Northern Ireland
Life Sciences

Pharmaceutical Industry
Clinical Research Visit
15th and 16th September 2014
Northern Ireland

Life Sciences

Northern Ireland has developed as a prime location for biotechnology and pharmaceutical companies, thanks to a long history of technological innovation, backed by a highly educated, young workforce and an internationally recognised research base.

Life Sciences is one of the priority sectors that will drive the future growth of Northern Ireland's economy. Over the past few years, Northern Ireland industry, academia and government have made significant commitments to the development of Life Science capabilities. In excess of $600 million has been committed for infrastructure enhancement, collaborative research, new product development and staff training initiatives.

The construction of major new science parks and incubator facilities and the execution of a sector strategy that embraces the aspirations of all major stakeholders have been fundamental in establishing Northern Ireland as a leading location for Life Science businesses.

The Northern Ireland Life Sciences sector as a whole comprises approximately 60 businesses employing 4100, with sales of $600 million of which exports account for 95%. Key clients include The Almac Group, Randox Laboratories, Norbrook Laboratories, Warner Chilcott, CaridianBCT and Perfecseal.

As part of its strategy to develop the Life Sciences sector, Northern Ireland can provide high levels of support for companies. This is underpinned by a culture of innovation and by government-led action to promote the transfer of leading edge technologies from laboratory to production line.

The success to date has been based on a model of collaboration in which Government, academia, clinical and the private sector have worked together in partnership in developing a vibrant Life Sciences sector. We look to continue this success into the future through building on these existing partnerships and developing new ones in new and challenging areas of growth.
Interesting Facts on Northern Ireland

Life Sciences

- Our clinical research networks operate across all Health & Social Care Trusts and Primary Care in Northern Ireland and as part of the UK wide infrastructure. To date we have enabled some 25,000 people to participate in clinical trials of potentially beneficial new disease prevention strategies, diagnostics, treatments or care practices.

- The Northern Ireland Centre for Stratified Medicine based at the University of Ulster will undertake personalised medicine research in areas such as heart disease and stroke; diabetes; bone disorders; inflammatory diseases; mental health, dementia and cancer. It is offering the first ever undergraduate degree course in Stratified Medicine and the first distance learning MSc on Stratified Medicine in the UK.

- Queen’s University of Belfast Cancer Group was the first to develop a test based on Pea3, which identifies the likelihood of cancer metastasis occurring.

- Almac have developed a novel gene expression test “ALM AADx” which identifies a molecular subgroup of high grade serous ovarian cancer (HGSOC) patients that has better survival rate following standard chemotherapy and will be made available for clinical use in 2015.

- Randox Laboratories Ltd manufacture the widest range of innovative assays in the diagnostic industry, export to 145 countries and each year over 350 million people are diagnosed using Randox tests.

- This year, BioKinetic Europe received what is believed to be the largest ever FP7 Health grant awarded to a private Northern Irish company for the development of a novel vaccine against Group B Streptococcus (GBS).

- The first portable defibrillator was developed in the 1960’s by Professor Frank Pantridge in Belfast, Northern Ireland.
Contents

• Northern Ireland Life Sciences
• Interesting facts
• Clinical Research Visit Agenda
• Session summaries
• NI Clinical Trials ecosystem
• Presenter Biographies
• Notes
NI Clinical Research Visit Agenda

Northern Ireland’s Health & Social Care R&D Division in collaboration with ABPI NI Innovation Group, Queen’s University and University of Ulster are pleased to invite you to Northern Ireland for a Pharmaceutical Industry Clinical Research Visit.

This is an opportunity for Medical and Scientific Industry staff to engage with key Government, Health & Social Care and Academic stakeholders. There will be an opportunity to gain insight to Northern Ireland’s unique capabilities, meet with key Investigators and debate what Industry needs from Northern Ireland.

