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LATE PHASE DRUG DEVELOPMENT WORLD 2009

1- 4 December 2009, The Bloomsbury Hotel, London, UK

Hear from

Dr Ellen Strahlman
Chief Medical Officer
GlaxoSmithKline

Dr Clive Morris
Medical Science Director
AstraZeneca

Mark Latymer
Scientific Advisor
Pfizer

Amy Sing
Associate Group Director-Post Marketing
Genentech

Professor Markus Kosch
Associate Medical Director
Wyeth Pharma

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

Real life

Driving value in phase IIIb & IV trials

- Hear from and meet leaders in late phase research including: **GlaxoSmithKline, Pfizer, AstraZeneca, UCB Pharma, Wyeth and more** pages 4 and 5 >>
- **Key strategic drivers:** benchmark your strategies against top pharma and biotech companies pages 4 and 5 >>
- **Don't just sit there!** Interactive and flexible agenda with networking opportunities, panel discussions and workshops page 6 >>

Pre & post conference workshops

1 December 2009
Developing and writing a risk management plan

4 December 2009
Effective project management in late phase development

All details page 6 >>

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See page 8

"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.

As a result, Health Network Communications is delighted to announce the **first ever strategic forum addressing the major challenges in conducting strategic and compliant late phase studies.**

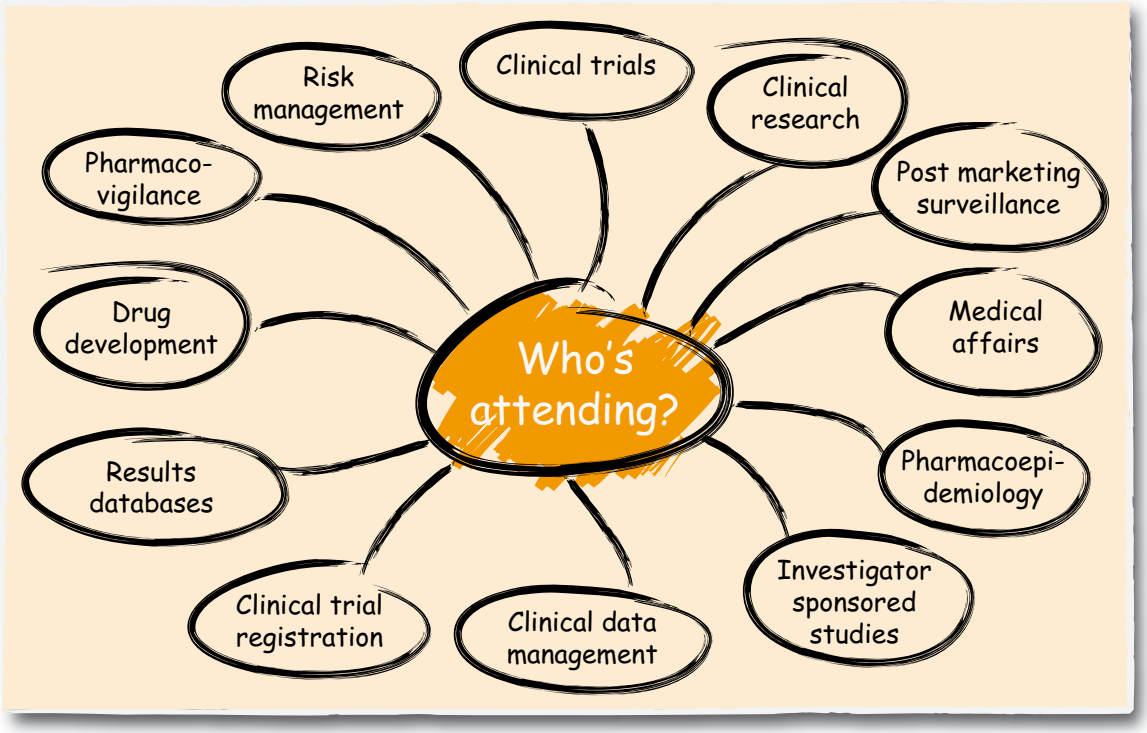
Key issues to be addressed:

- 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
- Analysing and interpreting observational studies – how do you effectively collect, validate and analyse 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?

