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April 28-30, 2009 • Rosen Shingle Creek Hotel • Orlando, FL

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Fidela Ll. Moreno, MD
VP, Global Development Operations, Clinical Monitoring, ALLERGAN INC

Cynthia Kearney
VP, Strategic Alliances, RPS, INC

Rare Opportunity

Private Luncheon and Q&A with Keynote Speaker Clayton M. Christensen HARVARD BUSINESS SCHOOL

First Time Speakers!

Peter B. Corr, PhD
Co-Founder and General Partner, CELTIC THERAPEUTICS

Jack H. Dean, PhD, ScD
President, U.S. Science and Medical Affairs (R&D), SANOFI-AVENTIS (Ret.)

Jeffrey Kasher, PhD
VP, CDO, Global Clinical Development, ELI LILLY & CO

Elliott Levy, MD
VP, Clinical Development, BRISTOL-MYERS SQUIBB

Charles Morris, MD
VP, Worldwide Clinical Research, CEPHALON

Michael F. Smith, PhD
VP, Global Site Management, WYETH RESEARCH
INTRODUCING THE 18TH ANNUAL PARTNERSHIPS

PHARMA/BIOTECH

Colleen Anderson, Clinical Program Director, SHIRE PHARMACEUTICALS

Solomon Babani, Director of Contracts & Supplier Management, CELTIC PHARMA

Kathie Balinski, Vice President, Clinical Operations, MEDAREX

Peter DiBiaso, Senior Director, Clinical Operations, SHIRE PHARMACEUTICALS

David Bartholomew, Senior Director & Department Head, Global Clinical Trial Logistics, WYETH

Larry Blankstein, Senior Director, Clinical Research, GENZYME

Anthony Carita, Director, Clinical Outsourcing, OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION

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Stephanie Charbonneau, Associate Director, Functional Sourcing Manager, Pfizer INC

Owen Charles, RN, BA, MBA, Manager, Outsourcing Management, Global Clinical Development, Bristol-Myers Squibb

Gavin Choy, Vice President, Clinical Operations, SUPERGEN

Jessie Cox, Associate Director, Clinical Research, Abbott Vascular

Allan M. Cohen, Director, Legal Services, CELTIC PHARMA DEVELOPMENT SERVICES

Vanessa Cooke, Global Head of External Supplier Management, Bavarian PLC

Peter B. Corr, PhD, Co-Founder and General Partner, CELTIC THERAPEUTICS MANAGEMENT COMPANY LLC; Formerly Senior Vice President, Science and Technology, Pfizer

Jack H. Dean, PhD, ScD (Hon.), DABT, Fellow ATS, President, U.S. Science and Medical Affairs (R&D), Sanofi-Aventis

Christina DiArcangelo, Associate Director, Clinical Contracts & Outsourcing, Fibrogen

Hansu Dong, Senior Manager, Business Operations, Valeant Pharmaceuticals

Sue Dubman, Senior Director, Chief Data Officer, Genzyme Corporation

Julie Duffy, Associated Director, Clinical Contracts & Finance Research, Gilead Sciences, Inc

Deborah Bisio Deyer, MBA, Associate Director of Clinical Outsourcing, Cerexa

Joye Emmens, Director, Global Strategic Sourcing, AMGEN

Jane Fayer, Associate Director, Outsourcing Management, Novartis Pharmaceuticals

Larry Fori, Associate Director, Clinical Trial Outsourcing & Compliance, Compliance & Quality Management, Boehringer Ingelheim Pharmaceuticals

Mark Fowler, Global Executive Director, Strategic Sourcing, AMGEN

Ken Francis, Director, Global Strategic Sourcing, AMGEN

Lauren Goldsmith, Senior Manager, Strategic Outsourcing, MannKind Corporation

Jennifer R. Goodfellow, Senior Director, Global Head of Outsourcing, Sanofi Pasteur

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The Partnerships with CROs team would like to extend a special thanks to our program advisors for their time enthusiasm and dedication to this event.

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- MIDDLE ROW: Mary Rose Keller, Kevin Skare, Deirdre BeVard, Elisabeth Overend-Freeman, Mike Laird

- FRONT ROW: Samir Shah, Rhonda Griscti, Steven Whittaker, Debbie Kerr-Leatham, Solomon Babani, Rebekah Wooley, Fredrick Naidis
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Rebekah Wooley, Executive Director, Strategic Accounts, INC RESEARCH

* Not pictured

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Mike Laird, Senior Vice President, Business Development, PHARMA NET

Jon Lee, Executive Director, Strategic Operations, CEREXA

John Hubbard, PhD, Global Present, ICON CLINICAL RESEARCH

Fredrick L. Naids, PhD, Senior Strategic Sourcing Director, SHIRE PHARMACEUTICALS

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Steven Whittaker, Director of Project Management and Operations, CV/Acute Care, ELI LILLY & CO

Rebekah Wooley, Executive Director, Strategic Accounts, INC RESEARCH

* Not pictured
Dear Clinical Development Partner:

The pharmaceutical industry is at a crossroads. With a perfect storm of expiring patents and generic competition, lackluster R&D pipelines and drug safety issues, times have never been tougher for the pharmaceutical industry. With this, Pharma has been hemorrhaging human capital – whether by strategic downsizing and restructuring, or by employees seeking more stable opportunities.

All of this places great pressure on organizations to change. In the course of interviewing hundreds of industry executives while researching the 2009 program agenda, one theme surfaced loud and clear. The pharmaceutical paradigm is changing and companies, both on the sponsor and supplier side must work together, now more than ever, to face the challenges that lie ahead in today’s uncertain environment.

Strategic partnering is front and center in the relationship value chain among biopharmaceutical companies, CROs and other outsourcing providers. Sponsors are operating with fewer resources and need to outsource more but must do so with less money—and with a high number of product failures, available dollars for outsourcing are being threatened. With the cost of doing business and budget constraints on the rise, clinical professionals need to do more with less, while still maintaining the highest levels of quality. With increasing regulatory demands and decreasing productivity, successful partnerships are essential.

Sourcing is not driving change, but it can be part of the solution. Each year the Partnerships with CROs event examines critical issues and decisions around different sourcing models, which ones to implement, who to outsource our clinical research to, and best practices in successfully managing these relationships—all a means to the greater goal of developing a valuable product and getting them in the hands of patients quickly and safely. Now entering its 18th year, Partnerships with CROs has set the standard in outsourcing and clinical development conferences and we are proud to bring you THE event that explores best practices on forming, managing, and sustaining clinical outsourcing partnerships.

We invite you to review our agenda for 2009 and choose from a wide array of 8 pre-conference workshops and 5 breakout tracks that delve deep into the issues most challenging to clinical operations and outsourcing professionals today – remember it’s “your priorities – your choice.” With a comprehensive program, expansive topic selections and an outstanding 150+ strong Pharma, Biotech and Supplier expert speaking faculty that give you access to key outsourcing leaders, influencers and decision-makers, you can expect to come away with new ideas and immediate solutions for your business needs.

Join the longest running and most respected clinical development outsourcing conference and register today. Partner with us in April in Orlando,

Lesly Atlas
Program Director
Partnerships with CROs

Cynthia Kearney
Vice President, Strategic Alliances, RPS, INC
Event Co-Chairperson

Fideia Li. Moreno, MD
Vice President, Global Development Operations, Clinical Monitoring, ALLERGAN INC
Event Co-Chairperson

Parcehip with CROs is the premiere forum for meaningful conversation about our industry and its future development.

—Glenn Kerkhof, Chief Executive Officer, CHILTERN
### Agenda-at-a Glance

**Monday, April 27, 2009 4:30-6:00pm — BEAT THE RUSH AT PRE-REGISTRATION**

**Tuesday, April 28, 2009: PRE-CONFERENCE EVENTS**

<table>
<thead>
<tr>
<th>Time</th>
<th>Workshop Registration and Morning Coffee</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td><strong>Full Day Workshops 9:00-4:30</strong></td>
</tr>
<tr>
<td>8:15</td>
<td><strong>Morning Workshops 9:00-12:30</strong></td>
</tr>
<tr>
<td>8:45</td>
<td><strong>Afternoon Workshops 1:30-4:30</strong></td>
</tr>
</tbody>
</table>

#### TRACK A
**PARTNERING FOR COLLABORATIVE SOLUTIONS**

<table>
<thead>
<tr>
<th>Time</th>
<th>STRATEGIC SOURCING: ALTERNATIVE DEVELOPMENT MODELS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:15</td>
<td>Innovation in a Reduced Cost and Enhanced Efficiency Environment</td>
</tr>
<tr>
<td>2:00</td>
<td>Developing Efficiencies Using a Central Lab and CRO Together</td>
</tr>
<tr>
<td>2:45</td>
<td>Early Sponsor - Supplier Team Collaboration for More Effective Design of Your Clinical Program</td>
</tr>
</tbody>
</table>

#### TRACK B
**RAISING THE BAR ON QUALITY AND PATIENT SAFETY**

| Time  | | |
|-------|--------------------------------------------------|
| 1:15  | Wall Street’s 2009 Forecast and Analysis of Outsourcing Trends |
| 2:00  | Ensuring Quality Work at the Sponsor, Site and CRO Levels |
| 2:45  | Transforming Drug Development Outsourcing with a Virtual Model |

#### TRACK C
**GLOBALIZATION AND TRIAL COMPLEXITY**

| Time  | | |
|-------|--------------------------------------------------|
| 1:15  | Defining and Managing Quality in Clinical Trials |
| 2:00  | Successfully Applying Technology to Clinical Trials Across World Regions |
| 2:45  | The Implications of Post-Marketing Requirements on the Future of Drug Development Partnerships |

#### TRACK D
**OPTIMIZING OUTSOURCING CONTRACTS, BUDGETS AND PROCESSES**

| Time  | | |
|-------|--------------------------------------------------|
| 1:15  | Leading Virtual Teams Around the Globe |
| 2:00  | RFP Management & Contracting with CRO's to Minimize Change Orders |
| 2:45  | Developing Scope of Work for Solid Project Foundation and Minimal Project Setbacks |

### Wednesday, April 29, 2009: MAIN CONFERENCE DAY ONE - KEYNOTES

<table>
<thead>
<tr>
<th>Time</th>
<th>Registration and Morning Coffee</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00</td>
<td>Welcome from Event Chairpersons</td>
</tr>
<tr>
<td>8:15</td>
<td>Leading Through Change: Innovation and the Future of the BioPharmaceutical Industry</td>
</tr>
<tr>
<td>10:00</td>
<td>Morning Opening of Exhibit Hall</td>
</tr>
<tr>
<td>10:45</td>
<td>Virtual Pharma: Addressing Challenges and Opportunities in Biomedical R&amp;D</td>
</tr>
<tr>
<td>11:15</td>
<td>Understanding the Concepts of Disruptive Innovation, It’s Impact and What Pharma Can Do to Get Ahead of It</td>
</tr>
<tr>
<td>12:15</td>
<td>Lunch and Networking in the Exhibit Hall</td>
</tr>
</tbody>
</table>

### Thursday, April 30, 2009: MAIN CONFERENCE DAY TWO - KEYNOTES

<table>
<thead>
<tr>
<th>Time</th>
<th>Registration and Morning Coffee</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30</td>
<td>Welcome from Event Chairpersons</td>
</tr>
<tr>
<td>8:15</td>
<td>Leveraging Relationship Structures to Optimize Sponsor-CRO Collaborations</td>
</tr>
<tr>
<td>10:00</td>
<td>Morning Opening of Exhibit Hall</td>
</tr>
<tr>
<td>10:45</td>
<td>Inspirational Patient Perspective with NFL Legend Terry Bradshaw</td>
</tr>
<tr>
<td>11:30</td>
<td>How to Make Change Part of Your Competitive Advantage</td>
</tr>
<tr>
<td>12:15</td>
<td>Lunch and Networking in the Exhibit Hall</td>
</tr>
</tbody>
</table>

### 4:00 Event Concludes
Coming from a small company, I needed, and received, good information on contracting and metrics/performance management

—Brian Gilmore, Associate Manager, Clinical Projects, PHARMION CORP
This workshop addresses the basics of outsourcing from targeted RFI preparation to selecting vendors for an RFP; what the RFP should contain and to how to conduct a face-to-face proposal defense meeting. The workshop presenters also discuss making the vendor selection, building and maintaining successful relationships, setting and managing project expectations and oversight of the CRO. Also discussed are the unique challenges of small pharma and biotech in getting the right level of attention from the CRO.

