Due Date for Poster Abstract Submissions EXTENDED TO FEB. 14, 2011

See page 8 for submission guidelines.

DIA/FDA CDER/CBER Computational Science Annual Meeting

March 14-15, 2011

Sheraton National Hotel | Arlington, VA, USA

PROGRAM 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

PROGRAM COMMITTEE

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

Jingyee Kou, PhD
Mathematical Statistician (Biomed), Vaccine Evaluation Branch, CBER, FDA

Patricia Koussis, RN, CMRP
Coordinator, CDER Computational Science Center, FDA

Timothy Kropp, PhD
Toxicologist, Office of Oncology Drug Products, CDER, FDA

Amy Malla, MT(ASCP), CQA, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

Susan McCune, MD
Deputy Director, Office of Translational Sciences, CDER, FDA

Thomas Moreno
Project Management Officer, Division of Scientific Investigations, CDER, FDA

Armando Oliva, MD
Senior Biomedical Informatics Advisor
CDER Computational Science Center

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

WHO SHOULD ATTEND

- Physicians, biostatisticians, epidemiologists, clinical pharmacologists, and other drug development and review scientists
- Professionals involved in data management, programming, information management, and software tool design who work in environments where drugs and biological products are studied, developed, and regulated
- Pharmaceutical industry professionals (nonclinical, pre-market, post-market development, IT)
- Contract research organizations
- Government organizations (FDA, NIH)
- Information management and bioinformatics companies
- Academics
- Toxicologists

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200, Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

Review Progress on Data Standards, Comparative Effectiveness Research, and Tools that Support Analysis and Collaboration.

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. This annual meeting will have an FDA-centric focus on the current needs and implementation plans to help the broader community both align and share knowledge/tools to advance Computational Science.

FEATURED TOPICS

Regulatory submissions

- Share quality metrics and case studies regarding data submission quality
- Discuss, recommend and evaluate process and tools designed to assure adequate data quality supporting a successful review

Tool development and evaluation

- Discuss the need and propose specifications for new tools
- Provide a forum for new tools to be introduced

Impact

- Promote regulatory data submissions using standardized data
- Promote development of a bioinformatics FDA platform enabling electronic regulatory review of routine submissions and emerging safety and product quality concerns
- Promote the ability to learn from prior knowledge and apply this learning to improving the quality and productivity of both product development and regulation

SPECIAL BREAKOUT SESSIONS

In addition to the featured meeting topics, breakout sessions will drill down and explore the requirements, standards, tools, and activities needed to support specific aspects of drug development. These breakout sessions will form the foundation for working groups that can collaborate to discuss issues on and find solutions to challenges in:

- Clinical Data
- Comparative Effectiveness Research
- Post-market Data
- Community Repository of Program Code
- Electronic Case Report Forms and Data Standards
- Nonclinical Data

EXHIBIT OPPORTUNITY AVAILABLE

Contact **Jeff Korn**, Exhibits Associate | Phone +1.215.442.6184
Fax +1.215.293.5924 | email: Jeff.Korn@diahome.org

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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 CEU for this program.

If you would like to receive a statement of credit, you must attend the program, scan your name badge at each session you attend, 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 **March 29, 2011.**

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 progress on data standards development and implementation between regulators and regulated industries; • Discuss best practices for developing data submissions to facilitate effective and efficient regulatory review; • Discuss the needs and proposed specification for new tools and solutions

SUMMARY OF BREAKOUT SESSIONS

MONDAY, MARCH 14, 2011 | **1:00-2:45 PM BREAKOUT SESSION 1**			
TRACK 1: Clinical: Submission and Management of Clinical Data in Electronic Standard Format	TRACK 2: Overview of CER	TRACK 3: Post-market Safety	TRACK 4: Collaboration: Not Just a Buzz Word Anymore
MONDAY, MARCH 14, 2011 | 3:15-5:00 PM BREAKOUT SESSION 2			
TRACK 1: Clinical: Submission and Management of Clinical Data in Electronic Standard Format	TRACK 2: FDA Partnership in Applied Comparative Effectiveness Science (PACES) and Comparative Effectiveness Research	TRACK 3: Post-Market Safety	TRACK 4: Submission and Management of Nonclinical Study Data in Electronic Standard Format
TUESDAY, MARCH 15, 2011 | 8:30-10:15 AM BREAKOUT SESSION 3			
Track 1: Clinical: Submission and Management of Clinical Data in Electronic Standard Format	Track 2: Developing Disease Specific Data Standards	TRACK 3: Post-Market Safety	TRACK 4: Review Process and Capabilities Using Nonclinical Study Data in Electronic Standard Format

