

WITH STANDARDS – UNLOCK THE POWER OF DATA



2022

EUROPE

INTERCHANGE

27-28 APRIL | VIRTUAL EVENT

OpenStudyBuilder

Mikkel Traun, Principal System Developer
Sinna Lisa Vange,
Novo Nordisk A/S

Meet the Speakers

Mikkel Traun

Title: Principal System Developer

Organization: Novo Nordisk A/S

Mikkel is one of the product owners for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.



Sinna Lisa Vange

Title: Medical Writing VP

Organization: Novo Nordisk A/S

Sinna has been the other product owner for the new study builder and data standards repository solution. Sinna is a senior principal specialist and has been involved as clinical submission team leader and communication and submission expert on numerous regulatory applications for over the past 9 years. Previously, she was Vice President for the medical writing function at Novo Nordisk driving the development of medical writing and clinical publishing as well as the transition from paper to electronic submissions. Sinna has been involved in a wide range of IT projects over the years bringing in the end-to-end business understanding.





Disclaimer and Disclosures

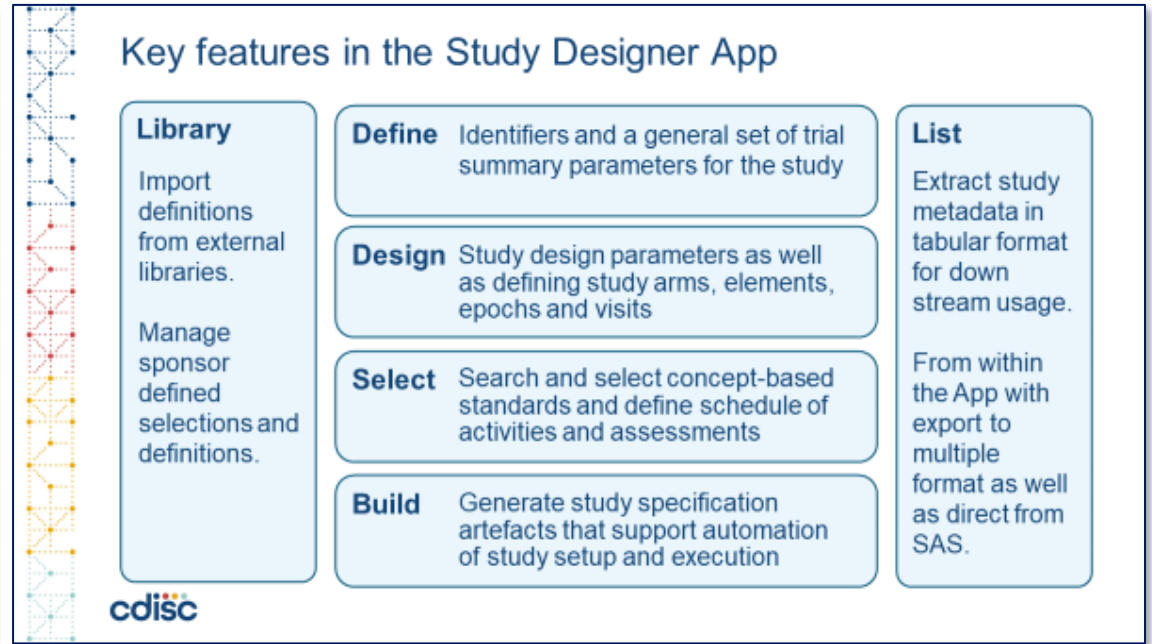
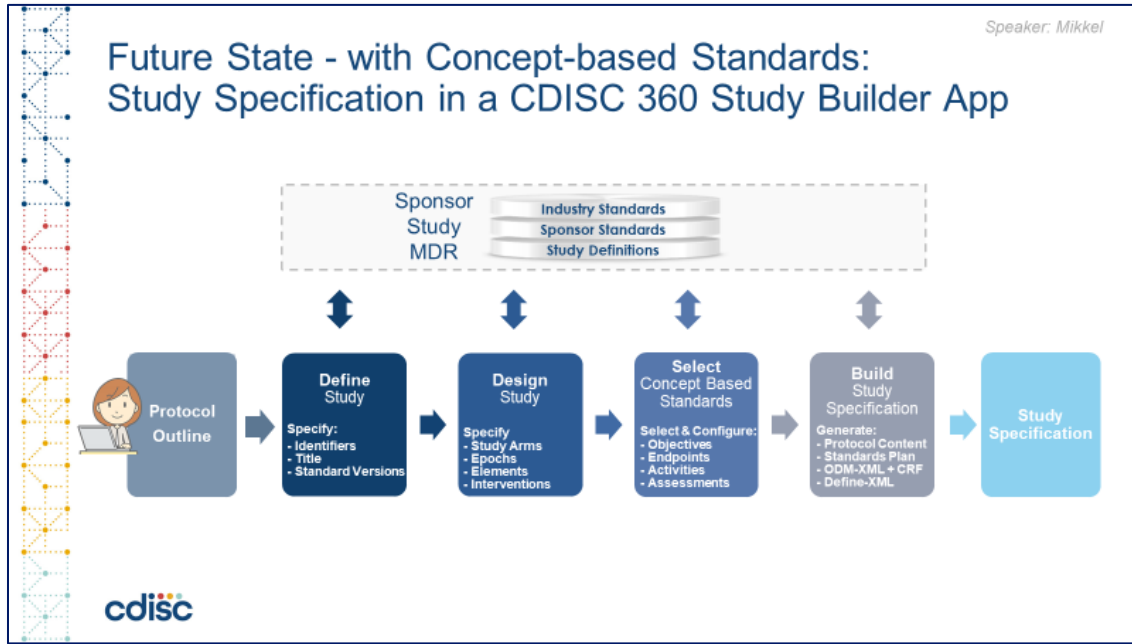
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Project scope

