The 3rd Annual Biomarkers Congress

www.biomarkers-congress.com

Maximising applications, technologies, tools and diagnostics to accelerate and integrate drug discovery, validation and clinical development

14-15 May 2008, Manchester, UK

The pharmaceutical industry is facing high clinical development costs and declining drug discovery success rates. To stay competitive, they are re-evaluating their drug development process to reduce attrition rates. Biomarkers promises to transform drug discovery, clinical development and molecular diagnostics in the R&D process as effective use of biomarkers at each stage of R&D can improve decision-making, increase clinical trial success rates and productivity.

The 3rd annual Biomarkers World Congress 2008, presented by Oxford Global Conferences, provides a first class educational and networking opportunity for over 200 attendees to gain knowledge and insights into the Biomarkers marketplace.

It explores core topics such as integration of applications and enabling technologies, molecular diagnostics and assay development, imaging in preclinical and clinical development; biomarker discovery & validation in different therapeutic areas such as Oncology, CNS and Cardiovascular, biomarkers in translational discovery and clinical development, and toxicity biomarkers. Do not miss out on the opportunity to learn insights on how you can streamline your R&D process and identify potential cost savings through successful biomarker discovery, validation and clinical development. Over the 2 days, the comprehensive and scientific conference programme will feature key note addresses, case study presentations, panel and roundtable discussions of over 65 senior level industry speakers from leading pharmaceutical, biotechnology, diagnostics, clinical research companies and academic institutions covering the following hot topics:

Plenary Session:

- Integration of technologies & applications to bridge the gap between Discovery, Validation and Development
- Biomarker Discovery and Development in Translational Research

Stream One:

Biomarker Discovery and Validation: Accelerating discovery and validation through Genomics, Protein, Metabolic biomarkers as well as application of biomarker technologies in different therapeutic areas such as Oncology, CNS, Cardiovascular.

Stream Two:

Molecular Diagnostics, Data Integration, Data Analysis, Modelling and Bioinformatics: Exploiting tools and technologies to deliver personalised medicine, and successful integration of these tools within the preclinical and development process

Imaging in Preclinical and Clinical Development & Assay Validation & Development: Profiting from application of imaging technologies and techniques in preclinical and clinical drug development

Stream Three:

Biomarkers in Clinical Development: Aligning biomarker discovery clinical development, and clinical trial activity to improve safety and efficacy

Toxicity Biomarkers: How biomarkers lower attrition rates and adverse events in preclinical and clinical development activities

WHO YOU WILL MEET

Over 200 senior attendees from leading pharmaceutical, biopharmaceutical, biotechnology, diagnostics, academics, government, CRO and solution provider companies will be attending. Meet senior VPs, Directors, and Managers from the following job titles:

Biomarker, Toxicity, Safety, Clinical Pharmacology, Translational Research, Clinical Discovery, Clinical Research, Molecular Informatics, Diagnostics, Pharma Development, Genomics, Proteomics, Biomarker Discovery, R&D, Statistical Biomarker Research, Molecular Biology, CSO, Metabolomics, Toxicoinformatics Pharmacogenomics, Pharmacogenetics, Experimental Medicine, Imaging, Discovery Oncology, Clinical Oncology, Discovery Medicine, Biological Sciences, Pharmaometrics, Pharmacokinetics

THE NEW EVENT FORMAT: NETWORKING AND BUSINESS MEETING OPPORTUNITIES

Meet the speakers and your peers

In addition to the full conference agenda, this event offers you the chance to meet face-to-face with leading industry solution providers and senior-level industry peers through a series of formal and informal networking opportunities.

Meet the speakers and delegates through roundtable discussions

A selection of our key speakers will be hosting focused discussion groups to drill down into their areas of expertise. Lasting for 40 minutes to an hour, each session will start with a brief presentation from the speaker followed by a roundtable debate.

