



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Buy One – Get Three! Rule-Based Naming and Standardization of SoA, SDTM, and ADaM Metadata

Martin Gram, Associate Standards Developer Director, Novo Nordisk

Speakers

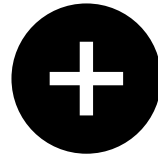


Martin Gram

Associate Standards Developer Director
Novo Nordisk



Add new metadata





We want metadata that is:

- Defined once, used many times, without manual editing
- Suitable across use cases (data and documents)
- Aligned to external standards, don't reinvent the wheel
- Support automation
- Fast to create
- High quality
- Easy to maintain

Concept Based!

Type : _____

----- **not connected**

Value: [MISSING]

Data ID _____

----- **not curated** !

DETAILS null

----- **not suitable for pooling data** !

Source: UNKNOWN

tag : ??? / ??

Value 2 0.00

OpenStudyBuilder Activity Concept - Documents

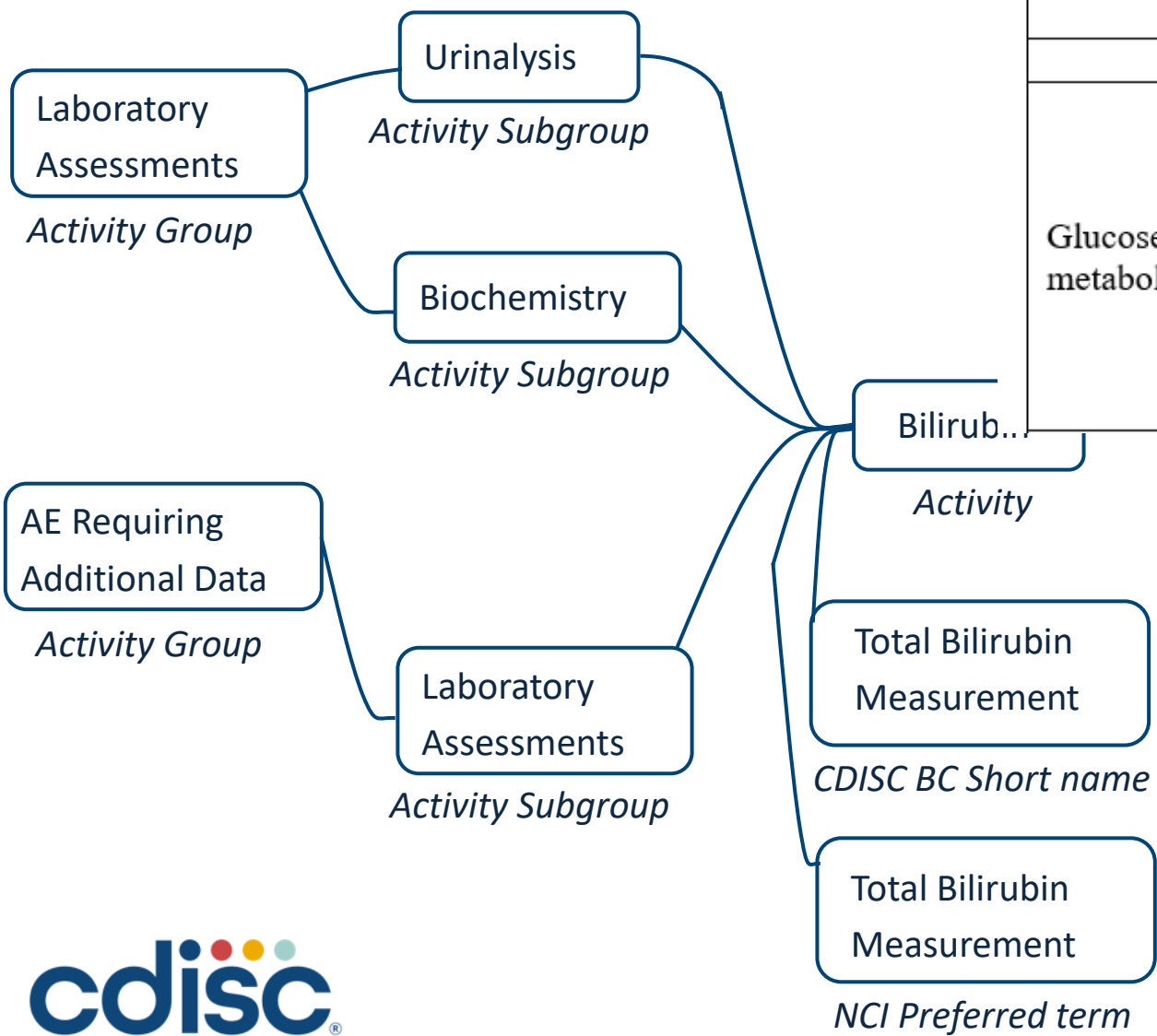
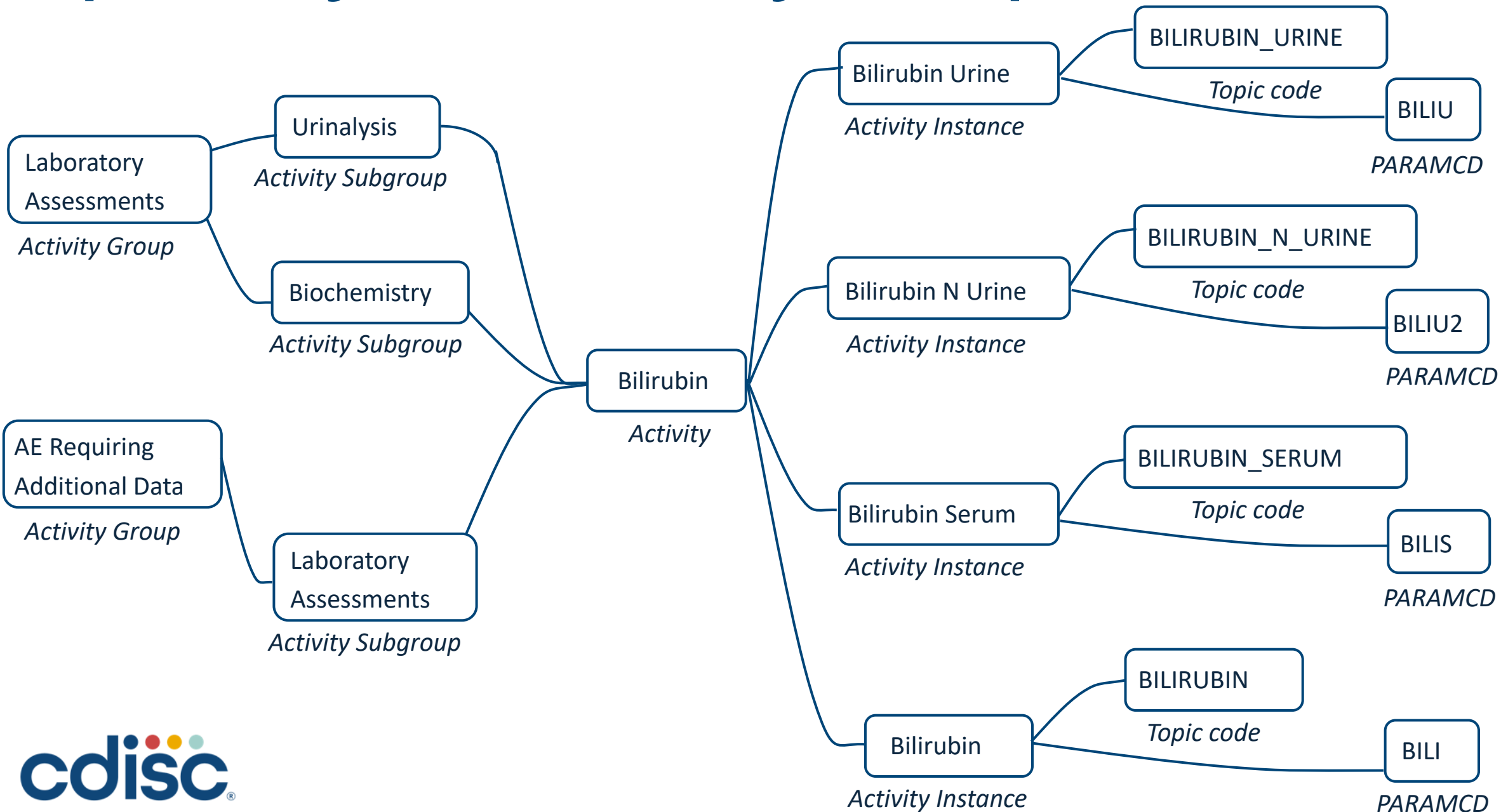


