Molecular Medicine Ireland was established under the Higher Education Authority’s Programme for Research in Third Level Institutions.
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Molecular Medicine Ireland Board

MMI welcomed four new appointments to the Board of Directors during 2009. Helen Ryan, CEO of Cre-eganna Tactx Medical, became a director of the MMI Board at the Board meeting of 2 February while Professor Hannah McGee, Dean of the Faculty of Medicine and Health Sciences and Professor of Psychology at the Royal College of Surgeons in Ireland, joined as a director and attended her first Board meeting on 2 June. Dave Shanahan, who is Global Head of Life Science at IDA, joined and attended his first Board meeting on 6 July and Dr Marina Zvartau-Hind, Director of GlaxoSmithKline’s Neurosciences Medicines Development Centre, became a director in November and attended her first Board on 1 December.

MMI Guidelines for Standardised Biobanking

MMI developed guidelines to standardise the collection, processing and storage of biological materials donated for use in research, the aim of which is to ensure sample quality, consistency and integrity of bio-collections at different clinical and research centres in Ireland. The guidelines, which contribute towards a more strategic national approach to biobanking and build on the work undertaken in the Design Phase of GeneLibrary Ireland which was carried out by MMI in 2008, were approved by the MMI Board and a consultation phase was initiated to invite the input of the research community engaged in biobanking prior to their publication in 2010.

MMI Technology Platform Web-Portal

MMI launched a technology platform web-portal in December 2009. The web-portal was developed with the input of the research community to promote and showcase the breadth of technology platforms and associated expertise that support clinical and translational research in molecular medicine in our partner institutions and collaborators. It features technologies in proteomics, medical and pre-clinical imaging, genomics/transcriptomics, mass spectrometry, flow cytometry, data management and IT support.

MMI Clinician Scientist Fellowship Programme

Twenty two medical graduates continued their PhD research combined with national structured training modules and the first Annual Scientific Meeting, (see pages 20-23). The programme, funded by the HEA under PRTLI Cycle 4, underwent its first external review and there was significant progress in mainstreaming this important investment, with the development of a structured curriculum that will be accessible to all medical graduates undertaking clinical and translational PhD research in the medical schools of the MMI partners.
MMI Highlights 2009

**MMI Course: Techniques & Strategies in Molecular Medicine**

The year ended on a high note with the seventh run of the Techniques & Strategies in Molecular Medicine course attracting an audience of 114 to hear lectures covering multiple techniques and technologies from RNA interference to systems biology, taking in gene expression, transgenics and knockouts, proteomics, imaging and immunodetection and many more. A total of 691 people have attended this course since it began in 2003 (see pages 25-27).

**Irish Clinical Research Infrastructure Network**

Two new appointments were made to the ICRIN team in 2009. In August, Marie Mellody was appointed as ICRIN Co-ordinator to complete the preparatory phase of the clinical research infrastructure in Ireland and to represent Ireland in the European Clinical Research Infrastructure Network. Fionnuala Gibbons was appointed in April as Clinical Trials Liaison Officer in an Enterprise Ireland funded post to support and assist SMEs, indigenous companies and start-ups in biotechnology to navigate access to the clinical resources required to bring their products to the market place.

**ICRIN Irish Situation Analysis and Clinical Research Roadmap**

The Irish Situation Analysis was published in March and provides a comprehensive overview of the requirements for undertaking clinical research in Ireland. In July, the Clinical Research Roadmap, which contains recommendations aimed at enhancing Ireland’s research capacity, was circulated for comment to key stakeholders in the health research community. As a result of the consultation process, ICRIN’s objectives were re-evaluated to ensure partnership and synergy with the Department of Health and Children’s Action Plan for Health Research 2009-2013 and the HRB’s Strategic Business Plan 2010-2014.

**MMI/ICRIN hosted Workshops**

Two workshops were organised by ICRIN/MMI in 2009. The first was co-hosted with the State Claims Agency in April and addressed the area of indemnity in clinical research and successfully resulted in the clarification of the many issues associated with indemnity and the role of the clinical indemnity scheme. In October, a further workshop entitled “Impacting healthcare through facilitating clinical studies of medical devices/diagnostics in Ireland” was organised specifically for the medical device industry. It provided an overview of how to navigate the clinical trial process in Ireland through a greater understanding of the current infrastructure, the regulatory requirements and other key aspects of the medical device clinical trial process.

**Dublin Centre for Clinical Research**

2009 saw the finalisation of the tri-partite agreement between the Wellcome Trust, TCD and St. James’s Hospital paving the way for the flow of Wellcome Trust funds to build the Clinical Research Centre at St. James’s Hospital in 2010. In September, the RCSI Certificate Course in Research Nursing was launched with student recruitment from the Dublin Centre for Clinical Research, Cork and Galway. On 23 June, the DCCR and the RCSI CRC at Beaumont Hospital jointly hosted a road show exhibiting the UK Clinical Research Facilities Network Information Portal. It featured presenters from England and Ireland (north and south of the border) and was attended by over 30 researchers.
During 2009, we spent much time defining MMI’s strategy and unique selling point in this difficult period of recession. A strong message from the heads of our partner institutions, policy makers and stakeholders was the need to mobilise the strengths and resources of our five partner institutions and their associated hospitals to help build the national system for clinical and translational research that everyone agrees is needed but which remains incomplete. A national system for clinical and translational research will enhance the health of the people, increase our reputation in biomedical research internationally and facilitate the transfer of ideas from the research bench into products and processes that add value and jobs to the Irish economy. While there is a mountain to climb, all associated with MMI are clearer today that we have a unique contribution to bring to this task and about our part in fostering innovation and accelerating the smart economy.

At a strategic level, we welcomed the publication by Mary Harney TD, the Minister for Health and Children, of the Action Plan for Health Research 2009-13 and by the Health Research Board of its Strategic Business Plan 2010-12. Both documents prioritised the development of clinical and translational research and committed to build capacity by means of better coordination, legislation and funding. We look forward to working closely with the Department of Health and Children, the Health Research Group and the Health Research Board as they provide national leadership in building capacity in clinical and translational research.

The Irish Clinical Research Infrastructure Network (ICRIN) is putting the structures and processes in place to facilitate the conduct of investigator-led studies in multiple sites across the country and across a range of diseases. ICRIN is funded by the HRB and the HSE and operates as a business unit of MMI. The ICRIN Situation Analysis was published and the Clinical Research Roadmap was circulated for comment to key stakeholders. As a result of this initiative, the Department of Health and Children has invited MMI to publish the Roadmap as a contribution to the implementation of the Government’s Action Plan for Health Research 2009-13 and to be a partner in building national clinical research capacity. During the year Marie Mellody joined MMI as ICRIN Coordinator, bringing a wealth of international experience in the organisation of clinical research to bear on the challenge of developing a national infrastructure in this country. She immediately engaged with the clinical research community to agree a strategy for the development of the existing and emerging clinical research centres (CRCs) as research hubs for their hospitals and to provide a ‘research readiness’ programme to the partner institutions and associated hospitals that promotes best practice and targets services for development.

MMI secured funding from Enterprise Ireland to offer a service to SMEs, indigenous companies and start-ups in biotechnology to assist them navigate access to the clinical expertise needed to bring their products to market. Fionnuala Gibbons joined the ICRIN team in this role as Clinical Trials Liaison Officer and has already supported firms to either begin or move closer to clinical trials. As the year ended, ICRIN was making its expertise in clinical trial organisation, research readiness and sponsorship available to the clinical research community to build capacity and to move to a standardised and harmonised approach to research. ICRIN was actively involved during the year with our European colleagues in building the preparatory phase of the European Clinical Research Infrastructure (ECRIN) and benefitting from their approach to supporting multi-centre clinical studies across Europe.

It is particularly good news that the Wellcome Trust/HRB funded Dublin Centre for Clinical Research (DCCR) is open for business, under the leadership of Professor Dermot Kelleher as Principal Investigator. The DCCR is a key part of the infrastructure for clinical and translational research, linking the CRCs associated with UCD (St Vincent’s and the Mater Misericordiae University Hospitals), the RCSI CRC in Beaumont Hospital and a new CRC being built by TCD at St James’s Hospital. Four studies are underway across the network; five disease groups have been established or recognised and are conducting and/or planning studies to be conducted through the network. Work on a clinical information and data management system for the network is at an advanced stage. The legal agreement for the new CRC at St James’s has been signed by TCD, St James’s and the Wellcome
“It is particularly good news that the Wellcome Trust/HRB funded Dublin Centre for Clinical Research (DCCR) is open for business, under the leadership of Professor Dermot Kelleher as principal Investigator.”

MMI put much effort during the year towards forging a strategic approach to biobanking. The design phase for an all-island, control biobank known as GeneLibrary Ireland, was completed and submitted to the Health Research Board and the Research and Development Office of the Northern Ireland Health and Social Services Central Services Agency. Unfortunately, they did not have the funding to move to the next phase of constructing the biobank. Responding to the need for a more strategic approach to biobanking, MMI developed Guidelines on Standardised Biobanking for the benefit of all involved in biobanking in this country. Our hope is that the Guidelines will be adopted as the standards for the collection of all new biological samples, both in Ireland and through our involvement in the EU supported Biobanking and Biomolecular Resources Infrastructure, in Europe. We hope that under the Action Plan for Health Research 2009-13, a more strategic, national approach will be taken to the funding and accessibility of bio collections in Ireland, in the best interests of patients, academic investigators, the healthcare industry and taxpayers.

I would like to thank my fellow directors for their commitment, advice and support during 2009. I would like to extend my special thanks to Professor Jochen Prehn, Chairman of the Department of Physiology and Medical Physics at RCSI, Dr Jackie Hunter, Senior Vice-President of GlaxoSmithKline’s Science Environment Development Division and Barry O’Leary, CEO of IDA Ireland, all of whom stepped down as directors during the year. The Board was pleased to welcome Helen Ryan, CEO of Creganna, Professor Hannah McGee, Dean of the Faculty of Medical and Health Sciences and Professor of Psychology at RCSI, Dr Marina Zvartau-Hind, Director at GlaxoSmithKline’s Neurosciences Medicines Development Centre and Dave Shanahan, Global Head of Life Science at the IDA, as new directors. May I also extend my thanks to the staff of MMI who work with great commitment and skill to achieve the mission of MMI.

Damian O’Connell MD BSc PhD
Chair of Molecular Medicine Ireland
The vision of Molecular Medicine Ireland’s strategy 2009-11 is improved healthcare through the development of diagnostics and therapies from concept to realisation. The mission of MMI is to mobilise the strengths of the five partner institutions and their associated hospitals to build a sustainable national system to coordinate, support and promote translational and clinical research to achieve its vision.

MMI’s unique selling point is its potential to mobilise the strengths of the partner institutions and its associated hospitals to build a national system for clinical and translational research. This national system is necessary to translate research into innovative diagnostics, therapies and devices that will improve the health of the population and contribute to economic development. In MMI we believe that a national system for clinical and translational research can become a virtuous circle for innovation. The same system can serve the needs of academic researchers, industry-led research and those SMEs and start-ups that need access to clinical resources to bring their prototypes to market. MMI’s greatest contribution to innovation is to integrate the capacity and expertise of the partner institutions and associated hospitals to complete this national system and make it accessible to all who need access to clinical resources.

Much work was done in 2009 to build the human capital for clinical and translational research. MMI is coordinating the Clinician Scientist Fellowship Programme (CSFP), funded under the Programme for Research in Third Level Institutions Cycle 4, under which 22 medical graduates are undertaking a PhD in one of MMI’s five partner medical schools and participating in a structured curriculum that adds depth and breadth to their training. We commissioned an external review of the CSFP by Professor John Iredale of the University of Edinburgh and Dr Diana Dunston, formerly of the Medical Research Council, which was very complementary of what the CSFP had achieved and which provided useful recommendations for maximising the impact of the programme. MMI coordinated a successful week long programme for the fellows and organised their first annual scientific meeting in July in NUI Galway. The shared curriculum for the CSFP is currently being mainstreamed as a programme to be available to all medical graduates undertaking PhDs in clinical and translational research in MMI’s partner medical schools.

