Digital Data Flow (DDF) Project Public Review Webinar

Presenters:

Dave Evans, CDISC President & CEO

Dave Iberson-Hurst, CDISC DDF Technical Product Owner

Alison Luckman, TransCelerate co-Product Owner/Lead for the DDF Delivery/Build Team

John Owen, CDISC Head PMO

1. **Webinar Introduction**
2. TransCelerate and DDF
3. CDISC DDF standards for public review
4. Public Review Process
5. Q&A

Why is CDISC partnering with TransCelerate on DDF?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

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CDISC Data Standards Lifecycle

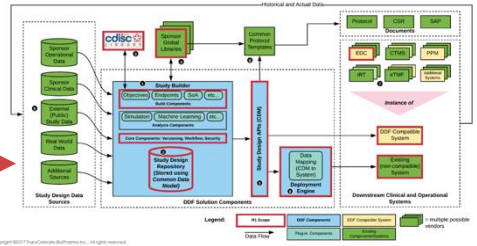
Automation requires:

- *Standard Machine-executable content for Useability*
- *Standard Technology Interfaces for Integration for Accessibility*
- *Standard Verification and Conformance Rules for Integrity*
- *Standard Trial Design Specifications for Total Automation of the Digital Data Flow*

cdisc

CDISC Library

Connect with Digital Data Processes through Open-API

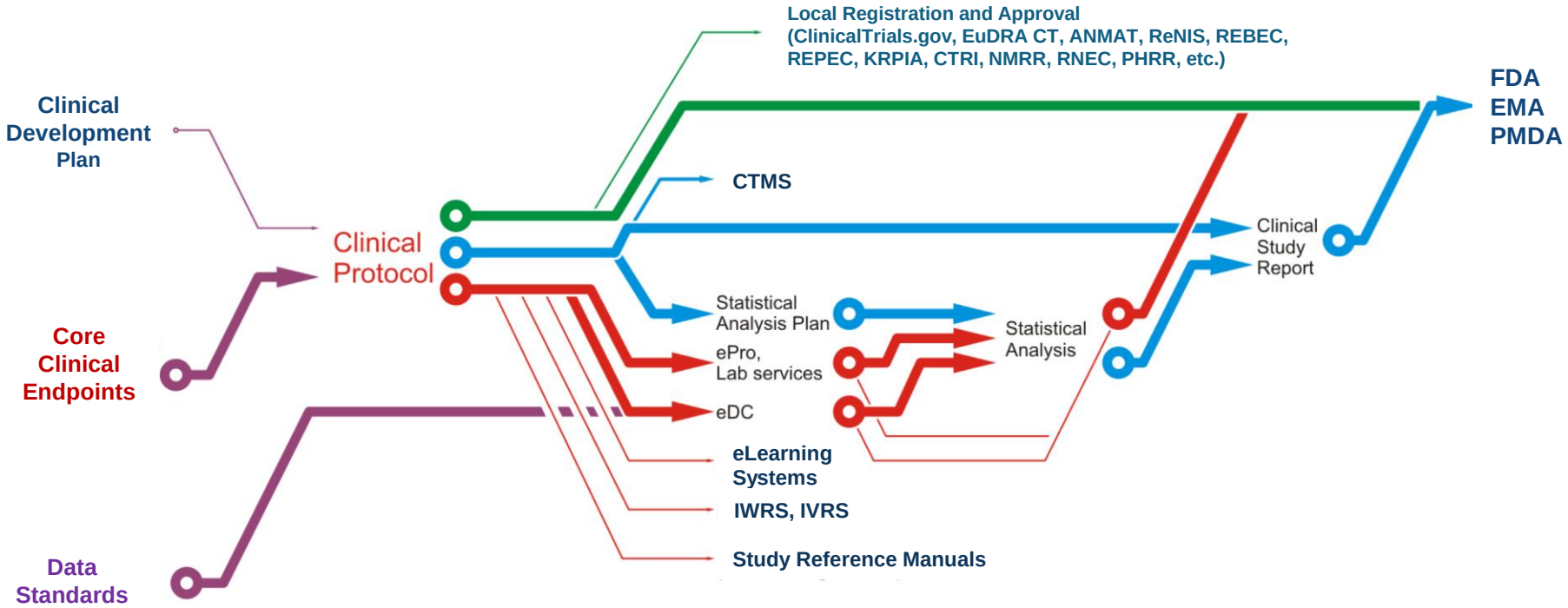


Executable Conformance Rules

Biomedical Concepts	Codelist Subsets	Tables, Listings, and Figures	Implementation Guide Text	FHIR to CDISC Mappings
Analysis Concepts	TAUG Metadata	Derivations and Mappings	Machine-readable Examples	LOINC Code Mappings
Templates	Digitized Study Definitions		CRF Collection	Diff Content Between Versions

