3rd annual event

Exploratory Clinical DEVELOPMENT WORLD Europe 09

12 - 15 May 2009, London, UK
Conference 13 & 14 May - Olympia Conference Centre
Workshops 12 & 15 May - Hilton Olympia Hotel

Limited special offer save £540.50 Gold Pass until 20 February 2009

Prices, packages and booking form on back page

Hear from

Dr Damian O'Connell
Executive Director, Clinical R&D, **Pfizer Global Research and Development**

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

Professor Robert Lechler
Chairman, Expert Advisory Group on Novel Biological Agents, **Committee for Safety of Medicine**

Dr Joel Scherer
Managing Director of Chorus, **Eli Lilly**

Dr Valerie Kitchens
Vice President, Clinical Pharmacology & Discovery Medicine, **GlaxoSmithKline**

More highlights Page 3 >>
Full programme Pages 4 - 6 >>

Europe's largest early development congress

Management and R&D strategies for early clinical development page 4

Over 35 sessions addressing the key issues in early development; including case studies on biomarkers, rational design of exploratory studies, safety pharmacology, accelerated proof of concept pages 4 and 5

Meet the experts shaping the regulatory framework for phase I trials – including MHRA, BfArM and AFMPS page 5

2 workshops:

Pre-conference workshop 12 May
Management strategies of outsourced early phase trials

Post-conference workshop 15 May
Regulatory guidelines on strategies to identify and mitigate risk in first in man clinical trials

All details page 6 >>

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See page 8

"Topics of interest, well covered with practical examples"
Director Early Drug Development, **Prosensa Therapeutics**

"Excellent speakers with focused coverage of cutting edge topics in exploratory clinical development"
Senior Director, Global Head Imaging Biomarkers, **Eisai**

"Excellent helicopter view of exploratory clinical development with appropriate landings for a closer view of topical areas"
Medical Director, **Parexel**

Addressing the key challenges in early clinical development

The 3rd annual *Exploratory Clinical Development World Europe* follows the huge success of our European events in 2007 & 2008 to which a record number of early clinical development scientists and decision makers attended to explore the challenges of phase I trials.

The cost of discovery and development of new candidates continues to increase at an alarming rate. The total cost of bringing a drug candidate to market is **rapidly approaching $900 million,** an average **success rate of 11%** and takes between **10 to 15 years.**

Extensive research with the senior members in clinical development clearly identified the core issues that need airtime and discussion in May – here are some of the questions that our exceptional speaker faculty will be addressing

Interact with industry experts in the Q&A sessions

What will you learn?

- How should we be developing drugs in the 21st century? What is the way forward to accelerate R&D and the appropriate implementation of experimental medicine?
- What are the **management strategies** to revolutionise R&D and what role should the clinical pharmacologist play?
- How do we eliminate the uncertainty in early clinical development and what are the tools used in translational medicine to assess **proof of concept and proof of mechanism?**
- What is the optimal trial design for early phase studies? What potential can **adaptive clinical trials** offer in early development?
- What are the operational and ethical issues in **using patients in phase I** clinical trials?
- How to improve your understanding of the design and analysis of thorough **QT trials**
- What are the challenges with **outsourcing early phase clinical trials?** Strategy implementation and experience with service providers
- What is the future in **personalised healthcare?** How are companies using pharmacogenomics and disease genetics in early development?
- How will the **Innovative Medicines Initiative Critical Path Initiative** aid drug development?
- **Regulatory review** of first in man studies and review of the updated ICH-M3 (R2) guidelines
- How can **biomarker development and validation** be used in early development decision making? What can biomarker imaging add to drug development?
- When do you characterise and evaluate **drug metabolites** and how can these be used to better understand the ADME of your drug? Review of the regulatory guidelines safety testing of metabolites
- What is the role of and use of **model based drug development** and can strategic modelling and simulation reduce the uncertainty in drug response?

Senior Directors and Heads working in the pharmaceutical & biotech industry

8 REASONS

8 reasons not to miss the meeting that your peers will be attending

Fantastic speaker panel including top pharmaceutical, biotech and regulatory representatives

Packed agenda – over 35 sessions confirmed so far

Quality of content – we listen to you and your peers to ensure our programme addresses the topics you want to hear

A choice of streams, workshops and seminars – tailor the congress to meet your information and networking needs

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

A proven track record – the success of the 3rd annual *Exploratory Clinical Development World* speaks for itself – read the testimonials elsewhere in this brochure!

