August 2012 eNewsletter

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

The CDISC August Newsletter Presents the Following Topics:

- CDISC International Interchange 2012 - "Accelerating Therapies Through Standards"
- Announcing the Inaugural CDISC Asia-Pacific Interchange 2013 - "Streamlining Global Research Through Standards"
- CDISC, HHS/ONC and FDA Issue Challenge: Regulated Clinical Research Study using EHRs
- CDISC Technical News - New Therapeutic Area Standards Updates

Attend our webinars to receive the latest updates on the CDISC standards open for public review and comment. View the Global Events and Education Opportunities section for further details on the upcoming webinar on 23 August.

Frequently Asked Questions

CDISC Success Story - Interview with Susan Mitchell, RN, Florida Hospital - Using EHRs for Research

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CDISC International Interchange 2012

"Accelerating Therapies Through Standards"

Registration for the CDISC International Interchange 2012 is now open. The International Interchange this year will have a new format 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.

The first day of the Interchange will revolve around the Disease Area Standards. The first day of the Interchange will revolve around Therapeutic Area Standards. Dr. Janet Woodcock of FDA will be the Interchange Keynote Speaker, launching CFAST during the opening session. Ann Martin of the Innovative Medicines Initiative (IMI) in Europe will also provide a keynote during this session. Panelists will include representatives from FDA, NIH, Industry, Academia and Patient Advocacy Groups and researchers from around the globe. Further details on the interchange program, sponsorship and exhibitor opportunities and event registration can be accessed here.

Announcing the Inaugural CDISC Asia-Pacific Interchange 2013

"Streamlining Global Research Through Standards"

Join us on 18-22 February 2013 in Singapore! 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 Interchange is intended to encourage those in the biomedical research arena in the Asia Pacific region to engage with CDISC directly by participating in this educational networking event. The program committee is now accepting abstracts for presentations at the conference, click here for further details on this interchange.

CDISC, HHS/ONC and FDA Issue Challenge: Regulated Clinical Research Study using EHRs

CDISC, HHS/ONC and FDA issued a ‘challenge’ to use EHRs for regulated clinical research during a Session on 26 June at the Annual DIA meeting in Philadelphia. Specifically, clinical research study sponsors were challenged to use at least two different electronic health record systems at different sites to conduct a multi-site, multi-visit, standards-based regulated.
clinical research study. The panelists at DIA spoke on the feasibility of this challenge, based upon technology and data standards and processes that have been developed over the past decade. Despite the potential and demonstrated benefits of this approach, the clinical research industry has not yet embraced these new methods and standards to conduct clinical research studies.

This challenge will provide FDA, HHS/ONC and CDISC a means to assess the remaining barriers as well as the opportunities to streamline regulated clinical research and increase its capacity throughout the US and the world as EHR adoption is being encouraged and increasing rapidly. Wayne Kubick, Chief Technology Officer (CDISC), spoke first at the DIA session: "CDISC has been doing demonstrations of its Healthcare Link methodology for years now, at HIMSS and at DIA. By adopting the CDISC-IHE profiles used in the CDISC Healthcare Link solution, EHRs can readily implement the standards and profiles to enable the collection of a high quality clinical research dataset that is needed for any regulated clinical research study." Follow the link to view the press release [3].

Also, see the related blog here [18].

CDISC Technical News [19]

To best serve its members and stakeholders of the global research and healthcare industries, CDISC is continuously progressing its standards and innovations. Constant updates on the CDISC standards open for public review and comments [20] are available on the CDISC website [21]. This month we would like to draw your attention to the following published standards that are now available on the CDISC website:

- CDISC Tuberculosis Therapeutic Area User Guide Provisional Release [22].
- CDISC Pain Therapeutic Area User Guide Now Available! [23].
- SDTM v1.3 and SDTM Implementation Guide v3.1.3 Final Release [22].
- Updated SDTM and Questionnaire Controlled Terminology Files [22].
- SDTMv3.1.4 Draft Supplements - Batch 1 [22]. Documents are now available for public review.
- CDISC Parkinson’s Disease Therapeutic Area User Guide Released for Public Review and Comment [22].

Further details on our most-up-date technical news are available here! Several other projects are nearing completion and expected to become available soon. Stay tuned!

More Technical Updates: (please consider responding to the following RFIs)

1. CDISC SHARE Request for Information (RFI) [22].
2. ODM Certification Services Request for Information (RFI) [26].

Frequently Asked Questions [27]

Who Owns CDISC Standards? [22].

