OXFORD GLOBAL

# 10th Annual Biomarkers Congress

23rd & 24th February 2015, Manchester, UK

**10th Annual Biomarkers Congress**
**Day 1 Stream 1 – Biomarkers in Discovery & Development**

- Case studies in biomarkers in drug discovery & development: chronic disease & onco-immunology
- Safety biomarkers for the detection of drug-induced toxicity
- Predictive biomarkers: IMI PREDECT update
- Translational Biomarkers: Preclinical to Clinical
- Imaging biomarkers: disease diagnostics and monitoring diseases progression

**Day 1 Stream 2 – Developing Companion Diagnostics**

- Updates on companion diagnostics development
  - Rheumatology
  - Cancer
  - Fibrosis
- Molecular imaging based companion diagnostics
- Integration of diagnostics into drug development
- Commercial update: diagnostic deals

**Day 2 Stream 1 – Biomarker Discovery, Verification & Validation**

- Biomarker discovery: proteomic, genomic and metabolomics markers
- Biobanking: obtaining sample collections for biomarker discovery
- Biomarker assay development and validation
- Translational research for biomarker validation
- Novel technologies: simultaneously identify and quantify candidate biomarkers in biological samples

**Day 2 Stream 2 – Innovations in Biomarker Research**

- Therapeutic area case studies:
  - Oncology
  - CNS
  - Chronic pain, Alzheimer's, rheumatism
- IMI project updates: biomarker initiatives and collaborations
- New advances in biomarker technologies and platforms

**2nd Annual Biomarkers in Clinical Development Congress**
**Day 1 – Biomarkers in Clinical Development & Diagnostics**

- Cytokines as biomarkers for clinical trials
- Translating scientific discoveries to improve therapies
- Diagnostics: strategies for new clinical targets
- Novel technologies: exploring biomarker analysis in the clinic
- Latest developments in blood-circulating microRNA

**Day 2 – Clinical Trials & Personalised Medicine**

- Implementing biomarker data into clinical development strategies
- Transforming clinical development through biomarker driven clinical trials design
- Predictive biomarker discovery in proof – of concept clinical studies
- Personalised healthcare: translating scientific innovation into patient benefit
- Targeting the right therapy to the right patient

## Benefits to Attending

***Oxford Global are pleased to announce the 10th Anniversary of the prestigious Biomarkers Congress. Attend the congress and sign up to present a poster for the chance to win an award of £3,000***

✓ **Hear from and meet with the key innovators in biomarkers, companion diagnostics and personalised medicine.** Previous attendees include: Vice President, Preclinical Safety, Abbvie; Vice President Immunology Biomarkers, Janssen; Vice President, Clinical Development, Pfizer

✓ **Discover collaborative solutions to biomarker challenges.** Our industry leaders will discuss the latest opportunities in genomic biomarker discovery, companion diagnostics development and clinical validation methods of biomarkers

✓ **Discuss the latest innovations in biomarkers,** including integration of diagnostics in drug development, application of safety biomarkers for toxicity testing and utilisation of biomarkers to establish clinical endpoints

✓ **Unparalleled networking opportunities.** The two-day congress offers an interactive platform for high-level scientific and business discussions. Participate in formal or informal discussions during our networking breaks and pre-organised 1-2-1 meetings

✓ **A high quality programme devised with the help of our esteemed advisory board.** Presentations will cover areas including biomarker technologies and platforms, biomarker assay development and personalised medicine

✓ Co-located with the **2nd Annual Biomarkers in Clinical Development Congress**

**2015 Speakers Include…**

**Michael Merz**
**Novartis**

**James Matcham**
**AstraZeneca**

**Elena Izmailova**
**Takeda**

**Meet Senior Decision Makers**
250 VPs, Directors & Senior Managers from leading pharmaceutical organisations, biotech companies and academic institutions will attend the event. Delegate job titles include:

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| Biomarker Discovery | Imaging Technologies |
| Biomarker Validation | Personalised Medicine |
| Companion Diagnostics | Preclinical Safety |
| Clinical Biomarkers | Translational Medicine |

**Discover New Solutions**
Formal and informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Services to be discussed include:

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| Assay Validation | Patient Selection Markers |
| Biomarker Verification | Regulatory Services |
| Biomarker Data Management | Genomic Biomarkers |
| Diagnostic Development | Clinical Validation |

**Venue:** The Biomarkers Congress will take place on the 23rd & 24th February 2014 at Manchester Central, UK
www.biomarkers-congress.com

**2015 Confirmed Speakers:**

- Yoshiya Oda, Unit President of Biomarkers & Personalized Medicine Core Function Unit, Eisai Inc.
- Elena Izmailova, Senior Director, Takeda
- Lakshmi Amaravadi, Senior Director, Translational Sciences, BiogenIdec
- John Waterton, Professor of Translational Imaging, Biomedical Imaging Institute, The University of Manchester and co-ordinator, IMI QuIC-ConCePT consortium
- Susanta Sarkar, Director, Translational/Clinical Imaging, Translational and Experimental Medicine, Sanofi Oncology
- Celine Pallaud, Director, Global Correlative Sciences Leader, Novartis
- Liz Harrington, Director, Translational Science, AstraZeneca
- Jill Richardson, Director, External Alliances, Neurosciences Therapeutic Area and EFPIA coordinator of the IMI PharmaCog project
- Holly Soares, Group Director CV, Fibrosis and Genetically Defined Diseases, BMS
- Stanko Skrtic, Medical Science Director, CVMD Early Clinical Development, AstraZeneca R&D
- Michael Merz, Project Coordinator IMI SAFE-T consortium, Novartis Institutes for BioMedical Research
- Dirk Cerneus, Science Director Clinical Pharmacology, Astellas Pharma Global Development
- Fabien Gaire, Global Head of Pathology & Tissue Analytics, Roche
- Märta Segerdahl, Chief Medical Specialist, H. Lundbeck A/S
- Sally Mountain, Associate Director, Global Outsourcing Lead of Correlative Science, Novartis
- Ralph Graeser, Associate Director, Janssen
- Joseph Arron, Associate Director, Biomarker Discovery, Genentech, Inc
- James Matcham, Head, Early Clinical Biometrics, AstraZeneca
- Richardus Vonk, Head of Research and Clinical Sciences Statistics, Bayer Pharma AG
- Shian-Jiun Shih, Director, Molecular Biomarkers and Diagnostics, MSD
- Paul Germann, Head Preclinical Safety Germany, Abbvie
- Fiona Thomson, Director, University of Glasgow
- Suzanne Jenkins, Associate Director, Diagnostics, AstraZeneca
- Peter Groenen, Head of Translational Science, Actelion Pharmaceuticals Ltd.
- Michael-Friedrich Boettcher, Global Clinical Project Lead, Bayer
- Andreas Popp, Senior Principal Pathologist, Abbvie
- David Henderson, IMI Liaison Manager, Bayer Pharma AG
- Axel Ducret, Principal Scientist, F. Hoffmann-La Roche Ltd
- Fengrong Zuo, Principal Scientist, MedImmune
- Gary Gilmour, Principal Research Scientist - In Vivo Pharmacology, Lilly UK
- Chris Harbron, Principal Statistical Scientist, Roche
- Mark Jairaj, Principal Scientist, UCB
- Luc Van Rompaey, VP Translational Medicine, arGEN-X BVBA
- Stephen J Blakemore, Senior Director, Translational Medicine, Epizyme, Inc.
- Afrodite Lourbakos, Senior Director Biomarkers, Prosensa
- Robert Nelson, Head of Bioanalytical Assay Laboratory, NovImmune SA
- Kim Henriksen, Head of Musculoskeletal Diseases, Nordic Bioscience
- Morten Karsdal, Head of R&D, CEO, Nordic Bioscience, Professor of molecular medicine, Southern Danish University (SDU), Odense, Denmark
- Anne-Christine Bay-Jensen, Principal Scientist, Head of Rheumatology, Nordic Bioscience
- Mads Almose Røpke, Senior Scientific Advisor, LEO Pharma A/S
- Nicole St Jean, Corporate Business Development Manager, AstraZeneca Pharmaceuticals LP
- Matthias Hackl, Chief Operating Officer, TAmiRNA GmbH
- John Wise, Executive Director, Pistoia Alliance
- Richard O'Kennedy, Scientific Director, Biomedical Diagnostics Institute, Dublin City University
- Stephen Roy Pennington, Professor of Proteomics, University College Dublin
- Romain Micol, Business Development Director (China), Transgene S.A.
- Alain van Gool, Professor Personalized Healthcare, Radboud University Medical Center, TNO