Case studies hear industry experiences from top pharma and biotechs on early clinical development

Additional features – attend the evening seminar on day 1 and breakfast briefing on day 2

The Health Network difference

Health Network events create exciting places to...

- interact and grow knowledge
- meet and make contacts
- become inspired and reenergised

use your brain

A-list industry experts

***Exploratory Clinical Development World Europe* brings together a record number of early development experts.**

Open innovation in pharma / biotech: a way forward to accelerate R&D and create new opportunities

Dr Thomas Senderovitz, VP Global Exploratory Development, **UCB, R&D**

Approach to FIM studies a regulatory review

Dr Walter Janssens, Senior Assessor Preclinical, Research and Development, **Federal Agency for Medical & Health Products Belgium**

Personalised health care in early development

Dr. Gerd Maass, President & Chief Executive Officer, **Roche NimbleGen, Inc**

Life along the Critical Path (Initiative): how the PSTC is changing drug development?

Dr William Mattes, Director of Toxicology, **The Critical Path Institute**

The development of the Innovative Medicines Initiative

Dr Jackie Hunter, Senior VP & Head of Neurology and Gastrointestinal CEDD, **GlaxoSmithKline**

Potential of using adaptive clinical trial design in early development

Dr Mike Hale, Head of Global Medical Sciences Biostatistics group, **Amgen**

Value of preclinical models and data when transitioning to man

Prof Johan Luthman, Head of Exploratory Medicine Neurology, PoC Management & Liaison, **MerckSerono**

"Diverse, relevant, interesting topics"

Director Business Development, **AAI Pharma Inc.**

"Excellent knowledgeable experienced speakers"

Assistant Director, Biostatistics Development Partners, **GlaxoSmithKline**

Your event contact is Karen Williams
+44 (0) 207 608 7056
kwilliams@healthnetworkcommunications.com

Europe's largest phase I congress

Day One Wednesday 13 May 2009

8.00 **Registration & coffee**

8:30 Keynote: **Commission of Human Medicines: review of FIM studies**
Professor Robert Lechler, Chairman, Expert Advisory Group on Novel Biological Agents, **Committee for Safety of Medicine**

8:55 Keynote: **Experimental medicine in the pharmaceutical industry**
- Appropriate implementation of experimental medicine
- Getting the right people together early

Dr Damian O'Connell, Executive Director, Clinical R&D, **Pfizer Global Research and Development**

9:20 **Open innovation in pharma/biotech: a way forward to accelerate R&D and create new opportunities?**
- Open Innovation – pros and cons
- The need to open up – biomarkers, diagnostics, monitoring
- What can we learn from other industries?

Dr Thomas Senderovitz, VP Global Exploratory Development, **UCB, R&D**

9:45 Keynote: **innovating management strategies to revolutionise early phase R&D**
- An autonomous early phase drug development group
- Transition of assets between Lilly and Chorus
- Keys to the success

Dr Joel Scherer, Managing Director of Chorus, **Eli Lilly**

10:10 **The power of model-based proof-of-concept (PoC) trials**
- What information do we need in a PoC trial?
- The "population" approach; pro's and con's
- Model-based approaches to improve PoC trials

Professor Anders Grahnen, Chief Scientific Officer, **Quintiles**

10:40 SPEED NETWORKING **and morning tea**

STREAM 1

APPLICATION OF BIOMARKERS IN EARLY DEVELOPMENT

11:30 **Opening remarks from the chair**
Dr Steve Ramael, Medical Director, **SGS**

11:40 **Application of POM biomarkers in selection of FIM dose**
Dr Mohammad Tabrizi, Director, Translational Sciences, Global PK-PD & Bioanalysis, **MedImmune**

12:10 **Cerebral spinal fluid sampling for phase I and experimental research: a review of experience**
Dr Steven Ramael, Medical Director, **SGS**

12:40 **Biomarkers in early development – value and pitfalls**
Dr Michael-Friedrich Boettcher, Global Clinical Pharmacological Project Leader, **Bayer Healthcare**

13:10 **Lunch**

14:10 **Nerve excitability; a pain biomarker in early drug development**
Dr Liz Allen, Director of Scientific Affairs, **Quintiles GDRU**

