cdisc

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INTERCHANGE
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Extending Biomedical Concepts to Analysis

Presented by Kirsten Walther Langendorf, Partner at data4knowledge

Meet the Speaker

Kirsten Walther Langendorf

Title: Partner

Organization: data4knowledge

Worked 20 years in the pharmaceutical industry within programming, IT implementation, process improvement, standards implementation, and statistics.

Advices and implements better solutions and processes for use re-use of data and metadata.

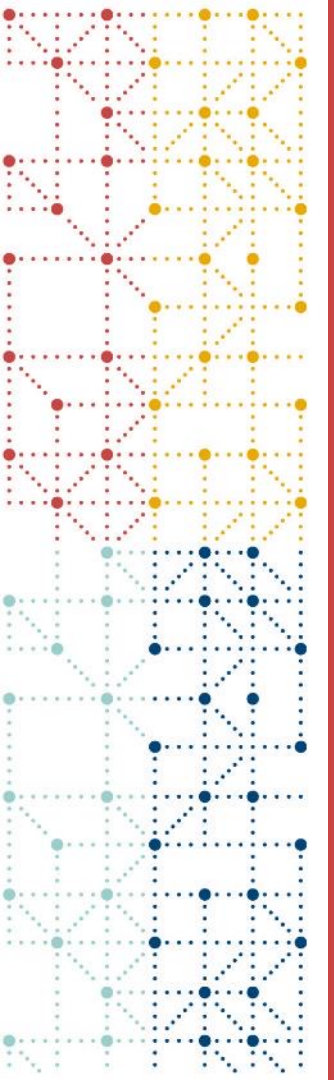
Is motivated and driven by implementation of linked-data, metadata-driven solutions, and automated end-2-end process for clinical data.

It should be simple and straight forward to use CDISC standards while working with clinical data.

Supports CDISC in the development of Biomedical Concepts.

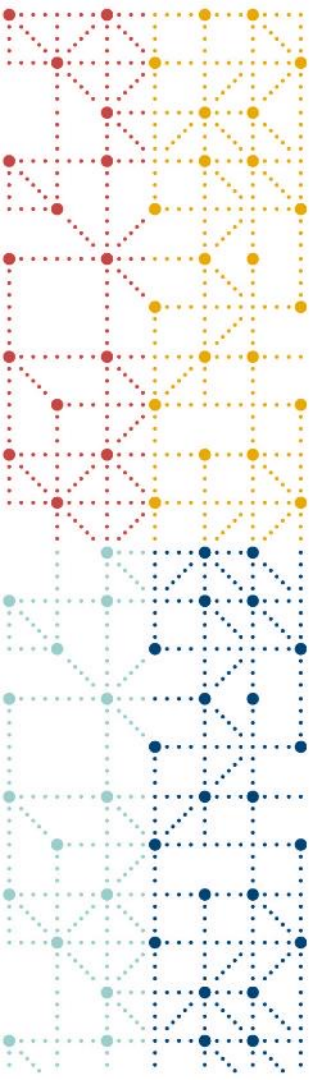
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

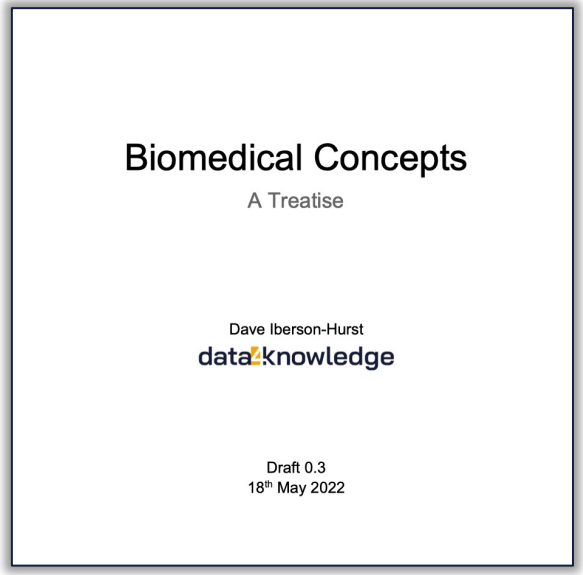
1. Background
2. End-2-end data flow with BCs – extended to analysis
3. Derivation Concepts - examples
4. Proof-of-concept implementation
5. Summary



Background

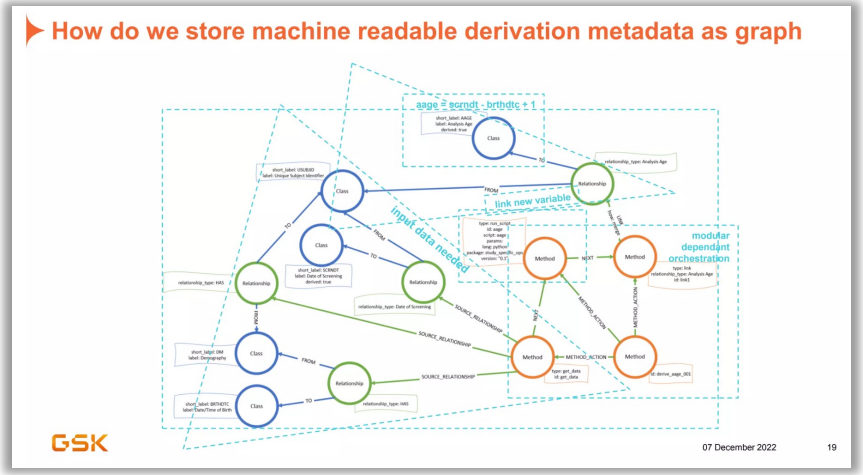
The input and inspiration

Paper by Dave Iberson-Hurst

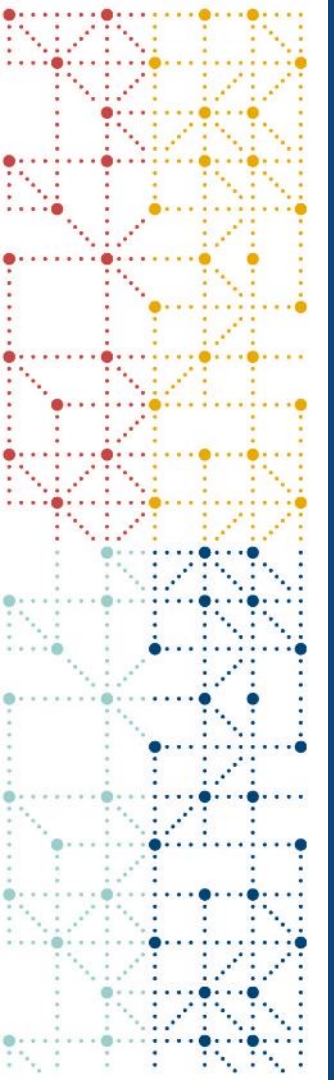


Alexey Kuznetsov and Jorine Putter PhUSE EU 2022

https://www.slideshare.net/neo4j/how-will-knowledge-graphs-improve-clinical-reporting-workflows



