Traceability and AI for Improved Understanding, Communication and Quality Control of Clinical Trials

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2024-05-30

https://github.com/Bayer-Group/phuse-verisian

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Contents

Clincial Statistical Programming

I. Introduction

II. Improving Today

III. Building the Future

I. Introduction

Why are we here?

To **communicate** our quantitative measures of therapy safety and efficacy in patients to third parties for evaluation of health value.

To change for the better how we do this.

Statistical progamming

[as-is]

a. People: statistical programmers / **[SAS ninjas]**

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Statistical progamming

[as-is]

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b. Actions: work with a mountain of SAS code

Statistical progamming

[as-is]

a. People: statistical programmers / **[SAS ninjas]**

b. Actions: work with a mountain of SAS code

c. Deliverable: a **Clinical Study Report**

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Challenges in 2024

Legacy Processes: 2024 or 1994? [as-is]

a. Data Storage

b. Data Transformation

c. Processes: the solo programmer & double programming

d. Silo everything: challenges unique to the Domain (data privacy): Data and code and tools are closed source

II. Improving Today

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Learn from the best

The software dev / tech industry

[to-be]

a. Version control: code *and data*

b. **Agile development methods**: collaboration and iteration

c. Openish source: democratize the tools and processes that we use to make money with, not from. *SAS macros anyone?*

Impediments to change

a. Incumbents: legacy technologies and infrastructure

b. Mindset: lethargic and closed [source]

c. Generation change

d. Existant SAS code: **highly complex**

e. Motivation

“Change happens when the pain of staying the same is greater than the pain of change” -Tony Robbins

What can and should we do today?

Accept the **as-is**:

a. Work with what we've got

b. Commit what's need to change, i.e. time, money and people.

Objective judgement, now, at this very moment.
Unselfish action, now, at this very moment.
*Willing **acceptance** - now, at this very moment - of all external events. That's all you need.*

-Marcus Aurelius

III. Building the Future

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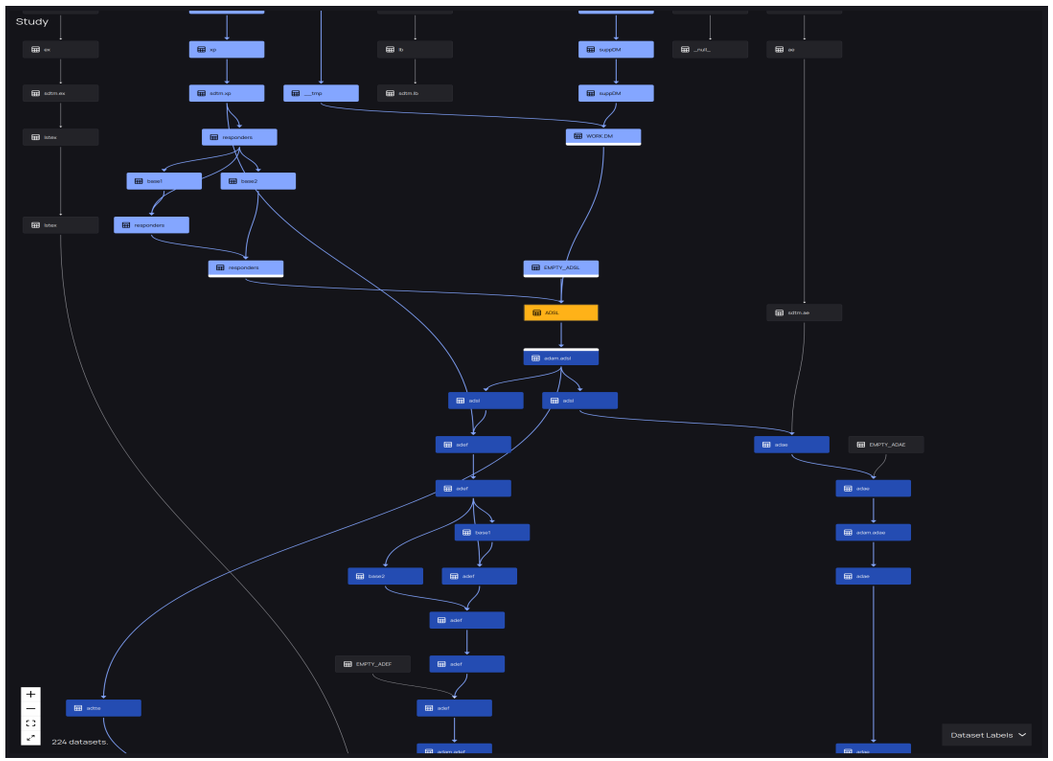
Clinical trials as knowledge graphs

overlay a semantic data model on existing data and code



- Knowledge graphs add relationships or *edges* to data points or *nodes*
- This enables one to *traverse* the *topology* of the database

