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CDISC Conformance and Compliance: So Many Resources, So Little Time!

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ABSTRACT

If you are new to CDISC you may be overwhelmed by the variety and scope of reference resources required to produce a CDISC-compliant data package for submission to regulatory authorities. Or if you have been doing CDISC for a while, you may be realizing that it is time to expand your research beyond the implementation guides (IGs). Where to start? What if there is a conflict in the information provided? Which resources take precedent? How do I keep current? And how do I know what resources are out there? This paper attempts to answer those questions and more, putting the wide array of guidelines, software, educational tools, and contributing parties in one place. The paper will also provide links and descriptions so that when you are ready you will have the proverbial "CDISC World" at your fingertips.

INTRODUCTION

At the start of a CDISC submission project, you likely dive first into the SDTM and ADaM Implementation Guides (IGs). These are valuable documents and should be your primary tools as you begin the process of programming your SDTM and ADaM data files. But the IGs do not hold all the answers you will need. CDISC standards are a set of complex and multifaceted criteria, with different components that are guided by a variety of reference materials. Some of these include documents from regulatory agencies, CDISC documents, CDISC standards validation software, and process organizations. This paper assumes the reader has a beginner to intermediate (1 year or less) experience with CDISC concepts.

CONFORMANCE VS. COMPLIANCE

Before consulting the various CDISC-related resources, it is important to understand the difference between "conformance" and "compliance" in the context of what is non-negotiable vs. what is best practice/recommended but not likely to risk an all-out rejection of your submission. *Conformance* is defined as voluntary adherence to a standard, rule, specification, requirement, design, process, or practice. Conformance to standards is absolutely recommended – after all what is the point of developing standards if we don't all use them? – but not required specifically by laws and regulations that could result in penalties if not strictly adhered to. *Compliance* is enforced adherence to a law, regulation, rule, process, or practice with the potential for penalties or rejection of the data submission. CDISC compliance is enforced by the authority to which the submission is made and following that authority's compliance rules is mandatory.

The purpose and audience of the data also contributes to the level of adherence required for the various rules and guidance. If the data is intended for a journal publication, grant application, or data warehousing, the requirements are less stringent. And sometimes the sponsor must make a judgement call. Perhaps a Phase 1, exploratory clinical trial is not intended for immediate submission; however, if the intervention proves worthy of further research, it will be more efficient in the long run to submit standardized and CDISC-compliant data from the beginning.

CDISC RESOURCES

The official CDISC website,CDISC.org, provides extensive documentation and examples of everything CDISC, from the commonly used tools to the documents being developed for future publication. As pictured in Figure 1, when you hover over the "Standards" tab you can quickly glance at and select from several key topics.

