



Digital Data Flow (DDF) Project – Phase 3 Public Review Webinar

Presented by

Bill Illis, Novartis, DDF Workstream Lead

John Owen, Head PMO, CDISC

Dave Iberson-Hurst, DDF Technical Product Owner, CDISC

Berber Snoeijer, DDF Technical Lead, CDISC

1st February 2024



Today's Speakers



Bill Illis

DDF Workstream Lead
Novartis



Dave Iberson-Hurst

CDISC DDF Product Owner
CDISC



Berber Snoeijer

DDF Technical Lead
CDISC



John Owen

DDF Project Manager
CDISC



Agenda

1. TransCelerate Introduction to DDF (Bill Illis)
2. CDISC Project Introduction and Status (John Owen)
3. Overview of the USDM v3.0 (Dave Iberson-Hurst/Berber Snoeijer)
4. Public Review Information (John Owen)
5. Upcoming Events Related to DDF (John Owen)



TransCelerate Introduction to DDF

Bill Illis

Digital Data Flow Initiative Introduction

CDISC USDM Phase 3 Public Review Webinar

February 1, 2024



William Illis

**Global Head, Collaboration & Technology
Strategy, Clinical Development & Analytics,
Novartis**

Digital Data Flow, Workstream Initiative Lead



Content

01 DDF Overview

02 Getting Involved



Digital Data Flow Ambition: Breaking the Document Paradigm

Documents to Data / Write Once, Read Many

Digital - standard representation of study protocol

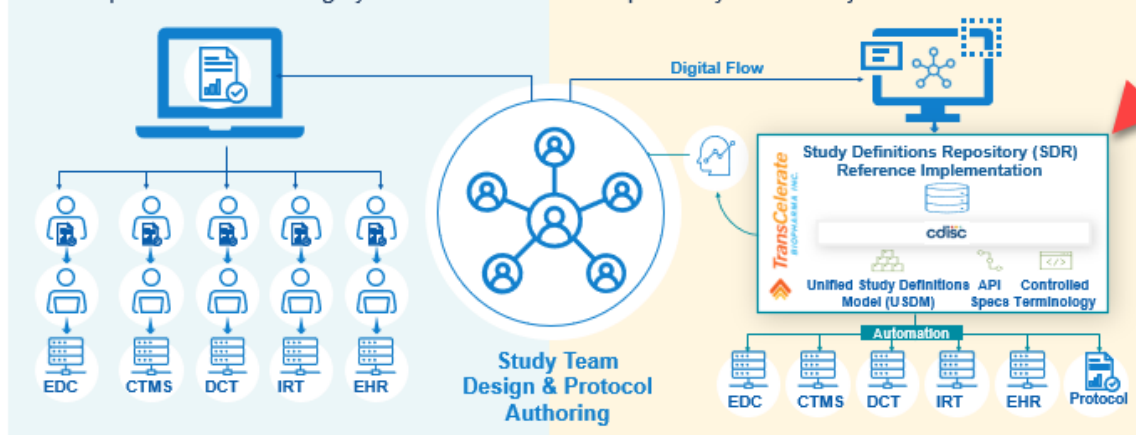
- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability

- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems

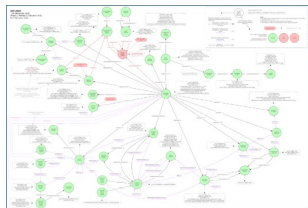


Eliminate non-value added activities

Enable automation of downstream study startup and conduct processes

Create foundation for study design analytics insights

DDF Initiative encompasses technical delivery, change management, and industry engagement



cdisc
 Unified Study
 Definitions Model
 (USDM) Reference
 Architecture

TransCelerate's
 Study Definitions
 Repository (SDR)

Study ID	Study Name	Study Type	Study Phase	Study Status	Study Start Date	Study End Date	Study Location	Study Sponsor	Study Investigator
101	Study 101	Phase 1	Phase 1	Completed	2020-01-01	2020-12-31	USA	TransCelerate	John Doe
102	Study 102	Phase 2	Phase 2	In Progress	2021-01-01	2021-12-31	USA	TransCelerate	Jane Smith
103	Study 103	Phase 3	Phase 3	Planned	2022-01-01	2022-12-31	USA	TransCelerate	Bob Johnson

**Digital Data
 Flow Initiative**

Suite of DDF Adoption
 Resources, Videos &
 Change Management Tools

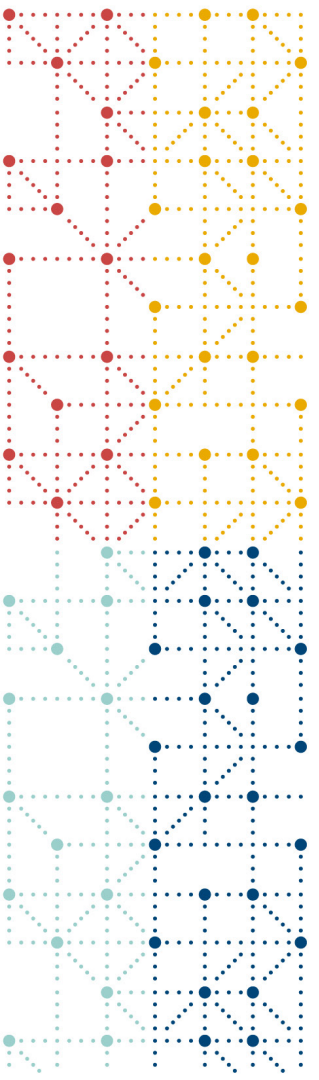
Continued Industry Collaboration
 between TransCelerate, CDISC
 ICH, and HL7



Growing Solution
 Collaboration Forum (SCF)*



**Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.*



CDISC Project Introduction and Status

John Owen



Digital Data Flow

• Phase 1

- Base model design
 - UML
 - API
 - Controlled Terminology
- Topics
 - Objectives and endpoints
 - High Level Study Design
 - Eligibility criteria
 - Activities and assessments
 - Basic schedule of activities and assessments
 - Basic data collection configuration related to activities and assessments

• Phase 2

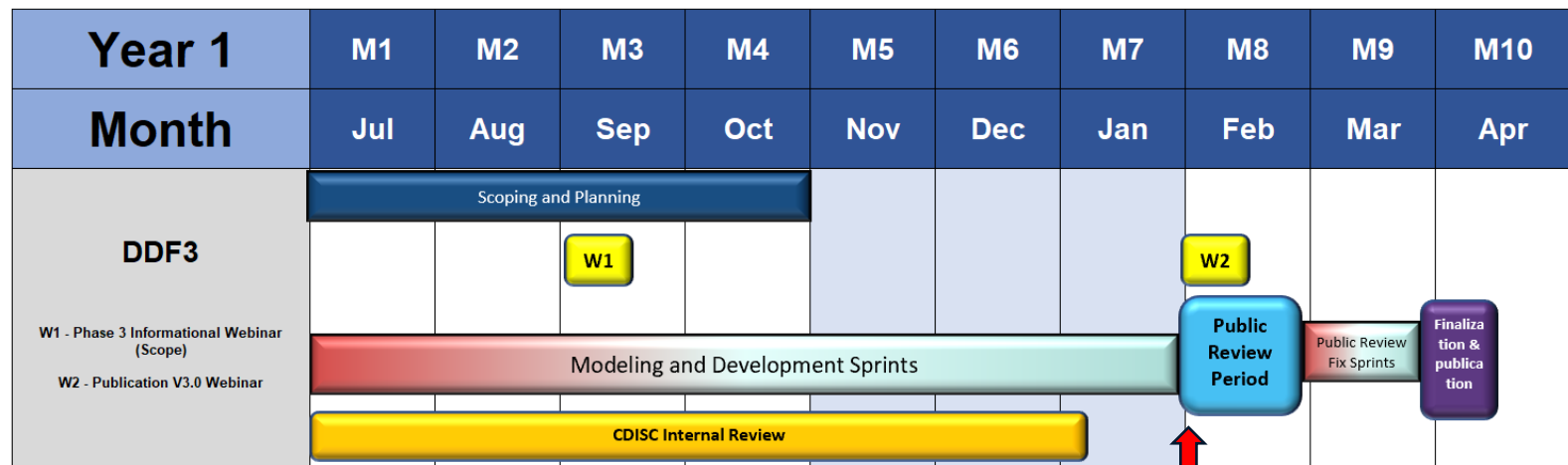
- Extended model
 - UML
 - API
 - Controlled Terminology
 - USDMIG ★
 - Example Data ★
- Topics
 - Enable greater population of study set-up elements
 - Represent structured study design information for more complex trials
 - Handling of complex study timing
 - Support electronic data capture (EDC) automation
 - Expand model to include Biomedical Concepts
 - Demonstrate population of the TransCelerate Common Protocol Template (CPT)
 - Demonstrate population of SDTM Trial Design Domains

2021

2022

2023

DDF Phase 3 Timelines



DDF 3 USDM Scope



Represent ICH M11 in USDM



SDTM Trial Design Population



Clinical Trial Registry Population



Complex Studies/Cohorts



Model Enhancements

Future Value Streams for Digital Data Flow

Team will begin to address all three at varying degrees (in priority order)



