August 2011 eNewsletter

**CDISC International Interchange: “Standards for Patients”**

The CDISC International Interchange [1] this fall in Baltimore will highlight “Standards for Patients”. The Conference on 12-13 October features three prominent keynote speakers, presentations from CDISC leaders and volunteers from around the globe and interactive panels on streamlining clinical research and using EHRs for research. Colloquia to discuss standards for specific disease areas, CDISC authorized education programs and other networking opportunities will take place on 10, 11 and 14 October.

An opening keynote presentation on a Learning Healthcare System will be delivered by Dr. Charles Friedman, Professor and Director of the Health Informatics Program in the Schools of Information and Public Health at the University of Michigan and formerly Chief Scientific Officer from the U.S. Office of the National Coordinator (ONC) of Health Information Technology. This keynote will be preceded by an opening statement from CDISC Board Chair, Dr. Frank Rockhold.

“CDISC is pleased to host this important and popular International Interchange to further their important work in streamlining the clinical research process to improve patient care and safety”, stated Dr. Rockhold. “The theme ‘Standards for Patients’ is particularly appropriate since researchers can only properly and morally serve the patients who participate in clinical research if they can make good use of the data for the purpose of learning. That is the value of standards.” Follow the link [2].

**Colloquia for Development of Standards on Therapeutic Areas (around the Interchange) – Invitation from CDISC, C-Path and ACRP/APPI**

CDISC, C-Path and ACRP are pleased to host six (6) Therapeutic /Testing Area Colloquia around the CDISC International Interchange. Topics will include TB, Virology (Hep C/Hep B/HIV) and Pain/Analgesics (Tuesday, 11 October) and Oncology, Imaging and Diabetes (Friday, 14 October). If you are interested in actively participating in any of these Colloquia, please click here [3] for more information, and follow the link to fill out an Application to Attend form [4].

**CDISC/University of Rochester Pain/Analgesic Standards**

CDISC initiated the Pain/Analgesics Standards project with the University of Rochester Scholl of Medicine and Dentistry, NY, in December 2010. The University of Rochester received a contract from FDA to launch the Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership. ACTTION is currently sponsoring the development of “STandardized ANalgesic DAtabase for Research, Discovery, and Submissions” (STANDARDS) that involves the preparation of a comprehensive CDISC-compliant clinical trial database structure for analgesic clinical trials. Please visit the newly revised and updated ACTTION website [5] for more information about ACTTION and all of its activities. The major objectives of STANDARDS include facilitating transformation and pooled analyses of data from analgesic trials that have already been submitted to FDA, and also providing a recommended database format for the preparation and submission of future analgesic trials.
In order to accomplish this objective, the University of Rochester has subcontracted with CDISC, which is spearheading the project. The STANDARDS Working Group was established in February, consisting of 17 members representing 11 organizations in the Pharmaceutical Industry, Academia and FDA. Follow the link [6] for the full article.

Virology Standards Development – Draft Products from FDA/CDER and CDISC for Comment (for Colloquia)

FDA/CDER has recognized a critical need for the development of standards to accommodate the virology data accompanying submissions in multiple therapeutic areas and has worked with CDISC to develop a possible solution. Proposed are two new SDTM domains to house virologic genotypic (VG) and phenotypic (VP) data. These two domains are structured as findings domains and can stand alone or be folded into the constellation of SDTM domains called PGx (currently in draft). Where PGx is designed to house subject-level data, VP and VG are intended to house pathogen-level data.

To prepare for the Virology Colloquia in October, CDISC and CDER ask for comments on the work that can be found at the following link [7]. Specifically, please consider the following:

1. Do these proposed structures accommodate enough data elements to serve a majority of therapeutic areas data collection and analysis needs (ex. HIV, HCV, HBV, flu, H1N1, etc)?

2. Do VP and VG link adequately and independently to a subject and to each other (i.e., you don’t need a record in both domains to make sense of a record in either or link to Demographic Domain / DM?

3. Do VP and VG need to harness some of the data elements in PGx (sample collection and handling)?

4. We are seeking feedback on if it would be better to have certain data elements as column (or field) or row (as novel - TEST name) (ex. ‘mutation’, ‘substitution’, etc.)

