Digital Data Flow (DDF) Project
CDISC Team Meeting

John Owen, CDISC Head of Project Management Office
Dave Iberson-Hurst, CDISC DDF Product Owner
Chris Upkes, DDF Developer
4th April 2022
Timelines for the MVP*

*Minimal Viable Product

<table>
<thead>
<tr>
<th>Year</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
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<tbody>
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</tr>
</tbody>
</table>

- **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

Public Webinars:
1. Scoping Results
2. Public Review
3. Publication
Public Review Timetable

- **Tuesday 22\textsuperscript{nd} March 2022** – DDF Public Review Webinar
- **Tuesday 29\textsuperscript{th} March 2022** – DDF Materials sent out for review – Start of 30-day public review
- **Monday 4\textsuperscript{th} 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\textsuperscript{th} 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

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 enhance cross-disciplinary research for the renewable energy by allowing for broad comment by the general public. Anyone interested may review and submit comments which must be received and addressed by teams before proceeding to publication (DS162-2015.0).

Additional information is available in the Transcribe project website about the DDF project.

Introduction

Timelines

Webinar

Materials

Commenting
Digital Data Flow Model Walkthrough
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)

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)
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
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 UNIQUE,
    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)
);
```
Application Programming Interface (API) Specification
The API definition (normative) in JSON and HTML forms

```
GET /studydefinitionrepository/v1/studyhistory

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

Return type
inline_response 200 1

Example data
Content-Type: application/json

{  
  "study" : [  
    "studyVersion" : [ 1, 1 ],  
    "studyId" : "e3e8e9e9-927e-42da-9625-e4f18bc4b7a4",  
    "studyTitle" : "Example study title"
  ],  
  "studyVersion" : [ 1, 1 ],  
  "studyId" : "e3e8e9e9-927e-42da-9625-e4f18bc4b7a4",  
  "studyTitle" : "Example study title"
}

Produce
This API call produces the following media types according to the Accept request header; the media type will be conveyed as
application/json

