cdisc

2022
US
INTERCHANGE
26-27 OCTOBER | AUSTIN

Concept-based standards in OpenStudyBuilder supporting structured protocol content and submission deliverables

Mikkel Traun, 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.

What is the OpenStudyBuilder …

The OpenStudyBuilder is the new approach to study specification that will:

- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation and content reuse

The OpenStudyBuilder comprises three elements:

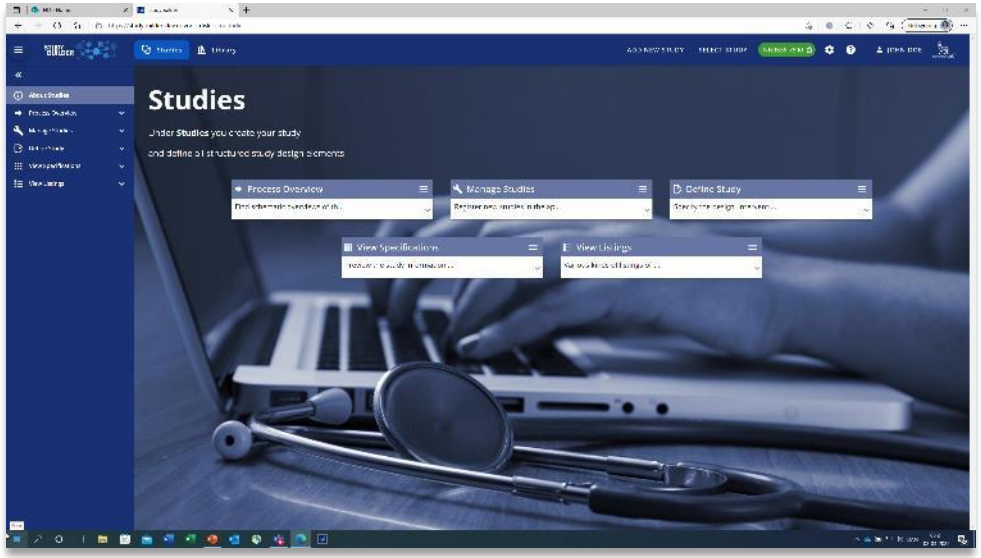
- **Clinical Metadata Repository (clinical MDR)** (central repository for all study specification data)
- **OpenStudyBuilder application** (web-based user interface)
- **API layer** (allowing interoperability with other applications) (DDF API Adaptor – enabling DDF SDR Compatibility)

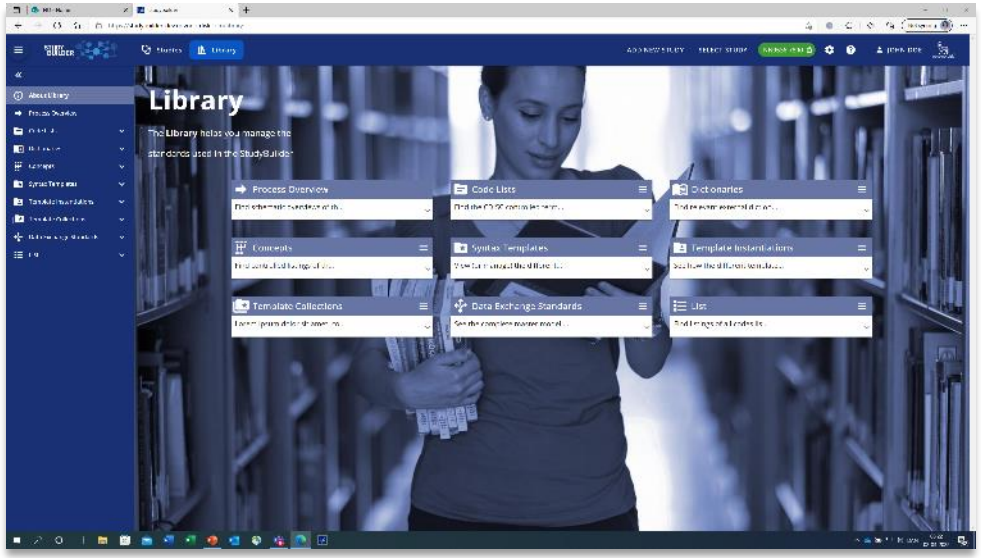
The OpenStudyBuilder includes:

- A **Studies** part for specification of studies
  (incl. 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)

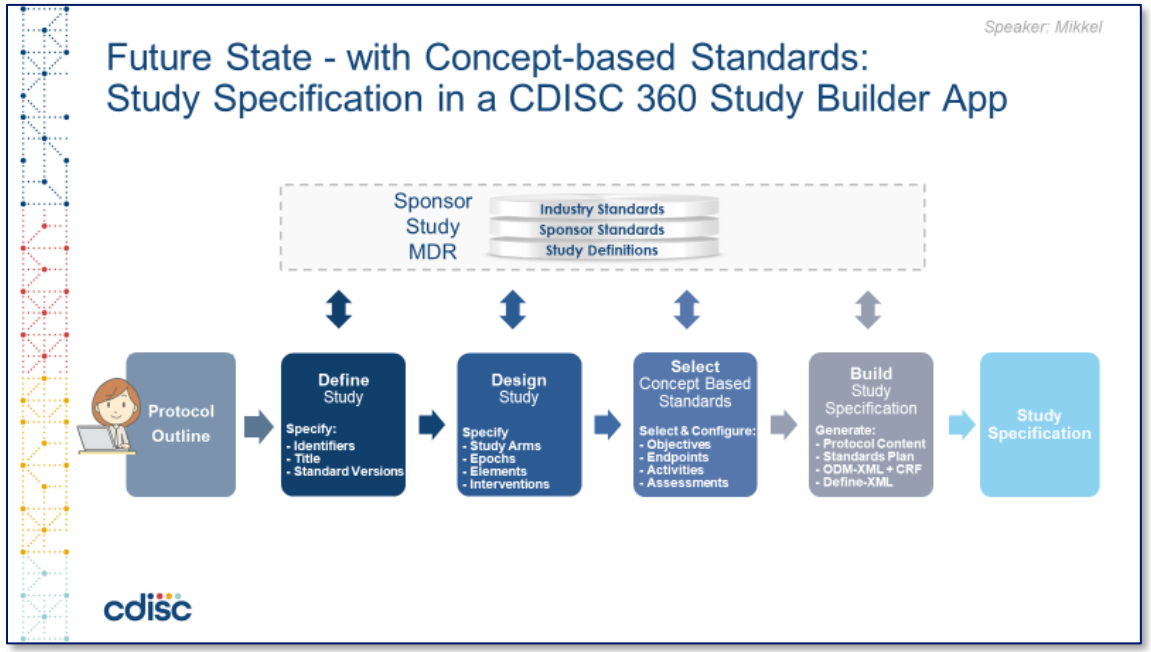
- A **Library** part for maintenance of terminology standards
  (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study and cross-project harmonisation)

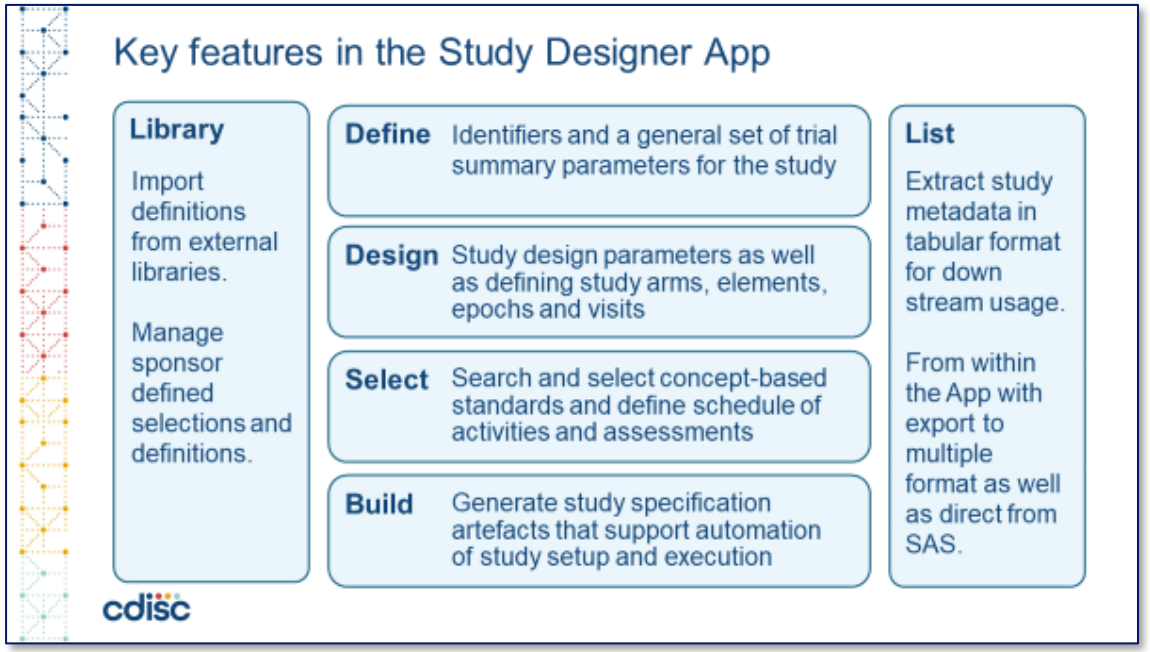
- An underlying **knowledge database**
  (enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end)





We are building OpenStudyBuilder as an open-source MDR and SDR solution based on the CDISC 360 POC

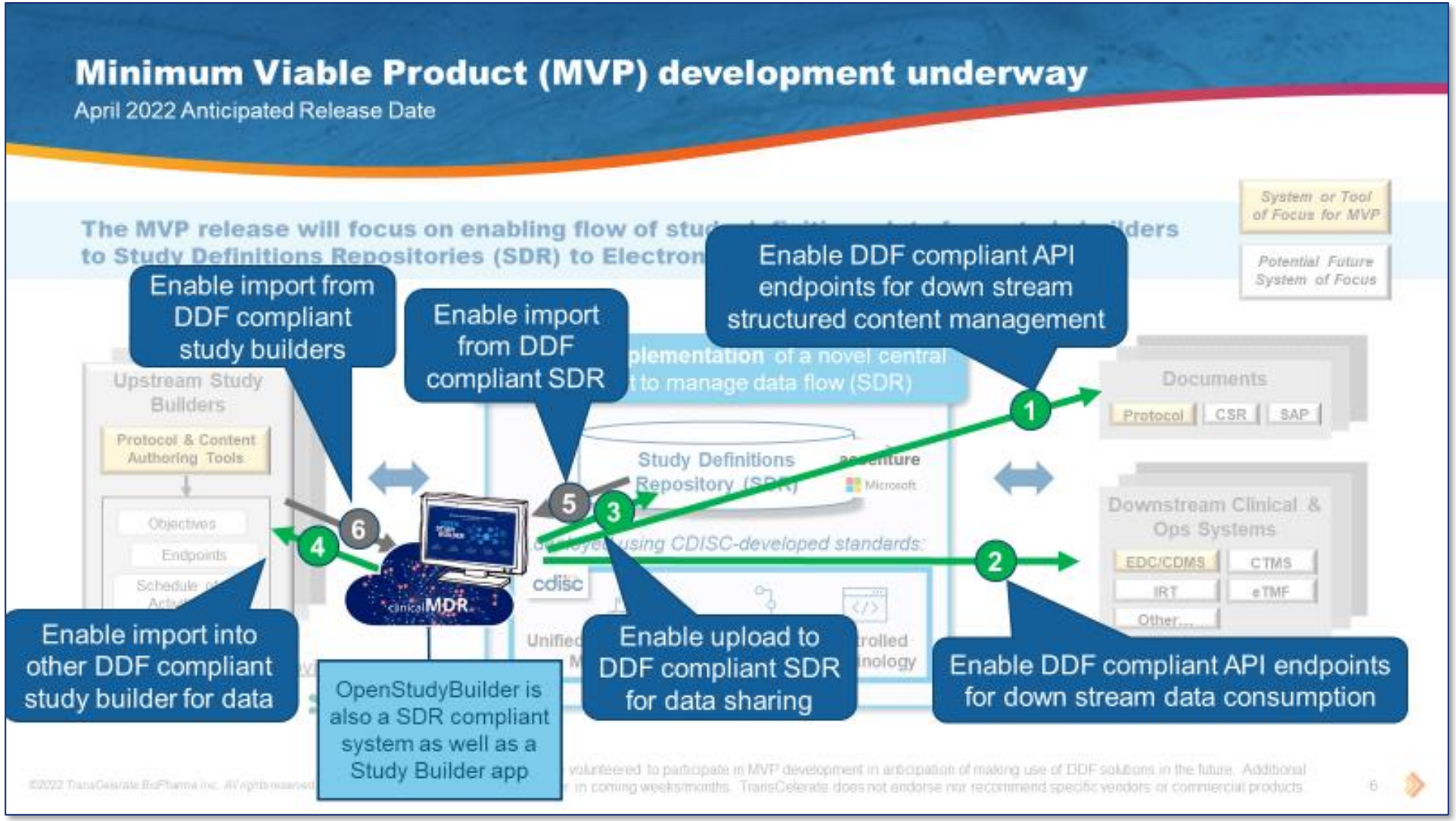




https://www.cdisc.org/cdisc-360

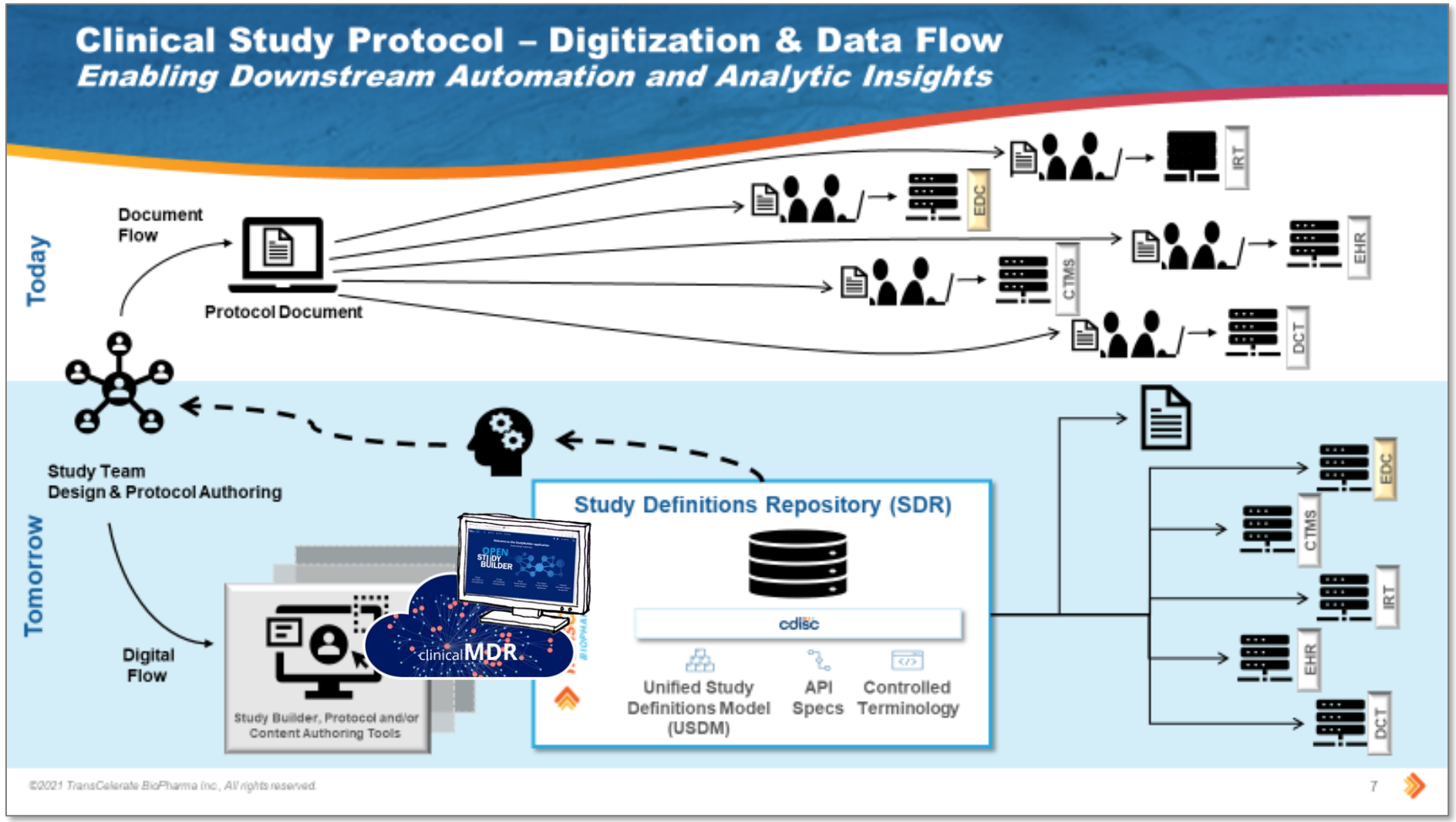
- Our goal is to replace our legacy MDR solution with a new modern solution
- As an open-source project in collaboration with CDISC, TransCelerate DDF and suppliers

