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 from the basis of the first load into the Share repository. Finally, the governance team has made good progress in detailing the governance use-cases.

Here’s a snapshot of where we are today. There are now 5 active sub teams and a 6th sub team is planned to start soon with the goal of identifying lab metadata.

Following is a brief description of each sub team’s remit and goals:
• **Content Team** – This team, led by Erin Muhlbradt, is focused on developing the needed metadata for CDASH/SDTM domains, based on the BRIDG model and the ISO 21090-datatype standard. Where CDISC terminology for test codes exists, the team is developing a detailed specification for each test, or scientific concept, including CDISC terminology for associated variables.

Currently this sub team is focusing on completing those SDTM domains that have a CDASH component, i.e. the safety domains. The team anticipates completion at the end of August.

• **Governance Team** - This team, led by Barry Cohen, is focused on developing the governance process and participant roles for a simple first use case, adding a new term to an existing code list and the accompanying basic administrative and participant roles defined. This use case is near completion and the team will move to apply the principles to the more complex case of adding a scientific concept to a domain and the development of a new domain soon.

• **Study Construction Concepts Team** – This recently started sub-team, led by Diane Wold, will develop prototypal trial design elements to be used in describing the structure of a study, i.e. visits, arms, epochs, elements, cells, etc.

• **Model Team** - The remit of the model sub-team, led by Dave Iberson-Hurst, is to ensure that SDTM and CDASH metadata can be exported in both the familiar pdf standards documents and in a machine-readable format. It is envisioned that users of the first release of Share will be able to upload Share metadata.

• **User Interface Team** – The recently started UI team, led by Melissa Cook and Rhonda Facile, will identify the information and views that key user groups/functions will need to effectively search and retrieve CDASH and SDTM from the CDISC Share metadata repository.

• **Lab Team** – This team, led by Phil Pochon and Erin Muhlbradt, will start soon and is tasked to develop lab metadata for the most common clinical lab tests.

The deliverables from each team will inform the detailed software requirements. The product of each team will form the foundation for the first release of CDISC Share (R1) targeted for 2012.

In parallel, the CDISC Share project team is exploring ways to collaborate and coordinate with other similar initiatives in the healthcare space.

CDISC wishes to acknowledge and thank all CDISC Share project team volunteers and the NCI-EVS organization for their generous support of CDISC projects.
For more information on the CDISC Share project and how you can get involved, please contact Rhonda Facile (rfacile@cdisc.org).

ABOUT CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website. Additional information on CDISC can be found on the CDISC website at www.cdisc.org.

The CDISC Vision: Informing patient care and safety through higher quality medical research