Today’s Experience and Tomorrow’s Expectations

1 - 5 November

Renaissance Harborplace Hotel

202 Pratt Street

Baltimore, MD 21202

USA

The CDISC Interchange is kindly sponsored by:

ORACLE

HEALTH SCIENCES
Dear Valued Interchange Participant:

We are very pleased to welcome you to the CDISC activities at the 2010 Interchange in Baltimore. We hope that you enjoy an exciting week, with the main conference on Wednesday and Thursday and CDISC educational courses across the rest of the week. We have three very special keynote speakers—Drs. Theresa Mullin (FDA), Raymond Woosley (Critical Path Institute) and Doug Fridsma (U.S. Office of the National Coordinator for Health Information Technology, HHS), who will be joined by a wealth of other excellent speakers who were recruited and/or selected based upon submitted abstracts. We would like to give a special thanks to the Program Committee for their diligence in organizing the program and to our Interchange Sponsors this year—HP, Oracle, SAS, Business & Decision & Percept Pharma Services—who have generously contributed to the success of this year’s CDISC Interchange.

Themes for the 2010 Interchange include standards implementations and looking beyond the traditional uses of standards towards:

- Accelerating medical research and development of new therapies through process improvement and workflow integration
- Standards-inspired innovation
- A focus on the Patient

And, of course, there will be a global perspective in keeping with the realm of clinical research.

This conference comes soon after an important Board meeting, where a new CDISC vision was created and endorsed through the work of the CDISC Board Strategy Committee over the past year. The Board and Operations have also been exploring new revenue streams to ensure sustainability of CDISC in the future. As we begin our 2011 planning cycle, we hope that you will all be a part of this process and continue to contribute to CDISC in any way that suits you. 2011 promises to be an interesting year for CDISC, with several new FDA projects, participation in the SHARP grant with Mayo Clinic and Intermountain Healthcare and the launch of SHARE with the National Cancer Institute. Learn more about these collaborations and others throughout the Interchange.

The CDISC Advisory Board (representatives of our Benefactors and Sponsors) will meet on 2 November to vote on their CDISC Board member and Board Committee members, after which they will spend two hours in discussions with FDA representatives. If your organization does not have a CDISC membership, please consider this opportunity to join. If your organization is already a member of CDISC, we very much appreciate your support.

So, please take advantage of the networking and learning this week. As always, we recognize that CDISC would not be possible without YOU.

Best regards,

Rebecca Kush, PhD, President and CEO
CDISC 2010 INTERCHANGE NORTH AMERICA

CONFERENCE-AT-A-GLANCE

MONDAY 1 NOVEMBER

09:00 - 17:00  SDTM Theory & Application Training Course
09:00 - 17:00  ODM Implementation Training Course
13:30 - 17:00  Introduction to BRIDG Training Course

TUESDAY 2 NOVEMBER

08:30 - 12:00  Introduction to Protocol Representation Training Course
09:00 - 17:00  SDTM Theory & Application Training Course (cont’d)
09:00 - 15:00  EHRs for Medical Research Course
10:30 - 14:00  CAB Meeting with FDA (Benefactor & Sponsor Companies Only by Invitation)
14:00 - 18:00  **New** CDISC: A Global Approach to Accelerating Medical Research Course

WEDNESDAY 3 NOVEMBER

08:30 - 18:00  Interchange Conference Presentations
07:30 - 18:30  Industry Exhibitors
18:30 - 20:30  Networking event at the Baltimore Science Museum

THURSDAY 4 NOVEMBER

08:30 - 17:30  Conference Presentations
07:30 - 15:30  Industry Exhibitors

FRIDAY 5 NOVEMBER

08:30 - 17:00  CDASH Implementation Course
08:30 - 17:00  ADaM Implementation Training Course
08:30 - 17:00  LAB Implementation Training Course
09:00 - 12:00  CDISC & HL7 Training Course
09:00 - 12:00  Legacy Data Conversion Workshop

Contents are subject to change.
Training 1: SDTM Theory & Application Course

The Study Data Tabulation Model (SDTM) is a specification in the FDA electronic Common Technical Document (eCTD) Guidance as the model for submitting clinical and preclinical data to the FDA in support of marketing applications. This two-day course consists of:

- A detailed review of SDTM concepts, SDTM domain models, and relationship tables
- A discussion of common implementation issues
- Exercises including CRF-annotations and creation of datasets that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide.

