May 2012 eNewsletter

It is the CDISC vision to inform patient care and safety through higher quality medical research. The goal is to accelerate the cycle through which research informs healthcare and thus the opportunity to bring new therapies to patients sooner.

The CDISC May Newsletter Presents the Following Topics:

- CDISC European Interchange and CDISC Success Stories
- Release of CDISC New Protocol Representation Toolkit
- CDISC FAQs
- Technical News

1. Updates on Standards Open for Review and Comment
2. The CDISC Standards Review Council
3. CDISC: Setting Standards for the Study of Pain
4. Watch for the TB Therapeutic Area Package coming this week!

- CDISC Members: New Organizations in 2012
- CDISC User Networks Update
- Current Opportunities Volunteers
- CDISC Global Events and Education
- CDISC Website Enhancements
- Join our CDISC Social Media!

CDISC European Interchange and Success Stories

Over 200 people attended the CDISC European Interchange in Stockholm, Sweden the week of 16 April. Productive networking is the essence of the CDISC Interchanges, and people came to this event in Sweden representing their global organizations from Austria, Belgium, Bulgaria, Canada, China, Denmark, France, Germany, Italy, Japan, Lithuania, Netherlands, Scotland, Spain, Sweden, Switzerland, United Kingdom and United States of America.

CDISC would like to cordially thank the CDISC European Coordinating Committee (E3C) for the great effort they put into this event. The excellent presentations were examples of CDISC Success Stories. These presentations and responses by Expert Panelists were shared with the fortunate interchange attendees. For those who missed this educational event, we have prepared blogs from many of the sessions. Please enjoy and comment on these blogs (listed below) and watch this space for more yet to come.
• CDISC Interchange Europe 2012 - “Standards Accepted for Progress; CDISC the Reliable Partner” - State of the CDISC Union [1]
• FDA Presentation at the CDISC European Interchange [3]
• 2012 Europe Interchange--Session 3, Parallel Track 1: BRIDG [4]
• The Development and Status of SEND - Lessons Learned during the FDA-SEND Phase 2 Pilot [6]
• 2012 Europe Interchange - ODM/XML Session [6]
• “Ask the Expert” Session at the CDISC European Interchange – April 2012 [7]
• Greetings from the CDISC European Interchange in Stockholm [8]

We will be posting additional blogs [1] and updates on the CDISC European Interchange within the next couple of weeks. Stay tuned!

The next CDISC Interchanges will be in Japan in mid-July, in Baltimore in October and in Singapore in February 2013. Follow the link [9] to know more. Sponsorship opportunities are available. Don’t miss these opportunities to network, provide your ideas and learn more about CDISC.

### CDISC Releases New Protocol Representation Toolkit

CDISC is pleased to announce the release of the first iteration of a Protocol Representation “Toolkit” for clinical research. The purpose is to make it easy for authors of the research plan or protocol to reap the benefits of the Protocol Representation Model (PRM), which has been developed over the past decade by global clinical research experts from academia, industry and government.

Using such a model can save time and resources for research studies by enabling electronic re-use of protocol information.
for other purposes such as clinical trial registration, study tracking, regulatory information and study reports. The current release of the “Toolkit” includes a standard Study Outline Template in MS Word format, a standard list of Study Outline Concepts, and a complete mapping of the Study Outline Concepts to both the Biomedical Research Integrated Domain Group (BRIDG) model and the CDISC Study Data Tabulation Model (SDTM) Trial Summary (TS) Domain. Follow the link [10].

CDISC Frequently Asked Questions (FAQs)

In an effort to provide the most current, and up-to-date information about our standards and innovations to both our members and the public, we are in the process of actively updating the FAQ section of the CDISC website. As we update, we will also include this new information in the eNewsletter to bring attention to sections of the FAQ that have been updated. We invite all of our members to assist us in this process by sending us your questions and comments to info@cdisc.org [11], that we may begin further broadening the FAQ section of the website. For this newsletter, we are providing three new questions and answers – on the topic of Protocol Representation Model, in response to questions generated from the recent press release on the PRM toolkit. Follow the link [12].

Technical News

CDISC will be issuing monthly announcements about “Standards for Review”. These will be issued mid-month and will be in addition to our eNewsletters, which will now be sent out at the beginning of each month as of May 2012. Due to this change in publication schedules and the April CDISC Board Meeting and European Interchange, there was no April 2012 eNewsletter.

Follow the link [13] to access the CDISC standards latest updates and standards open for public comments.

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials [14]. Please see the latest on “Healthcare and Research” at the following link [15].

The CDISC Standards Review Council - Ensuring Quality Standards

One of my initial priority tasks as CTO was to examine CDISC standards development and governance processes, making sure we continue to do the things we already do well, while also looking for ways to improve where it makes sense. From the outset it was clear to me that CDISC would benefit from adding some specific quality checkpoints in the process, and identifying a small group of wise advisors to help make sure that our standards work together effectively with minimal
overlap, reflect well on our organization and give our user community the best opportunity to use them effectively. So we have established the Standards Review Council (SRC) to help us do just that. Follow the link [16].

CDISC: Setting Standards for the Study of Pain

CDISC recently posted a draft Therapeutic Area Standard for pain on the CDISC website, for public review. Hopefully, this tool will allow for the organization of standard pain clinical trial data submitted to regulatory bodies such as the United States Food and Drug Administration (FDA). This is important, as one hypothesis as to the failure of so many pain-relief medications when studied in clinical trials centers on the inconsistent quality of the type of data collected.

