OpenStudyBuilder break-out group

- Demonstrate DDF API adaptor and discuss DDF API alignment
- How to start evaluate and use OpenStudyBuilder, deployment options, system operations and integrations

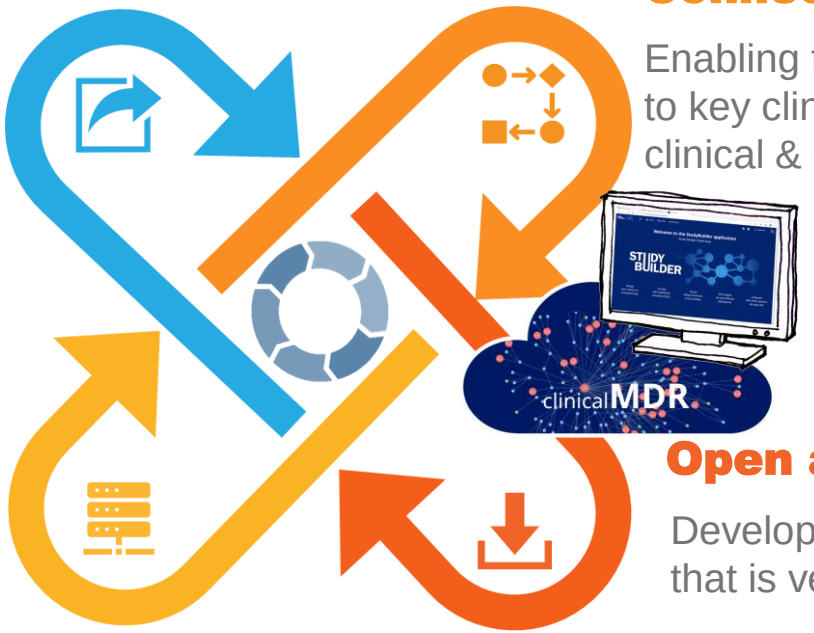
The Digital Data Flow Initiative (DDF) aims to catalyze digital transformation; breaking the document paradigm to enable seamless flow of the data within

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements allows industry to move to digital protocols

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)



Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Open and Flexible Solution

Developing a dynamic, fully automated solution that is vendor agnostic, open and flexible

Development principles to enable broad collaboration, stakeholder input, and sustainability

- Open Source
- Vendor Agnostic
- Agile Development
- Dynamic Alignment to Standards

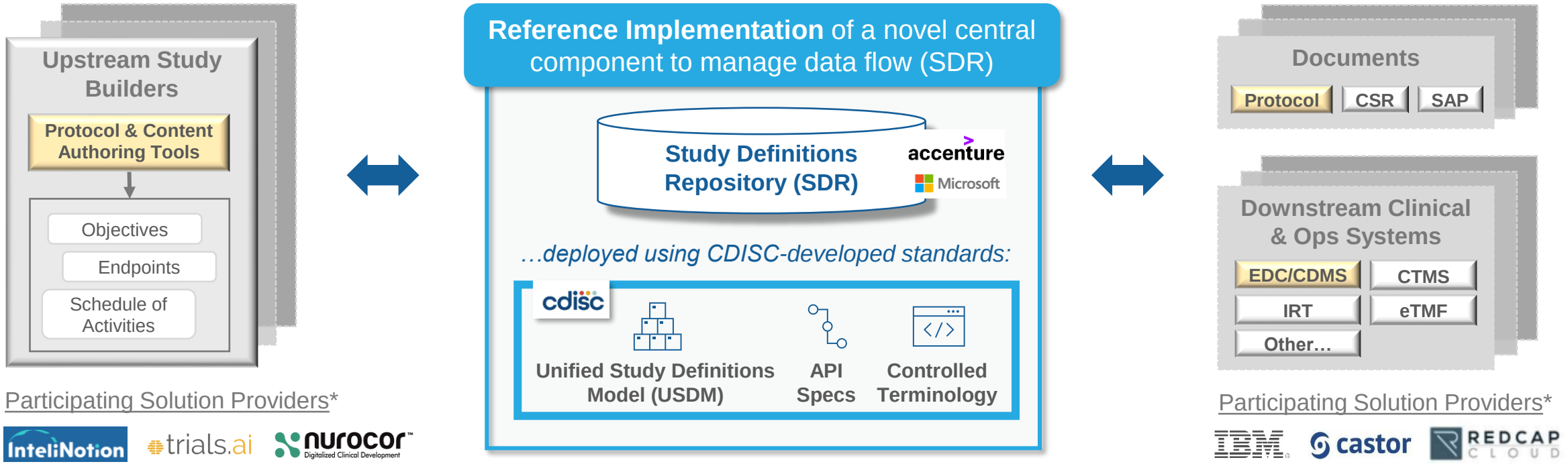
Minimum Viable Product (MVP) development underway

