DIA/FDA CDER/CBER Computational Science Annual Meeting

March 22-23, 2010
Bethesda North Marriott, Bethesda, MD, USA

PROGRAM CO-CHAIRPERSONS

Charles Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

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CDER, FDA

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Associate Director for Statistical Science and Policy
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Pharmacometrics Team Leader, CDER, FDA

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FDA Forum to Promote Progress in Computational Science from Regulatory and Product Development Perspectives

One of the most important and unrecognized issues contributing to drug development and regulatory productivity and quality is the ability to acquire, store, analyze, share and report information needed to make the most informed and rapid decisions in pharmaceutical companies, contract research organizations, and international regulatory agencies. This meeting will review progress on topics such as data standards, best practices-driven analytical tool development, business processes driving information systems development, and user experience/evaluation of current tools.

Highlights

- Breakout Sessions:
  - Nonclinical preapproval
  - Clinical preapproval
  - Postmarket safety
  - Product quality
  - Data quality
- Formation of ongoing Working Groups to address computational science issues and solutions from the Breakout Sessions
- Poster Presentations
- Interactive Exhibit Hall
- Software Showcase and Demonstrations: SDTM Validation Tool Demo- please refer to the Exhibitor Summary to identify which companies are participating in this demonstration

continued

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Featured Topics

- Quality metrics and cases regarding data submission quality
- Processes and tools designed to assure adequate data quality supporting a successful review
- Specifications for new tools
- Effectiveness of current tools
- Need-driven levels of tool training
- Impact of processes and tools on problem-solving quality, efficiency, and cost
- Regulatory data submissions that are efficiently loaded into the JANUS warehouse
- FDA and sponsor needs and plans
- Development of a bioinformatics FDA platform enabling electronic regulatory review of routine submissions and emerging safety and product quality concerns

Who Should Attend

- Physicians
- Biostatisticians
- Epidemiologists
- Clinical pharmacologists
- Data management professionals
- Information technology professionals
- Pharmaceutical industry (preclinical, premarket, postmarket development, regulatory, IT) professionals
- Contract research organizations

CONTINUING EDUCATION

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Drug Information Association designates this activity for up 13.25 contact hours or 1.325 CEUs. 286-000-10-005-L04-P

Type of Activity*: Knowledge*

To receive a statement of credit, participants must attend the program and complete the online 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. Complete details and instructions for accessing My Transcript will be included in the final program.

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.

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

- Assess progress in data standards development and implementation between regulators and regulated industries
- Describe best practices for developing data submissions to facilitate effective and efficient regulatory review
- Outline the needs and proposed specification for new tools and solutions
- Explain best practice (process, tools) implementation experiences and the subsequent impact on organizational performance

Call for Poster Abstracts

Suggested Poster Abstract Topics

- Data submission standards development, implementation, and best practices
- User experience/evaluation of current processes and tools and the subsequent impact on organizational performance
- Needs and specifications for proposed new tools and processes
- Business processes driving information systems development
- Impact of processes and tools on problem solving quality, efficiency, and cost

Poster Abstract Submission Guidelines

Please submit all poster abstracts using the online form at:

http://www.diahome.org/DIAHOME/GetInvolved/AbstractSubmissionLauncher.aspx

All abstracts must be received by **March 1, 2010.**

Authors of selected abstracts will be notified by **March 8, 2010.**

General Submission Requirements

(Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.)

1. All poster presentations must be noncommercial and scientific in nature and may not be used as a marketing opportunity. Mention of drug products must be limited to generic names, with no inclusion of brand names in any area of the poster, including poster titles and handouts. Logos and advertising may not appear anywhere on the poster.
2. Please provide the following information on the website abstract form:
   - Author Information: Name, Degrees, Job Title, Affiliation, Mailing Address, Phone Number, Fax Number, eMail
   - Primary Topic Area
3. Submitted abstracts must include the following sections:
   - Abstract Title (250 characters)
   - Abstract Objective (300 characters)
   - Abstract Method (300 characters)
   - Abstract Results (300 characters)
   - Abstract Conclusion (300 characters)
4. If an abstract is accepted, one author or coauthor must attend the meeting to present the poster.
5. Preference will be given to submitted abstracts that address real-life applications and case studies.
6. Poster boards are four feet high and eight feet wide (4'x8').

DISCLOSURE INFORMATION

All speakers must disclose any significant financial interest or other relationship with the manufacturer(s) of any commercial product(s) and/or providers of commercial services discussed in an educational presentation, as well as any discussion of unlabeled or unapproved drugs or devices.

