

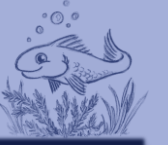
Katja Glass
Consulting

OpenStudyBuilder

Experimentation Examples



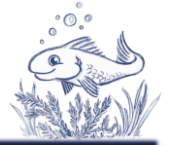
Agenda



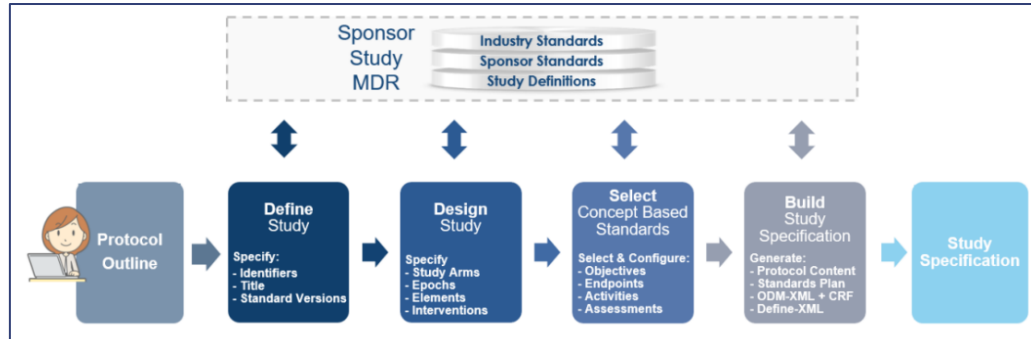
- Introduction
 - Use cases
 - MDR
 - SDR
 - Other
 - Summary
-



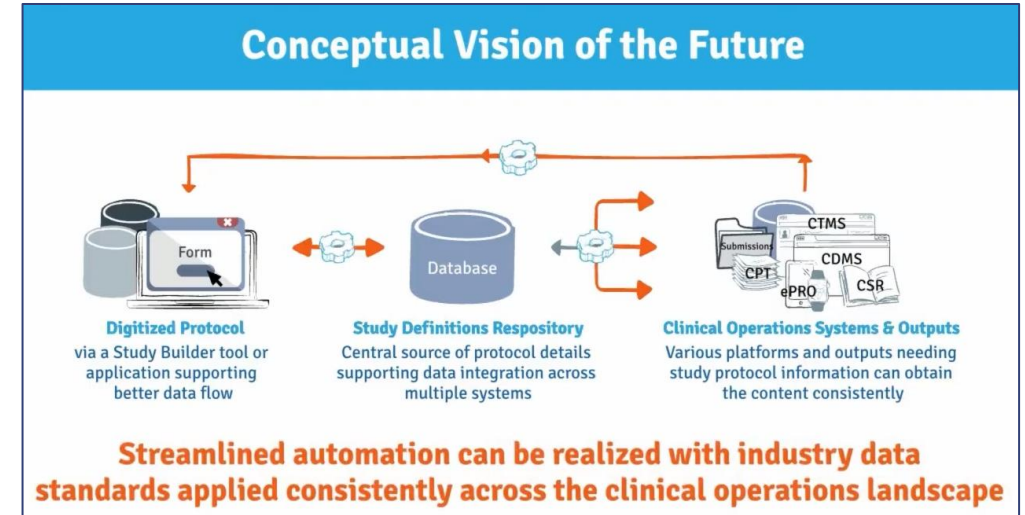
Introduction



CDISC 360°

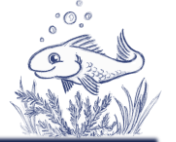


TransCelerate Digital Data Flow



OpenStudyBuilder
Open-Source by Novo Nordisk

Introduction



The OpenStudyBuilder comprises three elements:

- **Clinical Metadata Repository (clinical MDR) & Study Definition Repository (SDR)**
(graph database, 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)

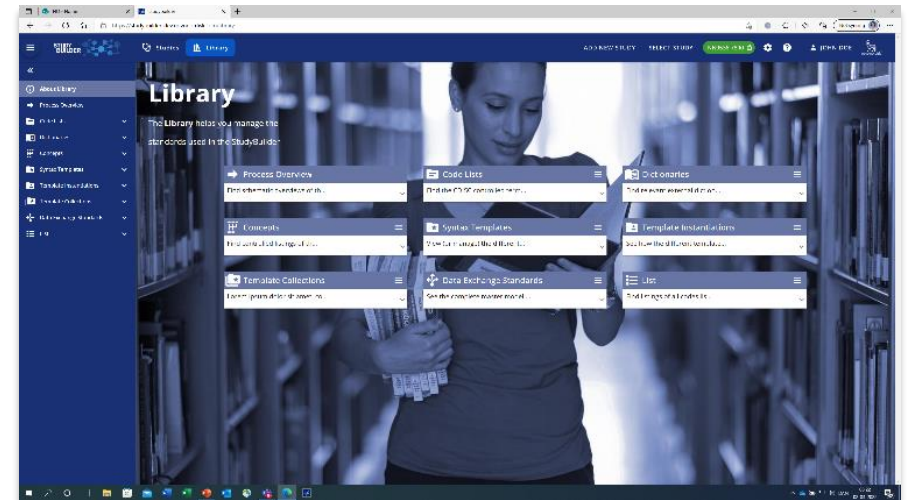
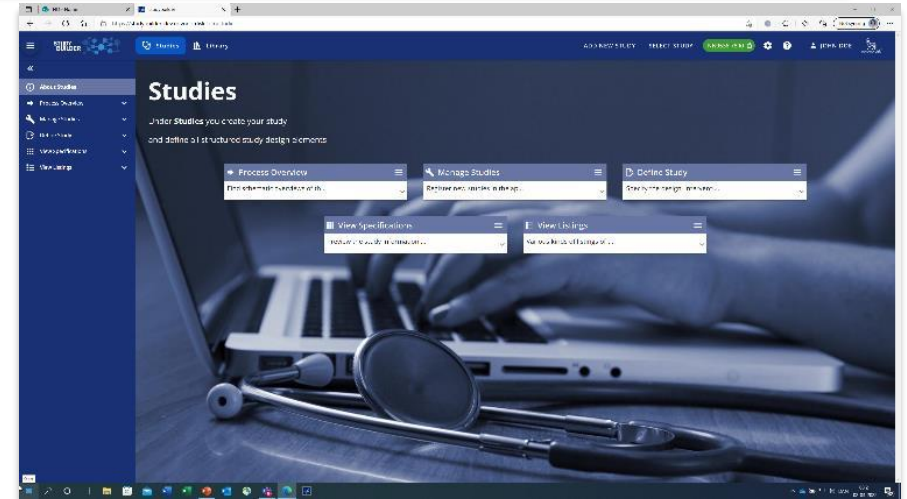


