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CLINICAL OUTSOURCING WORLD

Europe 2009

27 - 30 January 2009, Earls Court Conference Centre, London, United Kingdom

Hear from



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



Adrian Otte,
Vice President Global
Development Operations,
Amgen



Doug Price,
Global Procurement Lead,
AstraZeneca



David Rosen,
Executive Director Worldwide
Business Development
Alliances, **Pfizer**



Gangadhar Sunkara,
Associate Director
Translational Sciences and
Lead Coordinator TS India
Business Strategy, **Novartis**

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

Synergy



The congress for outsourcing executives and decision makers

Strategic outsourcing drug development

Are we there yet? Hear from thought leaders [page 4>>](#)

Does one size fit all?

Hear from big, medium and small pharma & biotech [page 4 & 5>>](#)

Don't just sit there!

Interactive & flexible agenda with unique networking opportunities,
panel discussions, workshops and high level brainstorming [page 6>>](#)

Pre-conference workshop: 27 January 2009

Increasing pharma-CRO partnership's success using
value analysis and deliverable budgets

Post-conference workshop: 30 Jan 2008 30 January 2009

Project management of outsourced clinical trials

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

Speaker line up – more details	page 3
Full conference programme	pages 4 - 5
Pre-conference workshops	page 6
Sponsorship & exhibition	page 7

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"Very
comprehensive"**Johan Luthman**
Exploratory
Medicine,
MerckSerono"Very well
organised and
very interesting
speakers"**Tilly Sharp**
Project Manager,
Total Scientific"Good list of
topics & well
managed"**Priya Govekar**
Senior Regulatory
Affairs Associate,
UCB CelltechBring your team
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page for details

Productive partnerships: stronger together

Outsourcing plays a crucial part in clinical R&D. All major drug development projects rely on one or more partners to aid the passage of successful therapeutics to market. The

question to answer is not "should we outsource?" but "what should we outsource?"

Making the right outsourcing decision for your business promises to streamline clinical R&D practices by improving development times, increasing efficiency and strengthening weaker operational areas. A poorly chosen or ill-managed partnership is destined to be a burden on both sponsor and vendor and place a huge strain on stretched resources.

The 2nd annual *Clinical Outsourcing World Europe* 2009 addresses all the key strategic and operational considerations that you need to ensure you make the right decision when entering into an outsourcing partnership. *Clinical Outsourcing World Europe* 2009 promises to be even better than 2008! One year on from the brilliantly received inaugural event, we bring you an agenda packed with a larger speaker panel, more sessions, wider-reaching content and additional specialist networking opportunities with the key decision makers that you need to meet. The packed four-day event brings together top pharmaceutical, biotechnology and CRO representatives in a forum that will tackle the crucial challenges faced by the industry. Through a number of case studies, industry experiences will be given on the development and management of outsourcing partnerships and will identify the criteria that can be implemented to overcome challenges and strengthen your outsourcing strategy.

***Clinical Outsourcing World Europe* is focused on the topics you need to hear!**

Extensive industry research with senior representatives from the global clinical outsourcing industry has clearly identified the core challenges and areas of interest that need airtime and discussion in January. Below are some of the hot topics that will be the focus of the event:

- The strategic rationale driving the choices the industry needs to make
- Assessing the efficiency of the partnership before, during and after the project
- What can be done to improve strategic partnerships used in the clinical outsourcing process?
- Expansion of available partnership models and styles of contract management
- Working with the increasing complexity in the operational management and culture of outsourced clinical projects
- Improving partnering and driving effective relationship management
- Choosing and implementing off-shoring opportunities to improve operations
- Practicalities of the globalisation of the pharmaceutical industry and running trials in emerging and low cost countries
- How to improve overall R&D efficiency and performance using outsourcing & offshoring

Industry sectors: pharmaceutical, biotech and CRO



8 REASONS

8 reasons why you should attend *Clinical Outsourcing World Europe 2009*:

Top notch speaker panel Hear insights into the industry from our expert speaker panel which includes some of the top pharmaceutical and biotech representatives!

Packed agenda We have over 30 sessions confirmed so far, keep track on our website as this number looks set to grow

Quality of content We listened to you and your peers to ensure our programme confronts the topics you want to hear...and no sales pitches!

Wide global reach We have representatives from Europe, America and Asia to give a much needed view of international operations

Pre and post conference workshops, focused networking sessions, panel discussions, delegate driven discussion sessions and four streams Tailor the packed congress to meet your own information and networking needs

A proven track record continuing from our success in 2008 this event promises to be bigger and better

Extensive networking opportunities Plan who to meet and arrange meeting before the conference with 'the contact system', take part in 'speed networking' to meet more people in less time and continue those conversations into the complimentary evening drinks session

Case studies Hear industry experiences from top pharma, biotech and CROs and utilise them to strengthen your own 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 of industry experts

Clinical Outsourcing World Europe brings together a record number of health policy experts.



Outsourcing Phase I healthy volunteer studies: the good, the bad and the ugly

Larry Blankstein,
Senior Director, Clinical Research,
Genzyme



Ensuring the project runs smoothly: project management and SMOs

Marion Leibbrandt,
Clinical Project Manager, **Baxter**



Clinical Outsourcing Considerations for the biotechnology industry

Guy Holliday,
Director, Supplier Governance,
Amgen



Quality risk management of outsourced trials

Brian O'Neill,
CQA Management External Alliances,
F. Hoffman La Roche



Pharma / CRO relationships

Rikke Winther,
Head of Outsourcing Management,
H. Lundbeck A / S



Case study: the road to the use of CRO preferred provider solutions

Paul Quinn,
Senior Clinical Programs Director,
Shire Pharmaceutical



Costing commercial contract research - the UKCRN Industry Costing Template

Clare Morgan,
Director of Industry,
UKCRN

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

Sam Kerk,
Clinical Director of Neurology & Pain,
Allergan Limited

"Good diversity & interactive"

Jean Penson
Assistant Director R&D, **Johnson & Johnson**

Your event contact is **Karen Williams**
+44 (0) 207 608 7056

kwilliams@
healthnetworkcommunications.com

25 industry representatives confirmed on our speaker platform

Day One Wednesday 28 January 2009

GLOBAL OUTSOURCING DRIVERS AND SOLUTIONS

08.45 Registration & coffee

09.15 Opening remarks from the chair

09.30 How can strategic outsourcing address the current and future challenges in drug development? An industry perspective;

- The need for effective outsourcing strategies
- Partner better, lower R&D costs & increase speed

Dr Adrian Otte, Global Development Operations, Amgen

10.00 Clinical outsourcing state of play: industry trends and developments driving drug development partnerships

- Building effective partnerships in a challenging environment
- Learning from strategic outsourcing in other business sectors

Doug Price, Global Procurement Lead, AstraZeneca

10.30 Morning coffee

11.00 Outsourcing models: is there room for innovation?

- Is your outsourcing approach aligned with your development strategy?
- Can innovation change how the industry is working?

Pasi Piitulainen, Director Global Clinical Development Affairs, Actelion Pharmaceuticals

11.30 Options available for pharma in progressing clinical development programs and the development of parallel clinical development portfolios

- Advancing R&D portfolios using partnering options and business structures
- Sharing risk and reward in partnering R&D portfolios

David Rosen, Executive Director, Worldwide Business Development, Pfizer

12.00  **PANEL SESSION** Strategic outsourcing in drug development; are we there yet?

12.30 Lunch

Stream 1: STRATEGIC OUTSOURCING

OR

Stream 2: CLINICAL OUTSOURCING PERFORMANCE MANAGEMENT

1.30 Opening remarks from Quintiles

1.40 How can strategic outsourcing address the current and future challenges in drug development? A CRO perspective;

- How has the pharmaceutical services community responded to industry challenges?
- What is the true value of a strategic partnership with a CRO?
- How will the industry-CRO relationship change as global studies increase?

James Featherstone, Vice President, Quintiles Consulting

2.10 India case study 1: clinical trials outsourcing to India planning for the decade ahead

- Success stories from global trials outsourced to India, contributing factors and improving efficiencies

Kamala Rai, Head Clinical Development, Novartis India

2.40 Ensuring quality with service providers - inspections and case study examples

Jacqueline Marovac, Global Clinical Project Manager, UCB Pharma

3.10 

4.00 Key legal issues and trends in global clinical outsourcing

- When should powers of attorney be given?
- Warranties and undertakings: does your CRO have the experience & how to cover your company legally?

Leigh Hanif, Senior Legal Counsel, Sanofi-Aventis

4.30 Quality risk management of outsourced trials


- Risk management processes vs. traditional auditing
- Increasing efficiencies in quality management of CRO's
- Can sponsors & service providers collaborate to minimise duplication of effort in quality management?

Dr Brian O'Neill, CQA Management External Alliances, F-Hoffmann-La Roche

5.00 Assessing the true value of clinical outsourcing

- Outsourcing vs. in-house
- What to outsource - piecemeal or full-service and its effect on value
- Decisions for the short and long-term

Adam Ruskin, former Director Clinical Research & Operations, Maxygen, President of FocusMonitors.com

5.30  Drinks reception

1.30 Opening remarks from the chair

1.40 Relationship management: conditions for building a strong partnership

- Good relationships; how can they boost your business?
- Opening communication routes and trust building

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

2.10 Clinical outsourcing relationship management

- Aligned objectives between sponsor and CRO/vendor
- Interactive relationships, shared responsibility and transparent communication

Gaby Anthonijs, Associate Director Clinical Pharmacology Exploratory Development, Astellas

2.40 Outsourcing considerations for virtual and small companies

- Outsourcing trials by small or virtual pharma
- How do small pharma / CRO relationships & cooperation vary from those of big pharma?

Frank Henke, Head of Clinical Operations, Elbion GmbH

3.10 

4.00 Pharma / CRO relationships

- Key elements of success...and failure
- Setting the scene, expectations and teamwork
- Preferred providers - create the value!

Rikke Winther, Head of Outsourcing Management Corporate Project Management R&D, H. Lundbeck A/S

4.30 Case study: experience of mid-sized pharma in the cooperation with CROs


- Grünenthal's latest clinical outsourcing experiences and the operational considerations for a mid sized organisation

Uwe Schneider, Global Head of Sourcing Management, Grunenthal

5.00 Ensuring the project runs smoothly: project management and SMOs

- Skills & challenges
- Learning to manage the CRO's managers
- Managing the project timelines

Marion Leibbrandt, Clinical Project Manager, Baxter

5.30  Drinks reception

Day Two Thursday 29 January 2009

MORNING PLENARY

08.45 Registration and coffee

09.15 Opening remarks from the chair

9.30 Clinical outsourcing considerations for the biotechnology industry

What additional considerations are required during clinical outsourcing partnerships with biotechs?

Guy Holliday, Director SPM, Amgen

10.00 Implementing off-shoring strategies into your business model off shoring data management in India

- Review of Eisai's move to offshore data management to India
- The major considerations for assessing the sourcing options available, the model used, how this was finally implemented and lessons learnt.

Lan Bandara, Associate Director Contracts, Eisai

10.30 Creating a clear and transparent process for costing industry contract research

- The UKCRN Industry Costing Template: calculates the prices associated with commercial contract research
- Using the template to speed up the initiation of commercial contract trials by reducing the time required for site-by-site negotiations

Dr Clare Morgan, UKCRN Director Industry, UKCRN

11.00 Morning tea

11.30 Clinical outsourcing; what can we learn from other industries?

- How has outsourcing been integrated into other industries and improved business operations?
- What lessons can be utilised in the pharmaceutical industry?

Audra Nichols, Global Strategic Sourcing Leader, PriceWaterhouseCoopers

Stream 1: STRATEGIC OUTSOURCING

OR

Stream 2: CLINICAL OUTSOURCING PERFORMANCE MANAGEMENT

12.00 Opening remarks from the chair

12.10 India case study 2: early development clinical trials in India

- Strategic and operational factors for conducting and managing early phase clinical trials in India will be reviewed

Gangadhar Sunkara, Associate Director Translational Sciences and Lead Coordinator TS India Business Strategy, Novartis Pharmaceuticals

12.40 Vendor selection in outsourced trials navigating clinical trial outsourcing from within a biotech start-up

- Cost effective and timely clinical proof of concept through clinical outsourcing within a venture capital-backed biotech start-up
- Solace case study; how a "virtual" yet multinational structure and mission command operating principles aid in clinical trial outsourcing
- Get it right the first time and build lasting partnerships with CRO's - RFP's and contracts

Kevin Pojasek, Senior Director Development Programs Leader, Solace Pharmaceuticals

12.00 Opening remarks from the chair

12.10 Outsourcing Phase I healthy volunteer studies: the good, the bad and the ugly

- Protocol design impact on CRO selection
- Factors to consider in selecting a Phase I Unit and support services
- Organising your service and provider team for success
- How to optimise your team's performance

Dr Larry Blankstein, Senior Director of Clinical Research, Genzyme

12.40 Ensuring quality in clinical trials already in the contracting phase


- What to take into account when contracting
- Different contract types and their quality aspects
- Practical considerations regarding each contract type

Anne Marie Ylissari, Head of In and Outsourcing, Orion Pharma

AFTERNOON PLENARY

1.10 Lunch

2.10 Opening remarks from the chair

 **This is your opportunity to create your own conference agenda to be discussed at the second day of conference.**

2.50 Optimising time and money in clinical trials - patient recruitment in Russia, Ukraine and Belarus

- What are the benefits of running outsourced trials in this region?
- What is the current environment for recruiting patients in this region?
- Key criteria for a successful partnership

David Passov, President and COO, ClinStar LLC

3.20 Case study: the road to the use of CRO preferred provider solutions

- Move from the use of full-service CROs to niche providers for many services such as labs, clinical services, data management and statistics, ECGs
- Resulting need to review bids, assess and manage many CROs with the associated resource burden
- Shire's move to preferred providers for biometrics and pharmacovigilance activities identified allowing work to be allocated

Paul Quinn, Senior Clinical Programs Director, Shire Pharmaceuticals

4.20 Closing remarks

4.30 Afternoon tea and end of conference

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Meet and talk about the business issues on your brain.



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4 day Gold Pass.
The earlier you book the more you save.
See page 8.

Pre and post-conference workshops

Tuesday 27 January 2009

Increasing pharma-CRO partnership's success using value analysis and deliverable budgets

9.00 Registration & coffee

MORNING SESSION

Contracting issues

- Tactical
- Strategic
- Principal agent theory

10.30 Morning tea

Current contract types

- Fixed
- Fixed unit priced
- Variable

12.00 Lunch

AFTERNOON SESSION

Planning

- Key performance indicators
- Deliverables (exercise in defining deliverables)
- Metrics
- Identifying risk
- Defining project success
- Identifying stakeholders

Earned Value Analysis (EVA) using deliverable budgets

- History of EVA
- Mapping task related budgets to deliverables
- Measuring project performance using EVA.

2.30 Afternoon tea

Other uses of deliverable budgets

- Comparing CRO prices
- Accruals
- Income recognition
- Forecasting
- Payment schedules

Your workshop leader



Roger Joby, Managing Director, **1to1to1**

Roger has extensive know-how of the pharmaceutical industry with over 30 years experience ranging from the areas of clinical operations, project management, proposal generation and third party contracts at all levels. He has experience working for a number of major pharmaceutical companies and CROs and now works as an independent consultant with proficiency in value. Roger also undertakes: Risk Analysis, Project Pricing, Forecasting, and Stakeholder analysis.

Friday 30 January 2009

Project management for outsourced clinical trials

9.00 Registration & coffee

MORNING SESSION

Effective Project Management

10.30 Morning tea

Contracts for success

12.00 Lunch

AFTERNOON SESSION

Project Team dynamics

Project Progress Monitoring

2.30 Afternoon tea

Project Management Risk in a clinical context

Objectives

To provide a stimulating update on Project Management for outsourced clinical trials

This workshop includes presentations and interactive sessions.

Your workshop leader



Bodiam Consulting Limited

Keith is CEO of Bodiam Consulting Limited and an accomplished director, Consultant, Senior

Executive and Project Management professional with an MBA and a background gained primarily within the pharmaceutical, biotechnology, diagnostic, device and packaging sectors over 25 years, 20 of these working for Wellcome and Glaxowellcome. His range of expertise includes vision, strategy, and professional project management. He has provided strategic consulting to project management groups, which has included Enterprise Portfolio and Project Management systems, and delivered complex projects both within budget and to tight time scales.



