     | January 2009  |
| <b>Annual Competitiveness Report 2008, Volume Two: Ireland's Competitiveness Challenge</b><br>National Competitiveness Council    | January 2009  |
| <b>A Review of the Employment and Skills Needs of the Construction Industry in Ireland</b><br>Expert Group on Future Skills Needs | December 2008 |
| <b>The Cost of Running Retail Operations in Ireland</b><br>Forfás   | December 2008 |
| <b>The Science Budget 2007/2008</b><br>Forfás   | December 2008 |
| <b>Ireland's International Engagement in Science, Technology and Innovation</b><br>Advisory Science Council                       | December 2008 |
| <b>Raising National Mathematical Achievement</b><br>Expert Group on Future Skills Needs   | December 2008 |
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