**2015 Confirmed Sponsors:**

If you're on Twitter, make sure to follow us **@BMD_Congress** and join the Congress conversation on **#BIOM15**

For more information please contact marketing@oxfordglobal.co.uk

**2015 Confirmed Sponsors Continued:**

































**10th Annual Biomarkers Congress**
**Day One – 23rd February 2015**

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| **07.30 – 08.20** | **Registration: Charter Foyer** | | |
| | **Conference Room: Charter Room 1** | | |
| **08.20 – 08.25** | **Oxford Global's Welcome Address** | | |
| **08.25 – 08.30** | **Chairperson's Opening Address: Lakshmi Amaravadi, Senior Director, Translational Sciences, BiogenIdec** | | |
| **08.30 – 09.00** | **Keynote Address:**<br>**Biomarker Discovery And Translational Research By Multi-Omics**<br>Biomarkers can play very important roles for drug development, because biomarkers can show the data for target engagement, target modulation, patient stratification and drug efficacy. Targeted Omics analysis is a powerful tool to identify biomarkers in human specimens. Our multi-omics capability could elucidate promising biomarkers for our drug development. Some of them are translational biomarkers or circulating biomarkers. DNA, RNA, proteins and lipid examples will be shown during the presentation.<br><br>**Yoshiya Oda, Unit President of Biomarkers & Personalized Medicine Core Function Unit, Eisai Inc.** | | |
| | **Conference Room: Charter Room 1** | **Conference Room: Charter Room 2** | **Conference Room: Charter Room 4** |
| | **Biomarkers in Discovery & Development** | **Developing Companion Diagnostics** | **Biomarkers in Clinical Development & Diagnostics** |
| | **Stream Chair: Lakshmi Amaravadi, Senior Director, Translational Sciences, Biogen Idec** | **Stream Chair: Gareth Williams, Medical Director, OncoLogica Ltd** | **Stream Chair: Johanness Vanhooren, Director Global Contract Management BARC & Didier Pitsi, Chief Scientific Officer, BARC** |
| **09.00 – 09.30** | ***Milieu Intérieur* - Defining The Boundaries Of A Healthy Immune Response**<br>• To identify genetic and environmental determinants of natural immune variance we have applied TruCulture assays to probe the induced immune response to a range of microbial stimuli in a cohort of 1000 well characterized healthy individuals<br>• Initial results have identified common non-response phenotypes following stimulation with bacteria, TLR adjuvants, or T cell agonists<br>• Current experiments are probing the intracellular pathways responsible for these perturbed phenotypes<br>Future studies will associate these phenotypes with genetic, microbiotic, and lifestyle factors<br><br>**Darragh Duffy, Senior Scientist, Institut Pasteur**<br><br>MYRIAD RBM | **Development Of Personalised Infertility Treatment – Collaborative Efforts By Pharmaceutical And Diagnostics Industries**<br>• The use of biomarkers for identifying patients at risk of high or low response should facilitate the establishment of individualized gonadotropin dosing regimens for ovarian stimulation in women undergoing an assisted reproductive technology programme. This strategy may improve the predictability of ovarian response, reduce the risks of overstimulation and increase the efficacy and efficiency of treatment.<br>• Anti-Müllerian hormone (AMH) has consistently been shown to be a robust biomarker for predicting ovarian response to gonadotropins. In the past, only manual AMH enzyme linked immunosorbent assays (ELISA) were available to determine AMH levels. Since September 2014 the first fully automated AMH assay on the Roche cobas e electrochemiluminescence immunoassay platform is available in countries accepting the CE mark in Europe, Latin America, Middle East, Asia and Africa. The development of a highly sensitive and fully automated AMH immunoassay was a prerequisite for routine and wide-spread use of this test in clinical practice.<br>• In the future, the Elecsys AMH immunoassay is also intended to be used in combination with the new human recombinant follicle-stimulating hormone (human rFSH) treatment currently in phase III development at Ferring Pharmaceuticals. This combination, which will make possible individualized dosing of human rFSH based on a woman's specific AMH level, may provide an improved option for couples seeking to conceive through in vitro fertilization.<br>• In order for a pharmaceutical company to incorporate biomarker recommendations in the drug product labelling, several clinical and diagnostic assay requirements must be fulfilled. Similarly, the diagnostics company need clinical data with the drug to document the utility of the biomarker for the intended use. Furthermore, new drugs and diagnostic assays have to be co-developed taking into account specific regulatory requirements in each region.<br>• In conclusion, aligned collaborative efforts from both the pharmaceutical company and the diagnostics company are required to achieve personalised infertility treatment incorporating the use of biomarker(s) together with a drug in the clinical management of patients.<br><br>**Joan-Carles Arce, Vice President, Reproductive Health, Global Clinical & Non-Clinical R&D, Ferring Pharmaceuticals**<br><br>**Martin Hund, Global Medical Leader Women's Health, Roche Professional Diagnostics, Roche Diagnostics International Ltd**<br><br>Roche | **Cytokine Assay For Central Lab Testing : A New Frontier**<br>• Cytokines as useful biomarkers for clinical trials in various therapeutic areas<br>• One single method is not available for combining both the requirements of extreme sensitivity and multiplexing<br>• White paper results presented on various available methods comparison<br><br>**Els Decoster, Head of Molecular Biology and R&D, BARC**<br><br>BARC Global Central Laboratory |

