May 2013 eNewsletter

The CDISC May Newsletter Presents the Following Topics:

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- CDISC 2012 Annual Report
- CDISC Success Story: A Cytel Case Study: The Use of CDISC Standards in Unilever’s Cosmetics and Food Products Trials
- Read our blogs on the success of the CDISC European Interchange in April 2013 in Bad Nauheim, Germany and at the Partnerships Conference in Orlando:
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Join us at the CDISC International Interchange in Bethesda, MD on 4-8 November 2013

“SHAREing Data: Data is Meaningless unless it’s SHAREed” is the theme of the CDISC International Interchange 2013. Join us at this event and stay abreast of the latest achievements and updates from CDISC. Hear from experts and leaders of healthcare who will be available to provide feedback and share experiences with the audience. This year’s International Interchange will be unique, watch the CDISC website for details on the program and please consider submitting an abstract if you have a case study to share with others.

CDISC is now accepting abstracts on case studies that include metrics on utilizing the CDISC standards. Click here to submit an abstract. The deadline for abstract submission is 16 July 2013.

Increase the global awareness of your organization’s mission and goals by sponsoring and/or exhibiting at our interchanges.

CDISC 2012 Annual Report

Focused around the central theme of Teamwork, CDISC is proud to announce the release of the 2012 Annual Report. Features include a 2-page spotlight on our CDISC Teams and the efforts that they have made in standards development during 2012, as well as our Global Organization and the way in which different groups within CDISC interact with each other. Also included are 2012 Milestones, 2012 Collaborations, and updated information on our success in the areas of CDISC Education, Membership, Communications, and an overview of our Financials. Also, don’t forget to check out our “Team Roster” on the back page to see your organization’s name listed and to find out how long each member organization has been a supporter of CDISC! If you should have any questions regarding the 2012 Annual Report, please do not hesitate to email Andrea Vadakin, CDISC Manager of Public Relations at avadakin@cdisc.org. Click here to view the CDISC 2013 Annual Report.

CDISC Success Story

In an attempt to increase value for its stakeholders, CDISC initiated the feature of Success Stories in 2012, and we are continuing these in 2013. These stories reflect experiences with the CDISC standards and how they 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 Diana Harakeh. This month, we will feature Cytel with a case study about their implementation experiences with the CDISC standards for cosmetics. In addition, see the blogs below for a summary of our successful 2013 CDISC European Interchange, which was recently held in April in Bad Nauheim, Germany and a summary of our
experiences at the concurrent Partnerships Conference in Orlando.

A Cytel Case Study: The Use of CDISC Standards in Unilever’s Cosmetics and Food Products Trials

Cytel is a technology services provider that develops statistical software, clinical trial programming and analytic services. The company has extensive experience in clinical development and expertise in biostatistics, operations research, SAS programming, medical writing, data management and software development, and is a leader in the design and implementation of adaptive clinical trials.

With experience migrating over 150 studies as part of 20 U.S. Food and Drug Administration (FDA) submissions, Cytel’s CDISC Implementation Team efficiently develops CDISC SDTM and ADaM data sets that are compliant with required guidelines. The CDISC Implementation Team is comprised of expert programmers and statisticians that understand the analytical requirements of complex trials and have extensive experience preparing data for submissions to regulatory authorities. All studies in which Cytel has led migration and submission to the FDA have been accepted. Click here to view the full article.

CDISC Europe Interchange 2013 - Very Pleasant Start (by Diana Harakeh)

CDISC Europe Interchange 2013 started with very pleasant weather in Germany---the beginning of the spring season! Our attendees enjoyed the beautiful location in the heart of Bad Nauheim (a lovely small town north of Frankfurt where Elvis Presley spent two years of his life), and the special event of the 10th CDISC European Interchange this year!

As for previous CDISC Interchanges, the CDISC team spent the prior weekend on final preparations, making sure to keep the conference running smoothly and efficiently while providing the best possible support to our attendees.

Click here to read more.

