



# Biotechnology Clinical Trials Outsourcing

March 20, 2009 | Hyatt Regency San Francisco Airport Hotel, Burlingame, CA, USA

#### PROGRAM CO-CHAIRS

**JOHN R. VOGEL, PhD**  
Drug Development Consultant  
John R. Vogel Associates, Inc.

**NANETTE NANJO-JONES, MBA**  
Outsourcing Consultant

#### PROGRAM COMMITTEE

**DAVID KIGER**  
Regional Director, Business Development (West)  
Perceptive Informatics

**MARIANNE R. PLAUNT, PhD**  
Vice President, Global Operations  
Paragon Biomedical, Inc.

**NANCY A. HAVRILLA, MS, RN**  
Senior Director, Clinical Operations  
ACHAOGEN, Inc.

**BRUNO GAGNON, BPHARM, MSC**  
Senior Director, Clinical Operations  
Roche Molecular Systems, Inc.  
Formerly Senior Director at FibroGen, Inc.

#### CONTACT INFORMATION

**Conference:** Ben Zaitz, Phone +1-215-293-5803/email Benjamin.Zaitz@diahome.org

**Exhibits:** Jeff Korn, Phone +1-215-442-6184/email Jeff.Korn@diahome.org

## *Finding Solutions to Challenges Faced by Smaller Pharmaceutical and Biotechnology Companies*

Successful outsourcing of clinical drug development activities is critical to smaller companies who typically lack the infrastructure and personnel to perform these functions in-house.

This one-day conference was designed and the location chosen specifically for smaller companies located on the West Coast. The program will provide highly interactive discussion from sponsor companies and service providers from "both sides of the fence." Participants can share their insights and experiences and learn how to apply outsourcing concepts and strategies to their own projects and corporate culture.

#### HIGHLIGHTS

- How to achieve greater value from outsourcing
- Small group environment
- Highly interactive
- Emphasis on decision-making and strategy for smaller companies
- Latest outsourcing challenges and opportunities
- Brief presentations followed by in-depth discussions
- Practical tools you can use on current projects
- Ample networking opportunities with experienced industry professionals

#### WHO SHOULD ATTEND

This program will benefit individuals involved in:

- ▶ Clinical researchers
- ▶ Data managers
- ▶ Biostatisticians
- ▶ Project managers
- ▶ Outsourcing managers
- ▶ Finance professionals
- ▶ Executive managers
- ▶ CRO professionals
- ▶ Technology providers
- ▶ Laboratory service providers
- ▶ Independent consultants providing specialized services (e.g., stats, programming, writing) to pharmaceutical and biotechnology companies

#### LEARNING OBJECTIVES

- ▶ Define a risk management approach to evaluate or develop an outsourcing strategy
- ▶ Discuss alternative outsourcing options in order to control expenditures
- ▶ Recognize how to manage change in a strategic partnership
- ▶ Describe processes in order to clearly understand sponsor and provider roles, responsibilities, and expectations

**VISIT [WWW.DIAHOME.ORG](http://WWW.DIAHOME.ORG) FOR A COMPLETE SCHEDULE OF EVENTS!**

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: [dia@diahome.org](mailto:dia@diahome.org)

### Accreditation and Credit Designation

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**To receive a statement of credit, please visit [www.diahome.org](http://www.diahome.org). Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.**

**Disclosure Policy:** It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

See cover for Learning Objectives.

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## THURSDAY • MARCH 19

4:00-6:00 PM REGISTRATION

## FRIDAY • MARCH 20

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS AND AGENDA REVIEW  
**Welcome and Opening Remarks**  
 PROGRAM CO-CHAIRPERSON  
**John R. Vogel, PhD**  
 Drug Development Consultant  
 John R. Vogel Associates, Inc.