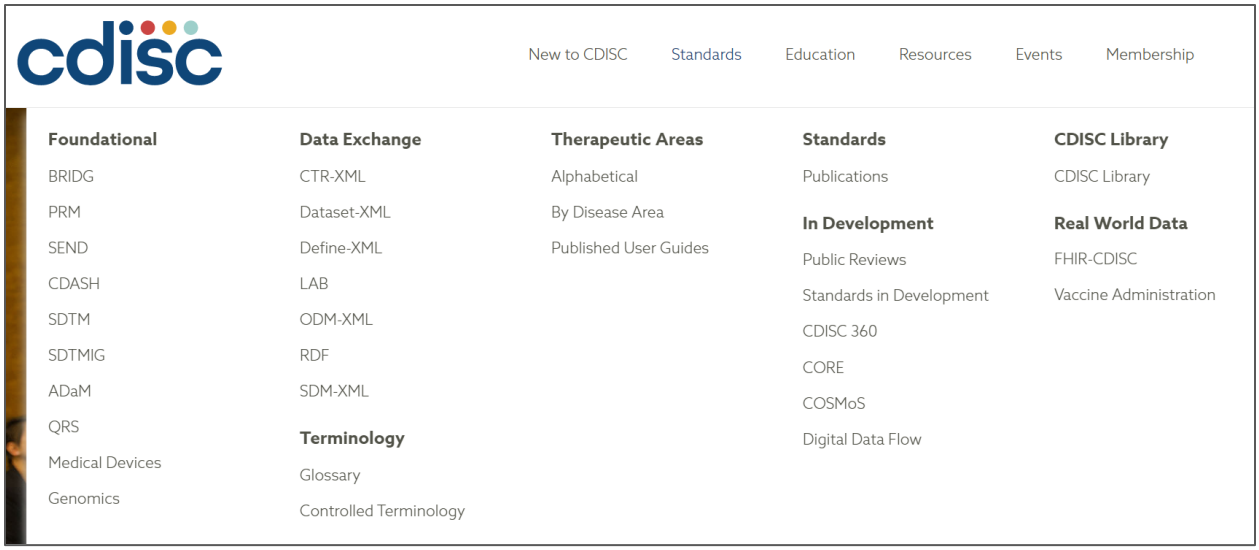

Figure 1. The Standards tab on CDISC.org

MODELS AND IMPLEMENTATION GUIDES

CDISC's foundational models are your starting point for any regulated data submission. Under the "Standards" tab on the CDISC website there is a list of subjects called "Foundational." Here you can find information about case report forms (CDASH), collected data (SDTM), analysis files (ADaM), nonclinical data (SEND), and more. For each of these items a model document is provided, which details the fundamental structure of the standard. Some of the foundational items including SEND, SDTM, and ADaM are paired with one or more IGs. The model and IG work hand-in-hand. The IG supplements the sections in the model document with detailed instructions and examples. If the IG does not include a specific concept needed for a study and domain, the user can review the model for "model-permissible" variables that can be adapted as needed for multiple domains. In addition, these documents can be downloaded or accessed directly using application programming interface (API) from the CDISC Library (with a current account, free to the public) in two formats: Excel spreadsheets or CSV files. These can then be used as the basis of your project's CDISC specifications (or "specs document") and as part of programming to get accurate and efficient results.

THERAPEUTIC AREA USER GUIDES (TAUGS)

TAUGs are user guides focused on specific diseases of interest, developed in cooperation with disease experts. TAUGs are also found on the Standards tab under the heading "Therapeutic Areas." You can select whether to look at the TAUGs alphabetically or by disease area. Numerous TAUGs have been published and more are constantly being developed. The TAUGs supplement the IGs by providing additional background, guidance, and examples. The TAUGs often answer the very study-specific questions you cannot find in the IGs. If you ever encounter an apparent conflict in the rules for developing CDISC data when comparing a TAUG and the model/IG, the model/IG take precedent.

CONFORMANCE RULES

The Study Data Tabulation Model Implementation Guide (SDTMIG) Conformance Rules spreadsheet, which CDISC released on January 27, 2017 as a supplement to the SDTMIG, provides a more rigorous set of parameters by which to validate your SDTM data and assess objectively whether there are areas that need improvement or correction. The SDTMIG Conformance Rules both complement and overlap with the various validation and business rules regulatory authorities provide. The Conformance Rules offer a way to assess the level of compliance with CDISC standards. Validation software such as Pinnacle 21 will incorporate CDISC Conformance Rules as well as conformance rules from other sources such as the FDA, to check data and provide an informative report that explains precisely which rule(s) have been violated. As illustrated in Figure 2, the document includes an ID for each rule, and traces each

rule back to the specific SDTMIG version number as well as the section and specific item (where applicable), class, domain, and variable affected. Guidance for how to correct a rule violation is also provided.

