February 2012 eNewsletter

The February CDISC newsletter communicates key timely topics about CDISC, with an opening letter from our new CTO and current opportunities for interested parties to volunteer for CDISC activities; updates on CDISC Membership; a press release on CDISC expanded efforts in Europe with an update on the April CDISC European Interchange; the second in a series of CDISC Case Studies; an announcement about CDISC Standards translated into Japanese and updates to CDISC standards. We also include opportunities to comment on draft standards and/or engage in our CDISC Education opportunities and User Networks. And please don’t miss our new CDISC Social Media announcement at the end!

Letter from CDISC Chief Technology Officer - Technology and CDISC

As I enter my second month as CDISC Chief Technology Officer, it's worth spending a few moments to discuss why I'm here. Why does CDISC need a Chief Technology Officer anyway?

Well, in a nutshell, CDISC needs a CTO to define the future vision and direction of CDISC standards development, and to work to provide CDISC with improved tools and processes to help us get there. Here at CDISC, technology comes into play in three major areas:

1. The tools and processes we need to develop and maintain standards efficiently
2. The technological underpinnings of the standards we create
3. The applications we use to effectively operate the CDISC organization.

Recognizing that the demand for new standards (especially in therapeutic areas) has increased strikingly, and the number of standards projects we're involved with is rapidly mushrooming, we need to find ways to better support our volunteers to streamline the effort of standards development. This includes moving to a more collaborative online environment. Having better online collaborative tools will allow us to keep better track of our discussions and decisions, and allow more involvement from volunteers all around the world. One of the first tools we're rolling out in this area is an online commenting tool for reviewing drafts of new standards that we received from the US Office of the National Coordinator (via ANSI), which is currently being tested by team leads. Follow the link. [1]

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**

The CDISC XML Technologies team is looking for new contributors to contribute to the development and documentation of XML transport standards including ODM, Define.XML, SDM and others. Contributors should be familiar with CDISC foundational standards and the use of XML to represent clinical data, with some previous exposure to ODM, Define.xml or both. XML technology meetings for the full-team and project sub-teams occur weekday mornings (to accommodate European and US participants and have several significant planned deliverables this year which will require development, testing and documentation of XML schemas.

**Technical Writers**

Most CDISC standards are published as documents, but it takes a lot of effort to put these documents together. While the content of our standards are prepared by our teams, we need additional help from writers familiar with Word, Acrobat and document assembly and publishing to help us get these standards out into the hands of users. You'll be working with specific technical teams on publications, helping to compile, format, set up hyperlinks and swap out content with updated material. If you think you can help us with this important task, we need to hear from you!

**Protocol Representation**

The CDISC Protocol Representation Group is looking for new volunteers to assist them in the expansion of the protocol representation standard and development of new tools for representing protocol information. Contributors should be familiar with study designs and the protocol authoring process, including understanding basic protocol information submitted to registries, study objectives, endpoints, schedules of activities and inclusion/exclusion criteria.

Follow the link [2] to know more about how to volunteer! Further questions are welcome at the following link [3].

**CDISC Member Updates**

2012 - 2013

Thank you and a warm welcome to our new members in January. 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.
CDISC Broadens Efforts in Europe

CDISC significantly expanded its presence in Europe in 2011 and anticipates this trend will continue. CDISC has long had a presence in Europe through its European CDISC Coordinating Committee (E3C) founded in 2002, annual CDISC European Interchanges and partnerships with European organizations in the global healthcare and medical research industries. CDISC now adds to this list a newly established CDISC entity in Brussels, Belgium, a recently signed Memorandum of Understanding (MOU) with the EU’s Innovative Medicines Initiative (IMI), and a new relationship with the European Organisation for Research and Treatment of Cancer (EORTC), the EU’s largest cancer research network.

