CDISC Italian User Network TC

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Presented by Silvia Faini (Cytel), Mauro Cortellini (Chiesi) and Angelo Tinazzi (Cytel)

21.02.2024

Agenda

1. CDISC EU Interchange 2024 Agenda
2. CDISC Italian UN F2F Meeting
3. Estimands and Data Standards (draft PHUSE white paper)
4. CDISC CORE Update
5. SOGI - Sexual Orientation and Gender Identity
6. WHO-DD and CDISC
7. CDISC and Regulatory Data Submission What's New
8. Other Topics and Q&A

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CDISC EU Interchange 2024 Agenda

CDISC EU Interchange 2024

24-25 April 2024 – Berlin – Main Conference

22-23-26 April 2024 – Berlin – Trainings

Early bird discount until February 23rd

https://www.cdisc.org/events/interchange/2024-cdisc-tmf-europe-interchange

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CDISC EU Interchange 2024

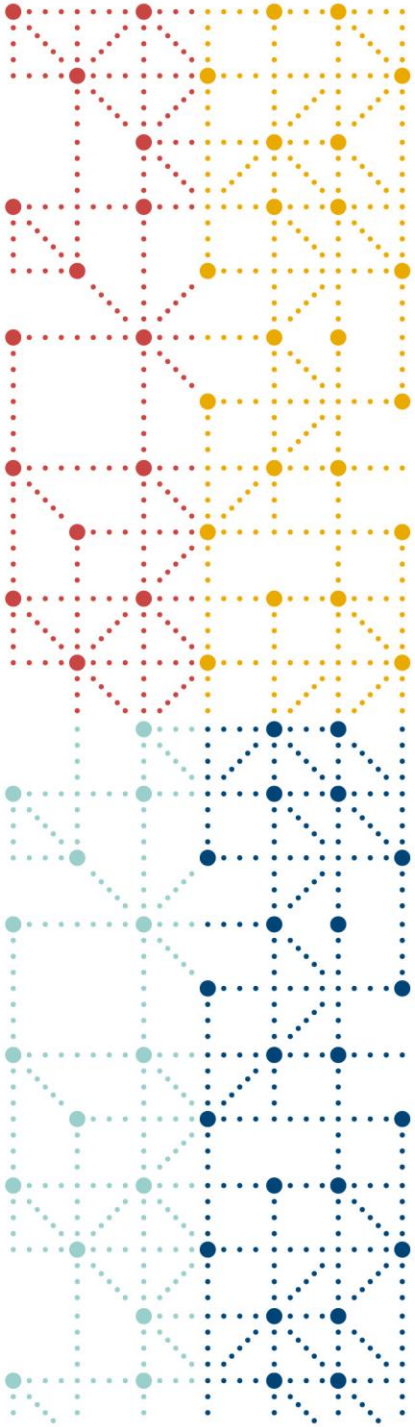
Discounted Tickets

- 3 discounted passes
- Applicable to anyone from the Italian UN who have not attended a CDISC Interchange (virtual or in-person) over the past 3 years
- 50% special passes for 900$
- Email Angelo or Silvia if interested

CDISC EU Interchange 2024 – Agenda

- 3 «Italians» presenting + 1 Poster
- Discounted tickets: Applicable to anyone from the Italian UN who have not attended a CDISC Interchange (virtual or in-person) over the past 3 years
- Email Angelo or Silvia if interested

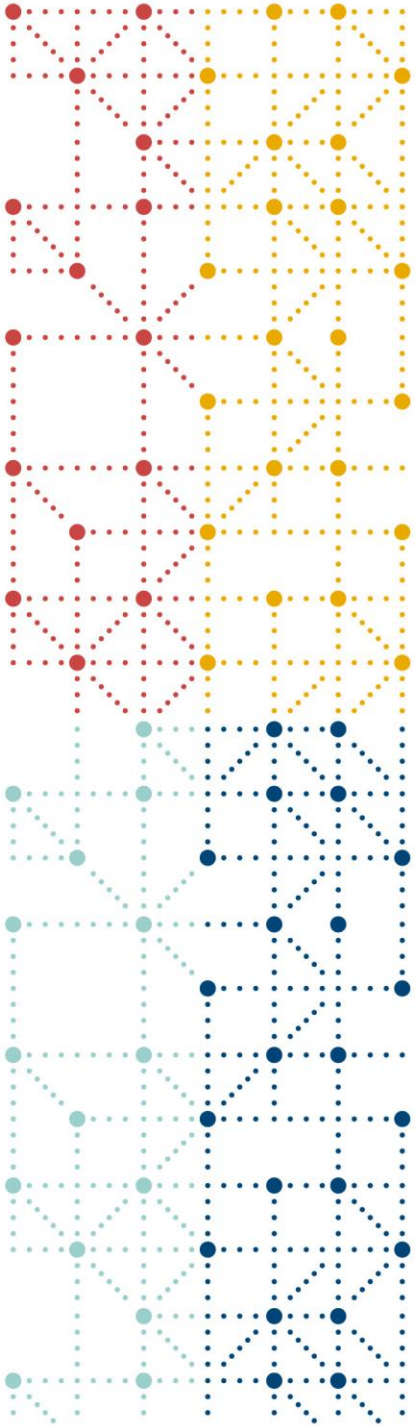
https://www.cdisc.org/events/interchange/2024-cdisc-tmf-europe-interchange/program



CDISC Italian UN F2F Meeting

CDISC Italian UN F2F Meeting

- SAS Institute Milan to confirm
- 15,17,22 or 24 May
- Contact us if you have any topic you would like to cover / discuss
- Possible idea
  - Open Source
  - Standards Adoption
  - Estimands



PHUSE white paper - Implementation of ICH E9(R1) Estimands Framework using Data Standards

ICH E9 (R1) and PHUSE White Paper

30JUL2020 → ICH E9(R1) Date for coming into effect

12MAY2023 → ICH E9(R1) estimand framework & CDISC - Marian Mitroiu, PhD - IX CDISC Italian User Network

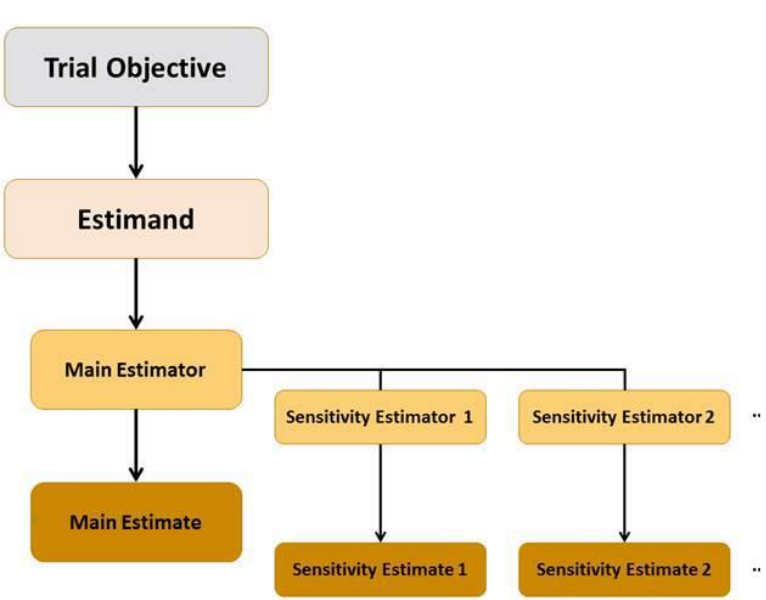
15NOV2023 → White paper draft out for feedbacks' collection by 17JAN2024
[…] recommendations and examples to illustrate the implementation of the estimands framework using data standards.

