Today’s Experience and Tomorrow’s Expectations

PROGRAM
Interchange North America
2009

9 - 13 November 2009
Baltimore Marriott Waterfront
Baltimore, MD
USA
Dear Valued CDISC Interchange Participant,

On behalf of the CDISC Board of Directors and Operations, we extend to you a very warm welcome to our fall CDISC Interchange 2009. We are extremely pleased that you have been able to take the time from your busy schedule to learn, contribute, enjoy and converse at this annual event. We realize that the economic climate has changed since last year, and we sincerely appreciate your memberships and continuing participation in CDISC. Now more than ever, we need standards to improve efficiencies and data quality, bearing in mind the value in what we do to streamline the path for clinical research results to inform healthcare for the benefit of patients everywhere.

Once again this year, we have an excellent variety of offerings, from the expertise of our keynote speakers, to updates from the team leaders and our leaders from the CDISC Coordinating Committees around the globe, to the new courses that have been added this year. Within this exciting program, there will be two tracks with presentations based on submitted abstracts selected by our excellent Program Committee, which is comprised of members from the CDISC Advisory Board; these individuals will also chair sessions that they organized.

Our keynoters include the new Deputy Commissioner of the FDA, Dr. Joshua Sharfstein, who will speak on “CDISC and the Public Health”; Dr. Christopher Chute from Mayo Clinic, who is a member of the U.S. Health Information Technology Standards Committee and Dr. Frank Rockhold from GlaxoSmithKline, who is incoming chair of the CDISC Board of Directors. Updates on CDISC key collaborations will be presented by Dr. Charles Jaffe, CEO of HL7 and John Speakman of NCI. As usual, we will have our special FDA Panel following Dr. Sharfstein’s presentation.

CDISC is very pleased to roll out the Protocol Representation Model this month, many thanks to the entire PR Team, which is led by Lisa Chatterjee and David Gemzik; Diane Wold, Leader Trial Design Model Team; Art Gertel, leader of the Glossary Group; and Julie Evans, who leads the CDISC BRIDG activities. We are also holding new courses, which have not yet been taught in the U.S. One of these is the Healthcare Link Course, which covers all of the activities that CDISC is doing to link clinical research with healthcare, including hands-on training around the IHE Integration Profile, Retrieve Form for Data Capture (RFD). We are also offering the new SDTM 3.1.2 course, which highlights the differences between this version and 3.1.1. In addition, there is a significantly updated ADaM course based on the soon to be released ADaM Implementation Guide.

Last and certainly not least, CDISC will host several demonstrations in the exhibition area and would like to encourage you to spend a bit of time during breaks to see all of these. We hope that you find this Interchange rewarding and educational, taking advantage of the opportunities to have fruitful discussions with the CDISC experts and implementers and those new to our community, especially while enjoying our reception at the National Aquarium!

With sincere appreciation to each and each and every one of you, who contribute more than you may realize to the CDISC collective strength and progress,

Rebecca (Becky) Kush

P.S. Don’t forget purchase your copy of our CDISC book: Introducing the CDISC Standards: New Efficiencies for Medical Research. This is a ‘must have’ for anyone interested in learning about and/or implementing CDISC Standards! You can order it directly from our new website: www.cdisc.org, or purchase at the Interchange with discount!
CONFERENCE-AT-A-GLANCE

MONDAY 9 NOVEMBER
09:00 - 17:00  SDTM Theory & Application Training Course
13:30 - 17:00  Introduction to CDISC Training Course

TUESDAY 10 NOVEMBER
09:00 - 17:00  SDTM Theory & Application Training Course (cont’d)
09:00 - 17:00  ODM Implementation Training Course
09:00 - 12:00  Introduction to BRIDG Training Course
09:00 - 12:00  Introduction to CDASH and Terminology Training Course
13:30 - 17:00  Introduction to Protocol Representation Training Course*
13:30 - 17:00  CDISC and HL7 Workshop

WEDNESDAY 11 NOVEMBER
08:30 - 17:30  Interchange Conference Presentations
10:00 - 18:30  Industry exhibitors
19:00 - 22:00  Networking event at the Baltimore Aquarium

THURSDAY 12 NOVEMBER
08:30 - 17:30  Conference Presentations
07:30 - 16:00  Industry exhibitors

FRIDAY 13 NOVEMBER
08:30 - 12:30  Legacy Data Conversion Workshop
09:00 - 15:00  Healthcare Link Course
09:00 - 17:00  ADaM Implementation Training Course
09:00 - 17:00  LAB Implementation Training Course

Contents are subject to change.