CDISC Standards *Informative Content*

The Clinical Trial Information Flow



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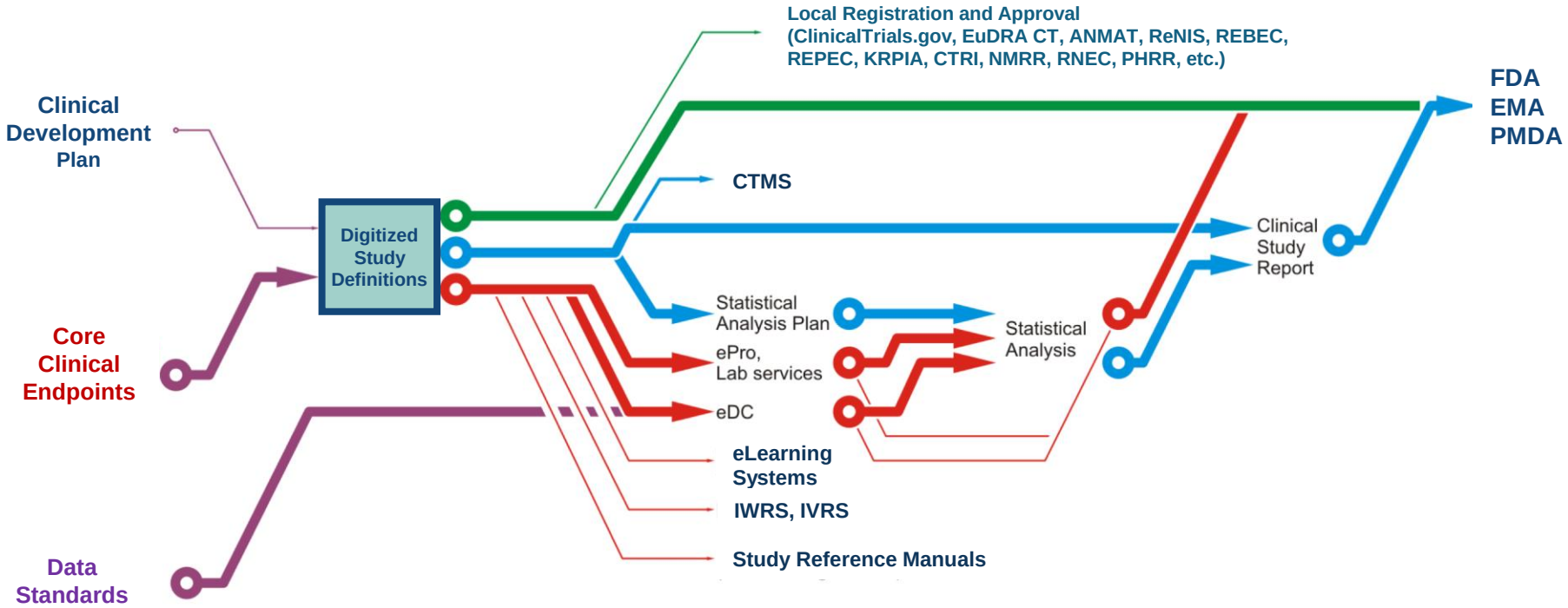

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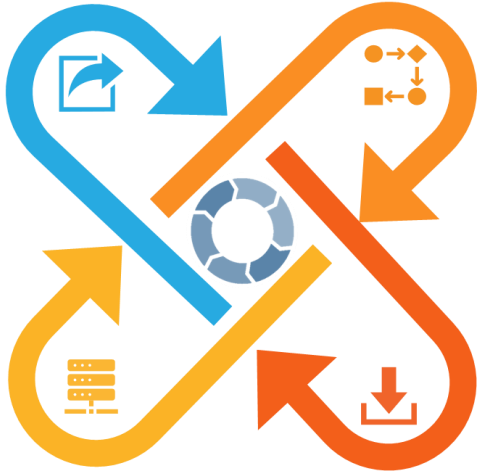
The Digital Data Flow Initiative (DDF) aims to catalyze digital transformation; breaking the document paradigm to enable seamless flow of the data within:

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements allows industry to move to digital protocols

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)



Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Open and Flexible Solution

Developing a dynamic, fully automated solution that is vendor agnostic, open and flexible

Development principles to enable broad collaboration, stakeholder input, and sustainability

