

# Open-Source MDR and SDR Managing Your Standards with the OpenStudyBuilder



**Birmingham, Monday 6 November 2023**

Nicolas de Saint Jorre

Mikkel Traun

# What is the OpenStudyBuilder?...

## A NEW APPROACH TO STUDY SPECIFICATION

- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

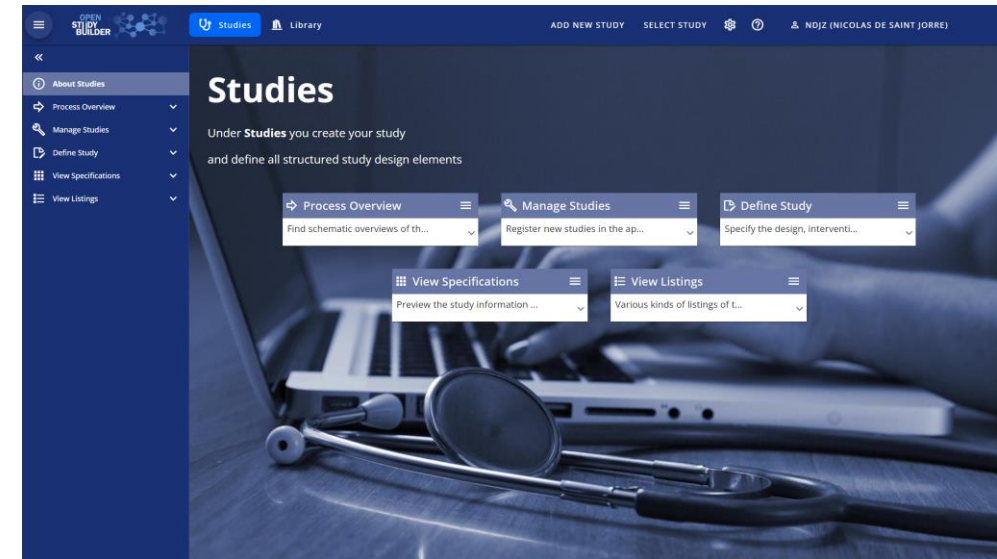
