



Droice Labs

Scaling ECAs from ad hoc projects to the enterprise: multicenter, multisource infrastructure for external control arms

Jussi Leinonen, MD, Ph.D., Bayer

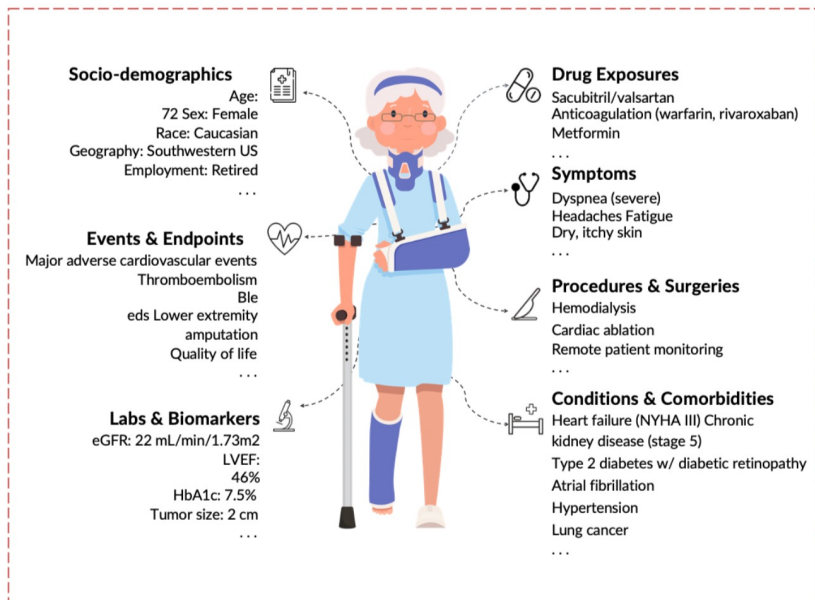
Mayur Saxena, Ph.D., Droice Labs



PATIENT PROFILE

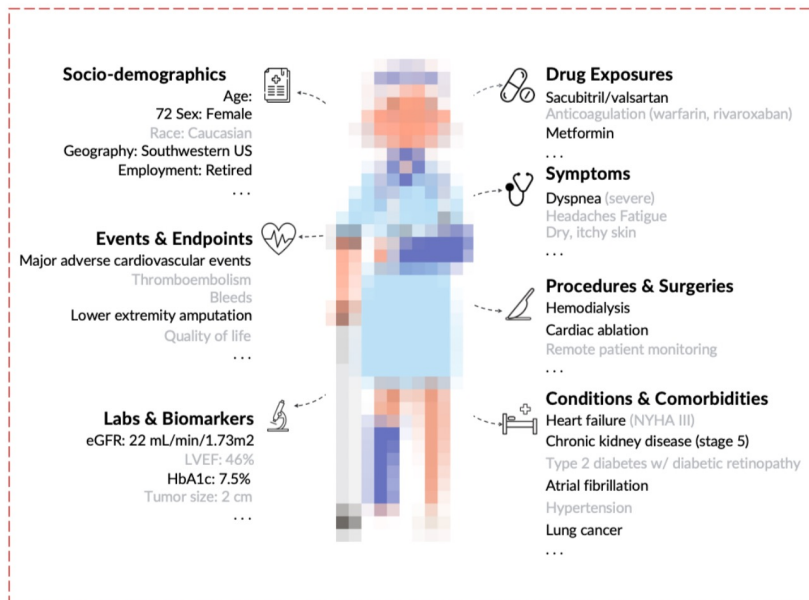
Need

An accurate & complete patient data

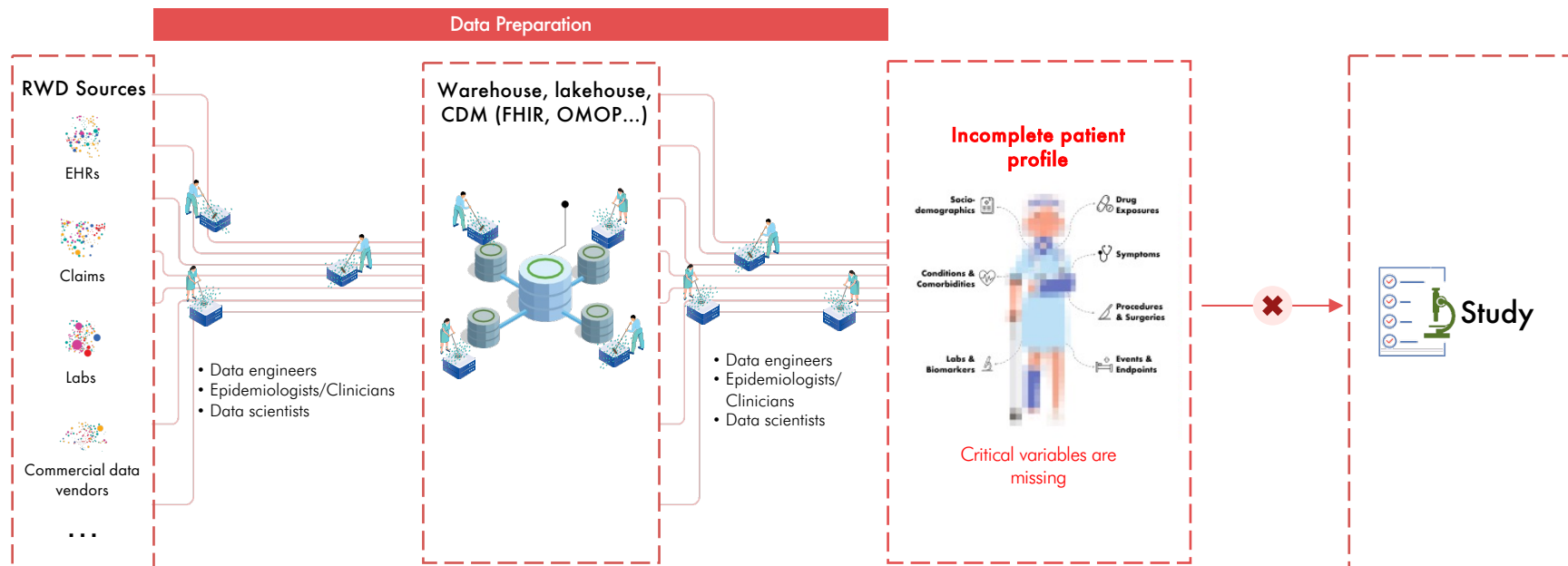


Reality

Unreliable; missing critical pieces of information



TRADITIONAL PROCESS



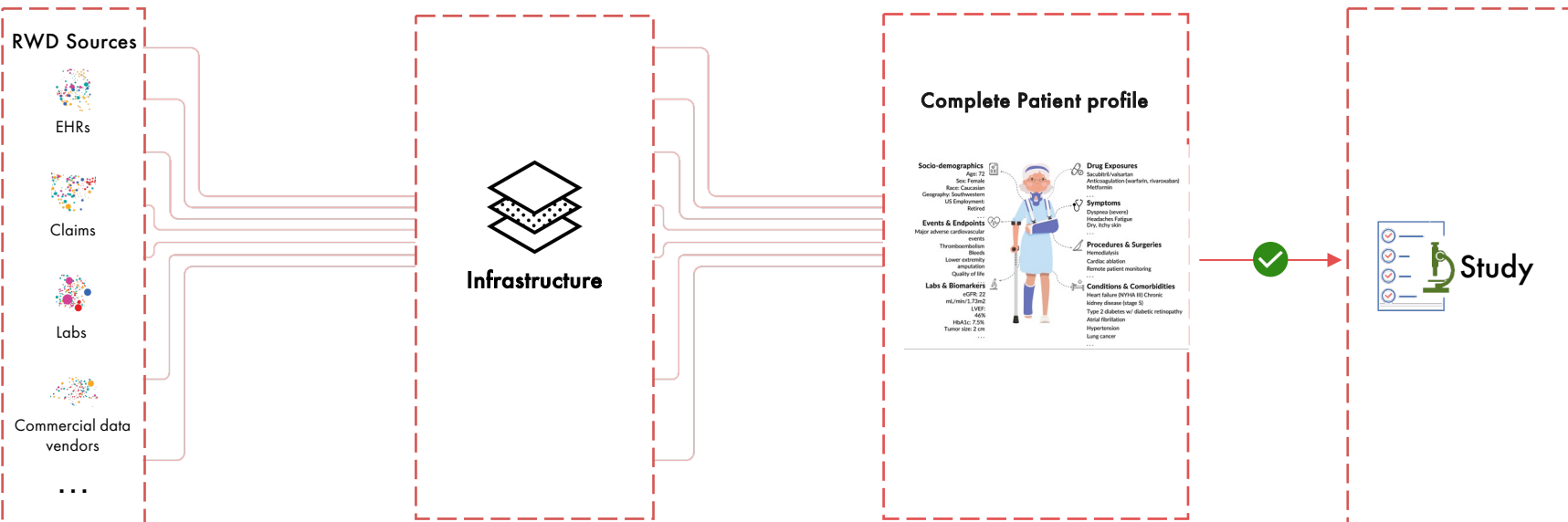
Loss in data transformations



Data quality issues

THE INFRASTRUCTURE SOLUTION

Data Preparation

