

## **1.0 Background to the organisation**

The National University of Ireland Galway, the Royal College of Surgeons in Ireland, University College Cork, University College Dublin and Trinity College and their associated academic hospitals have recognised the strategic value for Ireland of establishing an inter-institutional, biomedical research partnership. They created Molecular Medicine Ireland to accelerate the translation of biomedical research into improved diagnostics and therapies for patients. Molecular Medicine Ireland (MMI) was formally established as a not for profit company in April 2008, through funding from the Higher Education Authority's (HEA) Programme for Research in Third Level Institutions (PRTL) Cycle 4 and builds on the achievements of the Dublin Molecular Medicine Centre (DMMC) established by UCD and TCD in 2002 and which the RCSI joined in 2005. The key achievements of MMI and DMMC are substantial and are listed in Appendix 1.

## **1.2 Vision**

MMI's vision is the creation of an all-island, standardised and carefully phenotyped repository of biological specimens and associated clinical data, accessible to academic and industry researchers and to start-up and spin-out companies to underpin biomedical research and to fuel innovation and commercialisation. This world-class, All-Island Bio-resource Infrastructure will provide the large standardised biological materials with linked clinical data needed to drive advances in pharmacogenetics, disease screening tools, biomarker discovery and validation and to ensure our competitiveness in the era of personalised medicine.

## **1.1 Objective**

The objective of this paper is to outline the importance of biobanking to drive biomedical research; the value to be realised by the creation of an All-Island Bio-resource Infrastructure that will provide the large standardised biological collection required to fuel the innovation and commercialisation of research and how such an all-island bio-resource infrastructure could be delivered by GeneLibrary Ireland.

## **1.3 Background**

A biobank is a collection of blood and/or tissue donated by healthy volunteers and/or patients with linked medical information which is made available for medical research and commercialisation of the products of medical research. Biomedical researchers need to study information and samples from large numbers of people, particularly in the understanding of complex disease processes and in investigating the role that different genes play in health and disease. Such information and large numbers of samples are not easily obtained and their collection often proves costly and time consuming. These biomedically-relevant and quality assured biological specimens also provide a powerful and valuable resource for the biotechnology and pharmaceutical industry to develop and validate new biomarkers for screening, monitoring and treating diseases. Such biological resources along with the information derived from the human genome are playing a key role in the development of more targeted therapies for patients based on understanding an individual's genetic make-up, a particular example being herceptin in HER2-overexpressing breast cancer. The increasing demand and recognised value of biological samples with associated clinical and environmental information has led to the establishment of large collections of bio-resources to

form biobanks. A number of European countries have established population-based and/or disease orientated biobanks including the HUNT in Norway, the UK Biobank, the Estonian Population Biobank and Generation Scotland. These biobanks with linked medical data are providing the large biological samples required to drive the commercialisation of research and the advancement of personalised medicine internationally.

#### 1.4 Building Ireland's smart economy

The Irish Government, through the Strategy for Science, Technology and Innovation 2006-2013, has recognised the need to *'upgrade existing infrastructure and develop new facilities to support research'* and has invested significantly towards the establishment of a world class research infrastructure for Ireland. In defining the infrastructural needs to develop Ireland as an internationally renowned centre of excellence in research and innovation, the Irish Government commissioned reports which identified *'biobanking'* as a key requirement. In particular the report of the Advisory Council on Science, *'Towards Better Health: Achieving a step change in Health Research in Ireland'* recommended the provision of *'biobanking'* and a *'gene library'*. In addition, the HEA and Forfás commissioned report *'Research Infrastructure in Ireland – Building for Tomorrow 2007'* recognised that *'genebanks and biobanks'* are a specific research infrastructure requirement for the instrument and medical devices industry in Ireland. In a report to Enterprise Ireland in 2007, the CIRCA group recommended *'biobanking'* as an infrastructural initiative needed to improve the environment for the creation of economic activity from the expertise and research and technology development in the Irish healthcare system. In March 2009 Time Magazine named *'Biobanks'* as one of the *'10 Ideas Changing the World Right Now'* recognising their crucial role in the progress of research and personalised medicine. The importance of biobanks as an *'integral component of a growing knowledge-based economy'* was recognised in a recent report published by Forfas, entitled *Health Life Sciences in Ireland – An Enterprise Outlook 2009*. This report also stated that *'it is essential that Ireland develops a national approach to biobanking'* and the need for *'all Irish research centres and hospitals to adopt standardised biobanking practices as a matter of priority'*.

#### 1.5 Current biobanking situation in Ireland

There is no population based biobank in either Ireland or Northern Ireland and no all-island clinical biobank. A number of disease specific bio-collections in oncology, cardiovascular disease, neuropsychiatric disorders and HIV have been funded by research funding bodies when supporting research into disease or as part of developing a clinical research facility. The Prostate Cancer Research Consortium is an example where a bio-resource has been established as a multi-disciplinary, trans-institutional collaboration with a view to sharing tissue, blood and DNA from patients with prostate cancer across Dublin for medical research. It is difficult to estimate the investment to date in biobanking by the major funding agencies but significant funding has been committed over the years to assemble individual bio-collections. For the most part, these ad hoc bio-collections have not been assembled with a view to being made available as a national and/or all-island resource but rather are used mainly by the researchers in the institution(s) involved in their assembly or their collaborators.

