



# Digital Data Flow (DDF) Project CDISC Team Meeting

John Owen, CDISC Head of Project Management Office

Dave Ibersen-Hurst, CDISC DDF Product Owner

Chris Upkes, DDF Developer

4<sup>th</sup> April 2022





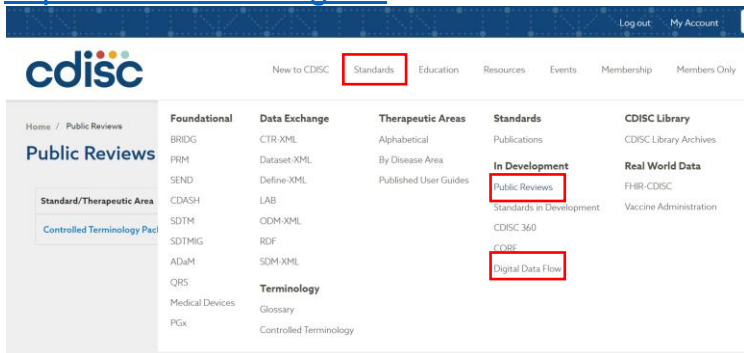


# Public Review Timetable

- **Tuesday 22<sup>nd</sup> March 2022** – DDF Public Review Webinar
- **Tuesday 29<sup>th</sup> March 2022** – DDF Materials sent out for review – Start of 30-day public review
- **Monday 4<sup>th</sup> April 2022** – 10:00-11:00 US Eastern Time - DDF Public Review Workshop – open invite (details on the DDF Public Review Webinar Page)
- **Friday 29<sup>th</sup> April 2022** – DDF Public Review Commenting Period ends

# Public Review Materials

- Email will be sent from CDISC Communications
- Public Review information will also be available from the Public Review section of the CDISC website
  - <https://www.cdisc.org/public-reviews>
  - <https://www.cdisc.org/ddf>



The screenshot shows the CDISC website's navigation bar and a grid of menu items. The 'Standards' link in the navigation bar is highlighted with a red box. In the main content area, the 'In Development' section is highlighted with a red box, and the 'Public Reviews' link within it is also highlighted with a red box. The 'Digital Data Flow' link is highlighted with a red box.

Foundational	Data Exchange	Therapeutic Areas	Standards	CDISC Library
BRIDG	CTR-XML	Alphabetical	Publications	CDISC Library Archives
PRM	Dataset-XML	By Disease Area	<b>In Development</b>	<b>Real World Data</b>
SEND	Define-XML	Published User Guides	<b>Public Reviews</b>	FHIR-CDISC
CDASH	LAB		Standards in Development	Vaccine Administration
SDTM	ODM-XML		CDISC 360	
SDTMIG	RDF		CDISC	
ADaM	SDM-XML		<b>Digital Data Flow</b>	
QRS	<b>Terminology</b>			
Medical Devices	Glossary			
PGx	Controlled Terminology			

- Links will direct reviewers to the DDF Public Review Dashboard

# DDF Public Review Dashboard

## DDF Public Review Dashboard

Created by John Owen, last modified just a moment ago

### The CDISC standards Development Process



The DDF Standards are now entering the public review commenting period after completing the standards development and internal review phases.

The purpose of the Public Review is to develop widespread consensus for the proposed standard by allowing for broad comment by the general public. Anyone interested may review and submit comments which must be reviewed and addressed by teams before proceeding to publication (CDISC-COP-001).

- Additional information on the overall aims of the DDF project can be found on the [TransCelerate DDF Website](#)
- Additional information is available in the [TransCelerate press release](#) about the DDF project

### Public Review Timelines

The Public Review commenting period will be open for 30-days.

Public Review Commenting Start Date - (E) 29 Mar 2022

Public Review Commenting End Date - (E) 29 Apr 2022

### Public Review Webinar

A recording of the Public Review Webinar from 22nd March 2022 can be found [here < insert link >](#). It is recommended that you watch this recording to gain a deeper understanding of the materials that are being sent for Public Review. The [slide deck < insert link >](#) used in the webinar is also available.

Webinar Summary

Topic	Presenter	Timing
Webinar introduction	Dave Evans	
TransCelerate and DDF	Allison Luckman	
CDISC DDF standards for public review	Dave Ibersen-Hurst	
Public Review Process	John Owen	
Q&A	All	

### What should you review?

- ▲ Please be aware that some of the deliverables that are being developed may be out of your skill set.
- The DDF review team is made up of experts in all the areas that the deliverables cover.
- We appreciate any comments that you can provide that you feel you can provide input on.

Deliverable	CDISC Standard	What would people Review	Files Available for Public Review	Files
Unified Study Definitions Model (USDM) Class Diagram	Yes	The UML class diagram (informative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative) <input type="text" value="Need some info on UML?"/> If you are unfamiliar with UML, Section 5.6 of the <a href="#">BRDGG Users Guide</a> might be used as a model for a 'Basics of UML' guide for DDF	PDF export from Enterprise Architect	
API Specification	Yes	The API definition.	JSON and HTML formats	
Controlled Terminology	Yes	The controlled terminology (informative) developed for the project.	Excel format for ease of searching and filtering).	<a href="#">DDF Controlled Terminology_Public Review_FINAL.xlsx</a>
Essential User Stories	No	The User Stories.	PDF Document	
Architecture Principles	No	The architectural principles developed by the project.	PDF Document	<a href="#">DDF CDISC RA GGG - Architecture_Principles - 2021-02-23.pdf</a>
Supporting Materials	No	A set of informational materials in PDF format to help understand the deliverables being reviewed.	PDF documents or references.	

### Using the DDF JIRA project for commenting

- All Public Review comments should be entered into the [DDF JIRA Project](#), as JIRA tickets.
    - You will need to log in or register for the CDISC Wiki to provide comments.
      - Register for the Wiki. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account. Wiki and JIRA use the same login credentials. CDISC Wiki is a different login from [www.cdisc.org](#)
- ▶ [Click here to expand instructions for entering JIRA comments](#)

