

# OPEN STUDY BUILDER



## Introduction to OpenStudyBuilder

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# 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

# Project scope

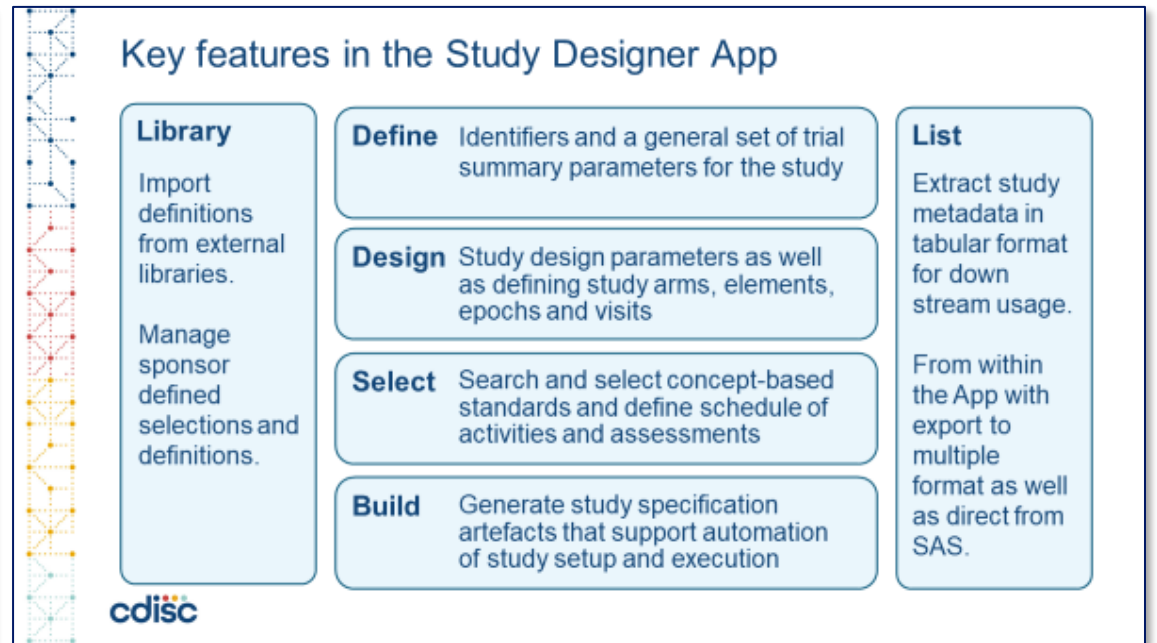
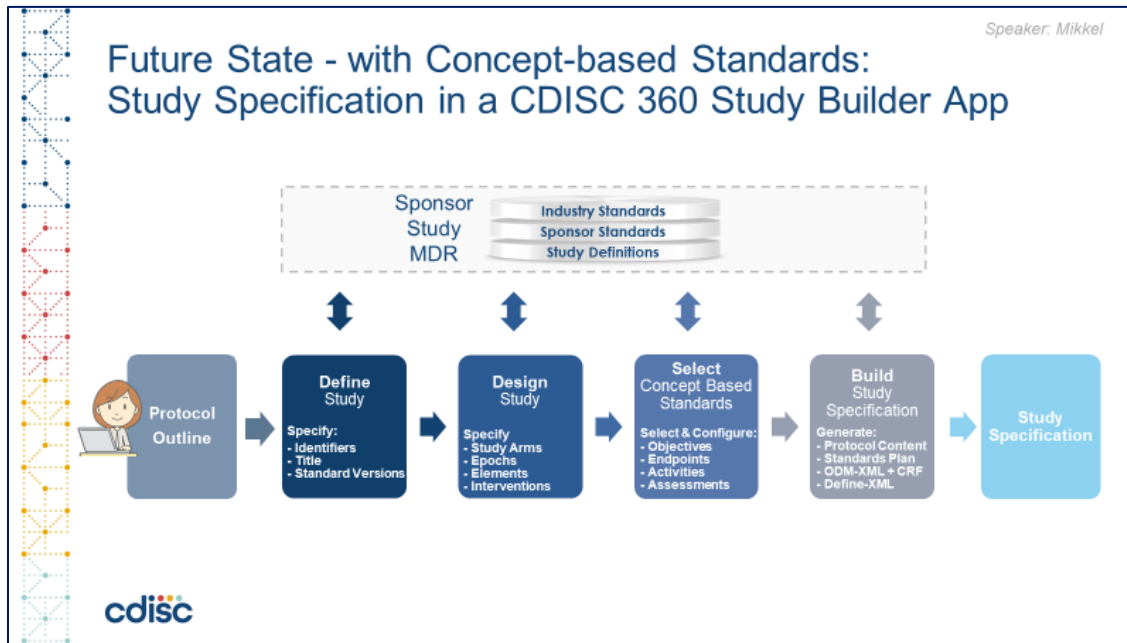
- **Establish a *study builder* solution**
  - To support the study specification process using concept based data standards *from* protocol development and CRF design *to* creation of submission datasets, analyses, reporting and public disclosure of study information
  - To promote seamless, cross-functional 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