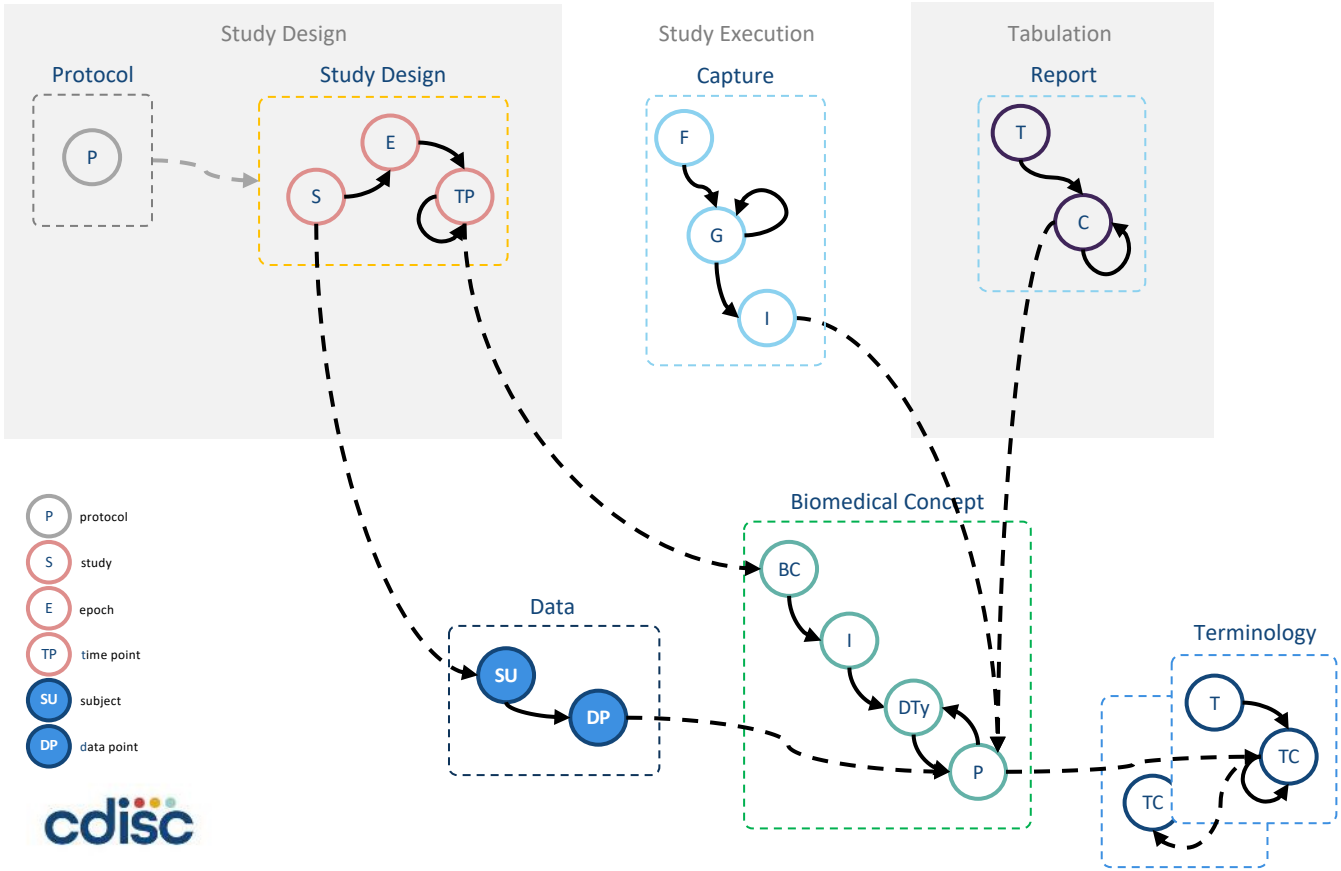
https://github.com/data4knowledge/biomedical_concepts/blob/main/docs/bc%20treatise/Biomedical%20Concepts%20Treatise.pdf