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| **09.30 – 10.00** | **Validation Of A Newly Developed Tool To Measure Urethral Pressure And Potential Application For The Development Of SUI Drugs**<br>• Several drugs used to improve symptoms of stress urinary incontinence (SUI), such as incontinence episodes, presumably act by increasing urethral pressure<br>• However, a correlation between the effect on clinical symptoms and urethral pressure of marketed products has not been well-documented<br>• Current study aims to examine the effect of reference SUI drugs on urethral pressure using a newly developed method, urethral pressure reflectometry<br><br>**Dirk Cerneus, Science Director Clinical Pharmacology, Astellas Pharma Global Development** | **Molecular Imaging Based Companion Diagnostics: A New Paradigm In Drug Development**<br>• Challenges of drug development<br>• How molecular imaging based companion diagnostics can help address these challenges<br>• Molecular imaging approaches to develop companion diagnostics<br><br>**Susanta Sarkar, Director, Translational/Clinical Imaging, Translational and Experimental Medicine, Sanofi Oncology** | **Translating Cancer Discoveries Into Targeted Therapies**<br>• Pharmacodynamic biomarker assessment to optimize the dose and schedule of targeted therapies<br>• Patient selection biomarkers: tailoring the right therapy for the right patient<br>• Identification and targeting of resistance mechanisms<br><br>**Liz Harrington, Director, Translational Science, AstraZeneca** |
| **10.00 – 11.20** | **Exhibition Room: The Gallery**<br>**Coffee & Refreshments: Poster Presentation Session: One to One Meetings x4** | | |
| **11.20 – 11.50** | **Biomarkers In Discovery And Drug Development: Choosing The Right CRO Partner**<br>There is a high attrition rate for drugs being developed through the discovery and development process. Less than 10% of new compounds studied in early development phases make it to late phases clinical trials. This has led to a constant low rate of new medicines being approved by the FDA and hitting the market over the years. The use of the right biomarkers in discovery and development is a key to getting a greater number of safer drugs approved more quickly; potentially reducing the cost of a new drug development currently estimated at an average $1.3B.<br><br>Choosing the right laboratory is critical for establishing a successful biomarker strategy. A well thought out strategy starts with a careful selection of biomarkers. Pre-analytical considerations such as consistent and controlled sample collection, transportation and storage procedures are essential to prevent ex-vivo variability, potentially leading to biased interpretation of results. The validation level of the biomarkers should match the purpose of its use; depending on the stage in the drug discovery or development continuum and its associated mandated regulatory environment. A smart approach to post analysis biobanking is also a key for bridging, retrospective and prospective studies.<br><br>The right CRO partner for biomarker should be able to provide the project management and scientific horsepower to not only drive the study through these different challenges but also to propose joint companion diagnostics development opportunities.<br><br>**Vincent Drouillon, Senior Director, Translational Biomarker Solutions and Hematology, Covance, Inc.**<br>  | **Minimally Invasive Multimodal Technologies For Patient Profiling And Disease Management**<br>• Accessing molecular signatures from biofluids presents an extremely useful & patient compliant approach to disease management<br>• Maximising sample utility through multimodal analysis<br>• Enhancing the Sample to actionable Insight continuum<br><br>**Patricia McLoughlin, Director Companion Diagnostic Partnerships, Global Business Development, QIAGEN**<br>  | **Multiplexed Biomarker Methods**<br>• Platforms and methods pros/cons<br>• Multiplex method validation – special considerations<br><br>**John L Allinson FIBMS, Head of Biomarker Strategy, LGC**<br>  |

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| **11.50 – 12.20** | **Patient-Derived Xenograft Models For Drug Testing & Biomarker Identification**<br>• Clinical relevance of patient derived xenografts<br>• Mouse clinical trials using PDX to identify biomarkers<br><br>**Rajendra Kumari, Chief Scientific Officer, Crown Bioscience Company**<br><br>Crown Bioscience Inc.<br>in life, for life | **The NanoString Cell Of Origin Subtyping Test: A Companion Diagnostic for Targeted Therapies in Diffuse Large B-Cell Lymphoma**<br>• Background on the NanoString nCounter Dx Analysis System<br>• DLBCL Cell of Origin<br>• Development of an IVD Cell of Origin assay for use as a CDx<br><br>**Sean Ferree, Vice President of Diagnostic Development, NanoString Technologies**<br><br>nanoString TECHNOLOGIES | **Biomarker Analysis In The Clinical laboratory: An Integrated Approach**<br>• Applications of Biomarker analysis in clinical studies<br>• The quality system applied: process specific vs study specific<br>• Clinical analyzer test or Home-brewed test<br>• Centralized analysis or Standardization of methodologies between sites<br><br>**Edwin Janssen, Head Scientific Affairs, Eurofins Central Laboratory**<br><br>eurofins \| Central Laboratory |
| **12.20 – 12.50** | **Five Years Of Collaborative Safety Biomarker Qualification: Output Of The IMI SAFE-T Consortium**<br>• The IMI SAFE-T consortium is approaching the completion of its clinical program to qualify new safety biomarkers for drug-induced kidney, liver, and vascular injury<br>• Initial results for some of the new markers will be presented<br>• An outlook on planned future activities will be provided<br><br>**Michael Merz, Project Coordinator IMI SAFE-T consortium, Novartis Institutes for BioMedical Research** | **Companion Diagnostic Development For A Breakthrough Therapy (AZD9291)**<br>• AZD9291 is in development for T790M positive, relapsed EGFR mutated advanced/metastatic NSCLC<br>• AstraZeneca have partnered with Roche Molecular Systems to develop a companion diagnostic for AZD9291<br>• A plasma ctDNA test is also in development to minimise the requirement for a repeat biopsy<br><br>**Suzanne Jenkins, Associate Director, Diagnostics, AstraZeneca** | **Biomarkers – Moving On**<br>• Need for Early Biomarker Identification.<br>• Innovative Statistical Methods for Biomarker Development<br>• From Qualitative to Quantitative Decision Making<br><br>**Richardus Vonk, Head of Research and Clinical Sciences Statistics, Bayer Pharma AG** |
| **12.50 – 13.50** | **Exhibition Room: The Gallery**<br>**Lunch** | | |

