3rd annual event

Exploratory Clinical DEVELOPMENT WORLD

Americas 2010

19 – 22 October 2010, Le Méridien Cambridge-MIT, United States

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Hear from

Zhaosheng Lin
Head of Biomarkers
Pfizer

Nadine Cohen
Head of Pharmacogenomics
Johnson & Johnson

Mitchell B. Friedman
Director of Toxicology
Takeda Global R&D

Malcolm Mitchell
Medical Director, Clinical Pharmacology
Eli Lilly

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

Achieving seamless first-in-man studies

- **Hear from the experts shaping early development**
  Engage with the thought leaders innovating early development and driving the industry forward pages 4 and 5 >>

- **Comprehensive content**
  Over 25 sessions addressing proof-of-concept, risk management, the adaptive trials & study design, biomarkers, QT, PK/PD, modeling and simulation pages 4 and 5 >>

- **Highly interactive four days**
  Flexible attendance, unique networking opportunities and interactive workshops page 6 >>

2 workshops:

Pre-conference workshop **19 October**
Strategies to identify and mitigate risk in early phase clinical trials

Post-conference workshop **22 October**
Biomarkers in early clinical development

All details page 6 >>

Part of the leading international *Exploratory Clinical Development World* series

Exploratory Clinical DEVELOPMENT WORLD Europe

Exploratory Clinical DEVELOPMENT WORLD Americas

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See page 8

"Good coverage of many early clinical development topics"

Clinical Pharmacologist,
Novartis

"Stimulates thinking of innovation"

Director,
Regeneron

"Good section of topics and speakers"

Clinical Research Physician,
CSL Ltd

Addressing the key challenges in early development; what are the strategies and principles

The ***Exploratory Clinical Development World*** *Series* is established as the leading strategic early clinical development event for pharmaceutical professionals worldwide. It targets the major challenges of the industry head on to find much needed solutions for best selection of drug candidates as early as possible.

Clinical development costs are still rising, 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 revolutionize R&D in order to make more effective and informed go/no-go decisions as early as possible, in order to reduce attrition rates shortening drug development timescales.

Extensive research carried out with thought leaders in early clinical development has highlighted some key information. These include identifying and developing biomarkers, innovative clinical trial design, healthy vs. patient populations for early phase studies, identifying POC criteria, dose selection and safety. This conference will address these key issues.

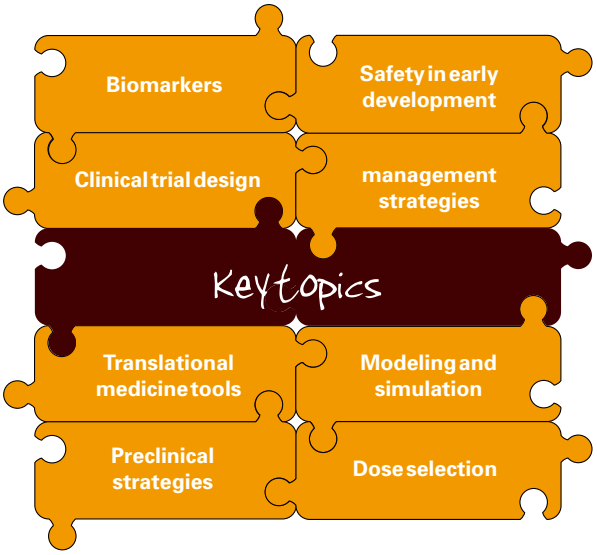
Learn from real life experiences

In the biomarkers session **Russell Weiner** from **Bristol-Myers Squibb** will discuss how to develop a fit for purpose assay and what you need to measure. **Zhaosheng Lin** from **Pfizer** will guide you through the challenges and key considerations in the application of biomarkers in clinical development. Whilst **Mark Day** from **Abbott** will demonstrate how biomarkers can be used in translation to guide dose selection and enhance benefit risk assessment. **Terri Binder** from **Eisai** will discuss how imaging can aid decision making.

