



# OpenStudyBuilder : Leveraging the Graph for Clinical Trials and Standards

Katja Glass, OpenStudyBuilder Community Manager  
Marius Conjeaud, Principal Consultant @ Neo4j

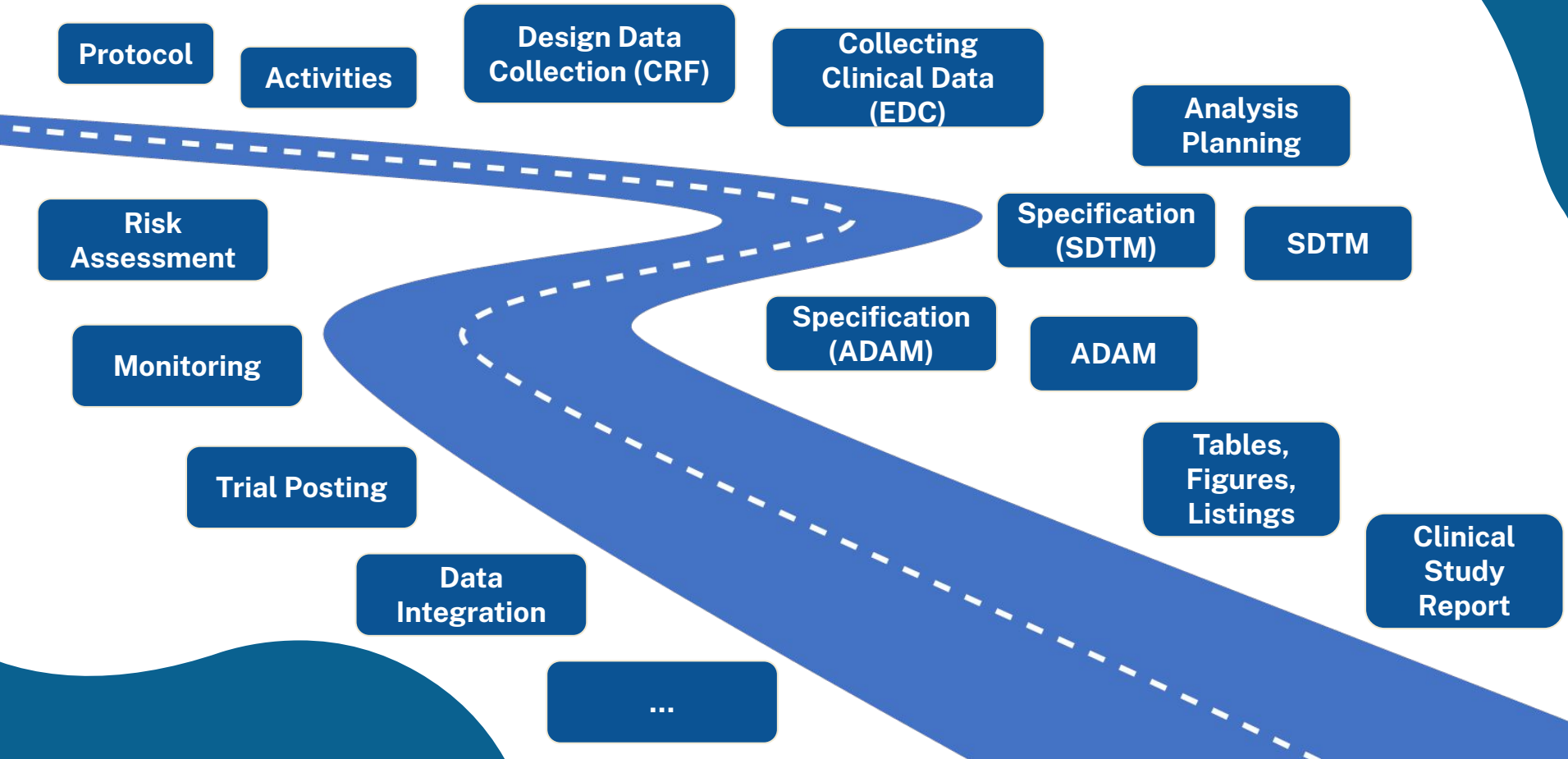


# OpenStudyBuilder?

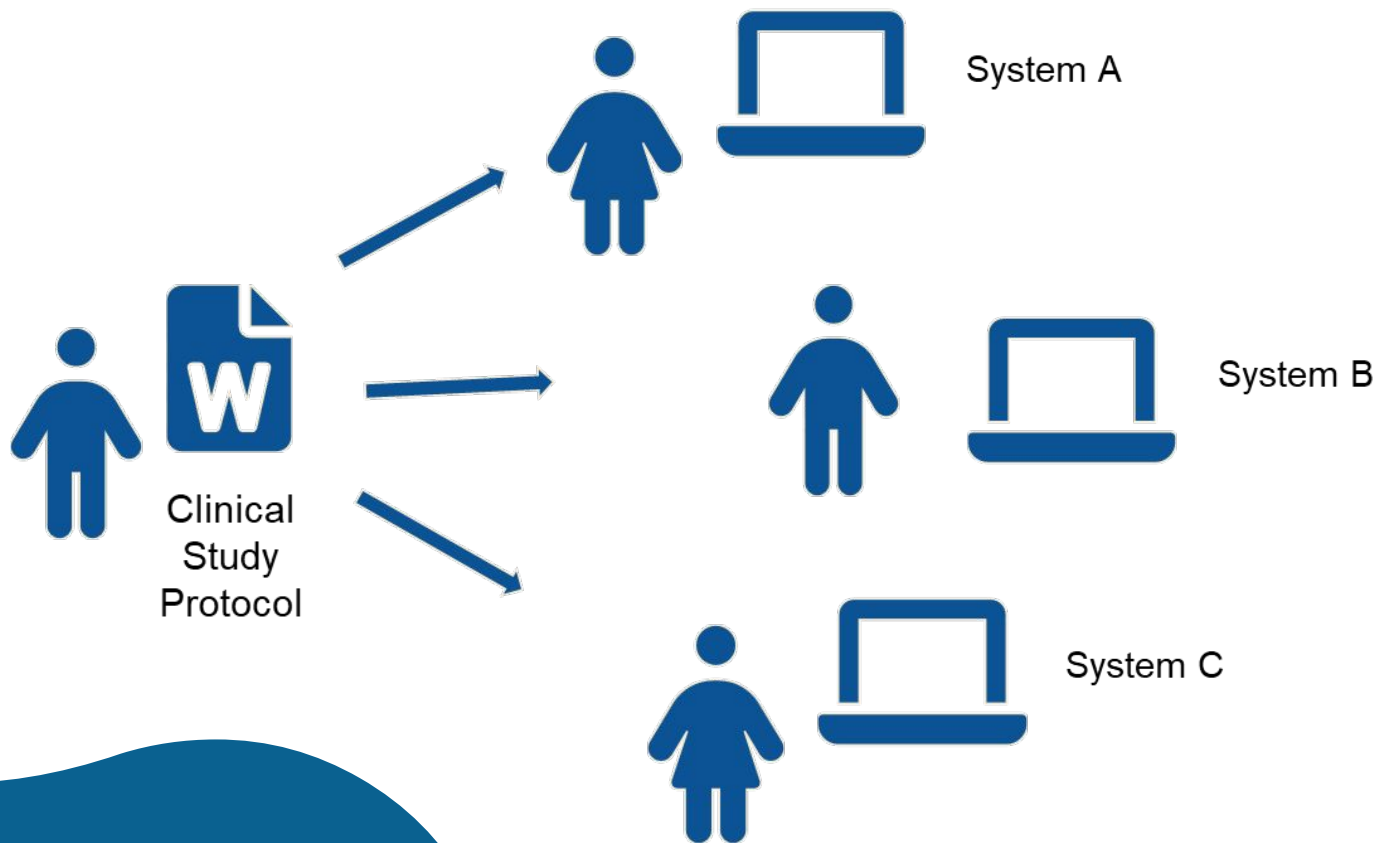
## What's that?



