Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 2.0 (Final)

Prepared by the
DDF Team

Notes to Readers

- This is the final version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0).

Revision History

Date	Version
2023-06-14	2.0 Final

Contents

1. Introduction
2. Purpose
3. Organization of this Document
4. How to Read this Document
5. Fundamentals of the USDM
6. Relationship to Other Standards and Formats
7. Relationship to Other CDISC Standards
8. Relationship to Other Standards
9. Use of USDM for Populating Protocol Content
10. USDM Features
11. Overview
12. Internal Identifiers Within the Model
13. Controlled Terminology
14. Study, Study Versions and Identifiers
15. Study Design
16. Arms and Epochs
17. Activities
18. Procedures
19. Biomedical Concepts
20. Study Timing
21. Indications
22. Study Estimands
23. Investigational Interventions
24. Study Objectives and Endpoints
25. Study Populations
26. USDM Data Dictionary
27. USDM API
28. Examples
29. Appendices
30. USDM Team
31. Glossary and Abbreviations
32. Revision History
33. Representations and Warranties, Limitations of Liability, and Disclaimers

1 Introduction

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

The aim of TransCelerate's digital data flow (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 study start-up 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 study start-up 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, CDISC, and Accenture 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 Study Definitions Repository, please visit the TransCelerate DDF GitHub site and the SDR Github Site.

1.1 Purpose

The Unified Study Definitions Model Implementation Guide (USDMIG) 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, 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 USDMIG.
- 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 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.
- Appendices provide additional background material and describe other supplemental material relevant to the USDM.

1.3 How to Read this Document

1. First, become familiar with the Digital Data Flow (DDF) project; see the TransCelerate Digital Data Flow Project web page and CDISC DDF resources. If new to DDF, visit the TranCelerate YouTube channel. which includes several videos describing DDF.
2. Next, visit the DDF Public Review page to download the USDM review material (note that this is a .zip file) from the CDISC DDF GitHub site. This page also provide additional information on the public review process, including how to comment in the DDF JIRA.
3. Read this guide all the way through (without skipping any sections) at least once.
    a. The USDMIG compiled provides a page-by-page view of the USDMIG.
    b. The USDMIG sections shows each section of the USDMIG. When making comments on the USDMIG, please use the USDMIG sections wiki. You will not be able to make comments in the compiled view.
4. Finally, revisit any sections of particular interest and provide any comments.

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 UML class diagram**
2. **Application Programming Interface (API) Specification**
3. **CDISC Controlled Terminology**
4. **Unified Study Definitions Model Implementation Guide (USDM-IG)**

Please note that USDM v1.0 did not have a corresponding Implementation Guide. The USDM-IG is new for USDM v2.0 .

USDM v1.0, released in August 2022, provided a base model of structured study design. Building on this foundation, USDM v2.0 has been developed to satisfy an agreed set of use cases based around

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

2.1 Support for More Complex Trials

The first version of the USDM provided a model for simple study designs. Version 2.0 implements additional elements that allow for representation in USDM of more complex study designs. One main area of development is the implementation of Study Timing within the model allowing for complex timing and visit structures to be represented. Section 4, USDM Features, provides an overview of enhancements that support increased trial complexity.

2.2 Enabling EDC Automation

In order to support EDC automation, the CDISC biomedical concept 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 concept 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 a form that matches.
Implementation of the biomedical concept 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).

2.3 Populating the CPT

Additional elements have been added to the model as a proof-of-viability (POV) exercise, demonstrating that structured study design information can 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 3.3, Use of USDM for Populating Protocol Content. Note that only a selected set of CPT elements is included for the POV; additional elements may be added to the USDM in a future release.

3 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. As part of the development process, these standards were used as input in order to try to ensure harmonization with these standards, where possible.

3.1 Relationship to Other CDISC Standards

The USDM development process relied on published CDISC standards and other products that served as references for modeling and naming conventions. To the extent possible, an effort was 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.

3.1.1 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 (see https://bridgmodel.nci.nih.gov/). 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.

3.1.2 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 model.

3.1.3 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. SDTM is one of the required standards that sponsors

must use, as specified in the FDA's Data Standards Catalog (see https://www.fda.gov/regulatory-information/), 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 of the ICH *Guideline for Industry: Structure and Content of Clinical Study Reports* (available at https://www.fda.gov/media/71271/download) 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 (see Annex IIIa and Annex IIIb). 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.

Trial design concepts include:

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

Although not a current use case for USDM v2.0, automated creation of SDTM Trial Design datasets may in the future be possible using data structed in USDM format. Therefore there is alignment between the USDM and SDTM Trial Design and controlled terminology elements related to study design. The following table provides a list of published Trial Summary (TS) parameters and their mapping to USDM elements (entities, attributes, or valid values). The table includes only those parameters for which there is a mapping. The table is based on the SDTM Controlled Terminology codelist C66738, from SDTM Terminology Version 2022-12-16.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term	USDM Entity Name	USDM Role	USDM Item Name
C101302	C66738		Trial Summary Parameter Test Code	THERAREA	Therapeutic Area	A knowledge field that focuses on research and development of specific treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual. (NCI)	Therapeutic Area	StudyDesign	Attribute	therapeuticAreas
C112038	C66738		Trial Summary Parameter Test Code	INDIC	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication	Indication	Entity	Indication
C112038	C66738		Trial Summary Parameter Test Code	INDIC	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication	Indication	Attribute	indicationDescription
C142175	C66738		Trial Summary Parameter Test Code	STYPE	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (clinicaltrials.gov)	Study Type	Study	Attribute	studyType
C48281	C66738		Trial Summary Parameter Test Code	TPHASE	Trial Phase; Trial Phase Classification	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 § 312.21; see ICH Guideline E8)	Trial Phase	Study	Attribute	studyPhase
C49652	C66738		Trial Summary Parameter Test Code	TINDTP	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent	StudyDesign	Attribute	trialIntentType

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term	USDM Entity Name	USDM Role	USDM Item Name
C49658	C66738		Trial Summary Parameter Test Code	TBLIND	Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial Blinding Schema; Trial Masking Design	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.	Trial Blinding Schema	StudyDesign	Attribute	studyDesignBlindingScheme
C49660	C66738		Trial Summary Parameter Test Code	TTYPE	Trial Scope; Trial Type	The nature of the interventional study for which information is being collected.	Trial Type	StudyDesign	Attribute	trialType
C49692	C66738		Trial Summary Parameter Test Code	PLANSUB	Anticipated Enrollment; Planned Enrollment; Planned Number of Subjects; Target Enrollment	The planned number of subjects to be entered in a clinical trial. (NCI)	Planned Subject Number	StudyDesignPopulation	Attribute	plannedNumberOfParticipants
C49693	C66738		Trial Summary Parameter Test Code	AGEMIN	Planned Minimum Age of Subjects	The anticipated minimum age of the subjects to be entered in a clinical trial. (NCI)	Planned Minimum Age of Subjects	StudyDesignPopulation	Attribute	plannedMinimumAgeOfParticipants
C49694	C66738		Trial Summary Parameter Test Code	AGEMAX	Planned Maximum Age of Subjects	The anticipated maximum age of the subjects to be entered in a clinical trial. (NCI)	Planned Maximum Age of Subjects	StudyDesignPopulation	Attribute	plannedMaximumAgeOfParticipants
C49696	C66738		Trial Summary Parameter Test Code	SEXPOP	Sex of Participants	The specific sex, either male, female, or mixed of the subject group being studied. (NCI)	Sex of Study Group	StudyDesignPopulation	Attribute	plannedSexOfParticipants
C49802	C66738		Trial Summary Parameter Test Code	TITLE	Official Study Title; Study Title; Trial Title	The sponsor-defined name of the clinical study.	Trial Title	Study	Attribute	studyTitle
C98746	C66738		Trial Summary Parameter Test Code	INTMODEL	Intervention Model	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	Intervention Model	StudyDesign	Attribute	interventionModel
C70793	C66738		Trial Summary Parameter Test Code	SPONSOR	Clinical Study Sponsor; Sponsor; Study Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study. (See ICH E6, WHO, 21 CFR § 50.3 (e), and IDMP)	Clinical Study Sponsor	Organization	Valid Value	Valid Value Set for Attribute organizationType
C85826	C66738		Trial Summary Parameter Test Code	OBJPRIM	Study Primary Objective; Trial Primary Objective	A principle objective of the study.	Trial Primary Objective	Objective	Valid Value	Valid Value Set for AttributeobjectiveLevel
C85827	C66738		Trial Summary Parameter Test Code	OBJSEC	Study Secondary Objective; Trial Secondary Objective	An auxiliary objective of the study.	Trial Secondary Objective	Objective	Valid Value	Valid Value Set for AttributeobjectiveLevel

3.1.4 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 Team has been developing and publishing the semantics for those 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.

3.1.5 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.
Although not a current use case for USDM v2.0, automated submissions for multiple clinical trials for clinical trial registry submissions may in the future be possible using data structured in USDM format. CTR was released in 2016 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 therefore may well subsume the CTR model and require an upgrade to the CTR XML exchange structures.

3.1.6 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. 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 v1.3.2 was released in 2013. ODM-XML v2.0 is currently in development and adds 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 USDM is a reference model and 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 v2.0 were investigated and, where possible, aligned with USDM.

3.1.7 SDM

Study/Trial Design Model in XML (SDM-XML) is an extension of 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: The current version of SDM (v1.0) was released in 2011. The SDM will be incorporated into ODM-XML v2.0 (still in development). SDM was used as an input reference model during the development of the USDM.