Responses
200  OK inline_response 200 1
```

JSON

```
{  
  "openapi": "3.0.0",  
  "info": {  
    "title": "Simple API for DDF",  
    "description": "This is a sample API for the DDF project - including sectioning (Accept)
    "license": {  
      "name": "MIT",  
      "url": "https://opensource.org/licenses/MIT"
    },  
    "version": "1.2.6"
  },  
  "servers": [  
    {  
      "url": "https://virts.server.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.studydefinitionrepository.sections",  
        "parameters": [  
          {  
            "name": "study",  
            "in": "path",  
            "description": "Study Builder Study",  
            "required": true,  
            "style": "simple",  
            "explode": false,  
            "schema": {  
              "type": "string",  
              "example": "ACME01"
            }
          }
        ]
      }
    }
  }
```

HTML
CDISC Controlled Terminology

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

<table>
<thead>
<tr>
<th>NCI-CT Terminology</th>
<th>UML Class Name</th>
<th>UML Item Name</th>
<th>Role</th>
<th>NCI-CT Identifier</th>
<th>CT Item Preferred Name</th>
<th>Synonym(s)</th>
<th>Definition</th>
<th>Has Value List</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY</td>
<td>study_title</td>
<td>Attribute</td>
<td>C40162</td>
<td>Study Title</td>
<td>Trial Title; Official Study Title; Study Title</td>
<td>The sponsor-defined name of the clinical study.</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>STUDY</td>
<td>study_version</td>
<td>Attribute</td>
<td>C68480</td>
<td>Study Protocol Version</td>
<td>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, biological, food product, cosmetic, care plan, or subject characteristics. (BRDG)</td>
<td>N</td>
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<tr>
<td>STUDY</td>
<td>study_status</td>
<td>Attribute</td>
<td>C86864</td>
<td>Protocol Status</td>
<td>A condition of the protocol at a point in time with respect to its state of readiness for implementation.</td>
<td>Y (C86864 Protocol Status Response)</td>
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<tr>
<td>STUDY_TYPE</td>
<td>STUDY_TYPE</td>
<td>Entity</td>
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<td>Study Type</td>
<td>Study Type; Study Type Classification</td>
<td>The nature of the investigation for which study information is being collected. (C8684175 StudyType)</td>
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<td>Entity</td>
<td>C682281</td>
<td>Trial Phase</td>
<td>Trial Phase; Trial Phase Classification</td>
<td>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 E6: NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMICPS0[985 March 1998)]</td>
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<td>STUDY_PHASE</td>
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<td>Trial Phase</td>
<td>Trial Phase; Trial Phase Classification</td>
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<td>N</td>
<td></td>
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<tr>
<td>STUDY_IDENTIFIER</td>
<td>STUDY_IDENTIFIER</td>
<td>Entity</td>
<td>C68108</td>
<td>Study Identifier</td>
<td>A sequence of characters used to identify, name, or characterize the study.</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STUDY_IDENTIFIER</td>
<td>org_code</td>
<td>Attribute</td>
<td>C86864</td>
<td>Study Identifier Organization Code</td>
<td>A coded value specifying the organization that creates and/or assigns the study identifier.</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
User Stories

Dave Iberson-Hurst, 21st March 2022

Changes

- 25th January 2022 – Initial draft
- 31st January 2022 – Updates after informal review
- 14th February 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?
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.
• **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

---

CRF Stylesheet courtesy of: Jørgen Mangor Iversen, Leo Pharma A/S
# CDISC Study Definition Repository RA Deliverables

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

<table>
<thead>
<tr>
<th>Specific Public Review Topics</th>
<th>No</th>
<th>Based on the remaining JIRA tickets a series of issues questions the CDISC team would like input from public reviewers</th>
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<tbody>
<tr>
<td>High-Level Model Overview</td>
<td>No</td>
<td>Aid to reviewing the model</td>
</tr>
<tr>
<td>Technical Notes</td>
<td>No</td>
<td>Technical notes on Schedule of Activities and ODM/CRF creation</td>
</tr>
<tr>
<td>UML Notes</td>
<td>No</td>
<td>Help for those reading the UML diagrams</td>
</tr>
</tbody>
</table>

**PDF Document**

- [2022 03 29 JIRA Public Review.pdf](https://wiki.cdisc.org/display/PUB/DDF+Public+Review+Dashboard)
- [2022 03 29b Model Walkthrough.pdf](https://wiki.cdisc.org/display/PUB/DDF+Public+Review+Dashboard)
- [2022 03 25 SoA and CRF Tech Note.pdf](https://wiki.cdisc.org/display/PUB/DDF+Public+Review+Dashboard)

**Links**

- BRIDG Users Guide
- [http://www.clinicaldata.org/artifacts/dascDiagram.htm](http://www.clinicaldata.org/artifacts/dascDiagram.htm)

**Public Review – JIRA Issues**

Dave Herren-Marot, 29th March 2022

Changes

- 09th March 2022 – Initial draft.