# Why open source

- Avoiding a v2 custom solution
  - Solution based on industry standards
  - By driving this as an collaborative open source solution
- Benefit from collaborations
- Benefit from future tools and extensions

# We are building an OpenStudyBuilder and MDR solution based on the CDISC 360 POC



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

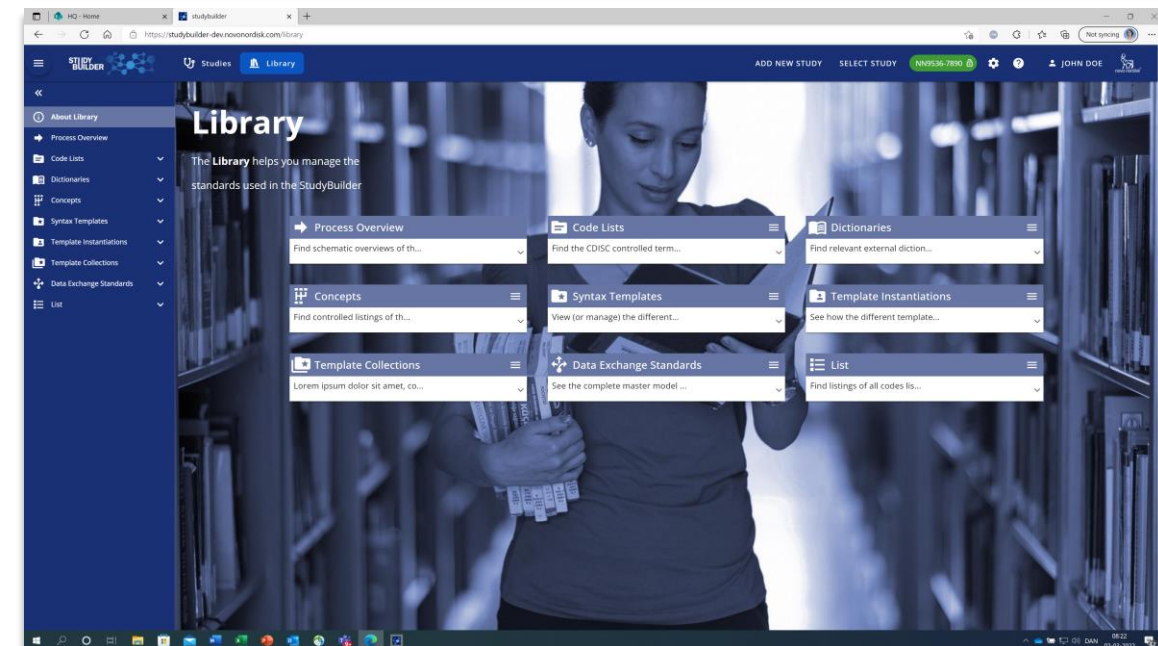
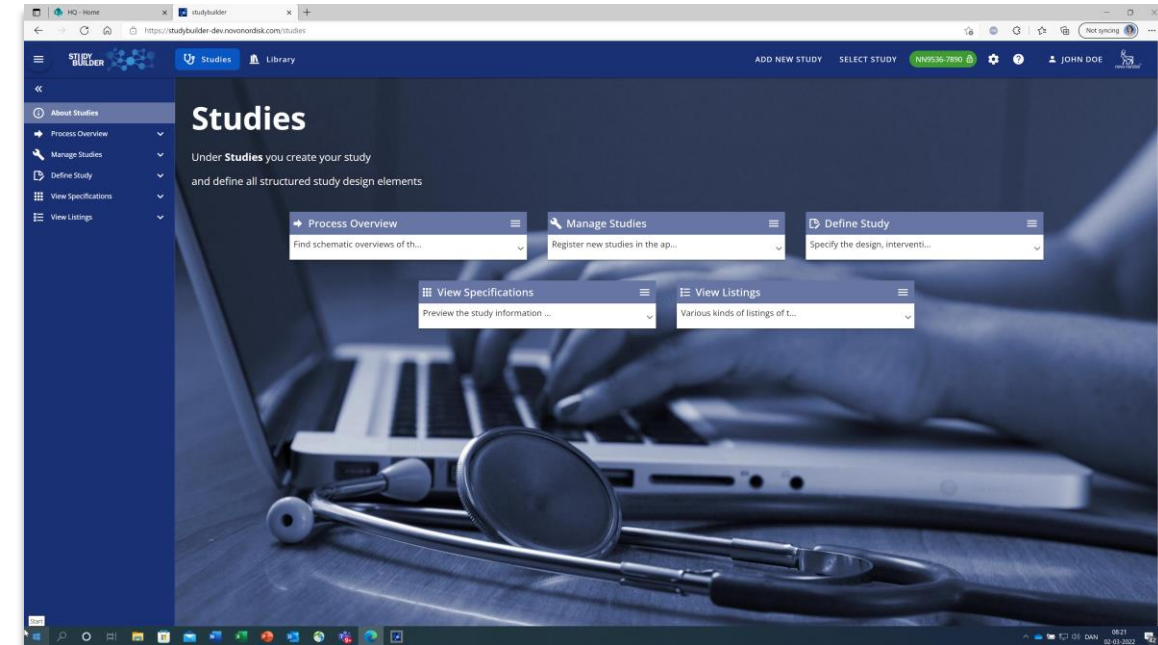
# What is the OpenStudyBuilder ...

