

PhUSE US Connect 2019

CDISC rules + FDA requests + PMDA requirements = Guaranteed Compliance?

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ABSTRACT

With more emphasis being placed on standardization of clinical trials data, an abundance of information must be considered by those involved in the preparation of submissions. This information is provided by multiple regulatory agencies and standardization groups. How do we interpret this information to develop a compliant submission? What exactly constitutes a compliant submission?

Depending on when and where the submission is to be sent, the path to compliance could be dramatically different. For example, the Pharmaceuticals and Medical Devices Agency (PMDA) and the Food and Drug Administration (FDA) have different rules for determining compliance, different versions of implementation guides and validation tools as well as different dates for when new versions of a standard are required. This paper will address some examples where the regulatory requests and the available standards seemingly contradict each other. In addition, ideas are presented on what constitutes compliance and how to determine whether a particular interpretation of compliance is actually compliant.

INTRODUCTION

Rules, requests, requirements, standardization committees, regulatory agencies and more - Preparing for a submission requires knowledge, interpretation and implementation of many factors. It is difficult at best to incorporate and consolidate this information, but seemingly impossible when we consider that changes and development are ongoing within the standards and agencies. In order to create a compliant submission, the definition of compliance for the planned submission needs to be determined. This paper will present some of the differences in requirements between and within PMDA and FDA that need to be addressed and some of the difficulties in interpretation of the requirements. Rules may differ from what is presented depending on the study design such as phase, integration studies, legacy studies, etc. Always refer to the latest guidance from the regulatory agency as applicable for the submission.

TIMING AND VERSIONING OF STANDARDS

The current requirements for a submission must be determined using the applicable date as specified by the agency. The below table has the date of the agency-initiated requirements for standardized submissions. The definition for the start of the requirement period applies to both the initial standards implementation and updates to existing standards required for the submission.

Agency	Initial Standards Requirement Date	Determination of Requirement Start Date
FDA	December 17, 2016	The requirement to submit using a particular standard is dependent on its support by FDA as listed in the Catalog at the time of study start. ¹
PMDA	April 1, 2020	The base date is the submission date recorded by the applicant on the FD application of the new drug application form. ²

Until April 1, 2020, PMDA is in a transitional phase. During the transitional phase, certain electronic data may be submitted and will be subject to all current applicable rules. When submitting electronic data, both SDTM and ADaM (ADaM when required for analyses) must be submitted for the entire study if implemented during this period.³

Both FDA and PMDA have their currently accepted versions of standards in their respective Data Standards Catalog.^{4, 5} The standard and the date to which it applies is documented in the catalog along with other information. When

multiple versions of a standard are accepted, it is best practice to use the newest version. For FDA submissions, the version at the study start will be compliant regardless of the date of submission but using the latest version will provide the most complete implementation and guidance. For PMDA submissions, it is possible that support for that version would end prior to submission which could necessitate updates in order to remain compliant.

COMPLIANCE

In order to plan a compliant submission, it is necessary to be aware of the checks the agency will do when the submission is delivered. Prior to delivery, validation should be performed to identify and resolve any issues that the agency has identified that may lead to rejection of the submission. These issues are identified in the standards requirements published by the agency. At times it may be difficult to determine the proper implementation of compliance requirements. There are multiple versions of guidance documents, multiple documents that cover related items, documents with circular references to each other, and more! There are instances where the related documents seemingly conflict – what is the compliant choice? If the standard says something “should” be done a certain way rather than “must”, is it non-compliant if it is not?

When differences are found in guidance documents it is important to know which should be followed. Possible considerations can be based on the publication dates of the conflicting documents, dates when the document is applicable, what type of study is involved and the type of the document. For example, the FDA Technical Conformance Guide (TCG) ⁶ and the Study Data Tabulation Model Implementation Guide (SDTMIG) ⁷ differ in the values for populating (or not populating) the variable ARM in DM (Demographics dataset). FDA documents are not always required to be followed. Typically documents that can be considered guidance rather than requirements will specify within the document that it contains nonbinding recommendations. Typically, documents that refer to statutes and regulations are requirements that must be followed. The FDA TCG does, in fact, contain nonbinding information.

