Strategic Planning and Partnering in Global Clinical Trials: Compliance with Ethical, Quality and Regulatory Standards

December 3-4, 2012
Sheraton Philadelphia Downtown Hotel | Philadelphia, PA

PROGRAM CO-CHAIRS

Barry Mangum, PharmD, FCP
Director Clinical Pharmacology
Duke Clinical Research Unit

Douglas J. Peddicord, PhD
Executive Director
Association of Clinical Research Organizations

PROGRAM COMMITTEE

Charlotte Coley, MACT, CIP
Director, Educational Programs
Duke Medicine Institutional Review Board

Yvonne Higgins, BS, CIP
Director, Quality Management
Copernicus Group, Western IRB

Ross Pettit
Vice President, Clinical Operations
AMAG Pharmaceuticals

Pia Stroeger
Director
PAREXEL Consulting UK

PROGRAM OVERVIEW

Globalization of clinical trials has increased dramatically in the past 20 years. High rates of failure, long development timelines, high costs for late stage trials, and the desire to market products globally have motivated sponsor companies to conduct studies in multiple regions, including emerging markets. Challenges, such as complex and changing regulatory requirements, concern for study quality, and human subject protection dilemmas in emerging regions, can threaten to outweigh the advantages of a multi-regional approach. Yet the ability to conduct high quality studies in multiple locations is much improved, making successful global programs feasible even for small and mid-size companies.

This two day conference will focus on the strategy and planning processes required for successful entry into multiple markets simultaneously. Experienced sponsor companies, CRO's, and regulatory agency staff will guide interactive sessions on strategic planning to achieve the goals of trial safety and quality while meeting the high standards necessary for regulatory approval of new products in major and emerging markets.

Regulatory requirements in major and emerging markets, including the United States, Europe, Asia (China, Korea, and Asia-Pacific), India and Latin America, will be addressed, focusing on:

- Human subject protection and ethical standards
- Quality of data
- Regulatory compliance
- Regulatory submissions

LEARNING OBJECTIVES

At the conclusion of this conference, participants should be able to:

- Describe the factors that should be considered when selecting regions and countries for a global program
- Describe various approaches to ensuring quality and efficiency of IRB reviews while adhering to regulations and international ethical standards
- Identify the key elements of effective plans for quality oversight in order to obtain quality data in multiregional clinical trials
- Plan a harmonized approach to entry while maintaining regulatory compliance in multiple regions simultaneously
- Identify regulatory requirements in specific regions and how they differ from those in the United States

TARGET AUDIENCE

This program will benefit individuals involved in:

Pharmaceutical and Biotechnology professionals and decision-makers, especially in small and mid-sized companies and CRO's, involved in:

- Global Clinical Operations
- Global QA/Compliance
- Clinical Translational Research
- Clinical Research & Development
- Strategic Planning
- Regulatory Affairs / Risk Management
- Clinical and Protocol Design
- Clinical Outsourcing
- Ethics/IRB Review
- Patient Recruitment/Enrollment
- Clinical / Regulatory Informatics
- Clinical Safety / Pharmacovigilance
- Data Standards / Data Management

DIA Worldwide Headquarters
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
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DIA'S CERTIFICATE PROGRAM

This program is part of DIA's Certificate Program and is awarded the following:
- Clinical Research Certificate Program: 6 Elective Units

For more information go to ***www.diahome.org/certificateprograms***

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It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

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MONDAY, DECEMBER 3

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

8:15-8:30 AM WELCOME AND OPENING REMARKS

Barry Mangum, PharmD, FCP
Director Clinical Pharmacology
Duke Clinical Research Unit

8:30-9:30 AM SESSION 1A

Ethical Standards and Human Subject Protection

First and foremost in any clinical trial is the need to meet standards to assure the protection of human subjects. Adhering to international ethical standards while adapting to local cultures, varying educational backgrounds and socioeconomic and medical conditions in multiple regions can seem daunting. This session will explore the elements of planning to ensure quality and effectiveness in human subject protection programs. Recent models and successful approaches in emerging regions will be presented.

Session Chairperson

Yvonne Higgins,
Vice President, Quality Management
Copernicus Group, IRB

Ethical Standards and Human Subject Protection

A. J. Allen, MD, PhD
Senior Medical Fellow, Bioethics & Pediatric Capabilities
Eli Lilly and Company

FDA Human Subject Protection

Michelle Roth-Cline, MD, PhD
Pediatric Ethicist, Office of Pediatric Therapeutics
FDA

9:30-10:00 AM REFRESHMENT BREAK

10:00 AM-12:00 PM SESSION 1B

Ethical Standards and Human Subject Protection – (Continued)

Session Chairperson

Yvonne Higgins
Vice President, Quality Management
Copernicus Group, IRB

Enhancing Human Research Protections: A Top-down Approach

Nicholas Slack, MBE
Vice President, Consulting Services
Western Institutional Review Board, Inc.

Human Research Protections in the Middle East

Stuart Horowitz, PhD, MBA
President, Institutions & Institutional Services
Western Institutional Review Board, Inc.