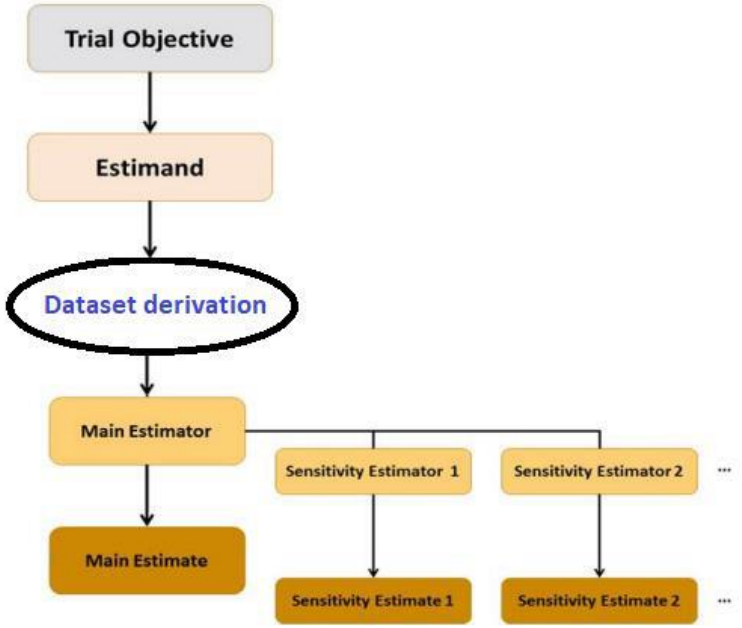
ICH E9 (R1) - Estimands Framework

Clarity for “treatment effect” understanding

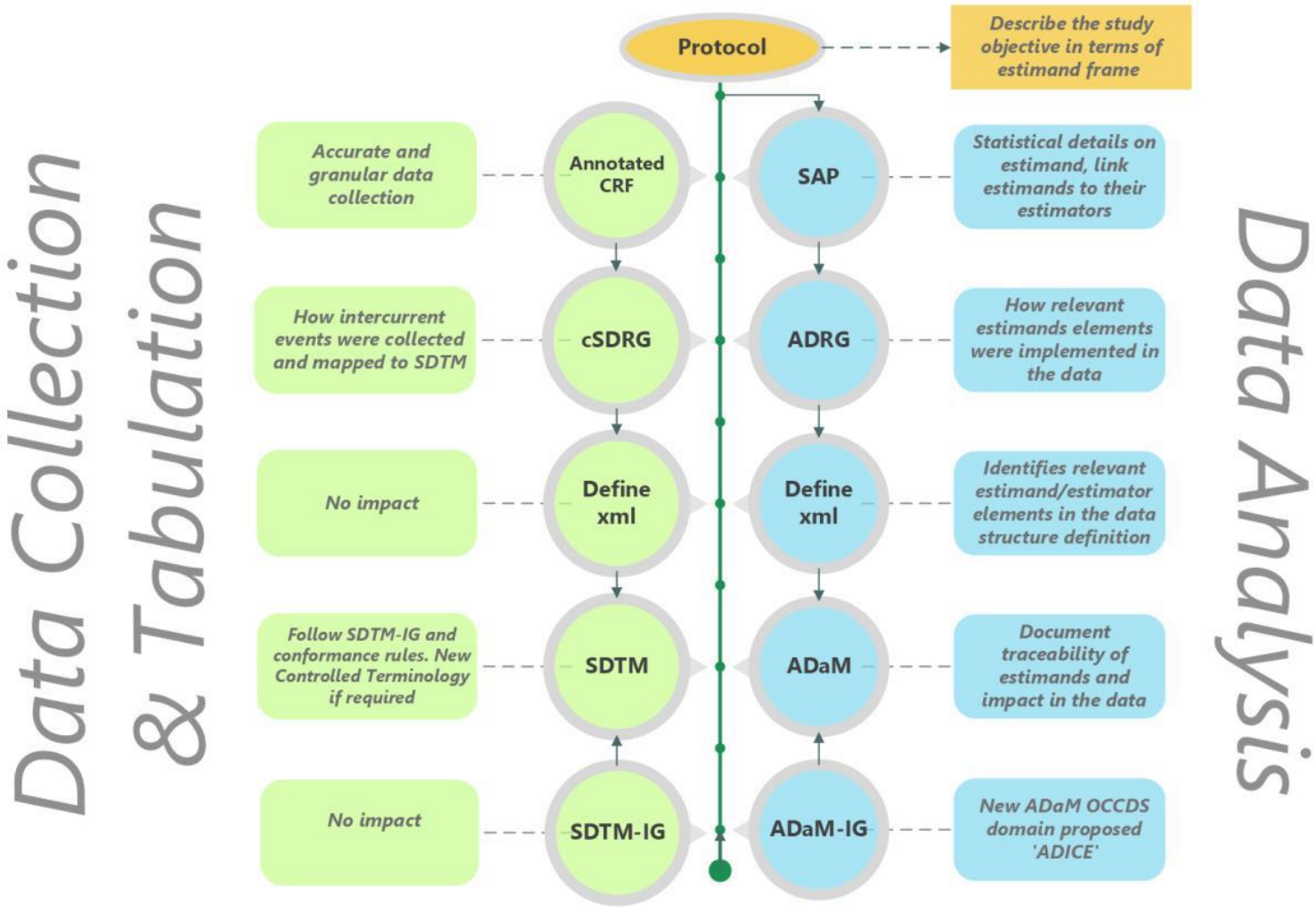
Precision in describing a treatment effect of interest is facilitated by constructing the “estimand” (see Glossary; A.3.) corresponding to a clinical question of interest. Clarity requires a thoughtful envisioning of “intercurrent events” (see Glossary; A.3.1.) such as discontinuation of assigned treatment, use of an additional or alternative treatment and terminal events such as death. The description of an estimand should reflect the clinical question of interest in respect of these intercurrent events, and this addendum introduces strategies to reflect different questions of interest that might be posed. The choice of strategies can influence how more conventional attributes of a trial are reflected when describing the clinical question, for example the treatments, population or the variable (endpoint) of interest.

ICH E9 (R1) and PHUSE White Paper



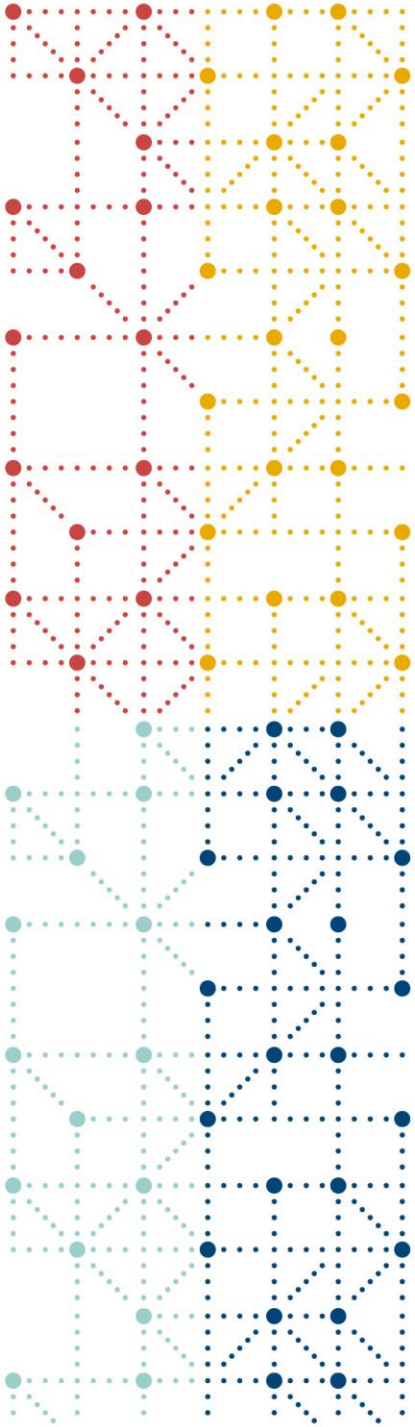


PHUSE White Paper – impacts overview



WP Figure 2 - Documentation to Data. The flow is organized according to the logical documentation hierarchy, from the perspective of the reviewer, rather than a sequential generation order.

Estimands impacts on Data Collection & Tabulation



Data Collection & Tabulation

Accurate collection of intercurrent events (ICE) is critical in defining estimands and constructing the estimations:

- enhance CFR standards – accurate and granular data collection – examples in WP
- Controlled terminology – proposed CT in WP for some ICEs → these will undergo into CT process for CDISC CT approval / update
- SDTM and define-xml – no specific impact
- CSDRG – section for ICE in “Additional contents of interest”

Data Collection & Tabulation – CRF

Disposition CRF Example

Document the subject's status for trial period. If the subject discontinued treatment prematurely, record the primary reason for discontinuation.	What was the subject's status? DS.DSDECOD DS.DSTERM	○ **COMPLETED** ○ **DEATH** ○ **ADVERSE EVENT. List the adverse event ID:** _____ ○ **PREGNANCY** ○ **LACK OF EFFICACY** ○ **SUFFICIENT EFFICACY** ○ **PROTOCOL DEVIATION** ▪ DID NOT MEET STUDY ELIGIBILITY CRITERIA AT ENROLLMENT ▪ TOOK PROTOCOL PROHIBITED CONCOMITANT MEDS ▪ NONCOMPLIANCE TO STUDY PROCEDURES ▪ NONCOMPLIANCE TO STUDY INTERVENTION ○ **LOGISTICAL PROBLEM** ▪ RELOCATION ▪ SCHEDULE CONFLICTS OR DIFFICULTY TRAVELING TO SITE ▪ PERSONAL/FAMILY REASONS NOT RELATED TO EFFICACY OR SAFETY OF THE STUDY DRUG/DEVICE ▪ UNSATISFIED WITH STUDY PROCEDURES ▪ UNSATISFIED WITH STUDY DRUG DELIVERY DEVICES/METHODS ▪ FEAR OF NEW OR RECURRENT ADVERSE EVENTS ▪ STUDY TERMINATION OR SITE CLOSURE ▪ CLINICAL TRIAL MATERIAL QUALITY ISSUE OR SHORTAGE ▪ GEOPOLITICAL LOGISTICAL RESTRICTIONS ▪ OPERATIONAL ERROR ▪ BLIND BROKEN ○ **LOST TO FOLLOW-UP**

WP Figure in section 5.1.1

Data Collection & Tabulation – CT

Eight primary categories from NCOMPLT:

- DEATH
- ADVERSE EVENT
- PREGNANCY
- LACK OF EFFICACY
- SUFFICIENT EFFICACY
- PROTOCOL DEVIATION
- LOGISTICAL PROBLEM
- LOST TO FOLLOW UP

To improve the accuracy and specificity of data collection, two primary categories, "PROTOCOL RESTRICTED DEVIATION" and "LOGISTICAL PROBLEM", have been further broken down into granular sub-categories.

Data Collection & Tabulation – cSDRG

Question and Answer Format

Intercurrent Events:

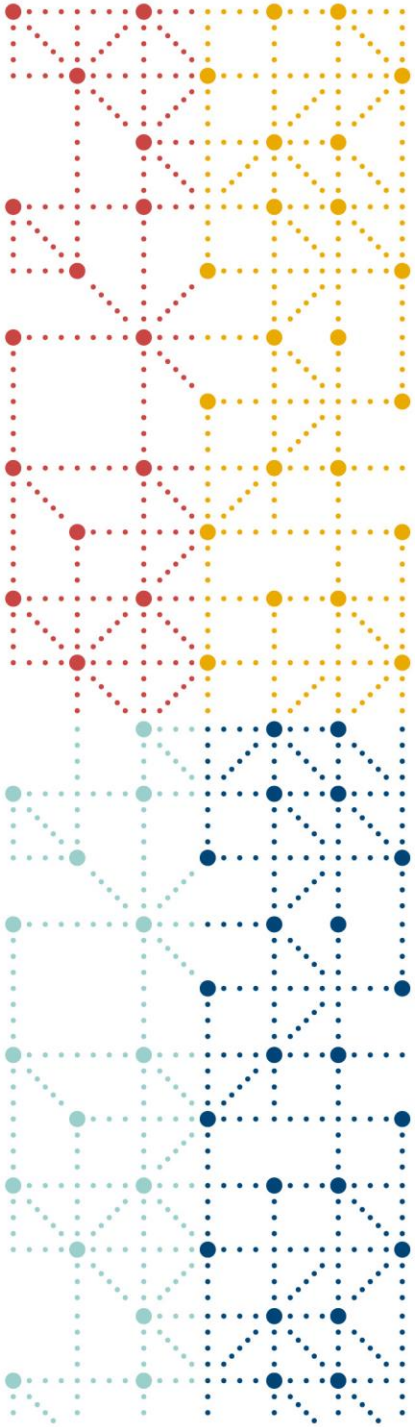
1. Are intercurrent events collected for this study? If so, what are the intercurrent events considered for implementation of estimands?
2. In which CRF forms were details of intercurrent events collected?
3. In which SDTM domains (and variables) were intercurrent events mapped?
4. What Controlled Terminology was used? Were there any additional terms included in the codelist?

