December 2011 eNewsletter

We are pleased to bring you this last CDISC eNewsletter of 2011 as we begin looking forward to 2012. Opportunities are open to participate in the April Interchange in Europe; productive collaborations continue with IMI, the Critical Path Institute and now CIMI; the long-awaited SDTMIG V3.1.2 Amendment is now available and draft device domains will be released soon for public review. Information is also included on CDISC User Networks and 2012 Events and Education. We sincerely thank all of the CDISC participants and supporters for your important role in our continuing progress and we wish you all ‘Happy Holidays’! Look for specifics on CDISC Goals for 2012 in the next CDISC eNewsletter in January and an announcement about CDISC Leadership changes for the New Year.

CDISC European Interchange 2012

CDISC Interchange events unite representatives from international organizations at one location to address the most up-to-date achievements attained by the global CDISC community, working together toward the CDISC mission and vision. CDISC Interchanges bring in nearly a thousand attendees around the world in a given year. We are looking forward to a promising 2012, starting with the first CDISC Interchange in an amazing location in Europe—Stockholm, Sweden. The CDISC Europe Interchange 2012 will be held on 16-20 April at the Elite Marina Tower, a magnificent location overlooking Stockholm’s bay.

Exhibitor and Sponsorship opportunities are available NOW through the following link. The preliminary Interchange program will be available on the CDISC website by the end of January 2012. The deadline for abstracts submission is 6 January 2012.
Further information on the Interchange topics will be published in the upcoming January eNewsletter! Stay tuned to our website as registration for Europe will open soon! And, mark your 2012 calendars for mid-July in Tokyo and the week of 21 October in Baltimore.

Teamwork: How Collaboration in the Medical Research and Healthcare Industries Supports Faster and Safer Drug Development

Last year Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) launched a landmark joint project to develop a successful Alzheimer’s Disease (AD) data standard and research database. Data from eleven AD clinical trials from seven of C-Path’s Coalition Against Major Diseases (CAMD) member organizations (who are also CDISC members), was converted into the CDISC SDTM standard. During the process, new formats were added to SDTM to create a resulting new therapeutic area specific standards package, the CDISC AD standard. The data were then ready to be aggregated, and the result was a database incorporating detailed data from over 4,100 individuals afflicted with AD, a groundbreaking achievement that will assist researchers in developing safer and more effective treatments for those suffering with AD.

The collaboration between CDISC, C-Path, government agencies, academia, patient groups and the AD clinical community in developing the CDISC AD standard is a valuable model of how a successful consortium can support faster and safer drug development. In much the same way that CDISC has collaborated with C-Path to develop Alzheimer’s data standards, CDISC and the Innovative Medicines Initiative (IMI) have recently signed a Memorandum of Understanding (MOU), agreeing to collaborate for the shared purpose of accelerating the development of new therapies for patients worldwide.

IMI, the largest public-private partnership in Europe, supports further innovation in healthcare through the formulation of partnerships between industrial and academic experts to aid in the creation of a more cooperative environment for R&D, encouraging the development of safer and more effective drugs for patients. IMI seeks to address certain inadequacies in R&D causing delay in the drug development pipeline through four research priorities: 1) predicting safety, 2) predicting efficacy, 3) knowledge management and 4) education and training. With knowledge management in particular, IMI seeks to more effectively utilize data to determine safety and success. Follow the link for full article.

CDISC and IMI Partner in Knowledge Management Towards Development of Innovative Medicines
The Innovative Medicines Initiative Joint Undertaking (IMI) and the Clinical Data Interchange Standards Consortium (CDISC) are pleased to announce that they have signed an agreement and initiated activities to enhance the use of information gathered for the purpose of developing safer, more effective innovative medicines for patients. The agreement was spearheaded by Ann Martin, Principal Scientific Manager for Knowledge Management at IMI. “To effectively manage information across a variety of projects requires a common format at the elemental level,” stated Ms. Martin. “Our stakeholders felt strongly that it is good practice to adopt data standards. CDISC already provides such standards enjoying wide adoption in the pharmaceutical industry. The CDISC standards therefore could be considered as a default standard for research conducted through the IMI projects. Moreover, CDISC not only focuses on global clinical research, but also collaborates to harmonise with global healthcare standards bodies such as the International Organization for Standardization (ISO), Health Level Seven International (HL7) and the European Committee for Standardization (CEN) through a Joint Initiative Council (JIC).”

