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Exploratory Clinical DEVELOPMENT WORLD

Europe 2010

18 – 21 May 2010, Hotel Sofitel, London Heathrow, United Kingdom

Hear from



Baroness Susan Greenfield
CBE, Director
Royal Institution



Dr Eckhard von Keutz
Senior Vice President, Head
Global Early Development
Bayer Schering Pharma AG



Dr Jackie Hunter
Senior Vice President Science
Environment Development
GlaxoSmithKline



Professor, Dr Michel Goldman
Executive Director,
Innovative Medicines
Initiative



Dr John Davis
Senior Director, Group Head
Research Clinical Pharmacology
Pfizer

More highlights Page 3 >>
Full programme Pages 4 - 9 >>

Breakthrough



Europe's largest early development congress

Meet the experts shaping the early clinical development environment

Hear fresh ideas addressing the bottlenecks in early development and bench mark your strategy against top pharmaceutical, biotech and regulatory agencies: [pages 4 to 7 >>](#)

Double the content, double the speakers, double the networking opportunities

Newly expanded and comprehensive programme [pages 4 to 7 >>](#)

Highly interactive 4 days

An interactive agenda with unique networking opportunities including speed networking, the online contact system, workshops and multiple presentation streams [pages 8 to 9 >>](#)

Pre-conference summit 18 May
Strategies to enable a smooth transition to early phase clinical trials

Post-conference workshop 21 May
Biomarkers and personalised medicine – is the focus changing in exploratory clinical development?

All details [page 8 >>](#)

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Addressing the key challenges in early development

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See page 12

“High quality of speakers all well prepared, covering a broad range of topics”

Clinical Project
Manager,
UCB Pharma S.A.

“Quality of the exploratory clinical development conference over the years – evolved into key meeting in the field”

Chief Executive
Officer,
GeNeuro

“Interactive session, wide range of topics covered”

Country Study
Manager,
GlaxoSmithKline

Streamlining your early clinical development strategy

The 4th annual *Exploratory Clinical Development World Europe* is the premier event for early development and phase I professionals to discuss strategy and solutions to overcome bottlenecks and fast track early development.

Clinical development costs are still rising at an alarming rate, **there is a decreasing success rate for new drug candidate approval** and the duration of development is increasing. Pharmaceutical companies are re-evaluating their strategies to revolutionise R&D in order to **make more effective and informed go/no-go decisions** as early as possible, in order to reduce attrition rates and shorten drug development timescales.

To produce this event, **extensive in-depth research has been carried out with senior representatives of the early clinical development community**; the following real experiences and key issues will be addressed by industry's best over the four-days:

Learn from real life experiences

- What role can exploratory clinical trials play in early clinical development? Are you planning to fail or to win and can they help pipeline attrition?
AstraZeneca's Dr Lewis Kinter will discuss the latest options as per ICH M3 (R2) and industry's experience with eCTAs.
- **The IMI has recently launched its second call for research proposals.** What are the lessons learnt and the way forward to rescue pharma's floundering R&D model? **Professor, Dr Michael Goldman will provide feedback from the IMI.**
- **How is the role of the clinical pharmacologist changing?** **Dr John Davis, Senior Director Clinical Pharmacology, Pfizer** will discuss the clinical pharmacologist's role and how quantitative

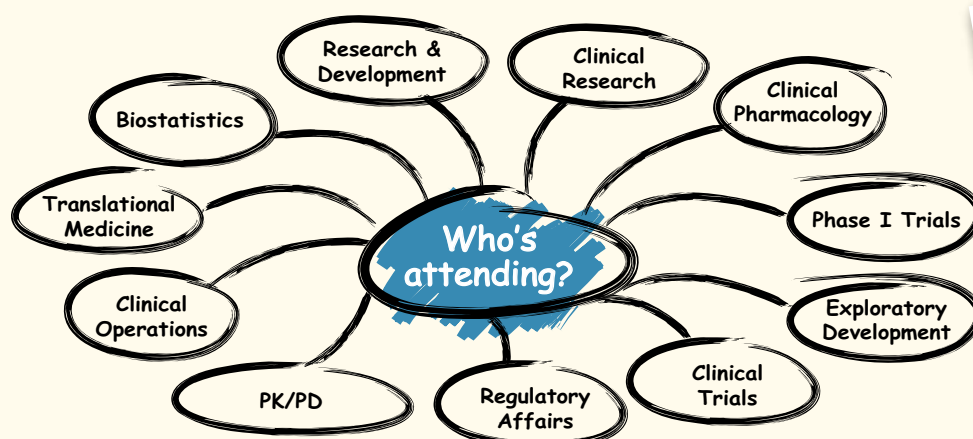
techniques are being used to meet new challenges in drug development and discovery.