MMI staff worked closely with Professor Larry Egan of NUI Galway as lead Principal Investigator, to prepare a proposal for a Clinical and Translational Scholars Programme for scientists in response to the Programme for Research in Third Level Institutions – Cycle 5, with strong input from our industry partners. An announcement by the Government on awards to be made under the Programme was awaited at the end of the year. MMI offered five courses on topics relevant to molecular medicine and translational research, including two new courses on biostatistics and medical imaging for research. A major gap in good clinical practice (GCP) training was filled through targeted courses offered by ICRIN in Dublin, Cork and Galway. Feedback from all courses was positive.

In response to the need to facilitate access by researchers in academia and industry to technology platforms for translational and clinical research available in our partner institutions and associated institutions, MMI developed a Web-Portal for Technology Platforms. The portal, developed on the MMI website with the input of the research community, promotes and showcases the breadth of technology platforms and associated expertise that support clinical and translational research in molecular medicine and provides details on how these platforms can be accessed.

During the year, MMI deepened its engagement with two important, emerging European Research Infrastructures – the European Clinical Research Infrastructures Network (ECRIN) and the Biobanking and Biomolecular Resources Infrastructure (BBMRI). MMI is the Irish scientific partner in both of these European Research Infrastructures, which are funded in their preparatory phase by the EU’s Seventh Framework Programme. ECRIN is networking national clinical research networks in member and associated states to create a European infrastructure for clinical research that will improve health by enabling investigator-led clinical research in multiple specialties on a scale that has not been possible up to now. By creating this European infrastructure for clinical research, ECRIN is also facilitating the health care
"In response to the need to facilitate access by researchers in academia and industry to technology platforms for translational and clinical research available in our partner institutions and associated institutions, MMI developed a Web-Portal for Technology Platforms."

industry, as the close links between the ECRIN partners and the Innovative Medicines Initiative demonstrates. BBMRI is networking biobanks and biobanking initiatives in member states into a European biobanking resource that will be standardised and accessible to all involved in research. MMI, as a scientific partner of both initiatives, is benefitting from the convergence of thinking about support for clinical research and biobanking at a European level, and contributing from Irish experience and expertise to solving some of the problems. The contribution by Ireland to the BBMRI of the Guidelines on Standardised Biobanking, as outlined in the Chair’s statement, is a good example of the kind of added value that MMI is bringing as a scientific partner. Both ECRIN and BBMRI will conclude their preparatory phase in 2010 and work is already underway to establish both research infrastructures as permanent features of the European clinical and translational research environment.

MMI improved its communications in 2009. We launched the MMI electronic newsletter to bring MMI’s messages to a wider audience. Four issues were circulated during the year. The website was developed in a way that supports the wider engagement of the research community. MMI also met the requirements of good corporate governance: MMI lived within its budget, agreed a budget for 2009/10 and the audit for 2008/9 demonstrated compliance with the required standards of financial management. All reports required by funders from MMI were completed to a high standard.

During 2009, I was pleased to welcome two new staff to MMI. Marie Mellody joined as ICRIN Coordinator and Fionnuala Gibbons took up the Enterprise Ireland funded post of Clinical Trials Liaison Manager with ICRIN. I would like to extend my thanks to them and to all my fellow staff members for their hard work and commitment to MMI’s mission in 2009. May I also thank the directors of the Board, and in particular the Chair of MMI, Dr. Damian O’Connell, for their stimulating challenges, support and encouragement during the year.

Ruth Barrington PhD
Chief Executive
Molecular Medicine Ireland (MMI) is a collaborative biomedical research partnership between National University of Ireland Galway (NUI Galway), Trinity College Dublin (TCD), University College Cork (UCC), University College Dublin (UCD) and The Royal College of Surgeons in Ireland (RCSI). MMI, established in 2008, replaced the Dublin Molecular Medicine Centre.

MMI was established in response to the need to create in Ireland a critical mass of excellence in molecular medicine research and education and to deploy a clinical research infrastructure to facilitate the transfer of advances in molecular medicine into new and more effective diagnostics, therapies and devices for patients. MMI is committed to supporting translational and clinical research, best described as research from ‘bench to bedside’ - ‘bench’ experiments being driven by clinical questions and findings at the ‘bench’ being put into practice through better diagnosis and treatment at ‘the bedside’ of the patient.

MMI is a joint venture company controlled by NUI Galway, TCD, UCC, UCD and RCSI and established with funding from the Higher Education Authority’s Programme for Research in Third Level Institutions, Cycle 4. Formally incorporated in 2008, MMI is a company limited by guarantee and has been registered without the word ‘Limited’ in its name. It is a registered charity founded for the promotion of molecular medicine research. MMI is governed by a Board of Directors supported by an Executive Management Team (EMT: see page 10) The EMT comprises the CEO of MMI and five directors who are leaders in medical research in the partner institutions.

At the end of 2009, the business of MMI was supported by a staff of 11 people, of whom 4.5 were funded from sources other than by the partner institutions. MMI has been successful in attracting funding from the Health Research Board, the Health Service Executive and the European Union to develop clinical research capacity in Ireland. The organisational structure of MMI is shown in the diagram below and the names of the members of staff are listed on page 45. Staff work closely with senior investigators in the partner institutions and associated hospitals to put MMI programmes into effect, including the Clinician Scientist Fellowship Programme, MMI’s suite of courses and workshops, the deployment of the Dublin Centre for Clinical Research, the preparatory phase of ICRIN and MMI’s support for biobanking, biomarker development and technology platforms.
VISION

In December 2008, MMI adopted a strategy to guide its direction and activities to the end of 2011. The strategic vision of MMI is improved healthcare through the development of diagnostics and therapies from concept to realisation.

The strategic mission of MMI is to mobilise the strengths of the five partner institutions and their associated hospitals to build a sustainable national system to coordinate, support and promote translational and clinical research.

MMI achieves this mission by:

- connecting the key players in health, research and industry
- attracting, training and retaining world-class researchers
- working to provide state-of-the-art facilities, bio-resources and harmonised processes
- representing Ireland in clinical and translational research infrastructures/networks in Europe and internationally, and building collaborative research initiatives and opportunities.

MMI’s unique selling point is its potential to mobilise the strengths of the partner institutions and their associated hospitals to build a national system for clinical and translational research. This national system is necessary to translate research into innovative diagnostics, therapies and devices that will improve the health of the population, contribute to economic development and create employment. A national system for clinical and translational research is a virtuous circle for innovation. The same system can serve the needs of academic researchers, industry-led research and those SMEs and start-ups that need access to clinical resources to bring their prototypes to market. MMI’s greatest contribution to innovation over the next few years will be to integrate the capacity and expertise of the partner institutions and associated hospitals to complete this national system and make it accessible to all who need access to clinical resources.

A focus on building a national system for clinical research maps well with the Health Research Action Plan’s deliverable of ‘fully functional and networked clinical research facilities in our main academic teaching hospitals, with a focus on accelerating research advances into benefits for patients and the population’.

OUTPUTS

The output of MMI’s activities are:

- the deployment of a sustainable system for clinical and translational research to support trans-disease, multi-site studies nationally and as part of the European Clinical Research Infrastructures Network (ECRIN)
- the creation of an internationally recognised community in molecular medicine and clinical research
- the creation of skilled translational and clinical researchers, both medical graduates and scientists
- the creation of high quality and standardised biological collections for patient and disease-focused research linked with the European Biobanking and Biomolecular Resources Infrastructure (BBMRI)
- the generation of new intellectual property to fuel Ireland’s biotechnology, biomedical device and pharmaceutical industry
- new diagnostics, devices and therapeutics and more effective patient intervention strategies.
The Executive Management Team (EMT) guides the scientific and operational strategy of MMI and comprises five MMI Board Directors, one each from NUI Galway, RCSI, TCD, UCC and UCD and the Chief Executive Officer of MMI.

**Professor Larry Egan**
Professor of Clinical Pharmacology, Head of Pharmacology and Therapeutics at NUI Galway, Consultant Clinical Pharmacologist and Gastroenterologist with the HSE Western Region and Interim Director of HRB Clinical Research Facility, Galway

Larry Egan took up his appointment with NUI Galway and the HSE in 2005 after having gained specialist experience in the USA in the areas of gastroenterology, internal medicine and clinical pharmacology and gastroenterology at the Mayo Clinic in Minnesota (1994-1999) and in the Laboratory of Mucosal Immunology at the University of California in San Diego. Currently, his research focuses on molecular characterisation of signalling pathways involved in intestinal epithelial cell stress, death and malignant transformation.

**Professor David Kerins**
Dean of the Medical School and Vice-Head of the College of Medicine and Health, Associate Professor of Therapeutics at University College Cork and Consultant Physician at Mercy University Hospital

David Kerins’ current positions at UCC and MUH were preceded by appointments in the USA at the Vanderbilt University Medical Center, at Nashville Veterans Affairs as Associate Professor of Medicine and Chief of the Cardiology Section, and at the Cardiovascular Magnetic Resonance Center, Beth Israel Deaconess Medical Center, Harvard Medical School as Visiting Scientist. Professor Kerins current research interests include the assessment of the role of platelet activation and of antithrombotic strategies in the setting of cardiovascular disease, including high risk conditions such as the metabolic syndrome and diabetes mellitus.

**Professor Dermot Kelleher**
Vice-Provost for Medical Affairs, Head of the School of Medicine & Director of the Institute of Molecular Medicine, Trinity College Dublin & St James’s Hospital

Dermot Kelleher was appointed Wellcome Senior Fellow in Clinical Science in 1989 at Trinity College Dublin and subsequently Professor of Clinical Medicine in 2001. With specialist training in Gastroenterology, Professor Kelleher’s widely published research has focused on the cell biology both of immune responses and of the inflammation-cancer sequence. He co-founded MMI’s predecessor, the Dublin Molecular Medicine Centre, in 2003 and obtained funding from the Wellcome Trust and Health Research Board to establish the Dublin Centre for Clinical Research.
Professor Gerry McElvaney

Professor of Medicine, Head of Department of Medicine, Royal College of Surgeons in Ireland and Director of the Respiratory Research Unit, Beaumont Hospital

Gerry McElvaney has a strong track record in translational research both in Ireland and the USA in the areas of Cystic Fibrosis, emphysema and lung inflammation with an emphasis on protease/anti protease interactions, signal transduction in bronchial epithelium, innate defences of the lung and gene therapy for lung diseases. He co-founded the Respiratory Research Unit in Beaumont Hospital in 1997 and the Alpha One Foundation of Ireland in 2003, both of which have attracted significant national and international funding and have resulted in a large number of publications as well as interactions with pharmaceutical companies interested in translational research.

Professor Bill Powderly

Head of School of Medicine & Medical Science and Professor of Medicine & Therapeutics at University College Dublin and the Mater Misericordiae University Hospital and Chief Academic Officer of Dublin Academic Health Care

Bill Powderly has been actively involved in HIV-related research in both Ireland and the USA and is widely published in this area. His recent research focuses on the emerging toxicities of treatment of HIV, especially the metabolic complications seen in patients receiving effective therapy, including the development of diabetes, lipid abnormalities and bone disease. Professor Powderly is a Fellow of the Infectious Diseases Society of America, the Royal College of Physicians of Ireland and the American Association for the Advancement of Science.

