

Preclinical  
& Clinical Series

Hear real industry  
experience and expert  
overviews from:



**John Parkinson**,  
Head of General  
Practice Research  
Database (GPRD),  
MHRA, UK



**Sarah Garner**,  
Associate Director  
R&D, National Institute  
for Health and Clinical  
Excellence (NICE), UK



**David Gillen**, Vice  
President, Medical  
Teams, Primary Care  
BU Europe Canada  
Australia NZ,  
Pfizer UK

**Bernard Hamelin**, AstraZeneca,  
Belgium

**Michal Konstacky**, Solvay AG,  
Switzerland

**Isabel Fonseca Santos**, Bayer  
Portugal SA, Portugal

**Merete Jorgensen**, Novo Nordisk,  
Denmark

**John Drake**, Roche, UK

**Jit Solanki**, Wyeth, UK

**Annette B Beiderbeck**, TGRD  
Europe, UK

**Maurício Silva de Lima**, Eli Lilly,  
UK

**Elizabeth Hernberg Stahl**, Shire  
HGT, UK

**Philippe Auby**, H. Lundbeck, France

**Rodrigo Escobar**, Eli Lilly, Spain

**Michael Forstner**, F. Hoffmann-La  
Roche, Switzerland

**Emma Venezian**, Sanofi-Aventis,  
Chile

**Saad Shakir**, Professor, Drug  
Safety Research Unit (DRSU), UK

# Phase IIIb and IV Strategy and Implementation

Practical industry strategies to maximise your Return on  
Investment, fulfil your regulatory commitments and extend the  
lifecycle of your products

13-14 April 2010 | NH Jolly St Ermins | London | UK

## Exclusive to this event:

- ✓ MHRA question and answer session
- ✓ Recommendations from NICE
- ✓ Paediatrics Investigation Plans (PIPs)
- ✓ Extending patent and label life
- ✓ Key Opinion Leader (KOL) advisory boards
- ✓ Health Technology Assessments (HTA)

## What makes this event unbeatable?

14 industry case studies from both large and small pharma

- ✓ Observational studies
- ✓ Real world data
- ✓ Comparative studies
- ✓ Large simple trials
- ✓ Clinical trials
- ✓ Health outcomes studies
- ✓ Risk Management Plans

## Don't miss:

Full day pre-conference workshop W:  
Monday 12 April 2010

### Practically Designing and Implementing Observational Studies

Led by:  
David Becedas,  
Scandinavian Outcomes,  
Sweden

Evening seminar Y:  
Tuesday 13 April 2010

### HTA & Health Economics Crossover to Phase IIIb-IV study protocols

Led by:  
Hubertus Rosery,  
AiM GmbH, Germany

Full day post-conference workshop X:  
Thursday 15 April 2010

### Risk Management Plans: Practical application

Led by:  
Saad Shakir &  
Deborah Layton,  
Drug Safety Research Unit  
(DRSU), UK

## Full-Day Pre-Conference Workshop W: Monday 12 April 2010 Practically designing and implementing observational studies

Registration 10:00 - Start 10:30 - Lunch 13:30 - Afternoon start 14:30 - Finish 18:00. All refreshments are included

### Design and effective implementation of observational studies and healthcare quality improvement initiatives in the Scandinavian countries

#### Why you should attend this workshop

The Scandinavian countries provide excellent conditions for implementing both post-launch observational studies and quality improvement initiatives. The target group for this workshop is clinical research professionals, medical advisors and other pharma staff involved in the planning and execution of such projects.

#### What will be covered at the workshop

- How to decide whether to conduct an observational study or a healthcare quality improvement initiative?

- Choosing the optimal project design
- Blending commercial and scientific objectives
- Impact of post-launch research projects on product adoption
- Creating value for patients, physicians, payers and products
- Effective implementation of observational studies and healthcare quality improvement initiatives
- Obstacles for undertaking post-launch research in the Scandinavian countries

Led by: **David Becedas**, Team Leader Observational Research, Scandinavian Outcomes, Sweden

For further details please see the conference website: <http://www.informa-ls.com/phase4>

## Conference day one: Tuesday 13 April 2010

**08:30** Conference registration

**09:00** Opening remarks from the chairperson  
**Maurício Silva de Lima M.D., Ph.D.**, Medical Director, **Eli Lilly**, UK and Ireland

### Developing and implementing a successful Phase IIIb and IV strategy

**09:10** **REGULATORY** **Combining the benefits of both observational data and clinical trials**

- Exploring the regulatory requirements from observational data
- Examining the clinical trial data and what it offers in the real world
- Guidance on how to combine observational data with clinical trials
- Understanding the regulatory perspective on combining observational data with clinical trials
- Questions and answers

