



## **Digitally Decentralized Reengineering Clinical Trials with Technology at the Core**

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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.



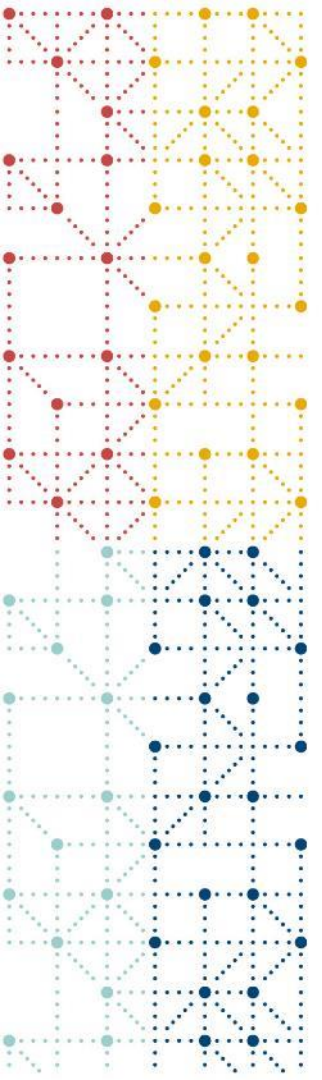
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- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC or Sycamore Informatics.*
- *The author has no real or apparent conflicts of interest to report.*



# 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

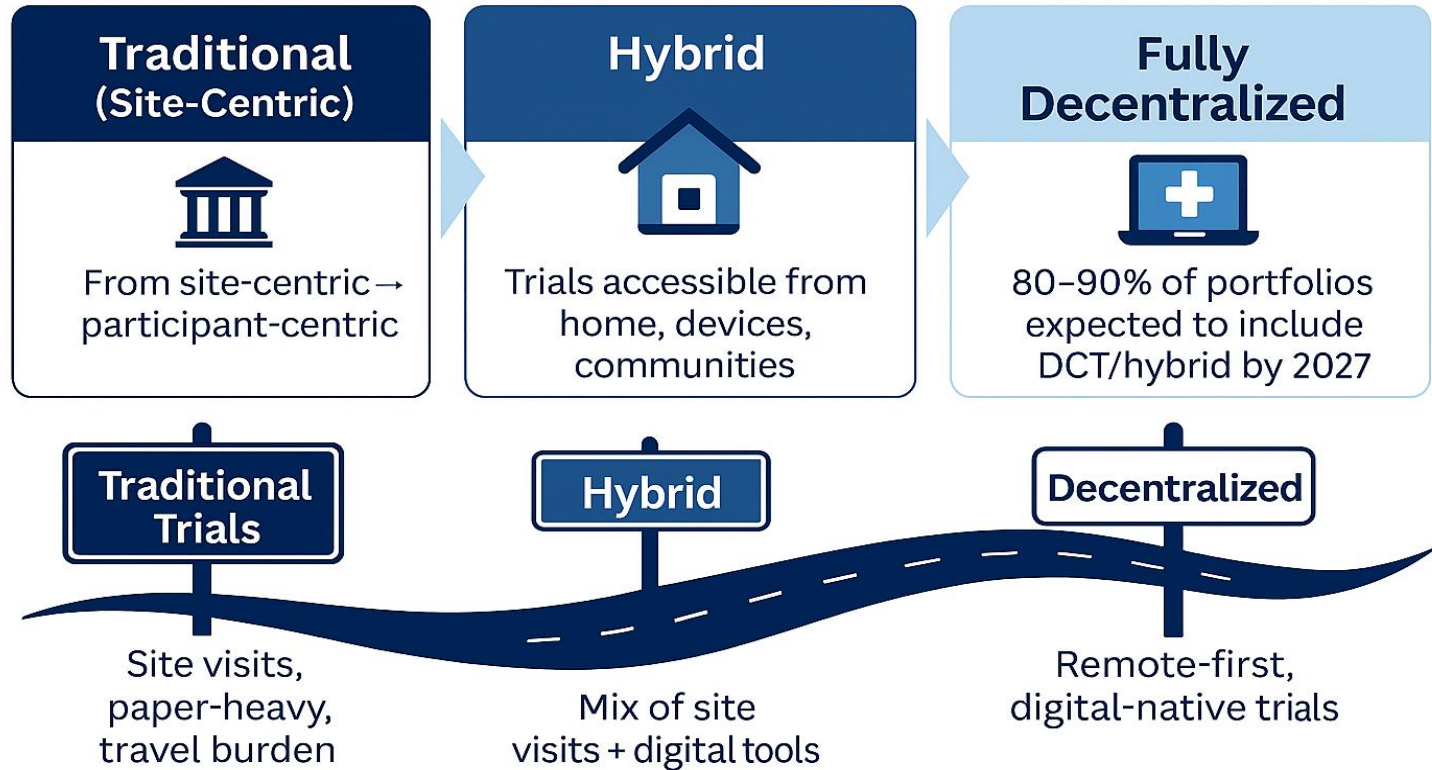
# Why to Shift to Decentralization in Clinical Trials?

