

Biographies

Dr. Ruth Barrington, CEO, Molecular Medicine Ireland

Ruth Barrington is Chief Executive of Molecular Medicine Ireland. MMI is a charitable company established by University College Cork, Trinity College Dublin, the Royal College of Surgeons in Ireland, National University of Ireland- Galway and University College Dublin to accelerate the translation of scientific advances into new therapies, devices and diagnostics to improve the health of patients and the population. MMI's mission is to mobilise the strengths of its partner institutions and associated hospitals to build a sustainable system of clinical and translational research.

Dr. Barrington was Chief Executive of the Health Research Board from 1998 to 2007. She is a member of the board of IPPOSI - the Irish Platform for Patients' Organisations, Science and Industry, of the Conway Institute for Biomedical Research at UCD and of CRANN – the Centre for Research on Adaptive Nanostructures and Nanodevices at TCD. She is Chair of the Irish Times Trust and a member of the Board of Irish Times Ltd.

Dr. Barrington is a graduate of University College Dublin and was awarded a Ph.D from the London School of Economics. She is the author of **Health, Medicine and Politics in Ireland, 1900-1970**. She was awarded an honorary degree in laws by the National University of Ireland, Maynooth in May 2005.

Dr. Thomas Barry, Principal Investigator of the Molecular Diagnostics Research Group (MDRG) at NUIG

Dr. Barry carried out his postgraduate studies under the guidance of Professor Frank Gannon and received his PhD degree from NUIG in 1990. In 1991 he undertook a masters in Business Studies at UCD. In 1992 he was appointed as a Wellcome Trust Postdoctoral Research Scientist at the Department of Zoology at UCD where he worked on Prion related research. In 1995 Dr. Barry was appointed as a full time Lecturer in the discipline of Microbiology at NUIG.

Dr. Barry is a founder member and Principal Investigator of the Molecular Diagnostics Research Group (MDRG) at NUIG. This research group consists of 2 senior research postdoctoral scientists, 10 postdoctoral scientists, 4 research assistants, 3 PhD and 1 MSc student.

Research interests of the group are primarily focused on the research, development and commercialisation of platform nucleic acid based diagnostics technologies for the detection and identification of bacterial and fungal agents.

Dr. Barry is the inventor of the microbial platform nucleic acid based diagnostics Spacer-Probe, RiboSEQ, MycoTECH, MycoSEQ, RiboTECH and MtSEQ technologies.

These technologies, over the past 5 years, have generated approximately €12 million in funding and revenue through industry driven commercial product development and contract R+D and through intellectual property licensing agreements. While agency research funding of approximately €2.5 million has also been generated over the past five years.

Dr. Donald M. Black, *President, Trialynx, Inc. and Director, Critical Markers of Disease (CMOD), Princeton, New Jersey*

Dr. Black is co-founder and President of Trialynx, and consulting and services company based in Ann Arbor MI and Princeton NJ. He received his Medical degree from the University of Michigan and completed his residency and fellowship at the University of Cincinnati, where he also studied business and law. Prior to founding Trialynx in 2010, Dr. Black was with GE Healthcare from November 2004 as Global head of Research and Development at GE Medical Diagnostics and as Head of Molecular Imaging for PET, Spin Signal and Optical product. Before joining GE in November 2004, Dr. Black was Vice President of Global Strategic Development at Merck and Co. He was Vice President of Clinical Research at Parke-Davis/Warner-Lambert Co. (now part of Pfizer) from 1990 to 2000, where he was responsible for the clinical development of Lipitor as well as cardiovascular, renal, pulmonary and thrombotic research. From 2000 to 2002, he was Executive Vice President and Chief Operating Officer of Medical Research Laboratories International (now part of PPDI) in Cincinnati and Bruxelles. Dr. Black is also a Director of CMOD (Critical Markers of Disease) a non-profit organization working with regulators, academia and industry to develop a common understanding of the utility of biomarkers.

