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Hear from

Dr Yale Mitchel
Vice President Clinical and Quantitative Science Cardiovascular Disease Dept
Merck Research Laboratories

Dr Danica Marinac-Dabic
Director, Division of Epidemiology
FDA

Dr Jens Rienhold
Head, Global Non Interventional Studies
Bayer Schering AG

Joseph Camardo
MD Senior VP, Global Medical Affairs,
Wyeth

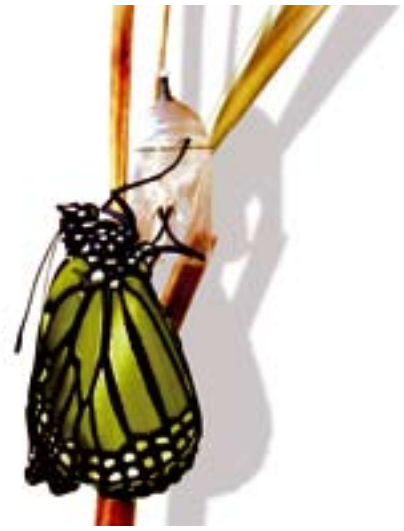
Dr Gilbert L'Italien
Executive Director, Global Health Outcomes
Bristol Myers Squibb

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

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2010

23 - 26 March 2010, Hyatt Regency, Princeton, United States

Real life



Driving value in phase IIIb & IV trials

- **Post approval strategy updates**
  Hear from and meet leaders in late phase research including: the **FDA, Merck, Pfizer, BMS and Wyeth** page 4 and 5 >>

- **Compare and contrast new models**
  Benchmark your strategies against top pharma and biotech companies page 4 and 5 >>

- **Highly interactive four days**
  Don't just sit there! Interactive and flexible agenda with **unique networking opportunities, panel discussions and workshops** page 6 >>

Pre & post conference workshops:

23 March 2010
Developing and writing a risk management plan

26 March 2010
Effective project management in late phase development

All details page 6 >>

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"Excellent speakers and programme / content"

Medical Information & Safety Officer, **Wyeth**

"Excellent – comprehensive" Director,

Global Health Outcomes, **GlaxoSmithKline**

"Excellent – good discussion"

Director of Risk Management, **Baxter**

Benchmark your late phase strategy alongside the industry's best

Late phase drug development is growing at around 20% annually, exceeding the growth rate of phase II and III trials. In excess of $12 billion is currently being spent on phase IIIb/IV studies as public concerns on the safety of approved drugs prevail together with the need to evaluate real world safety and effectiveness of marketed drugs. More than ever before there is the urgent need to detect, quantify and communicate patient risk with speed and efficiency.

This congress will provide a forum for discussion where top pharmaceutical and biotech companies can address the key challenges faced by industry. As with all Health Network events, extensive in depth research has been carried out to shape the programme for this event and we have spent many months working with senior representatives within the late phase community to ensure that the programme content is timely, practical and relevant.

