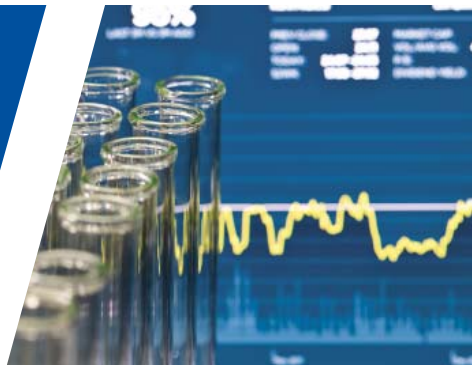
DIA/FDA: Revitalizing R&D Productivity in Drug Development

October 23-24, 2012

Bethesda Marriott Pooks Hill, Bethesda, MD, USA



PROGRAM CHAIRPERSONS

Yili L. Pritchett, PhD
Research Fellow
Director, Clinical Statistics
Abbott Laboratories

H. M. James Hung, PhD
Director, Division of Biometrics I
Office of Biostatistics
Office of Translational Sciences
CDER, FDA

PROGRAM ORGANIZING COMMITTEE

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Senior Director, Biostatistics and Research Decision Sciences
Merck & Co., Inc.

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Mathematical Statistician, Division of Biometrics III
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Drug Information Association, Inc.
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Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

Explore Initiatives That Champion the Continued Revitalization of R&D Productivity in Drug Development.

The focus of this conference is to review the status quo of pharmaceutical industry and to explore the initiatives that champion the continued revitalization of R&D productivity in drug development. With the rapid changes being experienced within this industry and the successes and failures in the challenging journey of drug development, this conference will provide a forum for industry, regulators and academia to come together to discuss challenges and opportunities, and to share visions, experience, and lessons learned. This conference will stimulate open dialogue between industry and regulators, and ultimately, will help enhance efficiency and right decision making in drug development.

SESSION TOPICS

- Designing Informative and Efficient Clinical Programs at the Learn Phase
- Enrichment of Clinical Study Populations in Confirmatory Phase
- Improving Efficiency and Quality of Clinical Research
- Leveraging Biomarker Data to Have a Meaningful Impact on Clinical Development Programs
- Lessons Learned from Clinical Development Programs-Regulatory and Industry Perspectives
- Path Forward: Regulatory and Industry Panelist Discussion

WHO SHOULD ATTEND

Professionals from industry, academia and government involved in drug development from learning to confirmatory phases or in new drug application review:

- Clinicians
- Pharmacologists
- R&D decision-makers in drug development
- Statisticians
- Regulatory Scientists

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CONTINUING EDUCATION CREDITS

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This program is part of DIA's Certificate Program and is awarded the following:

• Clinical Research Certificate Program: 8 Elective Units

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

LEARNING OBJECTIVES

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

- Identify challenges in drug development from infrastructure, decision making, and clinical trial design to operational quality and efficiency
- Discuss through case studies the FDA guidance on population enrichment in confirmatory clinical trials
- Discuss insights on translation between biomarkers and clinical outcomes and renew the approaches in the learning phase of the clinical program to improve overall efficiency
- Formulate innovative thinking to continue revitalizing R&D productivity

Disclosure Policy

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.

KEYNOTE SPEAKERS

Revitalizing R&D: What Could We Be Doing Differently?

Robert Temple, MD
Deputy Center Director for Clinical Science
Acting Director
Office of Drug Evaluation I (ODE-I)
CDER, FDA

Dr. Robert Temple is Deputy Center Director for Clinical Science of FDA's Center for Drug Evaluation and Research and is also Acting Director of the Office of Drug Evaluation I (ODE-I). Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972 he joined CDER as a review Medical Officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of Director of the Division of Cardio-Renal Drug Products. In his current position, Dr. Temple oversees ODE-1 which is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control trials, trials to evaluate dose-response, and trials using "enrichment" designs. He also has a long-standing interest in hepatotoxicity of drugs, having participated in the first detailed FDA-NIH-outside discussion of the subject in 1978.