Dr Ruth Barrington

Chief Executive of Molecular Medicine Ireland

Dr Ruth Barrington was appointed Chief Executive to the DMMC (now MMI) in October 2007. She was awarded a PhD from the London School of Economics and an honorary degree in laws by NUI Maynooth, and she is the author of Health, Medicine and Politics in Ireland, 1900-1970 and other publications on health, research policy and EU affairs. She was Chief Executive of the Health Research Board from 1998 to 2007. She is on the board of IPPOSI (Irish Platform for Patients’ Organisations, Science and Industry), the Conway Institute (UCD) and CRANN (TCD) and she is Chair of the Irish Times Trust.
MI Board of Directors

CHAIR
Dr Damian O’Connell
Vice President of Clinical Research and Development, Pfizer

DIRECTORS
Dr Willard Dere
Senior Vice-President and International Chief Medical Officer of Amgen

Prof Larry Egan
Professor of Clinical Pharmacology and Head of the Department of Pharmacology and Therapeutics, NUI Galway

Prof Desmond Fitzgerald
Professor of Molecular Medicine and Vice President for Research, University College Dublin

Dr Hannah McGee
Dean of Faculty of Medical and Health Sciences and Professor of Psychology, Royal College of Surgeons in Ireland

Prof Dermot Kelleher
Vice-Provost for Medical Affairs, Professor of Clinical Medicine, Head of School of Medicine and Director of the Institute of Molecular Medicine at Trinity College Dublin and St James’s Hospital

Prof Peter Kennedy
Dean of Research, University College Cork

Prof David Kerins
Dean of School of Medicine and Vice Head of the College of Medicine and Health, University College Cork

Dr Marina Zvartau-Hind
Director, Neurosciences Medicines Development Centre and Clinical Leader of Alzheimer Disease Projects, GlaxoSmithKline

Dr Stevo Knezevic
Chief Medical Officer, Wyeth Europe, Middle East and Africa

Dr David Lloyd
Head of the Molecular Design Group, School of Biochemistry & Immunology and Dean of Research, Trinity College Dublin

Prof Gerry McElvaney
Professor of Medicine, Royal College of Surgeons in Ireland and Director of the Respiratory Research Unit, Beaumont Hospital

Prof Tim O’ Brien
Professor of Medicine and Director of the Regenerative Medicine Institute, NUI Galway

Ms Helen Ryan
Chief Executive, Creganna

Prof Bill Powderly
Head of the School of Medicine & Medical Science at UCD and Professor of Medicine & Therapeutics at UCD and the Mater Misericordiae University Hospital

Mr David Shanahan
Global Head of Life Science, IDA

COMPANY SECRETARY
Mr John Coman
Corporate & Legal Affairs Secretary, University College Dublin
MMI Board Appointments

Helen Ryan

Ms Helen Ryan was appointed to the Board of Molecular Medicine Ireland in February 2009. She is the Chief Executive of Creganna Tactx Medical, a leading global supplier of products, technologies and services to medical device and life science companies with design and manufacturing facilities in Galway, USA and Singapore.

Ms Ryan has over 17 years of experience in the medical device industry having worked previously with Medtronic AVE and Tyco Healthcare. She is a fellow of the Institute of Engineers of Ireland and a board member of the Irish Medical Devices Association.

Professor Hannah McGee

Professor Hannah McGee joined the Board of Directors of Molecular Medicine Ireland in June 2009. She is the current Dean of the Faculty of Medicine and Health Sciences and is Professor of Psychology at the Royal College of Surgeons in Ireland. As a health psychologist, her research interests and publications focus on psychosocial aspects of health and illness, particularly on cardiovascular disease in population patterns of sexual health, and in ageing.

Professor Mc Gee was a former president of the European Health Psychology Society and is the current chair of the Cardiac Rehabilitation Section in the European Association of Cardiovascular Prevention and Rehabilitation. She was Principal Investigator on recent national projects including the first Irish National Audit of Stroke Care and SLÁN 2007 and was appointed by the Minister for Health and Children to chair the Department’s National Cardiovascular Health Policy Group.

Dave Shanahan

Dave Shanahan was appointed to the MMI Board of Directors in July 2009. He has held the position of Global Head of Life Science at the IDA since July 2009 where he is responsible for attracting multinational investment to Ireland in the areas of Pharma, Biopharmaceuticals, Medical Technologies and Devices, Food and Healthcare Services. Mr Shanahan has over 22 years of experience in Ireland’s healthcare industry having previously worked for J&J, ICI, Zeneca, the Charter Medical Group and Pfizer Healthcare Ireland. He.is a science graduate of UCC and a business graduate of Trinity College Dublin.

Dr Marina Zvartau-Hind

Dr Marina Zvartau-Hind was appointed to the Board of Molecular Medicine Ireland in November 2009. Dr Zvartau-Hind is the Director of GSK’s Neurosciences Medicines Development Centre and Clinical Leader of their Alzheimer disease projects.

A neurologist by profession, Dr Zvartau-Hind who specialises in neuroimmunology has published extensively in the area of neurosciences. She held the prestigious title of Sylvia Lawry Physician of the Multiple Sclerosis Society from 2001 to 2002 and is a member of both the Scientific Panel of Les Entreprises du Médicament (LEEM) Recherche/Inserm in France with involvement in translational research into Alzheimer disease, and of the International Alzheimer’s Disease Task Force.

Staff Appointments

Marie Mellody

Marie Mellody was appointed Coordinator of the Irish Clinical Research Infrastructure Network (ICRIN) in August 2009 with responsibility for leading the development of ICRIN as a national coordinating centre for clinical research in Ireland and representing Ireland in the European Clinical Research Infrastructure Network.

A science graduate of NUI Galway, Marie has held operations management positions in Hoechst Marion Roussel, Abbott and Serono International S.A. and has service provider experience at the Institute of Clinical Pharmacology, ClinTrials and ICON. Since 2004, Marie has developed an innovative, pan European clinical research network with the objective of identifying a more streamlined and fit for purpose approach to clinical operation and clinical trials. For the past three years, she has provided consultancy services to the UK non-commercial and academic sector to improve the organisation of their clinical studies and to coordinate regulatory compliance.

Fionnuala Gibbons

Fionnuala Gibbons took up the Enterprise Ireland funded position of Clinical trials Liaison Officer in April 2009, with responsibility for the development of clinical research process knowledge and awareness among the indigenous and multi-national pharmaceutical, medical devices, medical diagnostic, nutraceutical and biotechnology companies. Fionnuala brings to the position a wealth of experience in clinical research across the pharmaceutical industry. She initially began her career as a nurse, and then transitioned to clinical research working as a Research Coordinator in the Thrombosis Research Centre in Kings College Hospital, Clinical Research Associate in PPD Contract Research Organisation in Cambridge and Bristol-Myers Squibb (BMS), Dublin. Fionnuala has worked across a variety of therapeutic areas including cardiology, oncology, rheumatology, endocrinology, psychiatry, HIV and haematology. Prior to joining MMI, Fionnuala held the position of Oncology Scientific Advisor for sanofi-aventis.
**NUI Galway, Regenerative Medicine Institute**

The Regenerative Medicine Institute (REMEDI) was established at NUI Galway in 2004 as a Science Foundation Ireland funded Centre for Science, Engineering and Technology with a central focus on the development of novel therapies for treating major human diseases involving adult stem cell therapy and gene therapy.

It has developed a translational research effort with an emphasis on the delivery of therapeutic products to patients and is an integral part of the National Centre for Biomedical Engineering Science. It consists of a large multidisciplinary team of scientists, clinicians, engineers, technicians and veterinarians lead by Professor Tim O’Brien (Director) and Professor Frank Barry.

REMEDI has significant interest in addressing diseases of the vasculature and to this end, is currently looking at stents as a platform from which to deliver a therapeutic product to blood vessels. [www.nuig.ie/remedi/](http://www.nuig.ie/remedi/)

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**RCSI Research Institute**

The RCSI Research Institute is a multi-site infrastructure encompassing the research activities of RCSI at the St Stephen's Green campus and the RCSI Education and Research Centre (ERC) at Beaumont Hospital. This comprises a network of research centres and core facilities in peptide synthesis and labeling, solid phase chemistry, proteomics, clinical research and biobanking, molecular, live cellular and human imaging.

Through this infrastructure of laboratories, core technology platforms and staff, the RCSI Research Institute aims to facilitate and develop sustainable research programmes in translational research in the areas of Neuroscience, Cancer Cell Biology and Genetics, Vascular Biology, Imaging and Molecular Medicine, Population Health, Bio-Engineering, Infection and Immunity.

The Clinical Research Centre (CRC) at Beaumont Hospital, which combines dedicated research beds and laboratories equipped for cell and molecular biology, enables an integrated bench-to-bedside approach to biomedical research. [www.rcsi.ie/research](http://www.rcsi.ie/research)

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**TCD Institute of Molecular Medicine**

The Institute of Molecular Medicine (IMM) was established in 2003 as a state-of-the-art facility housed in a 4,500 sq metre building within the Trinity Centre for Health Sciences at St James’s Hospital. IMM is primarily designed as a molecular research facility. To date, IMM has been successful in bringing key research groups into a single location promoting interdisciplinary and complementary synergies.

IMM is a facility dedicated to research into the molecular basis of human disease with significant core technology platforms in: High Content Screening Analysis, Cell Signalling, High Throughput Genomics, Transcriptomics. It also houses the Irish Gene Bank. IMM’s key research themes are: Infection & Immunity, Cancer and Neurosciences. IMM offers structured postgraduate education programmes
in Molecular Medicine at Diploma, MSc, and PhD level, the latter a prestigious HRB funded 4-year PhD scheme.

IMM’s location on the St. James’s Hospital site permits close interaction between basic and clinical sciences promoting the bench to bedside approach in molecular medicine. IMM has strategically targeted the aggregation of research teams within the institute, and as a result, an excellent pool of academic researchers, clinician scientists, technologists and teaching resources has been assembled and aligned around a molecular level approach to medicine. Currently, IMM houses approximately 180 residents in 16 research teams. www.tcd.ie/IMM

UCD Conway Institute of Biomolecular & Biomedical Research

The UCD Conway Institute of Biomolecular & Biomedical Research is located on the Belfield campus of University College Dublin, the largest university in Ireland. This multidisciplinary centre for research brings together over 550 research staff from all over the University and its associated teaching hospitals.

The research focus of the UCD Conway Institute is the identification of molecular mechanisms underlying human and animal diseases primarily in the areas of Infection, Immunity & Repair, Diabetes & Vascular Biology and Neuroscience. The close collaboration of scientists and clinicians underpins the translational nature of this research from the bench to bedside which is supported by world-class proteomic, bioinformatic and transcriptomic core facilities.

The longer term objectives of the Institute are set on the integration of the biological sciences with those sciences not traditionally associated with biology, with a view to realising the synergistic benefits of such associations. These include computer science, applied mathematics, systems biology, engineering and economics. www.ucd.ie/conway

UCC BioSciences Institute

Basic and translational research at UCC have been greatly enhanced by the opening, in 2002, of the Biosciences Institute (BSI). The BSI provides research space for active investigators in the biomedical area and fosters, through its design and governance, a collaborative and interdisciplinary approach to research questions.

The Institute incorporates six major research programmes, including Neuroscience, Cancer Biology, Cell Signalling and Cardiovascular Health, Plant Biotechnology and Integrative Genomics, Food for Health and Microbe Host Interaction. The BSI houses over 250 scientists from eight different departments, as well as three research centres (APC, CCRC and BIOMERIT). Technology platforms at the BSI include functional genomics, proteomics, bioinformatics, advanced microscopy, cell imaging and transgenics. In addition, BSI is also home to a number of state-of-the-art core facilities such as the Advanced Microscopy Unit, MALDI-TOF (mass spectrometry) and Flow Cytometry. The major unifying theme of the BSI is the improvement of quality of life for patients, while the underlying strategy that ties all research groups together is teamwork. Adjacent to the BSI, and directly linked to it, the School of Pharmacy incorporates a designated industry suite to allow transfer of new pharmaceuticals to industry. www.bsi.ucc.ie
RCSI Clinical Research Centre

Dedicated to maintaining the highest standards in basic and applied research, the RCSI CRC recognises that vertical integration of basic research with pharmacy and therapeutics provides the greatest opportunity to translate basic medical research findings into clinical practice. The CRC, partly funded by Programme for Research in Third Level Institutions, is committed to providing state-of-the-art facilities and equipment to facilitate research, and vertical integration in partnership with academia and the commercial sector in order to gain a better understanding of how drugs work on humans, and to develop life-enhancing therapies through clinical trials and basic research. The driving force of the CRC is excellence in patient-orientated research. Opened in July 2000, the CRC, a facility of the Royal College of Surgeons in Ireland (RCSI), is located on the grounds of Beaumont Hospital, Dublin. The Centre provides physician investigators with a unique facility and a comprehensive range of equipment and services. The CRC is a fully integrated facility providing access to clinical trial services, products and expertise from the RCSI’s medical school, campus biotech companies and it is one of Ireland’s leading teaching hospitals. The CRC is a partner in the Dublin Centre for Clinical Research.

UCD Clinical Research Centre

The UCD clinical research centre is located at St Vincent’s University Hospital and the Mater Misericordiae University Hospital in Dublin in purpose-built facilities and is funded through the Programme for Research in Third Level Institutions. The CRC supports principal investigators, industry sponsored studies and provides researchers with research nursing services, data management and biobanking facilities. The development of Dublin Academic Health Care (an academic medical centre joining UCD’s School of Medicine, St. Vincent’s University Hospital and the Mater Misericordiae University Hospital as a single academic unit) provides common governance for clinical and translational research at both hospital campuses. The UCD CRC is a partner in the Dublin Centre for Clinical Research.