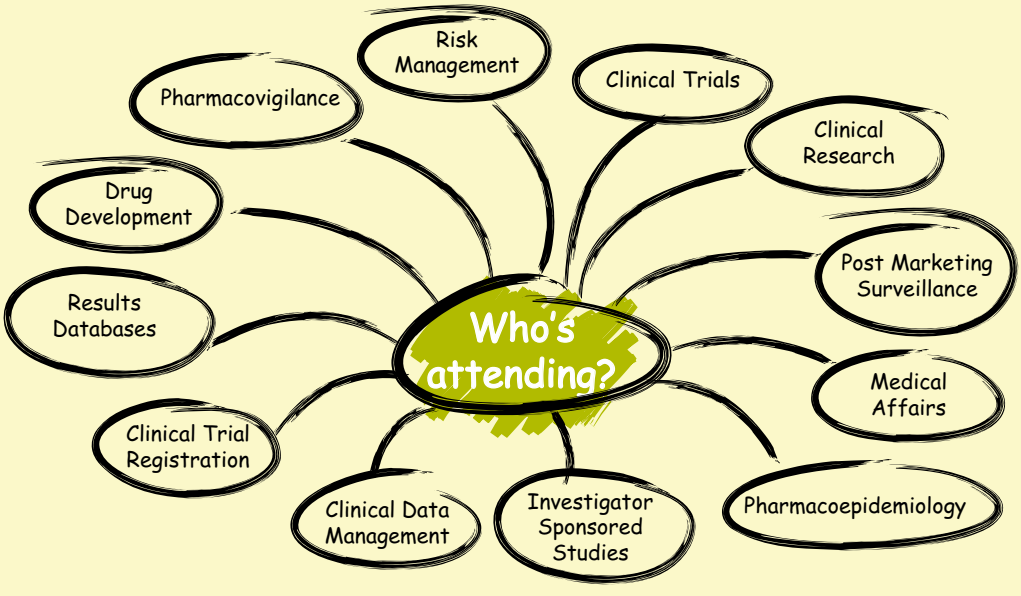
Following on from our successful European congress, Health Network is delighted to announce a unique strategic forum addressing the major challenges in conducting strategic and compliant late phase studies.

Key issues to be addressed:

- Strategic challenges in late phase trials – what are they and how can they be addressed?
- Planning for phase IIIb/IV – getting things in place to avoid costly surprises
- Non interventional trials – sharing new perspectives
- Analyzing and interpreting observational studies – how do you effectively collect, validate and analyze observational data?
- Disease registries – how do they contribute to late phase development?
- Patient communication strategies – getting it right
- Improving investigator site performance
- Operational issues in late phase study management
- Challenges and opportunities in emerging markets – what are the new markets and how should you operate in them?

As the first ever meeting of this kind we bring you a packed agenda, an unprecedented speaker panel, and wide reaching content. You will hear from industry thought leaders from an impressive list of companies including: **the FDA, Pfizer, Roche, Amgen, Bayer Schering AG, Merck, Wyeth, Novartis, Amylin, Bristol-Myers Squibb, Novo Nordisk and Ortho-McNeil Janssen** who will provide you with the best possible advice on how to improve performance in late phase research.

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



8 REASONS

why you should attend *Late Phase Drug Development World Americas 2010:*

1. **Comprehensive agenda** we have over 20 unique and informative sessions, keep track on our website for developments

2. **Roche, Pfizer, Amgen, Merck, Wyeth** hear industry insights from our expert speaker panel including pharmaceutical representatives!

3. **Quality content!** We listen to you and your peers to ensure our program confronts the topics you want to hear

4. **Case studies** hear therapeutic area specific presentations, including diabetes and CNS products

5. **Extensive global reach** We have speakers from America, Europe, and Asia to give a much needed view of the international landscape

6. **Pre and post conference workshops, focused networking sessions, panel discussions, delegate led questions.** Tailor the packed congress to meet your own information and networking needs

7. **Proven track record!** Health Network have a demonstrable track record in delivering high quality well attended events for the life sciences sector

8. **Extensive networking opportunities** make contact, plan who to meet and arrange meetings prior to the conference, take part in multiple networking sessions and continue to build these relationships following the event

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

Taking transparency in late phase clinical development from a "must do" to a "want to do" - a clinical quality case study

Beat Wilder, Global Head of Clinical Quality Assurance, **Hoffman La Roche**

Evolution of REMS post FDAAA

Dr Rekha Garg, Executive Director, Risk Intervention Strategy & Communication, Global Regulatory Affairs & Safety, **Amgen**

Incorporation of life cycle management in late phase trials

Dr Charlotte Kremer,
Vice President Specialty Neuroscience, Clinical Development and Medical Affairs, **Pfizer Inc**

Late phase development of a novel antidepressant

Tanya Ramey, Director, Clinical Development and Medical Affairs, **Pfizer**

Informing rather than promoting; challenges and opportunities

Dr Chris Allen, Head of Global Information Management, **Merck**

Optimizing and evaluating product safety in late phase studies

Peggy Schrammel, Vice President, Registries and Post Approval Development, **UBC**

Late phase development of an anti-diabetic treatment

Matthew Wintle, Director, Medical Programmes, **Amylin Pharmaceuticals**

Your event contact is
Karen Williams
+44 (0) 207 608 7055
kwilliams@healthnetworkcommunications.com

> "Lots of knowledge"
>
> Research Manager, **Lundbeck**

> "Good quality speakers/ experts in their field"
>
> Market Access Manager, **MSD**

20 top industry and policy experts under one roof and counting...

