September 2012 eNewsletter

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

The CDISC September Newsletter Presents the Following Topics:

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- FDA, IMI, and Patient Advocates to Present at CDISC 2012 International Interchange - Formal Launch of CFAST - Collaboration Between C-Path and CDISC
- Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) Announce Breakthrough in TB Drug Development Tools
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CDISC International Interchange and Asia-Pacific Interchange

The CDISC International Interchange is coming soon on 22-26 October 2012 in Baltimore, MD! Registration is open, reserve your seats! In addition to the hot topics and recent achievements on the CDISC standards and technical roadmap, the Coalition for Accelerating Standards and Therapies (CFAST) is the focus of the Interchange this year. Click here for more details on the conference and educational sessions that are offered during the interchange week.

Our CDISC Interchanges do not stop in Europe, Japan and the United States, the Inaugural CDISC Asia-Pacific Interchange (CAPI) will be offered in Singapore in February 2013! The CDISC Asia-Pacific Interchange will be held on 20-21 February and Educational Courses will be offered on 18, 19 & 22 February 2013. The program committee is accepting abstracts for the conference presentations. The deadline for submission of abstracts is extended till Friday, 5 October 2012.

The European CDISC Interchange 2013 will follow the Asia-Pacific Interchange! The CDISC Europe Interchange will be held on 22 to 26 April 2013 in Bad Nauheim, Germany. Details on abstracts, sponsorship and exhibitor opportunities are coming soon, stay tuned to the CDISC website.

FDA, IMI, and Patient Advocates to Present at CDISC 2012 International Interchange - Formal Launch of CFAST - Collaboration Between C-Path and CDISC

The Clinical Data Interchange Standards Consortium (CDISC) and Critical Path Institute (C-Path) announce the launch of the Coalition For Accelerating Standards and Therapies (CFAST), a follow-up to the partnership agreement signed earlier this year. The official launch of CFAST will take place at the CDISC 2012 International Interchange in Baltimore, Maryland (24-26 October 2012).
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. Upcoming releases will include therapeutic area standards packages for Polycystic Kidney Disease, Cardiovascular Disease and Schizophrenia. Follow the link for full details.

**Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) Announce Breakthrough in TB Drug Development Tools**

Critical Path Institute and CDISC (Clinical Data Interchange Standards Consortium) announce the availability of a breakthrough tool to help combat tuberculosis (TB)—a persistent disease resulting in 1.7 million deaths globally each year.

This new tool—a standardized way to report research data—is critical for advancing new TB drug regimens. For the first time, researchers are able to combine and evaluate data from multiple studies using a common approach. This will help accelerate the development of new TB drugs by enhancing the design of clinical trials and the evaluation of new drugs. The TB data standards will also assist the regulatory review process for new drug development tools, such as clinical trial simulation models and methods to evaluate treatment endpoints.

“The scope of this project was immense and its delivery in nine months was made possible by the smooth collaboration among C-Path, CDISC, FDA, industry partners and the many volunteers who participated in this effort through the Critical Path to TB Drug Regimens initiative,” says Dr. Carolyn Compton, President and CEO of Critical Path Institute. Follow the link for more details.

**Spotlight on CDISC Partnerships and Strategic Alliances**

Starting in October, we will be providing a monthly update featuring one of the key CDISC Partnerships or Strategic Alliances. Watch this space! Next month we will feature the National Cancer Institute’s Enterprise Vocabulary Services (EVS).

**CDISC Technical News**

CDISC is continuously progressing its standards and innovations. Regular updates on CDISC standards developments are available on the CDISC website. This month we would like to draw your attention to the following published standards that are now available on the CDISC website:

**Standards and Technical Announcements Posted for Public Comment:**

- CDISC Parkinson’s Disease Therapeutic Area User Guide Available for Public Comment – Comments due by 9 September 2012
- CDISC SHARE RFI Now Available – Comments due by 20 September 2012
- CDISC Terminology Package 12 Available for Public Review - Comments due by 28 September 2012
- Define-XML v2.0 Now Available for Comment - Comments due by 1 October 2012
- Virology Draft Standards for Public Review and Comment - Comments due by 5 October 2012

Follow the link for details on Standards and Technical Information Available for use, and gain knowledge on several other standards and project documents that are nearing completion and expected to be posted very soon.