3.2 Relationship to Other Standards

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

The ICH M11 guideline introduced the Clinical Electronic Structured Harmonised Protocol (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. At the time of scoping off for USDM v2.0, the content of the guideline was not publicly available and therefore could not be included as a scoping input for this version.
The guideline, clinical study protocol template, and technical specifications were released in October 2022 for public review; where possible, these were used a reference input during the USDM v2.0 development phase. It is anticipated that there will be additional alignment activates in future versions of the USDM.

3.2.2 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).
There are important connections between the USDM and the Vulcan SOA project: For USDM v2.0, elements relating to a schedule of activities were further developed in order to provide structured information that enable creating a visual representation of the this information in an SOA format. As a result, there is an ongoing collaboration to ensure alignment where possible.

3.3 Use of USDM for Populating Protocol Content

A secondary aim of USDM v2.0 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. A successful demonstration is anticipated to facilitate expanding future versions of the USDM for this purpose. The TransCelerate CPT was selected to conduct this proof of concept because it is a publicly available resource proposed to harmonize clinical trial protocol content in a streamlined format (https://www.transceleratebiopharmainc.com/assets/clinical-content-reuse-solutions/). The POC exercise relies on a prioritized set of structured fields within the CPT for content already existing in USDM v1.0 and extended in USDM v2.0. The following table lists a selection of structured CPT field names mapped to USDM v2.0 which are used in the POC.

CPT Section	CPT Variable Display Name	CPT Variable Name (compacted)	CPT Var Type	Mapping Type	USDM Field	USDM Field Type	Logic
Synopsis	Number of Participants	CPT:NumberofParticipants	Text	ManyToOne	plannedNumberOfParticipants	Integer	If multiple populations available in studyDesign, add all the numeric values.
Study Rationale	Study Rationale	CPT:StudyRationale	Rich Text	OneToOne	studyRationale	Text	Retrieve studyRationale value
Objectives and Endpoints	Objectives Endpoints and Estimands	CPT:ObjectivesEndpointsAndEstimands	RichText	OneToMany	objectiveDesc, endpointDesc	Text	See below fields.
Objectives and Endpoints	Primary Endpoints	CPT:EndpointsPrimary	RichText	OneToMany	endpointDesc | endpointPurposeDesc	Text	Take respective ObjectiveEndpoints from primary objective
Objectives and Endpoints	Primary Objectives	CPT:ObjectivesPrimary	RichText	OneToMany	objectiveLevel	Code	Take the objective whch has "Study Primary Objective" in the objectiveLevel as in screenshot below. Refer CDISC codes mentioned in Data Mapping spreadsheet.
Objectives and Endpoints	Secondary Endpoints	CPT:EndpointsSecondary	RichText	OneToMany	endpointDesc | endpointPurposeDesc	Text	Take respective ObjectiveEndpoints from secondary objective
Objectives and Endpoints	Secondary Objectives	CPT:ObjectivesSecondary	RichText	OneToMany	objectiveLevel	Code	Take the objective whch has "Study Secondary Objective" in the objectiveLevel as in screenshot below. Refer CDISC codes mentioned in Data Mapping spreadsheet.
Scientific Rationale for Study Design	Scientific Rationale for Study Design	CPT:ScientificRationaleforStudyDesign	RichText	OneToOne	studyDesignRationale	Text	Retrieve studyDesignRationale value
Inclusion Criteria	Planned Maximum Age of Subjects	CPT:PlannedMaximumAgeofSubjects	Text	ManyToOne	plannedMaximumAgeOfParticipants	Text	1. If all values are integers, then pick Maximum value from the list. 2. If multiple values available, atleast one non-integer value is present, then display blank in the output. 3. If only one value available, irrespective of Integer/Non-Integer, display the value as is in the output.
Inclusion Criteria	Planned Minimum Age of Subjects	CPT:PlannedMinimumAgeofSubjects	Text	ManyToOne	plannedMinimumAgeOfParticipants	Text	1. If all values are integers, then pick Minimum value from the list. 2. If multiple values available, atleast one non-integer value is present, then display blank in the output. 3. If only one value available, irrespective of Integer/Non-Integer, display the value as is in the output.
Inclusion Criteria	Sex of participants	CPT:Sexofparticipants	Choice	vs.CodeList<>	plannedSexOfParticipants	Code[]	1. Refer to CDISC code list for Sex and corresponding eCPT mapping values in Data mapping sheet 2. If multiple values available, consider distinct values from the valid codes and display Male/Female/Male or Female in the output 3. If only value is available and not a valid CDISC code, display decode value as is in the CPT output. 4. If multiple and all of the codes are invalid, then display blank.

CPT Section	CPT Variable Display Name	CPT Variable Name (compacted)	CPT Var Type	Mapping Type	USDM Field	USDM Field Type	Logic
Study Interventions Administered	Arm Description	CPT:ArmDescription	RichText	OneToOne ManyToOne	studyArmDesc	Text	studyArmDescription, ArmName and Decode Value of ArmType to be sent as an arrayList in response.
Study Interventions Administered	Arm Name	CPT:ArmName	RichText	OneToOne	studyArmName	Text	studyArmDescription, ArmName and Decode Value of ArmType to be sent as an arrayList in response.
Study Interventions Administered	Arm Type	CPT:ArmType	RichText	OneToOne	studyArmType	Code	studyArmDescription, ArmName and Decode Value of ArmType to be sent as an arrayList in response.
Study Interventions Administered	Intervention Description	CPT:InterventionDescription	RichText	OneToOne	interventionDesc	Code[]	Create model as mentioned in screenshot and just populate interventionDescription for now. There are other fields (e.g., intervention name, type, dosage) which are not available in USDM.
Populations for Analyses	Populations for Analyses	CPT:PopulationsForAnalyses	RichText	ManyToOne	populationDesc (analysisPopulation)	Text	Retrieve all analysisPopulationDescription as comma seperated (e.g Desc1, Desc2 and Desc3)
Page Header	Version Number	CPT:VersionNumber	Text	OneToMany	protocolVersion	Text, text	protocolVersion sort by EffectiveDate and Version
Protocol and Brief Title	Condition or Disease	CPT:ConditionDisease	Text	Proxy	indicationDesc	Text	Retrieve all indicationDescriptions as comma seperated (e.g Desc1, Desc2 and Desc3)
Title Page	Acronym	CPT:Acronym	Text	OneToOne	studyAcronym	Text	Retireve studyAcronym value
Title Page	Amendment Number	CPT:AmendmentNumber	Text	Proxy	protocolAmendment	Text	protocolAmendment sort by EffectiveDate and Version
Title Page	Protocol Short Title	CPT:ProtocolShortTitle	RichText	OneToOne	briefTitle	Text	briefTitle sort by EffectiveDate and Version
Title Page	Protocol Title	CPT:ProtocolTitle	RichText	OneToMany	studyTitle (else scientificTitle)	Text	studyTitle if available else pick from scientificTitle
Title Page	Regulatory Agency ID	CPT:RegulatoryAgencyID	Choice	vs.CodeList<>	organisationIdentifierScheme	Code	Retrieve organisationIdentifierScheme where Type = 'Regulatory Agency' (First element to be considered if multiple array elements)
Title Page	Regulatory Agency Number	CPT:RegulatoryAgencyNumber	Text	OneToMany	studyIdentifier	Text, text	Retrieve studyIdentifier where Type = 'Regulatory Agency' (First element to be considered if multiple array elements)
Title Page	Sponsor Legal Address	CPT:SponsorLegalAddress	Text	OneToOne	organizationLegalAddress	Text	To be retrieved from Organization class (attribute name of organizationLegalAddress, where Organization Type=Clinical Study Sponsor) and concatenate all Address properties Take First value if there are more than one.
Title Page	Sponsor Name	CPT:SponsorName	Text	OneToOne	organizationName	Text	To be retrieved from Organization class (attribute name of OrganizationName, where Organization Type=Clinical Study Sponsor)
Title Page	Study Phase	CPT:StudyPhase	Choice	vs.CodeList<>	studyPhase	aliasCode	Retrive decode Value from standardCode element. Transform into CPT master code value

4 USDM Features

- Overview
- Internal Identifiers Within the Model
- Controlled Terminology
- Study, Study Versions and Identifiers
- Study Design
- Arms and Epochs
- Activities
- Procedures
- Biomedical Concepts
- Study Timing
- Indications
- Study Estimands
- Investigational Interventions

- Study Objectives and Endpoints
- Study Populations

4.1 Overview

The USDM provides the ability to define a version of a clinical study that includes:

1. The main study details, such as:
    - Version of the external protocol that the study relates to
    - Various identifiers allocated to the study
2. One or more study designs within the study, with each study design detailing:
    - Arms and epochs within the design and the relationships between them
    - Encounters planned for the study and the relationship with the epochs of the study
    - A detailed data specification for the data to be captured as part of the study
    - Procedures to be performed as part of the study design
    - Timing of collection of data and the performance of procedures
    - Subject populations defined within the study design
    - Objectives and endpoints defined within the study design
    - Study estimands defined within the study design
    - Interventions defined as part of the study design
    - 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.

4.2 Internal Identifiers Within the Model

The USDM normative form is a unified modeling language (UML) 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 identifiers are important in that one of the main uses of the USDM has been to define the API for the Study Definitions Repository (SDR) implementation. This API is designed to transport a single study in its entirety. An issue arises as, within this large structure, the same instance may have relationships from several other instances. As such the content could be included (duplicated) at several places within the API (formatted as JSON) structure. 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 within. This mechanism relies on the unique identifiers.

The location of where instances will be included within the API structure and where they will be referenced is specified within the UML. The location where instances will be included is indicated by an attribute's type being the type of the class. Where an instance is referenced is indicated by the type of the attribute being "string" and the attribute name suffixed with "Id".