**Date:**
15th and 16th of September 2014

**Venue:**
Lanyon Building, University Road, Queen’s University, Belfast

**Agenda:**

**15th September 2014**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.15</td>
<td>Welcome Reception: Opening comments and welcome (Canada Room)</td>
<td>Dr Andrew McCormick, Permanent Secretary, Department for Enterprise, Trade and Investment</td>
</tr>
<tr>
<td>18.45</td>
<td>Research Capability Showcases (Council Chamber)</td>
<td>Chair: Professor Ian Young, Professor of Medicine and Director of the Centre for Public Health, Queen's University Belfast (QUB)</td>
</tr>
<tr>
<td></td>
<td>Development and performance of Radium-223 chloride: a Phase III study changing standard care</td>
<td>Professor Joe O'Sullivan, Professor of Radiation Oncology, QUB</td>
</tr>
<tr>
<td></td>
<td>Correcting Cystic Fibrosis. The first large scale trials of disease modifying therapies. Leading Phase III for Europe from Belfast</td>
<td>Professor J. Stuart Elborn, Dean, School of Medicine, Dentistry and Biomedical Sciences, QUB</td>
</tr>
<tr>
<td></td>
<td>An RCT of alternative treatments to inhibit VEGF in patients with age-related choroidal neovascularisation: The IVAN Study</td>
<td>Dr Giuliana Silvestri, Reader &amp; Consultant Ophthalmic Surgeon, QUB</td>
</tr>
<tr>
<td>19.45</td>
<td>Dinner (The Great Hall)</td>
<td>Professor Patrick Johnston, President and Vice-Chancellor, Queen’s University Belfast</td>
</tr>
<tr>
<td></td>
<td>Vice Chancellor's welcome</td>
<td>Mr Edwin Poots MLA, Minister for Health and Social Services</td>
</tr>
<tr>
<td></td>
<td>Minister’s comments</td>
<td>Dr Adrian Kilcoyne, Medical Director, UK &amp; Ireland, Celgene</td>
</tr>
</tbody>
</table>
### 16th September 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Chair/Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.15</td>
<td>Coffee &amp; Networking (Canada Room)</td>
<td></td>
</tr>
<tr>
<td>08.45</td>
<td>Northern Ireland Research Capabilities.</td>
<td><strong>Professor Danny McAuley</strong>, Professor and Consultant in Intensive Care Medicine at QUB and the Royal Victoria Hospital</td>
</tr>
<tr>
<td></td>
<td>Opening Comments and Welcome to Day 2 (Council Chamber)</td>
<td><strong>Mr Richard Pengelly</strong>, Permanent Secretary, Department of Health Social Services and Public Safety</td>
</tr>
<tr>
<td></td>
<td>The Northern Ireland clinical research ecosystem</td>
<td><strong>Dr Janice Bailie</strong>, Assistant Director, HSC R&amp;D Division</td>
</tr>
<tr>
<td></td>
<td>A review of Northern Ireland networks</td>
<td><strong>Q&amp;A Session</strong>, Interest Group Leads</td>
</tr>
<tr>
<td></td>
<td>Delivering Personalised Medicine Through Collaboration</td>
<td><strong>Professor Richard Kennedy</strong>, McClay Professor of Medical Oncology, QUB. VP and Medical Director, Almac Diagnostics</td>
</tr>
<tr>
<td>10.00</td>
<td>Coffee and Networking (Canada Room)</td>
<td></td>
</tr>
<tr>
<td>10.30</td>
<td>An 'Engagement': How can we increase Industry collaboration in NI? (Council Chamber)</td>
<td><strong>Professor Allan Gaw</strong>, Associate Director for Educational Quality Standards at the National Institute for Health Research Clinical Research Network (NIHR-CRN)</td>
</tr>
<tr>
<td></td>
<td>What Industry wants from NI</td>
<td><strong>Dr Stephen McDonough</strong>, UK and Ireland Medical Director, GSK</td>
</tr>
<tr>
<td></td>
<td>Facilitated Table discussions with Instant Report presentation</td>
<td><strong>Professor Jonathan Wallace</strong>, Professor of Innovation, University of Ulster</td>
</tr>
</tbody>
</table>
|       | Panel Debate on findings                                               | **Panel including:** **Dr Stephen McDonough**, UK and Ireland Medical Director, GSK  
**Professor Tony Bjourson**, University of Ulster and Northern Ireland Centre for Stratified Medicine  
**Mr Sam Kinghan**, R&D Manager Life Sciences, Invest Northern Ireland  
**Dr Janice Bailie**, Assistant Director, HSC R&D Division  
**Dr Richard Wilson**, Clinical Director, NI Cancer Trials Network |
| 12.15 | Buffet Lunch and Networking (Canada Room)                              |                                                                           |
| 13.00 | Clinical Research Workshops                                            | Each delegate will attend 3x 45 minute workshops. Please indicate main areas of clinical interest overleaf to support workshop development. |
| 15.45 | Closing comments and next steps                                        | **Dr Anne Kilgallen**, Deputy Chief Medical Officer, DHSSPS               |
| 16.00 | Close                                                                  |                                                                           |
Prostate cancer is the second most common cause of cancer death in men (after lung cancer) with almost 11,000 men dying from the disease every year in the UK. The vast majority of men with advanced prostate cancer have bone metastases and bone-seeking radionuclides (radioactive drugs) including Strontium-89 and Samarium-153 have been used to palliate bone pain in prostate cancer since the mid 1990's. While these agents are useful in the management of pain but are limited in terms of disease modification due to bone marrow toxicity. Radium-223 (trade name- Xofigo) is a first in class Alpha-particle emitting bone-seeking radionuclide which was developed by Algeta in Norway at the beginning of the century and has been undergoing clinical testing since then. Following an international randomised trial in which Radium-223 shown to improve survival in men with advanced prostate cancer metastatic to bone, with minimal toxicity, the drug was approved by the FDA and EMA. Under Professor O'Sullivan’s leadership, Belfast has been a major research site for Radium-223 development and was the largest single site recruiter to the ALSYMPCA trial. Further clinical and translational research in Radium-223 is ongoing in Belfast forming a major component of the Movember Prostate Cancer Centre of Excellence programme.

Correcting Cystic Fibrosis. The first large scale trials of disease modifying therapies. Leading Phase III for Europe from Belfast. Prof Stuart Elborn, Professor of Respiratory Medicine and Dean of the School of Medicine, Dentistry and Biomedical Sciences, QUB

Cystic fibrosis is one of the most common life-threatening inherited diseases, affecting 75,000 children and adults world-wide. Professor Stuart Elborn has led a number of studies in the development of CF therapies where treatment is based on a test for genetic mutations. Ivacaftor, also known as Kalydeco, was the first ever drug to target the underlying causes of Cystic Fibrosis rather than just its symptoms and is currently approved for people with the G551D genetic mutation also known as the ‘Celtic Gene’. Phase 3 studies of the drugs Ivacaftor and Lumacaftor, which included over 1,100 patients worldwide, have built on previous studies of Ivacaftor in patients with G551D and other related mutations. The results of a Phase III trial for people with cystic fibrosis aged 12 and over with two copies of the F508del mutation showed that a combination therapy using Ivacaftor and Lumacaftor led to an improvement in lung function and a significant reduction in the rate of pulmonary exacerbations. This trial, for which Professor Elborn was the European lead, represents a major breakthrough CF
therapy, by offering those with the most common type of cystic fibrosis an additional treatment option and a first therapy that targets the basic genetic defect.