**John Parkinson**, Head of General Practice Research Database (GPRD), MHRA, UK

**09:40** **Successfully integrating real world data into Phase IIIb and IV studies**

- To what extent should real world data be incorporated into Phase IIIb and IV studies?
- Examining the importance of trend analysis and modelling of real world data
- Investigating the importance of data on clinicians prescribing the drug for off label use e.g. indications, duration and new populations
- Establishing best practice in data mining for real world data

**Annette B Beiderbeck, PhD**, Director of Pharmacoepidemiology, **TGRD Europe**, UK

**10:10** **Examining the practicalities of observational or 'real world' Phase IV studies**

- Exploring the advantages of carrying out observational studies
- Best practice on conducting an observational study
- Trans-European studies - in combination or parallel
- What observational data can tell us e.g. off label use, response to publicity, prescribing trends

**Gillian Hall**, Independent Expert, UK

**10:40** Morning networking refreshments

**11:10** **Designing benefit-risk strategies for marketing authorisation and Health Technology Assessments (HTA)**

- Examining benefit-risk and how it has become of major importance in recent years
- Practical strategies for risk management and risk minimisation - as required for marketing authorisation approvals
- Implementing robust evaluation of benefit risk and addition to value for money assessment - as increasingly required for Health Technology Assessments
- Exploring strategies for the future

**John Drake MBChB, FFPM**, Global Safety Operations Physician Manager, Formerly Medical Director, **Roche**, UK

**11:40** **Practically applying Phase IIIb and IV studies in Risk Management Plans (RMP) / Risk Evaluation and Mitigation Strategies (REMS)**

- Getting an understanding of benefit vs risk
- Strategies and tactics for effective benefit-risk management
- Success factors for post-marketing pharmacoepidemiology practices
- How does the "benefit" part of the balance influence risk management planning?

**Michael Forstner, Ph.D.**, Integrated Safety Risk Manager, **F. Hoffmann-LA Roche Ltd.**, Switzerland

**12:10** **Synergistic and Cost-Effective approaches for post approval research - adding value to post approval research via market access and reimbursement strategic planning**

- Combining Post Authorisation safety and data collection needs with real-world cost effectiveness data collection required by payers
- Selection of the most suitable study design to collect real-world data in the clinic
- Fit for purpose study execution

**Andrea Spannheimer**, Vice President, International Late Phase Operations, **i3 Innovus**

**12:40** Networking lunch

**13:50** **Optimising Phase IIIb and IV studies according to choice of study and countries, and regulatory authority and healthcare agency requests**

- Overcoming the challenge of increasing requests from the regulatory authorities and health care agencies
- Closing the gap between what is required by regulatory authorities and by healthcare agencies
- Ensuring that the study can be used in different countries
- With the diverse choice of studies - which are the most effective to use in which situation?
- Examining the diversities in different countries including regulations and reimbursement, and designing Phase IIIb and IV studies accordingly

**Emma Venezian, MD**, Director Clinical Research, **Sanofi-Aventis**, Chile

### Fulfilling regulatory commitments post-approval

**14:20** **Strategies for closing the gap between regulatory authority and healthcare agency / payer requests in Phase IIIb and IV studies**

- Examining the differences between implementing requests from regulatory authorities and from health care agencies / payers
- Practical ways in which the gap between regulatory authority and health care agency / payer requests can be closed
- Exploring the influence of health care agencies / payers on Phase IIIb and IV studies
- Guidance on how health outcomes, required by health care agencies / payers, can be built into the Phase IIIb and IV program

**Bernard Hamelin**, Medical Director, Europe, **AstraZeneca**, Belgium

**15:10** **Round table discussion session**  
**How can regulatory commitments and health care agency submissions be implemented practically in Phase IIIb and IV studies?**

Your chance to discuss this important issue with your industry peers

- How has the FDAAA (Food and Drug Administration Amendments Act), enforcing Post Marketing Requirements (PMRs) rather than Post Marketing Commitments (PMCs) affected Phase IIIb and IV trials
- To what extent are post-approval commitments moving towards requirements in Europe?
- Overcoming the challenge of increasing requests from the regulatory authorities and health care agencies
- In what ways is the gap between what is required by regulatory authorities and by healthcare agencies closing?

Chaired by:

**Maurício Silva de Lima M.D., Ph.D.**, Medical Director, **Eli Lilly**, UK and Ireland

**15:40** Afternoon networking refreshments

**16:10** **Practical guidance on conducting a health outcomes study**

- How to combine a health outcomes study with other Phase IIIb and IV studies
- Fulfilling regulatory commitments with a health outcomes study
- Using health outcomes to complete a drug utilisation study
- Understanding the importance of including a Quality of Life (QoL) study, including justifying which QoL questionnaire to use
- What is the potential for Patient Reported Outcomes (PRO), drug utilisation studies, burden of illness studies and patient chart evaluations?

