

# OpenStudyBuilder DDF Connect-a-thon

OpenStudyBuilder as a DDF Compatible SDR solution

Connectathon Category: **Data Interoperability**

OPEN  
STUDY  
BUILDER



EVIDENTIQ  
CLINICAL DATA SCIENCE GROUP



REDCAP  
CLOUD

neo4j

# OpenStudyBuilder

OpenStudyBuilder is a DDF compatible implementation of a Study Definitions Repository including a standards MDR and Study Builder solutions.



## STUDY BUILDER

Welcome to the StudyBuilder application  
Study Specification made easy



Build  
your study in a  
consistent way

Comply  
with standards  
including CDISC

Reuse  
specification elements  
across studies

Get insights  
via user-defined  
dashboards

Integrate  
with other systems  
via open API

# THE ISSUE

The Challenge: Data standards exist, but they are inconsistently used and customized implementations prevent true data flow between systems and environments. This, combined with the overall lengthy process, pose a number of difficulties in the clinical trial world. Your mission is to demonstrate a real-world, applicable solution for processing data using Digital Data Flow technology.

# OUR MAGIC SOLUTION

The OpenStudyBuilder team will cover various aspects of the SDR and connections. This will cover:

- Managing the Study Definition set-up with reference to data standards
- A DDF API Adapter utilising SDR/USDM for integrations
- Standards management, integration into Common Protocol Template (CPT) using a Word add-in tool
- EDC integrations via various methods.

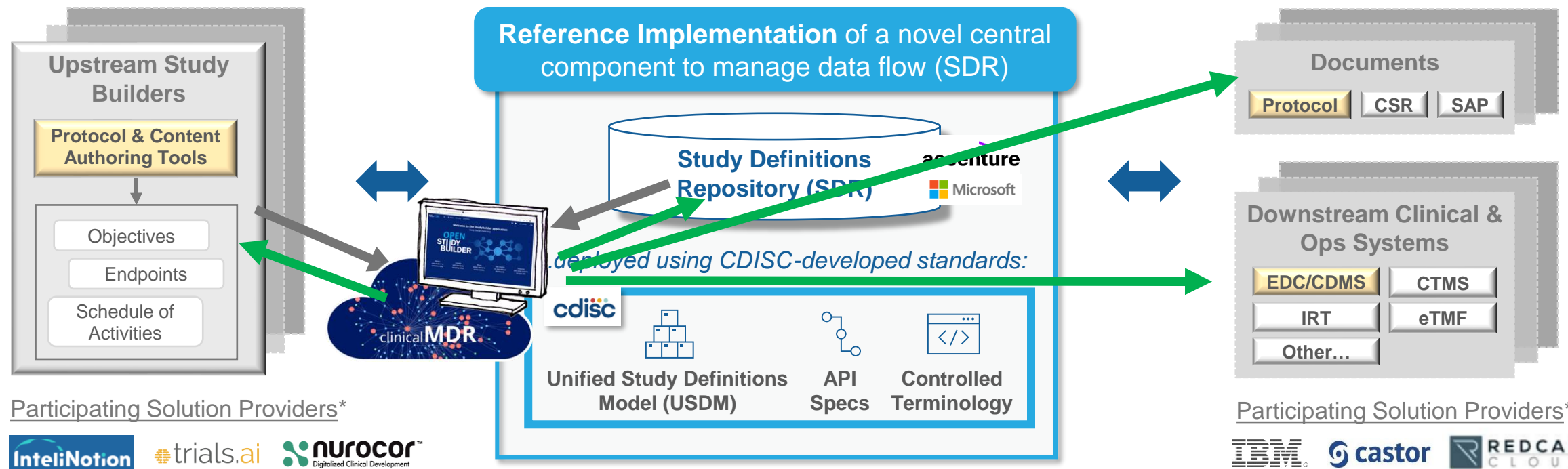
# Minimum Viable Product (MVP) development underway

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.