**10th Annual Biomarkers Congress**
**Day One – 23rd February 2015**

| | Stream Chair: Paul Germann, Head Preclinical Safety Germany, Abbvie | Stream Chair: Gareth Williams, Medical Director, OncoLogica Ltd | Stream Chair: Hans Vanhooren and Didier Pitsi, BARC |
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| **13.50 – 14.20** | **Translation Of Biomarkers In Neurology: A Case Study In Multiple Sclerosis Drug Development**<br>• Neurological indications can be particularly challenging due to the pathways related to the disease progression, under developed tools and challenges related to translation into the clinic.<br>• However, with the evolving understanding of molecular pathways, mechanistic basis of the disease and development of biomarker tools and methodologies, it is possible to apply translational biomarkers during drug development to understand pharmacodynamics, elucidate mechanism of action and to evaluate the relationship to efficacy and predictive ability of the biomarkers.<br>• A case study involving Multiple Sclerosis drug development will be presented to demonstrate application of biomarkers during drug development to evaluate mechanism of action and association of biomarker/s with clinical endpoints and predictive ability. Challenges related to biomarker's ability to predict efficacy from a scientific vs clinical utility point of view will be discussed.<br><br>**Lakshmi Amaravadi, Senior Director, Translational Sciences, Biogen Idec** | **Panel Discussion: Companion Diagnostics Development**<br>• Commercial and regulatory challenges with atypical biomarker modalities<br>• Biomarkers from high-dimensional data<br>• CDx in four core disease areas:<br>○ Oncology<br>○ Infection<br>○ Rare diseases<br>○ PGx<br>• FDA lists 20 approved drug-CDx pairs<br><br>**(Panel Chair) Elena Izmailova, Senior Director, Takeda**<br><br>**Susanta Sarkar, Director, Translational/Clinical Imaging, Translational and Experimental Medicine, Sanofi Oncology**<br><br>**John Waterton, Professor of Translational Imaging, Biomedical Imaging Institute, The University of Manchester and co-ordinator, IMI QuIC-ConCePT consortium**<br><br>**Alain van Gool, Professor Personalized Healthcare, Radboud University Medical Center, TNO**<br><br>**Romain Micol, Business Development Director (China), Transgene S.A.** | **Utilizing Biomarkers To Maximize The Value Of Phase 1 Studies To Investigate Novel Histone Methyl Transferase (HMT) Inhibitors**<br>• EPZ-5676 and EPZ-6438, targeting DOT1L and EZH2 respectively, are the first two HMT inhibitors to enter Phase 1 clinical development.<br>• CDx strategies to support the pre-clinically determined target indication for both molecule will be described.<br>• Utility of Phase 1 tumor and surrogate tissue collection strategies to enable investigation of trial emergent clinical phenomena will be discussed<br><br>**Stephen J Blakemore, Senior Director, Translational Medicine, Epizyme, Inc.** |
| **14.20 – 14.50** | **PREDECT– Better Characterized Models For More Predictive Biomarkers In Oncology**<br>• Oncology drug discovery suffers from inadequate pre-clinical in vitro and in vivo models<br>• PREDECT is a consortium made of Academia, Biotech, and Pharma, with the aim to better characterize and standardize such models<br>• An overview on goals, methods, and preliminary results will be presented<br><br>**Ralph Graeser, Associate Director, Janssen** | | **The Application Of Tau-fragments As Biomarkers Of Neuronal Loss**<br>• Tau fragments exist in serum<br>• Tau-A and Tau-C are novel brain-derived fragments of Tau<br>• The fragments are released into blood upon injury to the brain, and appear to predict severity of the incident<br>• Their levels can predict cognitive changes in early AD<br><br>**Kim Henriksen, Head of Neurodegenerative Diseases, Nordic Bioscience Biomarkers & Research** |
| **14.50 – 15.20** | **A Unified Platform for Biomarker Discovery and Validation**<br>• Introduction to Affimers and high complexity Affimer arrays<br>• Exemplification of Affimers in applications traditionally dominated by antibodies<br>• Description of Avacta HTP protein production process - currently producing 4000 Affimers per week<br>• Data from biomarker discovery and validation collaborations in a range of indications<br><br>**Paul Ko Ferrigno, CSO, Avacta Life Sciences**<br><br>Avacta LIFE SCIENCES | **Biomarker Strategies And CDx Development – Reality Or Aspiration?**<br>• Introduction to Tepnel – Hologic<br>• CDx Roadmap and Case Study<br>○ What do 'we' the supplier assume/think you need?<br>○ What do 'you' the contractor actually/really need?<br>• Interactive Q&A Session<br><br>**Bob Holt, Molecular Genetic Services Manager, Tepnel Pharma Services**<br><br>TEPNEL Pharma Services | **Integrated Precision Medicine Approaches In Clinical Development**<br>• Precision medicine challenges across the development lifecycle<br>• Opportunities for managing key risks and maximizing probability of success:<br>○ Planning for regulatory and commercial success<br>○ Preparing to deal constructively with outlier response<br>○ Efficiently identifying study subjects with low-prevalence biomarkers<br>○ Validating and incorporating next-generation sequencing panels<br><br>**Win Shaw, Senior Director, Precision Medicine Integration, Quintiles**<br><br>QUINTILES |