Complete Protocol Digitization & Regulatory Alignment

Includes collaboration through the Vulcan Working Group between ICH M11 & CDISC

- Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
- Begins with gap analysis between USDM and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
- Goal to capture "breadth" of ICH M11 completely within USDM, followed by greater "depth" of structured content within model (e.g. structured I/E criteria)



Expand Downstream Connectivity

Includes collaboration with expanding community of tech solution providers across range of critical solutions

- Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"
- Work collaboratively with the vendor ecosystem to better understand existing gaps and development requirements for the USDM



Alignment with Point of Care

Includes collaboration with Vulcan FHIR Accelerator

- Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource
- Comparative assessment of USDM and FHIR currently underway

Other Areas of Development for DDF Phase 3

• USDM Test Data Tool

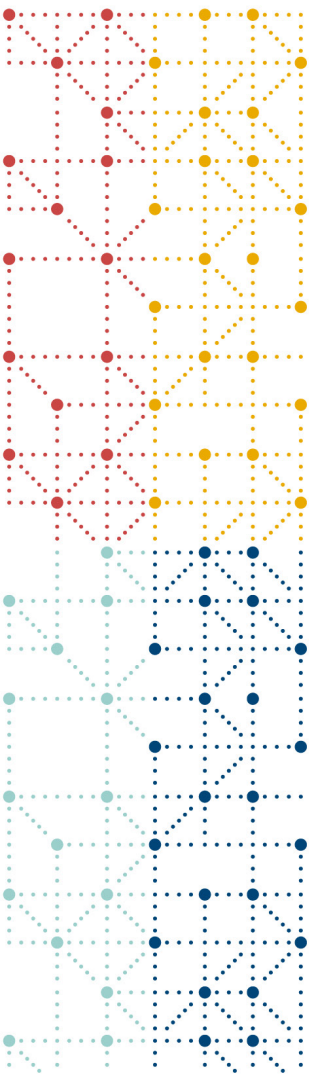
- Continued development to create USDM JSON test data from Protocols using an Excel and Python tool

• Biomedical Concepts

- Create Biomedical Concepts that would fully cover the LZTZ (CDISC Test Protocol)
- Allow ability to represent majority of LZTZ BCs in the LZTZ Test data

• DDF 3A

- USDM Conformance Rule Development POC using CORE
- Demonstrating that USDM JSON files are USDM compliant,
 - e.g., Transfer of USDM JSON file from one organization to another (e.g., Vendor to Sponsor)
- Scope
 - Develop a representative set of conformance rule specifications (up to 100)
 - Cover a wide breadth of the different types of rules required to demonstrate DDF conformance
 - Enhance the CORE open-source engine to run these Conformance Rules against a USDM JSON file
 - Scope CDISC Library modifications (to store DDF conformance rules and the USDM model)

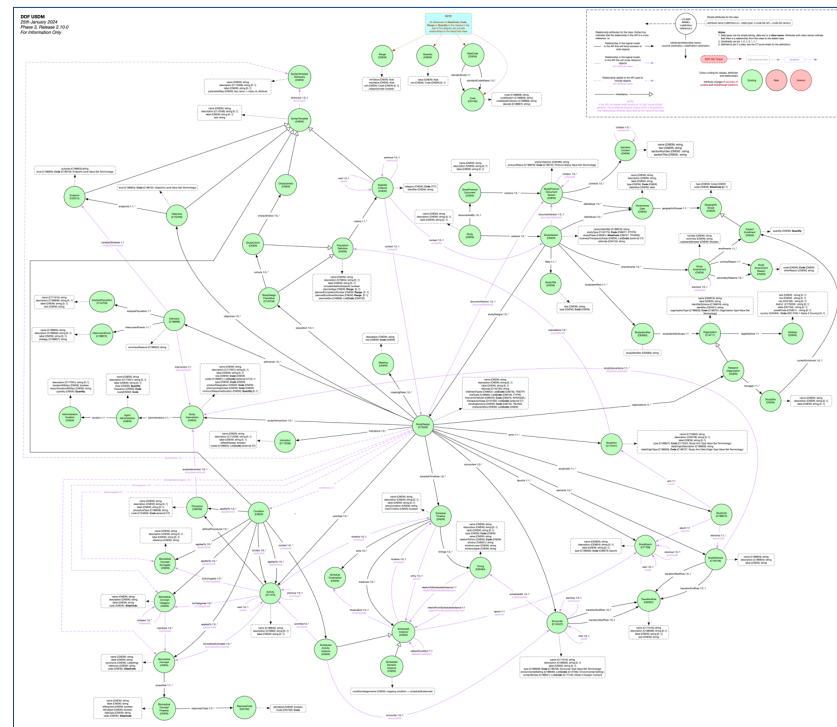


Overview of the USDM v3.0

Dave Ibersen-Hurst and Berber Snoeijer

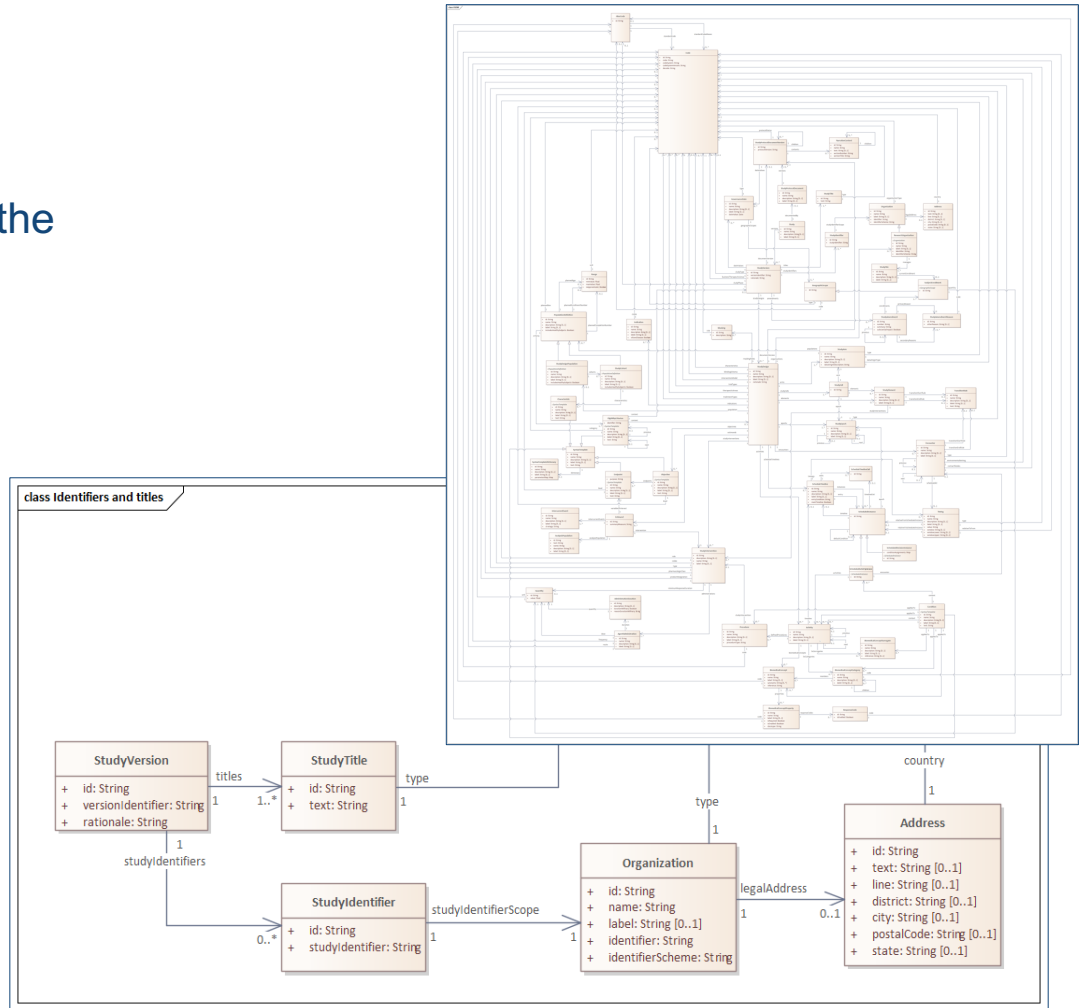
Shift of Focus

- 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



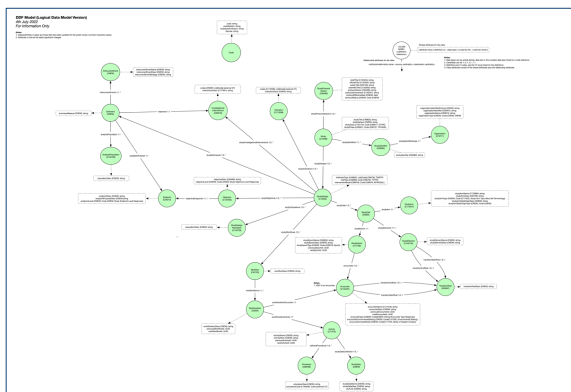
The Model and UML

- During Phase 3 we changed the way in which the UML is managed
- Moved from a tool that produced the diagram to Enterprise Architect
- Results in improved deliverables and ability to control the diagram layout
- Also allows for sub-views