A basic understanding of relational database design is helpful but not required.

NB. If you have already taken the v3.1.1 course you may take this updated course. However as an alternative, you can take the 3.1.1 to 3.1.2 vLearning Course available via the CDISC website.

Training 2: ODM Implementation Course

The Operational Data Model (ODM) is a vendor-independent format used to store, interchange between data management systems, or archive study data, study metadata or administrative data associated with clinical trials. The ODM has been presented to the FDA as the standard for data archiving. This one-day course consists of the technical framework for ODM, an in-depth understanding of the model structure, an overview of the XSL and other tools for working with XML, and strategies for implementing ODM within your organization.

Training 3: Introduction to BRIDG Course

The BRIDG Model is a Domain Analysis Model (DAM) that is being developed through a collaborative effort of stakeholders from CDISC, the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI), and the US Food and Drug Administration (FDA). This half-day course will cover a brief history of BRIDG, a quick look at basic UML modeling and an introductory look at the BRIDG model.

Training 1: SDTM Theory & Application Course Continued

Training 4: Protocol Representation Course

The protocol is the key to any research study. It describes the plan for all stakeholders – project managers, investigators, CRCs, CRAs, regulatory affairs personnel, data managers, IRBs, statisticians, medical writers and even the study subjects! Re-use of protocol sections to streamline clinical research processes is not inherent in the current typical paper-based or Word document format. However, a new protocol representation model now provides the potential to facilitate a number of key research processes, such as a) population of clinicaltrials.gov or EudraCT or other clinical trial registries;
b) identification of potential study subjects in a database; c) automation of CRF development, visit scheduling and other innovative steps in the research process. This half-day course describes the rationale and genesis for the Protocol Representation Model V 1.0, which is a core part of the collaborative Biomedical Research Model (BRIDG) for protocol-driven research, defined in the broadest sense. Anyone who develops or uses research protocols should take this course.

09:00 - 15:00  Training 5: EHRs for Medical Research Course

CDISC's Healthcare Link initiative is now mainstream with the original Retrieve Form for Data Capture (RFD) Integration Profile now incorporated into a Health Information Technology (HITSP) interoperability specification, augmented by additional integration profiles and hooked into HL7's successful strategy of standardized clinical documents called template CDAs.

This course will focus on the following:
• CDISC interactions with health informatics standards organizations such as HL7 and IHE
• Requirements and scenarios for the use of eSource EHRs for medical research based upon the electronic Source Data Interchange Initiative (eSDI), an FDA collaboration and now referenced by EMA in documentation for auditors
• The RFD (Retrieve Form for Data Capture), an IHE (Integrating the Healthcare Enterprise) integration profile in use now to support various EHR-research related use cases

14:00 - 18:00  Training 6: CDISC: A Global Approach to Accelerating Medical Research Course

Are you involved with medical research? Are you frustrated by a lack integrated solutions that will improve your processes? Does the thought of promoting change within your organization fill you with dread? Are you having issues around data quality? Then CDISC could provide your answers.

The existing typical process for biomedical research is antiquated and crying out for real technological transformation. Glaring inefficiencies remain to which solutions will require the adoption and implementation of key enablers; these enablers include workflow integration, eSource and efficient exchange of information from site to study sponsor to reviewer (whether this be a regulatory authority, an IRB or DSMB, an academic institution, a clinician investigator or scientist, or another reviewer of research information). In addition, addressing unnecessary data quality issues hinders workflow speed and uses excessive and expensive resources.

