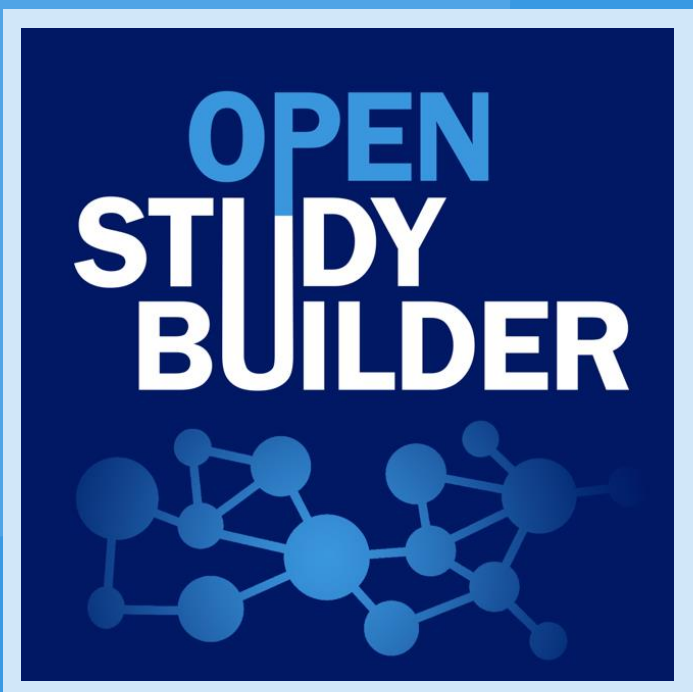# OpenStudyBuilder

OSB as MDR Collaboration

Vision, Status, MDR, Collaborations

Disclaimer

The concrete roadmap and plans underlies a continuous update due to priorities within Novo Nordisk
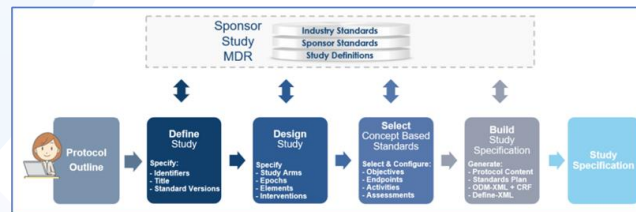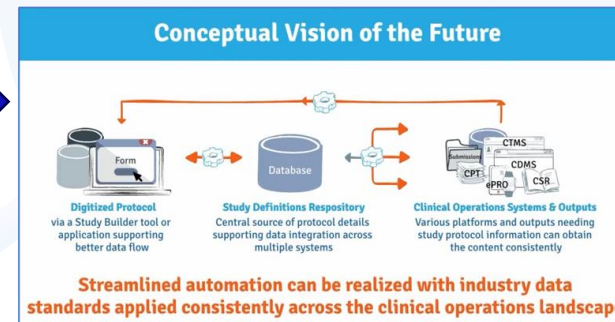
Scope & Status

OpenStudyBuilder - Connections

➢ Outcome of CDISC 360°

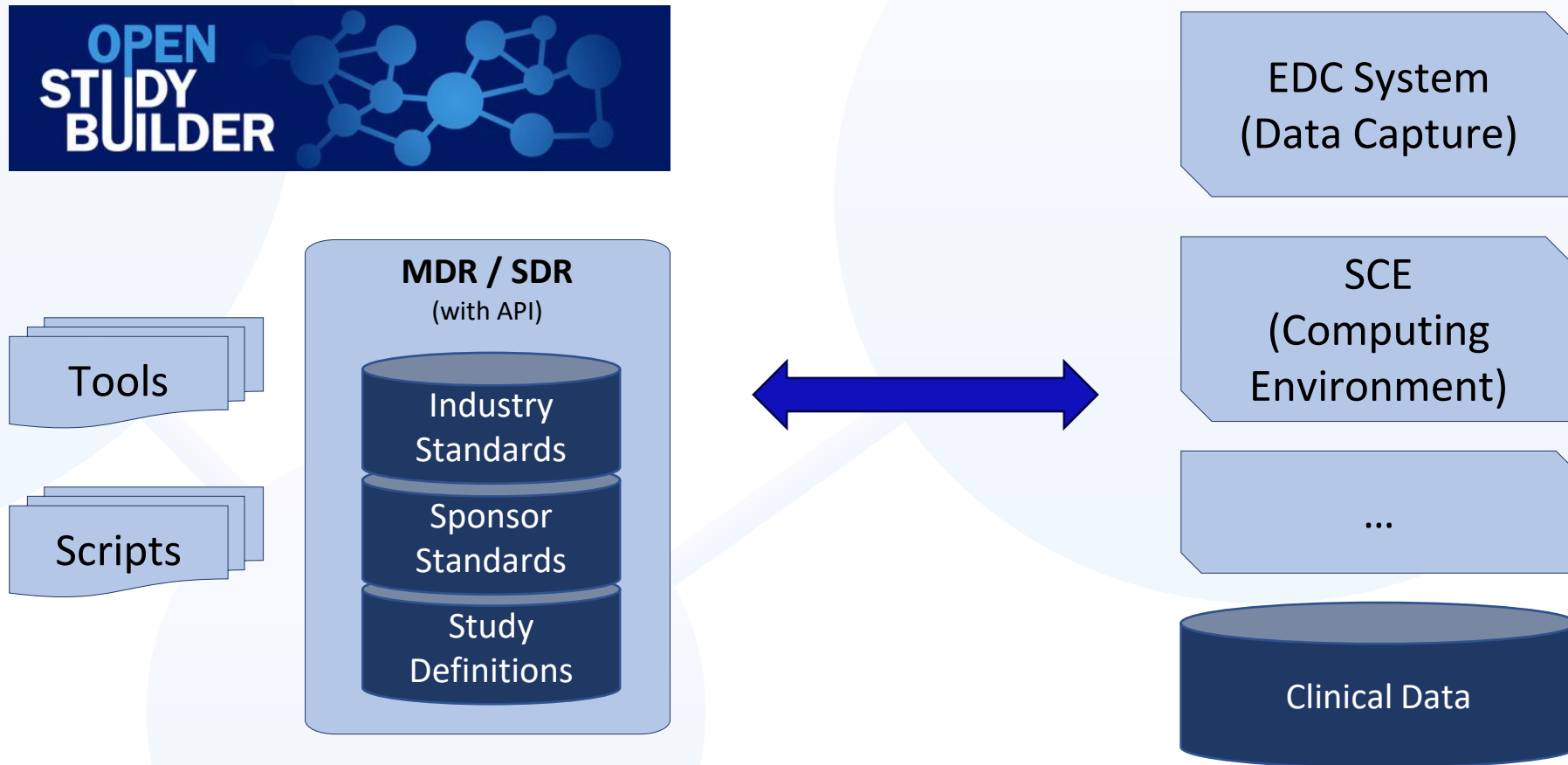➢ Linked to TransCelerate Digital Data Flow (DDF)