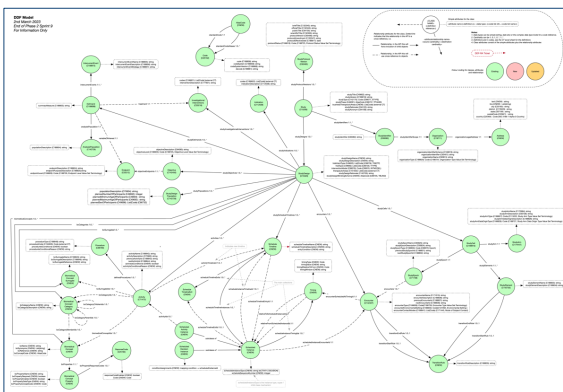
CDISC DDF / USDM, Phases One, Two and Three

Phase One



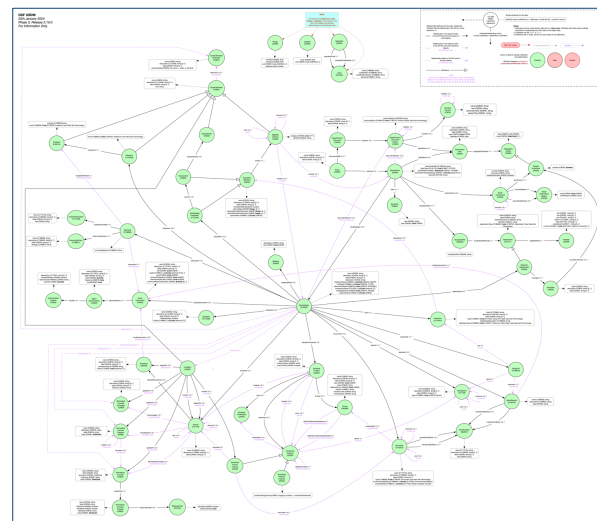
25 Classes

Phase Two



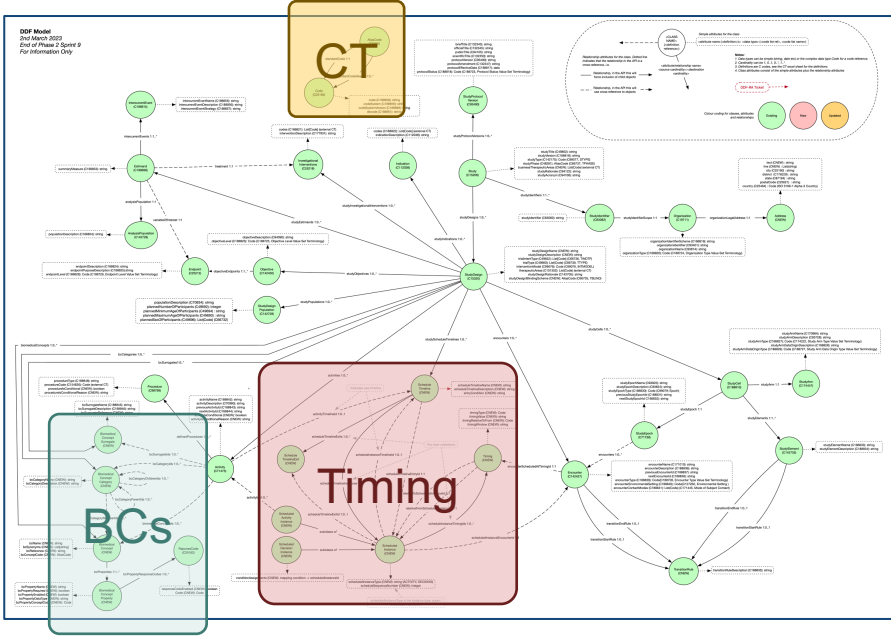
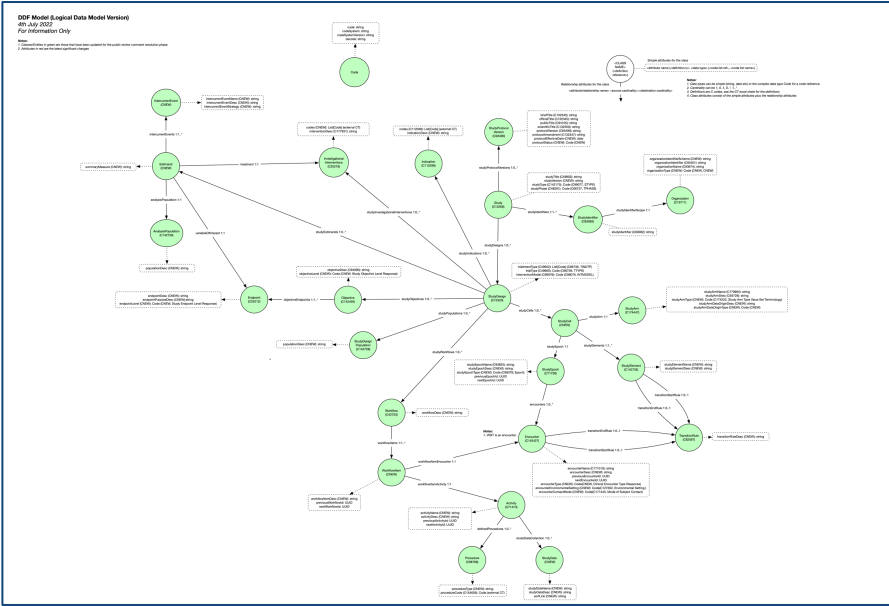
35 Classes

Phase Three

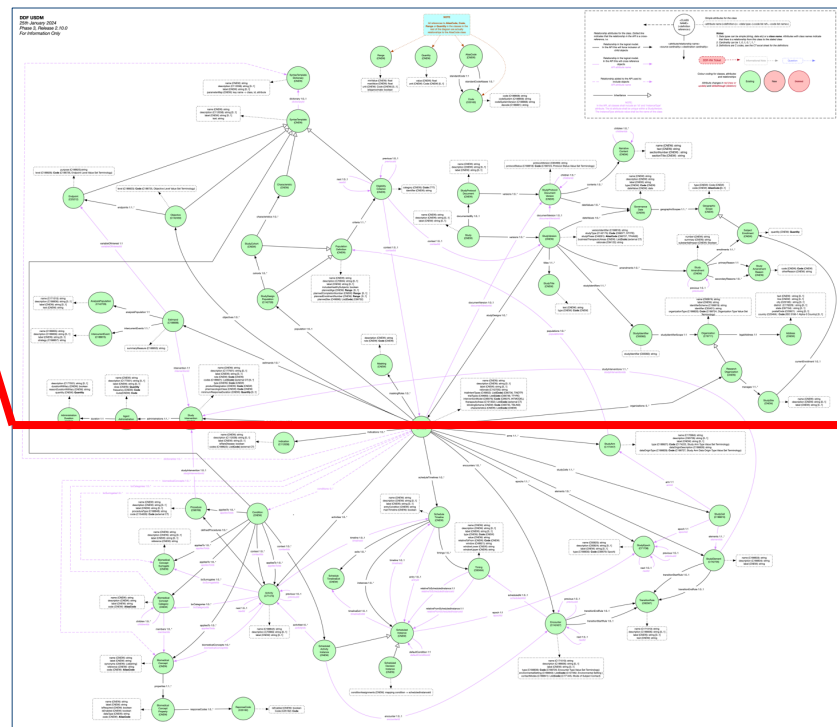
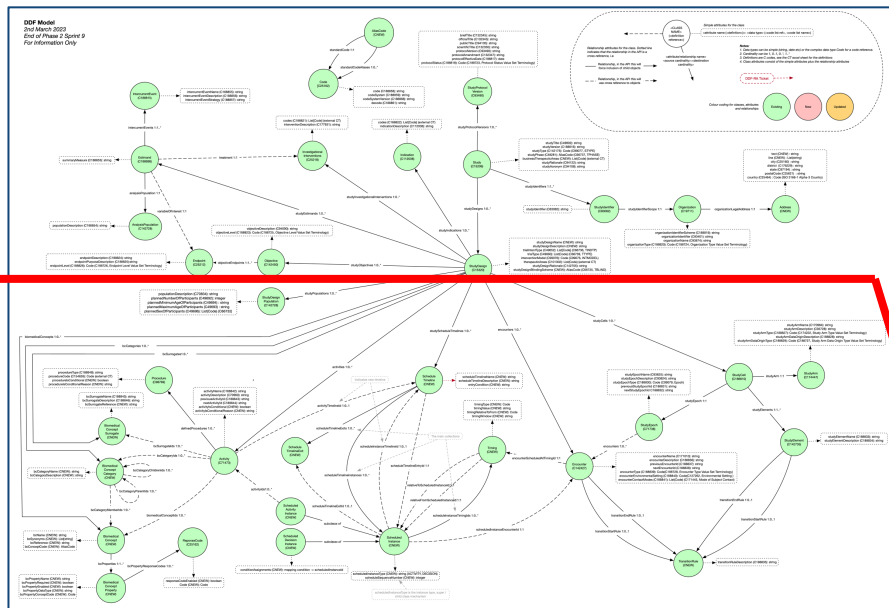


