



## Digital Decentralized Reengineering Clinical Trials with Technology at the Core

**Raj Kumar**, Senior Engineer  
Sycamore Informatics Inc.

# Meet the Speaker

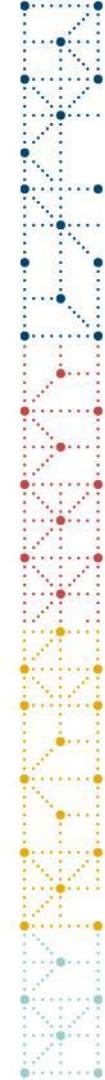
**Raj Kumar**

**Title:** Senior Engineer

**Organization:** Sycamore Informatics Inc.

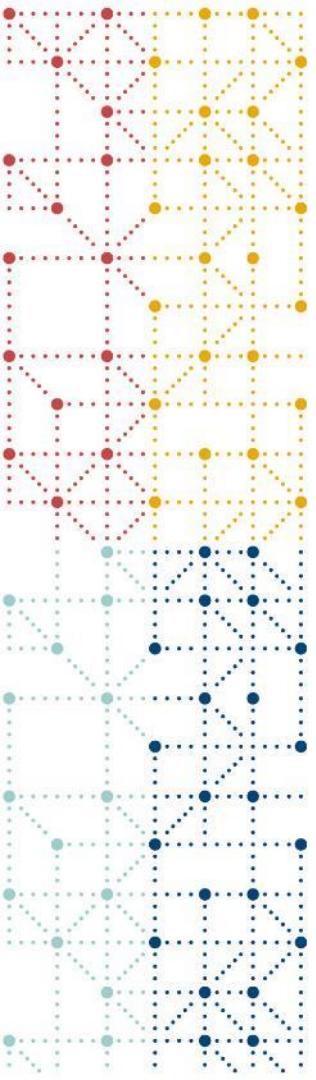


With over 15 years of experience in technology leadership and software engineering, I have served in senior positions including Chief Software Architect, Head of Engineering, and Director of Engineering. Currently, I am working as a Senior Engineer at Sycamore Informatics, bringing both hands-on expertise and strategic leadership to build scalable, secure, and high-performing solutions.



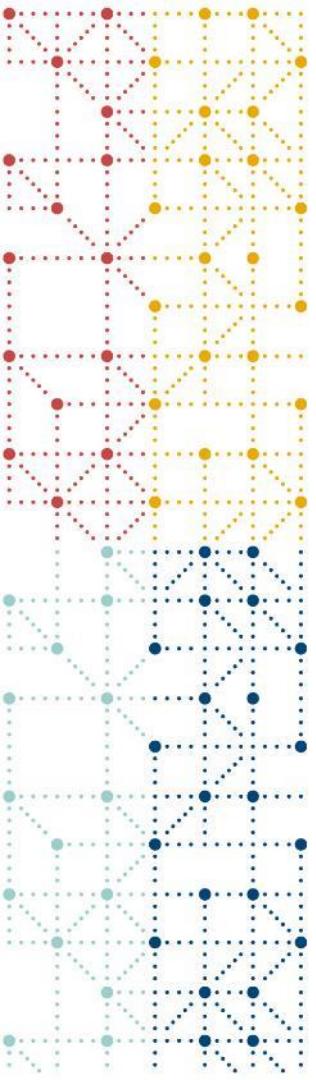
# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC or Sycamore Informatics.*
- *The author has no real or apparent conflicts of interest to report.*



# Agenda

1. Decentralization: What & Why
2. Technical Foundation
3. Challenges & Solutions
4. Future Roadmap

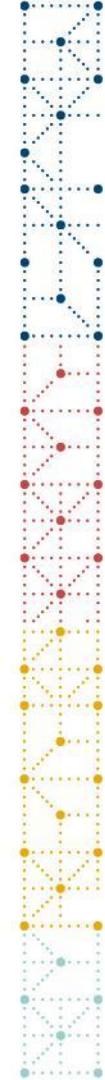


# Decentralization: What & Why

# What's Decentralization in Clinical Trials?

Decentralization means trials no longer revolve around the site — instead, *the participant is at the center*, enabled by digital tools that bring the trial to them.

