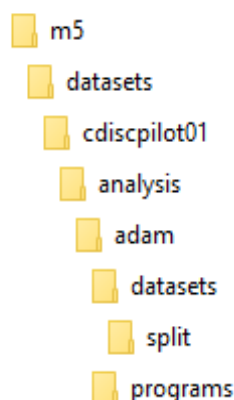


ADaM Metadata Submission Guideline (MSG) v1.0 Package for CDISC Publication

This is Version 1.0 of the CDISC ADaM Metadata Submission Guideline (MSG) Package for CDISC Publication.

The **ADaM_MSG_1_0_CDISCPublication.zip** file includes this Readme file and a folder "m5".

A) The folder "m5" has the following directory structure and individual files under the "datasets" and "split" sub-folders. Individual programs are under "programs" sub-folder. As the package does not have any split datasets, the split folder is not part of the package.



The "adam" folder includes:

1. The Define-XML v2.1 document (define.xml file).
2. The stylesheet published with the Define-XML 2.1 Specification.
3. Two examples of HTML renditions¹ of the define.xml file "define.xml_default.html" and "define.xml_prefixes.html" using the enclosed stylesheet.
 - a. These HTML files can be opened directly in case you experience issues to open the Define-XMLv2.1 document with any browser. Note that users may experience display and functionality issues in the rendered XML with some browsers. Adjusting browser settings or trying another browser can rectify this.
4. The data files (.xpt), 12 in total.
5. The "adrg.pdf" file.

¹ Refer to a) the 5.3.2 Stylesheet Reference section on the published Define-XML v2.1 standard for general information on stylesheet references, and b) the stylesheet documentation on the stylesheet PhUSE deliverable (<https://phuse.s3.eu-central-1.amazonaws.com/Deliverables/Optimizing+the+Use+of+Data+Standards/Define-XML+v2.0+Stylesheet+Recommendations.zip>, "readme.pdf" and "Stylesheet Documentation.pdf" documents) for a description on how the different html renditions can be obtained using the same stylesheet. This part of the documentation applies to the stylesheet published with the Define-XML v2.1 standard and included in this ADaM MSG 1.0 package.

The "programs" folder includes:

1. adsl-sas.txt file, sample program file part of the package.

In order to maintain the inter-document linking, the files within the "adam" folder must remain intact.

Standards Conformance Notes

1. The ADaMIG v1.1 datasets were evaluated manually and programmatically by the CDISC ADaM MSG Team.
2. The Define-XML document was evaluated manually and programmatically by the CDISC ADaM MSG Team. Please ensure that any official regulatory submission of a Define-XML document and accompanying data is done in accordance with the respective regulatory health authorities' requirements/guidance.