* Attendees must have taken the BRIDG Training to take this course
MONDAY, 9 NOVEMBER 2009

09:00 - 17:00  Training 1: SDTM Course

*New SDTM v3.1.2 Course being offered for the first time in the USA!*

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 do not need to take this course. You can take the 3.1.1 to 3.1.2 vLearning Course available via the CDISC website.

13:30 - 17:00  Training 2: Introduction to CDISC Course

This half-day course will give attendees the opportunity to learn about the history, organization, and philosophy of CDISC, the CDISC approach for standards development, the data modeling process, as well as the benefits of CDISC standards. There is a brief introduction to each of the currently published CDISC data standards/models and a discussion of future opportunities. The course is aimed at those who have little or no experience of CDISC and want an introduction to CDISC operations, data standards/models and objectives.
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 OMD within your organization.

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.

This half-day course will provide attendees with an overview of the CDASH and Terminology projects as well as covering history, organization, and philosophy. This course will provide attendees with the information needed to facilitate access, implementation and use of these important standards. Additionally the course will cover:

- The development approach
- Key collaborations
- The interrelationship of these projects
- The relationship to the Study Data Tabulation Model (SDTM)
- How to implement these standards
- Future plans and direction

The objective of the Protocol Representation Group is publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders. This course will describe the first release of the Protocol Representation Standard, which includes Clinical Trial Registry, Trial Design, and Eligibility Criteria.

CDISC & HL7: 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
WEDNESDAY 11 NOVEMBER 2009

07:00 - 10:00  Exhibition Booth Set-Up

10:00 - 18:30  Exhibition Open

08:30 - 10:00  Session 1
Opening Plenary & Keynote Presentations
Chair: Rebecca Kush, CDISC

• Keynote: The Importance of Communicating the Imperative and Principles of Data Standards to Mere Mortals
  Frank Rockhold, GlaxoSmithKline Pharmaceuticals
• Keynote: Standards and EHRs at the Interface between Practice and Research
  Christopher Chute, Mayo Clinic College of Medicine
• CDISC and Health Level 7 (HL7)
  Charles Jaffe, CEO HL7
• CDISC and the National Cancer Institute (NCI)
  John Speakman, NCI

10:00 - 10:30  Break

10:30 - 12:30  Session 2
CDISC Updates
Chair: Dave Iberson-Hurst, CDISC

• CDISC Global Update
  Rebecca Kush, CDISC
• CDISC Europe Update
  Pierre-Yves Lastic, Sanofi Aventis and E3C Chair Elect
• CDISC Japan Update
  Kiyoteru Takenouchi, CMIC Co., Ltd and J3C Chair & Hiroyuki Nishimoto, Takeda Pharmaceutical Co., Ltd. and J3C
• CDISC China Update
  Shawn Wang, MedxView
• CDISC Team Updates
  ADaM - John Troxell, Merck
  BRIDG - Julie Evans, CDISC
  CDASH - Rhonda Facile, CDISC
  Glossary - Art Gertel, Beardsworth Consulting
  Healthcare Link - Landen Bain, CDISC
  ISD Pilot - Chris Decker, d-Wise Technologies
  LAB - Phil Pochon, Covance
  ODM - Sam Hume, Astra Zeneca
  Protocol Representation - Lisa Chatterjee, Digital Infusion
  TDM - Diane Wold, GSK
  SDTM - Fred Wood, Octagon Research Solutions
  SEND - Lou Ann Kramer, Eli Lilly & Company
  Terminology - Chris Tolk, CDISC
• SDTM Validation Tools: Brief Introduction to the Tools Demo being held in the Exhibition area

12:30 - 14:00  Lunch

14:00 - 15:30  Parallel Track 1
Session 3A: BRIDG, Janus and Metadata
Chair: Julia Zhang, Genzyme

