



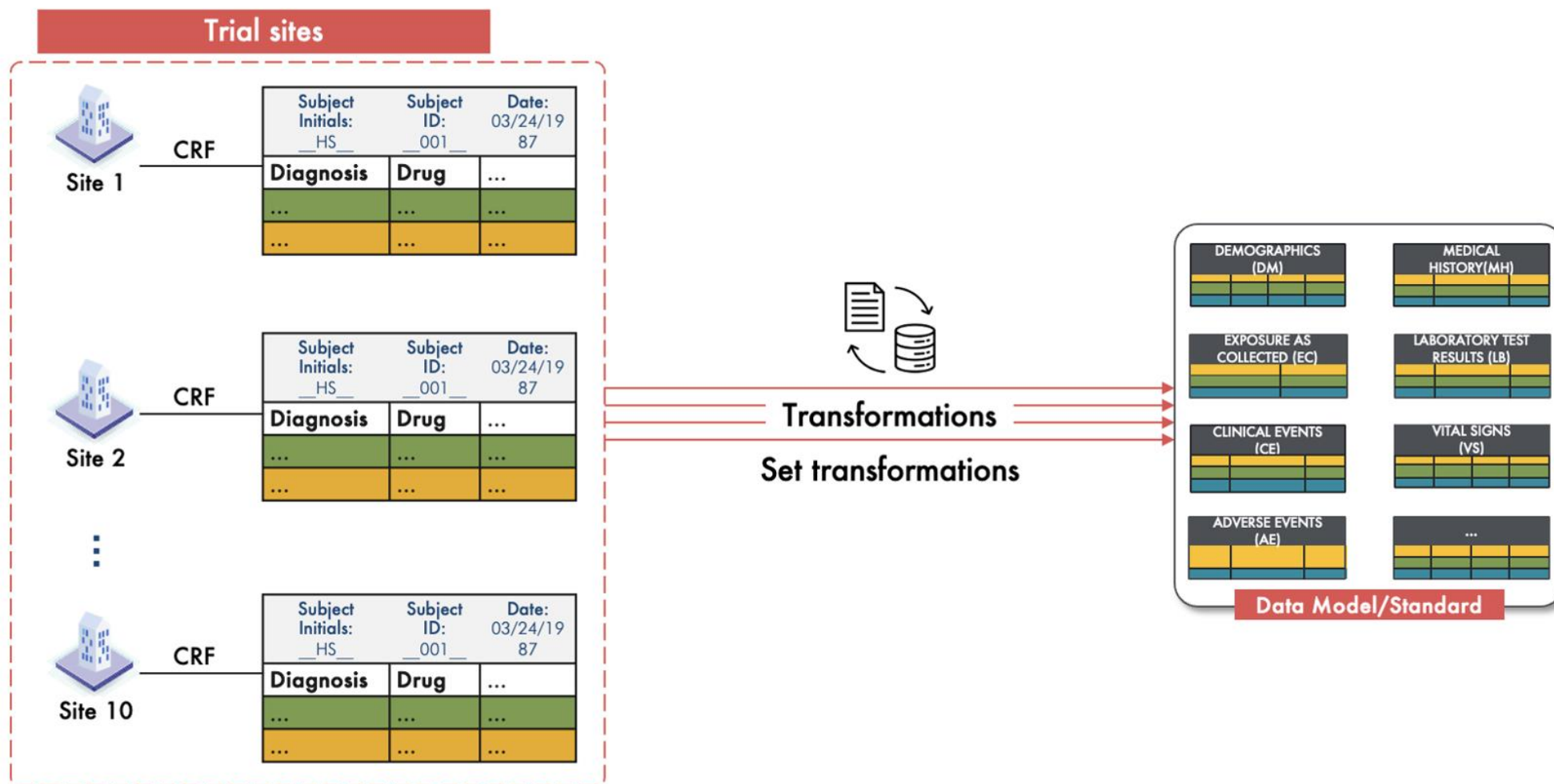
Solving real-world data (RWD) reliability challenges for use in regulatory decision-making

