July 2013 eNewsletter

The CDISC July Newsletter Presents the Following Topics:

- CDISC International Interchange 2013 - Call for Abstracts extended until 9 August - Early Discounts Available!
- CDISC Technical News and Latest Updates
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- FDA Data Standards Strategy DIA Session, Wednesday, 26 June 13 (3)
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- CDISC User Network Survey - Call for Feedback
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- Job Opportunities within CDISC
- Opportunity to Donate to CDISC
- CDISC Volunteer Opportunity
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- CDISC Social Media

CDISC International Interchange in Bethesda, MD on 4-8 November 2013

Lower Overall Rates Compared to Last Year and Early Bird Discount Rate Until 1 October.

Call for Abstracts Extended until 9 August 2013.

During this year's International Interchange, with a theme of SHAREing Data, CDISC will announce exceptionally important news representing the CDISC latest achievements. Do not miss out on the launch of SHARE (Shared Health and Research Electronic Library).

The CDISC International Interchange 2013 will be held at the Bethesda North Marriott Hotel and Conference Center. The main conference will take place on 6-7 November, and educational courses will be offered on 4, 5 and 8 November. You can find a provisional program on the CDISC website through this link. Abstracts on case studies that include metrics on utilizing the CDISC standards are being accepted until 9 August 2013. Click here to submit your abstract online.

Registration for the conference and educational courses is available here. As an appreciation to our followers and supporters, we have offered 15% early bird discount rate until 1 October 2013.

Opportunity for a free pass to the Interchange: Please respond to the User Network Survey through this link. See below for more information. Respondents will be entered into a drawing for two free passes to the International Interchange!

Promote your organization to over 300 CDISC member organizations and sponsor and/or exhibit at our event.

Follow this link for details on the CDISC International Interchange 2013.

Mark your calendars for the CDISC European Interchange on 7-11 April 2014 in Paris, France.

CDISC Technical News
All eyes this month are on the CDISC INTRAchange meeting in Silver Spring, MD from 30 July to 1 August, which will bring together over 100 volunteers from CDISC teams to meet with each other and among themselves to address key issues and learn more about new tools and processes to improve standards development.

Work continues on SHARE implementation, which is adding team members and moving rapidly forward toward a target release end of this year. Additional information on SHARE, which will be a local topic of our 2013 International Interchange, is being readyed for posting on the CDISC website.

In other standards news, Terminology Package 14 is now available, and Package 15 has been posted for comment. Final versions of SDTM 1.4/SDTMIG 3.1.4 and the CDASH SAE Addendum are being readyed for final posting later this summer. Asthma, the first TA project developed under the new CFAST process, should be posted for public review in August. Work continues on five other TA projects, and the CFAST Steering Committee is currently preparing a list of new projects for 2014. Stay tuned for an upcoming major revamp to the Therapeutic Area Standards page with more details on CFAST project status and details and easier access to older CDISC therapeutic area projects.

An updated CDISC technical plan schedule for 2013 will be posted in coming weeks, with many new project deliverables due in the second half of a very busy year.

Thanks to all of our many volunteers and supporters for helping us make all of this happen.

A special discount to the International Interchange is available to team members attending the INTRAchange.

Follow the link for 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.

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CDISC and HealthCarePoint Announce Launch of CDISC Online Education Courses

CDISC and HealthCarePoint (HCP) are proud to announce the launch of CDISC Online Education on 24 June 2013, the first day of the 2013 DIA conference in Boston. CDISC has long offered in-person Authorized Training Courses around the globe, and with the recent level of increased interest in CDISC Education, it was determined that offering courses online would be beneficial to those seeking CDISC Authorized Education and for which ongoing, traditional public and private training courses did not match the level of need.

“We are enthusiastic to begin the rollout of our online education courses with the initial SDTM and SDTMIG Basics Modules,” said Frank Newby, CDISC Executive VP of Education. “Our partnership with HealthCarePoint and the use of their unique Training Campus system will allow us to reach everyone who has a need for CDISC Education. Additionally, our new online training courses will feature the opportunity to become certified at the end of the CDISC Authorized Education course taken. This chance to reach new audiences with a need for CDISC Authorized Education, and also to ensure understanding of course material through certification will help to advance our mission to improve medical research and related areas of healthcare.”