**An RCT of Alternative Treatments to inhibit VEGF in patients with age-related choroidal neovascularisation: The IVAN Study.**

Professor Usha Chakravarthy, Professor of Ophthalmology and Vision Sciences, QUB

Wet or neovascular age-related macular degeneration (AMD) is a common cause of sight loss in older people, with at least 23,000 people diagnosed with the condition in the UK each year. Without treatment two thirds of people with wet AMD will experience severe loss of sight within two years of being diagnosed. The Inhibition of VEGF in Age-related choroidal Neovascularisation (IVAN) trial was a head-to-head comparison of the efficacy and safety of anti-VEGF drugs Avastin® (Bevacizumab) and Lucentis® (Ranibizumab) involving 610 people in a two-year study. The trial also studied whether the number of treatments needed could be reduced by comparing monthly anti-VEGF treatment for 2 years with monthly anti-VEGF treatment for 3 months only, with careful monthly review and re-starting treatment if any signs of disease recurred. This trial, led by Professor Usha Chakravarthy, Queen's University Belfast, and funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme, was one of the largest ever carried out in the field of eye disease in the UK. The study's two year results showed that sight was equally well preserved with either of the two drugs. Dr Giuliana Silvestri will present the results of the study which could lead to important changes to the way wet AMD is treated and is an example of research led from Northern Ireland with international significance.

**Delivering Personalised Medicine Through Collaboration.**

Professor Richard Kennedy, McClay Professor of Medical Oncology, QUB. VP and Medical Director, Almac Diagnostics

At Queen’s University Belfast we have recognized that much basic research performed in the academic setting fails to impact cancer patient care. One of the major issues we identified was that there was a disconnect between the type and quality of research being performed in the academic community and the ability of industrial partners to commercialize the results and introduce products into the clinic. We have therefore established a pipeline from basic research to the patient that involves collaboration with industrial partners throughout the process. The pipeline combines expertise in basic biology, tumour biobanking molecular pathology and biomarker discovery at CCRCB with industrial experience in commercial product development and provides support for first in man clinical trials that can be expanded throughout the UK ECMC network. I will give examples of biomarker and drug products that have been successfully developed using this innovative academic/industrial approach.
Northern Ireland has an international reputation for providing clinical trial services to the world's leading pharmaceutical companies. Companies, University centres and the Northern Ireland Health Service now offer a complete range of services including protocol design, management of clinical supplies, lead investigators, trial management, statistical analysis and production of reports.

The Northern Ireland Clinical Research Network (NICRN) provides single-point access to the NHS and encompasses the hospital, community and primary care sectors in Northern Ireland. The NICRN co-ordinating centre works with industry to remove barriers and reduce start-up times. It adds value by facilitating standard contractual agreements providing a cadre of expert clinical staff and assures delivery of target accruals.

**Dr Paul Biagioni**

T: +44 (0) 2890 638995  
E: info.nicrn@belfasttrust.hscni.net  
W: www.nicrn.hscni.net

The Northern Ireland Clinical Research Network develops and enables a well resourced network of skilled staff which provides investigators and patients from throughout Northern Ireland with access to and help in developing high quality clinical research studies across all Health and Social Care structures.

Funded by HSC R&D, the aims of the NICRN are:

- To promote research within Northern Ireland
- To develop close partnerships and productive working relationships with key individuals and groups across the Network and the wider research community
- To ensure that targets, including accrual of patients into trials, are achieved and maintained

**Dr Melanie Morris**

T: +44 (0) 28 9504 8654  
E: melanie.morris@belfasttrust.hscni.net  
W: www.qub.ac.uk/research-centres/nictc/

The mission of the Northern Ireland Cancer Trials Network is to deliver the highest quality and standard of care to cancer patients through leading edge clinical and translational research. We do that by:

- Ensuring high quality patient care by participation in clinical research
- Co-ordinating and promoting cancer clinical trial activity throughout Northern Ireland
- Driving the development of early phase cancer clinical research
- Integrating with Queen's University Belfast and University of Ulster basic science and translational research programmes
- Developing and training clinical research staff

**Dr George A Burke**

T: +44 (0) 028 9036 8081  
E: g.burke@ulster.ac.uk  
W: www.regenagraft.com

**Paul Kelly**

T: +44 (0) 28 9048 4848  
E: paul.kelly@sepha.com  
W: www.sepha.com
The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases. ABPI Northern Ireland was established in 2008 and has had a full-time Director and Office Manager in place since 2012. We operate as a unified Leadership Team, working with the Chairs and Deputy Chairs of our 3 Strategic Working Groups (Innovation, Value & Access, Partnership & Citizenship) and 7 Therapy Groups (Cancer, Immunology, Respiratory, Cardiovascular, Diabetes, Pain and Neurology) to develop and deliver strategy for ABPI NI.