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Clinical trials as knowledge graphs

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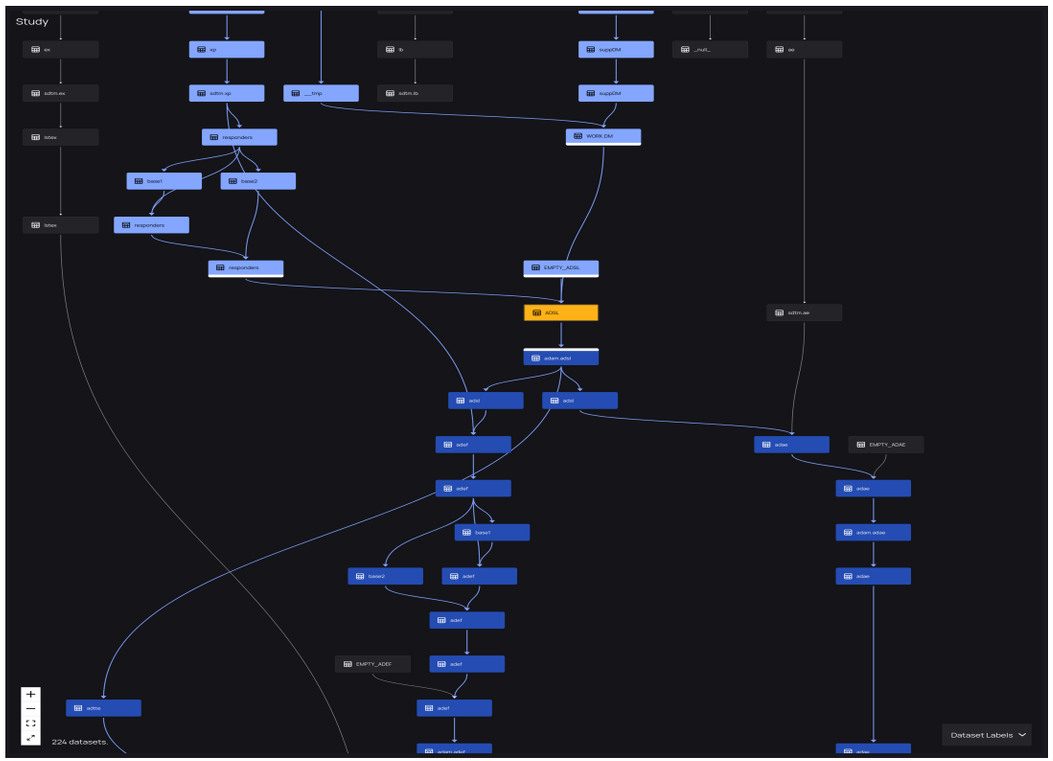

i. end-to-end tracability/ full dependency map

ii. instant root-cause-analysis

iii. trivial data model mapping

iv. trivial study pooling

v. navigate studies and pools *in toto*

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Clinical trials as knowledge graphs

overlay a semantic data model on existing data and code

Benefits previously demonstarted at PHUSE:

- PHUSE/Stardog – How Knowledge Graphs Will Transform the Pharmaceutical Industry
  Tim Williams, PHUSE & Guy Vorster, Stardog
- How will knowledge graphs improve clinical reporting workflows?
  Alexey Kuznetsov & Jorine Putter, GSK

No free lunch

Building an ontology and semantic model for clinical trials is highly specialized and **enormously labor intensive.**

