November 2012 eNewsletter

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

The CDISC November Newsletter Presents the Following Topics:

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- CDISC Asia-Pacific Interchange and Europe Interchange in 2013
- CDISC C-Path, FDA, TransCelerate and the Global CDISC Community Launch Initiative to Accelerate Therapies Through Standards
- CDISC Technical News
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Consider a Holiday Donation to Benefit Patients Worldwide

If you are thinking of the many holidays that will take place around the world between Thanksgiving (November 2012) and Chinese New Year (February 2013) and you would like to improve patient safety and medical research globally, OR if your company has some end of the year funds they would like to put to good use, please consider donating to CDISC. We are now a 501c3 charitable organization. Your contribution can be targeted, if you wish. For example:

- You can sponsor an Educational Course
- You can sponsor one of the Therapeutic Area standards
- You can sponsor one or more of our Interchanges
- You can suggest a sponsorship that is meaningful to you
- You can give a general contribution, which we will ensure is put to good use

Your name or logo will be shared or you can make an anonymous donation. Please e-mail Sheila Leaman or Andrea Vadakin if you have questions or need suggestions.

CDISC Asia-Pacific Interchange and Europe Interchange in 2013

CDISC will usher in 2013 with the Asia-Pacific Interchange on 18-22 February in Singapore. Join us for the Asia-Pacific Interchange, learn about CDISC and ACRES, and network with others in the research and healthcare arenas around the world. Promote your organization’s presence through our sponsorship and exhibitor opportunities available at this conference. Registration is open now! Click here to register. And follow the link for more details on the interchange which includes two-day conference as well as education courses offered to anyone interested in implementing the CDISC standards and streamlining global clinical research.
From Asia to Europe! The second CDISC Interchange in 2013 will be held in Bad Nauheim, Frankfurt, Germany. Don’t miss out; join us for the CDISC Interchange Europe on 22-26 April 2013 and hear from industry leaders and FDA representatives and play an essential role in supporting the CDISC vision: to Inform Patient Care & Safety Through Higher Quality Medical Research. Dr. Michele 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 is open until 10 January 2012; abstracts can be submitted through the following link. Education sessions will be provided throughout the week; they will be available to everyone interested in implementing the CDISC standards in their work environment. Registration for the conference and educational sessions will be open by the end of November; stay tuned to our website for further details.

New members of the CDISC European Coordinating Committee were elected recently. These members who are experts and strong supporters of the CDISC mission will attend their first face to face ESC meeting in Munich, Germany on 23-24 January 2012 to participate in the preparations for the upcoming CDISC Europe Interchange in April.

Sponsorship and Exhibitor opportunities are available for both interchanges. Why not attract the attention of the global community to your organization and its mission? By sponsoring and/or exhibiting at our interchanges, your organization’s visibility will be expanded to all our members and non-members worldwide. 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. And exhibiting at our event will provide your organization the privilege of interacting with key international organizations and global regulatory entities who will be attending the CDISC Interchange. Further details can be found here.

CDISC, C-Path, FDA, TransCelerate and the Global CDISC Community Launch Initiative to Accelerate Therapies Through Standards

The CDISC International Interchange in Baltimore, Maryland, held 22-26 October 2012, was the formal launch of the Coalition for Accelerating Standards and Therapies (CFAST). It also marked the 10th anniversary of these CDISC Interchanges. In 2003 at the first North American CDISC Interchange, Dr. Mark McClellan, then FDA Commissioner, gave the keynote speech, stating “I think that CDISC will be a big part of moving FDA onto an electronic information architecture where we can realize all of these opportunities [benefits of technology]. I think this will have a profound and positive impact on our drug review process, allowing us to design trials that can be less expensive and still tell us more about the risks and benefits of a new medical product. And I think that the most significant and perhaps enduring legacy to your efforts could be the very immediate and significant impact it has on improving the lives of patients.” Follow the link.

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 documents currently or soon to be available on the CDISC website:

- Polycystic Kidney Disease Therapeutic Area Standards Available for Comment until 26 November
- CFAST Therapeutic Area Program Steering Committee Charter and Cumulative Minutes
- CDISC Parkinson’s Disease Therapeutic Area Standards Provisional
- SDTMIG 3.1.4 Batch 2 for Comment. Will be available soon.
- SDTM Implementation Guide for Medical Devices Provisional
- CDISC Virology Therapeutic Area Standards Provisional

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

Join us for the CDISC Standards Webinar on 29 Nov 2012 at 11:00 AM U.S.A Eastern Time.
Agenda:

- CDISC, TransCelerate, and CFAST: New Process for Therapeutic Area Standards Development

Please follow the link to attend.