**Agenda Review**  
 PROGRAM CO-CHAIRPERSON  
**Nanette Nanjo-Jones, MBA**  
 Outsourcing Consultant

8:30-10:00 AM SESSION 1

### CASE STUDY: TAKING A RISK MANAGEMENT APPROACH FOR THE DEVELOPMENT OF AN OUTSOURCING STRATEGY

SESSION CHAIRPERSON

**Bruno Gagnon, BPharm, MSc**  
 Senior Director, Clinical Operations  
 Roche Molecular Systems, Inc.  
 Formerly Senior Director at FibroGen, Inc.

Clinical development plans and the outsourcing strategy needed to implement them require a careful risk management approach. Make or buy decisions should be made early and re-visited periodically based on milestones reached and growth rate. Small biotech com-

panies face a unique challenge in regards to resource availability and the maturity level of their infrastructure. They also tend to struggle with reaching the right balance between keeping tight control over study activities while transferring responsibilities to a service provider. This session will take the form of an interactive case study. We will discuss how to identify and develop core competencies, how to determine functions that are better to outsource, how to make decision about whose processes to follow, how to assess and mitigate risk and how to adapt the outsourcing strategy to manage the growth of the organization.

DISCUSSANTS:

**Stewart Hallet, MBA**  
 Director, Clinical Operations  
 Medivation

**Heidi Egelhoff**  
 Manager, Business Development  
 UBC, Clinical Technologies Group

**Steven R. Nelson, MBA**  
 Senior Director, Clinical Operations  
 FibroGen, Inc.

10:00-10:30 AM REFRESHMENT BREAK

10:30-12:00 PM SESSION 2

### WEIGHING ALTERNATIVE OUTSOURCING OPTIONS TO HELP CONTROL THE BURN RATE

SESSION CHAIRPERSON

**Nancy A. Havrilla, MS, RN**  
 Senior Director, Clinical Operations  
 ACHAOPEN, Inc.

Small, start-up bio-pharmaceutical companies face financial constraints that are more acute now than ever before. In the current economy these constraints have increased as the spending limits are more restricted with shortened timelines and limited resources. The survival of smaller companies is dependent on their ability to work with CROs in an efficient and cost effective manner. This session will

begin with identifying various outsourcing options with input from the audience and panel followed by a discussion of these options.

**DISCUSSANTS:**

**Pat Terek, MS**

Executive Vice President Business Development Americas  
Siro ClinPharm

**Pam Foster Willey, MBA**

Consultant, PFW Consulting

**Dorothy Dorotheo, CCDM**

Director, Clinical Data Management  
Intermune, Inc.

**12:00-1:30 PM LUNCHEON**

**1:30-3:00 PM SESSION 3**

**PREFERRED PROVIDERS: ACHIEVING THE BEST PRICE/SERVICE FROM STRATEGIC PARTNERING**

SESSION CHAIRPERSON

**David Kiger**

Regional Director, Business Development (West)  
Perceptive Informatics

Many small biotech companies implement a preferred provider program to build consistent processes where both companies achieve efficiencies. Sponsors invest a large amount of time and effort only to realize later that switching partners is the only alternative. Partners have a clear understanding and mutual shared goals. Communication is key so that vendors understand and focus on the items most important to a sponsor. In this session, we will discuss how to secure a good price and service, how to adapt the goals of the agreement as companies and personnel change, and how to ensure that the partnership sticks to its original intent.

**DISCUSSANTS:**

**Colleen Mccoy**

Senior Manager, Development Outsourcing and Contracts  
Genentech, Inc.

**Gary Laine**

Director, Outsourcing  
Elan Pharmaceuticals

**Ed Donaldson**

Director, Business Development  
ResearchPoint

**3:00-3:30 PM REFRESHMENT BREAK**

**TRAVEL AND HOTEL** The most convenient airport is San Francisco International Airport and attendees should make airline reservations as early as possible to ensure availability. The Hyatt Regency San Francisco Airport Hotel is holding a block of rooms at the reduced rate below until February 26, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

**Single \$149 Double \$149**

Please contact the Hyatt Regency San Francisco Airport Hotel by telephone at +1-650-347-1234 or +1-800-233-1234 and mention the DIA event. The hotel is located at 1333 Bayshore Hwy., Burlingame, CA 94010, USA.