HSC RESEARCH AND DEVELOPMENT DIVISION

Dr Janice Bailie
T: +44 (0) 28 9055 3612
E: janice.bailie@hscni.net
W: www.publichealth.hscni.net/directorate-public-health/hsc-research-and-development

HSC R&D supports research that provides high quality evidence to improve care for patients, clients and the general population, and adds to our understanding of health, disease, treatment and care. We work closely with clinical and academic researchers based in Health and Social Care Trusts and universities, policy-makers, practitioners and members of the public, including patients and clients. HSC R&D works in partnership with other public sector organizations, charities and businesses that are involved in health and social care research across the UK and internationally.

HSC Innovations provides an intellectual property and innovation management (also known as technology transfer) service for all Northern Ireland health and social care staff. The service works with HSC employees and industry to ensure that ideas that have the potential to improve patient care or offer benefits to healthcare providers are developed, with a focus on ideas that can be protected by a patent and are commercially viable.
Queen’s University Belfast (QUB) is part of the Russell Group of the UK’s 24 leading research-intensive universities with a dynamic world-class translational research and education portfolio and strong international connections. An emphasis is placed on the expansion of inter-disciplinary and multi-disciplinary activities and engagement with Industry. Life Science and Biomedical research is a strong research focus in the Institute of Health Sciences (comprising the Centre for Cancer Research and Cell Biology, Centre for Infection and Immunity; Centre for Public Health; Centre for Experimental Medicine and Wellcome Trust-Wolfson Northern Ireland Clinical Research Facility) and the School of Pharmacy. Recent investments in research infrastructure within the Institute have resulted in significant growth in the key strategic areas of oncology, respiratory medicine, vision science, diabetes and drug delivery and formulation. The many synergistic links between research and clinical scientists, industrial collaborators and the Belfast Health and Social Care Trust provide a roadmap for translation of unique technologies into therapies and diagnostics for improved patient care.

The University of Ulster has an international reputation for excellence and innovation. Its research is characterised by its capacity to shape the future of lives and society through relevant and pioneering research, delivering a range of economic, social or cultural benefit from research of the highest quality. The University spends £1 million per week on research and plays a major role in the local economy as a linchpin of investment and economic growth. To support its endeavors, Ulster has 15 Research Institutes specialising in areas such as health and rehabilitation sciences, intelligent systems, biomedical sciences, coastal and marine research and art and design. Ulster’s Biomedical Science Research Institute (BMSRI) undertakes cutting edge research on the prevention, diagnosis and treatment of degenerative and infectious diseases including cancer, diabetes, heart disease, blindness, osteoporosis and arthritis. The Institute focuses on translating their research for patient and societal benefit with a significant focus on clinical translation of research especially in the area of personalised medicine. The new Northern Ireland Centre for Stratified Medicine, a partnership between the BMSRI, C-TRIC and the Western Health and Social Care Trust aims to place Ulster and Northern Ireland at the forefront of pioneering medical research into chronic degenerative diseases. The £11.5 million facility, launched in October 2013, is focused on personalised medicine approaches to managing chronic diseases and will facilitate research that can better identify drugs or treatments that meet the specific needs of individual patients – marking a significant advancement in this strategic research area.
The Northern Ireland Clinical Trials Unit (NICTU) is a UK Clinical Research Collaboration (UKCRC) fully registered clinical trials unit. As a clinical trials unit our specific remit is to design, conduct, analyse and publish clinical trials and other well designed studies. With a core team of staff across the areas of statistics, health economics, trial management, monitoring and data management including clinical trial database development, we have expertise in the co-ordination of multi centre clinical trials involving investigational medicinal products (IMP). We are currently undertaking clinical trials in the areas of cancer, critical care, dentistry and dementia; working closely with academic clinicians and health service researchers by providing the infrastructure to facilitate the delivery of high quality clinical research.

The Clinical Translational Research and Innovation Centre (C-TRIC) is a unique facility promoting and facilitating translational and clinical research. The primary objective is to reduce both the time to market and the costs associated with research and development of innovative health technologies, medical devices and therapeutics. C-TRIC's unique infrastructure and key support staff facilitate clinical research and innovation, enabling the streamlining of developments from the laboratory to the market place through a focused 'bench to point of care' approach.

The vision of the biobank is to host and distribute a collection of well defined, quality assured biological samples to support translational research programmes in Northern Ireland and beyond. NIB has Ethics approval to collect, store and distribute samples to researchers and focuses on malignancies from the gastrointestinal tract, thoracic cavity, breast, lymphoreticular system, head and neck, genitourinary and gynaecological tracts. The NIB also has approval in place to collect samples of tissues and blood from individuals with premalignant or potentially malignant conditions and to access samples from hospital (BHSCT) pathology archives. BHSCT Tissue Pathology is fully CPA-accredited.

PathXL is a global leader in providing integrated image and data solutions for digital pathology. The company specialises in the analysis of tumour tissue sections with a number of key products which provide support for complex pathological decision processes in the research, education and clinical sectors.
The Almac Group is an established contract development and manufacturing organisation that provides an extensive range of integrated services to over 600 companies globally within the pharmaceutical and biotech sectors. The services range from R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply, IXRS® technology (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation that has organically grown over 30 years and now employs in excess of 3,500 highly skilled personnel. Almac is headquartered in Craigavon, Northern Ireland with operations across the US (Pennsylvania, North Carolina and California) and in Asia (Singapore and Tokyo).

