

11 February 2011



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Setting the Global Standard for Medical Research



Strength through Collaboration

CDISC - Membership and Education Offerings

Presented by Diana El Harakeh



Strength through Collaboration

CDISC

- The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of health care.
- The CDISC Vision is to Inform Patient Care and Safety Through Higher Quality Medical Research

CDISC Standards

- CDISC Standards are **freely available** and can be accessed here:
<http://www.cdisc.org/standards>.
- The Standards are regularly updated and these updates are announced in the CDISC newsletter and on the website, so make sure you check back regularly at www.cdisc.org and that you have signed onto our e-mail list via the website.

CDISC Standards

- [ADaM](#)
- [BRIDG Model](#)
- [CDASH](#)
- [Define.XML](#)
- [Healthcare Link Initiative](#)
- [LAB](#)
- [Operational Data Model](#)
- [Protocol](#)
- [SEND](#)
- [CDISC SHARE](#)
- [Study Data Tabulation Model](#)
- [Study/Trial Design Model](#)
- [Terminology](#)
- [Therapeutic Area Standards](#)
- [Glossary](#)

CDISC Standards/Innovations

- CDISC is also working on additional projects through which it feels it is adding value for its members. Included among these projects:
 1. Open template/tool for the protocol representation standard
 2. The Healthcare link initiative
(using EHRs for research)

How would you sum up what CDISC brings that you feel is most useful for you and/or your organization in about 10 words? CDISC International Interchange 2010 (Sample quotes from our > 320 Attendees)

- "Standards, Expertise, Vision, Opportunity to network, value in terms of efficiency"
- "Globalization of CDISC standards working with other regulatory agencies for worldwide adoption"
- "Enhances data quality by facilitating cross-functional collaboration in medical research"
- "Developing, promoting, and making standards available as well as helping to build a more transparent communication system with regulatory authorities (FDA)"
- "Modernizing clinical research for improved medical care"
- "CDISC provides a common language for diversified companies/agencies and even for individuals with different backgrounds, education, and experience"

Vital Role of Education and Membership

- CDISC Education and Membership are vital for maintaining and developing the standards.
- CDISC Education offerings are designed to give implementers a better understanding of how to apply the theory and practice of the CDISC Standards within their own organizations.

CDISC Membership

- CDISC has a range of members in various functional areas, which includes data managers, statisticians, IT professionals, and medical writers and program/project managers.
- CDISC Membership can be found via the following link:
<http://www.cdisc.org/membership>

A quote taken from the CDISC President and CEO, Dr. Rebecca Kush, message to the CDISC members: “***Your support has been invaluable, not only to CDISC as an organization, but also to the many organizations and clinical communities increasing their use of CDISC standards around the world.*** Read the full message on: <http://www.cdisc.org/membership>

CDISC Membership

- There are two levels of membership:
 1. Gold Member Level (receives 20% discount on all events and trainings) plus many additional benefits discussed in the following slides
 2. Platinum Member Level (receives 40% discount on all events and trainings) plus many additional benefits discussed in the following slides

For information about membership and how to join, please contact **Sheila Leaman** at sleaman@cdisc.org. Her contact info is under the Contact tab on the CDISC website.

Gold Level Membership Benefits

- Access to 'Members Only' area on the CDISC website for all of the organization
- Access to new documentation for CDISC standards
- CDISC Case Studies
- CDISC Business Case
- Tools, presentations and team Information
- Access to new data standards and useful information (e.g. Pharmacogenomics Domains, ADaM validation checks, FDA-CDISC pilot reports)
- 20% Discounts for CDISC Training Courses and CDISC sponsored events, e.g. Interchanges
- Opportunity be a CDISC Registered Solution Provider
- HL7 Member rates to HL7 Working Group Meetings
- Invaluable partnership prospects and networking opportunities with peers and visionaries
- Receipt of personalized plaque

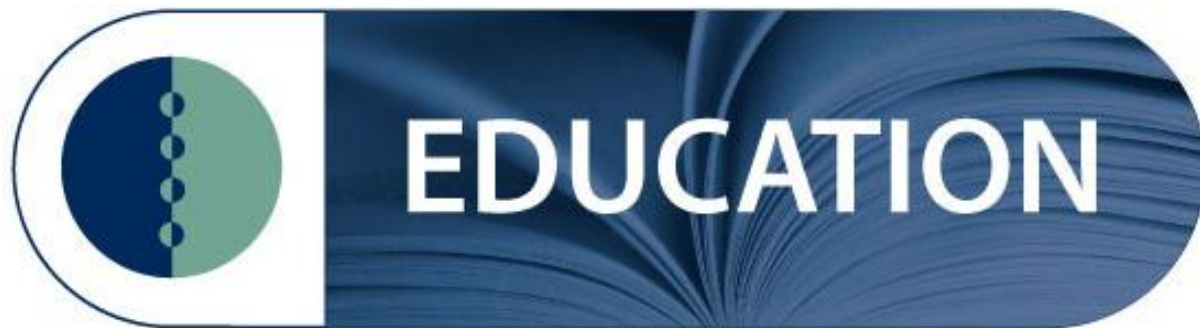
Platinum Level Membership Benefits

All of the benefits of Gold Level PLUS the following:

- Representation on the CDISC Advisory Board (CAB), through which the following benefits accrue:
- Opportunity to provide strategic advice to CDISC leadership
- Teleconferences that include implementation experiences from peers and CDISC updates from Operations staff
- Opportunity to be on Board Committees (Strategy, Technical, Financial)
- Opportunity to vote a Board Member onto the CDISC Board of Directors
- Opportunity to participate in Town Hall meetings with regulators
- Networking at face-to-face meetings
- Access to the Board area of the CDISC Portals
- Access to Team area of the CDISC Portals
- Additional 20% Discounts (i.e. 40 % total) for CDISC Training Courses and CDISC sponsored events,
- e.g. Interchanges
- Opportunity for a personal onsite delivery of the New “CDISC Global Approach to Accelerating
- Medical Research” at Members’ Request

CDISC Education

Look for this CDISC Education Logo...



...to be certain that you are receiving CDISC-authorized education!

What the CDISC Logo Means

- COP-005 controls
 - How training materials are developed
 - How trainers are qualified and selected
- Training materials
 - Developed under the authority of CDISC TLC
 - Developed by a multi-organizational team
 - Reviewed by the technical team
- Trainers
 - Assurance of minimum qualifications
 - In some cases the same trainers who train the FDA (SDTM/ADaM)



Opportunities for Public Training for the remainder of 2011

**10-14 October 2011, Baltimore, MD, USA
(CDISC International Interchange)**

- **1-4 November 2011, Beijing, China** (Hosted by Quintiles)
- **7-10 November 2011, Shanghai, China** (Hosted by Theorem)
- **14-18 November 2011, Tucson, AZ, USA** (Hosted by C-Path)

Information and Registration at

<http://www.cdisc.org/education-and-events>

Upcoming Events and Trainings

<http://www.cdisc.org/education-and-events>

2011 CDISC Events in Japan:

- CDISC session “CDISC Makes You Happy” at the 3rd Global Quality Assurance conference on November 13 in Kyoto.
- Legacy Data Conversion workshop is planned on November 14 in Tokyo.
- CDISC public training course on SDTM implementation on November 15-16 in Tokyo.

NEW Request Private Training online –
visit <http://www.cdisc.org/private-training>

CDISC Interchange North America

10 – 14 October 2011

Renaissance Harborplace Hotel

Baltimore, MD



For more information and to register

<http://www.cdisc.org/interchange>



Strength Through Collaboration

CDISC Interchange Europe 2012
Elite Hotel Marina Tower
Stockholm, Sweden
16 - 17 & 20 April Training and Workshops
18 - 19 Conference



CDISC Interchange Japan 2012
10-11 July Interchange Conference, and
12-13 July Training courses

For more information and to register
<http://www.cdisc.org/interchange>



CDISC Interchange, North America
10 - 14 October 2011 | Baltimore

Interchange North America

What's New

****New** Call for Public Review SDTMIC Trial Summary Dataset 27 July 2011**
[Learn More>](#)

NEW Onsite Private Training Request Page
Click here for more information on how to request information about CDISC training onsite at your location.

****New** Call for Public Review SDTM Non-Subject Data Implementation Guide**
[Learn more>](#)

In Members Only Area: Terminology Implementation User Guide!
Terminology Implementation User Guide available now!

CDISC 2011 North American Interchange
10-14 October 2011
Exhibition Space and Sponsorship Now Open
Registration will begin soon

Transforming Medical Research with Electronic Health Records
By Dr. Rebecca Kush, President and CEO of CDISC.

June Newsletter
Most Recent Updates and Articles in the June Newsletter. Stay Tuned to the July Newsletter!

New Standard Released!
The SDN Implementation Guide Version 3.0 is now available!
[Download it here.](#)

FDA Announces Release of the CDER Data Standards Common Issues Document
[Learn More>](#)

****New** Terminology Update as of 22 July 2011**
[Learn More>](#)

****New** 22 July 2011 - Terminology Call for Public Review**
[Learn More>](#)

Call for BRIDG Subject Matter Experts
Learn more about the BRIDG Subject Matter Experts Group

CDASH Standard Version 1.1 Released
[Download it now!](#)

The Official CDISC Primer

Everything you need to know in one accessible text! Order yours today!

[Click here to read excerpt text.](#)

[more...](#)

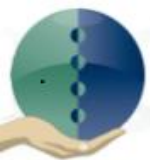
Join CDISC!

Read about the benefits of membership and how to join here [more...](#)

Join Our E-mail List

[Follow us on Twitter](#)

Browse through the CDISC website



Strength Through Collaboration

CDISC Latest News and the CDISC eNewsletter

- Stay tuned to the latest CDISC news from all around the world, read our latest press releases, blogs, latest news, and monthly newsletters via the following link:

<http://www.cdisc.org/news>

- Access the CDISC Monthly eNewsletter:
August Newsletter just issued <http://www.cdisc.org/news>
- Follow us on Twitter through www.cdisc.org

For Questions about CDISC News, please contact Diana Harakeh at dharakeh@cdisc.org. Please refer to the Contact tab on the CDISC website.

Question & Answer