## 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

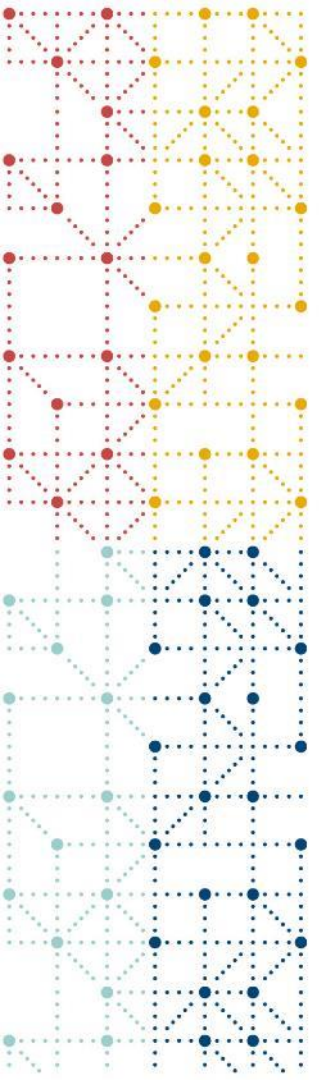




# Why Now?

- 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



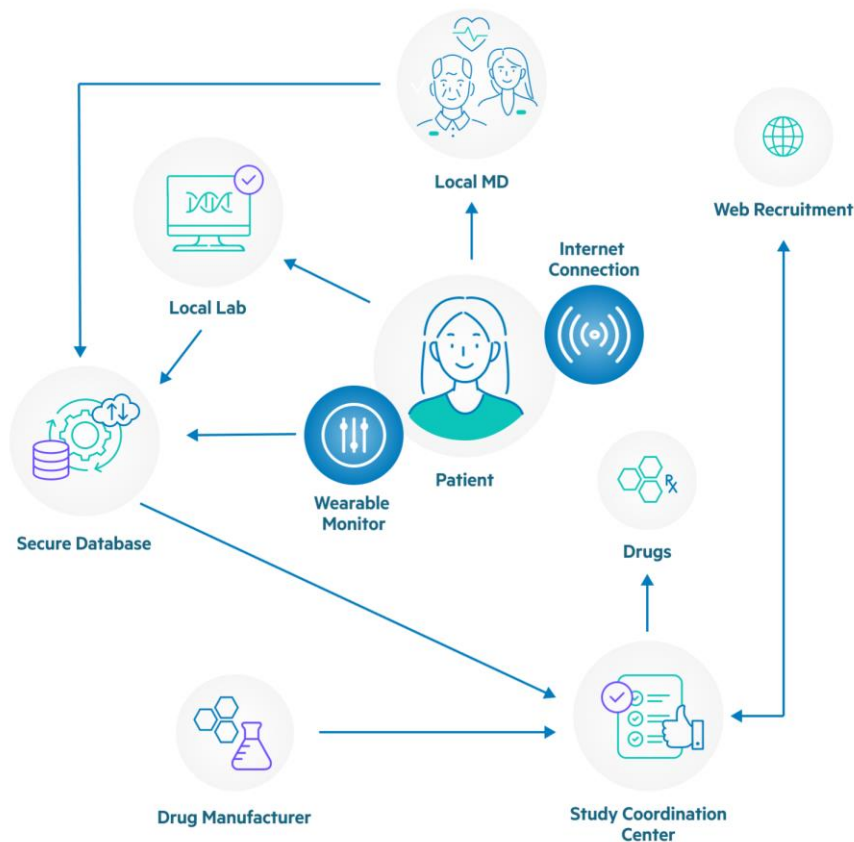


# The Technical Foundation

# 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

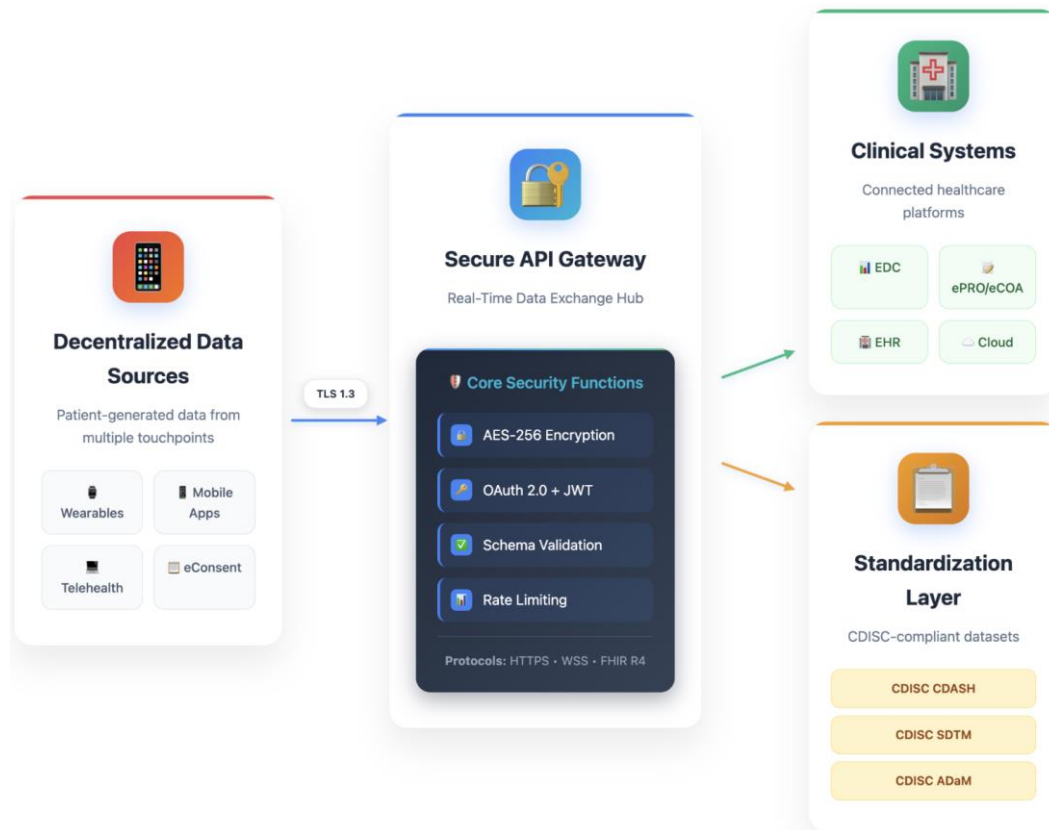
Designing systems that prioritize confidentiality and ethical data use from the ground up.

*"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)