Introduction



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)



Introduction



➤ Connections

- CDISC Library (CT, Models and Implementation Guides)
- DDF Compatible (API-Adapter)
- Biomedical Concepts
 - COSMoS (Conceptual and Operational Standards Metadata Services)
- COSA project (CDISC Open Source Alliance)

➤ Follow / to connect

- ICH M11 (protocol representation)
- OAK (CDASH -> SDTM)
- Admiral (SDTM -> ADAM)
- ARM

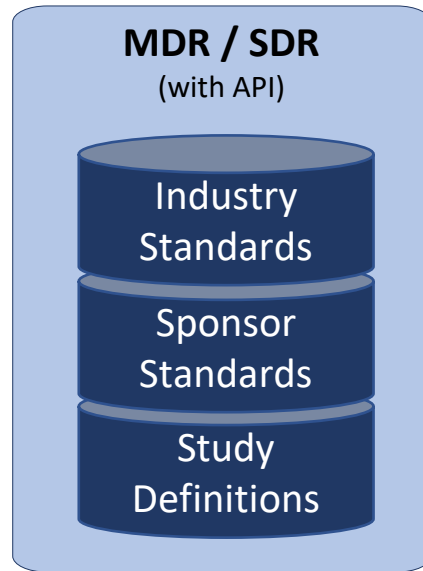


Introduction



Tools

Scripts



EDC System
(Data Capture)

SCE
(Computing Environment)

Clinical Data

Introduction - Links



- [LinkedIn Newsletter](#)
- Project Homepage: <https://openstudybuilder.com/>
 - Information
 - Guides
 - References
 - Events
- Demonstration Video ([YouTube](#))
- [GitLab Source Code](#)
- Slack ([invite Link](#))
- E-Mail: openstudybuilder@gmail.com

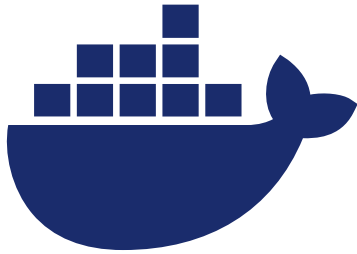
Public Sandbox:

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

Introduction



How to get the “software”?



Local/Server
Installation

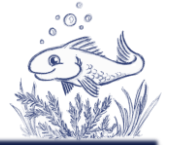
Access Public
Sandbox



Dedicated Hosted
Environment

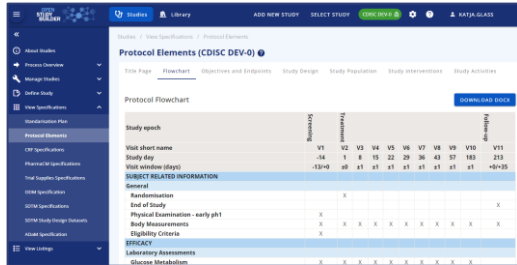
- Associated costs (Neo4j hosting)
 - PoC option through Novo possible
-

Introduction



What do I get?