- 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)



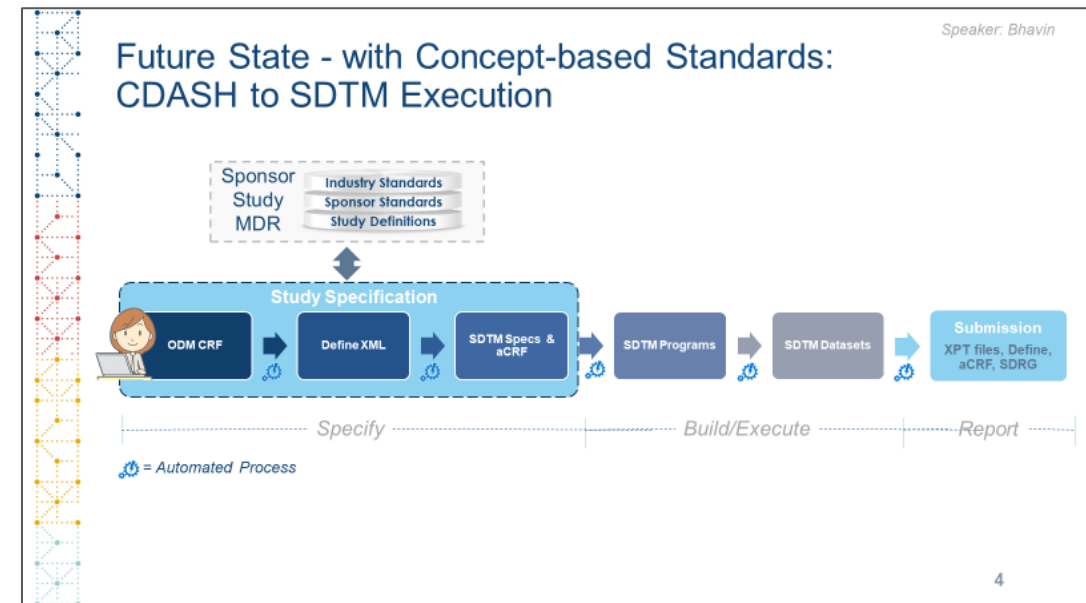
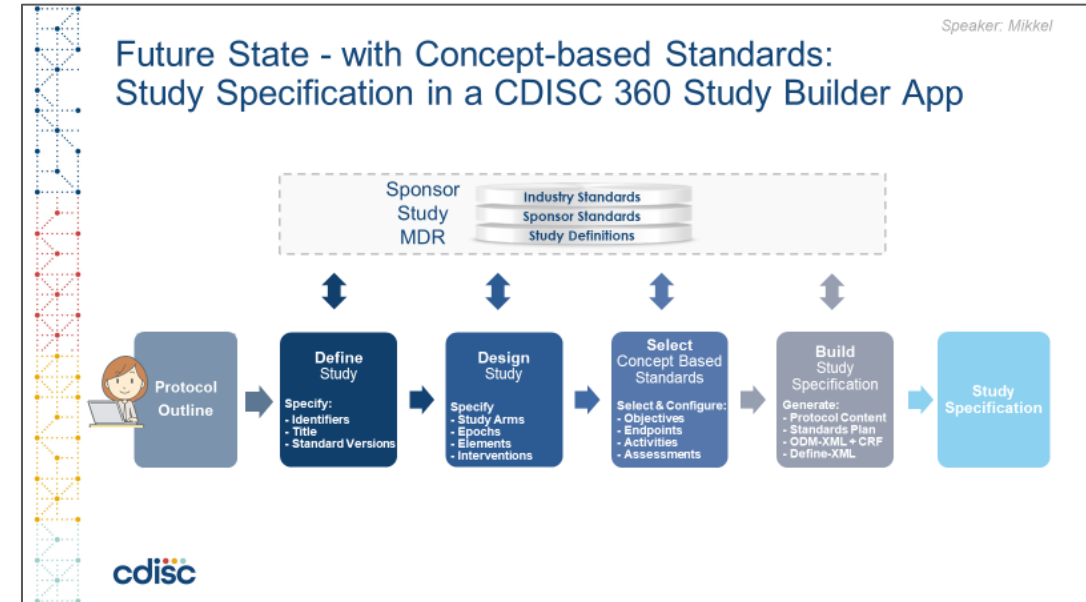
# The OpenStudyBuilder includes