At the time of electronic submission of abstracts, all speakers must complete the speaker disclosure section of the electronic submission form.

For further information, contact
Benjamin Zaitz, Program Manager
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email Benjamin.Zaitz@diahome.org

Showcase Your Products or Services to Key Decision Makers

Exhibit Hall Hours

Monday, March 22	9:00 AM-7:00 PM
Networking Reception	*5:00-7:00 PM*
Tuesday, March 23	9:00 AM-3:45 PM

Coffee breaks, lunch, and the reception will be held in the Exhibit Hall.

Exhibitors (as of March 4, 2010)

Applied Clinical Trials
Business & Decision Life Sciences
CDISC
Distributed Compliance Solutions
Integrated Clinical Systems, Inc.
Kestrel Consultants, Inc.
Kforce Clinical Research
MaxisIT, Inc.
Octagon Research Solutions, Inc,
OpenCDISC
Phase Forward
RPS, Inc.
Society for Clinical Data Management

For additional information, contact **Shannon Lewis**, Exhibits Associate
Phone **+1.215.442.6149** • Fax **+1.215.442.6199** • eMail **shannon.lewis@diahome.org**

SUNDAY, MARCH 21, 2010

4:00-6:00 PM REGISTRATION AND EXHIBIT HALL SET-UP

DAY 1 | MONDAY, MARCH 22, 2010

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

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

8:30-10:00 AM PLENARY SESSION 1

The Current State: Description of Current State, Defining the Gap, 3-year Plans

CHAIRPERSON

ShaAvhree Buckman, MD, PhD, FAAP
Director, Office of Translational Sciences, CDER, FDA

Introduction
ShaAvhree Buckman, MD, PhD, FAAP
Director
Office of Translational Sciences
CDER, FDA

CBER Needs and Plans
Karen Midthun, MD
CBER, FDA

CDER Needs and Plans
Janet Woodcock, MD
Center Director
CDER, FDA

10:00-10:30AM REFRESHMENT BREAK AND EXHIBITS

10:30 AM-12:00 PM PLENARY SESSION 2

Keynote Presentations

NCI caBIG Scope, Plans and Impact
Ken Buetow, PhD
Associate Director for Bioinformatics and Information Technology
National Cancer Institute, NIH

BTRIS: NIH Biomedical Translational Research Information System
James Cimino, MD
Chief, Laboratory for Informatics Development, NIH

Panel Discussion
All Session Speakers

12:00-1:00 PM LUNCHEON AND EXHIBITS

1:00-2:30 PM PLENARY SESSION 3

Data Standards: Working on the Vision and Taking the Next Steps

CHAIRPERSON

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

Data standards are the foundation of almost everything we are trying to do to improve drug development and review. They are needed for the science, the tools, healthcare, and review. To "get there," to have the standards that we need and will use, we must think about current requirements for review, plan the next steps, use what we have developed and figure out how to continuously improve. This session will bring together representatives from CDER, industry, the vendor community and the data standards organizations to understand what we need to do and how we can collaborate to get the standards that we need, the standards we will use.

Developing a CDER/CSC Data Standards PlanPresenters
Theresa Mullin, PhD
Director
Office of Planning and Informatics
CDER, FDA

Data Stewardship and the Art and Science of Explaining Standards So That Everyone Gets It
Frank W. Rockhold, PhD
Senior Vice President
Global Clinical Safety and Pharmacovigilance
GlaxoSmithKline

Planning the Clinical Research Program with Your Submission in Mind
Rebecca D. Kush, PhD
President and CEO
CDISC

Panel Discussion
All Session Speakers and
Stephen Bamford
President, Pharmaceutical Users Software Exchange
Charles Cooper, MD
Medical Officer, Office of Translational Sciences
CDER, FDA
Eric S. Herbel
President
Integrated Clinical Systems, Inc.

Charles Jaffe, MD, PhD
CEO, Health Level 7 International

Gary Walker
Associate Director, Enterprise Data Standards
Quintiles Transnational Corp.

