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LIFE & HEALTH SCIENCES HORIZON PANEL REPORT

PROSPERITY AND HEALTH DELIVERED BY SCIENCE

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PROSPERITY AND HEALTH DELIVERED BY SCIENCE

NORTHERN IRELAND S LIFE & HEALTH SCIENCES COMMUNITY IS READY TO MEET THE SECTOR S GLOBAL CHALLENGES.

The Life & Health Sciences Horizon Panel was formed in 2007 to recommend actions that will accelerate the development of our vibrant life and health sciences sector, boosting economic benefits for the region, and improving the quality of health and wellbeing products and services available.

With the trend towards individuals taking increased responsibility for their own health and vitality increasing amid the spectre of new or re-emerging infectious diseases and the need for new treatments, this sector can be hugely important.

Our work highlights the strength and depth of the sector and advances made to date. Comprising around 60 companies with a combined turnover of some £400 million, the industry is growing. These businesses create wealth through products as diverse as medical devices and diagnostics, pharmaceuticals, bio-pharmaceuticals and medical disposals, as well as biotechnology-based services and clinical trials.

The whole sector employs around 4,000 people, many in genuinely sustainable, high-value jobs. Around 30 companies in the region have a clear focus on research and development (R&D) - some very intensively so - and in 2005 they spent some £33 million on the area, directly employing 600 R&D staff in the process. It is no secret that in recent years major opportunities have resulted from rising investment in R&D.

Given our region's small size in the context of this vast global industry, we accept that we cannot excel at everything. However, this report puts forward strategic recommendations that identify the key R&D capabilities and future market opportunities to exploit for maximum economic return for the decades ahead.

By implementing these recommendations we can ensure not just our continued success but look forward to the time when Northern Ireland will feature in the world rankings of significant participants in the huge global healthcare and pharmaceuticals market. This would provide great economic benefits and position us to meet the challenges that our healthcare systems are facing.

Over the past 18 months our intensive work with colleagues from academia, industry and healthcare has led to many insights and a real understanding of how best to move this sector forward. For us, this was a pleasure and a privilege.

We would like to thank all of those who participated in the compilation of this report and to acknowledge the work of Phil Towers and Diana Iacob of PricewaterhouseCoopers who assisted at all stages in the work of the Life & Health Sciences Horizon Panel.

Bernie Hannigan & Albert Sherrard
Joint Chairs - Life & Health Sciences Horizon Panel

LIFE & HEALTH SCIENCES HORIZON PANEL REPORT

EXECUTIVE SUMMARY

THE ECONOMIC IMPORTANCE OF THE HEALTH TECHNOLOGIES & LIFE SCIENCES SECTOR

Importance to the Northern Ireland economy: high value-add, export oriented sector

Over the past five years, Northern Ireland industry, academia and government have made significant commitment to the development of life sciences capabilities. According to Invest NI data, in excess of $160 million has been budgeted for infrastructure enhancement, collaborative research, new product development and staff development initiatives. This illustrates the local stakeholders' determination to maximise the opportunities deriving from a long history of technological innovation, backed by a highly educated, young workforce and an internationally recognised research base.

The business sector counts approximately 60 companies, offering a very diverse range of products, services and capabilities. Data from Invest NI and DETI suggests that the industry, as a whole, has a combined turnover of around £310m and employs approximately 4,000 people. This tends to be a high value-add sector and export-oriented, with around 80% of sales generated from external markets.

The academic sector offers a strong science base, both in life sciences and related sectors, through its two world class Universities and the six regional Colleges of Further & Higher Education. Examples are the Nanotechnology and Advanced Materials Research Institute (that includes NIBEC and the Centre for Advanced Cardiovascular Research), Biomedical Sciences Research Institute, Centre for Cancer Research and Cell Biology, the Northern Ireland Clinical Cancer Centre and the McClay Research Centre for Pharmaceutical Sciences.

In addition to its intrinsic clinical practice expertise, the clinical sector is placing an increasing focus on clinical research and development (also known as translational medicine) and commercialisation of innovation arising from its activities. Its strengths lie in the seven Recognised Research Groups and the Northern Ireland Clinical Research Network that includes HSC Innovations.

A growing global market

At global level, the sector is set to benefit from rising demand for effective medicines as the population ages, new medical needs emerge and the disease burden of the developing world increasingly resembles that of the developed world. By 2020, the global pharmaceuticals market is projected to be worth some $1.3 trillion. A number of key trends are anticipated to shape-up the future of this industry:

- **Changes in disease patterns put more pressure on healthcare costs.** Increase in chronic diseases as a result of ageing population, rise of obesity and previously terminal diseases becoming chronic through therapy development; emergence of new diseases due to increased global travel and climate changes; growing antibiotic resistance in some existing diseases.
- **Focus on prevention and pay-for performance.** In a bid to control spiralling costs, a growing number of governments, in both developed and developing countries, are trying to shift the focus from the treatment of disease to its prevention. At the same time, industry will be expected to prove to healthcare payers that its products really work and provide value for money.
- **Increasing role of Information Technology (IT).** This is anticipated to become a key enabler to more effective storage and retrieval of patient records, improved tracking of medical research and therapy outcomes, and better remote care.
- **Pharma industry crisis.** The pharmaceutical industry is undergoing a period of change as it seeks to increase the pace of innovation in face of its collapsing blockbuster model and financial pressure from healthcare funders. Biotechnology and gene therapy are anticipated to yield more new products than the traditional molecular chemistry-based R&D activity.
- **Globalised market place.** Collaborative product development across boundaries and companies is anticipated to become more pervasive. India and China are fast becoming preferred centres of product development and manufacturing activity.

WHAT IS PERSONALISED MEDICINE?

At its most basic, Personalised Medicine refers to the use of information about a person's genetic makeup to tailor strategies for the detection, treatment, or prevention of disease.*

People vary from one another in many ways - what they eat, the types and amount of stress they experience, exposure to environmental factors, and their DNA. Many of these variations play a role in health and disease. The combination of these variations across several genes can affect each individual's risk of developing a disease or reacting to something in the environment, and can be one of the reasons why a drug works for one patient and not another.

Personalised medicine aims to use these variations - both in the patient and in the molecular underpinnings of the disease itself - to develop new treatments and to identify the sub-groups of patients for whom they will work best. It can also help determine which groups of patients are more prone to developing some diseases and, ideally, help with the selection of lifestyle changes and/or treatments that can delay onset of a disease or reduce its impact. Personalised medicine is expected to transform healthcare over the next several decades. New diagnostic and prognostic tools will increase ability to predict the likely outcomes of drug therapy, while the expanded use of biomarkers - biological molecules that indicate a particular disease state - could result in more focused and targeted drug development. Personalised medicine also offers the possibility of improved health outcomes and has the potential to make healthcare more cost-effective.

THE PARADIGM OF PERSONALISED MEDICINE

Source: Personalised Medicine Coalition

BENEFITS OF PERSONALISED MEDICINE

A PERSONALISED APPROACH TO MEDICINE OFFERS SIGNIFICANT BENEFITS FOR EACH OF THE MAJOR STAKEHOLDER GROUPS - PATIENTS, GOVERNMENTS, AS WELL AS INDUSTRY. THESE ARE SUMMARISED BELOW.

GOVERNMENT/HEALTHCARE SYSTEMS	PATIENTS	INDUSTRY
Detect disease at an earlier stage, when it is easier and more economic to treat effectively	Effective and specific therapies	Improve the selection of targets for drug discovery
Rational therapeutic decisions based on pathomechanism of disease rather than on trial-and-error approach	Less risk of adverse effects	Reduce the time, cost and failure rate of clinical trials
Incorporate diagnostic guidance to treatment	Less time lost compared to trial-and-error approach to treatment	Monopoly in a specified segment of the market - early entry and longer dominance of market niche; no competition from generics
Reduced adverse drug reactions and complications of treatment	Lower cost of treatment (in the longer term)	Increased drug effectiveness will command higher prices
Shift the emphasis in medicine from reaction to prevention	Facilitates preventive medicine	Increased revenues from combination of diagnostics packaged with therapeutic products
Reduce the overall cost of healthcare	Improvement of quality of life	Increase patient compliance with therapy prescribed
Increased professional satisfaction		Revive drugs that failed clinical trials or were withdrawn from the market
		Expanding demand for enabling products and technologies, such as ICT, Agri-food, nanotechnology.

KEY DRIVERS AND CHALLENGES TO DEVELOPMENT OF PERSONALISED MEDICINE

	PROGRESS OF SCIENTIFIC CAPABILITY	ADOPTION IN HEALTHCARE SYSTEMS	ADOPTION BY INDUSTRY
KEY DRIVERS	Scientific progress - whole genome sequencing, rapid gene characterisation, molecular diagnostics. Declining cost of sequencing the human genome. Advances in information technology and management of health information.	Shift to prevention and early intervention in a bid to manage spiralling costs. Current drugs are not effective for all patients. Bid to reduce costs associated with Adverse Drug Reactions (ADRs). The 2004 General Practitioner contract links remuneration with clinical outcomes.	The 'blockbuster' model of one drug fits all is under pressure; improved effectiveness levels are required for better defined patient populations. The need for enhanced pace of innovation, as current R&D methods are yielding fewer new products. Financial pressure is mounting, as governments press for lower prices.
KEY CHALLENGES	Mapping of the genome is still in its infancy. Current availability of bio-banks may restrict the pace of research. There are non-genomic factors involved in the development of personalised medicine, which require additional scientific research.	Payment/Reimbursement policies are not tailored to such a system. Personalised medicine is more expensive and more clinical data is needed on associated health outcomes and costs benefits. Education and resources implications - including changes to medical curricula, GP practices, and other healthcare providers. Policy framework - ethical and privacy concerns regarding gathering, using and storing genetic information need addressed.	Perceived fragmentation of drug markets. Intellectual property ownership difficult to secure, particularly if derived from collaborative projects. Scale of adoption is uncertain - a niche rather than all-encompassing adoption may be envisaged, at least in the shorter term.

COMMERCIAL PROSPECTS FOR PERSONALISED MEDICINE

The market for personalised medicine is multifaceted, with overlaps between components and disciplines, and interdependencies with associated sectors - e.g. pharmaceutical, advanced materials, information technology etc. The diagram below captures the main constituents of this complex sector.

Personalised Medicine has the potential to transform healthcare over the next several decades.

The commercial opportunity for companies involved in Personalised Medicine can be viewed as coming from a number of key areas:

- Molecular diagnostics as a stand-alone market;
- Remarket of existing drugs (generic and patented);
- Development of new biologic drugs; and
- Development of new therapies, such as cell therapy, gene therapy, monoclonal antibodies etc.

Companies may specialise in certain disease areas or provide technologies that cut across a number of disease groups. Cancer is the area generating the greatest interest for pharmacogenomic therapies, as it is a very complex and heterogeneous disease which requires better classification, and because the therapies currently available are, by and large, ineffective and disruptive for patients. Strong demand is also anticipated from other fields, such as central nervous system disorders, cardiovascular disease and inflammatory disease.

Assuming a scenario where Personalised Medicine will grow to account for a quarter of total pharmaceutical market value, this indicates a market potential in excess of $200bn.

However, the evolution of the market is expected to follow a gradual trend. A personalised approach to medicine has far-reaching implications, and a re-examination of current approaches to a wide range of industry practices and policies will be required to allow its promises to be fully realised.

Markets & Technologies

Molecular Diagnostics
DNA Sequencing
Gene expression profiling
SNP Genotyping
Biochips and microarrays
Biomarkers
Molecular imaging etc.

Personalised Therapies
Pharmaceuticals
Recombinant human proteins
Therapeutic monoclonal antibodies
Gene and cell therapy etc.

Disease Areas
Cancer
Diabetes
Obesity
Cardiovascular
Central nervous system etc.

Underlying Disciplines

Genomics
Pharmacogenetics
Pharmacogenomics
Pharmacoproteomics
Pharmacometabonomics

Systems biology
Bioinformatics
Nanotechnology

THE PARADIGM OF PERSONALISED MEDICINE

NORTHERN IRELAND CURRENT CAPABILITY IN PERSONALISED MEDICINE

A NUMBER OF KEY BUILDING BLOCKS IN THE DEVELOPMENT OF PERSONALISED MEDICINE ALREADY EXIST IN NORTHERN IRELAND, ACROSS THE ACADEMIC, PRIVATE BUSINESS AND CLINICAL (ABC) SECTORS. OVER THE PAST FEW YEARS, NORTHERN IRELAND INDUSTRY, ACADEMIA AND GOVERNMENT HAVE MADE SIGNIFICANT COMMITMENT TO THE DEVELOPMENT OF LIFE SCIENCES CAPABILITIES.

The Northern Ireland business sector has a number of leading players, providing highly innovative products and services. The sector has witnessed a period of growth since 2000, with a number of new companies having been set-up to exploit the opportunities offered by this exciting sector; they consist of both university spin-outs and pure industry ventures.

The academic sector offers a strong science base, both in life sciences and related sectors through its two world class Universities and the six Colleges of Further and Higher Education. Examples are the Nanotechnology and Advanced Materials Research Institute (that includes NIBEC and the Centre for Advanced Cardiovascular Research) and Biomedical Sciences Research Institute at the University of Ulster and the Centre for Cancer Research and Cell Biology, the Northern Ireland Clinical Cancer Centre and the McClay Research Centre for Pharmaceutical Sciences at Queen's University Belfast.

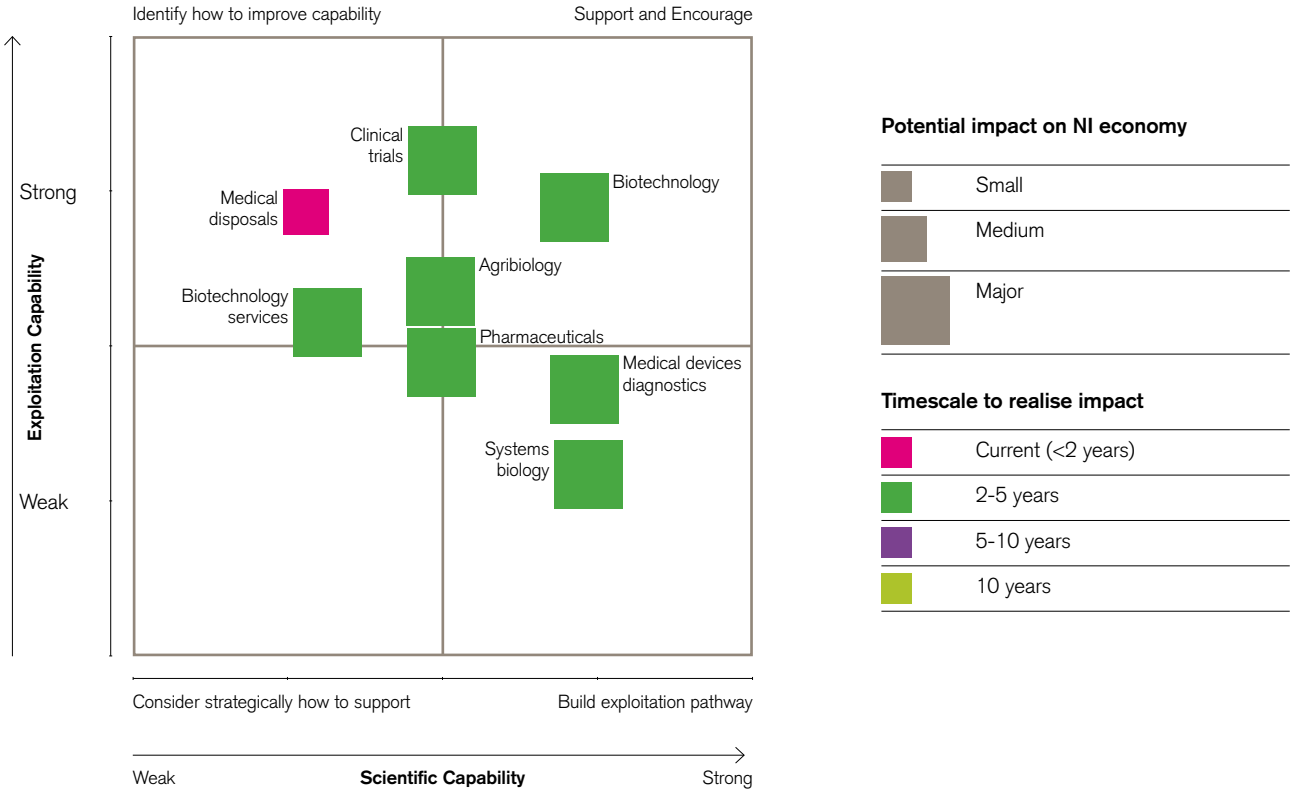
The health service is placing an increasing focus on clinical research and development, and commercialisation of innovation arising from the clinical sector. It has enormous potential to underpin the development of Personalised Medicine in Northern Ireland, for example through its seven recognised Research Groups, the Northern Ireland Clinical Research Support Centre and the Northern Ireland Cancer Research Centre.

The diagram opposite suggests that in areas such as clinical trials and biotechnology the commercial sector is more advanced in successfully exploiting the local scientific capability. However, a focused effort is required to more fully realise the potential offered by the scientific strengths in areas such as systems biology and diagnostics. This could be achieved through collaborative programmes for knowledge and skill transfer, technology licenses, or creation of well supported spin-off companies.