Meet solution providers

Use our online appointment system to contact solution providers prior to the event and to pre-arrange one-to-one meetings with them. Discuss technologies, services and solutions that address your key business concerns.

Draft Conference Programme

Confirmed Speakers:

- **Dr. Iman El-Hariry, Group Director, Oncology MDC, Europe, GlaxoSmithKline R&D**
- **Dr. Ronenn Roubenoff, MD, Senior Director, Immunology Medical Research, Biogen Idec, Inc.**
- **Dr. Stuart Freeman, Director of Worldwide Toxicology, GlaxoSmithKline UK**
- **Dr. Michael Shi, Director and Biomarker Project Leader of Exploratory Oncology Development, Novartis**
- **Dr. Alain van Gool, Director Genomics & Proteomics, Chair Biomarker Platform, N.V. Organon**
- **Dr. Ruth March, Personalized Healthcare Science & Technology Director, Personalized Healthcare Team, AstraZeneca UK**
- **Dr. Koustubh Ranade, Director, Pharmacogenomics & Human Genetics, Pharmaceutical Research Institute, Bristol-Myers Squibb Company**
- **Jean Pierre Valentin, Director, Safety Pharmacology, Safety Assessment, UK, Astra Zeneca Chair of the ILSI-HESI Cardiovascular Subcommittee**
- **Brian Henry, Director of Translational Imaging, N.V. Organon**
- **Dr. Magnus Sjogren, Associate Professor, Psychiatrist, Director Clinical Research CNS, N.V. Organon**
- **Dr. Jochen Theis, Global Head, Biomarkers and Experimental Medicine, Clinical Research and Exploratory Development, F. Hoffmann-La Roche Ltd**
- **Dr. Hugh Salter, Associate Director, Pharmacogenomics, Astra Zeneca**
- **Dr Arijit Chakravarty, Department of Cancer Pharmacology, Millennium Pharmaceuticals Inc**
- **Dr. Paul Whiting, Head of Biomarkers and Translational Biology, Discovery Biology, Pfizer UK**
- **Dr. Jeanne Kehren, Head of Integrated Analysis, Biomarker Development, Novartis Pharma AG**
- **Dr Bernard Leblanc, Head, Regulatory Submissions & External Relations Safety Sciences, Pfizer**
- **Dr George Wensing, Head, Pharmacodynamics, Clinical Pharmacology, Bayer Healthcare**
- **Dr Martin Grigorov, Head of Bioinformatics, Nestle Research Centre**
- **Dr. Nicolas Frey, Head of the Modelling and Simulation Group, F. Hoffmann-La Roche**
- **Dr. Ehud Hauben, Head of Molecular Medicine Unit, Clinical Sciences and Biomarkers, Exploratory Medicine, Merck Serono Research**
- **Dr. Detlef Stiller, Head, In vivo Imaging, Boehringer Ingelheim Germany**
- **Dr. Björn Riefke, Head Laboratory Diagnostics Non-Clinical Drug Safety, Bayer Healthcare**
- **Dr. Antony Gee, Head of PET and Radiotracer Development, GlaxoSmithKline**
- **Dr. Hermann-Josef Huss, Head, Data Acquisition & Management Europe & Overseas, Bayer Healthcare**
- **Dr Dorothee Foernzler, Biomarker - Experimental Medicine Leader, F. Hoffmann-La Roche**
- **Dr. Martin Oleksiewicz, Team Leader, Molecular Toxicology, Novo Nordisk A/S**
- **Dr Stefan Sultana, Translational Medicine Leader for GU Therapeutic Area, Pfizer**
- **Dr. Jean Tessier, Clinical Imaging Scientist, Discovery Medicine, AstraZeneca**
- **Dr. François Iris, Founder, Chairman & CSO, Bio-Modeling Systems**
- **Prof. Dario Neri, Professor, Department of Chemistry and Applied Biosciences ETH Zurich, Chairman of the Board and Founder, Philogen SpA**
- **Dr. William Gallagher, Associate Professor, University College Dublin**
- **Prof. Stig Linder, Professor, Karolinska Institute**
- **Dr Julian Matthews, Head, Data Analysis, Wolfson Molecular Imaging Centre, The University of Manchester**
- **Prof. Heinz Zwierzina, Professor, Innsbruck Medical University (IMU)**

