International Interchange
“Standards for Patients”

10 – 14 October 2011
Renaissance Harborplace Hotel
Baltimore, MD 21202

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Strength Through Collaboration
INTERCHANGE SCHEDULE

MONDAY, 10 October 2011

SDTM Theory & Application Course (day 1 of a two-day training)
Monday, 10 October: 08:30 - 17:00

The CDISC Study Data Tabulation Model (SDTM) is a specification for the submission of pre-clinical and clinical data to the U.S. Food and Drug Administration in support of marketing applications. This two-day course consists of:

- A detailed review of SDTM concepts, SDTM-based domain models for human clinical data, relationship tables, and trial design
- A discussion of common implementation issues
- Exercises including the annotation of CRFs and the creation of datasets that reinforce attendees’ understanding of the SDTM and the SDTM Implementation Guide for clinical data

Recommendation: A basic understanding of relational database design and clinical data flow is helpful but not required.

ODM Implementation Course
Monday, 10 October: 08:30 - 17:00

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. 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
- Strategies for implementing ODM within your organization

Recommendation: A working knowledge of XML or other mark-up languages is helpful to understanding the material presented.

LAB Implementation Course
Monday, 10 October: 8:30 - 17:00

The LAB Data Model is a vendor-independent format used to store and interchange LAB data between clinical LAB vendors and sponsor companies. 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
- Strategies for implementing LAB within your organization

Recommendation: Knowledge of clinical laboratory data is helpful to understanding the material presented.
TUESDAY, 11 October 2011

SDTM Theory & Application Course (day 2 of a two-day training)
Tuesday, 11 October: 08:30 - 17:00

Controlled Terminology Course
Tuesday, 11 October: 08:30 - 12:00

The CDISC Controlled Terminology Course covers the means by which the CDISC codelists were
developed and are maintained. This half-day course consists of:

- Brief history of the CDISC terminology initiative, primary objectives and guiding principles
- The working relationship with the NCI Enterprise Vocabulary Services (EVS)
- How CDISC controlled terminology is developed and how new terms are added
- The Implementation Guide and how codelists are maintained for SDTM, CDASH, ADaM, SEND,
  and other CDISC codelists.
- How to access and use controlled terminology.

Protocol Representation Course
Tuesday, 11 October: 13:00 - 17:00

The CDISC Protocol Representation Model provides a standard, machine-readable model for protocol
representation that enables interchange of protocol information among systems and stakeholders. The
model focuses on the characteristics of a study and the definition and association of activities within
protocols. The content scope of this model includes: Study Design, Eligibility Criteria, and trial registry
requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries. This half-day
course describes:

- The Protocol Representation standard
- The relationship of Protocol Representation to other CDISC models including BRIDG
- The uses of the Protocol Representation model

Prerequisite: A general knowledge of the clinical trial process and protocol development is helpful to
understanding the material presented.

ADaM Implementation Course
Tuesday, 11 October: 08:30 - 17:00

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
- How to apply ADaM to common analysis situations

Recommendation: A basic understanding of statistical principles used in clinical research is helpful to
understanding the material presented.
Charles Friedman is Professor and Director of the health informatics program in the Schools of Information and Public Health at the University of Michigan. The new program will have a distinctive focus on consumer and population health informatics.

Prior to going to Michigan, Dr. Friedman served for four years in executive positions at the Office of the National Coordinator for Health IT in the U.S. Department of Health and Human Services. From 2007 to 2009 he was Deputy National Coordinator and from 2009 to 2011 he was ONC’s Chief Scientific Officer. While at ONC, Dr. Friedman oversaw a diverse portfolio of nationwide activities that included the ‘learning health system’ supporting research, public health, and quality improvement; the health IT workforce development program; the SHARP health IT research program; initiatives in usability and clinical decision support; evaluation of ONC’s programs; and international cooperation for eHealth. He was the lead author of the first national health IT strategic plan which was released in June of 2008.

Prior to his work at ONC, Dr. Friedman held various senior positions at NIH, was Professor and Associate Vice Chancellor for Biomedical Informatics at the University of Pittsburgh, and served for many years in faculty and administrative roles at the University of North Carolina at Chapel Hill.

CDISC Advisory Board Meeting with FDA Town Hall
(CDISC Platinum Member CAB Representatives Only – BY INVITATION)
Tuesday, 11 October: 16:00 - 20:00

The CDISC Advisory Board (CAB) meeting will begin with a ‘Town Hall’ with FDA Representatives, followed by a dinner meeting of the CAB.