- Open Source
- Vendor Agnostic
- Agile Development
- Dynamic Alignment to Standards

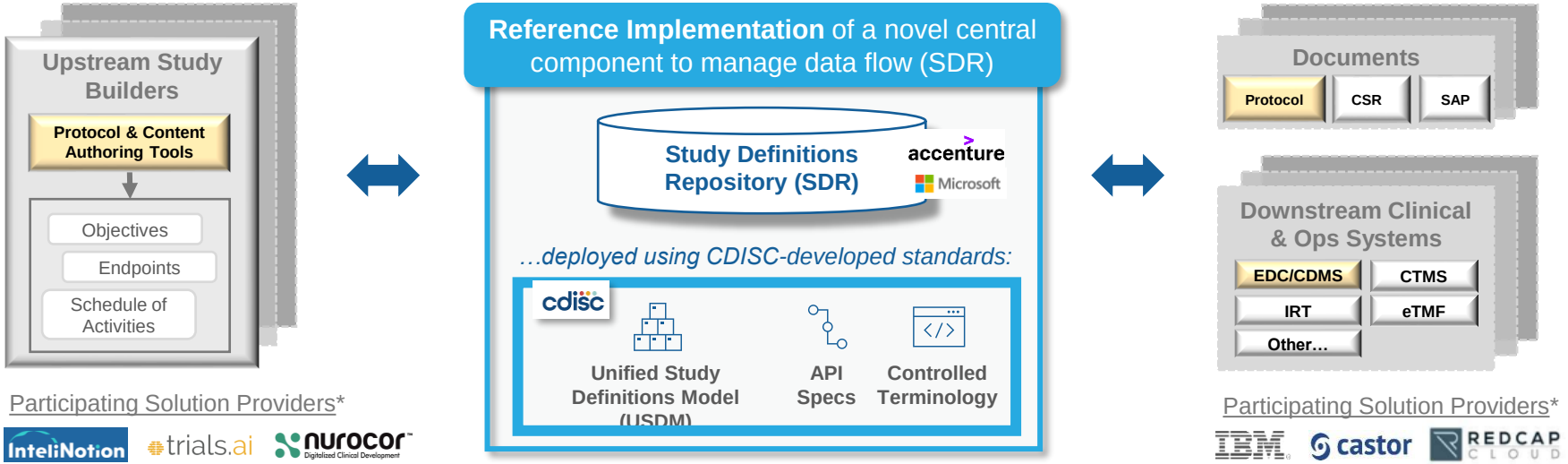
Minimum Viable Product (MVP) development underway

April 2022 Anticipated Release Date

The MVP release will focus on enabling flow of study definitions data from study builders to Study Definitions Repositories (SDR) to Electronic Data Capture (EDC)/CDMS

System or Tool of Focus for MVP

Potential Future System of Focus



* Solution Providers above have volunteered to participate in MVP development in anticipation of making use of DDF solutions in the future. Additional Solution Providers may volunteer in coming weeks/months. TransCelerate does not endorse nor recommend specific vendors or commercial products.

Enabling DDF – Where are we on the DDF journey?

2022 >>

Deliver MVP → **Pilot, Learn/Adapt & Continue Development**

- **MVP Release (Q2)**
- **Public Connectathon (Q2/Q3)**

Study Builder & EDC Vendor Design Collaboration

Initial discussions and alignment between technical solution teams (RA/RI for USDM, SDR) and Study Builders, EDC vendors to collaborate on SDR design compatibility to receive and send data

Digitized Protocol

Digitizing a portion of the study data elements included in the Common Protocol Template significantly facilitates for automated Protocol Document enablement

Limited EDC Integration

Digitizing a portion of the study data elements enables partial automated EDC build

Engaging with DDF

What's Coming?

- **DDF GitHub Launch for Open-source (OS) Collaboration**

  Launch of DDF GitHub site to foster, develop, and maintain an open-source community of active DDF project contributors. GitHub repository will be the central destination for OS material & future collaboration.

- **DDF Connectathon**

  Planned Connectathon event in 2022 will encourage demonstrations of use/connectivity to the Study Definitions Repository & CDISC standards by anyone in the vendor community.

Resources to Learn More

(Click on any of icons/links below.)

