CDISC News: New Standards & Pipeline

German CDISC User Network F2F / 14-Mar-2024

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Standard/Therapeutic Area Version	Published Date
SDTM for Observational Studies v1.0	28 February 2024
Glossary v18.0	15 December 2023
Rare Diseases Therapeutic Area User Guide	14 December 2023
Basic Data Structure for ADaM popPK Implementation Guide v1.0	6 October 2023
ADaM Conformance Rules v5.0	6 October 2023
CDASHIG v2.3	28 September 2023
CDASH Model v1.3	28 September 2023
COVID-19 Therapeutic Area User Guide v2.0	7 September 2023
Dataset-JSON v1.0	23 August 2023
ODM v2.0	23 August 2023
CT-XML v1.2 (Controlled Terminology)	23 August 2023
TMF Reference Model v3.3.1	15 August 2023
SEND Conformance Rules v5.0	28 June 2023
SENDIG-DART v1.2	28 June 2023
SENDIG-Genetox v1.0	28 June 2023
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	6 June 2023
ADaM Metadata Submission Guidelines v1.0	18 April 2023
Pediatrics User Guide v1.0	22 February 2023

[Publications | CDISC](#)

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Year	Working Group	Deliverable Types	Deliverable Format	Title	Status	Links
2023	Optimizing the Use of Data Standards	Reference	Template	(E) Validation Error	Current	(E)_Validation_Error_E2023.pdf
2023	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	BDRG V3.0 Package	Current	BDRG+V3.0+Package.zip
2023	Optimizing the Use of Data Standards	Regulatory Referenced Deliverable	Template	iADRG	Current	iADRG V1 Package.zip

[Deliverables | PHUSE](#)

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Agenda

Selected CDISC/PHUSE Publications since Jan-2023

- NSV Registry
- Controlled Terminology Relationships v1.0 for SDTM v1.4 and SDTMIG v3.2
- Considerations for SDTM Implementation in Observational Studies and Real-World Data v1.0.pdf (cdisc.org)
- ADaM Metadata Submission Guidelines v1.0
- Basic Data Structure for ADaM popPK Implementation Guide v1.0
- CDASH Model v1.3 /CDASHIG v2.3
- ODM v2.0 / Dataset-JSON v1.0
- (E)_Validation_Error_E2023.pdf (PHUSE)

Pipeline

- Standards Roadmap | CDISC

NSV Registry

What is it?

- Registry of standard values/fragments for QNAMs in SUPP– datasets
  - [Approved Non Standard Variables 2023-04-20](#)
  - [Approved Fragments 2023-04-20](#)

Variable Name	Label	Description	Notes	Status of the NSV Review	Source(s)	Status of the Source Document	Publication Date of the Source Document	Requester Remarks	Curator Remarks	Role	Qualifying Variable(s)
ATC1CD	ATC Level 1 Code	The assigned dictionary code denoting the first level grouping from the ATC Classification System.	The ATC Level 1 Code indicates the anatomical main group.	Approved	CDASHIG vX.Y	Published			https://www.whocc.no/atc/structure_and_principles/	Non-Standard Variable Qualifier	ATC1
ATC1CD	ATC Level 1 Code	The assigned dictionary code denoting the first level grouping from the ATC Classification System.	The ATC Level 1 Code indicates the anatomical main group.	Approved	CDASHIG v2.2	Published			https://www.whocc.no/atc/structure_and_principles/	Non-Standard Variable Qualifier	ATC1
ATC1	ATC Level 1 Name	The first level of grouping from the Anatomical Therapeutic Chemical (ATC) Classification System	Indicates the anatomical main group.	Approved	CDASHIG vX.Y	Published		This has codes for ATC1-5 and then ATCnCD were n is 1-5.	Making a new NSV for each ATC code.	Non-Standard Variable Qualifier	TRT
ATC1	ATC Level 1 Name	The first level of grouping from the Anatomical Therapeutic Chemical (ATC) Classification System	Indicates the anatomical main group.	Approved	CDASHIG v2.2	Published		This has codes for ATC1-5 and then ATCnCD were n is 1-5.	Making a new NSV for each ATC code.	Non-Standard Variable Qualifier	TRT

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Controlled Terminology Relationships

What is it?