Day One Wednesday 24 March 2010

STRATEGIC DRIVERS

08:30 **Registration & coffee**

09:00 **Opening remarks from the chair**
Dr Marc Hoffman, Vice President, Scientific & Medical Affairs, **Covance Periapproval Services**

09:15 **Post approval challenges in the new biopharmaceutical landscape**
- How can industry address the need for more real world data?
- What are the new opportunities and how are they being faced?
- How can industry and regulators work together to ensure that the challenges in the post approval environment are met?

Dr Yale Mitchel, Vice President Clinical and Quantitative Science Cardiovascular Disease Dept, **Merck Research Laboratories**

09:45 **Managing risk in late phase studies**
Dr Joseph Camardo, Senior Vice President, Global Medical Affairs, **Wyeth**

10:15 **Operationalizing a late phase study**
- Setting clearly defined study objectives
- What are the infrastructure requirements for a flexible trial design in late phase?
- How can you balance medical need and commercial concerns?
- Setting clear endpoints, identifying them and measuring them

Eileen Moran, Senior Director, Clinical Operations, **Covance Periapproval Services**

10:45 SPEED NETWORKING Fun, high speed breaks in the conference day for making new contacts and exchanging details. Bring plenty of business cards!

11:15 **Morning tea**

11:45 **Taking transparency in late phase clinical development from a "must do" to a "want to do" - a clinical quality case study**
- Leveraging the accumulated body of evidence collected through late phase activities
- Ensuring that the quality assurance and management approach is an "intelligence game" and delivers an inference about the degree of quality risk of any entity involved in a process or trial
- Developing a process that manages errors as long as these do not represent "show-stoppers" and prevents errors that have the potential to become "show-stoppers"
- Sharing of quality related information

Beat Wilder, Global Head of Clinical Quality Assurance, **Hoffman La Roche**

12:15 **Best practice in post approval research; fit-for-purpose quality and stakeholder management**
- Dealing with different stakeholder requirements and governance
- Fit-for-purpose methods of quality management in post approval research
- Outlook: new regulatory requirements and organizational implications

Dr Jens Reinhold, Head Global Non-Interventional Studies, **Bayer Schering AG**

12:45 **Lunch**

REGULATORY & POLICY ENVIRONMENT

13:45 **Opening remarks from the chair**
Maria Harrison, Global Head, Late Phase Services, **PRA International**

14:00 **Demonstrating cost effectiveness & quality of life in late phase trials**
Jerome Wilson, Ph.D, Senior Scientific Affairs Director, Epidemiologist**, PRA International**

14:30 **Strategic use of PROs in late phase studies: regulatory perspective**
- The value of PROs in drug development
- Requirements for using PRO data in the label and promotion
- Incorporating PRO Activities into the development timeline

Dr Robert DiGregorio, Director II, Women's Health Therapeutic Area Lead Global Regulatory Affairs, **Wyeth**

15:00 **Post approval challenges: regulatory perspective**
- US regulatory framework for post approval studies
- Coordination with international bodies
- Challenges for industry
- Engaging with all stakeholders

Danica Marinac-Dabic, Director, Division of Epidemiology, **FDA**

15:30 **Afternoon tea**

16:00 **Evolution of REMS post FDAAA**
- High level overview of REMS
- Status of current REMS
- Challenges and Issues with REMS Implications of the FDAAA

Dr Rekha Garg, Executive Director, Risk Intervention Strategy & Communication, Global Regulatory Affairs & Safety, **Amgen**

16:30 PANEL SESSION **Regulatory challenges in post approval studies**
Panellists:
Dr Rekha Garg, Executive Director, Risk Intervention Strategy & Communication, Global Regulatory Affairs & Safety, **Amgen**
Danica Marinac-Dabic, Director, Division of Epidemiology, **FDA**

17:00 **Closing remarks from the chair**

17:15 **Drinks reception; join your peers and relax with a drink after a busy conference day.**
To sponsor the drinks reception contact Roope Ghosh on +44 (0) 207 608 7037.