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on “CDISC Responds to TransCelerate Questions”.

CDISC eJournal Articles 2012

A number of CDISC stakeholders contributed articles to the CDISC eJournal 2012; these articles were distributed via a CD during the International Interchange 2012 and can be found on the website through the following link. CDISC is the leading standards developing organization (SDO) focusing on data standards for medical research. These eJournal articles represent case studies and success stories reflecting the implementation of CDISC standards and their value and adoption towards our CDISC vision to inform patient care and safety through higher quality medical research. If you would like to contribute an article for the CDISC eJournal 2013, please contact Diana Harakeh.

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.

CDISC, a Four-Leaf Clover: the SGS Finder’s Story

SGS Life Science Services (SGS) is one of the “early bird” Clinical Research Organizations that embraced the CDISC standards from the very beginning. SGS originally focused on submission related CDISC standards and therefore started the Submission Data Model v3.0 implementation in 2003. However, for quite some time now, SGS has been looking at the CDISC standards from a different perspective. The original idea that CDISC standards would always be pure “submission standards” has turned into the understanding that CDISC standards are there to guide users in their daily jobs. CDISC has offered the industry invaluable benefits; for SGS these benefits can be categorized in four key topics:

Follow the link for the full success story.
CDISC Member Updates

Our New Members in October:

- Akros Pharma - USA
- Brightech International LLC - USA
- Nth Analytics - USA
- Philip Morris Products SA - SWITZERLAND
- World Programming - UK

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

Star Members in November:

- Greenway Medical Technologies, Inc.
- Purdue Pharma L.P.

CDISC announces a Membership Drive in conjunction with our Asia-Pacific Interchange in Singapore, Feb-2013!!

Membership contributions are the primary funding mechanism for CDISC; we offer many advantages to our members: Discounts on Interchanges and Educational courses, Registered Solution Provider posting and ODM Certification opportunities, Access to Member’s Only area, Seat on the CDISC Advisory Board for Platinum members as well as Recognition by peers and regulators that you support the CDISC Mission and Vision. CDISC is a 501(c)3 non-profit and your membership fee may be tax deductible as a charitable contribution.

To usher in our inaugural Asia-Pacific International in Singapore in 2013, we are holding a special Membership Drive. If your organization joins - or upgrades to a Platinum membership - by 31-Dec-2012 you will be entered into a drawing to receive one of the following awards to the CDISC Asia-Pacific Interchange being held in Singapore, 18 - 22 February, 2013:

- For a new or upgraded membership that totals $10,000 or more - a paid trip which includes a round trip economy air
fare, hotel for 2 nights and free attendance for 1 person

- For a new or upgraded membership that totals $3,000 - $9,999 - 2 free attendees to the Interchange
- For a new or upgraded membership that totals $1,200 - $2,999 - 1 free attendee to the Interchange

Please join CDISC as a member or upgrade to Platinum level by filling out this form:
http://www.cdisc.org/extranet/register.php; or contacting Sheila Leaman or Frank Newby.

FDA at the CDISC Interchange – a 10th Anniversary!

Apparently we were so focused on making this the best Interchange ever that we failed to realize it was our 10th CDISC International Interchange. It dawned on some of us mid-week. The first CDISC Interchange was held in 2003, and Dr. Mark McClellan was the keynote speaker. Dr. McClellan was the FDA Commissioner at the time and, in speaking about the benefits of technology during his keynote, he was quoted as saying: "I think that CDISC will be a big part of moving FDA onto an electronic information architecture where we can realize all of these opportunities. I think this will have a profound and positive impact on our drug review process, allowing us to design trials that can be less expensive and still tell us more about the risks and benefits of a new medical product. And I think that the most significant and perhaps enduring legacy to your efforts could be the very immediate and significant impact it has on improving the lives of patients." Follow the link.

FDA Public Meeting on Transport Standards – 5 November 2012

FDA Public Meeting on Transport Standards – 5 November 2012 On 5 November, the Food and Drug Administration (FDA) announced a meeting entitled "Regulatory New Drug Review: Solutions for Study Data Exchange Standards" with the purpose of soliciting input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. The meeting was held at the FDA's White Oak Campus in a large room with ~ 15 round tables, each seating 5-8 individuals (i.e. about 100 attendees). There were at least a dozen FDA representatives present, 5 with speaker/facilitator/presenter roles. This is simply a brief summary with the key points that came across to me, with a goal of reporting this objectively. Follow the link.

