

## Recommended Contents of a Sample CDISC Submission

Please follow the sample guidelines below so that we may provide you with a meaningful, comprehensive analysis of your submission and help to ensure you are able to submit according to specifications. This evaluation does not involve any regulatory review of the content of the submission. It is intended only to resolve technical and conformance issues.

The sample package should include the following items and those items must comply with FDA study data standards, formats, and terminologies described in FDA Data Standards Catalog. The sample can either be included within an eCTD sample or submitted as a standalone CDISC study.

<b>At a minimum, relevant data from at least one study from one of the CDISC standards (SDTM/ADaM or SEND) should be included, but metadata associated with the data, including the reviewer’s guide, define.xml, and aCRF, are recommended to be included.</b> Please do not submit legacy (non-CDISC standard) data.	
For the CDISC/SDTM evaluation, please submit:	
SDTM conformant datasets in xpt format according to the <b>supported SDTM version and SDTM implementation guide version described in FDA Data Standards Catalog</b>	
Define.xml	
Clinical Study Data Reviewer’s Guide (cSDRG) in PDF format	
Annotated Case Report Form (aCRF) in PDF format	
For the CDISC/ADaM evaluation, please submit:	
ADaM conformant datasets in .xpt format according to the <b>supported ADaM version and ADaM implementation guide version described in FDA Data Standards Catalog</b>	
Define.xml	
Analysis Data Reviewer’s Guide (ADRG) in PDF format	
For the CDISC/SEND evaluation, please submit:	
SEND conformant datasets in .xpt format according to the <b>supported SEND version and SEND implementation guide version described in FDA Data Standards Catalog</b>	
Define.xml	
Non-clinical Study Data Reviewer’s Guide (nSDRG) in PDF format	

**Note:** If we are unable to evaluate your sample, load it onto our server, perform validation, or cannot view the sample, you will be contacted and asked to resubmit according to specifications.

**Submitting a successful sample will help ensure successful submissions in the future.**

If you have questions, please contact the electronic submissions staff at [esub-Testing@fda.hhs.gov](mailto:esub-Testing@fda.hhs.gov)

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