NUI Galway Clinical Research Facility

The NUI Galway Clinical Research Facility, funded by the Health Research Board and the Health Service Executive, opened in temporary accommodation in 2008 and provides key hard and soft infrastructure to enable translational and clinical research. The purpose of the Clinical Research Facility (CRF) is to improve human health through the generation of new medical knowledge from patient based research. The guiding philosophy of the CRF is to stimulate, engage and support health care professionals from diverse areas of expertise to undertake high quality clinical research. The new CRF will be built with translational research laboratories funded by NUI Galway in a building of approximately 5000m² on the campus of University Hospital Galway. This joint clinical and translational research facility will comprise state of the art facilities for patient-based research and for the processing and analysis of bio-specimens such as blood samples from those patients. Planning permission has been received and it is expected construction of the facility will begin shortly.

Centre for Advanced Medical Imaging

The Centre for Advanced Medical Imaging (CAMI) at St James’s Hospital (TCD) was funded by the Health Research Board and opened in the Autumn of 2008. CAMI, which is a national centre open to researchers from other institutions, focuses on three research themes:

1. Cardiovascular imaging techniques that allow visualisation of the vascular tree and assessment of heart function and the viability of heart tissue.
2. Brain MRI imaging techniques that help understand and assess conditions such as stroke, epilepsy, depression and multiple sclerosis.
3. Whole body screening of patients with cancer through new methods that identify abnormal water diffusion in tumours. Prostate and breast imaging in particular have potential to benefit from MRI developments.

CAMI is located close to where the planned Wellcome Trust and HRB Clinical Research Centre and TCD’s Institute of Cardiovascular Science will be built.
Above: RCSI Clinical Research Centre

Above: UCD Clinical Research Centre at the Mater Misericordiae University Hospital

Above: NUI Galway Clinical Research Facility

Above: Centre for Advanced Imaging
Molecular Medicine Ireland has a well-developed Education & Training Programme that began in 2003 as a Dublin Molecular Medicine Centre initiative. Investment from PRTLI has resulted in the creation of a strong cross-institutional postgraduate and postdoctoral structured education and training platform that provides short MMI Courses and Workshops in translational biomedical research. In 2007, the five partner institutions of Molecular Medicine Ireland received funding from the HEA to organise through MMI a Clinician Scientist Fellowship Programme (CSFP). 22 MMI Clinician Scientist Fellowships were awarded in 2008.
Molecular Medicine Ireland - Annual Report 2009

Education & Training

MMI Structured PhD Training for Clinician Scientists

The five Molecular Medicine Ireland partner institutions are collaborating to train a key group in clinical and translational research – Clinician Scientists. In 2009 this collaboration progressed through the MMI Clinician Scientist Fellowship Programme (CSFP), funded by the Higher Education Authority under PRTLI Cycle 4. Twenty two medical graduates continued their PhD research combined with national structured training modules and an Annual Scientific Meeting. The programme underwent its first external review, with a very positive outcome. The year also saw important progress in mainstreaming this investment, with the development of a structured training curriculum that, when implemented, will be accessible to all medical graduates undertaking clinical and translational PhD research in the medical schools of the MMI partners.

MMI Courses and Workshops Supporting Clinical and Translational Research

Mainstreaming of the PRTLI Cycle 3 investment continues to develop and deliver widely accessible short courses and workshops for postgraduate students and postdoctoral staff, with faculty from the five MMI partner institutions and further afield, and with major input and support from industry. In 2009 this collaboration progressed through courses and workshops that provided continuing professional development skill sets to apply a wide range of techniques and technologies to research. Key offerings explored the complexities of drug design and delivery, with both small molecules and biopharmaceuticals featured and with considerable opportunities for participants to engage with faculty based in academia and industry. Further development of the MMI web portal for education delivery in 2009 provided course participants with secure access to course materials and enabled online feedback to assist course development.
Structured PhD Training for Clinician Scientists

Clinician Scientist Fellowship Programme (CSFP)

The five Molecular Medicine Ireland partner institutions are collaborating to train a key group in clinical and translational research through the MMI Clinician Scientist Fellowship Programme (CSFP), funded by the Higher Education Authority under PRTLI Cycle 4 and organised through MMI. The programme provides a systematic way to train this essential group of clinician researchers through a structured three-year PhD programme for medical graduates. It provides unparalleled access to the top biomedical researchers in the country and to state-of-the-art basic and clinical research facilities. For more information on the MMI Clinician Scientist Fellowship Programme, please visit the Education section of the MMI website.

Three new MMI Fellows appointed at the end of 2008, based in University College Cork, began their research in 2009 and joined the original cohort of nineteen fellows for structured training and the first Annual Scientific Meeting.

CSFP Annual Scientific Meeting

MMI Clinician Scientist Fellows presented their research at the first Annual Scientific Meeting (captured in photographs above), held on 11 July 2009 in NUI Galway and opened by the Vice-President for Research, Professor Terry Smith. The Table overleaf gives an indication of the breadth of research in the CSFP. Descriptions of progress in 2009 from five MMI Fellows (pages 32-35) provides a more in-depth look at some of the research and its relevance to patients.

Left: At the CSFP Annual Meeting; Dr Geraldine Boylan (UCC), Dr Ruth Barrington (MMI) with MMI Clinician Scientist Fellows Dr Brian Walsh (UCC), Dr Fergus McCarthy (UCC) and Dr Daniel Schmidt (UCC), who joined the programme in 2009.
Research Presentations from MMI Fellows during the 2009 CSFP Annual Meeting

<table>
<thead>
<tr>
<th>Host Institution</th>
<th>MMI Fellow</th>
<th>Title of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NUI Galway</td>
<td>Dr Aoife Lowery</td>
<td>Breast Cancer Associated microRNAs - Classification using Expression Profiling and Artificial Neural Networks</td>
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<tr>
<td></td>
<td>Dr Aonghus O’Loughlin</td>
<td>Novel Cell Based Approaches in the Treatment of Diabetic Foot Ulcers</td>
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<tr>
<td></td>
<td>Dr Gerard Curley</td>
<td>Investigation of the Effects of Hypercapnic Acidosis, the Role of NF-κB, and the Therapeutic Potential of Gene and Stem Cell Strategies to Modulate NF-κB Activity During the Repair Profile following Ventilation Induced Lung Injury</td>
</tr>
<tr>
<td></td>
<td>Dr Mark Coyne</td>
<td>Myeloma: Cell Cycle Dysregulation</td>
</tr>
<tr>
<td></td>
<td>Dr Ruth Murrell</td>
<td>The Potential Therapeutic Role of BH3 Mimetics in Overcoming Bcl2 Resistance in Haematological Malignancies</td>
</tr>
<tr>
<td>RCSI</td>
<td>Dr Oliver Schubert</td>
<td>Neuroproteomic Analysis of Schizophrenia and Disease-Associated Neuronal Signalling Defects</td>
</tr>
<tr>
<td></td>
<td>Dr Damian McCartan</td>
<td>HDXc11: a Non Steroidal Mediator of Endocrine Resistance in Breast Cancer?</td>
</tr>
<tr>
<td></td>
<td>Dr Finian O’Brien</td>
<td>The Neurobiology of Psychogenic Non-Epileptic Seizures</td>
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<tr>
<td></td>
<td>Dr Mazen Al-alawi</td>
<td>Effect of Lipoxin A4 in Modifying the Airway Surface Liquid Layer</td>
</tr>
<tr>
<td></td>
<td>Dr Sanjay Chotirmall</td>
<td>Oestrogen in Cystic Fibrosis (CF): an Old Hormone up to New Tricks?</td>
</tr>
<tr>
<td>TCD</td>
<td>Dr David Pritchard</td>
<td>Ursodeoxycholic Acid – a Molecular Modulator of the Inflammation-Cancer Sequence in the Oesophagus?</td>
</tr>
<tr>
<td></td>
<td>Dr Fionnuala Ni Ainle</td>
<td>The Anticoagulant Properties of Protamine are Enhanced by Activated Protein C</td>
</tr>
<tr>
<td></td>
<td>Dr Jane McGrath</td>
<td>Brain Function and Connectivity During Attention Orienting in Autism Spectrum Disorder</td>
</tr>
<tr>
<td></td>
<td>Dr Nial Conlon</td>
<td>Immune Variation in idiopathic Bronchiectasis</td>
</tr>
<tr>
<td>UCC</td>
<td>Dr James Ryan</td>
<td>Cellular Mechanisms of Insulin Resistance due to the r432w Mutation of the Insr Gene in Familial Partial Lipodystrophy, Dunnigan Variety (fpld)</td>
</tr>
<tr>
<td></td>
<td>Dr John O’Sullivan</td>
<td>Cytokine Therapy for Myocardial Infarction</td>
</tr>
<tr>
<td></td>
<td>Dr Fergus McCarthy</td>
<td>The Role of PPAR-Y in the Pathogenesis of Pre-eclampsia</td>
</tr>
<tr>
<td></td>
<td>Dr Daniel Schmidt</td>
<td>Do the Dynamics of Quasispecies Complexity and IP-10 Concentration in Chronic Hepatitis C Provide an Opportunity to Individualise Treatment Strategies?</td>
</tr>
<tr>
<td></td>
<td>Dr Brian Walsh</td>
<td>BHV1e Study, Biomarkers in Hypoxic-isaemic Encephalopathy</td>
</tr>
<tr>
<td>UCD</td>
<td>Dr Aidan Ryan</td>
<td>Novel Fibro-suppessant Activities of Lipoxin A4 in Renal Cells</td>
</tr>
<tr>
<td></td>
<td>Dr Eoin Feeney</td>
<td>Human and in vitro Studies Examining the Early Effects of Antiretroviral Drugs on Mitochondrial DNA and Genes Regulating Lipid Metabolism</td>
</tr>
<tr>
<td></td>
<td>Dr Patrick Collier</td>
<td>Unraveling Cardiac Fibrosis – is it Initiated by Activated Endothelium, Perpetuated by Serum Factors and Unmasked by Natriuretic Peptides?</td>
</tr>
</tbody>
</table>

The 2009 CSFP Annual Meeting included a Keynote Lecture from Professor Sherine Gabriel (William J. and Charles H. Mayo Professor of Medicine and Epidemiology, Mayo Clinic, US). Professor Gabriel also joined a judging panel with Dr Christine Dingivan (Executive Vice President and Chief Medical Officer, PPD Inc.) and Professor Matthew Griffin (Professor of Transplant Biology at NUI Galway) to award the MMI CSFP medal for best presentation to Dr Aoife Lowery (NUI Galway). Second prize went to Dr Fionnuala Ni Ainle (TCD), and Dr Oliver Schubert (RCSI) received third prize. Both Dr Dingivan and Professor Griffin gave keynote presentations during the CSFP structured training period preceding the annual meeting.
CSFP Structured Training

Coordinated by MMI and developed with an Education Committee that includes representation from each MMI partner institution, this national element to the CSFP comprises a structured taught course curriculum delivered by experts in biomedical research and also providing important transferable skills.

The 2009 Annual Meeting was preceded by a week of Structured Training (6-10 July) delivered by NUI Galway (see Table opposite). This included an intensive hands-on workshop in Biostatistics that was opened to a wider audience through the MMI Courses & Workshops Programme.

## Modules

- Workshop in Biostatistics
- Functional Biomaterials based approaches for Tissue Engineering and Regenerative Medicine
- BioEngineering
- Bibliometrics: Finding the Needle in the Information-Stack
- How to Review a Scientific Manuscript
- Grant Writing
- Advanced Imaging
- Intellectual Property and Patents in Ireland’s Smart Economy
- The Road Less Travelled: A Career in Medical Education

### Techniques Workshops:
- Basic Molecular Biology Techniques
- Real Time PCR
- Immunohistochemistry/Immunocytochemistry
- Flow Cytometry (FACs)
- DNA, RNA & Protein Isolation
- Microarrays
The external reviewers were impressed with the vision and delivery of the Clinician Scientist Fellowship Programme

Dr Diana Dunstan (formerly Director of Research & Training at the UK Medical Research Council) and Professor John Iredale (Professor of Medicine at the MRC Centre for Inflammation Research, University of Edinburgh) undertook an external review of the MMI Clinician Scientist Fellowship Programme on 11-12 June 2009.

