

# Digital Data Flow

Last Updated: 4th November 2023

WITH STANDARDS – UNLOCK THE POWER OF DATA

This initiative aims to move the drug development process from a current state of manual, study start-up asset creation (i.e. Case Report Forms, Procedure Manuals, Statistical Analysis Plans, and Schedule of Activities) to a future state of fully automated, dynamic, study start-up readiness via an open-sourced, vendor-agnostic technical solution that will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators.

## Links

- Transcelerate Digital Data Flow page
  - <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/>
- CDISC DDF Page
  - <https://www.cdisc.org/ddf>
- CDISC Github
  - <https://github.com/cdisc-org/DDF-RA>

## Main Elements

- Reference Architecture (CDISC)
  - Unified Study Definitions Model (USDM)
  - Controlled Terminology (CT)
  - Application Programming Interface (API)
  - Implementation Guide (IG)
- Reference Implementation (Accenture), the Study Definitions Repository (SDR)



2022  
US  
INTERCHANGE  
26-27 OCTOBER | AUSTIN



CDISC's Activities on DDF, Benefits for the Community, and Looking Ahead

Presented by D Iberson-Hurst  
Partner d4k & CDISC DDF Product Owner

## Project Background (see slide deck above)

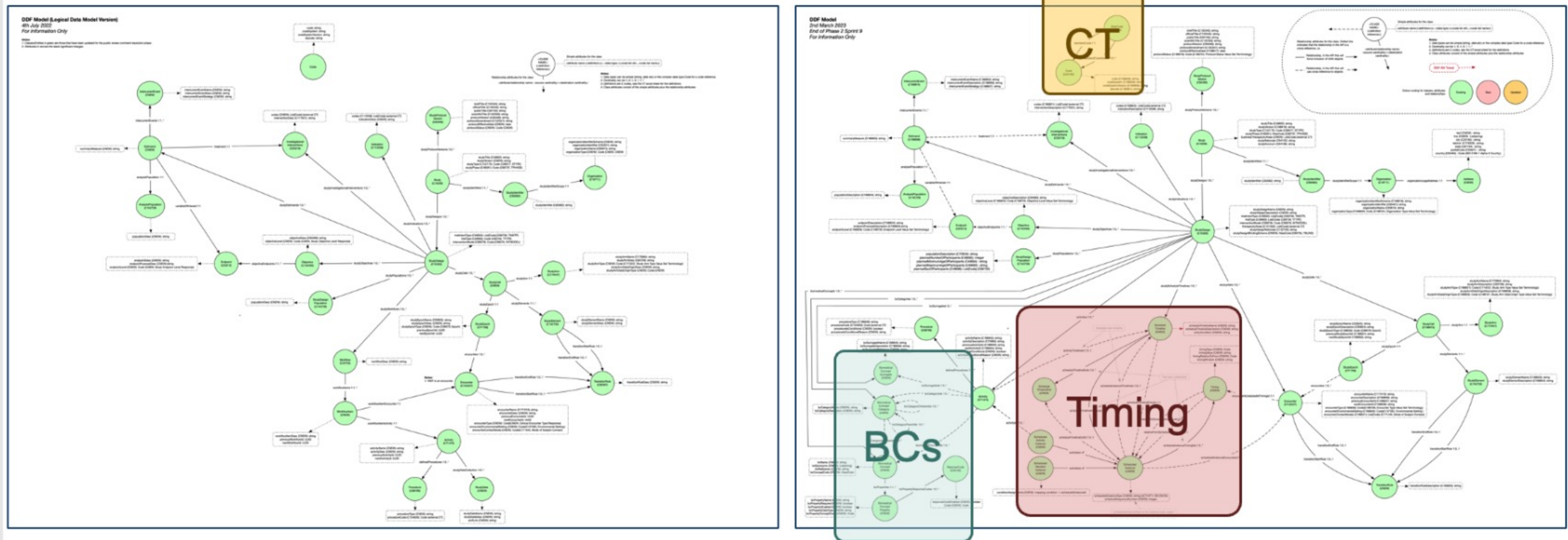
- Phase 1 -> USDM V1
- Phase 2 -> USDM V2
- Phase 3 -> USDM V3
- **In development until end of 2023**
- **V3 to be published April 2024 approx.**

## MIRO Board Status

- Used for technical run throughs
- Staging zone for Implementation Guide content
- **Status: Informational. Updated regularly**

# Phase One and Two

## CDISC DDF Phase One v Two



### CDISC DDF Phase One

July, 2021 – July 2022

- Unified Study Definitions Model (USDM) Class Diagram**  
The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)
- Application Programming Interface (API) Specification**  
The API definition (normative) in JSON and HTML forms
- CDISC Controlled Terminology**  
The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.
- Reference Architecture Conformance Tests**  
Provided by the functionality provided by tools such as SwaggerHub and Postman
- Essential Users Stories**  
The User Stories. PDF document
- Architecture Principles**  
The architectural principles developed by the project. PDF Document
- Supporting Materials**  
A set of informational materials in PDF format to help understand the deliverables being reviewed. PDF documents or references.



V1.0 Provisional  
<https://www.cdisc.org/ddf>

### Phase One & Two

- Small slide deck re Phase One and Two

### Changes Between Phase One and Two

- Addition of timing within studies to schedule activities accurately
- Addition of Biomedical Concepts (BCs)
- Improvements to CT handling
- Additional attributes in some classes to support TCB CPT

# Phase Three

Come to the session at PHUSE EU Connect 2023

- Tuesday 7th November, 11:30am, Hall 10A

## Tuesday 7 November

Time (GMT)	Hall 6a	Hall 7	Hall 9	Hall 10A
06:30	PHUSE 5k Run Around Birmingham – Meet Outside the ICC <i>All abilities welcome</i>			
09:00 - 10:30	Keynote Speaker – Gareth Thomas   Plenary Room – Hall 1			
10:30–11:00	Morning Break			
11:00–11:30	<b>TT06: Red Pill or Blue Pill? Assessing the Impact of Artificial Intelligence on Pharmaceutical Programming</b> <i>Katalyze Data</i>	<b>PM04: Navigating Unprecedented Challenges: Journey Through a Pandemic and International Conflict</b> <i>Veramed</i>	<b>Panel Discussion</b> Let's Discuss Open Source Openly: A New Path in Pharma	<b>Connect Theme Presentations (DS)</b> Digital Data Flow – From Vision to Reality  <b>DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality</b> <i>CDISC</i>
11:30–12:00	<b>TT14: Automation and Orchestration of Data Science Applications Using OpenAPI</b> <i>Entimo</i>	<b>PM05: An Agile Approach to Onboarding</b> <i>GSK</i>		<b>DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs</b> <i>data4knowledge &amp; CDISC</i>
12:00–12:30	<b>TT16: Taking Down the Fence Between Biostatistics and Medical Writing</b> <i>GSK</i>	<b>PM06: Statistical Programming – Hiring Mission Made Possible</b> <i>Johnson &amp; Johnson</i>		<b>DS03: The Digital Protocol Is Just the Beginning. Or Is It?</b> <i>Instem</i>

## The TransCelerate / CDISC Digital Data Flow Project: Practical Electronic Study Designs

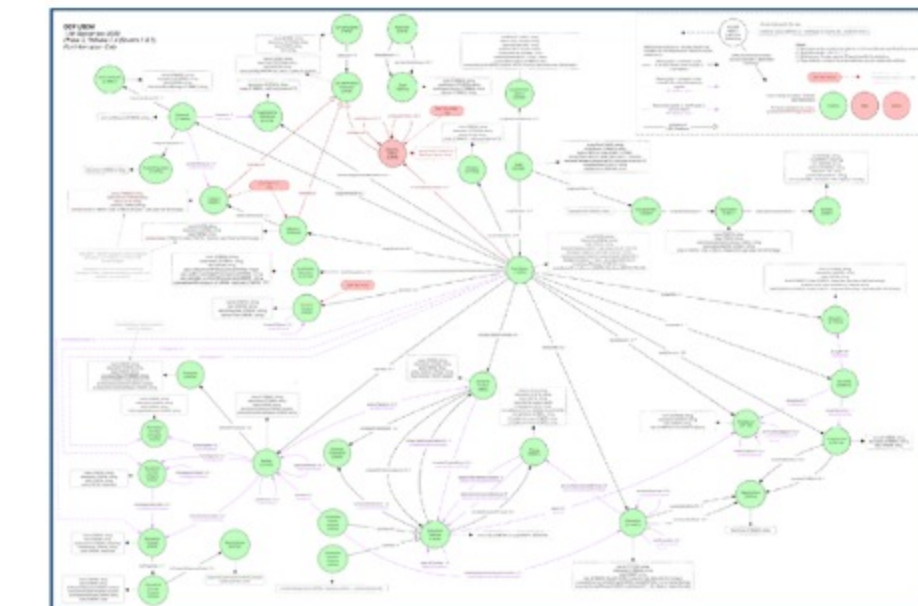
PHUSE EU Connect 2023 (DS02)

Dave Iberson-Hurst, CDISC Product Owner  
7<sup>th</sup> November 2023, Version 3



## Shift of Focus

- Phases One & Two
  - Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA)
  - The protocol document was an external entity into which the structured content could be exported
- Phase Three
  - Now contains structured and unstructured elements
  - The entire protocol document is held within the USDM
  - Allows for the protocol document to be generated from the model



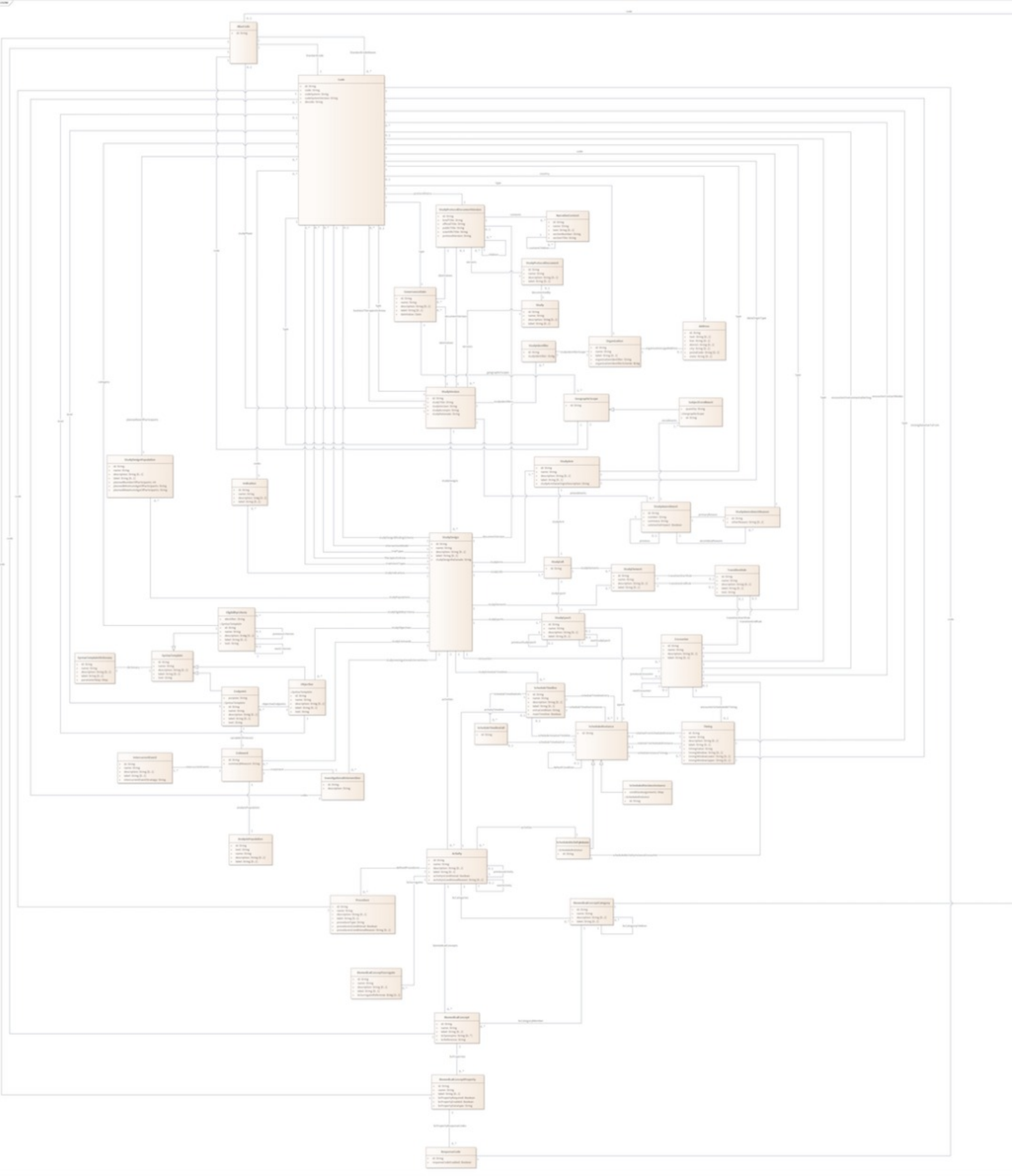
# UML Model

## UML

- The normative Unified Study Definitions Model (USDM)
- Available from Github

## Links

- CDISC Github
  - <https://github.com/cdisc-org/DDF-RA/tree/main/Deliverables/UML>



# Controlled Terminology

	A	B	C	D	E	F	G	H	I
1	Row #	Entity Name	Role	Logical Data Model Name	NCI C-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List
12	StudyProtocolVersion	Entity	StudyProtocolVersion	C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	N	
13	StudyProtocolVersion	Attribute	briefTitle	C132345	Brief Protocol Title	Abbreviated Protocol Title	The short descriptive name for the protocol.	N	
14	StudyProtocolVersion	Attribute	officialTitle	C132346	Official Protocol Title		The formal descriptive name for the protocol.	N	
15	StudyProtocolVersion	Attribute	publicTitle	C94105	Public Protocol Title		The descriptive name of the protocol that is intended for the lay public, written in easily understood language.	N	
16	StudyProtocolVersion	Attribute	scientificTitle	C132350	Scientific Protocol Title		A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.	N	
17	StudyProtocolVersion	Attribute	protocolVersion	C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	N	
18	StudyProtocolVersion	Attribute	protocolAmendment	C132347	Study Protocol Amendment		A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)	N	
19	StudyProtocolVersion	Attribute	protocolEffectiveDate	C188817	Study Protocol Amendment Effective Date		The date and time specifying when the protocol amendment takes effect or becomes operative.	N	
20	StudyProtocolVersion	Attribute	protocolStatus	C188818	Protocol Status		A condition of the protocol at a point in time with respect to its state of readiness for implementation.	Y (C188723)	
21									

## CT

- Provides a list of all classes and attributes
- Provides a definition
- Provides CT references
- Available from Github
- IG now has a UML and CT "merge" summary

## Links

- CDISC Github
  - <https://github.com/cdisc-org/DDF-RA/tree/main/Deliverables/CT>

# API

## Simple API for DDF 1.7 Provisional (0.31) OAS3

/openapi.json

A simple TransCelerate Digital Data Flow (DDF) Study Definitions Repository API.

### Production Routes that form the production specification.

POST	/v1/studyDefinitions	Create a study	∨
GET	/v1/studyDefinitions/{uuid}	Return a study	∨
PUT	/v1/studyDefinitions/{uuid}	Update a study	∨
GET	/v1/studyDefinitions/{uuid}/history	Returns the study history	∨
GET	/v1/studyDesigns	Study designs for a study	∨

## API

- OpenAPI specification
- Bulk API
- Available from Github

## Links

- CDISC Github
  - <https://github.com/cdisc-org/DDF-RA/tree/main/Deliverables/API>

# Implementation Guide

## Implementation Guide

- Note that the IG is version 2
- There was no IG with version 1 of the USDM
- Available from Github

## Links

- CDISC Github
  - <https://github.com/cdisc-org/DDF-RA/tree/main/Deliverables/IG>



## Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 2.0 (Draft for Internal Review)

Prepared by the  
DDF Team

### Notes to Readers

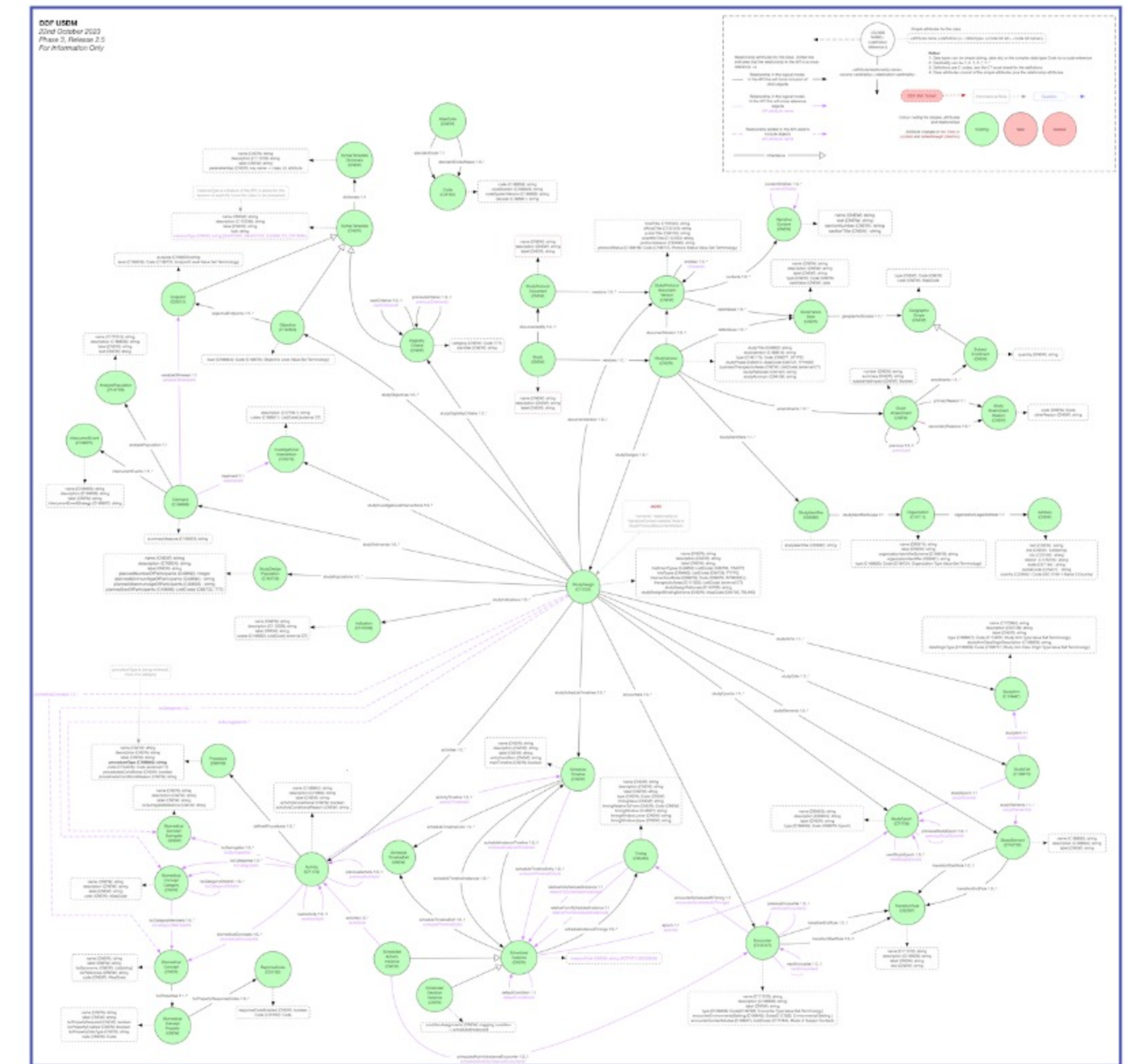
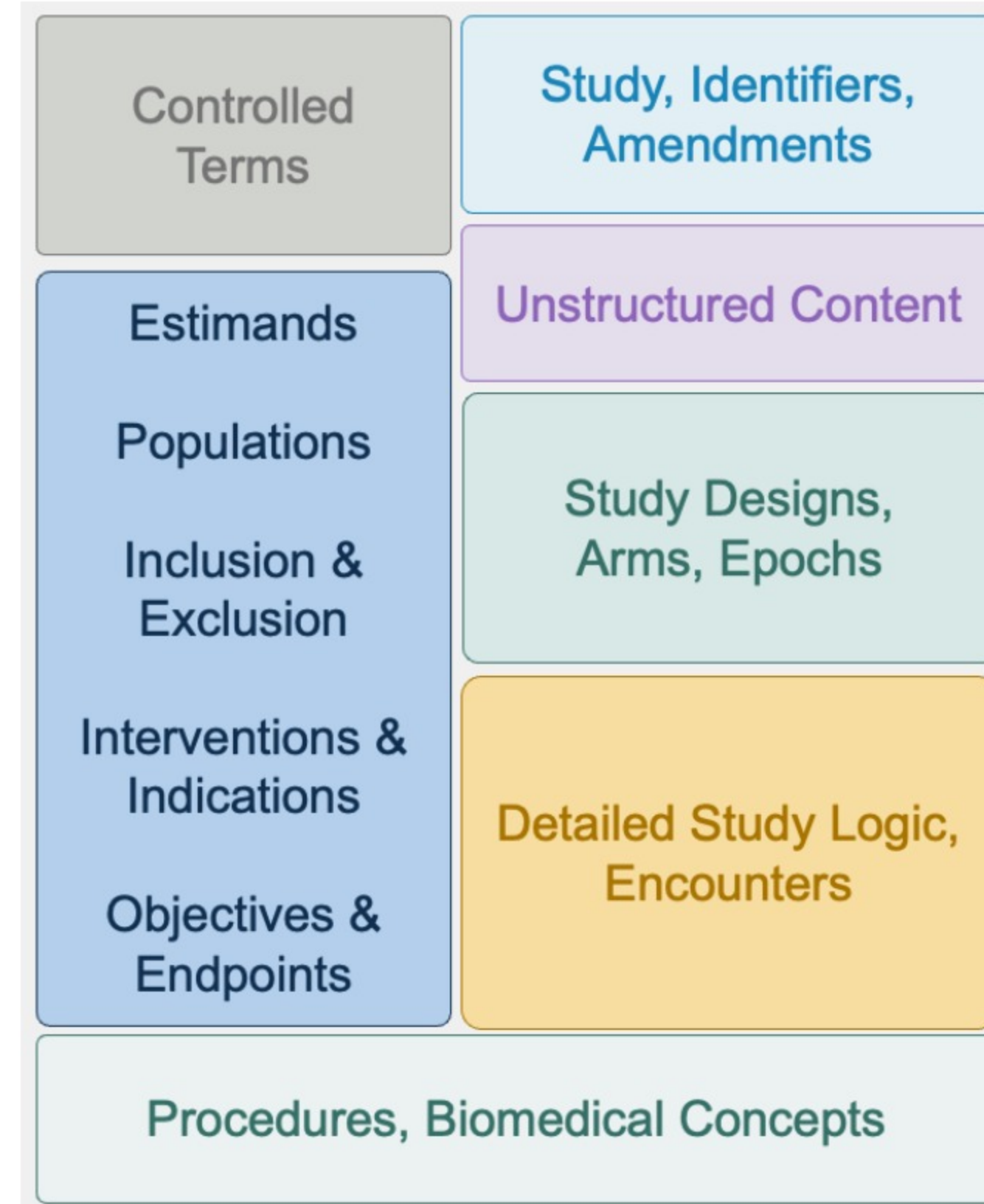
- This is the draft version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0). It is intended for Internal Review only and is not a final version.

### Revision History

Date	Version
2023-03-08	2.0 Draft for Internal Review

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# Overview

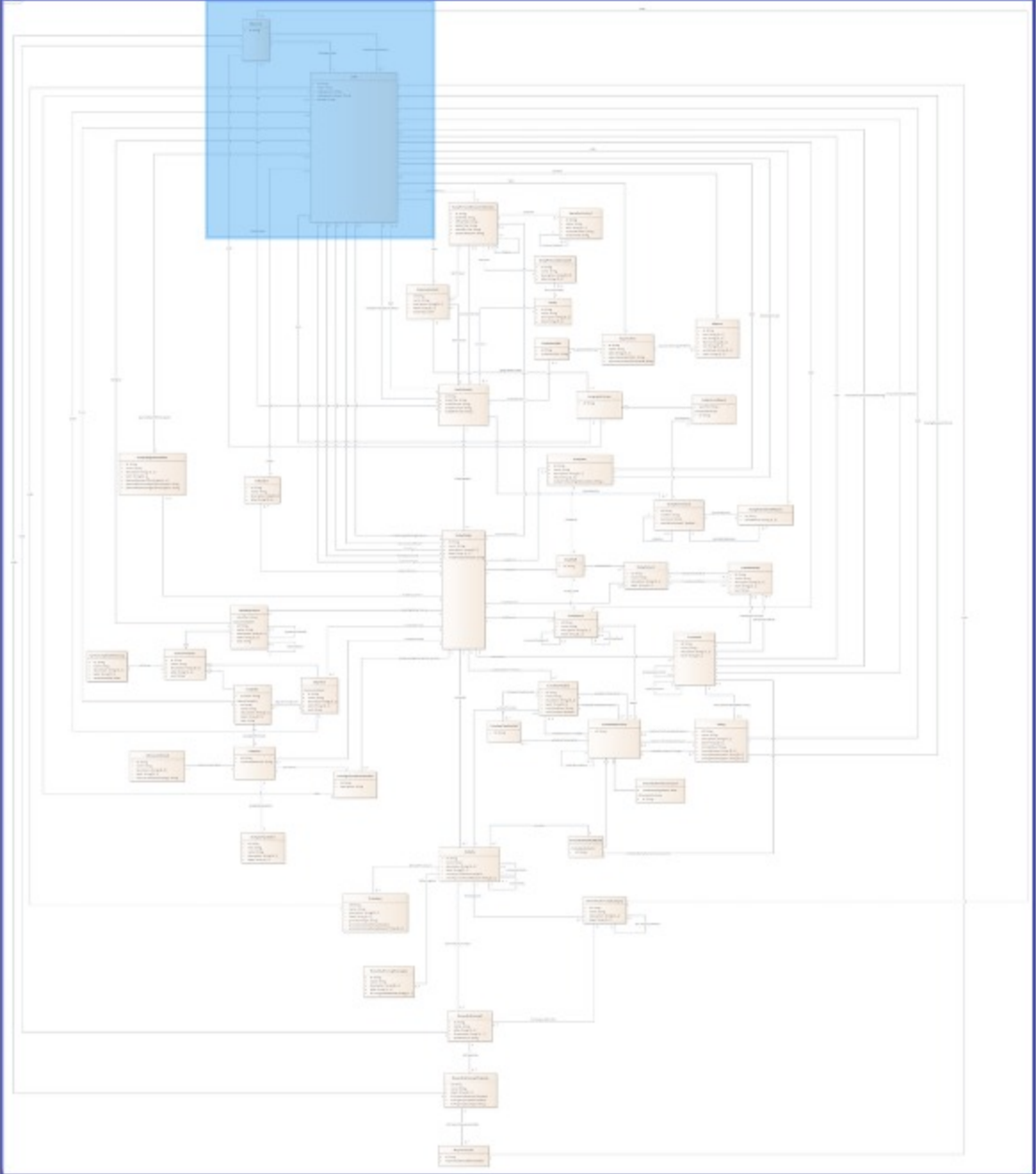


## "Green Blob" Diagram

- **Informative view. The UML is the Normative form**
- Used to discuss ideas before putting into normative UML
- Used as a cross-check of normative deliverables at end of sprints
- <https://github.com/cdisc-org/DDF-RA/blob/main/Documents/DDF%20USDM%20Model%20Informative.png>



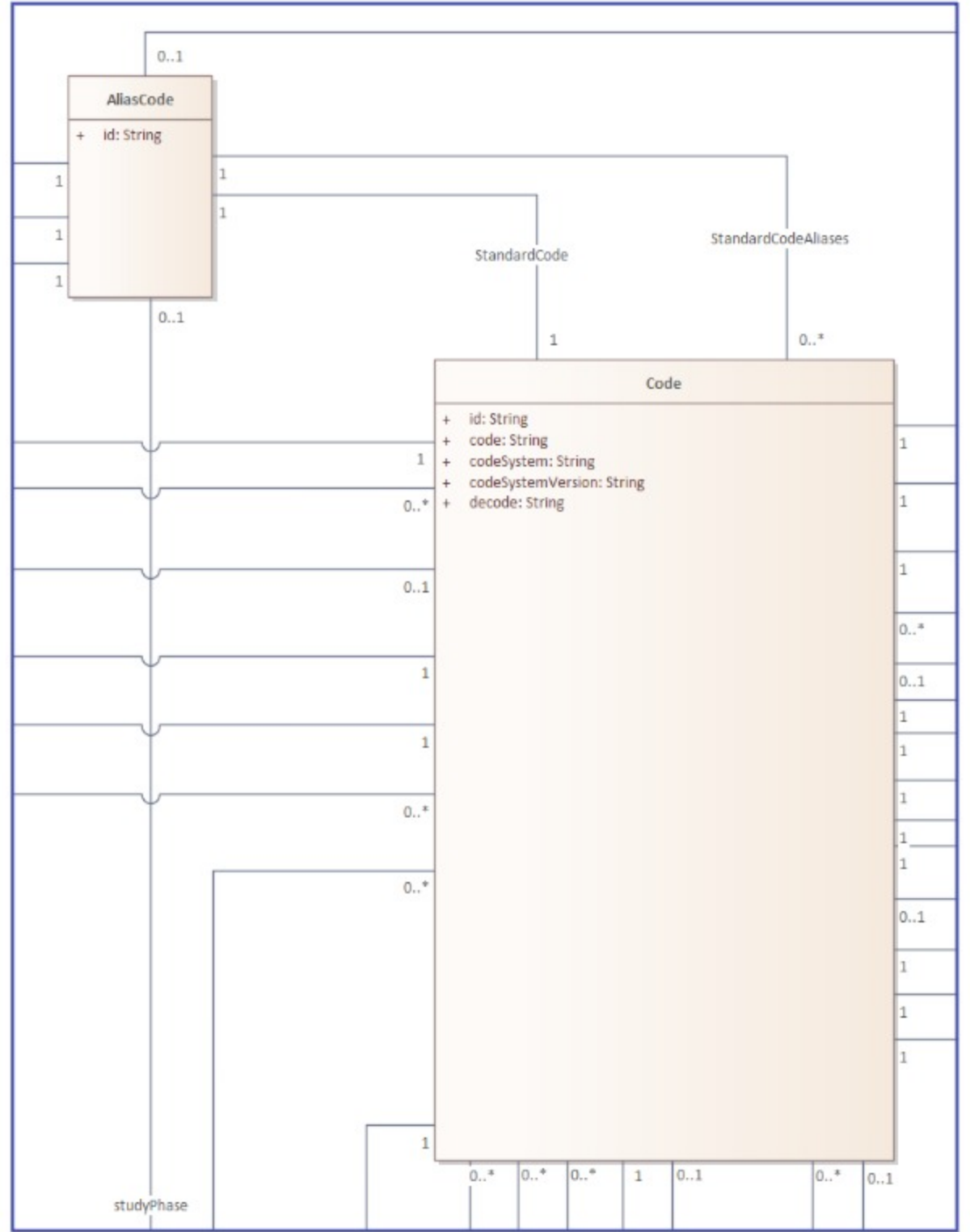
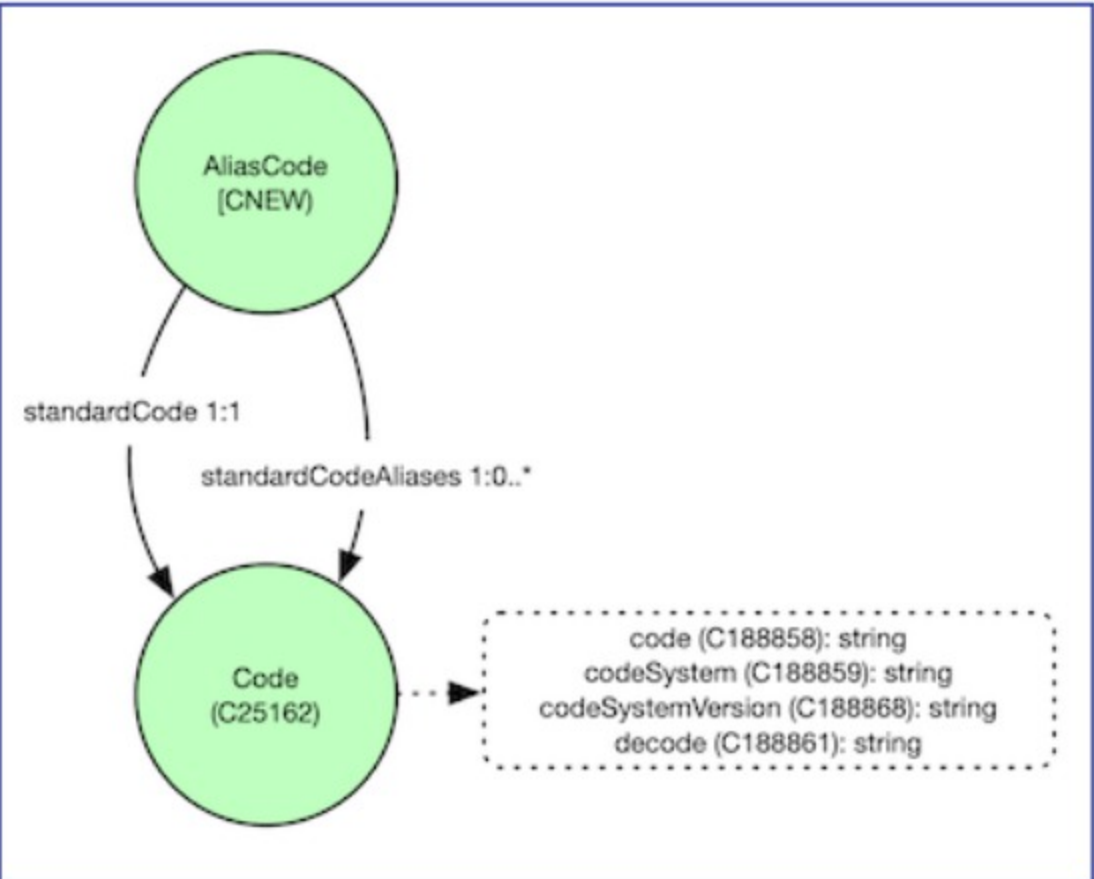
# AliasCode and Code



```

{
  "id": "id_123",
  "standardCode": {
    "id": "code_29",
    "code": "C25299",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2022-03-25",
    "decode": "Diastolic Blood Pressure"
  },
  "standardCodeAliases": [
    {
      "id": "code_30",
      "code": "8462-4",
      "codeSystem": "http://loinc.org/",
      "codeSystemVersion": "2022-03-25",
      "decode": "Diastolic Blood Pressure"
    },
    {
      "id": "code_31",
      "code": "271650006",
      "codeSystem": "SNOMED-CT",
      "codeSystemVersion": "2003",
      "decode": "Diastolic Blood Pressure"
    },
    {
      "id": "code_32",
      "code": "4154790",
      "codeSystem": "OHSDI",
      "codeSystemVersion": "",
      "decode": "Diastolic Blood Pressure"
    }
  ]
}

```



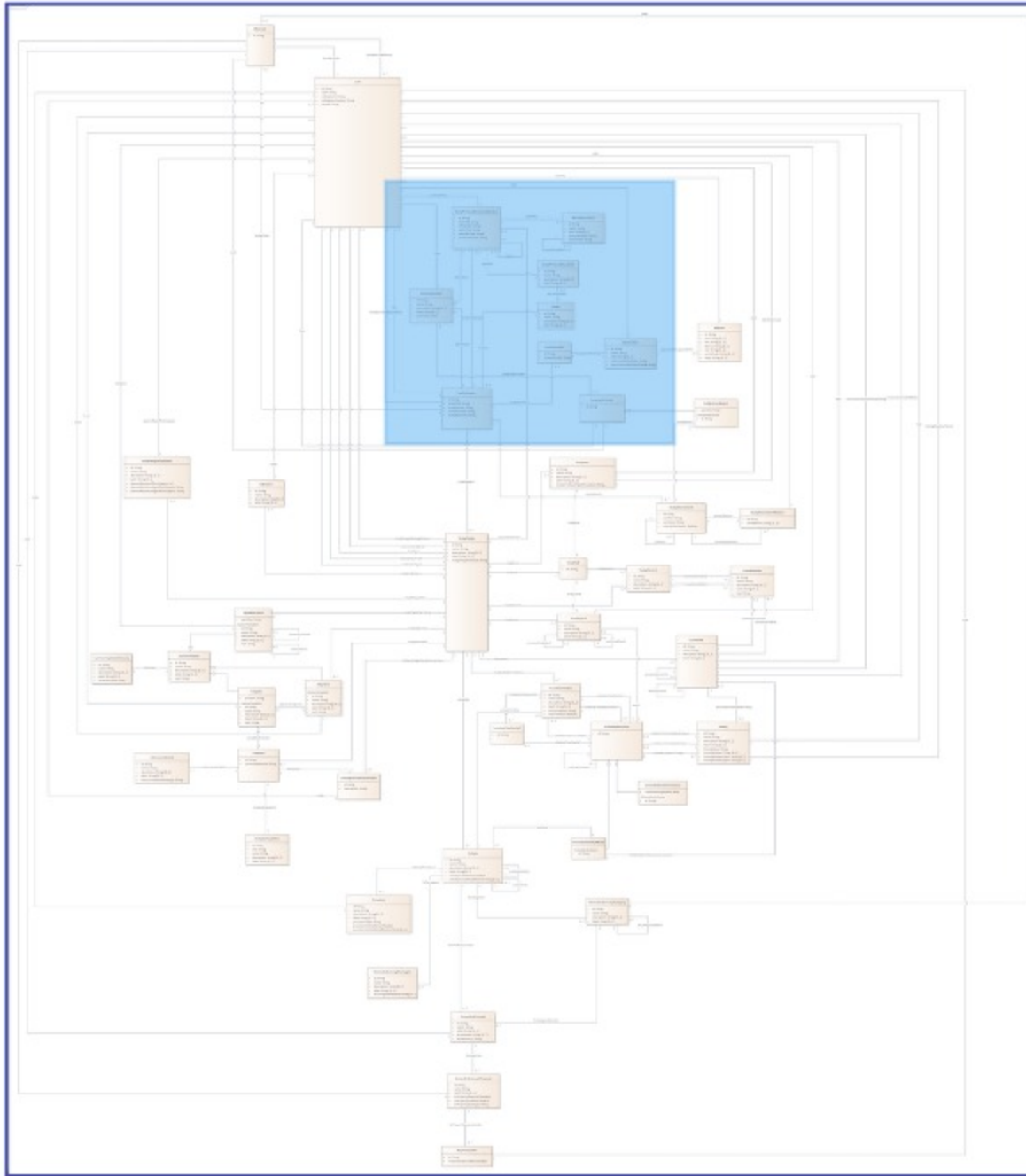
## AliasCode and Code

- Code is a standard code reference
  - CDISC CT
  - All other CT
- AliasCode is a mechanism to align a CDISC Code with codes from other CT
  - One standard (CDISC) code
  - Many alternatives

