

Introduction to OpenStudyBuilder

A CDISC Open Source Alliance Project

Katja Glaß, Katja Glass Consulting, OpenStudyBuilder@gmail.com

OpenStudyBuilder – a Metadata Data and Study Definition Repository End-to-end automation from structured protocol to submission deliverables using concept-based standards



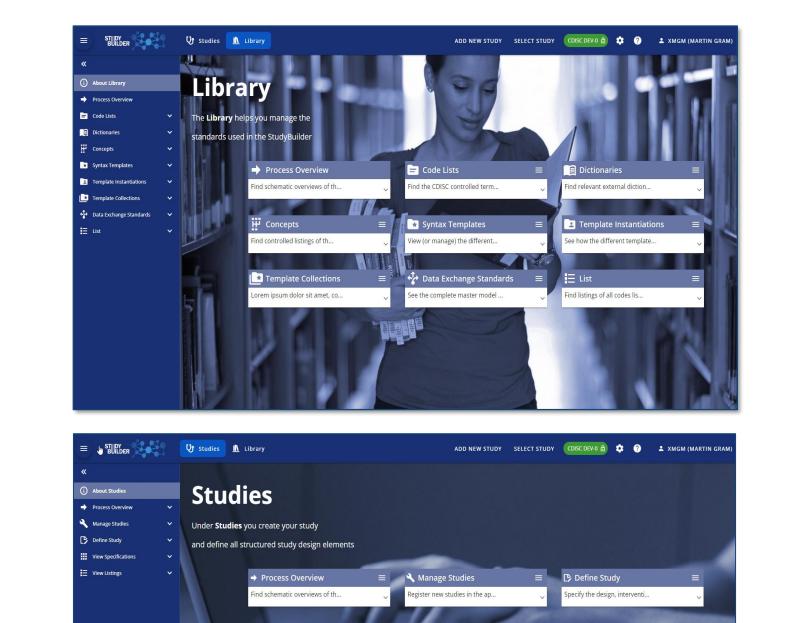
OpenStudyBuilder Solution



- A Clinical Metadata Repository (as a graph database)
- An API layer
- The OpenStudyBuilder Application (web application)

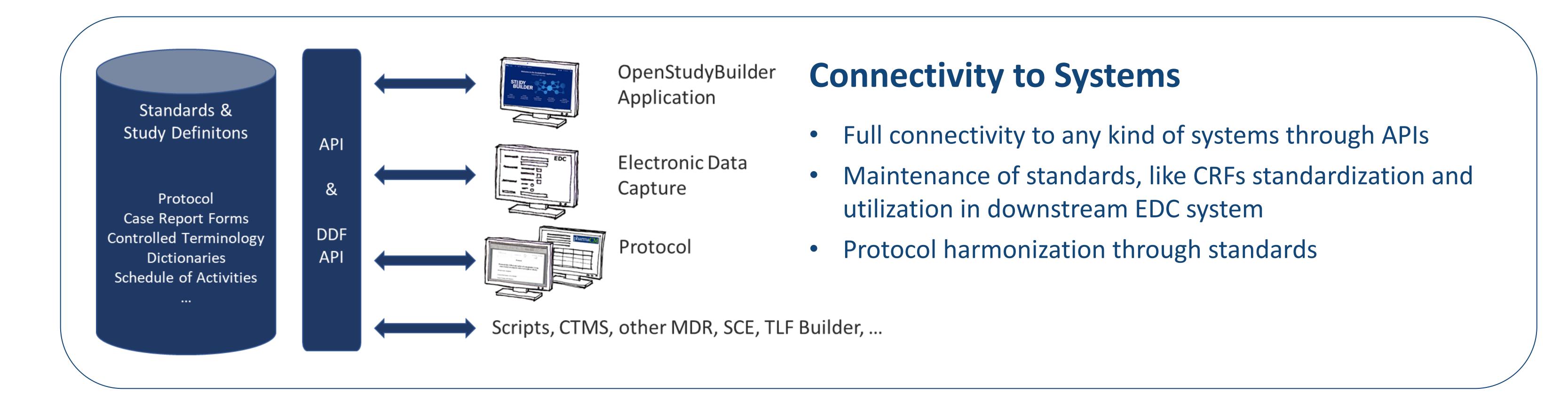
Study Specifications & Standards Management

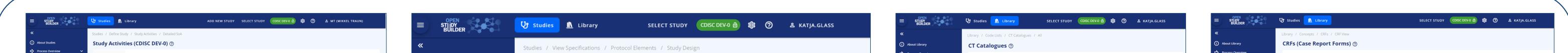
- Single metadata source for key deliverables e.g. protocol, CRF, SDTM, ADaM, CTR, TFL
- Standardization through controlled terminology, dictionaries, templates
- Built-in compliance with external and internal standards
- A higher degree of end-to-end consistency due to re-usability and linkage
- Facilitation of more automation and content reuse through open interface (API)
- Metadata driven creation of structured protocol content











🗳 Manage Studies 🗸 🗸	Study Activities Study Activity Instances Detailed SoA SoA footnotes Protocol SoA Activity Instructions		Process Overview	All ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT PROTO >
Define Study	O Expand table O Collapse table Hide SoA groups	About Studies	Protocol Elements (CDISC DEV-0) ⑦	
Study Title		Process Overview	Dashboard	Select rows + V I · V I · KELOAD · KE
Registry Identifiers	Epoch Screening Treatment Follow-up		Title Page Protocol SoA Objectives and Endpoints Study Design Study Population Study >	Operator Concepts Template NN Annotated CRF
Study Properties	Visit V1 V2 V3 V4 V5 V6 V7 V8 V9 V10 V11 Day -14 1 8 15 22 29 36 43 57 183 213	Study List	CT Packages	Search with terms or Carteria Activities
Study Structure	Activities Window -13/+0 ±0 -1/+1 -1/+1 -1/+1 -1/+1 -1/+1 -1/+1 0/+35	8	CDISC	Library Sponsor preferred name Template parameter Code list status Name m
Study Population	> SUBJECT RELATED INFORMATION	🔏 Manage Study 🗸 🗸	Study Design DOWNLOAD DOCX	CRFs (OID=F-DM, Version=0.1)
Study Criteria	✓ EFFICACY [™]	Define Study 🗸 🗸	Dictionaries	AX: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, AX: rms AM AX: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [*] = Item is required. Sex: Populated by
Study Interventions	Laboratory Assessments		Screening Treatment Follow-up	CDISC Relationship to Subject No Enclose the subject No Enclose the subject No Enclose the subject No Populated by IWRS and mapped from ENR to Inf Cons/DemogOracle item design notes: Kiel tem design notes:
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Study Activities	V C Glucose Metabolism	Protocol Elements	Human Insulin Screening Human Insulin Follow-up	
View Specifications 🗸			Metformin	
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	🗌 Mean Plasma Glucose 🕸 O O O O O O O O O O		Screening Treatment Follow-up	CDISC QS-Brief Psychiatric Rating No Final Oct 13, 20 Scale-A
	> SAFETY 🚫		Week -2 Week 1 Week 31	typically captured on a CRF, it should be displayed on a
				This field can be included into
				Rows per page: 10 1-10 of 1374 < > the database or populated during SDTM-based dataset
				creation before submission.



Open Source

- OpenStudyBuilder is shared as open source under COSA by Novo Nordisk
- Collaborate with TransCelerate as a Digital Data Flow (DDF) compatible solution
- Collaborate with CDISC, e.g. for Biomedical Concept Development & Enhancements

