April 2013 eNewsletter

The CDISC April Newsletter Presents the Following Topics:

- CDISC Europe Interchange 2013 - Offline Registration Still Open this Week!
- Nominations Open for CDISC Board of Directors
- CDISC Success Story: Sharing Clinical Research Data
- CDISC Technical News
- CDISC Press Release: C-PATH AND CDISC LAUNCH VERSION 1.0 OF THE POLYCYSTIC KIDNEY DISEASE THERAPEUTIC USER GUIDE
- CDISC Blog: Healthcare and Research: A Venn Situation

Frequently Asked Questions:
1. How do I become a CDISC member?
2. How do I get into the CDISC Members Area?
3. What is in the CDISC Members Area?
4. What types of organizations are CDISC members?
5. Why should an organization join CDISC?

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CDISC Europe Interchange 2013

The CDISC Europe Interchange will be held next week on 22-26 April 2013 in Bad Nauheim, Frankfurt, Germany. Offline registration is still open through this link.

Our Interchange Keynote speaker, Dr. Michel Goldman, the head of the Innovative Medicines Initiative (IMI) will provide an overview on the State of the IMI Project. Frank Petavy of the European Medicines Agency (EMA) will present on the Clinical Data Transparency Initiative. And Dr. Charles Cooper of the U.S. Food and Drug Administration (FDA) will present on the Challenges and Process in relation to Data Standards at FDA. Leaders and experts from well-known international organizations will be speaking at this event.

If you have still not registered, click here to view the benefits of attending this interchange.

The interchange final program is available through this link. The main conference will be held on 24 & 25 April, while CDISC education courses will be offered throughout the week on 22, 23 & 26 April 2013. Click here for more details on the courses offered.

Join us at our Networking Event & Celebrate the 10th European Interchange this Year!

Join us in our celebration of the 10th CDISC European Interchange and attend our special evening event on Wednesday, 24 April 2013. You will be treated with 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). Dinner will be offered on stage with background live music indulging our attendees with a nice atmosphere of networking and chatting.
Hotel Reservation

- Hotel reservation is available through this link.

Mark your calendars! The CDISC International Interchange will take place in Bethesda, MD on 4-8 November 2013. Information and further details will be coming very soon; stay tuned to the CDISC website.

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

Board of Directors Call for Nominations

As an interested party of CDISC, you have the opportunity to participate in the process of nominating candidates for the CDISC Board of Directors. CDISC needs dedicated and committed people willing to become candidates for the board election to be held in the last quarter of 2013. Please take some time to think about those individuals that you believe would make good board members, verify that they would be willing to serve and then fill out the board profile grid (through this link) and submit this along with their current CV and a letter stating why they want to be on the Board and what they can bring to the Board. We must have all three documents for each nominee. This is your opportunity to ensure the quality of candidates who will shape the future of CDISC. Click here for full details on the call for nominations.

Nominations must be submitted via email to swilliams@cdisc.org by 30 June 2013.

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, our topic is a bit different; we are sharing a prepublication release of an Institute of Medicine (IOM) workshop that was focused on sharing clinical research data highlighting various perspectives on this important topic that is closely related to the importance and benefits of CDISC standards.

Sharing Clinical Research Data - Prepublication Release: IOM Workshop, October 2012

Dr. Rebecca Kush, President and CEO of CDISC stated: "The Institute of Medicine (IOM) held a workshop in October 2012 that was one of the best meetings I have ever attended. I participated in a great session that was chaired by Dr. Frank Rockhold (GSK, CDISC Board Past-Chair) and Dr. Lynn Hudson (Critical Path Institute). Dr. Hans Joerg Eichler was there to announce the EU Data Transparency Initiative (which we will hear more about at our European Interchange next week – see p. 58) and there were many other enlightening presentations with robust discussion. It was an overflow crowd and presentations were shown on video in a second room. Below is a slide that I developed, based upon this workshop, for a subsequent meeting at NIH; all of these topics were covered in the IOM Workshop and I especially liked Dr. Eichler’s quote!"

The summary report from this workshop, Sharing Clinical Research Data, was released by the IOM on 29 March 2013. Follow the link to view the prepublication version.

CDISC Technical News
CDISC standards development teams are currently working on dozens of new projects to develop or enhance standards to support our mission and vision. Visit our [website](http://www.c-path.org) for frequent updates on CDISC standards currently posted for public comment or available for use and the current Technical Plan.

The initial list of CFAST Therapeutic Area projects slated to begin in 2013 is now available on the Therapeutic Areas page. Work on Asthma, Alzheimer’s, Multiple Sclerosis, Cardiovascular and Diabetes is currently in progress. Additional details (project descriptions and charters) will be posted soon.