CDISC 360°

TransCelerate Digital Data Flow

OpenStudyBuilder
Open-Source by Novo Nordisk

Introduction

Scope & OpenStudyBuilder Status
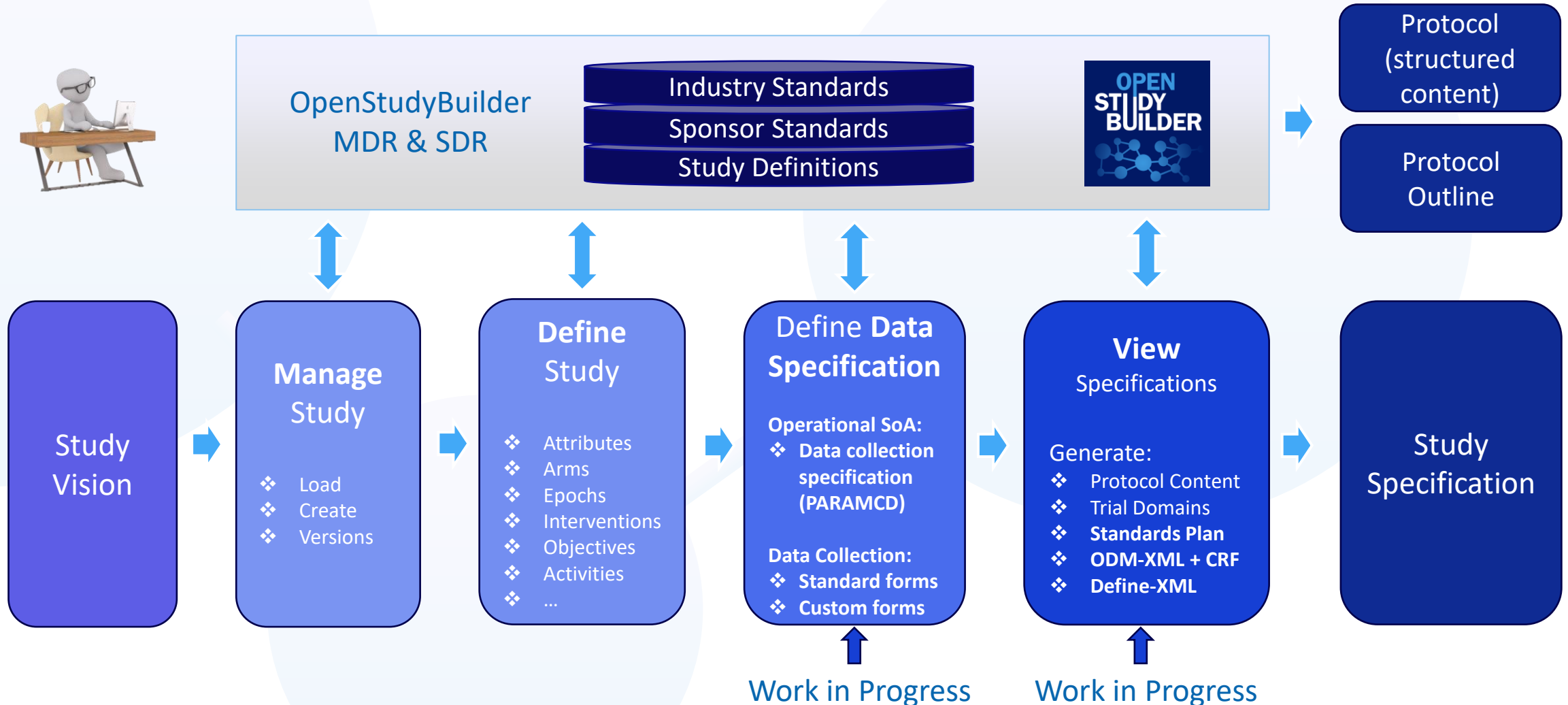
Scope & OpenStudyBuilder Status

Protocol (structured content)	**Structured Protocol**	Many items covered, syntax templates, Schedule of Activities, …
Protocol Outline	**CRF Design**	Work in Progress, available for library
	EDC Data Collection	Work in Progress
Study Specification	**SDTM Mapping**	Future, OAK with metadata
	ADAM Mapping	Future, Admiral metadata driven
	TLF Generation	Future, ARM driven

Scope & OpenStudyBuilder Status

OpenStudyBuilder
MDR & SDR

Industry Standards

Sponsor Standards

Study Definitions

OPEN STUDY BUILDER

Protocol (structured content)

Title Elements

Objectives & Endpoints

Study Population

Study Interventions

Protocol Schedule of Activities

Study Design

Study Activities

Work in Progress
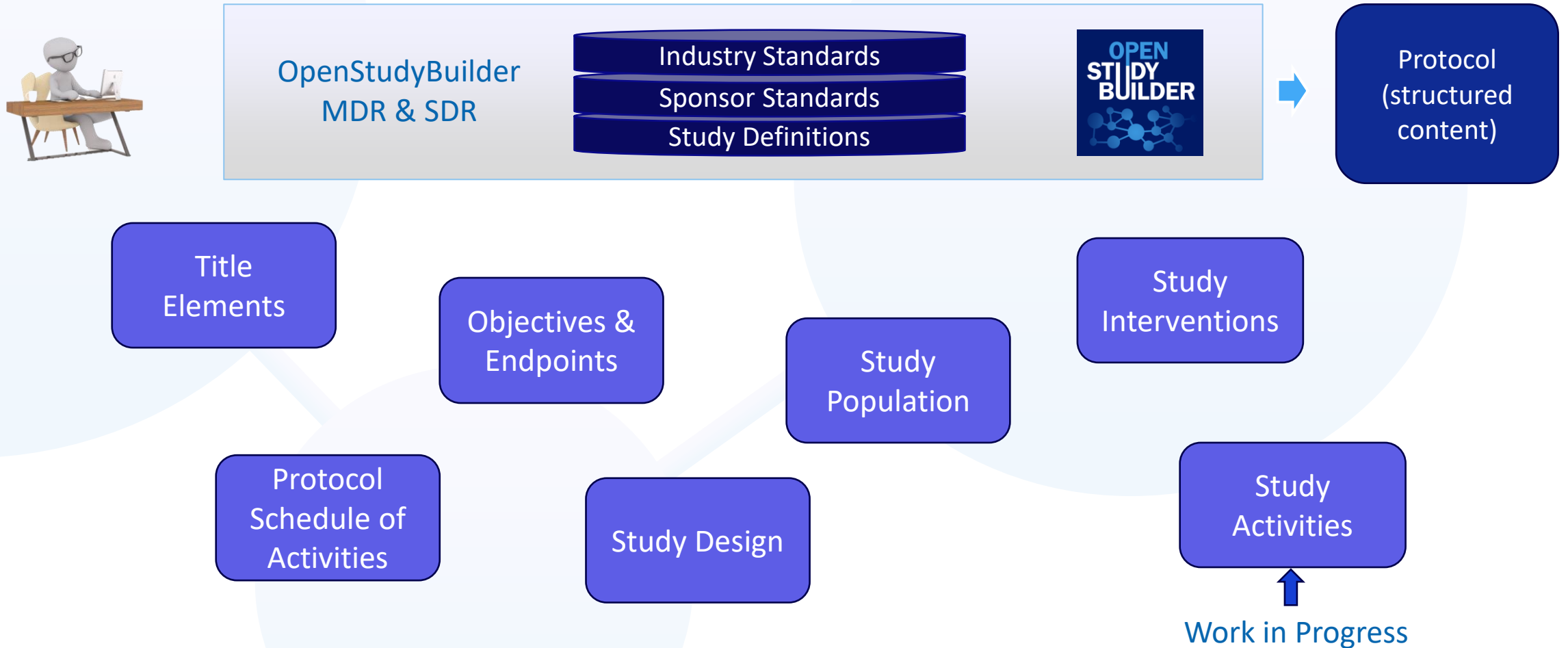
Standardization through Controlled Terminology & Templates

