

Precision Medicine in Northern Ireland

Precision medicine is an area of substantial and rapidly growing focus within the Northern Ireland Life and Health Sciences sector, and is benefitting from the core strengths that underpin the region's research and development infrastructure. The UK has shown its ambitions in this field, as demonstrated by the introduction of a Precision Medicine Catapult and Northern Ireland is both committed and primed to drive forward these ambitions. The Departments for Health and Enterprise are actively encouraging organisations within the UK and beyond to invest in the research and commercialisation opportunities that are already providing our current partners with a four fold return on R&D spend.

Northern Ireland has a number of unique strengths as a centre for health-related research and development. We have the advantage of an integrated health and social care system, the HSC, which facilitates person-centred, joined-up care and lends itself to the adoption and scaling up of new approaches and interventions. We know that the success of precision medicine is dependent on understanding more about patients and genomic data. As a region we are at the forefront of understanding patient data which can accelerate the development of precision and personalised medicines.

Northern Ireland is also a national leader in having implemented a regional electronic patient record. This provides a patient level view across all NI hospitals, diagnostics and imaging at a level which is having a real impact on clinical decision on a daily basis. The level of clinical buy-in for this has been unprecedented. Beyond this we have launched a regional data sharing initiative (Honest Broker Service) to streamline the ethics and approval of data sharing across all Health and Social Care Trusts through anonymised and deanonymised data. This creates significant new potential for condition or population-based research studies which could complement and measure the effectiveness of precision medicine developments.

Strong international links have also been fostered across Europe and the U.S. Uniquely within the UK we have access to the Republic of Ireland's research infrastructure and have recently been recognised as a 3 star reference site by the European Innovation Partnership on Active and Healthy Ageing in the area of medicines management which is clearly of relevance to precision medicine.

Drawing on these strengths, this paper highlights the fact that Northern Ireland is open for business as the centre for trialling and validating new treatments and why organisations across the UK should seek to explore the opportunities Northern Ireland can deliver for both precision medicine related patient care and commercial success.

THE NORTHERN IRELAND ADVANTAGE

Northern Ireland has a strong track record of growing indigenous companies, with 3 L&HS global leaders who have developed their own unique supply chains

10% growth per annum over the past 3 years in the NI Life & Health Sciences sector

12.5% of all NI R&D expenditure is in Life & Health Sciences

10% of all NI exports (increasing 12% pa)



Unique Memorandum of Understanding between Government departments



World class telecoms infrastructure

High Internal & External Connectivity with well established relationships in place

THE ECONOMIC ADVANTAGE

THE ACADEMIC ADVANTAGE

THE STRATEGIC ADVANTAGE

THE "LIVING LAB" ADVANTAGE



A range of world class academic and clinical research centres, including:

- Clinical Translational Research & Innovation Centre
- NI-Molecular Pathology Lab & BIOBANK
- Wellcome/ Wolfson Centre for Experimental Medicine
- Northern Ireland Centre for Stratified Medicine
- Centre for Functional Brain Mapping
- NI Clinical Research Facility
- Nanotechnology & Integrated Bio-Engineering Centre
- The Centre for Cancer Research & Cell Biology

Academic Excellence

In the 2014 Research Excellence Framework, Queens University Belfast and Ulster University achieved impressive life sciences results.

4,000

LHS Graduates each year

Unique, Integrated Health & Social Care System

Small & Complete Demographic - Population of 1.8million



"Closed Loop System" - ideal conditions for Public/Private collaboration

Microcosm for National Health Service & social services across the rest of UK

Global opportunities for Northern Ireland health innovations

Introduction

Precision medicine is of great significance, in both the immediate and long term, to the health and competitiveness of the global medical and life sciences sector.