SUNDAY | MARCH 13, 2011

3:00 PM EXHIBITOR SET UP

3:00-6:00 PM REGISTRATION

MONDAY | MARCH 14, 2011

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

8:30-10:00 AM PLENARY SESSION 1

Welcome and Keynote Addresses

PROGRAM 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

- **Keynote Address: CDER Perspective**

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

- **Keynote Address: CBER Perspective**

  Mark O. Walderhaug, PhD
  Associate Office Director for Risk Assessment, CBER, FDA

- **Keynote Address: NIH Perspective**

  Ken Buetow, PhD
  Associate Director for Bioinformatics and Information Technology, National Cancer Institute, NIH

10:00-10:30 AM REFRESHMENT BREAK

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

Computational Science: A Changing Landscape

Session Chairperson:

Armando Oliva, MD
Senior Biomedical Informatics Advisor
CDER Computational Science Center, FDA

Computational Science in a regulatory environment continues to evolve quickly. This session will explore current and future trends in data standards and FDA's Sentinel Initiative.

CDISC SHARE: Improving the World of Standards Development
Dave Iberson-Hurst
Technical Architect, CDISC

An Update on the Collect Once, Reuse Many Times Paradigm and Other Data Standards Initiatives
Donald T. Mon, PhD
Vice President, Practice Leadership
American Health Information Management Association

Update on FDA's Sentinel Initiative
Judith A. Racoosin, MD, MPH
Sentinel Initiative Scientific Lead, Office of Medical Policy, CDER, FDA

12:00-1:00 PM LUNCHEON

BREAKOUT SESSIONS

Employing four, parallel breakout groups, participants will have 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 these various interest areas. All attendees are encouraged to participate in these interactive and discussion-driven breakout groups. It is hoped that these breakouts will form the nuclei 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

1:00-2:45 PM TRACK 1: CLINICAL

Submission and Management of Clinical Data in Electronic Standard Format

Session Chairpersons:

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

Amy Malla, MT(ASCP), CQA, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

The standardized clinical data affects the review processes by improving a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage and reporting of regulatory data. Improved data quality, accessibility and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions and address late-emerging issues. Standardized data will allow reviewers to increase review consistency and perform evaluations across the product lifecycle. These improvements will improve the Agency's performance across key regulatory functions and ongoing business operations. The Clinical session is designed to address the changes surrounding Business/Analytic needs, Standards Development activities, and Quality Control and Conformance Checking. In this session, both CDER and CBER will give their Center's perspective and update on defining business and analytic needs.

CDER Perspective and Update on Defining Business and Analytic Needs
Helena Sviglin, MPH
Regulatory Information Specialist, Office of Translational Sciences, CDER, FDA

CBER Perspective and Update on Defining Business and Analytic Needs
Amy Malla, MT(ASCP), CQA, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

1:00-2:45 PM TRACK 2

Overview of CER

Session Chairpersons:

Jingyee Kou, PhD
Mathematical Statistician (Biomed), Vaccine Evaluation Branch
CBER, FDA

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

This session will give an overview of the efforts of CER and describe the 4 main components in conducting CER: the clinical data, a repository to enable data analysis, the tools and the researchers.

Overview of CER
Lilliam Rosario, PhD
Associate Director, Office of the Chief Scientist
Office of the Commissioner

Data Standardization Efforts in Support of CER
Colleen Ratliffe, MS, PMP
Project Management Officer, Office of Business Informatics/ Computational Science Center, CDER, FDA

Janus as the Clinical Trial Repository in Support of CER
Bobbie Witczak, PMP
Project Manager, Office of Translational Science/Computational Science Center, CDER, FDA

Use of Modern Analytical Tools and Methods in CER
B. Sue Bell, PhD
Director, CDER Computational Science Center, Office of Translational Science/Computational Science Center, CDER, FDA

FDA Partnership in Applied Comparative Effectiveness Science (PACES) Initiative
Trang Gisler, MS, CCRP, PMP
Senior Project Manager/Project Officer, Office of the Chief Scientist, Office of the Commissioner, FDA