TransCelerate DDF Solutions Webpage

FAQs

FAQ: Digital Data Flow

Provide Input, Sign up for updates: DDF Information Form

DDF Information Form

Overview

Overview: Digital Data Flow

DDF Public Webinars

Press Release

DDF Launch: Press Release

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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

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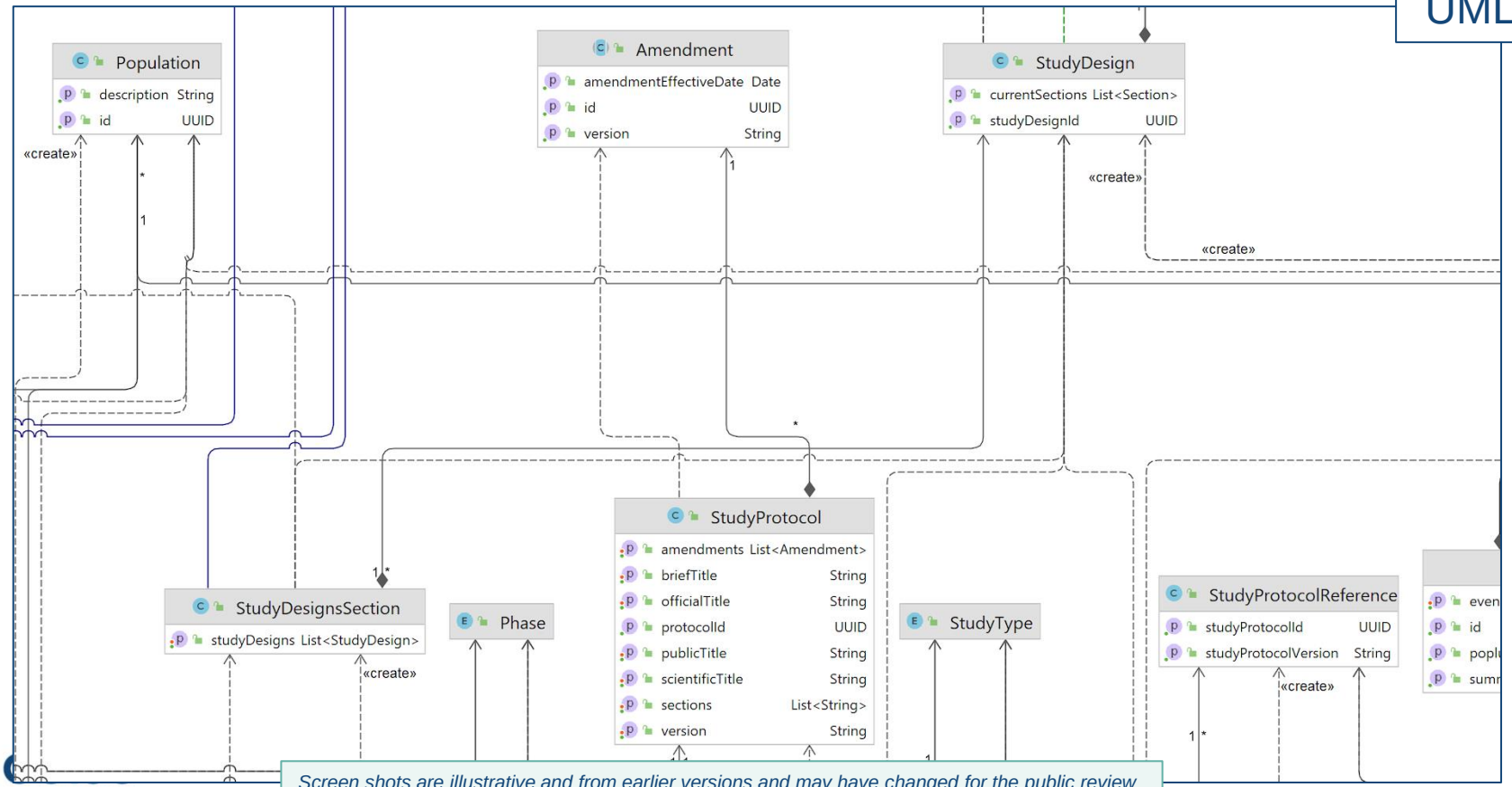
UML