Table Format

Intercurrent Events:

Intercurrent Event collected in the Study	In which CRF forms were details of intercurrent events collected?	In which SDTM domains (and variable) were intercurrent events mapped?	What Controlled Terminology was used? Were there any additional terms included to the codelist?

Estimands impacts on Data Analysis



Data Analysis

The Addendum mentions that: *"Clarity is introduced by carefully defining the treatment effect of interest in a way that determines both the population of subjects to be included in the estimation of that treatment effect and the observations from each subject to be included in the analysis considering the occurrence of intercurrent events."* That extra clarity translates into **new requirements in the analysis datasets for proper support of the estimands framework**.

Data Analysis

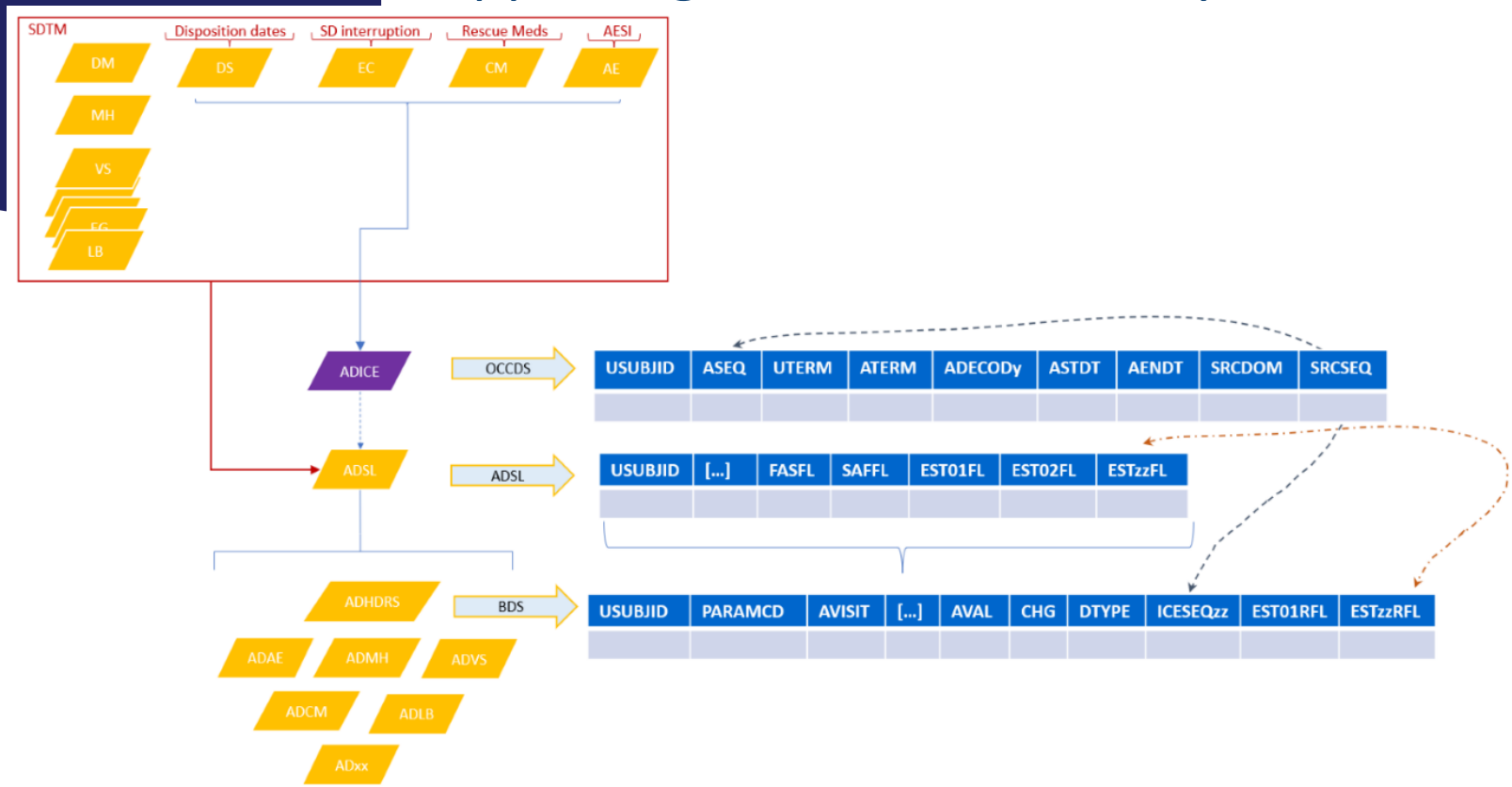
The new requirements that are supported by the ADaM estimands implementation framework are:

- **Intercurrent Events:** provides ways to organise, identify, and document intercurrent events, their relationship with each estimand and the related handling strategy.
- **Datapoints:** provides ways to document datapoints affected by intercurrent events and if they can be considered for analyses.
- **Population:** support for estimand's specific definition of the population of subjects used for estimations.

All existing features of the ADaMIG are acknowledged and no existing ADaM feature is prevented or discouraged from being used.

Data Analysis – Dataset level

The **ADSL** and **ADICE** datasets are ideally built at the very beginning of the analysis data flow to serve **as support for** documenting the impact of intercurrent events into the **other ADaM datasets** supporting the statistical analyses



Data Analysis – ADICE

Intercurrent events data is a **collection of intercurrent events occurrences, recording**: the name of the intercurrent event, along with the start and end date/time and relevant identification, traceability, and classification information; including standardised name/category per estimand and handling strategy per estimand.

Occurrence Data Structure (OCCDS) class → consequently a dedicated ADICE structure, as a sub-class of the OCCDS class, is proposed.

Data Analysis – ADICE

Three approaches:

- including the ADICE structure into existing OCCDS dataset, e.g., a dataset already built to collect some events;
- using several OCCDS datasets to document the intercurrent events.
  - The framework and its documentation features support such cases of multiple intercurrent events documentation datasets.
- adding the intercurrent events information directly into ADSL → only potentially be suitable for the simplest cases of intercurrent events, such as single occurrences of single events.

	Variable	Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
	ADSL					
	Population flags					
*	ESTzz*FL [1, 2]	Estimand zz* Population Flag	Char	YN	Perm	Subject considered for estimand zz* in ADSL. Useful when only a subset of subjects must be considered for the estimand, e.g. selection based on a baseline characteristic, principal stratum strategy. Can be copied into other datasets.
	ADICE structure					
	Identifiers					
	STUDYID	Study Identifier	Char		Req	
	USUBJID	Unique Subject Identifier	Char		Req	
	Sequence numbers					
	ASEQ		Num		Req	Unique number per record, per subject, per intercurrent event
*	ICEzzGID	Intercurrent Events Grouping zz ID			*Perm*	*Identifier used to group intercurrent events affecting jointly a datapoint. More than one ICEzzGID variable would be needed only in the situation where some intercurrent events could be part of multiple groupings. This variable is reserved for future use not detailed in this whitepaper.*
	Record topic (event)					
	--TERM	{Reported Term}	Char		Cond[3]	Original intercurrent event term when there is only one source event domain.
	UTERM	Unmodified Reported Term	Char		Cond [3]	Original intercurrent event term when there are multiple source events domains.
	--TRT	{Reported Name of Drug, Med, or Therapy}	Char		Cond [3]	Original intercurrent event when there is only one source intervention domain.
	UTRT	Unmod. Rep. Name of Drug, Med, or Thrpy.	Char		Cond [3]	Original intercurrent event when there are multiple source intervention domains.
*	ATERM	Analysis Term	Char		Cond [3]	Analysis term describing the intercurrent event. A more granular description of the intercurrent event, close to the source. This would be used when: • **There are intercurrent events that are not directly an SDTM reported event or** intervention. E.g. A lab finding above some threshold, an AE that is severe. In such cases an intercurrent event is derived: E.g., lab test <xxx> above <yyy> threshold, <aeterm> with grade <y>. • In general, when there are multiple sources of intercurrent event of different SDTM
						intake of some concomitant medications are intercurrent events, then ATERM is used and could contain either an AE or a medication. When present, it must be filled for all records.

Data Analysis – Variable level

	Record start/end date and time					
*	ASTDT	Analysis Start Date	Num		Cond [5]	Source start date of the intercurrent event in numerical format. One of ASTDT/ASTDTM must be present.
	ASTDTM	Analysis Start Datetime	Num		Cond [5]	Source start datetime of the intercurrent event in numerical format. One of ASTDT/ASTDTM must be present.
	AENDT	Analysis End Date	Num		Perm	Source end date of the intercurrent event in numerical format. Included if the intercurrent event end-date is relevant to assess the impact of the intercurrent event on datapoints.
	AENDTM	Analysis End Datetime	Num		Perm	Source end datetime of the intercurrent event in numerical format. Included if the intercurrent event end-datetime is relevant to assess the impact of the intercurrent event on datapoints.
	Source code and classifications					
	--DECOD	Dictionary-Derived Term	Char	*	Perm	Source coding, single source, useful to support. --DECOD/UDECOD are mutually exclusive.
	UDECOD	Dictionary-Derived Term	Char	*	Perm	Source coding, multiple sources. --DECOD/UDECOD are mutually exclusive.
	*		Char	*	Perm	Any source classification if relevant for intercurrent event could be included, e.g., AEHLT, AEHLGT, AESOC, ATCy, ATCyCD ....
	Source code and classifications					
*	ADECODy	Analysis Dictionary Derived Term {y}	Char	*	Perm	Coded version of the intercurrent event, at lower level of granularity needed according to intercurrent event definition. Present the intercurrent event in a standardised way, related to the intercurrent event definition and policies. This is the lower level (more granular standard definition) across all estimands. There would be more than one variable such only if an intercurrent even would have a different standardised name for some estimands.
	ACATy	Analysis Category {y}	Char	*	Perm	Categorisation of the intercurrent events. Useful when there are different levels of granularity of intercurrent event across estimands. E.g. One has notion of "Treatment discontinuation due to AE" and "Treatment discontinuation due to Lack of Efficacy".
	Intercurrent event handling strategy					
*	ESTzz*STR [1, 2]	Estimand zz* handling strategy	Char	(ESTSTRAT) [4]	Req	Strategy for handling the intercurrent events related to estimand zz*. Blank if the intercurrent event is not related to estimand zz*. Else filled with the strategy to handle it.
	Traceability					
	--SEQ	Sequence Number	Num		Cond [6]	Single domain source of all intercurrent event s. One of --SEQ or the pair SRCDOM/SRCSEQ is required to point to source record for the intercurrent event.

