

DRAFT FOR PUBLIC REVIEW

Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 4.0 (Draft for Public Review)

Prepared by the
DDF Team

Notes to Readers

This is the draft version of the Unified Study Definitions Model Implementation Guide Version 4.0 intended for public review.

Revision History

| Date | Version |
|------|-----------------------------|
| | 4.0 Draft for Public Review |

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1 Introduction

CDISC is collaborating with TransCelerate through [TransCelerate's Digital Data Flow \(DDF\) initiative](#) to develop a Study Definition Reference Architecture called the Unified Study Definitions Model (USDM). The USDM will serve as a standard model for the development of conformant study definition technologies.

The DDF will help modernize clinical trials by enabling a digital workflow with protocol digitization. This initiative establishes a foundation for a future state of automated and dynamic readiness that can transform the drug development process. Additional information can be found on the [TransCelerate Digital Data Flow Solutions](#) and the [CDISC DDF](#) web pages.

The collaborative effort between TransCelerate and CDISC has enabled the development of the USDM reference architecture in conjunction with development of a Study Definitions Repository (a reference implementation of the USDM architecture). For more information on the SDR, visit the [TransCelerate DDF GitHub site](#) and the [SDR Github site](#).

1.1 Purpose

The USDM Implementation Guide (USDM-IG) is intended for companies and individuals involved in the set-up of clinical studies—sponsors or stakeholders involved in upstream (protocol and content authoring tools)—and downstream consumers of system (e.g., electronic data capture (EDC), clinical trial management, trial master file) and document (e.g., protocol, clinical study reports, statistical analysis plans) standardized digitized study definitions.

This document provides users with sufficient information to understand the USDM and also its potential implementations with the study design process by showing examples of the types of study definition information that can be represented in the USDM.

1.2 Organization of this Document

This document is divided into the following sections:

- Section 1, [Introduction](#), provides an overall introduction to the purpose and goals of the USDM-IG.
- Section 2, [Fundamentals of the USDM](#), provides a boundary of the scope of this version of the USDM and what use cases this version is intended to support.
- Section 3, [Relationship to Other Standards and Formats](#), describes at a high level how the USDM relates to other standards (both CDISC and non-CDISC) and to the TransCelerate Common Protocol Template.
- Section 4, [USDM Features](#), provides an overview of enhancements that support increased trial complexity.
- Section 5, [USDM Data Dictionary](#), illustrates the types of information that can be represented using the USDM, and includes various study designs ranging in complexity.
- Section 6, [USDM API](#), provides information on the USDM application programming interface.
- Section 7, [Mapping to Other Standards and Formats](#), describes the alignment between the USDM and Study Data Tabulation Model (SDTM) Trial Design domains and controlled terminology elements, and provides definitions for protocol registration data elements submitted to ClinicalTrials.gov.
- [Appendices](#) provide additional background material and describe other supplemental material relevant to the USDM.

Examples of use of the model in JSON, .PNG, and .XLS format as well as other information can be found [here](#).

1.3 How to Read this Document

1. First, become familiar with the DDF project; see the [TransCelerate DDF Project web page](#) and [CDISC DDF](#) resources. If you are new to DDF, visit the [TransCelerate DDF Initiative Solutions](#) site which includes a video describing DDF.

2. Read this guide all the way through (without skipping any sections) at least once.
3. Finally, revisit any sections of particular interest.

2 Fundamentals of the USDM

The USDM comprises 5 parts, which are official CDISC standards:

1. Unified Study Definitions Model (USDM) class diagram represented as a unified modeling language (UML) class diagram
2. Application programming interface (API) specification
3. CDISC Controlled Terminology
4. Unified Study Definitions Model Implementation Guide (USDM-IG)
5. CDISC USDM Conformance Rule Specifications

3 USDM v1.0

USDM v1.0 (released August 2022) provided a base model of structured study design.

Please note that USDM v1.0 did not have a corresponding implementation guide. The USDM-IG was initially developed for USDM v2.0 and further updated for USDM v3.0.

4 USDM v2.0

Building on the USDM v1.0 foundation, USDM v2.0 (released June 2023) was developed to satisfy an agreed set of use cases based around

- updates to the USDM that enable greater population of study startup (SSU) elements and represent structured study design information for more complex trials,
- updates to the USDM that support EDC automation, and
- updates to the USDM that demonstrate population of the TransCelerate Common Protocol Template (CPT).

4.1 Support for More Complex Trials

The first version of the USDM provided a model for simple study designs. Version 2.0 implemented additional elements that allow for representation of more complex study designs in USDM. Section 4, [USDM Features](#), provides an overview of enhancements that support increased trial complexity. One main area of development has been the implementation of study timing (see [Section 4.14](#)) within the model, allowing for complex timing and visit structures to be represented.

4.2 Enabling EDC Automation

In order to support EDC automation, the CDISC [Biomedical Concepts model](#) was adapted and included as a submodel in the USDM. The addition of biomedical concepts to the model adds a machine-readable "data" layer to the study design. This data layer can be used in a variety of ways to inform about what data relates to particular assessments within a study design. This biomedical concepts model not only assists in informing an EDC system as to the individual data items required for an assessment (e.g., automating identification of a form in an EDC library with the same/similar set of biomedical concepts) but also provide basic information required to build a new form should there be no EDC library, or no form that matches.

Implementation of the biomedical concepts model in the USDM provides a machine-readable data specification that can support other data-source use cases such as digital health technologies, electronic patient-reported outcomes (ePROs), and electronically supplied data (e.g., central lab, central ECG data).

4.3 Populating protocol standards

In Version 2.0, additional elements were added to the model as a proof-of-viability (POV) exercise, demonstrating that structured study design information could be moved from an upstream study design application into USDM format and then used to populate the TransCelerate CPT. Additional information on the USDM elements used for this POV can be found in Section 7.3, [Use of USDM for Populating Protocol Content](#). Note that only a selected set of CPT elements is included for the POV.

5 USDM v3.0

USDM v3.0 development topics included:

- Ability to represent the draft ICH Clinical electronic Structured Harmonised Protocol (CeSHarP) developed by the ICH M11 group in USDM
- Add elements to expand population of SDTM trial design datasets
- Identify elements within USDM that can assist in population of trial planning elements for clinical trial registration in trial registries
- Addition of elements and model amendments required to represent structured study design information for more complex studies, including complex cohort trial designs
- Model enhancements to support use of the USDM and ensure consistency within the model

5.1 Representation of ICH M11 CeSHarP in USDM

Working closely with ICH, USDM v3.0 was aligned to cover the breadth of sections found in the ICH M11 CeSHarP template. This allows a USDM study design to be represented in the ICH CeSHarP template. **Note:** At the time of publication of USDM v3.0, ICH CeSHarP was still in the development phase. In future phases of USDM development, CDISC will continue to collaborate with the ICH team in order to ensure that USDM remains aligned with the ICH M11 CeSHarP template.

5.2 SDTM Trial Design Population

During development of USDM v2.0, elements within the USDM were identified that would allow data from a USDM compliant system to be used to populate SDTM Trial Design datasets related to trial planning. This was expanded during USDM v3.0 development to include additional elements that could be used for SDTM Trial Design population. Additional information can be found in Section 7.1, [Creation of SDTM Trial Design Domains](#).

5.3 Clinical Trial Registry Population

Working alongside clinical trial registry subject-matter experts (SMEs), an evaluation was performed to determine how USDM could be used to assist in the population of elements required for clinical trial registries. In Version 3.0, this was restricted to ClinicalTrials.gov. Additional information can be found in Section 7.2, [Informing ClinicalTrials.gov Registry](#)

5.4 Support for More Complex Trials

An evaluation was performed to determine model changes that could support more complex cohort trials designs. This resulted in new USDM classes being developed (i.e., Population Definitions, Study Cohort, Characteristic) to support these types of studies. Additional information can be found in Section 4.19, [Populations, Cohorts, and Eligibility Criteria](#).

5.5 Model Enhancements

Version 3.0 included model enhancements to support use of the USDM and ensure consistency within the model, such as updating the unified modeling language (UML) to make it a more logical model, removing the API implementation elements and links, and making naming more consistent between classes. Additional information

can be found in Section 4.2, [Principles](#); Section 4.3, [Naming Conventions](#); Section 4.4, [Internal Identifiers Within the Model](#); and Section 4.5, [Controlled Terminology](#).

6 USDM v4.0

USDM v4.0 development topics included:

- Continued representation of CeSHarP in USDM
- Participation in Utilizing the Digital Protocol (UDP) project with TransCelerate, ICH, and HL7 Vulcan
- Development of USDM Conformance Rule specifications to support USDM v3.0 and v4.0
- Continue support and development of test data and test tools
- Development of training and education materials in conjunction with TransCelerate's Change and Engagement team to foster adoption of DDF
- Model enhancements to support use of the USDM and ensure consistency within the model

6.1 Representation of ICH M11 CeSHarP in USDM

Working closely with ICH, USDM v4.0 has been aligned to cover the breadth of sections found in the latest versions of the ICH M11 CeSHarP template and Technical Specification. This will allow a USDM study design to continue to be represented in the ICH CeSHarP template. **Note:** At the time of publication of USDM v4.0, ICH CeSHarP was still in the development phase. In future phases of USDM development, CDISC will continue to collaborate with the ICH team in order to ensure that USDM remains aligned with the ICH M11 CeSHarP template and Technical Specification

6.2 Utilizing the Digital Protocol (UDP)

The Vulcan accelerator [UDP project](#) is a collaborative effort between TransCelerate, CDSIC USDM, and HL7 Vulcan to ensure alignment and interoperability between the ICH M11 CeSHarP template and Technical Specification, the UDP FHIR Implementation Guide, and the CDISC USDM deliverables.

6.3 USDM Conformance Rule Specifications

CDISC Conformance Rules are an integral part of any CDISC foundational standard and serve as the specific guidance to Industry for the correct implementation of the standards. During this phase CDISC has developed a set of conformance rule specifications to support USDM v3.0 and v4.0 that will aid implementers to ensure solutions conform with the RA, purchasers to ensure products being acquired meet the requirements, and collaborating organizations to ensure that their study builds are interoperable at least in terms of the scope of the RA.

6.4 Test Data and Test Tools

Test data and tooling, although not an official standard deliverable for USDM, provide examples of how study design information can be represented in USDM and provide implementers with guidance on mapping study design elements to USDM. A series of publicly available protocols have been mapped to USDM (see the [USDM GitHub Examples](#)).

6.5 Training and Education Materials

CDISC is developing an official CDISC education course which when developed will offer both in-person and on-demand USDM training opportunities.

6.6 Model Enhancements

Version 4.0 includes model enhancements to support use of the USDM. Details of model changes can be found in Appendix D, [Revision History](#). Enhancements developed for USDM v4.0 include enhanced support for:

- Notes and criteria
- Activity groups

- Multiple template support (M11 alignment)
- Abbreviations
- Interventions, identifiers, and roles (M11 alignment)
- Amendments (M11 alignment)
- Estimands (M11 alignment)
- Observational and device studies

7 Relationship to Other Standards and Formats

The USDM covers a wide range of concepts related to study design that also appear in other published standards such as trial registry standards ([EudraCT](#), [ClinicalTrials.gov](#)), [HL7 FHIR](#) standards, and [ICH](#) guidance documents. As part of the development process, these standards were used as input in order to try to ensure harmonization with these standards, where possible.

7.1 Relationship to Other CDISC Standards

The USDM development process relies on published CDISC standards and other products that serve as references for modeling and naming conventions. To the extent possible, an effort has been made to align or be compatible with these sources where the content was determined to be conceptually identical or closely related to those being developed for the USDM.

7.1.1 BRIDG

The Biomedical Research Integrated Domain Group (BRIDG) is a CDISC, [HL7](#), and [ISO](#) information model "used to support development of data interchange standards and technology solutions that will enable semantic (meaning-based) interoperability within the biomedical/clinical research arena."^[1] BRIDG can be used for various purposes: as a reference model, a data integration/mapping solution, an exchange format, an ontology, or to create a BRIDG-based database. The use of BRIDG helps support the meaningful exchange of data between software systems and databases.

When BRIDG is used as a reference model to create or add new content to a standard, it can help ensure that relationships between and among biomedical research concepts represented using the standard are consistently modeled.

7.1.2 PRM

The [Protocol Representation Model](#) (PRM) provides a standard for planning and designing a research protocol with focus on study characteristics such as study design; eligibility criteria; and requirements from [ClinicalTrials.gov](#), [World Health Organization](#) (WHO) registries, and [EudraCT](#) registries. The PRM assists in automating CRF creation and EHR configuration to support clinical research and data sharing.

Note: The PRM was released in 2012 and includes some overlap with the USDM. It is anticipated that the USDM will develop to be more content rich and implementable as a model and will therefore supersede the PRM.

7.1.3 SDTM and SDTMIG

The [SDTM](#) provides a standard for organizing and formatting data to streamline processes in collection, management, analysis, and reporting. Implementing SDTM supports data aggregation and warehousing, fosters mining and reuse, facilitates sharing, helps perform due diligence and other important data review activities, and improves the regulatory review and approval process. The SDTM provides a standard for organizing and formatting data for human and animal studies; the [SDTM Implementation Guide](#) (SDTMIG) is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets. The SDTMIG was developed to support data submitted to a regulatory authority, such as the US Food and Drug Administration (FDA), but is not restricted to use in regulated submissions. The SDTM is 1 of the required standards that sponsors must use, as

specified in the FDA's Data Standards Catalog,[2] for New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and certain Biologics License Applications (BLANDAs).

The SDTMIG includes a section related to Trial Design Model datasets. Section 9.1 (Annex IIIa and Annex IIIb) of the ICH *Guideline for Industry: Structure and Content of Clinical Study Reports*[3] calls for a brief, clear description of the overall plan and design of the study, and supplies examples of charts and diagrams for this purpose. Each annex corresponds to an example trial and provides a diagram describing the study design and a table showing the schedule of assessments. The Trial Design Model provides a standardized way to describe aspects of the planned conduct of a clinical trial shown in the study design diagrams of these examples. Standard Trial Design datasets allow reviewers to

- clearly and quickly grasp the design of a clinical trial,
- compare the designs of different trials,
- search a data warehouse for clinical trials with certain features, and
- compare planned and actual treatments and visits for subjects in a clinical trial.

Modeling a clinical trial in this standardized way requires the explicit statement of certain decision rules that may not be addressed or may be vague or ambiguous in the usual prose protocol document. Prospective modeling of the design of a clinical trial should lead to a clearer, better protocol. Retrospective modeling of the design of a clinical trial should ensure a clear description of how the trial protocol was interpreted by the sponsor.

Automated creation of SDTM Trial Design datasets is possible using data structured in USDM v3.0 format as detailed in Section 7.1, [Creation of SDTM Trial Design Domains](#).

7.1.4 Controlled Terminology

CDISC, in collaboration with the [National Cancer Institute's \(NCI\) Enterprise Vocabulary Services \(EVS\)](#), supports the controlled terminology (CT) needs of the CDISC standards. *Controlled terminology* is the set of codelists, definitions, and valid values used with CDISC model elements. Within CDISC there are many volunteer teams that evaluate and manage CDISC CT. For example, the Protocol Entities Terminology Team develops and publishes the semantics for concepts found in clinical research protocols; the CDISC Glossary Team harmonizes the semantics and definitions for concepts commonly found in CDISC standards documents. The DDF terminology subset of CDISC CT is one of the main deliverables supporting the USDM, and development of CDISC CT for the USDM has been harmonized with existing, published CDISC CT (including SDTM, Protocol, and CDISC Glossary) in order to ensure maximum reuse of terms and definitions. Any new CT that has been developed for the USDM has undergone review from the Protocol Entities and CDISC Glossary Teams. USDM-related CT is developed and published using the same process as all other CDISC CT, in order to ensure a consensus-based, fit-for-use, and harmonized set of terms.

7.1.5 CTR

[Clinical Trial Registry \(CTR\)-XML](#) lets technology vendors implement tools that support a “write once, use many times” solution based on a single XML file that holds the information needed to generate submissions for multiple clinical trials for clinical trial registry submissions, primarily to the WHO, the European Medicines Agency (EMA), the EudraCT registry, and [ClinicalTrials.gov](#) (US).

Working alongside clinical trial registry SMEs, an evaluation was performed to determine how USDM could be used to assist in the population of elements required for clinical trial registries. In Version 3.0, this was restricted to [ClinicalTrials.gov](#). Additional information can be found in Section 7.2, [Informing ClinicalTrials.gov Registry](#).

7.1.6 ODM

[Operational Data Model \(ODM\)-XML](#) is a vendor-neutral, platform-independent format for exchanging and archiving clinical and translational research data, along with their associated metadata, administrative data, reference data, and audit information. The ODM-XML facilitates the regulatory-compliant acquisition, archival, and exchange of metadata and data. It has become the language of choice for representing CRF content in many EDC tools. ODM-XML v2.0 (released August 2023) added significant functionality to the ODM standard, including:

- Multilingual support
- Data query support
- Traceability (Trace-XML features) support
- HL7 FHIR interoperability

- Study/Trial Design Model in XML (SDM-XML) integration and enhancement
- CDISC 360 support
- Data capture

Although the USDM is a reference model and the ODM is a transport model, there is overlap between the standards in terms of elements related to study design (e.g., biomedical concepts) and elements related to EDC build (e.g., visits, forms, variables). Therefore, during the development of the USDM, areas of development for ODM-XML v2.0 were investigated and, where possible, aligned with USDM.

7.1.7 SDM

Study/Trial Design Model in XML (SDM-XML) is an extension of the ODM-XML and allows organizations to provide rigorous, machine-readable, interchangeable descriptions of the designs of their clinical studies, including treatment plans, eligibility, and times and events. SDM-XML defines 3 key submodules (i.e., structure, workflow, timing), permitting various levels of detail in any representation of a clinical study's design.

Note: SDM v1.0, released in 2011, was incorporated into ODM-XML v2.0. The SDM was used as an input reference model during the development of the USDM.

7.2 Relationship to Other Standards

7.2.1 ICH M11 Guideline, Clinical Study Protocol Template, and Technical Specifications

The ICH M11 guideline[4] introduced CeSHarP; the technical specification ensures that protocols are prepared in a consistent fashion and provided in a harmonized data-exchange format acceptable to regulatory authorities. The guideline, clinical study protocol template, and technical specifications were released in October 2022 for public review; where possible, these were used as reference input during USDM v4.0 development. Working closely with ICH, USDM v4.0 has been aligned to cover the breadth of sections found in the ICH M11 CeSHarP template. This allows a USDM study design to be represented in the ICH CeSHarP template. **Note:** At the time of publication of USDM v4.0, the ICH CeSHarP was still in the development phase. In future phases of USDM development, CDISC will continue to collaborate with the ICH team in order to ensure that USDM remains aligned with the ICH M11 CeSHarP template.

7.2.2 HL7 FHIR SOA

The Vulcan Schedule of Activities (SoA) Project defines a pattern for a clinical trial SOA structure using FHIR resources and processes that enables sharing, interpretation, and implementation in healthcare (EHR, PHR) systems. When a subject is enrolled in a study, research personnel will be able to attach them to the ResearchSubject and ResearchStudy, connecting the CarePlan with the schedule of activities (the research visits and corresponding tests/activities).

IDMP

The ISO IDMP standards specify the use of standardized definitions for the identification and description of medicinal products for human use. The EMA is implementing the standards in a phased program while the FDA evaluated compatibility with currently used standards and is taking next steps for further alignment. USDM v4.0 includes a new extended intervention part that aligns with administrable product, ingredient, substance, and medical device parts of IDMP. However, not all required elements for IDMP could be included in USDM since some of these elements are the outcome of the clinical trials that are designed (e.g., drug indication, effective dose).

8 USDM Features

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8.1 Overview

The USDM normative form is a UML model. The USDM provides the ability to define a version of a clinical study that includes:

1. The main study details, such as:
 - a. Versions and content of study definition documents (e.g., a protocol that the study relates to)
 - b. Various identifiers allocated to the study
 - c. Study roles and organizations
 - d. Study amendment details
2. One or more study designs within the study, with each study design detailing:
 - a. Arms and epochs within the design and the relationships between them
 - b. Encounters planned for the study and the relationship with the epochs of the study
 - c. Timing of collection of data and the performance of procedures
 - d. A detailed data specification for the data to be captured as part of the study
 - e. Procedures to be performed as part of the study design
 - f. Subject populations defined within the study design
 - g. Objectives, endpoints, and estimands defined within the study design
 - h. Interventions defined as part of the study design
 - i. The relevant indications
 - j. Biospecimen retention information

Although the USDM is designed to hold and exchange a single version of a study, the model can be used to implement systems that hold multiple versions of multiple studies.

Note: The use of the terms above and their respective definitions are defined within the USDM class definitions and the related controlled terms.

8.2 Principles

The main principles applied to the development of the USDM include:

- Try not to reinvent the wheel. At the same time, improve. Use and learn from existing models.
- Align with existing CDISC models as much as possible but do not be constrained by them.
- Where sensible, provide standardized codes from CDISC CT. Allow for aliases.
- Allow for references to any CT where sensible.
- Do not recreate the paper world.
- Be aware of model versus presentation.
- The model should represent a complete protocol, not a partially completed one. Implementors should be able to relax constraints if they are building protocols.
- The model should not prevent implementors from extending the model.
- Keep the approach simple at the start; iterate, learn, and add complexity as it is understood.
- Support the planned design, not subsequent execution.
- Support the whole protocol document.

With respect to terminology, principles include:

- Standardize on a codelist/value set; be prescriptive.
- Where there is misalignment, standardize on the best global standard.
- Allow for regional differences (e.g., FDA in the US).

8.3 Naming Conventions

8.4 General

The USDM defines standard naming conventions. This includes improving the names of classes and, in particular, attributes to make the model more implementation friendly.

This section details the conventions used for naming and the use of attribute data types.

8.5 Class and Attribute Naming

The naming convention as currently used is:

- Nouns are used for class names.
- Every class has an attribute named "id" such that a unique identifier, within the scope of a study, can be allocated to instances of the class.
- A class can have a number of standard attributes. The attribute names should not be used for any other purpose than:
 - name: the literal identifier (i.e., distinctive designation) for an instance of the class
 - description: a narrative representation for an instance of the class
 - label: the short descriptive designation for an instance of the class
 - notes: a USDM relationship between the class and the CommentAnnotation class which provides the set of notes related to the class

Note: a class may employ these attributes if they are required and thus not all classes use them.

- A class can have additional attributes.

8.6 Data Types

Attributes have been provided with simple data types or 1 of the following complex data types:

- Code: Including a reference to the corresponding code system, code system version, and decode value
- AliasCode: Allowing to refer to a standard code and 1 or more standard code aliases
- Quantity: Including a value and an optional unit
- Range: Including a minValue and maxValue quantity and an indication whether the range is approximate
- CommentAnnotation: Including free text and optional codes as needed for the purpose

The complex datatypes are further specified via separate classes in the data model.

8.7 Relationships

Relationships have, in general, been formed from the names of the class at either end of the relationship with singular names used for one-to-one relationships and plural names used for one-to-many relationships.

8.8 Internal Identifiers Within the Model

Each class defined within the UML has an identification attribute that can be used to provide a unique identifier for an instance of the class. The identifier should be unique and self-consistent within the scope of a version of a study. No attempt is made to define the form, type, or structure of these identifiers; the attributes are defined as strings. The only exception is the identifier at the head of the model within the Study class. Implementors are free to allocate the value to this field using, for example, a UUID, to ensure uniqueness within the implementation.

8.9 Controlled Terminology

Controlled terminology is referenced in multiple places across the USDM. So as to provide a mechanism to refer to controlled terms in a consistent manner, the USDM employs the Code class. The Code class uses 4 attributes to define the term being used (a code and decode pair), the terminology from which the term is taken, and the version of that terminology. This allows for any controlled term—whether CDISC, SNOMED, LOINC, or other—to be referred to in a consistent manner.

Certain attributes within the USDM Code class have been constrained to using terms from a given codelist from specified terminologies; these are specified in the controlled terminology spreadsheet. Although most of the terms referenced are CDISC CT, some other controlled vocabularies are referenced.

Where a standard code (typically a CDISC code but not always) is demanded by the model but flexibility is desirable/needed, users may include other terms (aliases) using the AliasCode class. Here 1 standard term is required but zero, 1, or more aliases can be provided. One particular instance is geographic references. The standard code should be from [ISO 3166](#); other code aliases (e.g., [GENC](#)) can be provided.

8.10 Study, Protocols, and Amendments

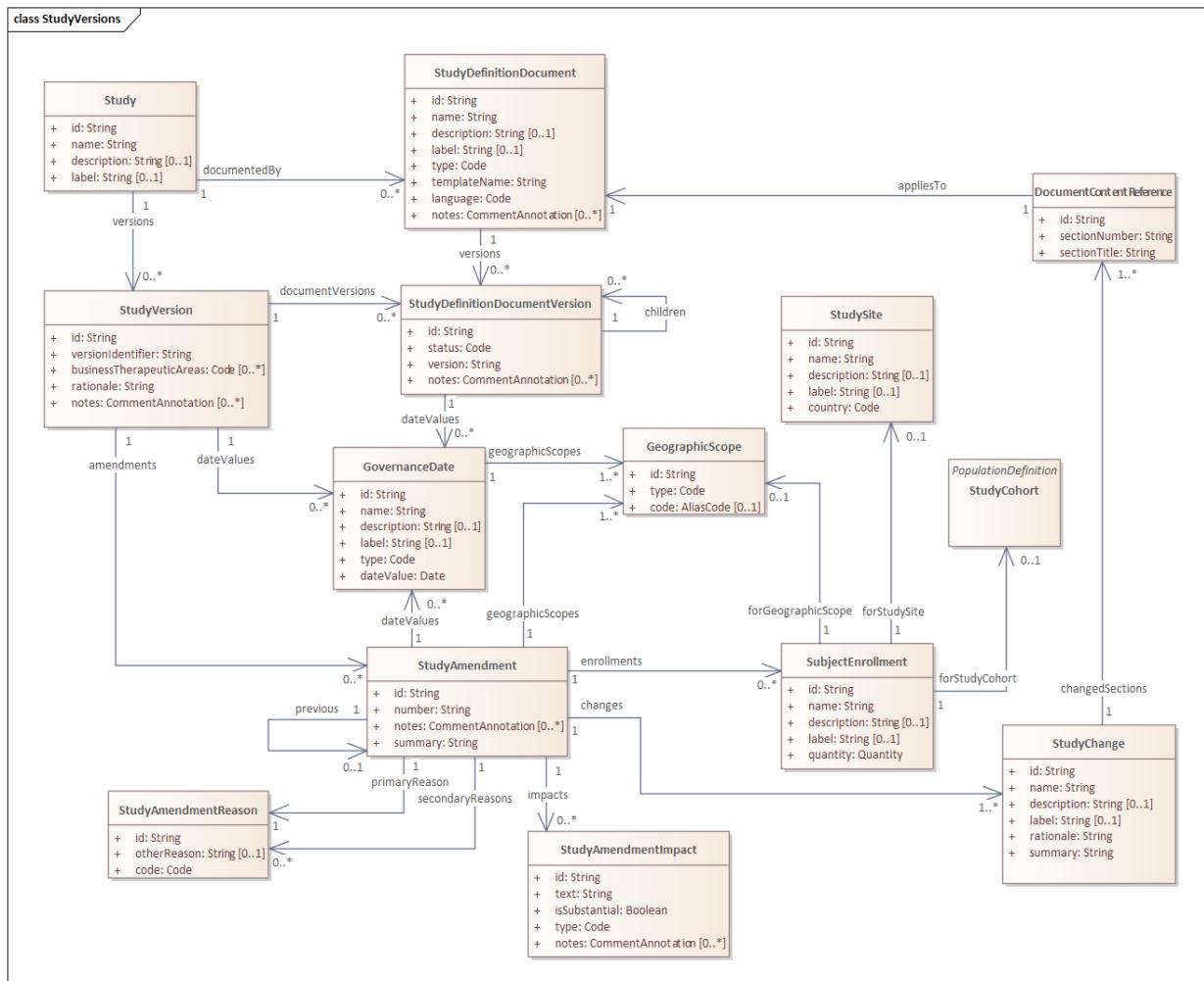
The Study class is the root of the USDM, collecting together the definition of the study and its corresponding versions as a whole. A study is documented by a study definition document, which usually is a protocol but could be of other types. The overarching study and the study definition document each have their versioning with corresponding governance dates. These dates are to be focused to a specific geographic scope (e.g. global, regional, country).

Because the traditional paper/PDF protocol document has been split into 2 parts (i.e., the document and an electronic design using the USDM), there is a need to link which electronic definition is valid with which version of the document. The study version links the study with its constituent parts that include 1 or more study designs (see [Section 4.8](#)), amendments, identifiers, and titles (see Section 4.7, [Study Identifiers and Titles](#)) for the study. The Study Version class or Study Design class refers to the corresponding instance in the StudyDefinitionDocumentVersion class to define to which versions of an external document the study definition relates. The StudyVersion class allows for stating the business therapeutic area. **Note:** The business therapeutic area is provided for downstream processes and for sponsor organizations to define the business areas within the enterprise handling the study. It should be noted that business therapeutic area is not the same as the therapeutic area defined in the StudyDesign class.

A study version may represent an amendment. Corresponding amendment details—including reasons for the amendment, number or percentage of subjects enrolled at time of amendment, list of amendment changes, and substantial impact per type—are captured in the StudyAmendment class and corresponding subclasses. All

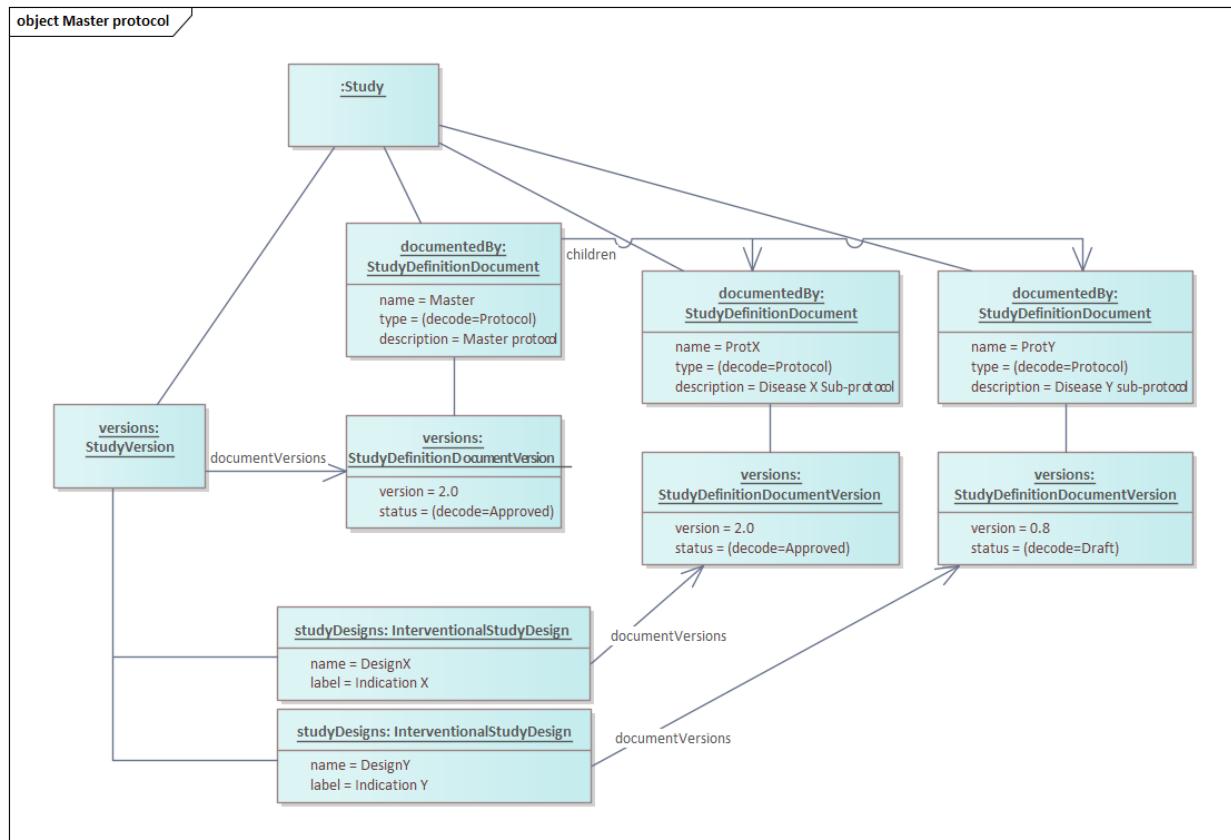
amendment details may be reflected in the corresponding study definition document version. The content of this study definition document version is captured in the USDM as unstructured content (see [Section 4.20](#)) and may include direct linkage to the specific study amendment information. Each amendment includes 1 or more changes. Each change can be detailed with a summary, a rationale, and 1 or more references to specific sections of the current study definition document that are changed.

Abbreviations that are used to describe the study design are defined at the study-version level and can be reused (e.g. referenced) both in the syntax template text (e.g., for eligibility criteria or assessment conditions) as well as in unstructured document content. Some examples are presented in Section 4.19, [Abbreviations](#). The full list defined for the study can also be used to automatically create the full list of abbreviations in the study protocol.



Typically, there would be a one-to-one relationship between study version and study design with 1 or more protocol versions related to the study covering the different designs. Multiple study designs are permitted so as to accommodate multiple designs that test, for example, multiple drugs and/or multiple subpopulations in parallel under a single (master) protocol without a need to copy all study details for each subtrial.

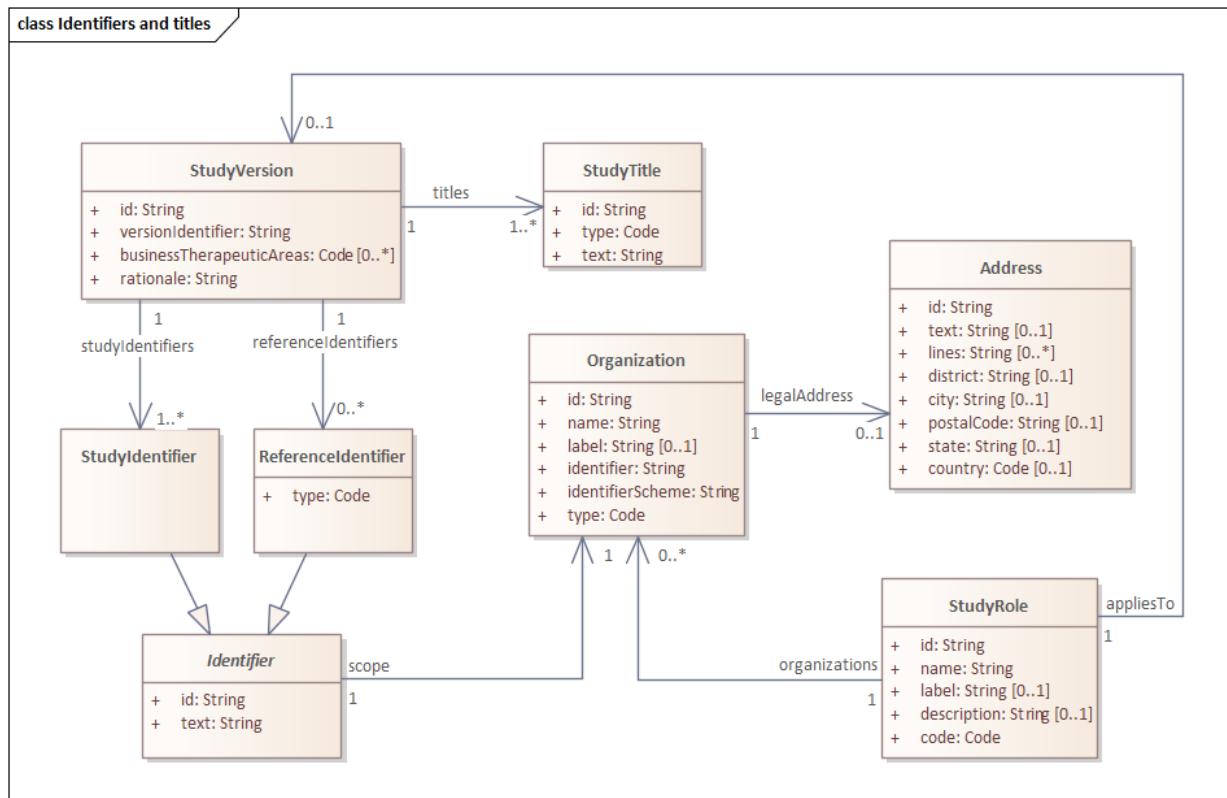
The following instance diagram shows an example of a study with multiple designs involving multiple study definition documents. In this diagram, there is 1 master basket trial protocol referred to from the **StudyVersion** class. This master protocol has several children which in this case specify the specific details for the different indications that are included for the same experimental intervention. Each study design is in this case specific for an indication and points to the corresponding document versions of the child protocols. Note that for each version the maturity status may differ (e.g., draft, approved), which reflects a staged approach of study designs for multiple indications (basket), multiple drugs (umbrella), or multiple phases.



Note that instance diagrams are created to show a single use case. Not all required attributes and relationships are presented in the instance diagrams.

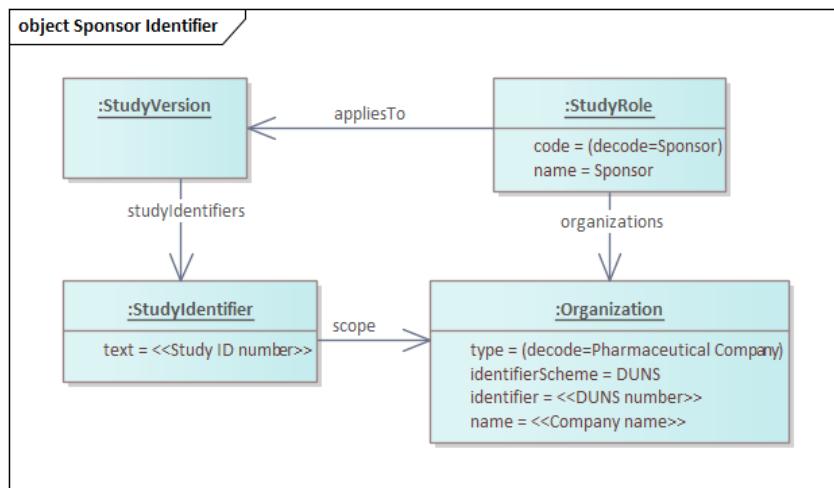
8.11 Study Identifiers and Titles

Study identifiers, reference identifiers, and titles are stored in separate dedicated classes as presented in the UML below and are referred to from out of the StudyVersion class. A study identifier specifically identifies the study represented in the data model. A reference identifier is optional and identifies an overarching (e.g., pediatric investigational plan number, clinical development plan number).

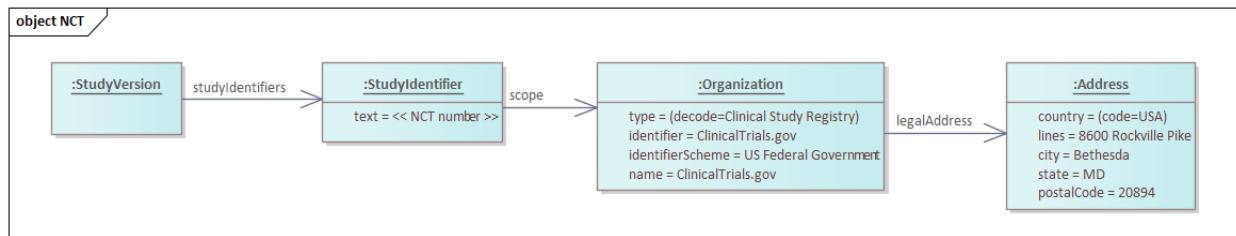


One or more study titles are required for a study. They can be of different types (e.g., official, scientific, short titles). If available, the acronym should be stored as a title as well, specifying the type as acronym.

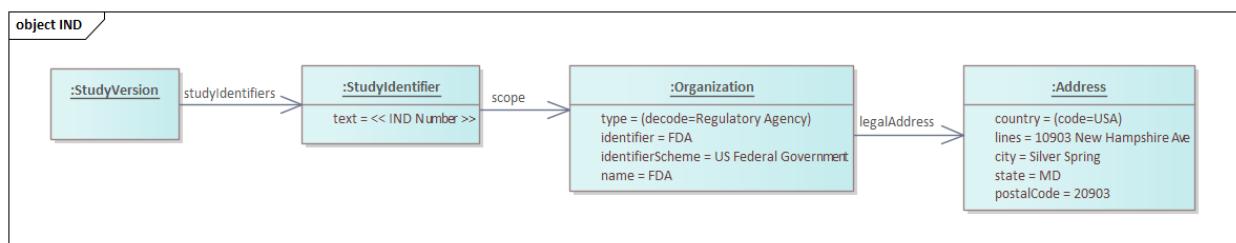
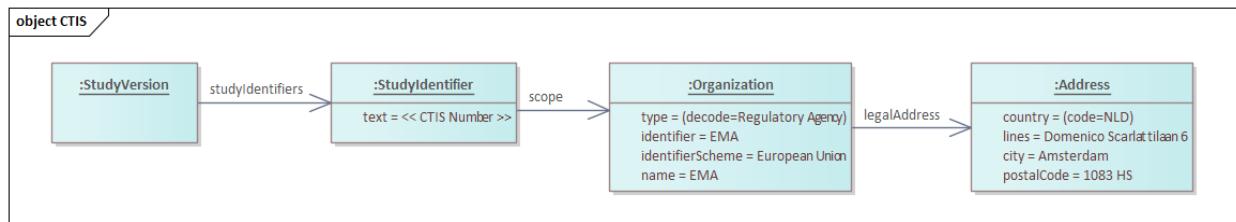
The **StudyVersion** class allows for including 1 or more study identifiers. Although multiple identifiers are permitted, the study definition should have 1, and only 1, sponsor identifier. A sponsor identifier is identified by its scope of an organization that has the Sponsor study role as shown in the following instance diagram. Identifiers of co-sponsors may be linked in a similar fashion to the co-sponsor study role.



Registry identifiers (e.g., NCT and EudraCT numbers) should refer to a clinical study registry organization type as presented in the following diagram.



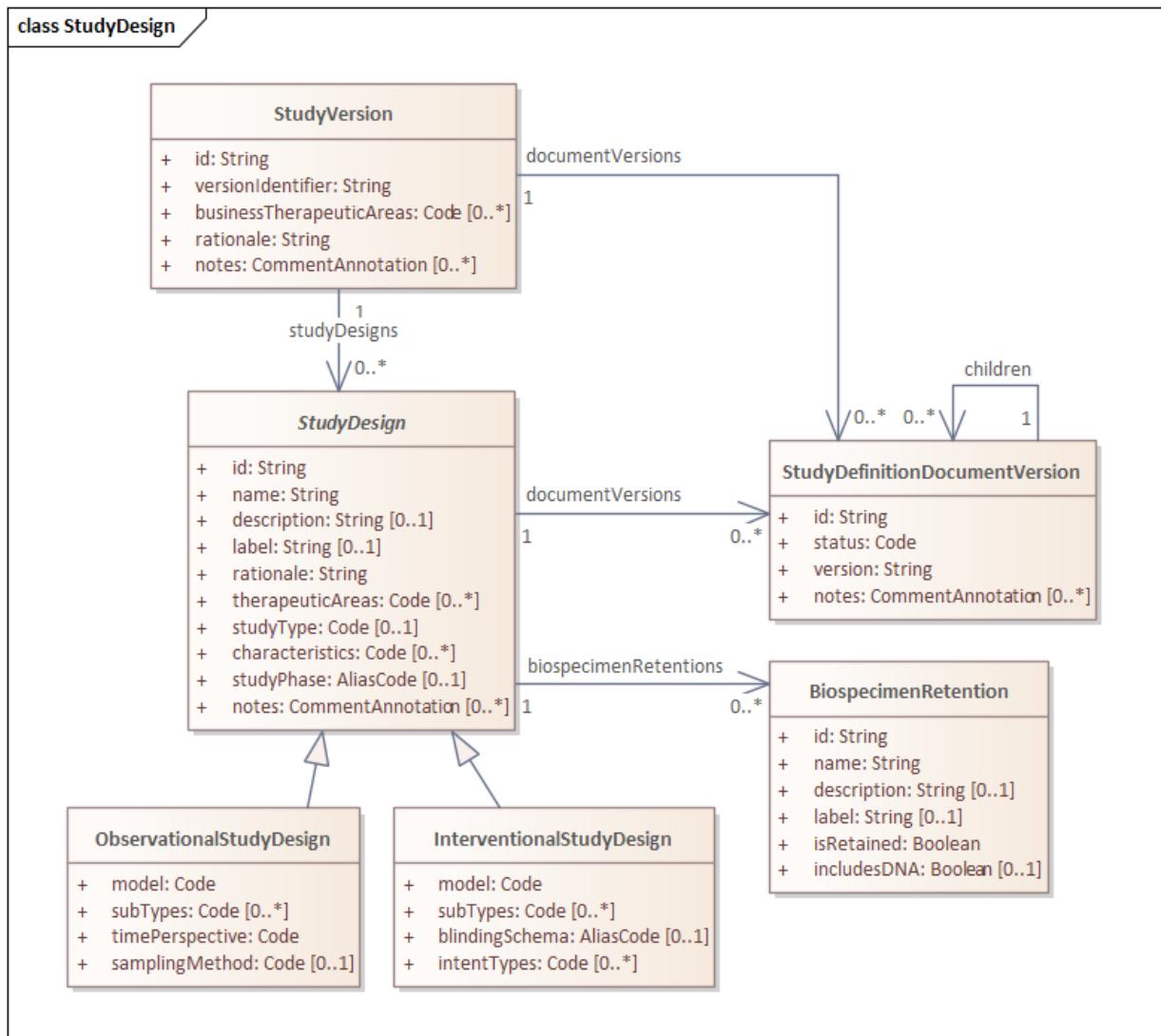
Regulatory agency identifiers (e.g., CTIS, NCT) should refer to a regulator agency organization type:



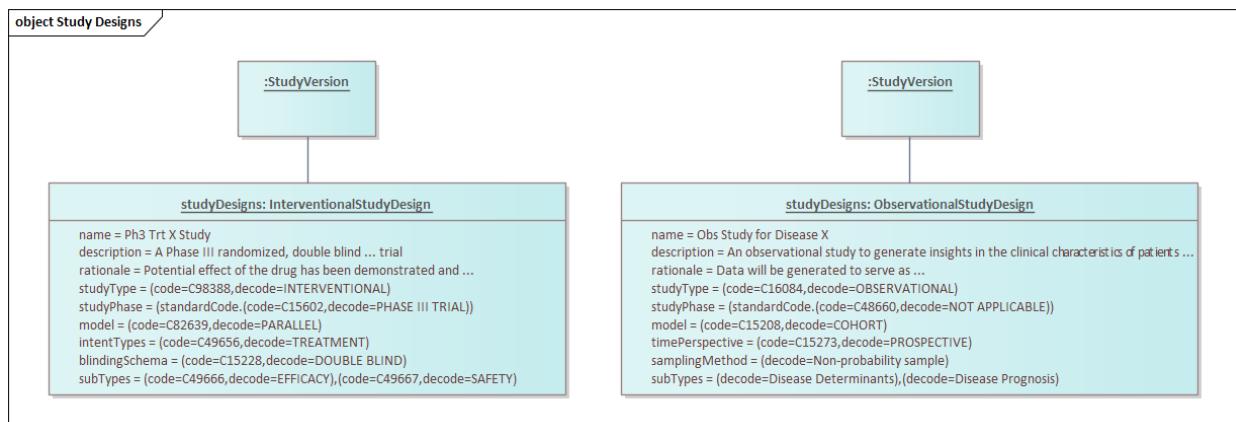
Note that not all attributes (required and optional) and relationships are presented in these instance views. Also note the use of [ISO 3166-1 country codes](#) within the address field referenced by the organization class.