**Join us for the CDISC Standards Webinar - Latest Updates and Additions** on Tuesday 18 September 2012 at 11:00 AM U.S.A Eastern Time.

The webinar topics will cover:

- 2012 International Interchange Preview
- Overview of the Final SDTM Device Standard
- Brief review of SDTM 3.1.4 Batch 2 posting

Please follow the link to register and attend.
Please check back to the CDISC website for more updates.

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

CDISC Success Story

In an attempt to increase value for its stakeholders, CDISC has initiated the feature of Success Stories in 2012. These stories reflect 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.

Extracting the value of Standards: The Role of CDISC in a Pharmaceutical Research Strategy (by Frank Rockhold and Simon Bishop)

"Information is our most expensive and valuable resource. When patients are asked to sign an informed consent to enrol in one of our trials, they are assured we will use the information gathered to better the health of future patients. If we cannot store, find and retrieve the information in a reliable way we are not meeting our commitment to patients or supporting the business of R&D and GlaxoSmithKline.

CDISC is an organization that was created and is tasked with being in the middle of solving this most critical piece of transforming the data from trials into a true information-based model that will allow subject matter experts to derive practical wisdom on behalf of patients," is what Frank Rockhold and Simon Bishop emphasized in light of the major role CDISC plays in the healthcare industry.

Follow the link for the full story.

SDO Spotlight in U.S. HHS/ONC Newsletter: Clinical Data Interchange Standards Consortium (CDISC)

CDISC was featured in the S&I Framework Newsletter that was issued in August 2012. The newsletter main topics revolved around the SDOs and the importance of standards and EHRs within the clinical arena.

"The inception of CDISC has empowered the collaboration of individuals across the healthcare continuum to develop consensus-based standards that enabled interoperability to improve medical re-search and healthcare delivery" was mentioned the introduction about CDISC to the global community through the newsletter. The CDISC standards are the essence that makes collaboration happens within the clinical research life cycle. They facilitate and organize the process from planning to submission while eliminating errors and reducing the production time effectively. Follow the link to read more.

CDISC Member Updates

Our New Members in August

- aCROnordic Research Clinic - DENMARK
- CD3 Inc. - USA
Thank you and a warm welcome to our new members in August. The CDISC community continues to grow and we encourage you to reach out and connect with fellow members and CDISC staff via the various forums provided by CDISC Communications.

Non-Members can enjoy all our benefits and more by joining CDISC! Please contact membership@cdisc.org for further details.

BEGINNING WITH OUR SEPTEMBER ISSUE OF OUR ENEWSLETTER, WE WOULD LIKE ACKNOWLEDGE OUR STAR MEMBERS (ORGANIZATIONS WHO HAVE BEEN CDISC MEMBERS FOR 5 YEARS OR MORE). WE ARE VERY GRATEFUL FOR THE SUPPORT THESE MEMBERS HAVE GIVEN TO US OVER THE YEARS WHICH ALLOWS US TO CONTINUE TO SERVE THE INDUSTRY THROUGH OUR WORK IN EXPANDING THE WORLDWIDE ADOPTION OF CDISC STANDARDS.

FREQUENTLY ASKED QUESTIONS

Q: What social media channels does CDISC use to communicate official messages?

A: CDISC currently has LinkedIn, Facebook, YouTube, and Twitter pages where official CDISC messages and videos are posted. We encourage anyone interested in receiving official updates and announcements from CDISC to consider joining these groups. Below are the direct links to our official pages, and you can additionally find buttons that will link you directly to these pages on the CDISC homepage and in every CDISC eNewsletter:

On sites like LinkedIn and Facebook, interested third parties have the ability to create and manage CDISC-related pages, which are usually developed by individuals that are supportive of CDISC and have experience implementing or assisting in the development of CDISC standards. Some of these groups have information that is pertinent to specific teams or interested parties, but management of these groups rests with the creator and is outside the purview of CDISC. The content of these pages is not managed by CDISC staff and does not necessarily reflect the views of the organization. For all official messages from CDISC, please visit and join the official CDISC group pages listed above.
In addition, CDISC also offers RSS feeds on all of its standards pages, as well as the News pages. Choosing to subscribe to the RSS feed for a certain CDISC section, allows for all updates to be either saved to your favorites or sent via an email to your email address. RSS feed subscription depends on the kind of browser you are using, to subscribe to one of our RSS feeds, look on right hand side of the standards page of your choice for the RSS button. After clicking on the RSS button, look for the link, “Subscribe in Mail” or “Save to your Favorites” to subscribe.

