CDISC 2012 International Interchange

“Accelerating Therapies through Standards”

22-26 October 2012
Renaissance Harborplace Hotel
Baltimore, Maryland
USA
# CDISC Official Training Courses

## MONDAY, 22 October 2012

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<tr>
<th>Time</th>
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<tr>
<td>09:00 - 17:00</td>
<td>SDTM Theory &amp; Application Course (Day 1 of a 2 day training)</td>
<td>Shannon Labout</td>
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<td>09:00 - 17:00</td>
<td>ODM Implementation Course</td>
<td>Sally Cassells</td>
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<tr>
<td>09:00 - 17:00</td>
<td>ADaM Implementation</td>
<td>Dana Soloff</td>
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## TUESDAY, 23 October 2012

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<tr>
<td>09:00 - 17:00</td>
<td>SDTM Theory &amp; Application Course (Day 2 of a 2 day training)</td>
<td>Shannon Labout</td>
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<td>09:00 - 17:00</td>
<td>CDASH Implementation Course</td>
<td>Kit Howard</td>
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<td>09:00 - 17:00</td>
<td>Deep Dive BRIDG Workshop</td>
<td>Smita Hastak</td>
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<td>09:00 - 12:00</td>
<td>Controlled Terminology Implementation Course</td>
<td>Bron Kisler Erin Muhlbradt</td>
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<tr>
<td>13:00 - 17:00</td>
<td>Global Approach to Accelerating Medical Research</td>
<td>Bron Kisler and Frank Newby</td>
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<tr>
<td>15:00 - 18:00</td>
<td>CDISC Advisory Board Meeting</td>
<td>CDISC Platinum Member Representatives - by invitation only</td>
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CDISC Interchange Conference

WEDNESDAY, 24 October 2012

08:00 - 18:00  Exhibition Open
08:00 - 18:00  Conference Registration
08:30 - 10:30  Session 1: Opening Plenary
Facilitators: Dr. Rebecca Kush (CDISC) and Dr. Carolyn Compton (C-Path)

Opening Remarks
Paula Brown Stafford (CDISC Board Chair, Quintiles)

INTERCHANGE KEYNOTES
-The Future of Data Standards by Dr. Janet Woodcock (FDA - CDER)
-Ann Martin (IMI)

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

10:30 - 11:00  Coffee Break

11:00 - 12:15  Session 2: Stakeholder Perspectives on Disease Area Standards
Facilitator: Dr. Carolyn Compton (C-Path)
This session will focus on the various perspectives of those who use CDISC standards for clinical research and those who may potentially use them to link with healthcare. The ideas and suggestions from these different perspectives will be discussed in consideration for the launch of new therapeutic area standards development projects through CFAST. There will be a brief opening presentation to stimulate the discussion by a facilitated panel.

Panelists:
Dr. Ron Fitzmartin (FDA-CDER)
Dr. Douglas Peddicord (Association of Clinical Research Organizations-ACRO)
Peter Loupos (Sanofi)
Sue Dubman (Genzyme – Sanofi, and Michael J. Fox Foundation volunteer)
John Dwyer (USAagainstAlzheimer’s)
Dr. Steven Hirschfeld (NICHD/NIH)
Steven Posnak (HHS/ONC)
12:30 - 13:30  Lunch Break, Posters & Exhibits

13:30 - 14:45  Session 3: Experiences with Disease Area Standards to Date
Facilitator: Bron Kisler (CDISC)
The experiences to date in developing and implementing disease areas standards will be the focus of this session. There will be opening remarks from those who have had different ‘experiences’ – positive and constructive, followed by a facilitated panel discussion on the barriers, the successes and the remaining needs for those who will develop new disease area standards and put them to use.

Panelists:
- Enrique Aviles (C-Path)
- Dr. Youji Nagai (Japan Translational Research Informatics Institute)
- Margaret Haber (NIH/NCI)
- Dr. Chuck Cooper (FDA-CDER)
- Jane Diefenbach (Pharmastat)
- Dr. Meredith Nahm (Duke University)

14:45 - 15:15  Coffee Break

15:15 - 16:30  Session 4: Where Should We Be Going?
Facilitator: Dr. Rebecca Kush (CDISC)
This session will explore where CDISC/CFAST should be heading. What has the greatest potential for success? How could standards be beneficial to society? Each of these presenters will show 1-5 slides and a facilitated Q&A session will follow.