The reviewers were impressed with the vision and delivery of the CSFP. They felt that the cohesion MMI has achieved between the direct stakeholders across Ireland was highly impressive, and they noted that the centralised appointments process was perceived as fair and essential in assuring quality. The reviewers identified particular strengths of the programme: the high quality, well-motivated and dedicated cohort of fellows, the structured training modules, and the co-supervision of research projects that brought together basic and clinical scientists.

The reviewer’s report is available on the MMI website, together with MMI’s responses to their recommendations.

Structured PhD Curriculum for Clinician Scientists

The experience gained and expertise assembled in developing and delivering the CSFP structured training will be sustained through the development of a collaborative structured PhD curriculum. When implemented, this will be accessible to all medical graduates undertaking clinical and translational PhD research in the medical schools of the MMI partner institutions. A curriculum outline was agreed in 2009 and we are proceeding to identify existing and develop new postgraduate education modules to deliver the curriculum.
Courses & Workshops Supporting Clinical and Translational Research

The widely available short courses and workshops began in 2003 as a Dublin Molecular Medicine Centre (DMMC) initiative. Investment from PRTLI has been sustained as a strong cross-institutional postgraduate and postdoctoral structured education and training platform that supports clinical and translational research.

<table>
<thead>
<tr>
<th>MMI Course / Workshop Title</th>
<th>Dates</th>
<th>Venue</th>
<th>No. of Attendee(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biostatistics * (in collaboration with HRB Clinical Research Facility Galway)</td>
<td>6-10 July 2009</td>
<td>NUI Galway</td>
<td>56</td>
</tr>
<tr>
<td>Magnetic Resonance Imaging Applications in Research (in collaboration with CAMI **)</td>
<td>17 Sep 2009</td>
<td>TCD Institute of Molecular Medicine</td>
<td>39</td>
</tr>
<tr>
<td>Drug Design &amp; Delivery</td>
<td>12-13 Oct 2009</td>
<td>Royal College of Surgeons in Ireland</td>
<td>59</td>
</tr>
<tr>
<td>Molecules to Medicines: How Biopharma Delivers (Course &amp; Workshop in collaboration with Pfizer)</td>
<td>5-6 Nov 2009</td>
<td>William Stokes Postgraduate Centre, St James’s Hospital</td>
<td>25</td>
</tr>
<tr>
<td>Techniques &amp; Strategies in Molecular Medicine</td>
<td>8-9 Dec 2009</td>
<td>UCD Conway Institute</td>
<td>114</td>
</tr>
</tbody>
</table>

* Developed for the CSFP and opened to a wider audience. Those attending comprised 21 MMI Clinician Scientists Fellows, 2 HRB-funded Fellows and 33 other attendees.

** HRB Centre for Advanced Medical Imaging, St James’s Hospital, Dublin.
Development and delivery of MMI courses and workshops in 2009 built on and extended the successes of previous years in bringing together the expertise of five academic institutions and affiliated hospitals, major engagement from industry and top international speakers. The high quality faculty developed modules to engage a wide cross-institutional audience of postgraduate students and postdoctoral staff. The new interactive MMI website was utilised to first attract and then engage with course and workshop participants, as well as providing the tools to automate complex administrative tasks. There were 287 attendances to MMI courses and workshops in 2009, including participants based in institutions outside the MMI partnership (e.g. Queen’s University Belfast, Dublin City University, NUI Maynooth, Dublin Institute of Technology and Industry).

Provision of discipline-specific skill sets, a core continuing professional development activity of MMI, was to the fore in 2009 with a new intensive practical workshop in Biostatistics (developed with the HRB Clinical Research Facility Galway as part of the PRTLI Cycle 4 funded MMI Clinician Scientist Fellowship Programme and opened to a wider audience), the fourth run of the Drug Design & Delivery course, a new Magnetic Resonance Imaging Applications workshop (with the HRB Centre for Advanced Medical Imaging, St James’s Hospital), the fourth run of the MMI/Pfizer Molecules to Medicines: How Biopharma Delivers course and workshop. The year ended on a high note with the seventh run of the Techniques & Strategies in Molecular Medicine course attracting an audience of 4 to hear lecturers covering multiple techniques and technologies from RNA interference to systems biology, taking in gene expression, transgenics and knockouts, proteomics, imaging and immunodetection and many more. A total of 691 people have attended Techniques & Strategies in Molecular Medicine since it began in 2003.

Faculty breakdown in 2009

Since 2003, 239 individuals have assembled as faculty on over 55 DMMC/MMI courses and on structured training for the MMI Clinician Scientist Fellowship Programme. There were 62 faculty members in 2009.

Companies who provided speakers to the MMI Faculty in 2009:

- BCM Hanby Wallace
- Elan
- Merrion Pharmaceuticals
- Pfizer
- PPD Inc.
- Sanofi-Aventis
- Servier

Above: During the MMI Techniques & Strategies in Molecular Medicine course (December 2009): from left to right, Dr Mark Watson (MMI), Professor Pierre De Meyts (Hagedorn Research Institute, Denmark), Professor Boris Kholodenko and Professor Walter Kolch (both Systems Biology Ireland). Professor De Meyts’ keynote lecture was sponsored by Novo Nordisk.
Discovery, development and manufacturing of both small-molecule drugs and biopharmaceuticals were examined in-depth in two courses. Both featured a strong input from industry, with faculty from Pfizer, BCM Hanby Wallace, Elan, Merrion Pharmaceuticals, Sanofi-Aventis and Servier. *Drug Design and Delivery*, held in October, focused on the structural basis for drug activity,(including the use of computer-aided design, with a follow-up visit to the TCD 3D Visualisation Facility), considerations for optimal drug delivery (lectures by the SFI-funded Irish Drug Delivery Network), overviews of clinical trials (from ICRIN) and the regulatory process. *Molecules to Medicines: How Biopharma Delivers*, which took place in November, is a long-standing collaboration with Pfizer (formerly Wyeth) that incorporates overview lectures, a small-group workshop with problem sets devised and discussion led by Pfizer staff and a visit to the Grange Castle facility.

All MMI Courses and Workshops taking place in 2009 obtained financial support from commercial sponsors, co-organisers, or participant fees. During 2009, MMI also made places available to a wider audience on selected institutional postgraduate education modules in UCD and UCC.

Reports of all these courses and workshops are available on the MMI website. For more information please visit: www.molecularmedicineireland.ie/education/courses

**Courses and Workshops**

**Attendances breakdown since 2003 (Total=2942): Position**

**Attendances breakdown for 2009 (Total=287): Institutional Affiliation**
In 2009 MMI continued its focus on biobanking recognising the strategic importance of biobanking as a key pillar to support clinical and translational research.

The Design Phase Report of GeneLibrary Ireland was submitted to the Health Research Board and the Research and Development Office of the Health & Social Care Service in Northern Ireland. As proposed GeneLibrary Ireland would be an all-island control biobank with 10,000 DNA and blood samples from healthy volunteers, together with key phenotypic information which would provide an invaluable control population to study the genetic determinants of common diseases that significantly impact patients in Ireland and Northern Ireland.

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 overall view of the GeneLibrary Ireland international Scientific Advisory Board was that ‘the design phase of GeneLibrary Ireland is an excellent plan how to establish a world-class all-island biomedical research infrastructure that is well embedded in the emerging European research infrastructure landscape’. A copy of the GeneLibrary Ireland Design Phase report is available at http://www.molecularmedicineireland.ie/page/gt1/4.

MMI hosted a Stakeholder Seminar entitled ‘GeneLibrary Ireland - building an all-island biobanking framework through collaboration’ in May 2009 to provide an overview of the vision for GeneLibrary Ireland and to promote the benefits of a structured framework for harmonised biobanking to support clinical and translational research studies on the island of Ireland. As part of this seminar a representative from the Department of Health and Children presented an outline of the principles in the proposed Human Tissue Bill and the implications of this legislation for research involving human tissue donated from living donors and biobanks in the future.

Unfortunately due to the severe fiscal environment and despite exploring every possibility, funding could not be secured to move to the implementation phase of GeneLibrary Ireland.

Current biobanking situation in Ireland

There is no population based biobank in either Ireland or Northern Ireland and no all-island clinical biobank. However a number of disease specific bio-collections in oncology, cardiovascular disease, neuropsychiatric disorders and HIV have been funded by research funding bodies to support 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. 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 therefore 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
Research - A strategic approach to Biobanking

resource. This has led MMI to agree a position paper on a strategic approach to the development of biobanking on the island of Ireland with the following vision:

To create 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.

In 2009, MMI also contributed to a joint biobanking submission to the Government’s Innovation Task Force coordinated by IDA.

MMI Guidelines for Standardised Biobanking

As a contribution towards a more strategic national approach to biobanking, and building on the work undertaken in the Design Phase of GeneLibrary Ireland, MMI has developed guidelines to standardise the collection, processing and storage of biological materials donated for use in research. The aim of the Guidelines is to ensure sample quality, consistency and integrity of bio-collections at different clinical and research centres in Ireland. The use of standardised protocols for sample collection, processing and storage will help to ensure consistency and harmonisation across the different sites. These Guidelines have been drafted with reference to international best practice in biobanking.

By the end of 2009 the draft Guidelines were approved by the Board of MMI and a consultation phase initiated to invite the input of the research community engaged in biobanking to these draft Guidelines prior to finalisation and publication in the first quarter of 2010.

MMI is pleased to note that these Guidelines have attracted great interest in Europe with Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) agreeing to adopt them as a first version of the laboratory manual for BBMRI. The guidelines once finalised will be submitted as a joint submission from Ireland and the UK as part of the deliverables for Work Package 3.

MMI believes that the adoption of these Guidelines, once finalised, for all new bio-collections would be a first step towards harmonising biological collections across different research/clinical centres and a contribution towards a more strategic approach to biobanking nationally. MMI hopes that all those who support or are engaged in research that involves biobanking, including research funding agencies, hospitals and clinical research centres, clinical networks and disease groups will adopt these Guidelines as the basis for all newly funded collections of biological material. If the Guidelines are adopted in this way, we will have taken a significant step towards a more strategic approach to biobanking in Ireland and ensure a greater return for public investment in biobanking.
Research Highlights across MMI Partner Institutions

**SCOPE - SCreening fOr Pregnancy Endpoints**
Dr Louise Kenny (UCC)

University College Cork are part of the SCOPE (SCreening fOr Pregnancy Endpoints) programme which aims to recruit 10,000 patients globally, taking samples from mothers, fathers and babies to build a pregnancy biobank. The overall aim of the SCOPE scientists is to develop predictive tests for common disorders of late pregnancy.

SCOPE Ireland is funded by the HRB and is directed by Dr Louise Kenny, a HRB Clinician Scientist and a Senior Lecturer and Consultant Obstetrician and Gynaecology at the Anu Research Centre in UCC. In total UCC are contributing 3000 women to the global SCOPE biobank.

The research on the biobank at UCC is focused on discovering and developing predictive tests for pre-eclampsia and intra-uterine growth restriction. Dr Richard Horgan, a HRB Clinical Training Fellow undertaking a PhD with Dr Kenny, is using a variety of mass spectrometry techniques allied to advanced machine learning to discover novel metabolomic biomarkers in pregnancies complicated by intrauterine growth restriction and pre-eclampsia. Early results are extremely encouraging and Dr Kenny has recently been awarded a Translational Award from the Wellcome Trust to develop a platform that will form the basis of a clinically useful commercial test.

**TILDA - The Irish Longitudinal Study on Ageing**
Profs Rose Anne Kenny and Brendan Whelan, TCD

The Irish Longitudinal Study on Ageing (TILDA) is a major inter-institutional initiative led by Trinity College Dublin which aims to produce a massive improvement in the quantity and quality of data, research and information relating to older people and ageing in Ireland. The study is being carried out through a collaboration of scientific researchers, with expertise in various fields of ageing, from Dundalk Institute of Technology, Economic and Social Research Institute (ESRI), National University of Ireland Galway (NUIG), Queens University Belfast (QUB), Royal College of Surgeons in Ireland (RCSI), Trinity College Dublin (TCD), University College Cork (UCC), University College Dublin (UCD), and Waterford Institute of Technology.