An Overview of the Future for Drug Development Under the New Imperatives Delivered by Both Commercial and Regulatory Pressures

Steve Arlington, PhD
Global Advisory Leader
Pharmaceutical and Life Sciences
Pricewaterhouse Coopers (PwC)

Dr. Arlington leads the global advisory team at PwC focused on the pharmaceutical and life sciences industry. Based in London, he has worked in the industry for over 13 years and has consulted to both pharmaceutical and biotech companies for 17 years. He specializes in the areas of strategy, discovery research, new product and process development, boardroom strategy and transformation. Dr. Arlington received a BSc, PhD and is a visiting professor at UCL. He has been a faculty member of the ECPM for 12 years and is a member of the Royal Society of Medicine and the DIA. Steve has led the firms forward thinking thought leadership series Pharma 2005, Pharma 2010 and currently leads the Pharma 2020 series. These papers have been met with widespread acclaim across the industry. Dr. Arlington has led complex assignments for almost all of the major pharmaceutical players; he has worked extensively across Europe, USA and Japan and more recently in the growing markets of Asia. Dr. Arlington works across the value chain of the Pharma company and regulators across the world. Areas of Expertise Pharma R&D, Strategy, Cost Effectiveness, Futures analysis, and Transformation.

How Do We Revitalize R&D in New Drug Development?

Frank Rockhold, PhD
Head of Global Clinical Safety and Pharmacovigiliance at GSK

Frank Rockhold is currently the Head of Global Clinical Safety and Pharmacovigiliance at GlaxoSmithKline Pharmaceuticals Research and Development. Previously he was Senior Vice President, Drug Development Sciences at GlaxoSmithKline Pharmaceuticals Research and Development. This includes statistics, epidemiology and health care informatics. In his 18 years at GSK he has also held management positions within the Statistics Department and Clinical Operations both in R&D and in the U.S. Pharmaceutical Business. Frank is currently vice chair of the Board of Directors of the Clinical Data Interchange Standards Consortium (CDISC), a member of the WHO Scientific Advisory Group on Clinical Trial Registration, a member of the Institute of Medicine Committee on Clinical Trial Registers, a member of the National Library of Medicine Advisory group for the ClinicalTrials.Gov, and a member of the PhRMA Clinical Leadership Committee. He is a Fellow of the American Statistical Association and on the Board of Trustees of the National Institute of Statistical Sciences.

Collaborative Approaches to Advancing Clinical Development

Charley Beever, MBA
Booz & Company

A New York-based Partner, Charley Beever leads Booz & Company's efforts to serve pharmaceutical clients worldwide. He has more than 20 years of experience working with leading U.S., European, and Japan-based pharmaceutical, biotechnology, diagnostic, health care, and medical device/supply companies to resolve strategic, organizational, and performance improvement issues. Mr. Beever received Booz & Company's Professional Excellence Award in recognition of his exceptional and innovative client service on assignments for Quest Diagnostics and an HIV/AIDS epidemic strategic simulation. A recognized thought leader, Mr. Beever has contributed to many publications, including the following strategy+business articles: "U.S. Health Care's Technology Cost Crisis," "The Prescription for Drug Costs," "What's Driving Prescription Drug Costs?," and "Patient Safety: A Data-Driven Prescription," and the IN VIVO magazine article "Competing in a Retail Health Consumer Marketplace." Mr. Beever also was involved in the Booz & Company studies: "The Global AIDS Crisis—A Strategic Simulation to Explore Public/Private Partnerships in the Fight against HIV/AIDS" and "The Cost of Medical Technologies—Maximizing the Value of Innovation." Mr. Beever holds an M.B.A. from the Harvard Graduate School of Business Administration and a B.A. in economics from Haverford College, where he was elected to Phi Beta Kappa.

DAY ONE | TUESDAY, OCTOBER 23, 2012

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

8:30 AM-8:45 AM OPENING REMARKS AND INTRODUCTION OF KEYNOTE SPEAKERS

Yili L. Pritchett, PhD
Research Fellow
Director, Clinical Statistics
Data and Statistics Sciences
Abbott Laboratories

H.M. James Hung, PhD
Director, Division of Biometrics I
Office of Biostatistics
Office of Translational Sciences
CDER, FDA

8:45 AM-9:30 AM KEYNOTE ADDRESS I

Revitalizing R&D: What Could We Be Doing Differently?

