USDM-IG compiled

Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 4.0 (Draft)

Prepared by the
DDF Team

Notes to Readers

- This is the draft version of the Unified Study Definitions Model Implementation Guide (intended to be USDMIG v4.0).
- This version has been created using a simple print from the USDMIG Wiki version and not the full copy edited version. This copy editing step will take place before public review and publication.
- Note that the Data Dictionary section contains a table that is truncated. Please refer to the the Wiki version to see the full table.

Revision History

Date	Version
	4.0 Draft

Contents

1 Introduction

CDISC, in collaboration with TransCelerate Biopharma and Accenture as a part of TransCelerate's Digital Data Flow (DDF) Project, have developed a Study Definition Reference Architecture called the Unified Study Definitions Model (USDM).

The aim of TransCelerate's DDF initiative is to optimize study start-up (SSU) processes and automate system configuration and readiness. The current state typically involves disconnected study design services and assets and transcription or re-entry of the same information into many systems across sponsors, contract research organizations,

and systems vendors. This inefficiency results in systems configuration falling onto the critical path for SSU and adds risks for transcription errors and unnecessary delays.
Ideally, a solution would enable interoperability across multiple systems in a clinical study, improve efficiency and data quality, and reduce cycle times. That solution should capture protocol elements and present them in standardized formats to enable automated configuration of downstream systems and efficient consumption of protocol information across the study ecosystem.
The challenge is that SSU system configuration workflow and asset creation is currently not automated, which makes it inefficient and increases the risk of error. Current workflows also include a number of redundant, manual activities. Sponsors are not able to utilize resources efficiently due to the siloed, document-based environment.
Additional information can be found on the TransCelerate Digital Data Flow Solutions web page.
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 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 new to DDF, visit the TranCelerate YouTube channel, which includes several videos 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 4 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)

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 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 has been aligned to cover the breadth of sections found in the ICH M11 CeSHarP template. This will allow 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 can 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 can be utilized 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 includes model enhancements to support use of the USDM and ensure consistency within the model, such as updating the 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 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.

6.1 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.

6.1.1 BRIDG

The Biomedical Research Integrated Domain Group (BRIDG) is a CDISC, HL7, and ISO "standard for biomedical research concepts designed to support computable semantic interoperability."[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.

6.1.2 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.

6.1.3 SDTM and SDTMIG

The Study Data Tabulation Model (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 model 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 one 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.

6.1.4 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.

6.1.5 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 World Health Organization (WHO), the European Medicines Agency (EMA), the EudraCT Registry, and United States ClinicalTrials.gov.
Working alongside clinical trial registry SMEs, an evaluation was performed to determine how USDM could be utilized 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.

6.1.6 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.

6.1.7 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.

6.2 Relationship to Other Standards

6.2.1 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 v3.0 development. Working closely with ICH, USDM v3.0 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 v3.0, 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.

6.2.2 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).

7 USDM Features

7.1 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. Version of the external protocol that the study relates to
    b. Various identifiers allocated to the study
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. A detailed data specification for the data to be captured as part of the study
    d. Procedures to be performed as part of the study design
    e. Timing of collection of data and the performance of procedures
    f. Subject populations defined within the study design
    g. Objectives and endpoints defined within the study design
    h. Study estimands defined within the study design
    i. Interventions defined as part of the study design
    j. The relevant indication

Although the USDM is designed to hold 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.

7.2 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. Implementators should be able to relax constraints if they are building protocols.
- The model should not prevent implementators 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).

7.3 Naming Conventions

7.4 General

USDM v3.0 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.

7.5 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.

7.6 Data Types

Attributes have been provided with simple data types. The USDM generally avoids the use of complex data types. Where there is a need for a complex data type, a separate class is created.

7.7 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.

7.8 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. Implementations are free to allocate the value to this field using, for example, a UUID, to ensure uniqueness within the implementation.

7.9 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 one 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.

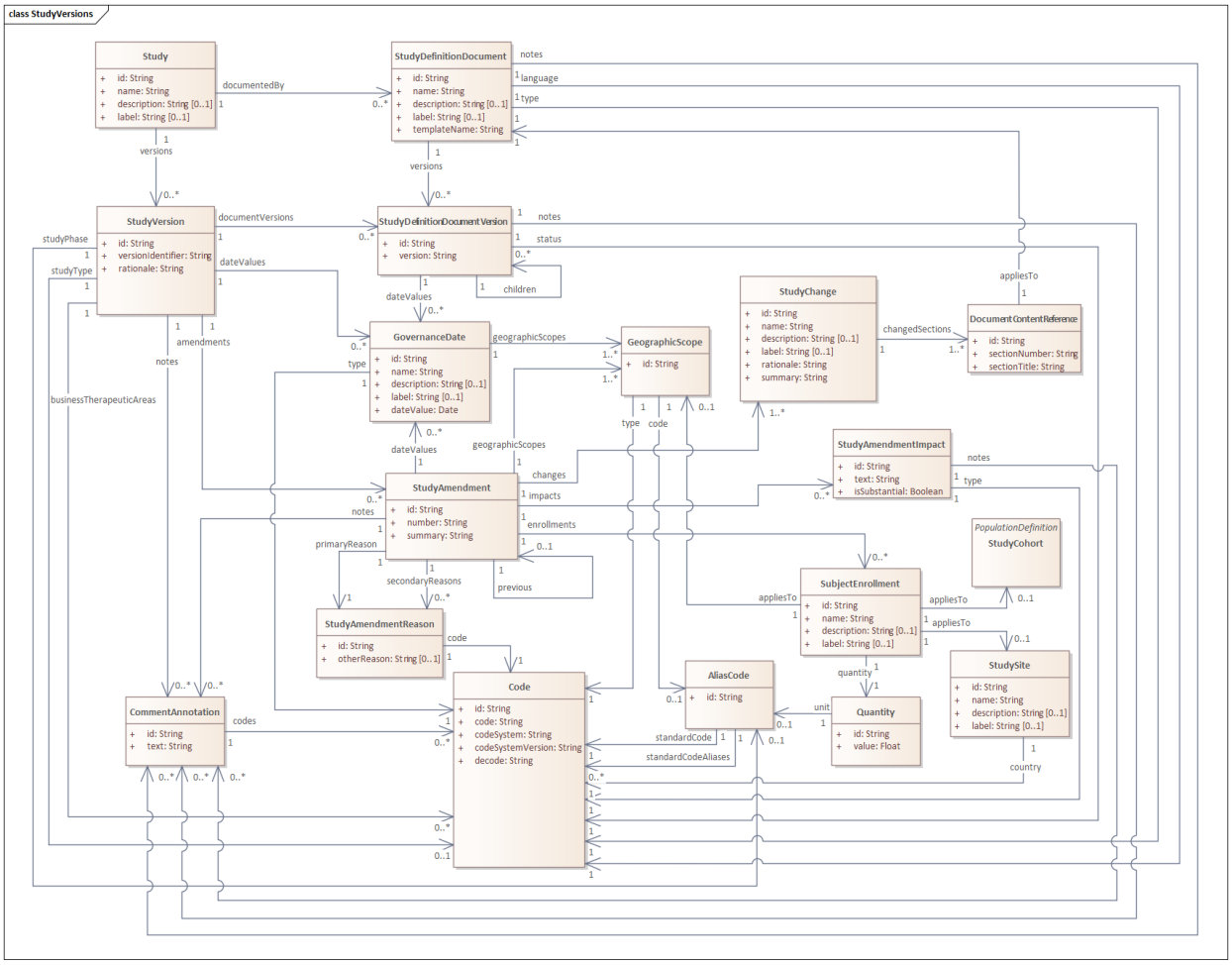
7.10 Study, Protocols, and Amendments

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 as well. 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 class links to the StudyDefinitionDocumentVersion class to define to which versions of an external protocol document the study definition relates. The study version provides a few basic study details (e.g., type, phase, rationale) and links the study with its constituent parts that include 1 or more study designs (see Section 4.8), identifiers, and titles (see Section Study Identifiers and Titles) for the study.

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 sub classes. All amendment details may be reflected in the corresponding study definition document version via the StudyVersion class. 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 one ore more changes. Each change can be detailed with a summary, a rationale and one or more references to specific sections of the current study definition document that are changed.



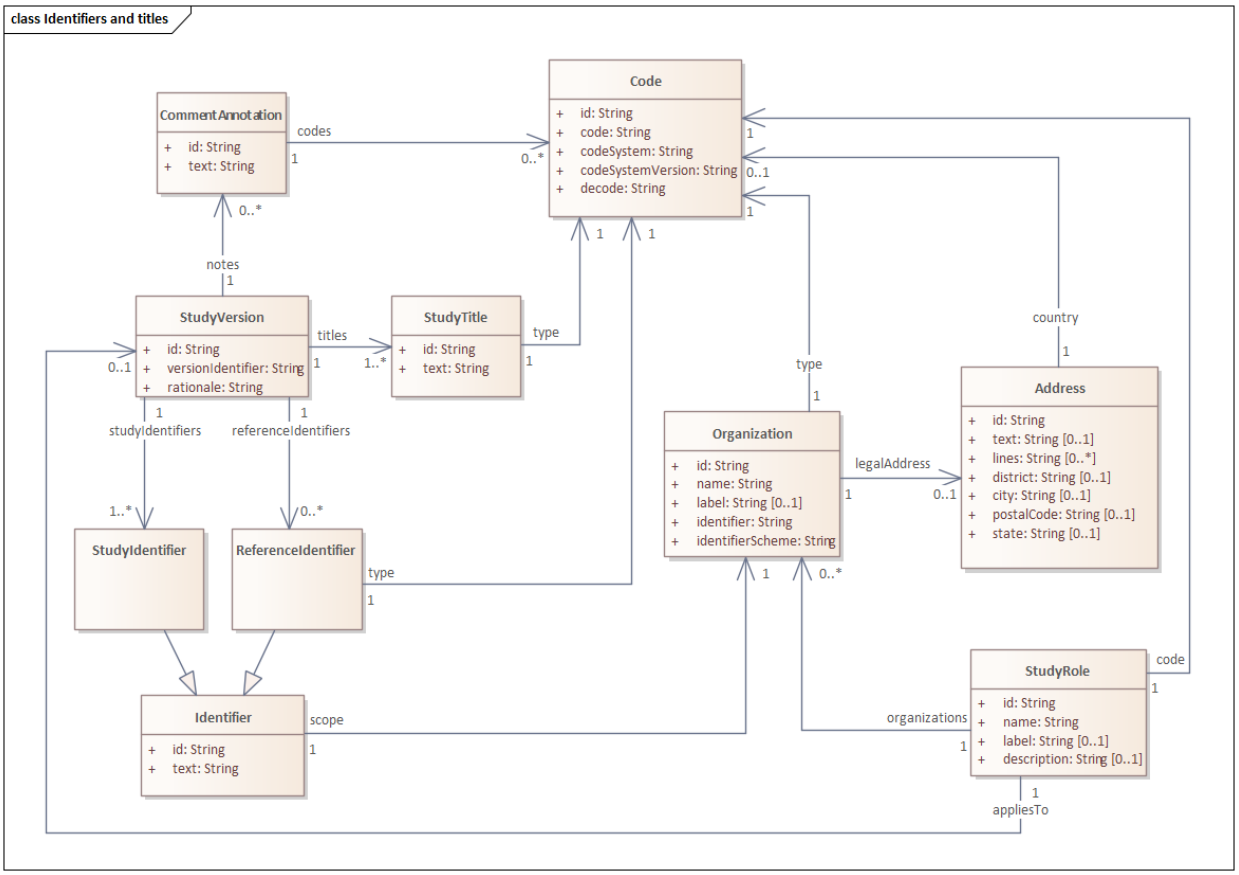
Abbreviations that are used to describe the study design are defined at the study version level and can be reused (e.g. referenced) both in the syntax template text (e.g. for eligibility criteria or assessment conditions) as well as in unstructured document content. Some examples are presented in the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

The StudyVersion class also 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.

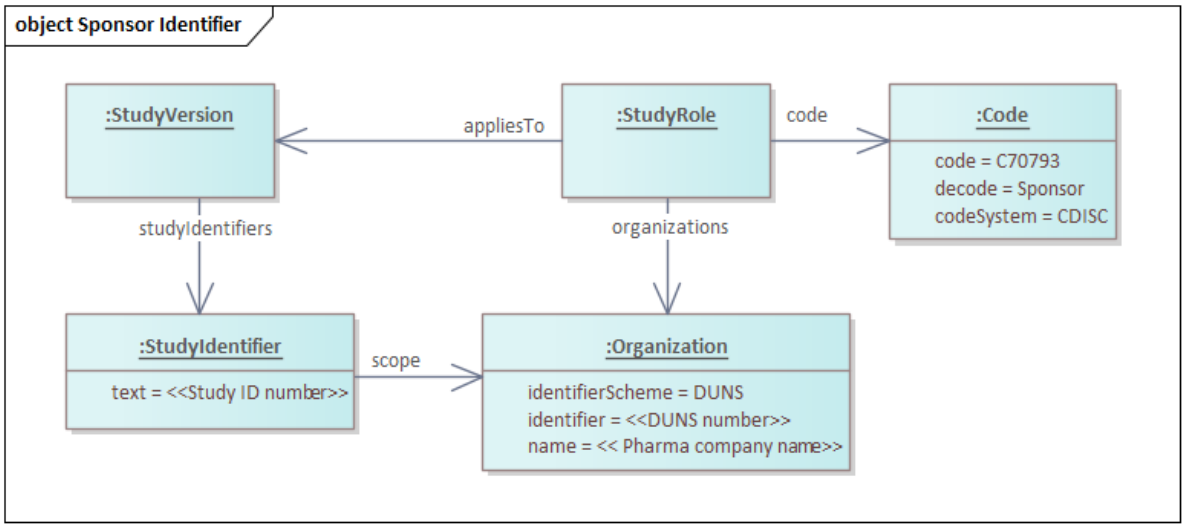
The Study class allows for 1 or more study designs to be included. This provides a single mechanism for master and umbrella studies. Multiple study designs are permitted so as to accommodate multiple designs that test multiple drugs and/or multiple cancer subpopulations in parallel under a single protocol without a need to develop new protocols for every trial. 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. The studyDesign can refer to the study protocol version directly related to the specific design.

7.11 Study Identifiers and Titles

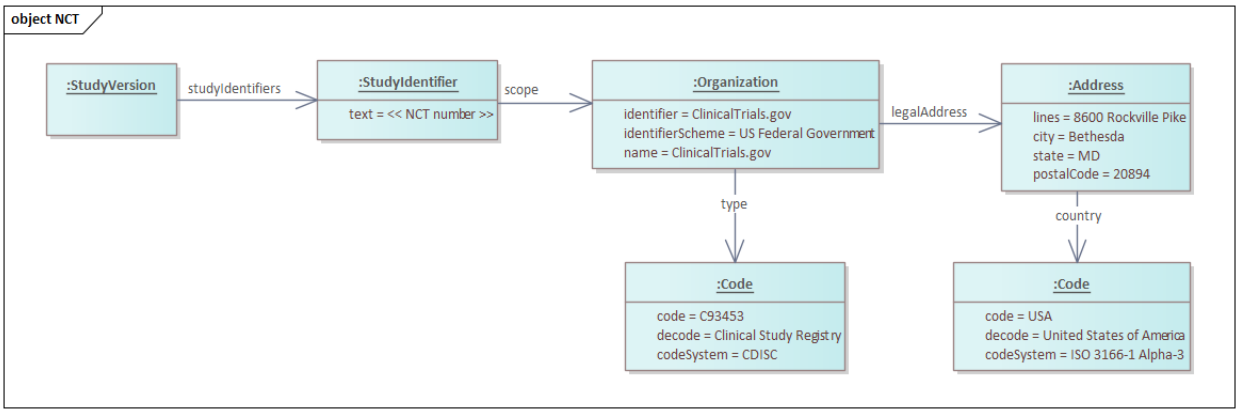
Study identifiers, reference identifiers and titles are stored in separate dedicated classes as presented in the UML below and are referred to from out of the StudyVersion class.

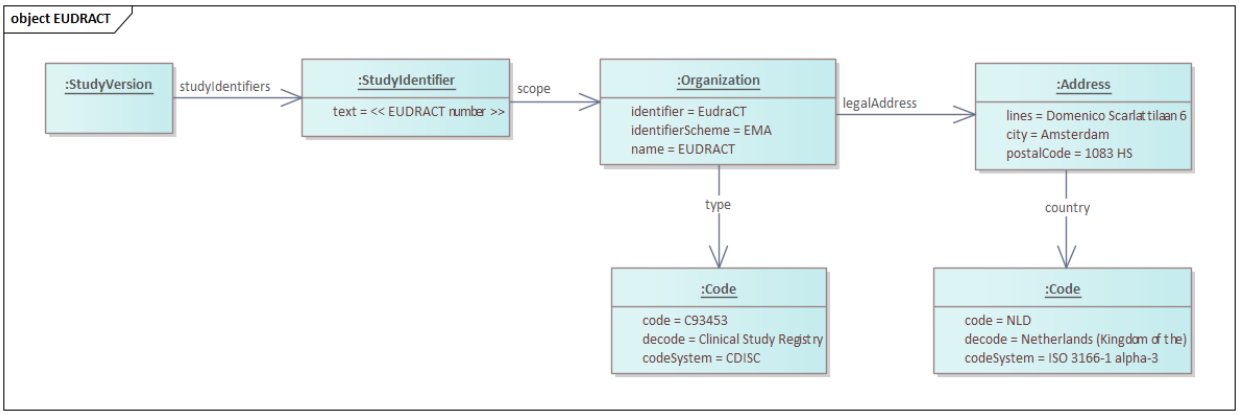


A study identifier specifically identifies the study represented in the data model. The StudyVersion class allows for including one or more study identifiers. Although multiple identifiers are permitted, the study definition should have 1, and only 1, sponsor identifier. A sponsor identifier is identified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

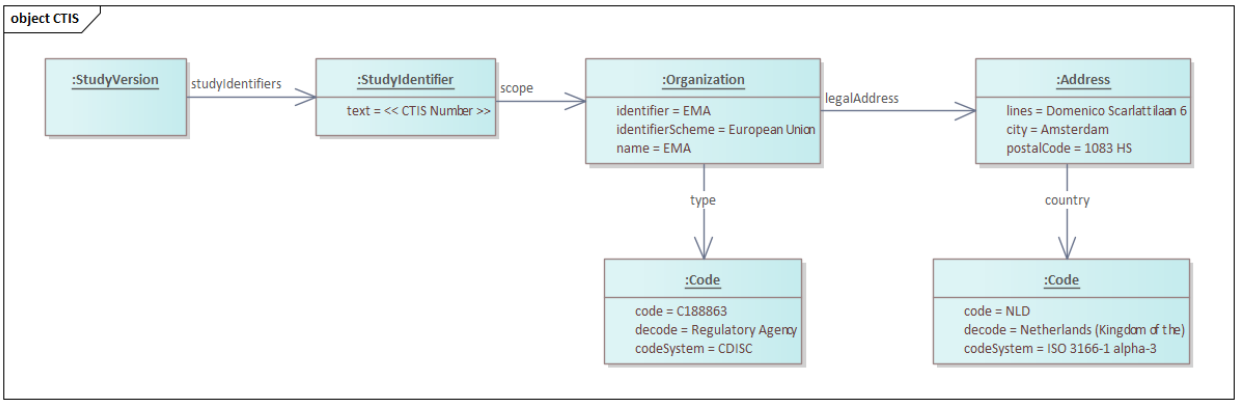


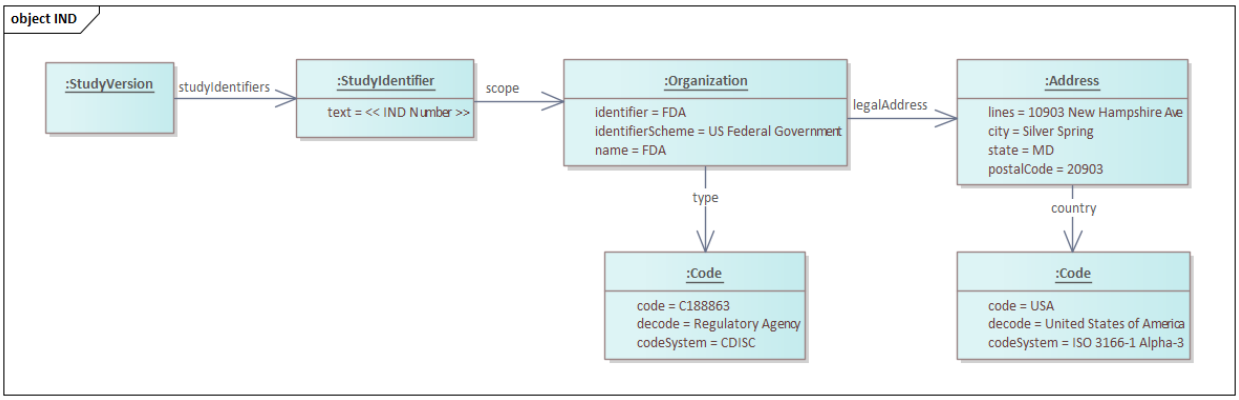
Registry identifiers like NCT and EUDRACT numbers should refer to a Clinical Study Registry organization type as presented below.





Regulatory agency identifiers like CTIS and NCT should refer to a Regulator Agency Organization type as presented below.