Data Analysis – Variable level

	SRCDOM	Source Data	Char		Cond [6]	Name of the parent dataset holding the intercurrent event. Normally the name of the parent SDTM domain. It could also be another ADaM dataset. Include if SRCSEQ is included.
	SRCSEQ	Source Sequence Number	Num		Cond [6]	Sequence number of the intercurrent event record in parent domain. Normally value of --SEQ or of ASEQ if the parent is another ADaM dataset. One of --SEQ or the pair SRCDOM/SRCSEQ is required to point to source record for the intercurrent event.
	Analysis Datasets supporting the estimators					
	Records included in estimand zz* estimations					
*	ESTzz*RFL [1,2]	Estimand zz* Record-Level Flag	Char	Y	Perm	Datapoint included for estimand zz* estimation; can appear in ADaM datasets (BDS/OCCDS/OTHER).
	Intercurrent event impacting datapoints					
*	ICESEQzz* [1]	Impacting ICE seq. Num. for Est. zz*	Num		Req	Point to the intercurrent event(s) impacting the datapoint for estimand zz* estimations - it can depend on the strategy defined for each intercurrent event that can impact estimand zz*. The variable is filled with the intercurrent event identifier impacting the datapoint for estimations; that is typically the value of ASEQ from the intercurrent event record. Refer to the implementation consideration section for more details on documenting impact of intercurrent events on datapoints.
	ICEDOMzz* [1]	Dataset of Impacting ICE for Est. zz*	Char		Cond	Dataset holding the intercurrent event(s) impacting the datapoint for estimand zz*. Name of the dataset holding the intercurrent events. Must be present and filled only if there is more than one intercurrent event dataset present in the package. This variable can appear in ADaM datasets containing endpoints affected by intercurrent events.
	ICEVARzz* [1]	Impac. ICE seq. Num. Var. for Est. zz*	Char		Cond	Variable holding the intercurrent event(s) identifier impacting the datapoint for estimand zz*. Must be present and filled only if the record identifier variable in the intercurrent event dataset can be different from ASEQ.
	Analysis variables					
*	ANLzzFL	Analysis Flag {zz}	Char	Y	Cond	Analysis variable per ADaMIG. Per ADaMIG rule, it is related to analyses (i.e., estimators). It is optional, only if extra selection of records is needed for some analyses that cannot be performed with existing variables. It could be used instead of or in addition to the ESTzz*RFL. Note that the zz is used as usual here and related to analysis needs, it is not tied to the estimand number. The zz index of the analysis flag has its usual meaning, that is analysis related. It is not tie to the estimands numbering. There could be one zz value per estimator, or the variable could be shared across several estimators, or an analysis flag may not be used at all. Eventually, the record selection criteria for each estimator will be detailed in the ARM and/or ADRG.

Data Analysis – Variable level

Variable name	Variable Label	Variable Type	Source	Derivation
USUBJID	Unique Subject Identifier	text	DM.USUBJID	
ASEQ	Analysis Sequence Number	integer		Unique number per record, per subject.
ATERM	Analysis Term	text		See Value-level Metadata below, split out by SRCDOM
ASTDT	Analysis Start Date	integer		See Value-level Metadata below, split out by SRCDOM
AENDT	Analysis End Date	integer		If CMINDC= 'RESCUE THERAPY' then AENDT = CM. CMENDTC. Convert to numeric SAS date.
ADECOD1	Analysis Dictionary Derived Term 1	text		Starting other pharmacological treatments, Treatment discontinuation due to adverse events, Treatment discontinuation due to lack of efficacy, See Value-level Metadata below, split out by SRCDOM.
ACAT1	Analysis Category 1	text		Starting other pharmacological treatments, Treatment discontinuation If ADECOD1 in ('Treatment discontinuation due to lack of efficacy', 'Treatment discontinuation due to adverse events'), then ACAT1=' Treatment discontinuation'. Else if ADECOD1 = 'Starting other pharmacological treatments' then ACAT=ADECOD1.
ACAT2	Analysis Category 2	text		Treatment discontinuation due to Adverse Event/Lack of efficacy, if ADECOD1 in ("Treatment discontinuation due to adverse events", "Treatment discontinuation due lack of efficacy") then ACAT2 = "Treatment discontinuation due to Adverse Event/Lack of efficacy" Else empty.
EST01STR	Estimand 01 handling strategy	text		Hypothetical, Treatment Policy Strategy for handling the intercurrent events related to estimand 01. If ADECOD1 = 'Treatment discontinuation due to lack of efficacy' or 'Treatment discontinuation due to adverse events', then EST01STR ='Treatment Policy'. Else if ADECOD1 = 'Starting other pharmacological treatments' then EST01STR ='Hypothetical'. Based on Section 1.1, 4.2.2 of the SAP.
EST03STR	Estimand 03 handling strategy	text		Composite Strategy for handling the intercurrent events related to estimand 03. If ADECOD1='Treatment discontinuation due to adverse events' or 'Treatment discontinuation due to lack of efficacy' then EST03STR="Composite". Else if ADECOD1='Starting other pharmacological treatments' then EST03STR="Composite". Based on Section 1.1, 4.2.2 of the SAP.
SRCDOM	Source Data	text		Populate with the domain name that is the source of the record (DS or CM).
SRCSEQ	Source Sequence Number	integer	CM.CMSEQ, DS.DSSEQ	Populate with the sequence number from each source dataset.

Data Analysis – ADICE Variables

Variable	Where	Type	Codelist	Controlled Terms	Source/Derivation/Comment
ATERM	SRCDOM="DS"	text			DS.DSTERM
ATERM	SRCDOM="CM"	text			CM.CMDECOD
ADECOD1	SRCDOM="DS"	text			If DSDECOD='LACK OF EFFICACY' then ADECOD1= Treatment discontinuation due to lack of efficacy. If DSDECOD='ADVERSE EVENT' then ADECOD1= 'Treatment discontinuation due to adverse events'.
ADECOD1	SRCDOM="CM"	text			ADECOD1 =' Starting other pharmacological treatments'.
ASTDT	SRCDOM="DS"	integer			ASTDT =DS. DSSTDTC. Convert to numeric SAS date.
ASTDT	SRCDOM="CM"	integer			ASTDT = CM. CMSTDTC. Convert to numeric SAS date

Data Analysis – ADICE Value Level

Data Analysis – ADRG

Section 3.1 Estimands and Estimators

New section whose purpose is to group in a single location key information related to estimands and estimators implementation.

This links definition in the protocol and SAP with their implementation in the analyses datasets and results.

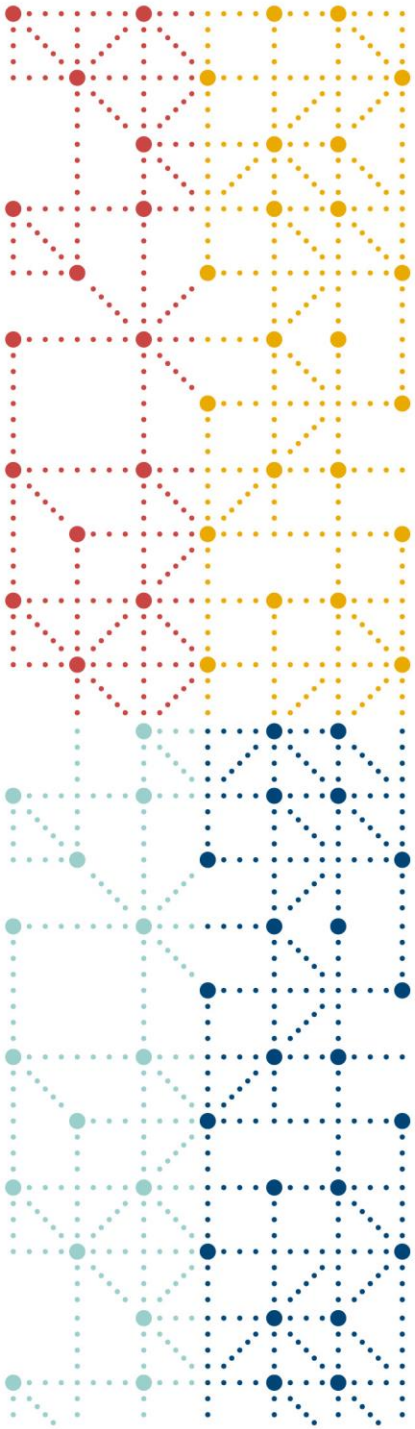
Other impacted sections: 3.2 Core variables, 3.6 Imputation/Derivation Methods, 4.2 Data Dependencies, 5.1 Overview, 5.2 Analysis Datasets

References

- “ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials”, Step 5, EMA/CHMP/ICH/436221/2017

- M.Mitroiu, “ICH E9(R1) estimand framework & CDISC”, IX CDISC Italian User Network

- PHUSE White Paper “Implementation of ICH E9(R1) Estimands Framework using Data Standards” V1.0 dated 2023-11-15



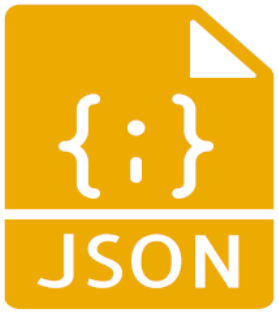
Core: CDISC Open Rule Engine

CDISC and FDA Collaboration Announcement

COSA – 2 Main Big Projects

- Conformance Rules – CORE

- Dataset JSON



Slide already presented at 25Oct2023 CDISC ITA UN mtg; today we focus on CORE

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CORE

https://www.cdisc.org/news/cdisc-proud-announce-research-collaboration-incorporate-fda-business-rules-cdiscs-open-rules

CDISC is Proud to Announce a Research Collaboration to Incorporate FDA Business Rules into CDISC's Open Rules Engine (CORE)

Austin, TX – January 16, 2024 – CDISC is proud to announce a research collaboration with the U.S. Food and Drug Administration's Office of Translational Sciences in the Center for Drug Evaluation and Research and Office of Regulatory Operations in the Center for Biologics Evaluation and Research to incorporate FDA Business Rules into CDISC's Open Rules Engine (CORE).