Robert Temple, MD
Deputy Center Director for Clinical Science
Acting Director, Office of Drug Evaluation
CDER, FDA

9:30 AM-10:15 AM KEYNOTE ADDRESS II

An Overview of the Future for Drug Development Under the New Imperatives Delivered by Both Commercial and Regulatory Pressures

Steve Arlington, PhD
Global Advisory Leader
Pharmaceutical and Life Sciences
PricewaterhouseCoopers

10:15 AM-10:30 AM MORNING REFRESHMENT BREAK

10:30 AM-11:00 AM KEYNOTE QUESTION AND ANSWER DISCUSSION

11:00 AM-12:30 PM SESSION 1

Designing Informative and Efficient Clinical Programs at the Learn Phase

Session Chairperson

Peter Ouyang, PhD
Vice President, Biostatistics and Programming
Celgene Corporation

Dionne Price, PhD
Team Lead, Division of Biometrics II
Office of Biometrics
Office of Translational Sciences
CDER, FDA

Before drug development enters the confirmatory phase, one must have a good understanding of the disease type, patient population, dose/dosing regimen, and treatment effect. All of these components need be properly planned in the clinical program during the learn phase based on the information from the pre-clinical program, knowledge of early biomarker data and its potential diagnostic value, the disease pathways, and the drug's mechanism of action. Various design options, including adaptive designs, may be used at this phase. The possibility of tailored therapeutics and companion diagnostics may also be considered. The time frame and the size of the learn phase program are usually limited. Therefore, an informative and efficient clinical program at the learn phase is instrumental to advance the development program through GO/NO GO decisions before reaching the confirmatory phase. This session will discuss various design options of efficient and informative clinical programs at the learn phase.

Session Presenters

Learning with a Two-Stage Design with Multiple Arms: Adaptive and Manageable

Anastasia Ivanova, PhD
Associate Professor
Department of Biostatistics
University of North Carolina at Chapel Hill

Evaluating the Impact of Dose Selection on Overall Program Success

Jose C. Pinheiro, PhD
Senior Director, Quantitative Decision Strategies
Janssen Research & Development, LLC

Bayesian Adaptive Designs for Early Stage Trials

Scott Berry, PhD
Statistical Scientist
Berry Consultants

Question and Answer Discussion

12:30 PM-1:45 PM LUNCHEON AND NETWORKING OPPORTUNITY

1:45 PM-3:15 PM SESSION 2

Population Enrichment in Confirmatory Clinical Trials

Session Chairpersons

Rajeshwari Sridhara, PhD
Director , Division of Biometrics V
CDER, FDA

Vladimir Dragalin, PhD
Senior Vice President
SVP Innovation Center
Aptiv Solutions

There is an increasing interest in targeted therapies directed to specific biomarker guided subgroup of patients in whom detection of a treatment effect, if present, is possible. This has created a demand on a paradigm shift in clinical trial design and a focus on patient subpopulations with potentially greater treatment effect. As often the biomarker of interest is unknown or not characterized at the beginning of a clinical trial, instead of limiting the enrollment only to the enriched population, prospectively specified adaptive designs may be used to consider the effect of the experimental treatment both in this subpopulation and in the whole patient population under investigation that allow modification of enrollment at an interim analysis if data suggest the biomarker is predictive. Regulatory position and issues related to population enrichment strategies highlighted in the recently released FDA Draft Guidance for Industry on Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products will be discussed. The Pharmaceutical Industry reflections on the FDA Guidance as well as on the new opportunities, scope and challenges of enrichment strategies in drug development will be presented. FDA's recent experience with two drug-diagnostic successful submissions will be reported.