Protocol Template via Word add-in tool

The OpenStudyBuilder Word add-in is used primarily by Medical Writers to **automate the transfer of information** from the **StudyBuilder system into Word documents**. The tool is expected to be shared as open-source during 2024.
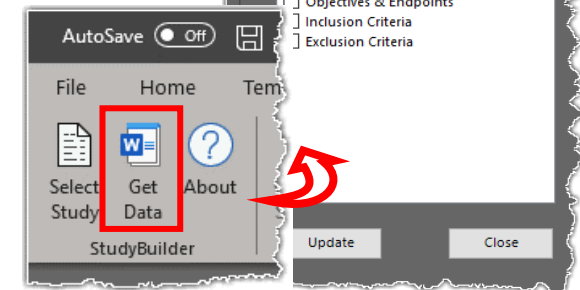
Protocol content built in OpenStudyBuilder

- **Study purpose** (objectives, endpoints)
- **Population** (disease area, indication, sex, age, …)
- **Selection criteria** (eligibility, withdrawal, …)
- **Study type** (interventional, observational, …)
- **Study design** (randomisation, blinding, arms, …)
- **Interventions** (drug, dose, route, other …)
- **Schedule of Activities** (naming, timing, type, windows)

Supported by library capabilities for endpoints, eligibility criteria and assessments.
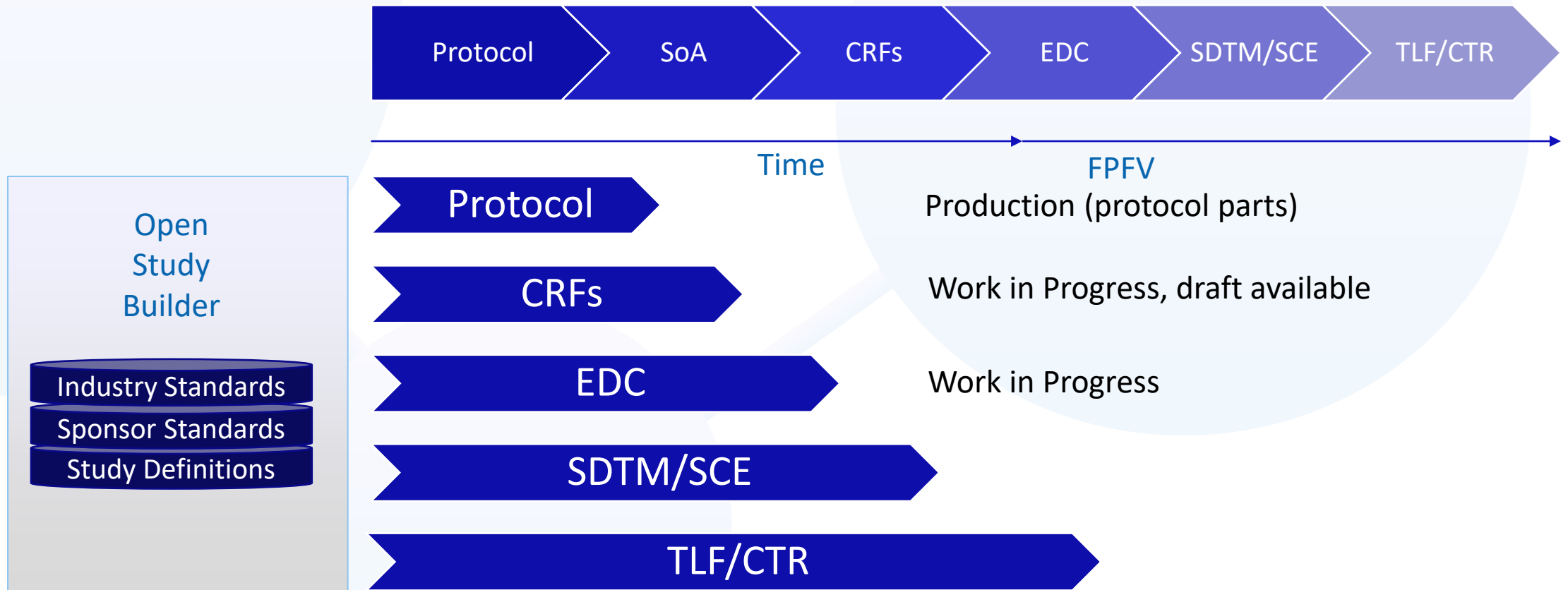
StudyBuilder **Word Add-in** in **Protocol Template**

- One-way connection (from StudyBuilder to Word)*
- Code recognizes the document type
- User-friendly ribbon and 'fly-out' in Word
- Styles ensure proper formatting in Word

Get Data

Currently saved: INS-007

Select all
- Protocol Title
- Universal Trial Number
- EudraCT Number
- IND Number
- StudyBuilder Flowchart
- Objectives & Endpoints
- Inclusion Criteria
- Exclusion Criteria

Update   Close

AutoSave Off

File   Home   Tem

Select Study   Get Data   About

StudyBuilder

* Any updates to study specification should ALWAYS be done in OpenStudyBuilder, to ensure it served as the source of truth

Enable Parallelization

➢ Digitized Processes Over Manual Processes

| Protocol | SoA | CRFs | EDC | SDTM/SCE | TLF/CTR |

Time → FPFV

Open Study Builder

- Industry Standards
- Sponsor Standards
- Study Definitions

Protocol	Production (protocol parts)
CRFs	Work in Progress, draft available
EDC	Work in Progress
SDTM/SCE	
TLF/CTR	

