June 2011 eNewsletter

Join us for the CDISC North America Interchange in Baltimore, MD on 10-14 October 2011

Following on the heels of success of the CDISC European Interchange in Brussels -April 2011 and CDISC Interchanges from the previous years, we are pleased to announce the upcoming CDISC Interchange in Baltimore, MD on the week of October 14.

Many of us are aware of the value and progress of the CDISC mission toward the global healthcare and medical research industry, and we are very delighted to support the new CDISC vision: Informing patient care and safety through higher quality medical research.

CDISC provides not only standards-inspired innovation, but also focuses on standards development and implementation to streamline the research process from protocol through analysis and reporting, providing for more efficient and effective use of medical information for biomedical research. Join us for the CDISC North America Interchange conference for its intriguing topics where you will be able to network and exchange opinions and experiences with our outstanding knowledgeable speakers.

At this year’s CDISC Interchange in Baltimore, we will again feature keynote speakers, presentations by representatives of the FDA (followed by the popular FDA Panel with Q&A from the floor) and updates from CDISC leadership. New this year, we will feature two interactive panels: one moderated by leaders of Faster Cures on how we can streamline the search for new therapies and one moderated by Jonathan Andrus (of SCDM and the CDISC Interchange Program Committee) on eSource and the FDA’s draft eSource Guidance.

Strategic Themes identified at the CDISC Board of Directors meeting in April will drive the main topics of the sessions. These include not only the Healthcare Link initiative (using EHRs as eSource and linking healthcare and research), but also progress on SHARE (Shared Health and Research Electronic Library), the value of data standards for data aggregation and analysis, standards to support regulatory submissions, and the development of therapeutic area standards such as Alzheimer Disease, cardiovascular diseases, Parkinson’s Disease, Tuberculosis, Polycystic Kidney Disease and analgesics for pain.

There could not be a better time to learn how “enablers” (such as data standards) can yield quality and efficiency, saving time and money throughout the medical research process. The CDISC Interchange is not only a conference, but an experience that continues to connect our global community and extend opportunities for ongoing education and training. Workshops and public training courses will be offered throughout the week, expanding the CDISC knowledge from various industry experts and certified CDISC trainers to reach out to anyone working within healthcare or medical research. And, last but not least, exhibitors from various companies from all the around the world will be demonstrating their services at the CDISC exhibition area where everyone can be apprised of rich information about how standards are implemented through various technologies used by many pharmaceutical and biotech companies and clinical research organizations.

Be one of our valuable attendees, share your experiences with us and gain knowledge from the warm and productive CDISC Interchange experience. Also, some of you may want to consider being a sponsor or an exhibitor, perhaps sponsoring one of the therapeutic areas!

Stay tuned; our draft program will be posted and registration will open soon.

CDISC Partners with DIA and IHE to Demonstrate EHRs for Medical Research
The Clinical Data Interchange Standards Consortium (CDISC) is pleased to announce its collaboration with DIA and Integrating the Healthcare Enterprise (IHE) to bring a state-of-the-art demonstration of the implementation of electronic health records (EHRs) to streamline medical research. This process represents a simple yet powerful means towards shortening the current 17 year gap in translating research results into clinical care decisions.

“CDISC has been a leader in demonstrating the value of EHRs in the research arena,” stated Dr. Doug Fridsma, Director, Office of Interoperability & Standards at the U.S. HHS Office of the National Coordinator for Health IT (ONC). “Linking clinical care with clinical research sets the stage for novel ways of leveraging patient care information using more granular metadata approaches.”

The currently available solution is being demonstrated by EHR vendors along with clinical trial technology and service providers, CDISC and HIMSS at DIA 2011 in Chicago on June 19-23. DIA 2011 provides educational and networking opportunities to more than 8,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related health care products. Follow the link [2].

CDISC Implementation News and Workshops in China

Business & Decision Life Sciences will be offering two 1-day workshops on the Practical Use of CDISC Data Standards for Clinical Trials. These will be offered at two different locations in China— in Beijing on 28 June 2011 and in Shanghai on 30 June 2011. Please follow the link [3] to register. The topics presented will include: Data Management in Clinical Studies, Updates about CDISC, CDISC Data Standards Implementation Approaches, the CDISC Business Case and CDISC China Activities. There will be demonstrations on Legacy Data Conversion Demo and CDISC Data Model Compliance. Please click here [4] for further agenda details.

Click here [5] for Top Tips on CDISC Implementation.

Boston Area CDISC Users Network (BACUN) Meeting Announcement

The next meeting of the Boston Area CDISC Users Network (BACUN) is scheduled for Wednesday, July 20th from 1 PM-4PM at Genzyme Center (500 Kendall Street, Cambridge, MA).

We have two topics for this meeting. The first focuses on implementing standards end to end, with an overview and demonstration of a structured (protocol) authoring proof of concept. Based on a topic-based structuring content approach that leverages standards and approved best practices, the capability demonstrates opportunities to ensure the consistent and efficient reuse of information throughout the clinical data lifecycle. The approach also enables “quality by design” for content development — whether a protocol, set of CRFs, or CTT registration — by ensuring the “right” information is presented in the “right” place. The second provides an overview and update on the CDISC SHARE project. CDISC SHARE seeks to link CDISC standards via concise definitions and richer metadata. Over the last year CDISC SHARE sub-teams have focused on semantically linking the SDTM and CDASH models to ensure that all definitions are in alignment and developing and testing the SHARE metadata model on SDTM classes. The Content Team is focused on developing rich metadata for CDASH/SDTM domains, based on the BRIDG model and the ISO 21090-datatype standard. This presentation will provide a focus on content development for SHARE over the last year. Please follow the link for more details [6].

CDISC SHARE – Putting the (Metadata) Pieces Together
It's time for an update on where we are with the CDISC Share project. For those readers who have not been involved with Share, this project seeks to link CDISC standards via concise definitions and richer metadata. Share will facilitate improvements in data quality and compliance by creating reusable definitions and content, layered/structured metadata based on BRIDG, machine readability, faster standards development processes and simpler standards maintenance.

Over the last year the CDISC Share project team has accomplished much. We now have a metadata model that has been tested on all SDTM classes and the approach looks promising. The content sub-team has completed the foundational work of linking semantically the SDTM and CDASH standards (i.e. definitions are in alignment) and the team is now working on templates that will form the basis of the first load into the Share repository. Finally, the governance team has made good progress in detailing the governance use-cases. Follow the link for full details. [7]

CDISC Controlled Terminology Package 7

CDISC Controlled Terminology Package 7 is ready for public review. The public review package consists of three spreadsheets one for Laterality, Directionality and Portion/Totality, one for SEND, and one for terms from the New Term Request Page. The Laterality, Directionality and Portion/Totality spreadsheet consists of 3 codelists with approximately 43 new terms. The SEND spreadsheet consists of 4 codelists with approximately 300 terms.

Please go to the CDISC website [8] for the review documents. The comment period closed on Wednesday, 13 July 2011. For additional information, please contact Chris Tolk, ctolk@cdisc.org [9]

Study Design in XML

The CDISC Study Design Model in XML (SDM-XML) standard, version 1.0, the first release of CDISC’s newest XML standard, will be made available on June 24th for public review and comment. The review period starts June 24th, and will continue until July 22nd, please refer to the following link [10]. The review package includes a specification document, a set of XML Schemas, several examples, an SDM-XML element and attribute reference, and a spreadsheet for review comments.

SDM-XML allows organizations to provide rigorous, machine-readable, interchangeable descriptions of the designs of their clinical studies. As an extension to the existing CDISC Operational Data Model (ODM) specification, SDM-XML affords implementers the ease of leveraging existing ODM concepts and re-using existing ODM definitions. SDM-XML defines three key sub-modules – Structure, Workflow, and Timing – permitting various levels of detail in any representation of a clinical study’s design, while allowing a high degree of authoring flexibility.


Several productive CDISC meetings took place in May in various regions of the world. See our blog [11] from earlier this week to know more about the CDISC Global Relations in China and our blog [11] from today on Europe and Japan, for the most recent updates.

Spring (May) updates from CDISC can be reviewed through this blog. And more CDISC activities are already taking place in June, launching the CDISC summer in good form as we try to stay out of the Austin heat! We hope that you don’t miss the DIA Annual meeting and, in particular the Interoperability Town Hall and the Interoperability Showcase with demonstrations of EHRs as eSource for Clinical Research [12]. And last but not least, Dr. Rebecca Kush, President and CEO of CDISC, will be heading for Washington, DC, where she is honored to have been invited by the Secretary of HHS and the new leader of the HHS/ONC to “represent research” as a new member on the U.S. HIT Standards Committee.
In Terms of **Education**, we are honored to invite you to our public trainings for 2011 in the Netherlands and in China, as well as our **CDISC Interchange North America** in Baltimore, MD on 10-14 October 2011. We are also pleased to announce the upcoming **CDISC Medical Device Standard webinar** on August 18, 2011; webinar registration is free of charge. Please stay tuned to our Events and Education via the following link.

---

Please read this very interesting article Titled **CDISC SDTM v3.1.2 Theory and Application by Programming Consultancy Team**. The article is written by a member of the programming consultancy team of **Quanticate** and includes their feedback on the SDTM Theory and Application course that was offered during the CDISC Interchange held in Brussels on 11-12 of April 2011.

---

Source URL: [http://www.cdisc.org/node/2759](http://www.cdisc.org/node/2759)

Links:
[1] [http://www.cdisc.org/interchange?a=2437#2437](http://www.cdisc.org/interchange?a=2437#2437)
[5] [http://www.pharma-iq.com/clinical/articles/top-tips-for-cdisc-implementation/?amp;shownewwindow=1&amp;utm_source=PharmaIQ&amp;utm_medium=SMO&amp;mac=PMIQ_Twitter_SMO_2010&amp;utm_campaign=Twitter&amp;utm_term=DLC](http://www.pharma-iq.com/clinical/articles/top-tips-for-cdisc-implementation/?amp;shownewwindow=1&amp;utm_source=PharmaIQ&amp;utm_medium=SMO&amp;mac=PMIQ_Twitter_SMO_2010&amp;utm_campaign=Twitter&amp;utm_term=DLC)
[8] [http://www.cdisc.org/terminology](http://www.cdisc.org/terminology)
[9] [mailto:ctolk@cdisc.org](mailto:ctolk@cdisc.org)
[10] [http://www.cdisc.org/study-trial-design](http://www.cdisc.org/study-trial-design)
[12] [http://www.cdisc.org/cdisc-dia-the-ehr](http://www.cdisc.org/cdisc-dia-the-ehr)
[14] [http://www.cdisc.org/webinars?a=2740#2740](http://www.cdisc.org/webinars?a=2740#2740)