**Participants with Disabilities:** DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

**DRUG INFORMATION ASSOCIATION** <http://www.diahome.org>

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email: diaindia@diaindia.org

**3:30-5:00 PM SESSION 4**

**WHO'S DOING WHAT? BEST PRACTICES FOR CLEARLY DEFINING ROLES, RESPONSIBILITIES, AND EXPECTATIONS**

SESSION CHAIRPERSON

**Marianne R. Plaunt, PhD**

Vice President, Global Operations  
Paragon Biomedical, Inc.

Does everyone within the sponsor and CRO know what is expected of them? The outsourcing process can be fraught with issues if roles, responsibilities and expectations are not clearly defined during the early stages of a relationship or project. Accurate specifications in the request for proposal and the Statement of Work will lead to a realistic project budget at the beginning and will facilitate communication between the sponsor and the provider about the roles and responsibilities of each. In addition, mapping out the process and defining hand offs between working groups is essential. In this session we will discuss best practices in:

- Defining work specifications
- Roles and responsibilities
- Shared expectations
- Process mapping
- Ongoing effective management of expectations

**DISCUSSANTS:**

**Todd Reul**

Sr. Manager, Clinical Outsourcing  
Facet Biotech

**Kathy Feldkircher, PhD, MA**

Senior Director, Clinical Operations  
Actelion Pharmaceuticals US, Inc.

**Kenneth Wilson**

Senior Director, Business Development  
Clinimetrics Research Associates, Inc.

**5:00-5:15 PM CLOSING REMARKS**

PROGRAM CO-CHAIRPERSON

**Nanette Nanjo-Jones, MBA**

Outsourcing Consultant

**5:15-6:15 PM NETWORKING RECEPTION**

**6:15 PM CONFERENCE ADJOURNED**

**GROUP DISCOUNTS\*** Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

- ▶ **To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.**

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Event ID #09011

Hyatt Regency San Francisco Airport,  
Burlingame, CA, USA

March 20, 2009

## HIGHLIGHTS

- How to achieve greater value from outsourcing
- Emphasis on decision-making and strategy for smaller companies
- Latest outsourcing challenges and opportunities

Register online or fax this page to +1-215-442-6199

### ▶ CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and during receptions (if applicable).

**Event information:** Contact Ben Zaitz at the DIA office by telephone +1-215-293-5803, fax +1-215-442-6199 or email Benjamin.Zaitz@diahome.org.

**Tabletop exhibit information:** Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For tabletop exhibit space, please check the box below.

To receive a tabletop exhibit application, please check.

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**Registration Fees** If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

### MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only.

	On or before	After
	FEB. 27, 2009	FEB. 27, 2009

Member Fee	US \$775 <input type="checkbox"/>	US \$865 <input type="checkbox"/>
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US \$ 130

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Nonmember Fee	US \$995 <input type="checkbox"/>
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### Discount Fees

	<b>MEMBER</b>	<b>NONMEMBER*</b>
Government (Full-time)	US \$ 365 <input type="checkbox"/>	US \$ 495 <input type="checkbox"/>
Charitable Nonprofit/Academia (Full-time)	US \$ 565 <input type="checkbox"/>	US \$ 695 <input type="checkbox"/>

\*If paying a nonmember fee, please check one box above, indicating whether you want membership.

### ▶ CANCELLATION POLICY: On or before MARCH 14, 2009

**Administrative fee that will be withheld from refund amount:**

Member or Nonmember = \$200  
Government or Academia or Nonprofit (Member or Nonmember) = \$100  
Tutorial (if applicable) = \$50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

▶ DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

I cannot attend but please keep me informed of DIA's future events.  
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Please check the applicable category:

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Last Name  Check if part of group registration First Name M.I.

Degrees  Dr.  Mr.  Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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Visa  MC  AMEX Exp Date \_\_\_\_\_

Card # \_\_\_\_\_

Name (printed) \_\_\_\_\_

Signature \_\_\_\_\_

**CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

**BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.