## JSON

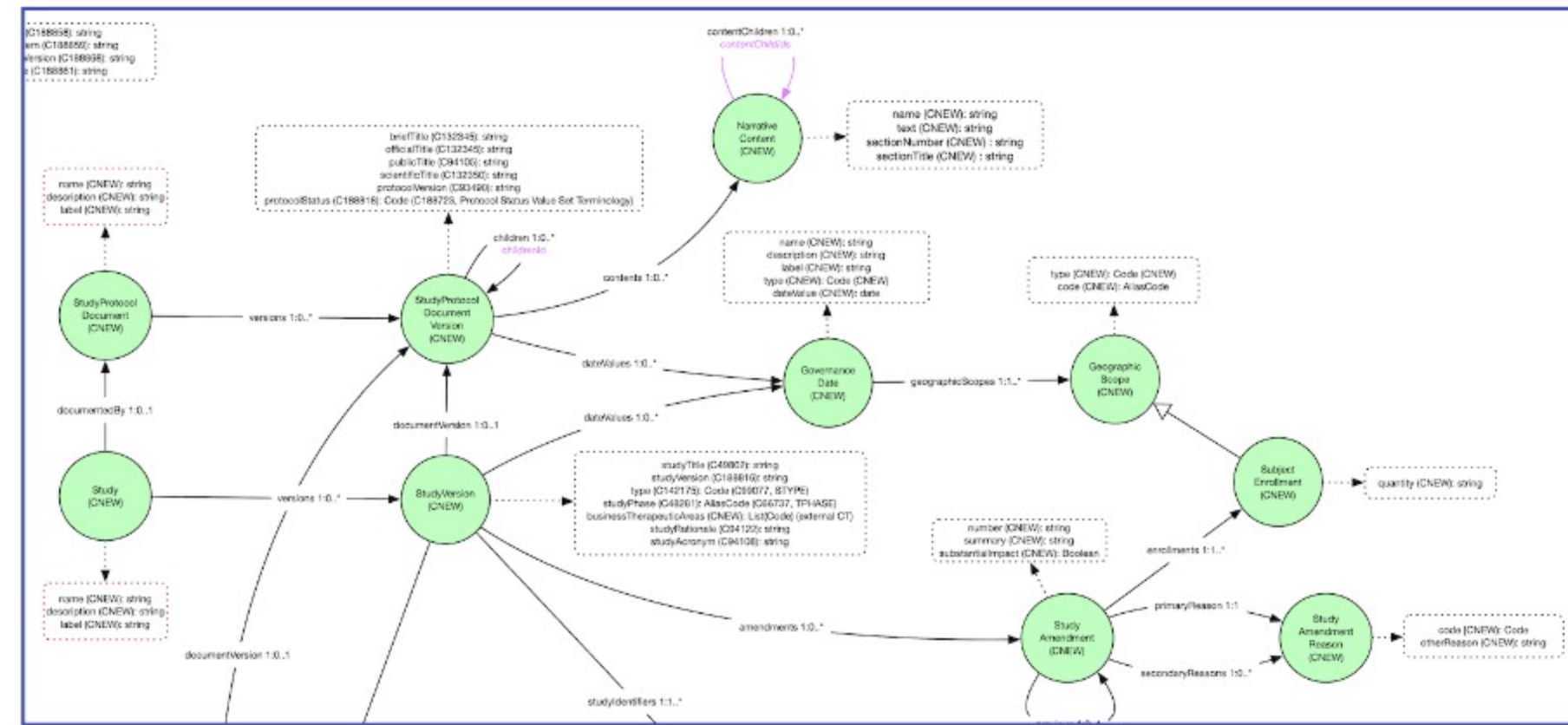
- Machine Format
- Human readable ... ish
- AliasCode
  - Has an id
  - Has one standardCode
    - A single Code
  - Has many standardCodeAliases
    - An array of Code
  - All other CT
- Code has
  - An id
  - code
  - codeSystem
  - codeSystemVersion
  - decode
- Note the indentation

# Study



## Study

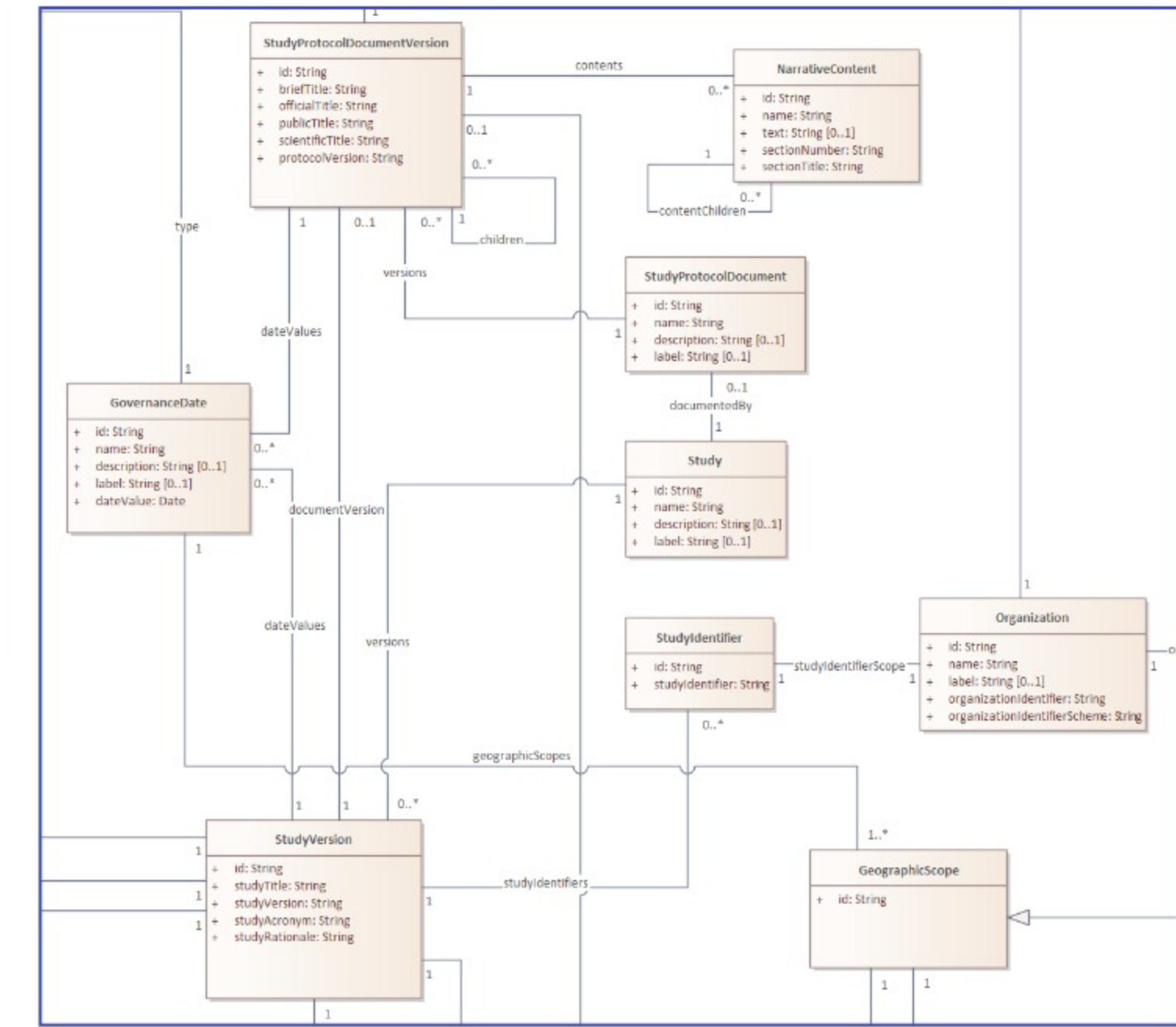
- Study is the root of the whole model
- Study is the overall container that links to many study versions and the protocol document
- Protocol document is a container linking to many protocol document versions



```

{
  "study": {
    "id": <UUID HERE>,
    "name": "Study_SCOPE1",
    "description": null,
    "label": null,
    "versions": [
      ...
    ],
    "documentedBy": {
      "id": "StudyProtocolDocument_1",
      "name": "Protocol_Document_SCOPE1",
      "label": null,
      "description": null,
      "versions": [
        ...
      ]
    }
  }
}

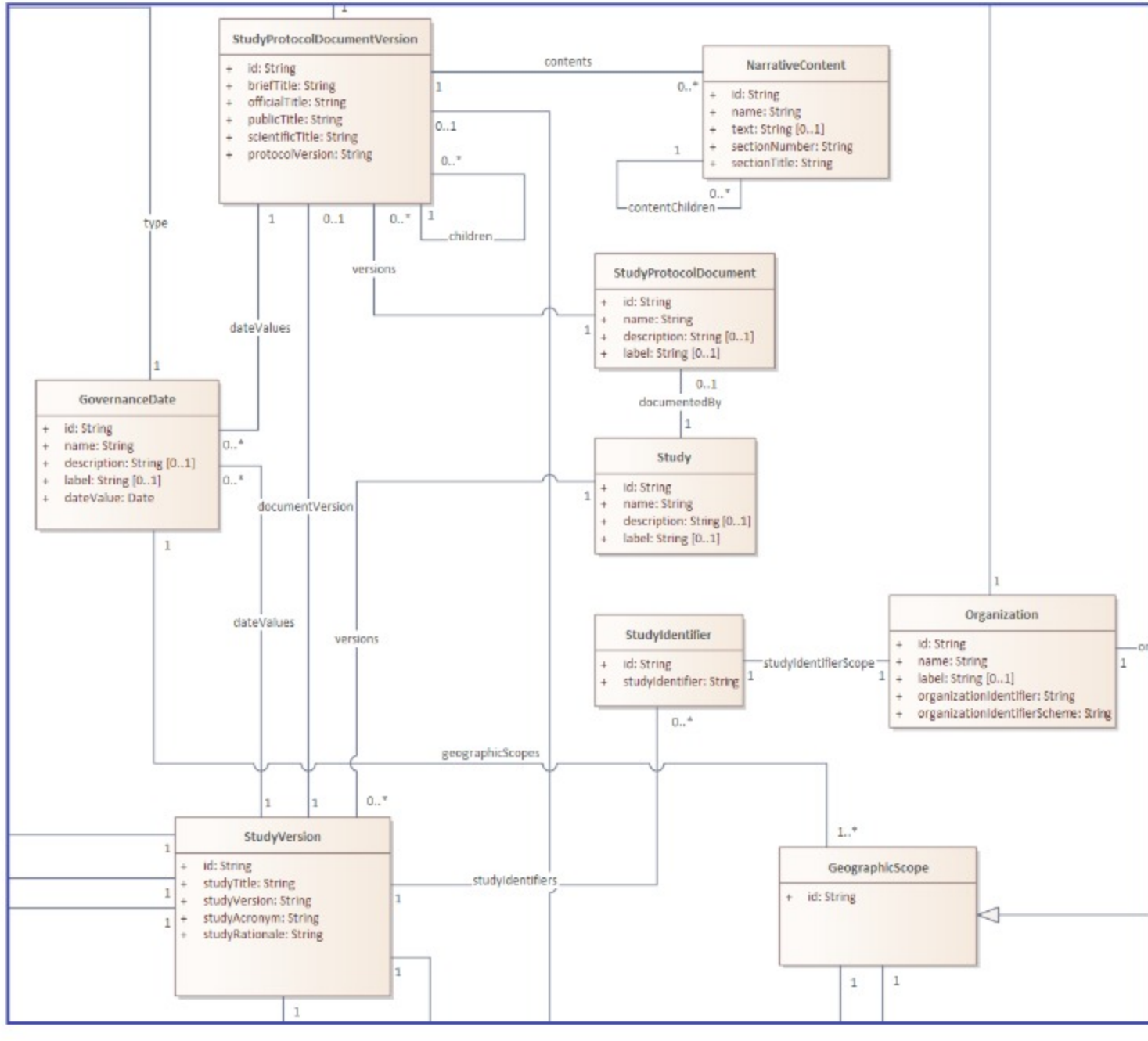
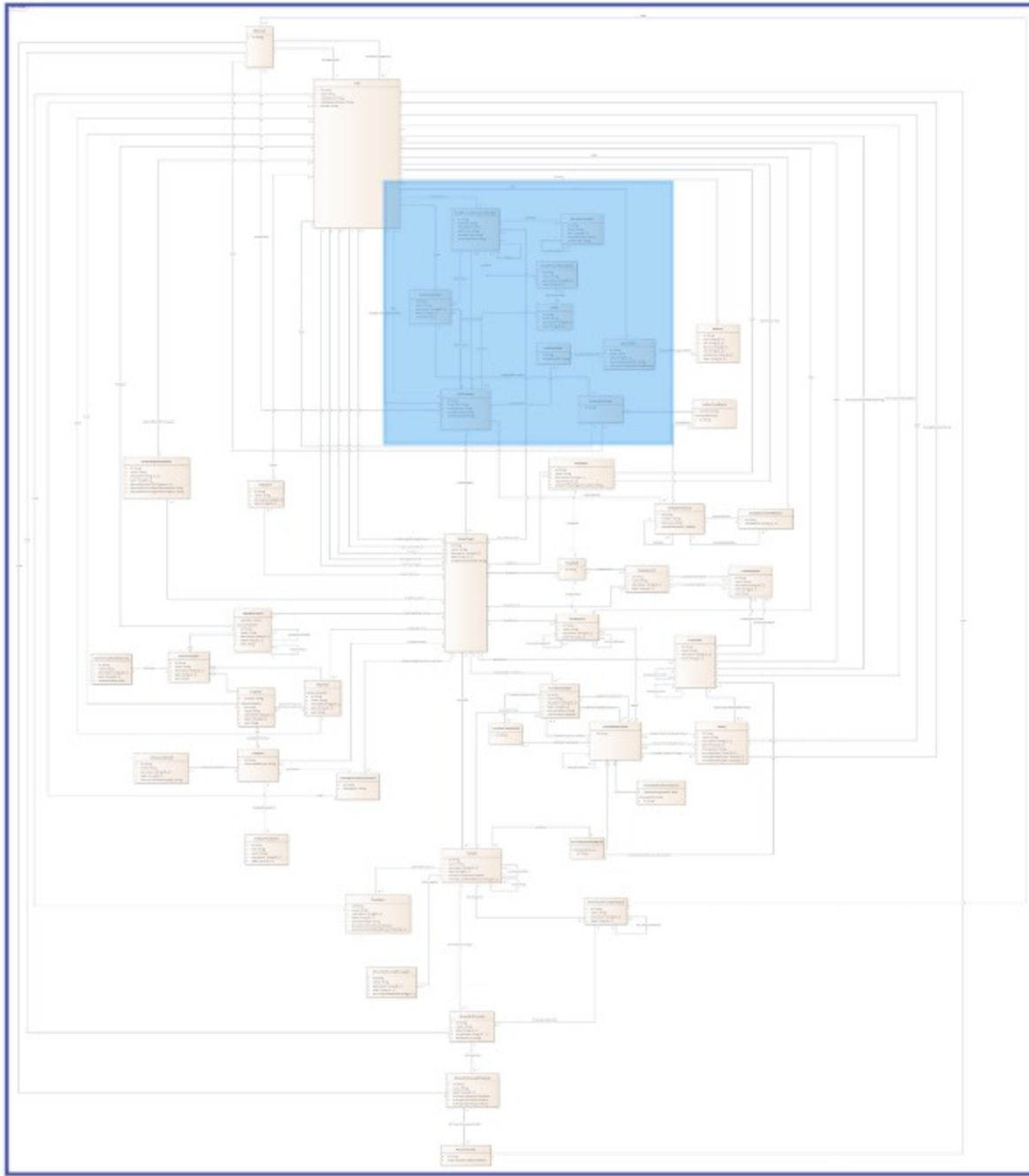
```



## Instance Identifiers

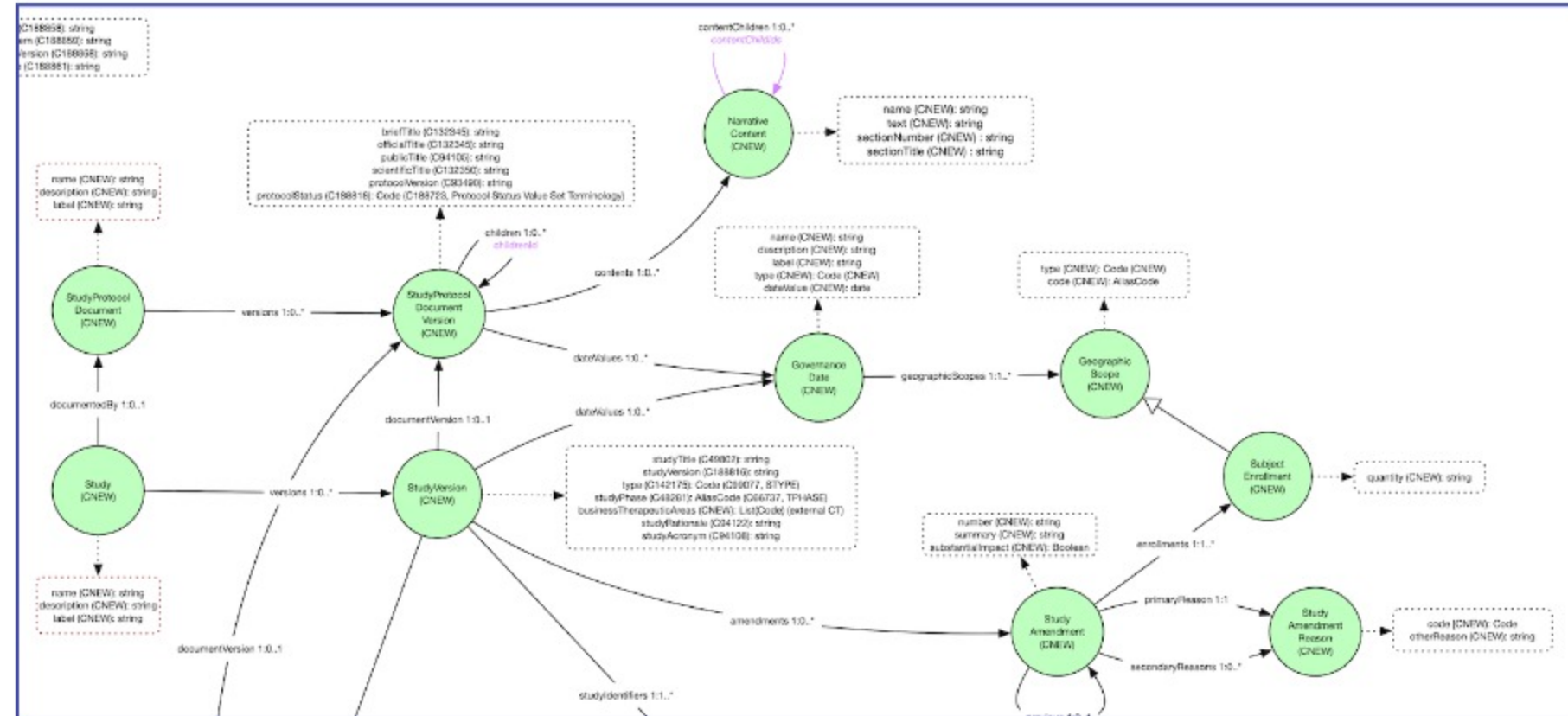
- Study has a UUID (allocated by the SDR for example)
- All other objects have internal ids that should be unique across the study
- Ids are used to
  - Uniquely identify an instance
  - For cross-references so that content is only defined in one place when an entire study is serialised into JSON

# Document



## Document

- Container for the document versions
- Currently envisaged to be the protocol document
- Could be extended to multiple document types

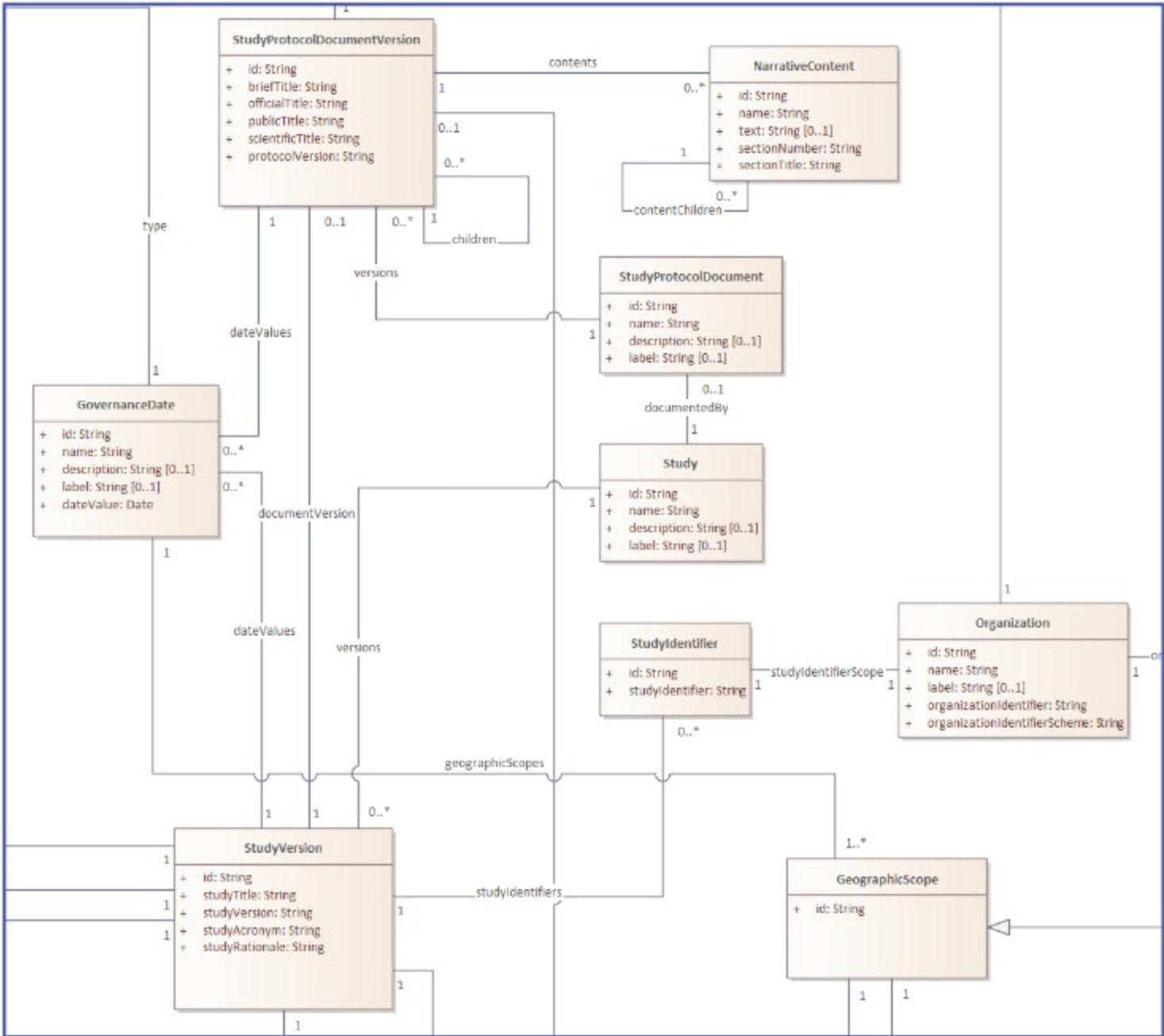
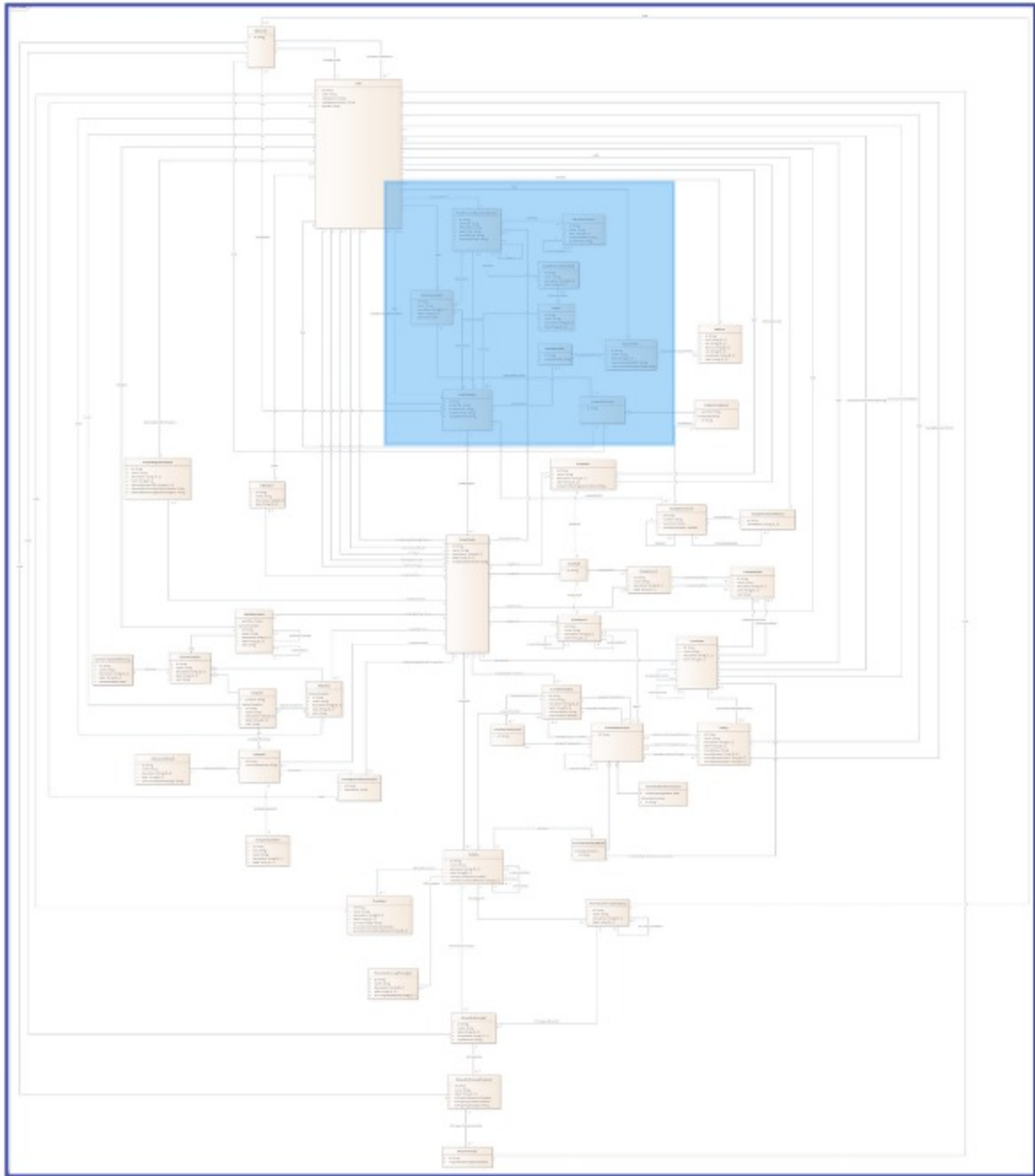


```

{
  "study": {
    "id": null,
    "name": "Study_CDISC PILOT - LZTZ",
    "description": null,
    "label": null,
    "versions": [ ... ],
    "documentedBy": {
      "id": "StudyProtocolDocument_1",
      "name": "Protocol_Document_CDISC PILOT - LZTZ",
      "label": null,
      "description": null,
      "versions": [
        { ... }
      ]
    }
  }
}

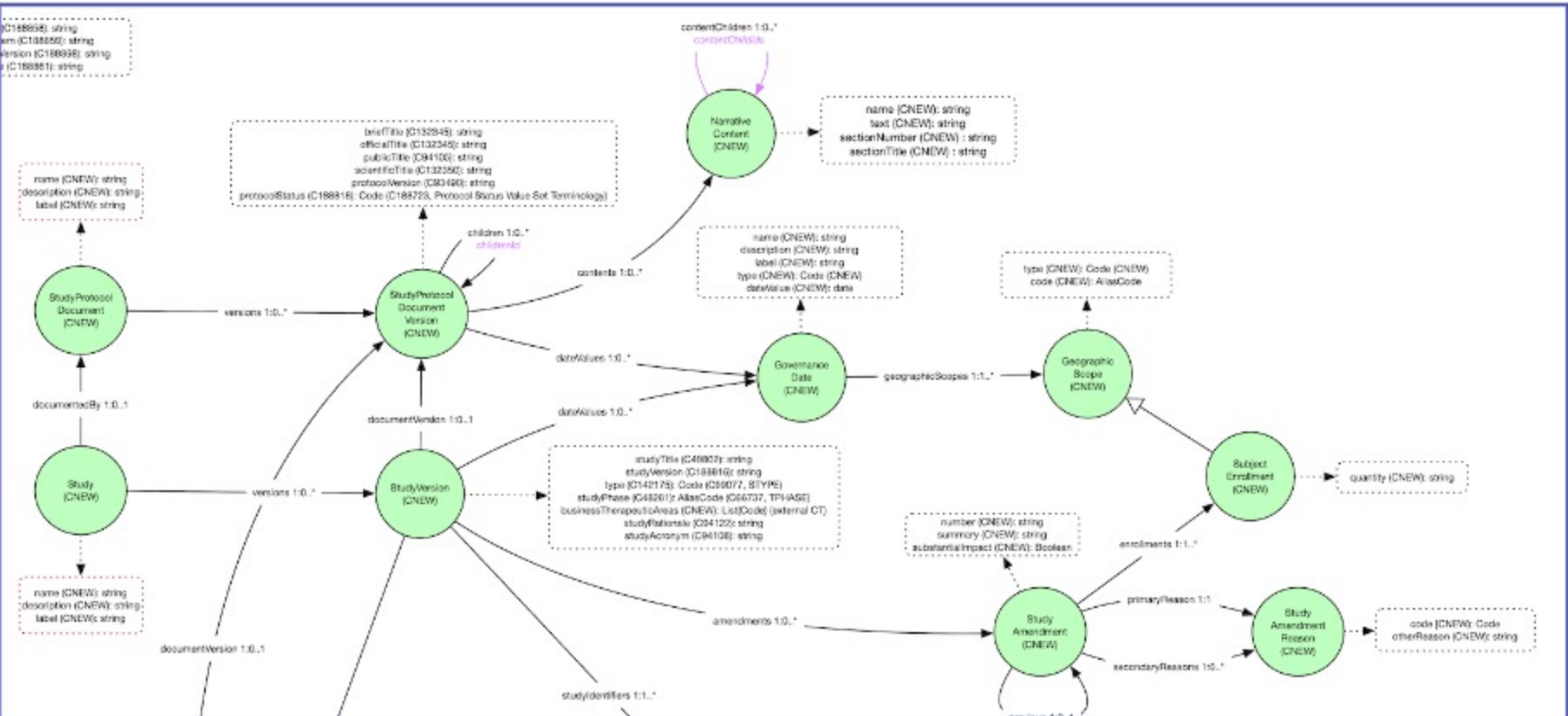
```