	Day One – 14th May 2008		
8.40	**Plenary Session:** Integration of Technologies & Applications to Bridge the Gap between Discovery, Validation and Development **Plenary Keynote Address** **The Role of Translational Medicine and Biomarkers in Modern Drug Discovery and Development** • Biomarkers as tools for progressing the efficacy of target validation by linking it more closely to clinical outcomes • Translating from discovery to clinical trials and avoiding the same pitfalls in the translational medicine model **Invitation to**: Dr. Claudio Carini, Vice President, Global Head of Biomarkers, Global Development, F. Hoffman-La Roche Ltd.		
9.10	**Solution Provider Plenary Address** **CONFIRMED:** Senior Representative, Rules Based Medicine		
	Conference Room 1	**Conference Room 2**	**Conference Room 3**
	Stream 1: Biomarker Discovery & Validation *This session looks at using biomarkers as tools for improving the effectiveness of target validation by connecting it more closely with clinical outcomes. It also covers various types and applications of current and emerging biomarkers and discusses industry's interest in the uses of these tools in drug discovery and validation. These tools include proteomics, metabolomics, genomic and bioinformatics biomarkers. We will also explore regulatory and business issues that impact the development of the biomarker discovery market sector.*	**Stream 2: Molecular Diagnostics, Modelling, Data Integration and Informatics** *Biomarkers used in the drug development process can be developed into diagnostic tools to identify a patient population for a particular drug. This session evaluates the developments in the molecular diagnostics market and the business models based on molecular diagnostics for pharmacogenomic testing as the driving force behind the shift toward personalized medicine. This session also looks at data integration, informatics and statistics as the foundation of personalised medicine, and contributing to the efficiency and productivity of new drug development*	**Stream 3: Biomarkers in Clinical Drug Development** *Biomarkers help to increase R&D productivity and clinical trial success rates. Biomarker can be used to assess the biological effect, safety and allow better monitoring of clinical efficacy in the early and late stages of the programme. This session looks at successful integration of validated biomarkers into clinical trials, aligning biomarker discovery and development effort within the clinical trial activity to maximise the value of biomarkers. The session also looks at biomarkers in eradicating toxic compounds early in the development process and to improve patient selection in clinical trials*
9.40	**Keynote Address** **Regulatory Updates in Biomarker Drug Development** • Regulatory Updates in Biomarker Drug Development • Acceptance of end points for regulatory approval • Categorising compounds **CONFIRMED:** Bernard Leblanc, Head, Development and Regulatory Strategy Europe, Drug Safety R&D, Pfizer	**Stream Keynote Address** **Biomarker Data Analysis and Integration -Information Based-Medicine as Foundation of Personalized Medicine** **CONFIRMED**: Jeanne Kehren, Head of Integrated Analysis, Biomarker Development, Novartis Pharma AG	**Stream Keynote Address** **Safety and Efficacy Biomarkers – Drivers to Personalised Medicine** • Challenges and opportunities of Personalised Healthcare • Experience with safety biomarkers • Experience with efficacy biomarkers **CONFIRMED**: Dr Ruth March, Personalized Healthcare Science & Technology Director, Personalized Healthcare Team, AstraZeneca
10.05	**Successful Strategies of Biomarker Discovery and Development in Translational Research** • Prioritising early biomarker discovery/candidate development to drive research productivity	**Advancing Discovery & Development with Protein Microarrays - The Opportunities and Limitation of Microarray Data Analysis Techniques** • Examining potential hepatotoxicity markers using microarray data taken from in vitro samples	**Improving Predictability of Safety and Efficacy: Understanding Disease Variability to Increase Success Rates** • High development attrition rates indicating