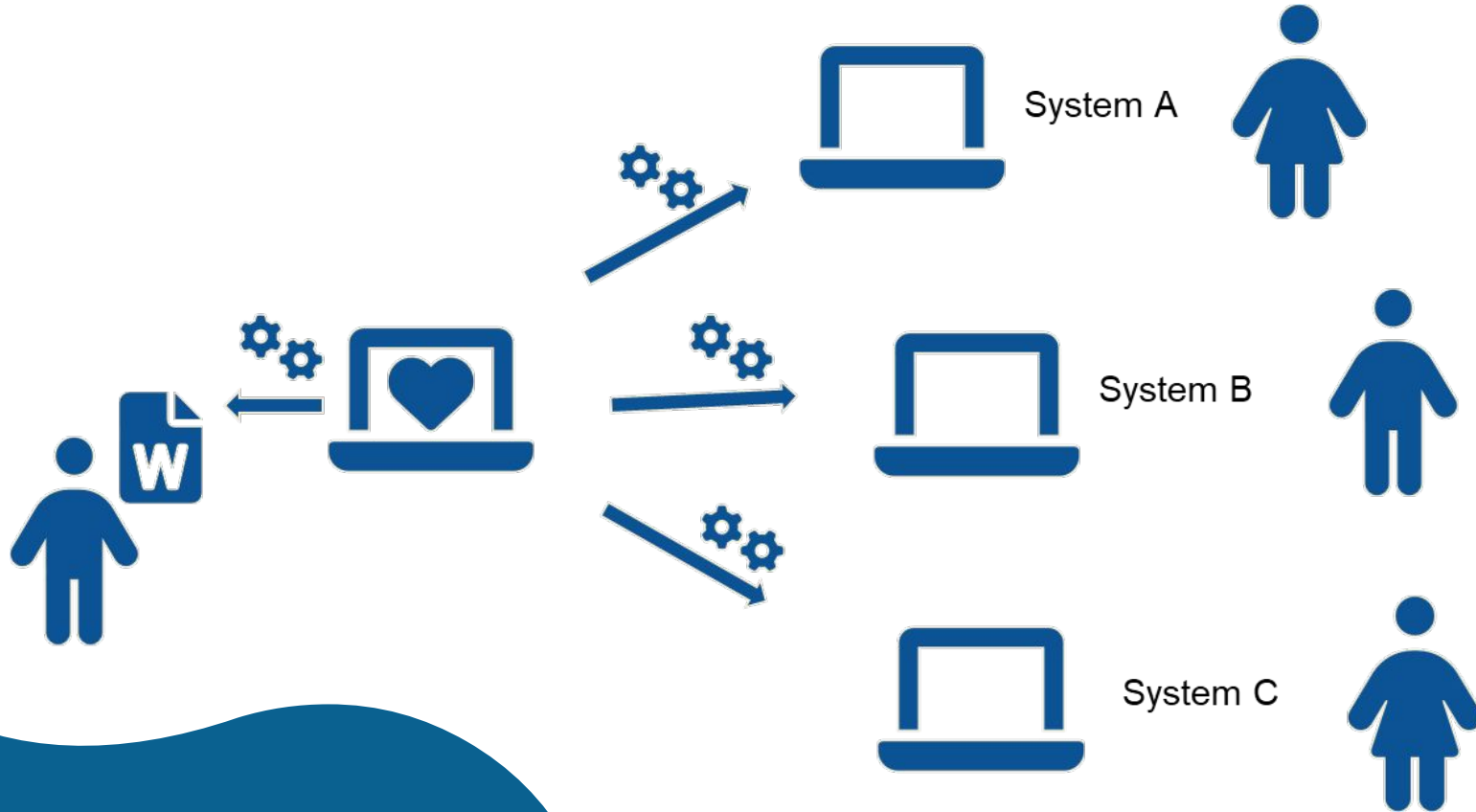
# Clinical Trials Flow



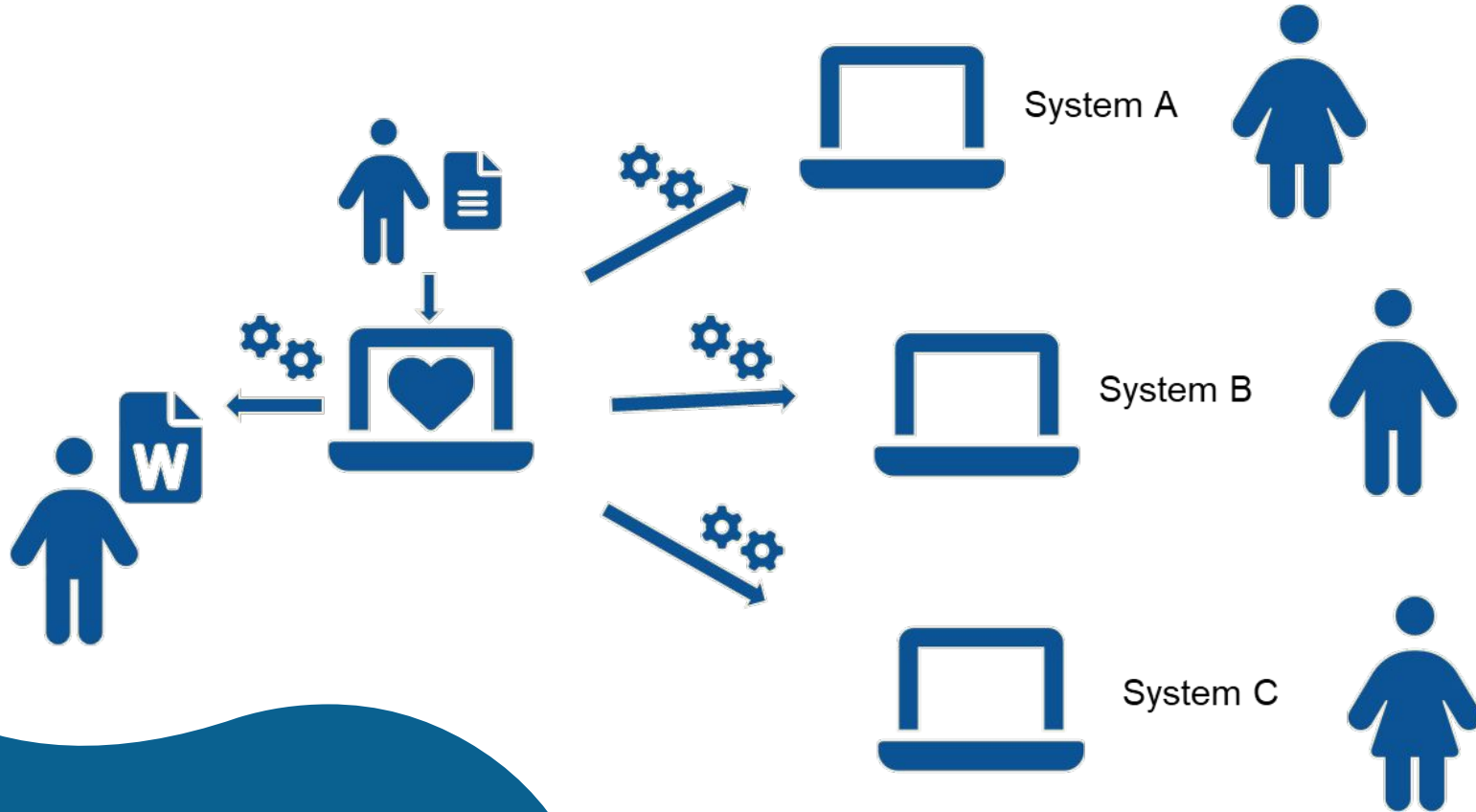
# Past Processes



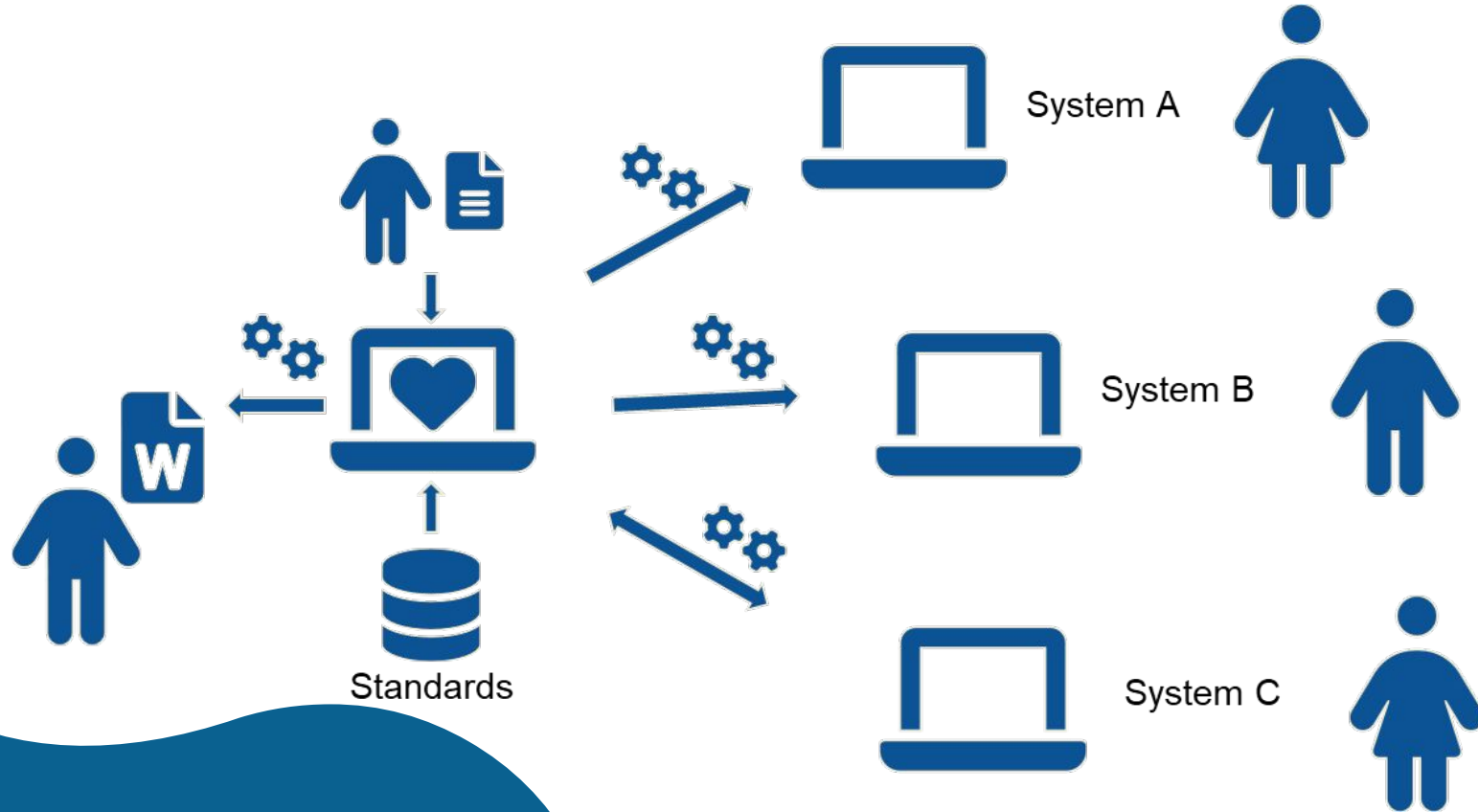
