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with CROs & Other Outsourcing Providers

100+ influential decision-makers speaking from the following companies:

PHARMA/BIOTECH:

- Abbott Laboratories
- Allos Therapeutics
- Amgen
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- Aventis
- Biogen Idec
- Centocor
- Chiron Corporation
- Congressional Pharmaceuticals
- CV Therapeutics
- Eli Lilly
- Endo Pharmaceuticals
- Forest Research Institute
- Genentech
- Genzyme
- Gilead Sciences
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- ICOS Corporation
- Inspire Pharmaceuticals
- Johnson & Johnson
- Medimmune
- Millennium Pharmaceuticals
- NPS Pharmaceuticals
- OSI Pharmaceuticals
- Pfizer
- Procter & Gamble
- Regeneron Pharmaceuticals
- Roche
- Schering-Plough Research Institute
- Sepracor
- TAP Pharmaceutical Products
- Vertex Pharmaceuticals
- Wyeth Pharmaceuticals

CROS:

- Biostorage Technologies
- Cato Research
- ClinTec International
- Covance Inc.
- ICON Clinical Research
- INC Research
- Inveresk
- MDS Pharma Services
- Omnicare Clinical Research
- Paragon Biomedical
- Parexel International
- Pharmaceutical Research Plus
- PharmaNet
- PRA International
- Quintiles Transnational
- ReSearchPharmaceuticalServices, Inc.

OTHER OUTSOURCING PROVIDERS:

- ARIS Global
- Data Spectrum
- EPharmaLearning
- Lifetree Technology & FFF Enterprises
- MediciGroup
- Midwest Clinical Support, Inc.
- Perceptive Informatics
- PharmData
- Thywill Latin Solutions
- StatProbe

CENTRAL LABS:

- LabCorp
- Quest Diagnostics

SPECIALTY CONSULTANTS AND RESEARCH GROUPS:

- Clinical Research Management Services, Inc.
- IBM Business Consulting Services
- IBM Life Sciences
- IBM Global Energy and Utilities
- John R. Vogel Associates
- Langley Research Center, NASA
- PharmaMediation
- Vantage Partners
- Willis, Inc.

LEGAL/REGULATORY:

- FDA
- Mintz, Levin, Cohn, Ferris, Glovsky, & Popeo PC

April 26-28, 2004 • Caribe Royale All-Suites Resort & Convention Center • Orlando, FL

Recognizing Clinical Development Outsourcing Professionals for over 12 Years

- Facilitate process improvements through results-focused, workshop-style dialog
- Maximize the CRO role in delivering productivity, quality and on-time efficiencies
- Acquire take-away tools, templates, strategies, and practical advice from seasoned experts
- Benchmark best practices with industry peers in both clinical and outsourcing groups
- Take a balanced partnerships approach to addressing and solving process-oriented challenges
- Learn how to creatively differentiate your competitive advantages in an arena moving toward standardization
- Gain recognition for your critical role in outsourced clinical development projects
- Meet and learn from current and potential clients, customers and partners in a relaxed atmosphere

Featured Strategic Presentations from:



Christopher C. Gallen, MD, PhD, Vice President and Chief of Operations WYETH RESEARCH



Dennis Gillings, PhD, Chairman and CEO QUINTILES TRANSNATIONAL



Renu Gupta, MD, Senior Vice President, Development ANTIGENICS, INC.

2004 Senior Executive Panel Led by:



James A. Bannon, PharmD, Corporate Senior Vice President and President, Late Stage Clinical Services COVANCE INC



John Climax, PhD, Executive Chairman ICON CLINICAL RESEARCH



Dr. R. Adrian Otte, MB, BCH, FFFPM Senior Vice President, Worldwide Development Operations PFIZER GLOBAL RESEARCH & DEVELOPMENT



Jeremy G. Chadwick, PhD, Vice President, Drug Evaluation Operations, Drug Evaluation & Approval (DEA) VERTEX PHARMACEUTICALS, INC.

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Recognizing Clinical Development Outsourcing Professionals for over 12 Years

Dear Pharmaceutical Professional,

Welcome to the 13th annual Partnerships with CROs and Other Outsourcing Providers event, the leading US pharmaceutical industry gathering on outsourcing and the development of effective clinical partnerships. Our mission is to present best practices on creating, managing and sustaining clinical outsourcing partnerships that enable more efficient and safe trials, leading to the availability of new life-saving and life-extending therapeutics. Partnerships is a knowledge-led networking forum where senior professionals from outsourcing and clinical groups from pharmaceutical and biotech companies, CROs and niche providers and investigative sites meet to build stronger ties and improve partnerships.

2004 KEYNOTE ADDRESSES

Changing the Paradigm of R & D through a Breakthrough Partnership, presented by Christopher C. Gallen, MD, PhD. Vice President and Chief of Operations, Wyeth Research and David Boath, Partner, Health & Life Sciences, Accenture

The Partnering Paradigm Advances: Delivering on Pharma's Promise, presented by Dennis Gillings, PhD, Chairman and CEO, Quintiles Transnational

Enhancing Partnership Opportunities through New Levels of Customer Service, presented by Renu Gupta, MD, Senior Vice President, Development, Antigenics, Inc.

2004 SENIOR EXECUTIVE KEYNOTE PANEL

Strategic Insights into the Evolution of Outsourcing in Clinical Development

Moderated by Stuart Kliman, Partner, Vantage Partners, this keynote panel brings together two of the top five global CROs, a large pharma and a biotech company to present a provocative look at current outsourcing strategy. Hear insights from James A. Bannon, PharmD, Corporate Senior Vice President and President, Late Stage Clinical Services, Covance Inc.; John Climax, PhD, Executive Chairman, ICON Clinical Research; Dr. R. Adrian Otte, MB, BCH, FFPM, Senior Vice President, Worldwide Development Operations, Pfizer Global Research & Development; and Jeremy G. Chadwick, PhD, Vice President, Drug Evaluation Operations, Drug Evaluation & Approval (DEA); Vertex Pharmaceuticals, Inc.

2004 BEST PRACTICE SPOTLIGHT

Lessons Learned from Outsourcing Experts in other Industries

Moderated by James Taylor, Global Head of Outsourcing, Drug Innovation and Approval, Aventis Pharma, other industries that share pharma's R & D or regulated characteristics team up to demonstrate business process improvements, transferable to pharma. Learn leading practices from Vicki Crisp, Head, Vehicle Analysis Branch, Langley Research Center, NASA; and Geoff Jue, Global Solutions Offering Executive, IBM Global Energy and Utilities Industry, and more.

2004 PULSE OF PHARMA'S USE OF CROS

What Does Pharma Value in the CRO Industry: A Roundtable Discussion Among Seasoned Outsourcing Experts

Participate in a discussion with a group of veteran outsourcing professionals from Pfizer Global R & D, GlaxoSmithKline, Inspire Pharmaceuticals and more to debate the type of short and long-term value contributed by CROs and how these perceptions impact your partnerships.

2004 EYE ON THE FUTURE

Transforming the Pharmaceutical/Life Sciences Entity: An In-Depth Overview of "Pharma 2010 – The Threshold of Innovation," presented by Sam Barnett, EdD, Americas Lead Partner, Life Sciences/Pharmaceuticals, IBM Business Consulting Services

WHAT YOUR EVENT EXPERIENCE INCLUDES

We understand that you attend annually to gain practical knowledge, recognize and share your sponsor/provider team successes and identify and bridge the disconnects that prevent your relationships from yielding the best possible results. As we enter our 13th year, our goal is to take even greater strides towards operational excellence in clinical outsourcing.

2004 Pre-Event Workshops

B1: Efficient Problem-Solving in an Outsourced Project: Design Your Own Workshop

B2: Provider Selection and the RFP Process

B3: Outsourcing Phase IV and other Late Phase Studies

B4: Creating and Customizing Cost Models for CRO Contracts

B5: Establishing the Outsourcing Function in Your Company: Strategy & Operations

B6: Senior Forum on Sponsor/CRO Partnerships: Examining Strategic Opportunities to Take Partnering to the Next Level

New Concurrent Tracks in 2004 for Customized Information-Gathering

Track A: Outsourcing Globally for International Trials

Track B: Optimizing Outsourcing Contracts and Budgets

Track C: E-Clinical Initiatives in Outsourcing Clinical Development

Track D: Maximizing Relationships with Investigative Sites

Track E: Measuring and Managing the Outsourced Relationship

Varied and Non-Traditional Value-Added Learning Opportunities

This is your opportunity to spend three days learning, collaborating and networking on ways to facilitate positive change and shared expectations and goals through:

Panel and Group Discussions: We understand the importance of presenting many perspectives on the issues, so most sessions are addressed by three or more topic leaders.

Interactive Voting: Cast your anonymous vote on a series of timely questions and learn the collective views of your peers in real time. Gain a valuable resource after the event by downloading survey results from the Partnerships website.

Lunch and Learn Roundtables: If you prefer to share your input in a more informal, relaxed setting, opt to participate in optional, moderated lunch table discussions. Interact at your own comfort level, and make sure your voice is heard.

Networking Breaks and Receptions: Effective partnerships are furthered by extending the relationship formally, through well strategized business objectives, and informally, through handshakes and conversations had over refreshments with your project teams and potential new partners.

We invite you to take this opportunity to review the agenda for 2004. We plan to meet and exceed your expectations with a comprehensive program, topic choices, and a 40% larger speaking faculty to give you access to key outsourcing leaders, influencers and decision-makers. Join us April 26-28, 2004 in Orlando. We look forward to partnering with you.

Sincerely yours,

Pam Sobotka, Event Director
13th Annual Partnerships

THE 13TH ANNUAL PARTNERSHIPS ADVISORY BOARD

We are proud to be working closely with an advisory board of outsourcing experts. Their insight and recommendations, together with the feedback and suggestions we have collected from you, our audience, have translated into a 2004 program that challenges existing processes and inspires you to achieve partnerships that will propel your projects to success.

Janet L. Brennan
Chief Operating Officer,
RPS (RESEARCH PHARMACEUTICAL
SERVICES, INC.)

Jeremy Chadwick, PhD
Vice President, Drug Evaluation Operations,
Drug Evaluation & Approval (DEA),
VERTEX PHARMACEUTICALS

William F. Colman, PMP
Director, Sourcing Group, Acting Head, Global
Clinical Outsourcing, Acting Global Account
Manager, US Drug Development,
ASTRAZENECA

Cindy Kearney
Director, Alliance Strategy Clinical Research,
JOHNSON & JOHNSON

Dr. R. Adrian Otte, MB, BCH, FFPM
Senior Vice President, Worldwide
Development Operations,
PFIZER GLOBAL RESEARCH &
DEVELOPMENT

Charleen Pagel Jue
Director of Clinical Operations,
OSI PHARMACEUTICALS

Holly Jerome
Senior Manager, Marketing Communications,
COVANCE INC.

Gena Reed
Executive Vice President,
PARAGON BIOMEDICAL

Paul Spreen
Vice President, CDS National Sales,
QUINTILES

Sue Stempien, MBA, CPM
Senior Manager, Head, Clinical Outsourcing,
GENENTECH, INC.