For example, for the Encounter class, all instances are included from the StudyDesign class using the attribute

```
encounters List<Encounter>
```

whereas the StudyEpoch references the instances using the attribute

```
encounterIds List<string>
```

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.

4.3 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, 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 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 controlled terms, some other controlled vocabularies are referenced.

Where a CDISC code is demanded by the model but flexibility is needed, users may include other terms (aliases) using the AliasCode class. Here 1 standard term is required but zero, 1, or more aliases can be provided.

4.4 Study, Study Versions and Identifiers

The Study class is the root of the USDM, collecting together the definition of the study as a whole. It provides a few basic study details (e.g., study title, type, phase, rationale, acronym), links the study with its constituent parts that include 1 or more study designs, the identifiers for the study, and the relationship with external protocol documents. The Study class also allows for the Business Therapeutic Area to be stated. **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 this is not the same as the therapeutic areas defined in the StudyDesign class.

The Study class links to the StudyProtocolVersion class to define to which versions of an external protocol document the study definition relates. 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 class allows for links to the 1 or more identifiers related to the study. Although multiple identifiers are permitted, they must be of 1 of 3 types: sponsor, registry, or regulatory authority. The study definition should have 1, and only 1, sponsor identifier but multiple other identifiers are permitted. Note the use of ISO 3166-1 country codes within the address field.

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 and study design with one or more protocol versions related to the study.

4.5 Study Design

The StudyDesign class is the container for a single design within a study definition. It provides the slots for key parameters such as the trail type, trial intent type, blinding scheme, and intervention model. The class also provides a place to store 1 or more codes defining the therapeutic area to which the study design relates. No controlled terminology is provided for the population of this field; the following controlled vocabularies are available for users to populate these fields. A sponsor's own controlled terms can also be used.

Dictionary / Terminology Name	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

4.6 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 also related to the study encounters (a more generic term for visits).
StudyElements and Encounters have entry and exit rules that are defined using the TransitionRule class. It should be noted that although theStudyElements 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 parts of the SDTM Trial Design domains.

4.7 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. The Activity class can be linked to 1 or more procedures, 1 or more biomedical concepts, 1 or more groups of biomedical concepts, and/or 1 or more surrogate biomedical concepts. Activities can be reused across multiple points within a study timeline.

4.8 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. Procedures can be optional with a text representation for the condition being provided.

4.9 Biomedical Concepts

The Biomedical Concept (BC) 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, 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 CDISC BC model has been represented in a manner consistent with the rest of the USDM itself. For example, the 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).

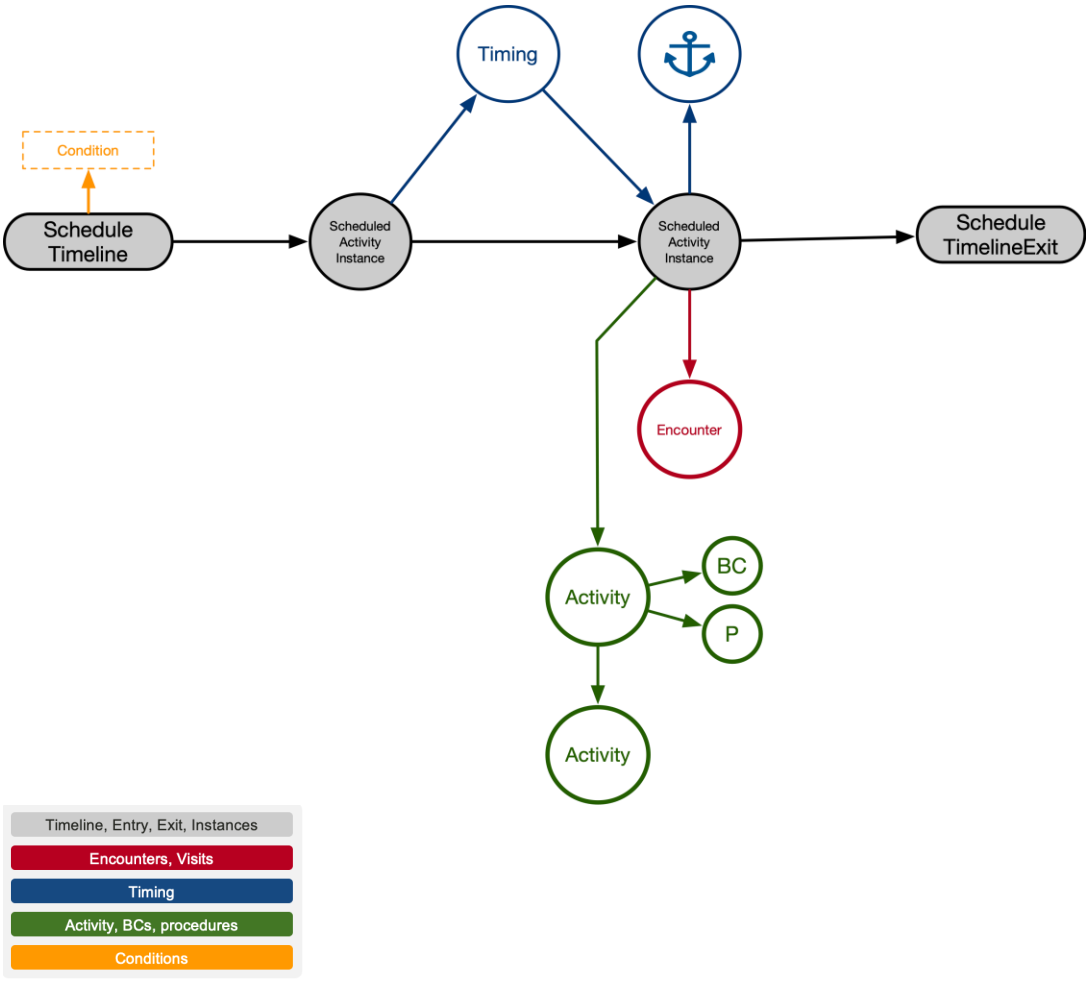
Note: Constraints can be applied to the content placed into the USDM but when those constraints are applied is not specified. A protocol may leave everything in the BCs unconstrained and only when deployment in capture systems happens will those constraints be applied.
The USDM allows for the inclusion of a single BC (e.g., heart rate), a collection of BCs (e.g., vital signs preconfigured to include height, weight, heart rate, and other tests), or surrogate BCs. Surrogate BCs are a placeholder mechanism for when a BC definition is not available. This allows the name of a test to be specified but no further detail need be provided. Surrogates can contain a name and description pair for the concept required. A reference field is also provided to allow for links to reference materials (e.g., a URL for an external resource).
A single BC uses the BiomedicalConcept class as its root instance connected to 1 or more BiomedicalConceptProperty instances to define the various properties of the BC (e.g., result value, units, qualifiers). Some of the property nodes will require controlled terminology references; these are placed within ResponseCode instances which then onward refer to a Code instance holding the actual term reference.
One or more BCs can be grouped using a BiomedicalConceptCategory . It is assumed that, to be useful, more than a single BC should be added to a grouping such as Vital Signs described above. These groupings are expected to be sponsor defined but, in the future, some can be expected to be industry defined.

4.10 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. USDM v2.0 replaces the workflow mechanism used in USDM v1.0 that linked encounters with activities with a mechanism for building timelines that can be reused within a study and, given external library management, across studies.