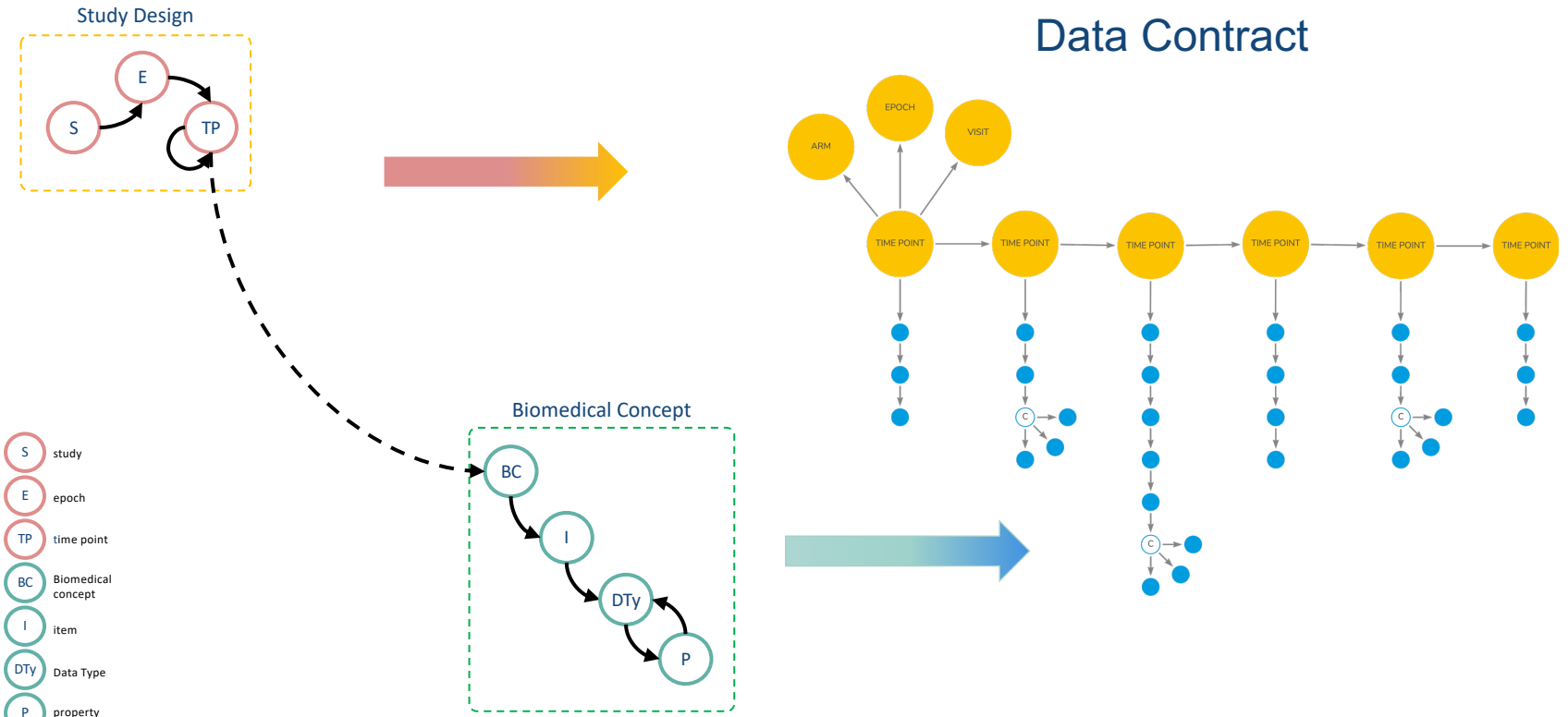
End-2-end data flow

with Biomedical Concepts - extended to Analysis

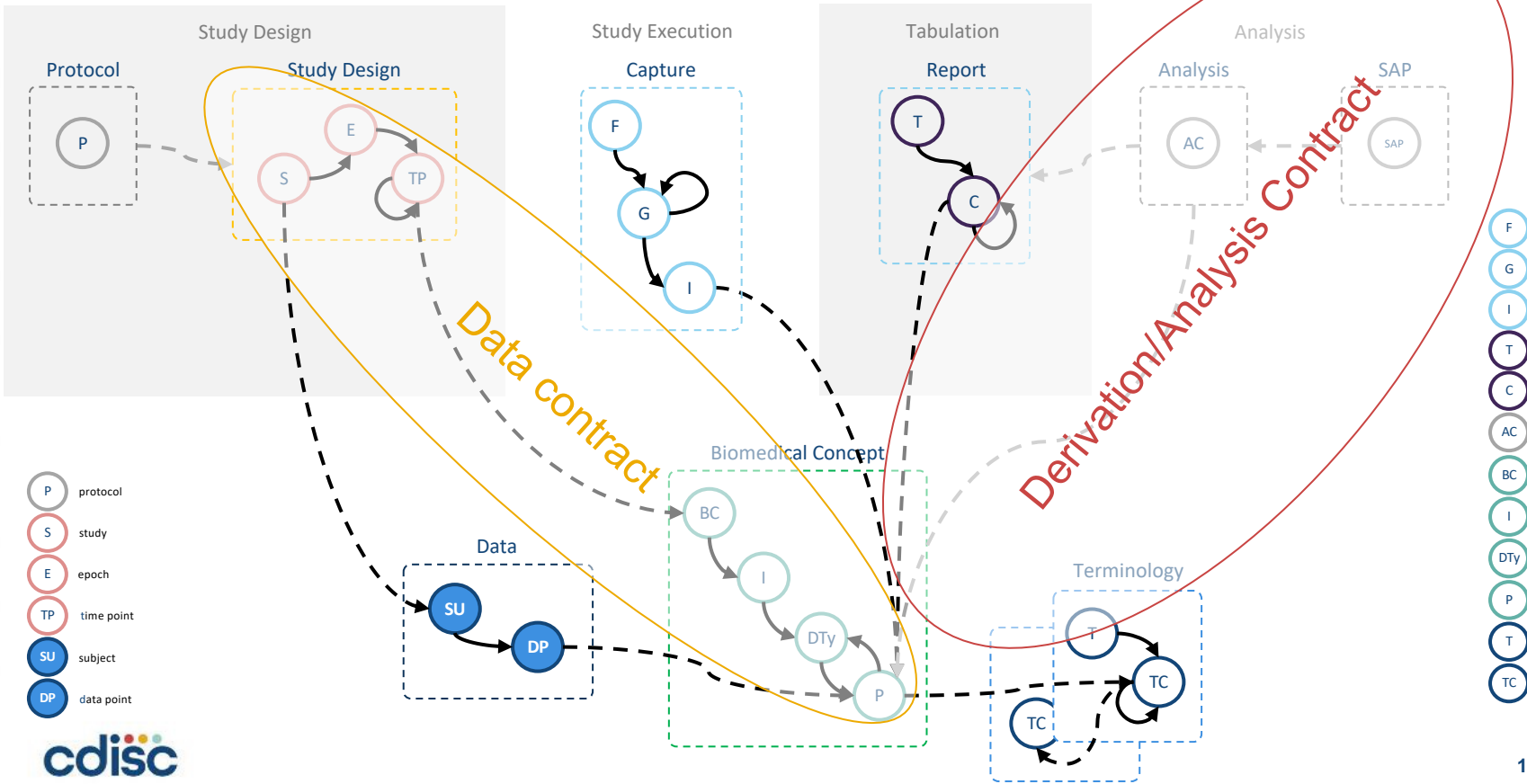
The end-to-end view – also focus for CDISC Digital Data Flow