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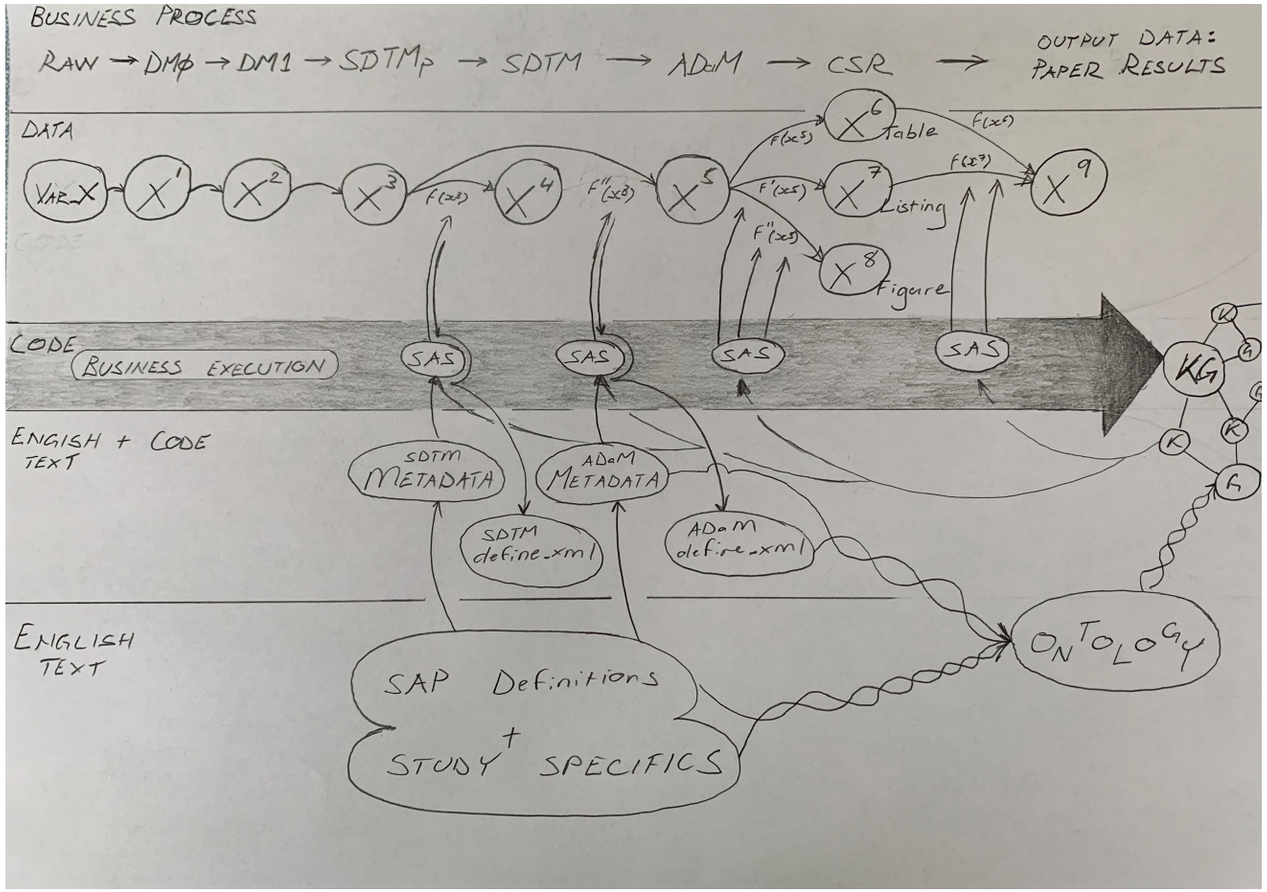
No free lunch

Building an ontology and semantic model for clinical trials is highly specialized and enormously labor intensive.

If we want to be faster we'll need a different approach:
Build it *bottom up*, from the code.

How bottom up?



- *top down* places human text at the top of the process, defining standard ontologies etc.
- *bottom up* places executed machine code at the top, of the process, form which standards are defined

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Bottom up *Knowledge Graphs*: **under**pin a sematic data model on existing data and code

a. Not lost in translation: **code is *the* business execution** that delivers value (not the so much the other stuff)

b. Machines parse the code and deterministically extract all process logic

c. Works with *all* previous and current code
Change the *wheels* while the car is driving

Deterministically read machine parsed code

a. Deterministic vs probablistic

b. 100% explainable, no halucinations

c. Universal code logic extraction

d. Fully automate the graph creation **[upgrading while driving]**

e. Single source of truth feeds other processes

   i. Documentation creation: definitions and descriptions for **humans**

   ii. Translate to other languages: R, Python (SAS 👋)

And what of LLMs?

Can they replace stat programmers?

a. In short **no**, because they are probabilistic; determinism is at the heart of drug development especially for back translation

b. But they will be valuable for accelerating support tasks

Summary

- The challenges communicating clinical trial outcomes to authorities have exceeded our industries existing capabilities
- These challenges can be overcome by weaving clinical trials into knowledge graphs
- Automated knowledge-graph generation from code offers important benefits over top-down ontologically built graphs
- LLMs are finding many use-cases outside those requiring full explainability

Verisian Demo

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Acknowledgements

Tomas Sabat Stöfsel & Henning Kuich **Verisian**
Oliver Wirtz, Cornelia Fulgenzi, Peter Bonata & Richardus Vonk **Bayer**
Paul Vervuren & Jules van der Zalm **Phuse**

Q&A

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