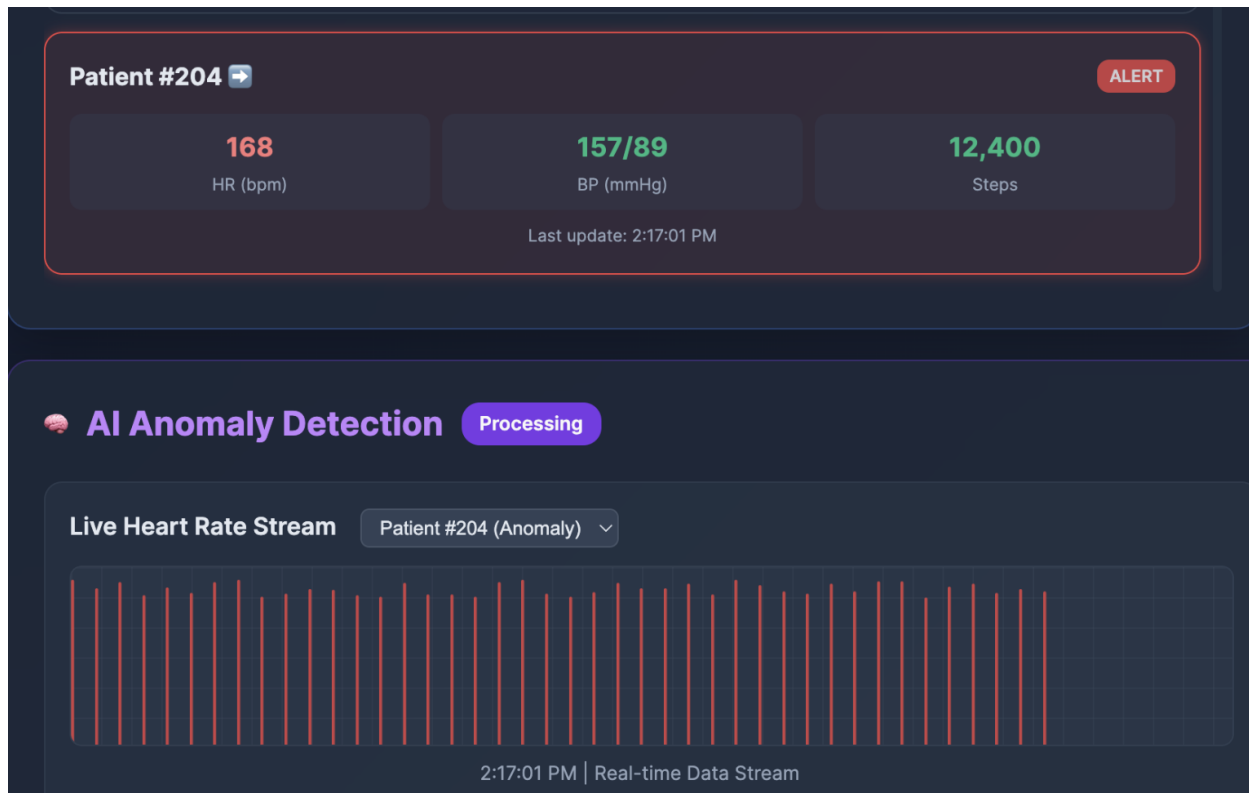
Human-centric data flow designed to serve patient needs while maintaining the highest standards of