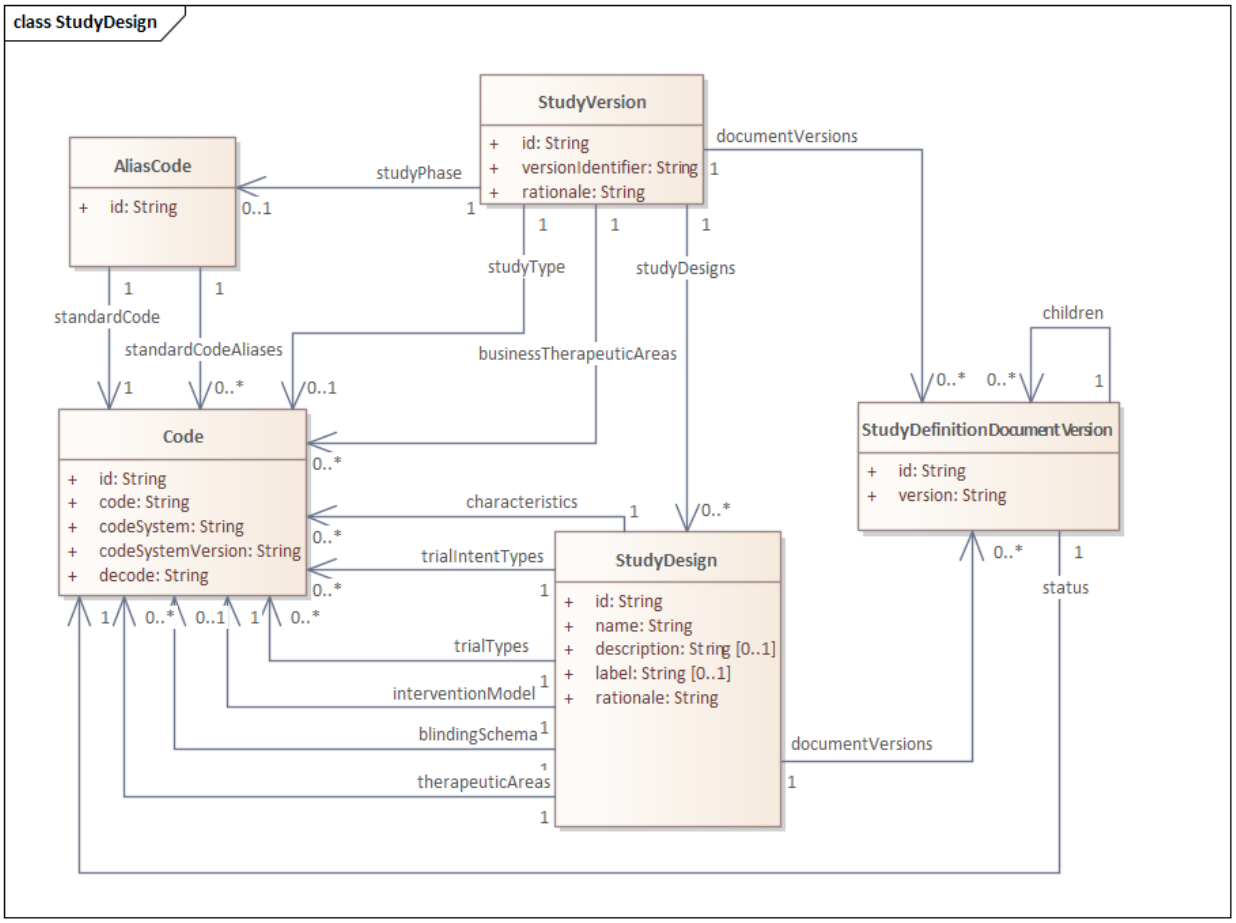




Note the use of ISO 3166-1 country codes within the address field referenced by the organization class.
A reference identifier is optional and identifies an overarching plans like a pediatric investigational plan number or a clinical development plan number.
One or more study titles are required for 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, with specifying the type as acronym.

7.12 Study Design

The StudyDesign class is the container for a single design within a study definition and includes references to Study Timelines (see Study Timing), Objectives and endpoints (Study Objectives and Endpoints), Populations (see Populations, Cohorts, and Eligibility Criteria), Study Interventions (see Study Interventions), and design elements like arms, epochs and encounters (See Arms and Epochs). It provides the slots for key parameters such as the trial types, trial intent types, blinding schema, intervention model and other study design characteristics such as whether the design is adaptive, and/or randomized.
The Study Design may be documented at the Study Design level or at the complete study version level.



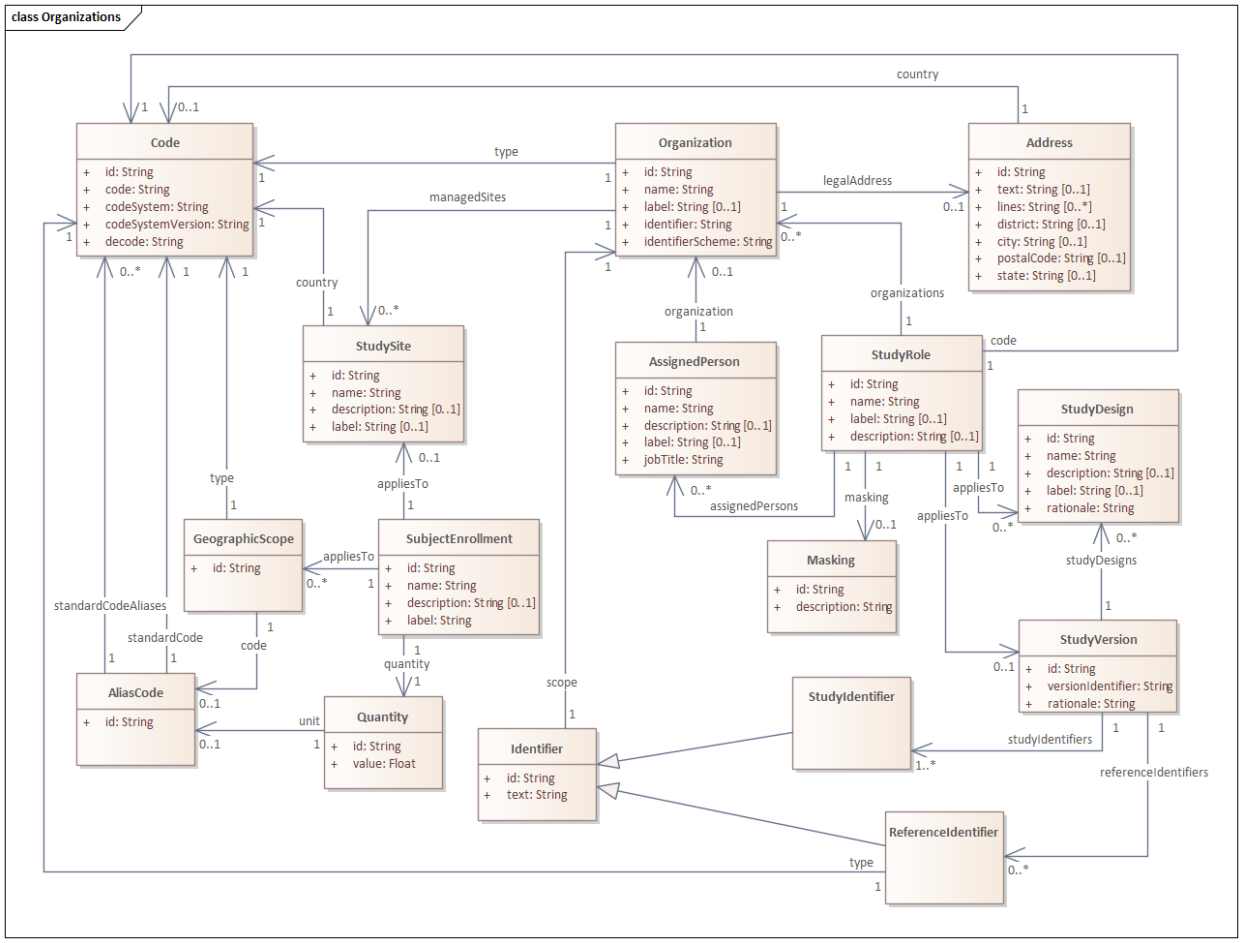
The class also provides a place to store 1 or more codes defining the therapeutic area to which the study design relates from a regulatory perspective. No controlled terminology is provided for the population of this therapeutic area field; the following table details controlled vocabularies that are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

Dictionary/Terminology	**URL**
EudraCT	https://eudract.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

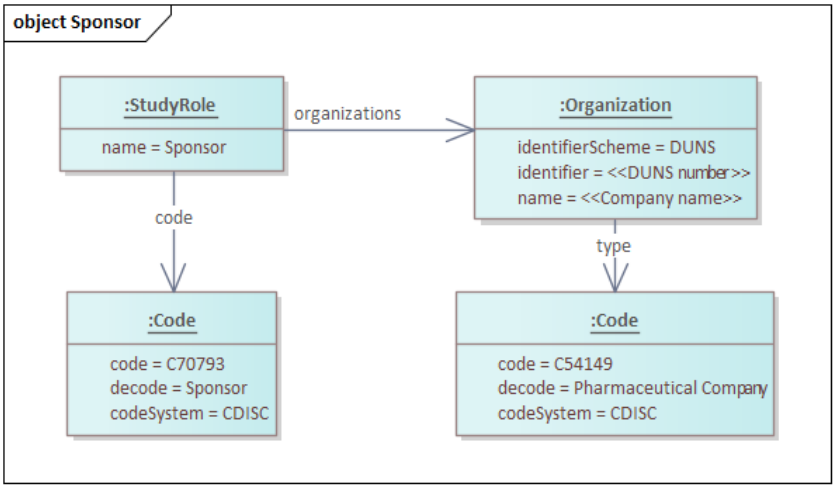
7.13 Study Roles and Organizations

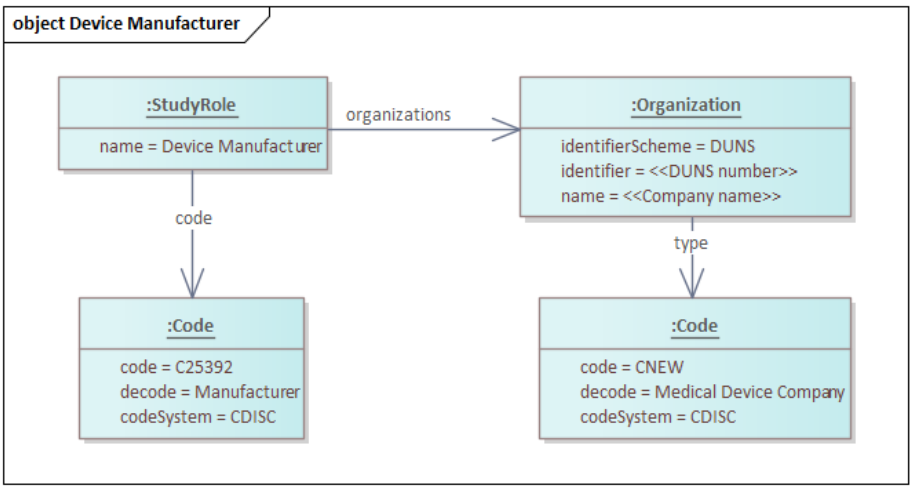
A clinical study may include a number of different roles on different levels. This includes sponsors, investigators, monitoring committees, and more. These roles are stored in the StudyRole class. A role may apply to the study as a whole or to one or more study designs specified within that study. Specific 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, Regulatory Agency, etc.). An identifier should be referring to one of the defined organizations as it's 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 Study, Protocols, and Amendments). If a role is masked in a study then this should be identified by an entry and corresponding description in the masking class.

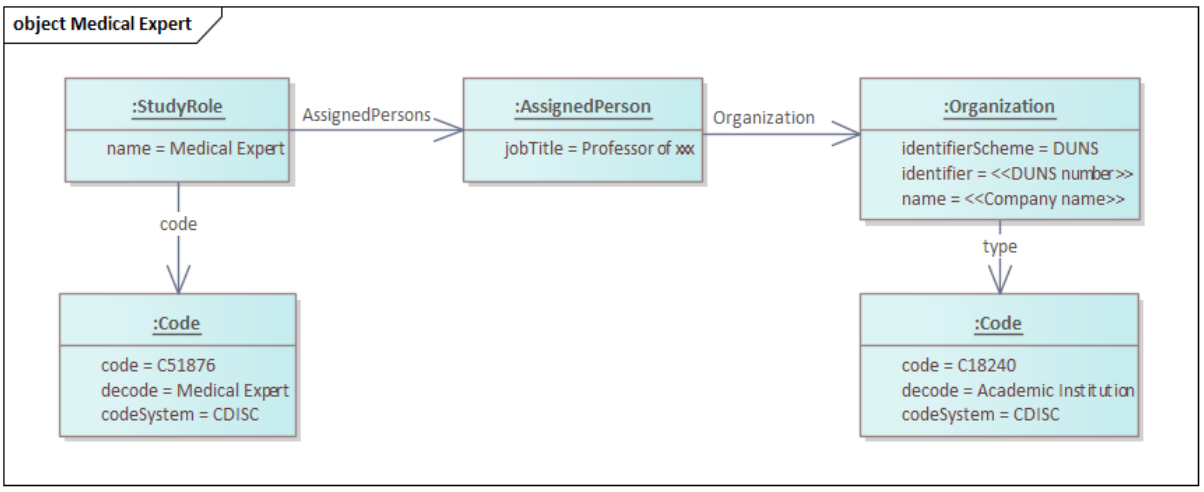


Examples of a sponsor entry and a device manufacturer entry are presented below. In case of a commercial organization, the DUNS number is expected to be specified to uniquely identify the commercial entity.

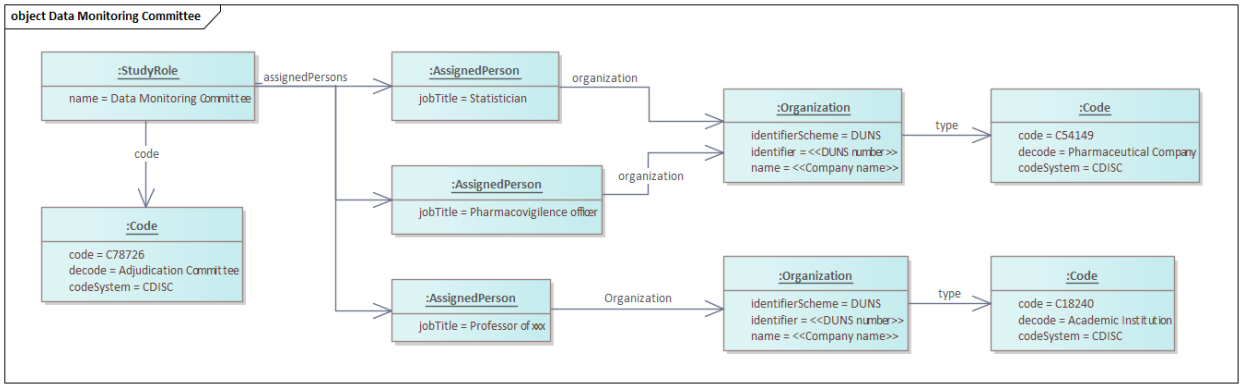




The study role may include either one or more organizations as a whole or one or more assigned persons. Assigned persons are specified in the AssignedPerson class which then subsequently may link to the corresponding organization as depicted in the example below.

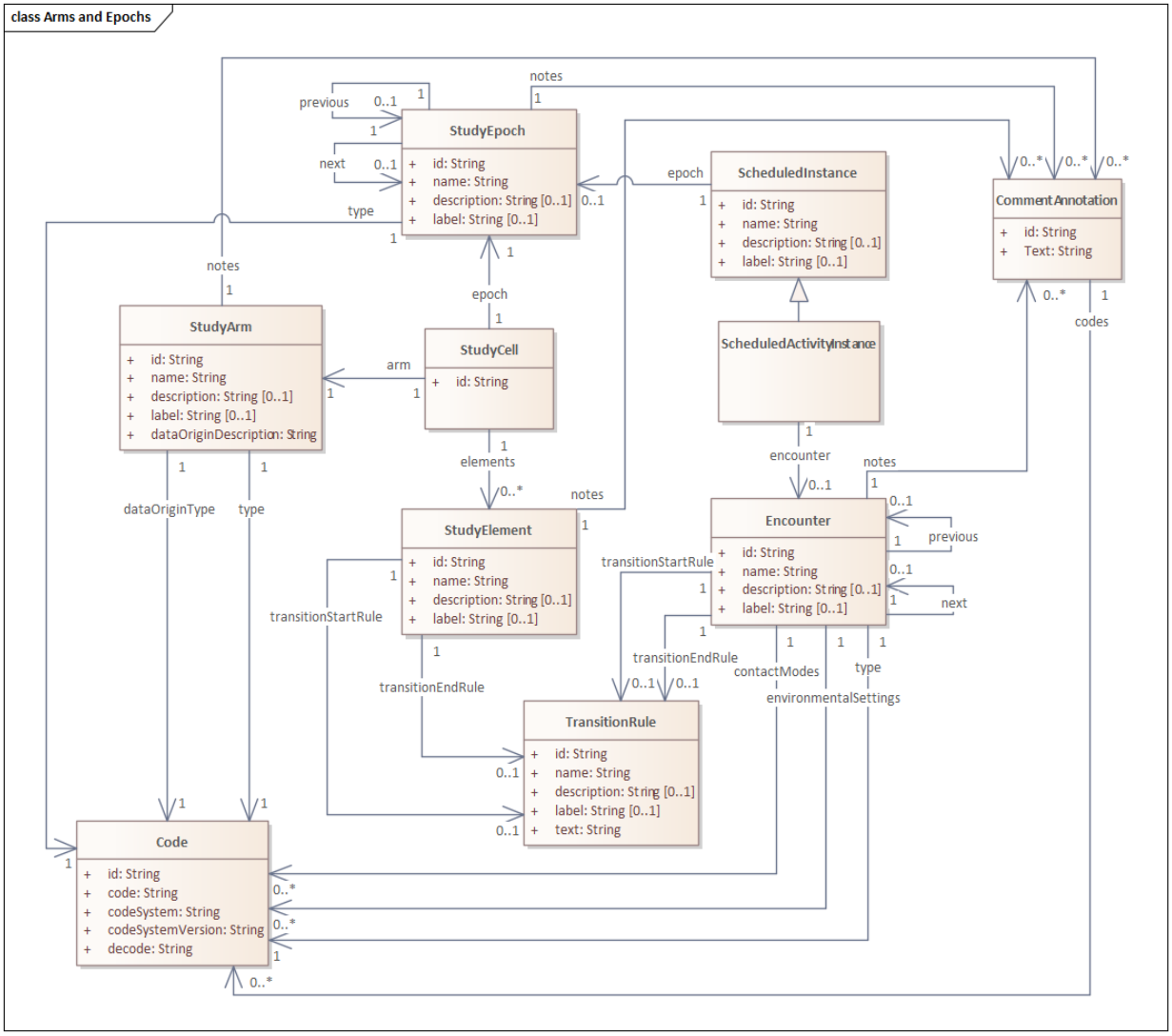


The below example shows how a data monitoring committee includes more assigned persons referring to their respective organizations.



7.14 Arms and Epochs

The high-level study design consisting of the 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 (for more information 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).

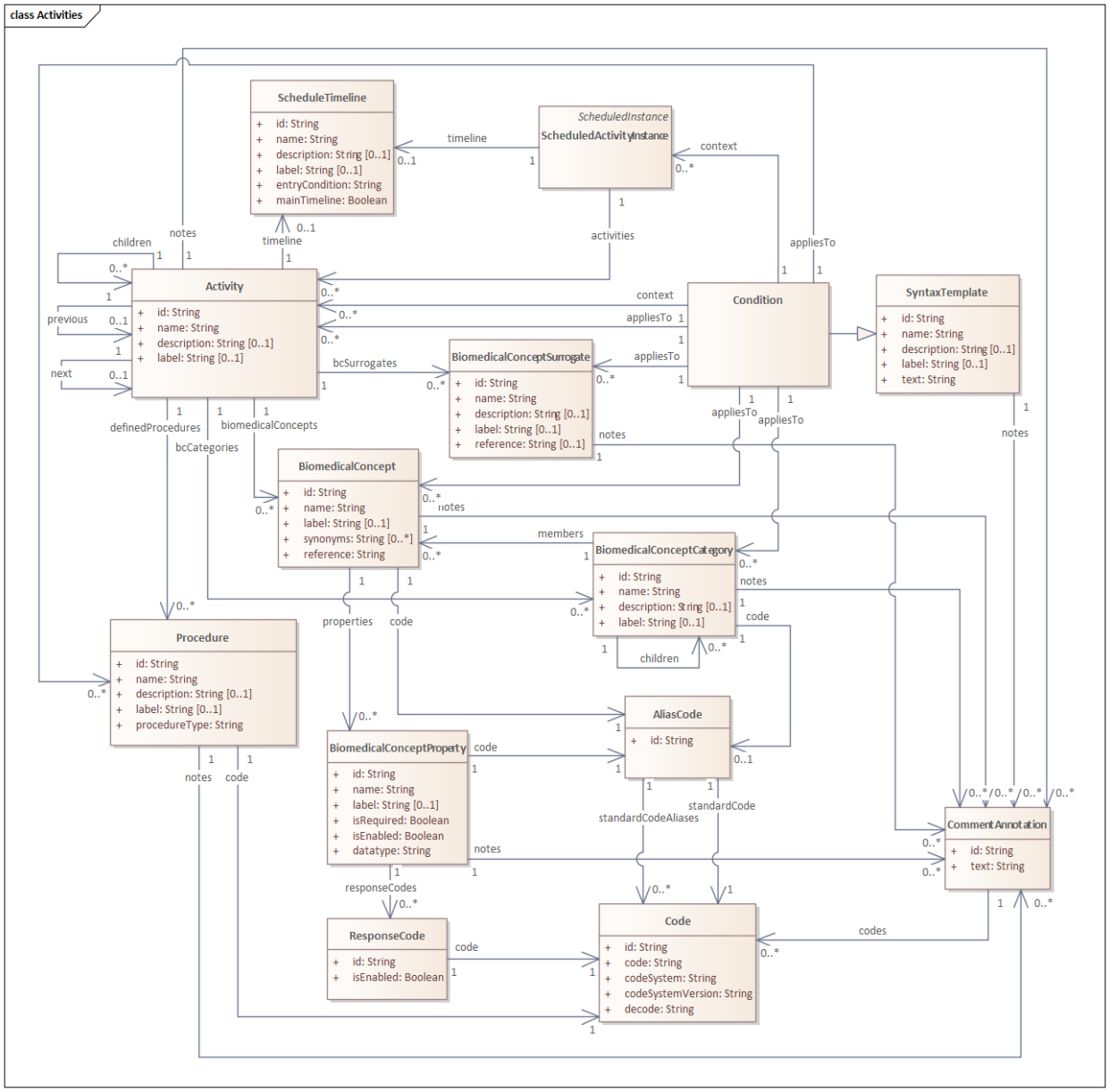


7.15 Activities

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 sub timeline. A sub timeline referred to from an activity would typically be a sequency of actions covered by the activity description (e.g. blood glucose profiles, sitting/standing vital signs sequences etc.).

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 timepoint it is scheduled) or to a specific timepoint 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 an scheduled activity instance or to point to biomedical concepts or procedures. It is recommended that only two 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 dispension		X	X
Drug accountability		X	

Corresponding activity class content

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 dispension	id_17	id_16	id_18	
Drug accountability	id_18	id_17		

7.16 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.

7.17 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 a enabled boolean flag. Some properties, such as a result, are always required. Required properties are indicated by a second boolean flag.