Introduction

Timelines

Webinar

Materials

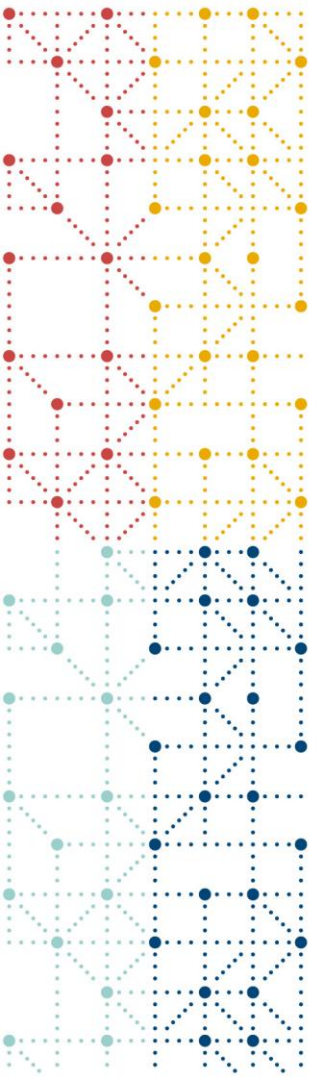
Commenting



# Digital Data Flow Model Walkthrough

**cdisc**





# Review Materials

Slides from public review

# CDISC Study Definition Repository RA Deliverables



## 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.

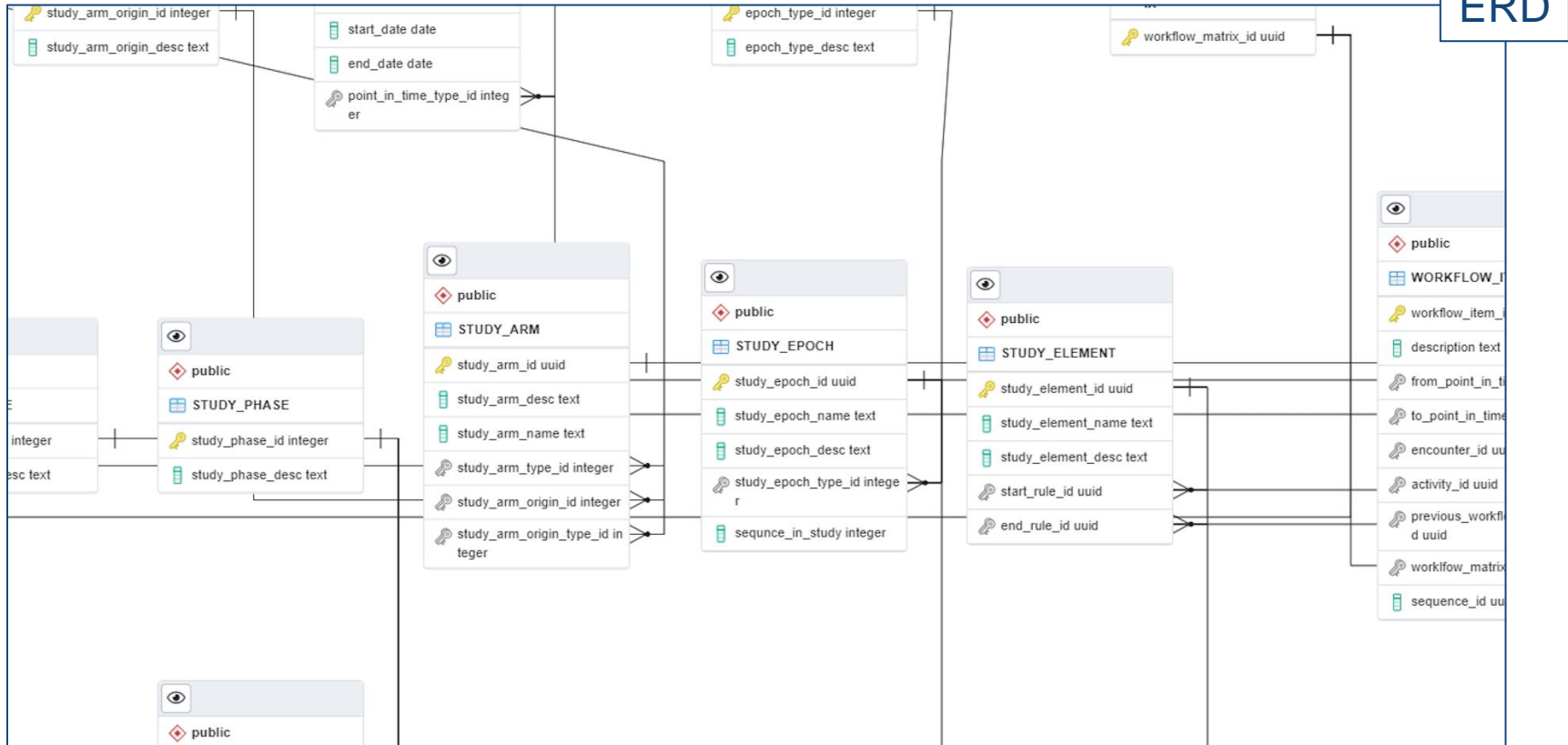






# Unified Study Definitions Model (USDM) Class Diagram

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)





## 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)

### SQL DD

```
-- This script was generated by a beta version of the ERD tool
-- Please log an issue at https://redmine.postgresql.org/projects/
BEGIN;

CREATE TABLE IF NOT EXISTS public."STUDY"
(
    study_id uuid NOT NULL,
    study_title text NOT NULL,
    study_version text NOT NULL,
    study_tag text,
    study_type_id integer NOT NULL,
    study_phase_id integer NOT NULL,
    study_status text NOT NULL,
    study_protocol_id uuid,
    study_protocol_version text,
    CONSTRAINT pk_study_id PRIMARY KEY (study_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_TYPE"
(
    study_type_id integer NOT NULL,
    study_type_desc text NOT NULL,
    PRIMARY KEY (study_type_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_PHASE"
(
    study_phase_id integer NOT NULL,
    study_phase_desc text NOT NULL,
    CONSTRAINT pk_study_phase_id PRIMARY KEY (study_phase_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_IDENTIFIER"
(
    study_identifier_id uuid NOT NULL,
    org_code text NOT NULL,
    study_identifier_type_id integer NOT NULL,
    study_identifier_name text,
    study_id uuid,
    PRIMARY KEY (study_identifier_id)
);
```

### JSON

```
{
  "studyTitle": "Study Number One",
  "studyType": "INTERVENTIONAL",
  "studyPhase": "PHASE_1_TRIAL",
  "studyStatus": "this is a study status",
  "studyIdentifiers": [
    {
      "id": "f1aae4a0-2ddf-44cc-9f65-f3077f3f5939",
      "orgCode": "2.16.840.1.113883.3.1077",
      "name": "ClinicalTrials.gov",
      "idType": "REGISTRY_STUDY"
    },
    {
      "id": "74bab1ed-9439-4467-83a3-284727e0b0e9",
      "orgCode": "2.16.840.1.113883.3.1077",
      "name": "ClinicalTrials.gov",
      "idType": "SPONSOR_ID"
    }
  ],
  "studyProtocolReferences": [
    {
      "studyProtocolId": "a5709f39-dcf1-40a0-bd40-5164a96e07b8",
      "studyProtocolVersion": "1.0"
    }
  ],
  "studyVersion": "1.0",
  "studyTag": null,
  "studyId": "8bf37e48-cbf0-49f5-a113-4c5a15b2cd90",
  "currentSections": [
    {
      "id": "bd8e986a-d7cd-4289-bc14-f05e05e3342f",
      "sectionType": "STUDY_INDICATIONS",
      "studyIndications": [
        {
          "id": "f192251c-a732-44b5-b63a-6f3b99bd7c99",
          "description": "Alzheimer's disease",
          "coding": [
            {
              "code": "26929004",
              "codeSystem": "SNOMED-CT",
              "codeSystemVersion": "4.0.6.4",
              "decode": "Alzheimer's disease (disorder)"
            }
          ]
        }
      ]
    }
  ]
},
```



# Application Programming Interface (API) Specification

The API definition (normative) in JSON and HTML forms

## JSON

### GET /studydefinitionrepository/v1/studyhistory

Get history of all studies (get.studydesignrepository.history)

Get history of all studies

Return type

[inline\\_response\\_200\\_1](#)

Example data

Content-Type: application/json

```
{
  "study" : [ {
    "studyVersion" : [ 1, 1 ],
    "studyId" : "e3e84e94-927e-42da-9625-e4f18bc4b7a4",
    "studyTitle" : "Example study title"
  }, {
    "studyVersion" : [ 1, 1 ],
    "studyId" : "e3e84e94-927e-42da-9625-e4f18bc4b7a4",
    "studyTitle" : "Example study title"
  } ]
}
```

Produces

This API call produces the following media types according to the Accept request header; the media type will be conveyed in the response.

- application/json

Responses

200

OK [inline\\_response\\_200\\_1](#)

## HTML

```
{
  "openapi": "3.0.0",
  "info": {
    "title": "Simple API for DDF",
    "description": "This is a sample API for the DDF project - including sectioning (Acc",
    "license": {
      "name": "MIT",
      "url": "https://opensource.org/licenses/MIT"
    },
    "version": "1.2.6"
  },
  "servers": [
    {
      "url": "https://virtserver.swaggerhub.com/CDISC1/DDF/1.2.6",
      "description": "SwaggerHub API Auto Mocking"
    }
  ],
  "paths": {
    "/studydefinitionrepository/v1/{study}": {
      "get": {
        "tags": [
          "default"
        ],
        "summary": "Get study build sections",
        "description": "Get Study Build Sections",
        "operationId": "get.studydesignrepository.sections",
        "parameters": [
          {
            "name": "study",
            "in": "path",
            "description": "Study Builder Study",
            "required": true,
            "style": "simple",
            "explode": false,
            "schema": {
              "type": "string",
              "example": "ACME001"
            }
          }
        ]
      }
    }
  }
}
```

This Set

Default

- [GET /studydefinitionrepository/v1/studyhistory](#)
- [GET /studydefinitionrepository/v1/{study}/sectionhistory](#)
- [GET /studydefinitionrepository/v1/{study}](#)
- [GET /studydefinitionrepository/v1/{study}/studydesign/{s](#)
- [GET /studydefinitionrepository/v1/{study}/studyprotocols](#)
- [POST /studydefinitionrepository/v1](#)
- [POST /studydefinitionrepository/v1/{study}/studyprotocol](#)

Ignore!

Hidden

- [POST /studydefinitionrepository/v1/components](#)
- [DELETE /studydefinitionrepository/v1/{study}/studyassessmentgroup/{assessmentgroupId}](#)
- [DELETE /studydefinitionrepository/v1/{study}/biomedicalconcepts/{biomedicalConceptId}](#)





# CDISC Controlled Terminology

The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.

Row #	UML Class Name	UML Item Name	Role	NCIC-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List
1	STUDY	STUDY	Entity	C15206	Clinical Study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [http://ClinicalTrials.gov/CDISC_Glossary]	N
2	STUDY	study_title	Attribute	C49802	Study Title	Trial Title; Official Study Title; Study Title	The sponsor-defined name of the clinical study.	N
3	STUDY	study_version	Attribute	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
4	STUDY	study_status	Attribute	CNEW	Protocol Status		A condition of the protocol at a point in time with respect to its state of readiness for implementation.	Y (CNEW Protocol Status Response)
5	STUDY	study_protocol_version	Attribute	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
6	STUDY_TYPE	STUDY_TYPE	Entity	C142175	Study Type	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	N
7	STUDY_TYPE	study_type_desc	Attribute	C142175	Study Type Classification	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Y (C99077 STYPE)
8	STUDY_PHASE	STUDY_PHASE	Entity	C48281	Trial Phase	Trial Phase; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	N
9	STUDY_PHASE	study_phase_desc	Attribute	C48281	Trial Phase Classification	Trial Phase; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	Y (C66737 TPHASE)
10	STUDY_IDENTIFIER	STUDY_IDENTIFIER	Entity	C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.	N
11	STUDY_IDENTIFIER	org_code	Attribute	CNEW	Study Identifier Organization Code		A coded value specifying the organization that creates and/or assigns the study identifier.	N
12	STUDY_IDENTIFIER	study_identifier_name	Attribute	CNEW	Study Identifier Name		The literal identifier (i.e., distinctive designation) of the sequence of characters used to identify, name, or characterize the study.	N



# User Stories

Dave Iberson-Hurst, 21<sup>st</sup> March 2022

## Changes

- 25<sup>th</sup> January 2022 – Initial draft
- 31<sup>st</sup> January 2022 – Updates after informal review
- 14<sup>th</sup> February 2022 – Updates after initial Transclerate (TCB) review. Includes better alignment with TCB terminology. Also the Essential User Stories and those raised as JIRA tickets have been incorporated such they can viewed in context.
- 21<sup>st</sup> March 2022 – Updates after further review.