Successful development of Personalised Medicine in Northern Ireland is dependent on the sector's ability to draw on and develop local capability in complementary sectors and technologies, particularly ICT (e.g. bioinformatics) and Advanced Materials (e.g. nanostructures). In turn, developments in life sciences can be a source of innovation and development for the Agri-food sector (e.g. functional foods, personalised diets etc)

Source: Technology Capabilities Study for Northern Ireland, MATRIX, 2007

FIGURE 11: LIFESCIENCES CAPABILITY IN NORTHERN IRELAND



REALISING THE PERSONALISED MEDICINE OPPORTUNITY FOR NORTHERN IRELAND

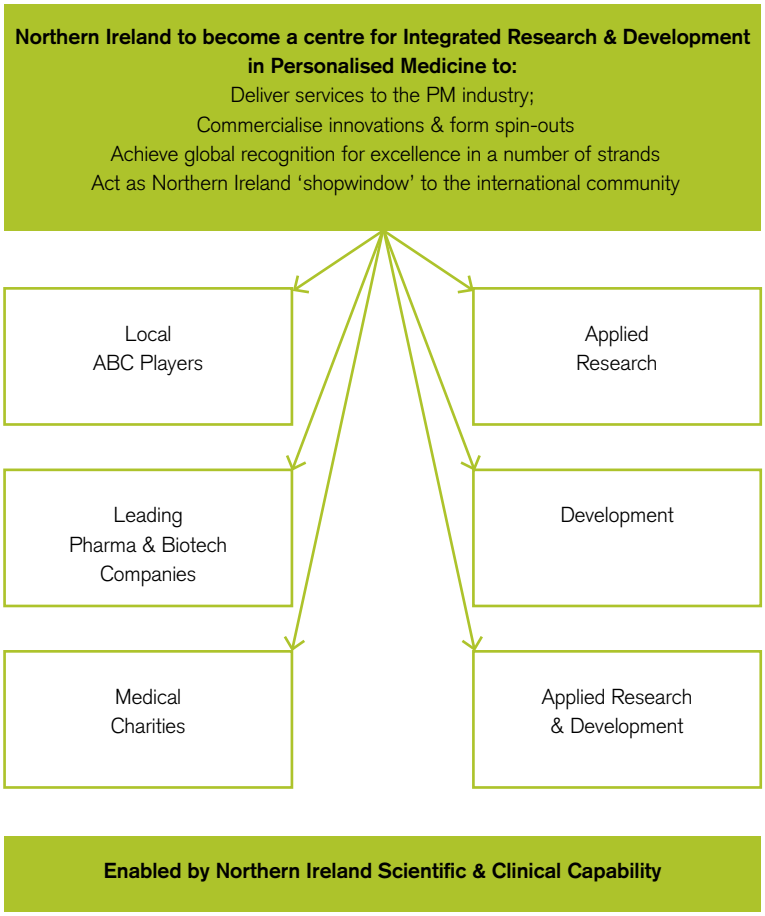
As the market intelligence indicates, in the longer term this sector has the potential to transform the way medicine is delivered. Many nations have identified the opportunities offered by this high risk - high reward sector, and investment in research and commercialisation in this space has intensified in recent years.

The Life and Health Sciences Horizon Panel has identified an opportunity for Northern Ireland to carve out a share of this growing market, by becoming a centre for Integrated Research & Development in Personalised Medicine. This would fuel the development of Personalised Medicine in Northern Ireland, and place the local cluster on the international map in this highly dynamic sector. The competitive advantage would be conferred by the integrated nature of the services provided, harnessing academic scientific expertise, clinical data and practice and a focus on commercialisable outputs.

The Panel believes that the sector could be stimulated locally by creating the environment for the initiation of commercially-targeted R&D projects, focussing funding and support towards applied research not elsewhere funded and the gap between initial Proof of Concept and Phase II Clinical trials. Being open to the full spectrum of the Personalised Medicine technologies and practices, is expected to stimulate interest from across the sector and allow the most economically valuable proposals to emerge.

It is believed that, given the recent developments in local infrastructure, a 'virtual' support mechanism would be sufficient, providing leadership, funding and expert support rather than new physical infrastructure.

A highly focused approach to the development of this exciting sector would help drive closer cooperation and capability transfer across the ABC boundaries, thus enhancing the exploitation capability within the local sector and raising its position in the international arena. The sector would also be able to communicate with a single voice and engage in a coherent manner with the local support mechanisms and stakeholders, for example to promote skills development and raise the profile of the local cluster.



KEY STAKEHOLDER INPUTS & OUTPUTS

THE IMPLICATIONS IN TERMS OF COMMITMENT, RESOURCES AND BENEFITS FOR EACH OF THE LOCAL STAKEHOLDER GROUPS IN REALISING THE PERSONALISED MEDICINE MARKET OPPORTUNITY CAN BE SUMMARISED AS FOLLOWS:

GOVERNMENT	ACADEMIC STAKEHOLDERS	BUSINESS SECTOR	CLINICAL SECTOR
Inputs • Creating an innovation- and business-friendly environment • Help raise the profile of the local capability • Attract lead scientists from abroad and international research partners	**Inputs** • Academic research staff • Enhanced PhD pool • Research facilities • IT capability • International research partners	**Inputs** • Business expertise • Research expertise & facilities • Financial investment	**Inputs** • A commitment towards adoption within the local clinical practice • Clinical research expertise • Clinical data • Research facilities
Outputs • Development of existing businesses, by accessing expertise from the local and international scientific community • Spin-out companies, generating associated tax revenues and employment • FDI traction • Emergence and recycling of local entrepreneurs • International reputation, which in turn generates new business.	**Outputs** • IP creation, which can be commercialised through spin-out companies or licensing deals • Spin-out companies • Skills development & export • Enhanced international profile	**Outputs** • Extended new product pipeline • Reduced R&D costs • IP creation, which can be commercialised through spin-out companies or licensing deals • Attract and retain talent • Industry cross-fertilisation (e.g. ICT, Advanced Materials, Agri-food)	**Outputs** • IP creation, which can be commercialised through spin-out companies or licensing deals • Improved patient care, through rational therapeutic decisions rather than trial-and-error approach • Cost savings in the long-term, through increasing emphasis on prevention and early intervention

WHAT IS HOME-BASED CARE?

THE CORE PROPOSAL FROM THE HORIZON PANEL CONCERNS THE LINK BETWEEN PATIENTS IN THEIR HOMES AND THE HEALTH SYSTEM. THIS LINK CAN BE CONSIDERED TO INCLUDE THE FOLLOWING THREE MARKET COMPONENTS.

1 Telehealth
Telehealth monitoring is the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis, progress monitoring and prevention of various conditions. Specific product examples include home-based blood pressure monitors that relay information to the patients GP surgery. Their immediate applications tend to lie in the management of chronic disease (e.g. diabetes, cardiovascular etc). The preventative and personal health management aspects are expected to become more pervasive in the longer term.

2 Telecare
Telecare is the continuous, automatic and remote monitoring of real time lifestyle changes and emergencies over time, in order to manage the risks associated with independent living. Telecare is usually designed to create home environments which meet the needs of older or disabled people. Specific product examples include fall or bed sensors.

3 Secure web messaging and e-visits
This technology usually acts as an enabler for the previous two areas of remote care. Consumer familiarity with the Internet and e-mail allows for more efficient communication with medical staff and for novel healthcare solutions. A specific example of an e-visit could be an email exchange between a doctor and patient. The market also includes technologies and services based exclusively within the health system (telemedicine) or within the patients' physical home infrastructure (assistive devices). These do not form part of the Panel's core proposals, but instead are recommended for consideration in the longer term.

KEY MARKET DRIVERS AND CHALLENGES TO DEVELOPMENT

KEY MARKET DRIVERS	KEY CHALLENGES TO DEVELOPMENT
• Current healthcare systems are unsustainable, in great part due to an ageing, more chronically-ill population • There have been numerous pilot studies that have demonstrated social and financial benefits associated with the home care concept • Advancement of technologies and IT infrastructures has led to higher IT spend within healthcare budgets, in a bid to achieve efficiencies and improve service delivery • Rising expectations of consumers with regards to own health status and involvement in their healthcare decisions • Adoption of Electronic Health Records (EHR) will act as an enabler for remote care	• Slow adoption by healthcare systems, due to factors such as resistance to adoption of information technology and new work practices, and difficulties in changing reimbursement systems within the GP community; significant policy issues therefore remain to be addressed • Integration into existing structures is made more difficult by the need for a joined-up approach across health, housing and social care • Maintaining individual privacy - there are concerns regarding surveillance and possible loss of privacy and autonomy, and legal issues relating to data confidentiality and protection. • Lack of coherent approach - both within health systems (so far based on regional, small scale pilots) and industry (interoperability issues among devices and telecommunications providers) • Level of technology development - there is a need for further development for example to provide more consumer-friendly devices • Country variations in policies and structures make exporting more difficult

COMMERCIAL PROSPECTS FOR THE HOME-BASED CARE MARKET

THE CORE PROPOSAL FROM THE HORIZON PANEL CONCERNS THE LINK BETWEEN PATIENTS IN THEIR HOMES AND THE HEALTH SYSTEM.

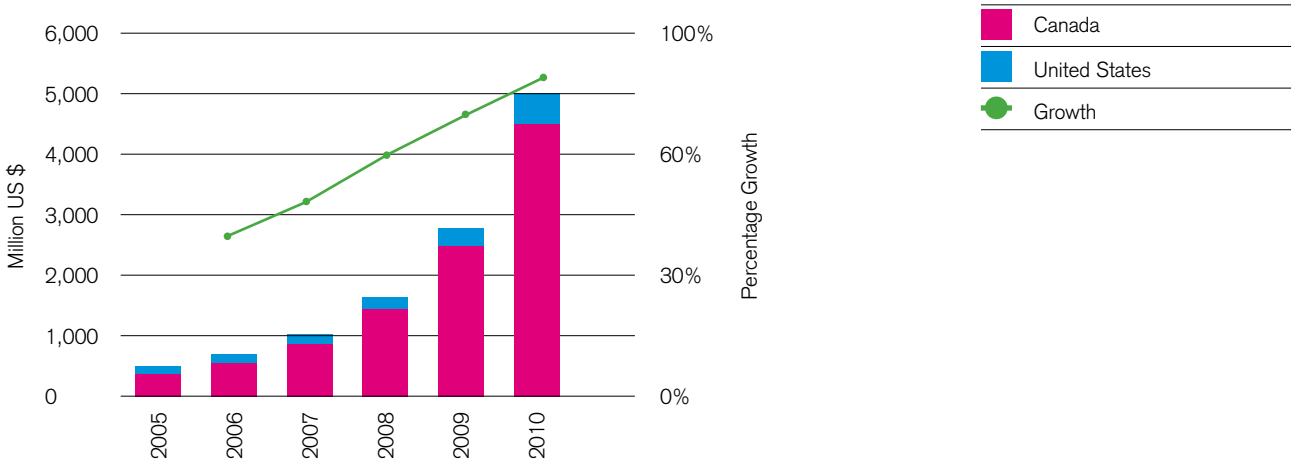
The US is, and will remain, easily the largest national market for telehealth, reaching $4.51 billion in 2010 according to Datamonitor forecasts. It will also show faster growth than Canada at 64% CAGR, compared with 32% for the latter. This very high growth and large market share are the result of two main features of the US market:

- Very high overall US healthcare spending, given the private care and insurance-based system;
- High and rapidly growing rates of chronic diseases such as diabetes.

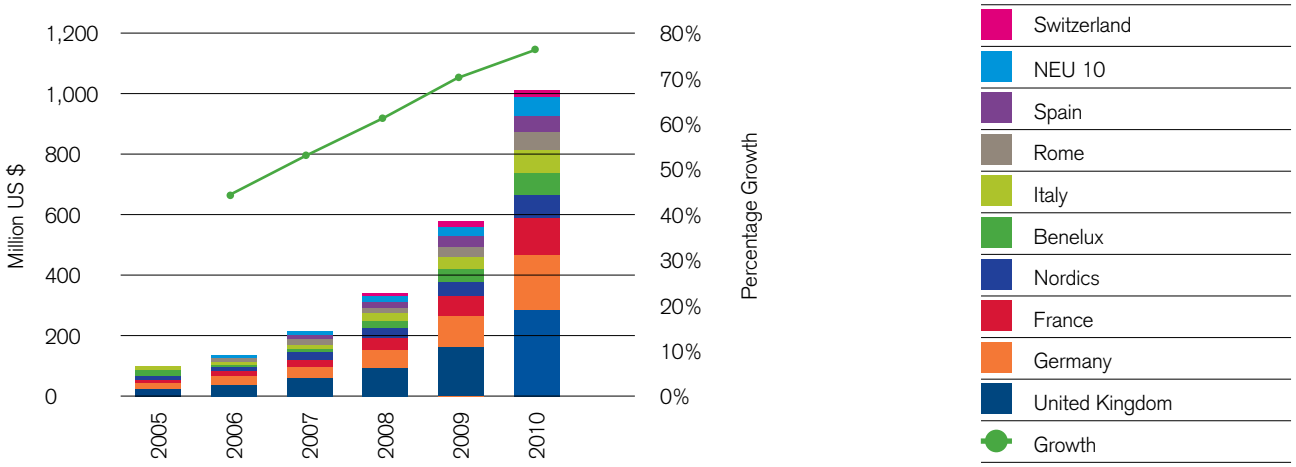
In comparison, the entire European market is expected to only reach about $1.00 billion by 2010, despite having a projected 502 million people.

The European market may be smaller than that in the North America, but it will still show very rapid growth, with an expected CAGR of 60% over the period. The UK is the largest single market at $23 million and will grow by 66% CAGR to $286 million in 2010. The ten new EU nations (NEU 10) will be the fastest growing market, with a CAGR of 69%, but will still only reach a value of $60 million in 2010.

TELEHEALTH MARKET IN NORTH AMERICA BY COUNTRY (2005-2010)*



TELEHEALTH MARKET IN EUROPE BY COUNTRY (2005-2010)**



* Source: From report

** Source: Datamonitor, Extending the delivery of healthcare beyond the hospital setting, June 2006

REALISING THE HOME-BASED CARE OPPORTUNITY FOR NORTHERN IRELAND

The Life and Health Sciences Horizon Panel recommends that Northern Ireland becomes the first UK region committed to the early adoption of a telehealth system within the Health and Social Care practice. This means establishing a strong local capability across the telehealth continuum, and deploying this locally to achieve whole connectivity between the health sector and the home within 15-20 years.

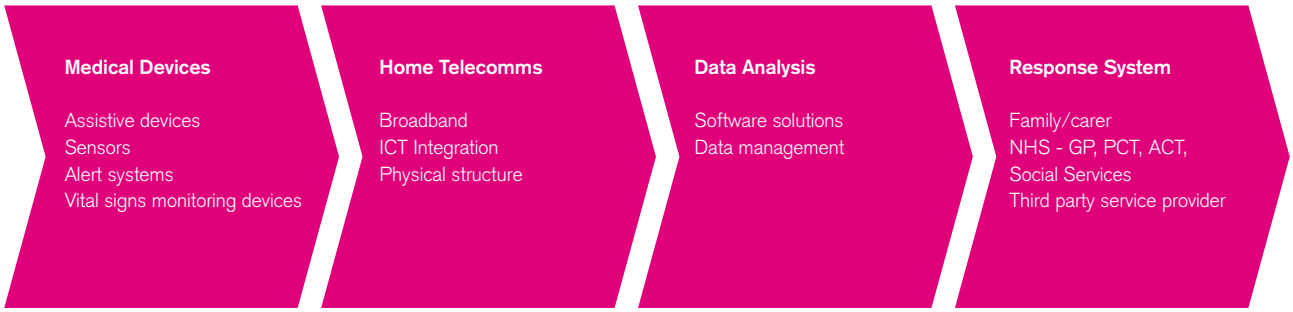
The Home-based care market encompasses a wide range of products and services. The underpinning technologies and systems necessary to deliver those services can be sub-divided into four key domains along the telehealth continuum, as summarised in the diagram below.

The overall aim of the model proposed for Northern Ireland is to join up local capability across all four of these domains in an integrated manner and in a real clinical setting.

The Panel concluded that to maximise the market opportunity in this area, telehealth technology should be implemented within our own health system.

- This would allow the DHSSPS to benefit from savings achieved from the delivery of health services in this manner, whilst improving patient care; and
- At the same time, it would create an attractive Whole System Integration Test Bed for local and international technology providers, who could use Northern Ireland as a gateway to UK and European home care export markets.

NORTHERN IRELAND POSITION ALONG THE HOMECARE CONTINUUM: WHOLE SYSTEM CONNECTIVITY



The Panel considered the Northern Ireland capability's strengths and gaps against the four key areas judged to constitute the home based care continuum, and the level of support and commitment provided by the local government.

Medical Devices

- The panel noted that a local capability existed within Northern Ireland within the medical device sector. However, it was also noted that these companies lacked a scale within the market. All of the companies had to seek an export market as there was currently little potential for growth domestically.
- It was acknowledged that a strategy could be developed to build upon the existing capability by seeking additional foreign direct investment into the province and by developing partnership agreements.

Home-based Telecommunications

- The development of a Home-based care market will require a high speed telecommunications infrastructure. The panel members judged that Northern Ireland was already well served in this area compared to other regions in the UK given the existing 100% broadband coverage. However, the ability to generate a economic capability by developing companies to compete within the technology infrastructure sector was not judged to be strong given the dominance of the existing technology competitors.

Data Analysis

- The development of a Home-based care market will require a capability in managing and analysing large volumes of data. The Panel judged this was not an area were a significant capability existed locally at present but from preliminary discussions with the Horizon ICT Panel it was an area that could be further explored for future investment.

Response System

- The specific circumstances of each patient group and the economic case for each initiative will determine the response system employed. The options to consider would include:
  - Response to be delivered within the DHSSPS; if so, what are the interface points, e.g. GPs, Social services, others;
  - Response to be provided by a family member;
  - Response to be delivered by a 3rd party provider; if so, what type of activities specifically and associated governance; or
  - Combination of service delivery;
- The Panel considered that the most important success factor was not the creation of infrastructure. Instead, it was ensuring that the existing response resources (e.g. GP surgeries, District nurses etc) were motivated and incentivised to adopt this way of working.

Government support

- The announcement made in January 2008, regarding the development of an European Centre for Connected Health supported by three Northern Ireland government departments, is a powerful springboard for future development of the concept. The project has significant buy-in from the private sector locally and internationally.

KEY STAKEHOLDER INPUTS & OUTPUTS

THE TABLE BELOW SUMMARISES THE COMMITMENT NECESSARY FROM GOVERNMENT, ACADEMIA, BUSINESS AND THE CLINICAL FIELD TO SUCCESSFULLY DELIVER HOME-BASED CARE WITHIN THE NORTHERN IRELAND ECONOMY. THE TABLE ALSO HIGHLIGHTS THE POTENTIAL RETURN FOR EACH RESPECTIVE GROUP.

GOVERNMENT	ACADEMIC SECTOR	BUSINESS SECTOR	CLINICAL SECTOR
Inputs • A commitment to a 'connected health' agenda and establishment of NI as a test-bed for associated technology • A commitment to a joined up approach to the market opportunity • Embrace an attitude of change	**Inputs** • Social studies • ICT capability • Curricula for new disciplines in eHealth	**Inputs** • An investment in new technologies • A long-term contractual commitment to the public sector	**Inputs** • A commitment to changing working practices • Adjusting reward structures
Outputs • Stimulate indigenous companies • Create a knowledge base from which export potential can be exploited • Attract FDI companies, interested in using NI as a gateway to UK and European markets • Demonstration of the government's commitment to smarter working practices to improve patient care	**Outputs** • Graduates to fulfil a new model of health delivery • Growing reputation in the Connected Health field	**Outputs** • An opportunity to participate in a locally significant market • Potential to export proven technology and know-how to US and European markets	**Outputs** • A new model of healthcare management • Improved health and quality of life for relevant patient groups through enhanced independent living • Improved work practices for health professionals • Realisation of cost savings which can be redistributed towards other priority areas, thus increasing productivity levels

FRAMEWORK CONDITIONS

The health technologies and life sciences sector has the potential to become a major contributor to Northern Ireland's knowledge-based economy. There are however a number of prerequisites to successfully realising the market opportunities identified by the Horizon Panel.

