November 2011 eNewsletter

CDISC International Interchange 2011 Updates - and the Upcoming CDISC Europe Interchange 2012

For those who did not have the chance to attend the CDISC International Interchange in Baltimore, MD on the week of October 14, you have missed very interesting presentations by key individuals in healthcare and medical research. To find out more, you can still read our series of blogs. And, whether you attended or not, please do provide your valuable comments and feedback!

Specifically, these blogs are on the following topics:

• FDA Interchange Keynote; Panel Encourages use of CDISC Standards

• CDISC Global Updates

• Interchange Keynote on a Learning Healthcare System

• Virology Colloquium

• Metadata and SHARE Presentations

• CDISC Advisory Board Meeting and Town Hall

• (Coming) – Oncology Colloquium

The conference started with the opening remarks by Dr. Frank Rockhold (Chair of the CDISC Board of Directors and Senior Vice President, Drug Development Sciences, Medicines Development at GlaxoSmithKline). A robust program was organized by the Program Committee to focus on “Standards for the Patient”. The presentations and interactive panel discussions had very fresh information on new topics including transforming the clinical research process, eSource, and the value that standards play in enabling the meaningful use of clinical data for research and other purposes.

Various CDISC training courses were offered throughout the week on Monday, Tuesday and Friday. Six colloquia sessions were provided on Tuesday and Friday of that week covering Diabetes, Oncology, Virology, Pain, TB and Imaging. The Colloquia sessions were very interesting and productive; presenters were from FDA, CDISC, as well as CDISC standards developers and followers representing their global organizations, many of which are also CDISC members. The Colloquia were made possible by CDISC, C-Path, and ARCP/APPI. To stay abreast of these activities, follow our blogs on the International Interchange as well as the colloquia on Therapeutic Areas will still be posted within the coming weeks, stay tuned!
Stay tuned to the upcoming CDISC Europe Interchange 16-20 April 2012 which will be held in the heart of Stockholm, Sweden at the Elite Hotel Marina Tower.

Submit Your Abstracts Now!

Registration will open soon!
JOIN US on 30 NOVEMBER and 1 December for the Creating Consensus Science C-Path Conference!

Collaborations between industry, regulatory agencies, and academia are generating consensus on the value of innovative tools for drug development (data standards, open databases, biomarkers, patient-reported outcome measures, quantitative disease progression models, clinical imaging, and others). These tools will accelerate the development of efficacious medicines with optimal risk profiles. This cross-sector conference will feature state-of-the-art drug development tools while reviewing the lessons learned from Public Private Partnerships (PPPs) and scanning the landscape for the most pressing needs in drug and diagnostic development. Follow the link for event details and agenda. And click here to find more information about speakers and presentations.

This event is made possible by the Critical Path Institute (C-Path), the Clinical Data Interchange Consortium (CDISC) and the Food and Drug Administration (FDA).

Critical Path Institute and Clinical Data Interchange Standards Consortium Announce Release of Data Standard for Alzheimer’s Disease Research

First in a series of therapeutic area data standards

Austin, TX, 19 October 2011 - Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) announced the release of version 1.0 of the Alzheimer’s disease (AD) Therapeutic Area Standard (SDTM AD/Mild Cognitive Impairment User Guide). This was developed for the clinical research community to facilitate analysis and learning from clinical studies for treatment or prevention of AD.

The User Guide outlines a standardized set of data elements so that pharmaceutical companies and other medical researchers can more easily, and consistently, collect data that can be reliably pooled and compared.

Lynn Hudson, PhD, C-Path’s Chief Scientific Officer and Executive Director of C-Path’s Coalition Against Major Diseases (CAMD) noted, “Ultimately, this will result in increased efficiencies so that the U.S. Food and Drug Administration (FDA) and other regulatory agencies can more quickly and accurately review new applications for AD therapies, making it possible for medicines to reach patients more quickly and with greater assurances of safety and effectiveness.”