Cutting edge content

- Organisational models to support R&D
- Building clinical confidence in basic molecule properties
- Review of policy initiatives driving innovation in early development
- Fast tracking to proof of concept – what are the tools and approaches?
- Can Bayesian probability help predict trial outcomes?
- Minimising risk in the transition between pre-clinical and first in man studies
- Review of the regulatory status for first-in-man trials
- How do you develop biomarkers to the status of true surrogates and what are the possibilities
- Design considerations and preclinical safety testing requirements for safety pharmacology studies
- Mechanism-based PK/PD modelling and simulation
- What are the first lessons from the Innovative Medicines Initiative?
- Biomarker qualification strategies and assessment on return on investment

The 4th annual *Exploratory Clinical Development World Europe* will build on the great success of previous events and brings you a packed agenda, larger speaker panel, more sessions and wider reaching content. You will hear industry leaders from; **Pfizer, GlaxoSmithKline, Novartis, AstraZeneca, Merck & Co., Schering Plough, Takeda, Abbott Laboratories, UCB Pharma, Roche, Daiichi Sankyo, PanGenetics, Ferring, Bayer Schering, MHRA, BfArM, AFSSAPS and FAMHP** who will provide you with discussion, summary and knowledge of the best current practices that will help you drive compounds through phase I.

This event will be attended by Senior Directors and Heads working in the pharmaceutical & biotech industry in the following departments:



ment; what are the strategies and principles?

8 REASONS...

....not to miss the meeting that your peers will be attending

- 1. Fantastic speaker panel** – including top pharmaceutical, biotech and regulatory representatives
- 2. Comprehensive agenda** – we have an unprecedented number of in-depth sessions, keep track on our website as the number is set to grow
- 3. Tailor the packed congress to meet your own information and networking needs** – pre and post conference workshops, focused networking sessions, panel discussions, plenary and streamed sessions, evening seminar, breakfast briefing and gala dinner
- 4. Quality content** – we listened to you and your peers to ensure our programme addresses the issues of key importance
- 5. Regulatory update** – on phase I trials from the MHRA, BfArM, AFSSAPS and FAMHP
- 6. Extensive networking opportunities** – plan who to meet and arrange meetings before the conference with the 'contact system' take part in 'speed networking' to meet more people in less time and continue those conversations into the evening drinks reception and gala dinner
- 7. A proven track record** – the success of *Exploratory Clinical Development World Europe* speaks for itself – read the testimonials throughout this brochure!
- 8. Learn how to overcome the latest issues** shaping exploratory clinical development from leading industry speakers



A-list industry experts

The 4th annual *Exploratory Clinical Development World Europe* brings together a record number of early development leaders.



Dr David Jones, Principal Scientific Officer, **MHRA**

Review of new ICH guidelines and impact on phase I clinical trials



Dr Lewis Kinter, Senior Director Safety Assessment, **AstraZeneca**

Using exploratory clinical trials in pharmaceutical discovery: planning to fail or to win?



Dr Lars Grundemar, Associate Vice President, Head Experimental, **Ferring Pharmaceutical**

The role of experimental medicine in development



Dr Richard Sachse, Clinical Program Director, **UCB Group**

Biomarkers as an efficacy endpoint in clinical development



Dr Jeroen Elassaiss-Schaap, Senior Modelling & Simulation Expert, Translational Pharmacometrics, **Schering-Plough**

Forecasting clinical utility in early development by translational pharmacometrics



Dr Ignacio Rodriguez, Director Clinical Safety, **Roche**

Clinical safety and risk management in early development



Dr Mitchell B Friedman, Director of Toxicology, **Takeda Global R&D**

Predictive value of preclinical animal models



Dr Yili L Pritchett, Research Fellow, Director, Clinical Statistics, **Abbott Laboratories**

Optimal trial design for early phase clinical trials

Your event contact is Bernadette Stansfield

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bstansfield@healthnetworkcommunications.com

MORNING PLENARY

- 8:20 Opening remarks from Willem Jan Drijfhout**, Senior Vice President Early Development Services, **PRA International**
- 8:30 The changing R&D process; the need to move from a linear model to highly interactive drug discovery and development**
- Organisational models to support the interactive R&D concept
 - Introduce novel methodologies
 - Time to assess return on investment for biomarker strategies
- Dr Johan Luthman**, Vice President Neuroscience & Ophthalmology R&D Franchise Integrator, **Merck & Co Inc**
- 9:00 Organisational models for innovative research and development**
- Informed decisions about new early development organisational models
 - What are the ideal organisational models?
 - Should the organisation be around functional capabilities?
- Dr Jackie Hunter**, Senior Vice President, Science Environment Development, **GlaxoSmithKline**
- 9:30**  **and morning coffee**



- 10:30 New approaches in early clinical development**
- Where we stand and where we are heading?
 - Introducing the latest advanced approaches and technologies
 - Cases / applications of combined approaches like IVMS BCS / IVVC for efficient POC, FIM, and early clinical development
- Dr Dongzhou (Jeffery) Liu**, Principal Clinical Investigator, Medical Affairs and Clinical Development, **GlaxoSmithKline**
- 11:00 Using exploratory clinical trials in pharmaceutical discovery**
- Summary of latest eCTA options as per ICH M3 (R2) 2009
 - Regulatory and industry experience with eCTAs
 - Impact of eCTAs on pharmaceutical pipeline attrition
- Dr Lewis Kinter**, Senior Director Safety Assessment, **AstraZeneca**
- 11:30 The fast track way to Proof of Concept – should you still use healthy volunteers if you can get patients?**
- Fast track designs in practice
 - Test tube approach vs. real clinical endpoints
 - Increasing demand, where is the supply?
- Dr Willem Jan Drijfhout**, Senior Vice President Early Development Services, **PRA International**
- 12:00 Lunch**