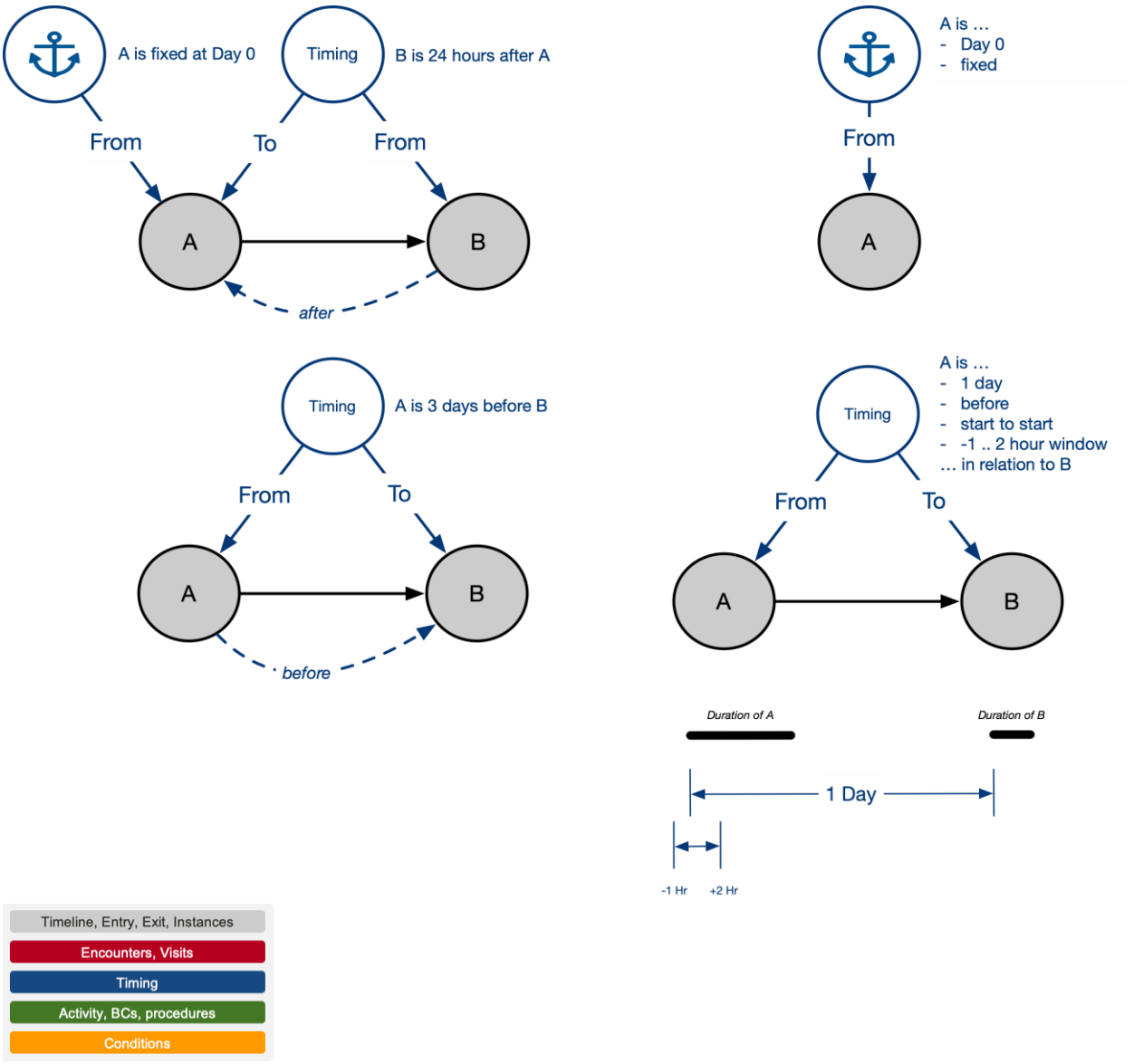
4.10.1 Timelines

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 condition (ScheduledTimeline class), a sequence of steps (the ScheduledActivityInstance class), possible branches to allow for multiple paths and cycles (not shown in the figure), timing relating the steps (the Timing class), and 1 or more exits (the ScheduleTimelineExit class). 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 defines 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.



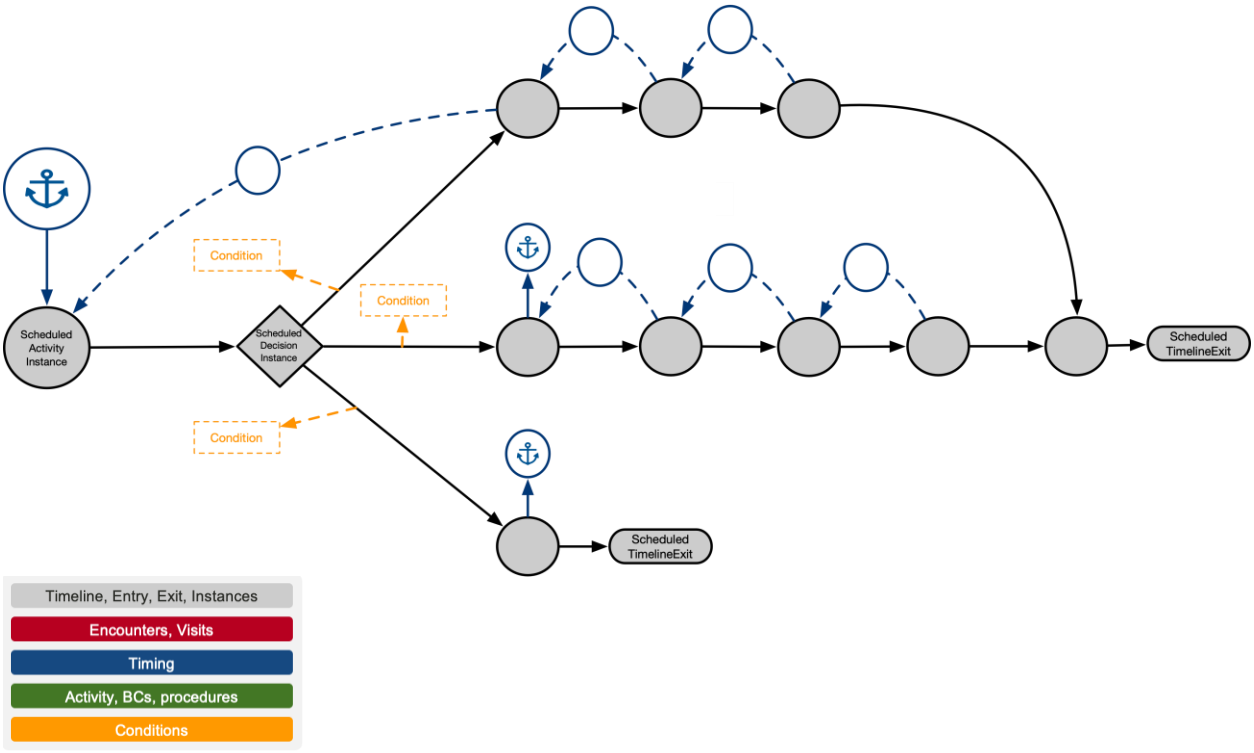
4.10.2 Timing

The timing between steps comes in 2 flavours, a relative time of before or after, and an anchor time that is fixed. The following figure illustrates the timing capabilities. DDF-399 UNDER TEAM REVIEW
The timing class allows for explicit timing to be built into a timeline using a combination of anchors (fixed timing) and relative timing.



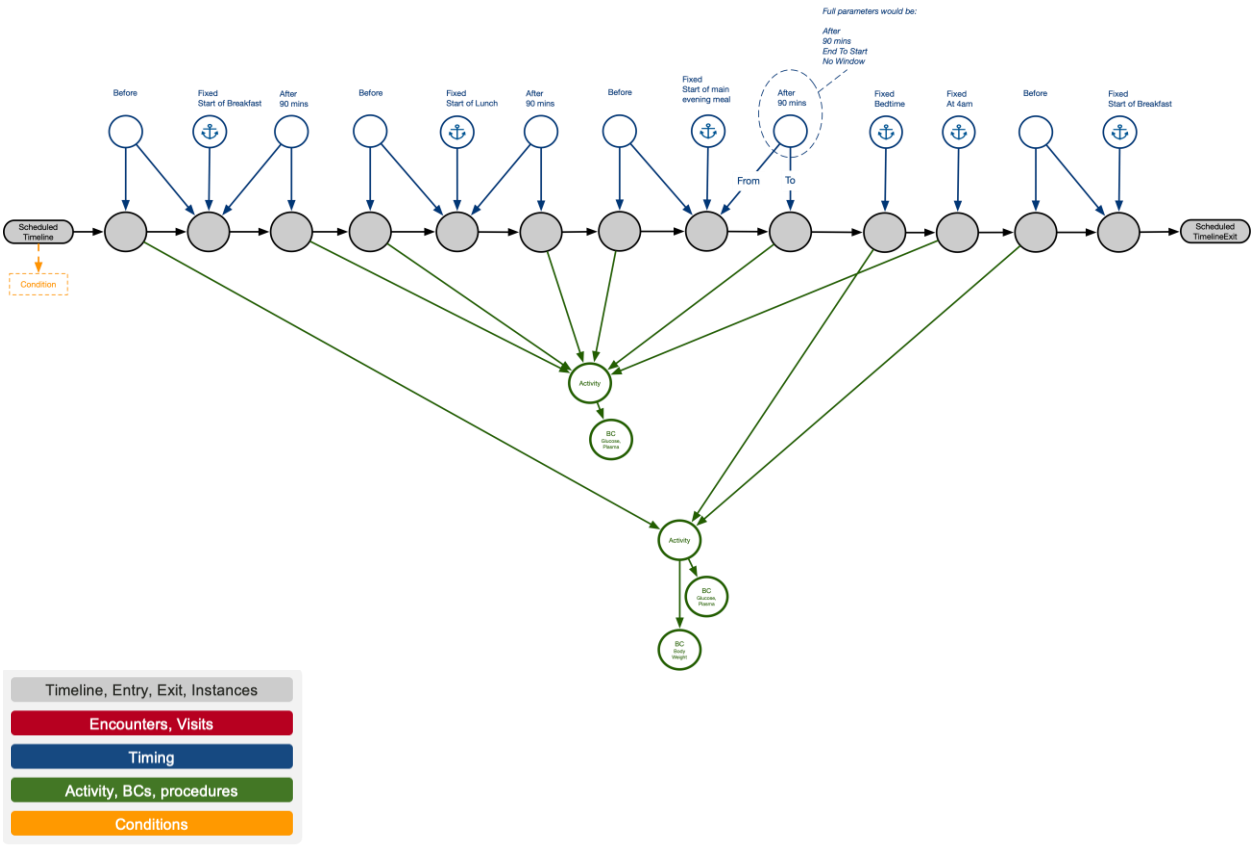
4.10.3 Decisions and Branching

Decisions and branching is handled using the ScheduledDecisionInstance class and using instances of the class within a timeline as shown in the following figure. Each decision point can handle multiple conditions; for example, simple yes/no decisions can be handled 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.