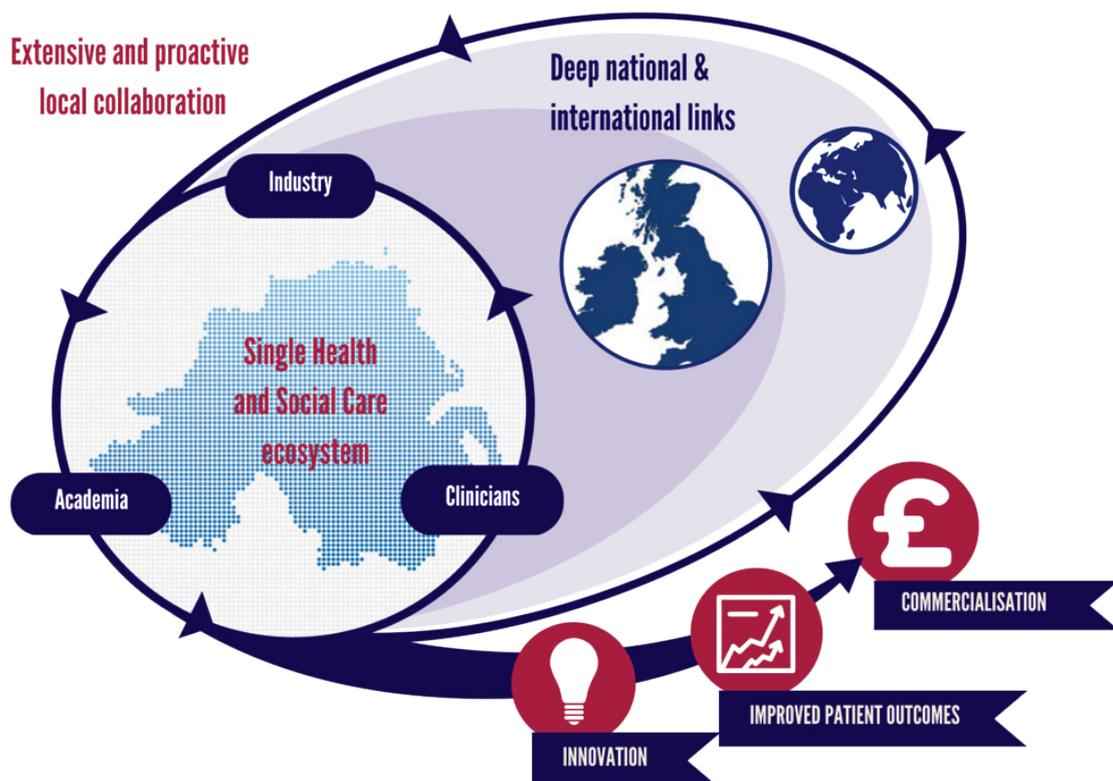
Through its demonstrable track record of regional, national and global collaboration between industry, clinicians and academia, coupled with resident expertise and unique research data stores, Northern Ireland is exceptionally positioned to develop and leverage the significant opportunities precision medicine presents.

The Northern Ireland Executive is prioritising the Life & Health Sciences Sector as a major area of specialisation for our future knowledge based and advanced manufacturing economy. This strategic approach will build on existing capabilities in genomics, data ethics, device development and local specialisms in, for example, cancer and cardiology.

The region is also at the forefront of collecting and utilising individual patient data in order to realise benefits for all – “every patient is a research patient”, an objective set out by the prime minister, has been embraced within NI to drive personalised medical innovation.

In this paper we present a snapshot of how Northern Ireland is already proactively involved in precision medicine development, how it is primed to expand this contribution, and why increasing numbers of national and global organisations are partnering with Northern Ireland to realise the full benefits precision medicine can deliver.

