October 2011 eNewsletter

CDISC International Interchange: “Standards for Patients”

CDISC International Interchange – Highlights

For those of you who have registered for the CDISC International Interchange, which will take place in Baltimore 10-14 October, following are some of the highlights you can expect. [For those of you who have not registered, although online registration has closed, you can still register in person at the event!]

The complete program can be accessed here.

Opening remarks by Dr. Frank Rockhold (Chair of the CDISC Board of Directors and Senior Vice President, Drug Development Sciences, Medicines Development at GlaxoSmithKline), will launch the event. A robust program was organized by the Program Committee to focus on “Standards for the Patient”. The presentations and interactive panel discussions will bring you 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. These will complement the traditional topics on case studies and implementation experiences with respect to the CDISC standards. Click here for highlights.

Presentation to FDA, Office of Scientific Investigation (OSI), Center for Drug Evaluation and Research (CDER), by George Cole (IHE and Allscripts)

George Cole, Landen Bain (CDISC) and Becky Kush (CDISC) gave a presentation at FDA in White Oak, MD on Tuesday, 27 September 2011. This was at the request of Dr. Leslie Ball, acting head of OSI, based upon the favorable impression members of FDA had of the Retrieve Form for Data Capture (RFD) profile demonstrated at the Drug Information
Association (DIA) Interoperability Showcase in June. Dr. Ball, and others from OSI, saw the Clinical Research and also Device Safety uses of RFD at the DIA Annual meeting and asked for this follow up to specifically address two issues: 1) additional security and auditing constraints; 2) real world use of RFD.

George Cole and Landen Bain have led a weekly meeting of the ad hoc Clinical Research, RFD Security Workgroup, to identify both issues and solutions concerning security and auditing specific to the Clinical Research use of RFD. This group consists of industry experts from EHR, Electronic Data Capture (EDC) companies, Integrating the Healthcare Enterprise (IHE), CDISC, an FDA OSI Safety Officer, and a recognized device security expert from Oak Ridge National Laboratory. The group identified three main concerns with the RFD profile’s security considerations and recommended strengthening the requirements for the use of existing, off the shelf, IHE Profiles to ameliorate the concerns.

Present at the meeting on the 27 September were Dr. Ball, several other members of OSI, as well as representatives from several other FDA centers, including CDRH (devices). Becky Kush opened the presentation with a review of the CDISC standards in use for Clinical Research. Becky also introduced the existing work on RFD, which are the IHE Profile itself, plus use of the profile in the HITSP Clinical Research Interoperability Specification 158, TP50 and C156 specifications. [This Interoperability Specification was the January 2010 output of the HITSP Use Case for Clinical Research for EHRs to be able to output a core set of research data, i.e. CDASH.] George Cole followed with a brief overview of RFD. George and Landen then presented the details results of the Clinical Research, RFD Security Workgroup.

The recommendations presented met the needs and requirements of all FDA individuals involved. It was generally agreed that implementation of the recommendations would provide for Clinical Research (by EHRs) using RFD to be conducted in a manner well within all of the regulatory requirements.

Three outcomes from this meeting:

1) Dr. Ball, Becky Kush will write a white paper to communicate the message that clinical research conducted using RFD with the security and auditing recommendations will meet all regulatory requirements (a compliance angle).

2) FDA will have a representative attend the 2012 North America Connectathon to observe the testing of RFD and the early adopters of these security recommendations.

3) Landen Bain will bring to FDA a protocol for a Clinical Research Study to be conducted using RFD with the security enhancements. The site, the study, and the sponsor are still to be determined.

U.S. HIT Standards Committee - 28 September 2011

I was appointed to the U.S. Health Information Technology (HIT) Standards Committee, with ratification of this appointment in May of this year. This was just in time to observe “Summer Camp” activities and review the progress that committee had made since the time it was created (along with the HIT Policy Committee) in 2009. These achievements were particularly impressive when summarized at this 28 September meeting; they were acknowledged at a reception at the White House later that afternoon. Aneesh Chopra began the praise at this reception and continued to bring in a number of senior White House staff to reinforce their satisfaction with the productivity, civility and commitment of these two FACAs….“unprecedented” was the consistent underlying theme.

I had mixed feelings, having been too new to serve on the committees that had been formed prior to my appointment. I felt guilty to have been in the midst of those who truly deserved the praise. On the other hand, I felt pleasure that at least a couple of us from CDISC (Bron Kisler and myself) had given prior testimony to Task Forces of the HIT Standards
Committee. I also felt fear and concern, hoping that the ‘train that has left the station’ has not already gone too far ahead for us to cleanly bring in the clinical research standards work that we have been doing for the past 14 years. Most of all, I felt opportunity… that there is now an acknowledgement of the importance of global clinical research in this critical effort to encourage the adoption of EHRs across the U.S. and beyond. Many of the members of the HIT Standards Committee are well aware of the efforts of CDISC and of our willingness to collaborate, including two key players who have served on the CDISC Board of Directors.

Here are a few notes and quotes from the meeting that preceded the reception --- the culmination of “Summer Camp”--- during which friendship bracelets and whistles were distributed! Follow the link [3].

**Therapeutic Area Standards - Alzheimer's disease/Mild Cognitive Impairment User Guide**

The purpose of this project is to develop Alzheimer's disease (AD) / Mild Cognitive Impairment (MCI) clinical content data standards for regulated clinical research and clinical trials data. This work was done in collaboration between the Clinical Data Interchange Standards Consortium (CDISC) and the Coalition Against Major Diseases (CAMD)--a program of the Critical Path Institute.

The version 1.0 of the Alzheimer's Disease--specific Therapeutic Area Supplement User Guide to the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMUG-ALZHEIMERS v1.0) is found on the CDISC Website [5], (non-members should contact Sheila Leaman [6]). This guide describes the explicit implementation of a subset of the existing and new SDTM safety domains. This User Guide is aimed at the CDISC user community as an informative document for retrospective, current or future implementation of Alzheimer's Disease / Mild Cognitive Impairment studies.
with the CDISC SDTM domain models. The UG describes the assumptions and rules for the SDTM domains, a data example of specific domains and a SDTM mapping strategy as necessary. Other Therapeutic Areas Standards will be available soon. Please click [here](#) for further information.

The San Diego CDISC Users Network Meetings

The San Diego CDISC Users Network will hold its inaugural meeting on 3 November 2011 from 1:00 – 4:30 at Neurocrine Biosciences in San Diego.

The meeting will include an introduction and discussion of the goals of the Network, sharing of Network member impressions from the CDISC International Interchange that will have just taken place in Baltimore, and presentations on “Managing a Submission” and the “CDER Common Data Standards Document and the SDTM Impact”.

A CDISC Representative has been invited to give a presentation on CDASH. To RSVP or to receive additional information about the network please e-mail [Micky Gomez](mailto:Micky Gomez). Network updates will also be posted on LinkedIn (Group: San Diego CDISC Users Network) and in the CDISC Portal. Please RSVP by 31 October to allow our host ample time to prepare.

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 International Interchange](#).
Please stay tuned to our Events and Education via the following [link](#).

*NEW* Request Private Training online - click [here](#) for more information

**SPECIAL OPPORTUNITY Deep Dive BRIDG** Course at the CDISC International Interchange in Baltimore, MD on Friday, 14 October 2011. Registration is open till Thursday, 13 October 2011**

CDISC Interchanges:

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

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

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 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

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 Japan:
Public Training in Tokyo, Japan in November 2011

Public Training in Europe:

Public Training in Brussels, Belgium in September 2012

Follow our blogs - More information on the CDISC International Interchange 2011 in Baltimore will be posted here during the month of October!

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