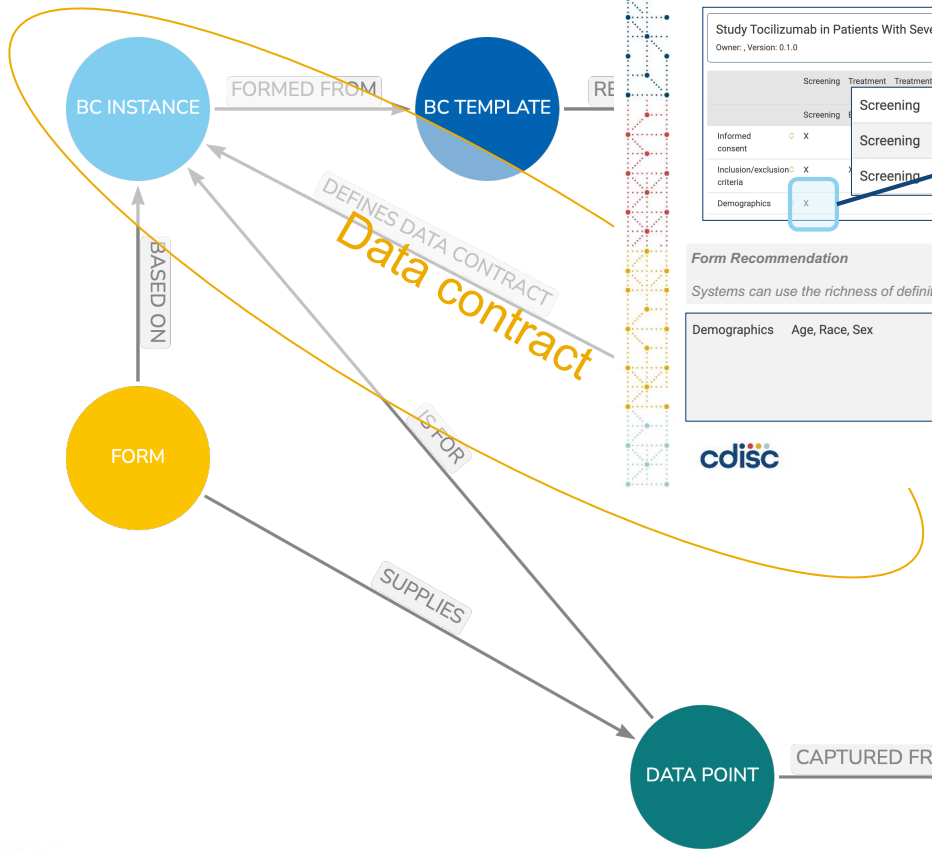
BC and the data contract



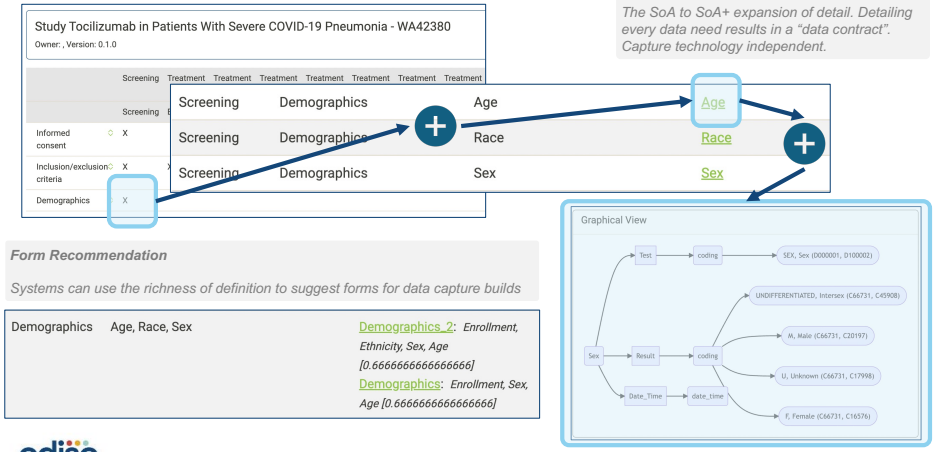
The end-to-end view – extending to Analysis



The data contract



Increasing Detail – Data Contract



Increasing Detail

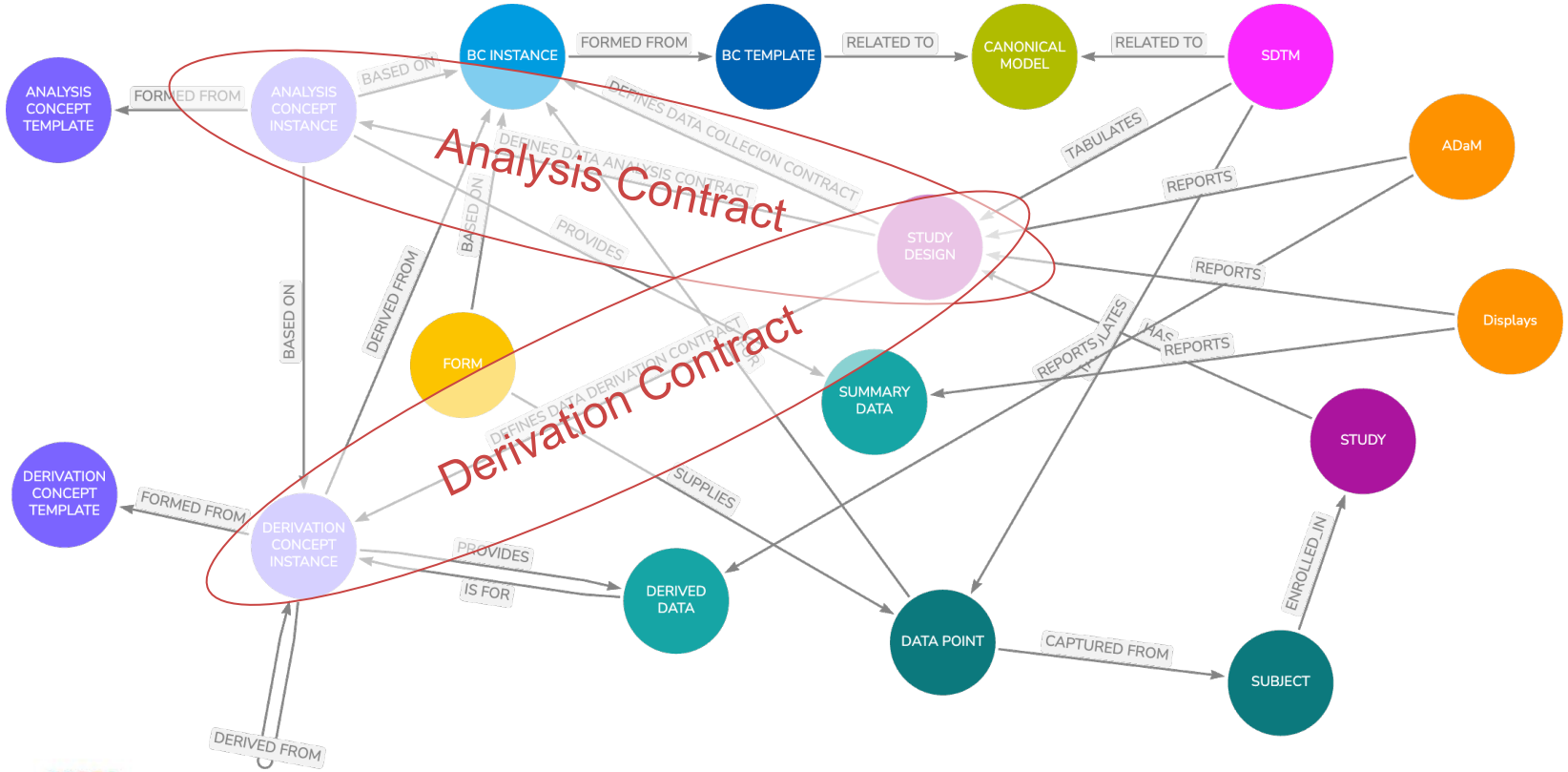
The SoA to SoA+ expansion of detail. Detailing every data need results in a "data contract". Capture technology independent.