8.12 Study Design

The StudyDesign class is the container for a single design within a study definition. It can be populated as either an observational study design (ObservationalStudyDesign class) or interventional study design (InterventionalStudyDesign class). Both classes inherit all the study design features from the StudyDesign class and include references to study timelines (see Section 4.14, [Study Timing](#)); objectives and endpoints ([Section 4.16](#)); populations (see [Section 4.18](#)); study interventions (see [Section 4.15](#)); and design elements like arms, epochs, and encounters (see [Section 4.10](#)). It provides the slots for key parameters such as therapeutic area, study phase, and study type. Specific interventional or observational study design parameters referring to their own specific controlled terminology are stored in the corresponding classes. Trial types are stored as subTypes in the InterventionalStudyDesign class as well as intent types, blinding schema, and intervention model. Observational subtypes and model are stored in the ObservationalStudyDesign class together with timePerspective and samplingMethod.



The following instance examples show how study design elements may be populated for interventional and observational studies.



Note that instance diagrams are created to show a single use case. Not all required attributes and relationships are presented in the instance diagram.

The StudyDesign class provides a place to store 1 or more codes defining the therapeutic area to which the study design relates from a regulatory perspective. No controlled terminology is provided for the population of this therapeutic area field; the following table details controlled vocabularies that are available for users to populate 1 or more values into the attribute.

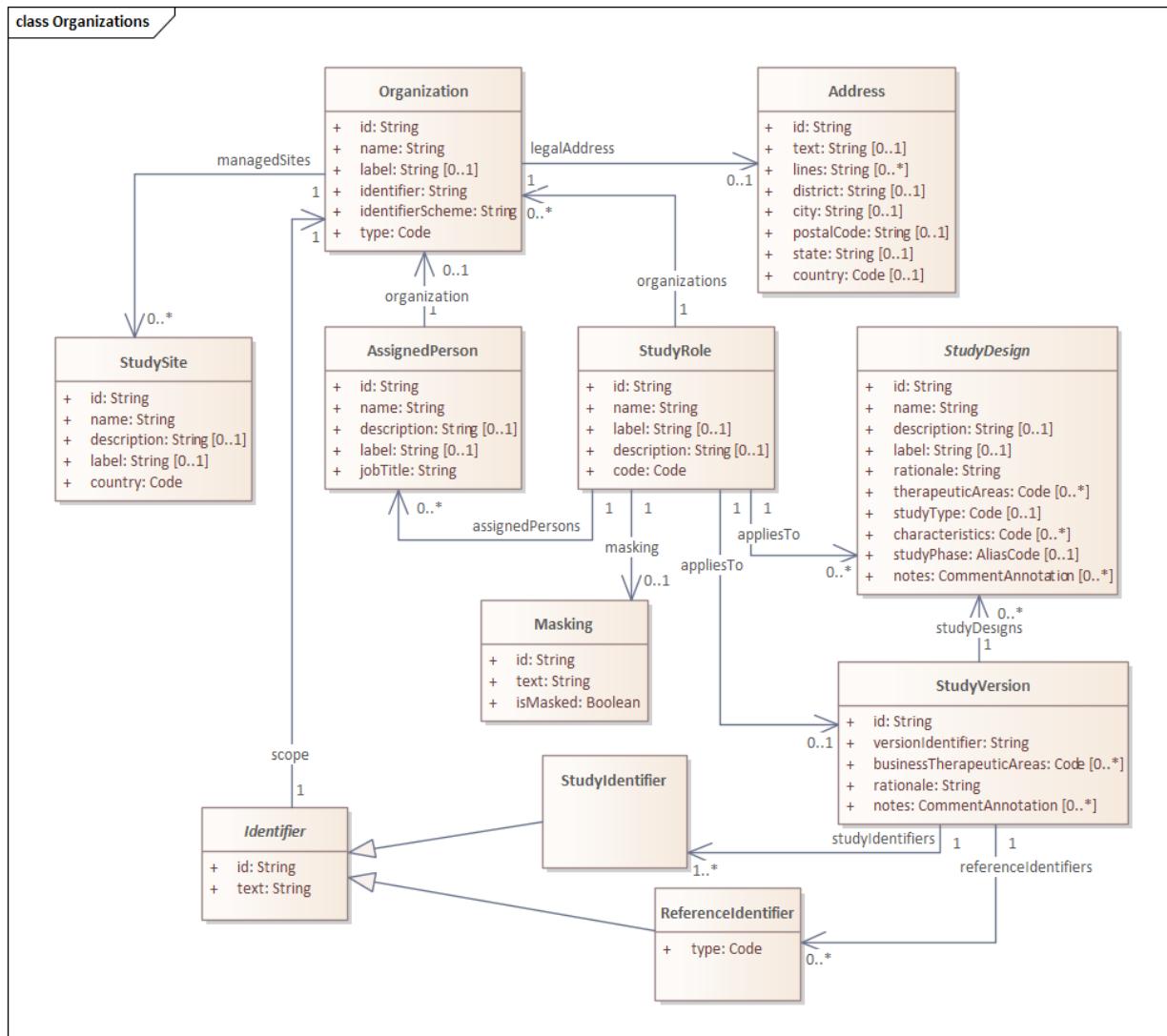
| Dictionary/Terminology | URL |
|------------------------|---|
| EudraCT | https://eudraact.ema.europa.eu/docs/technical/EUDRACT_Eutct_Pick_Lists_and_coded_values_v1_0.xls |
| ICD-10 | https://www.icd10data.com/ICD10CM/Codes |
| MedDRA | https://www.meddra.org/ |
| MeSH | https://www.ncbi.nlm.nih.gov/mesh/ |
| NCI Thesaurus | https://ncit.nci.nih.gov/ncitbrowser/ |
| SNOMED-CT | https://www.nlm.nih.gov/healthit/snomedct/index.html |
| US FDA | https://www.fda.gov/drugs/development-resources/spectrum-diseasesconditions |

8.13 Study Roles and Organizations

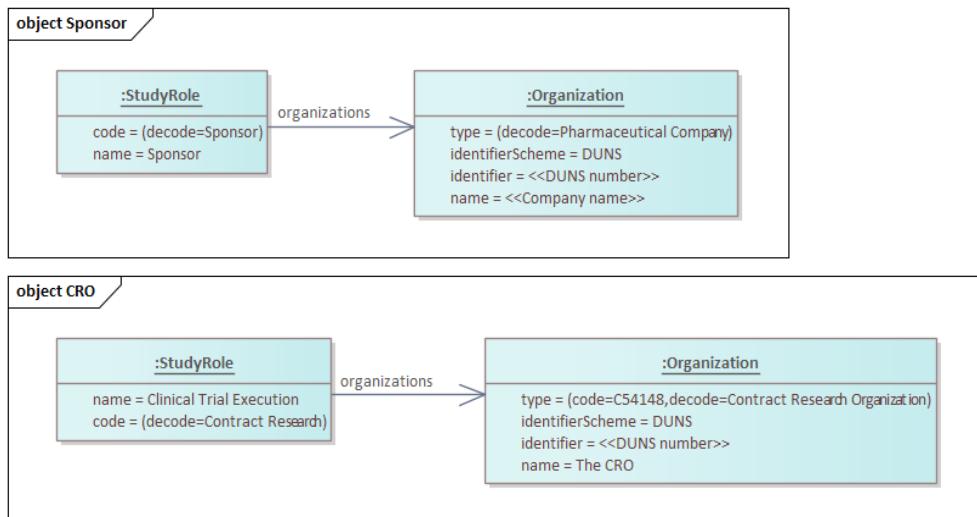
A clinical study may include a number of different roles on different levels (e.g., sponsors, investigators, monitoring committees). These roles are stored in the StudyRole class. A role may apply to the study as a whole or to 1 or more study designs specified within that study.

Names of persons assigned to a study role are specified in the AssignedPerson class. If no specific persons are assigned then the StudyRole may directly link to an organization being responsible for the role as a whole. The organization type identifies what kind of organization is specified (e.g., pharmaceutical company, healthcare facility, contract research organization (CRO), regulatory agency). An identifier should be referring to 1 of the defined organizations as its scope (see [Section 4.7](#)).

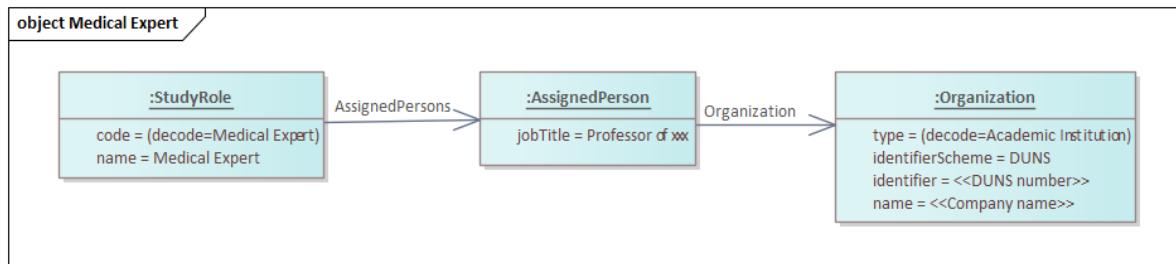
An organization can optionally manage 1 or more study sites. These study sites may be referred to in case a subject enrollment status for an amendment is specific for a site (see Section 4.6, [Study, Protocols, and Amendments](#)). If a role is masked in a study then this can be further specified in the Masking class.



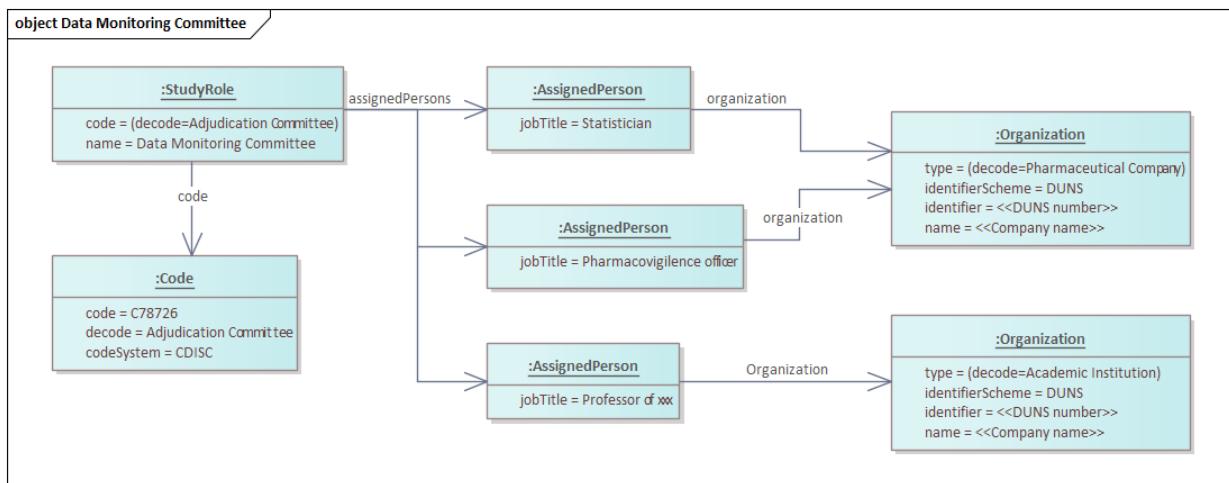
Examples of a sponsor entry and a CRO entry are presented below. In case of a commercial organization, the DUNS number is expected to be specified to uniquely identify the commercial entity.



The study role may include either 1 or more organizations as a whole or 1 or more assigned persons. Assigned persons are specified in the AssignedPerson class which then subsequently may link to the corresponding organization as depicted in the following example.



The following example shows how a data monitoring committee includes more assigned persons referring to their respective organizations.



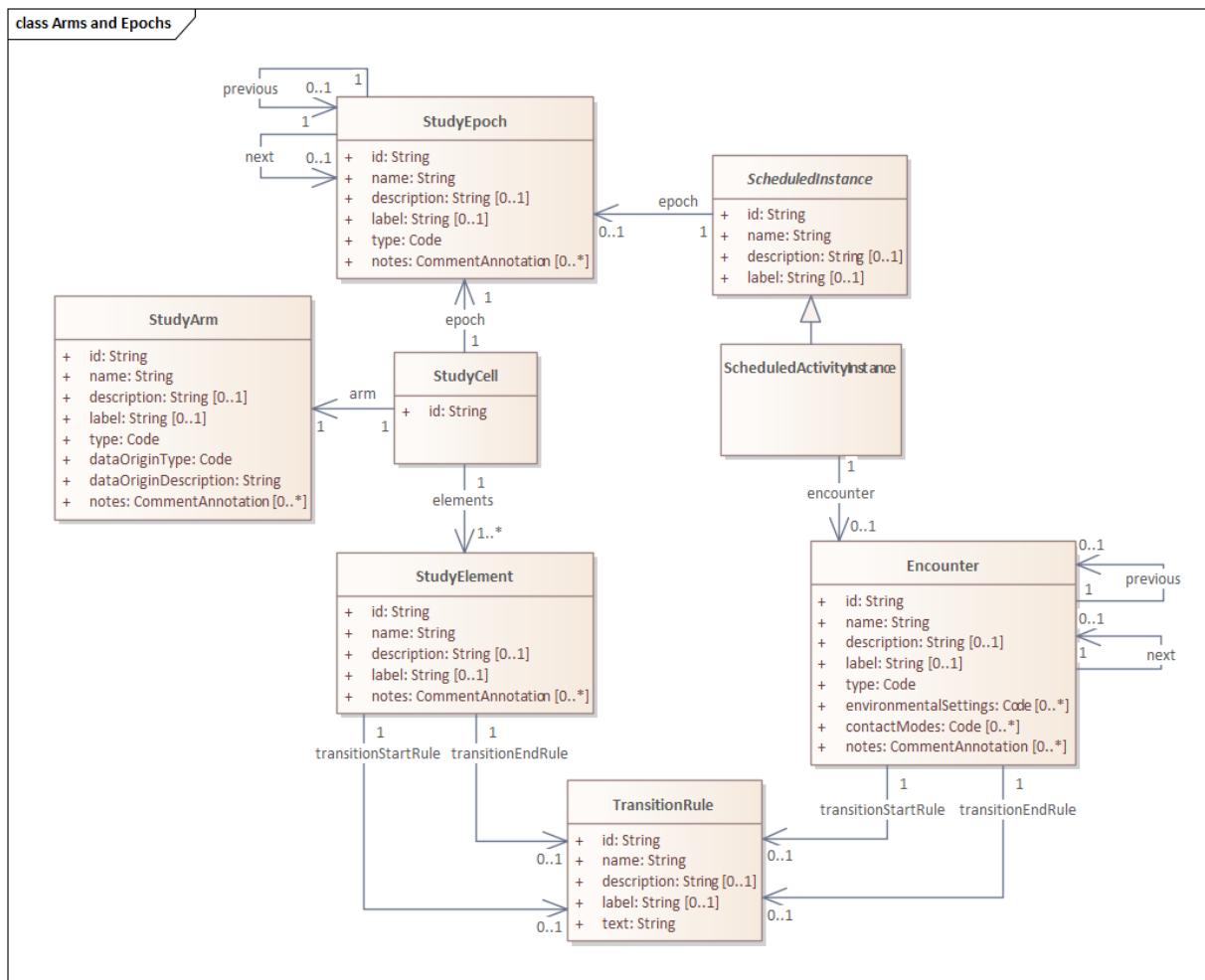
Note that instance diagrams are created to show a single use case. Not all required attributes and relationships are presented in the instance diagrams.

8.14 Arms and Epochs

The high-level study design based on arms and epochs is defined using the `StudyArm`, `StudyEpoch`, `StudyCell`, and `StudyElement` classes. The manner in which the classes are used follows the CDISC SDTM. Epochs are related to the study encounters (a more generic term for visits) via `ScheduledInstances` that form a `ScheduleTimeline` (see Section 4.14, [Study Timing](#)). `StudyElements` can relate to the corresponding `studyInterventions` that are planned for the specific `StudyArm` and in the specific `StudyEpoch`.

`StudyElements` and `Encounters` have entry and exit rules that are defined using the `TransitionRule` class. It should be noted that although the `StudyElements` and `Encounter` classes share the use of the `TransitionRule` class, it is not expected that the instances within any study design will overlap; they are, most likely, distinct sets.

Given that the use of the classes is based on the SDTM, the information within these classes can be used to populate the SDTM Trial Design domains (see [Section 7.1](#)).

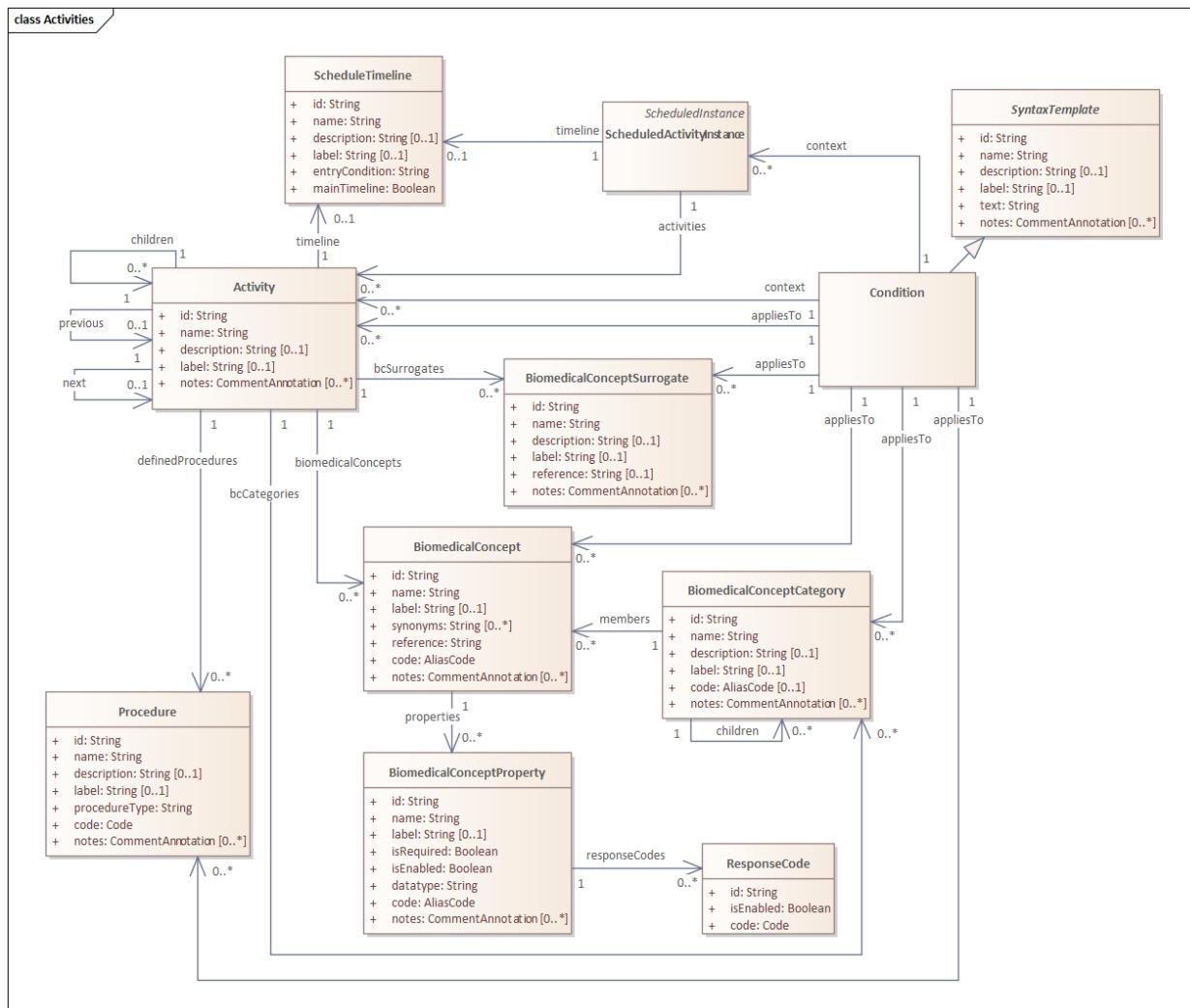


8.15 Activities

Activities are the means by which the procedures to be performed and the data to be captured are specified at a detailed level. The Activity class is used to group together data capture and procedures. The composition of these groupings is left to those designing studies and may align with the activities presented in the schedule of activities. The presentation ordering in the schedule of activities can be handled with the previous and next attributes. Any presentation groupings can be handled with the children attribute. Activities can be reused across multiple points within a study timeline via the ScheduledActivityInstance class (see Section 4.14, [Study Timing](#)).

The Activity class can be linked to 1 or more procedures (see [Section 4.12](#)), 1 or more biomedical concepts (see [Section 4.13](#)), 1 or more groups of biomedical concepts, 1 or more surrogate biomedical concepts, and/or a subtimeline. A subtimeline referred to from an activity would typically be a sequence of actions covered by the activity description (e.g., blood glucose profiles, sitting/standing vital signs sequences).

Activities or the corresponding assessments and procedures may be conditional. These conditions, specified in the Condition class, apply to at least 1 activity, biomedical concept, group of biomedical concepts, biomedical concept surrogate, or procedure. The context of the condition can be to the activity in general (at every time point it is scheduled) or to a specific time point in the timeline via ScheduledActivityInstance.



The example below shows how the values for activities that are typically present in the first column of the schedule of activities are stored in the USDM activity class and how "grouping" headings can be accommodated. The previous and next attribute is used to identify the order of presentation while the children attribute is used to identify the group members, for example "Efficacy" or "Safety". This grouping activity (e.g., having children) is typically only used for presentation purposes and is not expected to be referred to from a scheduled activity instance or to point to biomedical concepts or procedures. It is recommended that only 2 levels of grouping (i.e, parent and child) are used.

| Schedule of activities | Screening | Day 1 | |
|-----------------------------|-----------|-------|------|
| Subject related Assessments | | | |
| Informed consent | X | | |
| In/Exclusion criteria | X | X | |
| Demography | X | | |
| Medical history | X | | |
| Randomisation | | X | |
| Efficacy | | | |
| Lab efficacy assessments | | X | X |
| PRO questionnaire | | X | X |
| Safety | | | |
| Vital signs | X | X | X |
| ECG | X | X | |
| Hematology | X | X | |
| Biochemistry | X | X | |
| Adverse events | X | X | X |
| Intervention | | | |
| Drug dispensation | | X | X |
| Drug accountability | | X | |

| label | id | previous | next | children |
|-----------------------------|-------|----------|-------|-----------------------------------|
| Subject related Assessments | id_01 | | id_02 | id_02, id_03, id_04, id_05, id_06 |
| Informed consent | id_02 | id_01 | id_03 | |
| In/Exclusion criteria | id_03 | id_02 | id_04 | |
| Demography | id_04 | id_03 | id_05 | |
| Medical history | id_05 | id_04 | id_06 | |
| Randomisation | id_06 | id_05 | id_07 | |
| Efficacy | id_07 | id_06 | id_08 | id_08, id_09 |
| Lab efficacy assessments | id_08 | id_07 | id_09 | |
| PRO questionnaire | id_09 | id_08 | id_10 | |
| Safety | id_10 | id_09 | id_11 | id_11, id_12, id_13, id_14, id_15 |
| Vital signs | id_11 | id_10 | id_12 | |
| ECG | id_12 | id_11 | id_13 | |
| Hematology | id_13 | id_12 | id_14 | |
| Biochemistry | id_14 | id_13 | id_15 | |
| Adverse events | id_15 | id_14 | id_16 | |
| Intervention | id_16 | id_15 | id_17 | id_17, id_18 |
| Drug dispensation | id_17 | id_16 | id_18 | |
| Drug accountability | id_18 | id_17 | | |

8.16 Procedures

The procedures linked to the Activity class allow for the procedures required by the activity to be detailed. A procedure consists of a free-text name and description; procedures can be classified using a free-text type attribute and coded using the code attribute. In cases where the procedure includes a study intervention (e.g., drug administration), the corresponding study intervention can be referenced.

8.17 Biomedical Concepts

The CDISC [Biomedical Concepts model](#) defines a clinical concept in a standardized and reusable manner; it is a specification focused on the data, not how the data are captured or processed. As such, biomedical concepts (BCs) are atomic entities and should not be split apart; to do so causes a loss of meaning. A BC is identifiable (has an identifier) and is complete (contains everything needed to use it).

A BC defines an observation but it requires context: the context of a clinical study. This is why, in the USDM, BCs are linked to activities and thus the remainder of a study design.

Within the USDM, the BC model has been represented in a manner consistent with the rest of the USDM. For example, controlled terminology references use the Code object to be compatible with all of the CT references across the USDM. Additional attributes have been added to allow for configuration as part of a study to enable or disable certain qualifiers or to constrain terminology responses to match the needs of a study (e.g., constraining units to metric values).

When a BC is included within a study design the BC can be constrained if the BC definition allows for such. When those constraints are applied or by whom is not dictated by the model; that is an implementation and process concern. For example, a study definition may leave everything in the BCs unconstrained and only when the study design is deployed in capture systems will any constraints be applied. Constraints take the form of disabling optional properties; for example, the method used for an observation does not need to be captured, or the terms for a property can be constrained (e.g., body position is always going to be supine for a particular observation and so standing can be disabled as an option). The constraints are applied via an enabled boolean flag. Some properties, such as a result, are always required. Required properties are indicated by a second boolean flag.

The USDM allows for the inclusion of a single BC (e.g., heart rate), a collection of BCs (e.g., vital signs preconfigured to include height, weight, heart rate, and other tests), or surrogate BCs. Surrogate BCs are a placeholder mechanism for when a BC definition is not available. This allows the name of a test to be specified but no further detail need be provided. Surrogates can contain a name and description pair for the concept required. A reference field is also provided to allow for links to reference materials (e.g., a URL for an external resource).

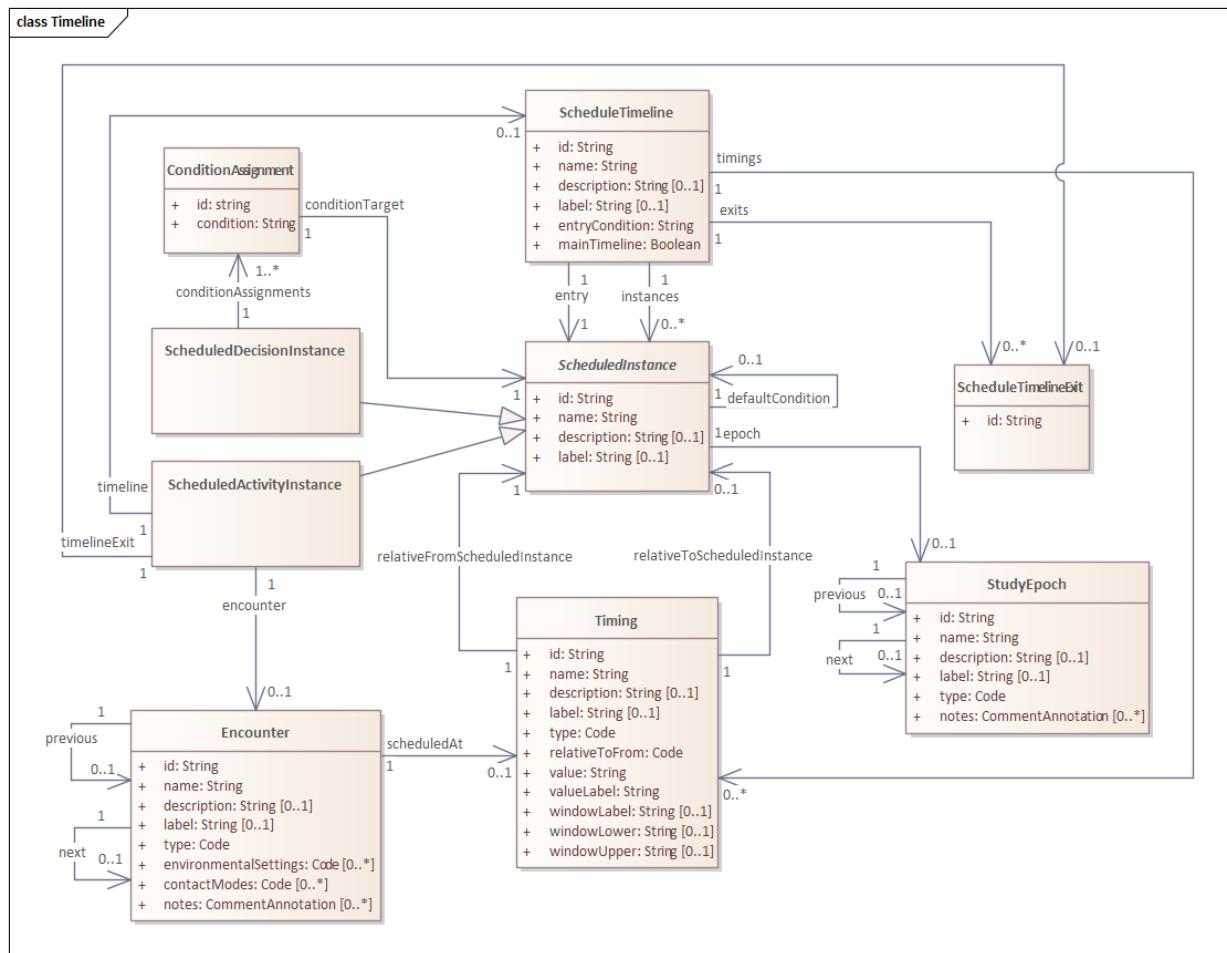
A single BC uses the BiomedicalConcept class as its root instance connected to 1 or more BiomedicalConceptProperty instances to define the various properties of the BC (e.g., result value, units, qualifiers).

Some of the property nodes will require controlled terminology references; these are placed within ResponseCode instances which then onward refer to a Code instance holding the actual term reference.

One or more BCs can be grouped using a BiomedicalConceptCategory. It is assumed that, to be useful, more than a single BC should be added to a grouping (e.g., vital signs). These groupings are expected to be sponsor defined but, in the future, some can be expected to be industry defined.

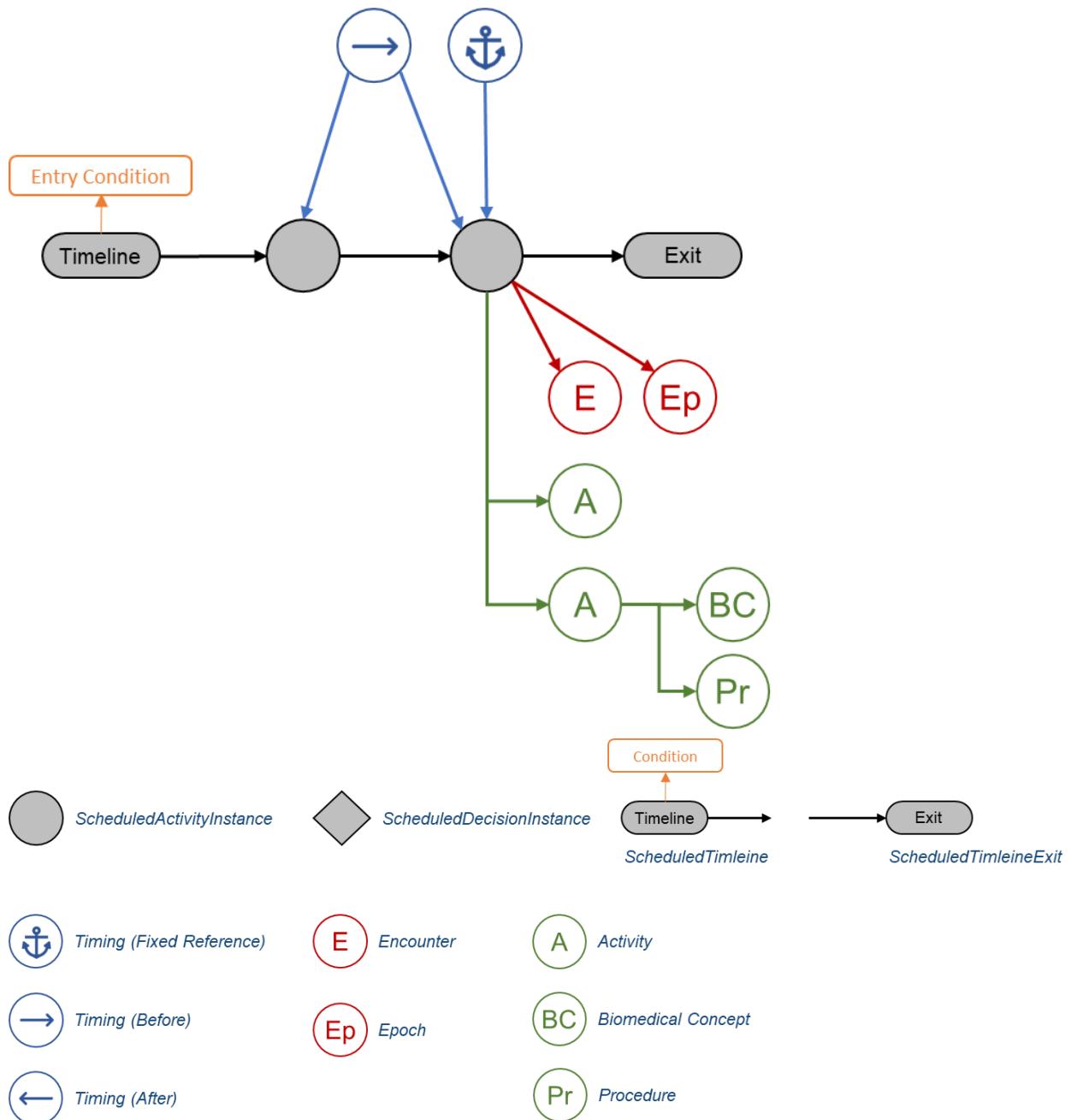
8.18 Study Timing

One of the key aspects of a study design is the timing of encounters (visits) and the activities to be performed within those encounters. The USDM includes a mechanism for building timelines that can be reused within a study and, given external library management, across studies. The corresponding classes and attributes are shown in the following UML diagram. This model allows for multiple planned timings within an encounter as well as for decision points in the study process. The corresponding information is stored in a timeline as scheduled activity instances and scheduled decision instances, respectively. Both inherit all attributes and relationships from the ScheduledInstance class (indicated by the closed arrows in the UML) and can be linked to the corresponding study epoch. The Timing class includes all timing information with details on time between instances and corresponding windowing. One or more scheduled activity instance can be related to a corresponding encounter, which is usually presented as a visit in the schedule of activities.



8.18.1 Timelines

The study timing mechanism depicted in the following figure is based on the notion of a timeline. A *timeline* is composed of an entry point with an associated entry condition (see ScheduleTimeline class), a sequence of steps (the ScheduledActivityInstance class and scheduledDecisionInstance class), timing relating the steps (the Timing class), and 1 or more exits (the ScheduleTimelineExit class) that mark the end of timeline processing. A timeline is named and can be referenced or reused within other timelines. The steps within a timeline link the encounters with the activities required for each step and thus define the timing for the encounters. The ScheduledActivityInstance class is the link between the high-level study design defined by the StudyArms and StudyEpochs classes, the Encounter classes, and the detailed study design defined by the Activity class.



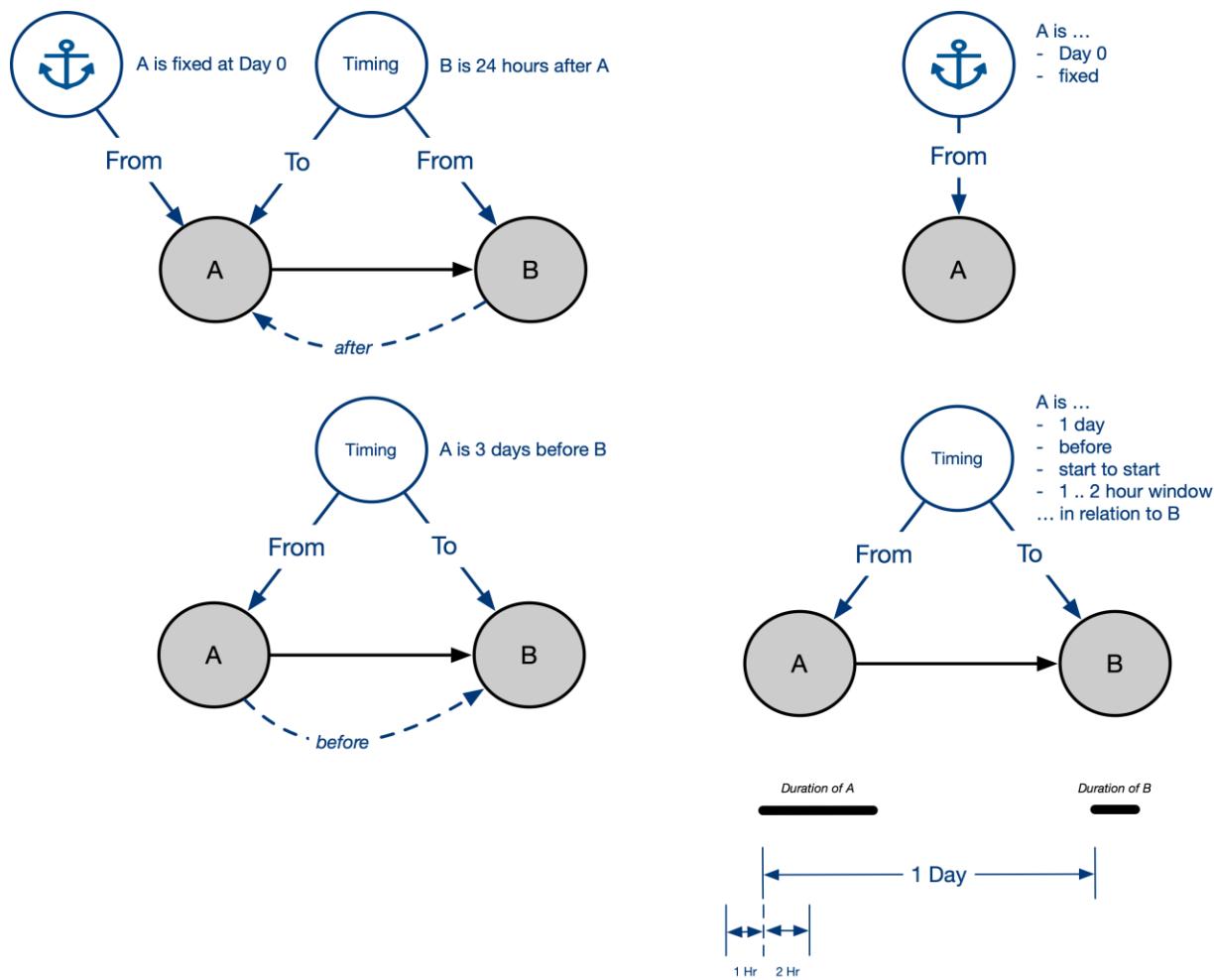
8.18.2 Timing

The timing between steps comprises a relative time of before or after, and an anchor time that is fixed. The following figure illustrates the timing capabilities. The Timing class allows for explicit timing to be built into a timeline using a combination of anchors (fixed timing) and relative timing. The timing definitions should be read as "the <Timing.relativeFromScheduledInstance> node is <Timing.value> <Timing.type of before or after> the <Timing.relativeToScheduledInstance> node". The timing definition allows for further precision in the timing by specifying the relativeToFrom type.

For anchors, the relativeFrom node refers to the scheduled instance that provides the fixed reference. The corresponding relativeTo node should either refer to the same scheduled instance or should be missing.

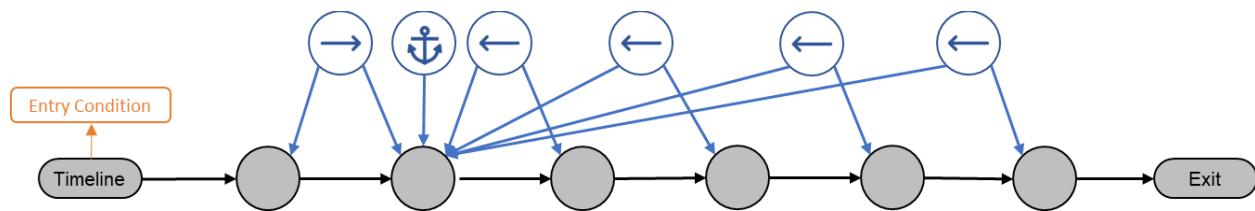
A timing may be referenced from an Encounter using the scheduleAt attribute allowing for a specific encounter timing and corresponding windowing to be defined and presented in a scheduled of activities. An Encounter timing might potentially overarch multiple scheduledInstances representing different blocks of activities within an encounter.

Note that in the timing diagrams the relativeFromScheduledInstance and relativeToScheduledInstance relationships have been shortened ("From" and "To," respectively) so as to make the diagrams readable.



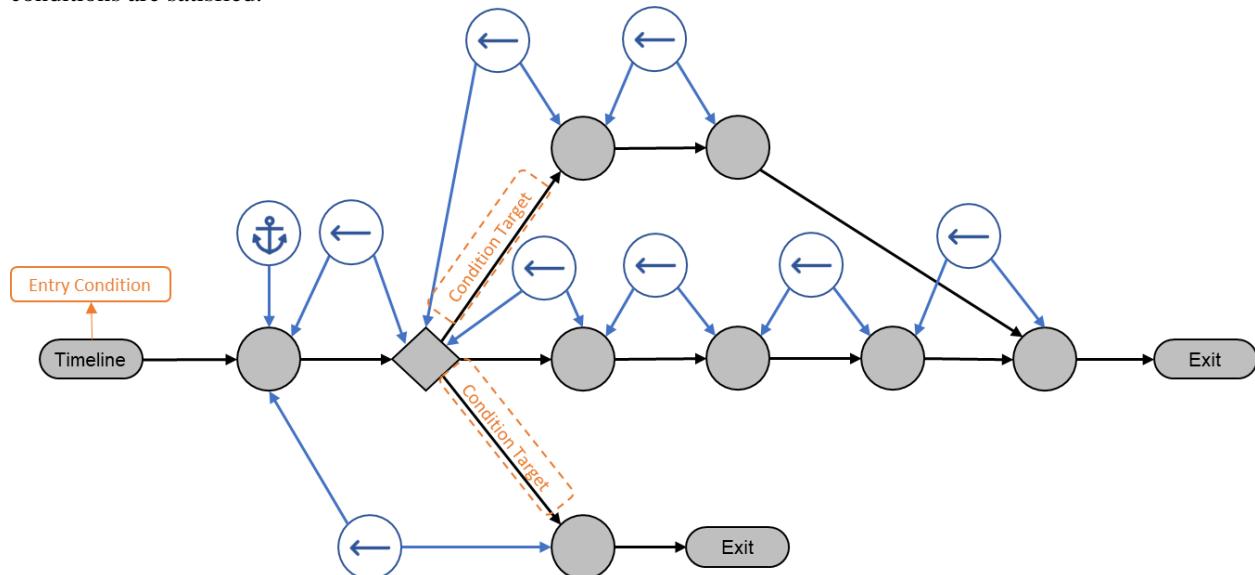
Planned timings are stored in the value attribute of the Timing class and are expected to be formatted according to ISO 8601. A corresponding window can be identified using the window attributes. The windowLower and windowUpper attributes are also expected to be formatted according to ISO 8601. Textual representations of these values can be stored in the valueLabel and windowLabel attributes, respectively.

Note that timings can be defined between each consecutive scheduled instance or all or part of the timings can be related to a fixed (anchor) timepoint:

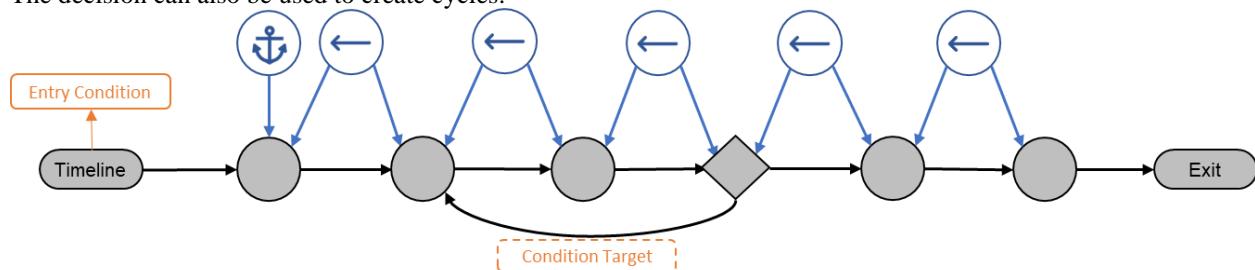


8.18.3 Decisions and Branching

Decisions and branching are handled using instances of the `ScheduledDecisionInstance` class within a timeline as shown in the following figure. Each decision point can handle multiple conditions; for example, simple yes/no decisions as well as a complex switch with multiple paths. Each possible route is set up with an associated destination. For switches, there should be a "default" condition specified for the case when none of the other conditions are satisfied.



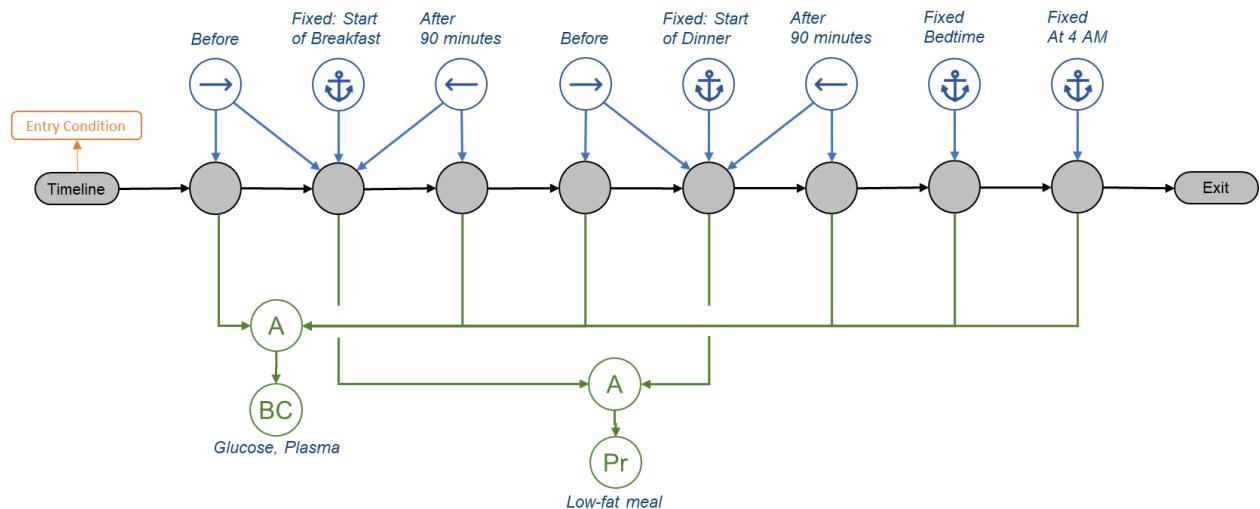
The decision can also be used to create cycles:



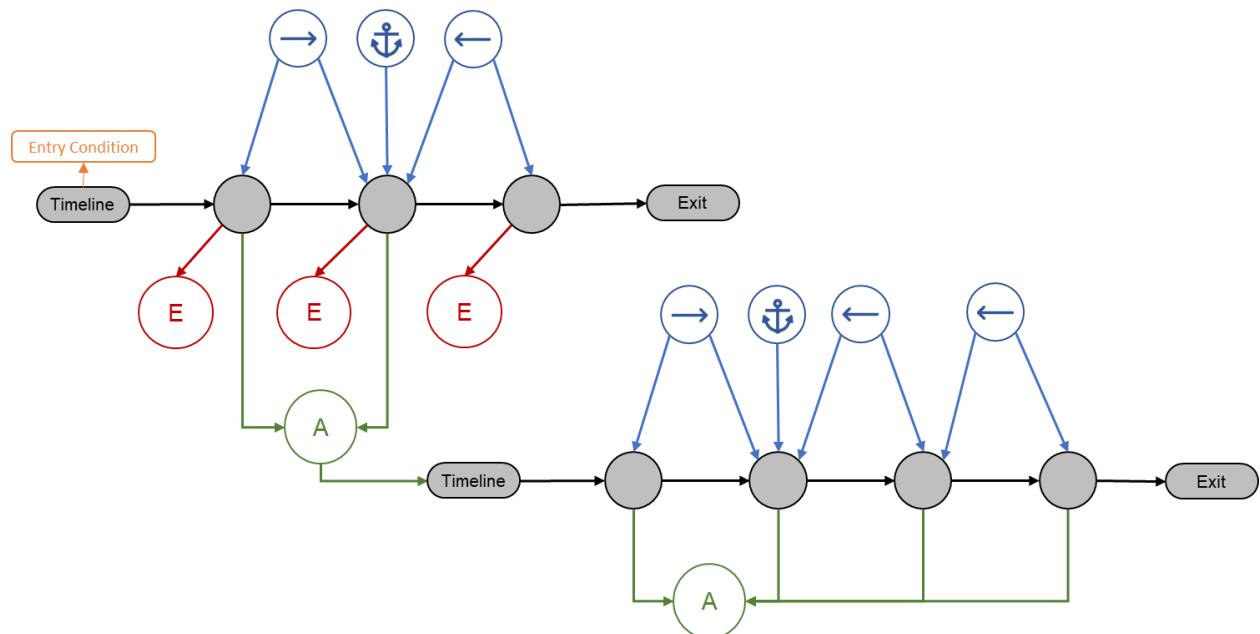
Descriptions of the decision and pointer are defined using the `conditionAssignment` class. This class includes 2 attributes: a description of a condition and the reference to the target instance of the `scheduledActivityInstance` class that it points to once this condition is met—for example: "not reached cycle 12 and fulfilling eligibility to enter next cycle", "ScheduledActivityInstance_2".