With CDISC’s expanded efforts in Europe, there is great excitement and anticipation surrounding the upcoming 2012 CDISC European Interchange, set for 16-20 April in Stockholm, Sweden. The Plenary session will begin with opening remarks by the CDISC Board Chair, Paula Brown Stafford and Chair-elect Pierre-Yves Lastic, who has also led the E3C for the past two years. Plenary speakers will be an expert line-up: Professor Marie Lindquist of the Uppsala Monitoring center, who is working with CDISC and the World Health Organization (WHO) on an important project; Dr. Bernard de Bono of the European Bioinformatics Institute, who will speak about some of the IMI initiatives in which CDISC is involved; Ms. Lisa Spellman, Secretariat of the International Standards Organisation’s (ISO) Technical Committee on healthcare standards (TC215); representatives from the U.S. Food and Drug Administration (FDA); CDISC President, Dr. Rebecca Kush and new CDISC Chief Technology Officer, Wayne Kubick. The EU Interchange week will also include the Annual Meeting of the CDISC Board of Directors and a CDISC Advisory Board (CAB) meeting. “We are extremely pleased to have such a qualified, diverse and relevant set of Plenary session speakers, and the presentations to follow have been carefully selected from excellent abstracts on real-world implementation experiences with CDISC standards globally,” commented Dr. Lastic of Sanofi. “We hope to attract those who have attended before in addition to a new set of attendees in new areas where CDISC standards are now developing significance, such as devices, biotechnology and therapeutic areas. With the CDISC entity in Europe, the opportunities for CDISC continue to expand exponentially here.” Follow the link [6].
Plan now to participate in the CDISC Interchange in Stockholm, Sweden in April with keynoters representing ISO, IMI, FDA, Uppsala Monitoring Center and WHO. The CDISC European Interchange 2012 provides the opportunity to share progress, implementation experiences, and strategic ideas on worldwide data interchange standards across the global healthcare industry. There will be educational courses in addition to a CDISC Advisory Board meeting (with an expert panel for a private Q&A session). Hundreds of attendees from various regions of the world attend the CDISC interchanges in a given year providing excellent networking and learning opportunities. We are looking forward to a promising year, starting with the first interchange in Stockholm, Sweden in an amazing location, Elite Marina Tower, overlooking Stockholm’s bay.

The main conference will be held on 18-19 April. Extensive training courses will be conducted on 16, 17, and 20 April where CDISC authorized trainers will provide you the opportunity to learn about the implementation experiences, theory and application of the CDISC standards.

Registration is now open, follow the link! Sponsorship and Exhibitor opportunities are available too. There will be a networking opportunity with dinner and boat ride for those who register first.
Stay tuned to our website and mark your 2012 calendars for mid-July in Tokyo and the week of 21 October in Baltimore. Sponsorship opportunities are still available; contact Andrea Vadakin.

CDISC Case Study

CDISC is initiating a new feature in the eNewsletters in 2012 – Case Studies. These have been a popular request/suggestion in our surveys on how CDISC can increase value for its stakeholders. We have a list of those who are willing to provide such Case Studies from the CDISC Advisory Board (CAB), which has heard such useful presentations during its teleconferences throughout the past two years. If you would like to offer a case study for a future CDISC eNewsletter, please contact Diana Harakeh. These can be submitted in written format or created through a phone interview with CDISC Communications Staff.

Biogen Idec Adoption of CDISC Standards to Create Standard Case Report Form Libraries

Case Study on Biogen Idec Experience with CDISC

The Case Report form (CRF) is a tool used to record data in a clinical study. Data in a CRF should be collected in a specific format in harmony with the protocol and in agreement with regulatory requirements. The importance of standardized CRFs is revealed in facilitating the exchange of data across drug compounds, disease indications as well as across companies. Standardized CRFs which are harmonized with the CDISC CDASH model require minimal mapping (if at all) in order to exchange the data. If a well-designed CRF is adopted, it will provide improved productivity in processing and analyzing clinical data from start-up throughout all down-stream processes. Saving time and money in collecting and analyzing clinical trial data is the main outcome of using well-designed CRFs where data could be reused effectively.

Biogen Idec Experience with the CDISC Standards

The Biogen Idec experience with CDISC started in 2003 when the company made the decision to utilize CDISC SDTM Standard to build their standard Case Report Form libraries. As Idec and Biogen merged to become one company, Data Management and Biometrics team members recognized that having two distinctive “company specific” CRF libraries would
result in inefficiencies in their processes, time and resources! A cross-functional team (called the Data Standards Team) was formed including data managers, clinical operations, statisticians and statistical programmers who worked together - under the principle of organization and collaboration- to build a new CRF library that could be used for all studies (regardless of disease indication) moving forward based on CDISC SDTM standard. The CDISC standards could then be easily used as part of all the downstream activities including mapping to their SAS datasets and analysis of data in their programming world, these standards facilitate the creation of analysis datasets, the clinical trial results, and their submission. Follow the link [11].