James E. Taylor
Global Head of Outsourcing Drug Innovation
and Approval,
AVENTIS

Pamela Wohlberg
Senior Director, Regional Head Contracts and
Outsourcing,
PFIZER



YOUR 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
- Interactive panel discussions
- Interactive Voting Session
- Refreshments and luncheons
- Networking refreshment breaks
- Private area for partnering meetings
- Evening receptions
- Documentation including speaker presentations and handouts

OUR EXHIBIT HALL BRINGS YOU:

- A comprehensive array of companies who can meet your outsourcing needs, under one roof
- Many provider companies new to the Partnerships exhibit floor
- The opportunity to discover new companies, product offerings, service providers and partnership strategies
- Private areas for project development meetings
- A relaxed environment for the exchange of knowledge and business cards
- Internet stations in our E-Business Center
- Massage chairs in our Relaxation Center
- The Partnerships News Stand, a collection of pertinent industry magazines and journals
- Coffee, refreshments, and luncheons
- Receptions and entertainment

Project Management for Pharmaceuticals

The 13th Annual Partnerships with CROs event is pleased to welcome the **Project Management**

for Pharmaceuticals conference, co-presented with The Project Management Institute's Pharmaceutical SIG as their first annual meeting independent of the annual PMI Congress. For details, visit www.iirusa.com/projectmanagement

The mission of this conference is to further project management in the pharmaceutical, biotech and CRO industries by providing best practices approaches to managing time, resources and budgets. Cross-functional project management strategies, tools and techniques are addressed.

If you are attending Partnerships and wish to send a project management colleague to the co-located Project Management for Pharmaceuticals conference, your colleague will receive 15% off registration fees.

PRIME EXHIBIT HOURS:

MONDAY	TUESDAY	WEDNESDAY
April 26, 2004	April 27, 2004	April 28, 2004
5:00 – 6:30	7:00 – 8:00	7:45 – 8:15
Opening Reception	10:00 – 10:45	10:00 – 10:45
	1:00 – 2:00	12:30 – 1:30
	3:45 – 4:30	

*Exhibit hours are subject to change

Interested in exhibiting? Contact Casey Greenzweig at 212-661-3500 ext. 3057; email cgreenzweig@iirusa.com.

Free Exhibit Hall Passes Available

See page 15 for Details

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The 13th Annual Partnerships is specifically designed for senior level professionals at:

Pharmaceutical and biotechnology companies in the following departments:

- Clinical R & D
- Clinical Operations
- Outsourcing
- Global Outsourcing and Procurement
- Strategic Sourcing
- Strategic Planning
- Project Management/Planning
- Contract Administration
- Finance/Accounting/Budgets
- Clinical Site Management
- Patient Recruitment
- Legal Affairs
- Business Development
- Medical/Scientific Affairs
- Clinical Affairs
- Data Management
- Regulatory Affairs
- Biostatistics
- Purchasing
- Pre-Clinical Development
- Quality Assurance/Control

Outsourcing Providers in the following departments:

- Business Development
- Sales & Marketing
- Market Research
- Strategy
- Client Relations
- Analytical Services
- Operations
- Tools and Technology
- Internet Development
- Privacy Officers
- Corporate Communications

The event is also relevant to the following markets who have a stake in clinical development partnerships:

- Clinical Research Associates and Investigators
- Clinical Sites
- Data Management and Computer Software Vendors
- E-Technology Providers
- Outsourcing Consultants

EVENT-AT-A-GLANCE

Sunday, April 25, 2004

5:00 – 6:00 *Beat the rush: Pre-registration*

Monday, April 26, 2004

FULL-DAY PRE-CONFERENCE WORKSHOPS

7:30 *Workshop Registration and Morning Coffee*

8:30 – 5:00 **Efficient Problem-Solving in an Outsourced Project: Design Your Own Workshop**

John R. Vogel, PhD, *Drug Development Consultant*, JOHN R. VOGEL ASSOCIATES, INC.
 Meryl Wiernick, *Associate Director, Strategic Sourcing and Procurement*, AMGEN
 Jim Powers, *Executive Vice President*, PRA INTERNATIONAL

8:30 – 5:00 **Provider Selection and the RFP Process**

Holly B. Kooyman, ND, *Associate Director Clinical Operations*, NPS PHARMACEUTICALS, INC.
 Martin (Jay) Joyce, MBA, CPM, *Senior Purchasing Manager, Health Care Global R & D Purchases*, PROCTOR & GAMBLE PHARMACEUTICALS, INC. (Invited)
 Dennis J. LaCroix, JD, *Director and Senior Counsel, Clinical Contracts and Vendor Management*, GENZYME
 Carolyn Saffer, *Contracts Manager*, GENZYME
 Ralph Munyan, *Principal*, PHARMAMEDIATION, INC.
 Scot Stubenhofer, *Principal*, PHARMAMEDIATION, INC.
 Janet L. Brennan, *Chief Operating Officer*, RESEARCHPHARMACEUTICALSERVICES, INC.

MORNING HALF-DAY PRE-CONFERENCE WORKSHOPS

7:30 *Workshop Registration and Morning Coffee*

8:30 – 12:00 **Outsourcing Phase IV and Other Last Phase Studies**

For presenters, visit www.cropartners.com

8:30 – 12:00 **Creating and Customizing Cost Models for CRO Contracts**

Gil Price, MD, *CEO*, CONGRESSIONAL PHARMACEUTICALS, INC.
 John Buerger, *Clinical Business Manager*, ICOS CORPORATION
 Barbara Birch, *Director of Clinical Business Development*, STATPROBE, INC.

12:00 *Luncheon for Delegates Attending both Morning and Afternoon Workshops*

AFTERNOON HALF-DAY PRE-CONFERENCE WORKSHOPS

12:00 *Workshop Registration*

1:00 – 5:00 **Establishing the Outsourcing Function in Your Company: Strategy and Operations**

Sue Stempien, *Senior Manager, Head, Clinical Outsourcing*, GENENTECH
 David Gilligly, *Director, Clinical Operations*, TAP PHARMACEUTICAL PRODUCTS
 Warren Myers, *Director, Medical Research, Department Head, Outsourcing and Contract Administration*, AMGEN
 Madeline Miller DVM, *Director, Medical Affairs Operations*, GILEAD SCIENCES, INC.

1:00 – 5:00 **Senior Forum on Sponsor/CRO Partnerships: Examining Strategic Opportunities to Take Partnering to the Next Level**

Steven Whittaker, *Director of Project Management Excellence*, ELI LILLY AND COMPANY
 Steven Chmielewski, *Manager of Clinical Project Sourcing, Project Management Excellence*, ELI LILLY AND COMPANY
 Michael Arlotto, *Senior Vice President of Project Management*, QUINTILES CLINICAL DEVELOPMENT SERVICES

5:00 - 6:30 **Grand Opening of Exhibit Hall Welcoming Reception**

Tuesday, April 27, 2004

7:00 *Main Conference Registration and Welcoming Breakfast Buffet, Hosted by COVANCE INC.*

8:00 *Chairpersons' Welcome*

8:30 **KEYNOTE ADDRESS**

Changing the Paradigm of R & D through a Breakthrough Partnership

Christopher C. Gallen, MD, PhD, *Vice President and Chief of Operations*, WYETH RESEARCH
 David Boath, *Partner, Health & Life Sciences*, ACCENTURE

9:15 **KEYNOTE ADDRESS**

The Partnering Paradigm Advances: Delivering on Pharma's Promise

Dennis Gillings, PhD, *Chairman and CEO*, QUINTILES TRANSNATIONAL
Refreshment and Networking Break, Opportunity to Visit Exhibit Hall

10:45 **SENIOR EXECUTIVE KEYNOTE PANEL**

Strategic Insights on the Evolution of Outsourcing in Clinical Development

Stuart Kliman, *Partner*, VANTAGE PARTNERS
 James A. Bannon, *PharmD, Corporate Senior Vice President and President, Late Stage Clinical Services*, COVANCE INC
 John Climax, PhD, *Executive Chairman*, ICON CLINICAL RESEARCH
 Dr. R. Adrian Otte, MB, BCH, FFPM, *Senior Vice President, Worldwide Development Operations*, PFIZER GLOBAL RESEARCH & DEVELOPMENT
 Jeremy G. Chadwick, PhD, *Vice President, Drug Evaluation Operations, Drug Evaluation & Approval (DEA)*, VERTEX PHARMACEUTICALS, INC.

11:45 **INTERACTIVE VOTING TOWN MEETING**

Michael Minor, *VP, Regional Operations*, ICON CLINICAL RESEARCH
 Mark Sanders, *Associate Director, Outsourcing Operations*, PFIZER, INC.
 Dan Ernest, *Sourcing Associate*, ELI LILLY & COMPANY
 Jody Fleisig, *Global Strategic Account Director*, OMNICARE CLINICAL RESEARCH, INC.
 Nick Reed, *CEO*, PARAGON BIOMEDICAL, INC.

1:00 – 2:00 *Luncheon in Exhibit Hall, Hosted by PRA INTERNATIONAL*

Concurrent Tracks	TRACK A: Outsourcing Globally for International Trials	TRACK B Optimizing Outsourcing Contracts and Budgets	TRACK C E-Clinical Initiatives in Outsourcing Clinical Development	TRACK D Maximizing Relationships with Investigative Sites	TRACK E Measuring and Managing the Outsourced Relationship
2:00	Hot Topics for Conducting Trials in Key Geographical Regions Barbara J. Geiger, <i>President and Clinical Director</i> , CLINICAL RESEARCH MANAGEMENT SERVICES, INC. Sue Tremlett ROCHE (invited) Robert Teoh, <i>VP of Asia</i> , PPD PHARMA (invited) Maria Fernandez Freire, <i>Director</i> , THYWILL LATIN SOLUTIONS	How Much Oversight Should an Outsourced Trial Have? Charleen Pagel Jue, <i>Director, Clinical Operations</i> , OSI PHARMACEUTICALS Bruno Gagnon, <i>Director, Clinical Operations</i> , CHIRON CORPORATION Jim Powers, <i>Executive Vice President</i> , PRA INTERNATIONAL, INC.	Optimizing EDC: Build It, Buy It or Outsource It? Bruce L. Maloff, PhD, <i>Chief Clinical Officer</i> , LIFETREE TECHNOLOGY & FFF ENTERPRISES Michael Fauntleroy, <i>Director for Electronic Submissions</i> , US FDA-CBER David Detoro, <i>Senior Director, Clinical Data Management</i> , SCHERING-PLOUGH RESEARCH INSTITUTE James R. Weston, <i>Vice President, Corporate and Regulatory Strategy, Managing Director</i> , CATO RESEARCH	Changing the Site Paradigm and Improving Performance Robert J. Davie, PhD, <i>Vice President Service Delivery Europe</i> , COVANCE INC. Janis Witzleb, <i>Contracts Manager</i> , WYETH RESEARCH Sandra S. Vose, <i>Director, Clinical Operations, Regional Monitoring Services, NA</i> , COVANCE INC. SallyAnn Crann, <i>Director, Clinical Affairs</i> , RPS	Optimizing Relationships in a Therapeutically Focused Environment: Current Trends and Challenges Thomas G. Schlagheck, PhD, <i>Vice President, Clinical Operations</i> , ENDO PHARMACEUTICALS Jennifer Harris, <i>PharmD, Clinical Pharmacology and Discovery Medicine, Oncology</i> , GLAXOSMITHKLINE Kari Leonard, PhD, <i>Senior Program Manager</i> , INC PEDIATRICS Julianne Hull, <i>Director, Clinical Data Management Outsourcing</i> , WYETH PHARMACEUTICALS Anne Wiles, <i>President</i> , DATA SPECTRUM
3:00	Critical Success Factors when Working with Geographically Focused CROs Gena H. Reed, <i>Executive Vice President</i> , PARAGON BIOMEDICAL Pawel Dyras, MD, PhD, <i>Vice President</i> , CLINTEC INTERNATIONAL Debra Echlin, <i>Program Director</i> , ABBOTT LABORATORIES Rebecca McMillian, <i>VP, Strategic Development</i> , PARAGON BIOMEDICAL	Increasing Efficiencies around Contract Negotiation and Change Order Amendments Holly B. Kooyman, ND, <i>Associate Director Clinical Operations</i> , NPS PHARMACEUTICALS, INC. and <i>President</i> , PHARMACEUTICAL DEVELOPMENT PARTNERS, LC Nathan Ternus, <i>Senior Contracts and Outsourcing Associate</i> , NPS PHARMACEUTICALS, INC. Francis Wouters, PhD, DDS, <i>Senior Director of Business Development</i> , PHARMANET, LLC Tara Fitzgerald, <i>Vice-President, Operations</i> , PHARMDATA, INC.	Preparing an IT Infrastructure for Optimal Global Logistics Management Robert Oyler, <i>Exec - Information Technology Services for Healthcare</i> , IBM LIFE SCIENCES Rob Goodwin, <i>Director of Clinical Operations Strategy, Worldwide Development</i> , PFIZER GLOBAL R & D	Overcoming Recruitment Hurdles in Challenging Therapeutic Areas Gina M. Zappolo, <i>Director, Strategic Operations</i> , RPS (RESEARCH PHARMACEUTICAL SERVICES, INC.) Sue Hocker, <i>VP and General Manager of Patient and Clinical Communications</i> , PAREXEL MEDICAL MARKETING SERVICES <i>Additional panelists to be announced</i>	Managing the Highest Level, Long-Term Relationship to Meet your Strategic Goals Patrick Phillips, <i>Head, Global Supplier and Governance</i> , GLAXOSMITHKLINE Harris Koffer, <i>VP Clinical Trials and Pharma Business Development</i> , QUEST DIAGNOSTICS