Follow the link [17] to read an interesting article by Dr. Mark Borigini, M.D. in Overcoming Pain

Watch for the new Therapeutic Area standard on Tuberculosis (TB), which should be posted for review later this week!

CDISC Member Updates

Gold Members

- Cross Metrics SA
- DF/Net Research, Inc.
- Ephicacy Corporation
- EPS Corporation
- GCP-Service International Ltd. & Co. KG
- Innovative Analytics, Inc.
- Pierre Fabre Biometrie
- Zifo Technologies Private Limited

Non-Members can enjoy all our benefits [18] and more by joining CDISC! Please contact Sheila Leaman [19] for further details.
CDISC User Networks

Self-formed CDISC User Networks have been developed in Africa, Asia, Europe and the United States of America. User Networks enable face-to-face interactions by promoting the CDISC international presence and encouraging the adoption of CDISC standards through sharing implementation experiences in various global communities and regional areas.

The CDISC English User Network will be meeting on the 28th of May 2012 at Brunel University, Uxbridge in London. The topic of the presentation will be “Submissions: The Holy Grail”. Presentation topics will demonstrate practical examples on how standards have been used in submissions including legacy data conversion experiences, end to end solutions, automated SDTM generation, application of the ADaM model, along with challenges and solutions of using the CDISC standards. The ESUG would like to thank Formedix for kindly sponsoring this meeting.

Stay tuned to the upcoming South African User Network meeting in September. Updates will be available in the next newsletter.

For any questions about the meeting, please send an email to the following address: committee@esug.org.uk

For any questions regarding the ESUG and how to join, please contact Amanda de Montjoie.

To find out about joining 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 different CDISC User Networks and their meetings around the world.

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 are welcome at the following link.
The Official CDISC Primer is available now for a lower price [27]

Benefit from the discounted price and buy the CDISC book now! **Current Price is $15** [27].

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 2012 Global Events and Education Opportunities

CDISC is delighted to invite you to the upcoming public trainings for 2012 [28] as well as our CDISC Interchanges in 2012 [29]. Please stay tuned to our CDISC Events and Education via the following link [29].

**CDISC Interchanges:**

- **CDISC Japan Interchange, 10 - 13 July 2012** [30] - Accepting Abstracts Now - Sponsorship and Exhibitor Opportunities Available!

- **CDISC International Interchange 2012 in Baltimore, MD, 21 - 26 October 2012** [31] - Sponsorship and Exhibitor Opportunities Available!

- **CDISC Asia Interchange in Singapore, 18 - 22 February 2013** [32]. Information coming soon!

**Public Trainings in the U.S.:**

- **Public Training in Audubon, PA** [33] in May 2012
- **Public Training in Palo Alto, CA** [34] in June 2012

**Public Trainings in Europe:**

- **Public Training in Brussels, Belgium** [36] in September 2012

*Our 2013 Public Training schedule is firming up. Please be on the lookout for new public training locations for 2013!*
CDISC Private Training

CDISC-authorized education and training courses are only available from the CDISC Education team, and are identified by the CDISC Education logo. The logo is your assurance that the training has been developed by and will be delivered by CDISC staff or qualified industry experts who have passed a rigorous qualification process.

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research. In order to achieve this vision, we know it is vital that the CDISC standards be implemented as process enablers and innovations that support the research process. With this in mind, from its inception, CDISC has developed educational courses that provide foundational training on the theory and practice of using the CDISC standards, and which are designed to give implementers a better understanding of how to apply the theory and practice within their own organizations.

Private training is available to any organization, regardless of membership status. CDISC member organizations will receive discounted pricing on private training. To request information about private training, please click on the link below.

Request Private Training online - click here for more information.

More trainings opportunities to come soon. Please stay tuned to our Education and Events page.

Non-CDISC Related Events

PharmaSUG China 1st Conference in Beijing, China on 6 - 7 July 2012. Follow the link for details.

CDISC Website Enhancements

The CDISC website has been improved in an attempt to make it easier to understand the CDISC innovations and work scope. The Standards and Innovations pages have been reorganized allowing anyone to understand the CDISC standards and how they are connected through a clickable graphic on each subpage under the Standards and Innovations tab. New RSS feeds have been added to the Standards and Innovations pages allowing everyone to subscribe for the purpose of getting the latest updates on a constant basis. Other RSS feeds have been added to the CDISC Newsletter page and the Latest News page in order to be alerted on the latest news and blogs! In addition to the RSS feed added to the CDISC homepage in order to send updates on each and every CDISC related matter.

In an attempt to value its members, CDISC has displayed a rotating banner displaying all the Platinum members on the homepage as well as the Newsletter page.
CDISC Social Media

Stay connected with the CDISC community through the new CDISC social media. Join CDISC Facebook [39] and LinkedIn [40] and follow us on Twitter [41] and YouTube [42]! Also follow our Blogs [1] and most recent News through our website [43]!

Further questions are welcome through the following email [48].

CDISC Communications and Public Relations [46]

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1. http://www.cdisc.org/cdisc-blog
2. http://www.cdisc.org/content4654
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6. http://www.cdisc.org/content4656
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8. http://www.cdisc.org/content4226
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[42] http://www.youtube.com/user/CDISCInc
[45] mailto:communications@cdisc.org