February 2013 Newsletter

The CDISC February Newsletter Presents the Following Topics:

- CDISC Asia-Pacific Interchange 2013 - Offline Registration and Extra Discounts Available This Week
- CDISC Europe Interchange 2013 - Conference Preliminary Program and Registration Available
- CDISC Press Release - Coalition for Accelerating Standards and Therapies (CFAST) Announces a Resource for Parkinson’s Disease Clinical Development
- CDISC Member Success Story - Formedix: Clinical Trial Efficiency Using CDISC Standards
- CDISC Technical News
- RSP Program Updates
- CDISC ODM Certification Program Re-Launch in 2013
- CDISC and RFD Featured in HHS/ONC Initiative Launch
- Structured Data Capture Initiative: Adverse Event Reporting
- Frequently Asked Questions
- CDISC Members Updates
- CDISC User Networks
- Opportunity to Donate to CDISC
- CDISC Volunteer Opportunity
- Global Events and Education Opportunities
- CDISC Partner Events - Join CDISC at the FDA/PhUSE Computational Sciences Symposium 18-19 Mar, 2013 in Silver Springs, MD
- CDISC Official Primer for a Lower Price
- CDISC Social Media

Last Chance to Register for the Inaugural CDISC Asia-Pacific Interchange: “Streamlining Global Research through Standards”

The CDISC Asia-Pacific Interchange is next week on 18-22 February 2013 in Singapore! We have a stellar line-up of presenters and opportunities to network and learn how to streamline clinical research through standards. Time passes quickly and our seats are limited, register now and do not miss out on our inaugural event!

Offline Registration is still open this week and extra discounts are offered:

- **CDISC Members**: in addition to the original Member discount rate (40% for Platinum, 20% for Gold members), will be eligible for an extra 20% discount.
- **Individuals from Non-member companies** will get 25% discount on the original price. Please use the Offline Registration Form and your invoice will reflect this discount.

Benefit from the CDISC Discounted Hotel Rate and make your reservation through this link. For questions and more information, please contact Sheila Learner or Shirley Williams.

Date:
18-22 February 2013

CDISC Authorized Education Courses on 18-19 & 22 February

Main Conference 20-21 February

Location:
The Interchange will highlight the mission and vision of CDISC and will present Case Studies with CDISC Standards. Presentations on the Status of Clinical Research around the Globe, Clinical Research and Hospital Information Systems, Clinical Research using EHRs, Global Standards Harmonization and Therapeutic Area Standards will be offered during this Interchange. [PROGRAM AVAILABLE HERE](#).

Our Interchange is not just a conference; it is a blend of presentations on our latest achievements in the global healthcare and a variety of courses offered throughout the week to train you on how to implement our standards in your daily work. Description and schedule of educational courses offered can be found through this [link](#).

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### CDISC Europe Interchange 2013

The [CDISC Europe Interchange 2013](#) will be held on 22-26 April 2013 in Bad Nauheim, Frankfurt, Germany. Don’t miss out! This year’s Interchange will include a distinguished panel of presenters from various government and healthcare organizations. 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. The conference will continue with notable presenters from various sectors of the healthcare industry who will be presenting on the CDISC data standards latest achievements and their impact on healthcare and patients safety worldwide. Below are some examples of the presentations topics that will be discussed during this Interchange:

- EHR4CR and Healthcare Link
- Governance Standards
- Data Standards Latest Achievements and News
- The Expert Panel Session (an opportunity to allow our audience to share their experiences and ask any related questions about the CDISC standards and their impact on the industry).

[Preliminary Program Available Here](#).

**Registration for the conference and authorized CDISC educational courses is available through this [link](#).**

As with previous years, CDISC education courses will be offered during the Interchange week to familiarize our audience on how to implement the CDISC standards within their work environments. CDISC education courses will be offered on Monday 22 April, Tuesday 23 April and Friday 26 April 2013. The BRIDG Deep Dive, SDTM Theory and Application, ADaM Implementation, CDASH Implementation, Controlled Terminology and ODM Implementation courses will be offered during the Interchange week. [Click here](#) for more details on the courses offered.

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

Hotel Reservation

Don’t forget to make your hotel reservations through this link. Benefit from the CDISC discounted rate, please make sure to use the CDISC Discount Rate Code provided through the same link.