# Document Version



## Document Version

- Single version of the protocol document

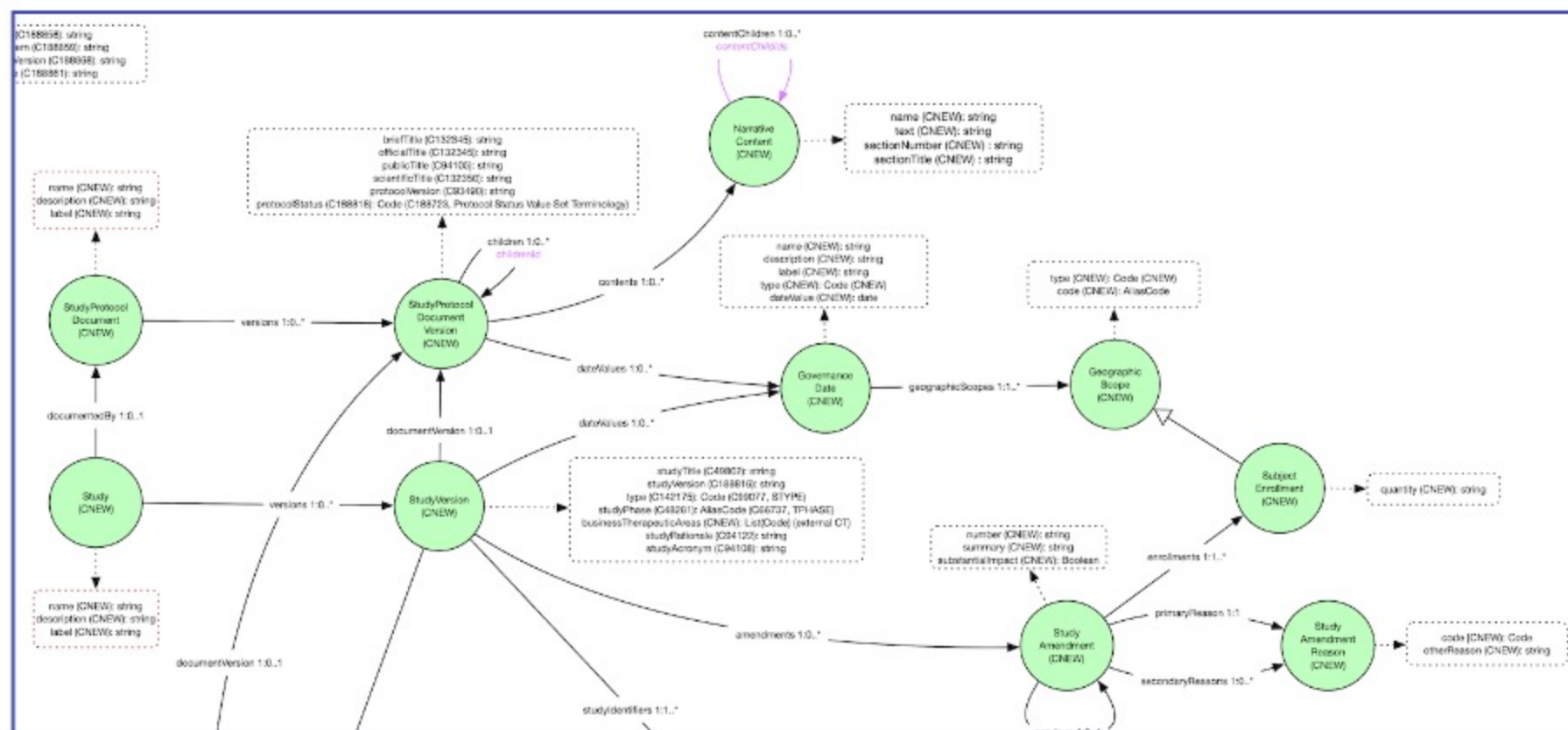
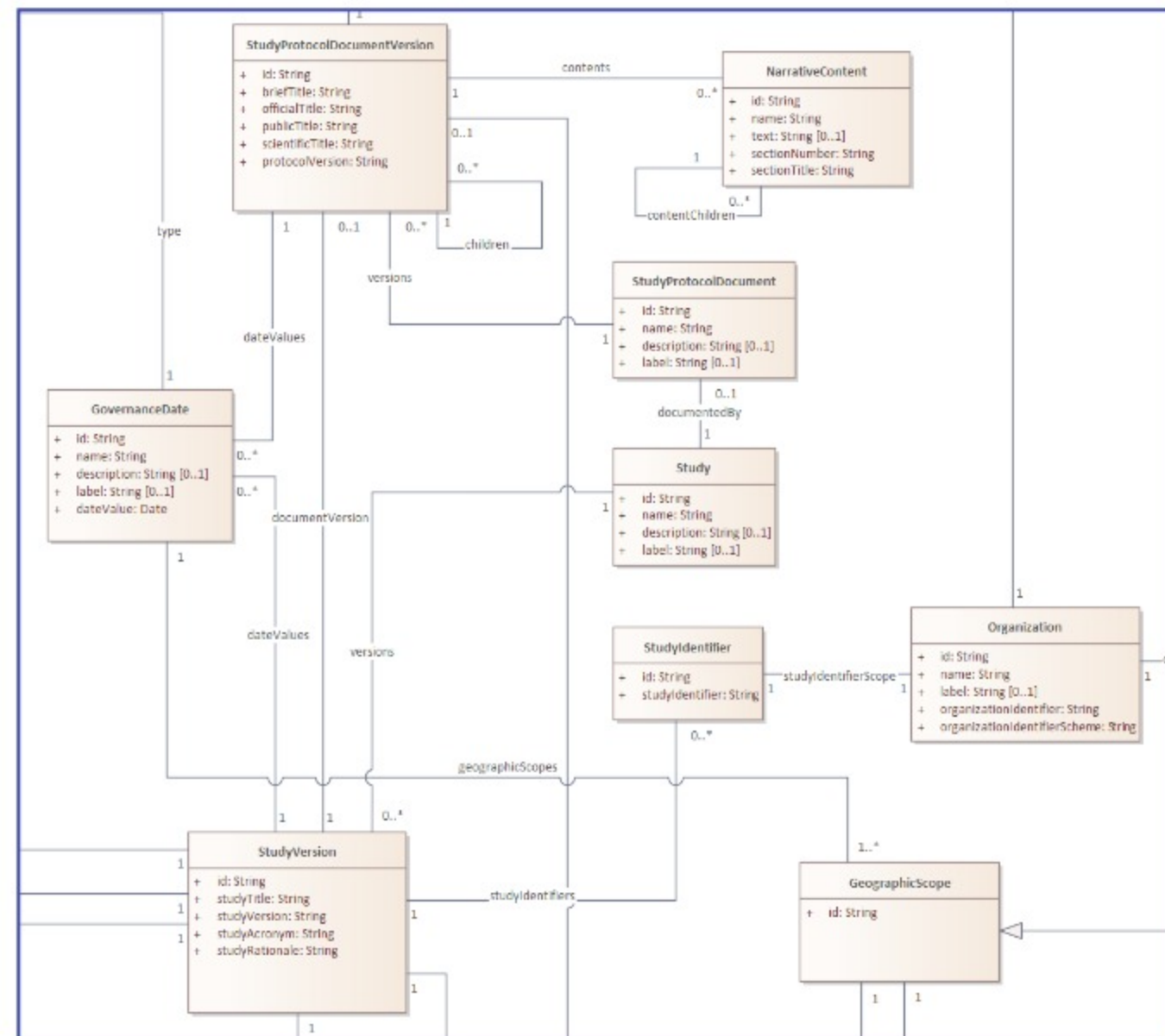
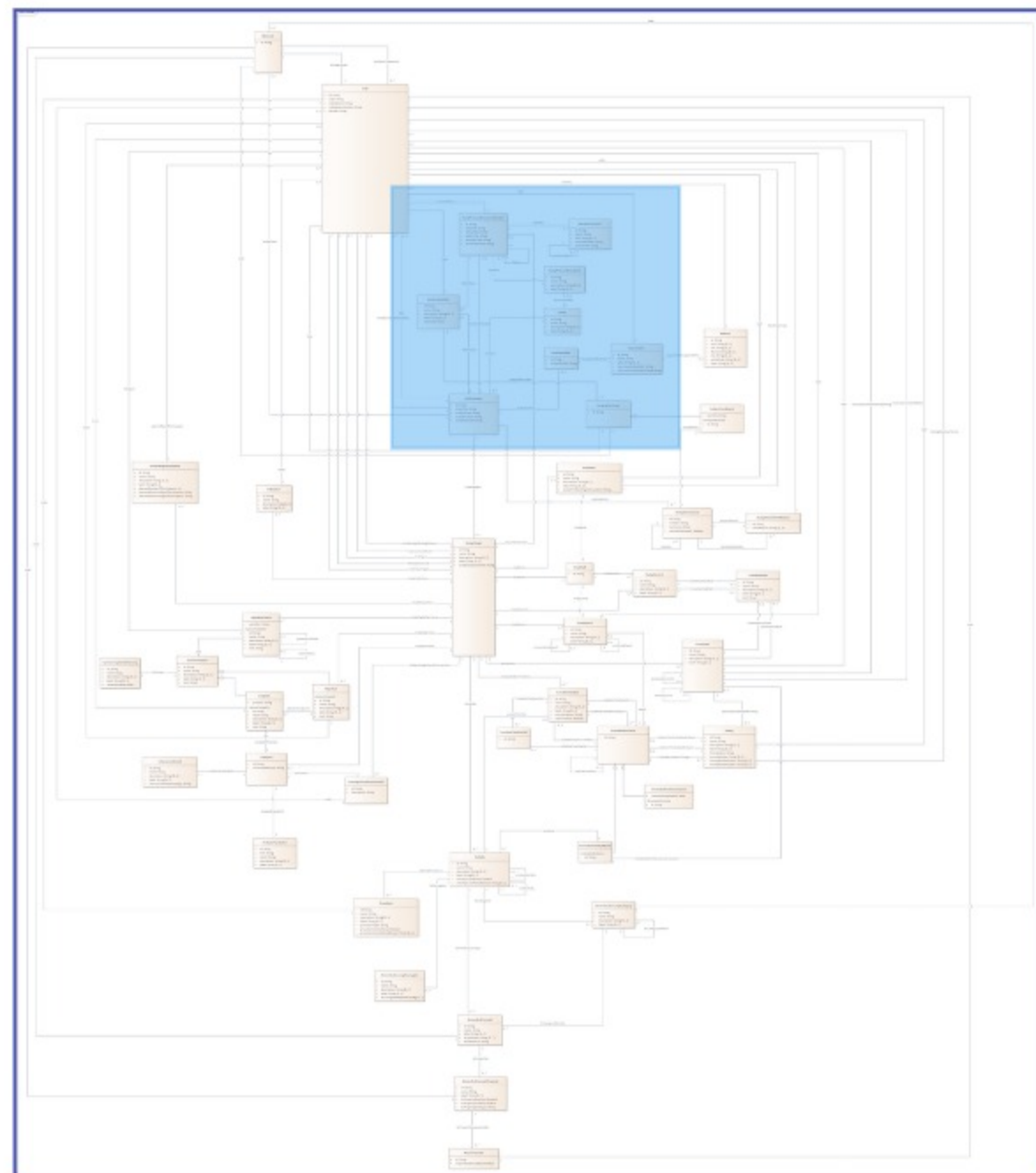


```

{
  "id": "StudyProtocolDocumentVersion_1",
  "briefTitle": "Xanomeline (LY246708)",
  "officialTitle": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
  "publicTitle": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
  "scientificTitle": "",
  "protocolVersion": "2",
  "protocolStatus": {
    "id": "Code_4",
    "code": "C25508",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Final"
  },
  "dateValues": [ ... ],
  "contents": [ ... ],
  "childrenIds": []
}

```

# Document Amendments



```

{
  "id": "StudyAmendment_1",
  "number": "1",
  "summary": "Updated inclusion criteria",
  "substantialImpact": true,
  "primaryReason": {
    "id": "StudyAmendmentReason_1",
    "code": {
      "id": "Code_10",
      "code": "C99904x3",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "IRB/IEC Feedback"
    },
    "otherReason": null
  },
  "secondaryReasons": [
    { ... as per primary ... }
  ],
  "enrollments": [ ... ]
  "previousId": null
}

```

```

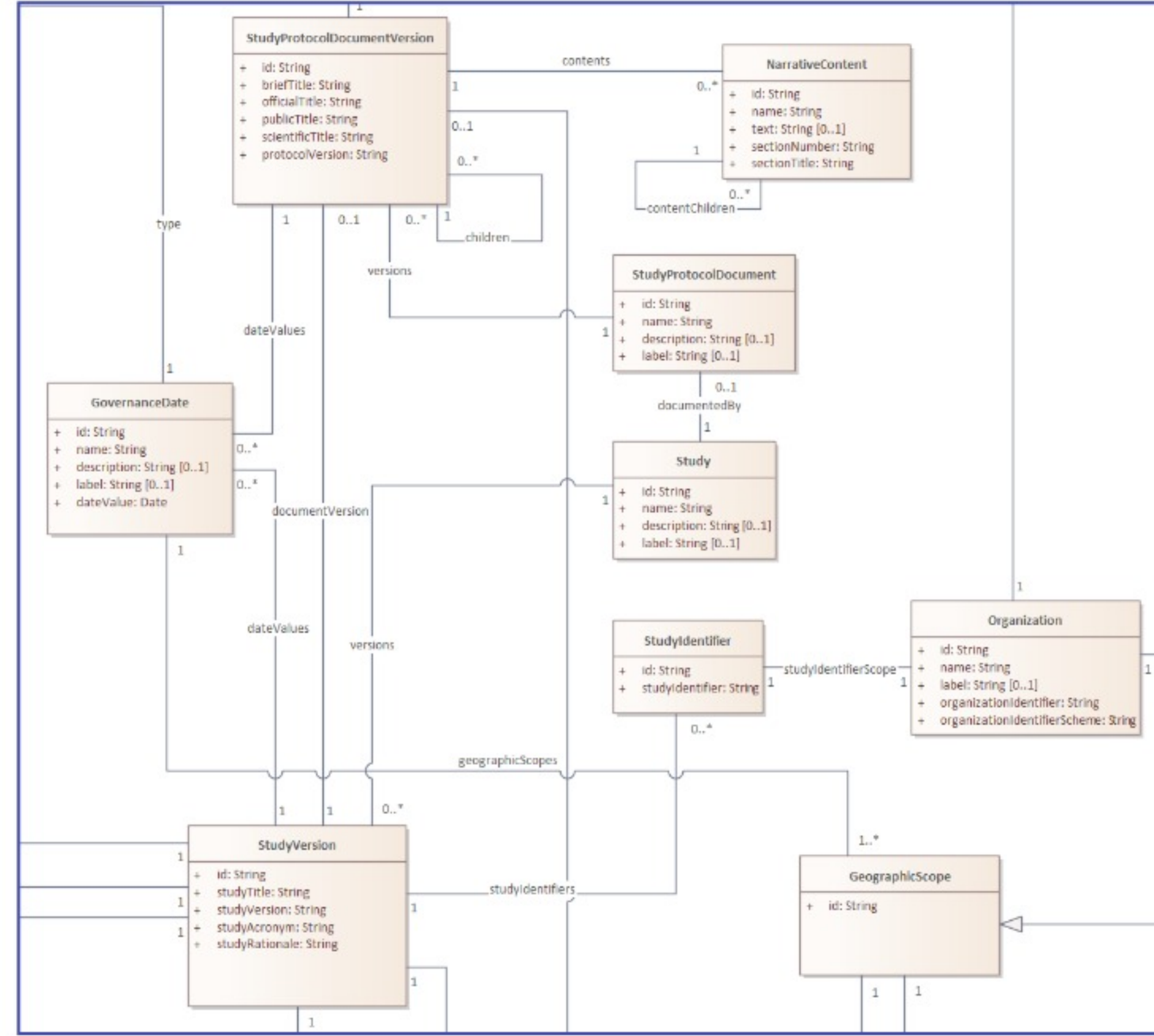
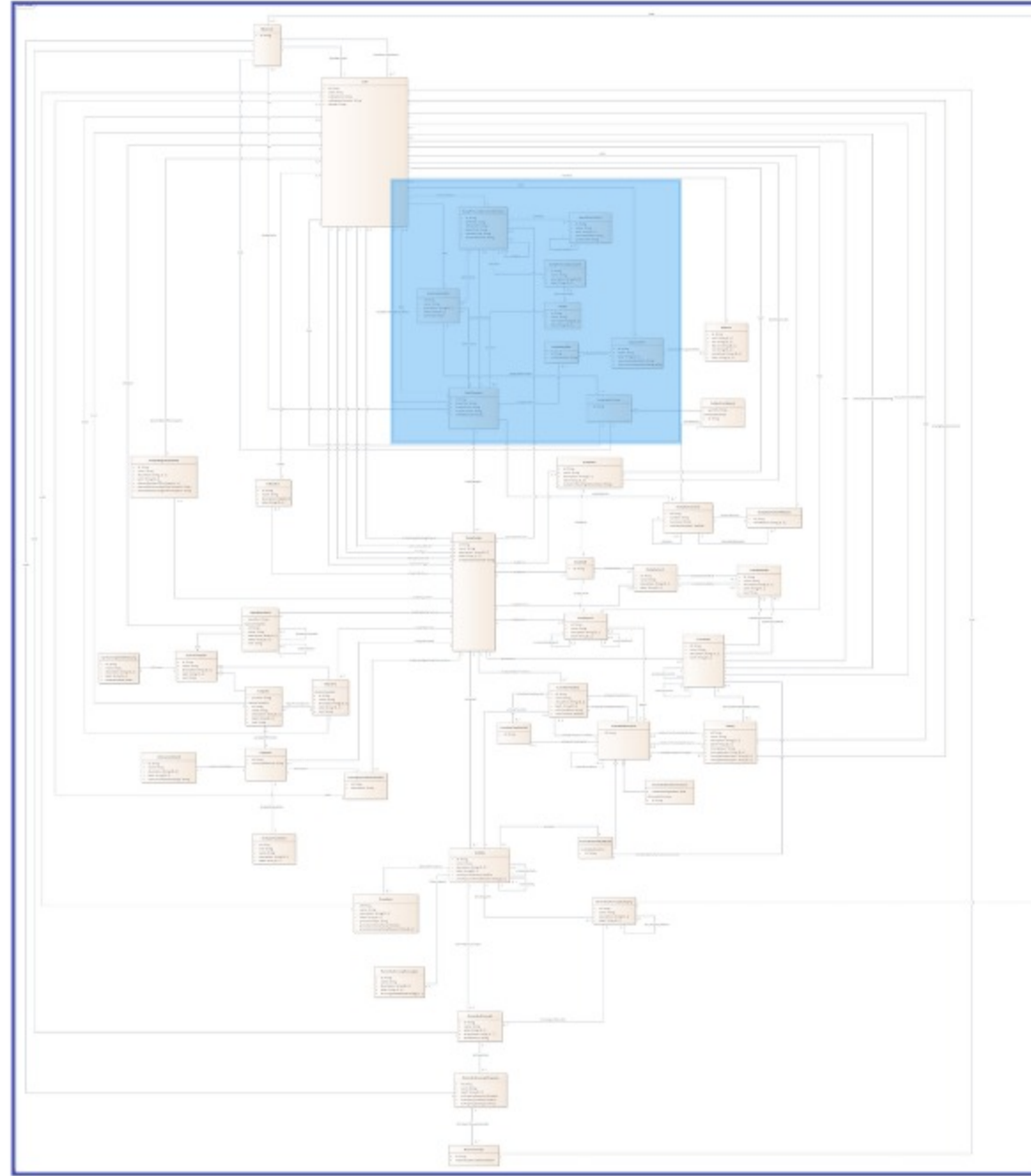
{
  "enrollments": [
    {
      "id": "SubjectEnrollment_1",
      "type": {
        "id": "Code_13",
        "code": "C41129",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2023-09-29",
        "decode": "Region"
      },
      "code": {
        "id": "AliasCode_3",
        "standardCode": {
          "id": "Code_12",
          "code": "150",
          "codeSystem": "ISO 3166 1 alpha3",
          "codeSystemVersion": "2020-08",
          "decode": "Europe"
        },
        "standardCodeAliases": []
      },
      "quantity": "15"
    },
    { ... }
  ],
}

```

## Document Version

- One or more amendments
- Hangs off the Study Design not the document

# Dates



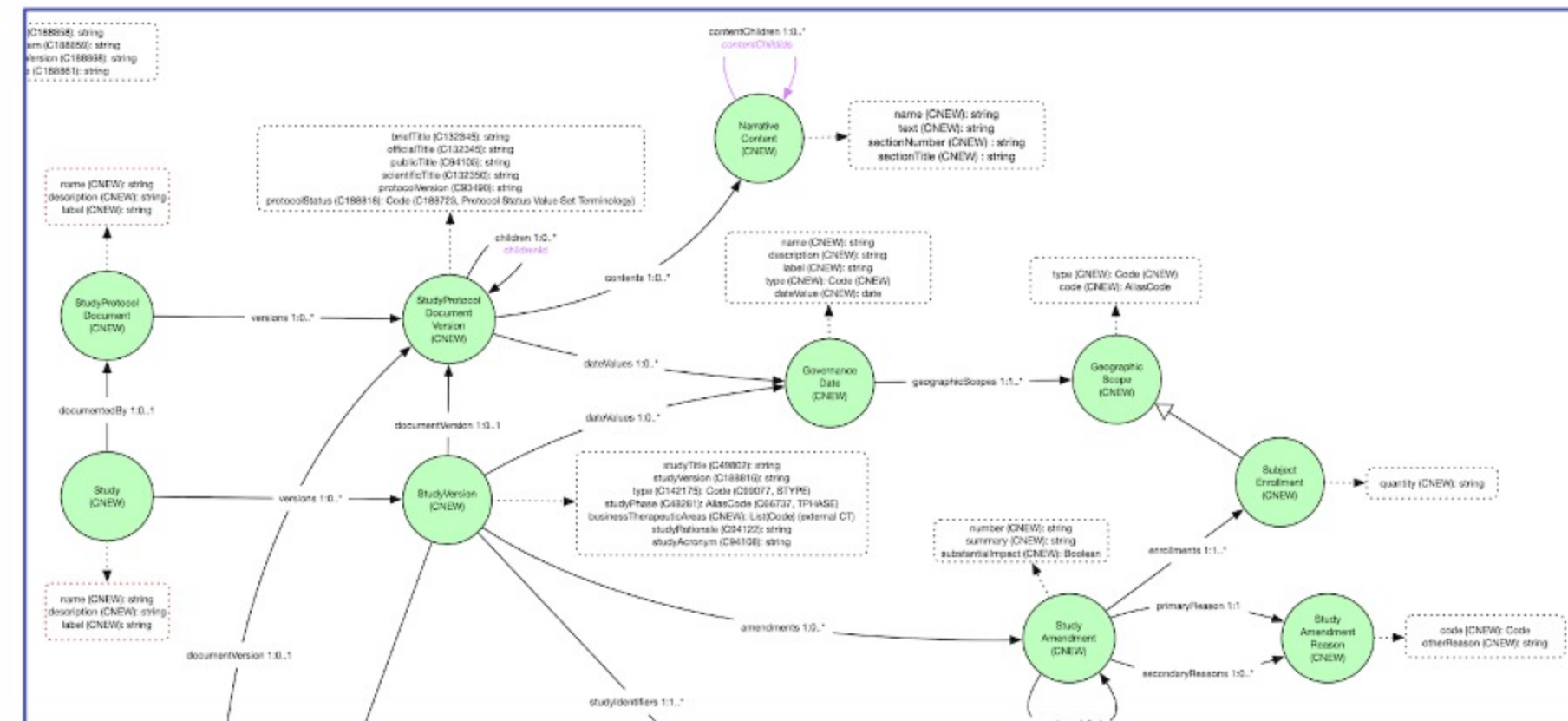
```

"dateValues": [
  {
    "id": "GovernanceDate_1",
    "name": "Approval",
    "label": "Design Approval",
    "description": "Design approval date",
    "type": {
      "id": "Code_5",
      "code": "C132352",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "Sponsor Approval Date"
    },
    "dataValue": "2006-07-01",
    "geographicScopes": [
      {
        "id": "GeographicScope_1",
        "type": {
          "id": "Code_6",
          "code": "C68846",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2023-09-29",
          "decode": "Global"
        },
        "code": null
      }
    ]
  }
]

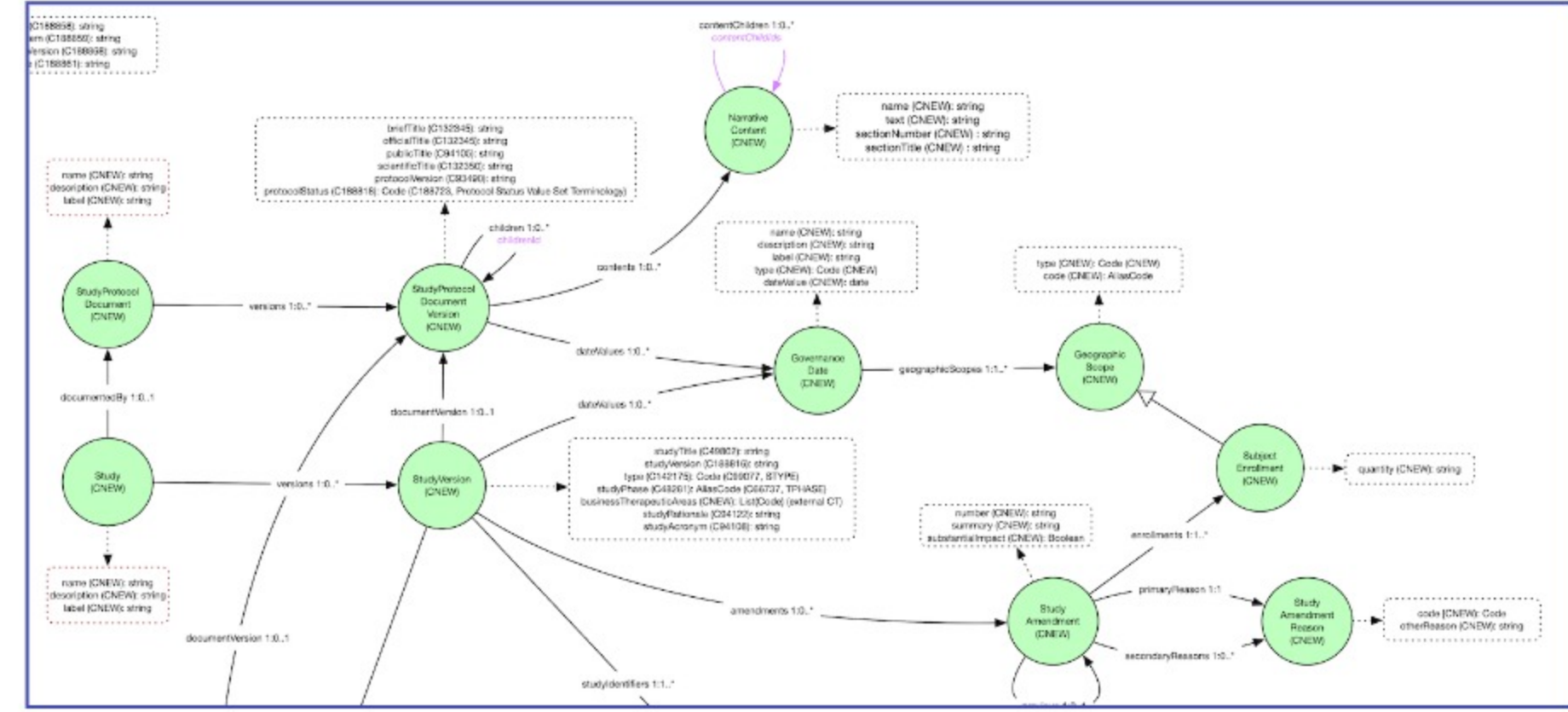
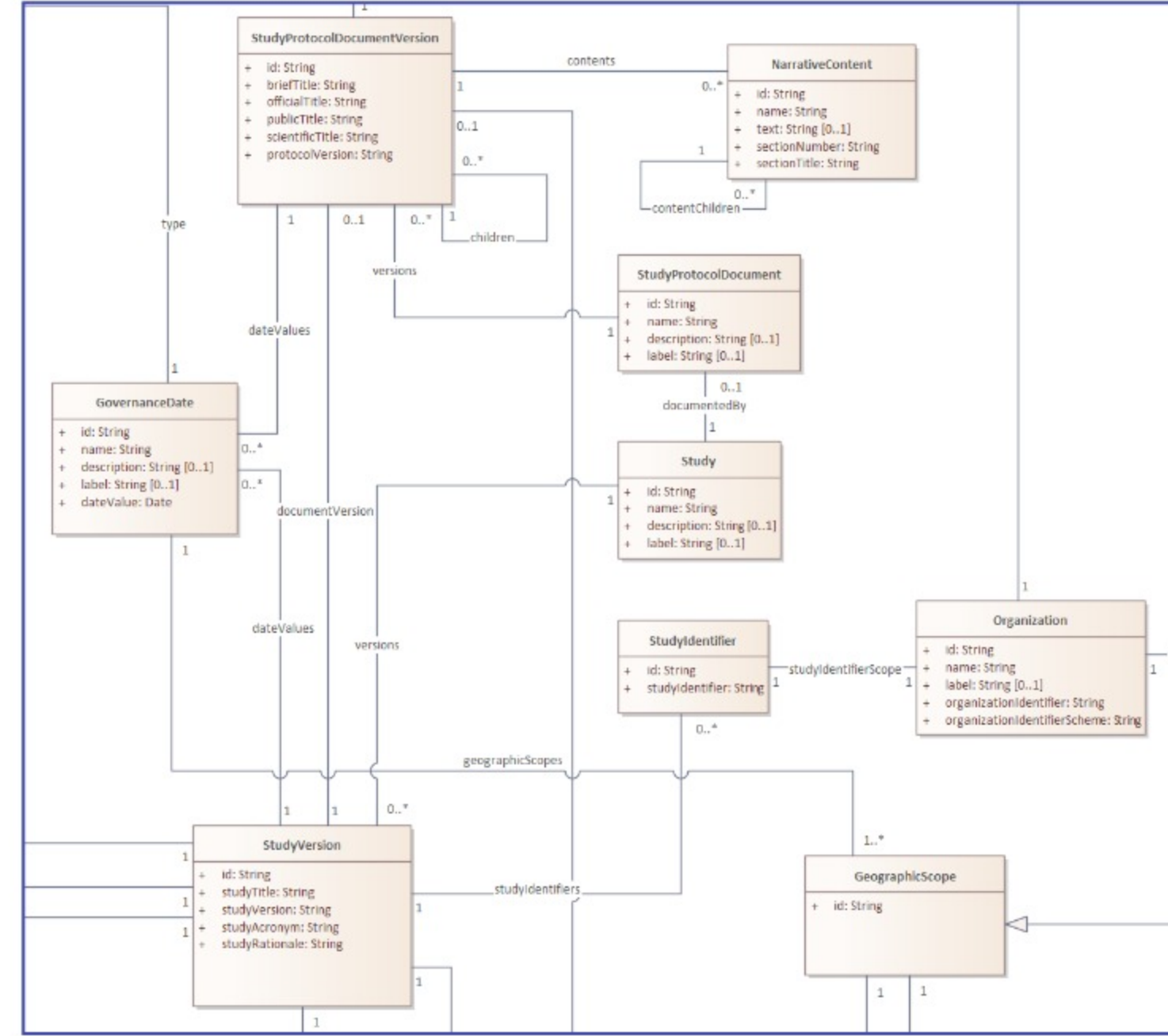
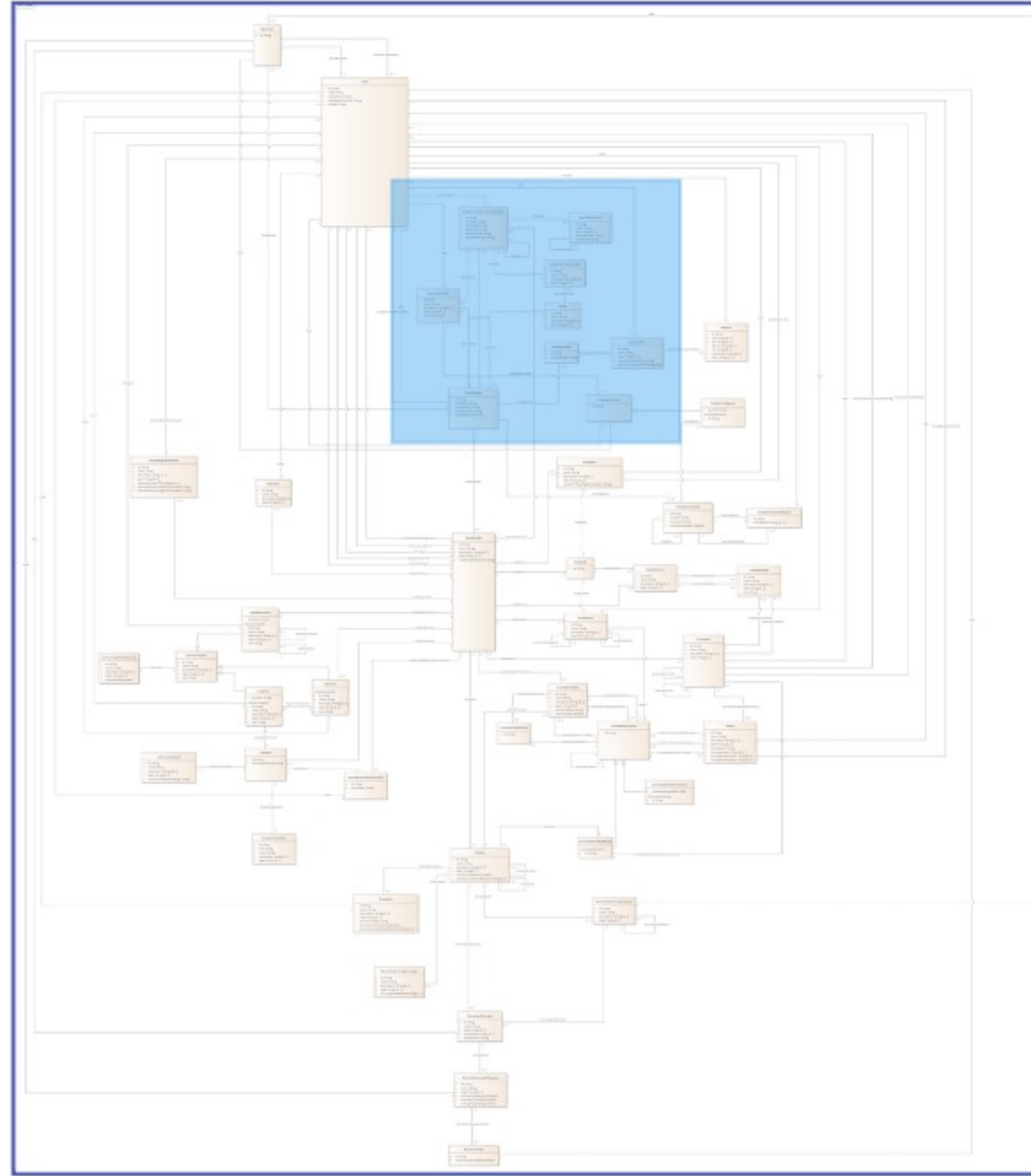
```

## Dates

- Used for documents
- Used for amendments
- Dates have geographic scope (Global, Regional, Country)



# Geographic Scope



## Document Version

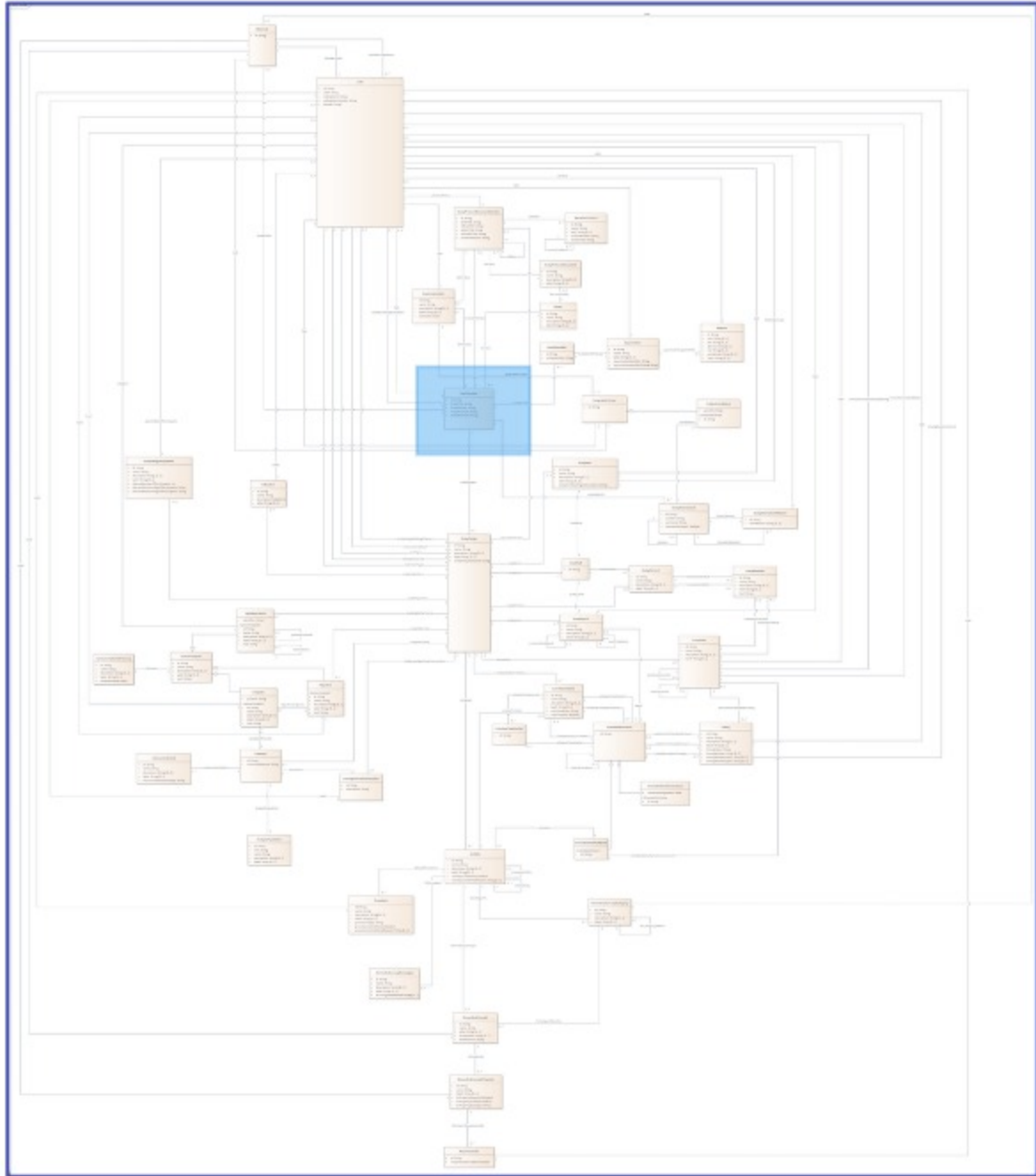
- Allows for a date or an enrollment figure to be constrained to a Geographic Scope
- Scopes are Global, Regional, Country

```

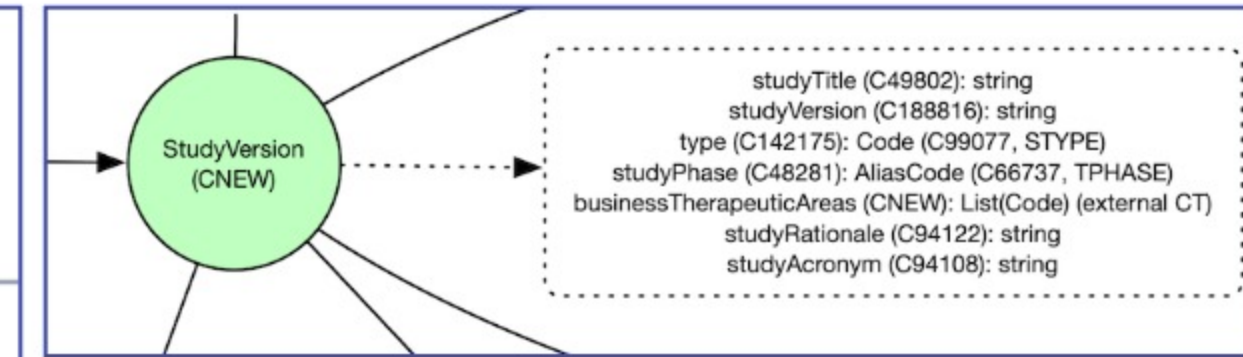
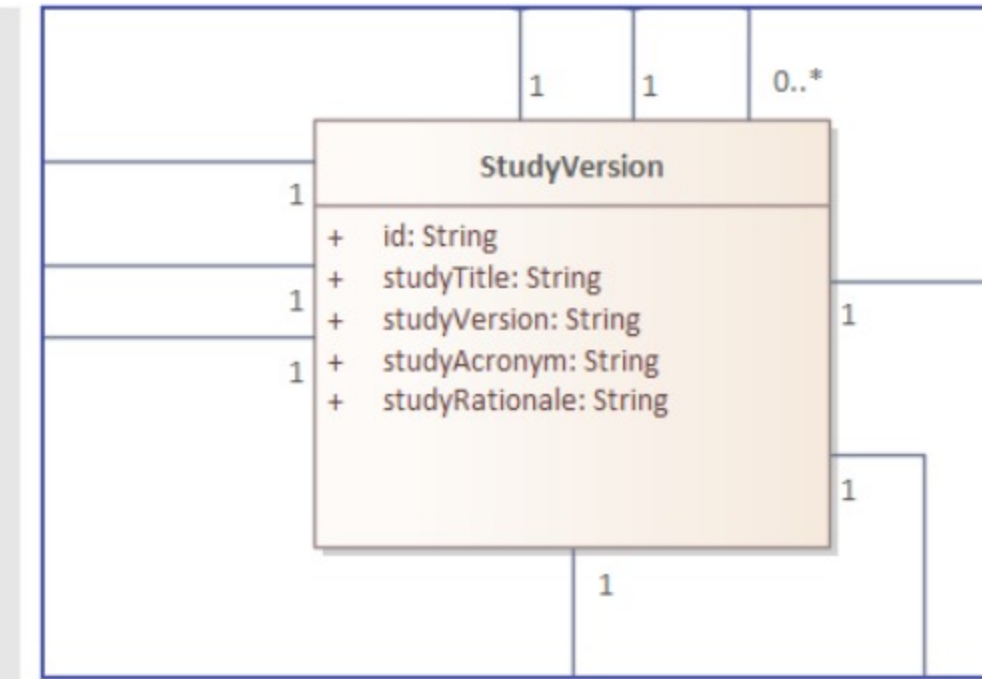
{
  "id": "GeographicScope_2",
  "type": {
    "id": "Code_9",
    "code": "C41129",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Region"
  },
  "code": {
    "id": "AliasCode_2",
    "standardCode": {
      "id": "Code_8",
      "code": "150",
      "codeSystem": "ISO 3166 1 alpha3",
      "codeSystemVersion": "2020-08",
      "decode": "Europe"
    },
    "standardCodeAliases": []
  }
}

```

# Study Version



```
{
  "study": {
    "id": null,
    "name": "Study_SCOPE1",
    "description": null,
    "label": null,
    "versions": [
      {
        "id": "StudyVersion_1",
        "studyTitle": "Simple Test 1",
        "studyVersion": "1",
        "studyRationale": "A simple test",
        "studyAcronym": "SIMPLE",
        "type": {
          "id": "Code_1",
          "code": "C98388",
          "codeSystem": "http://www.cdisc.org",
          "codeSystemVersion": "2023-09-29",
          "decode": "Interventional Study"
        },
        "studyPhase": {
          "id": "AliasCode_1",
          "standardCode": {
            "id": "Code_2",
            "code": "C15602",
            "codeSystem": "http://www.cdisc.org",
            "codeSystemVersion": "2023-09-29",
            "decode": "Phase III Trial"
          },
          "standardCodeAliases": []
        },
        "documentVersionId": "StudyProtocolDocumentVersion_1",
        "dateValues": [...],
        "amendments": [...],
        "businessTherapeuticAreas": [...],
        "studyIdentifiers": [...],
        "studyDesigns": [...]
      }
    ],
    "documentedBy": {...}
  }
}
```



## Business Therapeutic Area

- Sponsor requested. More for downstream processes
- Not the same as StudyDesign therapeuticAreas attribute

## One Study Version, Many Study Designs

- USDM allows for many study designs within a single study
- This accommodates master, umbrella studies etc.

