March 2012 eNewsletter

CDISC March Newsletter Presents the Following Topics:

- **CDISC Interchange Europe, Stockholm, Sweden on 16-20 April 2012 - Two FDA Presenters**
- **Updates on CDISC Membership:**
  
  New Organizations in 2012.

  Opportunity for Device Companies to Join at Discount through April 2012!

- **CDISC-based Implementations Receive Sanofi’s Global R&D IS Innovation Awards: Internal Business Value and Value to Patients**
- **BRIDG Release 3.1 Now Available**
- **CDISC and Japan’s Translational Research Informatics Institute - Blog**
- **Accepting Abstracts for the CDISC Japan Interchange in July 2012 - Sponsorship and Exhibitor Opportunities Available**

- **CDISC Standards for Review and Comment by 30 March:**
  
  CDISC Draft Pain Standard.

  - **NINDs Headache Common Data Element**
  - **Current opportunities for interested parties to volunteer for CDISC activities**
  - **Engage in our CDISC Education opportunities and User Networks**
  - **CDISC Employment Opportunity Available**
  - **CDISC Website Enhancements Coming soon**
  - **Join our CDISC Social Media!**

CDISC Interchange Europe 2012 Stockholm, Sweden 16-20 April - FDA Presents at the Interchange in Stockholm!!

Don’t miss the lineup of Plenary Session speakers at the CDISC Interchange Europe on 18-19 April in Stockholm Sweden:
Other presentations selected from submitted abstracts will focus on implementation and achievements using CDISC standards.

Join us on our journey to improve global healthcare and medical research and attend the CDISC Europe Interchange in Stockholm. Register now! Share your experiences and broaden your organization’s visibility in Europe and the rest of the world. Ask the Expert session will be open to anyone interested in discussing the latest achievements with a panel of CDISC experts representing worldwide organizations and numerous entities of the global healthcare industry. We invite you to have fun and network with us! Join us on a relaxing boat ride on the inlet to Stockholm with dinner included on Wednesday, 18 April from 19:00 – 22:30!

Online conference registration will close on 4 April 2012, register soon! View the program here.

Follow this link to know more!

CDISC Member Updates
Platinum

- Alexion Pharmaceuticals

Gold

- Advanced Bio-Logic Solutions Corporation
- Colorado Prevention Center
- OncoGenex Pharmaceuticals, Inc.
- J.D. Young Consulting, Inc.

Non-Members can enjoy all our benefits and more by joining CDISC! Please contact Sheila Leaman for further details.

Membership Discount for Device Companies joining CDISC by 30 April 2012.

CDISC-based Implementations Receive Sanofi’s Global R&D IS Innovation Awards: Internal Business Value and Value to Patients

CDISC standards (BRIDG, CDASH, SDTM, ADaM and more) were at the core of two recent Global R&D Innovation Awards at Genzyme/Sanofi. Out of 208 dossiers submitted, GetSMART won in the ‘Internal Business Value’ category and RegistryNXT! won in the ‘Value to Patients’ category where the former involved implementation of a number of CDISC standards and the latter was based on the collaborative CDISC BRIDG model.

PK Tandon, Clinical Science Officer, Clinical Development, and an Executive Sponsor of both the GetSMART and
RegistryNXT! Programs at Genzyme stated that CDISC standards have helped to streamline their information handling processes, facilitated exchange with external parties, and improved their ability to create integrated datasets to speed answers to regulatory and scientific questions.

CDISC issued a press release on the 23rd of March highlighting the details of this magnificent incident. Follow the link [8].

**BRIDG Release 3.1 Now Available** [9]

The Clinical Data Interchange Standards Consortium (CDISC), Health Level Seven (HL7), the U.S. Food and Drug Administration (FDA) and the U.S. National Cancer Institute (NCI) are pleased to announce the release of version 3.1 of the collaborative Biomedical Research Integrated Domain Group (BRIDG) model of the semantics of protocol-driven clinical research. Version 3.1 of the model is available for download at the following link [10].

See a description of the changes represented in this new version here [9].

**CDISC Presentation at Government-sponsored Conference in Japan**

CDISC President and CEO, Dr. Rebecca Kush was invited to speak in Tokyo on 3 March at a session organized by Dr. Fukushima and the Translational Research Informatics Institute (TRI), based in Kobe, Japan. The “Progress Conference” on Coordination, Support and Training Program for Translational Research was organized by the Foundation for Biomedical Research and Innovation (FBRI) and Ministry of Education, Culture, Sports, Science and Technology (MEXT). A total of about 600 participants from various fields visited this conference, and Dr. Fukushima sent a personal letter of appreciation for the “inspiring and informative” slides. The TRI is implementing CDISC standards to streamline their research processes. Read the blog by Dr. Kush here [11].