14:40 **Imaging biomarkers: potential uses in early clinical development**
Patricia Cole, Senior Director, Global Head, Imaging Biomarkers, **Eisai Medical Research, Inc.**

15:10 **Regulatory perspective: biomarkers and pharmacogenomics**
Prof Krishna Prasad, Clinical Medical Assessor, **MHRA**

15:40 **Afternoon tea**

QT ASSESSMENT IN EARLY DEVELOPMENT

16:10 **Opening remarks from the chair: Dr Jeffrey Litwin,** Executive Vice President and Chief Medical Officer, **ERT**

16:15 **Predictive pre-clinical cardiac safety data**
Dr Gilles Hanton, Senior Director Preclinical Toxicology, **Tibotec**

16:45 **The latest trends in cardiac safety**
Dr Jeffrey Litwin, Executive Vice President and Chief Medical Officer, **ERT**

17:15 **Cardiac safety strategies for FIM studies for biopharmaceuticals**
Dr Alexander Breidenbach, Global Coordinator Safety Pharmacology, **F. Hoffman-La Roche**

17:40 **Drinks reception**

OR

STREAM 2

RATIONAL DESIGN OF EXPLORATORY STUDIES

11:30 **Opening remarks from the chair**

11:40 **The role of the clinical pharmacologist in alleviating challenges in drug development**
Dr Don Nichols, Executive Director, Head of Clinical Pharmacology for Pain Therapeutic Area, **Pfizer Global Research & Development**

12:10 **Optimal trial design for early phase studies**
Dr Heinz Schmidli, Senior Expert Statistician, Pharma Clinical Development, **Novartis Pharma**

12:40 **Potential of using adaptive clinical trial design in early development**
Dr Mike Hale, Head of Global Medical Sciences Biostatistics group, **Amgen**

13:10 **Lunch**

14:10 **Patient vs. healthy volunteers in early phase trials**
Dr Kamilla Buchberg Petersen, Specialist, Clinical Pharmacology & Pharmacokinetics, **Lundbeck**

14:40 **Evolving trends in phase I - the drive to include patients**
Dr Anthony Priestly, Medical Director, **LCG Bioscience**

15:10 **Safety testing of drug metabolites**
Dr Richard J Weaver, Head of Metabolism & Pharmacokinetics, **Servier R&D**

15:40 **Afternoon tea**

16:10 **Pharmacogenomics and disease genetics application in exploratory development**
Dr Ansar Jawaid, Global Group Leader, R&D genetics and Personalised medicine, **AstraZeneca**

16:40 Keynote: **translational medicine and the rational design of exploratory studies**
Dr Valerie Kitchens, VP, Clinical Pharmacology & Discovery Medicine, **GlaxoSmithKline**

17:10 **Translational medicine and the rational design of exploratory studies**
Dr Håkan Wennbo, Global Project Director, Cardiovascular & Gastrointestinal, **AstraZeneca**

17:40 **Drinks reception**

18:15 Evening Seminar: **Rapid development and clinical validation of oral formulations to support early clinical development**
Facilitated by Pharmaceutical Profiles See page 6 for more information >>

Day Two Thursday 14 May 2009

08:00 **Breakfast Briefing: PET as a decision making tool in early clinical development of CNS molecules**
Facilitated by Aepodia and UCB
See page 6 for more information >>

9:15 **Opening remarks from the chair**

9:20 **The development of the Innovative Medicines Initiative impact of early drug development**
- What is the IMI and how will it aid drug development?
- Implementation and partnerships
- What does it offer big pharma?

Dr Jackie Hunter, Senior VP & Head of Neurology and Gastrointestinal CEDD, **GlaxoSmithKline**

9:50 **Life along the Critical Path (Initiative): how the PSTC is changing exploratory drug development**
- Tools make the difference: safety assessment past and future
- Biomarker discovery vs. qualification
- Power of scale: collaboration for robust biomarker data sets
- Bridging the preclinical and clinical divide

Dr William Mattes, Director of Toxicology, **The Critical Path Institute**

REGULATORY REVIEW

10:20 **Keynote: Review of ICH-M3 (R2)**
- Understanding the ICH's new areas of non-clinical data required for phase I applications
- How much easier will this guideline make it to register phase I clinical trials?
- How is phase I affected by new regulations around inclusion of women of child bearing potential clinical trials?