2:30-3:00 PM **REFRESHMENT BREAK AND EXHIBITS**

3:00-4:50 PM **PLENARY SESSION 4**

Learning from the NCI caBIG® Experience

CHAIRPERSON

Ram Tiwari, PhD
Associate Director for Statistical Science and Policy, CDER, FDA

The National Cancer Institute initiated its Cancer Biomedical Informatics Grid (caBIG®) program in 2004 as a bold initiative to create "a virtual web of interconnected data, individuals, and organizations that redefines how research is conducted, care is provided, and patients/participants interact with the biomedical enterprise." NCI recognized that the ability to connect people, organizations, and data through information technology would be critical to fulfilling NCI's mission and to taking advantage of the research opportunities offered by 21st century science. Two years into its enterprise phase, this session seeks to take one of the several domain areas of caBIG®, that of clinical trials, and present some concrete achievements, including a demonstration of working software created according to the caBIG architecture, as well as to highlight some lessons learned along the way.

John Speakman, MS
Associate Director for Bioinformatics and Information Technology
National Cancer Institute, NIH

William T. Dyer, Jr.
caBIG® Clinical Trials Management Systems Representative
National Cancer Institute, NIH

Edward D. Helton, PhD, MA
Associate Director
Center for Biomedical Informatics and Information Technology
National Cancer Institute, NIH

Panel Discussion
All Session Speakers and

Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products
CDER, FDA

Robert T. O'Neill, PhD
Director, Office of Biostatistics
CDER, FDA

Christoffer Wenzel Tornoe, PhD
Pharmacometrics Team Leader
CDER, FDA

Tarek A. Hammad, MD, PhD, MSc, MS
Associate Director of Epidemiology
Division of Epidemiology, Office of Surveillance and Epidemiology
CDER, FDA

Amy Abernethy, MD
Associate Director, Duke Comprehensive Cancer Center
Associate Professor of Medicine, Division of Medical Oncology
Director, Duke Cancer Care Research Program, Duke University

4:50-5:00 PM **SUMMARY AND CLOSE OF DAY 1**

5:00-7:00 PM **NETWORKING RECEPTION AND EXHIBITS**

DAY 2 | TUESDAY, MARCH 23, 2010

7:30-8:15 AM **REGISTRATION**

8:15-9:45 PM **PLENARY SESSION 5**

Janus: Moving Forward and Planning for Transition

CHAIRPERSON

Edward D. Helton, PhD, MA
Associate Director, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH

The Janus study data repository is being developed by FDA and the National Cancer Institute (NCI) through an Interagency Oncology Task Force (IOTF) to enable the two organizations to share knowledge and resources to facilitate the development of new drugs and speed their delivery to patients. The Janus data repository is part of a larger effort to implement a common, standards-based electronic infrastructure that supports the submission, validation, data warehousing, access, and analysis of clinical and non-clinical study data. This session will cover technical, planning, and policy aspects of the effort to develop Janus. It will also describe current experiences with Janus at NCTR.

Technical Aspects of the Janus 2.0 Data Model
Clyde Ulmer
National Center for Toxicological Research (NCTR), FDA

DA Planning and Policy Aspects of Janus 2.0 Adoption
Lilliam Rosario, PhD
Associate Director
Office of the Chief Scientist
FDA

Using Janus Server Technology to Improve Public Health
Edward D. Helton, PhD, MA
Associate Director
Center for Biomedical Informatics and Information Technology
National Cancer Institute, NIH

Christo Andonyadis
Associate Director, Clinical Trials Application Engineering
NCI, NIH

Panel Discussion
All Session Speakers and

Jonathan G. Levine, PhD
Senior Scientist
OC/OCPP, FDA

B. Sue Bell, PhD
Director, CDER Computational Science Center
CDER, FDA

Wayne Kubick
Vice President
PhaseForward, Inc.

9:45-10:15 AM **REFRESHMENT BREAK AND EXHIBITS**

10:15 AM-12:15 PM SESSION 6: BREAKOUT SESSIONS

In both CDER and CBER the Computational Sciences associated with regulatory activities cover a wide range of programmatic needs. This session, employing five, parallel "breakouts," will provide participants with the opportunity to "drill down" and think hard about a specific set of topics, to specialize their thoughts in the activities, requirements, standards and tools needed to support pre-approval (both non-clinical and clinical) post-market safety assessment, product quality or data quality. It is hoped that these breakouts will form the nuclei to for working groups that will continue to collaboratively think about and work on issues and solutions associated with the computational sciences needed for these interest areas.