# OpenStudyBuilder Vision



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# OpenStudyBuilder

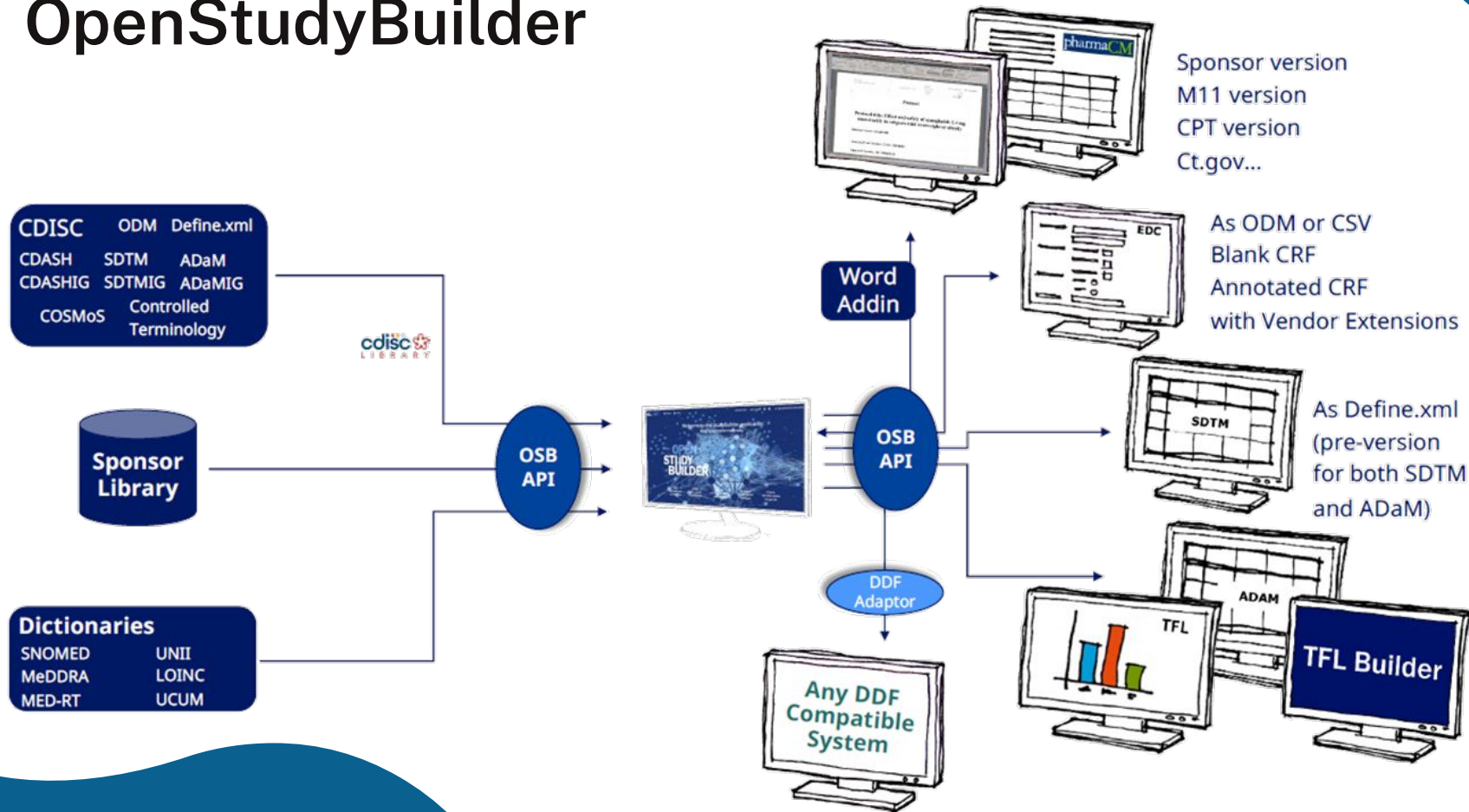
## 3 Elements of OpenStudyBuilder

- **Clinical Metadata and Study Definition Repository**  
(central repository)
- **OpenStudyBuilder application**  
(User Interface)
- **API layer**  
(allowing interoperability with other applications)