**10th Annual Biomarkers Congress**
**Day One – 23rd February 2015**

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| **15.20 – 15.50** | **A Universal Assay Platform For Biomarkers From Screening To Validation**<br>• Data from Biomarker Screening of more than 100 biomarkers on a single platform<br>• Examples of Ultra High Sensitivity S-PLEX™ assay<br>• Description of Development of Validated Tests for the Clinic<br>• Examples from a new flexible multiplexing technology: U-PLEX™<br><br>**Pankaj Oberoi, Vice President, Commercial Assays, Meso Scale Discovery** | **The Translational Role of Molecular Pathology in Cancer Theranostics**<br>Molecular Pathology is a key tool for the successful development of cancer diagnostics and now plays a major role in drug development programmes as a result of the drive for patient stratification and personalised medicine. Here we present a case study involving the exploitation of the DNA replication machinery in a wide range of theranostic applications in which we demonstrate how pathology has been central to the successful development and commercialisation of a range of cancer detection, prognostic and predictive biomarker tests. These biomarker discovery, verification and validation studies resulted in the identification of novel therapeutic targets in a broad range of tumour types which has provided a spring board for the development of novel therapeutic intervention strategies targeting the DNA replication machinery. Finally we show how tumour morphology, a powerful prognosticator and predictor of response used in routine clinical practice for over a century, can be combined with phenotypic read-outs from functional genomic screens to identify new cancer genes.<br><br>**Gareth Williams, Medical Director, OncoLogica Ltd** | **Emerging role of Biomarkers and Companion Diagnostics in Drug Development**<br>• Importance of Biomarkers and Companion Diagnostics in Oncology/Neurology drug development<br>• Shifting gears from a transactional strategy to consultative strategy from lab partners<br>• Brief highlights on innovative technologies for multiplex biomarker assessment.<br>• Quest Innovative solutions across multiple TAs for biomarkers- A FOCUS ON GENOMIC solutions<br>• Quest Innovative solutions for clinical trial enrolment rate optimization<br><br>**Kamala Maddali, Director of Scientific Development, Quest Diagnostics Clinical Trials** |
| **15.50 – 16.50** | **Exhibition Room: The Gallery**<br>**Afternoon Refreshments: One to One Meetings x 3**<br>**Poster Presentation Judging Session** | | |
| **16.50 – 17.20** | **Accurate And Specific Protein Quantification From FFPE Tissue. *Quantification Of HER2 In FFPE Breast Cancer Tissue Using Selection Reaction Monitoring Mass Spectrometry.***<br>• Selection Reaction Monitoring Mass Spectrometry (SRM-MS): potential for quantitative measurement of proteins in FFPE tissue<br>• Build and qualification of research-grade SRM-MS assays.<br>• Targeted, specific and quantitative multiplexed measurement of HER2 in FFPE breast cancer tissue: a case study.<br><br>**Axel Ducret, Principal Scientist, F. Hoffmann-La Roche Ltd** | **Biomarkers Of Diagnosis, Prognosis And Efficacy Of Intervention For Different Fibrotic Disorders**<br>• Remodeling of the extra cellular matrix is a key event in fibrotic disorders<br>• It is essential to asses tissue formation and tissue degradation separately for accurate assessment of fibrotic disorders<br>• The collagen turnover profile is different in different fibrotic disorders<br>• Assessment of the collagen degradation profile are able to identify repose to treatment and fast progressors<br><br>**Morten A. Karsdal, Professor, CEO, Nordic Bioscience A/S** | **Biomarker Strategy Supporting The Development Of The Immunotherapeutic ARGX-110 In Oncology**<br>• CD70, a TNF family member modulating immune response via interaction with CD27, is highly expressed by multiple tumor types<br>• ARGX-110 antibody, targeting CD70, provides a multi-pronged approach to tackle tumors and their microenvironment<br>• Biomarker strategy developed to measure target-mediated biological response and disease modification for ARGX-110 oncology trials<br><br>**Luc Van Rompaey, VP Translational Medicine, arGEN-X BVBA** |
| **17.20 – 17.50** | **Translational Biomarkers In Dermatological Drug Development**<br>• Strategy for using biomarkers at the various R&D stages described in a biomarker stage-gate model<br>• Translate biomarkers from the discovery stages into exploratory clinical testing<br>• How our translation platforms can be used to improve the quality of development candidates<br><br>**Mads Almose Røpke, Senior Scientific Advisor, LEO Pharma A/S** | **Collaborating To Deliver Personalized Healthcare To Patients**<br>• Our pipeline - AZ/MEDI separated by therapy areas<br>• Companion Diagnostics – what does it take from both parties to create and maintain a successful partnership?<br>• Challenges & Future Trends we see in Personalized Healthcare<br><br>**Nicole St Jean, Corporate Business Development Manager, AstraZeneca Pharmaceuticals LP** | **Identification Of Blood-circulating microRNAs With Clinical Utility For The Management Of Bone Disease**<br>• Osteoporosis describes a systemic loss of bone mass, which leads to increased bone fragility and high risk of bone fractures<br>• MicroRNAs (miRNAs) that regulate bone metabolism are secreted into the bloodstream, thereby providing accessible information on local pathological processes<br>• The clinical utility for managing bone diseases was explored within exploratory and validation studies in the context of osteoporosis and type-2 diabetes<br><br>**Matthias Hackl, Chief Operating Officer, TAmiRNA GmbH** |

**10th Annual Biomarkers Congress**
**Day One – 23rd February 2015**

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| **17.50 – 18.20** | **Models Of Biomarker Analysis Outsourcing**<br>• Selection and Qualification of Laboratories<br>• Vendor Oversight<br>• Risk Management<br><br>**Sally Mountain, Associate Director, Global Outsourcing Lead of Correlative Science, Novartis** | **Biomarkers In Personalised Health(care): Moving Beyond Targeted Medicine.**<br>• The future of medicine<br>• Applications of biomarkers in personalised health(care)<br>• Crossing the biomarker innovation gap<br><br>**Alain van Gool, Professor Personalized Healthcare, Radboud University Medical Center, TNO** | **Proteomics To Address Unmet Needs And Deliver Biomarker Solutions In Prostate Cancer**<br>• Effective delivery of clinical tools to address unmet needs should 'Start at the End': example from Prostate Cancer will be articulated<br>• Human Proteomics has advanced significantly in the last year: key advances in Proteomics will be introduced<br>• Proteomics can provide solutions - both mechanisms for drug target identification and markers for development of clinical diagnostics: discovery and evaluation of multiplexed protein biomarkers for Prostate Cancer will be described<br>• The challenge of scaling for delivery of proteomic solutions is achievable: on-going efforts and future plans for scaling solutions will be presented.<br><br>**Stephen Pennington, Professor of Proteomics, University College Dublin** |
| **18.20** | **Exhibition Room: The Gallery**<br>**End of Day One: Networking Drinks**<br>**Poster Presentation Winner To Be Announced** | | |

