USDM Handbook 2: Creating a Digital Schedule of Activities (USDM-HB2 v1.0)

Version 1.0 (Final)

Prepared by the USDM Team

Notes to Readers

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See Appendix E for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

In the evolving landscape of clinical research, the schedule of activities (SoA) is the operational heart of the clinical study protocol: It defines which assessments are performed, at which visits, and at which times during the study. Historically, the SoA has been authored as a table in a word-processing document and then reinterpreted, rekeyed, and revalidated by every downstream function that uses it. The Unified Study Definitions Model (USDM) is rapidly becoming the backbone of digital study design, promising a "single source of truth" from protocol to downstream implementation. One of the highest-value digital data flow (DDF) use cases is the digital authoring and exchange of the SoA as a USDM schedule timeline, from which protocol renditions, data capture configurations, and standards deliverables can be derived.

This implementation handbook provides a strategic framework for representing the clinical study SoA in USDM v4.0 as defined in the USDM Implementation Guide (USDM-IG; https://github.com/cdisc-org/DDF-RA/blob/v4.0.0/Deliverables/IG/USDM-IG.pdf), including:

- Visit schedule: encounters, scheduled activity instances, timings, timing windows, and anchors
- Assessments: activities, their ordering and grouping, and their association with CDISC Biomedical Concepts
- Conditional logic: conditions, footnotes, and scheduled decision instances
- Change management: study versions, amendments, and automated comparison of schedule versions

1.1 The Business Value Proposition

Transitioning to a USDM-based workflow for the SoA is not merely a technical upgrade; it is a business imperative. In the traditional workflow, the same schedule is manually re-entered into multiple systems: the protocol document, the electronic data capture (EDC) system, trial management and payment systems, and the statistical programming environment. Each re-entry is a transcription risk, and every protocol amendment multiplies the reconciliation effort. Because the SoA drives site budgets, subject burden assessments, data collection, and submission datasets, inconsistencies between these copies create operational, compliance and cost risks if information is not well documented or interpreted from the SoA. There are significant benefits to capturing the SoA once as structured USDM metadata, including:

- **Single source of truth:** The schedule exists once, as a machine-readable timeline. Protocol tables, EDC visit structures, visit calendars, and the related Study Data Tabulation Model (SDTM) Trial Design domains become renditions of the same source rather than independent reinterpretations.
- **Downstream automation:** Structured visits, timings, and activity assignments allow study build activities (e.g., EDC configuration, visit projection, monitoring plans) to start in parallel with protocol finalization rather than after it.
- **Faster, safer amendments:** When schedule versions are structured, they can be compared automatically, and the downstream impact of each change (e.g., on data collection, on standards deliverables) can be inferred and reported instead of rediscovered manually.
- **Consistency across studies:** A standardized schedule representation enables reuse of visit structures and assessment panels across studies and sponsors and enables the community to converge on common patterns for complex designs such as cyclical schedules.

1.2 Navigating the Digital Transformation

Although the technical representation of the schedule timeline is a core component of this handbook, the focus is on the integration of people, processes, and technology. Successful implementation requires a shift in how study teams collaborate: The SoA is no longer just a table in a document; it is a structured dataset that informs the entire clinical lifecycle. Study designers and medical writers become the authors of machine-readable study definitions, and downstream functions become consumers and reviewers of generated renditions rather than manual transcribers.

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Key Insight: *In a USDM-driven environment, the schedule of activities is not a table in a document; it is a machine-readable timeline. If the timeline is captured accurately at the source, every downstream consumer—data capture, clinical operations, statistical programming, and submission—works from the same, unambiguous schedule.*

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2 Relevant Workflows and Processes

2.1 Business Level

Current Business Flow

The following figure illustrates the typical current business flow of SoA information from study design to study execution and regulatory submission.

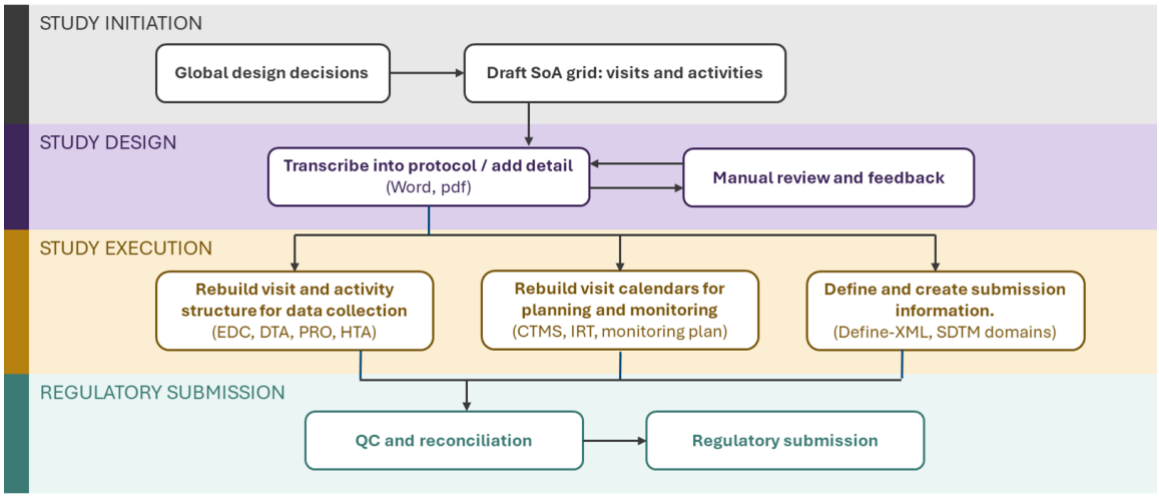
Study initiation: The study team decides on the global design of the study (i.e., indication, objectives, endpoints, arms, epochs) and drafts a first visit-and-assessment grid, typically in a spreadsheet, as part of the study design outline.

Study design: The draft grid is interpreted and copied manually into the protocol template by the medical writer. Detail (e.g., footnotes) is added and the proposed schedule is reviewed and iterated by the study design team. Footnotes capture conditional logic, windows, and operational nuances that do not fit in the grid.

Study execution: After protocol finalization, each downstream function re-extracts the schedule manually: The data manager or EDC programmer rebuilds the visit structure in the EDC system, clinical operations builds visit calendars and monitoring plans, and the clinical programmer creates the SDTM datasets and corresponding metadata based on the SoA and detail described in the protocol narrative.

Regulatory submission: Output from the different processes needs to be aligned before regulatory submission. Based on that, protocol deviations and violations are identified in the last stage when time is limited.

The SoA is one of the most frequently used sections of the protocol, and every consumer performs an independent interpretation of the same table. Ambiguities—undocumented anchor days, footnotes with conditional logic, visit windows expressed inconsistently—are resolved separately by different teams and roles, meaning resolutions may not be fed back into the source document. Depending on the complexity of the study, the initial build and reconciliation of schedule information across systems typically consumes days to weeks of effort, and each protocol amendment restarts a large part of this work.



Future Business Flow

Digitizing the study design and the corresponding SoA significantly improves the process, in terms of both quality and efficiency. The following figure shows the envisioned digital data flow of schedule information from study design to downstream consumption.

Study initiation: The study team decides on the global design of the study (i.e., indication, objectives, endpoints, arms, epochs) and drafts a first visit-and-assessment grid in the study design solution as part of the study design outline.

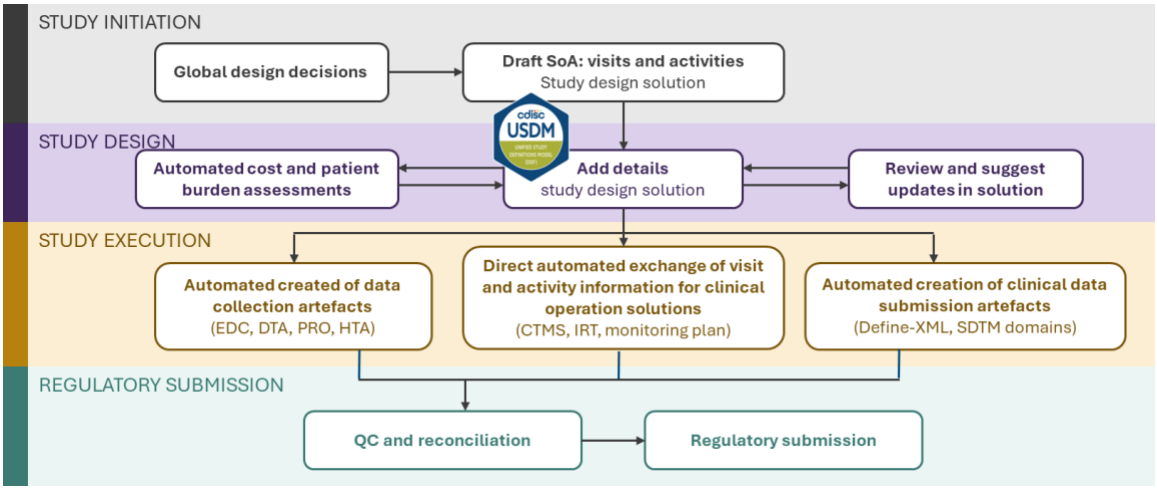
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Study design: The draft grid is reviewed by the medical writer, and updated with activity and timing details. The study design team reviews interactively and suggests updates. Simulataneously automated cost and burden impact assessments can be directly retrieved and inform further updates to the SoA. Timing details originally stored in footnotes can be directly digitized and more univocally inform downstream processes.

Study execution: Downstream systems consume the USDM schedule timeline automatically via an application programming interface (API): The EDC visit structure, visit calendars, and other artifacts are generated from the same source. Reviewers adjust and approve generated outputs rather than recreating them. Compared to the current business flow, this approach reduces each downstream process build from an independent interpretation exercise to a review of generated output.

Regulatory submission: Review and reconciliation times before regulatory submission are lessened as all artifacts are originated from the same digital source and generation is less manual, reducing the number of inconsistencies and issues. Full digitalization of the protocol and SoA improves the consistency between study artifacts, thereby reducing protocol deviations.

When the protocol is amended, the study design solution creates a new study version. These versions are compared, and an impact analysis report is generated identifying which study artifacts require attention as a result of the change. One of the largest gains materializes at amendment time: Instead of rereading the full protocol to find schedule changes, downstream functions receive a machine-generated difference report scoped to the entities that changed.



Transitioning and Process Change

As described in the TransCelerate white paper on implementing DDF[1], 2 methods for the digital protocol have surfaced: (1) protocol digitization, which converts an analog protocol to a digital format; and (2) protocol digitalization, a deeper transformation that harnesses digital technology to create and manage digital protocols from their inception. Both approaches apply to the SoA. Digitization—extracting a schedule from a PDF protocol, increasingly with the assistance of artificial intelligence (AI)—is helpful for legacy studies and for organizations beginning the transition; it always requires human verification of the extracted schedule against the source. Digitalization—authoring the schedule digitally from the start in a study design solution—is the target state. A hybrid approach might be beneficial for the transition period to allow for testing and familiarization with new solutions and procedures. The new approach will also affect company and organizational standard operating procedures, particularly those governing protocol authoring, review, and amendment; this needs to be addressed in the change process as well.

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2.2 User Level

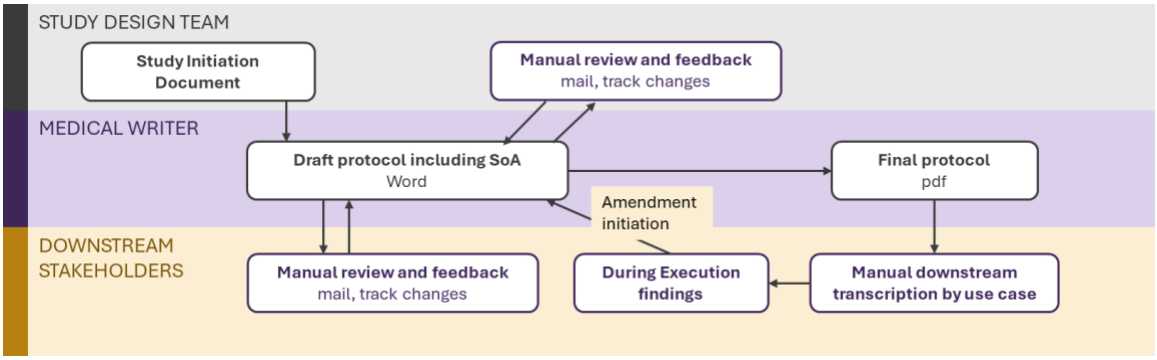
Current Process

From a user and functional perspective, the creation and maintenance of the SoA in the study protocol follows a multistep process performed by multiple stakeholders as illustrated by the following figure.

The **study design team** creates a study initiation document including a draft of the main visits and activities to be performed during the clinical study. This document is the starting point for the **medical writer**, who creates a full protocol with all study details in a word-processing document. This document is then reviewed by the study design team and d**ownstream stakeholders** (e.g., statistician, regulatory, clinical operations). Feedback is provided by tracking changes and adding comments to the document, or via email.

After approval, a final protocol version is signed off; downstream stakeholders receive a PDF of this version. They read the protocol, interpret the information for their purposes, and set up their own systems based on that interpretation. Downstream clarification questions (e.g., "Is the week 4 visit anchored to randomization or to first dose?") are answered by the medical writer and/or the study design team. This communication often lives only in email and/or subdocuments.

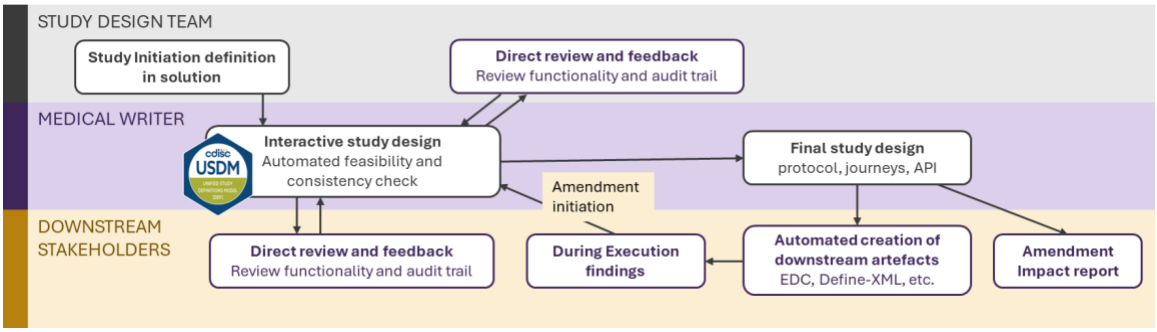
During execution, findings limiting the consistency or execution of a study may need to be addressed in the protocol, resulting in the requirement of an amendment. The amendment process typically follows the same review cycle as the initial protocol, which can cause delays in the execution of the trial.



Future Process

In the future process (see following figure), the study design team, medical writer, and downstream stakeholders directly work within a study design solution. The study initiation definition can be directly created in the solution by the **study design team** and passed to the **medical writer** as a starting point to further define and detail the study. Automated feasibility checks for costs and patient burden can be included in the solution as well as automated consistency checks, reducing the time needed for development. The review of the study design by the study design team and **downstream stakeholders** can be directly performed in the solution with direct audit trial and feedback functionality. After the design is finalized, it can be authorized and passed through in the formats that are required downstream. This may be a protocol format for the investigator, a patient journey for patient insights, and/or the agnostic exchange of study design information between systems in USDM API format. If an amendment is needed, the process repeats itself. A direct amendment impact report can be generated for downstream stakeholders by comparing different study versions and indicating the relevant changes for specific processes.

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As described here, the impact of the design can be tested faster and sooner in the future process. Alignment with other stakeholders (e.g., data scientists, statisticians, regulatory) also can be done faster and more efficiently. This in turn should reduce downstream changes and potentially avoid protocol amendments. The user remains in control of the clinical content; what changes is that consistency checking, rendition formatting, and change tracking are performed by the solution instead of by hand. The many downstream use cases benefiting from this digitized study design approach include the automatic generation of EDC build; data transfer agreements; Define-XML (discussed in USDM Handbook 3); SDTM creation; and table, listings, and figures (TLF) creation.

2.3 Technical level

Current Tooling

The current process is supported by general-purpose tools rather than schedule-aware ones. Typical technical characteristics include:

- SoA tables maintained in word-processing documents, with formatting (e.g., merged cells, symbols, footnote markers) that carries meaning a machine cannot recover reliably
- Spreadsheet trackers that duplicate the protocol table for operational planning, with no controlled link to the protocol version
- Manual EDC visit-structure builds and per-study programs for visit projections
- Manual selection and modification of EDC forms from a repository of preconfigured artifacts based on activities specified in the protocol
- Amendment comparison performed with document redlines, showing text changes rather than schedule changes and impact

Future Tooling

A study design solution supporting the SoA use case provides the following functionalities:

- Capturing the visit schedule as USDM entities (epochs, encounters; schedule timelines with scheduled activity instances and timings) rather than as formatted text
- Using controlled terminology such as CDISC CT and Biomedical Concepts, external vocabularies (e.g. CPT-4, ICD-10-PS, SNOMED-CT), or internal sponsor-defined controlled terminology as applicable
- Rendering the protocol SoA table and other user-specific views automatically from the structured schedule
- Exchanging the schedule using a USDM JSON export through the USDM API, so downstream systems consume the schedule programmatically
- Creating new versions of the study without losing additions and validation of information not changed, and comparing any 2 schedule versions
- Maintaining a full audit trail of a study's design and its artifacts
- Validating the schedule content using the applicable USDM CORE (CDISC Open Rules Engine; https://www.cdisc.org/core) rules and solution-specific consistency checks

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See the User Requirements and Technical Implementation sections for additional details and discussion.

2.4 Maturity Matrix

The SoA automation feature in the study design solution can be implemented at increasing levels of maturity. Organizations do not need to implement the highest maturity level to obtain value; a basic digitized schedule already removes most transcription risk. The following matrix indicates which features are typically covered at each maturity level.

The maturity levels can be interpreted as follows:

- **Low:** Started with the digitized collection of the visits, activities, and footnotes, enabling rendering of the main SoA.
- **Medium:** All timings, windows, and activity descriptions are structured in USDM format, enabling comparison of details between study versions. Activity details are added in the form of procedures and BCs.
- **High:** Complex schedule logic (e.g., conditional visits, branching, cycles, subtimelines) is included, enabling full validation, downstream automation, and amendment impact analysis.

Feature implementation	Low	Low-medium	Medium	Medium-high	High[a]
Study identifier and title	Direct capture in USDM format		+ Capture in relation to sponsor scope		
Study versioning			Version identifiers and dates		+ Full amendment details[b]
Main study visits, periods and timings	Direct capture and ordering of visit information in USDM format	+ Direct capture of epoch (study period) information	+ Direct capture of timing information in relation to visits	+ Enabling timing granularity within visits	
Additional timelines			Creation of unscheduled visit timelines	+ Creation of PK/PD subtimelines and relationships to main timeline	+ Flexible design of alternative subtimelines as needed by the user
Modeling alternative timeline routes			Modelling of cycles in a timeline	+ Modelling of recurrent visits in a timeline	+ Modelling of branching and other alternative pathways in a timeline.
Activities	Direct capture and ordering of described activities in USDM format	+ Enabling activity headers (groupings)	+ Store references from time points (visits) to activities indicating the crosses in the SoA matrix		
Procedures			Adding procedure details to activities using company specific procedure codes	+ Reference to corresponding interventions (if applicable)	+ Enabling detailed overview of what intervention is happening when during the trial
Assessment details (biomedical concepts)			References from activities to biomedical concepts from the CDISC Library	+ Biomedical concept configuration according to study requirements	+ Enabling addition of custom assessment properties allowing for downstream automation + Enabling configuration of custom biomedical concepts (see CDISC BC training, https://learnstore.cdisc.org/product?catalog=BiomedicalConceptsHOIT)
Footnotes	Direct capture of all footnotes in USDM format	+ References from footnotes to the corresponding activities and timepoints in the SoA	+ Digitization of the assessment related footnotes (reference to biomedical concepts)	+ Digitization of time-related footnotes (timing granularity and subtimelines)	+ Digitization of branching, skipping, repeating footnotes + Tagging of cohort information to allow for sub-selection of assessments.
Amendment management		Design comparison across versions	+ Snapshot (freeze) of schedule versions	+ Automated version comparison	+ Automated impact analysis reporting
All features					+ Full validation functionality including formal verification

[a]Each level is assumed to include the maturity descriptions described for the previous level.
[b]Not described in this handbook.

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3 User Requirements

This section describes the requirements for the SoA use case from the perspective of the stakeholders. When evaluating or building a solution for this use case, these requirements can serve as a starting point for a fit-for-purpose assessment.

3.1 Relevant Stakeholders

The following stakeholders are involved in or affected by digitization of the SoA.

Role	Responsibility	Viewpoint	High-level interests
Management	Overall delivery of the study; investment decisions on tooling and process change	Strategic	• Reduced cycle times and rework • Compliance and inspection readiness • Return on tooling investment
Study designer/medical writer	Authoring the study design and the protocol SoA	Content owner	• Intuitive schedule authoring • Study feasibility assessments • Automatic, correct protocol rendition • Controlled amendment process
Clinical operations	Study conduct, site management, visit planning	Consumer	• Reliable visit calendars and windows • Early visibility of schedule changes • Subject burden assessment
Data manager/EDC programmer	Study database build and maintenance	Consumer	• Machine-readable visit structure • Activity-to-visit assignments • Assessment details and conditions • Scoped amendment impact
Clinical and statistical programmers	SDTM datasets, including the Trial Design domains Creation of TLF	Consumer	• Standard USDM schedule export • Traceability from protocol to datasets • Stable identifiers across versions • Traceability from protocol to report + the stable identifiers
Quality control	Verification of consistency between protocol and derived artifacts	Reviewer	• Single source of truth • Audit trail and data lineage • Automated comparison reports
System developer	Implementation and integration of solutions	Implementer	• Clear USDM mapping • Clear user and system requirements • API-based exchange • Validation rules and reference examples
Study biostatistician	Statistical study design, including endpoints, estimands, analysis methods, and sample-size assumptions	Design contributor	• Alignment of endpoints with scheduled assessments and timepoints • Early confirmation that the planned data collection supports the statistical analyses • Traceability from study objectives and endpoints to the SoA and downstream analyses • Early assessment of the statistical impact of schedule changes

3.2 Requirements for the Study Design SoA Feature

This section describes user requirements for the study design solution regarding capturing the SoA. The requirements are grouped by feature. Minimum requirements enable a basic, complete USDM schedule export; more advanced solutions may provide the higher-maturity capabilities identified in the Maturity Matrix section. The items described here are functional requirements for a solution to include a SoA feature, and do not include other requirements such as reliability and security. The list presented here can be seen as a starting point for alignment between users and implementers.

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Study Identification

As a minimum, the solution needs to include storage of study identifiers, study titles, and the sponsor organization, enabling unambiguous identification of the study to which the schedule belongs. The technical implementation requirements for these general study design features are shared with the other use cases and are described in the USDM-IG and the USDM Handbook 1 (USDM-HB1). Note that this is the minimal need to enable the SoA feature of a study design solution. USDM as a whole has a more extensive requirements list to enable the full representation of a study design.