IMI, a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), is the world’s largest public-private partnership initiative aiming to speed up the development of better and safer medicines. With its €2 billion research fund, IMI supports collaborative projects through consortia comprising academic experts, small and medium-sized enterprises, patients’ organisations, pharmaceutical companies, and regulators to support innovation in research and development in Europe. The IMI projects range from finding new biomarkers for the development of safer and more effective treatments for patients, to educating researchers and using electronic health records for various research purposes. Follow the link [7].

CDISC Participates in International Collaboration: Clinical Information Modeling Initiative (CIMI)

CDISC and a number of other organizations have been participating in a global initiative led by Dr. Stan Huff of Intermountain Healthcare. A public statement was recently released to describe the initiative and associated principles:

The Clinical Information Modeling Initiative (CIMI) is an international collaboration that is dedicated to providing a common format for detailed specifications for the representation of health information content so that semantically interoperable information may be created and shared in health records, messages and documents. CIMI has been holding meetings in various locations around the world since July, 2011. All funding and resources for these meetings have been provided by the participants. At its most recent meeting in London, 29 November - 1 December 2011, the group agreed on the following principles and approach. Read more [8].

Follow the link for the full article [9].

Recent CDISC Activities in Japan

The CDISC Coordinating Committee in Japan (the J3C) has been very busy, particularly in November. CDISC President and CEO Dr. Rebecca Kush, was invited to Japan to participate in a number of the CDISC-related activities last month:
On Friday evening, 11 November, she spoke at Kyushu University Medical Center to fulfill a longstanding invitation from Mr. Ken Toyoda, who leads Japan ISO TC 215 Committee. Dr. Kiyoteru Takenouchi, a Director on the CDISC Board, was invaluable in organizing logistics around this event and the following one on Saturday.

On Saturday, 12 November, she met with Dr. Fukushima and his leadership team from the Translational Research Informatics (TRI) organization (based in Kobe) to discuss their use of CDISC standards and encouragement of CDISC standards implementations by academic institutions in Japan.

On Sunday, 13 November, Mr. Yoshio Tsukada chaired a pre-conference workshop for the Global QA Conference in Kyoto; the workshop, entitled “CDISC Makes You Happy” included speakers from JPMA, CDISC (Dr. Kush), Pharma, CRO, Vendor and Academia.

On Monday, 14 November, the Japan CDISC Coordinating Committee (J3C) held a symposium with a theme on Legacy Data Conversion, with openings by Mr. Tsukada and Dr. Kush and featuring Peter Van Reusel (CDISC instructor from Business and Decision, who also taught the SDTM course in Japan for the following two days).

Stay tuned for blogs and photos of these activities in Japan in the coming weeks!

Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2

CDISC is pleased to announce the posting of “Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2” which can be found here. Amendment 1 contains new variables for certain domains as well as instructions and clarifications. This was a collaborative effort between CDISC and FDA and is a companion document to the “CDER Common Data Standards Issues Document V1.1” which can be found here.

Draft Device Supplement to the SDTM IG V3.1.2 to be Released for Public Review

The CDISC device team was originally a SDS sub-team led by Carey Smoak. In 2009 the team was expanded to include other CDISC team members and AdvaMed member device companies. The goal of the team is to identify the basic data collection fields (CDASH), the submission (SDTM) variables, associated metadata and mappings to support the majority of device studies and modalities, i.e. diagnostic devices, implantable devices and imaging devices.

Significant progress has been made and the device team plans to post a draft Device Supplement to the SDTMIG v3.1.2 for a 30-day public review early next year. Once the 30-day public review is completed and all comments have been addressed the first version of Device Supplement to the SDTM IG v 3.1.2 will be published on the CDISC website.