# OpenStudyBuilder



# OpenStudyBuilder

- Open Source tool developed and maintained by Novo Nordisk
- Highly linked to standards & initiatives
  - CDISC Standards
  - Member of CDISC Open Source Alliance (COSA)
  - TransCelerate DDF implementation
- Looking for collaborators

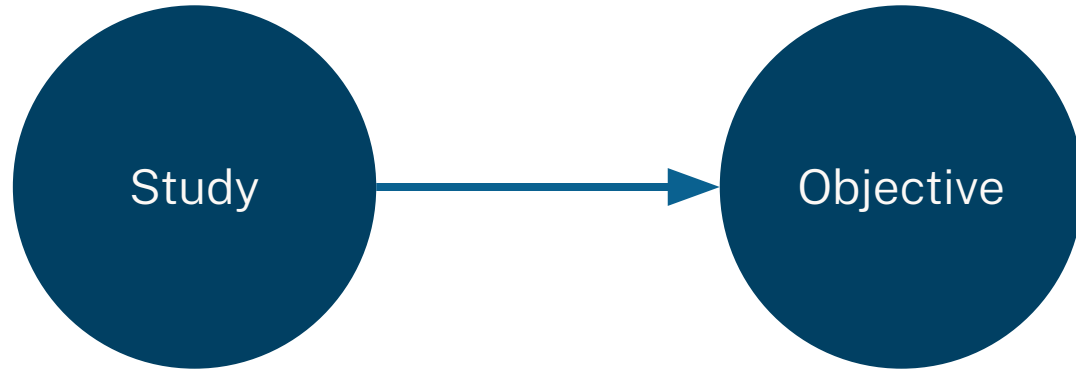


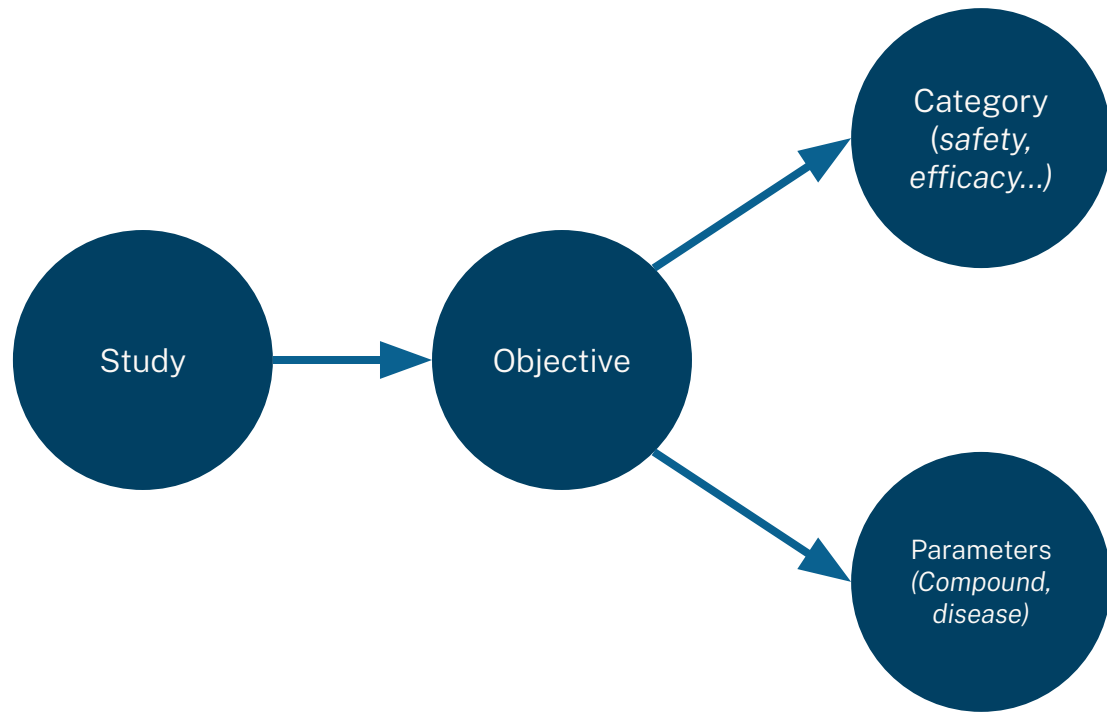
# A graph ? Why ?

