A Joint Venture:

DRG-XML

A machine readable PhUSE Data Reviewers Guide (e.g. cSDRG) as XML. Developed using portions of existing CDISC ODM. Providing a new capability to further integrate and propagate interoperability of such content.

ODM4Submission

Using CDISC ODM and extensions (SDM, Dataset, Define, Trace, ORCS, etc.) as the mechanism to modernize the exchange of data in support of regulatory submission requirements. Creating greater data flow efficiencies utilizing a single model.

What makes this joint venture mutually beneficial?

- Provides machine readable content of additional supporting information not currently found in the CDISC Define-XML
- Utilizes aspects of CDISC ODM to ensure common elements and/or attributes are reused
- Can eventually become a formal extension to CDISC ODM
- Initially developed for the Clinical Study Data Reviewers Guide (cSDRG), but intended to eventually capture Non-Clinical Study Data Reviewers Guide (nSDRG) and Analysis Data Reviewers Guide (ADRG)
- Human readability of content using flexible stylesheet rendering
- Allows for hyperlinking between supporting documents (e.g. define.xml, dataset.xml, csdrg.xml, etc.)

- CDISC ODM is an established data exchange model within industry
- CDISC Define-XML & ARM provide the supporting metadata describing the data itself
- CDISC Dataset-XML supports the exchange of data in a clinical research application setting
- Used to capture collected and operational data that can integrate into systems within and across organizations
- Human readability of content using flexible stylesheet rendering
- SDM-XML allows the study design model as machine readable, which can be applied downstream
- Trace-XML provides an ability for full end-to-end traceability of data and linkages across them

What does this provide implementers and consumers?

Capability to integrate within technology systems to manage, track, and produce submission content in a more efficient and consistent manner.

Single common standard as an operational building block to achieve fully machine readable data flow. More flexible integration into technology stacks within organizations.

Easily share data and metadata using a single model and format (XML). Allows for greater adaptability for future format changes.

Ecosystem of linked metadata and data from one or more sources (e.g. define.xml, csdrg.xml, dataset.xml, etc.)

Access content as either machine readable code or rendered for human view ability (print if necessary). Ability to create ODM visually rendered eCRFs.

Possibilities to conduct an end-to-end spectrum of validation and conformance rules (e.g. ORCS) as either planned or real-time basis.

Format alignment with eCTD (XML based). Faster generation of all data points into submission ready format.

cdisc

A joint venture that provides greater end-to-end non-proprietary submission capable efficiencies while allowing for machine readable content for consuming stakeholders and systems.