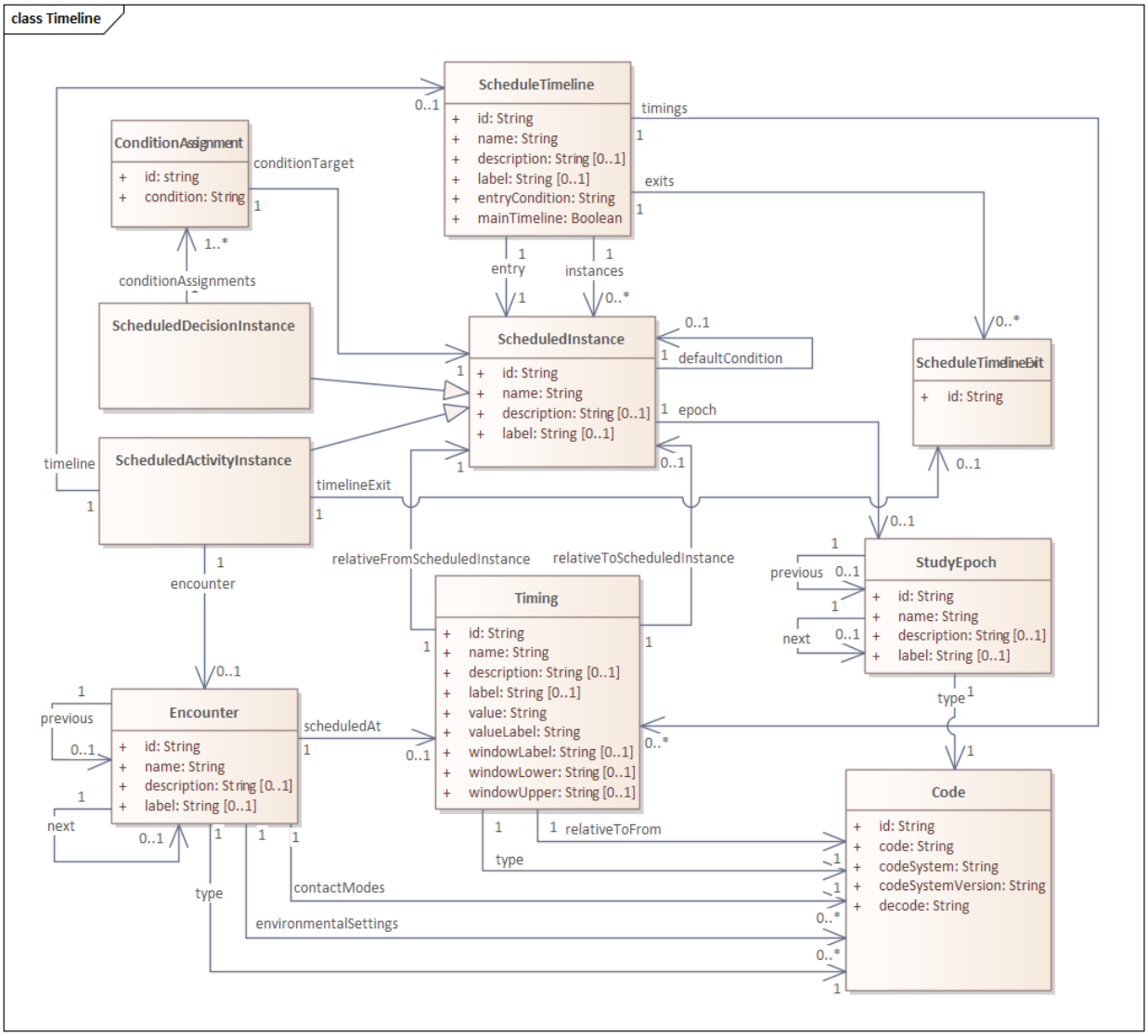
The USDM allows for the inclusion of a single BC (e.g., heart rate), a collection of BCs (e.g., vital signs preconfigured to include height, weight, heart rate, and other tests), or surrogate BCs. Surrogate BCs are a placeholder mechanism for when a BC definition is not available. This allows the name 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 one 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 such as the vital signs described above. These groupings are expected to be sponsor defined but, in the future, some can be expected to be industry defined.

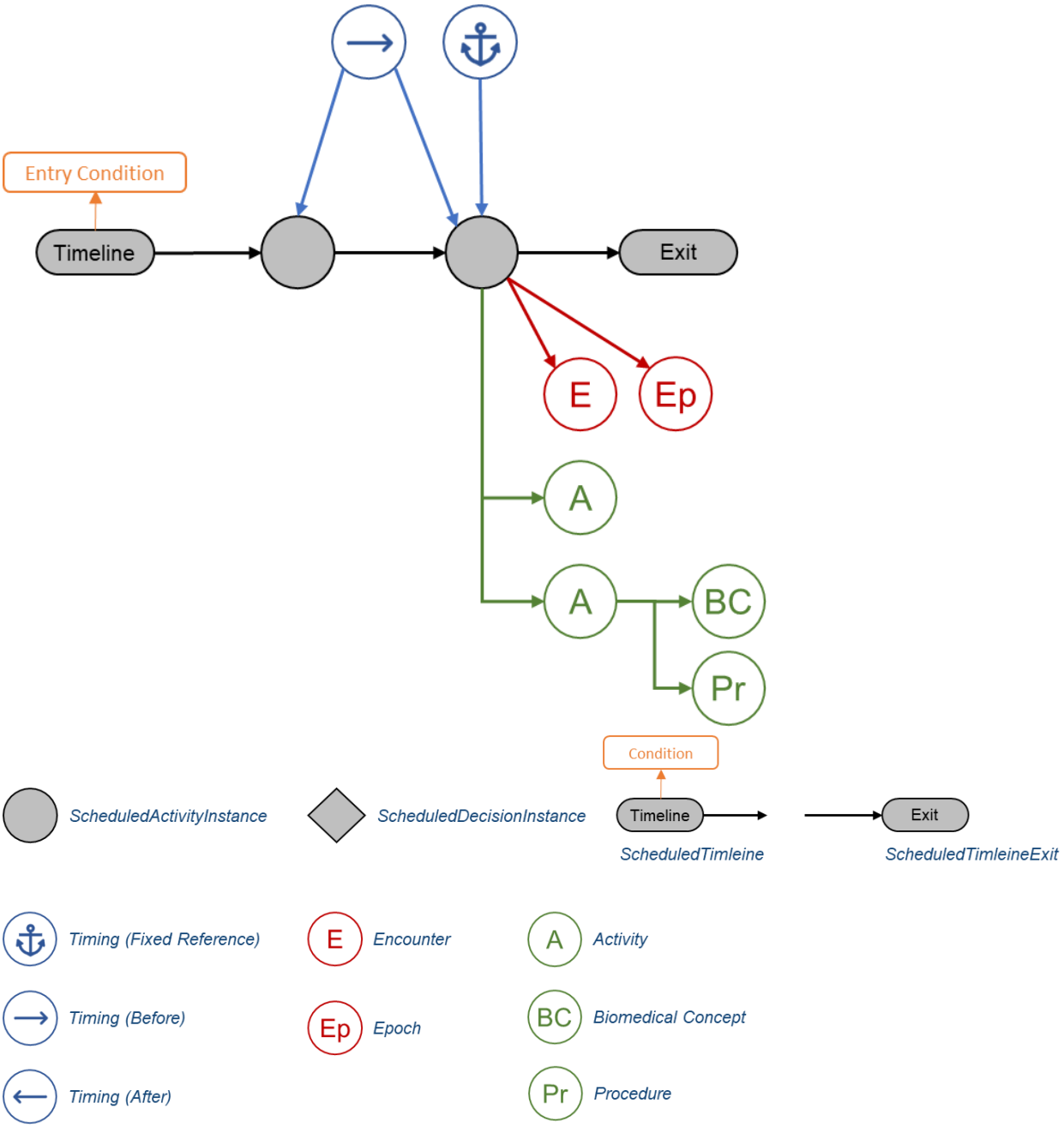
7.18 Study Timing

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.



7.18.1 Timelines

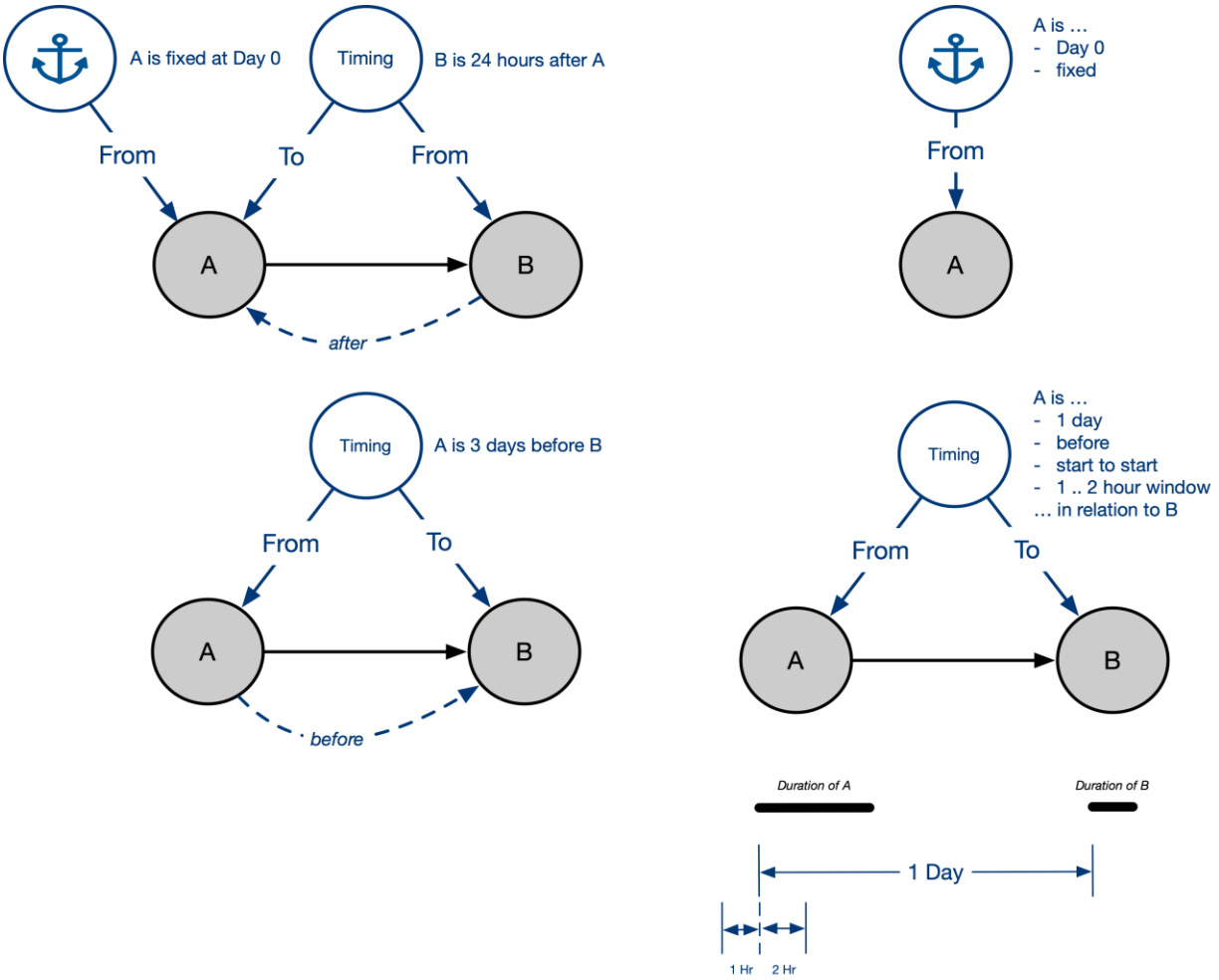
The study timing mechanism depicted in the following figure is based on the notion of a timeline. A *timeline* is composed of an entry point with an associated entry condition (see ScheduleTimeline class), a sequence of steps (the ScheduledActivityInstance class and scheduledDecisionInstance class), 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.



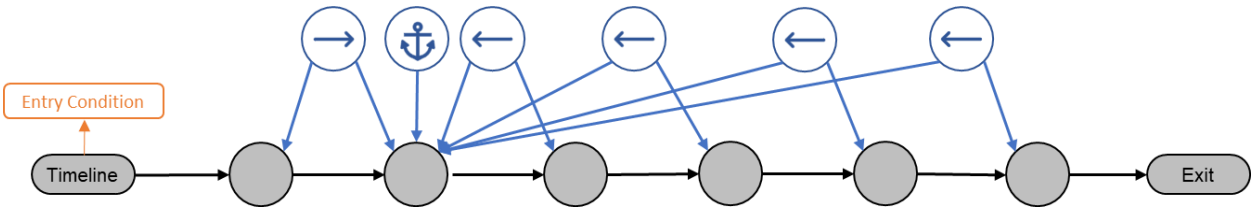
7.18.2 Timing

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.

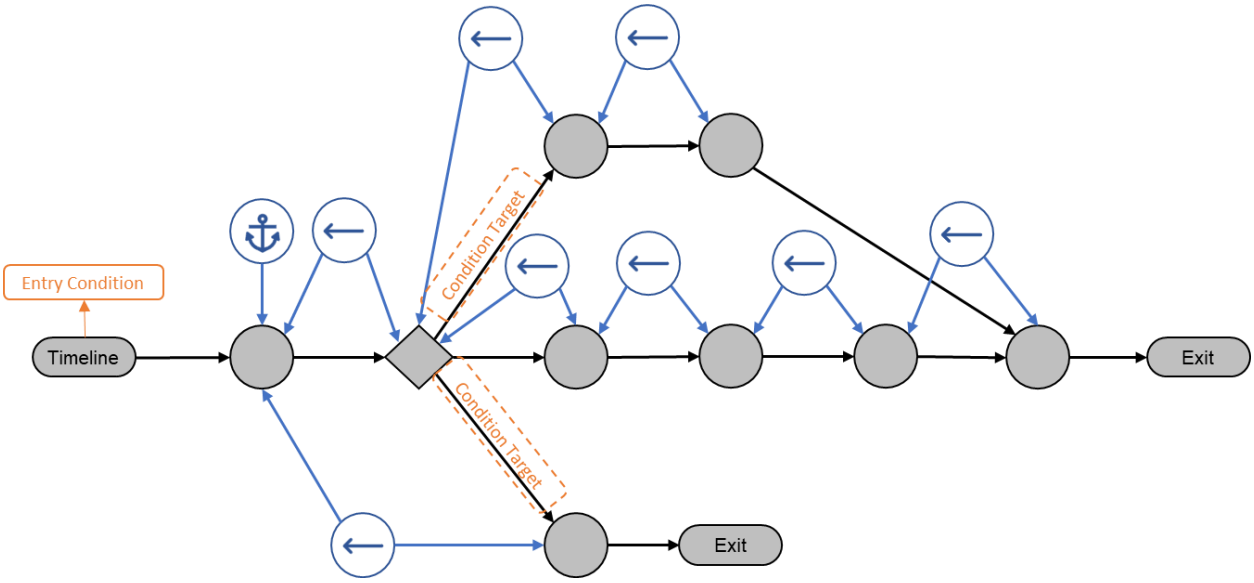


Planned timings are stored in the value attribute of the Timing class and are expected to be formatted according to ISO 8601. A corresponding window can be identified using the window attributes. The windowLower and windowUpper attributes are also expected to be formatted according to ISO 8601. Textual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

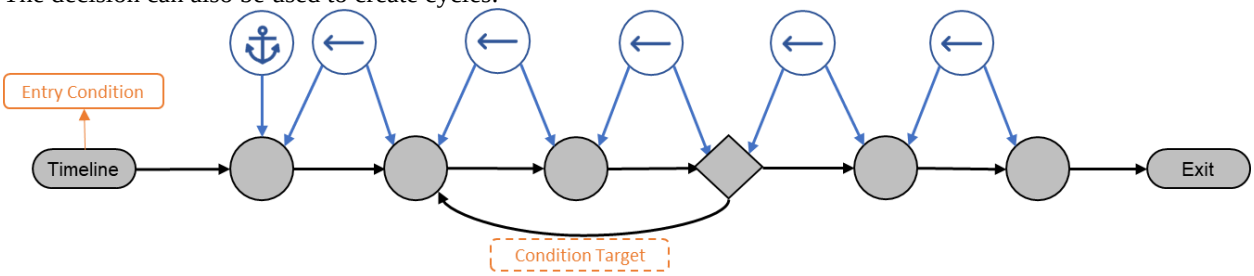


7.18.3 Decisions and Branching

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.



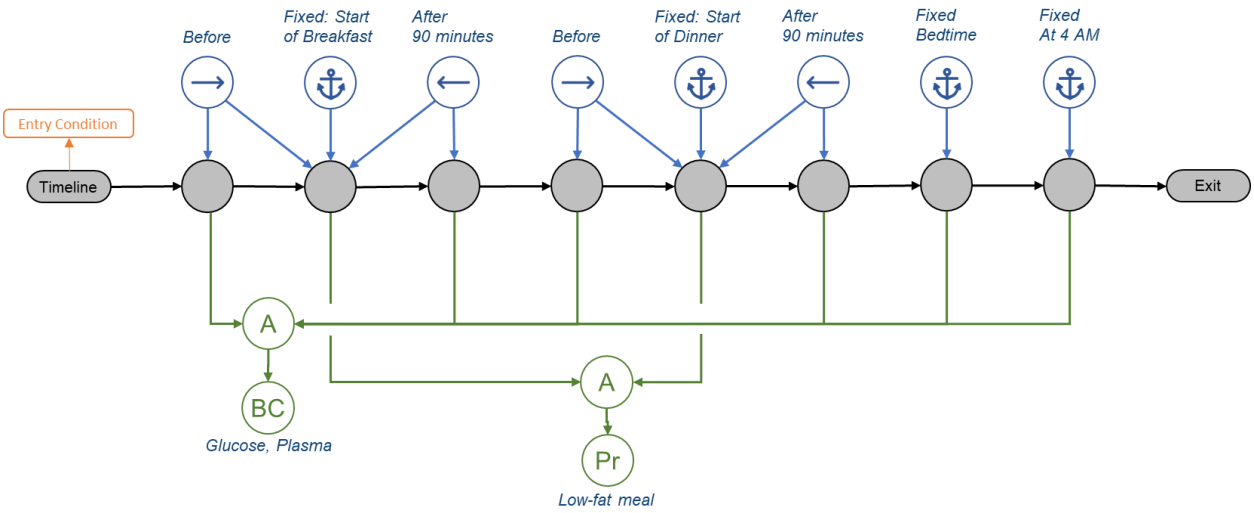
The decision can also be used to create cycles:



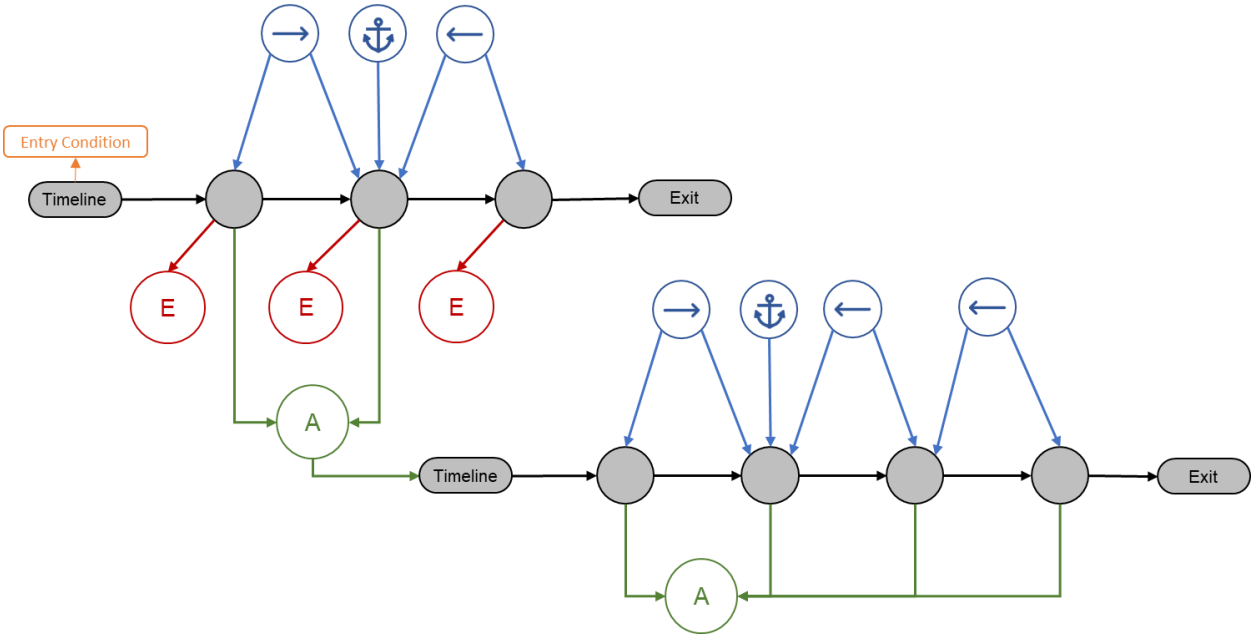
Descriptions of the decision and pointer are defined using the conditionAssignment class. This class includes 2 attributes: a description of a condition and the reference to the target instance of the scheduledActivityInstance class that it points to once this condition is met—for example: "not reached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

7.18.4 Profiles

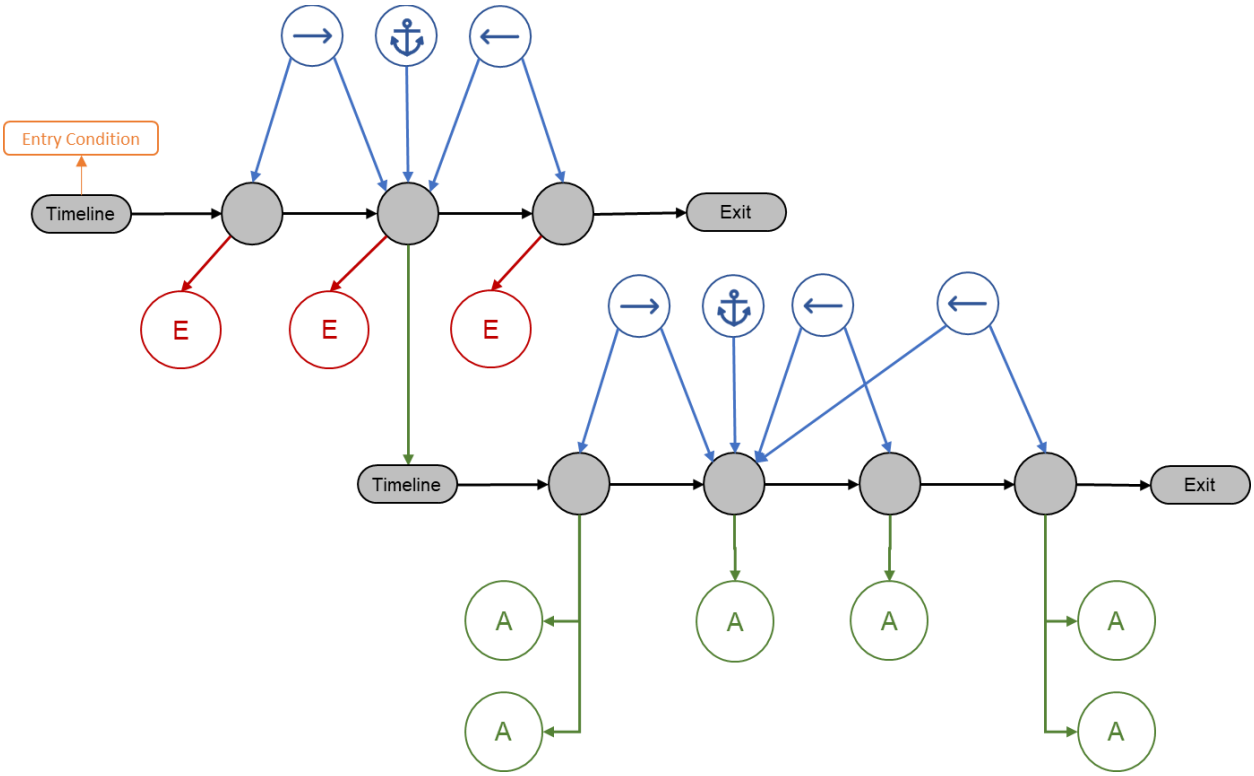
Profiles can be created using the various classes, as depicted in the following figure. A profile is another use of the timeline pattern and may reflect a sub-timeline within an encounter. A condition for entry can be defined but need not be. In this example, anchors are used to fix meal times over a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

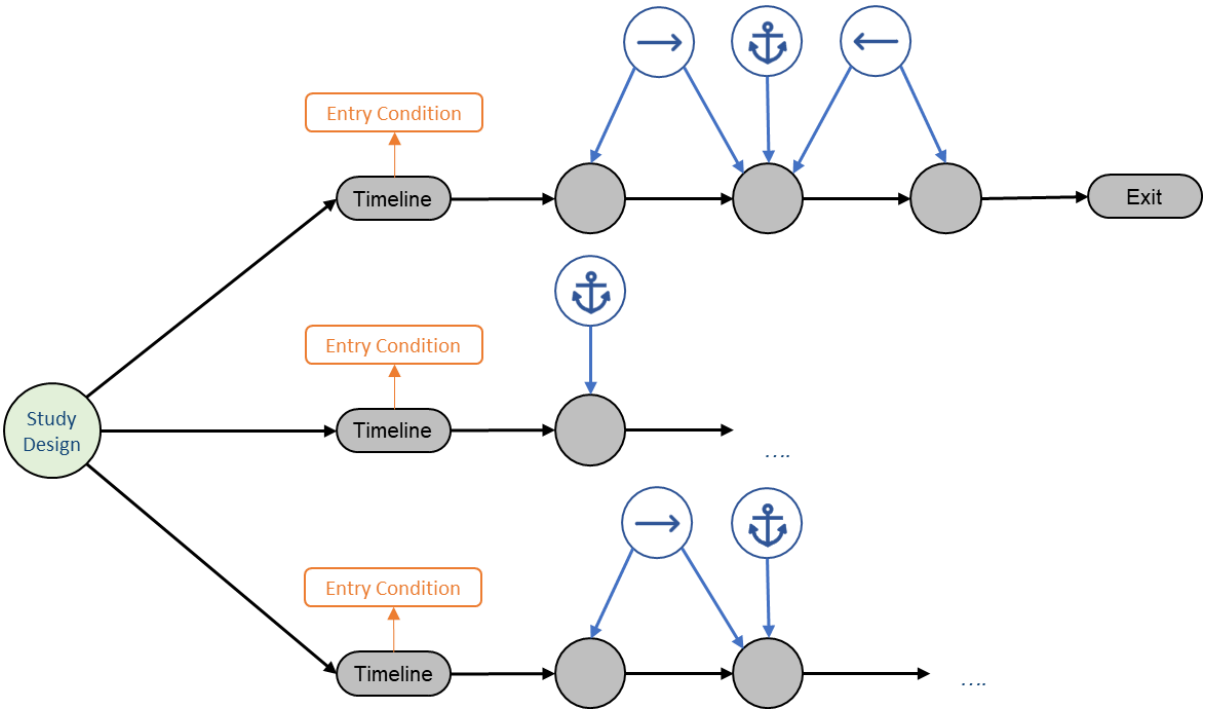


The timeline can also be attached to a ScheduledActivityInstance from another timeline using the timeline reference, thus allowing timepoints within a visit to be constructed, as shown in the following figure.



