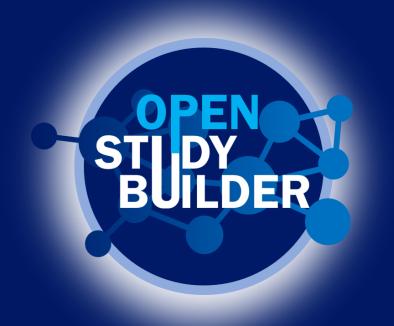




# Introduction to OpenStudyBuilder

A CDISC Open Source Alliance Project



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



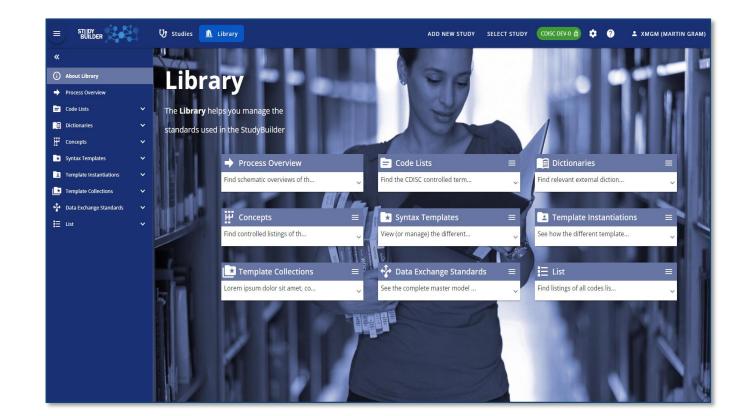
### OpenStudyBuilder Solution

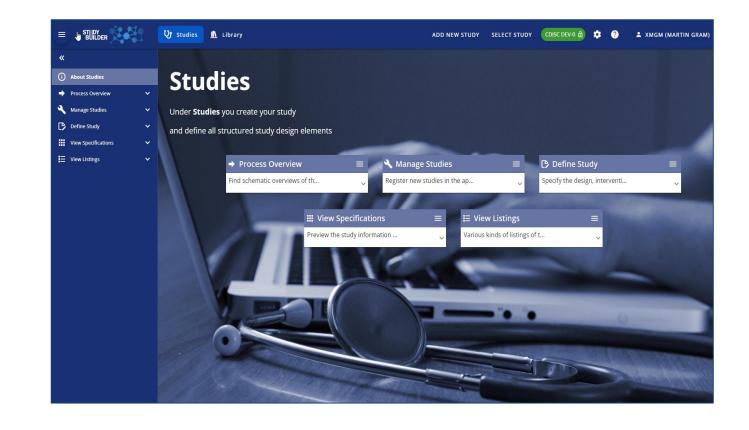
- A Clinical Metadata Repository (Neo4j graph database)
- The OpenStudyBuilder Application (web application)
- An API layer