- 12th March 2022 – Updated with additions of DDF-226, DDF-228, DDF-237, DDF-196 and DDF-185
- 09th March 2022 – Updated with additions of DDF-274, DDF-239, DDF-238, DDF-235, DDF-179, DDF-237
- 11th March 2022 – Add in DDF-226 and DDF-227
- 13th March 2022 – Add in DDF-226 and DDF-227
- 25th March 2022 – 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.
- 24th March 2022 – Add in DDF-183
- 28th March 2022 – Add in DDF-123 and DDF-236
- 29th March 2022 – Address 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 expert 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, 29th March 2022, third draft

Changes

- 28th March 2022 – First draft
- 29th March 2022 – Second draft after an initial review
- 29th 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

<table>
<thead>
<tr>
<th>Row</th>
<th>UML Class Name</th>
<th>UML Item Name</th>
<th>Role</th>
<th>NCI C-code</th>
<th>CT Item Preferred Name</th>
<th>Synonym(s)</th>
<th>Definition</th>
<th>Has Value List</th>
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<tr>
<td>6</td>
<td>STUDY_TYPE</td>
<td>STUDY_TYPE</td>
<td>Entity</td>
<td>C142175</td>
<td>Study Type</td>
<td>Study Type; Study Type Classification</td>
<td>The nature of the investigation for which study information is being collected. (After clinical trials.gov)</td>
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<td>study_type_desc</td>
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<td>Study Type Classification</td>
<td>Study Type; Study Type Classification</td>
<td>The nature of the investigation for which study information is being collected. (After clinical trials.gov)</td>
<td>Y (C99077 TYPE)</td>
</tr>
</tbody>
</table>

MODEL UML

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 ERD

CT EXCEL
## USDM Model Walkthrough

**Informational**

|--------------------------------|-----------------------------------|-------------------------------------------------------------------------------------------------|---------------|

Currently the USDM defines the STUDY, STUDY_PROTOCOL and AMENDMENT classes to hold the relationships and information to relate a study and the associated protocol. 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.

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.
## USDM Model Walkthrough

### Informational

**TRIAL_INTENT_TYPE**

<table>
<thead>
<tr>
<th>Row #</th>
<th>UML Class Name</th>
<th>UML Item Name</th>
<th>Role</th>
<th>NCI C-code</th>
<th>CT Item Preferred Name</th>
<th>Synonym(s)</th>
<th>Definition</th>
<th>Has Value List</th>
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<tbody>
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<td>99</td>
<td>TRIAL_INTENT_TYPE</td>
<td>TRIAL_INTENT_TYPE</td>
<td>Entity</td>
<td>C49652</td>
<td>Trial Intent Type</td>
<td>Trial Intent Type</td>
<td>The planned purpose of the therapy, device, or agent under</td>
<td>N</td>
</tr>
<tr>
<td>100</td>
<td>TRIAL_INTENT_TYPE</td>
<td>trial_intent_type</td>
<td>Attribute</td>
<td>C49652</td>
<td>Trial Intent Type</td>
<td>Trial Intent Type</td>
<td>The planned purpose of the therapy, device, or agent under</td>
<td>Y (C86736 TINDTP)</td>
</tr>
<tr>
<td>101</td>
<td>TRIAL_TYPE</td>
<td>TRIAL_TYPE</td>
<td>Entity</td>
<td>C49660</td>
<td>Trial Type</td>
<td>Trial Scope; Trial Type</td>
<td>The nature of the interventional study for which information is</td>
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<tr>
<td>102</td>
<td>TRIAL_TYPE</td>
<td>trial_type</td>
<td>Attribute</td>
<td>C49660</td>
<td>Trial Type</td>
<td>Trial Scope; Trial Type</td>
<td>The nature of the interventional study for which information is</td>
<td>Y (C86739 TTYPE)</td>
</tr>
</tbody>
</table>

```
 STUDY_DESIGN
   m

 TRIAL_INTENT_TYPE

 TRIAL_TYPE
   1
```
The current USDM contains the notion of sections and section history. Some reviewers have raised concerns that this is not a necessary feature and that such capability should not be part of an industry model.
<table>
<thead>
<tr>
<th>External CT</th>
<th>DDF-227, DDF-103, DDF-200, DDF-93</th>
<th>Tickets relating to the use of external CT and how CT is referenced. Once particular example is procedure types and using external CT.</th>
<th>Public Review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
null
USDM Model Walkthrough

Informational
We would like to ask the community to consider the classes `STUDY_ARM_ORIGIN` and the associated `TYPE` class and consider the values that the origin type should cover.

We would also ask the community to note that this notion does not directly relate to the source data origin seen within the `define.xml` but that there is a link between the two ideas and comment on those aspects as well.
USDM Model Walkthrough
Informational
### USDM Model Walkthrough

#### Informational

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>PROCEDURE_TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Data</td>
<td>Public Review</td>
</tr>
<tr>
<td>DDF-208, DDF-152</td>
<td>The whole Study Data area was simplified during development to reduce the scope and thus maintain the timeline. This needs to be revisited.</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>
Thank You
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)?

- 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