Bring Global Awareness to Your Organization and Sponsor at Our Interchanges!

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

Furthermore, exhibiting at our event will provide your company the opportunity of interacting with key international organizations and global regulatory entities that will be attending the CDISC Interchange. Follow the link if you are interested in exhibiting at the CDISC Europe Interchange 2013.

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 soon, stay tuned to the CDISC website.

Coalition for Accelerating Standards and Therapies (CFAST) Announces a Resource for Parkinson’s Disease Clinical Development

Tucson, AZ and Austin, TX – January 29, 2013 - The Coalition for Accelerating Standards and Therapies (CFAST), a joint effort between the Clinical Data Interchange Standards Consortium (CDISC) and Critical Path Institute (C-Path), in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), announces the availability of an important new resource in the fight against Parkinson’s disease (PD). Parkinson’s disease is a debilitating condition that affects an estimated 1,000,000 in the U.S. and as many as 7,000,000 people worldwide. Follow this link to read the rest of the press release.

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 primarily focused on ODM and CDASH implementation experiences by Formedix.

Formedix: Clinical Trial Efficiency Using CDISC Standards

Formedix develops clinical trial automation software and services to promote efficiency for CROs, Pharmaceutical and Biotech companies, and EDC vendors. Formedix has been involved in using CDISC standards for over 10 years, and their Technical Standards Director (who has won 2 awards with CDISC) is currently working heavily on CDISC’s Define.xml. CDISC standards have been integral in ensuring that Formedix’s clients see large-scale reuse, and substantial reductions in resources, set-up and EDC build time. In this article, Formedix proves that you can automate clinical trials anywhere using the CDISC standards.
Using CDISC standards is all about making the clinical trial process more efficient, saving time and money. Through the content libraries that Formedix has established for many of its clients, from small biotechs to large multinational firms, they have found that there is significant content reuse, as much as 70-80% reuse in some cases, with 20% less maintenance cost. These content libraries span the entire clinical trial process end-to-end, and have been found to have a quick ROI in one case in as little as eight months. Follow the link for the full story.

CDISC Technical News

CDISC is continuously working on many projects to develop or enhance standards to support our mission and vision. Visit our website for frequent updates on CDISC standards currently posted for public review and comment or available for use.

CDISC has just posted an update to the SDTM/ADaM Pilot Submission package for use by CDISC members. The pilot package has been updated for consistency with current versions of SDTMIG v3.1.3, ADaM v1.1, and the ADaM IG.

In the coming weeks, CDISC expects to post the provisional user guide for Polycystic Kidney Disease v1.0 and Define-xml v2.0. Drafts to be issued for comment include the CV therapeutic area user guide the CDASH supplement for collecting Serious Adverse Event data consistent with ICH E2B.

We will soon be posting project team charters for 2013, beginning with the recently approved project charters for Asthma v1 and Alzheimer’s v1.1 therapeutic area standards. Asthma is the first CFAST project that directly involves TransCelerate Biopharma.

CDISC will also soon be posting a 2013 technical plan to with major projects and deliverables targeted for this year.

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.

Join us for the CDISC Standards Webinar on Thursday, 7 March 2013 at 11:00 AM U.S.A Eastern Time.

Agenda:

- Asthma Therapeutic Area Standard
- And more!

You will have the opportunity to ask questions to CDISC standards experts! Please prepare your questions for this webinar.

Click on this link to register.

Click here to view the system specifications needed to attend this webinar.

DEPARTMENT OF HEALTH AND HUMAN SERVICES - Food and Drug Administration

Electronic Study Data Submission; Data Standard Support End Date

AGENCY: Food and Drug Administration, HHS. ACTION: Notice.

FDA encourages sponsors to submit standardized study data using Agency-supported data standards (follow this link). An Agency-supported data standard means that FDA has established processes and technology infrastructure to support the receipt, processing, review, and archiving of study data using the standard. As data standards evolve, FDA will periodically end support for old standards in favor of newer standards that are better suited to meet FDA data management and review needs. FDA maintains a catalog of the supported data standards for study data submissions through this link.

RSP Program Update!

The purpose of the RSP program is to advertise information about organizations and companies with CDISC.
CDISC will be promoting its Registered Solution Providers through its various communication channels including its official website, monthly newsletters, interchange programs, educational courses and webinars. Promote the visibility of your organization and become a CDISC RSP! See below for further details.