OpenStudyBuilder will also be DDF Compatible



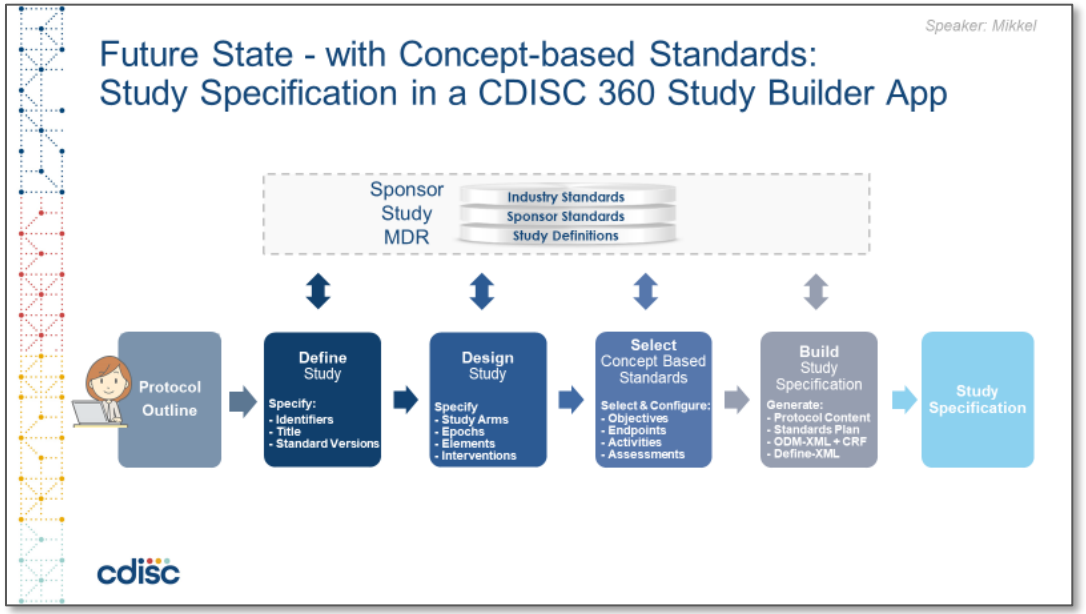
https://transcelerate.github.io/ddf-home/

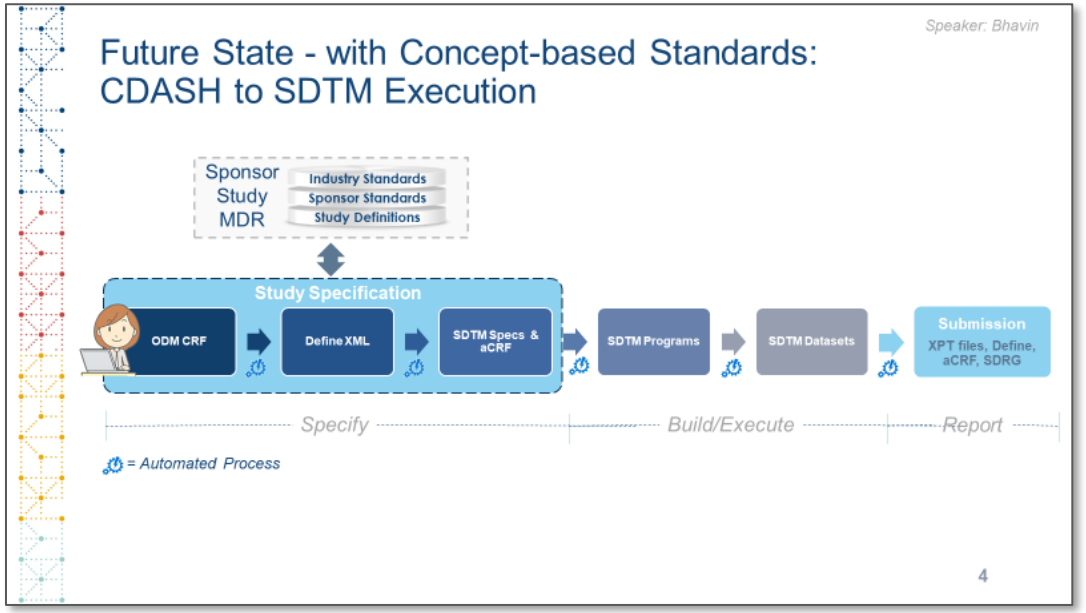
DDF is moving away from Document focused processes to Connected Data Driven processes



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 aggregaation of study specification details for insights





OpenStudyBuilder Demo

CDISC US Interchange

Mikkel Traun, Novo Nordisk A/S

27 October 2022

Welcome to the StudyBuilder application

Study Specification made easy

OPEN STUDY BUILDER

Build your study in a consistent way

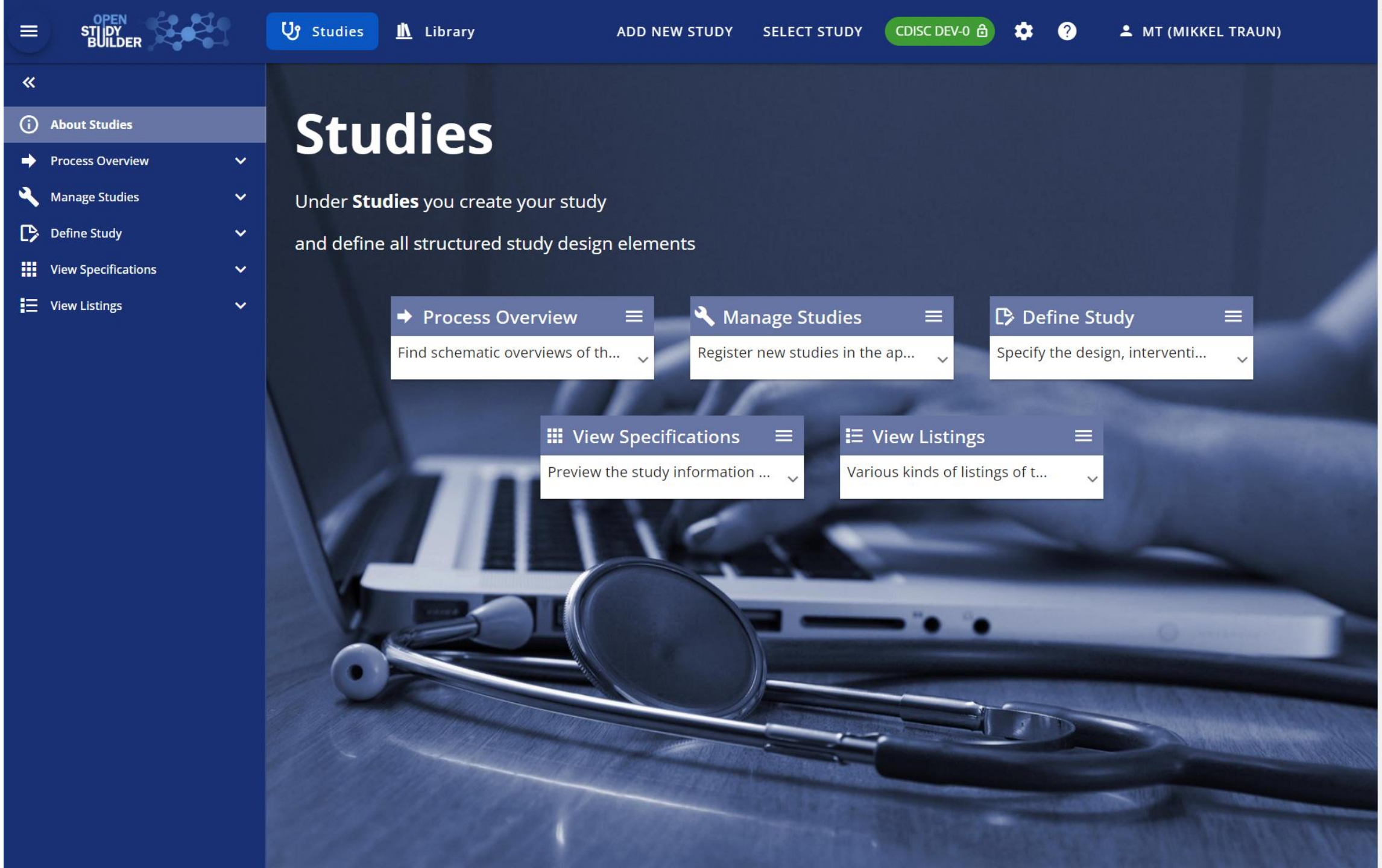
Comply with standards including CDISC

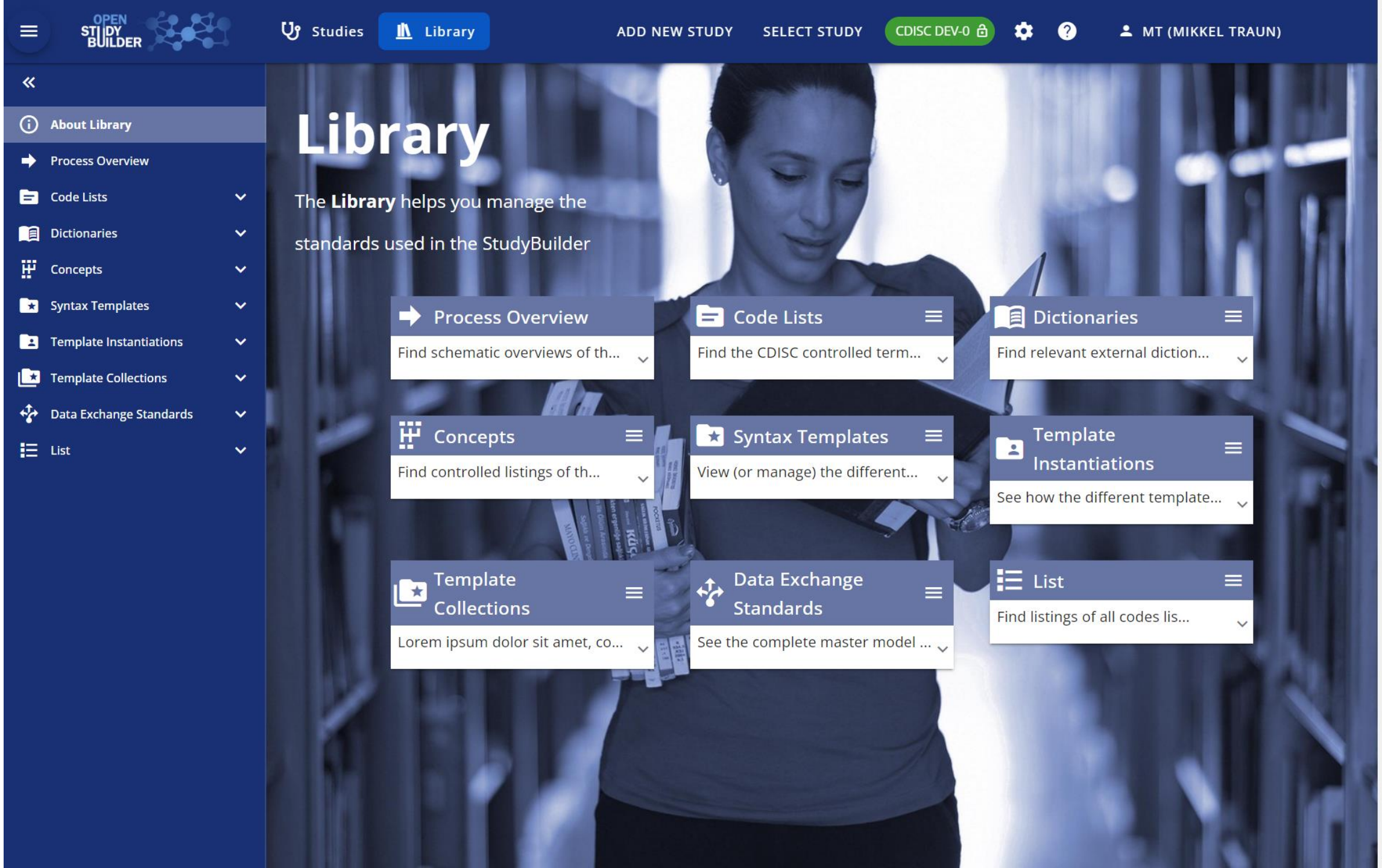
Reuse specification elements across studies

Get insights via user-defined dashboards

Integrate with other systems via open API

LICENSE


OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Studies
Process Overview
Manage Studies
Define Study
View Specifications
View Listings
Studies
Under Studies you create your study
and define all structured study design elements
Process Overview
Find schematic overviews of th...
Manage Studies
Register new studies in the ap...
Define Study
Specify the design, interventi...
View Specifications
Preview the study information ...
View Listings
Various kinds of listings of t...


OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library
The Library helps you manage the standards used in the StudyBuilder
Process Overview
Find schematic overviews of th...
Code Lists
Find the CDISC controlled term...
Dictionaries
Find relevant external diction...
Concepts
Find controlled listings of th...
Syntax Templates
View (or manage) the different...
Template Instantiations
See how the different template...
Template Collections
Lorem ipsum dolor sit amet, co...
Data Exchange Standards
See the complete master model ...
List
Find listings of all codes lis...

Studies

GET	`/studies`	Returns all studies in their latest/newest version.
POST	`/studies`	Creates a new Study Definition.
GET	`/studies/headers`	Returns possibles values from the database for a given header
GET	`/studies/{uid}`	Returns the current state of a specific study definition identified by 'uid'.
PATCH	`/studies/{uid}`	Request to change some aspects (parts) of a specific study definition identified by 'uid'.
GET	`/studies/{uid}/fields-audit-trail`	Returns the audit trail for the fields of a specific study definition identified by 'uid'.
GET	`/studies/{uid}/protocol-title`	Retrieve all information related to Protocol Title
PATCH	`/studies/{uid}/copy-component`	Copy study form from another study
GET	`/studies/{study_uid}/design.svg`	Builds and returns a Study Design visualization image in SVG format
GET	`/studies/{uid}/flowchart`	Returns Study Protocol Flowchart table
GET	`/studies/{uid}/flowchart.html`	Builds and returns an HTML document with Study Protocol Flowchart table
GET	`/studies/{uid}/flowchart.docx`	Builds and returns a DOCX document with Study Protocol Flowchart table
GET	`/studies/{uid}/interventions`	Returns Study Protocol Interventions table
GET	`/studies/{uid}/interventions.html`	Builds and returns an HTML document of Study Protocol Interventions table
GET	`/studies/{uid}/interventions.docx`	Builds and returns a DOCX document of Study Protocol Interventions table

Study Selections

OpenStudyBuilder Dashboard

Select Activity Concep

Select Activity Instance

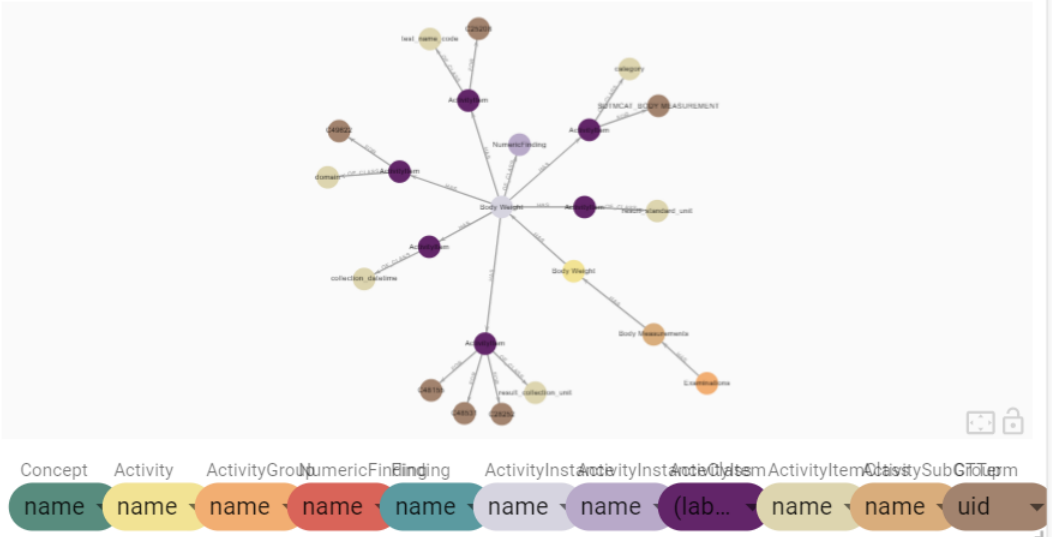
Body Weight

Activity Grouping

Field	Value
ActivityGroup	Examinations
ActivitySubGroup	Body Measurements
Activity	Body Weight
ActivityInstance	Body Weight

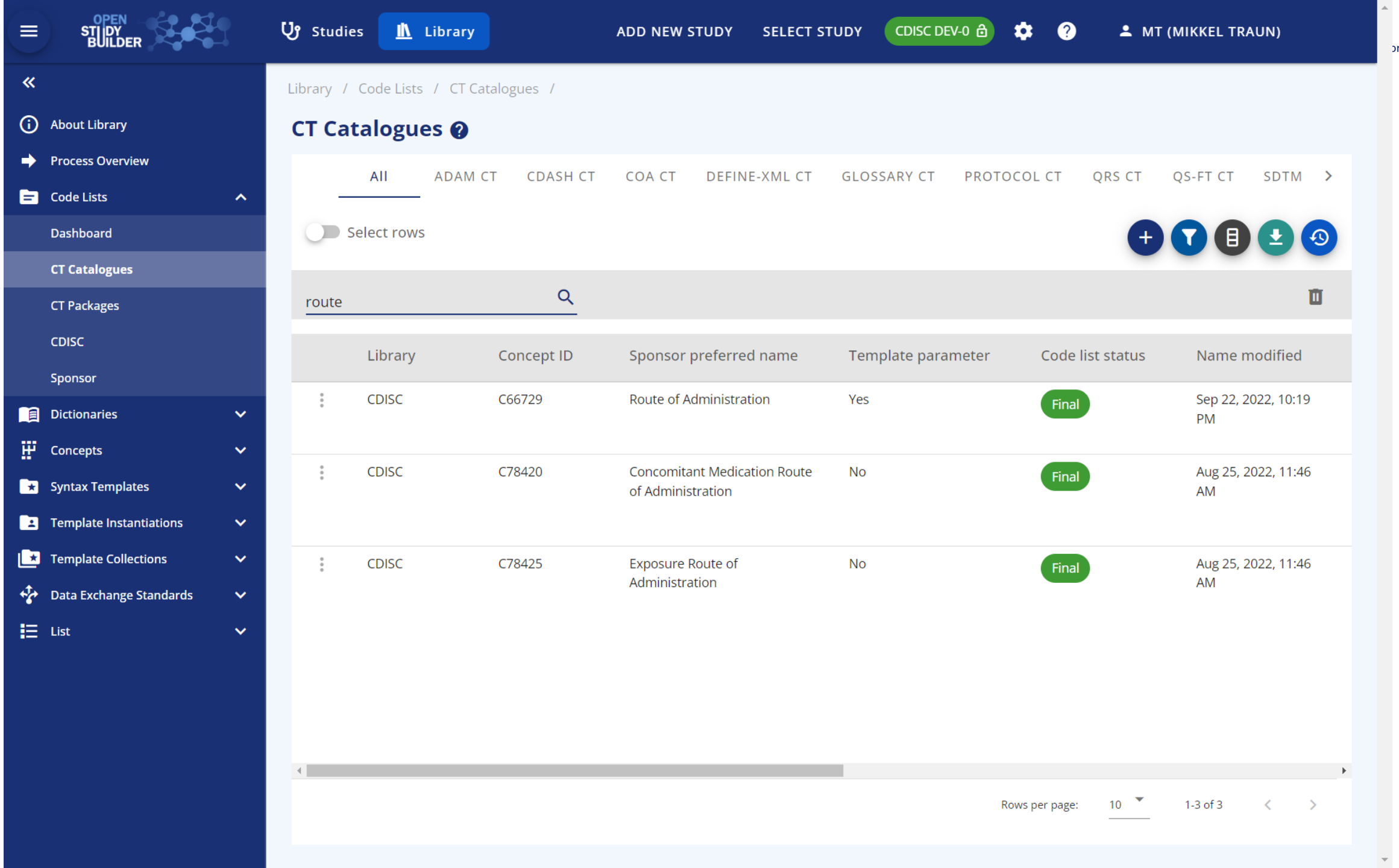
1–4 of 4

Activity Concept Graph Model



List Generic Activity Concept Definition

ActivityInstance	ActivityItemClass	aitmc.mandatory	aitmc.order	DataType	Role	aitmc.data_collection
Body Weight	collection_datetime	Yes	5	DATETIME	TIMING	Yes
Body Weight	result_standard_unit	No	16	FLOAT	RESUQUAL	No
Body Weight	test_name_code	Yes	4	CTTERM	TOPIC	Yes
Body Weight	result_collection_unit	No	15	FLOAT	RESUQUAL	Yes
Body Weight	category	Yes	6	CTTERM	GROUQUAL	No


OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dashboard
CT Catalogues
CT Packages
CDISC
Sponsor
Dictionaries
Concepts
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Code Lists / CT Catalogues /
CT Catalogues
All
ADAM CT
CDASH CT
COA CT
DEFINE-XML CT
GLOSSARY CT
PROTOCOL CT
QRS CT
QS-FT CT
SDTM
Select rows
route
Library
Concept ID
Sponsor preferred name
Template parameter
Code list status
Name modified
CDISC
C66729
Route of Administration
Yes
Final
Sep 22, 2022, 10:19 PM
CDISC
C78420
Concomitant Medication Route of Administration
No
Final
Aug 25, 2022, 11:46 AM
CDISC
C78425
Exposure Route of Administration
No
Final
Aug 25, 2022, 11:46 AM
Rows per page:
10
1-3 of 3

Route of Administration Response (C66729) - ROUTE / Terms listing

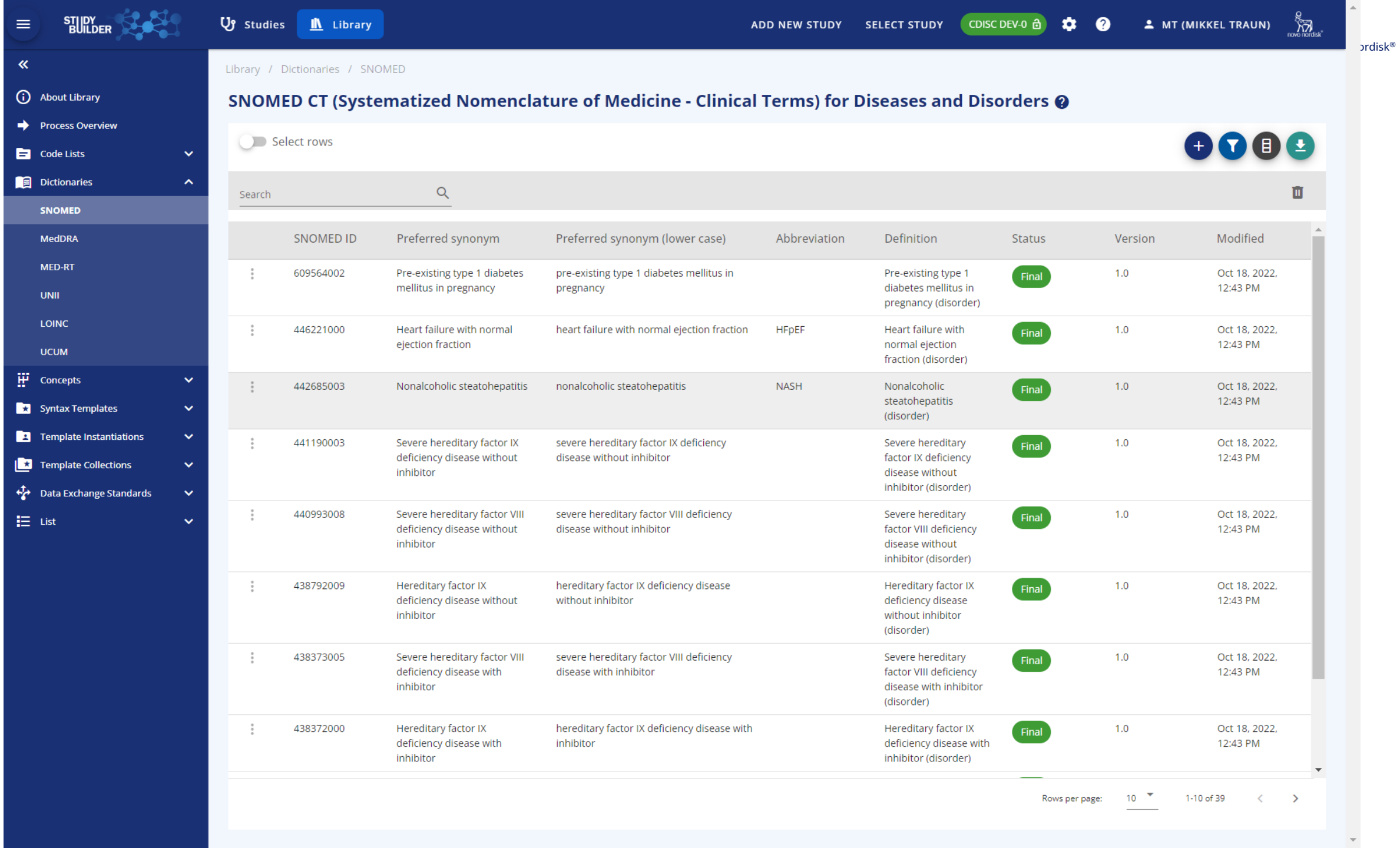
Code List Summary

Select rows

intrave

	Library	Concept ID	Sponsor name	Code submission value	NCI Preferred name	Definition	Attributes status
⋮	CDISC	C38192_AURICULAR (OTIC)	Auricular	AURICULAR (OTIC)	Auricular Route of Administration	Administration to or by way of the ear. (FDA)	Final
⋮	CDISC	C38193_BUCCAL	Buccal	BUCCAL	Buccal Route of Administration	Administration directed toward the cheek, generally from within the mouth. (FDA)	Final
⋮	CDISC	C38194_CONJUNCTIVAL	Conjunctival	CONJUNCTIVAL	Conjunctival Route of Administration	Administration to the conjunctiva, the delicate membrane that lines the eyelids and covers the exposed surface of the eyeball. (FDA)	Final
⋮	CDISC	C38675_CUTANEOUS	Cutaneous	CUTANEOUS	Cutaneous Route of Administration	Administration to the skin. (FDA)	Final
⋮	CDISC	C38197_DENTAL	Dental	DENTAL	Dental Route of Administration	Administration to a tooth or teeth. (FDA)	Final
⋮	CDISC	C78373_DIETARY	Dietary	DIETARY	Dietary Route of Administration	Administration by way of food or water.	Final
⋮	CDISC	C38633_ELECTRO-OSMOSIS	Electro-osmosis	ELECTRO-OSMOSIS	Electro-osmosis Route of Administration	Administration of through the diffusion of substance through a membrane in an electric field. (FDA)	Final
⋮	CDISC	C38205_ENDOCERVICAL	Endocervical	ENDOCERVICAL	Endocervical Route of Administration	Administration within the canal of the cervix uteri. Synonymous with the term intracervical. (FDA)	Final
⋮	CDISC	C38206_ENDOSINUSIAL	Endosinusial	ENDOSINUSIAL	Endosinusial Route of	Administration within the nasal	Final

Rows per page: 100 1-100 of 135


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
SNOMED
MedDRA
MED-RT
UNII
LOINC
UCUM
Concepts
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Dictionaries / SNOMED
SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) for Diseases and Disorders
Select rows
Search
SNOMED ID
Preferred synonym
Preferred synonym (lower case)
Abbreviation
Definition
Status
Version
Modified
609564002
Pre-existing type 1 diabetes mellitus in pregnancy
pre-existing type 1 diabetes mellitus in pregnancy
Pre-existing type 1 diabetes mellitus in pregnancy (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
446221000
Heart failure with normal ejection fraction
heart failure with normal ejection fraction
HFpEF
Heart failure with normal ejection fraction (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
442685003
Nonalcoholic steatohepatitis
nonalcoholic steatohepatitis
NASH
Nonalcoholic steatohepatitis (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
441190003
Severe hereditary factor IX deficiency disease without inhibitor
severe hereditary factor IX deficiency disease without inhibitor
Severe hereditary factor IX deficiency disease without inhibitor (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
440993008
Severe hereditary factor VIII deficiency disease without inhibitor
severe hereditary factor VIII deficiency disease without inhibitor
Severe hereditary factor VIII deficiency disease without inhibitor (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
438792009
Hereditary factor IX deficiency disease without inhibitor
hereditary factor IX deficiency disease without inhibitor
Hereditary factor IX deficiency disease without inhibitor (disorder)
Final
1.0
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Severe hereditary factor VIII deficiency disease with inhibitor
severe hereditary factor VIII deficiency disease with inhibitor
Severe hereditary factor VIII deficiency disease with inhibitor (disorder)
Final
1.0
Oct 18, 2022, 12:43 PM
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Hereditary factor IX deficiency disease with inhibitor
hereditary factor IX deficiency disease with inhibitor
Hereditary factor IX deficiency disease with inhibitor (disorder)
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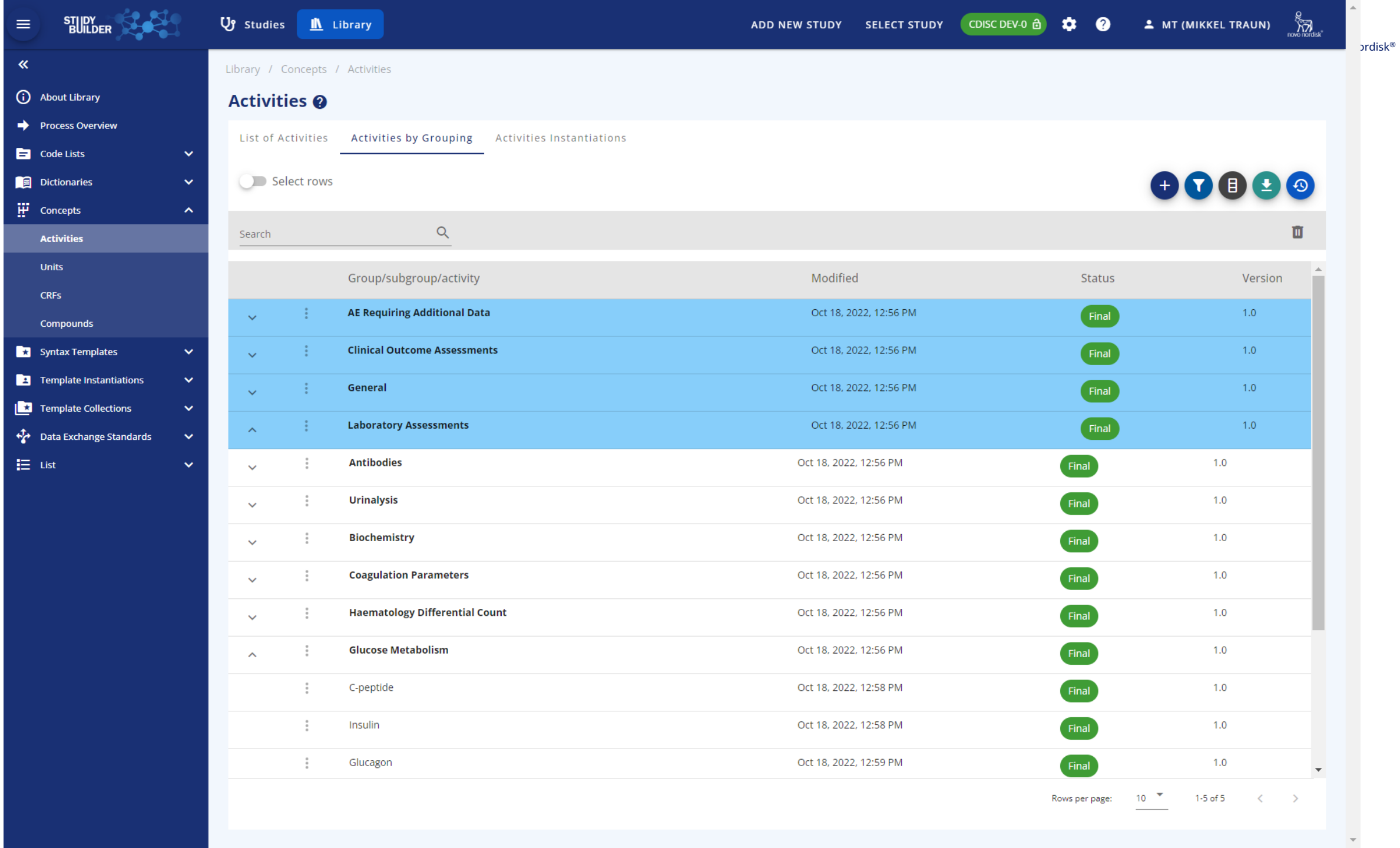
STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Compounds
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Concepts / Activities
Activities
List of Activities
Activities by Grouping
Activities Instantiations
Select rows
Search
Group/subgroup/activity
Modified
Status
Version
AE Requiring Additional Data
Oct 18, 2022, 12:56 PM
Final
1.0
Clinical Outcome Assessments
Oct 18, 2022, 12:56 PM
Final
1.0
General
Oct 18, 2022, 12:56 PM
Final
1.0
Laboratory Assessments
Oct 18, 2022, 12:56 PM
Final
1.0
Antibodies
Oct 18, 2022, 12:56 PM
Final
1.0
Urinalysis
Oct 18, 2022, 12:56 PM
Final
1.0
Biochemistry
Oct 18, 2022, 12:56 PM
Final
1.0
Coagulation Parameters
Oct 18, 2022, 12:56 PM
Final
1.0
Haematology Differential Count
Oct 18, 2022, 12:56 PM
Final
1.0
Glucose Metabolism
Oct 18, 2022, 12:56 PM
Final
1.0
C-peptide
Oct 18, 2022, 12:58 PM
Final
1.0
Insulin
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Final
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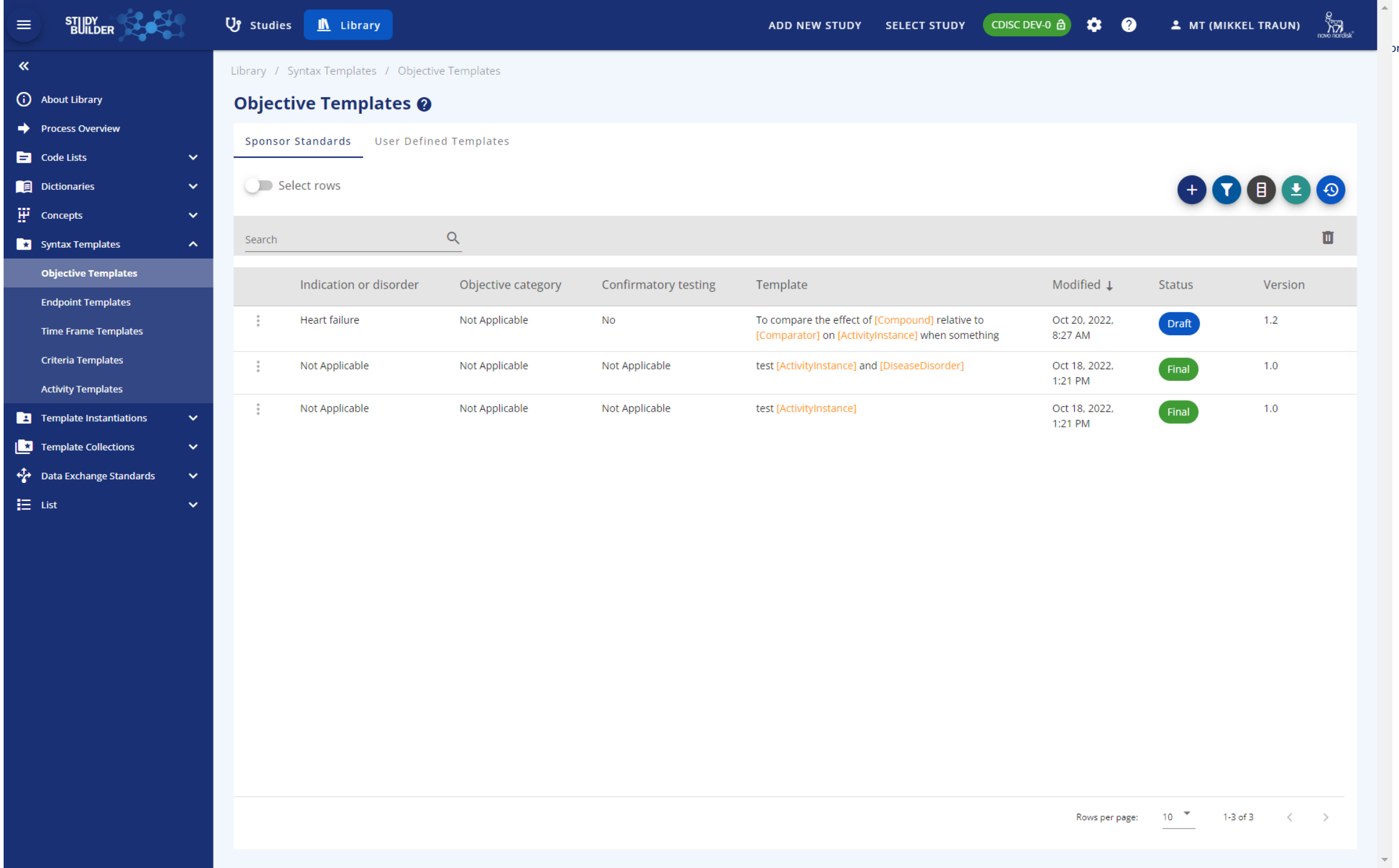
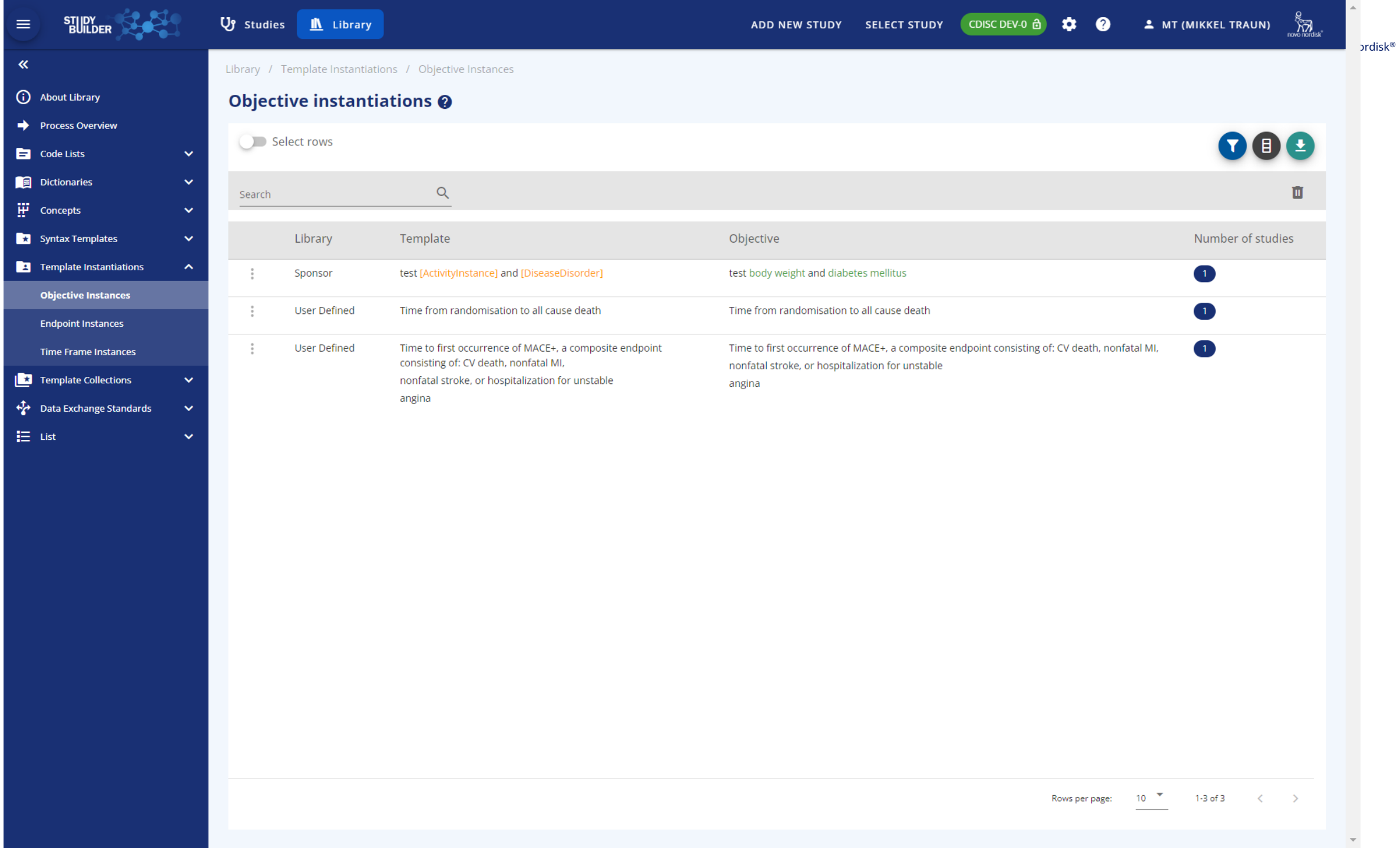

STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Syntax Templates
Objective Templates
Endpoint Templates
Time Frame Templates
Criteria Templates
Activity Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Syntax Templates / Objective Templates
Objective Templates
Sponsor Standards
User Defined Templates
Select rows
Search
Indication or disorder
Objective category
Confirmatory testing
Template
Modified
Status
Version
Heart failure
Not Applicable
No
To compare the effect of [Compound] relative to [Comparator] on [ActivityInstance] when something
Oct 20, 2022, 8:27 AM
Draft
1.2
Not Applicable
Not Applicable
Not Applicable
test [ActivityInstance] and [DiseaseDisorder]
Oct 18, 2022, 1:21 PM
Final
1.0
Not Applicable
Not Applicable
Not Applicable
test [ActivityInstance]
Oct 18, 2022, 1:21 PM
Final
1.0
Rows per page:
10
1-3 of 3


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Syntax Templates
Template Instantiations
Objective Instances
Endpoint Instances
Time Frame Instances
Template Collections
Data Exchange Standards
List
Library / Template Instantiations / Objective Instances
Objective instantiations
Select rows
Search
Library
Template
Objective
Number of studies
Sponsor
test [ActivityInstance] and [Disease Disorder]
test body weight and diabetes mellitus
1
User Defined
Time from randomisation to all cause death
Time from randomisation to all cause death
1
User Defined
Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina
Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina
1
Rows per page:
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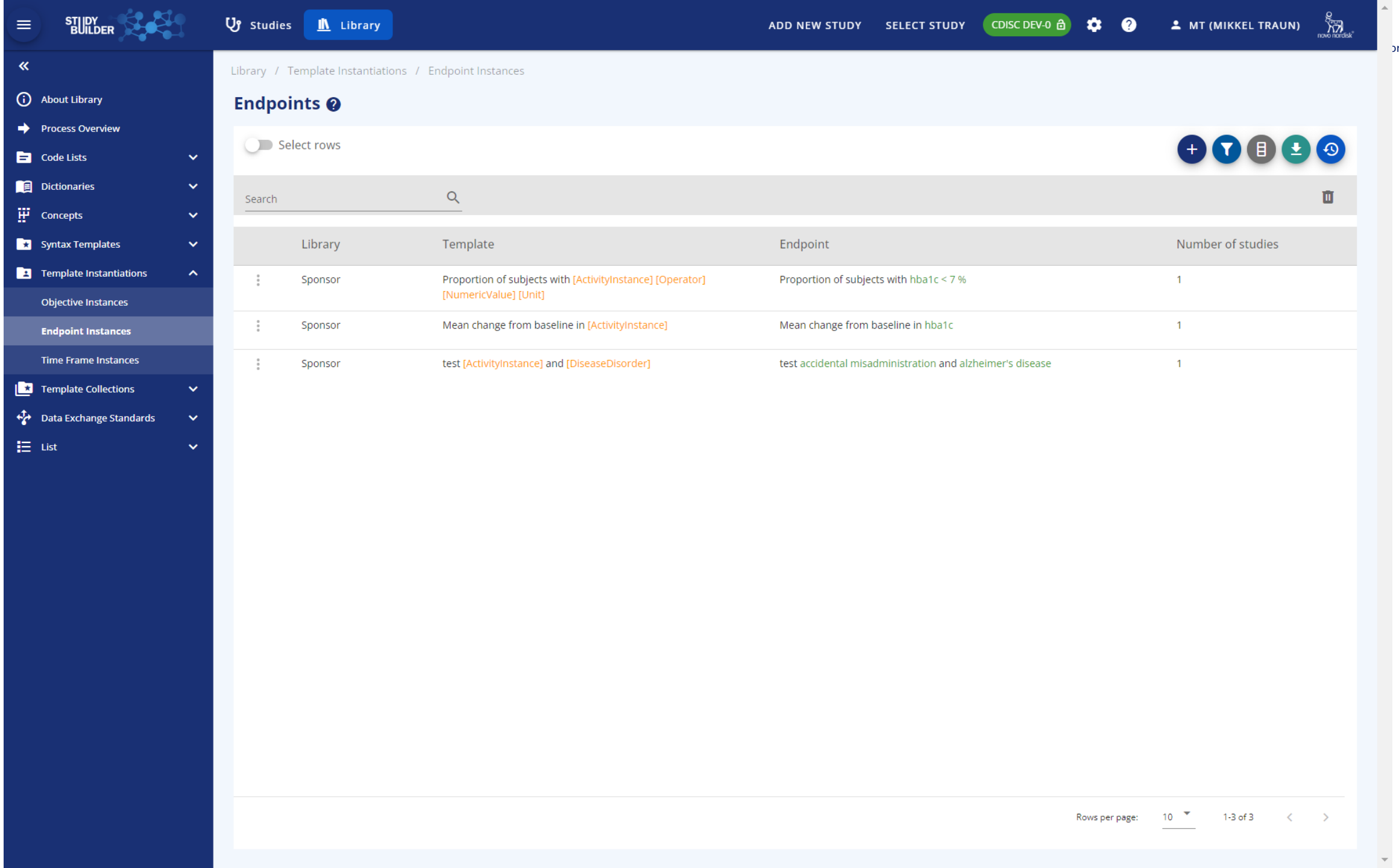
1-3 of 3


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
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Dictionaries
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Endpoint Instances
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Template Collections
Data Exchange Standards
List
Library / Template Instantiations / Endpoint Instances
Endpoints
Select rows
Search
Library
Template
Endpoint
Number of studies
Sponsor
Proportion of subjects with [ActivityInstance] [Operator] [NumericValue] [Unit]
Proportion of subjects with hba1c < 7 %
1
Sponsor
Mean change from baseline in [ActivityInstance]
Mean change from baseline in hba1c
1
Sponsor
test [ActivityInstance] and [DiseaseDisorder]
test accidental misadministration and alzheimer's disease
1
Rows per page:
10
1-3 of 3

About Studies
Process Overview
Manage Studies
Define Study
Specification Overview
Study Title
Study Properties
Study Structure
Registry Identifiers
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
Terminology
View Specifications
View Listings

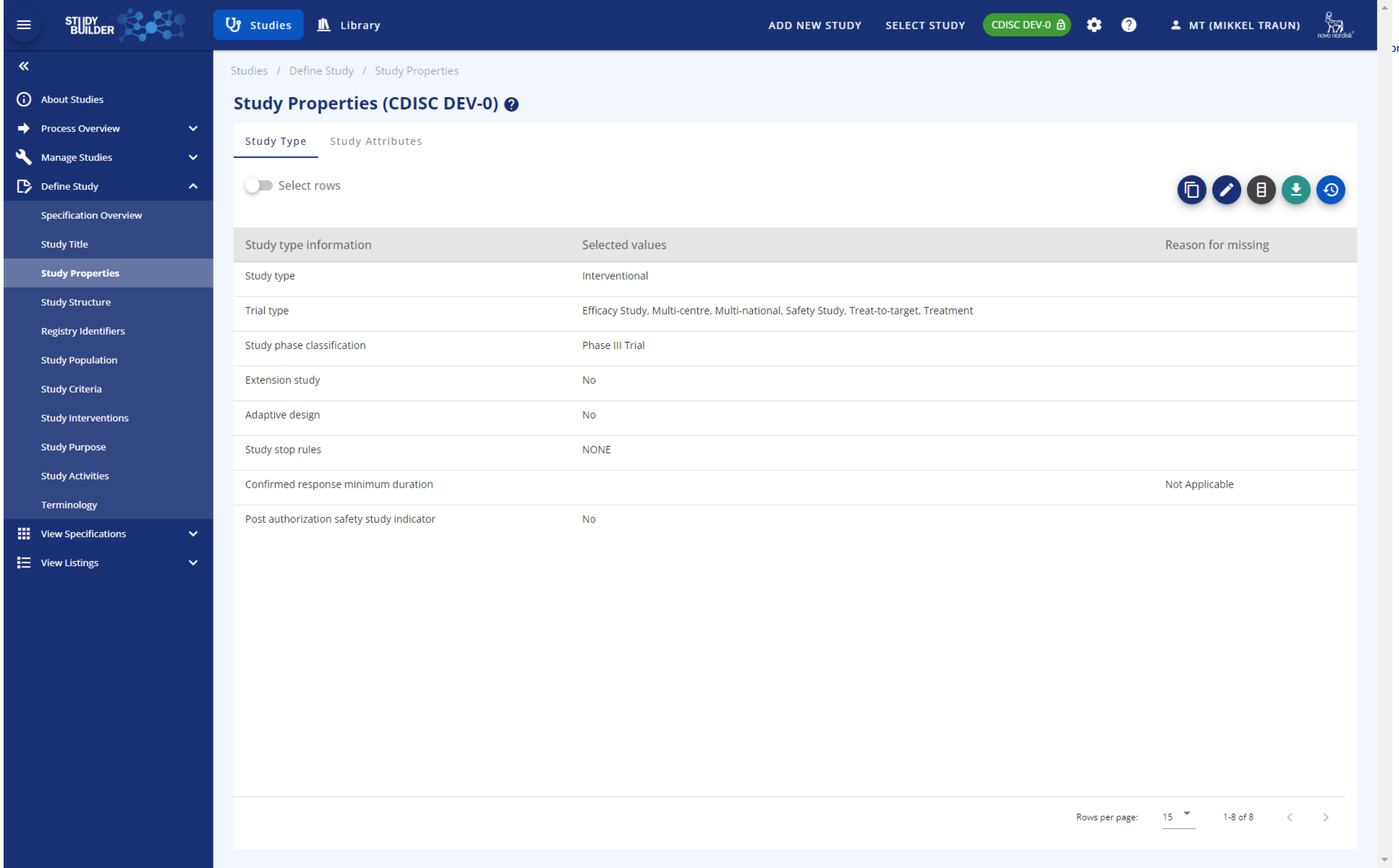
Study Title (CDISC DEV-0)