- **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 MDR 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 NN custom solution



We are building an OpenStudyBuilder 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 solution

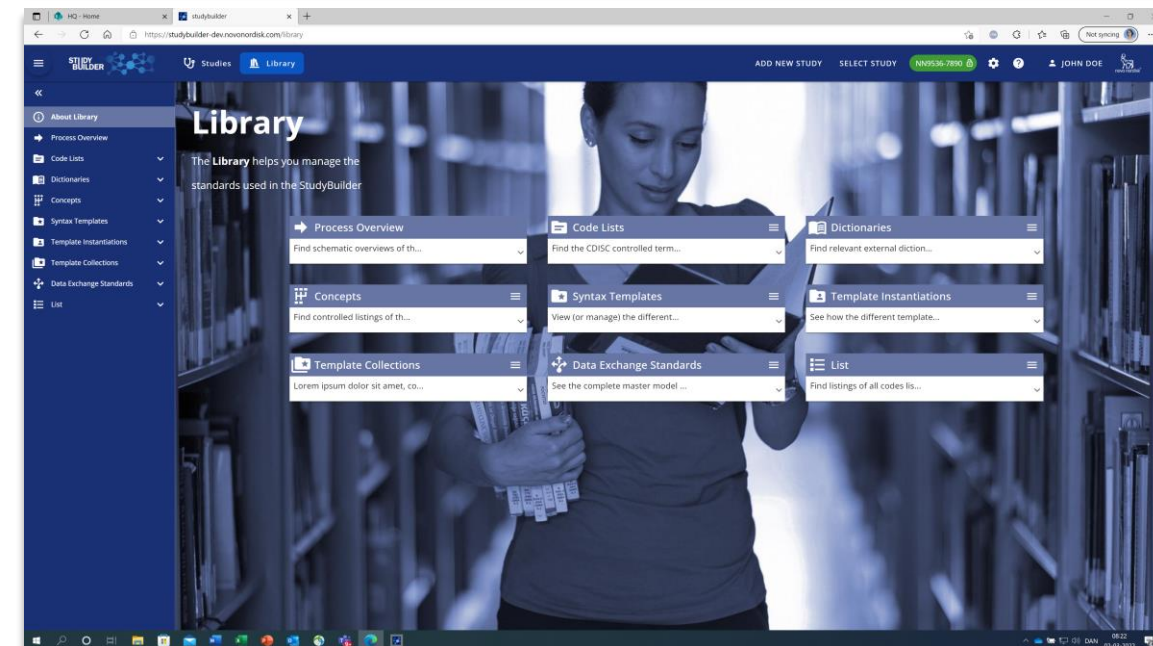
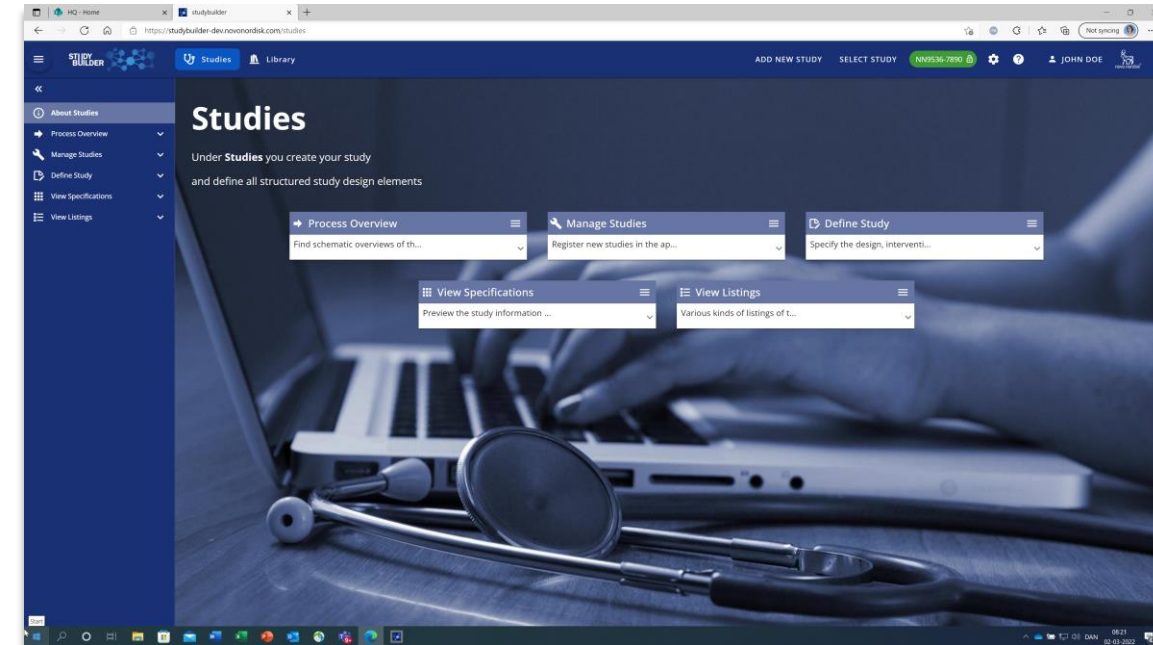
What is the OpenStudyBuilder ...