General enabling factors:

- Most importantly, accomplishing the healthcare opportunities identified by the Life & Health Sciences Panel is dependent on the sector's ability to exploit and develop local capability in a number of allied areas. This is an era of convergence of technologies, and Life & Health Sciences sits right at the interplay of technologies from related sectors - Advanced Materials, ICT, Advanced Engineering etc;
- The competitive position of Northern Ireland is dependent on the ability to provide an integrated service and product portfolio. This means a joined-up approach among the private sector companies, but also the use of academic and clinical capability as a catalyst to innovation and science. Collaboration with international partners, including RoI and GB, would also help address some of the gaps that may exist in the local capability;
- The availability of an adequate skills base is of paramount importance. The right quality and volume of skills is necessary to fuel the growth of the sector. The education system has been engaging a lot more with the industry in the last few years, but even more can be done to align the curriculum to the changing needs of the industry; and
- Supportive policy environment - this would involve the creation of an innovation- and business- friendly environment, which would support indigenous existing and new companies, as well as overseas companies considering operating in Northern Ireland.

Personalised medicine specific factors:

- Participation from the clinical sector would be critical to help demonstrate the economics and clinical benefits of pharmacogenetics in clinical practice;
- Application in existing vs. new drugs would imply forming public-private partnerships to enable enhancements of existing generic drugs; and
- Addressing the ethical framework - safeguards need to be put in place to prevent the misuse of genetic information.

Home-based care specific factors:

- Scalable approach to roll-out - it is recommended that DHSSPS retains the control over the patient groups and the parts of the healthcare system impacted at each stage;
- Defining technology standards and protocols - common technology standards and protocols need developed to provide interoperability of devices;
- Stakeholder engagement - existing response resources (e.g. GP surgeries, District nurses etc) need motivated and incentivised to adopt this way of working; and
- Adjusting funding policy - aim to use and adjust the existing reward and operational structures (e.g. GP contracts) as much as possible, rather than creating a new, parallel system.

SUMMARY OF PROPOSALS

TWO DISTINCT MARKET OPPORTUNITIES HAVE BEEN IDENTIFIED BY THE HEALTH AND LIFE SCIENCES HORIZON PANEL: PERSONALISED MEDICINE AND HOME-BASED CARE. WHILST THEY HAVE A NUMBER OF COMMON FEATURES, IN THAT BOTH ADDRESS ISSUES FACING THE GLOBAL HEALTH AND ECONOMY IN THE LONG-TERM, AND THEY ULTIMATELY COMPLEMENT EACH OTHER WITHIN THE INTEGRATED HEALTHCARE CONCEPT, THE TWO MODELS OFFER DIFFERENT PROPOSITIONS IN TERMS OF TYPE OF CAPABILITY IMPACTED LOCALLY, ECONOMIC IMPACT, TIMESCALE AND RISK FACTORS. THE TWO MARKET PROPOSALS ARE SUMMARISED BELOW.

PERSONALISED MEDICINE	HOME-BASED CARE
Market rationale • Large, emerging market across all segments, driven by need for more effective treatments & shift to preventative medicine, and the innovation & patent crisis in the pharmaceuticals sector • Obstacles: costs, data availability, ethical concerns, reimbursement policy • Number of players & government investment increasing globally • High risk, high reward market • NI has some of the building blocks in place, but lacking critical mass	**Market rationale** • Developing market, driven by the need for more efficient healthcare provision and increasing consumer demand for enhanced quality of life • Market currently dominated by pilots. Proven benefits, but also show that 'one size doesn't fit all' • Main technology platforms exist, albeit requiring further development • Obstacles to adoption: Device & IT Interoperability, Variation in regional policy, Healthcare system resistance to technology & change, Reimbursement policy • Northern Ireland capability lagging behind
Northern Ireland Opportunity • Focus on clear commercialisable applications in the Personalised Medicine space • Open/Bottom-up approach - based on competitive projects • Create a virtual mechanism, using existing physical infrastructure & tech transfer structures • Support collaborative networks, resource development, profile raising • Use funding to incentivise collaboration, technology transfer and attract international players	**Northern Ireland Opportunity** • Focus on telehealth and telecare segments (excludes telemedicine and house aids) • Adoption within mainstream healthcare system to become Northern Ireland's competitive differentiator • Top-down approach, with decision on policy and strategic approach to roll-out resting exclusively with DHSSPS. • Phased roll-out

PERSONALISED MEDICINE	HOME-BASED CARE
Advantages • Potential for immediate engagement of existing companies and impact on their commercially-targeted R&D activity • Draws on and stimulates R&D in related and complementary fields • Additional funding leveraged through public sources (UK, RoI and European sources) and major international players • Attract PhD and other highly skilled professionals. Retain indigenous talent • Longer term - creation of new companies	**Advantages** • High FDI traction prospects • Technology platforms available internationally, albeit requiring improvement • Lower risk and more immediate economic impact on both patient care and local economy (3 years +) • Significant interest in full adoption from DHSSPS locally, which would be a key competitive advantage compared to other pilot-based schemes.
Draw-backs • Long-term economic impact (10 years +) • High risk portfolio	**Draw-backs** • Limited indigenous scientific capability locally • Global market prospects dependent of adoption rates in each country
Key success factors • Building critical mass and profile through sustained investment • Combining academic and clinical capability will confer a strong competitive advantage • Commitment from all stakeholders	**Key success factors** • Adjust reimbursement strategy to incentivise adoption • Embedding behavioural changes - among healthcare professionals and patients

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INTRODUCTION

1

THE ECONOMIC IMPORTANCE OF THE HEALTH TECHNOLOGIES & LIFE SCIENCES SECTOR

NORTHERN IRELAND CONTEXT

As technologies converge, 'life sciences' represents an all-encompassing title capturing a wide range of industry sub-sectors such as pharmaceuticals, biotechnology, medical devices and diagnostics, drug delivery, clinical trials etc. The sector in Northern Ireland comprises organisations across the Academic, Business and Clinical (ABC) sectors.

The business sector counts approximately 60 companies, offering a very diverse range of products, services and capabilities. Data from Invest NI and DETI suggests that the industry as a whole has a combined turnover of around £310 million and employs approximately 4,000 people. This tends to be a high value-add sector and export-oriented, with around 80% of sales generated from external markets.

The top five companies by size account for some two thirds of the sector's turnover and 3,838 of its employees. The majority of companies in the sector are small, with turnovers of under £500,000.

The issues facing local industry include:

- Difficulty of gaining access to early stage funding, due to the higher risk and longer lead times to commercialisation that apply to this sector
- Skill shortages in certain areas
- Long and costly product development, due to compliance with a strict regulatory regime
- The need for stronger links with academia and clinicians in order to bolster technology transfer and innovation
- Shortage of 'veteran' entrepreneurs in Northern Ireland, with the experience and time to mentor life science businesses
- Need to remain at the forefront of R&D, in light of increasing competition from low cost manufacturing regions

The academic sector offers a strong science base, both in life sciences and related sectors through its two world class Universities and the six regional Colleges of Further & Higher Education. Examples are the Nanotechnology and Advanced Materials Research Institute (that includes NIBEC and the Centre for Advanced Cardiovascular Research), Biomedical Sciences Research Institute, Centre for Cancer Research and Cell Biology, the Northern Ireland Clinical Cancer Centre and the McClay Research Centre for Pharmaceutical Sciences.

In addition to its intrinsic clinical practise expertise, the clinical sector is placing an increasing focus on clinical research and development and commercialisation of innovation arising from the clinical sector. Its strengths lie in the seven recognised Research Groups, the Northern Ireland Clinical Research Support Centre and multiple joint programmes with equivalent organisations in Ireland and the UK as well as the local academic and business sectors.

Over the past five years Northern Ireland industry, academia and government have made significant commitment to the development of life sciences capabilities. In excess of $160 million has been budgeted for infrastructure enhancement, collaborative research, new product development and staff development initiatives.

In the same timeframe, Northern Ireland life science companies have committed to strategic investment expenditure in the order of $340 million including approved government assistance of $70 million. In a country with a population of just 1.7 million people, employing around 4,000 in life sciences, this level of investment (almost $125,000 per employee) is impressive.

This illustrates the local stakeholders' determination to maximise the opportunities deriving from a long history of technological innovation, backed by a highly educated, young workforce and an internationally recognised research base.

GLOBAL CONTEXT

A growing market
At global level, the sector is set to benefit from rising demand for effective medicines as the population ages, new medical needs emerge and the disease burden of the developing world increasingly resembles that of the developed world. By 2020, the global pharmaceuticals market is projected to be worth some $1.3 trillion. The market is anticipated to be shaped up by a number of key trends:

Changes in disease patterns put pressure on healthcare costs
Increase in chronic diseases. The global population is projected to rise from 6.5 billion in 2005 to 7.6 billion in 2020. It is also aging rapidly; by 2020, about 719.4m people - 9.4% of the world's inhabitants - will be 65 or more, compared with 477.4 million (7.3%) two years ago. Older people typically consume more healthcare products and services than younger people, as they tend to develop multiple chronic diseases. Obesity, especially in the US, is another driver of higher costs, as it tends to lead to chronic diseases such as diabetes, coronary heart disease and osteoarthritis.

More new diseases.
Greater population density, increased travel and climate changes have increased the appearance of new pathogens. These are often viral, initially difficult to treat, and highly dangerous. Examples include ebola, SARS and potentially avian flu.

Growing antibiotic resistance in existing diseases.
The overuse of antibiotics, and the limited number of new ones in the pipeline, has left little defence against several previously contained pathogens. Examples include hospital infections and tuberculosis.

Industry innovation crisis
Currently, it appears that the global pharmaceutical industry is not in a strong position to capitalise on the market opportunities, unless it can change the way in which it operates. Its core problem is the slowing pace of innovation in providing effective new therapies for the world's unmet medical needs.

The industry's best hope of earning higher returns lies in the development of packages of products and services targeted at patients with specific disease subtypes and that, if it was to make such "targeted treatments", it would have to start by focusing on diseases rather than compounds.

Biotechnology research is anticipated to deliver more new products than the traditional molecular R&D activities. Gene therapy is likely to move from treatment of conditions to cures by modifying patient DNA. Previously untreatable conditions could therefore find a treatment, as is, for example, the case of cancer and other genetic conditions.

However, the human genome has proved more complex and less amenable to mechanistic analysis than many scientists anticipated, when the draft map was completed in 2001. Hence the fact that Pharma is still struggling to apply the insights it has gleaned from the molecular sciences - genomics, proteomics, metabonomics and the like - to improve its performance. The industry requires a fresh approach to its R&D processes, and identification of target molecules and compounds.

Globalising marketplace
Globalisation will bring fundamental changes, particularly in the area of product development. With an inexpensive supply of highly trained researchers and improving intellectual property norms, China and India look likely to become a focus of product development and manufacturing activity in life sciences.

Changing relationships
Co-operation will be a critical element of success in life sciences. Biotech and big pharma will work together to bring new products to market. Teams will co-operate globally on processes such as product development or test analysis. Increasing levels of patient choice and knowledge will place a premium on successful relationships between physicians and those in their care.

Increasing Role of Information Technology (IT)
More pervasive use of IT will lead to more effective storage and retrieval of patient records, improved tracking of medical outcomes and better remote care. Automation of simpler processes is also anticipated to free up physicians' time to focus on higher-value activities such as diagnosis and patient communication.

Blurring Healthcare Boundaries
Changes in the way healthcare is delivered will arguably play an a critical role in shaping the industry's future. The primary-care sector is expanding and becoming more regimented, as general practitioners perform more minor surgical procedures and healthcare payers increasingly mandate the treatment protocols they must follow, including the drugs they can prescribe. Conversely, the secondary-care sector is contracting, as clinical advances render previously terminal diseases chronic; healthcare providers like Clinovia in the UK, and Gentiva in the US, deliver secondary care at home; and hospitals focus on the specialist care that cannot be supplied anywhere else. The self-medication sector is also growing, as more and more products that would once have been available only on prescription are sold in OTC formats.

Pay-for-performance
The provision of healthcare is not all that is changing; so is the way in which it is measured. Several countries have set up agencies specifically to compare the safety and efficacy of different forms of intervention and promote the use of evidence-based medicine. The US Agency for Healthcare Research and Quality is one such body, as is the UK Centre for Health Technology Evaluation - a division of the National Institute for Clinical Health and Effectiveness (NICE). The industry will have to prove to healthcare payers, who are increasingly interested in establishing best medical practice, that its products really work and provide value for money.

Focus on prevention
A growing number of governments in both developed and developing countries are trying to shift the focus from the treatment of disease to its prevention. For example, at least 18 countries have already introduced nationwide bans on smoking in enclosed public places, as have a number of US states. Similarly, some countries are waging war against rising levels of obesity. The role of genetics in identifying those at risk and in early interventions is also expected to play a major role in preventative medicine.

THE HORIZON PANEL OBJECTIVES

The Life and Health Sciences Horizon Panel is one of the five technology horizon scanning panels established under the auspices of the Northern Ireland Science Industry Panel - MATRIX. The other four Horizon panels represent the following sectors: ICT, Advanced Materials, Agri-food and Advanced Engineering (Transport).

MATRIX is an expert advisory panel reporting to DETI and the DETI Minister on matters pertinent to the exploitation and commercialisation of science, technology and R&D. It is led by high-technology and R&D intensive industry and advises Northern Ireland Government on the development of improved interfaces between Northern Ireland business and the research, science and technology base, with a view to ensuring the region's science and R&D strengths are exploited for maximum economic and commercial advantage.

The Life and Health Sciences Horizon Panel was tasked to deliver on the following objectives:

i Identify the sustainable market opportunities that could be exploited distinctively by the NI science and industry base;

ii Identify the research and technology strengths of the Northern Ireland science and industry base relevant to the identified market opportunities;

iii Determine the opportunities for external collaboration that would supplement critical gaps in NI research and technology capability in ensuring early delivery of potential outputs;

iv Engage with key stakeholders and partners critical to the success of relevant market opportunities (public, private and academic) in Northern Ireland to assist in the prioritisation of the key technology enabled business opportunities for the sector;

v Identify internal and external networks (including those networks wider than the life and health sciences sector) essential to deliver technology and business growth and establish processes to build and sustain these networks; and

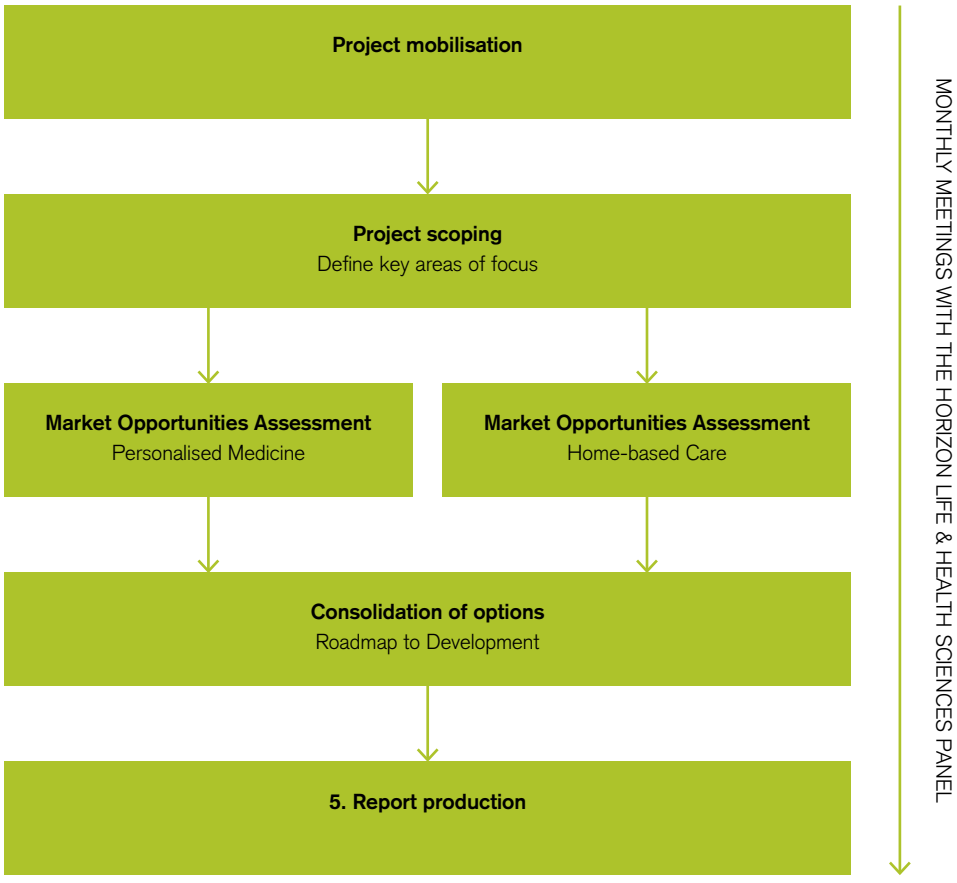
vi Identify investment opportunities in the sector.

APPROACH TO DELIVERY

We adopted a step driven approach to achieving the project deliverables, underpinned by monthly Panel working meetings. The 12-strong Panel brought together leading representatives from across the local industry - academics (6), clinical sector R&D representatives (2), and private sector companies (2 large businesses and 2 SMEs). The Panel was co-chaired by leaders from business and academia.

1 Project Mobilisation
An initial meeting was held with the Matrix secretariat to agree the approach to delivering and managing the project. This was then captured in the Project Initiation Document.

2 Project Scoping
Given the broad and complex nature of the health technologies and life sciences sector, it was important to select the most appropriate



approach to identifying the relevant market opportunities for Northern Ireland. It was ultimately agreed that the most effective means to achieving this was through a brainstorming session, which would harness the collective knowledge of the Panel members and the market acumen of the PwC core team and expert advisors. The event was held in May 2007 and elicited views on 'Sustainable Market Opportunities for Northern Ireland plc' from a wide number of standpoints: World disease prevalence, Key industry trends, Emerging and cross-cutting technologies, Policy & regulation, and Northern Ireland competitive position.

Over 100 innovative ideas were generated, which were then analysed and found to cluster around 11 principal market-related themes. The Panel filtered these further and selected the top priorities through a voting process. The results were discussed at the Panel meeting in June, when the top two key areas of focus for Northern Ireland were agreed as: Personalised Medicine and Home-based Care.

3 In-depth Market Analysis

In-depth market research was carried out within the two selected themes, to explore specific technology application opportunities within each. The research used analysis of extensive market intelligence and interviews with international and local industry experts, to establish: Key areas of market growth, Emerging technology applications, Key players, and Potential collaboration partners.

The profile of the local sector capability was also analysed, drawing information from DETI's parallel study on Northern Ireland Technology capability, and the BioBusiness and Invest NI Sector review conducted in 2006.