Application

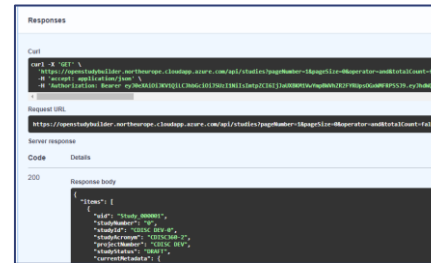


Neo4j database

- Including example data



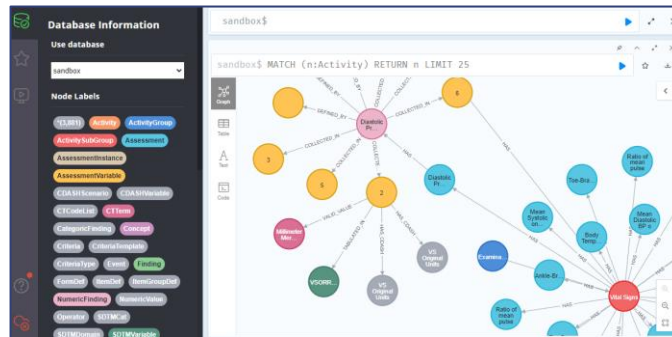
API



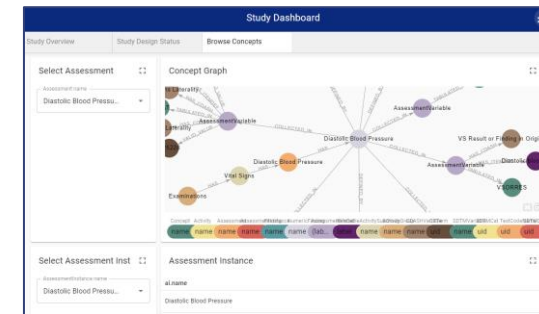
Documentation

- Project Homepage
- Tool documentation
- GitLab documentation
 - Database design
 - Architecture design
 - Instructions

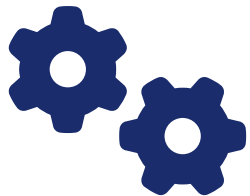
DB Browser



Neo4j dashboard*

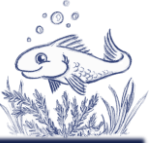


Scripts



*available in sandbox, can be installed on other environments

Introduction



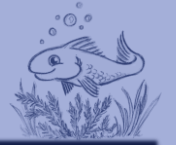
What can I do?

- What do you do with your current MDR?
- Where do you use study metadata?

➔ Use Cases



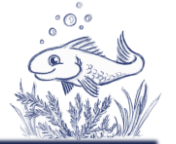
Agenda



- Introduction
 - **Use cases**
 - **MDR**
 - SDR
 - Other
 - Summary
-



MDR Use Cases

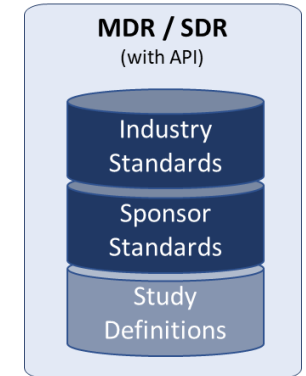


Manage **Controlled Terminology**

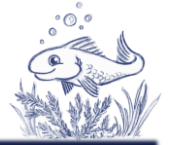
- Load CDISC CT (+ sponsor name)
- Sponsor extensions
- Sponsor CT

- Downstream usage:
 - Export to SAS / R
 - e.g. SAS formats, checks

- Automation
 - Import from another MDR or source

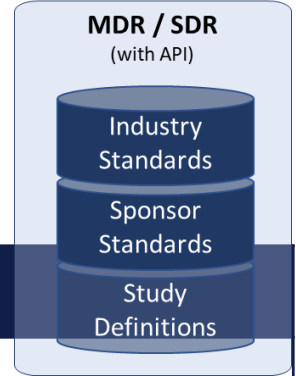


MDR Use Cases



Manage **Controlled Terminology**

No Yes Response (C66742)



Sponsor Name	Sponsor Name - Sentence Case	Code Submission Value	NCI Preferred Name	Definition
No	no	N	No	The non-affirmative response to a question. (NCI)
Not Applicable	not applicable	NA	Not Applicable	Determination of a value is not relevant in the current context. (NCI)
Unknown	unknown	U	Unknown	Not known, not observed, not recorded, or refused. (NCI)
Yes	yes	Y	Yes	The affirmative response to a question. (NCI)

VisitType (CTCodelist_000005) - TIMELB / Terms listing

Library	Sponsor name	Code submission value	Name submission
⋮ Sponsor	End of treatment	EOTRT VISIT TYPE	EOTRT VISIT TYPE
⋮ Sponsor	End of trial	EOTRIAL VISIT TYPE	EOTRIAL VISIT TYPE
⋮ Sponsor	Follow-up	FU VISIT TYPE	FU VISIT TYPE

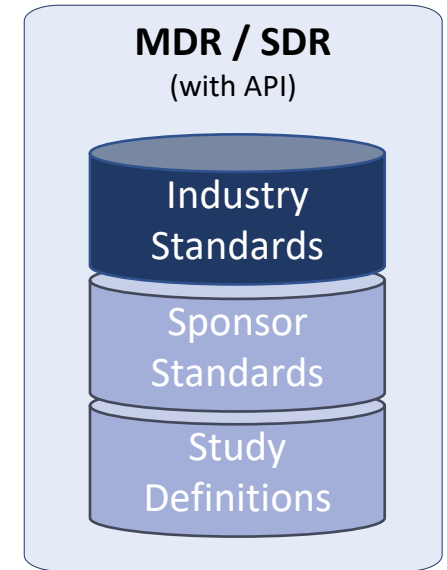
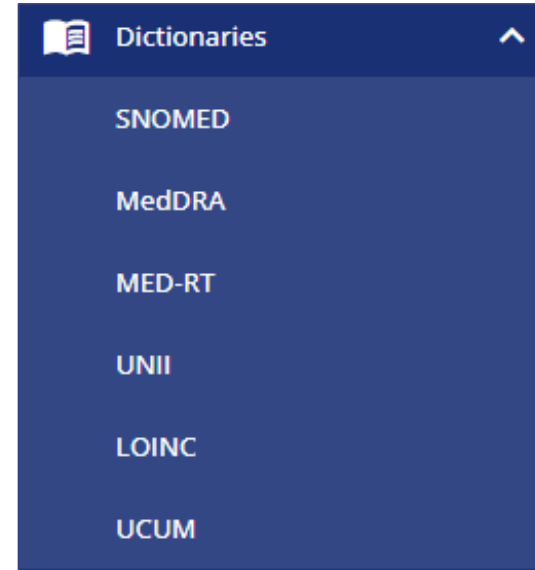
MDR Use Cases



