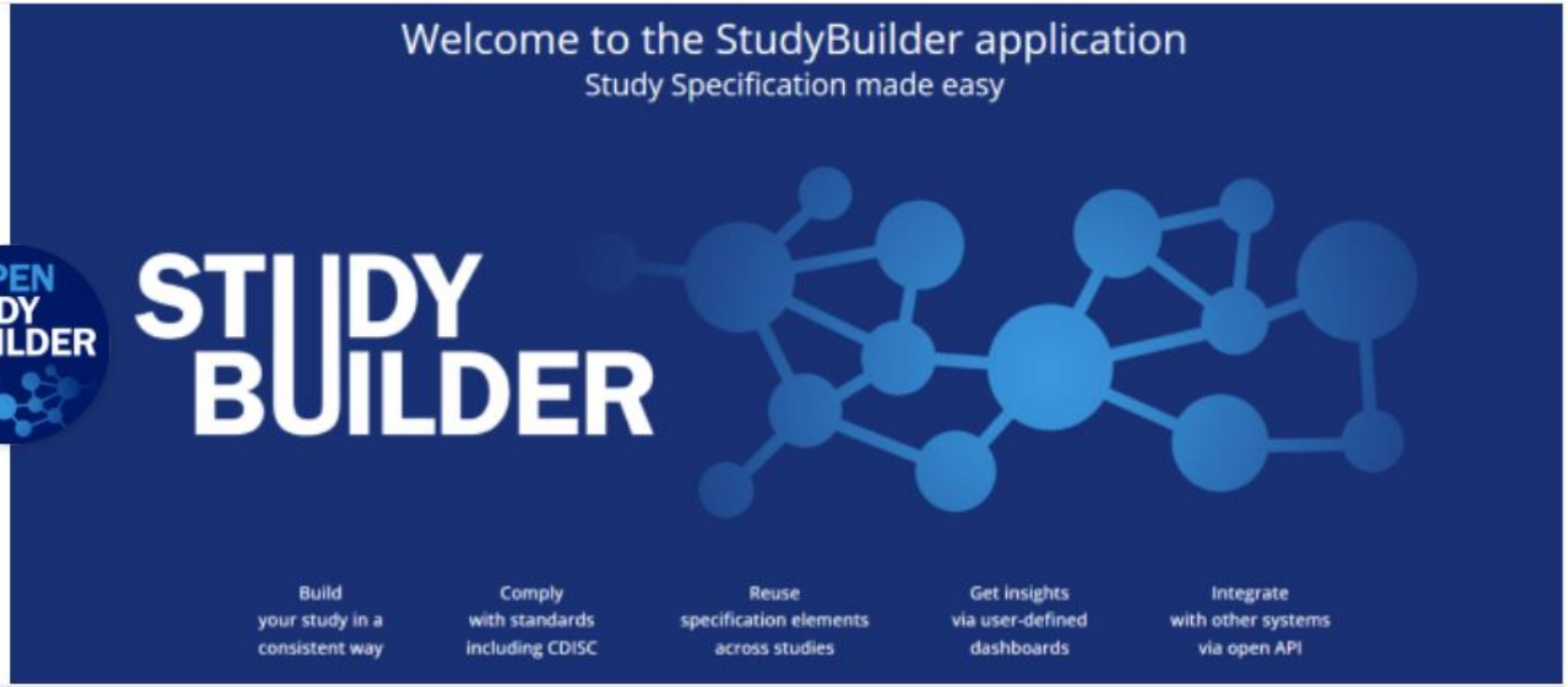
OpenStudyBuilder DDF Connect-a-thon

OpenStudyBuilder as a DDF Compatible SDR solution

Connectathon Category: **Data Interoperability**

OpenStudyBuilder

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



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.