STREAM 1: APPLICATION OF BIOMARKERS IN EARLY DEVELOPMENT



STREAM 2: SAFETY PHARMACOLOGY BEST PRACTICE

- 12:55 Opening remarks from Dr Jochen Theis**, Principal Physician & Principal Consultant, **InHeCon**
- 13:00 Biomarkers in drug development**
- How biomarkers can be used to determine Proof of Mechanism
 - Translational biomarkers
 - Biomarkers to enable increased efficacy and decreased adverse events
- Dr Gabriel Vargas**, Biomarker Expert, **Roche**
- 13:30 Biomarkers as an efficacy endpoint in clinical development**
- Need for biomarkers to guide dose selection
 - Need for biomarkers to enhance benefit-risk assessment
 - Biomarkers for internal decision making vs regulatory purposes
 - Biomarker qualification
- Dr Richard Sachse**, Clinical Programme Director, **UCB Group**
- 14:00 Validating biomarkers for effective clinical development**
- The desired properties of biomarkers and how these can be assessed
 - Using pre-clinical data from in-vitro systems and samples from undosed volunteers to increase the robustness of biomarkers in the clinic
 - The implications of these inputs for the design of the clinical programme
- Chris Harbron**, Technical Lead Statistician, **AstraZeneca**
- 14:30 Early development standards for global drug development**
- FDA Critical Path Initiatives pertaining to clinical trial design – biomarkers and streamlining clinical trial designs
 - Key variables in early clinical trials on which national reviewing agencies may differ
 - The role of pre-IND consultation and scientific advice
 - Case study
- Dr John C Andrews**, Director of Regulatory Affairs, Americas, **Chiltern International**

- 12:55 Opening remarks from Medifacts**
- 13:00 QT issue in oncology programmes - a hERG trafficking case study**
- Current challenges in preclinical safety
 - HDAC therapeutic hypothesis
 - HDAC and hERG trafficking inhibition - mechanisms
 - Case study
- Dr Bérengère Dumotier**, Translational Science / Preclinical Safety, **Novartis**
- 13:30 Pharmacology studies for early selection of drug candidates**
- Safety pharmacology and drug development
 - Target knowledge for early safety prediction
 - Receptor profiling
 - Cardiovascular safety - in particular addressing the QT issue
 - Future perspectives
- Bronagh Heath**, Manager Safety Pharmacology, **GlaxoSmithKline**
- 14:00 De-risking drug candidates in early clinical development**
- What are the critical cardiac safety data questions (in addition to QT) to address in early clinical development?
 - How can preclinical studies best guide early clinical development?
 - How to address drug-induced changes in heart rate?
- Dr Gary Gintant**, Senior Group Leader, Department Integrative Pharmacology, Chairman, **Abbott QT Working Group**, **Abbott Laboratories**
- 14:30 Regulatory trends in designing and analysing QT studies**
- Identifying requirements and novel methods
 - When is the optimum time to conduct a QT study and what is the optimum design?
 - Regulatory position on QT studies and how to interpret the guideline
- Dr Boaz Mendzelevski**, Chief Medical Officer and Vice President Cardiology, **Medifacts International, Inc.**

Friday 19 May 2010

STREAM 1: CLINICAL TRIAL DESIGN

OR

STREAM 2: MODELLING AND TRANSLATIONAL MEDICINE

15:25 Opening remarks from Kendle

15:30 Understanding the importance of preclinical studies for clinical success



- New approaches to effectively support FIM studies
 - Opportunities for better investigations
 - Opportunities for cross-functional cooperation
- Dr Eckhard von Keutz**, Senior Vice President, Head Global Early Development, **Bayer Schering Pharma AG**

16:00 Clinical safety and risk management in early development

- Clinical safety starts before entry into humans
- Proactive early risk management will optimise benefit / risk profile
- Crucial in early development are: risk prediction, early identification and quick response

Dr Ignacio Rodriguez, Director Clinical Safety, **Roche**

16:30 Optimal trial design for early phase studies

- Early phase studies vs. phase I studies
- Optimal trial designs are tailor made
- Factors influencing trial designs
- Trial designs for high risk compounds

Jolanda van de Logt, Research Physician, Phase IIa, **Kendle Netherlands**

17:00 Patients vs. healthy volunteers in early phase trials

- What is the relevant population to study?
- Possible differences in PK/PD and safety between patients and healthy volunteers
- Patient segmentation; early clinical trials in subpopulations

Nuala Brennan, Vice President, Clinical Trials, **PanGenetics BV**

17:30 Closing remarks

17:35  Networking drinks reception

Join your fellow phase I peers and relax after a busy conference day

15:25 Opening remarks from the chair

15:30 Safety testing of drug metabolites

- When and how to identify, characterise and evaluate metabolites
- Identifying metabolites to better understand the ADME of a drug
- Impact of regulatory guidelines

Dr Gareth Shackleton, Assistant Research Director, Global Metabolism and Pharmacokinetics, **sanofi aventis**

16:00 The dogma of metabolites

- What do we know about pharmacologically active metabolites?
- Reactive toxic metabolites and the impact of dose and duration
- Exploring and addressing safety implications

Denis Smith, Academic Research Fellow, **Pfizer**

16:30 Application of PK/PD modelling and simulation to aid early development

- PK/PD modelling to provide answers on efficacy and safety of new drugs faster
- The role of mechanism-based PK/PD modelling and simulation in translational research

Dr Mendel Jansen, Director Modelling & Simulation, Translational Medicine & Clinical Pharmacology, **Daiichi Sankyo**

