The CDISC October Newsletter Presents the Following Topics:

- CDISC International Interchange coming in less than 3 weeks! Asia-Pacific Interchange abstracts due this week!
- CDISC Technical News
- Key CDISC Partnerships - NCI EVS
- The Joint Initiative Council (JIC) for Standards Harmonization
- Pediatric Terminology Conference
- CDISC Member Updates, New Members and CDISC STAR Members
- CDISC Success Stories
- CDISC eJournal Articles 2012
- CDISC User Networks
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- CDISC Global Events and Education Opportunities
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Asia-Pacific Interchange Abstracts Due This Week!

The CDISC International Interchange is coming in less than a month! Join us on 22-26 October 2012 in Baltimore, MD. Online registration closes on Friday, 12 October 2012. If you have not registered, register now through the following link.

What will you miss if you do not attend?

- Keynote presentation by Dr. Janet Woodcock, FDA/CDER
- Keynote presentation by Ann Martin, IMI
- Launch of the Coalition for Accelerating Standards and Therapies (CFAST), an initiative of CDISC and the Critical Path Institute to speed the development of standards for specific therapeutic/disease areas.
- Panel discussions by various stakeholders on what disease area standards mean to them and what we have learned thus far in developing therapeutic/disease area standards.
- FDA panel discussions and more details on CDISC BRIDG and SHARE (Shared Health and Research Electronic Library).
- Presentations on where we should be going by representatives of One Mind for Research, DataSphere and the CEO Roundtable on Cancer, TransCelerate Biopharma, TX eHealth Alliance, Joseph H. Kanter Family Foundation and the Learning Health Community and the CTO of CDISC!

Please click here for the program to see the rest of the opportunities.

In addition, the CDISC Advisory Board (representatives of each CDISC Platinum Member Organization) will meet on 23 October from 3-6 pm. If you are not a member of CDISC, you can join CDISC, support the standards work and save 40% on your meeting and public courses registration.

Why Should You Attend?

If you are not yet convinced you should attend, please click here to see more reasons.

And, follow this link to view the highlights from our most recent webinar on the CDISC International Interchange.

The CDISC International Interchange is not just a conference! It is a combination of presentations, panel discussions and educational sessions. It is a place to meet and interact with regulators, professionals and experts in clinical research and the global healthcare industry. Our educational courses, offered on Monday and Tuesday, 22 and 23 October, will train attendees on how to implement the CDISC standards within their work environments.

Another chance to respond, click here to register! Don't forget to make your hotel reservations through the following link; the CDISC discounted rate code is provided here.

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.
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. Partake in this interchange and gain knowledge on how CDISC, the common language for global clinical research, works! Anyone interested in medical research expansion in the Asia Pacific region can benefit from attending this conference.

The European CDISC Interchange 2013 will follow the Asia-Pacific Interchange! The CDISC European 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.

CDISC Success Stories

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.

This month we would like to share an Interview with the current Chair of the CDISC Board of Directors, Paula Brown Stafford, Quintiles. This article was recently published in PharmaVoice. Success stories from 2012 (along with eJournal Articles) will be provided in CD format to Interchange attendees!

CDISC Technical News

CDISC is continuously working to release new standards and innovations to support our mission. Visit our website for frequent updates on the CDISC standards open for public review and comment. This month we would like to draw your attention to the following postings that will soon be available on the CDISC website:

- SDTM Implementation Guide for Medical Devices (Provisional)
- CDISC Parkinson’s Disease Therapeutic Area Standards (Provisional)
- SDTMIG 3.1.4 Batch 2 for Comment
- Polycystic Kidney Disease Therapeutic Area Standards for Comment

Follow the link to view Standards open for review and comment as well as new standards available for use.

Please Support CDISC at the 5 November FDA Public Meeting on Study Exchange Standards

FDA has scheduled a public meeting on November 5 to discuss Solutions for Study Exchange Standards. CDISC is requesting our members and volunteers to support of the use of CDISC ODM for study data exchange with FDA. If you are willing to sign our letter of support, or would like a copy, please click here.

CDISC will also be submitting a direct response to the questions posed by FDA in the Federal Register notice regarding these exchange standards. Responses to the docket are due on Friday, 5 October. If you would like to request a copy of the CDISC response to the Docket to help you prepare your own response, please click here.

CDISC encourages you to respond to the FDA Docket and hopes to see many of our members and volunteers at the public meeting.

Join us for the CDISC Standards Webinar - Latest Updates and Additions on Thursday 29 November 2012 at 11:30 AM U.S.A Eastern Time.

A meeting, entitled “Sharing Clinical Research Data” has been organized by the Institute of Medicine (IOM), National Academy of Sciences; this meeting will take place 4-5 October in Washington, DC. There will be a webcast available for those who wish to listen.