TRI CDISC Standards in Japanese

TRI CDISC Standards in Japanese is the official Japanese translation of CDISC Standards by the Translational Research Informatics Center [12] (TRI), Foundation for Biomedical Research and Innovation (FBRI). TRI has translated the CDISC Standards to make them widely available for the Japanese researchers, with a vision to promote clinical trials and consolidate the infrastructure in Japan.

Located in Kobe, Japan, TRI was founded in 2002, by the Ministry of Education, Culture, Sports, Science and Technology (MEXT), and Kobe city. The goal of TRI is to improve the prognosis for intractable human disease, focusing on developing activities for the following domains: “Promotion & Management of Translational Research”, “Management & Operation of Clinical Trials & Outcome Research”, and “Information Services for Therapeutic & Clinical Research”.

Since 2009, as one of the CDISC Platinum Members (Previously identified as Corporate Sponsors), TRI has launched the Japanese website called “CDISC Standards Promotion Project”, which contains implementation tests on CDISC Standards and a Translation of the CDISC Glossary. During the 2010 CDISC International Interchange in Baltimore, a Memorandum of Understanding (MOU) was signed between CDISC and TRI to proceed with the translation of CDISC Standards into Japanese. In 2012, TRI has published the TRI CDISC Standards in Japanese with the support of the J3C (Japan Coordinating Committee).

Through translating and disseminating TRI CDISC Standards in Japanese, TRI hopes to support clinical trials and studies, and contribute to better health in Japan.

We would like to express our sincere appreciation to the Japan CDISC Coordinating Committee (J3C) and the CDISC Japan Users Group (CJUG) for their kind cooperation on the translations produced by TRI. Follow the link [13].

For accessing the CDISC Standards in Japanese, please contact Sheila Leaman [5].

CDISC Device Draft Standard for Public Review and Comment Period - Comment Period Extended to 9 March 2012

The draft Devices Supplement to the Study Data Tabulation Model Implementation Guide (SDTMIG) defines recommended standards for the submission of data from clinical trials in which medical devices were used. These domains cover both studies where the device is under study and where approved devices are used to generate study
measurements but the device is not under study.

This is the first attempt by CDISC to develop submission standards for device trials, so it is expected that there will be gaps and areas for further development. To this end the CDISC Device team requests that the clinical research community review these proposed standards and submit comments for further improvement and development. Reviewers are encouraged to model these standards with test data and provide detailed feedback on what did and did not work. Follow the link [14] to know more and to access the Draft Document and the Comments Spreadsheet.

Release of Revised SDTMIG Trial Summary Dataset, Including Null Flavor Enumeration

CDISC is pleased to announce the availability of an Updated Trial Summary Dataset, which includes a new null flavor enumeration method. This updated version is an advance release of revised and supplemental material that is planned for incorporation in the forthcoming SDTM v1.3 and SDTMIG v3.1.3. Follow the link [14].

CDER Common Data Standards Issues Document Updated Version

FDA recently posted an updated version of the “CDER Common Data Standards Issues Document V1.1”, follow the link [15].

If you have any questions or comments on this document please send to the following email [16]. Please note that this is a central email address to collect all comments and questions. If you send an email anywhere else it may not be processed.

NINDS Headache Common Data Element Review through 30 March

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH) is requesting your input on the Headache Common Data Elements being developed through its partnership with headache experts. NINDS recently assembled an external working group of nearly 50 national and international experts to develop the Headache CDEs (Headache Common Data Elements), and they are now ready for feedback from the larger Headache clinical research community. We hope you will take the time to review the CDEs. [CDISC is directly participating with NINDS on the standards for Parkinson’s Disease and through reviews such as these on other standards.]

The NINDS CDE Website [17] fully describes the NINDS CDE Project and its goals. In summary, the CDE Project aims to develop content standards, both generic and disease-specific, to enable clinical investigators to systematically collect, analyze, and share data across the research community. Over the past 8 months, the Headache CDE Working Group has identified and defined a catalog of CDEs which investigators can choose from when assembling their clinical study
The Headache CDE Working Group has not attempted to define the complete universe of variables a clinical study might collect but rather to isolate elements that will be useful across clinical studies.