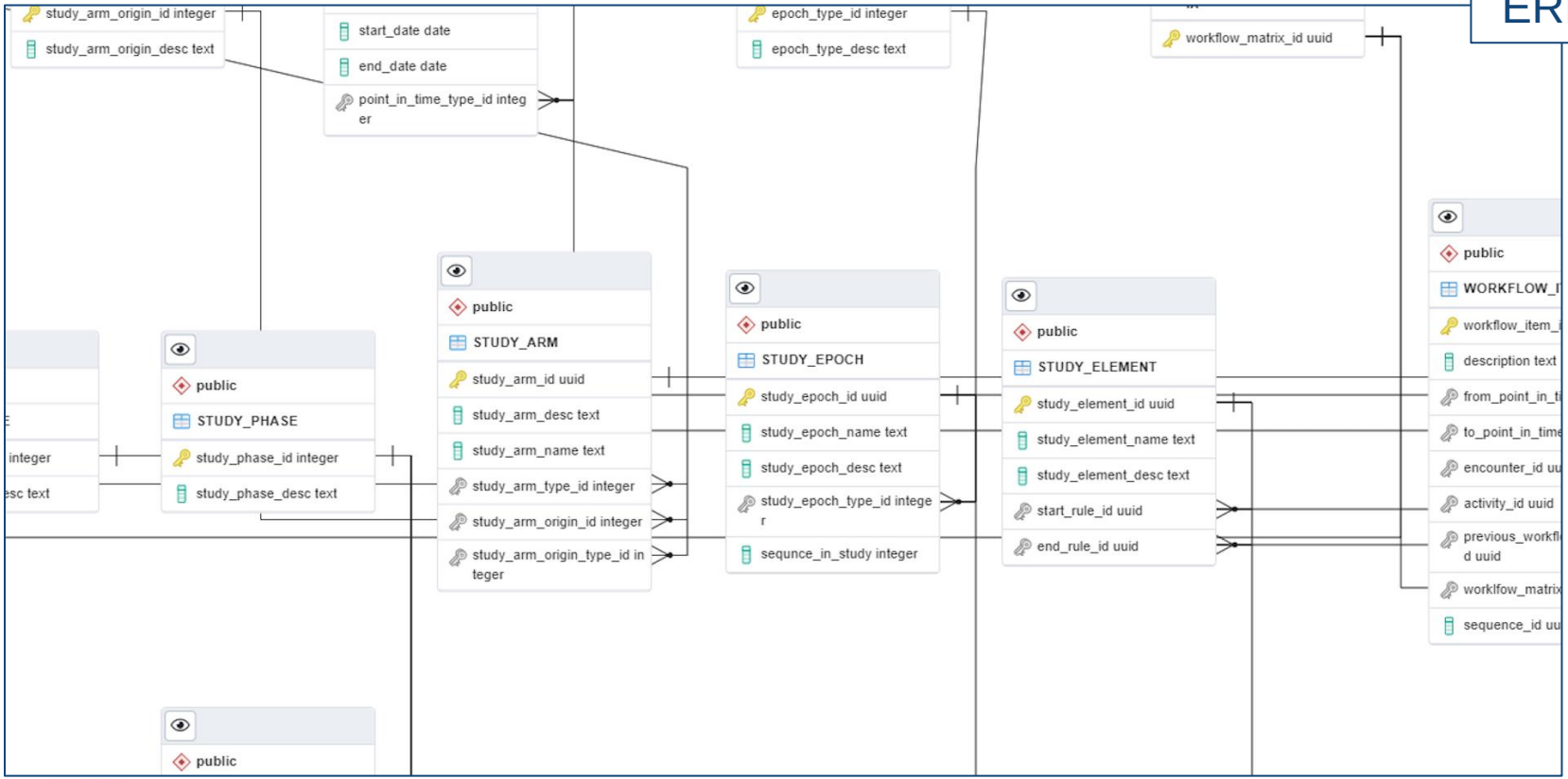


Screen shots are illustrative and from earlier versions and may have changed for the public review

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)

ERD



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 too
-- Please log an issue at https://redmine.postgresql.org/proj
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