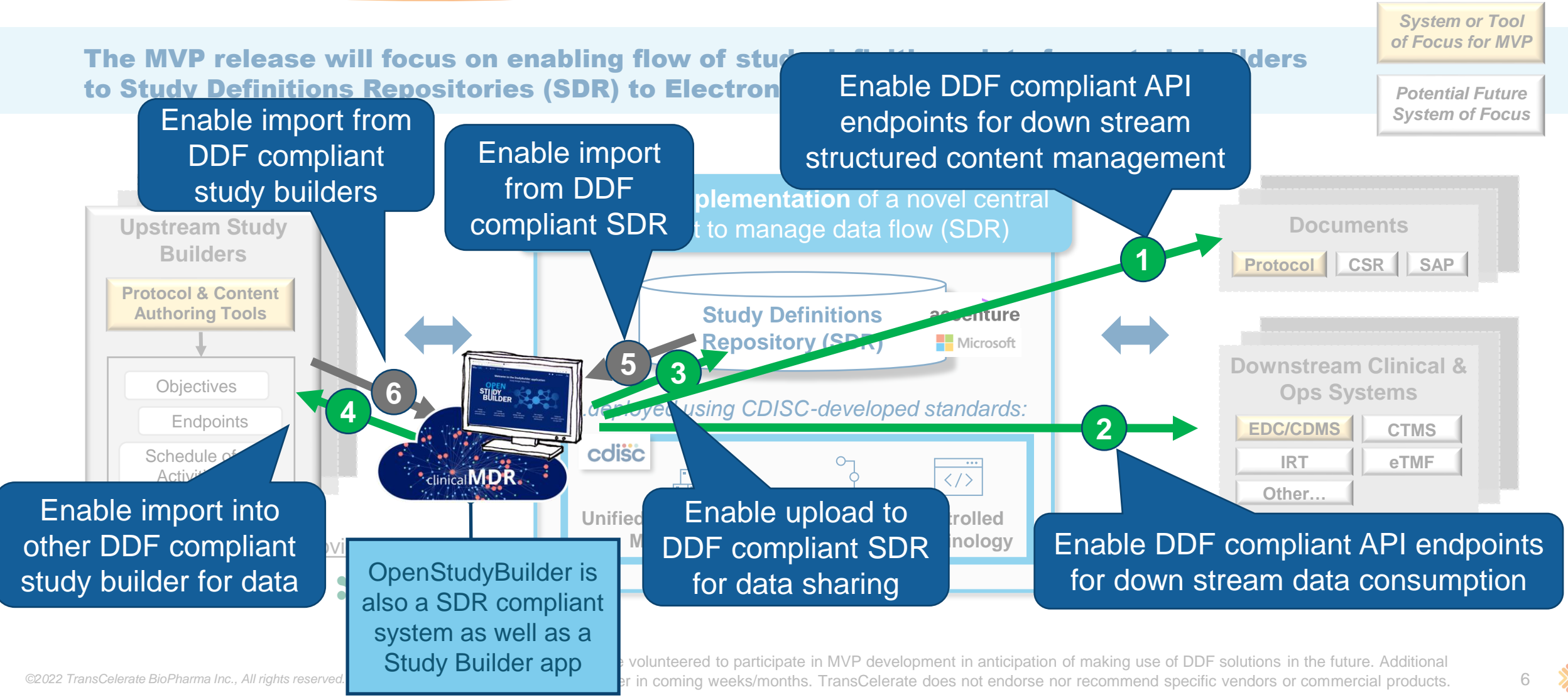


# Minimum Viable Product (MVP) development underway

April 2022 Anticipated Release Date

The MVP release will focus on enabling flow of study definitions from Upstream Study Builders to Study Definitions Repositories (SDR) to Electronic Data Capture (EDC) and Downstream Clinical & Ops Systems

System or Tool of Focus for MVP  
Potential Future System of Focus



Enable import from DDF compliant study builders

Enable import from DDF compliant SDR

Enable DDF compliant API endpoints for down stream structured content management

Documents  
Protocol | CSR | SAP

Downstream Clinical & Ops Systems  
EDC/CDMS | CTMS  
IRT | eTMF  
Other...