SoA Grid

Visits and Timings

As a minimum, the solution should be able to store the following information in USDM format and present it in a SoA grid presentation form in the solution:

- Enter and modify study phase (trial period) information in (one of the) top rows of the main SoA. This needs to be stored as epochs in the USDM with the corresponding ordering logic (see USDM-HB1)
- Move and modify study phase information
- Enter and modify visit names as columns in the SoA. They need to be nested within study phases if applicable, for the main SoA.
- Enter and modify visit timings and windowing of planned visits and refer the timing to the timepoint/visit to which it is applicable (e.g., visit 3 is 5 days after visit 1, follow-up is 28 days after last dosing visit) and which is either either before or after the defined time. Indicate both the timing label as well as the exact timing in ISO 8601 format.
- Move and modify study visit information
- Insert or delete visit information
- Store 1 or more contact modes for each visit according to CDISC CT (codelist C171445)
- Store 1 or more environmental settings for each visit according to CDISC CT (codelist C127262)

For full functionality and applicability to most clinical studies, the following requirements are recommended:

- Define reusable cycles for a study
- Define unscheduled and early termination visits
- Define subtimelines for a study (e.g., PK/PD, phase 1 safety profiles)
- Define repeated visits for a study
- Indicate branching for a study, preferably linked to a corresponding cohort of patients
- Copy and reuse of visit information
- Add visit start and end rules, needed for the SDTM trial design domains (see USDM-HB1)
- Option to indicate the reference frame by indicating whether the relationship is between the starts of the variable length timepoint; the ends; or a start-end, end-start combination
- Enable more granular timings within a visit (e.g., predose vs postdose) and enable the corresponding views as a single column for a visit and as separate columns per timepoint (collapse/expand options)
- Validate timing labels against the corresponding ISO-formatted values and/or transform the ISO-formatted value and window attributes to timing labels (e.g., "Day 15 (±2 days)", "Week 2"), including negative presentation for pre-anchor visits (e.g., "Day -14")

Activities

Activities are represented by rows in the SoA: the assessments and procedures performed during the study. The solution must enable:

- Definition of each activity with a name, display label, and description

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- Explicit ordering of activities as they should appear in the SoA rendition
- Grouping of related activities (parent/child); for example, grouping individual laboratory panels under a "Laboratory assessments" parent
- Assignment of activities to scheduled timepoints, which the solution presents as the interactive SoA matrix

More advanced activity features could be included, such as:

- Efficient entry, including bulk import of activity lists from prior studies or therapeutic-area templates
- Enabling definition of an activity duration
- Enabling definition of repetitive and/or multiple actions within activities

Assessments and Procedures

To make the schedule semantically unambiguous and enable the downstream digital data flow, each activity should be linked to the corresponding standardized assessments in the form of CDISC Biomedical Concepts (BCs; https://www.cdisc.org/cdisc-biomedical-concepts) that define what is observed or measured. The solution should enable browsing and searching a metadata repository linked to the CDISC Library (https://www.cdisc.org/cdisc-library) for applicable concepts, assigning 1 or more concepts (or concept categories or groupings) to an activity, and defining concept surrogates for assessments for which no published concept yet exists. This includes the following requirements:

- Specify and configure a set of BCs for reuse across studies (to be stored in a metadata repository (MDR)).
- Select groups or categories of configured BCs that relate to the activity from a MDR linked to the CDISC Library.
- View each BC with its properties and enable adjustment of labels.
- Review properties and enable or disable them as needed for the study.
- Review proposed responses (e.g., units, specimen types) and enable or disable them according to the needs of the study.
- Enable the addition of properties and responses as needed for clarity and/or downstream automation.
- Add alias codes for BCs to select assessment data from external data sources.

Note that the configuration of assessments in the form of biomedical concepts might be an activity for data managers, who may want to preconfigure sets of assessments according to standard study needs and/or postconfigure sets when already included in the design.

Not all assessments might be available in the latest set of BCs from the CDISC Library. In those cases, an alternative path is needed which

- enables the specification of new biomedical concepts following the BC process as outlined in the CDISC Biomedical Concept training (e.g., start with finding the corresponding code from the NCI Thesaurus and add standardized data element concepts), and/or
- enables the specification of a temporal concept. This includes a label and corresponding description and can be utilized in USDM as BC surrogate. Note that BC surrogates are less granular and therefore less informative for downstream automation.

In addition, procedures may be required to be added in cases where no data are needed to be collected except for a date or time of the procedure. This may be applicable to activities such as hospital admission, treatment allocation, and/or administration. This in turn results in the following requirements:

- Specify procedures for a specific activity and/or select from a preconfigured set.
- Add codes for the procedures (either internal codes or codes from external codelists like LOINC or SNOMED).
- If treatments are detailed in the solution, enable the reference to the corresponding treatment.
- Indicate a procedure type.

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Based on the assessments and procedures feature, users may also require the automated calculation of costs and patient burden based on number of assessments, repeats in the study, and assessment properties. This topic is not addressed in this handbook, but can be enabled with an extension of the USDM data model and the solution capabilities.

Footnotes

SoAs typically include different kinds of footnotes. Addressing these footnotes is described in the USDM IG (https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/IG/USDM-IG.pdf). Although a number of the footnotes can be addressed more structurally by the timeline functionality (i.e., scheduling logic), including the textual footnote functionality must still be enabled. This includes the following user requirements:

- Enable the addition of textual footnotes to a specific SoA.
- Enable the linking of the footnotes to 1 or more specific activities in the SoA.
- Enable the linking of the footnotes to 1 ore more specific visits and/or timepoints in the SoA.

More advanced footnotes feature requirements could include

- enabling text formatting of footnotes,
- enabling linking footnotes to specific assessments instead of the complete activity,
- structuring of information in the footnotes (tagging) for cohorts to enable subselection of requirements for the corresponding patient group,
- structuring of information in the footnotes for document references to enable quick navigation to the corresponding text,
- automated rendering and addition of markers including the ordering of footnotes based on where they are referenced in the SoA (e.g., activities, visits, cells to which they apply),
- recognizing entered footnote texts that could be handled by the timeline functionality (e.g., timing windows, predose indicators) and suggesting or including in the corresponding logic, and
- Enabling addition of footnotes to (multiple) epochs instead of individual visits/timepoints.

Note: The structuring of footnotes is not handled in this handbook. See the USDM-IG and Understanding USDM training for explanation of the syntax template feature of the USDM, which is needed for tagging and structuring footnotes.

Versioning and Amendments

In order to enable versioning and perform impact analyses from amending a study, the following requirements are applicable:

- The solution will include a full audit trail enabling tracing back any changes performed to the design.
- The solution will be able to timestamp and lock a full study version, preferably signed via electronic signature.
- The solution will be able to compare locked study versions and create an overview of changes, which is useful for amendment documentation.
- The solution will be able to create a change report identifying added, removed, and modified visits, activities, timings, and assignments, with an assessment of downstream impact (e.g., on data collection, on standards deliverables).

In addition, if collaboration is needed with other study design solutions and features, the solution must be able to ingest a new version of the study in USDM format without losing the additions and validation of information that was not changed.

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Reuse and Configuration

- The solution will provide the schedule as an USDM JSON (complete study definition or individual components) output suitable for system agnostic exchange with other solutions and as human-readable renditions (e.g., HTML, spreadsheet, PDF).
- The solution will provide a feature for configuring and reusing predefined artifacts with specific purposes (e.g., study type, therapeutic area) such as
  - an activity, with all its assessment details;
  - assessment subtiming details (e.g., repeats, collection length);
  - a visit, with all its assessments; and
  - cycle timeline definitions.

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4 Technical Implementation

This section describes the technical implementation of the SoA use case: the implementation requirements for the upstream study design solution, the mapping between the SoA as presented in protocols and its USDM v4.0 representation, the implementation requirements for the downstream SoA automation feature, and the validation of the resulting content. Code and structure examples in this section are taken from, or modeled on, the output of the open-source SoA Workbench described in the Examples and Use Cases section.

4.1 Study Design Solution Functional Implementation Requirements

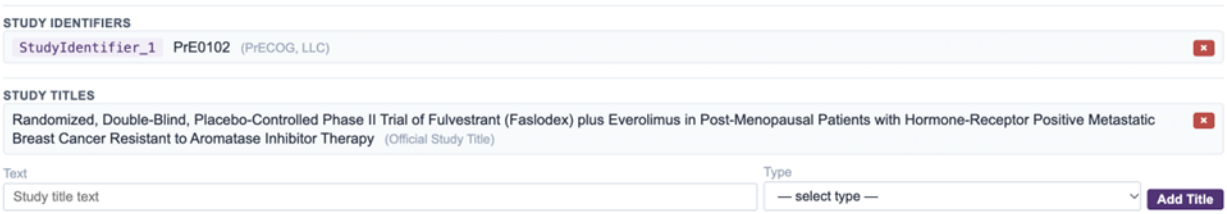
4.1.1 General Requirements

The study design solution needs to include general study characteristics in order to be able to distinguish a specific study and its version. As a minimum, this includes the unique sponsor identifier, the study version identifier, and the study version date. The official study title is helpful in further identifying the study.

Functional requirement	Relevant USDM classes and attributes	USDM nested in	Implementation notes
Store the study identifier in the scope of the sponsor organization.	StudyIdentifier/@text	study version	Ensure that the sponsor study identifier is stored with a scope of the sponsor organization. See the USDM-IG for examples (https://github.com/cdisc-org/DDF-RA/blob/v4.0.0/Deliverables/IG/USDM-IG.pdf).
Store the study version date.	GovernanceDate/@dateValue	study version	Multiple dates of different types are possible for each version. Ensure that the corresponding GovernanceDate type is aligned with the date that is used for the solution version comparison functionality. "Effective Date" might be the best option, but if only "Approval Date" or "Issued Date" is used; instead, this should be consistently recognized by the solution.
Store the study version identifier.	StudyVersion/@versionIdentifier	study version	This attribute stores the user -ecognizable identification of a version and is therefore important to utilize in the compare functionality.
Store the official study title.	StudyTitle/@text	study version	Use DDF controlled terminology (https://evs.nci.nih.gov/ftp1/CDISC/DDF/) to correctly indicate the official study title.

Stable identifiers for all information stored in USDM are what make the digitized schedule comparable across versions. For example, the SoA Workbench uses the convention {ClassName}_{n} (e.g., Encounter_4, ScheduledActivityInstance_12), where n increases monotonically and identifiers are never reused after deletion. Whatever convention a solution adopts, 2 properties of an identifier are essential: once assigned, it is immutable, and it is never recycled for a different entity. Without these properties, version comparison and downstream traceability degrade into name matching.

The following screenshot shows how the study identifier and study titles are presented and can be entered in the SoA Workbench. The company name which is the scope of the identifier needs to be specified before and is indicated in the light gray text. For each title, a type needs to be indicated (also presented in light gray).



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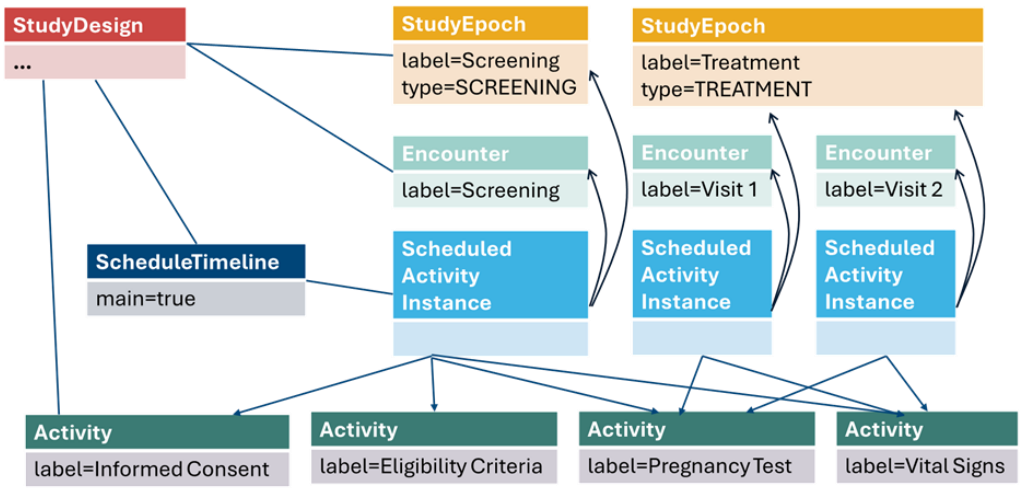
Note: The SoA Workbench is an open-source example solution. Professionally developed solutions need to address the user experience as one of their main focuses in development in order to ease the entry and make the solution intuitively sound.

4.1.2 Defining Epochs, Visits and Time Points

As illustrated in the following screenshot, epochs are usually presented in the top row of an SoA. Epochs represent defined study phases which are also used in the patient pathway representation of a study (see USDM-HB1). All epoch information is stored in the USDM StudyEpoch class. Visits are typically represented as columns in an SoA and are stored in the USDM Encounter class.

<<StudyEpoch>> / <<Encounter / Visit ScheduledActivityInstance>>	Information visit	Screening	Randomisation	Treatment						End of treatment	Treatment Discontinuation[f]
Visit ScheduledActivityInstance>>	V0	V1	V2	P3	V4	P5	V6	V7	V8	V9	V9X
Timing of Visit <<Timing>>	Minimum 1 day prior to V1	-2W	0W	1W	2W	3W	4W	6W	9W	12W	
Visit Window <<Timing>>	-7/0D	0/13D	±0D	±3D	±3D	±3D	±3D	±3D	±3D	±3D	
Informed Consent and Demography[a]	X										
Eligibility Criteria		X	X								

To enable more granular timings (e.g., distinguishing predose from postdose timepoints within a visit), the USDM uses the ScheduledActivityInstance class. The information stored in this class binds all the timing information together; each instance in this class may point to a visit stored in the Encounter class, to an epoch in the StudyEpoch class, and to 1 or more activities in the Activities class. A set of instances will form a chain of timepoints to form the timeline as represented in a SoA. Each chain of instances is nested in a distinct instance of the ScheduleTimeline class. The following figure shows how the information is logically related and stored. Note that each reference to a defined activity will resolve into a cross in the diagram and each activity can be referred to multiple times. The solution should be able to store and render this information to show an SoA grid with epochs, visits, activities, and crosses.



Note: This visualization is intended for explanation of the principle and does not include all required USDM information.

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The following table lists functional requirements applicable to storing epoch, visit, and timepoint information in the USDM.

Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Store a unique literal identifier for the epoch.	StudyEpoch/@name	study design	
Store the epoch label for presentation purposes.	StudyEpoch/@label	study design	The label is typically shown in the header of a schedule of activities.
Store the epoch type.	StudyEpoch/@type	study design	Store the StudyEpoch type according to the corresponding NCI codelist.
Indicate the epoch order.	StudyEpoch/@previous; StudyEpoch/@next	study design	In cases where an epoch is inserted, then the previous and next references should be adjusted in the solution to correctly represent the epoch order.
Store a unique literal identifier for the visit.	Encounter/@name	study design	
Store the encounter label for presentation purposes.	Encounter/@label	study design	The label is typically shown in the header of an SoA.
Store the encounter type.	Encounter/@type	study design	The encounter type is required and can be standard set to "Visit" (C25716). In the case of alternative encounters which do not include an actual interaction between study personnel and the participant, other custom types may be defined and suggested for future USDM CT updates.
Store the encounter environmental setting.	Encounter/@environmentalSettings	study design	Enable the optional selection of 1 or more environmental settings from the standard CDISC CT codelist C127262.
Store the encounter contact modes.	Encounter/@contactModes	study design	Enable the optional selection of 1 or more contact modes from the standard CDISC CT codelist C171445.
Indicate the encounter order.	Encounter/@previous; Encounter/@next	study design	In cases where an encounter is moved or inserted, then the previous and next references should be adjusted in the solution to correctly represent the epoch order.
Indicate the encounter start and end rule.	Encounter/@transitionStartRule; @transitionEndRule	study design	Although optional in the USDM, these fields are required for the submission of SDTM Trial Design domains.
Enable creation of 1 ore more SoAs (timelines).	ScheduleTimeline	study design	Each schedule should be stored as a separate timeline. This can be the main timeline, a subtimeline (e.g., pharmacokinetic or pharmacodynamic assessments), an unscheduled timeline, or a subtimeline that further details a specific activity assessment.
Indicate whether a timeline is the main timeline.	ScheduleTimeline/@mainTimeline	study design	The overall SoA, including the visits and epoch information, can be indicated as the main timeline. One and only 1 main timeline is expected per study design. If multiple overall SoAs are defined for a study, then this probably reflects multiple overall designs which can be stored as separate instances in the StudyDesign class.
Indicate the entry condition of a main timeline.	ScheduleTimeline/@entryCondition	study design	This is a textual field which is expected to contain information that indicates the triggering of the timeline. For the main timeline this could be "Informed Consent signed". For an unscheduled visit it could be "Adverse event occurred" or "Early termination", depending on how this is described in the design.
Enable the indication of the planned duration of a timeline.	ScheduleTimeline/@plannedDuration	study design	The planned duration is an optional attribute of the ScheduleTimeline class. However, it is included in the ICH M11 guideline[2], which makes it an expected feature.
Define the id(s) for indicating the exit of the timeline.	ScheduleTimeline/@exits	study design	

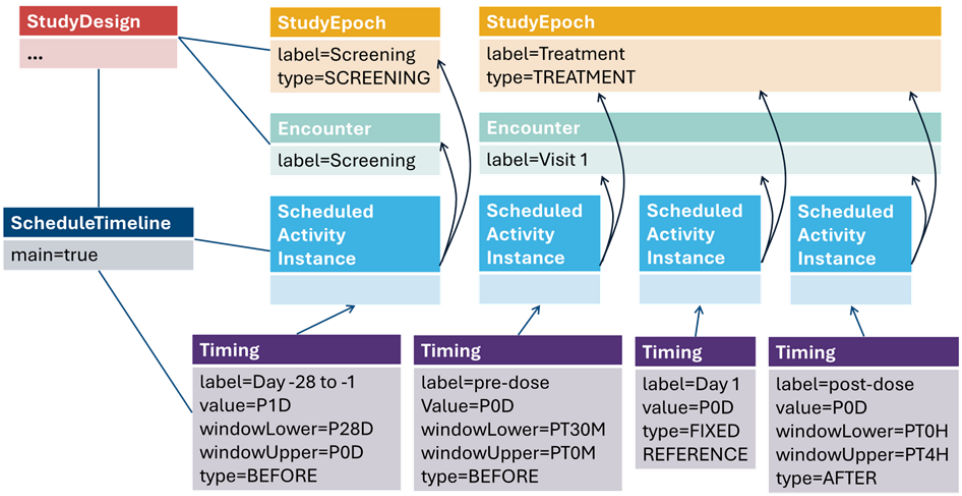
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Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Create instances for each distinctive timepoint in the study.	ScheduleTimeline/@instances	study design	At a minimum, 1 instance for each visit and column should be indicated in subtimeline schedules. However, to address more granular information (e.g., distinguishing predose from postdose assessments), multiple instances can be created for the same visit. In such a case, it would be helpful to have a collapse/expand functionality that shows the overall SoA with 1 column per visit (collapsed) and, when expanded, shows each timepoint separately.
Indicate the order of instances in the timeline.	ScheduledActivityInstance/@defaultCondition	schedule timeline	This needs to align with the order of epochs and encounters.
Relate scheduled activity instances of the main timeline to the corresponding encounters and epochs.	ScheduledActivityInstance/@epoch; ScheduledActivityInstance/@encounter	schedule timeline	Each timeline will have its own list of instances. However, instances from multiple timelines could point to the same visits and/or encounters. Usually, subtimelines do not include the references to epochs and encounters, whereas for the main timeline it is expected.
Indicate the last instance in the chain.	ScheduledActivityInstance/@timelineExit	schedule timeline	Refer to the exit id defined in the ScheduleTimeline class.

[a]USDM Class names start with a capital and are followed with the attribute name starting with lower case and preceded by /@. Reference attribute names may differ in the API representation of the model to distinguish between nesting and cross-referencing (see the USDM-IG and Understanding USDM training)

Adding Timepoint Granularity to Visits

In the current PDF protocols, footnotes may hold additional timepoint information such as "assessments should be performed predose" or "assessments should be performed within 30-60 minutes postdose." To inform downstream systems in the set-up of the EDC system and for monitoring instructions, adding this information in a computer-readable format aids the overall digital data flow and process efficiency. For each distinguishable timepoint, a separate instance can be created. Multiple instances may pointing to the same visit (encounter) information, indicating that they actually belong to the same visit. A solution may be able to use an extend/collapse function in which multiple timepoints are combined for a visit (collapsed) or the granular timing detail within a visit is shown (expand). This will provide a good general overview, while timing details can also be viewed and adjusted. This method can also be used when the timing is equal but corresponding windows differ for different activities. The schematic example that follows shows how, for a specific visit, 3 different timepoints (instances) are created. Although the corresponding timing value is equal (P0D) for all 3 instances, the label and ISO-formatted window information indicates the variation in timing in relation to dosing. These scheduled activity instances then point to the corresponding activities to which this timing information is applicable. A solution may present them in a single column (combined by timing value), with indications of the different windowing for the corresponding activities—which keeps the oversight for users while storing information in the background in a standardized and granular fashion.



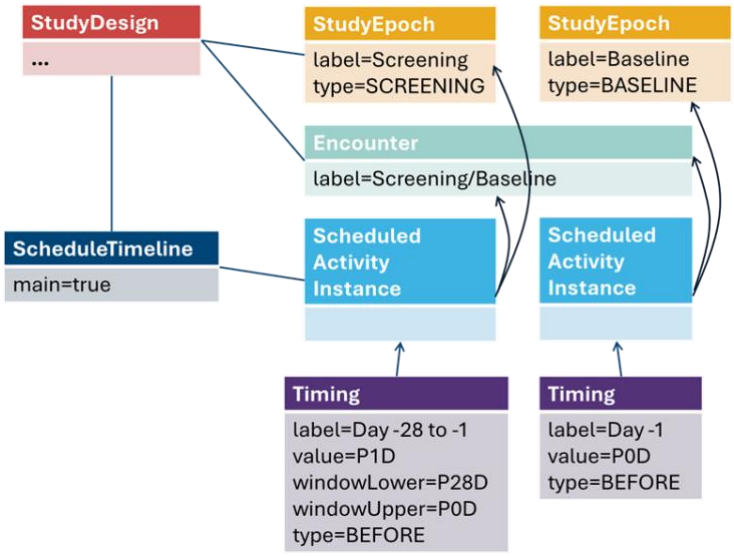
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Note: This visualization is intended for explanation of the principle and does not include all required USDM information.

The USDM flexibility enables switching easily from a single instance to multiple instances for 1 encounter. The solution needs to be able to easily insert or delete an instance when timing and/or windowing changes. The order of the instances should be logically maintained to whichever comes first based on the timing. If instances are planned at the same time, then the one that has the larger windowLower value is expected to come first.

One Visit, Multiple Epochs

In some cases, a unique visit can include multiple epochs. In such a case, while it is the same visit, it is advised to create separate timepoints in the form of scheduled activity instances for the relationship to each epoch. These timepoints can refer to the same visit but also to separate epochs. As illustrated in the following figure, the related activities then can be more granular, assigned to the corresponding epoch.



Note: This visualization is intended for explanation of the principle and does not include all required USDM information.

4.1.3 Adding Timing Details

Every scheduled instance (timepoint) is positioned in time by timings. A *timing* relates one scheduled instance to another. At least 1 of the instances needs to be anchored as a fixed reference to which the other timings relate. Most SoAs will only need 1 fixed reference, as the timings are logically directly or indirectly related. However, occasionally, multiple references might be needed, such as in event-driven studies. By capturing this information explicitly, downstream systems can be automatically configured for the execution and monitoring of the study. The following table presents requirements for storing the timing information.

Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Store the timing for each time point (instance) in the timeline.	Timing/@relativeFromScheduledInstance	schedule timeline	For each instance in the ScheduledActivityInstance or ScheduledDecisionInstance class, a corresponding instance in the timing class is expected. The relationship between them is formed by the relativeFromScheduledInstance attribute.
At least 1 timepoint (instance) must be defined as an anchor by the related timing.	Timing/@type	schedule timeline	Enable designation of at least 1 fixed-reference timepoint per timeline (e.g., day 1, first dose) from which other timings are calculated directly or indirectly. The corresponding type must be set to "Fixed Reference", C201358.

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Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Indicate what timepoint (instance) the specified timing duration relates to.	Timing/@releativeToScheduledInstance	schedule timeline	Although many timings will refer to the fixed-reference timepoint (e.g., 28 to 1 day before dosing, day 4), there are also occasions where the timing is related to another timepoint (e.g., cycle 2; day 8 relates to cycle 2, day 1 and not to the first dose of cycle 1). Therefore, the user must be able to indicate where the specified timing relates to. As a default, the fixed reference might be specified for standard studies to ease the SoA design process.
If not the anchor, indicate if the timepoint (instance) to which the timing relates is before or after the related timing.	Timing/@type	schedule timeline	Based on the order of instances and the reference, this can be automatically derived by the solution. When the related instance (indicated by relativeFromScheduledInstance) is before the referenced instance (indicated by the relativeToScheduledInstance), the type should be "Before", C201357. When the related instance (indicated by relativeFromScheduledInstance) is after the referenced instance (indicated by the relativeToScheduledInstance), the type should be "After", C201356.
Add a label (e.g., "Day 1", "Day -28 to -1", "4 hrs") to the timing used for presentation.	Timing/@label; @windowLabel; @valueLabel	schedule timeline	The timing class allows for a general timing label, a specific value label, and/or a windowLabel. Based on the preference of the solution and/or user, 1 or more of these can be used. Note that the valueLabel is a required attribute and the windowLabel is required when a window is specified.
Add the ISO 8601 duration-formatted timing value (e.g., P14D) for calculation and monitoring purposes.	Timing/@value	schedule timeline	The ISO 8601 duration-formatted value is not directly used for presentation purposes. The start of the study is usually indicated as "Day 1"; however, the corresponding timing value should be P0D. Correspondingly, "Day 2" will be indicated as "P1D". This allows for monitoring, and calculating visit intervals. Note that it is up to the implementation to use standard notations in days, weeks, or other time units.
Add the ISO-formatted window values for calculation and monitoring purposes.	Timing/@windowLower; @windowUpper	schedule timeline	The windowLower and windowUpper attributes indicate how much time is allowed before and after the ISO timing stored in the value attribute. Note that a window should not be specified for an anchor (stored with type "Fixed Reference").
Add the reference frame.	Timing/@relativeToFrom		Enable specification of whether the timing relationship between the 2 timepoints (instances) is measured start to start, start to end, end to start, or end to end. Note that the first indication in the reference name refers to the relativeFromScheduledInstance and the second to the relativeToScheduledInstance. So, a start-to-end indication indicates that the timing is relevant to the start of the instance indicated by the relativeFromScheduledInstance reference and the end of the instance indicated by the relativeToScheduledInstance. This might be needed, for example, in challenging studies where the timing and duration of activities is not fixed and certain blood levels need to be reached before the next activity can start.