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 convey

- application/json

Responses
200
OK inline_response_200_1

HTML

JSON


```
{
  "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	NCI C-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		Attribute	CNEW	Study Identifier Name		The literal identifier (i.e., distinctive designation) of the sequence	

DDF Entities&Attributes | DDF Valid Value Sets

EXCEL

PDF

User Stories

Dave Iberson-Hurst, 21st March 2022

Changes

- 25th January 2022 – Initial draft
- 31st January 2022 – Updates after informal review
- 14th Febraury 2022 – Updates after initial Transcelerate (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.
- 21st 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?*

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.

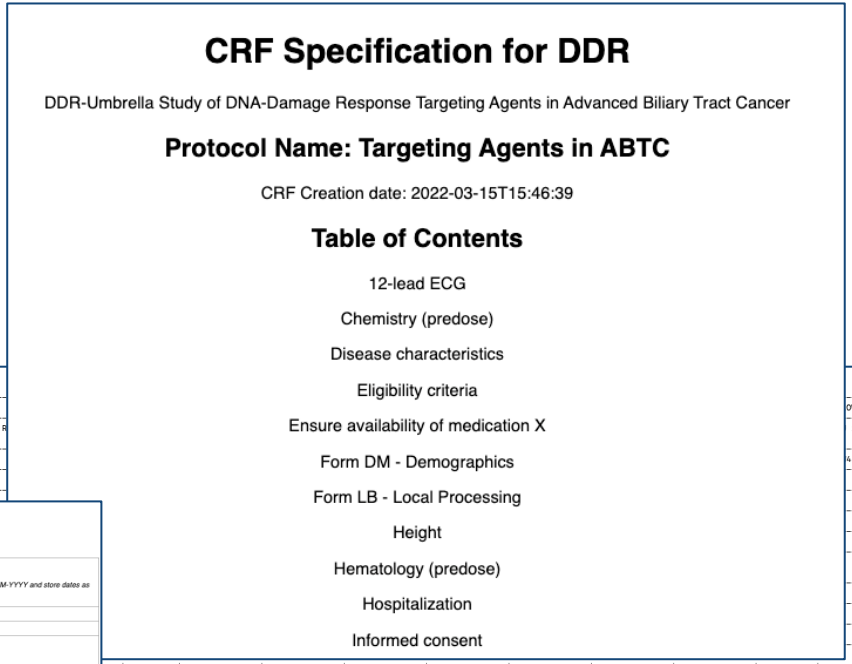
Summary of work to be performed during scoping

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

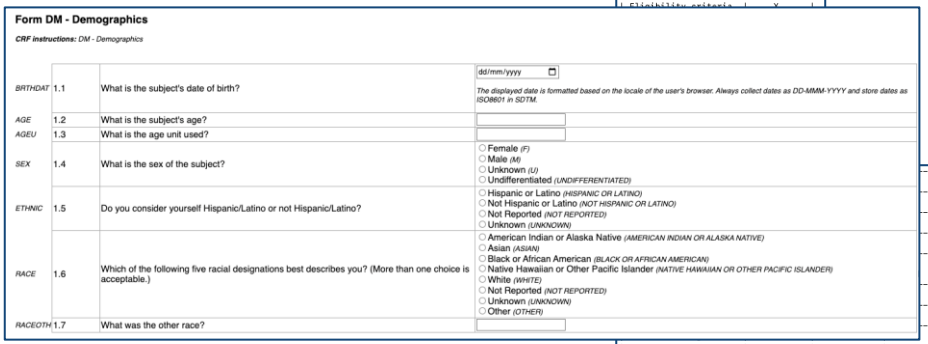
Form LB - Local Processing

Height

Hematology (predose)

Hospitalization

Informed consent



Form DM - Demographics

CRF instructions: DM - Demographics

BRTHDAT	1.1	What is the subject's date of birth?	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.*