18:30 **End of day one**

Hear from and meet your industry peers

Day Two Thursday 25 March 2010

COMMERCIAL AND MARKETPLACE ISSUES

08:30 **Registration & coffee**

09:00 **Chairman's opening remarks**
Peggy Schrammel, Vice President, Registries and Post Approval Development, **UBC**

09:15 **Patient registries and observational studies**
- Strengths and weaknesses vis-à-vis clinical trials
- Patient registries as a means of evaluating comparative effectiveness, evaluating long-term safety, and supporting market access
- Operational strategies to ensure success
- Maximizing value of registry results
- Case studies

Peggy Schrammel, Vice President, Registries and Post Approval Development, **UBC**

09:45 **Rare disorder registries: a common challenge**
- Think outside the box about design and implementation of a rare disorder registry
- Review case studies illustrating challenges and solutions
- Identify and overcome challenges proactively

David L Cooper, MD MBA, Director, Medical Affairs, CMR-biopharmaceuticals, **Novo Nordisk Inc**

10:15 **Designing naturalistic studies that meet reimbursement goals in Europe: the STAR example**
- Highlight an example of a naturalistic effectiveness study
- The history of STAR: strategy, design, results
- STAR's impact on reimbursement in Europe
- Strengths / limitations

Dr Gilbert L'italien, Executive Director, Global Health Outcomes, **Bristol Myers Squibb**

10:45 **Morning tea**

11:15 **Getting meaningful information from observational studies in late phase trials**
- Real life data: what is it and what is it not?
- Comparing and contrasting observational with clinical trial data
- How can observational research be used to shape drug development programmes?
- Providing data to stakeholders, challenges and opportunities

Dr Joseph Hulihan, MD, Vice President, Medical Affairs, CNS, **Ortho-McNeil Janssen**

11:45 **PROMIS initiative for patient-reported outcomes**
- Standardized measurement in numerous chronic diseases
- Integration of cognitive, qualitative, and survey research methods
- Integration of the advances in measurement theory and the power of computer technology
- Developing new research partnerships

Elizabeth Hahn, M.A., Associate Professor, **Northwestern University**

12:15 **Lunch**

13:15 PANEL SESSION **Patient registries and observational studies**
Facilitated by:
Sean Kennedy, Director, Registries & Observational Studies **Covance Periapproval Services**

13:45 **Balancing scientific and commercialization objectives in the conduct of late phase studies**
- Strategic and scientific considerations
- Observational study designs
- Safety surveillance
- Post marketing risk assessment and management

Dr Erhan Berber, Sr. Pharmacovigilance Leader, Brand Safety Leader a.i., **Novartis**

14:15 **Communication strategies for late phase research**
Kevin Flynn, Director, Scientific Communications, **Analgesic Research**

14:45 **Informing rather than promoting; challenges and opportunities**
- Who do you trust to provide you with information?
- How do you search out information?
- What defines how you provide medical information?
- How may the field evolve?

