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# CLINICAL OUTSOURCING WORLD

Europe 2010

2 – 5 February 2010, Victoria Park Plaza, London, United Kingdom

## Hear from



**Julia Santos**

Director, Head of Worldwide  
Strategic Outsourcing  
**Johnson & Johnson**



**Coreen Oei**

Vice President Scientific and  
Clinical Operations, Virtual POC  
Discovery Performance Unit  
**GlaxoSmithKline**



**Janet Edwards**

Director Global Clinical  
Outsourcing  
**AstraZeneca**



**Jacek Nowak**

Executive Medical Director,  
Eastern Europe  
**Amgen**



**Dianne Kikta**

Vice President, Global Clinical  
Strategic Resourcing  
**Wyeth**

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



## Synergy

### The congress for outsourcing executives and decision makers

#### Strategic clinical outsourcing in drug development

Are we there yet? Where are we heading? [page 2 >>](#)

#### Does one size fit all?

Clinical outsourcing strategies from big, medium and small pharma [page 4 & 5 >>](#)

#### Don't sit there!

Flexible attendance options; interactive agenda; unique networking opportunities; panel discussions; workshops; high level brainstorming and much more [page 6 >>](#)

#### Pre & post conference workshops:

**2 February 2010** Contract and cost management  
for outsourced clinical trials

**5 February 2010** Project management of clinical  
outsourced trials

All the details [page 6 >>](#)

Speaker line up – more details [page 3](#)

Full conference programme [pages 4 – 5](#)

Pre & post conference workshops [page 6](#)

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# Innovation and opportunities for your clinical outsourcing strategy

The pharmaceutical industry is operating in an increasingly pressurised, challenging environment with growing demands to drive productivity, speed up time to market, improve efficiency and maintain high level clinical research quality while increasing R&D cost effectiveness. Making the right outsourcing decisions promises to streamline clinical practices, improve development times and efficiency and strengthen weak operational areas. *Clinical Outsourcing World Europe 2010* addresses all of these universal issues and more.

- ✓ Top industry speakers
- ✓ High level speaker seniority
- ✓ Strategy led content
- ✓ Plentiful panel discussions
- ✓ In-depth case studies
- ✓ Extensive networking opportunities
- ✓ Solutions-based discussions

A **strong relationship** is such a critical element for clinical outsourcing success. How have **Amgen and Quintiles** aligned expectations and established such a thriving partnership and what did it take to get there?

**GSK's** use of the **virtual pharma** model for their early phase clinical development is very novel, while in comparison **Solace's** use of the virtual model is more traditional in their smaller pharma setting. Choosing the correct outsourcing model is a potentially challenging and confusing process. What was the decision making process and how successful have these choices been?

### Your issues addressed!

You cannot afford to miss it; every part of the event is designed to benefit you and your outsourcing strategy. The meeting will also address:

- Clinical outsourcing industry trends and global developments
- Assessing the true value of clinical outsourcing for your organisation
- Complexities of effective partner selection and assessment
- Strategic rationale driving the industry's outsourcing choices
- Outsourcing models and styles of contract management
- Assessing partnership efficiency before, during and after the project
- Operational management for the lifecycle of the partnership
- Improving effective relationship management
- International outsourcing approaches including an emerging markets review
- And much more!

### Real experiences from the industry's best

The global downturn has created enormous strain on the industry. What impact has this had on clinical outsourcing? **Wyeth's** Dianne Kikta brings her **unique experience** to bear on these critical issues.

With Asia rapidly developing into an outsourcing hub of choice, how did **Pfizer India** put a clinical trial into operation in the sub continent?

**Outsourcing partnerships** live or die by the quality of information between sponsor and vendor. What practical steps did **Biogen Idex** take to overcome the communication barriers?