Interact with industry experts in the Q&A sessions

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: **GlaxoSmithKline, Actelion, Wyeth Pharma, Quintiles, Medidata Solutions, Novo Nordisk, UCB Pharma, Genzyme, Genentech, AstraZeneca, Pfizer & Amylin Pharmaceuticals** 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 2009:*

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

2. GlaxoSmithKline, Pfizer, AstraZeneca, UCB Pharma, 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 programme confronts the topics you want to hear

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

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

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

7. Proven track record! Health Network has a demonstrable track record in delivering high quality well attended events to 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 those 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 industry executives

Challenges and lessons from a large late phase clinical trial in Sub Saharan Africa

Dr Allan Pamba, Director, Clinical Development, **GlaxoSmithKline**

Late phase development of a novel anti-depressant

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

Maintaining pace with the regulators and the evolving industry safety strategies to meet regulatory developments

Dr Rudi Scheerlinck, Director Global Medical Safety & Risk Management, **UCB Pharma S.A.**

IT as an enabler in trial disclosure - how to maintain control in an ever changing world

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

The use of observational research in late phase

Kaisa Taipale, Therapy Lead Oncology, Health Outcomes, Europe, **Eli Lilly & Co**

HTA and late phase development – IQWiG update

Dr Peter Kolominsky-Rabas, former Head of Department, **IQWiG**

Powering post-marketing studies with electronic data capture

Patrick G. Chassaigne, Director, Late Phase Solutions
Medidata Solutions, Inc

Your event contact is
Prithibah Irving
+44 (0) 207 608 7055
pairving@
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 2 December 2009

STRATEGIC DRIVERS

08:30 **Registration & coffee**

09:00 **Opening remarks from the chair**
Dr Jeff Trotter, Principal, **J Trotter Research and Consulting**

09:15 **Keynote: strategic challenges in late phase clinical trials**
This session will look at how industry can 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 Ellen Strahlman, Chief Medical Officer, **GlaxoSmithKline**

09:45 **Strategic planning for a phase IIIb/IV trial**
- Defining the study objectives
- Infrastructure requirements for a flexible trial design in late phase
- Balancing medical need and commercial concerns
- Setting clear endpoints

Alma Rubio, Clinical Operations Manager, Global Medical Science & Communication, **Actelion Pharmaceutical**

10:15 **Non-interventional trials and post-authorisation safety studies: a new perspective in phase IV**
- Non-interventional trials (NIT)
- Post approval safety studies (PASS)
- RCTs vs. NIT – pros and cons
- Sharing best practice

Professor Markus Kosch, Associate Medical Director, **Wyeth Pharma**

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

11:45 **New solutions for a new reality – strategies to design and run cost-effective late phase studies**
Post-Marketing studies are becoming more critical and complex, regulators and payors are becoming more demanding, and resources are tight for this often unplanned research. This session will explore design, statistical and operational strategies to meet regulatory and payor needs in a cost-efficient manner.
John R. Hall, MD, Vice President, Global Medical Affairs, Epidemiology and Outcomes Research, **Quintiles**

12:15 PANEL SESSION **Panel discussion: meeting the challenges in the new post approval environment**
Chair: John R. Hall, MD, Vice President, Global Medical Affairs, Epidemiology and Outcomes Research, **Quintiles**

12:45 **Lunch**

ENABLING TECHNOLOGIES IN LATE PHASE DEVELOPMENT

13:45 **Powering post-marketing studies with electronic data capture**
This session will showcase best practices to implement EDC in post-marketing studies so that sponsors can reap valuable results, including increased site satisfaction and retention, better access to real-time data for analysis and improved decision making. Several case studies will also be presented to illustrate some key benefits obtained through the use of EDC
Patrick G. Chassaigne, Director, Late Phase Solutions, **Medidata Solutions, Inc**

14:15 **IT as an enabler in trial disclosure - how to maintain control in an ever changing world**
- Managing the company's clinical trial information for external disclosure
- Ensuring compliance dealing with many different moving deadlines
- Keeping consistency of the information released to several external websites

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

REGULATORY AND POLICY ENVIRONMENT

14:45 **Maintaining pace with the regulators and the evolving industry safety strategies to meet regulatory developments**
- Industry response to evolving regulatory framework for European and international drug safety

