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Summary

Problem statement: How might we establish methodologies to validate the reliability and relevance of Real-World Data (RWD) when used in clinical trial submissions, particularly as a substitute for placebo in control arms?

Our objective: Our objective is to ensure that this healthcare data is representative of the population, curated ethically, and rigorously analyzed throughout the processes of collection, analysis, and submission.

Key Takeaway: Cryptographic certificates present a comprehensive framework for validating data authenticity and enabling traceability across systems, essential for secure and efficient data governance in diverse applications.

Working Groups



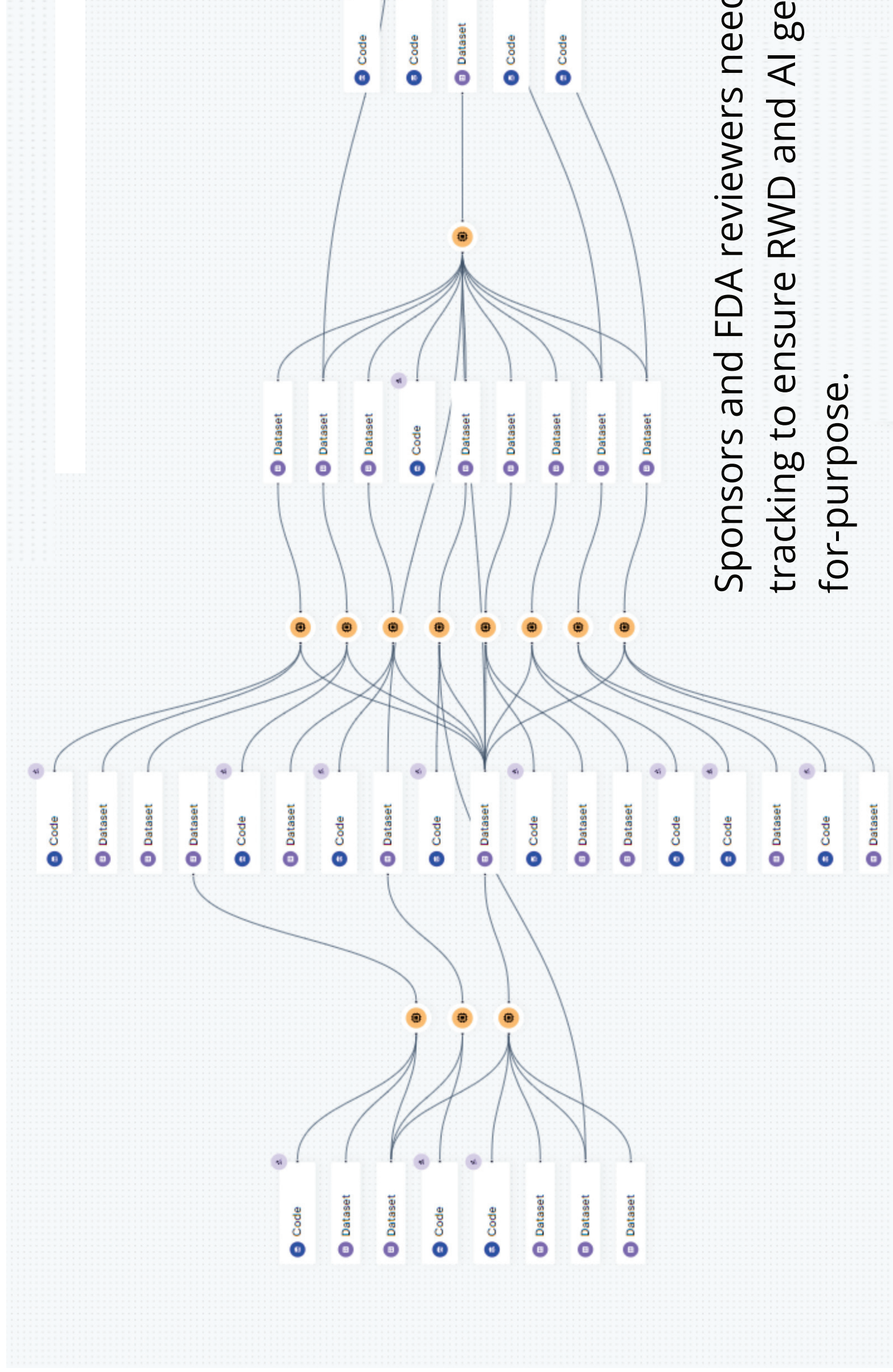
Collaborations with individuals through working groups at PHUSE, Transcelerate, Vulcan, CDISC that contain sponsors, data vendors, CROs and FDA employees have provided input on RWD control arms, potentially replacing placebo groups with predictive digital twins. The output of the collaboration is a functional prototype to demonstrate the proof of control over RWE.

Concept

An Integrity Fabric provides sponsors, data providers and EHR vendors ability to prove data and process integrity to regulators, ensuring fit-for-purpose RWE submissions.

The quality score of real world data has cryptographic integrity through mathematical proof. Digital twins and RWE integrated submissions have end-to-end verified trust for use as a control/placebo replacement.

Full Lineage & Traceability



Full-Transparency Needed

A unified and real-time view of your data across the entire workflow is needed where the data or any AI models are deployed.

Sponsors and FDA reviewers need modern tools that do not require manual tracking to ensure RWD and AI generated transformations are accurate and fit-for-purpose.

Governing RWE Prototype

Licensing: Healthcare system licenses Real-World Data (RWD) population dataset to a data provider.

Exporting RWD: Healthcare system exports RWD in FHIR HL7 standard from their EHR.

Secure Data Transfer: Encrypted transfer of RWD from healthcare system to data provider.