## Notes:

- [FDA guidance](#) talks about master protocols
- [Master Protocols for Precision Medicine in Oncology: Overcoming Methodology of Randomized Clinical Trials](#)

## Study Version

- A single version of the study
- One study version links to many study designs
- Study version also links to the study identifiers

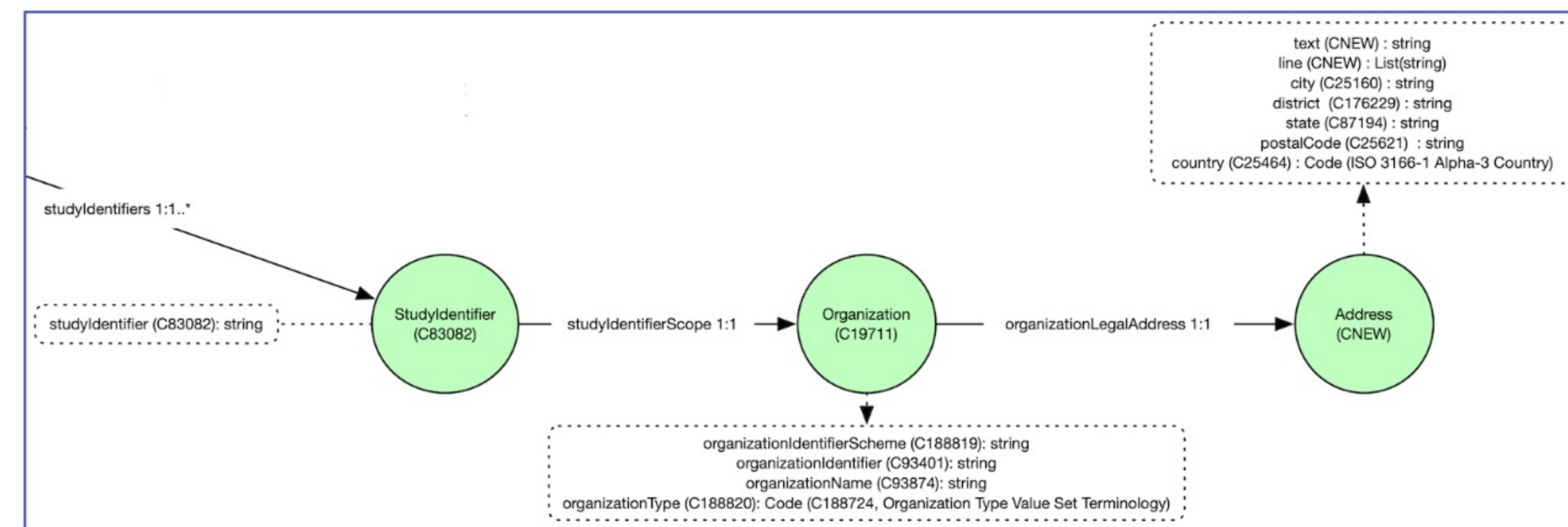
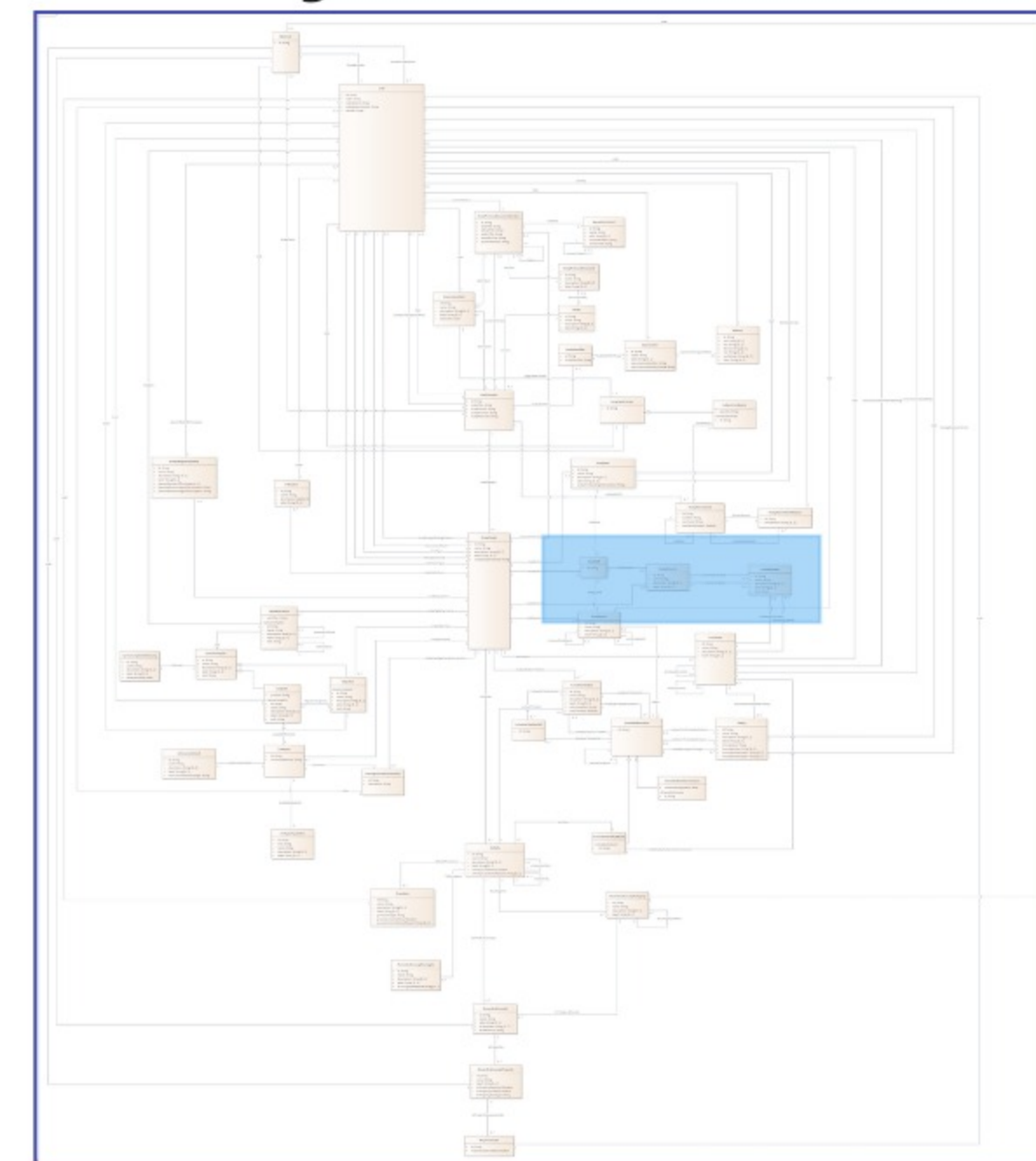


# Study Identifiers

## Study Identifiers

- Multiple identifiers permitted, various types
  - Sponsor
  - Registry
  - Regulatory Authority
- Should have a Sponsor Id
- Should only have one Sponsor Id
- Note the country code (ISO 3166-1)

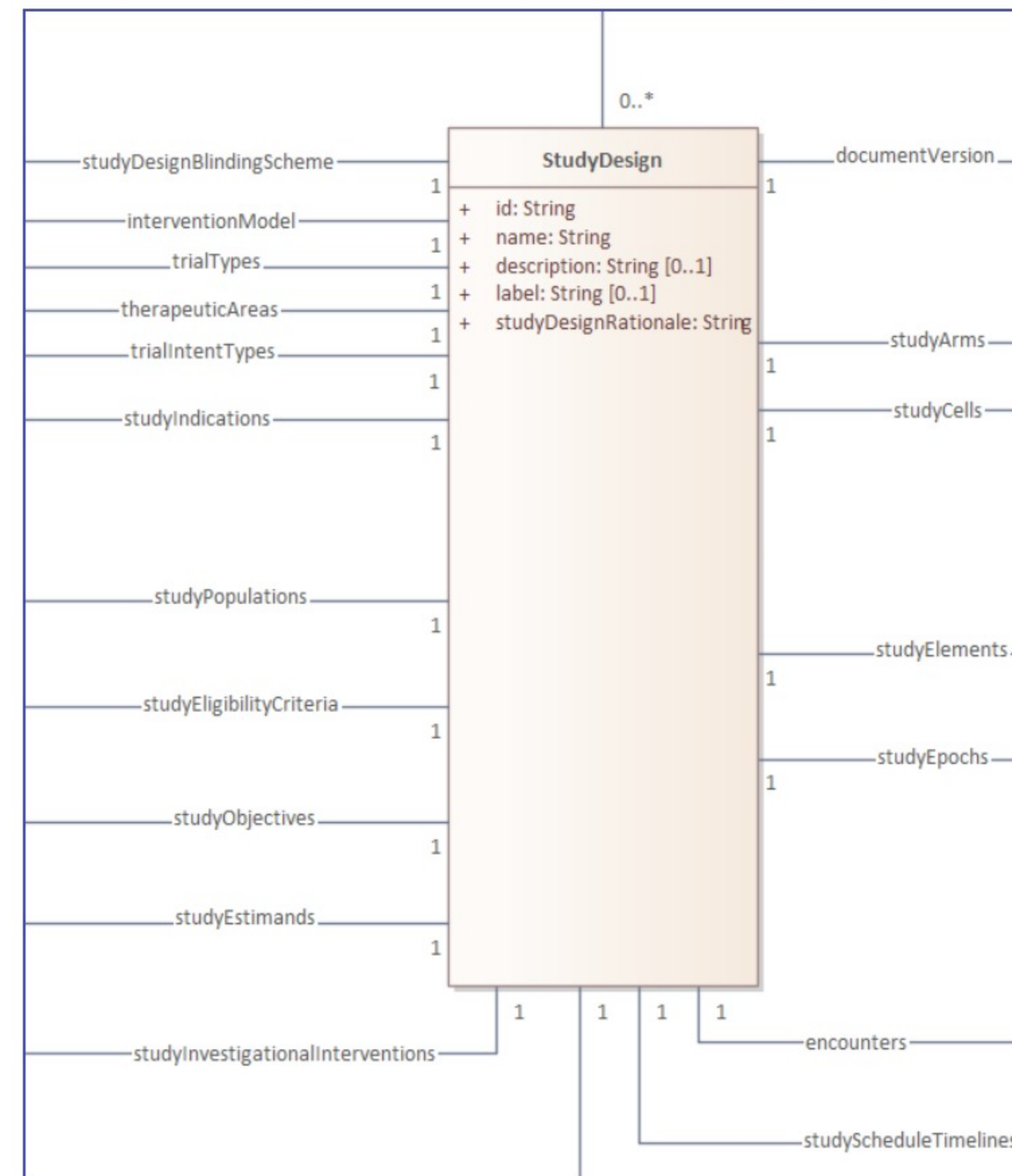
```
{
  "id": "StudyIdentifier_1",
  "studyIdentifier": "H2Q-MC-LZZT",
  "studyIdentifierScope": {
    "id": "Organization_1",
    "name": "Eli Lilly",
    "label": "",
    "type": {
      "id": "Code_16",
      "code": "C70793",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "Clinical Study Sponsor"
    }
  },
  "organizationIdentifierScheme": "DUNS",
  "organizationIdentifier": "00-642-1325",
  "organizationLegalAddress": {
    "id": "Address_1",
    "text": "Lilly Corporate Ctr, Indianapolis, -, IN, 4628, United States of America",
    "line": "Lilly Corporate Ctr",
    "city": "Indianapolis",
    "district": "-",
    "state": "IN",
    "postalCode": "4628",
    "country": {
      "id": "Code_17",
      "code": "USA",
      "codeSystem": "ISO 3166 1 alpha3",
      "codeSystemVersion": "2020-08",
      "decode": "United States of America"
    }
  }
}
```



# Study Design

## Study Design

- Root of a single design
- Links all the pieces together using relationships



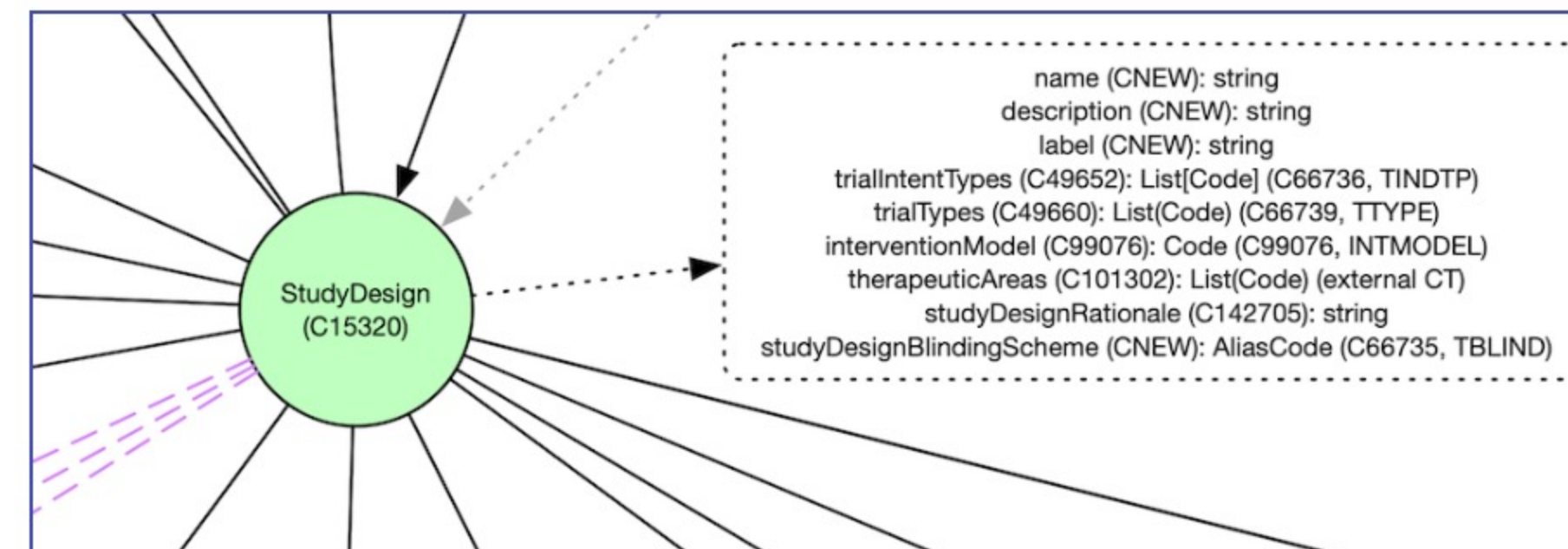
```

"studyDesigns": [
  {
    "id": "StudyDesign_1",
    "name": "Study Design 1",
    "label": "",
    "description": "The main design for the study",
    "trialIntentTypes": [...],
    "trialTypes": [...],
    "therapeuticAreas": [...],
    "interventionModel": {...},
    "encounters": [...],
    "activities": [...],
    "biomedicalConcepts": [...],
    "bcCategories": [],
    "bcSurrogates": [...],
    "studyArms": [...],
    "studyCells": [...],
    "studyDesignBlindingScheme": {...},
    "studyDesignRationale": "Basic study",
    "studyEpochs": [...],
    "studyElements": [...],
    "studyEstimands": [...],
    "studyIndications": [...],
    "studyInvestigationalInterventions": [...],
    "studyObjectives": [...],
    "studyPopulations": [...],
    "studyScheduleTimelines": [...],
    "documentVersion": null,
    "studyEligibilityCriteria": [...],
    "dictionaries": [...]
  }
]

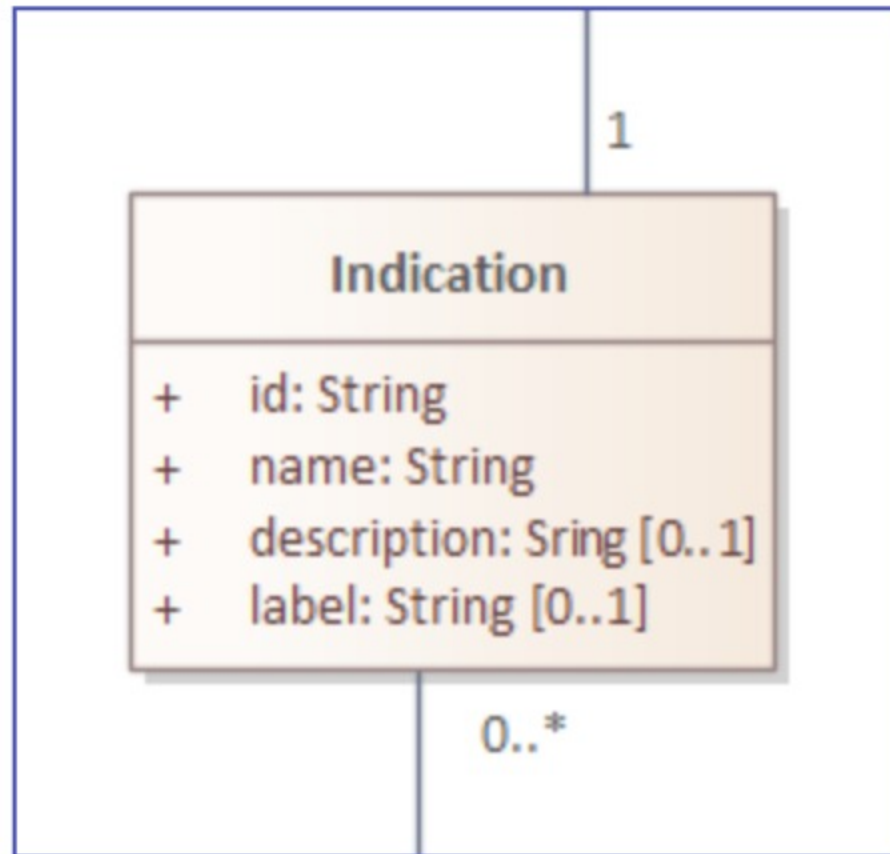
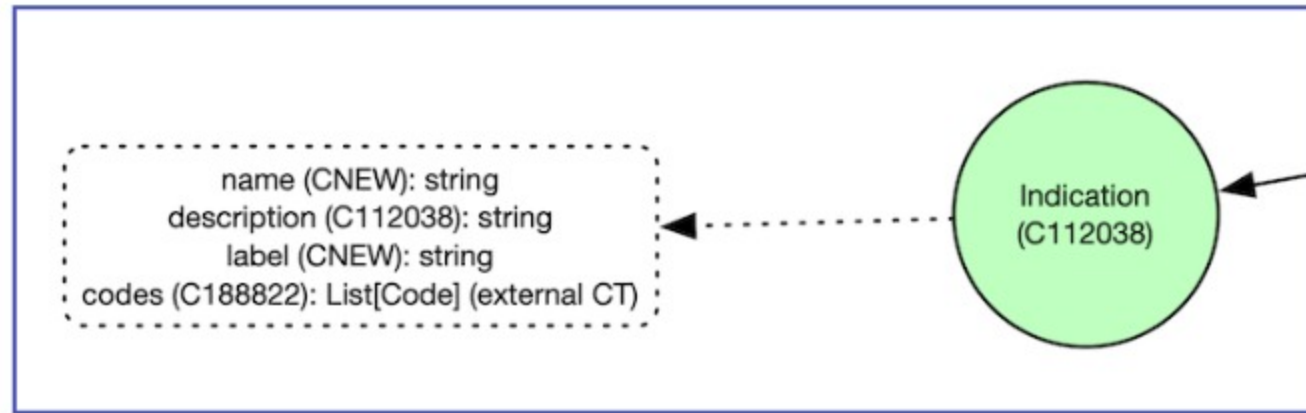
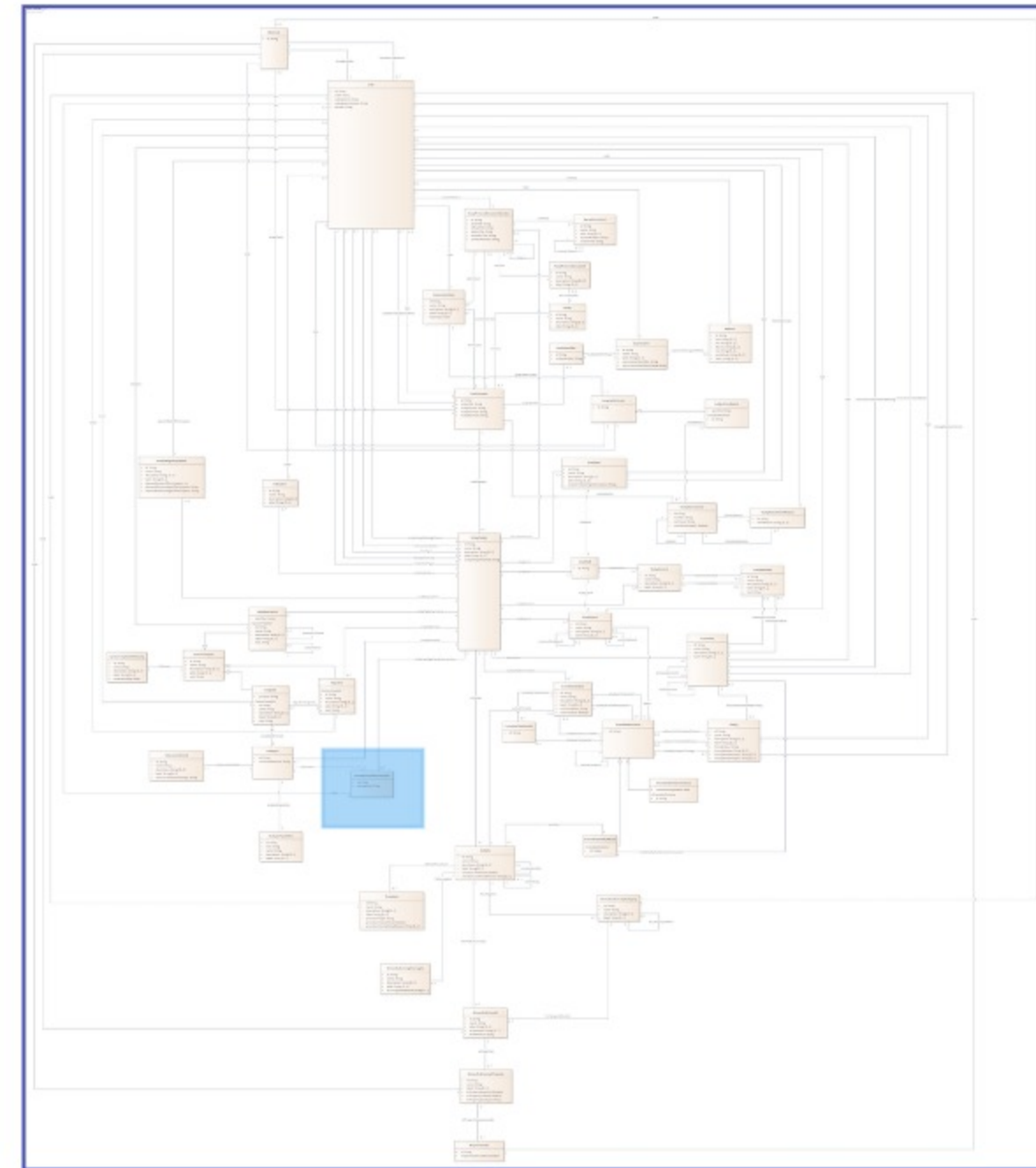
```

## Therapeutic Areas

Dictionary / Terminology Name	URL
EUDRACT	<a href="https://eudract.ema.europa.eu/docs/technical/EUDRACT_Eutct_Pick_Lists_and_coded_values_v1_0.xls">https://eudract.ema.europa.eu/docs/technical/EUDRACT_Eutct_Pick_Lists_and_coded_values_v1_0.xls</a>
ICD-10	<a href="https://www.icd10data.com/ICD10CM/Codes">https://www.icd10data.com/ICD10CM/Codes</a>
MEDDRA	<a href="https://www.meddra.org/">https://www.meddra.org/</a>
MeSH	<a href="https://www.ncbi.nlm.nih.gov/mesh/">https://www.ncbi.nlm.nih.gov/mesh/</a>
NCI Thesaurus	<a href="https://ncit.nci.nih.gov/ncitbrowser/">https://ncit.nci.nih.gov/ncitbrowser/</a>
SNOMEDCT	<a href="https://www.nlm.nih.gov/healthit/snomedct/index.html">https://www.nlm.nih.gov/healthit/snomedct/index.html</a>
US FDA	<a href="https://www.fda.gov/drugs/development-resources/spectrum-diseasesconditions">https://www.fda.gov/drugs/development-resources/spectrum-diseasesconditions</a>

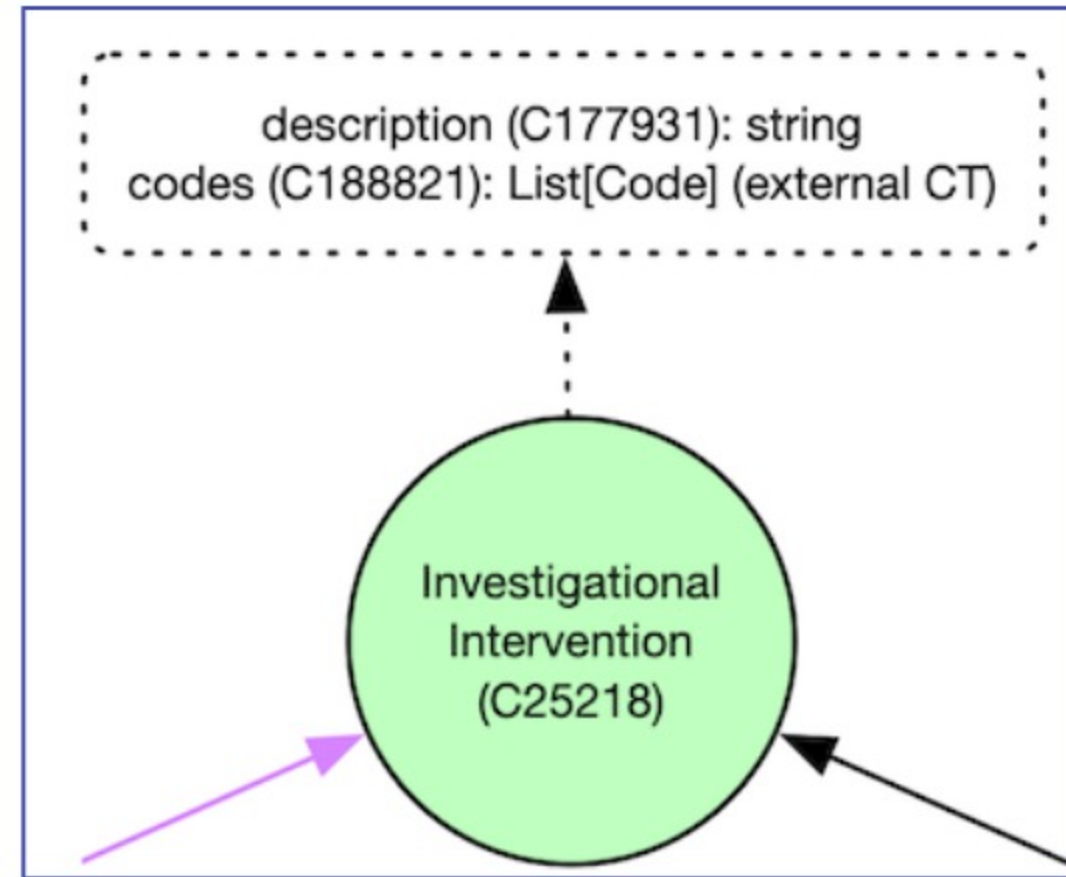
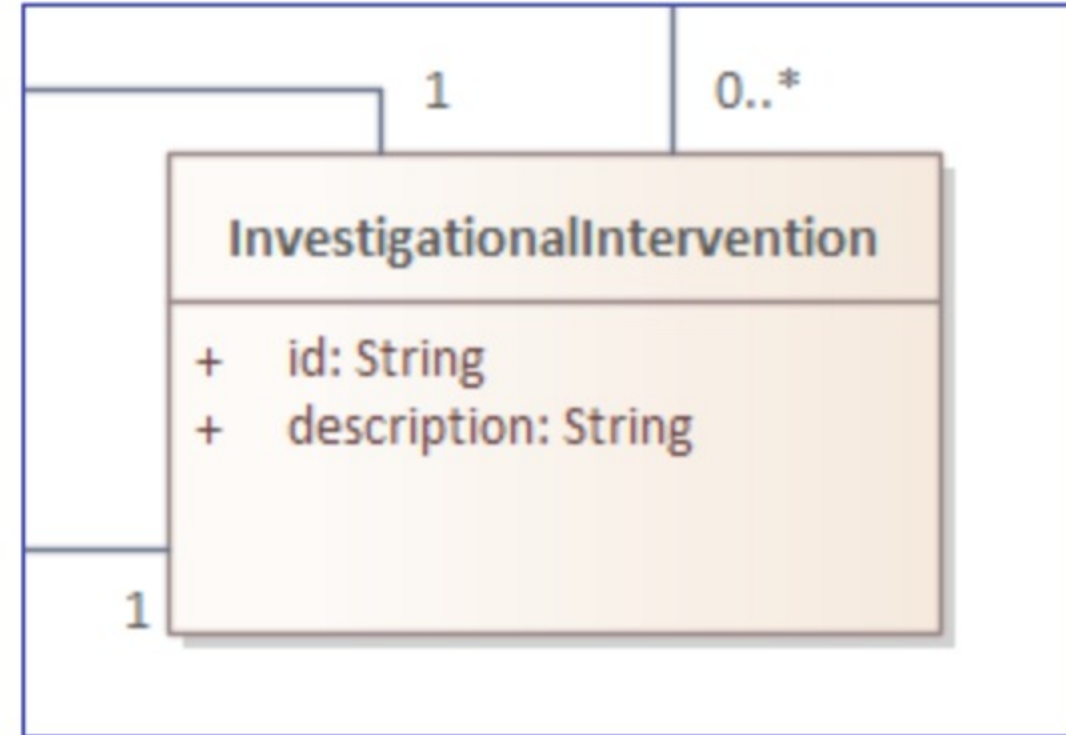
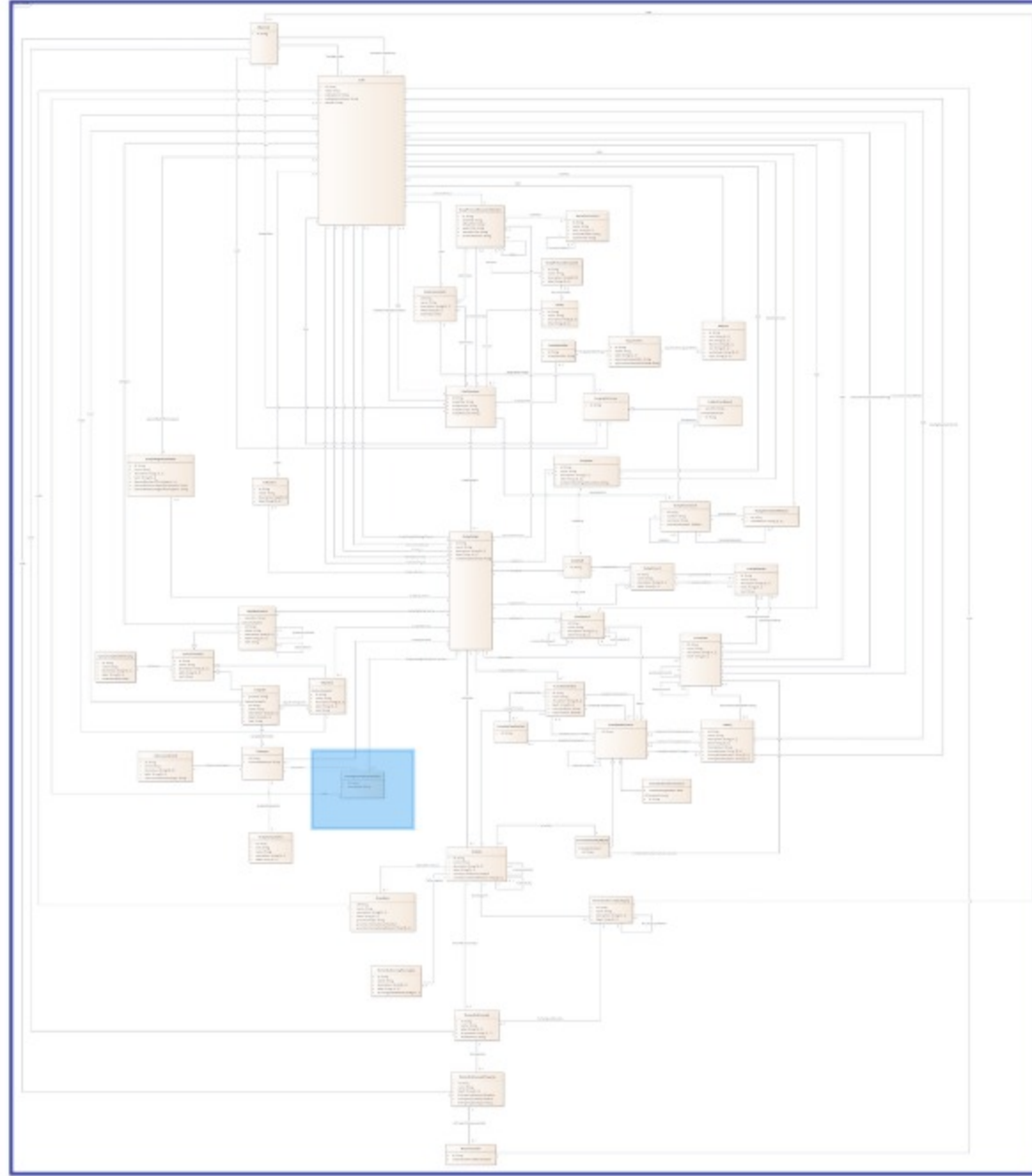


# Indications



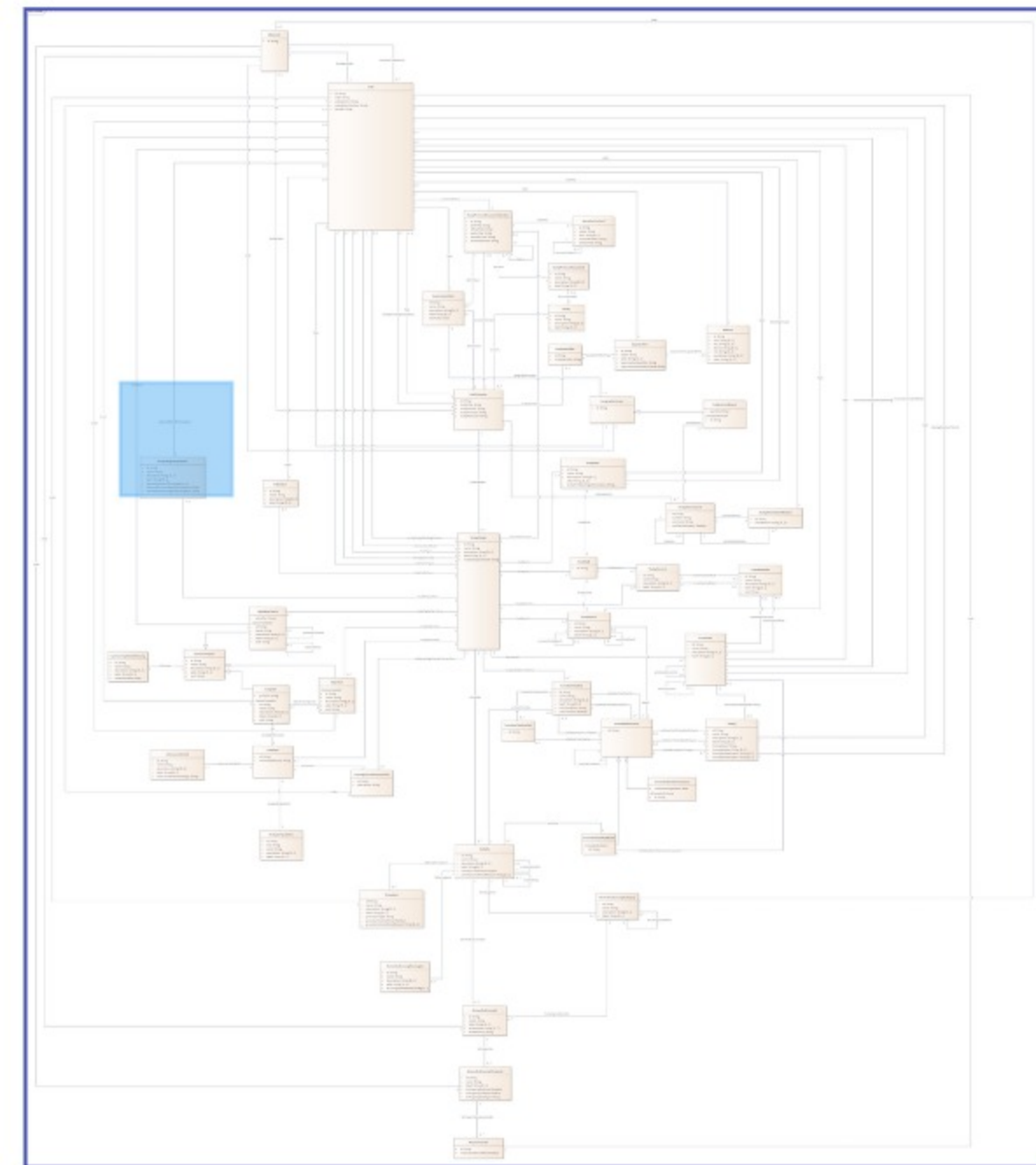
```
"studyIndications": [  
  {  
    "id": "Indication_1",  
    "codes": [  
      {  
        "code": "E11",  
        "codeSystem": "ICD-10-CM",  
        "codeSystemVersion": "10",  
        "decode": "Type 2 diabetes mellitus"  
      },  
      {  
        "code": "44054006",  
        "codeSystem": "SNOMED",  
        "codeSystemVersion": "2022",  
        "decode": "Diabetes mellitus type 2 (disorder)"  
      }  
    ],  
    "description": "Diabetes Type II"  
  },  
  {  
    "id": "Indication_2",  
    "codes": [  
      {  
        "code": "E10",  
        "codeSystem": "ICD-10-CM",  
        "codeSystemVersion": "10",  
        "decode": "Type 1 diabetes mellitus"  
      },  
      {  
        "code": "44635009",  
        "codeSystem": "SNOMED",  
        "codeSystemVersion": "2022",  
        "decode": "Diabetes mellitus type 1 (disorder)"  
      }  
    ],  
    "description": "Diabetes Type I"  
  }  
]
```