CDISC's CORE project provides an open-source version of the CDISC Conformance Rules in a machine-executable format. These rules, published and managed by CDISC, create a single source for conformance rules and allow external vendors and sponsor companies to implement and extend these rules within their tools. **FDA Business Rules** are currently written in a plain text, non-machine executable format and describe the business requirements for regulatory review to help ensure that clinical trial study data is compliant and useful and supports meaningful review and analysis.

The goal of this effort, which began on November 3, 2023 and has term of three (3) years, is to collaborate on providing input on machine-executable formats of the FDA Business Rules and on the development and ongoing governance of this set of executable rules within CORE that can be used by sponsors of medical product applications.

"CDISC is grateful for the opportunity to partner with CDER and CBER to establish a single source for machine-executable Conformance Rules and drive the implementation by the industry," said Peter Van Reusel, Chief Standards Officer at CDISC.

The benefits of creating a single comprehensive and credible source of validation rules include increasing access, transparency, and visibility of validation rules used to ensure the quality and usability of study data in FDA. This will enable sponsors to submit high quality study data that will be ready for regulatory review saving time and effort for all parties involved.

"Our research collaboration with CDISC is an important step to ensure that study data validation rules are understandable and accessible to all," said Lilliam Rosario, Ph.D., Director, Office of Computational Science, Office of Translational Sciences, CDER.

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SOGI: Sexual Orientation and Gender Identity

Public Review closes **22 February 2024**

https://wiki.cdisc.org/display/SOGI/Instructions+for+Reviewers

SOGI: why?

1.Baker, KE, Streed, CG, and Durso LE. Ensuring That LGBTQI+ People Count — Collecting Data on Sexual Orientation, Gender Identity, and Intersex Status. N Engl J Med; 384; 1 April 2021

https://www.nejm.org/doi/10.1056/NEJMp2032447?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9483721/
Example in Parkinson's disease

Alan M Jette, The Importance of Collecting Data on Sexual Orientation and Gender Identity (SOGI) in Rehabilitation Research, *Physical Therapy*, Volume 100, Issue 8, August 2020, Pages 1235–1236, https://doi.org/10.1093/ptj/pzaa104

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SOGI

https://protect-de.mimecast.com/s/q-5ICw0oZ4fJgKWQU9f2nf?domain=wiki.cdisc.org

aCRF. SOGI (Sexual Orientation and Gender Identity)

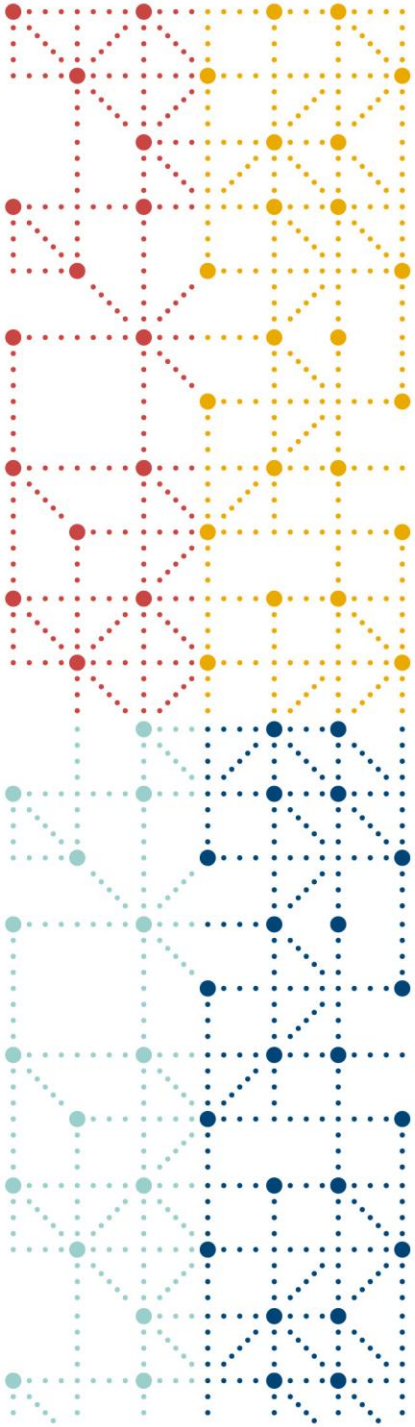
Indicate if Sexual Orientation and Gender Identity data was collected. If Yes, record the appropriate details	Was SOGI (Sexual Orientation and Gender Identity) data collected? SCPERF If SCPERF = "Y", NOT SUBMITTED. If SCPERF = "N", SCSTAT where SCTESTCD = "SCALL"	○ Yes ○ No *<NY codelist>*
Record the date of collection using the format (DD-MON-YYYY)	What [is/was] the date of the collection? SCDAT SCDTC	
Record the (study) [subject's/participant's] Sex Assigned at Birth	Sex Assigned at Birth SEXABRTH_SCORRES SCORRES where SCTESTCD = "SEXABRTH"	○ Female ○ Male ○ Intersex ○ Unknown ○ Not Reported *<SEXABRTH codelist>*
Indicate the (study) [subject's/participant's] Sexual Orientation	Sexual Orientation SEXORIE_SCORRES SCORRES WHERE SCTESTCD = "SEXORIE"	○ Lesbian ○ Gay ○ Straight or Heterosexual ○ Bisexual ○ Queer ○ Pansexual ○ Asexual ○ Aromantic ○ Unknown ○ Not Reported

SOGI

Indicate the (study) [subject's/participant's] Gender Identity	Gender Identity GENIDENT_SCORRES SCORRES WHERE SCTESTCD = "GENIDENT"	○ Cis Woman/Girl ○ Cis Man/Boy ○ Transgender Woman/Gir ○ Transgender Man/Boy ○ Gender Queer ○ Gender Fluid ○ Non-Binary ○ Unknown ○ Not Reported *<GENIDENT codelist>*
Indicate if (study) [subject/participant] has been diagnosed with DSD by a medical doctor or other health professional.	Have you ever been diagnosed by a medical doctor or other health professional with an intersex condition or a difference of sex development (DSD) or were you born with (or developed naturally in puberty) genitals, reproductive organs, or chromosomal patterns that do not fit the standard definitions of male or female? ISXDXIND_SCORRES SCORRES WHERE SCTESTCD = "ISXDXIND"	○ Yes ○ No ○ Unknown ○ Not Reported *<ISXDXRS codelist>*

View CRF Metadata

CDASH Variable	Order	Question Text	Prompt	CRF Completion Instructions	Type	SDTMIG Target Variable	SDTM Target Mapping
SCPERF	1	Was SOGI (Sexual Orientation and Gender Identity) data collected?	Subject Characteristics Collected	Indicate if Sexual Orientation and Gender Identity data was collected. If Yes, record the appropriate details	Text	SCSTAT	If SCPERF = "Y", NOT SUBMITTED. If SCPERF = "N", SCSTAT where SCTESTCD = "SCALL"
SCDAT	2	What [is/was] the date of the collection?	Date of Collection	Record the date of collection using the format (DD-MON-YYYY)	Text	SCDTC	SCDTC



WHO-DD and CDISC

How to use WHODrug for Compliance with CM Domain in the CDISC SDTM standard

cdisc

2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

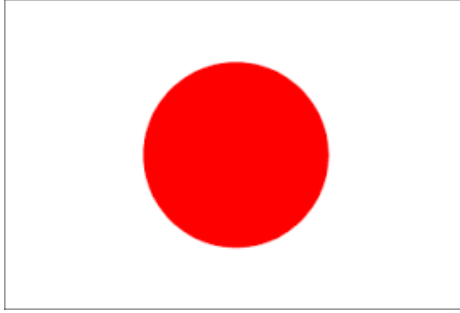
How to use WHODrug for Compliance with CM Domain in the CDISC SDTM standard

Sohye Yoon, Uppsala Monitoring Centre

CDISC and WHODrug Global

Meeting regulatory expectations with WHODrug

cdisc



Japan, PMDA – Notification on Handling of Submission of Electronic Study Data for New Drug Applications [1]

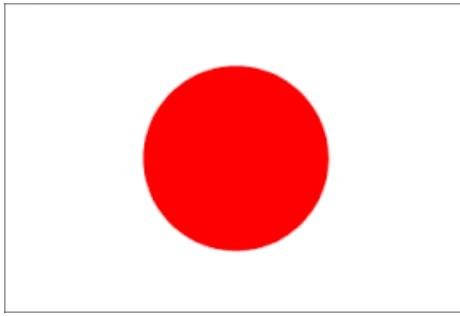
エ　推奨される統制用語、辞書及び単位について
申請電子データを作成する際、CDISC において推奨される統制用語、事

d. Controlled terminology, dictionaries and units that are recommended

When preparing electronic study data, encoded information must also be included for data that can be encoded using the controlled terminology recommended by the CDISC, MedDRA for events, and WHODrug Global for drugs. The values are to be in SI units, in principle.

Please refer to the PMDA's website (https://www.pmda.go.jp/) for the list of acceptable codes.

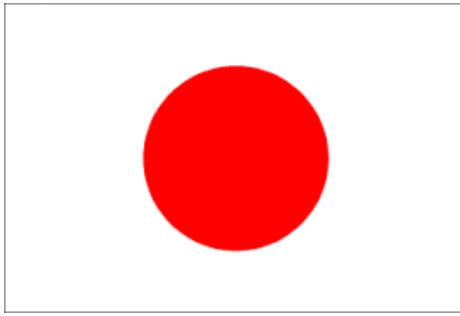
象については MedDRA、薬剤については WHODrug Global を使用してコード化が可能なデータについては、コード化された情報も含めること。また、単位については SI 単位を使用することを原則とする。
使用可能なコードのリストについては、PMDA のウェブサイト（https://www.pmda.go.jp/）を参照すること。



Japan, PMDA – Data Standards Catalog[2]

PMDA Data Standards Catalog (2023-02-28) - Terminology Standards

Terminology Standard	Version(s)	Date Support Begins (YYYY-MM-DD)	Date Support Ends (YYYY-MM-DD)	Notes
CDISC Controlled Terminology	Between 2009-02-17 (inclusive) and 2011-06-10 (exclusive)	2016-10-01	2017-06-30	When using the version indicated in "Version(s)" column, consult PMDA at the consultation on data preparation of the submission of electronic study data.
CDISC Controlled Terminology	2011-06-10 or later	2016-10-01		
MedDRA	8.0 or later	2016-10-01		
WHODrug Global (since 2017 March)/ WHO Drug Dictionary Enhanced	2008:4 (2008-12-01) or later	2016-10-01		



Japan, PMDA – FAQs on Electronic Study Data Submission[3]

Q4-7: In Section 4 (2) d of the notification on electronic study data, it states, that encoded information must also be included for data that can be encoded using "the WHODrug Global for drugs". Please explain the background of the need to use WHODrug Global, and give an example of how to store WHODrug Global data under the CM domain of SDTM.