Session Presenters

FDA Guidance

Robert O'Neill, PhD
Senior Statistical Advisor
Office of Translational Sciences
CDER, FDA

New Opportunities, Scope and Challenges of Enrichment Strategies in Confirmatory Clinical Trials

Vlad Dragalin
SVP Innovation Center
Aptiv Solutions

Vemurafenib Case Study

Geoffrey Kim, MD
Medical Officer
Division of Oncology Products
Office of Hematology and Oncology Products
CDER, FDA

Crizotinib Case Study

Shakuntala Malik, MD
Medical Officer
Division of Oncology Products
Office of Hematology and Oncology Products
CDER, FDA

Question and Answer Discussion

3:15 PM-3:30 PM AFTERNOON BREAK

3:30 PM-5:00 PM SESSION 3

Improving the Efficiency and Quality of Clinical Research

Session Chairperson

Kenneth Koury, PhD
Senior Director
Biostatistics and Research Decision Sciences
Merck & Co., Inc

Despite the increasing pressure to contain the rising cost of health care in the current and foreseeable economic and political environment, the cost of conducting clinical research also continues to rise sharply, and these trends diminish the prospect of providing an attractive return for investors in pharmaceutical research and development. Consequently, it is not surprising that key stakeholders are engaged in collaborations which focus on improving the efficiency and quality of clinical trials. This session will explore several themes that are important to clinical and quantitative scientists in the pharmaceutical industry. These include designing effective monitoring procedures for clinical trials that improve data quality, as well as increase efficiency, and enhancing the role of Data Monitoring Committees. The session will also examine the growing need to develop simpler, efficient, and cost-effective collaborative models with external partners that maximize the value of limited internal resources.

Session Presenters

Trial Monitoring and Improving Data Quality

Ann Meeker-O'Connell
Acting Division Director, GCP Compliance
CDER, OC, FDA

Enhancing the Value of Data Monitoring Committees

Lee-Jen Wei, PhD
Professor of Biostatistics, Department of Biostatistics
Harvard University

Panel Discussion: Increasing Efficiency in the Clinical Research Process to Optimize Outcomes

Paul DeLucca, PhD
Director, Late Development Statistics
Merck Research Laboratories

Ann Meeker-O'Connell

Lee-Jen Wei, PhD

Question and Answer Discussion

5:00 PM-6:00 PM NETWORKING RECEPTION

DAY TWO | WEDNESDAY, OCTOBER 24, 2012

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

8:30 AM-8:40 AM OPENING REMARKS AND INTRODUCTION OF KEYNOTE SPEAKERS

8:40 AM-9:15AM KEYNOTE ADDRESS III

How Do We Revitalize R&D in New Drug Development?

Frank W. Rockhold, PhD
Senior Vice President
Global Clinical Safety & Pharmacovigilance
GlaxoSmithKline

9:15 AM-9:50 AM KEYNOTE ADDRESS IV

Collaborative Approaches to Advancing Clinical Development

Charles Beever, MBA
Vice President
Booz and Company

9:50 AM-10:10 AM KEYNOTE QUESTION AND ANSWER DISCUSSION

10:10 AM-10:30 AM MORNING REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 4

Leveraging Biomarker Data to Have a Meaningful Impact on Clinical Development Programs

Session Chairpersons

Mike Hale
Executive Director Medical Sciences - Biostatistics
Amgen

Freda Cooner, PhD
Mathematical Statistician, Division of Biometrics III
Office of Biostatistics
Office of Translational Sciences
CDER,FDA

Demands for increased R&D productivity have spurred many initiatives for increased efficiency, often for small incremental gains. Such gains are unlikely to adequately answer the challenges facing drug development. If we agree fundamental changes are needed in our approaches, we examine whether we are effectively using biomarker insights to have a significant impact on the way we design and execute our clinical development programs; or if our clinical development programs are largely "business as usual" with biomarkers leading to only minor changes. This session will consider alternatives to conventional methodologies to help fully utilize biomarkers for a better informed and more effective clinical development program.

Session Presenters

From Learning to Inference: How Can Biomarker Data Enhance Clinical Development Program?

Sue-Jane Wang, PhD
Associate Director, Pharmacogenomics and Adaptive Design, Biostatistics Lead for CDER Biomarker Qualification Program
Office of Biostatistics
Office of Translational Sciences
CDER, US FDA

How to Maximize the Usefulness of Predictive Biomarker Data in Development of Personalized Medicines?

Cong Chen, PhD
Director, Late Development Statistics - Oncology
Merck & Co., Inc.

Validation of Biomarkers in Clinical Trials – Easier Said than Done!

