Digital Data Flow (DDF) - Connectathon

R0.5 Supporting Documentation

Document History

|  |  |  |  |
| --- | --- | --- | --- |
| Version No. | Date | Author | Revision Description |
| V1.0 | 11-Aug-2022 | Mike Rippin | Initial Version |
|  |  |  |  |

Table of Contents

[1. Introduction 3](#_Toc111148985)

[2. Documentation References 3](#_Toc111148986)

[2.1 Background to DDF 3](#_Toc111148987)

[2.2 Unified Study Data Model (USDM) V1.0 3](#_Toc111148988)

[2.3 Study Data Repository (SDR) R0.5 4](#_Toc111148989)

[3. Quick Guide: Getting Connected to DDF-SDR 5](#_Toc111148990)

1. Introduction

In support of the TransCelerate Connectathon for the Digital Data Flow (DDF) project, this document provides a summary listing of the supporting documents for the following components

* Background to the Digital Data Flow project
* Unified Study Data Model (USDM) V1.0
* Study Data Repository (SDR) R0.5

The links and references provided are aimed at the technical user intending to connect to, interact with, or install the SDR. Casual users simply looking to understand more about the DDF, its history, goals, and roadmap, will be served by accessing the Background links which include links to the Website, Documents and YouTube videos.

Additionally, this document specifically provides a quick reference to the process for getting connected to the system, and the relevant documents to support this step.

1. Documentation References

The following tables provide links to the core documentation.

## Background to DDF

|  |  |
| --- | --- |
| Resource | Link |
| **TransCelerate Website** | <https://www.transceleratebiopharmainc.com/> |
| **CDISC DDF Page** | <https://www.cdisc.org/ddf> |
| **DDF TransCelerate GitHub Page** | <https://transcelerate.github.io/ddf-home/index.html> |
| **Connectathon TransCelerate GitHub Page** | <https://transcelerate.github.io/ddf-home/CaT_home.html> |
| **YouTube: Digital Data Flow Playlist** | <https://www.youtube.com/playlist?list=PLMXS-Xt7Ou1KNUF-HQKQRRzqfPQEXWb1u> |

## Unified Study Data Model (USDM) V1.0

|  |  |
| --- | --- |
| Resource | Link |
| [**USDM RA v1.0 (Provisional)**](https://www.cdisc.org/sites/default/files/2022-08/USDM_RA_v1.0_%28Provisional%29.zip) **Documentation Package (zip file):**   * **USDM V1.0 UML** * **USDM V1.0 API** * **USDM V1.0 CT** * **USDM Technical Notes** * **User Stories for USDM** * **Architecture Principles for USDM** | <https://www.cdisc.org/ddf>  [tab:files] |
| **DDF API Simulator** | <https://byrikz.deta.dev/docs> |
| **GitHub Repository for SDR Simulator** | <https://github.com/data4knowledge/ddf_service> |
| **SwaggerHub API** | <https://app.swaggerhub.com/apis/CDISC1/DDF/V1.0-Provisional> |
| **Sample Study Definition Data Files** | <https://github.com/data4knowledge/ddf_service/tree/main/study> |

## Study Data Repository (SDR) R0.5

|  |  |
| --- | --- |
| Resource | Link |
| **DDF Github Home Page** | <https://github.com/transcelerate> |
| **Certificate Creation** | <https://github.com/transcelerate/ddf-sdr-support/blob/main/documents/DDF_SDR_Certificate-Creation-for-accessing-SDR-UI-and-API.pdf> |
| **Certification Installation** | <https://github.com/transcelerate/ddf-sdr-support/blob/main/documents/DDF_SDR_Certificate-Installation-for-accessing-SDR-UI.pdf> |
| **Access and Incident Management** | <https://github.com/transcelerate/ddf-sdr-support/blob/main/documents/DDF_SDR_Access-and-Incident-Management.pdf> |
| **UI User Guide** | <https://github.com/transcelerate/ddf-sdr-ui/blob/main/documents/ddf-sdr-user-guide-ui-v3.0.pdf> |
| **API User Guide** | <https://github.com/transcelerate/ddf-sdr-api/blob/main/documents/ddf-sdr-user-guide-api-v3.0.pdf> |
| **Sample Study Data** | <https://github.com/transcelerate/ddf-sdr-api/blob/develop/DataModel/API_UserGuide_JSON_Files/Request-POST-AddStudyDefinitionV1.json> |
| **API Migration Guide** | <https://github.com/transcelerate/ddf-sdr-api/blob/main/documents/DDF_SDR_API-Migration-Guide.pdf> |
| **SDR Code Repositories** | <https://github.com/transcelerate/ddf-sdr-api/tree/main>  <https://github.com/transcelerate/ddf-sdr-ui/tree/main> |
| **Conformance Rules** | <https://github.com/transcelerate/ddf-sdr-api/blob/main/DataModel/USDM_ConformanceRules_SDR_Reference_ImplementationV1.xlsx> |
| **SDR Architecture** | <https://github.com/transcelerate/ddf-home/tree/main/architecture> |

1. Quick Guide: Getting Connected to DDF-SDR

Registering for the Connectathon will automatically kick off a process to get you added to the TransCelerate DDF environment, with the following key setup steps:

1. The details you provide during Connectathon registration, including your name, email address and organization, will automatically be registered in the SDR Azure Active Directory
2. You will receive an email inviting you to connect to SDR, with details on next steps, a URL link to the SDR, and several links to core documentation (see Section 2.3)
3. In the email, you will be told that you need to create an Authentication Certificate, for which links to a [document with instructions are provided](https://github.com/transcelerate/ddf-sdr-support/blob/main/documents/DDF_SDR_Certificate-Creation-for-accessing-SDR-UI-and-API.pdf). *Importantly, only a single Authentication Certificate needs to be created for your Organization*, and it is up to you how you decide this amongst your colleagues.
4. Once a member from your Organization has created the Certificate:
   * They send this back by replying to the Invite email
   * They internally share the Certificate with all users in your Organization, and each user installs the Certificate as per the [document provided](https://github.com/transcelerate/ddf-sdr-support/blob/main/documents/DDF_SDR_Certificate-Installation-for-accessing-SDR-UI.pdf).
5. When received, the Certificate will be installed in the SDR, and a confirmation email is sent to the user who provided it.
6. All users in your organization will then be able to access the system.