CDISC owns the Intellectual Property of all of its standards (data, metadata and transport) per the CDISC IP Policy [28]. This includes all translations that are done of the CDISC standards into different languages. By retaining ownership, CDISC ensures its standards can remain open and free, which will encourage adoption and, therefore, better and more useful standards.

How Does CDISC Offer its Standards Openly and Freely? [27].

There are different parts to this answer.

a) CDISC has an IP Policy to ensure that no one else can own the CDISC standards or their translations, only CDISC. No one can charge royalties for the use of the CDISC standards.

b) CDISC raises funds to continue to enhance and maintain the standards and to offer them openly. This includes monies contributed by generous supporters and member organizations, as well as other sources of revenue, such as education and grants.

c) CDISC standards development is largely done by volunteers and individuals ‘loaned’ to CDISC by its supporters. CDISC has a small staff to assist volunteers, to provide leadership and education, to obtain sufficient funding and to ensure appropriate processes.

d) No other standards developing organization (SDO) in healthcare or research has completely open standards. CDISC is the only SDO dedicated to standards for clinical research. CDISC appreciates the generous contributions of all of its member organizations for making it possible to maintain open and free standards.
CDISC Intellectual Property

CDISC retains IP ownership of all of its standards to ensure that CDISC Standards remain open and free. Even when the standards are translated into other languages, the IP belongs to CDISC. CDISC standards are created through a consensus-based process that includes many different people who contribute their time and expertise. Thus, the value should serve everyone and the IP be protected. Some standards in other industries were developed in a manner that included proprietary portions such that users were charged royalties. The desire to prevent royalty charges or ownership by any one organization or individual formed the basis for the CDISC IP Policy that is now posted on our website. Read more.

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.

Interview with Susan Mitchell, RN, Florida Hospital - Using EHRs for Research

Using EHRs for research is not a thing of the future. It is being done in the present. Read below about the success Florida Hospital has had in utilizing EHRs for research.

On 19 June, CDISC (Landen Bain, CDISC Liaison to Healthcare) participated in a meeting with representatives of FDA Office of Scientific Investigation, CDER, where Susan Mitchell, Senior Manager of Research Information Systems at Florida Hospital, spoke about how her organization is already utilizing EHRs for research. Jane Griffin from Cerner and representatives from Quintiles also participated in this meeting at FDA. FDA representatives who attended this meeting were very pleased with this progress and the opportunity that is afforded by using EHRs for research, including the ability to support auditing/monitoring from afar. Follow the link.

CDISC Member Updates

Gold Members

- ATLANSTAT - France
- ArisGlobal LLC - USA

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

CDISC Global Updates

Notes from the Korean Workshop and Symposium
Greetings from Seoul! Members of our CDISC team. We have began our Asian journey with a trip to Seoul, South Korea, where Dr. Rebecca Kush, CDISC President and CEO, Wayne Kubick, CD ISC Chief Technical Officer, Dr. Pierre-Yves Lastic, CD ISC E3C Past-Chair and Chair-elect of the CDISC Board of Directors, and Dr. Kiyoteru Takenouchi, CDISC J3C Past-Chair and Board Member, have all given presentations to the K3C and interested parties from the Korean Society of Clinical Development at the CDISC Korea Workshop/Symposium about the importance of using CDISC standards for clinical research. A general overview of the standards and activities was given on the first day, and in-depth training over the standards and how the work together end-to-end was offered the second day.

Stay tuned for an update from Europe and the E3C next month, but our European colleagues are on vacances this month…anyone jealous?

Join the Challenge, and Gain the First Mover Advantage! Winner gets the CDISC Innovation Award with Recognition from HHS-ONC, DIA, FDA and CDISC!

At this year’s DIA meeting in Philadelphia on 26 June, CDISC, HHS/ONC and FDA issued a ‘challenge’ to use EHRs for regulated research. Specifically, research study sponsors were challenged to use at least two different electronic health record systems at different sites to conduct a multi-site, multi-visit, standards-based regulated research study. The panelists at DIA spoke on the feasibility of this challenge, based upon technology and data standards and processes that have been developed over the past decade. In addition, a case study was presented during this session about a research study being conducted currently at Florida Hospital using the Cerner EHR system. Despite the potential and demonstrated benefits of this approach, the clinical research industry has not yet embraced these new methods and standards to conduct research studies.


CDISC Coordinating Committees Worldwide

In an attempt to add value to the CDISC Coordinating Committees (3Cs), CDISC would like to present and highlight the 3Cs by stating their accomplishments and the key role they play in the global healthcare industry. A special area will be created on the CDISC website for this purpose. We will be publishing and announcing this new area within the next couple of weeks, stay tuned!

