CDISC Interchange Europe

“Standards Accepted for Progress; CDISC the Reliable Partner”

16 – 20 April 2012
Elite Hotel Marina Tower
Stockholm, Sweden

The Interchange is kindly sponsored by

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INTERCHANGE SCHEDULE

MONDAY, 16 April 2012

SDTM Theory & Application Course (first day of a two-day training)
Monday, 16 April: 09:00 – 17:30

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, 16 April: 09:00 - 17:30

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.

12:30 – 14:00       Lunch

Strength Through Collaboration
**TUESDAY, 17 April 2012**

**SDTM Theory & Application Course (day 2 of a two-day training)**  
*Tuesday, 17 April: 09:00 - 17:30*

**Protocol Representation Course**  
*Tuesday, 17 April: 09:00 - 12:30*

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, 17 April: 09:00 - 17:30*

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.

12:30 – 14:00    Lunch

*Strength Through Collaboration*
**CDISC Advisory Board Meeting with Private Q & A**  
*(CDISC Platinum Member CAB Representatives Only – BY INVITATION)*  
*Tuesday, 17 April: 16:30 – 18:00*

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**INVITATION**

You are cordially invited to attend a meeting of the CDISC Advisory Board (CAB) and the European CDISC Coordinating Committee (E3C).

Enjoy a private Question & Answer Session with CDISC Board Members, CDISC Operations Leadership and Interchange Plenary Session speakers (e.g., FDA, C-Path, ISO) on CDISC Technical Strategy, CDISC Strategic Goals, Collaborations and development of Therapeutic Area Standards.

16:30-18:00 on Tuesday, 17 April 2012 (reception 16:00-16:30)  
Elite Hotel Marina Tower - Stockholm, Sweden

*Please RSVP by no later than 5 April to Sheila Leaman (sleaman@cdisc.org)*  
*If you cannot attend, please consider designating an alternate in Europe.*

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**WEDNESDAY, 18 April 2012 – Interchange Conference**

- **08:00 - 17:00**  
  Exhibition Open

- **07:30 – 17:00**  
  CONFERENCE REGISTRATION

- **09:00 - 10:30**  
  Session 1: Opening Plenary  
  Paula Brown Stafford, Chair, CDISC Board of Directors

  *Session Chair: Pierre-Yves Lastic, CDISC Board of Directors*

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

  **CDISC Technical Roadmap**  
  *Wayne Kubick, Chief Technical Officer, CDISC*

  **International Perspectives on Data Standards**  
  *Professor Marie Lindquist, CEO of Uppsala Monitoring Centre*

  **Connectivity between CDISC and ISO**  
  *Lisa Spellman, ISO*

- **10:30 – 11:00**  
  Break
11:00 – 13:00  
**Session 2: Second Plenary Session**  
*Session Chair: Rebecca Kush, President and CEO, CDISC*

- **Data Standards in FDA – Challenges and Process**  
  *Mary Ann Slack, Charles Cooper, FDA*

- **State of the IMI Projects**  
  *Bernard de Bono, European Bioinformatics Institute*

- **CDISC and C-Path Partnership on Therapeutic Area Projects**  
  *Bron Kisler, CDISC*

- **History of CDISC Standards – Implementation at AstraZeneca**  
  *Johannes Ulander, AstraZeneca*

13:00 - 14:30  
**Lunch**

14:30 – 16:00  
**Parallel Tracks: Session 3 & 4**

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<thead>
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<th><strong>Wednesday, 18 April: 14:30 – 16:00</strong></th>
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<tr>
<td><strong>Parallel Track 1</strong></td>
<td><strong>Parallel Track 2</strong></td>
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<tr>
<td><strong>Session 3: BRIDG</strong></td>
<td><strong>Session 4: CDASH</strong></td>
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<tr>
<td><em>Chair: Dave Iberson-Hurst, Assero</em></td>
<td><em>Chair: Barry Burnstead, SelectCRO</em></td>
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</table>
| BRIDGing to Improve Connection with Patients and Providers: A Case Study  
  *Sue Dubman, Genzyme*  
  Implementing a BRIDG based canonical data model as the core of system integration: a concrete approach with lessons learned  
  *Isabelle Zegher, Perceptive*  
  Under the Umbrella of HL7 and BRIDG: Future of data integration between PV(E2B) and CDM  
  *Joerg Dillert, Oracle* | CDASH – Linking Data Management to Programming and vice-versa  
  *Caroline Francis, Quanticate International Ltd*  
  CDASH-E2B  
  *Sonia Araujo & Gary Walker, Medidata Solutions & Quintiles*  
  CDISC-AdvaMed Device Project: Building Consensus to Define Device CDASH and SDTM Standards  
  *Rhonda Facile, CDISC* |