The Northern Ireland Advantage: Collaborative, commercialised, and connected

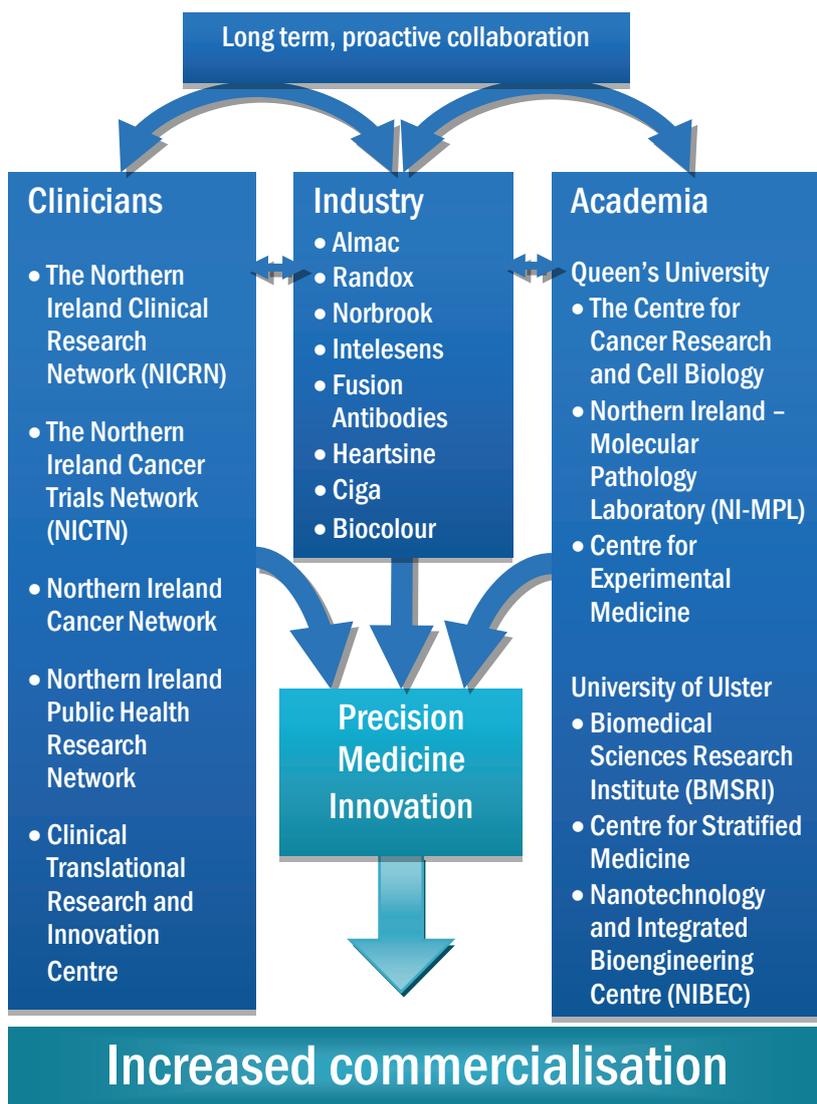


Collaborative Working

Precision medicine in Northern Ireland is underpinned by a long and successful history of work across industry, clinicians and academia.

Within the region a significant number of major collaborative projects and Competence Research Centres have been established which are driving the translation of priority research, including precision medicine, into patient benefits and market growth. The Centre for Experimental Medicine in Belfast, for example, is developing self-sustaining, multidisciplinary, collaborative translational research programmes. The centre incorporates an integrated mixture of approaches ranging from molecular cell biology, disease phenotyping, genetic epidemiology, pathology, drug discovery, patient-based investigation and clinical trials.

Academic, Business & Clinical Collaboration



Case Study

CCRCB & ALMAC

The Centre for Cancer Research & Cell Biology (CCRCB) is a leading cancer research centre for stratified medicine and specialises in a range of core technologies in the areas of genomics and translational proteomics & chemical biology. Its research infrastructure includes:

- Microarray facility
- DNA sequencing facility
- Real-time PCR
- Bioinformatics Suite
- Molecular pathology
- Biobanking

Since its launch in 2007, it has developed a number of key academic-industrial partnerships with the objective of developing diagnostics and novel therapeutic agents to underpin precision medicine. One of these partnerships is with Almac, an NI based global healthcare provider with over 3,000 employees, who together have collaborated on a £13m programme in the development of biomarker informed drug discovery.