Deliverables View

Deliverables

Protocol

M11 Protocol

Schedule of Activities

CRF Design

ODM.xml

aCRF

EDC Setup

Trial Budget Patient Burden

Statistical Analysis Plan

SDTM Specs Define.xml

SDTM

Trial Domains

Risk Assessment

ADAM Specs Define.xml

Monitoring

ADAM

Trial Posting

Data Integration
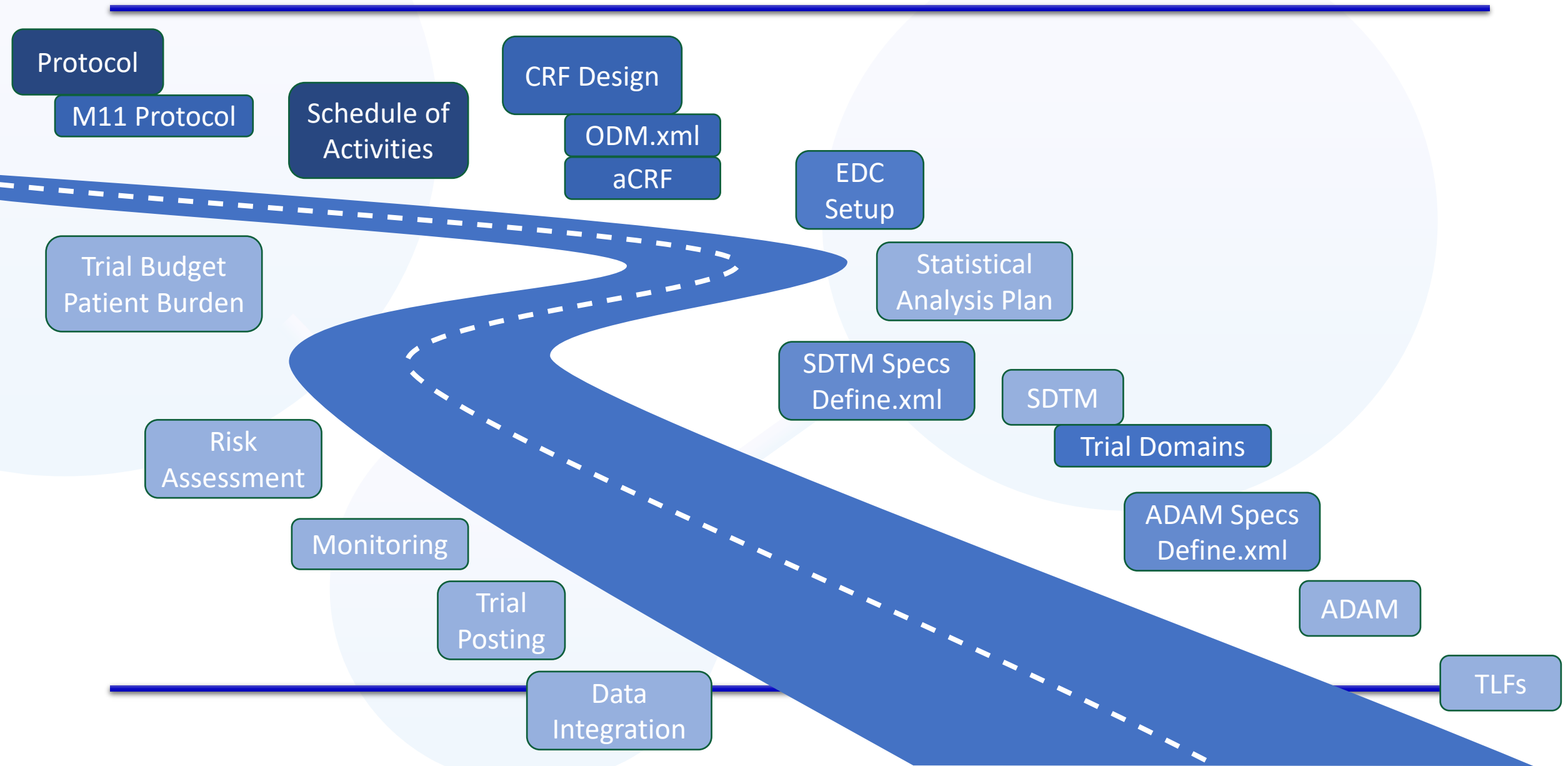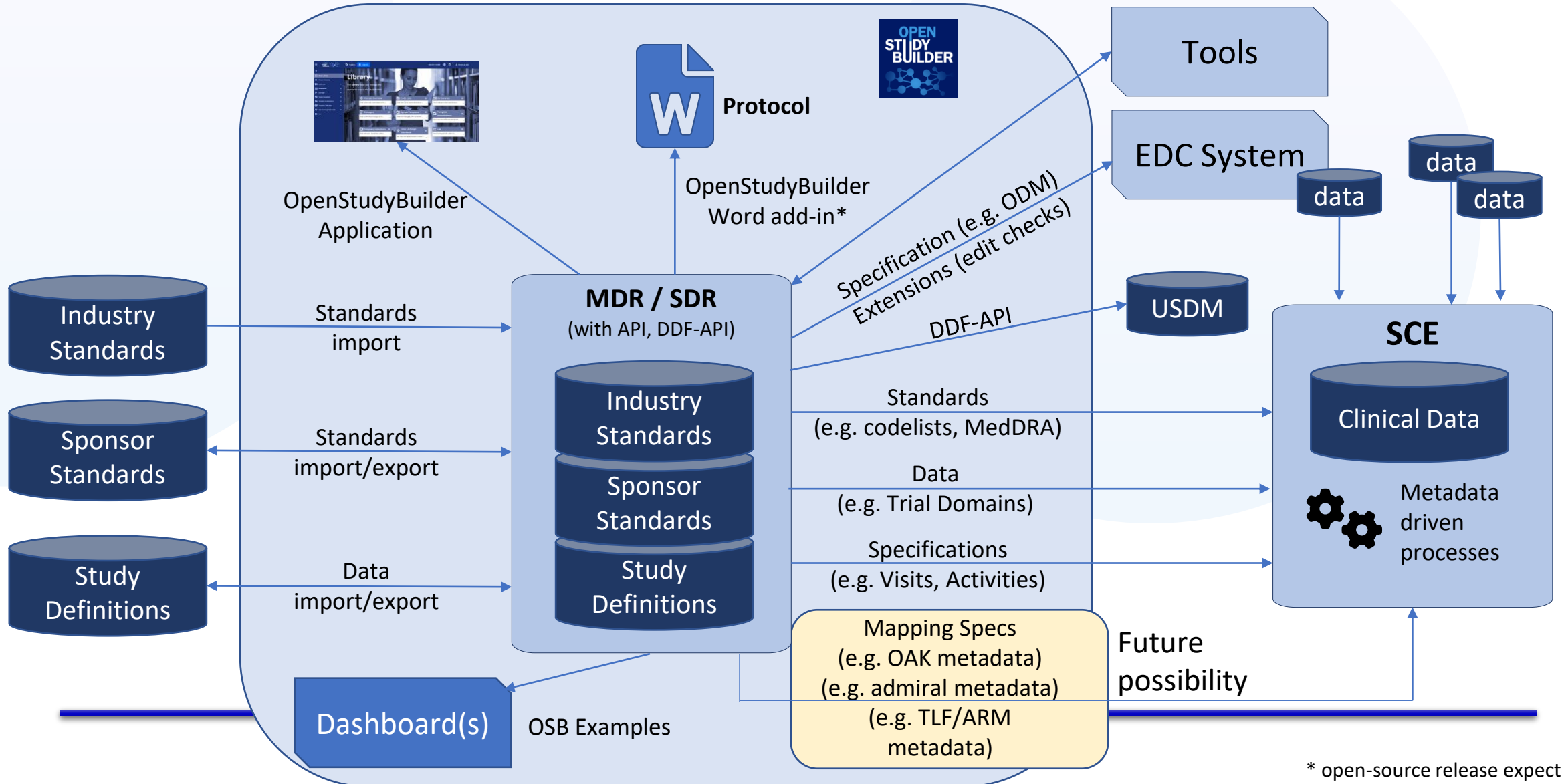
TLFs
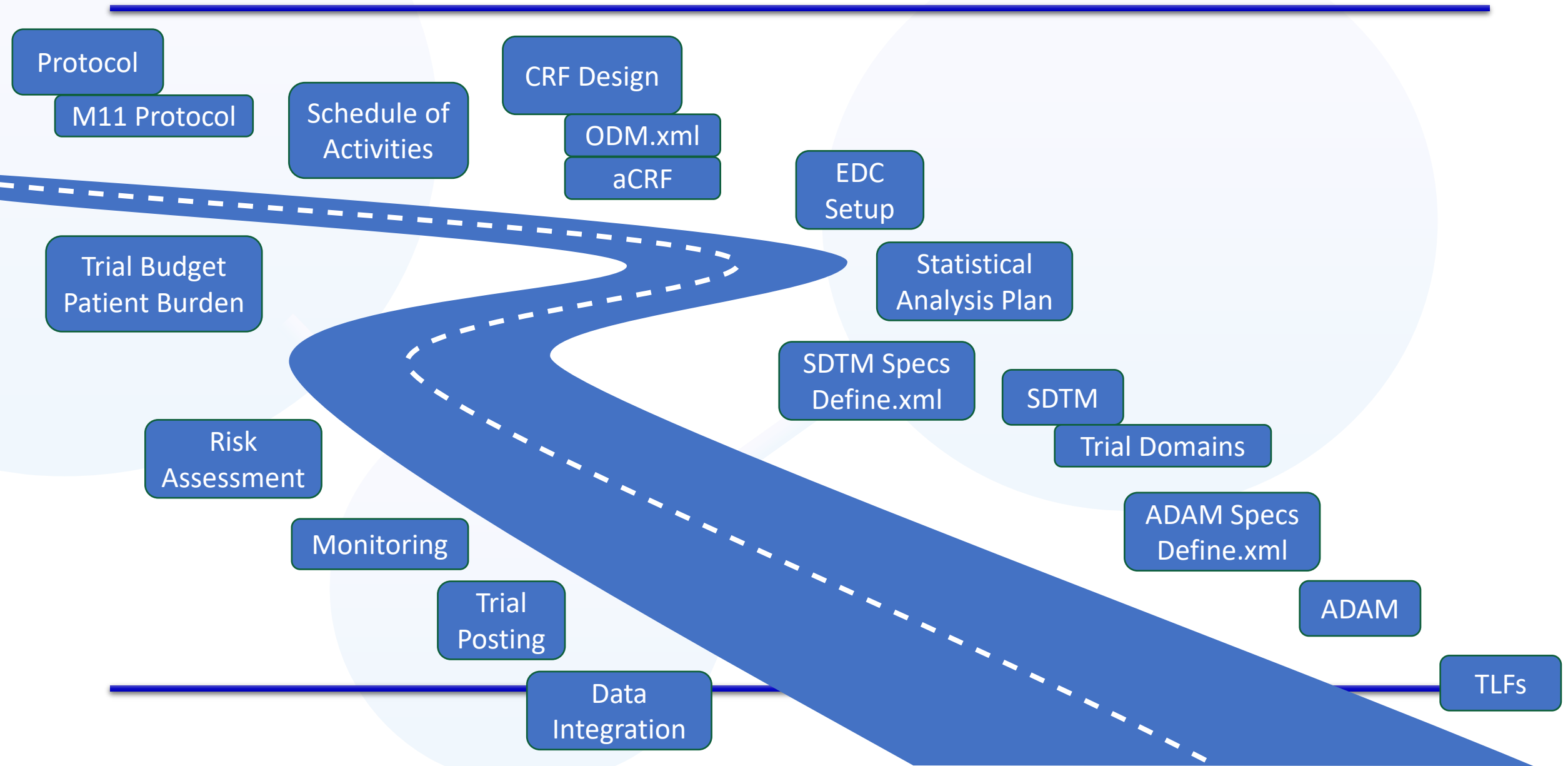
Deliverables