CONFORMANCE CHECKS PERFORMED BY AGENCY

With the initial submission, the FDA focuses more on the technical aspect of the submission, while the PMDA includes additional checks for compliance to Clinical Data Interchange Standards Consortium (CDISC) standards ⁸.

FDA CONFORMANCE

With the initial submission, the FDA will assess conformance at a high level. Rejection criteria for study data and eCTD validation criteria are assessed at this point. Failure of these checks will lead to rejection of the submission. Once the submission is accepted, the agency will further assess conformance with required standards and can refuse to file (RTF) during the review. ⁹

FDA Technical Rejection Criteria for Study Data ⁹:

1. You have not submitted a Trial Summary (TS) dataset for each study in Module 4, section 4.2 or in Module 5, section 5.3 (Severity level high)
2. You have submitted XPT files without correct file tag. (Severity level medium) Valid file tags are:
 - a. data-tabulation-dataset-sdtm
 - b. data-tabulation-dataset-send
 - c. analysis-dataset-adam
3. You have not submitted Demographic dataset (DM) and define.xml for each study in Module 4, section 4.2. You have not submitted Demographic dataset (DM), Subject level analysis dataset (ADSL), and define.xml for each study in Module 5, section 5.3. (Severity level high)
4. For each study in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2, no more than one dataset of the same name should be submitted as new. (Severity level medium)

The above checks are also documented in the Specifications for eCTD Validation Criteria ¹⁰ in addition to numerous checks specific to the structure and requirements of eCTD. Within the specification, a severity and its associated action is defined as follows.

Severity	Description
High	The error is a serious technical error which prevents the processing of the submission and will require resubmission. The submission is considered not received by FDA.
Medium	The error may impact the reviewability of the submission but cannot be determined without further inspection by the review staff. The submission might be considered received by FDA.
Low	The error is a technical error which may or may not impact the reviewability or the integrity of the submission. The submission will likely be considered received by FDA.

To illustrate the complexity of interpretation and implementation of compliance, the following example will focus on a violation of Rule 2 (Officially this rule is number 1735 in the guidance).

The Description associated with this rule:

The correct STF file-tags must be used for all standardized datasets in module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in module 5, sections 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2

This rule refers to file tags (Study Tagging Files or STF). The Data Standards Catalog contains a hyperlink to the reference for the current standard - The eCTD Backbone File Specification for Study Tagging Files 2.6.1 ¹¹ as shown below.

Use	Standard	Exchange Format	Standards Development Organization	Supported Version	Implementation Guide Reference	Date Support Begins (yyyy-mm-dd)	Date Support Ends (yyyy-mm-dd)	Date Requirement Begins	Date Requirements Ends	Regulatory References
This table contains a listing of the specifications and supportive files for eCTD submissions to both CDER and CBER. Last updated: 11/30/2018										
STF Specification	eCTD	XML	ICH	2.6.1		6/3/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		The eCTD Backbone File Specification for Study Tagging Files 2.6.1

Although this rule is applicable to all standardized datasets in module 4 and 5, the example will only refer to analysis datasets.

Section 3 defines information on elements for the STF as follows.

The *file-tag* element contains the attributes *name* and *info-type*. The text value of the *file-tag* element's *name* attribute indicates the subject matter of the document. The value of the *file-tag* *name* attribute should be selected from the values in the table below. For the value of the *info-type* attribute, you should use "ich" if using an ICH value or one of the regional values if the value is not defined in ICH. The table below shows the specified *name* attribute values for the *file-tag* element.

name attribute values for the file-tag element (name=" ")	info-type value	Content of Document
analysis-dataset	us	Analysis datasets
analysis-program	us	Program file for analysis dataset
analysis-data-definition	us	Data definition for analysis datasets

The values listed in the reference document do not match the valid values listed in this rule. Although the guidance is provided for the attributes, it is difficult to determine how and when changing the values may affect compliance. There is information on applying categories to file tags within the document, but it does not specifically refer to the analysis tags. There is also information on the user defined values for the property element but the guidance states that this element should only be used for site identification within a study.

