June 2012 eNewsletter

*The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research.*

The CDISC June Newsletter Presents the Following Topics:

- CDISC Interchanges - Join us for Japan Interchange Next Month!
- CDISC Landmark Annual Report and Strategic Goals
- Latest Technical News: Tuberculosis: Global Public Health Imperative
- CDISC Board of Directors Call for Nominations
- Success Story: Implementation of CDISC Standards at AstraZeneca
- Updates on the Learning Health System Summit in DC and the JIC and ISO Meetings in Vancouver
- CDISC Members: New Organizations in May 2012
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- NEW - Opportunity to Donate to CDISC
- Current Volunteer Opportunities
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CDISC Japan Interchange

Don’t forget to register for the [2012 Japan Interchange](http://www.cdisc.org)! This Interchange will be held at the KPP Yaesu Building in Tokyo, Japan, with training sessions in SDTM and ADaM on 10-11 July and the Main Conference running from 12-13 July. Space is limited, so make sure to visit the CDISC website to reserve your seat today!

In addition to registration for attendance, there are still sponsorship opportunities available at this year’s Japan Interchange. Sponsorship of the Japan Interchange is an advantageous opportunity for your company to broaden visibility of its operations within Asia, effectively marketing your organization to nearly 300 CDISC member organizations. Sponsors enjoy extensive benefits at CDISC Interchanges, and depending upon the level of sponsorship, can enjoy such benefits as:

- Free exhibitor booths
- Conference passes
- Evening event passes
- Advertorials delivered to each interchange participant
- Your logo on both the interchange program and CDISC website
• Plus more!

What's more, sponsorship of international Interchanges aids CDISC in meeting its mission, vision and goals. Proceeds from these events further the development and support of global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

If you should be interested in signing up to be a sponsor and/or exhibitor for this year's CDISC Japan Interchange, we would be happy to assist you. Sponsorship information and further details can be found on the CDISC website [1]. Should you have any questions please contact our Communications department [2].


CDISC Announces Landmark Annual Report and Strategic Goals

In honor of the 15 year anniversary of the founding of the Clinical Data Interchange Standards Consortium (CDISC) and the recently approved CDISC status as a 501(c)(3) charitable foundation, the Annual Report for year 2011 has been released and is available for download on the CDISC website [5].

Key successes CDISC has had over the past 15 years are displayed graphically in a two-page timeline detailing major achievements since the organization’s founding in 1997. The report includes the mission and vision of CDISC, milestones for year 2011, and information about CDISC-certified education. Trends in CDISC membership and current leadership information are also detailed. Fascinating insight is given in the Annual Report to the rapid growth and productivity of CDISC since its beginnings as a strictly volunteer organization. Follow the link [6].

CDISC Technical News

To best serve its members and stakeholders of the global research and healthcare industries, CDISC is continuously progressing its standards and innovations. Visit our website [7] for constant updates on the CDISC standards open for public review and comments. This month we draw your attention to the TB standards that are open for public review.

Tuberculosis: Global Public Health Imperative
Tuberculosis (TB) is a global pandemic, killing 1.4 million people every year and over 3,800 people every day. That is one person every 25 seconds. At any given moment, more than 12 million people around the world are suffering from active TB infection. TB is second only to HIV as the leading infectious killer of adults worldwide. It is among the three greatest causes of death of women aged 15-44 and is the leading infectious cause of death among people with HIV/AIDS.

Unfortunately, current treatment of TB is inadequate. Today’s TB drug regimen takes too long to cure, is too complicated to administer, and can be toxic. Despite the flaws with and growing resistance to current TB treatments, no new TB drugs have been approved in nearly 50 years. A faster, simpler cure for TB is needed and will save millions of lives and have tremendous global benefits. A shorter TB regimen could improve treatment compliance, stop the spread of drug-resistant tuberculosis, and enable the global scale-up of MDR-TB treatment.

There is a historic opportunity to develop new combination treatments for TB. The pipeline of new TB drugs is stronger than ever, with nine promising compounds from at least six antibiotic classes in clinical trials or late pre-clinical development. This is thanks to government and philanthropic investments in TB R&D and increased focus on TB by the industry over the past decade. Through their participation in the Critical Path to TB Drug Regimens (CPTR) initiative, industry, academia, and civil society organizations are maximizing this critical moment by working together to test promising combinations of individual TB drug candidates, regardless of sponsor, to identify the best new TB drug regimens. This signals unprecedented cooperation among all those involved so that innovation and patient need drive every aspect of TB drug development.

Data Standards are an important enabler in the development of new TB drug regimens, facilitating data collection in new TB clinical trials as well as the pooling and analysis of TB data from around the world. CDISC is co-leading the CPTR Data Standard Workgroup (DSI-WG) with the Critical Path Institute and US Food & Drug Administration. The workgroup recently released TB Data Standard V1.0 for public review. The final standard will be released in early July. The standard will facilitate regulatory analysis and review of TB clinical trial data as well as regulatory qualification of new biomarkers. Follow the link [8] for more details on the CPTR data standards work. And to view the recent webinars, go to the following link [9].