Dr Chris Allen, Head of Global Information Management, **Merck**

15:15 **Incorporation of life cycle management in late phase trials**
- External environment
- Life cycle management plan: what, how and how?
- Phase IV: a special focus
- Critical success factors

Dr Charlotte Kremer, Vice President Specialty Neuroscience, Clinical Development and Medical Affairs, **Pfizer Inc**

15:45 **Afternoon tea**

CASE STUDIES

16:15 **Late phase development of an anti-diabetic treatment**
- Developing innovative diabetes therapies in an environment of change
- Demonstrating efficacy, "guesstimating" cost-effectiveness, and understanding effectiveness in the real world
- New horizons for the treatment of Type 2 diabetes and Cardiometabolic disease

Matthew Wintle, Director, Medical Programmes, **Amylin Pharmaceuticals**

16:45 **Late phase development of a novel anti-depressant**
- Placebo response in major depressive disorder phase III trials
- Moderators and mediators of placebo response
- Examples of recent successful MDD trials
- Keys to success in designing and conducting successful MDD trials

Dr Tanya Ramey, Senior Clinician, Pfizer Inc

17:15 **Closing remarks from the chair**

17:30 **End of conference**

Hear from and meet your industry peers

Get the most from your conference

SPEED NETWORKING

Fun, high speed break in the conference day for making new contacts and exchanging details.

contact

Arrange meetings online before you arrive. Access event resources, such as papers and presentations, after you've left.

PANEL SESSION

Meet and talk about the business issues on your brain.

The workshops create a relaxed environment for you to network with your peers and focus more directly on topical issues

Pre & Post Conference Workshops

Tuesday 23 March 2010

Pre-conference workshop

Pragmatic approaches to FDAAA

This interactive workshop will present you with facts and challenges about a safety issue from early identification of the signal to design and implementation of a Risk Evaluation and Mitigation Strategy (REMS).

The workshop will begin at 09:30 and end at 16:30. Lunch and refreshments will be provided

Agenda

- How to lead an organization in REMS decisions (Decision Tree Approach), creation, documentation, evaluation and implementation activities
- Discussion: key considerations for risk assessment studies
- Establishing a process pathway to gain multifunctional cooperation
- Identifying key decision points for risk management during product development
- Deciding which risks require long-term assessment (but not immediate mitigation) - conducting post-marketing observational studies for risk assessment
- Deciding which risks are worthy of mitigation
- Designing and evaluating risk management tools
- Establishing an infrastructure for risk minimization
- Understanding results of a risk management program evaluation
- Reporting effectiveness of risk management programs to regulatory agencies

Your workshop leaders

Abbe Steel, Executive Director, Trial Enhancement Services, **United BioSource Corporation**

Bob Sharrar, Executive Director, Epidemiology and Risk Management, **United BioSource Corporation**

Cathy Sigler, Senior Director, Epidemiology Risk Management, **United BioSource Corporation**

Friday 26 March 2010

Post-conference workshop

Effective project management in late phase development

This interactive workshop will focus on the strategies required to run a successful clinical trial through effective project management. It will be delivered through a series of interactive sessions and a mini case study, designed to keep you active and enabling you to put into practice lessons learnt from the day.

What you will learn from this workshop

- How to optimize the chances of success on your project
- Practical and realistic strategies to run your projects effectively and efficiently
- Application of project management techniques to clinical trials
- Defining accurate clinical trial timelines and budgets
- Reporting and metrics used (including enrolment forecasting)

8.30 **Registration & coffee**

9.00 **Develop project management skills**
Prepare and enhance the skills of a project manager: anticipate problems, balance priorities, make decisions, manage change and manage across organisational boundaries

10.30 **Morning coffee**

10.45 **Organise the project**
Ensure that the clinical trial will be planned and managed in an appropriate manner, translate the initial project request into a project charter that engages the project team

12.30 **Lunch**

13.30 **Plan the project**
Understand and integrate the components of a project plan – time, cost, scope, quality, risk, procurement, communication and human relations

15.15 **Afternoon tea**

15:45 **Deliver results**
- Manage the data and ensure that decisions are punctual and well-informed
- How to close the project successfully and ensure continuous improvement

17:00 **End of day**

Your workshop leader

Ian Stokes, Project Management Specialist, **Metanaction,** France

Save $755 on the 4 day Gold Pass.
Register before 8 Jan 2010.
See page 8 for details

Becoming a sponsor or exhibitor

The 2010 launch of Health Network Communications' *Late Phase Drug Development World Americas* has been met with unprecedented interest. With a history of developing high level / high participant launches in focused and strategic events, we are expecting another record turn out!