	• Minimising research cost and enhancing efficiency in your research process • Strategies in minimising your investment risks • Using ROI to make the business case for biomarkers **CONFIRMED:** Paul Whiting, Head of Biomark ers and Translational Biology, Discovery Biology, Pfizer	• Examination of microarray data analysis techniques • The building of predictive models • Opportunity and limitations **CONFIRMED:** Hugh Salter, Associate Director, Pharmacogenomics, Astra Zeneca	inadequate target validation • Improving success rates requires better target validation which requires better understanding of the variability in diseases • Increasing development success rates and optimised drug use • Is it better to identify the patients in whom a new drug works or the patients in whom the new drug should be tested? • What approaches are available for identifying responders and understanding the drivers of response? **CONFIRMED:** Dr Ronenn Roubenoff, Senior Director, Immunology Medical Research, Biogen Idec, Inc.
10.30	**Using Systems Biology to Enable Biomarker Discovery** • The application of systems biology enables discovery of novel biomarkers and the development of biological pathway knowledge for detecting disease and monitoring of response in preclinical and clinical systems • Integrating data from transcriptomics, proteomics, imaging, PK/PD etc within and between projects Use of such data to drive preclinical and clinical research • Optimising bioinformatics systems to enable data analysis and integration **CONFIRMED:** Alain van Gool, Director Genomics & Proteomics, Chair Biomarker Platform**,** N.V. Organon	**Biomarker Data Integration in Clinical Development** • Specialities of Biomarker data in clinical data integration • Challenges • Future trends **CONFIRMED**: Hermann-Josef Huss, Head, Data Acquisition & Management Europe & Overseas, Bayer Healthcare	**Effective Use of Biomarkers in Clinical Decision-Making** • Implementation of a biomarker strategy and a biomarker development plan • Criteria for clinical useful biomarkers • Biomarker validation – the key issue for clinical use • Examples for clinical useful biomarkers • Regulatory aspects for the clinical use of biomarkers **CONFIRMED:** Dr Dorothee Foernzler, Biomarker - Experimental Medicine Leader, F. Hoffmann-La Roche
10.55	**Morning Coffee**		
11.15	**Using Systems Biology to Discover Biomarkers in a Neurodegenerative Disease in Vivo Mechanisms of Creutzfeld-Jakob Pathogenesis and Disease Progression** What happens during the long, symptom-less, latency period and why the sudden, short, and always fatal clinical phase) that then lead to the identification of early clinical biomarkers (symptom-less phase). **CONFIRMED: Dr. François Iris, Founder, Chairman & CSO, Bio-Modeling Systems**	**Applying Metabolomics to Pre-Clinical Studies and its Transition into the Clinic** **CONFIRMED:** Dr. Björn Riefke, Head Laboratory Diagnostics Non-Clinical Drug Safety, Bayer Healthcare	**Using Biomarkers as a Decision Making Tool in the Early Drug Development Process** • How clinical biomarkers can be used to make cost-effective go/no go decisions in early development • PK/PD modelling of biomarker data to characterise dose response • Using biomarkers to bridge between animal model data and clinical outcome **CONFIRMED**: Dr Stefan Sultana, Translational Medicine Leader for GU Therapeutic Area, Pfizer
11.40	**Assay Validation and Development- Filling the Gap between Discovery and Clinically Validated Biomarkers** • Issues arising from Biomarker assay validation	**Statistical Validation of Biomarkers** **Invitation to:** Dr Huub Hoefsloot, Associate Professor, University of Amsterdam	**Overcoming Patient Recruitment Hurdles for Innovative Biologics** **CONFIRMED**: Dr Iman El-Hariry, MD, PhD