security and compliance



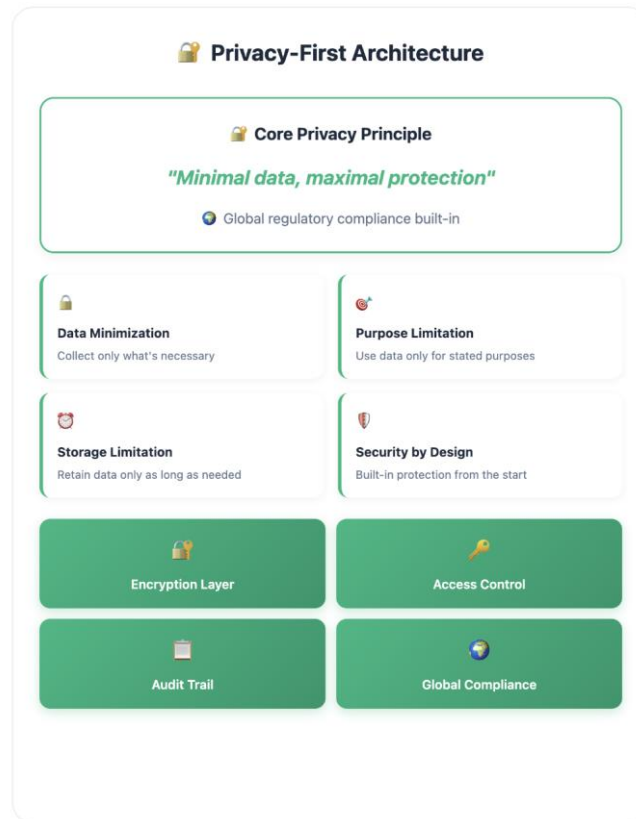
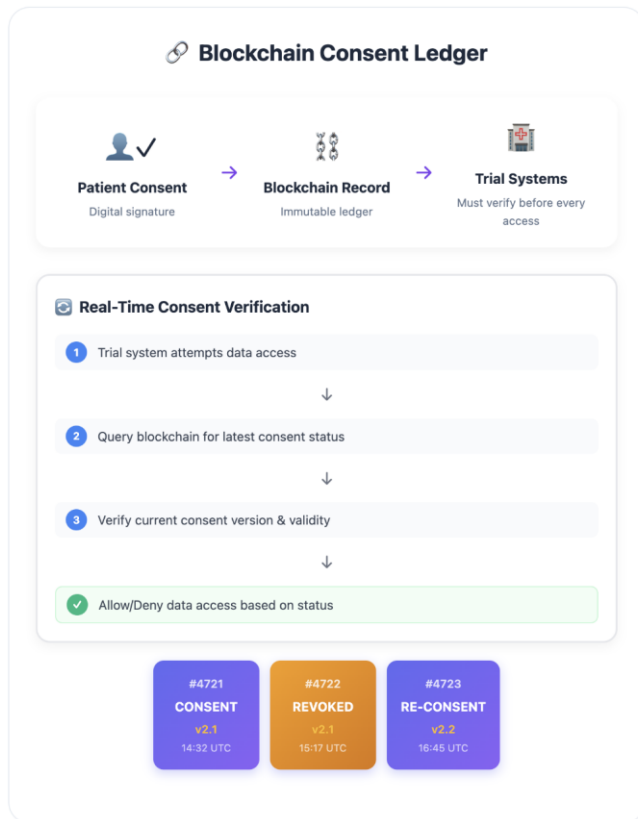
# AI & ML – From Reactive to Proactive