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Document	Section	Item	Cited Guidance	Release Notes
CG0151	3.2	1	SPC	DM	USUBJID		USUBJID unique within a submission	IG v3.2	5	Specification	Identifier used to uniquely identify a subject across all studies	
CG0151	3.3	1	SPC	DM	USUBJID		USUBJID unique within a submission	IG v3.3	5.2	Specification	Identifier used to uniquely identify a subject across all studies	

Figure 2. Example SDTMIG Conformance Rules

The ADaM team has also released conformance rules to accompany the ADaM Model and IG documentation. One notable difference from the SDTM Conformance Rules pointed out on the CDISC website is: “ADaM Conformance Rules… are intended to be used for single studies. They are not meant to define the full spectrum of ADaM conformance as they cannot evaluate the content of ADaM datasets vs. external systems to ensure, for example, that all observed and derived rows for a given analysis parameter are included.” Examples of “external systems” include the full list of lab tests or list of items in a questionnaire for a study, or items that are described in a statistical analysis plan that are needed for a specific type of analysis.

CONTROLLED TERMINOLOGY

Next on the Standards tab of the CDISC website, look for the heading “Terminology”. CDISC, in collaboration with the National Cancer Institute’s Enterprise Vocabulary Services (EVS), supports Controlled Terminology that provides values in the form of codelists to use with the foundational models to promote consistency across all data submissions. This means, for example: SDTM is very text-based, such as using “N” and “Y” for “No” and “Yes,” respectively. CDISC has standards for the exact letters and case, and synonyms are not allowed. As stated on CDISC.org: “Controlled Terminology does not tell you WHAT to collect; it tells you IF you collected a particular data item, how you should submit it in your electronic dataset.” Figure 3 provides a sample of the components of a Controlled Terminology code list. From the early stages of developing a protocol, to creating data collection forms and programming the data package, Controlled Terminology must be consulted and adhered to where applicable. SDTM Controlled Terminology files are updated quarterly. Several types of terminology files including SDTM, ADaM, SEND, CDASH, and Protocol can be downloaded from the CDISC Library.

Code	Codelist Cod	Codelist Extensible (Yes/No	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66742		No	No Yes Response	NY	No Yes Response	A term that is used to indicate a question with permissible values of yes/no/unknown/not applicable.	CDISC SDTM Yes No Unknown or Not Applicable Response Terminology
C49487	C66742		No Yes Response	N	No	The non-affirmative response to a question. (NCI)	No
C48660	C66742		No Yes Response	NA	NA; Not Applicable	Determination of a value is not relevant in the current context. (NCI)	Not Applicable
C17998	C66742		No Yes Response	U	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C49488	C66742		No Yes Response	Y	Yes	The affirmative response to a question. (NCI)	Yes

Figure 3. Controlled Terminology Example

DEFINE-XML RELEASE INFORMATION WITH FILES AND LINKS

The “Data Exchange” heading on the Standards tab is where you will find information to help you produce the required Define-XML package, which includes the style sheet, reviewer’s guide, annotated Case

Report Forms (aCRFs), and other ancillary documents such as the document that describes complex algorithms. Define-XML provides metadata to accompany and describe the CDISC data prepared for submission. CDISC.org states: “Define-XML is required by the United States Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for every study in each electronic submission to inform the regulators which datasets, variables, controlled terms, and other specified metadata were used.” From here you can download the latest Define-XML updated release package which includes not only a PDF describing the latest specifications for Define-XML, but the schema and stylesheets (files that enable the XML code to appear with the desired colors, fonts, layout, and expected structure) as well as examples. Note that several software products are on the market that can generate a Define-XML file for you. But these CDISC-provided references are still worth reviewing to ensure that you understand the purpose and format of the file and can feel comfortable that this important required component of your CDISC package has been created correctly.