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

10:50 **Morning tea**

11:20 **Panel discussion: approach to FIM studies a regulatory review**
- Regulatory requirements for FIM studies
- New challenges: multi-centre studies, phase 0 studies, oncology studies, biotechnology products

Dr Walter Janssens, Senior Assessor Preclinical, Department Research & Development, **Federal Agency for Medicinal and Health Products**
Dr Christian Steffen, Medical Assessor, **BfArM**
Dr David Jones, Principal Scientific Officer, **MHRA**

12:00 **Review of safety requirement for exploratory clinical trials**
- Why do we need Exploratory Clinical Trial Applications (eCTAs)?
- What are eCTAs?
- What about the preclinical requirements for eCTAs?
- Safety of early clinical drug development in general and eCTAs in particular

Prof Dr Jan de Hoon, Head of Department, Centre for Clinical Pharmacology, **University of Leuven**

EARLY DEVELOPMENT CASE STUDIES

12:30 **Personalised health care in early development**
- Focus on selected biological disease areas
- Provide a broad diagnostic tool box
- Start at research stage of drug development
- Examples from Roche Oncology

Dr. Gerd Maass, President & Chief Executive Officer, **Roche NimbleGen, Inc**

13:00 **Lunch**

14:00 **Outsourcing in phase I; a sponsor perspective**
- Factors to consider in selecting a phase I unit
- Implementation and experience with service providers
- Benefits and lessons learnt

Rachael Grose-Hodge, Senior Clinical Scientist, **Shire**

14:30 **Value of preclinical models and data when transitioning to man**
- Implementation of organisational solutions with integrated R&D processes
- The need for high translational value of data to support major transitions
- Comprehensive evaluation of pharmacodynamic actions
- Drug-disease modelling

Prof Johan Luthman, Head Exploratory Medicine Neurology, PoC Management & Liaison, **MerckSerono International S.A.**

15:00 **Model based early drug development of therapeutic monoclonal antibodies**
- Quantitative pharmacology for drug development
- Mechanistic PK/PD models in immunology
- Case study

Dr Chee Ng, Model-Based Drug Development (MBDD), Oncology Programs, **Bristol Myers Squibb & Co.**

15:30 **Pharmacokinetic/pharmacodynamic modelling and simulation in early development**
- The role of mechanism-based PK/PD modelling and simulation
- Utilisation of preclinical pharmacology, biomarker, efficacy, and safety models
- Case studies from various therapeutic areas

Dr Piet van der Graaf, Research Fellow, Preclinical Modelling & Simulation, **Pfizer Global Research & Development**

16:00 **Afternoon tea**

16:30 **From fragments to clinical candidates**
- Fragment discovery and optimisation
- In-vitro and in-vivo profile
- PoM of action of pre-clinical biology
- Biomarker support and early clinical data

Dr John Lyons, VP translational research, **Astex Therapeutics**

17:00 **Case study address on the development of aCD40**
- Background to CD40 pathway & potential clinical utility
- Prior clinical experience with chimaeric Mab
- Regulatory strategy and current clinical experience with PG102

Dr Kevin Johnson, Chief Executive Officer, **Pangenetics**

17:30 **Closing remarks from the chair**

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Pre & Post Conference Workshops

Hilton London Olympia, London, UK

Tuesday 12 May 2009

Management strategies of outsourced early phase trials

Objectives
This practical and interactive session will provide a stimulating update on project management of outsourced early phase clinical trials.

9:00 **Phase I outsourcing challenges**

10:15 **Morning tea**

10:30 **Strategic project management**

12:00 **Lunch**

13:00 **Effective project management for successful phase I studies**

14:15 **Afternoon tea**

14:30 **Enterprise portfolio programme project management and the impact on clinical trials**

Your workshop leader:

Bodiam Consulting Limited

Keith Rodgers, CEO, **Bodiam Consulting Limited**

An accomplished director, Consultant, Senior Executive and Project Management Professional with an MBA and a background gained primarily within the pharmaceutical, biotechnology, diagnostic, device and packaging sectors over 25 years, 20 of these working for Wellcome and GlaxoWellcome.