# Interventions

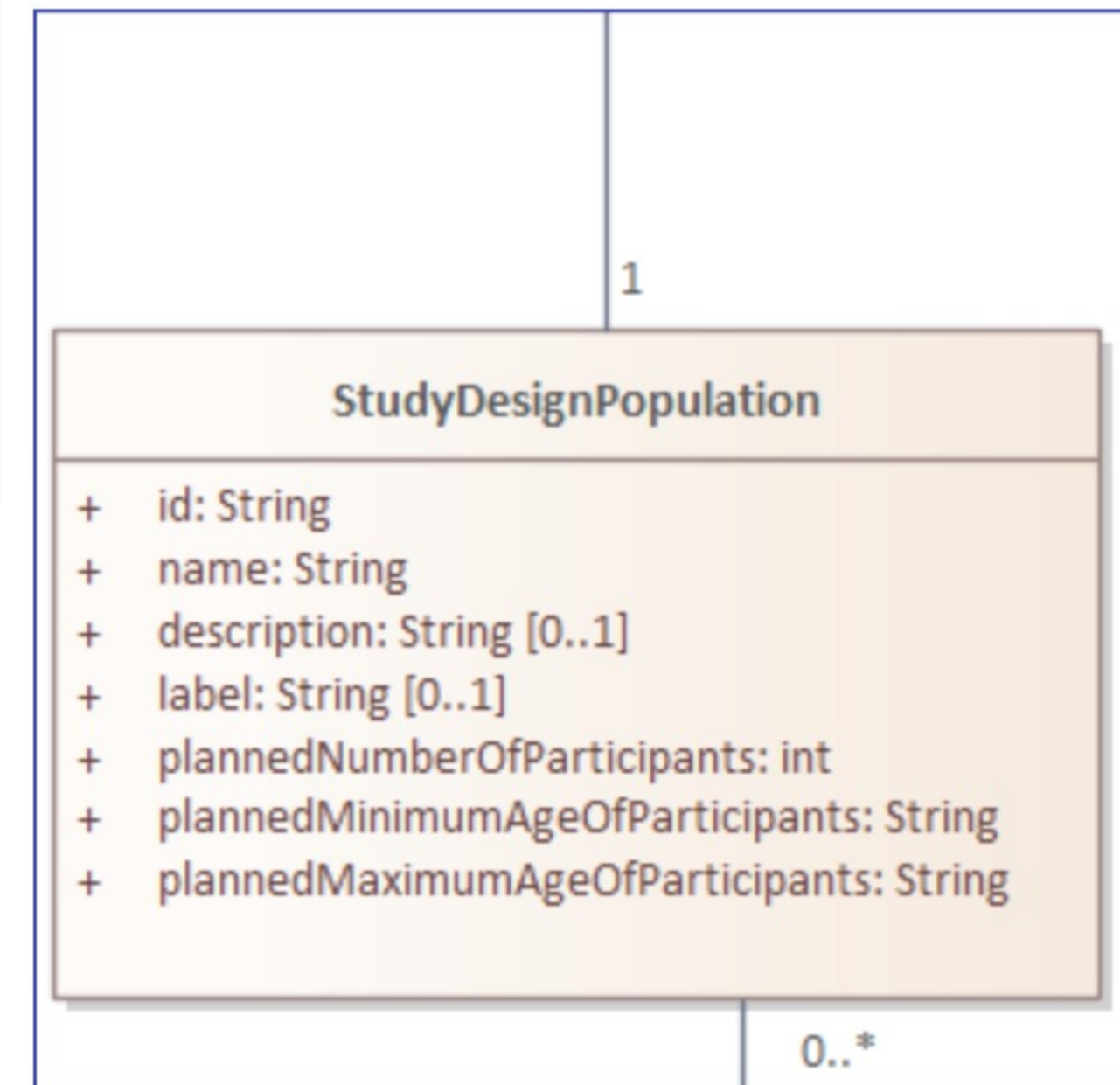
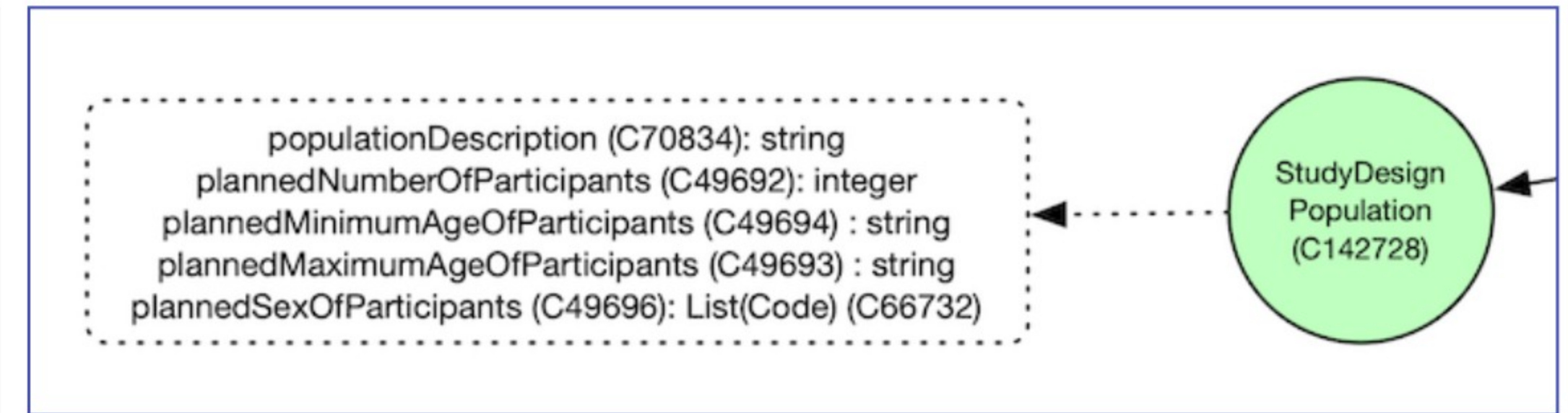


```
"studyInvestigationalInterventions": [  
  {  
    "id": "InvestigationalIntervention_1",  
    "codes": [  
      {  
        "code": "XX031ZA",  
        "codeSystem": "ATC",  
        "codeSystemVersion": "2021",  
        "decode": "SubstX"  
      }  
    ],  
    "description": "Treatment with substX"  
  }  
]
```

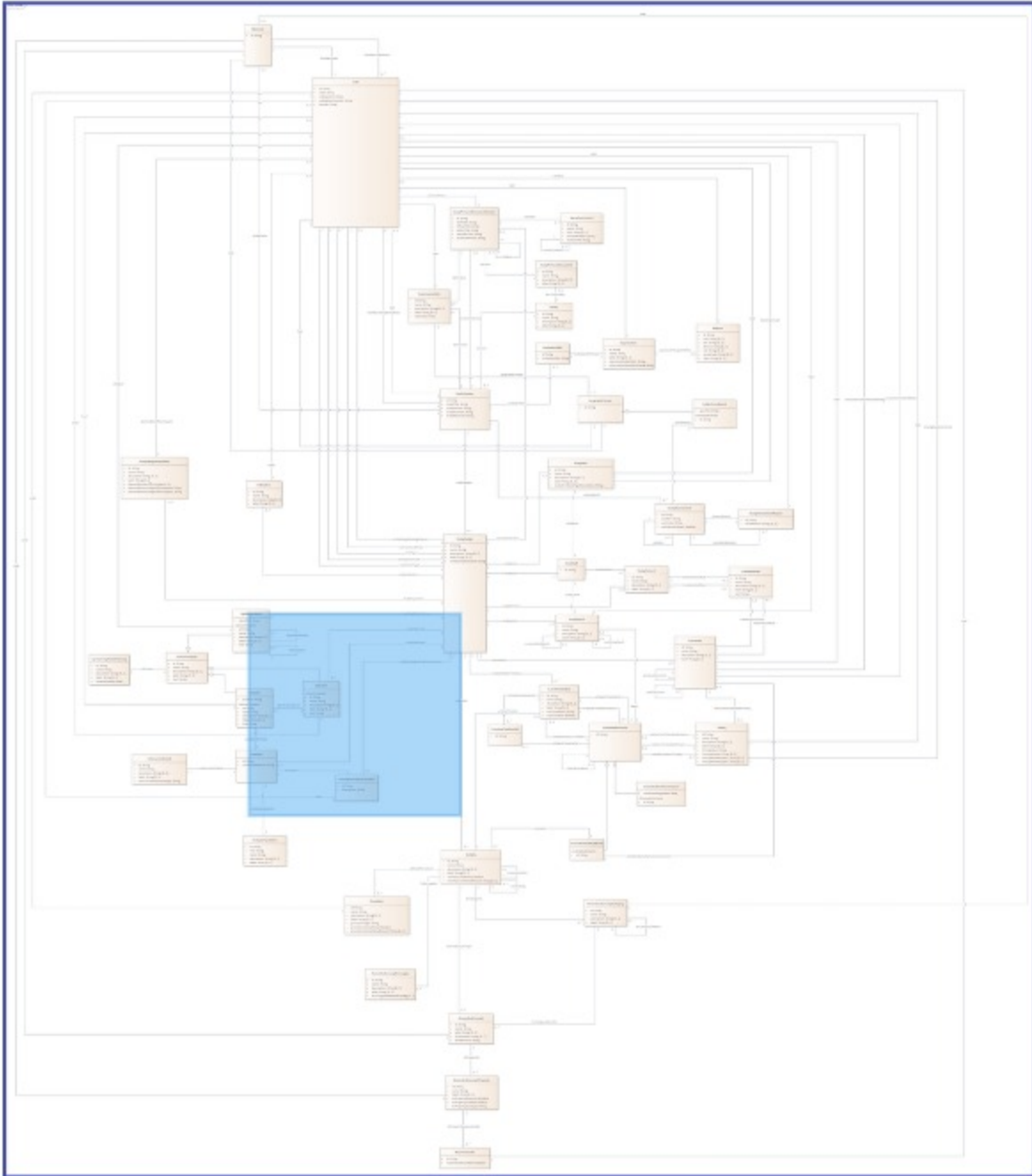
# Study Populations



```
{
  "id": "StudyDesignPopulation_1",
  "name": "POP1",
  "label": "",
  "description": "Population One, low age group",
  "plannedNumberOfParticipants": 100,
  "plannedMaximumAgeOfParticipants": "40 years",
  "plannedMinimumAgeOfParticipants": "18 years",
  "plannedSexOfParticipants": [
    {
      "id": "Code_104",
      "code": "C49636",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "Both"
    }
  ]
}
```



# Eligibility Criteria



## Eligibility Criteria

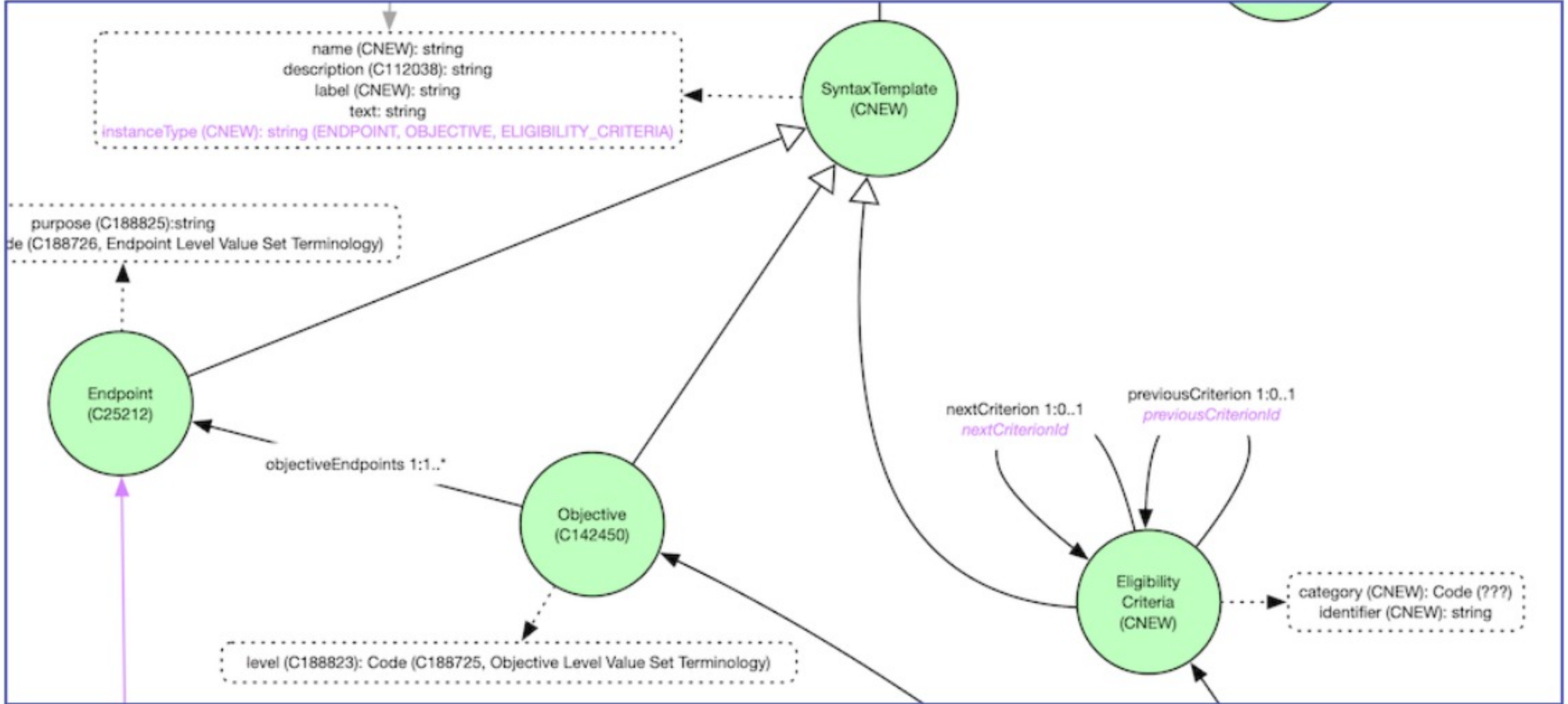
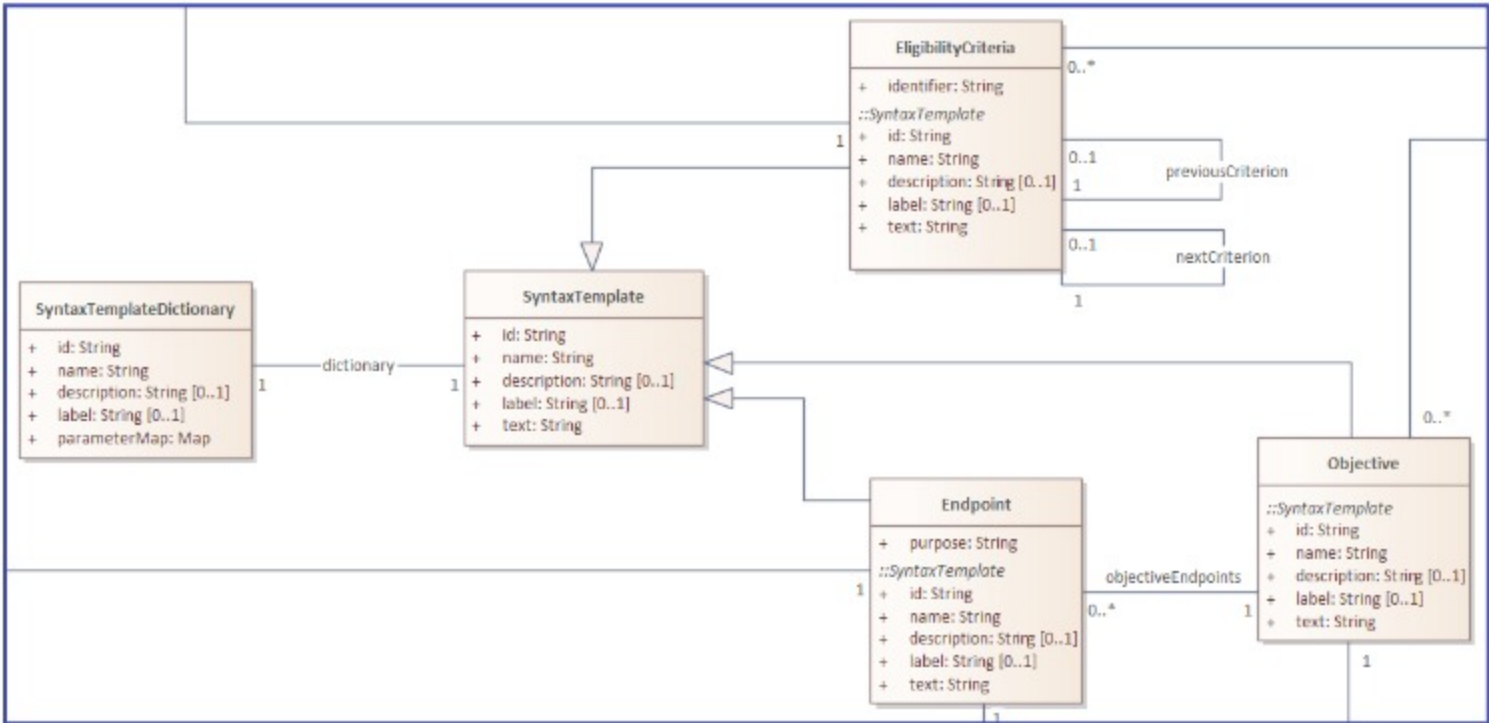
- Employs the syntax template mechanism
- Embedded tags within the text attribute

"text": "Subjects shall be between [min\_age] and [max\_age]"

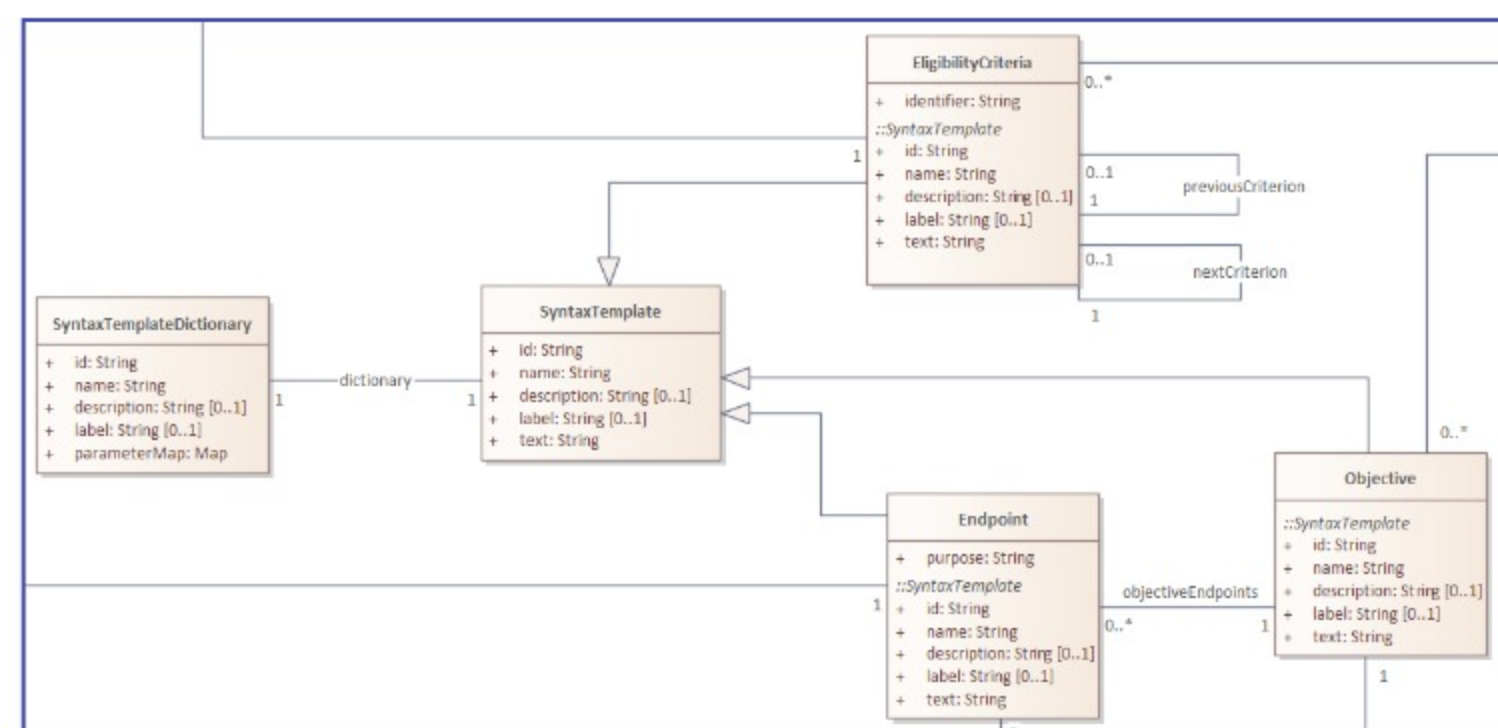
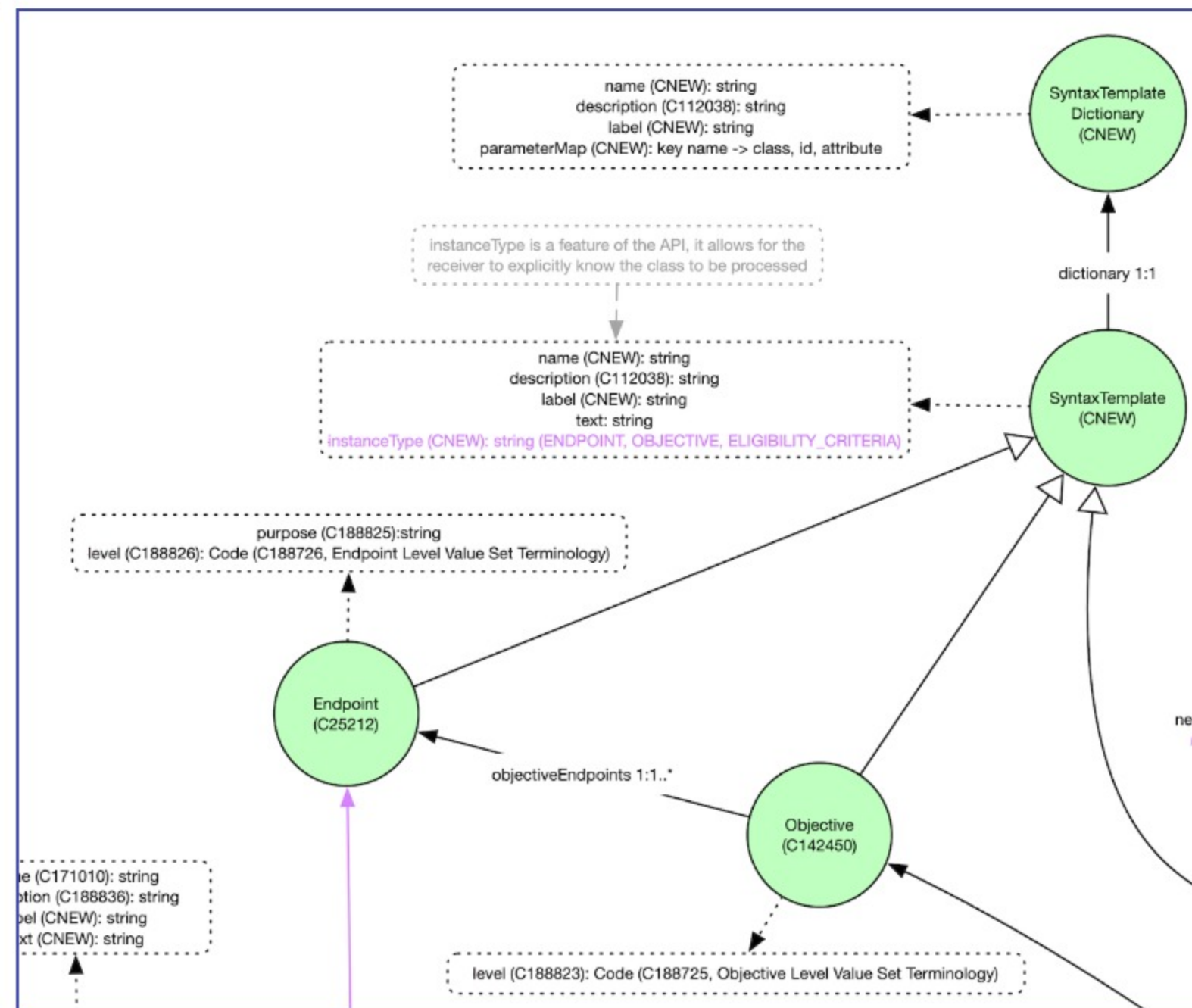
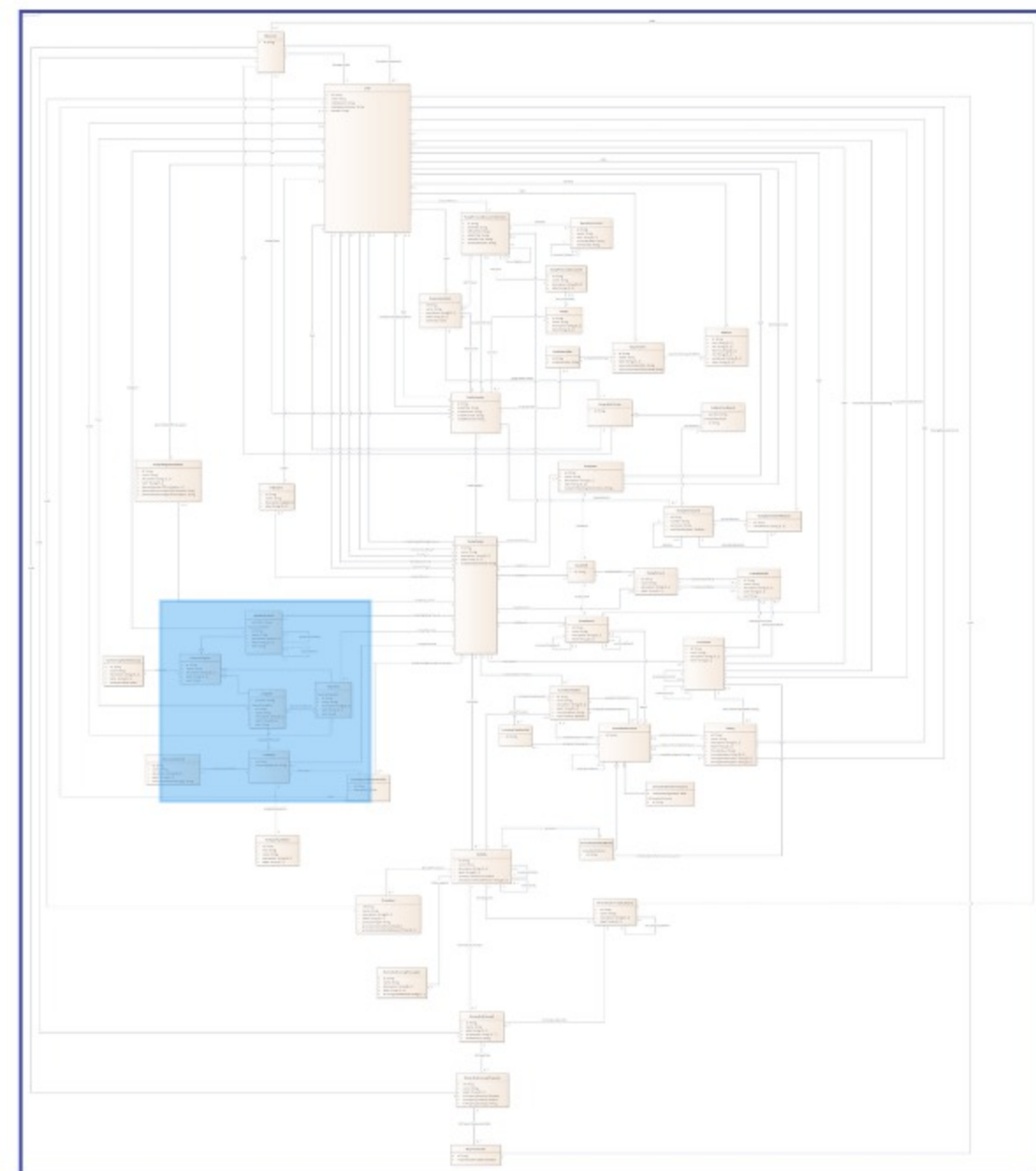
```

{
  "id": "EligibilityCriteria_1",
  "name": "Age Criteria",
  "label": "",
  "description": "The study age criterion",
  "instanceType": "ELIGIBILITY_CRITERIA",
  "text": "Subjects shall be between [min_age] and [max_age]",
  "dictionaryId": "SyntaxTemplateDictionary_1",
  "category": {
    "id": "Code_112",
    "code": "C25532",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Inclusion Criteria"
  },
  "identifier": "1",
  "nextCriterionId": null,
  "previousCriterionId": null
}

```



# Study Objectives and Endpoints

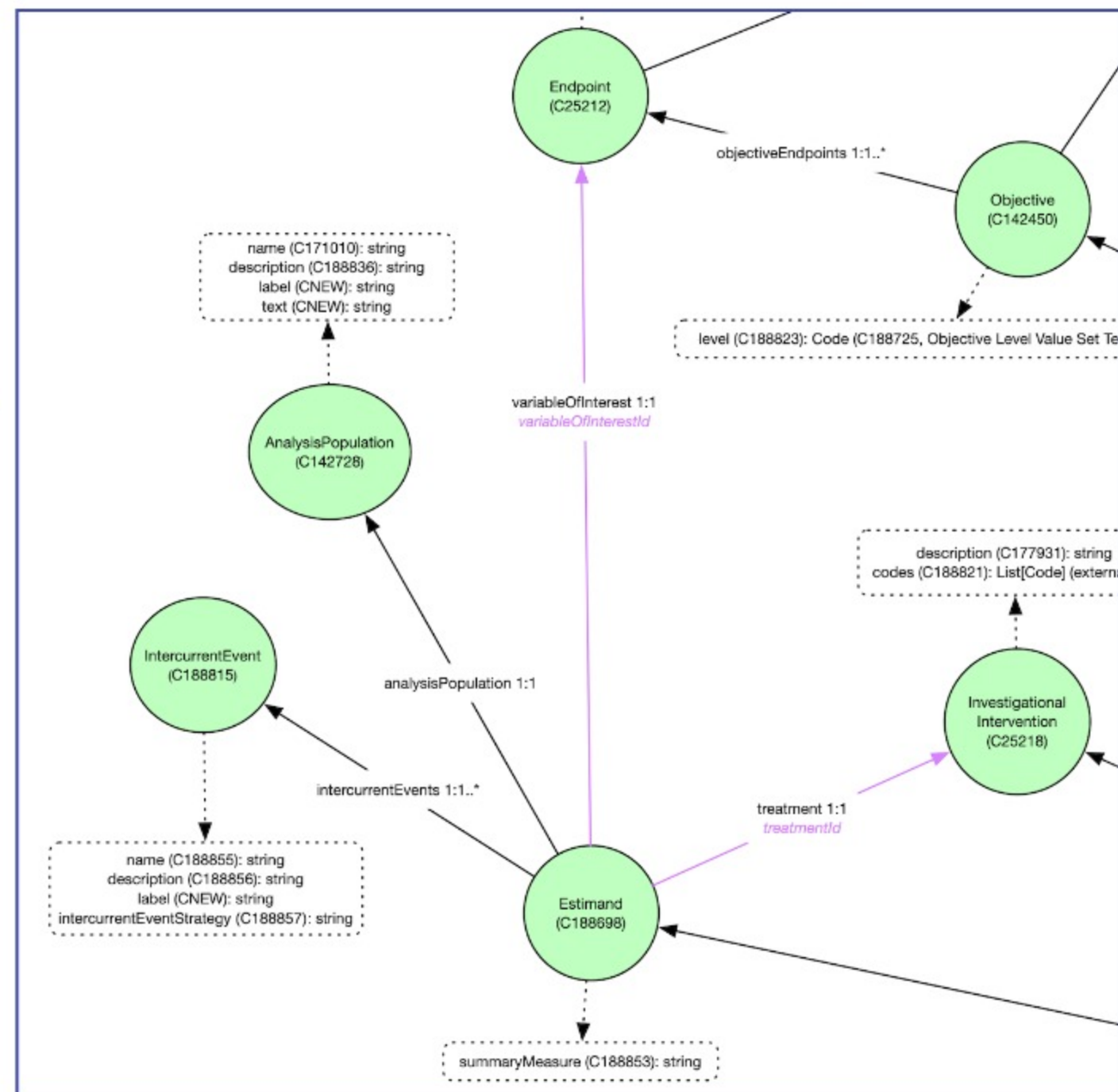
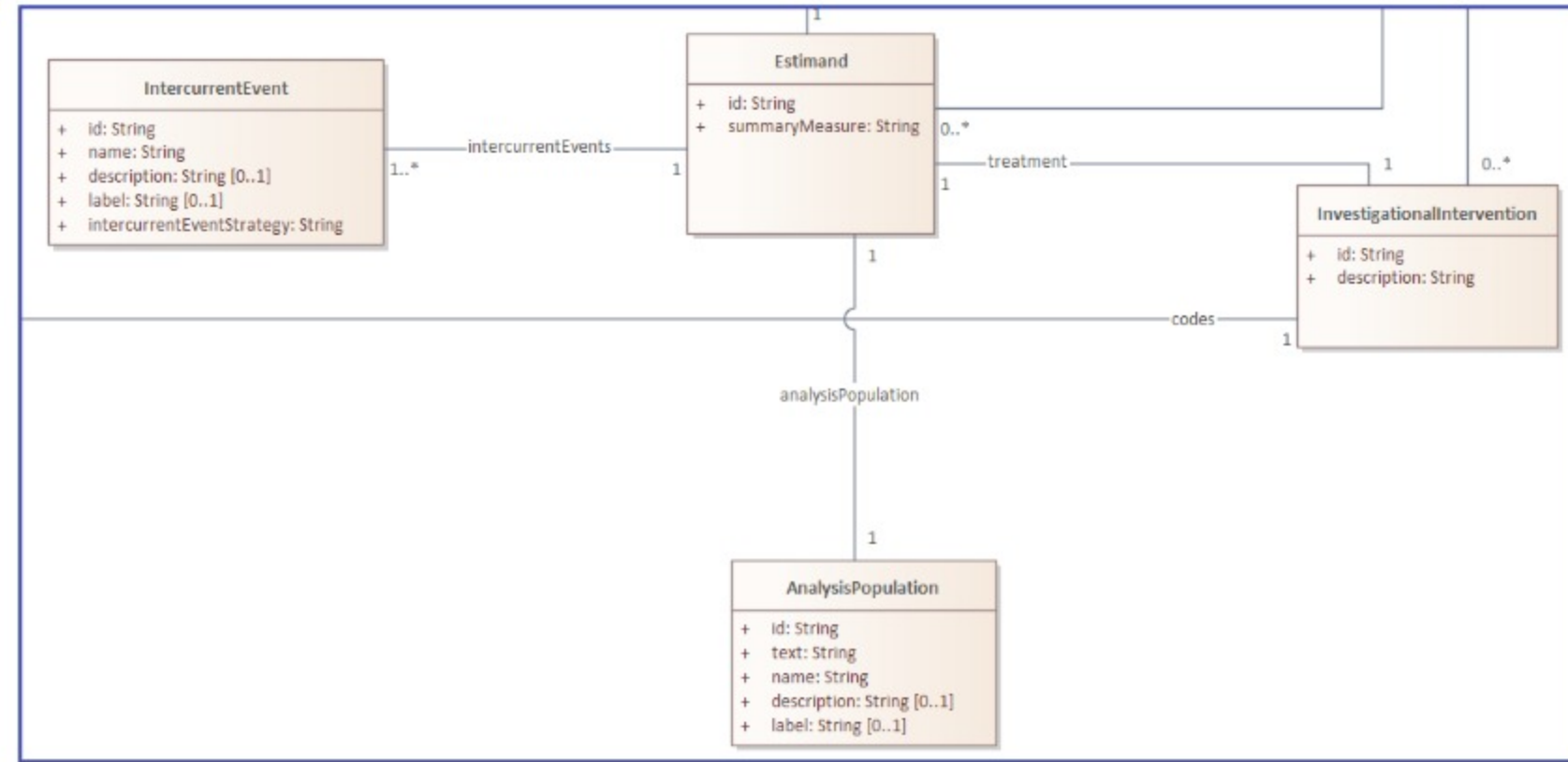
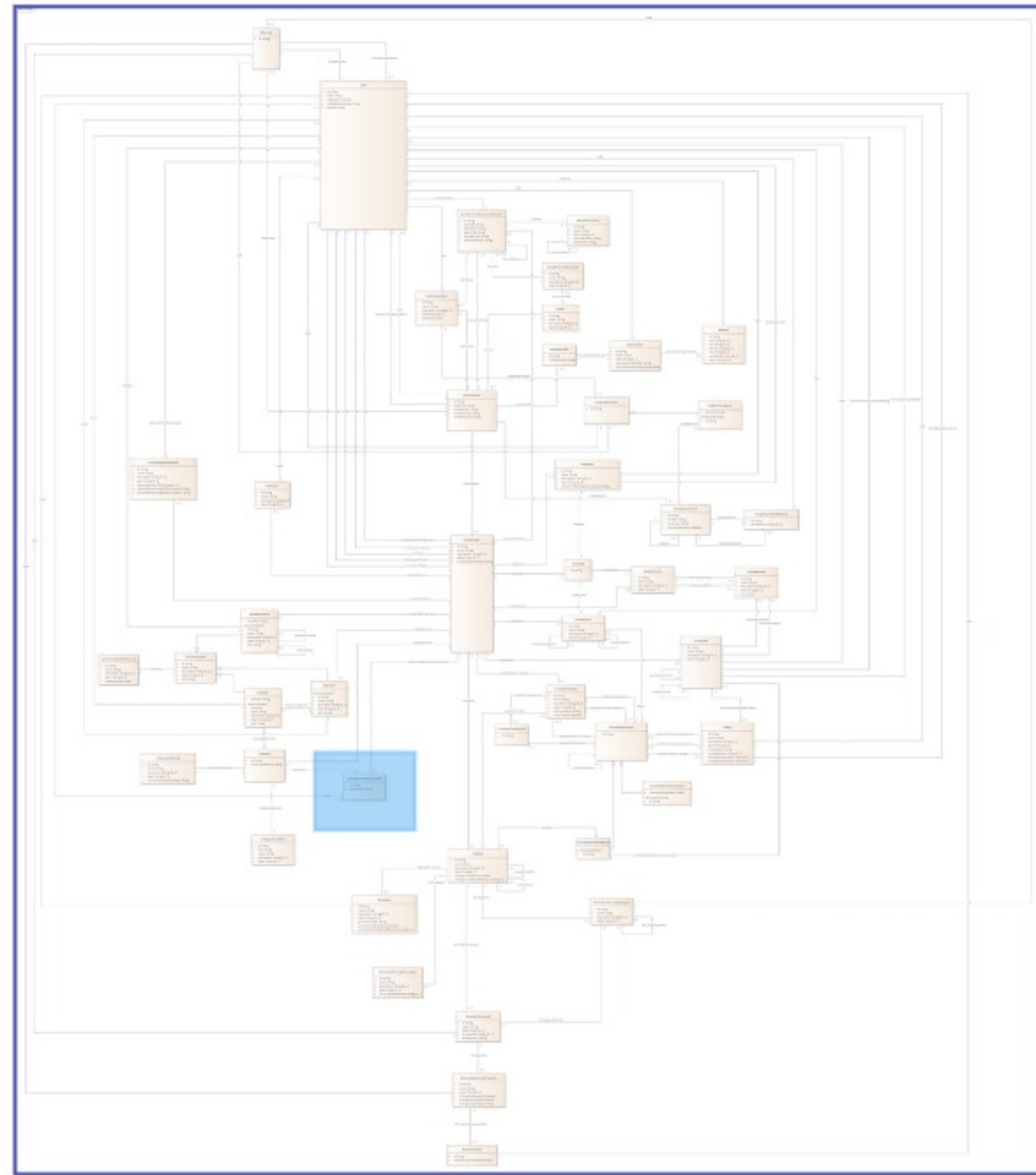


```

{
  "id": "Objective_1",
  "name": "OBJ1",
  "label": "",
  "description": "Primary",
  "instanceType": "OBJECTIVE",
  "text": "The primary efficacy objective for this study is to evaluate the efficacy of TCZ compared with placebo in combination with SOC for the treatment of severe COVID-19 pneumonia",
  "dictionaryId": null,
  "level": {
    "id": "Code_108",
    "code": "C85826",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Trial Primary Objective"
  },
  "objectiveEndpoints": [
    {
      "id": "Endpoint_1",
      "name": "END1",
      "label": "",
      "description": "Day 28, 7 category scale",
      "instanceType": "ENDPOINT",
      "text": "Clinical status assessed using a 7-category ordinal scale at Day 28",
      "dictionaryId": null,
      "purpose": "",
      "level": {
        "id": "Code_107",
        "code": "C94496",
        "codeSystem": "http://www.cdisc.org",
        "codeSystemVersion": "2023-09-29",
        "decode": "Primary Endpoint"
      }
    }
  ]
}