The public review period for the Headache CDEs will take place through March 30, 2012. During this time, Version 1.0 of the Headache CDEs will be publically available on the NINDS CDE Website. To access and review the Headache CDE recommendations, please follow the steps below:

1. Navigate through the following link
2. From the Headache CDE Standards page, on the Data Standards Tab, download the zip file containing the review package
3. Unzip the zip file and read the "Overview document" for tips on how to conduct the review and submit your comments

The Headache CDE review package is categorized into five different domains. Please feel free to provide comments on as many domains as you wish. We look forward to your feedback and ask that you please submit your comments by Friday, March 30, 2012. Please note, the review package represents only a beta version of the Headache CDEs. The CDEs will require refinement and validation, and the Call for Public Review is an important step in that ongoing process.

Thank you in advance for taking the time to review the Headache CDEs. We hope that you will share this announcement with your colleagues and encourage them to provide feedback as well.

Thank you for your interest in this important Therapeutic Area project.

CDISC Operations

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 compared to the $25 original price.

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

CDISC User Networks

In tandem with CDISC’s efforts to ensure higher quality medical research on a global basis, self-formed 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. Three user networks represent CDISC in Asian countries (China, Japan and Korea), while the CDISC English, French, German, Italian and Nordic User Networks represent CDISC in Europe. In the United States, ten user networks cover the continent from the East to the West coast and focus on CDISC users in various regions. In late 2011, two new user networks have been initiated one in San Diego, California and one in South Africa.
The South African User Network will be having the first meeting on **28 March 2012**. If you would like to be notified on the meeting details or if you would like to become a member of the South African User Network, please contact **Dianne weatherall**, **Marielle Knott** and **Richard Roodman** before **29 February 2012**.

User Networks discuss draft standards and provide comments to CDISC, discuss mature standards and provide feedback to CDISC on their usefulness as well as deliberate new ideas to be channeled into CDISC; network among colleagues; and share recent conference participation and learning experiences. If you are not a member of any of the CDISC User Networks and would like to be actively involved with one of them, you can join the one in your area and contribute to the CDISC mission. You may also launch a user network in your area and spread the knowledge about CDISC in your local community! To find out more about joining, 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.

### CDISC 2012 Global Events and Education Opportunities

CDISC is delighted to invite you to the upcoming **public trainings for 2012** as well as our **CDISC Interchanges in 2012**. Please stay tuned to our CDISC Events and Education via the following [link]. In addition, CDISC is partnering with FDA and PhUSE on the annual FDA Computational Science Center meeting in March 2012, as indicated below.

**CDISC to Collaborate with FDA and PhUSE to Improve Product Lifecycle**

Meeting: FDA/PhUSE Annual Computational Science Symposium, Silver Spring, MD, 19-20 March 2012.

Meeting title: Update on Standards, Tools, and Process Initiatives Across Regulatory Review and Collaboration with Key Working Groups to Improve the Product Lifecycle.

The foundation of the product development process is the ability to efficiently acquire, store, and analyze the data and documents to make informed and timely decisions. The focus of the 3rd Annual Computational Science Symposium is to continue the work initiated at the previous annual meetings by bringing FDA, industry, and academia together to provide an update on current initiatives ongoing within the FDA and establish collaborative working groups to address current challenges related to the access and review of data to support product development. These groups will work on possible solutions and practical implementations with the goal of helping the broader community align and share experiences to advance computational science. Follow the [link] for further information.
CDISC Interchanges:

CDISC Europe Interchange 2012 in Stockholm, Sweden, 16 - 20 April 2012

CDISC Japan Interchange, 10 - 13 July 2012

CDISC International Interchange 2012 in Baltimore, MD, 21 - 26 October 2012

Public Trainings in the U.S.:

**SPECIAL OPPORTUNITY 10% DISCOUNT AVAILABLE TILL FEBRUARY 6 ON ALL THE PUBLIC TRAININGS**
REGISTER NOW.

Public Training in Austin, TX in April 2012
Public Training in Audubon, PA in May 2012
Public Training in Palo Alto, CA in June 2012
Public Training in RTP North Carolina in Aug 2012

Public Trainings in Europe:

Public Training at the European Interchange in April 2012
Public Training in Brussels, Belgium in September 2012

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, CDSC 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* for more information.

*More trainings opportunities to come soon. Please stay tuned to our Education and Events page.*

**CDISC Social Media**

Social media platforms, such as blogs, Facebook, Twitter, LinkedIn and YouTube are quickly becoming indispensable media for any organization. CDISC recognizes that through social media, we fortify the relationship of our members and followers and can work more efficiently toward the CDISC mission and the CDISC vision of informing patient care and safety through higher quality medical research.

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**

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