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



* 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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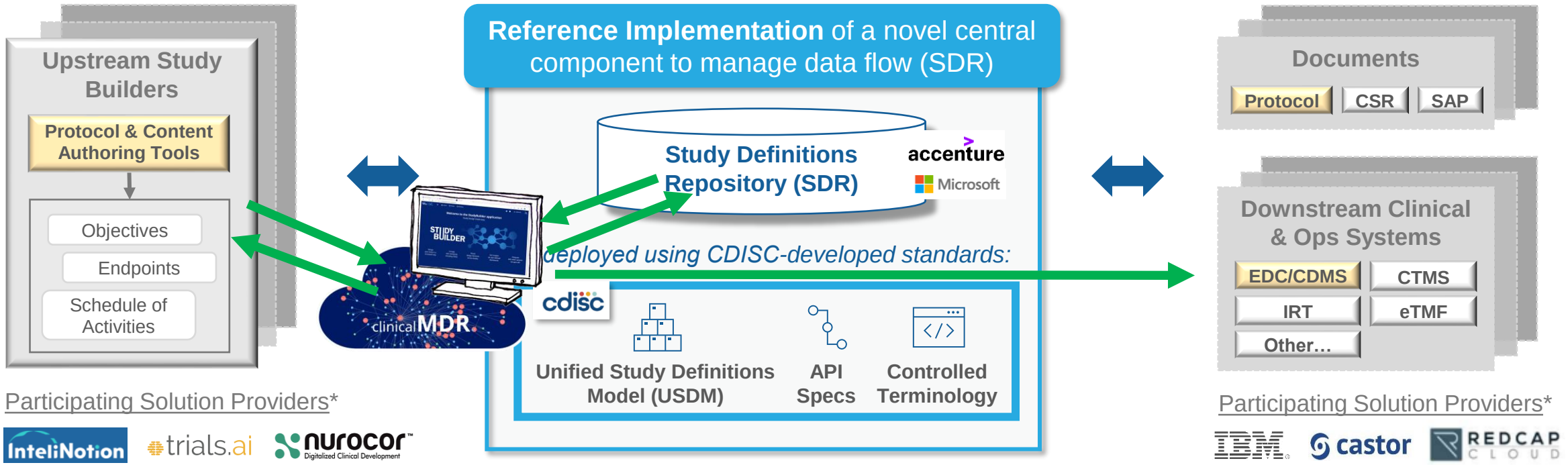