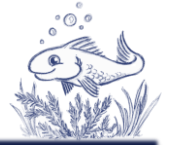
Manage **Dictionaries**

- Manage at one place
- Benefit from connections

- Downstream usage:
 - Export / Import

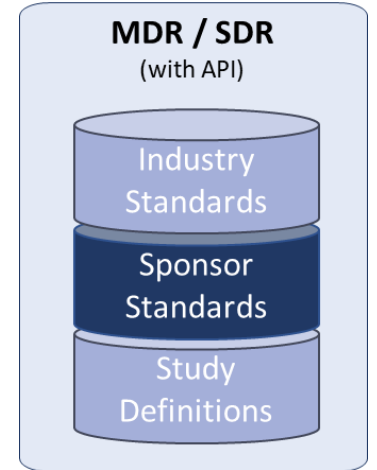


MDR Use Cases



Manage **Unit Conversions**

- Manage, export, import
- **Collaboration**
 - Enhance
 - Enrich



Name	Unit subsets	UCUM unit	CT Unit terms	Unit dimension	Conversion factor to master
⋮ LB		[lb_av]	LB	Weight	0.45359237
⋮ kg		kg	kg	Weight	1
⋮ oz	Dose Unit	[oz_av]	oz	Weight	0.028
⋮ lb		[lb_av]	LB	Weight	0.45359237

MDR Use Cases



Manage **Standard CRFs***

- Manage, export, import
- ODM Standard
- Connect to EDC**

General Demographic item group [OID=G.DM.DM, Version=0.1]		DM (Demographics Domain)	
Please complete this General Demographic item group at the very beginning of the study			
🔒	Previous Subject No. [OID=I.PREVSUB], Version=0.1	<input type="text"/>	10 digit(s)
		PREVSUBJ	
🔒	Subject No. [read-only] [OID=I.SUBJID], Version=0.1	<input type="text"/>	10 digit(s)
		SUBJID	
🔒	Date of birth [OID=I.BRTHDTC], Version=0.1	tt.mm.jjjj	10 digit(s)
	<i>If collected, please provide the most complete Date of birth</i>	BRTHDTC	
🔒	Age [OID=I.AGE, Version=0.1]	<input type="text"/> 3 digit(s)	Unit : <input type="radio"/> years [OID=years, Version=1.0]
	<i>The Age could be derived from the Date of Birth</i>	AGE	

*CRF on study level is WIP (Work in Progress)

**EDC Connection PoC finished, more WIP

MDR Use Cases

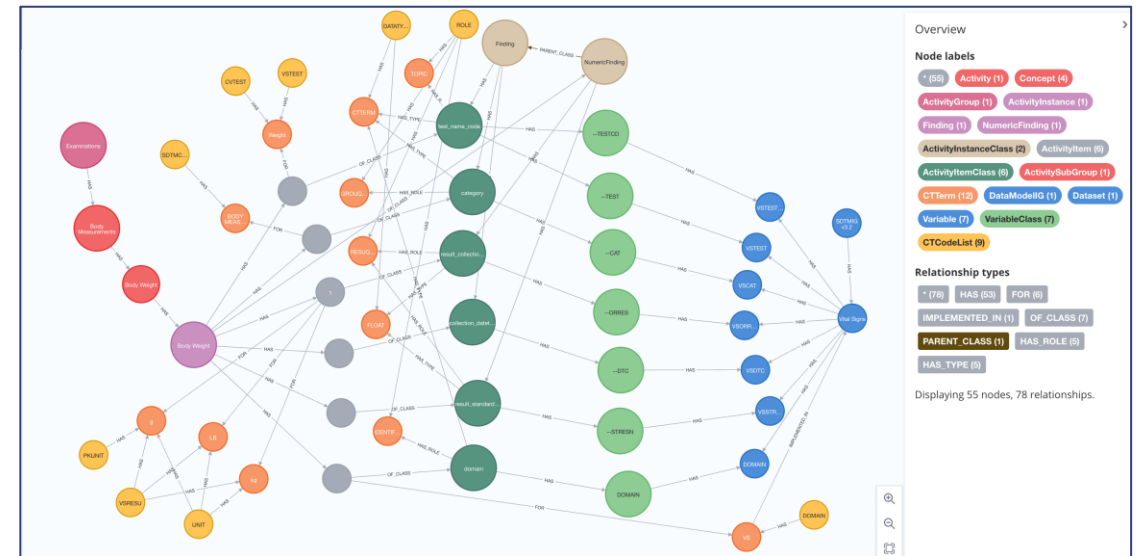


Manage **Activities** / **Biomedical Concepts**

- Connected to CDISC COSMoS Model
- Standardization tasks
- Meant to be used by studies

➤ **Collaboration**

- Discussion
- Curation
- Processes



MDR Use Cases



Manage **Protocol Standard Texts**

➤ Objectives

Objective

To compare the effect of [Compound] relative to [Comparator] on [ActivityInstance]

➤ Endpoints

➤ Criteria

Endpoint

Occurrence of [Activity] (yes/no)

➤ Re-usability

Endpoint

Mean change from baseline in [ActivityInstance]

➤ Standardization

➤ Search capabilities

Criteria

Age [NumericValue] [Age Unit] or above at the time of signing the informed consent.