“ It was a very positive experience with a lot of interaction ”

Associate Director Clinical Pharmacology Exploratory Development  
**Astellas Pharmaceuticals**

“ Good mix of presentations, discussions and networking ”

Vice President Global Clinical Strategic Resourcing,  
**Wyeth**

“ Very good and stimulating speakers and good panel discussions ”

Regional CRO Consultant, **Lilly Deutschland GmbH**

“ Audience interaction was high ”

Vice President Global Development Operations, **Amgen**

## Industry sectors: pharmaceutical, biotech and CROs



# 8 REASONS

## Why you should attend *Clinical Outsourcing World Europe 2010:*

**35+ industry speakers** Learn from the industry's best including GSK, AstraZeneca, Pfizer, Novartis, Amgen, Johnson & Johnson and many more

**Top quality content** The conference has been built around you and addresses the topics you need to hear about

**Packed agenda** Well over 30 sessions and multiple streams to chose from

**Global viewpoint** Learn about outsourcing in Europe, America, the emerging markets and more

**The conference to match your needs** Conference workshops, extensive networking sessions, panel discussions, case studies, delegate driven discussion and multiple streams for you to tailor the congress to meet your own agenda

**A proven track record** Following the successes of 2008 and 2009, the meeting promises to be bigger and better than ever before

**Extensive networking opportunities** Plan meetings and make contact prior to the meeting with 'contact', utilise 'speed networking' to meet fellow conference participants and continue those conversations into the complimentary evening drinks session

**Case studies** Hear the good, bad and ugly experiences from the industry's best and utilise them to strengthen your outsourcing strategy

## The Health Network difference

Health Network events create exciting places to...

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

use your brain 

## A-list industry experts



Successful outsourcing partnership, what does it take?

**Maria Lynock**, Executive Director, Head of Global Supplier Performance Management, **Amgen**



Risk-shared financing, out licensing and divestiture as approach to clinical outsourcing

**David Rosen**, Head Out Licensing, **Pfizer**



Strategic partnerships - building new relationships

**Yvonne Ulrich**, Head of Operations, Development Strategic Sourcing, **Novartis**



Practical steps to breaking down the barriers between a strategic partner CRO and sponsor during the proposal process

**Andrew Ecob**, Senior Contracts and Outsourcing Manager, International Clinical Business Operations, **Biogen Idec**



Regulatory environment, processes and requirements for outsourcing clinical trials in India

**Arun Mishra**, Associate Director, Worldwide Regulatory Strategy-Emerging Market, **Pfizer**



Small pharma/biotech with a large pharma development program; outsourcing considerations

**Maarten Beekman**, Vice President Clinical Development & Medical Affairs, **NicOx S.A**



Information tools for improving strategic relationships

**Lauren Meyers**, Strategic CRO Leader, Product Development Operations, **Genentech**

“The balance of speakers (regulatory, pharma & CRO) and hearing their different perspectives was great”

Clinical Director of Neurology & Pain, **Allergan Limited**

“ Good diversity & interactive ”  
Assistant Director R&D, **Johnson & Johnson**

## Your event contact is

**Prithibah Irving**  
+44 (0) 207 608 7055  
pairving@healthnetworkcommunications.com

**29**  
**individual**  
**companies**  
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## Day One Wednesday 3 February 2010

## 8.00 Registration &amp; refreshments

## GLOBAL OUTSOURCING DRIVERS AND SOLUTIONS

## 9.00 Opening remarks from the chair

## 9.10 Clinical outsourcing: industry trends and global developments



- Current trends in clinical outsourcing
- Factors influencing outsourcing decisions
- Global changes in clinical outsourcing practices
- Future opportunities for clinical outsourcing

**Dr Dianne Kikta**, Vice President Global Clinical Strategic Resourcing, **Wyeth**

## 9.40 How can strategic outsourcing address the current and future challenges in drug development? The sponsor's perspective



- The challenges facing the pharmaceutical industry have never been higher and there is a critical need for effective outsourcing
- How can the industry partner better, improve cost efficiency and drive time to market?

**Dr Janet Edwards**, Director Global Clinical Outsourcing, Global EPMT Support, **AstraZeneca**

10.10  and morning refreshments

## STREAM 1: STRATEGIC CLINICAL OUTSOURCING

OR

## STREAM 2: CLINICAL OUTSOURCING PERFORMANCE MANAGEMENT

## 11:10 Opening remarks from the chair

## 11.15 What is the true value of clinical outsourcing? Internal vs. vendor capabilities and limitations

**David Gillogly**, Senior Director Pharma Development, **Daichi Sankyo**

## 11.45 The vendor selection process – choosing the right CRO and aligning partnership objectives

**Dr Deven Parmar**, Vice President Clinical Research, **Wockhardt**

## 12.15 Clinical staff resourcing models: are we selecting the best fit?

**Kieran Canisius-Engels**, European Director, Business Development, **DOCS International**  
**Hellen Boering**, Director Clinical Research Resources Management, **Genzyme**