58 Classes

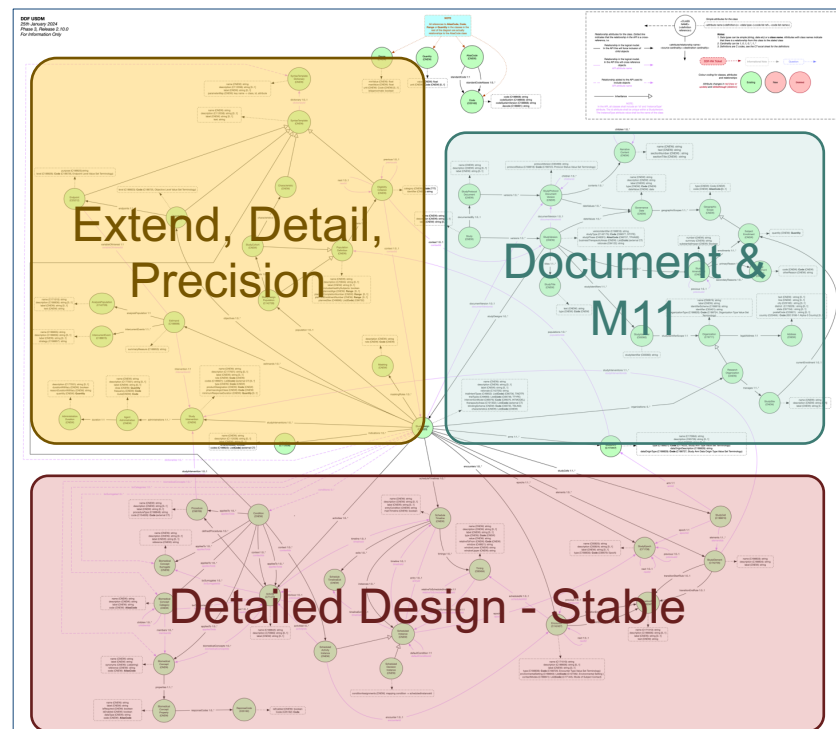
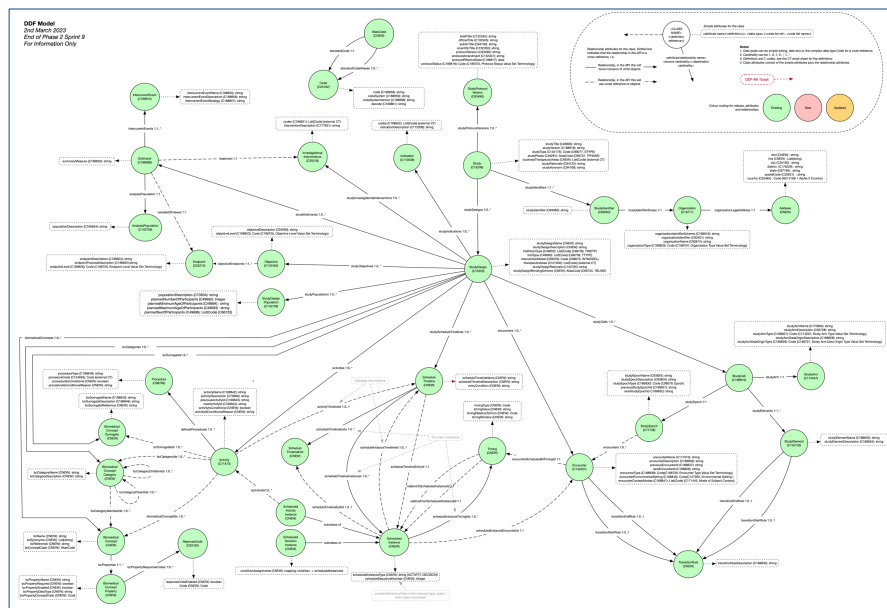
CDISC DDF / USDM, Phase One v Two



CDISC DDF / USDM, Phase Two v Three

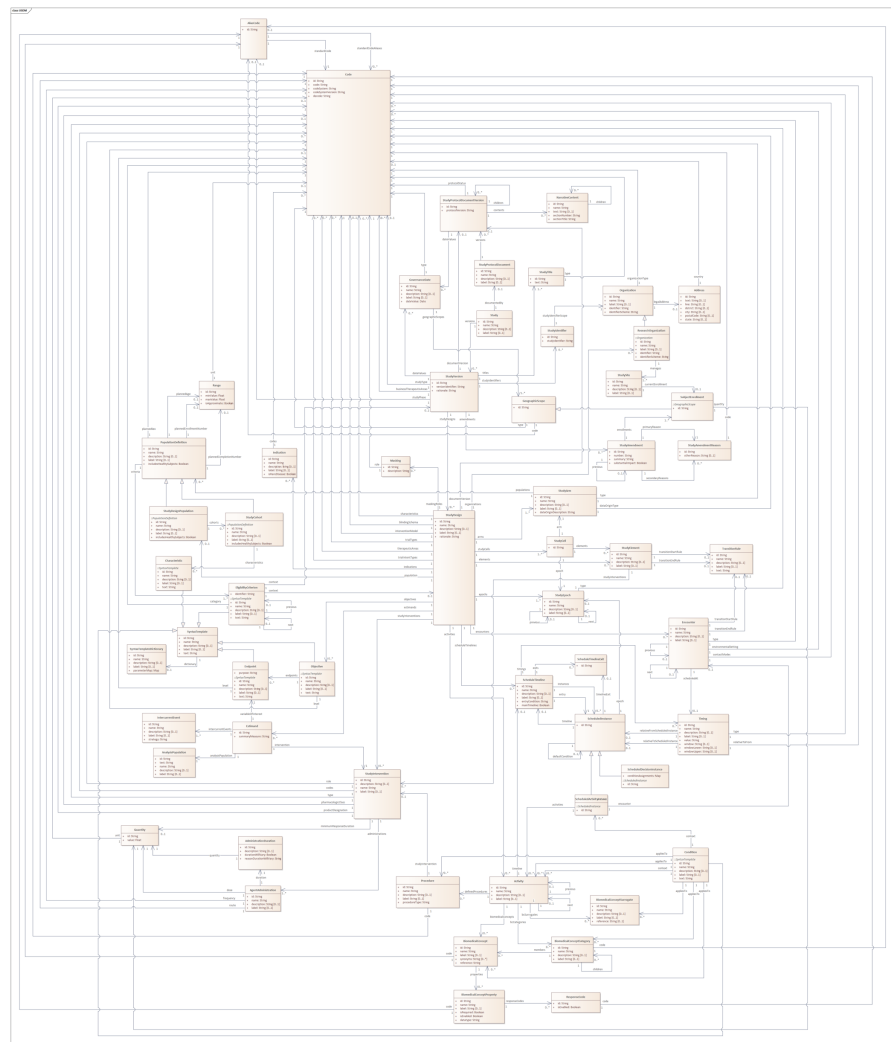


CDISC DDF / USDM, Phase Two v Three



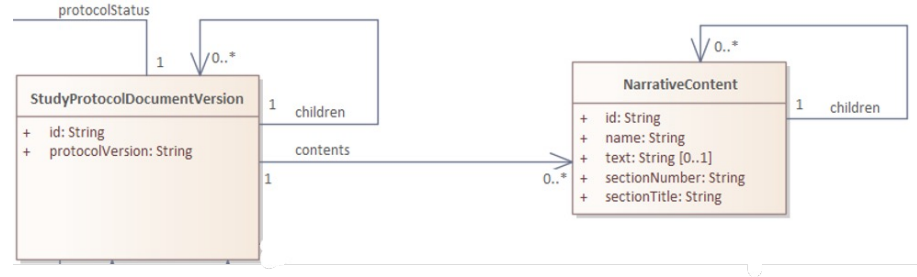
Changes for USDM v3.0

- Major model changes
 - Narrative Content
 - Syntax Templates
 - Eligibility criteria
 - Versioning, Study documents and Amendments
 - Intervention and administration
 - Study population and cohorts
 - Research Organization and Study sites
 - Conditionality
- Other
 - UML formatting
 - API and model improvements
 - Test data tool
 - IG updates and improvements
 - New paragraphs
 - Mapping
 - Handling footnotes
 - Mapping and alignment to
 - M11
 - Clintrials.gov
 - SDTM trial summary domains