- **Site → Patient:** Shifts focus from site-centric to participant-centric
- **Remote-first:** Telehealth, wearables, mobile apps, eConsent
- **Continuous data:** Patient-generated health data flows in real time
- **Inclusive by design:** Enables access for diverse & remote populations

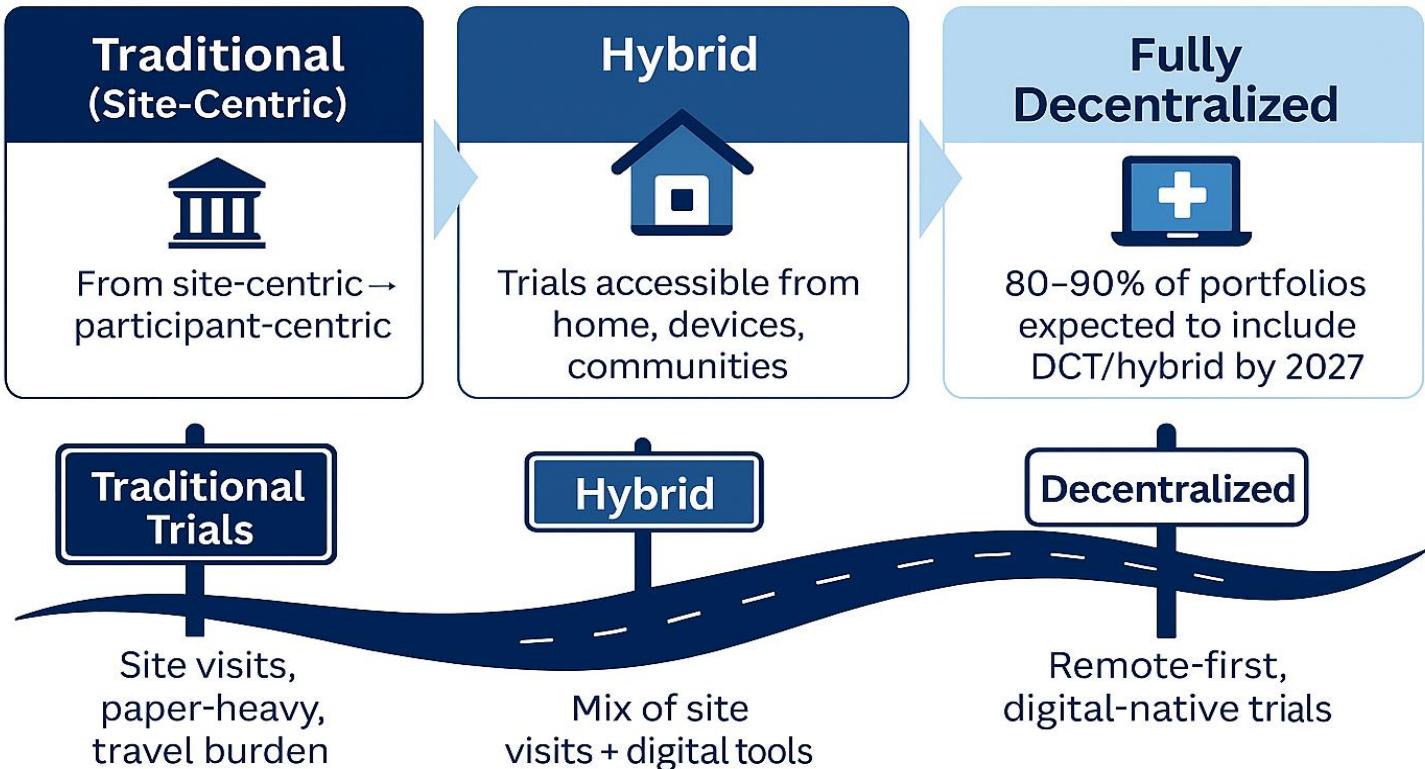


# Why to Shift to Decentralization in Clinical Trials?

**Here's why decentralization is reshaping clinical research:**

- From *site-centric* models to *participant-centric* engagement.
- Trials increasingly accessible from home, mobile, and community settings
  - Rapid adoption of hybrid and decentralized elements across portfolios.
  - Strong sponsor momentum: 80–90% of portfolios expected to include DCT/hybrid by 2027 (Everest Group).
  - Shift driven by patient expectations, cost pressure, and regulatory support.