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



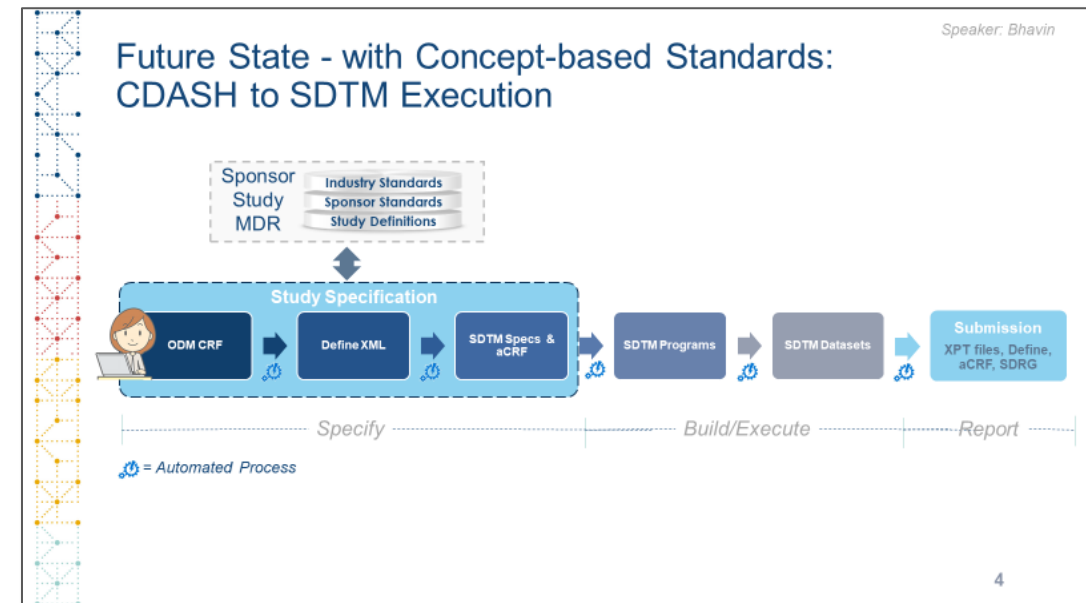
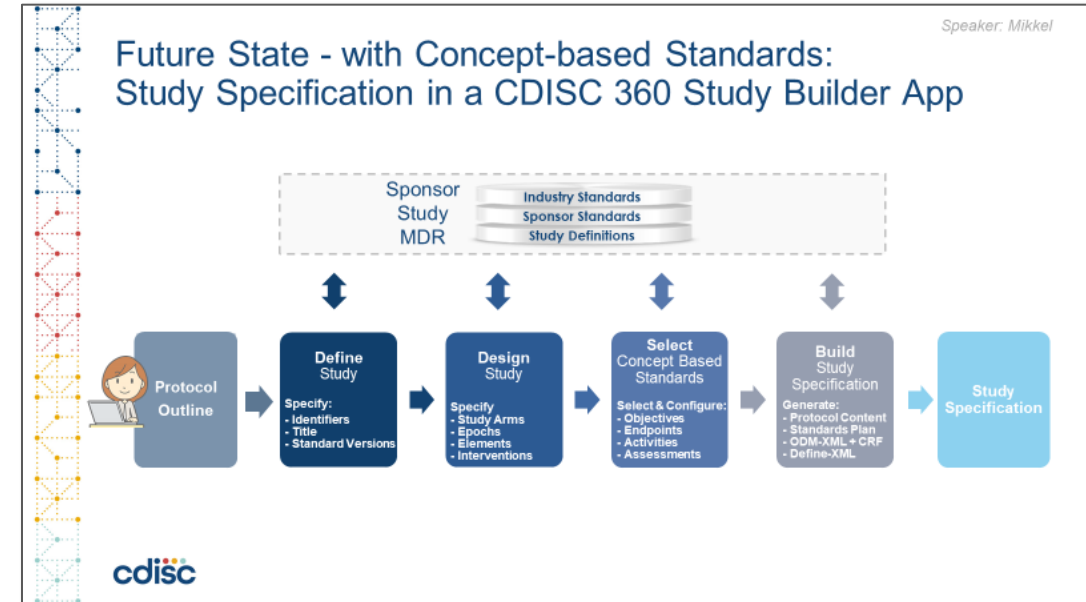
The OpenStudyBuilder includes

- A **Studies** part for specification of studies, including disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions
- A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study and cross-project harmonisation
- An underlying **knowledge database** enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end