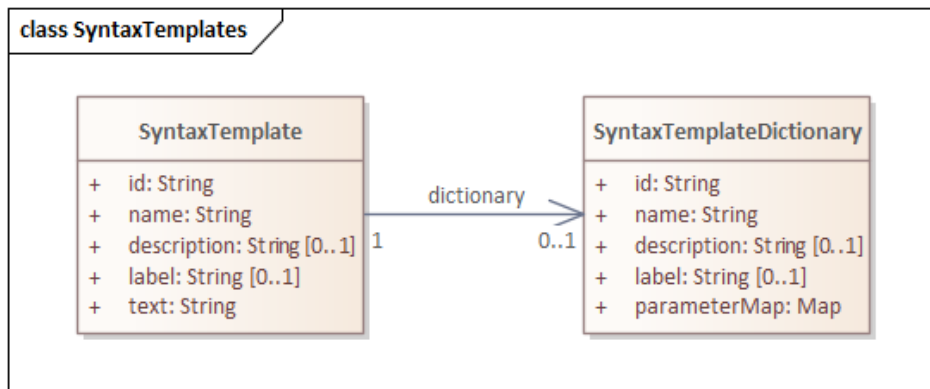
Narrative content

- Storage of protocol content in a specific format like:
 - M11
 - CPT
 - Sponsor defined formats
- Content of a specific protocol document version:
 - Section number
 - Section title
 - Formatted section content
- Nesting of subsections
 - Children
- Can refer to items stored elsewhere in the USDM data model using HTML cross-referencing



Syntax templates

- HTML formatted Text including parameterized elements
- Parameters stored in dictionary enabling reuse
 - optionally mapped to elements stored elsewhere in the data model.
- Syntax template class elements inherited by classes using this capability, in version 3.0 used for:
 - Eligibility criteria
 - Cohort characteristics
 - Objectives
 - Endpoints
 - Activity Conditions



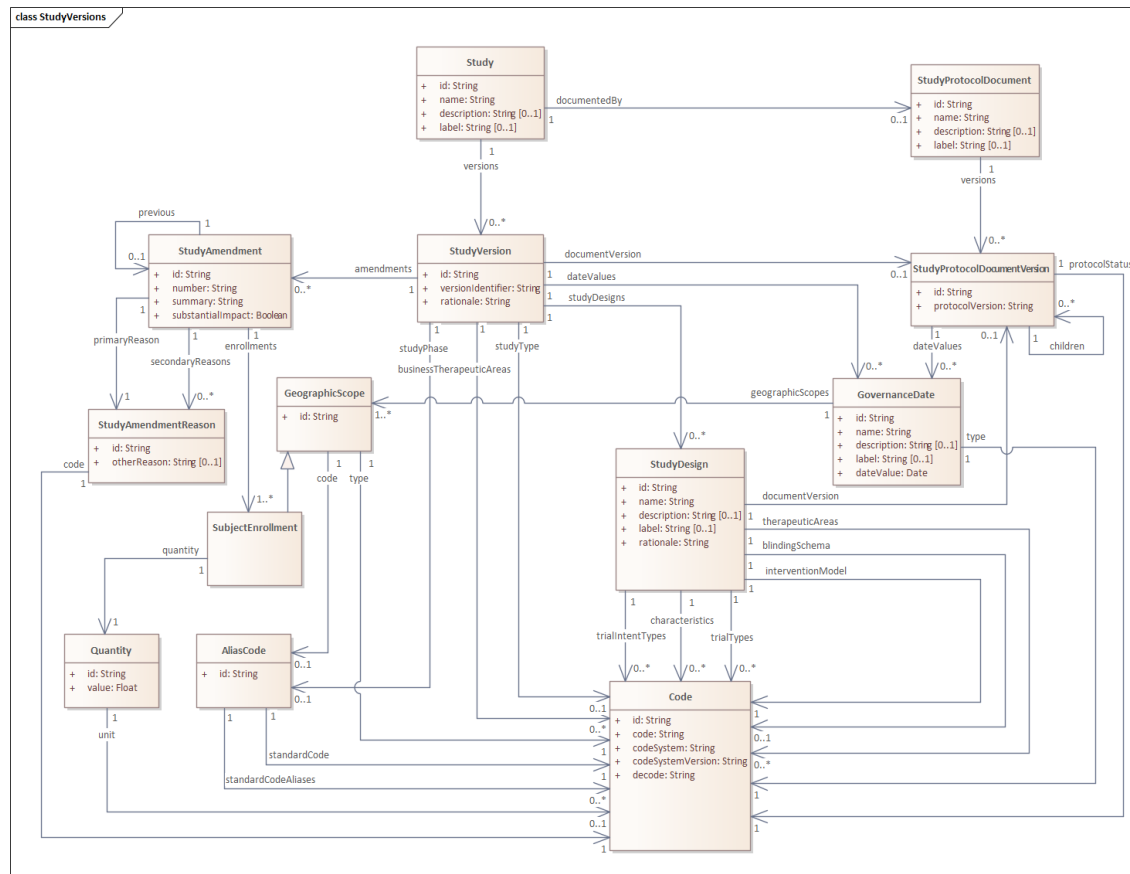


Eligibility Criteria

- Inherits syntax Template attributes
- Ordered by previous/next attributes
- Includes a category and identifier attribute to align with SDTM TI domain
- Are directly referenced from out of the study population or a specific cohort
- Are put in context of the whole study or a specific study design

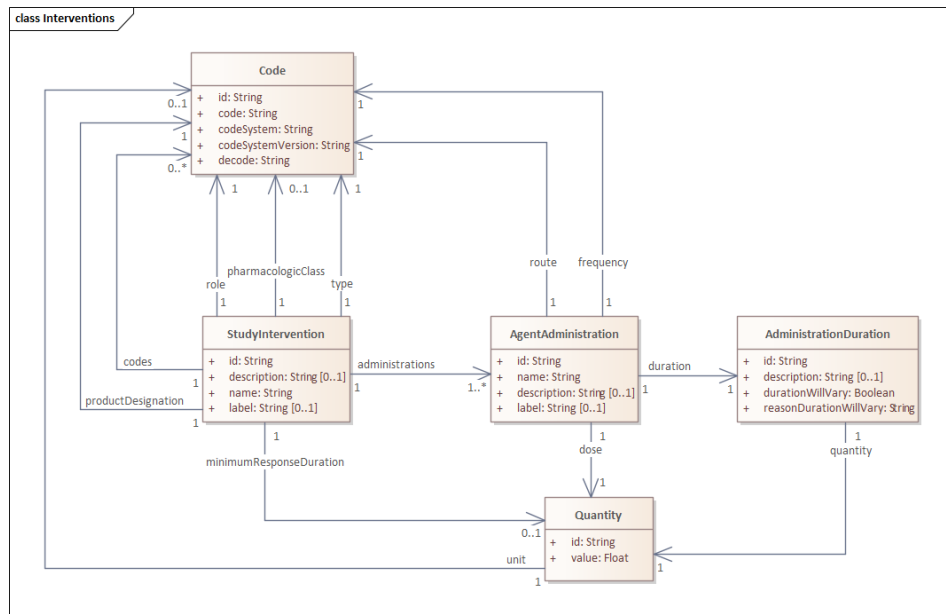
Versioning, study documents and amendments

- Study -> StudyVersion
 - Only 1 to be submitted
- StudyProtocolDocument -> StudyProtocolDocument Version
- Amendments
 - Reason
 - No or % of patients enrolled per geographic area
- Dates
 - Type
 - Geographic scope



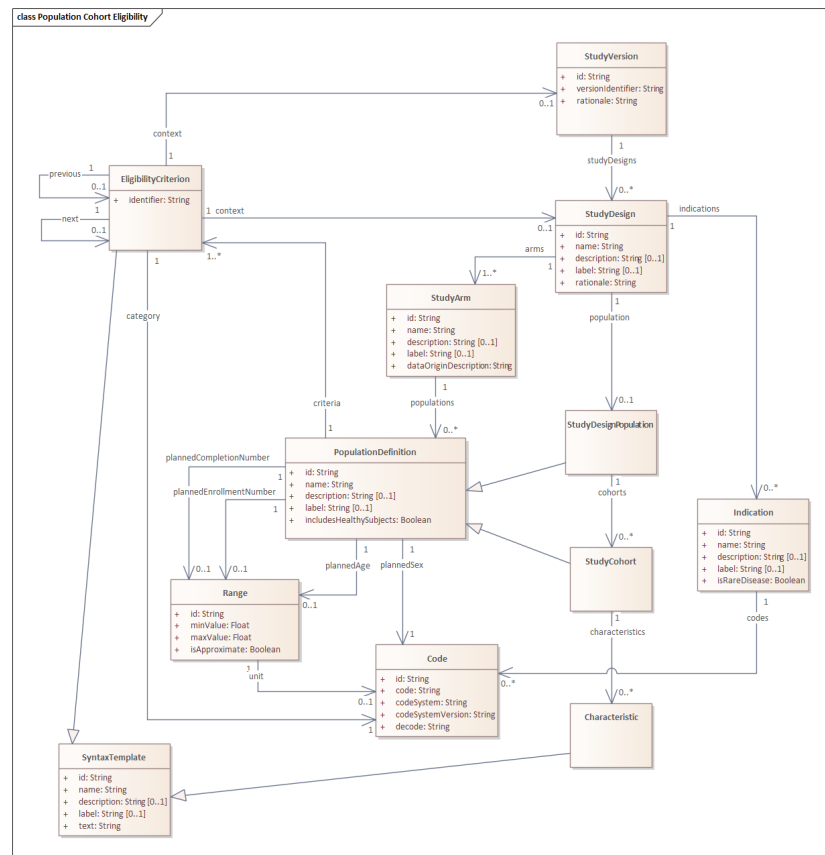
Intervention and administration

- Generalized to Study Intervention
 - Before: Investigational Intervention
- Added attributes to characterize the intervention
 - role, type and productDesignation
- Agent administration
 - Route, frequency, duration
- M11 and standards alignment
 - MinimumResponseDuration
 - AdministrationDuration