17:00 Forecasting clinical utility in early development by translational pharmacometrics

- Quantification of biomarker response
- Model-based integration with animal efficacy to enhance decision making
- How a strong focus yields awareness and organisational changes

Dr Jeroen Elssaïss-Schaap, Senior Modelling & Simulation Expert, Translational Pharmacometrics, **Schering-Plough**

17:30 Closing remarks

17:35  Networking drinks reception

Join your fellow phase I peers and relax after a busy conference day

18:00 - 19:00 EVENING SEMINAR – RE-DEFINING THE PHASE I LANDSCAPE

The conduct of First-in-Human and phase I studies is undergoing a process of change. With industry-wide pressure to reduce phase II/III attrition rates there is increased focus on strategies to extract maximum value from the earliest clinical stages. Such strategies, based on identification of gaps between the target product profile and emerging biomarker, PK and safety data, include building in flexibility to enable real-time responses to emerging clinical data.

To achieve the necessary increase in phase I efficiency, the industry is employing a number of enabling technologies, supporting services, novel designs and study populations, focused on defining exposure, delivery, mechanism and efficacy, all of which is made possible through a more flexible regulatory approval process.

This presentation will showcase examples of increased efficiency in early clinical evaluations, where this has been achieved through:

- Multi-part, fusion or umbrella protocols for maximising data quality, dose escalation, subject use and time
- Flexibility in the CMC (formulation) platform in order to provide optimum exposure and delivery
- Metabolism in phase I through ¹⁴C-labelled and non-labelled assay methodologies
- Determination of absolute bioavailability via ¹⁴C-IV microtracer techniques to facilitate pharmacokinetic modelling, simulation and interpretation



Facilitator:

Dr Lloyd Stevens
Senior Research Fellow
Quotient Clinical

20:00 GALA DINNER



Exploratory Clinical Development World delegates are invited to attend a 3 course dinner, where you get the chance to relax and socialise with your colleagues and peers. Places are limited and are on a first come first served basis, see back page for booking details. You are able to reserve tables of 8 or 10 to invite colleagues or clients to join you.

08:00 - 9:00 BREAKFAST BRIEFING - ARE PAIN MODELS PREDICTIVE OF EFFICACY? MYTH OR REALITY?

The current and major challenge in developing new medication for chronic pain is the characterisation and validation of translational links from animal models to patients and vice versa, pain diseases to pain mechanisms and lastly pain diseases and symptoms. Designing an optimal early clinical development plan for a chronic pain compound is complex and challenging. It should test for various pain mechanisms as well trying to translate these mechanisms in very well characterised patient populations. Each characterisation represents an equivalent of proof of mechanism per se, if successful.

We will review translational animal and human pain models approaches and will present examples of strategies (including their limitations) for developing new pain molecules. Inclusion of healthy volunteers vs. patients will be evaluated and commented, as well as examples of various pain models (from the simplest to the most complex).

Facilitators:



Dr Alvaro Pereira
Clinical Research
Scientist Advisor
Aepodia



Professor Lars Arendt-Nielsen
Founder and Director of the Centre
for Sensory-Motor Interaction
Aalborg University Denmark

MORNING PLENARY

9:00 Coffee break

9:10 Opening remarks from Baroness Susan Greenfield, CBE, Director, Royal Institution

9:15 Fostering creativity in scientific research



Baroness Susan Greenfield, CBE, Director, Royal Institution

Baroness Greenfield is Director of the Royal Institution of Great Britain (the first woman to hold that position) and Professor of Pharmacology at the University of Oxford, where she leads a multi-disciplinary team investigating neurodegenerative disorders. In addition she is Director of the Oxford Centre for the Science of the Mind, exploring the physical basis of consciousness.

Her books include "The Human Brain: A Guided Tour" (1997), "The Private Life of the Brain" (2000), and "Tomorrow's People: How 21st Century Technology Is Changing the Way We Think and Feel" (2003) and "'ID' - The Quest for Identity in the 21st Century" published in May 2008 by Hodder Publishing. She has spun off four companies from her research, made a diverse contribution to print and broadcast media, and led a Government report on "Women In Science".

She has received 29 Honorary Degrees, Honorary Fellowship of the Royal College of Physicians (2000), a non-political Life Peerage (2001) as well as the Ordre National de la Legion d'Honneur (2003). In 2006 she was installed as Chancellor of Heriot-Watt University and voted 'Honorary Australian of the Year'.

In 2007 she was made a Fellow of the Royal Society of Edinburgh. Susan Greenfield is an outstanding keynote speaker on creativity and leadership, human behaviour, and science and the future.

9:45 The role of the clinical pharmacologist in meeting new challenges facing drug discovery and development

- CP role in identifying the best targets
- CP role in identifying the best candidates
- CP role in identifying risks in exploratory development

Dr John Davis, Senior Director, Group Head – Research Clinical Pharmacology, **Pfizer**

10:15 The role of experimental medicine in development



- Experimental medicine / clinical pharmacology can play an integrated role in many parts of the R&D stages
- Experimental medicine's role is about building clinical confidence in basic molecule properties
- In full development the experimental medicine support is to generate clinical data to ensure "regulatory readiness"
- Experimental medicine has also important bridging functions in diverse areas

Dr Lars Grundemar, Associate Vice President, Head Experimental Medicine, **Ferring Pharmaceuticals**

10:45 Morning coffee

11:15 Will public-private partnerships rescue pharma's floundering R&D model? First lessons from the Innovative Medicines Initiative



- Open innovation as a new model for pharmaceutical development
- Personalised medicine: opportunities and challenges for health stakeholders
- New approaches to drug safety: an urgent need
- Is the European Union back at the forefront of biomedical research?