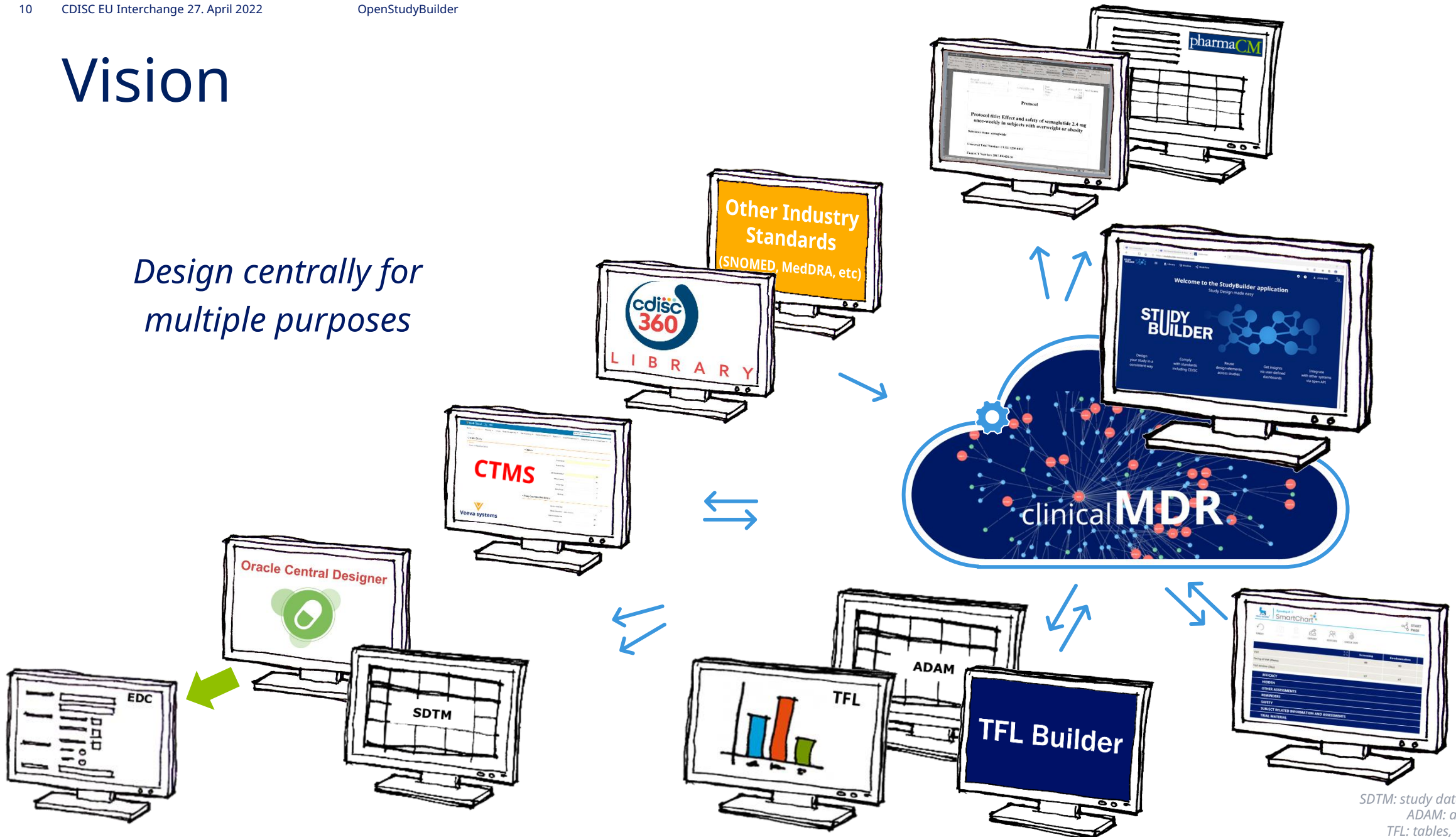
To apply concept-based data standards end-to-end

- From protocol preparation through study conduct to reporting and submission of applications to health authorities
 - and with reference to externally-compliant concept-based data standards and terminology
- Ensuring build-in compliance, and enabling more automation, efficient reuse across studies and projects, and aggregation of study specification details for insights