8.18.4 Profiles

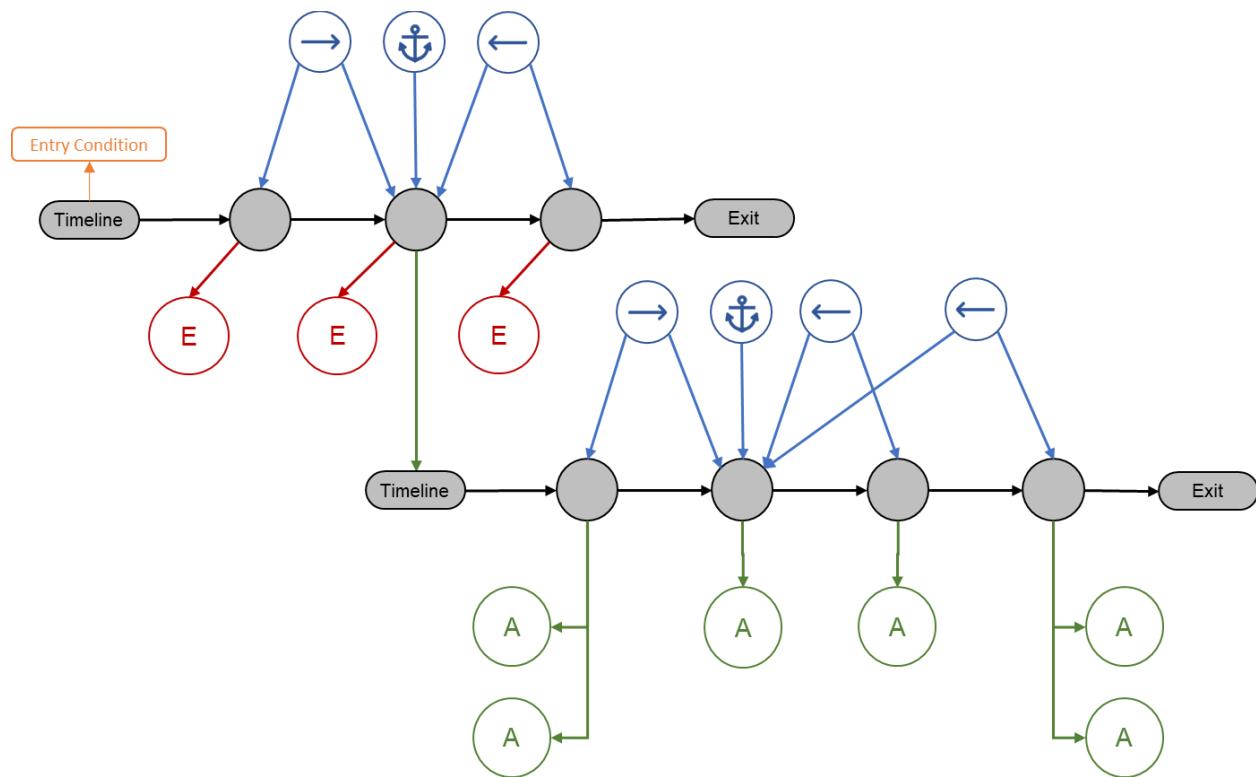
Profiles can be created using the various classes, as depicted in the following figure. A profile is another use of the timeline pattern and may reflect a sub-timeline within an encounter. A condition for entry can be defined but need not be. In this example, anchors are used to fix meal times over a single day and the associated observations scheduled in relation to the fixed meal times. The activities are shared across the steps within the profile.



The profile can be "attached" to an activity using the `ActivityTimeLineId` attribute so that it is executed as part of that activity, as illustrated in the following figure. This is useful for a sequence of repeated measures within the same activity.

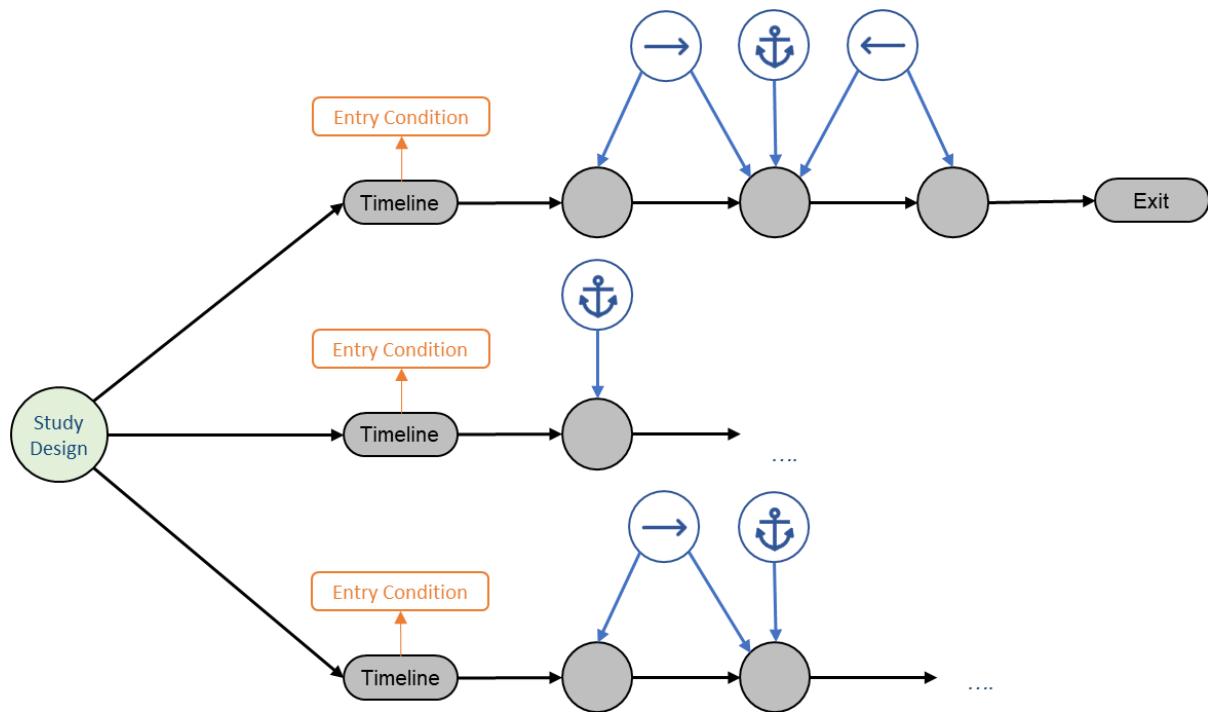


The timeline can also be attached to a `ScheduledActivityInstance` from another timeline using the `timelineReference`, thus allowing timepoints within a visit to be constructed, as shown in the following figure.



8.18.5 Unscheduled Visits

Unscheduled visits within a study are handled by creating separate timelines for each unscheduled "event" that needs to be handled within the study design. A study design would typically have 1 "main" timeline with a condition such as "subject identified". Further timelines can be created and linked to the StudyDesign instance with the timeline having an appropriate condition (e.g., "Adverse event", "Lost contact with subject"). Each timeline is then free to detail the steps taken under the respective circumstances.



8.18.6 Timeline Exit

It should be noted that the ScheduledTimelineExit instance does not perform any role other than marking the end of a timeline. It is linked from the last ScheduledActivityInstance instances in the timeline.

8.19 Study Interventions

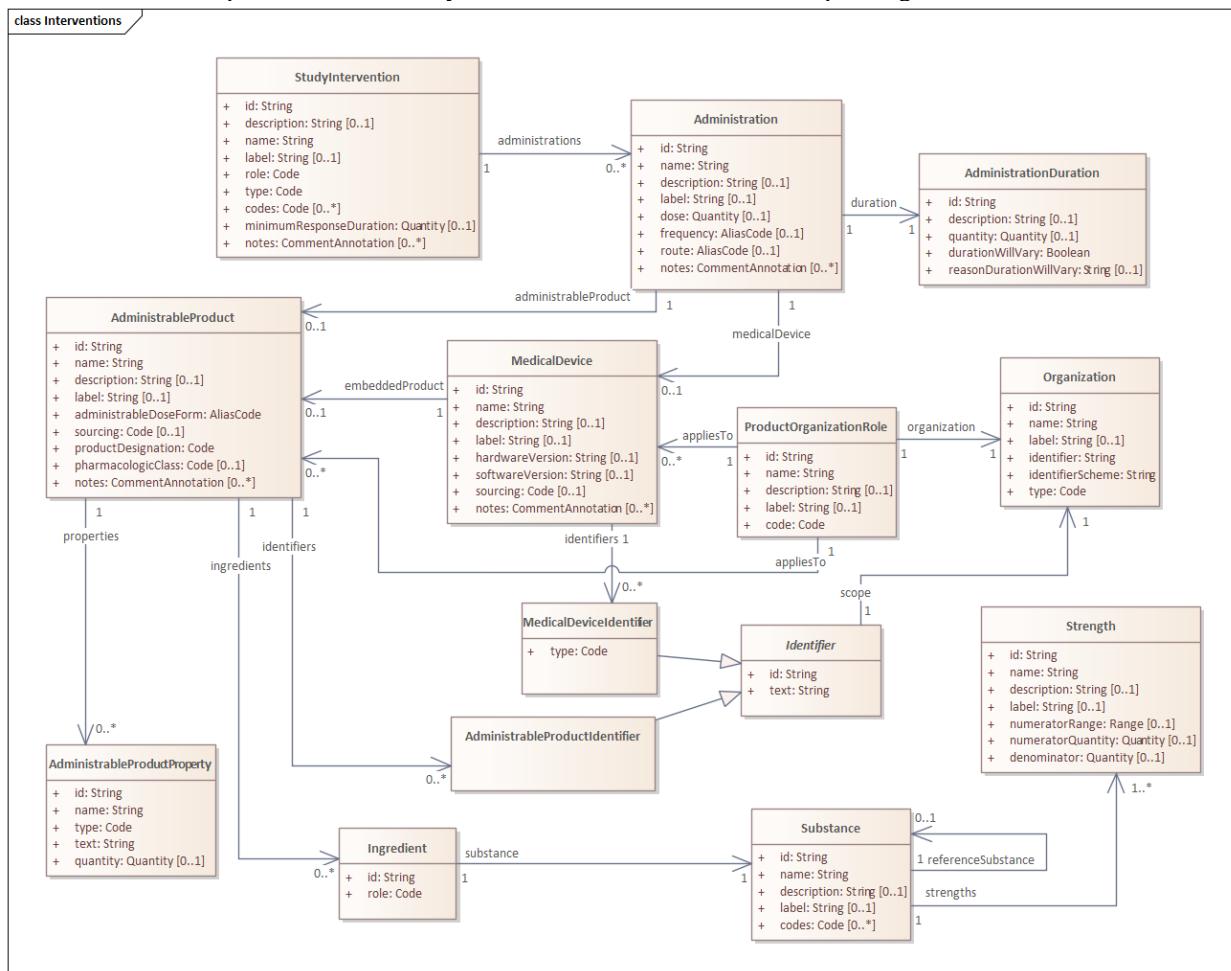
The interventions for a study are stored in the StudyIntervention class. Each intervention needs to be defined by role and type. Optionally, information on 1 or more codes from external coding systems and the expected duration to minimum response can be added. Corresponding administration details are specified in the Administration class. The frequency, dose, route, administrable product, medical device, and duration can be specified for each administration. If the administrable product is embedded (e.g., inseparable) in the medical device then the administrable product are expected to be defined via the medical device as an embedded product and not directly via the administration class.

For each medical device, information on sourcing, embedded products, and medical device identifiers may be specified. For each administrable product, information on the product designation (IMP/NIMP); pharmacological class; sourcing; and 1 or more administrable product identifiers, properties, and ingredients may be specified. Note that the internal sponsor code or compound number for the administrable product can be stored as the administrable product identifier.

Each ingredient specified by its substance may have a reference substance. The corresponding reference strength represents the strength (quantitative composition) of the active moiety of the active substance or of another substance used to express the strength of the product. There are situations when the active substance and active moiety are different resulting in different expression of the strength. The strength of each substance is specified in the strength class using a quantity or range numerator and preferably a denominator. In case the strength is not exact but estimated to be within a range, the numerator can be expressed as a range using minValue and maxValue attributes. For IDMP, the strength value or minValue and corresponding denominator value refers to the IDMP strength lower limit, while, if applicable, the strength maxValue and corresponding denominator value, refers to the strength upper limit.

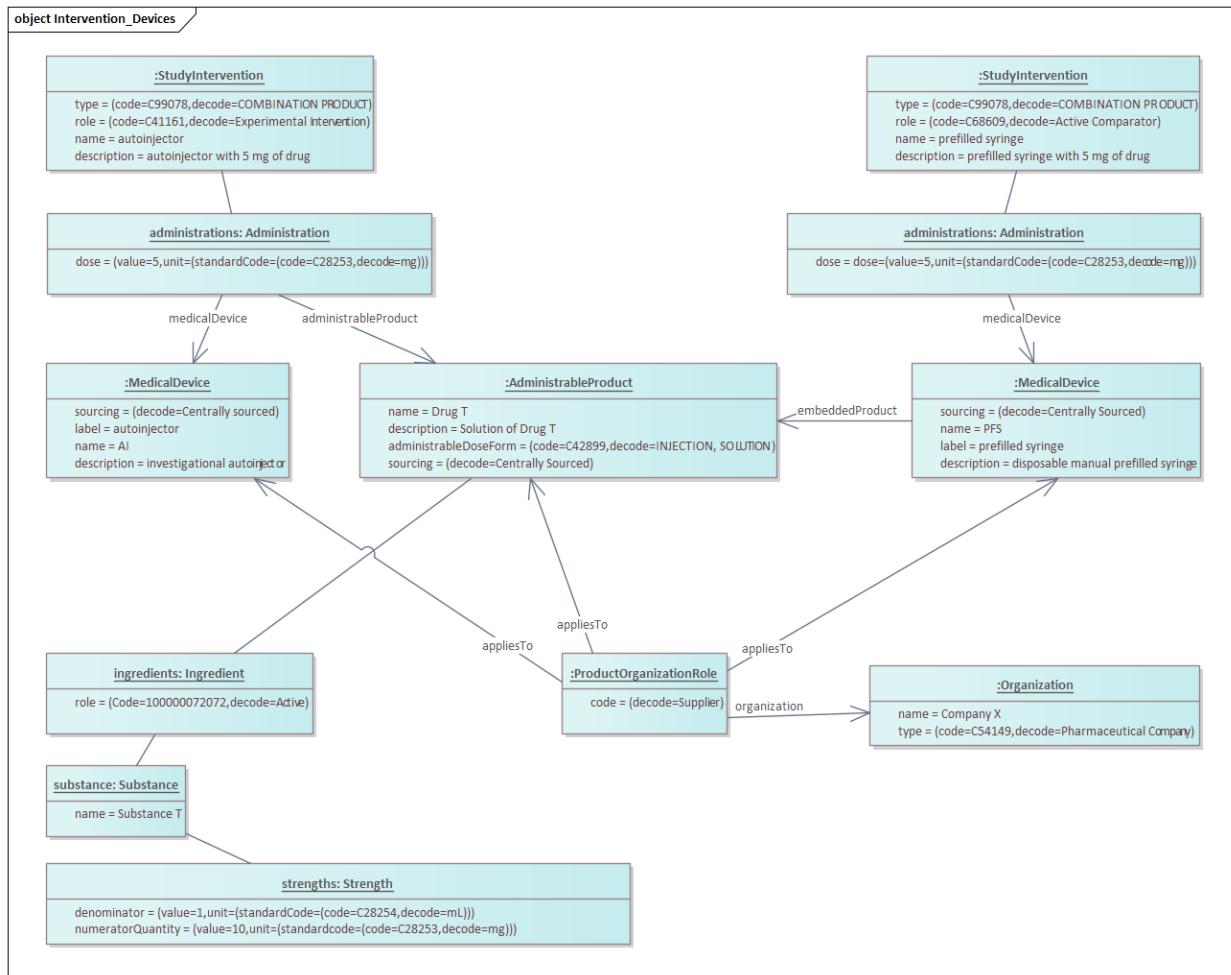
Product related organization roles like manufacturer and supplier may be defined in the ProductOrganizationRole class which refers to the corresponding defined organization and applies to one or more medical devices and/or administrable products.

Study interventions need to be directly referred to from the Study Design class. In addition, they can be directly related to estimands, procedures, and study elements as defined for the corresponding classes.



An example of an bioequivalence study comparing the bioavailability of one drug administered via different devices is shown below. The test (experimental intervention) and reference (active comparator) interventions are stored as two separate instances in the StudyIntervention class both as a combination product type of intervention. The experimental intervention includes a device which can be refilled with the administrable product. Hence the medical device and administrable product are separately linked to the corresponding administration class. Contrary, for the active comparator study intervention, the product is prefilled and therefore specified as an embedded product for the medical device.

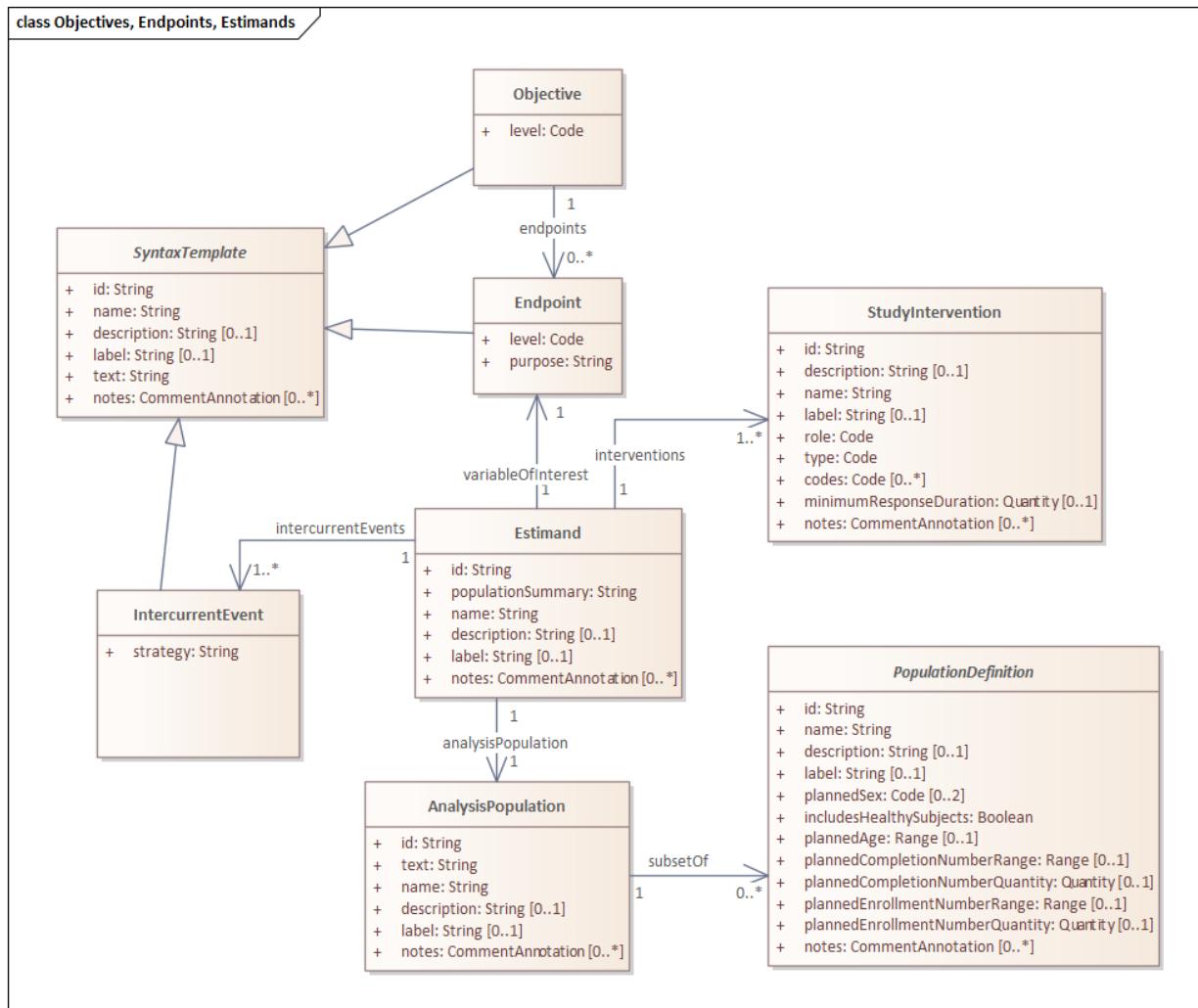
The actual dose given for both administrations is equal and set to 5 mg. Both interventions refer to the same administrable product with a strength specified (via its ingredients/substance and strength nominator and denominator) to be 10 mg/mL. All products are centrally sourced and in this case only one product organization role as supplier was specified which applies to all products. The corresponding organization in this case is a pharmaceutical company with the hypothetical name Company X.



Note that the instance diagrams are created to show single use cases. Not all (required) attributes, relationships and properties are presented in the instance diagrams. Cross-references between instances are presented by arrows while nested instances are represented by straight lines.

8.20 Study Objectives and Endpoints

The study design objectives and endpoints can be defined within the Objective class and the Endpoint class. The Objective class allows for the textual description of the objective and its level (e.g., primary, secondary, exploratory) and a link to 1 or more associated endpoints containing the endpoint definition in textual form. Both the objective and endpoint class inherit from the syntax template (see [Section 4.21](#)), allowing for references to information stored elsewhere in the data model. The endpoint may be a variable of interest for the study estimand (see [Section 4.17](#)).



8.21 Study Estimands

Aligning to the ICH guideline E9 (R1) addendum,^[5] study estimands and the definition of the treatments to be investigated, the population, the variable, the population summary, and the handling of intercurrent events (ICEs) are handled within the Estimand, IntercurrentEvent, and AnalysisPopulation classes along with the relationships to the corresponding endpoints (for the variable of interest; see [Section 4.17](#)) and study interventions (e.g., treatment; see [Section 4.15](#)).

The AnalysisPopulation may be defined as a subset of a study design population or study cohort which inherit their features from the population Definition class (see [Section 4.18, Populations, Cohorts, and Eligibility Criteria](#)).

8.22 Populations, Cohorts, and Eligibility Criteria

Populations and cohorts are a (sub-)group of subjects that take part in the study. The parent class `PopulationDefinition` is used to define a group of subjects in general. This class includes references to the eligibility criteria that are applicable to the population. All the elements of the `PopulationDefinition` class are inherited by both

the StudyDesignPopulation class, which stores the population details for a specific study design; and the StudyCohort class, which stores the details of subpopulations that, based on their characteristics, may deviate in how they are treated, assessed, or analyzed.

In addition to the inherited attributes from the PopulationDefinition class, the StudyDesignPopulation class may refer to the corresponding subgroups stored as study cohorts. The standard PopulationDefinition attributes criteria, PlannedCompletionNumberRange or PlannedCompletionNumberQuantity and/or plannedEnrollmentNumberRange or plannedEnrollmentNumberQuantity, plannedAge, and plannedSex are either defined at the StudyDesignPopulation level or at the StudyCohort level. The allowed coded values for plannedSex are "male" or "female"; either or both can be specified for a study design population or for a study cohort.

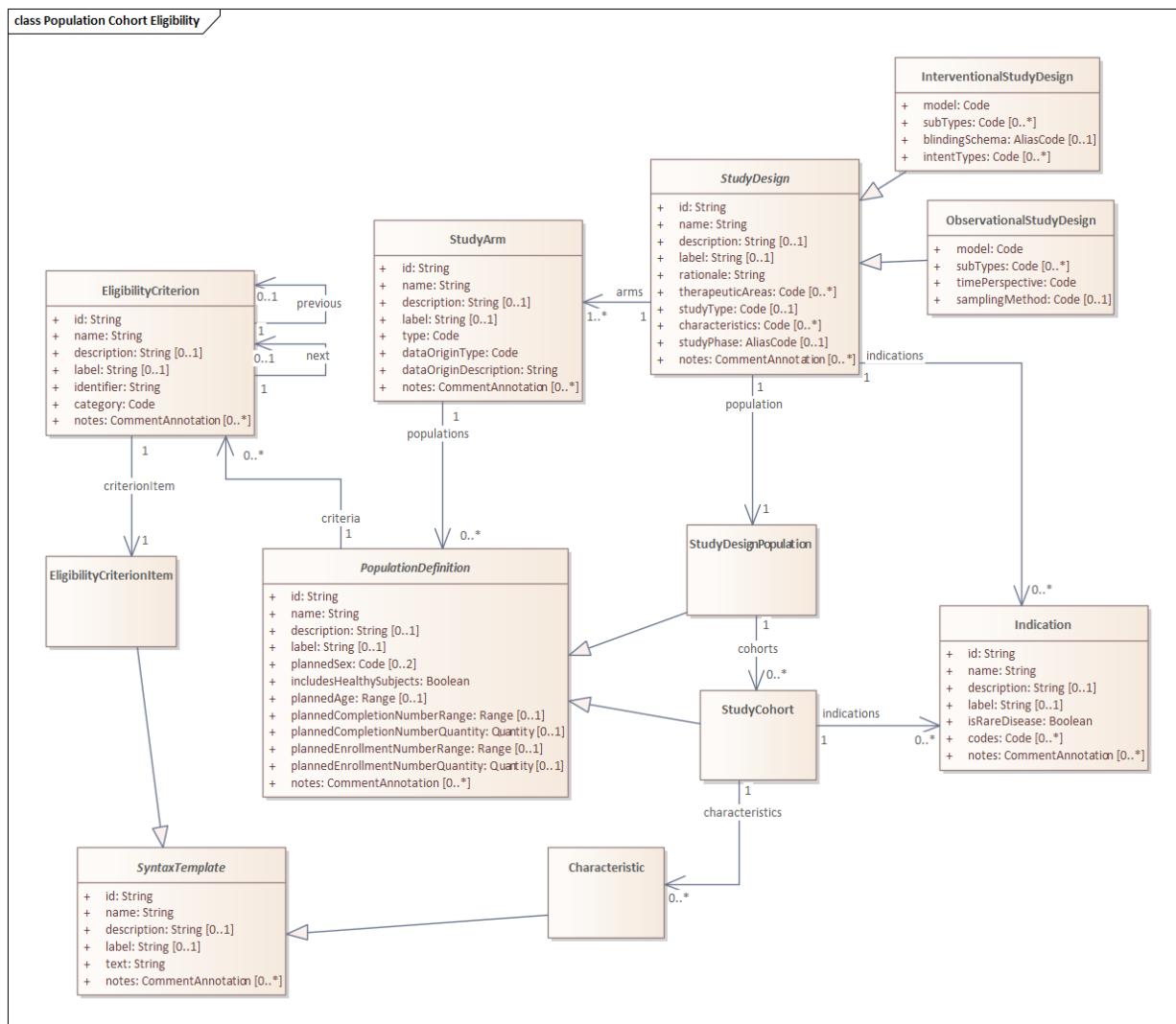
The StudyCohort class may refer to additional characteristics not defined by any other attributes in the PopulationDefinition class. These characteristics are stored in the Characteristic class, which inherits its attributes from the Syntax Template class (see [Section 4.21](#)) and thus can refer to any item stored elsewhere in the USDM.

Eligibility criteria items inherit from the Syntax Template class as well, allowing for referencing any item stored in the USDM (e.g., assessments stored as BCs). The previous and next attributes in the EligibilityCriterion class referring these items define the presentation ordering within an eligibility criterion category or overall for a specific study design. The identifier attribute may be used to store the short name used for mapping to the SDTM Trial Inclusion/Exclusion Criteria domain (see Section 7.1, [Creation of SDTM Trial Design Domains](#)).

The indication for a study design can be placed into the Indication class. Each indication has a textual description plus the ability to define 1 or more codes from external code systems (including a sponsor's own terminology) that define the indication. The corresponding attribute isRareDisease can be used to indicate whether an indication is regarded as a rare disease according to applicable registries (e.g., the NIH [Genetic and Rare Diseases Information Center](#)(GARD)). Indications stored in the indication class are applicable to the whole study design population.

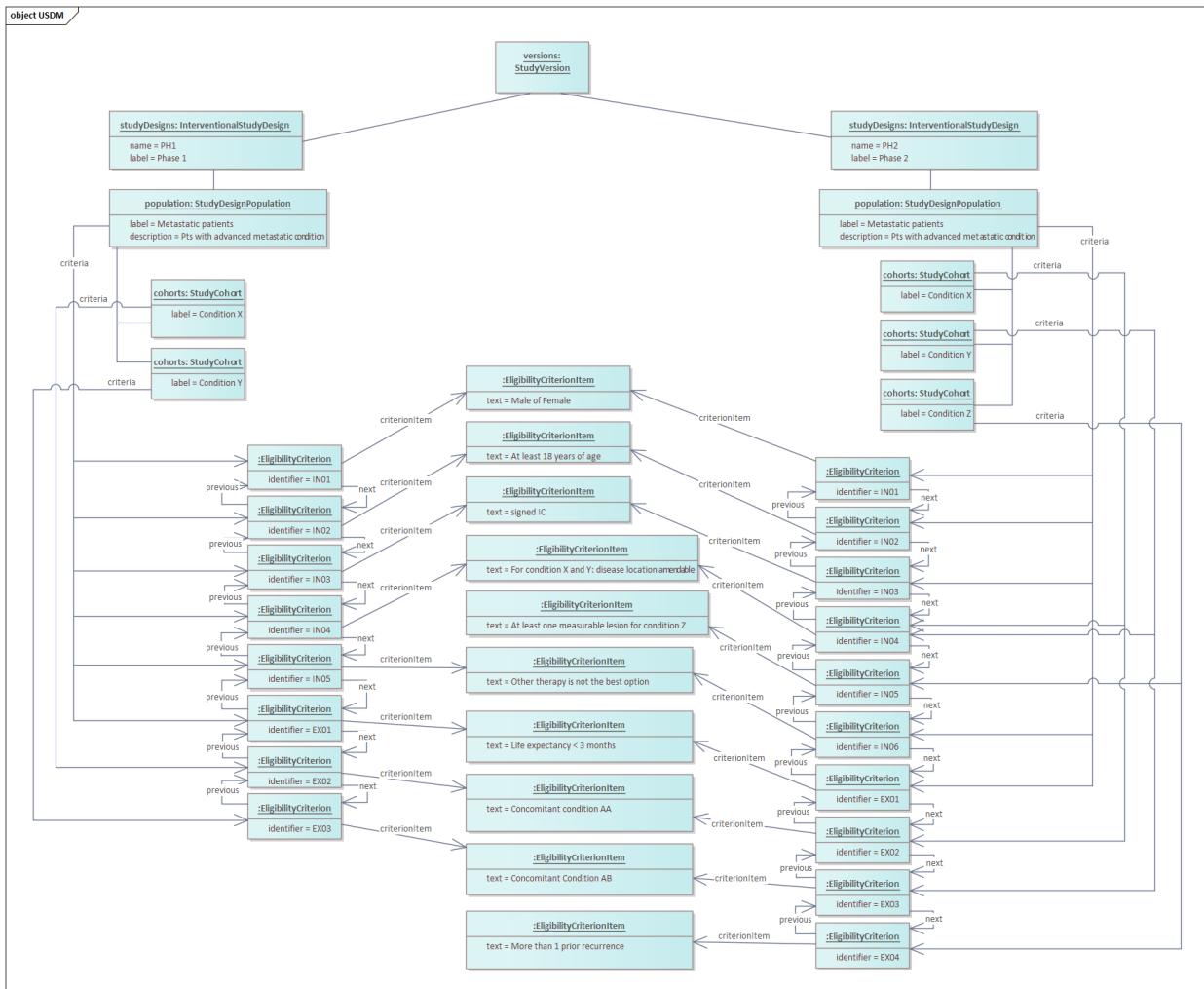
Cohorts may optionally point to 1 or more indications applicable to the specific cohort.

In case needed, specific notes for example for grouping, mapping, or providing additional information can be added to the items in a class. Corresponding codes can be added to these notes aligning with internal or external standards that are applicable to the notes.



The following instance diagram shows a complex design study including 2 different phases and corresponding interventional study designs. Each design includes a definition of the corresponding study design population and nests 2 or 3 cohorts. The diagram shows that the collection of unique eligibility criterion items specifying the actual textual descriptions of the criteria is stored independently from the study designs. The eligibility criteria applicable to the specific study designs are further defined at the study design level and include the identifier and category specifications (category is not shown in the instance diagram), which can be matched to the corresponding SDTM TI domain variables IETESTCD and IECAT, respectively. Each definition refers to the corresponding eligibility criterion item text. The document-based ordering information for presentation purposes is defined using the next and previous relationships. The USDM allows for different ordering and presentations for different subdesigns, which might be needed in case of different subprotocols and/or submissions for different parts of the study.

Further, in this case, most criteria are applicable to the whole study population while a few (e.g., EX02, EX03) are only applicable to a specific cohort. This is indicated by referring to these criteria from the study cohort instead of from the study design population. In the following example, the criterion applicable to both condition X and Y (see criterion IN04) is referred to from the whole study design population for the phase 1 design since it applies to all the cohorts in the design. However, for the phase 2 design, where the criterion only applies to 2 of the 3 cohorts, it is referred to from each of the cohorts with condition X and Y, but not from the third cohort with condition Z, where it does not apply. This example also shows that multiple cohorts may refer to the same eligibility criterion. Whether a criterion is referred to from the study design population or from 1 or more cohorts is up to the implementation. However, each criterion must be referred to from either the study design population or from 1 or more cohorts.



Note that instance diagrams are created to show single use cases. Not all required attributes, relationships, and properties are presented. Cross-references between instances are presented by arrows while nested instances are represented by straight lines.

8.23 Abbreviations

9 General

Abbreviations are usually included in protocol documents. To ensure consistency of definitions throughout the study definition documents as well as in downstream processes, the USDM allows for abbreviations to be defined at the study version level (see Section 4.6, [Study, Protocols, and Amendments](#)).

Abbreviations can be reused (i.e., referenced) both from within unstructured document content and from within syntax template text (e.g., for eligibility criteria or assessment conditions). In addition, the full list of abbreviations can be easily used to automatically create the full list of abbreviations in the corresponding protocol document section.

10 Abbreviations

Abbreviations consist of 2 parts: the abbreviated text and the expanded text. The following table provides examples of Abbreviation instances.

| Abbreviation | | |
|--------------|------------------------|---|
| id | abbreviatedText | expandedText |
| Abbr_1 | AD | Alzheimer's disease |
| Abbr_2 | MMSE | Mini-Mental State Examination |
| Abbr_3 | CDR | Clinical Dementia Rating Scale |
| Abbr_4 | FCSRT | Free and Cued Selective Recall Reminding Test |
| Abbr_5 | AChE-Is | Acetylcholinesterase inhibitors |
| Abbr_6 | DAT | Dementia of Alzheimer type |

11 Referencing From Unstructured Text

Unstructured text (held within NarrativeContentItem instances) can directly reference an abbreviation (abbreviatedText) and/or the expanded text (expandedText) using XHTML referencing (see Section 4.22, [XHTML Attributes](#)). The following is an example of a text item concerning the rationale; this example references the preceding example abbreviations.

| NarrativeContentItem | | |
|----------------------|-------------|--|
| id | Name | text |
| Item001 | Rationale1 | <div xmlns=" http://www.w3.org/1999/xhtml ">Currently approved <usdm:ref klass="Abbreviation" id="Abbr_1" attribute="abbreviatedText"/> treatment is purely symptomatic. Registered symptomatic treatment consists of <usdm:ref klass="Abbreviation" id="Abbr_5" attribute="expandedText"/> (<usdm:ref klass="Abbreviation" id="Abbr_5" attribute="abbreviatedText"/>) and memantine. <usdm:ref klass="Abbreviation" id="Abbr_5" attribute="abbreviatedText"/> in general and donepezil in particular can be currently regarded as gold standard for treatment of mild-to moderate <usdm:ref klass="Abbreviation" id="Abbr_6" attribute="abbreviatedText"/> and is considered as reference drug. </div> |

A solution can resolve the in-text references for reading purposes which then will result in the following protocol text "Currently approved AD treatment is purely symptomatic. Registered symptomatic treatment consists of AChE-Is and memantine. AChE-Is in general and donepezil in particular can be currently regarded as gold standard for treatment of mild-to-moderate DAT and is considered as reference drug."

12 Referencing From Syntax Templates

Abbreviations can also be referenced from [syntax templates](#). Two examples, referencing the preceding example abbreviations, are provided in the following sections.

12.1 Objective

The objective class is based on syntax templates and therefore can be tagged with attributes stored with the associated dictionary and parameter maps. Instead of using AD as text, it is replaced by a corresponding tag: Objective.text= '<div>To assess the efficacy, safety and tolerability of different doses of Study Drug compared to placebo in treatment of prodromal <usdm:tag name="_AD"/></div>'

12.2 Inclusion Criterion

The inclusion criterion for the same study is defining the diagnosis and the corresponding definition. The EligibilityCriterion class which stores these criteria is also based on syntax templates and therefore these abbreviations also can be replaced by the corresponding tags:

EligibilityCriterion.text= '<div>Patients with a confirmed diagnosis of prodromal <usdm:tag name="_AD"/> on neuropsychological testing defined as: - Mini-Mental State Examination <usdm:tag name="_MMSE"/> score: ≥

24 and - a global <usdm:tag name="_CDR"/> -score of 0 or 0.5 and - Free and Cued Selective Recall Reminding Test (<usdm:tag name="_FCSRT"/>) score: o free recall test: ≤ 20 (out of 48) and o total recall test: ≤ 42 (out of 48).</div>

The reference from the tag used in the syntax template texts to the specific instance in the Abbreviation class is specified in the SyntaxTemplateDictionary and the ParameterMap instances:

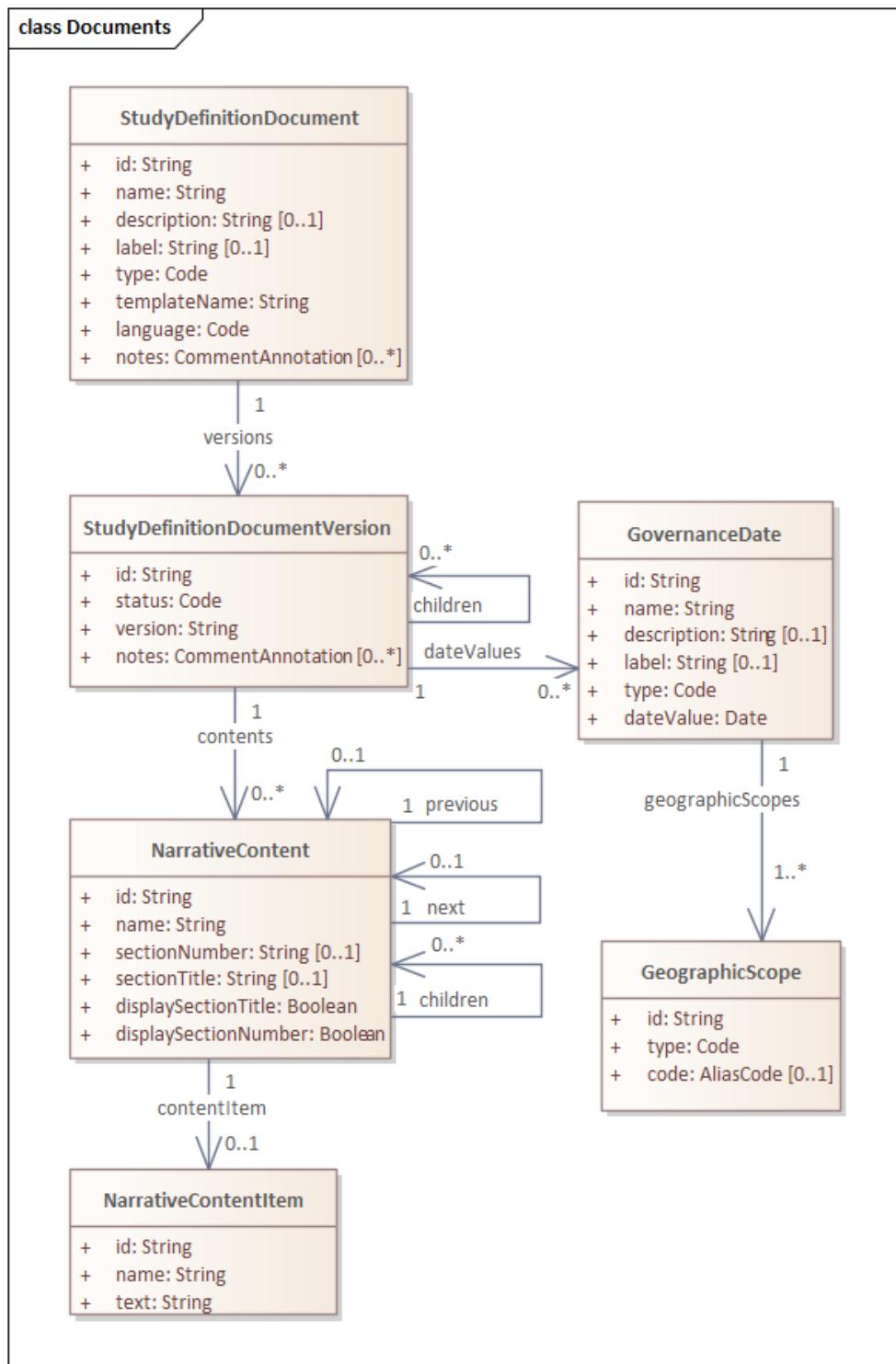
| ParameterMap | | |
|--------------|-------|--|
| id | tag | reference |
| Param001 | AD | <usdm:ref klass="Abbreviation" id="Abbr_1" attribute="abbreviatedText"/> |
| Param002 | MMSE | <usdm:ref klass="Abbreviation" id="Abbr_2" attribute="abbreviatedText"/> |
| Param003 | CDR | <usdm:ref klass="Abbreviation" id="Abbr_3" attribute="abbreviatedText"/> |
| Param004 | FCSRT | <usdm:ref klass="Abbreviation" id="Abbr_4" attribute="abbreviatedText"/> |

12.3 Unstructured Content

Study protocols and other study definition documents include content that is best described as "unstructured content". The USDM grants considerable flexibility in determining what information to include, the level of detail it will contain, the order in which it is introduced and discussed, and how it will be presented. Blocks of unstructured content can range from short text statements to many paragraphs which may also contain figures and tables.

The NarrativeContent class in the UML is modeled to contain such blocks of user-defined unstructured content using HTML format. The recursive nature of this class with its attribute children provides the user the ability to add multiple named blocks of unstructured content, allowing for a hierarchy of related information to be built up and ordered by the section number and/or the previous and next attributes. The actual blocks of unstructured content are stored in the NarrativeContentItem class allowing for reuse within and between documents.

The HTML format of the text attribute and the section ordering provides the capability for organizing the information in a way that is compatible with any required document structure such as ICH M11,[4] the TransCelerate CPT, or a sponsor's internally defined template. Structured elements stored elsewhere in the model can be included and reused anywhere in the unstructured text using the format explained in Section 4.22, [XHTML Attributes](#).



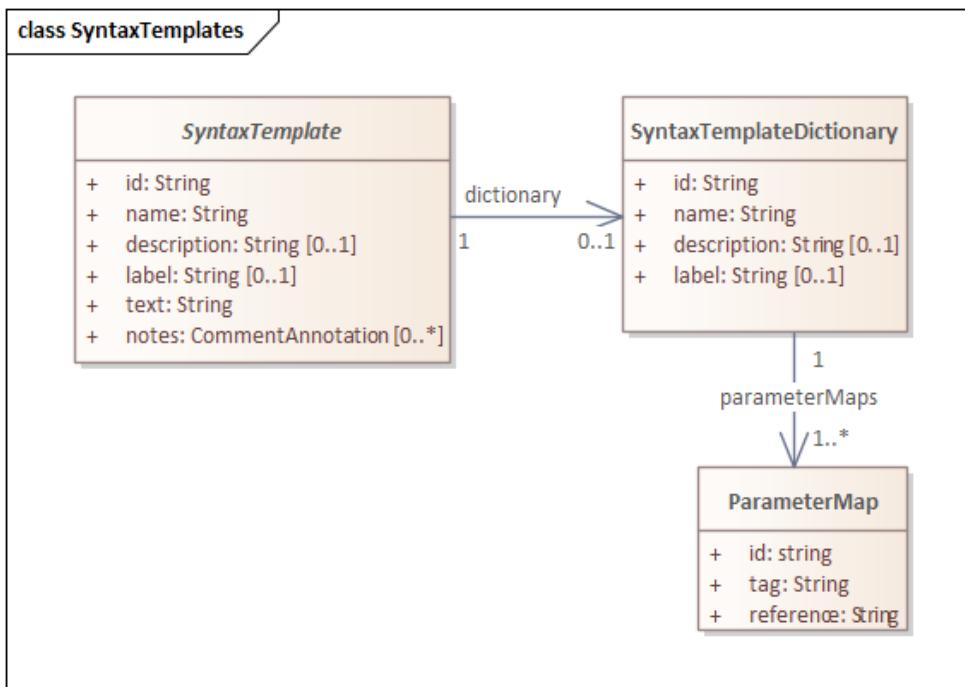
12.4 Syntax Templates

With syntax templates, human-interpretable plain text sentences are structured and linked to structured items held elsewhere in the USDM. Examples of items typically represented in the protocol as plain text that might be structured include:

- Endpoints that can be linked to a corresponding assessment and timing
- Objectives that can be linked to corresponding interventions and indications
- Eligibility criteria referring to an indication, a population, minimum and maximum age, and/or 1 or more assessments
- Conditions that can be linked to a corresponding BC or indication
- Cohort characteristics that can be linked to corresponding BCs or indications

The links are achieved by inserting tags into the plain text that reference structured content that is to be inserted into the text. These tags can be reused multiple times. This allows for consistency throughout the study design. In addition, the structured items can be more readily processed in downstream systems. The intent is that structured text allows for eligibility criteria, endpoints, objectives, and so on to be standardized and thus reused across studies, facilitating comparison and meta-analyses.

The syntax template classes are presented in the following UML.