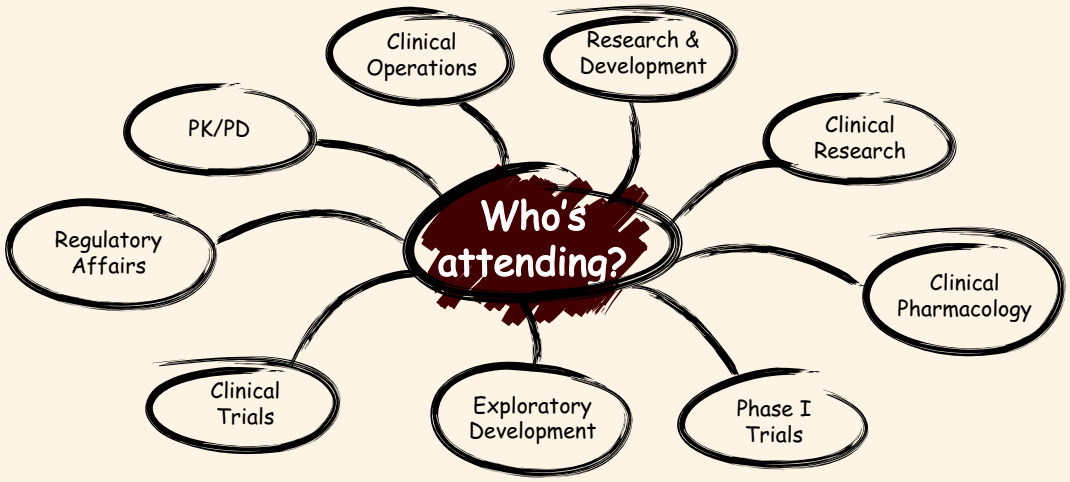
During ***Exploratory Clinical Development World Americas*** you will hear about the tools that companies are implementing in early clinical development to establish proof of concept quicker: **Jeffrey Paul** from **Pfizer** will discuss how enriched patient populations can be used. The integration of quantitative knowledge can help to establish dose selection and **Alaa Ahmad** from **Bristol-Myers Squibb** will explain how. **Yili Pritchett** from **Abbott** will discuss how to test several compounds for POC in the same study.

Key speakers

Exploratory Clinical Development World Americas 2010 boasts an excellent speaker line up – including **GlaxoSmithKline, AstraZeneca, Merck, Bristol-Myers Squibb, Abbott, Genentech, Amgen, Takeda, Eli Lilly, Eisai, Pfizer, Novartis, Gilead** and **Hoffmann-La Roche.** Who better to provide you with a summary of the best current practices to select the most appropriate candidates in early clinical development?



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



8 REASONS

not to miss the meeting that your peers will be attending

1. **Fantastic speaker panel** – highest level of speakers delivering insight and knowledge for possible solutions to bottlenecks in early development
2. **Comprehensive agenda** – We have an unprecedented number of sessions, keep track on our website as the number is set to grow
3. **Quality content** – we listened to you and your peers to ensure our program addresses the topics you want to hear
4. **A choice of streams and workshops** – tailor the congress to meet your information and networking needs
5. **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 throughout the conference.
6. **Ground breaking and innovative content** – over 25 sessions discussing issues that matter
7. **A proven track record** – the success of *Exploratory Clinical Development World* speaks for itself – read the testimonials elsewhere in this brochure!
8. **Case studies –** hear industry experiences from top pharmaceutical and biotech that's shaping exploratory clinical development

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 of industry experts

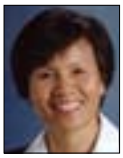
Exploratory Clinical Development World Americas brings together a record number of early development leaders.

Opportunities and challenges to clinical pharmacologist in optimal drug development

Dr Alan Xiao, Director Clinical Pharmacology, **AstraZeneca**

Practical considerations when implementing a fit-for-purpose biomarker assay development paradigm

Dr Russell Weiner, Group Director, **Bristol-Myers Squibb**



Statistical and strategic approaches for early phase clinical trials

Yili L. Pritchett, Ph.D., Research Fellow, Director, Clinical Statistics, **Abbott Laboratories**

How imaging can aid decision making in early clinical development

Terri Binder, Director Imaging, **Eisai**

Safety pharmacology best practices and the use of preclinical QT data to impact clinical study design and decision making

Dr Philip Sager, Vice President and Head Cardio pulmonary and Metabolic Clinical Development, **Gilead**

Realizing the promise of experimental medicine in early clinical development

Samuel C. Blackman, MD, PhD Associate Director, Experimental Medicine/Oncology, **Merck Research Laboratories**

Your event contact is

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kwilliams@healthnetworkcommunications.com

> "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**

Improve decision making in early clinical trials

Day One Wednesday 20 October 2010

Morning plenary

8:50 **Opening remarks from the chair**

9:00 **Innovating management strategies to revolutionize early phase R&D**
- An autonomous early phase drug development group
- Transition of assets between Lilly and Chorus
- Keys to the success