16:00 – 16:30  
**Break**

*Strength Through Collaboration*
<table>
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<tr>
<th>Time</th>
<th>Parallel Track: Sessions 5 &amp; 6</th>
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<tr>
<td><strong>16:30 – 18:00</strong></td>
<td><strong>Parallel Track 1</strong></td>
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<tr>
<td><strong>Wednesday, 18 April: 16:30 – 18:00</strong></td>
<td><strong>Session 5: ODM / XML</strong></td>
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<td><strong>Session Chair: Philippe Verplancke, Xclinical</strong></td>
<td><strong>Parallel Track 2</strong></td>
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<tr>
<td><strong>Wednesday, 18 April: 16:30 – 18:00</strong></td>
<td><strong>Session 6: Requirements of Early Phase Research</strong></td>
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<tr>
<td><strong>Session Chair: Joerg Dillert, Oracle</strong></td>
<td><strong>Wednesday, 18 April: 16:30 – 18:00</strong></td>
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<tr>
<td>Multipurpose usage of the new &quot;Study Design Model in XML&quot; (SDM-XML)</td>
<td>The Development and Status of SEND. Lessons learned during the FDA-SEND phase 2 pilot</td>
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<tr>
<td><strong>Jozea Aerts, University of Applied Sciences FH Joanneum</strong></td>
<td><strong>Gitte Frausin, Novo Nordisk</strong></td>
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<tr>
<td>EDC System migration using CDISC ODM</td>
<td>Introducing an eSource system in a Phase I unit and processing eSource data downstream</td>
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<tr>
<td><strong>Alan Yeomans, Pharma Consulting Group</strong></td>
<td><strong>Els Cochez &amp; Joris De Bondt, SGS Life Science Services</strong></td>
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<tr>
<td>Impact of CDISC ODM on the Vendor Selection Process for an eClinical Solution</td>
<td>Visit numbering in SDTM for Early Phase trials</td>
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<tr>
<td><strong>Stephane Auger, Danone</strong></td>
<td><strong>Berit Ulbrich-Bortfeldt, Parexel</strong></td>
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<tr>
<td>Ask the Expert Panel Session</td>
<td>Protocol Representation Model in the Real World</td>
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<td></td>
<td><strong>Michelle Marlborough, MDS</strong></td>
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**19:00 – 22:30 NETWORKING EVENT**

**CDISC Boat Dinner**
**THURSDAY, 19 April 2012 – Interchange Conference**

**09:00 – 10:30**  
Parallel Tracks: Session 7 & 8

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<th><strong>Thursday, 19 April: 09:00 – 10:30</strong></th>
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<tr>
<td><strong>Parallel Track 1</strong></td>
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<tr>
<td><strong>Session 7: SDTM</strong></td>
<td><strong>Session 8: EHR</strong></td>
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<tr>
<td><em>Chair: Herbert Noack, Boehringer Ingelheim Pharma GmbH &amp; Co. KG</em></td>
<td><em>Chair: Isabelle deZegher, Perceptive</em></td>
</tr>
<tr>
<td>CDER Common Data Standards Issues and SDTMIG 3.1.2 Amendment 1</td>
<td>Clinical Trials powered by electronic Health Records</td>
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<tr>
<td><em>Peter Van Reusel, Business &amp; Decision Life Sciences</em></td>
<td><em>David Moner, Universitat Politècnica de València</em></td>
</tr>
<tr>
<td>Can Clinical Data Survive the CDISC Submission Standards?</td>
<td>Japanese Sentinel and MIHARI Project</td>
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<tr>
<td><em>Thierry Lambert, AdClin</em></td>
<td><em>Michio Kimura &amp; Kiyoteru Takenouchi, Hamamatsu University School of Medicine &amp; CMIC</em></td>
</tr>
<tr>
<td>SDTM and ADaM domains and impact of Adaptive Trials</td>
<td>Report from the EHR4CR Project</td>
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<tr>
<td><em>Peter Abbe, Theorem Clinical Research</em></td>
<td><em>Pierre-Yves Lastic, Sanofi Aventis, CDISC Board Chair</em></td>
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**10:30 – 11:00**  
Break

**11:00 – 13:00**  
Parallel Track: Sessions 9 & 10

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<tr>
<th><strong>Thursday, 19 April: 11:00 – 13:00</strong></th>
<th><strong>Thursday, 19 April: 11:00 – 13:00</strong></th>
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<tr>
<td><strong>Parallel Track 1</strong></td>
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<tr>
<td><strong>Session 9: ADaM</strong></td>
<td><strong>Session 10: Metadata</strong></td>
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<tr>
<td><em>Session Chair: Peter Van Reusel, Business &amp; Decision Life Sciences</em></td>
<td><em>Session Chair: Jason Housley, Shire Plc.</em></td>
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<tr>
<td>ADaM &amp; SDTM in CDER; Needs &amp; Challenges</td>
<td>Semantic Models for CDISC Based Standards and Metadata Management</td>
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<tr>
<td><em>Charles Cooper, FDA</em></td>
<td><em>Frederick Malfait and Kerstin Forsberg, IMOS &amp; AZ</em></td>
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<tr>
<td>Define.xml: Moving from SDTM to ADaM, Challenges and opportunities of a metadata driven approach</td>
<td>What Does Meta-Data Processing actually mean?</td>
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<tr>
<td><em>Dimitri Kutsenko, Entimo AG</em></td>
<td><em>Barry Cohen, Octagon</em></td>
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<td>Defining the Development Process and Governance of Implementing ADaM within an Organization</td>
<td>SHARE Content Development</td>
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<tr>
<td><em>Chris Decker, d-Wise Technologies</em></td>
<td><em>Melissa Cook &amp; Rhonda Facile, Octagon &amp; CDISC</em></td>
</tr>
<tr>
<td>ADAE – Top to Bottom Guide from Planning to Usage</td>
<td>Preparing the old world for the new in a mid-sized Pharmaceutical Company</td>
</tr>
<tr>
<td><em>Nate Freimark, Theorem Clinical Research</em></td>
<td><em>Dave Iberson-Hurst &amp; Francesca Massa-Rolandino, Assero &amp; Actelion</em></td>
</tr>
</tbody>
</table>
13:00 – 14:30  Lunch