```

# Study Estimands



```

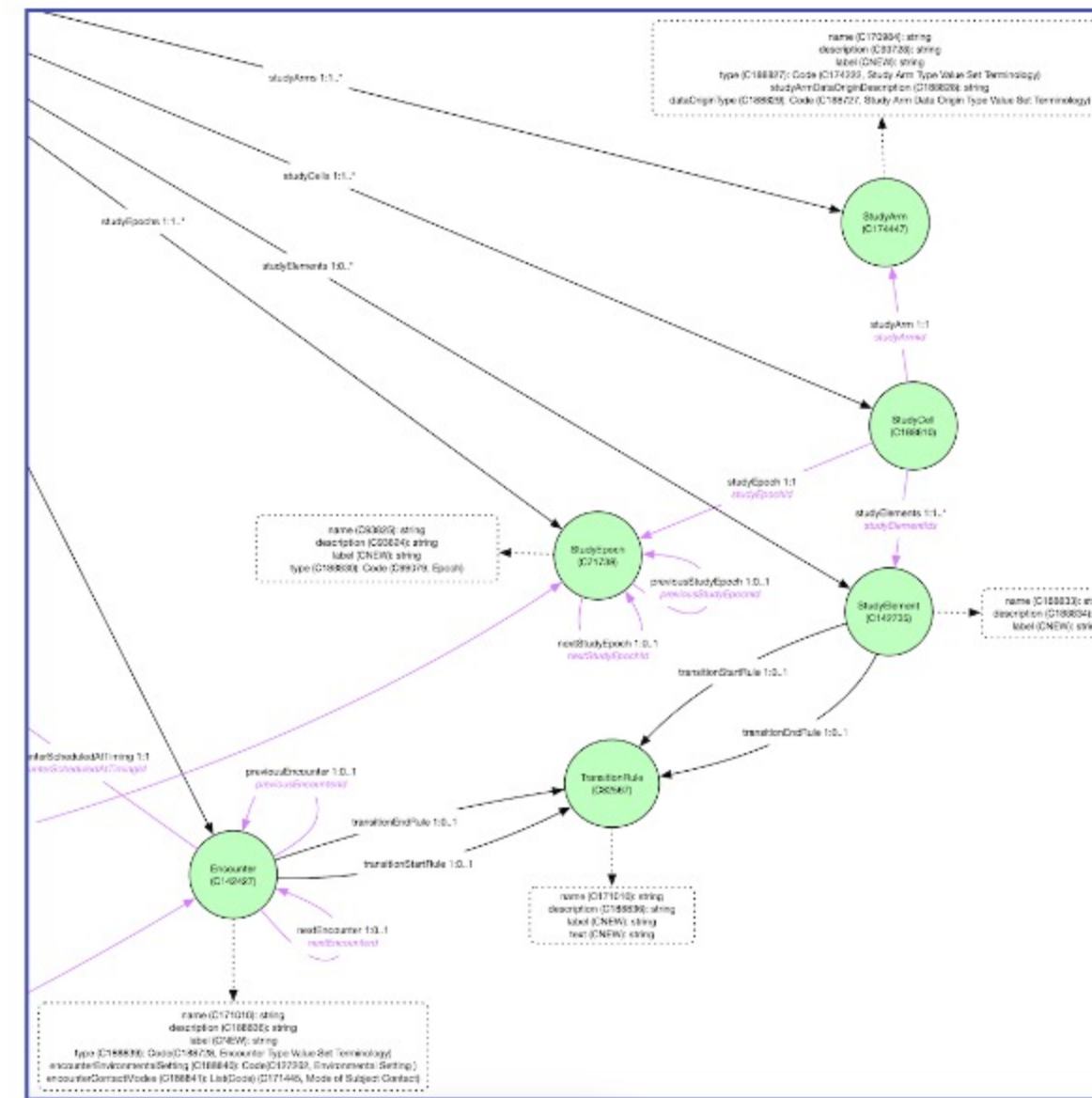
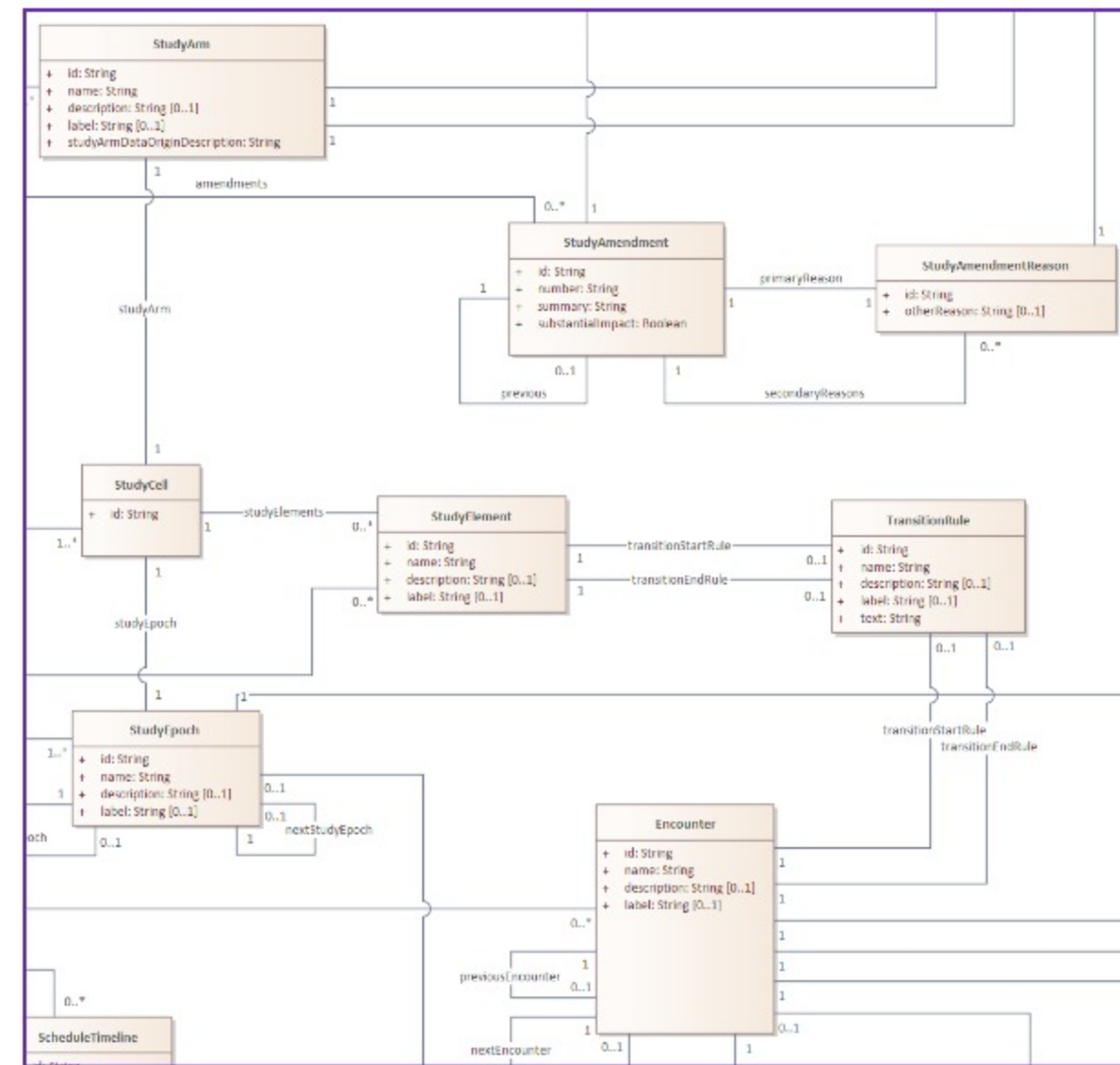
{
  "id": "Estimand_1",
  "summaryMeasure": "Survival of all patients",
  "analysisPopulation": {
    "id": "AnalysisPopulation_1",
    "name": "AP_1",
    "label": null,
    "description": null,
    "text": "ITT"
  },
  "treatmentId": "InvestigationalIntervention_1",
  "variableOfInterestId": "Endpoint_1",
  "intercurrentEvents": [
    {
      "id": "IntercurrentEvent_1",
      "name": "termination",
      "label": "",
      "description": "IC Event Description",
      "intercurrentEventStrategy": "Patients with out of range lab values before dosing will be excluded"
    }
  ]
}
  
```



# Arms, Epoch etc

## High Level Study Design

- Arms & Epochs
- Cells
- Elements
- Encounters (Visits)
- Entry and Exit Rules
- Can be used as a start of SDTM Trial Design Domain population
- Also T domains can be imported to build a study design "framework"



```

{
  "id": "StudyArm_1",
  "name": "Active",
  "label": "Active Substance",
  "description": "Active Substance",
  "type": {
    "id": "Code_57",
    "code": "C174267",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Active Comparator Arm"
  },
  "studyArmDataOriginDescription": "Data collected from subjects",
  "dataOriginType": {
    "id": "Code_58",
    "code": "C188866",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Data Generated Within Study"
  }
}

```

```

{
  "id": "StudyEpoch_1",
  "name": "Screening",
  "label": "Screening",
  "description": "Screening Epoch",
  "type": {
    "id": "Code_61",
    "code": "C48262",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Trial Screening"
  },
  "previousStudyEpochId": null,
  "nextStudyEpochId": "StudyEpoch_2"
}

```

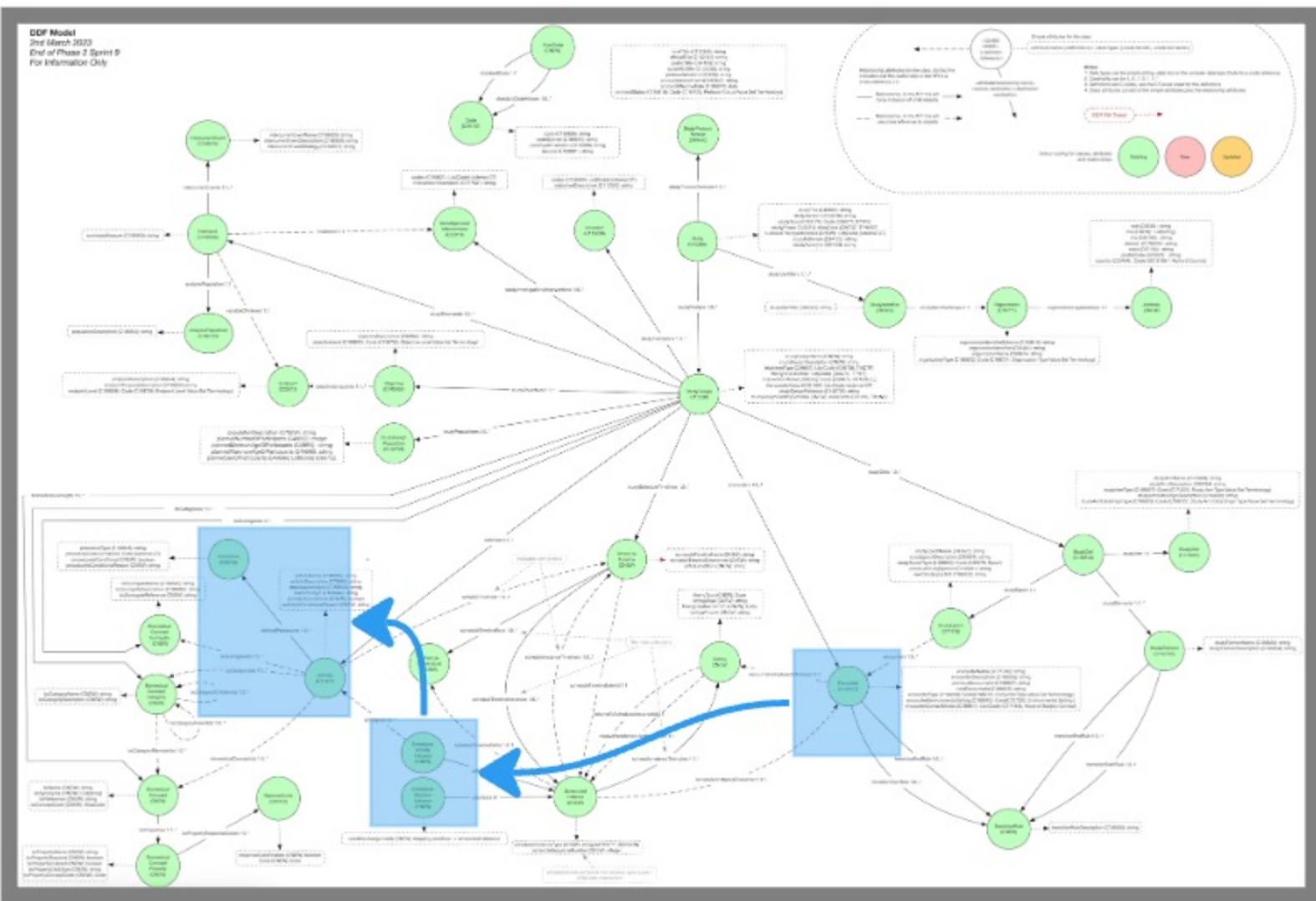
# Trial Summary Domain

## Trial Summary (TS) Domain

- Initial mapping
- In the IG

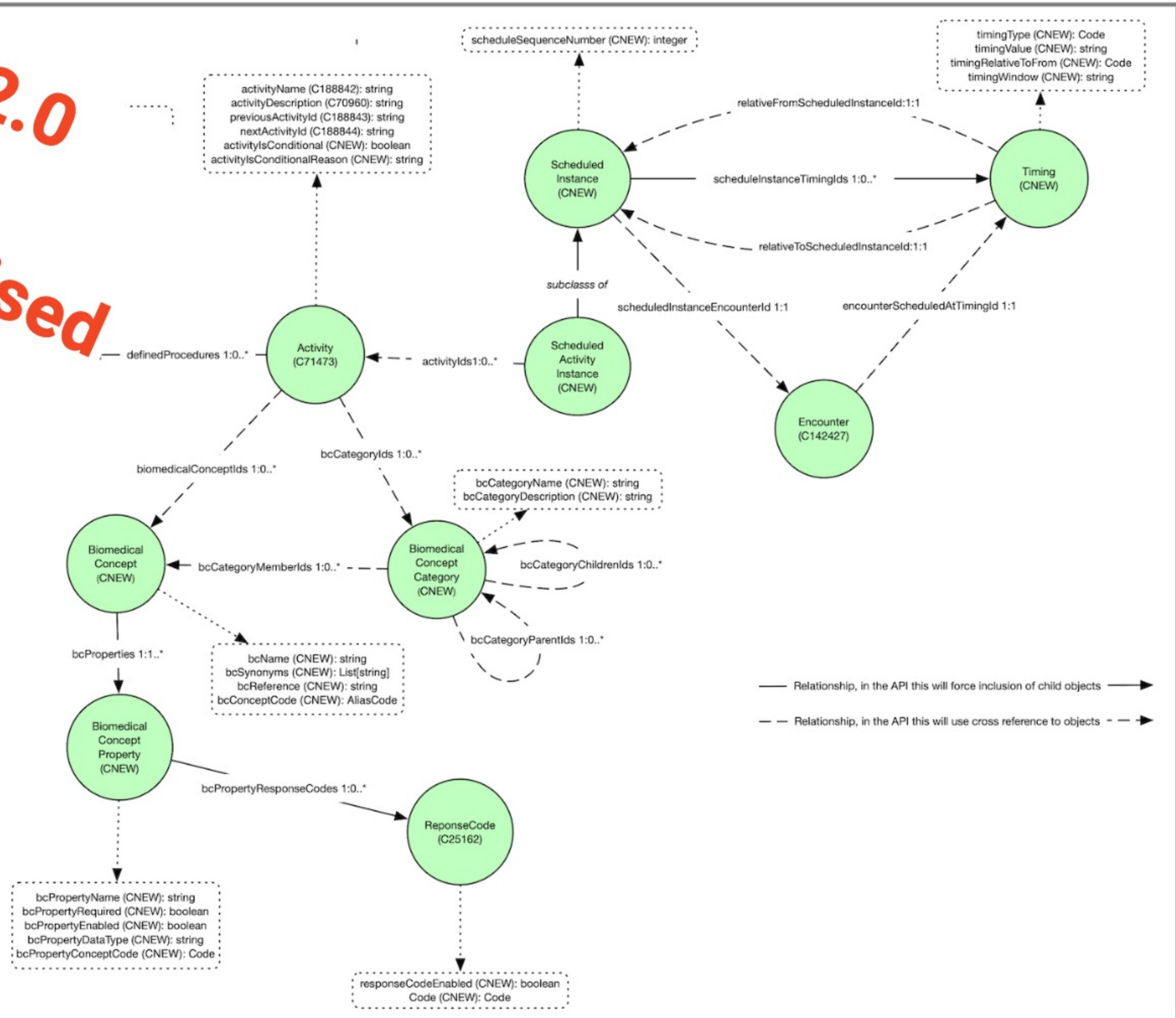
Code	CDISC Submission Value	CDISC Synonym(s)	NCI Preferred Term	USDM Entity Name	USDM Role	USDM Item Name
C101302	THERAREA	Therapeutic Area	Therapeutic Area	StudyDesign	Attribute	therapeuticAreas
C112038	INDIC	Trial Disease/Condition	Trial Indication	Indication	Entity	Indication
C112038	INDIC	Trial Disease/Condition	Trial Indication	Indication	Attribute	indicationDescription
C142175	STYPE	Study Type; Study	Study Type	Study	Attribute	studyType
C48281	TPHASE	Trial Phase; Trial Phase	Trial Phase	Study	Attribute	studyPhase
C49652	TINDTP	Trial Intent Type	Clinical Study by Intent	StudyDesign	Attribute	trialIntentType
C49658	TBLIND	Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial Blinding Schema; Trial Masking Design	Trial Blinding Schema	StudyDesign	Attribute	studyDesignBlindingScheme
C49660	TTYPE	Trial Scope; Trial Type	Trial Type	StudyDesign	Attribute	trialType
C49692	PLANSUB	Anticipated Enrollment; Planned Enrollment; Planned Number of Subjects; Target Enrollment	Planned Subject Number	StudyDesignPopulation	Attribute	plannedNumberOfParticipants
C49693	AGEMIN	Planned Minimum Age of Subjects	Planned Minimum Age of Subjects	StudyDesignPopulation	Attribute	plannedMinimumAgeOfParticipants
C49694	AGEMAX	Planned Maximum Age of Subjects	Planned Maximum Age of Subjects	StudyDesignPopulation	Attribute	plannedMaximumAgeOfParticipants
C49696	SEXPOP	Sex of Participants	Sex of Study Group	StudyDesignPopulation	Attribute	plannedSexOfParticipants
C49802	TITLE	Official Study Title; Study Title; Trial Title	Trial Title	Study	Attribute	studyTitle
C98746	INTMODEL	Intervention Model	Intervention Model	StudyDesign	Attribute	interventionModel
C70793	SPONSOR	Clinical Study Sponsor; Sponsor; Study Sponsor	Clinical Study Sponsor	Organization	Valid Value	Valid Value Set for Attribute organizationType
C85826	OBJPRIM	Study Primary Objective; Trial Primary Objective	Trial Primary Objective	Objective	Valid Value	Valid Value Set for Attribute objectiveLevel
C85827	OBJSEC	Study Secondary Objective; Trial Secondary Objective	Trial Secondary Objective	Objective	Valid Value	Valid Value Set for Attribute objectiveLevel

VERSION 2.0  
 Will be updated for  
 Version 3



# Activities, Encounters & "Glue"

**VERSION 2.0**  
**Needs to be revised**  
**Ignore! :)**



## Linking Encounters with Activities

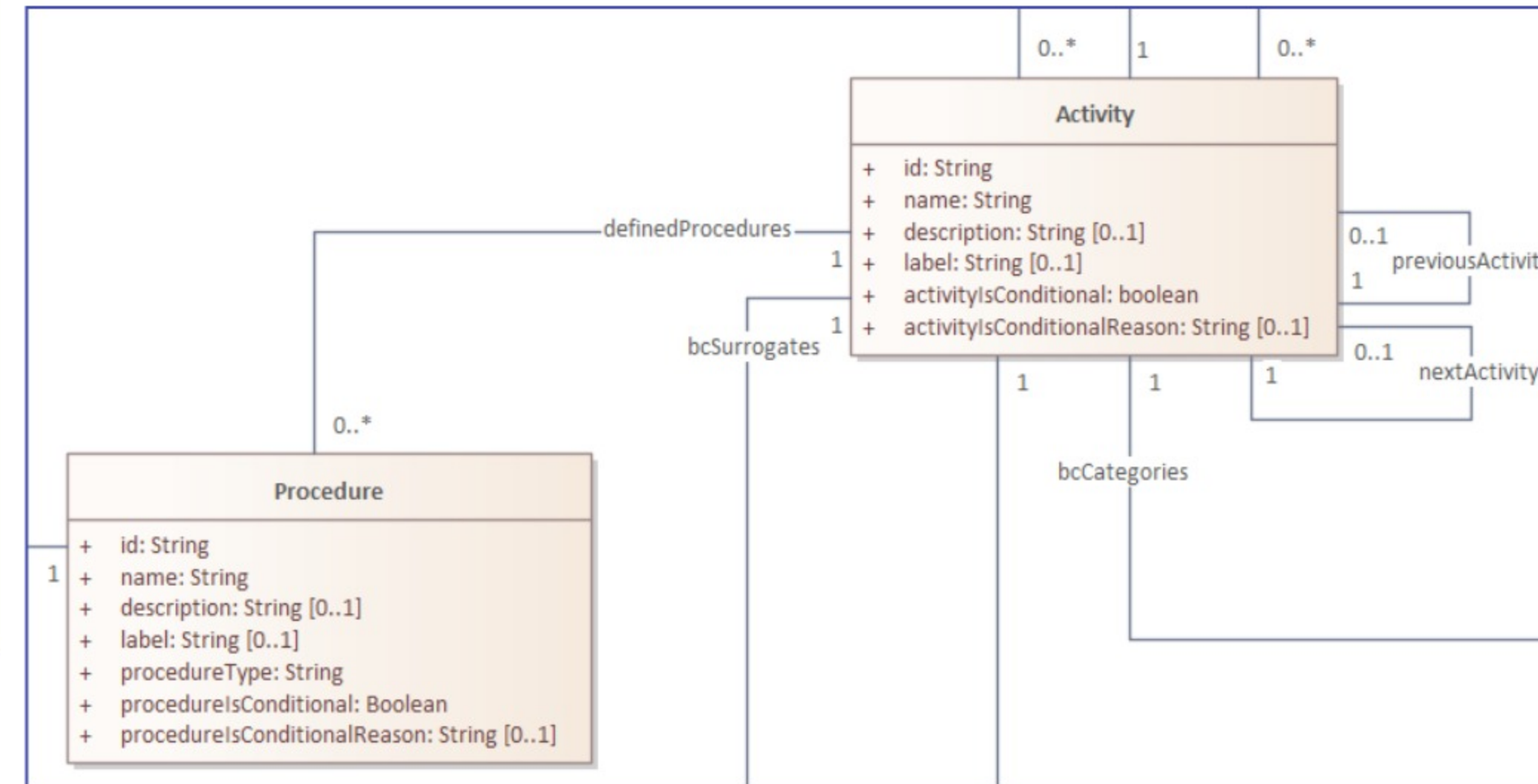
- Scheduled Activity Instance links encounters with Activities
- Timing also provided by linking Scheduled Activity Instance to Timing
- Activity links onto Procedures and BCs
- Important piece is the Activity <-> "timing" <-> Encounter linkage

— Relationship, in the API this will force inclusion of child objects —>  
 - - - Relationship, in the API this will use cross reference to objects - - ->

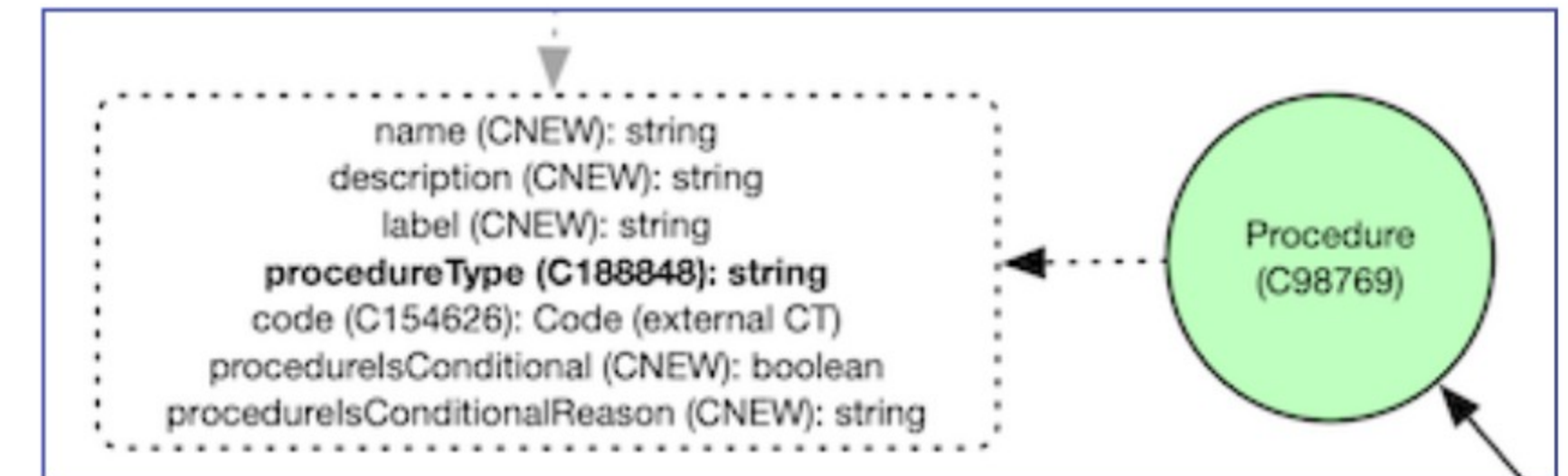
# Procedures

## Procedures

- Linked from activities with multiple procedures per activity
- Name and description added during internal review
- Can be conditional with condition expressed as text



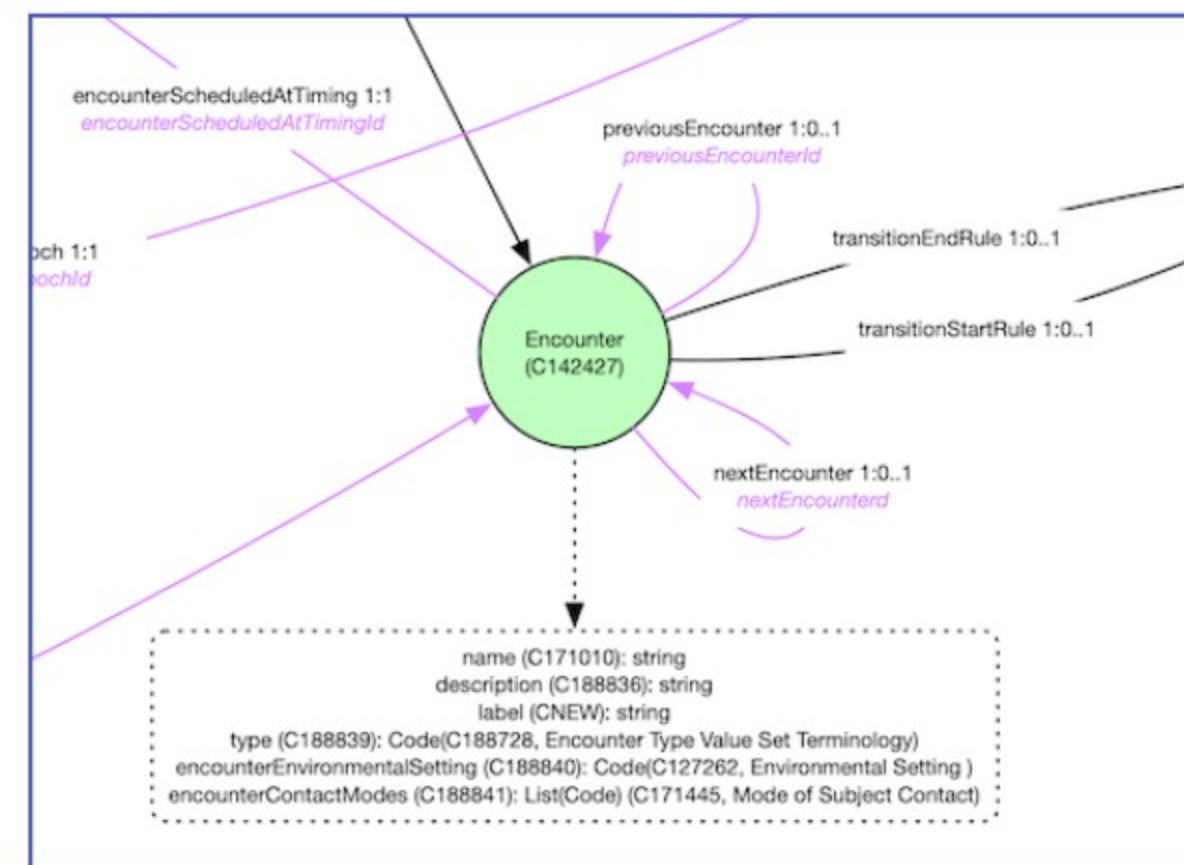
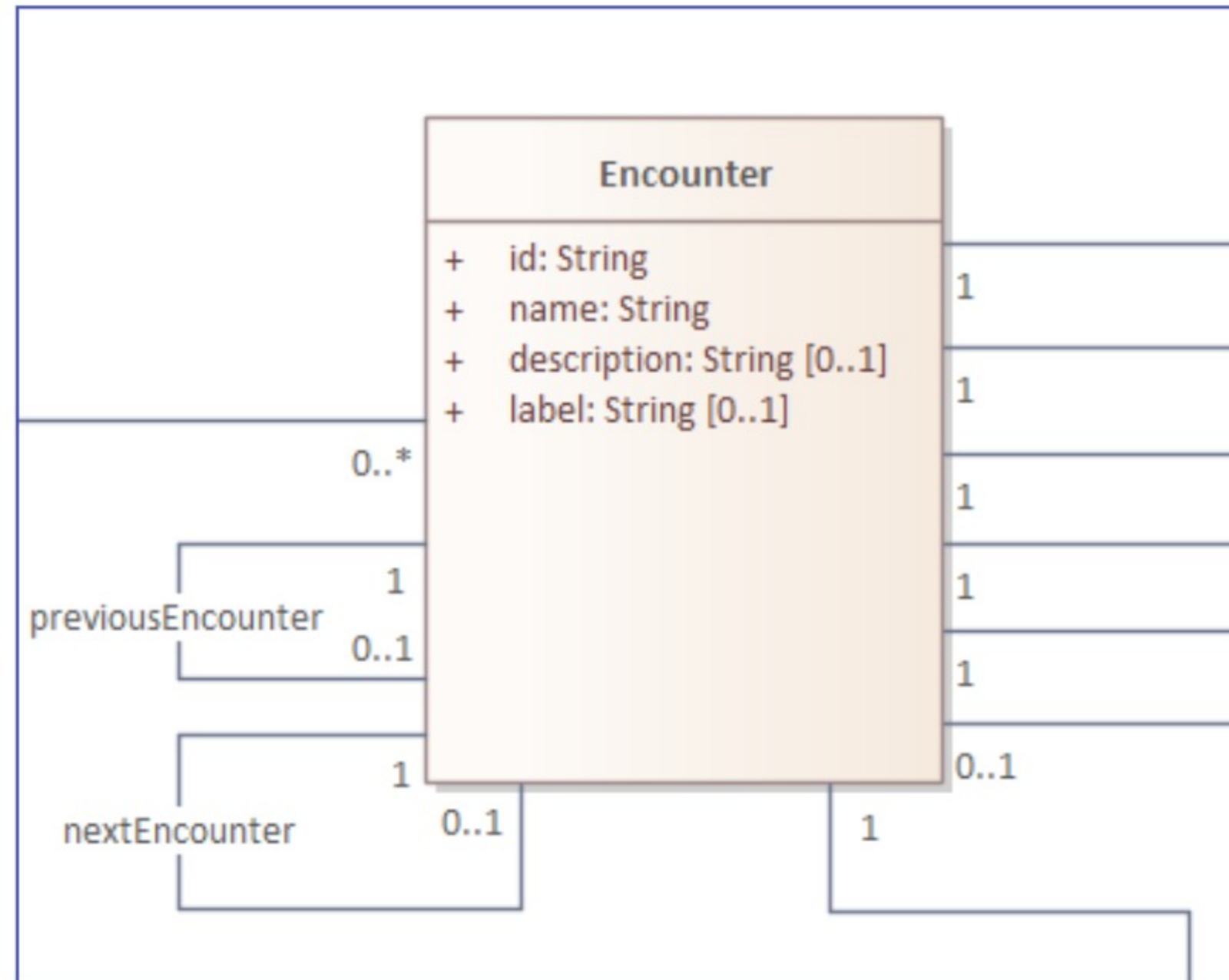
```
{
  "id": "Procedure_2",
  "name": "PR2",
  "label": "6MWT",
  "description": "6min Walk Test conducted after the stress test",
  "procedureType": "Stress",
  "code": {
    "id": "Code_38",
    "code": "12345679",
    "codeSystem": "SNOMED",
    "codeSystemVersion": "January 31, 2018",
    "decode": "Test"
  },
  "procedureIsConditional": true,
  "procedureIsConditionalReason": "Only if stress test passed"
}
```