	• The latest guidelines on BM assay validation • Technologies enabling the validation approach • Successful strategies in validation arising from assay translation **Invitation to:** Dr. Chris B. Russell, Molecular Sciences, Amgen, Inc.		Group Director, Oncology MDC, Europe GlaxoSmithKline R&D
12.05	**Panel Discussion: Toxicity Biomarker Discovery & Development** • The use of toxicity data in the design of molecules • Screening for toxicity biomarkers for new chemical entities • Endpoints – Approaches in different therapeutic areas **CONFIRMED:** **Moderator:** Stuart Freeman, Director of Worldwide Toxicology, GlaxoSmithKline UK	**Panel Discussion: Integrating Data Analysis in Biomarker Development by using Metabolomics and Proteomics Data** **Moderator: Invitation to:** Prof. Douglas Kell, University of Manchester **Panellists: Invitation to:** • Friedrich Lottspeich, Head of Department for Protein Analytics, Max Planck Institute for Biochemistry Germany **CONFIRMED** • Nicolas Frey, Head of the Modeling and Simulation Group, F. Hoffmann-La Roche • Dr Martin Grigorov, Head of Bioinformatics, Nestle Research Centre	**Panel Discussion** **Managing Risk in Early Drug Development**
12.45	**Solution Provider Presentation**	**Solution Provider Presentation**	**Solution Provider Presentation**
13.10	**Lunch**		
14.10	**Applying and Validating Biomarkers in Exploratory Research** • Tools and best practices in effective drug discovery and early clinical development decision-making • Integration of biomarker in the early stages of discovery • Effective biomarker validation strategies **CONFIRMED**: Dr George Wensing, Head, Pharmacodynamics, Clinical Pharmacology, Bayer Healthcare	**One to Computer-Based Predictive Models in Clinical Drug Development** • Highlighting the current state of the art on biomarkers • Integration of systems biology, modelling and simulation • Illustrating the applications of these emerging tools in increasing the efficiency and productivity of new drug development **CONFIRMED:** Nicolas Frey, Head of the Modeling and Simulation Group, F. Hoffmann-La Roche	**Translating Preclinical Biomarkers into CNS Clinical Drug Development and Clinical Trials** **CONFIRMED:** Dr. Magnus Sjogren, Associate Professor, Psychiatrist, Director Clinical Research CNS, N.V. Organon
14.35	**One to One meetings x 7 and Afternoon Tea**		
16.55	**Solution Provider Presentation**		
17.20	**The Role of Pharmacogenomics in Discovery Translational Medicine: From Target Validation to Patient Selection** **CONFIRMED:** Dr Koustubh Ranade, Director, Pharmacogenomics & Human Genetics, Pharmaceutical Research Institute, Bristol-Myers Squibb Company	**Datamining of Omics for Nutri-Genomics and Applications** • Nutrition – analysis of Omics data • Applications – what we are searching • Drivers behind current data analysis	**Using Serum Efficiacy Biomarker for Clinical Trials and Cancer Therapy** **CONFIRMED:** Stig Linder, Professor, Karolinska Institute