**Part I: How to Decide Who to Outsource To: Finding the Right Mix for Your Company’s Needs**
- Choosing an outsourcing model (full or functional) depending on your corporate/project goals
- Targeted RFIs
- Provider selection and the RFP process
- Using score cards to create an objective process
- Managing the bid defense to get what you need from the CRO
- Making the right selection
- Setting expectations
- How to best set up the oversight process

**Part II: Relationship Management**
When Big Pharma runs into problems with suppliers who are not delivering, they can pull business back in house. Small pharma and biotechs don’t have the same luxury. This session offers strategic and tactical advice for approaching problems prospectively, cultivating better relationships with vendors, and setting expectations and performance specifications clearly ahead of time.

- Project and control mechanisms with high staff turnover
- How to best set up team structure, monitoring performance, metrics
- How do you avoid micro-managing the CRO but still get the project goals?
- How to develop long-term productive relationships for the Sponsor and the Provider

**Part III: Governance**
How does a Sponsor and CRO work collaboratively as a Partnership? One of the ways is to develop a Governance Committee. The Governance Committee will cultivate a better relationship and partnership between the CRO and Sponsor. Our speaker discusses:

- When should a governance committee be put in place?
- How do you determine the membership of the Governance Committee?
- What should be in the Charter?
- Determine what the frequency should be.
- Measure the value of the Governance Committee

**Part IV: Small Fish in a Big Pond: Strategies for Small Pharma and Biotech to Get the Right Level of Attention from Large CROs**
Biotech companies usually do not have their own outsourcing or procurement groups and clinical staffs are burdened with trying to be experts in everything from protocol writing, budgeting, and selecting a CRO. They don’t have the expertise in house and often make tragic mistakes, sometimes getting burned in the process, making it difficult to move forward. While the traditional CRO model does not lend itself to meeting smaller company challenges, the increasing Big Pharma trend toward functional outsourcing and unbundling services is forcing the tide of change. The industry has seen a re-emergence of special branches at large CROs focusing on biotech and catering to their different needs, personalities, and functions on full service outsourcing basis. Biotech is an extremely important piece of the market and grouping segment, far outpacing big pharma.

- How can biotechs “sell” themselves to the CRO partner to make their importance as a client known?
- Defining the scope of the work, expectations and responsibilities
- How to work more effectively in an outsource model
- Dealing with high turnover on both sides/consistency of teams

**Moderator:**
Rikki Bouchard, President and CEO, RH BOUCHARD & ASSOCIATES

**Workshop Faculty:**
Gavin Choy, Vice President, Clinical Operations, SUPERGEN
Paul Colvin, Senior Vice President Clinical Development, PPD, INC
Christina DiArcangelo, Associate Director, Clinical Contracts & Outsourcing, FIBROGEN
Deborah Bisio, MBA, Associate Director of Clinical Outsourcing, CEREXA
Jennifer R. Goodfellow, Senior Director, Global Head of Outsourcing, SANOFI PASTEUR
B3 CRO Strategies for Adapting To The Changing Tides in Pharma

Part I. Perfecting the Business Development Role
The first part of this interactive workshop is centered around dialogue from Pharma/Biotech Executives (“straight from the source”) to business development and sales professionals at service companies to gain a better understanding of positioning and creating the right value proposition to serve their clients through discussions, proposals, presentation, and management styles. Topics to include:

- Penetration of the Message: Understanding the Needs of the Clients – this needs to penetrate deeper within the service organization
- Building a Business Development team
- Knowledge Training: Identifying, recruiting and managing people
- How to separate yourselves from the rest of the herd
- Accessing the right people (decision makers) in an organization to approach for new business opportunities and getting them to return your call
- How to demonstrate value to Sponsors who are increasingly pushed to make decisions based solely on cost
- Providing customers insight into what delivers overall value as opposed to single project discounts or savings
- Preferred Provider Myths and Realities
- Has the growth of some CROs impacted their ability to satisfy customer needs (internal and external)?
- How smaller supplier companies can convey service expertise and flexibility to potential clients

Part II. How Is The Role of the CRO Project Manager Changing?
In the second half of this workshop, the focus turns to the PM. Sponsors are increasingly looking to CROs to provide expertise – with dramatic downsizing, micro-managing will go by the wayside as CROs take over as the ‘doer.’ Strategic relationship management enables CROs to become an integral part of the client organization. Not all CRO project managers however are equipped to offer the level of service for the client seeking high-level engagement vs simply executing what they are told to do. In addition, there’s increasing turnover at CROs as well and concerns about training at the project manager level. Our distinguished panel discusses:

- What level of experience do CRO project managers need when there is less oversight by the Sponsor company?
- Raising the bar on critical thinking – project managers need to understand how to go around the SOP manual when a crisis occurs
- Cultural change – how do you move an organization from being doers to managers?

Workshop Faculty:
Solomon Babani, Director of Contracts & Vendor Management, CELTIC PHARMA
John W. Hubbard, Ph.D. FCP, Global President, ICON CLINICAL RESEARCH
Duane Schmitz, Director, Business Operations, Clinical Development Organization, ELI LILLY & COMPANY
Samir Shah, Vice President, Strategic Development, RPS, INC

B4 Working In Partnership with Sites for Increased Productivity

Our industry has focused its efforts to move sponsor and CRO relationships from a tactical commodity to a collaborative partnership; something that will benefit the world of clinical development. In that effort, however, it is important not to lose sight of some of the most important stakeholders—the patients. The access to these patients comes through the clinical sites with whom a partnership and effective relationship is critical for success. This workshop will address the need to extend the collaborative partnership to the relationship between sites and Sponsors/CROs. We will discuss some of the challenges that US sites face in conducting clinical trials in today’s regulatory and financial environment and how the sponsor-CRO partnerships can impact them. Understanding what it takes to successfully conduct a study at investigative sites and how to work with them as business partners can help you work more productively with them. We all share the goal of wanting to improve the healthcare of the patient population and it will take a partnership between all parties to achieve that.

Join our distinguished panel to:

- Understand trends occurring across the investigative site landscape and their implications
- Assess new strategies and tactics are needed to address and leverage these trends
- Anticipate new ways to more effectively and efficiently manage investigative site relationships
- Understand the types of sites available and how to determine which relationship best suits your protocol needs (e.g. private practice, university, community-based, clinics, independent sites, SMOs, physician collaborative, etc.)
- Discuss the cost of doing research (contracts and budgets): timely payment and the effect it may have on enrolment and/or performance; insurance reimbursement and compliance concerns
- Learn about monitoring performance and compliance—it takes a team
- Ensure your monitors are enhancing the relationship and improving quality
- Know how to manage the poor performing site

Moderator:
Deirdre BeVard, Formerly of Physician Alliance for Clinical Research

Workshop Faculty:
Kenneth Getz, Research Fellow, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT and Chair, CISCRP
Nadina C. Jose, MD, CPI, MBA, President/CEO, RESEARCH STRATEGIES INC.
Jeffrey Rosen, MD, Medical Director, CLINICAL RESEARCH OF SOUTH FLORIDA
William Smith, MD, President, NEW ORLEANS CENTER FOR CLINICAL RESEARCH (NOCCR)
CRO Representative to be announced.

B5 Clinical Trial Finance: Fundamentals of Budgets in Clinical Contract Management

This half day workshop walks participants through financial considerations for clinical outsourcing. This will include the mechanics of creating study budgets and accurately anticipating study costs by using a standardized RFP across vendors. Also, budgetary considerations when entering into a partnership relationship will be presented. Highlights include:

- Project planning budget management
- Budget issues during bidding and vendor selection
- Standard financial processes and considerations when submitting the RFP
  - Choosing the right contract model: avoiding the one-size-fits-all pitfall
  - Managing vendor performance by using metrics and service level agreements that drive payment
  - Increasing Investigator enrollment through sound payment management

Applying consistent methodology to your budget development, review and contract administration processes can improve your contribution to the corporate budget and accrual process. The workshop is comprised of lectures and examples and will be an open discussion format. Clinical Outsourcing, Contract Resource Management, Procurement, and Clinical Operations department heads and staff with increasing financial responsibilities for budget oversight will benefit from this workshop. Note: Attendees should have some basic familiarity with study costing.

Moderator:
Tiffany Sizemore Cherry, JD, MBA, Chief Executive Officer, CONTRAX CONSULTING, LLC

Workshop Faculty:
Julie Duffy, Associate Director, Clinical Contracts & Finance Research, GILEAD SCIENCES, INC
Debbie Kerr-Leathem, Director, Clinical Logistics, Data Generation Division, ORTHO-MCNEIL-JANSSEN SCIENTIFIC AFFAIRS, LLC
Alan H. Stowe, Associate Director, Financial Planning & Analysis, PDL BIOPHARMA
Driving Global Growth: Strategic Considerations for Conducting Clinical Trials in Non-Traditional Markets

According to clinical trial data, 66% of all trial sites are located in traditional regions or countries—North America, Western Europe and Australia. In recent years, however, there has been an increasing shift in clinical trials to non-traditional or emerging regions. The prevailing assumptions about conducting trials in these non-traditional areas are that sponsors will be able to reduce operational costs, access a greater number of treatment-naïve patients and shorten time to market. However, conducting clinical trials in non-traditional areas present their own unique operational, regulatory and ethical challenges. In this half-day workshop, industry panelists will discuss the challenges in deciding to conduct clinical trials in these non-traditional regions. During the discussion, panelists will focus on benefits and issues in five key areas:

- **Costs**
  - Beyond investigator fees and clinical research staff salaries, the factors that need to be evaluated to determine the true cost to conducting clinical trials in a particular region
- **Regional considerations**
  - Examine whether there are particular types of studies that are better suited to specific regions
  - Applicability of efficacy data in one region to the broader global population
  - How regional socio-economic differences can impact patient safety and trial data
  - Factors to evaluate to more accurately determine patient availability in a geographic region
  - The role that the patient’s knowledge about clinical trials plays in recruitment and retention success
- **Regulatory considerations**
  - Local regulatory challenges that can slow down the study start up process even if patient recruitment can be completed quickly
  - Examine the benefits of including countries with longer regulatory timeframes and how to ensure sites in these countries can participate in the study when saving time is the key driver
- **Ethical considerations**
  - Ethical considerations of conducting trials in a country if the drug will not be commercialized there or if the drug is too expensive for the general population
  - Sponsors’ responsibilities to the patient after the trial is completed
  - Potential impact on the trial if the medical history of patients is not well-documented
  - Evaluating whether standard of care is equal to or worse than in more traditional countries and the impact on the trial
  - How the sponsor and CRO can ensure language, cultural and literacy barriers are evaluated and overcome to ensure proper informed consent is being collected

**Moderator:** Mark Roseman, Vice President, Account Management, PPD, INC  
**Workshop Faculty:**  
Simon Britton, Vice President, Clinical Development, PPD, INC  
Visit www.cropartners.com for additional speaker updates.

Governance and Supplier Relationship Management

Most organizations have gone through some form of strategic sourcing over the last few years and are now looking to see how they can continue to improve and deliver additional value to their organizations. Best practice companies in many industries, including pharmaceuticals, are looking at SRM (Strategic Relationship Management) as a way to more fundamentally address a key concern—effective management of suppliers. Effectively managing suppliers provides significant benefits including:

- **Improved management of supply risks** – maintain supply of critical items or capacity of key service
- **Shift to more strategic relationships** – beyond sourcing, “beyond the S-Curve”
- **Joint business process improvements to lower costs for supplier and customer**
- **Standardized processes and tools, scalable to support company growth, internal and M&A**
- **Continuous improvement for longer-term, sustainable benefits**

In this workshop, we will talk about real life examples of how to utilize SRM governance, performance management and other tools to derive benefits in one of the most important pharmaceutical sourcing categories – CRO.