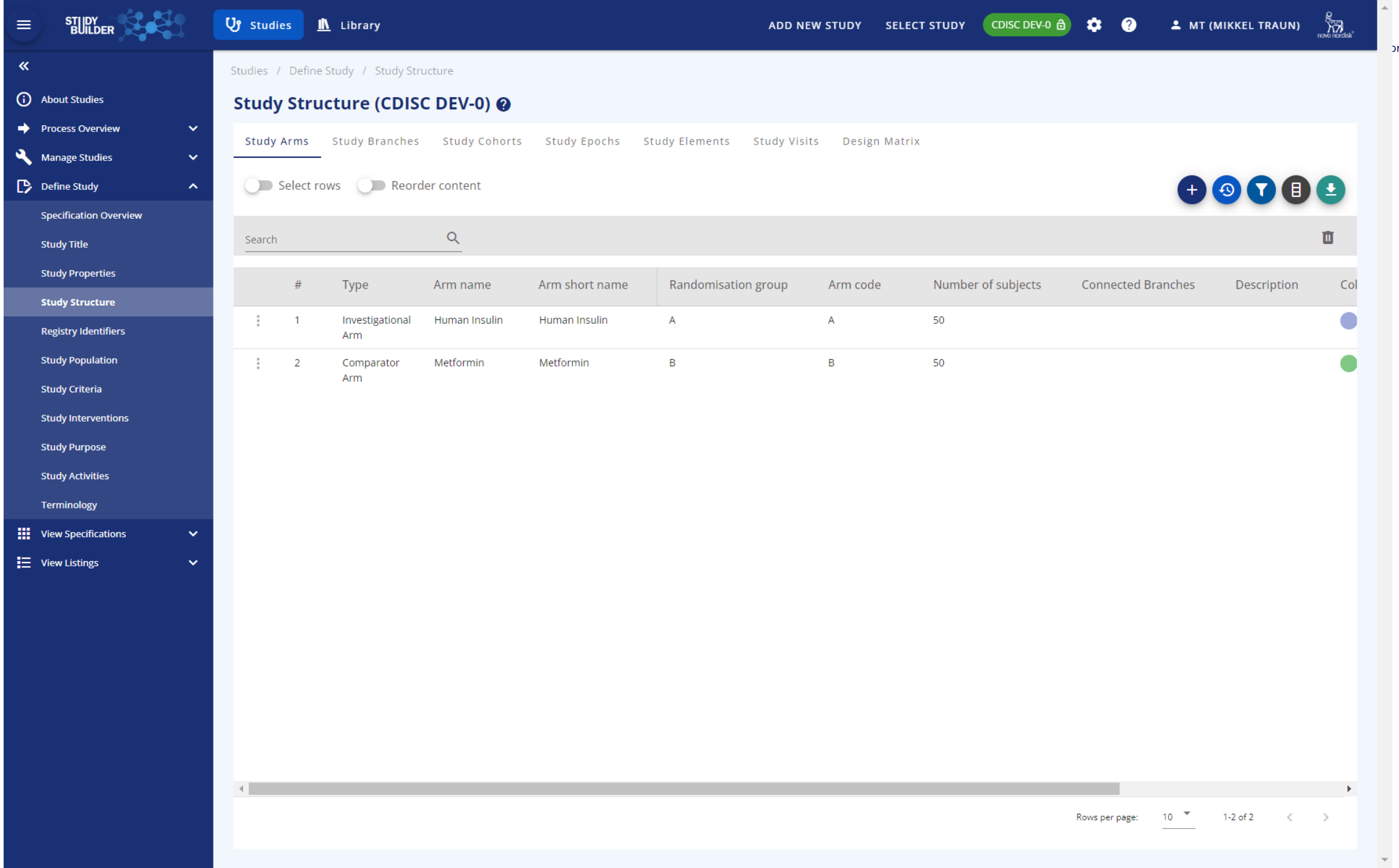
Study Title

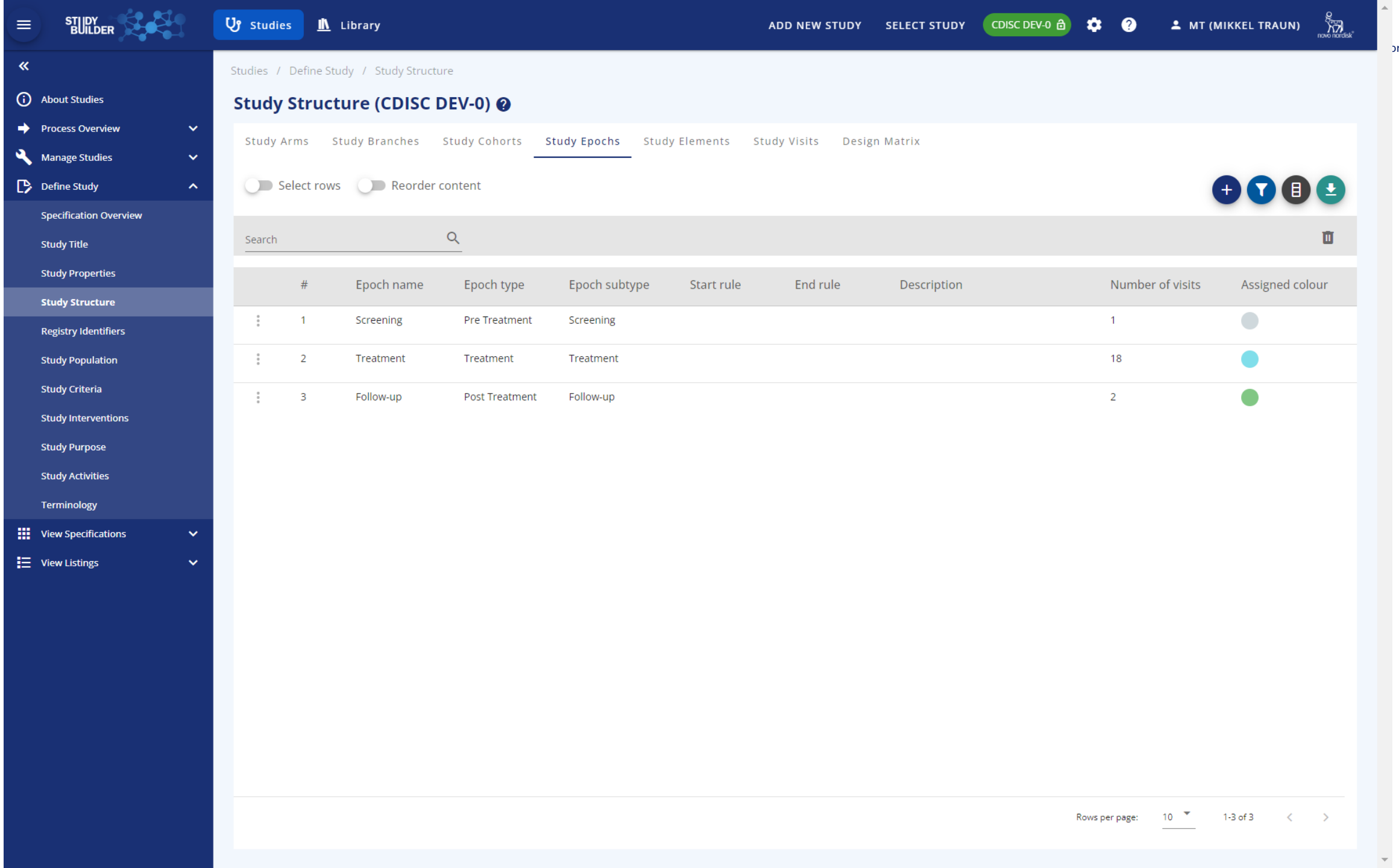
A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events

Study Short Title

A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Studies
Process Overview
Manage Studies
Define Study
Specification Overview
Study Title
Study Properties
Study Structure
Registry Identifiers
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
Terminology
View Specifications
View Listings
Studies / Define Study / Study Properties
Study Properties (CDISC DEV-0)
Study Type
Study Attributes
Select rows
Study type information
Selected values
Reason for missing
Study type
Interventional
Trial type
Efficacy Study, Multi-centre, Multi-national, Safety Study, Treat-to-target, Treatment
Study phase classification
Phase III Trial
Extension study
No
Adaptive design
No
Study stop rules
NONE
Confirmed response minimum duration
Not Applicable
Post authorization safety study indicator
No
Rows per page:
15
1-8 of 8


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Studies
Process Overview
Manage Studies
Define Study
Specification Overview
Study Title
Study Properties
Study Structure
Registry Identifiers
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
Terminology
View Specifications
View Listings
Studies / Define Study / Study Structure
Study Structure (CDISC DEV-0)
Study Arms
Study Branches
Study Cohorts
Study Epochs
Study Elements
Study Visits
Design Matrix
Select rows
Reorder content
Search
Type Arm name Arm short name Randomisation group Arm code Number of subjects Connected Branches Description Col
1 Investigational Arm Human Insulin Human Insulin A A 50
2 Comparator Arm Metformin Metformin B B 50
Rows per page: 10
1-2 of 2


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0
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Study Arms
Study Branches
Study Cohorts
Study Epochs
Study Elements
Study Visits
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Select rows
Reorder content
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Epoch name Epoch type Epoch subtype Start rule End rule Description Number of visits Assigned colour
1 Screening Pre Treatment Screening 1
2 Treatment Treatment Treatment 18
3 Follow-up Post Treatment Follow-up 2
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  - Study Activities
  - Terminology
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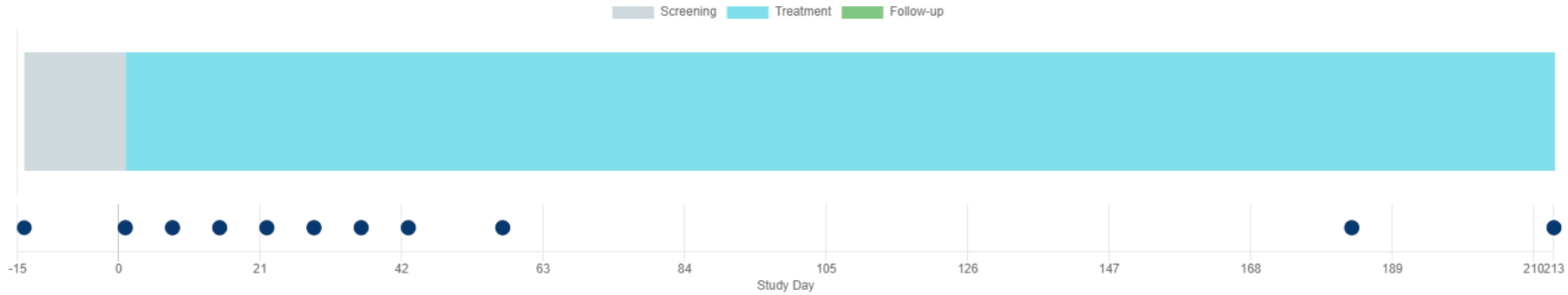
Study Arms | Study Branches | Study Cohorts | Study Epochs | Study Elements | Study Visits | Design Matrix

Study Visits



Select rows

Search

	Epoch	Visit type	Visit Class	Anchor visit in visit group	Visit group	Global anchor visit	Contact mode	Time reference	Timing
⋮	Screening	Screening	SINGLE_VISIT	No		No	On Site Visit	Global anchor visit	-14 days
⋮	Treatment	Treatment	SINGLE_VISIT	No		Yes	On Site Visit	Global anchor visit	0 days
⋮	Treatment	Treatment	SINGLE_VISIT	No		Yes	On Site Visit	Global anchor visit	0 days
⋮	Treatment	Treatment	SINGLE_VISIT	No		No	On Site Visit	Global anchor visit	7 days
⋮	Treatment	Treatment	SINGLE_VISIT	No		No	On Site Visit	Global anchor visit	7 days

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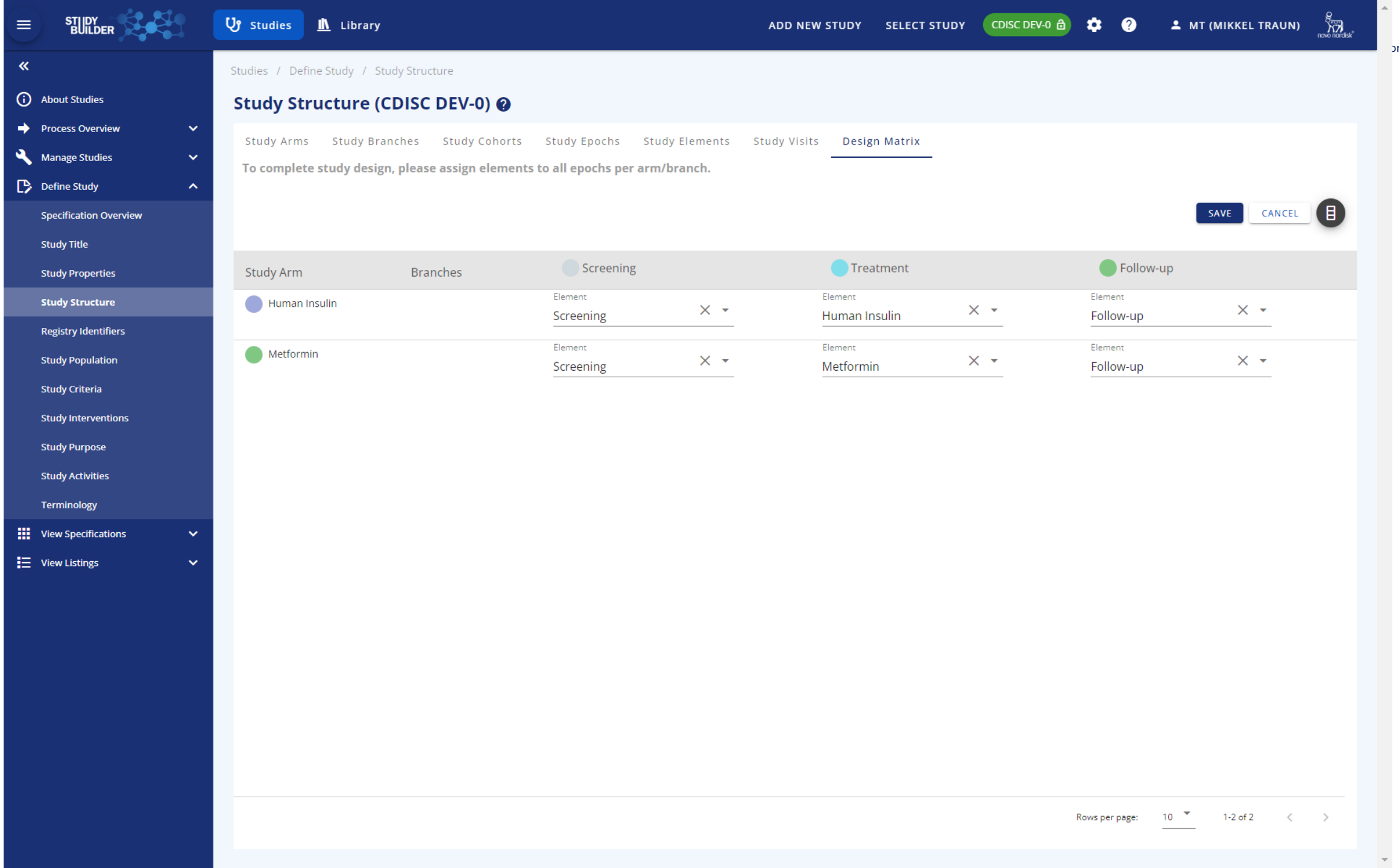
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To complete study design, please assign elements to all epochs per arm/branch.
SAVE
CANCEL
Study Arm
Branches
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Treatment
Follow-up
Human Insulin
Element
Screening
Element
Human Insulin
Element
Follow-up
Metformin
Element
Screening
Element
Metformin
Element
Follow-up
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10
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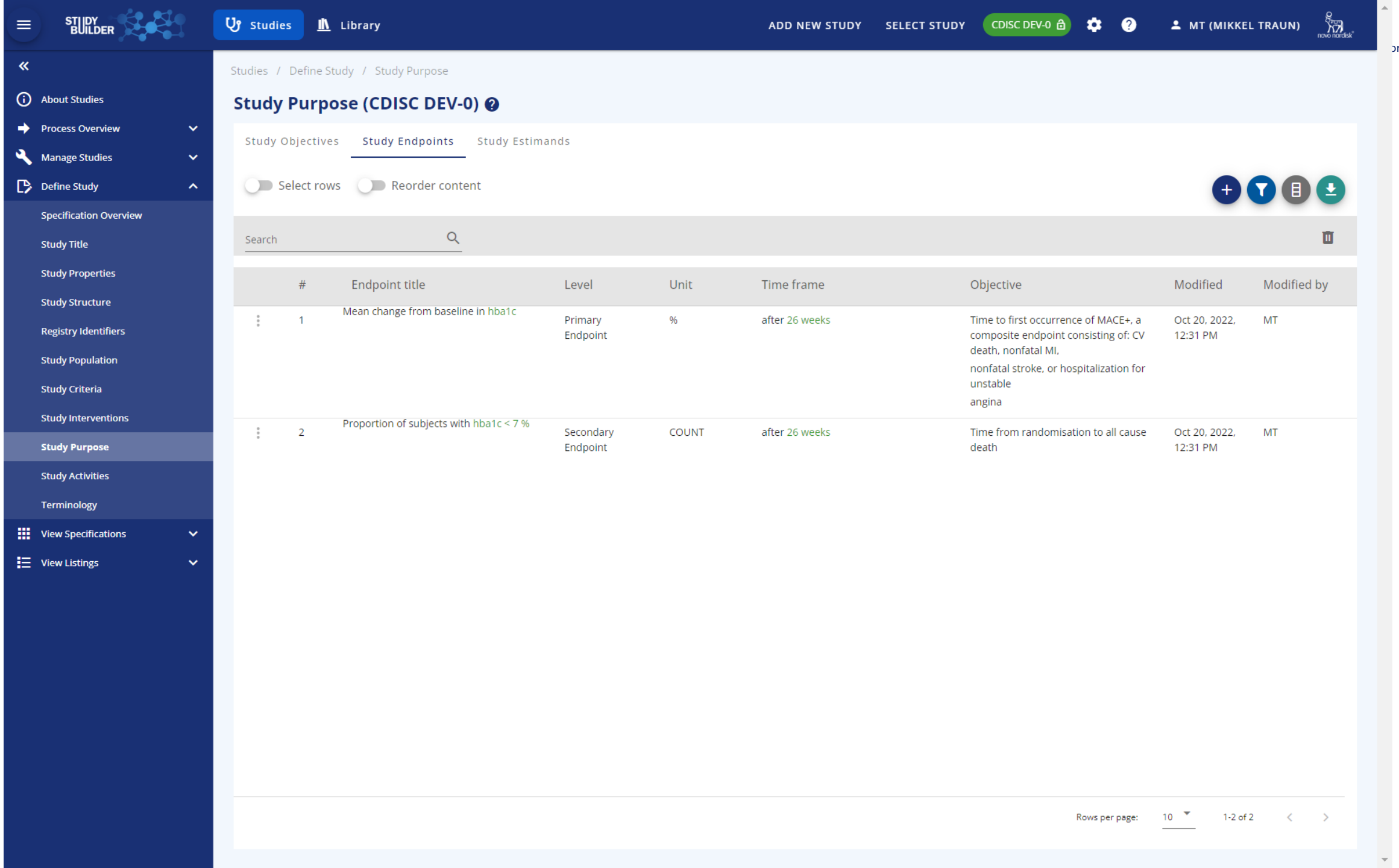
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Select rows
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Endpoint title Level Unit Time frame Objective Modified Modified by
1 Mean change from baseline in hba1c Primary Endpoint % after 26 weeks Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina Oct 20, 2022, 12:31 PM MT
2 Proportion of subjects with hba1c < 7 % Secondary Endpoint COUNT after 26 weeks Time from randomisation to all cause death Oct 20, 2022, 12:31 PM MT
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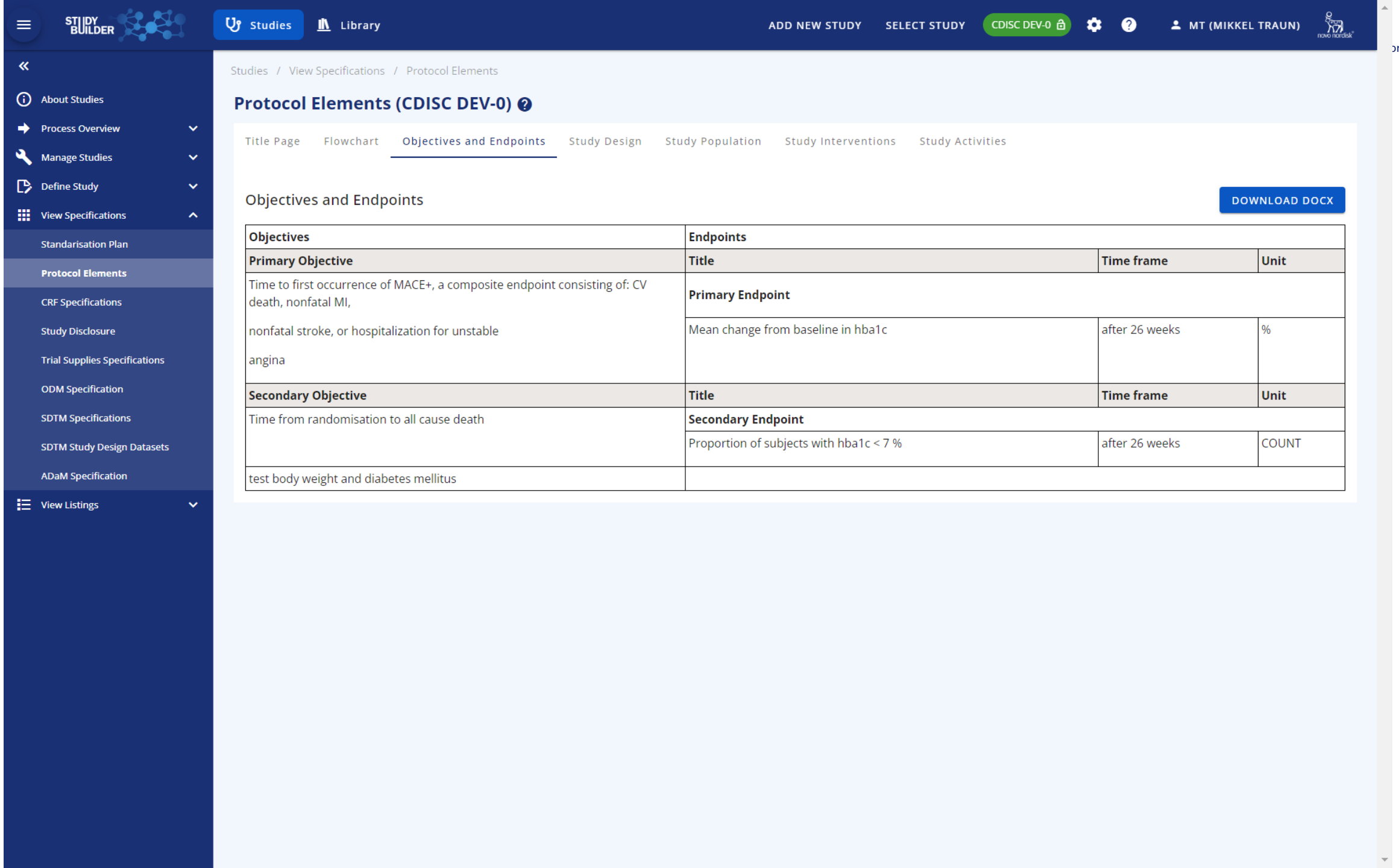
Protocol Elements (CDISC DEV-0)