		• Overview of current projects **CONFIRMED:** Dr Martin Grigorov, Head of Bioinformatics, Nestle Research Centre	
17.45	**Presentation & Roundtable Discussion** **Outsourcing Projects & Strategic Alliances in Biomarker Discovery & Development** • Exploiting opportunities in outsourcing in Biomarker drug discovery and development • Business models in Biomarker discovery and development: early adoption by coordinating product development with business strategy & R&D departments Invitation to: Sam O' Connor, Associate Director Strategic Alliances, Pfizer	**Roundtable Discussion: Collaboration between Diagnostics and Pharma companies** • Challenges of implementing collaboration • Regulation • Protecting Intellectual Property	**Roundtable Discussion**
18.30	**Welcome Drinks and Gala Dinner -** RBM RULES•BASED MEDICINE		
	DAY TWO – 15th May 2008		
	Stream 1: Biomarker Discovery & Validation – Therapeutic Areas *This session looks at the role and application of biomarker technologies in the Oncology, CNS, Cardiovascular, Infectious Diseases and other therapeutic areas.*	**Stream 2: Imaging in Preclinical and Clinical Development & Assay Validation & Development** *The session addresses key developments in the application of imaging technologies and techniques in preclinical and clinical drug development. It will also addresses critical requirements and procedures of assay development and validation, quality assurance (e.g. GLP) requirements to ensure the consistency in producing the biomarker assays and enabling the assays to be used for clinical trials and down-stream commercialization.*	**Stream 3: Toxicity Biomarkers** *The ability to predict the safety of a drug in the preclinical stage, prior to human testing, has been one of the major bottlenecks in drug development. The integration of novel and traditional approaches to preclinical toxicity assessment will have a major impact on the ability to predict compound behaviour in humans, reduce clinical trial failure, and cut both risk and cost in drug development. This session looks at the uses of toxicity biomarkers in drug development, clinical trials, its aid in go/no-go decision making, identify off-targets, select lead compound, choose the best animal model, identify interspecies biomarkers of toxicity, stratify patients, adjust schedule/dose.*
9.00	**Stream Keynote Address** **Translational Medicine: An Integrated Approach** The role of Biomarkers in translational research & experimental medicine • Managing projects from the pre-clinical phase to clinical phase • Bridging the gap between discovery and clinical	**Stream Keynote Address** **The Role of Imaging in Pre-Clinical Studies and Development** • How Imaging in pre-clinical studies impacts on clinical development • Application of imaging technologies and techniques in preclinical and clinical drug development	**Opening Address: Chairman** Invitation to: Peter O'Brien, Veterinary Clinical Pathologist, University of Dublin **Keynote Address** **Toxicity Biomarker Discovery & Development** • Predicting the safety of a drug in the preclinical

	processes • The standards for regulatory approval on biomarker endpoints as well as validation **CONFIRMED:** Dr. Jochen Theis, Global Head, Biomarkers & Experimental Medicine, Clinical Research and Exploratory Development, F. Hoffmann-La Roche Ltd		stage, prior to human testing • Toxicology Biomarkers aiding in go/no-go decision making • Identifying off-targets • Selecting lead compound • Choosing the best animal model **Invitation to:** Dr. Eric Fedyk, Associate Director of Immunotoxicology, Millennium
9.25	**Solution Provider Presentation**	**Solution Provider Presentation**	**Solution Provider Presentation**
9.50	**The Role of HTS in Biomarker Drug Targeting and Validation** • Early assessment of hits from HTS using biomarkers must be cost-effective and reliable to facilitate triage of both hits and lead series in therapeutic areas such as cancer, rheumatoid arthritis and other diseases • Increasing the robustness of the candidate biomarkers can be achieved by combining methods used in compound HTS with microarray data analysis Invitation to: Mischa Houtkamp, Head IHC & HTS, Genmab	**Optimising a Translational Approach: How Imaging in Pre-Clinical Impacts on Clinical Development** **CONFIRMED**: Brian Henry, Director of Translational Imaging, N.V. Organon	**Biomarkers of Functional Toxicities: Identification and Assessment of Their Translation to Humans** • Functional toxicities - definitions, models & examples • QT interval duration - a surrogate of drug-induced Torsades de Pointes? • Translation of non-clinical data to humans - review of existing data and on-going initiatives • Case studies demonstrating the utilisation of biomarkers to assess functional toxicities - Successes, threats & opportunities **CONFIRMED:** Jean Pierre Valentin, Director, Safety Pharmacology, Safety Assessment, UK, Astra Zeneca Chair of the ILSI-HESI Cardiovascular Subcommittee
10.15	**Morning Coffee**		
10.35	**One to One Meetings x 7**		
12.55	**Lunch**		
14.00	**Using Biomarkers for Key Decision-Making in Oncology Development** • Using biomarkers for key decision-making in oncology development: Are we there yet? • Traditional drug development for oncology is less applicable to new agents • Early determination of biological activity is increasingly determined from biomarkers rather than clinical endpoints • Biomarker development and validation needs to occur early in the research process so we have biomarkers to support drug development	**Developing and Integrating In vivo Imaging in Preclinical Studies** • Imaging as an important area in translational research for neuroscience drug discovery and development • The uses of imaging in selecting candidate drug molecules during drug discovery • Clinically facilitating optimization of resources through prioritization of decision making • Development of new therapeutics Invitation to: Dr Peter Allegrini, Head Laboratory Magnetic	**Development of Novel Safety Biomarkers for Preclinical Development of Recombinant Blood Clotting Factor XIII** • How to find biomarkers: Screening or intelligent design? • Anchoring safety biomarkers in the mechanism of toxicity • Planning ahead for clinical translation **CONFIRMED:** Martin Oleksiewicz, Team leader, Molecular Toxicology, Novo Nordisk A/S