**Moderator:**  
Warren Myers, Consultant, Former Executive Director, Strategic Sourcing, AMGEN  
**Workshop Faculty:**  
Mark Fowler, Executive Director, Global Strategic Sourcing, AMGEN  
Frances Grote, Director of Global Development, Strategic Sourcing, BRISTOL-MYERS SQUIBB  
Cynthia Kearney, Vice President, Strategic Alliances, RPS, INC

Contract Approach and Development: Key Terms and Negotiating Strategies

In the highly regulated pharma sector, understanding the key points of negotiation and drafting a proper contract can be challenging, especially when you don’t have a law degree. As Clinical Outsourcing managers are leading negotiations, drafting and managing key contracts on a daily basis, it is essential to have a firm grasp of the basic terms and tactics for creating effective contracts. This interactive workshop delves deep into:

- **Determining the terms and conditions**
- **Creating timelines**
- **Grasping contract language and legal terms**
- **Understanding payment and business terms**
- **Regulatory, financial and legal considerations**
- **Utilizing strategic sourcing concepts and tools**
- **Financial review, profit margins, cost savings**
- **Master Agreements, rate cards, discount/penalties**

**Interested in Speaking at this Workshop?**
8:15 Welcome from the Event Chairpersons

8:30 Leading Through Change: Innovation and the Future of the BioPharmaceutical Industry

- What will be the impact of the new administration in the White House?
- What are the key drivers in the sector that are leading to change?
- How has the role of sector uncertainty added an additional layer of complexity to Pharma consolidation, generic competition, globalization, and other challenges facing the industry?
- How should we be re-evaluating corporate strategies, operational processes, critical skill sets, development investments, and maintaining career growth/loyalty?
- Is the Big Pharma model broken? What does the business model of the future look like?
- How will partnerships between pharma and biotech companies change the face of drug development?
- How should companies be preparing for the future?

Moderator: Christopher C. Gallen, MD, PhD, President & Chief Executive Officer, NEUROMED
Panelists:
- Jack H. Dean, PhD, ScD (Hon.), DABT, Fellow ATS, President, U.S. Science and Medical Affairs (R&D), SANOFI-AVENTIS (Ret.)
- Elliott Levy, MD, Vice President, Clinical Development, BRISTOL-MYERS SQUIBB


The Biopharmaceutical industry is facing significant challenges driven by declining R&D productivity, increasing drug development risks, patent expirations and shorter product lifecycles and the need to globalize its business model. In response to these challenges, novel methods of managing and executing development pipelines are emerging that are directed at key measures of performance: Cost, Quality, Speed, and achieving a Competitive Advantage in the marketplace. In 2005, Wyeth and RPS partnered to create MMaX (Maximizing Monitoring Availability and Excellence), an innovative model providing site management services throughout the Americas. MMaX was established to provide a scalable, flexible, integrated site management solution in support of Wyeth’s growing pipeline and to reduce the dependency and cost associated with managing multiple, traditional full-service providers. The mission of MMaX is to provide the highest quality, most cost-effective site management services; the flexibility to match resources with pipeline/workload needs; and the establishment of strong relationships with clinical investigators/sites in support of speeding the development and marketing of important new products for patients in need. Since its inception, MMaX has grown to over 200 FTEs supporting Wyeth’s entire pipeline in the Americas and has yielded savings in the millions of dollars.

This presentation will focus on:
- Building a Flexible, Scalable, Sustainable, Experienced Workforce that now numbers more than 200
- Improving Key Metrics through intense joint senior management focus/involvement
- Implementing innovative change including adoption of a Site Management monitoring model
- Achieving significant savings in overall program costs compared with previous operating model
- Employing additional process improvements to foster further improvements in productivity and reduce overall program costs

Michael F. Smith, PhD, Vice President, Global Site Management, WYETH RESEARCH
Harris Koffer, Pharm D, President and COO, RPS, INC.

10:00 Morning Opening of the Exhibit Hall, Refreshments Hosted by CHILTERN

10:45 Virtual Pharma: Addressing Challenges and Opportunities in Biomedical R&D

Pharmaceutical companies are facing unprecedented challenges to their discovery and development pipelines and ultimately to their bottom lines. The heavy fixed cost base and lack of flexibility of their R&D organizations make quick and focused decision-making very difficult. The innovative and timely Celtic model is designed to address these challenges. Celtic Therapeutics has assembled a first-class team of biomedical and financial industry leaders to bridge the gap between academia, biotechnology companies and the pharmaceutical industry. Hear from one of the most respected R&D executives in the global pharma industry today, as he discusses:
- Creating a development scheme with higher risk and opportunities for high probability successful candidates
- Implementing a sourcing strategy that allows you to maintain a larger portfolio of development
- Challenge: Can Big Pharma develop a virtual scheme to complement its portfolio?

Peter B. Corr, PhD, Co-Founder and General Partner, CELTIC THERAPEUTICS MANAGEMENT COMPANY LLLP; Formerly Senior Vice President, Science and Technology, PFIZER

11:15 Understanding the Concepts of Disruptive Innovation, It’s Impact and What Pharma Can Do to Get Ahead of it

The pharmaceutical industry is on the precipice of major change where strategic sourcing/partnering approaches that provoke or complement disruptive change could be an important solution. Join esteemed academician, business thought leader and bestselling author, Clayton Christensen as he enlightens us on:
- How to create new growth markets
- Better methods for understanding customers and building brands
- Outsourcing and insourcing the right things
- Organizing for innovation
- Assessing the value of potential innovations
- Predicting competitors’ actions

Clayton M. Christensen, Robert and Jane Cizik Professor of Business Administration, HARVARD BUSINESS SCHOOL

12:15 -1:15 Lunch in the Exhibit Hall Hosted by TFS
7:30
Morning Coffee

8:15
Welcome from Event Chairpersons

Cynthia Kearney
Vice President, Strategic Alliances, RPS, INC

Fidela Ll. Moreno, MD
Vice President, Global Development Operations - Clinical Monitoring, ALLERGAN INC

8:30
Leveraging Relationship Structures to Optimize Sponsor-CRO Collaborations

This session explores evolving sponsor-CRO relationship structures – from traditional project capacity-seeking approaches to functional service and alliance relationships. Panel members from small, medium and large biopharmaceutical companies and CROs will discuss their respective organization’s use of various relationship structures. In addition, the Tufts Center for the Study of Drug Development will present the results of a recent study comparing different sponsor-CRO relationship structures and their impact on performance (e.g., cycle time, efficiency).

- Share insights on various sponsor-CRO relationships – their advantages and limitations
- Discuss senior management expectations over the next several years for FSP and alliance relationships
- Compare the impact of relationship types on drug development performance

Moderator:
Kenneth Getz, MBA, Senior Research Fellow, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT; Founder & Chairman, CISCRP

Panelists:
John W. Hubbard, Ph.D. FCP, Global President, ICON CLINICAL RESEARCH
Jeffrey Kasher, PhD, Vice President and Chief Operating Officer, Global Clinical Development, ELI LILLY & COMPANY
Charles Morris, MD, Vice President, Worldwide Clinical Research, CEPHALON
Daniel M. Portman, CEO and Chairman, RPS INC
Dr. R. Adrian Otte, MB, BCH, Vice President, Global Development Operations, AMGEN

10:00
Morning Opening of the Exhibit Hall and Networking Break, Refreshments Hosted by

10:45
Inspirational Patient Perspective with NFL Legend Terry Bradshaw

Terry Bradshaw has made a career out of exceeding expectations. He has earned a world record, four Super Bowl rings, a spot on the Billboard charts, multiple Emmys, a star on the Hollywood Walk of Fame and countless other honors. While he originally gained fame as a star quarterback for the Pittsburgh Steelers in the 1970s, these days he’s a well-loved football analyst, breeder of world champion stallions and antidepressant spokesman. Having reached the heights of success and survived the depths of depression, Terry Bradshaw discusses how to thrive despite adversity and relentless competition, reminds us of the importance of what we do every day in helping bring critical drugs to market.

Terry Bradshaw, Co-Host and Analyst, FOX NFL SUNDAY

11:30
How to Make Change Part of Your Competitive Advantage

In today’s uncertain biopharmaceutical environment, managing change is no longer good enough. Today’s global economy demands that business leaders successfully navigate complex change on an ongoing basis in order to survive. It’s the organization that seizes change and makes it part of their competitive advantage that differentiates itself. Changing the organization’s culture is a static reaction that puts the organization behind before it begins. This session will illustrate the foundational change process and how to equip people with the skills, knowledge and behaviors to contribute to a Change Adaptive Culture. Our speaker, the author of six books on change management issues has worked on five continents with dozens of organizations, large and small. Join us as he shows you how to make change part of your competitive advantage. Key takeaways include:

- Addressing the need for constant change in the Pharmaceutical/Biotech environment
- Leveraging change adaptiveness in the clinical research arena
- The importance of Change Adaptability to business partners inside and outside the organization
- How to increase individual accountability for organizational culture

Karl Schoemer, President and Founder, VISION QUEST

12:15-1:15
Lunch in the Exhibit Hall

“Great content. Good networking. Fun”

—Mark Milberg, Contract Manager, Clinical Contracts and Alliance Management, MEDTRONIC
**Partnering for Collaborative Solutions**

1:15  **CASE STUDY**  Innovation in a Reduced Cost and Enhanced Efficiency Environment

With the increasing cost of doing business and budget constraints, clinical professionals need to do more than ever before with less, while still increasing productivity and maintaining quality. Sponsors are operating with fewer resources and need to outsource more but must do so with less money. And with a high number of product failures, available dollars for outsourcing are being threatened – this being especially true in smaller companies. Due to the increase in outsourcing, CROs and Labs have a surplus of business right now and rate structures and pricing have risen because of this. To top it all off, ever-rising turnover for both sponsors and providers causes increased time and cost to complete studies. Centerwatch reports that 94% of projects run over either or both time and budget. How can we do better?

- How can CROs and Sponsors collaborate to reduce non-value added activities so that more and better resources can be directed to more important work?
- How is large pharma employing cost saving innovations internally as well as externally e.g. Flexible staffing from CROs for monitoring, data management, safety, off-shoulding, etc.
- How can suppliers be more proactive in creating new business models to reduce costs and maintain quality?
- Forecasting outsourcing demand and matching capacity increases with demand growth and managing that growth - better planning with more transparency allows partners to more effectively forecast the outsourcing demand and its impact on both parties
- Identifying and implementing operational efficiencies to contain cost and keep on timelines

2:00  **CASE STUDY**  Developing Efficiencies Using a Central Lab & CRO Together

Pharmaceutical and biotech companies often independently select central lab and CRO suppliers. Considering the cross-industry tradition of achieving efficiencies in only two of the three project drivers: time – quality – cost, this session will present a case study of efficiencies realized in all three drivers when using a resource partner which provides both central lab and CRO services. Specifically discussed will be the unique efficiencies provided to the pharma client by the central lab and the CRO data vendor perform real-time data management via a proprietary connection. In addition, this session will highlight how resource partnerships are welcomed within a pharma company's support areas of finance and operations.

2:45  **Early Sponsor/Supplier Team Collaboration for More Effective Design of Your Clinical Program**

Large pharma companies are moving toward engagement on a strategic level in the early design and feasibility work by bringing partners in early. As many are going into a new territory, whether geographic or therapeutic, with new molecules, they want the CRO input that much sooner. Smaller and mid size companies also want a more collaborative relationship with CROs because they don’t have the throughput to gain the experience the CROs have and while there are large gaps in time between when they have to perform certain tasks, CROs are expected to keep up with regulations, etc. In addition, small companies want participation from CROs at time of RFP and appreciate the time, energy and thought put into proposals in addition to cost.