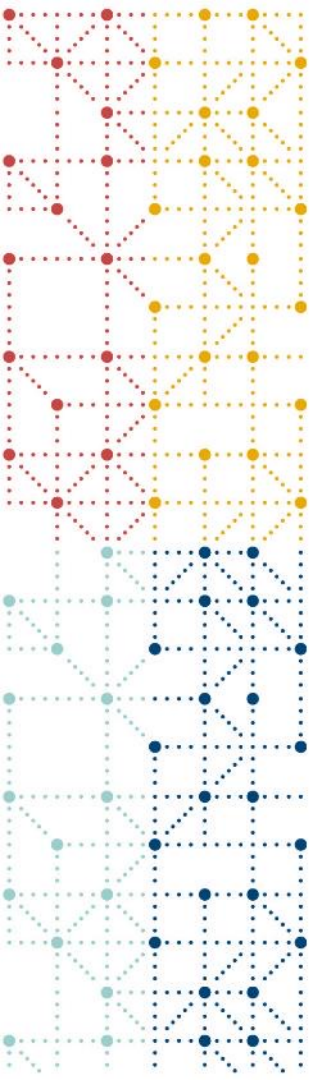
Form Recommendation

Systems can use the richness of definition to suggest forms for data capture builds

Demographics	Age, Race, Sex	Demographics_2: *Enrollment, Ethnicity, Sex, Age [0.6666666666666666]* Demographics: *Enrollment, Sex, Age [0.6666666666666666]*