His academic appointments include Associate Professor of Pediatric Cardiology at the University of Michigan (1990-2000) and Professor of Medicine at the University of Cincinnati (2000-2003). Dr. Black has over 150 abstracts, presentations, chapters and publications in journals such as the Journal of Lipid Research, Journal of Clinical Investigation, New England Journal of Medicine, and Journal of the American Medical Association, and has served on the editorial board of Atherosclerosis. Dr. Black received the Biolink Irish-American Bioscience Award in 2005.

Dr Isabella Bray, *Post-doctoral Researcher in the Department of Cancer Genetics at the Royal College of Surgeons in Ireland*

Dr Bray's main focus is the investigation of the molecular events that lead to the development and progression of neuroblastoma, one of the most common solid tumours in children. In particular, she has been looking at microRNAs as potential biomarkers in neuroblastoma. MicroRNAs regulate gene expression at a post-transcriptional level and their dysregulation has been associated with the pathogenesis of many forms of cancer. Isabella has been involved in the identification of a 15 miRNA signature predictive of survival in neuroblastoma. This signature has prognostic potential, and novel therapeutic application for the disease".

Professor Dolores J. Cahill, *Professor of Translational Science, School of Medicine and Medical Sciences, UCD Conway Institute, University College Dublin, Ireland*

Prof. Cahill's research areas include proteomics, technology development and automation, high content protein and antibody/binder arrays and their biomedical applications, including in biomarker discovery and validation. She and her group have been developing high-density protein and antibody array technologies and demonstrated their applications in biological and medical research. The research application areas are in the characterisation of the specificity of antibodies (including therapeutic antibodies), biomarker discovery and validation, assay development, protein-interaction studies, proteomics, large scale and systems biology research. Prof. Cahill developed this research area in the Max-Planck-Institute of Molecular Genetics in Berlin, Germany and while there, she received the prestigious BMBF 'BioFuture' Award from the German Minister of Science. She patented high content recombinant array technologies and their applications in 1997, which were granted worldwide including USA and Europe. In 1999, while in the Max-Planck, she co-founded a biotechnology company, Protagen AG (www.protagen.de) in Dortmund, Germany to

commercialise this technology. She returned to Ireland in 2003 and is continuing to develop this technology for research and biomedical applications.

She is a member of a number of scientific advisory boards, including the Human Proteome Resource, Sweden (www.proteinatlas.org) and Systems Biology Institute, Helmholtz Centre for Environmental Research, Leipzig, Germany. She participates in national and international funding agencies reviews, including BMBF, Germany; BBSRC, UK; Vinnova, Sweden. She has been involved in the past five years in the peer review for large research funding in the UK (BBSRC), Sweden (Vinnova) and Germany (BMBF) in the areas of Systems Biology, Cancer Research and Translational Medicine. Since 2003, she is a Member of the Advisory Science Council (ASC) to the Irish Government (www.sciencecouncil.ie), appointed by the Minister for Industry, Trade and Employment. She chaired the ASC Task Force on Researcher Careers, and its report 'Towards a Framework for Researcher Careers' was published in October 2008, which included recommendations to improve the researcher career structure within the Irish Higher Education Institutes,

She has been involved as Principal Investigator in seven successful EU funded research programmes, since 1998 (FP5-FP7). She has been invited by the EU Commission to act as Independent Observer of the EU FP7 Health theme, presenting this report with recommendations for improvements to the EU-27 FP7 Health Programme Committee in Brussels (April 2008). In 2009, she was invited as Independent Observer for the FP7 Health Theme for the One stage (June 2009) and Two-stage proposals (September 2009). She is a member of national and international scientific conference organising committees including in the past year, Cancer Proteomics 2009, 1st and 2nd Irish Proteomics Workshop (Dublin, 2008 and 2009), Network Biology, (Hinxton, 2008), European Biomarker Summit (Lisbon, 2008), Proteomics Forum (Berlin, 2009), Proteomics Europe (Barcelona, 2009). She was invited by the Norwegian Biochemical Society to give the FEBS National Lecture (Røros, January 2009) and she was presented with the Federation of European Biochemical Societies (FEBS) Award for her research and its significance. Also presented with the FEBS Award 2009 at this meeting were Prof. J. Craig Venter and Prof. Robert Huber (http://www.febs.org/fileadmin/Newsletter_PDF/March2009.pdf).