- Providing Sponsors with feedback based on experience and expertise versus making decisions on budgets
- Avoiding the ‘cookie cutter’ proposal
- Collaborating with suppliers in the planning stage to set the team up for success

3:30  Networking Break in the Exhibit Hall; Refreshments Hosted by MakroCare

4:15  **Shared Risk: Getting Beyond the Sponsor/Vendor Paradigm**

Trust can not be built on transactional relationships. It is built on transparency and commitments between companies where relationship management is blended with a very candid understanding of business interests for both CROs and Sponsors. When Sponsors and CROs do not share the same end goal (e.g. completion of high quality clinical trials on time) or the same risks, how can their interests be aligned? Would pharma companies be willing to put in significant incentives, monetary or otherwise, tied to approval if the CRO is charged with running a registration trial? Are Sponsors adept at identifying the risks appropriate to transfer to CROs? Are CROs prepared to take the risk burden or is it a gamble?

- Developing and maintaining relationships: sharing and understanding your partners’ interests, and fostering a commitment to share risks
- Constructing an agreement that fosters shared risk and demonstrates a commitment to partnership
- How do you get to this level of trust with your supplier? At what stage in a relationship should risk/reward discussions take place?
- KPIs for relationship building, performance management and service level agreements that constitute a risk/reward scenario
5:00  CASE STUDY  Streamlining the Outsourcing Process and Minimizing Internal Resources through the Use of External Provider Management Teams

In order to streamline the outsourcing process and the delivery of clinical trials, AstraZeneca created External Provider Management Teams (EPMTs). EPMTs are delivery teams comprised of a limited number of AstraZeneca and CRO members who direct CRO study teams to deliver a portfolio of studies. One external partner was selected to work with each therapy area EPMT to deliver all the outsourced work within that area. While still in the early stages, the model has already provided substantial internal resource savings. This panel discussion will take you through the model and its current, as well as future, expected benefits.

- No more RFPs!
- Save internal resources
- One outsourcing model
- Increase partnerships with external providers
- Maximize synergies and improved quality

5:45 – 6:45  Wednesday Evening Reception Hosted by

THURSDAY, APRIL 30, 2009

1:15  Adapting to Constant Change: How Partners are Working through the Organizational Stages

Changes are more dramatic than ever before in today’s pharmaceutical industry with layoffs impacting resources and mergers effecting increased competition and long periods of inactivity. The trickle down delay to CROs is frightening. From a business development perspective dealing with change management as the industry deals with ever increasing pressures on trial design, timelines and budgets can be frustrating and costly when a study is delayed or cancelled, or when new management comes in changing strategy and objectives. As Sponsors increasingly share more responsibility with CRO partners and have less time/resources for oversight, how are companies dealing with the changes that ensue?

- Changing doors into managers - How providers need to change to respond to this
- Risk tolerance providers must bear in an uncertain environment
- IP, manpower, time management
- Dealing with sometimes inexperienced or difficult teams on both sides

2:00  Small BioPharma Partnerships: Challenges and Opportunities for Transactional vs. Strategic Approaches

Small pharma and biotech companies tend to bring in partners very early to discuss development and often gravitate to biggest most global CROs who can run the entire study. Is this the best operational choice? Small company clinical operations look to the project manager at the CRO to be their virtual internal clinical leader but CROs are not all set up to engage in this way. Many small companies do not have the pipeline to engage in strategic relationships, and must be transactional, however how do those companies get attention from a large CRO? The issues are the same as those at Big Pharma, however large companies have different perspectives and engage CROs on multiple strategic levels (e.g. feasibility, expertise etc.). Who is the person at the supplier who will advocate to senior management for your organization when things go wrong? How have small and mid-size pharma/biotech partnered for success as they have more to lose if a clinical trial and/or provider relationship does not go well due to poor planning, miscommunication, etc? When strategic outsourcing/partnerships don’t resonate with small companies, sponsors and suppliers must have a meeting of the minds on the challenges that small companies face on a tactical level.

- How emerging Biotechs have managed to stay top of mind when working with a large CRO
- What are the benefits and challenges of working with a smaller CRO? Or multiple CROs (e.g. network of small regional CROs rather than one large global one)?
- Is there any one right model or does it depend on what phase you’re working in?
- How does the CRO get the right team to its clients?
- How are CROs staffing their organizations to deliver to smaller companies?
- What technology and infrastructure is needed among partners?

2:45

Late Breaking Developments

Does your company have an interesting story to tell based on recent developments with your partner? To inquire about discussing a new or unique case study with your partner

3:30  Track Chair Wrap Up Session

In this closing session, our track chair will summarize session highlights from the past two days.
1:15

**Wall Street’s 2009 Forecast and Analysis of Outsourcing Trends**

Back by popular demand and with double the dedicated time, our Wall Street perspective offers an assessment of the outsourcing environment from 2008–2009 as well as an outlook for the next few years. Our presenters each offer a brief commentary to kick off this very interactive session that welcomes audience questions and comments.

Special focus is given to the following issues, with a Wall St and Private Equity view on:

- The CRO industry, summarizing 2008 financial trends
- Outlook for 2009 and beyond
- The issue of CRO consolidation and the trade-offs of being public vs. private, given the growing role of private equity finance
- Assessment of the pharmaceutical landscape and how it impacts CROs
- Other industry trends such as risk-sharing, etc.

2:45

**Transforming Drug Development Outsourcing with a Virtual Model**

Virtual companies essentially outsource every component of development. Historically, virtual companies have been comprised of only a handful of individuals (e.g., researchers who have come from larger companies) or venture capitalists. These new companies are being formed by those who are recognizing that the big pharma model is losing its sustainability, and so they move their ideas (brain trust) outside of the big company to start their own initiative. Now the model is beginning to move into a construct where there is a whole portfolio of products being managed virtually. As the industry aspires to a lower cost basis for drug development, CROs must find ways to accommodate this by having a real stake in the success of the client with risk-sharing models of rising interest.

- Is the rise of the Virtual Pharma business model a “fad” or a permanent change in the Pharma industry?
- Changing the mindset of those who have ‘grown up’ in big pharma to results driven vs. task driven
- Virtual pharma’s expectation of the CRO
- CRO understanding of how the virtual model differs from traditional models and having an internal ‘champion’ looking out for the interests of the virtual pharma company
- Empowering CROs to drive the outcome of the outsourced work
- Lessons from virtual companies that can benefit big pharma

3:30  

**Networking Break in the Exhibit Hall; Refreshments Hosted by MakeCare**

4:15

**Creating Collaborative Partnerships for Strategic Outsourcing, Forecasting and Decision Making**

Otsuka Pharmaceutical Development and Commercialization (OPDC) has embarked on an ambitious plan to create collaborative partnerships with a very few CROs. This strategy includes a staffing forecasting model that allows Otsuka to forecast internal, outsourc and outsourcemanagement requirements and a risk reduction methodology for ensuring better project performance. This talk will focus on the research that led us to take this path, the approach we have used to select an initial partner and the relationship that we have built. Learn about OPDC’s:

- Implementation and Methodology
- Supplier selection process
- Staffing model to forecast sponsor and partner needs based on the pipeline

5:00

**Creating a Competitive Advantage through Sourcing**

The speaker will share his personal insights on how Sourcing can be a catalyst for driving transformational performance that can be seen and measured by the business. He will discuss how Sourcing professionals can increase their sphere of influence within the businesses they serve to enable change, how to gain the endorsement of their business leaders, and important components of delivering a successful outcome.

- What is an SME
- How collaboration makes the difference
- Seizing the opportunity
- Insuring a successful outcome

5:45-6:45  

**Wednesday Evening Reception Hosted by EDS**
1:15
Evolving the Key Strategies of Clinical Development Sourcing -- Current and Future Direction
Our presenters discuss ÉLAN and the alliance model resourcing strategy, including:
• Decision point/ROI to move to this model from a clinical development strategy perspective
• Applying operational learnings from large to mid-size organizational strategies
• Adoption curve to newer strategic resourcing directions
• Measuring operational success and continuous opportunities
• Governance and operating model with RPS

2:00
CASE STUDY  How Do Mergers, Acquisitions and Licensing Impact Outsourcing Decisions and the Role of the CRO?
With so many Big Pharmas working within M&As and constantly changing portfolios, mid-size companies no longer developing their own compounds but acquiring them instead, and small companies seeking only enough drug registrations so that another company can buy them out, there is a change in the business we need to respond to which opens the door for thinking about sourcing differently. The lack of history and emotional attachment which comes with acquired compounds affords the opportunity for culture change. No matter what size company however, for successful development, partners need to understand what the ultimate goal is.
• What can Big Pharma learn from small companies?
• What is the role of the CRO in helping a sponsor develop a compound that has been acquired or licensed?
• After the service provider is chosen, how do you build trust – when in the process of selecting, how much info are companies willing to provide and share so they can collectively make a good decision?
• How do IP and commercial implications factor in for more sophisticated portfolios rather than simply a virtual company with one compound?
• In the case of M&A, what happens to the Suppliers working with the company being acquired? Does it affect their position/relationship with the company? Does the company keep them informed about their status as the event progresses? Are they in a more secondary role?
• What if the M&A is on the CRO side?

2:45
ACADEMIC OVERVIEW: “Sourcing 2015: Projecting Sponsor-CRO Relationships of the Future”
Biopharmaceutical R&D outsourcing is poised to change dramatically over the next decade as sponsor companies look for additional capacity, standardization and efficiency, and higher levels of infrastructure utilization. This session looks at macroeconomic trends, strategies and practices as well as analogies drawn from other R&D intensive industries to project where sponsor-CRO relationships are headed. Particular emphasis will be placed on relationship models and their implications for small, medium and large biopharmaceutical companies.
• Review major trends impacting outsourcing relationships in biopharmaceutical R&D
• Project changes in discovery, preclinical, early clinical and later stage clinical outsourcing
• Discuss outsourcing strategies and practices in similar R&D intensive industries
• Apply implications from outsourcing analogies

3:30
Track Chair Wrap Up Session
In this closing session, our track chair will summarize session highlights from the past two days.

Event Concludes at 4:00

“Great introductions, good ability to drill down in tracks and fun after hours sponsored activities.”
—Jane Brennan, Associate Contracts Manager, Corporate Purchasing, GENZYME CORP
Raising the Bar on Quality and Patient Safety

1:15
Defining and Managing Quality in Clinical Trials
Timelines to get drugs to market are being shortened, budgets are decreasing, and quality expectations are increasing. Most of outsourcing focus is on time, cost and scope but a major challenge is in the quality of the process and the major deliverables. There is no doubt quality is front of mind with drug companies and regulatory agencies alike. Though it must be conceded that many current practices were reactively triggered in response to quality problems, the future will require that quality management be more proactively and comprehensively integrated into study planning and execution. Quality must be considered not as something imposed upon us, but as something that helps us. But how does one go about defining quality, changing the mindset, specifying quality standards and maintaining a team to those standards? This session sets out to explore this key question and others including:

- How can quality be defined and measured?
- How do we manage the apparent contradiction between increasing quality and reducing cost?
- How can teams focus on quality while dealing with competing priorities on multiple studies they are managing?
- What skills/characteristics are needed for team leaders and team members (on both the Sponsor and Provider sides)?
- In a sourcing relationship who is primarily responsible for quality?
- How do partners work together to achieve quality goals?

2:00
Ensuring Quality at the Sponsor, Site and CRO Levels
Achieving quality in a highly regulated and scrutinized industry where time, patients, resources and sometimes funding are limited is a major challenge facing companies today. Choosing suppliers who deliver quality work, while following FDA and GCP guidelines, SOPs and monitoring plans and training to ensure personnel understand their responsibilities and are in compliance is at top of minds. This interactive discussion explores:

- How do you establish an appropriate quality standard?
- Is Quality Assurance/Management a standard part of your project team? Is quality management fee-for-service or the cost of doing business?
- Successfully partnering with CROs, labs, and sites to conduct efficient yet effective studies as quickly as possible and ensure data integrity
- Meeting regulatory expectations for quality and company expectations of timeliness and cost effectiveness
- Working with project team and sites to educate sites on the importance of adhering to the protocol

2:45
The Implications of Post-Marketing Requirements on the Future of Drug Development Partnerships
Post-marketing requirements (PMRs) required by FDA and other regulatory authorities are becoming more demanding and increasing in complexity. While the information ascertained by PMRs is crucial to expanding safety and efficacy information on the drug, they are not always adhered to. PRMs place a large burden on the R&D function already struggling to get new products launched and the cost of these added trials is great. While traditional Phase IV trials are done primarily for marketing purposes, FDA is now looking for signals in large scale studies for adverse events in real world situations. The parameters are not relative to Phase IV so companies can’t use phase IV approach for PMRs. Instead, they are conducted by the same groups who do the initial pre-registration work. What is the best approach to get the work done effectively? Sponsors are looking to CROs to provide solutions, but many are still presenting their Phase IV teams for these demanding trials. What used to be the exception is increasingly becoming the rule for new drug approvals and the FDA will now have the ability to impose financial penalties on pharma companies who do not comply. This development is critical to the Pharma/CRO relationship as the CRO must be on board with the time commitments and deliverables.