- Get our standards latest updates here
- Get the latest news here

Should you have any questions or concerns regarding our social media, please do not hesitate to contact Andrea Vadakin, CDISC Manager of Public Relations, or Diana Harakeh, CDISC Manager of Communications and Marketing for further assistance.

Support CDISC at Upcoming FDA Meeting Solutions for Study Exchange Standards

The FDA recently published their announcement of a public meeting to discuss Solutions for Study Exchange Standards. The notice includes directions for how to register to attend the meeting (the email address, however is incorrect. Please refer to correct address through this link), and also a list of questions related to the use of standards, including asking for input on comparing HL7 transport standards to CDISC ODM.

This may be our best opportunity to convince FDA that an XML transport standard based on ODM for CDISC SDTM, SEND and ADaM content would be a better solution for submitting data than use of HL7 healthcare standards. We believe this forum will highlight the advantages of using the CDISC Operational Data Model (ODM), which is the basis for define.xml and a current component of the FDA study data standards. ODM has been successfully adopted by many researchers in both industry and academia, as well as technology vendors for transferring clinical data, metadata and terminologies with audit trail in a fully compliant manner.

Update: Final Rejection of DataSci Patent Application

CDISC would like to thank all those who followed the metadata patent issue. Late last week the US Patent Office officially issued a “Final Rejection” notice to the patent applicant. According to the US Patent Office: “A final Office action,” in this case a final rejection, “issues when the applicant's response to the prior Office action fails to address or overcome all issues. An applicant’s only response to a final Office action is either compliance with the requirements or appeal to the Trademark Trial and Appeal Board.”

Please note that the applicant has a 3 month window in which to reply to this “final action” so we will continue to follow any further progress. We have consulted the formerly mentioned IP attorney about this issue and have been cautioned that patents can be saved from “final” rejections through amending the claims, filing a continuation, etc. We are hopeful, however, that based on the description above of what is meant by a “final rejection” that this application will not have a chance to move forward. We will report back on any further developments. Thanks again for your support on this issue.

The CDISC Coordinating Committees (3Cs) - Update

Two of the CDISC Coordinating Committees (3Cs) are coming into their second decade of existence with many new plans and ideas, and those that are newer are forging ahead with their own energy and activities while learning from their predecessors. The 3Cs took their lead from the E3C (Europe) and their charters thus reflect the base charter from the E3C that was launched in 2001 under the leadership of Udo Siegmann, who has since retired. Because CDISC has grown significantly since 2001 and there are new initiatives within the CDISC Global offerings (for example, the CDISC Education program), it was felt that there should be a new charter for the 3Cs. This has been drafted with input, from many who have been involved in the 3Cs, and all of the 3Cs are in the process of reviewing this draft charter and providing input to improve it. This is important in the context of discussions that are occurring within the CDISC Advisory Board (CAB) about its structure and also with respect to the CDISC User Networks, so stay tuned! And, if you are interested in being involved as a 3C member or a reviewer of the new charter, please don’t hesitate to let us know. (Contact Diana Harakeh).

Here are more specifics on each of the 3C activities and plans for this fall. Follow the link for more details.

CDISC User Networks

CDISC User Networks have been formed all around the globe in Africa, Asia, Europe and the United States of America.
User Networks enable face-to-face interactions to encourage the adoption of CDISC standards by sharing implementation experiences in various global communities and regional areas. They play an essential role in expanding the CDISC international presence.

This month, the South African CDISC User Group will hold a face-to-face meeting on 27 of September in Bloemfontein, South Africa. The invitation is open to all those who could attend in person and to anyone interested in joining through a teleconference.

- To sign up for this event by 19 of September, 2012, please complete the attached registration form to confirm your spot. Follow the link for further registration details and event schedule.

To join a 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 Education Team Invited to Thailand to Provide Authorized Courses**

Every year, CDISC instructors deliver education courses all around the world, they perform training in Asia, Australia, Europe, the United States and any other place as requested. Our instructors performed training in Thailand for the first time in 2012, the Thailand Center of Excellence for Life Sciences (TCELS) and the Mahidol University Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS) hosted a CDISC workshop from 14-17 August 2012 at the Pullman King Power Hotel in Bangkok.