The Rejection Criteria Description only specifies application to "standardized datasets". The sections listed in the description include the following folders:

Data tabulation

Data tabulation dataset legacy

Data tabulation dataset sdtm

Data tabulation data definition

Data listing dataset (E3 16.4)

Data listing dataset

Data listing data definition

Analysis datasets

Analysis dataset adam

Analysis dataset legacy

Analysis program

Analysis data definition

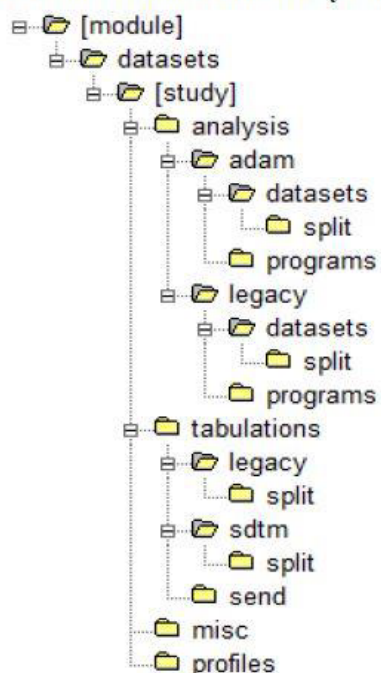
The STF specification ¹¹ states:

An STF should be provided with the submission of any file, or group of files belonging to a study in Modules 4 and 5. STF's are required by the United States, are not required in Europe and are not allowed in Japan.

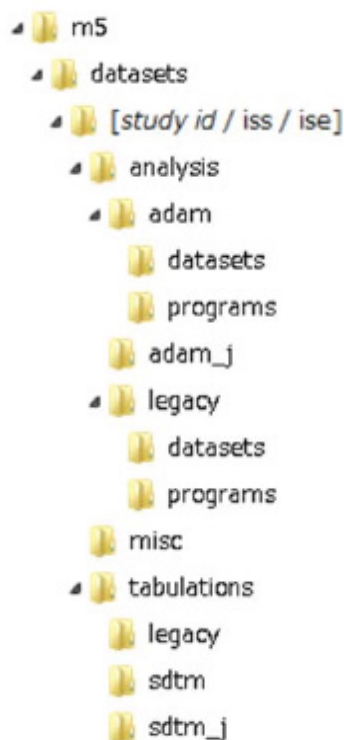
eCTD folder structures for Modules 4 and 5 are included for reference below.

eCTD folder structure for FDA:

Figure 1: Folder Structure for Study Datasets



eCTD folder structure for PMDA:



Legacy dataset folders are included in modules 4 and 5. Although not specifically mentioned in the rejection criteria, STF's are required for these folders. If legacy data are submitted in XPT, one implementation suggestion is to follow the convention of the STF given for ADaM datasets and apply the STF value to legacy datasets as analysis-dataset-legacy.

PMDA CONFORMANCE

As the PMDA requirements for standards is in the transition period, there are different conformance checks based on the type of submission (eCTD, data format, etc.). During the transition period, the specific requirements and type of

submission must be agreed upon in advance of the submission. The agreed upon requirements will dictate the conformance evaluation.

Technical conformance will be performed based on the submission type and failure of the criteria would result in rejection of the submission. This section will only focus on electronic data submitted to PMDA in CDISC format. Technical conformance includes checks for items such as folder structure and names, file names, file size, length of file paths, required documents in the correct folder and more.

As mentioned previously, the PMDA will assess conformance of all requirements at the time of the initial delivery of the submission. Conformance criteria for SDTM, ADaM and Define-XML are published in the PMDA Study Data Validation Rules.¹² The details of testing for CDISC compliance is discussed in the next section.

CONFORMANCE TESTING FOR CDISC COMPLIANCE

This section will focus on the validation of SDTM and ADaM datasets and the define-XML. Both the FDA and the PMDA utilize Pinnacle 21 Validator for testing CDISC compliance. Compliance checks for ADAMIG version 1.1 have not been implemented in P21 as of the date of this paper. Currently PMDA only officially accepts ADAMIG version 1.0. In some cases, the use of ADAMIG version 1.1 for submissions to PMDA may be acceptable. Any validation findings would be handled as specified in the next section, and the submission must still be classified as ADAMIG version 1.0 in the define and reviewer's guide. The FDA accepts both version 1.1 and version 1.0.