1:00-2:45 PM TRACK 3

Post-Market Safety

Session Chairperson:

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

There are many scientific challenges to effectively analyzing post-market data, especially in relation to extreme data complexity and size that result from (1) heterogeneous approaches for medical data generation and capture and (2) the inherently multi-scale nature of clinical science reflecting the interdependency between drug and/or biologic exposures, adverse event outcomes, and confounders. Further, the size and complexity of post-market data are increasing exponentially. These post-market sessions are designed to address the needs, challenges, and next steps surrounding major aspects of handling extreme-scale post-market safety data, which include high performance distributed computing, safety signal detection, evaluation and validation methods in large databases, and advances in data mining methodology of longitudinal data. This session will address some of the computational challenges in mining observational medical outcome data and will explore the value of a shared platform for storing, managing, and analyzing extreme-scale observational data.

Introduction

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

Computational Challenges in Mining Large Scale Observational Medical Outcome Data

Wael Abd-Almageed, PhD, MSc
Assistant Research Scientist, Institute for Advanced Computer Studies, University of Maryland

Utility of Shareable Distributed Mega-computing Platform for Storing, Managing, and Analyzing Extreme-scale Observational Data

Brian Fitzgerald
Supervisory General Engineer; Acting Director of the Division of Electrical and Software Engineering, Office of Science and Engineering Laboratories, CDRH, FDA

Session Participant:

Marian Callaham, MS
Operations Research Analyst, Office of Surveillance and Epidemiology, CDER, FDA

1:00-2:45 PM TRACK 4

Collaboration: Not Just a Buzz Word Anymore

Session Chairperson:

Mat Soukup, PhD
Acting Team Lead, Biometrics 7
CDER, FDA

Working towards a collaborative state and model have been presented and discussed at past meetings. In this session we will provide updates on several ongoing collaborative efforts which involve the industry, regulatory bodies, and academic centers. Speakers will present how the collaboration model has helped them achieve project goals along with lessons learned as the project has evolved. Additionally, speakers will discuss the IT platform being used for their respective efforts and how it plays a role in achieving the goals of the project.

The PhUSE Wiki Platform: Collaboration on Global Standards

Benjamin Szilagyi, MSc
Global Head, ED Statistical Programming
F. Hoffmann-La Roche Ltd., Switzerland

Wiki Keys to the Growth of a Collaborative Working Environment

Mary Banach, PhD, MPH
Program Manager CTSpedia
University of California, Davis

OpenCDISC: Building an Open Source Community of CDISC Developers and Users

Max Kanevsky, MS
Founder and President, OpenCDISC

2:45-3:15 PM REFRESHMENT BREAK

BREAKOUT SESSION 2

3:15-5:00 PM TRACK 1: CLINICAL

Submission and Management of Clinical Data in Electronic Standard Format

Session Chairpersons:

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

Amy Malla, MT(ASCP), CQA, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

The standardized clinical data affects the review processes by improving a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage and reporting of regulatory data. Improved data quality, accessibility and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions and address late-emerging issues. Standardized data will allow reviewers to increase review consistency and perform evaluations across the product lifecycle. These improvements will improve the Agency's performance across key regulatory functions and ongoing business operations. The Clinical session is designed to address the changes surrounding Business/Analytic needs, Standards Development activities, and Quality Control and Conformance Checking. In this session, the speakers will address the development of new data standards, including therapeutic domains and how to align CDISC with HL7 and will also discuss CDER/CBER strategies for standards development to address reviewer needs.

Development of New Domains and Aligning CDISC with HL7

Armando Oliva, MD
Senior Biomedical Informatics Advisor, CDER Computational Science Center, FDA

Strategies in CDER for Standards Development to Address Reviewer Needs

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

3:15-5:00 PM **TRACK 2**

FDA Partnership in Applied Comparative Effectiveness Science (PACES) and Comparative Effectiveness Research

Session Chairpersons:

Trang Gisler, MS, CCRP, PMP
Senior Project Manager/Project Officer
Office of the Chief Scientist, Office of the Commissioner, FDA

Jingyee Kou, PhD
Mathematical Statistician (Biomed), Vaccine Evaluation Branch
CBER, FDA

This session will provide overview of the FDA Partnership in Applied Comparative Effectiveness Science Initiative in support of comparative effectiveness evaluation. This session is designed to highlight some of the opportunities and challenges in conducting CER.