[a]USDM Class names start with a capital and are followed with the attribute name starting with lower case and preceded by /@. Reference attribute names may differ in the API representation of the model to distinguish between nesting and cross-referencing (see the USDM-IG and Understanding USDM training)

The following table shows how typical protocol timing expressions are encoded. The ISO 8601 duration formats stored in the value, windowLower, and windowUpper attributes can express duration in different units. For example, 12 weeks (P12W) is equal to 84 days (P84D). As this information is used for calculation purposes and not for display purposes, during implementation the solution can choose what is most efficient. It might be convenient to align the units with the presentation and/or align units of the value with those of the corresponding windowLower and windowUpper attributes.

Protocol presentation (label)	Timing type	value	valueLabel	windowLower / windowUpper	windowLabel
Day 1 (baseline, anchor)	Fixed Reference	P0D	Day 1	— (not allowed on anchors)	—

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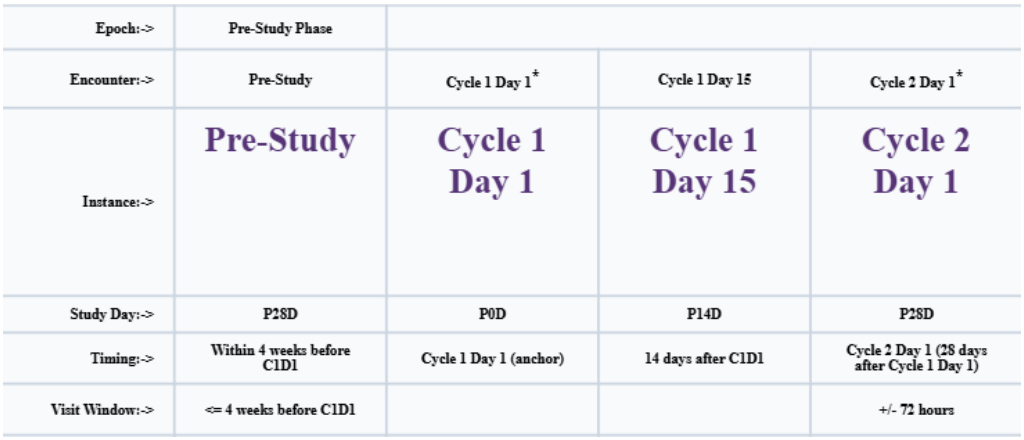
Protocol presentation (label)	Timing type	value	valueLabel	windowLower / windowUpper	windowLabel
Day 15 ± 2 days	After	P14D	Day 15	P2D / P2D	±2 days
Day -14 to Day -1 (screening)	Before	P14D	Day -14	P0D / P13D	Day -14 to Day -1
Week 12 (−3/+7 days)	After	P12W	Week 12	P3D / P7D	−3/+7 days

The following abbreviated extract shows a scheduled activity instance and its timing as exported in USDM v4.0 JSON (code objects are shortened for readability).

```
{
  "id": "ScheduledActivityInstance_3",
  "name": "SAI_3",
  "label": "Week 2",
  "timelineId": "ScheduleTimeline_1",
  "encounterId": "Encounter_3",
  "epochId": "StudyEpoch_2",
  "activityIds": ["Activity_1", "Activity_4", "Activity_7"],
  "defaultConditionId": "ScheduledActivityInstance_4",
  "instanceType": "ScheduledActivityInstance"
}

{
  "id": "Timing_2",
  "name": "TIMING_2",
  "label": "Day 15",
  "type": { "decode": "After", ... },
  "value": "P14D",
  "valueLabel": "Day 15",
  "relativeToFrom": { "decode": "Start to Start", ... },
  "relativeFromScheduledInstanceId": "ScheduledActivityInstance_3",
  "relativeToScheduledInstanceId": "ScheduledActivityInstance_1",
  "windowLower": "P2D",
  "windowUpper": "P2D",
  "windowLabel": "±2 days",
  "instanceType": "Timing"
}
```

The following visualization shows how the example Open source SoA tool, available in the CDISC COSA library, renders information that is stored in USDM format to create the upper timing rows of a SoA. It includes the information stored in the studyEpoch class, the Encounter class, the ScheduledActivityInstance class, and the corresponding information stored in the Timing class (iso formatted timing value, label and window label).



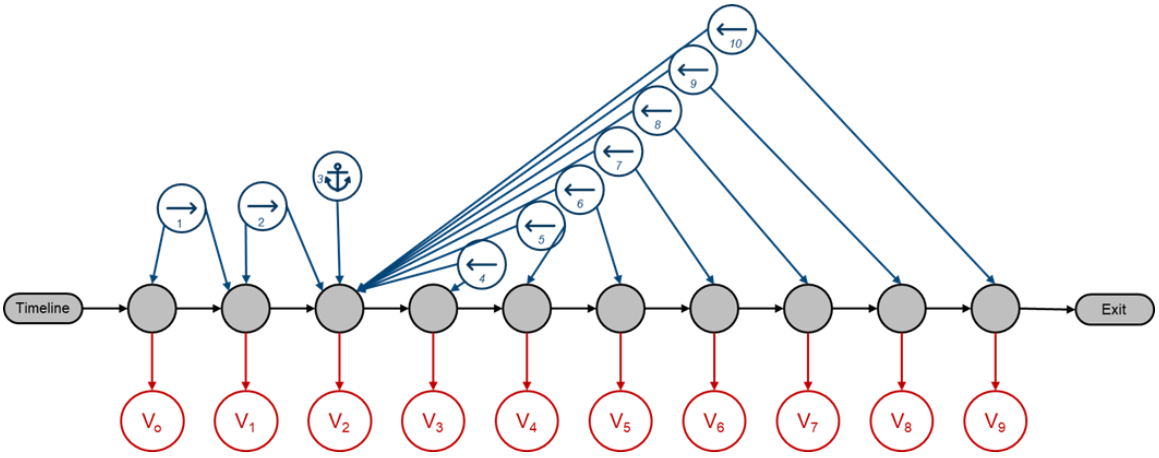
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Direct or Indirect Timing Relationships to the Anchor

The timings represented in an SoA may all relate to the first treatment day or they may be indirectly related. In the following example, the timings of visit 1 (V1) to visit 9 (V9) are related to the timing of visit 2 (V2) which indicates 0W (indicated in the protocol as the time of first treatment). However, the timing of visit 0 (V0) is related to that of visit 1 (V1); it indicates minimum 1 day prior to V1 with a corresponding window of -7/0D.

In the diagram following the table, each visit is stored as an encounter in USDM (red circles) and is related to a corresponding instance (gray circles). The timings (blue circles) of visit 1 (V1) to visit 9 (V9) all relate to the anchor (0W). Only the timing of V0 is not related to the anchor, but to V1, representing the timing information in the SoA table. For the corresponding USDM JSON of this example, see Appendix A1, Timeline with Direct and Indirect Relationships to the Anchor.

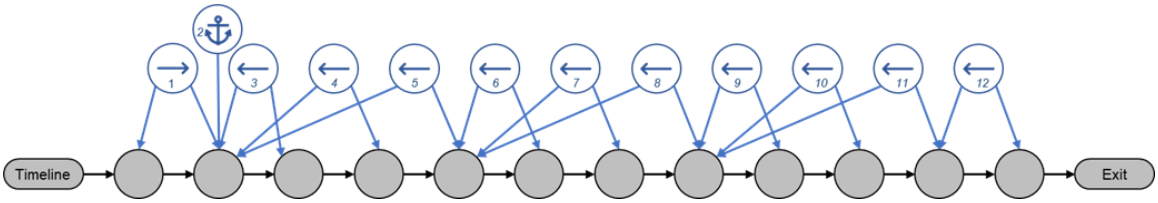
<<StudyEpoch>>	Information visit	Screening	Randomisation	Treatment						End of treatment	Treatment Discontinuation[f]
<<Encounter / Visit ScheduledActivityInstance>>	V0	V1	V2	P3	V4	P5	V6	V7	V8	V9	V9X
Timing of Visit <<Timing>>	Minimum 1 day prior to V1	-2W	0W	1W	2W	3W	4W	6W	9W	12W	
Visit Window <<Timing>>	-7/0D	0/13D	±0D	±3D	±3D	±3D	±3D	±3D	±3D	±3D	
Informed Consent and Demography[a]	X										
Eligibility Criteria		X	X								



Another good example of timings that are not related to the anchor are oncology studies. Although often not mentioned in the SoA itself, a cycle has a standard length which is documented elsewhere in the protocol. This cycle length can be used to relate the cycles to each other. In the following example, timing 5 indicates the cycle length (e.g., time between cycle 2 and cycle 1). However, timing 6 (cycle 2 day 8) and 7 (cycle 2 day 15) are related day 1 of cycle 2 and not to day 1 of cycle 1. If the start of cycle 2 is delayed, then it is clear and computer readable that day 8 and day 15 of cycle 2 should be delayed as well.

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	Screening	Treatment Phase								End of Treatment	Post treatment Follow-up	
		Cycle 1			Cycle 2			Cycle 3 and Beyond			Safety Follow-up	Survival Follow-up
Activity	Up to 28 days before Day 1	D1	D8	D15	D1	D8	D15	D1	D15	45 Days after last treatment	90 days after last treatment	Every 90 Days after last safety follow-up
...												
Vital Signs	X	X		X	X		X	X		X	X	X
Laboratory tests	X	X	X	X	X	X	X	X	X	X	X	X
Drug administration		X			X			X				



Note: This schematic representation of the cycle SoA is a simple one, and does not include recurrence of cycles.

Solutions may already have implemented a similar timing principle. However, in some cases the first visit/instance is often indicated as the anchor and then each following visit is related to the previous visit with its timing. That is, however, less representative of the actual study logic represented in the SoA; moreover, this solution does not account for the proper windowing and logic in case of delayed schedules. By properly relating the timings, it is clear if the next visit after a delay relates to the first study day, or needs to be delayed as well (e.g., cycles in an oncology study).

Overlapping Windows

The solution must be able to duplicate timepoints (instances) in order to define different windows for subsets of assessments. For example, the screening visit can have a set of assessments that need to be done within 4 weeks before dosing and a set of assessments that has to be done within 2 weeks before first dosing. Another example is predose assessments which have the be done within 30 minutes before dosing while others have to be done within 10 minutes before dosing. Correct storage in the USDM requires duplicating the timepoint (instance) and corresponding timing for the same planned time but adjusting the window according to the specifications. The timepoint can then refer to the activities to which the alternative timing applies. For an example of such a timeline, see the Activities Feature section.

4.1.4 Additional Timelines

Unscheduled Visits

Unscheduled visit patterns (e.g., an unscheduled safety visit that may be triggered at any time, early termination visits) are represented as separate, non-main timelines with an entry condition describing the trigger. Although they may be presented in an SoA, for these visits, usually an encounter is not defined and stored in the Encounter class as they do not need to be submitted as an scheduled visit in the SDTM Trial Visits domain (see USDM-HB1). The solution should present them distinctly from planned visits and must exclude them from these types of outputs.

The unscheduled visit timeline usually has only 1 scheduled activity instance, which then becomes the anchor. However, if extra follow-up visits are needed related to an adverse event or early termination, then multiple timepoints (stored as instances) can be added. In addition, if the activities to be performed after an event are dependent upon progress in the study or other characteristics, then adding decision instances to the timeline may be helpful to distinguish the different pathways. (See also Alternative Timeline Patterns (Cycles and Branching).)

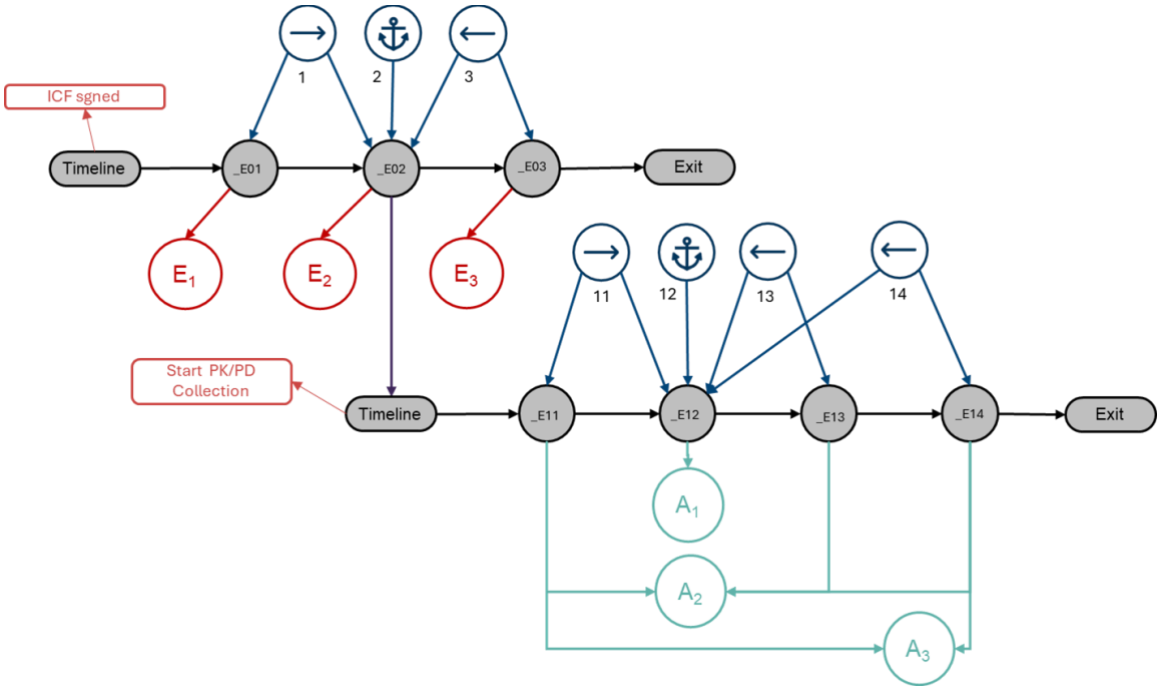
For an example of an unscheduled visit timeline in USDM JSON format, see Appendix A2, Unscheduled Visit Timeline).

Subtimelines

The main timeline can also point to subtimelines using the timeline reference attribute in the scheduledActivityInstance class. These subtimelines may represent subsampling details (e.g., pharmacokinetic, pharmacodynamic, or biospecimen sampling). Phase I/II studies are more likely to include those subtimelines since

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the safety of patients needs to be monitored more closely at preconfigured times in such studies. These timelines typically do not refer to an epoch or visit and can be reused if needed. The following schematic example shows how a simple main timeline with 3 visits (E_1: screening, E_2: treatment, E_3: follow-up) points to a subtimeline which includes a sequence of PK/PD samples at planned timepoints (11: predose, 13: 1 h after dose, 14: 4h after dose). The dosing reference anchor is included as well (12). The PK samples (A_2) need to be taken at all 3 sampling timepoints, while the PD samples (A_3) are only scheduled at predose and 4 hours after dosing.



This type of subtimeline is typically represented in footnote descriptions or as a sub-SoA in the study protocol, such as:

Activity	Predose	1h	4h
PK Sample	X	X	X
PD Sample	X		X

For an example of the corresponding USDM JSON timeline, see Appendix A3, Subtimelines.

Timeline Type and Corresponding Content

There are 3 types of timelines: the main timeline, timelines initiated from the main timeline, and timelines initiated from an activity. Although not specifically indicated in the USDM-IG and/or required as such, the best practices for what to store in what type of timeline are presented in the following table.

Timing information	Timeline type
SoA or flow chart in original protocol representing the visits throughout the study; typically includes screening and follow-up visits[a]	Main timeline
A separate SoA that indicates multiple predefined timepoints in 1 or more days	Subtimeline referenced from the corresponding main timeline instance
A footnote indicating repeats of the assessment at multiple predefined timepoints in 1 or more days	Subtimeline referenced from the corresponding main timeline instance
A further specification of a collection interval duration	Subtimeline referenced from the corresponding activity (activity timeline)

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Timing information	Timeline type
A further specification of the activity regarding multiple repeats around the same planned time and, if applicable, corresponding actions (e.g., sitting, standing)	Subtimeline referenced from the corresponding activity (activity timeline)

[a]Note that if there are multiple schedules applicable to different patient groups (cohorts), the information should be stored in separate study designs in the USDM, each pointing to the corresponding SoA timeline.

4.1.5 Alternative Timeline Patterns (Cycles and Branching)

The USDM includes a second type of instance, the "decision instance." Decision instances share most of the features of the scheduled activity instance, but instead of pointing to activities they can be used to describe alternative routes in a timeline. Their condition assignments pair a condition with the target instance. This may be presenting cycles, branching, skipping a visit, and/or repeats of follow-up visits. The feature should render decision points visibly in operational views even when the protocol table hides them in footnotes. The functional requirements for defining these are presented in the following table.

Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Indicate the order of the instances in the timeline.	ScheduledDecisionInstance/@defaultCondition	schedule timeline	The scheduled decision instance is another timepoint in the timeline. It can be placed logically at a timepoint that represents the actual time (frame) when the decision is made.
Define the condition that should be fulfilled for the alternative route to take place.	ConditionAssignment/@condition	scheduled decision instance	This is a textual description. Computer-readable conditions (e.g., number and/or maximum number of repeats) are not included in USDM v4.0 and can be added as extensions to this class.
Indicate the target timepoint (instance) in the timeline when the condition is fulfilled.	ConditionAssignment/@conditionTarget	scheduled decision instance	Note that this should point to an instance in the same timeline. It defines the alternative route that should be followed when the condition is met.

[a]USDM Class names start with a capital and are followed with the attribute name starting with lower case and preceded by /@. Reference attribute names may differ in the API representation of the model to distinguish between nesting and cross-referencing (see the USDM-IG and Understanding USDM training).

Adding Cycles to the Timeline

Oncology studies typically include a limited or unlimited number of treatment cycles. These cycles can be represented

- by explicitly instantiating every planned cycle (see the example presented in Adding Timing Details);
- by including the cycle visits in the main timeline, adding a decision instance after those visits to indicate the repeat length, and pointing back to the start of the cycle if still fit to continue; or
- by defining one cycle as a subtimeline that is reentered while its entry condition holds.

The third approach is presented in the schematic timeline in this section.

E1 denotes the screening visit with its corresponding time point _E01. The timing for this will probably be a window (e.g., day -28 to -1) and indicates the timing to the start of the first cycle.

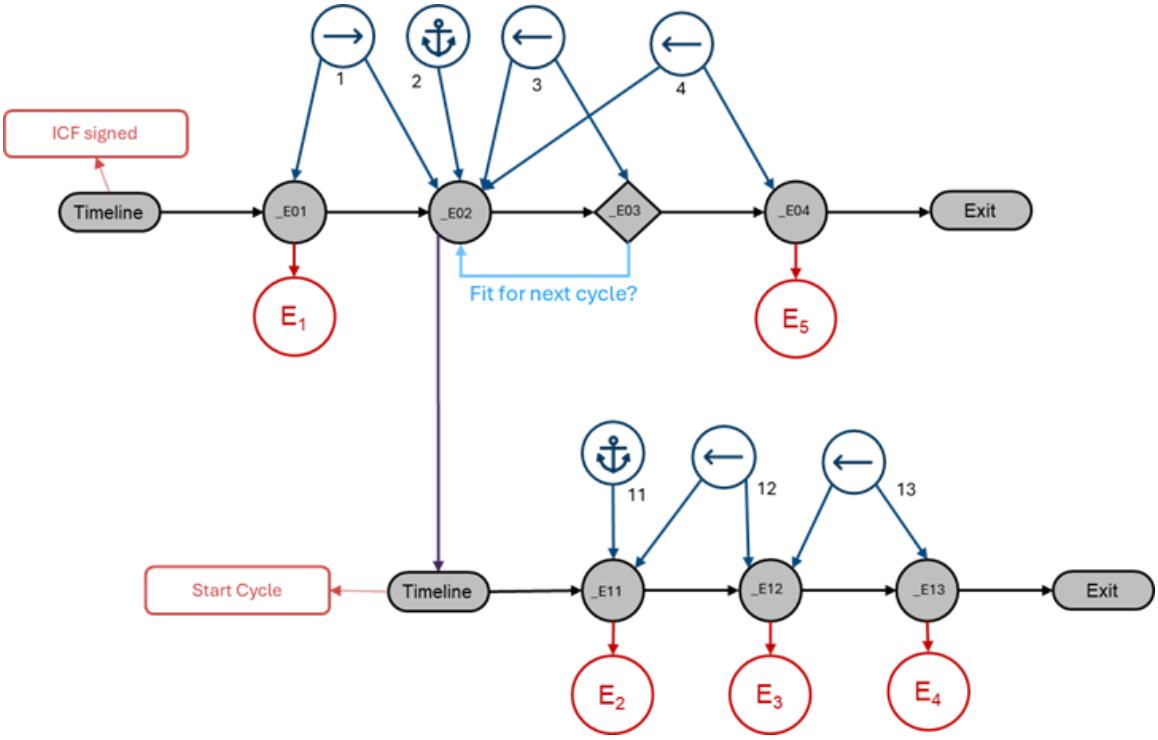
Instance _E02 indicates the cycle. The start of the first cycle is the anchor of the main timeline. Each cycle can have multiple visits. These are modeled in the subtimeline representing the cycles (e.g., E2-E4 could represent days 1, 8, and 15 within a cycle).

Instance _E03 is a decision instance (note the diamond shape instead of circle). The corresponding timing indicates the length of a cycle. If the patient is still fit to continue, then the patient is expected to repeat the cycle; the decision instance points back to the previous start cycle timepoint _E02.

Instance _E04 is the follow-up/end-of treatment visit. The corresponding timing usually refers to the start of the last cycle.

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This is a simple example showing 1 cycle pattern. Multiple subtimelines might be needed to represent different cycle patterns. The corresponding JSON example of this timeline is presented in Appendix A4, Modeling Cycles with a Subtimeline.



Explicit instantiation is simpler to render and consume but becomes unwieldy when the number of cycles is unbounded ("until progression"); the subtimeline pattern is compact and faithful to the protocol logic but requires consumers to understand timeline nesting. The feature should render the conventional presentation ("Cycle 1 Day 1", "Cycles 2+ Day 1") in both cases and may offer expansion of a cycle definition into projected calendar visits for operational planning. See the Challenges and Considerations section for a fuller discussion.

Repeating Visits

Like cycles used in oncology studies to represent 1 or more visits related to a treatment cycle, other assessments and/or visits can be scheduled according to a repeat pattern. This may typically happen for follow-up visits and/or assessments. The solution must be able to include this repetition information as well and may handle that in a similar way to the oncology cycles presented above.

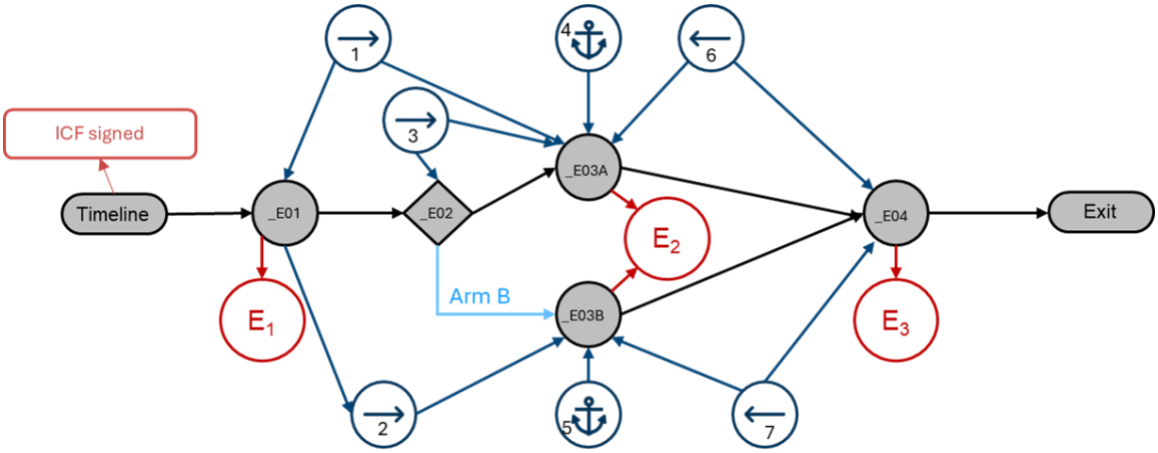
Branching a Timeline

As described in USDM-HB1, branching can be recognized by a difference between arms in the study elements selected for a specific study period (StudyEpoch). When a study is blinded, all activities of all arms will likely be equal apart from the (blinded) treatment that patients receive. In those cases, branching does not have to be handled in the timeline. Moreover, it is not feasible to handle this in the timeline as the goal is to promote only 1 study schedule to the downstream solutions who use it for the blinded audience.