It is not mandated by either agency that a sponsor must use Pinnacle 21 for validation. However, it is beneficial to utilize the same checks as the agency, especially considering the same tool is available to the industry. Multiple versions of the validator are available that are specific to PMDA (reports the severity classifications used by PMDA) and several versions of CDISC. Regardless of the tool used, it is always best to run validation checks "early and often". It is easier to rectify findings early in development in order to limit the number of updates that may be required.

CLASSIFICATION OF FINDINGS

PMDA utilizes 3 levels of severity (listed below) for validation findings as defined in their TCG¹³:

The rules used for validation have been classified by the level of importance taking into consideration the characteristics of each rule and based on conformity to the standards, ease of use of the data in review, quality of the clinical study data which the PMDA must know beforehand, and future uses of the clinical data by the PMDA. The levels of importance are shown below.

- (a) Rules which, if violated, will cause the review to be suspended until corrections have been made. Very basic rules such as the presence/absence of necessary datasets for each clinical study
- (b) Rules which, if violated without any prior explanation, will cause the review to be suspended until corrections have been made. In many cases, these rules are clearly stated in each standard and implementation guide, and if violated, the applicant should consult the PMDA before the application about the reason for the violation and the reason why it is not possible to correct it. These rules must also be explained in the data guide.
- (c) Rules which, even when violated, will not necessarily require any explanation. The reason for the violation may be requested separately for the above (c) from the perspective of the quality of the clinical study data.

The level of importance is applied to the severity and its associated action when validating the data¹².

Severity for the above levels:

- (a) Reject
- (b) Error
- (c) Warning

Any finding with a severity of Reject or Error must typically be fixed prior to submission. The exception would be an Error that was discussed with PMDA prior to submission and agreed that it could not be fixed. In this case the error and an explanation would be added to the reviewer's guide. Although severity of Warning is defined as not necessarily needing explanation, it is preferable to add the findings to the reviewer's guide with a comment.

The FDA has 2 documents containing their rules. The FDA Study Data Validator Rules¹⁴ contain rules for conformance with CDISC and the FDA Business Rules¹⁵ describe the business requirements for regulatory review to help ensure that study data is compliant and useful and supports meaningful review and analysis. Neither provides an action that would result from findings. In fact, the FDA TCG⁶ states that sponsors may "wish to use" the

rules and that they should correct discrepancies or explain meaningful discrepancies in the reviewer's guide. Regardless, any finding with a severity of Error should be fixed where possible. Findings with severity of Warning should be fixed if possible but is not mandatory.

VALIDATION FINDINGS

The point of running compliance checks is to determine if the study is in fact compliant to the required standards. Often, too much importance is placed on computational results of compliance checks rather than true compliance. While checks are written for machine readable criteria, there will always be a need for manual review. For example, P21 has only developed checks for certain data structures in ADaM. In order to determine the structure of a dataset, certain key variables are identified. The Basic Data Structure (BDS) contains required variables in reference to the analysis value (AVAL). The checks will identify a dataset with BDS variables and run checks according to that structure. This will sometimes result in false findings. Since P21 also checks controlled terminology and other potentially valuable checks, it is preferable to deal with false findings rather than miss true findings. The false findings can be simply explained with a comment in the reviewer's guide.

It is important to remember some key points in dealing with findings.

1. Compliance to a required standard is mandatory. The standard has been developed to improve the quality of our results, analysis and ultimately the safety of those who benefit from our approved products.
2. FDA and PMDA reviewers are involved in developing the standards and are therefore very familiar with the requirements.
3. Validation testing and addressing findings before "it is too late to make changes" is crucial to a compliant submission.
4. Understanding the standards related to the finding is key to determining the action required.

One of the checks performed looks for the existence of variables in BDS as mentioned above. Below is an example of handling findings.