A Flavor of the CDISC Europe Interchange (by Dr. Rebecca Kush)
Each year for the past 10 years, the European CDISC Coordinating Committee (E3C) has organized a CDISC Interchange. This year’s was touted as the best Interchange held in the last 5 years by many long-time attendees, and was highly regarded by those who have not had the opportunity to attend the earlier Interchanges. The success can be attributed to a program of interest to everyone, excellent keynote speakers and panel discussions that allowed the opportunity for all to participate. The venue should also be noted—many thanks to Dominik Ruisinger, who selected a comfortable hotel with a large conference area in an absolutely lovely area in Bad Nauheim, Germany, near Frankfurt. Spring was in the air and the trees and flowers were blooming in the park that surrounded this hotel. When I arrived in Frankfurt and was en route to the hotel, I was told by one of the locals that “Bad” in front of a town name in Germany means you should go there to relax. I commented that perhaps I could relax after our meetings with the E3C, the CDISC Advisory Council and the Interchange, and how I wish I had taken a day of vacation at the end of the week to do just that!

The atmosphere at the Interchange was anything but what I would call relaxing. It was stimulating, enjoyable, educational, informative and very productive. The attendees and exhibitors had great ideas for CDISC, from how to better engage the User Networks and additional projects that the E3C would like to achieve this year, to excellent suggestions from the CDISC Advisory Council members or their alternates in Europe on how they could be more effective in assisting and advising CDISC. This blog merely seeks to give one a flavor of the Interchange—one really had to be there to experience it appropriately! Mark your calendars for next year: 7-11 April 2014 in Paris, and don’t forget that we have one in Bethesda, MD on 4-8 November 2013, for which we are currently inviting speakers and calling for abstracts! Click here to read more.

The Tenth CDISC European Interchange - An Outstanding Experience (by Diana Harakeh)

Attending the CDISC European Interchange this year was a unique and very successful experience. Many attendees declared that this event was one of the best CDISC European Interchanges that they have attended throughout the past 10 years. CDISC celebrated the anniversary of the 10th European Interchange this year in Bad Nauheim, Germany.

We had a great exhibition area in which our exhibitors, presenters and attendees met and communicated about recent accomplishments, including tools and service providers that support CDISC standards.

"With the power of our volunteers, CDISC has developed additional standards in the past 4 years including therapeutic area standards. We have been listening to your input on how we can provide additional value to CDISC stakeholders. We enhanced collaboration and education and are providing a Protocol Representation Tool and others are coming. Patients are waiting for therapies and their time is precious! We need to make sure that they understand the value of data standards", Dr. Kush, President and CEO of CDISC stated at the opening session of the CDISC European Interchange in April in Germany. Dr. Kush also mentioned that CDISC standards are cited in the Structured Data Capture (SDC) Initiative of the U.S. Health and Human Services Office of the National Coordinator of Health IT, which offers incentives for meaningful use of electronic health records. And, CDISC has endorsed the movement of the Learning Health System (LHS) and is now leading the Essential Standards to Enable Learning (ESTEL) Initiative while participating in Europe in the IMI EHR4CR project. Communication is key, she stated at the end of her State of the CDISC Union presentation. Click here to read more.

Notes from Partnerships in Clinical Trials (by Andrea Vadakin)

While most of the CDISC staff were in Europe supporting the 2013 Europe Interchange, Sheila Leaman (CDISC Director of Global Relations) and I went to Orlando for the 2013 Partnerships in Clinical Trials conference. At the conference, we met with current CDISC members, handing out “Proud to be a CDISC Member” signs for their booths and engaging with them to gain information on their experiences with CDISC. We also had the opportunity to liaise with potential members to convey the benefits of membership and answer any questions they might have. In all, this was a fantastic experience, and personally having the occasion to meet face to face with those that utilize and support CDISC standards development was tremendously rewarding.
In addition to meeting with current and potential members, we took the time to sit in on one of the discussions, “The Evolution of Clinical Trial Partnerships – Initiative to Forge Innovative Collaborations across the Entire Healthcare Chain.” Speakers during this session were Kathleen Ford of Merck Serono, Ed Pezalla of Aetna, Christine Dingivan of PPD, Kelly Davis of Express Scripts and Dalvir Gill of TransCelerate Biopharma. Sheila and I had had the opportunity to have a very successful discussion with Dr. Gill earlier in the day about the collaboration between CDISC and TransCelerate Biopharma in the area of Therapeutic Area Standards development, and were excited to hear him speak on the panel during this session. Follow the link to read more.[4]

CDISC Technical News

CDISC standards development teams continue to work on many new projects to develop or enhance standards that support the CDISC mission. Visit our website[17] to review the technical plan and check for updates on CDISC standards currently posted for public comment or available for use.