- 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

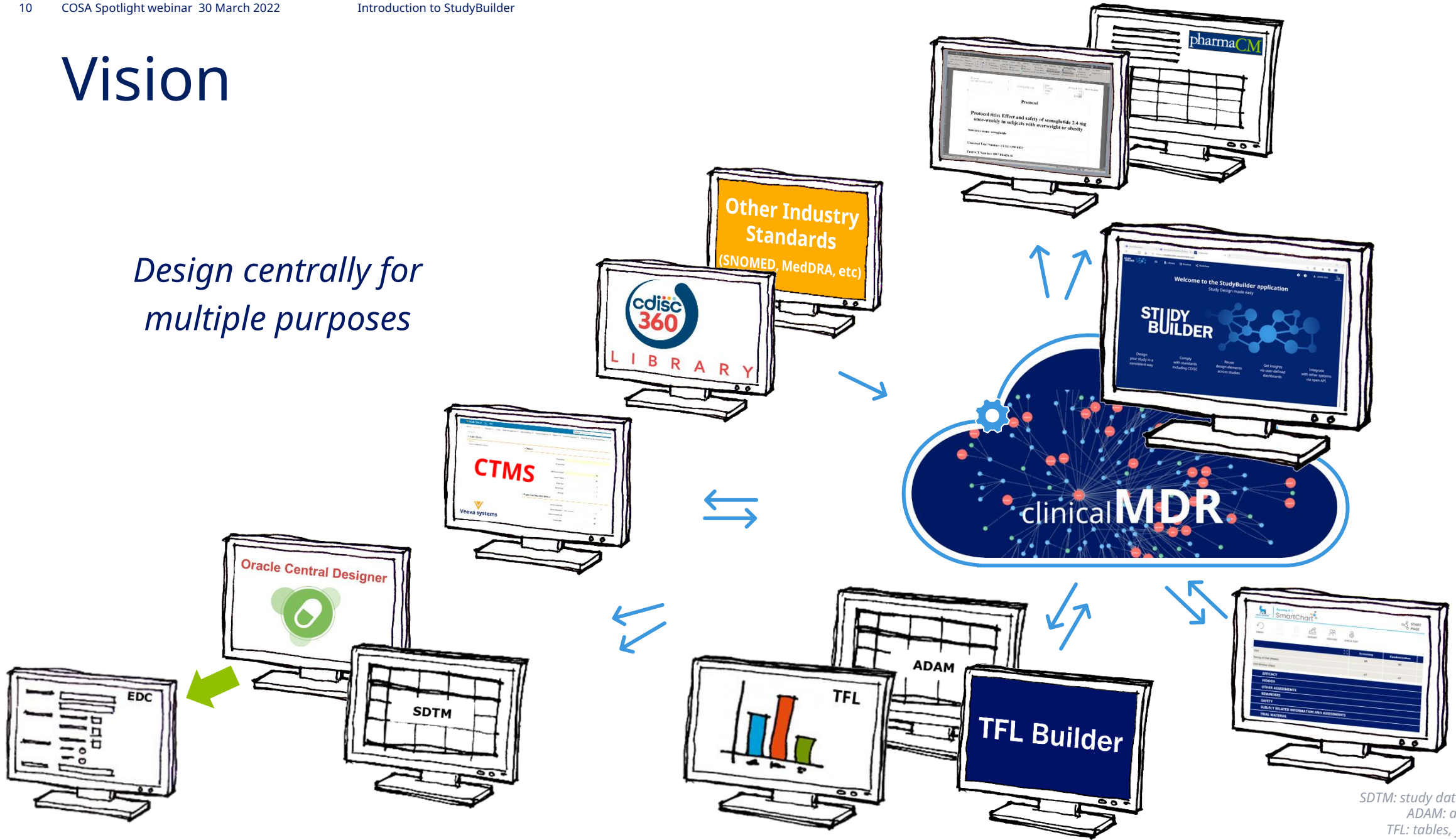
- From protocol preparation through study conduct to reporting and submission of applications to health authorities
  - and with reference to externally-compliant concept-based data standards and terminology
- Ensuring build-in compliance, and enabling more automation, efficient reuse across studies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





