December 2012 eNewsletter

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

The CDISC December Newsletter Presents the Following Topics:

- CDISC Asia-Pacific Interchange and Europe Interchange in 2013. Registration is Open.
- CDISC Announces Launch of Inaugural Asia-Pacific Interchange in Singapore.
- CDISC Technical News
- Success Story - Translational Research Informatics Center Featured in this eNews.
- CDISC Members Updates
- Meeting of the Institute of Medicine of the National Academy of Sciences - Large Simple Trials and Knowledge Generation in a Learning Health System.
- CDISC User Networks
- Opportunity to Donate to CDISC
- CDISC Volunteer Opportunity
- Global Events and Education Opportunities
- CDISC Official Primer for a Lower Price
- CDISC Social Media

CDISC Asia-Pacific Interchange and Europe Interchange in 2013

Around the globe, CDISC will be holding its annual interchanges in Asia, Europe and the US in 2013. Registration is open for the Asia-Pacific Interchange on 18-22 February in Singapore and the CDISC Europe Interchange on 22-26 April in Germany.

"Streamlining Global Research through Standards" is the theme of the Asia-Pacific Interchange 2013.

Join us in Singapore on 18-22 February 2013, learn about CDISC and ACRES, and network with research and healthcare experts from around the world. Case studies on using the CDISC standards, along with explanations on how our standards can streamline clinical research using EHRs and latest updates on therapeutic area standards development will be presented at this conference. Follow the link for more details on the interchange week which includes the two-day conference and three days of CDISC authorized education courses. Anyone interested in implementing the CDISC standards and streamlining global clinical research should attend. Click here for preliminary program details.

Germany is our next prime location in 2013! The CDISC Europe Interchange 2013 will be held on 22-26 April in Frankfurt, Germany.
Don’t miss out! Hear from industry leaders, FDA and IMI representatives and play an essential role in supporting the CDISC vision: to Inform Patient Care & Safety Through Higher Quality Medical Research. Dr. Michel Goldman, head of the Innovative Medicines Initiative (IMI) will be our keynote speaker. The latest achievements and recent regulations in research will be presented at the conference allowing our audience to share experiences and ask related questions.

Submission of abstracts for the CDISC European Interchange is open until 10 January 2012 through this link.

Registration for the conference and authorized CDISC educational courses - available through this link.

Join us at our EU Interchange Evening Networking Event

CDISC Interchanges bring joy to its loyal members and audiences. At this EU Interchange, you will be treated to a live music show featuring Elvis Presley music (in honor of the Interchange location at the site where Elvis spent two years of his life). This Networking Event will take place on the evening of the first conference day; the live music show will be followed by dinner on stage with background live music indulging our attendees with a nice atmosphere of networking and chatting.

Sponsorship Opportunity at Our Interchanges.

Bring greater awareness of your organization’s mission and involvement in the global healthcare community. Expand the visibility of your organization to all our international members and non-members through sponsoring and/or exhibiting at our events. Benefits of sponsorship are significantly revealed through displaying your logo on our press releases, programs and website, as well as on our Interchange signage and through the screens at the conference venue. Further details on sponsorship can be found here.

Furthermore, exhibiting at our event will provide your company the privilege of interacting with key international organizations and global regulatory entities who will be attending the CDISC Interchange.

Follow the link if you are interested in exhibiting at the CDISC Europe Interchange 2013.

And view the following link for exhibiting opportunities at the Asia-Pacific Interchange 2013.

December Press Release - CDISC Announces Launch of Inaugural Asia-Pacific Interchange in Singapore

The Clinical Data Interchange Standards Consortium (CDISC) is proud to announce the launch of the inaugural CDISC Asia-Pacific Interchange to be held 18-22 February 2013 in Singapore. Singapore was chosen for its central location in this region, the epicenter of some of the most booming economies in the world.
"We are excited to offer this Interchange in Singapore, an event which essentially brings CDISC to the doorstep of our many loyal members and supporters throughout the Asia-Pacific region. This Interchange will offer companies in Asia-Pacific the rare opportunity to collaborate with and gain information about best practices in clinical data standards implementation from their peers in the region," said Paula Brown Stafford, President of Clinical Development at Quintiles and CDISC Board Chair. Follow the link [2].