The CDASH team has recently posted the CDASH SAE Addendum for comment, while the SDS team continues to prepare SDTM v3.1.4 Batch 3, which will include the updated SDTM v1.4, a new Healthcare Encounters domain, and an IG for representing data for persons associated with clinical study subjects (such as family members). The final release of SDTM v1.4 and SDTMIG v3.1.4 is expected later this summer.

Under the CFAST therapeutic area initiative, work continues on Asthma, Alzheimer’s, Multiple Sclerosis, Cardiovascular and Diabetes with the Asthma team planning to post its User Guide for comment mid summer.

Updated team charters will also begin to be posted in May.

Mark your calendars for an upcoming webinar on 6 June[18] that will describe how you can participate more fully in CDISC team activities. And for those of you who are already active on teams, we hope you will join us at an upcoming Intra-Change working meeting planned for 30 July & 1 August in beautiful and balmy Silver Spring, MD, where teams will be meeting together to sort out current hot topics and learn about some of the new processes and tools we’re providing to support team interactions, including SHARE.

Follow the link for standards open for review and comment as well as new standards available for use[19]. Stay tuned to our homepage[20] for details on Standards and Technical updates as well as current CDISC information.

Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards. Click here to view the scheduled webinars in 2013.[16]

Our next webinar is scheduled on 6 June 2013. Click here to see more details on the topics and registration information.[21]

CDISC Foundational Standards (CDASH, SDTM, ADaM) in Chinese version

The China CDISC Coordinating Committee (C3C) and CDISC Standards Translation and Review (C-STAR) project team are pleased to announce the release of CDASH (v1.1), SDTM (SDTM v1.2 /SDTMIG v3.1.2) and ADaM (ADaM 2.1 /ADaMIG 1.0) for public review after 2 years of effort. (See below for the Chinese version of this announcement).

C-STAR was setup in May 2011 to review the Chinese translation of CDISC Foundational Standards which were provided by Absolute Systems Clinical Data Co., Ltd. All participants are volunteers from CRO, pharmaceutical companies and academia who are CDISC standard experts or practitioners experienced in this area. In order to ensure the highest quality of the translation and the adherence to the original English version, a very strict translation process was developed: translation, editing, proofreading, review and then cross review.

CDISC Foundational Standards provide the basis for the complete CDISC suite of standards, supporting the clinical research process from protocol through data collection, data management, data analysis and reporting. The Clinical Data Acquisition Standards Harmonization (CDASH) Standard defines basic standards for the collection of clinical trial data. The Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets submitted to a regulatory authority such as
the US Food and Drug Administration (FDA). The SDTMIG should be used in close concert with the current version of the CDISC Study Data Tabulation Model (SDTM) that describes the general conceptual model for representing clinical study data that is submitted to regulatory authorities. The ADaM document explains the purpose of the Analysis Data Model. It describes fundamental principles that apply to all analysis datasets, with the driving principle being that the design of analysis datasets and associated metadata facilitate explicit communication of the content of, input to, and purpose of submitted analysis datasets. The Analysis Data Model supports efficient generation, replication, and review of analysis results.

The translation of CDISC standards is expected to greatly increase CDISC awareness in China clinical research industry, including academia and regulatory agencies. In addition, C3C and C-STAR are making every effort to introduce and facilitate CDISC standards into practice in China, so China can gradually improve the data quality of clinical trials and play a more important role in the global clinical research environment.

Please note that comments are being requested on the translation into Chinese, NOT on the standards themselves.

Click here to view the standards for review. [22]

Please send your comments by 16 July 2013 using the CDISC comment templates below:

1. Comment for ADaM [23]
2. Comment for SDTM [24]
3. Comment for CDASH [25]

Please send your comments on these Chinese versions of CDISC standards to CDISCChina@cdisc.org [26].