The attributes and relationships of the `SyntaxTemplate` class are inherited by any class that is reusing its capabilities (e.g., `Endpoint`, `EligibilityCriterion`, `Characteristic`, termed "template instances"). The `text` attribute stores the structured text of the corresponding endpoint, criterion, or characteristic. The `text` attribute contains free text with embedded XHTML tags that refer to the mapping in the `SyntaxTemplateDictionary`. Within the `SyntaxTemplateDictionary` class, dictionaries can be defined that link the tags to the corresponding structured data references (to data stored elsewhere in the USDM) or to a fixed value.

The tags used within the `text` attribute of `SyntaxTemplate` are formatted as follows:

`<usdm:tag name="parametername"/>`

These tags are used as illustrated in the following example:

Subjects shall be between `<usdm:tag name="min_age"/>` and `<usdm:tag name="max_age"/>`

Instances of the `SyntaxTemplateDirectory` class are linked to 1 or more `ParameterMap` class instances. Each `ParameterMap` instance includes the tag (stored in the `tag` attribute) and a single reference or fixed value (stored in the `reference` attribute):

`<usdm:ref klass="klassName" id="idValue" attribute="attributeName"/> or 'fixedValue'`

in which:

- *klassName* is the name of the class that holds the referenced structured data.
- *idValue* is the id attribute value of the referenced instance of *klassName*.
- *attributeName* is the name of the referenced data attribute within *klassName*.
- *fixedValue* is a fixed string.

Some examples of ParameterMap references are (formatted here as tag: reference or fixedValue):

```
min_age: <usdm:ref klass="Range" id="Range_3" attribute="minValue"/>
max_age: <usdm:ref klass="Range" id="Range_3" attribute="maxValue"/>
StudyPopulation: <usdm:ref klass="StudyDesignPopulation" id="StudyDesignPopulation_1"
attribute="description"/>
RefHbMax: "7.0"
```

It should be noted that instances of classes that inherit from SyntaxTemplate, the template instances, inherit the dictionary relationship to the SyntaxTemplateDictionary class. Each of these template instances references a single dictionary but the dictionary can be shared across 1 or more of the template instances. Thus it is possible that a single dictionary instance—named, for example, StudyDictionary—containing a wide range of tags might be used by all the template instances or 1 dictionary instance could be created for the IE instances (named, for example, IE Dictionary), 1 dictionary instance for the Objectives and Endpoints template instances (named, for example, OEDictionary), or some mix thereof as required by implementers.

12.5 XHTML Attributes

The SyntaxTemplate and NarrativeContentItem classes each contain an attribute that contain XHTML formatted text:

- SyntaxTemplate text attribute
- NarrativeContentItem text attribute

The content held within these attributes should be treated at XHTML content and processed as such. It is recommended that a single root `<div xmlns="http://www.w3.org/1999/xhtml">` element is used to wrap the content of the attribute. These attributes can also contain `<usdm:ref>` elements used to reference content held within the remainder of the model. These elements use 3 attributes to form a complete reference:

```
'<usdm:ref klass="klassName" id="idValue" attribute="attributeName"/>'
```

where:

- *klassName* is the name of the class that holds the referenced data element.
- *idValue* is the id value of the referenced data element within *klassName*.
- *attributeName* is the attribute name of the referenced data element within *klassName*.

Further details of the use of these references can be found in Sections 4.20, [Unstructured Content](#), and 4.21, [Syntax Template](#).

12.6 Addressing Footnotes

Information represented by footnotes in a schedule of activities (SOA) can be stored structurally in the USDM and as such can be parsed and presented as footnotes when feasible. By using this computer-readable format, the often complex and extensive footnote information is more usable for downstream processes. This section describes the following different types of footnotes that may be identified in SOAs and how they can be stored in the USDM:

- Footnotes representing sub-timelines
- Footnotes representing timing and/or order of activities
- Footnotes representing alternative visit schedules
- Footnotes representing conditional activities, assessments, and procedures
- Repeated activities not presented in the SOA
- Footnotes representing optional alternative encounter methods
- Footnotes representing measurements to be done for a specified activity
- Footnotes representing optional alternative measurement methods

- Additional instructions for procedures and/or performing assessments
- Visit and timing window information
- Eligibility requirements
- Complex combinations

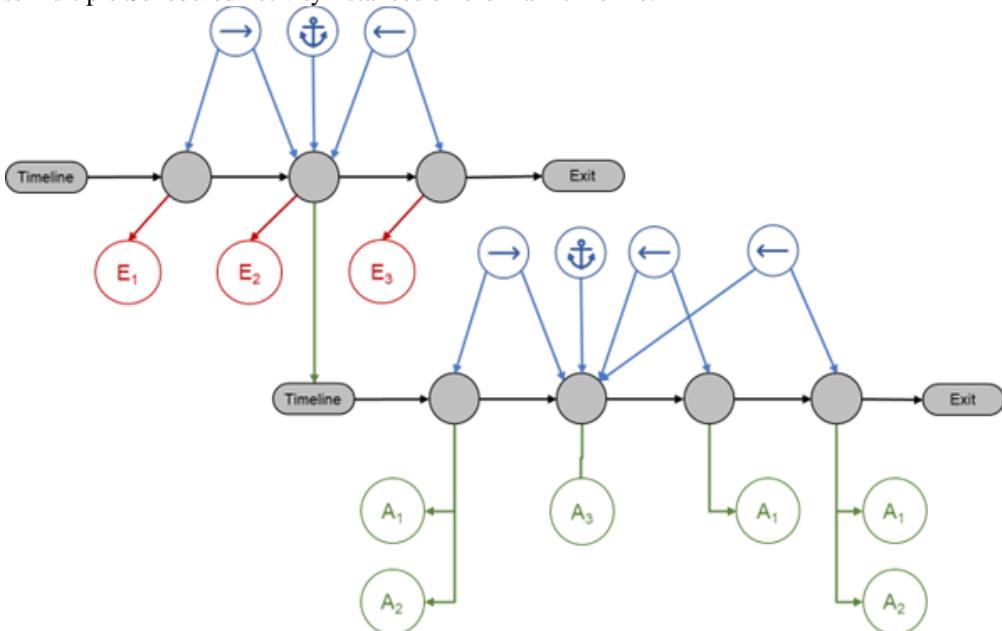
12.7 Footnotes Representing Sub-timelines

These footnotes indicate at what exact timepoints activities not presented in the SOA should be performed, for example:

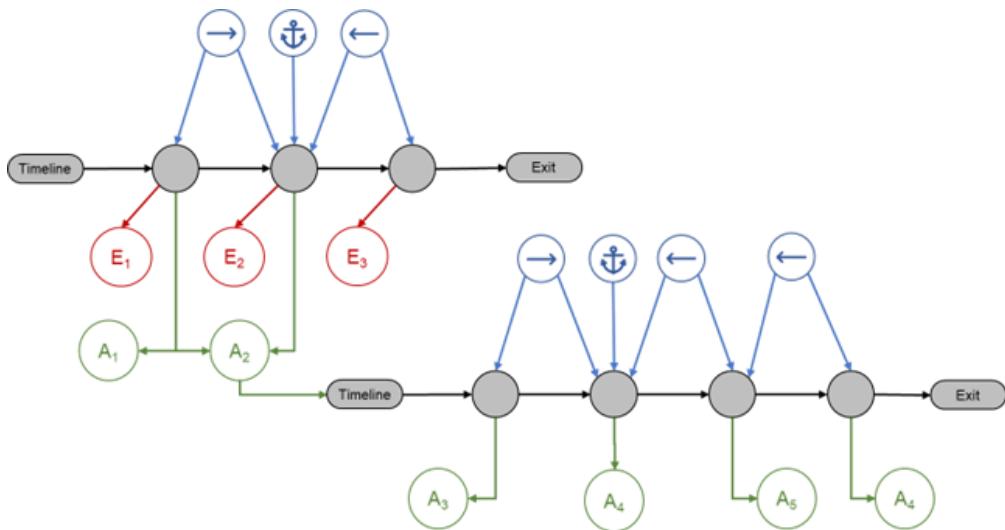
1. Blood samples for ... predose, 1h, 24 h, ...
2. X assessment to be performed predose and at 40 minutes and 1.5h postdose
3. Measurement after 5 minutes in supine position and after 3 minutes in standing position

In case of assessments relating to dosing (examples 1 and 2), individual timepoints can be stored as

ScheduledActivityInstances forming together a sub-timeline (see following diagram). This sub-timeline is referred to from a ScheduledActivityInstance on the main timeline. The time relationships (->, <- in the diagram) of these instances will be defined using the corresponding Timing classes. The timing related to the instance for the dosing activity (A_3) is defined as the anchor. Activities such as pharmacokinetic samples (A_1) and vital signs measurements (A_2) can then be added as needed, reflecting the correct timings related to dosing. Sub-timelines can be reused across multiple ScheduledActivityInstances on the main timeline.



In case of an assessment sequence relating to 1 activity (e.g., repeated blood pressure measurements in different positions), a sub-timeline can be directly referenced from the corresponding activity using the timeline relationship in this class (see following diagram). The activity A_2 (e.g., vital signs), refers to the sub-timeline indicating the corresponding positioning and assessment actions. For example, put subject in supine position (A_3), assess blood pressure (A_4); put subject in standing position (A_5) and repeat the blood pressure assessments (A_4). The timings in between are defined by the information in the corresponding Timing class.



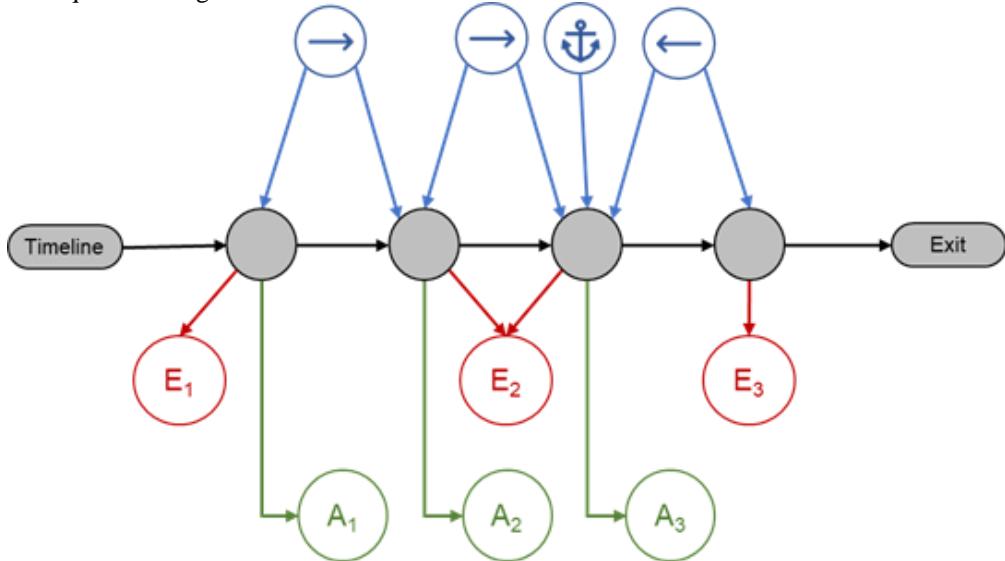
See Section 4.14, [Study Timing](#), for more information on timelines.

12.8 Footnotes Representing Timing and/or Order of Activities

These footnotes indicate an order of activities and what should be done first, for example:

1. Informed consent must be obtained prior to any study-related procedure
2. Assessment X should be done before all other
3. Assessments to be done on day of admission

A simple sequence of 1 activity or groups of activities can be represented by separate instances of the scheduledActivityInstance class in the main timeline pointing to the same encounter. For example, in the following diagram, encounter E2 includes 2 scheduledactivityInstances. The first links to activities that need to be done prior to any other activity (e.g., informed consent) and the second scheduledActivityInstance relates to all other activities that are required during that encounter.



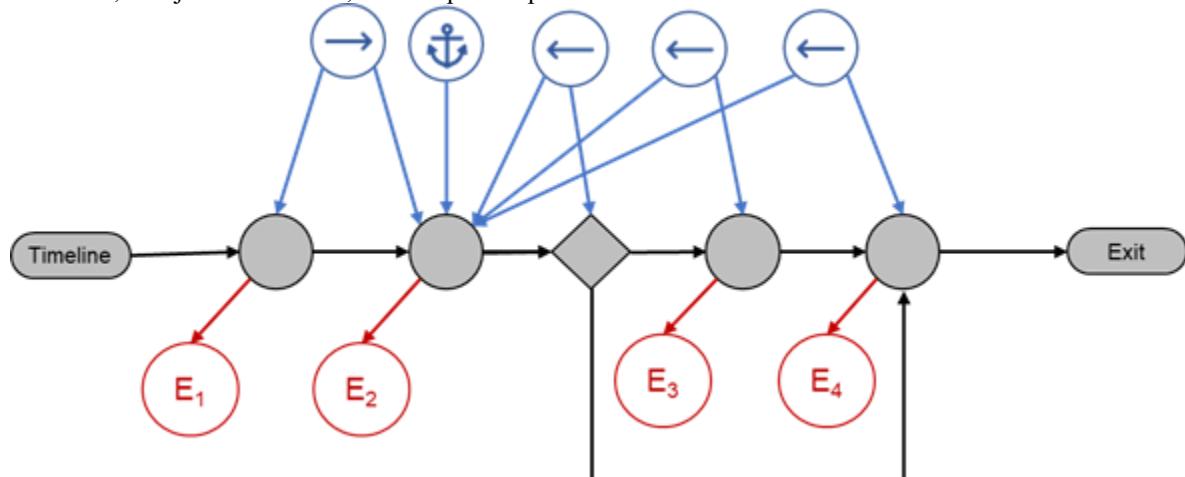
12.9 Footnotes Representing Alternative Visit Schedules

These footnotes indicate optional alternative visits based on conditions, for example:

1. Visits in case of events, inability to continue, or withdrawal (early-withdrawal visit)

2. An additional optional period of up to 3 weeks is permitted
3. Visits can occur on same day if no additional period is needed

To optionally add a visit, a scheduledDecisionInstance needs to be added to the timeline. Apart from the default next step in the timeline (defined by a defaultCondition), this scheduledDecisionInstance includes a condition and corresponding alternative next step that can be defined. In the following diagram, encounter E₃ is skipped when the condition is met. This condition as defined in the attribute conditionAssignments could then be “inability to continue”, “subject withdrawn”, or “no optional period of 3 weeks”.



Example 3, visits occurring on the same day, is more complex. Visits can optionally be combined; the ScheduledDecisionInstance needs to be set to “no additional period needed?” If yes, then the next visit (E₃) can be skipped. In cases where activities were planned at this skipped visit E₃ (and not at the previous visit E₂), these should be added to the previous visit E₂ with the conditionality that they only need to be done when the next visit is skipped.

12.10 Footnotes Representing Conditional Activities, Assessments, and Procedures

These footnotes indicate conditions for a specified activity to be performed (or not), such as:

1. Assessments only for women with childbearing potential
2. At the discretion of the investigator
3. Assessments only if within x days after y
4. Only in case of extra wash-out needed; all others to perform assessment at end of week x
5. Discharge after criteria for discharge are met
6. Only if dipstick urinalysis is positive
7. Assessment to be done every 3 cycles
8. Only for subjects electing to participate in the additional substudy
9. If needed

These footnotes can be stored in the Condition class. The footnote text is stored in the text attribute and can optionally link to other elements stored in the USDM as described for syntax templates (see [Section 4.21](#)). Each specified condition in this class applies to the whole activity, a BC, a BC category, a BC surrogate, or a procedure. The context indicates to what part of the SOA it applies. This relates to where the footnote indicator is placed in the SOA. A footnote directly linked to the activity description is applicable for all occasions of that activity and should therefore have the context related to that activity. If the condition holds for a specific timepoint of that activity, then the context should be set to the corresponding scheduledActivityInstance to indicate when it is applicable. See Section 4.11, [Activities](#), for more information.

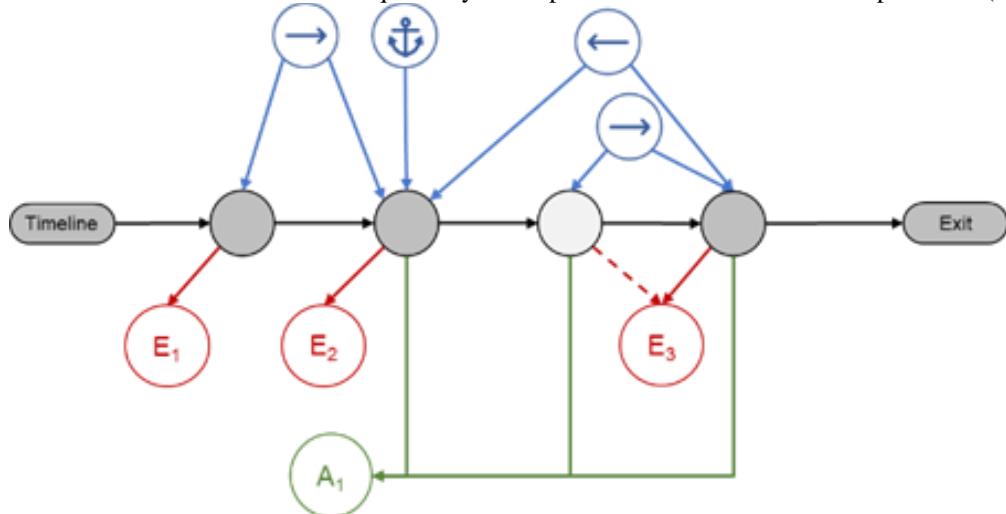
12.11 Additional timepoints Not Presented in the SOA

These footnotes specify activities that are not directly presented in the SOA because they need to be done in between regular visits, for example:

1. Questionnaire will be filled in every 2 weeks until ...

2. During run-in period, patients will perform XX measurements and inhale placebo medication at approximately 12-hour intervals for a minimum of 14 days and maximum of 21 days.

The first step in mapping these activities is to identify instances where they do not match the regular encounters represented in the SOA. These instances need to be added as ScheduledActivityInstances to the timeline with the corresponding timing information. The implementer can choose to create a separate encounter for them or to link them to the last or next encounter as required by the implementation and downstream processes (e.g., EDC setup).



12.12 Footnotes Representing Optional Alternative Encounter Methods

These footnotes specify potential encounter methods, such as:

1. Performed by telephone by qualified staff
2. If regulatory allowed, visits may take place at home

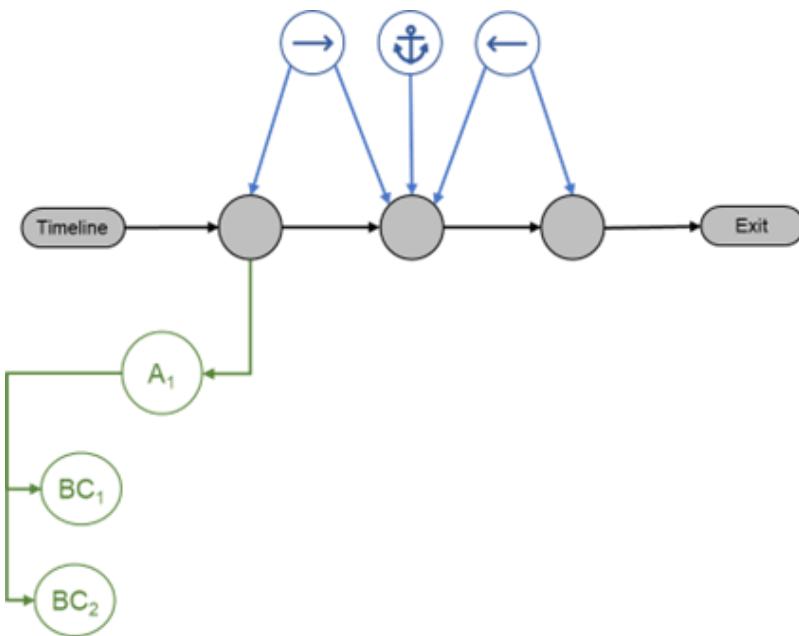
The encounter methods are specified by the attributes environmentalSetting and contactModes in the Encounter class. If optional alternative encounter methods are allowed then more than 1 contactMode and/or environmental setting may be specified.

12.13 Footnotes Representing Measurements to Be Done for a Specified Activity

In most protocols the exact assessments to be done are specified in dedicated paragraphs. However, in some cases, they are specified in the footnotes of the SOA, for example:

1. Hematology must include CBC with differential including but not limited to
2. T/B/NK cell count (i.e. CD3, CD4, CD8, CD19, CD16/56)

These assessments can be specified as BCs and linked to the corresponding SOA activity as shown in the following diagram.



12.14 Footnotes Representing Optional Alternative Measurement Methods

These footnotes indicate more than 1 alternative for an assessment, for example:

1. Diagnosis confirmed with either chest x-ray or CT scan
2. Urine or plasma pregnancy test

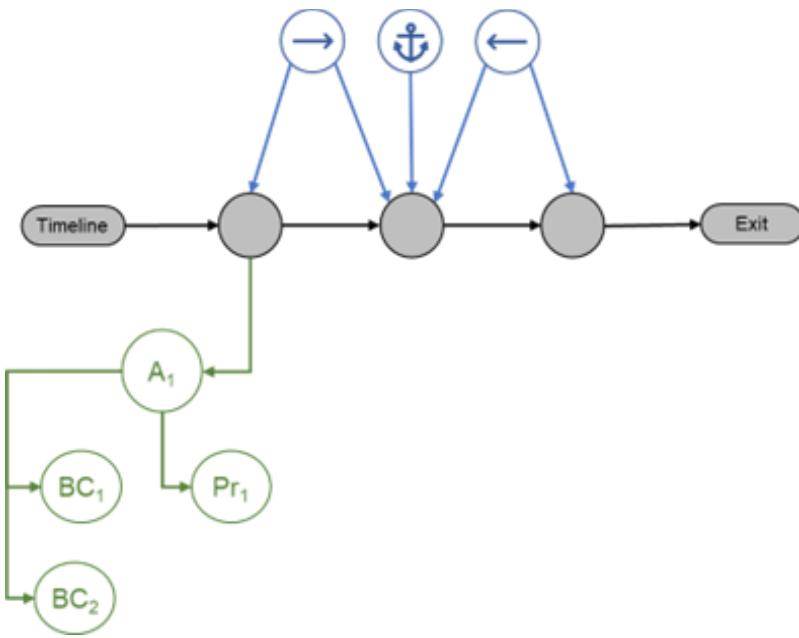
As with conditional footnotes, these footnotes can be handled using the Condition class. The text can then be stored in the corresponding text attribute. Both assessments need to be specified as a BC, procedure, or BC surrogate. The specified condition then can be related to both using the appliesTo relationship.

12.15 Additional Instructions for Procedures and/or Performing Assessments

These footnotes give details on how assessments need to be done, for example:

1. A ruler will be provided to assess ...
2. Samples will be sent to ...
3. Subjects should adhere to low-fat diet on day of sample collection
4. In order to assess y, the add-on medication should be continued for at least x weeks
5. X will be assessed by a blinded assessor
6. Patients should be instructed to use the inhaler in the morning at approximately the same time

Depending on the nature and level of instruction, this can be included in the BC when directly related to a specific assessment or added as a procedure (Pr_1) to the same activity as illustrated in the following diagram.



12.16 Visit and Timing Window Information

Visit window information is often shown in the column header of the corresponding visit, but in some cases may be added as footnotes; for example:

1. Assessments need to be done within 10 minutes after dosing
2. Visits need to take place between 5 and 10 days after dosing

As explained in Section 4.14, [Study Timing](#), all specific groups of activities that occur at a specific timepoint are stored as separate scheduledActivityInstances and are linked to the corresponding timing. This timing class has attributes that can be used to specify the timing window. The window attribute is used to store the textual value of the window (e.g., “within 10 minutes after dosing”) whereas the windowLower and windowUpper attributes are used for the computer readable version in ISO 8601 format (e.g., “T0M”, “T10M”).

12.17 Eligibility Requirements

Eligibility criteria are stored in the EligibilityCriteria class (see Section 4.18, [Populations, Cohorts, and Eligibility Criteria](#)). In some cases they are repeated in the SOA; for example:

1. Screening spirometry must demonstrate a value of In the morning of the first day of treatment value must also be in range
2. Patients must demonstrate $\geq 15\%$ reversibility of FEV1 within .. following inhalation of ...

The EligibilityCriteria class uses text templates for the specifications of the criteria. Using these text templates, criteria can refer to the corresponding activity or assessment (BC) in the SOA. If required, these cross-references could be used by an implementation to link the criteria to the SOA and present them with the corresponding activities in the SOA.

12.18 Complex Combinations

Footnotes are often complex, long text that includes different kinds of requirements (e.g., a combination of timing, duration, conditionality, and/or methods), such as:

1. All subjects will perform a X profile for any 3 days (not required to be consecutive) during week (-2) to week (01), week 11-12, week 23-24 and week 51-52. Blood glucose readings will consist of 3 preprandial measurements (1-15 minutes before breakfast, 1-15 minutes before lunch, and 1-15 minutes before dinner) AND 3 postprandial measurements (1~1-2 hours after breakfast, 1~1-2 hours after lunch, and 1~1-2 hours

after dinner).) The initial preprandial 6-point glucose measurement on the x day should be a fasting plasma glucose reading.

2. SpO₂ before activity (baseline), during activity until the end of anaesthesia, and during postoperative recovery

For the purpose of comprehensibility of the SOA and for consistency throughout the study process, it is helpful to deduct the separate requirements from these footnotes and digitize them according to the solutions presented in this section.

12.19 Complex Study Designs

A complex study design is not a delineated concept. Although not exhaustive, the aim of this section is to provide insights in how complex aspects of study designs can be modeled in the USDM, including:

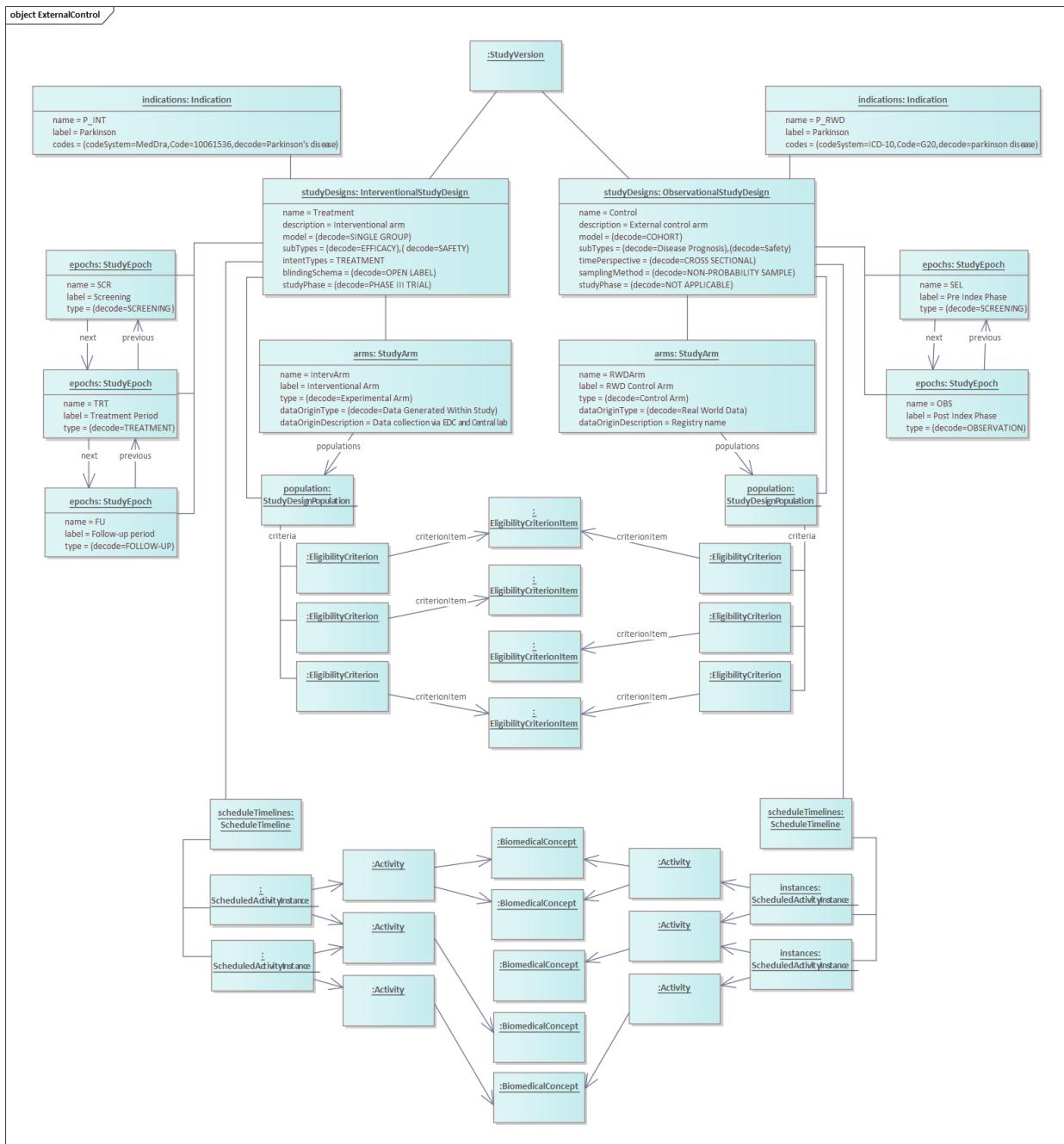
- External control arms
- Multiple cohorts
- Multistep intervention schedules
- Basket, umbrella and multiphased studies
- Decentralized trials

12.20 External control arms

An study with an external control usually includes an arm that follows an interventional trial schedule and an arm that is based on real-world data, synthetic data, or historical control trial data. Although the aim is to have a similar design for both the interventional arm and the control arm, the different nature of the data collection has an influence on study design elements like eligibility criteria, study epochs, timeline visits, and corresponding windowing and assessment details. Therefore, although it is up to the implementer how it is modeled, storing both arms in a separate study design is recommended. This aligns with the observed usual practice that the control arm is described in a separate protocol.

The following instance diagram shows basic principles of how an external control arm design can be stored in the USDM. It includes the following features:

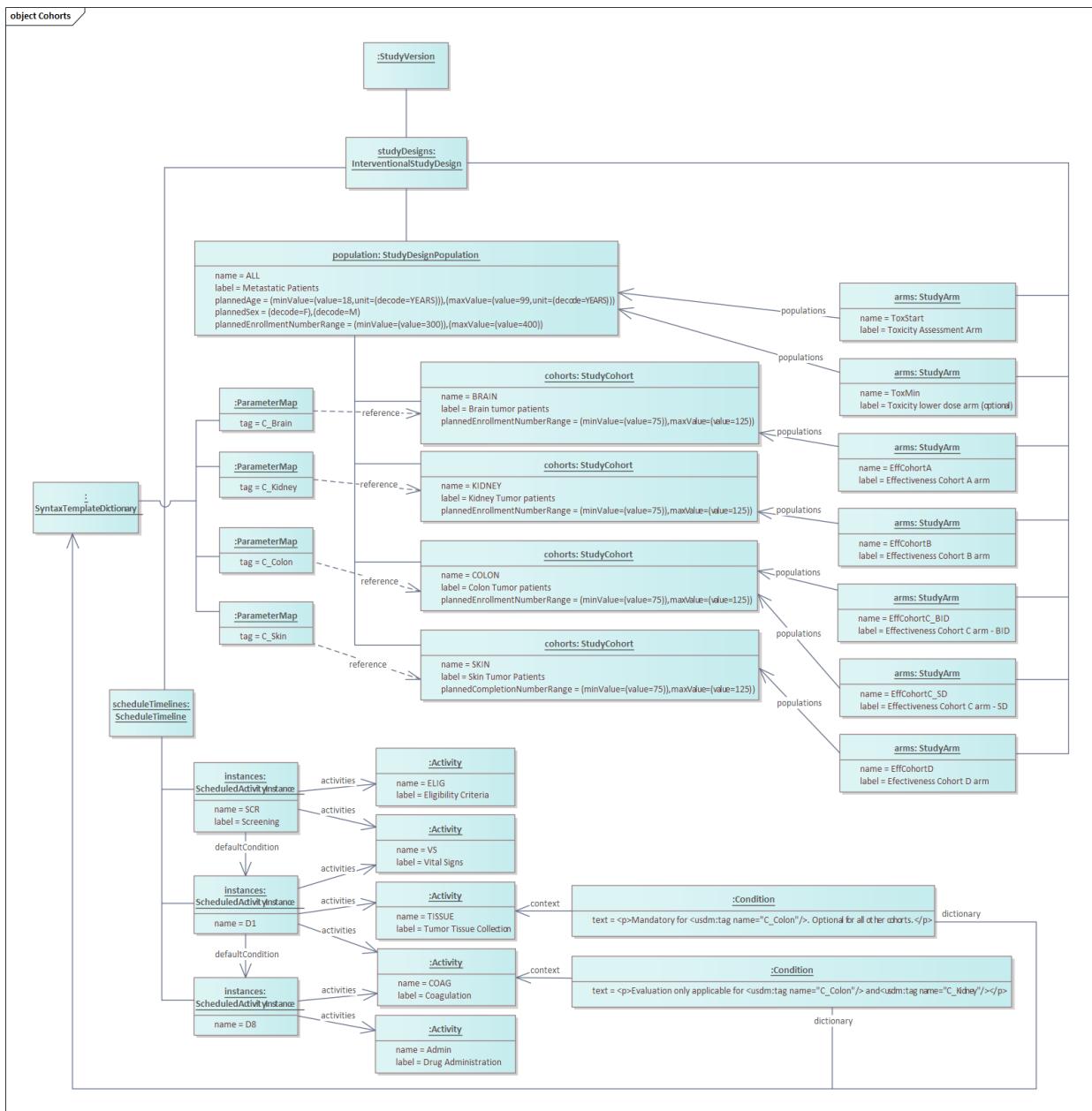
1. The interventional arm is specified in the InterventionalStudyDesign class with corresponding design specific attributes while the observational real-world data control arm is specified in the ObservationalStudyDesign class.
2. The indication is specified for each of the study design separately. Although the same indication is intended for both arms, coding can be adjusted to the specific source data used for the arm. In this example, the MedDRA code is specified for the interventional arm while the corresponding ICD-10 code is specified for the real-world data control arm.
3. Epochs (study periods) are specified per design and therefore may reflect differences between arms. Whereas an external control arm may not have a treatment phase and/or a clear distinction between treatment and follow-up, the interventional arm has typically separate epochs for treatment and follow-up. In the example, these epochs for the interventional arm match the observation epoch of the control arm.
4. Although expected to be similar, study population details are specified per design. The corresponding eligibility criteria may point to shared items or may be specific to the interventional or observational nature of the design. (See Section 4.18, [Populations, Cohorts, and Eligibility Criteria](#), for a more detailed example of shared criteria.)
5. External control arms usually have similar time points as the interventional arm. However, due to the nature of the data, larger windows may be applicable, and number of assessments and visits might be limited in the external control arm. Therefore, the timelines and corresponding activities are defined within the design with the option to refer to shared assessments stored in BC. Note that if assessments differ in some aspects, this would require separate BC specifications although they usually will refer to the same controlled terminology. If needed, both arms can be matched according to equal time point values which are computer readable and specified in ISO 8601 format.



12.21 Multiple Cohorts

As presented in Section 4.18, [Populations, Cohorts, and Eligibility Criteria](#), a population can be divided into multiple cohorts when feasible for the study design. In case assessments and schedules differ greatly between the cohorts, it is better to model them into separate designs as illustrated in the preceding external control arm example. However, if all cohorts and arms follow the same schedule with few exceptions, it is more efficient to combine them into a single design. This example is based on a number of oncology phase 1-2 designs obtained from ClinicalTrials.gov. Such designs usually start with an arm that combines different indications to test for toxicity while the follow-up arms are looking at the effectiveness per disease area. The instance diagram shows basic principles for such a design. It includes the following features:

1. The general study design population is divided into cohorts. Characteristics of the study population and corresponding cohorts can either be defined at the study population level or the cohort level, or both. In this case the planned age and gender were defined at the study design population level and the planned enrollment number both at the study design population level (300-400) and at the cohort level (75-125).
2. The 2 toxicity assessment arms point to the general study design population because patients with any of the study design indications are included in these arms. The effectiveness arms, however, point to the corresponding cohorts because these are specific for the corresponding cohort disease indication. For 1 of those cohorts, 2 different dosing regimens are tested in separate arms. Therefore, both arms point to the same study cohort defined for the indication. Note that this is an example; the USDM is flexible and modeling of cohorts is not necessarily bound by disease indication. In addition, a study arm may also point to multiple cohorts if needed.
3. In this example, all arms are following the same schedule of activities, which is represented in the USDM schedule timeline and corresponding activities. The simplified example shows 3 different time points referring to a number of activities. Note that these activities are typically shown in the left column of an SOA and that the USDM subsequently links them to the corresponding procedures and assessments (see Section 4.14, [Study Timing](#)) that may be further described elsewhere in the protocol.
4. Some of the activities are conditional for a specific cohort. This is noted in conditions which inherited the syntax template feature (see [Section 4.21](#)). To enable a direct link between the condition and the corresponding cohort, a syntax template parameterMap was created for each studyCohort label. The actual cohort name in the condition text is replaced by the corresponding tag. This has 2 major advantages:
 - a. If cohort labels are changed, this is directly reflected in the condition text (usually shown as footnotes to the SOA).
 - b. Conditions can be filtered based on tags for a specific condition, allowing for the creation of cohort- or patient-specific journeys.



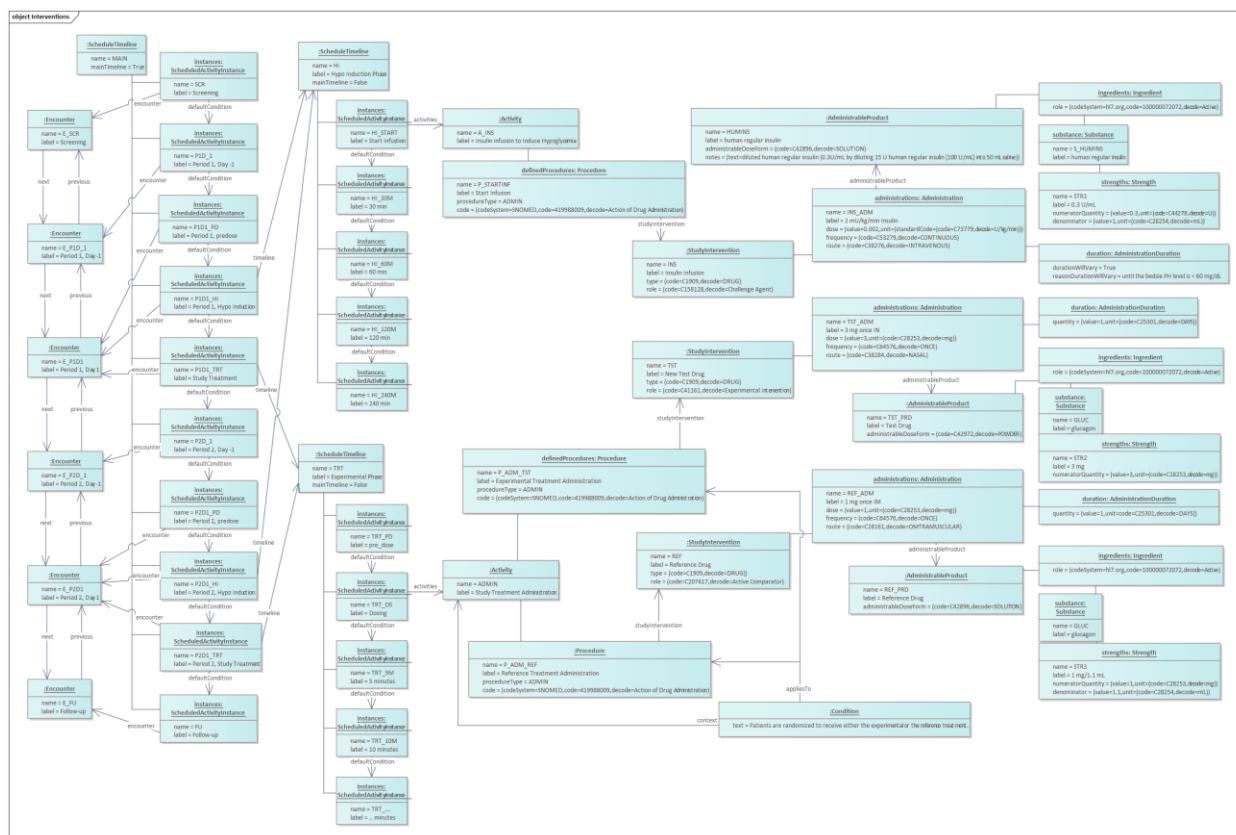
12.22 Multistep Intervention Schedules

Study designs become more complex from an interventional perspective when they include multiple intervention steps. An example of this are studies where all patients start with the same treatment but are randomized afterwards to get a different follow-up treatment and/or a different add-on treatment. The following instance diagram shows such a study in which patients are first challenged with insulin to reach hypoglycemic levels and thereafter are randomized to get the test or control treatment to test their effectiveness on restoring glycemic levels. The study is also a randomized crossover study, which adds an extra layer of complexity because both the challenge and the treatment phase are repeated for both periods. The instance diagram shows how this can be represented in USDM. It includes the following features:

1. The main timeline represents the main schedule of activities in the protocol. The day 1 visit (stored in the encounter class) is divided into 3 different scheduled activity instances to indicate the different periods during the day (i.e., predose phase, hypoglycemic induction phase, treatment phase). Note that in a

document representation of the SOA this can be combined again and explained using footnotes, while a study design solution allows one to follow the logic within an encounter using expand functionalities.

2. The specific assessments within each phase are modeled using sub-timelines (see section 4.14, [Study Timing](#)) for both the hypoglycemic induction phase and the treatment phase. This allows for clearness in timing in relation to the specific administration. In a document representation, these sub-timelines are often represented as separate tables or as footnote instructions.
3. The additional advantage of a sub-timeline is that they can be referenced multiple times (e.g., in a crossover study or repeat-cycle study). In this crossover example, each sub-timeline is referenced both from period 1 and from period 2.
4. All activities and corresponding labels (usually presented in the left column of the SOA) are stored in the Activity class. In this example, only the dosing activities are shown.
 - a. The activity "Insulin infusion to Induce Hypoglycemia" includes a specific start-administration procedure which refers to the corresponding study intervention instance.
 - b. The activity "Study Treatment Administration" includes 2 different procedures, 1 for the new test drug administration and 1 for the reference drug administration. A condition in the context of the activity is applicable to both procedures to indicate that the administration of either is based on randomization.
5. For each kind of intervention, a separate StudyIntervention instance is stored in the StudyIntervention part of the USDM. This includes details on administration duration, administrable product, and corresponding ingredients and strengths. Additional notes may be added if helpful for downstream processes, for example to include more instructions on preparation and administration as shown in the example for the human regular insulin administrable product. (For more information on this part of the model, see [Section 4.15, Study Interventions](#).)



12.23 Basket, Umbrella, and Multiphased studies

Basket trials are trials in which a specific intervention is tested for multiple indications; in umbrella trials, multiple interventions are tested for a single indication. These kinds of trials allow for more efficiency and consistency

because basic parts of the study design can be fixed and/or controlled; only subparts need to be flexible and adjusted for the specific indication or intervention. *Multiphased trials* are trials in which multiple objectives and study phases are combined into a single design, again combining multiple (sub-)trials for efficiency and consistency. Moreover, combinations of these types of complex designs also are possible. The preceding multiple cohort is a good example of a combination of a multiphase and umbrella trial.

The USDM is flexible in storing the study design information for these complex trials. Depending on how flexible the subpart is, one can decide to store and exchange it as 1 design or as multiple designs. If the timeline is equal for all the designs, it is probably more efficient to store it in a single design (as in the multiple cohort example).

Regarding the documentation, a master protocol with corresponding subprotocols might be applicable to these kinds of studies. For an example of the storage of these documents in the USDM, see Section 4.6, [Study, Protocols, and Amendments](#).

12.24 Decentralized Trials

Decentralized trials are characterized by more remote activities (e.g., informed consent, visits, drug supplies). Although more challenging from a trial execution perspective, the design aspects are similar to regular clinical trials. To address the remoteness, the USDM encounter contact modes and environmental settings identify how patients are contacted and where they are located during the visit. If more options are allowed per design then more contact modes and/or environmental settings can be specified. Conditional and/or optional activities can be handled in the conditions class, similar to regular trial design, and optional assessment features can be enabled for each assessment using the BC features (see Section 4.11, [Activities](#)).

12.25 Schedule of Activity Views

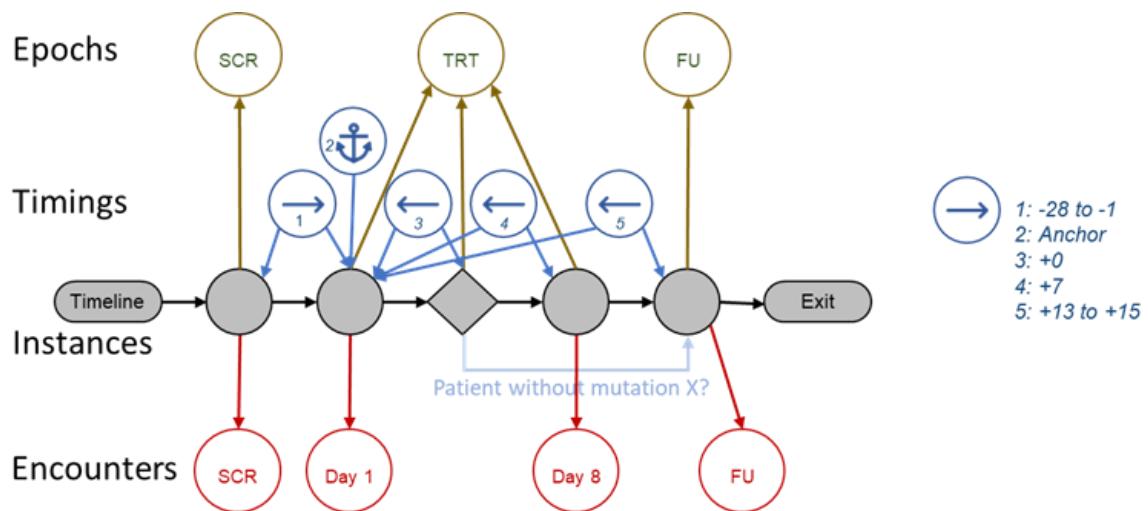
Based on the objectives and endpoints of a study, the assessments, procedures, and the corresponding timings are planned and described in the study design and corresponding protocol. The SOA provides a broad overview of the timeline and activities at each time point. However, for a visual representation of this timeline and corresponding details, options are limited by space (e.g., document page, screen) and by the aim of visual clearness. For this reason many details of a timeline are currently handled in footnotes and/or in-text. Stakeholders in downstream processes, however, may require a different view on the SOA than the study investigator who approves the design and protocol.

This section provides an example of how SOA details can be presented in and outside a document.

