CDISC 2013 Asia-Pacific Interchange

“Streamlining Global Research through Standards”

18-22 February 2013
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MONDAY, 18 February 2013

09:00 - 17:00  SDTM v3.1.3 Theory & Application Course (Day 1 of a 2-day class)
Instructor: Peter Van Reusel
The 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

TUESDAY, 19 February 2013

09:00 - 17:00  SDTM v3.1.3 Theory & Application Course (Day 2 of a 2-day class)
Instructor: Peter Van Reusel

09:00 - 17:00  Healthcare Link
Instructor: Landen Bain
Healthcare Link focuses on the mission of interoperability between healthcare (the EHR) and clinical research. CDISC and Integrating the Healthcare Enterprise (IHE) have created the inaugural working link between EHRs and clinical research systems. This is accomplished through use of the CDISC/IHE developed integration profile, Retrieve Form for Data-Capture profile (RFD), along with CDISC standards to collect relevant data from the electronic health record for critical secondary uses such as Safety Reporting (and Biosurveillance), Clinical Research, and Disease Registries. Reaching through to the EHR in this way to pull key data of interest to clinical research that is already existing in the EHR creates system interoperability and improves data quality, and most importantly timeliness of data sharing (key in safety reporting), while alleviating the Investigator site from supporting and entering data into multiple redundant data collection tools for the purpose of secondary uses.
09:00 - 12:00  Controlled Terminology Implementation Course
Instructor: Bron Kisler
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

FRIDAY, 22 February 2013

09:00 - 17:00  ADaM Implementation
Instructor: Tineke Callant
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

09:00 - 17:00  CDASH Implementation Course
Instructor: Lauren Shinaberry
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
# CDISC Interchange Conference

**WEDNESDAY, 20 February 2013**

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<th>Time</th>
<th>Event</th>
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<tr>
<td>07:30 - 17:30</td>
<td>Exhibition Open</td>
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<tr>
<td>07:30 - 18:00</td>
<td>Conference Registration</td>
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<td>08:00 – 09:00</td>
<td>Session 1: Opening Remarks</td>
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<td><strong>Speakers:</strong></td>
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<td>Dr. Kiyoteru Takenouchi (CDISC Board, CMIC)</td>
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<td>Paula Brown Stafford (CDISC Board Chair, Quintiles)</td>
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<td>Dr. Low Cheng Ooi (Singapore Ministry of Health)</td>
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<td>09:00 – 10:00</td>
<td>Session 2: Keynote Addresses</td>
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<td><strong>Facilitator:</strong> Dr. Rebecca Kush (CDISC)</td>
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<td><strong>Speakers:</strong></td>
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<td>Dr. Greg Koski (Harvard, ACRES)</td>
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<td>Dr. Yasuo Ohashi (University of Tokyo)</td>
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<td>10:00 – 10:30</td>
<td>Coffee Break</td>
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<td>10:30 – 12:00</td>
<td>Session 3: State of the CDISC Union</td>
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<td>This session will offer an abbreviated version of the CDISC introductory course “A Global Approach to Accelerate Medical Research” and an overview of the CDISC Strategy and Technical Roadmap.</td>
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<td><strong>Speakers:</strong></td>
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<td>Dr. Rebecca Kush (CDISC President and CEO)</td>
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<td>Wayne Kubick (CDISC Chief Technical Officer)</td>
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<td>12:00 - 13:00</td>
<td>Lunch Break</td>
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<td>13:00 - 15:15</td>
<td>Session 4: Case Studies with CDISC Standards</td>
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<td><strong>Facilitator:</strong> Wayne Kubick (CDISC)</td>
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<td><strong>Speakers during this session will present case studies on the utilization of CDISC standards based upon submitted abstracts</strong></td>
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<td><strong>Speakers:</strong></td>
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<td>Kunihito Ebi (Fujitsu)</td>
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<td></td>
<td>“The Value of CDISC Standards End to End”</td>
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<td>Peter Van Reusel (Business &amp; Decision Life Sciences)</td>
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<td>“Getting the Most Out of CDASH and SDTM”</td>
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<td>Gaurab Chakraborty (Theorem Clinical Research)</td>
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<td>“Building ADaM from SDTM: A Case Study”</td>
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Use of CDISC by the Japan Translational Research Informatics Center (TRI): Jyouno, Tsuji and Yamada (TRI)