However, if the study is not blinded and visits and/or activities are different between the arms, then it might be necessary to also present the branching process in the timeline. This can be handled using the scheduledDecisionInstance class. The following schematic example includes a study with 3 visits (E1, E2, E3) where a decision is included to move patients into different arms. Arm B will go to the timepoint (instance) _E03b while the other arm, arm A, will follow the _E03A path. Each has their own defined anchor timing since their day 1 activities are different and the branching started before. Both branches have their own timings, which may lead to more timings per timepoint (e.g., timing 1 and 2, timing 6 and 7). The day 1 timepoints (_E03A and _E03B) for both branches point to the same defined visit stored in the Encounter class, making it a unique nonduplicated item to be submitted in the SDTM TV domain (See HB1). In this example, the visit 3 (E3) activities are equal again; therefore, the branched timepoints for both arms point to the _E04 timepoint as their default condition.

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This is a simple 3-visit SoA that illustrates how branching can be handled in USDM. More visits and complexities can be included as required. The corresponding JSON example is presented in Appendix A5, Branching within a Timeline.



4.1.6 Activities Feature

The leftmost column of the SoA typically shows activities that should be performed at predefined timepoints (instances) directly related to corresponding encounters (visits). Currently there is no controlled terminology for these activities and there is a large variation between and within sponsors and therapeutic areas in expressing them. Medical writers and study design teams interested in maintaining flexibility and creativity generally capture these activities as free text. These activities are then further linked to the corresponding structured information in the form of procedures, biomedical concepts, and/or activity timelines. However, a company may want to use standardized company or therapeutic area-specific activity codelists which then need to be handled by the solution. The USDM-IG describes how activities should be stored in the USDM; the following table presents functional requirements.

Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Store and adjust the activity label as presented in the left column of the SoA.	Activities/@label	Study Design	Note that activities are stored at the study design level, which enables reuse of activities for different timelines within the design. This improves consistency among specified activities, for example between the main timeline and reuse of those activities in the unscheduled timeline. However, if the execution details for activities are different (e.g., the unscheduled visit includes an extra analyte), then the activities should be defined separately as well. In general, an automated copy feature in case of changes in configuration for a specific visit is advised.
Enable selection of standard texts from predefined lists.	Activities/@label	Study Design	Related to an MDR, this ensures consistency between and within study designs.
Enable additional activity descriptions and/or notes.	Activities/@description; @notes	Study Design	This can be implemented based on sponsor needs. Sponsors may want to add additional descriptions and/or notes to their SoAs. If these are simple descriptions, then the description attribute will work. For more complicated and/or multiple additions, the notes attribute is more suitable. However, if the notes are more like footnotes and/or cross-references are to be included (e.g., referenced paragraph numbers), they should be stored as footnotes in the Condition class. These can be refer to the corresponding activity and, if needed, the timepoint to which it is applicable (see Defining the SoA Footnotes).
Enable the addition of grouping labels above a group of activities.	Activities/@label; @children	Study Design	The implementation of grouping labels is described and illustrated in the USDM-IG. The grouping label text itself is stored as well in the label attribute of the activities class. However, this activity is expected to point to other activities (the ones that it groups) and is not expected to have any references to assessments, procedures, or subtimelines.

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Functional requirement	Relevant USDM classes and attributes[a]	USDM nested in	Implementation notes
Add and change the presentation order of activities in the left column of the SoA.	Activities/@previous; @next	Study Design	Users should be able to quickly change the presentation order of activities to make the order logical for the readers of the SoA. In the USDM, the activity should point to its previous and next activity in the presentation order. This includes grouping labels.
Define the crosses in the SoA.	ScheduledActivityInstance/@activities	Scheduled Timeline	Each reference represents a cross in the diagram. This feature, in combination with the timeline and activities it is related to, enables rendering of the full SoA. Users will expect to see the timeline in relation to the activities in a table format where the encounters and/or timepoints (instances) are the columns and the activities are the rows.

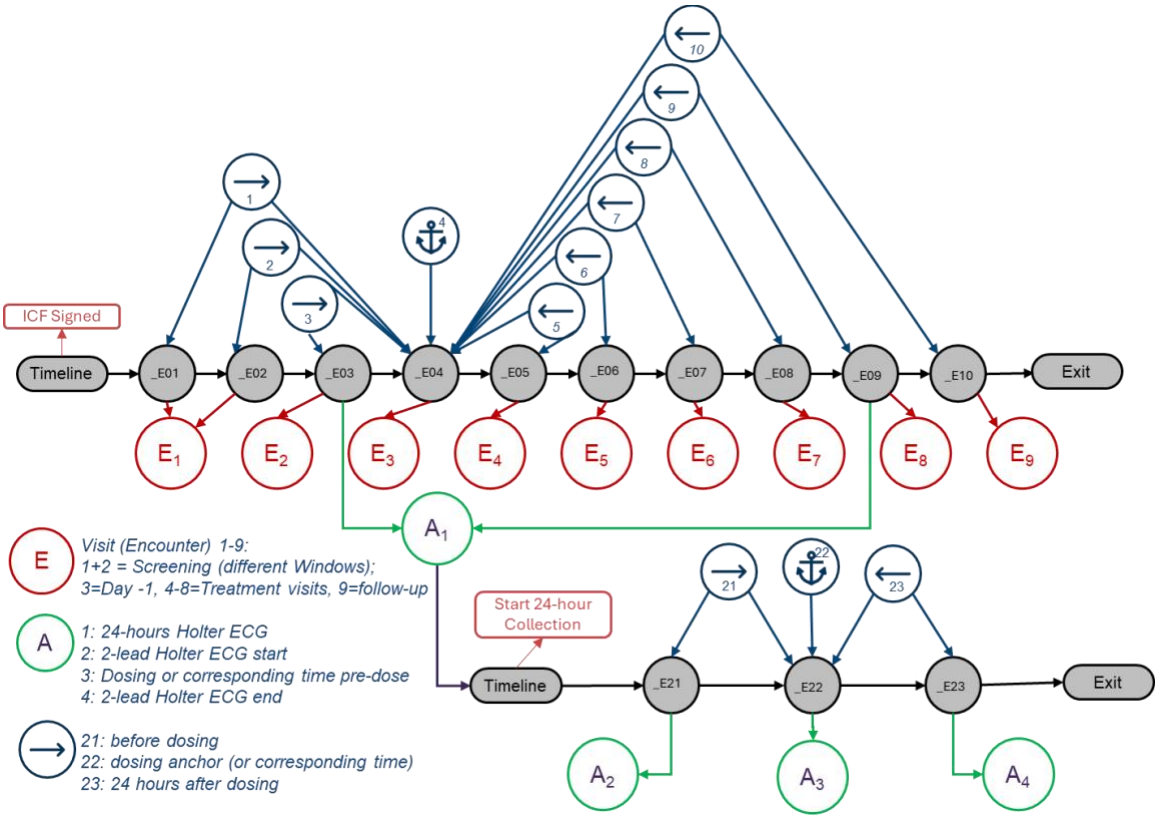
[a]USDM Class names start with a capital and are followed with the attribute name starting with lower case and preceded by /@. Reference attribute names may differ in the API representation of the model to distinguish between nesting and cross-referencing (see the USDM-IG and Understanding USDM training).

Defining an Activity Duration

Activities may represent a single, short-duration assessment (e.g., blood sampling, body weight measurement) or longer duration assessments like a 24-hour collection or observation interval. To automate downstream processes such as setting up the EDC system or automated monitoring, it is necessary to also model the corresponding duration. This enables the systems to indicate and collect information on when the start and end of the activity should take place. The study design solution should enable configurations of these duration activities in detail and then enable their selection for a specific activity. This configuration is more likely to be done by data experts than by study designers and medical writers. Storing the configured activity timelines in an MDR enables reuse and consistency between and within studies. Easy configuration and storing of predefined activity timelines represents the efficient utilization of this feature.

The following is a schematic example of an "24-hours Holter" ECG Activity (A_1) which refers to an activity subtimeline. The subtimeline exactly details the start (A_2) and end (A_4) of the collection interval in relation to dosing or a similar timepoint (A_3). As for the main timeline, timing values are stored in ISO format, which enables relating them back to the main timeline; they also can be used for monitoring the correctness of the assessment in practice. The start of the interval (A_2) is modeled with a window before dosing and the end of the interval (A_4) is defined in relation to the dosing anchor as specified in the text "until 24 hours after dosing." All timeline features of the main timeline also apply to an activity timeline, although references to epochs and encounters are not expected in an activity timeline. For an example of the corresponding JSON file, see Appendix A6, Defining an Activity Duration by a Timeline.

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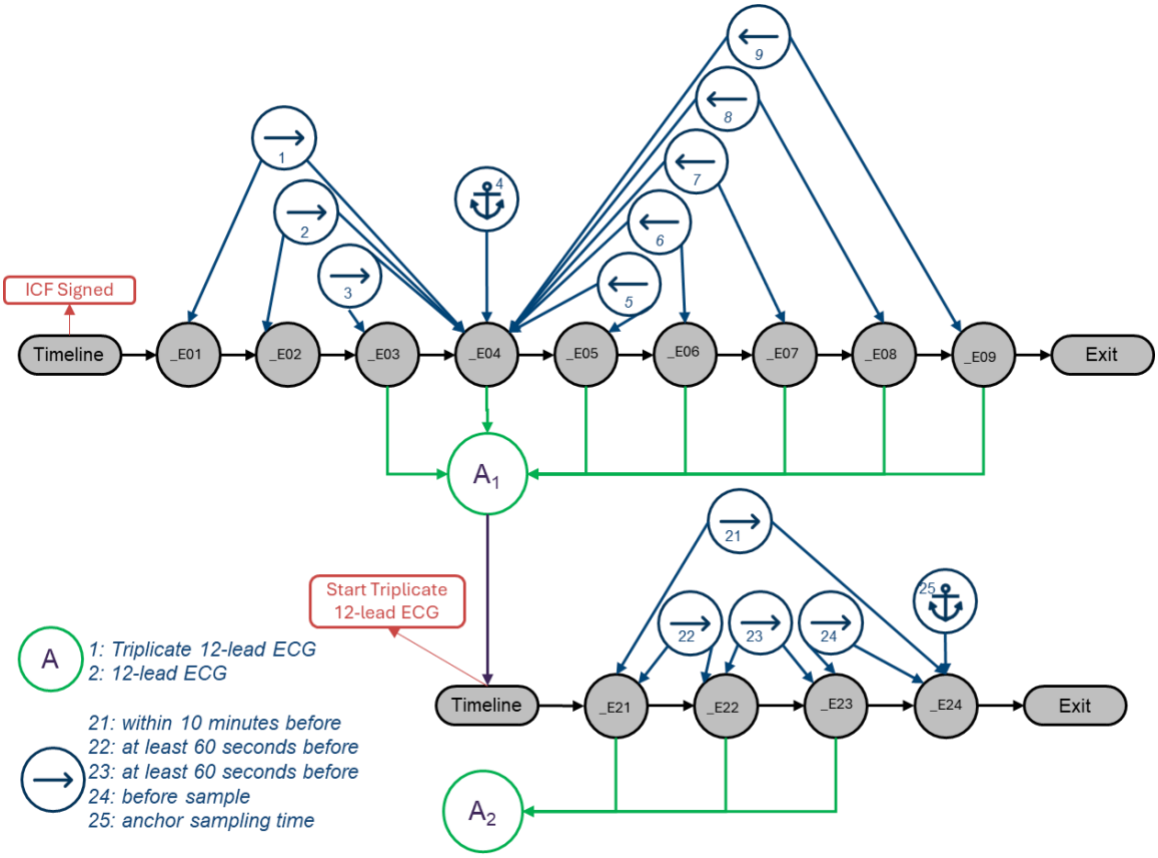


Defining Multiple Actions and/or Repetitive Assessments for an Activity

A single activity description can also indicate multiple actions such as repeated vital signs blood pressure measurements or triplicate ECG measures. These timing and subactivity details can also be modeled using an activity subtimeline. Again, the solution must enable users to (pre-)specify activity subtimelines in an intuitive way. For a study designer or medical writer, defining these types of subtimeline details is less feasible, so it is more likely they are preconfigured by a data specialist. As previously mentioned, the study design solution should be able to store standard activity timeline definitions in a repository in order to easily use them within and across study designs. Users need to be able to specify timings between each measure, the activity per timepoint (which might be equal or different for each timepoint), and overall timing in relation to a reference timepoint (anchor).

The following example shows the activity subtimeline for the specification "Triplicate measurement (3 recordings of 10 seconds each, at least 60 seconds apart, within 10 minutes before each sample)." The activity (A_1), triplicate ECG measurement, is mentioned in the main SoA. The repetition and corresponding timing details of this activity are specified in the activity subtimeline. This informs the EDC system that 3 entries are needed for performing a 12-lead ECG measurement (A_2) with corresponding timing constraints (timings 21-25). Note that this example shows that, similar to a main timeline, occasionally more timing constraints may be applicable to the same timepoint (instance). The first ECG measurement needs to be within 10 minutes of the sample (rthe eference timepoint) and at least 60 seconds before the next measure. The corresponding ISO-formatted timing values enable direct instructions and automated validation checks during study execution.

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For an example of the corresponding USDM JSON, see Appendix A7, Defining Multiple Actions for an Activity by a Timeline.

The example SoA Workbench available in the CDISC Open-Source Alliance (COSA) Library (https://cosa.cdisc.org/directory/soa_workbench) enables the creation of activity timelines. The following example is a representation of a repeated vital signs activity timeline. This solution shows it in a grid similar to the SoA; based on the timeline information stored in the USDM, other visual representations are also possible.

Select Timeline: Main Timeline (Main) | Adverse Event Timeline | Early Termination Timeline | **Vital Sign Blood Pressure Timeline**

Matrix: Vital Sign Blood Pressure Timeline

	Epoch:->	None					
	Encounter:->	None	None	None	None	None	None
	Instance:->	5 minute supine	Vital signs supine	1 minute standing	Vital signs after 1 min standing	2 minute standing	Vital signs after 3 min standing
	Study Day:->						
	Timing:->	None	None	None	None	None	None
	Visit Window:->						
Activity	**Concepts**						
Supine	Concepts 1	X					
Vital Signs Supine	Concepts 3		X				
Stand	Concepts 1			X		X	
Vital Signs Standing	Concepts 3				X		X

4.1.7 Procedure and Assessment Details

The activity description that is presented in the SoA is stored in the Activity class. However, the details of the activity are often presented in footnotes or narrative text, or added after protocol finalization in a later interpretation

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stage. The USDM enables storing assessment details for a study and directly relating them to the specified activities in SoA. The assessment details are stored in the form of procedures and biomedical concepts. This informs the downstream systems in an uniform and structured way about the information to be collected.

In general, the following can be used to identify where this information is stored:

- A description and corresponding code that indicates what needs to be done at a certain point in time without the intention to collect data (e.g., hospitalization, discharge, randomization) can be stored as a **Procedure** in the USDM.
- An assessment available in the CDISC Biomedical Concept Library can be stored as a **Biomedical Concept** in the USDM.
- An assessment not available in the CDISC BC Library but available in the NCI thesaurus can be added as a **custom Biomedical Concept** in the USDM (and can be submitted for inclusion in a future CDISC BC release). See the CDISC BC training (https://learnstore.cdisc.org/product?catalog=BiomedicalConceptsHOIT)
- Any other assessment can be stored as a **Biomedical Concept surrogate** in the USDM.

For downstream connectivity, activity details need to be defined as much as possible by means of the BCs. USDM-HB3 describes how this can be used to create the Define-XML file which provides the metadata for creating the SDTM-aligned regulatory submission datasets, and is also needed for submissions.

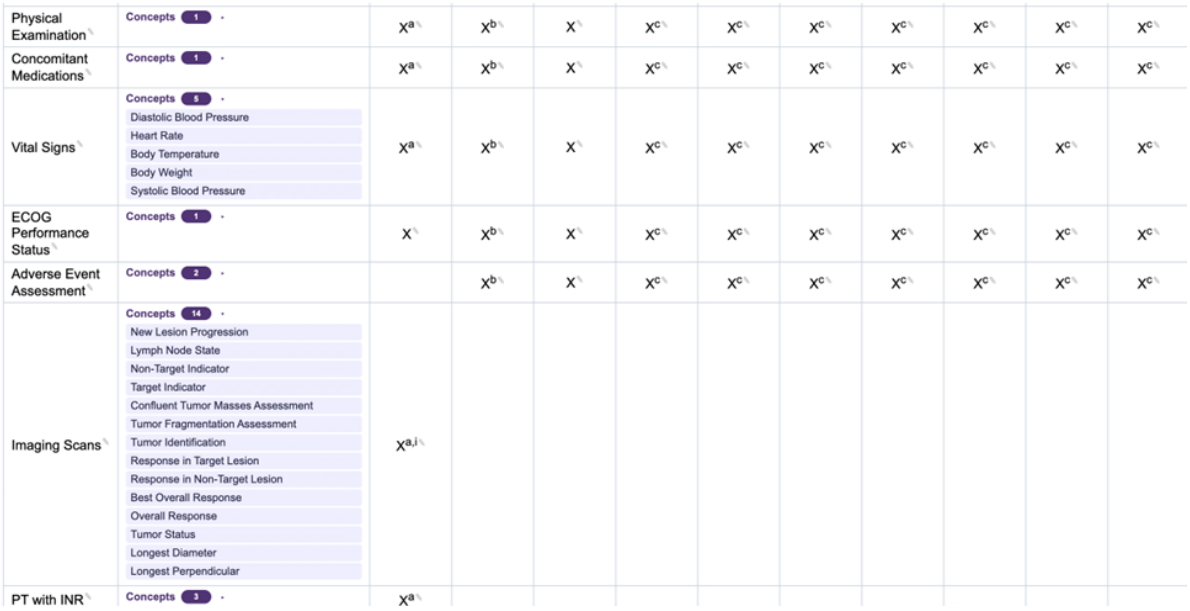
The following table specifies how the information from CDISCs BC Library maps to the USDM BiomedicalConcept and related classes. For a corresponding JSON example, see Appendix A8, Adding Activity Details by Procedures and Assessments.

CDISC Biomedical Concept Library path	USDM Biomedical Concept path	Implementation notes
BiomedicalConcept.ConceptId		Generate unique id in new USDM BiomedicalConcept dataset
BiomedicalConcept.Href	BiomedicalConcept.reference	
BiomedicalConcept.Categories	BiomedicalConceptCategory.label	If categories are helpful, categories defined in the CDISC BC Library can be stored in the USDM but it is not required. Alternative BC groupings needed for downstream use cases can be defined instead and stored in the BiomedicalConceptCategory class.
BiomedicalConcept.ShortName	BiomedicalConcept.label + BiomedicalConcept.code.standardCode.decode	The short name should be stored as the decode value and can be proposed as the presentation label. However, it would be helpful to allow changes to the label value in order to align to the preferred presentation of the assessment.
BiomedicalConcept.Synonyms	BiomedicalConcept.synonyms	
BiomedicalConcept.ResultScale	BiomedicalConcept.notes.text	The resultScale is not covered in the USDM. If needed, it can be stored in the BiomedicalConcept notes and/or can be added as an extension variable.
BiomedicalConcept.Definition	BiomedicalConcept.notes.text	The Biomedical Concept Definition is not covered in USDM. If needed it can be stored in the BiomedicalConcept notes and/or can be added as an extension variable.
ncitcode	BiomedicalConcept.code.standardCode.code	
BiomedicalConcept.Coding.code	BiomedicalConcept.code.standardCodeAliases.code	
BiomedicalConcept.Coding.systemname	BiomedicalConcept.code.standardCodeAliases.codeSystem	Alternative codes presented in the BC Library, like LOINC codes, only include the system name and the code. The corresponding decode value and codeSystem version needs to be derived

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CDISC Biomedical Concept Library path	USDM Biomedical Concept path	Implementation notes
		from the corresponding library when used.
BiomedicalConcepts.DataElementConcepts .conceptid	BiomedicalConcept.BiomedicalConceptProperty. code.standardCode.code	
BiomedicalConcepts.DataElementConcepts .shortname	BiomedicalConcept.BiomedicalConceptProperty. code.standardCode.decode BiomedicalConcept.BiomedicalConceptProperty.l abel	The short name should be stored as the decode value and can be proposed as the presentation label. However, it would be helpful to allow changes to the label value in order to align to the preferred presentation of the assessment.
BiomedicalConcepts.DataElementConcepts .Datatype	BiomedicalConcept.BiomedicalConceptProperty. datatype	
BiomedicalConcepts.DataElementConcepts .ExampleSet	BiomedicalConcept.BiomedicalConceptProperty.r esponseCodes.label	Each value in the ExampleSet (delimited by ;) will be a new instance in the responseCode entity. The full list of potential codes can be downloaded from the NCI website.

The example SoA tool available in COSA shows the activities with the bound assessments in the form of BCs in the second column. The list of assessments bound to an activity can be collapsed and/or expanded upon need.



Adding Properties for Collection or Submission

The BCs in the CDISC Library include the basic collection concepts for each assessment. However, EDC collection and SDTM storage might require adding more properties. Because BC codelists are extensible, these additional properties can be added in the USDM with a custom code. Examples of helpful additional properties include:

- Corresponding test (__TEST), test code (__TESTCD), or test category (__CAT) properties which can be used to populate the corresponding SDTM dataset
- Corresponding coding variables
- Flagging variables, for example for an indication if the value is clinically significant (__CLSIG)

If the properties refer to SDTM and/or CDASH variables, then it is helpful for downstream automation to store the corresponding variable name as the property label. The USDM is flexible, so other types of properties can be added as well, if needed.

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Preconfiguring and Standardizing Activities

An activity may refer to one assessment, a group of related assessments, or multiple distinct assessments and/or groups of assessments.

Many activities, especially safety assessments, are standard for a company and/or therapeutic area. For efficient implementation of an SoA utility, it is helpful to enable preconfiguration of sets of assessments related to the corresponding activity. This has the following advantages:

- It saves time of detailed configuration for each new study.
- It ensures consistency within and between studies.
- The meaning of an activity and what it includes is defined in every detail, limiting the chance of misinterpretation.
- The study design team does not have to get into the weeds of configuring an activity to its details.

This preconfiguration can be done by data specialists (e.g., data manager, clinical programmer). The set can then be picked up as a whole by the study designers or medical writers. However, to enable study-specific adaptations, the medical writer must be able to review and adapt the preconfiguration for study-specific needs. To enable this process, the study design solution needs to provide a feature to build these preconfigured sets of assessments or pick them up from a MDR-related solution. The selection and storing of BCs is showcased in the following tooling published on COSA (https://cosa.cdisc.org/):

- USDM Biomedical Concept Mapper: Using AI to select the proper BC and store in USDM packages
- BC to USDM configurator: Building and exporting preconfigured sets of BCs that can be utilized and linked to activities in USDM
- SoA Workbench: Creating custom groupings of BCs which can be linked to activities

The BCs defined in the CDISC BC Library include a set of data element concepts that indicate which features of the assessment need to be recorded and/or measured. As previously mentioned, these data element concepts are mapped to USDM BC properties. However, what properties need to be included and recorded for a study has to be defined during configuration. Depending on the activity and study, properties can be set to required and/or enabled in USDM. The isRequired attribute is a definitional BC-level item. It indicates whether the BC definition demands that this information is present within the data. For example, for a method qualifier, isRequired may be set to

1. False, if method is not required (i.e., we can just use the result and don't care about the method used to record it) or
2. True, if we definitely do need the method to make sense of the data.

The isEnabled attribute is a study-level use item and it indicates whether the information is to be collected in the study. If a property is required, then isEnabled must be true; if it is not required, you can choose.

Response codes also can indicate if a particular response is enabled. For example, if the vital signs position for the study is indicated to be "Standing", then this response will be enabled; for other responses (e.g., "Supine", "Sitting"), the isEnabled value can be set to False if they are not needed for the study.

This prespecification will inform downstream systems in what is needed as execution requirements and/or answer options.

The study design solution must enable configuration of BCs in the repository as exemplified in the BC-to-USDM configurator to set the company and/or therapeutic area default.

Grouping and Categories of Biomedical Concepts

The preconfigured groupings of assessments can be stored in USDM BC categories. This may be a grouping that is aligned to the categories presented in the BC Library, but could also be a subset or a custom grouping defined for specific use cases. Groupings are very helpful in selecting a preconfigured set of BCs which align to a prescribed activity.