CDISC Board of Directors Call for Nominations

As an interested party of CDISC, you have the opportunity to participate in the process of nominating candidates for the CDISC Board of Directors for a 3 year term beginning in January 2013. CDISC needs dedicated and committed people willing to become candidates for the board election to be held in the last quarter of 2012. Please take some time to think about those individuals you believe would make good board members, verify that they would be willing to serve and then fill out the board profile grid and submit this, along with a current CV and a letter stating why they want to be on the Board and what they can bring to the Board. We must have all three documents for each nominee. This is your opportunity to ensure the quality of candidates who will shape the future of CDISC. Follow the link [10].

Notes from the Field: Implementation of CDISC Standards at AstraZeneca
“There is an increasing demand for standardized clinical information, as well as an increasing need to scale our CDISC standards capabilities,” noted Alex Hromcenco and Sam Hume of AstraZeneca (AZ) at the beginning of their presentation at the 2011 CDISC International Interchange in Baltimore, Maryland. Mr. Hromcenco and Mr. Hume went on to discuss these issues as well as how AZ had successfully implemented CDISC standards and become a major contributor to CDISC.

Before the implementation of CDISC standards, AZ started by standardizing the way data was collected in house. This activity began on a per project basis and eventually developed into corporate standards. These corporate standards were created using best practices from both Astra and Zeneca, two separate companies until their merger in 1999. Yet this very project-focused approach did not support end-to-end standards outside of a project; there were significant variations in standards between projects and not enough supporting technology. Compliance and support were weak due to these factors. Follow the link [11].

The Learning Health System Summit in Washington, DC and the JIC and ISO meetings in Vancouver, Canada

Two recent meeting updates [12] by Dr. Rebecca Kush, CDISC President and CEO, have been posted as CDISC blogs. One of these is on the Learning Health System Summit that took place in DC 17-18 May and other is on the JIC and ISO meetings that were held in Vancouver, Canada on 5-9 May 2012.

The Learning Health System Summit took place on 17-18 May at the National Press Club in Washington, DC. It was the culmination of intense planning that occurred via phone several times monthly from the time of the CDISC Interchange in October 2011 (and even before, but that is when CDISC learned about this initiative). Dr. Charles Friedman gave a keynote address on his vision of the Learning Health System (LHS) at the CDISC International Interchange in Baltimore in October 2011 and spoke afterwards with then Board Chair, Dr. Frank Rockhold and Dr. Rebecca Kush about his plans to take this concept forward. [He had recently left his position as chief scientist in the Office of the National Coordinator to assume a position at the University of Michigan.] Chuck has published about the LHS in Science Translational Medicine (10 November 2010); directly aligned with the CDISC Vision, the LHS focuses on the fact that research data comes from healthcare and, in turn, should inform clinical care decisions. This cycle is said to take 17 years currently (for research results to end up in clinical decision support). As Chuck would say, we would like to see this go to 17 months, weeks or minutes! Follow the link [13] to read more.

At the JIC and ISO meetings in Canada [14], important goals for CDISC to accomplish included:

1. to enhance the governance of the JIC
2. to get BRIDG through the entire process to become an ISO/CEN standard

CDISC Member Updates
Gold Members

- Fred Hutchinson Cancer Research Center
- Integrated Nonclinical Development Solutions, Inc.
- PDS Preclinical Data Systems, Inc.
- Pleiad Devices
- Yuxi Pacific Group

Non-Members can enjoy all our benefits and more by joining CDISC! Please contact Sheila Leaman for further details.

CDISC Frequently Asked Questions (FAQs)

We have started adding one FAQ in each of our eNewsletters recently. If there is a question you would like us to answer or to include in one of the coming months, please contact Diana Harakeh. This month’s question is: "Where does CDISC get its funding?"

Donate to CDISC

The U.S. Internal Revenue Service (IRS) approved CDISC as a 501(c)(3) organization in December 2011, recognizing it as a charitable organization retroactive to May 2011.

With our current ability to receive tax-deductible contributions from individual and corporate donors, we will promote CDISC’s message to a broader audience, enhancing CDISC’s capacity to locate funds through diverse means. Your contribution will help us accelerate the availability of new medical therapies to patients in need. Follow the link to know more about your valuable donation and matching gifts.
CDISC Depends on Volunteers to Develop and Maintain Our Open Standards

Engage yourself with the CDISC mission and vision to inform patient care and safety through higher quality medical research and join our working teams by volunteering to any of the following areas:

- XML Afficionados
- Technical Writers
- Protocol Representation
- Device Terminology Specialist

Follow the link [20] to know more about how to volunteer! Further questions are welcome at the following link [21].