Partnership in Applied Comparative Effectiveness Science (PACES) Initiative
Jodi Segal, MD, MPH
Associate Professor of Medicine, Johns Hopkins University

A Methodological Framework for Comparative Effectiveness Research
Robert B. Giffin, PhD
Senior Research Director, Center for Medical Technology Policy

Evolving Data Sources for Comparative Effectiveness Research: Opportunities and Challenges
Clifford Goodman, PhD
Senior Vice President, The Lewin Group

Innovative Methods in Comparative Effectiveness Research
Rachael Fleurence, PhD
Executive Director, Comparative Effectiveness Research
United BioSource Corporation

3:15-5:00 PM **TRACK 3**

Post-Market Safety

Session Chairperson:

Ram Tiwari, PhD
Associate Director of Statistics, Office of Biostatistics, CDER, FDA

There are many scientific challenges to effectively analyzing post-market data, especially in relation to extreme data complexity and size that result from (1) heterogeneous approaches for medical data generation and capture and (2) the inherently multi-scale nature of clinical science reflecting the interdependency between drug and/or biologic exposures, adverse event outcomes, and confounders. Further, the size and complexity of post-market data are increasing exponentially. These post-market sessions are designed to address the needs, challenges, and next steps surrounding major aspects of handling extreme-scale post-market safety data, which include high performance distributed computing, safety signal detection, evaluation and validation methods in large databases, and advances in data mining methodology of longitudinal data. In this session, attendees will discuss active surveillance methods performance and challenges and the application of likelihood ratio test (LRT) to signal detection in AERS data.

Active Surveillance Methods Performance and Challenges: Lessons from the Observational Medical Outcomes Partnership
Patrick Ryan, MEng
Associate Director, Epidemiology, Johnson & Johnson

Application of Likelihood Ratio Test (LRT) to Signal Detection in AERS Data
Lan Huang, PhD
Mathematical Statistician, Office of Biostatistics, CDER, FDA

Session Participant:

Marian Callaham, MS
Operations Research Analyst, Office of Surveillance and Epidemiology, CDER, FDA

3:15-5:00 PM **TRACK 4**

Submission and Management of Nonclinical Study Data in Electronic Standard Format

Session Chairpersons:

Timothy Kropp, PhD
Toxicologist, Office of Oncology Drug Products, CDER, FDA

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

The landscape of nonclinical computational science is rapidly changing. The development and deployment of data standards, tools, and improved data management will be accelerating during 2011. This nonclinical session is designed to address the changes surrounding data management, submission, and communication. Emphasis will be on learning what all parties can do to sustain momentum in this area and effectively communicate with each other.

Nonclinical Data Initiatives Driving Change, Present, and Future: CRO Perspectives
Troy Smyrnios
Senior Information Technology Professional, MPI Research

Nonclinical Data Initiatives Driving Change, Present, and Future: Sponsor Perspectives
Susan DeHaven
Head, Global Applications and Information Management for Disposition, Safety and Animal Research, sanofi-aventis

Session Panelists:

Louis Norton, PhD
Enterprise Architect, Covance

William Houser, PE, PMP
Capability Manager, Bristol-Myers Squibb

Paul Brown, PhD
Associate Director for Pharmacology/Toxicology. Office of New Drugs, CDER, FDA

5:00 PM **DAY 1 CONCLUDES**

5:00-6:00 PM **NETWORKING RECEPTION IN EXHIBIT HALL**

TUESDAY | **MARCH 15, 2011**

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

BREAKOUT SESSION 3

8:30-10:15 AM TRACK 1: CLINICAL

Submission and Management of Clinical Data in Electronic Standard Format

Session Chairpersons:

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

Amy Malla, MT(ASCP), CQA, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

The standardized clinical data affects the review processes by improving a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage and reporting of regulatory data. Improved data quality, accessibility and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions and address late-emerging issues. Standardized data will allow reviewers to increase review consistency and perform evaluations across the product lifecycle. These improvements will improve the Agency's performance across key regulatory functions and ongoing business operations. The Clinical session is designed to address the changes surrounding Business/Analytic needs, Standards Development activities, and Quality Control and Conformance Checking. In this session, attendees will discuss the methods and approaches for validation of CDISC data checking, hear about CDER/CBER data validation activities, and learn more about the CDISC advisory board validation certification project.