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External Codelist References

If users need to be able to connect and select assessments from external data sources, this would require matching CDISC CT with external dictionary codes. This should be implemented by the code attributes in the BiomedicalConcept, BiomedicalConceptProperty, and/or BiomedicalConceptCategory class. The code attribute in these classes uses the AliasCode datatype which implies that, next to the CDISC code, an external code may be specified (see the USDM-IG for further specifications). The solution should enable the specification of external codes and may even suggest a code using AI based on the BC configuration. Note that CDISC BC codes might not match one to one to an external codelist like LOINC. However, the configured properties can inform which corresponding code to pick and, in addition, multiple codes from external codelist that in combination match the configured BC can be specified.

4.1.8 Footnote Utility

SoAs often include a list of footnotes. Although a number of these—such as footnotes relating to timing, windowing, and assessment—can be addressed in a structured form, there will still be footnotes, narrative text not (yet) efficient to store as structured items. These can be stored in the narrative form in the USDM Condition class. The footnote text is stored in the text attribute of the Condition class and is HTML formatted. This in turn allows for formatting and tagging; tagging of cohorts and/or document section numbers can be helpful in subselection of assessments (cohort tagging). Cross-references can then be automatically added in the protocol document (see the USDM-IG and USDM trainings for more information).

The solution should enable users to define these footnotes and refer them to the corresponding activity, assessment (BC), or assessment group (BC category) with the appliesTo reference. Further, the solution should enable users to refer the footnotes to a specific timepoint in the SoA with the context reference. In the following example, footnote a) refers both to vital signs activity (with its appliesTo reference) and to the scheduledActivityInstance of day 8 (with its context reference indicating that the footnote condition is only applicable to day 8 for that activity). Footnote b) in refers to the pregnancy test activity (with the appliesTo reference) and includes the context reference that this is applicable to all timepoints where the activity is referenced.

	Screening	Treatment Phase		Follow-up
Activity	Day -28 to -1	**Day 1**	**Day 8**	**Day 15 (+/- 1 day)**
Informed Consent	X			
Vital Signs	X	X	X[a)]	X
Pregnancy test[b)]	X	X		X
Drug administration		X		

a) Only applicable for patients with mutation X

b) Only for women with childbearing potential

See Appendix A9, Defining the SoA Footnotes, for the corresponding JSON instance.

Conditions attached to activities or scheduled instances (“pregnancy test only for subjects of childbearing potential”) are rendered as footnotes but remain available as structured logic for consumers such as EDC configuration. The solution should be able to store and render this information and put in the corresponding footnote marks (e.g., a), b), c)) in the logical order of appearance in the SoA (e.g., starting from left top to right bottom marks may be indicated as a, b, c or 1, 2, 3 depending on the preference).

Footnotes Referring to the Complete SoA, Complete Visits, or an Epoch

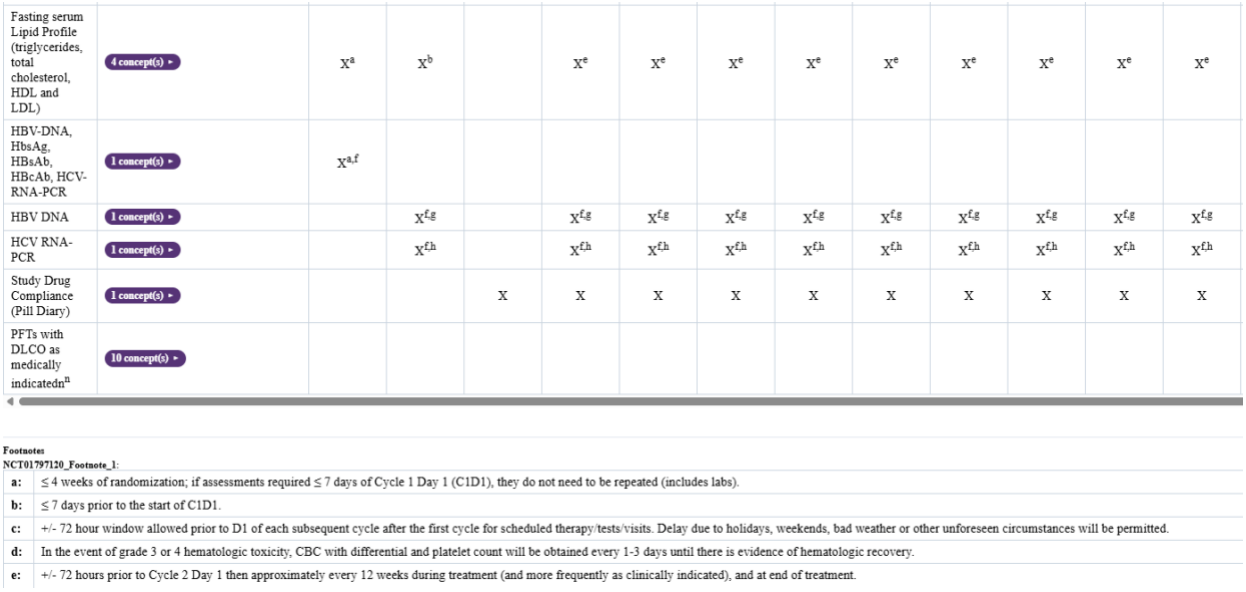
Some SoA examples include footnote indicators for the whole SoA, the visit column, or an epoch column. The recommended approach to store this information in the USDM is presented in the table below.

Feature	appliesTo attribute	contextId attribute
Footnote applicable to whole SoA	Refer to all activities applicable to the SoA	leave empty
Footnote applicable to a whole visit	Refer to all activities applicable to the SoA	refer to all the scheduledInstance(s) that are referring to the corresponding visit

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Feature	appliesTo attribute	contextId attribute
Footnote applicable to a whole epoch	Refer to all activities applicable to the SoA	refer to all the scheduledInstance(s) that are referring to the corresponding epoch
Footnote applicable to 1 or multiple activities for the whole study	Refer to all activities concerned	refer to all activities concerned
Footnote applicable to one or multiple activities for 1 visit and/or timepoint	Refer to all activities concerned	refer to the scheduledInstance for the corresponding time point
Footnote applicable to multiple timings for 1 or multiple activities	Refer to all activities concerned	refer to the scheduledInstances for the corresponding time points

The solution should be able to render specification such as these, and place the corresponding footnote indicators at the right place in the SoA grid. The example SoA tool available via the CDISC COSA website renders footnotes automatically and adds corresponding footnote indicators in the grid where applicable, as illustrated in the following screenshot.



Fasting serum Lipid Profile (triglycerides, total cholesterol, HDL and LDL)	4 concept(s)	X[a]	X[b]		X[e]	X[e]	X[e]	X[e]	X[e]	X[e]	X[e]	X[e]	X[e]
HBV-DNA, HbsAg, HBsAb, HBcAb, HCV-RNA-PCR	1 concept(s)	X[a,f]											
HBV DNA	1 concept(s)		X[f,g]		X[f,g]	X[f,g]	X[f,g]	X[f,g]	X[f,g]	X[f,g]	X[f,g]	X[f,g]	X[f,g]
HCV RNA-PCR	1 concept(s)		X[f,h]		X[f,h]	X[f,h]	X[f,h]	X[f,h]	X[f,h]	X[f,h]	X[f,h]	X[f,h]	X[f,h]
Study Drug Compliance (Pill Diary)	1 concept(s)			X	X	X	X	X	X	X	X	X	X
PFTs with DLCO as medically indicated[n]	10 concept(s)												

Footnotes
NCT01797120_Footnote_1:

a:	≤ 4 weeks of randomization; if assessments required ≤ 7 days of Cycle 1 Day 1 (C1D1), they do not need to be repeated (includes labs).
b:	≤ 7 days prior to the start of C1D1.
c:	+/- 72 hour window allowed prior to D1 of each subsequent cycle after the first cycle for scheduled therapy/tests/visits. Delay due to holidays, weekends, bad weather or other unforeseen circumstances will be permitted.
d:	In the event of grade 3 or 4 hematologic toxicity, CBC with differential and platelet count will be obtained every 1-3 days until there is evidence of hematologic recovery.
e:	+/- 72 hours prior to Cycle 2 Day 1 then approximately every 12 weeks during treatment (and more frequently as clinically indicated), and at end of treatment.

4.1.9 Additional Implementation Requirements

Storing Standard Configurations in an MDR

Storing standard configurations in a metadata repository enables easy set-up and reuse of study elements, especially when they are already formatted into the flexible USDM format. This is feasible for preconfigured sets of activities and activity descriptions—and also for higher level standard visit configurations (e.g., screening and follow-up visits). Another use case, less related to the SoA, is a standardized set of objectives, endpoints, and estimands or standardized protocol texts aligned to M11. Selected endpoints referring to the corresponding timing and assessment may even trigger the set-up and or validation of the SoA design.

A study design solution that enables the selection, specification, review, and easy reuse of this information will likely be more useful than users repeatedly having to specify every study detail.

Rendering the SoA Matrix from the USDM

The USDM stores the SoA in a logical form. However, clinical research stakeholders are used to viewing the SoA in a grid format which allows them to quickly see what happens when. Therefore, the SoA matrix needs to be reconstructed from a USDM study definition as follows:

1. Locate the schedule timeline with mainTimeline = true within the study design.
2. Traverse the scheduled activity instances of that timeline in execution order, following each instance's default condition reference from the timeline entry to an exit.

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3. Resolve each instance's encounter reference; encounters define the columns. An encounter with multiple instances yields subcolumns or repeated marks; depending on the rendition convention, the solution may also add an expand/collapse function to enable the combined view and the sub-timepoint view when needed.
4. Take the union of the activity references across all instances and order the activities using their previous/next references, keeping parent activities as group headers above their children; activities define the rows.
5. Mark each cell where the row's activity appears in the column's instance activity list.
6. Resolve the timings that reference each instance to produce the day/week header row and the window row, using the label attributes for presentation.
7. Attach footnote markers from notes and conditions and band the columns by epoch using each instance's epoch reference.

Because the rendition is derived, it is always consistent with the structured content; there is no separate table to maintain.

In case of subtimelines, the rendering can be included in the main timeline (for cycles stored in subtimelines) or as a separate grid that represents the subtimeline (e.g., PK/PD assessment schedules). If no encounters or epochs are referred in the USDM timeline, the corresponding row headers can be removed or hidden.

Activity timelines are, from a user perspective, quite different features than main or other subtimelines. Therefore, although they are saved using the same logic, it may be wise to present activity timelines as a separate feature in the solution. Activity timelines in the USDM can be identified by the way they are referenced (e.g., from out of an activity instead of out of a scheduledInstance).

Amendment Management and Impact Analysis

Structured schedules make amendment management trackable. The recommended pattern, implemented in the SoA Workbench, is:

1. Snapshot: For each final protocol version, an immutable snapshot of the complete schedule state should be stored, bound to the corresponding study version and amendment metadata.
2. Compare: Compute the difference between any 2 snapshots at the entity level: visits; activities; timings; windows; and assignments added, removed, or modified.
3. Assess: Classify each difference by its downstream impact. Impact can be direct (the changed entity itself feeds a deliverable), strongly inferred, or weakly inferred, with a severity rating (high/medium/low) per affected standards layer.
4. Report: Generate a human-readable amendment impact report from the comparison, for review and sign-off by the affected functions.

This turns the amendment question from "re-read the protocol and find what changed" into "review the machine-generated change report," and it is only possible because identifiers are stable across versions (see the discussion in the General Requirements section).

Directly linking the downstream solution also directly addresses any differences between versions automatically and defines what has an impact on the corresponding downstream solution.

System Integration: APIs and AI Agents

Downstream consumption should be API-first: The schedule is queried programmatically rather than exchanged as documents. In addition to conventional REST APIs, schedule tooling can expose its content through agent-oriented interfaces such as the model context protocol (MCP), allowing AI agents, operating under human supervision, to query the schedule, populate a draft schedule from a legacy protocol (the digitization pathway), or verify consistency between a protocol document and its structured counterpart. All agent-initiated changes must flow through the same audit trail and human review checkpoints as manual edits.

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Addressing Multiple Designs Within a Study

Modern study designs are getting more and more complex. Multiple study phases and schedules may be combined into a single study and corresponding protocol. Storing these types of designs consistently in USDM can be challenging. The USDM requires only 1 main timeline per design. If multiple distinctive SoAs are defined, each applicable to a specific subset of the study population, it is feasible to store the SoAs as separate designs within the study defined in USDM. However, if the differences between those SoAs are only small, branching or conditioning by means of footnotes which include tagging the corresponding cohort may be more efficient. Although the technical implementation of this can be challenging, the study design solution needs to offer such options to be a flexible tool that can be used in complex settings.

4.2 Validation

Validation of the digitized schedule operates at three levels: conformance of the USDM export to the USDM schema, conformance to the published USDM CORE rules, and solution- or company-specific consistency checks. Automated validation with the CDISC Open Rules Engine (CORE; https://www.cdisc.org/core) should be integrated into the authoring workflow so that issues are found at design time, not at export time.

Schema Validation

The exported JSON must validate against the USDM API specification schema for the targeted version (USDM v4.0). Schema validation catches structural defects (e.g., missing required attributes, wrong datatypes, malformed identifiers) and is a precondition for meaningful rule-based validation (see USDM Core rules DDF00081, DDF00082, DDF00125, and DDF00126).

USDM Validation Rules Related to the SoA

The following table lists the USDM CORE conformance rules (v4.0) that apply to the SoA entities described in this implementation handbook. The rules are taken from the DDF-RA CORE Conformance Rules catalog[3] and are grouped by the primary entity to which they apply.

CORE rule ID	Rule description (USDM v4.0)	ERROR/ WARNING	Relevant USDM classes	Relevant USDM attributes
DDF00006	Timing windows must be fully defined: if 1 of the window attributes (label, lower, upper) is defined, then all must be specified.	ERROR	Timing	windowLabel, windowLower, windowUpper
DDF00007	If the timing type is “Fixed Reference”, then it must point to only 1 scheduled instance.	ERROR	Timing	relativeToScheduledInstance
DDF00008	A scheduled activity instance must refer to either a default condition or a timeline exit, but not both.	ERROR	ScheduledActivityInstance	timelineExit, defaultCondition
DDF00009	Each schedule timeline must contain at least 1 anchor (fixed time): at least 1 scheduled activity instance referenced by a Fixed Reference timing.	ERROR	Timing	type
DDF00011	Anchor timings (type “Fixed Reference”) must be related to a scheduled activity instance via a relativeFromScheduledInstance relationship.	ERROR	Timing	relativeFromScheduledInstance
DDF00012	Within a study design, there must be exactly 1 schedule timeline which identifies as the main timeline.	ERROR	ScheduleTimeline	mainTimeline
DDF00013	If a biomedical concept property is required, then it must also be enabled; if not enabled, it must not be required.	ERROR	BiomedicalConceptProperty	isRequired, isEnabled
DDF00018	An instance of a class must not reference itself as one of its own children.	ERROR	Activity, BiomedicalConceptCategory, and others	children
DDF00019	A scheduled activity/decision instance must not refer to itself as its default condition.	ERROR	ScheduledActivityInstance, ScheduledDecisionInstance	defaultCondition

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CORE rule ID	Rule description (USDM v4.0)	ERROR/ WARNING	Relevant USDM classes	Relevant USDM attributes
DDF00021	An instance of a class must not refer to itself as its previous instance.	ERROR	StudyEpoch, Encounter, Activity, and others	previous
DDF00022	An instance of a class must not refer to itself as its next instance.	ERROR	StudyEpoch, Encounter, Activity, and others	next
DDF00023	When both previous and next attributes are available, the previous id value must match the next id value of the referred instance.	ERROR	Activity, Encounter, StudyEpoch, and others	previous, next
DDF00024	An epoch must only reference epochs specified within the same study design.	ERROR	StudyEpoch	previous, next
DDF00025	A window must not be defined for an anchor timing (type “Fixed Reference”).	ERROR	Timing	windowLabel, windowLower, windowUpper
DDF00026	A scheduled activity instance must not point (via “timeline”) to the timeline in which it is specified.	ERROR	ScheduledActivityInstance	timeline
DDF00027	The same instance must not be referenced more than once as previous or next.	ERROR	Activity, Encounter, StudyEpoch, and others	previous, next
DDF00028	An activity must only reference activities specified within the same study design.	ERROR	Activity	previous, next
DDF00029	An encounter must only reference encounters specified within the same study design.	ERROR	Encounter	previous, next
DDF00031	If the timing type is not “Fixed Reference”, then it must point to 2 different scheduled instances (from and to).	ERROR	Timing	relativeFromScheduledInstance, relativeToScheduledInstance
DDF00036	If the timing type is “Fixed Reference”, then relativeToFrom must be “Start to Start”.	ERROR	Timing	relativeToFrom
DDF00037	At least 1 scheduled activity instance within a timeline must point to a timeline exit.	ERROR	ScheduledActivityInstance	timelineExit
DDF00038	A scheduled decision instance must refer to a default condition.	ERROR	ScheduledDecisionInstance	defaultCondition
DDF00040	Each study element must be referenced by at least 1 study cell.	ERROR	StudyCell	elements
DDF00046	A timing must only be specified as relative to/from a scheduled activity/decision instance defined within the same timeline as the timing.	ERROR	Timing	relativeFromScheduledInstance, relativeToScheduledInstance
DDF00047	A study cell must only reference elements defined within the same study design.	ERROR	StudyCell	elements
DDF00050	A study arm must only reference study populations or cohorts defined within the same study design.	ERROR	StudyArm	populations
DDF00051	A timing’s type must be specified using the Timing Type Value Set Terminology (C201264) DDF codelist.	ERROR	Timing	type
DDF00054	Within an encounter there must be no duplicate contact modes.	ERROR	Encounter	contactModes
DDF00060	The value for each timing must be a non-negative duration in ISO 8601 format.	ERROR	Timing	value
DDF00061	When specified, the lower limit of a timing window must be a non-negative duration in ISO 8601 format.	ERROR	Timing	windowLower
DDF00062	When specified, the upper limit of a timing window must be a non-negative duration in ISO 8601 format.	ERROR	Timing	windowUpper
DDF00069	Each combination of arm and epoch must occur no more than once within a study design.	ERROR	StudyCell	arm, epoch
DDF00071	A study cell must only reference an arm defined within the same study design.	ERROR	StudyCell	arm

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CORE rule ID	Rule description (USDM v4.0)	ERROR/ WARNING	Relevant USDM classes	Relevant USDM attributes
DDF00072	A study cell must only reference an epoch defined within the same study design.	ERROR	StudyCell	epoch
DDF00075	An activity is expected to refer to at least 1 procedure, biomedical concept, biomedical concept category or biomedical concept surrogate.	WARNING	Activity	definedProcedures, biomedicalConcepts, bcCategories, bcSurrogates
DDF00076	If a biomedical concept is referenced from an activity, it is not expected to also be referenced by a biomedical concept category referenced from the same activity.	WARNING	Activity, BiomedicalConceptCategory	biomedicalConcepts, members
DDF00080	All scheduled activity instances in the main timeline are expected to refer to an epoch.	WARNING	ScheduledActivityInstance	epoch
DDF00087	Encounter ordering (previous/next) is expected to be consistent with the order of corresponding scheduled activity instances per their default conditions.	WARNING	Encounter	previous, next
DDF00088	Epoch ordering (previous/next) is expected to be consistent with the order of corresponding scheduled activity instances per their default conditions.	WARNING	StudyEpoch	previous, next
DDF00090	The same biomedical concept category must not be referenced more than once from the same activity.	ERROR	Activity	bcCategories
DDF00091	When a condition applies to a procedure, activity, biomedical concept, biomedical concept category, or biomedical concept surrogate, an instance must exist in the corresponding class with the specified id.	ERROR	Condition	appliesTo
DDF00099	All epochs are expected to be referred to from a scheduled activity instance.	WARNING	ScheduledActivityInstance	epoch
DDF00102	A scheduled activity instance must only reference a timeline exit defined within the same schedule timeline.	ERROR	ScheduledActivityInstance	timelineExit
DDF00104	A timing's relative to/from property must be specified using the Timing Relative To From Value Set Terminology (C201265) DDF codelist.	ERROR	Timing	relativeToFrom
DDF00105	A scheduled activity/decision instance must only reference an epoch defined within the same study design.	ERROR	ScheduledActivityInstance, ScheduledDecisionInstance	epoch
DDF00106	A scheduled activity instance must only reference an encounter defined within the same study design.	ERROR	ScheduledActivityInstance	encounter
DDF00107	A scheduled activity instance must only have a subtimeline defined within the same study design.	ERROR	ScheduledActivityInstance	timeline
DDF00108	There must be at least 1 exit defined for each timeline.	ERROR	ScheduleTimeline	exits
DDF00114	If specified, the context of a condition must point to a valid instance in the activity or scheduled activity instance class.	ERROR	Condition	context
DDF00127	An encounter must only be scheduled at a timing defined within the same study design.	ERROR	Encounter	scheduledAt
DDF00136	An encounter's contact modes must be specified according to the extensible Mode of Subject Contact (C171445) SDTM codelist (e.g. an entry with a code or decode used from the codelist should be consistent with the full entry in the codelist).	ERROR	Encounter	contactModes

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CORE rule ID	Rule description (USDM v4.0)	ERROR/ WARNING	Relevant USDM classes	Relevant USDM attributes
DDF00149	A study arm data origin type must be specified per the extensible data origin type (C188727) DDF codelist.	ERROR	StudyArm	dataOriginType
DDF00150	An encounter type must be specified per the extensible encounter type (C188728) DDF codelist.	ERROR	Encounter	type
DDF00152	An activity must only reference timelines specified within the same study design.	ERROR	Activity	timeline
DDF00153	A planned duration is expected for the main timeline.	WARNING	ScheduleTimeline	plannedDuration
DDF00156	Within an encounter, if more environmental settings are defined, they must be distinct.	ERROR	Encounter	environmentalSettings
DDF00157	An encounter's environmental settings must be specified per the extensible Environmental Setting (C127262) SDTM codelist.	ERROR	Encounter	environmentalSettings
DDF00160	An activity with children must not refer to a timeline, procedure, biomedical concept, biomedical concept category, or biomedical concept surrogate.	ERROR	Activity	children
DDF00161	Activity ordering (previous/next) must place parents (activities referring to children) before their children.	ERROR	Activity	previous, next
DDF00236	If a synonym is specified, it is not expected to equal the label of the biomedical concept (case insensitive).	WARNING	BiomedicalConcept	synonyms
DDF00243	Each StudyArm is expected to have one StudyCell for each StudyEpoch.	WARNING	StudyCell	arm, epoch
DDF00246	Any parameter name referenced in a tag in the text should be specified in the data dictionary parameter maps.	ERROR	Condition, Objective, Endpoint, and others	text
DDF00247	Syntax template text is expected to be HTML formatted.	WARNING	Condition, Objective, Endpoint, and others	text
DDF00252	A study element must only reference study interventions referenced by the same study design.	ERROR	StudyElement	studyInterventions
DDF00254	An activity must only reference child activities specified within the same study design.	ERROR	Activity	children

Beyond the published CORE rules, a solution should implement consistency checks that reflect the semantics of a well-formed schedule, including:

- Every activity defined in the study design is referenced by at least 1 scheduled activity instance (orphan activity check)
- Every encounter is referenced by at least 1 scheduled activity instance
- Warning when timing windows for different encounters overlap

Companies may add checks reflecting internal standards (e.g., naming conventions, mandatory footnote categories, required biomedical concept coverage for specific assessment types). As with the CORE rules, these checks are most valuable when run continuously during authoring.

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5 Challenges and Considerations

Flexibility of the USDM Timeline Model

The USDM deliberately provides a flexible timeline model so that it can represent the full variety of study designs. The consequence is that the same protocol schedule can be represented in more than one valid way: 1 visit as 1 instance versus several instances; a cycle as explicit repetitions versus a subtimeline; conditional logic as conditions versus decision instances. Flexibility without conventions undermines interoperability, because consumers must then handle every variant. Organizations should adopt and document internal representation conventions, and the community should converge on shared patterns; the CDISC USDM SoA project is developing normative guidance in this area, and its deliverables should be adopted when published.

Cycles and Repeating Schedules

At design time, the number of treatment cycles is frequently unbounded ("until progression or unacceptable toxicity"), so the planned schedule cannot simply enumerate all cycles. The subtimeline pattern represents the cycle once, with an entry condition governing repetition; the explicit pattern enumerates a planned number of cycles and handles the remainder by convention. Each choice moves complexity: subtimelines are compact but demand more of consumers; enumeration is simple to consume but obscures the protocol logic and inflates the schedule. Whichever pattern is chosen, it needs to be applied consistently and documented in the export so that downstream automation can rely on it.

Unscheduled Visits

Unscheduled visits are, by definition, not planned at specific times, yet they carry planned content (which assessments to perform when they occur). Representing them as separate timelines with entry conditions preserves this distinction, but implementers must take care to exclude them from planned-schedule outputs (e.g., SDTM TV domain) and to include them where operationally relevant (e.g., EDC configuration, which must be able to capture an unscheduled visit at any point). The boundary between an unscheduled visit pattern and a conditional planned visit is a recurring design discussion and should be settled per study during design, not left to downstream interpretation.