Tasha Nagamine, MS, Droice Labs
tasha@droicelabs.com

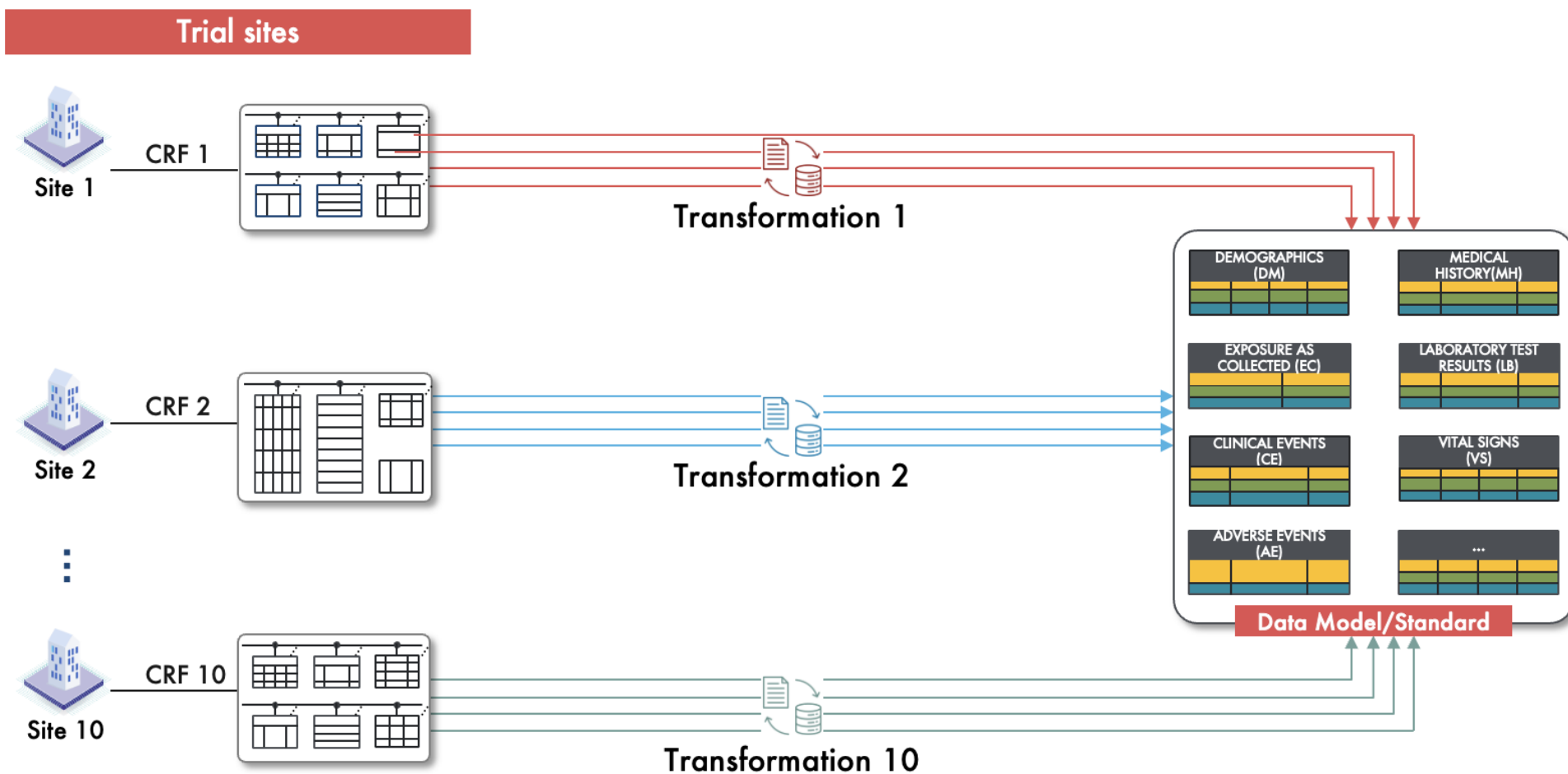
Mayur Saxena, Ph.D., Droice Labs
mayur@droicelabs.com