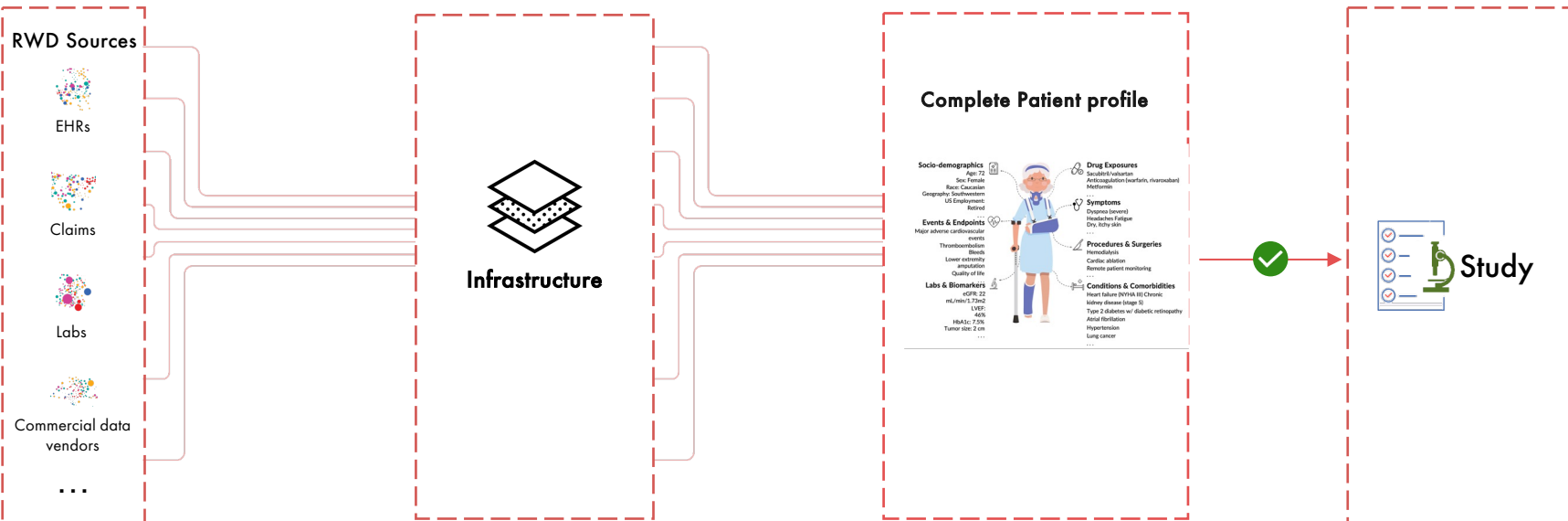


THE INFRASTRUCTURE SOLUTION

1

Software

Data Preparation



THE INFRASTRUCTURE SOLUTION

1

Software

2

Integration of complex and diverse
RWD inputs

Data Preparation

Hospitals
...

EHRs
...

Vendors
...

Site implementations
...

Geographies
...

Languages
...



Complete Patient profile

Socio-demographics
Age, Sex, Ethnicity
Height, Weight
Demographics, Socioeconomic
Status, Insurance
History

Events & Endpoints
Major adverse cardiovascular
events
Thromboembolism
Bleeds
Liver enzymes
amplification
Biomarkers

Lab & Biomarkers
CPT2, CPT3
eGFR, Creatinine, Cholesterol
Lipids
HbA1c, HbC, Iron
Tumor size, Tumor

Drug Exposures
Prescription medications, Over-the-counter
Medications

Symptoms
Dyspnea, Cough
Headache, Fatigue
Dry, Itchy skin

Procedures & Surgeries
Hemodialysis
Pacemaker, Stent
Breast cancer resection

Conditions & Comorbidities
Heart failure, Diabetes, COPD, Cancer
Hypertension, Stroke, ID
Type 2 Diabetes, Acute coronary syndrome,
Atrial fibrillation,
Hypertension,
Lung cancer



THE INFRASTRUCTURE SOLUTION

1

Software

2

Integration of complex and diverse
RWD inputs

3

Multiplicity of research requirements
for analysis data outputs

Data Preparation

Hospitals
...

