January 2012 eNewsletter

With the first Newsletter of the New Year, CDISC would like to wish you a happy, prosperous and healthy 2012! We are looking forward to a successful year through the significant participation of those on our working teams, our members, and others who contribute to CDISC in many different ways. Your participation plays a major role toward achieving the CDISC mission and vision to inform patient care and safety through higher quality medical research!

Our January Newsletter holds very exciting news with a note from our President; updates on CDISC Membership; a press release on new CDISC Leadership; articles on the CDISC European Interchange, CDISC in Japan and the CDISC SDTM Amendment 1 as well as an Update to the CDER Data Standards Issues Document; an opportunity to provide comments on standards for Devices and Multiple Sclerosis; our first in a series of CDISC Case Studies; and CDISC Education and User Networks.

President's Letter to Our Valued CDISC Members

Dear Valued CDISC Member,

On behalf of the CDISC Operations Staff and CDISC Board of Directors, I would like to take this opportunity to express our sincere appreciation for the support we receive from our CDISC member organizations and team participants. This continuing support is invaluable, not only to CDISC as an organization, but also to the many clinical communities increasing their use of CDISC standards around the world. CDISC has become much “more than standards,” making a clear impact on improving the medical research process and helping to bring new safe and effective therapies to patients sooner. We are now truly living our vision coined in 2010: “Informing patient care and safety through higher quality medical research.”

Please read the entire letter [1] from Dr. Kush, CDISC President to our valued CDISC Members. Included is a summary of our new Strategic Goals 2012-2015. (Watch our website for an analogous update on these goals in the near future.)

If you are not yet a CDISC member, please see our website [2] or contact Sheila Leaman [3] to find out the benefits that you may be missing.

CDISC Member Updates
New CDISC Platinum Members 2011

- Booz Allen Hamilton
- EORTC (European Organisation for Research and Treatment of Cancer)
- IMI (Innovative Medicines Initiative)
- Integrated Clinical Systems, Inc.
- Medtronic, Inc.
- Onyx Pharmaceuticals
- Private Access, Inc.
- Santen, Inc.

Upgraded (from Gold to) Platinum Members 2011

- Abbott Laboratories
- Astellas Pharma, Inc.
- d-Wise Technologies
- Dainippon Sumitomo Pharma Co., Ltd
- Endo Pharmaceuticals
- Pinnacle 21, Inc.
- SGS Life Sciences Services

New Gold Members 2011

- Aptiv Solutions
- Arrowhead Electronic Healthcare, LLC
- Clinical DataFax Systems Inc.
- Clinical Trial Center Maastricht
- Clinicalprojects International GmbH
- Clinovo, Inc.
- CNI Professional Services, LLC
- CROS NT s.r.l.
- Dlcore Group, LLC
- DM-STAT, Inc.
- DynPort Vaccine Company LLC
- e-Novex BVBA
- Emboma Corporation
- Evado Clinical Trials Software
- Fast-Track Drugs & Biologics, LLC
CDISC Announces New Board Members and Chief Technology Officer

CDISC ushers in the New Year with changes to its leadership. The addition of three highly qualified individuals to its Board of Directors will bring invaluable expertise to the CDISC organization for the term 2012 - 2015, and Ms. Paula Brown Stafford has assumed the position of Chair of the CDISC Board as of January 2012.

In addition, CDISC is pleased to announce the addition of Mr. Wayne Kubick as Chief Technology Officer (CTO) for CDISC as of 9 January 2012.

In case you missed this Press Release, please read more about these outstanding additions to the CDISC leadership here.

CDISC European Interchange 2012

Plan now to participate in the CDISC Interchange in Stockholm, Sweden in April with keynoters representing ISO, IMI, FDA, Uppsala Monitoring Center and WHO. CDISC Interchange events unite people and organizations from all around the world to address the most up-to-date achievements attained by the global CDISC community, working together toward the CDISC mission and vision reflected in achieving patient care and safety through higher quality medical research. 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. *There will be a networking opportunity with dinner and boat ride for those who register first.*

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.

Highly qualified experts in the research and healthcare industries will be speaking at this interchange, including representatives from the Food and Drug Administration (FDA), the World Health Organization (WHO) and the International Standards Organization (ISO). There will also be presentations selected from submitted abstracts on implementation experiences with the CDISC standards. Panel of experts will be ready to answer your questions and allow you to share your experiences with them. We are looking forward to seeing you in Stockholm!
Stay tuned to our website as registration for Europe will open within the coming week! And, mark your 2012 calendars for mid-July in Tokyo and the week of 21 October in Baltimore.

**CDISC in Japan**

As promised in the December eNewsletter, two blogs on CDISC activities in Japan (Kyushu, Kyoto, Kobe and Tokyo) have now been posted.

**Amendment 1 and the Evolution of SDTM**

You may have noticed that "Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2" was posted on the CDISC website recently. This document, which describes some additional variables added to the Demographics and Adverse Events domains to help FDA reviewers work more effectively with SDTM data, provides a glimpse into how the process of releasing certain CDISC standards is evolving over time.