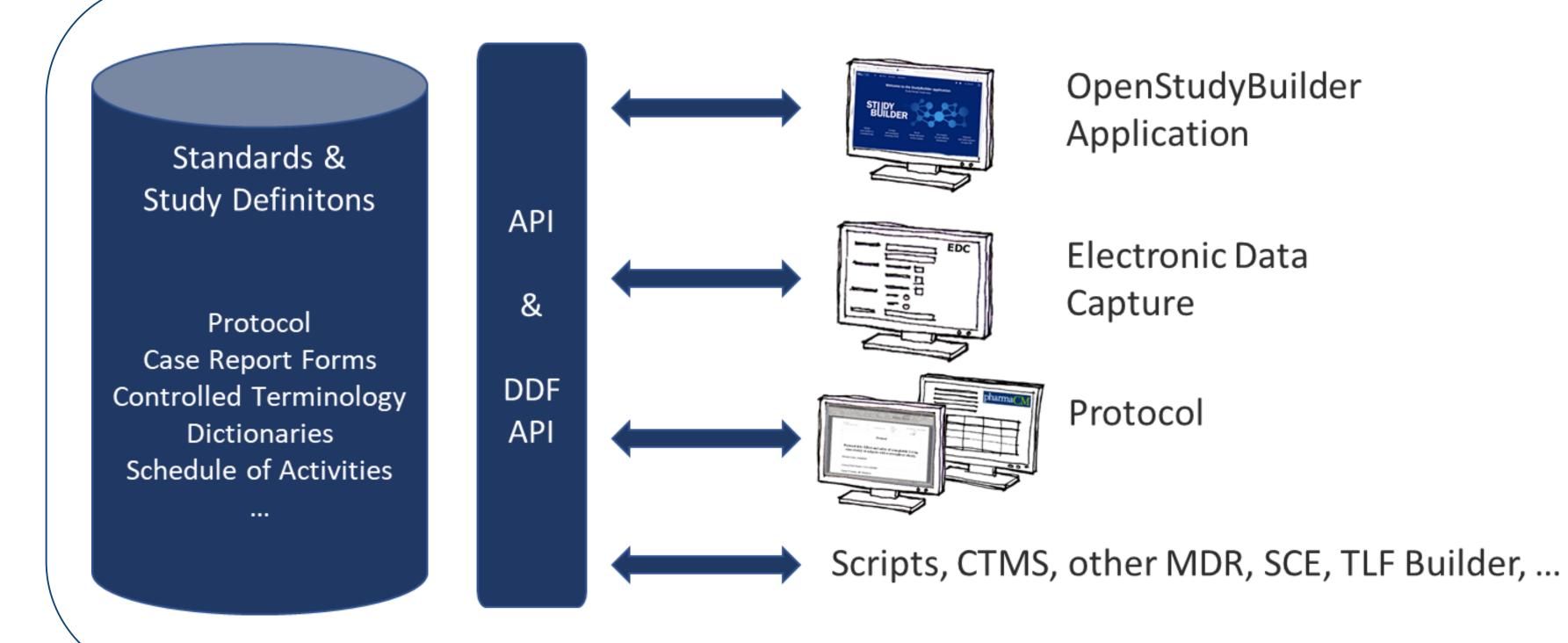


#### Study Specifications & Standards Management

- 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

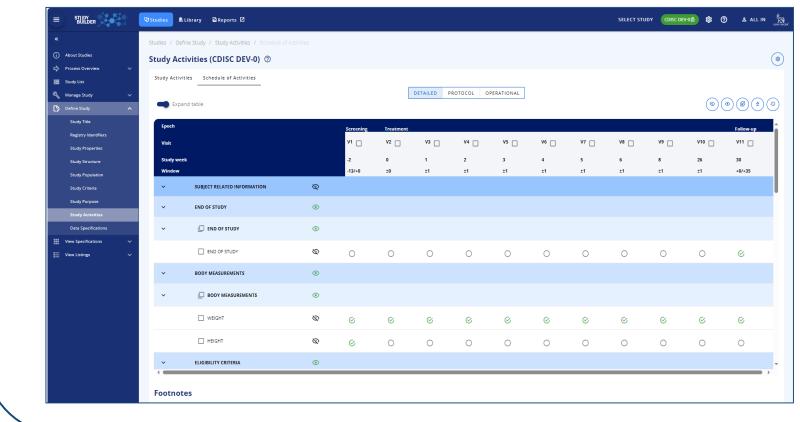






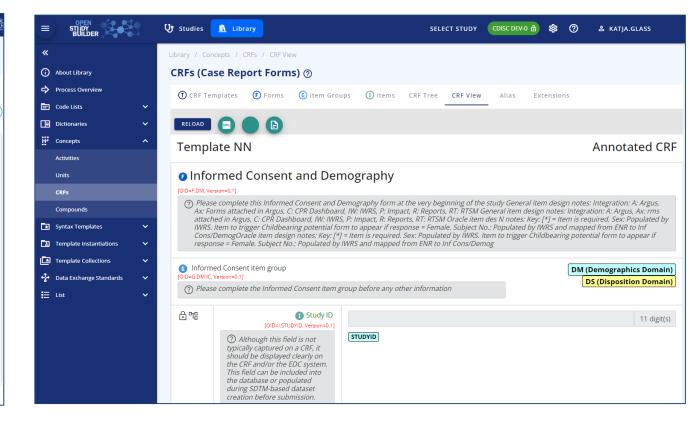
#### Connectivity to Systems

- Full connectivity to any kind of systems through APIs
- Maintenance of standards, like CRFs standardization and utilization in downstream EDC system
- Protocol harmonization through standards





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) About Library	СТ	Catalogu	es ②									
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Dictionaries  Concepts			QS-Alzheimer's Disease	No		Jul 15, 2024, 9:33 AM	C100131	ADCTN	Alzheimer's Disease	CDISC Questionnaire ADAS-Cog CDISC Version Test Name Termino	No	Final
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			QS-European Quality of Life						European Quality of Life Five Dimension	CDISC Questionnaire EQ-		_
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			QS-Hamilton Depression						Hamilton Depression Rating	CDISC Clinical		
		CDISC	Rating Scale - 17 Item Test	No	Final	Jul 15, 2024, 9:33 AM	C100137	HAMD1TN	Scale - 17 Item	Classification HAMD 17	No	Final





#### 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