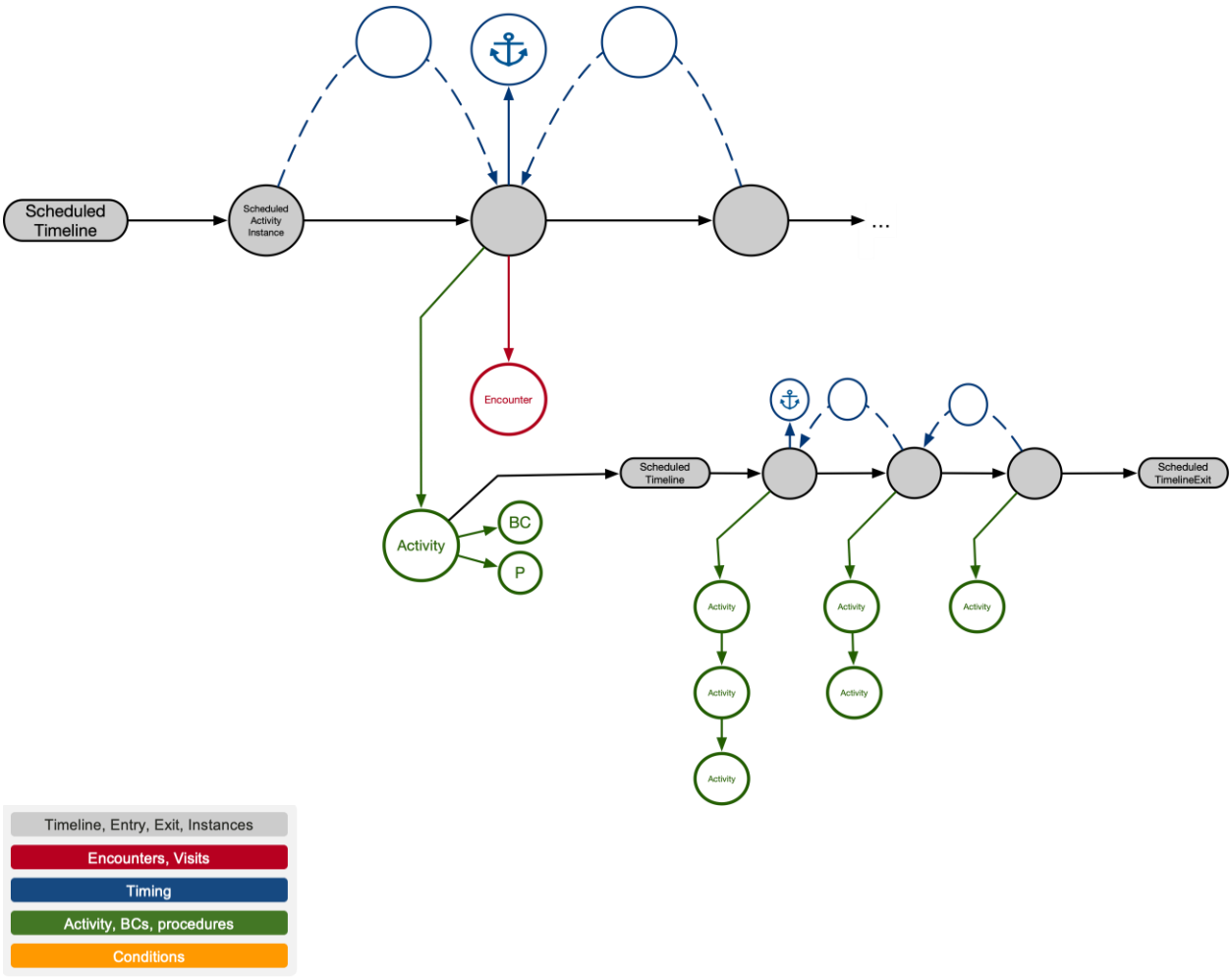


4.10.4 Profiles

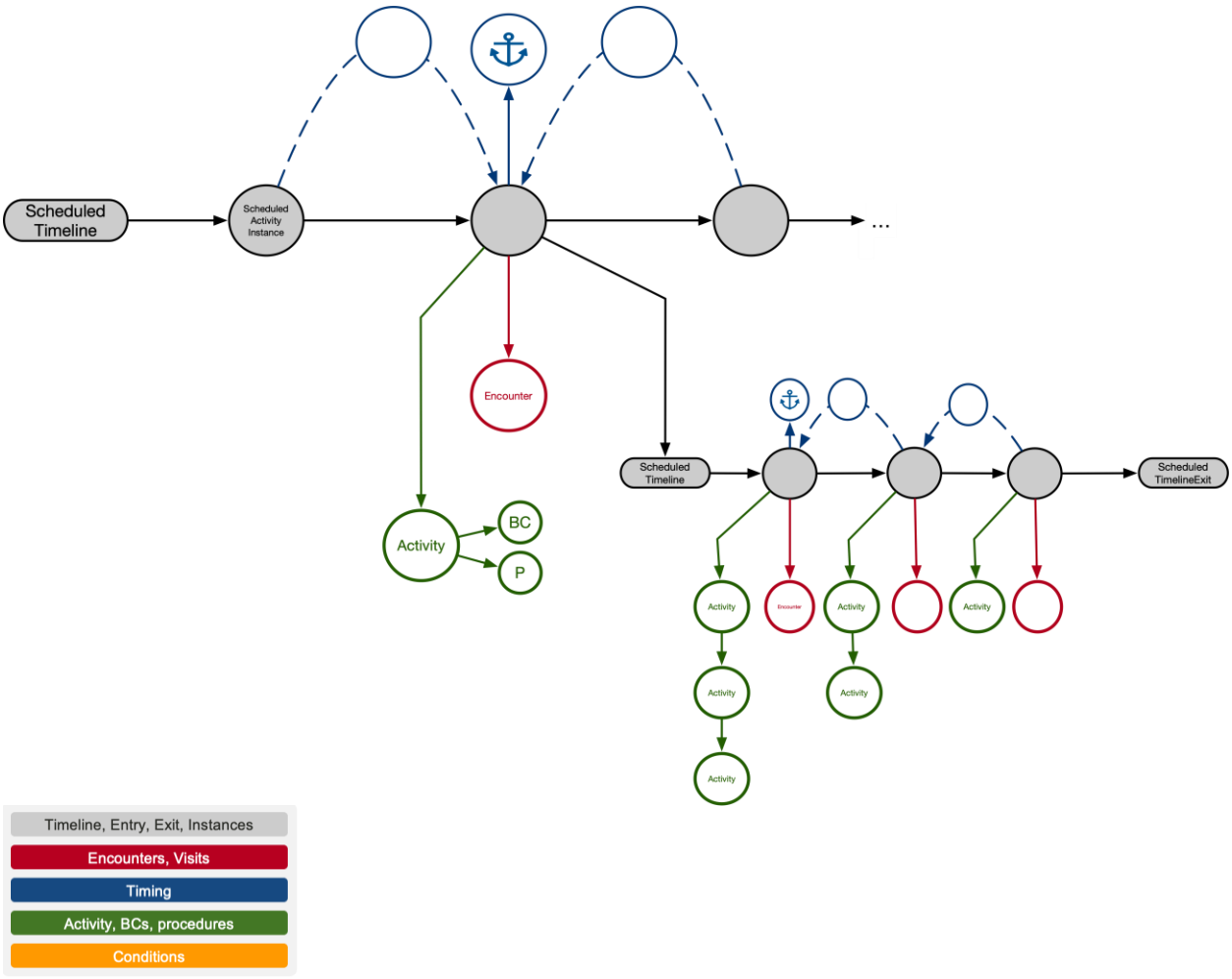
Profiles can be created using the various classes as depicted within the following figure. A profile is another use of the timeline pattern. A condition for entry can be defined but need not be. In this example, anchors are used to fix meal times over a single day and the associated observations scheduled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

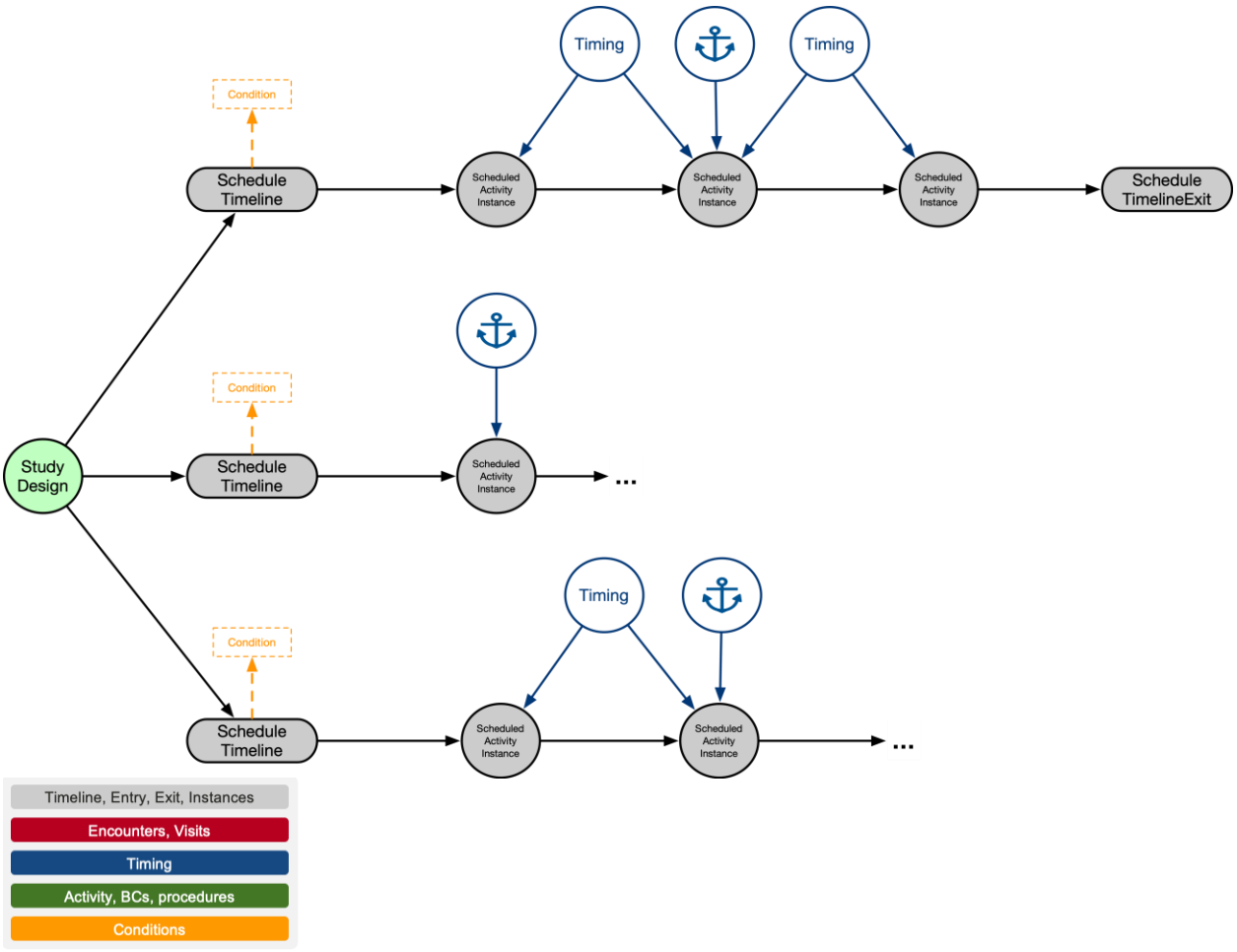


The timeline can also be attached to a ScheduledActivityInstance using the scheduledInstanceTimelineId attribute for execution from another timeline, thus allowing subvisits to be constructed, as shown in the following figure.