MDR Use Cases

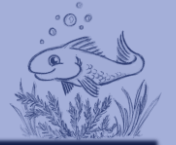


Manage **Protocol Standard Texts**

- Objectives
- Endpoints
- Criteria
- **Collaboration**
 - Catalog of common objectives, endpoints, criteria
- Re-usability
- Standardization
- Search capabilities



Agenda



- Introduction
 - **Use cases**
 - MDR
 - **SDR**
 - Other
 - Summary
-



SDR Use Cases



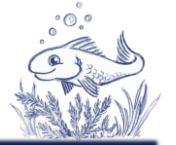
Protocol Automation

- All structured protocol information in OSB
- Fill protocol with OSB content

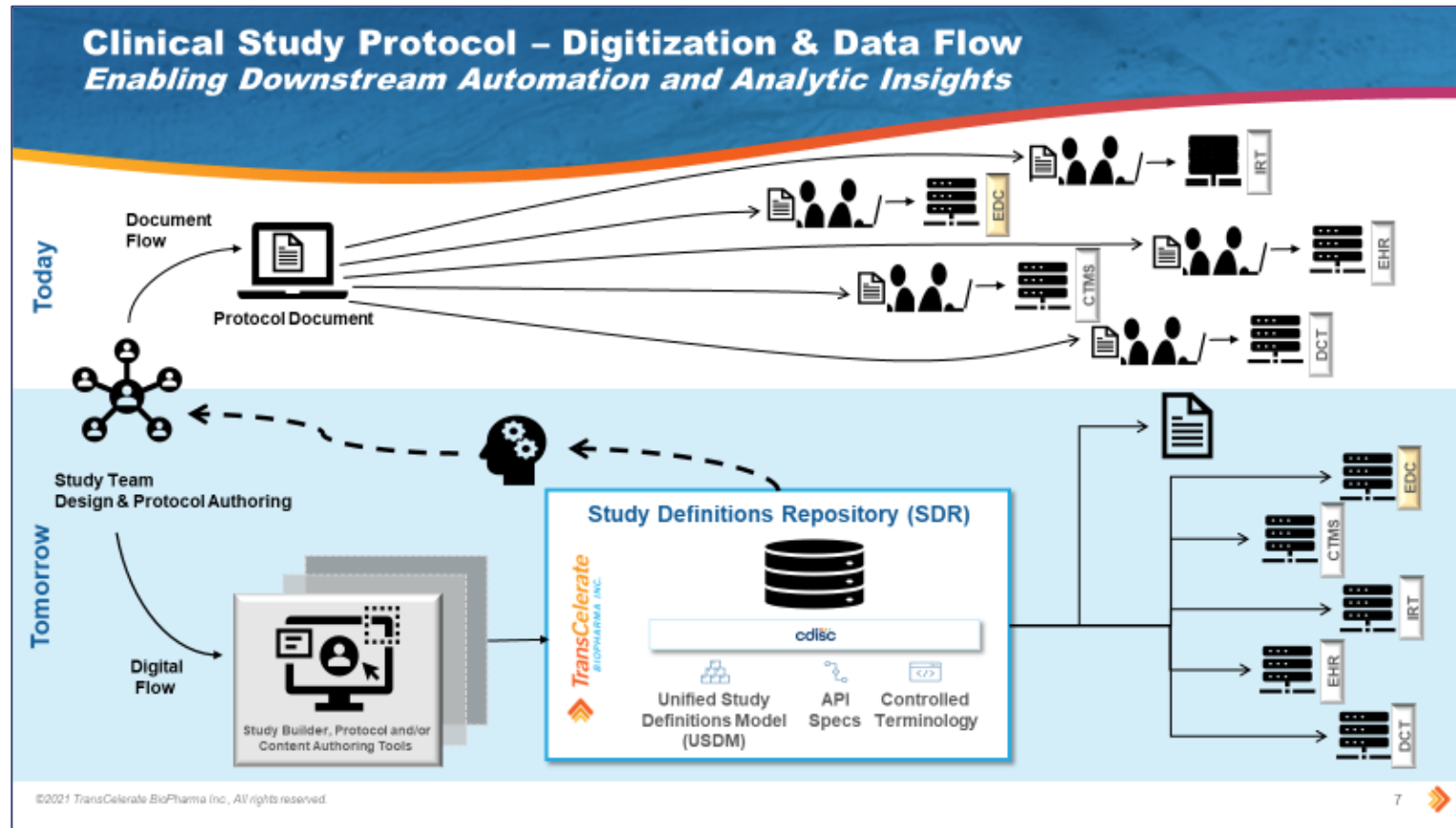
Study Protocol	
Study Title:	
Test Facility Name:	
Study Number:	
Sponsor:	

	Study Number:
Table of Contents	
Table of Contents	4
Approval	6
1. Objective.....	7
2. Proposed Study Schedule	7
3. Sponsor/Test Facility/Test Site Information.....	7
4. Key Personnel.....	7
5. Test Item/Article and Vehicle Control Item/Article.....	8

SDR Use Cases



Protocol Automation



TransCelerate Vision:
Downstream from SDR,
not from protocol

SDR Use Cases



Protocol Automation

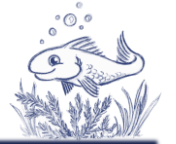
- Using standards (e.g. study type)
- Using harmonized sentences (e.g. objective templates)
- Select activities
- Build your “visualization”