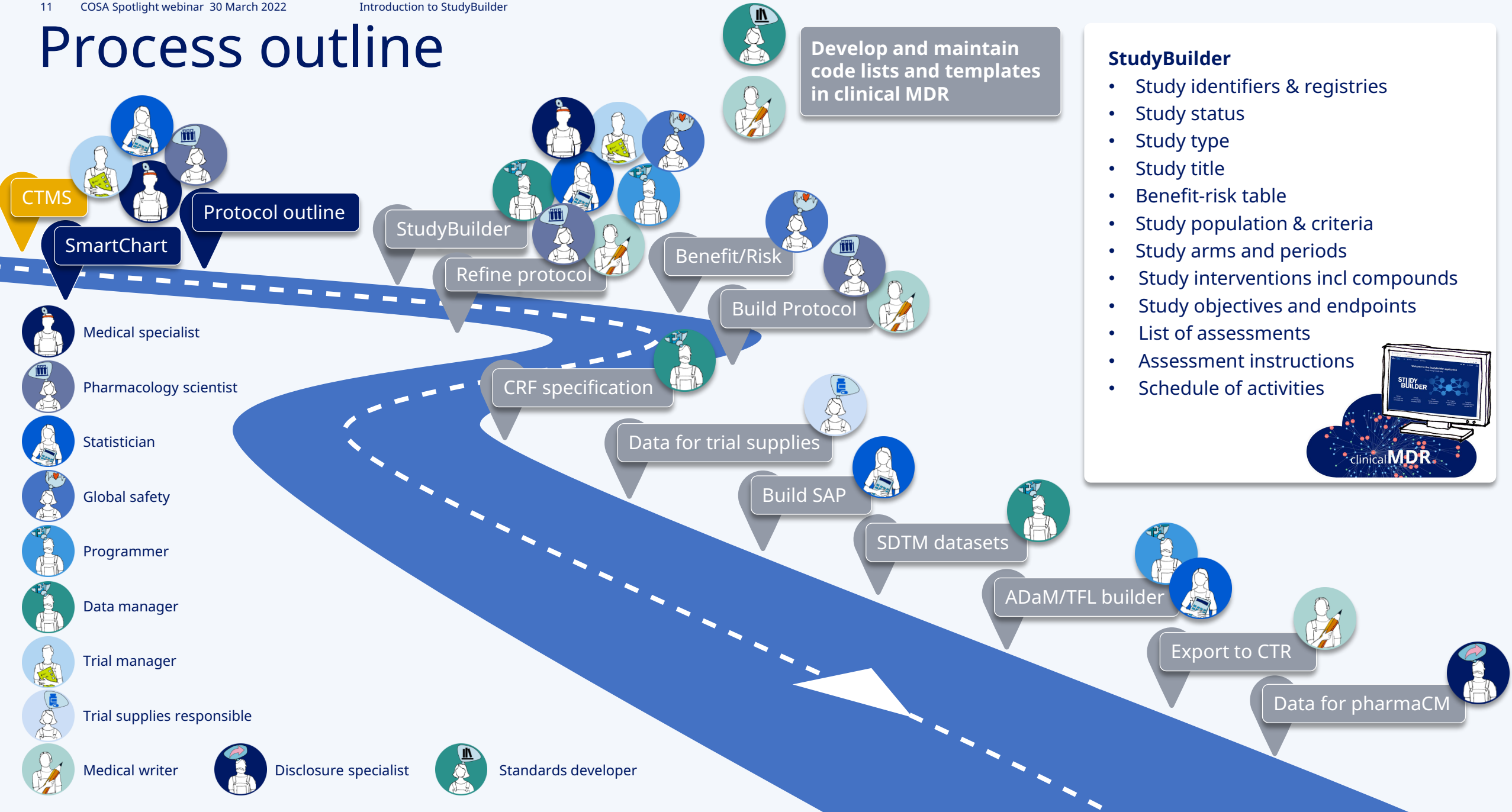
# Vision

*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



# 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 collage of screenshots from the StudyBuilder application interface, illustrating various modules and their functionalities. The interface is dark-themed with a blue sidebar and a main content area.

- Select or Add Study:** A table listing study details such as Project ID, Project name, Brand name, Study number, Study ID, Study acronym, Study title, Status, Modified, and Modified by. The table includes rows for different study phases like Clinical Programme, Modern Insulin, and CDISC Development programme.
- Protocol Process:** A flowchart titled 'Overview of protocol elements' showing the sequence: 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: Study Population, Inclusion Criteria, Inclusion Criteria, Randomisation Criteria, Dosing Criteria, Withdrawal Criteria, and Other Criteria.
- Study Schedules (CDISC DEV-0):** A Gantt chart showing study phases: Baseline, Randomisation, and Follow-up, with a timeline from week 0 to 100.
- Study Objectives (CDISC DEV-0):** A table listing objectives with columns for Objective level, Objective, Endpoint count, Modified, and Modified by. It shows a Primary Objective and a Secondary Objective.
- Protocol Elements (CDISC DEV-0):** A detailed view of objectives and endpoints. It includes a table for 'Objectives and endpoints' with columns for Title, Time frame, and Unit. It lists Primary and Secondary Objectives and various Additional Endpoints like 'Change in body weight', 'Number of adverse events', and 'Number of clinically significant hypoglycaemic episodes'.
- Protocol Elements (CDISC DEV-0):** A table showing a timeline of visits and events. The columns represent visits (V1-V24) and events (E1-E12). The table lists various events such as 'Visit 1 (All study day randomisation)', 'Visit 2 (Randomisation)', 'Eligibility Check', 'Randomisation Check and Randomisation', 'Annual Visit Fasting', 'Medical History/Current Status', 'Concomitant Therapy', 'Visit Sign', 'Physician Assessment', and 'Body Measurements'.