Title Page | Flowchart | Objectives and Endpoints | Study Design | Study Population | Study Interventions | Study Activities

Title Page Information

Title page elements	Values
Protocol title	A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events
Protocol short title	A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events
Substance name	NPH Insulin
Universal Trial Number	
EudraCT number	2019-123456-42
IND number	
Study phase	Phase III Trial



Objectives	Endpoints		
Primary Objective	**Title**	**Time frame**	**Unit**
Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	**Primary Endpoint**		
	Mean change from baseline in hba1c	after 26 weeks	%
Secondary Objective	**Title**	**Time frame**	**Unit**
Time from randomisation to all cause death	**Secondary Endpoint**		
	Proportion of subjects with hba1c < 7 %	after 26 weeks	COUNT
test body weight and diabetes mellitus			

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Protocol Elements (CDISC DEV-0)

Title Page | Flowchart | Objectives and Endpoints | Study Design | Study Population | Study Interventions | Study Activities

Study Design

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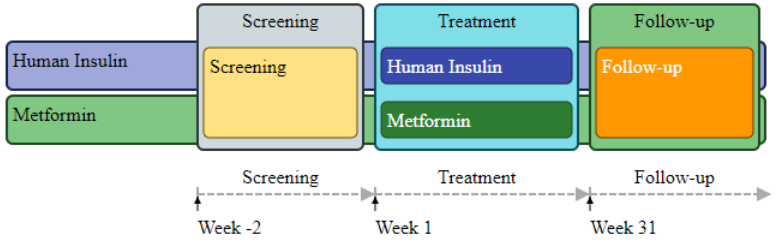


Protocol

Protocol Title: A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events

Short Title: A trial comparing cardiovascular safety of human insulin versus metformin in subjects with type 2 diabetes at high risk of cardiovascular events

Substance: NPH Insulin

Table of Contents

3 Objectives, endpoints and estimands

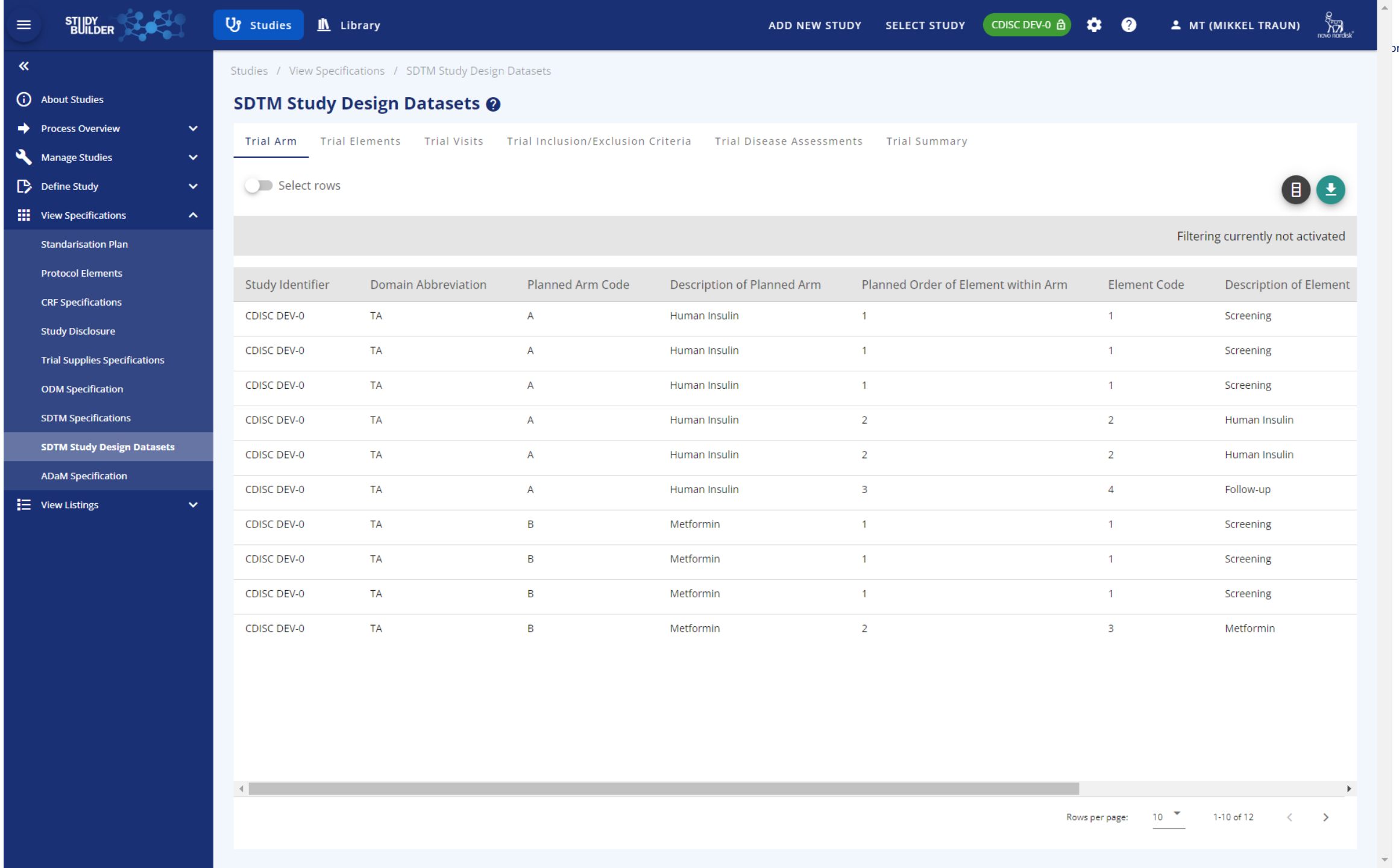
Table 3-1 ***Objectives and endpoints***

Objectives & Endpoints

Objectives	**Endpoints**		
Primary Objective	Title	Time frame	Unit
Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Primary Endpoint		
	Mean change from baseline in hba1c	after 26 weeks	%
Secondary Objective	Title	Time frame	Unit
Time from randomisation to all cause death	Secondary Endpoint		
	Proportion of subjects with hba1c < 7 %	after 26 weeks	COUNT