Eligible respondents for this study include individuals aged 50 and over (or their spouses/partners) and resident in Ireland, collecting detailed information on all aspects of their lives, including the economic (pensions, employment, living standards), health (physical, mental, service needs and usage) and social aspects (contact with friends and kin, formal and informal care, social participation). Both survey interviews and physical and biological measurements are utilised. The study is closely harmonised with leading international research so as to ensure adoption of best practice and comparability of results.

TILDA commenced its field work in September 2009 with the first wave of data collection. A Dublin-based and a national pilot study had previously been conducted.

For more information, please see www.tilda.ie
Five year milestone reached by the Prostate Cancer Research Consortium
Prof William Watson (UCD) and Prof Mark Lawler (TCD)

In 2009 the Prostate Cancer Research Consortium (PCRC) celebrated its fifth year of Research and Collaboration. To mark this important milestone in the consortium’s development it has prepared a report of its activities and achievements to date. This report will be launched in May 2010. As a result of this review the consortium has published over 30 papers, leveraged 18 additional grants contributing over €4M in funding to the core grant from the Irish Cancer Society and mentored and trained 33 PhD and MD students (18 completed and 15 in progress). This research activity has a strong focus on addressing clinically relevant questions that will impact on patient diagnosis and treatment. Central to the consortiums activities is the bio-resource which has recruited over 550 patients who have donated tissue, blood, urine and DNA samples to the resource and which has been central to the translational focus of the consortium’s activities. Recently the PCRC has been accepted by the Dublin Centre for Clinical Research (DCCR) as a clinical interest group, providing the infrastructure and the motivation to advance the consortium’s discoveries into the clinical arena. This collaboration will ensure the continued development of this vital resource supporting research nurses in each of the clinical sites and the continued development of the Biobank Information Management System (BIMS) database which is key to linking the individual clinical and research sites.
The five MMI partner institutions are collaborating to train a key group in clinical and translational research though the Clinician Scientist Fellowship Programme.

Funded by the Higher Education Authority under PRTLI Cycle 4 and organised through MMI, the programme provides a systematic way to train medical graduates in research through a three year PhD project combined with national structured training modules. Twenty two MMI Fellows are undertaking research in the five MMI partner institutions. Here, a representative sample of the Fellows research and progress made in 2009 is highlighted. See page 20 for more information on the CSFP and visit the MMI website to view descriptions of research from the other MMI Fellows.

Dr Fionnuala Ni Ainle (TCD)
Supervisors: Dr James O’Donnell / Dr Roger Preston
Title: Generation and Characterisation of Activated Protein C Variants with Altered Functional Properties and Enhanced Therapeutic Potential.

The only effective therapy currently available for patients admitted to intensive care units with severe sepsis is a recombinant anticoagulant protein, Activated Protein C (APC). Interestingly, studies have shown that the beneficial effects of APC in such patients are not entirely attributable to the anticoagulant effects of APC. Rather, APC also has a separate “cytoprotective” function and can directly modulate the inflammatory response by initiating complex intracellular signalling.

The aims of my project are to generate and characterize novel APC variants with enhanced functional properties that could be utilized for potential therapeutic gain. Furthermore, these variants will provide further insight into the molecular and cellular basis through which the anticoagulant and anti-inflammatory effects of APC are mediated.

Major findings to date include generation of a novel APC variant which lacks anticoagulant function but exhibits enhanced cytoprotective properties. This variant has potential as an improved therapy in sepsis because administration of APC in this setting is frequently limited by bleeding.

An important interaction between APC and the heparin-reversing agent protamine sulphate was also characterized. This work led to the elucidation of the molecular mechanism through which protamine can cause bleeding, an unwanted side effect often occurring immediately after cardiothoracic surgery.

Ongoing work is directed towards discovering novel approaches to enhance the therapeutic potential of APC and ultimately to improve its efficacy in sepsis treatment.
Cystic Fibrosis (CF) is a genetic disorder affecting many organs with the leading cause of mortality being recurrent infection and airway destruction. Ireland has the highest incidence and carrier rate of CF worldwide. Females with CF have more aggressive disease particularly with the onset of puberty. They have worse lung function, increased mortality and earlier bacterial colonization compared to male CF patients. An explanation for this “gender gap” in CF remains elusive. This research investigated the role of the female sex hormone oestrogen as a potential cause of the CF gender gap. This work has found that exposing the cells which line the airways of the lungs (epithelial cells) to oestrogen produces an inhibition of an important inflammatory protein (interleukin-8) in CF. This IL-8 protein is normally released by the epithelial cells in response to bacterial and viral infection in the CF lung. Oestrogen acts on cells by binding to two types of receptors, oestrogen receptor alpha (ERα) and oestrogen receptor beta (ERβ).

The expression of both of these receptors in CF epithelial cells grown in the laboratory and also from samples obtained from the lungs of CF patients was measured. Both types of oestrogen receptors were detected in CF cells although ERβ receptor expression was greater than the expression of the ERα type. Using drugs which activate or inhibits these different oestrogen receptors, this work showed that oestrogen acting through the ERβ receptor caused the inhibition of IL-8 release from CF cells in response to an inflammatory stimulus. This research also showed that amounts of another protein called secretory leucoprotease inhibitor (SLPI) in the cell increased after exposure to E2 and that this protein moves into the nucleus of CF cells after exposure to oestrogen. The SLPI protein acts to prevent the release of IL-8 from the CF epithelial cells. In summary, E2 inhibits IL-8 release through the ERβ receptor in CF cells by increasing the amounts of SLPI protein in the cell. This research shows a novel anti-inflammatory mechanism for E2 in females with CF, which may predispose to infection and colonization. These data may at least in part explain the gender differences observed in CF.
Research Highlights from 
MMI Clinician Scientist Fellows

Dr Aidan Ryan (UCD)
Supervisors: Prof Catherine Godson / Dr Denise Sadlier
Title: An investigation of the therapeutic potential of lipoxins and lipoxin analogues in diabetic nephropathy

Tubulo-interstitial fibrosis is the final common pathway in chronic kidney disease (CKD) leading to end-stage kidney disease (ESKD). This process results in replacement of the functional unit of the kidney with scar tissue resulting in a requirement for either dialysis or transplantation. At present there is a limited number of available effective therapies that limit this process. The aim of this research project is to explore the therapeutic potential of lipoxin A4 (LXA4) as a novel suppressant of renal fibrosis.

Renal fibrosis may reflect recruitment of circulating fibrocytes, activation and proliferation of resident renal fibroblasts and transition of epithelial cells to a mesenchymal phenotype [EMT]. This research group has previously reported that the novel anti-inflammatory and proresolution eicosanoid LXA4 can attenuate EMT in models of fibrotic injury (Rodgers et al., Am J Pathol 167(3): 683-94; 2005). Here we have explored whether LXA4 might also impact on aldosterone and TGF-\(\beta\)1- driven renal fibroblast proliferation, activation and extracellular matrix (ECM) production.

Recent research suggests a growing appreciation of the role of aldosterone as a key mediator in renal fibrosis, however the exact molecular mechanisms involved remain unknown. This research provides novel evidence of the key role of TGF-\(\beta\)1 in aldosterone induced fibroblast activation and CTGF induction. In summary this research indicates the potential of LXA4 as a novel suppressant of renal fibrosis, which we will further explore using a relevant in vivo model.
Cardiovascular disease remains the leading cause of death in the western world. This research is investigating new mechanisms of heart tissue repair and regeneration following a “heart attack” or myocardial infarction (MI), and new methods of imaging the damaged heart tissue in this context.

Promising cardioprotective effects of both Insulin-like Growth Factor-1 (IGF-1) and Nitrite are being demonstrated using the latest generation 64-slice CTPET to image myocardial function, remodelling, and tracking of therapies to the infarct zone.

At 24 hours a significant reduction in cell death in damaged heart tissue was noted and an improvement in heart function with IGF-1 treatment. This benefit was sustained long term, since at two months, a significant reduction in infarct size, heart wall thinning, wall motion defects and a significantly reduced impairment of heart contractility was observed with IGF-1 treatment.

Using Nitrite, which is the precursor to nitric oxide used by angina patients, a significant cardioprotective effect independent of blood flow was demonstrated via myocardial perfusion on CT. Using microscopic fluorescent microspheres which can travel down the smallest heart vessels, it was demonstrated that nitrite increases flow into the core of the heart attack area, known as the “microvascular obstruction” area. This has significant implications for future therapeutic delivery, as it literally “opens up” this area for drug delivery.
Technology Platform Web-Portal

MMI’s Translational Research Strategy for 2009, identified the creation of a Web-Portal as an important contribution to mapping the state-of-the-art technologies and expertise that have been funded to support and advance biomedical research in molecular medicine in Ireland. MMI launched the Technology Platform Web-Portal in December 2009.

The Web-Portal was developed, with the input of the research community, to promote and showcase the breadth of Technology Platforms and associated expertise that support clinical and translational research in our partner institutions and collaborators. The Web-Portal also provides details on how these Technology Platforms can be accessed.

The MMI Technology Web-Portal includes technologies in proteomics, medical and pre-clinical imaging, genomics/transcriptomics, mass spectrometry, flow cytometry, data management and IT support to name a few.

MMI recognises that the list of Technology Platforms currently uploaded onto the Web-Portal is by no means complete but is an important first step. We view this as a work in progress and are keen to learn of additional Technology Platforms and to upload these onto the Web-Portal in order to provide as complete a listing as possible. MMI will continue to work with our partner institutions and the development agencies, to ensure that the Technology Platform Web-Portal provides a comprehensive overview of the enabling technologies and associated expertise that is available to support clinical and translational research in molecular medicine in Ireland.

To view the MMI Technology Platform Web-Portal, please click on the following link; www.molecularmedicineireland.ie/tp_web_portal

To update your Technology Platform onto the Web-Portal, follow the link on the home page which will allow you to upload your information electronically.

The MMI Technology Platforms Web-Portal has also been designed to promote ‘news items’ and ‘events’ related to Technology Platforms. News items and/or events for inclusion on the Web-portal should be submitted to tp@molecularmedicineireland.ie

MMI believes that the Web-Portal will prove a useful information resource for the research community, industry, development agencies and funding bodies.
In vivo imaging of molecular events in animal models holds significant potential in areas like oncology, cardiovascular disease, neurology, diabetes, infectious disease and inflammation research. Molecular imaging is also an essential tool for translational research and new drug development, with the rapid emergence of imaging-based biomarkers. The development of multi-modality methodologies based on PET/SPECT, MRI, CT and optical imaging is the single biggest focus in many imaging centres worldwide. UCD has made major progress in recent years in establishing a comprehensive preclinical imaging platform via two SFI Equipment Awards in 2006 and 2007 (>1.84 million euro in total from SFI, plus 170k euro from UCD). This dedicated small animal-focused Molecular Imaging Facility houses an optical imaging system (IVIS Spectrum) based at the UCD Conway Institute, as well as a microPET/CT and microSPECT/CT within UCD’s dedicated Biomedical Facility. The optical imaging system has been widely used by a number of research groups both within UCD and other external institutions (RCSI, TCD) to examine key pathophysiological events in cancer and inflammation, as well as for novel drug evaluation studies in these therapeutic domains. The microPET/CT and microSPECT/CT facilities are going through the final stages of commissioning, with first scans to take place in Q2 of 2010. Initial support staff has been funded through SFI, UCD and other external research grants to facilitate access to these facilities by external investigators on a collaborative research basis.

The Pre-Clinical Molecular Imaging Facility’s primary expertise is in the area of tumour biology, but has also interacted closely with groups applying optical imaging approaches to assess inflammatory responses in vivo. The Facility has an interest in applying in vivo imaging technologies in other therapeutic areas via collaborative interactions with experts in these fields, particularly in relation to the use of imaging for stem cell tracking and evaluation of drug responses. Further information: http://www.ucd.ie/conway/research/coretechnologies/pre-clinicalimaging/

Contact: Prof. William Gallagher (william.gallagher@ucd.ie) with regard to the use of the Pre-Clinical Molecular Imaging Facility, including collaborative research studies.
Research Technology Platforms

ABCRF High Resolution Mass Spectrometry Centre, ABCRF and Chemistry Department, UCC.