- 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

### CT Catalogues

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	C108129	Category of Questionnaire	No	True	Sep 30, 2021, 12:00 PM	Category of Questionnaire	OSCAT	CDISC Questionnaire Category for Survey	Yes	True	Mar 28, 2021, 12:00 AM	
CDISC	C108130	Relationship to Subject	No	True	Sep 30, 2021, 1:18 PM	Relationship to Subject	RELSUB	CDISC Subject Relationship to Subject Terminology	Yes	True	Sep 26, 2014, 12:00 AM	
CDISC	C108131	Adherence Disease Assessment Scale - Cognitive CDISC Version	No	True	Sep 30, 2021, 1:20 PM	Adherence Disease Assessment Scale - Cognitive CDISC Version	ADCTN	CDISC Questionnaire ADSC Cog CDISC Version Terminology	No	True	Mar 28, 2021, 12:00 AM	
CDISC	C108132	Adherence Disease Assessment Scale - Cognitive CDISC Version	No	True	Sep 30, 2021, 1:20 PM	Adherence Disease Assessment Scale - Cognitive CDISC Version	ADCTC	CDISC Questionnaire ADSC Cog CDISC Version Terminology	No	True	Mar 28, 2021, 12:00 AM	
CDISC	C108133	Brief Psychiatric Rating Scale - CDISC Classification Test Code	No	True	Sep 30, 2021, 1:20 PM	Brief Psychiatric Rating Scale - CDISC Classification Test Code	BPR5A17N	CDISC Clinical Classification Test Code Terminology	No	True	Sep 28, 2014, 12:00 AM	
CDISC	C108134	Brief Psychiatric Rating Scale - CDISC Classification Test Code	No	True	Sep 30, 2021, 1:20 PM	Brief Psychiatric Rating Scale - CDISC Classification Test Code	BPR5A17E	CDISC Clinical Classification Test Code Terminology	No	True	Sep 28, 2014, 12:00 AM	
CDISC	C108135	European Quality of Life Five Dimension Three Level Scale	No	True	Sep 30, 2021, 1:20 PM	European Quality of Life Five Dimension Three Level Scale	EQ5D17N	CDISC Questionnaire EQ5D-3L Test Code Terminology	No	True	Sep 28, 2014, 12:00 AM	
CDISC	C108136	European Quality of Life Five Dimension Three Level Scale	No	True	Sep 30, 2021, 1:20 PM	European Quality of Life Five Dimension Three Level Scale	EQ5D17E	CDISC Questionnaire EQ5D-3L Test Code Terminology	No	True	Sep 28, 2014, 12:00 AM	
CDISC	C108137	Hypertension Questionnaire Code	No	True	Sep 30, 2021, 1:20 PM	Hypertension Questionnaire Code	HQMD17N	CDISC Clinical Classification Test Code Terminology	No	True	Sep 28, 2014, 12:00 AM	

### CT Packages

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	C127259	Observational Study Model	No	True	Sep 30, 2021, 1:20 PM	Observational Study Model	OBSDMO	CDISC OTM Observational Study Model Terminology	Yes	True	Mar 28, 2021, 12:00 AM	
CDISC	C103268	Physical Address	No	True	Sep 30, 2021, 1:18 PM	Physical Address	PHYSADRES	CDISC Protocol Address Physical Address Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C103269	Study Protocol Address	No	True	Sep 30, 2021, 1:18 PM	Study Protocol Address	STUDPROTADRES	CDISC Protocol Address Study Protocol Address Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C103270	Protocol Entry	No	True	Sep 30, 2021, 1:18 PM	Protocol Entry	PROTENTRY	CDISC Protocol Address Protocol Entry Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C103668	Clinical Trial Address	No	True	Sep 30, 2021, 1:20 PM	Clinical Trial Address	CLINTRIALADRES	CDISC Protocol Address Clinical Trial Address Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C142191	Clinical Study Address	No	True	Sep 30, 2021, 1:20 PM	Clinical Study Address	CLINCLSTADRES	CDISC Protocol Address Clinical Study Address Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C147664	Study Design Address	No	True	Sep 30, 2021, 1:20 PM	Study Design Address	STUDDESIGNADRES	CDISC Protocol Address Study Design Address Terminology	No	True	Mar 31, 2015, 12:00 AM	
CDISC	C147673	Study Purpose Code List	No	True	Sep 30, 2021, 1:20 PM	Study Purpose Code List	STUDPURPOSECL	CDISC Protocol Address Study Purpose Code List Terminology	No	True	Mar 31, 2015, 12:00 AM	