## Purpose

This note presents a set of user stories for the Digital Data Flow Project based on the essential user stories produced by the project to date. The presented user stories try and respond to comments raised on the essential user stories such as the following JIRA ticket.

*However the users of the USDM are the upstream and downstream systems and not directly the users of those systems. So search and add/remove functions like described in user story L1 to L5 are not directly applicable to the USDM and RA. However, the data structure must make it possible for the upstream system to provide this functionality. So a logical data structure and API requests are in scope. Can the user stories be adjusted to reflect this?*





## Architecture Principles

The architectural principles developed by the project. PDF Document

PDF

# Architecture Principles

## Description of the Deliverable for the Development Phase

The architecture principles aim to help implementers understand how to create conformant solution architectures through the implementation of the DDF Study Definition Reference Architecture (RA). They inform solution architects of the approach expected by the RA stakeholders to ensure consistency across Study Definition implementations and to ensure alignment with the business and technology objectives. Architecture principles define the fundamental assumptions regarding the RA and aid in developing a framework for decision making by solution architects implementing the RA.

## Summary of work to be performed during scoping

A framework for the architecture principles was developed during the scoping period.





## Supporting Materials

A set of informational materials in PDF format to help understand the deliverables being reviewed. PDF documents or references.

- **Issues and Questions:** Based on the remaining JIRA tickets a series of issues and question to be addressed during the review.
- **Technical Notes:** Technical notes on Schedule of Activities and ODM/CRF creation
- **High-Level Model Overview:** Aid to reviewing the model
- **UML Notes:** Help for those reading the UML diagrams

## CRF Specification for DDR

DDR-Umbrella Study of DNA-Damage Response Targeting Agents in Advanced Biliary Tract Cancer

### Protocol Name: Targeting Agents in ABTC

CRF Creation date: 2022-03-15T15:46:39

#### Table of Contents

- 12-lead ECG
- Chemistry (predose)
- Disease characteristics
- Eligibility criteria
- Ensure availability of medication X
- Form DM - Demographics
- Form LB - Local Processing
- Height
- Hematology (predose)
- Hospitalization
- Informed consent

SCREENING VISIT	
Informed consent	X
Eligibility criteria	X

**Form DM - Demographics**  
CRF instructions: DM - Demographics

dd/mm/yyyy

The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM

**BIRTHDATE** 1.1 What is the subject's date of birth?

**AGE** 1.2 What is the subject's age?

**AGEU** 1.3 What is the age unit used?

**SEX** 1.4 What is the sex of the subject?

Female (F)  
 Male (M)  
 Unknown (U)  
 Undifferentiated (UNDIFFERENTIATED)  
 Hispanic or Latino (HISPANIC OR LATINO)  
 Not Hispanic or Latino (NOT HISPANIC OR LATINO)  
 Not Reported (NOT REPORTED)  
 Unknown (UNKNOWN)

**ETHNIC** 1.5 Do you consider yourself Hispanic/Latino or not Hispanic/Latino?

American Indian or Alaska Native (AMERICAN INDIAN OR ALASKA NATIVE)  
 Asian (ASIAN)  
 Black or African American (BLACK OR AFRICAN AMERICAN)  
 Native Hawaiian or Other Pacific Islander (NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)  
 White (WHITE)  
 Not Reported (NOT REPORTED)  
 Unknown (UNKNOWN)  
 Other (OTHER)

**RACE** 1.6 Which of the following five racial designations best describes you? (More than one choice is acceptable.)

**RACEOTH** 1.7 What was the other race?

X									X
X	X			X			X		X
X									X
X									
	X			X			X		
	X			X			X		X
X	X	X	X	X	X	X	X	X	X



# CDISC Study Definition Repository RA Deliverables



## 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

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## Reference Architecture Conformance Tests

Provided by the functionality provided by tools such as SwaggerHub and Postman



## Essential Users Stories

The User Stories. PDF document



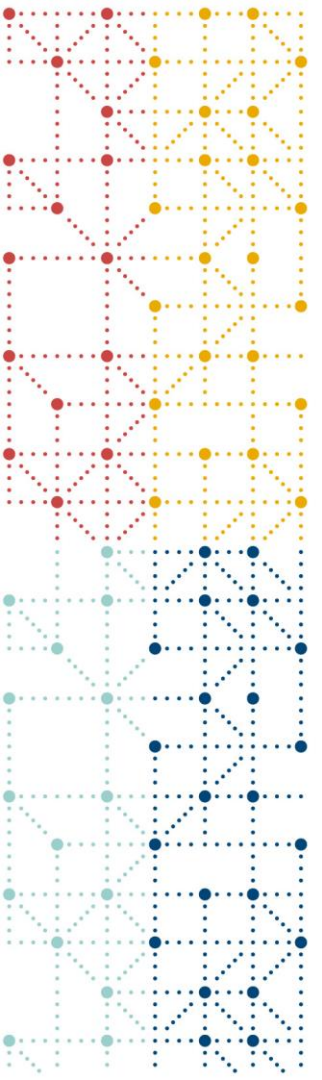
## Architecture Principles

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.



# Walkthrough

Informational



### Note

- The following diagrams are for information only
- The diagrams may contain errors, the UML is the normative artefact
- Many to many tables not shown to aid understanding





### Recommend

- Walk through the model and use the Excel CT file at the same time



# USDM Model Walkthrough

Informational

Supporting Materials - A set of informational materials in PDF format to help understand the deliverables being reviewed.				
Specific Public Review Topics	No	Based on the remaining JIRA tickets a series of issue questions the CDISC team would like input from public reviewers	 	<ul style="list-style-type: none"> <li>• <a href="#">2022 03 29 JIRA Public Review.pdf</a></li> </ul>
High-Level Model Overview	No	Aid to reviewing the model	 	<ul style="list-style-type: none"> <li>• <a href="#">2022 03 29b Model Walkthrough.pdf</a></li> </ul>
Technical Notes	No	Technical notes on Schedule of Activities and ODM/CRF creation	PDF Document	<ul style="list-style-type: none"> <li>• <a href="#">2022 03 25 SoA and CRF Tech Note.pdf</a></li> </ul>
UML Notes	No	Help for those reading the UML diagrams	Links	<ul style="list-style-type: none"> <li>• <a href="#">BRIDG Users Guide</a></li> <li>• <a href="https://en.wikipedia.org/wiki/Class_diagram">https://en.wikipedia.org/wiki/Class_diagram</a></li> <li>• <a href="http://www.agilemodeling.com/artifacts/classDiagram.htm">http://www.agilemodeling.com/artifacts/classDiagram.htm</a></li> </ul>

<https://wiki.cdisc.org/display/PUB/DDF+Public+Review+Dashboard>



## Public Review – JIRA Issues

Dave Ibersson-Hurst, 29<sup>th</sup> March 2022

### Changes

- 9<sup>th</sup> March 2022 – Initial draft.
- 15<sup>th</sup> March 2022 – Updated with addition of DDF-228, DDF-219, DDF-197, DDF-196 and DDF-185
- 17<sup>th</sup> March 2022 – Updated with addition of DDF-224, DDF-198, DDF-186, DDF-185, DDF-133, DDF-102
- 21<sup>st</sup> March 2022 – Add in DDF-226 and DDF-227
- 23<sup>rd</sup> March 2022 – Add in DDF-106 and DDF-114. Restructure the Topic Areas section to facilitate what needs to be undertaken for public review and the questions that are to be posed to reviewers.
- 24<sup>th</sup> March 2022 – Add in DDF-103
- 28<sup>th</sup> March 2022 – Add in DDF-221 and DDF-225
- 29<sup>th</sup> March 2022 – Add in review questions and fix an incorrect reference.

### Purpose

This note assembles all the DDF JIRA tickets that have not been processed prior to the first CDISC public review of the USDM. The note provides an overview of the tickets, groups the tickets into topic area and provides a detailed export for each of the tickets.

Those participating in the public review are requested to note the questions in **red text** in the Topic Areas section below.