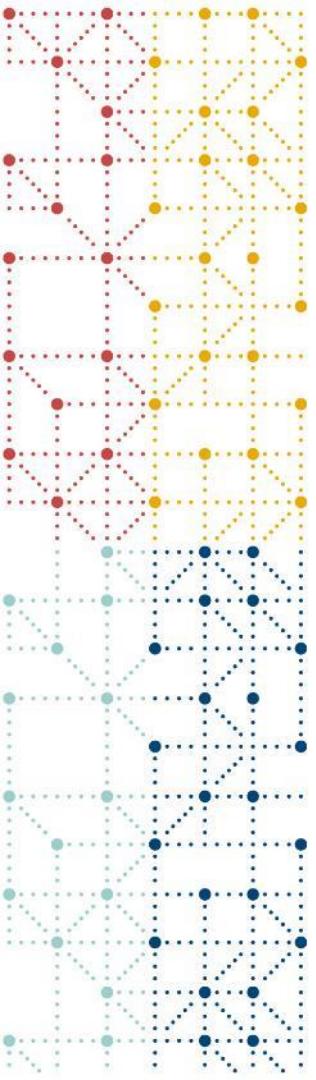
# The Shift to Decentralization



# Why Now?

- Trials with DCT elements beat timeline expectations
- DCTs improve diversity
- ~80% see better recruitment; ~75% report better retention
- Adoption rising: 43% → 55%, projected 66%+ in next few years



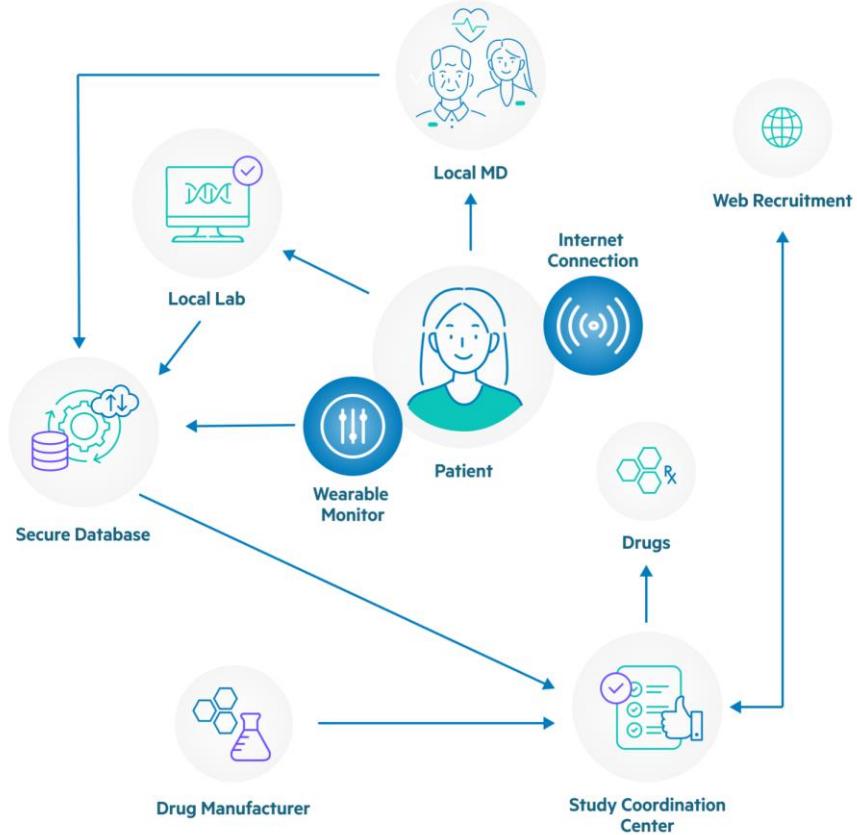


# The Technical Foundation

# The Connected Ecosystem

From device to database —  
seamless, standardized data flow

- Patient-facing tools
  - Wearables & home devices
  - Telehealth & mobile apps
  - eConsent
- Data backbone
  - Electronic Patient-Reported Outcomes (ePRO)
  - Electronic Clinical Outcome Assessment (eCOA)
  - Secure APIs → Cloud/EHR
- Standards
  - CDISC-compliant data flow



# Pillars of Decentralized Trials

## APIs for Real-Time Data Exchange

Enabling seamless interoperability across platforms and stakeholders.

## AI/ML for Oversight & Predictive Analytics

Harnessing intelligence to ensure compliance, detect risks, and predict trial outcomes.

## Blockchain for Secure Consent

Ensuring immutable, transparent, and verifiable patient consent records.

## Privacy-First Architectures

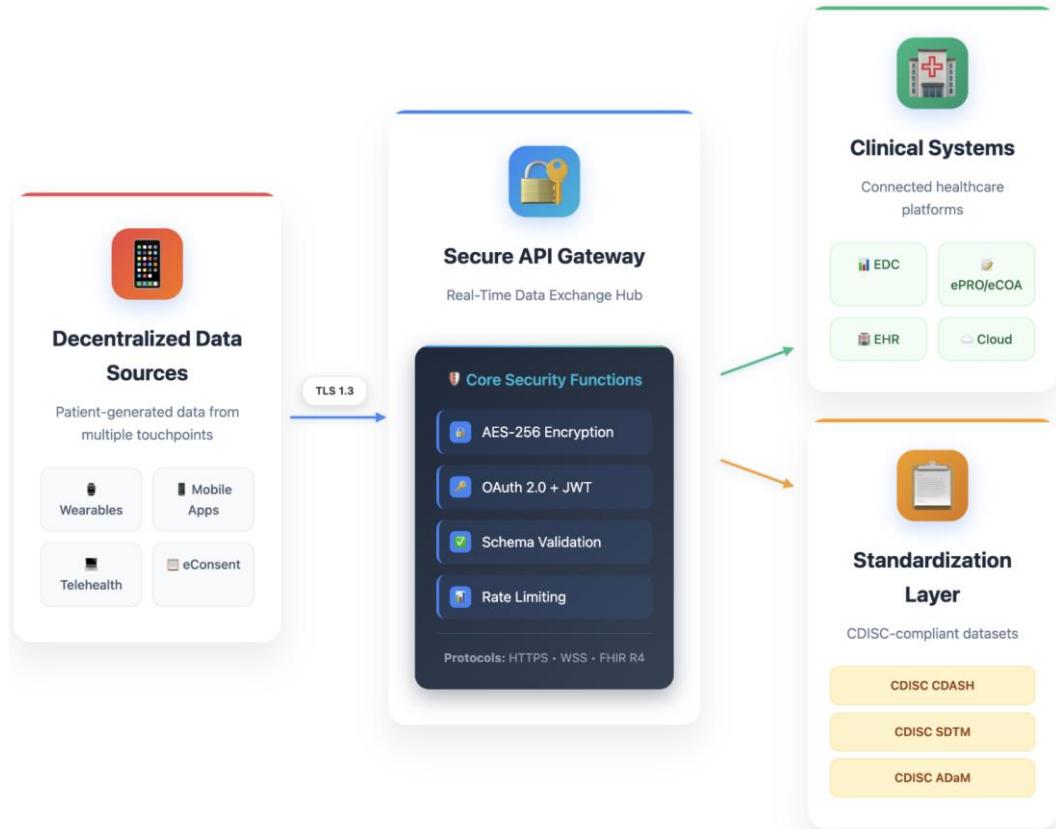
Designing systems that prioritize confidentiality and ethical data use from the ground up.

*“These four pillars form the digital backbone of a decentralized trial.”*

# Secure APIs – The Digital Glue

- Real-time data flow across platforms
- Connect wearables, ePRO/eCOA, EDC, EHR
- Ensure compliance + security (HIPAA/GDPR)

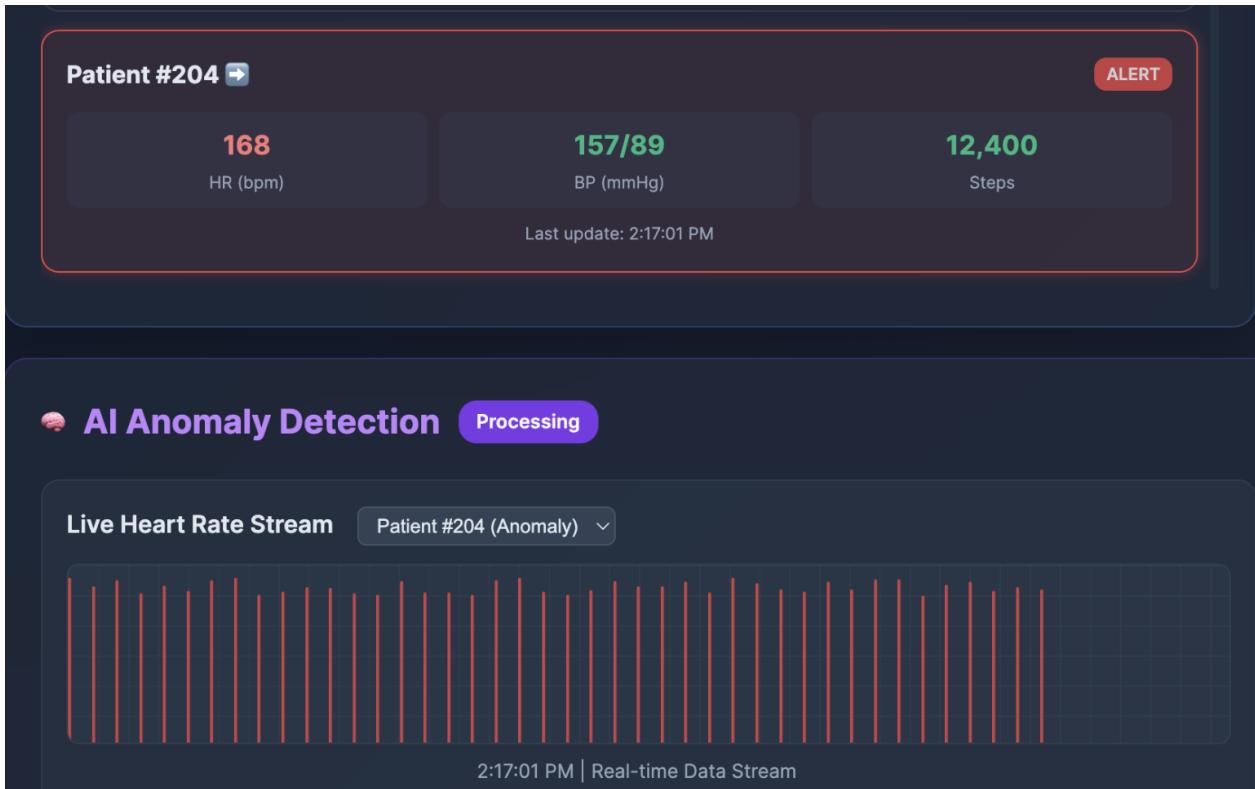
Human-centric data flow designed to serve patient needs while maintaining the highest standards of security and compliance



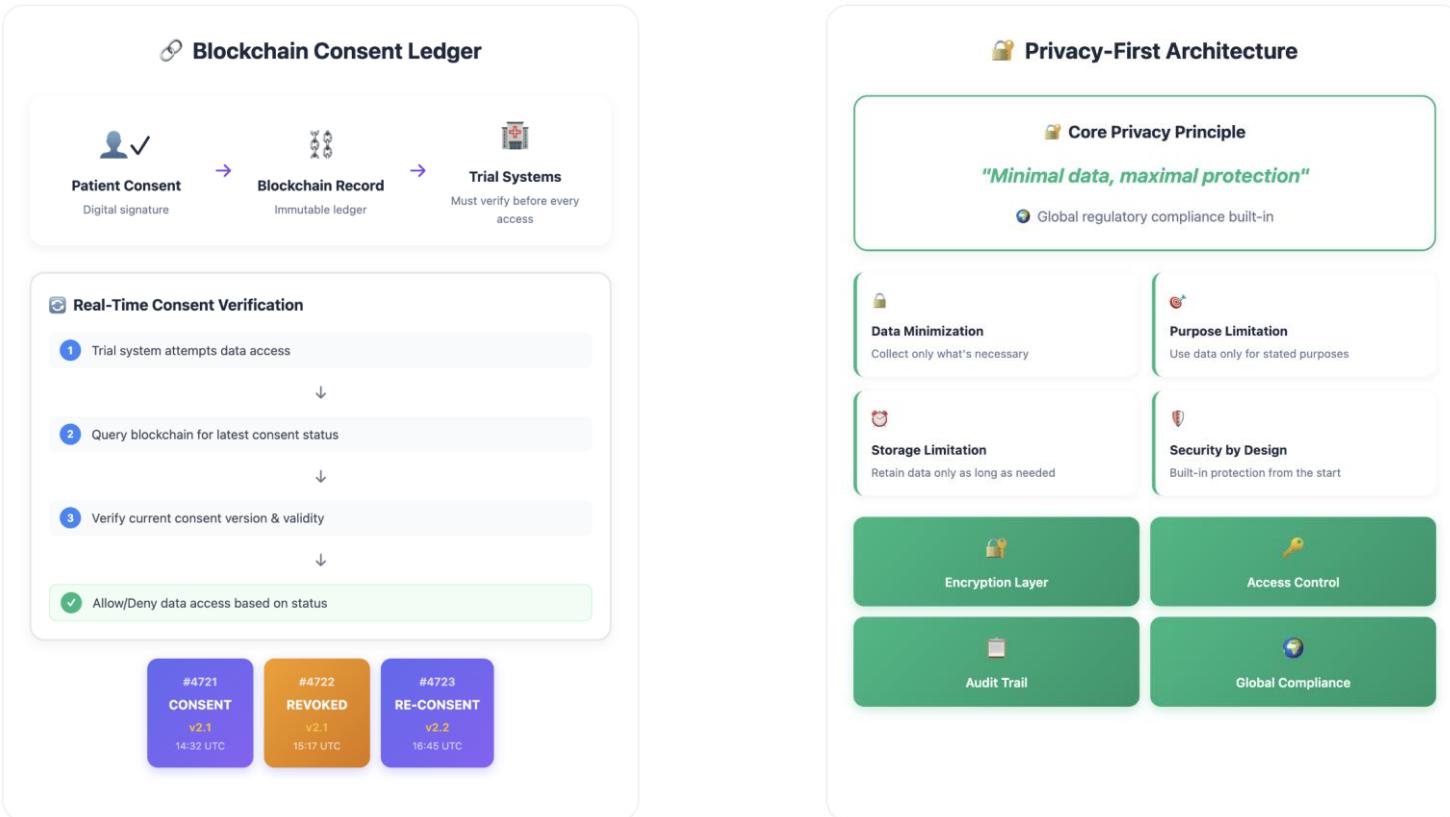
# AI & ML – From Reactive to Proactive

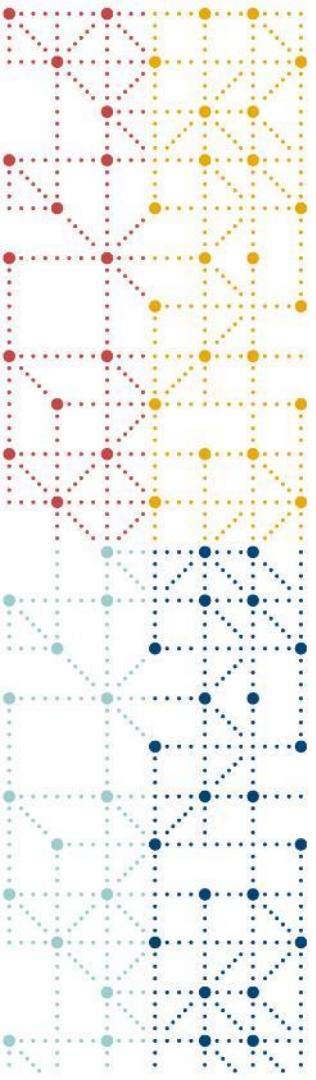
Intelligent oversight  
that prevents trial  
derailments before  
they happen

AI moves us from  
reactive to proactive  
oversight – spotting  
risks before they  
derail trials



# Trust & Privacy-First Architecture





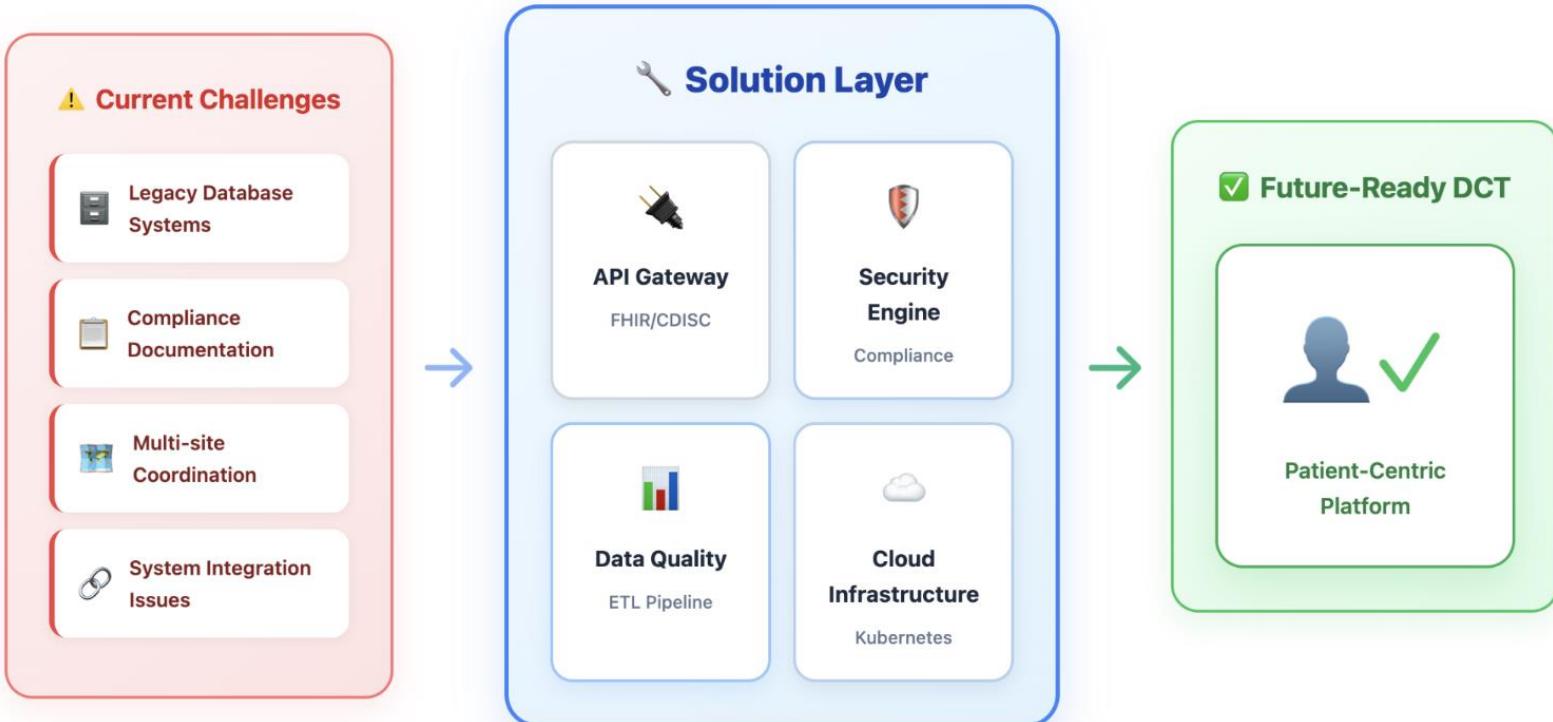
# Key Challenges & Solutions

# Challenges

- Scalability across multi-site environments
- Integrating legacy systems
- Regulatory uncertainty
- Data quality & standardization
- Patient engagement & retention
- Site & staff readiness



# Solutions



# Solutions (...continued)

## Implementation Strategies

### Hybrid Models

On-site + remote data capture with configurable visit windows

### Global Compliance

Privacy-by-design, automated GDPR/HIPAA checks

### Legacy Integration

Secure middleware, ETL pipelines, API wrappers

### Interoperable Platforms

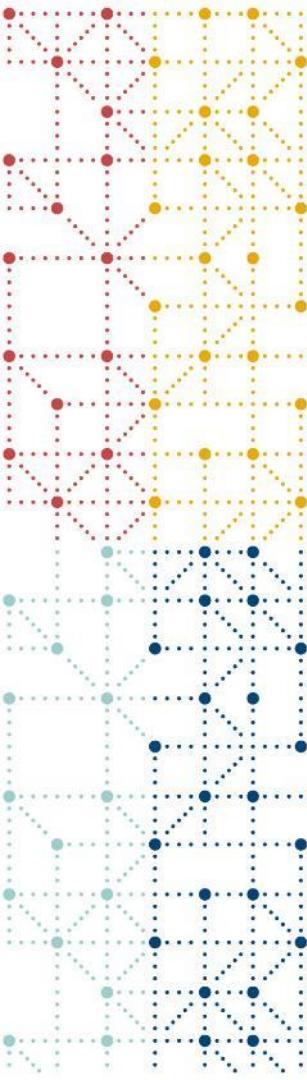
HL7 FHIR, CDISC ODM/SDTM, API-first design

### Data Quality & Validation

Real-time anomaly detection, schema enforcement

### Scalability

Containerized microservices, cloud-native orchestration (K8s)



Too Much  
Talking!



Too Many

Slides Presented

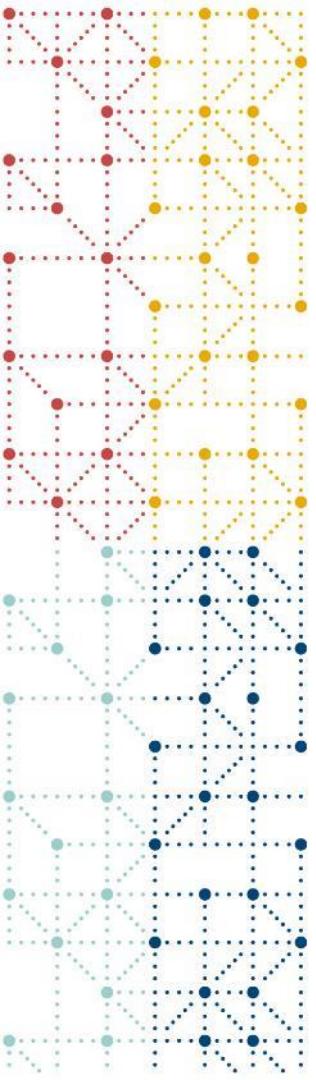


Technical Terms



Audience Energy

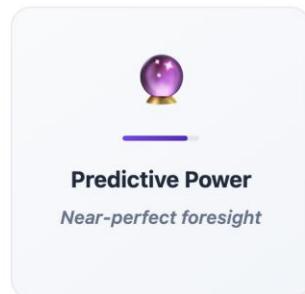
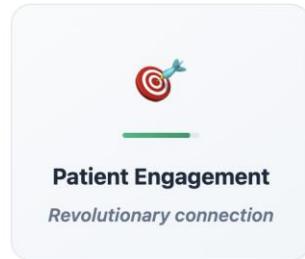
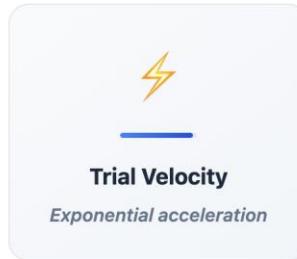
*Enough theory! Time to see AI catch anomalies in real-time...*

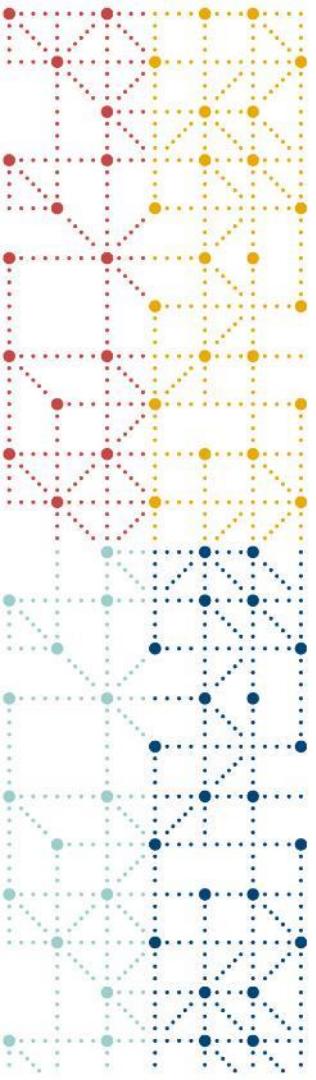


# Future Roadmap

# The Future of Decentralized Trials

- **AI Copilots**
  - Real-time protocol oversight, automated monitoring
- **Adaptive Protocols**
  - Dynamically adjusting based on incoming data
- **Patient Data Wallets**
  - Participants control and share their own data
- **Digital Twins**
  - Simulate trial arms and predict outcomes





# Key Takeaways

# Key Takeaways

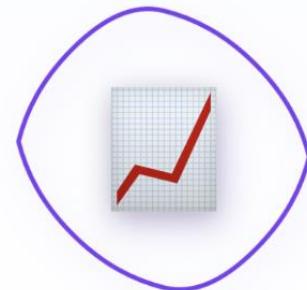
- DCTs are **essential**, not optional
- Tech is the enabler, **trust** is the currency
- Start small, **scale** smart, stay compliant



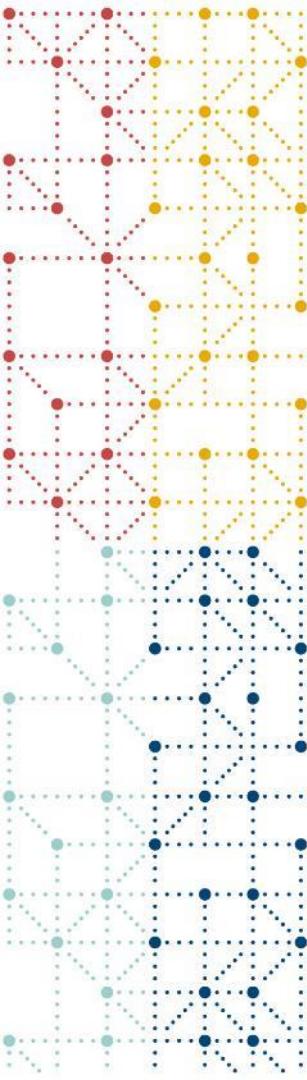
**Essential Evolution**



**Trust Foundation**



**Smart Scaling**



# Thank You!

## My Upcoming Talks



EU 2025  
Shanghai SDE

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