4.10.5 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.



4.10.6 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.

4.11 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.

4.12 Study Estimands

Study estimands and the definition of the treatments to be investigated, the population, the variable, and the handling of intercurrent events (ICEs) are handled within the Estimand, IntercurrentEvent, and AnalysisPopulation classes along with the relationships to Endpoints (for the variable of interest) and InvestigationalIndications (for the treatment)

4.13 Investigational Interventions

The interventions for a study design can be placed into the InvestigationalIntervention class. Each intervention 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 intervention.

4.14 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) and a link to 1 or more associated endpoints containing a the endpoint definition in textual form.

4.15 Study Populations

The USDM currently implements a mechanism to define the subject population for a study design using the StudyDesignPopulation class. The population definition consists of a text description plus a set of properties related to the age and sex of the population.

5 USDM Data Dictionary

Any property without a description in the table below, are either relationships or instance identifiers and were deemed to be out of scope for terminology development. Please see 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
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.	
	activityIsConditionalReason	string	CNEW		Study Activity is Conditional Reason	The explanation for why the study activity is subject to or dependent upon something else.	
	activityId	string		1..1			
	activityIsConditional	boolean	CNEW		Study Activity is Conditional	An indication as to whether the study activity is subject to or dependent upon something else.	
	bcCategoryIds	List\<string>		0..*			
	definedProcedures	List\<Procedure>		0..*			
	activityName	string	C188842		Clinical Study Activity Name	The literal identifier (i.e., distinctive designation) of the clinical study activity.	
	previousActivityId	string		0..1			
	biomedicalConceptIds	List\<string>		0..*			
	activityDescription	string	C70960		Clinical Study Activity Description	The textual representation of the study activity.	
	bcSurrogateIds	List\<string>		0..*			
	activityTimelineId	string		0..1			
	nextActivityId	string		0..1			
Address			C25407		Address	A standardized representation of the location of a person, business, building, or organization. (NCI)	
	country	Code	C25464		Country	A sovereign nation occupying a distinct territory and ruled by an autonomous government.	(Point out to ISO 3166-1 Alpha-3 Country code)
	city	string	C25160		City	A relatively large and/or densely populated area of human habitation with administrative or legal	

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
						status that may be specified as a component of a postal address.	
	line	string	CNEW		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.	
	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.	
	text	string	CNEW		Address Full Text	A standardized representation of the complete set of components denoting the physical address of the person, business, building, or organization.	
AliasCode			CNEW		Alias Code	An alternative symbol or combination of symbols which is assigned to the members of a collection.	
	standardCodeAliases	List\<Code>		0..*			
	aliasCodeId	string		1..1			
	standardCode	Code					
AnalysisPopulation			C188854		Target Study Population for Analysis	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)	
	analysisPopulationId	string		1..1			
	populationDescription	string	C188854		Target Study Population for Analysis Description	The textual representation of the study population for analysis.	
BiomedicalConcept			CNEW		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.	
	bcConceptCode	AliasCode	CNEW		Biomedical Concept Concept Code	A concept unique identifier assigned to a biomedical concept that points to the meaning of that biomedical concept.	
	bcProperties	List\<BiomedicalConceptProperty>		0..*			
	bcSynonyms	List\<string>	CNEW	0..*	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.	
	bcReference	string	CNEW		Biomedical Concept Reference	A citation to an authoritative source for a biomedical concept.	
	biomedicalConceptId	string		1..1			
	bcName	string	CNEW		Biomedical Concept Name	The literal identifier (i.e., distinctive designation) of the biomedical concept.	
BiomedicalConceptCategory			CNEW		Biomedical Concept Category	A grouping of biomedical concepts based on some commonality or by user defined characteristics.	
	bcCategoryCode	AliasCode	CNEW		Biomedical Concept Category Code	A symbol or combination of symbols which is assigned to the biomedical concept category.	
	bcCategoryChildIds	List\<string>		0..*			
	bcCategoryDescription	string	CNEW		Biomedical Concept Category Description	The textual representation of the biomedical concept category.	
	bcCategoryMemberIds	List\<string>		0..*			
	bcCategoryName	string	CNEW		Biomedical Concept Category Name	The literal identifier (i.e., distinctive designation) of the biomedical concept category.	
	biomedicalConceptCategoryId	string		1..1			
BiomedicalConceptProperty			CNEW		Biomedical Concept Property	A characteristic from a set of characteristics used to define a biomedical concept.	
	bcPropertyDatatype	string	CNEW		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)	
	bcPropertyName	string	CNEW		Biomedical Concept	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
					Property Name		
	bcPropertyId	string		1..1			
	bcPropertyConceptCode	AliasCode	CNEW		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.	
	bcPropertyResponseCodes	List\<ResponseCode>		0..*			
	bcPropertyEnabled	boolean	CNEW		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.	
	bcPropertyRequired	boolean	CNEW		Biomedical Concept Property Required Indicator	An indication as to whether the biomedical concept property is required.	
BiomedicalConceptSurrogate							
	bcSurrogateName	string	CNEW		Biomedical Concept Surrogate Name	The literal identifier (i.e., distinctive designation) of the biomedical concept surrogate.	
	bcSurrogateId	string		1..1			
	bcSurrogateDescription	string	CNEW		Biomedical Concept Surrogate Description	The textual representation of the biomedical concept surrogate.	
	bcSurrogateReference	string	CNEW		Biomedical Concept Surrogate Reference	A citation to an authoritative source for a biomedical concept surrogate.	
Code			C25162		Code	A symbol or combination of symbols which is assigned to the members of a collection.	
	codeId	string		1..1			
	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.	
Encounter			C142427		Clinical Encounter	Contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual.	
	previousEncounterId	string	C188837	0..1	Previous Encounter Identifier	A system identifier assigned to a clinical encounter that occurs immediately prior to the current clinical encounter.	
	encounterName	string	C171010		Clinical Encounter Name	The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.	
	encounterScheduledAtTimingId	string		0..1			
	transitionStartRule	TransitionRule					
	encounterEnvironmentalSetting	Code	C188840		Environmental Setting	The environment/setting where the event, intervention, or finding occurred.	C127262
	nextEncounterId	string	C188838	0..1	Next Encounter Identifier	A system identifier assigned to a clinical encounter that occurs immediately after the current clinical encounter.	
	encounterDescription	string	C188836		Clinical Encounter Description	The textual representation of the protocol-defined clinical encounter.	
	encounterContactModes	List\<Code>	C188841	0..*	Contact Mode	The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).	C171445
	encounterId	string		1..1			
	transitionEndRule	TransitionRule					
	encounterType	Code	C188839		Clinical Encounter Type	A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed.	C188728
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)	
	endpointId	string		1..1			

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
	endpointLevel	Code	C188826		Study Endpoint Level	A characterization or classification of the study endpoint that determines its category of importance relative to other study endpoints.	C188726
	endpointDescription	string	C188824		Study Endpoint Description	The textual representation of the study endpoint.	
	endpointPurposeDescription	string	C188825		Study Endpoint Purpose Description	The textual representation of the study endpoint purpose.	
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)	
	estimandId	string		1..1			
	summaryMeasure	string	C188853		Population-Level Summary	A synopsis of the clinical endpoint of interest within the analysis target study population.	
	analysisPopulation	AnalysisPopulation					
	treatment	InvestigationalIntervention					
	variableOfInterest	Endpoint					
	intercurrentEvents	List\<IntercurrentEvent>		0..*			
Indication			C112038		Trial Disease/Condition Indication Description	The condition, disease or disorder that the clinical trial is intended to investigate or address.	
	codes	List\<Code>	C188822	0..*	Disease Indication Code	A short sequence of characters that represents the disease indication.	(point out to multiple Biomedical coding dictionaries such as SNOMED CT (for FDA), MedDRA, NCIt, ICD's, etc.)
	indicationId	string		1..1			
	indicationDescription	string	C112038		Trial Disease/Condition Indication Description	The condition, disease or disorder that the clinical trial is intended to investigate or address.	(point out to multiple Biomedical coding dictionaries such as SNOMED CT (for FDA), MedDRA, NCIt, ICD's, etc.)
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)	
	intercurrentEventStrategy	string	C188857		Intercurrent Event Strategy	A textual description of the planned strategy to manage and/or mitigate intercurrent events.	
	intercurrentEventId	string		1..1			
	intercurrentEventName	string	C188855		Intercurrent Event Name	The literal identifier (i.e., distinctive designation) of the intercurrent event.	
	intercurrentEventDescription	string	C188856		Intercurrent Event Description	The textual representation of the intercurrent event.	
InvestigationalIntervention			C25218		Intervention	The drug, device, therapy, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). //grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm	
	codes	List\<Code>	C188821	0..*	Investigational Intervention Code	A short sequence of characters that represents the investigational intervention.	(point out to multiple Biomedical coding dictionaries such as WHODrug, ATC, UNII, etc.)
	investigationalInterventionId	string		1..1			
	interventionDescription	string	C177931		Intervention Description	The textual representation of the study intervention.	