RCT DATA JOURNEY

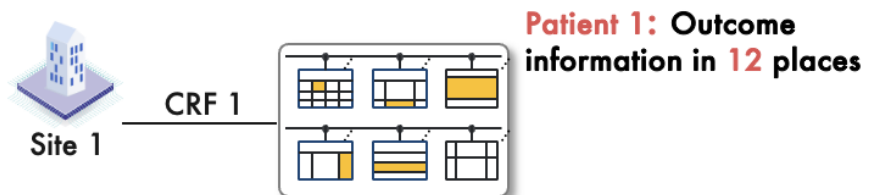


RCT DATA JOURNEY: STRUCTURE VARIATION

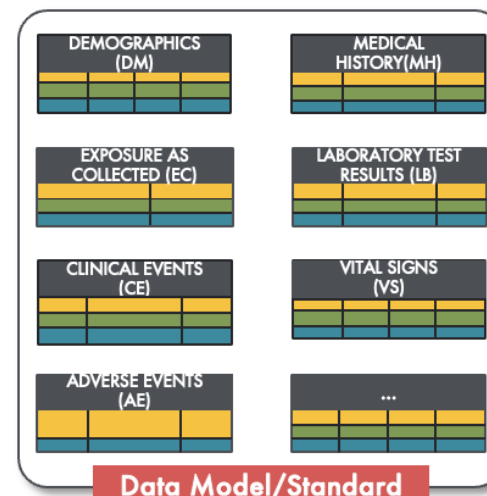


RCT DATA JOURNEY: CONTENT VARIATION

