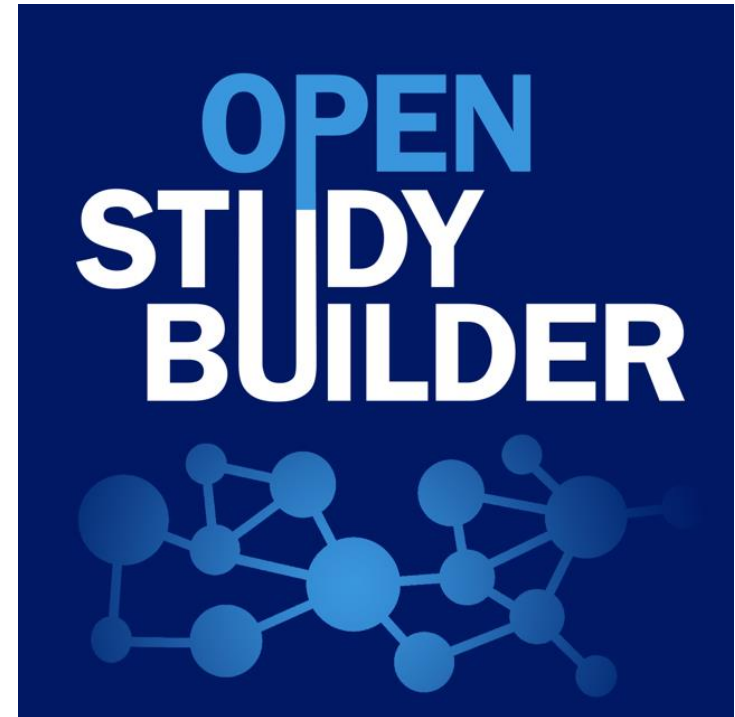# COSA OpenStudyBuilder Workshop

CDISC EU Interchange 29th April 2022

- **9:00 – 9:30 Introduction**
  - Welcome
  - Why use OpenStudyBuilder
  - Why share OpenStudyBuilder as an open source project
  - Why use and contribute to the OpenStudyBuilder
  - Short Demo
  - Practicalities

- **9:30 – 11:30 Breakout sessions**
  - Present and discuss your focus in each break-out group
  - Prepare a 10 minutes presentation
  - Remember breaks

- **11:30 – 12:50 Presentation by each break-out group**

- **12:50 – 13:00 Wrap-up, next steps and closure**
  - Follow-up on Slack chat sessions, surveys, share presentations
  - Prepare sharing of breakout outcome / deliverables / videos for all participants as well as public on COSA web site

# Why should you use the OpenStudyBuilder solution?

# Because it will be a Digital Data Flow (DDF) compliant solution enabling digitalisation in clinical development!

# 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)



clinicalMDR

## 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**
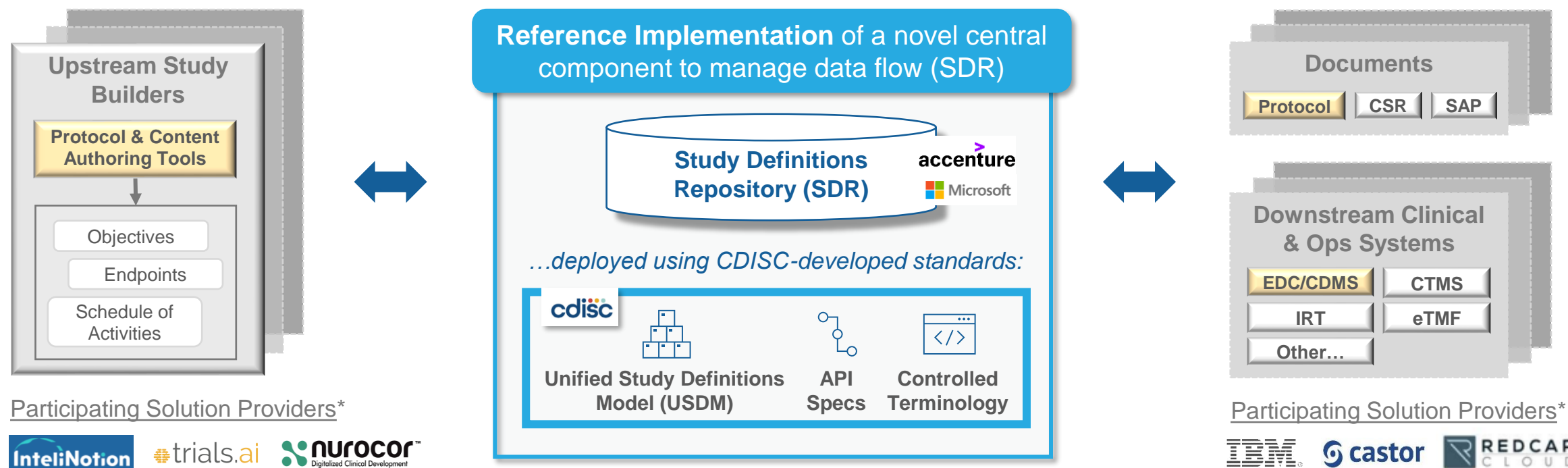
# Minimum Viable Product (MVP) development underway