- Big Excel File with relationships between
  - published Controlled Terminology codelists (mainly SDTM CT 2021-03-26)/ terminology subsets and those CDISC variables, Tests, Parameters, and NSVs that are published in SDTM v1.4, SDTMIG v3.2, Therapeutic Area User Guides, and regulatory documents

Use Cases

- Improve process automation to create Trial Design datasets for submissions
- Single source input to data validation software for terminology requirements
- Enable data to comply to Controlled Terminology requirements upfront

CT Relationships – "How to read" Examples

One variable, one codelist scenario

Domain	Variable	CDISC CT Codelist Short Name	CDISC CT Codelist C-Code	CDISC CT Codelist Long Name
AE	AEACN	ACN	C66767	Action Taken with Study Treatment
For the AEACN variable in domain AE, use the Action Taken with Study Treatment (ACN) codelist, c-code C66767. No further code term restrictions apply				

Codelist subset

Domain	Variable	CDISC CT Codelist Short Name	CDISC CT Codelist C-Code	CDISC CT Codelist Long Name	Allowed Subset of Value(s) from CDISC CT	C-Code for Allowed Subset of Value(s) from CDISC CT
AE	AECONTRT	NY	C66742	No Yes Response	N; Y	C49487; C49488
For the AECONTRT variable in domain AE, use the No Yes Response (NY) codelist, c-code C66742. Only the values of N (C49487) and Y (C49488) are permissible.						

Conditional codelist

Domain	Variable	Condition 1	C-Code for Value in Condition 1	CDISC CT Codelist Short Name	CDISC CT Codelist C-Code	CDISC CT Codelist Long Name
SUPPAE	QVAL	QNAM EQ "AETRTEM"		NY	C66742	No Yes Response
For the QVAL variable in domain SUPPAE, where QNAM is equal to "AETRTEM", use the No Yes Response (NY) codelist, c-code C66742. No further code term restrictions apply. The value AETRTEM does not have a c-code.						

➤ More Examples in "Read Me" sheet of [Controlled Terminology Relationships v1.0 for SDTM v1.4 and SDTMIG v3.2 (XLSX)](#)

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SDTM for Observational Studies v1.0

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Considerations for SDTM Implementation in Observational Studies and Real-World Data v1.0.pdf (cdisc.org)

ADaM MSG v1.0

ADaM popPK (ADPPK) IG v1.0

➢ Population Pharmacokinetics - ADaM Implementation

Table 3.1. Data Structure

Data Structure Name	Data Structure Description	Class of Dataset	SubClass of Dataset	CDISC Notes
ADPPK	Basic Data Structure Population Pharmacokinetic Analysis	BASIC DATA STRUCTURE	POPULATION PHARMACOKINETIC ANALYSIS	Dataset designed to support PPK. Sourced from SDTM (e.g., PC, DM, EX, LB) and ADaM (e.g., ADSL and ADEX datasets).

- contains multiple stacked analysis variables, multiple time indices, numerous cofactors
- supports exclusion of specific records to facilitate model-based sensitivity analyses
- data from single studies or a pool of studies
- template for input into a software package for PopPK (e.g., NONMEM)
  - creation of the input file for a specific software may require some adaptations
  - some variable names are based on names required by NONMEM and other PopPK software (e.g., DV, EVID, MDV)
- Source for some TLFs included in the population PK report
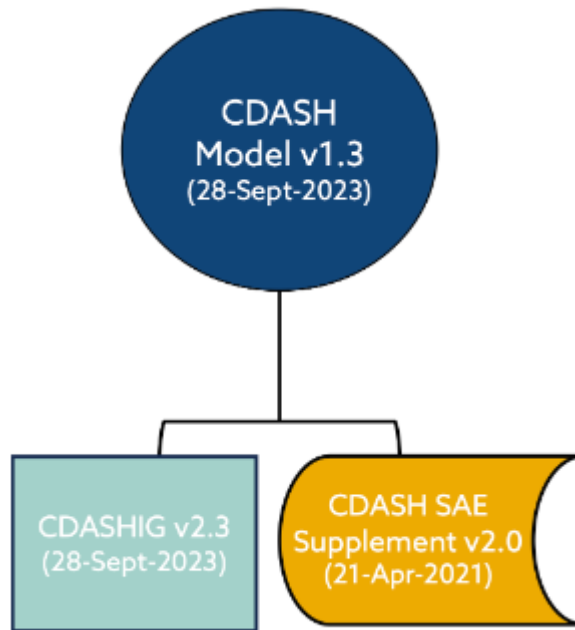
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ADaM popPK (ADPPK) IG v1.0 (cont.)