7.18.5 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.



7.18.6 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.

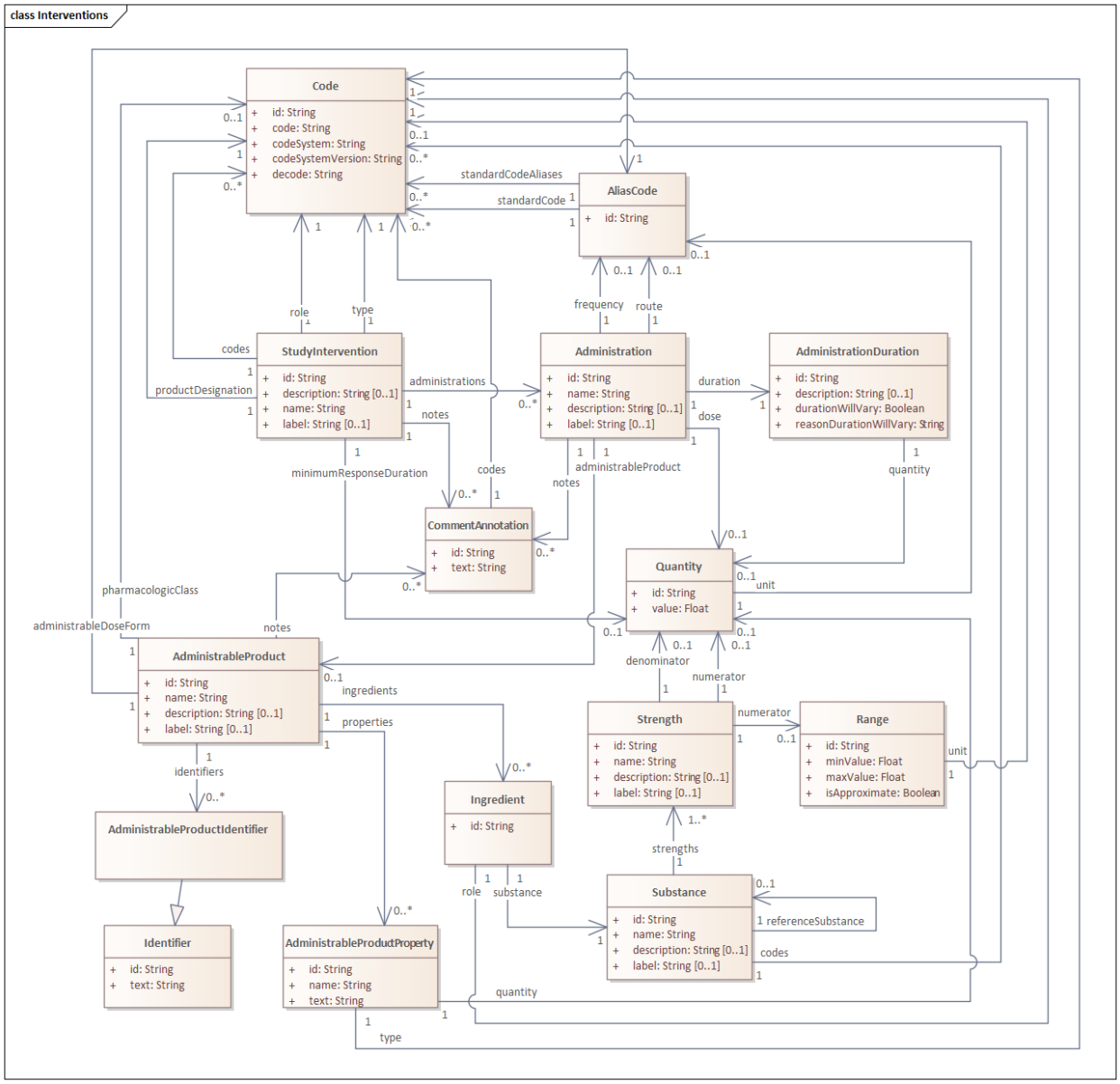
7.19 Indications

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 attribute isRareDisease can be utilized to indicate whether an indication is regarded as a rare disease according to applicable rare disease registries (e.g., NIH GARD, Genetic and Rare Diseases Information Center).

7.20 Study Interventions

The interventions for a study can be placed into the StudyIntervention class. Each intervention needs to be defined by role, type and productDesignation. Optionally, information on 1 or more codes from external coding systems and the expected duration to minimum response can be added. Corresponding administration details can be specified in the Administration class. The frequency, dose, route, administrable product and duration can be specified for each administration.
For each administrable product optionally, information on the pharmacological class, and 1 or more identifiers, properties and ingredients may be specified. 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 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

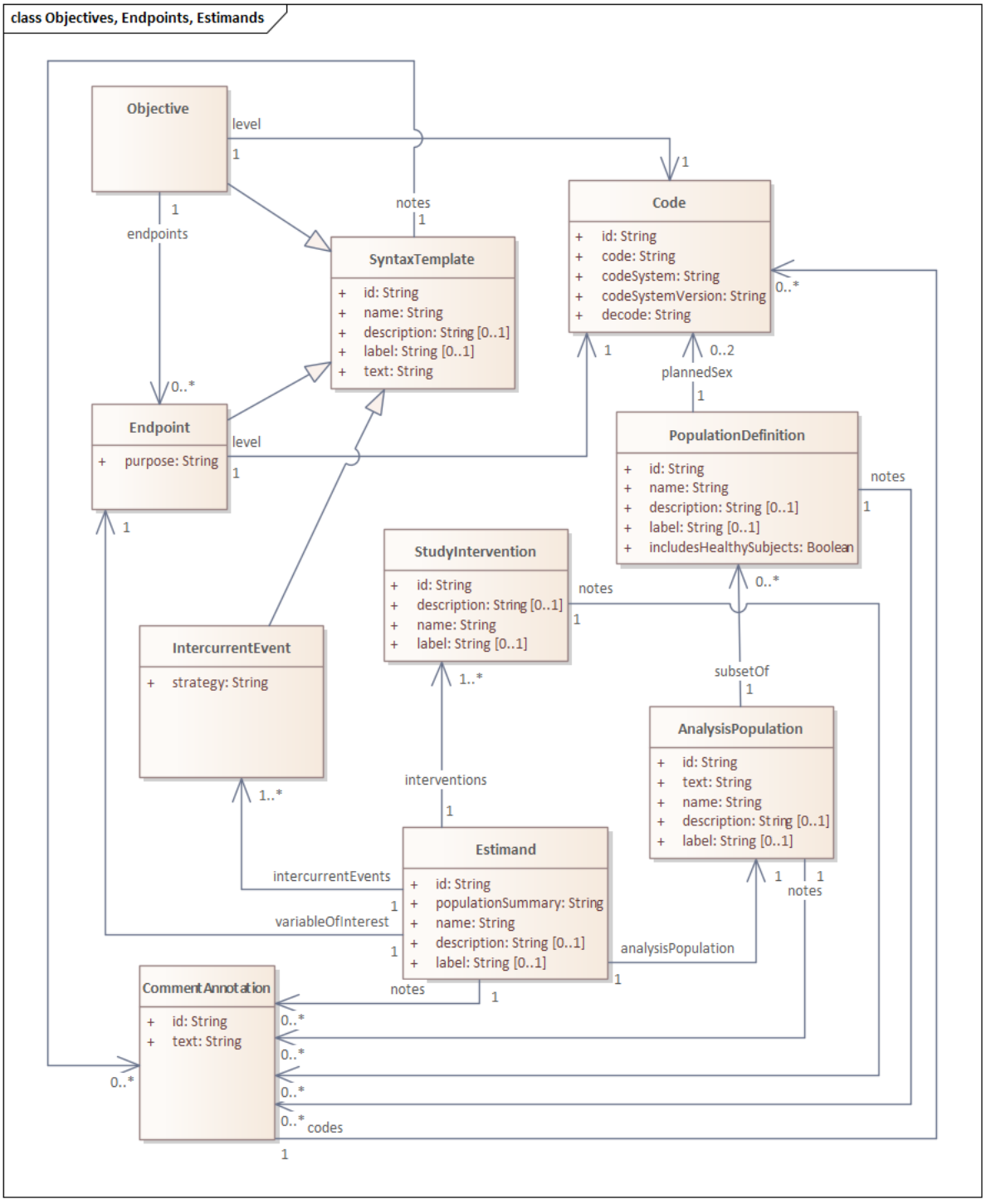
minValue and maxValue attributes instead of the quantity value attribute. For IDMP, the strength value or minValue and corresponding denominator value refers to the IDMP strength lower limit, while, if applicable, the strength maxValue and corresponding denominator value, refers to the strength upper limit.
Note that the internal sponsor code or compound number for the administrable product can be stored as the administrable product identifier.
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.



7.21 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 4.18).

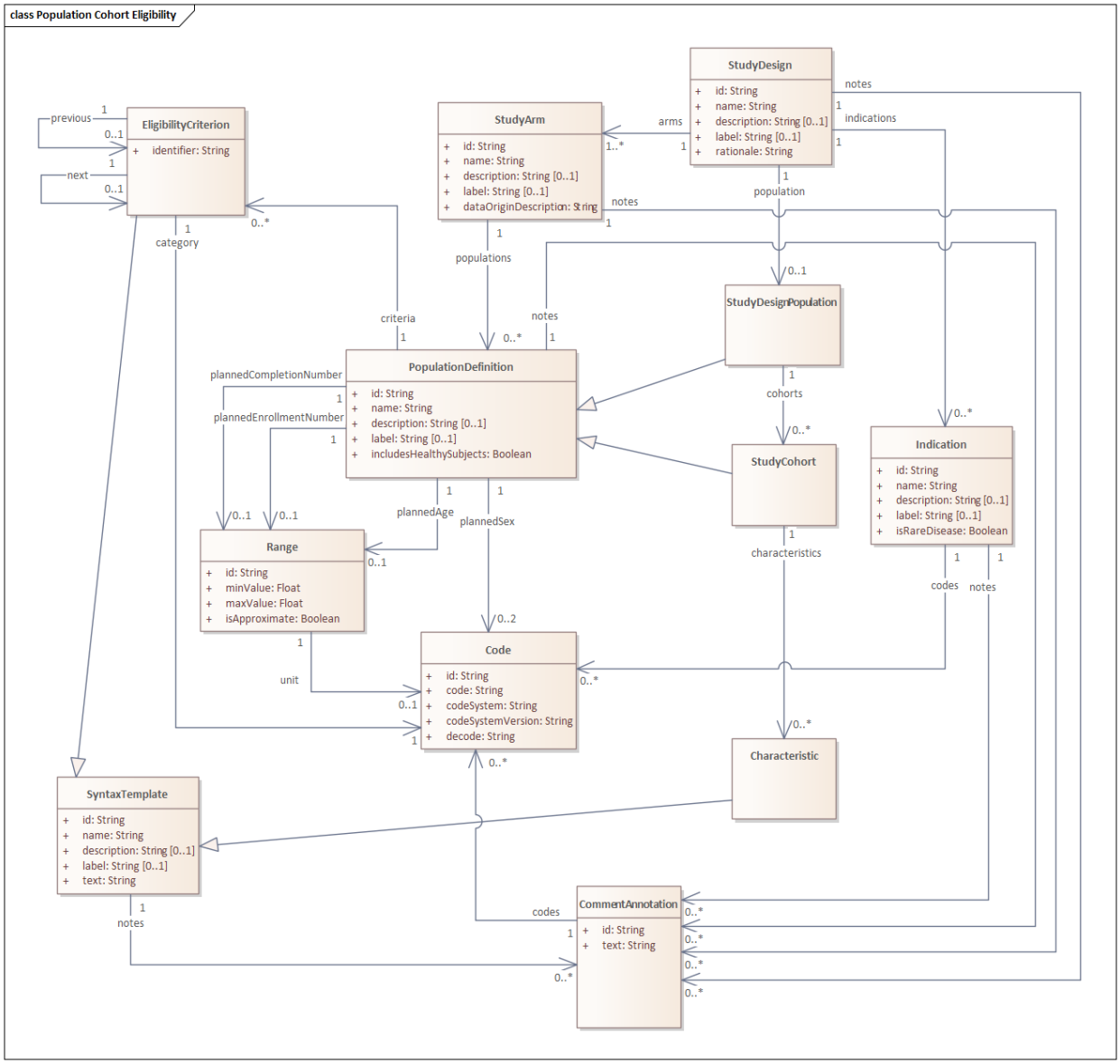


7.22 Study Estimands

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 intervention (see Section 4.16) for the treatment.
The AnalysisPopulation may be defined as a subsetOf a Study Design Population or Study Cohort which inherit their features from the population Definition class (See Populations, Cohorts, and Eligibility Criteria).

7.23 Populations, Cohorts, and Eligibility Criteria

Population and cohort definitions define a (sub-)group of subjects that take part in the study. The parent class PopulationDefinition is used to define a group of patients in general. This class includes references to the eligibility criteria that are applicable to this 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, PlannedCompletionNumber and/or plannedEnrollmentNumber, 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 one, 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 of the 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 can thus refer to any item stored elsewhere in the USDM. Eligibility criteria inherit from the Syntax Template class as well, allowing for referencing any item stored in the USDM, such as assessments stored as BCs or an indication stored in the Indication class. They are defined within a study version which allows reuse within different study designs and different cohorts. The previous and next attributes define the presentation ordering within an eligibility criterion category or overall. The identifier attribute may be used to store the short name used for mapping to SDTM TI domains (see Creation of SDTM Trial Design Domains).
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 optionally be added to these notes aligning with internal or external standards that are applicable to the notes.



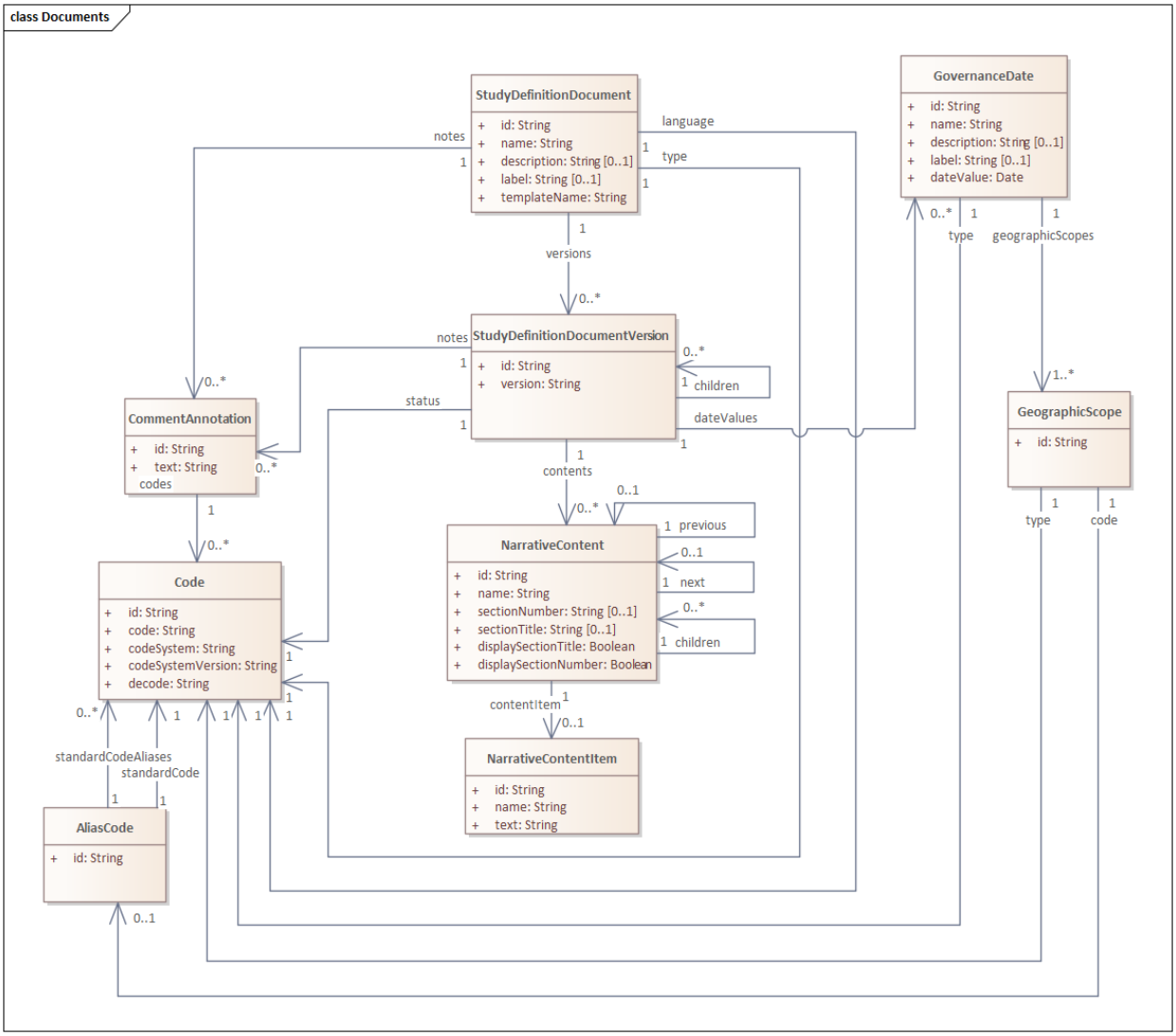
7.24 Unstructured Content

Study protocols and other study definition documents include content that is best described as "unstructured content", granting the author 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 Narrative Content 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 at any desired place in the unstructured text using the format explained in Section 4.23, XHTML Attributes.



7.25 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

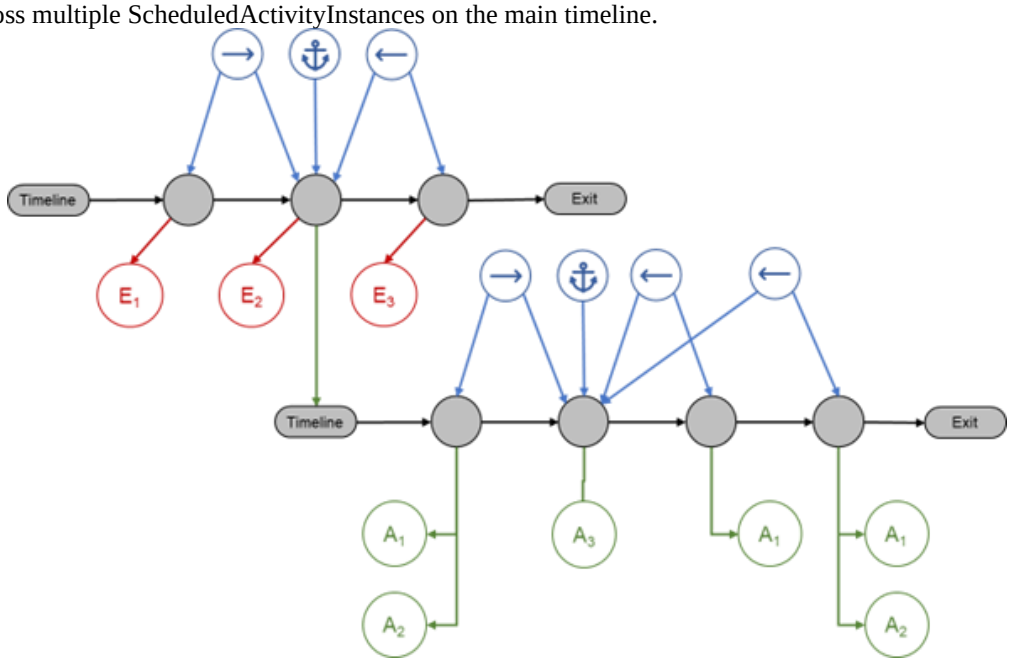
- Footnotes representing optional alternative encounter methods
- Footnotes representing measurements to be done for a specified activity
- Footnotes representing optional alternative measurement methods
- Additional instructions for procedures and/or performing assessments
- Visit and timing window information
- Eligibility requirements
- Complex combinations

7.26 Footnotes Representing Sub-timelines

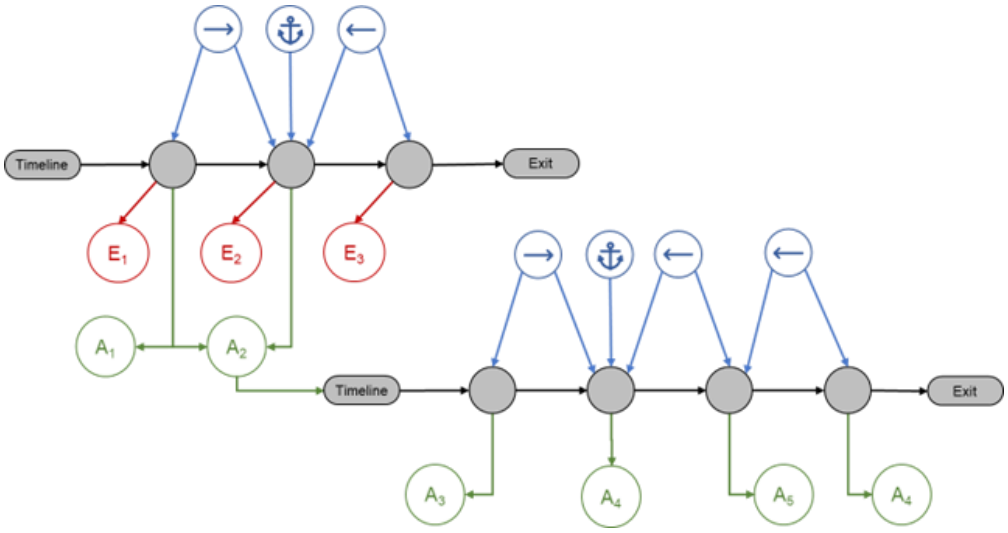
These footnotes indicate at what exact timepoints activities not presented in the SOA should be performed, for example:

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.