EVENT-AT-A-GLANCE

3:45 45 Minute Break Hosted by **PAREXEL**

	TRACK A: continued	TRACK B: continued	TRACK C: continued	TRACK D: continued	TRACK E: continued
4:30	Drivers behind the Decision to Take Clinical Trials International Alan Horgan, <i>Group Vice President of Late Stage Development</i> MDS PHARMA SERVICES William F. Colman, PMP, <i>Director, Sourcing Group, Acting Head, Global Clinical Outsourcing, Acting Global Account Manager, US Drug Development</i> ASTRAZENECA LP Vailla Clements, <i>Vice President of Corporate Development</i> QUINTILES TRANSNATIONAL John Mills, MD, PhD, <i>Chief Executive Officer</i> , BIOSTORAGE TECHNOLOGIES	Resolving Legal Issues, Risks and Challenges Facing Sponsors when Contracting with Service Providers Blaine Templeman, Esq., <i>Attorney, Business and Finance/Biotech Practice Group</i> MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO P.C. Lyn Rossano, MPH, <i>Vice President, Clinical Trial Coverages</i> WILLIS, INC. Robyn Philip Norton, <i>Manager of Medical Affairs</i> , OSI PHARMACEUTICALS James Lovett, <i>Corporate Senior Vice President, General Counsel and Secretary</i> , COVANCE INC.	Standardizing the Capture, Measurement and Storage of Medical Images for Improved Quality and Efficiency Mark A. Goldberg, MD President, PERCEPTIVE INFORMATICS, INC. (A PAREXEL Company) Max Rosen, MD, MPH, <i>Associate Professor of Radiology - Harvard Medical School</i> BETH ISRAEL DEACONESS MEDICAL CENTER	Alternatives to Investigator Meetings: Can Webcasts and other Technology Advances Be More Effective than In-Person Meetings? Lisa Laluna, <i>VP of Business Development</i> EPHARMALEARNING Colleen Gorman, <i>Manager of Clinical Research</i> PFIZER, INC. LuAnn Vanaman, <i>Clinical Study Leader</i> ASTRAZENECA Michael Schwartzman, <i>Senior Contracts Associate</i> AVENTIS Rochelle Suffern, <i>Clinical Research Manager</i> GLAXOSMITHKLINE (<i>invited</i>)	Building and Implementing a Key Pharma/CRO Relationship Management System Cindy Kearney, <i>Director, Alliance Strategy Clinical Research</i> JOHNSON & JOHNSON Stu Kliman, <i>Partner</i> VANTAGE PARTNERS
5:30	Close of Day				
5:30 – 7:00	Evening Reception, Hosted by Paragon Biomedical				

Wednesday, April 28, 2004

7:45	Morning Coffee in Exhibit Hall
8:15	Chairpersons' Opening Remarks and Recap of Day One
8:30	FEATURED ADDRESS Transforming the Pharmaceutical/Life Sciences Entity: An In-Depth Overview of "Pharma 2010 – The Threshold of Innovation" Sam Barnett, EdD, <i>Americas Lead Partner, Life Sciences/Pharmaceuticals</i> , IBM BUSINESS CONSULTING SERVICES
9:15	KEYNOTE ADDRESS Enhancing Partnership Opportunities through New Levels of Customer Service Renu Gupta, MD, <i>Senior Vice President, Development</i> , ANTIGENICS, INC.
10:00 – 10:45	Morning Refreshment Break; Opportunity to Visit Exhibits
10:45	2004 BEST PRACTICE SPOTLIGHT Lessons Learned from Outsourcing Experts in other Industries James Taylor, <i>Global Head of Outsourcing Drug Innovation and Approval</i> , AVENTIS PHARMA Vicki Crisp, <i>Head, Vehicle Analysis Branch</i> , LANGLEY RESEARCH CENTER, NASA Geoff Jue, <i>Global Solutions Offering Executive</i> , IBM GLOBAL ENERGY AND UTILITIES INDUSTRY
11:45	2004 PULSE OF PHARMA'S USE OF CROs What Does Pharma Value in the CRO Industry: A Roundtable Discussion among Seasoned Outsourcing Experts Peter A. Carberry, MD, MBA, <i>VP, Clinical Trials</i> , JOHNSON & JOHNSON PHARMACEUTICAL R & D Fred Naidis, PhD, <i>Senior Director, Contracts & Outsourcing, Development Operations</i> , PFIZER GLOBAL RESEARCH & DEVELOPMENT John F. Covin, <i>Head, Global Grants and Contacts</i> , GLAXOSMITHKLINE Don Kellerman, PharmD, <i>Senior Vice President of Development</i> , INSPIRE PHARMACEUTICALS Dan Perlman, <i>President and CEO</i> , RPS
12:30 – 1:30	Luncheon and Optional Lunch and Learn Roundtable Sessions
1:30	Exhibit Hall Closes

Concurrent Tracks	TRACK A: Outsourcing Globally for International Trials	TRACK B Optimizing Outsourcing Contracts and Budgets	TRACK C E-Clinical Initiatives in Outsourcing Clinical Development	TRACK D Maximizing Relationships with Investigative Sites	TRACK E Measuring and Managing the Outsourced Relationship
1:30	Developing Japanese Pharmaceutical Clinical Research with Global Affiliates Presenters to be announced See www.cropartners.com for updates	Pros and Cons of Bonuses and Penalties in Outsourcing Contracts Linda Donahoe, <i>Associate Director, Strategic Resource Management</i> BIOGEN IDEC MA, INC. Lynn McGovern, <i>Senior Manager, Clinical Procurement</i> MILLENNIUM PHARMACEUTICALS Rick O'Hara, MBA, <i>Senior Manager, Business Operations</i> CENTOCOR, INC. (<i>Invited</i>) Jonathan Koch, <i>Vice President, Global Commercial Services</i> INVERESK	Improving Workflow to Optimize a Web-Based Clinical Trial Management System Lorraine D. Ellis, MS, MBA, <i>President/CEO</i> RESEARCH DYNAMICS CONSULTING GROUP, LTD. John D. Kofoed, <i>Director, globalTRIALS™ Management Solutions</i> ARIS GLOBAL Ambrish Mathur, <i>VP Product Development</i> ARIS GLOBAL	Managing the Domino Effect: The Interface of Sponsors, Sites and Vendors for Study Success Audrey Rossow, <i>Senior Clinical Project Manager, Clinical Operations</i> SEPRACOR, INC. Elizabeth Moench, <i>President</i> MEDICIGROUP Dan Ulrey, <i>President and CEO</i> MIDWEST CLINICAL SUPPORT, INC. (MCSI)	Leveraging Outsourcing from Pre-Clinical to Submission Beverly Dale, <i>Director, Business Development, Clinical Genomics Marketing Group</i> , ROCHE Andrew Ginsberg, <i>Managing Director, The Americas, Clinical Trials Division</i> LABCORP
2:30	Selecting, Managing and Communicating Effectively with Vendors to Facilitate International Studies Rafael Escandon, PhD, MSc, <i>Senior Director, Clinical Operations</i> , CV THERAPUTICS Additional panelists to be announced	Managing the Contractual and Budgetary Challenges of Outsourcing in a Small Company Solomon Babani, MBA, <i>Manager, Finance and Outsourcing, Clinical Sciences</i> REGENERON PHARMACEUTICALS Jennifer Carver, RN, MBA, <i>Manager, Clinical Finance and Outsourcing</i> ALLOS THERAPEUTICS Srilu M. Ravi, MPH, <i>Manager, DEA Outsourcing and Planning</i> VERTEX PHARMACEUTICALS Laurie Tibbets, <i>Associate Director, Clinical Contract and Finance</i> GILEAD SCIENCES, INC. Paulette Wilson, <i>Comptroller</i> ALLOS THERAPEUTICS	Innovation versus Risk: How Much Innovation Do We Embrace? David Ng, PhD, <i>Vice President of Data Management/Biostatistics Consultative Services</i> PPD DEVELOPMENT Additional presenters to be announced	Employing an Innovative Approach to Successful Patient Recruitment Elaine Richardson, <i>Director, Internal Medicine Therapeutic Area</i> FOREST RESEARCH INSTITUTE a division of FOREST LABORATORIES, INC. Ann Kottcamp, <i>Vice-President Client Relations</i> PRP - PHARMACEUTICAL RESEARCH PLUS	Using Performance Metrics to Improve Outsourcing and Evaluate the Success of a Project Ed Cannon, <i>Global Account Manager</i> ASTRAZENECA LP Additional panelists to be announced
3:30	Event Concludes				

PRE-CONFERENCE WORKSHOPS

SUNDAY, APRIL 25, 2004

5:00 – 6:00 pm Beat the rush --Pre-register for the conference and meet the Partnerships 2004 team

MONDAY, APRIL 26, 2004

The purpose of the Partnerships workshops is to encourage pharmaceutical and biotech professionals to work through a particular subject for a half or whole day to gain detailed guidance on problem-solving, provider selection, contracting, managing and more. Workshops present quality-driven, in-depth agendas in selected areas of interest to support professional growth and strengthen project success. The workshop leaders are dedicated, seasoned experts in their topic areas who share their wealth of experience in an interactive format.

FULL-DAY PRE-CONFERENCE WORKSHOPS

7:30	Workshop Registration and Morning Coffee	12:00–1:00	Luncheon for Delegates and Workshop Leaders
8:30	Workshops B1 and B2 Begin	2:30	30-Minute Break
10:00	30-Minute Break	5:00	End of Workshops

UPDATED!

