CLINICAL OUTSOURCING WORLD Americas 2008

21 - 23 October 2008, Hilton Philadelphia City Avenue Hotel, Philadelphia, United States

Key speakers include

Dr Kenneth Kaitin
Director
Tufts CDSS

Dr Janet Edwards
Director of Global Clinical Outsourcing
AstraZeneca

Dr Amrit Ray
Vice President of Medical Safety Global Medical Affairs and Pharmacovigilance
Bristol-Myers Squibb

Dr Adam Ruskin
Director of Clinical Research and Operations
Maxygen, Inc

Dr Mark Evans
Executive Director of Clinical Research Operations US
Merck

Dr Fred Naids
Senior Strategic Sourcing Director
Shire Pharmaceuticals

Dr William Haddad
Chief Executive Officer
Biogenerics

Dr Dianne Kikta
Vice President of Global Clinical Strategic Resourcing
Wyeth

Driving development through outsourcing

- Gain insight on how to improve your global outsourcing strategy: hear the latest developments from global industry leaders
- Strengthen relationships: benefit from case studies of successes and failures
- Expand your horizons: outsourcing strategies outside pharma
- Drive your business forward: implement novel and profitable strategic alliances
- Address the major challenges for outsourcing biotechnology and biosimilars: how you can excel in this complex arena
- Plus fantastic networking opportunities with a programme built around enabling you to meet peers, share knowledge and do business

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Driving development

Productive partnerships: stronger together

Outsourcing remains a critical aspect of clinical development. All major drug development projects rely on one or more partners to aid the passage of successful therapeutics to the market. The question is not "should we outsource?" but "when should we outsource?"

Utilizing these solid partnerships during clinical trials can streamline the process as it improves development times and efficiency, as well as strengthen weaker operational areas. However, the increased burden stemming from a poorly chosen or ill managed partnership can be felt on both sides and place a huge strain on stretched resources.

Clinical Outsourcing World Americas addresses all the key strategic and operational considerations that you need to make the right decision when entering into a partnership. Following a triumphant launch in Europe, *Clinical Outsourcing World Americas* is set to parallel this success in the US. The three day event brings together top pharmaceutical, biotechnology, academic and CRO representatives in a forum that will tackle the crucial challenges as highlighted by the industry. The comprehensive agenda tackles broad ranging topics including sourcing factors, available partnership models, globalization of clinical trials, contractual and legal matters as well as relationship management techniques.

Clinical outsourcing: critical issues to be addressed

- Improving strategic partnerships in the clinical outsourcing process
- Assessing the true value of clinical outsourcing
- Complexities of effective partner selection and assessment
- Expansion of available partnership models and styles of contract management
- Increasing complexity in the operational management and culture
- Improving partnering and driving effective relationship management
- Balancing out the strengths and weaknesses of patient enrolment in developed and developing economies
- Choosing and implementing off-shoring opportunities to improve operations
- Practicalities of the globalization of the pharmaceutical industry and running trials in emerging and low cost countries

healthnetwork COMMUNICATIONS Health Network Communications is an international events company dedicated to providing conferences, training courses and seminars for the life science community. Through our network of advisors in industry, academia and the regulatory authorities, we are able to develop quality events that discuss and find solutions to some of the most pressing issues in the life science sector today. For further information please visit www.healthnetworkcommunications.com

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>
> **Frank J. Cattie,**
> Vice President, **Fast Track Systems**

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08.30 **Registration & coffee**

08.50 **Opening remarks from the chair**

GLOBAL OUTSOURCING DRIVERS AND SOLUTIONS

09.00 **Clinical outsourcing state of play: industry trends and developments driving drug development partnerships**
- Industry overview, challenges, business models, drive for productivity improvements, evolving marketplace, budget management & delivering value
- How do you determine the scope of outsourced studies?
- Evolution of relationships

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

09.30 **Industry trends in clinical outsourcing**
- What are the economic and regulatory drivers of change for drug developers today?
- What are current drug development metrics on times, costs, and risks?
- How can clinical outsourcing and offshoring improve R&D efficiency and performance?

Dr Kenneth Kaitin, Director, **Tufts CDSS**

10.00 **Review of the CRO industry: a financial analyst's perspective**
- Key trends of the pharmaceutical and CRO industry: past and future

David Windley, Managing Director Healthcare Equity Research, **Jefferies & Company**

10.30 **Morning tea**

11.00 **How can strategic outsourcing address the current and future challenges in drug development? An industry perspective**
- What are the key challenges for the industry?
- Strategic vs. tactical
- Program outsourcing vs. study outsourcing
- Is functional outsourcing a thing of the past?