Dr. Jaranit Kaewkungwal, Associate Professor Waranya Wongwit, Mr. Amnat Khamsiriwatchara, Dr. Saranath Lawpoolson and 34 other physicians, Researchers and students from TCELS, BIOPHICS and various other hospitals, public health organizations and research centers in Thailand were in attendance. The four-day workshop included an overview of CDISC, a 2-day SDTM course and a 1-day CDASH course. The CDISC instructors were Shannon Labout, CDISC Sr. Director of Education, and Kit Howard, Owner and Principal of Kestrel Consultants.

In a continuous attempt to enhance the delivery of CDISC education courses, CDISC regularly surveys its attendees who constantly provide invaluable feedback that ultimately helps in improving our education process and eventually works to the best of our audience in this global environment. One of the interesting quotations provided by one of our valuable attendees who attended the Global Approach to Accelerating Medical Research course in Bangkok stated the following: “I have gained more knowledge about clinical data management in terms of universal data standards and data submission to US-FDA. I also truly believe that this standard will ease data management in terms of data collection and validation in the near future.” This is one of numerous feedback messages that inspire the CDISC community to work harder towards the CDISC mission and vision, it boosts the enthusiasm of our teams to realize that CDISC is heading in the right direction toward the ultimate benefit of our patients.

**CDISC eJournal Articles 2012**

A number of CDISC stakeholders contributed articles to the CDISC eJournal 2011, which is distributed via the CDISC website. These articles were provided in CD format during the International Interchange 2011.
We are now collecting articles for the CDISC eJournal 2012 and would like to issue these articles on our website prior to the International Interchange 2012 in Baltimore, MD. If you are interested in submitting articles, please contact Diana Harakeh. Deadline for submitting articles is 24 September 2012.

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 how to make your valuable donation.

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 Global Events and Education Opportunities

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

1. CDISC Free Webinars:

Join us for the CDISC Standards Webinar - Latest Updates and Additions on Tuesday 18 September 2012 at 11:00 AM U.S.A Eastern Time.

The webinar topics will cover:

- 2012 International Interchange Preview
- Overview of the Final SDTM Device Standard
- Brief review of SDTM 3.1.4 Batch 2 posting

Please follow the link to attend.

More webinars coming in 2012, stay tuned for the latest on CDISC Therapeutic Area Standards development and get our latest CDISC team updates through the following link.

2. CDISC Interchanges and International Events:

- CDISC International Interchange 2012 in Baltimore, MD, 22 - 26 October 2012 - Registration is Open! Sponsorship and Exhibitor Opportunities are Available!
- CDISC Asia Interchange in Singapore, 18 - 22 February 2013 - Call for Abstracts Open Now! Further information coming soon!
- CDISC Europe Interchange in Germany, 22 - 26 April 2013 - Information coming soon.

3. CDISC Educational Sessions
a. In-House education on CDISC Standards:

CDISC can provide authorized education courses in-house to any organization, anywhere in the world, regardless of membership status. CDISC member organizations will receive discounted pricing on private education courses. To request information about private education courses, please click on the link below.

Request Private In-House Education Courses online - click here for more information.

b. Public Training in the US:

Public Education Courses at the CDISC International Interchange in Oct 2012
Public Education Courses in Tucson, AZ in January 2013
Public Education Courses in Morrisville, NC in Feb 2013
Public Education Courses in South San Francisco in March 2013
Public Education Courses in Cambridge, MA in July 2013
Public Education Courses in Canton, MI in August 2013
Public Education Courses in Seattle, WA in September 2013

c. Public Training in Europe:

Public Education Courses during the CDISC European Interchange in April 2013

d. Public Training in Asia:

Public Education Courses during the Asia-Pacific Interchange in February 2013

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

More education opportunities coming soon. Please stay tuned to our Education and Events page.

The Official CDISC Primer is available 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 CDISC social media. Join CDISC Facebook and LinkedIn and follow us on Twitter and YouTube! And follow our Blogs and most recent News through our website!

Further questions are welcome through the following email.

CDISC Communications and Public Relations