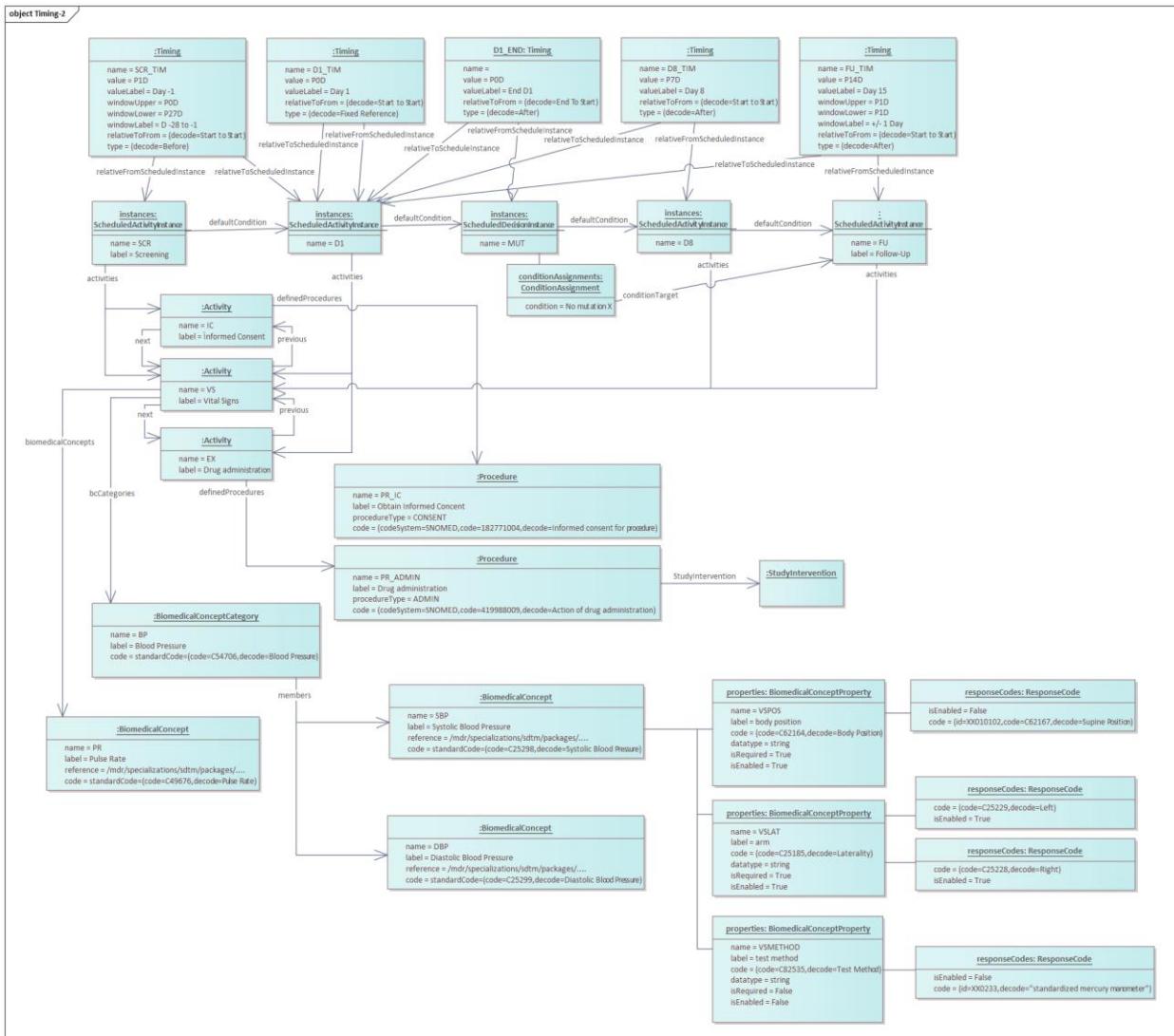
| | Screening | Treatment Phase | | Follow-up |
|---------------------|---------------|-----------------|-----------------|--------------------|
| Activity | Day -28 to -1 | Day 1 | Day 8 | Day 15 (+/- 1 day) |
| Informed Consent | X | | | |
| Vital Signs | X | X | X ^{a)} | X |
| Drug administration | | X | | |

a) Only applicable for patients with mutation X

From a logical USDM perspective, this simple SOA can be presented as depicted in the following diagram (see Section 4.14, [Study Timing](#), for details around timeline and USDM representation). The instances of the main timeline refer to an encounter and an epoch. The timing between these instances is defined and the footnote indicating the optionality of a visit is added as a decision instance in the diagram. Note that multiple instances may refer to the same encounter (visit) and/or epoch.



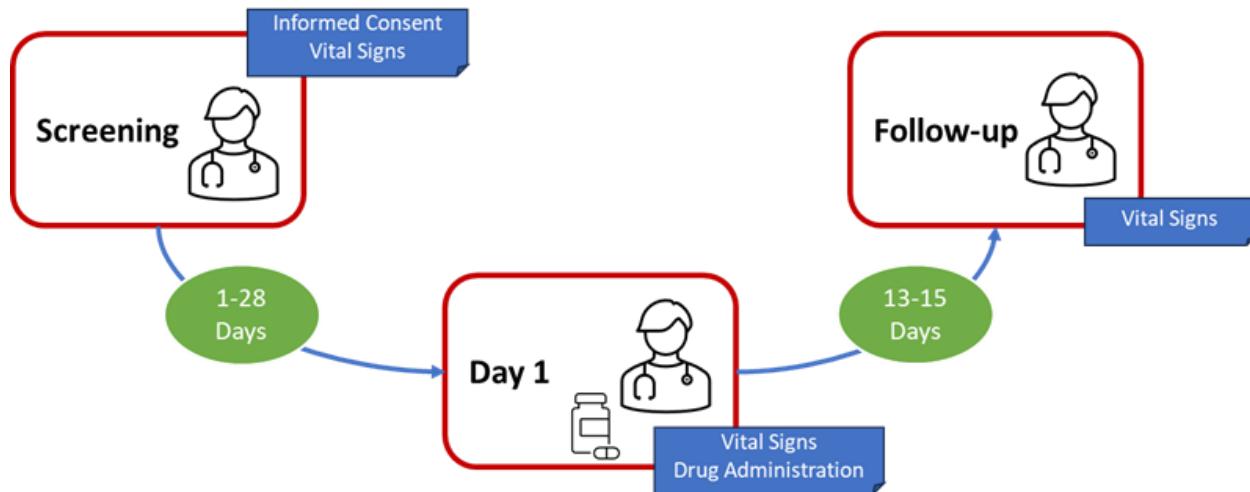
The following diagram aligns to the SOA timeline. Although epoch and encounter references are not included, activity details like procedures and BC are. Although not presented in the SOA, this information can automatically be linked to the activity by a solution and then represented in any way needed for a specific view on the SOA. Some of these examples are presented here.



Note that instance diagrams are created to show single use cases. Not all required attributes, relationships, and properties are presented. Cross-references between instances are presented by arrows while nested instances are represented by straight lines.

SOA information stored in USDM format facilitates the creation of patient journeys based on the decision instances and conditions defined in the USDM. For an example of conditional assessments, see the multiple cohort example in Section 4.24, [Complex Study Designs](#).

The following patient journey diagram is created based on the information presented in the instance diagram. It illustrates the journey for patients without mutation X. Note that visit 8 for these patients is automatically excluded based on the scheduled decision instance and corresponding condition assignment which directly points to the follow-up assessment. The timing between the visits is stored in ISO 8601 format and can therefore be used to automate the calculation of the period between the subsequent visits.

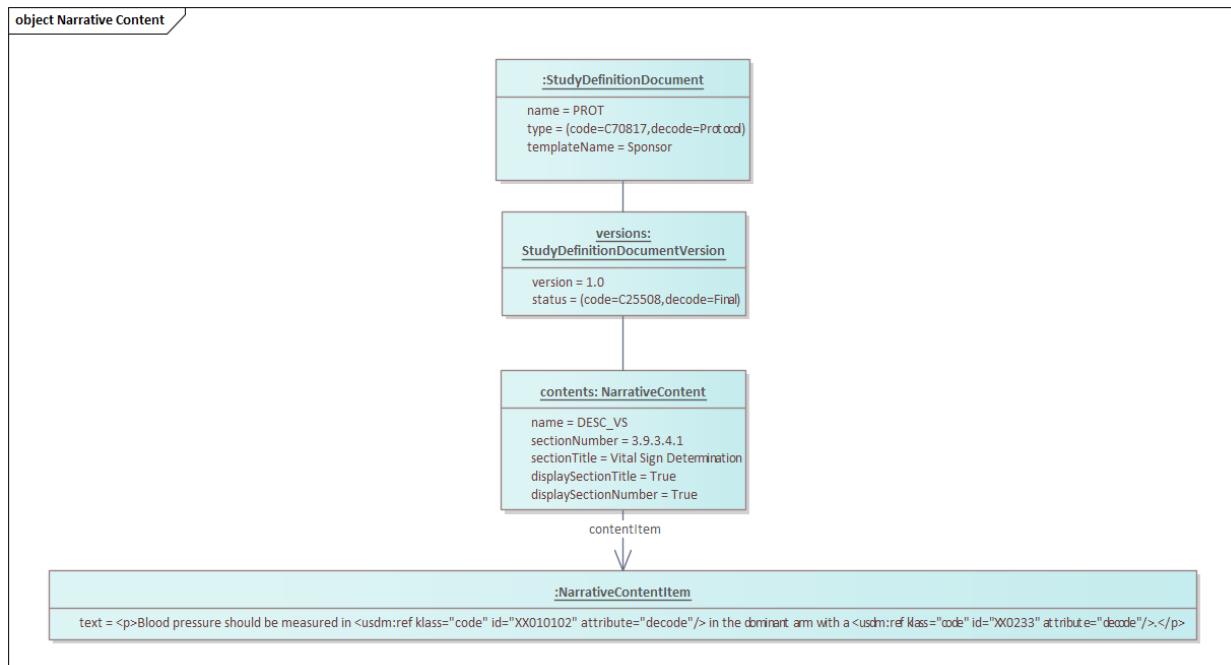


As shown in the instance diagram, an activity description in the SOA may point to one or more procedures and assessments. Details of these procedures are usually described in footnotes, separate tables (for lab), and in-text. The following protocol text snippet describes details on the vital signs measurement to be performed. These described details of the vital signs measurements are actually aspects of the BCs linked to the corresponding activities.

3.9.3.1 Vital Sign Determination

Blood pressure should be measured in supine position in the dominant arm with a standardized mercury manometer.

The protocol text may refer to these details stored in the BCs. This allows for automation in text construction and for consistency in alignment between text and structured content which then can be used in downstream processes. The following instance diagram shows how the text from this snippet refers to specific codes and corresponding attributes stored in the BC property and response code class. The flexible text tagging approach of the USDM (see Section 4.22, [XHTML Attributes](#)) enables automated text construction based on the information stored in the BCs or, alternatively, BC property and response enabling can based on specifications in the structured text elements.



All details stored in the timeline—including encounter (visit), epoch, activity, and corresponding procedure and assessment (BC) information—can be used by the EDC system for EDC design and user views. The level of detail in the USDM can be chosen based on the use case and implementing system. This includes the following options:

- Store the activities within a visit into separate activity instances to structure the order of assessments during the visit and provide a means to create separate corresponding EDC entry pages. The order will be determined by the defaultCondition while all instances can be bound to the same encounter. (For an example of how to handle multiple activity instances within the visit, see the multistep intervention schedule example in Section 4.24, [Complex Study Designs](#).)
- Use the BC properties and corresponding enabled response codes to automate the selection and/or design of entry forms.
- Provide an overview of timeline assessments and procedures for a specific caregiver and/or third party (e.g., investigator activities, lab assessments).

Finally, the SOA encounter details and corresponding planned activities can be used to create SDTM Trial Design domains (see [Section 7.1](#)) and build the outline for other SDTM domains.

13 USDM Data Dictionary

Note: Properties without a description in the following table are either relationships or instance identifiers and were deemed to be out of scope for terminology development. Please see Section 4.4, [Internal Identifiers Within the Model](#), for additional information on the use of identifier variables in the model.

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------|--------------------|-------------------|------------|-------------|----------------------------|--|--------------|----------------|
| Abbreviation | | | C42610 | | Abbreviation | A set of letters that are drawn from a word or from a sequence of words and that are used for brevity in place of the full word or phrase. (CDISC Glossary) | | |
| | id | string | | | | | | |
| | abbreviatedText | string | C42610 | | Abbreviation | A set of letters that are drawn from a word or from a sequence of words and that are used for brevity in place of the full word or phrase. (CDISC Glossary) | | |
| | expandedText | string | CNEW | | Abbreviation Long Name | The full literal representation of the abbreviation. | | |
| | notes | CommentAnnotation | CNEW | | Abbreviation Notes | A brief written record relevant to the abbreviation. | | |
| Activity | | | C71473 | | Study Activity | An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study. | | |
| | id | string | | | | | | |
| | name | string | C18884_2 | | Study Activity Name | The literal identifier (i.e., distinctive designation) of the study activity. | | |
| | description | string | C70960 | | Study Activity Description | A narrative representation of the study activity. | | |
| | label | string | C20745_8 | | Study Activity Label | The short descriptive designation for the study activity. | | |
| | notes | CommentAnnotation | CNEW | | Activity Notes | A brief written record relevant to the activity. | | |
| | definedProcedures | Procedure | | 0..* | | A USDM relationship between the Activity and Procedure classes which identifies the set of defined procedures associated with the activity. | | |
| | biomedicalConcepts | BiomedicalConcept | | 0..* | | A USDM relationship between the Activity and BiomedicalConcept classes which identifies the set of biomedical concepts associated with the activity. | | |
| | next | Activity | | 0..1 | | A USDM relationship within the Activity class which identifies the activity that follows the current activity in the display order. | | |
| | timeline | ScheduleTimeline | | 0..1 | | A USDM relationship between the Activity and ScheduleTimeline classes which provides the details associated with an instance of the scheduled timeline related to the activity. | | |
| | children | Activity | | 0..* | | A USDM relationship within the Activity class which identifies the set of child activities associated with an activity. | | |
| | previous | Activity | | 0..1 | | A USDM relationship within the Activity class which identifies the activity that precedes the activity. | | |

CDISC [Title] (Version n [Status])