METADATA SUBMISSION GUIDELINES

A metadata submission guideline (MSG) has been developed by CDISC for SDTM and is currently under development for ADaM. While the previous references instruct how to collect, compile, and format the data for submission, the MSG provides guidance for putting together the actual submission package once it has been completed. “The purpose of the …SDTM MSG is to provide guidance for preparing the components of the International Conference on Harmonisation (ICH) electronic Common Technical Document (eCTD) Module 5 (M5) Clinical Study Reports ‘sdtm’ folder.” For example, the MSG describes how files should be named, including upper/lower case, ordering of datasets in the Define-XML, and the folder naming and structure for all the included files. And it provides detailed guidance for annotating case report forms to create the required acrf.pdf file, and for writing the reviewer guides.

KNOWLEDGE BASE ARTICLES AND EXAMPLES

A new and valuable addition to the CDISC website is called Knowledge Base, which provides articles, examples, and known issues. Authorized CDISC volunteers and subject matter experts write the articles. The Examples Collection are curated by CDISC based on their standards documents and may even include aCRFs and metadata samples. The “Known Issues” lists are problems or concerns that CDISC is aware of and include updates as to the status of resolution. The Knowledge Base also includes the eCRF Portal, where you can download CDASH-compliant aCRFs to use directly in your study. The tab for Knowledge Base can be found on the page for each individual foundational item. These can be a great resource if, for example, you are having trouble interpreting an instruction in an IG or would like to see if anyone else has encountered a specific data challenge.

The CDISC website has even more great information including standards in development, information about a major initiative called CDISC 360, and the latest news and innovations for real-world data. Materials on the website are frequently updated but revisions and versioning are clear and well documented. You will likely become a regular visitor to CDISC.org.

REGULATORY RESOURCES (FDA AND PMDA)

The following FDA resources are also critical to CDISC standards conformance and compliance. This Study Data Standards Resources | FDA webpage (Figure 4) features an introduction and links to the most important FDA standards documents regarding data submissions. More details and direct links are included below.

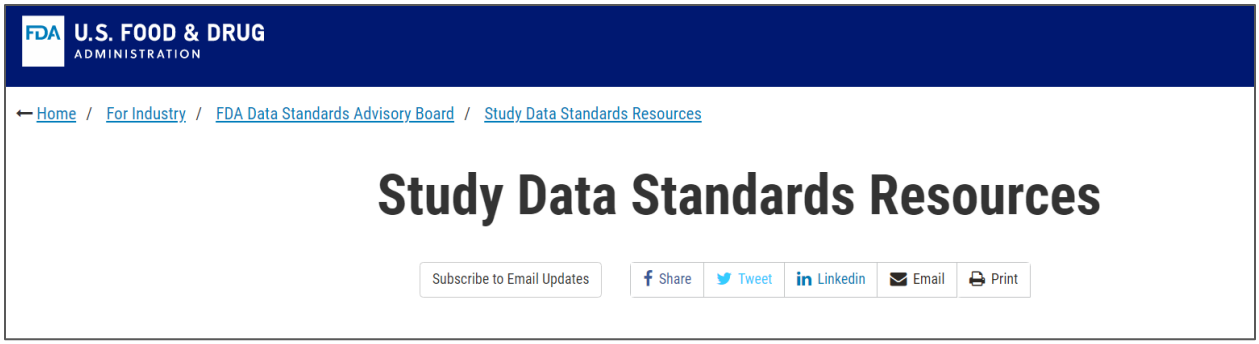

Figure 4. FDA Study Data Standards Resources Webpage

DATA STANDARDS CATALOG

Data Standards Catalog v9.0 | FDA

If you have any questions about which version of a model, IG, or terminology the FDA currently supports and/or requires, look at the Data Standards Catalog. Its introduction states: "The FDA Data Standards Catalog (Catalog) lists the data standards and terminologies that FDA supports for use in regulatory submissions to better enable the evaluation of safety, effectiveness, and quality of FDA-regulated products. In addition, the FDA has the statutory and regulatory authority to require certain standards and terminologies, and these are identified in the Catalog with the date the requirement begins and, as needed, the date the requirement ends, and information sources. The submission of data using standards or terminologies not listed in the Catalog should be discussed with the Agency in advance."