CDISC Registered Solutions Providers are consultants, system integrators, and subject matter experts that claim to have sufficient knowledge and experience implementing the various CDISC standards to be included in the RSP list.

CDISC will provide the following for RSP organizations:

- Information you provide in the current spreadsheet-type format on our website with links to your web site.
- Periodic announcements in our eNewsletter reminding those who need your type of expertise to check out the RSPs posted on our web site.
- Enhancements to our web site to more prominently display RSP information.
- Advertising of RSPs at our various Interchanges.

The requirements to be listed as a RSP:

- Your organization/company must be a CDISC member.
- Fill out the RSP application form
- Pay the annual fee.

More details on our current RSPs and the application form to become a RSP can be found here [3].

CDISC ODM Certification Program Re-Launch Q1 2013!

CDISC began the original ODM Certification Program in 2007. We believe the ODM certification program is valuable for the industry as well as the companies that have ODM-capable products and wish to provide potential customers with the assurance that their products are ODM compliant by way of the CDISC ODM Certification program. Additionally, FDA has expressed renewed interest in ODM, and many have proposed ODM as an alternative to SAS V5 Transport file format, which FDA plans to replace.

The re-launch of the CDISC ODM Certification program will take place in Q1 2013 with an updated set of certification tools capable of testing products against the latest ODM version requirements! Watch the next eNewsletter, our web site and the various social media outlets for more information coming soon!

CDISC and RFD Featured in HHS/ONC Initiative Launch [2]

On 23 January, the U.S. Department of Health and Human Services Office of the National Coordinator (ONC) of Health IT launched a new initiative: Structured Data Capture (SDC). The specific challenge that the SDC initiative is addressing is that electronic health record (EHR) data has been of limited use for purposes outside of the direct care of a particular patient due to “a lack of uniformity in the terminology and definition of data elements across EHRs.” Thus, the SDC Scope Statement is: “To define the necessary requirements that will drive the identification and harmonization of standards to facilitate the collection of supplemental EHR-derived data.” The initial use cases are electronic case report forms (eCRFs) for research and safety reports. The value of this initiative was cited in the slides and the draft SDC charter:

“The identification and harmonization of standards for the structured data capture within EHRs will […] help reduce a) the data collection burden on health care providers by enabling secure, single-point data entry that populates to multiple systems and b) the need to make site-specific modifications to EHR system capabilities in order to enable participation in important reporting and research activities.” Follow the link [2].

Structured Data Capture Initiative: Adverse Event Reporting [3]

On 23 January, the U.S. Health and Human Services Office of the National Coordinator held the Standards and Interoperability Framework’s kickoff webinar for their new Structured Data Capture Initiative. This initiative seeks to define “necessary requirements that will enable clinical data captured in an electronic health record during episodes of care to be combined with additional data to supplement other purposes.” One of these purposes is to ensure the reporting of serious adverse events, with the aim of developing an Incident Report for the reporting of such instances. Follow the Link [3].

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:

- Does CDISC have a Certification Program?
- What is a Registered Solution Provider? What do they do?
- Are there Online Educational Courses Available?

Follow this link for answers.

CDISC Members Updates

CONGRATULATIONS TO WINNERS OF OUR MEMBERSHIP DRIVE – 1 November, 2012– 10 January, 2013

We are pleased to announce the results of the drawing for the Membership Drive announced in November, in conjunction with our CDISC Asia-Pacific Interchange. Congratulations go to:

- **Sarah Cannon Research Global Services** - 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
- **Exelixis, Inc.** - For a new or upgraded membership that totals $3,000 - $9,999 - 2 free attendees to the Interchange
- **ClinData International** - For a new or upgraded membership that totals $1,200 - $2,999 - 1 free attendee to the Interchange

The above winners have a choice of attending the CDISC Asia-Pacific Interchange (18 - 22 February 2013 in Singapore), the CDISC European Interchange (22 – 26 April 2013 in Frankfurt, Germany) or the CDISC International Interchange (4 - 8 November in Bethesda, MD).

A big thank you to all our new members who joined during the Membership Drive. We look forward to seeing you at one of our interchanges.