Follow the link for the full article.
Progress Continues on Therapeutic Area Standards

There were six Colloquia sessions held during the CDISC International Interchange 2011, focused on 6 therapeutic areas: Oncology, Virology, Pain, Diabetes, TB and Imaging. A blog [15] on the Virology Colloquia was posted previously. This work continues with funding from an NIH/FDA grant. Oncology standards were discussed at one of the Colloquia sessions. See a recent blog posting here [16]. An update on TB standards will be included in the January eNewsletter.

FDA recently posted a list of their therapeutic area priorities (55 in number). Plans to approach these areas in collaboration with the Critical Path Institute have been discussed and presented to FDA representatives. Watch for a coming blog review of the recent meeting held by the Critical Path Institute 30 November - 1 December in Silver Spring, MD in particular the Standards Panel session.

CDISC Approved as 501(c)(3) Non-profit Organization

One of the CDISC goals for 2011 was to obtain approval from the U.S. IRS to become a 501(c)(3) organization. Therefore, in May of 2011, we applied for a review of our non-profit status and a change in status from a 501(c)(6) to a 501(c)(3) was approved on 21 November. This change is in concert with our recent 2010+ vision of informing patient care and safety through higher quality medical research. CDISC activities in the therapeutic area standards development are also focused on global standards for the benefit of patients and will be better served through the new non-profit status. A recent CDISC press release on this topic [17] describes the benefits of this status change for CDISC and its members/stakeholders.

From the perspective of Europe, in July 2011, CDISC initiated the CDISC Europe Foundation, which is based in Brussels, Belgium – the EU capital. It is this through this foundation that CDISC will be actively participating in standards-related projects in Europe, including IMI-directed projects. See the prior article and recent press release on the CDISC- IMI Agreement [18]. Additional information will be forthcoming on the CDISC Europe Foundation. Follow the link [17].

CDISC User Networks

The CDISC User Networks promote CDISC international presence and adoption of CDISC standards by spreading CDISC knowledge and encouraging the sharing of implementation experiences in global communities and regional areas throughout the United States. These user networks represent CDISC in Asian countries (China, Japan and Korea), while the CDISC English, French, German 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. Recently, two new user networks have been initiated, one in South Africa and one in San Diego, California. The latter was inaugurated on 3 November at Neurocrine Biosciences.

User Networks share CDISC implementation experiences periodically in a given region or language; discuss draft
standards and provide comments to CDISC; discuss mature standards and provide feedback to CDISC on their usefulness; discuss 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 public trainings for 2012, as well as our CDISC Interchanges in 2012. Please stay tuned to our 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, March 19-20, 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 on April 16 - 20 2012. Call for Abstracts is still open, deadline for submission is 6 January 2011.

CDISC Japan Interchange 2012 on July 10 - 13, 2012

Public Training in the U.S.:

Public Training in Carlsbad, CA in Feb 2012
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 Training in Europe:

Public Training in Brussels, Belgium in September 2012

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 Education Update

CDISC authorized training can be offered any place in the world. CDISC educational courses are developed to provide foundational training on the theory and practice of using the CDISC standards. They are designed to give implementers a better understanding of how to apply the theory and practice of these standards within their respective organizations.

CDISC Public training offerings have been growing over the past few years. With the goal of having at least two public training sessions in Asia, two in Europe and four in the United States, we have exceeded that goal in 2011 with a total of eleven public training sessions. Taking into account all of our private and public courses, CDISC Education has issued around 1000 training certificates throughout 2011.

We are working hard to make it easier for people who need authoritative training to access it. We have added information and functionality to our website that make it easier for organizations and individuals to find course descriptions, find and register for public training, and to request private training, and more website improvements are coming soon by the beginning of 2012. The goal of the CDISC Education Team is to ensure authoritative training is available and accessible to
our global community of users. We hope to see you in class soon!

The CDISC Education Team