Complex and Adaptive Designs

Multiphase studies, dose-escalation designs, cohort expansions, and adaptive designs stretch any schedule representation. Challenges include:

- Designs in which different cohorts follow structurally different schedules, which may be represented as multiple timelines or multiple study designs
- Adaptive decision points at which the schedule itself changes based on accumulating data
- Decentralized elements, where the same assessment may occur through different contact modes and settings depending on the visit

For such studies, it is advisable to model a minimal example early and validate it end to end with the intended consumers before committing to a representation for the full protocol.

Impact of Amendments

A USDM dataset, by definition, contains 1 study version. Managing the schedule across amendments therefore happens above the level of a single export: The solution must maintain the version history, and comparisons operate on pairs of versions or snapshots. Two practices make this reliable: identifiers must remain stable across versions (an amended visit keeps its identifier; a new visit gets a new one), and every snapshot must be immutable once taken. Where these practices are not followed, automated comparison produces noise (renames indistinguishable from delete-and-add) and amendment impact analysis loses its value.

Maturity of Biomedical Concepts

The value of linking activities to BCs depends on coverage of the CDISC Library for the study's assessments. Coverage is growing but not complete, particularly for novel or therapeutic area-specific assessments. Concept

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surrogates fill the gap, but they are placeholders: Organizations should track surrogate usage and replace surrogates with published concepts as they become available. Assessment-level semantics can also change between library versions; recording the library version used at design time is necessary for reproducibility.

Digitization of Legacy Schedules

AI-assisted extraction of schedules from PDF protocols accelerates the transition for legacy studies, but SoA tables are among the most error-prone protocol content to extract: Merged cells, footnote markers, and symbols carry meaning that extraction can silently lose or invert. Extracted schedules must therefore always be verified by a human against the source before downstream use, and the verification must cover the footnotes, not only the grid. Digitization is a bridge to digitalization, not a substitute for it.

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6 Examples and Use Cases

Study Design Solution

Existing open-source examples of study design solutions can be found in the CDISC COSA Repository Directory (https://cosa.cdisc.org/). Two examples with SoA-relevant functionality are the Study Definitions Workbench (https://cosa.cdisc.org/directory/SDW), which is closely aligned with the ICH M11 protocol template, and OpenStudyBuilder, which includes study structure and schedule management. The implementation example used throughout this handbook is the SoA Workbench.

SoA Workbench

The SoA Workbench (https://github.com/pendingintent/soa-workbench) is an open-source Python web application created within the CDISC 360i project, which focuses on study pathways and timelines. It demonstrates the upstream authoring and downstream automation features described in this implementation handbook: study structure (arms, epochs, elements, study cells), visit and timing definition with windows, an interactive SoA matrix for activity-to-visit assignment, BC assignment from the CDISC Library, and one-click export of the study definition as USDM v4.0 JSON (complete or per component). Downstream features include schedule renditions (spreadsheet, HTML, PDF), derivation of the SDTM Trial Design domains (TA, TE, TV), a Dataset Definition Specification (formerly Define-JSON) serialization built from the assigned BCs, snapshot-based version management with automated comparison, and a machine-generated amendment impact report classifying changes by inferred downstream impact. The workbench also exposes its content to AI agents through an MCP server, demonstrating the agent-assisted digitization pathway discussed in the Technical Implementation section.

Although not complete, the workbench shows most of the required features described in this implementation handbook. Known limitations at the time of publication include the absence of eligibility criteria entities and incomplete population of some study-level attributes (e.g., study type and phase) in the export; these are documented in the project's own validation reports and illustrate the value of validating exports against the schema and CORE rules described in the Validation section.

Example Studies

The SoA Workbench distribution includes worked example studies that can be used to explore the concepts in this implementation handbook. The primary example is PrE0102 (NCT01797120), a phase II randomized study of fulvestrant with or without everolimus in hormone-receptor-positive metastatic breast cancer, provided with its protocol, digitized schedule, and USDM export. In addition, the CDISC Pilot Study (H2Q-MC-LZZT) is available as a published USDM v4.0 reference dataset that passes the USDM CORE conformance checks and serves as a useful target when verifying a new implementation (https://github.com/cdisc-org/DDF-RA).

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Appendices

Appendix A: USDM Example JSON

Appendix A1: Timeline with Direct and Indirect Relationships to the Anchor

This JSON example shows an instance of a timeline as presented in Adding Timing Details. Note that an instance of the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file.


```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "description": "This is the main timeline: example direct or indirect
relationships (USDM HB2).",
    "mainTimeline": true,
    "entryCondition": "Potential subject identified",
    "entryId": "ScheduledActivityInstance_1",
    "exits": [
      {
        "id": "ScheduleTimelineExit_1",
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_1",
        "extensionAttributes": [],
        "name": "TIM1",
        "label": "Minimum 1 day prior to V1",
        "description": null,
        "type": {
          "id": "Code_20",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "P1D",
        "valueLabel": "1 day",
        "relativeToFrom": {
          "id": "Code_21",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_1",
```


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```
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_2",
      "windowLower": "P7D",
      "windowUpper": "P0D",
      "windowLabel": "-7/0D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_2",
      "extensionAttributes": [],
      "name": "TIM2",
      "label": "-2W",
      "description": null,
      "type": {
        "id": "Code_10",
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "P14D",
      "valueLabel": "14 days",
      "relativeToFrom": {
        "id": "Code_21",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_2",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
      "windowLower": "P0D",
      "windowUpper": "P13D",
      "windowLabel": "0/13D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_3",
      "extensionAttributes": [],
      "name": "TIM3",
      "label": "0W",
      "description": "Week 0 anchor",
      "type": {
        "id": "Code_61t",
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_62",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
```


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```
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_3",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_4",
      "extensionAttributes": [],
      "name": "TIM4",
      "label": "1W",
      "description": null,
      "type": {
        "id": "Code_61t3",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P7D",
      "valueLabel": "7 Days",
      "relativeToFrom": {
        "id": "Code_62_t3",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_4",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
      "windowLower": "P3D",
      "windowUpper": "P3D",
      "windowLabel": "+/-3D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_5",
      "extensionAttributes": [],
      "name": "TIM5",
      "label": "2W",
      "description": null,
      "type": {
        "id": "Code_61t4",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P14D",
      "valueLabel": "14 Days",
```


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```
      "relativeToFrom": {
        "id": "Code_62_t4",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_5",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
      "windowLower": "P3D",
      "windowUpper": "P3D",
      "windowLabel": "+/-3D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_6",
      "extensionAttributes": [],
      "name": "TIM6",
      "label": "3W",
      "description": null,
      "type": {
        "id": "Code_61t5",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P21D",
      "valueLabel": "21 Days",
      "relativeToFrom": {
        "id": "Code_62_t5",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_6",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
      "windowLower": "P3D",
      "windowUpper": "P3D",
      "windowLabel": "+/-3D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_7",
      "extensionAttributes": [],
      "name": "TIM7",
      "label": "4W",
      "description": null,
      "type": {
        "id": "Code_61t6",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
```


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```
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 Days",
          "relativeToFrom": {
            "id": "Code_62_t6",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_7",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
          "windowLower": "P3D",
          "windowUpper": "P3D",
          "windowLabel": "+/-3D",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_8",
          "extensionAttributes": [],
          "name": "TIM8",
          "label": "6W",
          "description": null,
          "type": {
            "id": "Code_61t7",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P42D",
          "valueLabel": "42 Days",
          "relativeToFrom": {
            "id": "Code_62_t7",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_8",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
          "windowLower": "P3D",
          "windowUpper": "P3D",
          "windowLabel": "+/-3D",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_9",
          "extensionAttributes": [],
          "name": "TIM9",
          "label": "9W",
          "description": null,
          "type": {
```


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```
            "id": "Code_61t8",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P63D",
          "valueLabel": "63 Days",
          "relativeToFrom": {
            "id": "Code_62_t8",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_9",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
          "windowLower": "P3D",
          "windowUpper": "P3D",
          "windowLabel": "+/-3D",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_10",
          "extensionAttributes": [],
          "name": "TIM10",
          "label": "12W",
          "description": null,
          "type": {
            "id": "Code_61t9",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P84D",
          "valueLabel": "84 Days",
          "relativeToFrom": {
            "id": "Code_62_t9",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_10",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
          "windowLower": "P3D",
          "windowUpper": "P3D",
          "windowLabel": "+/-3D",
          "instanceType": "Timing"
        }
      ],
      "instances": [
```


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```
    {
      "id": "ScheduledActivityInstance_1",
      "extensionAttributes": [],
      "name": "INFORM1",
      "label": "Information Visit",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_2",
      "epochId": "StudyEpoch_1",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_1", "Activity_2"],
      "encounterId": "Encounter_1"
    },
    {
      "id": "ScheduledActivityInstance_2",
      "extensionAttributes": [],
      "name": "SCREEN",
      "label": "Screening Visit",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_3",
      "epochId": "StudyEpoch_1",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_3", "Activity_4", "Activity_5", "Activity_6"],
      "encounterId": "Encounter_2"
    },
    {
      "id": "ScheduledActivityInstance_3",
      "extensionAttributes": [],
      "name": "WK0",
      "label": "Week 0",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_4",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_3"
    },
    {
      "id": "ScheduledActivityInstance_4",
      "extensionAttributes": [],
      "name": "WK1",
      "label": "Week 1",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_5",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_4"
    },
    {
      "id": "ScheduledActivityInstance_5",
      "extensionAttributes": [],
      "name": "WK2",
      "label": "Week 2",
```


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```
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_6",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_5"
    },
    {
      "id": "ScheduledActivityInstance_6",
      "extensionAttributes": [],
      "name": "WK3",
      "label": "Week 3",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_7",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_6"
    },
    {
      "id": "ScheduledActivityInstance_7",
      "extensionAttributes": [],
      "name": "WK4",
      "label": "Week 4",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_8",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_7"
    },
    {
      "id": "ScheduledActivityInstance_8",
      "extensionAttributes": [],
      "name": "WK6",
      "label": "Week 6",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_9",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [],
      "encounterId": "Encounter_8"
    },
    {
      "id": "ScheduledActivityInstance_9",
      "extensionAttributes": [],
      "name": "WK9",
      "label": "Week 9",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_10",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
```


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```
        "timelineExitId": null,
        "activityIds": [],
        "encounterId": "Encounter_9"
      },
      {
        "id": "ScheduledActivityInstance_10",
        "extensionAttributes": [],
        "name": "WK12",
        "label": "Week 12",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_3",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": [],
        "encounterId": "Encounter_10"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```


Appendix A2: Unscheduled Visit Timeline

This JSON example shows an instance of a timeline as presented in Additional Timelines . Note that an instance of the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file.


```
{
    "id": "ScheduleTimeline_6",
    "extensionAttributes": [],
    "name": "Adverse Event Timeline",
    "label": "Adverse Event Timeline",
    "description": "This is an adverse event timeline example for USDM HB 2",
    "mainTimeline": false,
    "entryCondition": "Subject suffers an adverse event",
    "entryId": "ScheduledActivityInstance_11",
    "exits": [],
    "timings": [
      {
        "id": "Timing_17",
        "extensionAttributes": [],
        "name": "TIM17",
        "label": "Adverse Event",
        "description": "Adverse Event Timing",
        "type": {
          "id": "Code_105",
          "extensionAttributes": [],
          "code": "C201358",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-03-27",
          "decode": "Fixed Reference",
          "instanceType": "Code"
        },
        "value": "P0D",
        "valueLabel": "AE day",
```


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```
        "relativeToFrom": {
          "id": "Code_106",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-03-27",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_11",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_11",
        "windowLower": null,
        "windowUpper": null,
        "windowLabel": null,
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_11",
        "extensionAttributes": [],
        "name": "AE",
        "label": "Adverse Event",
        "description": "Occurrence of Adverse Event",
        "defaultConditionId": null,
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["AE_Activity_1",
                        "AE_Activity_2",
                        "AE_Activity_3"],
        "encounterId": null
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
```


Appendix A3: Subtimelines

This JSON example shows an instance of a timeline as presented in Additional Timelines. Note that the instances of the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file.


```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "description": "This is the main timeline: example sub-timeline (USDM HB2).",
    "mainTimeline": true,
    "entryCondition": "ICF Signed",
    "entryId": "ScheduledActivityInstance_E01",
    "exits": [
      {
        "id": "ScheduleTimelineExit_1",
```


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```
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_1",
        "extensionAttributes": [],
        "name": "TIM1",
        "label": "Day -28 to -1",
        "description": null,
        "type": {
          "id": "Code_10",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "P28D",
        "valueLabel": "13 days",
        "relativeToFrom": {
          "id": "Code_11",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
        "windowLower": "P0D",
        "windowUpper": "P27D",
        "windowLabel": "-28 to -1",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_2",
        "extensionAttributes": [],
        "name": "TIM2",
        "label": "Treatment Visit",
        "description": "Treatment start - main timeline anchor",
        "type": {
          "id": "Code_12",
          "extensionAttributes": [],
          "code": "C201358",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Fixed Reference",
          "instanceType": "Code"
        },
        "value": "P0D",
        "valueLabel": "Anchor",
        "relativeToFrom": {
          "id": "Code_13",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
```


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```
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E02",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": "",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_3",
          "extensionAttributes": [],
          "name": "TIM3",
          "label": "4 Weeks",
          "description": "Timing of follow-up visit related to Treatment start",
          "type": {
            "id": "Code_14",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 Days",
          "relativeToFrom": {
            "id": "Code_15",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E03",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
          "windowLower": "P4D",
          "windowUpper": "P4D",
          "windowLabel": "+/-4D",
          "instanceType": "Timing"
        }
      ],
      "instances": [
        {
          "id": "ScheduledActivityInstance_E01",
          "extensionAttributes": [],
          "name": "SCREEN",
          "label": "Screening Visit",
          "description": "-",
          "defaultConditionId": "ScheduledActivityInstance_E02",
          "epochId": "StudyEpoch_1",
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": null,
          "activityIds": [
            "Activity_101",
            "Activity_102",
            "Activity_103",
            "Activity_104"
```


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```
        ],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E02",
        "extensionAttributes": [],
        "name": "TREATMENT1",
        "label": "Treatment Day",
        "description": null,
        "defaultConditionId": "ScheduledDecisionInstance_E03",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": "ScheduleTimeline_2",
        "timelineExitId": null,
        "activityIds": [],
        "encounterId": "Encounter_2"
      },
      {
        "id": "ScheduledActivityInstance_E03",
        "extensionAttributes": [],
        "name": "FU",
        "label": "28 days after last dosing",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_3",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": [],
        "encounterId": "Encounter_3"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  },
  {
    "id": "ScheduleTimeline_2",
    "extensionAttributes": [],
    "name": "PKPD",
    "label": "PK/PD Timeline",
    "description": "This timeline provides the granular planned timepoints for
PK/PD sampling",
    "mainTimeline": false,
    "entryCondition": "Start PK/PD collection",
    "entryId": "ScheduledActivityInstance_E11",
    "exits": [
    {
      "id": "ScheduleTimelineExit_2",
      "extensionAttributes": [],
      "instanceType": "ScheduleTimelineExit"
    }
    ],
    "timings": [
      {
        "id": "Timing_11",
        "extensionAttributes": [],
        "name": "TIM11",
        "label": "Pre-dose",
        "description": null,
        "type": {
          "id": "Code_16",
```


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```
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Dose",
      "relativeToFrom": {
        "id": "Code_17",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E11",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E12",
      "windowLower": "PT30M",
      "windowUpper": "PT0M",
      "windowLabel": "Within 30 minutes before",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_12",
      "extensionAttributes": [],
      "name": "TIM12",
      "label": "Dosing",
      "description": "This is the dosing anchor of the PK/PD timeline",
      "type": {
        "id": "Code_18",
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_19",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E12",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E12",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_13",
      "extensionAttributes": [],
```


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```
        "name": "TIM13",
        "label": "1 hr",
        "description": "1 hour after dosing +/- 5 minutes (note that this
information is often in narrative protocol text)",
        "type": {
          "id": "Code_20",
          "extensionAttributes": [],
          "code": "C201356",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "After",
          "instanceType": "Code"
        },
        "value": "PT60M",
        "valueLabel": "1 hour after dosing",
        "relativeToFrom": {
          "id": "Code_21",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledDecisionInstance_E13",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E12",
        "windowLower": "PT5M",
        "windowUpper": "PT5M",
        "windowLabel": "+/- 5 minutes",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_14",
        "extensionAttributes": [],
        "name": "TIM14",
        "label": "4 hrs",
        "description": "4 hours after dosing (+- 10 minutes).",
        "type": {
          "id": "Code_22",
          "extensionAttributes": [],
          "code": "C201356",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "After",
          "instanceType": "Code"
        },
        "value": "PT4H",
        "valueLabel": "14 Days after Day 1",
        "relativeToFrom": {
          "id": "Code_23",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E14",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E12",
        "windowLower": "PT10M",
        "windowUpper": "PT10M",
```


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```
        "windowLabel": "+/- 10 minutes",
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_E11",
        "extensionAttributes": [],
        "name": "PREDOSE",
        "label": "Pre-Dose",
        "description": null,
        "defaultConditionId": "ScheduledActivityInstance_E12",
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_2",
          "Activity_3"
        ],
        "encounterId": null
      },
      {
        "id": "ScheduledActivityInstance_E12",
        "extensionAttributes": [],
        "name": "DOSING",
        "label": "Dosing",
        "description": null,
        "defaultConditionId": "ScheduledActivityInstance_E13",
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_1"
        ],
        "encounterId": null
      },
      {
        "id": "ScheduledActivityInstance_E13",
        "extensionAttributes": [],
        "name": "1HR",
        "label": "1 hour",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E14",
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_2",
        "activityIds": [
          "Activity_2"
        ],
        "encounterId": null
      },
      {
        "id": "ScheduledActivityInstance_E14",
        "extensionAttributes": [],
        "name": "4HR",
        "label": "4 hours",
        "description": "-",
        "defaultConditionId": null,
```


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```
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_2",
        "activityIds": [
          "Activity_2",
          "Activity_3"
        ],
        "encounterId": null
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```

Appendix A4: Modeling Cycles with a Subtimeline

This JSON example shows 2 instances of a timeline, as described in Alternative Timeline Patterns (Cycles and Branching). One of the timelines is the main timeline (mainTimeline=true) and includes a reference from ScheduledActivityInstance_E02 to the second subtimeline (ScheduleTimeline_2). This subtimeline represents the activities to be performed during a cycle. Note that the instances of the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file.

```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "description": "This is the main timeline: example cycle sub-timeline (USDM
HB2).",
    "mainTimeline": true,
    "entryCondition": "ICF signed",
    "entryId": "ScheduledActivityInstance_E01",
    "exits": [
      {
        "id": "ScheduleTimelineExit_1",
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_1",
        "extensionAttributes": [],
        "name": "TIM1",
        "label": "Day -28 to -1",
        "description": null,
        "type": {
          "id": "Code_10",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
```

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```
      },
      "value": "P28D",
      "valueLabel": "13 days",
      "relativeToFrom": {
        "id": "Code_11",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
      "windowLower": "P0D",
      "windowUpper": "P27D",
      "windowLabel": "-28 to -1",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_2",
      "extensionAttributes": [],
      "name": "TIM2",
      "label": "Cycle Start",
      "description": "First Cycle start Anchor",
      "type": {
        "id": "Code_12",
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_13",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E02",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_3",
      "extensionAttributes": [],
      "name": "TIM3",
      "label": "28 Days",
      "description": "Cycle Length representation: 28 Days",
      "type": {
        "id": "Code_14",
        "extensionAttributes": [],
```


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```
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 Days",
          "relativeToFrom": {
            "id": "Code_15",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledDecisionInstance_E03",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": "",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_4",
          "extensionAttributes": [],
          "name": "TIM4",
          "label": "4 Weeks",
          "description": "Timing of follow-up visit related to last cycle start time
-> 28 +/- 4 Days",
          "type": {
            "id": "Code_16",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 Days",
          "relativeToFrom": {
            "id": "Code_17",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
          "windowLower": "P4D",
          "windowUpper": "P4D",
          "windowLabel": "+/-4D",
          "instanceType": "Timing"
        }
      ],
      "instances": [
        {
```


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```
        "id": "ScheduledActivityInstance_E01",
        "extensionAttributes": [],
        "name": "SCREEN",
        "label": "Screening Visit",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E02",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_3", "Activity_4", "Activity_5", "Activity_6"],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E02",
        "extensionAttributes": [],
        "name": "CYCLE",
        "label": "Cycle 1-*",
        "description": "Unlimited number of cycles.",
        "defaultConditionId": "ScheduledDecisionInstance_E03",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": "ScheduleTimeline_2",
        "timelineExitId": null,
        "activityIds": [],
        "encounterId": null
      },
      {
        "id": "ScheduledDecisionInstance_E03",
        "extensionAttributes": [],
        "name": "CYCLE_REP",
        "label": "Cycle 1-* Repeat",
        "description": "Decision i",
        "defaultConditionId": "ScheduledActivityInstance_E04",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledDecisionInstance",
        "conditionAssignments": [
          {
            "id": "ConditionAssignment_1",
            "extensionAttributes": [],
            "condition": "Fit for next cycle?",
            "conditionTargetId": "ScheduledActivityInstance_E02",
            "instanceType": "ConditionAssignment"
          }
        ]
      },
      {
        "id": "ScheduledActivityInstance_E04",
        "extensionAttributes": [],
        "name": "FU",
        "label": "28 days after last dosing",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": [],
        "encounterId": "Encounter_5"
      }
    ],
```


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```
      "plannedDuration": null,
      "instanceType": "ScheduleTimeline"
    },
    {
      "id": "ScheduleTimeline_2",
      "extensionAttributes": [],
      "name": "CYCLE1-x",
      "label": "Cycle timeline",
      "description": "This is the within cycle timeline: example cycle sub-timeline
(USDM HB2). Multiple cycle sub-timelines are required if there are different
activity and/or visit patterns within them",
      "mainTimeline": false,
      "entryCondition": "Start Cycle",
      "entryId": "ScheduledActivityInstance_E11",
      "exits": [
        {
          "id": "ScheduleTimelineExit_2",
          "extensionAttributes": [],
          "instanceType": "ScheduleTimelineExit"
        }
      ],
      "timings": [
        {
          "id": "Timing_11",
          "extensionAttributes": [],
          "name": "TIM11",
          "label": "Cycle Day 1",
          "description": "Start Cycle Anchor",
          "type": {
            "id": "Code_42",
            "extensionAttributes": [],
            "code": "C201358",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Fixed Reference",
            "instanceType": "Code"
          },
          "value": "P0D",
          "valueLabel": "Anchor",
          "relativeToFrom": {
            "id": "Code_43",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E11",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E11",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": "",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_12",
          "extensionAttributes": [],
          "name": "TIM12",
          "label": "Day 8",
          "description": "Day 8 within each cycle",
```


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```
      "type": {
        "id": "Code_44",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P7D",
      "valueLabel": "7 Days after Day 1",
      "relativeToFrom": {
        "id": "Code_45",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledDecisionInstance_E12",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E11",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_13",
      "extensionAttributes": [],
      "name": "TIM13",
      "label": "Day 15",
      "description": "Day 15 within each cycle.",
      "type": {
        "id": "Code_46",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P14D",
      "valueLabel": "14 Days after Day 1",
      "relativeToFrom": {
        "id": "Code_47",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E13",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E11",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    }
  ],
```


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```
    "instances": [
      {
        "id": "ScheduledActivityInstance_E11",
        "extensionAttributes": [],
        "name": "DAY1",
        "label": "Cycle Day 1",
        "description": "Day 1 within each cycle",
        "defaultConditionId": "ScheduledActivityInstance_E12",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_5"],
        "encounterId": "Encounter_2"
      },
      {
        "id": "ScheduledActivityInstance_E12",
        "extensionAttributes": [],
        "name": "DAY8",
        "label": "Cycle Day 8",
        "description": "Day 8 within each cycle",
        "defaultConditionId": "ScheduledActivityInstance_E13",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": "ScheduleTimeline_2",
        "timelineExitId": null,
        "activityIds": ["Activity_5"],
        "encounterId": "Encounter_3"
      },
      {
        "id": "ScheduledActivityInstance_E13",
        "extensionAttributes": [],
        "name": "DAY15",
        "label": "Cycle Day 15",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_2",
        "activityIds": ["Activity_5"],
        "encounterId": "Encounter_4"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```


Appendix A5: Branching within a Timeline

This JSON example shows an instance of a timeline as presented in Study Design Solution Functional Implementation Requirements. Note that an instance of the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file.