## Model Walkthrough Technical Note

CDISC DDF Team, 29<sup>th</sup> March 2022, third draft

### Changes

- 28<sup>th</sup> March 2022 – First draft
- 29<sup>th</sup> March 2022 – Second draft after an initial review
- 29<sup>th</sup> March 2022 – Third draft after further comments received

### Purpose

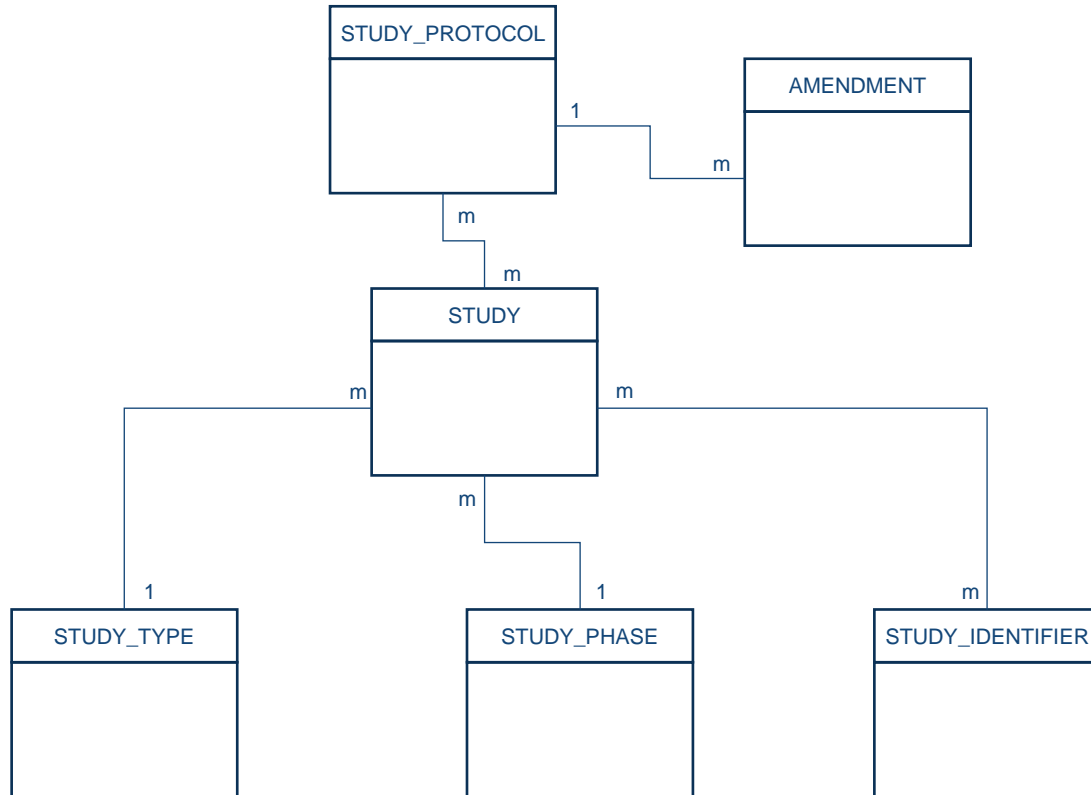
This note provides an overview and walkthrough of the CDISC and TransCelerate Digital Data Flow (DDF) Unified Study Definitions Model (USDM). The aim is to guide the non-technical reader when reviewing the model.

*Note: this an early draft of this note and it will be updated as comments are received, and review of the model takes place.*



# USDM Model Walkthrough

Informational





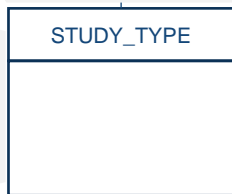
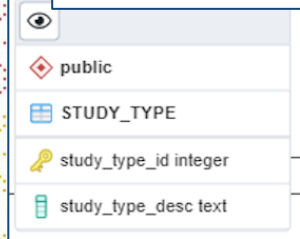
# USDM Model Walkthrough

Informational

CT EXCEL

Row #	UML Class Name	UML Item Name	Role	NCI C-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List
6	STUDY_TYPE	STUDY_TYPE	Entity	C142175	Study Type	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	N
7	STUDY_TYPE	study_type_desc	Attribute	C142175	Study Type Classification	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Y (C99077 STYPE)

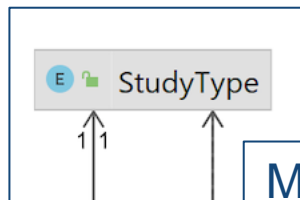
## MODEL ERD



```

CREATE TABLE IF NOT EXISTS public."STUDY_TYPE"
(
    study_type_id integer NOT NULL,
    study_type_desc text NOT NULL,
    PRIMARY KEY (study_type_id)
);
  
```

## MODEL SQL



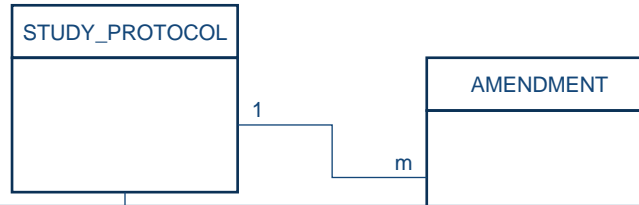
## MODEL UML





## USDM Model Walkthrough

Informational



<p>Study, Protocol and Amendments</p>	<p>DDF-228, DDF-224, DDF-187, DDF-102</p>	<p>The relationship between Study, Study Design, Protocol and amendments and version needs checking.</p>	<p>Public Review</p>	<p>Currently the USDM defines the <b>STUDY</b>, <b>STUDY_PROTOCOL</b> and <b>AMENDMENT</b> classes to hold the relationships and information to relate a study and the associated protocol.</p> <p>There is a need to improve this area, to better represent the needs of the community including the complexity of protocol amendments. We are therefore requesting reviewers pay attention to this area and consider their current practices of handling studies, protocols, and the associated amendments and what is needed in the USDM to support this.</p> <p>We would however also note that the current practices in a paper-based world may not make for the best practices in an electronic world and the community needs to strike the appropriate balance.</p>
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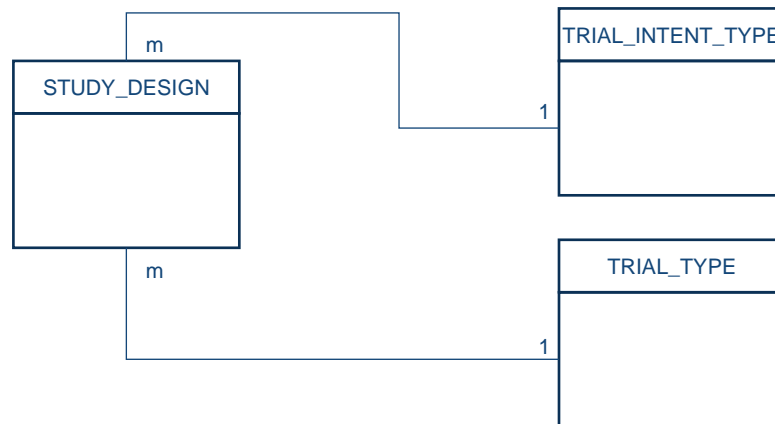




# USDM Model Walkthrough

Informational

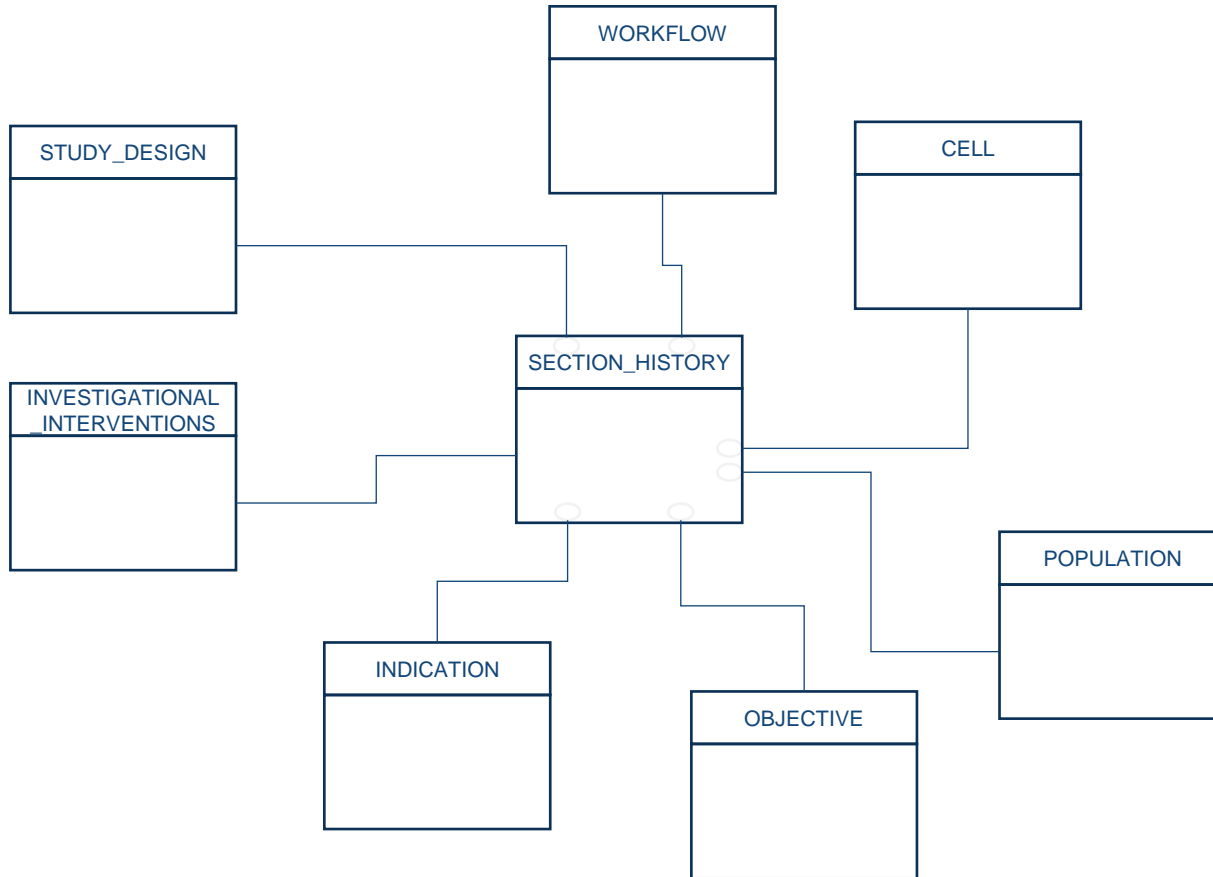
Row #	UML Class Name	UML Item Name	Role	NCI C-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List
99	TRIAL_INTENT_TYPE	TRIAL_INTENT_TYPE	Entity	C49652	Trial Intent Type	Trial Intent Type	The planned purpose of the therapy, device, or agent under	N
100	TRIAL_INTENT_TYPE	trial_intent_type	Attribute	C49652	Trial Intent Type	Trial Intent Type	The planned purpose of the therapy, device, or agent under	Y (C66736 TINDTP)
101	TRIAL_TYPE	TRIAL_TYPE	Entity	C49660	Trial Type	Trial Scope; Trial Type	The nature of the interventional study for which information is	N
102	TRIAL_TYPE	trial_type	Attribute	C49660	Trial Type	Trial Scope; Trial Type	The nature of the interventional study for which information is	Y (C66739 TTYPE)