## 12.45 Lunch

## 1.45 Strategic partnerships – building new relationships

**Yvonne Ulrich**, Head of Operations, Development Strategic Sourcing, **Novartis**

## 2.15 Information tools for improving strategic relationships

**Lauren Meyers**, Strategic CRO Leader Product Development Operations and **Jeff Marquis**, Key Account Manager, Product Development Operations Relationships, **Genentech**

## 2.45 Clinical outsourcing financials

**Pasi Piitulainen**, Senior Director, Business & Science Affairs, **Actelion Pharmaceuticals**

## 3.15 Afternoon refreshments

## 3.45 Small pharma/biotech with a large pharma development program – outsourcing considerations

**Dr Maarten Beekman**, Vice President Clinical Development & Medical Affairs, **NicOx S.A**

## 4.15 Outsourcing, insourcing or using internal resources in clinical development – special focus on CEE

**Dr Károly Faller**, Clinical Research Director (Bulgaria, Romania, Russia, Ukraine), **AstraZeneca**

## 11:10 Opening remarks from the chair

## 11.15 Managing your vendor – what are the options for the project team?

**Dr Paul Quinn**, Senior Clinical Programs Director, **Shire Pharmaceuticals**

## 11.45 Relationship management - conditions for building a successful and strong outsourcing partnership

**James Chennells**, Head of Global Strategic Sourcing Pharma Development Services, **Bayer Healthcare Procurement**

## 12.15 Sponsor / service provider collaboration in Quality Risk Management

**Dr Brian O'Neill**, Principal Quality Risk Specialist, External Alliances, **F-Hoffmann-La Roche**

## 12.45 Lunch

## 1.45 Case study: successful outsourcing partnerships, what does it take?

**Maria Lynock**, Executive Director, Head of Global Supplier Performance Management, **Amgen**  
**Richard Butterworth**, Senior Director, Global Sales Global Clinical Research Organization, **Quintiles**

2.15  How do you keep a relationship healthy throughout the lifecycle?

## 2.45 A strategic integrated approach to achieve predictable patient enrolment in clinical trials

**Lollo Eriksson**, Vice President, Start-Up and Accelerated Recruitment Team, **Parexel**

## 3.15 Afternoon refreshments

## 3.45 Efficiency measures in the conduct of exploratory development studies

**Gaby Anthonijs**, Associate Director Clinical Pharmacology, Exploratory Development Department, **Astellas Pharma**

## 4.15 Conducting a clinical trial in India: efficient planning and successful implementation

**Dr Viraj Rajadhyaksha**, Head of Operations Planning and Management, Clinical Research, **Pfizer**

4.45  **Drinks reception** The evening drinks reception is an opportunity to relax and network over drinks with your fellow conference attendees. To sponsor the drinks reception contact Roope Ghosh on +44 (0) 207 608 7037.

## Day Two Thursday 4 February 2010

**8.00 Registration & refreshments****9.00 Opening remarks from the chair****9.10 Risk-shared financing, out licensing and divestiture as approach to clinical outsourcing**

- More creative approaches are needed for drug development over the next decade including the need for drug manufacturers to be increasingly creative about financing
- Options for increasing clinical development output include out licensing clinical programs to small companies with development expertise, creation of new companies or joint ventures around core assets and risk-sharing partnerships
- Advantages to creating new development opportunities

**Dr David Rosen**, Head of Out Licensing, **Pfizer**

**9.40 The effective implementation and use of government models in the management of clinical outsourcing vendors**

- Types of governance models, recent developments and fresh considerations
- Choosing and implementing the right governance process to drive benefits for all participants

**Jennifer Goodfellow**, Senior Director & Global Head Clinical Outsourcing, **Sanofi Pasteur**

**10.10 Emerging countries – how long before we can elevate their status and accept them as full members of the clinical development community?**

**David Passov**, President and Chief Operating Officer, **ClinStar LLC**

**10.40 Morning refreshments****11.10 Revising operating and partnership models to increase efficiency in running clinical trials in Eastern Europe, a view from a sponsor's perspective**

- Eastern Europe: what has changed?
- Re-defining roles in partnership with external vendors
- Looking at the partner selection process
- Validating the model