Eyas Abu-Raddad, PhD, Research Advisor, Head, PK/PD and Clinical Trial Simulations, Chorus, **Eli Lilly**

9:30 **Development approaches used to achieve success with personalized medicine and targeted drugs**
- How far has personalized health care come?
- Paradigms of development of personalized medicine and companion diagnostics

Nadine Cohen, Head of Pharmacogenomics, **Johnson & Johnson**

TRANSLATIONAL MEDICINE

10:00 **The case for early failure studies**
- Planning to fail or to win
- Relevance of exploratory studies
- Impact of exploratory trials on candidate selection

Doina Roman, MD, Senior Medical Director, Translational Medicine, **Takeda Global Research & Development Center, Inc.**

10:30 SPEED NETWORKING **and morning coffee**

11:15 **Enriched patient tools to fast track POM and POC**
- Enrichment strategies to select subjects
- Therapeutic areas that have promise

Jeffrey Paul, PhD, Assistant Vice President, Early Development and Clinical Pharmacology- Neuroscience, **Pfizer**

11:45 **How to fail faster: Getting all the answers in phase I**
- Novel technologies to create innovative study designs
- Adaptive trial designs and flexible clinical protocols
- Patient populations to gain a greater understanding

Howard Goodall, Clinical Research Physician – Phase I, **Quotient Bioresearch, Clinical Services**

12:15 **The role of experimental medicine and translational medicine to reach go/no go decisions faster**
- Building clinical confidence in basic molecule properties
- Experimental medicine to support and generate clinical data

Dr Sandeep Athalye, Clinical Franchise Lead (Resp/NSO), **Novartis Pharmaceutical Corporation**

12:45 **Realizing the Promise of Experimental Medicine in Early Clinical Development**
- How experimental medicine can be used to break down therapeutic silos
- Building a biomarker pipeline

Dr Samuel C. Blackman, Associate Director, Experimental Medicine / Oncology, **Merck Research Laboratories**

13:15 **Lunch**

CLINICAL TRIAL DESIGN

14:10 **Opening remarks from the chair**

14:15 **Quantitative knowledge integration to inform dose selection in early clinical development**
- Quantitative knowledge integration in drug development
- Dose selection / design for non-oncology FIH studies
- Dose selection for proof-of-concept and phase 2 a studies

Alaa Ahmad, Ph.D., Associate Director, Clinical Pharmacology M&S, **Bristol-Myers Squibb**

14:45 **Statistical and strategic approaches for early phase clinical trials**
- Bayesian probability to predict trial outcomes
- Adaptive design delivering Phase 2a and 2b in one study
- Discussion of when to use what strategic approach

Yili L. Pritchett, Ph.D., Research Fellow, Director, Clinical Statistics, **Abbott Laboratories**

15:15 **Afternoon coffee**

15:45 **The fast track way to PoC – Adaptive design used in a creative way**
- Parallel conduct of study components
- Data driven adaptive designs
- Bringing in patients as early as you can

Willem Jan Drijfhout, Senior Vice President Early Development Services, **PRA International**

16:15 **Patients vs. health 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 sub populations

Speaker TBC

16:45 **Closing remarks from the chair**

OR

SAFETY PHARMACOLOGY & QT

14:10 **Opening remarks from Dr Philip Sager,** Vice President and Head Cardio pulmonary and Metabolic Clinical Deveopment, **Gilead**

14:15 **Drug safety strategy in early development**
- Product recalls, why drug withdrawals occur
- Proactive measures to mitigate risk

Dr Jonathan Deutsch, Safety Science Leader, Director, Pharma Development Safety, Licensing and Early Development, **Hoffmann-La Roche Inc.**

14:45 **Preclinical cardiovascular safety which would of course include QT testing**
- Safety pharmacology for small molecules vs. biologicals
- Preclinical cardiovascular evaluation and assessment
- Translation of preclinical data to the clinic- PK/PD modeling

Martin Sanders, Research Director, Safety Pharmacology, **Hoffmann-La Roche**

15:15 **Afternoon coffee**

15:45 **"Right-sized" assessment of cardiovascular safety in early clinical development**
- Common challenges of QT assessment
- Potential strategies for incorporating QT assessment
- Case examples and examples of cost-effectiveness

Sasha Latypova, Executive Vice President, **iCardiac Technologies, Inc.**

16:15 **Safety pharmacology best practices**
- Understand how preclinical safety testing can be used
- Early identification of risks and de-risking NCEs
- Design the most efficient early clinical trials