Primary estimand/co-primary estimands/multiple estimands

Secondary estimand(s)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Filtering currently not activated
Study Identifier | Domain Abbreviation | Planned Arm Code | Description of Planned Arm | Planned Order of Element within Arm | Element Code | Description of Element
CDISC DEV-0 | TA | A | Human Insulin | 1 | 1 | Screening
CDISC DEV-0 | TA | A | Human Insulin | 1 | 1 | Screening
CDISC DEV-0 | TA | A | Human Insulin | 1 | 1 | Screening
CDISC DEV-0 | TA | A | Human Insulin | 2 | 2 | Human Insulin
CDISC DEV-0 | TA | A | Human Insulin | 2 | 2 | Human Insulin
CDISC DEV-0 | TA | A | Human Insulin | 3 | 4 | Follow-up
CDISC DEV-0 | TA | B | Metformin | 1 | 1 | Screening
CDISC DEV-0 | TA | B | Metformin | 1 | 1 | Screening
CDISC DEV-0 | TA | B | Metformin | 1 | 1 | Screening
CDISC DEV-0 | TA | B | Metformin | 2 | 3 | Metformin
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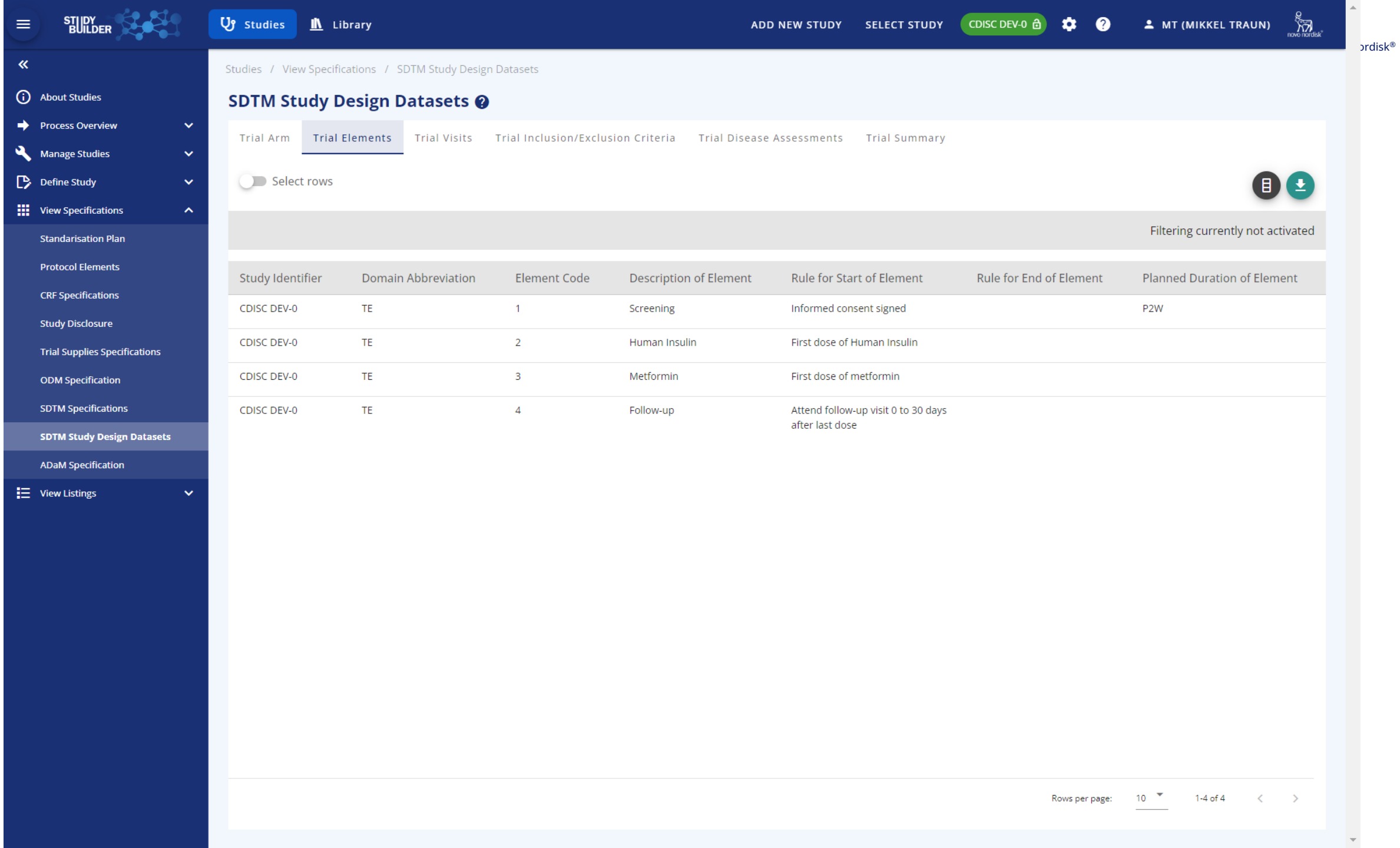
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Domain Abbreviation
Element Code
Description of Element
Rule for Start of Element
Rule for End of Element
Planned Duration of Element
CDISC DEV-0 TE 1 Screening Informed consent signed P2W
CDISC DEV-0 TE 2 Human Insulin First dose of Human Insulin
CDISC DEV-0 TE 3 Metformin First dose of metformin
CDISC DEV-0 TE 4 Follow-up Attend follow-up visit 0 to 30 days after last dose
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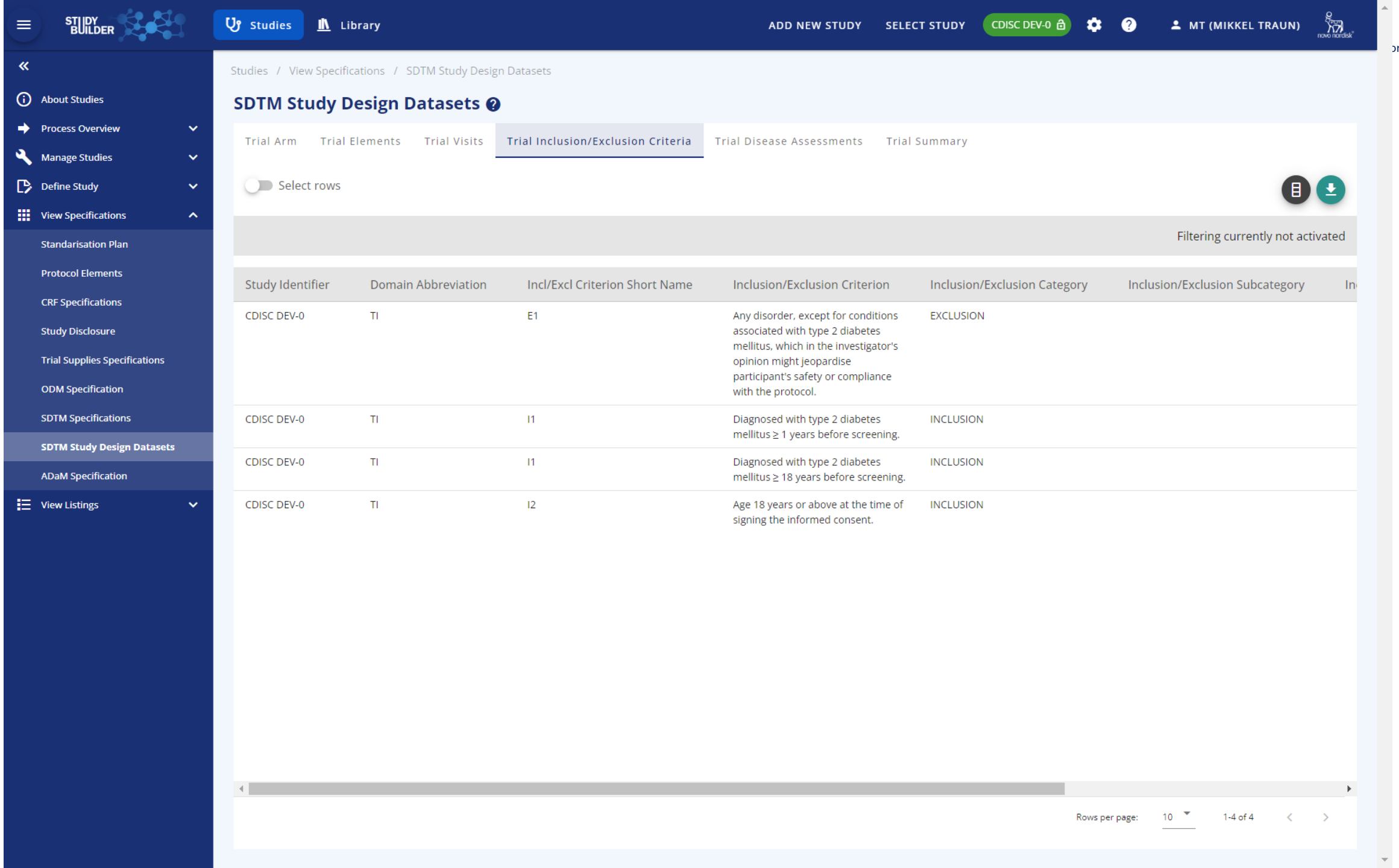
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Inclusion/Exclusion Criterion
Inclusion/Exclusion Category
Inclusion/Exclusion Subcategory
CDISC DEV-0 TI E1 Any disorder, except for conditions associated with type 2 diabetes mellitus, which in the investigator's opinion might jeopardise participant's safety or compliance with the protocol. EXCLUSION
CDISC DEV-0 TI I1 Diagnosed with type 2 diabetes mellitus ≥ 1 years before screening. INCLUSION
CDISC DEV-0 TI I1 Diagnosed with type 2 diabetes mellitus ≥ 18 years before screening. INCLUSION
CDISC DEV-0 TI I2 Age 18 years or above at the time of signing the informed consent. INCLUSION
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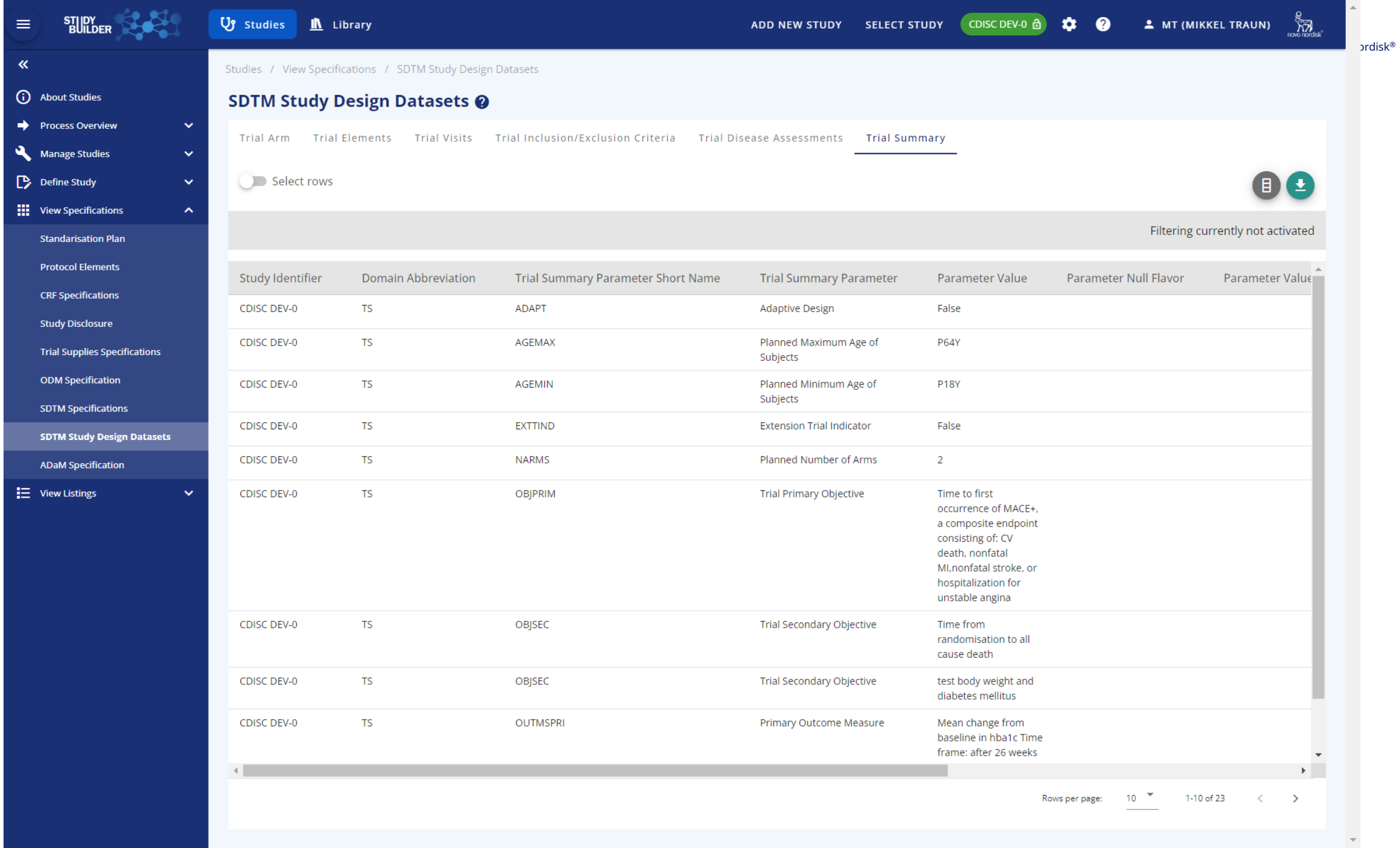
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Trial Summary Parameter
Parameter Value
Parameter Null Flavor
Parameter Value
CDISC DEV-0 TS ADAPT Adaptive Design False
CDISC DEV-0 TS AGEMAX Planned Maximum Age of Subjects P64Y
CDISC DEV-0 TS AGEMIN Planned Minimum Age of Subjects P18Y
CDISC DEV-0 TS EXTTIND Extension Trial Indicator False
CDISC DEV-0 TS NARMS Planned Number of Arms 2
CDISC DEV-0 TS OBJPRIM Trial Primary Objective Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI,nonfatal stroke, or hospitalization for unstable angina
CDISC DEV-0 TS OBJSEC Trial Secondary Objective Time from randomisation to all cause death
CDISC DEV-0 TS OBJSEC Trial Secondary Objective test body weight and diabetes mellitus
CDISC DEV-0 TS OUTMSPRI Primary Outcome Measure Mean change from baseline in hba1c Time frame: after 26 weeks
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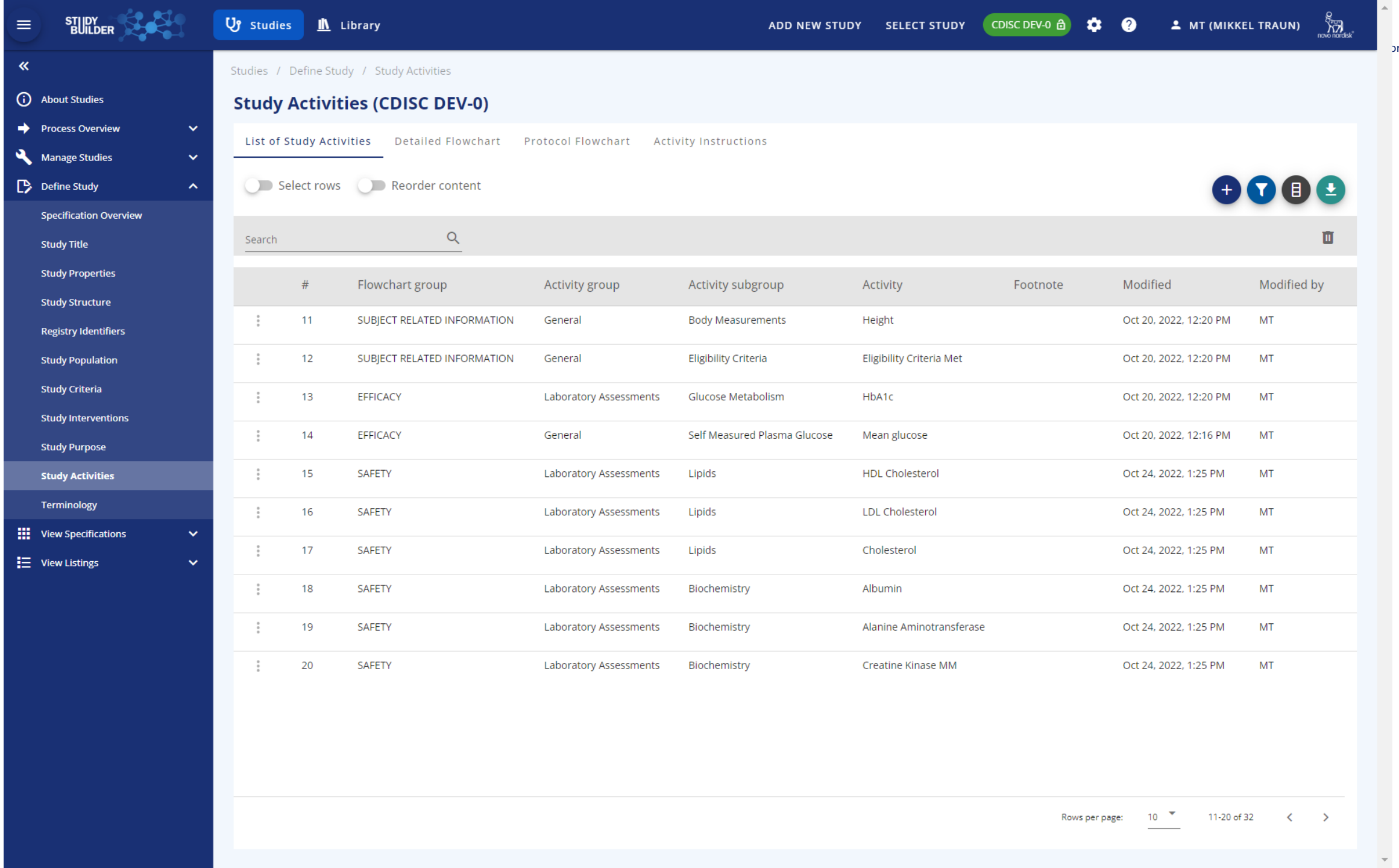
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Flowchart group Activity group Activity subgroup Activity Footnote Modified Modified by
11 SUBJECT RELATED INFORMATION General Body Measurements Height Oct 20, 2022, 12:20 PM MT
12 SUBJECT RELATED INFORMATION General Eligibility Criteria Eligibility Criteria Met Oct 20, 2022, 12:20 PM MT
13 EFFICACY Laboratory Assessments Glucose Metabolism HbA1c Oct 20, 2022, 12:20 PM MT
14 EFFICACY General Self Measured Plasma Glucose Mean glucose Oct 20, 2022, 12:16 PM MT
15 SAFETY Laboratory Assessments Lipids HDL Cholesterol Oct 24, 2022, 1:25 PM MT
16 SAFETY Laboratory Assessments Lipids LDL Cholesterol Oct 24, 2022, 1:25 PM MT
17 SAFETY Laboratory Assessments Lipids Cholesterol Oct 24, 2022, 1:25 PM MT
18 SAFETY Laboratory Assessments Biochemistry Albumin Oct 24, 2022, 1:25 PM MT
19 SAFETY Laboratory Assessments Biochemistry Alanine Aminotransferase Oct 24, 2022, 1:25 PM MT
20 SAFETY Laboratory Assessments Biochemistry Creatine Kinase MM Oct 24, 2022, 1:25 PM MT
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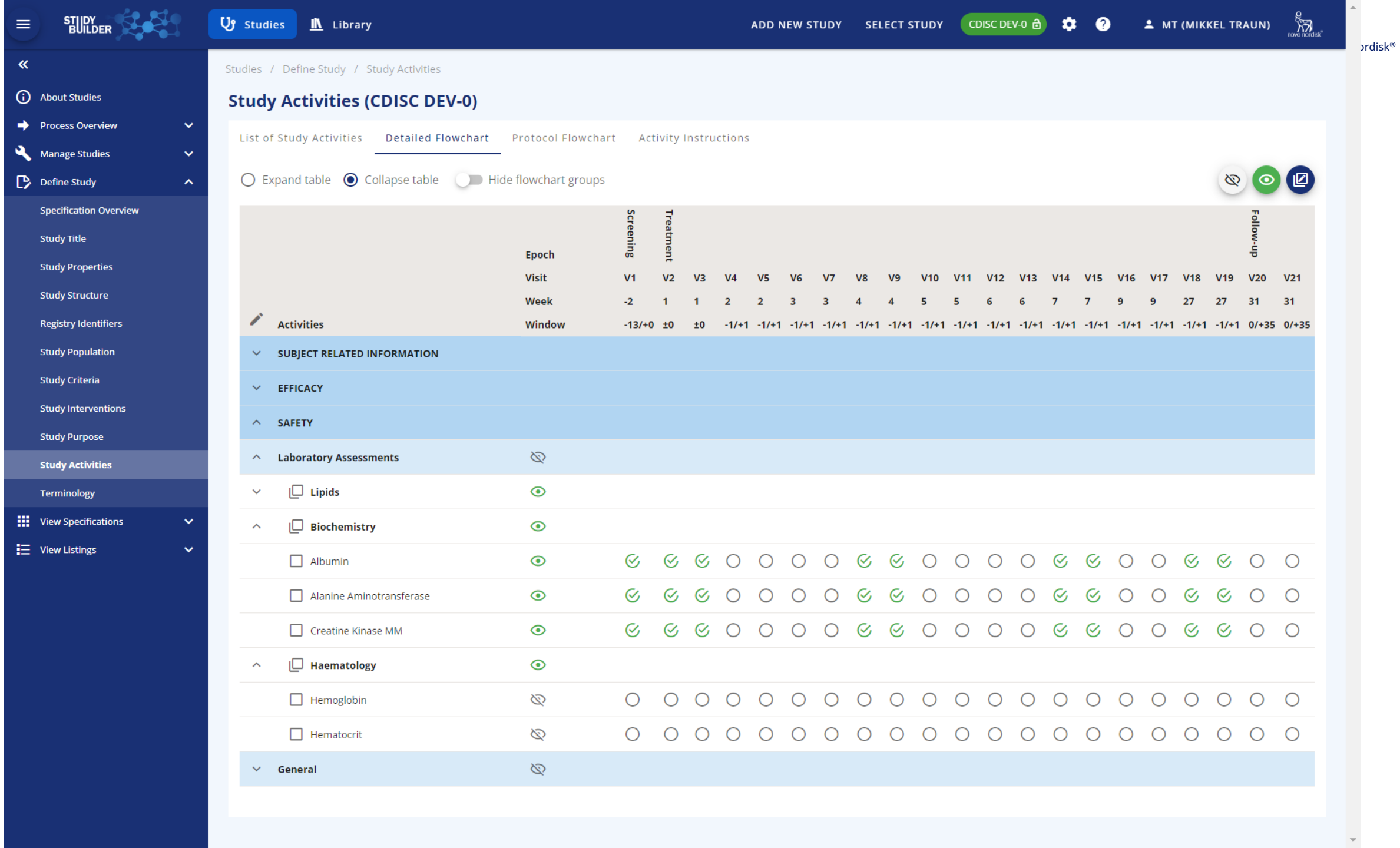
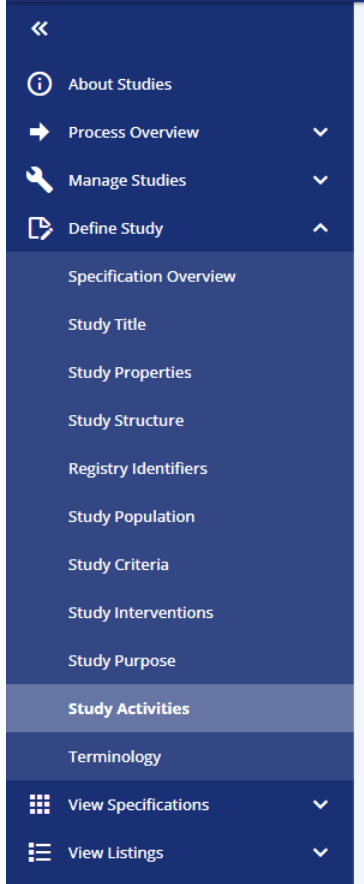


Activities	Epoch	Screening	Treatment																		Follow-up	
	Visit	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19	V20	V21
	Week	-2	1	1	2	2	3	3	4	4	5	5	6	6	7	7	9	9	27	27	31	31
	Window	-13/+0	±0	±0	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	0/+35	0/+35
SUBJECT RELATED INFORMATION																						
EFFICACY																						
SAFETY																						
Laboratory Assessments																						
Lipids																						
Biochemistry																						
Albumin		✓	✓	✓	○	○	○	○	✓	✓	○	○	○	○	✓	✓	○	○	✓	✓	○	○
Alanine Aminotransferase		✓	✓	✓	○	○	○	○	✓	✓	○	○	○	○	✓	✓	○	○	✓	✓	○	○
Creatine Kinase MM		✓	✓	✓	○	○	○	○	✓	✓	○	○	○	○	✓	✓	○	○	✓	✓	○	○
Haematology																						
Hemoglobin		○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Hematocrit		○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
General																						



Studies / Define Study / Study Activities

Study Activities (CDISC DEV-0)

List of Study Activities | Detailed Flowchart | **Protocol Flowchart** | Activity Instructions

Protocol Flowchart

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Study epoch	Screening	Treatment																		Follow-up	
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19	V20	V21
Study day	-14	1	1	8	8	15	15	22	22	29	29	36	36	43	43	57	57	183	183	213	213
Visit window (days)	-13/+0	±0	±0	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35	+0/+35
SUBJECT RELATED INFORMATION																					
General																					
Randomisation		X	X																		
End of Study																				X	X
Physical Examination - early ph1	X																				
Body Measurements	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Eligibility Criteria	X																				
EFFICACY																					
Laboratory Assessments																					
Glucose Metabolism																					
HbA1c	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
General																					
Self Measured Plasma Glucose	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
SAFETY																					
Laboratory Assessments																					
Lipids																					
HDL Cholesterol	X	X	X					X	X					X	X			X	X		
LDL Cholesterol	X	X	X					X	X					X	X			X	X		
Cholesterol	X	X	X					X	X					X	X			X	X		
Biochemistry																					
Albumin	X	X	X					X	X					X	X			X	X		
Alanine Aminotransferase	X	X	X					X	X					X	X			X	X		
Creatine Kinase MM	X	X	X					X	X					X	X			X	X		
Haematology																					
General																					
Adverse Event	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Study Overview | Study Design Status | Browse Concepts | Activity Concepts

Select Activity Concep

Select Activity Instance

Body Weight

Activity Grouping

Field	Value
ActivityGroup	Examinations
ActivitySubGroup	Body Measurements
Activity	Body Weight
ActivityInstance	Body Weight

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Activity Concept Graph Model

List Generic Activity Concept Definition

ActivityInstance	ActivityItemClass	aitmc.mandatory	aitmc.order	DataType	Role	aitmc.data_collection
Body Weight	collection_datetime	Yes	5	DATETIME	TIMING	Yes
Body Weight	result_standard_unit	No	16	FLOAT	RESUQUAL	No
Body Weight	test_name_code	Yes	4	CTTERM	TOPIC	Yes
Body Weight	result_collection_unit	No	15	FLOAT	RESUQUAL	Yes
Body Weight	category	Yes	6	CTTERM	GROUQUAL	No

OpenStudyBuilder Dashboard

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Select Activity Concep

Select Activity Instance: Diastolic Blood Pressure

Activity Grouping

Field	Value
ActivityGroup	Examinations
ActivitySubGroup	Vital Signs
Activity	Diastolic Blood Pressure
ActivityInstance	Diastolic Blood Pressure