Participating Solution Providers*

InteliNotion trials.ai nurocor Digitalized Clinical Development

Participating Solution Providers*

IBM castor REDCAP CLOUD

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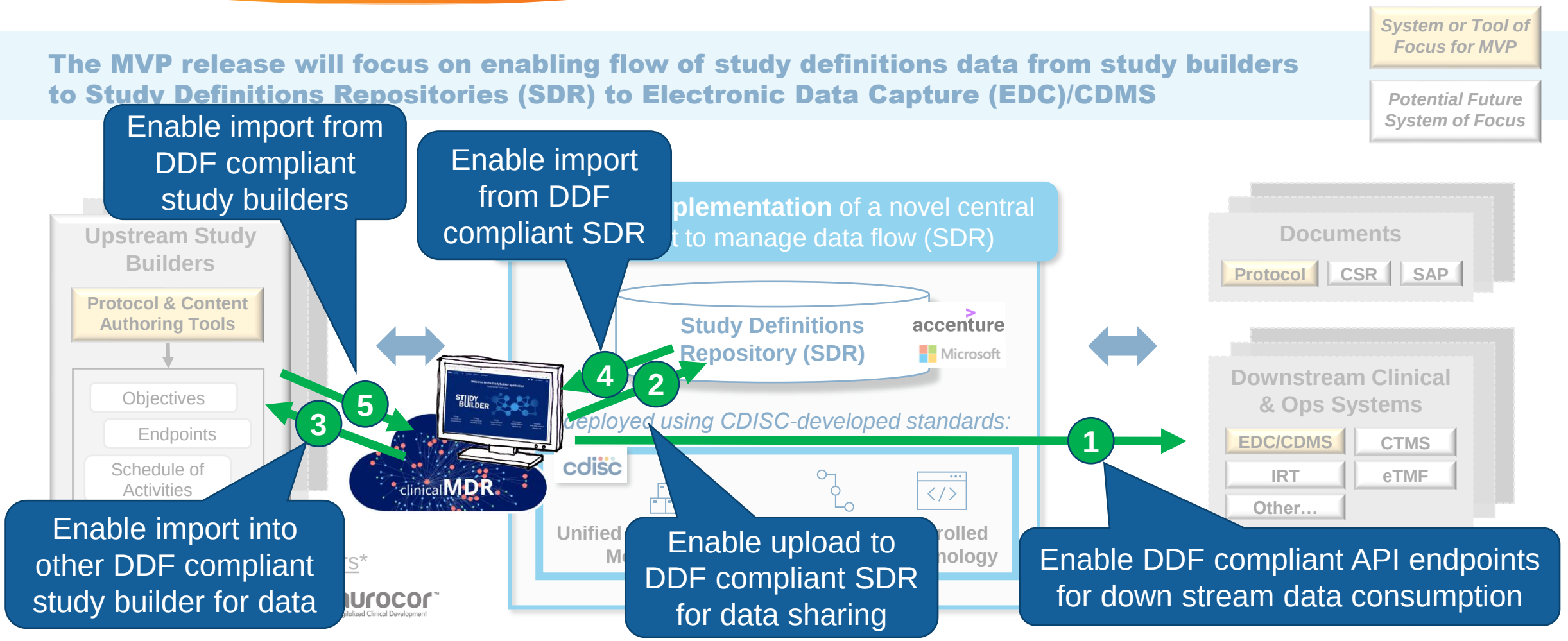