## 3 ELEMENTS OF OpenStudyBuilder

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

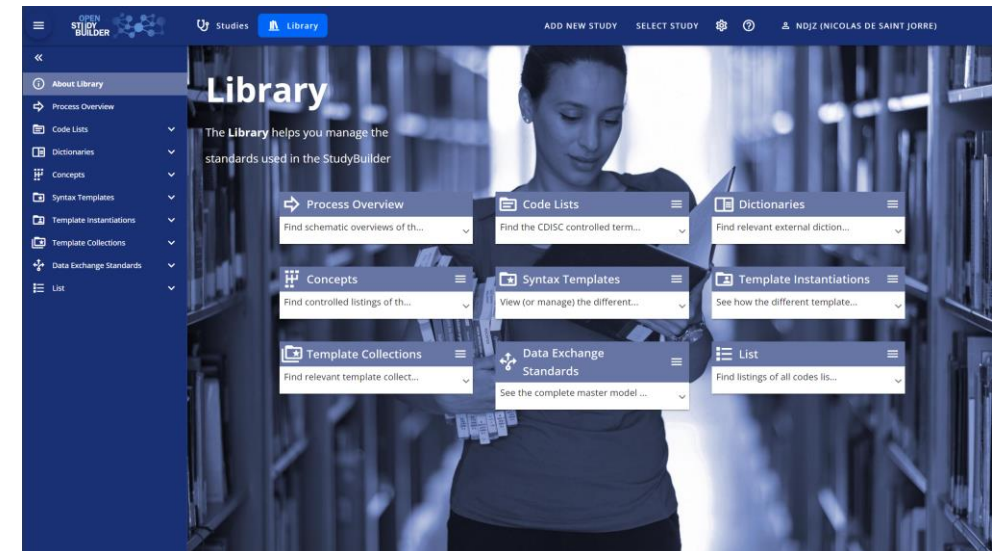


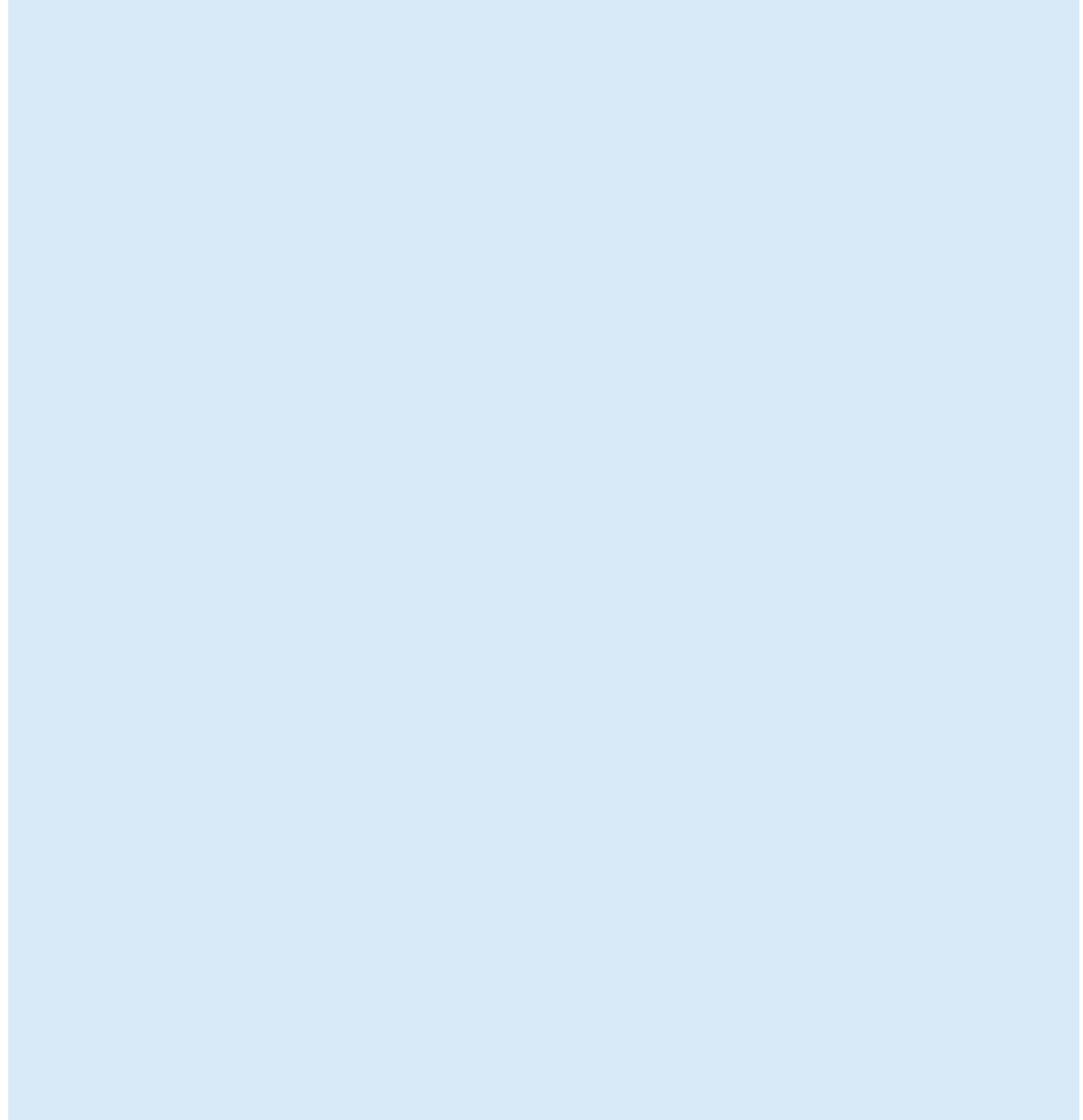
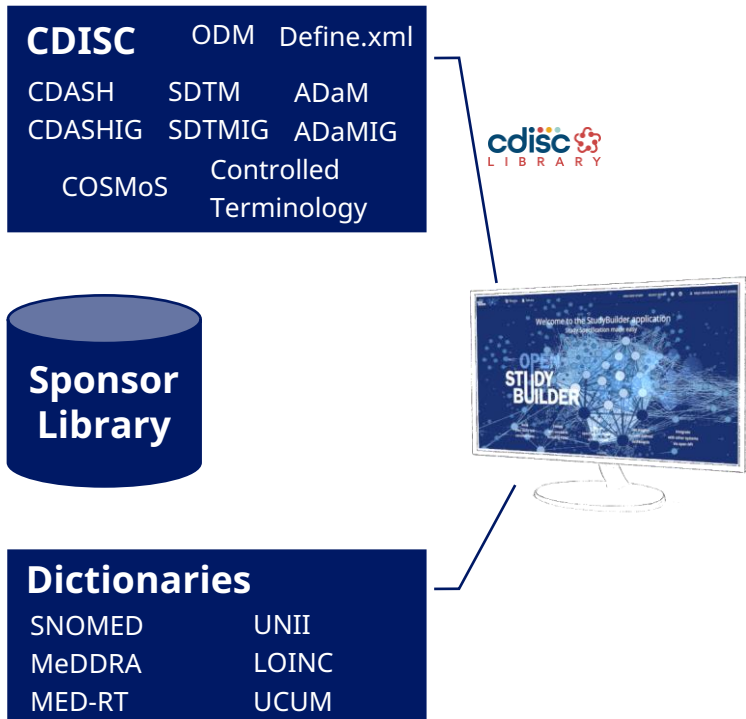
# OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	TEMPLATES
DATA EXCHANGE STANDARDS	