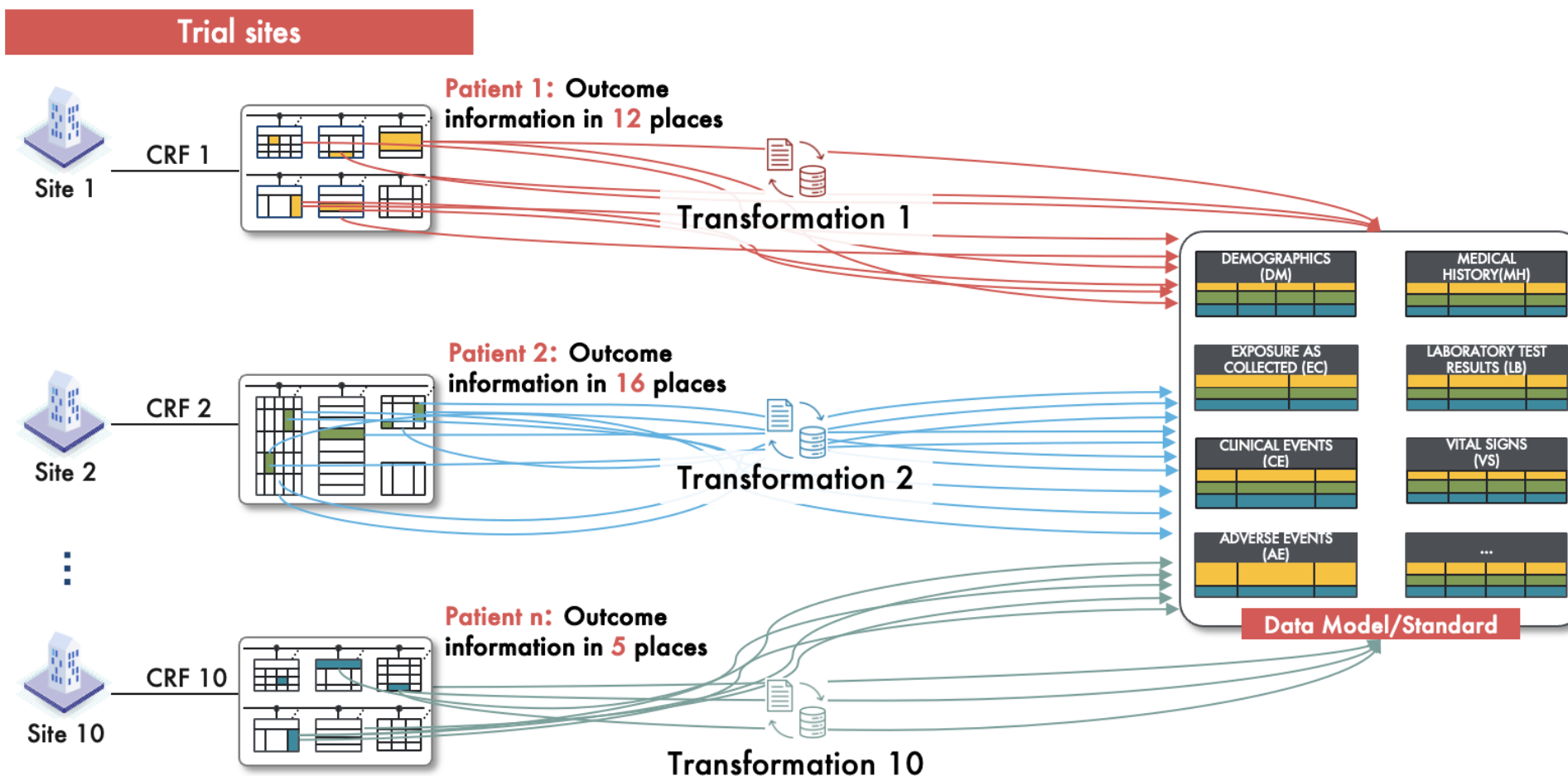
Trial sites



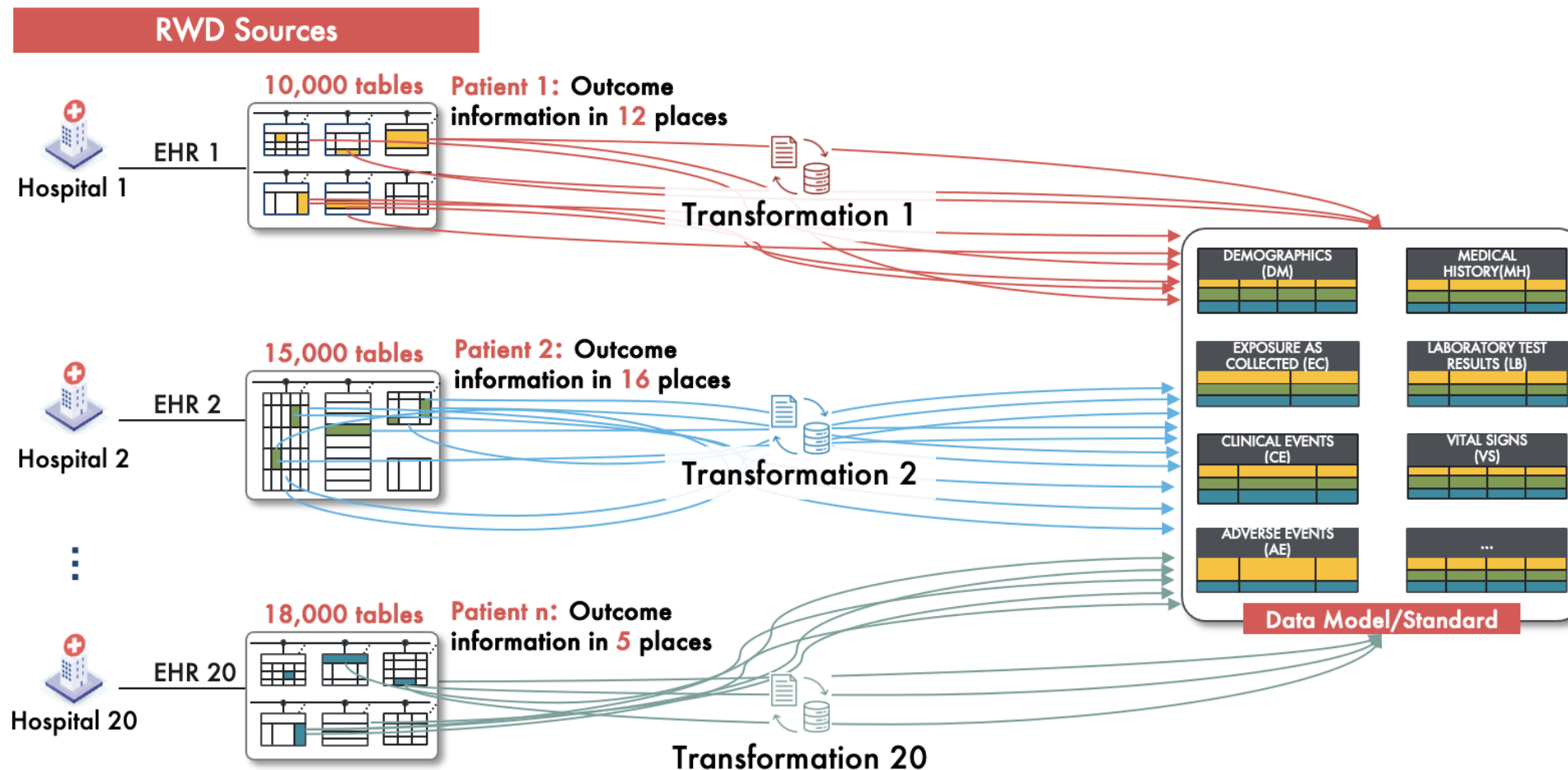
⋮



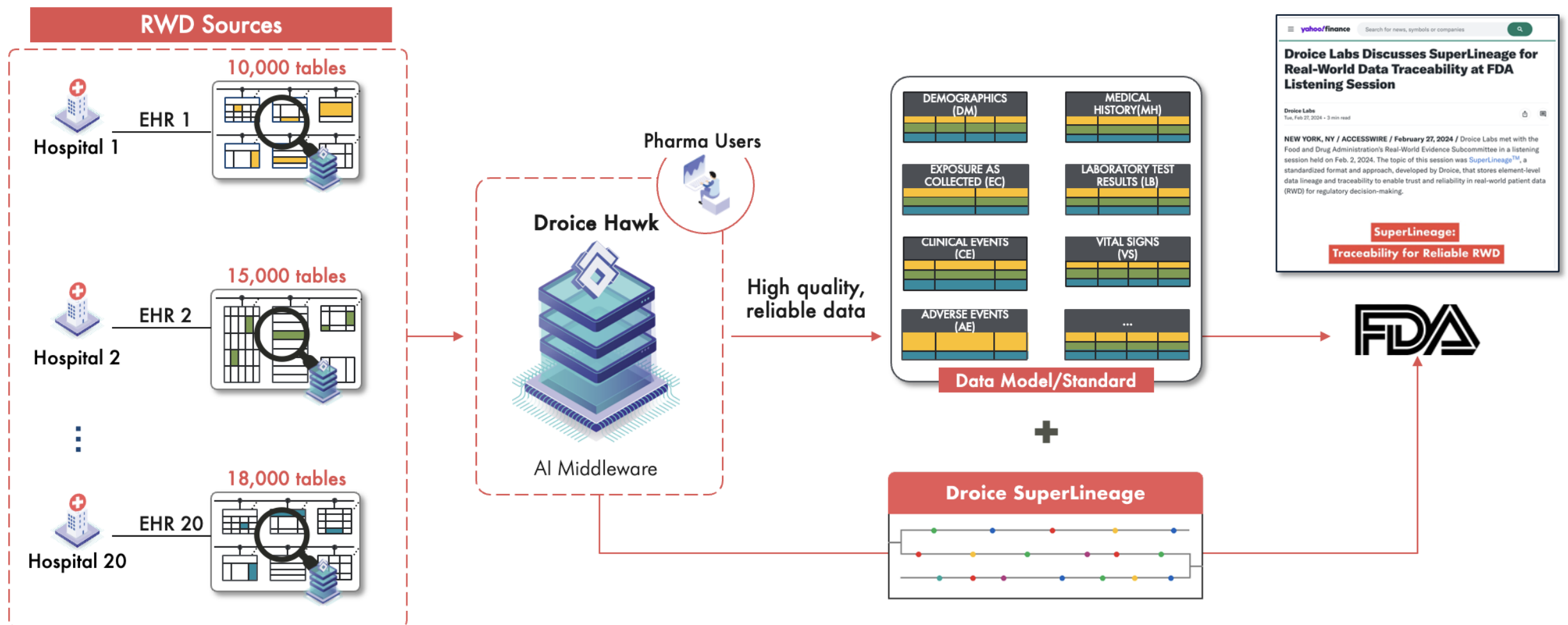
RCT DATA JOURNEY: CONTENT VARIATION



RWD: MASSIVE STRUCTURE AND CONTENT VARIATION



AI APPROACH



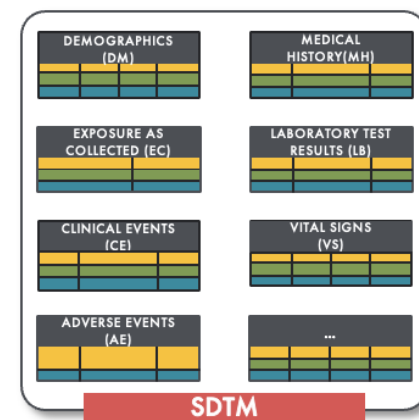
Building the global standard for RWD traceability