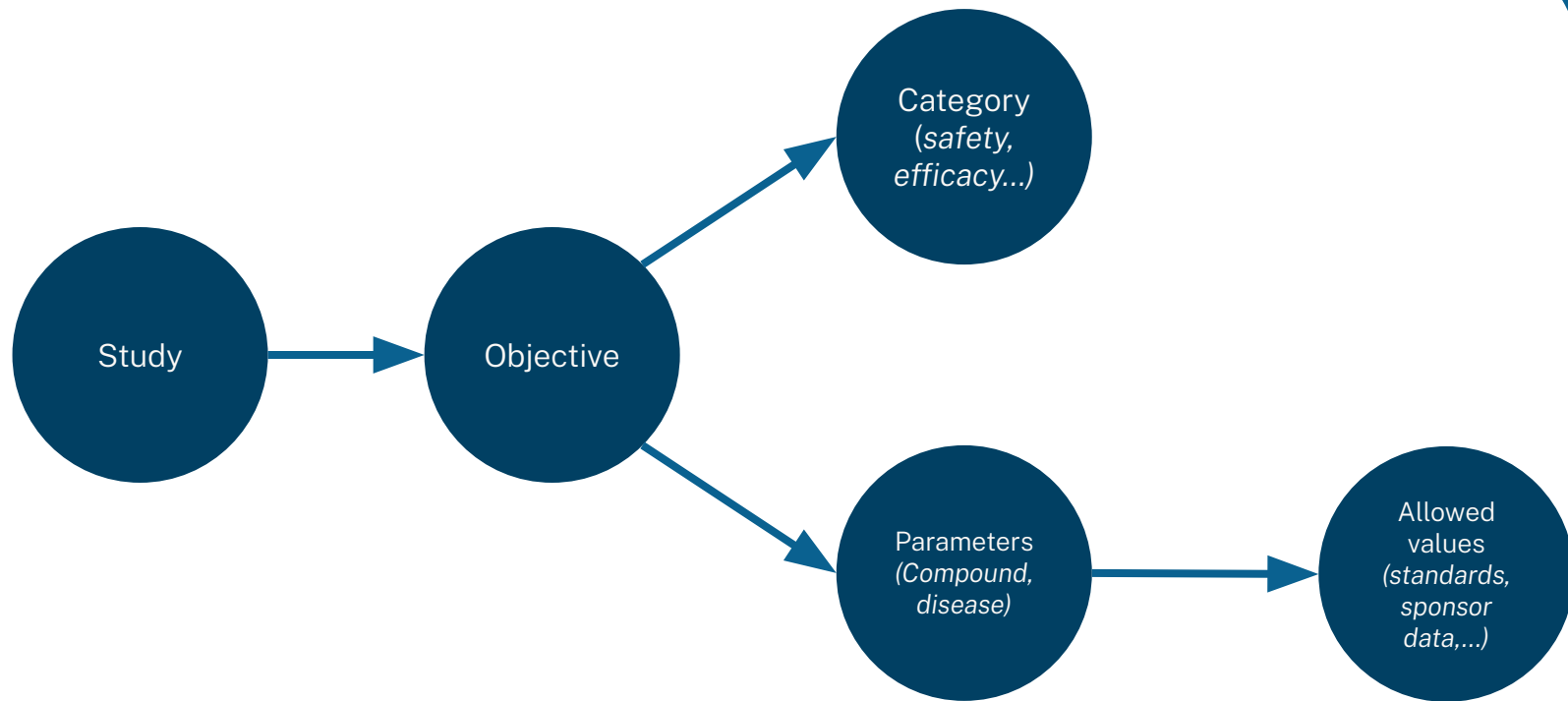




Study







...



## Study Activities (CDISC DEV-0)

## Study Activities

Detailed SoA

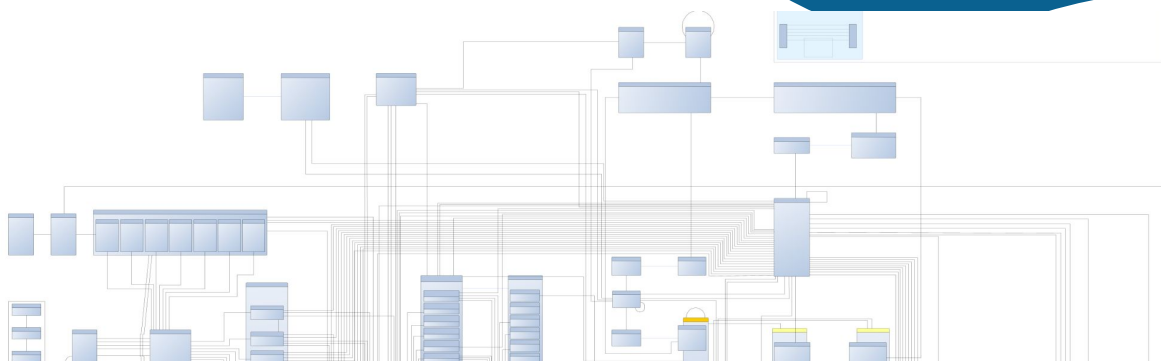
SoA footnotes

Protocol SoA

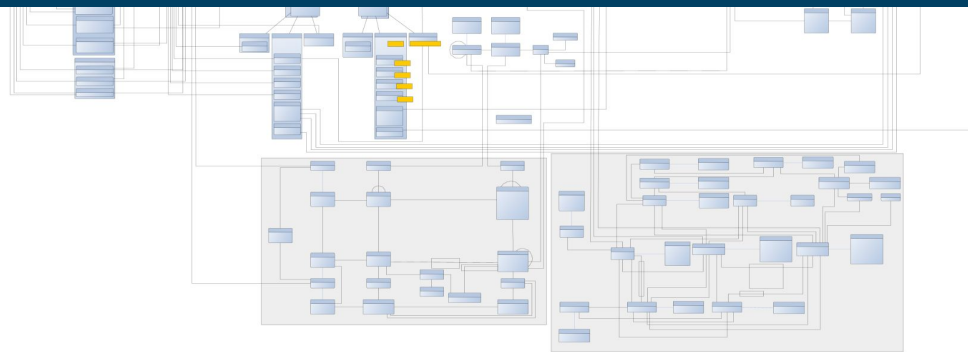
### Activity Instructions

☐ Expand table

Activities	Epoch	Screening	Treatment									Follow-up	
	Visit	V1 <input type="checkbox"/>	V2 <input type="checkbox"/>	V3 <input type="checkbox"/>	V4 <input type="checkbox"/>	V5 <input type="checkbox"/>	V6 <input type="checkbox"/>	V7 <input type="checkbox"/>	V9 <input type="checkbox"/>	V10 <input type="checkbox"/>	V11 <input type="checkbox"/>	V8 <input type="checkbox"/>	
	Study week	-2	1	2	3	4	5	6	7	9	27	6	
	Window	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35	
SUBJECT RELATED INFORMATION													
Randomisation													
End of Study													
Body Measurements													
Body Measurements													
<input type="checkbox"/> Weight					<input type="radio"/>			<input type="radio"/>		<input type="radio"/>			
<input type="checkbox"/> Height				<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Eligibility Criteria													
EFFICACY													
SAFETY													