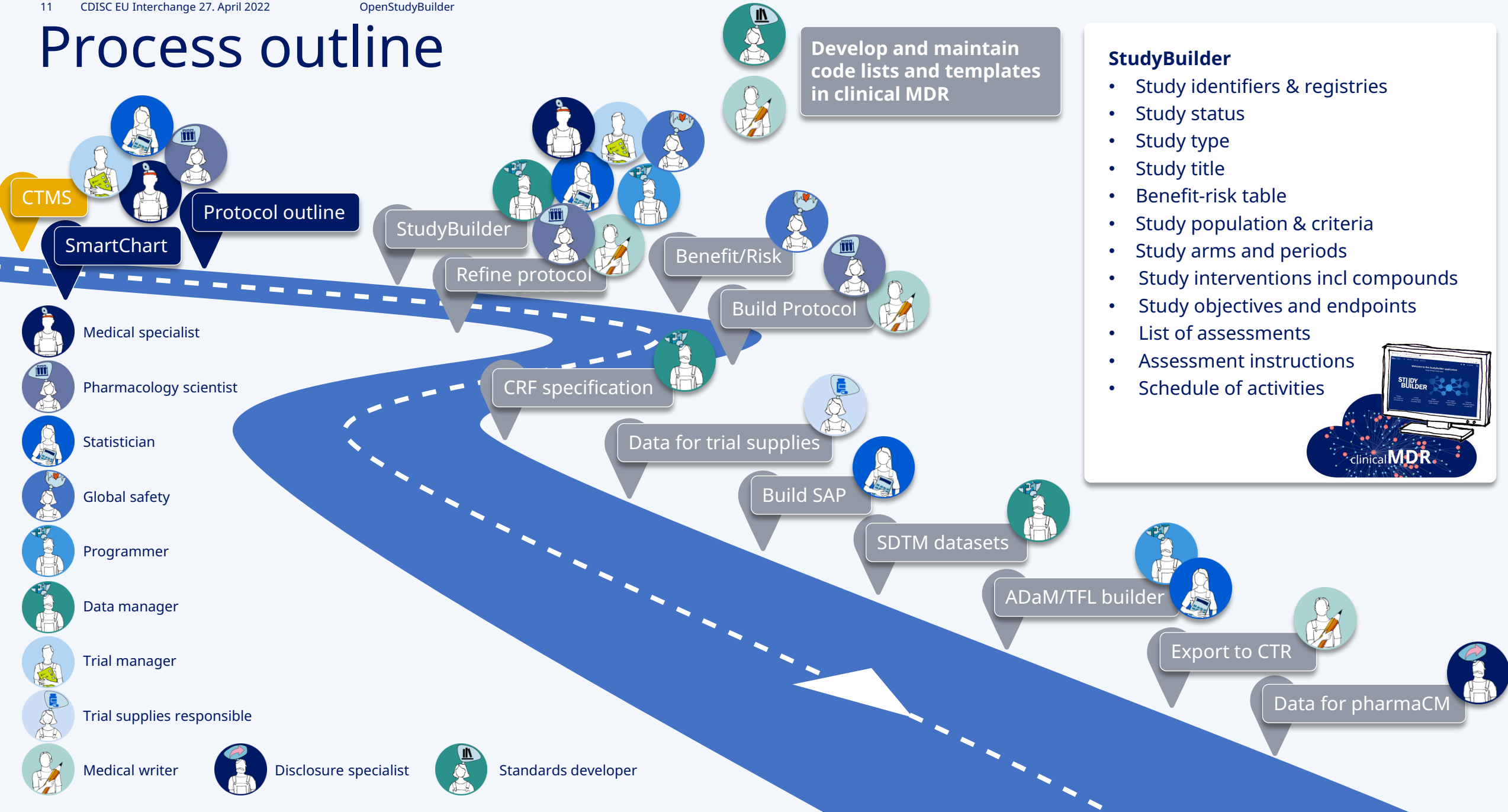
Vision

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



CTMS

SmartChart

Protocol outline

StudyBuilder

Refine protocol

Benefit/Risk

Build Protocol

CRF specification

Data for trial supplies

Build SAP

SDTM datasets

ADaM/TFL builder

Export to CTR

Data for pharmaCM

Develop and maintain code lists and templates in clinical MDR

StudyBuilder

- Study identifiers & registries
- Study status
- Study type
- Study title
- Benefit-risk table
- Study population & criteria
- Study arms and periods
- Study interventions incl compounds
- Study objectives and endpoints
- List of assessments
- Assessment instructions
- Schedule of activities