BREAKOUT SESSION 1
Preapproval – Nonclinical

CHAIRPERSONS

Lilliam Rosario, PhD
Associate Director, Office of the Chief Scientist, FDA

Lauren Murphree Mihalcik, PhD
Pharmacologist, Division of Metabolism and Endocrinology, CDER, FDA

This session will provide a current state of affairs for the review of pharmacology/toxicology information in support of premarket regulatory review of drugs and biologics. The session will provide a forum to share progress on ongoing initiatives including data standards development for animal toxicology data and tool development. The forum will be open to discuss steps forward to address the identified gaps in the current state and identify best practices for proposed tools and solutions.

Current State of Affairs: A Day in the Life of a PT Reviewer - The CDER Perspective
Paul Brown, PhD
Associate Director, Pharmacology and Toxicology, CDER, FDA

Current State of Affairs: A Day in the Life of a PT Reviewer – The CBER Perspective
Steve Kunder, PhD, DABT
Pharmacologist, Office of Vaccine Research and Review, CBER, FDA

Current Initiatives: SEND and ToxVision
Lou Ann Kramer
Eli Lilly and Company
Lauren Murphree Mihalcik, PhD
Pharmacologist, Division of Metabolism and Endocrinology, CDER, FDA
Shree Nath, PhD
VP, Pharmaceuticals, PointCross, Inc.

Future State of Affairs: JANUS - Initiative to Improve FDA's Management of Standardized Structured Scientific Data
Lilliam Rosario, PhD
Associate Director, Office of the Chief Scientist, FDA

Future State of Affairs: A Vision for a Day in the Life of a Reviewer
Tim Kropp, PhD
Toxicologist, Office of Oncology Drug Products, FDA

Panel Discussion
All Session Speakers and

Ron Wange
Pharmacologist, Division of Metabolism and Endocrinology Products, CDER, FDA

Theresa Allio
Pharmacologist, Division of Anti-Infective and Ophthalmology Products, CDER, FDA

Keith Peden
Microbiologist, Laboratory of Retroviruses, CBER, FDA

BREAKOUT SESSION 2
Preapproval – Clinical

CHAIRPERSON

Ghanshyam Gupta, PhD
Chief, Therapeutics Evaluation Branch
Office of Biostatistics and Epidemiology
CBER, FDA

This session will address the future informatics review state and the use of standardized data to improve the drug review process at both CBER and CDER. Conversion of legacy data for vaccine trials will be discussed, and a case study of the SDTM Vaccine Data Submission Pilot will also be presented.

The Future Desired Informatics Review State and Plans to Get There
Charles Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

SDTM Pilot Submission: A Clinical Reviewer's Perspective
Hon Sum Ko, MD
CBER, FDA

CBER's SDTM Business Process and Implementation Plans
Amy Malla
Review Management, Office of the Director, CBER, FDA

Converting Legacy Data for Vaccine Trials
Jingyee Kou, PhD
Mathematical Statistician (Biomed), Vaccine Evaluation Branch, CBER, FDA

An SDTM Vaccine Data Submission Pilot: A Case Study
Richard C. Lowry, PhD
Manager, Scientific Programming – Vaccines, Merck & Co., Inc.

Panel Discussion
All Session Speakers

Breakout Sessions continue on page 6

10:15 AM-12:15 PM SESSION 6: BREAKOUT SESSIONS *continued*

BREAKOUT SESSION 3
Postmarket Safety

CHAIRPERSON

Tarek A. Hammad, MD, PhD, MSc, MS
Associate Director of Epidemiology, Division of Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

This session focuses on scientific issues pertinent to CDER/CBER postmarketing safety data. Stakeholders that are represented include FDA, industry, and academia. Presenters will address the needs, challenges, and solutions for three major aspects of handling postmarketing safety data: data efficiencies (storing, retrieving, achieving, and sharing), analytic approaches (tools and solutions for signal detection and signal strengthening/verification), and oversight of postmarketing inspections and data verification.

Data Efficiencies and Analytic Approaches for Post-market Safety: An Introduction
Tarek A. Hammad, MD, PhD, MSc, MS
Associate Director of Epidemiology, Division of Epidemiology, Office of Surveillance and Epidemiology
CDER, FDA

Signal Detection for Product Safety: A Biomedical Informatics Challenge
Eric Brinsfield, MS
Director Health and Life Science Solutions
SAS Research and Development
Chris Diering
Technical Architect Health and Life Sciences
SAS Research and Development

A New Method for Signal Detection with Application to AERS Data
Ram Tiwari, PhD
Associate Director for Statistical Science and Policy, CDER, FDA

