July 2012 eNewsletter

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

The CDISC July Newsletter Presents the Following Topics:

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- **CDISC, C-Path and FDA Collaborate to Develop Data Standards to Streamline Path to New Therapies**
- **Latest Technical News - CDISC Tuberculosis User Guide Released**
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- **Success Story: Business and Decision Adopted CDISC Standards from the Start**
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**CDISC International Interchange - 24 - 26 October 2012 in Baltimore, MD**

"Accelerating Therapies Through Standards"

**CDISC International Interchange 2012 will be a new format this year, with a focus on launching the Coalition For Accelerating Standards and Therapies (CFAST).** Based upon a partnership between CDISC and the Critical Path Institute, CFAST is an initiative to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health.

Per the FDA website, “FDA, CDISC and the Critical Path Institute [C-Path] are collaborating on efforts to support development of therapeutic area standards. […] We encourage stakeholders to engage in and, where possible, support these data standardization efforts.” The Interchange will be an excellent venue for everyone to become engaged, if they have not already found a way to do so. The development of standards in disease/therapeutic areas will require not only data managers and statisticians, who were indispensable in the development of CDISC Foundational Standards, but now also clinicians, program managers, patients and patient advocacy groups, academics and anyone interested in streamlining the path to new therapies. [Click here for details, including Keynote Speaker, Dr. Janet Woodcock](http://example.com).

Opportunities for exhibitors and sponsors are open now. Registration for the International Interchange will open very soon. Stay tuned to our [website](http://www.cdisc.org).

Stay tuned for information on the [CDISC Asia-Pacific Interchange 2013](http://example.com) through our future eNews.

**CDISC, C-Path and FDA Collaborate to Develop Data Standards to Streamline Path to New Therapies**

The Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) announce the signing of a partnership agreement to establish the Coalition For Accelerating Standards and Therapies, or CFAST, an initiative to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health. Follow the [link](http://example.com).

**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](http://www.cdisc.org) for constant updates on the CDISC standards open for
public review and comments. This month we draw your attention to the Release of the Tuberculosis User Guide.

**CDISC Tuberculosis Therapeutic Area User Guide Released**

The Critical Path to TB Drug Regimens (CPTR) and the CDISC SDS team is releasing v1.0 of the Tuberculosis Therapeutic Area Supplement to the Study Data Tabulation Model User Guide. This supplement, when used with the SDTMIG, is intended to guide the organization, structure, and format of standard tuberculosis clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). Follow the link.

**Special Thanks to Our Team Members**

CDISC would like to cordially thank its team members and volunteers for their outstanding work and dedication to develop the Tuberculosis User Guide v1.0. We wish to recognize a number of individuals who worked tirelessly to make this happen: Bess LeRoy (C-Path), Diane Wold (GSK), Fred Wood (Octagon Research), Jane Diefenbach (Pharmastat) as well as key NCI Enterprise Vocabulary Services team members...Erin Muhlbradt, Terry Quinn and Arianne Motter.

The CDISC mission is made possible only through the invaluable contribution of team members who dedicate precious time within busy schedules to work on important CDISC projects with a shared vision for improving the lives of patients around the world.

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on "Buckthorn Wars and the Essence of Clinical Data".

Wayne Kubick, CDISC

**Frequently Asked Question: Are EHRs ready to support regulated clinical research studies?**

Answer: Yes! There have been demonstrations over the past 5 years showing how a regulated clinical research study can be done using an EHR. (See the CDISC Healthcare Link area of the website).

One key enabler for this process is the use of an integration profile developed by CDISC with IHE (Integrating the Healthcare Enterprise). It is called Retrieve Form for Data Capture (RFD). A number of EHRs support this profile and there is a letter of support for this novel yet easily implementable solution from the EHR Association on the CDISC website. Additional profiles are also now available, including those that address content and security in addition to the workflow piece.

Please see more about this opportunity in the Success Story from Florida Hospital and watch for more to come in the near future!

**Success Story**
In an attempt to increase value for its stakeholders, CDISC has initiated the feature of Success Stories in 2012. These stories reflect the experiences with the CDISC standards and how they continue to bring success and add efficiency to the work environment. If you would like to present your success story with CDISC in a future Newsletter, please contact the communications team.

Business and Decision Life Sciences Adopted CDISC Standards from the Start

Business and Decision Life Sciences is one of the well-known consulting companies and CROs in Europe that supports the adoption of CDISC standards. Their involvement with CDISC is very broad and not only limited to using data standards. They are active team members, leaders in the CDISC Advisory Board and the CDISC European Coordinating Committee and are authorized CDISC trainers. With their profound awareness of the CDISC data standards and their interest in improving healthcare and patient safety, B&D recognized that there is a strong need for adopting data standards. As a CRO/Service provider, they felt that there is a promising opportunity to help companies understand and adopt CDISC standards within their work environments. CDISC has now acknowledged B&D as a Registered Solutions Provider, which provides consultancy on implementing the various CDISC standards.