The requirement of the research and commercialisation sectors for access to large collections of standardised biological specimens will increase in the coming years. There is a need and

an opportunity to develop a joined-up, all-island approach to biobanking to ensure that all future investment in biobanking results in the collection of biological specimens in a linked, networked and harmonised manner and their use as a public resource. This approach would also maximise value for money by ensuring that this bio-resource would serve the requirements of research and innovation on the island of Ireland. It would facilitate the sharing of biological materials and linked medical data between academic researchers and industry under a defined governance and management structure. The creation of such an All-Island Bio-resource Infrastructure would be an important pillar in the clinical research capacity that is being built on the island and could be a key driver of competitiveness, innovation and commercialisation in the era of personalised medicine.

### **1.6 Delivering an All-Ireland Bio-resource Infrastructure**

The blueprint for the creation of such an All-Ireland Bio-resource Infrastructure has been defined in the report of the design phase report of GeneLibrary Ireland. This all-island control biobank will collect 10,000 DNA and blood samples from healthy volunteers, together with key phenotypic information. It will serve as the control population to study the genetic determinants of common diseases that significantly impact patients in Ireland and Northern Ireland (copy of the report of the GeneLibrary Ireland Design Phase is available at <http://www.molecularmedicineireland.ie/page/g/t/4> ). The preparation of the design phase of GeneLibrary Ireland, through MMI with Queen's University Belfast and the University of Ulster, has united representatives from seven institutions across two jurisdictions together with patient representatives, all of whom have contributed their significant expertise to the configuration of an all-island control biobank. The GeneLibrary Ireland design phase report has defined the following key elements which are fundamental to the establishment of an All-Island Bio-resource Infrastructure;

- Procedures for standardisation of an all-island bio-resource and access to samples and data
- Design of a centralised data management and IT infrastructure
- Governance, organisation and management framework involving the seven institutions
- Proposed legal entity for biological materials for the island of Ireland
- Model for central coordination of all biobanking activities on the island
- Access to the control sample by academic and industry researchers to study the genetic determinants of common diseases that significantly impact patients in Ireland and Northern Ireland
- Model for operation across two jurisdictions with differing legislative frameworks
- Harmonisation with international best practice
- An All-Ireland biobanking hub centrally linked to Europe through Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), the emerging pan-European biobanking infrastructure

The creation of GeneLibrary Ireland would serve as the foundation for the establishment of an All-Ireland Bio-resource Infrastructure. Once established, GeneLibrary Ireland would provide a structured framework that could unify disease specific bio-collections funded in the future (including the recommended National Cancer Biobank in Ireland) to a common standard and accessible to all interested parties according to agreed rules, and which would be dedicated to promoting research, innovation and commercialisation to the benefit of the people of this island and Ireland's economy.

## **1.6 Achieving the Innovation Island**

The creation of an All-Island Bio-resource Infrastructure incorporating a large collection of standardised biological specimens one of the key pillar required *'to make Ireland an innovation and commercialization hub of Europe'* as defined in the recently published paper, *'Building Ireland's Smart Economy, A Framework for Sustainable Economic Renewal 2009-2014'*. A key example whereby an all-Ireland bio-repository would add significant value to innovation is in the biomarker development pipeline. Biomarkers are routinely discovered by researchers and tested in small patient populations and published in the literature. At this point biomarkers, in and of themselves have limited value however by having access to large scale standardised bio-resources biomarkers can be validated for their clinical utility thereby moving a somewhat interesting molecule from a scientific perspective into a test used in the healthcare setting with real commercial value.

An All-Ireland Bio-resource Infrastructure will fuel disease research, innovation and commercialisation and maximise value for money by the;

- Creation of a vibrant all-island research partnership and enhance connectedness of the biomedical research community, North and South
- Enable innovative partnerships with the pharmaceutical and biotechnology industry with access to much needed standardised biological specimens
- Drive advances in pharmacogenetics, disease screening tools, biomarker discovery and validation and ensure our competitiveness in the era of personalised medicine.
- Implementation of an all-island standardised data management and IT strategy, to ensure standardisation and compliance with all legislative and data protection requirements
- Avoid duplication of efforts and resources through funding independent, fragmented bio-collections that are not harmonised and readily assessable for all-island disease research and innovation
- Drive Ireland and Northern Ireland's involvement in landmark EU wide research programmes

**November 2009**

## Appendix 1

- The establishment of the Programme for Human Genomics, a €40m project funded by PRTL Cycle 3 to build enabling technologies and bio-resources which transformed the research capacity of the partners institutions.
- The award to develop the Dublin Centre for Clinical Research (DCCR), a €23M project funded by the Wellcome Trust and the Health Research Board (HRB). The DCCR involves the building of a new clinical research facility at St James's Hospital and the deployment of a network across the city linking the existing clinical research facilities in RCSI/Beaumont Hospital, UCD/Mater Misericordiae University Hospital/St Vincent's Hospital
- The establishment of the Irish Clinical Research Infrastructure Network a €0.5M project funded by the HEA and HSE to facilitate the national coordination of clinical research and to participate on behalf of Ireland in the development of the European Clinical Research Infrastructures Network.
- The establishment of a clinician scientist fellowship programme with €10M funding from PRTL Cycle 4 to train the next generation of academic medical leaders in Ireland who will drive the translation of scientific advances into improved diagnostics and therapies for patients.
- The development of the design phase of an all-island control biobank, GeneLibrary Ireland a collaborative cross-border initiative between MMI, Queen's University Belfast, University of Ulster and the patient organisation funded by the HRB and the R&D Office.
- The establishment of the Prostate Cancer Consortium funded by the Irish Cancer Society.