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*

**Upstream Study Builders**

**Protocol & Content Authoring Tools**

Objectives

Endpoints

Schedule of Activities

Participating Solution Providers*

InteliNotion    trials.ai    nurocor Digitalized Clinical Development

**Reference Implementation** of a novel central component to manage data flow (SDR)

**Study Definitions Repository (SDR)**

accenture

Microsoft

*…deployed using CDISC-developed standards:*

cdisc

**Unified Study Definitions Model (USDM)**    **API Specs**    **Controlled Terminology**

**Documents**

Protocol    CSR    SAP

**Downstream Clinical & Ops Systems**

EDC/CDMS    CTMS

IRT    eTMF

Other…

Participating Solution Providers*

IBM    castor    REDCAP CLOUD

* 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.
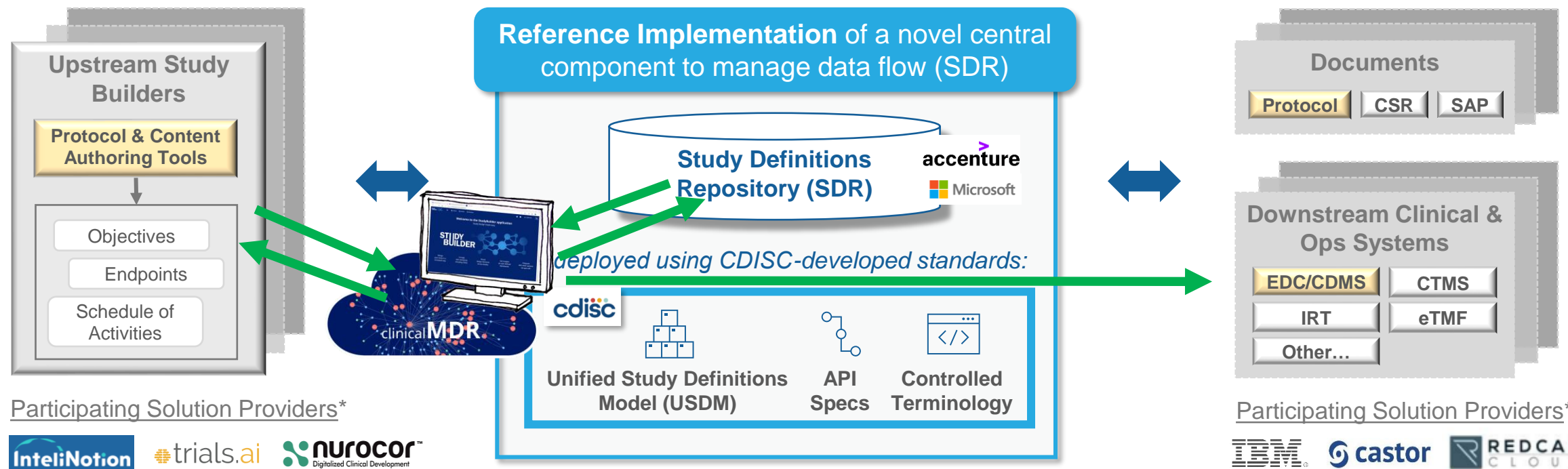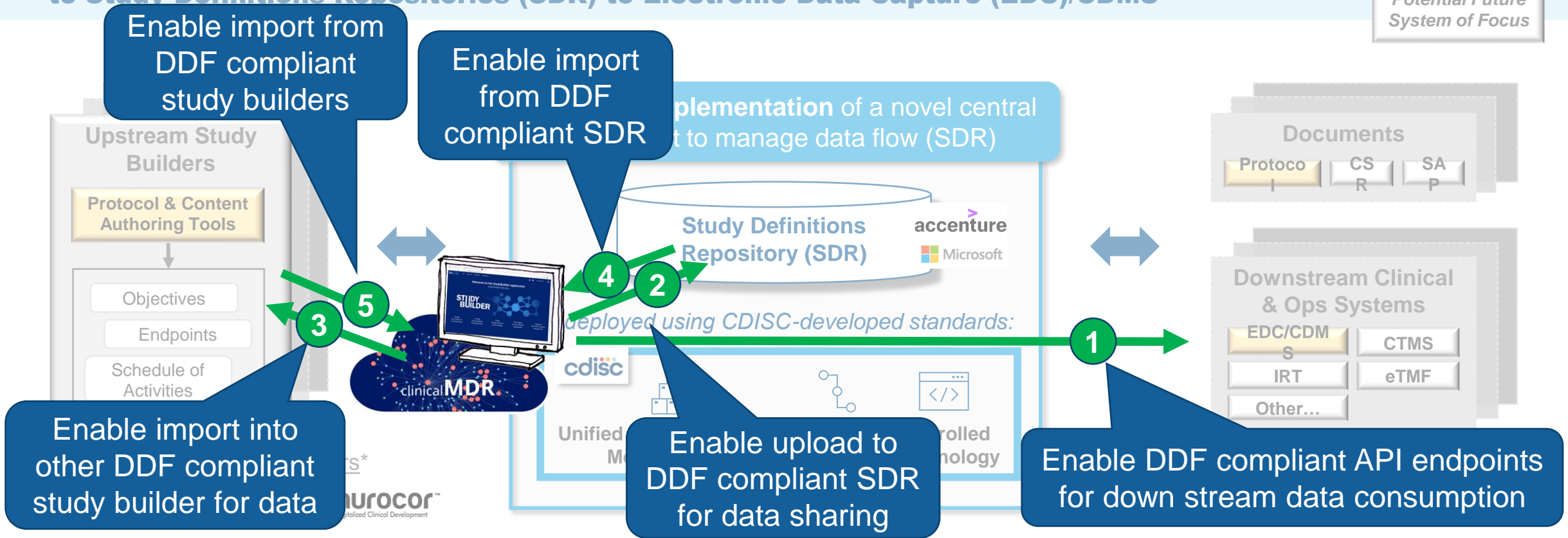
# Minimum Viable Product (MVP) development underway

April 2022 Anticipated Release Date

**The MVP release will focus on enabling flow of study definitions 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*

**Upstream Study Builders**

**Protocol & Content Authoring Tools**

Objectives

Endpoints

Schedule of Activities

Participating Solution Providers*

InteliNotion    trials.ai    nurocor Digitalized Clinical Development

**Reference Implementation** of a novel central component to manage data flow (SDR)

**Study Definitions Repository (SDR)**    accenture    Microsoft

STUDY BUILDER

clinicalMDR

*deployed using CDISC-developed standards:*

cdisc

**Unified Study Definitions Model (USDM)**    **API Specs**    **Controlled Terminology**

**Documents**

Protocol    CSR    SAP

**Downstream Clinical & Ops Systems**

EDC/CDMS    CTMS

IRT    eTMF

Other...