Medical specialist

Pharmacology scientist

Statistician

Global safety

Programmer

Data manager

Trial manager

Trial supplies responsible

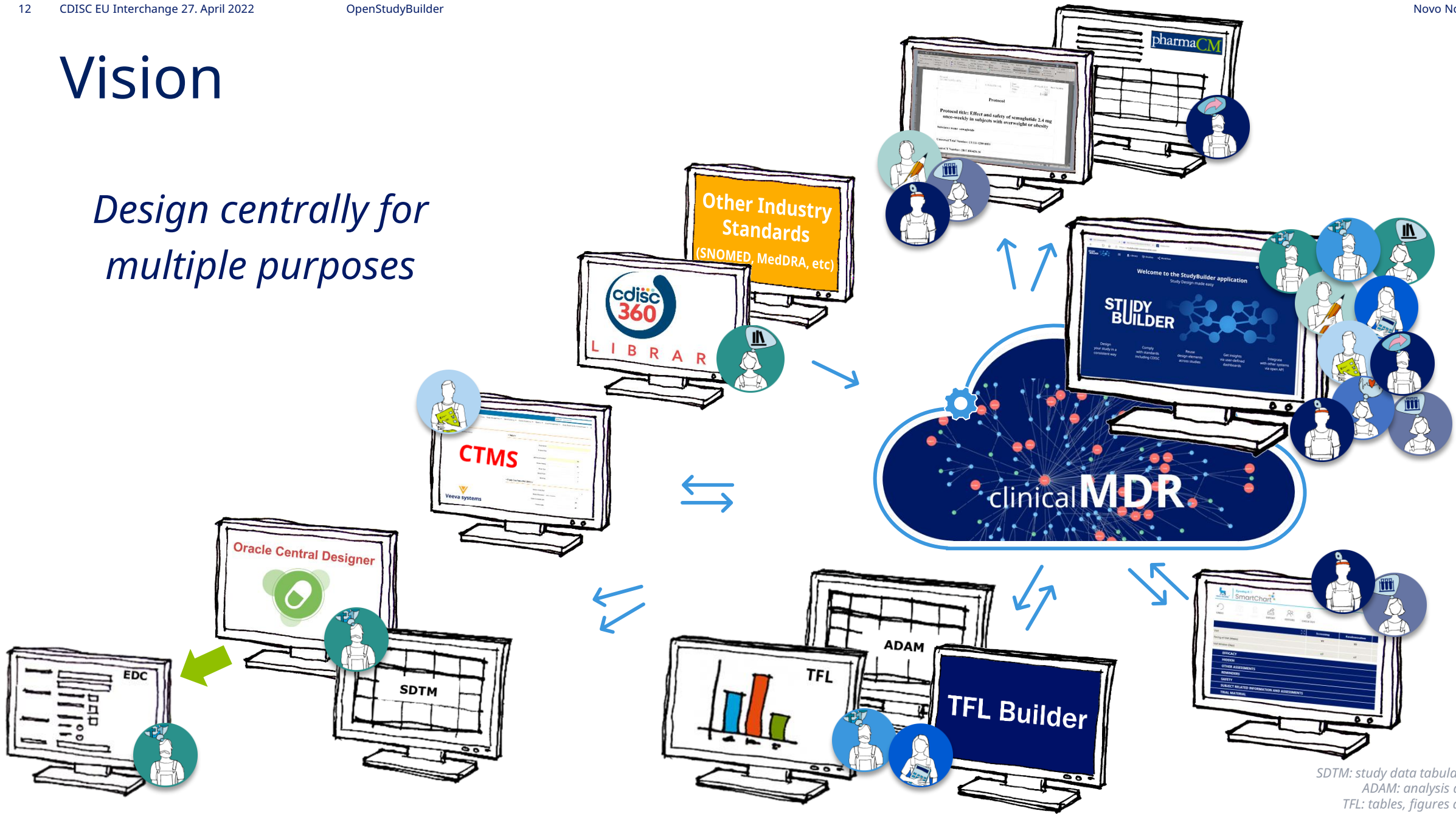
Medical writer

Disclosure specialist

Standards developer

Vision

Design centrally for multiple purposes



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

Core capabilities for a standards based OpenStudyBuilder

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

The image displays a comprehensive view of the OpenStudyBuilder application interface, which is used for creating and managing clinical study protocols. The interface is organized into several key sections:

- Navigation and Overview:** The top navigation bar includes 'About Studies', 'Dashboard', 'Manage Studies', and 'Define Study'. The user profile 'JOHN DOE' and system version 'CDISC DEV-0' are visible in the top right.
- Select or Add Study:** A table listing various study entries with columns for Project ID, Project name, Brand name, Study number, Study ID, Study acronym, Study title, Status, and Modified dates.
- Protocol Process:** A central flowchart illustrating the sequence of steps in protocol development: SELECT STUDY OR ADD NEW STUDY → STUDY PURPOSE → STUDY DESIGN → STUDY POPULATION → STUDY INTERVENTIONS → VISITS & PROFILES → ACTIVITIES & ASSESSMENTS. A dropdown menu for 'STUDY POPULATION' lists criteria such as Inclusion, Exclusion, Randomisation, Dosing, and Withdrawal.
- Study Schedules (CDISC DEV-0):** A Gantt-style chart showing the timeline of study events, including Baseline, Randomisation, and Follow-up periods.
- Study Objectives (CDISC DEV-0):** A table defining the study's goals, including Primary and Secondary Objectives, their descriptions, endpoint counts, and modification dates.
- Protocol Elements (CDISC DEV-0):** A detailed view of study specifications, including a table for Objectives and Endpoints, and a complex table for Protocol Elements (Phenomenon, Intervention, Assessment, etc.) over time.

- STUDY BUILDER
- Studies
- Library
- About Library
- Process Overview
- Code Lists
- Dashboard
- CT Catalogues
- CT Packages
- CDISC
- Sponsor
- Dictionaries
- SNOMED
- MedDRA
- MED-RT
- Assessment Templates
- Activity Templates
- Template Instantiations
- Template Collections
- Data Exchange Standards
- List

Library / Code Lists / CT Catalogues

Search

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	Actions
CDISC	C18029	Category of Questionnaire		Yes	Sep 30, 2021, 12:00 PM	Category of Questionnaire	OSCAT	CDISC Questionnaire Category for Survey	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18038	Relationship to Subject	No	Yes	Sep 30, 2021, 1:18 PM	Relationship to Subject	RELSUB	CDISC Subject Relationship to Subject Terminology	Yes	Yes	Sep 26, 2014, 12:00 AM	
CDISC	C18031	Adherence Disease Assessment Scale - Cognitive CDISC Version	No	Yes	Sep 30, 2021, 1:20 PM	Adherence Disease Assessment Scale - Cognitive CDISC Version	ADCTN	CDISC Questionnaire ADCTN Cognitive CDISC Version Terminology	No	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18032	Adherence Disease Assessment Scale - Cognitive CDISC Version	No	Yes	Sep 30, 2021, 1:20 PM	Adherence Disease Assessment Scale - Cognitive CDISC Version	ADCTC	CDISC Questionnaire ADCTC Cognitive CDISC Version Terminology	No	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18033	Brief Psychiatric Rating Scale - Clinical Classification Test Name	No	Yes	Sep 30, 2021, 1:20 PM	Brief Psychiatric Rating Scale - Clinical Classification Test Name	BPSR41N	CDISC Clinical Classification Test Name Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18034	Brief Psychiatric Rating Scale - Clinical Classification Test Code	No	Yes	Sep 30, 2021, 1:20 PM	Brief Psychiatric Rating Scale - Clinical Classification Test Code	BPSR41C	CDISC Clinical Classification Test Code Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18035	European Quality of Life Five Dimension Three Level Scale	No	Yes	Sep 30, 2021, 1:20 PM	European Quality of Life Five Dimension Three Level Scale	EQ5D3L	CDISC Questionnaire EQ5D3L Test Name Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18036	European Quality of Life Five Dimension Three Level Scale	No	Yes	Sep 30, 2021, 1:20 PM	European Quality of Life Five Dimension Three Level Scale	EQ5D3L	CDISC Questionnaire EQ5D3L Test Code Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18037	Hypertension Questionnaire	No	Yes	Sep 30, 2021, 1:20 PM	Hypertension Questionnaire	HQND1N	CDISC Clinical Classification Test Name Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	

