CDISC Update

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CDISC®

Setting the Global Standard for Clinical Data

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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CDASH

- The fourth set of domains (last set of safety domains) for CDASH was sent to the CDASH Collaborative Group last week for review by their constituents the end of January.
- The broad open public review of all 16 domains is still on track to take place the end of Q1 2008.
- The Collaborative Group will have a face-to-face meeting on 4 February at NCI in Rockville, MD.

Terminology

- CDISC has been collaborating with ISO, EMEA, ICH, FDA and others on Terminology harmonization.
- The CDISC Terminology Team just released another package of SDTM terminology for public review.
- CDISC has been working with DCRI on an NIH Roadmap Grant through which terminology and related products have been developed for the therapeutic area of Tuberculosis (Infectious Diseases).
  - The Gates-funded Global TB Alliance and several pharmaceutical companies have begun to use this TB terminology even though it is still in the final stages of consensus-based review and finalization.

CDISC all-team INTRAchange

- The CDISC all-team INTRAchange will be held on 5-7 February.
- An opening presentation will be given by Armando Oliva, FDA, and FDA representatives have been invited to work with the CDISC teams during these meetings.
- Focus areas will be on SDTM, CDASH, Terminology, SEND, Protocol, ADaM, ODM, Trial Design, LAB and Pharmacogenomics, and the CDISC EHR Technical Roadmap.

CDISC / FDA Communications Group

- Three CDISC representatives (Ed Helton, Dave Iberson-Hurst and Rebecca Kush) met with seven FDA representatives of various departments/centers on 13 December to form a “Communications Group”.
- The purposes of having this group meet are
  - to provide a forum from which a ‘coordinated’ FDA response can be provided to CDISC regarding matters that are important to both parties;
  - to ensure that all of the FDA groups and CDISC are aware of various CDISC-related projects that are occurring through FDA, CDISC, PhRMA and others.
- This group is in its infancy; however, FDA will be adding project management support to help move it forward.
- Another meeting is being planned for February, with a goal to post recommendations in some form from FDA regarding SDTM on the CDISC website (in addition to the Frequently Answered Questions that CDISC is posting on behalf of PhRMA).

CDISC Content to HL7 Message

- The CDISC Content to HL7 Message Project now has a Project Scope Statement approved by HL7 RCRIM, and a Charter is in progress. There is a Project Manager from FDA named as the leader of the overall project. Two groups have been formed to address a) requirements, storyboard, gap analyses (led by Jay Levine of FDA and Dave Iberson-Hurst) and b) message development (led by Jason Rock). These groups report progress on a monthly RCRIM call, led by the FDA Project Manager. The message development is to be based upon the BRIDG model.

FDA-CDISC Submission Pilot Report

- The first FDA-CDISC Submission Pilot Report (SDTM/ADaM pilot) has now been finalized and posted on the CDISC website.
  - http://www.cdisc.org/publications/SDTMADaMPilotProjectReport.pdf
- The macros and data will be posted in the Members area.
- A webinar, with speakers from CDISC and FDA, will be held to summarize the pilot and results.
  - The date is 25 February and the time is 10 EST.
  - This will be announced in the CDISC eNewsletter (to be released the week of 4 February).
  - Details and registration: http://www.bettermanagement.com/seminars/seminar.aspx?l=14684

- CDISC will be producing a webcast entitled ***Results and Lessons from the CDISC SDTM/ADaM Pilot Project*** on 25FEB08 @ 9:00 a.m. EST/3:00 p.m. London Standard Time.
- I am expecting that we will have excellent attendance for this webcast given topic and speakers!
- Here is the link to all the details and the registration page (below).

second FDA-CDISC Submission Pilot

- The second FDA-CDISC Submission Pilot is devoted to integrating safety data from pediatric studies for FDA submissions and review.
- The pilot team and sub-teams will have a meeting on 7-8 February.
- FDA participants will join this meeting on the morning of 8 February.

CDISC Healthcare Link

- The CDISC Healthcare Link initiative now has three actual (not pilot) implementations of the IHE profile in progress (in various stages):
  - one using CDASH-based data collection forms in an EHR (Cerner, Lilly, Quintiles),
  - one on safety reporting to FDA (Pfizer, Harvard Partners, etc) and
  - one on safety reporting for NIH and IRB purposes (NIH Center for Coordination and Policy).
- There will be a demo at HIMSS the end of February in Orlando.
  - Landen Bain attended the Connectathon this week to prepare for this.

Clinical Research Profile for EHRs

- Intent to ballot a Clinical Research Profile for EHRs was announced at the EHR-RCRIM joint TC meetings on 16 January, and this was approved by majority vote.
- The reconciliation will take place in May with RCRIM and EHR TCs involved.

AE standards into BRIDG

- Various AE standards are being harmonized into BRIDG and major progress has been made to date on this project, which was initiated in January 07 reported at AMIA in November.
- The standards include SDTM AE domain, ICSR, BAER and two from caBIG, and the goal for harmonization is to support integrated/interoperable safety data reporting, monitoring and surveillance from pre-approval through post-marketing.
- Commendations from the FDA representative to this work were paid to Julie Evans, CDISC, at the HL7 Working Group Meetings in January.

US Governement activities

- Ed Helton is now on the Board of the Health Information Technology Standards Panel (HITSP) Board as an SDO representative on behalf of CDISC
- Becky Kush was requested by the HITSP Chair to be a co-leader of the newly formed HITSP Education and Communications Committee.