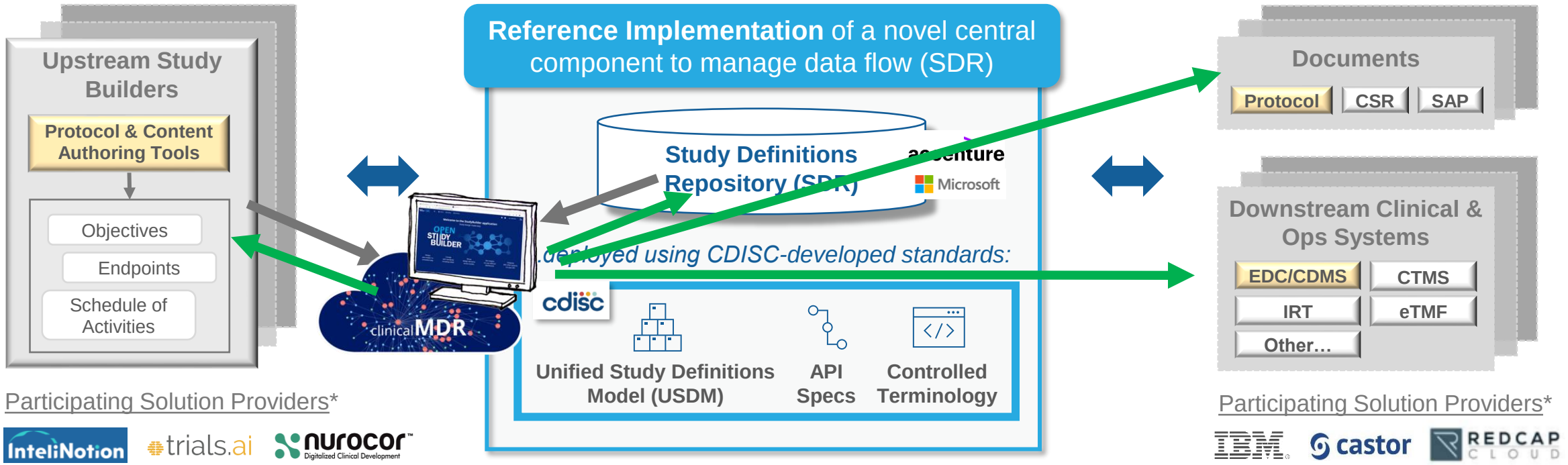
Minimum Viable Product (MVP) development underway

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



Participating Solution Providers*

InteliNotion trials.ai nurocor Digitalized Clinical Development

Participating Solution Providers*

IBM castor REDCAP CLOUD

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* 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.

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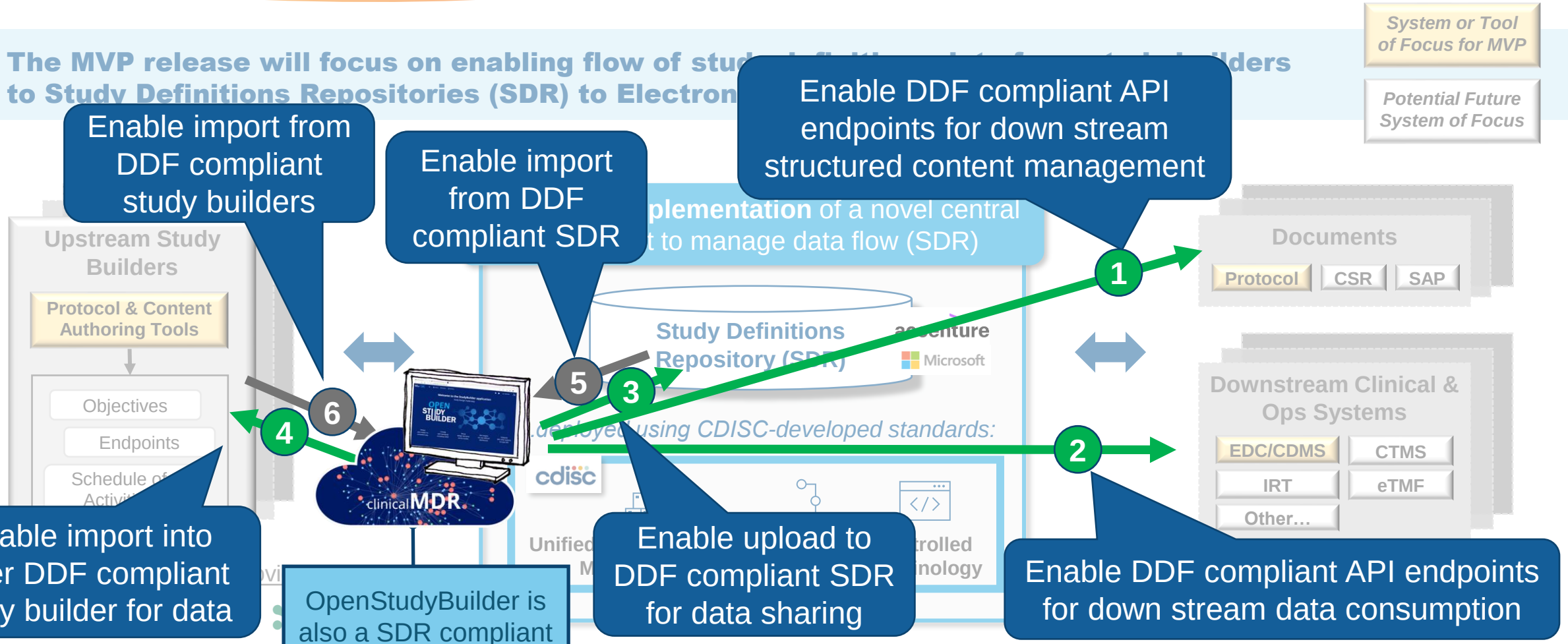