Read more >>

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FDA Data Standards Strategy DIA Session, Wednesday, 26 June 13

I did not attend many sessions at the DIA meeting because, as many attendees, I was busy meeting new people interested in CDISC and reconnecting with many old friends. I did, however, chair one session – on CFAST: Coalition For Accelerating Standards and Therapies and I attended the subsequent session chaired by Dr. Steve Wilson on the FDA Data Standards Strategy. This was a very informative session with three speakers and a ‘commenter’: Dr. Ron Fitzmartin (FDA), Bron Kisler (CDISC), Mitra Rocca (FDA) and Michael Brennan (J&J).

Dr. Fitzmartin spoke of FDASIA, the FDA Safety and Innovation Act. Specifically, Section 1136 allows FDA to require standardized eSubmissions. Also, it reauthorizes the fifth instance of the Prescription Drug User Fee Act (PDUFA V). The schedule for phasing in these eSubmission requirements is specified as 24 or 36 months after publication of the final guidance (time frame depending on the type of submission). Section XII under the PDUFA Goals states the following:

- Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards organizations (i.e., CDISC),...

Also, FDA is to publish a proposed project plan for stakeholder review and comment by 30 June 2013. Dr. Fitzmartin stated that this TA Standards Project Plan is in Clearance at FDA, along with the eStudy Data Guidance and an eSource
Guidance. He provided further specifics around the FDA Path to Required Study Data Standards.

Read more

CDISC in Europe – June 2013

We had the pleasure of meeting with a number of wonderful individuals in Europe in June. The theme from our perspective was CDISC, of course, but there were many threads of conversation that wove together a lovely tapestry of memory from this particular trip and, in turn, we feel was extremely helpful to CDISC.

The trip began in Paris, meeting with Dr. Michel Goldman and Dr. Olivier Arnaud. The topic was around the Juvenile Diabetes Research Foundation, for which Dr. Arnaud is providing scientific expertise in Europe. Dr. Goldman is an amazing individual who leads the Innovative Medicines Initiative. He had expert advice to lend during this meeting for the JDRF in Europe. CDISC has just launched a diabetes therapeutic area standards project and IMI has projects in diabetes, so a relationship is attractive to all of the organizations and the value of having standards for diabetes research is clear. On a recent call of the CFAST Scientific Advisory Committee, one attendee remarked of the data sharing initiative we were discussing: “The data are so much more valuable when they are in a common standard format”.

Read more

Standards and Changing Global Demographics

During my time abroad I was able to combine my most recent coursework—Western European Politics—with everything I learned about medical research standards on the trip. Specifically, in meetings with CDISC in both France and the U.K., I noticed similarities and differences between approaches to standards and markets. Regardless, as the majority of populations in countries become older, it is increasingly more difficult to maintain a prosperous welfare state. A welfare state is generally described as a country that provides assistance for citizens in need to buffer them from the negative consequences of age, unemployment, poverty and illness. In order to preserve the welfare state to which many citizens have become accustomed, it is imperative that European countries use information more efficiently; standards can play a key role, in this respect, in the area of medical research information.

As the populations in European countries age and governments must become increasingly sensitive to this, the need for standards in the European market will be imperative. Standards not only provide a way to get an accurate representation of the make-up of some of the most historically homogenized cultures, but they open up a broad market for researching and developing data and metadata to more appropriately serve the aging demographic of people in these countries. They can also help to address increasing diversity; in other words, to add complexity to the situation, the movement of individuals from country to country also affects the demographics of the population within and across European countries.

Read more

CDISC Member Updates

Our New Members in June

New Gold Members in June:

- Amphastar Pharmaceuticals Inc. - USA
- Bioskin GmbH - GERMANY
- Deloitte Services LLC - USA
- Nestle Clinical Development - SWITZERLAND
- University of California, San Diego - USA

Thank you and a warm welcome to our new members in June. 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 July:

5 years with CDISC:
A d-Wise Case Study: Validating Clinical Trial Data using the d-Wise Reveal Platform and OpenCDISC Validator for CDISC Compliance

A d-Wise Case Study: Validating Clinical Trial Data using the d-Wise Reveal Platform and OpenCDISC Validator for CDISC Compliance In June of 2013, d-Wise Technologies, Inc. (d-Wise), a solutions provider that offers product and consulting solutions for clinical trial optimization, metadata management and clinical data standards implementation, released the latest version of their web-based search platform, Reveal 2. d-Wise has found that Reveal, when combined with OpenCDISC Validator, a free utility for ensuring clinical data compliance with CDISC standards, can expedite the validation of clinical data in a compliant way.

