

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

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 6.25 *AMA PRA Category 1 Credit(s)*TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 6.25 contact hours or .625 continuing education units (CEU's). 286-000-09-020-L04-P.



The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. DIA is authorized by IACET to offer .6 CEUs for this program.

To receive a statement of credit, please visit 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.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

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

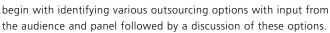
WEIGHING ALTERNATIVE OUTSOURCING OPTIONS TO HELP CONTROL THE BURN RATE

Session Chairperson

Nancy A. Havrilla, MS, RN

Senior Director, Clinical Operations ACHAOGEN, 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



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.

LUNCHEON 12:00-1:30 PM

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 рм REFRESHMENT BREAK

SESSION 4 3:30-5:00 РМ

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

NETWORKING RECEPTION 5:15-6:15 PM

6:15 рм CONFERENCE ADJOURNED

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.

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.

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.

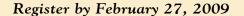
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SAVE \$90

Biotechnology Clinical Trials Outsourcing

Event ID #09011 Hyatt Regency San Francisco Airport, **Burlingame, CA, USA** March 20, 2009

HIGHLIGHTS

- Emphasis on decision-making and strategy for smaller companies
- Latest outsourcing challenges and opportunities

· How to achieve greater value from outsourcing

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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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. See page 3 for complete details.

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

On or before Available on nondiscount member fee only. FEB. 27, 2009

Member Fee US \$775 🔲 US \$865 🔲

Join DIA now to qualify for the early-bird member fee! www.diahome.org/en/Membership/ AboutMembership/AboutMembership

MEMBERSHIP US \$ 130 🔲

FEB. 27, 2009

After

To qualify for the early-bird discount, registration form and accompanying payment must be

US \$995 🔲 Nonmember Fee

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

received by the date above. Does not apply to government/academia/nonprofit members.

I want to be a DIA member

I do NOT want to be a DIA member 🔲

Government (Full-time)

Discount Fees

US \$ 365 🚨 US \$ 565 🚨

MEMBER

US \$ 495 🔲 US \$ 695 🔲

NONMEMBER*

Charitable Nonprofit/Academia (Full-time) *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. (requires completion of name, postal address and email address on this form)

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Group Registrant #4 Last Name	First Name	Completed form re	equired for each grou	ıp registrant

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- 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.