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Dataset-XML

New Dataset-XML Standard v1.0 Now Available

The CDISC XML Technologies team is pleased to announce the release of the Dataset-XML v1.0 specification for production use. Dataset-XML, released for comment under the name “StudyDataSet-XML”, and renamed to avoid confusion with the CDISC SDS team, is a new standard used to exchange study datasets in an XML format. Dataset-XML supports the interchange of tabular data for clinical research applications using ODM-based XML technologies. The Dataset-XML model is based on the CDISC Operational Data Model (ODM) standard and should follow the metadata structure defined in the CDISC Define-XML standard.

Dataset-XML can represent any tabular dataset including SDTM, ADaM, SEND, or non-standard legacy datasets. Noteworthy items relating to Dataset-XML v1.0 include:

- Alternative to SAS Version 5 Transport (XPT) format for datasets
- ODM-based model for representation of SEND, SDTM, ADaM or legacy datasets
- Capable of supporting CDISC regulatory data submissions
- Based on Define-XML v2 or v1 metadata, easy to reference
- Dataset-XML supports all language encodings supported by XML
- For information on tool support see http://wiki.cdisc.org/display/PUB/CDISC+Dataset-XML+Resources

Please read the PDF document ReadMe first, which provides information about organization of the release package, responses to the public review comments, and other important notes.

Dataset-XML 1.0 release package

FDA “Transport Format for the Submission of Regulatory Study Data” Pilot Now Underway

The FDA has begun a pilot project with six sponsors to test the CDISC Dataset-XML standard for the submission of clinical study data as an alternative to the SAS V5 XPORT format. Details on the pilot

CDISC thanks the many sponsors who expressed interest in participating in this pilot to provide feedback to
FDA on this proposed replacement for the decades-old SAS XPORT format, which will enable many new efficiencies and capabilities for both the FDA and sponsors.