In light of the research findings, a number of suggestions were made on potential areas of focus for the Northern Ireland cluster, and models for implementation.

4 Consolidation Of Options

The options on the best approach for Northern Ireland approaching this market and establishing a competitive position were deliberated with the Panel members. A number of options to the implementation models were discussed, together with the implications for the local stakeholders.

The emerging thoughts were shared and tested with a limited number of key sector leaders in the local economy. These discussions helped gauge their views on how the proposed models could be effectively deployed, and initiated early buy-in and engagement across the industry community.

5 Reporting

The final report explores the recommendations of the Life and Health Sciences Horizon Panel in the areas of Personalised Medicine and Home-based Care and summarises the market rationale for these recommendations.

PERSONALISED MEDICINE - THE OPPORTUNITY FOR NORTHERN IRELAND

2

WHAT IS PERSONALISED MEDICINE?

At its most basic, Personalised Medicine refers to the use of information about a person's genetic makeup to tailor strategies for the detection, treatment, or prevention of disease.*

People vary from one another in many ways - what they eat, the types and amount of stress they experience, exposure to environmental factors, and their DNA. Many of these variations play a role in health and disease. The combination of these variations across several genes can affect each individual's risk of developing a disease or reacting to something in the environment, and can be one of the reasons why a drug works for one patient and not another.

Personalised Medicine aims to use these variations - both in the patient and in the molecular underpinnings of the disease itself - to develop new treatments and to identify the sub-groups of patients for whom they will work best. It can also help determine which groups of patients are more prone to developing some diseases and, ideally, help with the selection of lifestyle changes and/or treatments that can delay onset of a disease or reduce its impact.

Personalised Medicine is expected to transform healthcare over the next several decades. New diagnostic and prognostic tools will increase the ability to predict the likely outcomes of drug therapy, while the expanded use of biomarkers - biological molecules that indicate a particular disease state - could result in more focused and targeted drug development. Personalised Medicine also offers the possibility of improved health outcomes and has the potential to make healthcare more cost-effective.

The illustration arrow reflects the current and anticipated flow of healthcare services, and changing points of intervention, as medicine becomes more personalised. Early detection testing will play an increasing role, with expanded screening programmes for detecting specific genetic risk for certain diseases. A key factor that will drive the integration of diagnostics and therapeutics is the availability of improved and more precise diagnostic methods, which are easy to perform and are not prohibitively expensive.

Although scientific advances such as the mapping of the human genome and computation technology are underpinning fast scientific developments, adoption in the mainstream clinical system lags behind. If Personalised Medicine is to realise its potential, it will require an extensive system of support. This system will include new regulatory approaches, revamped medical education curricula, integrated health information systems, legislation to protect against genetic discrimination, insurance coverage for sophisticated molecular diagnostic tests, and a reimbursement system that encourages proactive care.

THE PARADIGM OF PERSONALISED MEDICINE**

* (Source: Personalised Medicine Coalition)
** (Source: Personalised Medicine Coalition)

APPLICATIONS OF PERSONALISED MEDICINE

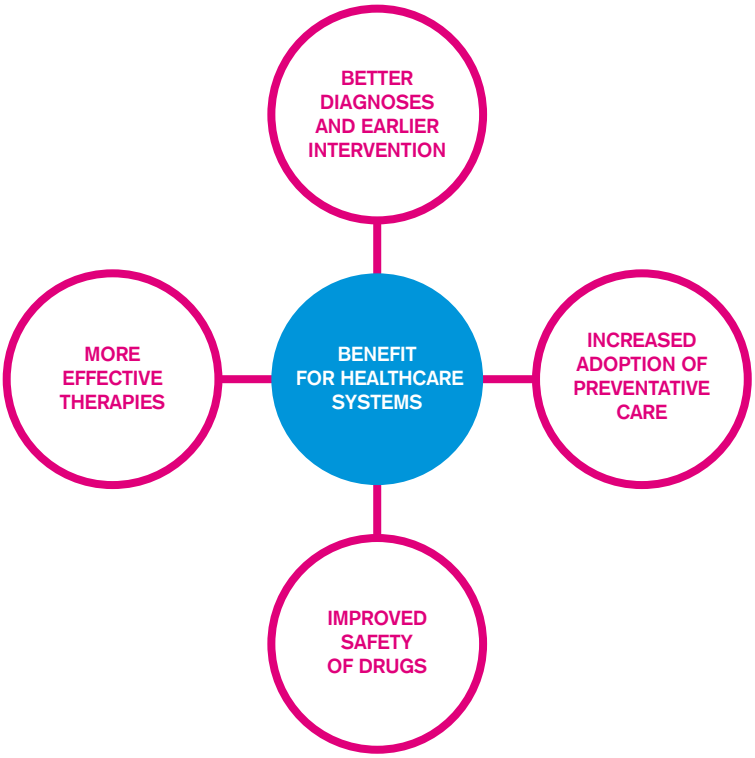
A PERSONALISED APPROACH TO MEDICINE PROMISES A NUMBER OF BENEFITS IN ADDRESSING THE KEY CHALLENGES FACING HEALTHCARE SYSTEMS WORLDWIDE:

Currently, physicians often have to use trial and error methods to find the most effective medication for each patient. As more is learnt about which molecular variations best predict how a patient will react to a treatment, and develop accurate and cost-effective tests, doctors will have more information to guide their decision about which medications are likely to work best. Testing is already being used to find the one in four women likely to respond to a particular breast cancer drug. In addition, testing could help predict the best dosing schedule or combination of drugs for a particular patient.

Molecular analysis could determine precisely which variant of a disease a person has, or whether they are susceptible to drug toxicities, to help guide treatment choices. For preventive medicine, such analysis could improve the ability to identify which individuals are predisposed to develop a particular condition - and guide decisions about interventions that might prevent it, delay its onset or reduce its impact.

Toxicity associated with inappropriate use of approved drugs is a real problem and a cost to healthcare systems, that Personalised Medicine can provide a partial solution to. In the USA alone, adverse drug reactions (ADRs) are responsible for approximately 100,000 drug-related deaths and 2.2 million hospitalisations per year, representing a cost of roughly $100 billion.

Governments and medical communities are increasingly stressing preventive medicine as the most cost-effective approach to improving the quality of life. Developments in molecular diagnostics and genetic testing will drive this market. The design and validation of preventive screening programmes and diagnostic tests at personal and General Practitioner level would enable people to be more in charge of their own health and health practitioners to recommend life style, nutritional and medical action at an early stage.



PERSONALISED MEDICINE ALSO HAS THE POTENTIAL TO HELP THE PHARMACEUTICAL INDUSTRY TO IMPROVE ITS PERFORMANCE AROUND BOTH NEW PRODUCT R&D AND EXISTING DRUGS.

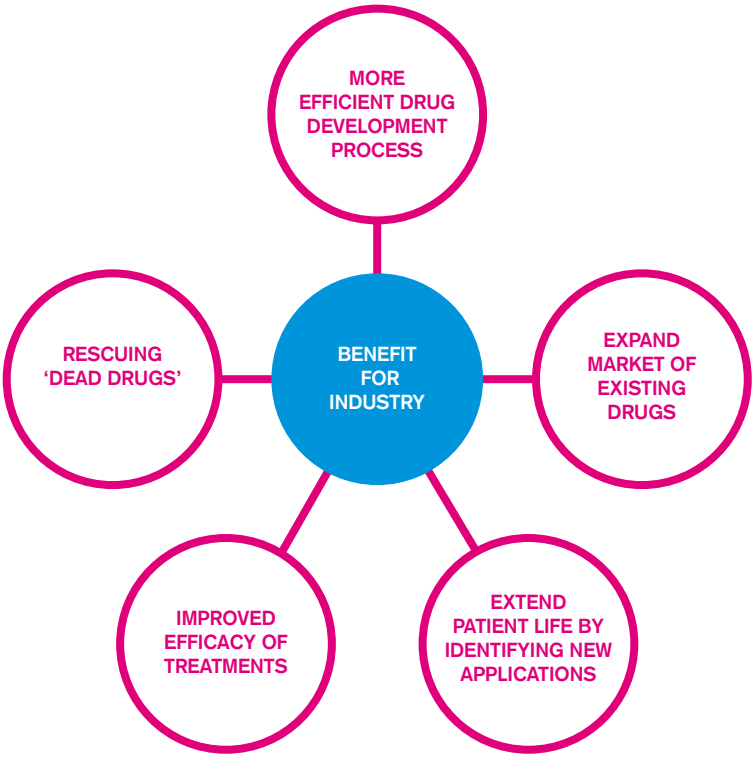
Genotyping may be used for rescuing 'dead drugs' that have failed clinical trials because of lack of efficacy and toxicity problems. New indications can be explored in defined populations groups where the drug use is safe and effective.

Redefining the patient population for marketed drugs would enhance effectiveness and safety. Upper figures for efficacy of medical treatment of most diseases are less than 100%. Example percentage of patients that show lack of response to current therapy in key disease areas: Epilepsy - 70%, Hypertension - 65%, Depression - 60%, Diabetes mellitus - 55%, Rheumatoid arthritis - 50%, Alzheimer's disease - 30%. Improvement in treatment is an opportunity for development of Personalised Medicines.

A better understanding of genetic variations could help scientists identify new disease subgroups and their associated molecular pathways, and design drugs that target them. Molecular analysis could also help select patients for inclusion in, or exclusion from, late stage clinical trials - helping gain approval for drugs that might otherwise be abandoned because they appear to be ineffective in the larger patient population.

Pharmacogenomics may be applied to expand markets for approved drugs with generally restricted use because of limited efficacy and toxicity in some patients. By defining the genotypic characteristics, patients who are non-responders and those liable to adverse reactions, can be excluded.

Repositioning of a drug through pharmacogenomics can extend the patent life of a drug. A drug with redefined new indications for a particular group of patients would start a new patent life.



BENEFITS OF PERSONALISED MEDICINE

A PERSONALISED APPROACH TO MEDICINE THEREFORE OFFERS THE PROSPECT FOR SIGNIFICANT BENEFITS FOR EACH OF THE MAJOR STAKEHOLDER GROUPS - PATIENTS, GOVERNMENTS, AND INDUSTRY. THESE ARE SUMMARISED BELOW.

GOVERNMENT/HEALTHCARE SYSTEMS	PATIENTS	INDUSTRY
Detect disease at an earlier stage, when it is easier and more economic to treat effectively	Effective and specific therapies	Improve the selection of targets for drug discovery
Rational therapeutic decisions based on pathomechanism of disease rather than on trial-and-error approach	Less risk of adverse effects	Reduce the time, cost and failure rate of clinical trials
Incorporate diagnostic guidance to treatment	Less time lost compared to trial and error approach to treatment	Monopoly in a specified segment of the market - early entry and longer dominance of market niche; no competition from generics
Reduced adverse drug reactions and complications of treatment	Lower cost of treatment (in the longer term)	Increased drug effectiveness will command higher prices
Shift the emphasis in medicine from reaction to prevention	Facilitates preventive medicine	Increased revenues from combination of diagnostics packaged with therapeutic products
Reduce the overall cost of healthcare	Improvement of quality of life	Increase patient compliance with therapy prescribed
Increased professional satisfaction		Revive drugs that failed clinical trials or were withdrawn from the market
		Expanding demand for enabling products and technologies, such as ICT, Agri-food, nanotechnology.

KEY MARKET DRIVERS AND CHALLENGES TO DEVELOPMENT - PROGRESS OF SCIENTIFIC CAPABILITY

KEY DRIVERS

Scientific progress
Practical pharmacogenomics has only become possible in recent years due to whole genome sequencing and rapid gene characterisation. By testing for gene variation, gene expression, proteins and metabolites it is now possible to find new uses for existing drugs, enhance efficacy of new drugs with the aid of molecular diagnostics and expand the area of prevention with predictive medicine.

Declining cost of sequencing the human genome
Currently it costs nearly $1 million to sequence the 3.2 billion base pairs of DNA found in humans. Therefore, large scale sequencing is carried out mostly at special sequencing centres and is restricted to major expensive projects. The US NIH's National Human Genome Research Institute (NHGRI) is supporting research into breakthrough technologies that will enable a human-sized genome to be sequenced for $1,000 by 2015. The process can then be used in routine medical tests and allow physicians to tailor diagnosis, prevention, and treatment to a patient's individual genetic makeup.

Advances in technology and management of health information
Costs of genomics sequencing and bioinformatics analyses are decreasing, whilst their capabilities are expanding substantially.

The development and use of semantic technologies which will enable scientists to move seamlessly from one database to another and connect genomic, proteomic and metabonomic data with clinical data along with increased capability of predictive analytics which will identify trends and patterns and predict future outcomes.

More and more government initiatives to move patient records onto electronic format - for example the UK aims to have its health information system operational by 2012, US by 2014.

KEY CHALLENGES

Mapping of the genome is still in its infancy
Recent research has shown that there is substantial undescribed variation in the human genome which has implications for personalised genome sequence as reliable 'reference' human genomes will be required. In addition, other research has shown that there are large scale disparities in the DNA of healthy people revealing a largely ignored source of genome variation.

Availability of bio-banks
Ideally researchers should have an extensive tissue repository from which they can pull material to determine genetic markers responsible for specific disease states. Some countries, but not all, have established bio-banks and this shortage of research material could prove to be a limiting factor in the development of personalised medicines.

Non-genomic factors in the development of personalised medicine
Although Personalised Medicine is considered to be mostly based on pharmacogenomics, a number of other factors that vary among individuals need to be taken into consideration, such as: circadian rhythms, cytomics, intestinal microflora and role of drug delivery in Personalised Medicine.

KEY MARKET DRIVERS AND CHALLENGES TO DEVELOPMENT - ADOPTION IN HEALTHCARE SYSTEMS

KEY DRIVERS

Shift to prevention and early intervention in a bid to manage spiralling costs
With an ageing population, current healthcare systems cannot be sustained long term, and alternative models are required. The bias towards treatment will become increasing unsustainable and there will be a growing emphasis on promoting wellness rather than managing illness. As a consequence, Personalised Medicine and the information it provides could underlie a healthcare strategy focused on prevention and early intervention rather than reaction.

Current drugs are not effective for all patients
It is considered that blockbuster drugs may be efficacious in only 40-60% of the general population. Essentially traditional drugs cannot differentiate among different types of patients (Source PwC Personalised Medicine). In the United States, it is currently estimated that 50% of individuals fail to respond to drug therapies as initially prescribed.

Bid to reduce cost associated with Adverse Drug Reactions
In the US Adverse Drug Reactions (ADRs) are responsible for some 100,000 drug-related deaths and 2.2 million hospitalisations per year, representing a cost to the economy of over $100 billion. Deaths in England and Wales from prescription errors and ADRs have increased 500% over ten years, resulting in 1,100 deaths in 2002.

Pharmacogenetics offers the opportunity to reduce some of the burden of ADRs by identifying patients at high risk, leading either to reduced dose or use of alternative treatments.

The 2004 General Practitioner contract links remuneration with clinical outcomes in the areas of cardiovascular disease, stroke, asthma, diabetes and epilepsy. These are difficult challenges for the practitioner and would likely welcome the future promise of pharmacogenetics to deliver better-targeted medicines and therapies.

KEY CHALLENGES

Payment/Reimbursement policy
Personalised Medicine tends to be more expensive than other treatments - already many primary care trusts in the UK have refused to fund treatment with Herceptin (for breast cancer) citing cost issues.

At the same time, national healthcare services and private insurers generally do not have policies to cover pre-emptive care. More clinical data is required on the health outcomes and cost benefits for predictive screening and associated treatments, to justify coverage.

Ultimately, a lack of clarity over who will pay for these drugs and tests may limit the development of personalised therapies.

Education and resources
Extensive education and resources will be required to implement Personalised Medicine in everyday care facilities. This is pertinent for all the components along the healthcare chain - from medical schools' curricula, to practices within GPs and other healthcare providers.

Ethical framework
Ethical and privacy concerns regarding gathering, storing and using genetic information. The implications of being identified as predisposed towards a certain condition or non-responsive to available treatments may impact upon insurance coverage, work opportunities etc.

Regulatory framework
Pharmaceutical industry governance and regulations are currently built around the blockbuster business model and strategy - for the last 40 years. Clear guidelines will need to be in place to foster innovation and to build confidence in the process by which products are developed and regulated. In addition, if a much higher number of drugs are to be approved than previously then this could push the regulatory bodies' ability to cope, in their current structures.

KEY MARKET DRIVERS AND CHALLENGES TO DEVELOPMENT - ADOPTION BY INDUSTRY

KEY DRIVERS

1. The blockbuster model* of 'one drug fits all' is under pressure
It is increasingly recognised by the pharmaceutical industry that better defining the target patient population would enhance effectiveness and safety of drugs. Molecular diagnostics and Pharmacogenomics are beginning to provide the tools that allow better patient profile and control and monitoring of drug reaction.

2. The need for enhanced pace of innovation
The impact of patents ending and the accelerated entry into market of 'me too' drugs causes a further dent in a blockbuster drug/company's profitability. There has been little apparent innovation in the last number of years and this dearth of new products is debilitating for pharmaceutical companies who must continually seed their product pipeline due to the significant cost and time to market of a blockbuster drug.

Pharmacogenomics based drugs would provide and enhance the pipeline. Although the markets may be smaller, there will be more of them. Pharmacogenomics could also be used to reintroduce terminated late stage products back into clinical trials to try to identify the genotypic reason for the product's failure.

3. Financial pressure is mounting
Pharmaceutical companies come under increasing pressure from governments to reduce prices.

Pharmacogenomics could reduce the most cost intensive part of new drug development, clinical trials. Stratifying clinical trial participants, to include those most likely to benefit from the drug, will enable more specific results with a smaller number of patients and, most importantly, may reduce or eliminate adverse events. Estimates state that this approach could reduce clinical development time from 8-12 years to 3-5 years.

KEY CHALLENGES

Scale of adoption
Some large pharmaceutical companies remain sceptical about adoption of Personalised Medicine on an all-encompassing scale for a number of reasons: scientific barriers, fear that addressing individual niches implies a multiplication of R&D costs, and uncertainty over the reimbursement prospects.

Industry can be expected to continue to favour drug candidates that avoid the effect of genetic variation. However, where that is not possible (for example in cases of limited efficacy levels and high ADRs), the development of drugs with an associated diagnostic test is expected to become routine in the next ten to twenty years.

Perceived fragmentation of drug markets
Segmentation of a common disease into subcategories on pharmacogenomic basis might create a small population for a certain drug (known as the 'orphan drug syndrome'). The economic impact of a reduction in market size is believed to be overcome by the monopoly that can be established within each niche and the higher product price that is consequently chargeable.

Intellectual property ownership
A number of issues arise as bio-tech companies, life science companies, clinical centres and pharmaceutical companies work closely together: Who owns the intellectual property rights? How should these be shared?