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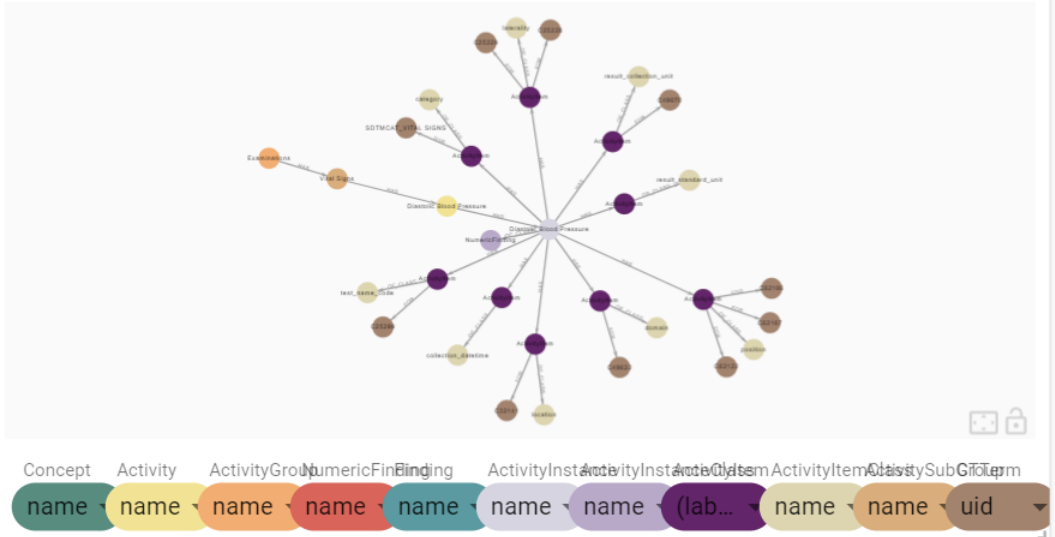
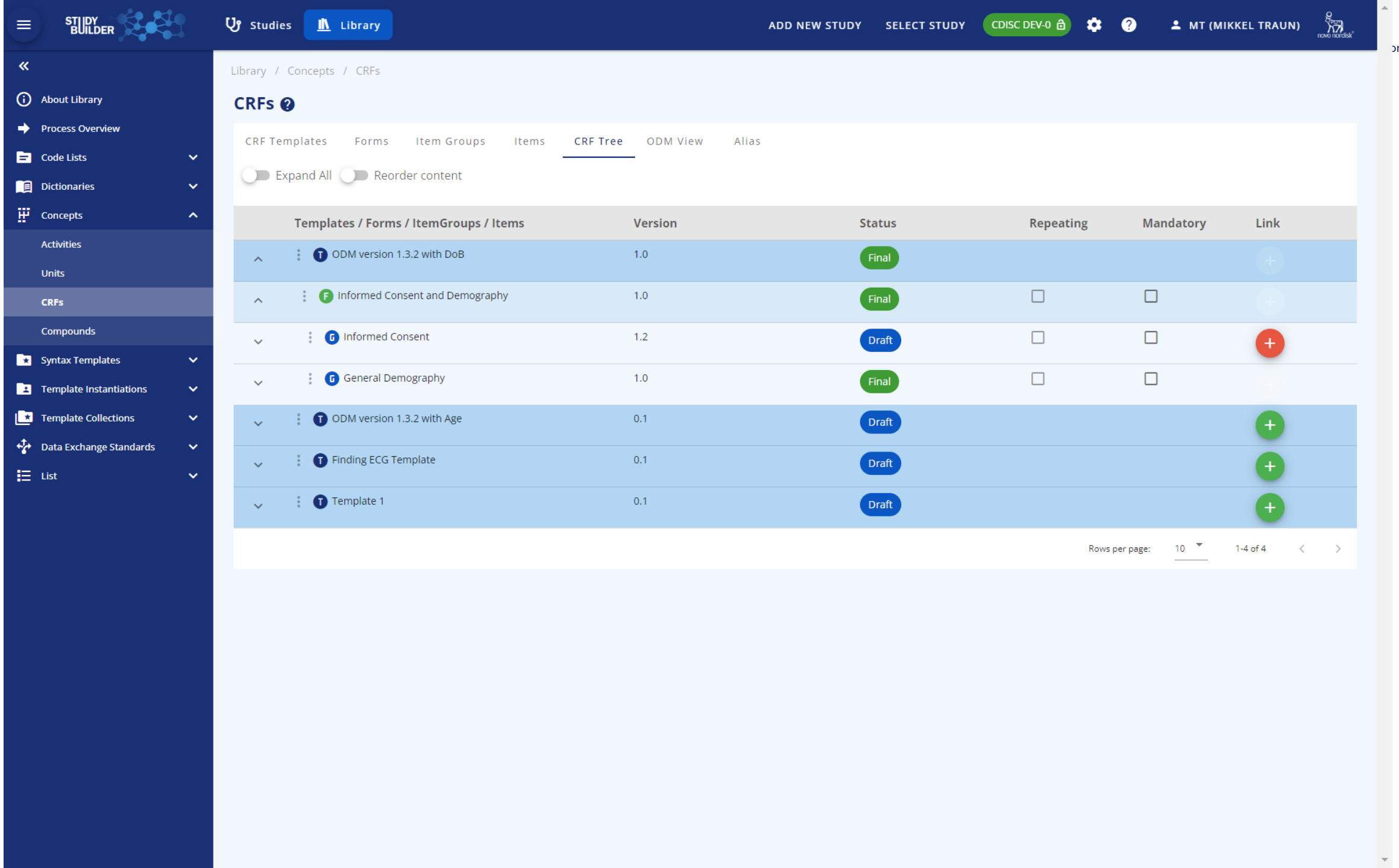
Activity Concept Graph Model



List Generic Activity Concept Definition

ActivityInstance	ActivityItemClass	aitmc.mandatory	aitmc.order	DataType	Role	aitmc.data_collection
Diastolic Blood Pressure	result_standard_unit	No	16	FLOAT	RESUQUAL	No
Diastolic Blood Pressure	collection_datetime	Yes	5	DATETIME	TIMING	Yes
Diastolic Blood Pressure	test_name_code	Yes	4	CTTERM	TOPIC	Yes
Diastolic Blood Pressure	laterality	No	11	CTTERM	RECOQUAL	Yes
Diastolic Blood Pressure	position	No	9	CTTERM	RECOQUAL	Yes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1.0
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Informed Consent
1.2
Draft
General Demography
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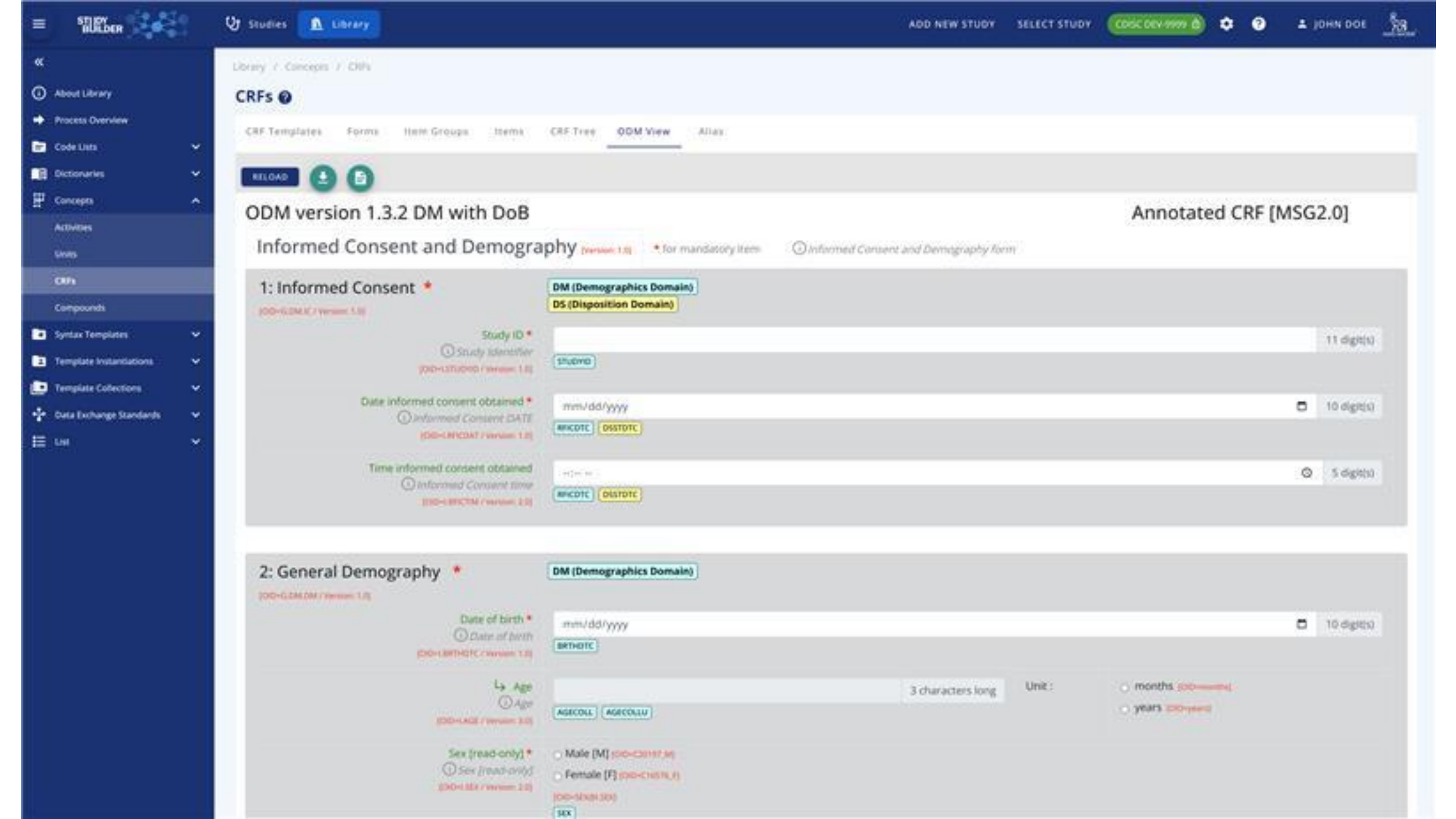
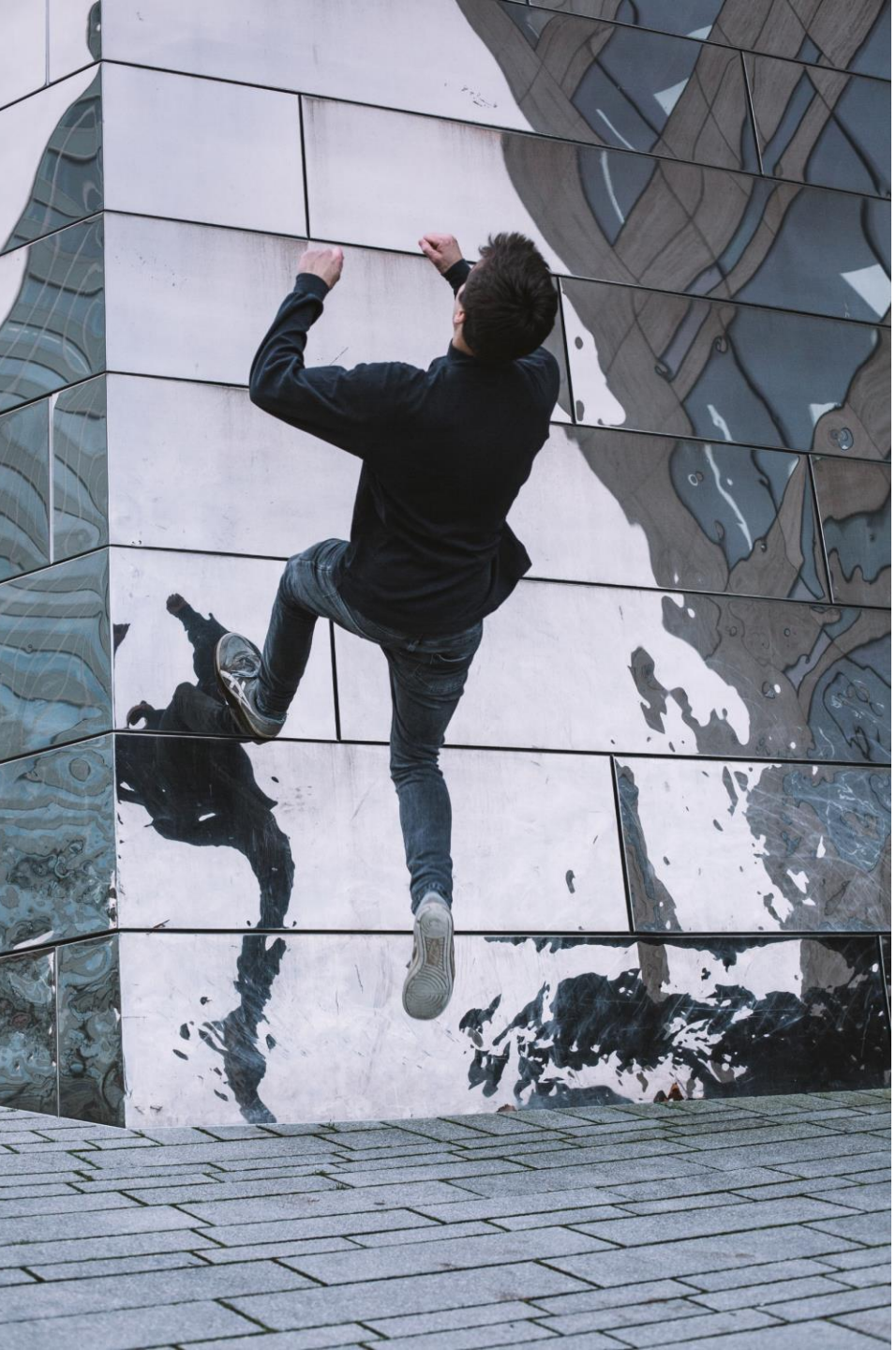

Studies
Library
ADD NEW STUDY
SELECT STUDY
JOHN DOE
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Compounds
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Concepts / CRFs
CRFs
CRF Templates
Forms
Item Groups
Items
CRF Tree
ODM View
Alias
RELOAD
ODM version 1.3.2 DM with DoB
Annotated CRF [MSG2.0]
Informed Consent and Demography
* for mandatory item
Informed Consent and Demography form
1: Informed Consent *
DM (Demographics Domain)
DS (Disposition Domain)
Study ID *
Study Identifier
STUDYID
11 digit(s)
Date informed consent obtained *
Informed Consent DATE
RFICDTC
DSSTDTC
mm/dd/yyyy
10 digit(s)
Time informed consent obtained
Informed Consent time
RFICDTC
DSSTDTC
5 digit(s)
2: General Demography *
DM (Demographics Domain)
Date of birth *
Date of birth
BRTHDTC
mm/dd/yyyy
10 digit(s)
Age
Age
AGECOLL
AGECOLLU
3 characters long
Unit :
months
years
Sex [read-only] *
Sex [read-only]
Male [M]
Female [F]
SEX

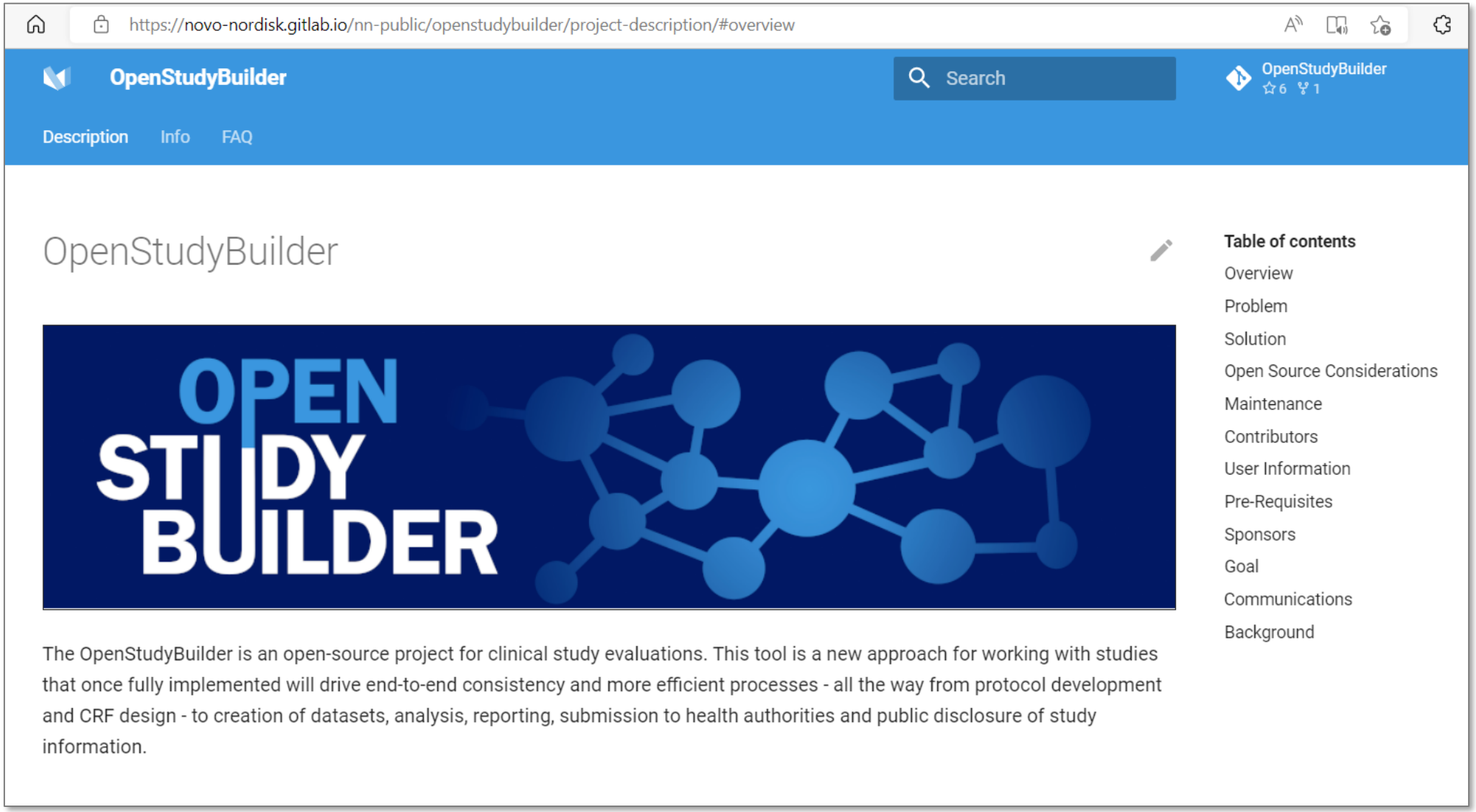


OpenStudyBuilder next steps

- Non-GCP MVP released internally at Novo Nordisk in September 2022
- Plan a GCP release
- Shared as open source project under COSA and source code under GitLab this Monday
  - https://cosa.cdisc.org/directory/openStudyBuilder
  - https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

  Currently only containing a project description
- Continue to actively collaborate with CDISC, TransCelerate DDF, peers and vendors

How do I get started on OpenStudyBuilder?



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

Thanks!
Questions?