And Dr. Yoji Nagai (TRI)
“Application of CDISC Standards to Alzheimer’s Disease Study: Lessons and Achievements”

15:15 - 15:45  Coffee Break

15:45 - 17:30  Session 5: The Status of Clinical Research around the Globe
Facilitator: Dr. Greg Koski (Harvard, ACRES)

During this session, panelists will give a short update on the status of clinical research in their country. Topics will include the situation of the past and current usage of CDISC standards in clinical research, the strategy of regulatory authorities in these nations, alliances between industry and academia, and discussion of the future of CDISC in each country.

Panelists:
Singapore: Foo Yang Tong (Singapore Health Sciences Authority)
India: Dr. Sauren Das (Excel Life Sciences)
Japan: Dr. Yoshio Tsukada, (GlaxoSmithKline, J3C) and Yumiko Asami (Daiichi Sankyo, CJUG)
China: Victor Wu (Covance) and Yao Chen (Beijing University)
Australia: Dr. Ric Day (University of New South Wales)
Thailand: Dr. Jaranit Kaewkungwal (Mahidol University)
South Korean Speaker Invited

17:30 - 17:45  Session 6: Closing Remarks

Dr. Kiyoteru Takenouchi (CDISC Board, CMIC) will give the closing remarks.

18:00 - 19:00  NETWORKING RECEPTION
THURSDAY, 21 February 2013

08:00 - 16:00  Exhibition Open
08:00 - 17:30  Conference Registration
08:30 - 10:00  Session 7a: Clinical Research and Hospital Information Systems/EHRs
Facilitator: Dr. Ken Toyoda (CReS Kyushu)
Dr. Ken Toyoda of CReS will lead the discussion for Session 7, to be followed by time for panel discussion.

Speakers:
Dr. Michio Kimura (Hamamatsu University, Japan)
“Japanese Sentinel Project”
Dr. Jaranit Kaewkungwal (Mahidol University, Thailand)
“EHRs for Tracking Outbreaks (e.g. TB) and Other Safety Surveillance”
Singapore Speaker Invited

10:00 - 10:30  Coffee Break
10:30 - 12:00  Session 7b: Clinical Research and Hospital Information Systems/EHRs
Facilitator: Dr. Ken Toyoda (CReS Kyushu)

Speakers:
Dr. Pierre-Yves Lastic (CDISC Board, Sanofi)
“IMI EHR4CR Project”
Landen Bain (CDISC)
“CDISC Healthcare Link”
Panel Discussion with all Session 7 speakers to follow presentations

12:00 - 13:00  Lunch Break
13:00 - 15:15  Session 8: Global Standards Harmonization
Facilitator: Partha Chakraborty (Cognizant)
This session will cover the topics of global standards harmonization, terminology and use cases.

Speakers:
Michael Glickman (ISO TC 215 and IHE, CDISC Board)
Dr. Ramesh Krishnamurthy (World Health Organization)
SFDA Representative Invited
FDA Representative Invited

15:15 - 15:45  Coffee Break
15:45 - 17:15  Session 9: Therapeutic Area Specific Standards
Facilitators: Bron Kisler, CDISC
This session will cover experiences developing the CDISC therapeutic area standards, progress that has been made in this arena, implementation of the standards, and future plans.

Speakers:
Bron Kisler (CDISC)
“Coalition for Accelerating Standards and Therapies”

Dr. Yuji Kumagai (Kitasato University, Japan)
“Clinical Trials in Cardiovascular Research Utilizing Biomarkers”
“Traditional Chinese Medicine Standards”
Speaker Invited

“IMI and Therapeutic Area Standards”
Innovative Medicines Initiative Speaker Invited

17:15 - 17:30  Session 10: Closing Remarks
Dr. Kiyoteru Takenouchi (CDISC Board, CMIC) will give the closing remarks.