**Rodrigo Escobar**, Medical Fellow, Neurosciences European Medical Team, **Eli Lilly**, European Medical Team, Spain

**16:40** **Exploring the advantages of using patient registries for small patient populations**

- Using patient registries for small patient populations: orphan drugs and rare diseases
- What criteria are the regulatory authorities and healthcare agencies looking for from patient registries?
- Successfully managing patient registries

**Elizabeth Hernberg-Ståhl, M.Sc.**, Director, Global Outcome Surveys, **Shire HGT**, Sweden

**17:10** Closing remarks from the chair and end of conference day one  
**Maurício Silva de Lima M.D., Ph.D.**, Medical Director, **Eli Lilly**, UK and Ireland

### Promotional Opportunities:

This event provides your company with a unique opportunity to promote your business to an audience made up of your potential clients. Benefits can include:

- An exhibition stand
- A spotlight session presentation
- Hosting a lunch, networking drinks or a social function

For more information please contact: **Sukhvir Hayre**, Sales Director, Informa Life Sciences, [sukhvir.hayre@informa.com](mailto:sukhvir.hayre@informa.com), +44 (0) 20 7017 7131

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Evening Seminar Y: Tuesday 13 April 2010

## HTA & Health Economics Crossover to Phase IIIb-IV study protocols

Registration 17:45 - Start 18:00 - Finish 21:00 - Dinner included

### Why you should attend this seminar

The objective of the evening seminar is to trigger audience sensibility regarding mandatory requirements when considering health-economic piggy-back trials.

### What will be covered at the evening seminar

- HTA and Health Economics as a tool for reimbursement decisions
- Requirements given by European Reimbursement Decision Boards

- National and international guidelines on HTA
- National and international guidelines on Health Economics
- GCP/ICH and the relation to Health Economics
- PRO and Utility Measurement and its impact on measurement of costs
- What to consider when designing a cost questionnaire
- Finding evidence on study design with focus on Health Economics

Led by: **Hubertus Rosery**, *President & CEO, AiM GmbH*, Germany

## Conference day two: Wednesday 14 April 2010

**09:00** Opening remarks from the chairperson  
**Michael Forstner, Ph.D.**, *Integrated Safety Risk Manager, F. Hoffmann-La Roche Ltd.*, Switzerland

### Critical success factors for market profiling to maximise the return on investment

**09:10** **Developing NICE recommendations**

- Methods and processes in health technology appraisal and other NICE guidance
- Making recommendations close to marketing authorisation
- Overview of decisions made so far
- Implementing the patient access schemes in technology appraisals
- Exploring the role of patient registries and observational studies in technology appraisals

**Sarah Garner**, *Associate Director R&D, National Institute for Health and Clinical Excellence (NICE)*, UK

**09:40** **Phase IIIb and IV Pfizer case study**

For further details see [www.informa-ls.com/phase4](http://www.informa-ls.com/phase4)

**David Gillen**, *Vice President, Medical Teams Primary Care BU Europe Canada Australia NZ, Pfizer*, UK

**10:10** **Q&A session with NICE and Pfizer**

Your chance to put your most pressing questions to NICE and Pfizer representatives. Submit your questions in advance by email: [sarah.palit@informa.com](mailto:sarah.palit@informa.com)

**Sarah Garner**, *Associate Director R&D, National Institute for Health and Clinical Excellence (NICE)*, UK

**David Gillen**, *Vice President, Medical Teams Primary Care BU Europe Canada Australia NZ, Pfizer*, UK

**10:20** **Success strategies for implementing Paediatrics Investigation Plans (PIPs)**

- Exploring why PIPs have been introduced
- Practical guidance on what is required from a Phase IIIb and IV paediatrics study
- Strategies for working with the Paediatric Committee
- Best practice on extrapolating data from adults to children
- Overcoming the challenges currently faced in PIPs

**Philippe Auby**, *Director, International Clinical Research, Paediatric Neuro-Psychiatry, H. Lundbeck*, France

**10:50** Morning networking refreshments

**11:20** **Using Phase IIIb and IV studies to extend label and patent life**

- Defining life cycle management and how this can extend label and patent life
- Conducting a comparator Phase IV study to extend label and patent life
- Using health economics studies to extend label and patent life
- To what extent are the regulatory studies requesting comparator studies?
- Successfully generating evidence to extend label and patent life
- Guidance on extending into new markets and expanded access programmes

