Interactive, Team-based Approach to Understanding Drug Development Strategies for Small and Large Molecular Entities.

Learn proven concepts behind First-in-Human (FIH) dose selection and strategic considerations around issues for a spectrum of drug development programs. You will:

- Participate in break-out sessions where teams will discuss nonclinical programs for large and small molecules to support FIH dosing
- Discuss the challenges associated with clinical dosing and the outcomes of additional nonclinical data that may affect continued clinical development
- Develop strategies for consideration of FIH dose and interactions with FDA
- Evaluate toxicological and pharmacological data to provide an estimate of the FIH dose and justify the clinical dose escalation paradigm

FEATURED TOPICS

- Drug Development Process in the Current Regulatory Environment
  - General overview of the drug development process
  - Regulatory guidance for the design of nonclinical programs
  - Regulatory submissions and interactions in the IND phase
- Regulatory Guidelines and Interaction with Regulatory Authorities
  - CMC issues for small molecules and large molecules
  - Principles of FIH dose selection
  - Differences in pharmacology/toxicology expectations to support FIH dosing based upon product attributes

WHO SHOULD ATTEND

Professionals, especially from small- and mid-sized companies and nonclinical and clinical CROs, involved in:

- Regulatory affairs
- Clinical research
- Clinical pharmacology
- Project management
- Nonclinical
- Academia
CONTINUING EDUCATION CREDITS

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. (703) 506-3275.

DIA is authorized by IACET to offer 1.8 CEUs for this program.

If you would like to receive a statement of credit, you must attend the program, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on April 20.

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 (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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

• Describe First in Human (FIH) enabling toxicology package for large and small molecules to include relevant pharmacological and toxicological data and identification of the HED, PAD, NOAEL, MABEL
• Identify issues that often arise during early drug development of small and large molecules and learn different approaches for managing those issues
• Interpret nonclinical data supporting first-in-human (FIH) dose selection and clinical safety
• Describe the role of the clinician in FIH dosing and bridging of nonclinical to clinical considerations in FIH dose selection.
• Integrate the regulatory context, eg, guidance, into strategies for addressing emerging nonclinical and clinical issues in early stage drug development.
• Identify strategies to support FIH based on product attributes, therapeutic target, CMC, treatment duration, patient populations, etc. as they relate to small and large molecule pharmaceuticals
• Identify unique patient populations and how FIH dose selection is considered for these populations
• Apply hands-on experience with selected nonclinical data interpretation, clinical dose selection, IND sections and components of FDA meeting requirements and requests

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.

DAY 1 APRIL 4, 2011

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM INTRODUCTION AND OVERVIEW
William J. Brock, Ph.D., DABT, Fellow ATS
Principal
Brock Scientific Consulting

8:15 AM-12:00 PM SESSION 1
Drug Development Process in the Current Regulatory Environment
Lorrene Buckley, PhD, DABT
Research Fellow
Eli Lilly Company

9:00-9:45 AM An Overview of Regulatory Guidance for Nonclinical Programs
Bert Haenen, PhD
Senior Consultant, Non-Clinical Development
3D-PharmXchange

9:45-10:15 AM REFRESHMENT BREAK

10:15-11:00 AM Regulatory Submissions and Interactions
Ronald Wange, PhD
Pharmacologist, OND, CDER
FDA

11:00 AM-12:00 PM Q&A

12:00-1:00 PM LUNCHEON
DAY 2 | APRIL 5, 2011

7:30-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00 AM-12:00 PM SESSION 3
Nonclinical Development of Biopharmaceuticals
Melanie Hartsough, PhD
Senior Consultant
Biologics Consulting Group

8:00-8:45 AM
Biopharmaceuticals vs Small Molecules… Can You Spot the Differences?
Melanie Hartsough, PhD
Senior Consultant
Biologics Consulting Group

8:45-9:30 AM
Extrapolation of Preclinical Data: Normal Volunteers vs. Patients
Joy Cavagnaro, PhD, DABT, RAC, Fellow ATS, FRAPS
President
AccessBio

9:30-10:00 AM REFRESHMENT BREAK

10:00-10:45 AM
“One Size” Does NOT Fit All: Challenges and Opportunities in the Design of Nonclinical Safety Programs to Support First-in-Human Dosing
Laura Andrews, PhD, DABT, Fellow ATS
VP Pharmacology and Toxicology
Genzyme

10:45 AM-12:00 PM BREAKOUT SESSION #2:
Nonclinical Considerations in the IND – Large Molecules

FACILITATORS:
Melanie Hartsough, PhD
Joy Cavagnaro, PhD, DABT, Fellow ATS

12:00-1:00 PM LUNCHEON

1:00 PM-5:00 PM SESSION 4
FIH Dose Setting and Timelines for Drug Development in Special Populations
Bert Haenen, PhD
Senior Consultant, Non-Clinical Development
3D-PharmXchange

Breakout Sessions:
Attendees will break into groups that would represent a sponsor and a regulatory authority. Each group is to read the supporting information and discuss any potential emerging issues at this stage in the development of their drug. Team leaders will present the key points from their respective IND Items to the entire workshop for discussion. Using the background information, teams will identify potential risks/information gaps and decide whether or not they will request a pre-IND meeting and, if yes, the questions to form the basis of that meeting request. The breakout session will be followed by an entire workshop Q&A on their respective development programs and a brief discussion of any potential risks/gaps identified at this point.