Also, see this interesting blog written by David Gemzik of Medidata Solutions, who was a presenter/attendee at the FDA November 5th meeting. Follow the link to know more about Discussing Data Standards and Compatibility: A Day at the FDA.

Where Should CDISC be Going?

Session 4 of the CDISC International Interchange conference on 24 October was especially stimulating. It consisted of short, well-delivered and extremely inspiring and promising presentations from various organizations seeking faster and better therapies for patients. A key message: One of the crucial factors to expedite the process of finding new therapies is ensuring the sharing of accurate data through standards.

Everyone is going to be a patient, and we all happen to know someone with a brain disorder, Dr. Magali Haas of One Mind Research opened her presentation. Dr. Haas spoke of the ‘moon shot’ initiative of President John F Kennedy to put a man on the moon; it is based upon this successful challenge that Patrick Kennedy has now launched the One Mind initiative to cure brain disorders in this century. Dr. Magali stated, “We will not accomplish this without common standards for data. We need to integrate solutions and new practices to improve the quality of lives. CDISC is one of the key organizations that will ensure the development of common data elements for traumatic brain injuries.” 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 English Speaking User Group Committee is pleased to announce the Annual Face to Face Meeting, CDISC: Past, Present & Future at Brunel University, London, UK on 15th November 2012. The full program and details of how to register are available here.

The presentations will focus on the latest thoughts on metadata driven research methods, advances in SDTM and the latest news from the CDISC, USA Interchange. The Committee has been fortunate to secure excellent speakers and as a reminder, THE EVENT IS FREE TO ATTEND THANKS TO THE KIND SPONSOR/S.For further information, please contact committee@esug.org.uk.
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.

Call for Feedback - How to Maximize Usefulness of Non-Clinical Data

The PhUSE WG6 Nonclinical Standards Roadmap Team has created a survey to garner diverse perspectives from the healthcare industry on how to maximize usefulness of nonclinical data. Your feedback on how we can increase the value of data and which priorities to focus on is of great importance to us. Please answer this brief survey through the following link. We would appreciate your feedback by 15 December 2012. A summary of results will be available through the PhUSE Wiki page.

CDISC Global Events and Education Opportunities

You are cordially invited to attend the following webinars, interchanges and public education sessions in 2013.

1. **CDISC Free Webinars:**

Join us for the CDISC Standards Webinar on 29 Nov 2012 at 11:00 AM U.S.A Eastern Time.

Agenda:
- CDISC, TransCelerate, and CFAST: New Process for Therapeutic Area Standards Development

Please follow the link to attend.

More webinars are coming soon, stay tuned for the latest on CDISC Therapeutic Area Standards development and get our latest CDISC team updates through the following link.
3. CDISC Educational Sessions

a. In-House education on CDISC Standards:
CDISC can provide authorized education courses in-house to any organization, anywhere in the world, regardless of membership status. CDISC member organizations will receive discounted pricing on private education courses. To request information about private education courses, please click on the link below.

Request Private In-House Education Courses online - click here for more information.

b. Public Training in the US:
The Global Approach to Accelerating Medical Research Course in Austin, TX on 13 December 2012. Stay tuned, registration will open soon!
Hosted by C-Path in Tucson, AZ in January 2013
Hosted by Synteract in Morrisville, NC in February 2013
Hosted by Genentech in South San Francisco, CA in March 2013
Hosted by BioMedical Systems in St. Louis, MO in May/June 2013
Hosted by Genzyme in Cambridge, MA in July 2013
Hosted by MMS Holdings in Canton, MI in August 2013
Hosted by Cell Therapeutics in Seattle, WA in September 2013

d. Public Training in Asia:
Public Courses during the Asia-Pacific Interchange in February 2013

c. Public Training in Europe:
Public Courses during the CDISC European Interchange in April 2013
Hosted by Business & Decision Life Sciences in Brussels, Belgium in September 2013

Our 2013 Public Education Courses schedule is firming up. Please be on the lookout for new training locations for 2013!

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

The Official CDISC Primer is available for a lower price
Benefit from the discounted price and buy the CDISC book now! Current Price is $15.
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