

StudyBuilder

Next Generation MDR Solution for
Study Design and Configuration
Using Concept-based Standards



Agenda

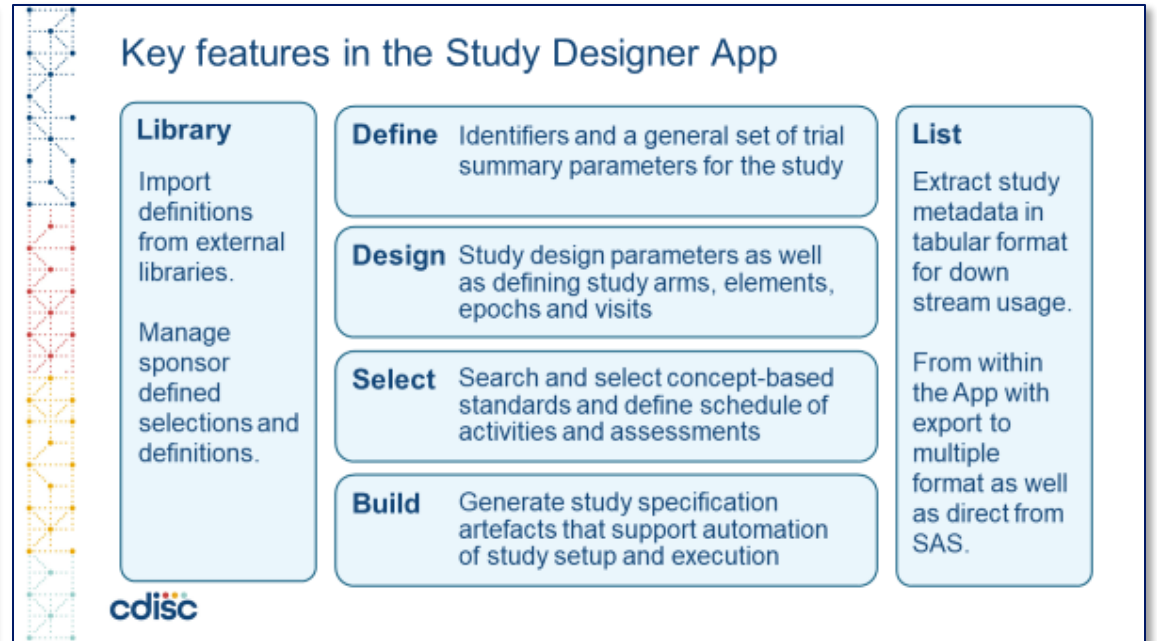
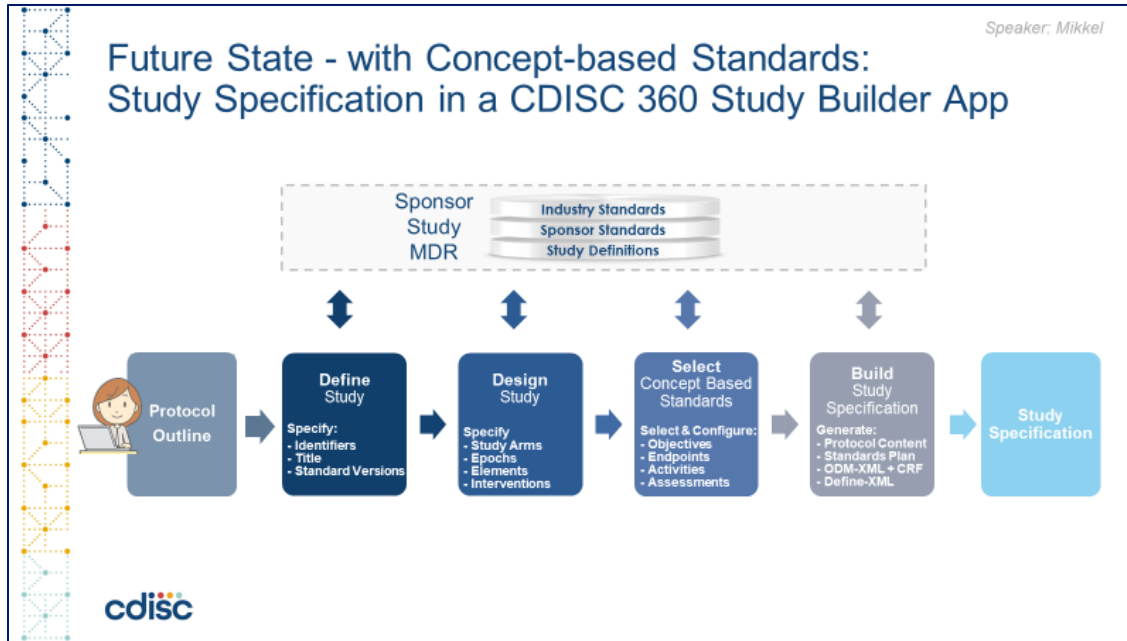
- Project scope, background and vision
- Core capabilities for a StudyBuilder and MDR solution
- Ligth demo
- Next steps