**Dr Jacek Nowak**, Executive Medical Director, Eastern Europe, **Amgen**

**11.40 Regulatory environment, processes and requirements for outsourcing clinical trials to India**

- Clinical trial regulation and legislation
- Harmonisation of the clinical trial approval process
- Market dynamics and key clinical trial regulatory changes

**Arun Mishra**, Associate Director, Worldwide Regulatory Strategy, Emerging Markets, **Pfizer**

**12.10  What are the benefits and challenges of regional vs. global outsourcing?**

In addition to a selection of our day's speakers hear from:

**Georgi Georgiev**, Clinical Research Manager, **AstraZeneca Bulgaria**

**Manuela Leone**, Head of Global Clinical Development, **Galderma**

**12.30 Practical steps to breaking down the barriers between a strategic partner CRO and sponsor during the proposal process**

- Is the RFP the best tool to communicate with your preferred provider?
- When to do cost comparison: the cost of a project is only the cost of the CRO you choose to run it
- Bid grids as a barrier to communication: why all negotiations need to be based on a common language

**Andrew Ecob**, Senior Contracts and Outsourcing Manager, International Clinical Business Operations, **Biogen Idec**

**1.00 Lunch****2.00 Case study: outsourcing of early phase clinical development activities – perspective from a large pharma virtual group**

- GSK's small expert virtual team progresses projects from target selection to phase 2A PoC mainly through using external CRO partners
- Case studies of outsourcing early phase studies

**Dr Coreen Oei**, Vice President Scientific and Clinical Operations Virtual POC Discovery Performance Unit, **GlaxoSmithKline**

**2.30 Case study: a small pharma's approach to outsourcing global clinical studies**

- Getting it right the first time: why smooth clinical trial implementation is essential for a virtual, venture capital backed pharma company
- Efficient clinical trial design within a small company
- Using specification-led contracting to streamline initial CRO interactions
- Strategies for building effective study team dynamics to ensure consistent global performance

**Dr Kevin Pojasek**, Executive Director, Clinical Development, **Solace Pharmaceuticals**

**3.00 Afternoon refreshments****3.30 Efficient electronic data capture - a possibility or a myth?**

- What is the value proposition for electronic capture?
- Can it be achieved? Can cost and quality be maintained?
- Case history examines these questions and addresses the true cost of EDC

**Jane Clarke**, Assistant Vice President, EDC System, Owner Global Development Support, **Wyeth**

**4.00  High-level relationship building – the key to success**

- R&D trends (marketplace, technical, regulatory, societal)
- Managing relationships across different cultures
- Difficult economic times - what can be done to drive innovation and value creation

**Julia Santos**, Worldwide Associate Director, Strategic Outsourcing, **Johnson & Johnson**



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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.



Meet and talk about the business issues on your brain.



An opportunity to relax and network over a few drinks with your fellow attendees.



Join at least one of the workshops. A relaxed environment for you to network with your peers and focus topical issues.

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See page 8.

## Pre & Post Conference Workshops

### Tuesday 2 February 2010

#### Contract & cost management for clinical outsourcing

This workshop encourages open discussions with industry experts and fellow professionals about the key considerations for the effective management of cost and contracts in clinical outsourcing.

##### 9.00 Defining desired outcomes

- Cost
- Quality
- Time
- Communication
- Clarity

##### 10.00 Morning tea

##### 10.30 Relationships matter

- One night stand
- Master & slave
- Preferred providers
- Partnerships

##### 12.00 Lunch

##### 1.00 An outcomes driven process

- Defining value
- Contract types
- Cost models
- Tracking spend

##### 1.30 Continuous improvement

- Key performance indicators
- Who measures what and when?
- Responding to outliers
- Using experience to improve performance

##### 2.00 Afternoon refreshments

##### 2.30 The clinic

This is intended as an opportunity for attendees to raise any questions that have not been covered in the workshop for which they seek a solution.

#### Your workshop leader:



**Richard Barrett**, Managing Director, Contract & Outsourcing Services Ltd

Richard is a Biomedical Scientist with more than 30 years experience in international pharmaceutical development and has held senior positions in Non-Clinical Toxicology, Safety, Quality, Outsourcing, Process Development and Marketing in both contract and major international pharmaceutical companies including Covance, SmithKline & French and Pfizer.

His experience in outsourcing scientific services led Richard to form an independent consultancy focusing on the development of internal organisational structures and processes to support outsourced work.