# Encounters

## Encounters

- Definition of an encounter
- Cross referenced from Epochs
- References timing to detail the encounter window
- Note encounter type, currently only value is "Visit"

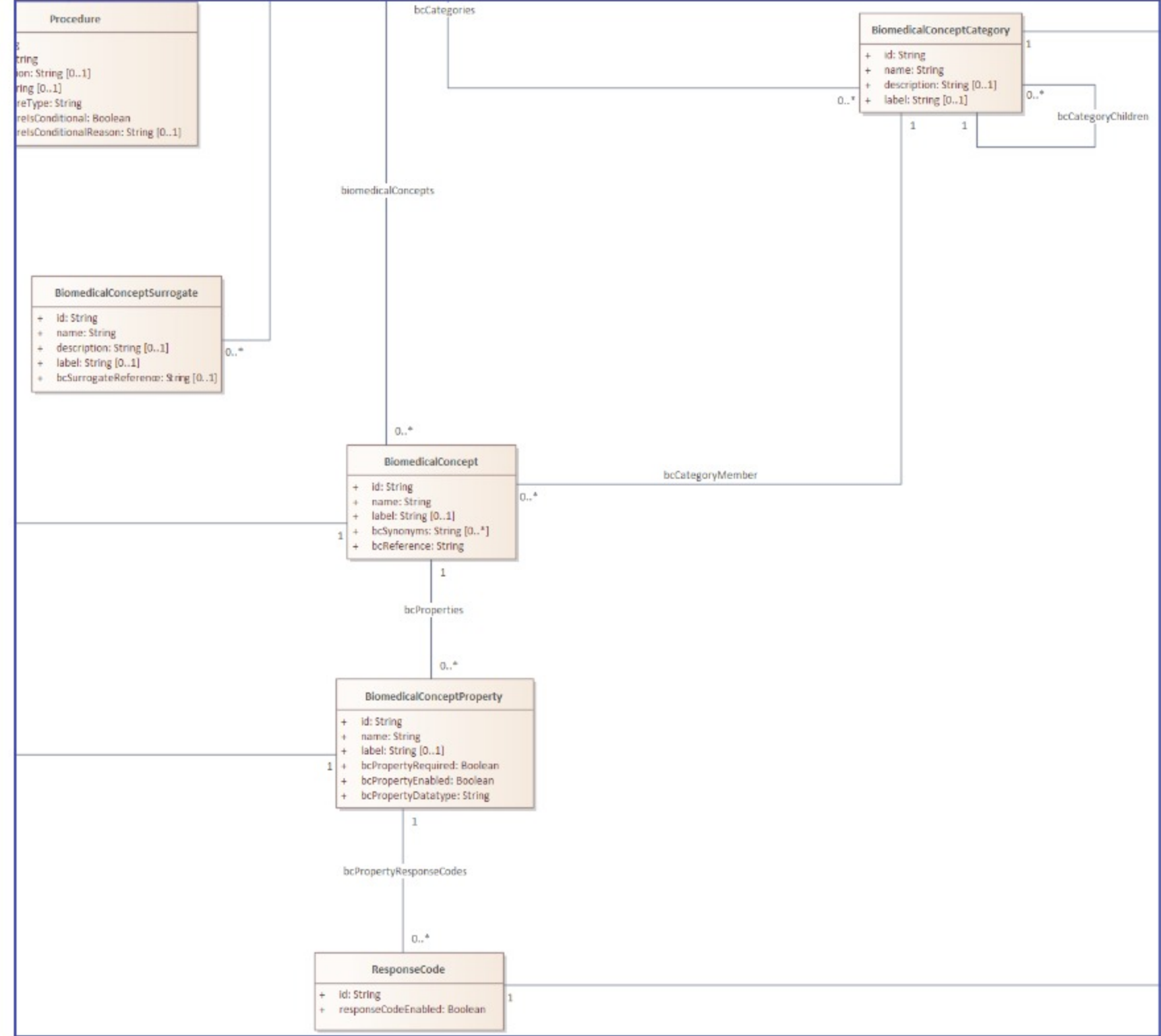
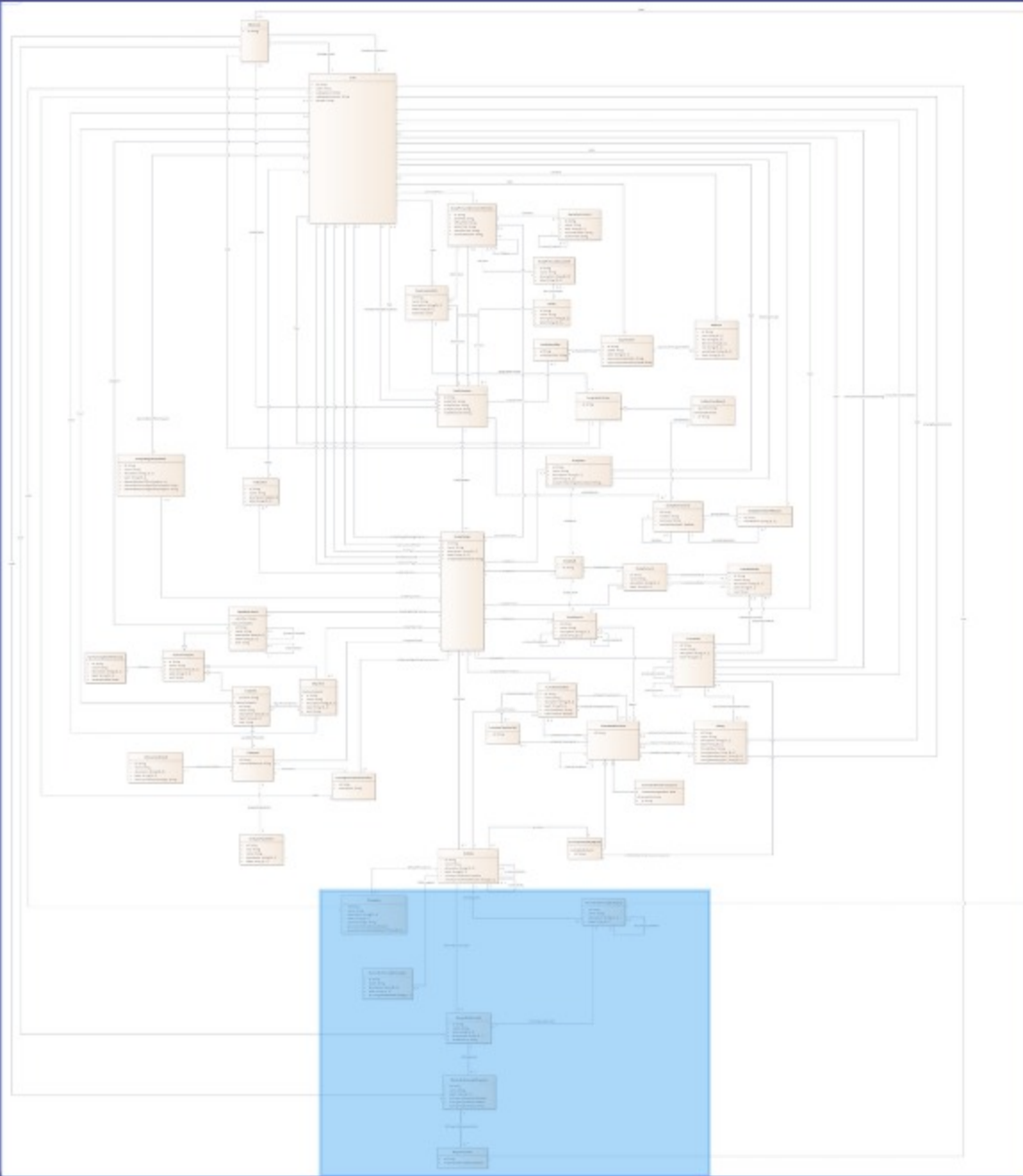


```

{
  "id": "Encounter_1",
  "name": "E1",
  "label": "Screening",
  "description": "Screening encounter",
  "type": {
    "id": "Code_39",
    "code": "C25716",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Visit"
  },
  "previousEncounterId": null,
  "nextEncounterId": "Encounter_2",
  "encounterScheduledAtTimingId": null,
  "encounterEnvironmentalSetting": {
    "id": "Code_40",
    "code": "C51282",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Clinic"
  },
  "encounterContactModes": [
    {
      "id": "Code_41",
      "code": "C175574",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2023-09-29",
      "decode": "In Person"
    }
  ],
  "transitionStartRule": {
    "id": "TransitionRule_1",
    "name": "ENCOUNTER_START_RULE_1",
    "label": null,
    "description": null,
    "text": "Subject identified"
  },
  "transitionEndRule": {
    "id": "TransitionRule_2",
    "name": "ENCOUNTER_START_RULE_1",
    "label": null,
    "description": null,
    "text": "IEs passed"
  }
}

```

# Biomedical Concepts I



## Biomedical Concepts

- Allows for
  - Single BC
  - Hierarchy of BCs
  - Surrogate BCs
- Based on CDISC BC Model
- See example of simple BC to the right



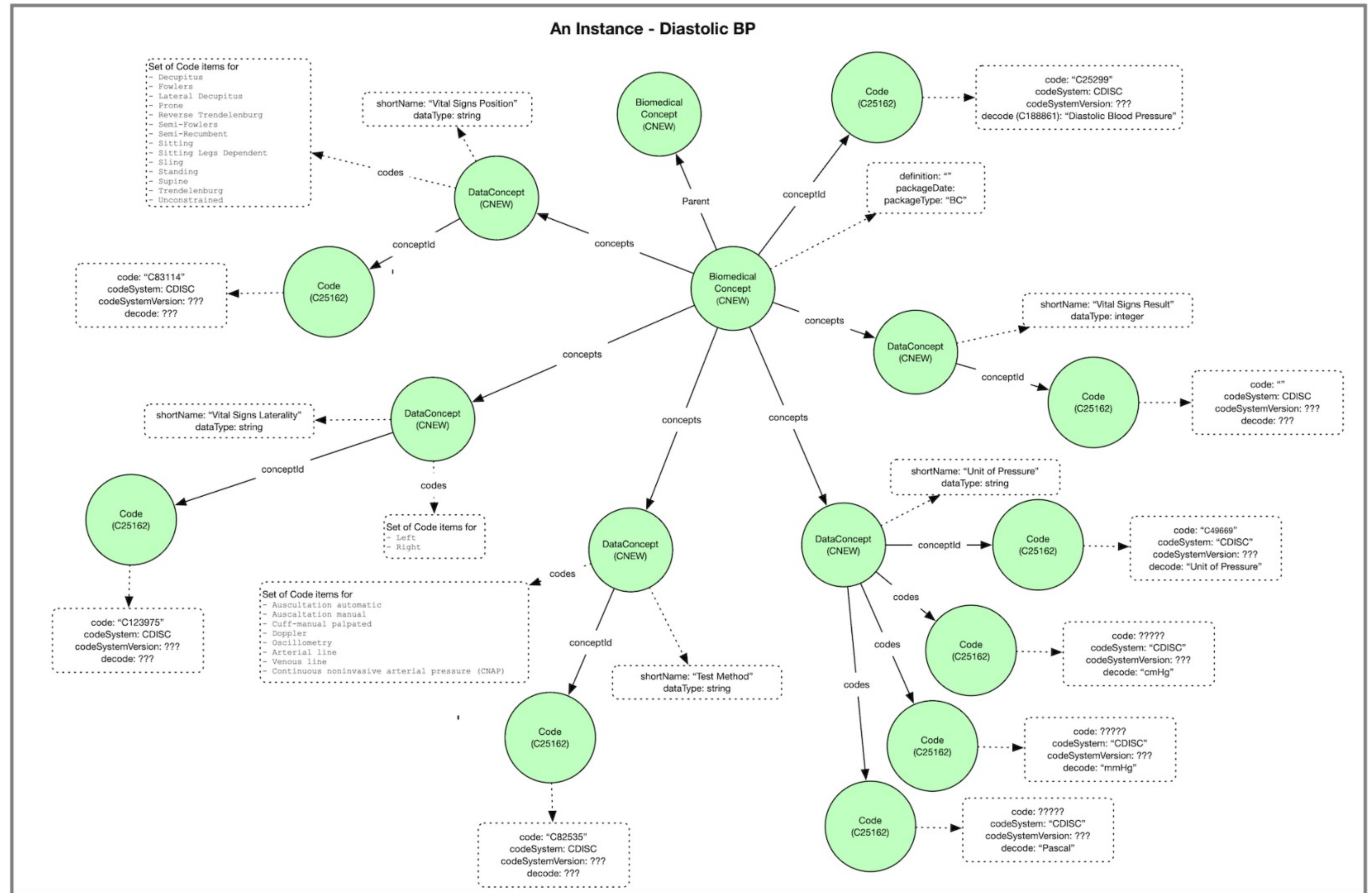
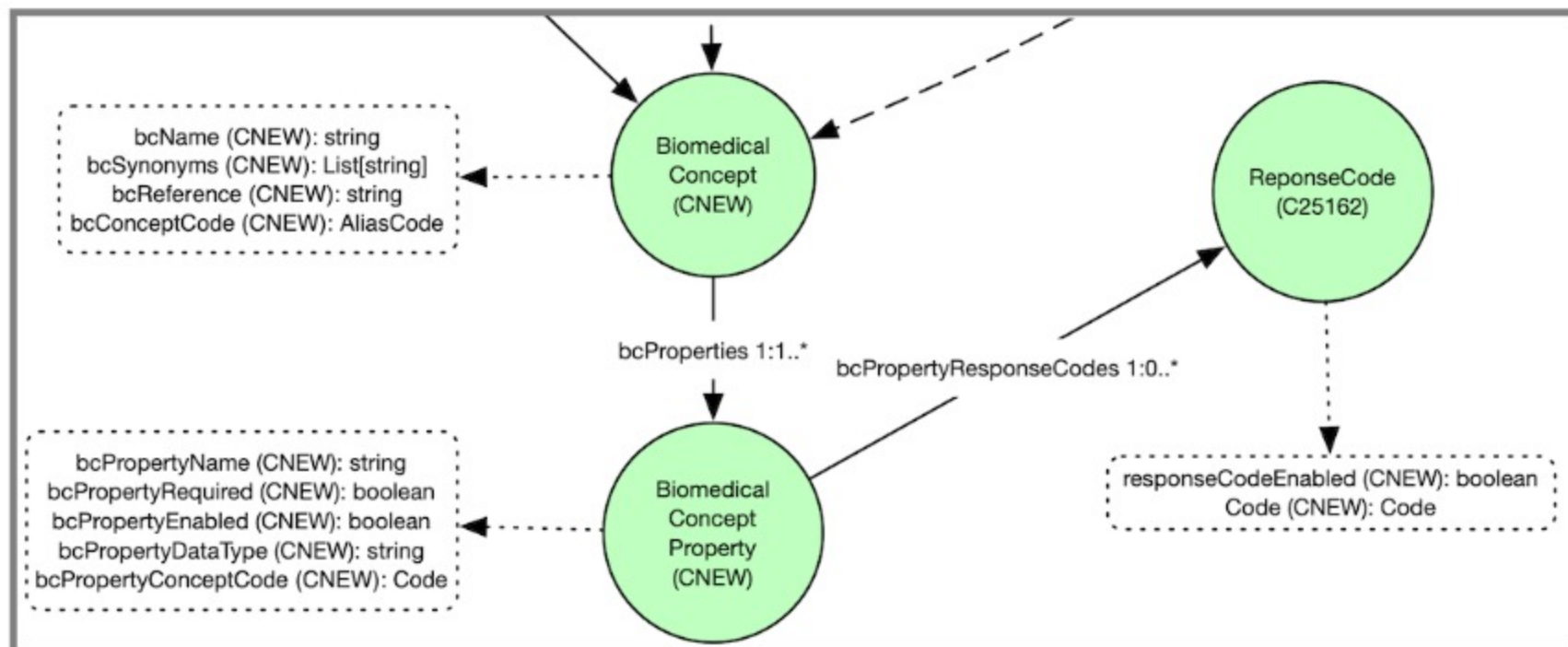
## Slide Deck

- Sets the scene for BCs
- Used several times to provide the background around BCs

# Biomedical Concepts II

## View of an CDISC API Instance

- Image is a little old now but useful if you are not familiar with the idea of BCs
- Note
  - Central node and the multiple "data concept" or "property" nodes
  - Code responses or definition, e.g.
    - identification is a single code
    - units has multiple codes
- USDM BCs have three levels, see model below



# Biomedical Concepts III

## Example BC Content

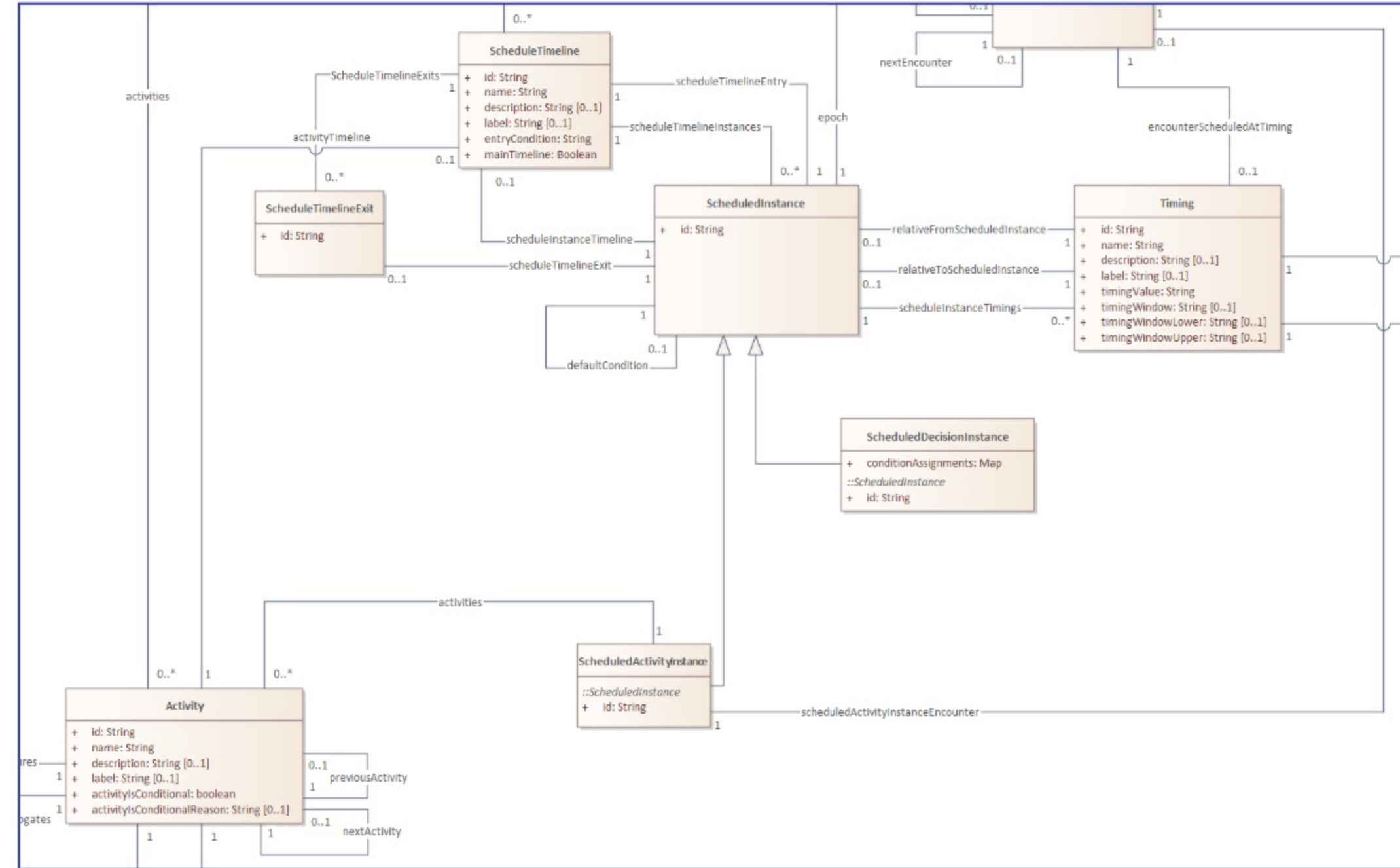
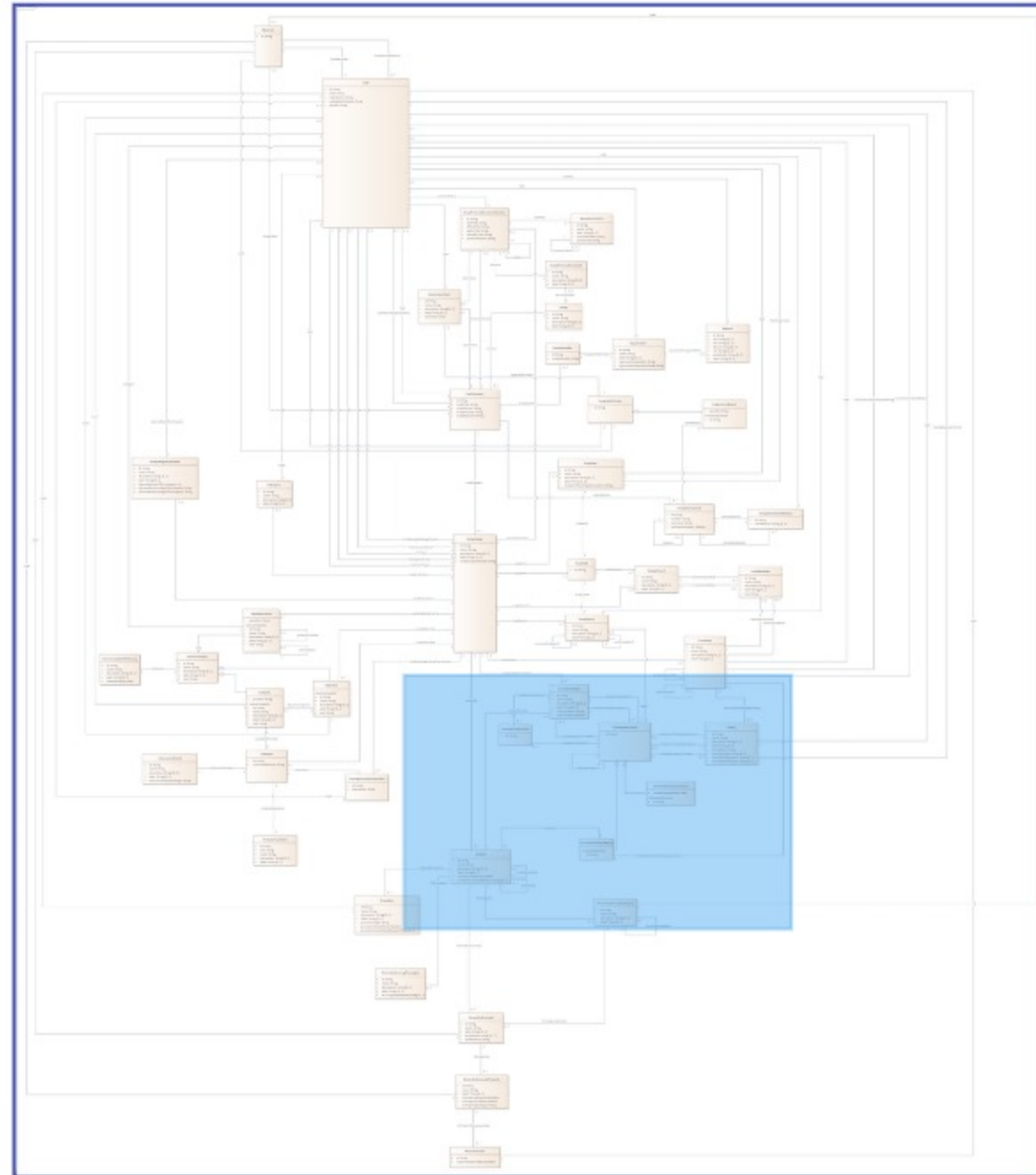
- Work ongoing to improve ISDM examples to use CDISC SDTM specializations
- Use these to fully populate USDM BC definitions

```
---
BiomedicalConcept:
  bcName: Diastolic Blood Pressure
  bcConceptId:
    standardCode:
      code: C25299
      codeSystem: http://www.cdisc.org
      codeSystemVersion: "2022-03-25"
      decode: Diastolic Blood Pressure
    standardCodeAliases:
      -
        code: 8462-4
        codeSystem: http://loinc.org/
        codeSystemVersion: "2022-03-25"
        decode: Diastolic Blood Pressure
      -
        code: 271650006
        codeSystem: SNOMED-CT
        codeSystemVersion: "2003"
        decode: Diastolic blood pressure
      -
        code: 4154790
        codeSystem: OHSDI
        codeSystemVersion:
        decode: Diastolic blood pressure
      -
    bcSynonyms:
      - DIABP
      - DIA BP
      - Blood pressure diastolic
      ...
  bcProperties:
    -
      ...
```

```
bcProperties:
  -
    bcPropertyName: Vital Signs Result
    bcPropertyEnabled: true
    bcPropertyRequired: true
    bcPropertyDataType: integer
    bcPropertyConceptId:
      code: C173522
      codeSystem: http://www.cdisc.org
      codeSystemVersion: "2022-03-25"
      decode: Vital Signs Result
    bcPropertyResponseCodes: []
  -
    bcPropertyName: Unit of Pressure
    bcPropertyEnabled: true
    bcPropertyRequired: true
    bcPropertyDataType: string
    bcPropertyConceptId:
      code: C49669
      codeSystem: http://www.cdisc.org
      codeSystemVersion: "2022-03-25"
      decode: Unit of Pressure
    bcPropertyResponseCodes:
      -
        responseCodeEnabled: true
        code:
          code: C49670
          codeSystem: http://www.cdisc.org
          codeSystemVersion: "2022-03-25"
          decode: mmHg
      -
        responseCodeEnabled: true
        code:
          code: C42547
          codeSystem: http://www.cdisc.org
          codeSystemVersion: "2022-03-25"
          decode: Pascal
```



# Study Design and Timing



## DDF, USDM, Study Design & "Timepoints"

Dave Iberson-Hurst

Version 5  
14<sup>th</sup> February 2023



### Slide Deck

- Outlines requirements (slides 7-26)
  - Complex timing
  - Branching
  - Cycles
- Slides 28-44 provide "instance" examples to explain the ideas
- **Things have moved on since the slide set was written**
  - **For example, class naming has changed**
  - **Still useful for overall concept**

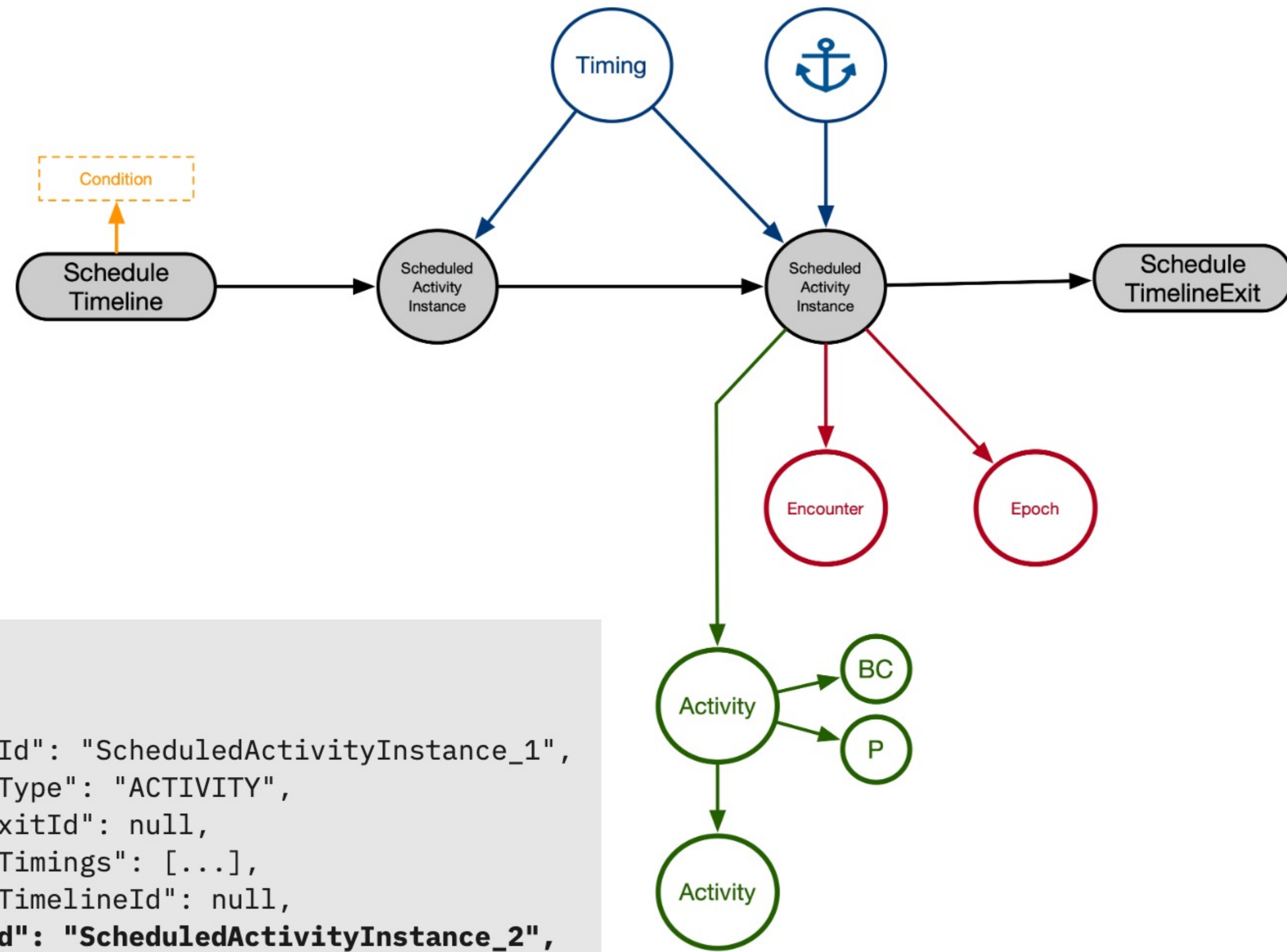
### "Timepoints"

- "Timepoints" was a label given to this area on the DDF project just for easy identification of an area of work.
- It is all about study timing

# Timeline

## Basics

- Based upon a “timeline” that uses
  - Entry and Exit
  - Conditions
  - Activity Instances
  - Condition Instances
  - Timing
- Activity Instances are linked by Timing information to position the instances in the timeline
- Linked to encounters, activities as per the current USDM
- Timelines can be referenced and reused



```
{
  ...
  {
    "scheduledInstanceId": "ScheduledActivityInstance_1",
    "scheduledInstanceType": "ACTIVITY",
    "scheduleTimelineExitId": null,
    "scheduledInstanceTimings": [...],
    "scheduledInstanceTimelineId": null,
    "defaultConditionId": "ScheduledActivityInstance_2",
    "epochId": "StudyEpoch_1",
    "activityIds": [ ... ],
    "scheduledActivityInstanceEncounterId": "Encounter_1"
  },
  ...
}
```

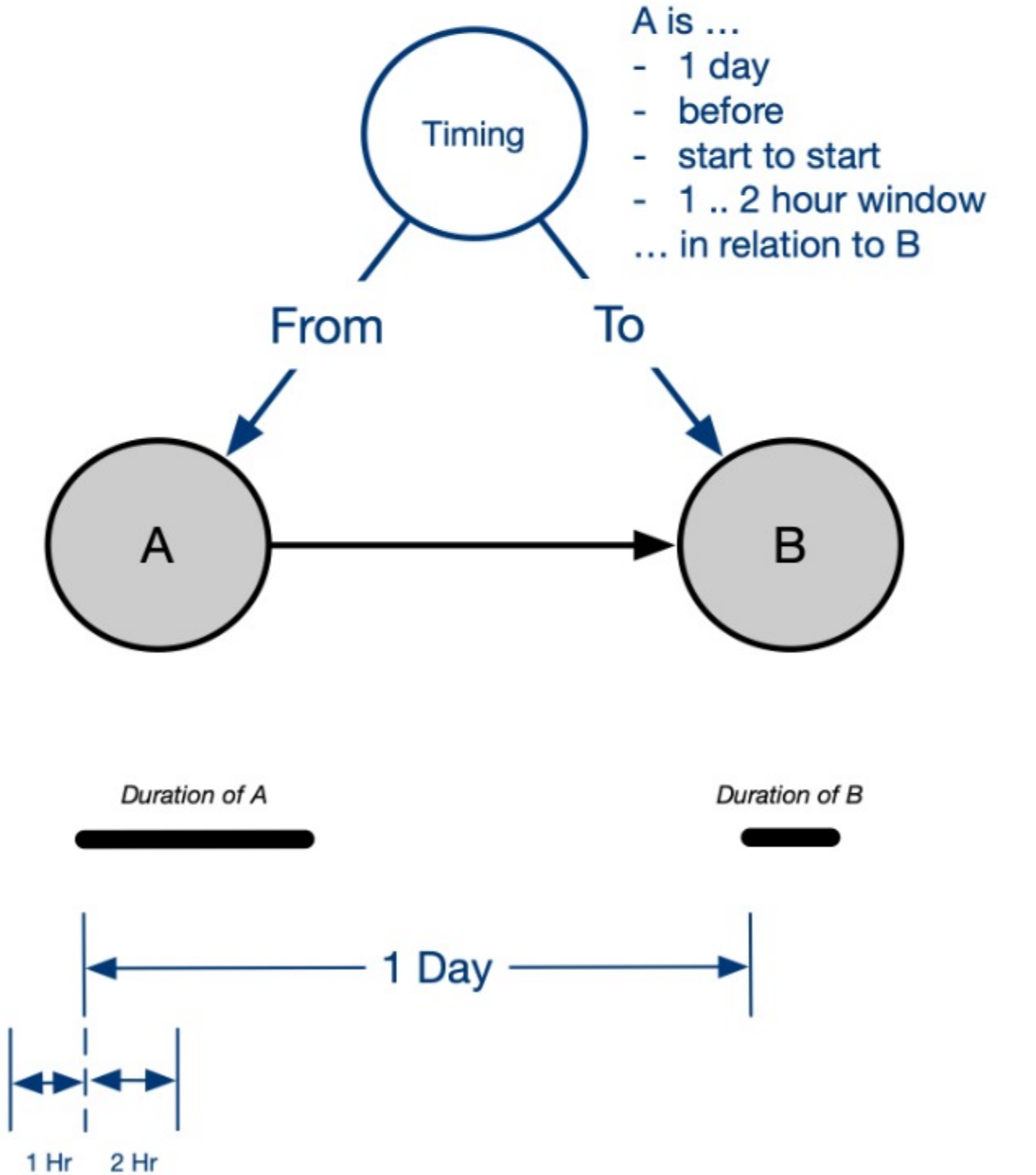
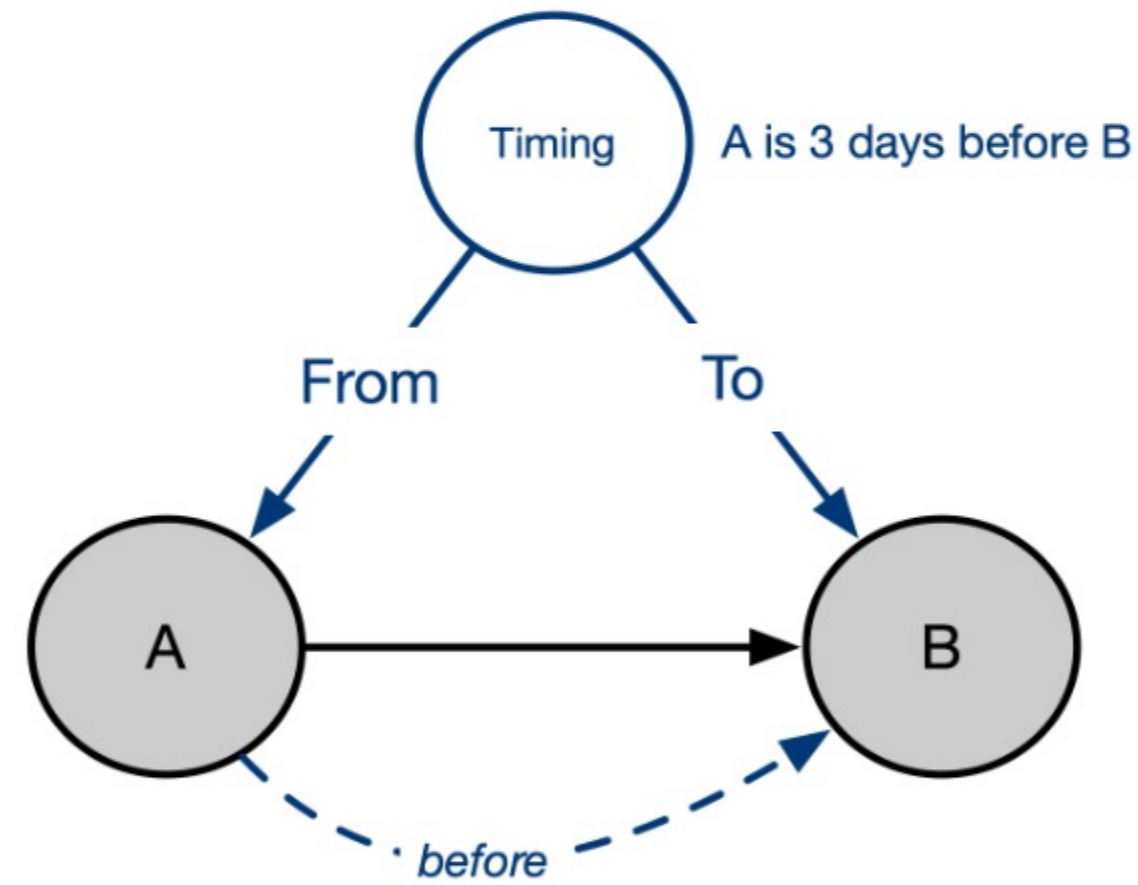
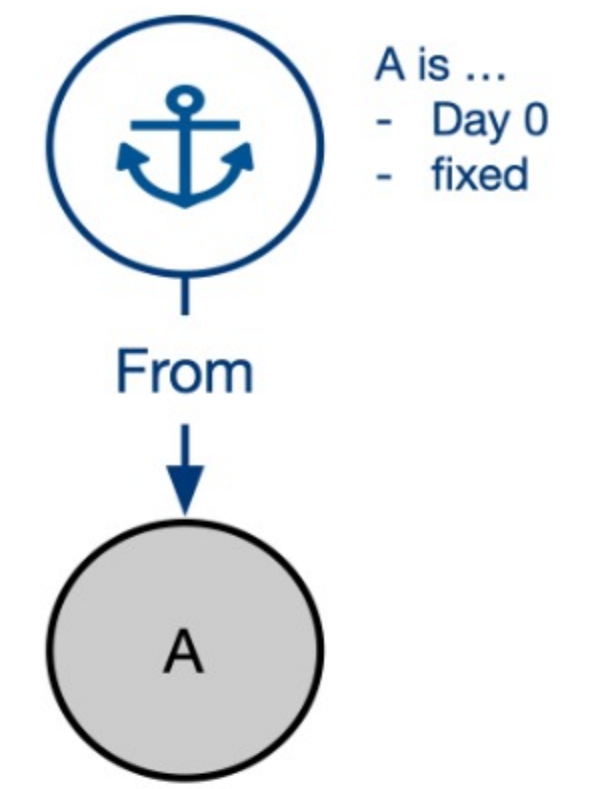
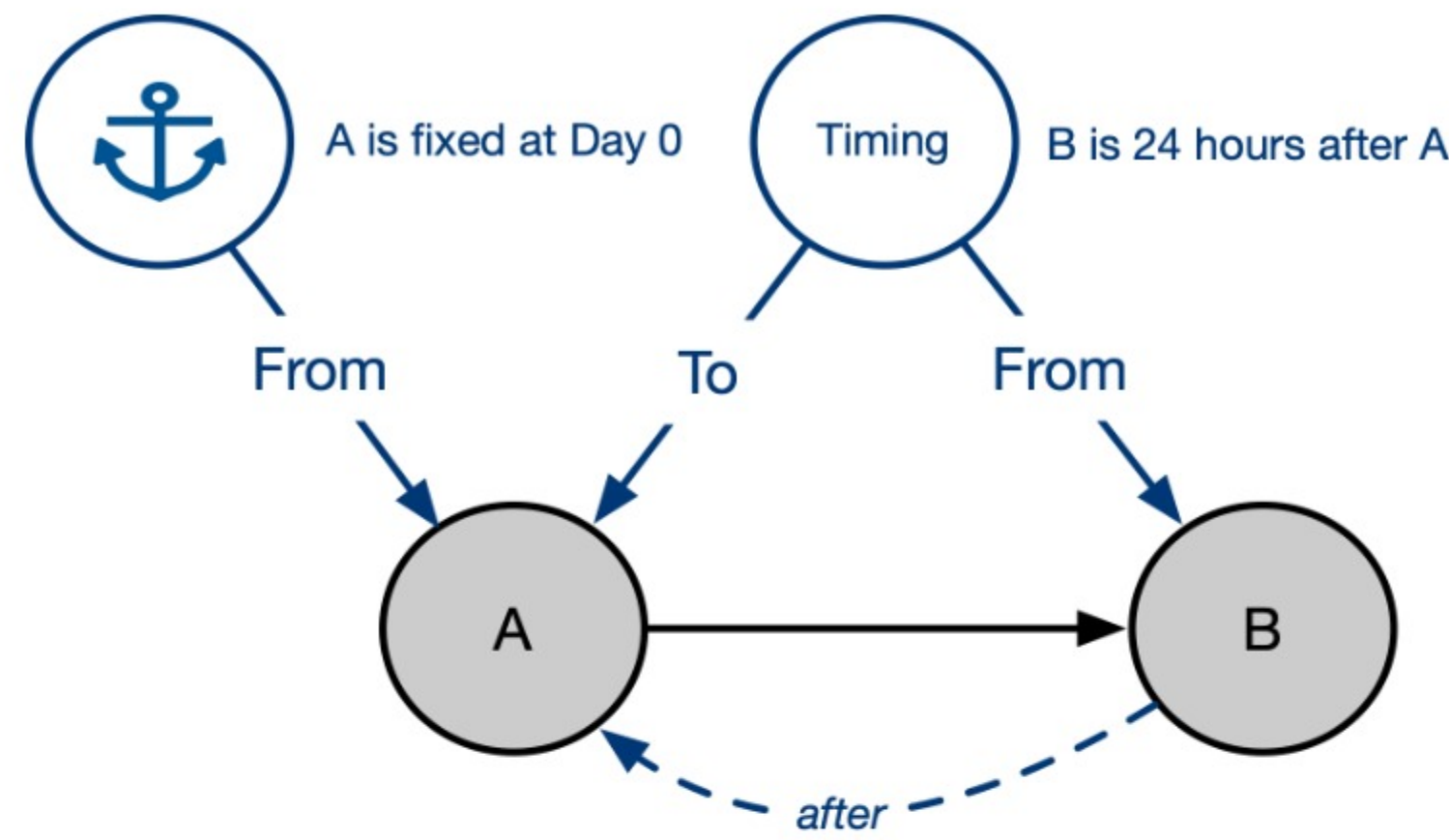
A **ScheduledActivityInstance** Example.  
Colour coding to match diagram