Project scope

- **Establish a *study builder* solution**
 - To support the study specification process using concept based data standards *from* protocol development and CRF design *to* creation of submission datasets, analyses, reporting and public disclosure of study information
 - To promote seamless, cross-functional collaboration during study milestones and processes
 - To be able to close the legacy CDW MMA
 - 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 NN custom solution



We are building the StudyBuilder and MDR solution based on the CDISC 360 POC



<https://www.cdisc.org/cdisc-360>

Our goal is to replace our legacy MDR solution with a new modern StudyBuilder and MDR

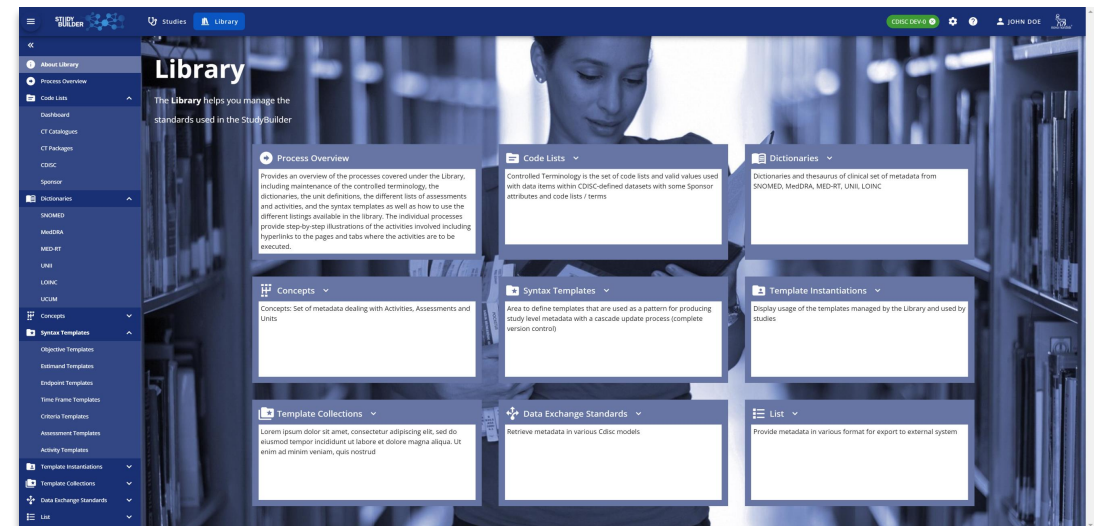
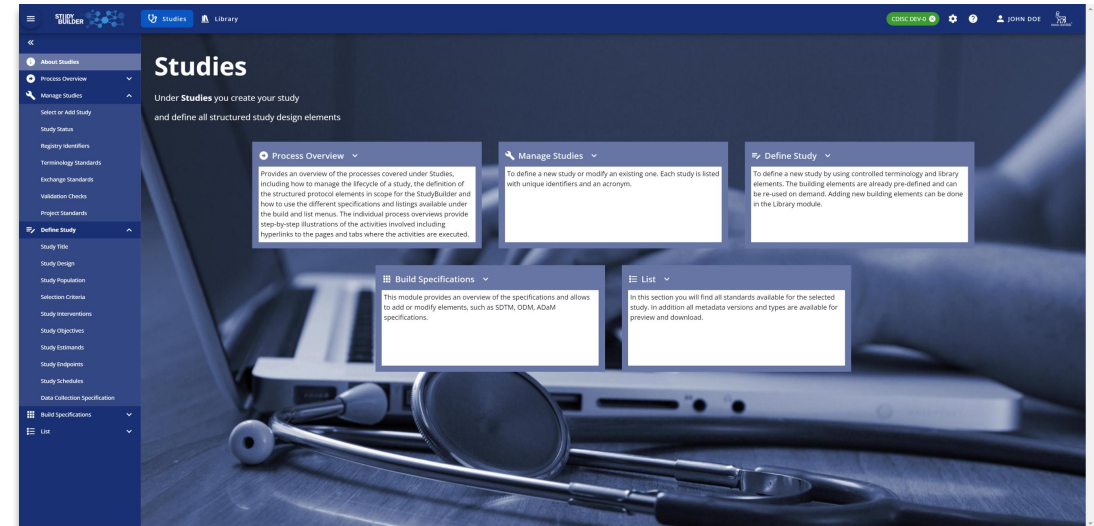
What is the StudyBuilder ...

