CDISC Europe Interchange

22 – 26 April 2013
Elvis-Presley-Platz 1
Bad Nauheim c/o Frankfurt
Germany

Strength Through Collaboration
INTERCHANGE SCHEDULE

MONDAY, 22 April 2012

SDTM Theory & Application Course (first day of a two-day training)
Monday, 22 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.

BRIDG Deep Dive Course
Monday, 22 April: 09:00 – 17:00

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.

TUESDAY, 23 April 2012

SDTM Theory & Application Course (day 2 of a two-day training)
Tuesday, 23 April: 09:00 - 17:30

ADaM Implementation Course
Tuesday, 23 April: 09:00 - 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.
CDISC Advisory Board Meeting with Private Q & A
(CDISC Platinum Member CAB Representatives Only – BY INVITATION)
Tuesday, 23 April: 16:00 – 18:00

Exhibition Booth Setup
Tuesday, 23 April: 18:00 – 20:00

WEDNESDAY, 24 April 2012 – Interchange Conference

08:00 - 17:00  Exhibition Open
07:30 – 17:00  CONFERENCE REGISTRATION
09:00 - 10:30  Session 1: Opening Plenary
  Session Chair: Peter Van Reusel, Chairman of CDISC E3C
  - The State of the CDISC Union
    Dr. Rebecca Kush, President and CEO, CDISC
  - State of the IMI Project
    Michel Goldman, IMI
  - Data Standards Initiative of TransCelerate/Biopharma (Hever Group)
    Dalvir Gill, CEO, TransCelerate Biopharma

10:30 – 11:00  Break

11:00 – 12:30  Session 2: Second Plenary Session
  Session Chair: Dr. Rebecca Kush, President and CEO, CDISC
  - Clinical Trial Data Transparency Initiative
    Frank Petavy, EMA
  - Data Standards in FDA - Challenges and Process
    Charles Cooper, FDA
  - CDISC Technical Roadmap
    Wayne Kubick, CTO, CDISC

12:30 - 14:00  Lunch
### Parallel Tracks: Session 3 & 4

#### Wednesday, 24 April: 14:00 – 15:30

**Parallel Track 1**

**Session 3: SDTM and ADaM**  
*Chair: Wayne Kubick, CDISC, CTO*

- What’s new in SDTMIG 3.1.3  
  Anne Sophie Bekx, Business and Decision
- ADLB: a real-life example  
  Pierre Dostie, Boehringer, Ingelheim
- Anonymizing Clinical Datasets for Publication  
  Pierre-Yves Lastie, Sanofi

**Parallel Track 2**

**Session 4: MDR**  
*Chair: Andrea Rauch, Boehringer-Ingelheim*

- The Right Stuff: A Jahrzehnt (Decade) of NCI Metadata Registry Lessons  
  Dianne Reeves, Denise Warzel & David Patton, NCI
- From Metadata to Workflow Automation  
  Jonathan Chainey & Frederik Malfait, Hoffmann-La Roche Ltd / IMOS Consulting
- Metadata Registry Implementation: Challenges of Developing and Using Trial-level Metadata  
  Barry Cohen, Octagon Research

#### 15:30 – 16:00

**Break**

#### 16:00 – 17:30

**Parallel Track: Sessions 5 & 6**

#### Wednesday, 24 April: 16:00 – 17:30

**Parallel Track 1**

**Session 5: Therapeutic Area Standards**  
*Session Chair: Bron Kisler, VP of Strategic Alliances, CDISC*

- Some Strategies for Filling, Managing, and Accessing SDTM Warehouses  
  Frank Roediger, SAS
- CFAST - Enhanced Standards Development Process and the Asthma Pilot Project  
  Rhonda Facile, CDISC
- Data Standards for Traumatic Brain Injury  
  Magali Haas, One Mind for Research

**Parallel Track 2**

**Session 6: End to End**  
*Session Chair: Wolfgang Summa, ERT*

- Achieving the ‘iTunes of Clinical Trials’: Storing and Sharing of Clinical Trial Content to Optimize the End-to-End Clinical Trial Process  
  Mark Wheeldon, Formedix
- It’s the semantics stupid! The last mile (or kilometer?) in interoperability between healthcare, clinical research and regulatory agencies  
  Jozef Aerts, University of Applied Sciences FH Joanneum
- Advantages of a real end-to-end approach with CDISC standards  
  Philippe Verplancke, XClinical
- Efficient Way to Generate Define.xml  
  Kanishk Singh, Cognizant