CCRCB
Centre for
Cancer Research
& Cell Biology



Innovation to Commercialisation

Emerging technologies, the rise of ‘big data’ and increased cost pressures are creating significant opportunities for precision medicine, and translating those into commercial products that improve patient outcome is at the forefront of Northern Ireland’s private sector agenda.

This sector has been nurtured through a highly supportive Northern Ireland Life Science infrastructure, which has facilitated the growth of multiple innovative global companies including Randox Laboratories, the Almac Group and Norbrook Laboratories. Together these companies employ 5,800 staff, operate in over 145 countries and produce annual sales in excess of £500 million.

Sector support includes innovation offices within the 2 major universities and access to a wide range of financing options – both public and private. One example is QUBIS, a Queen’s University fund which takes an equity stake in start ups and holds a highly impressive record of fostering commercial success. Key achievements include:

- Recently ranked number one in the UK and Ireland for revenue generated by spin out companies¹
- Has facilitated nearly £70 million of outside investment into these companies
- Directly led to the creation of 57 companies

Focus On

Multi-marker algorithms

RANDOX

Multiple Northern Ireland companies and research centres are involved in the commercialisation of multi-marker algorithm development and assessment.

Randox Laboratories, for example, has developed biochip array technology that enables multiplex testing (simultaneous testing on a single sample enabling earlier diagnosis). Through over 35 international collaborative research studies Randox gained the expertise in algorithm development and assessment that has led to the development and clinical validation of diagnostic arrays, alongside the commercialisation of new products.

Further commercialisation success in this single field is evidenced by the large number of NI algorithm based companies, including Intelesens and Heartsine.

Northern Ireland has one of the strongest diagnostics clusters, with 2 of the top 3 UK companies and 17 SMEs.

Case Study: translating innovation into patient outcomes

Each year over 16,000 people die from bowel cancer, making it the second most common cause of cancer death in the UK.

NI based biotech firm Randox, working in collaboration with researchers from the Biomedical Diagnostics Institute at Dublin City University, is developing a new biomarker test that promises to be a significant breakthrough in the diagnosis of bowel cancer.

Studies show that the identification of these very specific biomarkers will allow for a test which is more sensitive and accurate than existing screening. This means that the test will not only save lives through earlier, more reliable and faster diagnosis, but could also encourage higher screening rates.

The cost savings to healthcare budgets are also considerable – early bowel cancer identification and treatment can reduce costs by up to 50% compared to stage 3 treatment.

¹ HE-BCI Survey published jointly by DTI and HEFCE

Innovation to Commercialisation

Nanotechnology and Integrated Bioengineering Centre



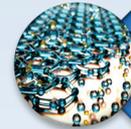
Nanotechnology and
Integrated Bioengineering
Centre

Equipping patients and healthcare practitioners with the tools to make medicine both personal and precise increasingly involves the application of sophisticated bioengineering and nanotechnology. NIBEC, which employs over 80 researchers in a 5000sqft purpose-built facility, uses some of the most sophisticated analysis, nano-fabrication, biological and characterisation equipment in the world.

NIBEC attracts on average £3m of research funding (EPSRC, TSB, INI, SFI, DEL, Wellcome Trust) each year, and is a proven commercial accelerator: it has produced 8 highly successful spin outs companies that generate over £25m in annual turnover.

An example of one of these is Intelesens - a leading international monitoring innovator. It has delivered the world's first intelligent, wearable, non-invasive, wireless vital signs monitoring device for use primarily in remote patient monitoring and personal telehealth applications.