The ABCRF High Resolution Mass Spectrometry Laboratory was established in 2006 through funding from the HEA and contains state of the art Liquid Chromatography Mass Spectrometers (LCMS) which provide the analytical tools for very detailed information to be collected from a HPLC chromatogram. The molecular ion (and consequently molecular weight) of any fraction in a mixture of components can be identified and characterised via low resolution measurements or fragmentation experiments while the elemental composition of components can be confirmed by high resolution measurements. The utility of the technique is widespread in the identification of unknowns and impurities in mixtures.

The Laboratory supports a broad range of research including the characterisation of novel compounds; identification of unknowns in a known matrix; impurity profiling of a process or mixture; quantification of biomarkers and other biomolecules; collection of significant quantities of new impurities for further analysis (NMR etc.). The Laboratory has well-established links with the Chemical and Pharmaceutical Industry and also with educational institutions throughout the country.

Further information: http://chemweb.ucc.ie/Mass%20Spec/mass%20specnew.htm

Contact: Dr. Florence McCarthy (f.mccarthy@ucc.ie) with regard to the use of this Facility.

Trinity Genome Sequencing Laboratory, Institute of Molecular Medicine, TCD

The Trinity Genome Sequencing Laboratory was established in 2008 through funding from SFI as a national platform and houses an Illumina Genome Analyzer II, a next-generation DNA sequencing platform. This national platform allows scientists to undertake studies in molecular biology and genetics research that were previously not technically or economically feasible. The range of genetics applications available with this ultra-high throughput sequencing technology includes (i) DNA Sequencing, (ii) Transcriptome Analysis and (iii) Studies of Gene Regulation and Control. This core facility is supported by full-time research staff and is available to all academic and industry-based researchers in Ireland.

This facility provides assistance to researchers interested in undertaking a project using the Illumina Genome Analyzer in the following key areas:

• Advice on study design and costs
• Advice and guidance on sample preparation
• Library preparation, cluster generation, sequencing and primary data analysis
• Advice and guidance on secondary data analysis

Further information: www.medicine.tcd.ie/sequencing

Contact: Dr Derek Morris (morrisdw@tcd.ie) or Dr Elaine Kenny (elaine.kenny@tcd.ie) for project enquiries/project quotes.
National Stem Cell Manufacturing Facility, REMEDI, NUI Galway

The National Stem Cell Manufacturing Facility was established in 2003 through funding from SFI and the HEA. The Facility is dedicated to the production of cellular and gene therapy investigational medicinal products for clinical use, such as adenoviral gene therapy vectors and adult mesenchymal stem cells, according to current Good Manufacturing Practice (GMP).

The Facility contains two separate production suites, allowing for the parallel manufacture of investigational medicinal products. The Facility has a complement of personnel comprising the following functional areas – Quality Assurance, Facilities, Production, Quality control.

The Facility encompasses a working floorspace of approximately 250 M2 and possesses two equipped production suites comprising of three processing rooms (Preparation Room, Downstream Process Room, Filling Room) for various stages of the mesenchymal stem cell isolation and culturing process. The Facility is serviced by a dedicated CO2 gasline and Liquid N2 generation plant, and highly filtered air is provided to both production suites by independent air handling systems. As dictated by current EU legislation for medicinal products, the processing rooms are classified as Grade B according to Annex I of the EU sterile medicinal product manufacturing guidelines, with open manipulations of the product being performed in a Grade A environment.

The Facility supports REMEDI’s translational research programme with particular focus in the areas of orthobiologics (osteoarthritis, cartilage repair), diabetes, cardiovascular disease and neural regeneration. The Facility presently supports the production of research-grade viral vectors to support gene therapy research, including adenoviral, retroviral and lentiviral vectors. In the future, the Facility also aims to produce clinical-grade viral vectors under licensed GMP conditions.

The GMP Facility offers the following services and expertise:

- Cleanroom operations
- GMP medicinal product manufacture
- Quality Management (QMS, documentation, audit, quality assurance, quality control)
- Regulatory affairs
- GMP training, validation and qualification


Contact: Prof. Timothy O’ Brien (Timothy.obrien@nuigalway.ie) with regard to the use of this Facility.
ICRIN - Irish Clinical Research Infrastructure Network

The Irish Clinical Research Infrastructure Network (ICRIN) was established in 2006 by five academic partners (NUI Galway, RCSI, TCD, UCC, UCD) and its preparatory phase is funded by the Health Research Board and the Health Service Executive with additional support from Enterprise Ireland. ICRIN operates as a business unit of Molecular Medicine Ireland.

ICRIN Coordinator Appointed

In August 2009, Marie Mellody joined MMI as ICRIN Coordinator to complete the work plan begun by her predecessor Margaret Cooney, to ensure delivery of ICRIN objectives and ICRIN’s obligations to the Irish and European stakeholder community.

Review of ICRIN Objectives

The objectives of ICRIN, as refined in 2009, are:

- Standardisation of approach to clinical research nationally, including the standardisation of biobanking and promotion of a technology platform web portal
- Driving the standardisation of clinical research education and training
- Enabling investigator led, multi-centre clinical trials and other research activities by networking of the clinical research centres (CRCs) of MMI’s five partner institutions and other research teams nationally
- Engaging with European and international research developments via the European Clinical Research Infrastructure Network (ECRIN) and the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)
- Supporting indigenous innovators and small to medium enterprises (SMEs) in accessing the clinical resources they need to bring their products to market.

During 2009, ICRIN and MMI focused on the more detailed elements of the work plan involved in establishing the appropriate elements of a research infrastructure prior to the end of the preparatory phase in February 2010. With the support of the MMI Board and the HRB, ICRIN initiated a ‘Research Readiness’ review of the research infrastructure elements.
available in the partners’ CRCs and other research networks. The overall goal of the Research Readiness programme is to evaluate the research systems which are already functioning well in Ireland, identify the areas where more consistency of approach will be of benefit (sharing best practice) and gain information from the research teams on the research infrastructure elements which would be best addressed at national level.

ICRIN – Supporting Researchers in Ireland

ICRIN’s mission is primarily to support and harmonise investigator-led research, academic innovators and indigenous small to medium enterprises (SMEs) in Ireland through the provision of general and bespoke advice, education, processes and tools in the following areas:

- Research project/trial risk assessment guidance to evaluate the appropriate level of quality management, trial management and monitoring systems which are needed for the wide variety of research performed by researchers nationally.
- Review of the approaches to governance and sponsorship arrangements nationally and the links with regulatory and ethical approval systems across the academic and commercial research landscape.
- Pragmatic input and advice on protocol development, informed consent and other core documents for use in research programmes.

Template documents for all the main clinical trial processes have been developed which are currently being validated with our research teams. The suite of documents will be made available to support all non-commercial researchers in Ireland on the MMI research portal under development.
- Standardised processes for biobanking, based on MMI’s Guidelines for Standardised Biobanking, to assist with protocol development for the collection, processing and storage of biological samples as part of clinical research.
- Good clinical practice training.

ICRIN’s goal is to support researchers during the conduct of their research programmes to deliver these activities efficiently and effectively and to international and national standards. ICRIN achieves this goal by transferring the necessary knowledge, skill sets and methodologies to the research teams during the Research Readiness programme.

ICRIN - Supporting Innovation and Enterprise

In April 2009, Fionnuala Gibbons was appointed Clinical Trials Liaison Officer (CTLO) to support indigenous innovators and small to medium enterprises (SMEs) to access the clinical resources they need to bring their products to market.

The ICRIN CTLO has focused on the development of enterprise and industry facing initiatives where a lot of
progress has been made in connecting the people and
the skills within Ireland to support the Irish innovators in
further developing their research ideas into commercial
opportunities. This work is performed with a very close
and successful working partnership with the Enterprise
Ireland teams.

New relationships and productive linkages have
been established through face to face meetings with
indigenous pharmaceutical, medical device and biotech
companies and start-up companies from academic/
university innovators.

An information service has been provided on the
clinical trials process including clinical research
legislation, ethics committee requirements and
essential documentation to support submissions to the
Irish Medicines Board and Ethics Committees.

ICRIN - the Irish Scientific Partner of ECRIN

ICRIN is the Irish scientific partner in the European
Clinical Research Infrastructures Network (www.
ECRIN.org ), contributing to the creation of a research
infrastructure for clinical research across Europe.
Participation in ECRIN provides ICRIN with up to date
knowledge of European and international research
trends and requirements of benefit to Irish researchers
who wish to increase the reach of their research
programmes internationally. ICRIN also facilitates
access to the ECRIN network partners in participating
member states, and if required, to the ECRIN Scientific
Review Board that assesses the suitability of research
proposals for participation by the ECRIN partners. If
a study is approved by the Review Board, ICRIN will
either facilitate participation by Irish researchers or if it
is a study initiated in Ireland, connect the researchers to
the European Correspondent network in each country
to assist in starting up the research programme.

One of the catalysts for the ‘Research Readiness’
programme was a request from ECRIN to showcase
European research capabilities on a web portal with
the aim of promoting access and linkages between
academic researchers at European level.

ICRIN is actively involved in the provision of the Irish
input and expertise to the European developments in
the following ECRIN programmes of work:

- Finance and Trial Costing which is developing
costing models for the conduct of investigator led
research projects in Europe as well as the business
plan for the operation of the ECRIN infrastructure
- Education and Training which is developing
harmonised training approaches and a web based
training portal for use by ECRIN members and
researchers in member countries.
- Risk Assessment, Quality Management and
Monitoring which are establishing a means of
identifying fit for purpose operating models and
oversight methods for research activities performed
using the ECRIN network members
- Capacity Building and Pilot Projects which
ensure all new ECRIN members benefit from the
expertise of the member networks in the set up of
their national research networks and services and
in performing trials within the ECRIN network
- Data Management and Safety which are
developing a data centre and pharmacovigilance
centre accreditation criteria to ensure national
data and safety centres meet minimum acceptable
criteria for use by ECRIN approved European
research programmes.

Irish authorship has been noted in two ECRIN
definition for categories of clinical research: a prerequisite for a survey on regulatory requirements by the European Clinical Research Infrastructures network (ECRIN) Trials 2009, 10:95” and “Hernandez et al 2009 - Harmonisation of ethics committees’ practice in 10 European countries JMed Ethics, 2009 35: 696-700”

ICRIN and the HRB have also had considerable input into the development of the ECRIN and Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) business plans for the legal framework to enable ECRIN and BBMRI to become fully operational as legal entities in 2011.

ICRIN Highlights in 2009

In March 2009, ICRIN published the Clinical Research, Irish Situation Analysis 2008, a report compiled by Margaret Cooney, former ICRIN Co-ordinator. This report which is the first of its kind provides a comprehensive overview of the requirements for undertaking clinical research in Ireland. It describes the legal and regulatory environment and outlines the day to day operational aspects of clinical research management, including ethics committee approval, safety reporting, data management and quality requirements. The report addresses clinical research involving pharmaceutical products, medical devices and nutriceuticals as well as observational and epidemiological studies.

In April 2009, ICRIN and the State Claims Agency jointly organised a well-attended workshop on insurance on indemnity of clinical research. The Workshop was particularly helpful in clarifying the scope of research covered by the Clinical Indemnity Scheme and the role of the State Claims Agency.

The Roadmap for the development of Clinical Research in Ireland was completed in 2009. There was extensive stakeholder input and discussion to ensure the Roadmap was aligned to the Action Plan for Health Research 2009 - 2013 and the HRB Strategic Business Plan 2010 - 2014. The Roadmap will be launched in 2010 as a complementary document to the national research strategies.

The ICRIN GCP training programme, consisting of four, one-day GCP training courses, was delivered in 2009 and was led by Siobhan Gaynor, the ICRIN European Correspondent. The courses were attended by a total of 88 participants and were very well received. The programme will be expanded to seven courses in 2010.

ICRIN members also participated in the development and delivery of modules for the RCSI research nurse certificate in clinical research. The course was launched in September 2009.
In June 2006 a DMMC bid involving TCD, RCSI and UCD, and led by Professor Dermot Kelleher succeeded in securing a multi-million Euro investment from the Wellcome Trust and the Health Research Board for the Dublin Centre for Clinical Research (DCCR). The aim of the DCCR is to provide the infrastructure – the physical space, facilities and trained staff – needed to support collaborative clinical research studies across Dublin. The investment is in the order of €23m with the Wellcome Trust covering the build and equipment costs for the Clinical Research Centre at St James’s Hospital. The HRB will support the initial running costs of the St James’s facility as well as the costs of the DCCR Clinical Research Network. As well as the new St James’s Hospital Clinical Research Centre, the DCCR network includes research activities taking place at the RCSI Clinical Research Centre at Beaumont Hospital and the UCD Clinical Research Centres at Mater Misericordiae University Hospital and St. Vincent’s University Hospital.

