



SPA MDR CDR SCE

Blockchain for Secure and Transparent Clinical Trials

Data Handling & Data Engineering | DH03

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The Clinical Data
Science Conference

EU 2025

16–19 November
CCH – Congress Center Hamburg



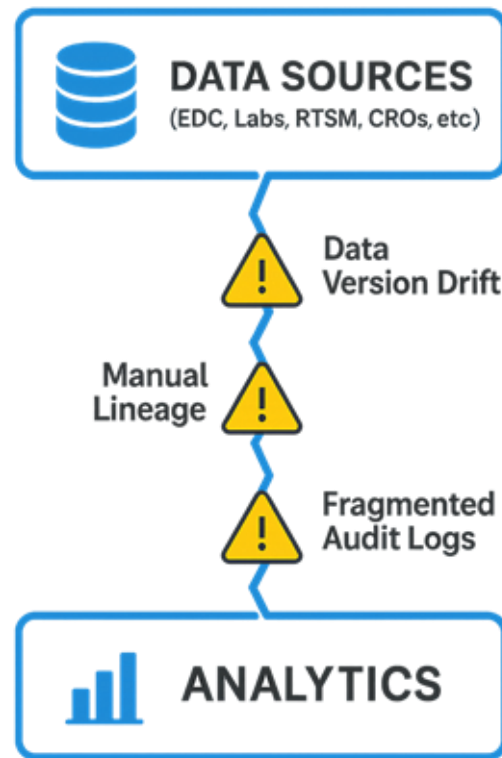
Agenda

- Why integrity matters more than ever
- Blockchain 101
- System-Driven Audit & Traceability Model
- Technical foundations
- Challenges
- Demonstration
- Benefits
- Key takeaways



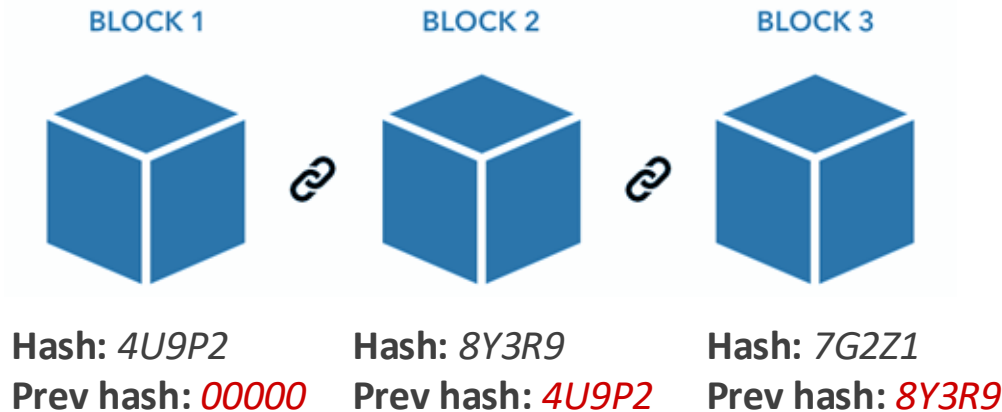
Why Integrity Matters More Than Ever

- Data fragmented across EDC, lab, and RWE systems
- Manual lineage reconstruction introduces risk
- Audit logs often editable or incomplete
- ICH E6(R3) and CSA now demand system-driven traceability



Blockchain in 90 Seconds

- Each block references the hash of the previous
- Any change breaks the cryptographic chain
- Consensus ensures shared agreement
- Integrity, not decentralization, is the takeaway



What Blockchain Promised

- Immutable ledger of every transaction
- Cryptographic fingerprints prevent tampering
- Shared verification across participants
- Trust becomes mathematical, not procedural



Immutable
Ledger



Shared
Trust

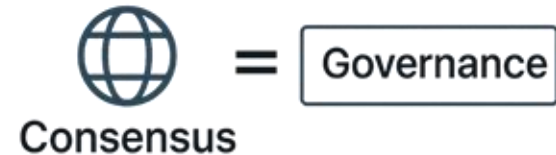
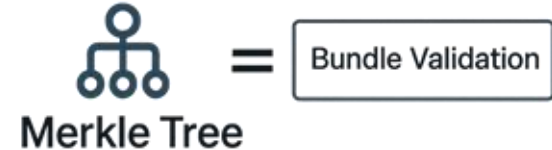
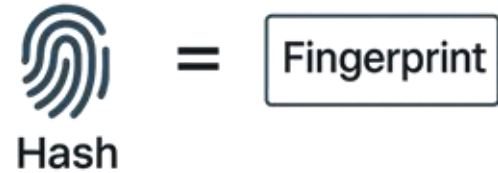