A: In order to promote international standardization of clinical study data, and to allow cross-product analyses in the future, use of WHODrug Global is required for electronic study data submission. It is possible to use applicant-defined codes if no WHODrug Global equivalent codes are identified; in this case, it will be necessary to specify in the reviewer's guide which applicant defined codes have been assigned to which variables.

Table 4-7 presents examples of how to assign WHODrug Global codes to the CM domain of SDTM. It is also necessary to store WHODrug Global ATC codes wherever possible.

In cases where it is impossible to identify the single ATC code in WHODrug Global due to not collecting indication for use of the concomitant drug, please store not only single ATC code but also all ATC codes that correspond to the drug using the "Supplemental Qualifier special-purpose dataset".

Table 4-7 Relationship between CM Domain and WHODrug Global

Variable Name	Variable Label	WHODrug Global
CMDECOD	Standardized Medication Name	Generic name
CMCLAS	Medication Class	ATC text
CMCLASCD	Medication Class Code	ATC code

U.S., FDA – Notice in the Federal Register[4]

Federal Register / Vol. 82, No. 204 / Tuesday, October 24, 2017 / Notices 49211

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data Guidance), posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*. The eStudy Data Guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act for study data contained in NDAs, ANDAs, BLAs, and certain INDs to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports the use of WHODG for the coding of concomitant medications in studies submitted to CBER or CDER in NDAs, ANDAs, BLAs, and certain INDs in the electronic common technical document format. Generally, the studies included in a submission are conducted over many years and may have used different WHODG versions to code concomitant medications. The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support of the most current B3-format annual version of WHODG is March 15, 2018. Although the use of the current B3-format annual version of WHODG is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the "date requirement begins." The Study Data Technical Conformance Guide provides addition information and recommendations on the coding of concomitant medications (*https://www.fda.gov/downloads/forindust...*) be updated to list March 15, 2019, as the "date support ends." Studies that start after March 15, 2019, will be required to use the most current B3-format annual version of WHODG.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23020 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0278]

Trand Doan Nguyen; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Trang Doan Nguyen's (Nguyen's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Nguyen for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Nguyen was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Nguyen's debarment, FDA has considered the relevant factors listed in the FD&C Act. Nguyen has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective October 24, 2017.

ADDRESSES: Any application by Nguyen for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

• *Federal eRulemaking Portal: https://www.regulations.gov.* [illegible] the instructions for submitting [illegible]

solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov*.

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA–2011–N–0278. An application will be placed in the docket and, unless submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available [illegible] public viewing and posted on [illegible]

"The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start."

"…the use of the current B3-format annual version of WHODrug is supported as of this Federal Register notice and sponsors or applicants are encouraged to begin using it"

"…the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019."

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U.S., FDA – Data Standards Catalog[5]

FDA Data Standards Catalog v10.1 - Submission Data Terminologies

For full description of column headings, see Instr. & Column Descriptions tab

Use	Terminology	Organization(s)	Accepted Version(s)	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]	Date Requirement Ends	Examples of Use	Statutory, Regulatory, or Guidance Authority Sources	Statutory, Regulatory, or Guidance Authority Sources	Information Sources	Information Sources
Medication	WHODrug Global	UMC	Current Version-B3 format	CBER, CDER	03/15/2018		03/15/2019		Use in SDTM CMDECOD and CMCLAS	Standardized Study Data		WHODrug Global	Study Data Technical Conformance Guide

WHODrug Global

Accepted Version(s)

Current Version-B3 format

Date Requirement Begins [10] [11]

03/15/2019

Examples of Use

Use in SDTM CMDECOD and CMCLAS

U.S., FDA – Study Data Technical Conformance Guide[6]

6.4.2 WHODrug Global

6.4.2.1 General Considerations

World Health Organization (WHO) Drug Global[61] is a dictionary maintained and updated by Uppsala Monitoring Centre. WHODrug Global contains unique product codes for identifying drug names and listing of medicinal product information, including active ingredients and therapeutic uses.

Typically, WHODrug Global is used to code concomitant medications. The variable --DECOD should be populated with the active substances from the WHODrug Global Dictionary, and --CLAS populated with the drug class.

When using WHODrug Global, --CLAS is recommended to be populated with the Anatomic Therapeutic Chemical (ATC) class most suitable per intended use, and the remainder of the ATC classes, if any, placed in SUPPCM. Alternately, the use of the SUPPCM or FACM domains to populate all ATC Classes associated with the --DECOD value is acceptable. ATC classes should be submitted at the fourth level or most specific available as defined within WHODrug Global.

Generally, studies included in a submission are conducted over many years and may have used different WHODrug Global versions to code concomitant medications. The expectation is the most current B3-format annual version of WHODrug Global at the time of study start will be used to code concomitant medications. There is no requirement to recode earlier studies to align with the WHODrug Global version of later studies.

CMDECOD longer than 200 characters

- For drugs with many ingredients, the generic name in WHODrug can be longer than 200 characters
- Supplemental dataset needs to be utilized in this scenario
- SDTMIG v. 3.4 states that the text **should be truncated between words** (4.5.3.2 Text Strings Greater than 200 Characters in Other Variables)
  - "Semicolons separate ingredients so text should be truncated after semicolon closest to 200 characters to improve readability"

Table 1. Illustration of SDTM dataset where CMDECOD is longer than 200 characters.

USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	1	....	...	Ascorbic acid;Biotin;Calcium;Carbohydrates nos; Chloride;Choline;Chromium;Colecalciferol; Copper;Cyanocobalamin;Docosahexaenoic acid; Fats nos;Folic acid;Fructooligosaccharides; Iodine;Iron;Magnesium;	....	....

Table 2. Illustration of supplemental dataset for CM domain where CMDECOD is longer than 200 characters.

USUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
AB-21-01	CM	CMSEQ	1	CMDECOD1	Standardized Medication Name 1	Manganese;Nicotinic acid;Pantothenic acid;Phosphorus;Phytomenadione; Potassium;Proteins nos;Pyridoxine; Retinol;Riboflavin;Selenium;Sodium; Thiamine;Vitamin e nos;Zinc

The SDTM permits one value for each Qualifier variable per record. If multiple values exist (e.g., due to a "Check all that apply" instruction on a CRF), then the value for the Qualifier variable should be "MULTIPLE" and SUPP-- should be used to store the individual responses.

If the sponsor has clearly documented that one response is of primary interest (e.g., in the CRF, protocol, or analysis plan), the standard domain variable may be populated with the primary response and SUPP-- may be used to store the secondary response(s).

From SDTMIG V3.4 section 4.2.8.3

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U.S., FDA – Validator rules[8]

version 1.6, finalized December 2022

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description	Domains
SD1344	FDA	FDAB017	Value for --DECOD not found in WHODrug dictionary	Value for the Standardized Medication Name (--DECOD) variable must be populated using a Drug Name from the WHO Drug dictionary version specified in the define.xml.	CM
SD1345	FDA	FDAB017	Value for --CLAS not found in WHODrug dictionary	Value for the Medication Class (--CLAS) variable must be populated using ATC Text from the WHO Drug dictionary version specified in the define.xml.	CM
SD1346	FDA	FDAB017	Value for --CLASCD not found in WHODrug dictionary	Value for the Medication Class Code (--CLASCD) variable must be populated using ATC Code from the WHO Drug dictionary version specified in the define.xml.	CM

FDAB017	Controlled terms should use the exact term (case, spelling, and punctuation) used by the terminology maintenance organizations (e.g., MedDRA, CDISC controlled terminology).

WHODrug Global Chinese

- ✓ Drug names, active substance(s), ATC code text, country and pharmaceutical form are shown in Chinese for drugs approved in China
- ✓ All Chinese records have an equivalent English drug name in WHODrug Global connected by the drug code
- ✓ Simplifies coding and regulatory submission both inside and outside China

Drug code	Drug name	Active substance(s)	ATC	Country of sales	Marketing authorisation holder	Pharmaceutical form	Strength	Medicinal Product ID
00002701559	伯基	乙酰水杨酸	B01AC, 血小板凝固抑制剂, 不包括肝素类	中国	永信药品股份有限公司	胶囊,肠溶	100 mg	1724492
00002701559	Bokey	Acetylsalicylic acid	B01AC, Platelet aggregation inhibitors excl. heparin	China	Yung shin	CAPSULES, ENTERIC-COATED	100 mg	1724492

WHODrug Global Chinese

WHODrug Global

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China, NMPA - Guidelines for submission of clinical trial data[9]

原始数据库通常包含从病例报告表和外部文件中直接收集的原始数据，还可能包含极少量的衍生数据，如序号。原始数据库中的缺失数据不应进行填补。为满足数据递交的要求，直接收集的数据可能需要进行必要的标准化或编码，例如调整数据库中数据集名称/标签/结构、数据集中变量名称/标签，或在适用的情况下对变量值进行标准化编码，如监管活动医学词典（Medical Dictionary for Regulatory Activities，MedDRA）等。

Provisional translation:

In order to meet the data submission requirements, collected data may be required to be standardized or coded

The provisional translation is unofficial and is provided solely to create a basic understanding

China, NMPA - Guidelines for submission of clinical trial data[9]

递交数据库中至少以下内容应为中文：数据集标签和变量标签；在临床总结报告等文件中出现的不良事件名称、合并用药名称、病史名称。

Provisional translation:

At least the following content in the submitted database should be in Chinese: data set labels and variable labels; names of adverse events, names of concomitant drugs, and names of medical history appearing in clinical summary reports and other documents.