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What is the OpenStudyBuilder …

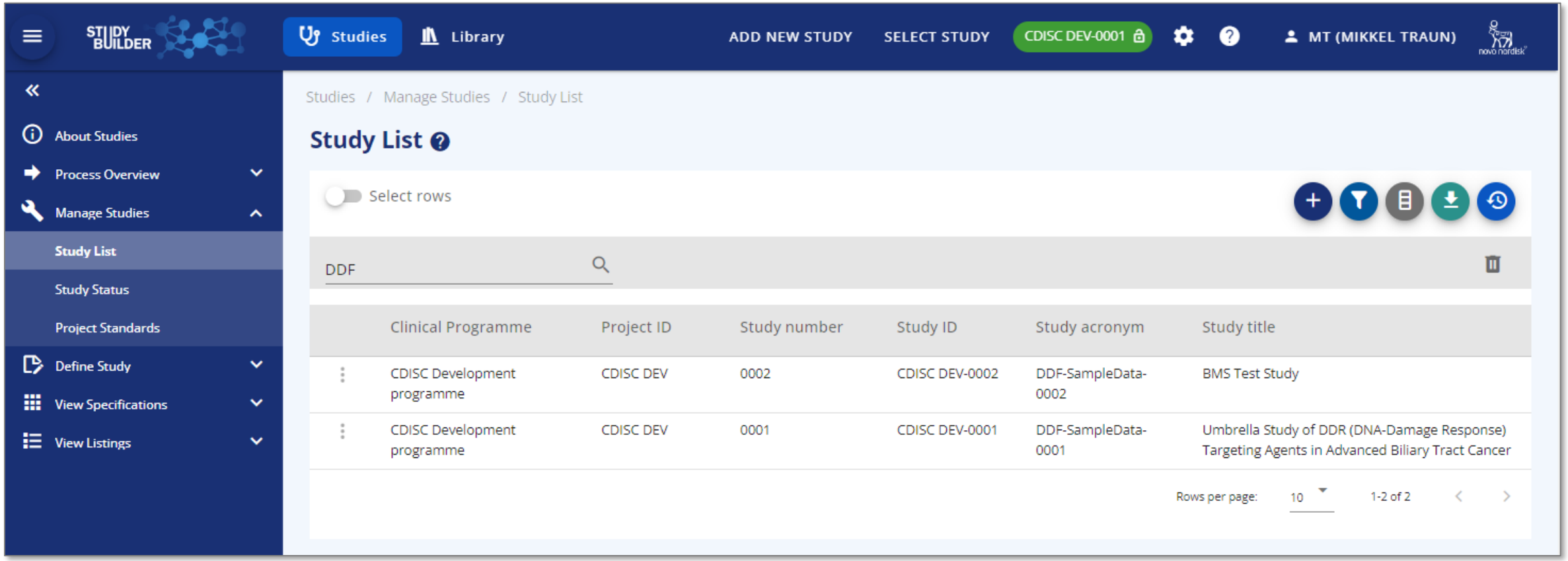
The OpenStudyBuilder is the new approach to study specification that will:

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

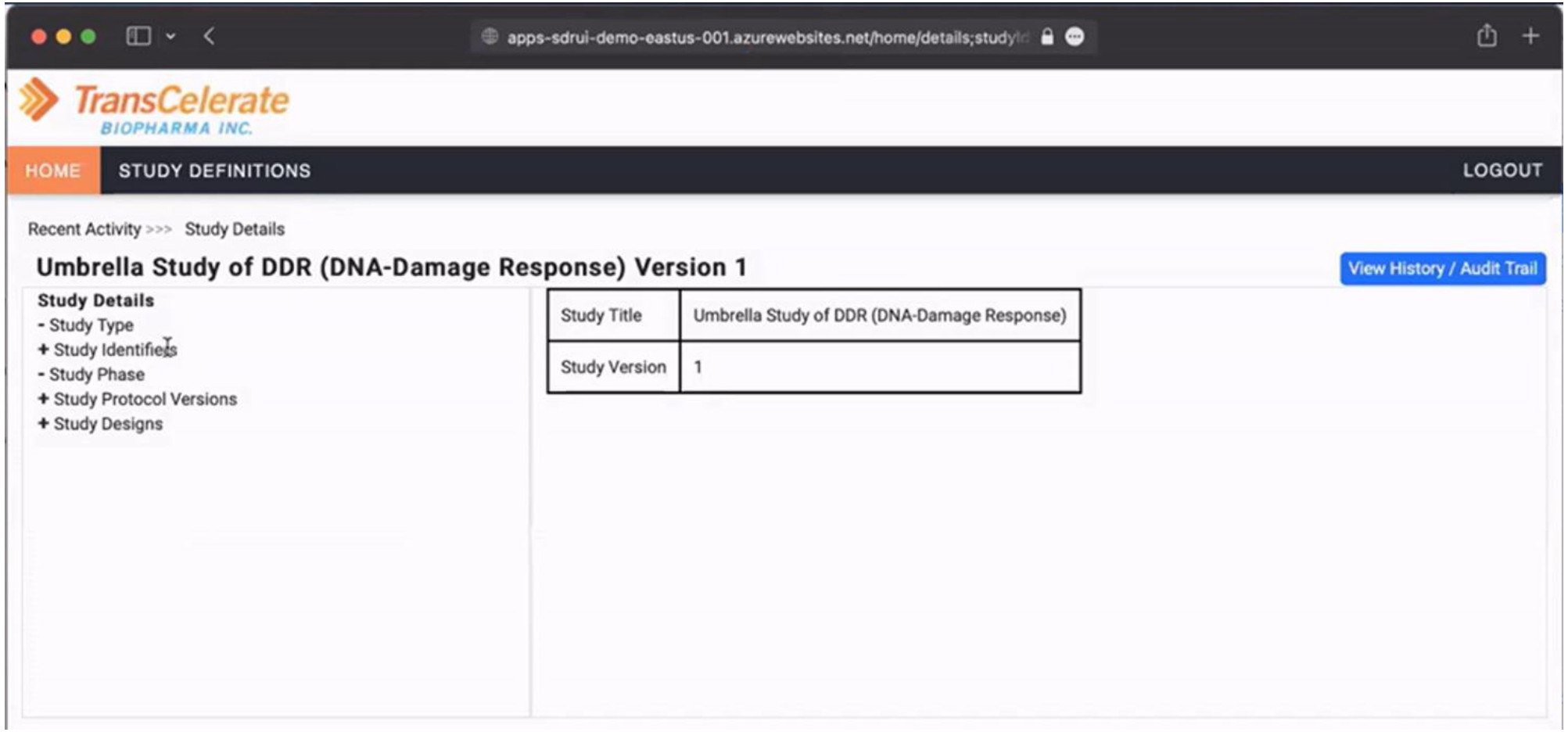
The OpenStudyBuilder comprises three elements:

- **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



OpenStudyBuilder to SDR POST demo



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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