The data contract – extended to derivation/analysis

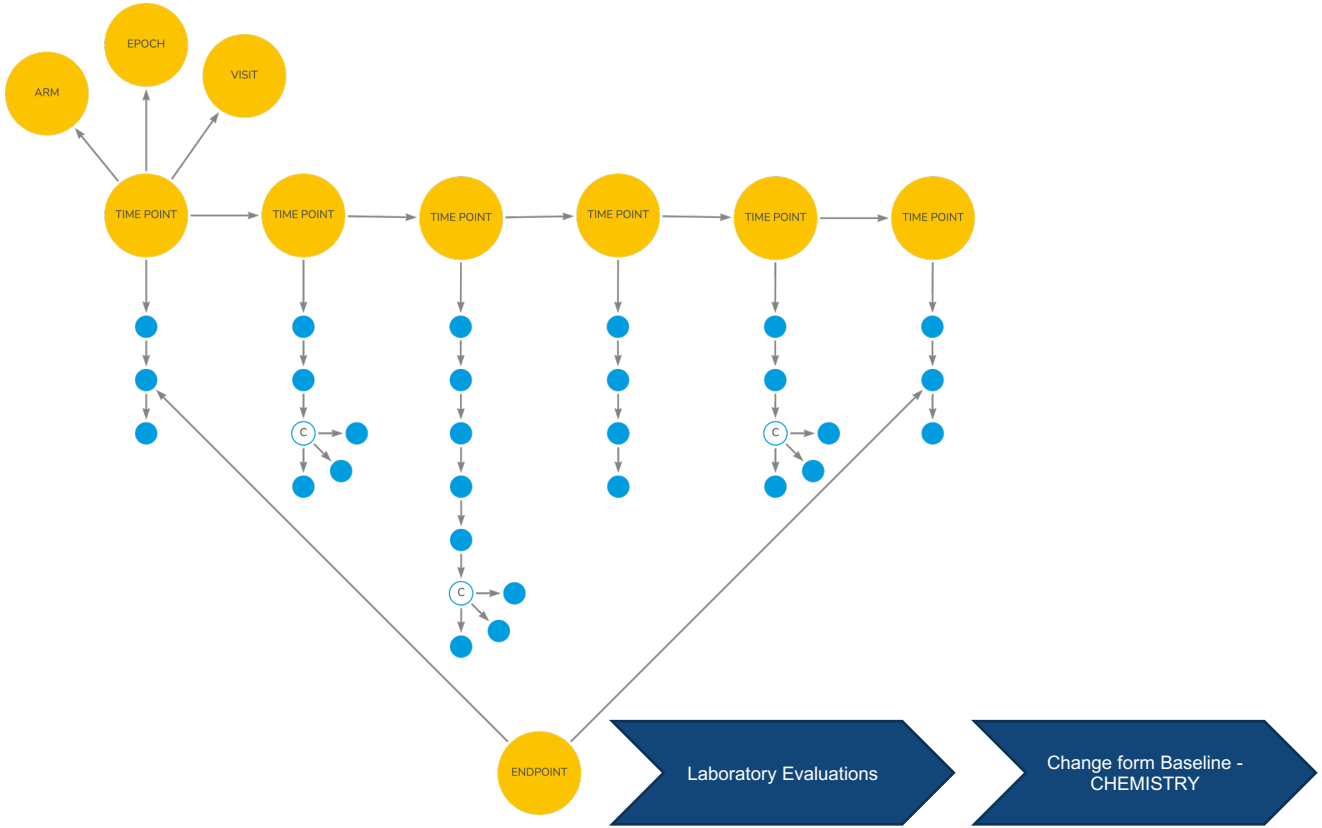




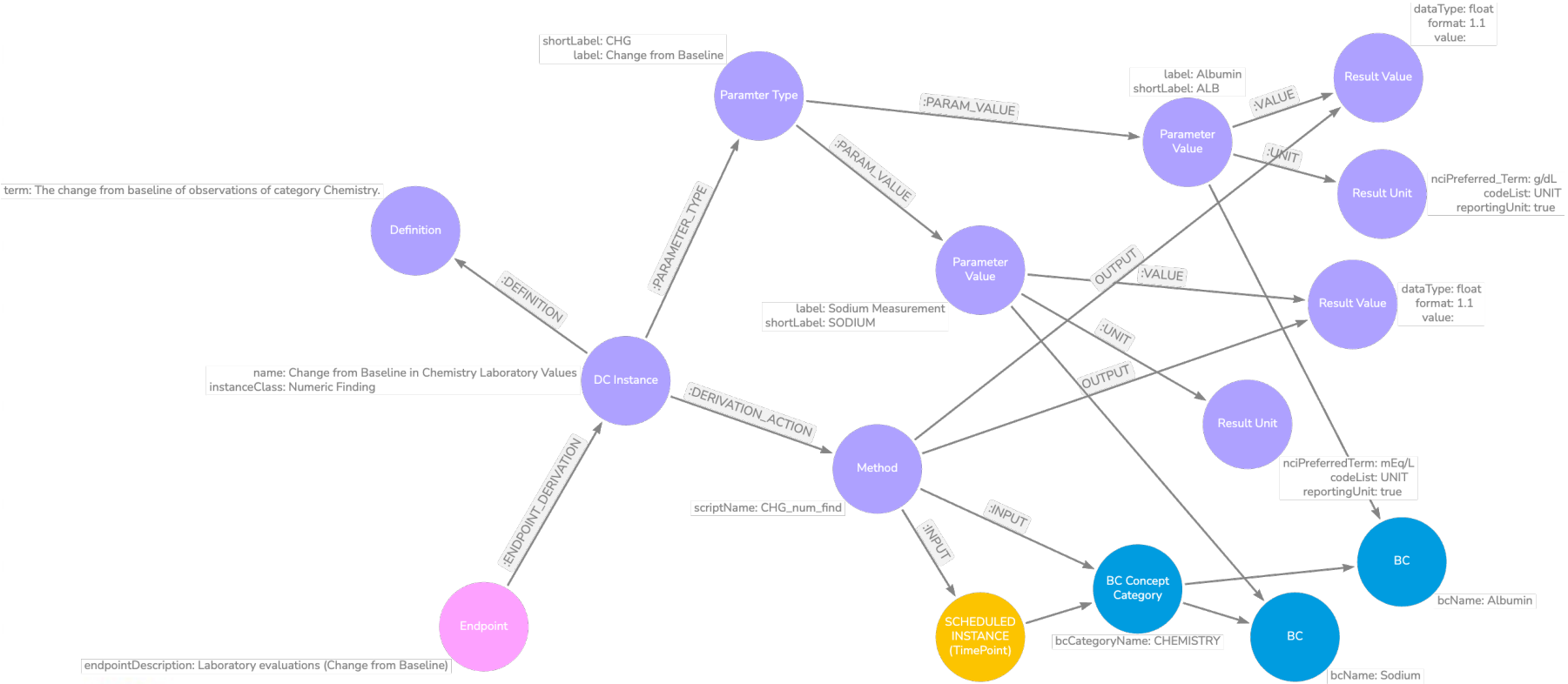
Derivation Concepts

Examples and some initial design

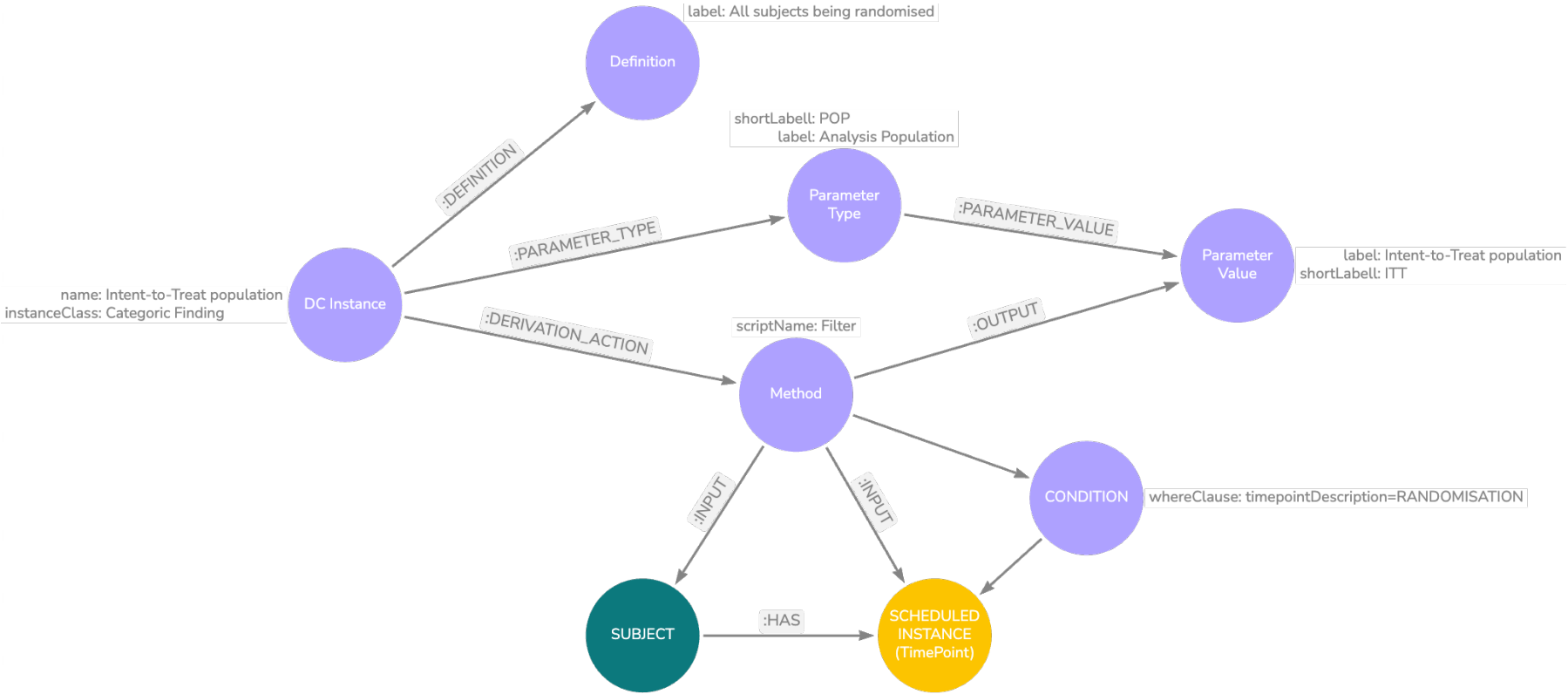
Change from Baseline in Chemistry Laboratory