# USDM Model Walkthrough

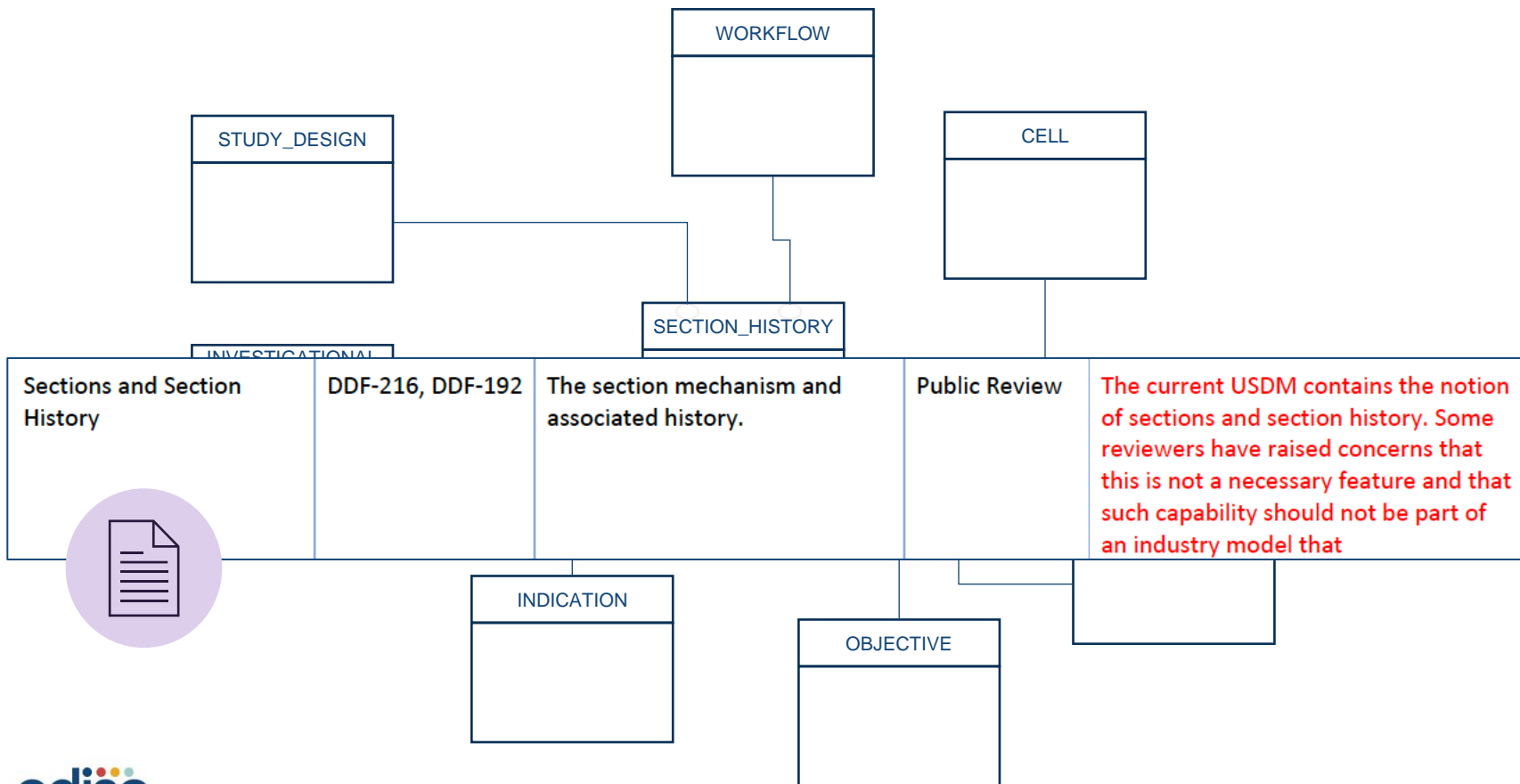
Informational





# USDM Model Walkthrough

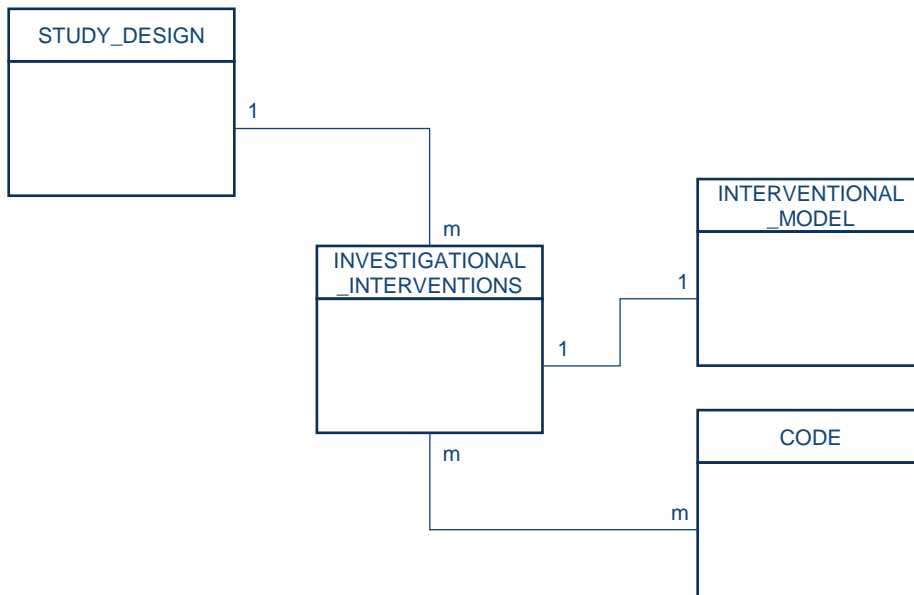
Informational





# USDM Model Walkthrough

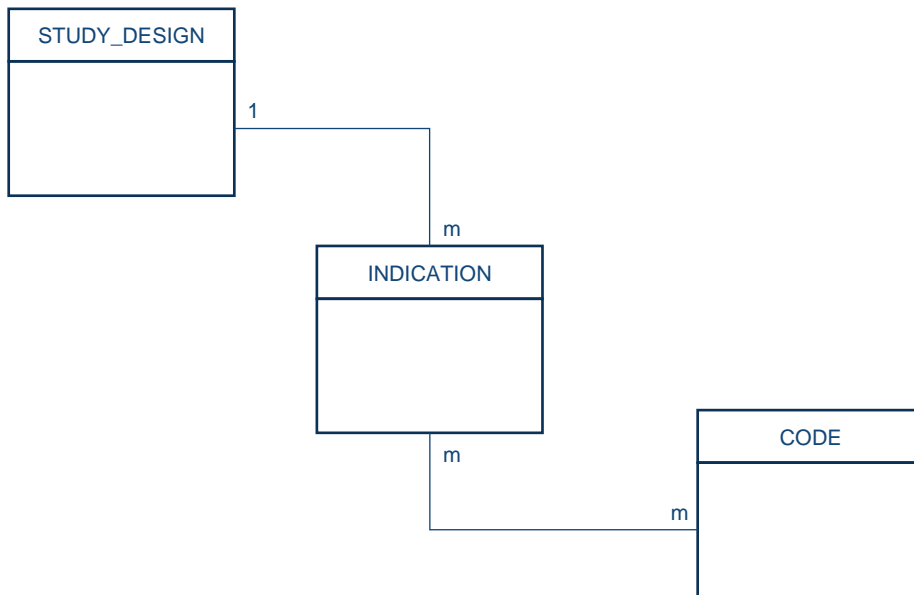
Informational





## USDM Model Walkthrough

Informational

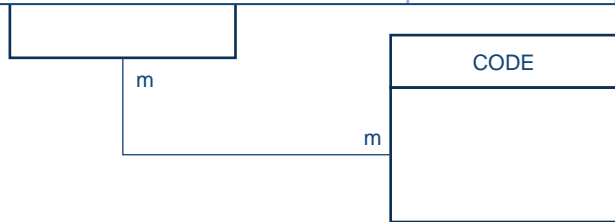




# USDM Model Walkthrough

Informational

External CT	DDF-227, DDF-103, DDF-200, DDF-93	Tickets relating to the use of external CT and how CT is referenced. One particular example is procedure types and using external CT.	Public Review  <p>Within the USDM there are places where the CODE class can be used to refer to external (to the USDM) terminology. The project has already received comments about expanding the ability to refer to external terminology for such items as interventions and procedures. As part of this review, it would be useful to know what the CT the community is using for such items with their current protocols or what may be useful as the community moves from a paper paradigm to an electronic one.</p>
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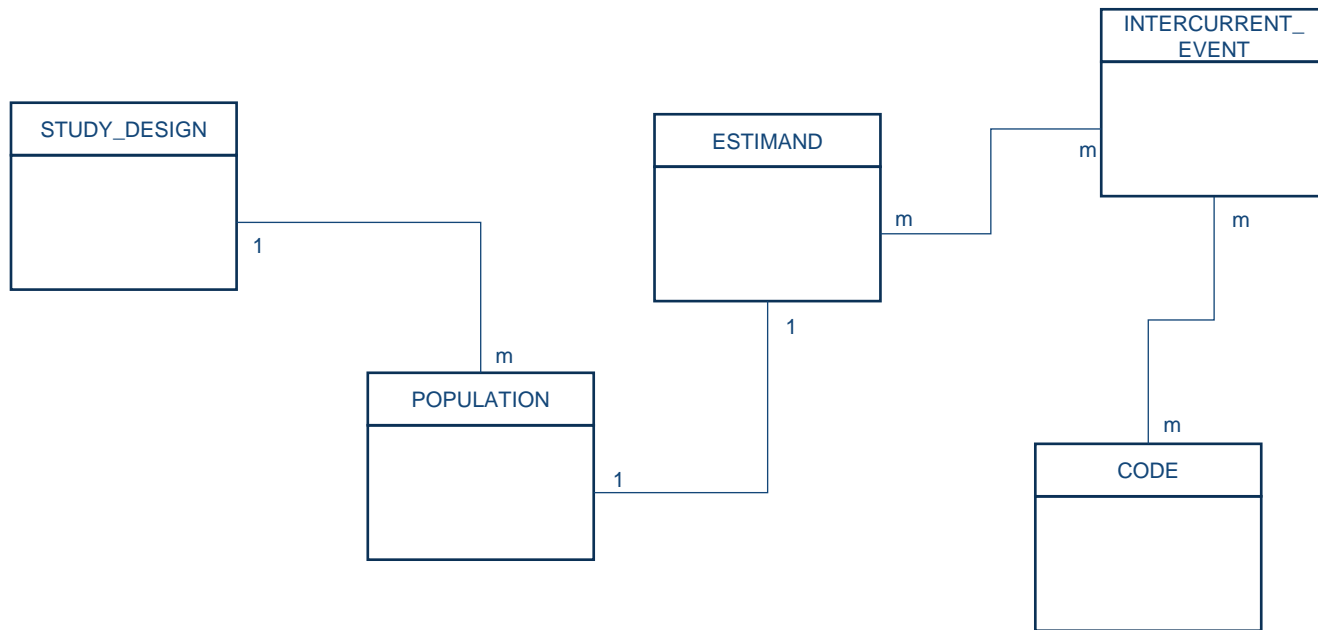