Define-XML v2.0 was posted in early March, and the XML Technologies team is currently working on an Implementation Guide for Define v2 along with an associated guide describing how to represent SDTM and ADaM datasets in XML format. Upcoming documents soon to be posted for comment include the CDASH SAE Addendum and SDTMIG v3.1.4 Batch 3, which will include SDTM v1.4, an Associated Persons guide, new material related to exposure and other new domains. A final version of SDTMIG v3.1.4 is planned for this summer.

Stay tuned for information updates on the SHARE metadata repository project.

Follow the link for [standards open for review and comment as well as new standards available for use](http://www.c-path.org), the Clinical Data Interchange Standards Consortium (CDISC), and the PKD Foundation announced today the launch of version 1.0 of the Polycystic Kidney Disease (PKD) Therapeutic Area User Guide, a clinical data standard that provides guidance on the implementation of the CDISC Study Data Tabulation Model (SDTM) to represent PKD data in regulatory submissions. This user guide, when used with the SDTM, is intended to guide the organization, structure, and format of standard PKD clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). This clinical data standard has also been used to aggregate data from several PKD patient registries and observational studies to analyze disease progression in PKD. “The development of the PKD Data Standard represents a major step forward in the development of therapies for PKD,” said Ron Perrone, Professor of Medicine at Tufts University School of Medicine, and Director of the Tufts Center for PKD and Co-Director of the PKDOC. “This kidney disease specific standard will shorten the time for initiation of clinical trials and will facilitate data interchange with regulatory agencies, thereby helping to speed the pace of therapeutics development and potentially improving outcomes for patients.” Perrone is also a member of the PKD Foundation’s Scientific Advisory Committee. The PKD Foundation provided funding for the PKDOC and the CDISC standards development effort.

CDISC standards are freely available via the CDISC website. To learn more about the PKD Therapeutic Area User Guide and to download the associated standards package, please visit the CDISC website.

Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards. [Click here to view the scheduled webinars for 2013](http://www.c-path.org).

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**CDISC Press Release - C-PATH AND CDISC LAUNCH VERSION 1.0 OF THE POLYCYSTIC KIDNEY DISEASE THERAPEUTIC USER GUIDE**

**New guide to assist in the collection, aggregation, and submission of clinical trial data**

_Tucson, AZ , Austin, TX - 17 April 2013 - Critical Path Institute’s (C-Path) Polycystic Kidney Disease Outcomes Consortium (PKDOC) (http://www.c-path.org/pkd.cfm), the Clinical Data Interchange Standards Consortium (CDISC), and the PKD Foundation announced today the launch of version 1.0 of the Polycystic Kidney Disease (PKD) Therapeutic Area User Guide, a clinical data standard that provides guidance on the implementation of the CDISC Study Data Tabulation Model (SDTM) to represent PKD data in regulatory submissions. This user guide, when used with the SDTM, is intended to guide the organization, structure, and format of standard PKD clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). This clinical data standard has also been used to aggregate data from several PKD patient registries and observational studies to analyze disease progression in PKD. “The development of the PKD Data Standard represents a major step forward in the development of therapies for PKD,” said Ron Perrone, Professor of Medicine at Tufts University School of Medicine, and Director of the Tufts Center for PKD and Co-Director of the PKDOC. “This kidney disease specific standard will shorten the time for initiation of clinical trials and will facilitate data interchange with regulatory agencies, thereby helping to speed the pace of therapeutics development and potentially improving outcomes for patients.” Perrone is also a member of the PKD Foundation’s Scientific Advisory Committee. The PKD Foundation provided funding for the PKDOC and the CDISC standards development effort._

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**Healthcare and Research: A Venn Situation**

Recent discussions concerning the Learning Health System (LHS), and particularly Essential Standards to Enable Learning (ESTEL), have exposed varying perspectives on the relative overlap standards should have between healthcare and research. There are those who feel research and healthcare have quite different standards requirements while, on the other end of the spectrum, there are still others who will indicate that it depends on the type of standards being referenced. Sixteen years after Bron Krisler and I developed a slide with two intersecting circles – one for healthcare and one for research – I am even more convinced that this is a Venn situation.

_From Wikipedia: A Venn diagram or set diagram is a diagram that shows all possible logical relations between a finite collection of sets (aggregation of things). Venn diagrams were conceived around 1880 by John Venn. They are used to teach elementary set theory, as well as illustrate simple set relationships in probability, logic, statistics, linguistics and computer science (see logical connectives)._
Frequently Asked Questions

We are constantly updating the Frequently Asked Questions area of the CDISC website to make it easier for our readers and CDISC followers to find their answers. This month we would like to draw your attention to the following areas:

Why should an organization join CDISC?