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|----------------------|-----------------------|--------------------------------|-------------|-------------|--|--|--|----------------|
| | | | | | | current activity in the display order. | | |
| | bcSurrogates | BiomedicalConceptSurrogate | | 0..* | | A USDM relationship between the Activity and BiomedicalConceptSurrogate classes which identifies the set of biomedical concept surrogates associated with the activity. | | |
| | bcCategories | BiomedicalConceptCategory | | 0..* | | A USDM relationship between the Activity and BiomedicalConceptCategory classes which identifies the set of biomedical concept categories associated with the activity. | | |
| Address | | | C25407 | | Address | A standardized representation of the location of a person, business, building, or organization. (NCI) | | |
| | id | string | | | | | | |
| | text | string | C20131 1 | | Address Full Text | A standardized representation of the complete set of components denoting the physical address of the person, business, building, or organization. | | |
| | lines | string | C25690 | | Address Line | The street name and number, building number, apartment or unit number, or post office box number where an entity is physically located. | | |
| | district | string | C17622 9 | | District | An administrative or territorial division of a city, town, county, parish, state, country, or other locality based on a shared characteristic. | | |
| | city | string | C25160 | | City | A relatively large and/or densely populated area of human habitation with administrative or legal status that may be specified as a component of a postal address. | | |
| | postalCode | string | C25621 | | Postal Code | An alphanumeric code assigned to a mail delivery area. | | |
| | state | string | C87194 | | State | A subdivision of a country that forms part of a federal union. States are usually, but not always, more autonomous than provinces and may have different laws from the central government. | | |
| | country | Code | C25464 | | Country | A sovereign nation occupying a distinct territory and ruled by an autonomous government. | Point out to ISO 3166-1 Alpha-3 Country code) | |
| AdministrableProduct | | | CNEW | | Administrable Product | Any study product that is formulated and presented in the form that is suitable for administration to a study participant. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Administrable Product Definition Name | The literal identifier (i.e., distinctive designation) of the administrable product. | | |
| | description | string | CNEW | | Administrable Product Definition Description | A narrative representation of the administrable product. | | |
| | label | string | CNEW | | Administrable Product Definition Label | The short descriptive designation for the administrable product. | | |
| | administrableDoseForm | AliasCode | CNEW | | Administrable Product Dose Form | The physical form in which formulated ingredient(s) are presented in the administrable product. | SDTM Terminology Codelist C66726 | |
| | sourcing | Code | CNEW | | Administrable Product Sourcing | An indication as to whether the administrable product is obtained from a local or central source. | CNEW - Product Sourcing Value Set | |
| | productDesignation | Code | CNEW | | Administrable Product Product Designation | An indication as to whether the administrable product is an investigational medicinal product or an auxiliary medicinal product. | C207418 | |
| | pharmacologicClass | Code | CNEW | | Administrable Product Pharmacologic Class | The pharmacological class of the administrable product. | Points to external codelists such as UNII, MED-RT) | |
| | notes | CommentAnnotation | CNEW | | Administrable Product Notes | A brief written record relevant to the administrable product. | | |
| | identifiers | AdministrableProductIdentifier | | 0..* | | A USDM relationship between the AdministrableProduct and AdministrableProductIdentifier classes which provides the set of identifiers related to the administrable product. | | |
| | properties | AdministrableProductProperty | | 0..* | | A USDM relationship between the AdministrableProduct and AdministrableProductProperty classes which provides the set of properties related to the administrable product. | | |
| | ingredients | Ingredient | | 0..* | | A USDM relationship between the AdministrableProduct and Ingredient classes which provides the set of ingredients related to the administrable product. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------------|------------------------|------------------------|------------|-------------|---|---|--|----------------|
| AdministrableProductIdentifier | | | CNEW | | Administrable Product Identifier | A sequence of characters used to identify, name, or characterize the administrable product. | | |
| | id | string | | | | | | Identifier |
| | text | string | CNEW | | Administrable Product Identifier Text | An instance of structured text that represents the administrable product. | | Identifier |
| | scope | Organization | | 1 | | A USDM relationship between the AdministrableProductIdentifier and Organization class which provides the details associated with which provides the details associated with each organization that has assigned the administrable product identifier. | | Identifier |
| AdministrableProductProperty | | | CNEW | | Administrable Product Property | A characteristic from a set of characteristics used to define an administrable product. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Administrable Product Property Name | The literal identifier (i.e., distinctive designation) of the administrable product property. | | |
| | type | Code | CNEW | | Administrable Product Property Type | A characterization or classification of the administrable product property. | CNEW Administrable Product Property Type | |
| | text | string | CNEW | | Administrable Product Property Text | An instance of structured text that represents the administrable product property. | | |
| | quantity | Quantity | CNEW | | Administrable Product Property Quantity Value | The numeric value associated with an administrable product property. | | |
| Administration | | | C25409 | | Administration | The act of dispensing, applying, or tendering a product, agent, or therapy. | | |
| | id | string | | | | | | |
| | name | string | C20746 5 | | Administration Name | The literal identifier (i.e., distinctive designation) for the administration of a product, agent, or therapy. | | |
| | description | string | C20746 3 | | Administration Description | A narrative representation for the administration of a product, agent, or therapy. | | |
| | label | string | C20746 4 | | Administration Label | The short descriptive designation for the administration of a product, agent, or therapy. | | |
| | dose | Quantity | C16719 0 | | Administration Dose | The value representing the amount of an agent given to an individual at one time. | | |
| | frequency | AliasCode | C89081 | | Dosing Frequency | The number of doses administered per a specific interval. | SDTM Terminology Codelist C71113 | |
| | route | AliasCode | C38114 | | Route of Administration | The pathway by which a substance is administered in order to reach the site of action in the body. | SDTM Terminology Codelist C66729 | |
| | notes | CommentAnnotation | CNEW | | Administration Notes | A brief written record relevant to the administration of the product, agent, or therapy. | | |
| | administrableProduct | AdministrableProduct | | 0..1 | | A USDM relationship between the Administration and AdministrableProductDefinition classes which identifies the administrable product associated with the administration of the product, agent, or therapy. | | |
| | duration | AdministrationDuration | | 1 | | A USDM relationship between the Administration and AdministrationDuration classes which provides the duration of an instance of product, agent, or therapy administration. | | |
| | medicalDevice | MedicalDevice | | 0..1 | | A USDM relationship between the Administration and MedicalDevice classes which identifies the medical device associated with an instance of product, agent, or therapy administration. | | |
| AdministrationDuration | | | C69282 | | Administration Duration | The amount of time elapsed during the administration of an agent. | | |
| | id | string | | | | | | |
| | description | string | C20745 9 | | Administration Duration Description | A narrative representation of the agent administration duration. | | |
| | quantity | Quantity | C20746 0 | | Administration Duration Quantity Value | The value representing the amount of time over which the administration of an agent occurs. | | |
| | durationWillVary | Boolean | C20746 1 | | Administration Duration Will Vary Indicator | An indication as to whether the agent administration duration is planned to vary within and/or across subjects. | | |
| | reasonDurationWillVary | string | C20746 2 | | Administration Duration Reason Duration Will Vary | The explanation for why the agent administration duration will vary within and/or across subjects. | | |
| AliasCode | | | C20134 4 | | Alias Code | An alternative symbol or combination of symbols which is assigned to the members of a collection. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|---------------------------|---------------------|---------------------------|------------|-------------|----------------------------------|---|--------------|----------------|
| | id | string | | | | | | |
| | standardCode | Code | CNEW | | Standard Code | A combination of symbols that is used to represent the standard code. | | |
| | standardCodeAliases | Code | CNEW | | Standard Code Aliases | Alternative combinations of symbols used to represent aliases or alternatives to the standard code. | | |
| AnalysisPopulation | | | C188814 | | Analysis Population | A target study population on which an analysis is performed. These may be represented by the entire study population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence (or non-occurrence, depending on context) of a specific intercurrent event. ^[5] | | |
| | id | string | | | | | | |
| | text | string | C207468 | | Analysis Population Text | An instance of unstructured text that represents the analysis population. | | |
| | name | string | C207467 | | Analysis Population Name | The literal identifier (i.e., distinctive designation) of the analysis population. | | |
| | description | string | C188854 | | Analysis Population Description | A narrative representation of the analysis population. | | |
| | label | string | C207466 | | Analysis Population Label | The short descriptive designation for the analysis population. | | |
| | notes | CommentAnnotation | CNEW | | Analysis Population Notes | A brief written record relevant to the analysis population. | | |
| | subsetOf | PopulationDefinition | | 0..* | | A USDM relationship between the AnalysisPopulation and PopulationDefinition classes which identifies the population definition of which the analysis population is a subset. | | |
| AssignedPerson | | | CNEW | | Assigned Person | An individual person who is allotted or appointed to a particular role, function, or other entity. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Assigned Person Name | The literal identifier (i.e., distinctive designation) of the assigned person. | | |
| | description | string | CNEW | | Assigned Person Description | A narrative representation of the assigned person. | | |
| | label | string | CNEW | | Assigned Person Label | The short descriptive designation for the assigned person. | | |
| | jobTitle | string | CNEW | | Assigned Person Job Title | An identifying designation related to the assigned person's occupation. | | |
| | organization | Organization | | 0..1 | | A USDM relationship between the AssignedPerson and Organization classes that identifies that organization to which the assigned person belongs. | | |
| BiomedicalConcept | | | C201345 | | Biomedical Concept | A unit of biomedical knowledge created from a unique combination of characteristics that include implementation details like variables and terminologies, used as building blocks for standardized, hierarchically structured clinical research information. | | |
| | id | string | | | | | | |
| | name | string | C201312 | | Biomedical Concept Name | The literal identifier (i.e., distinctive designation) of the biomedical concept. | | |
| | label | string | C207470 | | Biomedical Concept Label | The short descriptive designation for the biomedical concept. | | |
| | synonyms | string | C201314 | | Biomedical Concept Synonym | A word or an expression that serves as a figurative, symbolic, or exact substitute for a biomedical concept, and which has the same meaning. | | |
| | reference | string | C201313 | | Biomedical Concept Reference | A citation to an authoritative source for a biomedical concept. | | |
| | code | AliasCode | C207469 | | Biomedical Concept Concept Code | A concept unique identifier assigned to a biomedical concept that points to the meaning of that biomedical concept. | | |
| | notes | CommentAnnotation | CNEW | | Biomedical Concept Notes | A brief written record relevant to the biomedical concept. | | |
| | properties | BiomedicalConceptProperty | | 0..* | | A USDM relationship between the BiomedicalConcept and BiomedicalConceptProperty classes which identifies the set of properties associated with the biomedical concept. | | |
| BiomedicalConceptCategory | | | C201346 | | Biomedical Concept Category | A grouping of biomedical concepts based on some commonality or by user defined characteristics. | | |
| | id | string | | | | | | |
| | name | string | C201317 | | Biomedical Concept Category Name | The literal identifier (i.e., distinctive designation) of the biomedical concept category. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|----------------------------|----------------|---------------------------|------------|-------------|--|---|--------------|----------------|
| | description | string | C201316 | | Biomedical Concept Category Description | A narrative representation of the biomedical concept category. | | |
| | label | string | C207471 | | Biomedical Concept Category Label | The short descriptive designation for the biomedical concept category. | | |
| | code | AliasCode | C201315 | | Biomedical Concept Category Code | A symbol or combination of symbols which is assigned to the biomedical concept category. | | |
| | notes | CommentAnnotation | CNEW | | Biomedical Concept Category Notes | A brief written record relevant to the biomedical concept category. | | |
| | members | BiomedicalConcept | | 0..* | | A USDM relationship between the BiomedicalConceptCategory and BiomedicalConcept classes which identifies the set of biomedical concept members associated with the biomedical concept category. | | |
| | children | BiomedicalConceptCategory | | 0..* | | A USDM relationship within the BiomedicalConceptCategory class which identifies the set of child categories of a biomedical concept. | | |
| BiomedicalConceptProperty | | | C202493 | | Biomedical Concept Property | A characteristic from a set of characteristics used to define a biomedical concept. | | |
| | id | string | | | | | | |
| | name | string | C202494 | | Biomedical Concept Property Name | The literal identifier (i.e., distinctive designation) of the biomedical concept property. | | |
| | label | string | C207472 | | Biomedical Concept Property Label | The short descriptive designation for the biomedical concept property. | | |
| | isRequired | Boolean | C202495 | | Biomedical Concept Property Required Indicator | An indication as to whether the biomedical concept property is required. | | |
| | isEnabled | Boolean | C202496 | | Biomedical Concept Property Enabled Indicator | An indication as to whether the biomedical concept property is activated for use within a given usage context for a biomedical concept. | | |
| | datatype | string | C201319 | | Biomedical Concept Property Response Data Type | The structural format of the biomedical concept property response value. The datatype is carried in the attribute and influences the set of allowable values the attribute may assume. (HL7) | | |
| | code | AliasCode | C201318 | | Biomedical Concept Property Concept Code | A concept unique identifier assigned to a biomedical concept property that points to the meaning of that biomedical concept property. | | |
| | notes | CommentAnnotation | CNEW | | Biomedical Concept Property Notes | A brief written record relevant to the biomedical concept property. | | |
| | responseCodes | ResponseCode | | 0..* | | A USDM relationship between the BiomedicalConceptProperty and ResponseCode classes which identifies the set of response codes associated with the biomedical concept property. | | |
| BiomedicalConceptSurrogate | | | C207590 | | Biomedical Concept Surrogate | A concept that substitutes for a standard biomedical concept from the designated source. | | |
| | id | string | | | | | | |
| | name | string | C207474 | | Biomedical Concept Surrogate Name | The literal identifier (i.e., distinctive designation) of the biomedical concept surrogate. | | |
| | description | string | C201320 | | Biomedical Concept Surrogate Description | A narrative representation of the biomedical concept surrogate. | | |
| | label | string | C207473 | | Biomedical Concept Surrogate Label | The short descriptive designation for the biomedical concept surrogate. | | |
| | reference | string | C201321 | | Biomedical Concept Surrogate Reference | A citation to an authoritative source for a biomedical concept surrogate. | | |
| | notes | CommentAnnotation | CNEW | | Biomedical Concept Surrogate Notes | A brief written record relevant to the biomedical concept surrogate. | | |
| BiospecimenRetention | | | CNEW | | Biospecimen Retention | The continued possession, cataloging, and storage of collected biological specimens beyond their initial use. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Biospecimen Retention Name | The literal identifier (i.e., distinctive designation) of the biospecimen retention. | | |
| | description | string | C181231 | | Biospecimen Retention Description | A narrative representation of the biospecimen retention. | | |
| | label | string | CNEW | | Biospecimen Retention Label | The short descriptive designation for the biospecimen retention. | | |
| | isRetained | Boolean | C164620 | | Biospecimen Retention Indicator | An indication as to whether biospecimens were retained. | | |
| | includesDNA | Boolean | C127777 | | Biospecimen Retention Includes DNA Indicator | An indication as to whether retained biospecimens contain DNA. | | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------|-------------------|---|-------------|-------------|----------------------------|--|----------------|----------------|
| Characteristic | | | C25447 | | Characteristic | The distinguishing qualities or prominent aspects of an entity. | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | C20747 7 | | Characteristic Name | The literal identifier (i.e., distinctive designation) of the characteristic. | SyntaxTemplate | |
| | description | string | C20747 5 | | Characteristic Description | A narrative representation of the characteristic. | SyntaxTemplate | |
| | label | string | C20747 6 | | Characteristic Label | The short descriptive designation for the characteristic. | SyntaxTemplate | |
| | text | string | C20747 8 | | Characteristic Text | An instance of structured text that represents the characteristic. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Characteristic Notes | A brief written record relevant to the characteristic. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the Characteristic and SyntaxTemplateDictionary classes which provides the set of dictionary entries related to characteristics. | SyntaxTemplate | |
| Code | | | C25162 | | Code | A symbol or combination of symbols which is assigned to the members of a collection. | | |
| | id | string | | | | | | |
| | code | string | C18885 8 | | Code Value | The literal value of a code. | | |
| | codeSystem | string | C18885 9 | | Code System Name | The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes. | | |
| | codeSystemVersion | string | C18886 8 | | Code System Version | The version of the code system. | | |
| | decode | string | C18886 1 | | Decode | Standardized or dictionary-derived human readable text associated with a code. | | |
| CommentAnnotation | | | C44272 | | Comment Annotation | An explanatory or critical comment, or other in-context information (e.g., pattern, motif, link), that has been associated with data or other types of information. | | |
| | id | string | | | | | | |
| | text | string | CNEW | | Comment Annotation Text | An instance of unstructured text that represents the comment annotation. | | |
| | codes | Code | CNEW | | Comment Annotation Code | A symbol or combination of symbols which is assigned to the comment annotation. | | |
| Condition | | | C25457 | | Condition | A state of being. | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | C20748 3 | | Condition Name | The literal identifier (i.e., distinctive designation) of the condition. | SyntaxTemplate | |
| | description | string | C20748 1 | | Condition Description | A narrative representation of the condition. | SyntaxTemplate | |
| | label | string | C20748 2 | | Condition Label | The short descriptive designation for the condition. | SyntaxTemplate | |
| | text | string | C20748 4 | | Condition Text | An instance of structured text that represents the condition. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Condition Notes | A brief written record relevant to the condition. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the Condition and SyntaxTemplateDictionary classes which provides the set of dictionary entries related to conditions. | SyntaxTemplate | |
| | context | Activity, ScheduledActivityInstance | | 0..* | | A USDM relationship between the Condition and the ScheduledActivityInstance or Activity classes which identifies the scheduled activity instance or activity to which the condition belongs. | | |
| | appliesTo | Activity, BiomedicalConcept, BiomedicalConceptCategory, BiomedicalConceptSurrogate, Procedure | | 0..* | | A USDM relationship between the Condition and the Activity, Procedure, BiomedicalConcept, BiomedicalConceptSurrogate, or BiomedicalConceptCategory classes which identifies the procedure, activity, biomedical concept, biomedical concept surrogate, or biomedical concept category that applies to the condition. | | |
| ConditionAssignment | | | C20133 5 | | Condition Assignment | An allotting or appointment to a condition or set of conditions that are to be met in order to make a logical decision. | | |
| | id | string | | | | | | |
| | condition | string | C47953 | | Logical Condition | An assumption on which rests the validity or effect of something else. | | |
| | conditionTarget | ScheduledInstance | | 1 | | A USDM relationship between the ConditionAssignment and ScheduledInstance classes which identifies the scheduled instance associated with the condition assignment. | | |
| DocumentContentReference | | | CNEW | | Document Content Reference | A citation pointing to the location of specific content within a document. | | |
| | id | string | | | | | | |
| | sectionNumber | string | CNEW | | Document Content | The numeric identifier of a particular section for the document content reference. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------|-----------------------|--------------------------|------------|-------------|--|--|----------------------------------|----------------|
| | | | | | Reference Section Number | | | |
| | sectionTitle | string | CNEW | | Document Content Reference Section Title | An identifying designation for a particular section for the document content reference. | | |
| | appliesTo | StudyDefinitionDocument | | 1 | | A USDM relationship between the DocumentContentReference and StudyDefinitionDocument classes which identifies the study definition document to which the document content reference applies. | | |
| EligibilityCriterion | | | C16112 | | Study Eligibility Criterion | Characteristics which are necessary to allow a subject to participate in a clinical study, as outlined in the study protocol. The concept covers inclusion and exclusion criteria. | | |
| | id | string | | | | | | |
| | name | string | C20748 8 | | Study Eligibility Criterion Name | The literal identifier (i.e., distinctive designation) of the study eligibility criterion. | | |
| | description | string | C20748 6 | | Study Eligibility Criterion Description | A narrative representation of the study eligibility criterion. | | |
| | label | string | C20748 7 | | Study Eligibility Criterion Label | The short descriptive designation for the study eligibility criterion. | | |
| | identifier | string | C20748 9 | | Study Eligibility Criterion Identifier | A sequence of characters used to identify, name, or characterize the inclusion or exclusion criterion. | | |
| | category | Code | C83016 | | Study Eligibility Criterion Category | A classification of the inclusion exclusion criterion. | SDTM Terminology Codelist C66797 | |
| | notes | CommentAnnotation | CNEW | | Eligibility Criterion Notes | A brief written record relevant to the eligibility criterion. | | |
| | criterionItem | EligibilityCriterionItem | | 1 | | A USDM relationship between the EligibilityCriterion and EligibilityCriterionItem classes which identifies the item belonging to the eligibility criterion. | | |
| | next | EligibilityCriterion | | 0..1 | | A USDM relationship within the EligibilityCriterion class which identifies the eligibility criterion that follows the current eligibility criterion in the display order. | | |
| | previous | EligibilityCriterion | | 0..1 | | A USDM relationship within the EligibilityCriterion class which identifies the eligibility criterion that precedes the current eligibility criterion in the display order. | | |
| EligibilityCriterionItem | | | CNEW | | Eligibility Criterion Item | An individual item within the container that holds an instance of an eligibility criterion. | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | CNEW | | Eligibility Criterion Item Name | The literal identifier (i.e., distinctive designation) of the eligibility criterion item. | SyntaxTemplate | |
| | description | string | CNEW | | Eligibility Criterion Item Description | A narrative representation of the eligibility criterion item. | SyntaxTemplate | |
| | label | string | CNEW | | Eligibility Criterion Item Label | The short descriptive designation for the eligibility criterion item. | SyntaxTemplate | |
| | text | string | CNEW | | Eligibility Criterion Item Text | An instance of structured text that represents the eligibility criterion item. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Eligibility Criterion Item Notes | A brief written record relevant to the eligibility criterion item. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the EligibilityCriterionItem and SyntaxTemplateDictionary classes which provides the dictionary entry associated with a eligibility criterion item. | SyntaxTemplate | |
| Encounter | | | CNEW | | Study Encounter | Any physical or virtual contact between two or more parties involved in a study, at which an assessment or activity takes place. | | |
| | id | string | | | | | | |
| | name | string | C17101 0 | | Study Encounter Name | The literal identifier (i.e., distinctive designation) for a protocol-defined study encounter. | | |
| | description | string | C18883 6 | | Study Encounter Description | A narrative representation of the protocol-defined study encounter. | | |
| | label | string | C20749 0 | | Study Encounter Label | The short descriptive designation for the study encounter. | | |
| | type | Code | C18883 9 | | Study Encounter Type | A characterization or classification of the study encounter. | C188728 | |
| | environmentalSettings | Code | C18884 0 | | Environmental Setting | The environment/setting where the event, intervention, or finding occurred. | SDTM Terminology Codelist C12726 | |
| | contactModes | Code | C18884 1 | | Contact Mode | The means by which an interaction occurs between the | SDTM Terminology | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|------------|---------------------|--------------------------|------------|-------------|------------------------------------|---|------------------|----------------|
| | | | | | | subject/participant and person or entity (e.g., a device). | Codelist C171445 | |
| | notes | CommentAnnotation | CNEW | | Encounter Notes | A brief written record relevant to the study encounter. | | |
| | transitionEndRule | TransitionRule | | 0..1 | | A USDM relationship between the Encounter and TransitionRule classes which provides the details associated with a transition rule used to trigger the end of an encounter. | | |
| | next | Encounter | | 0..1 | | A USDM relationship within the Encounter class which identifies the encounter that chronologically follows the current encounter. | | |
| | transitionStartRule | TransitionRule | | 0..1 | | A USDM relationship between the Encounter and TransitionRule classes which provides the details associated with a transition rule used to trigger the start of an encounter. | | |
| | scheduledAt | Timing | | 0..1 | | A USDM relationship between the Encounter and Timing classes which provides information related to the scheduled timing of an encounter. | | |
| | previous | Encounter | | 0..1 | | A USDM relationship within the Encounter class which identifies the encounter that chronologically precedes the current encounter. | | |
| Endpoint | | | C25212 | | Study Endpoint | A defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. NOTE: A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined. [After BEST Resource] (CDISC Glossary) | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | C20749_2 | | Study Endpoint Name | The literal identifier (i.e., distinctive designation) of the study endpoint. | SyntaxTemplate | |
| | description | string | C18882_4 | | Study Endpoint Description | A narrative representation of the study endpoint. | SyntaxTemplate | |
| | label | string | C20749_1 | | Study Endpoint Label | The short descriptive designation for the study endpoint. | SyntaxTemplate | |
| | text | string | C20749_3 | | Study Endpoint Text | An instance of structured text that represents the study endpoint. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Endpoint Notes | A brief written record relevant to the study endpoint. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the Endpoint and SyntaxTemplateDictionary classes which provides the set of dictionary entries related to study endpoints. | SyntaxTemplate | |
| | level | Code | C18882_6 | | Study Endpoint Level | A characterization or classification of the study endpoint that determines its category of importance relative to other study endpoints. | C188726 | |
| | purpose | string | C18882_5 | | Study Endpoint Purpose Description | The textual representation of the study endpoint purpose. | | |
| Estimand | | | C18881_3 | | Estimand | A precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective. It summarises at a population level what the outcomes would be in the same patients under different treatment conditions being compared. (ICH E9 R1 Addendum) | | |
| | id | string | | | | | | |
| | populationSummary | string | C18885_3 | | Population-Level Summary | A synopsis of the clinical endpoint of interest within the analysis target study population. | | |
| | name | string | CNEW | | Estimand Name | The literal identifier (i.e., distinctive designation) of the estimand. | | |
| | description | string | CNEW | | Estimand Description | A narrative representation of the estimand. | | |
| | label | string | CNEW | | Estimand Label | The short descriptive designation for the estimand. | | |
| | notes | CommentAnnotation | CNEW | | Estimand Notes | A brief written record relevant to the study estimand. | | |
| | analysisPopulation | AnalysisPopulation | | 1 | | A USDM relationship between the Estimand and AnalysisPopulation classes which provides the details associated with an instance of the analysis population used to partially define a study estimand. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------|---------------------|--------------------|-------------|-------------|--|---|---|----------------|
| | variableOfInterest | Endpoint | | 1 | | A USDM relationship between the Estimand and Endpoint classes which provides the details associated with an instance of the variable of interest within a study endpoint used to partially define a study estimand. | | |
| | intercurrentEvents | IntercurrentEvent | | 1..* | | A USDM relationship between the Estimand and IntercurrentEvent classes which identifies the set of intercurrent events associated with a study estimand. | | |
| | interventions | StudyIntervention | | 1..* | | A USDM relationship between the Estimand and StudyIntervention classes which identifies the set of study interventions associated with the Estimand. | | |
| ExtensionAttribute | | | | | | | | |
| | id | string | | | | | | |
| | url | string | | | | | | |
| | valueString | string | | | | | | |
| | valueBoolean | Boolean | | | | | | |
| | valueInteger | Integer | | | | | | |
| | valueId | string | | | | | | |
| | valueRange | Range | | | | | | |
| | valueCode | Code | | | | | | |
| | valueQuantity | Quantity | | | | | | |
| | valueAliasCode | AliasCode | | | | | | |
| | extensionAttributes | ExtensionAttribute | | 0..* | | | | |
| | valueExtensionClass | ExtensionClass | | 0..1 | | | | |
| ExtensionClass | | | | | | | | |
| | id | string | | | | | | |
| | url | string | | | | | | |
| | extensionAttributes | ExtensionAttribute | | 1..* | | | | |
| GeographicScope | | | C20759 1 | | Geographic Scope | The extent or range related to the physical location of an entity. | | |
| | id | string | | | | | | |
| | type | Code | C20749 5 | | Geographic Scope Type | A characterization or classification of the geographic scope. | C207412 | |
| | code | AliasCode | C20749 4 | | Geographic Scope Code | A symbol or combination of symbols which is assigned to the geographic scope. | (Point out to external dictionaries; Standard Code is ISO-3166; Alias codes drawn from GENC, UN Region Codes, etc.) | |
| GovernanceDate | | | C20759 5 | | Study Governance Date | Any of the dates associated with event milestones within a clinical study's oversight and management framework. | | |
| | id | string | | | | | | |
| | name | string | C20749 9 | | Study Governance Date Name | The literal identifier (i.e., distinctive designation) of the study governance date. | | |
| | description | string | C20749 7 | | Study Governance Date Description | A narrative representation of the study governance date. | | |
| | label | string | C20749 8 | | Study Governance Date Label | The short descriptive designation for the study governance date. | | |
| | type | Code | C20749 6 | | Study Governance Date Type | A characterization or classification of the study governance date. | C207413 | |
| | dateValue | Date | C20750 0 | | Study Governance Date Value | The information contained in the date field. | | |
| | geographicScopes | GeographicScope | | 1..* | | A USDM relationship between the GovernanceDate and GeographicScope classes which identifies the set of geographic scopes associated with the governance date. | | |
| Identifier | | | C25364 | | Identifier | One or more characters used to identify, name, or characterize the nature, properties, or contents of a thing. | | |
| | id | string | | | | | | |
| | text | string | CNEW | | Identifier Text | An instance of structured text that represents the identifier. | | |
| | scope | Organization | | 1 | | A USDM relationship between the Identifier and Organization classes which provides the details associated with each organization that has assigned the identifier. | | |
| Indication | | | C41184 | | Disease/Condition Indication | The disease or condition the intervention will diagnose, treat, prevent, cure, or mitigate. | | |
| | id | string | | | | | | |
| | name | string | C20750 3 | | Disease/Condition Indication Name | The literal identifier (i.e., distinctive designation) of the disease/condition indication. | | |
| | description | string | C11203 8 | | Disease/Condition Indication Description | A narrative representation of the condition, disease or disorder that the clinical trial is intended to investigate or address. | | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|---------------------------|------------------|--------------------------|------------|-------------|---|---|---|----------------|
| | label | string | C20750_2 | | Disease/Condition Label | The short descriptive designation for the disease/condition indication. | | |
| | isRareDisease | Boolean | C20750_1 | | Disease/Condition Is Rare Disease Indicator | An indication as to whether the disease/condition indication under study is considered a rare disease. | | |
| | codes | Code | C18882_2 | | Disease/Condition Code | A short sequence of characters that represents the disease/condition indication. | (Point out to multiple Biomedical coding dictionaries such as SNOMEDCT (for FDA), MedDRA, NCI, ICD's, etc.) | |
| | notes | CommentAnnotation | CNEW | | Indication Notes | A brief written record relevant to the disease/condition indication. | | |
| Ingredient | | | C51981 | | Ingredient | Any component that constitutes a part of a compounded substance or mixture. | | |
| | id | string | | | | | | |
| | role | Code | CNEW | | Ingredient Role | The intended use of the ingredient within the context of the compounded substance or mixture. | (Point to FHIR value set: Ingredient Role) | |
| | substance | Substance | | 1 | | A USDM relationship between the Ingredient and Substance classes that identifies the substance associated with the ingredient. | | |
| IntercurrentEvent | | | C18881_5 | | Intercurrent Event | An event(s) occurring after treatment initiation that affects either the interpretation or the existence of the measurements associated with the clinical question of interest. (ICH E9 Addendum on Estimands) | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | C18885_5 | | Intercurrent Event Name | The literal identifier (i.e., distinctive designation) of the intercurrent event. | SyntaxTemplate | |
| | description | string | C18885_6 | | Intercurrent Event Description | A narrative representation of the intercurrent event. | SyntaxTemplate | |
| | label | string | C20750_4 | | Intercurrent Event Label | The short descriptive designation for the intercurrent event. | SyntaxTemplate | |
| | text | string | CNEW | | Intercurrent Event Text | An instance of structured text that represents the intercurrent event. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Intercurrent Event Notes | A brief written record relevant to the intercurrent event. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the IntercurrentEvent and SyntaxTemplateDictionary classes which provides the set of dictionary entries related to the intercurrent event. | SyntaxTemplate | |
| | strategy | string | C18885_7 | | Intercurrent Event Strategy | A textual description of the planned strategy to manage and/or mitigate intercurrent events. | | |
| InterventionalStudyDesign | | | CNEW | | Interventional Study Design | The strategy that specifies the structure of an interventional trial in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study. | | |
| | id | string | | | | | StudyDesign | |
| | name | string | CNEW | | Interventional Study Design Name | The literal identifier (i.e., distinctive designation) of the interventional study design. | StudyDesign | |
| | description | string | CNEW | | Interventional Study Design Description | A narrative representation of the interventional study design. | StudyDesign | |
| | label | string | CNEW | | Interventional Study Design Label | The short descriptive designation for the interventional study design. | StudyDesign | |
| | rationale | string | CNEW | | Interventional Study Design Rationale | Reason(s) for choosing the interventional study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design. | StudyDesign | |
| | therapeuticAreas | Code | CNEW | | Interventional Study Design Therapeutic Areas | A categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention, which is associated with the interventional study design. | (Point out to external dictionaries) | StudyDesign |
| | studyType | Code | CNEW | | Interventional Study Design Study Type | The study type associated with the interventional study design. | SDTM Terminology Codelist C99077 | StudyDesign |
| | characteristics | Code | CNEW | | Interventional Study Design Characteristics | The distinguishing qualities or prominent aspects of an interventional study design. | C207416 | StudyDesign |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|------------|-----------------------|--------------------------------|------------|-------------|---|--|----------------------------------|----------------|
| | studyPhase | AliasCode | CNEW | | Interventional Study Design Study Phase | The study phase associated with the interventional study design. | SDTM Terminology Codelist C66737 | StudyDesign |
| | notes | CommentAnnotation | CNEW | | Interventional Study Design Notes | A brief written record relevant to the interventional study design. | | StudyDesign |
| | activities | Activity | | 0..* | | A USDM relationship between the InterventionalStudyDesign and Activity classes which identifies the set of activities associated with the interventional study design. | | StudyDesign |
| | biospecimenRetentions | BiospecimenRetention | | 0..* | | A USDM relationship between the InterventionalStudyDesign and BiospecimenRetention classes which identifies the status of biospecimen retentions related to the interventional study design. | | StudyDesign |
| | encounters | Encounter | | 0..* | | A USDM relationship between the InterventionalStudyDesign and Encounter classes which identifies the set of encounters associated with the interventional study design. | | StudyDesign |
| | estimands | Estimand | | 0..* | | A USDM relationship between the InterventionalStudyDesign and Estimand classes which identifies the set of estimands associated with the interventional study design. | | StudyDesign |
| | indications | Indication | | 0..* | | A USDM relationship between the InterventionalStudyDesign and Indication classes which identifies the set of indications associated with the interventional study design. | | StudyDesign |
| | objectives | Objective | | 0..* | | A USDM relationship between the InterventionalStudyDesign and Objective classes which identifies the set of objectives associated with the interventional study design. | | StudyDesign |
| | scheduleTimelines | ScheduleTimeline | | 0..* | | A USDM relationship between the InterventionalStudyDesign and ScheduleTimeline classes which identifies the set of scheduled timelines associated with the interventional study design. | | StudyDesign |
| | arms | StudyArm | | 1..* | | A USDM relationship between the InterventionalStudyDesign and StudyArm classes which identifies the set of study arms associated with the interventional study design. | | StudyDesign |
| | studyCells | StudyCell | | 1..* | | A USDM relationship between the InterventionalStudyDesign and StudyCell classes which identifies the set of study cells associated with the interventional study design. | | StudyDesign |
| | documentVersions | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship between the InterventionalStudyDesign and StudyDefinitionDocumentVersion classes which identifies the version of the study definition documents associated with the interventional study design. | | StudyDesign |
| | elements | StudyElement | | 0..* | | A USDM relationship between the InterventionalStudyDesign and StudyElement classes which identifies the set of study elements associated with the interventional study design. | | StudyDesign |
| | studyInterventions | StudyIntervention | | 0..* | | A USDM relationship between the InterventionalStudyDesign and StudyIntervention classes which identifies the set of study interventions associated with interventional study design. | | StudyDesign |
| | epochs | StudyEpoch | | 1..* | | A USDM relationship between the InterventionalStudyDesign and StudyEpoch classes which identifies the set of study epochs associated with the interventional study design. | | StudyDesign |
| | population | StudyDesignPopulation | | 1 | | A USDM relationship between the InterventionalStudyDesign and StudyDesignPopulation classes which identifies the population associated with the interventional study design. | | StudyDesign |
| | model | Code | C98746 | | Intervention Model Type | The general design of the strategy for assigning interventions to subjects in a clinical study. (clinicaltrials.gov) | SDTM Terminology Codelist C99076 | |
| | subTypes | Code | C49660 | | Trial Type | The nature of the interventional study for which information is being collected. | SDTM Terminology Codelist C66739 | |
| | blindingSchema | AliasCode | C49658 | | Trial Blinding Schema | The type of experimental design used to describe the level of awareness of the study subjects and/ or study personnel as it relates to the respective | SDTM Terminology Codelist C66735 | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-------------------------|----------------------|-------------------------|------------|-------------|--|--|---|----------------|
| | | | | | | intervention(s) or assessments being observed, received or administered. | | |
| | intentTypes | Code | C49652 | | Trial Intent Type | The planned purpose of the therapy, device, or agent under study in the clinical trial. | SDTM Terminology Codelist C66736 | |
| Masking | | | C191278 | | Masking | The mechanism used to obscure the distinctive characteristics of the study intervention or procedure to make it indistinguishable from a comparator. (CDISC Glossary) | | |
| | id | string | | | | | | |
| | text | string | CNEW | | Masking Text | An instance of unstructured text that represents how the masking is performed and maintained. | | |
| | isMasked | Boolean | CNEW | | Masked Indicator | An indication as to whether the study role is masked. | | |
| MedicalDevice | | | C16830 | | Medical Device | Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for, one or more specific medical purpose(s). ^[6] | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Medical Device Name | The literal identifier (i.e., distinctive designation) of the medical device. | | |
| | description | string | CNEW | | Medical Device Description | A narrative representation of the medical device. | | |
| | label | string | CNEW | | Medical Device Label | The short descriptive designation for the medical device. | | |
| | hardwareVersion | string | CNEW | | Hardware Version | A form or variant of hardware; one of a sequence of copies of the physical components from which a computer is constructed, each incorporating new modifications. | | |
| | softwareVersion | string | C111093 | | Software Version | A form or variant of software; one of a sequence of copies of a software program, each incorporating new modifications. (NCI) | | |
| | sourcing | Code | CNEW | | Medical Device Sourcing | An indication as to whether the medical device is obtained from a local or central source. | CNEW - Product Sourcing Value Set | |
| | notes | CommentAnnotation | CNEW | | Medical Device Notes | A brief written record relevant to the medical device. | | |
| | embeddedProduct | AdministrableProduct | | 0..1 | | A USDM relationship between the MedicalDevice and AdministrableProduct classes which identifies the administrable product that is an integral component of the medical device. | | |
| | identifiers | MedicalDeviceIdentifier | | 0..* | | A USDM relationship between the MedicalDevice and MedicalDeviceIdentifier classes which provides the set of identifiers related to the medical device. | | |
| MedicalDeviceIdentifier | | | CNEW | | Medical Device Identifier | A sequence of characters used to identify, name, or characterize the medical device. | | |
| | id | string | | | | | | Identifier |
| | text | string | CNEW | | Medical Device Identifier Text | An instance of structured text that represents the medical device identifier. | | Identifier |
| | scope | Organization | | 1 | | A USDM relationship between the MedicalDeviceIdentifier and Organization classes which provides the details associated with each organization that has assigned the identifier. | | Identifier |
| | type | Code | CNEW | | Medical Device Identifier Type | A characterization or classification of the medical device identifier. | CNEW - Medical Device Identifier Type Value Set | |
| NarrativeContent | | | C207592 | | Narrative Content | The container that holds an instance of unstructured text and which may include objects such as tables, figures, and images. | | |
| | id | string | | | | | | |
| | name | string | C207507 | | Narrative Content Name | The literal identifier (i.e., distinctive designation) of the narrative content. | | |
| | sectionNumber | string | C207509 | | Narrative Content Section Number | The numeric identifier assigned to a particular document section containing narrative content. | | |
| | sectionTitle | string | C207510 | | Narrative Content Section Title | An identifying designation for the document section containing narrative content. | | |
| | displaySectionTitle | Boolean | CNEW | | Narrative Content Section Title Display Indicator | An indication as to whether the section title is to be displayed in the document containing narrative content. | | |
| | displaySectionNumber | Boolean | CNEW | | Narrative Content Section Number Display Indicator | An indication as to whether the section number is to be displayed in the document containing narrative content. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------|------------------|--------------------------|-------------|-------------|--|--|--------------------------------------|----------------|
| | contentItem | NarrativeContentItem | | 0..1 | | A USDM relationship between the NarrativeContent and NarrativeContentItem classes which identifies the content item associated with the narrative content. | | |
| | previous | NarrativeContent | | 0..1 | | A USDM relationship within the NarrativeContent class which identifies the narrative content that precedes the current narrative content in the display order. | | |
| | next | NarrativeContent | | 0..1 | | A USDM relationship within the NarrativeContent class which identifies the narrative content that follows the current narrative content in the display order. | | |
| | children | NarrativeContent | | 0..* | | A USDM relationship within the NarrativeContent class which identifies the set of child content associated with an instance of narrative content. | | |
| NarrativeContentItem | | | CNEW | | Narrative Content Item | An individual item within the container that holds an instance of unstructured text and which may include objects such as tables, figures, and images. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Narrative Content Item Name | The literal identifier (i.e., distinctive designation) of the narrative content item. | | |
| | text | string | CNEW | | Narrative Content Item Text | An instance of unstructured text that represents the narrative content item. | | |
| Objective | | | C14245 0 | | Study Objective | The reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study. | | |
| | id | string | | | | | SyntaxTemplate | |
| | name | string | C20751 2 | | Study Objective Name | The literal identifier (i.e., distinctive designation) of the study objective. | SyntaxTemplate | |
| | description | string | C94090 | | Study Objective Description | A narrative representation of the study objective. (BRIDG) | SyntaxTemplate | |
| | label | string | C20751 1 | | Study Objective Label | The short descriptive designation for the study objective. | SyntaxTemplate | |
| | text | string | C20751 3 | | Study Objective Text | An instance of structured text that represents the study objective. | SyntaxTemplate | |
| | notes | CommentAnnotation | CNEW | | Objective Notes | A brief written record relevant to the study objective. | SyntaxTemplate | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the Objective and SyntaxTemplateDictionary classes which provides the set of dictionary entries related to study objectives. | SyntaxTemplate | |
| | level | Code | C18882 3 | | Study Objective Level | A characterization or classification of the study objective that determines its category of importance relative to other study objectives. | C188725 | |
| | endpoints | Endpoint | | 0..* | | A USDM relationship between the Objective and Endpoint classes which identifies the set of endpoints associated with the study objective. | | |
| ObservationalStudyDesign | | | CNEW | | Observational Study Design | The strategy that specifies the structure of an observational study in terms of the planned activities (including timing) and statistical analysis approach intended to meet the objectives of the study. | | |
| | id | string | | | | | StudyDesign | |
| | name | string | CNEW | | Observational Study Design Name | The literal identifier (i.e., distinctive designation) of the observational study design. | StudyDesign | |
| | description | string | CNEW | | Observational Study Design Description | A narrative representation of the observational study design. | StudyDesign | |
| | label | string | CNEW | | Observational Study Design Label | The short descriptive designation for the observational study design. | StudyDesign | |
| | rationale | string | CNEW | | Observational Study Design Rationale | Reason(s) for choosing the observational study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design. | StudyDesign | |
| | therapeuticAreas | Code | CNEW | | Observational Study Design Therapeutic Areas | A categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention, which is associated with the observational study design. | (Point out to external dictionaries) | StudyDesign |
| | studyType | Code | CNEW | | Observational Study Design Study Type | The study type associated with the observational study design. | SDTM Terminology Codelist C99077 | StudyDesign |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|------------|-----------------------|--------------------------------|------------|-------------|--|--|--|----------------|
| | characteristics | Code | CNEW | | Observational Study Design Characteristics | The distinguishing qualities or prominent features of an observational study design. | C207416 | StudyDesign |
| | studyPhase | AliasCode | CNEW | | Observational Study Design Study Phase | The study phase associated with the observational study design. | SDTM Terminology Codelist C66737 | StudyDesign |
| | notes | CommentAnnotation | CNEW | | Observational Study Design Notes | A brief written record relevant to the observational study design. | | StudyDesign |
| | activities | Activity | | 0..* | | A USDM relationship between the ObservationalStudyDesign and Activity classes which identifies the set of activities associated with the observational study design. | | StudyDesign |
| | biospecimenRetentions | BiospecimenRetention | | 0..* | | A USDM relationship between the ObservationalStudyDesign and BiospecimenRetention classes which identifies the status of biospecimen retentions related to the observational study design. | | StudyDesign |
| | encounters | Encounter | | 0..* | | A USDM relationship between the ObservationalStudyDesign and Encounter classes which identifies the set of encounters associated with the observational study design. | | StudyDesign |
| | estimands | Estimand | | 0..* | | A USDM relationship between the ObservationalStudyDesign and Estimand classes which identifies the set of estimands associated with the observational study design. | | StudyDesign |
| | indications | Indication | | 0..* | | A USDM relationship between the ObservationalStudyDesign and Indication classes which identifies the set of indications associated with the observational study design. | | StudyDesign |
| | objectives | Objective | | 0..* | | A USDM relationship between the ObservationalStudyDesign and Objective classes which identifies the set of objectives associated with the observational study design. | | StudyDesign |
| | scheduleTimelines | ScheduleTimeline | | 0..* | | A USDM relationship between the ObservationalStudyDesign and ScheduleTimeline classes which identifies the set of scheduled timelines associated with the observational study design. | | StudyDesign |
| | arms | StudyArm | | 1..* | | A USDM relationship between the ObservationalStudyDesign and StudyArm classes which identifies the set of study arms associated with the observational study design. | | StudyDesign |
| | studyCells | StudyCell | | 1..* | | A USDM relationship between the ObservationalStudyDesign and StudyCell classes which identifies the set of study cells associated with the observational study design. | | StudyDesign |
| | documentVersions | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship between the ObservationalStudyDesign and StudyDefinitionDocumentVersion classes which identifies the version of the study definition documents associated with the observational study design. | | StudyDesign |
| | elements | StudyElement | | 0..* | | A USDM relationship between the ObservationalStudyDesign and StudyElement classes which identifies the set of study elements associated with the observational study design. | | StudyDesign |
| | studyInterventions | StudyIntervention | | 0..* | | A USDM relationship between the ObservationalStudyDesign and StudyIntervention classes which identifies the set of study interventions associated with observational study design. | | StudyDesign |
| | epochs | StudyEpoch | | 1..* | | A USDM relationship between the ObservationalStudyDesign and StudyEpoch classes which identifies the set of study epochs associated with the observational study design. | | StudyDesign |
| | population | StudyDesignPopulation | | 1 | | A USDM relationship between the ObservationalStudyDesign and StudyDesignPopulation classes which identifies the population associated with the observational study design. | | StudyDesign |
| | model | Code | C147138 | | Observation Study Design Model Type | The general design of the strategy for identifying and following up with participants during observational studies. (clinicaltrials.gov) | SDTM Terminology Codelist C127259 | |
| | subTypes | Code | CNEW | | Observational Study Type | The nature of the observational study for which information is being collected. | CNEW - Observational Study Type Response | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|----------------------|---------------------------------|----------------------|------------|-------------|---|---|-----------------------------------|----------------|
| | timePerspective | Code | C126065 | | Observational Time Perspective | The temporal relationship between the observation period and time of subject enrollment. (ClinicalTrials.gov) | SDTM Terminology Codelist C127261 | |
| | samplingMethod | Code | C126067 | | Observational Study Sampling Method | The sampling method used to assign study participants into groups or cohorts within an observational study. | SDTM Terminology Codelist C127260 | |
| Organization | | | C19711 | | Organization | A formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose. (BRIDG) | | |
| | id | string | | | | | | |
| | name | string | C93874 | | Organization Name | The literal identifier (i.e., distinctive designation) of the organization. | | |
| | label | string | C207514 | | Organization Label | The short descriptive designation for the organization. | | |
| | identifier | string | C93401 | | Organization Identifier | A unique symbol that establishes identity of the organization. (BRIDG) | | |
| | identifierScheme | string | C188819 | | Identifier Provider Organization Name | The name of the organization that provides the identifier for the entity. | | |
| | type | Code | C188820 | | Organization Type | A characterization or classification of the formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose. | C188724 | |
| | legalAddress | Address | | 0..1 | | A USDM relationship between the Organization and Address classes which provides the legal address for an organization. | | |
| | managedSites | StudySite | | 0..* | | A USDM relationship between the Organization and StudySite classes which identifies the set of study sites managed by the organization. | | |
| ParameterMap | | | C207456 | | Parameter Map | The paired name and value for a given parameter. | | |
| | id | string | | | | | | |
| | tag | string | C207515 | | Programming Tag | Character strings bounded by angle brackets that act as containers for programming language elements. | | |
| | reference | string | C207516 | | Programming Tag Reference | The reference for a tag used in programming languages, such as a markup language (e.g., HTML, XML), to store attributes and elements. | | |
| PopulationDefinition | | | C207593 | | Population Definition | A concise explanation of the meaning of a population. | | |
| | id | string | | | | | | |
| | name | string | C207520 | | Population Definition Name | The literal identifier (i.e., distinctive designation) of the population definition. | | |
| | description | string | C207517 | | Population Definition Description | A narrative representation of the population definition. | | |
| | label | string | C207519 | | Population Definition Label | The short descriptive designation for the population definition. | | |
| | plannedSex | Code | C207523 | | Population Definition Planned Sex | The protocol-defined sex within the population definition. | SDTM Terminology Codelist C66732 | |
| | includesHealthySubjects | Boolean | C207518 | | Population Definition Includes Healthy Subjects Indicator | An indication as to whether the population definition includes healthy subjects, that is, subjects without the disease or condition under study. | | |
| | plannedAge | Range | C207701 | | Population Definition Planned Age | The anticipated age of subjects within the population definition. | | |
| | plannedCompletionNumberRange | Range | CNEW | | Population Definition Planned Completion Number Range | The range of values representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the population definition. | | |
| | plannedCompletionNumberQuantity | Quantity | CNEW | | Population Definition Planned Completion Number Quantity | The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the population definition. | | |
| | plannedEnrollmentNumberRange | Range | CNEW | | Population Definition Planned Enrollment Number Range | The range of values representing the planned number of subjects to be entered in a clinical trial, within the population definition. | | |
| | plannedEnrollmentNumberQuantity | Quantity | CNEW | | Population Definition Planned Enrollment Number Quantity | The value representing the planned number of subjects to be entered in a clinical trial, within the population definition. | | |
| | notes | CommentAnnotation | CNEW | | Population Definition Notes | A brief written record relevant to the population definition. | | |
| | criteria | EligibilityCriterion | | 0..* | | A USDM relationship between the PopulationDefinition and EligibilityCriterion classes | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-------------------------|-------------------|-------------------------------------|-------------|-------------|---------------------------------------|--|--|----------------|
| Procedure | | | C98769 | | Procedure | which identifies the set of eligibility criteria associated with the population definition. | | |
| | id | string | | | | | | |
| | name | string | C20132 5 | | Procedure Name | The literal identifier (i.e., distinctive designation) of the procedure. | | |
| | description | string | C20132 4 | | Procedure Description | A narrative representation of the procedure. | | |
| | label | string | C20752 4 | | Procedure Label | The short descriptive designation for the procedure. | | |
| | procedureType | string | C18884 8 | | Procedure Type | A characterization or classification of the study procedure. | | |
| | code | Code | C15462 6 | | Procedure Code | A symbol or combination of symbols which is assigned to medical procedure. | (Point out to external dictionary like CPT, MedDRA, SNOMEDCT , etc.) | |
| | notes | CommentAnnotation | CNEW | | Procedure Notes | A brief written record relevant to the procedure. | | |
| | studyIntervention | StudyIntervention | | 0..1 | | A USDM relationship between the Procedure and StudyIntervention classes which provides the details associated with an instance of an intervention performed during the conduct of a procedure. | | |
| ProductOrganizationRole | | | CNEW | | Product Organization Role | A designation that identifies the function of an organization within the context of the product. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Product Organization Role Name | The literal identifier (i.e., distinctive designation) of the product organization role. | | |
| | description | string | CNEW | | Product Organization Role Description | A narrative representation of the product organization role. | | |
| | label | string | CNEW | | Product Organization Role Label | The short descriptive designation for the product organization role. | | |
| | code | Code | CNEW | | Product Organization Role Code | A symbol or combination of symbols which is assigned to the product organization role. | - CNEW Product Organization Role Code Value Set | |
| | appliesTo | AdministrableProduct, MedicalDevice | | 0..* | | A USDM relationship between the ProductOrganizationRole and either the AdministrableProduct or MedicalDevice class that identifies the administrable product or medical device to which product organization role applies. | | |
| | organization | Organization | | 1 | | A USDM relationship between the ProductOrganizationRole and Organization classes which identifies the organization associated with the product organization role. | | |
| Quantity | | | C25256 | | Quantity | How much there is of something that can be measured; the total amount or number. | | |
| | id | string | | | | | | |
| | value | Float | C25712 | | Quantity Value | A numerical quantity measured or assigned or computed. | | |
| | unit | AliasCode | C44258 | | Quantity Unit | The type of unit of measure being used to express a quantity. | SDTM Terminology Codelist C71620 | |
| Range | | | C38013 | | Range | The difference between the lowest and highest numerical values; the limits or scale of variation. | | |
| | id | string | | | | | | |
| | minValue | Quantity | C25570 | | Minimum Value | The smallest value in quantity or degree in a set of values. | | |
| | maxValue | Quantity | C25564 | | Maximum Value | The largest value in quantity or degree in a set of values. | | |
| | isApproximate | Boolean | C20752 5 | | Value Range is Approximate Indicator | An indication as to whether the value range is almost, but not quite, exact. | | |
| ReferenceIdentifier | | | CNEW | | Reference Identifier | A sequence of characters used to identify, name, or characterize the reference. | | |
| | id | string | | | | | Identifier | |
| | text | string | CNEW | | Reference Identifier Text | An instance of structured text that represents the reference identifier. | Identifier | |
| | scope | Organization | | 1 | | A USDM relationship between the ReferenceIdentifier and Organization classes which provides the details associated with each organization that has assigned the reference identifier. | Identifier | |
| | type | Code | CNEW | | Reference Identifier Type | A characterization or classification of the reference identifier. | CNEW Reference | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|---------------------------|------------------|----------------------|-------------|-------------|---|---|--------------|-------------------|
| ResponseCode | | | C20134 7 | | Response Code | A symbol or combination of symbols representing the response to the question. | | Identifier Type |
| | id | string | | | | | | |
| | isEnabled | Boolean | C20133 0 | | Response Code Enabled Indicator | An indication as to whether the response code is activated for use within a given usage context. | | |
| | code | Code | C25162 | | Code | A symbol or combination of symbols which is assigned to the members of a collection. | | |
| ScheduleTimeline | | | C20134 8 | | Schedule Timeline | A chronological schedule of planned temporal events. | | |
| | id | string | | | | | | |
| | name | string | C20133 4 | | Schedule Timeline Name | The literal identifier (i.e., distinctive designation) of the schedule timeline. | | |
| | description | string | C20133 2 | | Schedule Timeline Description | A narrative representation of the schedule timeline. | | |
| | label | string | C20753 0 | | Schedule Timeline Label | The short descriptive designation for the schedule timeline. | | |
| | entryCondition | string | C20133 3 | | Schedule Timeline Entry Condition | A logical evaluation on which rests the validity of entry into a schedule timeline. | | |
| | mainTimeline | Boolean | C20133 1 | | Main Timeline Indicator | An indication as to whether the timeline or timeline component is part of the central or principal timeline. | | |
| | instances | ScheduledInstance | | 0..* | | A USDM relationship between the ScheduleTimeline and ScheduledInstance classes which identifies the set of scheduled instances (e.g., scheduled activity instances or scheduled decision instances) associated with the scheduled timeline. | | |
| | entry | ScheduledInstance | | 1 | | A USDM relationship between the ScheduleTimeline and ScheduledInstance classes which defines the entry into a scheduled instance (e.g., scheduled activity instances or scheduled decision instances) for a timeline. | | |
| | exits | ScheduleTimelineExit | | 0..* | | A USDM relationship between the ScheduleTimeline and ScheduleTimelineExit classes which identifies the set of exits from the scheduled timeline. | | |
| | timings | Timing | | 0..* | | A USDM relationship between the ScheduleTimeline and Timing classes which identifies the set of timings associated with the scheduled timeline. | | |
| ScheduleTimelineExit | | | C20134 9 | | Schedule Timeline Exit | To go out of or leave the schedule timeline. | | |
| | id | string | | | | | | |
| ScheduledActivityInstance | | | C20135 0 | | Scheduled Activity Instance | A scheduled occurrence of an activity event. | | |
| | id | string | | | | | | ScheduledInstance |
| | name | string | C20753 3 | | Scheduled Activity Instance Name | The literal identifier (i.e., distinctive designation) of the scheduled activity instance. | | ScheduledInstance |
| | description | string | C20753 1 | | Scheduled Activity Instance Description | A narrative representation of the scheduled activity instance. | | ScheduledInstance |
| | label | string | C20753 2 | | Scheduled Activity Instance Label | The short descriptive designation for the scheduled activity instance. | | ScheduledInstance |
| | defaultCondition | ScheduledInstance | | 0..1 | | A USDM relationship within the ScheduledActivityInstance class which identifies the default condition within a scheduled activity instance. | | ScheduledInstance |
| | epoch | StudyEpoch | | 0..1 | | A USDM relationship between the ScheduledActivityInstance and StudyEpoch classes which identifies the study epoch associated with a scheduled activity instance. | | ScheduledInstance |
| | activities | Activity | | 0..* | | A USDM relationship between the ScheduledActivityInstance and Activity classes which identifies the set of activities associated with a scheduled activity instance. | | |
| | encounter | Encounter | | 0..1 | | A USDM relationship between the ScheduledActivityInstance and Encounter classes which defines the subject encounter associated with the ScheduleActivityInstance. | | |
| | timeline | ScheduleTimeline | | 0..1 | | A USDM relationship between the ScheduledActivityInstance and ScheduleTimeline classes which provides the details associated with an instance of a scheduled timeline related to a scheduled activity instance. | | |
| | timelineExit | ScheduleTimelineExit | | 0..1 | | A USDM relationship between the ScheduledActivityInstance and ScheduleTimelineExit classes which provides the details associated with the exit | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|---------------------------|----------------------|-------------------------|------------|-------------|---|---|--------------|-------------------|
| ScheduledDecisionInstance | | | C20135_1 | | Scheduled Decision Instance | from a timeline related to a scheduled activity instance. | | |
| | id | string | | | | | | ScheduledInstance |
| | name | string | C20753_6 | | Scheduled Decision Instance Name | The literal identifier (i.e., distinctive designation) of the scheduled Decision instance. | | ScheduledInstance |
| | description | string | C20753_4 | | Scheduled Decision Instance Description | A narrative representation of the scheduled Decision instance. | | ScheduledInstance |
| | label | string | C20753_5 | | Scheduled Decision Instance Label | The short descriptive designation for the scheduled Decision instance. | | ScheduledInstance |
| | defaultCondition | ScheduledInstance | | 0..1 | | A USDM relationship within the ScheduledDecisionInstance class which identifies the default condition within a scheduled decision instance. | | ScheduledInstance |
| | epoch | StudyEpoch | | 0..1 | | A USDM relationship between the ScheduledDecisionInstance and StudyEpoch classes which identifies the study epoch associated with a scheduled decision instance. | | ScheduledInstance |
| | conditionAssignments | ConditionAssignment | | 1..* | | A USDM relationship between the ScheduledDecisionInstance and ConditionAssignment classes which identifies the set of condition assignments associated with a scheduled decision instance. | | |
| ScheduledInstance | | | C20129_9 | | Scheduled Instance | A scheduled occurrence of a temporal event. | | |
| | id | string | | | | | | |
| | name | string | C20745_5 | | Scheduled Instance Name | The literal identifier (i.e., distinctive designation) of the scheduled instance. | | |
| | description | string | C20745_3 | | Scheduled Instance Description | A narrative representation of the scheduled instance. | | |
| | label | string | C20745_4 | | Scheduled Instance Label | The short descriptive designation for the scheduled instance. | | |
| | defaultCondition | ScheduledInstance | | 0..1 | | A USDM relationship within the ScheduledInstance class which identifies the default condition within a scheduled instance. | | |
| | epoch | StudyEpoch | | 0..1 | | A USDM relationship between the ScheduledInstance and StudyEpoch classes which identifies the study epoch associated with a scheduled instance. | | |
| Strength | | | CNEW | | Substance Strength | The content of an substance expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dose form of the product. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Substance Strength Name | The literal identifier (i.e., distinctive designation) of the substance strength. | | |
| | description | string | CNEW | | Substance Strength Description | A narrative representation of the substance strength. | | |
| | label | string | CNEW | | Substance Strength Label | The short descriptive designation for the substance strength. | | |
| | numeratorRange | Range | CNEW | | Substance Strength Numerator Range | The lowest and highest numerical values that define a range for the substance strength. | | |
| | numeratorQuantity | Quantity | CNEW | | Substance Strength Numerator Quantity | The value representing the numerator for the substance strength. | | |
| | denominator | Quantity | C80489 | | Denominator | The divisor of a fraction. | | |
| Study | | | C15206 | | Clinical Study | A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. (CDISC Glossary) | | |
| | id | string | | | | | | |
| | name | string | C68631 | | Clinical Study Name | The literal identifier (i.e., distinctive designation) of the clinical study. | | |
| | description | string | C14270_4 | | Clinical Study Description | A narrative representation of the clinical study. | | |
| | label | string | C20747_9 | | Clinical Study Label | The short descriptive designation for the clinical study. | | |
| | versions | StudyVersion | | 0..* | | A USDM relationship between the Study and StudyVersion classes which identifies the set of versions associated with the study. | | |
| | documentedBy | StudyDefinitionDocument | | 0..* | | A USDM relationship between the Study and StudyDefinitionDocument | | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|----------------------|------------------|----------------------|-------------|-------------|--|--|---|----------------|
| | | | | | | classes signifying that the study is documented in a study definition document. | | |
| StudyAmendment | | | C20759 4 | | Study Amendment | A written description of a change(s) to, or formal clarification of, a study. | | |
| | id | string | | | | | | |
| | number | string | C20753 7 | | Study Amendment Number | A string of numerals that uniquely identifies a protocol amendment. | | |
| | notes | CommentAnnotation | CNEW | | Study Amendment Notes | A brief written record relevant to the study amendment. | | |
| | summary | string | C11562 7 | | Study Amendment Summary | A short narrative representation describing the changes introduced in the current version of the protocol. | | |
| | geographicScopes | GeographicScope | | 1..* | | A USDM relationship between the StudyAmendment and GeographicScope classes which identifies the set of geographic scopes associated with the study amendment. | | |
| | dateValues | GovernanceDate | | 0..* | | A USDM relationship between the StudyAmendment and GovernanceDate classes which provides the set of governance dates associated with the study amendment. | | |
| | impacts | StudyAmendmentImpact | | 0..* | | A USDM relationship between the StudyAmendment and StudyAmendmentImpact classes which identifies the set of impacts that the study amendment has on the study or study subjects. | | |
| | enrollments | SubjectEnrollment | | 0..* | | A USDM relationship between the StudyAmendment and SubjectEnrollment classes which provides the set of subject enrollments associated with the study amendment. | | |
| | secondaryReasons | StudyAmendmentReason | | 0..* | | A USDM relationship between the StudyAmendment and StudyAmendmentReason classes which identifies the set of secondary reasons for issuing the study amendment. | | |
| | changes | StudyChange | | 1..* | | A USDM relationship between the StudyAmendment and StudyChange classes which identifies the set of changes associated with the study amendment. | | |
| | previous | StudyAmendment | | 0..1 | | A USDM relationship within the StudyAmendment class which identifies the study amendment that chronologically precedes the current study amendment. | | |
| | primaryReason | StudyAmendmentReason | | 1 | | A USDM relationship between the StudyAmendment and StudyAmendmentReason classes which identifies the primary reason for issuing the study amendment. | | |
| StudyAmendmentImpact | | | CNEW | | Study Amendment Impact | The effect or consequence of an amendment on some aspect of the study. | | |
| | id | string | | | | | | |
| | text | string | CNEW | | Study Amendment Impact Text | An instance of unstructured text that represents the study amendment impact. | | |
| | isSubstantial | Boolean | C20753 8 | | Study Amendment Impact Substantial Indicator | An indication as to whether the study amendment's impact on the study is substantial. | | |
| | type | Code | CNEW | | Study Amendment Impact Type | A characterization or classification of the study amendment impact. | CNEW Study Amendment Impact Type Response | |
| | notes | CommentAnnotation | CNEW | | Study Amendment Impact Notes | A brief written record relevant to the study amendment impact. | | |
| StudyAmendmentReason | | | C20745 7 | | Study Amendment Reason | The rationale for the change(s) to, or formal clarification of, a protocol. | | |
| | id | string | | | | | | |
| | otherReason | string | C20753 9 | | Other Reason for Study Amendment | The rationale for the change(s) to, or formal clarification of, a protocol that is not otherwise specified. | | |
| | code | Code | C20754 0 | | Study Amendment Reason Code | A symbol or combination of symbols which is assigned to the study amendment reason. | C207415 | |
| StudyArm | | | C17444 7 | | Study Arm | A planned pathway assigned to the subject as they progress through the study, usually referred to by a name that reflects one or more treatments, exposures, and/or controls included in the path. | | |
| | id | string | | | | | | |
| | name | string | C17098 4 | | Study Arm Name | The literal identifier (i.e., distinctive designation) of the study arm. | | |
| | description | string | C93728 | | Study Arm Description | A narrative representation of the study arm. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-------------|---------------------------------|--------------------------|------------|-------------|--|---|---------------------------------------|----------------------|
| | label | string | C17245_6 | | Study Arm Label | The short descriptive designation for the study arm. | | |
| | type | Code | C18882_7 | | Study Arm Type | A characterization or classification of the study arm. | Protocol Terminology Codelist C174222 | |
| | dataOriginType | Code | C18882_9 | | Study Arm Data Origin Type | A characterization or classification of the study arm with respect to where the study arm data originates. | C188727 | |
| | dataOriginDescription | string | C18882_8 | | Study Arm Data Origin Description | The textual representation of the study arm data origin. | | |
| | notes | CommentAnnotation | CNEW | | Study Arm Notes | A brief written record relevant to the study arm. | | |
| | populations | PopulationDefinition | | 0..* | | A USDM relationship between the StudyArm and PopulationDefinition classes which identifies the set of populations associated with the study arm. | | |
| StudyCell | | | C18881_0 | | Study Design Cell | A partitioning of a study arm into individual pieces, which are associated with an epoch and any number of sequential elements within that epoch. | | |
| | id | string | | | | | | |
| | arm | StudyArm | | 1 | | A USDM relationship between the StudyCell and StudyArm classes which identifies the study arm associated with a study cell. | | |
| | epoch | StudyEpoch | | 1 | | A USDM relationship between the StudyCell and StudyEpoch classes which identifies the study epoch associated with a study cell. | | |
| | elements | StudyElement | | 1..* | | A USDM relationship between the StudyCell and StudyElement classes which identifies the set of study elements associated with the study cell. | | |
| StudyChange | | | CNEW | | Study Change | The act of alteration or modification to a study. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Study Change Name | The literal identifier (i.e., distinctive designation) of the study change. | | |
| | description | string | CNEW | | Study Change Description | A narrative representation of the study change. | | |
| | label | string | CNEW | | Study Change Label | The short descriptive designation for the study change. | | |
| | rationale | string | CNEW | | Study Change Rationale | An explanation as to the logical reasons for why a study change has occurred. | | |
| | summary | string | CNEW | | Study Change Summary | A short narrative representation describing the changes introduced in the current version of the study. | | |
| | changedSections | DocumentContentReference | | 1..* | | A USDM relationship between the StudyChange and DocumentContentReference class which provides the set of changed document sections related to the study change. | | |
| StudyCohort | | | C61512 | | Study Cohort | A group of individuals who share a set of characteristics (e.g., exposures, experiences, attributes), which logically defines a population under study. | | |
| | id | string | | | | | PopulationDefinition | |
| | name | string | C20754_4 | | Study Cohort Name | The literal identifier (i.e., distinctive designation) of the study cohort. | PopulationDefinition | |
| | description | string | C20754_2 | | Study Cohort Description | A narrative representation of the study cohort. | PopulationDefinition | |
| | label | string | C20754_3 | | Study Cohort Label | The short descriptive designation for the study cohort. | PopulationDefinition | |
| | plannedSex | Code | C20754_1 | | Study Cohort Planned Sex | The protocol-defined sex within the study cohort. | SDTM Terminology Codelist C66732 | PopulationDefinition |
| | includesHealthySubjects | Boolean | C20748_0 | | Study Cohort Includes Healthy Subjects Indicator | An indication as to whether the study cohort includes healthy subjects, that is, subjects without the disease or condition under study. | | PopulationDefinition |
| | plannedAge | Range | C20754_5 | | Study Cohort Planned Age | The anticipated age of subjects within the study cohort. | | PopulationDefinition |
| | plannedCompletionNumberRange | Range | CNEW | | Study Cohort Planned Completion Number Range | The range of values representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study cohort. | | PopulationDefinition |
| | plannedCompletionNumberQuantity | Quantity | CNEW | | Study Cohort Planned Completion Number Quantity | The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study cohort. | | PopulationDefinition |
| | plannedEnrollmentNumberRange | Range | CNEW | | Study Cohort Planned Enrollment Number Range | The range of values representing the planned number of subjects to be entered in a clinical trial, within the study cohort. | | PopulationDefinition |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------------|---------------------------------|--------------------------------|------------|-------------|---|---|--|----------------------|
| | plannedEnrollmentNumberQuantity | Quantity | CNEW | | Study Cohort Planned Enrollment Number Quantity | The value representing the planned number of subjects to be entered in a clinical trial, within the study cohort. | | PopulationDefinition |
| | notes | CommentAnnotation | CNEW | | Study Cohort Notes | A brief written record relevant to the study cohort. | | PopulationDefinition |
| | criteria | EligibilityCriterion | | 0..* | | A USDM relationship between the StudyCohort and EligibilityCriterion classes which identifies the set of eligibility criteria associated with the study cohort. | | PopulationDefinition |
| | characteristics | Characteristic | | 0..* | | A USDM relationship between the StudyCohort and Characteristic classes which identifies the set of subject characteristics associated with the study cohort. | | |
| | indications | Indication | | 0..* | | A USDM relationship between the StudyCohort and Indication classes which identifies the set of indications associated with the study cohort. | | |
| StudyDefinitionDocument | | | CNEW | | Study Definition Document | Any physical or electronic document that is related to defining a study or part of a study. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Study Definition Document Name | The literal identifier (i.e., distinctive designation) of the study definition document. | | |
| | description | string | CNEW | | Study Definition Document Description | A narrative representation of the study definition document. | | |
| | label | string | CNEW | | Study Definition Document Label | The short descriptive designation for the study definition document. | | |
| | type | Code | CNEW | | Study Definition Document Type | A characterization or classification of the study definition document. | CNEW Study Definition Document Type | |
| | templateName | string | CNEW | | Study Definition Document Template Name | The literal identifier (i.e., distinctive designation) of the study definition document template. | | |
| | language | Code | CNEW | | Study Definition Document Language | The language in which the study definition document is written. | (Point out to ISO 639 language value list) | |
| | notes | CommentAnnotation | CNEW | | Study Definition Document Notes | A brief written record relevant to the study definition document. | | |
| | versions | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship between the StudyDefinitionDocument and StudyDefinitionDocumentVersion classes which identifies the set of versions associated with the study definition document. | | |
| StudyDefinitionDocumentVersion | | | CNEW | | Study Definition Document Version | A representation of a particular edition or snapshot of the study definition document as it exists at a particular point in time. | | |
| | id | string | | | | | | |
| | status | Code | CNEW | | Study Definition Document Status | A condition of the study definition document at a point in time with respect to its state of readiness for implementation. | C188723 | |
| | version | string | CNEW | | Study Definition Document Version | A representation of a particular edition or snapshot of the study definition document as it exists at a particular point in time. | | |
| | notes | CommentAnnotation | CNEW | | Study Definition Document Version Notes | A brief written record relevant to the study definition document version. | | |
| | dateValues | GovernanceDate | | 0..* | | A USDM relationship between the StudyDefinitionDocumentVersion and GovernanceDate classes which provides the set of governance dates associated with the study definition document version. | | |
| | contents | NarrativeContent | | 0..* | | A USDM relationship between the StudyDefinitionDocumentVersion and NarrativeContent classes which identifies the set of narrative content associated with the version of the study definition document. | | |
| | children | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship within the StudyDefinitionDocumentVersion class which identifies the set of child documents of a study definition document version. | | |
| StudyDesign | | | C15320 | | Study Design | A plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach. | | |
| | id | string | | | | | | |
| | name | string | C201338 | | Study Design Name | The literal identifier (i.e., distinctive designation) of the study design. | | |
| | description | string | C147139 | | Study Design Description | A narrative representation of the study design. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|------------|-----------------------|--------------------------------|------------|-------------|-----------------------------|--|--------------------------------------|----------------|
| | label | string | C20754_8 | | Study Design Label | The short descriptive designation for the study design. | | |
| | rationale | string | C14270_5 | | Study Design Rationale | Reason(s) for choosing the study design. This may include reasons for the choice of control or comparator, as well as the scientific rationale for the study design. | | |
| | therapeuticAreas | Code | C10130_2 | | Therapeutic Areas | A categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention. | (Point out to external dictionaries) | |
| | studyType | Code | C14217_5 | | Study Type | The nature of the investigation for which study information is being collected. (After clinicaltrials.gov) | SDTM Terminology Codelist C99077 | |
| | characteristics | Code | C20754_7 | | Study Design Characteristic | The distinguishing qualities or prominent aspect of a study design. | C207416 | |
| | studyPhase | AliasCode | C48281 | | Trial Phase | A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998] | SDTM Terminology Codelist C66737 | |
| | notes | CommentAnnotation | CNEW | | Study Design Notes | A brief written record relevant to the study design. | | |
| | activities | Activity | | 0..* | | A USDM relationship between the StudyDesign and Activity classes which identifies the set of activities associated with the study design. | | |
| | biospecimenRetentions | BiospecimenRetention | | 0..* | | A USDM relationship between the StudyDesign and BiospecimenRetention classes which identifies the status of biospecimen retentions related to the study design. | | |
| | encounters | Encounter | | 0..* | | A USDM relationship between the StudyDesign and Encounter classes which identifies the set of encounters associated with the study design. | | |
| | estimands | Estimand | | 0..* | | A USDM relationship between the StudyDesign and Estimand classes which identifies the set of estimands associated with the study design. | | |
| | indications | Indication | | 0..* | | A USDM relationship between the StudyDesign and Indication classes which identifies the set of indications associated with the study design. | | |
| | objectives | Objective | | 0..* | | A USDM relationship between the StudyDesign and Objective classes which identifies the set of objectives associated with the study design. | | |
| | scheduleTimelines | ScheduleTimeline | | 0..* | | A USDM relationship between the StudyDesign and ScheduleTimeline classes which identifies the set of scheduled timelines associated with the study design. | | |
| | arms | StudyArm | | 1..* | | A USDM relationship between the StudyDesign and StudyArm classes which identifies the set of study arms associated with the study design. | | |
| | studyCells | StudyCell | | 1..* | | A USDM relationship between the StudyDesign and StudyCell classes which identifies the set of study cells associated with the study design. | | |
| | documentVersions | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship between the StudyDesign and StudyDefinitionDocumentVersion classes which identifies the version of the study definition documents associated with the study design. | | |
| | elements | StudyElement | | 0..* | | A USDM relationship between the StudyDesign and StudyElement classes which identifies the set of study elements associated with the study design. | | |
| | studyInterventions | StudyIntervention | | 0..* | | A USDM relationship between the StudyDesign and StudyIntervention classes which identifies the set of study | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-----------------------|---------------------------------|-----------------------|------------|-------------|---|---|----------------------------------|----------------------|
| | | | | | | interventions associated with study design. | | |
| | epochs | StudyEpoch | | 1..* | | A USDM relationship between the StudyDesign and StudyEpoch classes which identifies the set of study epochs associated with the study design. | | |
| | population | StudyDesignPopulation | | 1 | | A USDM relationship between the StudyDesign and StudyDesignPopulation classes which identifies the population associated with the study design. | | |
| StudyDesignPopulation | | | C14272-8 | | Study Design Population | The population within the general population to which the study results can be generalized. | | |
| | id | string | | | | | | PopulationDefinition |
| | name | string | C20755-3 | | Study Design Population Name | The literal identifier (i.e., distinctive designation) of the study design population. | | PopulationDefinition |
| | description | string | C70834 | | Study Design Population Description | A narrative representation of the study design population. | | PopulationDefinition |
| | label | string | C20755-0 | | Study Design Population Label | The short descriptive designation for the study design population. | | PopulationDefinition |
| | plannedSex | Code | C20755-1 | | Study Design Population Planned Sex | The protocol-defined sex within the study design population. | SDTM Terminology Codelist C66732 | PopulationDefinition |
| | includesHealthySubjects | Boolean | C20754-9 | | Study Design Population Includes Healthy Subjects Indicator | An indication as to whether the study design population includes healthy subjects, that is, subjects without the disease or condition under study. | | PopulationDefinition |
| | plannedAge | Range | C20745-0 | | Study Design Population Planned Age | The anticipated age of subjects within the study design population. | | PopulationDefinition |
| | plannedCompletionNumberRange | Range | CNEW | | Study Design Population Planned Completion Number Range | The range of values representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study design population. | | PopulationDefinition |
| | plannedCompletionNumberQuantity | Quantity | CNEW | | Study Design Population Planned Completion Number Quantity | The value representing the planned number of subjects that must complete the study in order to meet the objectives and endpoints of the study, within the study design population. | | PopulationDefinition |
| | plannedEnrollmentNumberRange | Range | CNEW | | Study Design Population Planned Enrollment Number Range | The range of values representing the planned number of subjects to be entered in a clinical trial, within the study design population. | | PopulationDefinition |
| | plannedEnrollmentNumberQuantity | Quantity | CNEW | | Study Design Population Planned Enrollment Number Quantity | The value representing the planned number of subjects to be entered in a clinical trial, within the study design population. | | PopulationDefinition |
| | notes | CommentAnnotation | CNEW | | Study Design Population Notes | A brief written record relevant to the study design population. | | PopulationDefinition |
| | criteria | EligibilityCriterion | | 0..* | | A USDM relationship between the StudyDesignPopulation and EligibilityCriterion classes which identifies the set of eligibility criteria associated with the study design population. | | PopulationDefinition |
| | cohorts | StudyCohort | | 0..* | | A USDM relationship between the StudyDesignPopulation and StudyCohort classes which identifies the set of study cohorts associated with the study design population. | | |
| StudyElement | | | C14273-5 | | Study Design Element | A basic building block for time within a clinical study comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element. | | |
| | id | string | | | | | | |
| | name | string | C18883-3 | | Study Design Element Name | The literal identifier (i.e., distinctive designation) of the study design element. | | |
| | description | string | C18883-4 | | Study Design Element Description | A narrative representation of the study design element. | | |
| | label | string | C20755-4 | | Study Design Element Label | The short descriptive designation for the study design element. | | |
| | notes | CommentAnnotation | CNEW | | Study Element Notes | A brief written record relevant to the study element. | | |
| | transitionEndRule | TransitionRule | | 0..1 | | A USDM relationship between the StudyElement and TransitionRule classes which provides the details associated with a transition rule used to trigger the end of a study element. | | |
| | studyInterventions | StudyIntervention | | 0..* | | A USDM relationship between the StudyElement and StudyIntervention classes which identifies the set of study interventions associated with the study element. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-------------------|-------------------------|-------------------|------------|-------------|--|--|---|----------------|
| | transitionStartRule | TransitionRule | | 0..1 | | A USDM relationship between the StudyElement and TransitionRule classes which provides the details associated with a transition rule used to trigger the start of a study element. | | |
| StudyEpoch | | | C71738 | | Study Epoch | A named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose. | | |
| | id | string | | | | | | |
| | name | string | C93825 | | Study Epoch Name | The literal identifier (i.e., distinctive designation) of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose. | | |
| | description | string | C93824 | | Study Epoch Description | A narrative representation of the study epoch. | | |
| | label | string | C20755_5 | | Study Epoch Label | The short descriptive designation for the study epoch. | | |
| | type | Code | C1883_0 | | Study Epoch Type | A characterization or classification of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose. | SDTM Terminology Codelist C99079 | |
| | notes | CommentAnnotation | CNEW | | Study Epoch Notes | A brief written record relevant to the study epoch. | | |
| | previous | StudyEpoch | | 0..1 | | A USDM relationship within the StudyEpoch class which identifies the study epoch that chronologically precedes the current study epoch. | | |
| | next | StudyEpoch | | 0..1 | | A USDM relationship within the StudyEpoch class which identifies the study epoch that chronologically follows the current study epoch. | | |
| StudyIdentifier | | | C83082 | | Study Identifier | A sequence of characters used to identify, name, or characterize the study. | | |
| | id | string | | | | | Identifier | |
| | text | string | CNEW | | Study Identifier Text | An instance of structured text that represents the study identifier. | | Identifier |
| | scope | Organization | | 1 | | A USDM relationship between the StudyIdentifier and Organization classes which provides the details associated with each organization that has assigned the study identifier. | | Identifier |
| StudyIntervention | | | C20764_9 | | Study Intervention | Any agent, device, or procedure being tested or used as a reference or comparator in the conduct of a clinical trial. | | |
| | id | string | | | | | | |
| | description | string | C20764_7 | | Study Intervention Description | A narrative representation of the study intervention. | | |
| | name | string | C20755_8 | | Study Intervention Name | The literal identifier (i.e., distinctive designation) of the study intervention. | | |
| | label | string | C20755_6 | | Study Intervention Label | The short descriptive designation for the study intervention. | | |
| | role | Code | C20756_0 | | Study Intervention Role | The intended use of the trial intervention within the context of the study design. | C207417 | |
| | type | Code | C98747 | | Study Intervention Type | The kind of product or procedure studied in a trial. | SDTM Terminology Codelist C99078 | |
| | codes | Code | C20764_8 | | Study Intervention Code | A symbol or combination of symbols which is assigned to the study intervention. | (Point out to multiple Biomedical coding dictionaries such as WHODrug, ATC, UNII, etc.) | |
| | minimumResponseDuration | Quantity | C20755_7 | | Study Intervention Minimum Response Duration | The value representing the minimum amount of time required to meet the criteria for response to study intervention. | | |
| | notes | CommentAnnotation | CNEW | | Study Intervention Notes | A brief written record relevant to the study intervention. | | |
| | administrations | Administration | | 0..* | | A USDM relationship between the StudyIntervention and AgentAdministration classes which identifies the set of agent administrations associated with the study intervention. | | |
| StudyRole | | | CNEW | | Study Role | A designation that identifies the function of study personnel or an organization within the context of the study. | | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------|--------------------------|--------------------------------|------------|-------------|----------------------------|--|--|----------------|
| | id | string | | | | | | |
| | name | string | CNEW | | Study Role Name | The literal identifier (i.e., distinctive designation) of the study role. | | |
| | label | string | CNEW | | Study Role Label | The short descriptive designation for the study role. | | |
| | description | string | CNEW | | Study Role Description | A narrative representation of the study role. | | |
| | code | Code | CNEW | | Study Role Code | A symbol or combination of symbols which is assigned to the study role. | CNEW Study Role Code | |
| | assignedPersons | AssignedPerson | | 0..* | | A USDM relationship between the StudyRole and AssignedPerson classes that identifies the set of individuals that are assigned to a particular role within the study. | | |
| | masking | Masking | | 0..1 | | A USDM relationship between the StudyRole and Masking classes which describes the masking associated with the study role. | | |
| | organizations | Organization | | 0..* | | A USDM relationship between the StudyRole and Organization classes which identifies the set of organizations associated with the study role. | | |
| | appliesTo | StudyDesign, StudyVersion | | 0..* | | A USDM relationship between the StudyRole and either StudyVersion or StudyDesign classes that identifies the study version or study design to which the study role applies. | | |
| StudySite | | | C80403 | | Study Site | The location at which a study investigator conducts study activities. | | |
| | id | string | | | | | | |
| | name | string | C20756_6 | | Study Site Name | The literal identifier (i.e., distinctive designation) of the study site. | | |
| | description | string | C20756_4 | | Study Site Description | A narrative representation of the study site. | | |
| | label | string | C20756_5 | | Study Site Label | The short descriptive designation for the study site. | | |
| | country | Code | C17099_0 | | Country of Study Site | The country in which the study site is located. | (Point out to ISO 3166-1 Alpha-3 Country code) | |
| StudyTitle | | | C49802 | | Study Title | The sponsor-defined name of the clinical study. | | |
| | id | string | | | | | | |
| | type | Code | C20756_8 | | Study Title Type | A characterization or classification of the study title. | C207419 | |
| | text | string | C20756_7 | | Study Title Text | An instance of unstructured text that represents the study title. | | |
| StudyVersion | | | C18881_6 | | Study Version | A plan at a particular point in time for a study. | | |
| | id | string | | | | | | |
| | versionIdentifier | string | C20757_0 | | Study Version Identifier | A sequence of characters used to identify, name, or characterize the study version. | | |
| | businessTherapeuticAreas | Code | C20132_2 | | Business Therapeutic Areas | A therapeutic area classification based on the structure and operations of the business unit. | (Point out to external dictionaries) | |
| | rationale | string | C94122 | | Study Rationale | A statement describing the overall rationale of the study. This field describes the contribution of this study to product development, i.e., what knowledge is being contributed from the conduct of this study. | | |
| | notes | CommentAnnotation | CNEW | | Study Version Notes | A brief written record relevant to the study version. | | |
| | abbreviations | Abbreviation | | 0..* | | A USDM relationship between the StudyVersion and Abbreviation classes which provides the set of abbreviations associated with the study version. | | |
| | dateValues | GovernanceDate | | 0..* | | A USDM relationship between the StudyVersion and GovernanceDate classes which provides the set of governance dates associated with the study version. | | |
| | referenceIdentifiers | ReferenceIdentifier | | 0..* | | A USDM relationship between the StudyVersion and ReferenceIdentifier classes which identifies the set of reference identifiers associated with the study version. | | |
| | amendments | StudyAmendment | | 0..* | | A USDM relationship between the StudyVersion and StudyAmendment classes which identifies the set of study amendments associated with the study version. | | |
| | documentVersions | StudyDefinitionDocumentVersion | | 0..* | | A USDM relationship between the StudyVersion and StudyDefinitionDocumentVersion classes which identifies the version of the study definition document associated with the study version. | | |
| | studyDesigns | StudyDesign | | 0..* | | A USDM relationship between the StudyVersion and | | |

