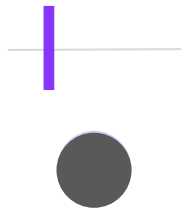




Reproducible RWE at Scale

From Fragmented Data to Regulatory-Ready Insight

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Current State - Where Most Guidance Stops

Manual & Disconnected

- Which data standards to use?
- Which governance checkpoints to follow?
- What pitfalls to avoid?
- How to document decisions?

Result: Reproducibility remains an afterthought



Ideal State - What Infrastructure Must Do

Unified & Automated

- Immutable, versioned data snapshots
- Container-locked computational environments
- Version-controlled, pre-specified cohort logic
- Automated audit trails as a workflow output

Result: Compliance becomes structural, not a separate effort

Key Questions to Consider

IS THE DATA FIT FOR PURPOSE?



OMOP-standardized vocabularies + immutable dataset snapshots with data quality profiling built in as a first-class pipeline step

IS THE STUDY DESIGN ADEQUATE?



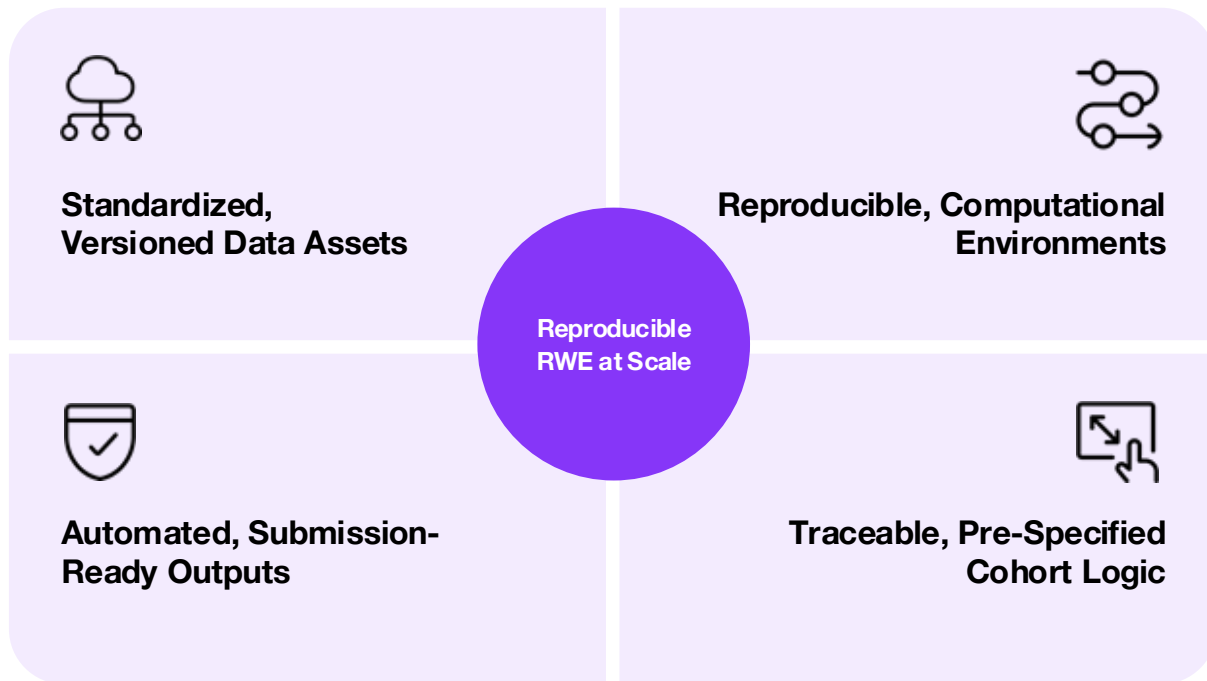
Version-controlled, pre-specified cohort definitions reviewed before the analysis runs — same rigor as SAP development

DOES THE ANALYSIS MEET REGULATORY REQUIREMENTS?



Controlled environments + complete, automatic audit trail from raw data to output

Four Corresponding Infrastructure Considerations



Making It All Stick - Governance

Treat cohort definitions as analytical code

Version-controlled, peer-reviewed, pre-specified before the analysis runs

Extend SAS environment discipline to full toolstack

R, Python, SQL-based cohort tools need same environment control as validated SAS environments

Identify governance champions early

Pick people who translate regulatory requirements into engineering norms and hold the line when timelines compress

Start where regulatory risk / reward is clearest

Label expansions, rare diseases, post-market surveillance: strongest precedent, best place to build and validate infrastructure



Build now, before the regulatory question arrives

Organizations best positioned for the FDA's expanding RWE program are those building this infrastructure today



Thank you !