- Word-Add-In: Novo Nordisk tool release (Q3/Q4)
- **Collaboration**, create your own process

Study Protocol

Study Title:	
Test Facility Name:	
Study Number:	
Sponsor:	

SDR Use Cases

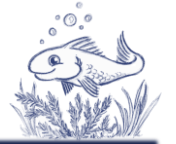


➤ Schedule of Activities

Protocol Flowchart [DOWNLOAD DOCX](#)

Study epoch	Screening	Treatment									Follow-up
	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Study day	-14	1	8	15	22	29	36	43	57	183	213
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
SUBJECT RELATED INFORMATION											
General											
Randomisation		X		X							
End of Study											X
Physical Examination - early ph1	X										
Cardiovascular System	X							X			
Abdomen	X						X				
Central and Peripheral Nervous System	X				X						

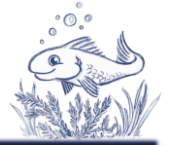
SDR Use Cases



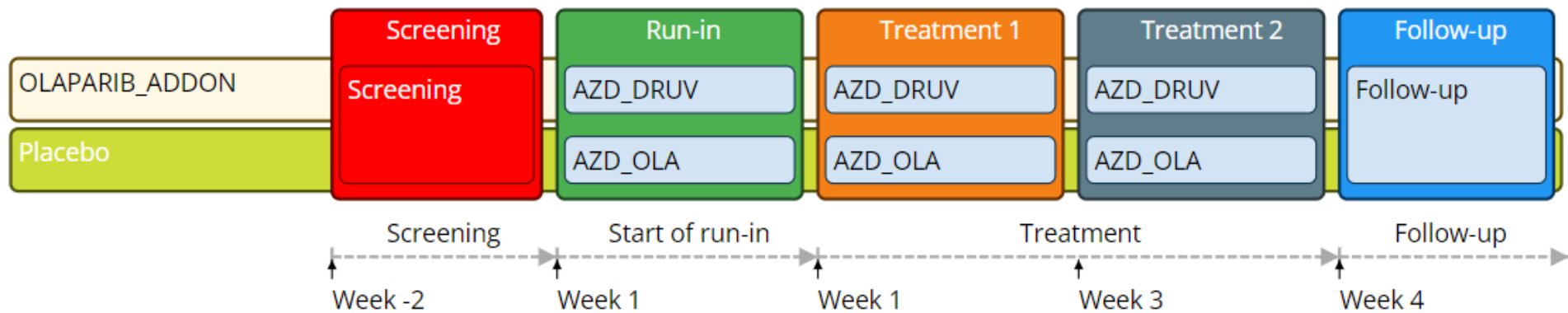
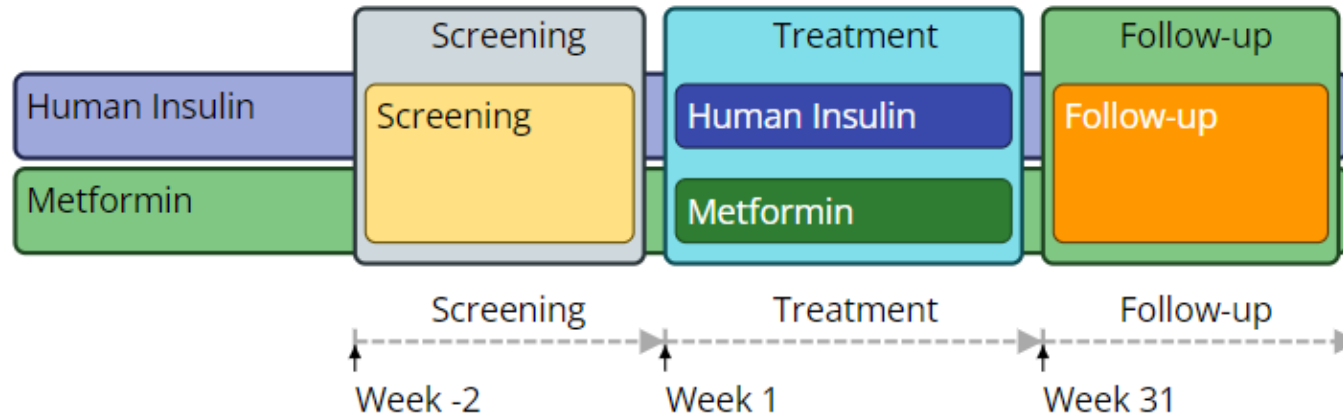
➤ Objectives & Endpoints

Objectives and Endpoints		DOWNLOAD DOCX	
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	

SDR Use Cases



➤ Study Design



SDR Use Cases



Protocol Automation

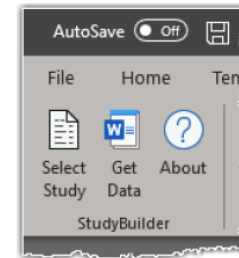
- Word Add-In open-source release planned by Novo Nordisk