Business and Decision Life Sciences is also one of the invaluable CDISC Platinum-level organizational members who are actively involved in the development and implementation of CDISC standards. Through their consulting services, they play a key role in helping companies implement the CDISC standards in their work environments, they assist these companies in creating their CRF libraries based on CDASH and they create their internal data standards library based on SDTM and ADaM. In addition, they provide guidance on implementing CDISC standards according to the data standards governance process; they also offer a clear understanding on the metadata repository and how to generate reports out of that. Follow the link.

CDISC Member Updates

Gold Members
- Clinpharma Clinical Research LLC
- Cancer Research and Biostatistics
- LINK Medical Research AS
- Quartesian LLC
- Samvit Solutions
- UCR

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

CDISC Global Meetings and Updates

Invited CDISC Presentation by C3C Member Zibao Zhang at China SFDA Workshop

China SFDA organized a workshop on clinical data management, data standards, and statistical analysis in Tianjin, a harbor city near Beijing, on 28-29 June 2012. This workshop was envisioned to promote data quality through clinical data management best practices and data standards. The recently published China SFDA clinical data management technical guideline was also reviewed and discussed. Approximately 500 clinical researchers from the regulatory agency, industry, clinical research sites and academia across China attended this workshop.

Dr. Zibao Zhang, an associate director from PPD and a member of C3C (China CDISC Coordinating Committee), was invited to present on CDISC standards. Follow the link for full details.
DIA 2012 – FDA eSubmissions Session

For those of you who were unable to attend the DIA 2012 Annual Meeting in Philadelphia at the end of June (or those of you who may have missed this session), there was an excellent set of presentations from FDA representatives. Here is my summary; I would welcome additions and/or comments. Follow the link.[9]

Where is caBIG Going?

Changes have been taking place with the Cancer Biomedical Informatics Grid (caBIG) initiative, a large program of the U.S. National Cancer Institute (NCI). I am writing this blog with assurance that the terminology that has been supported for CDISC (and FDA) through the NCI’s Enterprise Vocabulary Services (EVS) is ‘alive and well’ and freely available, as usual. I also want to make an effort to clarify the history and describe what is transpiring with respect to caBIG as I write.

In March 2011, a report by the NCI’s Board of Scientific Advisors, entitled ‘Assessment of the Impact of the NCI CaBIG’, was released. Follow the link.[10]

Who’s Yehoodi

On the inside cover of the CDISC 2011 Annual Report is a quote describing the power music has to provide structure to what would otherwise be nothing more than disconnected and incoherent noise:

“Music creates order out of chaos: for rhythm imposes unanimity upon the divergent, melody imposes continuity upon the disjointed, and harmony imposes compatibility upon the incongruous.”

These words were spoken by the famous American violinist and conductor, Yehudi Menuhin, who is considered to be one of the greatest violinists of the 20th century. Follow the link.[34] to view our 2011 Annual Report.

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.[35] 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 to know more about how to volunteer! Further questions, please email us here.

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 are interested in attending any of the CDISC English User Network meetings, please send an email to the following address: committee@esug.org.uk. If you are interested in joining the ESUG, please contact Amanda de Mortolice.

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.

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

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

CDISC Global Events and Education Opportunities

You are cordially invited to attend the following webinars, interchanges, and public training sessions in 2012 - 2013.

**CDISC Free Webinars:**

CDISC Team Updates – 26 July 2012

Follow the link to view the upcoming CDISC webinar sessions in 2012.

**CDISC Interchanges and International Events:**

**CDISC Workshop and K3C Symposium in Seoul, Korea**

This week, there was a CDISC Symposium in Seoul, Korea. This has been organized by the K3C and the Korea Society of Clinical Development (KSCD). Kiyoteru Takenouchi, Wayne Kubick, Pierre-Yves Lastic, Rebecca Kush and Andrea Vadakin are participating from Japan, United States and Europe.

**CDISC Japan Interchange**

The Japan Interchange will be held the same week on 10-13 July in Tokyo. Training courses on the CDISC standards will be offered on 10 and 11 July and the CDISC main conference will be held on 12 and 13 July. Presenters from the Japanese FDA, from China, Korea, Europe and the United States will be providing updates on the CDISC standards at this conference.

**CDISC International Interchange 2012 in Baltimore, MD, 21 - 26 October 2012 - Sponsorship and Exhibitor Opportunities are Available!**

**CDISC Asia Interchange in Singapore, 18 - 22 February 2013**. Information coming soon!
Public Training in the US:


Public Training in Europe:

- Public Training during the CDISC European Interchange [4] in April 2013

Public Training in Asia:

- Training sessions on SDTM and ADaM during the Japan Interchange [6] in July 2012

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


The Official CDISC Primer is available for a lower price [4]

Benefit from the discounted price and buy the CDISC book now! Current Price is $15 [6].

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!