



Single Day Event

From Data to Decisions

Leveraging Human–AI Synergy in Clinical Trial

Raj Kumar
Sycamore Informatics Inc.





Meet the Speaker

Raj Kumar

Title: Senior Engineer

Organization: Sycamore Informatics Inc.

Raj is a technology leader with over 15 years of experience in software engineering, architecture, and product development. He has led teams in building secure, scalable, and high-performance platforms across regulated industries. Currently a Senior Engineer at Sycamore Informatics, Raj focuses on applying emerging technologies like blockchain to enhance data integrity, compliance, and trust in clinical research.



Agenda

- The Challenge: From Data to Decisions
- Human–AI Collaboration in Action
- Intelligent Data Processing
- Advanced Analytics & Visualization
- Skill Evolution in the AI Era
- System-Driven Audit & Traceability Model
- Demo
- Key Takeaways

The Challenge: From Data to Decisions

Clinical trials generate massive, fragmented data, turning it into actionable insight is the real challenge.

Data volume doubling every 2 years across global studies

Manual review + siloed systems → slow decisions

Regulatory complexity (FDA, EMA, PMDA)

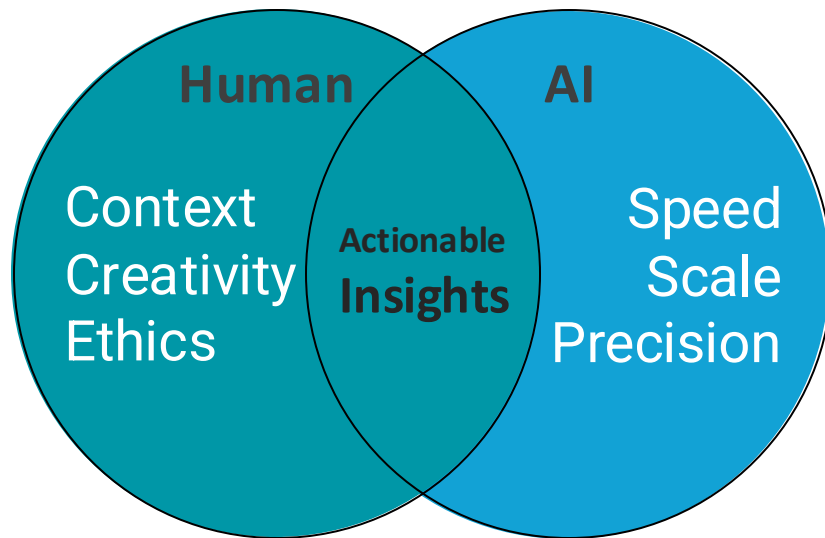
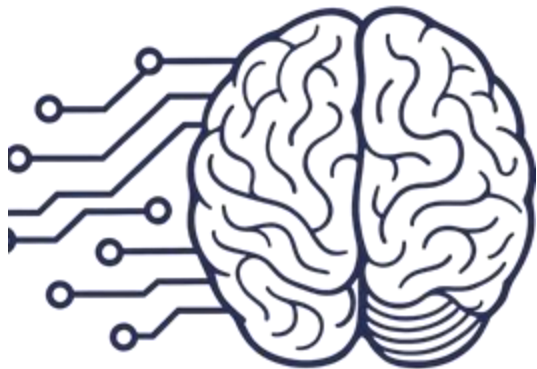
Pressure to maintain accuracy + auditability



Human–AI Collaboration in Action

Humans bring context.
AI brings computation.

Together, they create
INTELLIGENCE



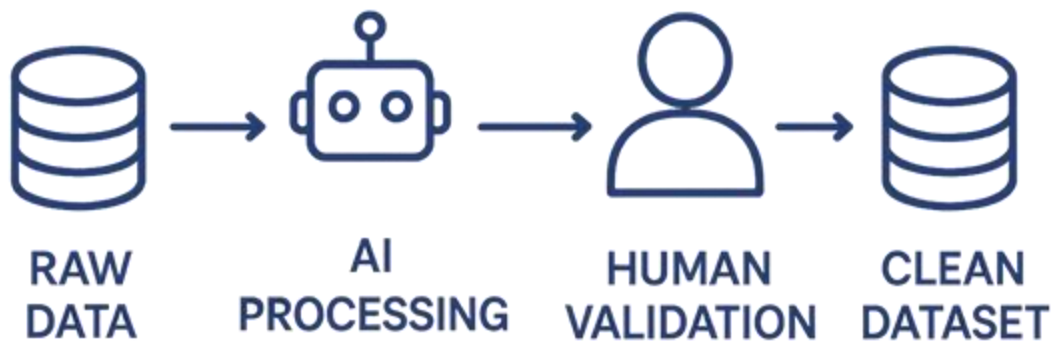
*How do we ensure every AI
output is verifiable?*