CDISC Technical News

CDISC is continuously working to release new standards and innovations to support our mission and vision. 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 documents currently or soon to be available on the CDISC website:

- SDTM Implementation Guide for Medical Devices v1.0 Provisional (now available)
- CDISC Virology Therapeutic Area Data Standards User Guide v1.0 Provisional (now available)
- CDISC Parkinson’s Disease Therapeutic Area Standards User Guide v1.0 Provisional (to be posted soon, stay tuned)
- ADaM Pilot 1 sample data updated to current ADaM standards (to be posted soon, stay tuned)
- SDTMIG 3.1.4 Batch 2 for Comment (to be posted soon, stay tuned)

Follow the link for Standards open for review and comment as well as new standards available for use [18]. Stay tuned to our homepage [19] for details on Standards and Technical updates as well as current CDISC information.

Join us for the CDISC Standards Webinar [20] on Tuesday, 18 December 2012 at 11:00 AM U.S.A Eastern Time.

Agenda:

- Protocol Representation Model Toolkit
- SDTMIG 3.1.4 Batch 2

Please follow the link to attend [20].

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on “Conducting Clinical Research in the Informational Age” [21].

Opportunity to Contribute to the CDISC Wikipedia

Teams and members of CDISC can contribute their accomplishments and updates at their leisure through the CDISC Wikipedia page [23]. Collaborative efforts in adding updates and achievements from the CDISC community to the CDISC wiki page will encourage additional input and feedback from our followers around the globe bringing more discussion and involvement in the CDISC mission and vision. Participate and provide your valuable input to boost further discussions and feedback to the CDISC Wikipedia page.

CDISC Office in Austin, TX!

We are delighted to announce the opening of the CDISC office located in Austin, TX, United States. Our new small office [24] is in the heart of Austin; it is in the Texas Medical Association Building [25], right next to the Texas State Capitol, a couple of blocks from the University of Texas, and in the middle of the commercial region of the city.

In November 2012, the CDISC staff who are Austin based, helped in opening and organizing the office. Thank you to Sheila Leaman, Andrea Vadakin, Diana Hanakeh, Saad Youssef, Jyoti Pillay and Ella Kamona who helped in organizing and preparing the office. And special thanks to our President and CEO, Dr. Rebecca Kush, and to Bron Kisler and Shirley Williams, VP of Strategic Alliances and VP of Finance, who also played key roles in opening this office.

The office in Austin will be the headquarters and the main address for the CDISC organization. Come visit at 401 West 15th Street, Suite 875, Austin, TX 78701. Our vital participation in the global community will continue to be pursued through our international members and teams working together towards achieving the CDISC mission and vision: to inform.
patient care and safety through higher quality medical research. We now have new resources to help us realize these, since our small office comes with access to TMA’s conference rooms, auditorium and neighbors with patient care and education expertise.

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 CDISC Communications team.

This month we would like to present the success story from the Translational Research Informatics Center in Japan.

Q1. What is TRI center, and what kinds of activities does it have?

Translational Research Informatics (TRI) center is one of the institutes that belong to the Foundation of Biomedical Research & Innovation in Japan. It was founded in 2003, given financial supports from the Japanese government and Kobe city. Particularly, TRI center is committed to the innovation of medical technology, construction of infrastructure and creation of new science, through the facilitation of translational and clinical researches. Also, it serves as the largest data center in Japanese academia, currently supporting 75 clinical studies of various kinds. To promote health and welfare of all people, we are open to all medical researchers and provide comprehensive study support services, including preclinical consultation, protocol development, data management, system development and statistical analysis.

Q2. Why did you embark on the world of CDISC?

Since the beginning in 2003, we have been supporting more than 160 clinical studies. However, the data formats were not standardized and we were dependent on several data management systems, imposing additional burdens to the staffs and precluding integration of the pooled data. Recently, in the face of increasing number of concurrent studies, we had practical needs to increase efficiency in the study operation, and to analyze combined data from relevant studies. Fortunately, we had kinds of opportunities, including skilled staffs and accumulated experiences. Thus, the circumstances surrounding us were maturated, and pressed by need and opportunity, we had decided to get into the world of CDISC.