The Clinical Data Interchange Standards Consortium (CDISC) has collaborated with numerous other organizations on a global basis to analyze research regulations and processes; through these collaborations and the work of thousands of volunteers worldwide over the past 14 years, a set of enablers that can recognizably accelerate the medical research process, from protocol through analysis and reporting has emerged.

This course outlines these enablers so that you can understand their benefits, can demonstrate how you can improve your data quality and can streamline workflow at investigative research sites and sponsoring organizations. This course also delivers relevant business information that demonstrates the real world value of CDISC. Anyone who is involved in medical research in any capacity, at any level, should take this course.
CAB Meeting with FDA (Benefactor & Sponsor Members Only by Invitation)

The CDISC Advisory Board (CAB) meeting will include a 2 hour ‘Town Hall’ with FDA Representatives: Amy Malla, Dr. Chuck Cooper, Dr. Armando Oliva and Gary Gensinger. CDISC Benefactors & Sponsors have a seat on the CAB and will be invited to attend this meeting. Anyone wishing to join CDISC or upgrade their membership to Benefactor or Sponsor level should contact: Shirley Williams, swilliams@cdisc.org

All CAB Members will also be invited to attend (with no registration charge) the new CDISC Course: A Global Approach to Accelerating Medical Research.

WEDNESDAY 3 NOVEMBER 2010

06:30 - 07:30  Exhibition Booth Set-Up
07:30 - 18:00  Exhibition Open
08:30 - 10:00  Session 1
Opening Plenary & Keynote Presentations
Chair: Rebecca Kush, CDISC

• Keynote
Enabling Meaningful Use: Developing Standards, Policies and Technologies for Secure Health Information Exchange

Doug Fridsma, M.D, Ph.D., Acting Director of the Office of Interoperability and Standards, Office of the National Coordinator for Health Information Technology

Dr. Fridsma completed his medical training at the University of Michigan in 1990, and his PhD in Biomedical Informatics from Stanford University in 2003. His research interests include the development of computational tools to study patient safety, clinical work processes, and methods to improve model-driven standards development processes. He has served on the Clinical Data Interchange Standards Consortium (CDISC) Board of Directors from 2005-2008, and was appointed to the HIT Standards Committee in 2009. He recently resigned from the HIT SC to become the acting director of the Office of Interoperability and Standards at ONC. He is currently on leave from the Department of Biomedical Informatics at Arizona State University and from his clinical practice at Mayo Clinic Scottsdale.

• Keynote
The FDA CDER Data Standards Plan

Theresa M. Mullin, Ph.D., Director, Office of Planning and Informatics, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration

Dr. Mullin directs strategic planning and business informatics for FDA CDER. The Office of Planning and Informatics plays a lead role in CDER long-range planning, budget formulation, program analysis, and informatics operations. Dr. Mullin is the CDER lead on development and evaluation of potential frameworks for benefit-risk assessment to support the regulatory review process. Her role in shaping FDA informatics strategy includes establishing and evolving the FDA IT governance function, co-chairing the CDER...
Dr. Raymond L. Woosley is the Founder and Chief Executive Officer of the Critical Path Institute (C-Path), a non-profit corporation formed by the Food and Drug Administration, SRI International and the University of Arizona to accelerate the development of safe innovative medicines. Since 1999, Dr. Woosley has directed one of fourteen federally funded Centers of Education and Research on Therapeutics (CERT). At Georgetown University he served as Chairman of the Department of Pharmacology and Associate Dean for Clinical Research. Dr. Woosley was later appointed Vice President for Health Sciences at the University of Arizona and Dean of the College of Medicine.