Participating Solution Providers*

IBM    castor    REDCAP CLOUD

* 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.
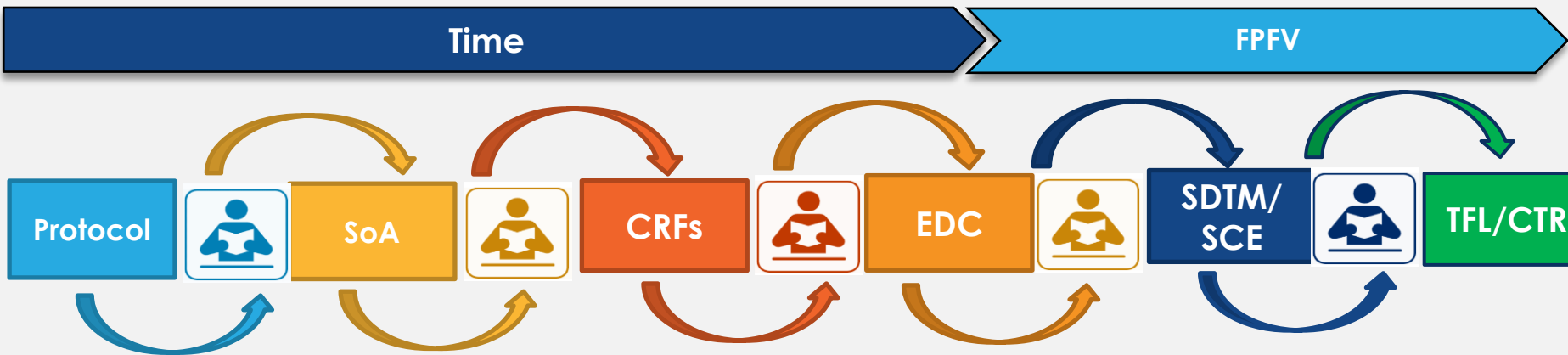
# Minimum Viable Product (MVP) development underway

April 2022 Anticipated Release Date

# Digital Data Flow: Current State vs. Future State (adapted)



**Time** → **FPFV**

Protocol → SoA → CRFs → EDC → SDTM/SCE → TFL/CTR
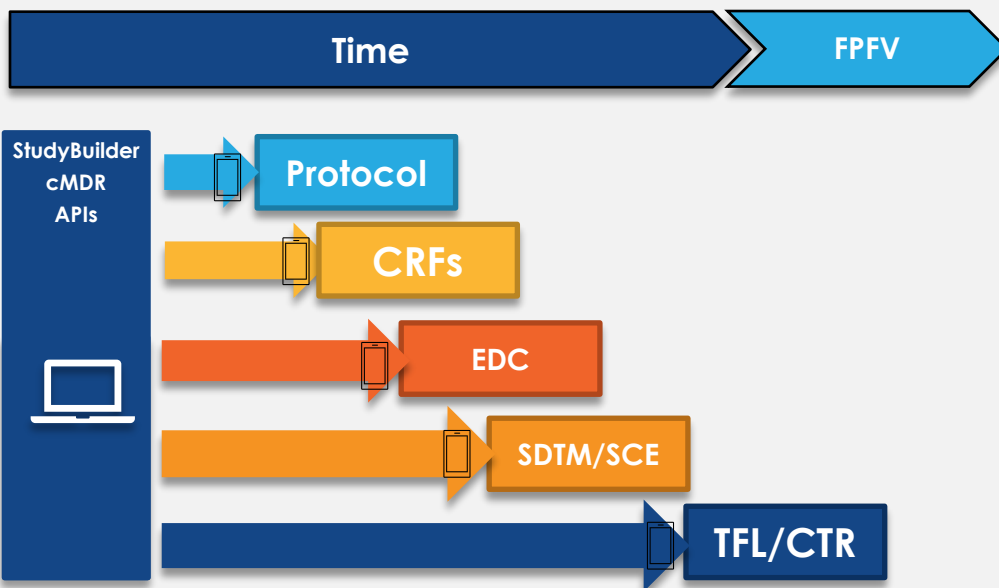
⚠️ **Manual Process**
- *Potential variances and data quality issues*
- *Re-entering same information multiple times*
- *Often sequential steps*
- *Inefficient*