Dr Philip Sager, Vice President and Head Cardio pulmonary and Metabolic Clinical Development, **Gilead**

16:45 **Closing remarks from the chair**

17:00 **End of day one and networking drinks reception**

Day Two Thursday 21 October 2010

8:50 **Opening remarks from the chair**

9:00 **The changing R&D process: The need to move from a linear model to highly interactive drug discovery and development**
- Organizational models to support the interactive R&D concept
- The need to balance the key drivers, medical need and innovation, with increased success rate
- Introduce novel methodologies, while improving established ways of working
- Time to assess return on investment for proof of concept and biomarker strategies

Johan Luthman, Vice President Neuroscience & Ophthalmology R&D, Franchise Integrator, **Merck & Co Inc**

9:30 **Opportunities and challenges to clinical pharmacologist in optimal drug development**
- Target identification and mechanism of disease
- Candidate selection and mechanism of action
- Preclinical-to-clinical and biomarker-to-outcomes translation
- Interpretation and integration of multiple biomarkers
- Trial design flexibility, trial operation complexity and real-time information integration
- Risk assessment and optimal decision-making

Dr Alan Xiao, Director Clinical Pharmacology, **AstraZeneca**

10:00 **A first look at efficacy: special populations in phase I/II Studies**
- Challenges in recruiting and retaining subjects in special population clinical trials
- Recent industry trends incorporating traditional clinical pharmacology safety, tolerability and pharmacokinetics parameters in early patient studies will be evaluated from the "real-world" research physician's perspective for feasibility and challenges.
- Safety assessments in proof of concept studies: addressing the competing needs of adequate dosing vs. safety in special population studies designed to demonstrate efficacy.

Bradley Vince D.O., President & Medical Director, **Vince and Associates Clinical Research**

10:30 **Morning coffee**

11:00 **Understanding the importance of preclinical studies for clinical success**
- Issues surrounding animal models in predicting safety and efficacy
- New approaches to effectively support FIM studies
- Post hoc use of animal models to address future concerns

Speaker to be confirmed

11:30 **Challenges and solutions to safety testing of drug metabolites**
- When and how to identify, characterize and evaluate metabolites
- Identifying metabolites to better understand the ADME of a drug
- Impact of regulatory guidelines

Larry J. Jolivette, Ph.D., Director DMPK, **GlaxoSmithKline**

12:00 **Modeling in early development**
- How can model-based integration with animal efficacy be used to enhance decision making?
- What are the new approaches to effectively support first in man studies and improve investigations?
- How can modeling and simulation be used to accurately forecast exploratory / phase I studies?

Suhasini Iyer, Group Leader, **Genentech**

12:30 **Lunch**

APPLICATION OF BIOMARKERS IN EARLY DEVELOPMENT

13:30 **Practical considerations when implementing a fit-for-purpose biomarker assay development paradigm**
- Practical examples of fit-for-purpose biomarker assays
- Pros and cons of in-house assay development versus using an off the shelf kits
- Case studies: issues encountered when using "for research only" kits
- Case studies: knowing what you need to measure-total-versus-free analyte

Dr Russell Weiner, Group Director, **Bristol-Myers Squibb**

14:00 **Values and challenges in applications of biomarkers for clinical development**
- Types of biomarkers that are commonly used in early clinical development
- Values of biomarker results for decision making during early development
- Challenges and key considerations for the selection of biomarkers in support of clinical development
- Challenges and significance of reliable biomarker assays in early clinical studies

Zhaosheng Lin, Head of Biomarkers, **Pfizer**

14:30 **Biomarkers and clinical translational approaches in early development**
- Need for biomarkers to guide dose selection
- Need for biomarkers to enhance benefit-risk assessment
- Biomarkers for internal decision making vs. regulatory purposes
- Biomarkers to enable increased efficacy and decreased adverse events

Mark Day, Associate Director, Head of Translational Neuroscience and Immunology Imaging, **Abbott Laboratories**

15:00 **Afternoon coffee**

15:30 **How imaging in can aid decision making in early clinical development**
- Does the drug reach/cover the intended target
- Does the drug affect the hypothesized biological pathway
- Does the biological effect lead to the desired clinical effect

Terri Binder, Director Imaging, **Eisai**

16:00 **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 program

Mike Hale, Head Global Medical Science, Biostatistics Group **Amgen**

16:30 **Closing remark from the chair**

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See page 8.