RANDOX LABORATORIES LTD

Dr Mary Jo Kurth

T: +44(0) 28 9442 2413
E: maryjo.kurth@randox.com
W: www.randox.com

Established in 1982, the principal activity of Randox Laboratories Ltd is the design, manufacture and marketing of a vast range of high quality products for laboratory medicine. Randox ranks 20th among clinical diagnostics companies globally. Randox’s extensive product portfolio includes clinical chemistry reagents and analysers, quality control material, internal quality control software, RIQAS – the largest global EQA scheme in the world- and Biochip Array Technology (BAT) that allows simultaneous detection of multiple analytes using a single sample for a complete patient profile and effective diagnosis. Randox won the McRobert Award for Engineering for BAT and has five Queen’s Awards for Export. Randox products are used worldwide by hospital and research laboratories, veterinary clinics/laboratories, pharmaceutical/CRO companies, forensic laboratories, and food and wine testing laboratories.

Randox offers

Clinical Trials and biomarker discovery
- Off-the-shelf and fully customised clinical diagnostic and biomarker solutions/reagents to allow for clinical trial patient selection and monitoring during trial
- Companion Diagnostics
- Custom Diagnostics - Single analyte and multiplex protein and nucleic acid arrays validated to clinical diagnostic grade with unrivalled precision, sensitivity and reproducibility
- Cost effective and collaborative assay development

BIOKINETIC EUROPE

Bronagh Cushnahan

T: +44 (0) 28 9081 8381
E: bronagh@biokineticeurope.com
W: www.biokineticeurope.com

BioKinetic is a 42 bed clinical pharmacology unit located in Belfast city centre. Being an independent CRO means we can provide the agility and responsiveness required for early phase decisions. As recognised experts in First in Man programmes and adaptive clinical trial design, our strengths lies in our integrity and personal service to ensure clinical trial objectives are met. Long-term senior staff, MHRA Supplementary Accreditation, GCP and GMP compliance assures our clients their trial is in safe hands. Types of Trials: FIM, SAD/MAD, biosimilars, inpatient/outpatient, BE/BA, DDI/food effect. Key therapeutic areas: Vaccines, Womens’ Health, Pain Management, Diabetes, Cardiology. Client Profiles: Small, medium & large Pharma, biotech, universities, university spin-outs, medical device companies, CRO partners, FP7 and H2020 consortia. With in-house experience of over 400 clinical trials and a volunteer database of over 19,000, BioKinetic is the CRO of choice for our global network of clients.
Celerion offers one of the most experienced clinical pharmacology research networks in the industry, with a global clinic capacity of more than 730 beds (24 in-hospital), efficient bioanalytical laboratories and experienced scientific staff. Experience and expertise:

- More than 25 years’ experience in conducting over 300 First-in-Human studies to provide confidence that the inherent risks of early clinical research are clearly understood and well managed.
- One of the largest clinical pharmacology sciences teams in the industry producing more than 200 clinical study reports annually and developed over 4,000 protocols in total.
- Execution of an integrated program of studies focusing on demonstrating early evidence of drug safety and effect.
- Regulatory strategy, technical and strategic support for clinical studies and product registrations in North America and Europe.

O4 Research is an innovative CRO and SMO which provides dynamic integrated trial management solutions to the Pharmaceutical, Biotechnology and Medical Device industries. Our focus is on delivering a personalised, high quality, cost effective service which extends across Phases II-IV, Non-Interventional and Investigator Initiated studies.

As a progressive organisation, operating throughout the UK/Ireland and with partners Europe wide, we provide an alternative, proactive trial management approach which is in sync with today’s unprecedented challenges. Our extensive experience ensures effective and creative solutions which consolidate timelines, facilitate timely patient recruitment and study progress while maintaining the optimal quality standards and professional levels of integrity.

The O4 Research team has an excellent track record in conducting clinical trials across a broad range of therapy areas with a particular focus on Analgesia, Cardiovascular, CNS, Dermatology, Endocrinology and Vaccines/Anti-infectives.

Venn Life Sciences is a European Clinical Research Organisation providing a suite of clinical trial services to pharmaceutical, biotechnology, academia, clinical research and medical device organisations. With operations in France, Germany, Ireland, the Netherlands and the UK, the Venn Group also includes a Clinical Resourcing business placing experienced clinical teams and individuals on projects throughout Europe.

As a full service CRO, Venn has over 25 years’ experience in the management and resourcing of clinical trials with services such as Protocol Development, Feasibility, Site Selection & Management, Monitoring, Project Management, Data Management, Biostatistics, Randomisation, Patient Recruitment & Quality Assurance. Venn has extensive therapeutic and medical device experience over a broad range of indications and is known for its commitment to quality and hands on management of clinical studies.
Speakers for the 15th September:

Dr. Andrew McCormick, Permanent Secretary, Department of Enterprise, Trade & Investment

Dr. Andrew McCormick was appointed as the Permanent Secretary of the Department of Enterprise, Trade & Investment (DETI) on 1st July 2014. Prior to this, he was the Permanent Secretary of the Department of Health, Social Services and Public Safety from 2005. He read Geology at University College, Oxford and completed a doctorate in geochemistry at Queen's University Belfast in 1980. He joined the Northern Ireland Civil Service in 1980 and worked in the Department of Finance & Personnel from 1980 to 1993. He was Head of Finance and Strategic Planning in the Department of Education for Northern Ireland from 1993 to 1998. He moved to DFP in 1998 and held the posts of Director, Central Finance Group Second Permanent Secretary, DFP between 1998 and 2002.