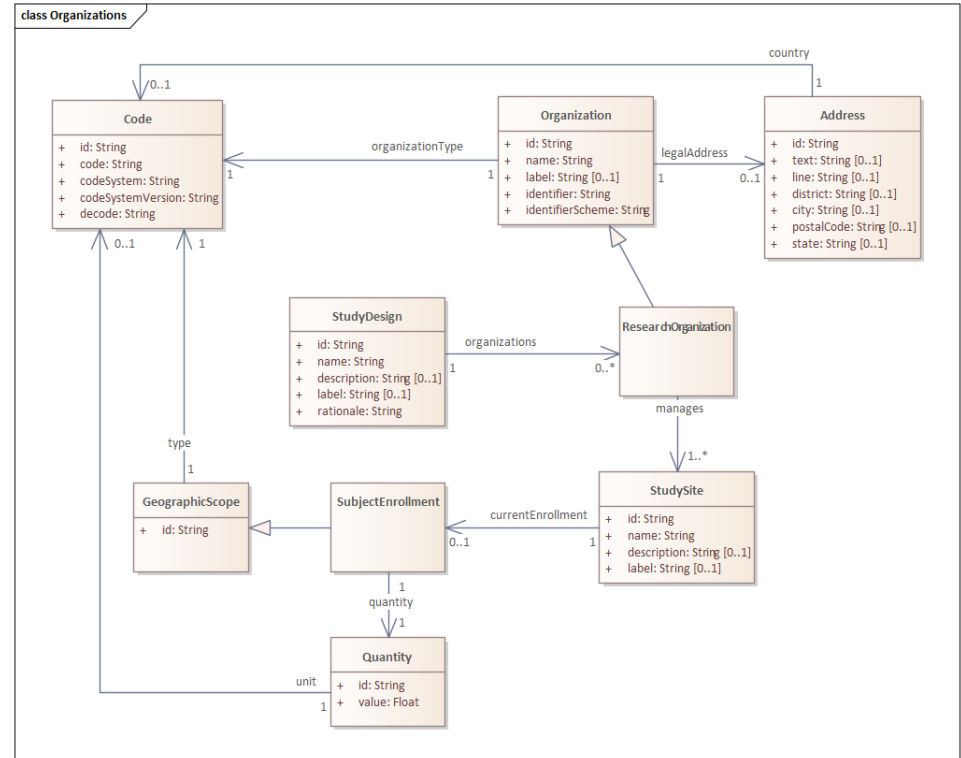
Study Population and cohorts

- 1 Study Population
- Optional cohorts
- Inheriting Population Definition attributes
 - Criteria
 - Age range
 - Planned enrollment number
 - Planned completion number
 - Planned sex
- Additional characteristics can be defined for cohorts
 - Referencing to other attributes in USDM using syntax template feature



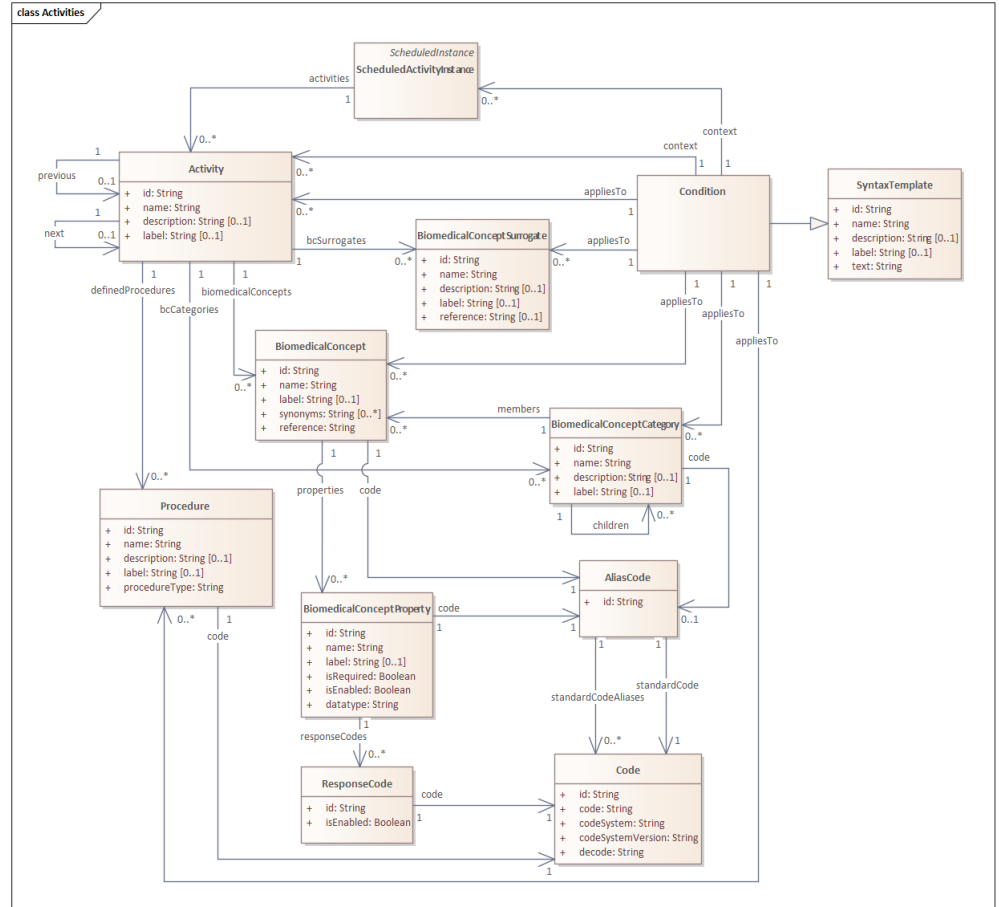
Research organization and study sites

- Can be defined per study design
- New Research Organization class
 - Inherits from the organization class
 - Manages study sites
- New Study Site class
 - Can define geographic scope
 - Can define current enrollment per site at time of design (0 at start of study, 0 or more in case of an amendment).



Conditionality

- Account for conditionality of activities at the following levels
 - Activity,
 - Assessment (BC or surrogate BC),
 - Procedure, or
 - Category of assessments (BC category)
- A condition relates to
 - An overall activity defined in the SoA, or
 - a specific timepoint in the SoA timeline.
- Handling of footnotes





API and model improvements

- Set of standard attributes
 - Name, Label, Description
- Standardization of attribute naming
 - Remove class name from attribute name if redundant
- Avoid repeats of information
 - Disconnected UML model from API in case of cross references, like:
 - InterventionId (API) instead of intervention (UML)
 - BiomedicalConceptIds instead of biomedicalConcepts
 - ChildIds instead of Children
- Include class name in the API
 - InstanceType

Mapping and alignment to other standards

- Uniform reference style
- All design parameters included for
 - SDTM trial design
 - CT.gov

TSPARM	TSPARMCD	Code	Codelist Code	TSVAL USDM Path and Attribute	Selection / Derivations	TSSEQ	TSGRPID
Adaptive Design	ADAPT	C146995	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@characteristics /code/@decode	If characteristics include "ADAPTIVE" then TSVAL="Y" and TSVALLCD="C49488" Otherwise TSVAL="N" and TSVALLCD="C49487"		
Planned Minimum Age of Subjects	AGEMIN	C49693	C66738	Study/@versions /StudyVersion/@studyDesigns /StudyDesign/@population /StudyDesignPopulation/@cohorts /StudyDesignPopulation StudyCohort/@plannedAge /Range/@minValue + @unit	Use minimum of minimum age values of all populations included (studyDesignPopulations and Cohorts). Transform according to ISO 8601 standards. If one or more populations have a null minValue then TSVAL should be set to null and TSVALLNF should be filled instead according to ISO 21090.		

The mapping to **Study Identification** is presented below. See Section 4.7, [Study Identifiers and Titles](#), for a description of the related features in the USDM.

CT.gov Path	CT.gov Variable	CT.gov Requirement	USDM path and attribute	Selection/Derivation
Study Identification	Brief Title	Required	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Brief Study Title" limit to 300 characters
Study Identification. Brief Title	Acronym	Required, If available	Study/@versions /StudyVersion/@titles /StudyTitle/@Text	..StudyTitle/@Type/Code/@decode="Study Acronym" limit to 14 characters

- Updated mapping of CPT to new style and USDM v3.0
 - No new mapping

Examples

- Will be updating and improving the examples as we go through public review, adding more detail
- Public workshops will also provide further information to implementors and more example materials
- Updated BC Library combined with improved CDISC library interface will allow CDISC Pilot example to be updated

USDMS Excel to JSON Utility STATUS

Excel File List

A list of files held within the system for which a converted USDMS JSON file can be downloaded.

File List.