Deliverables - Status

➢ Protocol information managed

➢ Protocol M11 export: work in progress (DDF Interface)

➢ Schedule of Activities managed for multiple use-cases
  ➢ Protocol
  ➢ Visit & test planning
  ➢ Data Capture

➢ CRF Design on Library level
  ➢ Design on study level: work in progress
  ➢ Export in ODM.xml
  ➢ Annotated CRF available

➢ EDC Support: work in progress

➢ Trial Domains, protocol content available

➢ SDTM / ADAM Specifications: partially work in progress – mapped specifications according CDISC Implementation Guides
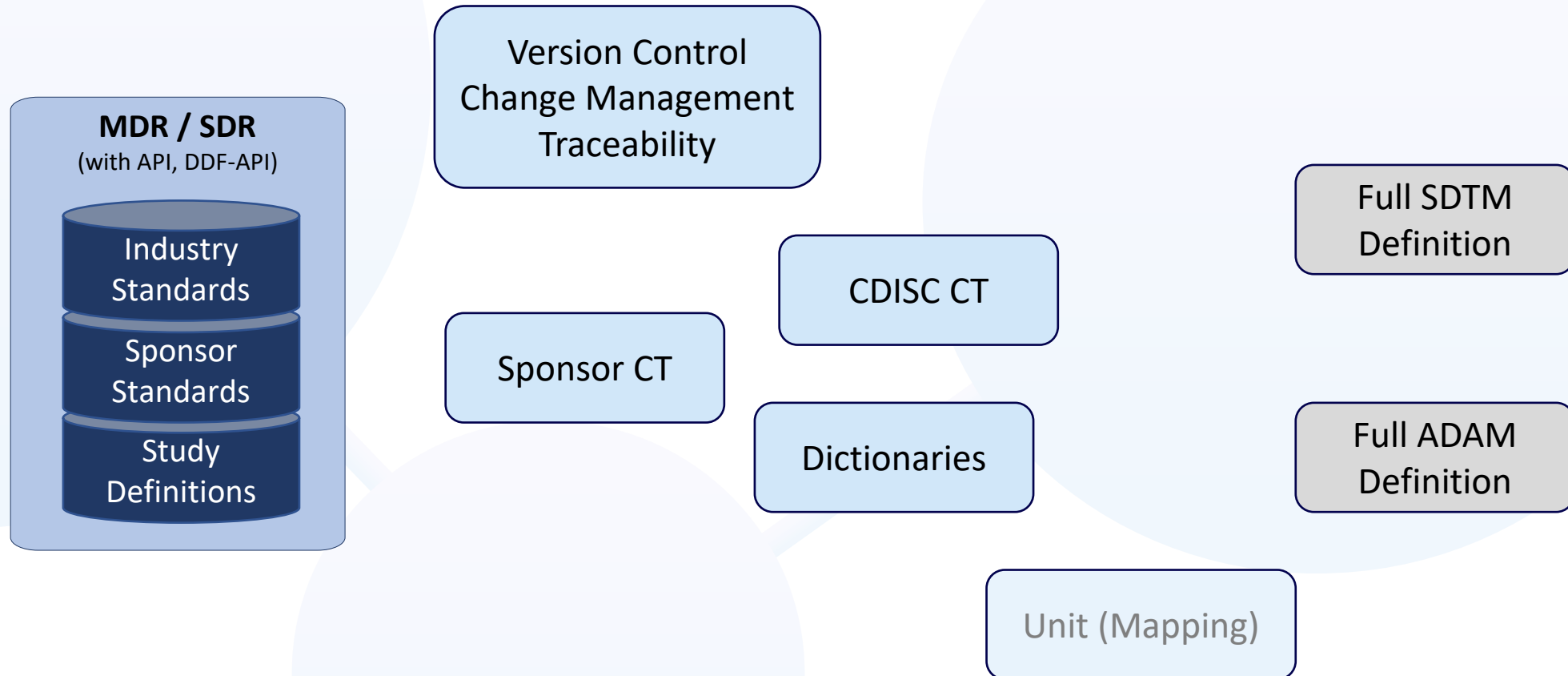
Environment

Environment

Metadata Repository

OpenStudyBuilder MDR

MDR / SDR
(with API, DDF-API)

Industry Standards

Sponsor Standards

Study Definitions

Version Control
Change Management
Traceability

Sponsor CT

CDISC CT

Dictionaries

Full SDTM Definition

Full ADAM Definition

Unit (Mapping)

OpenStudyBuilder MDR

➢ Version Control, change management, traceability

   ➢ Status: Draft, Final, Retired

   ➢ Version for all elements – timestamps

➢ CDISC CTs

   ➢ With sponsor extensions

   ➢ With sponsor additions (e.g. Y -> yes, N -> no)

➢ Sponsor CTs

   ➢ CT-Names

   ➢ CT-Terms

OpenStudyBuilder MDR

➢ Controlled Terminology Terms

   ➢ Library (coming from CDISC or „Sponsor")

   ➢ Sponsor name (alternative names)

   ➢ Order

   ➢ Code submission value

   ➢ Name submission value

   ➢ NCI Preferred name

   ➢ Definition

   ➢ Synonym(s)

Library	Sponsor Prefe	Or	Statu	Ver	Code Submission	Name Submiss	NCI Preferred Nam	Definition
CDISC	Screening	1	Final	3.0	SCREENING	None	Trial Screening	A period in a clinical study
CDISC	Run-in	2	Final	3.0	RUN-IN	None	Run-in Period	A period in a clinical study
Sponsor	Titration	3	Final	1.0	TITRATION EPOCH	TITRATION EPOC	UNK	
Sponsor	Dose Escalation	4	Final	1.0	DOSE ESCALATION EI	DOSE ESCALATIOI	UNK	
CDISC	Treatment	5	Final	3.0	TREATMENT	None	Treatment Epoch	A period in a study during
Sponsor	Maintenance	6	Final	1.0	MAINTENANCE EPOC	MAINTENANCE EI	UNK	
Sponsor	Extension	7	Final	1.0	EXTENSION EPOCH	EXTENSION EPOC	UNK	
CDISC	Observation	8	Final	3.0	OBSERVATION	None	Observation Study Ep	A period in a clinical study
CDISC	Wash-out	9	Final	3.0	WASHOUT	None	Washout Period	A period of time during a s
Sponsor	Elimination	10	Final	1.0	ELIMINATION EPOCH	ELIMINATION EPC	UNK	
CDISC	Follow-up	11	Final	3.0	FOLLOW-UP	None	Clinical Study Follow-	A period in a clinical study
Sponsor	Basic	12	Final	1.0	BASIC EPOCH	BASIC EPOCH	UNK	

OpenStudyBuilder MDR

> Version Control
>> Which terms changed
>>> CT history
>>> Sponsor history
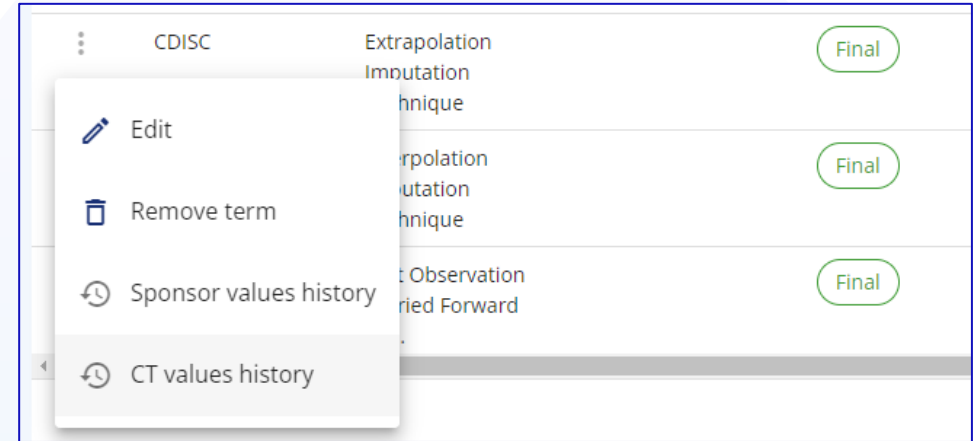
Code su	NCI preferred name	Definition	Status	Version	User	From	To
EXTRAP	Extrapolation Imputation Technique	A data derivation or imputation techn	Final	3.0	TEST	30.06.2023	
EXTRAP	Extrapolation Imputation Technique	A data derivation or imputation techn	Final	2.0	TEST	27.03.2020	30.06.2023
EXTRAP	Extrapolation Imputation Technique	A method of imputation involving po	Final	1.0	TEST	29.09.2017	27.03.2020