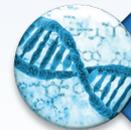
Areas of Focus:



Nanotechnology &
Nanofabrication



Connected Health
& Sensors



Tissue Engineering



Clean
Technologies

Clinical Translational Research & Innovation Centre

The Clinical Translational Research and Innovation Centre (C-TRIC) promotes and facilitates translational and clinical research, the primary objective of which is to reduce both the time to market and the costs associated with research and development of innovative health technologies, medical devices and therapeutics.

C-TRIC hosts the Centre for Stratified Medicine, a £11.5 million clinical research facility that focuses on personalised medicine approaches to managing chronic diseases - in essence tailoring healthcare to individual patient needs. It hosts extensive capabilities in genetics, genomics and epigenomics, and is equipped with multiple real-time PCR instruments, prosequencing for methylation analyses and 'next generation' sequencing equipment.

The Centre is highly acclaimed – it was ranked in the top 3 for biomedical research across the UK in a December 2014 Government report.

Spotlight On:

Commercial Partnering

In 2013 NI-based Almac and Nasdaq-listed Genomic entered a \$9 million licensing agreement allowing the latter to commercialise Almac's new groundbreaking breast cancer test.

This multi gene test provides information that enables Anthracycline-based chemotherapy regimens to be targeted at those who are most likely to benefit – including high risk patients eligible for chemotherapy based on genetic results.

The innovative test will also avoid the time, cost and side effects associated with therapy that has no benefit to a patient's outcome - enabling a focus on alternative, and potentially successful, treatments.

Focus On

Data Accessibility



The NI Electronic Care Record (NIECR) is a unique resource in the UK. It is a clinical portal-based single care record which provides clinicians with access to patient information regionally and across many different care settings. It represents a single source of patient data including laboratory test results, x-rays, full patient documentation and details of conditions including diabetes and related co-morbid disorders. Studies have shown:

- 94% of clinical users agreed that the use of the ECR improved patient care quality
- 83% of doctors reported a better clinical outcome as a result of the use of ECR
- Using the ECR to access data on 30 patients per day, compared to existing legacy systems, could save clinicians 53 minutes daily.

NI connected regionally with a suitable scale to innovate and refine

Northern Ireland is unique within the UK in that its health and social services are integrated, thus providing a unified approach to patient engagement. The five HSC trusts form a 'manageable' region where the main actors form a closed loop healthcare system.

This closed loop creates unique advantages for Northern Ireland regarding patient data analytics and forecasting, which leverage established IT and data mining capabilities. Northern Ireland also benefits from an extremely stable and defined patient and client population of 1.8m, which is ideally sized and managed to support initial precision medicine clinical rollouts and testing.

Research and Development

Northern Ireland is internationally recognised for its R&D capability in sensors, diagnostics, oncology, diabetes and vision science, respiratory medicine and clinical research aligned with its highly rated REF universities, Queen's University Belfast and Ulster University. This recognition is well placed as the region can evidence a high return on investment – for every £1 invested in R&D, £4 is generated in return.

“Every Patient A Research Patient”

In 2011 David Cameron set out his vision for the future of the life science sector, with an objective that “every patient [is] a research patient”. Already working from an advanced position, NI as a region has embraced this vision – below are some examples of the how patient information is collected, collated, and leveraged for the benefit of patients and the health sector as a whole:

- **Enhanced Prescribing Database (EPD)** – all prescriptions issued in NI are scanned and data collected to better inform prescribing by age, gender and co-morbidity. The data is being used in a number of initiatives, including a pharmaco-epidemiological study to describe the changing prevalence and mortality experience of patients with diabetes
 - **NILS (Northern Ireland Longitudinal Study)** – maintained by the NI statistical research agency, the NILS comprises 2 major data linkage studies, providing access to a comprehensive database for research purposes. To date, 83 projects have utilised the study's data, including policy makers across the UK
 - **The Honest Broker Service (HBS)** - The HBS provides streamlined, secure processes for data sharing for the HSC and wider research community. This resource includes data captured on Inpatients, Outpatients, Admissions and Discharges, Accident and Emergency systems and LABS systems
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NI connected nationally - a proactive region within the UK

Northern Ireland is an active region in the UK health research & development ecosystem and hosts a number of nationally connected institutions, centres and initiatives including the Northern Ireland Centre for Stratified Medicine, NI Clinical Research Facility and the Centre for Cancer Research and Cell Biology.