Droice Hawk



AI Middleware

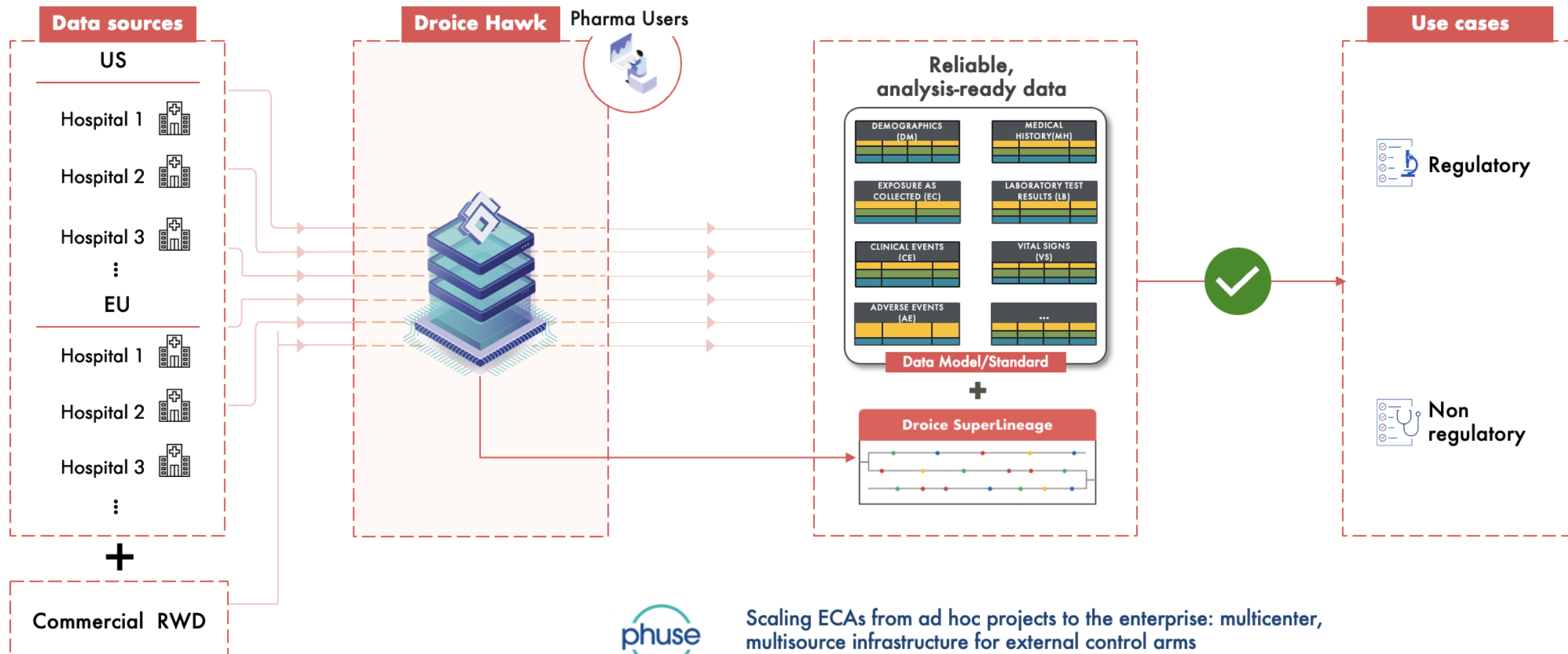


- Lossless representation of source data
- Standardized data structure for lineage across all sources



Transforming RWD for Regulatory Submissions: How to Use SDTM for RWD
Tasha Nagamine, Droice Labs & Sam Hume, CDISC. 2024.

AI MIDDLEWARE FOR RWD



Scaling ECAs from ad hoc projects to the enterprise: multicenter, multisource infrastructure for external control arms
Jussi Leinonen, Bayer & Mayur Saxena, Droice Labs. 2024.



Droice Labs

Thank you