### Code lists / Terms dashboard

# of Code Lists in CDISC: 1304  
# of Code Lists in Sponsor: 1  
# of Terms in CDISC: 12423  
# of Terms in Sponsor: 1

Match # of evaluation / code lists (%)  
Match # of evaluation / 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	C108130	Relationship to Subject	No	True	Sep 30, 2021, 1:18 PM	Relationship to Subject	RELSUB	Yes	True	Sep 28, 2014, 12:00 AM
CDISC	C108133	System Test Code Classification	No	True	Sep 30, 2021, 1:18 PM	System Test Code Classification	CTESTCLS	Yes	True	Sep 28, 2014, 12:00 AM
CDISC	C108134	System Test Code	No	True	Sep 30, 2021, 1:18 PM	System Test Code	CTESTSCTD	Yes	True	Sep 28, 2014, 12:00 AM

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

### SNOMED

Library	SNOMED	Name	Lower case name	Abbreviation	Definition	Status	Version	Modified	Actions
SNOMED	89394802	Pregnancy (type 1 diabetes mellitus in pregnancy)	pregnancy type 1 diabetes mellitus in pregnancy		Pregnancy (type 1 diabetes mellitus in pregnancy)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	440221000	Heart failure with normal ejection fraction (disorder)	heart failure with normal ejection fraction (disorder)	HFNFJ	Heart failure with normal ejection fraction (disorder)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	440222000	Heart failure with reduced ejection fraction (disorder)	heart failure with reduced ejection fraction (disorder)	HFNRJ	Heart failure with reduced ejection fraction (disorder)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	44110003	Severe hereditary factor IX deficiency (disorder without inhibitor)	severe hereditary factor ix deficiency (disorder without inhibitor)		Severe hereditary factor IX deficiency (disorder without inhibitor)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	44093509	Severe hereditary factor XI deficiency (disorder without inhibitor)	severe hereditary factor xi deficiency (disorder without inhibitor)		Severe hereditary factor XI deficiency (disorder without inhibitor)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	43871039	Severe hereditary factor XII deficiency (disorder without inhibitor)	severe hereditary factor xii deficiency (disorder without inhibitor)		Severe hereditary factor XII deficiency (disorder without inhibitor)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	43871040	Severe hereditary factor XIII deficiency (disorder without inhibitor)	severe hereditary factor xiii deficiency (disorder without inhibitor)		Severe hereditary factor XIII deficiency (disorder without inhibitor)	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	43830200	Hereditary factor XI deficiency disease with inhibitor	hereditary factor xi deficiency disease with inhibitor		Hereditary factor XI deficiency disease with inhibitor	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	43830300	Hereditary factor XII deficiency disease with inhibitor	hereditary factor xii deficiency disease with inhibitor		Hereditary factor XII deficiency disease with inhibitor	True	1.0	Sep 30, 2021, 1:57 PM	
SNOMED	43710406	Adult growth hormone deficiency	adult growth hormone deficiency		Adult growth hormone deficiency	True	1.0	Sep 30, 2021, 1:57 PM	