Professor, Dr Michel Goldman, Executive Director, **Innovative Medicines Initiative**

11:45 Translational medicine - bridging bench to bedside

- Translational medicine approaches to de-risking assets early in development
- The value of translational medicine in building confidence around critical areas of differentiation
- Approaches to optimising early development study design to maximise value

Dr Magnus Sjogren, Head Translational Medicine, ECREM, **Schering-Plough Research Institute**

12:15 **PANEL SESSION** New paradigms in early clinical development

- How can new technologies enhance early development?
- What impact will the need for faster proof of concept have on phase I trials design?
- Volunteers and patients – making the right choice

13:00 Lunch

May 20 May 2010

AFTERNOON PLENARY: REGULATORY REVIEW

14:00 Review of new ICH guidelines and impact on phase I clinical trials

- Understanding the ICH's new areas of non-clinical data required for phase I applications
- ICH S9 non-clinical evaluation for anti-cancer pharmaceuticals
- ICH S6 guidance on non-clinical safety evaluation of biotechnology derived pharmaceuticals
- ICH M3 guidance on non-clinical safety studies
- How much easier will the guidelines make it to register phase I clinical trials?

Dr David Jones, Principal Scientific Officer, **MHRA****14:30  PANEL SESSION European regulatory review: approaches to FIH studies**

- Starting dose selection
- Dose escalation
- Maximal dose
- Exploratory clinical trials as first in human study
- Relevant guidance
- Reasons to request supplementary information

Dr Walter Janssens, Senior Preclinical Assessor, Pre-authorisation, Coordinator Early Phase Development,**Federal Agency for Medicines and Health Products****Dr Christian Steffen**, Medical Assessor, **BfArM Germany****Dr Chantal Bélorgey**, Head of Division on Evaluation of Special Status Medical Products and Clinical Trials, **AFSSAPS****15:30 Afternoon coffee****16:00 Predictive value of animal models**

- Issues surrounding animal models in predicting safety and efficacy
- What should one look for to maximise the value of animal models?
- Post hoc use of animal models to address future concerns

Dr Mitchell B Friedman, Director of Toxicology, **Takeda Global R&D****16:30 Clinical translational approaches in early development**

- Strategies to bridge the translational gap in neuropsychiatry
- Development of new therapies for multiple sclerosis and depression
- Imaging and other exploratory studies for target investigation and validation in neuropsychiatry

Dr Paulo Fontoura, Translational Medicine Leader, **Roche****17:00 Value of biomarkers in the oncology therapeutic area in Proof-of-Concept clinical evaluations**

- Bridging basic pharmacology to clinical medicine by characterising the drug candidate to enable decisions affecting further development
- Achieving early decision making in phase I studies

Dr Chetan Lathia, Director, Global Clinical Pharmacology, **Bayer Corp****17:30 Closing remarks from the chair****Exploratory Clinical Development World past attendees include:**

AAI Pharma	CP International LLC	Manipal Acunova	Royal College of Physicians
ACLIRES	CRS Clinical Research Services	MDS Pharma Services	Rules-Based Medicine
Actelion	Mannheim	MHRA	Sanofi-Aventis
ActoGenix	Cytos Biotechnology	Medifacts International	Schering
Adolor	Daiichi Sankyo Development	MedImmune	Schwarz Biosciences
Aepodia	Dainippon Sumitomo Pharma	Mediscis	Scottish Enterprise
Allergan	Debiopharm	Merck Serono	Selcia
Altana Pharma	Eisai	Merck Sharp & Dohme	Serono International
Amgen	Eli Lilly & Co	Nicox	Servier R&D
Arandi Development	ERT	Nitec Pharma	SGS Life Sciences
Ascenion	Evotec	Norgine	Shire Pharmaceuticals
Ascent	F. Hoffman-La Roche	Novartis	Simbec
Astellas Pharma	Federal Agency for Medicinal and Health Products	Novo Nordisk	Singapore Ecobnomic Development Board
Astex Therapeutics	Ferring Pharmaceutical	Nucleus Network	Smith & Nephew
AstraZeneca	Focus Clinical Drug Development	NV Organon	Solvay Pharmaceuticals
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Cambridge Laboratories	InHeCon	Pharmaceutical Development Services Limited	Theagenio Cancer Hospital
Schwarz Biosciences	Insaf Respiratory Research Institute	PRA International	Tibotec (Johnson & Johnson)
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Charles River Laboratories	Kyowa Hakko	Quintiles	Veeda Clinical Research
Chiesi Farmaceutici	Lacer	Renovo	Wyeth
Clinical Research Projects	LCG Bioscience	Richmond Pharmacology	Xceleron
Clinical Trial Center North	Liplasome Pharma	Roche NimbleGen,	Xendo Drug Development
Cognitive Drug Research	Lundbeck	Roche Products	Zealand Pharma
Commission on Human Medicines		Rottapharm spa	
Committee for Safety of Medicine			
Covance			

Pre-conference summit Tuesday 18 May 2010**Strategies to enable a smooth transition to early phase clinical trials****Outline**

The safety of subjects in the transition to first-in-man studies presents particular risks with their safety being paramount. This practical and interactive session will provide a stimulating review on best practices used in safety management and early clinical development speeding products to phase II clinical trials.