Prof. Joe Duffy, Professor of Pathology and Laboratory Medicine, St. Vincent's University Hospital & UCD

Professor Joe Duffy is Principal Grade Biochemist at St Vincent's University Hospital Dublin and Professor in the School of Medicine and Medical Science at University College Dublin.

Joe has a national and international reputation for his work on tumor markers, having published >100 peer-reviewed papers on this topic. He is a member of a number of International Expert Panels for the writing of guidelines on the clinical use of tumor markers, including the National Academy of Clinical Biochemistry (NACB) (USA) and the European Group on Tumor Markers (EGTM).

For his work, Prof Duffy has received several major awards. These include the St Luke's Medal Lecture and The Conway Review Medal Lecture of the Royal Academy of Medicine in Ireland and the National Biochemistry Award Medal Lecture of the Royal Irish Academy.

Professor Paul Harkin, *President and Managing Director of Almac Diagnostics and is also Professor of Molecular Oncology within the Centre for Cancer Research and Cell Biology at Queen's University Belfast.*

He carried out his Postdoctoral training at the Massachusetts General Hospital Cancer Centre/Harvard Medical School, in the Laboratory of Professor Daniel Haber where he developed his interest in the emerging field of Functional Genomics. Professor Harkin's research has focused on hereditary breast cancer and in particular the BRCA1 tumour suppressor gene. His laboratory was the first to utilize high throughput genomic based technologies to help define downstream signalling pathways regulated by BRCA1 at a transcriptional level. His laboratory was also the first to demonstrate that BRCA1 deficient cells were hyper sensitive to platinum based compounds and resistant to taxanes. Professor Harkin has been a member of numerous funding boards including the Breast Cancer Campaign Scientific Advisory Board and the UK Stratified Medicines Initiative Technology Advisory Board. In 2004 he co-founded Almac Diagnostics, a personalized medicine company specializing in the discovery and validation of biomarkers. Almac Diagnostics was acquired by the Almac Group in 2006 and currently employs over 80 staff across three sites.

Dr. Francis Kalush, *Diagnostics and Personalized Medicine Network Leader, Office of Center Director CDRH, FDA*

Dr Francis Kalush currently is the "Diagnostics (*In vivo* and *In Vitro*) and Personalized Medicine Network Leader" in the Office Center Director, CDRH, FDA. She plans and manages the activities and strategic initiatives for the Network, encompassing premarket, post market, compliance, science and communications in order to enhance total product life safety.

She leads, coordinates and participates in national and international workshop committees and round tables with external stakeholders in biomarkers, genomics, pharmacogenomics, personalized medicine and companion drug-diagnostics. She delivers network leader presentations in support of center activities and regulatory programs.

Dr Kalush is the CDRH representative to Global Harmonization Task Force (GHTF) *In Vitro* Diagnostics working group

Before moving into the Network Leader position Dr Kalush coordinated submission of new drugs and the *in vitro* diagnostic devices that are intended to guide use of those drugs in the Office of *In Vitro* Diagnostics, CDRH, FDA. Prepared recommendations for mitigation of product submissions developed in accordance to the new Pharmacogenomics Guidances and FDA Critical Path Initiative.

Dr. Kalush has also had the opportunity to deliver multiple presentations in support of regulatory programs and coordinated Pharmacogenomics Roundtable meetings with various trade organizations such as AdvaMed, PhRMA, BIO and others to address regulatory and industry co-development concerns. She is the author of many publications and book chapters.

Moreover, Dr. Francis Kalush has developed and executed multiple outreaching activities such as NCI/FDA Educational Workshop on Cancer Biomarkers, FDA/NCI Proteomics Cancer MOU and Co-sponsorship agreement with academic institutions.