14:30 – 15:30  Session 11: Podium Discussion
Standards Accepted for Progress; CDISC the Reliable Partner - Ask the Experts from FDA, IMI and Industry Experts
Session Chair: Pierre-Yves Lastic, Chair, CDISC Board of Directors

15:30 – 16:00  Break

16:00 – 17:15  Session 12: Closing Plenary
Session Chair: Pierre-Yves Lastic, Chair, CDISC Board of Directors

Reports from the User Groups
Group Representatives

Reports from the Global CDISC ‘3 Cs’
Group Representatives

Feedback from the Expert Sessions
Facilitators

Announce Winner of Poster Session + short presentation on the topic
Author of Poster

Europe’s role in the CDISC Success
Pierre-Yves Lastic, Chair, CDISC Board of Directors

Strength Through Collaboration
FRIDAY, 20 April 2012

12:30 – 14:00      Lunch

CDASH Implementation Course
Friday, 20 April: 09:00 – 17:30

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.

BRIDG Deep Dive Workshop
Friday, 20 April: 09:00 – 17:30

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 workshop is a more detailed and advanced follow-up to the Intro to BRIDG course. This one day workshop will provide a stronger understanding of the BRIDG model and help in deciding how to leverage these domain semantics for clinical research related applications or other implementations at your organization.

This full-day workshop will cover:

• A high level overview of BRIDG Model Content
• A detailed review of the 5 sub-domains
• An introduction to the ISO data types Detailed walk-thru of the Model using some common processes of clinical research
• Open discussion period to identify semantics for an audience generated use case
• Introduction to the BRIDG harmonization process
• How to work with the BRIDG SCC and harmonize your project semantics

Prerequisites:

• Experience with modeling data structures--e.g, data models, ERD, UML, logical and physical database design, etc.
• Intro to BRIDG (CDISC training--optional)
• Basic knowledge of clinical trials concepts and processes
• Experience with requirements analysis/modeling tool (e.g., Rational Rose, Enterprise Architect, Oracle Designer, ERWin, etc. (Recommended, not required)
Legacy Data Conversion Workshop  
*Friday, 20 April: 09:00 – 12:30*

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

Controlled Terminology Implementation Course  
*Friday, 20 April: 13:30 – 17:30*

CDISC Controlled Terminology is a set of standard value lists that are used throughout the clinical research process from data collection through analysis and submission.

This half-day course will cover:

- Brief history of CDISC terminology
- Primary objectives, guiding principles
- How terminology is developed and maintained
- The Implementation Guide
- Basics of using terminology
- A discussion of codelist extensibility
- Accessing controlled terminology
- Requesting new terms

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

CDISC Interchange Japan 2012
10-13 July 2012
10-11 July Interchange Conference, and 12-13 July 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 16 April

09:00 - 17:30 SDTM Theory & Application Training Course (Day one)
09:00 - 17:30 ODM Implementation Training Course
12:30 - 14:00 Lunch

TUESDAY 17 April

09:00 - 17:30 SDTM Theory & Application Course (Day two)
09:00 - 17:30 ADaM Implementation Course
09:00 - 12:30 Protocol Representation Course
16:30 - 22:30 CAB Meeting with FDA (Platinum Members Only by Invitation)
12:30 - 14:00 Lunch

WEDNESDAY 18 April

08:00 - 17:30 Industry Exhibitors
09:00 - 18:00 Interchange Conference Presentations
19:00 – 22:30 Evening Event on a Boat Ride!
13:00 - 14:30 Lunch

THURSDAY 19 April

08:00 - 17:30 Industry Exhibitors
09:00 - 17:15 Interchange Conference Presentations
13:00 - 14:30 Lunch

FRIDAY 20 April

09:00 - 17:30 CDASH Implementation Course
09:00 - 17:30 BRIDG Deep Dive Workshop
09:00 - 12:30 Legacy Data Conversion Workshop
14:00 - 17:30 Controlled Terminology Implementation Course
12:30 – 14:00 Lunch

Strength Through Collaboration