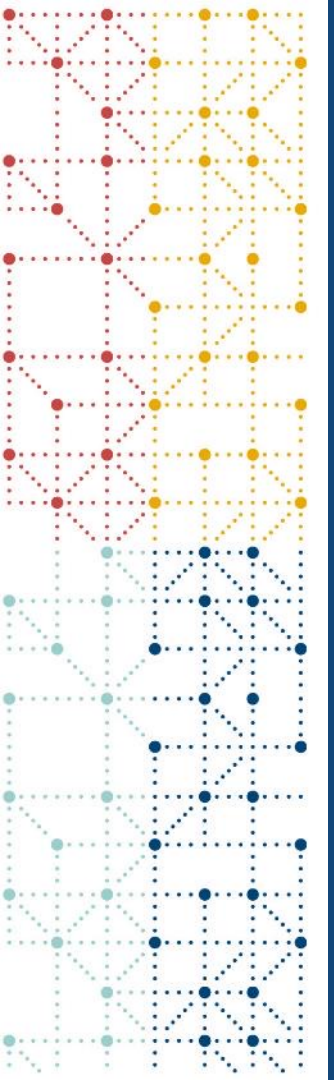


Derivation concept – Change form Baseline in Chemistry Laboratory Values



Derivation concept – ITT Population



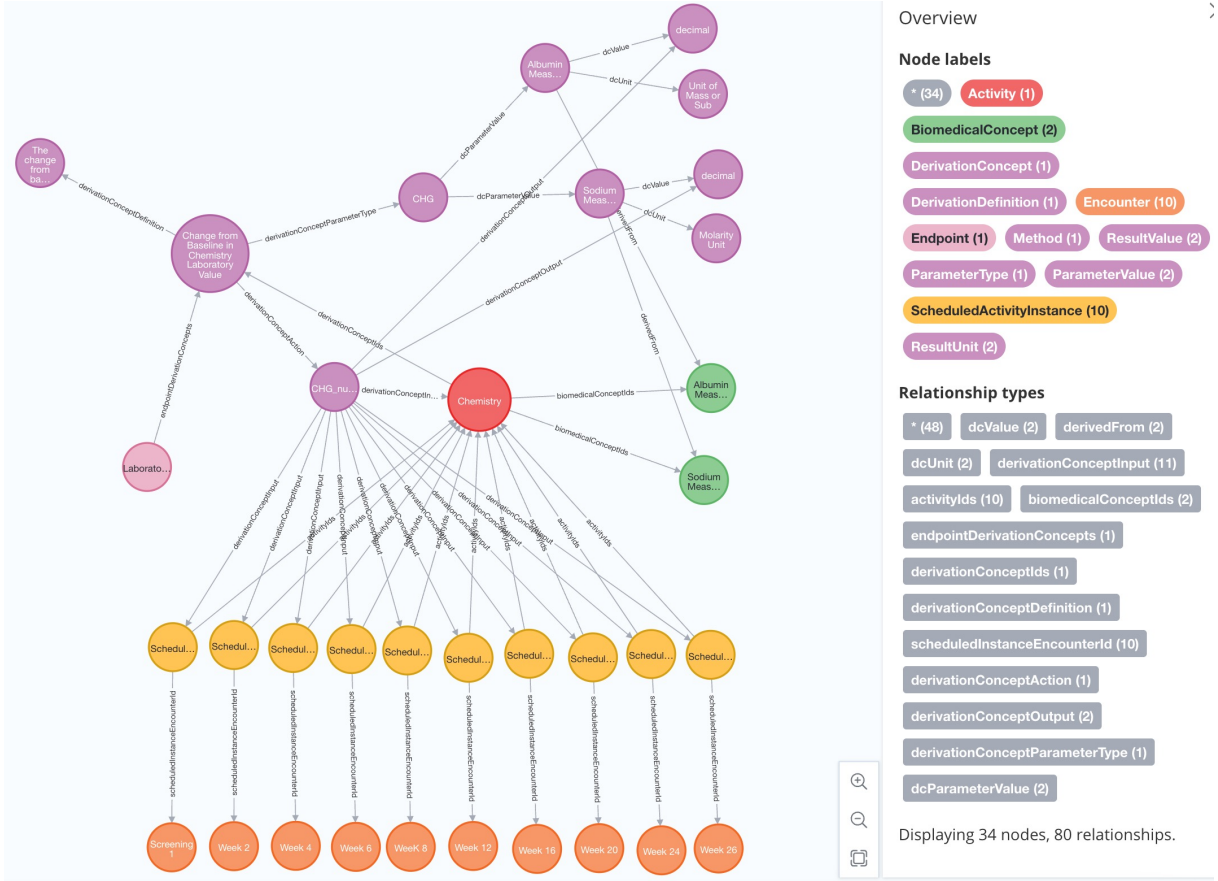


Proof of concept

Derivation examples in DDF model

-using CDISC pilot study

A derivation concept metadata into DDF model



Data contract

- Library of Biomedical Concepts
- During study protocol setup the user selects Activities
- Next step is to detail which of the BCs (linked to Activity) is applicable for study

```
$ //Data contract- Sodium and Albumin match(s:Study)-[:studyDesigns]→(sd:StudyDesign)-[:activities]→(a:Activity)←[:acti
```

Protocol	Study Design Name	Activity Name	BC Name	DC Name
"H2Q-MC-LZZT(c)"	"Study Design 1"	"Chemistry"	"Sodium Measurement"	"Change from Baseline in Chemistry Laboratory Values"
"H2Q-MC-LZZT(c)"	"Study Design 1"	"Chemistry"	"Albumin Measurement"	"Change from Baseline in Chemistry Laboratory Values"

Derivation Contract

- Library of Derivation Concepts – these are linked to library BC concept
- During study protocol the user can pick relevant DCs based on the Activitties/BCs selected
- DCs can be linked to Endpoints

```
Derivation contract- Sodium and Albumin match(s:Study)-[:studyDesigns]→(sd:StudyDesign)-[:activities]→(a:Activity)←…
```

Protocol	Study Design Name	Activity Name	BC Name	DC Name	Parameter
"H2Q-MC-LZZT(c)"	"Study Design 1"	"Chemistry"	"Sodium Measurement"	"Change from Baseline in Chemistry Laboratory Values"	"Sodium Measurement (Molarity Unit)"
"H2Q-MC-LZZT(c)"	"Study Design 1"	"Chemistry"	"Albumin Measurement"	"Change from Baseline in Chemistry Laboratory Values"	"Albumin Measurement (Unit of Mass or Substance Concentration)"