#### 19:00 – 22:00

**NETWORKING EVENT**
# Interchange Conference

**Thursday, 25 April 2012**

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

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<th>Time</th>
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<tr>
<td><strong>Thursday, 25 April: 09:00 – 10:30</strong></td>
<td><strong>Session 7: Validation</strong>&lt;br&gt;<em>Chair: Joerg Dillert, Oracle</em></td>
<td><strong>Session 8: Translational Medicine</strong>&lt;br&gt;<em>Chair: Nathalie Sabin, Clinical Data</em></td>
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<td>09:00 – 10:30</td>
<td>Checking the Checker: OpenCDISC says I need to do what&lt;br&gt;&lt;br&gt;<em>Kristi Garner, Theorem Clinical Research</em></td>
<td>Understanding and Optimizing the PRM Protocol Wizard&lt;br&gt;&lt;br&gt;<em>Joshua Pines, Medidata Solutions</em></td>
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<td>09:00 – 10:30</td>
<td>SDTM checks with a memory&lt;br&gt;&lt;br&gt;<em>Joris De Bondt, SGS</em></td>
<td>eTRIKS&lt;br&gt;&lt;br&gt;<em>Ian Dix, AstraZeneca</em></td>
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<td>09:00 – 10:30</td>
<td>Integrated Approach of Data and Metadata&lt;br&gt;&lt;br&gt;<em>Dimitri Kutsenko, Entimo AG</em></td>
<td>EHR4CR and Healthcare Link&lt;br&gt;&lt;br&gt;<em>INSERM</em></td>
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### 10:30 – 11:00 Break

### 11:00 – 12:30 Parallel Track: Sessions 9 & 10

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<th>Time</th>
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<tr>
<td><strong>Thursday, 25 April: 11:00 – 12:30</strong></td>
<td><strong>Session 9: Standards Governance in Pharma</strong>&lt;br&gt;<em>Session Chair: Mark Lambrecht, SAS</em></td>
<td><strong>Session 10: CDISC XML Standards</strong>&lt;br&gt;<em>Session Chair: Philippe Verplancke, XClinical</em></td>
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<td>11:00 – 12:30</td>
<td>Standards Governance at BI</td>
<td>The Future of ODM&lt;br&gt;&lt;br&gt;<em>Jozef Aerts, University of Applied Sciences FH Joanneum</em></td>
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<td>11:00 – 12:30</td>
<td>Standards Governance at Sanofi</td>
<td>Extracting CDISC ODM files from Oracle Based Clinical Data Management Systems&lt;br&gt;&lt;br&gt;<em>Iain Barnden, PharmaSOL</em></td>
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<td>11:00 – 12:30</td>
<td>Standards Governance at J&amp;J</td>
<td>Moving to Define.xml V2.0.0&lt;br&gt;&lt;br&gt;<em>Davy Baele, Business and Decision Life Sciences</em></td>
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### 12:30 – 14:00 Lunch
14:00 – 15:00  **Session 11: User Feedback Session**  
*Session Chair: Pierre-Yves Lastic, E3C and CDISC Board of Directors*

- Reports from User Groups  
  *Group Representatives*
- E3C Support in Europe  
  *Peter Van Reusel, E3C Chairman*
- Panel Session with CDISC, E3C and User Groups  
  *Bron Kisler and Diana Harakeh, CDISC, Philippe Verplancke, XClinical and Wolfgang Summa, E*

15:00 – 15:30  Break

15:30 – 17:15  **Session 12: Expert Panel, Q&A**  
*Frank Petavy, EMA, Charles Cooper, FDA, Wayne Kubick and Bron Kisler, CDISC, Dalvir Gill, TransCelerate Biopharm*

17:15 – 17:30  **Closing Plenary**  
*Peter Van Reusel. E3C Chairman*

*Strength Through Collaboration*
FRIDAY, 26 April 2012

CDASH Implementation Course
Friday, 26 April: 09:00 – 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 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.

Controlled Terminology Implementation Course
Friday, 26 April: 09:00 – 12:00

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

ODM Implementation Course
Friday, 26 April: 09:00 – 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. 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
- Strategies for implementing OMD within your organization

Recommendation: A working knowledge of XML or other mark-up languages is helpful to understanding the material presented.
CDISC International Interchange North America 2013
4 – 8 November 2013
Interchange Conference, Training and Workshops

Bethesda North Marriott Hotel and Conference Center
501 Marinelli Road
North Bethesda, MD 20852

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