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.
- Vital to developers for the Clinical Study Data Reviewers Guide (cSDRG), but intended to eventually capture Non-Clinical Study Data Reviewers Guide (nSDRG) and Analytical Data Reviewers Guide (ADRG).
- Human readability of content using flexible stylesheet rendering.
- Allows for hyperlinking between supporting documents (e.g. define.xml, csdrg.xml, dataset.xml, etc.).

**What does this provide implementers and consumers?**

- CDISC ODM is an established data exchange model within the industry.
- CDISC Define-XML & ARM provide the supporting metadata describing the data itself.
- CDISC Define-XML supports the exchange of data in a clinical research application setting.
- Easily share data and metadata using a single model and format (XML). Allows for greater adaptability for future format changes.
- Access content as either machine readable code or rendered for human viewability (print if necessary). Ability to create ODM visually rendered eCRFs.
- Format alignment with eCTD (XML based). Faster generation of all data points into submission ready format.