EHRs
...

Vendors
...

Site implementations
...

Geographies
...

Languages
...



Infrastructure

CDMs
...

Study teams
...

Therapeutic areas
...

Studies
...

Analysis datasets
...

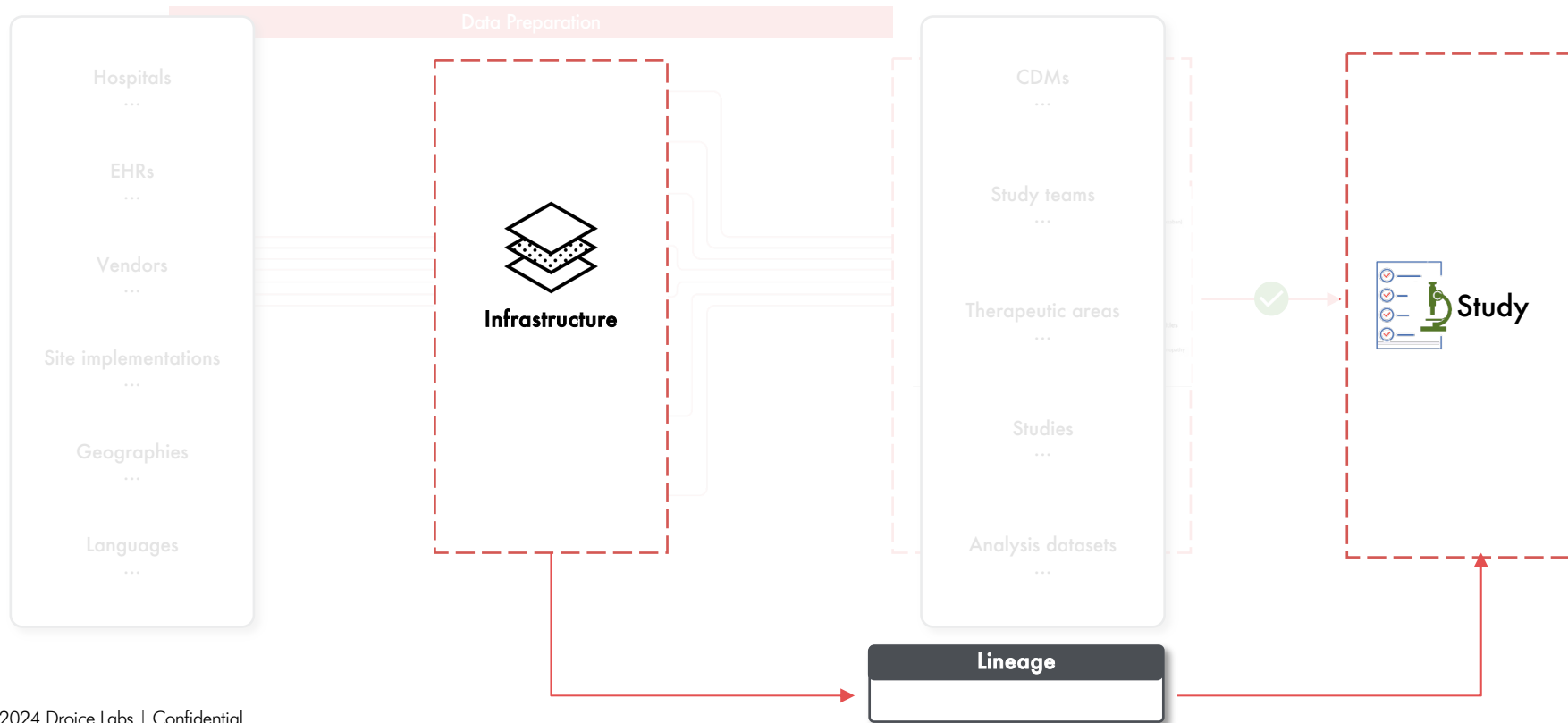


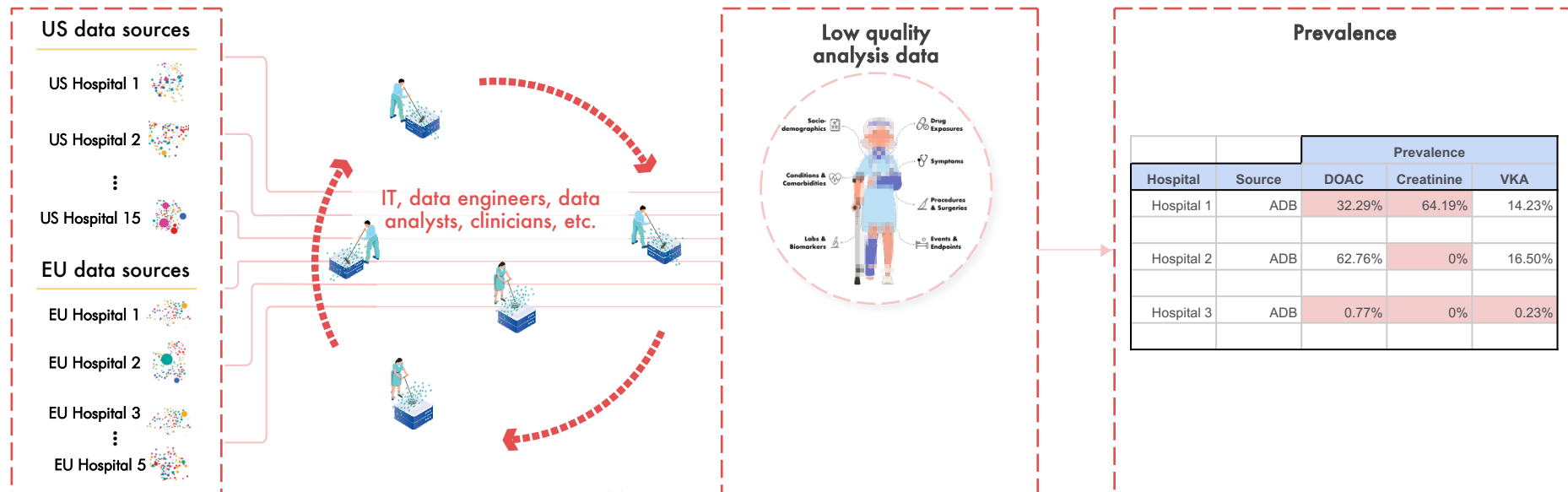
Study

THE INFRASTRUCTURE SOLUTION



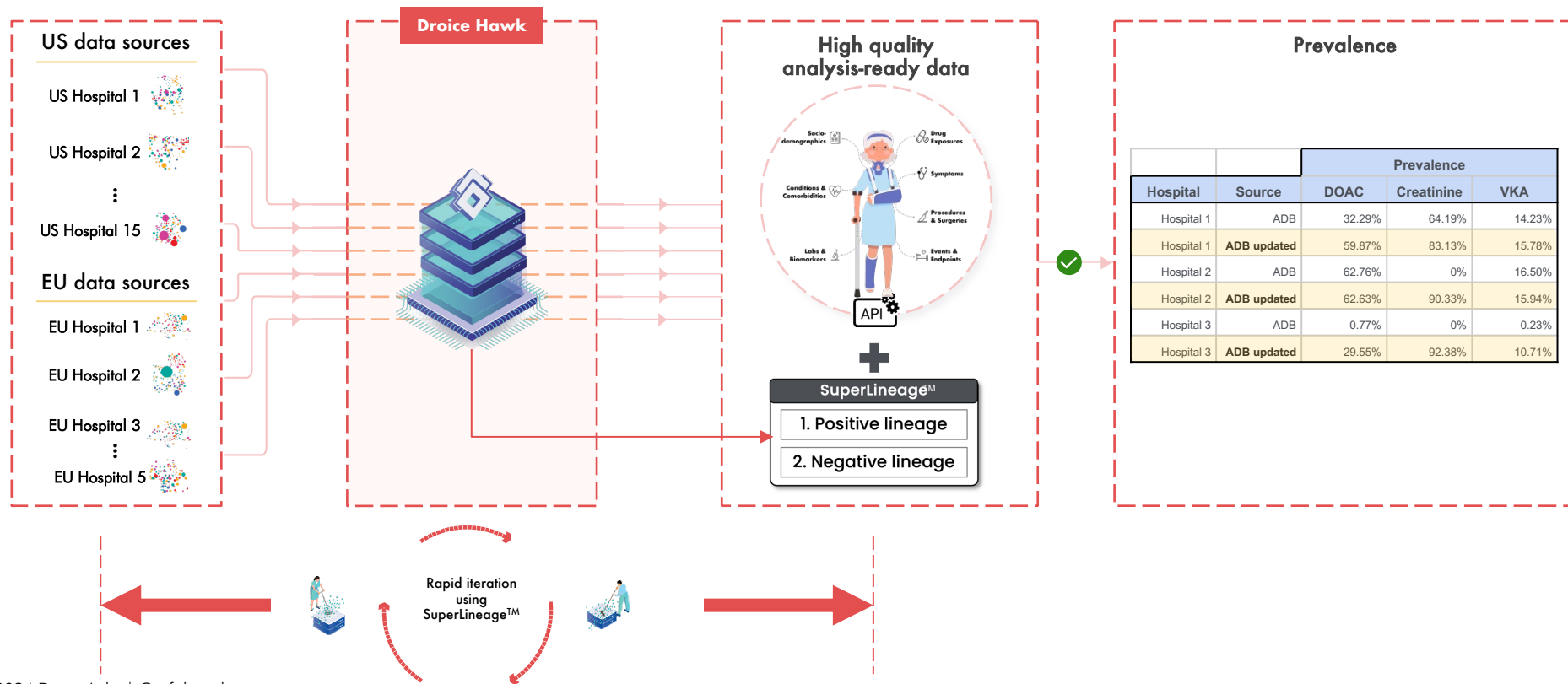
- 1 Software
- 2 Integration of complex and diverse RWD inputs
- 3 Multiplicity of research requirements for analysis data outputs
- 4 Auditability and measurable data quality