Keynote
Qualifying Science for Improved Drug Development

Raymond L. Woosley, M.D., Ph.D, CEO, Critical Path Institute

Introduction to CDISC Round Table Discussion Groups
Chris Decker, d-Wise Technologies & Dan Godoy, MedImmune

10:00 - 10:30 Break

10:30 - 12:00 Session 2
The World of CDISC
Chair: Bron Kisler, CDISC

- CDISC Global Update
  Rebecca Kush, CDISC
- CDISC Operations Update
  Frank Newby, CDISC
- CDISC Education Update
  Shannon Labout, CDISC
- CDISC Coordinating Committees
  Pierre-Yves Lastic, Chair, European CDISC Coordinating Committee
  Yoshio Tsukada, Chair, Japanese CDISC Coordinating Committee
  Simon Wang, Chair, Chinese CDISC Coordinating Committee
  Sukil Kim, Chair, Korean CDISC Coordinating Committee

12:00 - 13:30 Lunch - Kindly Sponsored by S.Sas

13:00 - 14:30 Round Table Discussion Sessions, Team Posters & Exhibits

14:30 - 16:00 Parallel Track 1
Session 3A: ODM Implementation
Chair: Wayne Kubick, Oracle | PhaseForward

- Neotor Project: A Real Academic Clinical Trial Using a CDISC ODM-based EDC
  Takahiro Kiuchi, UMIN Center, the University of Tokyo Hospital
- Using ODM Messages to Integrate Clinical Trial Systems and Improve Data Quality
  David Borbas, Jazz Pharmaceuticals
- Towards a Fully Machine-readable Protocol: from ODM-extension to Patient Study Calendar
  Jozef Aerts, XML4Pharma
Parallel Track 2
Session 3B: Standards from the Start: CDASH & Protocol
Chair: David Gemzik, Medidata Solutions

- Implementing CDASH Standards into Data Collection and Database Design
  Robert T. Stemplinger, ICON Clinical Research
- It Can Be Done! – Creating an Implementation Model Based on the Protocol Representation Model in BRIDG 3
  Lisa Chatterjee, Digital Infuzion
- Using a Protocol Model to Construct Study Documents
  Peter Abramowitsch, Medidata Solutions

16:00 - 16:30  Break
16:30 - 18:00  Parallel Track 1
Session 4A: The Submission Standards: SDTM & ADaM
Chair: Dave Evans, Octagon Research Solutions

- CDISC Advisory Board Presentation: Validation Tools, Assessment & Compliance
  Trisha Simpson, UCB, Marcelina Hungria, ISI, Chris Decker, d-Wise Technologies
- Growing into Standards: A Successful Grass Roots Campaign to Implement Data and Analysis Standards
  Lynn Difinizio, Biogen Idec
- Lessons Learned From Implementation Experience of ADaM An Oncology Case Study
  Zhuoye Xu & Susan Zhao, Genentech

Parallel Track 2
Session 4B: CDISC SHARE & Metadata Repositories
Chair: Chris Tolk, CDISC

- CDISC SHARE
  Dave Iberson-Hurst, CDISC
- Roles of a Next Generation Standards Metadata Repository
  Barry Cohen, Octagon Research Solutions
- Research Project on Metadata Extraction, Exploration and Pooling
  Dimitri Kutsenko, Entimo AG

18:30 - 20:30  Networking Event at The Maryland Science Center
Kindly Sponsored by Hewlett-Packard Company

THURSDAY, 4 NOVEMBER 2010

07:30 - 16:00  Exhibition Open
08:30 - 10:00  Session 5
eSource to Reporting: Building the Value of Standards
Chair: Gary Walker, Quintiles

- Leveraging CDISC Models to Drive Process Efficiency and Increase Product Quality
  Matthew Psioda & Edward Bakewell, Kendle
• The Value of BRIDG – Case Studies
  Sue Dubman, Genzyme
• The CDISC Healthcare Link
  Landen Bain, CDISC

10:00 - 10:30      Break

10:30 - 12:00      Session 6
Standards and the Patient
Chair: David Handelsman, SAS

• Data Standards and the National Cardiovascular Research Infrastructure Project
  Dana Pinchotti, American College of Cardiology
• Polycystic Kidney Disease and Data Standards
  Ron Perrone, Tufts University
• The Affordable Care Act: Opportunity for a Linked Health Data Network
  Jeff Allen, Friends of Cancer Research
• EHRs and the Learning Healthcare System
  Adam Clark, FasterCures