This document is an Excel spreadsheet that provides high-level information about Submission Data Standards and Submission Data Terminologies. You can filter to see only those data standards CDISC developed. After filtering, you will have valuable information at a glance such as the required exchange format (usually XPT) and appropriate FDA centers for oversight. It also provides the beginning and ending dates for both support and requirements for each version of the models and IGs. The Submission Data Terminologies tab provides similar information about various codelists and dictionaries including MedDRA, WHO Drug, and SNOMED.

FDA VALIDATOR RULES

FDA Validator Rules v1.6 December 2022_0.xlsx

The introduction to this spreadsheet states: "This document contains the rules used by the FDA study data validator (FDA Validator) to ensure data are standards compliant and support meaningful review and analysis. In addition, the document links a specific FDA Validator Rule to the published content study data is being validated against (ex. FDA Business Rules, CDISC Conformance Rules) to the study data validator rules. An FDA Validator Rule is the criteria used to ensure compliance to a business rule, a standard, or the Study Data Technical Conformance Guide."

This document contains specific rules about individual domains and variables, categorized by IG versions, and includes descriptions of the rules and their related error messages. Some examples are provided in Figure 5 below.

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description
CT2001	FDA	FDAB017	Variable value not found in non-extensible codelist	Variable must be populated with terms from its CDISC controlled terminology codelist. New terms cannot be added into non-extensible codelists.
CT2002	FDA	FDAB017	Variable value not found in extensible codelist	Variable should be populated with terms from its CDISC controlled terminology codelist. New terms can be added as long as they are not duplicates, synonyms or subsets of existing standard terms.
CT2003	FDA	FDAB009	Coded and Decoded values do not have the same Code in CDISC CT	Paired variables such as TEST/TESTCD must be populated using terms with the same Codelist Code value in CDISC control terminology. There is one-to-one relationship between paired variable values defined in CDISC control terminology by Codelist Code value.

Figure 5. FDA Validator Rules Examples

Validation software such as Pinnacle 21 incorporate these rules for checking data for CDISC compliance.

FDA BUSINESS RULES

FDA Business Rules v1.5 June 2019.xlsx

Where the Validator Rules provide checks on the individual dataset and variable levels, the Business Rules provide more overarching checks on the CDISC package as a whole. The introduction to this spreadsheet explains that "FDA Business Rules describe the business requirements for regulatory review to help ensure that study data is compliant and useful and supports meaningful review and analysis." While these business rules are "expected to be followed where applicable," they are not meant to take the place of conformance rules or good clinical practice (GCP). See examples in Figure 6.

FDA Business Rule ID	FDA Business Rule
Clinical and Nonclinical	
FDAB008	All treatment exposure date/time should be between first and last study treatment date/time.
FDAB009	All paired variables should have a one-to-one relationship. Examples include short name and name of test; parameter name and parameter code or number; variable name and variable label, etc.
FDAB011	All trial design data should be submitted as specified in the FDA Study Data Technical Conformance Guide (TCG).
FDAB012	Deprecated in v1.5.
FDAB013	Deprecated in v1.5.

Figure 6. FDA Business Rules Examples

TECHNICAL REJECTION CRITERIA

The Technical Rejection Criteria (TRC) for Study Data document has been incorporated into the FDA's Appendix F of the Study Data Technical Conformance Guide. The FDA provides this list of criteria to help sponsors understand how the validation rules specified in the Electronic Common Technical Document (eCTD) submission standards guidance are applied when a submission is uploaded to FDA's Electronic Submissions Gateway. The validation checks will determine if the submission may be technically rejected from upload to the portal. The FDA began enforcing the TRC for study data in September 2021. Currently the primary focus of each of the TRCs is the inclusion of the Trial Summary domain for any submission.