5. Can VP and VG link adequately and dependently to a record in any PGx domain?

6. Does LOINC provide sufficient terminology where identified as the CT?

7. Will reviewers find these structures useful?

8. Will sponsors be able to build business practice around these structures?

9. Other data elements needed? Please review these structures and comment before you consider attending the Fall Colloquia and be prepared to discuss.
Also, additional sample genotypic and phenotypic data is needed in all therapeutic areas to test these proposed structures.

To provide comments on this material, please fill out the comment spreadsheet included with the posting package and send to CDISC Review Comments by 4 October 2011.

Your participation is very much appreciated.

NIH's Office of Rare Diseases Global Rare Diseases Patient Registry (GRDR) Common Data Elements (CDE) Version 2 Now Available

Earlier this year, CDISC posted a request for review of the GRDR CDEs. The CDEs have now been updated based on the review comments and Version 2 is available for download from the link below.

The Office of Rare Diseases Research (ORDR), within the National Institutes of Health (NIH), is publishing Version 2 of the list of common data elements (CDEs) for patient data entry to be used in any rare disease registry in conjunction with the Global Rare Diseases Patient Registry (GRDR) being developed through the ORDR. CDEs are necessary to ensure that data are defined in the same way and use the same standards and vocabularies. The use of CDEs facilitates the standardization of data entry and allows for harmonization of sharing and exchange of information across registries, various analyses and studies of specific rare diseases.

The GRDR CDE list and information about the GRDR and CDEs are available here.

For more information, please contact Dr. Yaffa Rubenstein.

CDISC Device Standards Webinar - Smoothly Executed and Well Received

The CDISC Device Team held a well-attended webinar on 18 August, 2011 in collaboration with the Society of Clinical Data Management (SCDM). The webinar brought attendees up to date on the work of the team, reviewed the project background and accomplishments and oriented attendees to the 6 draft SDTM domains and the underlying data models. The primary goal was to inform attendees about these draft domains and announce the upcoming public review. A panel made up of device leadership team members then answered questions. With over 500 registered participants, it can be safely said that medical devices is an area of great interest.

Thanks to the device leadership team, (Kit Howard (Kestrel Consultants), Carey Smoak (Roche), Fred Wood (Octagon Research Solutions), Paul Franson (Medtronic), Marc Mucatel (W. L. Gore & Associates), Bob Pearsall (Sensors for Medicine and Science, Inc.) Jennifer Duggan (St. Jude’s Medical), Maureen Lyden (BioStat, Inc.) and Rhonda Facile (NCI-EVS) for their work in putting this webinar together.

Please click here to view this free webinar. The draft device standard will be posted on the CDISC website in September for a 30-day public review.
Japan CDISC Coordinating Committee (J3C) Updates

J3C Welcomes 3 New Members

A warm welcome to 3 new members who joined J3C in July 2011. They are:

- Manami Hashimoto from Novartis
- Noriko Kawamura from Dainippon Sumitomo
- Takeru Yamamoto from Medidata

J3C now has 10 full members and 2 administrative staff.

2011 CDISC Japan User Group (CJUG) Workshop

The Workshop organized by the J3C in June, was well attended by 81 participants from 42 companies ranging from academic, pharmaceutical, laboratory, IT and CRO. It was a great success with participants sharing their experiences, issues and best practices based on CDISC standard models.

J3C is honored to invite you for the upcoming 2011 CDISC Events in Japan in November 2011. Please see the Events and Education section below for more information.

China CDISC Coordinating Committee (C3C)

The China CDISC Coordinating Committee (C3C) is very pleased to welcome four new C3C members who have joined since June 2011:

- Linda Wang from Theorem Clinical Research
- Michele Zhang from Real Data Medical Research
- Wei Zhang from Otsuka Pharmaceutical
- Yazhong Deng from Covance

They all have very extensive experience in data management, programming, and/or statistics and use the CDISC standards in their daily work.

As C3C members, they will support global CDISC initiatives within China and provide regional feedback to the central CDISC organization. They will also work closely with all members of C3C as well as the CDISC China Advisory Council (CCAC) to advocate CDISC standards in China. We thank these new members for joining C3C and look forward to their support and contribution.
**C-STAR Set Up In China**

A CDISC Standards Translation and Review (C-STAR) team has been established by C3C (China CDISC Coordinating Committee) recently. The goal of the C-STAR project is to review the Chinese translation of CDISC Standards which were provided by Absolute Systems Clinical Data Co., Ltd.

The C-STAR team may also take the lead in future translation and to create C3C working groups for the promotion of CDISC Standards in China. C3C Vice Chair, Zibao Zhang, leads this project with support from industry experts and members from CDISC, C3C and CCAC. The C-STAR project kickoff meeting was held on May 31, 2011, attended by industry expert volunteers, some C3C members and representatives from CDISC (Sheila Leaman) and CCAC (Claire Tan). The background and purpose of the project was introduced and translation review process was discussed. Beginning with ADaM, an ADaM team was formed with co-leads Stanley Wei (Novartis) and Victor Wu (Covance). Other C-STAR members also include Pamela Chen (Macrostat), Crystal Cheng (Covance), Li Ding (Sanofi), Guozhu Geng (J&J), Daniel Peng (Roche), Zhenglong Tian (Sanofi Pasteur), Hui Wang (H&J CRO), John Wang (J&J), Liedong Xu (Merck Serono), Richard Xue (Eli Lilly), Zhixian Yang (H&J CRO) and Yanqiong Zhang (Novartis Oncology). It is expected that the review on ADaM and ADaM IG will be completed in Q3 and the Chinese version will be posted on the CDISC website thereafter.

Other Standards review teams (e.g. for SDTM, CDASH, ODM, and LAB) are being established. If you would like to join the team or contribute to this important project, please contact C-STAR project lead Zibao Zhang [13].

**CDISC Activities in Europe**

CDISC has been busy in Europe, specifically through activities with the Innovative Medicines Initiative (IMI) and the establishment of an entity in Brussels. The E3C has been actively planning their Interchange for April 2012 to be held in Stockholm, Sweden. Please watch for the September eNewsletter for more about these exciting CDISC activities in Europe.

**Registered Solution Provider Program Update**

CDISC is pleased to announce that the Registered Solution Provider (RSP) Program will be re-activated in early September. Please stay tuned to our website [12].

There are a couple of new components of the program:

- This will be a self-registration program – we will depend on the honor system to accurately reflect an applicant’s experience/expertise
- There will be a one-time fee when registering (or changing your registration) of 10% of the organizational annual membership fee

As with the previous program, applicants must be CDISC members and the information on the application from must be accurate and complete. The information will be added to the RSP table for quick review of capability areas.
We look forward to working with you on this re-activated RSP program!

**CDISC Global Events and Education Opportunities**

CDISC is delighted to invite you to our public trainings for 2011, as well as our CDISC International Interchange in Baltimore, MD on 10-14 October 2011. Please stay tuned to our Events and Education via the following link.

*NEW* Request Private Training online - click here for more information

**CDISC Days:**

PhUSE CDISC Event in San Francisco, CA on August 31, 2011

CDISC Day in San Diego, CA on September 14, 2011

**CDISC International Interchange:**

CDISC International Interchange 2011 in Baltimore, MD on October 10 – 14, 2011

**Public Trainings in China:**

CDISC Public Training in Beijing, China on November 1 - 4, 2011

CDISC Public Training in Shanghai, China on November 7 – 10, 2011

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

CDISC Public Training in Tucson, AZ on November 14 – 18, 2011

**2011 CDISC Events in Japan:**

Japan CDISC Coordinating Committee (J3C) is pleased to pre-announce the upcoming planned CDISC Events in November.

a) J3C organized CDISC session "CDISC Makes You Happy" at the 3rd Global Quality Assurance conference on November 13 in Kyoto.

b) Legacy Data Conversion workshop is planned on November 14 in Tokyo.

c) CDISC public training course on SDTM implementation is planned on November 15-16 in Tokyo.

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