CDISC Advisory Council Call for Nominations

The CDISC Advisory Council (formerly known as the CDISC Advisory Board) is now requesting nominations for Chair-elect of this Council. Please submit your qualified nominations (which must be from CDISC Platinum Member Organizations) to Sheila Leaman (sleaman@cdisc.org) no later than 16 July 2013.

CDISC Members Updates

Our New Members in April

New Gold Members in April:

- XOMA - USA
- Cognitive Research Corporation - USA

Thank you and a warm welcome to our new members in April. 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 May:

5 years with CDISC:

- Syne qua non, Ltd. - UK
- Asklep, Inc. - Japan
Formedix to Host Executive Breakfast Focused on CDISC Standards Implementation prior to Bay Area CDISC Network Meeting, May 23, 2013

Formedix, a leading provider of CDISC based clinical trial automation software and consultancy services, is hosting an executive breakfast on May 23, 2013 from 9 am, prior to the Bay Area CDISC Network Meeting, which will also be sponsored by Formedix. The event is being held in the South San Francisco Conference Center. Mark Wheeldon, of Formedix, will be joined at the morning event by CEO of CDISC Rebecca Kush and David Borbas, Senior Director of Data Management at Jazz Pharmaceuticals for presentations celebrating CDISC standards and their use within the clinical trial process. The breakfast will provide attendees with the opportunity to hear the opinions of industry specialists on CDISC standards and their application throughout a clinical trial and to enjoy high-level networking. Click here to view the full press release.

Register here if you would like to attend the Executive Breakfast meeting.

And see the User Network section below if you are interested in attending the Bay Area User Network meeting on 23 May 2013.

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.

CDISC Bay Area User Network Meeting on 23 May 2013

The CDISC Bay Area User Network meeting will take place on Thursday, 23 May 2013 from 12:30 PM to 4:30 PM at the South San Francisco Conference Center (at the same location where the Formedix CDISC Executive Breakfast meeting will be held on 23 May 2013). If you would like to join this meeting, please reply to this e-mail (jbrega@pharmastat.com) to help us get an accurate count for planning purposes. Attendees are advised to
arrive early to find a parking spot. The room will be open at 12:30 PM and the meeting will start at 1:00 PM. If you cannot attend in person, you have the option of joining the web conference meeting. A meeting link and teleconference number are provided through the following link. Click here for agenda details, directions and web conference information.

The CDISC Japan User Group Recent Meetings and Updates (by Yoshiteru CHIBA)

Recently held meetings:
The CDISC Japan User Group (CJUG) hosted a CDISC SDTM team meeting on Friday, 12 April 2013 at Dainippon Sumitomo Pharma Co., Ltd in Tokyo, Japan where 30 people attended this event. The conference started with an online presentation: “About PhUSE” provided by Mr. Senk Frank. During the second session, the team discussed the SDTM data implementation updates. And the last session was concluded with a presentation by Mr. Takashi MISAWA of ACRONET Corporation. Mr. MISAWA who is a member of LIaS (an SDTM Sub-Team) presented on the “SDTM Filesize Issue Updates”.

Another CJUG SDTM team meeting was held on Friday, 10 May 2013 at The Institute of Japanese Union of Scientists & Engineers (JUSE) in Tokyo where 32 people attended this conference.

Recently, four new members have joined the CJUG team:

- Mr. Yutoku KITAHARA of Bell Medical Solution Inc.
- Mr. Hideharu YOKOMACHI of Bell Medical Solution Inc.
- Ms. Hanae UEYAMA of Kyoto University Hospital
- Ms. Mariko DOI of Kyoto University Hospital

Various presentations were provided throughout the meeting on 10 May, among which was a talk by Dr. Hideto YOKOI of Kagawa University Hospital Department of Medical Information. Dr. Hideto presented through an online webinar as he was on a business trip in the U.S. attending a meeting with the U.S. Food and Drug Administration. His presentation topic was “Challenge of linking EHR to EDC”. During the second session, the team discussed the SDTM data implementation latest updates. The topics included creating a CRF sub-group, creating a Trial Design Model sub-group, EDC Builder sub-group and Protocol sub-group.