OpenStudyBuilder MDR

➤ Traceability

   ➤ Who changed what

      ➤ Scripts might run with „unknown-user"

Code list name	Submission	Definition	Status	Version	User	From	To
Null Flavor	NULLFLVR	(changed) A null flavor is a	Final	2.0	katja.glass	2024-01-2	
Null Flavor	NULLFLVR	(changed) A null flavor is a	Draft	1.2	katja.glass	2024-01-2	2024-01-22T13
Null Flavor	NULLFLVR	A null flavor is an ancillary	Draft	1.1	katja.glass	2024-01-2	2024-01-22T13
Null Flavor	NULLFLVR	A null flavor is an ancillary	Final	1.0	unknown-user	2023-11-0	2024-01-22T13
Null Flavor	NULLFLVR	A null flavor is an ancillary	Draft	0.1	unknown-user	2023-11-0	2023-11-01T12

OpenStudyBuilder MDR

- ➢ SDTM / ADAM Definitions
  - ➢ Not available as whole
  - ➢ CDISC Implementation Guides (IGs) read in
  - ➢ Sponsor data standard load (for SDTM)
    - ➢ Undocumented features (database content and API)
  - ➢ Activities as concepts
    - ➢ Partially SDTM / ADAM definitions
  - ➢ CRF Design
    - ➢ Partially SDTM definitions
    - ➢ Not fully linked yet

OpenStudyBuilder MDR

➢ SDTM / IG Definitions

OpenStudyBuilder MDR

➤ Sponsor Model Upload Example

	A	B	C	D	E	F	G	H	I	J	K
1	b	table	column	activ	label	order	type	length	displayformat	xmldatatype	xmlcodelist
2	Y	Associated__Persons-APRELSUB	STUDYID		Study Identifier	10	C	40		text	
3	Y	Associated__Persons-APRELSUB	DOMAIN		Domain Abbreviation	20	C	8		text	
4	Y	Associated__Persons-aPRELSUB	APID		Associated Persons Identifier	30	C	60		text	
5	Y	Associated__Persons-APRELSUB	__SEQ		Sequence Number	40	N	8		integer	
6	Y	Associated__Persons-APRELSUB	RSUBJID		Related Subject	50	C	60		text	
7	Y	Associated__Persons-APRELSUB	RDEVID		Related Device	60	C	40		text	
8	Y	Associated__Persons-APRELSUB	SREL		Subject, Device, or Study Relationship	70	C	40		text	RELSUB
9		Associated__Persons-APRELSUB	__SPID		Sponsor-Defined Identifier	80	C	40		text	
10	Y	Associated__Persons-APRELSUB	STUDYID		Study Identifier	10	C	40		text	
11	Y	Associated__Persons-APRELSUB	APID		Associated Persons Identifier	20	C	60		text	
12	Y	Associated__Persons-APRELSUB	RSUBJID		Related Subject or Pool Identifier	30	C	60		text	
13	Y	Associated__Persons-APRELSUB	RDEVID		Related Device Identifier	40	C	40		text	
14	Y	Associated__Persons-APRELSUB	SREL		Subject, Device, or Study Relationship	50	C	40		text	
15	Y	Special-Purpose-CO	RDOMAIN		Related Domain Abbreviation	10	C	8		text	
16	Y	Special-Purpose-CO	IDVAR		Identifying Variable	20	C	8		text	
17	Y	Special-Purpose-CO	IDVARVAL		Identifying Variable Value	30	C	40		text	
18	Y	Special-Purpose-CO	COREF	comme	Comment Reference	40	C	200		text	
19	Y	Special-Purpose-CO	COVAL	comme	Comment	50	C	200		text	
20		Special-Purpose-CO	COVAL1		Comment 1	60	C	200		text	
21		Special-Purpose-CO	COVAL2		Comment 2	70	C	200		text	
22		Special-Purpose-CO	COVAL3		Comment 3	80	C	200		text	
23		Special-Purpose-CO	COVAL4		Comment 4	90	C	200		text	

dataset_class_activity_instance_class_full.csv
sdtm_mastermodelsheet_3.2-NN15_ClassColumns.csv
sdtm_mastermodelsheet_3.2-NN15_ClassTables.csv
sdtm_mastermodelsheet_3.2-NN15_ReferenceColumns.csv
sdtm_mastermodelsheet_3.2-NN15_ReferenceEnrich.csv
sdtm_mastermodelsheet_3.2-NN15_ReferenceTables.csv
sdtm_mastermodelsheet_3.2-NN15_ReferenceTsparms.csv

Data models

GET /standards/data-models List all data-models
GET /standards/data-models/headers Returns possible values from the database for a given header
GET /standards/data-models/{uid} Get details on a specific data model

Data model implementation guides

Sponsor models

Sponsor model dataset classes

Sponsor model variable classes

APIs

Sponsor model datasets

Sponsor model variables

OpenStudyBuilder MDR

➢ Collaborations
  ➢ High interest in utilization OpenStudyBuilder as MDR
  ➢ Support community build up, planning, execution

Vendor / CRO

Pharma

Consultants

Collaboration &

Open Source

Collaboration

➤ Current implementation only by Novo Nordisk (front-2-end)
  ➤ Many processes running in the background
    ➤ Planning
    ➤ Implementation
    ➤ Testing

➤ Integration of collaborators in current team & processes recommended
  ➤ Bring developers into OSB Team (>=70%)
  ➤ Utilize partners, e.g. Neo4j

➤ Code contribution / side project possible
  ➤ Additional plan integration activities

Collaboration

Option 1 – full integration

Novo Nordisk Team
(their requirements)

Collaborators
(their requirements)

Collaboration

Option 2 – side-by-side implementation

Novo Nordisk Team
(their requirements)

Integrations

Collaborators
(their requirements)

Collaborators
(their requirements)
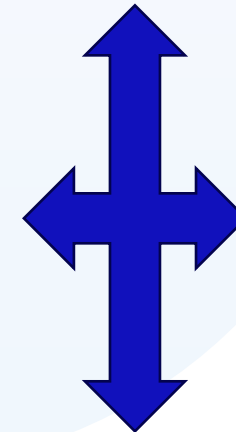
Open Source - License

➢ Functionality by configuration / plugin

➢ Fully integrated functionality

GPLv3

Style configuration (colors)

Config ABC   Private

Display

GPLv3

Style in tool implementation (color)

~~Private~~
GPLv3

Display
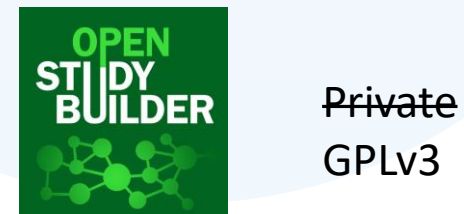
Open Source - License

➢ **Generic API update**
(GET/PUSH customer attributes)

OSB API
GPLv3

Customer attributes
- Study link to EDC
- Study link to SCE
- Study alternate number
- …

