CDISC Global Updates

Notes from the Korean Workshop and Symposium

Greetings from Seoul! Members of our CDISC team. We have began our Asian journey with a trip to Seoul, South Korea, where Dr. Rebecca Kush, CDISC President and CEO, Wayne Kubick, CDISC Chief Technical Officer, Dr. Pierre-Yves Lastic, CDISC E3C Past-Chair and Chair-elect of the CDISC Board of Directors, and Dr. Kiyoteru Takenouchi, CDISC J3C Past-Chair and Board Member, have all given presentations to the K3C and interested parties from the Korean Society of Clinical Development at the CDISC Korea Workshop/Symposium about the importance of using CDISC standards for clinical research. A general overview of the standards and activities was given on the first day, and in-depth training over the standards and how the work together end-to-end was offered the second day.

Stay tuned for an update from Europe and the E3C next month, but our European colleagues are on vacances this month…anyone jealous?

Join the Challenge, and Gain the First Mover Advantage! Winner gets the CDISC Innovation Award with Recognition from HHS-ONC, DIA, FDA and CDISC!

At this year’s DIA meeting in Philadelphia on 26 June, CDISC, HHS/ONC and FDA issued a ‘challenge’ to use EHRs for regulated research. Specifically, research study sponsors were challenged to use at least two different electronic health record systems at different sites to conduct a multi-site, multi-visit, standards-based regulated research study. The panelists at DIA spoke on the feasibility of this challenge, based upon technology and data standards and processes that have been developed over the past decade. In addition, a case study was presented during this session about a research study being conducted currently at Florida Hospital using the Cerner EHR system. Despite the potential and demonstrated benefits of this approach, the clinical research industry has not yet embraced these new methods and standards to conduct research studies.

Also see the press release and the success story for more information.
CDISC Coordinating Committees Worldwide

In an attempt to add value to the CDISC Coordinating Committees (3Cs), CDISC would like to present and highlight the 3Cs by stating their accomplishments and the key role they play in the global healthcare industry. A special area will be created on the CDISC website for this purpose. We will be publishing and announcing this new area within the next couple of weeks, stay tuned!

Four CDISC Coordinating Committees represent CDISC globally, China CDISC Coordinating Committee (C3C), Europe CDISC Coordinating Committee (E3C), Japan CDISC Coordinating Committee (J3C) and Korea CDISC Coordinating Committee (K3C).

Updates on the 3Cs’ international collaborations will be provided through the website. You will be informed on how these committees are involved with the CDISC interchanges and educational courses, and will gain the knowledge on their collaborations with regulatory authorities and other organizations such as academic research groups or government groups within their region to broaden the CDISC vision and mission through effective communications.

New Chair for CDISC Coordinating Committee in China

The CDISC China Coordinating Committee (C3C) was initiated in 2008 when Sandy Lei of J&J came to China and initiated a CDISC group. President, Rebecca Kush, also visited that year and a half-day workshop was held with Lei and Kush as speakers. The first Chair, Simon Wang of Parexel, was elected and a Charter was written. The C3C has since sponsored two Interchanges at Fudan University and more recently initiated a great group that has been validating translations (provided by Absolute Systems Clinical Data Co., Ltd.) and performing translations of the CDISC standards into Chinese. This group is known as CSTAR (CDISC Standards Translation and Review).
**CDISC Workshops in China in July – Thanks to IBM and AmCham**

In January 2012, CDISC was contacted by Nanping (Lisa) Li, Healthcare Strategy & Business Development Executive, IBM, who informed us that CDISC would be an important focus for IT standards in China, in particular, with respect to a new program that has been launched between China and the US through AmCham. Ms. Li sits on the Steering Committee of the Healthcare Cooperation Program (HCP).

![HCP Logo]

**CDISC 2012 Japan Interchange, Tokyo, Japan**

This year marks the 10th anniversary of the Japan CDISC Coordinating Committee (J3C), and in celebration of this milestone, CDISC honored their long-standing support at the 2012 Japan Interchange in Tokyo.

![Birthday Cake]
Regulatory Science in Japan

“Japan’s Strategy in the Era of Global Development” was the title of the presentation given at the CDISC Japan Interchange on Thursday, 12 July by Tatsuya Kondo, M.D., Ph.D., Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA). This leader of Japan’s Regulatory organization provided a very informative keynote presentation expressing appreciation of the value of standards. Many thanks to Dr. Fukushima, head of the Translational Research Informatics Institute (TRI) in Japan, for extending the invitation. After his presentation, Dr. Kondo and two of his staff met with leaders from CDISC Global Operations, TRI, CDISC Board (Dr. Lastic) and the CDISC Japan Coordinating Committee.

Metadata Patent - Invitation to the Entire Health Care Community To Participate

Last month CDISC sent a letter to many of its members alerting them to a potentially damaging and costly patent application which is currently under review by the United States Patent Office. The text of the letter is below and was prompted in part by a thread on Linkedin which can be found here.
The jist of the patent is this: a company, DataSci, filed a patent application in 2009 that effectively patents the use of metadata in clinical research. If this patent is granted there is a real possibility that a fee will be due to the patent holder for any use of metadata over the internet for every study done by any BioPharmaceutical company, academic research institution, government agency – basically ANY clinical research. See the original email below for more details and links that provide additional information.

Almost immediately after the email went out CDISC was contacted by Pharmaceutical, Biotech, Government, CRO and Technology company representatives asking how they could help prevent this patent from being approved. Most have forwarded the original email to their legal counsel and are looking into the process to protest this patent. Several of the large Pharma companies are also discussing how to combine efforts to fight this patent application.

CDISC appreciates all this effort and the support shown by our members. We will periodically update this blog with the status of these efforts. Follow the link to read the original email with further details and related links.