The provisional translation is unofficial and is provided solely to create a basic understanding

WHODrug Global Chinese allows for retrieval of applicable drug information in Chinese language

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Supporting data submission in dual languages

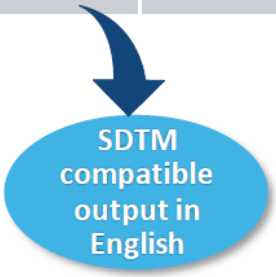
REPORTED TERM

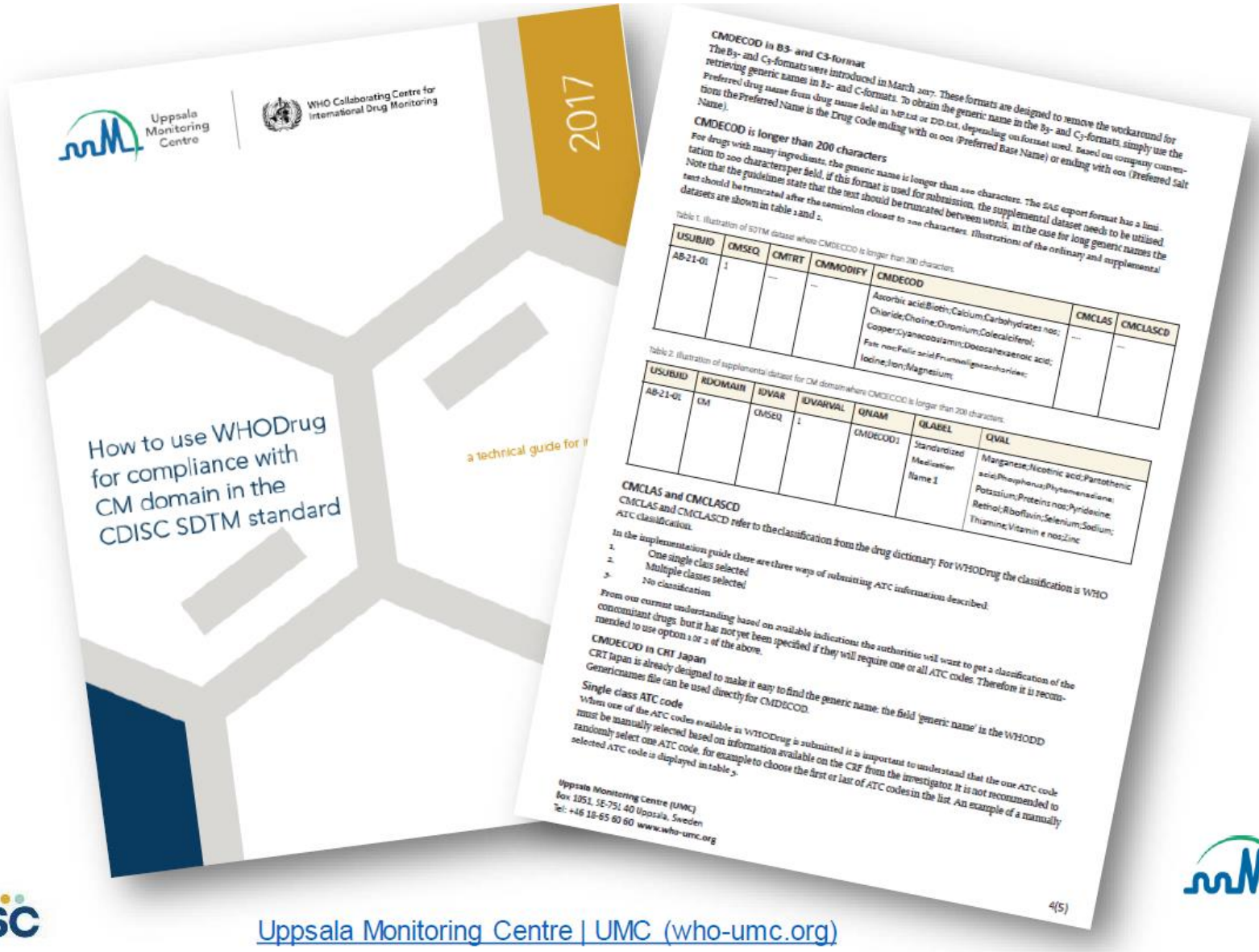
VFEND

CODED DRUG NAME IN WHODRUG GLOBAL

DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT	DRUG CODE
VFEND	Voriconazole	J02AC, Triazole derivatives	01510101002

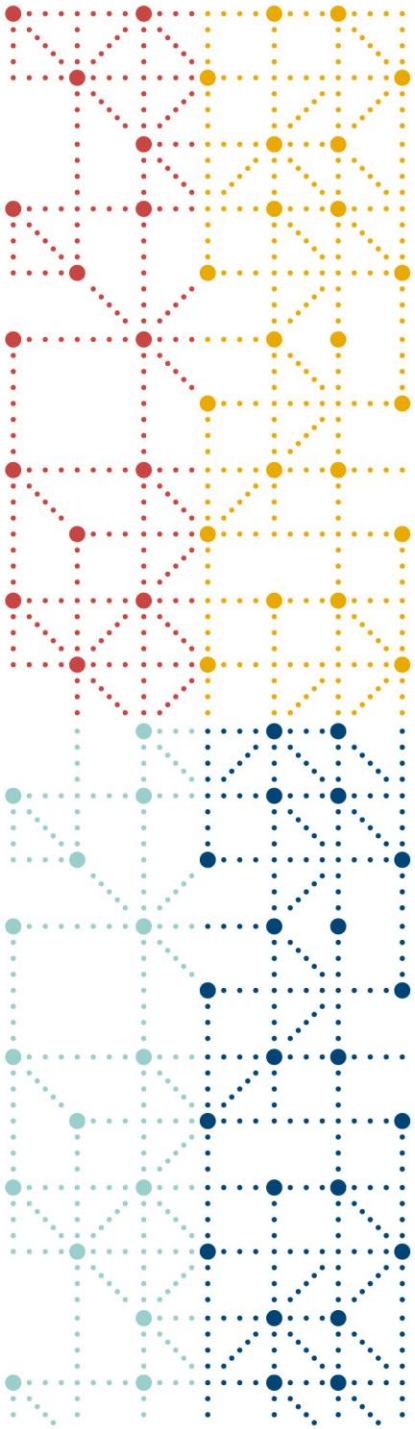
DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT	DRUG CODE	DRUG NAME	ACTIVE INGREDIENT	ATC CODE/TEXT
威凡	伏立康唑	J02AC, 三唑衍生物	01510101002	VFEND	Voriconazole	J02AC, Triazole derivatives





Uppsala Monitoring Centre | UMC (who-umc.org)

https://who-umc.org/media/2940/how-to-use-whodrug-for-compliance-with-cm-domain-in-the-cdisc-sdtm-standard-march-2017.pdf



CDISC and Data Submission What's New

Standards publication

https://www.cdisc.org/standards/publications

Standard/Therapeutic Area Version	Published Date
Glossary v18.0	15 DEC 2023
Rare Diseases Therapeutic Area User Guide	14 DEC 2023
ADaM Conformance Rules v5.0	06 OCT 2023

Standards under public review

https://www.cdisc.org/public-reviews

SOGI (Sexual Orientation and Gender Identity) CRF	Comments Due
SOGI (Sexual Orientation and Gender Identity) CRF	22 FEB 2024

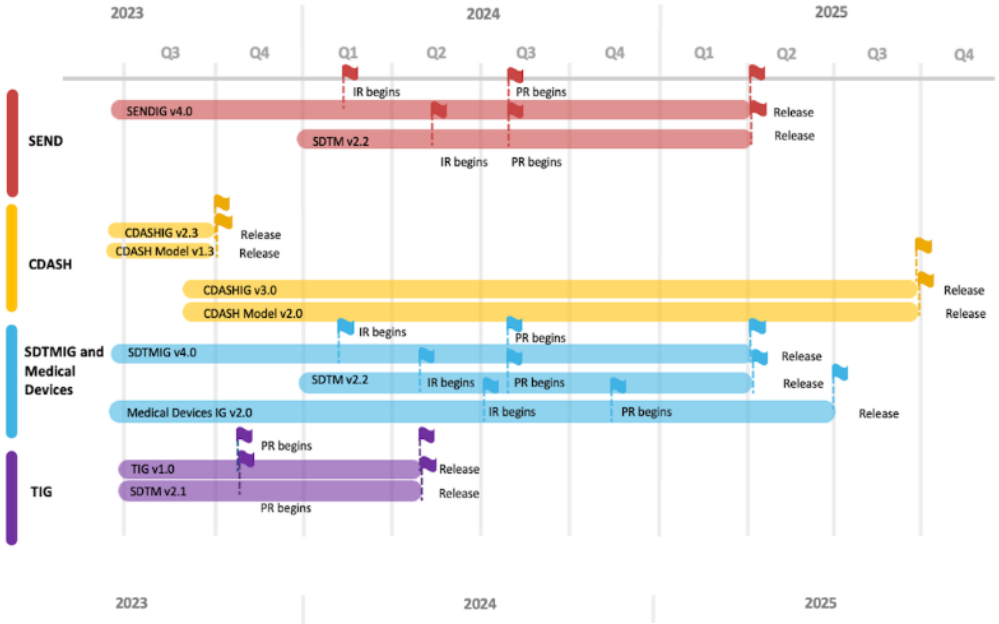
Standards in development

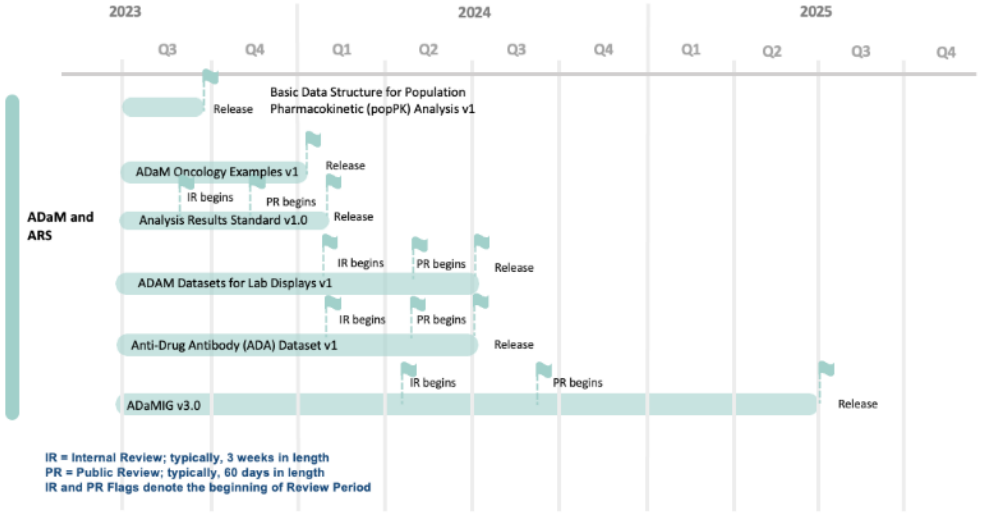
https://www.cdisc.org/standards/in-development