Cryptographic
Verification



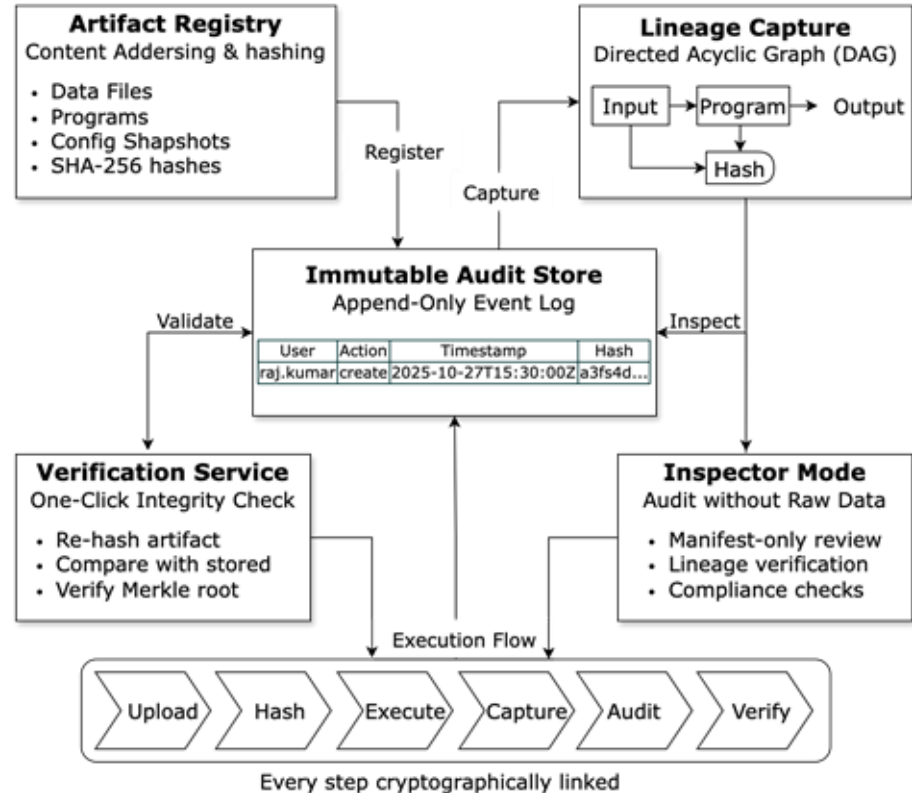
Rethinking Blockchain for Statistical Environments

- Append-only → Immutable audit logs
- Cryptographic hashes → Dataset and code fingerprints
- Merkle tree → Run-level bundle validation
- Consensus → Controlled internal governance



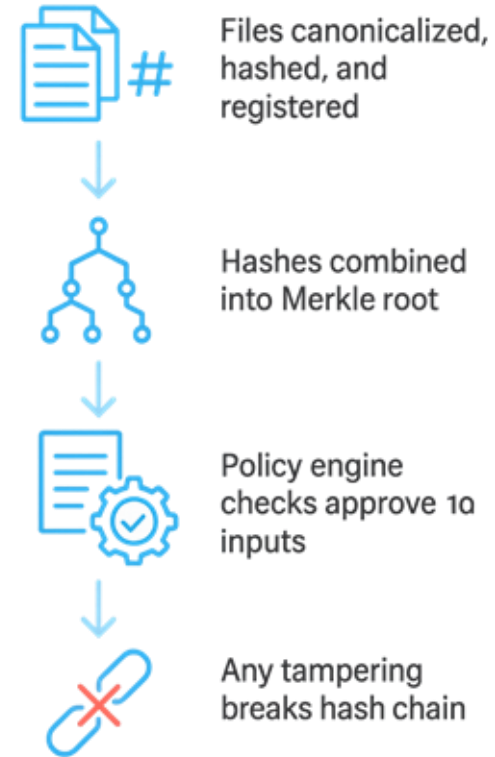
System-Driven Audit & Traceability Model (S-ATM)

- Version-controlled data and code with SHA-256 hashes
- Lineage registry for every run
- Merkle validation ensures bundle integrity
- Immutable audit dashboard for governance