3:45-5:00 PM BREAKOUT SESSION #1:
Nonclinical Considerations in the IND – Small Molecules

FACILITATORS:
Lorrenne A. Buckley, PhD, DABT
William J. Brock, Ph.D., DABT, Fellow ATS

3:00-3:45 PM How to Account for Size When Extrapolating Doses from Animals to Humans
Paul A. Andrews, PhD
Executive Director, Global Regulatory Affairs
Eisai, Inc.

2:30-3:00 PM REFRESHMENT BREAK

1:45-2:30 PM
Clinical Pharmacology Consideration in FIH Dose Selection
Suresh Mallikaarjun, PhD, FCP
Senior Director, Clinical Pharmacology
Otsuka Pharmaceutical Development & Commercialization, Inc.

1:00-1:45 PM
CMC Issues for Large and Small Molecules: The Role of Nonclinical Data
Todd Page, PhD, DABT
Senior Research Scientist, Toxicology and Drug Disposition
Eli Lilly and Company

1:00 PM-5:00 PM SESSION 2
Nonclinical Programs and FIH Principles
William J. Brock, PhD, DABT, Fellow ATS
Principal
Brock Scientific Consulting

7:30-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST
1:00-1:45 PM  
Nonclinical Data and FIH Dose Setting in Pediatric Patients  
Beatriz Silva Lima, PhD  
Professor, IMED Lisbon University and INFARMED, Portugal

1:45-2:30 PM  
Non-clinical Considerations for FIH Clinical Trials in Oncology Patients  
Alex Putman, PhD  
Pharmacologist  
Division of Hematology Products  
Office of Oncology Products  
FDA

2:30-3:00 PM  REFRESHMENT BREAK

3:00-3:45 PM  
NCEs in Patients – Practical Aspects, A Sites Perspective with Emphasis on Safety  
William B. Smith, MD, FACC  
Associate Professor of Clinical Medicine  
Tulane University School of Medicine  
Professor of Clinical Medicine, University of Tennessee Medical Center  
Medical Director, New Orleans Center for Clinical Research and Volunteer Research Group

3:45-5:00 PM  BREAKOUT SESSION #3:  
Nonclinical Considerations in the IND – Large and Small Molecules  
Facilitators:  
Bert Haenen, PhD  
Royce Morrison, MD, CPI

5:00-6:00 PM  NETWORKING RECEPTION

Receive Deep Discounts on ALL DIA Educational Offerings!  
For $140 you can take advantage of all the benefits of membership.  

- Subscription to the Drug Information Journal, DIA’s peer-reviewed, scholarly journal  
- Subscription to the Global Forum  
- Subscription to ePublications, including timely FDA and regulatory updates delivered to your inbox  
- Subscription to the Contract Service Organization Directory  
- Member registration discounts on all conferences and Annual Meetings, training courses, and webinars  
- Access to our comprehensive online career center  
- Career development and networking opportunities through DIA Connex and as a member of Special Interest Area Communities (SIACs)  
- Members-only searchable index of DIA articles  
- Opportunities to join committees and to volunteer as a speaker, session chair, or author  
- Discounts on industry products and services

For more information, visit www.diahome.org and click on Membership.
Nonclinical and Clinical Strategies in First-in-Human Dosing of Large and Small Molecules
Event #11013 • April 6-7, 2011
Hilton Washington Embassy Row, Washington, DC, USA

Registration Fees  If DIA cannot verify your membership, 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.

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<th>Member Early-bird Opportunity</th>
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**Member Fee**

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

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee  US $1680

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.

- I want to be a DIA member
- I do NOT want to be a DIA member

Discount Fees

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

**GROUP DISCOUNTS** Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and pay for 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.

- Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.

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

- CREDIT CARD number may be faxed to: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.
- 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 USD dollars. Your name and company, as well as the Event ID, must be included on the transfer document to ensure payment to your account.

**TRAVEL AND HOTEL** The most convenient airport is Ronald Reagan Washington National Airport and attendees should make airline reservations as early as possible. The Hilton Washington Embassy Row Hotel is holding a block of rooms at the reduced rate below until March 4, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

| Single $239 | Double $259 |

Attendees must make their own hotel reservations. Contact the Hilton Washington Embassy Row Hotel by telephone at +1.800.695.7460 and mention the DIA event. The hotel is located at 2015 Massachusetts Avenue, NW, Washington, DC 20036 USA.

**CANCELLATION POLICY:** On or before MARCH 28, 2011

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 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 canceling 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.

**EVENT INFORMATION**
Contact Ellen Diegel, Program Manager, Phone +1.215.293.5810
Fax +1.214.442.6199, email ellen.diegel@diahome.org

Please check the applicable category:

- □ Academy
- □ Government
- □ Industry
- □ CSO
- □ Student
（Call for registration information）

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