Library / Code Lists / CT Packages

Search

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	Actions
CDISC	C12729	Observational Study Model	No	Yes	Sep 30, 2021, 1:20 PM	Observational Study Model	OBSDMO	CDISC OTM Observational Study Model Terminology	Yes	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C18038	Physical Address	No	Yes	Sep 30, 2021, 1:18 PM	Physical Address	PHYSAD	CDISC Protocol Address Physical Address Terminology	No	Yes	Mar 31, 2015, 12:00 AM	
CDISC	C18259	Study Protocol	No	Yes	Sep 30, 2021, 1:18 PM	Study Protocol	STUDPRO	CDISC Protocol Address Study Protocol Terminology	No	Yes	Mar 31, 2021, 12:00 AM	
CDISC	C18039	Protocol Entry	No	Yes	Sep 30, 2021, 1:18 PM	Protocol Entry	PROTENTR	CDISC Protocol Address Protocol Entry Terminology	No	Yes	Mar 31, 2015, 12:00 AM	
CDISC	C18068	Clinical Trial	No	Yes	Sep 30, 2021, 1:20 PM	Clinical Trial	CLINTRIA	CDISC Protocol Address Clinical Trial Terminology	No	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C14214	Clinical Study	No	Yes	Sep 30, 2021, 1:20 PM	Clinical Study	CLINCLST	CDISC Protocol Address Clinical Study Terminology	No	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C14764	Study Design	No	Yes	Sep 30, 2021, 1:20 PM	Study Design	STUDDES	CDISC Protocol Address Study Design Terminology	No	Yes	Mar 28, 2021, 12:00 AM	
CDISC	C14767	Study Purpose	No	Yes	Sep 30, 2021, 1:20 PM	Study Purpose	STUDPUR	CDISC Protocol Address Study Purpose Terminology	No	Yes	Mar 28, 2021, 12:00 AM	

Library / Code Lists / Dashboard

Code lists / Terms dashboard

of Code Lists in CDISC: 1384
of Code Lists in Sponsor: 1

of Terms in CDISC: 12420
of Terms in Sponsor: 1

Mean # of evolution / code lists (%)
Mean # of evolution / terms (%)

Latest added code lists

Library	Concept ID	Sponsor preferred name	Template parameter	Name status	Modified	Code list name	Submission value	Extensible	Code list status	Modified
CDISC	C18038	Relationship to Subject	No	Yes	Sep 30, 2021, 1:18 PM	Relationship to Subject	RELSUB	Yes	Yes	Sep 28, 2014, 12:00 AM
CDISC	C18037	System Test Name	No	Yes	Sep 30, 2021, 1:18 PM	System Test Name	STESTN	Yes	Yes	Sep 28, 2014, 12:00 AM
CDISC	C18036	System Test Code	No	Yes	Sep 30, 2021, 1:18 PM	System Test Code	STESTC	Yes	Yes	Sep 28, 2014, 12:00 AM

different listings available in the library, provide step-by-step illustration of how hyperlinks to the pages and tasks are executed.

Assessments and Area to define templates that are used as a pattern for study level metadata with a cascade update procedure (version control)

Library / Dictionaries / SNOMED

Search

Library	SNOMED	Name	Lower case name	Abbreviation	Definition	Status	Version	Modified	Actions
SNOMED	8956802	Pregnancy type 1 diabetes mellitus in pregnancy	pregnancy type 1 diabetes mellitus in pregnancy		Pregnancy type 1 diabetes mellitus in pregnancy (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4802100	Heart failure with normal ejection fraction	heart failure with normal ejection fraction	HFNF	Heart failure with normal ejection fraction (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4401003	Nonalcoholic steatohepatitis	nonalcoholic steatohepatitis	NASH	Nonalcoholic steatohepatitis (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4410003	Severe hereditary factor II deficiency disease without inhibitor	severe hereditary factor II deficiency disease without inhibitor		Severe hereditary factor II deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4409509	Severe hereditary factor III deficiency disease without inhibitor	severe hereditary factor III deficiency disease without inhibitor		Severe hereditary factor III deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4387009	Severe hereditary factor IV deficiency disease without inhibitor	severe hereditary factor IV deficiency disease without inhibitor		Severe hereditary factor IV deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4387105	Severe hereditary factor VI deficiency disease without inhibitor	severe hereditary factor VI deficiency disease without inhibitor		Severe hereditary factor VI deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4387200	Hereditary factor IX deficiency disease without inhibitor	hereditary factor IX deficiency disease without inhibitor		Hereditary factor IX deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4389306	Hereditary factor VII deficiency disease without inhibitor	hereditary factor VII deficiency disease without inhibitor		Hereditary factor VII deficiency disease without inhibitor (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	4710806	Adult growth hormone deficiency	adult growth hormone deficiency		Adult growth hormone deficiency (SNOMED)	Yes	1.0	Sep 30, 2021, 1:57 PM	

Library / Dictionaries / MED-RT

Search

Library	MED-RT	Name	Lower case name	Abbreviations	Definition	Status	Version	Modified	Actions
MED-RT	N00007544	Lithium	lithium		Lithium (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007545	Zithromax	zithromax		Zithromax (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007546	Tuberculosis Agent	tuberculosis agent		Tuberculosis Agent (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00008196	Thrombolysis	thrombolysis		Thrombolysis (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007548	Sulfonamides	sulfonamides		Sulfonamides (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007549	Sulfonamides	sulfonamides		Sulfonamides (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007550	Sulfonamide Contingent 2 Inhibitor	sulfonamide contingent 2 inhibitor		Sulfonamide Contingent 2 Inhibitor (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007546	Recombinant Human Growth Hormone	recombinant human growth hormone		Recombinant Human Growth Hormone (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007547	Quinine Antimalarial	quinine antimalarial		Quinine Antimalarial (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N00007553	Proton Pump Inhibitor	proton pump inhibitor		Proton Pump Inhibitor (MED-RT)	Yes	1.0	Sep 30, 2021, 1:57 PM	