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials [12]. Please see the latest on “Big Data” at the following link [12]

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

**CDISC Standards for Review and Comment by 30 March 2012**

CDISC Draft Pain Standard for Public Review and Comment Period - Comments Due Monday, 30 March 2012 [14]
The draft Pain Therapeutic Area User Guide supplements the Study Data Tabulation Model Implementation Guide (SDTMIG) v. 3.1.2 with recommended standards for the submission of data from Pain-related clinical trials. This user guide was prepared by the Analgesic Clinical Trial Translations Innovations, Opportunities, and Networks (ACTTION) with participation from volunteer members of the Submissions Data Standards (SDS) team of the Clinical Data Interchange Standards Consortium (CDISC). It is intended to guide the organization, structure, and format of standard Pain clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA).

This is the first version of Pain Standards by ACTTION and CDISC, so it is expected that there will be gaps and areas for further development. To this end the CDISC requests that the clinical research community review these proposed standards and submit comments for further improvement and development. Reviewers are encouraged to model these standards with test data and provide detailed feedback on what did and did not work. Follow the link [19].

NINDS Headache Common Data Element Review

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH) is requesting your input on the Headache Common Data Elements being developed through its partnership with headache experts.

The public review period for the Headache CDEs will take place through March, 30 2012. During this time, Version 1.0 of the Headache CDEs will be publically available on the NINDS CDE Website. To access and review the Headache CDE recommendations, please follow the link [16].

CDISC Depends on Volunteers to Develop and Maintain Our Open Standards [17]

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 [17] to know more about how to volunteer! Further questions are welcome at the following link [18].

The Official CDISC Primer is available now for a lower price [19]
Benefit from the discounted price and buy the CDISC book now! **Current Price is $15** [19] compared to the $25 original price.

The CDISC Primer (Introducing the CDISC Standards / New Efficiencies for Medical Research) offers a detailed synopsis around everything you need to know about the CDISC standards! Order yours today!

## 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.

Three user networks represent CDISC in Asian countries (China, Japan and Korea), while five represent CDISC in Europe (English, French, German, Italian and Nordic User Networks). In the United States, ten user networks cover the continent from the East to the West coast and focus on CDISC users in the following regions:

- Atlantic (Tri-state: CT, NJ, NY)
- San Diego
- Bay Area (San Francisco)
- Boston Area
- Midwest (Chicago)
- Delaware Valley (Philadelphia Area)
- Heartland
- RTP (Raleigh)
- Seattle
- Washington DC

The South African User Network was formed in late 2011. Their first meeting will be held on 28 March 2012. If you would like to be notified on the meeting details or if you would like to become a member of the South African User Network, please contact Dianne Weatherall [20], Marielle Knott [21] and Richard Roodman [22].

The Bay Area User Network met on 7 March 2012. A blog on their meeting is posted [here][23].

RTP CDISC User Network met in March 2012, follow the [link][24] to read an interesting blog on that.

The Boston Area CDISC User Network (BACUN) met on 22 March 2012. Dr. Pierre-Yves Lastic and Rebecca Kush presented on the IMI EHR4CR project and the CDISC 2012-2015 Strategic Goals, respectively.

To find out about joining a CDISC User Network, feel free to contact Diana Harakeh [25]. The **User Network portal area** [26] is open to anyone and provides information on specific User Networks, including announcements of their next meetings.
CDISC 2012 Global Events and Education Opportunities

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

CDISC Interchanges:

CDISC Europe Interchange 2012 in Stockholm, Sweden, 16 - 20 April 2012

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

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

Public Trainings in the U.S.:

Public Training in Austin, TX in April 2012
Public Training in Audubon, PA in May 2012
Public Training in Palo Alto, CA in June 2012
Public Training in RTP North Carolina in Aug 2012

Public Trainings in Europe:

Public Training at the European Interchange in April 2012
Public Training in Brussels, Belgium in September 2012

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.

CDISC Employment Opportunity Available

CDISC has a part-time up to full-time position available for a Terminology Specialist – click here to see the position description.

CDISC Website Enhancements

Stay tuned to our website enhancements coming soon! New RSS feeds will be available to all our standards, our latest news and blogs! Additional website features will be displayed to further inform you about our most recent updates and news.

CDISC Social Media

Stay connected with the CDISC community through the new CDISC social media. Join CDISC Facebook and LinkedIn and follow us on Twitter and YouTube! Also follow our Blogs and most recent News through our website!

Watch for blogs on BACUN and IOM meetings within the next couple of weeks!
Further questions are welcome through the following email [46].

CDISC Communications and Public Relations [46]