*A block buster drug is currently defined as one worth more than $1 billion annual sales, and taking 8-12 years to reach market.

THE MARKET FOR PERSONALISED MEDICINE IS MULTIFACETED

THE MARKET FOR PERSONALISED MEDICINE IS MULTIFACETED, WITH OVERLAPS BETWEEN COMPONENTS AND DISCIPLINES, AND INTERDEPENDENCIES WITH ASSOCIATED SECTORS - E.G. PHARMACEUTICAL, ADVANCED MATERIALS, INFORMATION TECHNOLOGY ETC. THE DIAGRAM BELOW CAPTURES THE MAIN CONSTITUENTS OF THIS COMPLEX SECTOR.

Markets & Technologies

Molecular Diagnostics
DNA Sequencing
Gene expression profiling
SNP Genotyping
Biochips and microarrays
Biomarkers
Molecular imaging
Nanodiagnostics etc.

Personalised Therapies
Pharmaceuticals
Nutraceuticals
Recombinant human proteins
Therapeutic monoclonal antibodies
Gene and cell therapy
Personalised cancer vaccines
Antisense therapy etc.

Disease Areas
Cancer
Diabetes
Obesity
Cardiovascular
Central nervous system
Osteoarthritis etc.

Underlying Disciplines

Genomics
Pharmacogenetics
Pharmacogenomics
Pharmacoproteomics
Pharmacometabonomics

Systems biology
Bioinformatics
Nanotechnology

THE PARADIGM OF PERSONALISED MEDICINE

COMMERCIAL PROSPECTS

The market value forecasts for Personalised Medicine vary across industry sources. They all project significant growth in the longer term, albeit the timescale for realisation may differ from one source to another. Exact market size forecasts are difficult to pinpoint for two main reasons:

- The pace of market growth is dependent on scientific advancements, and the swiftness of industry and government developing a policy framework that would ease its adoption in mainstream practice; and
- Defining the market growth added by personalised medicine technologies is difficult to dissociate from the overall pharmaceutical and other associated disciplines which it interconnects with.

For example, Jain Biotech anticipates the market value to rise from $11.5 billion in 2006 to $40.5 billion by 2015. At the same time, the Technology Strategy Board quotes an estimated market value of $500 billion for regenerative medicine alone.

Pharmacogenetics is unlikely to revolutionise or personalise medical practice in the immediate future. Rather it will be a gradual process; as research identifies sub-groups of common diseases based on different genetic or environmental causes, and as the technology of applying information derived from complex multifactorial systems in the clinical context, it should become possible to introduce genetic testing to predict people's response to at least some drugs. Appropriate trials and cost analyses will first have to be performed on a case-by-case basis.

Assuming a scenario where Personalised Medicine will grow to account for a quarter of total pharmaceutical market value, this indicates a market potential in excess of $200 bn. (By 2020 the pharmaceutical market is estimated to be worth between $800 billion to $1.3 trillion).

Cancer is the area generating the greatest interest for pharmacogenomic therapies, because it is a very complex and heterogeneous disease which requires better classification, and because the therapies currently available are by and large ineffective and disruptive for patients. Strong demand is also anticipated from the fields of central nervous system disorders, cardiovascular disease and inflammatory disease.

The commercial opportunity from Personalised Medicine can be viewed as coming from four key areas:

- Molecular diagnostics as a stand-alone market;
- Remarket of existing drugs (generic and patented);
- Development of new biologic drugs; and
- Development of new therapies, such as cell therapy, gene therapy, monoclonal antibodies etc.

All segments offer vast and growing prospects, albeit they are progressing at different paces. For example, whilst the molecular diagnostics market is more advanced, the development of individualised drugs and therapies is still in its infancy, thus making it more difficult to forecast the associated market value.

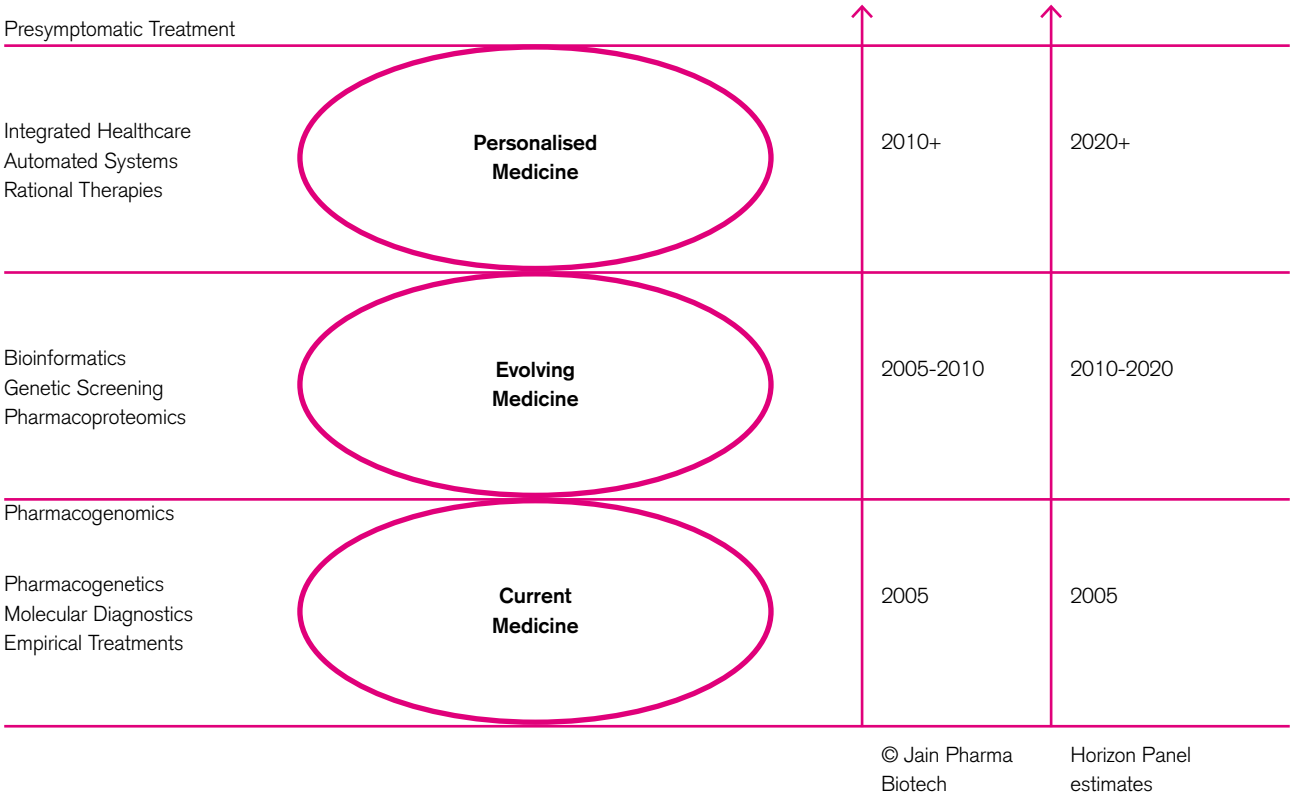
There is considerable overlap among the components, since all involve common fields and techniques, and are inter-related. For example, molecular diagnostics will increasingly become integrated in drug formulation development, as a pharmacogenomic test would be required to predict therapy response based on a patient's genomic profile.
Market size data available for individual fields and technologies is summarised in the tables overleaf.

EXAMPLES OF SUCCESSFUL PERSONALISED MEDICINE DRUGS, TREATMENTS, AND DIAGNOSTICS

THERAPY	BIOMARKER/TEST	INDICATION
Herceptin® (trastuzumab)	HER-2/neu Receptor	For the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease.
Anti-retroviral drugs	TruGene®-HIV 1 Genotyping Kit	Guides selection of therapy based on genetic variations that make the HIV virus resistant to some anti-retroviral drugs.
Cancer treatment regimens	Oncotype DXTM 21-gene assay	Quantifies the expression of 21 genes linked to the likelihood of breast cancer recurrence in women, and the magnitude of benefit from certain types of chemotherapy and hormonal therapy.
Camptosar® (irinotecan)	UGT1A1	Colon cancer: "Variations in the UGT1A1 gene can influence a patient's ability to break down irinotecan, which can lead to increased blood levels of the drug and a higher risk of side effects."
Drugs metabolised by cytochrome P450	Amplichip® CYP2D6/ CYP2C19	FDA classification 21 CFR 862.3360: "This device is used as an aid in determining treatment choice and individualising treatment dose for therapeutics that are metabolised primarily by the specific enzyme about which the system provides genotypic information."
Gleevec® (imatinib mesylate)	c-KIT	Gleevec is also indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors.
Immunosuppressive drugs	AlloMap® gene profile	Monitors patient's immune response to heart transplant to guide immunosuppressive therapy.
Pharmaceutical and surgical prevention options and surveillance	BRCA 1,2	Guides surveillance/preventive treatment based on susceptibility risk for breast and ovarian cancer.
Pharmaceutical and lifestyle prevention options	Familion® 5-gene profile	Guides prevention and drug selection for patients with inherited cardiac channelopathies such as Long QT Syndrome (LQTS), which can lead to cardiac rhythm abnormalities.
Pharmaceutical and surgical treatment options and surveillance	p16/CDKN2A	Guides surveillance/preventive treatment based on susceptibility risk for melanoma.
Tamoxifen	Oestrogen receptor	"The oestrogen and progesterone receptor values [in breast cancer patients] may help to predict whether adjuvant tamoxifen citrate therapy is likely to be beneficial."

*This list is not intended to be comprehensive, but reflects commonly used products as of September 2006. Chart is based on research and industry sources.
BCR-ABL = breakpoint cluster region – Abelson; BRCA 1,2 = breast cancer susceptibility gene 1 or 2; c-KIT = tyrosine kinase receptor; CYP = cytochrome P450 enzyme; HER2 = human epidermal growth factor receptor 2; TPMT = thiopurine S-methyltransferase; UGT1A1 = UDP-glucuronosyltransferase 1A1

ANTICIPATED SECTOR DEVELOPMENT



This diagram indicates the anticipated evolution of the sector on two different timescales: one provided by an industry report, and one adjusted by the Panel, who have a more cautious view of the rate of commercial growth within this sector.

Some technologies such as molecular diagnostics and SNP genotyping already have a fast rate of growth (in excess of 20% per year).

Companies providing toxicogenomic and pharmacogenetic services also enjoy good prospects, because the field is not as overcrowded and there is need for these services in the pharmaceutical sector.

Development of Personalised Medicine will also drive new business opportunities in related branches and industries, e.g.:

- ICT - Providers of information storage and data analysis technologies; Genetic information databases
- Consultants with background in medicine and biotechnology
- Clinical laboratories
- Intelligent materials, such as nanotechnology
- Healthcare counsellors
- Health insurance industry
- Venture capital companies
- Medical devices, e.g. Imaging
- Miniaturisation technology (inc in testing kits), sensors
- Point-of-care diagnostics

Collaboration between global pharmaceutical players and smaller biotechnology companies and academic researchers has increased in recent years, and it is expected to intensify in the future.

COMMERCIAL PROSPECTS - TECHNOLOGY MARKETS

GROWTH OF MARKETS RELEVANT TO PERSONALISED MEDICINE - SUMMARY BASED ON DATA COLLATED FROM A NUMBER OF INDUSTRY REPORTS.

TECHNOLOGY MARKETS	2006 (BILLION $)	2010 (BILLION $)	2015 (BILLION $)	SOURCE
Molecular Diagnostics	7.3	12.0	22.5/92.1 (2016)	Jain PharmaBiotech 2007, Kalorama, 2007
Pharmacogenomics	1.9	2.5	3.8	Jain PharmaBiotech 2007
SNP Genotyping	1.3	2.0	3.5	Jain PharmaBiotech 2007
Pharmacogenetics	0.9	1.8	2.3	Jain PharmaBiotech 2007
Pharmacoproteomics	0.6	1.5	3.8	Jain PharmaBiotech 2007
Point-of-Care Diagnostic Testing	9	11.0	15.0	Jain PharmaBiotech 2007
Genetic Screening	0.9	2.1	4.4	Jain PharmaBiotech 2007
Biomarkers	5.0 (2007)			Waldman & Terzic 2007
Biochips/Microarrays	0.6	4.0		Piribo, 2007
Monoclonal Antibodies	16.0			Arrowhead, 2007
RNAi	0.4 (2005)	0.9		Jain PharmaBiotech 2007
Nanohealthcare products		50.0 (2011)	107.0 (2016)	Freedonia 2007
Nanomedicines		41.0 (2011)	84.0 (2016)	Freedonia 2007
Biomaterials	22.2 (2007)	30.9 (2012)		Business Communications Company 2007
Systems Biology (products & services)		0.8 (2008)		Drug & Market Development Publishing 2004
Bioinformatics		3.0		RNCOS 2006
Epigenomics	0.3	4.1 (2012)		Business Communications Company 2007
Metabolomics		2.0 (2012)		Jain PharmaBiotech 2007
Functional Foods	72.0			Nutrition Business Journal, 2005
Regenerative medicine			$500bn (2020+)	Technology Strategy Board 2007

The figures are not totalled because of considerable overlap between markets, e.g. some technologies such as biochips are part of the overall diagnostic market.

COMMERCIAL PROSPECTS - GEOGRAPHICAL MARKETS

MARKETS FOR PERSONALISED MEDICINE FOR SELECTED THERAPEUTIC AREAS

THERAPEUTIC AREAS	2006 ($ BN)	2010 ($ BN)	2015 ($ BN)
Cancer	3.9	10.5	16.2
Nervous system	2.5	5.1	7.1
Cardiovascular system	1.2	2.2	3.5
Genetic disorders	0.6	1.3	3.3
Pain	0.4	0.7	1.2
Inflammatory disorders	1.3	2.5	3.5
Miscellaneous diseases	1.6	2.7	5.7
Total	**11.5**	**25**	**40.5**

Cancer is the area generating the greatest interest for pharmacogenomic therapies, because it is a very complex and heterogeneous disease which requires better classification, and because the therapies currently available are, by and large, ineffective and disruptive for patients.

Source: Jain PharmaBiotech, Personalised Medicine: Scientific and Commercial Aspects, July 2007

FORECAST GEOGRAPHICAL MARKETS FOR PERSONALISED MEDICINE

REGIONAL MARKETS	2006 ($ BN)	2010 ($ BN)	2015 ($ BN)
USA	7.0	13.2	19.5
Europe	2.7	6.1	10.2
Japan	1.1	1.5	2.0
Rest of the world	0.7	4.2	8.8
Total	**11.5**	**25**	**40.5**

This is still an immature market; there are only a few personalised medicines and therapies in the marketplace at present. Some of these are combinations of therapeutics and diagnostics. Their number, however, is anticipated to increase during the next decade.

In addition to the development of new drugs, the market will also see some of the existing drugs becoming used in a personalised manner.

Source: Jain PharmaBiotech, Personalised Medicine: Scientific and Commercial Aspects, July 2007

NORTHERN IRELAND CAPABILITY - LIFE SCIENCES SECTOR

The primary focus of the Life and Health Sciences Horizon Panel was to consider the global market opportunities within this sector. A parallel study commissioned by the broader Matrix panel examined the existing Northern Ireland capability within technology intensive sectors (Life sciences, Advanced Manufacturing; Advanced Materials; Sustainable Production and Consumption, including energy technologies, and Information and Communications Technology). BioBusiness Northern Ireland has also conducted a capability review of the local Health technologies cluster in 2006.
This section provides a snapshot of the local capability profile across the ABC sectors, with full details available in the two preceding capability studies.

Life Sciences Capability
A number of key building blocks in the development of Personalised Medicine already exist in Northern Ireland, across the private, academic and clinical (A B C) sectors, albeit they have developed by and large independently from each other and are lacking critical mass compared to other regions.

In the business sector, the emerging biotechnology sector is represented by a number of leading edge companies that operate entirely or in part in this space. Four of them are longer established (Almac Diagnostics - Cancer Diagnostics and contract genomic services; Fusion Antibodies - antibody-based therapeutics for cancer and recombinant proteins contract services, Randox laboratories – protein biochip multinanalyte diagnostics; Warner Chilcott – feminine care products) and two are smaller, more recent spin-off companies (Diabetica - Diagnosis and treatment of obesity and diabetes, and Gendel Ltd - Cancer treatment device).

The private sector also consists of a number of companies from related fields of life sciences that can both benefit from and feed into the development of the Personalised Medicine sector; these are: Pharmaceuticals, Diagnostics and Clinical research organisations. The boundaries between fields are expected to blur in the future, as more companies begin to incorporate a genomics-based approach to product development.

Northern Ireland lacks the presence of large multinational companies that would help drive demand locally and enhance the profile of the cluster.

The academic sector in Northern Ireland offers a strong scientific base. There are over 33 relevant research clusters and groups across QUB and UU, carrying out high standard research in areas such as molecular biology, cell biology, genomics, proteomics, metabolomics, bioimaging, bioinformatics, systems biology, human nutrition etc.

Understandably, the largest part of the research carried out within the two universities tends to be fundamental in nature. Most of the commercial research undertaken tends to be exported to leading companies in the UK and further afield. Whilst collaborative programmes with local companies are expanding (e.g. Almac, Warner Chilcott, Diabetica), there is scope for enhancing further the links with the local private sector.

An emerging research area in the FE sector is functional foods, which focuses on the convergence of pharmaceutical, health and agri-sciences and aims to develop a holistic system, integrating genomics and customised diets through to packaging and environmental management.

There is a call for the education sector overall to respond more closely to the skill needs within the industry, for example in terms of a mix of pure and applied science specialisms, recognition of converging technologies and fields, and volume and quality of graduates and PhDs.

The clinical sector capability could play a major role in supporting the development of Personalised Medicine locally. The clinical strengths stem from a number of key areas:

- Clinical research: through the seven Recognised Research Groups (Cancer, Child Health and Welfare, Vision, Diabetes, Endocrinology and Nutrition, Neuroscience and Mental health, Infectious Diseases; Trauma and Rehabilitation), the Northern Ireland Clinical Research Network, The Experimental Cancer Medicine Centre, and the Clinical Research Support Centre.
- Clinical data - The Northern Ireland Longitudinal study, the Nucleic Acid Extraction Centre (extraction and storage of DNA and RNA to support clinical genetics research)
- Clinical practice: clinical trials expertise, clinical chemistry and pathology, etc.

This diagram summarises the scientific capability in the Health technologies sector in Northern Ireland and the level of commercial exploitation; the dotted circle highlights those components that are of particular relevance for the development of Personalised Medicine. The diagram suggests that in areas such as clinical trials and biotechnology the commercial sector is more advanced in successfully exploiting the local scientific capability, However, a focused effort is required to more fully realise the potential offered by the scientific strengths in areas such as systems biology and diagnostics. This could be achieved through collaborative programmes for knowledge and skill transfer, technology licenses, or creation of well supported spin-off companies.