```
[
  {
    "id": "ScheduleTimeline_1",
```


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```
      "extensionAttributes": [],
      "name": "MAIN",
      "label": "Main Timeline",
      "description": "This is the main timeline: example branching (USDM HB2).",
      "mainTimeline": true,
      "entryCondition": "ICF Signed",
      "entryId": "ScheduledActivityInstance_1",
      "exits": [
        {
          "id": "ScheduleTimelineExit_1",
          "extensionAttributes": [],
          "instanceType": "ScheduleTimelineExit"
        }
      ],
      "timings": [
        {
          "id": "Timing_1",
          "extensionAttributes": [],
          "name": "TIM1",
          "label": "Day -28 to -1",
          "description": "Screening timing in relation to anchor Arm A",
          "type": {
            "id": "Code_10",
            "extensionAttributes": [],
            "code": "C201357",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Before",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 days",
          "relativeToFrom": {
            "id": "Code_11",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03A",
          "windowLower": "P0D",
          "windowUpper": "P27D",
          "windowLabel": "Day -28 to -1",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_2",
          "extensionAttributes": [],
          "name": "TIM2",
          "label": "Day -28 to -1",
          "description": "Screening timing in relation to anchor Arm B",
          "type": {
            "id": "Code_12",
            "extensionAttributes": [],
            "code": "C201357",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Before",
```


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```
        "instanceType": "Code"
      },
      "value": "P28D",
      "valueLabel": "28 days",
      "relativeToFrom": {
        "id": "Code_13",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03B",
      "windowLower": "P0D",
      "windowUpper": "P27D",
      "windowLabel": "Day -28 to -1",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_3",
      "extensionAttributes": [],
      "name": "TIM3",
      "label": "Pre-Dose",
      "description": "Branching decision timing: Pre-dose",
      "type": {
        "id": "Code_14",
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "PT1H",
      "valueLabel": "1 Hour Before",
      "relativeToFrom": {
        "id": "Code_15",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledDecisionInstance_E02",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03A",
      "windowLower": "PT7H",
      "windowUpper": "PT0H",
      "windowLabel": "Within 8 - 1 hour before dosing",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_4",
      "extensionAttributes": [],
      "name": "TIM4",
      "label": "Day 0 - Arm A",
      "description": "Anchor Timing Arm A",
      "type": {
        "id": "Code_16",
```


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```
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_17",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E03A",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03A",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_5",
      "extensionAttributes": [],
      "name": "TIM5",
      "label": "Day 0 - Arm B",
      "description": "Anchor Timing Arm B",
      "type": {
        "id": "Code_18",
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_19",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E03B",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03B",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_6",
      "extensionAttributes": [],
```


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```
      "name": "TIM_FU_A",
      "label": "Timing Follow-up visit Arm A",
      "description": null,
      "type": {
        "id": "Code_20",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P28D",
      "valueLabel": "28 Days",
      "relativeToFrom": {
        "id": "Code_21",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03A",
      "windowLower": "P3D",
      "windowUpper": "P3D",
      "windowLabel": "+/-3D",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_7",
      "extensionAttributes": [],
      "name": "TIM_FU_B",
      "label": "Timing Follow-up visit Arm B",
      "description": null,
      "type": {
        "id": "Code_22",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P28D",
      "valueLabel": "28 Days",
      "relativeToFrom": {
        "id": "Code_23",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E03B",
      "windowLower": "P3D",
      "windowUpper": "P3D",
      "windowLabel": "+/-3D",
```


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```
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_E01",
        "extensionAttributes": [],
        "name": "SCREEN",
        "label": "Screening Visit",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E02",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_3", "Activity_4", "Activity_5", "Activity_6"],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledDecisionInstance_E02",
        "extensionAttributes": [],
        "name": "BRANCHING",
        "label": "Branching Decision for Arm A or B",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E03A",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledDecisionInstance",
        "conditionAssignments": [
          {
            "id": "ConditionAssignment_1",
            "extensionAttributes": [],
            "condition": "Arm B?",
            "conditionTargetId": "ScheduledActivityInstance_E03B",
            "instanceType": "ConditionAssignment"
          }
        ]
      },
      {
        "id": "ScheduledActivityInstance_E03A",
        "extensionAttributes": [],
        "name": "D1_ARM_A",
        "label": "Day 1",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E04",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_3", "Activity_4"],
        "encounterId": "Encounter_2"
      },
      {
        "id": "ScheduledActivityInstance_E03B",
        "extensionAttributes": [],
        "name": "D1_ARM_B",
        "label": "Day 1",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E04",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
```


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```
        "timelineExitId": null,
        "activityIds": ["Activity_3", "Activity_5"],
        "encounterId": "Encounter_2"
      },
      {
        "id": "ScheduledActivityInstance_E04",
        "extensionAttributes": [],
        "name": "WK4",
        "label": "Follow-up (Week 4)",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_3",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": [],
        "encounterId": "Encounter_3"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```

Appendix A6: Defining an Activity Duration by a Timeline

This JSON example shows the main timeline (ScheduleTimeline_1) and sub-timeline (ScheduleTimeline_2) presented in the Activities Feature section. The second JSON example shows the instances of relevant activities referred in this timeline (Activity_1 to Activity_4). Note that Activity_1 belongs to the main timeline and refers to the id of the second timeline with the timelineId reference. Both the scheduled timelines and the activities are nested within a study design in the full JSON file.

```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "description": "This is the main timeline: example Activity Duration Timeline
(USDM HB2).",
    "mainTimeline": true,
    "entryCondition": "ICF SIgned",
    "entryId": "ScheduledActivityInstance_1",
    "exits": [
      {
        "id": "ScheduleTimelineExit_1",
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_1",
        "extensionAttributes": [],
        "name": "TIM1",
        "label": "Day -28 to -1",
        "description": "Full Screening period",
```

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```
      "type": {
        "id": "Code_10",
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "P28D",
      "valueLabel": "28 days",
      "relativeToFrom": {
        "id": "Code_11",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": "P0D",
      "windowUpper": "P27D",
      "windowLabel": "Day -28 to -1",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_2",
      "extensionAttributes": [],
      "name": "TIM2",
      "label": "Day -14 to -1",
      "description": "Last 2 weeks of Screening Period",
      "type": {
        "id": "Code_12",
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "P14D",
      "valueLabel": "14 days",
      "relativeToFrom": {
        "id": "Code_13",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E02",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": "P0D",
      "windowUpper": "P27D",
      "windowLabel": "Day -28 to -1",
      "instanceType": "Timing"
    },
    {
```


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```
      "id": "Timing_3",
      "extensionAttributes": [],
      "name": "TIM3",
      "label": "Day -1",
      "description": null,
      "type": {
        "id": "Code_14",
        "extensionAttributes": [],
        "code": "C201357",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Before",
        "instanceType": "Code"
      },
      "value": "P1D",
      "valueLabel": "Day -1",
      "relativeToFrom": {
        "id": "Code_15",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledactivityInstance_E03",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_4",
      "extensionAttributes": [],
      "name": "TIM4",
      "label": "Day 1",
      "description": "Anchor Day 1",
      "type": {
        "id": "Code_16",
        "extensionAttributes": [],
        "code": "C201358",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Fixed Reference",
        "instanceType": "Code"
      },
      "value": "P0D",
      "valueLabel": "Anchor",
      "relativeToFrom": {
        "id": "Code_17",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
```


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```
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_5",
      "extensionAttributes": [],
      "name": "TIM5",
      "label": "Day 2",
      "description": null,
      "type": {
        "id": "Code_18",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P1D",
      "valueLabel": "1 Day",
      "relativeToFrom": {
        "id": "Code_19",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E05",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_6",
      "extensionAttributes": [],
      "name": "TIM6",
      "label": "Day 4",
      "description": null,
      "type": {
        "id": "Code_20",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P3D",
      "valueLabel": "3 Days",
      "relativeToFrom": {
        "id": "Code_21",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
```


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```
      "instanceType": "Code"
    },
    "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E06",
    "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
    "windowLower": null,
    "windowUpper": null,
    "windowLabel": null,
    "instanceType": "Timing"
  },
  {
    "id": "Timing_7",
    "extensionAttributes": [],
    "name": "TIM7",
    "label": "Day 8",
    "description": null,
    "type": {
      "id": "Code_22",
      "extensionAttributes": [],
      "code": "C201356",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "After",
      "instanceType": "Code"
    },
    "value": "P7D",
    "valueLabel": "7 Days",
    "relativeToFrom": {
      "id": "Code_23",
      "extensionAttributes": [],
      "code": "C201355",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "Start to Start",
      "instanceType": "Code"
    },
    "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E07",
    "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
    "windowLower": null,
    "windowUpper": null,
    "windowLabel": null,
    "instanceType": "Timing"
  },
  {
    "id": "Timing_8",
    "extensionAttributes": [],
    "name": "TIM8",
    "label": "Day 15",
    "description": null,
    "type": {
      "id": "Code_24",
      "extensionAttributes": [],
      "code": "C201356",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "After",
      "instanceType": "Code"
    },
    "value": "P14D",
    "valueLabel": "14 Days",
    "relativeToFrom": {
      "id": "Code_25",
```


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```
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E08",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_9",
      "extensionAttributes": [],
      "name": "TIM9",
      "label": "Day 22",
      "description": null,
      "type": {
        "id": "Code_26",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P3D",
      "valueLabel": "3 Days",
      "relativeToFrom": {
        "id": "Code_27",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E09",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_10",
      "extensionAttributes": [],
      "name": "TIM10",
      "label": "Follow-up visit",
      "description": null,
      "type": {
        "id": "Code_28",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
```


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```
        },
        "value": "P28D",
        "valueLabel": "28 Days",
        "relativeToFrom": {
          "id": "Code_29",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E10",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
        "windowLower": "P3D",
        "windowUpper": "P3D",
        "windowLabel": "+/-3D",
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_E01",
        "extensionAttributes": [],
        "name": "SCREEN1",
        "label": "Screening -28 to -1",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E02",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_21", "Activity_22"],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E02",
        "extensionAttributes": [],
        "name": "SCREEN1",
        "label": "Screening -14 to -1",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E03",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_23",
          "Activity_24",
          "Activity_25",
          "Activity_26"
        ],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E03",
        "extensionAttributes": [],
        "name": "DAY_MIN1",
        "label": "DAY -1",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E04",
```


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```
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [
        "Activity_25",
        "Activity_26",
        "Activity_1",
        "Activity_27",
        "Activity_28"
      ],
      "encounterId": "Encounter_2"
    },
    {
      "id": "ScheduledActivityInstance_E04",
      "extensionAttributes": [],
      "name": "DAY1",
      "label": "Day 1",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E05",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_23", "Activity_24", "Activity_29"],
      "encounterId": "Encounter_3"
    },
    {
      "id": "ScheduledActivityInstance_E05",
      "extensionAttributes": [],
      "name": "DAY2",
      "label": "Day 2",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E06",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_23", "Activity_25"],
      "encounterId": "Encounter_4"
    },
    {
      "id": "ScheduledActivityInstance_E06",
      "extensionAttributes": [],
      "name": "DAY4",
      "label": "Day 4",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E07",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_23", "Activity_25"],
      "encounterId": "Encounter_5"
    },
    {
      "id": "ScheduledActivityInstance_E07",
      "extensionAttributes": [],
      "name": "DAY8",
      "label": "Day 8",
      "description": "-",
```


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```
        "defaultConditionId": "ScheduledActivityInstance_E08",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_23", "Activity_25"],
        "encounterId": "Encounter_6"
      },
      {
        "id": "ScheduledActivityInstance_E08",
        "extensionAttributes": [],
        "name": "DAY15",
        "label": "Day 15",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E09",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_23", "Activity_25"],
        "encounterId": "Encounter_7"
      },
      {
        "id": "ScheduledActivityInstance_E09",
        "extensionAttributes": [],
        "name": "DAY22",
        "label": "Day 22",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E10",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_1", "Activity_23", "Activity_25"],
        "encounterId": "Encounter_8"
      },
      {
        "id": "ScheduledActivityInstance_E10",
        "extensionAttributes": [],
        "name": "DAY28",
        "label": "Follow-up (Day 28)",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_3",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": ["Activity_1"],
        "encounterId": "Encounter_9"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  },
  {
    "id": "ScheduleTimeline_2",
    "extensionAttributes": [],
    "name": "ACT_COLL24H",
    "label": "24 Hour Collection Interval",
    "description": "This timeline is used for 24 hour collection Interval.",
    "mainTimeline": false,
```


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```
      "entryCondition": "Start 24-hour collection",
      "entryId": "ScheduledActivityInstance_1",
      "exits": [
        {
          "id": "ScheduleTimelineExit_2",
          "extensionAttributes": [],
          "instanceType": "ScheduleTimelineExit"
        }
      ],
      "timings": [
        {
          "id": "Timing_21",
          "extensionAttributes": [],
          "name": "TIM21",
          "label": "Pre-dose",
          "description": "Pre-dose or similar timepoint on other days.",
          "type": {
            "id": "Code_201",
            "extensionAttributes": [],
            "code": "C201357",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Before",
            "instanceType": "Code"
          },
          "value": "PT0M",
          "valueLabel": "0 Minutes",
          "relativeToFrom": {
            "id": "Code_202",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E21",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E22",
          "windowLower": "PT30M",
          "windowUpper": "PT0M",
          "windowLabel": "Within 30 Minutes Before",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_22",
          "extensionAttributes": [],
          "name": "TIM22",
          "label": "Dosing",
          "description": "Dosing or similar timepoint",
          "type": {
            "id": "Code_203",
            "extensionAttributes": [],
            "code": "C201358",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Fixed Reference",
            "instanceType": "Code"
          },
          "value": "PT0M",
          "valueLabel": "Anchor",
          "relativeToFrom": {
```


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```
            "id": "Code_204",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E22",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E22",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": "",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_23",
          "extensionAttributes": [],
          "name": "TIM23",
          "label": "24 hours",
          "description": null,
          "type": {
            "id": "Code_205",
            "extensionAttributes": [],
            "code": "C201356",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "After",
            "instanceType": "Code"
          },
          "value": "PT24H",
          "valueLabel": "24 Hours",
          "relativeToFrom": {
            "id": "Code_206",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E23",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E22",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": null,
          "instanceType": "Timing"
        }
      ],
      "instances": [
        {
          "id": "ScheduledActivityInstance_E21",
          "extensionAttributes": [],
          "name": "PREDOSE",
          "label": "Pre-dose or similar time",
          "description": "-",
          "defaultConditionId": "ScheduledActivityInstance_E22",
          "epochId": null,
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": null,
```


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```
        "activityIds": ["Activity_2"],
        "encounterId": null
      },
      {
        "id": "ScheduledActivityInstance_E22",
        "extensionAttributes": [],
        "name": "DOSINGTIME",
        "label": "Dosing time point",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E23",
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_3"],
        "encounterId": null
      },
      {
        "id": "ScheduledActivityInstance_E23",
        "extensionAttributes": [],
        "name": "24H",
        "label": "24 Hours after dosing",
        "description": "-",
        "defaultConditionId": null,
        "epochId": null,
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_2",
        "activityIds": ["Activity_4"],
        "encounterId": "Encounter_2"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```


Activities


```
[
  {
    "id": "Activity_1",
    "extensionAttributes": [],
    "name": "ACT_24H_Holter",
    "label": "",
    "description": "",
    "previousId": "Activity_26",
    "nextId": "Activity_27",
    "childIds": null,
    "definedProcedures": [],
    "biomedicalConceptIds": [],
    "bcCategoryIds": [],
    "bcSurrogateIds": [],
    "timelineId": "ScheduleTimeline_2",
    "notes": [],
    "instanceType": "Activity"
  },
  {
```


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```
      "id": "Activity_2",
      "extensionAttributes": [],
      "name": "ECGCol_Row1",
      "label": "Start 24-holter ECG",
      "description": "",
      "previousId": null,
      "nextId": "Activity_3",
      "childIds": [],
      "definedProcedures": [],
      "biomedicalConceptIds": ["BiomedicalConcept_33"],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    },
    {
      "id": "Activity_3",
      "extensionAttributes": [],
      "name": "ECGCol_Row2",
      "label": "Dosing",
      "description": "",
      "previousId": "Activity_2",
      "nextId": "Activity_4",
      "childIds": [],
      "definedProcedures": [
        {
          "id": "Procedure_1",
          "extensionAttributes": [],
          "name": "PR1",
          "label": "Drug Administration",
          "description": "",
          "procedureType": "Dosing",
          "code": {
            "id": "CodeX_3",
            "extensionAttributes": [],
            "code": "182832007",
            "codeSystem": "SNOMED",
            "codeSystemVersion": "2025-02-01",
            "decode": "Management of drug regimen",
            "instanceType": "Code"
          },
          "studyInterventionId": "StudyIntervention_01",
          "notes": [],
          "instanceType": "Procedure"
        }
      ],
      "biomedicalConceptIds": [],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    },
    {
      "id": "Activity_4",
      "extensionAttributes": [],
      "name": "ECGCol_Row3",
      "label": "End 24-hour ECG",
      "description": "",
      "previousId": "Activity_3",
```


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```
    "nextId": null,
    "childIds": [],
    "definedProcedures": [],
    "biomedicalConceptIds": ["BiomedicalConcept_33"],
    "bcCategoryIds": [],
    "bcSurrogateIds": [],
    "timelineId": null,
    "notes": [],
    "instanceType": "Activity"
  }
]
```

Appendix A7: Defining Multiple Actions for an Activity by a Timeline

This JSON example shows the main timeline (ScheduleTimeline_1) and subtimeline (ScheduleTimeline_2) presented in Activities Feature. The second JSON example shows the instances of relevant activities referred in this timeline (Activity_1 and Activity_24). Note that Activity_1 belongs to the main timeline and refers to the id of the second timeline with the timelineId reference. Both the scheduled timelines and the activities are nested within a study design in the full JSON file.

```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "descripThe below JSON example shows the main timeline (ScheduleTimeline_1)
and sub-timeline (ScheduleTimeline_2) presented in the paragraph Activities
Feature#DefininganActivityduration. The second JSON example shows the instances of
relevant activities referred in this timeline (Activity_1 to Activity_4). Note
that Activity_1 belongs to the main timeline and refers to the id of the second
timeline with the timelineId reference. Both the scheduled timelines and the
activities are nested within a study design in the full JSON file.tion": "This is
the main timeline: example Activity Repeated Assessment Timeline (USDM HB2).",
    "mainTimeline": true,
    "entryCondition": "Potential subject identified",
    "entryId": "ScheduledActivityInstance_1",
    "exits": [
      {
        "id": "ScheduleTimelineExit_1",
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_1",
        "extensionAttributes": [],
        "name": "TIM1",
        "label": "Day -28 to -1",
        "description": "Full Screening period",
        "type": {
          "id": "Code_10",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
```

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```
            "decode": "Before",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 days",
          "relativeToFrom": {
            "id": "Code_11",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
          "windowLower": "P0D",
          "windowUpper": "P27D",
          "windowLabel": "Day -28 to -1",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_2",
          "extensionAttributes": [],
          "name": "TIM2",
          "label": "Day -14 to -1",
          "description": "Last 2 weeks of Screening Period",
          "type": {
            "id": "Code_12",
            "extensionAttributes": [],
            "code": "C201357",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Before",
            "instanceType": "Code"
          },
          "value": "P14D",
          "valueLabel": "14 days",
          "relativeToFrom": {
            "id": "Code_13",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E02",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
          "windowLower": "P0D",
          "windowUpper": "P27D",
          "windowLabel": "Day -28 to -1",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_3",
          "extensionAttributes": [],
          "name": "TIM3",
          "label": "Day -1",
          "description": null,
          "type": {
```


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```
      "id": "Code_14",
      "extensionAttributes": [],
      "code": "C201357",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "Before",
      "instanceType": "Code"
    },
    "value": "P1D",
    "valueLabel": "Day -1",
    "relativeToFrom": {
      "id": "Code_15",
      "extensionAttributes": [],
      "code": "C201355",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "Start to Start",
      "instanceType": "Code"
    },
    "relativeFromScheduledInstanceId": "ScheduledactivityInstance_E03",
    "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
    "windowLower": null,
    "windowUpper": null,
    "windowLabel": null,
    "instanceType": "Timing"
  },
  {
    "id": "Timing_4",
    "extensionAttributes": [],
    "name": "TIM4",
    "label": "Day 1",
    "description": "Anchor Day 1",
    "type": {
      "id": "Code_16",
      "extensionAttributes": [],
      "code": "C201358",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "Fixed Reference",
      "instanceType": "Code"
    },
    "value": "P0D",
    "valueLabel": "Anchor",
    "relativeToFrom": {
      "id": "Code_17",
      "extensionAttributes": [],
      "code": "C201355",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2025-09-26",
      "decode": "Start to Start",
      "instanceType": "Code"
    },
    "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
    "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
    "windowLower": null,
    "windowUpper": null,
    "windowLabel": "",
    "instanceType": "Timing"
  },
  {
    "id": "Timing_5",
```


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```
      "extensionAttributes": [],
      "name": "TIM5",
      "label": "Day 2",
      "description": null,
      "type": {
        "id": "Code_18",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P1D",
      "valueLabel": "1 Day",
      "relativeToFrom": {
        "id": "Code_19",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E05",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_6",
      "extensionAttributes": [],
      "name": "TIM6",
      "label": "Day 4",
      "description": null,
      "type": {
        "id": "Code_20",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P3D",
      "valueLabel": "3 Days",
      "relativeToFrom": {
        "id": "Code_21",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E06",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
```


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```
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_7",
      "extensionAttributes": [],
      "name": "TIM7",
      "label": "Day 8",
      "description": null,
      "type": {
        "id": "Code_22",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P7D",
      "valueLabel": "7 Days",
      "relativeToFrom": {
        "id": "Code_23",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E07",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_8",
      "extensionAttributes": [],
      "name": "TIM8",
      "label": "Day 15",
      "description": null,
      "type": {
        "id": "Code_24",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P14D",
      "valueLabel": "14 Days",
      "relativeToFrom": {
        "id": "Code_25",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
```


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```
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E08",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
        "windowLower": null,
        "windowUpper": null,
        "windowLabel": null,
        "instanceType": "Timing"
      },
      {
        "id": "Timing_9",
        "extensionAttributes": [],
        "name": "TIM9",
        "label": "Follow-up visit",
        "description": null,
        "type": {
          "id": "Code_28",
          "extensionAttributes": [],
          "code": "C201356",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "After",
          "instanceType": "Code"
        },
        "value": "P28D",
        "valueLabel": "28 Days",
        "relativeToFrom": {
          "id": "Code_29",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E09",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E04",
        "windowLower": "P3D",
        "windowUpper": "P3D",
        "windowLabel": "+/-3D",
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_E01",
        "extensionAttributes": [],
        "name": "SCREEN1",
        "label": "Screening -28 to -1",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E02",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": ["Activity_21", "Activity_22"],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E02",
        "extensionAttributes": [],
        "name": "SCREEN1",
```


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```
      "label": "Screening -14 to -1",
      "description": "-",
      "defaultConditionId": "ScheduledDecisionInstance_E03",
      "epochId": "StudyEpoch_1",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [
        "Activity_23",
        "Activity_24",
        "Activity_25",
        "Activity_26"
      ],
      "encounterId": "Encounter_1"
    },
    {
      "id": "ScheduledActivityInstance_E03",
      "extensionAttributes": [],
      "name": "DAY_MIN1",
      "label": "DAY -1",
      "description": "-",
      "defaultConditionId": "ScheduledDecisionInstance_E04",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [
        "Activity_1",
        "Activity_25",
        "Activity_26",
        "Activity_27",
        "Activity_28"
      ],
      "encounterId": "Encounter_2"
    },
    {
      "id": "ScheduledActivityInstance_E04",
      "extensionAttributes": [],
      "name": "DAY1",
      "label": "Day 1",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E05",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": [
        "Activity_1",
        "Activity_23",
        "Activity_24",
        "Activity_29"
      ],
      "encounterId": "Encounter_3"
    },
    {
      "id": "ScheduledActivityInstance_E05",
      "extensionAttributes": [],
      "name": "DAY2",
      "label": "Day 2",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E06",
```