- The StudyBuilder is a new approach to working with studies that will promote end-to-end consistency and flow of **study specification information**
 - **StudyBuilder application**
(web-based user interface)
 - **Clinical Metadata Repository (MDR)**
(central repository for all study specification data)
 - **API layer**
(allowing interoperability with other applications)



The StudyBuilder includes

- A **Studies** part for specification of studies, including disease area and study type, objectives and endpoints, population, interventions, study design and schedule, activities and assessments
- A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology and external dictionaries for medical terms, pharmacological classes, units, etc.) as well as syntax templates for cross-study and cross-project standardisation
- An underlying **knowledge database** to enable complex queries and dashboards showing aggregated information



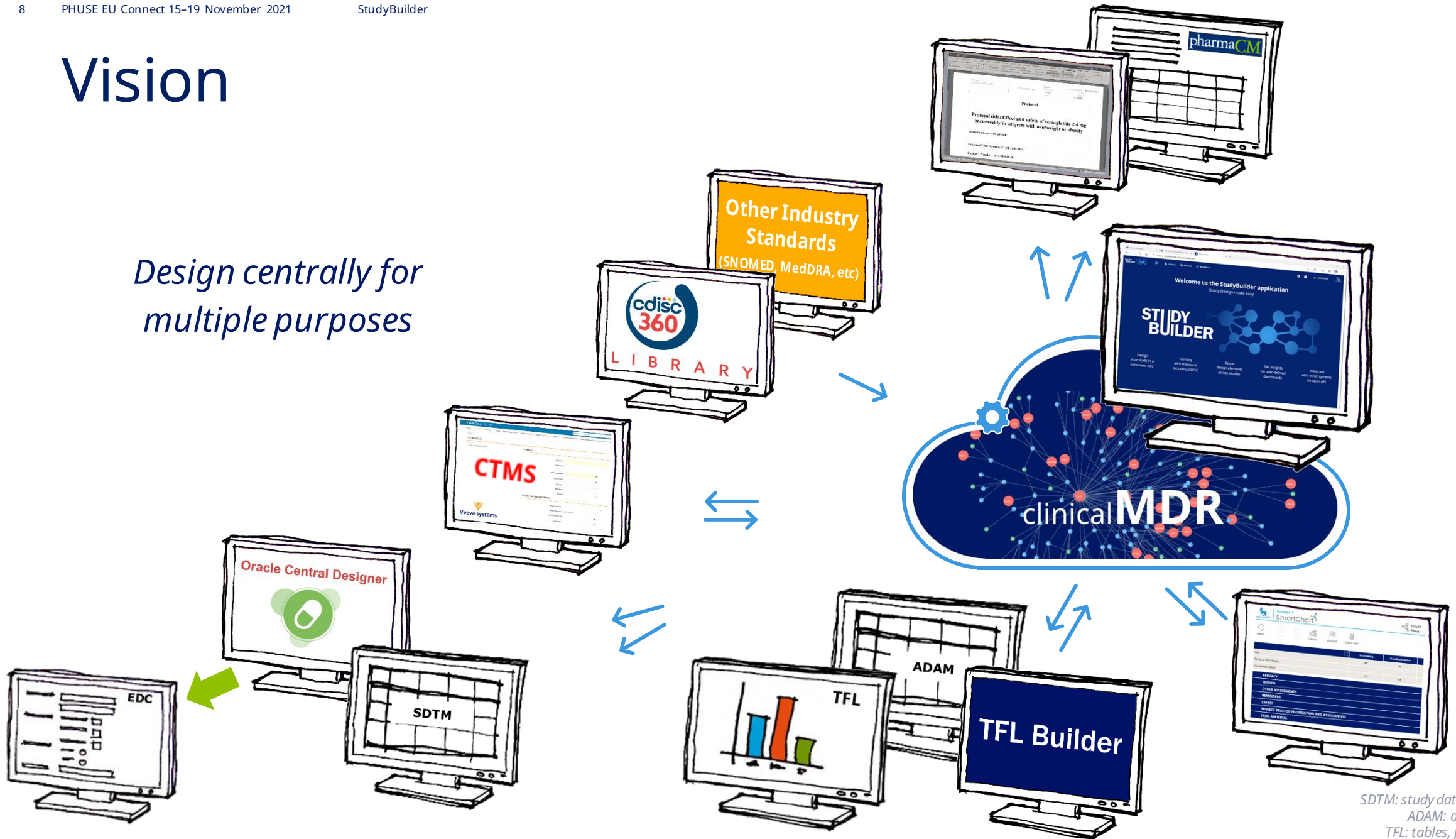
Meta data repository

- **Meta data** representing the **study design** and **definitions** with reference to **data standards**
- The **Meta Data Repository (MDR)** is used for:
 - Managing the CDISC standards and other external standards
 - Managing internal standards and project templates
 - Applying these standards when designing studies
 - Creating study specifications
- The MDR serves as a **meta data hub** for all related tools and systems requiring detailed study specifications