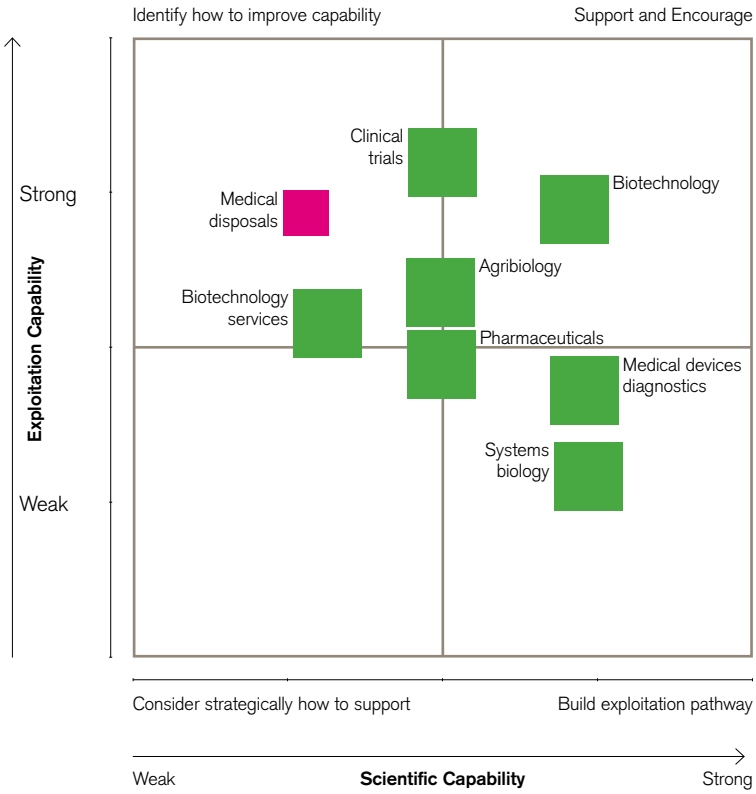
Where the local capability is weaker or gaps exist, Northern Ireland needs to be proactive in sourcing the necessary skills or resources, be it through acquisition (e.g. target leading scientists) or collaborative programmes with external research and commercial partners.

Whilst collaboration programmes between the local ABC sectors have intensified in recent years, most of the local players recognise the opportunity for further partnerships for mutual benefit. Examples of significant joint initiatives include: Nanotec Northern Ireland (QUB and UU), Northern Ireland Clinical Research Facility (QUB, UU and Royal Group of Hospitals Trust – due to commence in 2010), ABC Research Innovation Facility (UU and Altnagelvin Hospital), Advanced Biological Imaging Centre (North-South Collaboration).

Complementary capability

Adoption of Personalised Medicine in Northern Ireland should also draw on local capability in complementary sectors and technologies, particularly ICT (e.g. bioinformatics) and Advanced Materials (e.g. nanostructures). The diagrams overleaf summarise the scientific and exploitation capability of the two sectors. DETI's Technology Capability Study profiles these complementary sectors in more detail and indicates that there is scope for further strengthening the level of cross-sectoral collaboration in Northern Ireland, for mutual benefits.

LIFE SCIENCES CAPABILITY IN NORTHERN IRELAND



Potential impact on NI economy

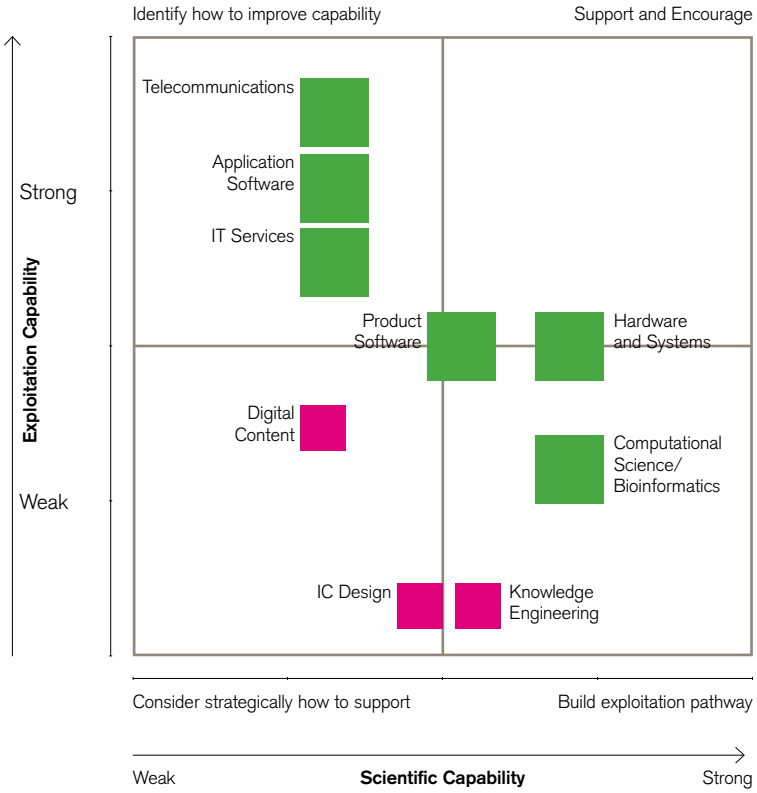
	Small
	Medium
	Major

Timescale to realise impact

	Current (<2 years)
	2-5 years
	5-10 years
	10 years

NORTHERN IRELAND CAPABILITY - COMPLEMENTARY SECTORS

ICT CAPABILITY IN NORTHERN IRELAND



Potential impact on NI economy

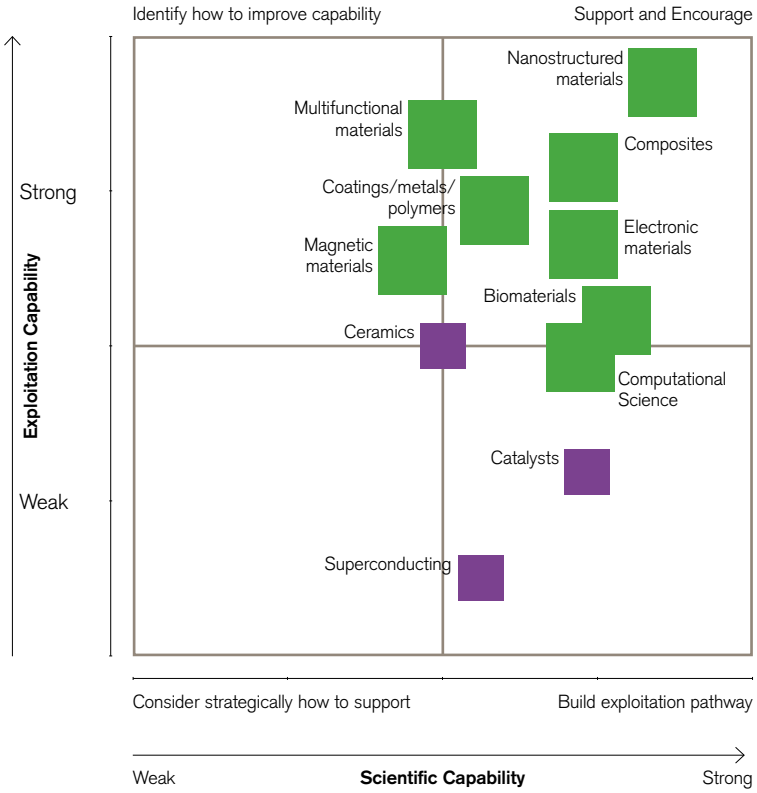
- Small
- Medium
- Major

Timescale to realise impact

- Current (<2 years)
- 2-5 years
- 5-10 years
- 10 years

Source: DETI Technology Capability Study, Nov 2007

ADVANCED MATERIALS CAPABILITY IN NORTHERN IRELAND



Potential impact on NI economy

	Small
	Medium
	Major

Timescale to realise impact

	Current (<2 years)
	2-5 years
	5-10 years
	10 years

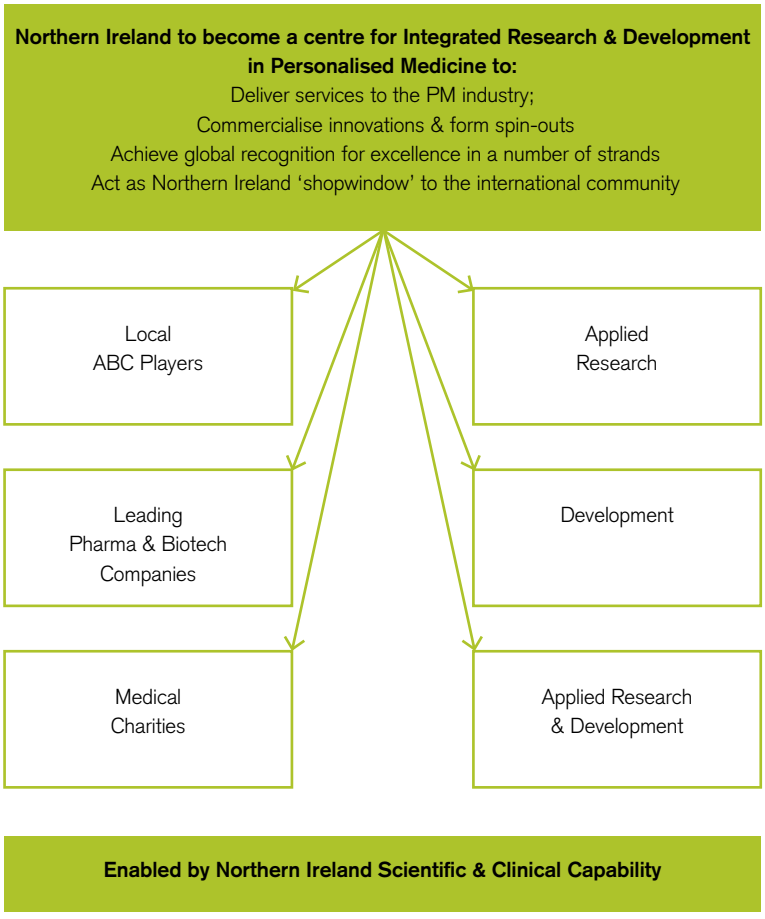
THE OPPORTUNITY FOR NORTHERN IRELAND

As the market intelligence indicates, in the longer term this sector has the potential to transform the way medicine is delivered. Many nations have identified the opportunities offered by this high risk - high reward sector, and investment in research and commercialisation in this space has intensified in recent years.

The Life and Health Sciences Horizon Panel has identified an opportunity for Northern Ireland to carve out a share of this growing market, by becoming a centre for Integrated Research & Development in Personalised Medicine. This would help fuel the development of Personalised Medicine in Northern Ireland, and place the local cluster on the international map in this highly dynamic sector. The competitive advantage would be conferred by the integrated nature of the services provided, harnessing academic scientific expertise, clinical data and practice and a focus on commerciable outputs.

This will allow the local cluster to develop in a number of ways:

- Development of existing businesses, by accessing expertise and knowledge from the local and international scientific community;
- Attracting high quality research and FDI to Northern Ireland; and
- Generating new company spin-outs from the existing science base.



REALISING THE PERSONALISED MEDICINE OPPORTUNITY FOR NORTHERN IRELAND

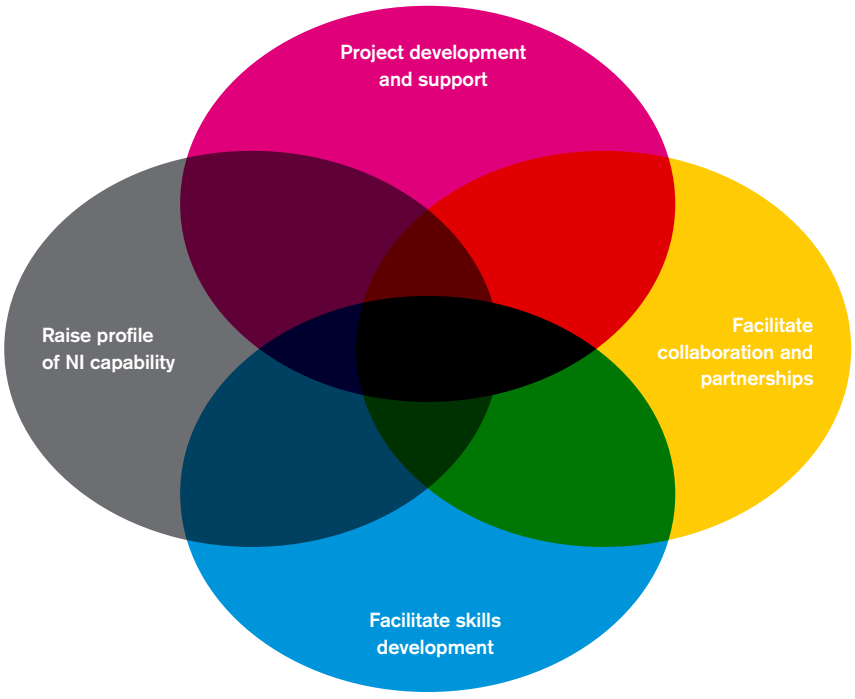
The Panel believes that the sector could be stimulated locally by creating the environment for the initiation of commercially-targeted R&D projects, focussing funding and support towards applied research not elsewhere funded and the gap between initial Proof of Concept and Phase II Clinical trials.

It is believed that, given the recent developments in local infrastructure, a 'virtual' support mechanism would be sufficient, providing leadership, funding and expert support rather than new physical infrastructure.

Being open to the full spectrum of the Personalised Medicine technologies and practices, would stimulate interest from across the sector and allow the best economically valuable proposals to emerge.

A highly focused approach to the development of this exciting sector would help drive closer cooperation and capability transfer across the ABC boundaries, thus enhancing the exploitation capability within the local sector and raising its position in the international arena. The sector would also be able to communicate with a single voice and engage in a coherent manner with the local support mechanisms and stakeholders, to promote skills development and raise the profile of the local cluster.

POTENTIAL HOLISTIC APPROACH TO REALISING THE PERSONALISED MEDICINE OPPORTUNITY IN NORTHERN IRELAND



KEY STAKEHOLDER INPUTS & OUTPUTS

THE IMPLICATIONS IN TERMS OF COMMITMENT, RESOURCES AND BENEFITS FOR EACH OF THE LOCAL STAKEHOLDER GROUPS CAN BE SUMMARISED AS FOLLOWS:

NI ECONOMY	ACADEMIC STAKEHOLDERS	BUSINESS SECTOR	CLINICAL SECTOR
Inputs • Creating an innovation- and business-friendly environment • Help raise the profile of the local capability • Attract lead scientists from abroad and international research partners	**Inputs** • Academic research staff • Enhanced PhD pool • Research facilities • IT capability • International research partners	**Inputs** • Business expertise • Research expertise & facilities • Financial investment	**Inputs** • A commitment towards adoption within the local clinical practice • Clinical research expertise • Clinical data • Research facilities
Outputs • Development of existing businesses, by accessing expertise from the local and international scientific community • Spin-out companies, generating associated tax revenues and employment • FDI traction • Emergence and recycling of local entrepreneurs • International reputation, which in turn generates new business	**Outputs** • IP creation, which can be commercialised through spin-out companies or licensing deals • Spin-out companies • Skills development & export • Enhanced international profile	**Outputs** • Extended new product pipeline • Reduced R&D costs • IP creation, which can be commercialised through spin-out companies or licensing deals • Attract and retain talent • Industry cross-fertilisation (e.g. ICT, Advanced Materials, Agri-food)	**Outputs** • IP creation, which can be commercialised through spin-out companies or licensing deals • Improved patient care, through rational therapeutic decisions rather than trial-and-error approach • Cost savings in the long term, through increasing emphasis on prevention and early intervention

HOME-BASED CARE MARKET - THE OPPORTUNITY FOR NORTHERN IRELAND

3

DEFINING THE MARKET

The terminology and definitions for this market vary across industry sources. The expressions 'eHealth', 'telemedicine', 'telecare', 'telehealth', and 'assistive technology' tend to be used interchangeably.

A brief description of the key market segments making up this broad sector is given below.

The first three market segments concern the link between patients in their home and the health system, and these fall within the scope of the Horizon Panel's core proposals.

Telehealth
Telehealth monitoring is the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis, progress monitoring and prevention of various conditions. Specific product examples include home-based blood pressure monitors that relay information to the patients GP surgery. Their immediate applications tend to lie in the management of chronic disease (e.g. diabetes, cardiovascular etc). The preventative and personal health management aspects are expected to become more pervasive in the longer term.

Telecare
Telecare is the continuous, automatic and remote monitoring of real time lifestyle changes and emergencies over time, in order to manage the risks associated with independent living. Telecare is usually designed to create home environments which meet the needs of older or disabled people. Specific product examples include fall or bed sensors.

Secure web messaging and e-visits
This technology usually acts as an enabler for the previous two areas of remote care. Consumer familiarity with the Internet and e-mail allows for more efficient communication with medical staff and for novel healthcare solutions. A specific example of an e-visit could be an email exchange between a doctor and patient.

The market also includes technologies and services based exclusively within the health system (telemedicine) or within the patients' physical home infrastructure (assistive devices). These do not form part of the Panel's core proposal, but instead are recommended for consideration in the longer term. They are defined as follows:

Telemedicine
Telemedicine refers essentially to doctor-to-doctor communications, and typically involves consultations with specialists at a distance (e.g. general hospital or General practitioner to Specialist doctors, Ambulance staff to Acute Care hospital). This includes the delivery of medical care, diagnosis, consultation and treatment, as well as health education using interactive audio, visual and data communications.

Assistive devices/Aids
Assistive technology products are designed to compensate for motor, sensory and cognitive difficulties frequently experienced by disabled people or older adults. Assistive technology encompasses a broad range of devices, from "low tech" products such as eyeglasses, large-print books or a walking stick, to technologically sophisticated products such as voice synthesisers, smart seats, and stair-climbing wheelchairs.

Intelligent houses
Intelligent houses provide a number of physical and electronic features which facilitate day-to-day activities in the house for older people or those suffering form certain disabilities. An example of such a device in a smart home may be a water tap that can be turned on and off using a button panel or a remote control device rather than the conventional tap.

KEY DRIVERS AND CHALLENGES IN THE DEVELOPMENT OF THE GLOBAL HOME-BASED CARE MARKET

KEY DRIVERS

In coming to their conclusion, the Panel members considered the key drivers and challenges influencing the development of the global Home-based care market.

Current healthcare systems are unsustainable
Healthcare systems in the developed world are under pressure due to an ageing, more chronically ill population that requires more and more medical attention. The traditional care delivery model is based on an acute care model (disease is only treated when it strikes) and is bound to healthcare facilities (patients have to go to hospitals or clinics to be treated). A shift in approach will be required to improve people's overall quality of life through preventive programmes, whilst at the same time significantly reducing medical costs.