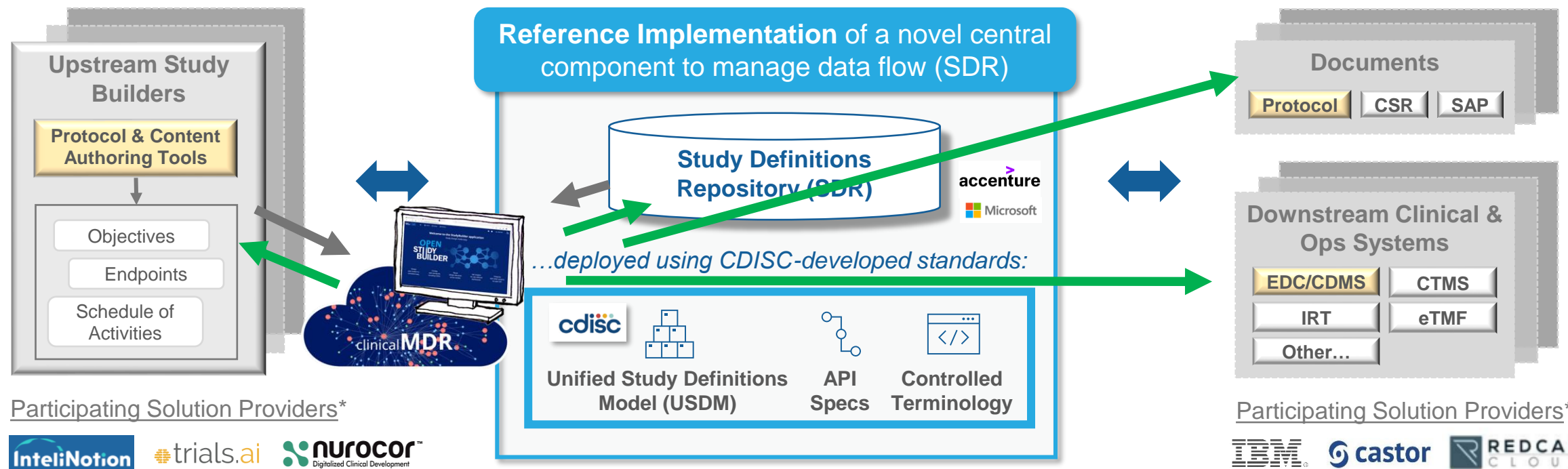
# Minimum Viable Product (MVP) development underway

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



Participating Solution Providers\*



Participating Solution Providers\*



\* 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.