These centres have a proven track record of national coordination and collaboration enabling synergies of effort across academic, clinical and industry inputs.

Against this background of already deep integration and mutually beneficial national collaboration, the MATRIX Life & Health Sciences Foresight report (February 2015) set out a clear vision for Northern Ireland supporting the UK as a global leader in precision medicine.

“NI has been chosen as one of four UK locations to host a new £7m ‘big data’ centre. This will unlock the vast amounts of administrative data routinely collected for the benefits of patients across the UK.

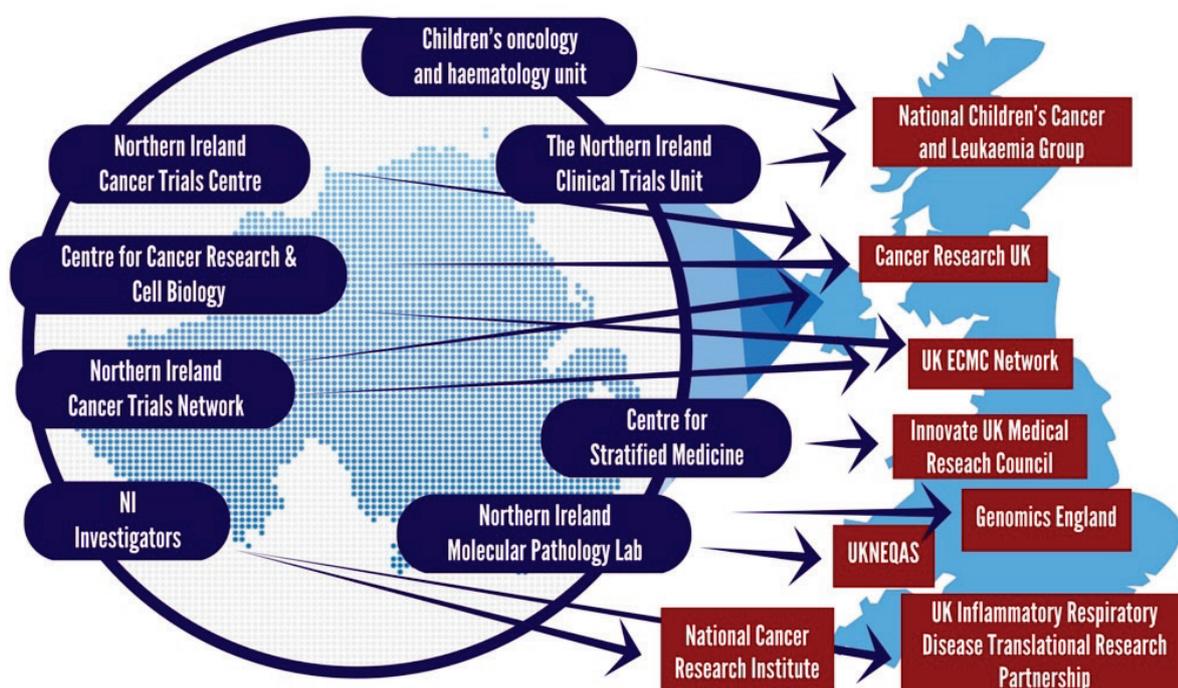
Focus on:

Prostate Cancer



Queens University Belfast is joining with the University of Manchester, Prostrate Cancer UK and the Movember Foundation to form the first regional Movember Centre of Excellence. This initiative will see an investment of £5M over a five-year period across Belfast and Manchester, where researchers will identify men at high risk of aggressive disease, and find which patients respond best to various treatment options. The Centre will ensure that lab breakthroughs in prostate cancer are translated into clinical benefits as quickly as possible.

