March 2015 Technical Update

As we move toward the second quarter of 2015, we’re advancing an exciting and highly ambitious technical agenda of new and updated products. To achieve this, we’ve outlined three primary goals for each CDISC standards team:

- Increase transparency
  - Publish and gather feedback on plans and requirements in advance, not just final outputs
  - Use collaboration tools more effectively to improve interactions within teams and with the broader CDISC global community
  - Make substantially expanded CDISC content more readily accessible through SHARE to improve end-to-end operational efficiency

- Move to agile development processes
  - Engage smaller teams working in parallel on a series of component sub-projects in sprints, all coordinated using our Jira Issue Tracking tool
  - Rollout a new SHARE Collaborative Curation Initiative – to accelerate and expand content development that will fill gaps in our current suite of standards
  - Continue to expand the volunteer community by enrolling a second class of CDISC Fellows

- Improve focus and execution
  - Do what’s necessary to improve our development processes so industry and regulatory authorities get what they need when they need it to realize the benefits of CDISC standards.

We’ll be emphasizing these themes at our IntraChanges this year, as we begin to actively migrate our standards teams into SHARE for new content development. Keep an eye on future monthly updates posted at www.cdisc.org/standards to see how we’re doing.

Recent and Upcoming Accomplishments

**Therapeutic Areas:**

- The CFAST TAUG for Schizophrenia, is now available for public comment, comments due 27 March.
- Coming next is the new Draft CFAST TAUG for Dyslipidemia, which should be posted for public comment in March.
- The provisional version of the TAUG for Chronic Hepatitis C is expected to be available by early April.
**Foundational Standards:**

- The ADaM Structure for Occurrence Data (OCCDS), which extends the ADaM ADAE Data Structure for Adverse Event Analysis to other occurrence data such as ConMeds, will be posted in March for provisional use.
- Next up from ADaM is the draft ADaM Data Structure for Integration (ADSL), due to be posted for comment later this spring.
- The CDISC PGx team is readying the provisional version of the SDTMIG for Pharmacogenomics/Genetics data for publication by April.
- The SEND Developmental and Reproductive Toxicology is still being readied for public comment later this spring.

**SHARE:**

- Prepared an updated metadata bundle for the TAUG-Asthma for publication on eSHARE in March.
- Research Concepts (RCs) discussed in 26 February 2015 Webinar; initial RC template for Lab data to be placed into initial use for new TAUGs in March.
- eSHARE catalog, listing all eSHARE content, now available on [www.cdisc.org](http://www.cdisc.org).
- New catalogs for domains and supplemental qualifiers in final QC prior to expected publication in March.

**Other:**

- The CDISC Winter Team IntraChange was held on 18-20 March in Silver Spring. The agenda included team training on tools including SHARE, individual team meetings for SDS, ADaM, CDASH, XML, COAs and Devices, and cross-team sessions on therapeutic area, submission and end-to-end standards. The event proceeded successfully, with many new ideas exchanged and much progress on standards development projects, with more than 120 volunteer participants attending.

*By Wayne Kubick, CTO, CDISC*