Anonymization: Data provider anonymizes the population dataset.

Cohort Dataset Creation: For clinical trial sponsor use.

Secure Cohort Transfer: Encrypted transfer of cohort dataset to sponsor.

Quality Review & Imputation: Conducted by sponsor.

Data Conversion: Mapping HL7 FHIR to CDISC SDTM

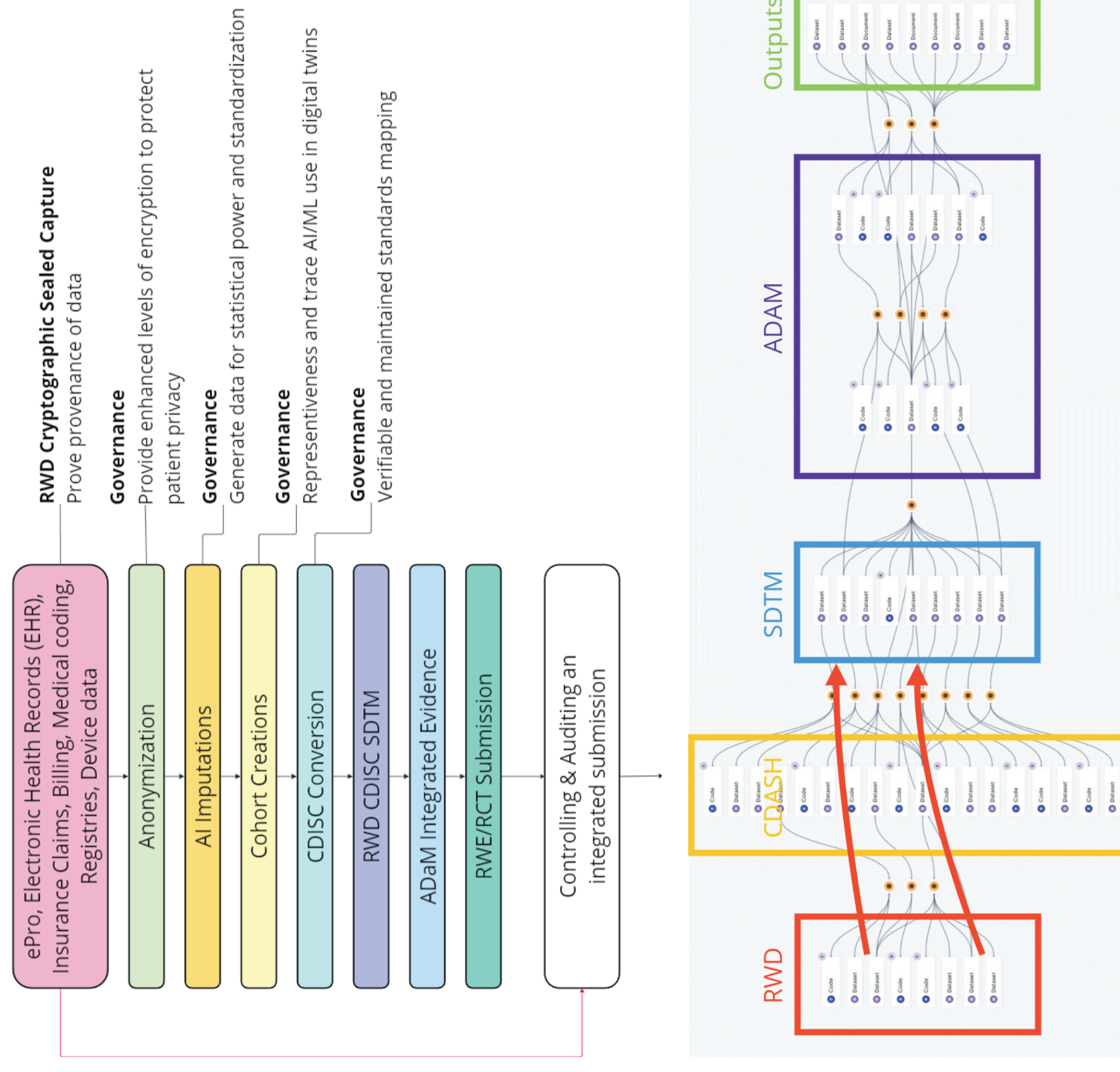
for regulatory submission via OMOP

Governance Adherence: data licensing and use, cohort representativeness, anonymization and mapping

Traceability & Compliance: Regulatory

reviewer/auditor verifies data quality and policy adherence

RWD Bypassing EDC



Cryptographic Certificates: Ensuring Data Authenticity & Interoperability

The Concept: Cryptographic hashing and signing allow data contributors to create tamper-proof attestations on the origin of data. This is done by deriving a unique digital fingerprint and signing it with a unique digital identification. This enables third-party verification without the need to copy or transfer the original authentic data.

The Process: The approach includes data ingestion, indexing, registration, and attestation. This process is fully automated and scalable, optimizing efficiency for handling large datasets.

The Output: This generates a certificate—a compact, portable, standardized output regardless of the original data size. Such standardization ensures integrity of data is preserved across systems, improving workflow integration.

The Advantages: Cryptographic certificates enhance security, transparency, and interoperability, building trust in real-world data sources:

- **Authenticity:** Provides verifiable proof of data authenticity.
- **Governance:** Allows all parties to attest to their role in a workflow and be accountable to policies and standards.
- **Interoperability:** Establishes a compatible data layer that enhances trust across different workflow stages.
- **Efficiency:** Ensures a streamlined and scalable process, ideal for large and diverse datasets.
- **Versatility:** Adapts to various data forms, including individual data points, files, programs, AI models, and entire systems.

Quality Controls