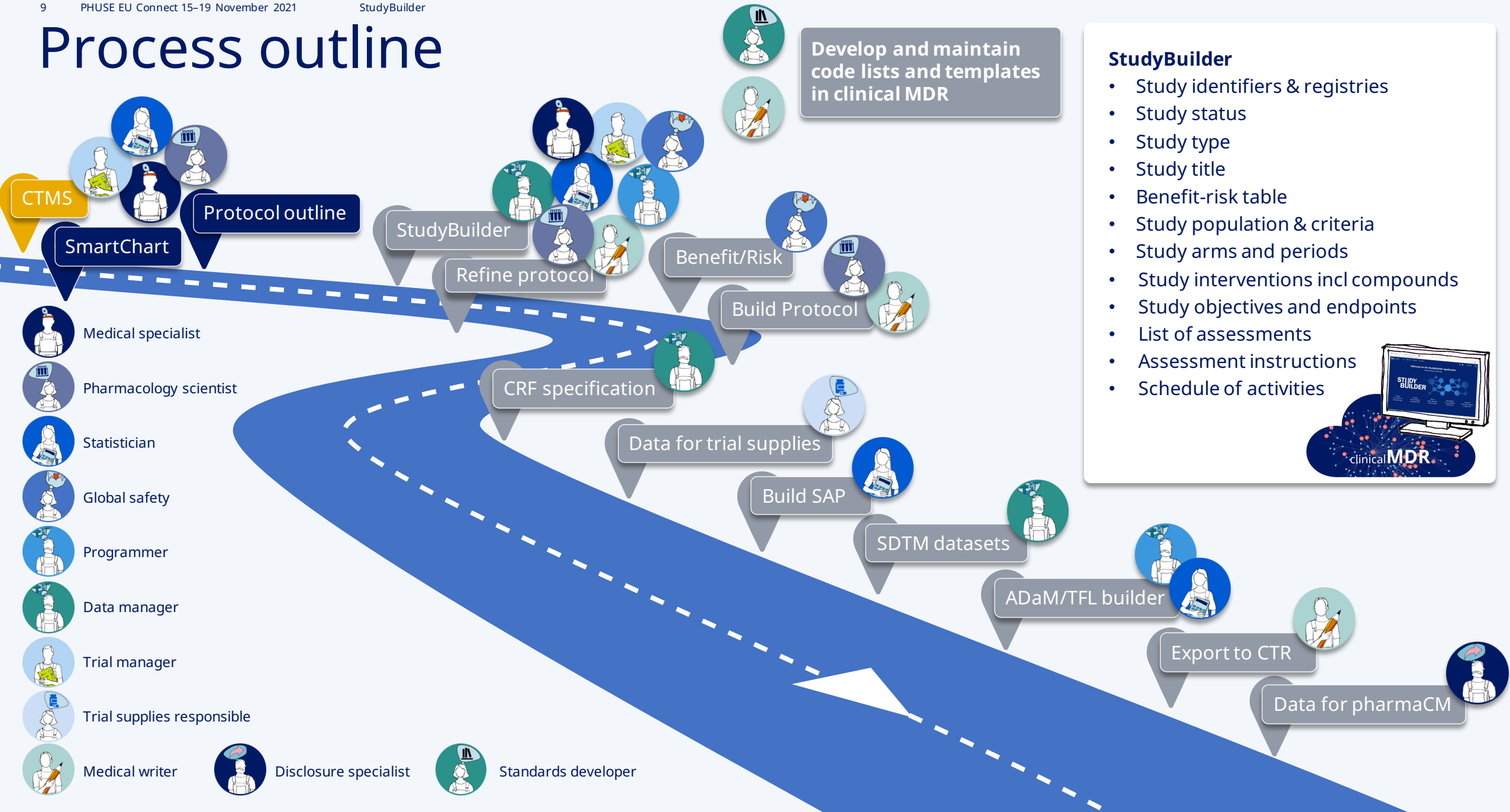
Vision

Design centrally for multiple purposes



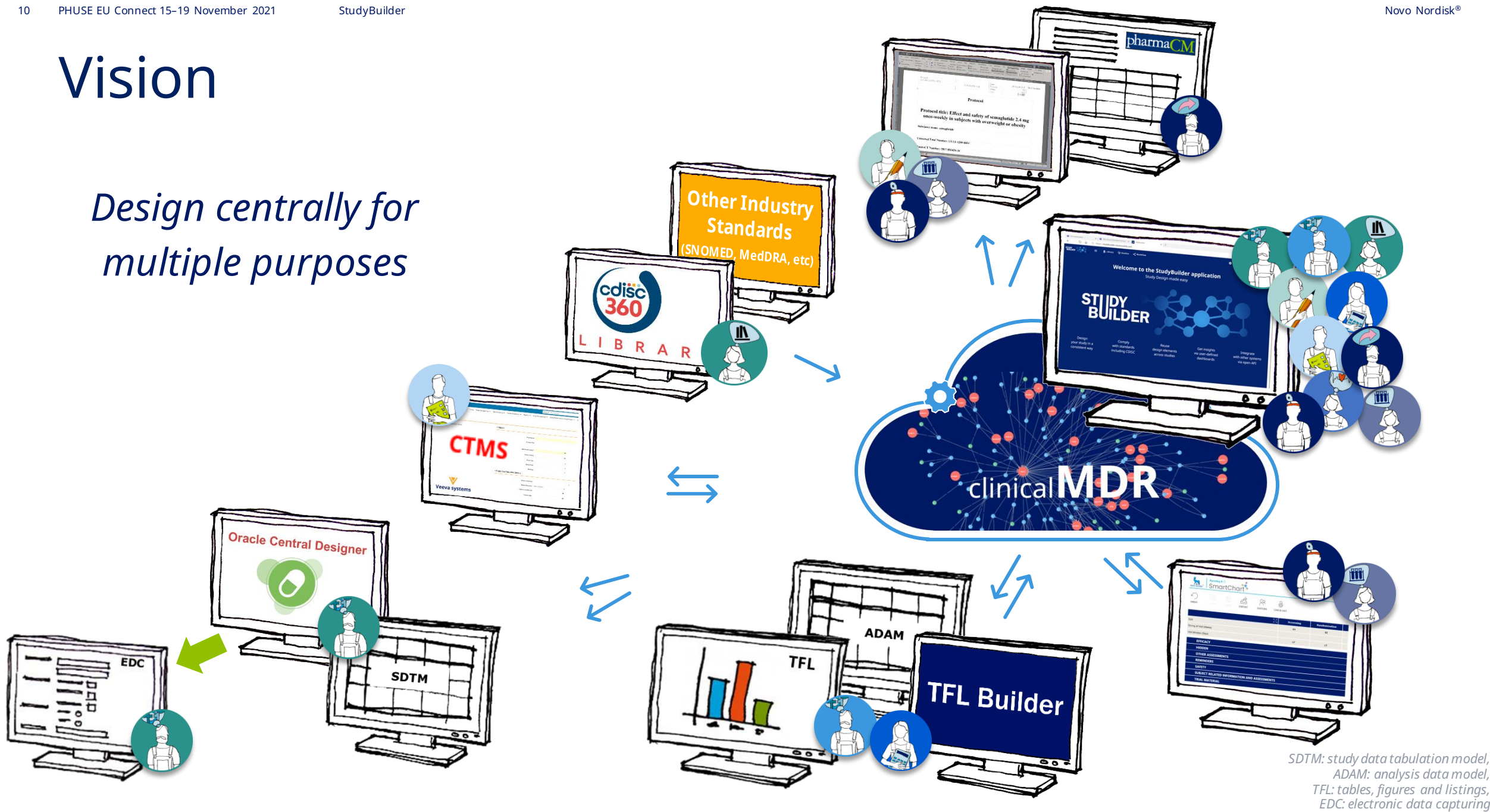
SDTM: study data tabulation model,
ADAM: analysis data model,
TFL: tables, figures and listings,
EDC: electronic data capturing

Process outline



Vision

Design centrally for multiple purposes



Core capabilities for a standards based StudyBuilder & MDR

Industry and sponsor standards

- CDISC and Sponsor defined controlled terminologies
- Subset of external dictionary terms
- Concept based standards (Biomedical Concepts)
- Syntax templates for standardising descriptions referring to terms
- Full versioning and audit trail on data element level
- Role based access and workflows

Study definition repository

- Select and define the study specification using concept based data standards
- All related to versioned library elements
- Version control and audit trail
- Integrations for up- and down stream usage

STUDY BUILDER

StudiesLibrary

CDISC DEV-0

JOHN DOE

OverviewStudiesLibrary

Search

Select rows

Table with 12 columns: Clinical Programme, Project ID, Project name, Brand name, Study number, Study ID, Study acronym, Study title, Status, Modified, Modified by, Actions

Protocol Process

Overview of protocol elements

The process map provides links to where you specify each element.