This is an early and landmark outcome from a joint C-Path/CDISC project to formalize and publish the CDISC AD standard based on the elements used in CAMD’s groundbreaking AD data repository. Collaborators in CAMD, which include global stakeholders from C-Path, CDISC, the AD clinical community, the pharmaceutical industry, government agencies, academia, and patient advocacy associations, reached consensus on the relevant pooled data domains, terminology, and definitions. Follow the link.

BRIDG Board of Directors Call for Nominations

The BRIDG Board of Directors (BRIDG BoD) is looking for dedicated people willing to become candidates for the December 2011 election. The term is for 3 years beginning January 2012.

You may nominate yourself or someone else. All nominees should send a current CV and a letter stating why you want to be on the BRIDG BoD and what you can contribute to the BRIDG BoD.
Nominations may be submitted via email to jevans@cdisc.org by 28 November 2011.

Board membership requires people from organizations who are implementing or planning to implement BRIDG; who will champion the use of BRIDG as the unifying, global, information model for protocol-driven biomedical research; and are willing and able to offer their time and expertise.

The role of the BRIDG BoD is to focus on the governing functions of the BRIDG model (functions that provide the direction, resources and structure to meet its mission). The BRIDG BoD has monthly one hour teleconferences as well as in-person meetings as needed (usually no more than one per year).

The BRIDG Board of Directors is made up of 7-11 members. Four members are appointed by the four founding stakeholders (NCI, CDISC, HL7 RCRIM, FDA). The remaining Board Members are elected by vote of the sitting Board members. Please see the attached BRIDG BoD Charter for more details. If you’d like to see the current Board membership, please see the [link](#).

Elections are held annually for vacant seats and new members begin their terms on 1 January. The nominations will be reviewed by the current BRIDG BoD, who will then elect one new member. The open position is for the term beginning 1 January 2012 and ending 31 December 2014.

The future of the BRIDG depends on the active participation of the community and the forward-thinking leadership of the BRIDG BoD. Thank you for your nominations!

**Partnering for Cures: A FasterCures Meeting - Grand Hyatt Hotel, New York City**

7-8 November 2011

Last week I had the privilege to represent CDISC at "Partnering for Cures," the 3rd annual FasterCures conference in New York City. During the conference, important themes came through on the need for data standardization to support collection, aggregation and utilization of medical data. Leaders from Microsoft, Oracle, Johnson & Johnson, Sanofi-Aventis, Patients Like Me, patient advocacy groups and others converged to discuss new innovations, progress made and barriers related to the development of faster cures.

One of the key messages throughout the conference and most significantly heard in the Health IT sessions was one of further engaging patient advocacy groups in the Health IT arena. Understood among these speakers was that advancements in the area of Health IT could significantly assist in speeding up the drug development pipeline, equaling quicker innovations from the lab to the bedside.

Many patient advocacy groups at the conference attended the "Patient Activism Thirty Years After HIV/AIDS" session. The focus of this session was to not only to encourage further collaboration across patient advocacy groups, but also to facilitate stronger partnerships with the organizations they support. One of the panelists, Michael Manganiello of HCM Strategists, put it best when he emphasized the importance of making the patient smarter, pressing that patients must be able to talk about the science involved in drug development with nearly the same eloquence of the scientists charged with its development.

Bron Kisler (CDISC Vice President, Strategic Initiatives) and Enrique Aviles (C-Path Director, Data Standards and Management) presented in the Innovator session on the evolving CDISC / C-Path partnership. As CDISC and C-Path move forward with a strategic initiative to develop standards for numerous therapeutic areas over the coming years, additional joint efforts with organizations representing the patients that live each day with these diseases is paramount. Collaboration between patient advocacy groups, foundations and CDISC would enable a platform for patients to learn the significant improvements data standardization can have upon drug development and bringing new treatments to market more quickly. This would assist CDISC in further advocating the benefits of data standards to new and larger audiences. Follow the [link](#) to watch a brief video.