- Managing post approval studies – what is the best approach with inherent regulatory uncertainty?
- Learning to perform these studies efficiently as the cost of these programs can exceed the cost of the drug registration program
- From a sourcing perspective, how do niche providers and CROs collectively work on this to support the PMR effort?
- Europe and other countries are also requiring more post-approval commitments – how are companies preparing?

3:30
Networking Break in the Exhibit Hall; Refreshments Hosted by MacroCare
Successful Collaborations for Fulfilling Post-Marketing Requirements

Post-marketing requirements (PMRs) required by FDA and other regulatory authorities are becoming more demanding and increasing in complexity. Newly-approved drugs average 3.5 PMRs each, mostly designed to seek additional safety data either in a long-term or niche patient population. FDAAA legislation has mandated that Sponsors take a more proactive approach to fulfilling these PMRs on a timely basis. Additionally, the level of rigor required for these studies has risen and many times, simple traditional commercially-oriented Phase IV approaches do not provide the necessary rigor for regulatory reporting of results. This session will discuss the challenges imposed by PMRs and will utilize case studies to illustrate how Sponsors and CROs can collaborate to meet a PMR within the required timelines and with the necessary rigor. Specifically, the following issues will be discussed:

- What is the outsourcing decision made within the Sponsor organization? What internal departments are charged with fulfilling the PMR? What specific CRO characteristics are important when choosing a partner for the PMR fulfillment?
- What level of rigor across study operations was selected and why? What typical Phase IV approaches work and don’t work?
- How was communication with FDA and/or other regulatory authorities handled? How was the PMR further defined from its initial communication to study completion?
- What lessons learned from both the Sponsor and the CRO can be applied to future PMR work?

Assuring Project Excellence through Quality Metrics Management

At Paragon, we meet and exceed the expectations of our clients by focusing on project excellence in all areas of service. To support our focus on project excellence, we have adopted a global metrics management approach that allows us to proactively identify potential problems and anticipate the need to develop strategic management plans to assure project success. In this session we will walk through our comprehensive approach to metrics management, share our Project Management Dashboard and discuss how metrics can benefit you and provide you peace of mind.

- Defining metrics for a global project
- Standardizing metrics tracking and reporting
- Metrics tools: Project Management Dashboard
  - Philosophy and Thresholds
- Metrics management
  - The Monthly Project Review
  - Issue escalation
- The benefit to you, the Sponsor
  - Early detection of potential issues
  - Proactive strategic planning to avoid project execution failures
  - Identification of process inefficiencies
  - Peace of mind

THURSDAY, APRIL 30, 2009

Adaptive Clinical Trials: Innovations in Trial Design and Management

With pharmaceutical companies facing the increasing challenge of diminishing pipelines, drug developers are always looking for new methods to shave time off of discovering and developing new molecules. Tools such as adaptive trial designs allow clinicians the ability to “fail faster.” This is accomplished by utilizing accumulating data to direct potential modifications to the trial as it progresses, while at the same time keeping the validity and integrity of the study in tact. In addition to cost and time savings, adaptive trials require fewer patients—a distinct benefit as patient enrollment is an ongoing obstacle to speedy trial management. Planning and executing these trials, however, can be much more intricate than traditional trial approaches and teams from clinical operations and trial management, data management, statistics and must align early in the process and work together judiciously for proper study conduct.

- Discuss the advantages and disadvantages of adaptive designs
- Learn how sponsors and suppliers are effectively collaborating on adaptive trials
- Understand the regulatory nuances of these special designs

What Does FDA Expect Regarding Quality Oversight of Third Parties?

Outsourcing of clinical research activities is increasingly common in FDA-regulated medical product development. Last year, Frost & Sullivan calculated that drug and biotech companies spent $57 billion on outsourcing; contract research organizations (CROs) got almost 30 percent, or $17 billion. U.S. companies in particular outsourced 40 percent of their clinical trials and that’s expected to rise to 65 percent by 2013. As a result, FDA has seen the emergence of an alarming trend regarding the submission of unreliable clinical research data to the agency. Therefore, FDA’s medical device center began analyzing this trend and found some common threads that lead to these unwanted situations. This presentation will uncover some of those warning signals and outline methods employed by industry to mitigate their occurrence.

Patient Recruitment: Understanding Internet Health Seekers and Why an Online Strategy is Important

Over 90% of clinical trials miss deadlines. Slow enrollment continues to be a leading cause of study delays. Slow enrollment costs sponsors hundreds of thousands of additional dollars every day. There are many factors and trends impacting clinical trial recruitment including niche product development, competing studies and protocol complexity. To meet current and future enrollment needs, organizations need to expand their strategies and reach out to a rapidly growing Internet health seeker audience. Internet health searches are growing at three times the rate of the Internet. More than 66% of users have searched online for health information and 33% search monthly. It is also important to note that 25% visit the Internet prior to a physician visit. Disease information along with alternative treatment options are frequently researched topics. Through the use of actual survey data, this presentation will enable individuals and organizations focusing on patient recruitment to build effective Internet based recruitment programs.

Track Chair Wrap Up Session

In this closing session, our track chair will summarize session highlights from the past two days.
Globalization and Trial Complexity

1:15
Leading Virtual Teams Around the Globe
- Companies are increasingly building teams, networks and groups that are working together virtually.
- How you manage and oversee outsourced work?
- How can we ensure regulations are being met with ex-US?
- Sourcing professionals and project managers need information on how to work with a virtual team with those sitting in other offices around the globe
- What does the future project manager/sourcing professional look like in today's complex trials?
- Are we providing team members with the right skills to work in these models?
- Having offices in global locations does not make you a “global company”; how to harmonize teams for a global project

2:00
Successfully Applying Technology to Clinical Trials Across World Regions
- Understand the application of technology in making traditional clinical research easier
- Identify cultural and infrastructural challenges
- Integrate modern technologies in developing nations
- Learn how to realistically integrate technology to local situations
- Manage technology globally at the site level

2:45
Approaches to Address the Impact of Increasingly Complex Clinical Trials
Increasingly complex clinical trial protocols demand more of investigative sites and study volunteers, leading to longer cycle times, more AEs and increasing difficulty in recruiting and retaining patients, according to research by Tufts CSDD. Combining the influx of less experienced investigators from emerging markets and increasing churn among ‘established’ investigators with not only an increase in the number of trials but also an increase in their complexity opens up a major grey zone for clinical trial quality. What are some of the pragmatic approaches to overcome these challenges? This session explores the answers and sets the stage for introducing a proactive approach to predict and prevent protocol violations, both from a drug development service provider perspective, and from a site/investigator perspective. Key clinical trial success factors to be discussed include:
- Successfully leveraging emerging market investigators who may be less experienced for trials that are becoming more complex and demanding
- Architecting a site management plan that promotes primary data quality and consistency yet allows flexibility based on country-specific differences
- Best practice for investigators to absorb a clinical trial into regular site operations
- Reducing non-core activities to free up resources to focus on their key responsibilities

3:30
Networking Break in Exhibit Hall; Refreshments Hosted by MakeCare

4:15
Supplier Selection: What Constitutes a Global CRO?
The first step in working with a global provider is analyzing whether working with one makes sense for your project. Once you’ve evaluated the criteria around your project’s needs, you must carefully investigate the growing range of providers offering global service. There are many CROs claiming to be global, but what constitutes this?
- How many studies?
- How do you identify the right partner on a regional basis?
- How do you best evaluate your needs as a sponsor?
- How much of the global CRO staff belongs to a “partnering CRO”?
- If the partners become financially unstable, what recourse is there for the sponsor?
- Are CROs always up front about their global capabilities?
- Who manages the partners? Should the sponsor have to cover management fees for the primary CRO to manage their partners?
- Even though the “global” CRO carries the contractual relationship with their partner, do they take and hold responsibility for performance?
- What due diligence is expected from the sponsor of these partners? Should the primary CRO hold the responsibility? How will the regulators view this?
Off shoring clinical trials to emerging markets around the world is receiving increasing attention as a very attractive alternative in the clinical development process. Do clinical research capabilities comparable to the US in terms of sophistication and FDA-compliance exist anywhere else in the world? And if they do, are they ready to handle the marked increase in demand from the US? Our panelists discuss in detail the demographics, challenges and opportunities, expertise of individual countries and the opportunities to optimize project budgets and reduce development time and regulations with global implications including:

- How cost control and investor expectations is leading to increased off-shoring opportunities
- Understanding regulatory and operating environment of emerging markets as well as cultural intricacies and how to place and execute clinical trials there
- How to offshore a project in such a manner that the work is seamless to the end user, i.e. the offshored partner performs the work in the same manner as an internal colleague
- Complexity of protocols vis-a-vis emerging country capabilities / infrastructure
- Coordination of projects across multiple companies on a global basis
- Must-have contractual requirements for commonly used international countries
- Managing multi-national projects with fluctuating timelines (enrollment, government regulations, IRB approvals, etc).
- Global integration of data, processes and cultures
- Utilization of low cost countries with available subject populations and GCP trained investigators
- Ethical considerations in deciding on trial placement

3:30

Track Chair Wrap Up Session

In this closing session, our track chair will summarize session highlights from the past two days.

“Partnerships, as a point of industry information sharing, is a quickly growing portal. Even more cutting-edge information, partners, and markets were presented in this forum this year then in years before. I believe that Partnerships with CROs has eclipsed other conferences to now become the premier conference in our industry.”

—Mark A. Lanfear, Regional Manager, rKFORCE® Alliance, ROCHE PHARMACEUTICALS
Optimizing Outsourcing Contracts, Budgets and Processes

1:15
**Standardization: The Holy Grail? The 2009 Update**
A major frustration across the industry is the different methodologies for the operations, conduct and management of clinical trials, site recruitment and management, communications and performance, audit readiness (site and sponsor), clinical project management, and the use of metrics to manage studies and training of CTM personnel. The problem runs even deeper for small companies with less resources, infrastructure and tools. There is little to no consistency across companies which in turn affect costs dictated by service providers as they must work on different platforms. Can the pharma and CRO industries work together to inspire a new level of standardization? This lively panel is in line up to last year’s serious-minded out-of-the-box discussion on the formation of standards.

2:00
**RFP Management & Contracting with CROs to Minimize Change Orders**
- What type of detail do CROs want in the RFP to help them get a better understanding of what is being outsourced?
- How to develop an RFP that allows the sponsor to compare like proposals while allowing the CRO to distinguish themselves and show creativity?
- Developing and creating contracts and RFPs that can be managed under metrics
- What type of information is useful to have in a proposal that is found lacking in the average CRO bid?
- The RFP and the budgeting process with government contracts
- RFP ethics – competitive underbidding with hidden change orders/equal sharing of information with all providers
- RFP process and budgeting for Big Pharma vs. smaller company
- Establishing the basis for paying sites
- Need for transparency in communication of the assumptions, responsibilities and budgeting process leads to more collaborative agreements

2:45
**Developing Scope of Work for Solid Project Foundation and Minimal Project Setbacks**
A solid scope provides the best project foundation and minimizes both the likelihood and impact of project upsets.
- Ripple effect beyond the contracting phase
- Avoiding costly change orders due to hurried or misinterpreted scopes
- Developing the scope with your partner leads to a well defined scope and strong foundation for success
- Proposal development as an exercise in collaborative solution seeking to develop a mutually agreeable and achievable plan

3:30
**Networking Break in the Exhibit Hall; Refreshments Hosted by: MakroCare**

4:15
**Supplier Identification and Selection**
- Using RFIs, vendor days, and capability presentations to identify service provider options
- Developing a vendor assessment and selection process
- RFPs, bid grids, scorecards, bid defenses, and more
- Successes/challenges of working with a functional outsourcing model
- Necessary time and skill set to partner with new CROs that are a good fit and provide what is expected without a number of change orders
- Selecting suppliers that really will do what the BD sales people promise

5:00
**Impact of Global Currency Fluctuation on Project Budgets: Who Holds the Risk?**
Global currency fluctuation has become an increasing challenge as more and more trials are conducted outside the United States which impacts charge rates regionally and daily. Multi-year contracts are becoming unwieldy, and R&D Finance has added the management of the fluctuations to its already full load of responsibilities.
- History and implications of currency fluctuations
- What happens when a once-cost effective country becomes more expensive?
- How currency fluctuations are being managed
- Operationalizing a plan to address this challenge
- Overcoming any distrust between sponsor and provider caused by fluctuations
- What is in scope for consideration as a currency risk
- Things to consider and “what if” scenarios
- Who is at risk?
- Strategies for managing risk: To hedge or not to hedge
- How is VAT managed/payment and reimbursement?
The Functional Service Provider Model: Exploring the Challenges and Benefits

As sponsor companies continue to feel the effects of increased performance pressures with flat or negative headcount growth, loss of exclusivity with fewer revenue replacement prospects, tightened regulatory environments with increasing scrutiny of obligations, and more intense cost containment demands, alternative sourcing paradigms are becoming the norm and no longer the exception. Specifically, the Functional Service Provider model of outsourcing has continued to grow in primarily large biopharmaceutical companies; however, mid and even small companies are looking toward the FSP model as a way to respond to the changing development environment. This session will focus on functional approaches seen in practice and in theory to present for discussion the value platform proposed by this model. From highly transactional, commodity-like services to the value-add hybrid approach, the panel will seek to engage the audience to debate the challenges and benefits in the FSP paradigm.

Educating Procurement and Outsourcing: How a Better Domain Knowledge Makes Your Job Easier and More Effective

Biomarkers is an innovative new tool that clinical operations and study management teams are increasingly utilizing which affords them the ability to cut down on costs and resources and make faster decisions within the overall drug development programs for clinical trial endpoints and timelines. In many cases, however, outsourcing/procurement professionals may not fully understand the use of such procedures/services: 1) why they are necessary and being utilized within drug development programs, 2) how the primary endpoints of a trial are enhanced by their use, 3) what the procedure/test/service/analysis actually is, and 4) the variety of services that exist. As the first and sometimes only contact reaching out to vendors, the education on the use of biomarkers and the impact they have on the clinical trial progression and deliverables is crucial to having Sponsors bulk up their knowledge of what’s out there to better support their respective, internal study management teams across all phases of trials.

Our speakers address:

- Ramping up for increasing internal customers’ request for Purchasing and Outsourcing assistance in this area of biomarkers
- Understanding and overcoming opposing needs; clinical operations’ pursuit of speed and quality vs. purchasing’s directive to save money vs outsourcing’s requirement of consistency of performance and quality deliverables.
- Understanding why certain services and capabilities exist and how these fit or are necessary within clinical trial work and the drug development process
- Building and maintaining alliances and relationships with internal stakeholders and external service providers so you are in communication and with current knowledge all the time
- Becoming more proactive in anticipating and meeting clinical research needs and the needs of the trial’s and/or program’s needs

Improving Outsourcing Effectiveness and Quality Through the Use of Data Standards

Sponsors of clinical research sometimes do not achieve the benefits anticipated from outsourcing because of many variations in processes from study to study. The result is that sponsors spend a considerable amount of time trying to understand, QC, reconcile and integrate supplier/CRO data. Data standards, while not a panacea, can help address these issues. If data are exchanged/delivered via an industry standard specification (e.g. the CDISC Study Data Tabulation Model (SDTM) or LAB Model), costs to develop specifications for data exchange are lower, there are fewer errors in specifications and less ambiguity as to what the biopharmaceutical company wants their partner(s) to deliver. There also are fewer communication breakdowns and hand-off delays, and it is easier to integrate data from a variety of providers, including CROs, laboratories and EDC suppliers.

In this presentation, we will consider the benefits of standards to improving the effectiveness of outsourcing by examining multiple different outsourcing scenarios or use cases including (1) data exchange during various phases of clinical research between a biopharmaceutical company and CRO(s); (2) laboratory data exchanged between a biopharmaceutical company and an external central lab; and (3) data exchanged between a biopharmaceutical company and an EDC supplier.

- Understand the role of data standards in improving the effectiveness, efficiency, and quality of clinical research outsourcing
- Examine several scenarios or use cases that demonstrate how to best employ standards in support of outsourcing
- Review best practices on when and how to use clinical data standards for help in establishing and communication expectations to an outsourcer in a structured way at project start

Track Chair Wrap Up Session

In this closing session, our track chair will summarize session highlights from the past two days.
WHO YOU WILL MEET

Delegates by Industry

- CRO: 50%
- Pharmaceutical/Biotechnology: 40%
- E-Technology: 5%
- Consulting: 3%
- Clinical Sites: 2%

Delegates by Title

- Outsourcing/Procurement: 21%
- Business Development: 17%
- Clinical Operations: 15%
- Contracts: 14%
- Budgets and Finance: 10%
- R & D: 10%
- Project Management: 8%
- Legal: 3%
- Quality Assurance: 2%

Seniority

Director: 40%  Vice President: 22%  C-Level/President: 13%

TARGET AUDIENCE

Pharmaceutical and Biotech Market:
- Clinical R & D
- Clinical Operations
- Global Outsourcing
- Procurement and Purchasing
- R & D Finance
- Strategic Sourcing
- Strategic Planning
- Project Management/Planning
- Contracts Administration
- Clinical Site Management
- Patient Recruitment
- Accounting/Budgets
- Legal Affairs

CRO Market:
- Business Development
- Medical/Scientific Affairs
- Clinical Affairs
- Data Management
- Regulatory Affairs
- Quality Assurance/Control

The event is also relevant to the following markets who have a stake in clinical development partnerships:
- Outsourcing Consultants
- Clinical Research Associates and Investigators
- Clinical Sites
- Data Management and Computer
- Software Vendors
- E-Technology Providers

The NEW Partnerships with CROs Website: Start Interacting Before the Event

Linked In

We’ve created the Partnerships with CROs group on Linked-In to encourage year-round discussion, knowledge sharing, and idea generation. At time of print, the group had over 1,000 members!

Don’t miss out on this great opportunity to discuss challenges, ideas, and solutions. Visit the Partnerships website and click on the “Linked In” icon.

Webinars

Now you can increase your learning before the event for free! Sign up for our monthly web seminars that are free of charge to provide you with additional learning opportunities from the comfort of your office. Visit the website for updates on upcoming webinar topics and registration details.

Online Networking

As a registered Partnerships with CROs attendee, you will receive access to hundreds of attendees already signed up so you can:
- Connect with Your Peers: Pre-networking with others attending the conference
- Schedule Meetings: Ensure you are able to meet with the companies and people in which you are most interested
- Build Your Contacts: Interact with other attendees and build business relationships

Blogs

The Partnerships blog RSS feed alerts you to crucial industry updates from the leading Clinical Trial publications and media outlets. Share your comments about what’s going on in the industry or participate as a guest blogger!

Email Allison Rigels at arigels@iirusa.com for guest blogging opportunities.
18 Reasons Why You Can’t Afford To Miss the 18th Annual Partnerships with CROs:

1. Get inside the minds of the industry's most prominent leaders on key drivers in the pharma sector leading to change and how companies should be preparing for the future

2. Learn how outsourcing leaders are creating competitive advantage through sourcing

3. Hear from sought-after Harvard Business School thought leader Clayton Christensen and join a private Q&A luncheon (space will be limited)

4. Find out what the FDA expects regarding quality oversight of third parties

5. Learn how to implement a sourcing strategy that will allow you to maintain a larger portfolio

6. Gain real life examples of how to utilize Supplier Relationship Management governance, performance management and other tools to maximize outsourcing benefits

7. Hear Wall Street’s assessment and forecast of the CRO industry and outsourcing trends and participate in an extended Q&A session

8. Discuss the latest thinking on the concept of shared risk in getting beyond the sponsor/vendor paradigm

9. Assess regional, regulatory, ethical, post-marketing and cost-related considerations for conducting trials in non-traditional markets

10. Find out how the industry is developing and implementing standardized CRO performance metrics to drive time, cost and quality and enhance partnership performance

11. Get insight into how and why pharma makes their selection of service provider

12. Learn how Pharma and Biotech companies are working their way through increasingly complex clinical trials and sourcing initiatives

13. Build stronger relationships with investigator sites

14. Understand the challenges and opportunities for transactional vs. strategic approaches in small biopharma partnerships

15. Overcome inconsistencies in proposals and avoid frequent scope of work change orders

16. Learn lessons from other industries on how they have implemented sourcing to become more efficient and effective

17. Implement practical tools found to be effective for planning and achieving objectives in successful CRO/Pharmaceutical partnerships

18. TAKE HOME NEW CONTACTS AND LEADS, RENEWED RELATIONSHIPS AND HUNDREDS OF BUSINESS CARDS!
TUESDAY, APRIL 28TH

Grand Opening Reception

Eat, drink and network in a relaxed setting –
Join us from 4:30-6:00pm

WEDNESDAY, APRIL 29TH

5:45-6:45 pm
NETWORKING RECEPTION
Mingle with colleagues and friends and network with new partners immediately following the close of sessions on Day One.

THURSDAY, APRIL 30TH

10:00-10:45 am
Don’t miss your opportunity to have your photo taken with NFL Hall-of-Famer TERRY BRADSHAW at the RPS booth

STAY IN TOUCH WITH THE OFFICE
Check your email at one of the internet kiosks hosted by Sprint

NEED A BREAK?
Visit the hall throughout the day for coffee, snacks and refreshments. Our breaks are graciously hosted by

GET BUFFED
– visit the shoe shine stand at the P&G booth

CATCH UP WITH PARTNERS OVER LUNCH!
Eat and network in a forum conducive for doing business and discussing the day’s sessions
Graciously hosted by TFS

ANALYZE THIS
Want to learn more about yourself? Get your handwriting analyzed at the MDS booth

FELLING LUCKY?
Visit over 250 booths in the hall and participate in raffles and giveaways throughout the event

CAREER DEVELOPMENT/ JOB POSTINGS
If you are interested in posting employment opportunities at your company, please drop off your announcement at the Partnerships with CR0s registration desk where a staff member will accept them for display at our Employment Center in the Exhibit Hall.