FDA Representatives: Amy Malla (CBER), Dr. Armando Oliva (CDER), Catherine Jansto (CDER), Dr. Chuck Cooper (CDER), Helena Stiglin (CDER), Mary Ann Slack (CDER), and Terrie Reed (CDRH)

CDISC Platinum Members hold a seat on the CAB and their CAB representatives will be invited to attend this meeting. Please RSVP to Shirley Williams (swilliams@cdisc.org).

Anyone wishing to join CDISC at the Platinum level or upgrade their membership to the Platinum level should contact: Sheila Leaman at sleaman@cdisc.org

All CAB Members will also be welcome to attend (with no registration charge) the new CDISC Course: A Global Approach to Accelerating Medical Research (Friday, 14 October, 08:30 – 12:00). Please contact Shirley Williams (swilliams@cdisc.org) if you or your colleagues are interested in attending.

Exhibition Booth Setup
Tuesday, 11 October: 19:00 - 22:00

WEDNESDAY, 12 October 2011 – Interchange Conference

06:30 - 07:30 Exhibition Booth Set-Up
07:30 - 18:00 Exhibition Open
07:30 – 17:00 CONFERENCE REGISTRATION
08:30 - 10:00 Session 1: Opening Plenary & Keynote
  Session Chair: Dr. Frank Rockhold, Chair, CDISC Board of Directors

Opening Remarks by Dr. Frank Rockhold

Keynote: Building a National Learning Health System
  Dr. Charles Friedman, Professor and Director of the Health Informatics program in the Schools of Information and Public Health at the University of Michigan

The State of the CDISC Union
  Dr. Rebecca Kush, President and CEO, CDISC

CDISC Technical Update
  Frank Newby, Chief Operating Officer, CDISC

10:00 – 10:30 Break
Session 2: CDISC Global Updates
Session Chair: Shannon Labout, Sr. Director, CDISC Education

- **CDISC Coordinating Committees Updates**
  - Dr. Sukil Kim, Korean CDISC Coordinating Committee (K3C)
  - Simon Wang, Chinese CDISC Coordinating Committee (C3C)
  - Dr. Yoshio Tsukada and Hiroshi Azuma, Japanese CDISC Coordinating Committee (J3C)
  - Peter Van Reusel, European CDISC Coordinating Committee (E3C)

- **CDISC Supporting Activities in Japan and Specialty Area Standards Development**
  Youji Nagai, Shinsuke Kojima and Takako Jono, Translational Research Informatics Center (TRI) and Dr. Kiyoteru Takenouchi, CMIC

- **National Cardiovascular Research Infrastructure**
  Dana Pincotti, American College of Cardiology

12:00 - 13:30  Lunch with Themes Discussion
Themes (by lunch table) organized by Peter Schaefer, CAB, Interchange Program Committee

13:30 – 15:30  Parallel Tracks: Session 3& 4

<table>
<thead>
<tr>
<th><strong>Wednesday, 12 October: 13:30 – 15:30</strong></th>
<th><strong>Wednesday, 12 October: 13:30 – 15:30</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parallel Track 1</strong></td>
<td><strong>Parallel Track 2</strong></td>
</tr>
<tr>
<td>Session 3: Metadata &amp; SHARE</td>
<td>Session 4: Implementation; Case Studies</td>
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<td>Chair: David Evans, Octagon, CAB Chair</td>
<td>Chair: Steve Kopko, Subject Matter Expert, CDISC</td>
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- **What Does Metadata-Driven Processing Actually Mean?**
  - Barry Cohen, Octagon Research

- **Demystifying BRIDG and ISO21090, the Foundational Standards used by SHARE**
  - Dr. Diane Wold, GlaxoSmithKline

- **How a Metadata Repository Maximizes Efficiencies Across the Clinical Domain**
  - Dr. Patrick Genyn, Johnson & Johnson and Peter Van Reusel, Business & Decision

- **Ontology-based Knowledge Management for Clinical Data: the RICORDO approach**
  - Bernard de Bono, European Bioinformatics Institute