# Timing

## Basics

- Two types of relationship
  - Anchor - A fixed point
  - Before or After - A relative point
- Window can be defined
- Descriptive and coded timing values
- Coded values are ISO8601 Durations

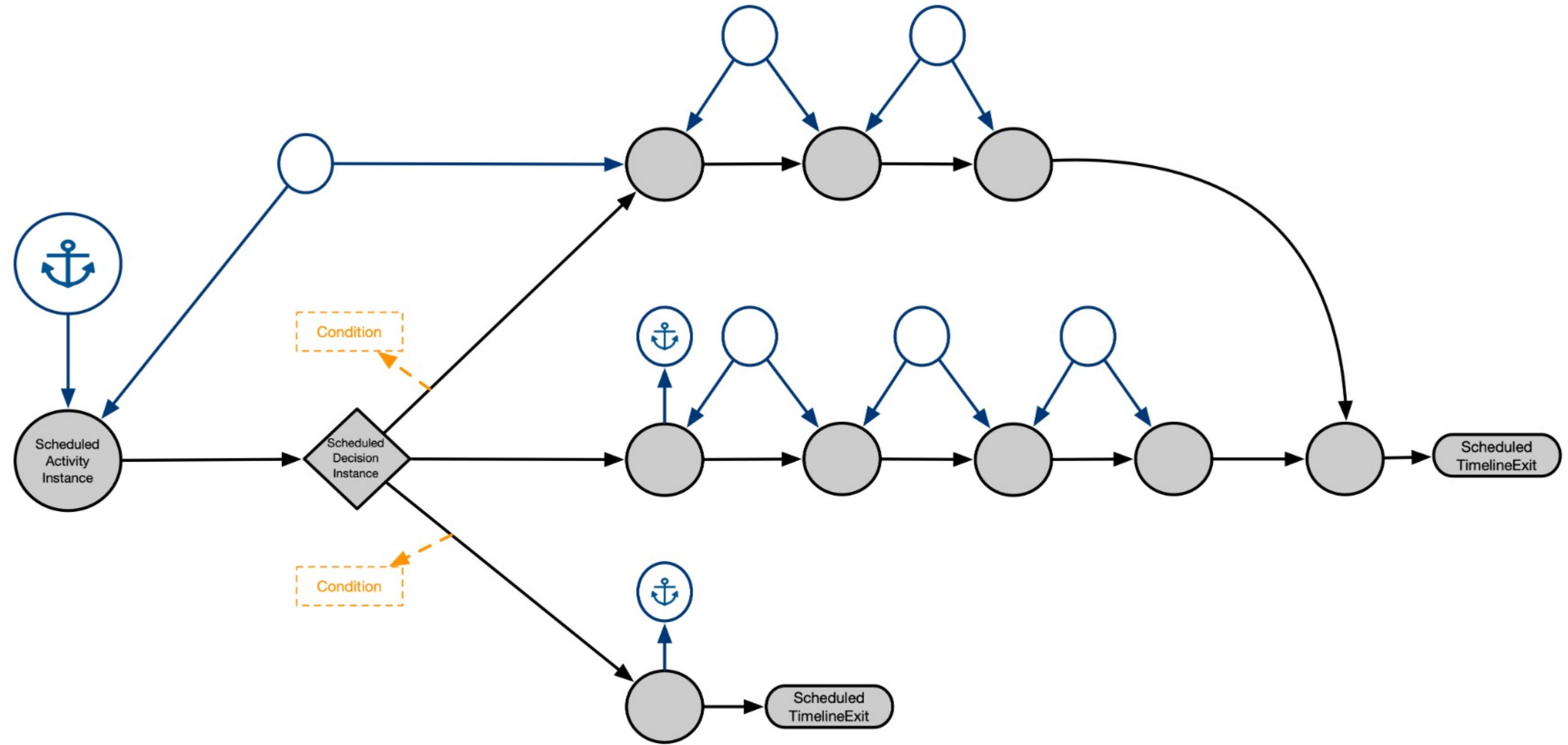
```
{
  "id": "Timing_2",
  "name": "TIM2",
  "label": "Pre dose",
  "description": "Pre dose timing",
  "type": {
    "id": "Code_67",
    "code": "C201264",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Before"
  },
  "timingValue": "PT15M",
  "timingRelativeToFrom": {
    "id": "Code_68",
    "code": "C201265",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2023-09-29",
    "decode": "Start to Start"
  },
  "relativeFromScheduledInstanceId": "ScheduledActivityInstance_2",
  "relativeToScheduledInstanceId": "ScheduledActivityInstance_3",
  "timingWindowLower": "PT4H",
  "timingWindowUpper": "PT0H",
  "timingWindow": "-4..0 hours"
}
```



# Branching

## Basics

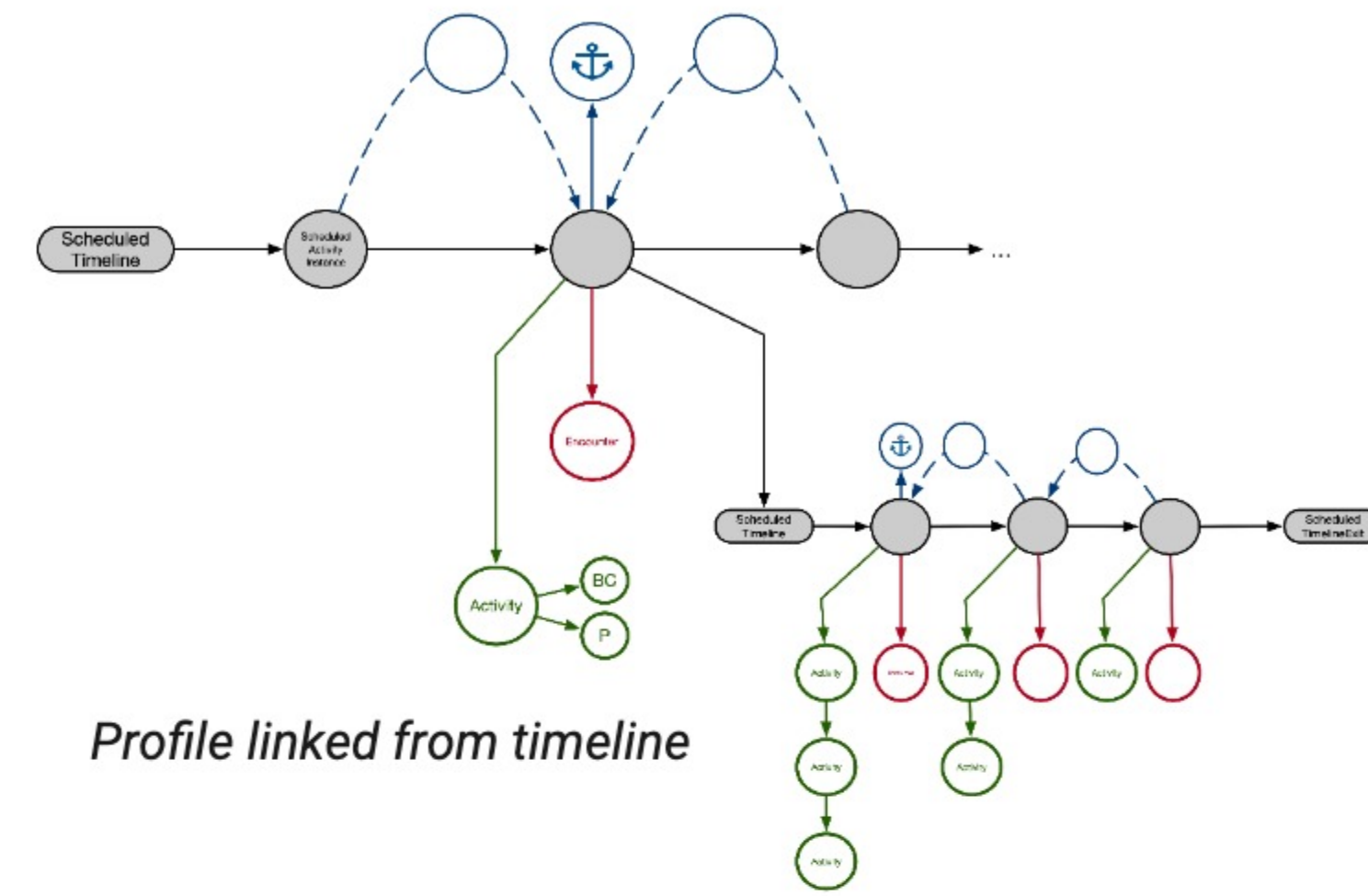
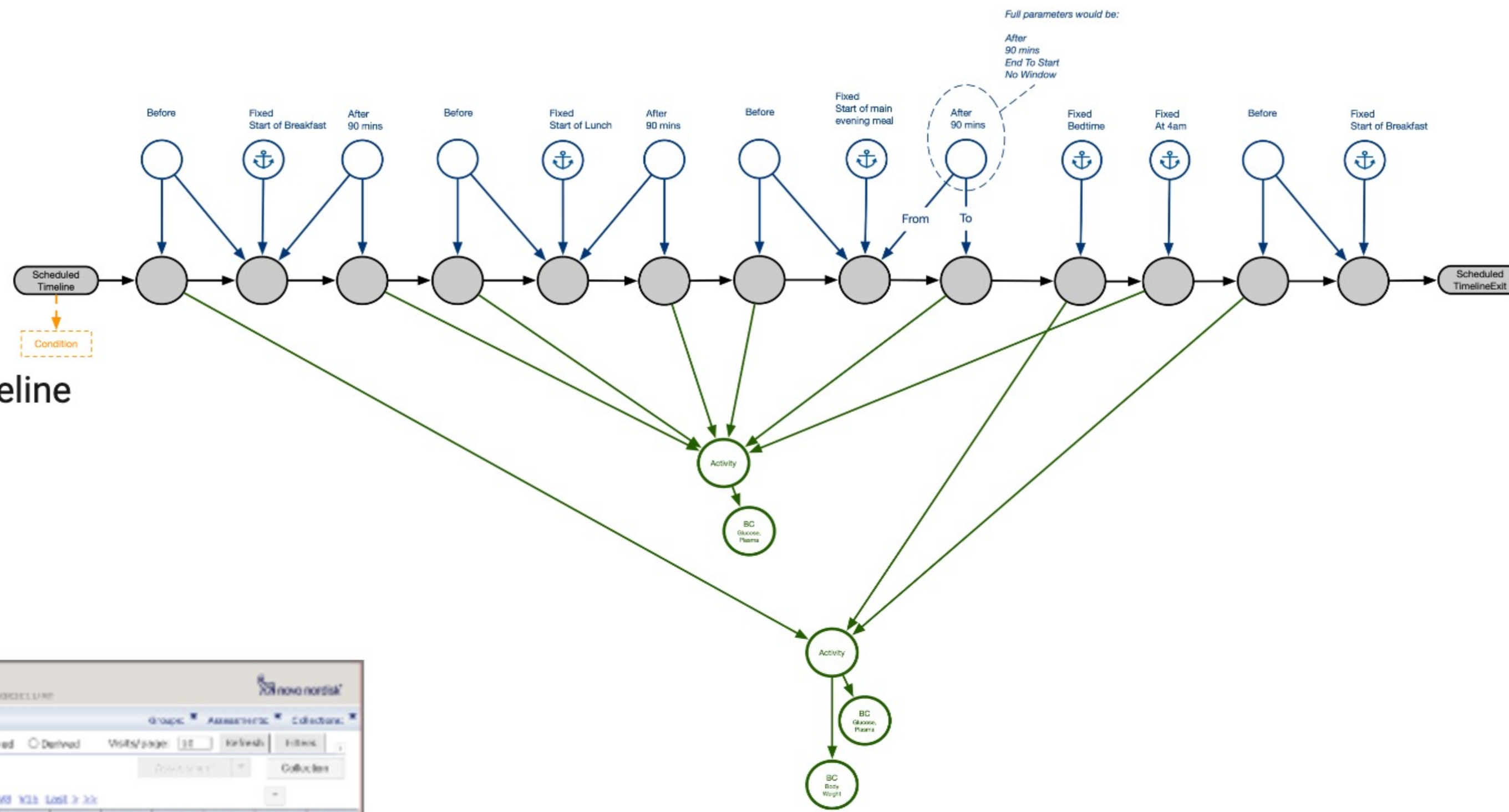
- Uses the Decision Instance
- Defined as a switch
- A set of (condition, destination) pairs
- A default link (if no condition is met)



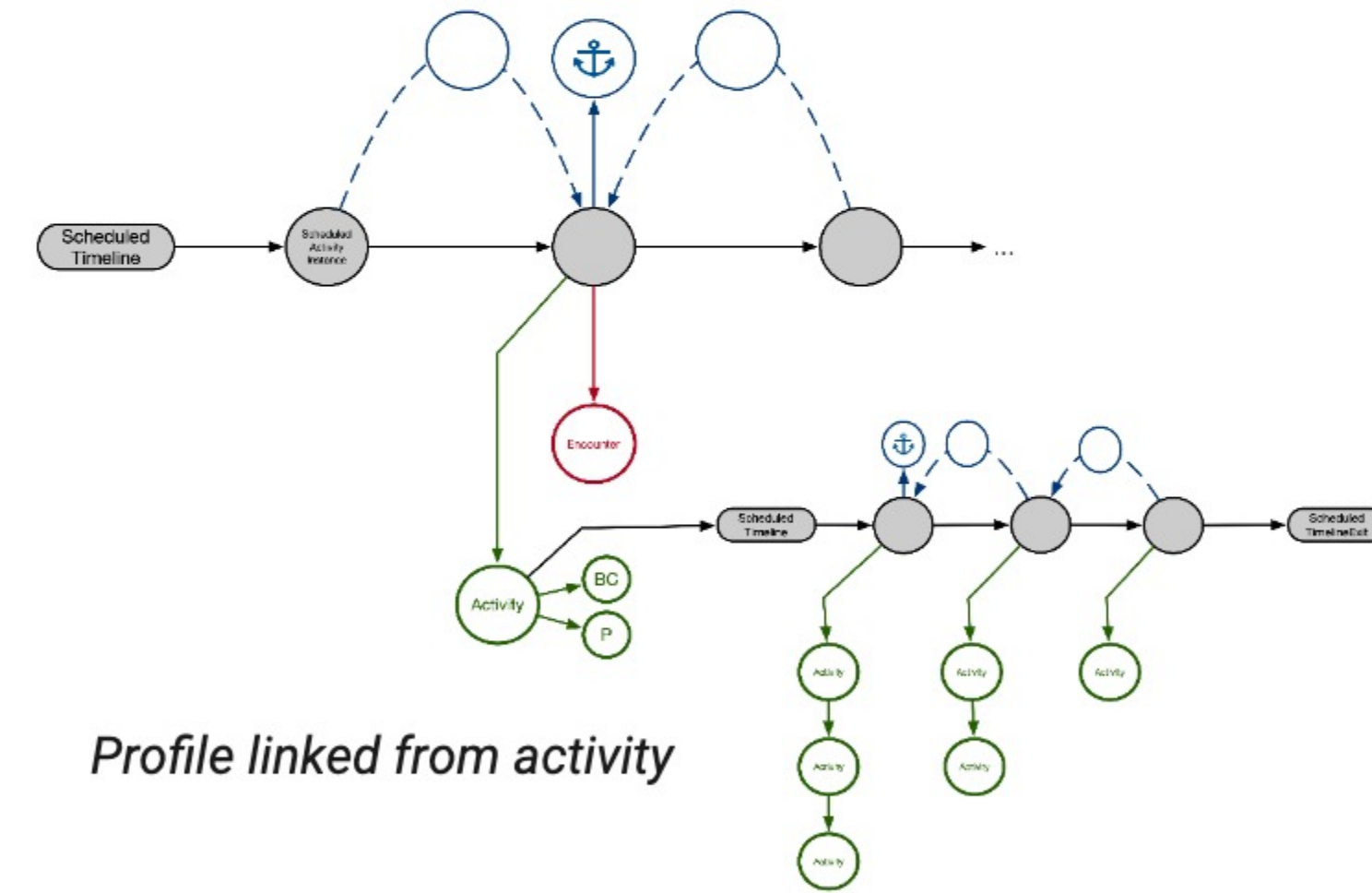
# Profile

## Basics

- Uses the timeline pattern
- Reusable
- Linked to an activity or timeline



Profile linked from timeline



Profile linked from activity

CDW Operations - Metadata Management

Trial Flowchart

Trial ID: CDISC360-2

Assessment	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10
Screening										
Baseline										
Treatment 1										
Treatment 2										
Treatment 3										
Treatment 4										
Treatment 5										
Treatment 6										
Treatment 7										
Treatment 8										
Treatment 9										
Treatment 10										
Treatment 11										
Treatment 12										
Treatment 13										
Treatment 14										
Treatment 15										
Treatment 16										
Treatment 17										
Treatment 18										
Treatment 19										
Treatment 20										
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Treatment 31										
Treatment 32										
Treatment 33										
Treatment 34										
Treatment 35										
Treatment 36										
Treatment 37										
Treatment 38										
Treatment 39										
Treatment 40										
Treatment 41										
Treatment 42										
Treatment 43										
Treatment 44										
Treatment 45										
Treatment 46										
Treatment 47										
Treatment 48										
Treatment 49										
Treatment 50										

Trial ID: CDISC360-2

Trial Definition ID: CTR

Trial Metadata: 4

Version: 4

Trial Definition: Draft

Status: Draft

Profile Name: 9-point profile

Profile Type: Sequence Profile

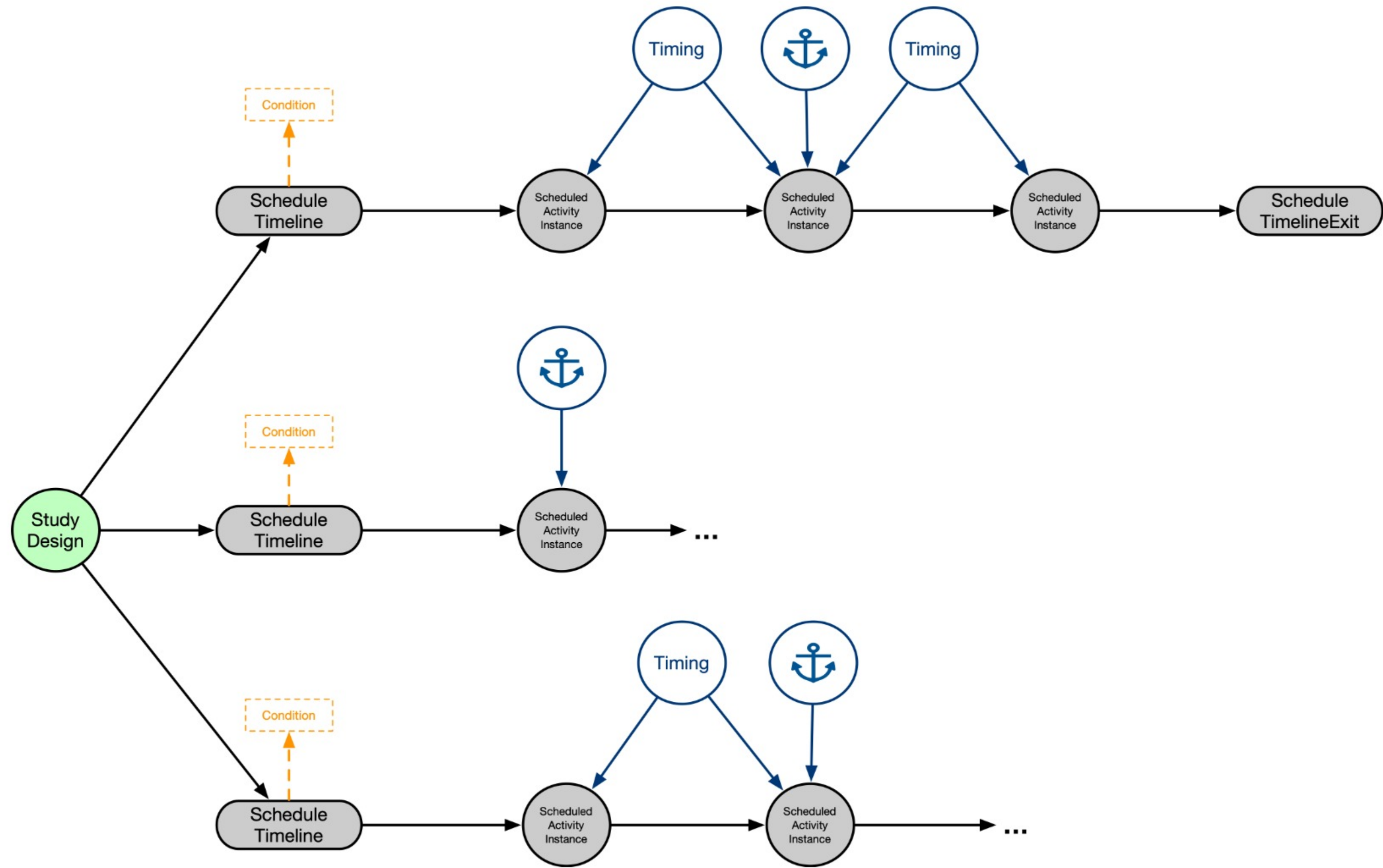
Time Point Sequence	Sequence Time
1	Before breakfast
2	90 minutes after start of breakfast
3	Before lunch
4	90 minutes after start of lunch
5	Before main evening meal
6	90 min after main evening meal
7	Bedtime
8	At 04:00 A.M.
9	Before breakfast the following day

Add Time Point Delete Time Point Save

# Unscheduled

## Basics

- Each potential unscheduled event handled as a timeline
- One main path
- Several child paths for unscheduled events
- A condition for each
- As many instances and timing as needed
- Linked to activities, encounters as needed
- Some instances need not be linked to encounters





# USDM Examples I

## Test Utility

- Developing a test utility:
  - Multi-sheet Excel file containing a full USDM definition (bar one or two pieces)
  - Intended to build the full USDM JSON
  - Also builds a visualisation
- Will be available as a python package

## Current Examples

- A Roche Study
- CDISC Pilot Study
- Eli Lilly Study
- Others
  - Simple example
  - Cycle example
  - Profile example

			Epoch	Screening	Baseline	Treatment	Follow-Up
			Cycle	-	-	-	-
			First Cycle Start	-	-	-	-
			Cycle Period	-	-	-	-
			Cycle End Rule	-	-	-	-
			Timing	N: 0..2 Days	N: Pre Dose	A:	P: +24 Hours
			Visit Label	Screening	Baseline	15 min	Day 24
			Visit Window		0..4 Hours	0..1 Hours	-3..3 Days
Parent Activity	Child Activity	BC/Profile					
-	Demographics	BC:Age, BC:Sex, BC:Race	X	-	-	-	-
-	Something Else	-	X	X	X	X	X

## Github Examples

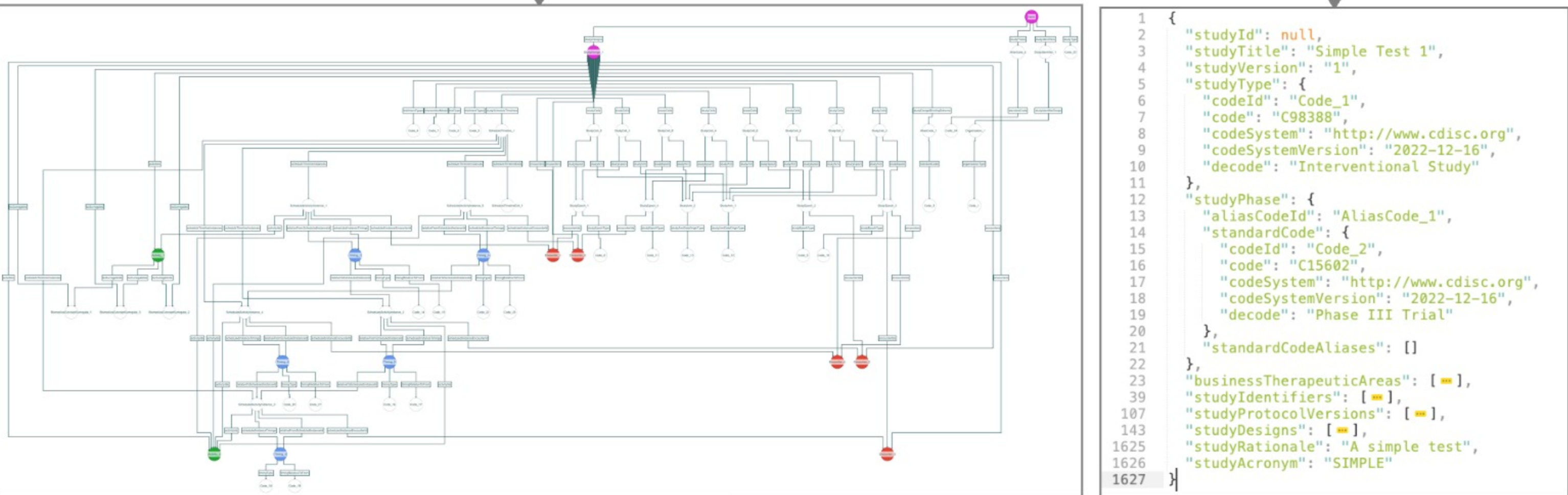
See JSON examples  
[main branch](#)

Name	Last commit message	Last commit date
..		
CDISC_Pilot	Update examples to align with model updates	2 months ago
NCT03421379	Update examples to align with model updates	2 months ago
NCT04320615	Update examples to align with model updates	2 months ago
Other	Update examples to align with model updates	2 months ago
README.md	Add examples to documents	5 months ago

## Examples Currently Being Updated to V2.5

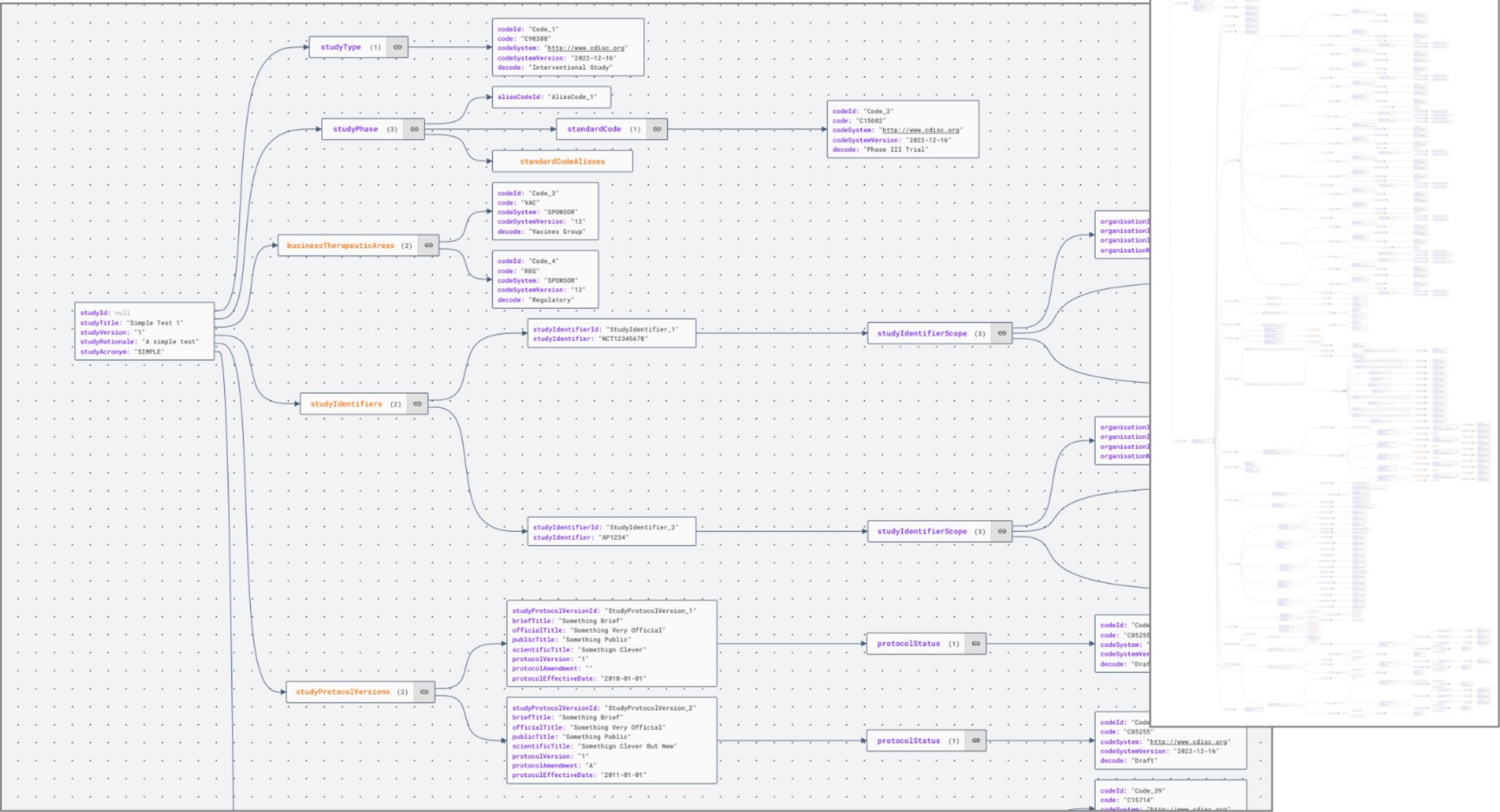
## Note

- No BC category example as yet





# USDM Examples II



Web Version  
Online conversion [tool here](#).

USDM Excel to JSON Utility STATUS

**Excel File List**  
A list of files held within the system for which a converted USDM JSON file can be downloaded.

File List.

Roche Phase 3 NCT04320615.xlsx, dated 2023-04-14	🗑️ 🌱
cycles_1.xlsx, dated 2023-04-14	🗑️ 🌱
simple_3.xlsx, dated 2023-04-14	🗑️ 🌱

Upload New Excel File

[CLICK TO UPLOAD NEW FILE](#)

## Online Utility

- Saves installing any software
- Will upload Excel file and return JSON equivalent
- No login as yet but will be added

## Visualise Examples

Useful JSON tool, [JSON Crack Editor](#)

## Online Utility

- Useful visualisation
- Does NOT do cross references
- **Limit on size of file**

# USDM Examples III

## Infographic

Download high resolution [version here](#)  
Further info will be added

### USDM Excel Sheet Formats & Links Infographic 2nd November 2023

Details the excel workbook format as used by the USDM python package.

Details of the package can be found at <https://github.com/data4knowledge/usdm>.  
Details for using the package and the sheet formats are detailed within the readme file within the repository.

All sheets are required to be present within the workbook and sheets are read automatically by the package. The diagrams are here to show the cross sheet references/links to aid in the assembly of study designs.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
name	SCOP1																		
studyTitle	Simple Test 1																		
studyPhase	1																		
studyType	Interventional Study																		
studyPhase	C15003																		
studyArmGroup	SAMPLE																		
studyArmGroup	A single test																		
studyArmGroup	SPONSOR: VACCINES GROUP;																		
studyArmGroup	SPONSOR: R01-Regulatory																		
studyArmGroup	Something brief																		
studyArmGroup	Something very official																		
studyArmGroup	Something Public																		
studyArmGroup	Something Clear But Not																		
studyArmGroup	Just																		
eligibility	name	description	label	type	date	status													
eligibility	Approval	Design approval date	Design Approval	Summary Approval Date	01/01/2023	Country: USA, Country: FRA, region: ADA, country: USA													
eligibility	Approval	Protocol document approval date	Protocol Approval	Protocol Effective Date	01/01/2023	Global													
eligibility	Approval	Protocol document approval date	Protocol Approval	Protocol Effective Date	01/01/2023	region: ada													

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
studyDesignName	Study Design 1													
studyDesignDescription	The main design for the study													
studyDesignPhase	C15003													
studyDesignType	Interventional Study													
studyDesignPhase	OPEN LABEL													
studyDesignType	BASIC SCIENCE, SEVERE FEASIBILITY													
studyDesignPhase	010001													
studyDesignType	010001													
studyDesignPhase	010001													
studyDesignType	010001													
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