A Pattern Recognition Framework for Signal Identification
Marianthi Markatou, MSc, PhD
Affiliate Professor of Biomedical Informatics, Columbia University
Former Scientific Advisor for CBER, FDA

FDA's Sentinel Initiative
Judith A. Racoosin, MD, MPH
Sentinel Initiative Scientific Lead
OC, FDA

Computational Science Needs for an Active Surveillance System: Lessons from the Observational Medical Outcomes Partnership (OMOP)
Christian Reich, MD, PhD
Project Manager IT
Observational Medical Outcomes Partnership
Foundation of the National Institutes of Health

ADE Reporting and FDA/CDER's Inspection Program
Gregg Claycamp
Director, Division of Compliance
CDER, FDA

Panel Discussion
All Session Speakers plus Panel Discussion Lead:
Jeremy Rassen, ScD
Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham & Women's Hospital, Harvard Medical School

BREAKOUT SESSION 4
Product Quality

CHAIRPERSON

Arzu Selen, PhD
Associate Director, Biopharmaceutics, Office of New Drug Quality Assessment, CDER, FDA

Product quality efforts are rapidly advancing, and highlighting the need for state-of-the art computational tools and technologies. The existing research and review oriented computational tools in the Office of Pharmaceutical Science display a wide range with respect to data handling and function. Implementation of new initiatives such as Quality-by-design emphasizes the need for greater access to data, sharing of knowledge and tools capable of linking data from multiple sources to enable rapid risk assessment.

In this forward-looking session, as we evaluate available computational tools and how they can be better utilized, additional computational tools suitable for molecular modeling, *in vitro* and *in silico* predictive modeling, simulation techniques and data mining will be explored. A platform/knowledgebase suitable for data storage and data analyses as described above, coupled with access to computational expertise and tools, will facilitate rapid, broad, and in-depth understanding of product quality data, enhance science- and risk-based decision making capabilities, support training, and knowledge transfer and sharing. The speakers, panel, and participants in the breakout session will review the current state and explore the future opportunities for product quality computational tools and technologies.

Session and Speaker Introduction
Christine Moore, PhD
Acting Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

Database and Computational Needs in the Office of Biotechnology Products
Steven Kozlowski, MD
Director, Office of Biotechnology Products, CDER, FDA

Simulations and Modeling in Product Quality Research
Mansoor Khan, PhD
Director, Division of Product Quality Research, OTR, OPS, CDER, FDA

Product Quality Informatics in Generic Drug Review
Robert Lionberger, PhD
Chemist, Office of Generic Drugs, CDER, FDA

Current Product Quality Computational Tools in the Office of New Drug Quality Assessment
Norman R. Schmuff, PhD
Chemist, Office of New Drug Quality Assessment, CDER, FDA

Panel Discussion

Exploring Evolving Tools and Approaches for Product Quality
Derek Lindsay, PhD
Director of Innovation, Britest Limited
Karen Moe
Program Manager
NASA Advanced Information Research Program

Panel Discussion
All Session Speakers and
Thomas Colatsky, PhD
Director, Division of Applied Pharmacology Research, CDER, FDA
John Kauffman, PhD
Research Chemist and Spectroscopy Team Leader at the FDA Division of Pharmaceutical Analysis
Luis G. Valerio, Jr., PhD
Toxicologist, Office of Pharmaceutical Science, FDA

Summary of Product Quality Track
Arzu Selen, PhD
Associate Director, Biopharmaceutics, Office of New Drug Quality Assessment, CDER, FDA
Helen Winkle, PhD
Director, Office of Pharmaceuticals, CDER, FDA

BREAKOUT SESSION 5
Data Quality

CHAIRPERSON

Leslie K. Ball, MD
Director, Division of Scientific Investigations
Office of Compliance
CDER, FDA

FDA decisions on drug approval depend on high-quality data from clinical trials. Validating and ensuring data quality begins upstream in the clinical trial process, while the study is ongoing so errors can be corrected in real time. These upstream assessments of data quality include monitoring of site data by sponsors or contract research organizations and auditing by quality assurance units. After the clinical trial is completed and a new drug application is submitted, the FDA uses inspections of clinical trial sites as an important method to assess data quality. Ensuring data quality both during and after clinical trials is necessarily risk-based due to limited resources. Advancements in computational methods have the potential to improve clinical trial data quality by the systematic assessment of risks to data quality and risk-based allocation of quality resources. This session will present innovative methods developed by government agencies (NIH, FDA), contract research organizations, and sponsors for detecting irregularities and patterns that signal risks to data quality and public health.