CDISC Basic Data Structure for ADaM PopPK Implementation Guide (Version 1.0 Final)

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CDASH v1.3 / CDASHIG v2.3

Model aligns with SDTM v2.0

IG aligns with SDTMIG v3.3 and SDTMIG v3.4

Appendix C: Revision History – Changes from Previous Version of CDASHIG and CDASH Model

The most significant changes are listed below:

- Inclusion of additional SDTMIG v3.3 domains (i.e., CV, MK, NV, UR)
- Inclusion of SDTMIG v3.4 domains (i.e., GF, CP)
- Adding SA domain and variables from the SAE Supplement v2.0
- Changes to CDASHIG and CDASH Model variable labels, where needed, to more closely align with SDTMIG and SDTM variable labels
- Updated HO date/time prompts to include HOTERM as an optional element
- Included "regulations" in definition and CRF Completion Guidelines for AESER
- Administrative updates that may include metadata consistency to standardize variable definitions across domains

ODM v2.0

"The Operational Data Model (ODM) is a vendor-neutral, platform-independent data exchange format, intended primarily for interchange and archival of clinical study data."

Includes clinical data, associated metadata, administrative data, reference data, audit information

ODM v2.0 breaks backward compatibility

ODM v2.0 can be serialized as XML, JSON, or other formats

Changes from Previous Versions (non-normative) - PUBLIC - Wiki (cdisc.org)

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Dataset-JSON v1.0

CDER and CBER, in collaboration with CDISC and PhUSE, has conducted preliminary testing of CDISC's Dataset JSON message exchange standard. Initial results indicate potential use as a replacement for XPT v5. As such, CBER and CDER will conduct further testing to evaluate Dataset JSON's capability to support the submission of regulatory study data. Results will be communicated, and we will engage stakeholders for input as we progress through this evaluation.

Study Data Standards Resources | FDA

Home / Dataset-JSON

Dataset-JSON

Pilot   **Specification**

CDISC and PHUSE are delighted to announce a new pilot project aimed at supporting the adoption of Dataset-JSON as an alternative transport format for regulatory submissions. This pilot builds upon the considerable amount of work done over the years to replace XPT as the default file format for clinical and device data submissions to regulatory authorities.

The pilot will be split into short-term goals of the acceptance of Dataset-JSON as a transport format option (in addition to existing XPT format), as well as the development of the future strategy relating to the adoption of advanced Dataset-JSON. An initial report is planned for Q1 2024.

Milestone 1: Short-Term

- Pilot submissions using the JSON format with existing XPT ingress/egress to carry the same data
- Same content, different suitcase, no disruption to business process on either side
- In parallel, evaluate with the FDA how their toolset can support JSON format and identify a tool upgrade roadmap

Milestone 2: Development of Future Strategy

- Evaluate how current and future industry standards can benefit without XPT limitations (e.g., Variable names > 8, labels > 40, data > 200)
- Evaluate combining metadata with data (e.g., Define-XML / Define-JSON based)
- Enhanced conformance rules
- Collaborate with the FDA to develop plans to retool their environment to natively consume JSON

https://www.cdisc.org/dataset-json

Dataset-JSON as Alternative Transport Format for Regulatory Submissions - WORKING GROUPS - PHUSE Advance Hub

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Template for Issue Explanations to be included in SDRG/ADRG