Key CDISC Partnerships - Featuring the NCI Enterprise Vocabulary Services (EVS)
As this is the first time to spotlight a CDISC partnership, it is only fitting to focus on one of our longest running and most fruitful partnerships; that is with the National Cancer Institute Enterprise Vocabulary Services (NCI EVS) organization, spanning nearly 10 years. This partnership has proved pivotal to CDISC’s success in providing controlled terminology and the semantic underpinnings for our global data standards. We have come a long way since releasing the initial set of several hundred terms for SDTM (Study Data Tabulation Model), CDISC’s standard for FDA Regulatory Submissions of Human Clinical Trial Information. There are now over 10,000 CDISC terms maintained and published in NCI Thesaurus supporting our core data standards: SDTM, CDASH (data collection), ADaM (analysis) as well as the SEND standard for non-clinical data collected in animal toxicology studies. This terminology is completely open for use in global clinical trials and can be accessed and downloaded via either the CDISC website http://www.cdisc.org/terminology or directly through the NCI website http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc.

Terminology Services

There is so much more to controlled terminology than what meets the eye. There is an incredible amount of work going on behind the scenes. The bundling of Controlled Terminology with Terminology Services is critical to meet the growing needs of CDISC’s global user community. NCI EVS provides an important suite of terminology services to CDISC as well as other Federal and International Partners:

- Subject Matter Expertise
  - Definition Writing and Analysis
  - Terminology Coding, Tagging and Subset Bundling
  - Terminology Maintenance and Versioning
  - Links to other Controlled Terminologies (e.g. MedDRA, LOINC, SNOMED-CT)
  - Terminology Harmonization and Cross-Sharing between Partner Organizations such as FDA and NIH Institutes
  - Facilitation of New Terminology Requests

Follow the link for the full article.

The Joint Initiative Council (JIC) for Standards Harmonization

At the opening session of the ISO TC/215 meeting in Vienna, Austria there was an overview of the Joint Initiative Council (JIC) status and plans, based upon the JIC Strategy Session that took place all day on 22 September 2012. Bron Kisler, CDISC VP, Strategic Initiatives and current Chair of the JIC, delivered this overview and facilitated discussions with panel representatives and a large audience representing National Member Bodies from around the world. He first introduced members of the JIC and gave special thanks to the Austrian Standards Organization for hosting this meeting at the Wirtschaftskammer Ostereich (WKO) Austrian Economic Chamber; to Christian Hay of GS1 for arranging for the meeting space for the JIC strategy session; and, to Lisa Spellman and AHIMA for supporting the secretariat needs of the JIC. Bron also gave special recognition to Richard Dixon Hughes (HL7, ISO, Australia), who is JIC Chair Elect, as well as IHE (Integrating the Healthcare Enterprise) for recently being voted the newest member of JIC.

Members of the JIC: With the recent addition of IHE there are now 7 global Standards Developing Organizations (SDOs) that make up the JIC. The founding members include - International Standards Organization Technical Committee 215 (ISO TC/215), Health Level Seven (HL7) and Committee European de Normalisation (CEN). When they became interested in the work of the ICH (International Conference for Harmonization) in the area of clinical research, CDISC was invited to apply and became a member in 2008. IHTSDO (International Health Terminology Standards Development Organization) and GS1 were voted-in as member of JIC in 2009 and 2010.

The JIC Purpose: “The Joint Initiative on SDO Global Health Informatics Standardization enables common, timely health informatics standards by addressing and resolving gaps, overlaps and counterproductive standards efforts.”

Vision: Speaking with one voice, facilitate achievement of coherent, coordinated and usable global health informatics standards providing value to member SDOs and their constituencies.

The Strategy Session: The theory behind JIC is to cooperate as global SDOs such that standards can be coordinated upfront and then ‘balloted’ simultaneously across different SDO processes, becoming a joint standard as an end product. This enables SDOs to work together above and beyond existing 1-to-1 Memorandum of Understandings. It is recognized that standards coordination is difficult work with room for improvement.

Pediatric Terminology Conference

The importance of research into prevention and cure of childhood diseases cannot be understated. Anything that can be done to speed that process should be a priority. One way to make this process more effective and efficient is to standardize where possible. Standardization of pediatric terminology was the focus of “Bridging the Terminology Gap in Pediatrics: Developing an Action Plan to Support the Continuum from Clinic to Research” – a conference held on Friday, 21 September 2012 at the Natcher Conference Center on the NIH main campus in Bethesda, MD.