ECTD SPECIFICATIONS

Electronic Common Technical Document (eCTD) v4.0 | FDA

This document describes how to organize the contents of a regulatory submission, including CDISC datasets in Module 5. On this webpage you will find: "… information on how to submit eCTD v4.0-based electronic submissions to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER)." The section on study data directs you to the Study Data Technical Conformance Guide.

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Study Data Technical Conformance Guide – Technical Specifications Document | FDA

This is an 80-page document that provides a detailed reference on numerous topics about on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog, including:

Planning and Providing Standardized Study Data: Discusses the Study Data Standardization Plan (SDSP) and Study Data Reviewer's Guides (SDRG) for clinical or nonclinical data.

Exchange Formats for Electronic Submission: Includes details about SAS® datasets including the transport format, restrictions on dataset size, dataset column length, variable and dataset descriptor length, variable and dataset names, and more.

Study Data Submission Format: Offers considerations and guidance on items such as model definitions, domain specifications, types of analysis data to include, handling imputed data, and more. The CDISC IGs expand on the information here to provide the more detailed instructions required to program datasets for submission.

Therapeutic Area Topics: Provides a list of TAUGs that are currently incorporated into FDA-supported CDISC foundational standards, with additional guidance for some specific TAUGs.

Terminology: Has general information about the use and maintenance of controlled terminology including CDISC controlled terminology and others such as MedDRA, WHODrug, SNOMED, and LOINC.

Electronic Submission Format: Includes the very important study dataset and file folder structures and descriptions, detailing exactly how to assemble the various CDISC-related files for submission.

Study Data Validation and Traceability: Discusses the use of the FDA Business and Validator Rules, and Technical Rejection Criteria, as well as an overview of the importance of study data traceability and standardization of legacy study data.

The conformance guide also includes several appendices that discuss the required and often challenging Trial Summary (TS) domain. Specifically, it includes the TS parameters for submission, which is no longer included in the IG that CDISC produced. Every effort should be made to include all of the parameters marked as “FDA Desired.”

The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that oversees the submission of clinical trials data as the FDA does in the United States.

The PMDA website: Technical information on electronic submission of application data (FAQs, data standard catalogs, etc.) | PMDA, pictured in Figure 7, includes links to numerous reference documents, web learning videos, rules, and examples for studies conducted in Japan.

Figure 7. PMDA Website with Information on Electronic Submission of Application Data

PROCESS ORGANIZATIONS AND VALIDATORS

There are also process organizations and CDISC standards data validators that provide useful guidance and checks, including:

PHUSE – The Global Healthcare Data Science Community: Provides templates for the Study Data Standardization Plan (SDSP) document, Study Data Reviewer’s Guide (SDRG) and Analysis Data Reviewer’s Guide (ADRG), plus white papers and a community forum.

TransCelerate – Pharmaceutical Research and Development (non-profit organization): Collaborates across the global biopharmaceutical research and development community.

Pinnacle 21 and PointCross: Provide CDISC standards validation software along with forums and informative articles.

HOW TO KEEP CURRENT

With so many resources that are frequently updated or appended, how can you stay current? CDISC.org is your first stop to view the latest standards and publications. You can set up a free account and sign up to receive emails from CDISC that will inform you of new document releases and educational opportunities. You can even participate in public reviews of upcoming standards and enhancements. Even better, when your company becomes a CDISC member, you will gain access to additional materials, as well as discounts on conferences and online classes. You can also apply on CDISC's website to become a CDISC volunteer. CDISC volunteer working group meetings are where the latest developments are formulated and discussed. CDISC's general information contact is info@cdisc.org. Note that while someone from CDISC may respond with general information, the CDISC organization does not offer consulting services directly.

Conferences such as the CDISC Interchanges and PhUSE Connect offer cutting edge information and announcements about upcoming enhancements. Other websites to consult frequently are Pinnacle's Community Forum and PhUSE's Blog or Archive.

And finally, take advantage of the many educational opportunities such as free and paid webinars on CDISC's Education page, trainings that Pinnacle and PhUSE produce, as well as classroom training and even training at your company.