B1: Efficient Problem-Solving in an Outsourced Project: Design Your Own Workshop

Design-Your-Own-Workshop

This hands-on workshop is designed to give participants real-world experience dealing with typical problems that occur in outsourced projects. New to this year's workshop is the ability for participants to choose the set of problems they are most interested in tackling.

The day-long program includes descriptions of first-hand experiences by workshop leaders, realistic role-plays, team assignments of case studies, group discussions, and an opportunity for delegates to present their own outsourcing problems. Workshop participants will learn how to recognize red flags, analyze problems, find solutions, assign responsibilities, measure outcomes, and measure follow up actions.

Case study/role-play exercises revolve around the following types of challenges. Workshop participants

may choose the "problem area" most common to their day-to-day responsibilities so they can walk away with actionable strategies for overcoming it:

Overcoming failure to define scope of work/expectations

- Obtaining a clear definition and understanding of scope of work
- Properly define expectations from a Sponsor for a CRO
- Overcoming failure to have best practice tools to generate weekly/monthly reports

Overcoming failure of the communication plan

- Resolving difficulty with virtual team collaboration
- Improving what was a lack of communication from vendors regarding expectations.
- Optimizing roles around issue escalation
- Improving meeting timelines on data transfers from CROs and labs: Who communicates the problem? How is root cause of the delay discovered?

Overcoming failure to manage scope change

- Tracking and managing out of scope activities
- Responsiveness of vendor in providing

change orders

- Getting buy in for scope of work, especially during staff changes

Overcoming inadequate staffing/training

- Coping with inexperienced project management teams and changes in personnel assigned to project
- Effectively managing staff transition
- Beating team turnover early in the project
- Misjudging CRO plans for resource requirements

WORKSHOP LEADERS:

John R. Vogel, PhD, *Drug Development Consultant*
JOHN R. VOGEL ASSOCIATES, INC.

Meryl Wiernick, *Associate Director, Strategic Sourcing and Procurement*
AMGEN

Jim Powers, *Executive Vice President*
PRA INTERNATIONAL

NEW!

B2: Provider Selection and the RFP Process

Selecting the right CRO for a clinical trial is a daunting job. Whether the sponsor has five days, five weeks or even five months to make their selection, there is a right way to manage the selection process. Key deliverables are fewer project risks, faster-smoother trials, with fewer surprises, while minimizing unsavory cost-impacts around unanticipated scope changes. The workshop examines specific provider selection processes and the critical role played by the RFP process. Our workshop leaders interactively address:

- Pre-Qualifying your CROs and soliciting lucid, data rich Requests For Information (RFIs)
- Optimizing the number of CROs in the bidding pool for a project
- Standardizing the RFP
- Timing the RFP correctly to minimize inefficiency

and friction

- Controlling money spent to win a study
- Making an effective CRO presentation: What matters most to sponsors?
- Using a knowledge management approach to selection: A CRO capabilities and metrics database
- Bid grids are standardized, but they may end up looking very "vanilla"; how do you demonstrate creativity?
- Competitive bid process: Managing the timeline, the documents and the people
- Metrics to measure your selection process performance

The workshop also provides a variety of tools, documents, templates and process maps that can provide a foundation for an evolving outsourcing group or can augment even the most robust collection of tools. The workshop arms the CRO community with the information necessary to give the Sponsor what it needs to make an informed selection. Properly equipped, the CRO gains the high

ground to compete and win more contracts.

WORKSHOP LEADERS:

Holly B. Kooyman, *Associate Director Clinical Operations*
NPS PHARMACEUTICALS, INC.
President, PHARMACEUTICAL DEVELOPMENT PARTNERS, LC

Martin (Jay) Joyce, MBA, CPM, *Senior Purchasing Manager, Health Care Global R & D Purchases*
PROCTOR & GAMBLE PHARMACEUTICALS, INC. (*invited*)

Dennis J. LaCroix, JD, *Director and Senior Counsel, Clinical Contracts and Vendor Management*
GENZYME

Carolyn Saffer, *Contracts Manager*
GENZYME

Janet L. Brennan, *Chief Operating Officer*
RPS (RESEARCH PHARMACEUTICAL SERVICES, INC.)

Ralph Munyan, *Principal*
PHARMAMEDIATION, INC.

Scot Stubenhofer, *Principal*
PHARMAMEDIATION, INC.

MORNING HALF-DAY PRE-CONFERENCE WORKSHOPS

7:30	Workshop Registration and Morning Coffee	10:00	30-Minute Break
8:30	Workshops B3 and B4 Begin	12:00	End of Workshops Luncheon for Delegates Attending both Morning and Afternoon Workshops

NEW!

B3: Outsourcing Phase IV and other Late Phase Studies

This workshop illustrates overcoming challenges associated with outsourcing Phase IIIb and Phase IV

clinical trials including:

- Overcoming challenges in conducting late phase studies and why outsource?
- Site evaluation and selection
- Collecting and analyzing safety and efficacy data for market approval and marketing

- Phase IV's contribution to risk management initiatives
- Effects of outcomes and pharmacoeconomic factors

Workshop faculty to be announced. Visit www.cropartners.com for updates

PRE-CONFERENCE WORKSHOPS

UPDATED!

B4: Creating and Customizing Cost Models for CRO Contracts

As outsourcing in the pharmaceutical and biotechnology industries continues to evolve, companies have become extremely savvy in creating and customizing methods to price outsourced activities. Where are we finding success? How are we improving the process? This interactive workshop shares practical experience with how different costing models are used and combined in various companies and evaluates positives and negatives. In response to feedback from previous attendees, this year's workshop on cost model includes more forum discussion and brainstorming than ever before to create additional and improved solutions. Short presentations by the workshop leaders are followed by scenario exercises and group discussion to ensure a good balance between lecture and interactive learning. Participants learn to apply costing methods based

on specific project needs and receive guidance on how to develop a customized costing model that will work for their own organization. Workshop leaders explore:

- How have different companies have applied various cost models—and with what outcome?
- What information and tools are needed?
- Is activity based costing or fixed unit pricing right for all projects?
- How and when does a dedicated staffing model work best?
- How are fixed and variable cost elements incorporated into a unit pricing model?
- When do payment schedules really work out as planned? And why / why not?
- What methods have been used successfully to reduce the burden of change management?

Also covered in greater depth:

- Utilizing advance payments, hybrid costing models and change order mechanisms
- Accelerating contract negotiation

- Simplifying the billing transactions without losing project tracking detail
- Making the contract closing process more efficient
- Customizing cost models to suit the project

Workshop leaders present specific tools and "hands-on" exercises for working with different costing models.

WORKSHOP LEADERS:

John Buerger, *Clinical Business Manager*
ICOS CORPORATION

Gil Price, MD, CEO
CONGRESSIONAL PHARMACEUTICALS, INC.

Barbara Birch, *Director of Clinical Business Development*
STATPROBE, INC.

AFTERNOON HALF-DAY PRE-CONFERENCE WORKSHOPS

12:00	Workshop Registration	2:30	30-Minute Break
1:00	Workshops B5 and B6 Begin	5:00	End of Workshops

NEW!

B5: Establishing the Outsourcing Function in Your Company: Strategy and Operation

This four-part workshop is presented by industry outsourcing veterans-professionals who paved the way in how outsourcing groups are created and maximized. Learn the fundamental functions and strategies and how to apply them to your unique organization.

Part I: Rationale behind Creating an Outsourcing Department

- Knowing what you want to accomplish
- How to maximize the department's effectiveness
- Capitalizing on the unique expertise in the department, different from clinical research

Part II: Creating an Outsourcing Strategy

- Seeking and obtaining input and support from stakeholders, clients and management
- Defining the strategy based on:
 - Corporate culture: What molecules are developed wholly in-house? By study phase? By need?
 - Not having the resources or expertise in-house
 - % of R& D budget fixed dollar amount, by

business unit or therapeutic area, by function

- Types of service providers
- Types of relationships/collaborations
- Types of contract?

- Understanding the interface with Corporate Compliance, Legal, Finance, Purchasing, Regulatory, non-clinops functions: Is your strategy in alignment with theirs?

Part III: Operationalizing the Group

- Defining the basic processes to implement
- Roles and responsibilities of any and all functions
- RFI, RFP, Vendor Selection, Contract Negotiation, Metrics collection, on-study/project issue resolution, change orders/amendments, lessons learned
- Providing training to clients, management, stakeholders in the process
- Maintaining access to decision makers
- Providing the means to obtain feedback from clients
- Providing regular feedback to management
- Ensuring an accurate determination of the volume of work
- Critically assessing the services you offer and questioning their value added
- Being open to new ideas and to the possibility that there are other ways to reach the same goal

Part IV: Creating and Utilizing Tools

- A process map and SOPs in process
- Standard templates of frequently used documents: RFIs, RFPs, due diligence checklist, metrics tracking database
- A process status tracking database
- A service provider/vendor information database
- Appropriate ongoing training on SOPs, tipsheets, training modules for clients, stakeholders, outsourcing group
- Forums to meet with clients and stakeholders to inform and share process improvements
- Benchmarking efforts with contacts in the industry

WORKSHOP LEADERS:

Madeline Miller DVM, *Director, Medical Affairs Operations*
GILEAD SCIENCES, INC.

Warren W. Myers, MSTM, *Director, Medical Research, Department Head, Outsourcing and Contract Administration*
AMGEN, INC.

David Gillogly, *Director, Clinical Operations*
TAP PHARMACEUTICAL PRODUCTS, INC.

Sue Stempien, MBA, CPM, *Senior Manager, Head, Clinical Outsourcing*
GENENTECH, INC.

NEW!

B6: Senior Forum on Sponsor/CRO Partnerships: Examining Strategic Opportunities to Take Partnering to the Next Level

In theory, as partnerships mature, they proceed from a tactical, transactional model to a strategic, integrated relationship that provides increasing value to both members. In practice, a majority of sponsor / CRO partnerships proceed only partially through this continuum and do not deliver the planned or reciprocal benefits.