Open Source Validation Tool for CDISC Data Checking

Max Kanevsky, MS
Founder and President, OpenCDISC

CDISC Advisory Board Validation Project

Trisha D. Simpson
Director, Global Biometry Standards, UCB

Session Panelist:

Marcelina Hungria
CDISC/SAS, Independent Data Submission Consulting Services

8:30-10:15 AM TRACK 2

Developing Disease-Specific Data Standards

Session Chairpersons:

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

Jingyee Kou, PhD
Mathematical Statistician (Biomed), Vaccine Evaluation Branch
CBER, FDA

Ranjit Thomas
Office of Planning & Informatics, Office of Planning & Analysis
CDER, FDA

Bron W. Kisler
CDISC Vice President, Strategic Initiatives

The March, 2010 draft of the CDER Data Standards Plan puts forth the bare bones of a collaborative process for developing "Disease-Specific Data Standards" – identifying and communicating priorities, engaging stakeholders, assessing controlled terminologies, identifying experts and publishing data elements. This is huge – a necessary, but very challenging effort that will require a large collaborative/scientific effort that will provide the terminological foundation for the information systems and productivity tools we need to improve the efficiency and quality of medical products development and regulatory decision processes. The work has begun. Many people are already devoting a great deal of their valuable time, effort and resources to develop these data standards (e.g., in tuberculosis, polycystic kidney disease, acute coronary syndrome, oncology, Alzheimer's disease, and Parkinson's disease). This session is intended to bring together these "players" and the organizations they represent – giving us the opportunity to examine how to "get it done" and "do it right."

Speakers:

Theresa M. Mullin, PhD
Associate Director, Office of Planning and Informatics
CDER, FDA

Chris Tolk
Director, Terminology
CDISC

Panelists:

Joshua S. Benner, PharmD, ScD
Research Director and Fellow
Engelberg Center for Health Care Reform
The Brookings Institution

Marc Cantillon, MD
Director of Coalition Against Major Disease (CAMD)

Petra Kaufmann, MD, MSc
Director of the Office of Clinical Research (OCR)
NIH/NINDS

Pierre-Yves Lastic, PhD
Senior Director
Data Privacy & Healthcare Interoperability Standards
Sanofi-aventis R&D

Myrl Weinberg, CAE
President, National Health Council

8:30-10:15 AM TRACK 3

Post-Market Safety

Session Chairperson:

Estelle Russek-Cohen, PhD
Deputy Division Director, CBER, FDA

There are many scientific challenges to effectively analyzing post market data, especially in relation to extreme data complexity and size that result from (1) heterogeneous approaches for medical data generation and capture and (2) the inherently multi-scale nature of clinical science reflecting the interdependency between drug and/or biologic exposures, adverse event outcomes, and confounders. Further, the size and complexity of post-market data are increasing exponentially. These post-market sessions are designed to address the needs, challenges, and next steps surrounding major aspects of handling extreme-scale post-market safety data, which include high performance distributed computing, safety signal detection, evaluation and validation methods in large databases, and advances in data mining methodology of longitudinal data. This session will address statistical methods for signal detection in longitudinal observational drug safety data and will offer some case-based methods for active surveillance.

Statistical Methods for Signal Detection in Longitudinal Observational Drug Safety Data

Ram Tiwari, PhD
Associate Director of Statistics, Office of Biostatistics, CDER, FDA

Case-based Methods for Active Surveillance

David Madigan, PhD
Professor, Columbia University

Session Participant:

Marian Callaham, MS
Operations Research Analyst, Office of Surveillance and Epidemiology, CDER, FDA

8:30-10:15 AM TRACK 4

Review Process and Capabilities Using Nonclinical Study Data in Electronic Standard Format

Session Chairpersons:

Timothy Kropp, PhD
Toxicologist, Office of Oncology Drug Products, CDER, FDA

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

The landscape of nonclinical computational science is rapidly changing. The development and deployment of data standards, tools, and improved data management will be accelerating during 2011. This nonclinical session is designed to address the changes surrounding nonclinical data review using currently available tools and addressing future capability needs. Emphasis will be finding where overlaps are among organizations for approaches and needs for capabilities and review processes to accelerate development of tools and databases.