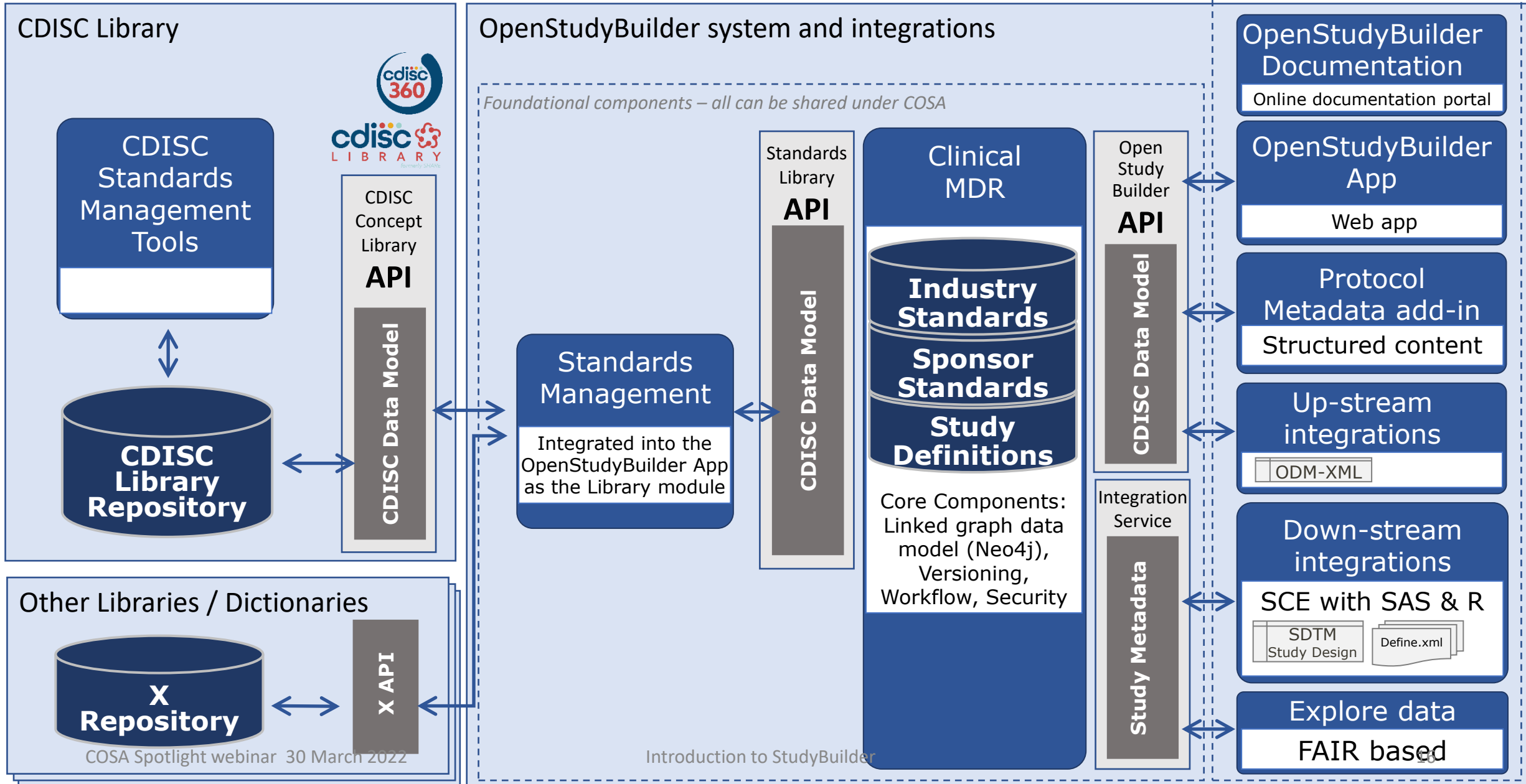
Library / System Templates / Objective Templates

Search

Indication or disorder	Study phase(s)	Objective category	Confirmatory testing	Template	Modified	Modified by	Status	Version	Actions
Diabetes mellitus	Phase I, Phase II	Efficacy	No	To explore the efficacy with respect to glycaemic control of [Compound] in participants with [Condition]. In combination with [Condition].	Oct 3, 2021, 12:47 PM		Open	0.1	
Diabetes mellitus, Obesity	Phase II	Efficacy	Yes	To demonstrate the appearance of [Condition] with respect to change in [Condition] from [Condition] to [Condition] in participants with [Condition].	Oct 3, 2021, 12:42 PM		Open	0.1	
Obesity	Phase I, Phase II	Safety	No	To compare the safety and tolerability of [Compound] and [Condition], both in combination with [Condition] and [Condition].	Oct 3, 2021, 12:34 PM		Open	1.0	
	Phase I	Bioprecursor	Yes	To confirm the bioprecursor of [Compound] and [Condition] with respect to AUC and Cmax in healthy individuals.	Oct 3, 2021, 12:28 PM		Open	1.0	
	Phase I	Bioprecursor	No	To demonstrate the bioprecursor of [Compound] with respect to AUC and Cmax in healthy individuals.	Oct 3, 2021, 12:24 PM		Open	1.0	

OpenStudyBuilder Conceptual Architecture

Add-on components
- some can be shared under COSA



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