Protocol	Objective	Endpoint	Activity Name	DC Name	Parameter
"H2Q-MC-LZZT(c)"	"To document the safety profile of the xanomeline TTS."	"Laboratory evaluations (Change from Baseline)"	"Chemistry"	"Change from Baseline in Chemistry Laboratory Values"	"Sodium Measurement (Molarity Unit)"
"H2Q-MC-LZZT(c)"	"To document the safety profile of the xanomeline TTS."	"Laboratory evaluations (Change from Baseline)"	"Chemistry"	"Change from Baseline in Chemistry Laboratory Values"	"Albumin Measurement (Unit of Mass or Substance Concentration)"

Data into DDF model – executing the derivation concept

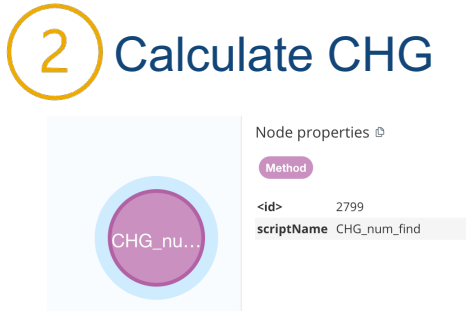
```
df= get_data('Sodium Measurement')
```

1 Get Data and metadata

	USUBJID	PARAM	ENCOUNTER_NAME	scheduledInstanceId	VALUE
1	"01-718-1150"	"Sodium Measurement"	"Screening 1"	"ScheduledActivityInstance_1"	138.0
2	"01-718-1150"	"Sodium Measurement"	"Week 12"	"ScheduledActivityInstance_11"	138.0
3	"01-718-1150"	"Sodium Measurement"	"Week 16"	"ScheduledActivityInstance_13"	139.0
4	"01-718-1150"	"Sodium Measurement"	"Week 20"	"ScheduledActivityInstance_15"	139.0
5	"01-718-1150"	"Sodium Measurement"	"Week 24"	"ScheduledActivityInstance_17"	140.0
6	"01-718-1150"	"Sodium Measurement"	"Week 26"	"ScheduledActivityInstance_18"	144.0

Data into DDF model – executing the derivation concept

```
df= get_data('Sodium Measurement')
df= CHG_num_find(df,'Screening 1')
```

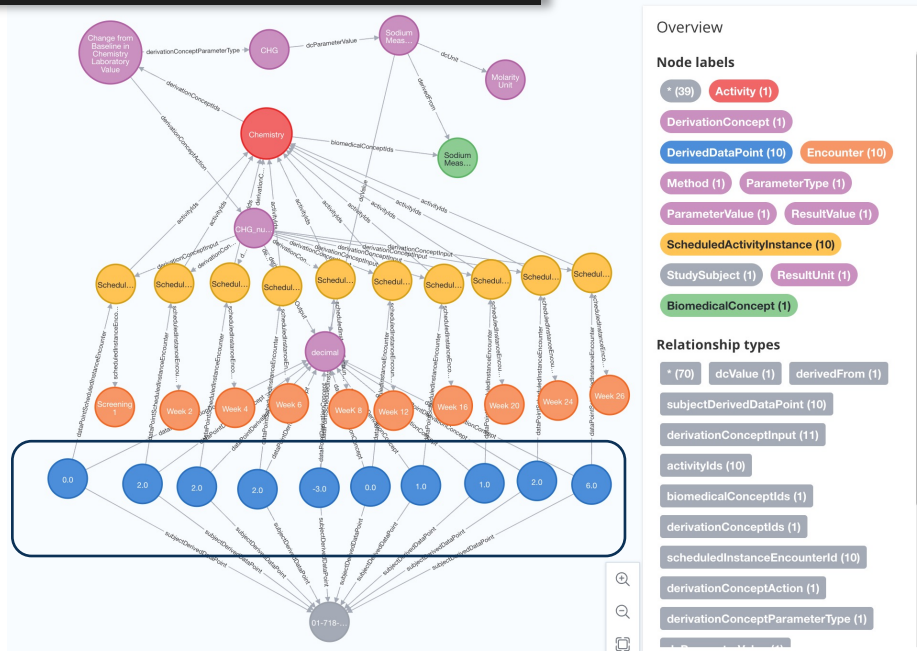


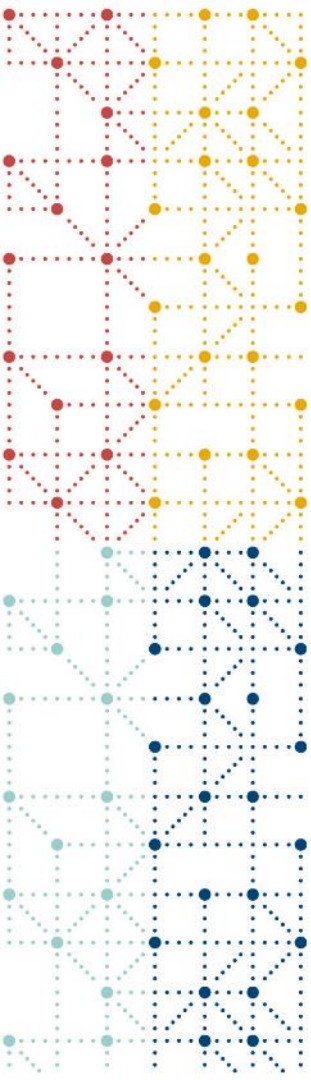
	USUBJID	PARAM	ENCOUNTER_NAME	scheduledInstanceId	VALUE	CHG
0	01-701-1015	Sodium Measurement	Screening 1	ScheduledActivityInstance_1	140.0	0.0
1	01-701-1015	Sodium Measurement	Week 12	ScheduledActivityInstance_11	139.0	-1.0
2	01-701-1015	Sodium Measurement	Week 16	ScheduledActivityInstance_13	141.0	1.0
3	01-701-1015	Sodium Measurement	Week 20	ScheduledActivityInstance_15	142.0	2.0
4	01-701-1015	Sodium Measurement	Week 24	ScheduledActivityInstance_17	140.0	0.0

Data into DDF model – executing the derivation concept

```
df= get_data('Sodium Measurement')
df= CHG_num_find(df,'Screening 1')
save_derived_to_dc(df,'Sodium Measurement')
```

3 Save back to graph





Summary

Summary

- Presented an idea – not a final model!
  - More testing and alignment to DDF model is needed.
- To enable end-2-end metadata driven data flow we can introduce derivation concepts
- Introducing derivations concepts helps tracing how derived data was created and from where it was collected

Future work

- Further work needs to be done testing and modelling
- Need to cover the analysis concepts

Thank You!

Kirsten Walther Langendorf

kwl@data4knowledge.dk

www.data4knowledge.dk