• A Relational Understanding of the BRIDG Model and the Roadmap to Achieve a “Semantically Interoperable System”
  Gabriel N Backianathan & John.R.Gerlach, Maxisit
The Janus Clinical Trial Data Repository -- What Is It and How Can It Benefit You?
Doug Del Prete, IBM

Roles of Metadata in a Repository-based Data Conversion Process to CDISC Models
Dimitri Kutsenko, Entimo

Parallel Track 2
Session 3B: CDASH
Chair: Patrick Genyn, Johnson & Johnson

- CDASH and SDTM Implementation: Achieving Efficiency Through Standardization
  Parag Shiralkar, eClinical Solutions Division of Eliassen Group
- CDASH Implementation Strategy Using Multiple Systems
  Casey Higgins, Omincare Clinical Research
- Case Report Form Harmonization and Standardization: Creation of a Library of CRFs that Implement caBIG® and CDASH Data Standards
  Dianne M. Reeves, NCI

15:30 - 16:00 Break

Parallel Track 1
Session 4A: CDISC Shared Health and Clinical Research Electronic Library (SHARE)
Chair: Dave Evans, Octagon Research Solutions

- Data Elements and Semantics
  Dave Iberson-Hurst, CDISC
- Technical Foundations of a Metadata Repository for Clinical Research
  Matthias Löbe, Institute for Medical Informatics (IMISE) Universität Leipzig, Jürgen Stausberg, IBE, Medical Faculty, Ludwig-Maximilians Universität München, Philippe Verplancke, XClinical, Johannes Drepper, Telematikplattform für Medizinische Forschungsnetze (TMF) e.V
- On Hoot72, a Mechanism for Creating OWL-defined Graphs from Healthcare Data Carried in HL7 v2.x Messages
  Conor Dowling, HOOT72.org

Parallel Track 2
Session 4B: Metadata & Terminology
Chair: Peter Van Reusel, Business and Decisions

- End-to-End, Standards-based, Metadata-driven Clinical Data Lifecycle
  Sue Dubman, Genzyme & Barry Cohen, Octagon Research Solutions
- Defining & Managing Data Elements and Permissible Values or CDISC Terminology - A Use Case
  Barrie Nelson, Amgen
- How Biopharmaceutical Companies are Utilizing Controlled Terminology for SDTM: A CRO Perspective
  Christine McNichol & Stephen Hamburg, Omnicare Clinical Research

19:00 - 22:00 Networking Event at the National Aquarium, Baltimore
THURSDAY, 12 NOVEMBER 2009

07:30 - 16:00  Exhibition Open

CDISC Healthcare Link Demo in the Exhibition Area Today

08:30 - 10:00  Parallel Track 1
Session 5A: Analysis of Clinical Data
Chair: Lynn Difinizio, Biogen Idec

- The ADaM Basic Data Structure
  John Troxell, Merck
- Navigating the Roadblocks: Constructing an Analysis Database from SDTM
  Susan Boyer, Ben Vaughn & Jeff Abolafia, Rho
- Patient Evaluability in the CDISC World
  Nate Freimark, Omnicare Clinical Research

Parallel Track 2
Session 5B: ODM & RFD
Chair: Gary Walker, Quintiles

- Shortening the CRF Design and Database Set-up Process with a CDISC ODM Metadata-driven Approach
  Claus Lindenau, XClinical
- Lessons Learned from Implementing RFD for a Multi-Site Clinical Study: Perspectives from both EHR and EDC
  Ilya Sterin, Nextrial, Jason Colquitt, Greenway Medical
- Adverse Event Report on IHE RFD (Retrieve Form for Data capture) with Japan's Ministry Project SS-MIX. an HL7 Standardized HIS Data Export Promotion
  Michio Kimura, Hamamatsu University, Kiyoteru Takenouchi, CMIC Co., Ltd