When paired with OpenCDISC Validator, Reveal can facilitate validation for CDISC SDTM, ADaM and Define.xml clinical data standards compliance. As organizations get closer to submitting new drug applications and amendments for eventual marketing approval from regulatory authorities, the ability to find and aggregate data and validate data to CDISC standards becomes increasingly important. With Reveal, organizations can accelerate their review and perform ad-hoc validation of their clinical trial data. Read More.

CDISC User Networks and Coordinating Committees

CDISC User Network Survey – “Call for Feedback”

A recent CDISC User Network Survey was set up by CDISC Communications and E3C members to obtain feedback from our users around the globe. The survey is intended to help CDISC strengthen communications between the CDISC User Groups and the CDISC organization in accordance with the CDISC User Network Operational Procedure (COP-11).

If you are a CDISC User Network member, please consider providing your feedback as it is of great value to our organization! Click here to answer the survey. If you provide your feedback before 15 August 2013, you may be entitled to a free pass to the CDISC International Interchange in November this year. Two free passes to the CDISC International Interchange 2013 will be selected through a random drawing and offered to two of our respondents as an appreciation of their time and valuable feedback.
Updates from our user group and colleagues in Japan:

A recent CDISC Japan User Group (CJUG) meeting was held on Wednesday, 10 July 2013 from 15:30 to 17:30 at CAC EXICARE Corporation in Tokyo. The CJUG SDTM team discussed various topics including the development of their guidelines and terms based on the CDISC User Networks Operational Procedure (COP-11). The team also discussed the CJUG Activity presentation that will be offered during the DIA Annual on 8 November 2013 in Tokyo. The team went through the details of another CJUG Activity presentation scheduled for the 33rd Joint Conference on Medical Information on 21-23 November 2013 in Kobe. And finally, the team members concluded the meeting by emphasizing their joint effort with the Japanese CDISC Coordinating Committee (J3C).

Upcoming CJUG meetings:

The next CJUG SDTM team meeting will be held on Friday, 9 August 2013 at Asahi Kasei Pharma Corporation. The meeting is scheduled from 13:00 to 17:00 where three sessions will be offered. The first session will start with a discussion on the SDTM implementation latest updates, the second session will follow with a presentation on the SDRG Trial Feedback, by Mr. MORIGUCHI of Santen Pharmaceutical Co. (a LiSAS sub-team member). And the day will end with a presentation on "Spotfire" by TIBCO Software. Additionally, CJUG team members will be presenting during the DIA Japan conference scheduled on 8 November 2013. An overview on CDISC SDTM will be presented by MR. Taku SHIMIZU, and another overview on CDISC ADaM will be provided by Ms. Yumiko ASAMI.

The Japanese CDISC Coordinating Committee is working on scheduling a CDISC Japan Interchange during the first week of December 2013. Information will be posted very soon on our website, stay tuned.

Read more on our updates from Japan... [25]

Update from the CDISC European Coordinating Committee (E3C):

The E3C meets through a monthly teleconference to prepare and discuss CDISC related activities or meetings in Europe. The E3C will be holding its annual face-to-face meeting this fall at SAS offices in Belgium. The E3C are planning for CDISC Days in Europe in Q4 2013/Q1 2014 in which various CDISC Overview sessions will be offered through different locations in Europe. We would like to extend our deep appreciation to SAS for hosting our face-to-face meeting and for sponsoring the CDISC Days in Europe. The E3C is a very active CDISC Coordinating Committee, which strongly supports and promotes CDISC in Europe through its strong liaisons with the local European industries. The committee has scheduled the 2014 CDISC European Interchange on 7-11 April in Paris, France and is planning to have the 2015 European Interchange in early May in Basel, Switzerland.

To join a CDISC User Network, 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.