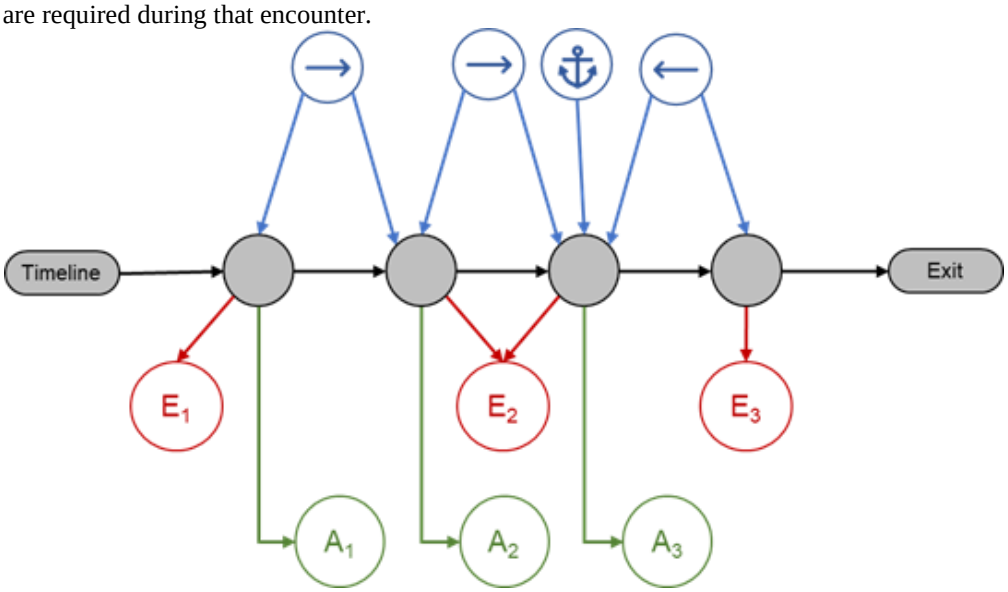
See Section 4.14, Study Timing, for more information on timelines.

7.27 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.



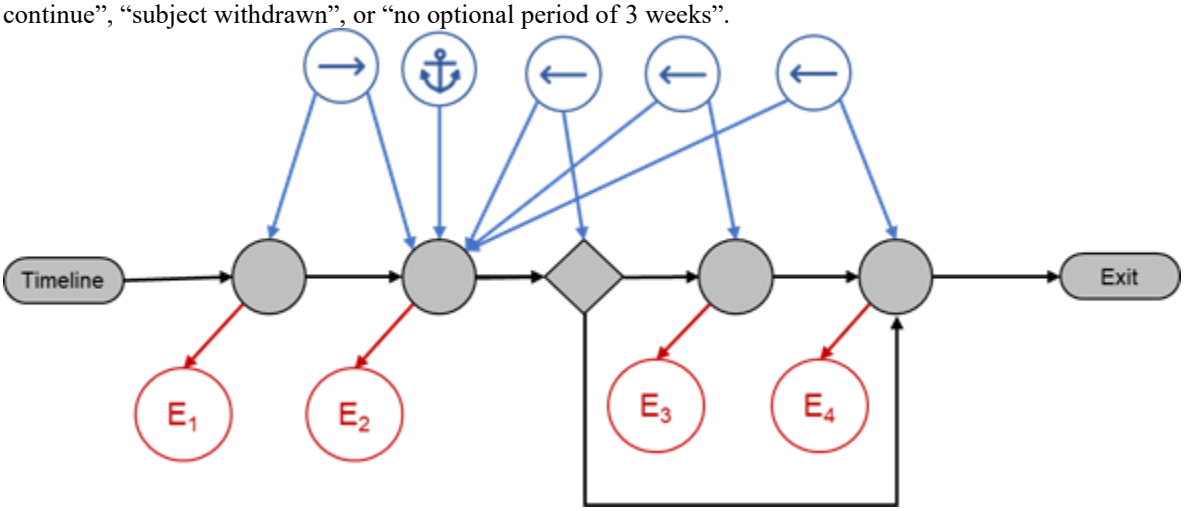
7.28 Footnotes Representing Alternative Visit Schedules

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 E_3 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 (E_3) can be skipped. In cases where activities were planned at this skipped visit E_3 (and not at the previous visit E_2), these should be added to the previous visit E_2 with the conditionality that they only need to be done when the next visit is skipped.

7.29 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.

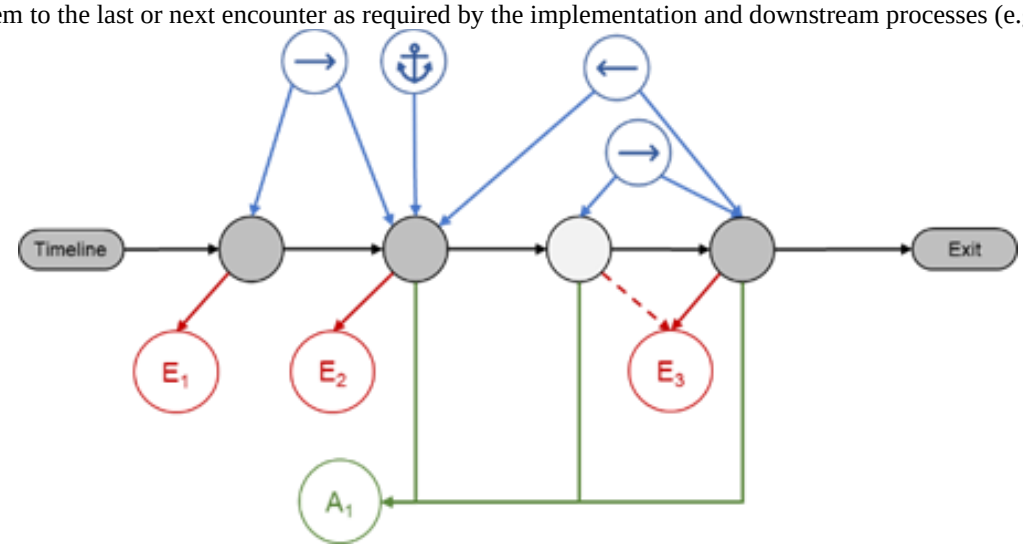
7.30 Repeated Activities Not Presented in the SOA

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).



7.31 Footnotes Representing Optional Alternative Encounter Methods

These footnotes specify potential encounter methods, such as:

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

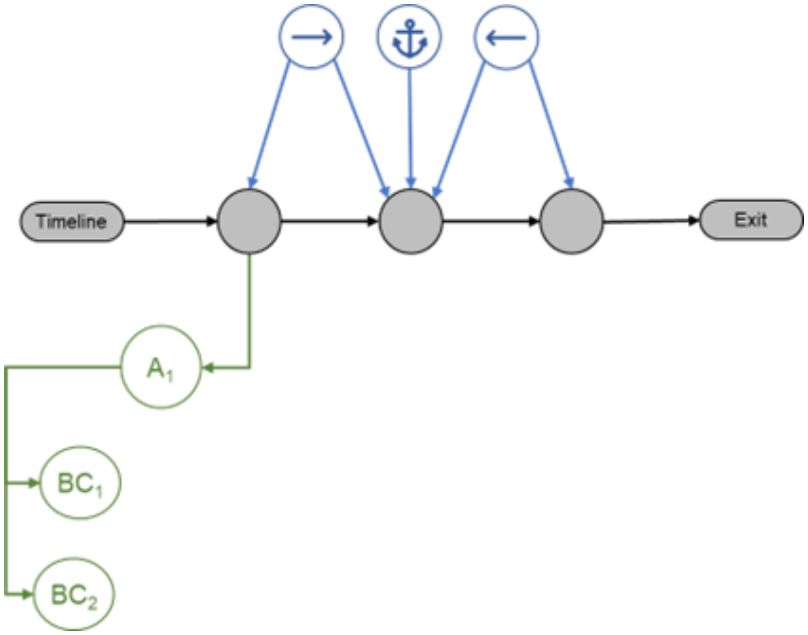
The encounter methods are specified by the attributes environmentalSetting and contactModes in the Encounter class. More than 1 contactMode may be entered if optional alternative encounter methods are allowed.

7.32 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.



7.33 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

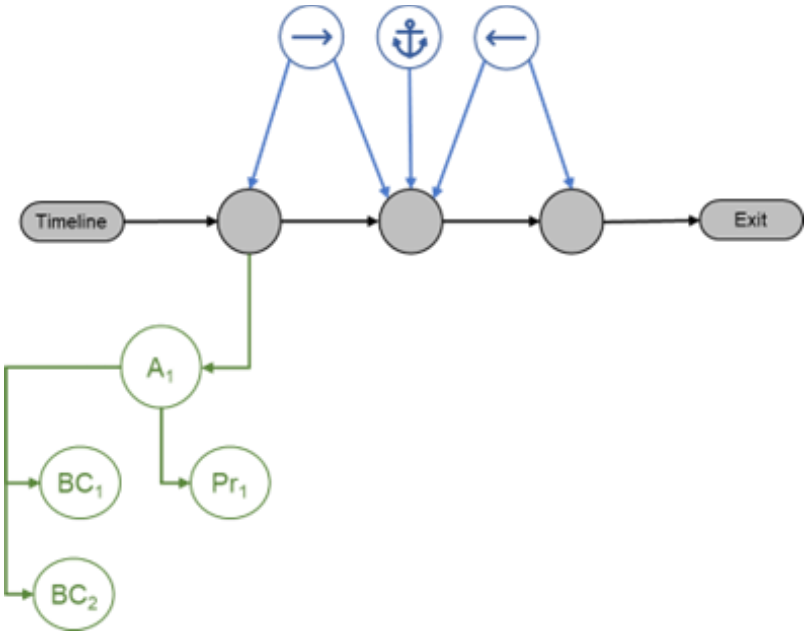
As with conditional footnotes, these footnotes can be handled using the Condition class. The text can then be stored in the corresponding text attribute. Both assessments need to be specified as a BC, procedure, or BC surrogate. The specified condition then can be related to both using the appliesTo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

7.34 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.



7.35 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").

7.36 Eligibility Requirements

Eligibility criteria are stored in the EligibilityCriteria class (see Section 4.19, 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 >= 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.

7.37 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.

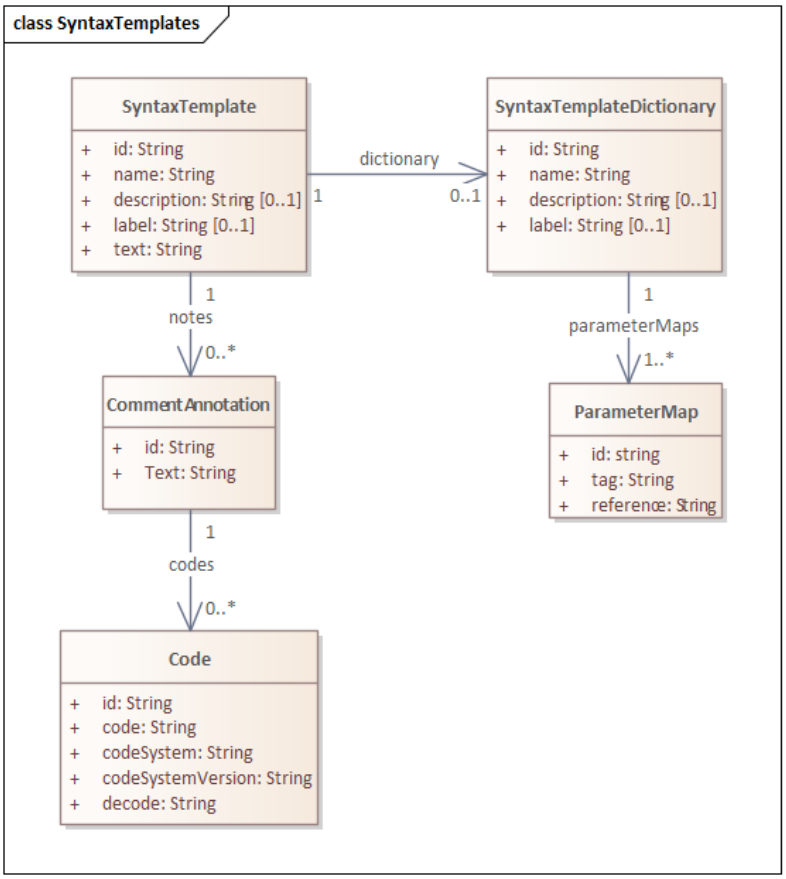
7.38 Syntax Templates

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 data model) 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) as follows:

<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 implementors.

7.39 XHTML Attributes

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

- 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 ** ** 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.

7.40 Abbreviations

8 General

Abbreviation are often used with protocol documents. So as to allow for 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. This is shown in the UML in paragraph Study, Protocols, and Amendments.
Abbreviations can be reused (i.e. referenced) both from within unstructured document content as well as 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.

9 Abbreviations

Abbreviations consist of two parts, the abbreviated text and the expanded text. Several examples of Abbreviation instances are shown below:

Abbreviation		
id	**abbreviatedText**	**expandedText**
Abbr_1	AD	Alzheimer 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

10 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 XHTML Attributes). An example of a text item concerning the rationale is shown below. Note the example references the above example abbreviations:

NarrativeContentItem		
id	**Name**	**text**
Item001	Rationale1	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.

11 Referencing From Syntax Templates

Abbreviations can also be referenced from syntax templates. Two examples are given in the following sections. Note the examples reference the above example abbreviations.

11.1 Objective

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

11.2 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 we can also replace all the abbreviations by the corresponding tags as follows.
EligibilityCriterion.text= ' 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). '
The reference from the tag used in the syntax template texts of Objective and EligibilityCriterion to the specific instance in the Abbreviation class is specified in the SyntaxTemplateDictionary and the ParameterMap instances specified within the dictionary as follows:

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 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		0..*		A USDM relationship between the Abbreviation and Comment Annotation classes which provides the set of notes related 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	C188842		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	C207458		Study Activity Label	The short descriptive designation for the study 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.		
	notes	CommentAnnotation		0..*		A USDM relationship between the Activity and CommentAnnotation classes which provides the set of notes related to the activity.		
	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 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	C201311		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	C176229		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 sub-division 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	0..1	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	1	Administrable Product Dose Form	The physical form in which formulated ingredient(s) are presented in the administrable product.	SDTM Terminology Codelist C66726	
	notes	CommentAnnotation		0..*		A USDM relationship between the AdministrableProductn and CommentAnnotation classes which provides the set of notes related to the administrable product.		
	pharmacologicClass	Code	CNEW	0..1	Administrable Product Pharmacologic Class	The pharmacological class of the administrable product.	(Points to external codelists such as UNII, MED-RT)	
	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.		
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.		
	text	string	CNEW		Administrable Product Property Text	An instance of structured text that represents the administrable product property.		
	type	Code	CNEW	1	Administrable Product Property Type	A characterization or classification of the administrable product property.	CNEW Administrable Product Property Type	

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	quantity	Quantity	CNEW	0..1	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	C207465		Administration Name	The literal identifier (i.e., distinctive designation) for the administration of a product, agent, or therapy.		
	description	string	C207463		Administration Description	A narrative representation for the administration of a product, agent, or therapy.		
	label	string	C207464		Administration Label	The short descriptive designation for the administration of a 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.		
	route	AliasCode	C38114	0..1	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	
	dose	Quantity	C167190	0..1	Administration Dose	The value representing the amount of an agent given to an individual at one time.		
	frequency	AliasCode	C89081	0..1	Dosing Frequency	The number of doses administered per a specific interval.	SDTM Terminology Codelist C71113	
	notes	CommentAnnotation		0..*		A USDM relationship between the Administration and CommentAnnotation classes which provides the set of notes related to 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.		
AdministrationDuration			C69282		Administration Duration	The amount of time elapsed during the administration of an agent.		
	id	string						
	description	string	C207459		Administration Duration Description	A narrative representation of the agent administration duration.		
	durationWillVary	Boolean	C207461		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	C207462		Administration Duration Reason Duration Will Vary	The explanation for why the agent administration duration will vary within and/or across subjects.		
	quantity	Quantity	C207460	0..1	Administration Duration Quantity Value	The value representing the amount of time over which the administration of an agent occurs.		
AliasCode			C201344		Alias Code	An alternative symbol or combination of symbols which is assigned to the members of a collection.		
	id	string						
	standardCode	Code		1		A USDM relationship between the AliasCode and Code classes which provides the details of the standard code.		
	standardCodeAliases	Code		0..*		A USDM relationship between the AliasCode and Code classes which identifies the set of standard code aliases associated with the alias 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. (ICH E9 R1 Addendum)		
	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.		
	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.		
	notes	CommentAnnotation		0..*		A USDM relationship between the AnalysisPopulation and CommentAnnotation classes which provides the set of notes related to the analysis population.		
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	1	Biomedical Concept Concept Code	A concept unique identifier assigned to a biomedical concept that points to the meaning of that biomedical concept.		
	notes	CommentAnnotation		0..*		A USDM relationship between the BiomedicalConcept and CommentAnnotation classes which provides the set of notes related 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.		
	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	0..1	Biomedical Concept Category Code	A symbol or combination of symbols which is assigned 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.		
	notes	CommentAnnotation		0..*		A USDM relationship between the BiomedicalConcept and CommentAnnotation classes which provides the set of notes related to the biomedical concept category.		
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.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	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. (After HL7)		
	code	AliasCode	C201318	1	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.		
	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.		
	notes	CommentAnnotation		0..*		A USDM relationship between the BiomedicalConcept and CommentAnnotation classes which provides the set of notes related to 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		0..*		A USDM relationship between the BiomedicalConcept and CommentAnnotation classes which provides the set of notes related to the biomedical concept surrogate.		
Characteristic			C25447		Characteristic	The distinguishing qualities or prominent aspects of an entity.		
	id	string						SyntaxTemplate
	name	string	C207477		Characteristic Name	The literal identifier (i.e., distinctive designation) of the characteristic.		SyntaxTemplate
	description	string	C207475		Characteristic Description	A narrative representation of the characteristic.		SyntaxTemplate
	label	string	C207476		Characteristic Label	The short descriptive designation for the characteristic.		SyntaxTemplate
	text	string	C207478		Characteristic Text	An instance of structured text that represents the characteristic.		SyntaxTemplate
	notes	CommentAnnotation		0..*		A USDM relationship between the Characteristic and CommentAnnotation classes which provides the set of notes related 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	C188858		Code Value	The literal value of a code.		
	codeSystem	string	C188859		Code System Name	The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.		
	codeSystemVersion	string	C188868		Code System Version	The version of the code system.		
	decode	string	C188861		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	0..*	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	C207483		Condition Name	The literal identifier (i.e., distinctive designation) of the condition.		SyntaxTemplate
	description	string	C207481		Condition Description	A narrative representation of the condition.		SyntaxTemplate
	label	string	C207482		Condition Label	The short descriptive designation for the condition.		SyntaxTemplate
	text	string	C207484		Condition Text	An instance of structured text that represents the condition.		SyntaxTemplate
	notes	CommentAnnotation		0..*		A USDM relationship between the Condition and CommentAnnotation classes which provides the set of notes related 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			C201335		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 Reference Section Number	The numeric identifier of a particular section for the document content reference.		
	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						SyntaxTemplate
	name	string	C207488		Study Eligibility Criterion Name	The literal identifier (i.e., distinctive designation) of the study eligibility criterion.		SyntaxTemplate
	description	string	C207486		Study Eligibility Criterion Description	A narrative representation of the study eligibility criterion.		SyntaxTemplate
	label	string	C207487		Study Eligibility Criterion Label	The short descriptive designation for the study eligibility criterion.		SyntaxTemplate
	text	string	C207485		Study Eligibility Criterion Text	An instance of structured text that represents the study eligibility criterion.		SyntaxTemplate
	notes	CommentAnnotation		0..*		A USDM relationship between the EligibilityCriterion and CommentAnnotation classes which provides the set of notes related to the eligibility criterion.		SyntaxTemplate
	dictionary	SyntaxTemplateDictionary		0..1		A USDM relationship between the EligibilityCriterion and SyntxTemplateDictionary classes which provides the set of dictionary entries related to eligibility criteria.		SyntaxTemplate
	identifier	string	C207489		Study Eligibility Criterion Identifier	A sequence of characters used to identify, name, or characterize the inclusion or exclusion criterion.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	category	Code	C83036	1	Study Eligibility Criterion Category	A classification of the inclusion exclusion criterion.	SDTM Terminology Codelist C66797	
	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.		
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	C171010		Study Encounter Name	The literal identifier (i.e., distinctive designation) for a protocol-defined study encounter.		
	description	string	C188836		Study Encounter Description	A narrative representation of the protocol-defined study encounter.		
	label	string	C207490		Study Encounter Label	The short descriptive designation for the study encounter.		
	environmentalSettings	Code	C188840	0..*	Environmental Setting	The environment/setting where the event, intervention, or finding occurred.	SDTM Terminology Codelist C127262	
	contactModes	Code	C188841	0..*	Contact Mode	The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).	SDTM Terminology Codelist C171445	
	type	Code	C188839	1	Study Encounter Type	A characterization or classification of the study encounter.	C188728	
	notes	CommentAnnotation		0..*		A USDM relationship between the Encounter and CommentAnnotation classes which provides the set of notes related to an 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	C207492		Study Endpoint Name	The literal identifier (i.e., distinctive designation) of the study endpoint.		SyntaxTemplate
	description	string	C188824		Study Endpoint Description	A narrative representation of the study endpoint.		SyntaxTemplate
	label	string	C207491		Study Endpoint Label	The short descriptive designation for the study endpoint.		SyntaxTemplate
	text	string	C207493		Study Endpoint Text	An instance of structured text that represents the study endpoint.		SyntaxTemplate
	notes	CommentAnnotation		0..*		A USDM relationship between the Endpoint and CommentAnnotation classes which provides the set of notes related 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
	purpose	string	C188825		Study Endpoint Purpose Description	The textual representation of the study endpoint purpose.		
	level	Code	C188826	1	Study Endpoint Level	A characterization or classification of the study endpoint that determines its category of importance relative to other study endpoints.	C188726	
Estimand			C188813		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	C188853		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.		
	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.		
	notes	CommentAnnotation		0..*		A USDM relationship between the Estimand and CommentAnnotation classes which provides the set of notes related to a study estimand.		
	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.		
GeographicScope			C207591		Geographic Scope	The extent or range related to the physical location of an entity.		
	id	string						
	code	AliasCode	C207494	0..1	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.)	
	type	Code	C207495	1	Geographic Scope Type	A characterization or classification of the geographic scope.	C207412	
GovernanceDate			C207595		Study Governance Date	Any of the dates associated with event milestones within a clinical study's oversight and management framework.		
	id	string						
	name	string	C207499		Study Governance Date Name	The literal identifier (i.e., distinctive designation) of the study governance date		
	description	string	C207497		Study Governance Date Description	A narrative representation of the study governance date.		
	label	string	C207498		Study Governance Date Label	The short descriptive designation for the study governance date.		
	dateValue	Date	C207500		Study Governance Date Value	The information contained in the date field.		
	type	Code	C207496	1	Study Governance Date Type	A characterization or classification of the study governance date.	C207413	
	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						