Prior to joining the FDA, Dr Francis Kalush was the Director, Pharmacogenomics at Celera Genomics. She directed the development of all Celera SNP databases, online support for Applera Genome Initiative and future products development in the field of pharmacogenomics/toxicogenomics and genetics for both academic and commercial markets.

As the Director, Integrated Science Strategy Development, she was responsible for strategy development for systems biology and integrated science across platforms and application areas. In the Medical Affairs department of Celera, she has worked on diagnostic and prognostic discovery programs to find polymorphisms & biomarkers associated with diseases such as breast cancer.

Dr. Kalush has a Ph.D in Chemical Immunology, an MSc on Human Microbiology and BSc in Chemistry and Biology.

Professor Dermot Kelleher, *Head of School and Vice-Provost for Medical Affairs and Professor of Medicine/Consultant Gastroenterologist St James's Hospital School of Medicine*

Professor Dermot Kelleher MD, FRCP, FRCPI, F Med Sci, graduated in Medicine from TCD in 1978 and completed specialist training in Gastroenterology in Dublin. He subsequently received a Fogarty Scholarship for a research fellowship at University of California San Diego. In 1989 he was appointed as a Wellcome Senior Fellow in Clinical Science at Trinity College Dublin and was subsequently appointed as Professor of Clinical Medicine in 2001.

Professor Kelleher's research has focussed on the cell biology of immune responses both in terms of basic lymphocyte function and in relationship to mucosal immunology. His research has been focussed on the immune response to many of the leading causes of infectious disease worldwide. He is the author of approximately 150 publications including papers in journals such as Nature Immunology, Nature, Journal of Experimental Medicine, Gastroenterology, Hepatology, Journal of Biological Chemistry and Journal of Immunology. He is also the author of 7 patents.

Prof Kelleher has been successful in obtaining funding from NIH, Wellcome Trust, European Union, Programme for Research in Third Level Institutions (Higher Education Authority), Health Research Board and Enterprise Ireland. Prof Kelleher in collaboration with Prof Hugh Brady at UCD has obtained collaborative grant funding to establish the Dublin Molecular Medicine Centre a joint venture between the three major medical schools in Dublin which provides a physical infrastructure for major developments in medical biotechnology in Ireland. This grant was for IR£23m. In this context Prof Kelleher obtained funding for the construction of and is the inaugural director of the Institute of Molecular Medicine, a TCD facility at St James's Hospital. This was further consolidated in the 3rd round of PRTL in collaboration with Prof Des Fitzgerald RCSI and Prof Brady in which a joint grant award of €45m was awarded for the Programme for Human Genomics. More recently, he has been successful in obtaining funding for a Wellcome Trust HRB funded Clinical Research Centre at St James's Hospital, a 22m€ grant.

Prof Kelleher was also the PI for the development of a 4 year PhD programme in molecular medicine funded by the Health Research Board. Recently his group was awarded a grant of approximately €600,000 by the European Union to integrate technologies of High Content Screening with siRNA screening technologies.

Prof Kelleher is a founding member of Opsona Therapeutics, a campus company at Trinity College Dublin based on development of therapeutic technologies founded on innate immunity and T-regulatory cells.

Prof Kelleher has served as a member of the Board of the Health Research Board Ireland, the European Medical Research Council and the Wellcome Trust Clinical Interest Group. He also serves on several National Bodies in the Health sector.

Professor Louise Kenny, *Professor of Obstetrics and Consultant Obstetrician and Gynaecologist, The Anu Research Centre, Cork University Maternity Hospital & UCC*

Louise Kenny is Professor of Obstetrics at University College Cork and a Consultant Obstetrician and Gynaecologist at Cork University Maternity Hospital. Louise has a longstanding clinical and research interest in uteroplacental insufficiency, adverse pregnancy outcome and pregnancy loss. In 2007, Louise was appointed as a Health Research Board Ireland Clinician Scientist. This 4 year award (of €1.6 million) is underpinning the Screening for Pregnancy Endpoints (SCOPE) Study- a prospective longitudinal case cohort of pregnancy outcome which also forms part of one of the world's most detailed global pregnancy biobanks.