SELECT STUDY OR ADD NEW STUDY → STUDY PURPOSE → STUDY DESIGN → STUDY POPULATION → STUDY INTERVENTIONS → VISITS & PROFILES → ACTIVITIES & ASSESSMENTS

Study Population

- Inclusion Criteria
- Inclusion Criteria
- Randomisation Criteria
- Dosing Criteria
- Withdrawal Criteria
- Other Criteria

Study Interventions (CDISC DEV-0)

Search

Select rows

Table with 2 columns: Study intervention type information, Selected values

Study Objectives (CDISC DEV-0)

Search

Select rows

Table with 6 columns: Objective level, Objective, Endpoint count, Modified, Modified by, Actions

Study Schedules (CDISC DEV-0)

Study visit overview

Timeline chart showing visit dates and durations

Table with 12 columns: Visit type, Visit number, Visit start date, Visit end date, Visit duration, Visit description, Visit location, Visit status, Visit comments, Visit actions

Protocol Elements (CDISC DEV-0)

Flow Chart

Objective, Endpoints and Estimands

Study Design

Study Population

Study Assessments

Table with 4 columns: Objectives and endpoints, Endpoints, Time Frame, Unit

Protocol Elements (CDISC DEV-0)

Flow Chart

Objective, Endpoints and Estimands

Study Design

Study Population

Study Assessments

Table with 12 columns: Visit, Visit type, Visit number, Visit start date, Visit end date, Visit duration, Visit description, Visit location, Visit status, Visit comments, Visit actions

The image displays a collage of screenshots from the StudyBuilder application interface, showcasing various modules and data views. The interface is designed for managing clinical trial metadata and standards.

CT Catalogues

This module displays a table of CT Catalogues with columns: Library, Concept ID, Sponsor preferred name, Template parameter, Code list status, Name modified, Code list name, Submission value, NCI Preferred name, Extensible, Attributes status, Attributes modified, and Actions. The table lists various CT Catalogues, including CDISC, EDC, and others, with their respective status and modification dates.

SNOMED

This module displays a table of SNOMED terms with columns: Library, SNOMED ID, Name, Lower case name, Abbreviation, Definition, Status, Version, Modified, and Actions. The table lists various SNOMED terms, including SNOMED CT, SNOMED PT, and others, with their respective status and modification dates.

MED-RT

This module displays a table of MED-RT terms with columns: Library, MED-RT ID, Name, Lower case name, Abbreviation, Definition, Status, Version, Modified, and Actions. The table lists various MED-RT terms, including MED-RT CT, MED-RT PT, and others, with their respective status and modification dates.

Objective Templates

This module displays a table of Objective Templates with columns: Indication or disorder, Study phase(s), Objective category, Confirmatory testing, Template, Modified by, Modified by, Status, Version, and Actions. The table lists various Objective Templates, including Objective Templates, Endpoint Templates, and others, with their respective status and modification dates.