This workshop brings together executives and opinion leaders from the Pharma/CRO industries to discuss opportunities for stretching partnerships from tactical, transactional modes of interaction to more fully integrated or strategic models. This is a highly participatory workshop where attendees should bring specific examples within their areas of focus that can be shared with the group. The workshop is designed to share information and ideas that could develop a Sponsor / CRO working group designed to move Pharma-CRO relationships to more strategic models of operating. Areas of focus include:

- Current "piecemeal" approaches to outsourcing: Value and limitation of this value when Sponsor / CRO tactical modes of operations are established. Additional costs in time and communication when

a project is contracted to several CROs

- Who's managing the project? Project management competence (or lack thereof) within the Sponsor / CRO team
- Resource redundancy between the Pharma / CRO team: Positive and negative impacts on project deliverables and methods to reduce excessive oversight required by sponsor companies to manage outsourced projects
- Data integration and transfer best practices: What works well? What does not? Does the development of standards (such as CDISC data management standards increase ease of outsourcing?
- Options for pharma companies to outsource entire capabilities (e.g. data management) across projects
- Virtual Clinical Development: Myth, Reality or a Bit of Both? Bring examples of outsourcing of entire projects across the value chain (pre-clinical, clinical (phase I, phase II-III, phase IV), CM&C, toxicology, PK, etc.)
- The very best projects and relationships between Sponsor / CRO: Characteristics and examples that lead to mutual trust, co-ownership and project efficiencies
- The very worst projects (horror stories) between Sponsors / CROs: Characteristics and examples
- Moving the Sponsor / CRO relationships consistently to the ideal strategic level: Is it possible now and what does or would it take to get there

PREREQUISITES:

Intended participants are Pharma and CRO executives who have significant experience in strategic partnerships and leadership of new outsourcing paradigms. Participants who are accepted into this workshop should, at a minimum, possess the following professional characteristics:

- 10 years Pharma and/or CRO experience
- Director level or above
- Able to facilitate, influence or direct change within their organization as it relates to how Pharma-CRO business is constructed and managed
- Able and willing to share specific experiences with the group as they relate to the course description below

WORKSHOP LEADERS:

Steven Whittaker, *Director of Project Management Excellence*
ELI LILLY AND COMPANY

Steven Chmielewski, *Manager of Clinical Project Sourcing, Project Management Excellence*
ELI LILLY AND COMPANY

Michael Arlotto, *Senior Vice President of Project Management*
QUINTILES CLINICAL DEVELOPMENT SERVICES

5:00 – 6:30
Grand Opening of Exhibit Hall
Welcoming Reception



TUESDAY, APRIL 27, 2004

7:00 Main Conference Registration and Welcoming Breakfast Buffet, Hosted by



8:00 **Chairpersons' Welcome**

Don Kellerman, PharmD, *Senior Vice President, Development*, INSPIRE PHARMACEUTICALS
Gena Reed, *Executive Vice President*, PARAGON BIOMEDICAL

KEYNOTE ADDRESS

8:30 **Changing the Paradigm of R & D through a Breakthrough Partnership**

With Industry pipelines thinning and costs rising, pharmaceutical companies are looking for ways to boost productivity of innovative drugs. To meet this challenge, Wyeth formed a landmark partnership with Accenture to streamline operations and improve the overall effectiveness of its R & D program. With the drug discovery phase of the partnership resulting in a 400% rise in productivity, it became time to make similar improvements in clinical development. Our speakers are spearheading a partnered business that will manage global clinical data management operations. Its goals are to reduce cycle time (example, reduce time between last patient, last visit and database lock by 80%) and reduce contracted costs by more than 30% through effective partnering while retaining very high quality levels. For the first time, our speakers present their experience to date in this forum.



Christopher C. Gallen, MD, PhD, *Vice President and Chief of Operations*
WYETH RESEARCH



David Boath,
Partner, Health & Life Sciences
ACCENTURE

KEYNOTE ADDRESS

9:15 **The Partnering Paradigm Advances: Delivering on Pharma's Promise**

Today's pharmaceutical industry faces unprecedented opportunities because of basic research breakthroughs in the life sciences - from genomics and proteomics to revolutionary diagnostics and nanotechnologies. But pharma's challenges are escalating as well. The industry faces rising R&D costs, a slowdown in product introductions and the added cost of implementing new technologies. The question is: Can pharma deliver on the scientific promise to improve healthcare? Dr. Gillings believes it can. The solution is in strategic alliances that increase the resources and efficiencies of drug development. This is the "Partnering Paradigm" he suggested two years ago as the basis of the CRO industry's transition from traditional service provider to true strategic partner. Today, Dr. Gillings tells the Partnerships audience how Quintiles is pursuing this vision. Their new partnering model offers financial solutions that support pharma with dollars, expertise, and research and marketing services. In exchange Quintiles shares in their partners' success. Dr. Gillings is staking Quintiles' future on this business strategy - which Quintiles pursuing now as a private company - and believes it will have a significant impact on the evolving pharma/CRO relationship.



Dennis Gillings, PhD, *Chairman and CEO*
QUINTILES TRANSNATIONAL

10:00 45-Minute Refreshment and Networking Break; Opportunity to Visit Exhibit Hall

SENIOR EXECUTIVE KEYNOTE PANEL

10:45 **Strategic Insights on the Evolution of Outsourcing in Clinical Development**

Senior level executives from two of the top five global CROs, a large pharma and a

small pharma gather to address the following key issues affecting today's partnerships:

- Changes in the CRO industry and outsourcing over the years
- Defining "strategic" in clinical development outsourcing
- The move towards offshore clinical trials in an effort to perform back office capabilities and find additional patients in regions such as China, Africa and India
- The strategic role technology plays in offshore outsourcing
- The evolution of outsourcing partnerships into strategic alliances
- Is bigger better? A look at pharma and CRO M&A growth

Moderator:

Stuart Kliman, *Partner*, VANTAGE PARTNERS

Panelists:

James A. Bannon, PharmD



Corporate Senior Vice President and President, Late Stage Clinical Services
COVANCE INC



John Climax, PhD,
Executive Chairman
ICON CLINICAL RESEARCH



Dr. R. Adrian Otte, MB, BCH, FPPM
Senior Vice President, Worldwide Development Operations
PFIZER GLOBAL RESEARCH & DEVELOPMENT



Jeremy G. Chadwick, PhD
Vice President, Drug Evaluation Operations, Drug Evaluation & Approval (DEA)
VERTEX PHARMACEUTICALS, INC.

11:45 **INTERACTIVE VOTING TOWN MEETING**

Due to the success of the 2003 Interactive Voting session, our panel has rejoined to ask a series of questions and thoughtfully comment on survey results. The session is structured to surface common misperceptions about sponsors and providers and focus on the issues that limit strategic outsourcing from delivering its full potential. The Partnerships Interactive Voting questions do not duplicate other industry surveys and center the dialogue on contemporary challenges in the drug development marketplace. Take this opportunity to attend this informative session, cast your votes anonymously and participate in a dynamic, open forum discussion. Goals of the session include:

- Sharing eye-opening, cross-functional information with sponsors and providers
- Providing CROs with insights on how to market more effectively to sponsors
- Benchmarking best practice outsourcing strategies to identify key success factors
- Providing a conduit and open forum that compels the audience into thought-provoking, honest conversation
- Being a premier source of insider information to relay back to your companies

Moderator:

Michael Minor, *VP, Regional Operations*, ICON CLINICAL RESEARCH

Panelists:

Mark Sanders, *Associate Director, Outsourcing Operations*, PFIZER, INC.

Dan Ernest, *Sourcing Associate*, ELI LILLY & COMPANY

Jody Fleisig, *Global Strategic Account Director*, OMNICARE CLINICAL RESEARCH, INC.

Nick Reed, *CEO*, PARAGON BIOMEDICAL, INC.

1:00 - 2:00

Luncheon in Exhibit Hall Sponsored by:



TRACK A: Outsourcing Globally for International Trials

CHAired BY:
Albert E. Boylan, *VP, Acquisitions and Global Initiatives*, RPS

2:00 **Hot Topics for Conducting Trials in Key Geographical Regions**

Drug development in 2004 often requires that we conduct global trials in order to meet aggressive timelines and obtain data that allows us to register products internationally. As the pharma industry increasingly places trials internationally-not merely regionally-it is important to understand the challenges to successfully implementing global trials, including having solid business reasons for why you should place your trials in specific regions. Our panel of

TRACK B: Optimizing Outsourcing Contracts and Budgets

CHAired BY:
Carol O'Brien, *Chief Financial Officer*, PARAGON BIOMEDICAL

SURVEY RESULTS SHARED!
2:00 **How Much Oversight Should an Outsourced Trial Have?**

A calculated level of oversight is a good investment of time and resources. This presentation examines industry trends on utilizing internal resources in outsourced clinical trials. One popular method of providing oversight is co-monitoring, defined as the assessment, for quality control purposes, of a CRO employee performing the duties of a site monitor during the conduct of a clinical trial. Although co-monitoring is not a

TRACK C: E-Clinical Initiatives in Outsourcing Clinical Development

FDA PERSPECTIVE!

2:00 **Optimizing EDC: Build It, Buy It or Outsource It?**

This session features a mock future case study on what would need to be done today to an RFP from a sponsor company to assure that performance metrics, data generation, project management, and adequate communications between all participants will indeed innovate and deliver. Perspectives from an EDC provider, a CRO, a Sponsor and the FDA are shared as to what elements are needed to make a trial successful. Insights are also shared about what industry analysts look for in generating success stories.

TRACK D: Maximizing Relationships with Investigative Sites

2:00 **Changing the Site Paradigm and Improving Performance**

Traditionally, clinical trials have been managed with a sponsor-centric focus and the investigative site treated as a component of the overall project plan. This session explores the benefits of shifting to a site-centered focus and reaping the benefits of improved site performance. Attendees can expect recommendations to assist them with:

- Identifying the right sites
- Understanding site burden and what can be done to address their challenges
- Using early site performance to predict the future

TRACK E: Measuring and Managing the Outsourced Relationship

CHAired BY:
Connie Andrews, *Director of Clinical Operations*, MEDIMMUNE, INC.

2:00 **Optimizing Relationships in a Therapeutically Focused Environment: Current Trends and Challenges**

This session explores several examples of best practices in the complex areas of CNS, oncology and pediatrics, comparing and contrasting lessons learned for optimal project execution. The panelists' unique perspectives are representative of the phases of decision-making, selection and relationship building associated with a multi-faceted Sponsor/CRO dynamic. Emphasis is placed on demonstrating how specific

**TRACK A:
Outsourcing Globally for
International Trials**

international experts offers their perspectives on:

- Are some regions saturated with trials thereby impeding rapid patient recruitment?
- How to adapt to specific country regulations
- Transportation and distribution of study drug and trial supplies
- Advantages and disadvantages of each key geographic region
- Misconceptions around cost: Do you save money by going overseas?

Moderator:

Barbara J. Geiger, *President and Clinical Director*
CLINICAL RESEARCH MANAGEMENT SERVICES, INC.

Panelists:

Sue Tremlett
ROCHE (invited)

Robert Teoh, *VP of Asia*
PPD PHARMA (invited)

Maria Fernandez Freire, *Director*
THYWILL LATIN SOLUTIONS

3:00 Critical Success Factors when Working with Geographically Focused CROs

Many companies have been using large global CROs to deliver International clinical trials with limited success. Learn how to gain competitive advantages by working with geographically focused CROs. Strategic use of local expertise can guarantee access to the best quality sites and patients in the least amount of time to speed trials to a successful conclusion. You can make your global trial a success by utilizing local expertise for the best quality work that is compliant with global and local ethical and safety regulations. In this session, local experts share the advantages of working using best practices to deliver your global clinical trials. Learn how and why these models of managing global clinical trials have been able to ensure the success of numerous clinical trials far exceeding expectations. Included in the discussion are:

- Evaluating the suitability of geographic expertise for projects
- Critical success factors: Reduction of project timelines, cost effective, quality data, ethical, safety and regulatory compliance, reliance on local experts, reduction of time to market
- Optimizing geographic expertise and leveraging existing relationships
- Maximizing sponsor affiliates
- Decentralized model advantages

Moderator:

Gena H. Reed, *Executive Vice President*
PARAGON BIOMEDICAL

**TRACK B:
Optimizing Outsourcing
Contracts and Budgets**

regulatory requirement per the Code of Federal Regulations or ICH GCP guidelines, most sponsors require it. Two real-life scenarios from a "hands on" sponsor approach to a risk-management method that reflects a better utilization of internal resources are presented. Results from a 2004 survey that queried CROs, pharmaceuticals and biotech on the number of FTEs and costs associated with oversight is shared.

Charleen Pagel Jue, *Director, Clinical Operations*
OSI PHARMACEUTICALS

Bruno Gagnon, *Director, Clinical Operations*
CHIRON CORPORATION

Jim Powers, *Executive Director*
PRA INTERNATIONAL

3:00 Increasing Efficiencies around Contract Negotiation and Change Order Amendments

A streamlined contract negotiation and change order process is an obvious, but often unachieved, goal in a Sponsor/CRO relationship. The purpose of this presentation is to highlight and discuss a number of key elements towards increasing efficiencies around this process, based on actual recent experiences encompassing:

- Senior management strategic vision
- Delegation and distribution of responsibilities
- Key contractual and budgetary parameters
- Communication
- Trust and ethics
- Performance metrics and project management tools

Holly B. Kooyman, *ND, Associate Director Clinical Operations*
NPS PHARMACEUTICALS, INC. and President
PHARMACEUTICAL DEVELOPMENT PARTNERS, LC

Nathan Ternus, *Senior Contracts and Outsourcing Associate*
NPS PHARMACEUTICALS, INC.

Francis Wouters, *PhD, DDS, Senior Director of Business Development*
PHARMANET, LLC

Tara Fitzgerald, *Vice-President, Operations*
PHARMDATA, INC.

3:45 45-Minute Break Hosted by PAREXEL INTERNATIONAL

4:30 Resolving Legal Issues, Risks and Challenges Facing Sponsors when Contracting with Service Providers

This panel explores pertinent issues, risks and challenges commonly encountered in negotiations between sponsors and providers. Our panelists analyze and discuss:

- Negotiating strategies for key issues such as

**TRACK C:
E-Clinical Initiatives in
Outsourcing Clinical
Development**

Moderator:

Bruce L. Maloff, *PhD, Chief Clinical Officer*
LIFETREE TECHNOLOGY & FFF ENTERPRISES

Panelists:

Michael Fauntleroy, *Director for Electronic Submissions*
US FDA-CBER

David Detoro, *Senior Director, Clinical Data Management*,
SCHERING-PLOUGH RESEARCH INSTITUTE

James R. Weston, *Vice President, Corporate and Regulatory Strategy, Managing Director*
CATO RESEARCH

3:00 Preparing an IT Infrastructure for Optimal Global Logistics Management

The purpose of this session is to illustrate why ease of use, a well managed roll-out, and a competent help desk are essential to successful e-Clinical deployments. In the case of EDC, the key is to minimize the distraction for the investigators, enabling them to concentrate on inputting data rather than wrestling with technology. This support must encompass not only the initial rollout of technology, but also help desk support for investigators using the laptop or Web browser solution. Our presenters discuss how:

- A below-par help desk can seriously compromise the success of an e-Clinical implementation
- Consistent global support is an essential element of the successful deployment of e-Clinical solutions
- Simplicity is required to foster widespread user adoption, a critical measure of success for the sponsor and CRO

Robert Oyler, *Exec - Information Technology Services for Healthcare*
IBM LIFE SCIENCES

Rob Goodwin, *Director of Clinical Operations Strategy, Worldwide Development*
PFIZER GLOBAL R & D

3:45 45-Minute Break Hosted by PAREXEL INTERNATIONAL

4:30 Standardizing the Capture, Measurement and Storage of Medical Images for Improved Quality and Efficiency

Medical imaging in clinical trials continues to grow as a tool for evaluating the safety and efficacy of new drugs, biologics, and devices. Imaging data can be used to support regulatory submissions as well as to inform go/no-go decision-making. This session discusses some of the practical aspects of implementing the imaging component of clinical trials and how sponsor organizations and

**TRACK D:
Maximizing
Relationships with
Investigative Sites**

Robert J. Davie, *PhD, Vice President Service Delivery Europe*
COVANCE INC.

Janis Witzleb, *Contracts Manager*
WYETH RESEARCH

Sandra S. Vose, *Director, Clinical Operations, Regional Monitoring Services, NA*
COVANCE INC.

SallyAnn Crann, *Director, Clinical Affairs*
RPS

3:00 Overcoming Recruitment Hurdles in Challenging Therapeutic Areas

Our panel addresses key recruitment challenges that plague some of the biggest therapeutic areas---oncology, CNS and others, where protocol design issues, competing trials, unrealistic enrollment projections and problems enrolling difficult populations all impact the success of your efforts. In addition to these key concerns, our panel addresses

- Innovative strategies for enrollment
- Overcoming barriers to recruitment and retention
- Competing for the limited number of patients
- Ethical/IRB issues

Panelists include:
Gina M. Zappolo, *Director, Strategic Operations*
RPS (RESEARCH PHARMACEUTICAL SERVICES, INC.)

Sue Hocker, *VP and General Manager of Patient and Clinical Communications*
PAREXEL MEDICAL MARKETING SERVICES

Additional panelists to be announced

3:45 45-Minute Break Hosted by PAREXEL INTERNATIONAL

4:30 Alternatives to Investigator Meetings: Can Webcasts and other Technology Advances Be More Effective than In-Person Meetings?

This session evaluates the effectiveness and efficiency of online Investigators' Meetings, as compared to traditional meetings, with a focus on both cost and quality measures. Case studies demonstrate quality of data, site performance and cost savings with online Investigator's Meetings. This interactive session also demonstrates several online solutions and reviews the process used at Investigators' Meetings to help predict the sites most (and least) likely to succeed in a particular study and the methods used to verify which patient recruitment campaign(s) will work best for each site. Virtual demonstrations illustrating the time and cost-

**TRACK E:
Measuring and Managing
the Outsourced
Relationship**

therapeutic experience across the entire team creates an environment of proactive trend analysis and problem solving. The panel involves the audience in a discussion evolving around trends and challenges faced in optimizing relationships, specifically in each therapeutically focused environment. Topics covered include:

- Understanding the measured selection process pharma utilizes in selecting the most appropriate outsourcing partner
- Examining the current therapeutic trends within pharma driving this selection process, such as therapeutic expertise, access to patients, knowledge of sites, experienced staff, stability, and efficient use of technology
- Proactively addressing regulatory challenges to plan for success, especially in CNS, oncology and pediatrics
- Integrating new technology, such as RDC, to improve overall quality and reduce timelines
- Identifying the critical factors Sponsors use to determine whether the relationship with the outsourcing partner has been successful

Thomas G. Schlagheck, *PhD, Vice President, Clinical Operations*
ENDO PHARMACEUTICALS

Jennifer Harris, *PharmD, Clinical Pharmacology and Discovery Medicine, Oncology*
GLAXOSMITHKLINE

John Potthoff, *PhD, Senior Vice President, CNS Therapeutics*
INC RESEARCH

Kari Leonard, *PhD, Senior Program Manager*
INC PEDIATRICS

Julianne Hull, *Director, Clinical Data Management Outsourcing*
WYETH PHARMACEUTICALS

Anne Wiles, *President*
DATA SPECTRUM

CASE STUDY

3:00 Managing the Highest Level, Long-Term Relationship to Meet your Strategic Goals

There is an ever-increasing need for pharmaceutical companies to build long-term outsourcing relationships. Today, virtually all laboratory testing is outsourced, forcing many companies to consider long-term agreements with their service providers. Once a Master Service Agreement is established, managing the relationship is the key to long-term success. Many different types of relationships can be created, ranging from single-study through strategic alliances. Through this case study, our presenters demonstrate the practical aspects of managing and maintaining the highest level of relationship, a strategic alliance. Issues such as planning, resource allocation, pricing, project management and communication are covered from the perspective of both sponsor and service provider, and real world examples are shared. In a

TRACK A: Outsourcing Globally for International Trials	TRACK B: Optimizing Outsourcing Contracts and Budgets	TRACK C: E-Clinical Initiatives in Outsourcing Clinical Development	TRACK D: Maximizing Relationships with Investigative Sites	TRACK E: Measuring and Managing the Outsourced Relationship
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Panelists:
 Pawel Dyras, MD, PhD, *Vice President*
CLINTEC INTERNATIONAL
 Debra Echlin, *Program Director*
ABBOTT LABORATORIES
 Rebecca McMillian, *VP, Strategic Development*
PARAGON BIOMEDICAL

3:45 **45-Minute Break**
 Hosted by **PAREXEL INTERNATIONAL**

4:30 **Drivers behind the Decision to Take Clinical Trials International**
 The growth of global trials continues at a rapid pace with a continued need for patients and investigator sites in therapeutic areas not easily satisfied in the US and Europe. What are the key drivers behind this expansion? An international panel of experts discuss the position from both the pharmaceutical company perspective as well as the CRO, and include views on the challenges presented by new technology, increasing regulatory complexity, the impact of the EU clinical trials directive, as well as an insight into the problems that can occur in complex trials across multiple continents.
 Alan Horgan, *Group Vice President of Late Stage Development*
MDS PHARMA SERVICES
 William F. Colman, *PMP, Director, Sourcing Group, Acting Head, Global Clinical Outsourcing, Acting Global Account Manager*
ASTRAZENECA LP
 Vaile Clements, *Vice President of Corporate Development*
QUINTILES TRANSNATIONAL
 John Mills, MD, PhD, *Chief Executive Officer*
BIOSTORAGE TECHNOLOGIES
 5:30 **Day One Concludes**

intellectual property ownership and indemnification
 ■ Risk allocation issues that ordinarily arise when negotiating key agreements
 ■ How to respond when the hospital and investigator don't want to sign your contract
 ■ How to use the negotiation process to ensure that both parties have prepared adequately for data protection and exchange
 ■ Issues raised when contracting in various parts of the world, including the EU, South America, Asia, Israel and Australia
 ■ What the parties can do when their relationship turns rocky
Moderator:
 Blaine Templeman, Esq., *Attorney, Business and Finance/Biotech Practice Group*
MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO P.C.
Panelists:
 Lyn Rossano, MPH, *Vice President, Clinical Trial Coverages*
WILLIS, INC.
 Robyn Phillip Norton, *Manager of Medical Affairs*
OSI PHARMACEUTICALS
 James Lovett, *Senior Corporate Vice President and Secretary*
COVANCE INC.
 5:30 **Day One Concludes**

imaging core labs can best collaborate. Topics to be addressed include:
 ■ Role of imaging and an imaging core lab in clinical trials
 - Understanding FDA's expectations
 - Defining an "imaging charter"
 - Ensuring the reproducible acquisition of imaging data within and across sites
 - Interacting with investigator sites on imaging related issues
 - Handling, processing, and analyzing images
 - Archiving images and supporting regulatory filings
 ■ Avoiding the common pitfalls
 ■ Assigning roles and responsibilities
 ■ Managing the sponsor/core lab relationship for success
 Mark A. Goldberg, MD, *President*
PERCEPTIVE INFORMATICS, INC. (A PAREXEL COMPANY)
 Max Rosen, MD, MPH, *Associate Professor of Radiology - Harvard Medical School*
BETH ISRAEL DEACONESS MEDICAL CENTER
 5:30 **Day One Concludes**

effectiveness of this approach are presented, including online site identification, selection and feasibility, and online protocol and procedure training. Our session presenters address:
 ■ Best practices for data-driven site identification, selection and feasibility
 ■ Online Investigators' Meeting demonstration
 ■ How adding interactivity can improve learning retention
 ■ Case studies to demonstrate time, cost and quality improvements
 ■ Cost benefit analysis vs. traditional methods
Moderator:
 Lisa Laluna, *VP of Business Development*
EPHARMALEARNING
Panelists:
 Colleen Gorman, *Manager of Clinical Research*
PFIZER, INC.
 LuAnn Vanaman, *Clinical Study Leader*
ASTRAZENECA
 Michael Schwartzman, *Senior Contracts Associate*
AVENTIS
 Rochelle Suffern, *Clinical Research Manager*
GLAXOSMITHKLINE (invited)
 5:30 **Day One Concludes**

long-term agreement, strategic objectives and corporate priorities change, therefore ideas are presented for managing change in both companies while preserving the alliance into the future.
 Patrick Phillips, *Head, Global Supplies and Governance*
GLAXOSMITHKLINE
 Harris Koffer, *VP Clinical Trials and Pharma Business Development*
QUEST DIAGNOSTICS
 3:45 **45-Minute Break**
 Hosted by **PAREXEL INTERNATIONAL**

CASE STUDY
 4:30 **Building and Implementing a Key Pharma/CRO Relationship Management System**
 Two years ago, Johnson & Johnson undertook major sourcing initiatives aimed at enabling it to achieve the best value possible for its overall outsourcing spend. After successfully negotiating new preferred CRO contracts, J&J's SourceLink Team faced the challenge of ensuring that work was shifted to the preferred providers, and also ensuring effective collaboration across J&J's Operating companies and its CROs.
 One of SourceLink's goals is to enable J&J to make the process of J&J and CROs working together more efficient and productive for both sides while simultaneously continually uncovering and capitalizing on new opportunities to create joint value through innovation, process improvements, new services, and the like. Working with Vantage Partners, the SourceLink team is deploying a collaborative workspace with a series of dashboards and job aids to support new joint business planning activities, metrics reporting, performance measurement, and relationship management. Participants learn:
 ■ Internal and external barriers to successfully implementing preferred CRO agreements
 ■ Best practices for managing collaborative pharma-CRO relationships
 ■ What software can do (and what it can't do) to support effective collaboration
 ■ Lessons for successful design and deployment of relationship management software
 Cindy Kearney, *Director, Alliance Strategy Clinical Research*
JOHNSON & JOHNSON
 Stu Kliiman, *Partner*
VANTAGE PARTNERS
 5:30 **Close of Day**


"This is one of the better conferences I attend all year, and will continue attending in the future. Thanks for a great job organizing and making it a worthwhile investment of time and money!"
Cindy Keisling, Purchasing Group Manager, Proctor & Gamble Pharmaceuticals

Attention POMA Members!

While in Orlando, take advantage of a POMA Roundtable Meeting, immediately following Partnerships on **Thursday, April 27, 2004, 8:30am - 4:00pm**, focused on Current Issues in Biopharmaceutical Clinical Trials.

Not a member of POMA? Take advantage of this offer! Pay the non-member registration fee of \$400 and get the following benefits:



- 12 month membership in POMA
- Opportunities to attend future POMA roundtables at no charge
- Access to "members only" area of the POMA website
- 20% discount to attend 13th annual Partnerships with CROs



The Pharmaceutical Outsourcing Management Association (POMA) is a non-profit organization comprised of outsourcing professionals from the pharmaceutical/biotechnology industries and the organizations that provide outsourcing products and services. With over 230 members from 60 pharmaceutical and biotechnology companies and 50 provider companies, POMA's primary goal is to provide outsourcing colleagues with opportunities for professional development, networking and the exchange of ideas, knowledge, and expertise regarding the field of outsourcing.

For additional information about POMA or to apply for membership, please visit their website www.pomasite.com.

5:30 - 7:00
Evening Reception, Hosted by

WEDNESDAY, APRIL 28, 2004

7:45 *Morning Coffee in Exhibit Hall*

8:15 **Opening Remarks and Recap of Day One**

Co-Chaired by:

Janet L. Brennan, *Chief Operating Officer*
RPS (RESEARCH PHARMACEUTICAL SERVICES, INC.)

2004 Eye on the Future

8:30 **Transforming the Pharmaceutical/Life Sciences Entity: An In-Depth Overview of "Pharma 2010 – The Threshold of Innovation"**

IBM Business Consulting Services predicts 5.3% growth rate by 2010, rather than 9% predicted by analysts. IBM Business Consulting Services' latest report, "Pharma 2010 – The Threshold of Innovation" predicts that a new business model for the pharmaceutical industry, based on Targeted Treatment Solutions, has the potential to achieve truly breakthrough growth. IBM argues that this new business model is needed to cross the new "Threshold of Innovation" that results from governments and insurers alike no longer being able or willing to pay high prices for "me too" medicines. This presentation provides an in-depth overview of the "Pharma 2010" strategies that will lead to a more adaptive and flexible way of conducting business and treating patients. Our presenter proposes:

- Slashing R & D costs per drug to a quarter of the current average of \$800 million
- Forging productive relationships with patients, physicians, payers and regulators
- Supporting new and innovative sales and marketing techniques (i.e., outcomes-based pricing schemes, smaller, well-trained sales force)



Sam Barnett, EdD, *Americas Lead Partner, Life Sciences/Pharmaceuticals*
IBM BUSINESS CONSULTING SERVICES

KEYNOTE ADDRESS

9:15 **Enhancing Partnerships Opportunities through New Levels of Customer Service**

One of the key drivers of successful partnerships is a realization of mutual goals and benefits. At the end of the day, new business is rewarded to partners who serve you best. Whether a large one-stop-shop CRO or boutique provider, whether a big pharma or small biotech, the relationships that are forged and ways in which partners engage each other will result in new or more effective and efficient relationships. Companies large and small should be viewed as first tier customers if they have proven or promise to enhance productivity and revenue. This address from an executive who brings



experience from both large and small pharma as well as provider-side experience is a call to sponsors and providers alike to deliver an improved level of customer service and to better establish and customize their business models to serve large and small customers who bring value to the drug development process.

Renu Gupta, MD, *Senior Vice President World Wide Development*
ANTIGENICS, INC.

10:00 *Morning Refreshment Break; Opportunity to Visit Exhibits*

2004 BEST PRACTICE SPOTLIGHT

10:45 **Lessons Learned from Outsourcing Experts in other Industries**

For the first time, outsourcing experts from NASA and IBM Global Energy and Utilities present together on insights and lessons learned from their unique outsourcing practices. Their experiences with developing partnerships, offering competitive advantage to their partners, evolving contracts into partnerships, valuing customer service, achieving trust and developing long term strategies for outsourcing provide examples from which our maturing industry can learn. A pharma industry moderator draws lines back to the pharmaceutical industry and

encourages the audience to propose take-away lessons pharma can apply to their outsourcing practices and relationships. Our industry learns:

- What it took to achieve successful partnerships
- What barriers or worse, failures, had to be overcome?
- What risks were taken?
- How much oversight do project require?
- How was the organization transformed to embrace the outsourcing model and its value?
- How is organizational memory maintained?
- How senior management was influenced to move from transactional to strategic outsourcing

Moderator:

James Taylor, *Global Head of Outsourcing, Drug Innovation and Approval*
AVENTIS PHARMA

Panelists:

Vicki Crisp, *Head, Vehicle Analysis Branch*
LANGLEY RESEARCH CENTER, NASA

Geoff Jue, *Global Solutions Offering Executive*
IBM GLOBAL ENERGY AND UTILITIES INDUSTRY

Additional panelists to be announced

2004 Pulse of Pharma's Use of CROs

11:45 **What Does Pharma Value in the CRO Industry: A Roundtable Discussion among Seasoned Outsourcing Experts**

Participate in a discussion with senior outsourcing industry professionals as they challenge commonly held theory and practice as they debate the real reasons behind CRO use and partnerships and how to maximize value. Experts address the following points:

- Productivity: Are CROs helping pipeline growth by accelerating drug development or is their value in the additional of resources?
- Competitive advantage: How should CROs best demonstrate that they can offer this to pharma? Is cost the final differentiator?
- Innovation: What can CROs bring to the table and is pharma ready?
- Operational excellence: What matters most among quality, productivity and on-time efficiencies?

Bring your own insight when the floor is opened to audience interaction.

Panelists:

Fred Naidis, PhD, *Senior Director, Contracts & Outsourcing, Development Operations*
PFIZER GLOBAL RESEARCH & DEVELOPMENT

John F. Covin, *Head, Global Grants and Contracts*
GLAXOSMITHKLINE

Don Kellerman, PharmD, *Senior Vice President, Development*
INSPIRE PHARMACEUTICALS

Peter A. Carberry, MD, MBA, *Vice President, Clinical Trials*
JOHNSON & JOHNSON PHARMACEUTICAL R&D

Dan Perlman, *President and CEO*
RPS (RESEARCH PHARMACEUTICAL SERVICES, INC.)

12:30 – 1:30 **Luncheon and Optional Lunch and Learn Roundtable Sessions**

Haven't been active in the event's Q & A sessions or moderated discussions yet? If you prefer to interact in an informal, relaxed setting, opt to participate in optional, moderated lunch table discussions. Interact at your own comfort level, and make sure your voice is heard. Participation will be on a first come, first serve basis, so visit the event website at www.cropartners.com for updates on how to join this dynamic lunch hour.

1:30 **Exhibit Hall Closes**

TRACK A: Outsourcing Globally for International Trials	TRACK B: Optimizing Outsourcing Contracts and Budgets	TRACK C: E-Clinical Initiatives in Outsourcing Clinical Development	TRACK D: Maximizing Relationships with Investigative Sites	TRACK E: Measuring and Managing the Outsourced Relationship
<p>CHAIR BY: Albert E. Boylan, <i>VP, Acquisitions and Global Initiatives</i>, RPS</p> <p>1:30 Developing Japanese Pharmaceutical Clinical Research with Global Affiliates</p> <p>The growth is of the Japanese market is exciting, and many new or enhanced compounds are being developed and introduced into the research community. With all of the growth, there are challenges that accompany the success. Our panel's shared experiences in working in this environment demonstrate the importance of respecting the cultural aspects of conducting research and</p>	<p>CHAIR BY: Carol O'Brien, <i>Chief Financial Officer</i>, PARAGON BIOMEDICAL</p> <p>1:30 Pros and Cons of Bonuses and Penalties in Outsourcing Contracts</p> <p>The inclusion of bonus and penalty clauses in CRO contracts is used to varying degrees in the industry, usually with the goal of accelerating timelines. Bonuses have been viewed as motivators whereas penalties are most often viewed as de-motivators. Our session leaders have had experience with various contracting styles including fixed price, cost plus, fixed unit pricing and more and discuss when it is appropriate to apply a bonus or penalty within a contract and where to apply within the contract. Attend this session to</p>	<p>1:30 Improving Workflow to Optimize a Web-Based Clinical Trial Management System</p> <p>In order to maximize the benefits of deploying e-clinical research technology, workflow and clinical research processes need to be analyzed and redesigned. Our presenters discuss the use of a web-based CTMS system for clinical trial management as well as improving the information flow for all team members including pharmaceutical companies, CROs, monitors, and investigator sites. Having real time trial status information for all team members will decrease the cost of the trial as key</p>	<p>1:30 Managing the Domino Effect: The Interface of Sponsors, Sites and Vendors for Study Success</p> <p>Sponsors' recruitment budgets are limited and their timelines fixed. Successful clinical trials rest with the sites selected, so you want to keep these sites happy. In return, you want sites to make your study their priority. The reality is that only two thirds of selected sites will actually perform to expectations. Non-performing sites might be cut loose and sites on the "B" list added, but the wait-and-see-approach to recruitment pushes your study into rescue-mode. This panel examines site and recruitment issues that influence study success and failure. Industry</p>	<p>CHAIR BY: Connie Andrews, <i>Director of Clinical Operations</i>, MEDIMMUNE, INC.</p> <p>1:30 Leveraging Outsourcing from Pre-Clinical to Submission</p> <p>Additional value can be gained by consolidating outsourcing across fewer partners. One often untapped avenue to increase leverage is to use the same partners, when applicable, across research and development. Vertical expansion of current partnerships can reduce costs and also have meaningful impact on development time. This session explores the barriers to increasing leverage through outsourcing, how to overcome them, and what benefits can be gained. Attendees gain a better</p>

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business between a parent Japanese Pharmaceutical company and affiliate offices in the U.S. and Europe. There are considerations that are unique to developing, maintaining and strengthening the working relationship between the parent company and affiliate offices versus the model that has the parent company based in the U.S. or Europe with the affiliate in Japan. Beyond the cultural and business practices, there are also legal and regulatory considerations that add a twist to the conduct of clinical research. Key concepts include:

- Clinical operations implementation
- Outsourcing and contracting
- Success factors in parent - affiliate relationship foundation
- Cultural awareness
- Business perspective
- Research perspective

Presenters to be announced see www.cropartners.com for updates

2:30 Selecting, Managing and Communicating Effectively with Vendors to Facilitate International Studies

This session examines best practices for planning, selecting, managing and liaising with sites, third-party vendors and other service providers in the EU and CEE and Latin America. Strategies to determine regions/countries that best fit the trial and development objectives are shared. In addition, participate in a discussion about how to identify practical and logistical benefits and non-starters.

Panelists include:
Rafael Escandon, PhD, MSc, Senior Director, Clinical Operations
CV THERAPEUTICS

Additional panelists to be announced

3:30 Event Concludes

"The information sharing from both sides is a great start to good partnerships."
Lynn Moore, Senior Buyer, Purchasing, Centocor

participate in an interactive discussion about a contract strategy that is seldom talked about, but which is of high interest as efforts to expedite clinical projects continue. Our panel catalyzes discussion around:

- How to define bonus goals
- Pros and cons to using bonus and penalty clauses
- Risks and rewards for sponsors and CROs
- Maintaining an equitable results for both sides
- When to apply bonuses and penalties
- Where to apply such clauses within a contract
- Are deliverables-based milestone payment schedules a good alternative?
- Recommendations and audience input

Linda Donahoe, Associate Director, Strategic Resource Management
BIOGEN IDEC MA, INC.

Lynn McGovern, Senior Manager, Clinical Procurement
MILLENNIUM PHARMACEUTICALS

Rick O'Hara, MBA, Senior Manager, Business Operations
CENTOCOR, INC. (Invited)

Jonathan Koch, Vice President, Global Commercial Services
INVERESK

2:30 Managing the Contractual and Budgetary Challenges of Outsourcing in a Small Company

At a biotech company or smaller pharma, professionals are finding themselves responsible for the range of strategic and tactical work surrounding contracts, outsourcing and finance and budgets. In such circumstances, those involved know all too well that establishing a streamlined process is of critical importance. Responsibilities such as developing a contract database, creating mechanisms for contract review, and managing the crossover between finance and accounting all require small companies to master this balancing act. Our session presenters interactively engage the audience in a discussion around establishing the following processes:

- Contract and contract amendment management – Contract database and P.O. system
- Study budget approvals/ revisions/tracking/reconciliation
- Vendor selection process and pre-qualification
- Preferred providers and the RFP process
- Tracking and reconciliation of investigator payments with IVRS, study enrollment logs
- Where do Contracts/ Outsourcing professionals fit in? Clinical? Finance/ Accounting/Purchasing?

Moderator:
Solomon Babani, MBA, Manager, Finance and Outsourcing, Clinical Sciences
REGENERON PHARMACEUTICALS

Panelists:
Jennifer Carver, RN, MBA, Manager, Clinical Finance and Outsourcing
ALLOS THERAPEUTICS

Srilu M. Ravi, MPH, Manager, DEA Outsourcing and Planning
VERTEX PHARMACEUTICALS

Laurie Tibbets, Associate Director, Clinical Contract and Finance
GILEAD SCIENCES, INC.

Paulette Wilson, Comptroller
ALLOS THERAPEUTICS

3:30 Event Concludes

decisions about execution can be made earlier and changes implemented faster. This presentation discusses:

- The value of web based information systems for all team members
- The work flow analysis and process changes that must be implemented to make the technology effective
- How real time information will improve trial execution and costs

Lorraine D. Ellis, MS, MBA, President/CEO
RESEARCH DYNAMICS CONSULTING GROUP, LTD.

John D. Kofoed, Director, globalTRIALS™ Management Solutions
ARIS GLOBAL

Ambrish Mathur, VP Product Development
ARIS GLOBAL

2:30 Innovation versus Risk: How Much Innovation Do We Embrace?

How much innovation do we really need? Are routine tools enough? This session discusses aligning systems and promoting standardization through the use of standard and innovative tools, including electronic data capture. Pros and cons of introducing additional innovation are discussed.

David Ng, PhD, Vice President of Data Management/Biostatistics Consultative Services
PPD DEVELOPMENT

Additional panelists to be announced

3:30 Event Concludes

"Information was very thorough and detailed. Extremely good presentation; very knowledgeable presenters."
Janis Dobbins, Contracts Associate, UCB Pharma, Inc.

representatives discuss study data, strategies and methods for building more productive partnerships between sites and sponsors. Our panelists address the following:

- Key economic issues: Increasing productivity - minimizing costs - achieving rapid enrollment and high retention
- Call centers: When and how can they be used more effectively?
- Collecting and using metrics data for identification, selection and termination of sites
- Motivating sites and sponsors to be better partners and to yield positive results

Audrey Rossow, Senior Clinical Project Manager, Clinical Operations
SEPRACOR, INC.

Elizabeth Moench, President
MEDICIGROUP, INC.

Dan Ulrey, President and CEO
MIDWEST CLINICAL SUPPORT, INC. (MCSI)

2:30 Employing an Innovative Approach to Successful Patient Recruitment

Patient recruitment poses many challenges for most biotech and pharmaceutical companies as increased competition makes it more difficult to enroll patients and complete studies according to established timelines. This case study demonstrates the importance of establishing and maintaining an effective partnering relationship between a Sponsor and Patient Recruitment firm in achieving successful enrollment, and introduces a brand new, innovative process that can potentially improve the quality of patients selected for enrollment in clinical trials. The presenters discuss:

- Challenges for the sponsor and sites in recruiting patients for a new therapeutic area
- Approaches and results
- Implementing a secondary screening process
- Implementing a successful media strategy
- Integration of services
- Assessing the benefits of integration and its impact on site staff and the project team
- Outcomes and conclusions

Elaine Richardson, Director, Internal Medicine Therapeutic Area
FOREST RESEARCH INSTITUTE
A DIVISION OF FOREST LABORATORIES, INC.

Ann Kottcamp, Vice-President Client Relations
PRP - PHARMACEUTICAL RESEARCH PLUS

3:30 Event Concludes

understanding of:

- When it is worth expanding the scope of outsourcing with partners
- How drug developers' organizational structure can help or hinder vertical collaboration
- Whether partners can help drug developers transition from research to development
- What role technology standardization plays across R&D

Beverly Dale, Director of Business Development, Clinical GenomicsMarketing
ROCHE

Andrew Ginsberg, Managing Director, The Americas, Clinical Trials Division
LABCORP

2:30 Using Performance Metrics to Improve Outsourcing and Evaluate the Success of a Project

Metrics collection and various types of scorecards are increasingly being used as a component of preferred provider relationships. This session explores from several perspectives on how to effectively measure clinical research performance. Critical areas are how to define key measures of quality, how to use the information collected in a fair and balanced manner and how to use this tool to jointly drive improvement in processes and mutual success. Participants learn how to:

- Provide objective feedback both to the CRO and pharma
- Measure internal studies by the same means as similar CRO-managed studies
- Use this tool to work together with a CRO to jointly improve our processes
- Ensure strategic placement of future studies

Ed Cannon, Global Account Manager
ASTRAZENECA LP

Additional panelists to be announced

3:30 Event Concludes

"Very diplomatic approach and focus on best practices."
Tony Gottschalk, Director, Business Development, Ninaza

The Partnerships event team would like to extend our gratitude to everyone who has contributed their efforts with the research and organization of this event; especially our distinguished advisory board, speakers and our affiliate partners.

SPONSORS & MEDIA PARTNERS

The 13th Annual Partnerships Event Would Like to Thank Our Partners for Their Support and Continuous Industry Leadership Please stop by the exhibit hall to learn more about these companies.


PLATINUM PARTNERS

 Paragon Biomedical, Inc. is a privately held, full-service contract research organization serving the pharmaceutical, biotechnology and device industries. This highly synergistic company offers a seamless comprehensive array of clinical trials services from protocol development to clinical summary. Paragon's mission is 'to deliver the finest research services possible, while building partnerships within the healthcare industry.' Founded in 1989, Paragon is an organization that is dedicated to establishing working relationships based on integrity, service and teamwork.


 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.

GOLD PARTNERS


 Covance, with headquarters in Princeton, New Jersey, is one of the world's leading drug development service companies with 36 sites in 18 countries and a staff of over 6,700. Covance provides innovative solutions to drug development challenges, enabling you to make crucial decisions, maximize economic objectives and speed time to market. Covance uses its comprehensive development experience and therapeutic expertise in the services we offer that encompasses every step of the development pathway. For more information, please contact us at 1.888.COVANCE, e-mail us at info@covance.com or visit our website at www.covance.com

 IBM Life Sciences is dedicated to bringing leading-edge technology out of the laboratory and into the marketplace for customers in pharmaceutical research, biotechnology, genomics, proteomics, health care, academic research and other life science areas. Combined with IBM's core strength in providing robust information technology, middleware, and services, IBM Life Sciences delivers innovative, scalable infrastructure solutions that are unique to the industry. Projects in areas such as computational biology, data analytics, and high performance computing at IBM Research Centers and the IBM Deep Computing Institute foster collaboration with life sciences organizations.


 PRA International, a top five global clinical development organization, provides a broad range of services to pharmaceutical, biotechnology and medical device companies. With over 2000 employees and 22 offices, PRA conducts clinical drug development and related services on six continents. For more information, visit our website at www.prainternational.com.

 Quintiles helps improve healthcare worldwide by providing a broad range of professional services, information and partnering solutions to the pharmaceutical, biotechnology and healthcare industries. As the world's leading pharmaceutical services company, we have helped develop or commercialize every one of the top 30 best-selling drugs. Quintiles offers unmatched breadth and depth of therapeutic expertise with a highly qualified team of more than 300 MDs and nearly 450 PhDs. With offices in 49 countries around the world, we combine strong local knowledge, established relationships and in-country resources with global quality standards. Worldwide, you can count on Quintiles to deliver the results you need. Visit us at quintiles.com.

BAG SPONSOR

 Averion assists biotech, pharmaceutical and medical device companies in the design, execution and reporting of clinical trials. Services include Program Planning, Study Design, Clinical Monitoring, Medical Monitoring, Data Management, Database Development, Biometrics, Medical Writing, Compliance and Validation, and FDA Representation. What makes Averion's services unique is the integrity of the processes supporting them and the personal commitment of the individuals on staff. Averion also continues to build upon its extensive alliance network which currently includes the "best of breed" of global CROs, EDC vendors, Investigational Review Boards, IVRS vendors, Central Laboratories, and Regulatory Affairs groups.

E-BUSINESS CENTER SPONSOR

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