**10th Annual Biomarkers Congress**
**Day Two – 24th February 2015**

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| | **Conference Room: Charter Room 1**<br>**Chairperson: Paul O'Riordan, Chief Executive Officer, Synexa** | | |
| **08.00 – 08.30** | **Keynote Address:**<br>**Using Translatable Biomarkers To Guide Drug Development For Complex Disorders: A Schizophrenia Case Study**<br>• Glycine type 1 transporter (GlyT1) transporter inhibition may represent a novel target mechanism for the treatment of schizophrenia.<br>• Translatable biomarkers of GlyT1 target engagement and target modulation were developed to support clinical proof of concept testing of the GlyT1 hypothesis.<br>• Pre-clinical/clinical studies are described to demonstrate how GlyT1 biomarkers aided dose selection for phase II efficacy studies in schizophrenic patients.<br><br>**Fiona Thomson, Director, University of Glasgow** | | |
| | **Conference Room: Charter Room 1** | **Conference Room: Charter Room 2** | **Conference Room: Charter Room 4** |
| | **Biomarker Discovery, Verification & Validation** | **Innovations in Biomarker Research** | **Clinical Trials & Personalised Medicine** |
| | **Stream Chair: Paul O'Riordan, Chief Executive Officer, Synexa** | **Stream Chair: John Wise, Executive Director, Pistoia Alliance** | **Stream Chair: Rasmus Werrnersson, Scientific Director, Intomics** |
| **08.30 – 09.00** | **Stream Keynote Address:**<br>**Why Does It Take So Long To Validate Imaging Biomarkers? Introducing A More Effective Roadmap**<br>• Imaging biomarkers have been extensively used for many decades in drug development and healthcare in many therapy areas. However the "menu" of trusted and validated imaging biomarkers remains small, and introduction of useful new imaging biomarkers has been disappointingly slow.<br>• Unlike biospecimen-derived biomarkers, the quality and validity of the imaging measurement as a biomarker often depends crucially on the use of a diagnostic imaging device, in the presence of the patient, in a manner for which the device (a) was not designed, (b) has not received regulatory approval and (c) is unfamiliar to the user in the trial site. Moreover, the identification of the 'objectively measured biomarker characteristic' with a quantifiable concentration of a specified analyte, is often difficult or impossible.<br>• We introduce a more effective and streamlined validation roadmap which disentangles technical (assay) validation, biological validation, and cost-effectiveness, to drive imaging innovations out of their specialist labs and across both the translational gaps.<br><br>**John Waterton, Professor of Translational Imaging, Biomedical Imaging Institute, The University of Manchester and co-ordinator, IMI QuIC-ConCePT consortium** | **Stream Keynote Address:**<br>**Prediction And Faster Assessment Of Functional Properties Of New Drug Candidates For Alzheimer's Disease In Early Clinical Development: The IMI PharmaCog Project**<br>• The PharmaCog consortium is providing a unique opportunity for the pharmaceutical industry, biotech and academia to combine their collective knowledge, expertise and data in a pre-competitive partnership to deliver a unique translatable platform for drug development in AD.<br>• The immediate benefits of such an interaction include the harmonisation of best-practice protocols, the integration of latest technologies and the definition and translation of novel endpoints from preclinical to clinical.<br>• A multi-centric clinical study to investigate MCI patients by assessing a broad range of translational endpoints (MRI, EEG, cognition, novel biomarkers) over a 2 year period is now generating some key data including the identification of a novel biomarker multiplex panel of 13 inflammatory proteins.<br><br>**Jill Richardson, Director, External Alliances, Neurosciences Therapeutic Area and EFPIA coordinator of the IMI PharmaCog project** | **Stream Keynote Address:**<br>**Clinical Biomarker Development and Validation: Challenges and Solutions**<br>• Challenges of generating clinical biomarker data<br>• Technological approaches for developing clinical biomarkers<br>• Case study of clinical assay development and validation<br><br>**Elena Izmailova, Senior Director, Takeda** |

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| **09.00 – 09.30** | **Clinical Metabolomics for Diagnostics and Drug Development**<br>• Metabolomics based Diagnosis of Congestive Heart Failure<br>• Metabolomics based Drug Target Identification<br>• Quality Control of Plasma Samples<br><br>**Philipp Schatz, Head of Biomarker Program, Metanomics Health**<br><br>metanomicshealth | **Innovation Through Regulation: How The recent FDA Biomarker Guidance Is Driving Changes In The Approach To Regulated Flow Cytometry Studies**<br>Flow cytometry has been used in a clinical diagnostic setting for many years and is now widely utilised during pharmaceutical development for biomarker assessment. The continually developing technology allows complex multi-parameter measurement, which can be used to combine phenotypic identification of cellular populations with assessment of biological activity and even assess drug-target binding interactions. The many formats of this technology provide a robust and powerful technique for bioanalysis.<br>The revised FDA guideline on Bioanalytical Method Validation issued in draft in September 2013 was the first regulatory document to specifically introduce a position on how to validate assays for biomarker assessment. This guideline is used in combination with the 'fit for purpose' approach to ensure that bioanalytical tests are designed and validated for use in pharmaceutical drug development and clinical assessment. This presentation will discuss what this change in paradigm means for flow cytometry assays and some of the innovative approaches the industry has developed to address the challenges posed by the guideline.<br>The focus will be on how progress in the areas of QC materials, appropriate analyser and operator checks to ensure data quality, important sample management decisions and techniques to allow longitudinal comparison between samples with limited stability, have been implemented to meet the new guidelines.<br><br>**David Lanham, Principal Scientific Director, Eurofins Pharma Bioanalysis Services**<br><br>eurofins \| Bioanalytical Services | **Using DNA Sequencing To Identify Responding Patients**<br>• Next Generation Sequencing (NGS) data holds great promise as a powerful tool for patient stratification, but important obstacles in using and interpreting NGS data for personalised medicine needs to be overcome.<br>• Main obstacles include incomplete biological knowledge, interpretation of functional impact of genetic variants, how different genetic variants and mutations collectively impact biological systems, and how predictive genetic variants are identified when there is only access to small patient numbers, e.g. in clinical trials.<br>• Integrative analysis strategies for how to access these obstacles through the use of network- and systems biology will be reviewed.<br>• A non-oncology clinical case study is presented, where integrative analysis of sequencing data is effectively used for patient stratification. Validation confirms the promises of NGS data - it is possible to effectively identify the responding patients, and improve the response rate in the clinical trial with 15 %.<br><br>**Thomas S. Jensen, CEO, Intomics A/S**<br><br>intomics from data to biology |
| **09.30– 10.00** | **How To Train Your Dragon: Turning Biomarkers Into Surrogate Endpoints Without Getting Burned**<br>• Surrogate endpoints (biomarkers which substitute for outcomes) such as HIV viral load, HBA1c in diabetes and blood pressure have improved drug development productivity and saved lives<br>• But the supply of new ones has dried up because of some spectacular failures and fears about failure<br>• Processes will be described (using the application of SomaLogic's SOMAscan assay in cardiovascular disease as an example) to discover, verify and validate biomarkers that have the right characteristics, and to mitigate the risk of failure.<br><br>**Steve Williams, Chief Medical Officer, SomaLogic**<br><br>SomaLogic | **Longitudinal Population Based Biobanks – A Unique Resource For Industry Biomarker Development**<br>• A unique Norwegian infrastructure for molecular & genetic epidemiology research<br>• HUNT - one of the largest and most comprehensive population based studies ever done<br>• Unmatched high-quality phenotype linking cohort & biobank data with health registries and electronic medical records<br>• Lifandis facilitates and professionalize industry access to Norwegian cohorts and biobanks<br>• Case studies for (1) early detection biomarkers and (2) prognostic patient stratification biomarkers<br><br>**Christian Jonasson, Chief Scientific Officer, Lifandis**<br><br>Lifandis<br>*Unlocking the Secrets of Disease* | **Reproducible Research in Clinical Bioinformatics**<br>• Precision Medicine aims at adapting therapies to patient's characteristics. It requires the early identification of biomarker predictive of treatment outcome from large-scale data generated in clinical trials.<br>• Such biomarker data analyses require specific biotechnological data quality controls, exploratory statistical approaches, and biological interpretation, all applied in compliance with established clinical standards.<br>• We have developed an analysis framework entirely based on statistical programming that fulfils the requirements of exploratory biomarker data analyses, finding the right balance between exploration and compliance, and implementing the principles of Reproducible Research in Clinical Bioinformatics.<br><br>**Jérôme Wojcik, CEO, Quartz Bio**<br><br>Quartz Bio |