- **The AstraZeneca Story**
  - Alex Hromcenco and Sam Hume, AstraZeneca

- **Enabling Pharmacometrics**
  - Erin Guinan and Peter Schaefer, Pharsight

- **Implementing ADaM – An Oncology Case Study**
  - Wei Dong, Genentech

- **Use the define.xml Standard from the Start for CRF design**
  - Dr. Phillippe Verplanke, X Clinical GmbH

15:30 - 16:00  Break
**Weekend, 12 October: 16:00 – 17:30**

**Parallel Track 1**

**Session 5: Standards ‘Up Front’**
*Session Chair: Chris Tolk, Director, Terminology, CDISC*

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>PRM Data Model; impact on the Regulatory Framework and co-relation to the BRIDG Model</td>
<td>Gabriel N Backianathan, eClinical Solutions</td>
</tr>
<tr>
<td>Utilizing ODM and BRIDG for eClinical Integrations</td>
<td>Richard Gleeson, Perceptive Informatics</td>
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<tr>
<td>CDISC Study Design Model in XML (SDM-XML)</td>
<td>Jan Joseph Kratky, SAS / CDISC XML Technologies Team</td>
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**Parallel Track 2**

**Session 6: Data Aggregation; eSubmission Standards**
*Session Chair: Marcelina Hungria, DImcore Group, LLC / CDISC Define.xml Team, SDTM Validation Team*

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<tr>
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<tbody>
<tr>
<td>Don’t Know Your ISE/ISS Submission Datasets from ADaM?</td>
<td>Mark Gummel, Theorem Clinical Research</td>
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<tr>
<td>Utilizing ODM and BRIDG for eClinical Integrations</td>
<td>Define.xml 2.0: Second to None</td>
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<tr>
<td>CDISC Study Design Model in XML (SDM-XML)</td>
<td>Mike Molter, d-Wise/ CDISC Define.xml Team</td>
</tr>
<tr>
<td>Creation of NONMEM datasets for population PK analysis: How CDISC standards can help to reduce time and effort</td>
<td>Elke Vansnick, SGS Life Sciences Services</td>
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</tbody>
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**17:30 – 19:00**

**NETWORKING RECEPTION**

**RENAISSANCE HARBORSIDE**

*Strength Through Collaboration*
THURSDAY, 13 October 2011 – Interchange Conference

07:30 - 16:00 Exhibition Open
07:30 – 17:00 Conference Registration
08:30 - 10:00 Session 7: Streamlining Medical Research
Chair: Bron Kisler, VP Strategic Initiatives, CDISC
• Keynote: A Global Network for Clinical Research...Really?
ACRES: The Alliance for Clinical Research Excellence and Safety
Dr. Edward “Greg” Koski, PhD, MD, CPI (Honorary)

• Interactive Panel Discussion
Moderator: Margaret Anderson, Executive Director, Faster Cures

Improving and Accelerating Cures through Patient-centered Standards Development and Regulatory Science

This panel discussion will explore the need to ensure patients are the centerpiece and common thread between related activities for improving the medical research system. This becomes more important as CDISC, FDA, NIH Institutes, Global Organizations and patient groups collaborate and seek new innovative ways to develop standards specifically focused on major disease area.

Panelists: Dr. Greg Koski (Harvard), Sue Dubman (Genzyme), Dr. Steven Hirschfeld (National Institute of Child Health & Human Development), Dr. Ron Perrone (PKD Foundation and Tufts University); others invited

10:30 - 12:00 Session 8: eSource and Healthcare Link
Chair: Jonathan Andrus, BioClinica

This interactive session will begin with an overview of the status of using healthcare data from electronic health records (EHRs) for purposes other than direct patient care, focusing on the use of eSource tools (particularly EHRs) for clinical research. A subsequent interactive panel session will include perspectives from Japan (Sentinel Project and use of EHRs for safety reporting); from a hospital in Florida using EHRs for research; and from FDA, CDISC and technology providers in the industry.