There are social and financial benefits associated with the home care concept
Comprehensive telecare is anticipated to reduce the scope of institutional approaches because it is less costly while also delivering greater benefits to people living in their own home.

Advancement of Technologies and IT infrastructures
There is a consensus that healthcare IT can transform the care delivery systems. IT will form a higher proportion of healthcare budgets as the sector tries to achieve the efficiencies seen in other industries;

Rising expectations of consumers
The developed world population is more educated and mobile. They demand more information regarding their health status and involvement in their healthcare decisions and telehealth can, in principle, allow them to have both.

Adoption of Electronic Health Records (EHR)
The adoption of EHR for more general medical record-keeping will act as a further driver of remote health in terms of the requirement to manage the large the volume and different types of data (text, sound, picture) that will be produced.

KEY CHALLENGES

Slow adoption by healthcare systems
Although the role that telecare could play in reducing costs and enhancing independent living is recognised at strategic level across European and other national governments, adoption in mainstream care is still limited. There are a wide range of explanations given for this including a resistance to the adoption of Information Technology and difficulties in changing reimbursement systems within the GP community.

Policy issues remain to be addressed
A viable model for implementation of telecare is yet to be fully defined. Prioritising certain patients for 'additional' services can only be achieved against established procedures. This is made more complex in circumstances were the intervention is preventative.

Integration into existing healthcare system
Telecare should be an integrated health, housing and social care service, and this raises a number of administrative and funding questions. Integration across public services has so far been slow.

Maintaining individual privacy
Telecare raises ethical questions about surveillance and possible loss of privacy and autonomy, and legal issues relating to confidentiality and data protection.

Lack of coherent approach
Many telecare pilots and initiatives have been run independently and on a small scale. The consequent lack of co-ordination has led to some technical incompatibility and duplication of effort. At the same time, in the private sector there is a lack of standardisation and inter-compatibility between markets and manufacturers.

Technology development
While currently available telehealth solutions are new and exciting, they are also undeveloped. As an emerging technology, telehealth has not reached its potential technological capabilities nor has it successfully targeted the different aspects of healthcare.

DRIVING POLICES AND INITIATIVES IN THE SECTOR

Whilst the USA leads in the adoption of telehealth technology, given the insurance-driven structure of the health sector, the benefits of telehealth are becoming of increasing interest to European countries and the rest of the world.

A high number of key driving policies and initiatives within this sector within the UK, Europe and the wider world have been identified and reviewed as part of this research. Three particular initiatives of direct relevance to the model proposed by the Panel should be noted:

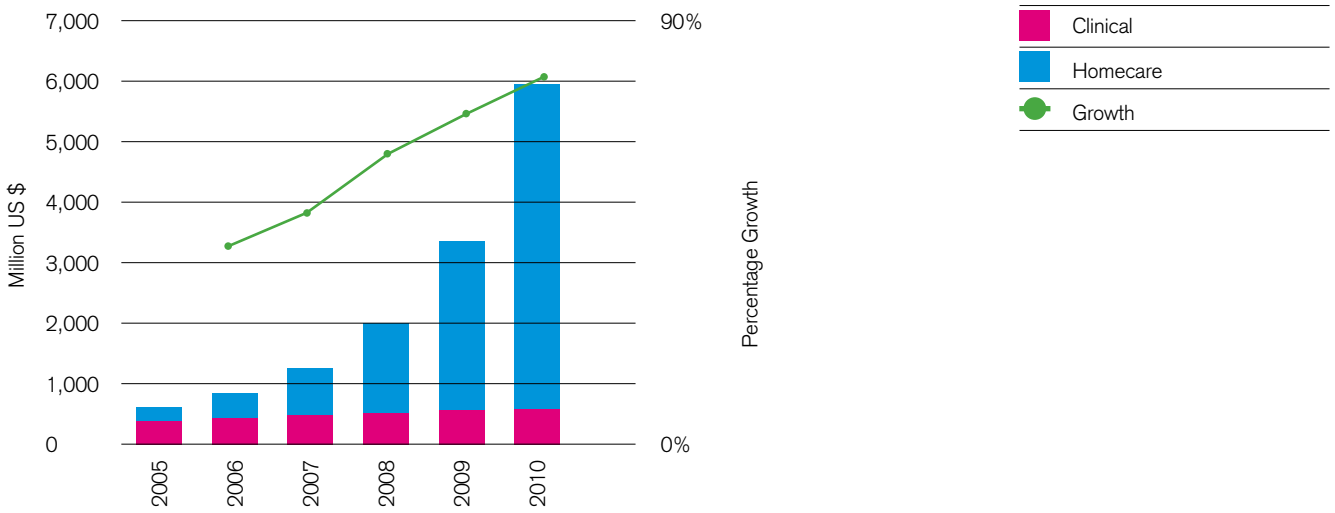
- In the UK, the Assisted Living Innovation Platform (ALIP) was launched in November 2007 and promises significant funding towards addressing the issues around deployment of technology in healthcare and user-centred delivery;
- The 'Whole System Long Term Conditions Demonstrator Programme' was announced in November 2006. This is the largest ever pilot of telecare and telehealth in the UK, covering three sites: Kent, Newham and Cornwall. Funding is worth £12 million and will cover a population of one million between 2007-2009. The first evaluation results from this programme will be available early in 2008;
- Locally, the DHSSPS recently supported a feasibility study on the establishment of a European Centre for Connected Health in Northern Ireland. The outcome of this study was published early in 2008 and is proceeding with stated support from DHSSPS, DETI and DEL as well as the private sector locally and internationally. Any assessment by the Matrix panel of the prospects offered by the Home-based Care market should consider concurrently the outcome of this study.

Examples of projects that have tested and demonstrated the viability of home-based care are provided below.

FUNDER	PROJECT	DESCRIPTION	OUTCOMES
Northants Council	'Safe at Home' Focused on individuals with some degree of cognitive impairment or dementia	Deployment of a variety of assistive devices; 15% of service users also received selected wireless monitoring sensors linked with a telecare response centre	Net saving of £6,458 per treatment per person over 21 months
West Lothian Council	'Opening Doors for Older People' Running from 1999: By 2006 assisting 2,150 elderly persons (+65) living at home, some with dementia	Participating households were supported with a 'community package' which included telecare technology, a 24/7 Council run alarm response facility and 10 hours/week of at home health care services	Net average saving of £14,719 Saving of £1.9 million annually on acute care hospital bed days Project's current target is to keep 10,000 people at home; it only needs to keep 40 people out of institution care per year to break even
Croydon Council and South London and Maudsley NHS Trust	Launched in February 2004 specifically for people with dementia; now expanded to other patient groups	Range of stand-alone assistive devices and telecare sensors linked with a 24-hour response team operated by a community alarm service	The average telecare package costs over £1,100 per service user but achieved savings of over £7,000 per service user. When care package costs are subtracted from nursing or residential care fees that would otherwise apply, this is equivalent to annual savings of £12,000/user.

COMMERCIAL PROSPECTS

OVERALL TELEHEALTH MARKET IN EUROPE AND NORTH AMERICA BY HOME AND CLINICAL SETTINGS (2005-2010)*



The overall market for telehealth in Europe and North America is anticipated to show rapid growth, rising from of $591 million in 2005 to $5.96 billion in 2010.

Clinical environments currently form the largest market. This is a more mature market, but is still forecast have an 8% CAGR to 2010. This will be driven by both new applications in the traditional remote treatment market and the extension to new environments such as hospital ICUs.

The homecare market is anticipated to show the highest growth, as installations in the home move from trials to full-blown implementations. With 20 million sufferers with Congestive Heart Failure (CHF), 34 million with Chronic Obstructive Pulmonary Disease (COPD) and 46 million with Diabetes, the sheer potential scale of the homecare market will help to power growth at a 91% CAGR. Homecare telehealth in Europe and North America is forecast to reach $5.39 billion by 2010.

The US is, and will remain, easily the largest national market for telehealth, reaching $4.51 billion in 2010. It will also show faster growth than Canada at 64% CAGR, compared with 32% for the latter. This very high growth and large market share are the result of two main features of the US market:

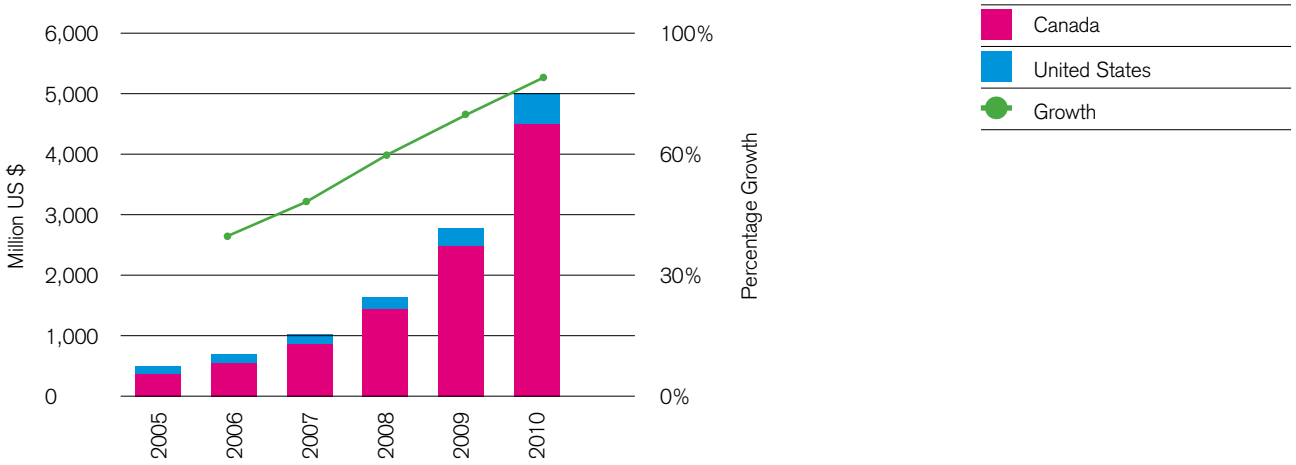
- Very high overall US healthcare spending, given the private care and insurance-based system;
- High and rapidly growing rates of chronic diseases such as diabetes.

In comparison, the entire European market is expected to only reach about $1.00 billion by 2010, despite having a projected population of 502 million people.

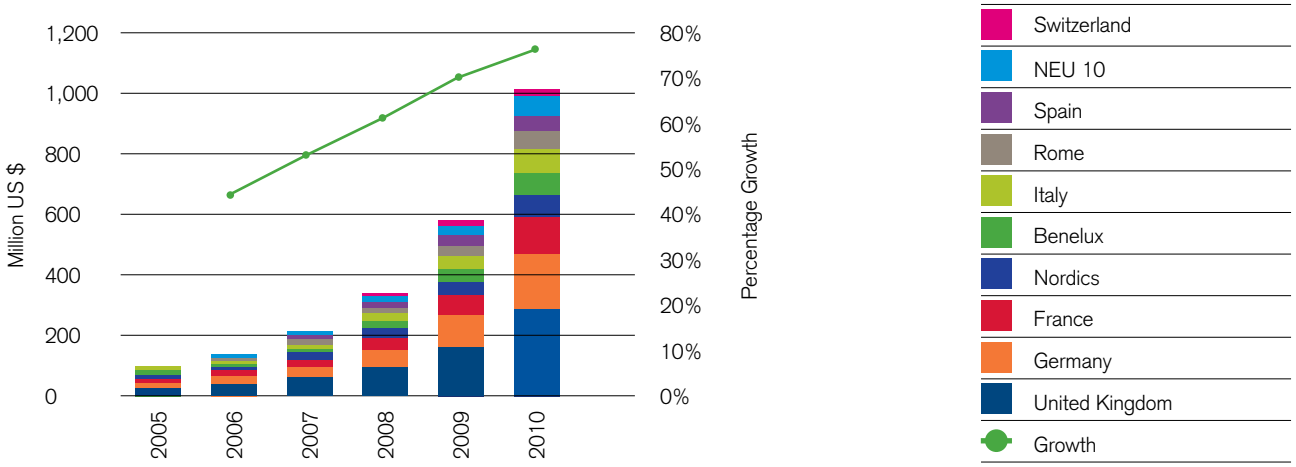
The European market may be smaller than that in the North America, but it will still show very rapid growth, with an expected CAGR of 60% over the period. The UK is the largest single market at $23 million and will grow by 66% CAGR to $286 million in 2010. The ten new EU nations (NEU 10) will be the fastest growing market, with a CAGR of 69%, but will still only reach a value of $60 million in 2010.

* Source: Datamonitor, Extending the delivery of healthcare beyond the hospital setting, June 2006

TELEHEALTH MARKET IN NORTH AMERICA BY COUNTRY (2005-2010)



TELEHEALTH MARKET IN EUROPE BY COUNTRY (2005-2010)



Source: Datamonitor, Extending the delivery of healthcare beyond the hospital setting, June 2006

THE OPPORTUNITY FOR NORTHERN IRELAND

The Life and Health Sciences Horizon Panel recommends that Northern Ireland becomes the first UK region committed to the early adoption of a telehealth system within the Health and Social Care practice. This means establishing a strong local capability across the telehealth continuum, and deploy this locally to achieve whole connectivity between the health sector and the home within 15-20 years.

The Panel considers that such a policy will accrue the following benefits to the Northern Ireland economy:

- Economic benefits - the establishment of Northern Ireland as a test bed for new technology is anticipated to attract Foreign Direct Investment, stimulate indigenous companies in the sector and create a knowledge base from which export potential can be exploited;
- Positioning Northern Ireland as a good place to live, hence retaining and attracting people to the local economy;
- Improved health and quality of life for relevant patient groups through enhanced independent living; and
- Realisation of cost-savings in the local healthcare system, which can be redistributed towards other priority areas within the healthcare system, thus increasing productivity levels.

The illustration provides a high level depiction of the proposed concept.

Such an approach would support and help accelerate the adoption of home-based care within the Northern Ireland. At the same time, it would provide a consistent and coherent message to the private sector, encouraging them to invest within the Province.

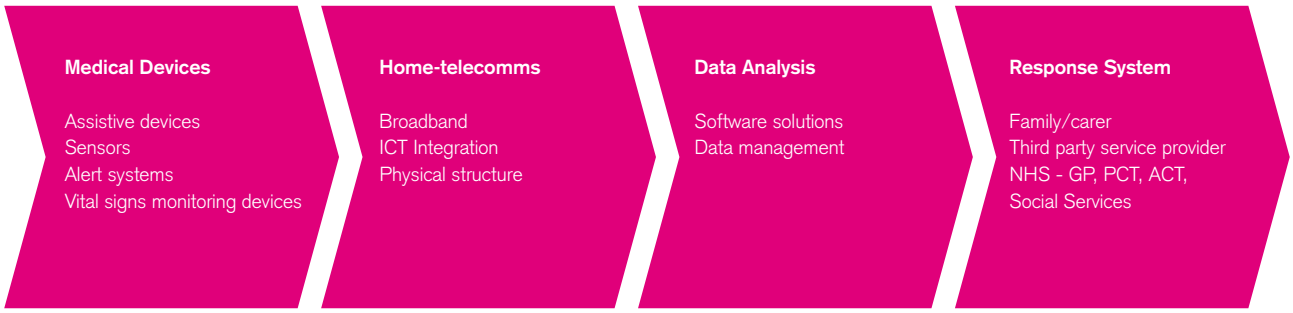
The Home-based Care market encompasses a wide range of products and services. The underpinning technologies and systems necessary to deliver those services can be sub-divided into four key domains along the telehealth continuum, as summarised in the diagram above.

The overall aim of the model proposed for Northern Ireland is to join-up local capability across all four of these domains in an integrated manner and in a real clinical setting.

The Panel concluded that to maximise the market opportunity in this area, telehealth technology should be implemented within our own Health system.

- This would allow the DHSSPS to benefit from savings achieved from the delivery of health services in this manner, whilst improving patient care; and
- At the same time, it would create an attractive Whole System Integration Test Bed for local and international technology providers, who could use Northern Ireland as a gateway to UK and European home care export markets.

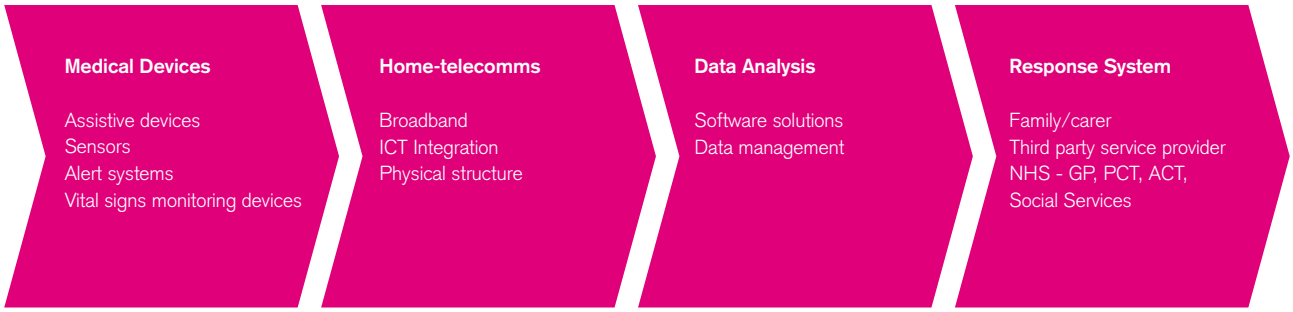
NORTHERN IRELAND POSITION ALONG THE HOMECARE CONTINUUM: WHOLE SYSTEM CONNECTIVITY



REALISING THE HOME-BASED CARE OPPORTUNITY FOR NORTHERN IRELAND

The Panel considered the market opportunity against the four key areas judged to be part of the home-based care continuum. Each of the four areas were examined in turn and the opportunities for exploitation considered. Each area is considered in more detail opposite.

DEMAND VS NORTHERN IRELAND POTENTIAL ALONG THE HOMECARE CONTINUUM



Support indigenous companies

Build partnership(s) with global leaders

FDI opportunities

Provide 'simple' broadband connection system or leverage existing connections

Broadband speed to match Europe and Japan

Ensure device fits around the family and not vice versa

IT/data management/ bioinformatics including nutritional data

e.g. NHS Direct capability

Link second generation solutions to shortcomings identified in large scale programs

Structural organisation

Take barriers away

Effective and efficient

Structure in place that rewards integrated healthcare system engagement

Medical Devices
The Panel noted that a local capability existed within Northern Ireland within the medical device sector. However it was also noted that these companies lacked a scale within the market. All of the companies had to seek an export market as there was currently little potential for growth domestically.