Panelists:
- Dr. Magali Haas (One Mind for Research)
- Dr. Charles Hugh-Jones (DataSphere, CEO Roundtable on Cancer)
- Dr. Dave Jordan (TransCelerate Biopharma)
- Nora Belcher (TX eHealth Alliance & Cancer Prevention Research Institute of Texas)
- Joshua Rubin (Joseph H. Kanter Family Foundation, Learning Health Community)

16:30 - 17:30  Session 5: CDISC Standards, Now and New
Wayne Kubick, CDISC Chief Technical Officer, will close the day’s discussion by discussing the current state of CDISC standards, recent team accomplishments and upcoming plans, the role of the Standards Review Council, and how these relate to the Technical Roadmap. He will also provide an introduction to our new standards development process for both Therapeutic Area and Foundational Standards, which will be explored in depth on Day 2.

18:00 - 20:00  NETWORKING RECEPTION
THURSDAY, 25 October 2012

08:00 - 17:30  Exhibition Open
08:00 - 18:00  Conference Registration
09:00 - 10:30  Session 6: Information Requirements for Therapeutic Area Standards

Opening Remarks
Wayne Kubick (CTO, CDISC)

Information Requirements for Therapeutic Area Standards
Facilitator: Rhonda Facile (CDISC)
This session will provide a practical introduction to the initial phase of the proposed new CDISC standards development process, including how to use concept models to understand the key data elements in therapeutic areas, relationships among these data elements, and how to use the BRIDG model in defining new standards. Speakers will demonstrate specific, practical examples of how this part of the new process can be applied to both new therapeutic area projects and the future work on foundational projects.

Panelists:
Dr. Diane Wold (GlaxoSmithKline)
Julie Evans (CDISC)
Smita Hastak (Samvit Solutions)

10:30 - 11:00  Coffee Break
11:00 - 12:15  Session 7: Producing Usable Therapeutic Area Standards

Facilitator: Rhonda Facile (CDISC)
This session will continue with practical demonstrations that explore the main development phase of the proposed new CDISC standards development process. Speakers will illustrate in detail how to use SHARE-based tools for representing information concepts and relationships and how this can drive an integrated end-to-end process of CDISC standards from protocol through data collection, tabulation and analysis.

Speakers
Dr. Diane Wold (GlaxoSmithKline)
Dave Iberson-Hurst (Assero)
Dr. Erin Muhlbradt (NCI-EVS)

Presentations followed by Panel Discussion on Developing CDISC Therapeutic Area Standards.

12:15 - 13:30  Lunch Break, Posters & Exhibits
13:30 - 15:00  
**Session 8: CDISC Standards at FDA**  
*Facilitator: Frank Newby (CDISC)*  
Our traditional FDA standards update session will feature FDA speakers discussing the impact of PDUFA V and how FDA is using CDISC standards for non-clinical and clinical review and analysis. The session will also include an update on the Computation Science Symposium Working Groups. Discussion and Q&A will follow.

**Speakers:**  
- Dr. Chuck Cooper (FDA-CDER)  
- Amy Malla (FDA-CDER)  
- Dr. Lauren Mihalcik (FDA-CDER)  
- Ted Peterson (FDA-CDRH)  
- Dr. Steve Wilson (FDA-CDER)

15:00 - 15:30  
**Coffee Break**

15:30 - 17:00  
**Session 9: Pulling It All Together: A Roundtable Discussion**  
*Facilitators: Dr. Pierre-Yves Lastic (Sanofi) and Dr. Steve Wilson (FDA-CDER)*  
This closing session will open with a presentation by Dr. Hirschfeld on the National Children’s Study, a massive, long-term research project, which demonstrates the importance of using standards from data collection through analysis.

**Speaker:**  
- Dr. Steven Hirschfeld (NICHHD)  

**Presentation followed by Q&A**  
Roundtable with FDA and CDISC leaders

**Overview of Day 3 Plans & Concluding Remarks**

**FRIDAY, 26 October 2012**

08:30 - 15:30  
**Session 10: CDISC Intrachange: A Dialogue Among Teams**  
*Facilitators: CDISC Team Leads*  
This special add-on session is open to all active CDISC team members and those interested in participating on CDISC standards development teams (newcomers will be asked to attend as observers and to sign up to participate in future team activities). The Intrachange will begin with a plenary session that reviews key points from the Interchange and other current topics of interest relevant to CDISC teams. Attendees will then break into sub-groups to discuss specific topics of importance to current foundational teams, to discuss plans for the coming year, and to explore the impact of therapeutic area and new processes on CDISC standards development. Breakouts will regroup in the afternoon to share what they have learned and discuss next steps in a closing plenary session.
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