Late Phase Drug Development World Americas 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 faced in phase IIIb/IV?
- Could you benefit from introductions to and time with decision makers in late phase?
- Are you actively looking for new leads and clients to work with in late phase drug development?

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.

Sponsorship opportunities can be tailored to your specific objectives and marketing requirements, let us know what you want to achieve and we will develop a promotional solution with you.

Roope Ghosh on
+ 44 (0) 207 608 7037 or email rghosh@healthnetworkcommunications.com

Meet and do business with industry decision makers.

About our sponsors

COVANCE

With over 30 years of post-approval experience, Covance's Periapproval Services professionals provide unique insights that integrate experience, expertise, and operational excellence of our talented and dedicated teams. We offer a suite of services with extensive expertise and experience in Phase IIIb/IV, Registries and Observational Studies, REMS and Product Safety.

UBC

UBC, United BioSource Corporation, is a global pharmaceutical services organisation that combines deep scientific knowledge with broad execution expertise across the entire lifecycle continuum. Our focus is on generating real-world data to support the development and commercialisation of medical products for emerging and established life science companies. UBC's areas of expertise include risk management consulting and implementation of post-approval studies, including product registries and large streamlined studies.

pra
PRA International

PRA's Late Phase Services group supports global and regional Post-Approval studies of all sizes. Our highly-experienced team assists sponsors with the Post-Marketing process by planning and conducting Post-Authorization Safety Studies/Safety-Surveillance Studies, Drug Utilization Studies, Registries, Restricted Access Programs, Risk Evaluation and Mitigation Strategies/EU-RMP, and Diagnostic and Biomarker Research.

Exhibitor

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Drug Safety

The venue

Enjoy classic elegance in the perfect location at **Hyatt Regency Princeton.** Ideally situated close to the train station and Route 1, this hotel in Princeton New Jersey offers both business travellers and vacationing guests all they need for a remarkable stay. Take advantage of the complimentary shuttle to nearby attractions and business centers. Tour Princeton University, historical sights and the quaint shops of New Hope and Peddler's Village. When it's time for work, you'll find generous desks and WiFi in the spacious guestrooms, stylish meeting venues, and the area's prime choices for dining with colleagues and clients.

> "Best organised event I have participated in during the last 12 months"
>
> Director of Observational Studies, **Covance**

> "Got several meeting requests, so have potential new clients from this event…..we will participate next year"
>
> Director, **Parexel**

Something to say?
Talk to us about speaker opportunities
Call Roope Ghosh on +44 (0) 207 608 7037

LATE PHASE DRUG DEVELOPMENT WORLD AMERICAS 2010

23 – 26 March 2010, Hyatt Regency Princeton, NJ, United States

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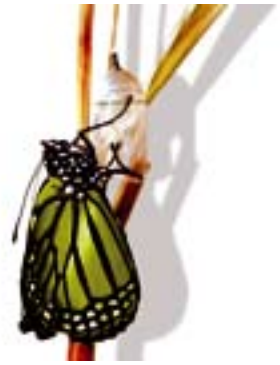

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You can use our online calculator to tailor your ticket and buy multiple tickets.
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Register now

Package	Before 8 Jan 2010	Before 12 Feb 2010	Before 5 Mar 2010	After 5 Mar 2010	How many	Calculate your ticket
Gold pass – all 4 days 23 – 26 March 2010	$3400	$3775	$3965	$4155	☐	
2 main days plus pre conference workshop 23 – 25 March 2010	$2595	$2885	$3030	$3175	☐	
2 main days plus post conference workshop 24 – 26 March 2010	$2595	$2885	$3030	$3175	☐	
2 day conference 24 – 25 March 2010	$1790	$1990	$2090	$2190	☐	

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If you reserve your ticket but pay by invoice or bank transfer payment must be received in 7 days