Intelligent Data Processing

AI-driven automation guided by human oversight

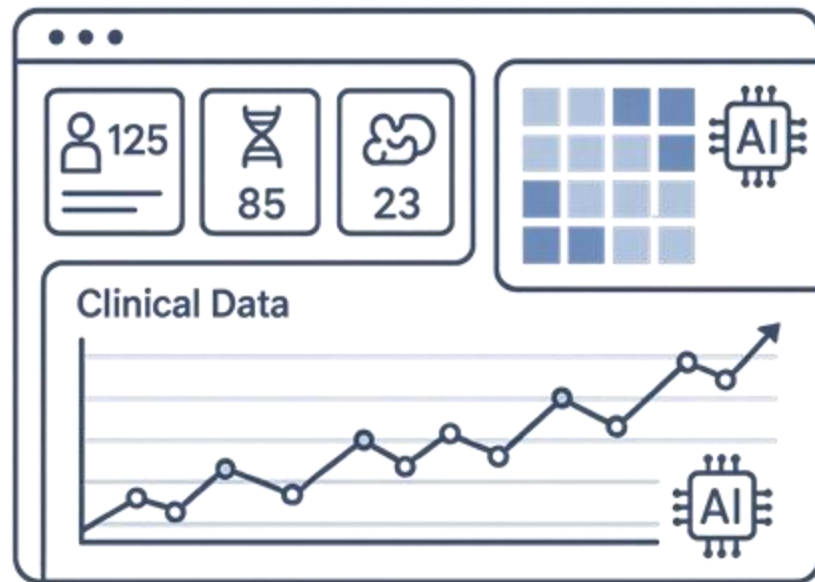
- Data cleaning, mapping, and standardization
- AI anomaly detection and validation
- Human review ensures quality and compliance



Advanced Analytics & Visualization

Turning data into dynamic decisions

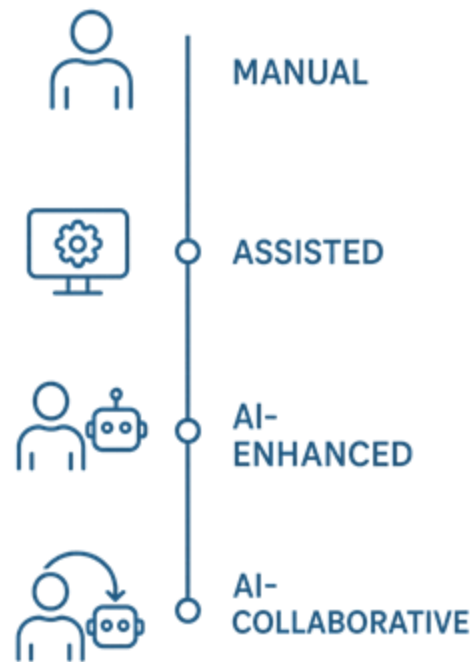
- Predictive analytics for trial optimization
- Interactive dashboards for real-time insight
- AI-driven anomaly and trend detection



Skill Evolution in the AI Era

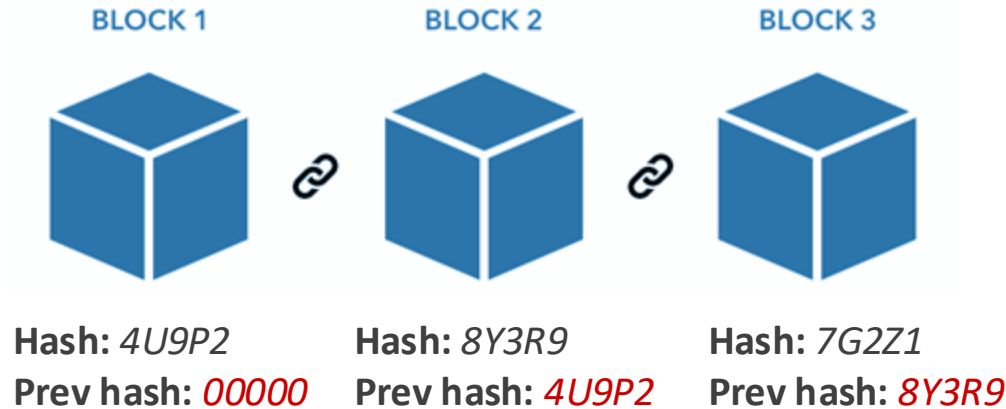
The clinical workforce is evolving into AI collaborators.

- Building AI literacy and data fluency
- Promoting critical validation and ethical awareness
- Cross-functional teamwork in human–AI workflows



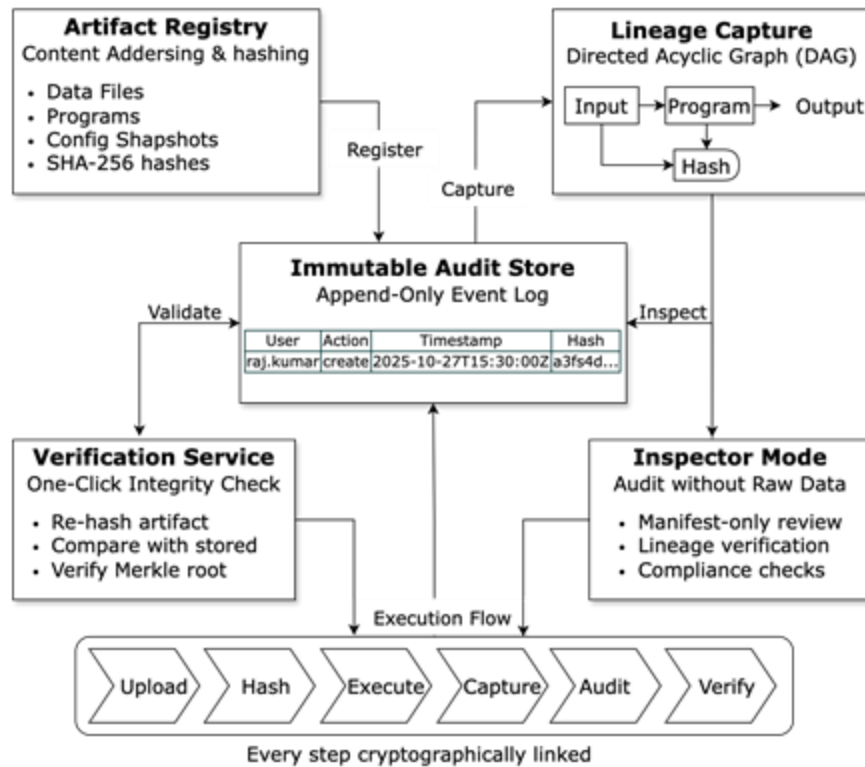
Blockchain in 90 Seconds

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



System-Driven Audit & Traceability Model

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

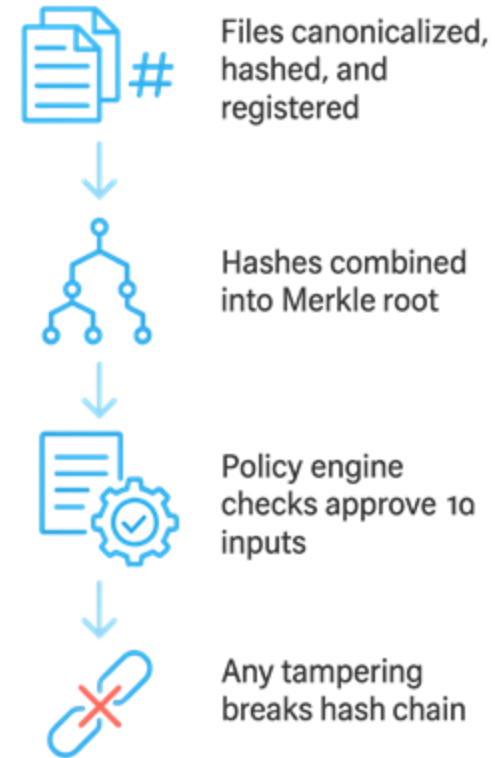


Key Benefits: 100% Traceability | Tamper Detection | Regulatory Compliance | Reproducibility

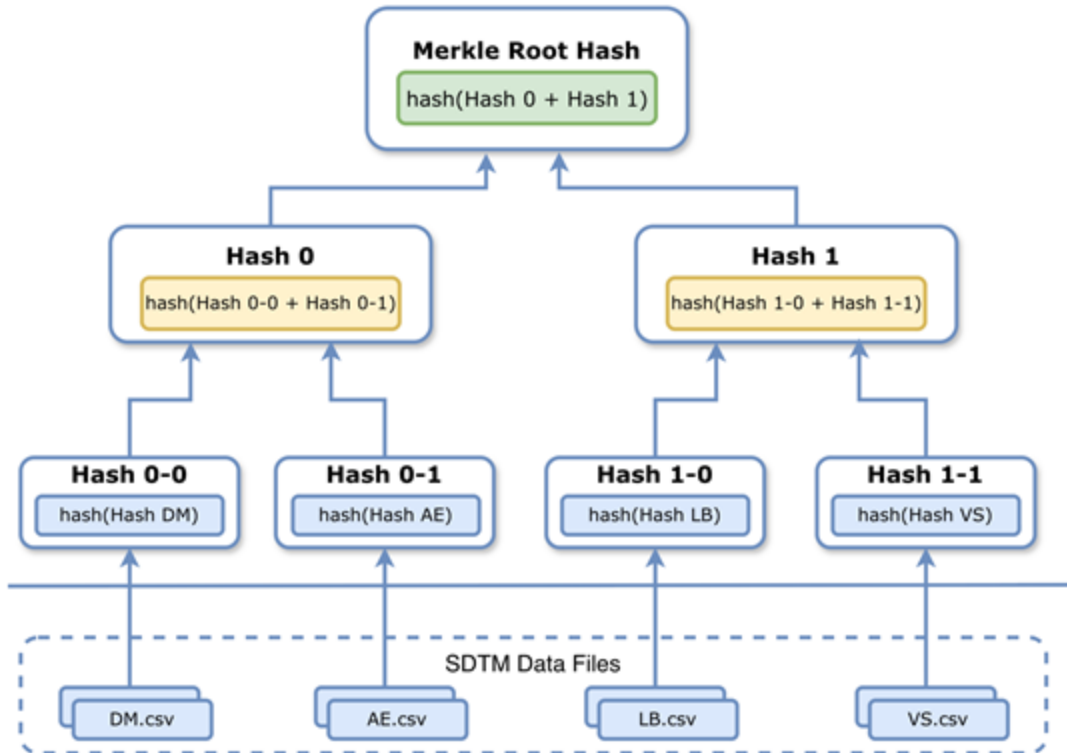


How It Works Technically

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



The Practical Challenge: Hashing

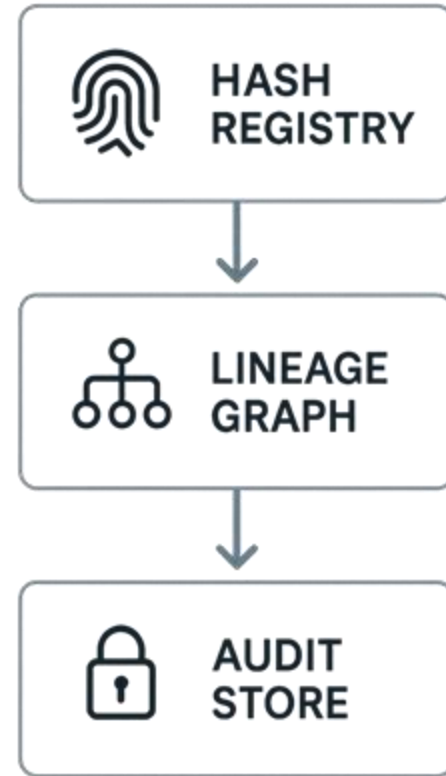


- Linear hashing is slow on GB-scale files
- Parallelization is key for analytics
- Merkle trees hash segments independently
- Only changed branches update root hash



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



File versions

Search

Filter

Show

#	Size	Comment
3	12 bytes	
2	4 bytes	
1	734 bytes	

#	Size
3	12 bytes
2	4 bytes
1	734 bytes

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



Key Takeaways

Collaboration is the new intelligence.

- Human + AI = *Smarter, faster, more reliable decisions.*
- AI amplifies, not replaces — human judgment.
- Sycamore Informatics bridges technology, compliance, and insight.



Thank You!



Join me!
phuse·connect
connect · share · advance

The Clinical Data
Science Conference

EU 2025

16–19 November
CCH – Congress Center Hamburg

Questions?

Contact



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