Analysis Results Metadata v1.0 for Define-XML v2 ReadMe

This is Version 1.0 of the CDISC Analysis Results Metadata extension to the Define-XML Version 2 standard. The primary focus in developing this version was to support the submission of Analysis Results Metadata as defined in the metadata model described in the CDISC ADaM Analysis Data Model Version 2.1 document.

This document is intended for companies and individuals involved in the analysis of clinical data that will be submitted to regulatory authorities.

Along with the Analysis Results Metadata v1.0 specification, the distribution package includes:

- The Analysis Results Metadata 1.0 schema
- An ADaM based Define-XML example and its HTML rendition
- A sample XSL stylesheet for the Define-XML example

Download Folder Structure

The top-level folder of the ARM-for-Define-XML folder includes 2 documents:

Analysis Results Metadata v1.0 for Define-XML v2.pdf	Specification document.
ReadMe.pdf	This file.

There is also a set of four sub- folders as shown in the table below. To view the sample ADaM define.xml file as rendered with the stylesheet, double click on the file **define2-0-0-example-adam-results.html** contained in the adam folder.

Folder	Contents
adam	• sample ADaM define.xml file (define2-0-0-example-adam-results.xml) • its HTML rendition (**define2-0-0-example-adam-results.html**) • the sample XSL stylesheet (define2-0-0.xsl) • sample ADaM datasets in XPT format (*.xpt) • dummy Analysis Data Reviewer's Guide in PDF format (analysis-data-reviewers-guide.pdf), see: http://www.phusewiki.org/wiki/index.php?title=Analysis_Data_Reviewer%27s_Guide
dummy-csr	A dummy Clinical Study Report in PDF format to illustrate how analysis displays or specific Statistical Analysis Plan sections can be referenced from the ADaM define.xml file
programs	Three dummy program files to illustrate how analysis display and analysis dataset generation programs can be referenced from the ADaM define.xml file
schema	Three sub-folders: • **cdisc-odm-1.3.2** contains the schema files for the current version of the CDISC ODM standard. • **cdisc-define-2.0** contains the schema files for the Define-XML extension to the ODM • **cdisc-arm-1.0** contains the schema files for the Analysis Results Metadata extension to the Define-XML

This folder structure is NOT the folder structure required for regulatory submissions. For details on submissions folder requirements, including specific files expected in each folder, consult the references section of the enclosed Analysis Results Metadata specification.

Example

The ADaM example (define2-0-0-example-adam-results.xml) was adapted from the customized Define-XML version 1.0 file provided with the updated SDTM/ADaM Pilot Project 2013 (see http://www.cdisc.org/sdtmadam-pilot-project).

Stylesheet notes

The sample XSL stylesheet document (define2-0-0.xsl) found in the adam folder in the download can be used with Define-XML 2.0 files. The stylesheet is an extended and improved version of the sample XSL stylesheet document (define2-0-0.xsl, version 2013-04-24) included in the Define-XML Version 2.0 release package. The stylesheet can be used with ADaM, including Analysis Results Metadata, but also with SDTM and SEND. Improvements in the stylesheet include bug fixes and better support for linking to physical pages or named destinations in external PDF documents.
The stylesheet uses Javascript to make the navigation menu dynamic. However, in cases where Javascript is not activated, there will be a fully functioning static menu available.

Browsers do not provide uniform support for XSL. Also note that not every browser will allow rendering of a local XML file by applying an XSL stylesheet. An example of a browser which does not allow rendering of a local XML file by applying an XSL stylesheet is Chrome.
The HTML file included is the result of applying the XSL stylesheet provided in this review package to the example XML file. The HTML file can be displayed in browsers such as Chrome that will not render the XML file.