Dr Rudi Scheerlinck, Director Global Medical Safety & Risk Management, **UCB Pharma S.A.**

15:15 **Afternoon tea**

15:45 **Implications of the FDAAA**
This presentation will look at the strategic implications of FDA Amendment Act on late phase strategy
Speaker to be confirmed

16:15 **HTA expectations in late phase development – IQWiG update**
- Use of evidence based information in the decision making process
- IQWiG recommendations and role out
- Method development impacting HTA in Germany

Dr Peter Kolominsky-Rabas, former Head of Department, **IQWiG**

16:45 **Adding value to post-approval research via market access and reimbursement strategic planning**
- How to effectively blend scientific, regulatory, and commercial objectives into study designs
- What 'real world' safety and effectiveness study designs are being requested in today's market place?
- How to leverage 'real world' outcomes data

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

17:15 PANEL SESSION **Panel discussion: how will the increasing regulatory pressure for post marketing data impact the industry?**

17:45 **Closing remarks from the chair**

18:00 **Drinks reception; join your peers and relax with a drink after a busy conference day**

19:00 **End of day one**

Network with your late phase peers during numerous networking sessions

Day Two Thursday 3 December 2009

OBSERVATIONAL RESEARCH AND ITS ROLE IN MARKET DEVELOPMENT

8:30 **Registration and coffee**

08:50 **Opening remarks from the chair**

09:00 **Observational research: areas of consensus and divergence**
- The results from a recent survey on observational research will be presented
- What operational concerns and expectations do sponsors have for observational studies?
- What challenges need to be addressed to optimise observational research?

Dr Jeff Trotter, Principal, **J Trotter Research and Consulting**

09:30 **The use of observational research in late phase**
Kaisa Taipale, Therapy Lead Oncology, Health Outcomes, Europe, **Eli Lilly & Co**

10:00 **Enhancing patient care through disease registries**
- What is a disease registry?
- The regulatory perspective: how do registries contribute to drug development?
- How do disease registries enhance patient care in rare diseases?

Dr Emma James, UK LSD Registry Co-ordinator, **Genzyme Therapeutics**

10:30 **Observational research case study**
This session will look at the challenges confronted in the collection and interpretation of observational data in a post marketing environment for a named therapeutic. Special attention will be given to providing insight that demonstrates real life results regarding safety, efficacy and patient compliance.
Speaker to be announced

11:00 **Morning tea**

11:30 PANEL SESSION **Panel discussion: The implications of post marketing research on the future of drug development**
Chair: Nayan Nanavati, Vice President, Peri-Approval Clinical Excellence, Americas, Clinical Research Services, **PAREXEL International**

OPERATIONAL ISSUES IN LATE PHASE STUDY MANAGEMENT

12:00 **Challenges designing, implementing, analysing and interpreting observational studies in oncology**
- The need for formal comparative effectiveness research in oncology
- Specific challenges in designing naturalistic and longitudinal studies in oncology
- Challenges in collecting data
- Issues with analysing incomplete data sets
- Challenges validating the observations from non-randomised studies

Dr Amy Sing, Associate Group Director-Post Marketing, **Genentech**

12:30 **Lunch**

13:30 **Operationalising a late phase study**
- This session will look at the key scientific and commercial challenges in rolling out a late phase programme

Dr Clive Morris, Medical Science Director, **AstraZeneca**

14:00 **Patient communication strategies for IIIb/IV trials**
- Clearly communicating the studies value proposition to patients
- Reinforcing the message throughout the trial
- The role of educational support material
- How do you improve patient motivation?
- Key learnings

Mark Latymer, Associate Director, IIIb/IV Trials, **Pfizer**

NEW MARKETS

14:30 **Challenges and lessons from a large late phase clinical trial in Sub Saharan Africa**
- Challenge of timely trial enrolment
- Experience with electronic data capture - can it work in Africa?
- Challenge of ensuring collection of quality data
- Trial subjects' safety
- Some results from Trial- Chlorproguanil Dapsone Artesunate [CDA] - 005

Dr Allan Pamba, Director, Clinical Development, **GlaxoSmithKline**

15:00 **Conducting a late phase trial in India**
- What are the opportunities and challenges in running a late phase programme in the subcontinent?