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	name	string	C207503		Disease/Condition Indication Name	The literal identifier (i.e., distinctive designation) of the disease/condition indication.		
	description	string	C112038		Disease/Condition Indication Description	A narrative representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.		
	label	string	C207502		Disease/Condition Indication Label	The short descriptive designation for the disease/condition indication.		
	isRareDisease	Boolean	C207501		Disease/Condition Indication Is Rare Disease Indicator	An indication as to whether the disease/condition indication under study is considered a rare disease.		
	codes	Code	C188822	0..*	Disease/Condition Indication 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, NCIt, ICD's, etc.)	
	notes	CommentAnnotation		0..*		A USDM relationship between the Indication and CommentAnnotation classes which provides the set of notes related 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	1	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			C188815		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	C188855		Intercurrent Event Name	The literal identifier (i.e., distinctive designation) of the intercurrent event.		SyntaxTemplate
	description	string	C188856		Intercurrent Event Description	A narrative representation of the intercurrent event.		SyntaxTemplate
	label	string	C207504		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		0..*		A USDM relationship between the IntercurrentEvent and CommentAnnotation classes which provides the set of notes related 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	C188857		Intercurrent Event Strategy	A textual description of the planned strategy to manage and/or mitigate intercurrent events.		
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						
	description	string	C207505		Masking Description	A narrative representation of the study masking strategy, based on a person's role within the study.		
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.		
	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			C142450		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	C207512		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	C207511		Study Objective Label	The short descriptive designation for the study objective.		SyntaxTemplate
	text	string	C207513		Study Objective Text	An instance of structured text that represents the study objective.		SyntaxTemplate
	notes	CommentAnnotation		0..*		A USDM relationship between the Objective and CommentAnnotation classes which provides the set of notes related 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	C188823	1	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.		
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.		
	legalAddress	Address		0..1		A USDM relationship between the Organization and Address classes which provides the legal address for an organization.		
	type	Code	C188820	1	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	
	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.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	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.		
	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.		
	plannedSex	Code	C207523	0..2	Population Definition Planned Sex	The protocol-defined sex within the population definition.	SDTM Terminology Codelist C66732	
	notes	CommentAnnotation		0..*		A USDM relationship between the PopulationDefinition and CommentAnnotation classes which provides the set of notes related to the population definition.		
	criteria	EligibilityCriterion		0..*		A USDM relationship between the PopulationDefinition and EligibilityCriterion classes which identifies the set of eligibility criteria associated with the population definition.		
	plannedAge	Range	C207701	0..1	Population Definition Planned Age	The anticipated age of subjects within the population definition.		
	plannedEnrollmentNumber	Range	C207522	0..1	Population Definition Planned Enrollment Number	The value representing the planned number of subjects to be entered in a clinical trial, within the population definition.		
	plannedCompletionNumber	Range	C207521	0..1	Population Definition Planned Completion Number	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.		
Procedure			C98769		Procedure	Any activity performed by manual and/or instrumental means for the purpose of diagnosis, assessment, therapy, prevention, or palliative care.		
	id	string						
	name	string	C201325		Procedure Name	The literal identifier (i.e., distinctive designation) of the procedure.		
	description	string	C201324		Procedure Description	A narrative representation of the procedure.		
	label	string	C207524		Procedure Label	The short descriptive designation for the procedure.		
	procedureType	string	C188848		Procedure Type	A characterization or classification of the study procedure.		
	code	Code	C154626	1	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		0..*		A USDM relationship between the Procedure and CommentAnnotation classes which provides the set of notes related to a procedure.		
	studyIntervention	StudyIntervention		0..1		A USDM relationship between the Procedure and StudyInterventionclasses which provides the details associated with an instance of an intervention performed during the conduct of a procedure.		
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	0..1	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	Float	C25570		Minimum Value	The smallest value in quantity or degree in a set of values.		
	maxValue	Float	C25564		Maximum Value	The largest value in quantity or degree in a set of values.		
	isApproximate	Boolean	C207525		Value Range is Approximate Indicator	An indication as to whether the value range is almost, but not quite, exact.		
	unit	Code	C25709	0..1	Unit of Measure	A named quantity in terms of which other quantities are measured or specified, used as a standard measurement of like kinds.	SDTM Terminology Codelist C71620	
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	1	Reference Identifier Type	A characterization or classification of the reference identifier.	CNEW Reference Identifier Type	
ResponseCode			C201347		Response Code	A symbol or combination of symbols representing the response to the question.		
	id	string						
	isEnabled	Boolean	C201330		Response Code Enabled Indicator	An indication as to whether the response code is activated for use within a given usage context.		
	code	Code	C25162	1	Code	A symbol or combination of symbols which is assigned to the members of a collection.		
ScheduleTimeline			C201348		Schedule Timeline	A chronological schedule of planned temporal events.		
	id	string						
	name	string	C201334		Schedule Timeline Name	The literal identifier (i.e., distinctive designation) of the schedule timeline.		
	description	string	C201332		Schedule Timeline Description	A narrative representation of the schedule timeline.		
	label	string	C207530		Schedule Timeline Label	The short descriptive designation for the schedule timeline.		
	entryCondition	string	C201333		Schedule Timeline Entry Condition	A logical evaluation on which rests the validity of entry into a schedule timeline.		
	mainTimeline	Boolean	C201331		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			C201349		Schedule Timeline Exit	To go out of or leave the schedule timeline.		
	id	string						
ScheduledActivityInstance			C201350		Scheduled Activity Instance	A scheduled occurrence of an activity event.		
	id	string						ScheduledInstance
	name	string	C207533		Scheduled Activity Instance Name	The literal identifier (i.e., distinctive designation) of the scheduled activity instance.		ScheduledInstance
	description	string	C207531		Scheduled Activity Instance Description	A narrative representation of the scheduled activity instance.		ScheduledInstance
	label	string	C207532		Scheduled Activity Instance Label	The short descriptive designation for the scheduled activity instance.		ScheduledInstance

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	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 from a timeline related to a scheduled activity instance.		
ScheduledDecisionInstance			C201351		Scheduled Decision Instance	A scheduled occurrence of a decision event.		
	id	string						ScheduledInstance
	name	string	C207536		Scheduled Decision Instance Name	The literal identifier (i.e., distinctive designation) of the scheduled Decision instance.		ScheduledInstance
	description	string	C207534		Scheduled Decision Instance Description	A narrative representation of the scheduled Decision instance.		ScheduledInstance
	label	string	C207535		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			C201299		Scheduled Instance	A scheduled occurrence of a temporal event.		
	id	string						
	name	string	C207455		Scheduled Instance Name	The literal identifier (i.e., distinctive designation) of the scheduled instance.		
	description	string	C207453		Scheduled Instance Description	A narrative representation of the scheduled instance.		
	label	string	C207454		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.		
	numerator	Quantity, Range		0..1		A USDM relationship between the Strength and the Quantity and Range classes that identifies the numerator's value or range of values associated with the substance strength.		
	denominator	Quantity		0..1		A USDM relationship between the Strength and Quantity classes that identifies the denominator associated with the substance strength.		
Study			C15206		Clinical Study	A clinical study involves research using human volunteers (also called subjects or 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. [http://ClinicalTrials.gov](CDISC Glossary)		
	id	string						
	name	string	C68631		Clinical Study Name	The literal identifier (i.e., distinctive designation) of the clinical study.		
	description	string	C142704		Clinical Study Description	A narrative representation of the clinical study.		
	label	string	C207479		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 classes signifying that the study is documented in a study definition document.		
StudyAmendment			C207594		Study Amendment	A written description of a change(s) to, or formal clarification of, a study.		
	id	string						
	number	string	C207537		Study Amendment Number	A string of numerals that uniquely identifies a protocol amendment.		
	summary	string	C115627		Study Amendment Summary	A short narrative representation describing the changes introduced in the current version of the protocol.		
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyAmendment and CommentAnnotation classes which provides the set of notes related to the study amendment.		
	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	C207538		Study Amendment Impact Substantial Indicator	An indication as to whether the study amendment's impact on the study is substantial.		
	type	Code	CNEW	1	Study Amendment Impact Type	A characterization or classification of the study amendment impact.	CNEW Study Amendment Impact Type Response	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyAmendmentImpact and CommentAnnotation classes which provides the set of notes related to the study amendment impact.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
StudyAmendmentReason			C207457		Study Amendment Reason	The rationale for the change(s) to, or formal clarification of, a protocol.		
	id	string						
	otherReason	string	C207539		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	C207540	1	Study Amendment Reason Code	A symbol or combination of symbols which is assigned to the study amendment reason.	C207415	
StudyArm			C174447		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	C170984		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.		
	label	string	C172456		Study Arm Label	The short descriptive designation for the study arm.		
	dataOriginDescription	string	C188828		Study Arm Data Origin Description	The textual representation of the study arm data origin.		
	dataOriginType	Code	C188829	1	Study Arm Data Origin Type	A characterization or classification of the study arm with respect to where the study arm data originates.	C188727	
	type	Code	C188827	1	Study Arm Type	A characterization or classification of the study arm.	Protocol Terminology Codelist C174222	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyArm and CommentAnnotation classes which provides the set of notes related 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			C188810		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		0..*		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	C207544		Study Cohort Name	The literal identifier (i.e., distinctive designation) of the study cohort.		PopulationDefinition
	description	string	C207542		Study Cohort Description	A narrative representation of the study cohort.		PopulationDefinition
	label	string	C207543		Study Cohort Label	The short descriptive designation for the study cohort.		PopulationDefinition
	includesHealthySubjects	Boolean	C207480		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
	plannedSex	Code	C207541	0..2	Study Cohort Planned Sex	The protocol-defined sex within the study cohort.	SDTM Terminology Codelist C66732	PopulationDefinition
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyCohort and CommentAnnotation classes which provides the set of notes related 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
	plannedAge	Range	C207545	0..1	Study Cohort Planned Age	The anticipated age of subjects within the study cohort.		PopulationDefinition
	plannedEnrollmentNumber	Range	C207702	0..1	Study Cohort Planned Enrollment Number	The value representing the planned number of subjects to be entered in a clinical trial, within the study cohort.		PopulationDefinition
	plannedCompletionNumber	Range	C207546	0..1	Study Cohort Planned Completion Number	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
	characteristics	Characteristic		0..*		A USDM relationship between the StudyCohort and Characteristic classes which identifies the set of subject characteristics 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.		
	templateName	string	CNEW		Study Definition Document Template Name	The literal identifier (i.e., distinctive designation) of the study definition document template.		
	language	Code	CNEW	1	Study Definition Document Language	The language in which the study definition document is written.	(Point out to ISO 639 language value list)	
	type	Code	CNEW	1	Study Definition Document Type	A characterization or classification of the study definition document.	CNEW Study Definition Document Type	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyDefinitionDocument and CommentAnnotation classes which provides the set of notes related 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						
	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.		
	status	Code	CNEW	1	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	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyDefinitionDocumentVersion and CommentAnnotation classes which provides the set of notes related 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.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
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.		
	label	string	C207548		Study Design Label	The short descriptive designation for the study design.		
	rationale	string	C142705		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.		
	activities	Activity		0..*		A USDM relationship between the StudyDesign and Activity classes which identifies the set of activities associated with the study design.		
	trialIntentTypes	Code	C49652	0..*	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	SDTM Terminology Codelist C66736	
	blindingSchema	Code	C49658	0..1	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 intervention(s) or assessments being observed, received or administered.	SDTM Terminology Codelist C66735	
	therapeuticAreas	Code	C101302	0..*	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)	
	characteristics	Code	C207547	0..*	Study Design Characteristic	The distinguishing qualities or prominent aspect of a study design.	C207416	
	trialTypes	Code	C49660	0..*	Trial Type	The nature of the interventional study for which information is being collected.	SDTM Terminology Codelist C66739	
	interventionModel	Code	C98746	1	Intervention Model Type	The general design of the strategy for assigning interventions to subjects in a clinical study. (clinicaltrials.gov)	SDTM Terminology Codelist C99076	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyDesign and CommentAnnotation classes which provides the set of notes 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 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		0..1		A USDM relationship between the StudyDesign and StudyDesignPopulation classes which identifies the population associated with the study design.		
StudyDesignPopulation			C142728		Study Design Population	The population within the general population to which the study results can be generalized.		
	id	string						PopulationDefinition
	name	string	C207553		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	C207550		Study Design Population Label	The short descriptive designation for the study design population.		PopulationDefinition
	includesHealthySubjects	Boolean	C207549		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
	plannedSex	Code	C207551	0..2	Study Design Population Planned Sex	The protocol-defined sex within the study design population.	SDTM Terminology Codelist C66732	PopulationDefinition
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyDesignPopulation and CommentAnnotation classes which provides the set of notes related 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
	plannedAge	Range	C207450	0..1	Study Design Population Planned Age	The anticipated age of subjects within the study design population.		PopulationDefinition
	plannedEnrollmentNumber	Range	C207452	0..1	Study Design Population Planned Enrollment Number	The value representing the planned number of subjects to be entered in a clinical trial, within the study design population.		PopulationDefinition
	plannedCompletionNumber	Range	C207451	0..1	Study Design Population Planned Completion Number	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
	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			C142735		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	C188833		Study Design Element Name	The literal identifier (i.e., distinctive designation) of the study design element.		
	description	string	C188834		Study Design Element Description	A narrative representation of the study design element.		
	label	string	C207554		Study Design Element Label	The short descriptive designation for the study design element.		
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyElement and CommentAnnotation classes which provides the set of notes related 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.		
	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.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
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	C207555		Study Epoch Label	The short descriptive designation for the study epoch.		
	type	Code	C188830	1	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		0..*		A USDM relationship between the StudyEpoch and CommentAnnotation classes which provides the set of notes related 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			C207649		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	C207647		Study Intervention Description	A narrative representation of the study intervention.		
	name	string	C207558		Study Intervention Name	The literal identifier (i.e., distinctive designation) of the study intervention.		
	label	string	C207556		Study Intervention Label	The short descriptive designation for 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.		
	type	Code	C98747	1	Study Intervention Type	The kind of product or procedure studied in a trial.	SDTM Terminology Codelist C99078	
	role	Code	C207560	1	Study Intervention Role	The intended use of the trial intervention within the context of the study design.	C207417	
	productDesignation	Code	C207559	1	Study Intervention Product Designation	An indication as to whether the investigational intervention is an investigational medicinal product or an auxiliary medicinal product.	C207418	
	codes	Code	C207648	0..*	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.)	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyIntervention and CommentAnnotation classes which provides the set of notes related to the study intervention.		
	minimumResponseDuration	Quantity	C207557	0..1	Study Intervention Minimum Response Duration	The value representing the minimum amount of time required to meet the criteria for response to study intervention.		
StudyRole			CNEW		Study Role	A designation that identifies the function of study personnel within the context of the study.		
	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.		
	assignedPersons	AssignedPerson		0..*		A USDM relationship between the StudyRole and AssignedPerson classes that identifies the set of individuals that are assigned to fill a particular role within the study.		
	code	Code	CNEW	1	Study Role Code	A symbol or combination of symbols which is assigned to the study role.	CNEW Study Role Code	
	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	C207566		Study Site Name	The literal identifier (i.e., distinctive designation) of the study site.		
	description	string	C207564		Study Site Description	A narrative representation of the study site.		
	label	string	C207565		Study Site Label	The short descriptive designation for the study site.		
	country	Code	C170990	1	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						
	text	string	C207567		Study Title Text	An instance of unstructured text that represents the study title.		
	type	Code	C207568	1	Study Title Type	A characterization or classification of the study title.	C207419	
StudyVersion			C188816		Study Version	A plan at a particular point in time for a study.		
	id	string						
	versionIdentifier	string	C207570		Study Version Identifier	A sequence of characters used to identify, name, or characterize the study version.		
	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.		
	abbreviations	Abbreviation		0..*		A USDM relationship between the StudyVersion and Abbreviation classes which provides the set of abbreviations associated with the study version.		
	studyPhase	AliasCode	C48281	0..1	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	
	businessTherapeuticAreas	Code	C201322	0..*	Business Therapeutic Areas	A therapeutic area classification based on the structure and operations of the business unit.	(Point out to external dictionaries)	
	studyType	Code	C142175	0..1	Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	SDTM Terminology Codelist C99077	
	notes	CommentAnnotation		0..*		A USDM relationship between the StudyVersion and CommentAnnotation classes which provides the set of notes related to 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.		

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref	Inherited From
	studyDesigns	StudyDesign		0..*		A USDM relationship between the StudyVersion and 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..		
	appliesTo	GeographicScope, StudyCohort, StudySite		0..1		A USDM relationship between the SubjectEnrollment and StudySite, StudyCohort, or GeographicScope classes which identifies the study site, study cohort, or geographic scope to which the subject enrollment applies.		
	quantity	Quantity	C207573	1	Subject Enrollment Quantity Value	The value representing the number of individuals enrolled in a study.		
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	0..*	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			C207596		Syntax Template	A standardized pattern used for the arrangement of words and phrases to create well-formed, structured sentences.		
	id	string						
	name	string	C207577		Syntax Template Name	The literal identifier (i.e., distinctive designation) of the syntax template.		
	description	string	C207575		Syntax Template Description	A narrative representation of the syntax template.		
	label	string	C207576		Syntax Template Label	The short descriptive designation for the syntax template.		
	text	string	C207578		Syntax Template Text	A structured text string containing prescribed text interspersed with user-defined parameter values.		
	notes	CommentAnnotation		0..*		A USDM relationship between the SyntaxTemplate and CommentAnnotation classes which provides the set of notes related 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.		
SyntaxTemplateDictionary			C207597		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	C207581		Syntax Template Dictionary Name	The literal identifier (i.e., distinctive designation) of the syntax template dictionary.		
	description	string	C207579		Syntax Template Dictionary Description	A narrative representation of the syntax template dictionary.		
	label	string	C207580		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	C207584		Timing Name	The literal identifier (i.e., distinctive designation) of the timing.		
	description	string	C164648		Timing Description	A narrative representation of the chronological relationship between temporal events.		
	label	string	C207583		Timing Label	The short descriptive designation for the timing.		
	value	string	C201341		Timing Value	The temporal value of the chronological relationship between temporal events.		
	valueLabel	string	C207585		Timing Value Label	The short descriptive designation for the timing value.		
	windowLabel	string	C207586		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	C201342		Timing Window, Lower	The earliest chronological value of an allowable period of time during which a temporal event takes place.		
	windowUpper	string	C201343		Timing Window, Upper	The latest chronological value of an allowable period of time during which a temporal event takes place.		
	relativeToFrom	Code	C201297	1	Timing Relative To From	The name of the reference event used to define the temporal relationship with another event.	C201265	
	type	Code	C201298	1	Timing Type	A characterization or classification of the chronological relationship between temporal events.	C201264	
	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	C207588		Transition Rule Name	The literal identifier (i.e., distinctive designation) of the transition rule.		
	description	string	C188835		Transition Rule Description	A narrative representation of the transition rule.		
	label	string	C207587		Transition Rule Label	The short descriptive designation for the transition rule.		
	text	string	C207589		Transition Rule Text	An instance of unstructured text that represents the transition rule.		

13 USDM API

13.1 General

The reference architecture API is designed as a mechanism for bulk transfer to allow for the creation of a study within the SDR, the reading of such a study, and the update of a study. 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.

13.2 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 series of 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.

13.3 API Additional Attributes

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

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.

13.4 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, scoped by an Organization of type Clinical Study Sponsor (C70793).
3. There is at least 1 StudyDesign within the StudyVersion.

14 Mapping to Other Standards and Formats

14.1 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 like Trial Disease Assessments (TD) and Trial Disease Milestones (TM) that are described in the SDTMIG contain information that is stored in the USDM as well; these, however, 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
STUDYID	Study Identifier	Char	Identifier	Req	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		study.studyVersion.studyIdentifier.organization. type.code=C188724 (Clinical StudySponsor)
DOMAIN	Domain Abbreviation	Char	Identifier	Req			Set to "TA"
ARMCD	Planned Arm Code	Char	Topic	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name		
ARM	Description of Planned Arm	Char	Synonym Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@description		
TAETORD	Planned Order of Element within Arm	Num	Timing	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@epoch /StudyEpoch/@previous | @next	..../StudyCell/@arm ..../StudyCell/@elements	Link epochs via StudyCell to the corresponding study elements. Order epochs and their related elements based on previous StudyEpoch and next StudyEpoch attributes and derive a corresponding ordering number.
ETCD	Element Code	Char	Record Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@name	..../StudyCell/@arm	
ELEMENT	Description of Element	Char	Synonym Qualifier	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@description	..../StudyCell/@arm	
TABRANCH	Branch	Char	Rule	Exp	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledDecisionInstance/@conditionAssignments	..../StudyCell/@epoch ..../StudyCell/@arm	ScheduledInstances in a timeline point to a StudyEpoch (see Section 4.14, Study Timing). Branching information can be stored as scheduledDecisionInstances using the ConditionAssignment that points to the first instance related to the next epoch.
TATRANS	Transition Rule	Char	Rule	Exp	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledDecisionInstance/@conditionAssignments	..../ScheduledActivityInstance/@epoch ..../StudyCell/@epoch ..../StudyCell/@arm	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 not being the default next instance on the timeline.