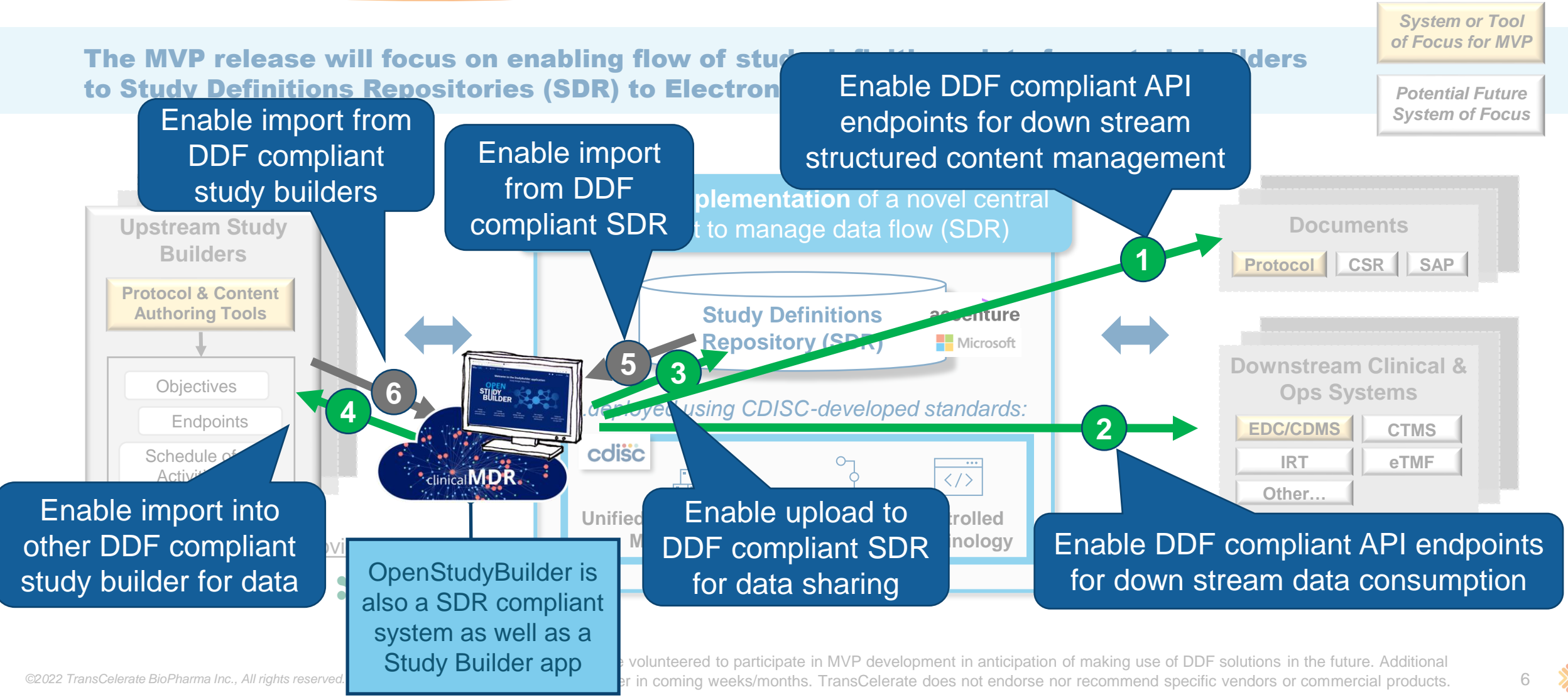


# Minimum Viable Product (MVP) development underway

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



# What is StudyBuilder in Digital Data Flow Context

