CDASH Version 1.1 Available Now!

As many of you may have seen, the CDASH team has now published CDASH V. 1.1. This new version builds upon the foundation established in the earlier version and takes a significant step towards seamless interoperability between CDISC and other international standards. For a complete listing of the improvements, clarifications and corrections please see the CDASH v. 1.1 document (http://www.cdisc.org/cdash). Following is a summary of these improvements:

- To make the standard more explicit and move towards standardizing the language that appears on CRFs, “Data Collection Field” has been replaced with “Question Text” and “Prompt”.
- In the Drug Accountability domain, the team has updated the metadata tables and added normalized and de-normalized structures in order to provide flexibility for implementers.
- Conformance rules have been added to provide implementers a checklist of items against which to measure compliance with the CDASH standard.
- A few new variables have been added in most domains as a result of implementation feedback.
- Similarly, a few derived variables have been deprecated.
- Regulatory references have been updated to include the recent FDA Drug Induced Liver Injury (DILI) guidance.
- BRIDG classifications have been added to introduce this standard to implementers and show how it connects to the CDASH standard.
- All variable definitions have been reviewed and when needed made more explicit.

The addition of BRIDG mappings, and focus on variable definitions, serves to foreshadow and prepare for the newest CDISC project, CDISC SHARE. With these BRIDG mappings implementers will, in addition to being automatically HL7/RIM compliant, be taking the first steps towards true semantic interoperability that will enable CDASH metadata to be moved into the CDISC SHARE metadata repository.

So what’s next for the CDASH project? The team will now focus on the following activities:

- **CDASH User Guide**
  The CDASH Team will complete the review of comments received from the public review and update all CRF screen shots based on the newly released version of CDASH.

- **CDASH-ODM**
  The CDASH-ODM team has developed the machine-readable metadata to accompany the CDASH standard and example CRFs created from their work are included in the CDASH UG and the updated CDASH training course.

- **CDISC Device Standard**
  The Device team is working to develop both the basic collection fields (CDASH) and the submission (SDTM) variables and mappings to support the majority of device studies. The Device team is working towards posting 5 new SDTM domains in Q111.

- **CDISC Therapeutic Area CRFs**
  The CDASH Team will continue to working with other CDISC teams to develop therapeutic area (TA) specific CRFs to be used with the basic safety fields described in the CDASH standard.
• **Drug Induced Liver Injury (DILI) CRF**
  Develop a standard DILI CRF.

• **E2B- Serious Adverse Event Domains**
  Develop a serious adverse event basic CRF to assist implementers in getting to a E2B compliant SAE report without repeat data entry.

In addition the team will assess the development of CDASH QS and PK domains.

If you are interested in participating in any of these projects, please contact Shannon Labout (slabout@cdisc.org) or Rhonda facile (rfacile@cdisc.org).

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The CDASH team thanks the CDISC standards develop teams for their collaboration in the production of CDASH V 1.1.

CDISC thanks all CDASH team volunteers and their affiliate companies for their support of the CDASH project.