**Johannes Lampe**, *Lampe Konieczny & Company GmbH*, Germany

**11:50** **SPOTLIGHT SESSION:**

Raise your corporate profile by sponsoring or exhibiting at this conference. This event provides opportunities to network and conduct business with key decision makers from all over Europe. For details on speaking in this session or other sponsorship opportunities at this conference please contact **Sukhvir Hayre**, *Sales Director, Clinical Series, Informa Life Sciences*, UK. Email: [sukhvir.hayre@informa.com](mailto:sukhvir.hayre@informa.com), Tel: +44 (0) 20 7017 7131

**12:20** Networking lunch

**13:30** **Establishing a Phase IIIb and IV investigator and Key Opinion Leader advisory board to assist commercial success**

- Guidance on working with investigators in Phase IIIb and IV trials and examining the main differences
- How to establish and set the agenda for a Phase IIIb and IV advisory board including investigators and Key Opinion Leaders
- Using the advisory board to aid design of trial including end points, where to conduct the study and to establish an effective marketing programme
- Overcoming challenges of the internal organisation of advisory boards and cultural differences

**Michal Konstacky, MD, PhD**, *Global Medical Affairs Director, Solvay Pharmaceuticals Marketing and Licensing AG*, Switzerland

### Optimising Phase IIIb and IV trial design

**14:00** **New directions in Phase IV studies: Conducting large simple trials**

- The importance of conducting large, simple, pragmatic pharmaceutical trials
- Too many customers, too many different demands: How to design simple trials that address regulatory, reimbursement, HCPs and patient's needs
- Important patient outcomes in clinical trials
- Other key end points in large simple trials

**Maurício Silva de Lima M.D., Ph.D.**, *Medical Director, Eli Lilly*, UK and Ireland

**14:30** **Examining the practicalities of implementing a comparative Phase IV study**

- Exploring the advantages of carrying out a comparative study
- Best practice on designing a comparative study
- How to balance scientific and commercial reasons for setting up an observational comparative trial
- Ethical considerations in observational studies

**Isabel Fonseca Santos**, *Medical Director Bayer Schering Pharma, Bayer Portugal SA*, Portugal

**15:00** Afternoon networking refreshments

**15:30** **Exploring whether companies are required to increase the transparency of studies conducted according to new regulations and policies**

- Examining under which requirements Phase IIIb, Phase IV and Observational studies should be posted at publicly available web-sites (including both negative and positive studies)
- Evaluating the increasing importance of Clinical Trial registrations – EudraCT and [clinicaltrials.gov](http://clinicaltrials.gov)
- Assessing the need for aligned local registry requirements and potential for information exchange across countries

**Merete Jorgensen**, *Project Director, Novo Nordisk*, Denmark

**16:00** **The role of the researcher in Phase IIIb and IV studies as part of a risk management plan**

#### Part 1

- Filling the gaps in safety specification
- Examples of Phase IIIb and IV studies which support risk management
- How can drug utilisation studies support risk management?

**Saad Shakir**, *Professor, Director, Drug Safety Research Unit (DRSU)*, UK

#### Part 2

- Designing Phase IIIb and IV studies for identified and potential risks
- Deborah Layton**, *Principal Research Fellow, Drug Safety Research Unit (DRSU)*, UK

**17:00** Closing remarks from chairperson and end of conference

**Michael Forstner, Ph.D.**, *Integrated Safety Risk Manager, F. Hoffmann-La Roche Ltd.*, Switzerland

## Full day post-conference workshop X: Thursday 15 April 2010

### Risk Management Plans: Practical application

Registration 08:00 - Start 08:30 - Lunch 13:00 - Afternoon start: 14:00 - Finish 16:00. All refreshments are included

#### Aim

- To explore methods used for risk management planning for known and potential risks of a new product, new indication(s), new formulation or use in additional populations(s)
- To optimise research methods to extend safety knowledge to address missing information
- To plan risk minimisation methods when needed

#### Objectives

- To introduce delegates to current challenges in the relationships between Pharmacovigilance plans, risk management and pharmacoepidemiology
- To discuss the design, practical application and methodological development of observational methods including drug utilisation studies as part of Phase IIIb and Phase IV research in support of risk management plans
- To address the methods and examples of risk minimisation

- To analyse challenges faced by marketing authorisation holders and regulators

#### Workshop contents

The workshop will include presentations from highly experienced speakers in the field, question and answer sessions, interactive discussions with feedback, working through real-life case examples (from both facilitators and delegates).

#### Why delegates should attend this workshop:

Persons working in the pharmaceutical industry in clinical drug development, pharmacovigilance or regulatory affairs who already have some experience of risk management planning would benefit in terms of professional learning offered from constructive alignment of past knowledge and exploration of new approaches.

Led by: **Saad Shakir & Deborah Layton**, *Drug Safety Research Unit (DRSU)*, UK  
For further details please see the conference website: [www.informa-ls.com/phase4](http://www.informa-ls.com/phase4)

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