CDISC Global Events and Education Opportunities

CDISC Interchanges

- CDISC International Interchange in North Bethesda, MD, 4 - 8 November 2013. We are now accepting abstracts on case studies that include metrics on utilizing the CDISC standards. Deadline for abstract submission is 16 July 2013. [Click here to submit your abstract online.]
- Mark your calendars for the next CDISC European Interchange on 7-11 April 2014 in Paris, France.

CDISC Standards Latest Updates Webinars

Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards. The next scheduled webinar is on Thursday, 8 August. Agenda and registration details will be posted soon, stay tuned to our website.
CDISC Education Courses Opportunities

CDISC is offering the following public education events in 2013. Future education events can be found on our [website](#).

**CDISC Public Course Offering in Cambridge, MA**

Courses Offered:
- ADaM Implementation (17 July 2013)

Only offline registration forms are being accepted for this training. Limited seats are available, so please [register](#) soon.

**CDISC Public Course Offering in Canton, MI**

Courses Offered:
- SDTM Theory and Application (6-7 Aug 2013)
- CDASH Implementation (8 Aug 2013)
- ADaM Implementation (9 Aug 2013)

Only Offline registration forms are being accepted for this training. [Register here](#).

**CDISC Public Course Offering in Brussels, Belgium**

Courses Offered:
- SDTM Theory and Application (9-10 Sep 2013); 2-day Course
- CDASH Implementation (11 Sep 2013)
- ADaM Implementation (12 Sep 2013)

Registration for this event ends on 9 August. [Register](#) now to reserve your seat. Offline registration for this event is available through [this link](#).

All other public course offerings in US, Asia, and Europe can be found by clicking on [this link](#).

**Private Courses**

CDISC 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](#).

**CDISC public education courses offered during the CDISC Interchanges**

- CDISC public education courses will be offered during the CDISC International Interchange in North Bethesda, MD on 4, 5 and 8 November 2013. Information will be posted very soon on the CDISC [website](#), stay tuned!
- CDISC public education sessions will be offered during the CDISC European Interchange on 7, 8 and 11 April 2014 in Paris, France. Stay tuned to our [website](#).

All other public course offerings in the U.S., Asia, and Europe can be accessed through [this link](#).

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

"The course effectively explained the structure of ADAM data in a way that increased the probability we can implement it better. It also demonstrated the importance of metadata for data and results."
-ADaM 'In-House' Private Course on 14 Jan 2013

"It was a very well organized 2-day course. It was full of information with great examples, and promotion of discussion (Q&A). The instructor was well versed in SDTM & CDASH, so any variation of question was understood by the instructor, and answered thoroughly. The USB notes were fantastic and kept attention focused on the instructor and her instructions."
-SDTM Public Course in South San Francisco, CA on 6 Mar 2013

"Very good speaker. She is highly accomplished and clearly an energetic driver behind CDISC. Don't often like to use the word in connections like this, but she is "passionate" about CDISC, it shows and it rubs off on the audience. Very open session. Great answers to questions, time flew by."
-CDASH Public Course in Morrisville, NC on 14 Feb 2013
CDISC Job Opportunities Available

CDISC is seeking candidates for two current job openings:

1. **CDISC Terminology Specialist Job Opportunity**: work with our NCI EVS partners and CDISC controlled terminology, foundational standards and therapeutic area teams to develop controlled terminology for CDISC standards.

2. **SHARE Metadata Curator**: This position will have responsibility for the creation, maintenance, curation and quality assurance of CDISC standard metadata in the SHARE Metadata Repository and lead CDISC teams developing metadata in SHARE.

Follow the link for details on these job openings.

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 Standards Need Volunteers Like You!

CDISC relies on volunteers to develop and improve data standards products. The best way to get involved is to download and use CDISC standards, and to participate as a reviewer of new standards posted for comment on our website.

The following CDISC teams are also currently looking for new participants:

- XML Aficionados
- Protocol Representation
- Terminology

Follow the link to know more about how to volunteer! Further questions, please email us here.

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 [49] and LinkedIn [50] and follow us on Twitter [51] and YouTube [52]! And follow our Blogs [53] and most recent News through our website [54]!

Further questions are welcome through the following email [55].

CDISC Communications and Public Relations [56]

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