CDISC User Networks

Self-formed CDISC User Networks have been developed in Africa, Asia, Europe and the United States of America. User Networks enable face-to-face interactions by promoting the CDISC international presence and encouraging the adoption of CDISC standards through sharing implementation experiences in various global communities and regional areas.

If you did not have the chance to attend the CDISC English User Network meeting that was planned for the 28 of May 2012 at Brunel University, Uxbridge in London, you have not missed that chance yet as the meeting will be rescheduled later in 2012. Stay tuned to our news for future updates. For any questions about the meeting, please send an email to the following address: committee@esug.org.uk [22]. If you are interested in joining the ESUG, please contact Amanda de Montjoie [23].

The South African User Network next meeting will be in September 2011. Stay tuned for our updates. If you are interested in joining the African User Network, please contact Dianne Weatherall [24].

To join a CDISC User Network, feel free to contact Diana Harakeh [18]. The User Network portal area [25] is open to anyone and provides information on specific User Networks, including announcements of their next meetings.

Follow the link [26] to know more about the purpose and benefits of the CDISC User Networks.

CDISC 2012 Global Events and Education Opportunities

CDISC is pleased to invite you to the upcoming webinars, interchanges, and public training sessions in 2012 - 2013.

CDISC Webinars:
CDISC Team Updates – 19 June 2012

This FREE webinar will provide an overview of the upcoming SDTMIG v. 3.1.3 document, revisions and amendments to the SDTMIG EX domain planned for SDTMIG v. 3.1.4, and an introduction to the Pain Therapeutic Area Standards, which will soon be posted for provisional use. Registration closes on Tuesday, 19 June 2012 at 11 am EST. Follow the link and register soon!

Tentative 2012 webinar schedule. Follow the link and stay tuned!

**CDISC Interchanges:**

**CDISC Japan Interchange, 10 - 13 July 2012** - Accepting Abstracts Now - Sponsorship and Exhibitor Opportunities Available!

**CDISC International Interchange 2012 in Baltimore, MD, 21 - 26 October 2012** - Sponsorship and Exhibitor Opportunities Available! Updates coming soon through our website.

**CDISC Asia Interchange in Singapore, 18 - 22 February 2013** - Information coming soon!

**Public Training in the US:**

- Public Training in Palo Alto, CA in June 2012
- Public Training in Morrisville, NC in Aug 2012
- Public Training at the CDISC International Interchange in Oct 2012
- Public Training in Tucson, AZ in January 2013
- Public Training in Morrisville, NC in Feb 2013
- Public Training in South San Francisco in March 2013
- Public Training in Canton, MI in March 2013
- Public Training in Seattle, WA in August 2013
- Public Training in South San Francisco in March 2013

**Public Training in Europe:**

- Public Training in Brussels, Belgium in September 2012

**Public Training in Japan:**
Training sessions on SDTM and ADaM during the Japan Interchange [1] in July 2012

Our 2013 Public Training schedule is firming up. Please be on the lookout for new public training locations for 2013!

CDISC Private Training

CDISC-authorized education and training courses are only available from the CDISC Education team, and are identified by the CDISC Education logo. The logo is your assurance that the training has been developed by and will be delivered by CDISC staff or qualified industry experts who have passed a rigorous qualification process.

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research. In order to achieve this vision, we know it is vital that the CDISC standards be implemented as process enablers and innovations that support the research process. With this in mind, from its inception, CDISC has developed educational courses that provide foundational training on the theory and practice of using the CDISC standards, and which are designed to give implementers a better understanding of how to apply the theory and practice within their own organizations.

Private training is available to any organization, regardless of membership status. CDISC member organizations will receive discounted pricing on private training. To request information about private training, please click on the link below.

Request Private Training online - click here [37] for more information.

More training opportunities coming soon. Please stay tuned to our Education and Events [38] page.

Non-CDISC Related Events

PhUSE East Hanover Single Day Event:

The CDISC standards were introduced over the decade ago with the goal of standardizing our clinical data and improving efficiencies in our process thus leading to faster approval times. The next step in that evolution would be the introduction of automated and generic, reusable code modules to leverage those standards and speed up the development process.

At the PhUSE Single Day Event in New Jersey, we will learn how a number of companies have leveraged standards, metadata, and tools to improve the process and discuss what challenges still exist in terms of development and maintenance of such tools, but also the challenges of people change management to this new way of working. Follow the link [39].
The Official CDISC Primer is available now for a lower price

Benefit from the discounted price and buy the CDISC book now! Current Price is $15.

The CDISC Primer (Introducing the CDISC Standards / New Efficiencies for Medical Research) offers a detailed synopsis around everything you need to know to get started with the CDISC standards! Order yours today!

CDISC Social Media

Stay connected with the CDISC community through the new CDISC social media. Join CDISC Facebook and LinkedIn and follow us on Twitter and YouTube! Also follow our Blogs and most recent News through our website!

Further questions are welcome through the following email.

CDISC Communications and Public Relations