Congrats ! It's a **graph** ! 🧠

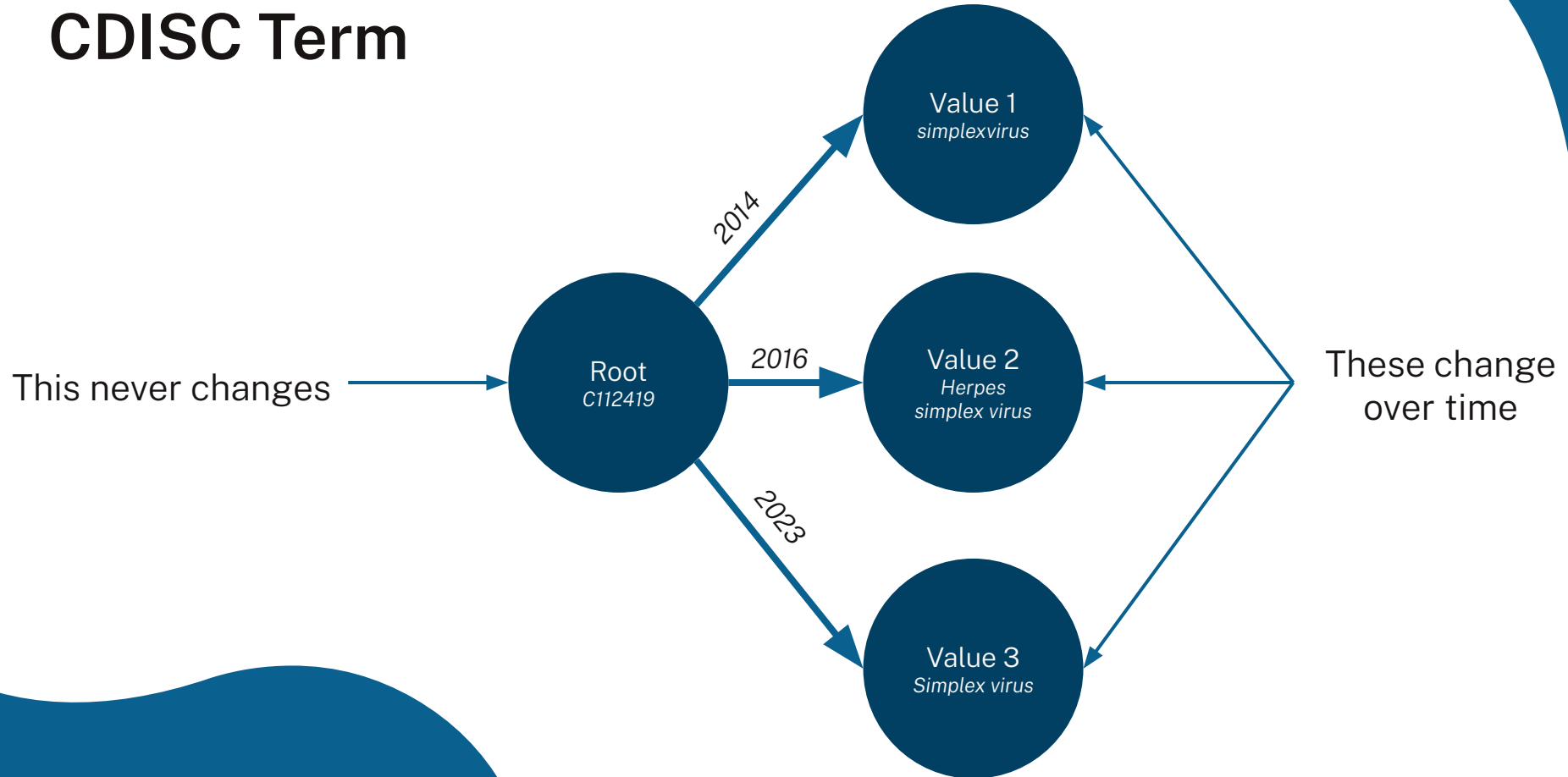




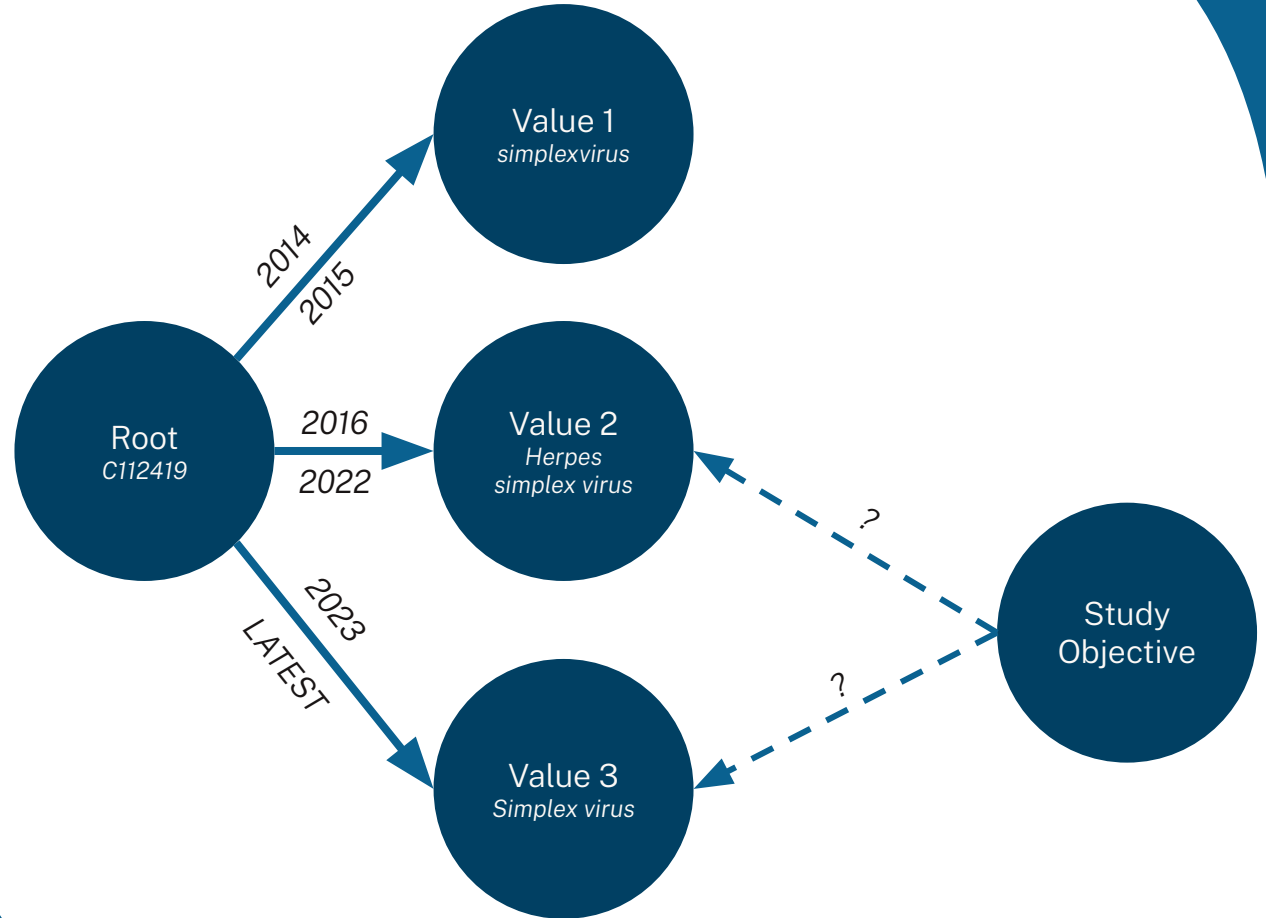
Next, add a pinch  
of versioning...