Four CDISC Coordinating Committees represent CDISC globally, China CDISC Coordinating Committee (C3C), Europe CDISC Coordinating Committee (E3C), Japan CDISC Coordinating Committee (J3C) and Korea CDISC Coordinating Committee (K3C).

Updates on the 3Cs’ international collaborations will be provided through the website. You will be informed on how these committees are involved with the CDISC interchanges and educational courses, and will gain the knowledge on their collaborations with regulatory authorities and other organizations such as academic research groups or government groups within their region to broaden the CDISC vision and mission through effective communications.

New Chair for CDISC Coordinating Committee in China

The CDISC China Coordinating Committee (C3C) was initiated in 2008 when Sandy Lei of J&J came to China and initiated a CDISC group. President, Rebecca Kush, also visited that year and a half-day workshop was held with Lei and Kush as speakers. The first Chair, Simon Wang of Parexel, was elected and a Charter was written. The C3C has since sponsored two Interchanges at Fudan University and more recently initiated a great group that has been validating translations (provided by Absolute Systems Clinical Data Co., Ltd.) and performing translations of the CDISC standards into Chinese. This group is known as CSTAR (CDISC Standards Translation and Review).
CDISC Workshops in China in July – Thanks to IBM and AmCham

In January 2012, CDISC was contacted by Nanping (Lisa) Li, Healthcare Strategy & Business Development Executive, IBM, who informed us that CDISC would be an important focus for IT standards in China, in particular, with respect to a new program that has been launched between China and the US through AmCham. Ms. Li sits on the Steering Committee of the Healthcare Cooperation Program (HCP).

CDISC 2012 Japan Interchange, Tokyo, Japan

This year marks the 10th anniversary of the Japan CDISC Coordinating Committee (J3C), and in celebration of this milestone, CDISC honored their long-standing support at the 2012 Japan Interchange in Tokyo.

Regulatory Science in Japan

“Japan’s Strategy in the Era of Global Development” was the title of the presentation given at the CDISC Japan Interchange on Thursday, 12 July by Tatsuya Kondo, M.D., Ph.D., Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA). This leader of Japan’s Regulatory organization provided a very informative keynote presentation expressing appreciation of the value of standards. Many thanks to Dr. Fukushima, head of the Translational Research Informatics Institute (TRI) in Japan, for extending the invitation. After his presentation, Dr. Kondo and two of his staff met with leaders from CDISC Global Operations, TRI, CDISC Board (Dr. Laetic) and the CDISC Japan Coordinating Committee.
Metadata Patent - Invitation to the Entire Health Care Community To Participate

Last month CDISC sent a letter to many of its members alerting them to a potentially damaging and costly patent application which is currently under review by the United States Patent Office. The text of the letter is below and was prompted in part by a thread on LinkedIn which can be found here.

The gist of the patent is this: a company, DataSci, filed a patent application in 2009 that effectively patents the use of metadata in clinical research. If this patent is granted there is a real possibility that a fee will be due to the patent holder for any use of metadata over the internet for every study done by any BioPharmaceutical company, academic research institution, government agency – basically ANY clinical research. See the original email below for more details and links that provide additional information.

Almost immediately after the email went out CDISC was contacted by Pharmaceutical, Biotech, Government, CRO and Technology company representatives asking how they could help prevent this patent from being approved. Most have forwarded the original email to their legal counsel and are looking into the process to protest this patent. Several of the large Pharma companies are also discussing how to combine efforts to fight this patent application.

CDISC appreciates all this effort and the support shown by our members. We will periodically update this blog with the status of these efforts. Follow the link to read the original email with further details and related links.

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 and in CD format at the International Interchange 2012 in Baltimore, MD. If you are interested in submitting articles, please contact Diana Harakeh. Deadline for submitting articles is 7 September 2012. Follow the link.

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.

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 Aficionados
- Technical Writers
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.

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 Interchanges and International Events:

- CDISC International Interchange 2012 in Baltimore, MD, 21 - 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.

In-House Training on CDISC Standards:

CDISC can provide authorized training in-house to any organization, anywhere in the world, 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 In-House Training online - click here for more information.

Public Training in the US:

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 Cambridge, MA in July 2013
Public Training in Canton, MI in August 2013
Public Training in Seattle, WA in September 2013

Public Training in Europe:

Public Training in Brussels, Belgium in September 2012
Public Training during the CDISC European Interchange in April 2013

Public Training in Asia:

Public Training during the Asia-Pacific Interchange in February 2013

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

More training 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