• Bridging the Gap: Using Healthcare Data for Research and Safety
Wayne Kubick, Oracle

• Interactive Panel Discussion
Panelists: Dr. Michio Kimura (Hamamatsu University School of Medicine), Dr. Kiyoteru Takenouchi (CMIC), Susan B. Mitchell, MSN, RN (Florida Hospital MIS), Dr. Sean Kassim (FDA, CDER/OSI), Wayne Kubick (Oracle), Landen Bain (CDISC Healthcare Liaison), Terrie Reed (FDA/CIRH)

12:00 - 13:30 Lunch: Exhibitor Bingo Draw & CDISC Awards

Greg Koski is Senior Scientist at the Institute for Health Policy and Associate Professor of Anesthesia, Massachusetts General Hospital, Harvard Medical School. He is the former and first Director of the Office for Human Research Protections, U.S. Department of Health and Human Services (OHRP), established in 2000. Dr. Koski is internationally recognized and respected authority in the realm of clinical research, research ethics, research integrity and human subjects protection. Upon his departure from public service, Dr. Koski was recognized by the Department of Health and Human Services with a Superior Service Award “for his tireless commitment and dedication to enhancing human subjects protection programs across the country and around the world”.

Dr. Koski received his undergraduate education, PhD, and MD from Harvard. He was a member of the first graduating class of the Harvard-Massachusetts Institute of Technology program in Health Sciences and Technology. Trained as a physiologist at Harvard Graduate School, Dr. Koski did post-doctoral work in biochemical pharmacology at the National Institutes of Health before returning to the MGH Department of Anesthesia to complete residency training and a fellowship in cardiothoracic anesthesia. He joined the faculty in 1984 and returned to Harvard (after leading OHRP) in 2002.

Dr. Koski continues to advise the WHO Special Program in Training and Research in Tropical Diseases as a member of its Strategic Quality Management Advisory Committee. He is frequently interviewed by the national press of a variety of topics related to human research ethics and regulations and has appeared on national media broadcasts such as the popular CBS program “60 Minutes” and National Public Radio’s “The Connection”. Most recently, Dr. Koski has launched a new initiative, the Alliance for Clinical Research Excellence and Safety (ACRES; www.acreglobal.net), a nascent not-for-profit organization working to build a global network for clinical research modeled after the global air transport system.
Dr. ShaAvhree Buckman is the Director of the Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration. OTS is comprised of the Office of Biostatistics, Office of Clinical Pharmacology, and provides oversight to CDER research involving human subjects as well as CDER regulatory science research. OTS is responsible for providing coordination for Critical Path initiatives across CDER in partnership with individual CDER offices. OTS also leads CDER’s Computational Science Center efforts to help streamline the use of data standards and analysis tools to support regulatory review.

Prior to serving as Director of OTS, Dr. Buckman served as Deputy Director for OTS and as medical team leader in the Division of Pediatric Drug Development, Office of Counter Terrorism and Pediatric Drug Development, CDER. Dr. Buckman received her MD and PhD degrees with an emphasis on molecular cell biology from Washington University School of Medicine. Dr. Buckman completed Pediatric specialty training at Baylor College of Medicine.

13:30 - 15:00  Session 9: FDA Related Initiatives
Chair: Frank Newby, COO, CDISC

- CDISC Advisory Board Validation Project
  Tricia Simpson, CDISC Advisory Board

- eSubmission File Size
  Dhananjay Chhatre, M.S., Regulatory Information Specialist, Electronic Data Team, FDA, CDER/OBI

- CBER and CDISC Standards
  Amy Malla, CBER, FDA

- CDER and CDISC Standards
  Mary Ann Slack, Deputy Director, Office of Planning and Informatics, CDER, FDA

- HL7, FDA and CDISC
  Dr. Charles Jaffe, CEO, HL7

- Critical Path Institute
  Enrique Aviles, Director, Data Standards and Management, Critical Path Institute

15:00 - 15:30  Break

15:30 - 17:00  Session 10: FDA Keynote and Panel
Session Chair: Dr. Edward Helton, NCI, Past-chair, CDISC Board of Directors

FDA Keynote: An Update on CDER’s Efforts to Support Innovation in Regulatory Review
Dr. ShaAvhree Buckman, Director of the Office of Translational Science, FDA Translational Science and Computational Science Center

FDA Panelists:

Amy Malla (CBER)
Dr. Armando Oliva (CDER)
Dr. Chuck Cooper (CDER)
Doug Warfield (CDER)
Gary Gensinger (CDER)
Helena Sviglin (CDER)
Mary Ann Slack (CDER)
Paul Okwesili (CDER)
Dr. Sean Kassim (CDER/OSI)
Dhananjay Chhatre (CDER/OBI)
Dr. ShaAvhree Buckman (CDER)
FRIDAY, 14 October 2011

CDASH Implementation Course  
Friday, 14 October: 08:30 - 17:00

The CDASH standard describes the basic data collection fields that are common to all therapeutic areas and all types of clinical research. This full-day course will provide attendees with an overview of the key concepts from the CDASH V1.1 standard. The one-day course also includes in-depth implementation information for all of the CDASH domains, with hands-on exercises.