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

### MED-RT

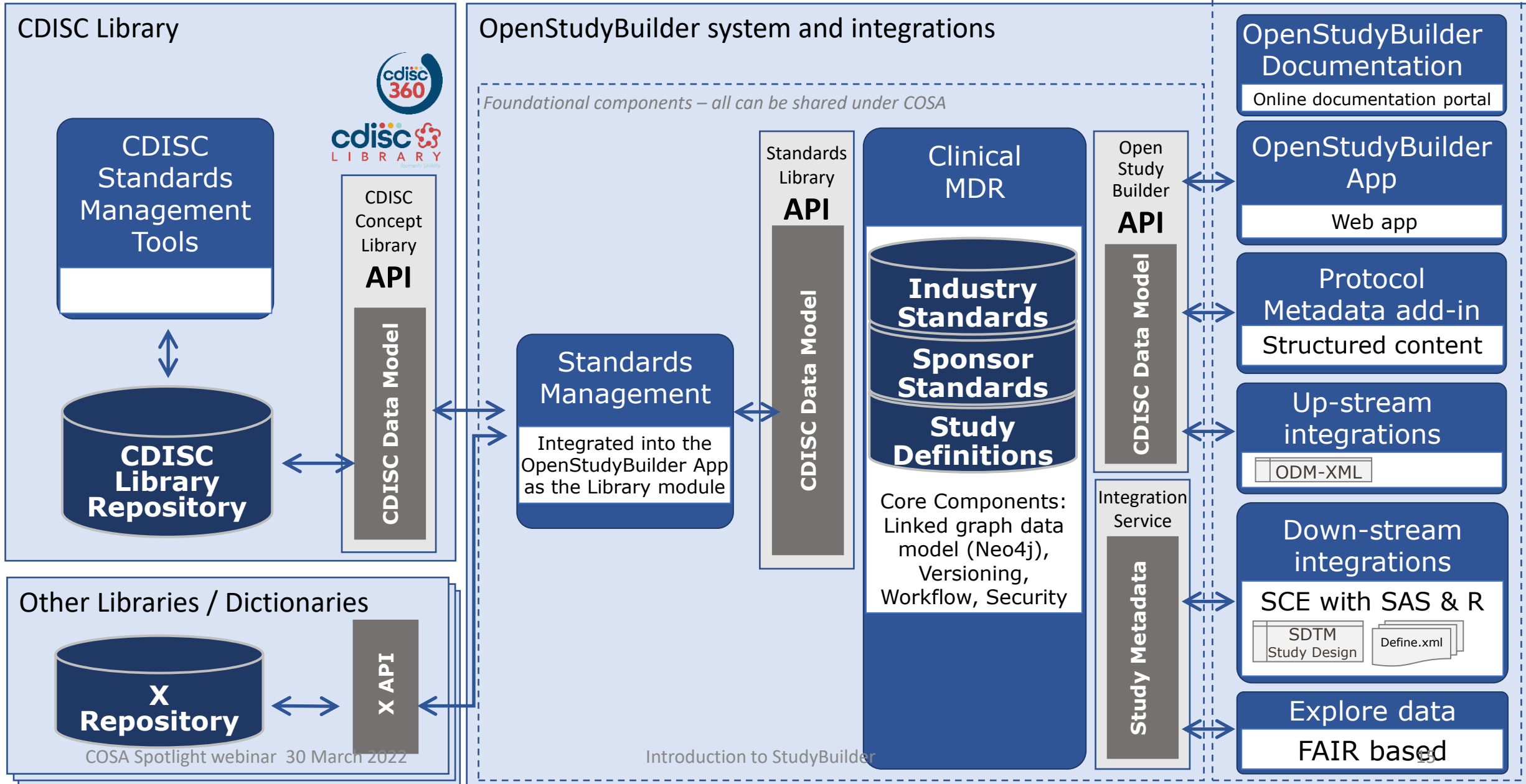
Library	MED-RT	Name	Lower case name	Abbreviations	Definition	Status	Version	Modified	Actions
MED-RT	N000017545	Lithiumine	lithiumine		Lithiumine	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017546	Zithromax	zithromax		Zithromax	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017548	Tuberculosis Agent	tuberculosis agent		Tuberculosis Agent	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000018196	Thrombolysis	thrombolysis		Thrombolysis	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017549	Sulfapyridine	sulfapyridine		Sulfapyridine	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017548	Sulfasalazine	sulfasalazine		Sulfasalazine	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000018758	Sodium-Glucose Cotransporter 2 Inhibitor	sodium-glucose cotransporter 2 inhibitor		Sodium-Glucose Cotransporter 2 Inhibitor	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017546	Recombinant Human Growth Hormone	recombinant human growth hormone		Recombinant Human Growth Hormone	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017547	Quinolone Antimicrobial	quinolone antimicrobial		Quinolone Antimicrobial	True	1.0	Sep 30, 2021, 1:57 PM	
MED-RT	N000017523	Protein Pump Inhibitor	protein pump inhibitor		Protein Pump Inhibitor	True	1.0	Sep 30, 2021, 1:57 PM	

### Objective Templates

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 [Component], in participants with [Component].	Oct 3, 2021, 12:47 PM	John Doe	Open	0.1	
Diabetes mellitus, Obesity	Phase II	Efficacy	Yes	To demonstrate the appearance of [Component] with respect to change in [Component], from [Component] to [Component] in participants with [Component].	Oct 3, 2021, 12:42 PM	John Doe	Open	0.1	
Obesity	Phase I, Phase II	Safety	No	To compare the safety and tolerability of [Component] and [Component], both in combination with diet and exercise, in participants with [Component].	Oct 3, 2021, 12:34 PM	John Doe	Open	1.0	
	Phase I	Bioprecursor	Yes	To confirm the bioprecursor of [Component] in participants with [Component].	Oct 3, 2021, 12:28 PM	John Doe	Open	1.0	
	Phase I	Bioprecursor	No	To demonstrate the bioprecursor of [Component] in participants with [Component].	Oct 3, 2021, 12:24 PM	John Doe	Open	1.0	
				To demonstrate the bioprecursor of [Component] in participants with [Component].	Oct 3, 2021, 12:20 PM	John Doe	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://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
  - Currently only containing a project description
- We seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors
- Join us at [COSA OpenStudyBuilder Workshop Breakout Session Selection | CDISC](#)