Fred Naids, Senior Strategic Sourcing Director, **Shire Pharmaceuticals**

11.30 **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?

Badhri Srinivisan, Vice President Enterprise Transformation Unit, **Quintiles**
Adrian K. McKemey, BSc, PhD Practice Leader, Product Development and Commercialization, U.S., **Quintiles Consulting**

12.00 **Clinical outsourcing considerations for the biotechnology industry**
- Additional considerations stemming from the increased complexity of biological products R&D partnerships
- Moving from a service only to a strategic partnership: advantages for biotechs
- How to identify your key needs from a partnership and ensuring your vendor can provide solutions to these

Dr Adam Ruskin, Director Clinical Research & Operations, **Maxygen**

12.30 **Panel discussion: strategic outsourcing in drug development: are we there yet?**
Have your say and hear from a selection of the keynote speakers in this interactive discussion session as they view their thoughts on the hot topics of the morning.

13.00 **Lunch**

STREAM I

STRATEGIC OUTSOURCING

14.00 **Financial considerations for clinical outsourcing**
- Standard processes and considerations when submitting the RFP
- Budgetary considerations when entering into a partnership

Visit website for full speaker list

14.30 **Performance metrics in outsourced clinical trials**
- Determining what is important to measure in a pharma-CRO relationship
- Using metrics to decrease risk and increase the probability of success

Dave Zuckerman, President, **Customized Improvement Strategies**

15.00 SPEED NETWORKING

15.45 **Afternoon tea**

16.15 **Vendor selection in outsourced trials**
- Clinical outsourcing considerations
- Outsourcing vendor requirement
- Establishing worthwhile partnerships

Dr Sylvester Wilkins, Sourcing Group Manager, **GlaxoSmithKline**

16.45 **Sourcing models for clinical trials**
- Pros and cons of global CROs vs. networks
- Financial incentives and risk sharing
- Relationships management for each model

John Farinacci, President and CEO, **ResearchPoint**

17.15 **Closing remarks from the chair**

17.30 **Networking drinks reception**

STREAM II

CLINICAL OUTSOURCING PERFORMANCE MANAGEMENT

14.00 **Case study: successful relationship management**
- Establishing the partnership: resources, communication, SOPs, challenges
- Relationship progression: changes to workload assignment, co-management of territories, interaction/ communication changes
- Current relationship: communication changes, region overlay, external sourcing, increasing governance

Dr Mark Evans, Executive Director Clinical Research Operations US, **Merck**
Michele Ingram, Director Merck Kforce Alliance, **Kforce**

15.00 SPEED NETWORKING

15.45 **Afternoon tea**

16.15 **Outsourcing considerations for small and mid-sized pharma**
- Operational models, vendor selection, contracts, management and infrastructure

Dr Uwe Schneider, Global Head of Sourcing Management, **Grunenthal**

16.45 **Contractual considerations**
- Available contract model insight: choosing the right contract model for you
- Contract management: eliminating mismatched partnership expectations at project launch to ensure the smooth running of a project

Visit website for full speaker list

17.15 **Closing remarks from the chair**

17.30 **Networking drinks reception**

Driving development

08.30 **Registration & coffee**

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

09.00 **Implementing off-shoring strategies in your business model**
- Case study: new pharmaceutical sourcing models in pharmacovigilance
- Major considerations during the development of the new sourcing model
- Resulting impact on business performance and lessons learnt

Dr Amrit Ray, Vice President Medical Safety Global Medical Affairs & Pharmacovigilance, **Bristol-Myers Squibb**

09.30 **Biosimilars: considerations for outsourcing**
- A number of exciting biological products are coming off patent over the next few years. What does this mean for biogenerics manufacturers?
- Clinical outsourcing; speed, efficiency and other considerations specific for this niche market

William Haddad, Chief Executive Officer, **Biogenerics**

10.00 **Relationship management in clinical outsourcing**
- Good relationship: why is it so important and how can they boost your business operations?
- Common industry issues: opening communication routes and build trust for a structured, productive and mutually beneficial partnership

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

10.30 **Morning tea**

11.00 **Globalization of clinical trials**
- Key considerations for running overseas trials in the emerging markets
- Patient enrolment benefits and pitfalls in emerging markets: why does it work and what can go wrong?

Dr Vinod Mattoo, Director Cardiovascular & Metabolics Global Development & Medical Affairs, **Bristol-Myers Squibb**

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 utilized in the pharmaceutical industry?

Audra Nichols, Global Strategic Sourcing Leader, **PriceWaterhouseCoopers**

12.00 **Panel discussion: global outsourcing: measuring and comparing the value gained from regional trials**
Have your say and hear from a selection of the keynote speakers in this interactive discussion session as they view their thoughts on the hot topics of the morning.

12.45 **Lunch**

STREAM I

STRATEGIC OUTSOURCING

14.00 **Contingency planning**
- Risk management and planning: what can be done to control the potential for risk?
- Moving contingency planning to the forefront of your operations in the early stages of the partnership

Anne Maria Ylisaari, Head of In and Outsourcing, **Orion Pharma**

14.30 **Risk management of CROs**
- What constitutes risk in a CRO-sponsor partnership?
- Risk assessment and audits in the selection of providers
- Ongoing management during the course of an outsourced trial

Olga Crowther, R&D QA Unit Manager, **AstraZeneca**

15.00 **Afternoon tea**

15.30 **Key legal issues and trends in global clinical outsourcing**
- Challenges accompanying overseas clinical trials
- Ensuring regulations are adhered to
- Globally recognized performances standards

Leslie Platt, Counsel, **Pillsbury Winthrop Shaw Pittman**

16.00 **Outsourcing global clinical trials: moving towards a f at world of integrated medicine**
- Focus on the outsourcing of a biomarker driven pivotal clinical trial
- Special attention will be given to the novel contract research model utilized between western pharma and India

Prof Meena Augustus, Executive Partner, **HeathCare Global (Oncology) Enterprises Inc. & Treista Sciences Bangalore**

16.30 **Closing remarks and end of conference**

STREAM II

CLINICAL OUTSOURCING PERFORMANCE MANAGEMENT

14.00 **Strategic outsourcing in virtual pharmaceutical organizations**
- Structural and logistical considerations
- Differences and communalities between clinical outsourcing in virtual & traditional organizations

Solomon Babani, Director Outsourcing & Vendor Management, **Celtic Pharma**

14.30 **Ensuring quality in outsourced trials**
- How to ensure quality standards in an outsourced trial?
- Obstacles & solutions

Dr Brian O Neill, Global Head CQA External Alliances, **F. Hoffman La Roche**

15.00 **Afternoon tea**

15.30 **Clinical outsourcing: resource management**
- Identifying the importance and considerations of effective planning

Robin A. Myers, Associate Director Clinical Study Planning & Resourcing Global Clinical Program, **Bayer Healthcare Pharmaceuticals**

16.00 **Strategies to reach the general public and heighten awareness of clinical trials**
- Strategies to provide public outreach and education to improve patient recruitment and retention
- Public perception of clinical research and opportunities for raising awareness and trust

Jill McNair, National Director AWARE for All, **CISCRP**

16.30 **Closing remarks and end of conference**

PRE CONFERENCE WORKSHOP:

Increasing pharma-CRO partnership success using balanced scorecard metrics

Tuesday 21 October 2008,
Hilton Philadelphia City Avenue Hotel, United States

How well are your outsourced trials working? How effective are your partnerships? Are you getting the best value? Where can you improve the overall value and efficiency of the trial?

Metrics are critical to answering these questions and assessing the status of outsourcing partnerships. In this full-day, hands-on workshop, we'll show you how to build a balanced scorecard metrics system that gives you the information you need to create and maintain successfully outsourced clinical trials. We'll look at metrics from a variety of angles and help you build your scorecard. We'll cover the following topics:

- How do metrics translate into increased R&D productivity?
- What metrics should you gather to get accurate information?
- What metrics are most appropriate for different types of outsourcing situations?
- What internal metrics should you maintain?
- How can you use metrics to manage and reduce risk?
- What are the ideal metrics to include?
- How do you build your scorecard to make it effective and successful?

The workshop will begin at 9:30am and finish at 5pm. Lunch and refreshments will be provided. For further information on the agenda and course leader visit **www.healthnetworkcommunications.com**

About your workshop leader:

Dave Zuckerman is the world's leading expert on pharmaceutical R&D and outsourcing metrics. He is president of Customized Improvement Strategies LLC, a consulting firm which supports clients in measuring and improving processes, teams, organizations and partnerships. Dave chairs annual conferences in the US and EU on R&D metrics and on protocol development, runs multi-day courses on R&D Balanced Scorecards for companies throughout the world and has published a number of magazine articles on metrics, process improvement, protocol development and R&D risk reduction. He is the author of Pharmaceutical Metrics published by Gower Press in 2006.

CIS helps clients improve their business performance by using the people and resources they already have in new more efficient ways. CIS will help you to become more agile, responsive and competitive by focusing on three keys to performance: leadership, process and organisation.