Learning objectives addressed in this course include:

- Purpose and basic concepts of the CDASH standard
- Relationship between CDASH and the other CDISC standards
- Conformance rules for CDASH implementations
- Challenges of collecting data in de-normalized structures
- CDASH Best Practice recommendations for data collection

Recommendation: A basic understanding of the clinical data collection process is helpful to understanding the material presented.

Global Approach to Accelerating Medical Research Course  
Friday, 14 October: 08:30 - 12:00

The Clinical Data Interchange Standards Consortium (CDISC) has collaborated with numerous other organizations on a global basis to analyze research regulations and processes for academic and regulated research. 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 3-hour course outlines these enablers so that you can:

- Understand the benefits of implementing enablers to improve medical research
- Demonstrate how you can improve your data quality
- Streamline workflow at investigative research sites and sponsoring organizations
- Understand and communicate relevant business information that demonstrates the real world value of CDISC enablers

Prerequisite: None. This is a high level course intended for anyone who is involved in medical research in any capacity, and at any level.

Legacy Data Conversion Workshop  
Friday, 14 October: 08:30 - 12:00

The FDA is encouraging sponsors to submit their data in the CDISC standards, such as SDTM, ADaM and define.xml. Since the original data is not collected in this format, legacy data conversions are needed in order to transform existing databases into the CDISC standards. The preparation, complexity and the workload of these conversions can be daunting. This workshop is designed to share information and experience and will be led by industry experts.

These are the main topics of the workshop:

- Implementing the CDISC standards: how, when and why
- Legacy data conversion process, including the role of data integration technology and lessons
- A live demonstration of a legacy data conversion methodology
- A sponsors’ perspective on legacy data conversions
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 with output of a core research dataset in CDASH format.

The Biomedical Research Integrated Domain Group (BRIDG) Model is a Domain Analysis Model (DAM) for protocol-driven research; it was developed through a collaboration of stakeholders from CDISC, the HL7 Regulated Clinical Research Information Management (RCRIM) Workgroup, 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 basic UML modeling tutorial
- An introductory look at the BRIDG model

**Prerequisite:** None
SAVE THE DATE
CDISC INTERCHANGES 2012
WWW.CDISC.ORG for more details

CDISC Interchange
Europe 2012
16-20 April 2012
18 - 19 Interchange Conference, and 16 - 17 & 20 April Training and Workshops
Elite Hotel Marina Tower
Stockholm, Sweden

CDISC Interchange
Japan 2012
10-13 July 2012
10-11 July Interchange Conference, and 12-13 July Training and Workshops

CDISC Interchange
China 2012
19 – 21 September 2012
Interchange Conference, Training and Workshops

CDISC International Interchange North America 2012
21 - 26 October 2012
Interchange Conference, Training and Workshops
Renaissance Harborplace Hotel
202 Pratt Street
Baltimore, MD 21202
MONDAY 10 October

08:30 - 17:00 SDTM Theory & Application Training Course
08:30 - 17:00 ODM Implementation Training Course
08:30 - 17:00 LAB Implementation Course

TUESDAY 11 October

08:30 - 17:00 SDTM Theory & Application Course
08:30 - 17:00 ADaM Implementation Course
08:30 - 12:00 Controlled Terminology Course
13:00 - 17:00 Protocol Representation Course
16:00 - 20:00 CAB Meeting with FDA (Platinum Members Only by Invitation)

WEDNESDAY 12 October

07:30 - 18:00 Industry Exhibitors
08:30 - 17:30 Interchange Conference Presentations
17:30 - 19:00 Networking Reception at the Renaissance Harborside

THURSDAY 13 October

07:30 - 16:00 Industry Exhibitors
08:30 - 17:00 Interchange Conference Presentations

FRIDAY 14 October

08:30 - 17:00 CDASH Implementation Course
08:30 - 12:00 Legacy Data Conversion Workshop
08:30 - 12:00 Global Approach to Accelerating Medical Research
13:00 - 17:00 BRIDG Training Course
13:00 - 17:00 EHRs for Medical Research (Healthcare Link) Course

Strength Through Collaboration