*Job postings accepted from registered companies only.
WITH CROs EXHIBIT HALL

18th Annual Partnerships with CROs (to date)

AAIPharma
AbCRO
Accelovance
ACM/Pivotal
ACORncro
ACR Image Metrix
ACRO (Association for Clinical Research Organizations)
Acurian
Advanced Biomedical Research (ABR)
Advanced Clinical Research Institute
Aerotek
Alphatec Clinical
Almac
Applied Clinical Trials
Aspire IRB
Averion International
BARC Labs
B. McLaughlin Associates
BBK Worldwide
Beardsworth CRO
Beckloff Associates
Bilcare
Bio-Imaging Technologies
Bio-Kinetic Europe
Biomedical Systems
blokin GmbH
BioStorage Technologies
Biotec Services International
C3i
CardioCare
Cardinal Health (Research Services)
Cedra
Cetera Research
Charles River
Chiltern
Cirion
ClearTrial
Clinical Trial Media
ClinForce
Clinical Resource Network, SPG
Clinlabs
ClinRx
Clinsys
Cogenics
Cognizant
Compass IRB
COMSYS
Copericus Group
Coram Clinical
Cordium Links
CORFO (Chilean Economic Development Agency)
Corporate Translations
Covance, Inc
CRF
CRL Medinet
DigiScript
Dokumeds CRO
DSG, Inc.
Duke Clinical Research Institute (DCRI)
eCast
Eisai Group
Elite Research Network
EMINENT Services Corp
Enthalpy Analytical
ePharmaSolutions
eResearch Technology
Esoterix
Essential Group
Eurolins Medinet
Exeucapharm
Exel PharmaStudies
Fisher Clinical Services
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Global Language Solutions
Goodwyn IRB
Harrison Clinical
Healthcare Communications Group (HCG)
I2
ICON
Imperial Clinical Research Services
INC Research
Inclinix
IndiPharm
Integrium
International Dermatological Institute
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IRL
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Kendle
KFORCE
KIK Medical
Kontrax Consulting
LAXAN
Lionbridge
M2S
MacroCare
Mayo Clinical Trials Services
MDS Pharma Solutions
Medfocus
Medfacts
Medpace
Medpoint
Medsource
Medtox
MESM
Metropolitan Research
Miami Research
MYODERM
NeoGenomics
NERI
NeuroRx
Nextrails
Novotech
Ocsas Logistics
Omnicare
OmniComm
On Assignment
Outcome
Pacific Biometrics
Paragon Biomedical
PAREXEL International
Patheen
Patient Interaction
Perceptive Informatics
Pharm-Olam
PharmaNet Development Group
Phase Forward
PHT
PPD
PRA International
PreAnalytIX
Premier Research
Progenitor International Research
PRL Central Laboratory
Prologue
Prudentas LLC
PSI
Quest Diagnostics
Quintiles
Quorum Review
Radiant Research
Radpharm
Recruitech
Registrat
ResearchPoint
Rhô
RPS
Rules Based Medicine
RxResearch Staffing
SAS
Semler Research
SGS
Simbec
SIRO Clinpharm
Smith Hanley
SNBL
Spacelabs Healthcare
Spectra Clinical
Striris Research
Study Manager
T+Medical
TFS - Trial Form Support
The Patient Recruiting Agency
ThermoFisher
Transperfect Translations
Tri Clinical Research
TTC, LLC
UBC - United Biosource Corp
Uppsala Monitoring Centre
VIASYS (now Cardinal Health)
VirtualScopics
Vitalograph
Yoh
Westat
Worldcare Clinical

*Companies in bold denote event sponsors.

Exhibit Hall Hours:

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<thead>
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RESERVE YOUR BOOTH – SPACE IS LIMITED

Join a wide range of US-based and global CROs, central labs, core labs, e-technology providers, clinical staffing companies, patient recruitment providers, and more, already confirmed to be in the exhibit hall.

The 18th Annual Partnerships with CROs offers you an excellent opportunity to promote your products and/or services in front of key decision-makers.

To learn more about these marketing opportunities...
RPS (ReSearch Pharmaceutical Services, Inc.) is the first and only Pharmaceutical Resource Organization (PRO) in the Pharmaceutical/ Biotechnology industry. Companies choose the PRO solution of RPS for the full range of clinical development services across multiple therapeutic specialties. The customized clinical teams of highly experienced RPS professionals operate with the Sponsor in a seamless and integrated manner. RPS combines the clinical expertise of a CRO and the resource management capabilities of a staffing firm. Since RPS is not a CRO, our Project Teams are fully committed to our Sponsors and are hand-selected according to Sponsor specifications. Our custom-designed Project Teams allow our Sponsors to take advantage of the industry’s top professionals within the functional areas required for the successful completion of their projects. http://www.rpsweb.com

Established in 1982, Chiltern is a leading global Contract Research Organization with extensive experience conducting and staffing international Phase I to Phase IV clinical trials across a broad therapeutic range for a wide variety of clients. Chiltern employs more than 1,200 people with 23 offices across the Americas, Europe, Latin America and in India. Chiltern provides services including Early Phase, Global Clinical Development, Late Phase, Biometrics, Medical and Regulatory Affairs and Resourcing Solutions. For more information about chiltern please visit www.chiltern.com.

Covance, with headquarters in Princeton, New Jersey, is one of the world’s largest and most comprehensive drug development services companies with global operations in more than 20 countries and more than 9,000 employees worldwide. Driven by a commitment to scientific, operational and service excellence, we help sponsors accomplish all of their drug development goals — from preclinical through commercialization. With a strategic focus on outstanding service quality, Covance is a compelling choice as a strategic partner. Our streamlined approach to drug development means high quality, error-free data designed to help bring your drug to market as quickly, safely and cost-effectively as possible. We focus on meeting sponsors’ timelines, delivering high-quality, error-free data, and providing exceptional customer service to successfully advance compounds through the drug development continuum. Strategic partnerships built on decades of success - Covance is dedicated to helping bring your miracles to market sooner.

ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. We specialize in the strategic development, management and analysis of programs that support Clinical Development - from compound selection to Phase I-IV clinical studies. Our services can be implemented separately or as part of a comprehensive full service clinical program.

Our global services are offered through the expertise of our five international divisions:
- **ICON Clinical Research**: phase Iib – IV Clinical trial management, biostatistics, data management, patient registries, health economics, outcomes research
- **ICON Development Solutions**: product development strategy/planning, early phase clinical development, regulatory affairs, pharmacokinetics/ biopharmaceutics
- **ICON Central Laboratories**: global central laboratory services dedicated exclusively to Clinical Trials
- **ICON Medical Imaging**: medical imaging based product development solutions
- **ICON Contracting Solutions**: contract and permanent staffing solutions for pharmaceutical and biotech companies. www.iconplc.com

For more than two decades, INC Research has been a therapeutically focused contract research organization with a high performance reputation for conducting global clinical development programs of the highest integrity. Pharmaceutical and biotechnology companies look to INC Research for a complete range of customized Phase I – Phase IV programs in therapeutic areas of specialty, and in innovative pediatric and women’s health trials. Our Trusted Process™ methodology and therapeutic foresight leads our customers to more confident, better-informed drug and device development decisions. INC Research is headquartered in Raleigh, North Carolina, with 25 offices and a presence in 36 locations worldwide. Whether the scope of your project is a full-service international study or requires only select regional services, INC Research can meet your needs. www.incresearch.com

PharmaNet Development Group, a global, drug development services company, provides expertise to the pharmaceutical, biotechnology, generic drug, and medical device industries. PharmaNet companies offer clinical development solutions including consulting services, Phase I clinical studies, bioequivalency and pharmacodynamic studies, bioanalytical analyses, and Phase II, III, and IV clinical development programs. With more than 2,500 professionals in 42 offices around the world, PharmaNet is a recognized leader in outsourced clinical development. For more information, please visit www.pharmananet.com.

As a leading global contract research organization providing development services and post-approval services, PPD employs forethought and flexibility to align with clients and provide customer-focused service and quality on-time deliverables. Our global central labs offer comprehensive laboratory services, project management and clinical expertise for proficient protocol design and harmonized project execution. With offices in 33 countries and more than 10,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and commitment to quality to help clients and partners maximize returns on R&D investments and accelerate delivery of safe, effective therapeutics.

i3 is a global business providing integrated scientific strategies and solutions throughout the biopharmaceutical product lifecycle. Our unique combination of services, products and knowledge helps companies gain sharper insights that lead to better patient care. http://www.i3global.com

Kforce Clinical Research, a unit of Kforce, Inc., provides customized outsourcing solutions in functional outsourcing, project solutions and traditional staffing to the biopharmaceutical industry. An intelligent partner, our intense focus on operational excellence assists our clients in reducing cycle times while maintaining study quality and safety. Established in 1988, Kforce Clinical Research is an industry leader in customized solutions. Kforce pioneered functional outsourcing in regional monitoring ten years ago and we have established functional outsourcing engagements with some of the world’s largest biopharmaceutical companies. Leveraging Kforce’s 45+ years of staffing expertise, Kforce Clinical Research matches the best talent in the industry with the best opportunities. Our functional areas include monitoring, site management, study management, drug safety, data management, data entry, clinical programming and biostatistics. To find out more, visit us at www.kforcclinicalresearch.com

MDS Pharma Services is committed to delivering quality service on time. We offer a full spectrum of resources to meet the drug discovery and development needs of the pharmaceutical and biotechnology industries. With numerous facilities strategically located around the world, we apply advanced scientific and technological expertise throughout the drug discovery and development process – from lead optimization, pre-IND research, early clinical research (bioequivalence, phases I-IIIa) and bioanalysis through to global clinical development (phases IIb-IV), central lab and centralized cardiac services. For more information, visit our website at www.mdspcs.com

Paragon Biomedical specializes in bringing innovation to market through impeccably managed Phase I-IV clinical trials management. Our global teams of highly experienced professionals bring localized expertise and a team-first mindset to every project. With an unwavering, company-wide commitment to excellence, we are dedicated to the success of your project.

Beardsworth® is a full-service CRO specializing in cancer & cancer supportive care trials with a specific focus on complex clinical trials & difficult therapeutic areas. A staff averaging 16 years experience & <10% turnover plus an 85% rate of repeat business attest to Beardsworth’s 23 -year track record of quality service & client satisfaction. Beardsworth is a WBENC-certified woman-owned business. http://www.beardsworth.com

Campbell Alliance is the leading management consulting firm specializing in the pharmaceutical and biotechnology industry. The firm’s clients include most of the world’s top-20 pharmaceutical companies, as well as numerous emerging and midsize firms. Campbell Alliance is organized into practice areas, each specializing in a critical industry function. Brand Management, Business Development, Clinical Development, Managed Markets, Sales, and Trade and Distribution. http://www.campbellalliance.com
OFFICIAL PUBLICATION

Applied Clinical Trials, with a BPA-qualified circulation of 18,250 clinical trial professionals worldwide, is the authoritative, peer-reviewed resource and thought leader for the global community that designs, initiates, manages, conducts, and monitors clinical trials. Industry professionals learn effective and efficient solutions to strategic and tactical challenges within the tightly regulated, highly competitive pharmaceutical environment.

The Association of Clinical Research Organizations (ACRO) is the professional organization of companies whose focus is clinical research. The association provides an active voice for the clinical research organization (CRO) industry, which provides specialized services that are integral to the development of drugs, biologics and medical devices. ACRO helps its members improve the quality, efficiency and safety of biomedical research. For more information, please visit www.acrohealth.org.

Pharmaceutical Outsourcing is a bi-monthly technical journal that is exclusively devoted to contract services and outsourcing in the life-sciences market. Our editorial comes from PhD's, senior level scientists, and thought-leaders in the biotech and pharmaceutical industry. We run topical articles that address issues the industry is talking about. Our topics include but are not limited to pre-clinical, drug development, analytical services, clinical trials, cold chain and logistics, data management, strategic partnering, and contract manufacturing. We have been serving the industry since 2000. Our circulation is 15,035 BPA audited subscribers and is 100% direct request.

BioSpace is globally recognized as the leading provider of web-based resources and information to the life science industry for over 20 years. With a well-established site infrastructure and loyal online audience of over 1 million unique monthly visitors, BioSpace.com offers an unparalleled distribution channel for recruitment, investment, product, event and other life science industry messages.

Bio-Outsourcing Asia© provides a comprehensive view of outsourcing issues facing the biopharmaceutical and biomedical industries as partnerships are formed with India, China, Taiwan, Malaysia, and other emerging Asian markets. http://www.canbiotech.com/CBB0A.asp


CenterWatch is a Boston-based publishing and information services company that focuses specifically on the clinical trials industry. Our fact-based and objective coverage and analyses have earned us the distinction of being viewed as an authoritative source for news, information and insight. CenterWatch provides a wide variety of publications and information services to pharmaceutical and biotechnology companies, CROs, SMOs, and investigative sites involved in the management and conduct of clinical trials. CenterWatch also provides educational materials for health professionals, patients and health consumers. We provide market intelligence services that many major companies have retained to help develop and implement new business strategies, to quit business as usual and participate in new clinical research-related initiatives, and to assist in due diligence activities.