Professor Ian Young, Professor of Medicine & Director of the Centre for Public Health, Queen's University Belfast

Professor Ian Young's research interests cover nutrition, lipid metabolism and oxidative stress, and he has published over 350 papers in these areas as well as speaking at many national and international meetings. In addition to serving as Professor of Medicine and Director of the Centre for Public Health at Queen's University Belfast, he is currently Associate Medical Director (Research and Development) for the Belfast Health and Social Care Trust. He is Associate Editor for Clinical Chemistry and a member of the Editorial Board of several other leading international journals. He is also Chair of the Scientific Division of the International Federation of Clinical Chemistry and Laboratory Medicine and a member of the UK Department of Health’s Scientific Advisory Committee on Nutrition. In addition, he chairs the DHSSPS Obesity Prevention Steering Group.

Professor Joe O'Sullivan, Professor of Radiation Oncology, Queen's University Belfast, Consultant Clinical Oncologist, Northern Ireland Cancer Centre

Professor Joe O'Sullivan graduated from University College Dublin medical School in 1993 and trained in Radiation Oncology in St. Luke's Hospital in Dublin. In 2000 he took up a Clinical research Fellowship at the Royal Marsden London, completing a Doctorate Thesis on the use of high doses of Rhenium-186HEDP in advanced prostate cancer. He was appointed as a clinical academic to Queen's University Belfast in 2004 and was appointed as Professor of Radiation Oncology in 2011. His research interests include bone-seeking radionuclide therapy in metastatic prostate cancer, translational research in prostate cancer and radiotherapy, and clinical trials in advanced prostate cancer. He is chair of the Northern Ireland Urology MDT and clinical lead for radiotherapy at the Northern Ireland Cancer Centre. He takes over as Clinical Director of Oncology at the Belfast Trust in September 2014.
Professor J Stuart Elborn, Dean, School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast

Professor Stuart Elborn is Professor of Respiratory Medicine at Queen’s University and Consultant Physician in the Belfast Health and Social Care Trust and was appointed Dean of the School of Medicine, Dentistry and Biomedical Sciences in 2014. Professor Elborn leads an internationally recognised clinical service and research programme in cystic fibrosis. He is President of the European Cystic Fibrosis Society. Professor Elborn is committed to achieving the best outcomes for people with CF through the delivery of optimal care and innovative research. He has other research interests in infection in bronchiectasis and COPD and the impact of immunodeficiency on infection in the lung. He has led numerous clinical trials in CF which have delivered new therapies including Ivacaftor and inhaled antibiotics into clinical practice. He was awarded a CBE for services to medicine in 2013.

Dr. Giuliana Silvestri, Reader, Queen’s University Belfast, Consultant Ophthalmic Surgeon, Belfast Health & Social Care Trust

Dr. Giuliana Silvestri’s programme of research has focused on genetic predisposition and causative genetic mutations in ophthalmic diseases with emphasis on age-related macular degeneration and inherited retinal disorders. Her group has gathered well-characterized patient DNA repositories and contributed to local and international genotyping programmes and has developed collaborations with leading groups in the USA. The groups’ work on genetic predisposition in AMD has contributed to the scientific background for a commercial assay for genetic risk testing in AMD. This work on AMD predisposition is clinically relevant as early predictive testing may allow preventative strategies thereby limiting visual loss. Dr. Silvestri Is Lead of the Northern Ireland Clinical Research Group for Vision which continues to grow and has a portfolio of commercial studies. Dr. Silvestri has just finished longstanding terms as Training Programme Director for Northern Ireland and as Head of Student Support for the Medical School. She hopes that her recent appointment as Clinical Director for Ophthalmic Services at the Belfast Health & Social Care Trust will allow her to reshape services and further integrate clinical and laboratory research.

Professor Usha Chakravarthy, Professor of Ophthalmology and Vision Sciences, Queen’s University Belfast

Professor Chakravarthy has a varied portfolio of research interests and she has worked on the cell and molecular biology of vasoactive retinal peptides and profiled the alterations in gene expression in the retina under conditions of simulated hyperglycemia in experimental in vitro and vivo studies. Her current research involves studies on understanding of retinal and choroidal vascular diseases as well as degenerative aging changes contributing to sight loss in older adults. She is recognised internationally for her work on age-related macular degeneration, its pathogenesis, key risk factors including gene and environment interactions and clinical management of the disorder. She has in excess of 190 publications and many book chapters. She is the current chairperson of the ophthalmology specialty group for UKCRN and is a member of the Royal College of Ophthalmologists Academic Group. On an international level she is on the advisory panel for the AMD alliance, Laskar Foundation, represents the international community in the Macula Society, is program committee member for the Association for Research and Vision in Ophthalmology and external examiner and advisor to the University of Malaya. She is a member of the scientific panel for German Medical Research Council and the Australian Health Foundation. Professor Chakravarthy has delivered many eponymous and other invited lectures in the UK and abroad and currently serves on the advisory boards of several national and international governmental organisations.
Professor Patrick Johnston, President and Vice Chancellor, Queen's University Belfast

Professor Patrick Johnston was educated at St. Columb's College, Derry and University College, Dublin, where he gained his MB BCh degree in Medicine in 1982. In 1987 he obtained a Fellowship at the National Cancer Institute at Bethesda, Maryland, where he began further clinical training in medical oncology. He returned to the UK and joined the staff of Queen's University Belfast in 1996 as Professor of Oncology, later leading the establishment of the Centre for Cancer Research and Cell Biology and becoming its Director. Until taking up the post of President and Vice-Chancellor of Queen's in March 2014, Professor Johnston was Dean of the School of Medicine, Dentistry and Biomedical Sciences. His own research focus over 25 years has been on the understanding of mechanisms of drug resistance to therapeutic agents.