Pre & Post Conference Workshops

Tuesday 19 October 2010

Pre-conference workshop

Strategies to identify and mitigate risk in first in man 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.

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 9:30 and finish late afternoon. 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 exploratory phase I 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 escalations

AFTERNOON SESSION

Safety requirements and risk management
- Developing the risk management plan
- What are the challenges with FIH trials

Clinical trial design
- How to do statistics for early phase, adaptive trials
- Use of Bayesian probability to predict trial outcome

Speaker panel:
Bill Mattes, Principal, **PharmPoint Consulting**
Malcolm Mitchell, Medical Director, Clinical Pharmacology, **Eli Lilly**
Mitchell B. Friedman, PhD DABT, Director of Toxicology, **Takeda Global R&D**
Andrea Pellacani, MD, Ph, Senior Director, Clinical Research, Therapeutic Area Lead, Early Development Biologics, **Merck**
Ram Suresh, Ph.D., Vice President, Late Development Statistics, Biostatistics and Research Decision Sciences, **Merck Research Laboratories**

Friday 22 October 2010

Post-conference workshop

Biomarkers in early clinical development

Outline
Biomarkers have become a central theme in the development process of the pharmaceutical industry. As pharmacodynamic biomarkers, they are expected to provide the basis for decision making in early clinical development and become commercial diagnostic assets. As disease and surrogate markers they are supposed to reduce the cost and length of development. This practical and interactive session will provide a stimulating review of developing and implementing biomarkers in early clinical development.

Objectives:
This interactive session will provide attendees with a clinical viewpoint on the effective discovery, characterization and clinical utilization of fit for purpose biomarkers.

The meeting will begin at 9:30 and finish late afternoon. Lunch and refreshments will be provided.

MORNING SESSION

Fit for purpose biomarker assay
- Practical examples of biomarker assays
- Biomarker technology evaluation
- Analytical validation of assays

Biomarkers in drug development
- Translational biomarkers
- How biomarkers can be used to determine proof of mechanism
- Biomarkers to enable increased efficacy and decreased adverse events

AFTERNOON SESSION

Validating biomarkers as efficacy endpoints
- Biomarkers to guide dose selection
- Biomarkers to enhance benefit-risk assessment
- Biomarker qualification

Estimate and measure ROI on biomarkers
- Advancing the most effective biomarkers to achieve successful outcomes
- Ensuring cost effective biomarker provision
Translating biomarker approaches into commercial value

Please visit the website
www.healthnetworkcommunications.com/2010/explorusa for updates on who will be presenting these topics.

Becoming a sponsor or exhibitor

Exploratory Clinical Development is where people come to look for advice, guidance and support to the key challenges they face. The high quality of speakers and cutting edge content attracts senior exploratory and phase one professionals and you will have the opportunity to meet meaningful prospects and new contacts, in a networking and business focused enviroment

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?
- Is it cost & time effective to meet multiple prospects & clients in one setting?

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

To sponsor or exhibit contact Claire Conway on + 44 (0) 207 608 7058 or email cconway@healthnetworkcommunications.com

"Great event – speakers and content were an excellent standard"

Director Corporate Marketing, **Quotient Bioresearch**

"One of the most informative, well-organized and well-attended events in the early pharmaceutical development area"

Executive Vice President, **iCardiac Technologies, Inc**

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

Senior Business Development Manager, **Parexel**

About our sponsors

Quotient Bioresearch is a leading provider of early stage and specialist drug development services to clients worldwide. Our early stage and specialist drug development services are underpinned by a combination of medical, chemical and biological expertise. We strive to deliver the highest quality service to support our clients in their development of new products.

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PRA's Early Development Services (EDS) provides comprehensive services for phase I-IIa clinical research, bioanalytical research and data support. Through harmonized 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.

iCardiac Technologies, Inc. is a next generation cardiac safety core lab. Its team of cardiac safety experts bring 100+ years of cardiology, electrophysiology, drug development, regulatory and academic experience. The iCardiac team pioneered the field of Highly Automated QT as well as autonomic nervous system effects on the QT interval, a phenomenon estimated to produce false-positive results in conventional QT studies. iCardiac's services are supported by the COMPAS technology platform which maximizes the precision and decreases the cost of cardiac safety assessment.

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Exploratory Clinical DEVELOPMENT WORLD Americas 2010

Breakthrough

19 – 22 October 2010, Le Méridien Cambridge-MIT, United States

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