A study contains an ADaM dataset ADLB which contains the results of subjects' lab tests to be used in analysis. The sponsor created BDS for this dataset and all output programming based on the structure, variables and values. At the end of the study, validation checks were run in order to populate the reviewer's guide section on findings. The following violation was found:

Source	Pinnacle 21 ID	Publisher ID	Message	Severity	Description
ADLB	AD0110	110	Inconsistent value for AVISIT	Error	Within a study, All AVISIT values must be the same for each unique value group of [PARAMCD,AVISITN] when PARAMCD and primary variable AVISIT are populated.

PMDA classifies AD0110 as an ERROR which leads to a rejection if this issue was not agreed upon prior to the submission. FDA does not list this check in their rules.

ADAMIG version 1.0 and 1.1 differ slightly on their text for the scope of the variables, although it was just a clarification and not a change in the implementation.

ADAMIG version 1.1 CDISC notes state in part the following:

Variable Name	CDISC Notes
AVISIT	The values and the rules for deriving AVISIT may be different for different parameters within the same dataset.
AVISITN	Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT. (Best practice would dictate that the mapping would be one-to-one within a study, but that is not an ADaM requirement.)

ADAMIG version 1.0 CDISC notes state in part the following:

Variable Name	CDISC Notes
AVISIT	The values and the rules for deriving AVISIT may be different for different parameters within the same dataset.
AVISITN	Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT.

The Revision History in ADAMIG version 1.1 classifies this as a clarification:

Category/Section	Type	Description
Section 3.1.1 General Variable Conventions, Items 5 and 6	Clarification	Clarified paired variables and one-to-one mapping.

Section 3.1.1 General Variable Conventions, item 5:

For variable pairs designated as having a one-to-one mapping within a specified scope (e.g., within a parameter, within a study), if both variables are present in the dataset and there exists a row in that scope on which both variables are populated, then there must be a one-to-one mapping between the two variables on all rows within the scope on which both variables are populated. The scopes noted in this document should be considered the minimum level for the mapping; it does not preclude the producer from using a broader level of scope. For example, if a one-to-one mapping is specified as within a PARAM, the producer may elect to use the same one-to-one mapping across all PARAMs within the dataset or study. In addition, note that “within a parameter” means “within a parameter within a dataset.”

As PMDA only accepts ADAMIG version 1.0, for the submission there would be no choice other than to fix this and update all issues resulting from this finding (if this issue was not discussed and agreed to not change prior to the submission). The submission will be delayed and the cost to the sponsor will be considerable.

For a submission to the FDA, if the inconsistency was not within the parameter and only within the dataset, it would be correct to provide a comment in the reviewer’s guide (for example): ADAMIG only requires the 1:1 relationship within a parameter and not within a dataset. All values in this dataset comply within each parameter.

If there are violations within a parameter, then this comment could not be used.

In our example, in order to deliver on time, the error was noted in the reviewer’s guide with a comment: This is not a BDS dataset, so this check does not apply.

Unfortunately, this is wrong on many levels. The most important fact is that the comment is not true as this dataset is a BDS. As mentioned previously, the reviewer is aware of the standards and they will know this is in fact a BDS and more than likely cause the reviewer to question why this comment was applied.

Secondly, even if it was not a BDS, and AVISIT/AVISITN are used, the scope of paired variables must still be 1:1 within (at least) a dataset. Any ADaM dataset, no matter the structure, must adhere to the rules and principles of ADaM in order to be compliant. ADaM Variable Convention rules apply to all structures of ADaM where the variable is used.

Regardless, since this violation is not listed in the FDA validator rules, and there is not a required resolution for this finding, it is reasonable to conclude that no action or response is necessary. However, this is not recommended as the finding will be identified to the reviewer during the P21 check and would more than likely cause the reviewer to question why this was not addressed in some way.

For submission to either PMDA or FDA, if the validation was done earlier in the study this would have been a relatively simple fix without much time involved. At the point of submission, it must be dealt with and any resolution will cause delays. It is possible to just enter an excuse that basically begs forgiveness, but no matter the reason provided it can affect the review and possibly (definitely for PMDA as per their rules) the filing status of the submission.