#### Additional contributors:

**Hasse Kromann**, Outsourcing & Contract Manager, Genmab  
**Lan Bandara**, Associate Director Contracts, Eisai

### Friday 5 February 2010

#### Project management of outsourced clinical trials

The day's objective is to develop a methodology for managing contractors in complex clinical development programmes.

The day will be a mix of short lectures, plenary and group discussions and structured exercises. In addition to the key topics listed, the day's agenda will be driven by you, as we invite you to list top project management challenges with outsourced clinical trials prior to the day.

##### 09:00 Registration and coffee

##### 09:30 Project management basics

- Agreeing what you want from your vendors
- Working relationships with vendors

##### 11:00 Morning refreshments

##### 11:30 Optimal contract planning

- What matters, work or results?
- Where do the numbers come from?
- Estimates you can believe

##### 12:30 Lunch

##### 13:30 Risk management

- Alternative approaches to managing risk
- Managing change

##### 15:00 Afternoon refreshments

##### 15:30 Project management

- Project control – who does it, client or vendor?
- Project completion and hand over to the client
- Participants' action planning

#### Your workshop leader:



**Les Rose**, Director and Consultant, Pharmavision Consulting Ltd

Les has over 35 years experience in the pharmaceutical industry. His early career was with multinationals as a CRA and Clinical Research Manager, after which he established his own contract research and training organisation for over 12 years. He moved into freelance consultancy almost 10 years ago, and his workload is a mix of interim project management, writing, training and consulting. His clients include CROs from small to global, various other service companies, and pharmaceutical companies of all sizes, most of whom contract out their clinical trials. He is a Fellow of the Institute of Biology, a Fellow of the Institute of Clinical Research, and a full member of the Association for Project Management.

# Sponsorship & exhibition opportunities

The 3rd annual *Clinical Outsourcing World Europe 2010* is where you will provide the solutions for the problems pharma and biotech companies face. **Make yourself 'front of mind' to key decisions makers in all aspects of outsourcing.** With an unrivalled faculty of 35+ industry speakers and regulators over the 4 days you won't find another event to equal this. This strategic event follows 2 years of successful outings and has received interest from large and small CRO's alike; the event has successfully been used as a platform to launch new CRO's in previous years and continues to do so.

## Questions to determine your involvement

1. Do you want to do business with senior decision makers from the leading pharmaceutical and biotechnology companies?
2. Do you offer outsourced solutions in clinical research and development?
3. Are you actively looking for new leads and clients to work with?

If your answer is yes, this event delivers:

- 75% senior professionals from pharmaceutical & biotech companies
- 10 hours of networking time
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**A limited number of sponsorship and exhibition opportunities exist for outsourced solution providers.** We will profile your brand as industry leaders, help you create new partnerships and strengthen existing relationships in the industry. This is your best chance of conducting business in the increasingly lucrative clinical outsourcing industry – can you afford not to be there?

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Meet and do business with industry decision makers.

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## The venue



The four-star, deluxe Park Plaza Victoria London hotel offers guests superior accommodations and friendly, professional service in a prime location. The hotel in London is centrally located just two minutes from Victoria Station and is within easy walking distance of some of London's main tourist attractions, including Buckingham Palace, Harrods, Westminster Abbey and Houses of Parliament.

“Good size... many delegates were people whom I would have targeted myself”  
Business Development Manager, **Tepnel**

“Good mix of delegates – The speed networking was brilliant”  
Business Development Manager, **LCG Bioscience**

“We want to make Trilogy better known in the world of outsourcing... We are meeting exactly the people you said we would and making valuable contacts”  
Managing Director, **Trilogy Writing**

**Something to say?**  
Talk to us about speaker opportunities  
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# CLINICAL OUTSOURCING WORLD

Europe 2010

Synergy



2 – 5 February 2010, Victoria Park Plaza, London, United Kingdom

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2 main days plus post conference workshop 3 – 5 February	£1800 + VAT £270 = £2070	£2000 + VAT £300 = £2300	£2100 + VAT £315 = £2415	£2200 + VAT £330 = £2530	<input type="checkbox"/>	
2 day conference 3 – 4 February	£1215 + VAT £182.25 = £1397.25	£1350 + VAT £202.50 = £1552.50	£1420 + VAT £213 = £1633	£1485 + VAT £222.75 = £1707.75	<input type="checkbox"/>	

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All tickets include refreshments, lunch and full conference documentation. The fee does not include hotel accommodation.

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