**DDF** := Foundation for cross company digitalisation tools  
for clinical study data handling



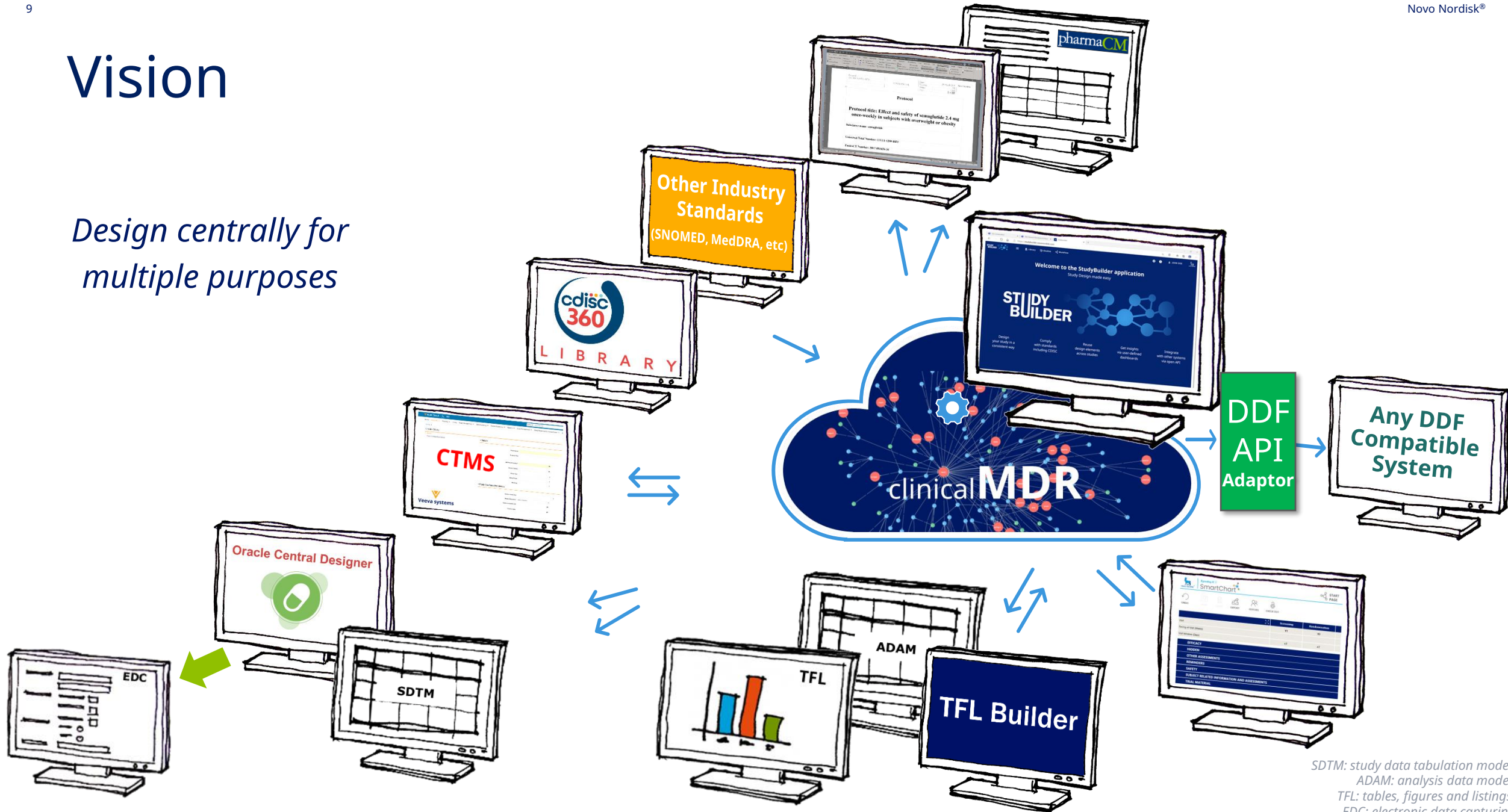
**OpenStudyBuilder** := **StudyBuilder@NN** := DDF @NN