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)*
ETHNIC	1.5	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	○ Hispanic or Latino *(HISPANIC OR LATINO)* ○ Not Hispanic or Latino *(NOT HISPANIC OR LATINO)* ○ Not Reported *(NOT REPORTED)* ○ Unknown *(UNKNOWN)*
RACE	1.6	Which of the following five racial designations best describes you? (More than one choice is acceptable.)	○ 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)*
RACEOTH	1.7	What was the other race?	

CRF Stylesheet courtesy of: Jørgen Mangor Iversen, Leo Pharma A/S

CDISC Study Definition Repository RA Deliverables

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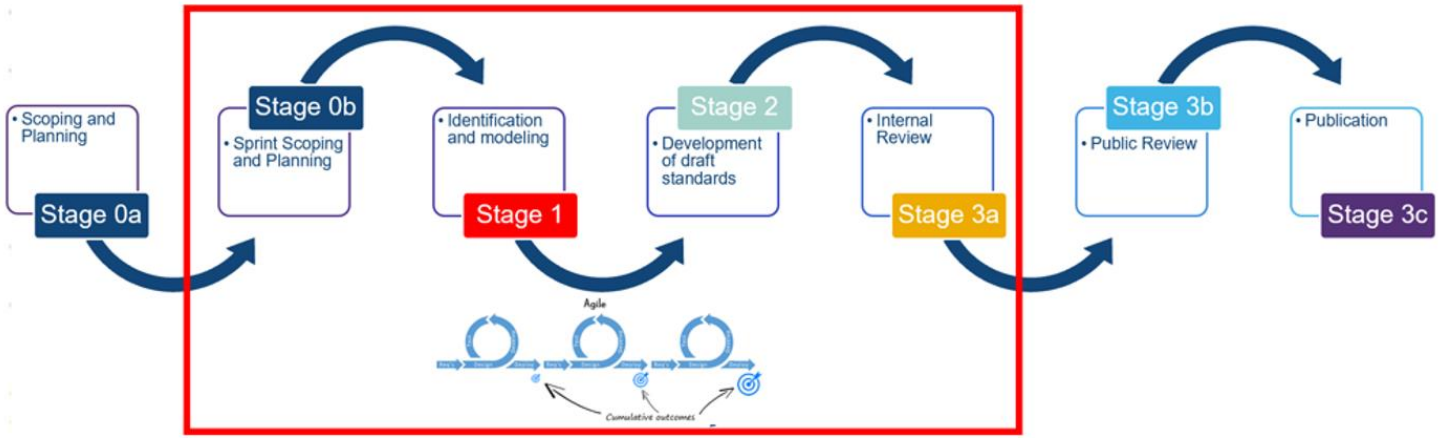
*Minimal Viable Product

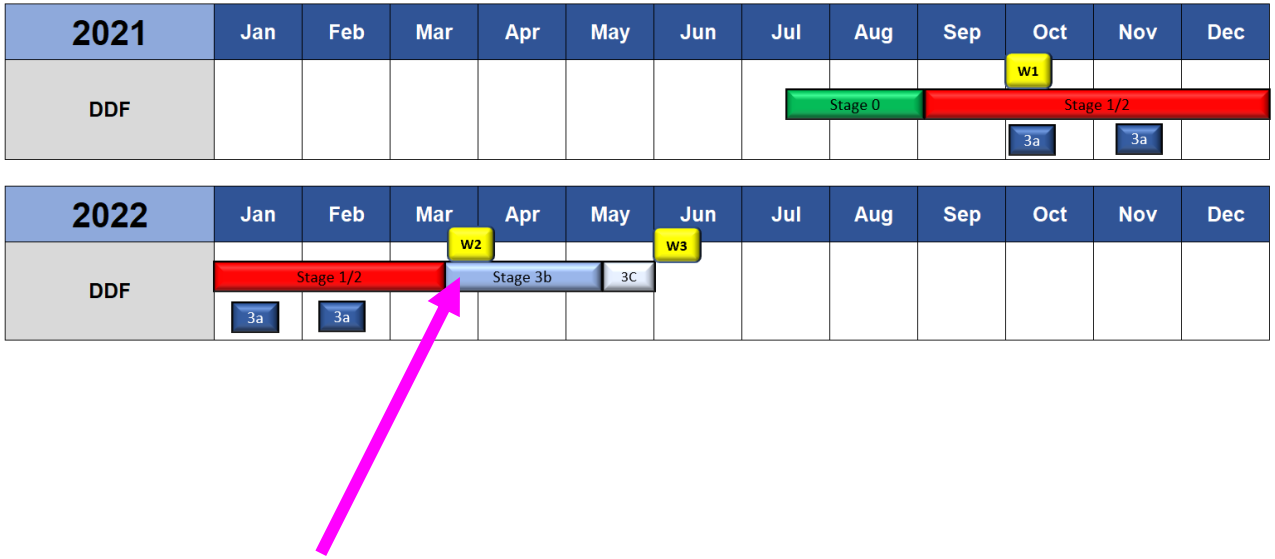
The Process for MVP



Parts of Stage 0b – 3a take place in each sprint.

- After Stage 0a, the sprints begin and a small scoping effort happens as part of the planning for each sprint
- A review step happens at the end of the sprint.

Timelines for the MVP*



Stage 0	Scoping and Planning
Stage 1/2	Identification/Modeling of Concepts Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

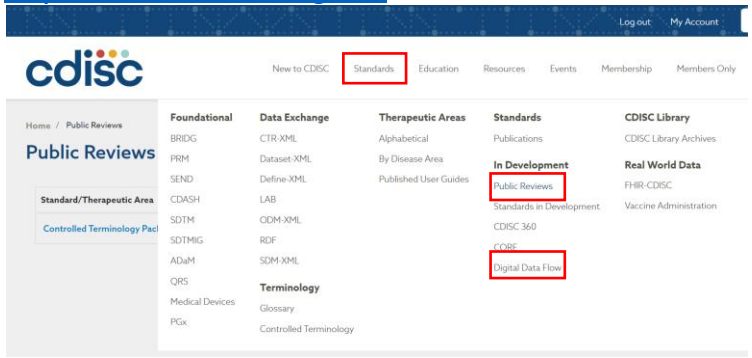
Public Review Timetable