CDISC_Pilot_Study_VS_Timeline.xlsx, dated 2024-01-25

Upload New Excel File

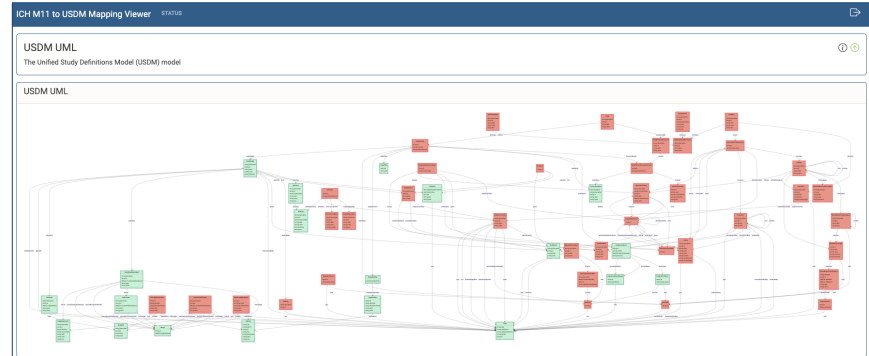
CLICK TO UPLOAD NEW FILE

```
9 ..... "id": "StudyVersion_1",
10 ..... "versionIdentifier": "2",
11 ..... "rationale": "The discontinuation rate associated with th
12 ..... "studyType": {
13 .....   "id": "Code_1",
14 .....   "code": "C98388",
15 .....   "codeSystem": "http://www.cdisc.org",
16 .....   "codeSystemVersion": "2023-09-29",
17 .....   "decode": "Interventional Study",
18 .....   "instanceType": "Code"
19 ..... },
20 ..... "studyPhase": {
21 .....   "id": "AliasCode_1",
22 .....   "standardCode": {
23 .....     "id": "Code_2",
24 .....     "code": "C15601",
25 .....     "codeSystem": "http://www.cdisc.org",
26 .....     "codeSystemVersion": "2023-09-29",
27 .....     "decode": "Phase II Trial",
28 .....     "instanceType": "Code"
29 .....   },
30 .....   "standardCodeAliases": [],
31 .....   "instanceType": "AliasCode"
32 ..... },
33 ..... "documentVersionId": "StudyProtocolDocumentVersion_1",
34 ..... "dateValues": [
35 .....   {
36 .....     "id": "GovernanceDate_1",
```

ICH M11 Protocol Specifications

- Original plan was to release USDM V3 at a similar time to the first issue of the ICH M11 specification
- ICH M11 Delivery timelines are currently being amended
- USDM V3 accommodates the latest available ICH M11 information
- ICH, HL7 Vulcan and CDISC now working together on the ICH Technical Implementation Guide (TIG) that will be part of the ICH release

The screenshot displays the 'ICH M11 to USDM Mapping Viewer' interface. The main window is titled 'M11 to USDM Mapping' and contains two panes. The left pane, 'M11 Section Detail', lists various fields for mapping, such as 'Sponsor Confidentiality Statement', 'Full Title', 'Trial Acronym', 'Protocol Identifier', 'Original Protocol', 'Version Number', 'Version Date', 'Amendment Identifier', 'Amendment Scope', 'Compound Code(s)', 'Compound Name(s)', 'Trial Phase', and 'Short Title'. Each field has a corresponding input field with a placeholder text and a small icon. The right pane, 'USD Mapping', shows a 'Mapping for Title, Trial Phase' and a 'Class: StudyVersion' with a 'Definition' and 'Terminology' section. Below this, a diagram shows the relationship between 'StudyVersion' and 'studyPhase', which in turn points to 'AliasCode'.



Thank You

CDISC DDF Team:


- Gerry Campion
- Drew Mills
- Erin Muhlbradt
- John Owen
- Berber Snoeijer
- Craig Zwickl

CDISC Controlled Terminology

Provides further semantics, complementing the UML model. Includes the definition of classes and attributes along with the definition of value sets

	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Descripti
	C188827	Study Arm Type
	C188828	Study Arm Data Origin Description
	C188829	Study Arm Data Origin Type
	CNEW	Study Arm Label
	C71738	Study Epoch
	C93825	Study Epoch Name
	C93824	Study Epoch Descripti
	C188830	Study Epoch Type
	CNEW	Study Epoch Le

on 2.0 Draft for Internal Review)



Unified Study Definitions Model Implementation Guide (USDM-IG)
Version 2.0 (Draft for Internal Review)

Prepared by the DDF Team

```
studyArms": [
  {
    "id": "StudyArm_1",
    "name": "Placebo",
    "label": "",
    "description": "Placebo",
    "type": {
      "id": "Code_61",
      "code": "C174268",
      "codeSystem": "http://www.cdisc.org/terminology/2022/01/01/CDISC-CT/20220101/Placebo-Comparison",
      "decode": "Placebo Comparison"
    },
    "studyArmDataOriginDescription": "Data Generated",
    "dataOriginType": {
      "id": "Code_62",
      "code": "C188866",
      "codeSystem": "http://www.cdisc.org/terminology/2022/01/01/CDISC-CT/20220101/Data-Generated",
      "decode": "Data Generated"
    }
  },
  {
    "id": "StudyArm_2",
    "name": "Xanomeline Low Dose",
    "label": "",
    "description": "Active Substance",
    "type": {
      "id": "Code_63",
      "code": "C174267",
      "codeSystem": "http://www.cdisc.org/terminology/2022/01/01/CDISC-CT/20220101/Active-Substance",
      "decode": "Active Substance"
    }
  }
]
```

Examples
Example protocols implemented using USDM with associated visualisations

API for DDF (2.4 Provisional (0.39))

Generate Digital Data Flow (DDF) Study Definitions Repository API.

Introduction Routes that form the production specification.

- POST** /v3/studyDefinitions Create a study
- PUT** /v3/studyDefinitions/{studyId} Update a study
- GET** /v3/studyDefinitions/{studyId} Return a study
- GET** /v3/studyDefinitions/{studyId}/history Returns the study history
- GET** /v3/studyDesigns Study designs for a study

Expand all object

Implementation Guide
Guidance on using the USDM model and ensuring conformance with the standard

Specification
Plans to exchange a study definition between machines using a JSON API





Public Review Information

John Owen

DDF Phase 3 Public Review Dashboard



CDISC, in continued collaboration with TransCelerate's Digital Data Flow Project, has updated the USDM reference architecture, which will serve as a standard model for the development of a Study Definitions Repository. The Repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards. CDISC invites you to submit comments on the draft v3.0 of the Unified Study Definitions Model (USDM) during the 30-day Public Review period.

The focus of Phase 3 is:

- Representation of draft ICH M11 CeSHarP (Clinical electronic Structured Harmonised Protocol) elements in USDM
- Addition of elements to the USDM to demonstrate automated population of selected SDTM Trial Design datasets
- Addition of elements to the USDM to demonstrate automated population of selected Clinical Trial Registry fields
- Updates to the USDM to cater for more Complex Studies/Cohort Studies
- USDM Model Enhancements

Deliverables include a logical data model, supporting Controlled Terminology, API specifications, and an associated Implementation Guide.

Public review is a key quality step in our Standards Development Process. CDISC relies on your input to ensure neutral, consensus-based data standards are developed and adopted by a diverse global community interested in improving research processes and quality for the benefit of all.

Thank you for contributing your time and expertise.

Public Review Dates

Public Review Comment Period Start: Tuesday 30 Jan 2024

Public Review Comment Period End: Thursday 22 Feb 2024

Comments received after 22 Feb 2024 may not be addressed during the public review period but will be deferred to the next version of the USDM.



DDF Phase 3 Public Review Dashboard



Location of Materials for Public Review

There are two ways to view the USDM materials for Public Review.

The first is to use the table below to navigate to the CDISC USDM GitHub and CDISC USDMIG Wiki site using the table below.