Marc Buyse, ScD
Chairman
International Drug Development Institute (IDDI)

Question and Answer Discussion

12:00 PM-1:00 PM LUNCHEON AND NETWORKING OPPORTUNITY

1:00 PM-2:30 PM SESSION 5

Lessons Learned from Clinical Development Programs—Regulatory and Industry Perspectives

Session Chairpersons

Peiling Yang
Team Lead, Division of Biometrics I
Office of Biostatistics
Office of Translational Sciences
CDER, FDA

Bruce Binkowitz
Senior Director, Late Development Statistics
Merck Research Laboratories

Drug sponsors have been faced with great challenges to effectively develop a clinical program. Failure rates of clinical trials are at an all-time high. Insufficient knowledge from learning clinical trials may lead to misinformed planning of confirming clinical trials, and therefore slow down the potential marketing approval or in the worst case result in the failure of a clinical program. In this session, causes and risks learned from some flawed and failed clinical programs will be shared and opportunities for improvement will be explored from regulatory perspectives as well as from drug developers' perspective.

Session Presenters

FDA Review Experience with Clinical Trials for Schizophrenia and Major Depressive Disorder

Ni Khin, MD
Team Lead, Division of Psychiatry Products,
Office of Drug Evaluation I
Office of New Drugs
CDER, FDA

FDA Perspective on what we have Learned from Anti-infective Clinical Trials

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products

Office of New Drugs
CDER, FDA

Inspection of Some Failed Phase 3 Studies Through a Retrospectoscope

Steve Snapinn, PhD
Vice President, Global Biostatistics & Epidemiology
Amgen

Question and Answer Discussion

2:30 PM-2:15 PM AFTERNOON REFRESHMENT BREAK

2:45 PM-4:15 PM SESSION 6

Path Forward: Regulatory and Industry Panelist Discussion

Session Chairpersons

Yili L. Pritchett, PhD
Research Fellow
Director, Clinical Statistics
Data and Statistics Sciences
Abbott Laboratories

H.M. James Hung, PhD
Director, Division of Biometrics I
Office of Biostatistics
Office of Translational Sciences
CDER, FDA

Regulatory

Robert Temple, MD
Deputy Center Director for Clinical Science
Acting Director, Office of Drug Evaluation (ODE-I)
CDER, FDA

Robert O'Neill, PhD
Senior Statistical Advisor
Office of Translational Sciences
CDER, FDA

Lisa LaVange, PhD
Director of Office of Biostatistics
Office of Translational Sciences
CDER,FDA

Industry

Steve Snapinn, PhD
Vice President, Global Biostatistics & Epidemiology
Amgen

Frank Rockhold, GSK
Head of Global Clinical Safety and Pharmacovigiliance
GSK

Christopher Brett
Lead, Cardiovascular & Atherosclerosis
Global Trial Management
Merck & Co., Inc

4:15 PM-4:30 PM PROGRAM CHAIRPERSON'S REMARKS AND CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

DIA/FDA: Revitalizing R&D Productivity in Drug Development

Event #12028

Bethesda Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814

REGISTRATION RATES

Industry	US $1295 ❑
Nonprofit/Academia (Full-time)	US $650 ❑
Government	US $390 ❑

Payment options: Register online at www.diahome.org or check payment method.

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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.

EVENT INFORMATION

For registration questions, please contact **Vicki Adkinson** by phone at **+1.215.442.6162** or by email at **Vicki.Adkinson@diahome.org.**
For agenda details, please contact Program Developer **Constance Burnett** by phone at **+1.215.293.5800** or by email at **Constance.Burnett@diahome.org**

TRAVEL AND HOTEL

The most convenient airport is the Ronald Reagan Washington National Airport - DCA and attendees should make airline reservations as early as possible. Bethesda Marriott Pooks Hill is holding a block of rooms at the reduced rate below until October 1, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $169 Double $169

Attendees must make their own hotel reservations. Contact the Bethesda Marriott Pooks Hill by telephone at +1.301.897.9400 and mention the DIA event. The hotel is located at 5151 Pooks Hill Road Bethesda, MD 20814.

CANCELLATION POLICY: On or before October 16, 2012

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: 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.

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student (Call for registration information)

Last Name

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**