Variable Name	Variable Label	Type	Role	Core	USDM Path and Attribute	Required USDM relationships	Selection / Derivation
EPOCH	Epoch	Char	Timing	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@epoch /StudyEpoch/@name	..../StudyCell/@arm	

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
STUDYID	Study Identifier	Char	Identifier	Req	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		study.studyVersion.studyIdentifier.organization. type.code=C188724 (Clinical StudySponsor)
DOMAIN	Domain Abbreviation	Char	Identifier	Req			Set to "TE"
ETCD	Element Code	Char	Topic	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@name		
ELEMENT	Description of Element	Char	Synonym Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@description		
TESTRL	Rule for Start of Element	Char	Rule	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@transitionStartRule /TransitionRule/@text		
TEENRL	Rule for End of Element	Char	Rule	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@elements /StudyElement/@transitionEndRule /TransitionRule/@text		
TEDUR	Planned Duration of Element	Char	Timing	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@scheduleTimelines /ScheduleTimeline/@instances /ScheduledActivityInstance/@timings /Timing/@value	..../ScheduledActivityInstance/@epoch ..../StudyCell/@epoch ..../StudyCell/@elements	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.

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
STUDYID	Study Identifier	Char	Identifier	Req	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		study.studyVersion.studyIdentifier.organization. type.code=C188724 (Clinical StudySponsor)
DOMAIN	Domain Abbreviation	Char	Identifier	Req			Set to "TV"
VISITNUM	Visit Number	Num	Topic	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@encounter /Encounter/@previous | @next		Order encounters based previous and next attributes and derive the visit order number correspondingly. Assign numbers based on applicable standard visit numbering rules.
VISIT	Visit Name	Char	Synonym Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@encounter /Encounter/@name		
VISITDY	Planned Study Day of Visit	Num	Timing	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@encounter /Encounter/@timing /Timing/@timingValue		
ARMCD	Planned Arm Code	Char	Record Qualifier	Exp	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@arm /StudyArm/@name	..../StudyCell/@epoch ..../ScheduledActivityInstance/@epoch ..../ScheduledActivityInstance/@encounter	In case visits differ by arm, the corresponding arm can be derived via the ScheduledActivityInstance relating the encounter via StudyEpoch and StudyCell to the corresponding StudyArm.
ARM	Description of Planned Arm	Char	Synonym Qualifier	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@arm /StudyArm/@description	..../StudyCell/@epoch ..../ScheduledActivityInstance/@epoch ..../ScheduledActivityInstance/@encounter	
TVSTRL	Visit Start Rule	Char	Rule	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@encounter /Encounter/@transitionStartRule /TransitionRule/@text		
TVENRL	Visit End Rule	Char	Rule	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@encounter /Encounter/@transitionEndRule /TransitionRule/@text		

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
STUDYID	Study Identifier	Char	Identifier	Req	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		study.studyVersion.studyIdentifier.organization. type.code=C188724 (Clinical StudySponsor)
DOMAIN	Domain Abbreviation	Char	Identifier	Req			Set to "TI"
IETESTCD	Incl/Excl Criterion Short Name	Char	Topic	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriteria/@identifier		Eligibility criteria might be directly linked to a study Population or via one of the corresponding cohorts. Therefore an alternative path is specified via the StudyCohort class.
IETEST	Inclusion/Exclusion Criterion	Char	Synonym Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriteria/@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.
IECAT	Inclusion/Exclusion Category	Char	Grouping Qualifier	Req	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriteria/@category /code/@decode		
IESCAT	Inclusion/Exclusion Subcategory	Char	Grouping Qualifier	Perm			Permitted value. Not available in USDM. Can be applied according to user preference.
TIRL	Inclusion/Exclusion Criterion Rule	Char	Rule	Perm	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriteria/@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.
TIVERS	Protocol Criteria Versions	Char	Record Qualifier	Perm	Study/@versions /StudyVersion/@documentVersion /StudyProtocolDocumentVersion/@protocolVersion		

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
STUDYID	Study Identifier	Char	Identifier	Req	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		study.studyVersion.studyIdentifier.organization. type.code=C188724 (Clinical StudySponsor)
DOMAIN	Domain Abbreviation	Char	Identifier	Req			Set to "TS"
TSSEQ	Sequence Number	Num	Identifier	Req	*See TSPARM mapping table below*		
TSGRPID	Group ID	Char	Identifier	Perm	*See TSPARM mapping table below*		
TSPARMCD	Trial Summary Parameter Short Name	Char	Topic	Req	*See TSPARM mapping table below*		
TSPARM	Trial Summary Parameter	Char	Synonym Qualifier	Req	*See TSPARM mapping table below*		
TSVAL	Parameter Value	Char	Result Qualifier	Exp	*See TSPARM mapping table below.If not otherwise specified:*...Code/@decode		
TSVALNF	Parameter Value Null Flavor	Char	Result Qualifier	Perm	*Fill in case of missing values with expected data as described in the SDTMIG*		
TSVALCD	Parameter Value Code	Char	Result Qualifier	Exp	*See TSPARM mapping table below.If not otherwise specified:*...Code/@decode		
TSVCDREF	Name of Reference Terminology	Char	Result Qualifier	Exp	*See TSPARM mapping table below.* *If not otherwise specified:*...Code/@codeSystem		
TSVCDVER	Version of the Reference Terminology	Char	Result Qualifier	Exp	*See TSPARM mapping table below.* *If not otherwise specified:*...Code/@codeSystemVersion		

The following table provides a list of published Trial Summary 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 Controlled Terminology codelist C66738, from SDTM Terminology Version 2023-09-29. For all synonyms and definitions, please see the corresponding terminology file.

TSPARM	TSPARMCD	Code	Codelist Code	TSVAL USDM Path and Attribute	Selection / Derivations	TSSEQ	TSGRPID
Adaptive Design	ADAPT	C146995	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode	If characteristics include "ADAPTIVE" then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487"		
Planned Minimum Age of Subjects	AGEMIN	C49693	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation |StudyCohort/@plannedAge /Range/@minValue + @unit	Use minimum of minimum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. If one ore more populations have a null minValue then TSVAL should be set to null and TSVALNF should be filled instead according to ISO 21090.		
Planned Minimum Age of Subjects	AGEMAX	C49694	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation |StudyCohort/@plannedAge /Range/@maxValue + @unit	Use maximum of maximum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. If one ore more populations have a null maxValue then TSVAL should be set to null and TSVALNF should be filled instead according to ISO 21090.		
Comparative Treatment Name	COMPTRT	C68612	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name	..StudyIntervention/@role/ Code/@Code<>"C41161" (not "Experimental Intervention") and ..StudyIntervention/@productDesignation/ Code/@decode="IMP"	Add Unique number if more than 1	If applicable, combine with the corresponding intervention variables by a common tsgrpid
Current Therapy or Treatment	CURTRT	C85582	C66738	Study/@versions /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 tsgrpid
Dose Level; Dose per Administration	DOSE	C25488	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@dose /Quantity/@value			If applicable, combine with the corresponding intervention variables by a common tsgrpid
Dosing Frequency	DOSFRQ	C89081	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@frequency			If applicable, combine with the corresponding intervention variables by a common tsgrpid
Dose Units	DOSU	C73558	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@dose /Quantity/@unit			If applicable, combine with the corresponding intervention variables by a common tsgrpid
Extension Trial Indicator	EXTTIND	C139274	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode	If characteristics include "Extension" then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487"		
Planned Country of Investigational Sites	FCNTRY	C98770	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@appliesTo /StudySite/@currentEnrollment /SubjectEnrollment/@code /AliasCode/@StandardCode	SubjectEnrollment/@type /code/@code=C25464 ("Country")	Add Unique number if more than 1	
Healthy Subject Indicator	HLTSUBJI	C98737	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation |StudyCohort/@includesHealthySubjects	If True then TSVAL="Y" and TSVALCD="C49488" If False then TSVAL="N" and TSVALCD="C49487"		
Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	INDIC	C112038	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@indications /Indication/@name or @description			
Intervention Model	INTMODEL	C98746	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@interventionModel			
Intervention Type	INTTYPE	C98747	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@type			If applicable, combine with the corresponding intervention

TSPARM	TSPARMCD	Code	Codelist Code	TSVAL USDM Path and Attribute	Selection / Derivations	TSSEQ	TSGRPID
							variables by a common tsgrpid
Trial Length	LENGTH	C49697	C66738	Study/@versions /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.		
Planned Number of Arms	NARMS	C98771	C66738	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyCohort	Count number of instances (each instance is an cohort) defined in StudyCohort class		
Trial Exploratory Objective	OBJEXP	C163559	C66738	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@objectives /Objective/@text	Objective/@level /code/@Code = C85826 ("Study 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
Study Secondary Objective; Trial Secondary Objective	OBJSEC	C85827	C66738	Study/@versions /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
Exploratory Outcome Measure	OUTMSEXP	C98724	C66738	Study/@versions /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 OUTMSEXP. Alternatively, the referenced biomedical concept can be used for OUTMSEXP.	Add Unique number	combine with the corresponding objective by a common tsgrpid
Primary Outcome Measure	OUTMSPRI	C98772	C66738	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/ @pharmacologicClass	Corresponding @productDesignation should correspond to IMP		If applicable, combine with the corresponding intervention variables by a common tsgrpid
Anticipated Enrollment; Planned Enrollment; Planned Number of Subjects; Target Enrollment	PLANSUB	C49692	C66738	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentADministration/@duration /AdministrationDuration/@quantity /Quantity/@value + @unit			If applicable, combine with the corresponding intervention variables by a common tsgrpid
Trial is Randomized	RANDOM	C25196	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode	If characteristics include "RANDOMIZED" then TSVAL="Y" and TSVALCD="C49488" Otherwise TSVAL="N" and TSVALCD="C49487"		
Rare Disease Indicator	RDIND	C126070	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@indications /Indication/@isRareDisease	If True then TSVAL="Y" and TSVALCD="C49488" If False then TSVAL="N" and TSVALCD="C49487"		
Registry Identifier	REGID	C98714	C66738	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier	..StudyIdentifier/@studyIdentifierScope /Organization/@type /Code/@code=C93453 ("Clinical Study Registry") Fill TSVCDREF with corresponding organization name. ..studyIdentifier/@studyIdentifierScope /Organization/@name	Add Unique number if more than 1	
Route of Administration	ROUTE	C38114	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@route			
Sex of Participants	SEXPOP	C49696	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex			
Clinical Study Sponsor; Sponsor; Study Sponsor	SPONSOR	C70793	C66738	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifierScope /Organization/@name	..Organization/@type /Code/@code=C70793 ("Clinical Study Sponsor") TSVALCD=..Organization/@identifier TSVCDREF=..Organization/@identifierScheme		
Sponsor's Study Reference ID	SPREFID	C135009	C66738	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier	..StudyIdentifier/@studyIdentifierScope /Organization/@type /Code/@code=C70793 ("Clinical Study Sponsor")		
Study Type; Study Type Classification	STYPE	C142175	C66738	Study/@versions /StudyVersion/@studyType			
Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial	TBLIND	C49658	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@blindingSchema			

TSPARM	TSPARMCD	Code	Codelist Code	TSVAL USDM Path and Attribute	Selection / Derivations	TSSEQ	TSGRPID
Blinding Schema; Trial Masking Design							
Control Type	TCNTRL	C49647	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@role	..StudyIntervention/@productDesignation/ Code/@Decode="NIMP" Map valid values of @role to TCNTRL		
Therapeutic Area	THERAREA	C101302	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@therapeuticAreas			
Trial Intent Type	TINDTP	C49652	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@trialIntentTypes		Add Unique number if more than 1	
Official Study Title; Study Title; Trial Title	TITLE	C49802	C66738	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Official Study Title"		
Trial Phase; Trial Phase Classification	TPHASE	C48281	C66738	Study/@versions /StudyVersion/@studyPhase /AliasCode/@standardCode			
Investigational Therapy or Treatment	TRT	C41161	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name	..StudyIntervention/@role/ Code/@Code="C41161"		If applicable, combine with the corresponding intervention variables by a common tsgrpid
Trial Scope; Trial Type	TTYPE	C49660	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@trialTypes		Add Unique number if more than 1	

14.2 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. Included topics and whether they are covered in USDM are presented in the table below.

CT.gov topic	USDM coverage
Study Identification	Yes
Study Status	No; not available at study design stage
Sponsor/Collaborators	No
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; Interventional Study design parameters
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

The mapping for the required data elements of topics that are covered is specified below.
The mapping to **Study Identification** is presented below. 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
Study Identification	Brief Title	Required	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Brief Study Title" limit to 300 characters
Study Identification. Brief Title	Acronym	Required, If available	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Study Acronym" limit to 14 characters
Study Identification	Official Title	Required	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Official Study Title" limit to 600 characters
Study Identification	Secondary ID	Required, If available	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier	..StudyIdentifier/@studyIdentifierScope /Organization/@type /Code/@code <> C70793 ("Clinical Study Sponsor") ..studyIdentifier/@studyIdentifierScope /Organization/@name <> "NCT" (or NCT alias)
Study Identification. Secondary ID	Type	Required, If secondary ID available	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifierScope /Organization/@name	Map organization name to corresponding CT.gov terminology.
Study Identification. Secondary ID	Description	Required, If secondary ID available	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifierScope /Organization/@name	
Study Identification	Study Type	Required	Study/@versions /StudyVersion/@Type /code/@decode	In case of "PATIENT REGISTRY" in USDM, map to "Observational" in CT.gov. Other Study types can be submitted as is.

The mapping to **Study Design, interventional study design parameters** is presented below. 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	Required USDM relationship	Selection/Derivation
Study Design. Interventional Study Design	Primary Purpose	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@trialTypes /code/@decode		See Primary objective: .. /StudyDesign/@objectives /objective/@text where /StudyDesign/@objectives /objective/@level /code/@code=C85826 Select the TrialType that relates to the primary objective. There are 2 options to do this: • repeat of decode terminology in objective text • reference from primary objective text to corresponding trialtype instance
Study Design. Interventional Study Design	Study Phase	Required	Study/@versions /StudyVersion/@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.
Study Design. Interventional Study Design	Interventional Study Model	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@interventionModel /code/@decode		Translate CROSS-OVER to CROSSOVER. Other decode values from SDTM terminology (codelist C99076) can be submitted as is.
Study Design. Interventional Study Design. Interventional Study Model	Model description		study/@versions /studyVersion/@documentVersion studyProtocolDocumentVersion/@contents /NarrativeContent/@text		...NarrativeContent/@sectionTitle="Intervention Model" limit to 1000 characters
Study Design. Interventional Study Design	Number of Arms	Required	Study/@versions /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	Study/@versions / StudyVersion/@studyDesigns /StudyDesign/@maskingRoles /Masking/@role /code/@decode		If no masking roles are defined in USDM then set Masking to "No Masking". If masking role in USDM = "Sponsor" then leave empty. All other values can be submitted as is
Study Design. Interventional Study Design. Masking	Masking Description		Study/@versions / StudyVersion/@studyDesigns /StudyDesign/@maskingRoles /Masking/@role /code/@decode + @description		If masking role in USDM = "Sponsor" then fill with "Sponsor" + corresponding description.
Study Design. Interventional Study Design	Allocation	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm and Study/@versions /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	Study/@versions /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.

The mapping to **Arms, Groups and Interventions** is presented below. See Section 4.10, Arms and Epochs, and Section 4.17, 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
Arms, Groups and Interventions. Arm Information	Arm Title	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name		Limit to 100 characters.
Arms, Groups and Interventions. Arm Information	Arm Type	Required	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@description		Limit to 999 characters.
Arms, Groups and Interventions. Group/Cohort Information	Group/Cohort Label	For observational studies only	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population / StudyDesignPopulation/@cohorts /StudyCohort/@label		Limit to 100 characters.
Arms, Groups and Interventions. Group/Cohort Information	Group/Cohort Description	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population / StudyDesignPopulation/@cohorts /StudyCohort/@description		Limit to 999 characters.
Arms, Groups and Interventions. Interventions	Intervention Type	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@type /Code/@decode	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@StudyArm	StudyCell relates StudyArm with corresponding element that relates to the corresponding intervention. From ClinicalTrials.gov: "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." Text transformation is needed for 1 to 1 mapping to ClinicalTrials.gov terminology.
Arms, Groups and Interventions. Interventions	Intervention Name	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@name		Limit to 200 characters.

CT.gov Path	CT.gov Variable	CT.gov Requirement	USDM path and attribute	Required USDM relationship	Selection/Derivation
Arms, Groups and Interventions. Interventions	Other Intervention Name	If any	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@StudyArm	From ClinicalTrials.gov: "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."

The mapping to **Outcome Measures** is presented below. See Section 4.17, 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
Outcome Measures. Primary Outcome Measure Information	Title	Required	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@objectives /objective/@endpoints /Endpoint/@text	Study/@versions /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.

The mapping to **Eligibility** is presented below. See Section 4.19, 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
Eligibility. Sex/Gender	Sex	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@plannedSex /code/@decode		Map 1 to 1 to corresponding ct.gov terminology.
Eligibility. Sex/Gender	Gender Based	If applicable	Not in USDM v3.0		ClinicalTrials.gov: "Gender means a person's self-representation of gender identity." In general, it can be decided whether this is 'No' for all trials governed by the sponsor.
Eligibility. Sex/Gender	Gender Eligibility Description		Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@criteria/ EligibilityCriteria/@text	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge / Range/@minValue		
Eligibility. Age Limits	Unit of Time	Required	Study/@versions /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	RequiredStudy/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge / Range/@maxValue		
Eligibility. Age Limits	Unit of Time	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@plannedAge / Range/@unit / code/@decode		Map 1 to 1 to corresponding ClinicalTrials.gov terminology.
Eligibility	Accepts Healthy Volunteers	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation /StudyCohort/@includesHealthySubjects		If any of the values for the StudyDesignPopulation or a StudyCohort is True then set to "Yes"; otherwise set to "No".
Eligibility	Eligibility Criteria	Required	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyPopulation/@criteria/ EligibilityCriteria/@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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@description		Limit to 1000 characters.
Eligibility	Sampling Method	For observational studies only	Not in USDM v3.0		

14.3 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 below table indicates how the USDM v3.0 *(updating to v4.0 during phase 4 of development)* 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 Addin.

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
Page Header / Title Page	Version Number	CPT:VersionNumber	Text	OneToMany	Study/@versions /StudyVersion/@documentVersion /studyProtocolDocumentVersion/protocolVersion	Text, text	protocolVersion sort by EffectiveDate and Version
Page Header / Title Page	Protocol ID	CPT:ProtocolID	Text	OneToOne	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifier		..studyIdentifier/@studyIdentifierScope /Organization/@organizationType /code/@code="C188724" (Clinical Study Sponsor)
Title Page	Acronym	CPT:Acronym	Text	OneToOne	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	Text	..StudyTitle/@Type/Code/@decode="Study Acronym"
Title Page	Protocol Short Title	CPT:ProtocolShortTitle	RichText	OneToOne	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	Text	..StudyTitle/@Type/Code/@decode="Brief Study Title"
Title Page	Protocol Title	CPT:ProtocolTitle	RichText	OneToOne	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	Text	..StudyTitle/@Type/Code/@decode="Official Study Title"
Title Page	Amendment Number	CPT:AmendmentNumber	Text	OneToOne	Study/@versions /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	*Will be added to USDM v4.0*		
Title Page	Sponsor Name	CPT:SponsorName	Text	OneToOne	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifierScope /Organization/@name	Text	..studyIdentifier/@studyIdentifierScope /Organization/@organizationType /code/@code="C70793" (Clinical Study Sponsor)
Title Page	Sponsor Legal Address	CPT:SponsorLegalAddress	Text	OneToOne	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@studyIdentifierScope /Organization/@legalAddress /Address/@text+@line+@district+ @city+@postalCode+@state	Text	..studyIdentifier/@studyIdentifierScope /Organization/@organizationType /code/@code="C70793" (Clinical Study Sponsor)
Title Page	Study Phase	CPT:StudyPhase	Choice	vs.CodeList	Study/@versions /StudyVersion/@studyPhase /AliasCode/@standardCode /code/@decode	Coded value	Retrieve decode Value from standardCode element. Transform into CPT master code value
Title Page / Synopsis	Blinding		Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@blindingSchema / code/@decode	Coded value	
Title Page / Synopsis	Primary Purpose	CPT:PrimaryPurpose	Text	OneToMany	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@trialIntentTypes / code/@decode	Coded value	See CDISC SDTM extensible codelist C66736 for USDM content aligning with CPT primary purpose codes. Note that USDM and the SDTM TS domain allows for multiple values. If more values are present in USDM then they need to be combined to fill Primary Purpose in CPT.
Title Page / Synopsis	Intervention Model	CPT:InterventionModel	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@interventionModel / code/@decode	Coded value	See CDISC SDTM extensible codelist C99076 for USDM content aligning with CPT primary purpose codes.
Title Page / Synopsis	Condition or Disease	CPT:ConditionDisease	Text	OneToMany	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@indications /indication/@name + @description	Text	
Title Page / Synopsis	Regulatory Agency ID	CPT:RegulatoryAgencyID	Text	OneToOne	Study/@versions /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	Study/@versions /StudyVersion/@studyIdentifiers /StudyIdentifier/@text	Text	..StudyIdentifier/@scope /Organization/@organizationType /code/@code="C188863" (Regulatory Agency)
Title Page / Synopsis	Pediatric Investigational Plan Number	CPT:PediatricInvestigationalPlanNumber	Text	OneToOne	Study/@versions /StudyVersion/@referenceIdentifiers /ReferenceIdentifier/@text	Text	..ReferenceIdentifier/@type /Code/@decode="Pediatric Investigation Plan"
Title Page / Study Population	Sex of participants	CPT:Sexofparticipants	Choice	OneToOne	Study/@versions /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	Study/@versions /StudyVersion/@documentVersion /studyProtocolDocumentVersion/@dateValues/GovernanceDate/@dateValue	Date	GovernanceDate/@type /code/@Code = C132352 ("Sponsor approval date")
List of Abbreviations	List of Abbreviations	CPT:ListOfAbbreviations	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 "List of Abbreviations".
Synopsis	Rationale	CPT:Rationale	Rich Text	OneToOne	Study/@versions /StudyVersion/@Rationale	Text	
Synopsis	Number of Participants	CPT:NumberofParticipants	Text	OneToOne	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /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	Study/@versions /StudyVersion/@studyDesigns/ StudyDesign/@maskingRoles /Masking/@role /code/@decode	Coded value	Combine decoded role(s) if more then 1. Align CPT coded values with DDF coded values for Masking roles.
Synopsis	Randomly Assigned / enrolled	CPT:RandomlyAssignedEnrolled	Text	OneToOne	Study/@versions /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. For CPT the section should be 2.1 with title "Study Rationale". This may include a reference to