CONCLUSION

The first question most sponsors will ask, given cost and time restrictions, is "Is it truly *required*?" The FDA Data Standards Catalog includes a column called "Date Requirement Begins" for each data standard listed. Another place to look is the Description tab for each item of the Standards section on CDISC.org. For example, as Figure 8 shows, the bold text clearly indicates that SDTM is a required standard for submission to both FDA and PMDA (for most studies that started after December 16, 2016). Note also that standards that are not required for submission today, such as CDASH, are likely to become a requirement soon. This is probably the most important reason for engaging in the CDISC community and assigning staff to report on important updates.

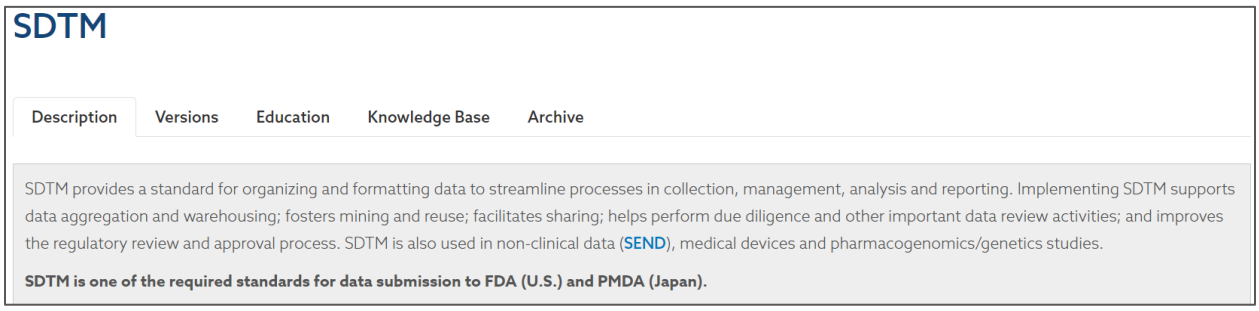

Figure 8. Description Tab

The second question after assessing the many CDISC-related resources is, "What do I do if there appears to be a conflict in the information provided by multiple documents?" Conflicts are rare because the various CDISC committees are well organized by a central governing group and consistency and flow between standards are a key discussion point during both development and updates of the models. The various resources discussed in this paper feed into the CDISC guidance documents, rather than competing. However, apparent conflicts are not unheard of and the general rule of thumb is that the CDISC model and accompanying IG are the definitive references. That said, it is important to confirm that you are using the most current version of each model at the time your study begins, and that you are using the version of the IG, controlled terminology, and other supporting documents linked to that version of the model. Otherwise, you may encounter conflicts in the rules caused by incorrect version control.

Two additional thoughts regarding conflicting rules/decisions: First, in the case of a conflict, the sponsor has the option to decide which rule to follow based on their own understanding of their study. It is recommended that the sponsor be consistent from project to project when such decisions are required. Some companies will compile their own set of Business Rules for CDISC programming to document their standard approaches. In such cases validation software such as Pinnacle 21 may report a warning message, which should be explained in the reviewer guide. Second, a regulatory authority such as FDA may on occasion request a change to the data structure that can conflict with existing standards and result in validation issues. In such cases it is best to comply with such requests and explain the conflicts in the documentation accompanying the data in your CDISC package.

This paper includes the most commonly referenced websites, while not an exhaustive list of everywhere helpful CDISC information may be found. The various information is all part of a network of related sources.

Certainly our lives would be easier if there were a single, definitive resource that held the answer to every CDISC standards question we have, including the critical challenges of conformance and compliance. But health research serves a variety of different needs, different customers, and different sources. CDISC standards are an ever growing and evolving set of criteria, and staying abreast of the wealth of available knowledge will continue to be key to successful data submissions.