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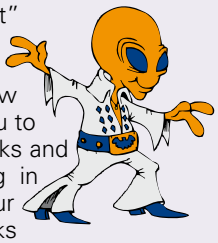
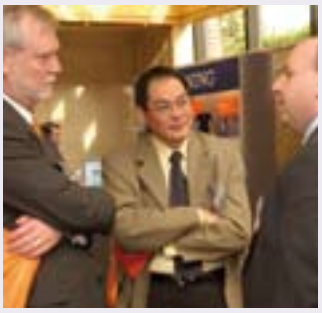
Our online "contact" system allows you to make initial contact, arrange meetings and begin your networking with your fellow delegates prior to the event. It allows you to take full advantage of the extended breaks and dedicated networking time by planning in advance the meetings that will drive your business. The system goes live 3 weeks before the event



SPEED NETWORKING

This is a revolutionary, exciting, quick and non-pressurized way to meet fellow delegates and industry peers in one 45 minute session. These brief meetings are the starting point for conversations and networking throughout the congress. Be sure to bring along plenty of business cards for this session, which is where long lasting and fruitful relationships begin.



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Health Network's drinks receptions allow you to continue the conversations you began during the conference. Join us to relax with your peers and experience toasting the developments in your industry.

THE VENUE

The Hilton Philadelphia City Avenue Hotel is recognized as one of the most luxurious and exquisite hotels offering unmatched elegance and impeccable service in Philadelphia, PA. Located on City Line Avenue, the Hilton Philadelphia City Avenue hotel is minutes from the sites and attractions of historic downtown Philadelphia, PA and just a short drive from 30th Street Amtrak Station and the Philadelphia International Airport.

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Speaker highlights

Industry trends in clinical outsourcing

Kenneth Kaitin, Director, **Tufts CDSS**
Dr Kaitin is Director of Tufts, an academic drug policy research group providing strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of the drug development process. He has extensive experience writing about factors that contribute to the slow pace and high cost of pharmaceutical R&D and the impact of regulatory and legislative initiatives to speed new drug development and review.

Relationship management in clinical outsourcing

Dianne Kikta, Vice President Global Clinical Strategic Resourcing, **Wyeth Research**
Dianne Kikta is currently the Vice President of Global Clinical and Strategic Resourcing at Wyeth. She is responsible for providing strategic oversight of opportunities for flexible resourcing for the clinical organization to meet objectives efficiently, especially through offshoring and outsourcing. She was the sponsor for a recent innovative initiative to determine how to work more effectively 24/7 which included expanding into India, implemented through a successful partnership.

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

Janet Edwards, Director Global Clinical Outsourcing, **AstraZeneca**
Janet is responsible for Global Clinical Outsourcing at AstraZeneca, including strategy, defining new operating models and ensuring operational delivery for all outsourced clinical work. Prior to AstraZeneca, she worked in several pharmaceutical companies and a CRO in a variety of project leadership and project and line management roles. Following her MBA, Janet worked as a management consultant delivering innovative business solutions on numerous projects along the pharmaceutical value chain to several pharma clients.

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

Fred Naids, Senior Strategic Sourcing Director, **Shire Pharmaceuticals**
In his current role as Senior Strategic Sourcing Director at Shire, Dr Naids is responsible for developing, implementing, and maintaining a global outsourcing strategy that supports all clinical trial activities, from Phase I through Phase IV. Working in partnership with Shire's Global Procurement Services group, Fred has established a streamlined process for supplier selection and he is currently developing a comprehensive supplier performance management program.

Review of the CRO industry: a financial analyst's perspective

David Windley, Managing Director Healthcare Equity Research, **Jefferies & Company**
Dave Windley is the managing director in the Equity Research Department at Jefferies, following companies in the pharmaceutical services and specialty pharmaceutical sectors. Prior to joining Jefferies in 2000, Dave was a Senior Analyst at J.C. Bradford & Co. from 1998 to 2000. Dave is a four-time Wall Street Journal Best on the Street selection, including a #1 ranking in Healthcare Providers in 2007 and #1 in Pharmaceuticals in 2005.

Case study: successful relationship management

Mark Evans, Executive Director Clinical Research Operations US, **Merck**
Dr Evans is Executive Director of Global Trial Execution, Clinical Research Operations, Merck Research Laboratories. In this role he is responsible for the conduct of Merck's global clinical research studies. Throughout his career, he has been involved in numerous process improvement and optimization initiatives, currently the Global Resource Alignment Project that is defining and implementing a clinical research resource optimization strategy for the company.