CDISC has become much “more than standards”, making a clear impact on improving the clinical research process and helping to bring new safe and effective therapies to patients sooner. Any organization interested in furthering the CDISC mission is welcome and encouraged to join CDISC as a member.

As a non-profit organization, although CDISC is continuously diversifying its revenue streams, membership remains our primary source of income. In order to support increased implementation of CDISC standards around the globe and to keep pace with growing industry and regulatory requirements for new standards, we need financial support from organizations in the industry.

In 2011, CDISC applied for and was approved as a 501(c)(3) organization by the IRS. This will permit direct individual and corporate contributions to CDISC in the form of donations or membership fees to be tax-deductible.

By being a CDISC Member your organization can:

- Support CDISC in serving the community as demonstrated by the fact we are the only SDO whose Standards are focused on research and provided free to the public and the growing CDISC global community
- Make it possible for CDISC to fulfill its mission; it is an integral requirement to continue the development and maintenance of the CDISC standards for the benefit of the global biopharmaceutical industry and clinical research, in addition to supporting CDISC communication and implementation services
- Increase recognition by your peers and regulators as an organization willing to support CDISC financially and contributing to the betterment of biomedical/clinical research overall
- Have direct influence on and input to the standards that are in development or those being enhanced
- Receive discounts (20% for Gold Members/40% for Platinum Members) for CDISC Educational Courses and annual Events (e.g. Interchanges in US, Europe, Asia-Pacific, Japan and China)
- Gain access to the Members Area of the website
- Enroll for the Registered Service Program
- Keep abreast of emerging technologies, standards, compliance requirements, regulations and continuous process improvements
- Platinum members have the opportunity for representation on the CDISC Advisory Council
- Leverage invaluable partnership prospects and networking opportunities with industry peers and visionaries
- Enable the important work of CDISC to continue around the world

How do I become a CDISC Member?

Just complete the simple Member Application at http://www.cdisc.org/membership-benefits-and-options (click ‘Become a Member’ for the form). Once we receive the form, we will send you membership information together with the annual fee which is based on the total number of employees in your company and the level at which your organization joins.

How do I get into the CDISC Members Area?
The Members Area is password protected. Anyone who belongs to a CDISC Member Organization can have the company username and password for the Members' Area. If you need your company’s login credentials, you can get it either from your company’s member contact person or you can use the “forgot password” option to retrieve the password information. However, you will need your company’s corporate email (eg. john.doe@healthcare.com) to gain access to the password information.

What is in the CDISC Members Area?

The “Members Area” of the CDISC web site is an area to which only CDISC members in good standing (membership fees are up to date) have access. The purpose is to provide added value to those who make CDISC possible, especially since all of the CDISC standards are open and free to anyone. The Members Area contains tools (eg. ODM viewer, Protocol Outline tool and more to come such as the Excel spreadsheet version of the SDTM domains); the Introduction to CDISC Course (Global Approach to Accelerating Medical Research course will be available online soon); Supplements (training, examples, data); Computer readable metadata; Project Schedules, Project Progress Reports and Plans, Team Minutes; Case Studies from companies demonstrating how they have implemented the CDISC Standards. There is also a quick link to the CDISC SDTM standard to avoid having a file sent via email.

What types of organizations are CDISC members?

CDISC has over 300 organizational members from 19 countries in 11 different industries. CDISC members include organizations from biopharmaceutical companies, clinical/contract research, healthcare, medical devices, academia, consulting companies, technology providers, and more. See the CDISC website for a complete list.

Click here for more FAQs.

CDISC Members Updates

Our New Members in March

New Gold Members in March:

- Advance Research Associates, Inc. - USA
- Almirall, S.A. - SPAIN
- Bell Medical Solutions, Inc. - JAPAN
- Center of Excellence for Biomedical and Public Health Informatics - THAILAND
- CRS Clinical Research Services Mannheim GmbH - GERMANY
- HSO Clinical, LLC - USA
- Kyoto University Hospital - JAPAN
- PHASTAR - U.K.

Thank you and a warm welcome to our new members in March. 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 ST★R Members

Star Members in March:

5 years with CDISC:

- BioMarin Pharmaceutical Inc. - USA
- Cliniti AG - Germany
- Dr. Oestreich + Partner, GmbH - Germany
- IDDI - Belgium
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.

The CDISC English Speaking User Group are holding their first Teleconference for 2013, the main topic will be about “Introducing the TransCelerate Biopharma Initiative”. The TC will take place on Tuesday 30 April 2013 at 2:00 PM UK time. Dave Jordan (Abbvie) and Simon Bishop (GSK), will be discussing how TransCelerate will support the development of therapeutic area standards with CDISC. For more information about TCB, please visit the following website: http://www.transceleratebiopharmainc.org/. If you would like to join this meeting, please register using the following email: registrations@esug.org.uk. And please use the committee@esug.org.uk for any other enquiries.