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| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|-------------------|--------------------|--------------------------|-------------|-------------|-----------------------------------|--|--|----------------|
| | | | | | | StudyDesign classes which identifies the set of study designs associated with the study version. | | |
| | studyIdentifiers | StudyIdentifier | | 1..* | | A USDM relationship between the StudyVersion and StudyIdentifier classes which identifies the set of study identifiers associated with the study version. | | |
| | titles | StudyTitle | | 1..* | | A USDM relationship between the StudyVersion and StudyTitle classes which identifies the set of study titles associated with the study version. | | |
| SubjectEnrollment | | | C37948 | | Subject Enrollment | The act of enrolling subjects into a study. The subject will have met the inclusion/exclusion criteria to participate in the trial and will have signed an informed consent form. (CDISC Glossary) | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Subject Enrollment Name | The literal identifier (i.e., distinctive designation) of the subject enrollment. | | |
| | description | string | CNEW | | Subject Enrollment Description | A narrative representation of the subject enrollment. | | |
| | label | string | CNEW | | Subject Enrollment Label | The short descriptive designation for the subject enrollment.. | | |
| | quantity | Quantity | C20757 3 | | Subject Enrollment Quantity Value | The value representing the number of individuals enrolled in a study. | | |
| | forGeographicScope | GeographicScope | | 0..1 | | A USDM relationship between the SubjectEnrollment and GeographicScope classes which identifies the geographic scope to which the subject enrollment applies. | | |
| | forStudyCohort | StudyCohort | | 0..1 | | A USDM relationship between the SubjectEnrollment and StudyCohort classes which identifies the study cohort to which subject enrollment applies. | | |
| | forStudySite | StudySite | | 0..1 | | A USDM relationship between the SubjectEnrollment and StudySite classes which identifies the study site to which the subject enrollment applies. | | |
| Substance | | | C45306 | | Substance | Any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical. | | |
| | id | string | | | | | | |
| | name | string | CNEW | | Substance Name | The literal identifier (i.e., distinctive designation) of the substance. | | |
| | description | string | CNEW | | Substance Description | A narrative representation of the substance. | | |
| | label | string | CNEW | | Substance Label | The short descriptive designation for the substance. | | |
| | codes | Code | CNEW | | Substance Code | A symbol or combination of symbols which is assigned to the substance. | Point out to multiple Biomedical coding dictionaries such as WHODrug, ATC, UNII, etc.) | |
| | strengths | Strength | | 1..* | | A USDM relationship between the Substance and Strength class which provides the values of the strengths of the substance. | | |
| | referenceSubstance | Substance | | 0..1 | | A USDM relationship within the Substance class that identifies the association between two substances, one of which is used as a reference for the other. | | |
| SyntaxTemplate | | | C20759 6 | | Syntax Template | A standardized pattern used for the arrangement of words and phrases to create well-formed, structured sentences. | | |
| | id | string | | | | | | |
| | name | string | C20757 7 | | Syntax Template Name | The literal identifier (i.e., distinctive designation) of the syntax template. | | |
| | description | string | C20757 5 | | Syntax Template Description | A narrative representation of the syntax template. | | |
| | label | string | C20757 6 | | Syntax Template Label | The short descriptive designation for the syntax template. | | |
| | text | string | C20757 8 | | Syntax Template Text | A structured text string containing prescribed text interspersed with user-defined parameter values. | | |
| | notes | CommentAnnotation | CNEW | | Syntax Template Notes | A brief written record relevant to the syntax template. | | |
| | dictionary | SyntaxTemplateDictionary | | 0..1 | | A USDM relationship between the SyntaxTemplate and SyntaxTemplateDictionary classes which provides the dictionary entry associated with a syntax template. | | |

| Class Name | Attribute Name | Data Type | NCI C-Code | Cardinality | Preferred Term | Definition | Codelist Ref | Inherited From |
|--------------------------|-------------------------------|-------------------|-------------|-------------|--|---|--------------|----------------|
| SyntaxTemplateDictionary | | | C20759 7 | | Syntax Template Dictionary | A reference source that provides a listing of valid parameter names and values used in syntax template text strings. | | |
| | id | string | | | | | | |
| | name | string | C20758 1 | | Syntax Template Dictionary Name | The literal identifier (i.e., distinctive designation) of the syntax template dictionary. | | |
| | description | string | C20757 9 | | Syntax Template Dictionary Description | A narrative representation of the syntax template dictionary. | | |
| | label | string | C20758 0 | | Syntax Template Dictionary Label | The short descriptive designation for the syntax template dictionary. | | |
| | parameterMaps | ParameterMap | | 1..* | | A USDM relationship between the SyntaxTemplateDictionary and ParameterMap classes which identifies the set of parameter maps (parameter map entries) associated with a syntax template dictionary. | | |
| Timing | | | C80484 | | Timing | The chronological relationship between temporal events. | | |
| | id | string | | | | | | |
| | name | string | C20758 4 | | Timing Name | The literal identifier (i.e., distinctive designation) of the timing. | | |
| | description | string | C16464 8 | | Timing Description | A narrative representation of the chronological relationship between temporal events. | | |
| | label | string | C20758 3 | | Timing Label | The short descriptive designation for the timing. | | |
| | type | Code | C20129 8 | | Timing Type | A characterization or classification of the chronological relationship between temporal events. | C201264 | |
| | relativeToFrom | Code | C20129 7 | | Timing Relative To From | The name of the reference event used to define the temporal relationship with another event. | C201265 | |
| | value | string | C20134 1 | | Timing Value | The temporal value of the chronological relationship between temporal events. | | |
| | valueLabel | string | C20758 5 | | Timing Value Label | The short descriptive designation for the timing value. | | |
| | windowLabel | string | C20758 6 | | Timing Window Label | The short descriptive designation for a time period, or other type of interval, during which a temporal event may be achieved, obtained, or observed. | | |
| | windowLower | string | C20134 2 | | Timing Window Lower | The earliest chronological value of an allowable period of time during which a temporal event takes place. | | |
| | windowUpper | string | C20134 3 | | Timing Window Upper | The latest chronological value of an allowable period of time during which a temporal event takes place. | | |
| | relativeToScheduledInstance | ScheduledInstance | | 0..1 | | A USDM relationship between the Timing and ScheduledInstance classes which identifies the scheduled instance (e.g., scheduled activity instances or scheduled decision instances) to which the timing is relative to. | | |
| | relativeFromScheduledInstance | ScheduledInstance | | 1 | | A USDM relationship between the Timing and ScheduledInstance classes which identifies the scheduled instance (e.g., scheduled activity instances or scheduled decision instances) to which the timing applies. | | |
| TransitionRule | | | C82567 | | Transition Rule | A guide that governs the allocation of subjects to operational options at a discrete decision point or branch (e.g., assignment to a particular arm, discontinuation) within a clinical trial plan. | | |
| | id | string | | | | | | |
| | name | string | C20758 8 | | Transition Rule Name | The literal identifier (i.e., distinctive designation) of the transition rule. | | |
| | description | string | C18883 5 | | Transition Rule Description | A narrative representation of the transition rule. | | |
| | label | string | C20758 7 | | Transition Rule Label | The short descriptive designation for the transition rule. | | |
| | text | string | C20758 9 | | Transition Rule Text | An instance of unstructured text that represents the transition rule. | | |

14 USDM API

- [General](#)
- [Serialization](#)

- [Additional Attributes and Required Content](#)
- [Extension Mechanism](#)

14.1 General

The reference architecture API is designed as a mechanism for bulk transfer to allow for the reading, updated and/or creation of a study within a target solution (e.g. study design solution, data repository). No other API features are defined, nor is a granular API defined at this time. The API has been defined using the [OpenAPI Specification](#). The various routes, rules, and constraints for the use of the API are contained within the API specification itself. If further routes, rules, and constraints are required, these will be added to the machine-readable specification.

14.2 Serialization

When expressing USDM data in a monolithic, hierarchical document format (e.g., JSON, XML), the same element will appear multiple times because the model uses only class references for USDM entities. This is not optimal for an API and, so as not to repeat the same information within the JSON structure, the API has been designed to include an instance once and only once and allow for zero, 1, or more references to it as dictated by the USDM and the relationships therein. This mechanism relies on the unique identifiers of each class.

To ensure no duplication of content in the API JSON format, the following steps are taken to translate the logical USDM into the JSON format:

1. Where content is shared (referenced from 2 or more places), the "natural parent" relationship is identified. An example is the Endpoint class that is referenced from both the Objective and Estimand classes. Objective is considered the natural parent.
2. If a natural parent can be identified in the API, then the content of the child is included in the corresponding item of the natural parent (attribute names remain unchanged) and other relationships are added as cross-references, with the attribute names modified with a suffix of "Id" (singular) or "Ids" (plural) relationships. The datatype is modified to string so as to accommodate the cross-references and the corresponding identifiers.
3. If the natural parent cannot be identified, then a "collection" from a logical higher level class is formed and all relationships to this class in the logical model are added as cross-references in the API with the corresponding naming modifications as specified in step 2. This results in an additional relationship in the API for the higher level class to the collection. An example is for the class BiomedicalConcepts, where a collection is placed within the StudyDesign class.

14.3 Additional Attributes and Required Content

14.4 API Additional Attributes

A number of additional attributes have been added to the API to aid processing. The following additional attributes are API-only artifacts and, as such, are not present within the UML specification or defined in CT:

1. An **instanceType** attribute, included within all classes and used to state the class name
2. Three attributes, included within the root node of the API:
 - a. **usdmVersion**: The version of the USDM to which the data transported have been generated from and conform to. This is a required attribute.
 - b. **systemName**: The name of the system that generated the data. This is an optional attribute.
 - c. **systemVersion**: The version of the system that generated the data. This is an optional attribute.

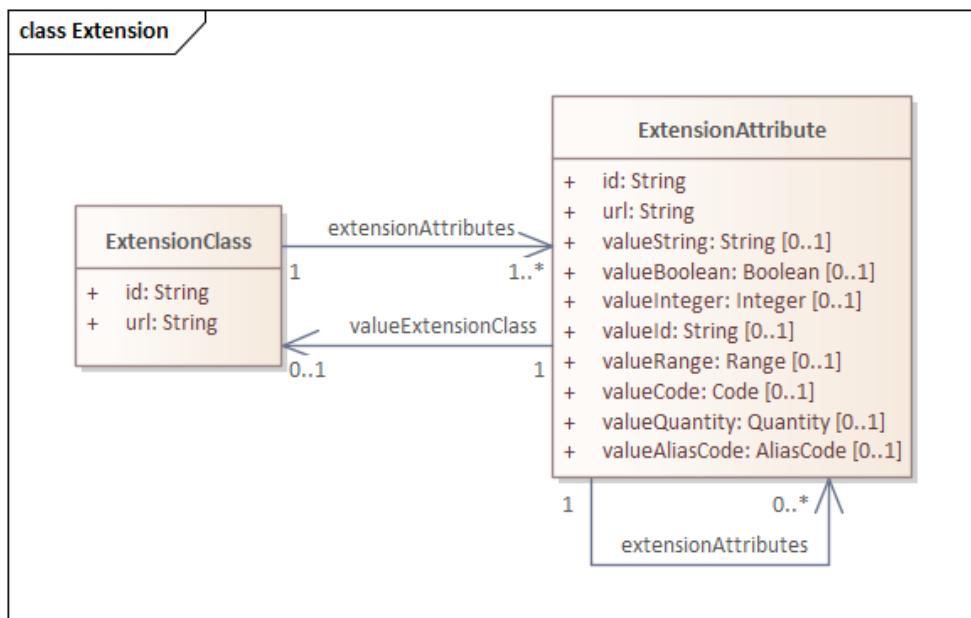
14.5 API Required Content

When sending data using the API, it is recommended that the data include the following:

1. There is only 1 StudyVersion.
2. There is 1 StudyIdentifier within the StudyVersion which is scoped by an organization that is referred to by the clinical study sponsor (C70793) role.
3. There is at least 1 StudyDesign within the StudyVersion.

14.6 Extension Mechanism

Although the USDM aims to store and exchange all study design information, additional information that is not stored in the USDM might be needed for a specific purpose. The API enables exchange of this extra information by its extension mechanism.



15 Mapping to Other Standards and Formats

- [Creation of SDTM Trial Design Domains](#)
- [Informing ClinicalTrials.gov Registry](#)
- [Use of USDM for Populating Protocol Content](#)

Draft Mappings to ICH-M11 and EMA CTIS are provided in separate Excel workbooks (please refer to the [DDF Phase 4 Public Review Dashboard](#) under document links).

15.1 Creation of SDTM Trial Design Domains

Alignment between the USDM and SDTM Trial Design domains and controlled terminology elements related to study design enables the (automated) creation of the SDTM Trial Design Domains. The [SDTM Implementation](#)

Guide (SDTMIG) includes a section related to Trial Design datasets. The corresponding trial design concepts include:

- Trial design
- Epoch
- Arm
- Study cell
- Element
- Branch
- Treatments
- Visit
- Criteria

These concepts are used for the following Trial Design Domains:

- Trial Arms (TA)
- Trial Elements (TE)
- Trial Visits (TV)
- Trial Inclusion/Exclusion Criteria (TI)
- Trial Summary (TS)

Other trials design domains (e.g., Trial Disease Assessments (TD), Trial Disease Milestones (TM)) are described in the SDTMIG contain information that is stored in the USDM as well but are not explicitly discussed in this section. The USDM structure that informs the TA, TE, and TV domains is described in Section 4.10, [Arms and Epochs](#).

The following table provides an overview of the mapping of USDM to the **SDTM TA domain**.

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 Change |
|---------------|-------------------------------------|------|-------------------|------|--|---|--|-------------|
| STUDYID | Study Identifier | Char | Identifier | Req | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@code /code/@code= C70793 (Sponsor) | where studyRole/@code /code/@code= C70793 (Sponsor) | Y |
| DOMAIN | Domain Abbreviation | Char | Identifier | Req | | | Set to "TA" | |
| ARMCD | Planned Arm Code | Char | Topic | Req | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name | | | |
| ARM | Description of Planned Arm | Char | Synonym Qualifier | Req | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@description | | | |
| TAETORD | Planned Order of Element within Arm | Numb | Timing | Req | StudyVersion/@studyDesigns /StudyDesign/@epochs /StudyEpoch/@previous @next | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch | Order epochs according previous/next attributes and select the ones that are referring to the corresponding specified arm. Assign corresponding order number for the included epochs. | Y |
| ETCD | Element Code | Char | Record Qualifier | Req | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@name | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch | | Y |
| ELEMENT | Description of Element | Char | Synonym Qualifier | Perm | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@description | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch | | Y |
| TABRANCH | Branch | Char | Rule | Exp | | | | DELETED |
| TATRANS | Transition Rule | Char | Rule | Exp | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledDecisionInstance/@conditionAssignments | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch | ScheduledInstances in a timeline point to a StudyEpoch (see Section 4.14, Study Timing). Transition rule information is stored as scheduledDecisionInstances using the ConditionAssignment that points to an instance | Y |

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 Change |
|---------------|----------------|------|--------|------|---|--|--|-------------|
| | | | | | | | not being the default next instance on the timeline. | |
| EPOCH | Epoch | Char | Timing | Req | StudyVersion/@studyDesigns /StudyDesign/@epochs /StudyEpoch/@name | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch | | Y |

The following table provides an overview of the mapping of USDM to the **SDTM TE domain**.

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 change |
|---------------|-----------------------------|------|-------------------|------|---|--|--|-------------|
| STUDYID | Study Identifier | Char | Identifier | Req | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations | where studyRole/@code /code/@code= C70793 (Sponsor) | Y |
| DOMAIN | Domain Abbreviation | Char | Identifier | Req | | | Set to "TE" | |
| ETCD | Element Code | Char | Topic | Req | StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@name | | | |
| ELEMENT | Description of Element | Char | Synonym Qualifier | Req | StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@description | | | |
| TESTRL | Rule for Start of Element | Char | Rule | Req | StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@transitionStartRule /TransitionRule/@text | | | |
| TEENRL | Rule for End of Element | Char | Rule | Perm | StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@transitionEndRule /TransitionRule/@text | | | |
| TEDUR | Planned Duration of Element | Char | Timing | Perm | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@timings /Timing/@value | StudyDesign/@studyCells /StudyCell/@elements StudyDesign/@studyCells /StudyCell/@epoch = StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledInstance/@epoch ScheduledTimeline/@timings /Timing/@relativeFromScheduledInstance = ScheduledTimeline/@instances /ScheduledInstance/@id | Select scheduleInstances that relate to start of the associated StudyEpoch associated with the corresponding study Element via StudyCell. Select the scheduleInstance associated with the start of the next studyEpoch. Use Timing.values of all related timings that specify the period in between for calculation of the total element duration. | Y |

The following table provides an overview of the mapping of USDM to the **SDTM TV domain**.

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 change |
|---------------|----------------------------|------|-------------------|------|--|---|--|-------------|
| STUDYID | Study Identifier | Char | Identifier | Req | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations | where studyRole/@code /code/@code= C70793 (Sponsor) | Y |
| DOMAIN | Domain Abbreviation | Char | Identifier | Req | | | Set to "TV" | |
| VISITNUM | Visit Number | Num | Topic | Req | StudyVersion/@studyDesigns /StudyDesign/@encounters /Encounter/@previous @next | | Order encounters based on previous and next attributes and derive the visit order number correspondingly. Assign numbers based on applicable standard visit numbering rules. | Y |
| VISIT | Visit Name | Char | Synonym Qualifier | Req | StudyVersion/@studyDesigns /StudyDesign/@encounters /Encounter/@name | | | Y |
| VISITDY | Planned Study Day of Visit | Num | Timing | Perm | StudyVersion/@studyDesigns /StudyDesign/@encounters | | | Y |

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| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 change |
|---------------|----------------------------|------|-------------------|------|--|--|------------------------|-------------|
| | | | | | /Encounter/@scheduledAt /Timing/@label | | | |
| ARMCD | Planned Arm Code | Char | Record Qualifier | Exp | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@arm /StudyArm/@name | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch ScheduledActivityInstance/@epoch ScheduledActivityInstance/@encounter | | Y |
| ARM | Description of Planned Arm | Char | Synonym Qualifier | Perm | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@arm /StudyArm/@description | StudyDesign/@studyCells /StudyCell/@arm StudyDesign/@studyCells /StudyCell/@epoch ScheduledActivityInstance/@epoch ScheduledActivityInstance/@encounter | | Y |
| TVSTRL | Visit Start Rule | Char | Rule | Req | StudyVersion/@studyDesigns /StudyDesign/@encounters /Encounter/@transitionStartRule /TransitionRule/@text | | | Y |
| TVENRL | Visit End Rule | Char | Rule | Perm | StudyVersion/@studyDesigns /StudyDesign/@encounters /Encounter/@transitionEndRule /TransitionRule/@text | | | Y |

The following table provides an overview of the mapping of USDM to the **SDTM TI domain**.

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 change |
|---------------|------------------------------------|------|--------------------|------|--|--|---|-------------|
| STUDYID | Study Identifier | Char | Identifier | Req | Study Version/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations | where studyRole/@code /code/@code=C70793 (Sponsor) | Y |
| DOMAIN | Domain Abbreviation | Char | Identifier | Req | | | Set to "TI" | |
| IETESTCD | Incl/Excl Criterion Short Name | Char | Topic | Req | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@identifier | | A subselection of criteria may be made based on population @ criteria for criteria referred by populations included in the specific design. | Y |
| IETEST | Inclusion/Exclusion Criterion | Char | Synonym Qualifier | Req | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem EligibilityCriterionItem/@text | | The eligibility criteria are based on the SyntaxTemplate class (see Section 4.21). Referenced values need to be replaced by actual values before creation of IETEST. | Y |
| IECAT | Inclusion/Exclusion Category | Char | Grouping Qualifier | Req | Study Version/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@category /code/@decode | | | Y |
| IESCAT | Inclusion/Exclusion Subcategory | Char | Grouping Qualifier | Perm | | | Permitted value. Not available in USDM. Can be applied using notes attributes according to use preference. | Y |
| TIRL | Inclusion/Exclusion Criterion Rule | Char | Rule | Perm | Study Version/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@text | | The eligibility criteria are based on the SyntaxTemplate class (see Section 4.21), which enhances computer readability. References values should not be replaced by actual values for TIRL. | Y |
| TIVERS | Protocol Criteria Versions | Char | Record Qualifier | Perm | StudyVersion/@documentVersions /StudyDefinitionDocumentVersion/@version | Study/@documentedBy /StudyDefinitionDocument/@versions=Study/@versions /StudyVersion/@documentVersions | where StudyDefinitionDocument/@type /code/@code=C70817 (Protocol) | Y |

The following table provides an overview of the mapping of USDM to the **SDTM TS domain**.

| Variable Name | Variable Label | Type | Role | Core | USDM Path and Attribute | Required USDM relationships | Selection / Derivation | v4.0 change |
|---------------|--------------------------------------|------|-------------------|------|---|---|--|-------------|
| STUDYID | Study Identifier | Char | Identifier | Req | Study Version/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations | where studyRole/@code /code/@code=C70793 (Sponsor) | Y |
| DOMAIN | Domain Abbreviation | Char | Identifier | Req | | | Set to "TS" | |
| TSSEQ | Sequence Number | Num | Identifier | Req | <i>See TSPARM mapping table below</i> | | | |
| TSGRPID | Group ID | Char | Identifier | Perm | <i>See TSPARM mapping table below</i> | | | |
| TSPARMCD | Trial Summary Parameter Short Name | Char | Topic | Req | <i>See TSPARM mapping table below</i> | | | |
| TSPARM | Trial Summary Parameter | Char | Synonym Qualifier | Req | <i>See TSPARM mapping table below</i> | | | |
| TSVAL | Parameter Value | Char | Result Qualifier | Exp | <i>See TSPARM mapping table below. If not otherwise specified...Code/@decode</i> | | | |
| TSVALNF | Parameter Value Null Flavor | Char | Result Qualifier | Perm | <i>Fill in case of missing values with expected data as described in the SDTMIG</i> | | | |
| TSVALCD | Parameter Value Code | Char | Result Qualifier | Exp | <i>See TSPARM mapping table below. If not otherwise specified...Code/@decode</i> | | | |
| TSVCDREF | Name of Reference Terminology | Char | Result Qualifier | Exp | <i>See TSPARM mapping table below. If not otherwise specified...Code/@codeSystem</i> | | | |
| TSVCDVER | Version of the Reference Terminology | Char | Result Qualifier | Exp | <i>See TSPARM mapping table below. If not otherwise specified...Code/@codeSystemVersion</i> | | | |

The following table provides a list of published TS parameters (TSPARM) and their mapping to USDM elements (i.e., entities, attributes, valid values). The table includes only those parameters for which there is a mapping. Frequently used and required parameters are included.

The table is based on the [SDTM CT codelist C66738](#). For all synonyms and definitions, please see the corresponding terminology file.

| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRPID | USDM v4.0 change |
|---------------------------------|-----------|---------|----------------|---|---|--------|---------|------------------|
| Adaptive Design | ADAPT | C146995 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@code | If the collection of characteristics/code/@code includes C98704 then TSVAL="Y" and TSVLCD="C49488" Otherwise TSVAL="N" and TSVLCD="C49487" | | | Y |
| Added on to Existing Treatments | ADDON | C49703 | C66738 | <i>Added as placeholder for potential alignment with M11</i> | | | | placeholder |

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| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRID | USDM v4.0 change |
|--|--------------|---------|-------------------|--|---|----------------------------------|---|------------------------|
| Planned Minimum Age of Subjects | AGEMIN | C49693 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /PopulationDefinition/@plannedAge /Range/@minValue + @unit | Use minimum of minimum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. | | | Y |
| Planned Minimum Age of Subjects | AGEMAX | C49694 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /PopulationDefinition/@plannedAge /Range/@maxValue + @unit | Use maximum of maximum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. | | | Y |
| Biospecimen Retention contains DNA Ind | BRDNAIN D | C127777 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@biospecimenRetentions /biospecimenRetention/@includesDNA | If True then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487" | Add unique number if more than 1 | If applicable, combine with the corresponding Biospecimen variables BRIND and RTSPCDES by a common unique tsgrid | NEW |
| Biospecimen Retention indicator | BRIND | C209699 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@biospecimenRetentions /biospecimenRetention/@isRetained | If True then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487" | Add unique number if more than 1 | If applicable, combine with the corresponding Biospecimen variables BRDNAIND and RTSPCDES by a common unique tsgrid | NEW |
| Comparative Treatment Name | COMPTRT | C68612 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name | StudyIntervention/@role /Code/@Code="C68609" ("Active Comparator") | Add unique number if more than 1 | If applicable, combine with the corresponding intervention variables by a common unique tsgrid | Y |
| Contact Name | CONNAME | C176373 | C66738 | StudyVersion/@roles /StudyRole/@assignedPersons /@name | | Add unique number if more than 1 | combine with CONROLE using a common unique tsgrid | NEW |
| Contact Role | CONROLE | C176372 | C66738 | StudyVersion/@roles /StudyRole/@code /code/@decode | where StudyRole/@assignedPersons not null | Add unique number if more than 1 | combine with CONNAME using a common unique tsgrid | NEW |
| Confirmed Response Minimum Duration | CRMDUR | C98715 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@minimumResponseDuration /Quantity/@value+@unit | | Add unique number if more than 1 | If applicable, combine with the corresponding intervention variables by a common unique tsgrid | NEW |
| Current Therapy or Treatment | CURTRT | C85582 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name | .StudyIntervention/@role/ Code/@Code="C165822" ("Background Treatment") | Add unique number if more than 1 | If applicable, combine with the corresponding intervention variables by a common unique tsgrid | |
| Data Monitoring Committee Indicator | DMCIND | C127790 | C66738 | StudyVersion/@roles /StudyRole/@code /code/@code | If StudyRole/@code/code/@code = "C142578" (Independent Data Monitoring Committee) then TSVAL="Y" Note: that if this is not available it should be verified with other roles and protocol text that there is no committee. | | | NEW |
| Dose Level; Dose per Administration | DOSE | C25488 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions | | Add unique number | If applicable, combine with the | Y |

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| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRID | USDM v4.0 change |
|--|--------------|---------|-------------------|--|---|---|--|------------------------|
| | | | | /StudyIntervention/@administrations /Administration/@dose /Quantity/@value | | r if more than 1 | correspondin g intervention variables by a common tsgrpid | |
| Dose Form | DOSFRM | C42636 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct /AdministrableProduct/@administrableDoseFor m /code/@decode | | Add unique numbe r if more than 1 | If applicable, combine with the correspondin g intervention variables by a common tsgrpid | NEW |
| Dosing Frequency | DOSFRQ | C89081 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@frequency | | Add unique numbe r if more than 1 | If applicable, combine with the correspondin g intervention variables by a common tsgrpid | Y |
| Dose Units | DOSU | C73558 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@dose /Quantity/@unit /AliasCode/@standardCode | | Add unique numbe r if more than 1 | If applicable, combine with the correspondin g intervention variables by a common tsgrpid | Y |
| Extension Trial Indicator | EXTTIND | C139274 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@code | If the collection of characteristics/code/@code includes C207613 then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487" | | | Y |
| Planned Country of Investigational Sites | FCNTRY | C98770 | C66738 | StudyVersion/@organizations /Organization/@managedSites /StudySite/@country | SubjectEnrollment/@type /code=@code=C25464 ("Country") | Select unique values and add unique numbe r if more than 1 | | Y |
| Healthy Subject Indicator | HLTSUBJI | C98737 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population (StudyDesignPopulation/@cohorts) /PopulationDefinition/@includesHealthySubjec ts | If one of the populations indicates True then TSVAL="Y" and TSVALCD="C49488" otherwise TSVAL="N" and TSVALCD="C49487" | | | Y |
| Trial Disease/Condit ion Indication; Trial Disease/Condit ion Indication Description | INDIC | C112038 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@indications /Indication/@name or @description | | | | |
| Intervention Model | INTMODEL | C98746 | C66738 | StudyVersion/@studyDesigns /InterventionalStudyDesign/@model | | | | Y |
| Intervention Type | INTTYPE | C98747 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@type /code/@decode | | | If applicable, combine with the correspondin g intervention variables by a common tsgrpid | Y |
| Trial Length | LENGTH | C49697 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledActivityInstance/@timings /Timing/@value | Select scheduleInstances that relate to start of the study. Select the scheduleInstance associated with the end of the study. Use Timing.values of all related timings that specify the period in between for calculation of the total trial length. | | | |
| Multiple Site EU Site Trial Indicator | MSEUTIND | C127794 | C66738 | StudyVersion/@organizations /Organization/@managedSites /StudySite/@country /code | If more distinct values of countries within the EU are specified then TSVAL="Y" and TSVALCD="C49488" Note that if this information is not available, it should be verified. | | | NEW |
| Planned Number of Arms | NARMS | C98771 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm | Count number of instances (each instance is an arm) defined in StudyArm class | | | |
| Number of Groups/Cohorts | NCOHORT | C126063 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort | Count number of instances (each instance is an cohort) defined in StudyCohort class | | | |

CDISC [Title] (Version n [Status])

| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRID | USDM v4.0 change |
|---|--------------|---------|-------------------|---|--|-------------------|--|------------------------|
| Number of Trial Sites EU State | NUMSEUST | C122779 | C66738 | StudyVersion/@organizations /Organization/@managedSites /StudySite/@country | Count distinct values of countries within the EU | | | NEW |
| Trial Exploratory Objective | OBJEXP | C163559 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text | Objective/@level /code/@Code = C163559 ("Exploratory Objective") Objectives are based on the SyntaxTemplate class (see Section 4.20). References values need to be replaced by actual values before creation of OBJEXP. | Add Unique number | combine with the corresponding outcome measures by a common tsgrpid | |
| Study Primary Objective; Trial Primary Objective | OBJPRIM | C85826 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text | Objective/@level /code/@Code = C85826 ("Primary Objective") Objectives are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of OBJPRIM. | Add Unique number | combine with the corresponding outcome measures by a common tsgrpid | Y |
| Study Secondary Objective; Trial Secondary Objective | OBJSEC | C85827 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text | Objective/@level /code/@Code = C85827 ("Study Secondary Objective") Objectives are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of OBJSEC. | Add Unique number | combine with the corresponding outcome measures by a common tsgrpid | |
| Observational Model | OBSMODEL | C126064 | C66738 | StudyVersion/@studyDesigns /ObservationalStudyDesign/@model | | | | NEW |
| Observational Time Perspective | OBSTIMP | C126065 | C66738 | StudyVersion/@studyDesigns /ObservationalStudyDesign/@timePerspective | | | | NEW |
| Obs Study Population Description | OBSTPOPD | C126066 | C66738 | StudyVersion/@studyDesigns /ObservationalStudyDesign/@population /StudyDesignPopulation/@description | | | | NEW |
| Observational Study Sampling Method | OBSTSMM | C126067 | C66738 | StudyVersion/@studyDesigns /ObservationalStudyDesign/@samplingMethod | | | | NEW |
| Exploratory Outcome Measure | OUTMSEX | C98724 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Endpoint/@level /code/@Code = C170559 ("Exploratory Endpoint") Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of OUTMSEX. Alternatively, the referenced biomedical concept can be used for OUTMSEX. | Add unique number | combine with the corresponding objective by a common tsgrpid | |
| Primary Outcome Measure | OUTMSPRI | C98772 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Endpoint/@level /code/@Code = C94496 ("Primary Endpoint") Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of OUTMSPRI. Alternatively, the referenced biomedical concept can be used for OUTMSPRI. | Add unique number | combine with the corresponding objective by a common tsgrpid | |
| Secondary Outcome Measure | OUTMSSEC | C98781 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Endpoint/@level /code/@Code = C139173 ("Secondary Endpoint") Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of OUTMSSEC. Alternatively, the referenced biomedical concept can be used for OUTMSSEC. | Add unique number | combine with the corresponding objective by a common tsgrpid | |
| Pharmacologic Class | PCLAS | C98768 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /administration/@administrableProduct /AdministrableProduct/@pharmacologicClass | Corresponding AdministrableProduct/@productDesignation should correspond to IMP | | If applicable, combine with the corresponding intervention variables by a common tsgrpid | Y |
| Pediatric Investigation Plan Indicator | PIPIND | C126069 | C66738 | StudyVersion/@referenceIdentifiers /ReferenceIdentifier/@type | if code/@decode="Pediatric Investigation Plan" then TSVAL="Y" and TSVALCD="C49488" | | | NEW |
| Anticipated Enrollment; Planned Enrollment; Planned Number of Subjects; Target Enrollment | PLANSUB | C49692 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedEnrollmentNumber /Range/@MinValue + @MaxValue | Combine MinValue and MaxValue. If equal or only 1 available then only show once. | | | |
| Planned Treatment Duration | PTRTDUR | C139276 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@duration /AdministrationDuration/@quantity /Quantity/@value + @unit | | | If applicable, combine with the corresponding intervention variables by | |

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| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRID | USDM v4.0 change |
|--|--------------|---------|-------------------|---|---|--|---|------------------------|
| | | | | | | | a common tsgrpid | |
| Trial is Randomized | RANDOM | C25196 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@code | If it includes C46079 ("Randomized") then TSVAL="Y" and TSVLCD="C49488" Otherwise TSVAL="N" and TSVLCD="C49487" | | | Y |
| Rare Disease Indicator | RDIND | C126070 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@indications /Indication/@isRareDisease | If True then TSVAL="Y" and TSVLCD="C49488" If False then TSVAL="N" and TSVLCD="C49487" | | | |
| Registry Identifier | REGID | C98714 | C66738 | StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier | .StudyIdentifier/@studyIdentifierScope /Organization/@type /Code/@code=C93453 ("Clinical Study Registry") Fill TSVCDEF with corresponding organization name. .studyIdentifier/@studyIdentifierScope /Organization/@name | Add Unique numbe r if more than 1 | combine with correspondin g organization name in TSVCDEF using a common tsgrpid | Y |
| Route of Administration | ROUTE | C38114 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@route | | | | Y |
| Retained Biospecimen Description | RTSPCDES | C126072 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@biospecimenRetentions /biospecimenRetention/@description | | | | NEW |
| Stable Disease Minimum Duration | SDMDUR | C98783 | C66738 | <i>Added as placeholder for potential alignment with M11</i> | | | | Placeholder |
| Sex of Participants | SEXPOP | C49696 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex | | | | |
| Clinical Study Sponsor; Sponsor; Study Sponsor | SPONSOR | C70793 | C66738 | StudyVersion/@studyRoles /StudyRole/@organization /Organization/@nam e | StudyRole/@code /Code/@code=C70793 ("Sponsor") TSVLCD=..Organization/@identifier TSVCDEF=..Organization/@identifierSch eme | | | Y |
| Sponsor's Study Reference ID | SPREFID | C135009 | C66738 | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations where studyRole/@code /code/@decode in ("Co-Sponsor", "Local Sponsor") | Add Unique numbe r if more than 1 | | Y |
| Single Site EU State Trial Indicator | SSEUTIND | C127800 | C66738 | StudyVersion/@organizations /Organization/@managedSites /StudySite/@cou try /code | If only one site within the EU is specified then TSVAL="Y" and TSVLCD="C49488" Note that this information should be verified for completeness. | | | NEW |
| Study Type; Study Type Classification | STYPE | C142175 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyType | | | | Y |
| Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial Blinding Schema; Trial Masking Design | TBLIND | C49658 | C66738 | StudyVersion/@studyDesigns /InterventionalStudyDesign/@blindingSchema | | | | |
| Control Type | TCNTRL | C49647 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@role | where StudyIntervention/@role /code/@decode in ("Placebo", "Active Comparator") Map applicable values of @role to TCNTRL | | | Y |
| Therapeutic Area | THERARE A | C101302 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@therapeuticAreas | | | | |
| Trial Intent Type | TINDTP | C49652 | C66738 | StudyVersion/@InterventionalStudyDesigns /StudyDesign/@intenTypes | | Add Unique numbe r if more than 1 | | Y |
| Official Study Title; Study Title; Trial Title | TITLE | C49802 | C66738 | StudyVersion/@titles /StudyTitle/@Text | StudyTitle/@Type/Code/@decode="Official Study Title" | | | |
| Trial Phase; Trial Phase Classification | TPHASE | C48281 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyPhase /AliasCode/@standardCode | | | | Y |
| Target Follow- up duration | TRGFUDU R | C126077 | C66738 | <i>Added as placeholder for potential alignment with M11</i> | | | <i>Added as placeholder for potential alignment with M11</i> | Placeholder |
| Investigational Therapy or Treatment | TRT | C41161 | C66738 | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name | StudyIntervention/@role/ Code/@Code="C41161" ("Experimental Intervention") | | If applicable, combine with the | Y |

| TSPARM | TSPARMC D | Code | Codelis t Code | TSVAL USDM Path and Attribute | Selection / Derivations | TSSE Q | TSGRID | USDM v4.0 change |
|----------------------------|--------------|--------|-------------------|--|-------------------------|----------------------------------|--------|--|
| | | | | | | | | corresponding intervention variables by a common tsgrpid |
| Trial Scope; Trial Type | TTYPE | C49660 | C66738 | StudyVersion/@studyDesigns /InterventionalStudyDesign/@subTypes | | Add Unique number if more than 1 | | Y |

15.2 Informing ClinicalTrials.gov Registry

The ClinicalTrials.gov registry can largely be filled with the study design information captured in the USDM. The definitions for protocol registration data elements submitted to [ClinicalTrials.gov](#) for interventional studies (clinical trials) and observational studies are provided on the corresponding [definitions site](#). This table lists included topics and whether they are covered in USDM.

| CT.gov topic | USDM coverage |
|---|---|
| Study Identification | Yes |
| Study Status | No; not available at study design stage |
| Sponsor/Collaborators | Yes; review and additional selection may be needed |
| Oversight | No |
| Study Description | No; protocol text covered by the Unstructured Content (see Section 4.20) class may be used for this. |
| Conditions and Keywords | No |
| Study Design | Yes |
| Arms, Groups, and Interventions | Yes |
| Outcome Measures | Yes |
| Eligibility | Yes; Interventional Study design parameters |
| Contacts, Locations, and Investigator Information | Limited; not presented in this overview |
| IPD Sharing Statement | No |
| References | No |

This table presents the mapping to **Study Identification**. See Section 4.7, [Study Identifiers and Titles](#), for a description of the related features in the USDM.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Selection/Derivation | USDM v4.0 updates |
|------------------------------------|-----------------|-------------------------------------|---|---|-------------------|
| Study Identification | Brief Title | Required | StudyVersion/@titles /StudyTitle/@Text | StudyTitle/@Type/Code/@decode="Brief Study Title" limit to 300 characters | |
| Study Identification. Brief Title | Acronym | Required, If available | StudyVersion/@titles /StudyTitle/@Text | StudyTitle/@Type/Code/@decode="Study Acronym" limit to 14 characters | |
| Study Identification | Official Title | Required | StudyVersion/@titles /StudyTitle/@Text | StudyTitle/@Type/Code/@decode="Official Study Title" limit to 600 characters | |
| Study Identification | Secondary ID | Required, If available | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | StudyIdentifier/@scope = studyRole/@organizations where studyRole/@code /code/@decode not ("Sponsor") | Y |
| Study Identification. Secondary ID | Type | Required, If secondary ID available | StudyVersion/@studyIdentifiers /StudyIdentifier/@scope /Organization/@type + name | Map organization type and name to corresponding CT.gov terminology. | Y |
| Study Identification. Secondary ID | Description | Required, If secondary ID available | StudyVersion/@studyIdentifiers /StudyIdentifier/@scope /Organization/@name | | Y |
| Study Identification | Study Type | Required | StudyVersion/@studyDesigns /StudyDesign/@studyType /code/@decode | | Y |

This table presents the mapping to **Sponsor/Collaborators**.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Selection/Derivation | USDM v4.0 updates |
|-------------------------------------|---------------------------------------|--|---|---|-----------------------------|
| Sponsor/Collaborators | Responsible Party / by Official Title | Required | Not structured in USDM - might be derived based on company logic | Define whether responsible party is Sponsor, Principal Investigator or Sponsor-Investigator | NEW - added for information |
| Sponsor/Collaborators | Investigator | Required, If responsible party is investigator or sponsor-investigator | StudyRole/@assignedPerson | where StudyRole/@code /code/@code="C19924" ("Principal Investigator") | NEW |
| Sponsor/Collaborators, Investigator | Investigator Name | Required, If responsible party is investigator or sponsor-investigator | StudyRole/@assignedPerson /AssignedPerson/@name | where StudyRole/@code /code/@code="C19924" ("Principal Investigator") | NEW |
| Sponsor/Collaborators, Investigator | Official Title | Required, If responsible party is investigator or sponsor-investigator | StudyRole/@assignedPerson /AssignedPerson/@jobtitle | where StudyRole/@code /code/@code="C19924" ("Principal Investigator") | NEW |
| Sponsor/Collaborators, Investigator | Investigator Affiliation | Required, If responsible party is investigator or sponsor-investigator | StudyRole/@assignedPerson /AssignedPerson/@organization /organization/@name | where StudyRole/@code /code/@code="C19924" ("Principal Investigator") | NEW |
| Sponsor/Collaborators | Name of the Sponsor | Required | StudyRole/@assignedPerson or @organization | where StudyRole/@code /code/@code="C70793" ("Sponsor") | NEW |

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| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Selection/Derivation | USDM v4.0 updates |
|-----------------------|-----------------|--------------------|--------------------------|--|-------------------|
| | | | | Only assigned person or organization may be filled for a role, take the one that is specified. | |
| Sponsor/Collaborators | Collaborators | | StudyRole/@organizations | where StudyRole@code /code/@code <= ("C70793","C19924") Selection and Presentation of collaborators based on StudyRole@code is to be confirmed. | NEW |