# Objects actually cover multiple nodes - CDISC Term



# Game : pick the right version



# Game : pick the right version

Value 1  
*simplexvirus*

Congrats ! It's **graphS** ! 🧒🧒🧒

2023  
LATEST

Value 3  
*Simplex virus*

Study  
Objective

?

**Where do I go from here ?**

# OpenStudyBuilder - Get Started

- Project homepage ([OpenStudyBuilder.com](https://OpenStudyBuilder.com))
  - Info  $\Rightarrow$  Resources
- Demonstration video
- Newsletter available in LinkedIn
- Slack & E-Mail
- Source available in GitLab





# OpenStudyBuilder - Get Started

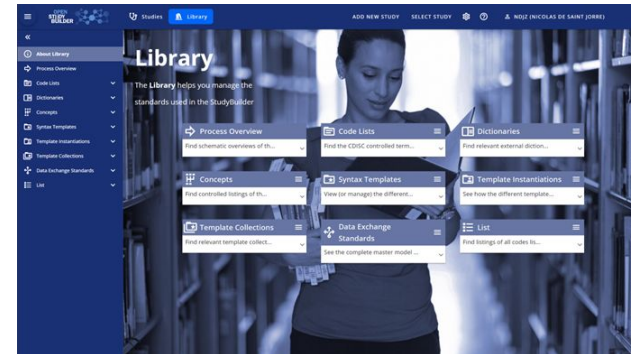
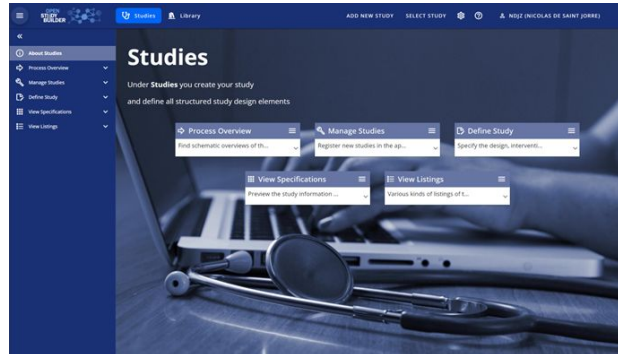


Local/Server  
Installation

Access Public  
Sandbox

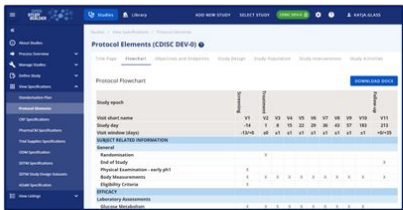


Dedicated Hosted  
Environment



# OpenStudyBuilder - Get Started

## Application

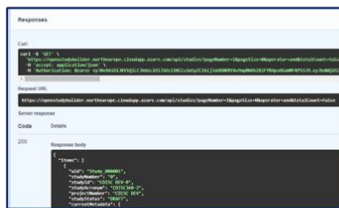


## Neo4j database

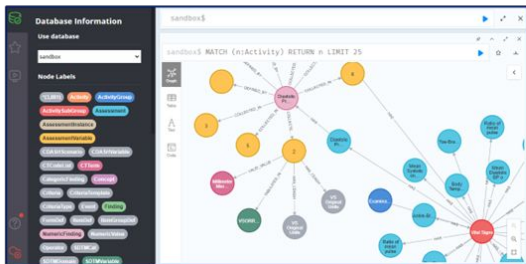
- Including example data



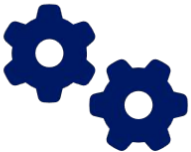
## API



## DB Browser



## Scripts



## Neo4j dashboard



## Documentation

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

# OpenStudyBuilder is customizable... and Neo4j can help you

## Library data:

- Controlled Terminology - Sponsor extensions to CDISC standards;
- Other library data imported from CSVs : Activities, Units, ...

## Custom mappers:

- Library data - Plug-in your own source of CT or Data Models;
- Map study format - e.g. OSB can output Studies in USDM compliant format;

## Extensions:

- The project is open source, so extending functionality is possible.

# Thank you!

[katja.glass@glacon.eu](mailto:katja.glass@glacon.eu)

[marius.conjeaud@neo4j.com](mailto:marius.conjeaud@neo4j.com)