Dr Mohanish Anand, Head Clinical Research, **Pfizer**

15:30 **Afternoon tea**

CASE STUDIES

16:00 **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**

16:30 **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, Director, Clinical Development and Medical Affairs**, Pfizer**

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

17:15 **End of conference**

Get the most from your conference

SPEED NETWORKING

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

contact

Arrange meetings and email conference attendees before you arrive. Access event resources, such as white papers and presentations after you leave.

PANEL SESSION

Meet and ask the panellists 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

4 day Gold pass. **Save up to £563.50** before 11 September 2009!

See Page 8

Pre and post-conference workshops

Tuesday 1 December 2009

Pre conference workshop

Developing and writing a risk management plan

Developing a risk management plan (RMP) can be a complex process, requiring the collation of information from various departments, using complex templates and complying with various guidelines. This workshop will guide you through the process of producing a RMP with opportunities to view differing approaches in industry.

What you will learn;

RMPs provide challenges and it is essential to understand the various issues including the interpretation of signals in the integrated safety summary, gathering external data on background rates of disease, drug use and the clinical management of the disease indication. Emphasis will be placed on the enhanced need to address the quantitative aspects of RMP and risk minimisation. Writing a RMP requires hands-on experience, hence this workshop will allow you to take part in real-life practical case studies and group discussions.

09:00 **Registration & coffee**

09:30 **Introductions and objectives**

09:45 **RMP EU and USA**

10:15 **EU- RM template**

10:45 **Practical case - group learning exercises**

11.00 **Morning coffee**

11:30 **EU- RM template continued**

13:00 **Lunch**

14:00 **Applying epidemiological and signal detection strategies to enhance RM**

15:00 **Practical case - group learning exercises**

15.30 **Afternoon tea**

16:00 **Risk minimisation**

16:30 **Summary and feedback**

Your workshop leader

Nawab Qizilbash, MBChB BSc MRCP(UK) MSc DPhil(Oxon.), Director of **OXON Epidemiology Ltd**

Friday 4 December 2009

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;

- How to optimise 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: anticipating problems, balancing priorities, decision making, managing change and managing 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 & human relations

15:15 **Afternoon tea**

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

17:00 **End of day**

Your workshop leader

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

Book all 4 conference days for maximum content and networking. use our online calculator www.healthnetworkcommunications.com/2009/lsdd

Becoming a sponsor or exhibitor

The 2009 launch of Health Network Communications' *Late Phase Drug Development World* 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 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.

To sponsor or exhibit contact

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Meet and do business with industry decision makers.

"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 at a higher level next year"

Director, **Parexel**

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The venue

The Lutyens-designed Bloomsbury Hotel in Bloomsbury puts the British Museum, Theatreland and Covent Garden within easy reach. Alternatively, browse the bookshops on Charing Cross Road or head for the National Gallery down in Trafalgar Square. Tucked between bustling Tottenham Court Road, gregarious Covent Garden and creative Clerkenwell, Bloomsbury is an enclave of calm contemplation and bookish reserve, right at the heart of the London metropolis.

LATE PHASE DRUG DEVELOPMENT WORLD 2009

Real life

1 – 4 December 2009, The Bloomsbury Hotel, London, United Kingdom

Use our online calculator at www.healthnetworkcommunications.com/2009/lsdd
You can use our online calculator to tailor your ticket and buy multiple tickets.
The calculator automatically selects the most favourable discount for you.
If you book and pay online you also save a further £100

Register now

Package	Before 11 Sept 09	Before 24 Oct 09	Before 14 Nov 09	From 15 Nov 09	How many	Calculate your ticket
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2 main days plus pre conference workshop 1 – 3 December	£1685 + VAT £252.75 = £1937.75	£1870 + VAT £280.50 = £2150.50	£1965 + VAT £294.75 = £2259.75	£2055 + VAT £308.25 = £2363.25	☐	
2 main days plus post conference workshop 2 – 4 December	£1685 + VAT £252.75 = £1937.75	£1870 + VAT £280.50 = £2150.50	£1965 + VAT £294.75 = £2259.75	£2055 + VAT £308.25 = £2363.25	☐	
2 day conference 2 – 3 December	£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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