The Belfast-Manchester nexus will also include the Manchester-based Christie NHS Foundation Trust, the largest single-site cancer centre in Europe.



Spotlight on:



Cross Atlantic Links

Northern Ireland's strong links with Science Foundation Ireland supports ongoing partnerships with the USA. There are a number of programmes which demonstrate recognition of NI's unique regional characteristics including the US-Ireland R&D Development Partnership.

This partnership is a unique initiative which facilitates the funding of high quality collaborative research projects between the USA, Ireland and Northern Ireland.

As of December 2014, £21.3m has been invested in a total of 19 projects, one of which has developed a ground breaking treatment for Cystic Fibrosis sufferers. The project research team, led by Queens University Belfast, have been the first in the world to show that treating the underlying cause of Cystic Fibrosis may have profound effects on the disease, even among people who have been living with it for decades.



NI connected internationally - a recognised regional entity with global links

NI is a trusted regional partner across the European Union and was recently accredited by the "European Innovation Partnership Active and Healthy Aging" as a 3 star Reference Site.

In Connected Health, NI is rightly regarded as a leader - the European Connected Health Alliance, for example, was formed in Northern Ireland and provides a unique partnership of

organisations, companies and government bodies to transform

"The collaboration between Campania and Northern Ireland has [focused]...on the activities of the Reference Site Collaboration Network, where novel opportunities emerged for collaborations in precision medicine diagnostic solutions."

Maddalena Illario, MD, PhD -
Campania EIP-AHA Reference
Site Coordinator (Italy)

"I am very proud to highlight the excellent collaborative relationship between Andalusia and Northern Ireland."

Aquilino Alonso, Health
and Social policies of
Andalucia (Spain)

healthcare delivery and create economic benefits. This alliance is seen as a leading body in driving the adoption of connected health practices within health care. Countries - most recently Finland - seek advice, guidance, insights and exemplars from Northern Ireland's lead.

International Research Access

Uniquely within the UK, Northern Ireland has an agreement that allows the use of the Republic of Ireland's research infrastructure. This allows NI to leverage these facilities for the benefit of the UK as a whole, including:

- The Biomedical Diagnostics Institute's technology for detecting low concentrations of target biomarkers for a range of currently unmet clinical needs
- The Insight Centre for Data Analytics next generation data acquisition and analytics solutions research, whose focus includes sensors and the sensor web, the Semantic web, decision support and optimisation.