PHUSE Deliverable

Related to White Paper
"Best Practices for the Submission of Data in Japan"
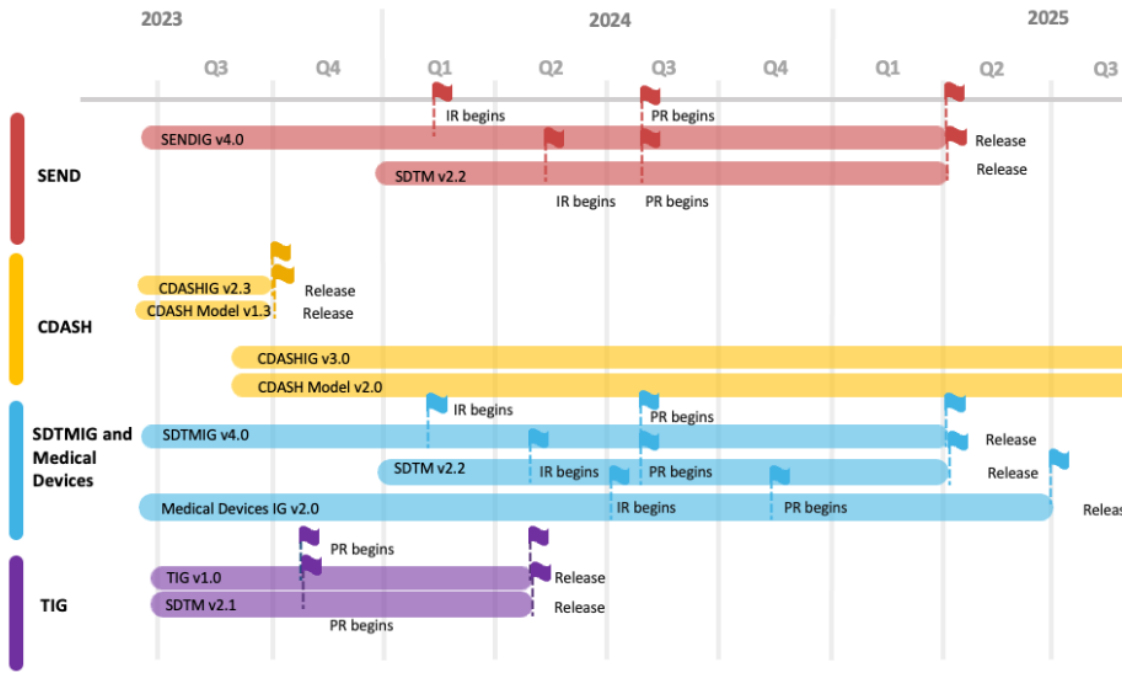(WP-071.pdf)

Initially developed in EXCEL

Converted to PDF for publishing

(E)_Validation_Error_E2023.pdf (phuse.s3.eu-central-1.amazonaws.com)
Electronic Data Submission in Japan - WORKING GROUPS - PHUSE Advance Hub

Foundational Standards Roadmap as of Q4 2023

Document	Proposed Scope/Change	Proposed Scope/Change Description	Impacts	Benefits
SDTMIG v4.0	SUPP to NSV	Prior to SDTMIG v4.0, SUPP datasets need to be transposed before appending to the parent dataset. The proposed structure of the new NSV datasets is already horizontal which will make it much easier for reviewers to join the data back to the parent. NSVs can have defined variable level metadata in addition to value level metadata.	Sponsors and the industry at large will need to update their tools and conformance rules to handle the creation of NSV datasets rather than SUPPQUAL. Review and validation tools will need to be updated as well. The post-processing steps would be simplified, and it would make the merge easier.	Easier for reviewers to join the data back to the parent NSV variable-level metadata - For example, data type or length vs only having 'text' for SUPP.QVAL, you can have numeric values and additional qualifiers. It aligns visually with the TAUG representations. Many sponsors already store their SDTM datasets in a structure that appends the NSVs to the parent domains.
SDTMIG v4.0	QRS Instrument Reference (QX) domain	Allow sponsors to provide information about a QRS instrument in a structured format. Currently, this metadata is stored in SUPPQUAL at the subject-level and is the same for every subject. This can result in large file sizes for trial level information. The QX domain will be able to manage instrument-level metadata such as upper and lower ranges for Visual Analog Scales (VAS).	New Domain	Provide a solution for storing QRS instrument metadata at the instrument level rather than the subject-level for a trial.
SDTMIG v4.0	Multiple Subject Instances - DC domain	Handling of data in studies where subjects can re-screen or participate in the same study more than once has been a longstanding issue. Guidance for how to handle the data is provided in the FDA sdTCG and the standards being developed will expand on the minimal guidance currently provided. There are also use cases that can be applied for SEND.	New Domain	Sponsors will have a standardized approach for submitting data for multiple subject instances that will facilitate review. SUBJID will be available in most domains where needed. Companies right now are handling it in an inconsistent manner - so everyone would need to adjust and handle it in a standardized manner using the new DC domain.

Standards Roadmap | CDISC

Thank You!

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