NIH/NCI Perspective: Real-time Monitoring of Clinical Trial Data
Edward D. Helton, PhD, MA
Associate Director, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH

Contract Research Organization: Central Statistical Monitoring and Triggered Approach to Site Monitoring
Badhri N. Srinivasan
Vice President, Enterprise Transformation Unit, Quintiles Inc.

Use of Electronic Health Records and Electronic Data Capture for Real Time Monitoring
Dave Iberson-Hurst
VP of Technical Strategy, CDISC

Sponsor Perspective: Innovative Tools for QA Auditing
Peter J. Schiemann, PhD
Global Head Quality Risk Management, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland
C. Grant Simmons
Global Head, CQA Operations, Novartis Pharmaceuticals Corporation

Regulator Perspective: CDER Risk Model for Inspection Site Selection
Tom Moreno
Office of Compliance/DSI, CDER, FDA
Faiad Rahaman
Office of Compliance/DCRMS, CDER, FDA

Panel Discussion
All speakers above and
Lisa Kammerman, PhD
Mathematical Statistician, Office of Biostatistics
CDER, FDA

12:15-1:15 PM LUNCHEON AND EXHIBITS

1:15-2:25 PM SESSION 6 BREAKOUT SESSIONS *continued*

2:25-3:15 PM SESSION 7

Summary of Breakout Sessions

CHAIRPERSONS

Gary M. Gensinger
Deputy Director, Office of Business Process Support, CDER, FDA
Robert Powell, PharmD
Scientific Advisor, Roche Shanghai

Each group will offer a 10-minute presentation to summarize the discussion points of their breakout session.

3:15-3:45 PM REFRESHMENT BREAK AND EXHIBITS

3:45-4:30 PM SESSION 8

Collaborative Environments for Statistical Methodology Development – The Wiki Way

CHAIRPERSON

Mat Soukup, PhD
Mathematical Statistician, Division of Biometrics III, CDER, FDA

Specialized analytical tools are essential for statistical and graphical computing. Software packages come with standard statistical and graphical capabilities, but development of analytical and graphical methods for cutting-edge approaches tailored to clinical trial research often take years to implement. In order to implement advanced statistical methodologies, statisticians have to write and customize their own computer codes to execute these specialized data analyses. Under such a paradigm most of these user-created functions are not validated nor shared with statistical colleagues making such a paradigm inefficient in terms of implementing the latest statistical methods in a production environment.

In this session, our speakers will present a new environment that allows for collaborative development of specialized analytical tools based on the "wiki" concept. A "wiki" is a website that uses wiki software, allowing easy creation and editing of any number of interlinked Web pages, using a simplified markup language. The use of wiki will allow a community of users (eg, the regulatory agency, academia, and industry) to create, edit, and potentially validate program codes that can be used in the entire life cycle of drug development. A demo of the wiki will be presented along with a presentation of the evolution of the wiki and its advantages for use in clinical trial research.

The Use of Collaborative Environments - Where We Are Today and Where We Want to Be in the Future
Mat Soukup, PhD
Mathematical Statistician, Division of Biometrics III, CDER, FDA

The Use of CTSpedia: Revisiting the Past to Designing it for the Future
Laurel A. Beckett, PhD
University of California, Davis

4:30-5:00 PM SUMMARY AND NEXT STEPS

5:00 PM CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

DIA/FDA CDER/CBER Computational Science Annual Meeting

Event #10014 • March 22-23, 2010

Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, USA

Contact Information

Event Information: Contact **Benjamin Zaitz** at the DIA office by telephone +1.215.293.5803, fax +1.215.293.5937 or email Benjamin.Zaitz@diahome.org.

Exhibits Information: Contact **Shannon Lewis** at the DIA office by telephone +1.215.442.6149, fax +1.215.442.6199 or email Shannon.Lewis@diahome.org.

Registration Fees

Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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❑ **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.

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.

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan Washington National Airport and attendees should make airline reservations as early as possible to ensure availability. The Bethesda North Marriott Hotel and Conference Center is holding a block of rooms at the reduced rate below until February 28, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $226 **Double $226**

Please contact the Bethesda North Marriott Hotel and Conference Center by telephone at +1.800.228.9290 or +1.301.822.9200 and mention the DIA event. The hotel is located at 5701 Marinelli Road, Bethesda, MD, 20852, USA.

CANCELLATION POLICY: On or before MARCH 15, 2010

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.

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**