Objectives

This session will provide attendees with clinical view points. The speakers will provide structured content with attendees having the opportunity to discuss and add their own contributions.

The meeting will begin at 9am and finish at 5pm. Lunch and refreshments will be provided.

MORNING SESSION**Non-clinical requirements and relevance of pre-clinical animal models**

- Pharmacokinetics, pharmacodynamics and metabolism
- Demonstration of relevance of the animal model
- Toxicology

Transition from pre-clinical to first-in-human trials

- New paradigms in the exploratory phase I environment that are helping the transition into first-in-man
- Considerations when deciding clinical study design and subject choice

Dose selection

- Calculation of the first dose in man
- Route and rate of administration
- Dose escalation scheme

Lunch**AFTERNOON SESSION****Risk management plan**

- Development of the safety review plan and targeted medical event list
- The risk management committee
- Development of the risk management plan

Review of safety requirements for early clinical trials

- How have recent regulatory guidelines affected early development trials?
- What are the challenges in FIH trials?

Adaptive trial design for early phase clinical trials

- Setting the scene: how to do statistics for early phase, adaptive trials
- Myth-busting: why many of the 'reasons not to be adaptive' do not hold water
- Use Bayesian probability to predict trial outcomes
- Consider testing POC for several compounds in the same study

Speaker panel:

Michèle Léonard, Senior Principal Scientist, **UCB Pharma SA**
Frederique Delannois, Senior Principal Scientist, **UCB Pharma SA**
Dr Orest Hurko, Assistant Vice President, Discovery Translational Research, **Pfizer**
Dr Roy Mansfield, Director, Safety and Risk Management, **Pfizer**
Graeme Archer, Director, Neurosciences Discovery Biomarkers, **GlaxoSmithKline**
Dr Yili L Pritchett, Research Fellow, Director, Clinical Statistics, **Abbott Laboratories**

Please visit the website for updates as this speaker panel is set to grow

Post-conference workshop Friday 21 May 2010**Biomarkers and personalised medicine – is the focus changing in exploratory clinical development?****Outline**

Biomarkers have become a central theme in the life science industry. As pharmacodynamic biomarkers they are expected to provide the basis for decision making in early clinical drug development. As disease and surrogate biomarkers they are supposed to reduce the cost and length of development. And as pharmacodynamic biomarkers they are not only expected to differentiate therapy responders from non-responders but also to become commercialisable diagnostic assets by themselves. Are these expectations realistic? And if they are, what does it take to realise the full potential of biomarkers in an effective way?

Objectives

This interactive session will provide attendees with a clinical viewpoint on the effective discovery, characterisation and clinical utilisation of fit for purpose biomarkers. It will address these core questions in a highly interactive way.

The meeting will begin at 9am and finish at 5pm. Lunch and refreshments will be provided.

MORNING SESSION**Subclasses of biomarkers - and their lifecycles**

- PD biomarkers
- Disease and surrogate biomarkers
- Predictive biomarkers and pharmacodiagnostics

Biomarker technologies overview – how can they provide clinical value?

- DNA, RNA, proteins, metabolites
- Imaging
- Others

Lunch**AFTERNOON SESSION****LOGISTICAL AND OPERATIONAL CHALLENGES OF BIOMARKER UTILISATION**

- Clinical studies
- Projects at various development stages
- Effective partnering

Commercial aspects of biomarkers

- Ensuring cost effective biomarker provision
- Translating biomarker approaches into commercial value
- Pharmacodiagnostics

**Your workshop leader:****Dr Jochen Theis**, Principal Consultant, **InHeCon**

Jochen Theis is a recognised expert in the area of biomarkers, pharmacodiagnostics and translational medicine. He has recently founded InHeCon, an integrated healthcare consultancy serving clients in the pharma / biotech, diagnostics and venture capital industries.

Jochen is a physician with clinical training in paediatrics and board certified clinical pharmacology. He held positions of increasing responsibility in all phases of clinical development in Boehringer Ingelheim, GlaxoSmithKline and F. Hoffmann La Roche. His last position in Roche prior to founding his consultancy was Global Head of Biomarkers and Experimental Medicine.

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This is the revolutionary, exciting and non-pressurised way to meet fellow conference attendees and industry peers in one hour long session and it is a part of the formal conference agenda. As you 'speed network', the introductions you make will become the starting point for conversations and networking throughout the conference. This is where long-lasting and profitable business relationships begin. We strongly advise that you bring plenty of business cards and take advantage of this session to meet as many people as possible.



The conference will include a number of panel sessions which are designed to be interactive. Please come with your key issues in mind and take this opportunity to put your questions to the panel.



Exploratory Clinical Development World delegates are invited to attend a 3 course dinner, where you get the chance to relax and socialise with your colleagues and peers. Places are limited and are on a first come first served basis. You are able to reserve tables of 8 or 10 to invite colleagues or clients to join you.



Immediately after closing remarks on day one, please join us for a drink in the exhibition area. Everyone is invited and this will be your chance to start unwinding from the day's conference and network with your fellow attendees. Everyone is invited and the reception is included in the cost of registration.