10:00 - 10:30  Break

10:30 - 12:30  Parallel Track 1
Session 6A: ODM
Chair: Dave Handelsman, SAS

- Standards-Based Approach to Creating One Elegant Multi-System Solution
  Carl Labb, Almac Clinical Technologies, Joseph Dustin, Medidata & Scott Bradley, PHT
- Technical Aspects of Conversion to ODM
  Michael J. Ward, Eli Lilly & Company
- Using ODM to Manage Clinical Data Content Standards
  Bruce R. Basson, Eli Lilly & Company
- Using Incremental ODM Transactions in Systems Integration
  Andrew Smith, Medidata

Parallel Track 2
Session 6B: CDISC in a Data Management System, Define.xml and SDTM
Chair: Steve Kopko, Wyeth

- CDISC integration in the Oracle Clinical/Remote Data Capture® (OC/RDC) clinical data management system
  Peter Van Reusel, Business & Decision
- Converting the Define.xml to a Relational Database to Enable Printing and Validation
  Lex Jansen, Octagon Research Solutions
- Backward Compatibility of SDTMIG
  Tang Li, TechData Service Company
- Our Experience with Transitioning from SDTM Version 3.1.1 to 3.1.2
  Sarah McLaughlin, Biogen Idec

12:30 - 14:00  Lunch
14:00 - 15:30  Session 7  
Regulations, FDA & CDISC Pilot Project  
Chair: Frank Newby, CDISC  

- Janus  
  Sue Bell, FDA  
- The CDISC/FDA Integrated Safety Data Pilot: A Case Study in Implementing CDISC Standards to Support an Integrated Review  
  Chris Decker, d-Wise Technologies  
- SEND Pilot  
  Lauren Mihalcik, FDA, Lou Ann Kramer, Eli Lilly & SEND Team Lead  

15:30 - 16:00  Break  

16:00 - 17:30  Session 8  
FDA Keynote Speaker & Panel  
Chair: Edward Helton, NCI, Chair of the CDISC Board of Directors  

- CDISC and the Public Health  
  Dr. Joshua M. Sharfstein, FDA Principal Deputy Commissioner  
- FDA Panel  
  Dr. Joshua M. Sharfstein,  
  Dr. Steve Wilson,  
  Chuck Cooper  
  Amy Malla  
  Additional FDA Panelists Invited  

16:00 - 19:00  Exhibit Booth Break-Down
FRIDAY, 13 NOVEMBER 2009

08:30 - 12:30 Workshop 2: Legacy Data Conversion

Fred Wood, Octagon Research Solutions, Karen Zieker, i3 Statprobe, Jagruthi Kasuganti, Take Solutions, Abhay Lal Jha, Cognizant, Peter Van Reusel, Business & Decision, Marcelina Hungria, ISI, Jan Hess from P&G and FDA Speakers from CDER eReview/eData & CBER Review Management Invited

This workshop on Legacy Data Conversion will provide information, experiences and a demonstration on the following topics:

- 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

09:00 - 15:00 Training 7: Healthcare Link Course

*Course being offered for the first time in the USA!*

The link between Healthcare and Medical Research is now closer than ever before. CDISC is at the forefront of initiatives that are bringing about considerable benefits to both communities. CDISC’s Healthcare Link project is now mainstream with the original RFD now incorporated in a 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 RFD as the pivotal technology that opens the link between healthcare and research. In addition, the new work that is being completed and incorporated in the larger picture includes the following:

- CDISC interactions with health informatics standards organizations such as HL7 and IHE
- The electronic Source Document Initiative (eSDI)
- Scenarios for the use of electronic health records for clinical research
- 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

09:00 - 17:00 Training 8: ADaM Implementation Course

*Including materials from the soon to be released ADaM Implementation Guide!*

The Analysis Dataset Model (ADaM) builds on the SDTM metadata model, adding attributes and examples specific to statistical analysis. This one-day course discusses the purpose of analysis datasets, the basic principles of the ADaM data standard, how ADaM fits in the CDISC framework, and the relationship between ADaM and SDTM. Attendees will learn the specifics about the subject-level analysis data model and how to start to apply the ADaM standards right now.

09:00 - 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.
SAVE THE DATE!

CDISC INTERCHANGES 2010
www.cdisc.org for more details and registration

Europe,
Royal Lancaster Hotel,
London
26 - 30 April 2010

Japan
Tokyo
27 - 30 July 2010