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
							Study/@versions /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	Study/@versions /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	Study/@versions /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	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 "Estimand(s) for Primary Objective(s)" and it should be a child within section 3. The text should link to the estimands corresponding population, endpoint, intervention and intercurrent events specified in the corresponding classes.
Objectives, Endpoints, and Estimands	Secondary Estimands	CPT:SecondaryEstimands	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 "Estimand(s) for Secondary Objective(s)" and it should be a child within section 3. The text should link to the estimands corresponding population, endpoint, intervention and intercurrent events specified in the corresponding classes.
Objectives, Endpoints, and Estimands	Tertiary Estimands	CPT:TertiaryEstimands	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 "Estimand(s) for Tertiary/Exploratory/Other Objectives" and it should be a child within section 3. The text should link to the estimands corresponding population, endpoint, intervention and intercurrent events specified in the corresponding classes.
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	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Planned Minimum Age of Subjects	CPT:PlannedMinimumAgeofSubjects	Text	OneToOne	Study/@versions /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	Study/@versions /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 and TSVALNF should be filled instead according to ISO 21090.
Study Population	Inclusion Criteria Type of Participants	CPT:InclusionCriteriaTypeOfParticipant	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Inclusion Criteria Weight	CPT:InclusionCriteriaWeight	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Inclusion Criteria Sex	CPT:InclusionCriteriaSex	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Inclusion Criteria Informed Consent	CPT:InclusionCriteriaInformedConsent	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Inclusion Criteria Other	CPT:InclusionCriteriaOther	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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

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
							custom code may indicate the grouping of the eligibility criteria.
Study Population	Exclusion Criteria Medical Conditions	CPT:ExclusionCriteriaMedicalConditions	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Exclusion Criteria Liver Safety	CPT:ExclusionCriteriaLiverSafety	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Exclusion Criteria Prior Concomitant Therapy	CPT:ExclusionCriteriaPriorConcomitantTherapy	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Exclusion Criteria Prior Concurrent Clinical Study	CPT:ExclusionCriteriaPriorConcurrentClinicalStudy	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Exclusion Criteria Diagnostic Assessments	CPT:ExclusionCriteriaDiagnosticAssessments	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Population	Exclusion Criteria Other	CPT:ExclusionCriteriaOther	Text	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population (/StudyDesignPopulation/@cohorts) /StudyDesignPopulation|StudyCohort/@criteria /EligibilityCriterion/@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.
Study Interventions Administered	Intervention Label	CPT:InterventionLabel	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@label	Text	
Study Interventions Administered	Intervention Name	CPT:InterventionName	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@name	Text	
Study Interventions Administered	Intervention Description	CPT:InterventionDescription	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@description	Text	
Study Interventions Administered	Intervention Type	CPT:InterventionType	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@type /code/@decode	Text	
Study Interventions Administered	Dose Formulation	CPT:DoseFormulation	RichText		*Will be added to USDM v4.0*		
Study Interventions Administered	Unit Dose Strength	CPT:UnitDoseStrength	RichText		*Will be added to USDM v4.0*		
Study Interventions Administered	Dosage Level	CPT:DosageLevel	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@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
Study Interventions Administered	Rout of Administration	CPT:RouteofAdministration	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@administrations /AgentAdministration/@route /code/@decode	Coded value	
Study Interventions Administered	Use	CPT:Use	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyInterventions /StudyIntervention/@role / code/@decode	Coded value	
Study Interventions Administered	IMP and NIMP	CPT:IMPandNIMP	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@studyCells /StudyCell/@elements /StudyElement/@studyInterventions /StudyIntervention/@productDesignation /code/@decode	Coded Value	
Study Interventions Administered	Sourcing	CPT:Sourcing	RichText		*Will be added to USDM v4.0*		
Study Interventions Administered	Packaging and Labeling	CPT:PackagingandLabeling	RichText		*Will be added to USDM v4.0*		
Study Interventions Administered	Current Former Names Aliases	CPT:CurrentFormerNamesAliases	RichText		*Will be added to USDM v4.0*		
Study Interventions Administered	Arm Name	CPT:ArmName	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@name	Text	
Study Interventions Administered	Arm Type	CPT:ArmType	RichText	OneToOne	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@arms /StudyArm/@type /code/@decode	Coded value	
Study Interventions Administered	Arm Description	CPT:ArmDescription	RichText	OneToOne ManyToOne	Study/@versions /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.
Statistical Considerations	Tertiary Exploratory Endpoint Analysis	CPT:TertiaryExploratoryEndpointAnalysis	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.

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
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.

15 Appendices

15.1 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
Gerry Campion	Senior Software Engineer, 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

15.2 Glossary and Abbreviations

The following abbreviations and terms are used in this document. Additional definitions can be found in the CDISC Glossary.

ADaM	Analysis Data Model
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

CDASH	Clinical Data Acquisition Standards Harmonization Project
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
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.
CTR	Clinical Trial Registry
DDF	Digital Data Flow (project)
Domain	A collection of observations with a topic-specific commonality about a subject
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
Foundational standards	The suite of CDISC standards that describe the clinical study protocol (Protocol), design (Study Design), data collection (CDASH), laboratory work (Lab), analysis (ADaM), and data tabulation (SDTM and SEND)
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
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
NIH	National Institutes of Health
ODM	Operational Data Model
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
SDR	Study Definitions Repository
SDTM	Study Data Tabulation Model

SDTMIG	SDTM Implementation Guide (for Human Clinical Trials)
SEND	Standard for the Exchange of Nonclinical Data
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

15.3 References

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15.4 Revision History

15.4.1 USDM Implementation Guide

The USDM v1.0 was released as part of the DDF Reference Architecture in August 2022. Version v1.0 of the USDM has no associated implementation guide therefore there is no revision history for the Implementation Guide. The first version of the USDMIG is therefore v2.0. This section details the changes made to the USDMIG between v2.0 and v3.0.

15.4.2 USDMIG Amendments between USDM v3.0 and USDM v4.0

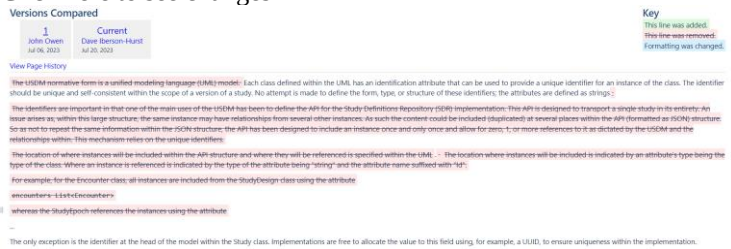
#	Release #	Overview	Notes
1	**3.2**	UML update for Arms and Epochs section	• Name of encounter attribute environmentalSetting changed to environmentalSettings • Added notes attributes to Encounter, StudyArm, StudyElement and StudyEpoch classes
2		UML update for Study Timing section	• Moved relationships 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	• Added relationship criteria from StudyVersion to EligibilityCriterion. • Changed criteria cardinality from PopulationDefinition to EligibilityCriterion from 1..* to 0..* in UML.

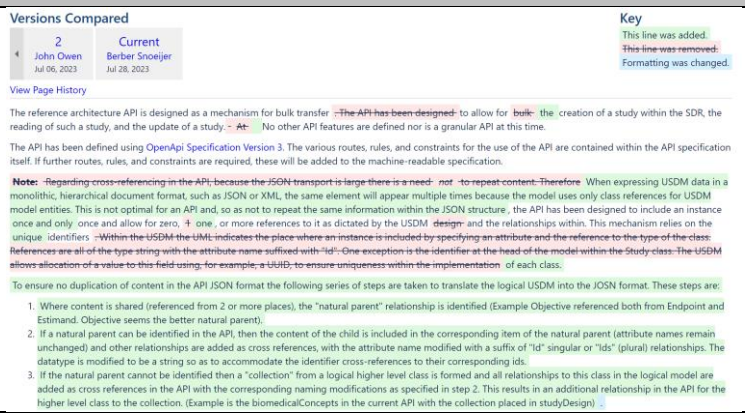
#	Release #	Overview	Notes
			• Added notes attributes to PopulationDefinition, SyntaxTemplate, Indication, StudyArm, StudyDesign and StudyVersion classes. • Updated text accordingly to specify that criteria should either be referenced from Study Population or from Study Cohort. • Updated text regarding 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	• Added notes attributes to StudyVersion and StudyDesign classes.
5		UML update for Study Identifiers and Titles	• Added notes attribute to StudyVersion class.
6		UML and text update for Activities section	• 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	• Added notes attributes to StudyIntervention and AgentAdministration classes.
8		UML update for Study Objectives and Endpoints section	• 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	• Added notes attribute to SyntaxTemplate class.
10	**3.3**	UML and text update for Activities section	• 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		UML and text update for for Study Timing section	• 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 version 3,0 and further alignment	
13		Updated Unstructured Content section to include multiple template support	• Added new UML view for documents. • Adjusted text to include new NarrativeContentItem and reusability of text across documents.
14		Updated Study, Protocols, and Amendments section to include multiple template support	• Updated UML. • Adjusted text to refer to the right classes.
15	**3.5**	Updated Study, Protocols, and Amendments section to include abbreviations	• Updated UML. • Added text to explain the use of the new abbreviation class and corresponding attributes.

#	Release #	Overview	Notes
16	**3.6**	Created Abbreviations section to give examples of how it can be used.	• Created new section with examples.
17		Updated Study, Protocols, and Amendments section.	• Created cross-reference to Abbreviations section.
18		Updated XHTML Attributes section.	• Referred to NarrativeContentItem instead of NarrativeContent.
19		Updated Study Identifiers and Titles section.	• 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	• Include mapping to pediatric investigational plan number. • Updated mappings based on changed attribute names.
21		Updated Study Interventions section	• 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	• 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	• 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	• 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	• Changed address line to lines in UML
26		Updated Study Roles and Organizations section	• Changed address line to lines in UML
27		Updated Study, Protocols, and Amendments section	• 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	• Added UML • Updated text to indicate all referenced areas not reflected in UML and explain other references
29	**3.8**	Updated Study Design section	• Updated UML to include studyDocumentVersions relationship • Added reference to Study, Protocols, and Amendments
30		Updated Study Objectives and Endpoints section	• updated UML to include new estimand changes
31		Updated Study Estimands section	• updated text to include new estimand changes
32		Updated Principles section	• Removed "(phase 3 onwards; not true for phases 1 and 2)" from "Support the whole protocol document".
33		Updated Study Identifiers and Titles section	• 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

#	Release #	Overview	Notes
34		Updated Study Roles and Organizations section	• 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	• Updated UML to include the relationship appliesTo from DocumentContentReference class to the StudyDefinitionDocument class.

15.4.3 USDMIG Amendments between USDM v2.0 and USDM v3.0

#	Release #	Overview	Notes
1	**2.1**	Created Naming Conventions section	1. This section details the conventions used for naming and the use of attribute datatypes 2. To support model split and element renaming
2		Edits to Internal Identifiers Within the Model	1. To support model split and element renaming Click here to see changes 
3		Edits to Overview	1. To support model split and element renaming Click here to see changes 
4		Edits to USDM API	1. To support model split and element renaming Click here to see changes

#	Release #	Overview	Notes
			 Versions Compared 2 John Owen Jul 06, 2023 Current Berber Snoeijer Jul 28, 2023 Key This line was added. ~~This line was removed.~~ Formatting was changed. View Page History The reference architecture API is designed as a mechanism for bulk transfer ~~. The API has been designed~~ to allow for bulk the creation of a study within the SDR, the reading of such a study, and the update of a study. ~~. At~~ No other API features are defined nor is a granular API at this time. The API has been defined using OpenApi Specification Version 3. 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. **Note:** ~~Regarding cross-referencing in the API, because the JSON transport is large there is a need~~ *not* ~~to repeat content. Therefore~~ When expressing USDM data in a monolithic, hierarchical document format, such as JSON or XML, the same element will appear multiple times because the model uses only class references for USDM model 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~~ one, or more references to it as dictated by the USDM ~~design~~ and the relationships within. This mechanism relies on the unique identifiers ~~. Within the USDM the UML indicates the place where an instance is included by specifying an attribute and the reference to the type of the class. References are all of the type string with the attribute name suffixed with "Id". One exception is the identifier at the head of the model within the Study class. The USDM allows allocation of a value to this field using, for example, a UUID, to ensure uniqueness within the implementation~~ of each class. To ensure no duplication of content in the API JSON format the following series of steps are taken to translate the logical USDM into the JOSN format. These steps are: 1. Where content is shared (referenced from 2 or more places), the "natural parent" relationship is identified (Example Objective referenced both from Endpoint and Estimand. Objective seems the better 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 name modified with a suffix of "Id" singular or "Ids" (plural) relationships. The datatype is modified to be a string so as to accommodate the identifier cross-references to their corresponding ids. 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. (Example is the biomedicalConcepts in the current API with the collection placed in studyDesign) .
5		UML Split Model and Model Naming Changes	• Replaced all String Id references in the UML to instances of the class. • Changed all class properties for Id, Name and Description to consistent across the model. Removed the class name prefix from these properties.
6	**2.3**	Added Unstructured Content section to the USDM Features	Added new section for unstructured content 1. This section introduces the content class that is used to store unstructured narrative content.
7		Add Syntax Templates" section to the USDM Features	1. This section introduces the classes that enable syntax text templates 2. It explains the how the syntax text templates can be used in the USDM 3. It explains how references can be made to data elements stored elsewhere in the data model. 4. It gives examples of text templates and corresponding examples.
8		Added label to Naming Conventions section.	
9	**2.4**	Change class name "Content" to "Narrative Content" in the Unstructured Content section of USDM Features	
10	**2.8**	Update to Controlled Terminology section	Added detail on standard codes and alias code
11		inserted Principles section	Added notes on principles. Needs further work
12		Update to API section	Improved text within API section and added details re the "instanceType" attribute
13		Update to Arms and Epoch section	Small updates to text, inserted UML and added links to related pages.
14		Update to Activities section	Small updates to text, inserted UML, added conditional class information and added links to related pages.
15		Update to Study Population section	Updates to text in accordance with model changes, added UML and cohort and eligibility description.
16		Update to Intervention section	updates to text in accordance with model changes and added UML

#	Release #	Overview	Notes
17		Added new section Addressing Footnotes	identified 12 types of footnotes and describing how they can be included in the USDM
18		Updated section Study Timing	Added UML, updated text and timeline figures
19		Updated section Relationship to Other CDISC Standards	Moved mapping to SDTM trial summary domains to Creation of SDTM Trial Design Domains
20		Updated USDM Team	Updated USDM Team page to include the latest team members for USDM v3.0
21		Added Creation of SDTM Trial Design Domains	
22		Updated Study, Version, Identifier section	Changed title to Study, Protocols, and Amendments. Added UML and description of protocol and amendment versions. Identifiers will be handled in new section.
23		Updated Syntax Templates	Updated content according to html reference style
24		Added Study Identifiers and Titles	Moved description of Study Identifiers here and added Titles description
25		Updated Procedures	Added reference to study intervention. Removed conditionality which is described more general for all related classes in Activities
26		Updated Indications	Added description of new attribute isRareDisease
27		Updated Study Objectives and Endpoints	Inserted UML and reference to syntax template class
28		Updated Study Estimands	updated reference names
29	**2.9**	Updated Fundamentals of the USDM	Added information on v3.0
30		Updated Arms and Epochs	Added link to Creation of SDTM Trial Design Domains
31		Updated Study Timing	Replaced UML based on changed relationship to timing class. Some minor textual changes.
32		Updated Study Objectives and Endpoints	Replaced UML based on changed reference name from Estimand to studyIntervention class.
33		Updated Populations, Cohorts, and Eligibility Criteria	Replaced UML based on chanced name of EligibilityCriterion class and small textual updates.
34		Updated Use of USDM for Populating Protocol Content	Adapted the POC mapping to v3.0 of USDM. No additional variables are mapped based on new features of USDM v3.0. This is indicated in the introduction.
35		Updated Study, Protocols, and Amendments	Removed study site information from UML and descriptions. Moved to new paragraph: Study Roles and Organizations
36		Added Study Roles and Organizations	Added UML and description of Organization class and corresponding research Organization and sites.
37	**2.11**	Updated Syntax Templates	Updated content requirements based on current reference strategy and JIRA comments.
38		Updated Arms and Epochs	Updated UML based on new version of ScheduleInstance class.
39		Updated Study Timing	Updated UML based on new ConditionAssignment class and updates in Timing class. Updated corresponding text.
40		Updated Study Interventions	Updated UML based on Jira tickets of public review. This includes cardinality updates and adding the option to add alias codes for unit, route and frequency.
41		Updated Study Objectives and Endpoints	Updated UML since objective level is required. Added option of exploratory objectives in the text.

#	Release #	Overview	Notes
42		Updated Populations, Cohorts, and Eligibility Criteria	Updated UML for plannedSex. Added requirement that plannedSex, plannedAge and plannedEnrollment or plannedCompletion number should be either filled at the studyDesignPopulation level or the studyCohort level.
43		Update to API section	Updated API to include initial rules for the minimum content to be included within the data sent via the API. Also added details with regard to the root attributes that includes the USDM version.
44		Updated Naming Conventions	Updated to reflect latest practice
45		Inserted XHTML Attributes	Inserted new section on XHTML attributes
46		Updated Biomedical Concepts	Updated to include more details on enabled and required flags
47		Updated Unstructured Content	Updated to refer to XHTML attributes paragraph
48		Updated Study Roles and Organizations	Updated UML - included AliasCode class

15.4.4 Amendments between USDM v1.0 and USDM v2.0 (UML, CT, API)

The following table lists at a high level the major changes that occurred between USDM v1.0 and USDM v2.0

#	Sprint #	Overview	Notes
1	1	Bugfixes and review comments from DDF Phase I	1. StudyEpoch Class: Add encounters relationship, 1 -> 0..* 2. IntercurrentEvent Class: strategy attribute rename to "intercurrentEventStrategy" and is of type String 3. PointInTime Class: remove from the model 4. Encounter Class Attributes "startRule" and "endRule" should be renames and prefixed with "transition", so "transitionStartRule", "transitionEndRule" 5. Workflow Class Attribute "workflowId" renamed to "uuid" 6. Estimand Class Attribute "variableOfInterest" type should be Endpoint not Encounter
2	1	Addition of Therapeutic Area	1. Class: Study Attribute businessTherapeuticArea 2. Class: StudyDesign Attribute therapeuticAreas
3	1	Allow for multiple trial types entries on the StudyDesign class	1. Class StudyDesign Attribute trialType amended to a list
4	2	Terminology Flexibility	1. Code and CodeAlias classes added to the model
5	2	Addition of name and description for StudyDesign class	1. Class: StudyDesign Attribute studyDesignName 2. Class: StudyDesign Attribute studyDesignDescription
7	3	Attribute name changes	1. Class: Study Attribute: studyIdentifier amended to studyIdentifiers 2. Class: Study Attribute: studyProtocolVersion amended to studyProtocolVersions 3. Class: Study Attribute: studyDesign amended to studyDesigns
9	3	Visit Contact Mode	1. Not sure what has changed here

#	Sprint #	Overview	Notes
10	4	Allow Study Phase to use the Code Alias	1. Class: Study Attribute studyPhase amended from Code to AliasCode
10	4	Add flag for Activity and Procedures being optional	1. Class: Activity Attribute activityIsOptional added 2. Class: Procedure Attribute procedureIsOptional added 3. Also see additional change to 16 below
12	5	Additional elements added in to support eCPT population	1. Class: Study Attribute; studyRationale added 2. Class: Study Attribute: studyAcronym added 3. Class: StudyDesignPopulation Attribute: plannedNumberOfParticipants added 4. Class: StudyDesignPopulation Attribute: plannedMaximumAgeOfParticipants added 5. Class: StudyDesignPopulation Attribute: plannedMinimumAgeOfParticipants added 6. Class: StudyDesignPopulation Attribute: sexOfParticipants added 7. Class: StudyDesign Attribute: studyDesignRationale added 8. Class: Organization Attribute: organizationLegalAddress added
15	6	New class for Address	Class: Address added with the following attributes • Text • Line • City • District • State • Postal Code • Country
16	6	Amend activityIsOptional and procedureIsOptional to conditional	1. Class: Activity Attribute activityIsOptional amended to activityIsConditional 2. Class: Procedure Attribute procedureIsOptional amended to procedureIsConditional
17	6	Addition of TBLIND/Trial Blinding Schema (valid values in codelist C66735) code to studyDesignBlindingScheme	1. Class: StudyDesign Attribute studyDesignBlindingScheme codelist TBLIND added
19	7	Biomedical Concepts sub model added	See Biomedical Concepts section for additional information. Addition of the following Classes (note that class StudyData was removed and replaced with the Biomedical Concept classes • BiomedicalConcept • BioemdcialConceptProperty • ResponseCode • BiomedicalConceptCategory • BiomedicalConceptSurrogate

#	Sprint #	Overview	Notes
20	9	Study Timing and "Timepoints" added to the model	See Study Timing section for additional information. Addition of the following Classes (note that class StudyData was removed and replaced with the Biomedical Concept classes • ScheduleTimeline • Timing • ScheduledInstance • ScheduledDecisionInstance • ScheduledActivityInstance • ScheduleTimelineExit
21	11	Internal Review Sprint Changes	• API only: studyStudyDesignPopulations changed to studyPopulations • StudyEpoch.encounters type List<Encounter> Amended to StudyEpoch.encounter**Ids** type List<**String**> • StudyEpoch.trialIntentType type List<Code> Amended to StudyEpoch.trialIntentType**s** type List<Code> • Procedure.procedureName type String Added • Procedure.procedureDescription type String Added
22	11-14	Public Review Sprint Changes	• StudyEpoch.encounters type List<Encounter> changed to StudyEpoch.encounterIds type List<String> • StudyDesign.trialIntentType type List<Code> changed to StudyDesign.trialIntentTypes type List<Code> • Procedure.procedureDescription type String added • Procedure.procedureName type String added

As part of the v2.0 updates, the elements of the RA (USDM, CT, API, and IG) are stored within a Github repository and version managed as a series of releases corresponding to the sprints, a subsequent release for internal review, a release for public review, and a release for the final publication as v2.0.

- **Controlled Terminology:** For a complete list of controlled terminology changes between USDM v1.0 and the public review version, see the USDM_CT_Changes.xlsx file in the controlled terminology deliverable folder.
- **UML:** A list of changes to the UML model between USDM v2.0 and the public review version can be found here. A list of model changes between Internal Review and Public Review can be found here. A list of changes between Public Review and Publication can be found here.
- **API:** For a complete list of API changes between USDM v1.0 and USDM v2.0, use a file-comparison tool to compare the API from USDM v1.0 and the API for USDM v2.0. Please refer to the USDM API.yaml files in the API deliverable folder.

15.4.5 Amendments between USDM v2.0 and USDM v3.0

- **Controlled Terminology:** For a complete list of controlled terminology changes between USDM v2.0 and the public review version, see the USDM_CT_Changes.xlsx file in the controlled terminology deliverable folder.
- **UML:** A list of changes to the UML model between USDM v2.0 and the public review version can be found here.

- **API:** For a complete list of API changes between USDM v2.0 and USDM v3.0, use a file-comparison tool to compare the API from USDM v2.0. and the API for USDM v3.0 Please refer to the USDM API.yaml files in the API deliverable folder.

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