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| **10.00 – 10.30** | **Urine & Blood Biomarker Research Without Understanding Preanalytical Variables. Can It Be Trusted?**<br>• The preanalytical phase (defined as the time from sample collection prior to sample analysis) has great potential for errors. In routine pathology (50-95%) of errors are related to the preanalytical phase. Many of these errors are outside of the laboratories & researchers control, and significantly impact the quality of the sample. Can we be sure of our research outcomes if we are using sub optimal samples?<br>• The use of specialist BD Vacutainer® sample collection tubes with the additives to stabilise proteins and RNA can ensure stability of the sample. However, controlling the collection device alone is not enough to ensure a consistently optimised sample. Specialist services, such as the BD Laboratory Consulting Services™, which identifies errors in the preanalytical process (sample collection methods, sample transportation, sample preparation & storage) conditions together with defined improvements can ensure a consistently optimise sample quality. Thereby enabling high quality whole blood and urine biomarker research.<br>**David Craft, Senior Manager Sciences, BD Life Sciences** | **Metabolic Phenotyping In Mouse And Man: Opportunities And Challenges**<br>• Concept of Metabolic Phenotyping: Its significance for the identification of biological markers<br>• Technological background: Reproducible, quality-controlled & quantitative metabolomics products<br>• Applications in translational research: From mouse to man – with courage and caution<br>**Denise Sonntag, Head of Contract Research, BIOCRATES**<br>**Florence Raynaud, Group Leader Pharmacokinetics and Metabolomics, Cancer Research UK Cancer Therapeutics Unit, The Institute of Cancer Research** | **Laboratory-Developed Tests And In-vitro Diagnostic Tests: Different Approaches For Companion Diagnostic Development And Personalised Medicine**<br>• Bridging diagnostic testing with clinical trials<br>• IVD and regulated Laboratory Developed Test (LDT)<br>• Scalable commercialization pathways<br>• Strategies to reduce CDx development timelines by up to 12 months<br>• Recent case studies with FDA submissions<br>**Alan Wookey, Associate Vice President and Executive Director of Companion Diagnostics, LabCorp Clinical Trials** |
| **10.30 – 11.00** | **ProtoTrials: An innovative translational research approach that helps to prioritise drugs for clinical development and refine biomarker strategy**<br>• Allowing **early insight** into the efficacy, safety and MOA of a drug.<br>• **Focusing** the clinical biomarker panel and analytical techniques.<br>• **Benchmarking** of product against other drug leads and commercially available competitor products.<br>**Justin Devine, Chief Medical Officer, Synexa Life Sciences** | **Cardiovascular Biomarkers – From Pathology To Physiology**<br>• Modern assays allow quantification of cardiovascular biomarkers in low risk healthy individuals<br>• These biomarkers can be used to assess physiological relationships in population based samples<br>• These analyses improve our understanding of cardiovascular risk factors and their progression over time<br>**David Conen, Assistant Professor University Hospital of Basel** | **Revolutionizing The Future Of Point-Of-Care Medicine: An Academic-Industry Partnership In Biosensors**<br>• Accelerating Biomarker and Biosensor Development through Academic-Industry Partnerships<br>• Innovations in Biosensor Technology, Pathogen Detection and Smart Pump Delivery<br>• The Pharmaco-Kinesis - OCTC Collaborative Partnership<br>**John Peterson, Executive Director, Ohio Clinical Trials Collaborative**<br>**Frank Adell, Founder, Chairman, President and Chief Executive Officer, Pharmaco-Kinesis Corporation** |
| **11.00 – 12.40** | **Exhibition Room: The Gallery: Morning Coffee & Refreshments: Poster Presentations: One to One Meetings x 5** | | |
| **12.40 – 13.40** | **Exhibition Room: The Gallery: Lunch: One to One Meetings x 2** | | |

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| **13.40 – 14.10** | **Biomarkers In Duchenne Muscular Dystrophy: Discovery And Clinical Development**<br>• Molecular Biomarkers; pharmacodynamic and disease modifying<br>• Development and use of pharmacodynamic biomarkers to demonstrate mechanism of action and limitations in clinical studies<br>• Application of exploratory imaging biomarkers during drug development and association with clinical endpoints will be discussed<br><br>**Afrodite Lourbakos, Director Bioanalysis and Biomarkers, Prosensa** | **The Variability of Clinical Laboratory Parameters and New Exploratory Biomarkers**<br>• Stability And Variability Of Laboratory Parameters<br>o Meta-analysis Of Phase I In-house Studies Performed Between 2000 -2013<br>o 2 Epidemiological Studies (IMI) Performed In:<br>▪ Healthy Volunteer And Elderly Patients With Under Hypertensive Therapy<br>▪ On Subjects (Using Over-The-Counter Pain-Relievers Or Non-Steroidal Anti-Inflammatory Agents/Analgesics) And Healthy Volunteers<br>o Biomarker (e.g. Osteopontin, NGAL, ..)<br><br>**Michael-Friedrich Boettcher, Clinical PD CV/PC, Bayer Pharma AG** | **Incorporating Biomarkers In Early Phase Trial Design**<br>• The challenges in the early clinical development of a product candidate will be described as well as options for including biomarkers into the decision making process<br>• The use of adaptive clinical trial design options will be discussed and their role in optimising clinical development decision making<br><br>**James Matcham, Head, Early Clinical Biometrics, AstraZeneca** |
| **14.10 – 14.40** | **RGM – From Target Side Effects To A New Indication – Anemia Of Chronic Diseases**<br>• Introduction to the Repulsive Guidance Molecule (RGM) family members<br>• Regulation mechanisms of iron homeostasis<br>• Pathological conditions, mechanisms and biomarker to detect the basis of imbalances in iron homeostasis<br>• Novel approaches to treat hepcidin induced anemia conditions<br><br>**Andreas Popp, Senior Principal Pathologist, Abbvie** | **Increasing Selectivity Of Mass Spectrometric Detection To Improve Confidence In Biomarker Quantitation**<br>• Recent developments in hyphenated Mass Spectrometric techniques allow for the multiplexed quantitation of endogenous and exogenous analytes of interest<br>• The challenge of absolute quantitation of proteins in complex matrices will be presented<br>• Advantages of different Mass Spectrometric techniques to improve selectivity will be showcased in selected case-studies<br><br>**Mark Jairaj, Principal Scientist, UCB** | **Implementing Biomarkers Into Early Clinical Development Strategies And Study Designs**<br>• One size doesn't fit all – different types of biomarkers implies different approaches<br>• When do you need them?<br>• What if you don't have any?<br><br>**Stanko Skrtic, Medical Science Director, CVMD Early Clinical Development, AstraZeneca R&D** |
| **14.40 – 15.10** | **The Scientific, Technical And Cultural Challenges Of Creating A Value For Biomarkers In Clinical Development**<br>• Biomarkers are like drugs faced with a huge attrition<br>• The scientific challenges of PD biomarkers for decision making in early clinical development are huge and besides the time constraint, internal strategy for biomarkers greatly determines the success<br>• Lacking specific guidance on analytical validation requirements for clinical assays requires a clear strategy of biomarker R&D<br>• An integrated biomarker approach is a prerequisite for most successful biomarker projects<br><br>**Peter Groenen, Head of Translational Science, Actelion Pharmaceuticals Ltd.** | **ModCell: In Silico Predictive Drug Response Modelling In The OncoTrack Project**<br>• Biomarker discovery for colon cancer<br>• Systems biology platform for biomarker discovery<br>• In silico prediction of drug response in cancer<br>• The interface between computer models and in vivo models in cancer drug and biomarker research<br><br>**David Henderson, IMI Liaison Manager, Bayer Pharma AG** | **Hedgehog Inhibitor: Development Of A 5 Gene Signature For Patient Selection**<br><br>**Celine Pallaud, Sr. Director Global Correlative Sciences - Hematology Disease area Lead, Novartis** |
| **15.10 – 15.30** | **Exhibition Room: The Gallery**<br>**Afternoon Refreshments: Poster Presentations** | | |