# USDM Model Walkthrough

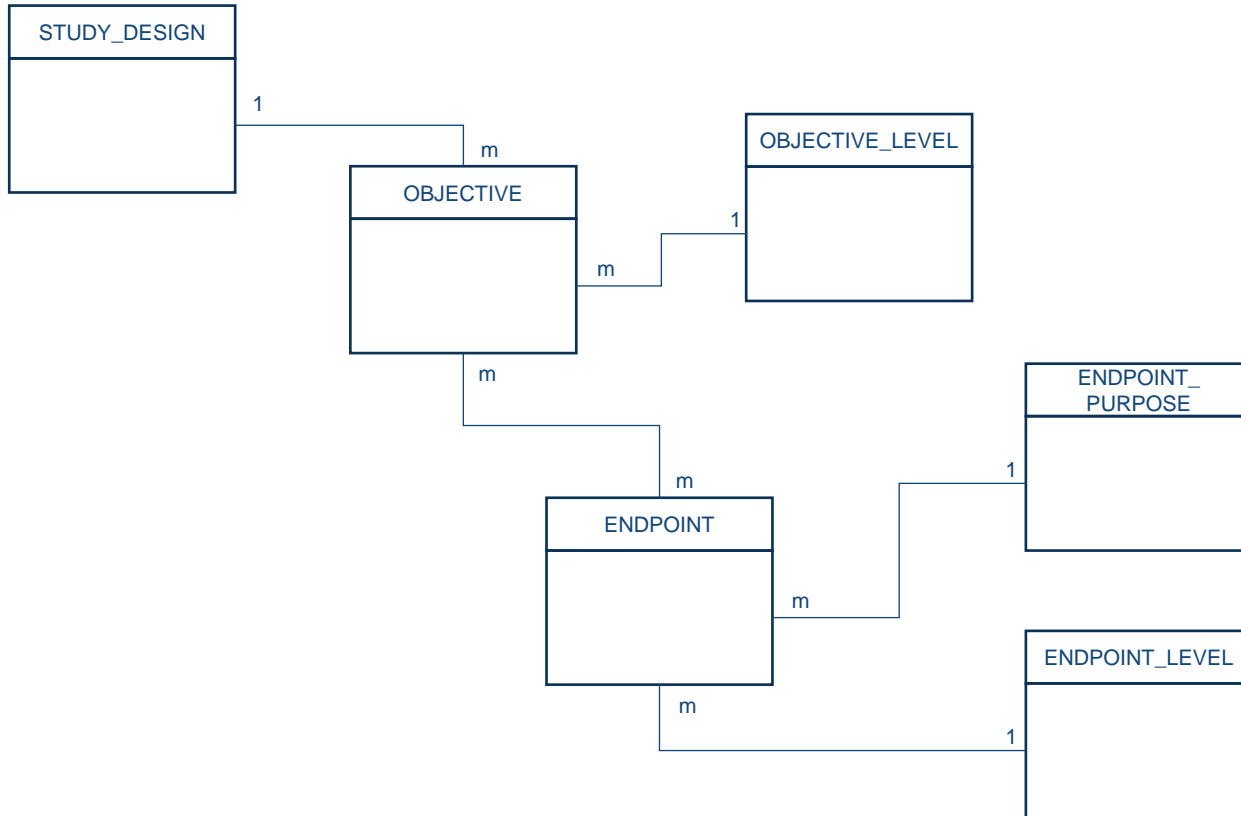
Informational





# USDM Model Walkthrough

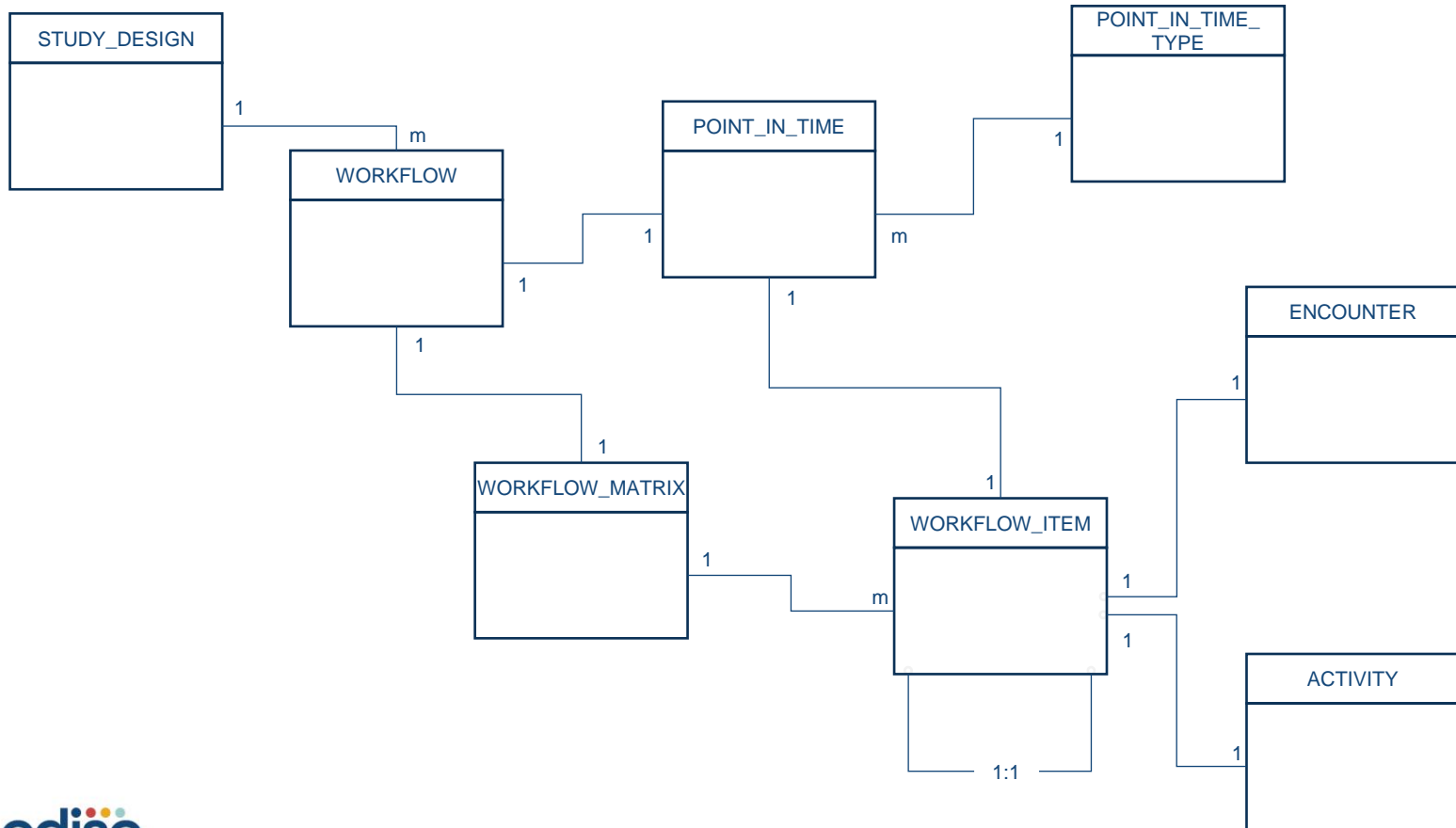
Informational





# USDM Model Walkthrough

Informational

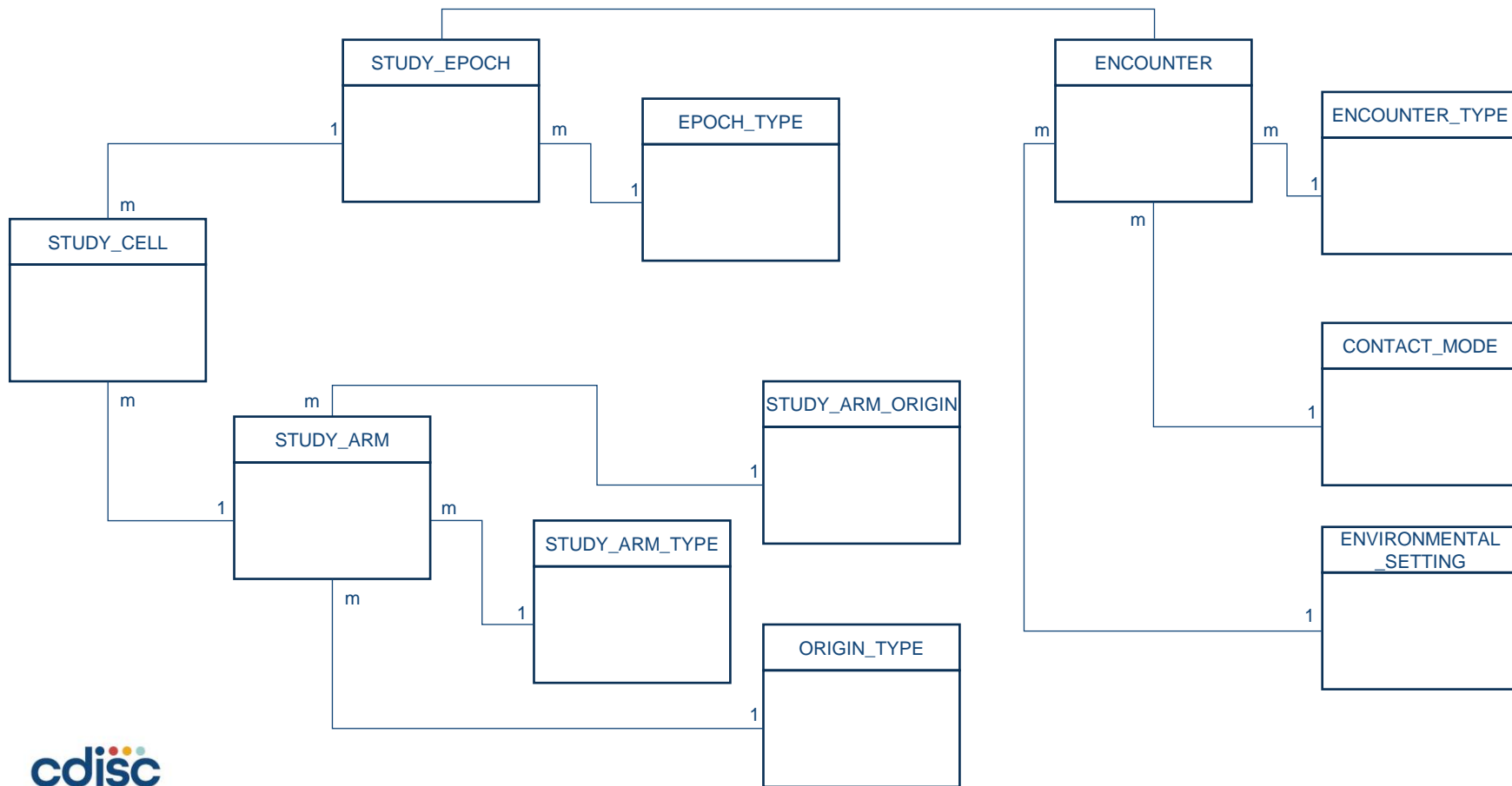






# USDM Model Walkthrough

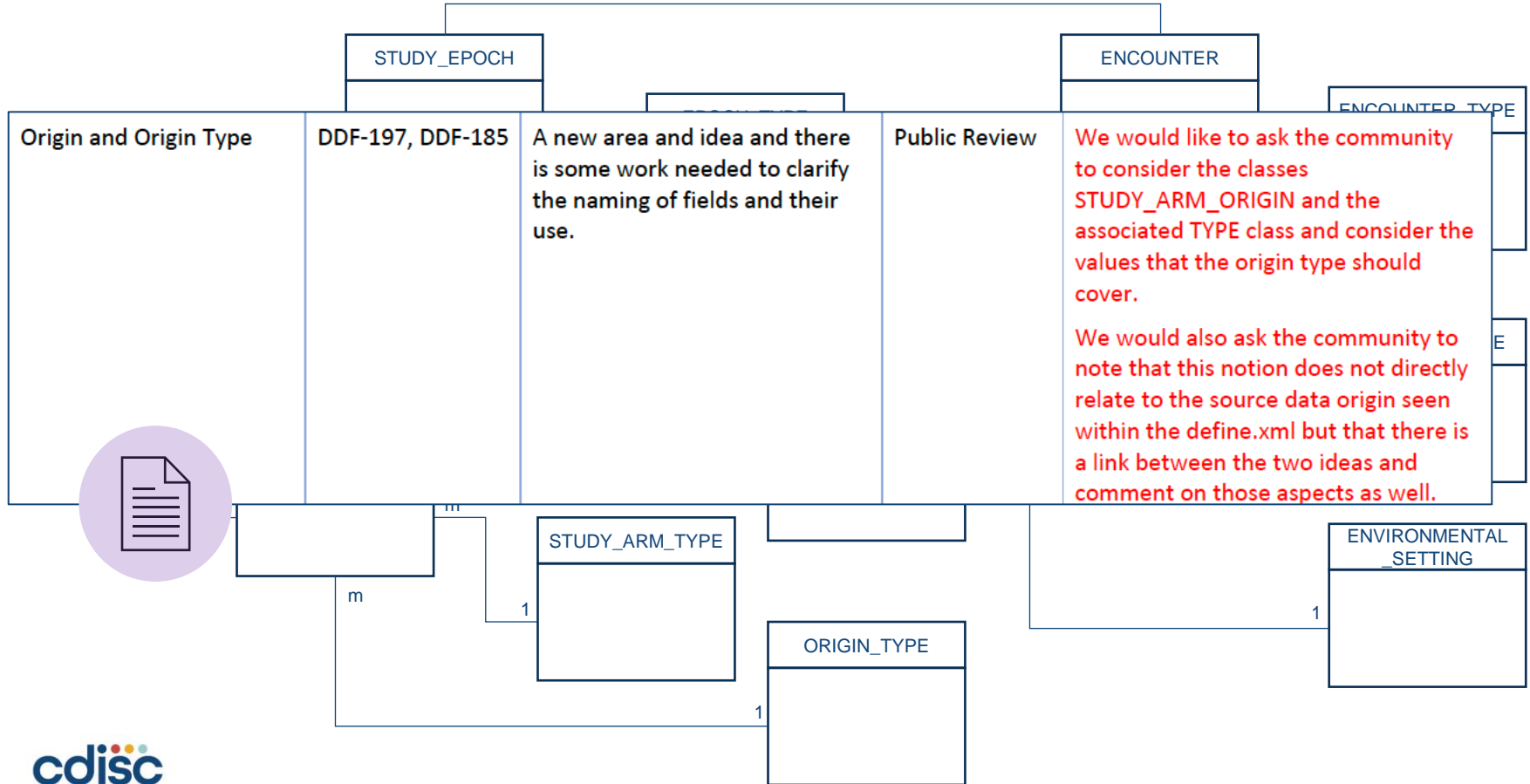
Informational





# USDM Model Walkthrough

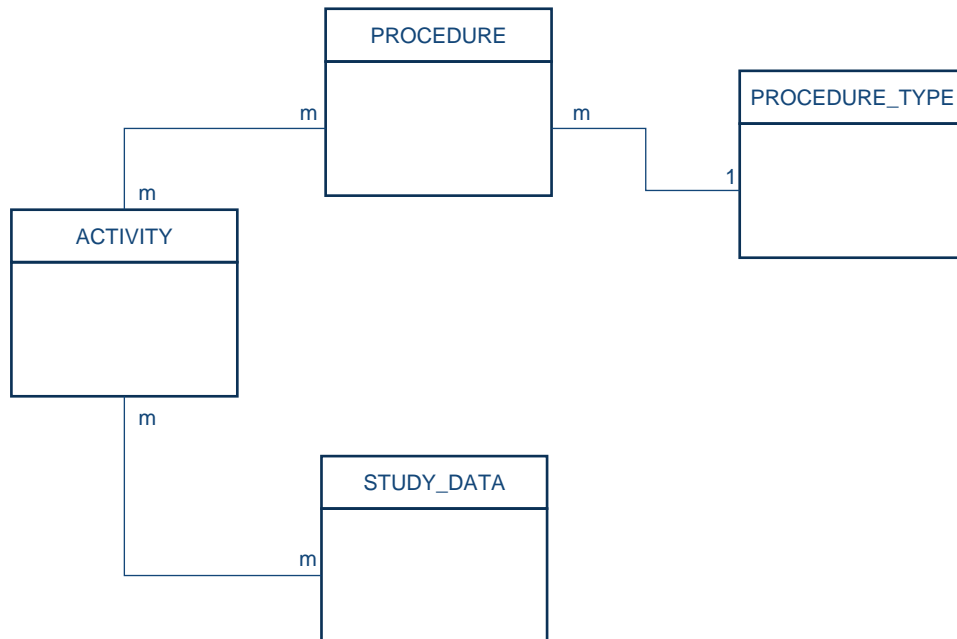
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## USDM Model Walkthrough

Informational

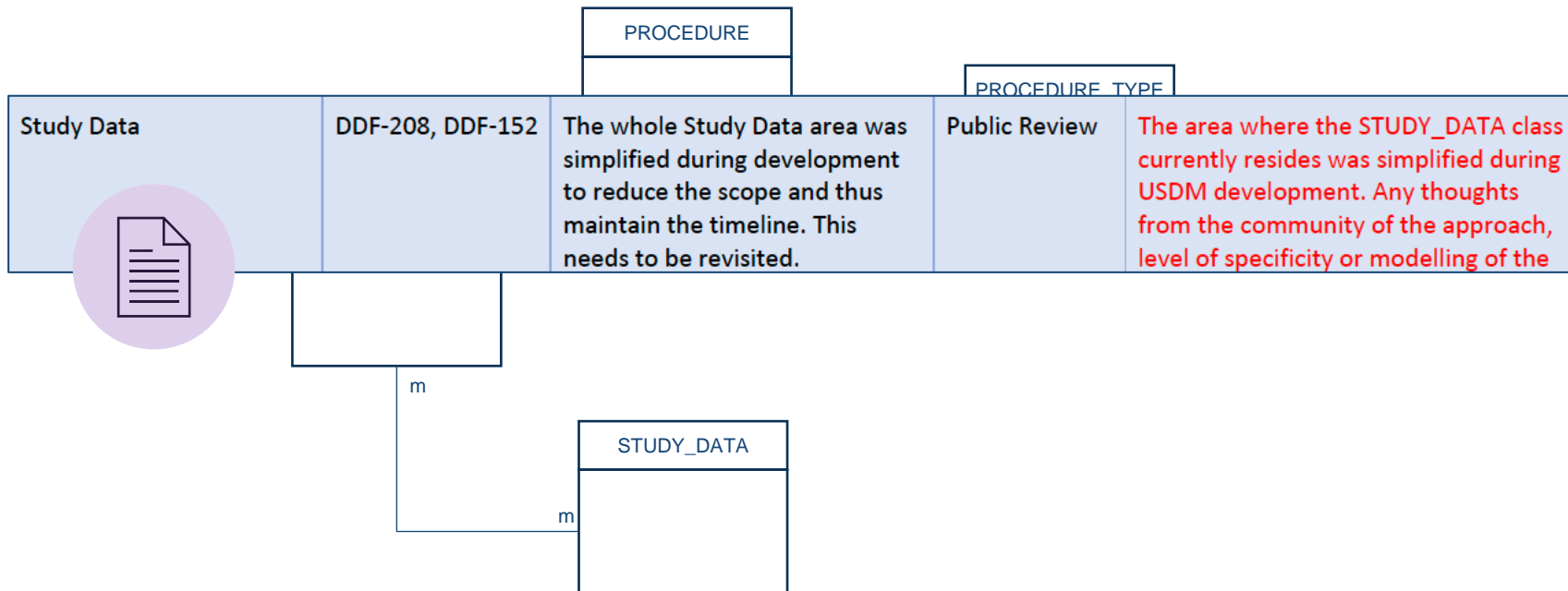




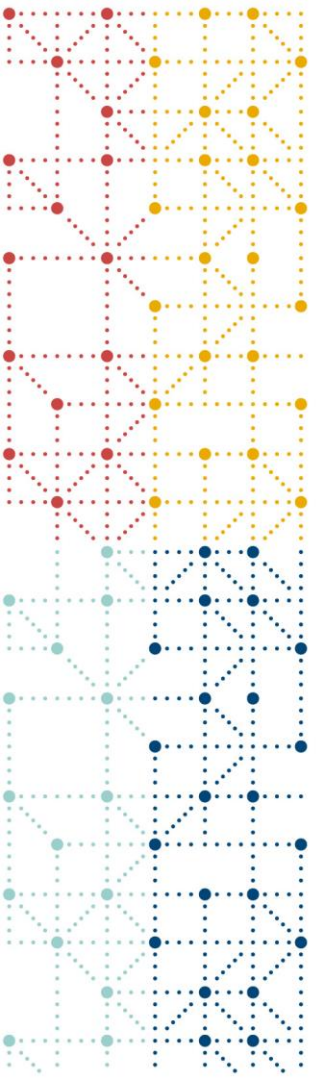


# USDM Model Walkthrough

Informational