Boston Area CDISC User Network (BACUN) is planning its next user network meeting on 8 May 2013 from 11:00 AM to 1:30 PM at Vertex in Cambridge, MA.

Join the Boston Area User Network for lunch, networking, and a discussion about ADaM implementation. Topics to be discussed during this meeting are:

- Define.xml 2.0 - Sally Cassells, Next Step Clinical Systems
- ADaM Mini-Topics with Roundtable Discussion
- ADSL and ISS: Questions and Challenges - Dana Soloff, Genzyme
- Building Traceability for End Points in ADaM Datasets Using SRCDOIM, SRCVAR, and SRCSEQ Triplet - Bob Cui, Vertex

To receive BACUN meeting announcements directly, subscribe to the BACUN Yahoo Group ‘BostonCDISC’, or send a request to join the mailing list to melissa.k.cook@accenture.com.

User Group Meetings Recently Held in Japan:

The CDISC Japan User Group (CJUG) recently hosted a CDISC SDTM Team meeting on 8 March 2013 at ASKLEP Inc. Akihabara Office in Tokyo, where 32 people attended this event. The meeting launched with an online presentation on “Managing Data Quality and Standards Compliance with OpenCDISC” by Max Kanovsky of OpenCDISC/PINNACLE21. During the second session, the team discussed latest updates on the SDTM data implementation. And finally, the conference concluded with a presentation “About PhUSE” by Hajime SHIMIZU of Takeda Pharmaceutical Company Limited, by LiSaS (a sub-team of SDTM).
Another CJUG Workshop was held on 12 March 2013 at CAC EXICARE where 80 attendees shared experiences and updates on the CDISC standards. The third SDTM Team meeting was held on 12 April 2013 at Dainippon Sumitomo Pharma Co., Ltd; during this half-day meeting, an online Presentation “About PHUSE” was provided by Senk Frank, in addition Yasutaka MORIGUCHI of Santen Pharmaceutical Co, presented on “SDTM Filesize Issue Updates” By LiSaaS, and finally an SDTM Data implementation activity sub-group meeting was held to discuss various topics about creating CRF sub-sub-group, creating Trial Design Model group, Protocol sub-group and EDC Builder sub-group.

**Future User Group Meetings in Japan:**

The SDTM team invited speakers to present on the following topics:

1. “Challenge of linking EHR to EDC”, the meeting will be held at Kagawa University Hospital on 10 May 2013.
2. The second presentation will be on the following topic: “About next eCTD”, the meeting will be held at Meta-cube Mr. Ohbayashi on 14 June 2013.
3. Another presentation will be offered on 12 July 2013 by a representative of the Ministry of Health, Labor and Welfare (MHLW), Office of Clinical Trial Promotion Research and Development Division Health Policy Bureau. Presentation topic will be determined soon, stay tuned to our website.

To join a CDISC User Network, contact Diana Harakeh [here]. 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 [here] to know more about the purpose and benefits of the CDISC User Networks.

**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.

Follow the link [here] 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 [here] 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 Europe Interchange in Germany, 22 - 26 April 2013. Offline and Online Registration are Available.
- CDISC International Interchange in North Bethesda, MD, 4 - 8 November 2013. Registration and details will be available next month.

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

CDISC EU Interchange in Frankfurt, Germany

Courses Offered:
- SDTM Theory and Application (22-23 April)
- BRIDG Deep Dive (22 April)
- ADaM Implementation Model (23 April)
- CDASH Implementation (26 April)
- ODM Implementation (26 April)
- Controlled Terminology (26 April)

Click here to register.

CDISC Public Course Offering in St. Louis, MO

Courses Offered:
- SDTM Theory and Application (21-22 May)
- CDASH Implementation (23 May)
- ADaM Implementation (24 May)

Click here to register.

Discount period ends 28 February.

CDISC Public Course Offering in Audubon, PA

Courses Offered:
- SDTM Theory and Application (4-5 June)
- CDASH Implementation (6 June)
- ADaM Implementation (7 June)

Click here to register.

Discount period ends 4 March.

All other public course offerings in US, Asia, and Europe can be found by clicking on the following link.
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.

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

Stay tuned for more feedback from our loyal attendees and be one of them!

Non-CDISC Events

PhUSE Annual Conference 2013:
The PhUSE Annual Conference 2013 will be held on 13 - 16 October 2013 in Brussels, Belgium – register now! The theme for this year’s conference is “Patient Centricity” and it will be held at the Radisson Blu Royal Hotel in the beautiful city of Brussels – benefit from the discounted hotel rate and make your reservation here. Sponsorship and Exhibitor Opportunities are available and details can be found here. Please also see the following link to view the PhUSE Single Day Events 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.