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| **15.30 – 16.00** | **Fit-for-Purpose Inflammatory Biomarker Assay Development And Validation**<br>• Scientific challenges of inflammatory biomarker assay development<br>• Evolution of a biomarker assay from exploratory to clinical validation<br>• Applying bioanalytical method standards to biomarker assay validation<br><br>**Robert Nelson, Head of Bioanalytical Assay Laboratory, NovImmune SA** | **Multifunctional Approaches For Personalized Medicine In Chinese Solid Advanced Cancer Patients (IMMUNOCAN Network)**<br>• Prognostic factors (cytokines) in non-small cell lung cancer patients<br>• Ongoing Research project in gastric, colorectal and breast cancer (circulating factors, peripheral immunes cells profile, intratumoral immune response)<br>• Toward prognostic index for cancer management<br><br>**Romain Micol, Business Development Director (China), Transgene S.A.** | **Predictive Biomarker Discovery In Proof-of-concept Clinical Studies In Inflammatory Diseases: 3 Case Studies**<br>• Asthma, inflammatory bowel disease, and age-related macular degeneration are heterogeneous<br>• We have discovered mechanism-related predictive biomarkers identifying subsets of patients with increased benefit in phase 2 proof-of-concept studies for targeted experimental therapies in each indication<br>• Peripheral blood proteins, tissue biopsy gene expression, and genetic polymorphisms can each be used as predictive diagnostics<br><br>**Joseph Arron, Associate Director, Biomarker Discovery, Genentech, Inc** |
| **16.00 – 16.30** | **Bringing fMRI Imaging Modalities To The Awake, Behaving Rodent: The Translational Potential Of *in vivo* Oxygen Amperometry**<br>• fMRI has revolutionized clinical cognitive neuroscience and offered great promise as a biomarker in the field of neuropsychiatric drug discovery, allowing assessment of novel drug effects on brain regions and circuitry thought to be dysfunctional in depression, schizophrenia and Alzheimer's Disease.<br>• Application of fMRI in animals is limited to anaesthetised or restrained subjects, limiting the ability to assess any but the simplest behavioural endpoints. In response to this, the technique of in vivo oxygen amperometry offers a surrogate of the BOLD fMRI signal in awake, behaving animals. Examples of how in vivo oxygen amperometry can be used to index pharmacological, event-related and functional connectivity measures will be described.<br>• Thus by effective alignment of in vivo oxygen amperometry and fMRI techniques, it is now possible to conduct identical behavioural assessments in rodents and humans with equivalent neuroimaging endpoints. Such studies may help to increase the confidence in translational biomarkers in neuropsychiatric disorder research.<br><br>**Gary Gilmour, Principal Research Scientist, Eli Lilly & Co Ltd** | **New Approaches for the Development of Diagnostic Systems For Prostate Cancer**<br>• Review of potential markers for early diagnosis<br>• Evaluation of glycosylation changes in markers and its significance<br>• Rapid multiplex detection platforms and their advantages<br>• Clinical evaluations of approaches described<br><br>**Richard O'Kennedy, Scientific Director, Biomedical Diagnostics Institute, Dublin City University** | **Efficient Approaches To Validating Biomarker Assays**<br>• Demonstrating low levels of variability is an essential pre-requisite for a biomarker to have clinical value<br>• Variability can arise from many different sources<br>• When evaluating a biomarker assay, it is important to cover the range of conditions that may be observed in practice<br>• Statistically efficient designs can help to sample an expanded range of experimental conditions under a fixed number of evaluations<br><br>**Chris Harbron, Principal Statistical Scientist, Roche** |

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| **16.30 – 17.00** | **Deep Phenotyping Of A Diet-induced Dyslipidemia Model In Non-human Primates For Translation To Human Cardiovascular Diseases**<br>• Biomarkers in Drug Development Process<br>• Non-human primates for translational research<br>• A case study of high fat diet-induced dyslipidemia model in non-human primates<br><br>**Shian-Jiun Shih, Director, Molecular Biomarkers and Diagnostics, Translational Medicine Research Centre, MSD (Merck)** | **Biomarkers For Rheumatic Diseases**<br>• Biomarkers of rheumatic disease; The value of measuring tissue derived biomarkers<br>• Identifying treatment responders at an early time point in rheumatoid rheumatoid arthritis (RA)<br>• Identifying those in most need of treatment with the biomarkers in RA and ankylosing spondylitis (AS)<br>• Detection of early efficacy in clinical trial of rheumatic diseases<br><br>**Anne C Bay-Jensen, Head of Rheumatology, Biomarkers and Research, Nordic Bioscience A/S** | Delegates are welcome to attend the co-located presentations |
| **17.00** | **End of Conference** | | |