Mr. Edwin Poots, MLA, Minister for Health, Social Services and Public Safety

Edwin Poots MLA was appointed Minister of the Department of Health, Social Services and Public Safety in the Northern Ireland Executive on 16 May 2011. He was born in 1965 and was educated at the Wallace High School, Lisburn, and then Greenmount Agricultural College. He is married with four children. He is a farmer and was a member of Lisburn City Council from 1997 to 2010. He was elected as member for Lagan Valley to the Northern Ireland Assembly in 1998. Edwin was a member of the Environment Committee and chaired the Committee of the Centre (i.e. Committee for the Office of the First and Deputy First Ministers) in the 1998-2003 Assembly. On 8 May 2007, he was appointed Minister of Culture, Arts and Leisure in the Northern Ireland Executive, a post he held until 9 June 2008. He was appointed Minister of the Environment in the Northern Ireland Executive on 30 June 2009, until May 2011. Shortly after becoming the Minister for Health in 2011, Edwin Poots announced a review of health and social care provision in Northern Ireland. This review – which has since become known as Transforming Your Care – made 99 proposals for change with the aim of enabling services to be structured around the needs of the individual.

Dr. Adrian Kilcoyne, Medical Director, UK & Ireland, Celgene

Dr. Adrian Kilcoyne graduated from Trinity College Dublin in 1995. Following time as a Registrar in Reproductive Medicine in London, he spent some time as a Specialist Registrar in Public Health Medicine in Oxford followed by some years as a GP. He completed a Masters in Public Health at the London School of Hygiene and Tropical Medicine and a Masters in Business Administration at Warwick Business School. He joined the pharmaceutical industry in 2006 to become a Senior Clinical Research Physician in Diabetes at Eli Lilly. He has since held Medical Director positions at Baxter Healthcare, Roche, and Sanofi Pasteur MSD. He is now Medical Director for UK/Ireland at Celgene. Adrian has completed the Diploma in Pharmaceutical Medicine and is a Member of the Faculty of Pharmaceutical Medicine and has completed Higher medical training in Pharmaceutical medicine.

Speakers for 16th September

Mr. Richard Pengelly, Permanent Secretary, Department of Health, Social Services and Public Safety

Richard Pengelly was appointed as Permanent Secretary at the Department of Health, Social Services and Public Safety in July 2014, having previously held the post of Permanent Secretary at the Department of Regional Development for 18 months.
Previous roles include Public Spending Director at the Department of Finance and Personnel and a post with the Northern Ireland Audit Office.

**Professor Danny McAuley, Professor and Consultant in Intensive Care Medicine, Queen's University Belfast and Royal Victoria Hospital**

Professor Danny McAuley graduated from Queen's University Belfast in 1992. He undertook his training in Belfast, Birmingham, London and San Francisco. He is Director of the NI Clinical Research Facility and the NI Clinical Trials Unit. He is Co-Director of Research for the UK Intensive Care Society and Chair of the Irish Critical Care Trials group. He has two main research interests, which include acute lung injury and clinical trials.

**Dr. Janice Bailie, Assistant Director HSC R&D Division, Public Health Agency**

Janice Bailie completed a PhD in Biochemistry at Queen's University in 1990, investigating the effect of Epidermal Growth Factor analogues in breast tumours. Her post-doctoral research examined gene expression in microvasculature, in the Department of Ophthalmology at Queen's, and in the Radiation Science Group, University of Ulster. From 1998-2005, she was Divisional R&D Manager in Molecular Biology at Randox Laboratories Ltd., led a research team developing biomarker-based microarrays for diagnosis of cancers and cardiovascular disease, and collaborated with national and international partners in clinical trials and technology development. She joined the HSC R&D Office as Programme Manager in January 2005, and has since managed a programme of infrastructure initiatives and funding awards such as the Northern Ireland Clinical Research Networks, the Northern Ireland Clinical Trials Unit, the Clinical Research Facility and the Northern Ireland Biobank. Janice has now been appointed to the role of Assistant Director of HSC R&D Division, Public Health Agency.