The pre and post conference workshops will take place in a more interactive environment that will focus directly on specific issues. They will be conducted in a relaxed and engaging way with participants being encouraged to play a central role.



Exploratory clinical Development World is CPD certified, allowing you to claim CPD points following your attendance at this conference. The public and business sectors are increasingly requiring all employees to undertake a continuing personal development programme. The prime role of the CPD accreditation is to certify that the content of training courses, papers delivered at conferences conforms to universally accepted CPD guidelines. It's certified CPD 'kite mark' is a recognised symbol of quality assured training. To find out more visit www.cpduk.co.uk

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The venue

The hotel Sofitel London Heathrow is the only Heathrow Airport hotel with direct access to terminal 5 via a covered walkway and terminals 1, 2, 3 and terminal 4 via courtesy Heathrow Express / Heathrow Connect rail connection. The Sofitel London Heathrow is only 21 minutes from Central London by train. The hotel boasts 605 bedrooms including 27 suites, 45 meeting rooms, two restaurants including Brasserie Roux, two bars as well as an exclusive Tea Salon. The Hotel also offers a state-of-the-art health spa and gym and onsite car park.



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“Excellent quality of speakers, good ratio between participants and exhibitors and great organisation!”

Director, **Aepodia**

“An excellent conference, with the right delegates for our business and excellent organisation”

Director, **Ascent**

“This is a right-sized event attracting the right sort of people – we made many excellent contacts”

Senior Business Development Manager, **Parexel**

“Excellent – as always Health Network Communications has organised another great event! Great networking opportunities with key contacts and great food again!”

Business Development,
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PRA International

PRA's Early Development Services (EDS) provides comprehensive services for phase I-IIa clinical research, bioanalytical research and data support. Through harmonised clinical and laboratory facilities in The Netherlands, the US, and CEE, PRA offers over 220 beds worldwide. Our expertise is primarily with more complex types of studies in which safety and intelligent design are critical factors. PRA EDS conducts more than 100 phase I-IIa studies and over 200 bioanalytical studies yearly for studies recruiting healthy volunteers or special patient populations.



Real people. Real results.

Kendle is a leading global clinical research organisation providing the full range of early- to late-stage clinical development services for the world's biopharmaceutical industry. Kendle's early stage expertise includes comprehensive global services, from first-in-human through phase IIa / proof-of-concept studies, with world-leading psychopharmacology expertise, in addition to bioequivalence and pharmacokinetic studies for established compounds. We have the agility to address your needs rapidly and can help you develop an optimal early stage plan. From initial protocol design through to regulatory submission, we can provide support at agency meetings and help you present and explain complex data.



Medifacts INTERNATIONAL

Medifacts International offers best-in-class science, service, and technology on a global basis in support of high-quality cardiac safety and efficacy data collection. With over 24 years of experience and offices in the US, Europe, and Asia, Medifacts is a global leader in cardiac safety monitoring services. Medifacts' comprehensive services include: ECG, Holter, Ambulatory Blood Pressure Monitoring (ABPM), Home and Office Blood Pressure Monitoring, Pulse Wave Analysis, and Diagnostic Telemonitoring. With unrivalled scientific leadership, Medifacts provides a full range of consultancy and analysis services throughout the development lifecycle and beyond.



CHILTERN

Established in 1982, Chiltern is a leading global clinical Contract Research Organisation with extensive experience conducting and staffing international phase I to phase IV clinical trials across a broad range of therapeutic areas for a wide variety of clients. Chiltern has conducted trials in more than 40 countries and employs 1,400 people in 29 countries. Chiltern provides early phase, global clinical development, late phase, biometrics, medical and regulatory affairs and resourcing solutions services.

QUOTIENT CLINICAL



Quotient Clinical, a strategic business unit of Quotient Bioresearch, specialises in early clinical drug development. With over 20 years experience, we offer a uniquely streamlined process to reduce the time from First-in-Human studies through to POC. We are at the forefront of innovative drug development using integrated study designs that provide invaluable information on multiple aspects of drug development in a single study, reducing the need for additional trials and substantially reducing time and cost.



Aepodia offers scientific and operational expertise in: early clinical plan development, execution of clinical phase to Proof of Concept (POC) studies, clinical pharmacology studies to support registration. A spin-out of a top 10 US pharma company, Aepodia offers you its experience in different therapeutic areas to develop and execute early phase clinical plan.

Sponsors & exhibitors



Why join us at *Exploratory Clinical Development World Europe 2010*?

With continually excellent feedback over 3 years, *Exploratory Clinical Development World Europe* has fast evolved as the premier early development conference in Europe and is now firmly established as the key meeting in the field.

Exploratory Clinical Development World Europe is where people come to look for advice, guidance and support to the key challenges they face. The event is well attended by senior exploratory and phase I professionals and you will have the opportunity to meet many meaningful prospects and new contacts. This conference will be highly interactive with panel discussions, Q&A sessions, speed networking, online contact system, meeting areas and an exhibition trail!

As a CRO, laboratory or technology provider, this conference represents an exceptional opportunity to develop new business relationships.

Questions to determine your involvement

- Do you offer services and solutions that support the challenges of early clinical development?
- Could you benefit from introductions to and time with early phase decision makers?
- Are you actively looking for new clients and leads to work with?