This table presents the mapping to **Study Design, interventional study design parameters**. See Section 4.6, Study, Protocols, and Amendments, for a description of the related features in the USDM.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Selection/Derivation | USDM v4.0 updates |
|---|----------------------------|-------------------------------------|--|--|-------------------|
| Study Design. Interventional Study Design | Primary Purpose | Required for interventional studies | StudyVersion/@studyDesigns /InterventionalStudyDesign/@subTypes /code/@decode | See Primary objective: .. /StudyDesign/@objectives /objective/@text where /StudyDesign/@objectives /objective/@level /code/@code = "CS8526" Select the TrialType that relates to the primary objective. This can be digitized by adding a syntax template reference in the objective text to the corresponding subType instance. | Y |
| Study Design. Interventional Study Design | Study Phase | Required for interventional studies | StudyVersion/@studyDesigns StudyDesign/@studyPhase /AliasCode/@standardCode /code/@decode | Remove "A" and "B" from SDTM terminology (codelist C66737) and map 1 to 1 to CT.gov terminology if possible. | Y |
| Study Design. Interventional Study Design | Interventional Study Model | Required for interventional studies | StudyVersion/@studyDesigns /InterventionalStudyDesign/@model /code/@decode | Translate CROSS-OVER to CROSSOVER. Other decode values from SDTM terminology (codelist C99076) can be submitted as is. | Y |
| Study Design. Interventional Study Design. Interventional Study Model | Model description | | StudyVersion/@documentVersion /StudyDefinitionDocumentVersion/@contents /NarrativeContent/@contentItem /NarrativeContentItem/@text | ...NarrativeContent/@sectionTitle = "Intervention Model" limit to 1000 characters | Y |
| Study Design. Interventional Study Design | Number of Arms | Required for interventional studies | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm | Count number of instances (each instance is an arm) defined in StudyArm class | |
| Study Design. Interventional Study Design | Masking | Required for interventional studies | StudyVersion/@studyRole /StudyRole/@masking | Each role that includes a masking relationship and corresponding description is considered masked. If masking role in USDM = "Sponsor" then leave empty. All other values can be submitted as is | Y |
| Study Design. Interventional Study Design. Masking | Masking Description | | StudyVersion/@studyRole /StudyRole/@masking | Add other roles that might be masked which are not included in the FDA standard list. | Y |
| Study Design. Interventional Study Design | Allocation | Required for interventional studies | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm and StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode | Count number of instances (each instance is an arm) defined in StudyArm class. If 1 or less then submission value is "N/A (not applicable)". Else If characteristics include "RANDOMIZED" then submission value is "Randomized" Otherwise submission value is "Nonrandomized" | |
| Study Design. Interventional Study Design | Enrollment | Required for interventional studies | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedEnrollmentNumber /Range/@MinValue + @MaxValue | Combine MinValue and MaxValue. If equal or only 1 of them available then only show once. | |
| Study Design. Observational Study Design | Observational Study Model | Required for observational studies | StudyVersion/@studyDesigns /ObservationalStudyDesign/@model /code/@decode | Add dashes (".") between words of "Case Control", "Case Only", "Case Crossover" and "Family Based". Add "studies" to "Ecologic or Community". | NEW |
| Study Design. Observational Study Design | Time Perspective | Required for observational studies | StudyVersion/@studyDesigns /ObservationalStudyDesign/@model /code/@timePerspective /code/@decode | Add dashes (".") between words of "Cross Sectional". | NEW |
| Study Design. Observational Study Design | Biospecimen Retention | | StudyVersion/@studyDesigns /StudyDesign/@biospecimenRetentions /BiospecimenRetention/@isRetained + @includesDNA | If no biospecimenRetentions are set to isRetained = True then value is "None Retained". Otherwise if includesDNA = True then set to "Samples With DNA" otherwise set to "Samples Without DNA". | NEW |
| Study Design. Observational Study Design | Biospecimen Description | | StudyVersion/@studyDesigns /StudyDesign/@biospecimenRetentions /BiospecimenRetention/@description | where BiospecimenRetention/@isRetained = True | NEW |
| Study Design. Observational Study Design | Enrollment | Required for observational studies | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedEnrollmentNumber /Range/@MinValue + @MaxValue | Combine MinValue and MaxValue. If equal or only 1 of them available then only show once. | NEW |
| Study Design. Observational Study Design | Target Follow-up Duration | Required for observational studies | StudyVersion/@studyDesigns /StudyDesign/@timeline /ScheduledInstance/@label | A scheduled Instance to indicate the end of follow-up will need to be in place. This last scheduledInstance will then indicate the target follow-up duration. | NEW |
| Study Design. Observational Study Design | Number of Groups/Cohorts | Required for observational studies | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort | Count number of instances (each instance is a cohort) defined in StudyCohort class | NEW |

This table presents the mapping to **Arms, Groups and Interventions**. See Section 4.10, Arms and Epochs, and Section 4.15, Study Interventions, for descriptions of the related features in the USDM.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Required USDM relationship | Selection/Derivation | USDM v4.0 updates |
|--|--------------------------|---|---|--|--|-------------------|
| Arms, Groups and Interventions. Arm Information | Arm Title | Required for interventional studies | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name | | Limit to 100 characters. | |
| Arms, Groups and Interventions. Arm Information | Arm Type | Required for interventional studies | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@type /code/@decode | | In case USDM arm types "Control" and "Treatment" are used they may be mapped to "Other" or any of the Experimental or Comparator types. All other USDM arm types can directly be used by moving the word "arm" from the USDM arm decode value. | |
| Arms, Groups and Interventions. Arm Information | Arm Description | If needed | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@description | | Limit to 999 characters. | |
| Arms, Groups and Interventions. Group/Cohort Information | Group/Cohort Label | Required for observational studies only | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort/@label | | Limit to 100 characters. | |
| Arms, Groups and Interventions. Group/Cohort Information | Group/Cohort Description | | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort/@description | | Limit to 999 characters. | |
| Arms, Groups and Interventions. Interventions | Intervention Type | Required | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@type /Code/@decode | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@StudyArm | StudyCell relates StudyArm with corresponding element that relates to the corresponding intervention. If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.[7] | |

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| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Required USDM relationship | Selection/Derivation | USDM v4.0 updates |
|---|--|--------------------|--|--|---|-------------------|
| | | | | | Text transformation is needed for 1 to 1 mapping to ClinicalTrials.gov terminology. | |
| Arms, Groups and Interventions. Interventions | Intervention Name | Required | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@name | | Limit to 200 characters. | |
| Arms, Groups and Interventions. Interventions | Other Intervention Name | If any | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@label | | Upon judgement of (system) user to decide whether label should be included as other intervention name. Limit to 200 characters. | |
| Arms, Groups and Interventions. Interventions | Intervention Description | Required | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@description | | Limit to 1000 characters. | |
| Arms, Groups and Interventions. Interventions | Arm or Group/Interventional Cross-References | Required | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/ | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@StudyArm | "If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group." [6] | |

This table presents the mapping to **Outcome Measures**. See Section 4.16, [Study Objectives and Endpoints](#), for a description of the related features in the USDM.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Required USDM relationship | Selection/Derivation | USDM v4.0 |
|---|-----------------|--------------------|---|---|---|-----------|
| Outcome Measures. Primary Outcome Measure Information | Title | Required | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@name | | ./Endpoint/@level /code/@code="C94496" Limit to 254 characters. | |
| Outcome Measures. Primary Outcome Measure Information | Description | If available | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | | ./Endpoint/@level /code/@code="C94496" The endpoint text is based on the SyntaxTemplate class (see Section 4.21). Referenced values need to be replaced by actual values before submitting. Limit to 999 characters. | |
| Outcome Measures. Primary Outcome Measure Information | Time Frame | Required | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@ScheduleInstance /Timing/@value | ./Endpoint/@level /code/@code="C94496" In case of reference to the corresponding Timing class, check and use the referenced timing for this attribute. Limit to 254 characters. | |
| Outcome Measures. Primary Secondary Measure Information | Title | If any | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@name | | ./Endpoint/@level /code/@code="C139173" Limit to 254 characters. | |
| Outcome Measures. Primary Secondary Measure Information | Description | If available | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | | ./Endpoint/@level /code/@code="C139173" The endpoint text is based on the SyntaxTemplate class. Referenced values need to be replaced by actual values before submitting. Limit to 999 characters. | |
| Outcome Measures. Primary Secondary Measure Information | Time Frame | If any | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@ScheduleInstance /Timing/@value | ./Endpoint/@level /code/@code="C139173" In case of reference to the corresponding Timing class, check and use the referenced timing for this attribute. Limit to 254 characters. | |
| Outcome Measures. Other Pre-specified Outcome Measures | Title | If any | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@name | | ./Endpoint/@level /code/@code="C170559" Limit to 254 characters. | |
| Outcome Measures. Other Pre-specified Outcome Measures | Description | If available | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | | ./Endpoint/@level /code/@code="C170559" The endpoint text is based on the SyntaxTemplate class. Referenced values need to be replaced by actual values before submitting. Limit to 999 characters. | |
| Outcome Measures. Other Pre-specified Outcome Measures | Time Frame | If any | StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text | StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@ScheduleInstance /Timing/@value | ./Endpoint/@level /code/@code="C170559" In case of reference to the corresponding Timing class, check and use the referenced timing for this attribute. Limit to 254 characters. | |

This table presents the mapping to **Eligibility**. See Section 4.18, [Populations, Cohorts, and Eligibility Criteria](#), for a description of the related features in the USDM.

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Required USDM relationship | Selection/Derivation | USDM v4.0 |
|-------------------------|--------------------------------|--------------------------------|--|---|--|-----------|
| Eligibility. Sex/Gender | Sex | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex /code/@decode | | Map 1 to 1 to corresponding ct.gov terminology. | |
| Eligibility. Sex/Gender | Gender | If applicable | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex /code/@decode | | Set to Yes if only Male or Female are included. | NEW |
| Eligibility. Sex/Gender | Gender Eligibility Description | | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@criteria/EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex | The eligibility text is based on the SyntaxTemplate class (see Section 4.21). Referenced values need to be replaced by actual values before submitting. Limit to 1000 characters. Select the criterium referencing to the corresponding plannedSex value, if any. | |
| Eligibility. Age Limits | Minimum Age | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge /Range/@minValue | | | |
| Eligibility. Age Limits | Unit of Time | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge /Range/@unit /code/@decode | | Map 1 to 1 to corresponding ClinicalTrials.gov terminology. | |
| Eligibility. Age Limits | Maximum Age | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge /Range/@maxValue | | | |
| Eligibility. Age Limits | Unit of Time | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge /Range/@unit /code/@decode | | Map 1 to 1 to corresponding ClinicalTrials.gov terminology. | |
| Eligibility | Accepts Healthy Volunteers | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort/@includesHealthySubjects | | If any of the values is True then set to "Yes"; otherwise set to "No". | |
| Eligibility | Eligibility Criteria | Required | StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@criteria/EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | | The eligibility text is based on the SyntaxTemplate class. Referenced values need to be replaced by actual values before submitting. Select limited list for submission and limit to 20000 characters. | |
| Eligibility | Study Population Description | For observational studies only | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@description | | Limit to 1000 characters. | |

| CT.gov Path | CT.gov Variable | CT.gov Requirement | USDM path and attribute | Required USDM relationship | Selection/Derivation | USDM v4.0 |
|-------------|-----------------|--------------------------------|--|----------------------------|----------------------|-----------|
| Eligibility | Sampling Method | For observational studies only | StudyVersion/@studyDesigns /ObservationalStudyDesign/@samplingMethod | | | NEW |

15.3 Use of USDM for Populating Protocol Content

A secondary aim of the USDM is to demonstrate that protocol-related content can be pulled from a reference implementation of the USDM and populated programmatically into the corresponding fields of a structured document. The TransCelerate CPT is a [publicly available resource](#) proposed to harmonize clinical trial protocol content in a streamlined format. The following table indicates how the USDM v4.0 content can be used to populate the structured CPT fields of CPT version v010 including the [CPT_BWE document](#) that is the base Word template and the [CPT_TEE document](#) that is required to be used with the add-in.

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USDM v4.0 change |
|-------------------------------|---------------------------------------|--|--------------|----------------------------|--|-----------------|---|------------------|
| Page Header / Title Page | Version Number | CPT:VersionNumber | Text | OneToMany | StudyVersion/@documentVersions /studyDefinitionDocumentVersion/@version | Text | StudyVersion/@documentVersions In (studyDefinitionDocument/@version s where studyDefinitionDocument/@type /code=@code= "C70817" (Protocol)) | Y |
| Page Header / Title Page | Protocol ID | CPT:ProtocolID | Text | OneToOne | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | Text | StudyIdentifier/@scope IN (studyRole/@organizations where studyRole/@code /code=@code= "C70793" (Sponsor)) | Y |
| Title Page | Acronym | CPT:Acronym | Text | OneToOne | StudyVersion/@titles /StudyTitle/@Text | Text | ..StudyTitle/@Type/Code/@decode = "Study Acronym" | |
| Title Page | Protocol Short Title | CPT:ProtocolShortTitle | RichText | OneToOne | StudyVersion/@titles /StudyTitle/@Text | Text | ..StudyTitle/@Type/Code/@decode = "Brief Study Title" | |
| Title Page | Protocol Title | CPT:ProtocolTitle | RichText | OneToOne | StudyVersion/@titles /StudyTitle/@Text | Text | ..StudyTitle/@Type/Code/@decode = "Official Study Title" | |
| Title Page | Amendment Number | CPT:AmendmentNumber | Text | OneToOne | StudyVersion/@amendments /StudyAmendment/@number | Text | protocolAmendment: use previous attribute for sorting and take the number of last amendment | |
| Title Page | Compound Number | CPT:CompoundNumber | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct /AdministrableProduct/@identifiers /AdministrableProductIdentifier/@text | Text | | NEW |
| Title Page | Sponsor Name | CPT:SponsorName | Text | OneToOne | StudyVersion/@studyRoles /StudyRole/@organization /Organization/@name | Text | StudyRole/@code /Code/@code= "C70793" (Sponsor) | Y |
| Title Page | Sponsor Legal Address | CPT:SponsorLegalAddress | Text | OneToOne | StudyVersion/@studyRoles /StudyRole/@organization /Organization/@legalAddress /Address@text+@line+@district+ @city+@postalCode+@state | Text | StudyRole/@code /Code/@code= "C70793" (Sponsor) | Y |
| Title Page | Study Phase | CPT:StudyPhase | Choice | vs.CodeList | StudyVersion/@studyDesigns StudyDesign/@studyPhase /AliasCode/@standardCode /code/@decode | Coded value | Retrieve decode Value from standardCode element. Transform into CPT master code value | Y |
| Title Page / Synopsis | Blinding | | Text | OneToOne | StudyVersion/@studyDesigns /InterventionalStudyDesign/@blindingSchema / code/@decode | Coded value | | Y |
| Title Page / Synopsis | Primary Purpose | CPT:PrimaryPurpose | Text | OneToMany | StudyVersion/@studyDesigns /InterventionalStudyDesign/@intenTypes / code/@decode | Coded value | See Primary objective: .. /StudyDesign/@objectives /objective/@text where /StudyDesign/@objectives /objective/@level /code/@code= "C85826" Select the TrialType that relates to the primary objective. This can be digitized by adding a syntax template reference in the objective text to the corresponding subType instance. | Y |
| Title Page / Synopsis | Intervention Model | CPT:InterventionModel | Text | OneToOne | StudyVersion/@studyDesigns /InterventionalStudyDesign/@model /code/@decode | Coded value | See CDISC SDTM extensible codelist C99076 for USDM content aligning with CPT primary purpose codes. | Y |
| Title Page / Synopsis | Condition or Disease | CPT:ConditionDisease | Text | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@indications /indication/@name + @description | Text | | |
| Title Page / Synopsis | Regulatory Agency ID | CPT:RegulatoryAgencyID | Text | OneToOne | StudyVersion/@studyIdentifiers /StudyIdentifier/@scope /Organization/@name | Text | ..studyIdentifier/@studyIdentifierScope /Organization/@organizationType /code/@code= "C188863" (Regulatory Agency) | |
| Title Page / Synopsis | Regulatory Agency Number | CPT:RegulatoryAgencyNumber | Text | OneToOne | StudyVersion/@studyIdentifiers /StudyIdentifier/@text | Text | ..StudyIdentifier/@scope /Organization/@organizationType /code/@code= "C188863" (Regulatory Agency) | Y |
| Title Page / Synopsis | Pediatric Investigational Plan Number | CPT:PediatricInvestigationalPlanNumber | Text | OneToOne | StudyVersion/@referenceIdentifiers /ReferenceIdentifier/@text | Text | ..ReferenceIdentifier/@type /Code/@decode= "Pediatric Investigation Plan" | Y |
| Title Page / Study Population | Sex of participants | CPT:Sexofparticipants | Choice | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex /code/@decode | Coded value | Refer to CDISC codelist for Sex and corresponding eCPT mapping values in Data mapping sheet | |
| Title Page | Protocol Approval Date | CPT:ApprovalDate | Text | OneToOne | StudyVersion/@documentVersions /studyDefinitionDocumentVersion/@dateValues /GovernanceDate/@dateValue | Date | StudyVersion/@documentVersions In (studyDefinitionDocument/@version s where | Y |

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USD M v4.0 change |
|---|----------------------------------|-----------------------------------|--------------|----------------------------|--|---------------------|---|-------------------|
| | | | | | | | studyDefinitionDocument/@type /code/@code= "C70817" (Protocol) GovernanceDate/@type /code/@Code= C132352 ("Sponsor approval date") | |
| List of Abbreviations | List of Abbreviations | CPT:ListOfAbbreviations | Rich Text | OneToMany | StudyVersion/@abbreviations /Abbreviation/@abbreviatedText + @expandedText | Text | | Y |
| Synopsis | Rationale | CPT:Rationale | Rich Text | OneToOne | StudyVersion/@rationale | Text | | |
| Synopsis | Number of Participants | CPT:NumberofParticipants | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedCompletionNumber /Range:@MinValue + @MaxValue | Integer | Combine MinValue and MaxValue. If equal then only one of both. | |
| Synopsis | Enrollment Target | CPT:EnrollmentTarget | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedEnrollmentNumber /Range:@MinValue + @MaxValue | Integer | Combine MinValue and MaxValue. If equal then only one of both. | |
| Synopsis | Number of Arms | CPT:NumberofArms | Text | Count | StudyVersion/@studyDesigns /StudyDesign/@arms | | Count the number of arms defined within the study design. | |
| Synopsis / Objectives, Endpoints, and Estimands | Primary Objectives | CPT:ObjectivesPrimary | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text | Text | Objective@level /code/@Code = "C85826" (Primary Objective) Objectives are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of ObjectivesPrimary | |
| Synopsis / Objectives, Endpoints, and Estimands | Primary Endpoints | CPT:EndpointsPrimary | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Text | Endpoint@level /code/@Code = "C94496" (Primary Endpoint) Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of EndpointsPrimary. They can be grouped with the corresponding objective via the objective-endpoint relationship. | |
| Synopsis / Objectives, Endpoints, and Estimands | Secondary Objectives | CPT:ObjectivesSecondary | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text | Text | Objective@level /code/@Code = "C85827" (Secondary Objective) Objectives are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of ObjectivesSecondary. | |
| Synopsis / Objectives, Endpoints, and Estimands | Secondary Endpoints | CPT:EndpointsSecondary | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Text | Endpoint@level /code/@Code = "C139173" (Secondary Endpoint) Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of EndpointsSecondary. They can be grouped with the corresponding objective via the objective-endpoint relationship. | |
| Synopsis | Overall Design Synopsis | CPT:OverallDesignSynopsis | Rich Text | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Overall Design Synopsis" and it should be a child within section 1.1 with title "Synopsis". | |
| Synopsis | Brief Summary | CPT:BriefSummary | Rich Text | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Brief Summary" and it should be a child within section 1.1 with title "Synopsis". | |
| Synopsis | Masking | CPT:Masking | Text | OneToMany | StudyVersion/@studyRoles/ StudyRole/@code /code/@decode | Coded value | include all roles for which studyRole@masking is defined. Combine decoded role(s) if more than 1. Align CPT coded values with DDF coded values for Masking roles. | Y |
| Synopsis | Randomly Assigned / enrolled | CPT:RandomlyAssignedEnrolled | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode | Coded value | If USDM decodes include "RANDOMIZED" then value for CPT will be randomized, otherwise depending on the study design it can be set to enrolled or assigned to investigational intervention. | |
| Synopsis | Intervention Groups and Duration | CPT:InterventionGroupsandDuration | Rich Text | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Brief Summary" and it should be a child within section 1.1 with title "Study Arms and Duration". The Narrative content text may include references to the corresponding arm descriptions in the arm class and timing of the last intervention day. | |
| Schema | Schema | CPT:Schema | Picture | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle. For CPT the section should be 1.2 with title "Schema". HTML content need to include the schema as picture. | |
| Study Rationale | Study Rationale | CPT:StudyRationale | Rich Text | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle | |

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USD M v4.0 change |
|--------------------------------------|---------------------------------------|---------------------------------------|--------------|----------------------------|--|---------------------|---|-------------------|
| | | | | | | | For CPT the section should be 2.1 with title "Study Rationale". This may include a reference to Study/@version /StudyVersion/@Rationale which is mapped to the rationale presented in the synopsis. | |
| Objectives, Endpoints, and Estimands | Objectives, Endpoints, and Estimands | CPT:ObjectivesEndpointsAndEstimands | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle. For CPT the section should be 3.0 with title "Objectives, Endpoints, and Estimands". This should include references to the objectives and endpoints stored in the corresponding classes. | |
| Objectives, Endpoints, and Estimands | Tertiary Exploratory Objectives | CPT:ObjectivesTertiaryExploratory | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Objective/@text | Text | Objective@level /code @Code = "C163559" (Exploratory Objective) Objectives are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of ObjectivesTertiaryExploratory. | |
| Objectives, Endpoints, and Estimands | Tertiary Exploratory Endpoints | CPT:EndpointsTertiaryExploratory | RichText | OneToMany | StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@endpoints /Endpoint/@text | Text | Endpoint@level /code @Code = "C170559" (Exploratory Endpoint) Endpoints are based on the SyntaxTemplate class. References values need to be replaced by actual values before creation of EndpointsTertiaryExploratory. They can be grouped with the corresponding objective via the objective-endpoint relationship. | |
| Objectives, Endpoints, and Estimands | Primary Estimands | CPT:PrimaryEstimands | RichText | OneToOne | StudyVersion/@StudyDesigns /StudyDesign/@estimands /Estimand/@name and/or @description | HTML formatted Text | Where /Estimand/@variableOfInterest in (studyDesign/objectives /Objective/@endpoints where Endpoint@level /code @code = "C94496" (Primary endpoint)) | Y |
| Objectives, Endpoints, and Estimands | Secondary Estimands | CPT:SecondaryEstimands | RichText | OneToOne | StudyVersion/@StudyDesigns /StudyDesign/@estimands /Estimand/@name and/or @description | HTML formatted Text | Where /Estimand/@variableOfInterest in (studyDesign/objectives /Objective/@endpoints where Endpoint@level /code @code = "C139173" (Secondary endpoint)) | Y |
| Objectives, Endpoints, and Estimands | Tertiary Estimands | CPT:TertiaryEstimands | RichText | OneToOne | StudyVersion/@StudyDesigns /StudyDesign/@estimands /Estimand/@name and/or @description | HTML formatted Text | Where /Estimand/@variableOfInterest in (studyDesign/objectives /Objective/@endpoints where Endpoint@level /code @code = "C170559" (Tertiary endpoint)) | Y |
| Study Design | Study Design | CPT:StudyDesign | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Study Design" with section number 4. The text may link to attributes that are stored elsewhere in the USDM and that are relevant to the study design. | |
| Study Design | Overall Design | CPT:OverallDesign | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Overall Design" with section number 4.1. The text may link to attributes that are stored elsewhere in the USDM and that are relevant to the overall design. | |
| Study Design | Scientific Rationale for Study Design | CPT:ScientificRationaleforStudyDesign | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Scientific Rationale for Study Design" with section number 4.2. | |
| Study Population | Inclusion Criteria Age | CPT:InclusionCriteriaAge | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. The criterion text may link to Minimum and Maximum age stored in the Study Design Population or Cohort classes. | Y |
| Study Population | Planned Minimum Age of Subjects | CPT:PlannedMinimumAgeofSubjects | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation /StudyCohort/@plannedAge /Range/@minValue + @unit | Text | Use minimum of minimum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. If 1 or more populations have a null minValue then TSVAL should be set to null and TSVALNF should be filled instead according to ISO 21090. | |
| Study Population | Planned Maximum Age of Subjects | CPT:PlannedMaximumAgeofSubjects | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation /StudyCohort/@plannedAge /Range/@maxValue + @unit | Text | Use maximum of maximum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. If 1 or more populations have a null maxValue then TSVAL should be set to null | |

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USD M v4.0 change |
|------------------|--|---|--------------|----------------------------|--|---------------------|--|-------------------|
| | | | | | | | and TSVALNF should be filled instead according to ISO 21090. | |
| Study Population | Inclusion Criteria Type of Participants | CPT:InclusionCriteriaTypeOfParticipant | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="INCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Inclusion Criteria Weight | CPT:InclusionCriteriaWeight | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="INCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Inclusion Criteria Sex | CPT:InclusionCriteriaSex | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="INCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. The criterion text may link to planned Sex stored in the Study Design Population or Cohort classes. | Y |
| Study Population | Inclusion Criteria Informed Consent | CPT:InclusionCriteriaInformedConsent | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="INCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Inclusion Criteria Other | CPT:InclusionCriteriaOther | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="INCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Medical Conditions | CPT:ExclusionCriteriaMedicalConditions | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Liver Safety | CPT:ExclusionCriteriaLiverSafety | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Prior Concomitant Therapy | CPT:ExclusionCriteriaPriorConcomitantT | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Prior Concurrent Clinical Study | CPT:ExclusionCriteriaPriorConcurrentClinicalStudy | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Diagnostic Assessments | CPT:ExclusionCriteriaDiagnosticAssessments | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |
| Study Population | Exclusion Criteria Other | CPT:ExclusionCriteriaOther | Text | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@criteria /EligibilityCriterion/@criterionItem /EligibilityCriterionItem/@text | HTML formatted Text | Select content based on EligibilityCriterion/@category/ code/@decode="EXCLUSION" and /EligibilityCriterion/@notes The CPT parameter may be indicated in the corresponding /CommentAnnotation/@text or a custom code may indicate the grouping of the eligibility criteria. | Y |

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USD M v4.0 change |
|----------------------------------|------------------------------|-------------------------------|--------------|----------------------------|--|---------------------|--|-------------------|
| Study Interventions Administered | Intervention Label | CPT:InterventionLabel | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@label | Text | | |
| Study Interventions Administered | Intervention Name | CPT:InterventionName | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name | Text | | |
| Study Interventions Administered | Intervention Description | CPT:InterventionDescription | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@description | Text | | |
| Study Interventions Administered | Intervention Type | CPT:InterventionType | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@type /code/@decode | Coded value | | |
| Study Interventions Administered | Dose Formulation | CPT:DoseFormulation | RichText | | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct /AdministrableProduct/@administrableDoseForm /code/@decode | Coded value | | Y |
| Study Interventions Administered | Unit Dose Strength | CPT:UnitDoseStrength | RichText | | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct /AdministrableProduct@ingredients /ingredient/@substance Substance/@strengths /strength/@numerator+@denominator /Quantity/@value+@unit /code/@decode | Coded value | where Ingredient/@role /code/@decode = "Active" | NEW |
| Study Interventions Administered | Dosage Level | CPT:DosageLevel | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@dose /Quantity/@value + ... Quantity/@unit /code/@decode + ... AgentAdministration/@frequency AliasCode/@standardCode /Code/@decode | Text + Coded values | Combine administration strength, corresponding unit and frequency to 1 variable for CPT | Y |
| Study Interventions Administered | Route of Administration | CPT:RouteofAdministration | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /Administration/@route /code/@decode | Coded value | | Y |
| Study Interventions Administered | Use | CPT:Use | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@role /code/@decode | Coded value | | |
| Study Interventions Administered | IMP and NIMP | CPT:IMPAandNIMP | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct AdministrableProduct/@productDesignation /code/@decode | Coded Value | | Y |
| Study Interventions Administered | Sourcing | CPT:Sourcing | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct AdministrableProduct@sourcing /code/@decode | Coded Value | | NEW |
| Study Interventions Administered | Packaging and Labeling | CPT:PackagingandLabeling | RichText | | may be stored in administrableProduct notes | | | |
| Study Interventions Administered | Current Former Names Aliases | CPT:CurrentFormerNamesAliases | RichText | | StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@administrations /Administration/@administrableProduct AdministrableProduct/@name or @label | Text | | NEW |
| Study Interventions Administered | Arm Name | CPT:ArmName | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name | Text | | |
| Study Interventions Administered | Arm Type | CPT:ArmType | RichText | OneToOne | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@type /code/@decode | Coded value | | |
| Study Interventions Administered | Arm Description | CPT:ArmDescription | RichText | OneToOne ManyToOne | StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@description | Text | studyArmDescription, ArmName and Decode Value of ArmType to be sent as an arrayList in response. | |
| Statistical Considerations | General Considerations | CPT:GeneralConsiderations | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "General Considerations" with section number 9.1. | |
| Statistical Considerations | Statistical Hypotheses | CPT:StatisticalHypotheses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Decision Criteria/Statistical Hypotheses" with section number 9.1.1. | |
| Statistical Considerations | Populations for Analyses | CPT:PopulationsForAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Analysis Sets" with section number 9.2. | |
| Statistical Considerations | Statistical Analyses | CPT:StatisticalAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Analyses Supporting Primary Objective(s)" with section number 9.3. | |
| Statistical Considerations | Primary Endpoint Analysis | CPT:PrimaryEndpointAnalysis | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Primary Endpoint(s)/Estimand(s)" with section number 9.3.1. | |
| Statistical Considerations | Secondary Endpoint Analysis | CPT:SecondaryEndpointAnalysis | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Analyses Supporting Secondary Objective [/label]" with section number 9.4.1. | |

| CPT Section | CPT Variable Display Name | CPT Variable Name (compacted) | CPT Var Type | Mapping Type (CPT to USDM) | USDM Path and Attribute | USDM Field Type | Selection / Derivations | USD M v4.0 change |
|----------------------------|--|---|--------------|----------------------------|--|---------------------|--|-------------------|
| Statistical Considerations | Tertiary Exploratory Endpoint Analysis | CPT:TertiaryExploratoryEndpointAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Analyses Supporting [/Tertiary/Exploratory/Other] Objective(s)" with section number 9.5. | |
| Statistical Considerations | Other Safety Analyses | CPT:OtherSafetyAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "[Other] Safety Analyses" with section number 9.6. | |
| Statistical Considerations | Other Analyses | CPT:OtherAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Other Analyses" with section number 9.7. | |
| Statistical Considerations | Interim Analyses | CPT:InterimAnalyses | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Interim [/Analysis/Analyses]" with section number 9.8. | |
| Statistical Considerations | Sample Size Determination | CPT:SampleSizeDetermination | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "Sample Size Determination" with section number 9.9. | |
| References | References | CPT:References | RichText | OneToOne | Study/@documentedBy /Document/@versions /DocumentVersion/@contents /NarrativeContent/@contentItems /contentItems/@text | HTML formatted Text | Select content based on NarrativeContent/@sectionNumber and/or @sectionTitle For CPT the sectionTitle should be "References" with section number 11. | |

16 Appendices

- [USDM Team](#)
- [Glossary and Abbreviations](#)
- [References](#)
- [Revision History](#)
- [Representations and Warranties, Limitations of Liability, and Disclaimers](#)

16.1 USDM Team

| Name | Institution/Organization |
|--------------------|--|
| John Owen | Project Manager, CDISC |
| Dave Iberson-Hurst | USDM Product Owner, CDISC |
| Berber Snoeijer | USDM Technical Team Lead, CDISC |
| Erin Muhlbradt | Controlled Terminology Expert, NCI-EVS |
| Craig Zwickl | Controlled Terminology Expert, CDISC |
| Richard Marshall | USDM Developer, CDISC |

The USDM has been developed in partnership with TransCelerate Biopharma and Accenture. CDISC would like to acknowledge the support and input from the following groups:

- TransCelerate DDF Core Team
- TransCelerate member company subject-matter experts
- Accenture DDF development team
- CDISC DDF volunteer teams and volunteer vendor organizations

16.2 Glossary and Abbreviations

The following abbreviations and terms are used in this document. Additional definitions can be found in Section 5, [USDM Data Dictionary](#), and in the [CDISC Glossary](#).

| | |
|-----------|---|
| API | Application programming interface |
| BRIDG | Biomedical Research Integrated Domain Group |
| BC | Biomedical concept: A unit of biomedical knowledge created from a unique combination of characteristics that include implementation details like variables and terminologies, used as building blocks for standardized, hierarchically structured clinical research information |
| CDISC | Clinical Data Interchange Standards Consortium |
| CeSHarP | (ICH) Clinical Electronic Structured Harmonised Protocol |
| Collected | “Collected” refers to information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. This term is a synonym for “captured.” |
| CPT | (TransCelerate) Common Protocol Template |
| CRF | Case report form (sometimes, case record form): A printed, optical, or electronic document designed to record all required information to be reported to the sponsor for each trial subject |
| CRO | Contract research organization |
| CT | Controlled terminology: A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. A codelist is a type of controlled terminology. |
| CTIS | Clinical Trials Information System (EMA) |
| CTR | Clinical Trial Registry |
| DDF | Digital Data Flow (project) |
| Domain | A collection of observations with a topic-specific commonality about a subject |
| DUNS | Data universal numbering system |
| eCRF | Electronic case report form |
| ECG | Electrocardiogram |
| EDC | Electronic data capture |
| EHR | Electronic health record |
| EMA | European Medicines Agency |
| ePRO | Electronic patient-reported outcome |
| EudraCT | European Union Drug Regulating Authorities Clinical Trial Database |
| FDA | (US) Food and Drug Administration |
| FHIR | (HL7) Fast Healthcare Interoperability Resources |
| GARD | (NIH) Genetic and Rare Diseases Information Center |
| GENC | (FDA) Geopolitical Entities, Names and Codes |
| HL7 | Health Level Seven International |
| HTML | HyperText Markup Language |
| ICE | Intercurrent events; events that occur after randomization and alter the course of the randomized treatment during the intended study treatment period |
| ICD | International Classification of Diseases |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| IDMP | (ISO) Identification of Medicinal Products (standards) |
| IMP | Investigational medical product |
| IOS | International Organization for Standardization |
| JSON | JavaScript Object Notation |
| LOINC | Logical Observation Identifiers Names and Codes |
| MedDRA | Medical Dictionary for Regulatory Activities. A global standard medical terminology designed to supersede, in regulatory submissions, other terminologies previously used in the medical product development process (such as COSTART and ICD9). |
| MeSH | Medical Subject Headings (thesaurus) |

| | |
|-------------------------|--|
| NCI EVS | (NIH) National Cancer Institute Enterprise Vocabulary Services |
| NCT | National clinical trial |
| NIH | National Institutes of Health |
| NMP | Noninvestigational medical product |
| ODM | Operational Data Model |
| On-Demand USDM Training | Official USDM educational material available for learners to access from the CDISC Learning Management System (LMS). Training materials and resources are available to learners at any time and from any location. This type of training allows individuals to access courses, videos, tutorials, and other educational content whenever they need it, rather than following a fixed schedule. |
| Patient | A recipient of medical treatment |
| PDF | Portable data format |
| PHR | Personal health record |
| POC | Proof of concept |
| POV | Proof of viability |
| PRM | Protocol Representation Model |
| PRO | Patient-reported outcome |
| SDM-XML | Study/Trial Design Model in XML, extension of ODM-XML |
| SDR | Study Definitions Repository |
| SDTM | Study Data Tabulation Model |
| SDTMIG | SDTM Implementation Guide (for Human Clinical Trials) |
| SME | Subject-matter expert |
| SNOMED | Systemized Nomenclature of Medicine |
| SOA | Schedule of activities |
| SSU | Study start-up |
| Subject | A participant in a study |
| UML | Unified modeling language |
| USDM | United Study Definitions Model |
| USDM-IG | USDM Implementation Guide |
| UUID | Universally unique identifier |
| WHO | World Health Organization |
| XML | Extensible markup language |

16.3 References

1. National Cancer Institute Biomedical Research Integrated Domain Group. About BRIDG. Accessed February 27, 2025. <https://bridgmodel.nci.nih.gov/about-bridg>
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6. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Accessed February 27, 2025. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745>
7. ClinicalTrials.gov. Protocol registration data element definitions for interventional and observational studies. National Library of Medicine. Updated June 27, 2024. Accessed February 27, 2025. <https://clinicaltrials.gov/policy/protocol-definitions>

16.4 Revision History

16.4.1 USDM Implementation Guide

This section details the changes made to the USDMIG between v3.0 and v4.0.

| # | Release # | Overview | Notes |
|---|-----------|--|--|
| 1 | 3.2 | UML update for Arms and Epochs section | <ul style="list-style-type: none"> • Name of encounter attribute environmentalSetting changed to environmentalSettings • Added notes attributes to Encounter, StudyArm, StudyElement and StudyEpoch classes |
| 2 | | UML update for Study Timing section | <ul style="list-style-type: none"> • Moved relationships timeline and timelineExit. • Name of encounter attribute environmentalSetting changed to environmentalSettings. • Added description for encounter timing - scheduledAt |
| 3 | | UML and text update for Populations, Cohorts, and Eligibility Criteria section | <ul style="list-style-type: none"> • Added relationship criteria from StudyVersion to EligibilityCriterion. |

| # | Release # | Overview | Notes |
|----|-----------|---|--|
| | | | <ul style="list-style-type: none"> Changed criteria cardinality from PopulationDefinition to EligibilityCriterion from 1..* to 0..* in UML. Added notes attributes to PopulationDefinition, SyntaxTemplate, Indication, StudyArm, StudyDesign and StudyVersion classes. Updated text accordingly to specify that criteria should either be referenced from Study Population or from Study Cohort. Updated text regarding eligibility criteria: removed reference to context attribute and specify that they are defined within a study version. Added explanation of previous/next criteria |
| 4 | | UML update for Study, Protocols, and Amendments section | <ul style="list-style-type: none"> Added notes attributes to StudyVersion and StudyDesign classes. |
| 5 | | UML update for Study Identifiers and Titles | <ul style="list-style-type: none"> Added notes attribute to StudyVersion class. |
| 6 | | UML and text update for Activities section | <ul style="list-style-type: none"> Added notes attribute to Activity, Procedure, BiomedicalConcept, BiomedicalConceptSurrogate, BiomedicalConceptCategory, and BiomedicalConceptProperty classes. Added ScheduleTimeline class to the UML view Explained the use of timeline attribute in the Activity class |
| 7 | | UML update for Study Interventions section | <ul style="list-style-type: none"> Added notes attributes to StudyIntervention and AgentAdministration classes. |
| 8 | | UML update for Study Objectives and Endpoints section | <ul style="list-style-type: none"> Added notes attributes to Estimand, AnalysisPopulation, IntercurrentEvent, StudyIntervention and SyntaxTemplate classes. Added name, description and label to Estimand class |
| 9 | | UML update for Syntax Templates section | <ul style="list-style-type: none"> Added notes attribute to SyntaxTemplate class. |
| 10 | 3.3 | UML and text update for Activities section | <ul style="list-style-type: none"> Added children attribute to Activity class Added example to explain how SoA activities are stored in the Activity class with respect to the previous, next and children attributes. |
| 11 | 3.3 | UML and text update for Study Timing section | <ul style="list-style-type: none"> Changed cardinality for relativeFromScheduleInstance relationship Added corresponding text for anchors relativeToScheduleInstance relationship should be equal to relativeFromScheduleInstance or missing. |
| 12 | 3.4 | Updated CPT mapping section for v3.0 and further alignment | |
| 13 | 3.4 | Updated Unstructured Content section to include multiple template support | <ul style="list-style-type: none"> Added new UML view for documents. Adjusted text to include new NarrativeContentItem and reusability of text across documents. |

| # | Release # | Overview | Notes |
|----|-----------|---|---|
| 14 | | Updated Study, Protocols, and Amendments section to include multiple template support | <ul style="list-style-type: none"> • Updated UML. • Adjusted text to refer to the right classes. |
| 15 | 3.5 | Updated Study, Protocols, and Amendments section to include abbreviations | <ul style="list-style-type: none"> • Updated UML. • Added text to explain the use of the new abbreviation class and corresponding attributes. |
| 16 | 3.6 | Created Abbreviations section to give examples of how it can be used. | <ul style="list-style-type: none"> • Created new section with examples. |
| 17 | | Updated Study, Protocols, and Amendments section. | <ul style="list-style-type: none"> • Created cross-reference to Abbreviations section. |
| 18 | | Updated XHTML Attributes section. | <ul style="list-style-type: none"> • Referred to NarrativeContentItem instead of NarrativeContent. |
| 19 | | Updated Study Identifiers and Titles section. | <ul style="list-style-type: none"> • Updated UML to include inheritance of identifier class and to add reference identifiers. • Updated text to add explanation of reference identifiers. |
| 20 | | Updated Use of USDM for Populating Protocol Content section | <ul style="list-style-type: none"> • Include mapping to pediatric investigational plan number. • Updated mappings based on changed attribute names. |
| 21 | | Updated Study Interventions section | <ul style="list-style-type: none"> • Updated UML to include all changes for the new model version. • Updated explanation of the model and included some references to IDMP. |
| 22 | | Updated Controlled Terminology section | <ul style="list-style-type: none"> • Small tweak to section on AliasCode to clarify that standard value sets do not have to be CDISC code lists. |
| 23 | | Updated Populations, Cohorts, and Eligibility Criteria section | <ul style="list-style-type: none"> • Updated UML to include small change on plannedSex relationship. • Updated text to explain the use of plannedSex (use Male and/or Female). |
| 24 | | Updated Study Roles and Organizations section | <ul style="list-style-type: none"> • Changed section name from 'Organizations' to 'Study Roles and Organizations'. • Updated UML to include significant changes in the model. • Updated text to explain this part of the model and expected use. |
| 25 | 3.7 | Updated Study Identifiers and Titles section | <ul style="list-style-type: none"> • Changed address line to lines in UML |
| 26 | | Updated Study Roles and Organizations section | <ul style="list-style-type: none"> • Changed address line to lines in UML |
| 27 | | Updated Study, Protocols, and Amendments section | <ul style="list-style-type: none"> • Updated UML and text to include studyAmendMentChange, StudyAmendmentImpact and changes to the studyEnrollment class • Moved abbreviation part out of UML and text to abbreviation section. |
| 28 | | Updated Study Design section | <ul style="list-style-type: none"> • Added UML • Updated text to indicate all referenced areas not reflected in UML and explain other references |
| 29 | 3.8 | Updated Study Design section | <ul style="list-style-type: none"> • Updated UML to include studyDocumentVersions relationship • Added reference to Study, Protocols, and Amendments |

| # | Release # | Overview | Notes |
|----|-----------|--|--|
| 30 | 3.9 | Updated Study Objectives and Endpoints section | <ul style="list-style-type: none"> • updated UML to include new estimand changes |
| 31 | | Updated Study Estimands section | <ul style="list-style-type: none"> • updated text to include new estimand changes |
| 32 | | Updated Principles section | <ul style="list-style-type: none"> • Removed "(phase 3 onwards; not true for phases 1 and 2)" from "Support the whole protocol document". |
| 33 | | Updated Study Identifiers and Titles section | <ul style="list-style-type: none"> • Updated UML view to include StudyRole class • Updated text regarding new StudyRole requirements for sponsor identifiers • Added instance diagrams to further explain the representation of identifiers |
| 34 | | Updated Study Roles and Organizations section | <ul style="list-style-type: none"> • Textual improvements aligning with new CT • Added instance diagrams to further illustrate the representation of roles and organizations |
| 35 | | Updated Study, Protocols, and Amendments section | <ul style="list-style-type: none"> • Updated UML to include the relationship appliesTo from DocumentContentReference class to the StudyDefinitionDocument class. |
| 36 | | Updated Study Interventions section | <ul style="list-style-type: none"> • Updated UML and corresponding text for addition of medical devices to the model. • Added instance diagram as an example with corresponding explanation. |
| 37 | 3.10 | Updated Populations, Cohorts, and Eligibility Criteria section | <ul style="list-style-type: none"> • Updated UML for change of range unit. |
| 38 | | Updated Study, Protocols, and Amendments section | <ul style="list-style-type: none"> • Updated UML for movement of StudyPhase and StudyType to StudyDesign class. |
| 39 | | Updated Populations, Cohorts, and Eligibility Criteria section | <ul style="list-style-type: none"> • Updated UML to reflect new StudyDesign subclasses. |
| 40 | | Updated Study Design section | <ul style="list-style-type: none"> • Updated UML to reflect new StudyDesign subclasses and other changes. • Updated text to align with changes and add observational study features. • Added Instance diagrams to show how data can be stored in the study. |
| 41 | | Updated Study Objectives and Endpoints section | <ul style="list-style-type: none"> • Updated UML to reflect dependency on StudyDesign class and the different subclasses. |
| 42 | | Updated Creation of SDTM Trial Design Domains section | <ul style="list-style-type: none"> • Updated mappings to align with USDM updates until v3.10 and SDTM CT version 2024-09-27 |
| 43 | | Updated Informing ClinicalTrials.gov Registry section | <ul style="list-style-type: none"> • Updated mappings to align with USDM updates until v3.10 |
| 44 | | Updated Use of USDM for Populating Protocol Content section | <ul style="list-style-type: none"> • Updated mappings to align with USDM updates until v3.10 |
| 45 | 3.11 | Updated Arms and Epochs section | <ul style="list-style-type: none"> • Updated UML to reflect updated relationship cardinality between StudyCell and StudyElement classes. • Updated UML to replace complex datatype relationships with attributes. |
| 46 | | Updated Study, Protocols, and Amendments section | <ul style="list-style-type: none"> • Updated UML to reflect updated subjectEnrollment appliesTo relationships. • Updated UML to replace complex datatype relationships with attributes. |

| # | Release # | Overview | Notes |
|----|-----------|--|--|
| | | | <ul style="list-style-type: none"> • Updated text to fully reflect all v4.0 changes. • Added an instance diagram and corresponding text to visualize an implementation of a complex study including a master protocol with several sub-studies and corresponding protocol versions. |
| 47 | | Updated Study Roles and Organizations section | <ul style="list-style-type: none"> • Updated UML to reflect updated subjectEnrollment appliesTo relationships. • Updated UML to replace complex datatype relationships with attributes. • Updated UML to reflect changes in masking class. |
| 48 | | Updated Study Interventions section | <ul style="list-style-type: none"> • Updated UML to reflect the change in strength numerator to numerator range or quantity • Small updates to text to reflect change in strength numerator • Updated UML to replace complex datatype relationships with attributes. • Updated instance diagrams to remove cross references to code class and include changes to the model. • Updated UML to reflect change for administrationDuration.reasonDurationWillVary to optional |
| 49 | | Updated Populations, Cohorts, and Eligibility Criteria section | <ul style="list-style-type: none"> • Updated UML to reflect the change in <ul style="list-style-type: none"> ◦ plannedEnrollment and plannedCompletion number ◦ referential integrity for study design population (now required) ◦ eligibility criterion class to allow for reuse of criterion items across designs • Updated text to reflect changes mentioned for the UML • Updated UML to replace complex datatype relationships with attributes. • Updated UML to correct blindingSchema datatype and align with API |
| 50 | | Updated Naming Conventions section | <ul style="list-style-type: none"> • Data Types description updated in alignment with UML simplification for complex data types. |
| 51 | | Updated Study Identifiers and Titles section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. • Restructured text order for readability purposes. |
| 52 | | Updated Study Design section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. • Updated UML to correct blindingSchema datatype and align with API |
| 53 | | Updated Activities section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. |
| 54 | | Updated Study Timing section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. |
| 55 | | Updated Study Objectives and Endpoints section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. |
| 56 | | Updated Unstructured Content section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. |
| 57 | | Updated Syntax Templates section | <ul style="list-style-type: none"> • Updated UML to replace complex datatype relationships with attributes. |
| 58 | | Moved Addressing Footnotes section | <ul style="list-style-type: none"> • Moved the section to the end of the USDM Features chapter to group the implementation sections at the end. |
| 59 | | Created Complex Study Designs section | <ul style="list-style-type: none"> • Added example of real-world data control arm study |

| # | Release # | Overview | Notes |
|----|-----------|---|--|
| | 60 | | <ul style="list-style-type: none"> Added example of oncology multiple cohort study Added example of multi-step treatment schedule Added description and references for Basket/Umbrella and multi-phased studies Added description for Decentralized trials |
| 60 | | Updated USDM API section | <ul style="list-style-type: none"> Updated text to align with version 4.0 Subdivided to allow for better document navigation Added description of extension mechanism |
| 61 | | Updated Overview section | <ul style="list-style-type: none"> Updated text to align with version 4.0 |
| 62 | | Created Schedule of Activity Views section | <ul style="list-style-type: none"> Pictured a simple SoA in different formats Described a number of suggestions for deploying USDM SoA information. |
| 63 | | Updated Relationship to Other Standards and Formats section | <ul style="list-style-type: none"> Added IDMP alignment text |
| 64 | | Removed Indication section | <ul style="list-style-type: none"> Moved text to Populations, Cohorts, and Eligibility Criteria section. Added cross-referencing information from cohort to indication to this information. |
| 65 | | Updated Abbreviations section | <ul style="list-style-type: none"> Improved textual description for readability purposes. |
| 66 | | Updated Addressing Footnotes section | <ul style="list-style-type: none"> Adjusted description for multiple environmental settings |
| 67 | | Updated the mapping to other standards sections | <ul style="list-style-type: none"> Added the new references to the EligibilityCriterionItem class. |

16.5 Representations and Warranties, Limitations of Liability, and Disclaimers

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