Standard (Expected Release Date)	Release Notes
ADaM Oncology Examples (2024)	Resolving Public Comments
ADaM v3.0 (2025)	In Development
Analysis Results Standards v1.0 (2024)	Public Review (closed)
CT Relationships for SDTM v1.7, SDTMIG v3.3, SDTMIG-MD v1.1 (2024)	Public Review (closed)
SDTM for Observational Studies v1.0 (2024)	Public Review (closed)
SDTM v2.1 (Q2-2024)	In Public Review (closed)
SDTMIG v4.0 (2025)	In Development
SENDIG v4.0	In Development
Tobacco Implementation Guide v1.0 (Q2 2024)	In Public Review (closed)

Standards Roadmap

https://www.cdisc.org/standards/roadmap





CDISC CT 2023-12-15 / IS Codetable 2023-09-29

Slides / Docs available also on CDISC Italian UN Wiki page

- Controlled Terminology P55 and P56 Public Review (Oct 3 2023) https://www.cdisc.org/events/webinar/controlled-terminology-updates-q3-2023
- LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology https://www.cdisc.org/events/webinar/lb-mb-domain-scope-changes-sdtmig-v3-4-and-impact-controlled-terminology

CDISC CT 2023-12-15 / IS Codetable 2023-09-29

The IS Domain Scope Update for the SDTMIG v3.4

- The current IS domain in the SDTMIG v3.4 is designed to collect data pertaining to *specimen-based* assessments that measure the "presence, magnitude and scale of the immune response upon ***any*** ***antigen*** stimulation or encounter".
- This effectively expands the scope of the IS domain from the pervious SDTMIG versions (3.2 and 3.3) where the IS domain was limited to "assessments that describe whether a (study) ***therapy*** provoked/caused/induced an immune response."

From "Controlled Terminology P55 and P56 Public Review" (Oct 3 2023)

CDISC CT 2023-12-15 / IS Codetable 2023-09-29

CODELIST_NAME_CODE	CODELIST_NAME	CODELIST_CODE	CDISC_SUBMISSION_VALUE	CDISC_SYNONYM	Code	Codelist Extensible (Yes)	CDISC_DEFINITION	NCI_PREFERRED_TERM	Current CT with latest version	CT Version when introduced	CT Version when removed
MBTESTCD	Microbiology Test Code	C120527	HAAB	Hepatitis A Virus Antibody	C92534	Yes	A measurement of the hepatitis A virus antibody in a biological specimen.	Hepatitis A Antibody Measurement	N	2019-09-27	2023-12-15
MBTESTCD	Microbiology Test Code	C120527	HAIGGAB	Hepatitis A Virus IgG Antibody	C163538	Yes	A measurement of hepatitis A virus IgG antibody in a biological specimen.	Hepatitis A Virus IgG Antibody Measurement	N	2019-09-27	2023-12-15
MBTESTCD	Microbiology Test Code	C120527	HAIGMAB	Hepatitis A Virus IgM Antibody	C92271	Yes	A measurement of hepatitis A virus IgM antibody in a biological specimen.	Hepatitis A Virus Antibody IgM Measurement	N	2019-09-27	2023-12-15

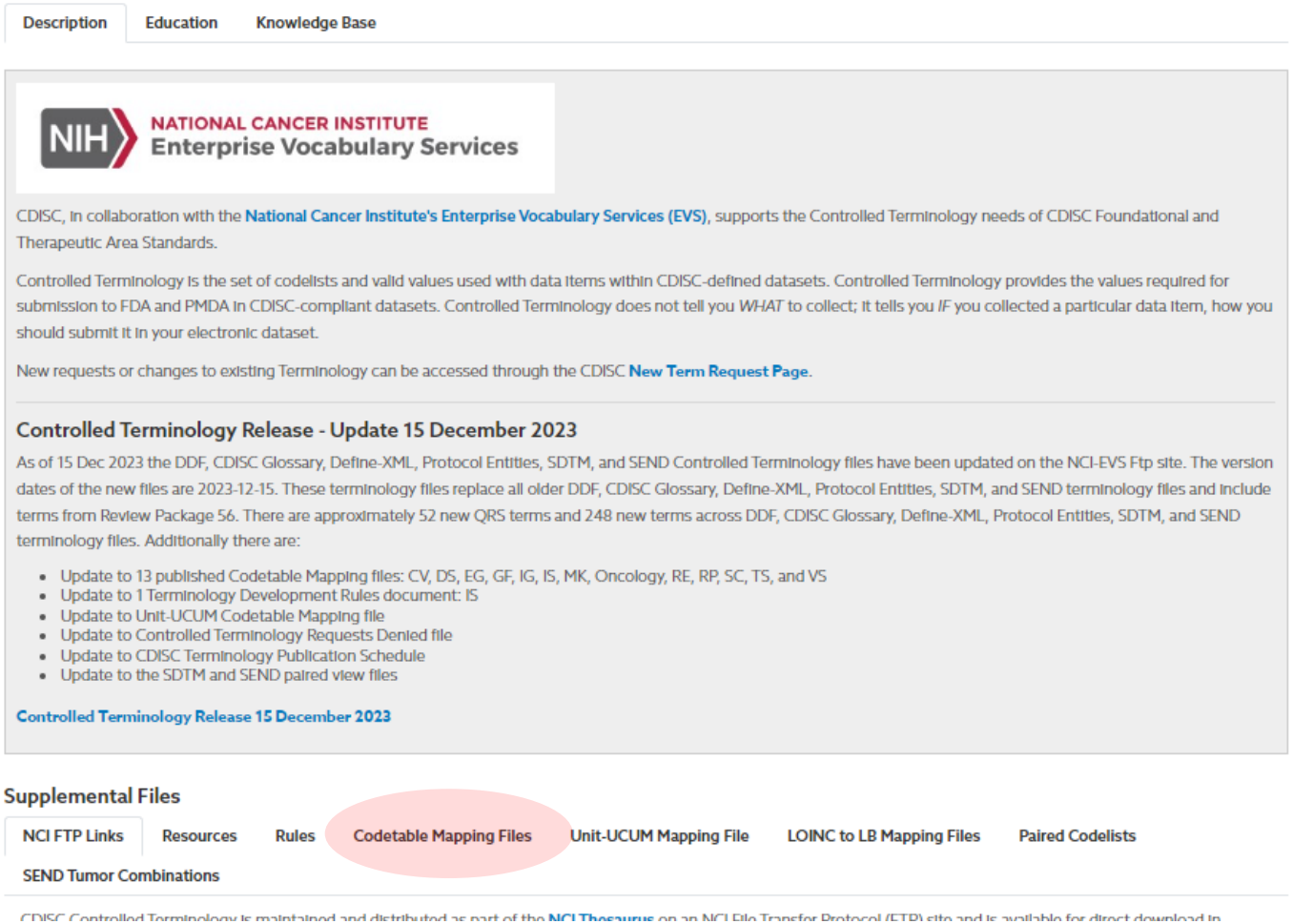
C-Code	MBTEST Terms for Deprecation Microbiology Test Name (codelist code = C120528)	C-Code (Concept Code)	When Varaible = ISTEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C-Code (Concept Code)	When Varaible = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)
C92534	Hepatitis A Virus Antibody	C187780	Microbial-induced Antibody	C14325	HEPATITIS A VIRUS

From SDTM Terminology Changes 2023-12-15

Deprecate from codelist. Per the SDTMIG v3.4, all antigen-stimulated humoral immune response tests should be represented by the IS domain. Refer to the "IS Terminology Mapping Codetable" file to see how this term is post-coordinated and re-mapped to the IS domain.

CDISC CT 2023-12-15 / IS Codetable 2023-09-29

https://www.cdisc.org/standards/terminology/controlled-terminology



Recent FDA CBER Request

7 CBER Comment [redacted]

You intend to not report HIV, Hep B and C results. Additionally, in study [redacted] we note that you intend to report these results in the MB dataset. We request that any immunogenicity results collected be reported in the IS dataset.

Sponsor Request (Comment [redacted]):

HIV, Hep B and C results are not part of immunogenicity assessment but have been measured as part of diagnostic tests to assess subjects eligibility at study entry and results reported in MB domain. Does CBER concur with this approach?

CBER Response: We do not agree. The results should be reported in the IS dataset. The EPOCH can be used to indicate that the results are from "Screening."

FDA Technical Conformance Guide

v5.5 October 2023 / v5.6 December 2023

- Two New Guidance released
  - Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessments (COA) Using Item Response Theory
  - Submitting Patient-Reported Outcome (PRO) Data in Cancer Clinical Trials
- **PC and PP** domains visits / timepoint reference aligned with other study domains

FDA Technical Conformance Guide

v5.5 October 2023 / v5.6 December 2023

- ***SV domain**, necessitating the inclusion of all scheduled visits, regardless of their occurrence*
  - **Deprecation of VE domain** initially recommended with the CDISC “Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic”
  - Variables **SVREASOC** (Reason for Occur Value), **SVEPCHGI** (Epi/Pandemic Related Change Indicator), and **SVCNTMOD** (Contact Mode), in SV rather than SUPPSV

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Thank You!

Silvia Faini

silvia.faini@cytel.com

Mauro Cortellini

m.cortellini@chiesi.com

Angelo Tinazzi

angelo.tinazzi@cytel.com