**New Gold Members in January:**
- BITech Factory GmbH
- Trium Analysis Online GmbH
- US Center for Disease Control and Prevention

**New Platinum Members in January:**
- UsualCare, LLC

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

**Star Members in January:**

**5 years with CDISC:**
- Applied Clinical Intelligence LLC
- Cognizant Technology Solutions, Inc.
- Grunenthal GmbH

**10 years with CDISC:**
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.

To join a CDISC User Network, feel free to contact Diana Harakeh. The User Network portal area is open to anyone and provides information on specific User Networks, including announcements of their next meetings.

Follow the link to know more about the purpose and benefits of the CDISC User Networks.

Donate to CDISC

The U.S. Internal Revenue Service (IRS) approved CDISC as a 501(c)(3) organization in December 2011, recognizing it as a charitable organization retroactive to May 2011.

With our current ability to receive tax-deductible contributions from individual and corporate donors, we will promote CDISC’s message to a broader audience, enhancing CDISC’s capacity to locate funds through diverse means. Your contribution will help us accelerate the availability of new medical therapies to patients in need. Follow the link to know more about how to make your valuable donation.

CDISC Depends on Volunteers to Develop and Maintain Our Open Standards

Engage yourself with the CDISC mission and vision to inform patient care and safety through higher quality medical research and join our working teams by volunteering to any of the following areas:

- XML Afficionados
- Technical Writers
- Protocol Representation
- Device Terminology Specialist

Follow the link to know more about how to volunteer! Further questions, please email us here.
CDISC Global Events and Education Opportunities - And CDISC Partner Events

CDISC Interchanges:
- CDISC Asia Interchange in Singapore, 18 - 22 February 2013. Offline and Online Registration are Available.
- 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 soon.

Join us for the CDISC Standards Webinar on Thursday, 31 January 2013 at 11:00 AM U.S.A Eastern Time. Please follow the link to attend.

CDISC Webinars for 2013 will be posted through this link. Stay tuned for more information!

Upcoming Public Course Offerings

Still interested in attending the CDISC public courses in Morrisville, NC on 12-15 February? Please contact Saad Yousef if you or your colleagues are still interested in attending.

CDISC Asia-Pacific Interchange in Singapore. Courses Offered:
- ADaM (22 Feb)
- CDASH (22 Feb)
- Controlled Terminology (19 Feb)
- Healthcare Link (19 Feb)
- SDTM (18 Feb)

Click here to register.

CDISC Public Course Offering in South San Francisco, CA. Courses Offered:
- SDTM (5-6 March)
- CDASH (7 March)
- ADaM (8 March)

Click here to register.

CDISC Public Course Offering in Bad Nauheim/Frankfurt, Germany. Courses Offered:
- BRIDG Deep Dive (22 April)
- SDTM (22-23 April)
- ADaM (23 April)
- CDASH (26 April)
- Controlled Terminology (26 April)
- ODM (26 April)

Click here to register.

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

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

Come Collaborate with FDA, PhUSE, and CDISC on March 18-19 in Silver Spring, MD!

The aim of the FDA/PhUSE annual Computational Science Symposium (CSS) is to provide updates on collaborations with project groups to improve standards, tools and processes across regulatory review and computational science.

Come Collaborate to Solve Challenges and Look for Opportunities

The annual Computational Science Symposium will bring FDA, industry and academia together for updates and work on collaborations established at previous symposiums and continued throughout the year. Additional collaborative projects have been created to address additional challenges related to the access and review of data to support product development. The groups will work on possible solutions and practical implementations with the goal of helping the broader community align and share experiences to advance computational science. More information about the working groups and their projects can be found here. Register Now!

There are only two weeks left until the Early Bird registration closes (16 February), so Register Now to receive the discounted rate.

Something to share?

Contribute to the CSS by submitting a Poster. Share your innovative ideas, cutting edge technologies used within your company, and receive a discount on registration. A poster provides a great way to share and discuss thought provoking concepts.

PharmaSUG Conference on 12-15 May 2013 in Chicago, IL

Wayne Kubick, Chief Technical Officer of CDISC, will present the keynote address for this year’s PharmaSUG conference on the current state and future strategic direction of CDISC standards, and how they are evolving to meet the challenge of FDA’s PDUFA-V mandate for defining therapeutic area data standards.

Register for the conference through the following link by 1 April 2013 to receive an early registration discount. And follow the link to know more about PharmaSUG.

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