Enable import into other DDF compliant study builder for data

OpenStudyBuilder is also a SDR compliant system as well as a Study Builder app

Enable upload to DDF compliant SDR for data sharing

Enable DDF compliant API endpoints for down stream data consumption



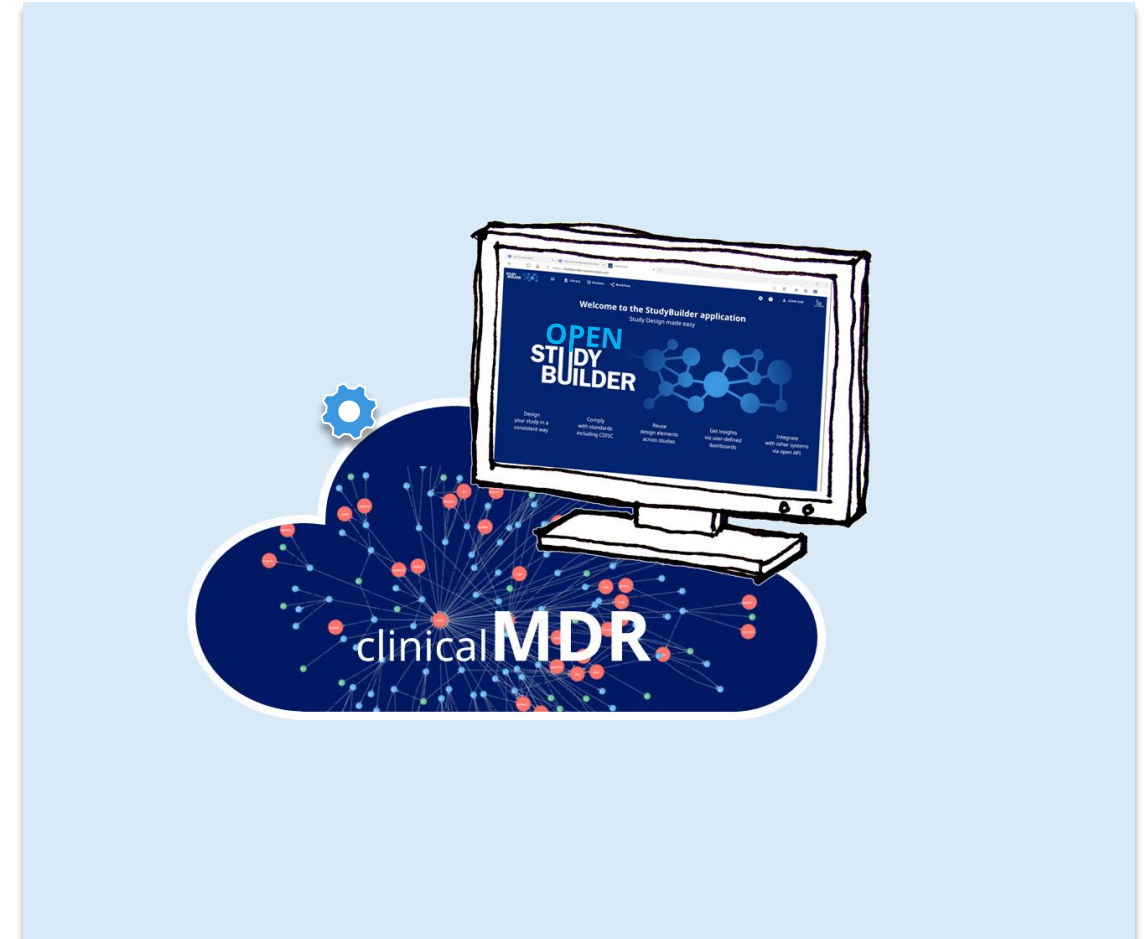
# What is the OpenStudyBuilder ...

The OpenStudyBuilder is the new approach to study specification that will:

- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation and content reuse

The OpenStudyBuilder comprises three elements:

- **Clinical Metadata Repository (clinical MDR)**  
(central repository for all study specification data)
- **OpenStudyBuilder application**  
(web-based user interface)
- **API layer**  
(allowing interoperability with other applications)  
(DDF API Adaptor – enabling DDF SDR Compatibility)



# Demo define the Study Definition

STUDY BUILDER

Studies Library

ADD NEW STUDY SELECT STUDY CDISC DEV-0001

MT (MIKKEL TRAUN)

Studies / Manage Studies / Study List

## Study List

Select rows

DDF

Clinical Programme	Project ID	Study number	Study ID	Study acronym	Study title
CDISC Development programme	CDISC DEV	0002	CDISC DEV-0002	DDF-SampleData-0002	BMS Test Study
CDISC Development programme	CDISC DEV	0001	CDISC DEV-0001	DDF-SampleData-0001	Umbrella Study of DDR (DNA-Damage Response) Targeting Agents in Advanced Biliary Tract Cancer

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# OpenStudyBuilder to SDR POST demo

The screenshot displays the OpenStudyBuilder interface for TransCelerate Biopharma Inc. The browser address bar shows the URL: `apps-sdrul-demo-eastus-001.azurewebsites.net/home/details;studyId`. The page header includes the TransCelerate logo and navigation links for HOME, STUDY DEFINITIONS, and LOGOUT. The main content area shows the study title "Umbrella Study of DDR (DNA-Damage Response) Version 1" and a "View History / Audit Trail" button. A table displays the study details:

Study Title	Umbrella Study of DDR (DNA-Damage Response)
Study Version	1

On the left side, there is a "Study Details" section with expandable items: Study Type, Study Identifiers, Study Phase, Study Protocol Versions, and Study Designs.

# OpenStudyBuilder as a DDF compatible SDR solution

## Connectathon Category: Data Interoperability

- ✓ **Managing the Study Definition specification**
- ✓ **Connectivity to DDF SDR RI**

Watch also the other videos:

- OpenStudyBuilder integration to Protocol and SDTM Study Design datasets
- OpenStudyBuilder and EDC Integrations

Visit our GitLab site for more information:

<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>



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