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```
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_1", "Activity_23", "Activity_25"],
      "encounterId": "Encounter_4"
    },
    {
      "id": "ScheduledActivityInstance_E06",
      "extensionAttributes": [],
      "name": "DAY4",
      "label": "Day 4",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E07",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_1", "Activity_23", "Activity_25"],
      "encounterId": "Encounter_5"
    },
    {
      "id": "ScheduledActivityInstance_E07",
      "extensionAttributes": [],
      "name": "DAY8",
      "label": "Day 8",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E08",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_1", "Activity_23", "Activity_25"],
      "encounterId": "Encounter_6"
    },
    {
      "id": "ScheduledActivityInstance_E08",
      "extensionAttributes": [],
      "name": "DAY15",
      "label": "Day 15",
      "description": "-",
      "defaultConditionId": "ScheduledActivityInstance_E09",
      "epochId": "StudyEpoch_2",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": null,
      "activityIds": ["Activity_1", "Activity_23", "Activity_25"],
      "encounterId": "Encounter_7"
    },
    {
      "id": "ScheduledActivityInstance_E09",
      "extensionAttributes": [],
      "name": "DAY28",
      "label": "Follow-up (Day 28)",
      "description": "-",
      "defaultConditionId": null,
      "epochId": "StudyEpoch_3",
      "instanceType": "ScheduledActivityInstance",
      "timelineId": null,
      "timelineExitId": "ScheduleTimelineExit_1",
      "activityIds": ["Activity_1"],
```


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```
        "encounterId": "Encounter_9"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  },
  {
    "id": "ScheduleTimeline_2",
    "extensionAttributes": [],
    "name": "ACT_COLL24H",
    "label": "Triplicate 12-lead ECG",
    "description": "This timeline is used for timing details of repetative 12-lead
ECG measurements.",
    "mainTimeline": false,
    "entryCondition": "Start Triplicate 12-Lead ECG",
    "entryId": "ScheduledActivityInstance_1",
    "exits": [
      {
        "id": "ScheduleTimelineExit_2",
        "extensionAttributes": [],
        "instanceType": "ScheduleTimelineExit"
      }
    ],
    "timings": [
      {
        "id": "Timing_21",
        "extensionAttributes": [],
        "name": "TIM21",
        "label": "Within 10 minutes before",
        "description": "Within 10 minutes before sampling - since it needs to
incldude 2 intervals of 60 seconds, the max start is 2 minutes before (which is
probably also too narrow as the action itself needs to be done as well).",
        "type": {
          "id": "Code_201",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "PT10M",
        "valueLabel": "10 Minutes",
        "relativeToFrom": {
          "id": "Code_202",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E21",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E24",
        "windowLower": "PT0M",
        "windowUpper": "PT8M",
        "windowLabel": "10-2 Minutes before",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_22",
```


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```
        "extensionAttributes": [],
        "name": "TIM22",
        "label": "Within 60 seconds before",
        "description": "At least 60 seconds between measurements - within 10
minutes allows for a max window of 9 minutes before",
        "type": {
          "id": "Code_203",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "PT60S",
        "valueLabel": "60 Seconds",
        "relativeToFrom": {
          "id": "Code_204",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E21",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E22",
        "windowLower": "PT8M",
        "windowUpper": "PT0M",
        "windowLabel": "9-1 Minutes before",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_23",
        "extensionAttributes": [],
        "name": "TIM23",
        "label": "Within 60 seconds before",
        "description": "At least 60 seconds between measurements - within 10
minutes allows for a max window of 9 minutes before",
        "type": {
          "id": "Code_205",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "PT60S",
        "valueLabel": "60 Seconds",
        "relativeToFrom": {
          "id": "Code_206",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E22",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E23",
```


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```
        "windowLower": "PT8M",
        "windowUpper": "PT0M",
        "windowLabel": "9-1 Minutes before",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_24",
        "extensionAttributes": [],
        "name": "TIM24",
        "label": "Within 60 seconds before",
        "description": "At least 60 seconds between measurements - within 10
minutes allows for a max window of 9 minutes before",
        "type": {
          "id": "Code_207",
          "extensionAttributes": [],
          "code": "C201357",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Before",
          "instanceType": "Code"
        },
        "value": "PT0M",
        "valueLabel": "0 Minutes",
        "relativeToFrom": {
          "id": "Code_208",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E23",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E24",
        "windowLower": "PT8M",
        "windowUpper": "PT0M",
        "windowLabel": "8-0 Minutes before",
        "instanceType": "Timing"
      },
      {
        "id": "Timing_25",
        "extensionAttributes": [],
        "name": "TIM25",
        "label": "Sample time",
        "description": null,
        "type": {
          "id": "Code_209",
          "extensionAttributes": [],
          "code": "C201358",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Fixed Reference",
          "instanceType": "Code"
        },
        "value": "PT0M",
        "valueLabel": "Anchor",
        "relativeToFrom": {
          "id": "Code_210",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
```


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```
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E24",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E24",
          "windowLower": null,
          "windowUpper": null,
          "windowLabel": "",
          "instanceType": "Timing"
        }
      ],
      "instances": [
        {
          "id": "ScheduledActivityInstance_E21",
          "extensionAttributes": [],
          "name": "MEAS1",
          "label": "Measurement 1",
          "description": "-",
          "defaultConditionId": "ScheduledActivityInstance_E22",
          "epochId": null,
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": null,
          "activityIds": ["Activity_2"],
          "encounterId": null
        },
        {
          "id": "ScheduledActivityInstance_E22",
          "extensionAttributes": [],
          "name": "MEAS2",
          "label": "Measurement 2",
          "description": "-",
          "defaultConditionId": "ScheduledActivityInstance_E23",
          "epochId": null,
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": null,
          "activityIds": ["Activity_2"],
          "encounterId": null
        },
        {
          "id": "ScheduledActivityInstance_E23",
          "extensionAttributes": [],
          "name": "MEAS3",
          "label": "Measurement 3",
          "description": "-",
          "defaultConditionId": "ScheduledActivityInstance_E24",
          "epochId": null,
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": null,
          "activityIds": ["Activity_2"],
          "encounterId": null
        },
        {
          "id": "ScheduledActivityInstance_E24",
          "extensionAttributes": [],
          "name": "SAMPLE",
          "label": "Sample time point",
          "description": "-",
```


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```
          "defaultConditionId": null,
          "epochId": null,
          "instanceType": "ScheduledActivityInstance",
          "timelineId": null,
          "timelineExitId": "ScheduleTimelineExit_2",
          "activityIds": null,
          "encounterId": null
        }
      ],
      "plannedDuration": null,
      "instanceType": "ScheduleTimeline"
    }
  ]
```


Activities


```
  [
    {
      "id": "Activity_1",
      "extensionAttributes": [],
      "name": "TRIP12ECG",
      "label": "Triplicate 12-lead ECG",
      "description": "",
      "previousId": "Activity_26",
      "nextId": "Activity_27",
      "childIds": null,
      "definedProcedures": [],
      "biomedicalConceptIds": [],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": "ScheduleTimeline_2",
      "notes": [],
      "instanceType": "Activity"
    },
    {
      "id": "Activity_2",
      "extensionAttributes": [],
      "name": "12ECG",
      "label": "12-lead ECG",
      "description": "",
      "previousId": null,
      "nextId": null,
      "childIds": [],
      "definedProcedures": [],
      "biomedicalConceptIds": ["BiomedicalConcept_34"],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    }
  ]
```


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Appendix A8: Adding Activity Details by Procedures and Assessments


```
{
  "id": "Activity_6",
  "extensionAttributes": [],
  "name": "VITAL SIGNS",
  "label": "Vital Signs",
  "description": "Vital Signs (Blood Pressure, Heart Rate, Temperature) and
Weight",
  "previousId": "Activity_18",
  "nextId": "Activity_4",
  "childIds": [],
  "definedProcedures": [],
  "biomedicalConceptIds": [
    "BiomedicalConcept_7",
    "BiomedicalConcept_8",
    "BiomedicalConcept_9",
    "BiomedicalConcept_10",
    "BiomedicalConcept_11",
    "BiomedicalConcept_128"
  ],
  "bcCategoryIds": [],
  "bcSurrogateIds": [],
  "timelineId": null,
  "notes": [],
  "instanceType": "Activity"
}
```



```
{
  "id": "BiomedicalConcept_7",
  "extensionAttributes": [
    {
      "id": "ExtensionAttribute_4",
      "url": "http://www.cdisc.org/usdm/extensions/specializations/sdtm",
      "valueString": "/mdr/specializations/sdtm/datasetspecializations/SYSBP",
      "instanceType": "ExtensionAttribute"
    },
    {
      "id": "ExtensionAttribute_85",
      "url": "http://www.cdisc.org/usdm/extensions/specializations/crf",
      "valueString":
"/mdr/specializations/crf/specializations/SYSBP_DENORMALIZED",
      "instanceType": "ExtensionAttribute"
    }
  ],
  "name": "Systolic Blood Pressure",
  "label": "Systolic Blood Pressure",
  "synonyms": [
    "SYSBP"
  ],
  "reference": "/mdr/bc/biomedicalconcepts/C25298",
  "properties": [
    {
      "id": "BiomedicalConceptProperty_252",
      "extensionAttributes": [],
      "name": "VSORRES",
      "label": "VSORRES",
      "isRequired": false,
```


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```
      "isEnabled": true,
      "datatype": "integer",
      "responseCodes": [],
      "code": {
        "id": "AliasCode_9650",
        "standardCode": {
          "id": "Code_10406",
          "extensionAttributes": [],
          "code": "C70856",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-05-26",
          "decode": "Observation Result",
          "instanceType": "Code"
        },
        "instanceType": "AliasCode"
      },
      "notes": [],
      "instanceType": "BiomedicalConceptProperty"
    },
    {
      "id": "BiomedicalConceptProperty_253",
      "extensionAttributes": [],
      "name": "VSORRESU",
      "label": "VSORRESU",
      "isRequired": false,
      "isEnabled": true,
      "datatype": "text",
      "responseCodes": [
        {
          "id": "ResponseCode_42",
          "instanceType": "ResponseCode",
          "name": "mmHg",
          "label": "mmHg",
          "isEnabled": true,
          "code": {
            "id": "Code_10408",
            "extensionAttributes": [],
            "code": "C49670",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2026-05-26",
            "decode": "mmHg",
            "instanceType": "Code"
          }
        }
      ],
      "code": {
        "id": "AliasCode_9651",
        "standardCode": {
          "id": "Code_10407",
          "extensionAttributes": [],
          "code": "C49669",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-05-26",
          "decode": "Unit of Pressure",
          "instanceType": "Code"
        },
        "instanceType": "AliasCode"
      },
      "notes": [],
      "instanceType": "BiomedicalConceptProperty"
    },
```


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```
    {
      "id": "BiomedicalConceptProperty_254",
      "extensionAttributes": [],
      "name": "VSPOS",
      "label": "VSPOS",
      "isRequired": false,
      "isEnabled": true,
      "datatype": "string",
      "responseCodes": [],
      "code": {
        "id": "AliasCode_9653",
        "standardCode": {
          "id": "Code_10409",
          "extensionAttributes": [],
          "code": "C62164",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-05-26",
          "decode": "Body Position",
          "instanceType": "Code"
        },
        "instanceType": "AliasCode"
      },
      "notes": [],
      "instanceType": "BiomedicalConceptProperty"
    },
    {
      "id": "BiomedicalConceptProperty_255",
      "extensionAttributes": [],
      "name": "VSLOC",
      "label": "VSLOC",
      "isRequired": false,
      "isEnabled": true,
      "datatype": "string",
      "responseCodes": [],
      "code": {
        "id": "AliasCode_9654",
        "standardCode": {
          "id": "Code_10410",
          "extensionAttributes": [],
          "code": "C13717",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2026-05-26",
          "decode": "Anatomic Site",
          "instanceType": "Code"
        },
        "instanceType": "AliasCode"
      },
      "notes": [],
      "instanceType": "BiomedicalConceptProperty"
    },
    {
      "id": "BiomedicalConceptProperty_256",
      "extensionAttributes": [],
      "name": "VSLAT",
      "label": "VSLAT",
      "isRequired": false,
      "isEnabled": true,
      "datatype": "string",
      "responseCodes": [],
      "code": {
        "id": "AliasCode_9655",
```


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```
          "standardCode": {
            "id": "Code_10411",
            "extensionAttributes": [],
            "code": "C25185",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2026-05-26",
            "decode": "Laterality",
            "instanceType": "Code"
          },
          "instanceType": "AliasCode"
        },
        "notes": [],
        "instanceType": "BiomedicalConceptProperty"
      },
      {
        "id": "BiomedicalConceptProperty_257",
        "extensionAttributes": [],
        "name": "VSDTC",
        "label": "VSDTC",
        "isRequired": false,
        "isEnabled": true,
        "datatype": "datetime",
        "responseCodes": [],
        "code": {
          "id": "AliasCode_9656",
          "standardCode": {
            "id": "Code_10412",
            "extensionAttributes": [],
            "code": "C82515",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2026-05-26",
            "decode": "Collection Date Time",
            "instanceType": "Code"
          },
          "instanceType": "AliasCode"
        },
        "notes": [],
        "instanceType": "BiomedicalConceptProperty"
      }
    ],
    "code": {
      "id": "AliasCode_22",
      "extensionAttributes": [],
      "standardCode": {
        "id": "Code_29",
        "extensionAttributes": [],
        "code": "C25298",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-12-16",
        "decode": "Systolic Blood Pressure",
        "instanceType": "Code"
      },
      "standardCodeAliases": [],
      "instanceType": "AliasCode"
    },
    "notes": [],
    "instanceType": "BiomedicalConcept"
  }
```


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Appendix A9: Defining the SoA Footnotes

This JSON example shows instances of a timeline, corresponding conditions, and corresponding activities as presented in Footnote Utility. Note that the instances of the Activity class and the ScheduledTimeline class like that presented here should be nested in the USDM StudyDesign class in the full USDM file; the Condition instances should be nested in the StudyVersion class.

Conditions


```
[
  {
    "id": "Condition_1",
    "extensionAttributes": [],
    "name": "COND1",
    "label": null,
    "description": null,
    "text": "<p>Only applicable for patients with mutation X</p>",
    "dictionaryId": null,
    "notes": [],
    "instanceType": "Condition",
    "contextIds": [
      "ScheduledActivityInstance_E03"
    ],
    "appliesToIds": [
      "Activity_2"
    ]
  },
  {
    "id": "Condition_2",
    "extensionAttributes": [],
    "name": "COND2",
    "label": null,
    "description": null,
    "text": "<p>Only for women with childbearing potential</p>",
    "dictionaryId": null,
    "notes": [],
    "instanceType": "Condition",
    "contextIds": [
      "Activity_3"
    ],
    "appliesToIds": [
      "Activity_3"
    ]
  }
]
```


Timeline


```
[
  {
    "id": "ScheduleTimeline_1",
    "extensionAttributes": [],
    "name": "MAIN",
    "label": "Main Timeline",
    "description": "This is the main timeline: example Footnote Utility (USDM
HB2).",
    "mainTimeline": true,
    "entryCondition": "ICF signed",
```


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```
      "entryId": "ScheduledActivityInstance_1",
      "exits": [
        {
          "id": "ScheduleTimelineExit_1",
          "extensionAttributes": [],
          "instanceType": "ScheduleTimelineExit"
        }
      ],
      "timings": [
        {
          "id": "Timing_1",
          "extensionAttributes": [],
          "name": "TIM1",
          "label": "Day -28 to -1",
          "description": "Full Screening period",
          "type": {
            "id": "Code_10",
            "extensionAttributes": [],
            "code": "C201357",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Before",
            "instanceType": "Code"
          },
          "value": "P28D",
          "valueLabel": "28 days",
          "relativeToFrom": {
            "id": "Code_11",
            "extensionAttributes": [],
            "code": "C201355",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Start to Start",
            "instanceType": "Code"
          },
          "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E01",
          "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
          "windowLower": "P0D",
          "windowUpper": "P27D",
          "windowLabel": "Day -28 to -1",
          "instanceType": "Timing"
        },
        {
          "id": "Timing_2",
          "extensionAttributes": [],
          "name": "TIM2",
          "label": "Day 1",
          "description": "Anchor Day 1",
          "type": {
            "id": "Code_16",
            "extensionAttributes": [],
            "code": "C201358",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2025-09-26",
            "decode": "Fixed Reference",
            "instanceType": "Code"
          },
          "value": "P0D",
          "valueLabel": "Anchor",
          "relativeToFrom": {
            "id": "Code_12",
```


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```
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E02",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": "",
      "instanceType": "Timing"
    },
    {
      "id": "Timing_3",
      "extensionAttributes": [],
      "name": "TIM3",
      "label": "Day 8",
      "description": null,
      "type": {
        "id": "Code_13",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
      },
      "value": "P7D",
      "valueLabel": "7 Days",
      "relativeToFrom": {
        "id": "Code_14",
        "extensionAttributes": [],
        "code": "C201355",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "Start to Start",
        "instanceType": "Code"
      },
      "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E03",
      "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
      "windowLower": null,
      "windowUpper": null,
      "windowLabel": null,
      "instanceType": "Timing"
    },
    {
      "id": "Timing_4",
      "extensionAttributes": [],
      "name": "TIM4",
      "label": "Day 15",
      "description": null,
      "type": {
        "id": "Code_15",
        "extensionAttributes": [],
        "code": "C201356",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2025-09-26",
        "decode": "After",
        "instanceType": "Code"
```


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```
        },
        "value": "P14D",
        "valueLabel": "14 Days",
        "relativeToFrom": {
          "id": "Code_16",
          "extensionAttributes": [],
          "code": "C201355",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2025-09-26",
          "decode": "Start to Start",
          "instanceType": "Code"
        },
        "relativeFromScheduledInstanceId": "ScheduledActivityInstance_E04",
        "relativeToScheduledInstanceId": "ScheduledActivityInstance_E02",
        "windowLower": "P1D",
        "windowUpper": "P1D",
        "windowLabel": "+/- 1 day",
        "instanceType": "Timing"
      }
    ],
    "instances": [
      {
        "id": "ScheduledActivityInstance_E01",
        "extensionAttributes": [],
        "name": "SCREEN1",
        "label": "Screening -28 to -1",
        "description": "-",
        "defaultConditionId": "ScheduledDecisionInstance_E02",
        "epochId": "StudyEpoch_1",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_1",
          "Activity_2",
          "Activity_3"
        ],
        "encounterId": "Encounter_1"
      },
      {
        "id": "ScheduledActivityInstance_E02",
        "extensionAttributes": [],
        "name": "DAY1",
        "label": "Day 1",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E03",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_2",
          "Activity_3",
          "Activity_4"
        ],
        "encounterId": "Encounter_2"
      },
      {
        "id": "ScheduledActivityInstance_E03",
        "extensionAttributes": [],
        "name": "DAY8",
```


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```
        "label": "Day 8",
        "description": "-",
        "defaultConditionId": "ScheduledActivityInstance_E04",
        "epochId": "StudyEpoch_2",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": null,
        "activityIds": [
          "Activity_2"
        ],
        "encounterId": "Encounter_3"
      },
      {
        "id": "ScheduledActivityInstance_E04",
        "extensionAttributes": [],
        "name": "DAY15",
        "label": "Follow-up (Day 15)",
        "description": "-",
        "defaultConditionId": null,
        "epochId": "StudyEpoch_3",
        "instanceType": "ScheduledActivityInstance",
        "timelineId": null,
        "timelineExitId": "ScheduleTimelineExit_1",
        "activityIds": [
          "Activity_2",
          "Activity_3"
        ],
        "encounterId": "Encounter_4"
      }
    ],
    "plannedDuration": null,
    "instanceType": "ScheduleTimeline"
  }
]
```


Activities


```
[
  {
    "id": "Activity_1",
    "extensionAttributes": [],
    "name": "IC",
    "label": "Informed Consent",
    "description": "",
    "previousId": null,
    "nextId": "Activity_2",
    "childIds": null,
    "definedProcedures": [],
    "biomedicalConceptIds": [
      "BiomedicalConcept_1"
    ],
    "bcCategoryIds": [],
    "bcSurrogateIds": [],
    "timelineId": null,
    "notes": [],
    "instanceType": "Activity"
  },
  {
```


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```
      "id": "Activity_2",
      "extensionAttributes": [],
      "name": "VS",
      "label": "Vital Signs",
      "description": "",
      "previousId": "Activity_1",
      "nextId": "Activity_3",
      "childIds": [],
      "definedProcedures": [],
      "biomedicalConceptIds": [
        "BiomedicalConcept_2",
        "BiomedicalConcept_3",
        "BiomedicalConcept_4",
        "BiomedicalConcept_5"
      ],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    },
    {
      "id": "Activity_3",
      "extensionAttributes": [],
      "name": "PREG",
      "label": "Pregnancy test",
      "description": "",
      "previousId": "Activity_2",
      "nextId": "Activity_4",
      "childIds": [],
      "definedProcedures": [],
      "biomedicalConceptIds": [
        "BiomedicalConcept_6"
      ],
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    },
    {
      "id": "Activity_4",
      "extensionAttributes": [],
      "name": "ADMIN",
      "label": "Drug administration",
      "description": "",
      "previousId": "Activity_3",
      "nextId": null,
      "childIds": [],
      "definedProcedures": [
        {
          "id": "Procedure_11",
          "extensionAttributes": [],
          "name": "PR11",
          "label": "Medication dispensed",
          "description": "",
          "procedureType": "Medication",
          "code": {
            "id": "CodeX_15",
            "extensionAttributes": [],
            "code": "373784005",
```


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```
            "codeSystem": "SNOMED",
            "codeSystemVersion": "2025-02-01",
            "decode": "Dispensing medication",
            "instanceType": "Code"
          },
          "studyInterventionId": "StudyIntervention_1",
          "notes": [],
          "instanceType": "Procedure"
        }
      ],
      "biomedicalConceptIds": null,
      "bcCategoryIds": [],
      "bcSurrogateIds": [],
      "timelineId": null,
      "notes": [],
      "instanceType": "Activity"
    }
  ]
```


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Appendix B: Implementation Handbook Team

Name	Institution/Organization
John Owen	Project Manager, CDISC
Berber Snoeijer	USDM Expert and Primary Technical Writer, CDISC
Darren Moreland	Co-technical Writer and Technical Reviewer, CDISC
Edwin van Stein	Co-technical Writer and Technical Reviewer, CDISC
Anthony Chow	Use Case SME, CDISC
Lorraine Sobson	Copy Editor, CDISC

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Name
Brian Harris
Ryan Hoag
Nicolas de Saint Jorre
Rachinnth Ravichandran

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Appendix C: Glossary and Abbreviations

The following abbreviations and terms are used in this document. Additional definitions can be found in the sections of this implementation handbook, in the USDM-IG v4.0, and in the CDISC Glossary (https://www.cdisc.org/standards/glossary).

Term	Description
AI	Artificial intelligence
AMA	American Medical Association
anchor	A defined timepoint in a study to which other timepoints are related either directly or indirectly. This is typically time 0 (e.g., first dosing day) or, for an observational study (part), the first timepoint in the observation period.
API	Application programming interface
BC	(CDISC) Biomedical Concept
CDISC	Clinical Data Interchange Standards Consortium
CDASH	CDISC CDASH (Clinical Data Acquisition Standards Harmonization) is a foundational standard that provides a universal, consistent way to collect raw data at the point of origin in clinical trials and research studies.
CORE	CDISC Open Rules Engine
COSA	CDISC Open Source Alliance
csv	comma-separated values
CPT-4	(AMA) Current Procedural Terminology, 4th Edition; unform language for describing and tracking medical and diagnostic services across a healthcare system
CT	(CDISC) Controlled Terminology
DDF	Digital data flow
Define-XML	Define-XML transmits metadata in an xml format that describes any tabular dataset structure. When used with the CDISC foundational standards, it provides the metadata for human and animal model datasets using the SDTM and/or SEND standards and analysis datasets using ADaM.
ECG	Electrocardiogram
EDC	Electronic data capture
HTML	Hypertext markup language
ICD-10-PS	(US) International Classification of Diseases, 10th Revision, Procedure Coding System, used to classify inpatient procedures performed in hospital settings
ISO 8601	International Organization for Standardization standard for dates, times, and durations (e.g., P14D for a period of 14 days)
JSON	JavaScript Object Notation, a lightweight, text-based data-interchange format designed to be human-readable and easy for machines to parse and generate
MCP	Model Context Protocol; an open protocol through which AI agents access tools and data sources
MDR	Metadata Repository
PDF	Portable document format
PK/PD	Pharmacokinetic/Pharmacodynamic : activities that include sampling, usually at multiple times a day, to assess the behavior of the drug concentration (PK) and it's effects (PD) through time.
Python	An interpreted, object-oriented, high-level programming language with dynamic semantics

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Term	Description
REST API	Representational state transfer API, an architectural design pattern that enables different software applications to communicate over the internet. First defined by computer scientist Roy Fielding in 2000, it serves as the universal standard translator for modern web and mobile applications to request and exchange data with servers.
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide
SoA	Schedule of activities
SoA automation feature	Software functionality to automatically render, distribute, compare, and validate the digitized schedule of activities, which may either be included in a study design solution or provided by separate downstream solutions
Study design solution	Either custom built software or commercially available software that aids in digitally capturing the study design which can be represented as a clinical study protocol and can utilize/export the design in USDM format
TDM	(SDTM) Trial Design Model
TV	Trial Visits; the SDTM Trial Design domain describing the planned visits of a study
USDM	Unified Study Definitions Model
USDM-IG	USDM Implementation Guide
USDM-HB1	USDM Implementation Handbook 1
USDM-HB2	USDM Implementation Handbook 2
USDM-HB3	USDM Implementation Handbook 3

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Appendix D: References

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