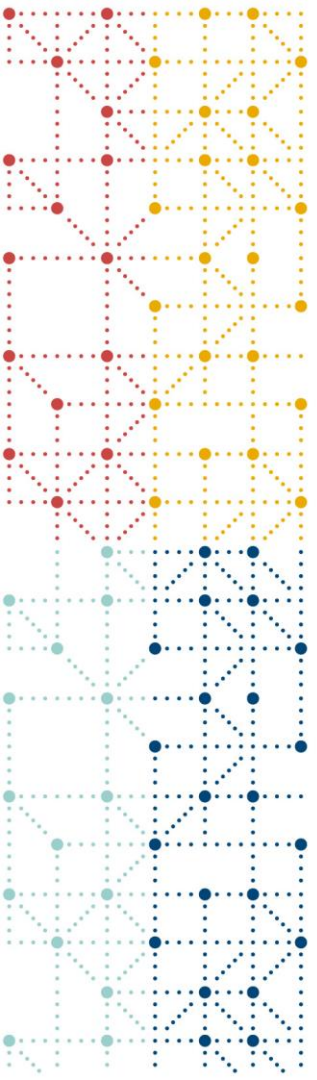


The area where the STUDY\_DATA class currently resides was simplified during USDM development. Any thoughts from the community of the approach, level of specificity or modelling of the



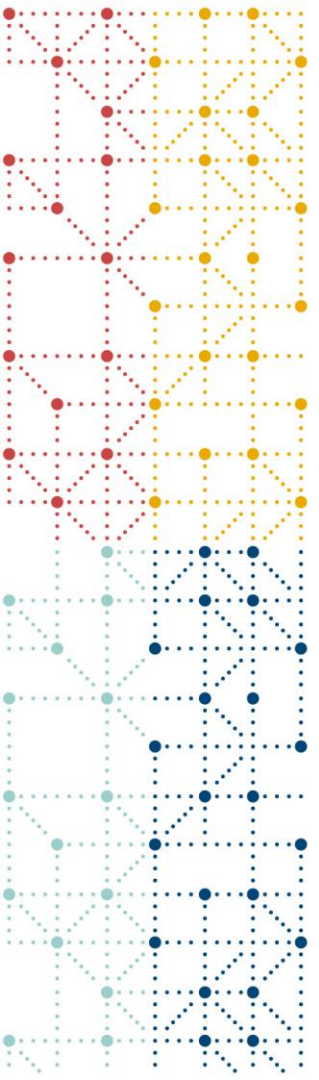
**Thank You**

**cdisc**



Q&A

cdisc



**Back-up**



# Additional Volunteer Opportunities

To help us manage and communicate opportunities dynamically, we would like to learn more about you!

- What aspects of this project are you interested in?
- Approximately, how much time are you able to commit to this project per week?
- Do you have experience and skill sets specific or related to project deliverables?
- [CDISC Volunteer Opportunities - Digital Data Flow \(DDF\) Team – Wiki](#)

For new volunteers, can you please provide answers above via email to John Owen ([jowen@cdisc.org](mailto:jowen@cdisc.org))?

- All volunteers are invited to reach out as interests, time commitment, and/or skill sets change!



# Additional Volunteer Opportunities

- DDF is dynamic agile project with tight timelines.
- Given this, additional volunteer opportunities are currently TBD and will be defined as the project progresses.
- Please note, post-MVP release there may also be opportunities to volunteer.
  - More information will be provided 2022