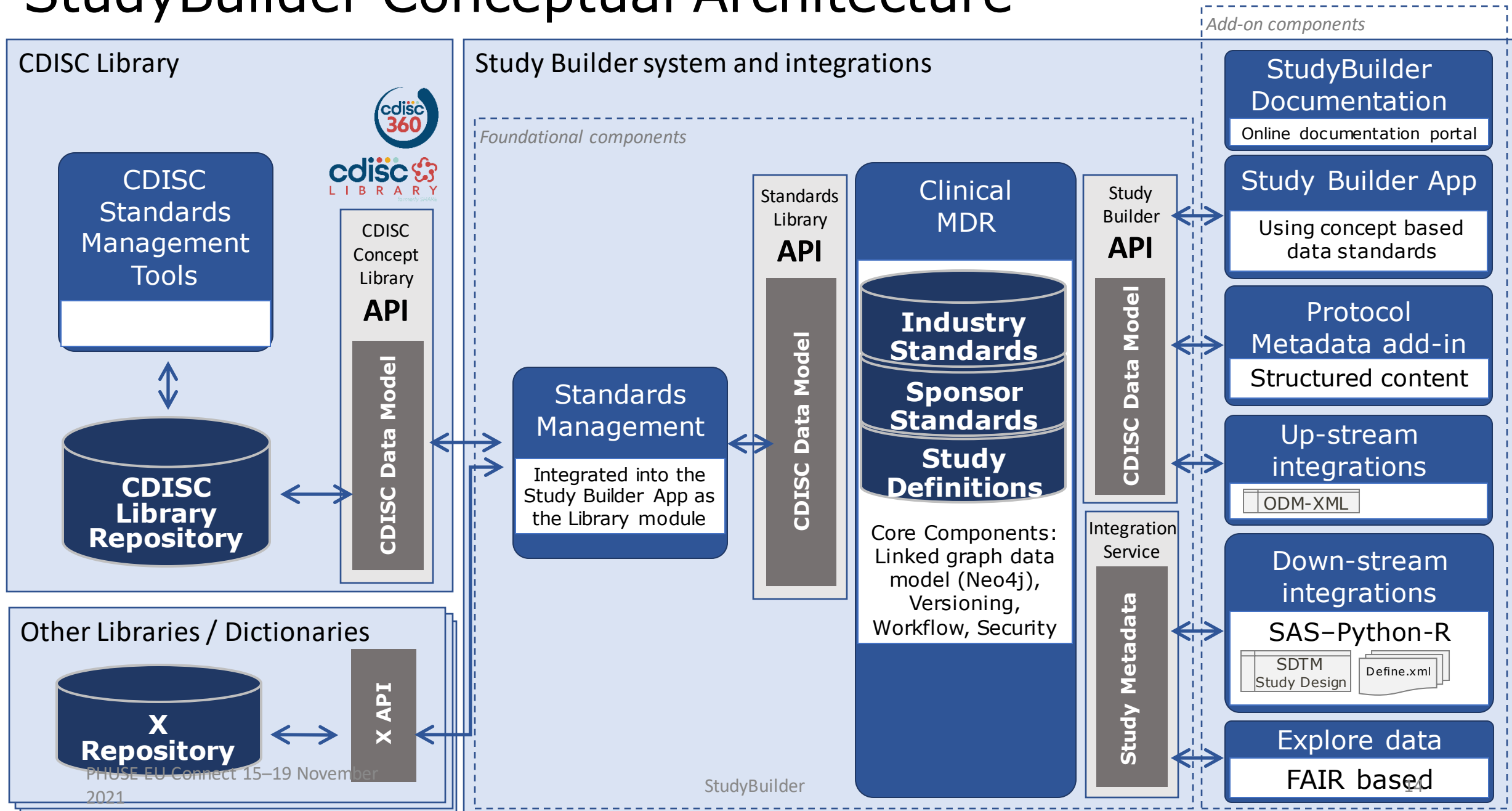
Code lists / Terms dashboard

This dashboard provides an overview of code lists and terms. It includes charts showing the evolution of code lists over time and the evolution of terms over time. The charts show the number of code lists and terms added over time, with a color-coded legend for different categories.

Latest added code lists

This table lists the latest added code lists with columns: Library, Concept ID, Sponsor preferred name, Template parameter, Name status, Modified, Code list name, Submission value, Extensible, Code list status, and Modified. The table lists various code lists, including CDISC, EDC, and others, with their respective status and modification dates.

StudyBuilder Conceptual Architecture





StudyBuilder next steps

- We will do a pilot release internally at Novo Nordisk end of year
- We plan a production release during 2022
- We intend to share the project as an open source project under COSA
- We seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors