

Single Day Event

Full Traceability and Faster Study Build Through
Graph Theory and Code Understanding

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Founding Team



Henning Kuich
CTO

- Eight years as Engineer and Scientist at Bayer
- Worked with biostats to accelerate FDA inquiry response cycles
- Trailblazed cloud adoption and infrastructure to power all bio literature and patent research
- PhD in Systems Biology, Uni of Virginia and Freie Universität Berlin



Tomás Sabat Stöf sel
CEO

- Former COO and Founding Team of open-source database TypeDB
- Sold to large pharma and small biotech companies, as well as other industries such as defence and robotics
- Engaged and presented to thousands of developers through open-source conferences and events
- MPhil University of Cambridge



Our starting hypothesis

Answering FDA inquiries takes too long



We conducted over 100 interviews





The problems we learned about

1. Data quality throughout analysis
2. Implementation of statistics that follow specification
3. Full end-to-end traceability at variable and dataset level
4. SDTM to ADaM to TFL automation
5. Limited number of expert statistical programmers
6. Understanding and communication of analyses
7. Real-time monitoring

What can we build?



With the community we built a roadmap

Sponsors

CROs

Boutique
consultancies

FDA

EMA

PDMA

...

builder

Faster study and report
building

monitor

Real-time monitoring and
decision making of studies

submitter

Faster regulatory review
cycles

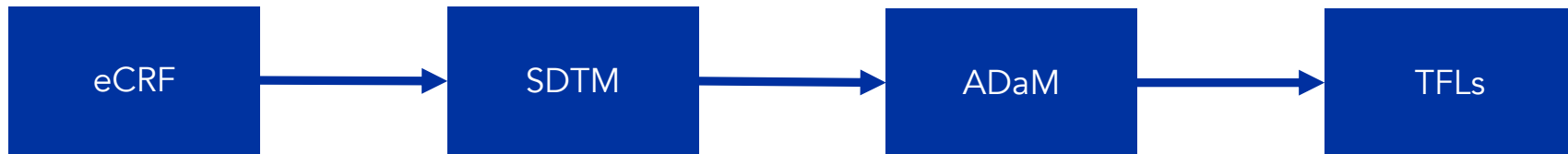
Clinical sites

EDC

How is this different?



Clinical Studies as ETL pipelines

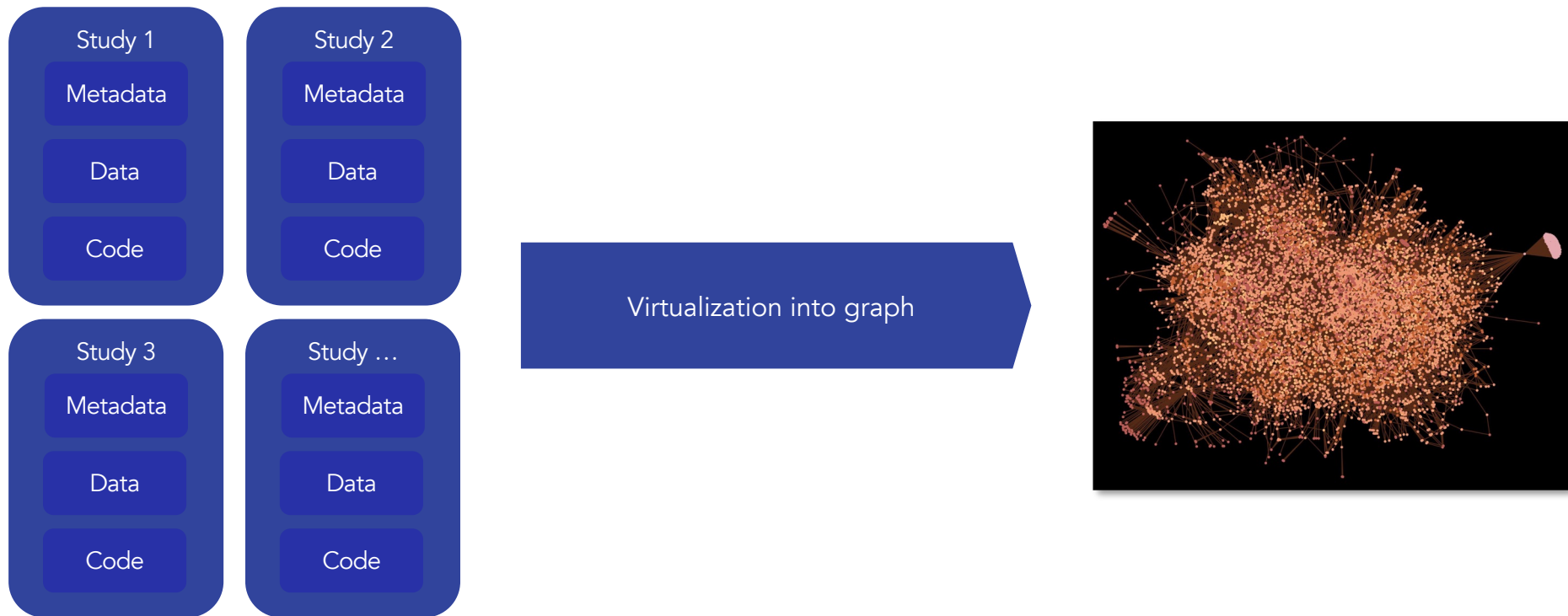


Extract, Transform, Load

Problem: How can we reuse those pipelines?



Parsing and virtualizing study code





Library of TFL and ADaM

Step 1:
Select TFL Template

Table ABC

Option 1

Option 2

Option 3

Option ...

Table XYZ

Option 1

Option 2

...

Option 1

Option 2

Option ...

Step 2:
Select from TFL Library

Table XYZ

gender	Col 2	Col 3	...
male	###	###	###
female	###	###	###
...	...	...	...

Required ADaM Derivations

EXPOS

aval["PFS"]

...

Step 3:
Choose from ADAM Library

EXPOS

Option 1

Option 2

Option ...

Step 4:
Modify If Needed

```
1 data add;
2   set asc;
3   if trisect1 then do;
4     select;
5     when (1 <= asc1 <= 100)
6       assignasc1;
7     when (101 <= asc1 <= 150)
8       assignasc2;
9     when (151 <= asc1 <= 200)
10      assignasc3;
11    when (201 <= asc1 <= 250)
12      assignasc4;
13    when (251 <= asc1 <= 300)
14      assignasc5;
15    when (301 <= asc1 <= 350)
16      assignasc6;
17    when (351 <= asc1 <= 400)
18      assignasc7;
19    when (401 <= asc1 <= 450)
20      assignasc8;
21    when (451 <= asc1 <= 500)
22      assignasc9;
23  end;
24 run;
```

aval["PFS"]

Option 1

Option 2

Option ...

```
1 data all_pfs(rename=(pfs1));
2   set events_final;
3   by modality;
4   length paramcd $8;
5   select (0);
6   when (0)
7     paramcd='pfs1';
8   when (1)
9     paramcd='pfs1';
10  when (2)
11    paramcd='pfs1c';
12  end;
13 if event='de' then eventcd='';
14 else if event='death' then eventcd='';
15 else if event='lung' then eventcd='';
16 if eventcd then attrcd='';
17 run;
```

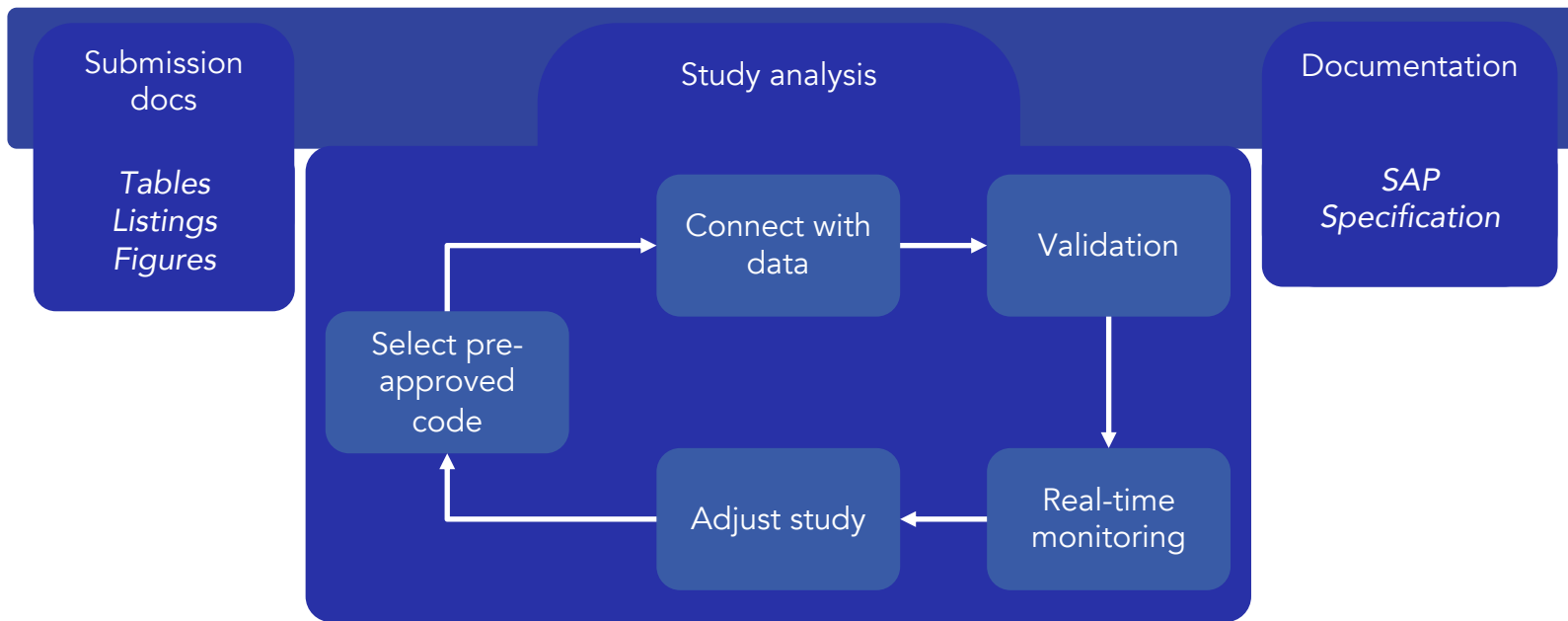
Option 1

Option ...

```
2 ....
3 ....
4 ....
```



What does this mean to how we build studies?





Roadmap 2023-2026

2023

Release of **Tracer** for end-to-end traceability

2025

- R translations
- Data reuse/study pooling
- CSR generation

2024

- ADaM, TFL library
- Define.xml automation
- Data quality controls

2026

- Centralized data and metadata repository
- Real-time study monitoring and endpoint simulation



Where we are right now

We have a study **virtualized** and
analyzed at a large pharma

We would love to **partner** with
anyone who shares our vision



The Global Healthcare Data Science Community

Contact Channels

- UK +44 1843 609600
- office@phuse.global
- phuse.global

Social Media

- [@phusetwitta](https://twitter.com/phusetwitta)
- [/phusebook](https://facebook.com/phusebook)
- [/phusetube](https://youtube.com/phusetube)
- [/company/phuse](https://linkedin.com/company/phuse)