In July 2009, Louise was awarded a Principal Investigator Programme grant from Science Foundation Ireland to develop predictive biomarkers of poor pregnancy outcome, pioneering a new approach to biomarker development by focusing on metabolic changes in plasma. Using the SCOPE cohort, Louise's team and her collaborators have discovered a consistent discriminatory metabolite signature in early pregnancy plasma preceding the onset of preeclampsia. This finding provides insight into disease pathogenesis, and offers the tantalizing promise of a robust presymptomatic screening test. Louise now holds a Translational Award from the Wellcome Trust to develop these biomarkers into a clinically useful predictive test.

In addition, together with her co-PIs in the Department of Paediatrics and UCC, Louise has established BASELINE (Babies After SCOPE, Evaluating Longitudinal Indices of Neurological and Nutritional Endpoints). Funded by the Children's Research Centre, the BASELINE study is the first longitudinal birth cohort study in Ireland. Babies are monitored from before birth, and information regarding their mother's health, lifestyle and environment is collected as part of the maternal SCOPE study. Follow up of the BASELINE children takes place in the Children's Research Centre at Cork University Hospital. The establishment of this birth cohort will offer many opportunities for further research as the children grow older. It will form a unique bio-bank of information from Irish children collected from soon after their conception.

Louise has filed three patent applications relating to pregnancy biomarkers. Her work has resulted in >60 peer reviewed original papers, reviews and book chapters. She is the Editor of the 19th Edition of 'Obstetrics by Ten Teachers'- the world's leading undergraduate textbook in obstetrics. In addition, Louise is a reviewer for a wide range of international journals including the American Journal of Obstetrics and Gynecology, the British Journal of Obstetrics and Gynaecology, the British Medical Journal, Clinical Chemistry, Reproductive Sciences and Hypertension and research funding bodies such as the Medical Research Council (UK), the Wellcome Trust, Action Research, the British Heart Foundation, Wellbeing, Sparks, the Health Research Board and Science Foundation Ireland.

Dr. Tom Lillie, *International Therapeutic Area Head for Oncology at Amgen, Inc*

Tom Lillie, MD, PhD is the International Therapeutic Area Head for Oncology at Amgen, Inc. Tom is responsible for oncology clinical research in Phase 2 – Phase 4 for the International region and oversees the clinical teams for Amgen programs in oncology and haematology.

Dr. Lillie completed his undergraduate degree in pharmacology, cell biology and immunology at Brasenose College, the University of Oxford, before earning his doctorate from the Department of Physiology at the University College of London. He then completed his medical education at the University College London Medical School, receiving honors distinction in clinical pharmacology and surgery. He is a member of the Royal College of Surgeons of England and the Faculty of Pharmaceutical Medicine of the Royal College of Physicians.

Dr. Lillie has held a variety of clinical research positions, specialising in oncology, in pharmaceutical companies in Europe and the USA.

Dr. Sarah O'Meara, *Pre-Clinical Assessor, Irish Medicines Board*

Sarah O'Meara has a PhD in Biochemistry with a specialization in cell and molecular biology (2004) from University College Dublin. Sarah was a Postdoctoral Research Fellow within the Conway Institute of Biomolecular and Biomedical Research, University College Dublin (2004-2007), in which her research involved the examination of LX- CysLT and RTK receptor cross-talk in the regulation of endothelial cell function by means of cellular, molecular and functional proteomic approaches. Sarah joined the Irish Medicines Board in 2007, where she initially worked as an assessor within the Pharmacovigilance division. Her current position is Pre-Clinical assessor within the Human Products Authorisation and Registration Department where she examines the pharmacology, pharmacokinetic and toxicology components of medicinal products, cosmetics and medical device applications. She is the Irish delegate for the "Cell Based Working Party" (CBWP) and an alternate delegate for the "Committee for Advance Therapy Medicinal Products" (CAT) in the European Medicines Agency (EMA).