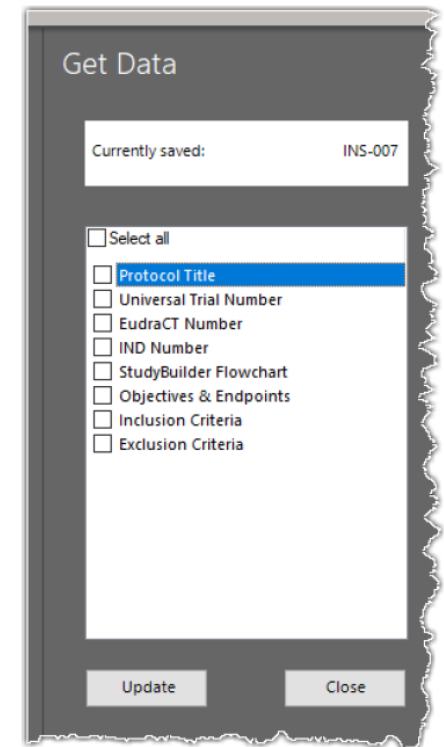
StudyBuilder ribbon (Word add-in)



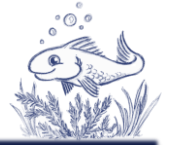
- ✓ One-way connection
- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and 'fly-out' in Word
- ✓ Styles ensure proper formatting in Word



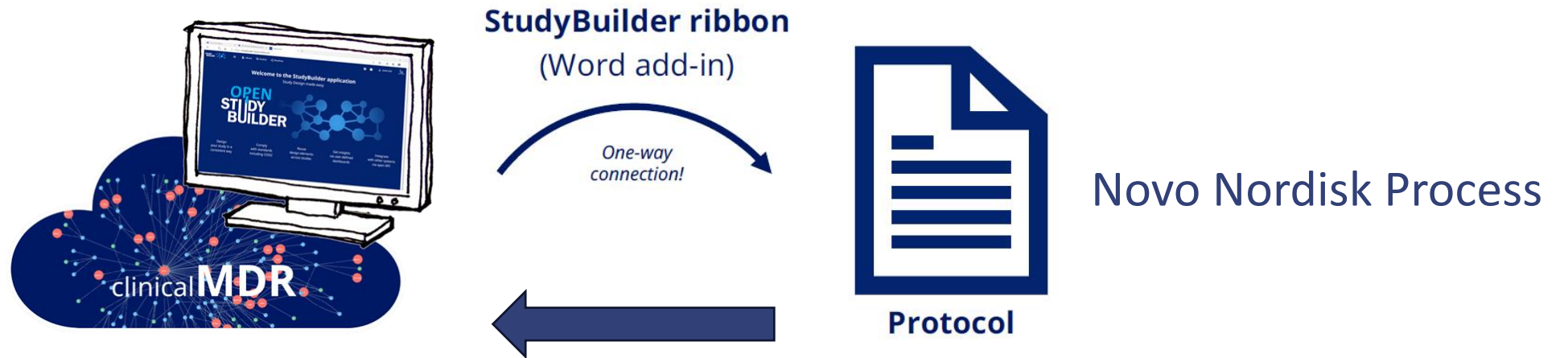
Protocol



SDR Use Cases



Protocol Automation Processes



Alternative Process
- Fill OpenStudyBuilder from Protocol

SDR Use Cases



Protocol information usage - **Trial Domains**

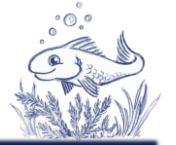
STUDYID	DOMAIN	TSPARMCD	TSPARM	TSVAL	TSVALCD	TSVCDREF
CDISC DEV-0	TS	ADAPT	Adaptive Design	N	C49487	CDISC
CDISC DEV-0	TS	AGEMAX	Planned Maximum Age of Subjects	P64Y		ISO8601
CDISC DEV-0	TS	AGEMIN	Planned Minimum Age of Subjects	P18Y		ISO8601
CDISC DEV-0	TS	COMPTRT	Comparative Treatment Name	METFORMIN	9100L32L2N	UNII

Trial Summary

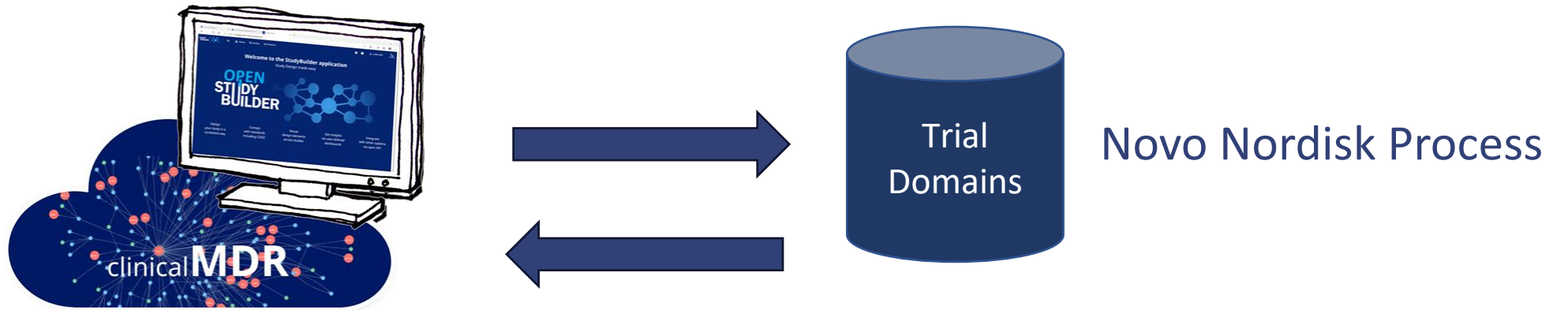
Trial Elements

Study Identifier	Domain Abbreviation	Element Code	Description of Element	Rule for Start of Element
CDISC DEV-0	TE	1	Screening	Informed consent signed
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 3 days after last dose