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



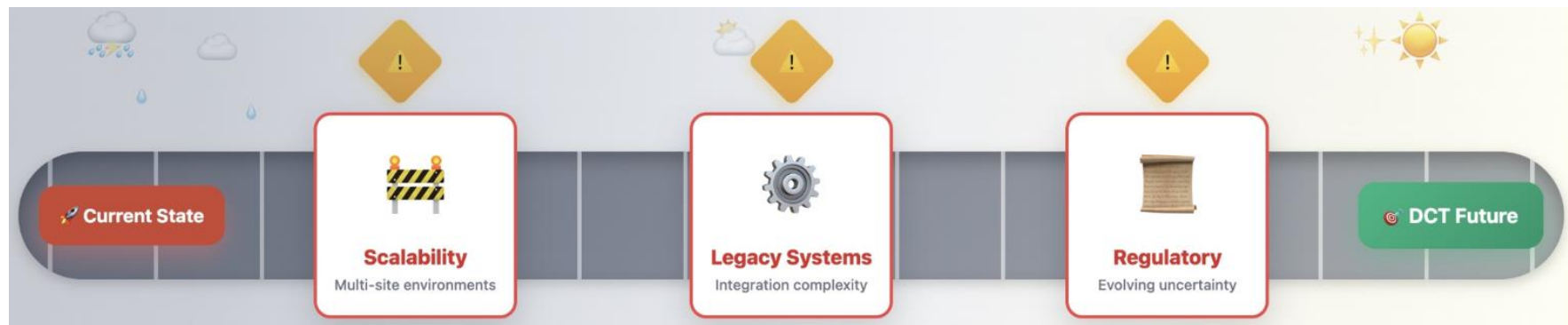


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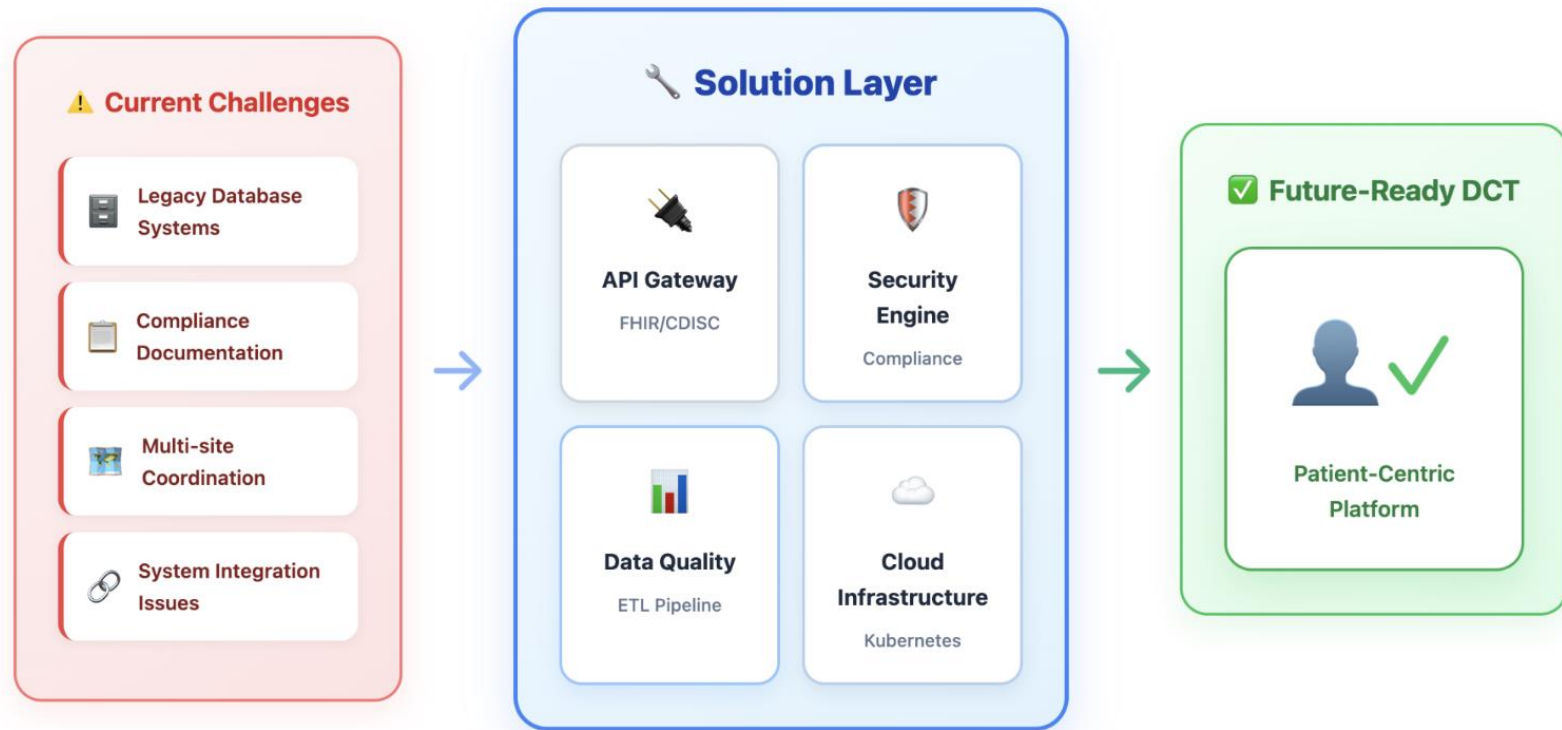
## Key Challenges & Solutions

# 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

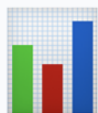
Real-time anomaly detection, schema enforcement



### Scalability

Containerized microservices, cloud-native orchestration (K8s)

**Too Much  
Talking!**



**Too Many**

Slides Presented

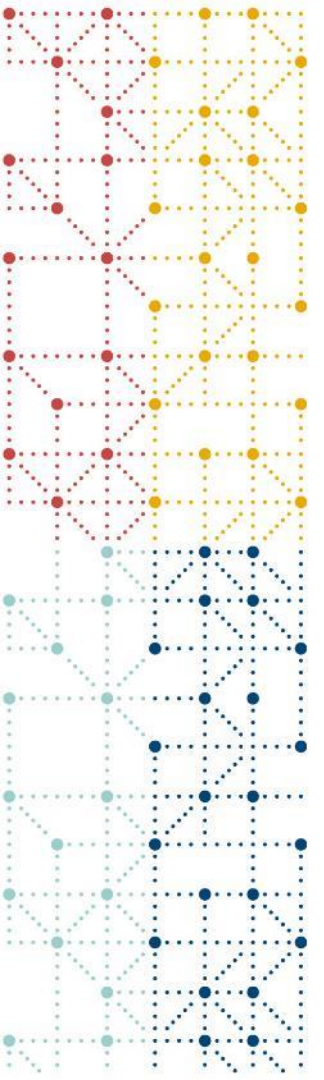


Technical Terms



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



## **Trial Velocity**

*Exponential acceleration*



## **Patient Engagement**

*Revolutionary connection*



## **Operational Efficiency**

*Dramatic optimization*



## **Predictive Power**

*Near-perfect foresight*



**2026**

**AI Copilots Rollout**



**2028**

**Integrated Ecosystem**



**2032**

**Predictive Medicine**





## 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!

## Contact us



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<https://www.sycamoreinformatics.com/>



Sycamore Informatics



## My Upcoming Talks



EU 2025

Shanghai SDE



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DSW



SCE



CDR



MDR



SPA