**Time** → **FPFV**

StudyBuilder cMDR APIs

Protocol
CRFs
EDC
SDTM/SCE
TFL/CTR

🔄 **Digitized Process**
- *Increased consistencies*
- *Quality improvements through information re-use*
- *Timely through automation and partially parallel steps*
- *Efficient*

# Why do we share OpenStudyBuilder as an open source project?

# Because we will benefit and get more value from the collaboration!

- **And we will not have the risk of vendor lock-in**

# Background and vision

- **Background** – today characterised by

  - Lots of IT systems and tools

  - Numerous manual steps which consume time and resources … and introduce errors

  - Costly system maintenance and integrations

- **Vision** – tomorrow characterised by

  - IT that enable seamless interoperability and cross-functional end-to-end collaboration

  - Driven by concept based data standards

  - Sustainable model for maintenance and integrations

# **Why open source**

- Avoiding a v2 custom solution

  - Solution based on industry standards
  - By driving this as an collaborative open source solution

- To be an active player in the industry transformation towards using concept based data standards for study specification and end-to-end digital data flow by collaborating externally with CDISC, TransCelerate DDF, vendors and peers as part of open source initiatives to avoid an Novo Nordisk custom solution

- Benefit from collaborations

- Benefit from future tools and extensions

*DDF: Digital Data Flow*

# Why should you use and contribute to the OpenStudyBuilder?

# Because you will get value from using it, and even more if you contribute!

# Why use and contribute to the OpenStudyBuilder

- High complexity of current tool landscape

  - Interfaces

  - Exchange of tools very tough

  - Mainly no "perfect" fits


- Open-source allows for much better

  - Integrations

  - Maintenance & Enhancements

  - Collaborations

  - Real option of taking over the project

# Why use and contribute to the OpenStudyBuilder

- OpenStudyBuilder

  - MDR "CORE"