Vendor selection in outsourced trials

Sylvester Wilkins, Sourcing Group Manager, North America, **GlaxoSmithKline**
As a Sourcing Group Manager in GlaxoSmithKline's Corporate Services Procurement Organization, Sylvester is responsible for all Contingent Workforce for North America. Sylvester has been on the cutting edge of developing and negotiating numerous oursourcing contracts, negotiating Master Service Agreements with preferred contingent workforce suppliers and developing preferred supplier strategies. He is responsible for developing preferred supplier strategies, which has yielded a cost savings of approximately $8 million over the last three years.

Clinical outsourcing considerations from the biotechnology industry

Dr Adam Ruskin, Director Clinical Research & Operations, **Maxygen**
Dr. Ruskin has experience developing over 50 clinical protocols ranging from first-in-human studies to global Phase III and IV trials in a wide array of therapeutic areas including vaccines, orphan drugs, MRSA antibiotics, oncologic and cardiovascular medications. Budgets have ranged from $100,000 to over $20M. His experience as a project leader for a global sponsor, large and small vendors has resulted in a unique perspective of partnering needs from both sides.

Outsourcing considerations for small and mid-sized pharma

Dr. Uwe Schneider, Head of Sourcing Management, **Grünenthal GmbH**
Dr. Schneider joined Grünenthal in 2000 as the Head of CRO Management for R&D. In his current role as Global Head of Sourcing Management, Dr. Schneider leads a team of 10 Outsourcing Manager and is responsible for sourcing management, strategic outsourcing, CRO contracting, performance management and benchmarking. He is a member of the PCMG (Pharmaceutical Contract Manager Group) and a Germany-based outsourcing manager meeting focusing on sharing experiences and best practices in outsourcing.

Strategic outsourcing in virtual pharmaceutical organizations

Solomon Babani, Director of Outsourcing and Vendor Management, **Celtic Pharma Development Services**
Solomon joined Celtic Pharma Development Services in 2006 as Director of Outsourcing and Vendor Management and is responsible for implementing and overseeing the entire outsourcing process and strategy for all functions. Additionally, Solomon is responsible for continuing to cultivate and build relationships with all of the vendors working with CPDS. Prior to this, Solomon worked for Regeneron Pharmaceuticals, Pfizer and then Novartis as an Associate Director in the CRO Management group.

Benefits of sponsoring *Clinical Outsourcing World Americas*

Clinical Outsourcing World Americas is where the pharmaceutical, biotech and contract research & development industries will come to look for opportunities to streamline processes and aid winning drugs to market.

Clinical Outsourcing World Americas aims to attract a significant gathering of leaders, decision makers and inf uencers in outsourcing and operations. Our delegates will be looking for guidance, answers, and new business relationships, representing a significant and exceptional business opportunity.

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

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Look at who attended *Clinical Outsourcing World Europe 2008*

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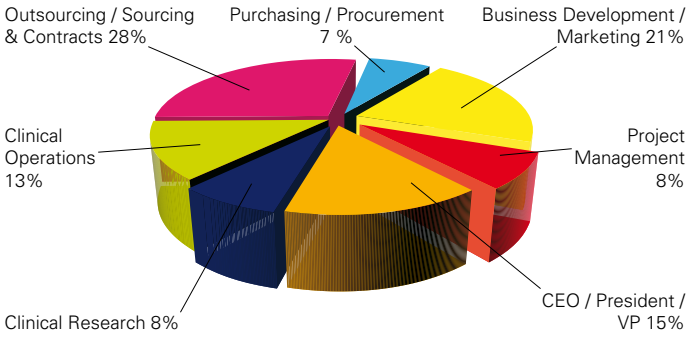
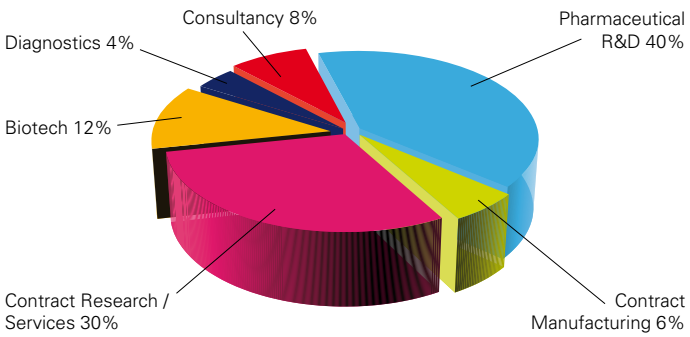


Company type



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CLINICAL OUTSOURCING WORLD Americas 2008

21 - 23 October 2008, Hilton Philadelphia City Avenue Hotel, Philadelphia, USA

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☐ **Gold pass** - all 3 days	21 - 23 October 2008	$2515.50	$2795	$2895	$2995
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Delegates	Package	Normal Price	Group Price	Total savings
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