Table 10-1 Protocol-required efficacy laboratory assessments

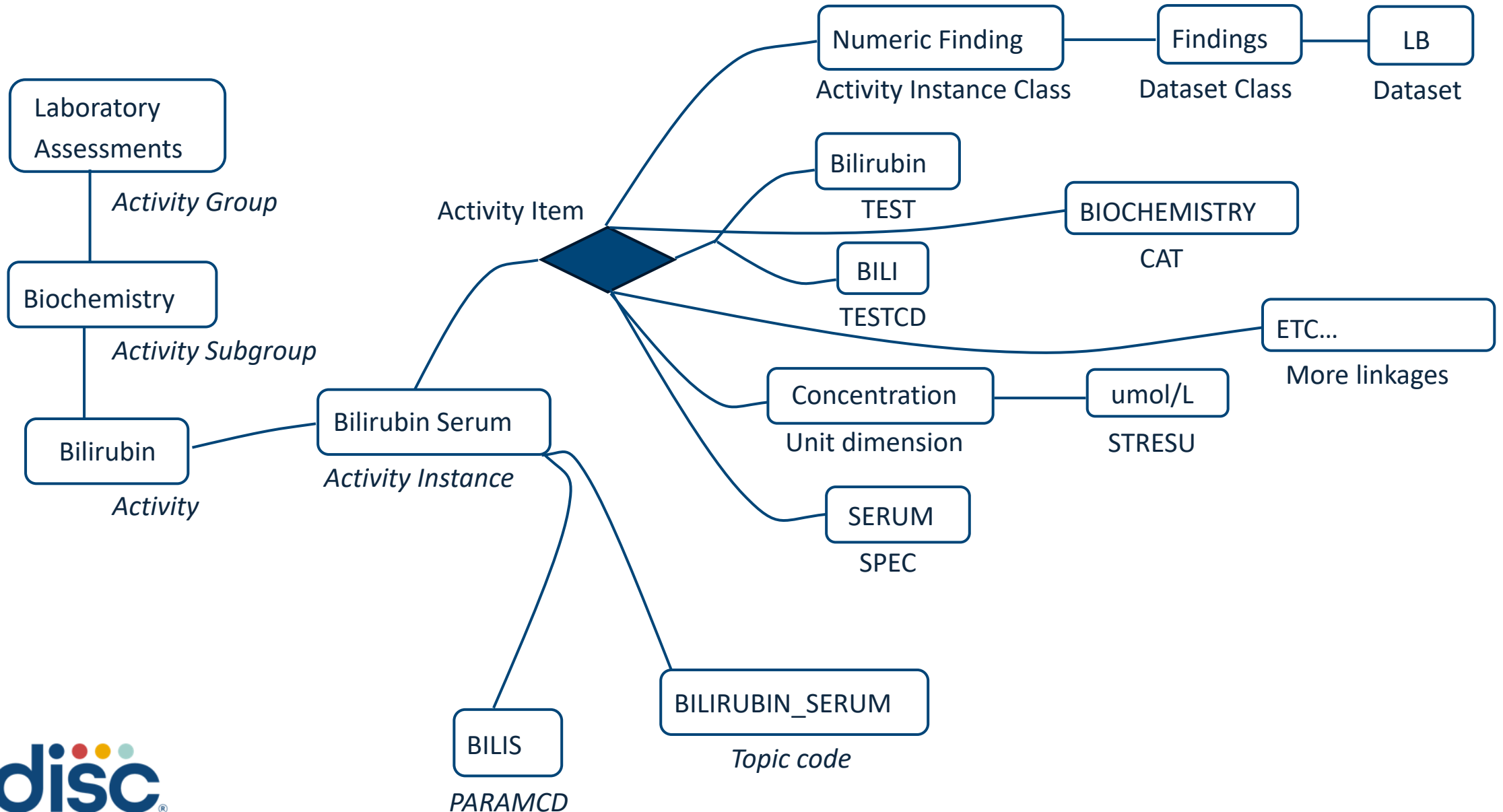
		Parameters		6
	Term ↑↓	Source ↑↓	Term Type ↑↓	
Glucose metabolism	BILI	CDISC	PT	
	Bilirubin	CDISC	PT	
	Bilirubin	CDISC	SY	
	Total Bilirubin	CDISC	SY	
	Total Bilirubin	GDC	PT	
	Total Bilirubin	PCDC	PT	
	Total Bilirubin Level	CPTAC	PT	
	Total Bilirubin Measurement	caDSR	SY	
	Total Bilirubin Measurement	NCI	PT	
	Total Bilirubin Measurement		(Preferred_Name)	