	CONFIRMED: Michael Shi, Director and Biomarker Project Leader of Exploratory Oncology Development, Novartis	Resonance Imaging, Novartis	
14.25	**Chemical Proteomics for the Identification of Vascular Markers of Disease** The discovery of vascular markers of pathology facilitates the development of antibody-based pharmaceuticals, which concentrate therapeutic agents at vascular sites of disease. Our lab has developed novel proteomics methods, based on a combined use of perfusion procedures with biotinylation reagents and mass spectrometric analysis, for the discovery of novel vascular targets **CONFIRMED:** Prof. Dario Neri, Professor, Department of Chemistry and Applied Biosciences ETH Zurich, Chairman of the Board and Founder, Philogen SpA	**Imaging Applications in CNS Discovery and Clinical Development** • Challenges in developing imaging biomarkers • Avoiding pitfalls in preclinical and clinical development • The role of neuro-imaging in translational research	**The Way to Safety Biomarkers by using Toxicology Biomarkers in Drug Development and Clinical Trials** **Invitation to:** Dr. Eric Blomme, Project Leader, Cell and Molecular Toxicology, Abbott
14.50	**Panel Discussion – The Role of Biomarkers, its Applications and Technologies in Drug Development Research** **Moderator:** **Invitation to:** Panellists: • Dr. Geoff Boxer, Laboratory Manager & UCL Business Fellow, University College London, UK • Peter Farmer, Cancer Biomedicine and Prevention Group, University of Leicester, Leicester, UK • Prof. John Coggins FRSE, Vice Principal for the Faculties of Biomedical & Life Sciences, Clinical Medicine and Veterinary Medicine, University of Glasgow • Jeremy Nicholson, Department of Chemistry, Division of Biomedical Sciences, Imperial College School of Medicine, London, UK **CONFIRMED:** Prof. Heinz Zwierzina, Professor, Innsbruck Medical University (IMU)	**Panel Discussion:** **Using Imaging Techniques to Accelerate Biomarker Drug Discovery & Development** • The role of imaging biomarkers in early development and decision making • Processes of validating biomarkers by using imaging technologies **Invitation to:** Moderator: Prof Steve Williams, Head, Centre for Neuroimaging Sciences, Kings College London Panelists: • Dr Patricia Cole, Senior Director and Head, Imaging Programmes, Eisai • Dr. Norbert Avril, Director, PET Centre, Department of Nuclear Medicine, Queen Mary, University of London • Dr Jimmy Bell, Group Head, In Vivo Imaging Section, Molecular Imaging, MRC Clinical Sciences Centre, Imperial College, London **CONFIRMED:** • Jean Tessier, Clinical Imaging Scientist, Discovery Medicine, AstraZeneca • Dr Julian Matthews, Head, Data Analysis, Wolfson Molecular Imaging Centre, The University of Manchester	**Panel Discussion** **The Roles and Uses of Toxicity Biomarkers in Drug Development, Clinical Trials, Its aid in Go/no-go Decision Making** **Invitation to:** Panellists: • Dr. Eric Blomme, Project Leader, Cell and Molecular Toxicology, Abbott • Joanna Rowland, Senior Toxicologist, GlaxoSmithKline