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
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.	
	objectiveEndpoints	List\<Endpoint>		0..*			
	objectiveId	string		1..1			
	objectiveDescription	string	C94090		Study Objective Description	The textual representation of the study objective. (BRIDG)	
	objectiveLevel	Code	C188823		Study Objective Level	A characterization or classification of the study objective that determines its category of importance relative to other study objectives.	C188725
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)	
	organizationId	string		1..1			
	organizationIdentifierScheme	string	C188819		Identifier Provider Organization Name	The name of the organization that provides the identifier for the entity.	
	organizationType	Code	C188820		Organization Type	A characterization or classification of the formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose.	C188724
	organizationName	string	C93874		Organization Name	A non-unique textual identifier for the organization. (BRIDG)	
	organizationIdentifier	string	C93401		Organization Identifier	A unique symbol that establishes identity of the organization. (BRIDG)	
	organizationLegalAddress	Address					
Procedure			C98769		Procedure	Any activity performed by manual and/or instrumental means for the purpose of diagnosis, assessment, therapy, prevention, or palliative care.	
	procedureIsConditionalReason	string	CNEW		Study Procedure is Conditional Reason	The explanation for why the study procedure is subject to or dependent upon something else.	
	procedureType	string	C188848		Procedure Type	A characterization or classification of the study procedure.	
	procedureCode	Code	C154626		Procedure Code	A symbol or combination of symbols which is assigned to medical procedure.	(Point out to external dictionary like CPT, MedDRA, SNOMED CT, etc.)
	procedureDescription	string	CNEW		Procedure Description	The textual representation of the procedure.	
	procedureIsConditional	boolean	CNEW		Study Procedure is Conditional	An indication as to whether the study procedure is subject to or dependent upon something else.	
	procedureName	string	CNEW		Procedure Name	The literal identifier (i.e., distinctive designation) of the procedure.	
	procedureId	string		1..1			
ResponseCode			CNEW		Response Code	A symbol or combination of symbols representing the response to the question.	
	code	Code	C25162		Code	A symbol or combination of symbols which is assigned to the members of a collection.	
	responseCodeId	string		1..1			
	responseCodeEnabled	boolean	CNEW		Response Code Enabled Indicator	An indication as to whether the response code is activated for use within a given usage context.	
ScheduleTimeline			CNEW		Schedule Timeline	A chronological schedule of planned temporal events.	
	scheduleTimelineName	string	CNEW		Schedule Timeline Name	The literal identifier (i.e., distinctive designation) of the schedule timeline.	
	scheduleTimelineId	string		1..1			
	entryCondition	string	CNEW		Schedule Timeline Entry Condition	A logical evaluation on which rests the validity of entry into a schedule timeline.	
	scheduleTimelineEntryId	string		0..1			
	scheduleTimelineDescription	string	CNEW		Schedule Timeline Description	The textual representation of the schedule timeline.	
	mainTimeline	boolean	CNEW		Main Timeline Indicator	An indication as to whether the timeline or timeline component is part of the central or principal timeline.	
	scheduleTimelineExits	List\<ScheduleTimelineExit>		0..*			
	scheduleTimelineInstances	List\<ScheduledInstance>		0..*			
ScheduleTimelineExit			CNEW		Schedule Timeline Exit	To go out of or leave the schedule timeline.	
	scheduleTimelineExitId	string		1..1			

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
ScheduledActivityInstance			CNEW		Scheduled Activity Instance	A scheduled occurrence of an activity event.	
	activityIds	List\<string>		0..*			
	scheduledActivityInstanceEncounterId	string					
ScheduledDecisionInstance			CNEW		Condition Assignments	An allotting or appointment to a set of conditions that are to be met in order to make a logical decision.	
	conditionAssignments	Map\<string, string>					
ScheduledInstance			CNEW		Scheduled Instance	A scheduled occurrence of a temporal event.	
	scheduledInstanceTimings	List\<Timing>		0..*			
	scheduledInstanceId	string		1..1			
	defaultConditionId	string		0..1			
	scheduledInstanceType	ScheduledInstanceType	CNEW		Scheduled Instance Type	A characterization or classification of the scheduled instance.	
	epochId	string		0..1			
	scheduleTimelineExitId	string		0..1			
	scheduledInstanceTimelineId	string		0..1			
Study			C15206		Clinical Study	A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [http://ClinicalTrials.gov](CDISC Glossary)	
	studyDesigns	List\<StudyDesign>		0..*			
	studyRationale	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.	
	studyType	Code	C142175		Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	C99077
	studyProtocolVersions	List\<StudyProtocolVersion>		0..*			
	studyPhase	AliasCode	C48281		Trial Phase	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. 21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998	C66737
	studyVersion	string	C188816		Study Version	A plan at a particular point in time for a study.	
	studyId	UUID		0..1			
	studyTitle	string	C49802		Study Title	The sponsor-defined name of the clinical study.	
	businessTherapeuticAreas	List\<Code>	CNEW	0..*	Business Therapeutic Areas	A therapeutic area classification based on the structure and operations of the business unit.	(point out to external dictionaries)
	studyAcronym	string	C94108		Study Acronym	A word or words formed from the beginning letters or a combination of syllables and letters of a compound term, which identifies a clinical study.	
	studyIdentifiers	List\<StudyIdentifier>		0..*			
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.	
	studyArmId	string		1..1			
	studyArmType	Code	C188827		Study Arm Type	A characterization or classification of the study arm.	C174222
	studyArmName	string	C170984		Study Arm Name	The literal identifier (i.e., distinctive designation) of the study arm.	
	studyArmDataOriginType	Code	C188829		Study Arm Data Origin Type	A characterization or classification of the study arm with respect to where the study arm data originates.	C188727
	studyArmDescription	string	C93728		Study Arm Description	The textual representation of the study arm.	
	studyArmDataOriginDescription	string	C188828		Study Arm Data Origin Description	The textual representation of the study arm data origin.	
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.	
	studyElementIds	List\<string>		0..*			

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
	studyArmId	string		0..1			
	studyEpochId	string					
	studyCellId	string		1..1			
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.	
	studyDesignId	string		1..1			
	studyObjectives	List\<Objective>		0..*			
	bcSurrogates	List\<BiomedicalConceptSurrogate>		0..*			
	studyElements	List\<StudyElement>		0..*			
	trialType	List\<Code>	C49660	0..*	Trial Type	The nature of the interventional study for which information is being collected.	C66739
	studyDesignBlindingScheme	AliasCode	C49658		Trial Blinding Schema	The type of experimental design used to describe the level of awareness of the study subjects and/or study personnel as it relates to the respective intervention(s) or assessments being observed, received or administered.	C66735
	studyPopulations	List\<StudyDesignPopulation>		0..*			
	studyInvestigationalInterventions	List\<InvestigationalIntervention>		0..*			
	studyArms	List\<StudyArm>		0..*			
	biomedicalConcepts	List\<BiomedicalConcept>		0..*			
	studyDesignName	string	CNEW		Study Design Name	The literal identifier (i.e., distinctive designation) of the study design.	
	studyDesignDescription	string	CNEW		Study Design Description	The textual representation of the study design.	
	studyScheduleTimelines	List\<ScheduleTimeline>		0..*			
	studyDesignRationale	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.	
	interventionModel	Code	C98746		Intervention Model Type	The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)	C99076
	encounters	List\<Encounter>		0..*			
	trialIntentTypes	List\<Code>	C49652	0..*	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	C66736
	activities	List\<Activity>		0..*			
	bcCategories	List\<BiomedicalConceptCategory>		0..*			
	studyCells	List\<StudyCell>		0..*			
	studyIndications	List\<Indication>		0..*			
	therapeuticAreas	List\<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)
	studyEpochs	List\<StudyEpoch>		0..*			
	studyEstimands	List\<Estimand>		0..*			
StudyDesignPopulation			C142728		Target Study Population	The population within the general population to which the study results can be generalized.	
	plannedSexOfParticipants	List\<Code>	C49696	0..*	Sex of Participants	The specific sex, either male, female, or mixed of the subject group being studied. (NCI)	C66732
	plannedNumberOfParticipants	int	C49692		Planned Number of Participants	The planned number of subjects to be entered in a clinical trial. (NCI)	
	plannedMaximumAgeOfParticipants	string	C49694		Planned Maximum Age of Subjects	The anticipated maximum age of the subjects to be entered in a clinical trial. (NCI)	
	studyDesignPopulationId	string		1..1			
	populationDescription	string	C70834		Target Study Population Description	The textual representation of the study population.	
	plannedMinimumAgeOfParticipants	string	C49693		Planned Minimum Age of Subjects	The anticipated minimum age of the subjects to be entered in a clinical trial. (NCI)	
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.	
	studyElementDescription	string	C188834		Study Design Element Description	The textual representation of the study design element.	
	transitionStartRule	TransitionRule					
	studyElementId	string		1..1			
	studyElementName	string	C188833		Study Design Element Name	The literal identifier (i.e., distinctive designation) of the study design element.	
	transitionEndRule	TransitionRule					