Previously, most teams, including the Submissions Data Standards (SDS) team, would typically create entirely new versions of documents when a standard needed to be changed. However, this process becomes more difficult as a standard matures and expands. While it took only 1 year to go from version 3.1 of the SDTM and SDTMIG to version 3.1.1, it took more than 3 years (and ~100 more pages) to get to 3.1.2. Now that CDISC is involved in developing standards in new areas, such as medical devices, and for specific therapeutic areas, the amount of new information that needs to be conveyed as part of the SDTM standard is growing exponentially. And the prospect of delivering a post 3.1.2 implementation guide is daunting indeed.

Of course, it's difficult to keep up with such rapid change, and, as documents become lengthier, it's often difficult for our user community to find when something has changed. So we feel the use of Amendments allows us to get new content into the community sooner, and allows people to build on what they're already using in the base 3.1.2 version more easily. Currently CDISC teams are working with our Technical Operations to put together a roadmap of planned publications including both new versions and amendments, to help everyone prepare for the many new capabilities we will soon be supporting. And we'll work to make it easier for lengthier standards like the SDTMIG to be accessed as a linked set of
component parts.

As we try to deliver more content more rapidly and efficiently by improving our internal processes, we need to look at new ways to help us develop, vet, and communicate our work. So we’ll be making better use of on-line commenting tools, and more advanced ways to represent our standards using the advanced modelling and representation capabilities of SHARE.

So stay tuned, some of the best work of CDISC is yet to come.

Wayne Kubick, CDISC CTO

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[10].

If you have any questions or comments on this document please send to the following email[11]. 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.

CDISC Data Standards Update Webinar will be held on 26 January 2012. Please see under CDISC Events section for further details.

CDISC Device Draft Standard for Public Review and Comment Period - Comments Due Tuesday, 21 February 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 [9] to know more and to access the Draft Document and the Comments Spreadsheet.

NINDS Multiple Sclerosis (MS) Common Data Element Review through 29 February

The National Institute of Neurologic Disease and Stroke (NINDS) is in the process of developing Common Data Elements (CDEs) for use in standardizing data capture in a number of Therapeutic Area’s. The following link [12] refers to the NINDS CDE effort in a number of Therapeutic Areas. [CDISC is directly participating with NINDS on the standards for Parkinson’s Disease and through reviews such as these on other standards.]

Currently, they have a draft set of MS CDEs that they have placed in public review for feedback. In order to reach the wider MS research community, they would like feedback on these CDEs from the CDISC community implementing data standards. Please provide your feedback to NINDS by 29 February 2012.

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

CDISC Operations

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 [13]. These can be submitted in written format or created through a phone interview with CDISC Communications Staff.

The emergence of open source technology for CDISC conversion - An innovative solution to easily convert clinical data to CDISC SDTM

Case Study kindly provided by Clinovo

Clinical trials have become increasingly complex and, as a result, costly. Only 333 drugs and biologics have been approved between 2000 and 2010 due to stricter regulatory procedures while spending has increase by 15 in the same period of time.

The need for innovation is critical in the pharmaceutical and biotechnology industry. Life science companies and service providers are looking for innovative solutions to improve study performance and minimize their risks.
Complying to CDISC standards is a way to streamline the clinical trial process. As the standard format recommended by the FDA for clinical trial data submission, using CDISC standards:

- Facilitates the FDA review process
- Improves efficiency for clinical data exchange
- Ultimately reduces costs and speeds up time to market

However, clinical conversion to CDISC SDTM is often done manually, which can quickly become error-prone and time-consuming. This article will demonstrate how open source technologies present an innovative solution to address this, and ultimately help bring medical innovations faster to patients. Follow the link [14].

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 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 South Africa and one in San Diego, California.

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 [13]. The User Network portal area [15] 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 a webinar on Thursday, 26 January 2012. In addition, posted on our website there are public trainings for 2012 [16], as well as our CDISC Interchanges in 2012 [17]. Please stay tuned to our CDISC Events and Education via the following link [18]. In addition, CDISC is partnering with FDA and PhUSE on the annual FDA Computational Science Center meeting in March 2012, as indicated below.
CDISC Data Standards Update Webinar:

Webinar Details: "Hot Topics" on using CDISC Standards in the Submission Process (to include FDA Presenters from CDER, CBER, and CDRH)

Follow the link to view the Q & A from July 2011 CDISC FDA Webinar. Please read this prior to the webinar! New questions are welcome during the upcoming webinar.

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.

Early Bird Registration Extended to 27 January!

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.

SPECIAL OPPORTUNITY Public Training [25] in Feb 2012
Public Training in Austin, TX [26] in April 2012
Public Training in Audubon, PA [27] in May 2012
Public Training in Palo Alto, CA [28] in June 2012

Public Trainings in Europe:

Public Training at the European Interchange [7] in April 2012

Request Private Training online - click here [31] for more information.

More trainings opportunities to come soon. Please stay tuned to our Education and Events [18] page.