15.20	**Afternoon Tea**		
15.40	**Biomarker Assay Development and Validation of Novel Breast Cancer Biomarkers – Best Practice, Method Validation and Sample Analysis** **CONFIRMED:** William Gallagher, Associate Professor, University College Dublin	**PET Methodology and Its Application to Drug Development in Oncology & Neuroscience** • Overview of PET technology • Pharmacokinetic measurement • In Vivo competition assays • Pharmacodynamic response • Other applications **CONFIRMED:** Dr Julian Matthews, Head, Data Analysis, Wolfson Molecular Imaging Centre, The University of Manchester	**Toxicogenomics - a Tool for Toxicity Prediction and Supports Classic Toxicity Tests for Rapid and Early Toxicity Screening** Invitation to: Peter O'Brien, Veterinary Clinical Pathologist, University of Dublin
16.05	**Development of an Antimitotic Agent as a Targeted Anticancer Therapeutic** MLN8054 is a novel small molecule Aurora A kinase inhibitor discovered and developed by scientists at Millennium for the treatment of human cancers. This presentation will cover: • Identification of the mechanism of action of MLN8054 in preclinical models • Translation of the mechanism of action into a biomarker strategy for preclinical development, including human dose projections • Leveraging the mechanism of action to build a high-content biomarker panel to measure the molecular sequelae of Aurora A inhibition in patients • Design of a clinical biomarker strategy for Phase I trials based on this panel of mechanistic biomarkers **CONFIRMED:** Dr Arijit Chakravarty, Department of Cancer Pharmacology, Millennium Pharmaceuticals Inc	**PET Biomarkers for Drug Discovery and Development** **CONFIRMED:** Antony Gee, Head of PET and Radiotracer Development, GlaxoSmithKline	**Finding Safety Biomarkers to Predict & Determine Toxicity** • Methodologies in identifying safety biomarkers • Successful implementation in early clinical development • Safety is at the forefront of clinical drug development. • Predictive methods of In vitro and in vivo non-human studies utilized to determine toxicity and optimize drug candidates • Managing risks and benefits. **Invitation to:** Dr. Frank Staedtler, Preclinical Safety-Toxicology/Pathology, Novartis
16.30	**Solution Provider Presentation**	**Solution Provider Presentation**	**Solution Provider Presentation**
16.55	**Identification of Novel Targets and Biomarkers for the Induction of Immune Tolerance** **CONFIRMED:** Dr. Ehud Hauben, Head of Molecular Medicine Unit, Clinical Sciences and Biomarkers, Exploratory Medicine, Merck Serono Research	**Practical Considerations For Oncology Imaging In Clinical Trials** • The use of Imaging modalities in clinical trials and the role of such technologies in clinical trials • Conducting a trial and best practices • The importance of public-private partnerships **Invitation to:** Dr Eric Perlman, M.D., Director, Molecular Imaging and Biomarkers, Medical Affairs, RADPHARM	**Proteomic and Genomic Approaches in Predictive Safety Assessment Techniques** **Invitation to:** Dr Stefan Otto Müller, Senior Toxicologist, Merck Serono
17.20	**Integrating Biomarkers in the Early Phase I & II of the Oncology Drug Development Process** **CONFIRMED:** Prof. Heinz Zwierzina, Professor,	**Targeting and Molecular Imaging in Preclinical Studies** • The use of PET technologies and applications in the preclinical studies	**Roundtable Discussion: Lowering Toxicity Rates: How Biomarkers Address Attrition in Clinical Trials** • In the lab

	Innsbruck Medical University (IMU)	**Invitation to**: Dr Joachim Feldwisch, Project Manager, Research, Affibody AB	• In Phase I • In Phase II • The potential and the reality in phase III and IV
18.00	**End of Day Two and Conference**		