HIV Program in Moshi, Tanzania

John Bartlett, MD
Professor of Medicine, Global Health and Nursing
Duke University Medical Center

12:00-1:00 PM LUNCH

1:00-3:00 PM SESSION 2

Quality (focus on clinical data quality) in clinical trials conducting in multiple regions

Quality by Design (QbD) has been incorporated by pharmaceutical entities into routine planning for the conduct of trials in a global environment. During this session, representatives from industry, academia and regulatory agency will discuss the key quality processes related to multiregional clinical trials and implementation of those processes at sites that have demonstrated reliable results in the key area of data quality.

Session Co Chairpersons

Douglas J. Peddicord, PhD
Executive Director
Association of Clinical Research Organizations

Ross Pettit
Vice President, Clinical Operations
AMAG Pharmaceuticals

Quality of Data Comparison Study

Pankaj Desai, PhD
Professor and Director
Drug Development Graduate Program
College of Pharmacy
University of Cincinnati

Douglas J. Peddicord, PhD
Executive Director
Association of Clinical Research Organizations

Implementation of Quality by Design in Clinical Trials in Emerging Markets

Peter Blaisdell, PhD
Executive Director, Global Study Management
Amgen

Preparing for an inspection

Jane Wood
Vice President, Quality Assurance
Johnson and Johnson

What Triggers a Health Authority Inspection in a particular region

Ann Meeker-O'Connell
Acting Division Director, Director, GCP Compliance, Office of Compliance
FDA

3:00–3:30 PM REFRESHMENT BREAK

3:30–5:00 PM SESSION 3

Regulatory Strategies

It is of essential importance for pharmaceutical companies to be compliant with the regulatory requirements in the countries where the company is acting. Non-compliance can have a critical influence on approvals in a negative way and lead to an immense amount of paper rework both for the authority and for the non-compliant company. EU and FDA are leading authorities and the following presentations will provide the audience with a high level overview on how to achieve and maintain regulatory compliance.

Session Chairperson

Pia Stroeger
Director
PAREXEL Consulting UK

Planning of global regulatory strategy as the foundation for entry into multiple regions

Pia Stroeger
Director
PAREXEL Consulting UK

Elements of strategic decision making for the selection of emerging markets

Susan Callery-D'Amico
Associate Vice President, Compliance
Reata Pharmaceuticals, Inc.

5:00–6:00 AM NETWORKING RECEPTION

TUESDAY, DECEMBER 4

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM SESSION 4

Regulatory Compliance

Attention to specific regulatory requirements and internal company requirements are needed to assure the best possible management and maintenance of global submissions. It is the aim of this presentation to provide the participants with a high level overview of the considerations that need to go into the strategy for a successful global approach.

Session Chairperson

Pia Stroeger
Director
PAREXEL Consulting UK

Importance of compliance with regulatory requirements of EU – via audio link

Agnes Saint Raymond, MD
Head, Human Medicines Special Areas
Human Medicines Development and Evaluation
European Medicines Agency, European Union

Importance of compliance with regulatory requirements of FDA

Speaker invited

10:00–10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 5

Regulatory Requirements for Registration

This session will provide the attendees a good understanding of potential critical topics that can be addressed prior to submission to assure the best possible submission strategy. This overview will focus on initiating submission work in emerging markets with specific emphasis on Asia (Korea, China, India) and LATAM (Brazil).

Pia Stroeger
Director
PAREXEL Consulting UK

12:00–1:00 PM LUNCH

1:00 – 3:00 PM SESSION 6

Regulatory Requirements: Reimbursement Considerations

In addition to fulfilling regulatory requirements, it is essential to consider reimbursement as a metric of commercial success. This session will feature the success and challenges of compounds that have met regulatory requirements but have had their use restricted by reimbursement decisions. We will also discuss emerging markets, such as China, Indonesia, Russia, and Brazil, and identify trends and requirements for reimbursement as these markets evolve.

Robert Paglia, RPh, MBA
Vice President, Commercialization
PAREXEL International, USA

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Strategic Planning and Partnering in Global Clinical Trials: Compliance with Ethical, Quality and Regulatory Standards
Event #12023 • December 3-4
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TRAVEL AND HOTEL

The Sheraton Philadelphia Downtown Hotel is holding a block of rooms at the reduced rate below until **November 17, 2012**, 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

Attendees must make their own hotel reservations. Contact the Sheraton Philadelphia Downtown Hotel by telephone at +1.215.448.2000 and mention the DIA event. The hotel is located at 201 North 17th Street, Philadelphia, PA 19103, USA.

CANCELLATION POLICY: On or before NOVEMBER 20
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.

Participants with Disabilities: Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

REGISTRATION QUESTIONS
Contact **Elizabeth Espich, Customer Service,** Phone **+1.215.293.5802**
Fax **+1.215.442.6199,** email **Elizabeth.Espich@diahome.org**

AGENDA AND EVENT DETAILS
Contact **Joanne Wallace, CMP, Content Lead,** Phone **+1.215.442.6180**
Fax **+1.215.293.5931,** email **Joanne.Wallace@diahome.org**

Contact **JoAnn Boilleau, Event Planner,** Phone **+1.215.442.6175**
Fax **+1.215.293.5940,** email **Joann.Boileau@diahome.org**

TABLETOP EXHIBIT INFORMATION
Contact **Jeff Korn,** Phone **+1.215.442.6184**
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