OpenStudyBuilder Activity Concept - Data



OpenStudyBuilder Activity Concept - Data



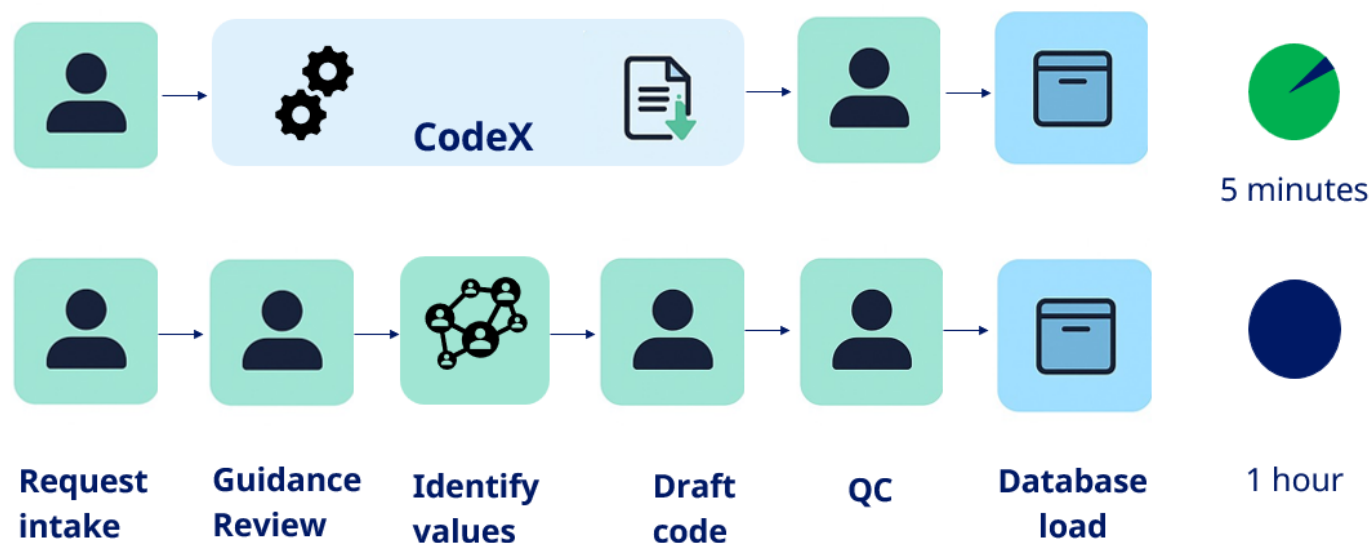


Demo CodeX



CodeX

- Focuses attention on the relevant details
- Reduces reliance on manual input
- Leverages predefined rules and AI
- Aligned with industry standards
- Automates the mechanical, enforces consistency and connects workflows