It was acknowledged that a strategy could be developed to build upon the existing capability by seeking additional foreign direct investment into the province and by developing partnership agreements.

Home-based telecommunications
The development of a home-based care market will require a high speed telecommunications infrastructure. The panel members judged that Northern Ireland was already well served in this area compared to other regions in the UK given the existing 100% broadband coverage. However, the ability to generate a economic capability by developing companies to compete within the technology infrastructure sector was not judged to be strong given the dominance of the existing technology competitors.

Data Analysis
The development of a Home-based care market will require a capability in managing and analysing large volumes of data. The Panel judged this was not an area were a significant capability existed locally at present but from preliminary discussions with the Horizon ICT Panel it was an area that could be further explored for future investment.

Response System
The specific circumstances of each patient group and the economic case for each initiative will determine the response system employed. The options to consider would include:

- Response to be delivered within the DHSSPS; if so, what are the interface points - e.g. GPs, Social services, others;
- Response to be provided by a family member;
- Response to be delivered by a 3rd party provider; if so, what type of activities specifically and associated governance; or
- Combination of service delivery;

The Panel considered that the most important success factor was not the creation of infrastructure. Instead, it was ensuring that the existing response resources (e.g. GP surgeries, District nurses etc) were motivated and incentivised to adopt this way of working.

Government support
The announcement made in January 2008, regarding the development of an European Centre for Connected Health supported by three Northern Ireland government departments, is a powerful springboard for future development of the concept. The project has significant buy-in from the private sector locally and internationally.

NORTHERN IRELAND CAPABILITY

A few examples of the Northern Ireland existing capability in this sector are provided below.

Private sector companies

Health Tek
Work in partnership with hospitals and other clinical units to provide clear, high quality, real time data on a variety of patient behaviours. Provide devices that automatically update a database at a control centre as the patient uses them.

Quality Health Care at Home
Use technology to remotely monitor patients with Congestive Heart Failure, COPD, Diabetes and CHD. Quality Healthcare monitor data transmitted to them from the patients home.

BootRooms.com
Experts in robotic home automation which includes adjusting the security, cooling, heating and lighting of a home automatically.

ST&D Ltd
Develop and manufacture non-invasive vital signs monitoring systems.

James Leckey Design
Design and manufacture positioning equipment for children with cerebral palsy, muscular dystropy, spina bifida and other special needs.

Bluescope Medical Technologies
Develop products for the cardio-pulmonary monitoring and care of patients including a non-invasive device for the long term continuous recording and monitoring of breath and heart sounds.

Diabetica
Innovative research in diabetes and obesity therapeutics.

Tomcat Systems
Provide tailored computerised information systems for managing all the clinical and administrative records of today's hospital departments.

A number of other companies operate in complementary areas, such as: IT, telecommunications (BT), precision engineering, contact centres, medical devices etc.

Academic & Clinical Developed Technologies

Diabetes - Di@log
Created by the UU Infor-MED team of PhD students and consultants and Dr Roy Harper, Ulster Hospital. The device allows doctors to monitor and track diabetes patients from home using intelligent spoken dialogue technologies which can relay patient data directly to the clinic through telephone conversations. The product has recently entered home patient trials.

Neurological conditions
Dr David Craig, QUB and Dr Victor Patterson, UU - involved in a major EU-funded international project which aims to develop and prototype a portable, easily configurable, device that is available to those people with memory lapses and other symptoms of early mild dementia and associated disorders.

Cardio conditions
Dr Frank Casey, UU

Similar to other regions of the UK, a number of telecare pilots and technology development programmes have taken place in Northern Ireland as well in recent years. Examples include:

Lisnaskea Information & Technology Enterprise (LITE) Centre
A cross-border initiative involving a number of public and private sector partners. The project is led by Fermanagh-based McElwaine SMART Technologies. Valentia Technologies (Ireland based) will deploy its CareMonXTM Home Appliance system in conjunction with McElwaine's newly-opened monitoring and services centre in Lisnaskea to provide elderly clients with a range of integrated healthcare and social services via a simple-to-use touch screen appliance that will be installed in clients' homes. The monitoring and response service will utilise a Bosch telecommunications platform and homecare monitoring devices. A University of Ulster team is also involved in developing new telehealth components.

Nestling Technologies project
A collaborative project between the University of Ulster and the Dundalk Institute of Technology. Aims to provide environments that promote and sustain independence and well-being for older people through the fusion of innovative accommodation, technology and integrated community care-based approaches. The project will run over a five year period and will consist of an integrated care demonstration model of 12 homes, in Dundalk.

Knockeden project
Based on a partnership between Craigavon & Banbridge Community HSS Trust , Fold Housing Association and Tunstall Group. Telecare devices such as epilepsy sensors were used to monitor patients remotely.

Going Home, Staying Home
A small scale programme supported by Foyle Health & Social Services Trust, the Northern Ireland Housing Executive and Fold Housing Association. The project run between 2002-2004 and involved three parts: telecare (tested a number of assistive devices in an elderly household), telehealth (reablement of two patients discharged early from hospital) and linking a GP practice to 10 users. (Source: www.tis.bl.uk)

ECONOMIC BENEFITS

Commercial benefits
The economic return from this sector must be viewed not only from the perspective of the savings that can be achieved within the local healthcare budget, but also from the perspective that, by generating a local capability to service our internal market, an export opportunity will have been created.

This is anticipated to happen as a result of attracting FDI companies to use Northern Ireland as a UK/European hub for their operations, and by enabling indigenous companies to expand their reach after successfully trialling their products within a Northern Ireland 'test bed'.

Benefits to the local healthcare system
The Panel concluded that to maximise the market opportunity in this area Home-based Care technology should be implemented within our own Health system. This would allow the DHSSPS to benefit from savings achieved from the delivery of health services in this manner.

The panel considered the evidence published by a number of pilot studies within the UK. In particular, a study in West Lothian entitled 'Experience Independent Living' was considered. The key highlights from that study were as follows;

- Hospital stays down to 30 days (cf. 112 Scottish ave.) for those assessed ready to leave;
- 3000+ hospital bed nights saved p.a. (net £0.3M saving p.a.);
- Private care home occupancy 18mths average (was 36mths); and
- 10% of users at home as alternative to 'institutional care' meeting demands for independence & choice (net saving £1.69M per annum)

Furthermore the Panel considered the evidence presented within a report prepared by Professor Barlow, Imperial College London, entitled 'A systematic review of the benefits of home telecare for frail elderly people and those with long-term conditions.' J Telemed Telecare. 2007;13(4):172-9.

This paper examined the results from 8,666 studies and concluded 'the most effective telecare interventions appear to be automated vital signs monitoring (for reducing health service use) and telephone follow-up by nurses (for improving clinical indicators and reducing health service use).'

The Panel also engaged with a number of leading experts in the Home-based Care market to validate the findings of the research undertaken.

The Panel acknowledged that savings that may be achieved as a result of the implementation of this technology were likely to be redistributed elsewhere within the Health service, which is under considerable budget constraint.

KEY STAKEHOLDER INPUTS & OUTPUTS

THE TABLE BELOW SUMMARISES THE COMMITMENT NECESSARY FROM GOVERNMENT, ACADEMIA, BUSINESS AND THE CLINICAL FIELD TO SUCCESSFULLY DELIVER HOME-BASED CARE WITHIN THE NORTHERN IRELAND ECONOMY. THE TABLE ALSO HIGHLIGHTS THE POTENTIAL RETURN FOR EACH RESPECTIVE GROUP.

GOVERNMENT	ACADEMIC STAKEHOLDERS	BUSINESS SECTOR	CLINICAL SECTOR
Inputs • A commitment to a 'connected health' agenda • A commitment to a joined up approach to the market opportunity • Embrace an attitude of change	**Inputs** • Social studies • ICT capability • Curricula for new disciplines in eHealth	**Inputs** • An investment in new technologies • A long-term contractual commitment to the public sector	**Inputs** • A commitment to changing working practices • Adjusting reward structures
Outputs • Stimulate indigenous companies • Create a knowledge base from which export potential can be exploited • Attract FDI companies, interested in using NI as a test bed for their technology and gateway to UK and European markets • A demonstration of the Government's commitment to smarter working practices to improve patient care	**Outputs** • Graduates to fulfil a new model of health delivery • Growing reputation in the field of Home-based Care	**Outputs** • An opportunity to participate in locally significant market with the potential to export know-how	**Outputs** • A new model of healthcare management • Improved independent living and quality of life for patients • Improved work practices for health professionals • Better management of healthcare costs

FRAMEWORK CONDITIONS

4

FRAMEWORK CONDITIONS

Whilst the emphasis of the Panel's work has been on identifying significant market opportunities that could be exploited by Northern Ireland health technologies sector, the local industry consultations have highlighted the importance of a number of enabling factors in realising the market opportunities identified.

The general conditions for success can be grouped in three key categories, which were also brought to the fore during the Capability Study carried out by BioBusiness Northern Ireland and Invest NI in 2006:

- Adequate skill base, both in terms of quality and volume;
- Effective networking to foster collaboration; and
- Supportive policy environment.

There are also a number of conditions pertaining specifically to the realisation of the two opportunities identified: Personalised Medicine and Home-based Care.

Personalised Medicine framework conditions:

- Adoption in clinical practice;
- Application in existing vs. new drugs;
- Adjusting the education system;
- Ethical framework;
- Intellectual property protection; and
- Joined-up approach and commitment

Home-based Care framework conditions:

- Scalable approach to roll-out;
- Defining technology standards and protocols;
- Stakeholder engagement; and
- Adjusting funding policy

Each of these framework conditions is discussed in the following pages.

FRAMEWORK CONDITIONS

GENERAL

Adequate skill base

Availability of the appropriate skill sets at all levels is crucial in this highly specialised industry. This is a pre-requisite for the future development of indigenous companies as well as in retaining and attracting international players.

Closer communications and integration between the education sector and industry is required to identify and address the key skills gaps. A number of specific suggestions for both the education and sector and industry players have bee put forward in this respect:

Actions by education sector/government:

- Develop and maintain a register of key skills needs and gaps (both in volume and quality terms) across the various sub-sectors, to help respond to the changing needs of the industry;
- Instil interest in science in general, and the health technologies industry in particular at the early stages of education;
- Raise awareness and promote career opportunities to students, parents, careers advisors;
- Place science at the heart of education curriculum from primary education through to further and higher education levels;
- Increase the number and quality of PhD throughout Universities;
- Balance graduates' technical skills with entrepreneurship/business/commercial awareness skills; and
- Support recruitment campaigns on behalf of local companies (e.g. 'returners' programmes).

The companies themselves also have a role to play in actively influencing the education agenda and transferring skills to the academic staff, students and graduates.

Actions by industry:

- Increase hosting of internships and modern apprenticeships;
- Upskill existing employees with short and sharp training - company, or industry specific, management skills;
- Attract back returners;
- Improve staff retention at Province level;
- Conversion of non-specific graduates;
- Work with other sectors on common problems;
- Work with further and higher education to raise awareness of career opportunities at all education levels;
- Highly targeted recruitment overseas and approach Northern Ireland natives working abroad.

Effective networking to foster collaboration

The emphasis is on putting in place mechanisms to help local players to identify collaboration opportunities themselves and to aid the success of individual projects. This is likely to be a long-term process, which needs consistent commitment across the sector. The actions suggested below would help create the forum for regular information sharing and assist with projects implementation:

- Centralised and easily accessible point of information on sector players, including complementary industries (e.g. IT, engineering, packaging). Provide controlled access to target contacts & international associations;
- Central signposting to available support mechanism (see Scottish Enterprise model);
- Special interest groups for experience sharing (business experience and opportunities for collaboration);
- University-run seminars on current research projects and opportunities for collaboration;
- Monthly e-newsletters to members & target investors;
- Guidance on IPR issues.

Northern Ireland, similar to regions like Scotland and Republic of Ireland, should capitalise on the small geographical size and establish stronger interfaces between the academic, business and clinical sectors to accelerate innovation and manage the costs of clinical trials. The role of already established mechanisms, such as the Recognised Research Groups and clinical trials cluster, should be leveraged.

Interfaces with other Horizon Panels would help draw out the opportunities for collaboration on a cross-sectoral basis. Examples of related sectors include:

- ICT;
- Advanced Materials/Engineering; and
- Agri-food.

The realm of collaboration should extend beyond Northern Ireland, particularly to Republic of Ireland and the rest of UK. This will strengthen capability and enhance the offer to potential international targets.

Supportive Policy Environment

A successful cluster is characterised by both dynamic start-up activity and existence of larger, more mature companies which generate demand in the local sector and act as 'success stories', hence helping raise the profile of Northern Ireland. This implies a balanced, three-prong approach for Northern Ireland:

- Facilitate seed companies spin out of Universities (for example by allowing commercially oriented researchers to take sabbaticals to concentrate on product development) and back these up, along with the young SME's already formed, with the appropriate mechanisms to increase their chance of survival – e.g. specialist mentors/business angels, VC contacts, business management skills.
- Support growth of established companies (for example by faster technology/ knowledge transfer from University research, enabling access to skilled workforce, greater support from the clinical capability)
- Focus on FDI targets with an interest in locating or sourcing high value added R&D activities (e.g. niche value-add processes, fundamental research for next generation products)

An innovative package of financial incentives and funding programmes will be required to support young SME's to develop (see SBIR programme in the USA as a means to sustaining costly R&D activity) and attract international players to locate or source in Northern Ireland (see for example packages offered by Republic of Ireland).

This would also involve the creation of an innovation- and business- friendly environment, which would support indigenous existing and new companies, as well as overseas companies considering operating in Northern Ireland, including:

- Cohesive policy across government departments and agencies;
- Timely decision making;
- Reduced bureaucracy and improved coordination surrounding business processes (e.g. planning applications, grant applications etc);
- Balance between FDI vs. and support of indigenous companies.
- Emphasis on the value added by the intellectual strength of the Province, rather than solely on volume of job creation
- An environment that enables and protects intellectual property rights
- Need for taking a long-term view to return on investment, and supporting risk taken by entrepreneurs;
- Help raise the profile of the local capability
  - Lobbying to Northern Ireland and UK governments;
  - Maintaining links with other national and international relevant organisations
  - Helping organise trade visits and industry exhibitions.

FRAMEWORK CONDITIONS

PERSONALISED MEDICINE

As Personalised Medicine becomes more pervasive, with far-reaching implications, re-examination of current approaches to a wide range of industry practices and policies will be required. Northern Ireland has the opportunity to be a leader or early adopter in some of these areas.

Adoption in clinical practice
To enable pharmacogenetics to enter the mainstream clinical practice, it will be necessary to demonstrate clinical benefits on a case-by-case basis, through well constructed and statistically significant clinical trials. Further information needs to be obtained on the economics of using pharmacogenetics in clinical practice; clinical trials therefore need the input of health economists to address issues of clinical cost effectiveness and the best use of public money.

Application in existing vs. new drugs
For new drugs, the clinical trials will be conducted by industry. However, information is also needed about the use of pharmacogenetic screening of existing medicines, including off-patent generic medicines, which constitute the bulk of those used in the National Health Service (NHS). Under the current arrangements, the pharmaceutical industry has no obvious motive to investigate the pharmacogenetics of most of these products on its own. Therefore an opportunity exists for public-private partnership to be developed to enable the use of pharmacogenetic testing to improve drug prescribing in routine clinical practice.

Education system
Education in genetics at undergraduate, postgraduate and continuing medical education levels has trailed behind the enormous scientific and technical advances in this field. In the future doctors, nurses and pharmacists will require a much stronger basic training in the fundamentals of human genetics.

Ethical framework
Studies of pharmacogenetic variability will require the analysis of large repositories of clinical data during and after a clinical trial. Industrial and academic researchers undertaking such studies will require an ethical framework that provides guidance on how to collect and store information and samples with proper consent, while protecting the rights and confidentiality of the individual. Governments will also need to put enough safeguards in place to prevent the misuse of genetic information, and consequent risks to patients.

Further engagement with the public is required both for educational purposes (disseminate information on the progress and benefits of Personalised Medicine), and for assessing ethical concerns and barriers.

Intellectual property protection
A strong intellectual property system is necessary to stimulate investment in innovation. It is essential that government patent systems offer protection for innovations relating to Personalised Medicine as well as high quality patent examination that allows patents of appropriate scope and quality.

Joined-up approach and commitment to developing the sector
Given the array of issues still to be addressed, it is important that the broad spectrum of stakeholders - pharmaceutical and biotechnology companies, researchers, medical educators, information technology suppliers, healthcare providers, policymakers and payers - participate in shaping the evolution of this new opportunity. Only through such joint efforts, will Personalised Medicine be able to fulfil its promise as rapidly as possible. (Source: Royal Society, 2005)

FRAMEWORK CONDITIONS

HOME-BASED CARE

Top-down & scalable approach to roll-out
The Panel suggests a 'top-down' approach to roll-out, which would provide DHSSPS with the control over the patient groups and the parts of the healthcare system impacted at each stage, and over selection of those technology propositions that demonstrate the highest levels of patient benefit and economic impact.

The adoption of Home-based Care would therefore occur incrementally both in terms of the type of patient groups targeted (disease/ condition type, risk of intervention etc), and the type of technology deployed (complexity, risk etc).

It is possible to initiate adoption relatively quickly, by deploying minimal infrastructure. For example, it would be expected that the initial phases would make use of off-the-shelf ICT hardware, such as wireless routers of existing broadband connections.

The Panel believes it is important that the project adopts a Province-wide approach from the outset, to prove the viability of the 'whole system connectivity' concept.

The roll out plan would benefit from the lessons drawn from pilots conducted in other UK and European regions, as and when these are completed.

Common Technology standards and protocols
A key issue in the adoption of Home-based Care in other regions has been the lack of interoperability between devices and the associated perceived risk that service buyers may become effectively tied to one supplier as a result of adopting an infrastructure not compliant with competitive products.

So that the deployment process is not constrained by or dependent on this factor, it is strongly recommended that any implementation model adopted in Northern Ireland is based on common technology standards and protocols. It is preferable that such standards are developed through an 'open-source' approach.

Initial discussions with the Connected Health feasibility team has indicated that the Continua Health Alliance, an organisation comprised of some of the leading global companies in the Home-based Care field, is seeking to agree common protocols for all members of the alliance.

Stakeholder engagement
The Panel considered that the most important success factor was not the creation and deployment of infrastructure. Instead, it was ensuring that the existing response resources (e.g. GP surgeries, District nurses etc) were motivated and incentivised to adopt this way of working.

Adjusted funding policy
The reimbursement strategy for each product and service would need to be assessed. The feasibility of charging patients, where the economic argument for implementation is not as strong should also be considered.

The Panel believes adoption of Home-based Care would be facilitated by using and adjusting the existing reward and operational structures (e.g. GP contracts) as much as possible, rather than creating a parallel system. This would risk increasing resistance to change by the health professionals and funders.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