Upcoming CJUG meetings:
The next CJUG SDTM Team meeting will be held on 14 June 2013 at the University of Tokyo. The meeting is scheduled from 13:00 to 17:00. During this conference, the SDTM data implementation activity sub group will discuss creating a CRF sub-group, EDC Builder sub-group, Trial Conductor sub-group and study reviewers guide sub-group. In addition, a presentation on “About next eCTD” will be provided by Ohbayashi. Furthermore, another talk about “VISITNUM/VISIT -SV vs. Other Domain:” will be provided by Mr. OHNO of CHUGAI clinical research center CO, LTD. Mr. OHNO is a member of LIaS which is an SDTM sub-team.

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 Job Opportunities Available

CDISC is seeking candidates for two current job openings:

1. **SHARE Project Manager**: this position will be responsible for implementing the SHARE metadata repository system and managing ongoing SHARE operations. Candidates should be familiar with CDISC standards, clinical research data and have experience implementing information systems projects.

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

3. **CDISC Software Applications Specialist**: this position will ideally be based in Austin, TX. Please contact Julie Evans at jevans@cdisc.org and mention the CDISC eNewsletter if you are interested in learning more about this position.

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 Afficionados
- Protocol Representation
- Terminology

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

Also stay tuned for an upcoming webinar where we will describe how to get more actively involved in CFAST Therapeutic Area Data Standards project teams. Details on our webinars can be found here.

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. Information will be posted soon on the CDISC website.

CDISC Standards Latest Updates Webinars
Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards. Click here to view the scheduled webinars in 2013.

Our next webinar is scheduled on 6 June 2013. Click here to see more details on the topics and registration information.

CDISC Education Courses Opportunities

CDISC is offering six public education events between now and the International Interchange in Bethesda, MD November 2013. The next three education offerings are listed below and limited seats are still available. Future education events can be found on our web site. As always, you can still request private training for your organization. For more information on CDISC private training, please visit the following webpage.

21-24 May - CDISC Public Training, St. Louis, MO Hosted by Biomedical Systems

Courses Offered:
- SDTM Theory and Application (21-22 May 2013); 2-day Course
- CDASH Implementation (23 May 2013)
- ADaM Implementation (24 May 2013)

Online registration has closed but you can still attend this education event by filling out offline registration form to attend this event.

Did you know: CDISC only authorizes the most qualified instructors to teach our CDISC Education courses. Our instructors come from various backgrounds and have taught CDISC Education courses worldwide.

4-7 June - CDISC Public Training, Audubon, PA Hosted by BioClinica

Courses Offered:
- SDTM Theory and Application (4-5 June 2013); 2-day Course
- CDASH Implementation (6 June 2013)
- ADaM Implementation (7 June 2013)

Online registration has closed but you can still attend this education event by filling out offline registration form to attend this event.

Did you know: This is the third consecutive year a CDISC Public Course offering is held at BioClinica in Audubon, PA. There is a strong demand for CDISC standards in the area and we expect the demand to grow in the coming years.

17-July - CDISC Public Training, Cambridge, MA Hosted by Sanofi (Genzyme)

Courses Offered:
- ADaM Implementation (17 July 2013)

Online Registration ends 17 June 2013. Click here to register. You can also register using the offline registration form by clicking here.

Did you know: Unsure if you should attend this event? Feel free to contact us at training@cdisc.org or feel free to stop by the CDISC booth at the DIA Annual Event in Boston, MA next month from 24-26 June.

9-12 September - CDISC Public Training, Brussels, Belgium Hosted by Business and Decision Life Sciences

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

Online Registration ends 9 August 2013. Click here to register. You can also register using the offline registration form by clicking here.
Did you know: This is the third consecutive year a CDISC Public Course offering is held at Business & Decision Life Sciences in Brussels, Belgium. Two authorized CDISC instructors who work for Business & Decision will conduct the SDTM and CDASH courses. Register now to reserve your slot!

CDISC Upcoming Standards Webinar and Other News & Updates:

- Next CDISC Standards and Updates Webinar scheduled for 6 June. Click here to register.
- SDTM Basics Online Training to be rolled out soon. Stay tuned for more info!
- Program and courses offered at International Interchange to come out in the summer.

For more information on upcoming CDISC Education events, please visit the CDISC Education webpage.

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

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