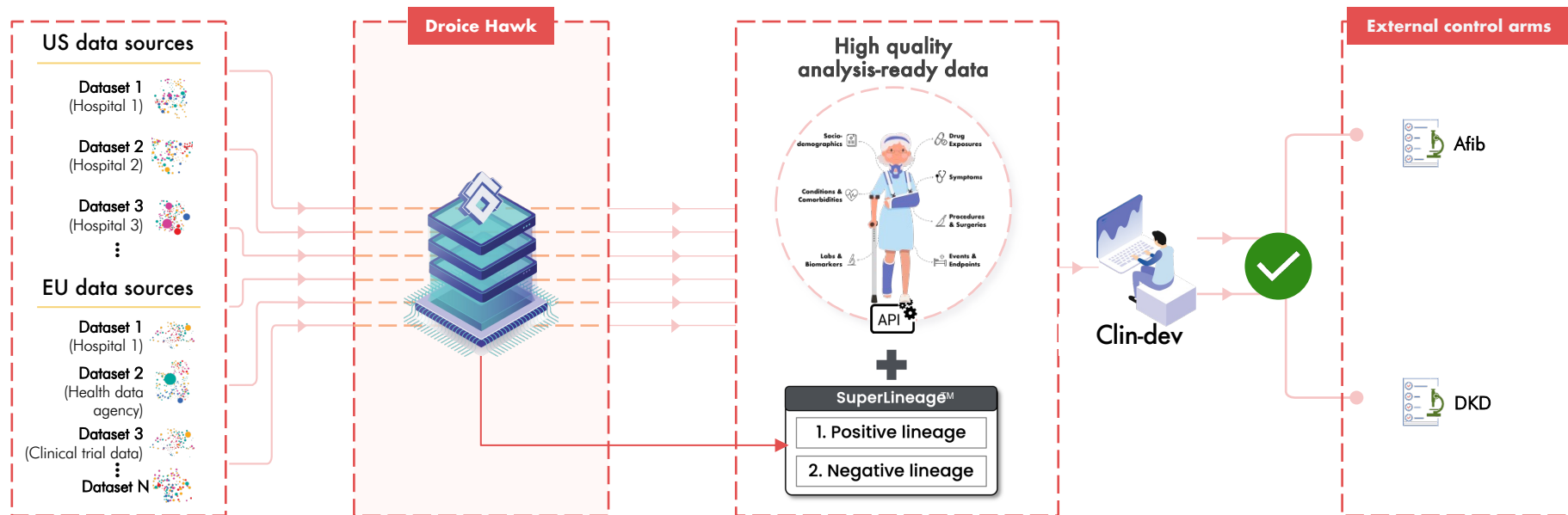


Converting RWD to a CDM:

- Resource intensive process
- Highly unstructured



ENTERPRISE INFRASTRUCTURE FOR HIGH-QUALITY RWD & ECA



Scalable



Reproducible



Auditable

Thank you

Jussi Leinonen, Bayer

jussi.leinonen@bayer.com

Mayur Saxena, Droice Labs

mayur@droicelabs.com