    - Graph data model, Biomedical Concept

    - Version, tracking management

    - One source of truth

  - Standard APIs

    - Imports, standards, sponsor specific

    - Setup, maintenance

    - Downstream usage

- Open-Source design
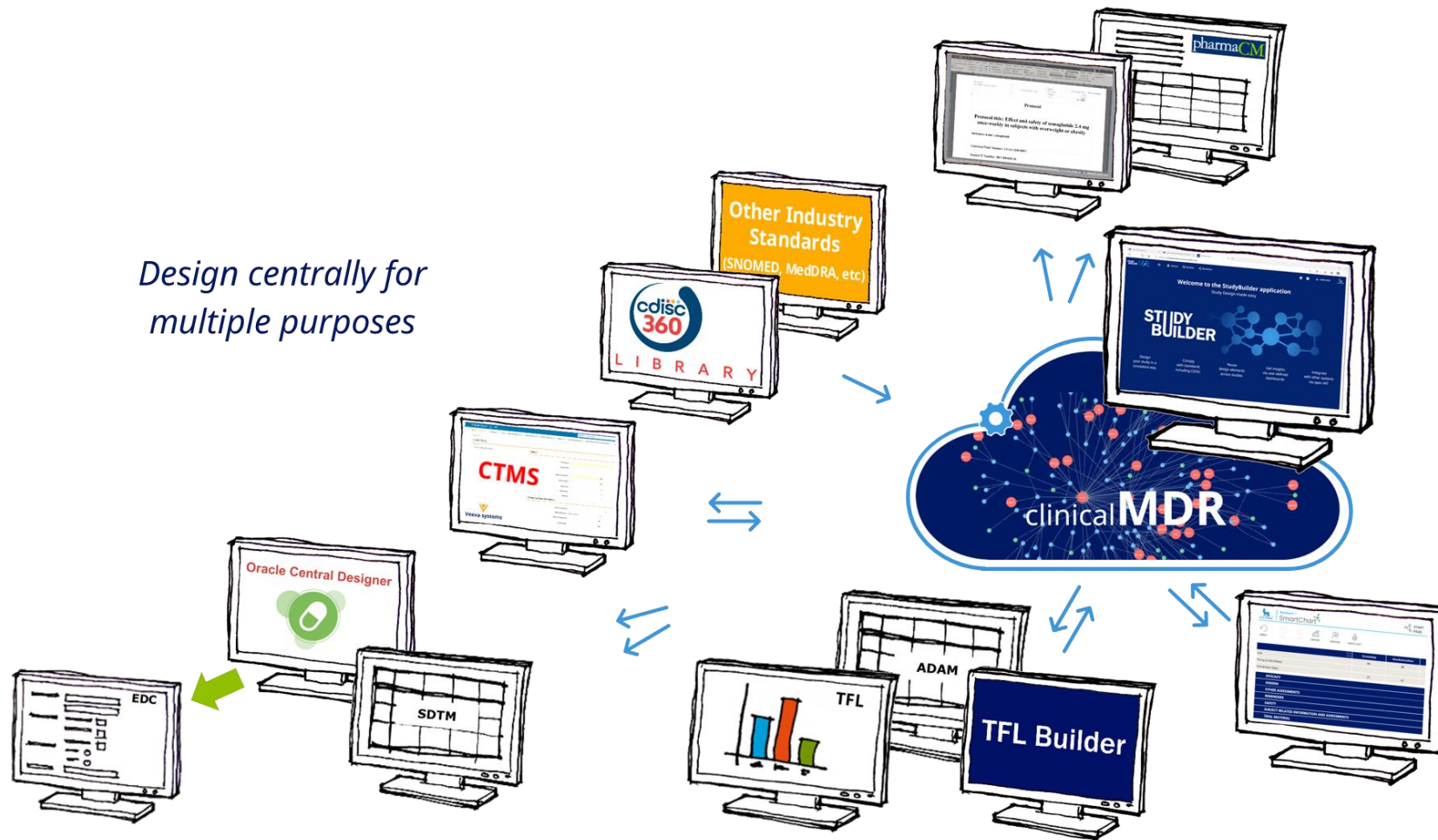
  - Modularized

  - Expecting changes

# Why use and contribute to the OpenStudyBuilder

- OpenStudyBuilder tools as collaborative best-fit toolset!

  - Bricks systems

  - "Plug" what fits best for your organization

  - Provide additional "apps"

  - Open-source enables enhancements

  - Modern development approach

# Why use and contribute to the OpenStudyBuilder



*Design centrally for multiple purposes*

# Why use and contribute to the OpenStudyBuilder

- **Open** collaborations

  - Variety only when others collaborate as well

  - Vendors can also create open source


  - Join/create open source collaboration

  - Allow vendors to collaborate
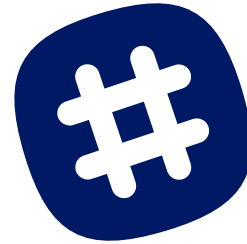
  - Contracts to create open source

# Breakouts

# Some practicalities

# Practicalities

- COSA Workshop – Participation Guide (mail & slack #workshop-cosa)

- Join Slack (openstudybuilder.slack.com)
  - #workshop-cosa (add-channel to join)
  - #workshop-cosa-issues

- All material created and shared during the meeting (no personal data and similar) may become published

# Practicalities

- Breakout groups
  - Join automatically
    - According selection
    - No selection -> assigned

- Please turn on the camera!

## Breakout Sessions

- Use OpenStudyBuilder to make study specification for structured protocol content
- Use OpenStudyBuilder to make study specification for CRF and data collection
- Use OpenStudyBuilder to make study specification for SDTM Study Design datasets
- Use OpenStudyBuilder to manage concept-based standards, ideate on BC definitions
- Use NeoDash reports for status reporting on study specifications, Ideate on format and meta-checks
- Demonstrate DDF API adaptor and discuss DDF API alignment
- How to start evaluate and use OpenStudyBuilder, deployment options, system operations and integrations
- Ideate on business opportunities for vendor services for OpenStudyBuilder

# OpenStudyBuilder next steps

- We will release a non-GCP MVP internally at Novo Nordisk in Q3 2022

- We plan a GCP release later

- We intend to share the project as an open source project under COSA in Q3 2022

  - https://cosa.cdisc.org/directory/openStudyBuilder

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

  Currently only containing a project description

- We seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors

# Wrap up and closing remarks