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

Public Review Materials

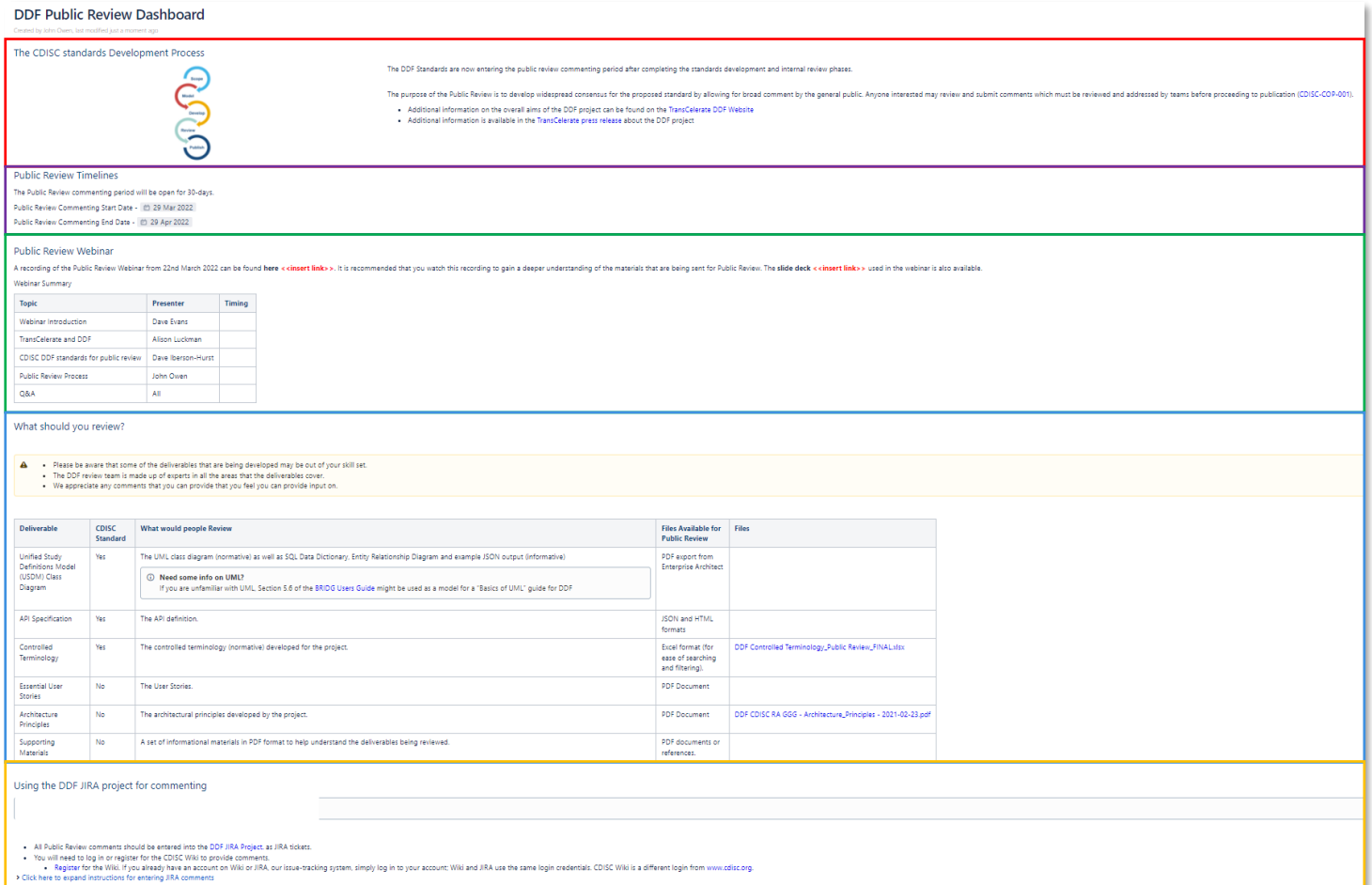
- Email will be sent from CDISC Communications

- 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



- 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 - 29 Mar 2022

Public Review Commenting End Date - 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	Alison Luckman	
CDISC DDF standards for public review	Dave Iberson-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 (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative) **Need some info on UML?** If 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	PDF export from Enterprise Architect	
API Specification	Yes	The API definition.	JSON and HTML formats	
Controlled Terminology	Yes	The controlled terminology (normative) developed for the project.	Excel format (for ease of searching and filtering).	DDF Controlled Terminology_Public Review_FINAL.xlsx
Essential User Stories	No	The User Stories.	PDF Document	
Architecture Principles	No	The architectural principles developed by the project.	PDF Document	DDF CDISC RA GGG - Architecture_Principles - 2021-02-23.pdf
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

Q&A

Thank You