Electronic Data Review, FDA:
What We Can Do Now and Where We Want To Go

Fred Alavi, PhD
Pharmacologist, Division of Metabolism and Endocrinology Products, CDER, FDA

Electronic Data Review, Industry:
What We Can Do Now and Where We Want To Go

Paul D. Cornwell, PhD, DABT
Senior Research Scientist, Eli Lilly and Company

Session Panelists:

Shree Nath, PhD
Vice President for Pharmaceutical Products, PointCross Inc.

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

Evi Struble, PhD
Pharmacologist, Office of Blood Research and Review CBER, FDA

10:15-10:45 PM REFRESHMENT BREAK

10:45 AM-12:30 PM NETWORKING AND POSTER SESSION WITH DEMOS (IN EXHIBIT HALL)

This interactive and open networking session will take place in the exhibit hall. Attendees are encouraged to visit the exhibitors and the poster presentations. The poster presenters will have an opportunity to give a live demonstration in support of their poster work.

12:30-1:30 PM LUNCHEON (POSTER WINNER WILL BE ANNOUNCED)

1:30-2:00 PM POSTER WINNER PRESENTATION

2:00-4:00 PM **PLENARY SESSION 3**

BREAKOUT SESSION REPORTING AND CLOSING

Session 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

Each breakout group will offer a presentation summarizing the discussion points of their breakout session.

4:00 PM **CONFERENCE ADJOURNED**

POSTER ABSTRACT SUBMISSION GUIDELINES

Please submit all poster abstracts using the online form at: www.diahome.org/DIAHOME/GetInvolved/AbstractSelectAMeeting.aspx
All abstracts must be received by **February 14, 2011. Abstracts will be reviewed and authors will be notified of results by February 28, 2011.**

Posters topics should describe innovative or creative ways to use new technology, methods, or approaches to improve data collection, assessment, analysis, or reporting of regulatory pharmaceutical science information/data.

Selected poster presenters are required to pay the applicable meeting registration fee and all related expenses. In addition, presenters must organize and pay for all shipping arrangements for their poster materials. DIA will not ship or store any materials. Posters will be presented during a dedicated session at the meeting. Presenters will be notified about the exact timing of the session once the agenda has been finalized.

Presenters will have the option to include a mini-demonstration along with their poster. This demonstration must be noncommercial and scientific in nature and may not be used as a marketing opportunity. Presenters must provide their own laptop computer for the demonstration. The mini-demonstration should be used to supplement and support the poster presentation. The mini-demonstration is optional and presenters are not required to include this with their poster presentation. A designated area will be set up for the mini-demonstration and each presenter will have a limited amount of time for their mini-demonstration.

The posters will be judged by the meeting organizers. The judging methods will be focused on identifying the posters which describe innovative or creative ways to use new technology, methods, or approaches to improve data collection, assessment, analysis, or reporting of regulatory pharmaceutical science information/data. The winner will be awarded an extra timeslot at the mini-demonstration area.

ONSITE REQUIREMENTS: Display boards are freestanding, with a surface that will allow push pins to secure the display. Presenters must prepare a poster to fit a 4'× 8' poster board (four feet high and eight feet wide). Presenters must prepare 25 copies of their poster abstract for distribution at the meeting.

ELIGIBILITY: Individuals eligible for Professional Posters include post-doctoral scholars, medical residents, fellows and professionals whose affiliation is consistent with the mission of DIA.

Specific instructions about abstract content and preparation can be found at
www.diahome.org/DIAHOME/GetInvolved/AbstractSelectAMeeting.aspx

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 #11014 • Workshop: March 14-15, 2011

Sheraton National Hotel, Arlington, VA, USA

Registration Fees

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

Industry Fee US $1295 ❑

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.

❑ **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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2. _____

3. _____

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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.

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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 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.

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible. The Sheraton National Hotel is holding a block of rooms at the reduced rate below until February 20, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $199 **Double $199**

Attendees must make their own hotel reservations. Contact the Sheraton National Hotel by telephone at +1.800.325.3535 and mention the DIA event. The hotel is located at 900 South Orme Street, Arlington, VA 22204, USA.

CANCELLATION POLICY: On or before MARCH 7, 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 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.

Contact Information

Event Information: Contact **Benjamin Zaitz, Program Manager** at the DIA office by telephone +1.215.293.5803 or fax +1.215.442.6199 or email Benjamin.Zaitz@diahome.org.

Exhibits Information: Contact **Jeff Korn, Exhibits Associate,** at the DIA office by telephone +1.215.442.6184 or email Jeff.Korn@diahome.org

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**