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
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.	
	nextStudyEpochId	string	C188832	0..1	Next Epoch Identifier	A system identifier assigned to the epoch that occurs immediately after the current epoch.	
	previousStudyEpochId	string	C188831	0..1	Previous Epoch Identifier	A system identifier assigned to the epoch that occurs immediately prior to the current epoch.	
	studyEpochDescription	string	C93824		Study Epoch Description	The textual representation of the study epoch.	
	studyEpochId	string		1..1			
	studyEpochType	Code	C188830		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.	C99079
	studyEpochName	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.	
StudyIdentifier			C83082		Study Identifier	A sequence of characters used to identify, name, or characterize the study.	
	studyIdentifierId	string		1..1			
	studyIdentifier	string	C83082		Study Identifier	A sequence of characters used to identify, name, or characterize the study.	
	studyIdentifierScope	Organization					
StudyProtocolVersion			C93490		Study Protocol Version	A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	
	publicTitle	string	C94105		Public Protocol Title	The descriptive name of the protocol that is intended for the lay public, written in easily understood language.	
	scientificTitle	string	C132350		Scientific Protocol Title	A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.	
	studyProtocolVersionId	string		1..1			
	protocolStatus	Code	C188818		Protocol Status	A condition of the protocol at a point in time with respect to its state of readiness for implementation.	C188723
	briefTitle	string	C132345		Brief Protocol Title	The short descriptive name for the protocol.	
	protocolAmendment	string	C132347		Study Protocol Amendment	A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	
	protocolVersion	string	C93490		Study Protocol Version	A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	
	protocolEffectiveDate	Date	C188817		Study Protocol Amendment Effective Date	The date and time specifying when the protocol amendment takes effect or becomes operative.	
	officialTitle	string	C132346		Official Protocol Title	The formal descriptive name for the protocol.	
Timing			C80484		Timing	The chronological relationship between temporal events.	
	timingRelativeToFrom	Code	CNEW		Timing Relative To From	The name of the reference event used to define the temporal relationship with another event.	CNEW
	timingDescription	string	CNEW		Timing Description	The textual representation of the chronological relationship between temporal events.	
	timingWindowLower	string					
	timingId	string		1..1			
	timingType	Code	CNEW		Timing Type	A characterization or classification of the chronological relationship between temporal events.	CNEW
	timingWindowUpper	string	CNEW		Timing Window, Upper	The latest chronological value of an allowable period of time during which a temporal event takes place.	
	timingWindow	string	C48921		Timing Window	A time period, or other type of interval, during which a temporal event may be achieved, obtained, or observed.	
	relativeFromScheduledInstanceId	string		0..1			
	relativeToScheduledInstanceId	string		0..1			
	timingValue	string	CNEW		Timing Value	The temporal value of the chronological relationship between temporal events.	

Class Name	Attribute Name	Data Type	NCI C-Code	Cardinality	Preferred Term	Definition	Codelist Ref
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.	
	transitionRuleId	string		1..1			
	transitionRuleDescription	string	C188835		Transition Rule Description	The textual representation of the transition rule.	

6 USDM API

The reference architecture API is designed as a mechanism for bulk transfer. The API has been designed to allow for bulk creation of a study within a Study Definitions Repository, 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, the API has been designed to include an instance once and allow for zero, 1, or more references to it as dictated by the USDM design and the relationships within. This mechanism relies on the 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.

7 Examples

For the purposes of public review, examples of use of the model in JSON, .PNG, and .XLS format can be found here.

8 Appendices

- USDM Team
- Glossary and Abbreviations
- Revision History
- Representations and Warranties, Limitations of Liability, and Disclaimers

8.1 USDM Team

Name	Institution/Organization
John Owen	Project Manager, CDISC
Dave Iberson-Hurst	USDM Product Owner, CDISC
Erin Muhlbradt	Controlled Terminology Expert, NCI-EVS
Craig Zwickl	Controlled Terminology Expert, CDISC

Name	Institution/Organization
Jared Schreibman	Software Engineer, CDISC
Chris Upkes	Principal Consultant, Neo4J
Gaston Guitart	Consulting Engineer, Neo4J

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 SMEs
- Accenture DDF development team
- CDISC DDF volunteer team

8.2 Glossary and Abbreviations

ADaM	Analysis Data Model
API	Application programming interface
BRIDG	Biomedical Research Integrated Domain Group
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
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."
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.
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
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
EDC	Electronic data capture
EHR	Electronic health record
EMA	European Medicines Agency
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); http://www.cdisc.org/
HL7	Health Level Seven International
ICE	Intercurrent events; events that occur after randomization and alter the course of the randomized treatment during the intended study treatment period
IOS	International Organization for Standardization
JSON	JavaScript Object Notation
LOINC	Logical Observation Identifiers Names and Codes

MedDRA	Medical Dictionary for Regulatory Activities. A global standard medical terminology designed to supersede, in regulatory submissions, other terminologies previously used in the medical product development process (such as COSTART and ICD9). DDF-422 UNDER TEAM REVIEW
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
SDS	Submission Data Standards. Also the name of the team that maintains the SDTM and SDTMIG.
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide (for Human Clinical Trials)
SEND	Standard for the Exchange of Nonclinical Data
SHARE	Shared Health and Clinical Research Electronic Library; CDISC's metadata repository
SNOMED	Systemized Nomenclature of Medicine
SOA	Schedule of activities
Subject	A participant in a study.
UML	Unified modeling language
USDM	United Study Definitions Model
USDMIG	USDM Implementation Guide
UUID	Universally unique identifier
WHO	World Health Organization
XML	Extensible markup language

8.3 Revision History

8.3.1 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.

8.3.2 Amendments between USDM v1.0 and USDM v2.0

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
10	4	Allow Study Phase to use the Code Alias	1. Class: Study Attribute studyPhase amended from Code to AliasCode
10	4	Add flaq 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

#	Sprint #	Overview	Notes
			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	Reference Biomedical Concepts 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
20	9	Study Timing and "Timepoints" added to the model	Reference Study Timing for additional information. Addition of the following Classes (note that class StudyData was removed and replaced with the Biomedical Concept classes • ScheduleTimeline • Timing

#	Sprint #	Overview	Notes
			• 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 (see https://github.com/cdisc-org/DDF-RA) 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 v1.0 and the Internal 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.

8.4 Representations and Warranties, Limitations of Liability, and Disclaimers

CDISC Patent Disclaimers

It is possible that implementation of and compliance with this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any claim or of any patent rights in connection therewith. CDISC, including the CDISC

Board of Directors, shall not be responsible for identifying patent claims for which a license may be required in order to implement this standard or for conducting inquiries into the legal validity or scope of those patents or patent claims that are brought to its attention.

Representations and Warranties

"CDISC grants open public use of this User Guide (or Final Standards) under CDISC's copyright."

Each Participant in the development of this standard shall be deemed to represent, warrant, and covenant, at the time of a Contribution by such Participant (or by its Representative), that to the best of its knowledge and ability: (a) it holds or has the right to grant all relevant licenses to any of its Contributions in all jurisdictions or territories in which it holds relevant intellectual property rights; (b) there are no limits to the Participant's ability to make the grants, acknowledgments, and agreements herein; and (c) the Contribution does not subject any Contribution, Draft Standard, Final Standard, or implementations thereof, in whole or in part, to licensing obligations with additional restrictions or requirements inconsistent with those set forth in this Policy, or that would require any such Contribution, Final Standard, or implementation, in whole or in part, to be either: (i) disclosed or distributed in source code form; (ii) licensed for the purpose of making derivative works (other than as set forth in Section 4.2 of the CDISC Intellectual Property Policy ("the Policy")); or (iii) distributed at no charge, except as set forth in Sections 3, 5.1, and 4.2 of the Policy. If a Participant has knowledge that a Contribution made by any Participant or any other party may subject any Contribution, Draft Standard, Final Standard, or implementation, in whole or in part, to one or more of the licensing obligations listed in Section 9.3, such Participant shall give prompt notice of the same to the CDISC President who shall promptly notify all Participants.

No Other Warranties/Disclaimers. ALL PARTICIPANTS ACKNOWLEDGE THAT, EXCEPT AS PROVIDED UNDER SECTION 9.3 OF THE CDISC INTELLECTUAL PROPERTY POLICY, ALL DRAFT STANDARDS AND FINAL STANDARDS, AND ALL CONTRIBUTIONS TO FINAL STANDARDS AND DRAFT STANDARDS, ARE PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND THE PARTICIPANTS, REPRESENTATIVES, THE CDISC PRESIDENT, THE CDISC BOARD OF DIRECTORS, AND CDISC EXPRESSLY DISCLAIM ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR ANY PARTICULAR OR INTENDED PURPOSE, OR ANY OTHER WARRANTY OTHERWISE ARISING OUT OF ANY PROPOSAL, FINAL STANDARDS OR DRAFT STANDARDS, OR CONTRIBUTION.

Limitation of Liability

IN NO EVENT WILL CDISC OR ANY OF ITS CONSTITUENT PARTS (INCLUDING, BUT NOT LIMITED TO, THE CDISC BOARD OF DIRECTORS, THE CDISC PRESIDENT, CDISC STAFF, AND CDISC MEMBERS) BE LIABLE TO ANY OTHER PERSON OR ENTITY FOR ANY LOSS OF PROFITS, LOSS OF USE, DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, WHETHER UNDER CONTRACT, TORT, WARRANTY, OR OTHERWISE, ARISING IN ANY WAY OUT OF THIS POLICY OR ANY RELATED AGREEMENT, WHETHER OR NOT SUCH PARTY HAD ADVANCE NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

Note: The CDISC Intellectual Property Policy can be found at: https://www.cdisc.org/sites/default/files/2020-09/cdisc_policy_003_intellectual_property_v2019.pdf