➢ **Specific API update**

OSB Updated API
GPLv3

Customer attributes
- Study link to EDC
- Study link to SCE
- Study alternate number
- …

Open Source - License

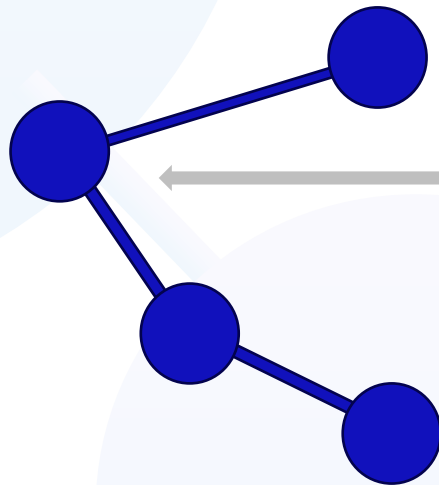➢ Plugin / Stand alone extension

OSB API
GPLv3

ABC API
Private

Customer attributes
- Study link to EDC
- Study link to SCE
- Study alternate number
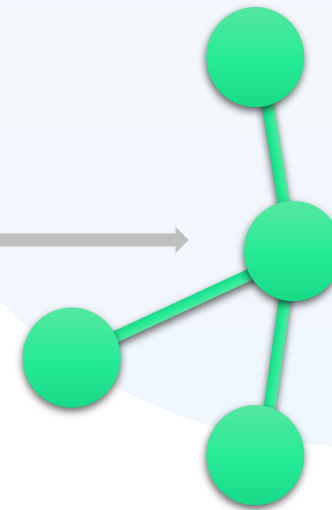- ...

Open Source - License

> STDM / ADAM specification as Standalone / Extension
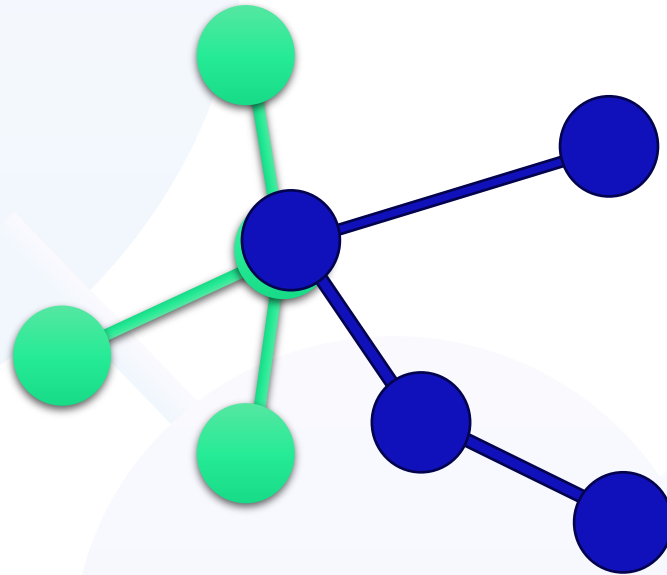
OpenStudyBuilder
Database Content

SDTM/ADAM Extension
Database Content

„Same as"

Open Source - License

➢ STDM / ADAM specification as Standalone / Extension

OSB API
GPLv3

SDTM/ADAM API
Private /
Collaborative

Open Source - License

➢ What do we want?

Harmonized Solution

Divergent Solutions

Divergent Solutions

Divergent Solutions

Plugins
Extensions
Apps

Collaboration

➤ What do we have?

➤ What do we need?

  ➤ Custom "attributes"

  ➤ Custom complex data

  ➤ Different context (OAK, linked-mapping, …)

➤ Do we want to collaborate?

Collaboration
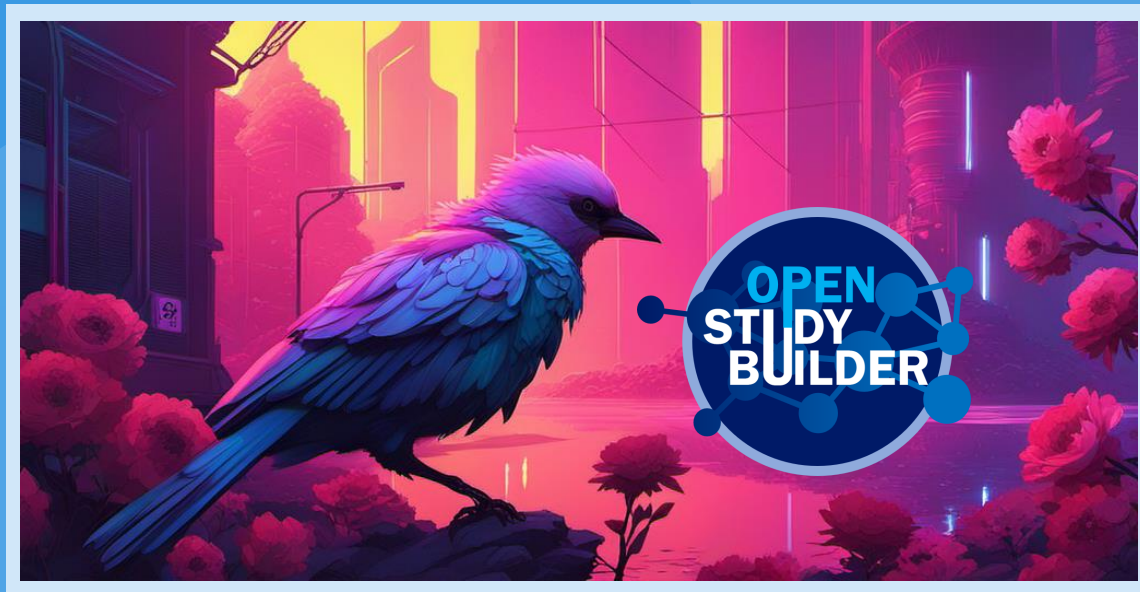
- ➢ Possible Steps
  - ➢ By-weekly / monthly meetings (recorded)
  - ➢ Knowledge sharing
  - ➢ Harmonization, coordination
  - ➢ Requirements / needs
  - ➢ Status updates

- ➢ Live meeting opportunity with Novo Nordisk representatives
  - ➢ 23.04.2024 17:00-18:00, Berlin, Germany - CDISC Interchange

Links

➤ Whiteboard: https://webwhiteboard.com/board/bxAWNTOia2b8uw2NItPxGYRwQnMtqH9H/

➤ Project Homepage: https://openstudybuilder.com/
➤ YouTube Demonstration (30'): https://youtu.be/dL5CY0BwfEs
➤ GitLab (Solution, Description): https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder
➤ Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw
➤ E-Mail: openstudybuilder@gmail.com

Sandbox:
➤ Mail openstudybuilder@neotechnology.com – Subject "Request Sandbox access"
➤ Note: when add/modify/delete, you mail might be exposed in the version history