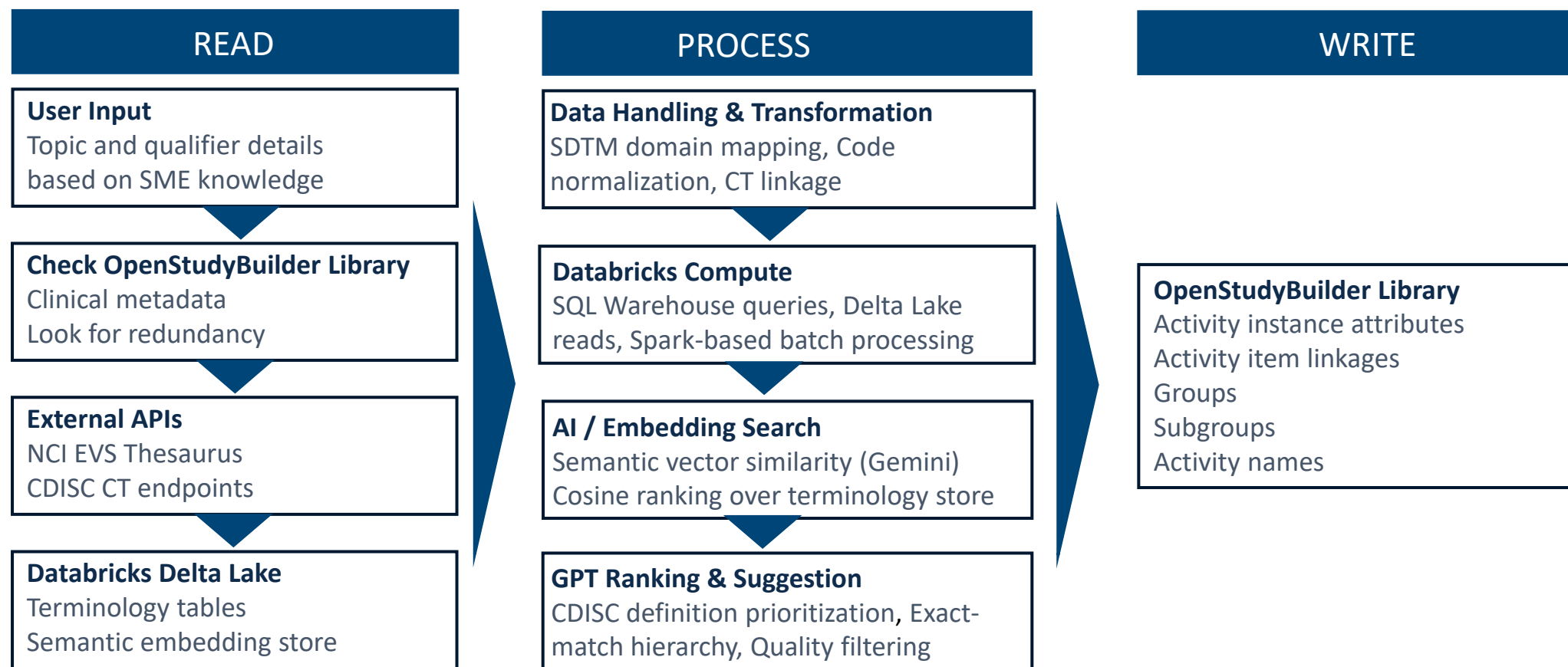


CodeX outside OpenStudyBuilder?

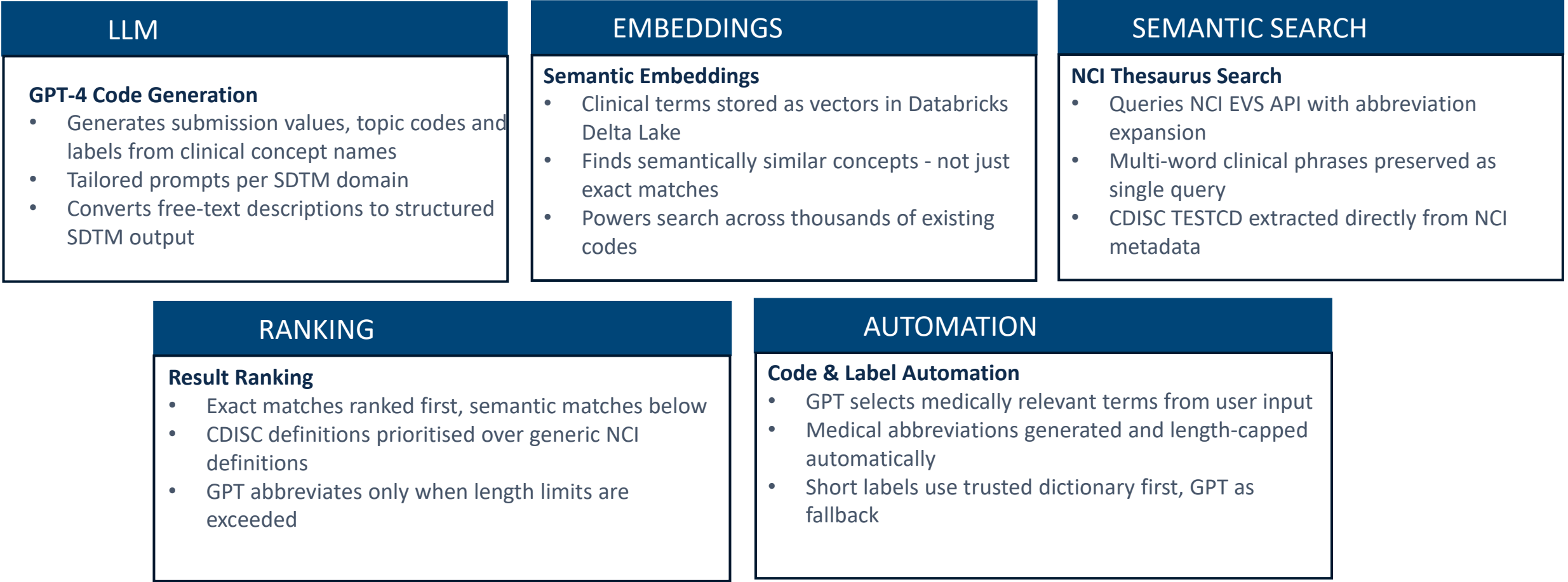
- Companies have custom business rules and logic when creating metadata
- When standards evolve updates to CodeX are faster
- CodeX could become part of the OpenStudyBuilder extensions framework



CodeX Application Architecture



CodeX AI Components



Acknowledgements

Angelica Prado for her major contribution to the technical implementation of CodeX and her continued input to improving the business logic





Questions?