12:00 - 13:30      Lunch - Kindly Sponsored by sas

13:30 - 15:00      Session 7
FDA Presentations, Implementation Plans & Global Regulatory Update
Chair: Dave Iberson-Hurst, CDISC

Dr. Vicki Seyfert-Margolis, Office of the Commissioner
Amy Malla, CBER
Chuck Cooper, CDER
Steve Wilson, CDER

15:00 - 15:30      Break

15:30 - 17:00      Session 8
FDA Panel
Chair: Frank Newby, CDISC

• FDA Panel
  Dr. Vicki Seyfert-Margolis
  Steve Wilson
  Chuck Cooper
  Ranjit Thomas
  Amy Malla
  Jonathan Levine

15:30 - 19:00      Exhibit Booth Break-Down

FRIDAY, 5 NOVEMBER 2010

08:30 - 17:00      Training 7: CDASH Training Course

The CDASH standard describes the basic recommended (minimal) data collection fields for common identifier and timing data, and 18 domains, including demographic, adverse events, and other safety domains that are common to all therapeutic areas and types of clinical research. This full-day course will provide attendees with an overview of both the CDASH V1.1 standard and key concepts from the CDASH User Guide V1.0. The course includes
in-depth implementation information for all of the CDASH domains, with hands-on exercises.

Learning objectives addressed in this course include:
• Understanding the purpose and basic concepts of the CDASH standard
• Understanding the relationship between CDASH and the other CDISC standards
• Understanding conformance rules for CDASH implementations
• Understanding the challenges of collecting data in de-normalized structures
• Understanding the CDASH Best Practice recommendations for data collection

08:30 - 17:00  Training 8: ADaM Implementation Course

The Analysis Dataset Model (ADaM) specifies principles for analysis datasets and standards for a subject-level analysis file and for a basic data structure, which can be used for a wide variety of analysis methods. This one-day course discusses the purpose of ADaM, the basic principles of the ADaM data standard, the standard ADaM dataset structures and variables, ADaM metadata, maintaining the relationship between ADaM and SDTM, and how to apply ADaM to common analysis situations.

08:30 - 17:00  Training 9: LAB Course

The LAB Data Model is a vendor-independent format used to store and interchange lab data between clinical lab vendors and sponsor companies. The LAB model is an approved HL7 model. This one-day course consists of the technical framework for LAB, an in-depth understanding of the model structure, an overview of the implementation modes, and strategies for implementing LAB within your organization.

09:00 - 12:00  Training 10: CDISC & HL7 Course

Collaborative Standards Initiatives for Clinical Research and Healthcare

Topics for discussion:
• Data Standards: The foundation of interoperability in information interchange
• The BRIDG Model: Representing the clinical research domain in the context of healthcare standards
• The HL7 Development Process
• CDISC and HL7 Collaborative Projects

09:00 - 12:00  Workshop: Legacy Data Conversion

This workshop on Legacy Data Conversion will provide information, experiences and a demonstration. Sample topics are below:
• Data Conversion to SDTM: What Sponsors Can Do to Facilitate the Process
• Converting legacy data into SDTM Datasets: Two Case Studies
• Sponsor-Vendor Collaboration in Legacy SDTM Conversion – A Case Study
• Converting Legacy Data to SDTM Using a Factory Model – A Case Study
• Converting Legacy Data to SDTM: Live Demo
• Converting Legacy Data to SDTM: Process Summary in the context of Regulatory Submissions
SAVE THE DATE!

CDISC INTERCHANGES 2011
www.cdisc.org for more details and registration

Europe,
11 - 15 April 2011
Crowne Plaza Brussels - Le Palace
Brussels, Belgium
11 - 12 & 15 April Training and Workshops
13 - 14 April Conference

Japan
12 - 15 July 2011
Tokyo

North America
9 - 12 October 2011
Baltimore

North America
21 - 26 October 2012
Baltimore