ClinPage is an online newsletter about technologies and services in clinical trials. Its coverage is daily and definitive. Articles and podcasts at ClinPage (www.clinpage.com) showcase thought leaders in the industry who help our editors analyze pivotal trends. Key topics include outsourcing, electronic data capture, contract research organizations, global trials, clinical data management, drug safety, FDA policy, clinical data standards, patient-reported outcomes and adaptive trial design. ClinPage was founded in 2006 by Mark Uehling, an award-winning technology journalist and former editor of BioIT World and its eClinique newsletter.

Drug Delivery Technology publishes scientific articles, special features, and market news covering the science and business of drug delivery including, formulation development, product life-cycle management, technology assessment, product development, contracting and licensing. Specialty Pharma is a self-contained featured section inside Drug Delivery Technology addressing the business strategies behind portfolio optimization, pipeline management, and partnering with contract service providers throughout the drug development process.

European Pharmaceutical Contractor (EPC) provides a dedicated platform of information for the international pharmaceutical contract market, consisting of articles and case studies written by eminent figures in contractor groups and traditional multinational pharmaceutical companies. Each quarterly edition, edited by Dr Graham Hughes, examines areas of importance — both economic and technical — to CROs, contract manufacturer, regulatory controls, consultants and analysts. This enables regulatory bodies to link directly with policy-makers both in major contractor groups and pharmaceutical companies, and thereby convey regulatory information directly from the governing bodies, but also ensure debate between the policy-makers and consultancy groups. www.samedanltd.com

FiercePharma is the pharma industry’s daily monitor, with a special focus on pharmaceutical company news and the market development of FDA approved products. Our daily e-mail newsletter covers FDA regulations, generic drug companies, pharmaceutical marketing, pharmaceutical contract manufacturing, drug safety, and more. www.FiercePharma.com

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International Clinical Trials (ICT) is a specialist journal designed to provide global coverage of key topics pertinent to the clinical trials sector. Published quarterly, and edited by Dr Graham Hughes, the journal offers a platform of communication and information-sharing for executive and strategic decision-makers, seeking out new trends and marketing opportunities, as well as putting a spotlight on the latest innovations coming to market. ICT is specifically designed to be of interest to those actively seeking to source services for improved efficiency in what is an increasingly competitive market. www.samedanltd.com

Clinical Trials: Journal of the Society for Clinical Trials (formerly Controlled Clinical Trials) is an international, peer reviewed journal, published both in print and electronic versions, whose primary aim is the dissemination and development of knowledge about the design, conduct, analysis, synthesis, history, ethics, regulation and clinical or policy impact of all types of clinical trials and related medical research methodologies. http://ctj.sagepub.com

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical and service provider organizations. The mission of MCC is to develop, through a collaborative process, performance metrics within the Biotechnology and Pharmaceutical industry with the intent to jointly encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls for both Sponsors and Service Providers.

PharmaVOICE magazine, reaching more than 17,500 U.S.-based life-sciences executives, is the forum that allows business leaders to engage in a candid dialogue on the challenges and trends impacting the industry. PharmaVOICE, and its supporting VIEW publications, provide readers with insightful and thought-provoking commentary in a multi-perspective format through forums, topics, and articles covering a range of issues from molecule through market. PharmaVOICE subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, White Papers, E-Surveys and E-Alerts. Additionally, PharmaVOICEMarketplace.com provides a comprehensive directory of products, services, and solutions for the life-sciences industry. To Raise Your VOICE, contact feedback@pharmavoice.com.

www.PharmCast.com is the world leading website designed specifically for pharmaceutical, clinical and biotechnology professionals. www.PharmCast.com brings up-to-date information on pharmaceutical patents, FDA, news, jobs and Buyer’s Guide to our visitors. It was created and is maintained by pharmaceutical and biotechnology professionals. Visit www.PharmCast.com and discover for yourself why it is so popular among professionals.

PharmSource© is a respected provider of business intelligence on contract drug development and manufacture, and helps pharma and biotech companies implement and manage sourcing strategies and programs. PharmSource© also provides business development products and services to companies that serve the bio/pharma industry. Since 1996, organizations involved in contract pharma services have continuously relied on PharmSource’s publications, databases, surveys and consulting services to provide timely, insightful information and analysis. PharmSource© is the publisher of the PharmSource Lead Sheet, Bio/Pharmaceutical Outsourcing Report, Emerging Markets Outsourcing Report and the PharmSource ADVANTAGE database of contract service providers. www.pharmsource.com.

For more than 10 years, R&D Directions has provided the busy pharmaceutical executive with need-to-know clinical research information. Each issue delivers broad coverage and penetrating analysis of issues, events, trends, and strategies shaping drug development and pharmaceutical pipelines. Published ten times annually, R&D Directions provides exclusive content examining historical trends pertaining to and current events affecting the research of potential medicines and the companies that develop them. To learn more about R&D Directions and other products from Canon Communications Pharmaceutical Media Group visit www.pharmalive.com or call 215-944-9800.

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ABOUT THE VENUE

Rosen Shingle Creek Hotel is situated on 230 acres of lush landscape. Rosen Shingle Creek in Orlando is Central Florida’s newest and most luxurious meeting destination. The history of Shingle Creek reveals the captivating tale of how its majestic cypress trees provided some much needed shelter for early settlers and their homes. Today, our stunning grand lobby welcomes you into a world of lavish choices, complete with luxury accommodations, enticing restaurants and a championship golf course.

*Photo provided courtesy of Rosen Shingle Creek.*

Airfare
Fly JetBlue to Orlando and receive a 5% discount off the lowest available fare. To receive this discount book online at www.jetblue.com/promo and enter the promotion code PartnershipCRO. Please visit www.crospartners.com for more information.

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For More Information please go to: www.crospartners.com

CO-LOCATED CONFERENCES | APRIL 28-30, 2009

13th Annual
EDC & Beyond
IIR’s 13th annual EDC & Beyond event puts the “beyond” into your e-clinical systems, addressing the full e-clinical spectrum of technology and usage for optimal synergistic performance. Case studies and panels focus on: integrating multiple technology platforms, engaging sites, reducing redundancies, implementing new standards, and incorporating safety reporting.

6th Annual
Project Management for Pharma & Bio
Project management in the pharmaceutical and biotech industries continues to achieve further maturity, evolving into a vital tool that allows companies to manage the progress of their project portfolios. As clinical trials become more expensive across the industry, there is added pressure on Project Management Professionals to do more and more with less. The 6th Annual Project Management for Pharma & Bio Conference is the only industry event partnering with PMI’s BioPharma PM (formerly Pharmaceutical LIG) and includes the Annual Membership Meeting, bringing you sessions rich in educational content and optimal networking opportunities with other Project Management Professionals.
ADMINISTRATIVE DETAILS

OUR FULL REGISTRATION INCLUDES:

- Choice of either a half day or full day of workshops
- Keynote presentations
- Plenary as well as concurrent tracks
- Exhibit Hall admission
- Panel discussions
- Refreshments and luncheons
- Networking refreshment breaks
- Private areas for partnering meetings
- Evening receptions
- Documentation including speaker presentations and handouts

Payment is due within 30 days of registering. If registering within 30 days of the event, payment is due immediately. You may pay by check, VISA, MasterCard, Discover, Diner’s Club or American Express. Please make all checks payable to the “Institute for International Research, Inc.” and write the name of the delegate(s) and our reference number P1400 on the face of the check. If payment has not been received prior to registration the morning of the conference, a credit card hold will be required.

DATES: April 28-30, 2009

VENUE: Rosen Shingle Creek Hotel
9939 Universal Boulevard
Orlando, FL 32819

HOTEL ACCOMMODATIONS:
A block of rooms will be held for a limited period of time at the Rosen Shingle Creek Hotel. All hotel bookings should be made through The Global Executive’s Internet booking site. Please visit www.globalexec.com/iir to make your reservation. If you do not have web access, or need additional assistance, please call The Global Executive at 800-516-4265 or 203-431-8950 or send them an email at conf@globalexec.com. If you do not have web access, or need additional assistance, please call The Global Executive at 800-516-4265 or 203-431-8950 or send them an email at conf@globalexec.com.

DRESS CODE:
Business casual attire is suggested. We recommend bringing a sweater or jacket, as the conference rooms may be cool.

CANCELLATION POLICY:
If you need to make any changes or have any questions, please feel free to contact us via email at register@iirusa.com. Cancellations must be in writing and must be received by IIR prior to 10 business days before the start of the event. Upon receipt of a timely cancellation notice, IIR will issue a credit voucher for the full amount of your payment, which may be applied towards registration fees at any future IIR event held within 12 months after issuance (the “Expiration Date”). All credit vouchers shall automatically expire on the Expiration Date and shall thereupon become void. In lieu of issuance of a credit voucher, at your request, IIR will issue a refund less a $795 processing fee per registration. Registrants are advised that no credit vouchers or refunds will be issued for cancellations received less than ten business days prior to start of the event, including cancellations due to weather or other causes beyond the Registrant’s control. IIR therefore recommends that registrants allow for unexpected delays in making travel plans. Substitutions are welcome at any time.

If for any reason IIR decides to cancel this conference, IIR accepts no responsibility for covering airfare, hotel or other costs incurred by registrants, including delegates, sponsors, speakers and guests.

Program content is subject to change without notice. All speakers and topics are confirmed as of press time. When substitutions must be made due to speaker cancellations, IIR makes every effort to find a replacement of equal caliber to present the scheduled topic.

Press permission must be obtained prior to the event and is dependent upon the speakers’ approval. The press may not quote speakers or delegates unless they have obtained their approval in writing. Press passes do not include admittance to pre-event workshops and symposia.

Any disabled individual desiring auxiliary aid for this Event should notify IIR at least 3 weeks prior to the Event in writing, by faxing to (212) 661-6045.

EVENT DOCUMENTATION ORDER:
If you are unable to attend the program, or would simply like to order additional sets of documentation for your colleagues, they are available for $495 per set, including taxes, postage and shipping in the US. The Documentation is a compilation of the speaker handouts including overheads, power point presentations, articles and charts. Please fill out the order form below. The documentation is available two weeks after the Event takes place. CREDIT CARD PAYMENTS ONLY.

EARLY REGISTRATION DISCOUNTS

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<th>Before Mar '09</th>
<th>Before Apr '09</th>
<th>Standard Apr '09</th>
<th>Supplier/Vendor Pricing:</th>
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<td>Conference Only</td>
<td>$2,095</td>
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These discounts apply to all and will be taken off the standard onsite pricing only.

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☐ I am registering now to take advantage of the Earliest Registration Pricing

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Yes! Please register the following delegate(s) for:

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  Choose One:  ☐ B1  ☐ B2

☐ Conference Plus Two Half-Day Workshops:
  AM: Choose One:  ☐ B3  ☐ B4  ☐ B5
  PM: Choose One:  ☐ B6  ☐ B7  ☐ B8

☐ Conference Plus One Half-Day Workshop:
  Choose One:  ☐ B3  ☐ B4  ☐ B5  ☐ B6  ☐ B7  ☐ B8

PRE-CONFERENCE WORKSHOPS:

Full-Day Workshops:

B1: Developing & Implementing Standardized CRO Performance Metrics to Drive Time, Cost and Quality and Enhance Partnership Performance

B2: Outsourcing 101: Successful Outsourcing Strategies for Small Pharma and Biotech

Morning Pre-Conference Workshops:

B3: CRO Strategies for Adapting To the Changing Tides in Pharma

B4: Working in Partnership with Sites for Increased Productivity

B5: Clinical Trial Finance: Fundamentals of Budgets in Clinical Contract Management

Afternoon Pre-Conference Workshops:

B6: Driving Global Growth: Strategic Considerations for Conducting Clinical Trials in Non-Traditional Markets

B7: Governance and Supplier Relationship Management

B8: Contract Approach and Development: Key Terms and Negotiating Strategies

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- Assess how companies are proactively integrating quality management into study planning and execution, and managing teams to new standards
- Pharma is increasingly building networks around the world – learn how executives are managing global virtual teams
- Understand how transparency in communication of assumptions, responsibilities and the budgeting process lead to more collaborative agreements