Follow the link for the full story. [28]

CDISC Members Updates

Our New Members in November

New Gold Members in November:

- CliniData International
- Prometrika LLC
- Dart NeuroScience, LLC

New Platinum Member in November:

- Sarah Cannon Research Global Services

Thank you and a warm welcome to our new members in November. 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.

Thank you to CDISC Star Members

Star Members in December:

- Baxter Healthcare Corporation
- Instem LSS
- Velos, Inc.
Meeting of the Institute of Medicine of the National Academy of Sciences -
Large Simple Trials and Knowledge Generation in a Learning Health System (blog by R. D. Kush)

“Large Simple Trials (LST) and Knowledge Generation in a Learning Health System” was the topic for a meeting organized by the Institute of Medicine of the National Academy of Sciences. This meeting took place on 27-28 November, and I was invited to give a presentation with the prescribed title: “Getting to Comparable, Computable Data” in a session on infrastructure needs.

The meeting topic was very specific because there is a perceived need to run more LSTs and the planning committee wanted to explore why there are so few of this type of study actually conducted. Although difficult to find, there were a few examples cited and/or described during the meeting, mostly observational studies conducted by academic universities: Harvard University (VITaminD/OmegA3 – VITAL), Brigham and Women’s Hospital (Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MIFREE), McMaster University (Heart Outcomes Prevention Evaluation -HOPE). There were no regulated research studies recounted. Follow the link.

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.

This month, the CDISC San Diego User Network will be meeting on Thursday, 13 December 2012 at Pfizer in La Jolla from 12:00 PM – 4:00 PM. The conference will start with a presentation on PDUFA V and the 2012 CDISC International Interchange, followed by Round Table Break Out session, and concluded with a presentation and panel discussion. Please follow the link for agenda and details.

In addition, our French Speaking User Group meeting will take place in Paris on Monday, 17 December 2012. More than 150 attendees will be available. Follow the link for more details about this event. Please register through this link and provide your company name and email address to confirm your seat.

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**

**Join us for the CDISC Standards Webinar** on Tuesday, 18 December 2012 at 11:00 AM U.S.A Eastern Time.

**Agenda:**
- Protocol Representation Model Toolkit
- SDTMIG 3.1.4 Batch 2

Please follow the link to attend.

**Authorized Courses:**

Did you know that CDISC Education provides the only authorized courses on CDISC standards? Find out more here.

**Private Courses:**

We can provide in-house courses to any organization, in most places in the world. To find out how you can bring CDISC Education to your organization – click here.

**Public Courses:**

We have a full schedule of public courses in the US, Asia and Europe in 2013. Click here for dates and locations to find one that is convenient for you!

**What our attendees are saying about CDISC courses:**

"The instructor was very knowledgeable and had a lot of personal experience with implementing ADaM so she was able to answer a lot of my questions. I liked the exercises - they really helped reinforce the material and gave us an opportunity to see how we might apply it to our work."

-ADaM ‘In-House’ Private Course on 18 July 2012

"The instructor was very knowledgeable and facilitated discussions that were very relevant to our situation. She also answered questions well and acknowledged where there were implementation challenges."

-CDASH ‘In-House’ Private Course on 15 March 2012

"The course did a great job of covering a lot of material in a relatively short amount of time. The instructor was very knowledgeable and took the time to explain things when necessary or questioned. Overall, it was a great course."

-SDTM Public Course in Palo Alto, CA on 12-13 July 2012
Early Bird Registration is now open for the FDA/PhUSE Computational Science Symposium, 17 – 19 March in Silver Spring, Maryland. Full details can be found here: http://www.phuse.eu/css

The annual Computational Science Symposium will bring FDA, industry and academia together for updates and work on collaborations established at previous symposiums and continued throughout the year. Additional collaborative projects will be created to address the latest challenges relating to the access and review of data to support product development. The 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.

CDISC Members are encouraged to join the working groups and to be part of these exciting developments as they move forward.


Exhibitor Opportunities http://www.phuse.eu/CSS-Exhibitors-2013.aspx. Please follow the links for full details and contact PhUSE office@phuse.eu for any further questions.

The Official CDISC Primer is available for a lower price

Benefit from the discounted price and buy the CDISC book now! Current Price is $10.

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