USDM Artefact	Location	Notes
USDM UML Logical Model	<ul style="list-style-type: none">The public review version of the UML diagram is available on the USDM GitHub site<ul style="list-style-type: none">usdm-uml.png - picture formatusdm-uml.xml - XML format (See here for more information on .XML format)usdm-uml.qea - New Enterprise Architect format	<ul style="list-style-type: none">An informative version of the USDM UML is available hereA list of UML model changes between USDM v2.0 and USDM v3.0 is available hereSmaller sub views of the model can be found hereIf you are unfamiliar with UML, Section 5.6 of the BRIDG Users Guide might be used as a model for a "Basics of UML" guide for DDF <p>› Read more information about the role of the UML class diagram</p>
USDM Controlled Terminology	<ul style="list-style-type: none">The public review version of the Controlled Terminology (CT) is available on the USDM GitHub site<ul style="list-style-type: none">usdm_ct.xlsx - Microsoft Excel format	<ul style="list-style-type: none">A list of CT changes between USDM v2.0 and USDM v3.0 is available hereThe link to the left takes you to the USDM GitHub - Click on the view raw link or the download icon  (top right) to download the Excel file <p>› Read more information about the role of USDM Controlled Terminology</p>
USDM API Specification	<ul style="list-style-type: none">The public review version of the API Specification is available on the USDM GitHub site<ul style="list-style-type: none">usdm_api.json - JSON format (learn more about JSON)usdm_api.yaml - YAML format (Learn more about YAML)	<ul style="list-style-type: none">Compare the updated API specification on the left to the USDM v2.0 API using a simple JSON Comparison tool <p>› Read more information about the role of USDM API</p>
USDM Implementation Guide	<ul style="list-style-type: none">The public review version of the USDM Implementation Guide (USDM-IG) is available on the CDISC WIKI<ul style="list-style-type: none">USDM Implementation Guide (USDM-IG) v3.0	<ul style="list-style-type: none">A PDF version of the USDMIG (USDM-IG.pdf) is also available in the USDM GitHub site if you prefer to review the USDMIG off-line (use the download icon  (top right) to download the pdf file).Please read the USDM Implementation Guide (USDM-IG) v3.0 landing page and Instructions for Reviewers for more information on how to review the USDMIG <p>› Read more information about the role of USDMIG</p>

The second way is to download the [single USDM.zip file](#)

DDF Phase 3 Public Review Dashboard



Public Review Webinar

- We invite you to register and attend the DDF Public Review Webinar on Thursday 01 Feb 2024 11:00am-12:30pm US Eastern Time, where representatives from the TransCelerate Biopharma and CDISC DDF teams will present on the updates made to the USDM during this phase of development, as well as providing information on how to provide public review comments.
- A recording of the webinar will be posted here

Other USDM Resources

The list below contains useful information if you are new to Digital Data Flow and the Unified Study Definitions Model (USDM) including:

- How to find introductory information on DDF
- Overview of the USDM
- Biomedical Concepts in the USDM
- Current developed test data
- Using your own study using the test data tools

› [Click here to find more USDM orientation information](#)

Instructions to create a JIRA comment for the USDM Implementation Guide

Note that the USDM Implementation Guide has been developed in the CDISC WIKI and therefore JIRA comments can be made direct in the WIKI

Please see the [USDM Implementation Guide \(USDM-IG\) v3.0](#) landing page and the [Instructions for Reviewers](#) section of the USDM IG

Instructions to create a JIRA comment for the UML, CT and API Deliverables

- Step 1 - Open JIRA
- Step 2 - Create Ticket
- Step 3 - Review Your Ticket
- Step 4 - Making Comments
- Q&A

- Navigate to the the [DDF JIRA Project](#)
- Click the **CREATE** button

The screenshot shows the JIRA interface for the 'Digital Data Flow' project. The top navigation bar includes 'cdisc Issue Tracker (JIRA)', 'Dashboards', 'Projects', 'Issues', 'Capture', 'Boards', 'Plans', and a 'Create' button which is highlighted with a red box. Below the navigation bar, the project name 'Digital Data Flow' is displayed. On the left, there is a sidebar with navigation options: 'Create board', 'Issues', 'Reports', 'Releases', 'Components', and 'Test sessions'. The main content area shows the 'Activity' section with a 'switch view' dropdown and a message: 'Comment tracker for the Digital Data Flow (DDF) Project'. Below this, there is a large banner with the text 'Let's get this project off the ground...' and a 'Create your first issue' button.



Upcoming events related to DDF

John Owen

Upcoming Events

Mark your calendars!



Major/
Interactive
Event



General
Awareness






Virtual option
available

Upcoming Events of 2024	Date
SCOPE Summit 2024 ● Digital Data Flow: Digitalizing Clinical Protocol Information to Accelerate Clinical Research and Pharma to Healthcare Interoperability SCOPE Summit 2024 February 11-14, 2024 Orlando, FL	11-14 February 2024
27th DIA Japan Annual Workshop for Clinical Data Management Workshop ● Event Page - Tokyo, Japan	19-20 February 2024
PHUSE US Connect 2024 , Bethesda, MD (Register Here) ◆ <ul style="list-style-type: none">[2/25] DDF Workshop: Mastering USDM Standards with an Interactive Demo and Hands-on Workshop[2/26 morning] DS: Digital Data Flow Track[2/26 afternoon] SM12: Embracing the Future of Digitization: Uninterrupted Data Flows from Protocol Design to Electronic Data Capture	25-28 February 2024
Data Driven, Hybrid and Full Decentralized Clinical Trials 2024 ● Event Page - Philadelphia, PA	16-17 April 2024
2024 CDISC + TMF Europe Interchange , Berlin, Germany ◆ Digital Data Flow Workshop – Tuesday, April 23, 2024; 9:00 AM – 3:00 PM CET 2024 CDISC + TMF Europe Interchange CDISC	22-26 April 2024



Sunday February 25

Time (EST)	Salon F/G	Salon H	Time (EST)
From 2:00pm	Registration – Main Level Foyer		From 2:00pm
2:30pm–4:00pm	Hands-on Workshop Step 1 to Becoming Multi-Lingual <i>Instem</i> 	Hands-on Workshop Mastering USDM Standards with an Interactive Demo and Hands-on Workshop <i>CDISC & TransCelerate</i>  	2:30pm–4:00pm

Monday February 26

Time (EST)	Salon A	Salon B	Salon C
9:00am-10:30am	Keynote Speaker – Peter Ronco, <i>Emmes</i> 'The Clinical Trial Process is Still Fundamentally Broken' Salon C		
10:30am-11:00am	Morning Break – Sponsored by Pinnacle 21 by Certara		
11:00am-11:30am	DH01: How to Monitor SDTM Data Health <i>Bioforum The Data Masters</i>	Connect Theme Presentations (DS) Digital Data Flow – From Vision to Reality DS01: ICH M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality <i>CDISC</i> DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs <i>CDISC</i>	ET01: Artificial Intelligence <i>IBM</i>
11:30am-12:00pm	DH02: Eliminating SDTM Double Programming by Using a Validation Tool and Dummy Data <i>SGS Health Science</i>		ET02: Generative AI in Clinical Research <i>Syne</i>
12:00pm-12:30pm	DH03: Addressing Challenges in Structuring CDISC SDTM and AdAM Datasets to Report Adverse Events Spanning Two Treatment Periods <i>MSD</i>	DS03: Digital Protocol Vision ... How Digital Information Can Transform and Automate Our Processes <i>Instem</i>	ET03: Webinars <i>Symyx</i>



PHUSE US Connect



CDISC EU Interchange 2024



Tuesday 23rd April

CDISC Workshops

Digital Data Flow Workshop

9:00 AM-3:00 PM CET



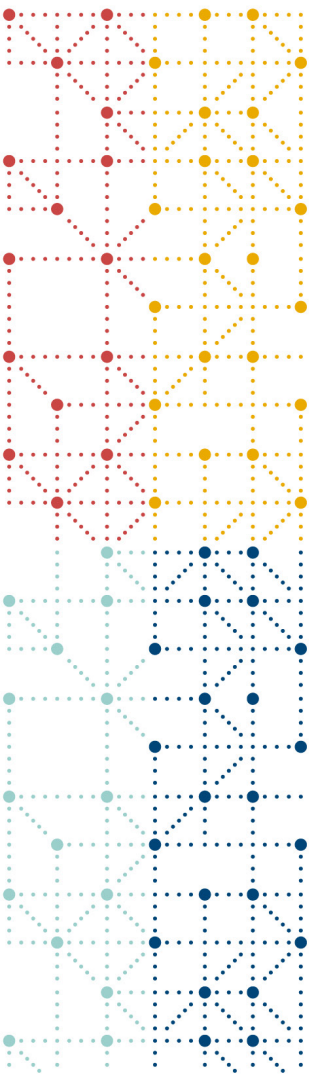
Day 2
25 April 2024

Deep dive into all aspects of the model and how study protocols and designs can be represented using the USDM

Focused sessions covering the theory on an individual aspect of the model combined with hands-on exercises and discussion

Timing, biomedical concepts, interventions, versioning, links with other standards such as SDTM, ICH M11, Trial Registries

11:00 - 12:30 Session 6A: Digital Data Flow	13:30 - 15:30 Session 7A: Digital Data Flow
Stijn Rogers, argenx Europa 5	Sujit Khune, Novo Nordisk A/S Europa 5
11:00 - 11:30 ICH M11 Presentation Peter Van Reusel, CDISC	13:30 - 13:50 Development of Unified Studies Definition Model (USDM) Through Translation of the Human-Readable Protocols Jasmine Kestemont, Innovicon
11:30 - 12:00 DDF Presentation Dave Iberson-Hurst, CDISC	13:50 - 14:10 Ripping up the Protocol: Pairing up USDM and ICH M11 to Inform Real-Time Study Builds Zaid Al-Jubour, Lindos Health
12:00 - 12:30 DDF: The Art of the Possible Becomes a Reality Bron Kisler, Nurocor	14:10 - 14:40 Demonstrating e2e Study Data Automation Using Extended USDM Model Kirsten Walther Langendorf, data4knowledge ApS
	14:40 - 15:00 From OpenStudyBuilder to the Digital Data Flow- USDM Format Maurizio Mazzei, Neo4J
	15:00 - 15:30 Panel Discussion



Thank You