U Turn is your turn. Because your knowledge and experience is important to us, this is where you select the topic and the presenters for a session.

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Sponsorship & exhibition information

Clinical Outsourcing World Europe 2009 is where pharmaceutical, biotech and contract research organisations will come to streamline processes aiding taking drugs to market.

This conference will attract a significant gathering of leaders, decision makers and influencers in outsourcing and operations. Our delegates will be looking for guidance, answers, and new business relationships, representing a significant and exceptional business opportunity.

You will increase your chances of becoming a clinical development partner

Questions to determine your involvement?

Q 1. Do you want to do business with senior decision makers from the leading pharmaceutical and biotechnology companies?

Q 2. Do you offer outsourced solutions in clinical research and development?

Q 3. Would it be cost & time effective to meet multiple prospects at one venue over a couple of days?

If your answer is yes to these questions you should be participating in this event.

Who has attended this event in the past?

The January 2008 conference attracted over 150 attendees, of these, close to 60% were from pharmaceutical and biotech organisations. 50% of this was made up of Outsourcing / Sourcing and Contract Managers / Business Development Managers, a further 15% were Chief Executive Officer / President and Vice President level. We consistently attract the key decision makers in this industry and are confident of repeating this success in 2009.

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ClinStar is an American CRO which was founded in 1999 and which manages clinical trials in Russia, Ukraine, Belarus and the Baltic States. We have 250+ employees spread throughout our offices in Moscow, St. Petersburg, Kiev, Minsk and San Francisco.

Media partners



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"Well represented by both pharma, biotech and CRO executives. Healthy exchange of ideas and strategies for meeting clinical business objectives"

Frank J. Cattie,
Vice President,
Fast Track Systems

"Quality presentations by industry leaders. Good chance to network. Good coverage of hot issues on the agenda.."

Rainer Lenz, VP
Finance, **Actavis**

Something to say?

Talk to us about speaker opportunities

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CLINICAL OUTSOURCING WORLD

Synergy

Europe 2009

27 - 30 January 2009, Earls Court Conference Centre, London, United Kingdom



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Package	Before 04 Nov 08	Before 16 Dec 08	Before 06 Jan 09	After 13 Jan 09	How many	Calculate your ticket
Gold pass – all 4 days 27 – 30 January 2009	£2337.30 + VAT £409.03 = £2746.33	£2497 + VAT £436.98 = £2933.98	£2547 + VAT £445.73 = £2992.73	£2597 + VAT £454.48 = £3051.48	<input type="checkbox"/>	
2 main days plus pre conference workshop 27 – 29 January 2009	£1798.20 + VAT £314.69 = £2112.89	£1898 + VAT £332.15 = £2230.15	£1948 + VAT £340.90 = £2288.90	£1998 + VAT £349.65 = £2347.65	<input type="checkbox"/>	
2 main days plus post conference workshop 28 – 30 January 2009	£1798.20 + VAT £314.94 = £2112.89	£1898.20 + VAT £332.15 = £2230.15	£1948 + VAT £340.90 = £2288.90	£1998 + VAT £349.65 = £2347.65	<input type="checkbox"/>	
2 day conference 28 – 29 January 2009	£1259.10 + VAT £220.34 = £1479.44	£1299 + VAT £227.33 = £1526.33	£1349 + VAT £236.08 = £1585.08	£1399 + VAT £244.83 = £1643.83	<input type="checkbox"/>	
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2. Should you wish to cancel completely a charge of 50% of the registration fee, plus £150 (+ VAT) administrative charge will be made for cancellations received in writing at least 30 days prior to the conference start date.
3. Alternatively, you may choose a letter of credit for the full value of the registration price (valid for 1 year), which may be put towards another Health Network Communications event.
4. The company regrets that no cancellations will be accepted within 30 days of the conference start date. Prepayments will not be refunded and invoiced sums will be payable in full, except in cases where it has been possible to mitigate loss.
5. Course documentation will, however be made available to the delegate. Health Network Communications reserves the right to alter the programme without notice.

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