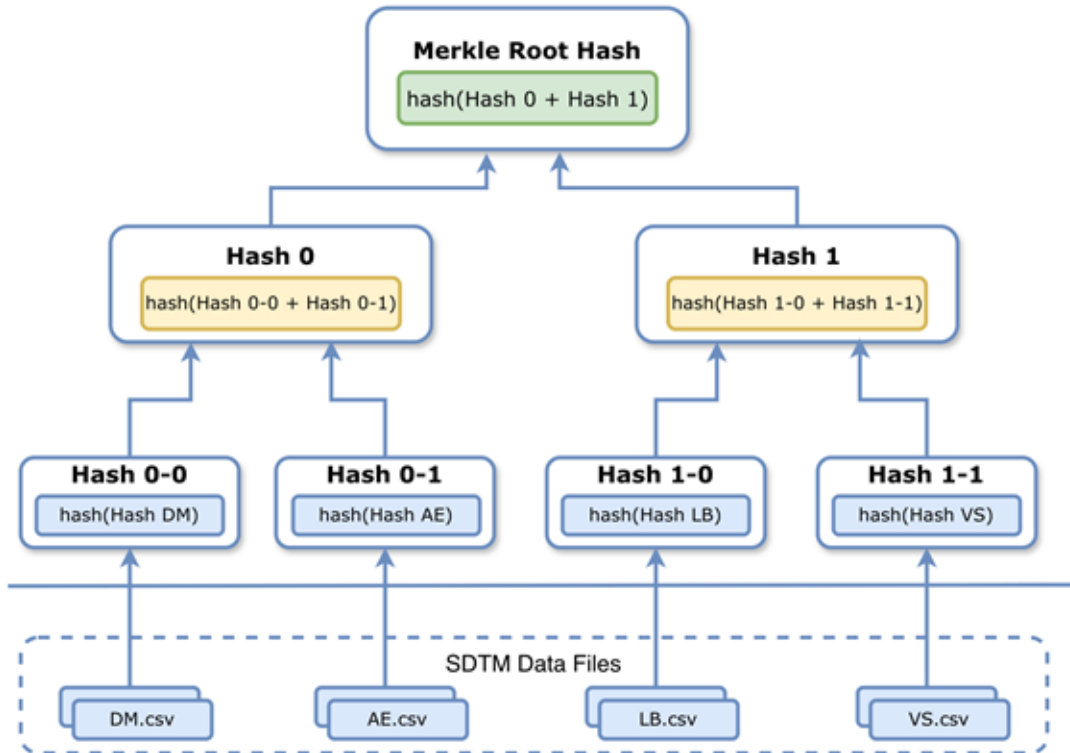


How It Works Technically

- Files canonicalized, hashed, and registered
- Hashes combined into Merkle root
- Policy engine checks approved inputs
- Any tampering breaks hash chain



The Practical Challenge: Hashing

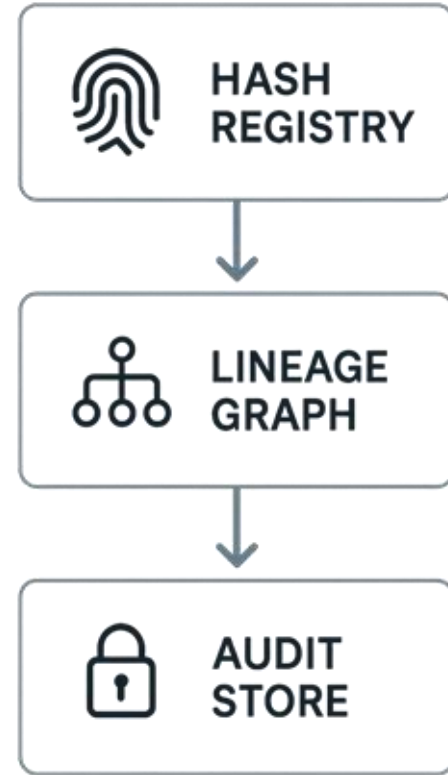


- Linear hashing is slow on GB-scale files
- Parallelization is key for analytics
- Merkle trees hash segments independently
- Only changed branches update root hash



What Happens Under the Hood

- Full-file hashing grows linearly with data volume
- Parallelizing across large SDTM/ADaM files is difficult
- Merkle trees enable segmented hashing and aggregation
- Changes in one segment update only part of the root hash



**Too Much
Talking!**



Too Many

Slides Presented



Technical Terms



Audience Energy



Glimpse Traceability & Versioning in Action

dm_sas7bdat.sas has 3 versions

dm_sas7bdat.sas has 3 versions

Modified (UTC)

28 Oct 2025 09:38:07 PM

28 Oct 2025 09:37:47 PM

04 Sep 2025 03:40:36 PM

Actions

View

Compare

Set current Version



View

Compare

Set current Version



View

Compare

Set current Version



Modified (UTC)

28 Oct 2025 09:38:07 PM

28 Oct 2025 09:37:47 PM

04 Sep 2025 03:40:36 PM

By

raj.kumar

raj.kumar

sivaganesh.r+1

raj.kumar

raj.kumar

sivaganesh.r+1

Actions

View

Compare

Set current Version



View

Compare

Set current Version



View

Compare

Set current Version



File versions

Search

Filter

Show

#

Size

Comment

Added headers

#

Size

3

12 bytes

2

4 bytes

1

734 bytes



Benefits



Automatic provenance and reproducibility



SCEs embed that trust automatically



Reduced compliance overhead



Inspection readiness by design

Key Takeaways



Blockchain
taught trust



SCEs
embed trust



System-
driven
traceability

- Blockchain taught us cryptographic trust
- SCEs embed that trust automatically
- Traceability must be system-driven
- Immutability enables reproducibility



Thank You!



Questions?

Contact



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DSW



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