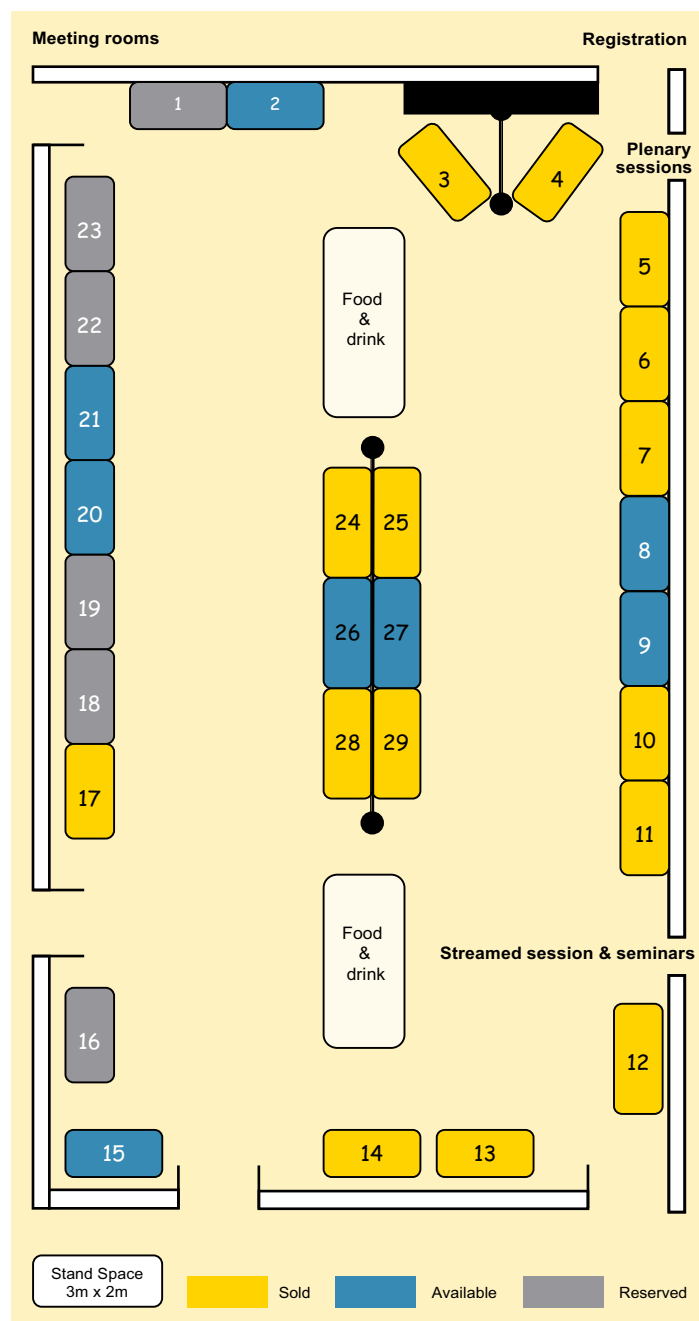
If your answer is yes to these questions you should be participating in this event, and by doing so you will increase your chances of being selected as a partner

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To sponsor or exhibit contact

Claire Conway on +44 (0)20 7608 7058
or email

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Key facts from *Exploratory Clinical Development World Europe*

100%
of attendees ranked
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or excellent

70%
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100%
increase in
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Register now

Package	Before 19 Feb 2010	Before 2 Apr 2010	Before 23 Apr 2010	After 23 Apr 2010	How many	Calculate your ticket
Gold pass – all 4 days 18 May – 21 May 2010	£2,385 + VAT £417.38 = £2,802.38	£2,650 + VAT £463.75 = £3,113.75	£2,785 + VAT £487.38 = £3,272.38	£2,915 + VAT £510.13 = £3,425.13	<input type="checkbox"/>	
2 main days plus pre conference workshop 18 May – 20 May 2010	£1,800 + VAT £315 = £2,115	£2,000 + £350 VAT £2,350	£2,100 + VAT £367.50 = £2,467.50	£2,200 + VAT £385 = £2,585	<input type="checkbox"/>	
2 main days plus post conference workshop 19 May – 21 May 2010	£1,800 + VAT £315 = £2,115	£2,000 + £350 VAT £2,350	£2,100 + VAT £367.50 = £2,467.50	£2,200 + VAT £385 = £2,585	<input type="checkbox"/>	
2 day conference 19 May – 20 May 2010	£1,215 + VAT £212.63 = £1,427.63	£1,350 + VAT £236.25 = £1,586.25	£1,420 + VAT £248.50 = £1,668.50	£1,485 + VAT £259.88 = £1,744.88	<input type="checkbox"/>	
Networking dinner (conference attendees only) 19 May 2010	£75 + VAT £13.13 = £88.13	£75 + VAT £13.13 = £88.13	£75 + VAT £13.13 = £88.13	£75 + VAT £13.13 = £88.13	<input type="checkbox"/>	

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How do you want to pay?

Credit / Debit card	<input type="checkbox"/>	£ 0
Cheque / Bank transfer	<input type="checkbox"/>	£ 100

Your voucher code

(you'll need to quote this for telephone and online bookings)

All tickets include refreshments, lunch and full conference documentation. The fee does not include hotel accommodation or travel.

Your details

Delegate name.....

Job title Organisation

Address

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