Friday 15 May 2009

The new EMEA guideline on strategies to identify and mitigate risks for FIM trials with investigational medicinal products

9:00 **Introduction to the new guideline from the CHMP**

10:15 **Morning tea**

10:30 **Quality aspects and characterisation**

12:00 **Lunch**

13:00 **Non-clinical requirements**

14:15 **Afternoon tea**

14:30 **Clinical requirements**

Your workshop leader:

Dr Stefano Persiani, Director, **Department of Translational Sciences and Pharmacokinetics Rottapharm-Madaus, Italy**

Dr Persiani's experience within pharmaceutical companies and CROs' ranges from drug discovery and lead optimisation to early pre-clinical and full clinical development in different therapeutic areas. Dr Persiani acts as an independent expert evaluator for the European Commission Seventh Framework Program and Innovative Medicine Initiative.

EVENING SEMINAR

Wednesday 13 May 2009

18:15 **Rapid development and clinical validation of oral formulations to support early clinical development**

Using an integrated formulation development, manufacture and clinical testing platform, timelines can be cut in half and costs significantly reduced. This seminar explores:

- Use of an integrated formulation development, manufacturing and clinical testing platform to deliver rapid clinical screening and validation of formulation prototypes
- Use of clinical diagnostic tools to investigate the causes of poor bioavailability and how these data can guide formulation development
- Acceleration of timelines and reduction of cost to optimise oral dosage forms

Facilitated by Pharmaceutical profiles

BREAKFAST BRIEFING

Thursday 14 May 2009

8:00 **PET as a decision making tool in early clinical development of CNS molecules**

This interactive presentation will review strategic, scientific and operational aspects for developing and integrating Positron Emission Tomography (PET) during first-in-man studies, as a biomarker to assess receptor occupancy, in order to achieve "go/no-go" decisions and dose regimen recommendations for further studies. Some practical examples of early clinical development plans including PET strategy associated with additional pharmacodynamic biomarkers will be illustrated with selected central nervous system (CNS) molecules.

Dr Tim Buchanan, Senior Experimental Medicine Scientist, Imaging, **UCB Pharma**
Dr Thomas Senderovitz, VP Global Exploratory Development, **UCB Pharma**
Dr Denis Gossen, Clinical Research Scientist Advisor, Director, **Aepodia**

Facilitated by aepodia

Becoming a sponsor or exhibitor

Record numbers of senior personnel from early phase development have attended this event over the past two years and it is commonly regarded as the premier early phase event in Europe.

Exploratory Clinical Development World Europe is where people come to look for advice, guidance and support to the key challenges they face. As a CRO or technology provider with solutions to offer, 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?
- Is it cost & time effective to meet multiple prospects & clients in one setting?

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"This event delivers great networking opportunities, excellent speakers and insightful presentations"
Marketing Manager, **LCG Bioscience**

"The 2008 meeting was excellent – good speakers and a really good opportunity to talk to fellow delegates with similar interests"
VP of Pharmaceutical Sciences, **Pharmaceutical Profiles**

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Quintiles have 25 years experience in the design, conduct and analysis of complex Phase I/IIa studies. Our key scientists are some of worlds the leading authorities in Early Phase research, so when we claim that our knowledge is as deep as it is broad, and can offer you the sharpest insights into your drugs development; we mean every word of it.

ERT provides unparalleled service and reliable solutions that ease the challenges of clinical research. Our work sets the industry standard in cardiac safety. Our global clients rely upon our expertise–including our EDC, ePRO, and Consulting Solutions. Our team provides proven scientific and regulatory leadership to biopharmaceutical, CROs and medical device companies around the world.

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Exploratory Clinical DEVELOPMENT WORLD Europe 09

Breakthrough

12 - 15 May 2009, London, UK
Conference 13 & 14 May - Olympia Conference Centre
Workshops 12 & 15 May - Hilton Olympia Hotel

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2 main days plus pre conference workshop 12 May – 14 May 2009	£1615 + VAT £242.25 = £1857.25	£1795 + VAT £269.25 = £2064.25	£1885 + VAT £282.75 = £2167.75	£1975 + VAT £296.25 = £227125	☐	
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2 day conference 13 May – 14 May 2009	£1145 + VAT £171.75 = £1316.75	£1270 + VAT £190.50 = £1460.50	£1335 + VAT £200.25 = £1535.25	£1395 + VAT £209.25 = £1604.25	☐	

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