REFERENCES

Resource	**Location (*Links are for the most current version as of writing of this paper*)**	**Purpose**
CDISC Official Website	https://www.cdisc.org/	All things CDISC including tools, documents, examples, education, and upcoming revisions
CDISC Models and Implementation Guides (IGs)	https://www.cdisc.org/standards	Model: details the fundamental structure of the standard; IG: supplements the sections in the model document with detailed instructions and examples
CDISC Therapeutic Area User Guides (TAUGs)	https://www.cdisc.org/standards/therapeutic-areas	Specialized user guides focused on specific diseases of interest
CDISC Conformance Rules	https://www.cdisc.org/standards/foundational/sdtmig/sdtm-and-sdtmig-conformance-rules-v2-0 https://www.cdisc.org/standards/foundational/adam/adam-conformance-rules-v4-0 https://www.cdisc.org/standards/foundational/send/send-conformance-rules-v4-0	Provides a more rigorous set of parameters by which to validate data; utilized by validation software
CDISC Controlled Terminology	https://www.cdisc.org/standards/terminology	Provides text values in the form of codelists to use with the foundational models to promote consistency across all data submissions
CDISC Define-XML Information	https://www.cdisc.org/standards/data-exchange/define-xml	Has information to help you produce the required Define-XML package

Resource	Location (*Links are for the most current version as of writing of this paper*)	Purpose
CDISC Metadata Submission Guidelines	https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0 https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v2-0	Provides guidance for putting together the actual submission package once it has been completed
CDISC Knowledge Base Articles and Examples (*Click on the foundational item of interest, and then the "Knowledge Base" tab*)	https://www.cdisc.org/standards	Provides articles, examples and known issues for various foundational items
FDA Study Data Standards Resources	https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources	Has a general page with an introduction and links to the most important FDA standards documents regarding data submissions
FDA Data Standards Catalog	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog-v90	Has an Excel spreadsheet that provides high-level information about required and permissible Submission Data Standards and Submission Data Terminologies
FDA Validator Rules	https://www.fda.gov/media/103587/download	Contains specific rules about individual domains and variables, categorized by IG versions, and including descriptions of the rules and their related error messages
FDA Business Rules	https://www.fda.gov/media/116935/download	Provides more overarching checks on the CDISC package as a whole
FDA Technical Rejection Criteria	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document	Provides this list of criteria to aid sponsors in understanding how the validation rules specified in the Electronic Common Technical Document (eCTD) submission standards guidance are applied when a submission is uploaded to FDA's Electronic Submissions Gateway
FDA eCTD Specifications	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd-v40	Describes how to organize the contents of a regulatory submission, specifically the inclusion of CDISC datasets in Module 5
FDA Study Data Technical Conformance Guide	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document	Provides a detailed reference on numerous topics about on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog

Resource	Location (*Links are for the most current version as of writing of this paper*)	Purpose
PMDA Official Website *(May need to click the "English" button in the upper right corner)*	https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0028.html	Includes links to numerous reference documents, web learning videos, rules and examples for studies conducted in Japan
Process Organization: PhUSE main website	https://phuse.global/	Provides templates for Study Data Reviewer's Guide (SDRG) and Analysis Data Reviewer's Guide (ADRG) as well as white papers and a community forum
Process Organization: PhUSE Blog	https://phuse.global/Communications/PHUSE_Blog/1	Features PhUSE events, working group news, and industry topics
Process Organization: TransCelerate (non-profit organization)	https://www.transceleratebiopharmainc.com/	Collaborates across the global biopharmaceutical research and development community
Validation Software: Pinnacle 21 main website	https://www.pinnacle21.com/	Offers Pinnacle 21 Validation Software, main website
Validation Software: Pinnacle 21 Community Forum	https://www.pinnacle21.com/forum	Offers various forums for news, general discussion, and support
Validation Software: PointCross	https://pointcrosslifesciences.com/edatavalidator/	Offers PointCross Validation Software, main website

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