**NN cannot** implement tools supporting digitalisation in  
clinical study data handling **alone!**

# Vision

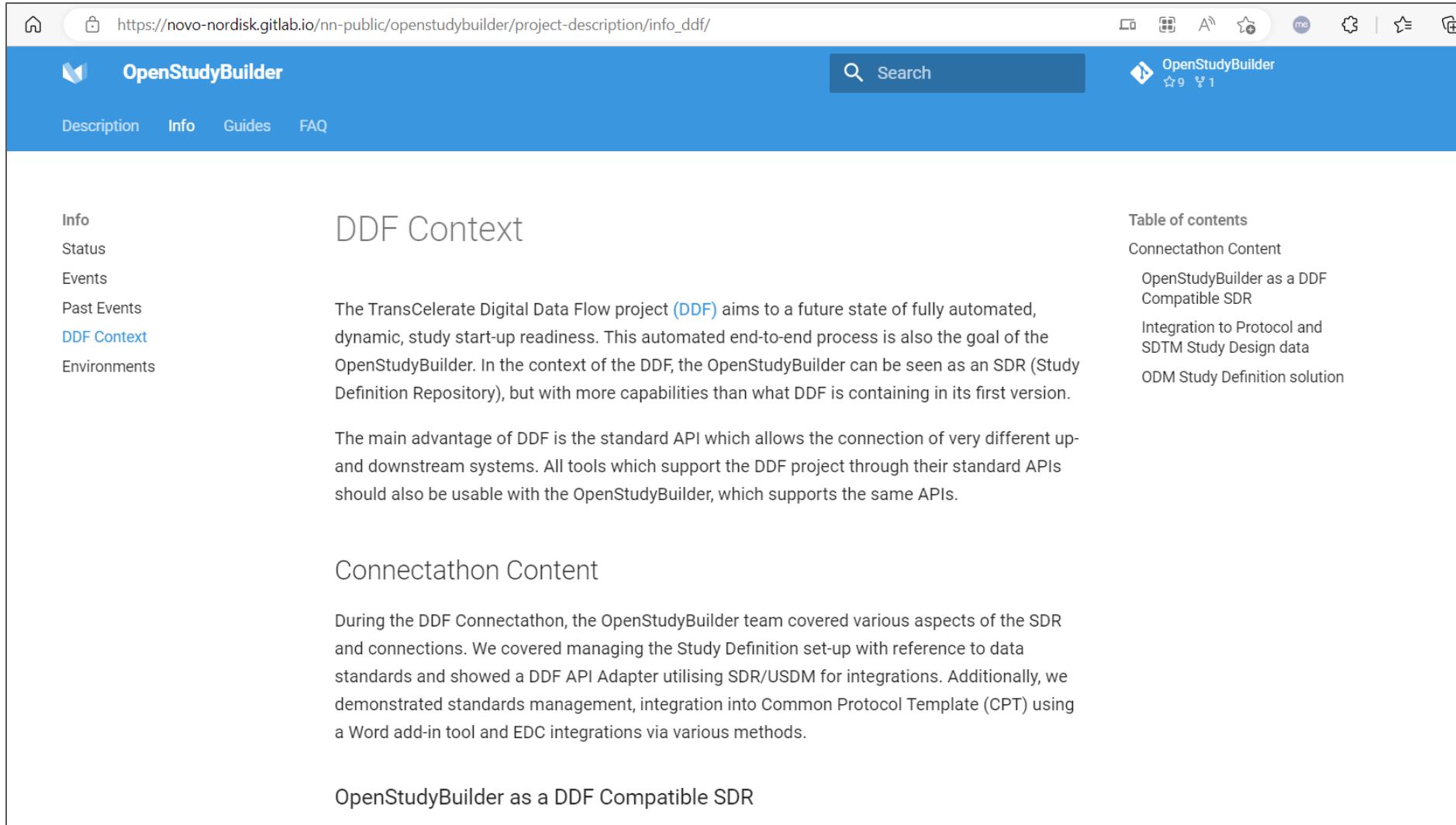
*Design centrally for multiple purposes*



*SDTM: study data tabulation model,  
 ADAM: analysis data model,  
 TFL: tables, figures and listings,  
 EDC: electronic data capturing*



# OpenStudyBuilder in DDF Context



The screenshot shows a web browser displaying the OpenStudyBuilder project page. The URL is [https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/info\\_ddf/](https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/info_ddf/). The page has a blue header with the OpenStudyBuilder logo and a search bar. Below the header, there are navigation links for Description, Info, Guides, and FAQ. The main content area is titled "DDF Context" and contains the following text:

**Info**  
Status  
Events  
Past Events  
[DDF Context](#)  
Environments

## DDF Context

The TransCelerate Digital Data Flow project ([DDF](#)) aims to a future state of fully automated, dynamic, study start-up readiness. This automated end-to-end process is also the goal of the OpenStudyBuilder. In the context of the DDF, the OpenStudyBuilder can be seen as an SDR (Study Definition Repository), but with more capabilities than what DDF is containing in its first version.

The main advantage of DDF is the standard API which allows the connection of very different up- and downstream systems. All tools which support the DDF project through their standard APIs should also be usable with the OpenStudyBuilder, which supports the same APIs.

### Connectathon Content

During the DDF Connectathon, the OpenStudyBuilder team covered various aspects of the SDR and connections. We covered managing the Study Definition set-up with reference to data standards and showed a DDF API Adapter utilising SDR/USDM for integrations. Additionally, we demonstrated standards management, integration into Common Protocol Template (CPT) using a Word add-in tool and EDC integrations via various methods.

### OpenStudyBuilder as a DDF Compatible SDR

**Table of contents**  
Connectathon Content  
OpenStudyBuilder as a DDF Compatible SDR  
Integration to Protocol and SDTM Study Design data  
ODM Study Definition solution

# Reflections on Change Management:

- Think **Change Management in EARLY!!** Creative CM solutions required in our situation moved to Agile methodology during development. CM framework still not fully landed.
- **Communication:** What DDF/StudyBuilder does and the benefits it brings communicated in layman terminology can be challenging. Recommend to make 5 -7 one liners and use consistently
- We're noticing **impact of Transcelerate DDF** – more vendors/CRO's are talking about DDF and are eager to collaborate