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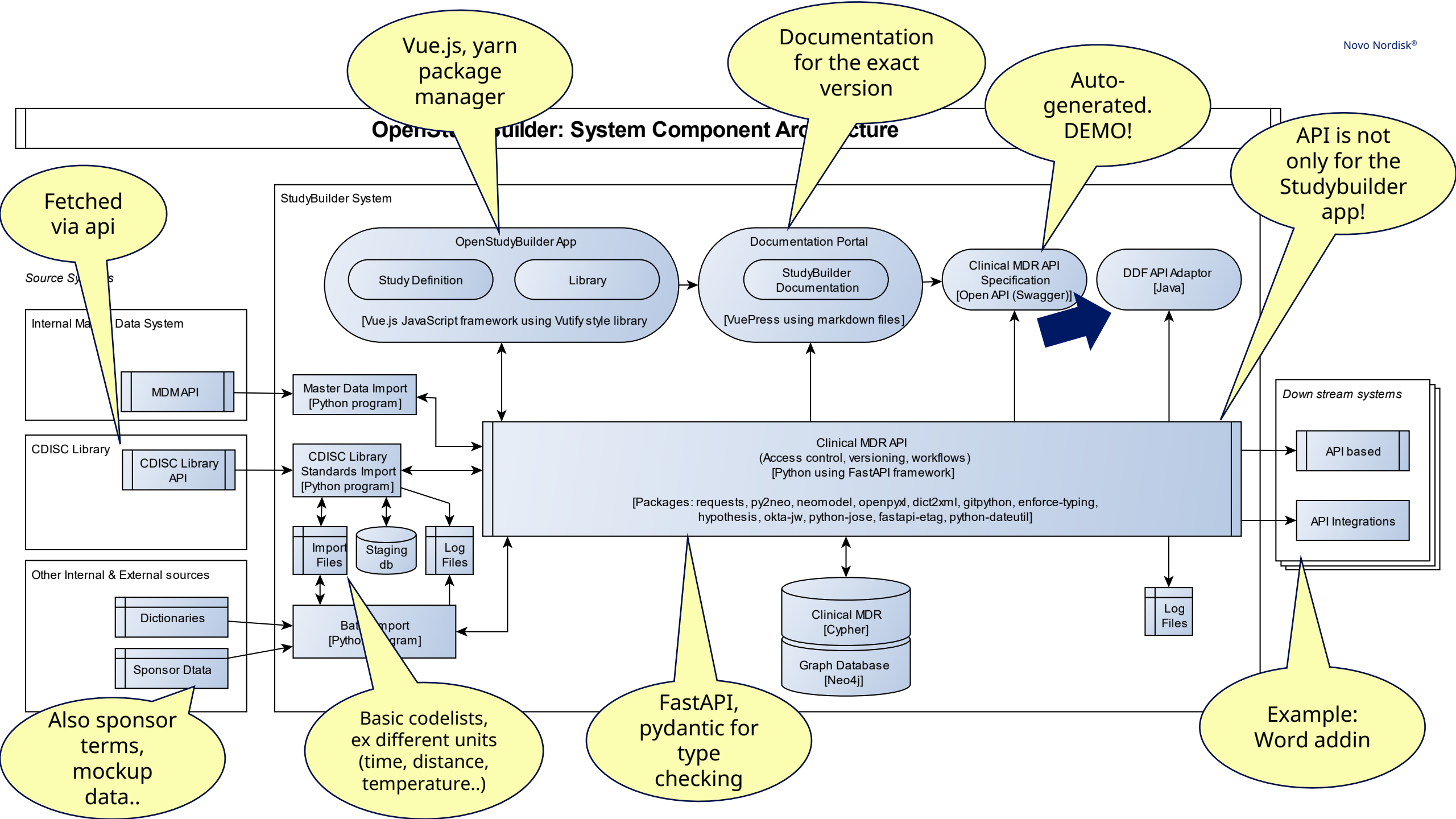
Novo Nordisk®



DDF <-> OpenStudyBuilder FAQ

- What is the similarity between DDF SDR and OpenStudyBuilder?
  - Both include a SDR component and a native interface to the study definition data
- What is the difference between DDF SDR and OpenStudyBuilder?
  - OpenStudyBuilder also include a data standards repository for terminology, dictionary terms, concepts – including sponsor defined extensions
  - OpenStudyBuilder is a full functioning app for managing sponsor standards and study definitions
- Can the OpenStudyBuilder app be used directly with a DDF SDR?
  - No, the OpenStudyBuilder app will only work with the internal Clinical MDR API
  - But the DDF API Adaptor can when fully implemented support import and export to and from another DDF SDR instance
- Can other DDF SDR compliant upstream and down stream tools connect to the OpenStudyBuilder API?
  - Yes, via the DDF API adaptor when this component is fully developed

Local and online technical setup

- Containerized setup
  - Limited software requirements locally
    - Windows, Linux, Mac
  - Agnostic to cloud provider; GCP, AWS, Azure, Private Cloud/On-prem

Local setup

docker-compose
Workable data scripted into docker

neo4j cloud

neo4j provides a cloud environment for trying out the OpenStudybuilder

Self-hosted

However you want to do it. Capability of containers needed.

SWOT summary

Strengths

- All standards in one place.
- Programmatic way to load DDF standards avoids confusion.
- Allows more efficient work, reduces manual work and inconsistencies.
- Open source, benefits from contributions from others.
- Can be tailored to meet own needs.

Weaknesses

- Not yet tested with a range of indications, will it cover the needs/requirements?
- CDISC model changes require software development work.
- Development requires active participation from companies using it.
- Risk of obsolescence of used frameworks.

Opportunities

- Support for nonclinical studies (both for Open Study Builder and CDISC).
- CDISC frameworks for validating software packages.

Threats

- Python and Java are foreign to statistical programmers.
- Inertia in IT setup in companies may prevent adoption.
- Competition from commercial Study builders.
- Resistance to funding Open-source projects.