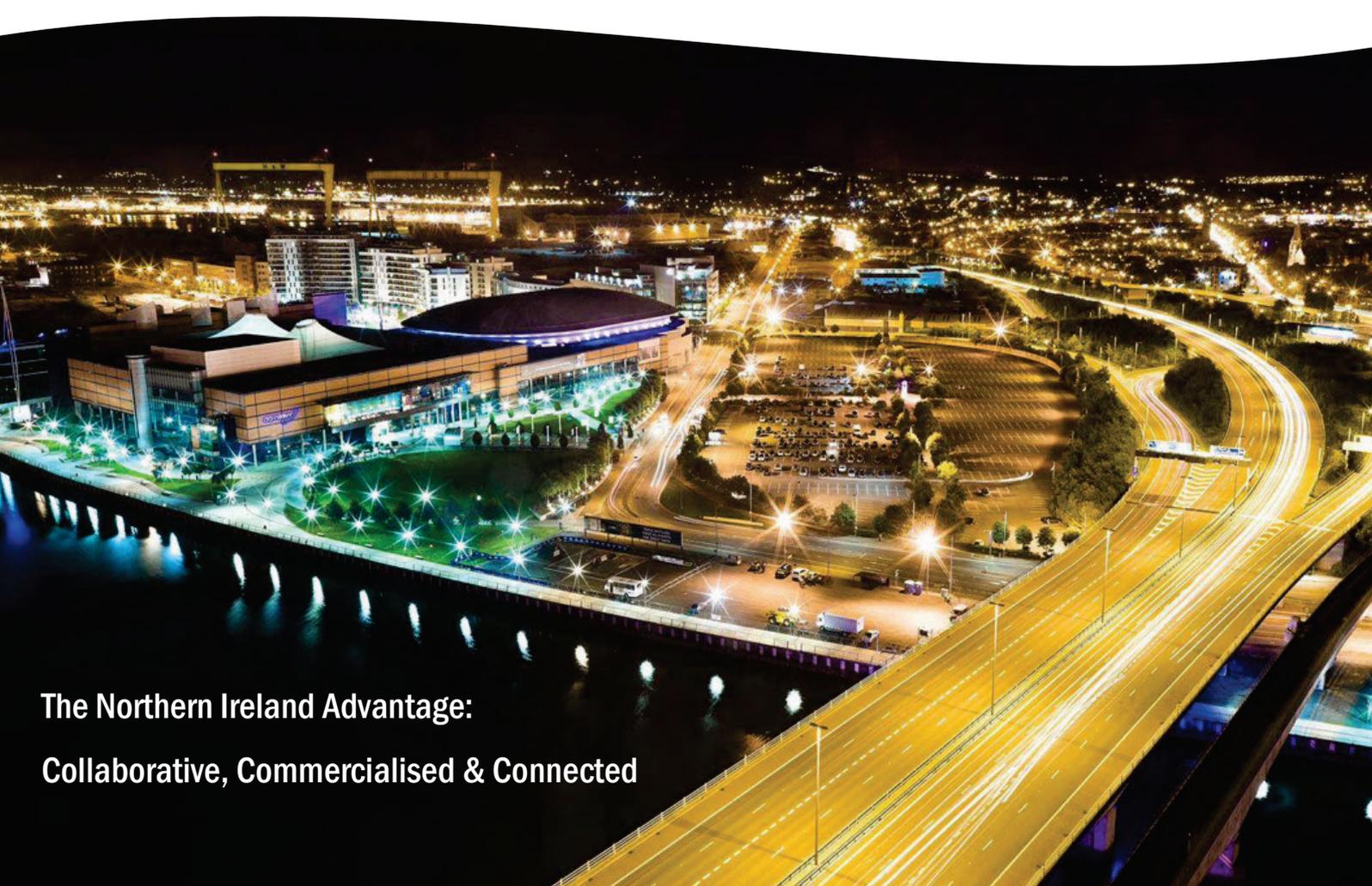
Conclusion

Northern Ireland holds a number of unique advantages for regions and organisations which seek to grow and accelerate precision medicine research and commercialisation.

Underpinned by a highly integrated and collaborative health and social care ecosystem, coupled with a strong political focus and unique patient data repositories, Northern Ireland can provide both researchers and investors with the infrastructure, skilled workforce and international access necessary to realise the full benefits precision medicine can deliver. These benefits range from improved patient outcomes, reduced care costs, wider macroeconomic benefits of a healthier population and high commercial returns on investment.

Significant financing in the region of £70 million has already been made by government in both academia and industry to promote this strategic research area, whilst indigenous companies have also made substantial investments into stratified medicine – just a few examples of which have been provided in this summary paper.

Northern Ireland already has a significant presence in the area of precision medicine and this will continue to be a priority in terms of health and economic policy as we seek to exploit the region's potential as a 'living lab' for the rest of the UK. Partnering with such a successful, committed region therefore presents a key opportunity to ensure both the success of UK life science initiatives, alongside the delivery of substantial and demonstrable R&D investment returns.

An aerial night photograph of a city, likely Belfast, showing a large stadium with a purple roof, a parking lot, and a multi-lane highway with light trails. The city lights are visible in the background.

**The Northern Ireland Advantage:
Collaborative, Commercialised & Connected**



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