Wellcome Trust - HRB Clinical Research Centre at St. James’s Hospital

The Tripartite Wellcome Trust Agreement between Trinity College Dublin, St James’s Hospital Board and the Wellcome Trust was signed in December 2009. This formal agreement provides for the Wellcome Trust to fund the building and equipping of the Clinical Research Facility at St James’s Hospital.

Following a tendering process six building contractors were shortlisted to build the facility. In December 2009 they were provided with detailed tender documentation and requested to submit their bids by 29 January 2010.

The CRC is now expected to open in the Autumn of 2011. Temporary accommodation for Dublin Centre for Clinical Research network staff has been found at the St. James’s Hospital campus. This will be used to accommodate a vanguard of staff who will prepare for the opening of the facility.

Dublin Centre for Clinical Research Network Activities

Over the course of 2009 the DCCR Network Management Team built on their 2008 work. In September, the DCCR delivered on one of its major objectives with the first intake of research nurses into the Certificate in Research Nursing offered by the RCSI School of Nursing. Research nurses from Cork, Galway, Beaumont, Mater St. James’s and St. Vincent’s hospitals are participating in the course. As well as building up skills and expertise in the field of clinical research, this cohort of nurses will form the professional relationships needed to develop an effective national clinical research infrastructure.

The course is organised around the following three modules:

- Research Design and Methodology
- Ethics and Regulations
- Clinical trials practice and Management

Modules are completed over a six-month period and are modeled on the European Credit Transfer System (ECTS). It is a Level 9 Certificate course and can be supplemented with further modules and a research project to facilitate the completion of masters level postgraduate qualifications. The aim of the course is to provide a high level of basic competency in the field of research nursing. It is an important strategic...
initiative aimed at enhancing the professional status of research nursing within the nursing profession. Following the success of the first year’s intake, a second group will commence in September 2010.

In May 2009 John McCourt joined the DCCR Network Operations Team as Clinical Informatics Manager. Based at the RCSI CRC at Beaumont Hospital, John has a network-wide role to develop the information systems required to support networked clinical research. His initial focus has been on identifying the IT infrastructure needs of the network, working with the Wellcome Trust CRC in Edinburgh to evaluate the suitability of their study management system for use across Dublin, and looking at data capture systems for clinical research.

DCCR Network Management Team

The purpose of the Network Management Team is to establish the strategic direction and key policies of the network. Throughout 2009 it was chaired by Dr. Ruth Barrington and it includes representatives from the three Dublin Medical Schools - Professors Nolan (TCD), Keane (UCD) and Kenny (RCSI), the PI (Professor Dermot Kelleher) as well as the Programme Manager, Jeremy Towns, and Finance Manager, Paul Barry. In 2009, the DCCR Network Management Team agreed policies and procedures in a number of areas including:

- The formation of DCCR clinical interest groups
- The DCCR study adoption and review process
- DCCR resource allocation process
- Authorship policy.

By the end of 2009, the Network Management Team has approved the formation of the following clinical interest groups:

- Diabetes and Metabolism (Chaired by Professor John Nolan)
- Pulmonary Medicine (Chaired by Professor Michael Keane)
- Neuropsychiatry (Chaired by Professor Michael Gill)
- HIV/TB (Chaired by Dr. Colm Bergin and Dr. Paddy Mallon)
- GI Medicine (Chaired by Dr. Ross McManus)
- Prostate Cancer Research Consortium (Chaired by Professor Mark Lawler)
- Inflammatory Skin Disease (Chaired by Professor Alan Irvine and Professor Brian Kirby)

In addition, the latter part of 2009 saw the development of city-wide groups focused on molecular therapies for rare eye conditions (Mr. David Keegan), young onset neurodegeneration (Professor Orla Hardiman) and rheumatoid arthritis (Professor Doug Veale).

A novel networking event was hosted by the Network Management Team on 2nd December involving representatives from the Biomedical Diagnostic Institute (BDI), an SFI funded CSET based at DCU; the Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN), a SFI CSET hosted at TCD. Professors Brian MacCraith (BDI) and Professor Yuri Volkov (CRANN) were welcomed by Professor Dermot Kelleher and introduced to representatives from the different DCCR Clinical Interest Groups. It was a valuable way for leading scientists to meet clinicians from the Dublin area teaching hospitals.
Later in December, the DCCR Network Management Team held its first joint meeting with the chairs of the clinical interest groups to provide an update of the DCCR’s progress and to highlight common issues being faced by these groups.

**DCCR Operations Team**

The DCCR Network Operations Team is responsible for the day to day activities of the network and supporting the DCCR clinical interest groups to achieve their research aims. It is chaired by Jeremy Towns, the DCCR Programme Manager, and includes representatives from each of the existing CRCs, the DCCR Clinical Informatics Manager and Finance Manager. It is focused on developing the city-wide infrastructure required to support city-wide clinical research and executing city-wide clinical research studies. The team has developed a shared study adoption process that promotes a consistent approach to starting and managing networked clinical research studies across the city.

DCCR studies are underway at six Dublin-area teaching hospitals and in 2009 four multi-site studies recruited 831 patients into DCCR Network Studies.

**Clinical Interest Group Reports**

The DCCR Clinical Research Network works within the framework of clinical interest groups. Scientists and clinicians with similar research interests come together to agree on research activity that is best conducted as a large group rather than in isolation. This works particularly well where large volumes of patients are required for a research project, or where a particular condition is rare and identifying suitable patients requires a collaborative effort. The following groups were active during 2009.

**Respiratory Medicine**

Led by Professor Michael Keane this group started collecting samples and clinical data from patients with Idiopathic Pulmonary Fibrosis (IPF) and Sarcoidosis, which are two relatively rare lung diseases. Respiratory medicine consultants at St. Vincent’s University Hospital, Beaumont Hospital, AMNCH, James Connolly Memorial Hospital and St. James’s Hospital all assisted with the recruitment of patients into this study. Standard Operating Procedures (SOPs) were also agreed between the laboratories at TCD and UCD so that either could accept and process blood samples on behalf of the network. Also in 2009, the respiratory group agreed to trial a medical device for asthma patients developed jointly by TCD engineers and an RCSI physician.

**Gastrointestinal Medicine**

Led by Dr. Ross McManus continued with its city-wide collection of whole blood samples from patients diagnosed with Celiac Disease. Samples were contributed by consultants based in Beaumont, Mater and St. Vincent’s University Hospital in Dublin as well as consultants in Galway. The samples contributed to a paper that was submitted to Nature Genetics for publication. In November 2009, the group was approached by a UK consortium to participate and contribute to a Genone-Wide Associated Study (GWAS) study of Barret’s Oesophagus and sample collection started at St James’s Hospital and the Mater Hospital at the end of the year.

**Prostate Cancer Research Consortium**

Chaired by Professor Mark Lawler, the Prostate Cancer Research Consortium (PCRC) has been in existence for some time and is one of the pioneers of multi-site clinical research in Ireland. Its work will
continue to be supported by the DCCR from 2010 and we are pleased to report that the group has agreed to become part of the DCCR. Its expertise in biobanking and establishing a multi-site research database will be invaluable to the DCCR Network as it develops.

**HIV/TB**

This group, which is chaired by Dr. Colm Bergin, is comprised of infectious disease specialists in St. James’s, Mater and Beaumont hospitals as well as Professor Joe Keane, a Respirologist dedicated to TB Research. They wish to explore how TB affects patients with HIV. In preparation for this study, the DCCR undertook a study to identify the prevalence of latent TB in the general population as well as its prevalence amongst hospital workers.

**Neuropsychiatry**

This is an established group with a track record of academic success. Led by Professor Michael Gill, its collaborative activities span Dublin and also include collaborators from across Ireland. This group is about to start a large scale study to identify gene mutations that give rise to schizophrenia. This is a study builds on work already funded by the Wellcome Trust and is to be funded by the US National Institute of Mental Health (NIMH) and Virginia Commonwealth University.

**Inflammatory Skin Disease**

A citywide group of dermatologists have agreed to come together to study inflammatory skin diseases such as eczema and psoriasis. This group is led by Professor Alan Irvine and Dr. Brian Kirby. In 2009, Professor Irvine led a successful application to the Wellcome Trust to undertake a GWAS study into eczema. This study will involve the collection of samples from patients attending clinical sites across Ireland and the UK.

In addition to these active groups, 2009 saw early development of city-wide groups with interest in the areas of neurodegeneration (Prof. Orla Hardiman), ophthalmology (Mr. David Keegan) and rheumatoid arthritis (Professor Doug Veale).

**Common Ethics Form**

The development of a Common Research Ethics form for research not governed by SI 190 is another initiative vital to the success of the DCCR and networked clinical research across Ireland. The DCCR has been supporting an initiative working with Research Ethics Committee (REC) administrators to develop a common form for the entire country so that investigators submitting applications to multiple RECs only have to complete a form once. Almost two thirds of RECs have agreed in principle to the concept of a common form and late in 2009 RECs at St. James’s/Tallaght, Mater Hospital, HSE South East and the Irish College of General Practitioners agreed to pilot the form in early 2010. This pilot will be evaluated later in 2010 and hopefully this will be followed by the widespread adoption of the common form by the country’s RECs. This will streamline the administration of research and boost the effectiveness of research funding.
**MMI Website**

The MMI Website www.molecularmedicineireland.ie is an interactive platform for the activities of Molecular Medicine Ireland. The website encompasses the online administrative infrastructure for MMI Education and Training and the new Technology Platform Portal. MMI activities in clinical research will increasingly utilise the website for dissemination of standards and protocols, access to resources, training and further engagement with the research community. The MMI website also provides researchers spread across multiple academic institutions and hospitals with the latest news, events and career opportunities. Users can register and maintain an up-to-date research profile, as well as apply for MMI Courses and Workshops. Collaborative groups working under the auspice of MMI can communicate and share documents via dedicated secure areas on the website.

**Traffic on the MMI Website**

![Traffic on the MMI Website](image)

*Please note that due to a server transfer in March no statistics were recorded for January and February 2009.*
MMI Online Newsletter

The MMI Newsletter features updates on all areas of MMI activity and is a forum for the clinical and translational research community in Ireland.

The MMI Newsletter also contains listings of forthcoming events (seminars, meetings, courses and workshops).

Three MMI Newsletters were issued in 2009 (January, May & October), distributed by email to various contacts and to over 2000 MMI website users who subscribe to the Newsletter.

Other communication tools include posters disseminated widely.

Left: MMI Courses & Workshops posters produced in 2009

Above: The First Issue of the new MMI newsletter appeared in January 2009
**INCOME AND EXPENDITURE ACCOUNT**  
*Year Ended 30th September 2009*

### INCOME

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<th>Income Source</th>
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### EXPENDITURE

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<td>Professional and consultancy fees</td>
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<td>Bank interest and charges</td>
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<td>Depreciation:</td>
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<td>- Fixtures and fittings</td>
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<td><strong>TOTAL EXPENDITURE</strong></td>
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**Profit for the year**  
0

*unaudited*
CONTACT INFORMATION

Molecular Medicine Ireland
Newman House
85a St. Stephen’s Green
Dublin 2, Ireland
Tel: (+353 1) 477 9820
Fax: (+353 1) 477 9823
Email: info@molecularmedicineireland.ie
Web: www.molecularmedicineireland.ie
<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>AdeNOS</td>
<td>Adenovirus-mediated delivery of eNOS</td>
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<td>AMNCH</td>
<td>Adelaide &amp; Meath incorporating the National Children's Hospital</td>
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<td>BMP</td>
<td>Bone Morphogenetic Protein</td>
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<td>CERVIVA</td>
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<td>CTLA4</td>
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<td>DNA</td>
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<td>Pigment Epithelium Derived Factor</td>
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<td>ZAG</td>
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Molecular Medicine Ireland was established under the Higher Education Authority’s Programme for Research in Third Level Institutions.