SDR Use Cases



Protocol information usage - **Trial Domains**



Alternative Process
- Fill OpenStudyBuilder from Trial Domains

SDR Use Cases



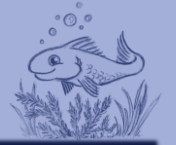
Protocol information usage – **Activities / Visits / ***

- Create Visit Codelist
- Plan / follow up on activities
- Re-use information automatically

Studies	
GET	<code>/studies</code> Returns all studies in their latest/newest version.
POST	<code>/studies</code> Creates a new Study Definition.
GET	<code>/studies/headers</code> Returns possible values from the database for a given header
POST	<code>/studies/{uid}/lock</code> Locks a Study with specified uid



Agenda



- Introduction
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-



SDR Use Cases



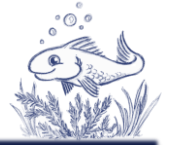
Any kind of use-case

- Develop as community
 - Pre-Clinical PHUSE working group on protocol-automation (upcoming)
- Develop on your own (share with community)
- Develop with vendors (share with community)

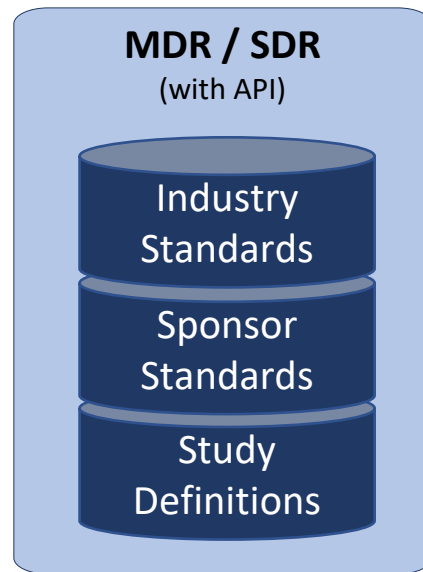
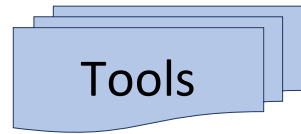
Collaboration



SDR Use Cases



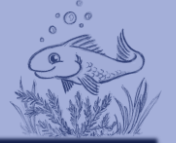
Within OpenStudyBuilder Universe



Plugin
Extension
Stand-alone tools



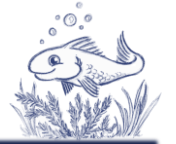
Agenda



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-



Summary



➤ OpenStudyBuilder

- Open-Source MDR & SDR
- Much Functionality
- Continuously enhanced
- Vision end-to-end automation (metadata driven)



➤ Use-Cases

- Standards management
- Protocol information
- More will be coming



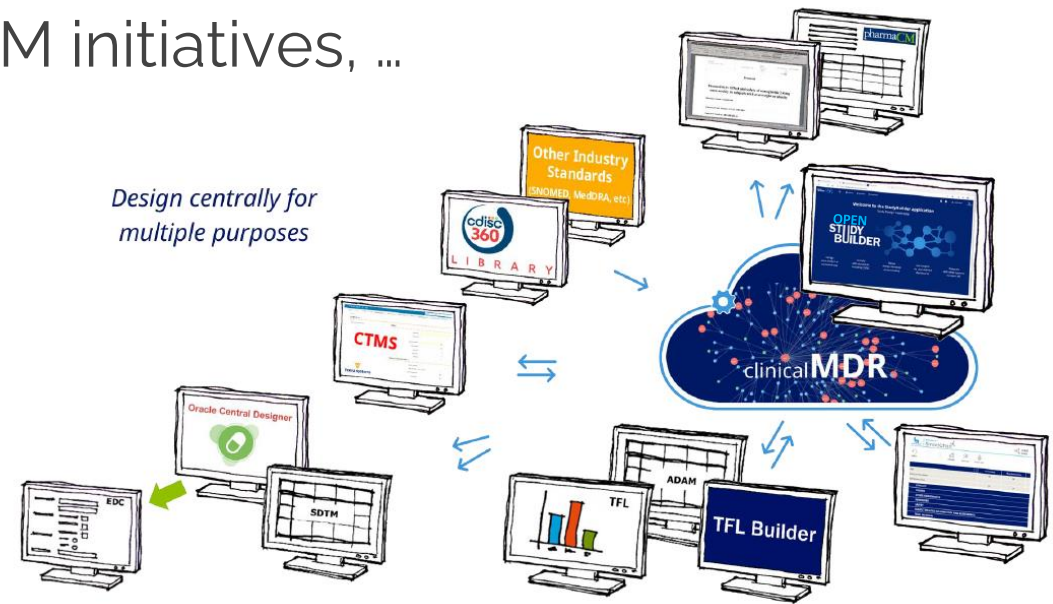
Summary



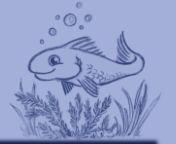
- Standardization
 - CDISC, COSMoS & more
 - TransCelerate, standard interfaces
 - Other open-source initiatives
 - Connecting OAK, admiral, ARM initiatives, ...

- **Collaboration**

- Enable additional use-cases
- Supporting various processes
- Simplify our world!



Questions?



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www.glacon.eu

www.glacon.eu/portal