Andrea Vadakin - Manager of Public Relations, Clinical Data Interchange Standards Consortium

9 November 2011
Experts Agree on Need to Harmonize Health Research Guidelines

Representatives of 35 organizations met on 1 November 1 2011, in Rockville, MD, at the invitation of Health Improvement Institute, to discuss the harmonization of health research guidelines. They represented guideline developers, guidelines users from industry and academe; guideline use-facilitators and end-users; regulators, funders, and providers. In his opening remarks, Dr. Peter G. Goldschmidt, President and Founder of the Institute, emphasized the potential contribution that harmonizing guidelines harbors for improving the quality of health research. The meeting's success in charting a way forward is the first step toward realizing this goal. Participants agreed on the need to establish a mechanism to coordinate guidelines' harmonization (to foster excellence), to involve relevant alliances, networks, etc. (to avoid duplication), and to work closely with standards development organizations like the Clinical Data Interchange Standards Consortium (to promote adoption); CDISC provided input to this initial meeting. Dave Gemzik, Leader of the CDISC Protocol Representation Group, gave one of the opening presentations.

The Online Diabetes Health Movement. Be Part of it!

CDISC, Octagon and ScenPro are working on developing data standards for Diabetes as part of the FDA Legacy Data Conversion project. A goal of the data standards is speeding up research in efforts of creating new therapies for those in need. Since November is American Diabetes Month please review the following reference to assist in this worthy cause. Follow the link [9].

CDISC Journal 2011

CDISC members, implementers and staff contributed articles to a CDISC Journal 2011, which was issued and distributed via CD during the CDISC International Interchange 2011 in Baltimore, MD. Contributions submitted and reviewed by peers, include the following:

- Generating a caBIG Patient Study Calendar from a Study Design in ODM with Study Design Model Extension - Article by Jozef Aerts
- Healthcare Link and eSource - Article by Landen Bain
- Genzyme’s GetSMART Program: Implementing Standards End-to-End - Article by Sue Dubman, Brooke Hinkson, Dana Soloff, David Fritsche and PK Tandon
The BRIDG Model and a “Model” Implementation: The Clinical Trial Registration and Results HL7 Message - Article by Julie Evans and Abdul-Malik Shakir
CDISC: Adoption Trends, Benefits and Addressing Barriers - Article by William Friggle, Feng Li, Shannon Labout, Rebecca Kush
The Value of CDISC: Results of a Brief Survey - Article by Diana Harakeh, Saad Yousef, Rebecca Kush
Data Model - the Trials and Tribulations of Implementing BRIDG in an Information Technology Environment - Article by Terry Hardin and Isabelle deZegher
Regulatory Submissions for Medical Devices and Diagnostics: The Basics - Article by Carey G. Smoak
Using CDISC ODM to Migrate Data - Article by Alan Yeomans.

Follow the link[10] for the articles, which are now posted on the CDISC website. CDISC would like to express sincere appreciation to those who took the time to develop these articles and had the patience to endure the wait for their publication!

CDISC to Collaborate with FDA and PhUSE to Improve Product Lifecycle

CDISC to Collaborate with FDA and PhUSE on March 2012 CSC Symposium

Meeting: FDA/PhUSE Annual Computational Science Symposium Silver Spring, MD, 19-20 March 2012

Meeting Title: Update on Standards, Tools, and Process Initiatives Across Regulatory Review and Collaboration with Key Working Groups to Improve the Product Lifecycle.

The foundation of the product development process is the ability to efficiently acquire, store, and analyze the data and documents to make informed and timely decisions. The focus of the 3rd Annual Computational Science Symposium is to continue the work initiated at the previous annual CSC meetings by bringing FDA, industry, and academia together to provide an update on current initiatives ongoing within the FDA and to establish collaborative working groups to address current challenges related to the access and review of data to support product development. These 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. Mark your calendars and follow the link[11] for more information.

CDISC User Networks - The San Diego CDISC Users Network Meeting Update

The inaugural San Diego CDISC Users Network meeting was held on the afternoon of 3 November at Neurocrine Biosciences in San Diego, CA. The San Diego CDISC Users Network, is a network that encourages the sharing of experiences, exchange of ideas, and distribution of information through active networking amongst friends and colleagues in our industry who share an interest in CDISC, submission standards, and regulatory affairs. The San Diego CDISC User Network would like to thank Neurocrine Biosciences for coordinating the location and arranging refreshments and breaks.

Presentations were provided on various hot CDISC topics ranging from an overview about the CDISC CDASH Standard and CDISC SHARE, the CDER Common Data Standards Issues Document: Implementation Impact, Managing a Submission and Impressions from the CDISC International Interchange October 2011. The meeting ended with fruitful group discussions. CDISC User Networks enable face to face interactions among CDISC users in the US, Europe, Asia, Africa, Australia—now covering various regions from all around the globe. CDISC User Networks can provide significant value to CDISC Users and the CDISC organization if there is a synergistic relationship and ongoing mutual benefit.

The CDISC User Networks can share CDISC implementation experiences periodically in a given region or language, discuss draft standards and comments to CDISC, discuss mature standards and feedback to CDISC on usefulness, discuss new ideas to be channeled into CDISC, network among colleagues and share recent conference participation and learning. Join our CDISC user networks to get more involved in the CDISC work and contribute to the CDISC global mission. You may also launch a user network in your area and spread the knowledge about CDISC further. To know more how to join, feel free to contact Diana Harakeh at dharakeh@cdisc.org[12]

CDISC Education
During nearly any week of the year, CDISC authorized training is going on somewhere in the world.

CDISC has increased the number of public training offerings over the past few years to meet a growing demand, with the goal of having at least two public training sessions in Asia, two in Europe and four in the United States every year. We will exceed that goal in 2011 with a total of eleven public training sessions by the end of November. Taking into account all of our private and public courses, CDISC Education has issued more than 780 training certificates in January through September of 2011, and we expect to have issued more than 1000 by the end of the calendar year.

We are working hard to make it easier for people who need authoritative training to access it. We have added information and functionality to our website that make it easier for organizations and individuals to find course descriptions, find and register for public training, and to request private training, and more website improvements are in the planning stages. Planned and in-process enhancements to the overall Education program include ongoing updates to all existing training materials, the development of new training courses to keep pace with the development of new CDISC standards, and the launch of online training in the near future. The goal of the CDISC Education Team is to ensure authoritative training is available and accessible to our global community of users. We hope to see you in class soon!

-- The CDISC Education Team

Global Events and Education Opportunities

CDISC is delighted to invite you to our public trainings for 2011-2012, as well as our CDISC Interchanges in 2012. Please stay tuned to our Events and Education via the following link.

Request Private Training online - click here for more information.

CDISC Interchanges:

CDISC Europe Interchange 2012 in Stockholm, Sweden on April 16 - 20 2012. Call for Abstracts is still open, deadline for submission is 9 December 2011.

CDISC Japan Interchange 2012 on July 10 - 13, 2012

CDISC China Interchange 2012 on September 19 - 21, 2012

CDISC International Interchange 2012 in Baltimore, MD on October 21 - 26, 2012

Public Training in the U.S.:

Public Training in Carlsbad, CA in Feb 2012
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 Training in Europe:

Public Training in Brussels, Belgium [26] in September 2012


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Links:
[5] mailto:jevans@cdisc.org
[9] http://campaign.r20.constantcontact.com/render?llr=b6766leab&amp;v=001Ak8mCirf2xxWstkzDZY0unxXGZxeDFZjJ2ZSeBRTtasEgg58dQy5eAK4Y9pheB5McgnCMJjBvVxv9RhoXyhhV5dVLJ7mQ_fqOPlubQR3xFTPQULycB29N7ZgfZ_4xgZ
[12] mailto:sharakeh@cdisc.org
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