CONCLUSION

This paper has only touched upon a few points to illustrate the complexity of a compliant submission. Representatives from the FDA and PMDA have been working closely with the standards groups to improve existing standards and guidance for implementation. Even where guidance is considered optional it is best practice to implement the recommendations wherever possible as this can ease the review which in turn will benefit both the sponsor and the reviewer.

REFERENCES

- ¹ US Food & Drug Administration. December 2014. "Providing Regulatory Submissions in Electronic Format – Standardized Study Data"
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- ³ Japan Pharmaceuticals and Medical Devices Agency. April 2015. "Question and Answer Guide Regarding Notification on Practical Operations of Electronic Study Data Submissions."
<https://www.pmda.go.jp/files/000206450.pdf>. Accessed January 5, 2019.
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<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM340684.xlsx>
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- ⁶ US Food & Drug Administration. March 2017. "Study Data Technical Conformance Guide V4.1. Accessed January 5, 2019. <https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf> .
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https://www.cdisc.org/system/files/members/standard/foundational/sdtmig/sdtmig_20v3.2_20noportfolio.pdf
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<https://www.cdisc.org/resources/global-regulatory-requirements>
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<https://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm366165.pdf>
- ¹¹ US Food & Drug Administration. June 2018. "The eCTD Backbone File Specification for Study Tagging Files 2.6.1". Accessed January 5, 2019.
<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163560.pdf>
- ¹² Japan Pharmaceuticals and Medical Devices Agency. November 2015. "Study Data Validation Rules." Accessed January 5, 2019. <https://www.pmda.go.jp/files/000208341.zip>
- ¹³ Japan Pharmaceuticals and Medical Devices Agency. August 2016. "Revision of Technical Conformance Guide on Electronic Study Data Submissions" Accessed January 5, 2019. <https://www.pmda.go.jp/files/000215100.pdf>



¹⁴ US Food & Drug Administration. "FDA Study Data Validator Rules." Accessed January 5, 2019.
<https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM546468.xlsx>

¹⁵ US Food & Drug Administration. "FDA Business Rules." Accessed January 5, 2019.
<https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM546467.xlsx>

ACKNOWLEDGMENTS

I would like to thank all the volunteers providing their time in order to develop and enhance industry standards. I would also like to thank members from PMDA and FDA who collaborate with the volunteers in assuring the standards are developed according to the needs and requirements of their agency. Without the work of these people, we would not have the tools and information we need to develop our products safely and efficiently to improve the lives of those who depend on our products.

RECOMMENDED READING

The following documents are supportive in understanding principles and implementation of standards for sponsors SDTM v1.4, SDTMIG v3.2 and SDTMIG: Associated Persons (AP) v1.0
https://www.cdisc.org/system/files/members/standard/foundational/sdtmig/sdtmig_203_2_20release_20package_today.zip

SDTM Terminology <https://evs.nci.nih.gov/ftp1/CDISC/SDTM/SDTM%20Terminology.xls>

ADaM v2.1 https://www.cdisc.org/system/files/members/standard/foundational/adam/analysis_data_model_v2.1.pdf

CDISC Define-XML Specification Version 2.0 <https://www.cdisc.org/standards/foundational/define-xml/define-xml-v20>

ADaM Terminology <https://evs.nci.nih.gov/ftp1/CDISC/ADaM/ADaM%20Terminology.xls>

ADaM Examples in Commonly Used Statistical Analysis Methods

https://www.cdisc.org/system/files/members/standard/foundational/adam/adam_examples_final.pdf

To ensure you have the most recent versions of standards, please verify at the following sites

US Food & Drug Administration <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

Japan Pharmaceuticals and Medical Devices Agency <http://www.pmda.go.jp/english/index.html>

CDISC <https://www.cdisc.org/standards>

National Cancer Institute <https://www.cancer.gov/research/resources/terminology/cdisc>

The following websites contain helpful information, examples and ideas from users

CDISC <https://www.cdisc.org/>

PhUSE <https://www.phuse.eu/>

Pinnacle 21 <https://www.pinnacle21.com/>

PharmaSUG <https://www.pharmasug.org/>

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