**Professor Richard Kennedy, McClay Professor of Medical Oncology, Queen's University Belfast, VP and Medical Director, Almac Diagnostics**

Professor Richard Kennedy graduated in medicine from Queen's University Belfast in 1995. As a post-graduate he trained as a medical oncologist and received a PhD in Molecular Biology in 2004. From 2004-2007 he worked as an instructor in oncology at Harvard Medical School, USA, where he identified novel biomarkers and drug targets for cancer treatment. This work was published in several high impact journals and the associated patent was in-licensed by a Boston-based start up company (DNAR) in 2007. In August 2007 he joined Almac Diagnostics as the director of a CLIA compliant diagnostics laboratory and has been responsible for the biomarker strategy in several international clinical trials. In June 2011 he joined Queen's University Belfast and has established a research group focused on various aspects of stratified medicine. He also continues to manage cancer patients as a Consultant in Medical Oncology at Belfast City Hospital. He is currently the Experimental Cancer Medicine Centre lead for Northern Ireland and is a member of the CR-UK new agents committee and clinical trials steering group.
Professor Allan Gaw, MB, ChB, MD, PhD, FRCPath, FFPM, PG Cert Med Ed, Associate Director for Educational Quality Standards, National Institute for Health Research Clinical Research Network (NIHR-CRN)

Professor Allan Gaw graduated with a degree in Medicine from the University of Glasgow and trained in Clinical Biochemistry before specialising in Clinical Lipidology. On completion of his PhD, he spent two years post-doctoral study funded by the British Heart Foundation (BHF) in the laboratories of the Nobel Laureates, Joseph Goldstein and Michael Brown in Dallas, Texas. He returned to the UK to take up a position, also funded by the BHF. In 1997 he was appointed Deputy Study Director of a major cardiovascular study, PROSPER, and in 2000 took over the leadership of the Clinical Trials Unit at Glasgow Royal Infirmary. In 2006, he was appointed as the founding Director of the Glasgow Clinical Research Facility and in 2011 he became the founding Director of the Wellcome Trust Clinical Research Facility in Northern Ireland, where he was appointed as Professor of Clinical Research at Queen's University Belfast. He now works as Associate Director for Education Quality Standards at the NIHR-CRN at the University of Leeds, and as a freelance medical educator and writer.

Dr. Stephen McDonough, UK and Ireland Medical Director, GSK

Dr. Stephen McDonough was appointed Vice President Medical Director for GSK UK and Ireland in March 2014. He studied medicine at the University of Nottingham. Before joining the pharmaceutical industry in 1998, Stephen worked as a GP in Northern Ireland and Scotland. He has an MSc in Health Economics, Policy and Management from the London School of Economics and Political Science.

Professor Jonathan Wallace, Professor of Innovation, University of Ulster

Professor Jonathan Wallace has for the last 12 years been Director of Knowledge and Technology Transfer for the Faculty of Computing and Engineering at University of Ulster, with direct responsibility for the commercialisation of the Faculty's research knowledge, industrial collaboration and consultancy provision. Under his leadership, the Faculty of Computing & Engineering has generated on average 45% of the total annual consultancy income for Ulster for the last decade. He has led the development of numerous software systems in diverse market sectors and has attained broad experience of managing research projects at both a local, national and international level. He has a significant track record in the field of Connected Health and is recognised as an innovator in the co-creation of user-centred Connected Health product and service solutions.

Professor Tony Bjourson, Director, Biomedical Sciences Research Institute, University of Ulster, Director, Northern Ireland Centre for Stratified Medicine

Professor Tony Bjourson obtained his MSc in Biological Sciences from the University of Ulster and his PhD from Queen's University Belfast. He has over 30 years of research experience with a focus on stratified and personalised medicine in the area of cancer, autoimmune disease and pharmacogenomics. Prior to joining Ulster in 2001, he established and managed genomic programmes for the DARDNI and Queen's University Belfast and participated in the first international eukaryotic genome project (EU Yeast Genome sequencing program 1994-1996). After joining Ulster he led the Pharmaceutical Biotechnology Research Group and subsequently established and led the Biomedical Genomics Research Group. Tony was appointed Director of the Biomedical Sciences Research Institute at Ulster in 2007 and currently manages 250 Researchers. He was founder and serves as a Director on the board of C-TRIC based in L/Derry aimed at translating biomedical research outputs from laboratory bench to patient bedside. He is also Director of the Northern Ireland Centre for Stratified Medicine, which he established at Altnagelvin (C-TRIC) in 2013 with an £11.5M investment.
Mr. Sam Kinghan, R&D Manager, Life Sciences, Invest Northern Ireland

Mr. Kinghan is R&D Manager for the Life and Health Sciences sector at Invest Northern Ireland. He is responsible for the full spectrum of InvestNI R&D grant support to the sector. InvestNI works with industry, the universities and other government departments to promote and encourage innovative R&D in Northern Ireland.

Dr. Richard Wilson, Clinical Director, NI Cancer Trials Network

Dr. Richard Wilson is the Director of both the Northern Ireland Cancer Clinical Trials Unit and the N. Ireland Cancer Trials Network. He also leads the colorectal cancer (CRC) clinical trials programme in NICCTU, where there are a portfolio of trials (NCRN, investigator-initiated and commercial) in the adjuvant setting, and in the first-, second- and third-line metastatic disease settings. He runs a mixture of phase I, II and III trials. He also collaborates on translational research studies in CRC with Professor Johnston and Dr. Waugh within the CCRCB.

Dr. Anne Kilgallen, Deputy Chief Medical Officer, DHSSPS

Dr. Anne Kilgallen was recently seconded into the role of Deputy CMO within the DHSSPS. She works as Medical Director and Responsible Officer for the Western Health and Social Care Trust and is the Trust’s executive lead for quality and safety. She is particularly interested in learning about leadership behaviours that can bring about genuine patient-centred organisations. Anne has spent almost 20 years specialising in health provision in Republic of Ireland and Northern Ireland. Most recently, she has played a significant role in reconfiguring her trust's hospital services to create a safer, more effective services model.
Notes:
Notes:
Notes:
Notes:
Notes: