CDISC Technical News

To best serve its members and stakeholders of the global research and healthcare industries, CDISC is continuously progressing its standards and innovations. Visit our [website](#) for constant updates on the CDISC standards open for public review and comments. This month we would like to draw your attention to the following published standards that are now available on the CDISC website:

- [CDISC Tuberculosis Therapeutic Area User Guide Provisional Release](#).
- [CDISC Pain Therapeutic Area User Guide Now Available](#).
- [SDTM v1.3 and SDTM Implementation Guide v3.1.3 Final Release](#).
- [Updated SDTM and Questionnaire Controlled Terminology Files](#).
- [SDTMIG v3.1.4 Draft Supplements - Batch 1](#). Documents are now available for public review.

In addition to these new standards now available for use, several other projects are nearing completion and expected to become available soon. Stay tune to the following:

- Virology Therapeutic Area User Guide Draft for Review
- Define.xml v2.0 Draft for Review
- ADaM Validation Checks v1.2 Final Release

**CDISC SHARE Request for Information**

CDISC will soon be issuing a Request for Information (RFI) to identify potential collaborators for its proposed SHARE Global Metadata Repository. SHARE is envisioned to eventually house comprehensive, well defined metadata and value sets for all CDISC standards from protocol through analysis, linking research concepts to healthcare, and will become the fundamental technology platform for developing, maintaining and accessing CDISC standards in the future.

CDISC is interested in hearing from respondents who can propose creative solutions for providing the SHARE infrastructure, as well as other potential stakeholders and collaborators who are interested in supporting the ongoing SHARE environment, which intends to make metadata standards for clinical research accessible to the global research community. The RFI will describe in broad terms the scope and major functions of SHARE, and ask respondents to reply to a short list of questions to describe the
respondent's organization, desired role, and potential product solutions to support the SHARE initiative.

Interested parties should indicate their interest by sending an email to SHARE@cdisc.org with Subject "SHARE RFI". The email should list the organization name, contact person with phone and email, and whether they are interested in replying as an implementer, collaborator or both. The email may also include links to relevant published materials. The RFI is expected to be published on the CDISC website by late August, 2012.

**ODM Certification Services Request for Information (RFI)**

**Objectives of this RFI**

The objective of this RFI is to solicit Information from those who can provide a service under CDISC’s aegis to test conformance of third party software products with the CDISC Operational Data Model (ODM) standard. This will be considered as an ODM Certification Service. Information solicitations for services to test conformance with other CDISC standards may be solicited at a future time.

**Who Should Respond**

CDISC encourages consultants or service providers with a deep and thorough understanding and experience implementing the ODM standard as well as an interest in providing ODM certification services to respond to this RFI. However, to avoid any potential conflict of interest, respondents must not offer a commercial product that uses ODM that would potentially compete with products submitted by others to CDISC for certification. The ODM Data Standard is increasingly recognized, as the ideal transport method for data across the entire clinical trial enterprise. The table below shows the products that have received ODM Certification. [Further details.]