The goal of the meeting was to bring together a broad constituency of pediatric researchers to organize a governance
structure and organizational model to work collectively within and across domains to address issues of terminology harmonization with the objective of linking clinical care and research terminologies to support data sharing and integration. The meeting initially focused on pediatric terminology efforts and real-world experiences, including use cases, successes, and challenges. The meeting then focused on developing a pediatric research terminology framework that aligns with clinical care terminologies.

CDISC representative, Frank Newby, Executive VP, Development, provided details on best practices to develop controlled terminology standards including establishing a well-defined process, controlling scope to develop an agreed list of data elements, engaging sufficient subject matter experts and other volunteers including NCI EVS personnel (see complementary article on NCI EVS in the eNews), employing a project manager, creating robust definitions for each data element then bundling the resulting output into documentation for public review. Once all public comments have been taken into consideration the package of terminology passed onto our partner at the National Cancer Institute and is loaded into their Enterprise Vocabulary Services (EVS) application. The package of terminology is then made freely available for public use.

The final component of the meeting was to determine a set of next steps and short-term goals to begin organizing a governance structure and prioritization mechanism so that the work of developing a robust set of pediatric terminology could continue. There was great energy around this work given the promise it holds to aid in the development of new medicines and devices which will improve the health of children!

CDISC Member Updates

Our New Members in September

- Adware Research Kft - HUNGARY
- Cerafor Ltd. - UK
- DP Clinical - USA
- Ecron Acunova GmbH - GERMANY
- Itwell Group - FRANCE

Thank you and a warm welcome to our new members from September. 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.

THANK YOU TO CDISC STAR MEMBERS

Beginning with our September 2012 issue of our eNewsletter, CDISC will be acknowledging our Star Members (organizations who have been CDISC members for 5 years and more). We are very grateful for the support these members have given to us over the years allows us to continue to serve the industry through our work in expanding the worldwide adoption of CDISC Standards.

Star Members in October

- Eisai, Inc.
- University Hospital Medical Information Network
CDISC constantly works toward adding value to its members and stakeholders. To expand the visibility of our member organizations, CDISC sheds a light on its members through various media including success stories which are mentioned through the monthly eNews, the CDISC website, and by listing the achievements of its member companies describing their contribution and experience with the CDISC standards. 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.

This year, we collected articles for the CDISC eJournal 2012 and plan to issue them on Compact Discs to be distributed during the International Interchange week (22-26) October in Baltimore, MD. These articles will be published on the CDISC website by the end of October 2012. Please stay tuned!

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. 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.

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**

Thank you to all those who have supported authorized CDISC Education in 2012. We are having a great year and there are still many opportunities available to attend CDISC educational courses. We have several of our most popular courses being offered at the beginning of the International Interchange (SDTM, ADaM, CDASH, and others) and there are still plenty of seats open for each of the courses offered. Be sure to register by 12 October to reserve your place. Click [here](#) for more information.

Our 2013 public training schedule is firming up nicely, too. Please see below for details about the 2013 schedule (click on links to see which courses are offered at each location):

1. **CDISC Free Webinars:**

   Join us for the [CDISC Standards Webinar - Latest Updates and Additions](#) on Thursday 29 November 2012 at 11:30 AM U.S.A Eastern Time.

   **Webinar Link:** [https://sasevent.webex.com/sasevent/onstage/g.php?d=667147443&t=a](https://sasevent.webex.com/sasevent/onstage/g.php?d=667147443&t=a)

   **Password:** CDISC

   Password is case sensitive.

   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:**

   we can come to you for in-house private classes at your company location anywhere in the world. Private, in-house courses involve an authorized instructor conducting a CDISC course at your company facility. In addition to the cost benefits the CDISC instructor will be able to answer questions related to the work being done in your company. To request a quote for an in-house course, please click [here](#).

   b. **Public Classes in the US:**

   Public Education Courses at the [CDISC International Interchange](#) in Oct 2012
   Public Education Courses in [Tucson, AZ](#) in January 2013 - [Hosted by C-Path]
   Public Education Courses in [Morrisville, NC](#) in Feb 2013 - [Hosted by Synteract]
   Public Education Courses in [South San Francisco](#) in March 2013 - [Hosted by Genentech]
   Public Education Courses in [Cambridge, MA](#) in July 2013 - [Hosted by Genzyme]
   Public Education Courses in [Canton, MI](#) in August 2013 - [Hosted by MMS]
   Public Education Courses in [Seattle, WA](#) in September 2013 - [Hosted by Cell Therapeutics]

   c. **Public Classes in Europe:**

   [6]
Public Education Courses during the CDISC European Interchange [v] in April 2013

Public Education Courses in Brussels, Belgium [v] in September 2013 - Hosted by Business and Decision

Public Classes in Asia:

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

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

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

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

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 [v]

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

Further questions are welcome through the following email [v].

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