CDISC International Interchange 2012

Renaissance Baltimore Harborplace Hotel
202 East Pratt Street
Baltimore, Maryland 21202 USA
CDISC Authorized Education
Monday & Tuesday, 22, 23 October 2012

CDISC Advisory Committee Meeting
(CDISC Platinum Member Representatives only)
3-6 pm Tuesday, 23 October

Conference on Wednesday, Thursday & Friday
(Days 1-3) 24, 25 & 26 October 2012:
Sign up for Day 1, Day 2, Day 3
or any combination of these three Conference Days!
CDISC 2012 Interchange Theme: Accelerating Therapies through Standards

In surveys on what CDISC can do to bring more value, we heard “Complete ALL of the Standards!”

PDUFA V Commitment Letter cites CDISC Standards

“Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards development organizations (i.e., the Clinical Data interchange Standards Consortium (CDISC)) with the goal of completing clinical data terminology standards and detailed implementation guides by FY 2017.”
FDA Perspective – Collaborating on a Shared Need

In 2011, Dr. Janet Woodcock stated that “the lack of clinical data standards and accurate databases that truly describe the progression of diseases is a major obstacle to rapid advances in the development of new therapies.”

Mary Ann Slack
Deputy Director, Office of Planning and Informatics
Center for Drug Evaluation and Research
Food and Drug Administration

July 2012
FDA Perspective – Collaborating on a Shared Need

- Using input from Industry, review of current INDs and discussions with reviewers, FDA identified a set of therapeutic/disease areas (referred to as TA or DA)

- 58 DAs currently identified and organized into priority groupings on a roadmap posted on FDA’s website

- FDASIA Section 1136: FDA final guidance requirements for electronic data standardization will be enforceable
  - Create a plan for distinct therapeutic area standards, their prioritization and development in collaboration with CDISC and other open standards organizations
  - Solicit input from the public; Issue draft and later final guidance
CFAST is an initiative to accelerate clinical research and medical product development by facilitating the creation and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health.

- To date, CDISC has either released draft or provisional standards packages covering five different disease areas: Parkinson’s, Alzheimer’s, Tuberculosis, Virology and Pain.
- Near-term releases will include therapeutic area standards packages for Polycystic Kidney Disease, Cardiovascular Disease and Schizophrenia.
- The next therapeutic areas are being determined now.
Wednesday, 25 October 2012, Conference Day 1
THE Day for Everyone, even those new to CDISC!

KEYNOTES: Dr. Janet Woodcock, FDA
and Ann Martin, IMI

Stakeholder Perspectives on Disease Area Standards
(FDA, CROs, Government, Biopharma, Patient Advocates)

Experiences to Date with Disease Area Standards
(TB, CV, Pain, Parkinson’s, Alzheimer’s, etc.)

Where Should We be Going?
One Mind for Research
DataSphere (biopharma Oncology Data Sharing)
Texas eHealth Alliance
The Hever Group

CDISC Standards, Now and Then – Wayne Kubick, CTO
Thursday, 25 October 2012
Conference Day 2

Information Requirements for Therapeutic Area Standards

Producing Usable Therapeutic Area Standards

CDISC Standards at FDA

Pulling it all Together: A Roundtable Discussion

Facilitated by Wayne Kubick, CDISC CTO
CDISC Team Leaders and
CDISC Board Chair-Elect, Pierre-Yves Lastic
with Multiple FDA Participants
**Friday, 25 October: CDISC INTRAchange**

- An opportunity to review, discuss and reflect with other CDISC users and team leaders
- Geared toward current and prospective team members
- Includes plenary and breakout sessions
- Topics for discussion will include:
  1. Coordinating new therapeutic area standards projects with existing SDTM, ADaM, CDASH, Terminology teams
  2. Delving into the details of developing new standards
  3. XML Technologies for transport of CDISC standards
  4. Integration of Clinical, Non-Clinical, Device and genomics data standards
  5. And more topics of interest within and among teams.
Why should you and your colleagues attend?

• To hear directly from the FDA representatives on how they are using CDISC standards, now and in the future, under PDUFA V

• To obtain the latest insight into the current status and plans for ALL of the CDISC standards, including the new Therapeutic Area standards

• To understand and discuss how the new CDISC processes will influence future development of both Foundational and Therapeutic Area CDISC standards (and the processes need all disciplines to be involved)

• To have the opportunity to interact with FDA, fellow adopters, and CDISC managers and team members to discuss future plans, resolve important issues, and become involved in standards development activities

• To gain firsthand knowledge of current and future CDISC team activities.
Why CDISC newcomers attend?

• To hear from patient advocates, stakeholders and industry and regulatory leaders about the value of standards for accelerating new therapies for patients
• To learn how CDISC global clinical research standards can streamline research from protocol through reporting and analysis
• To gain and provide insight into disease/therapeutic area standards and how they will be created through CFAST.
• To see what vendors have to offer in terms of tools for using the CDISC standards
• To have the opportunity to become part of the CDISC community – and learn how that can help you in the future.
CDISC Authorized Educational Courses

MONDAY, 22 October 2012
• SDTM Theory & Application Course (Day 1 of a 2 day training)
  ▪ ODM Implementation Course
  ▪ Healthcare Link Course
  ▪ ADaM Implementation

TUESDAY, 23 October 2012
• SDTM Theory & Application Course (Day 2 of a 2 day training)
  ▪ CDASH Implementation Course
  ▪ Deep Dive BRIDG Workshop
  ▪ Controlled Terminology Implementation Course
  ▪ Global Approach to Accelerating Medical Research
  ▪ CDISC Advisory Board Meeting

CDISC Platinum Member Representatives - by invitation only
Make sure to check arrival and departure dates

Make sure discount code = cdicdia
Support CDISC’s vital work and Promote your organization through:

- **Sponsorship** – a variety of sponsorship opportunities are available – see the CDSIC website for details

- **Exhibiting** – arrange an exhibit space to advertise your capabilities

Details can be found here: http://www.cdisc.org/interchange
Evening Event
All information on the CDISC International Interchange can be found here:

http://www.cdisc.org/interchange

Learn, Converse, Support the Mission at the Interchange!