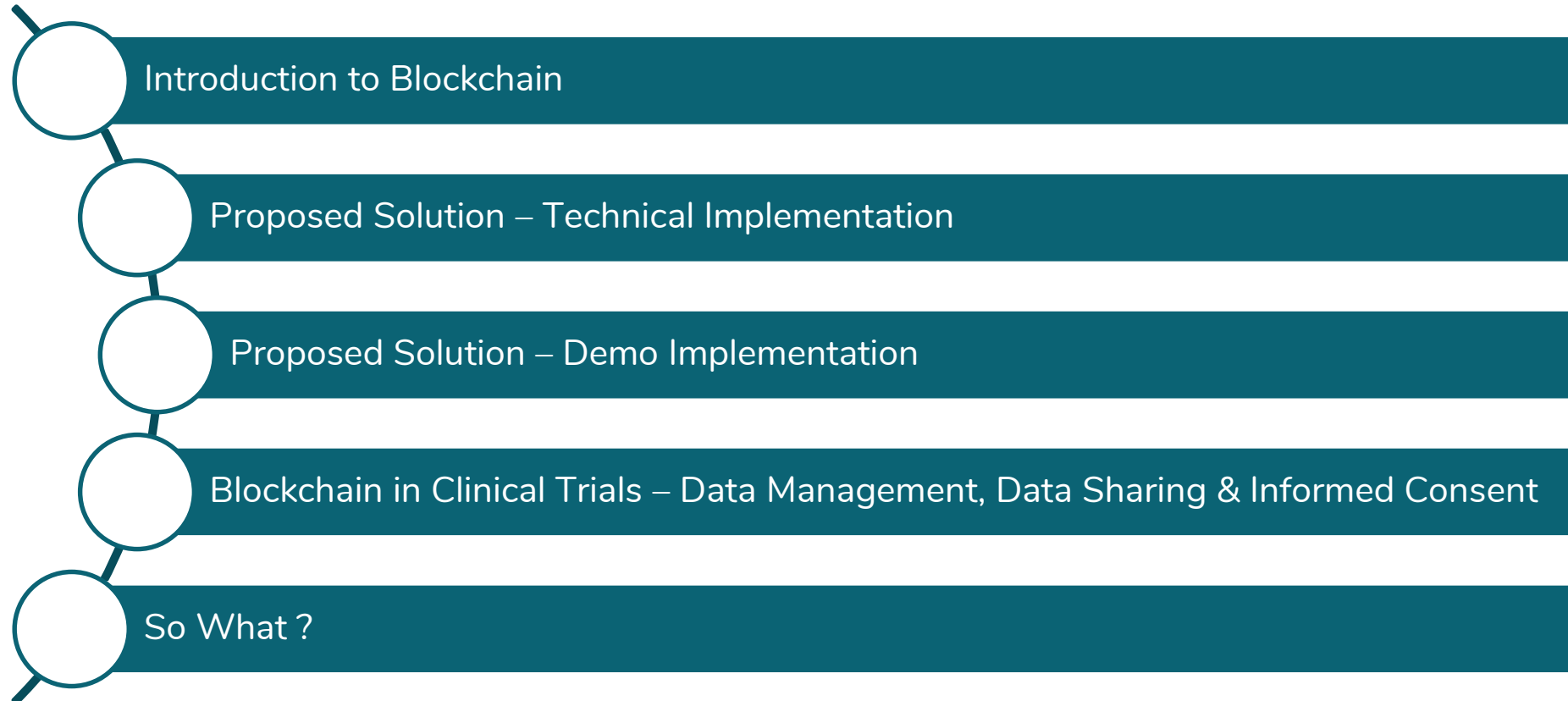


Clinical Trials on Blockchain

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Agenda



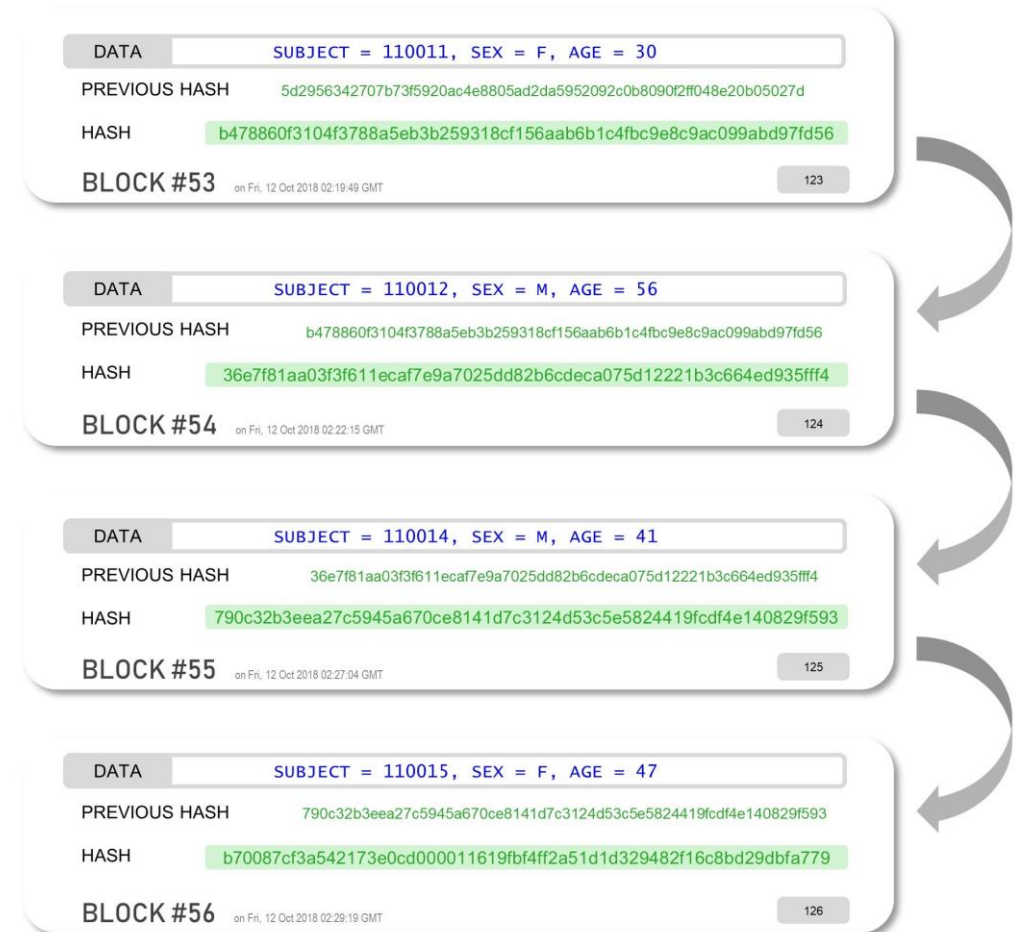
Introduction to Blockchain

Blockchain is a **distributed, decentralized** database

Each record provides reference to the previous record and the database is kept in sync through **consensus** algorithms

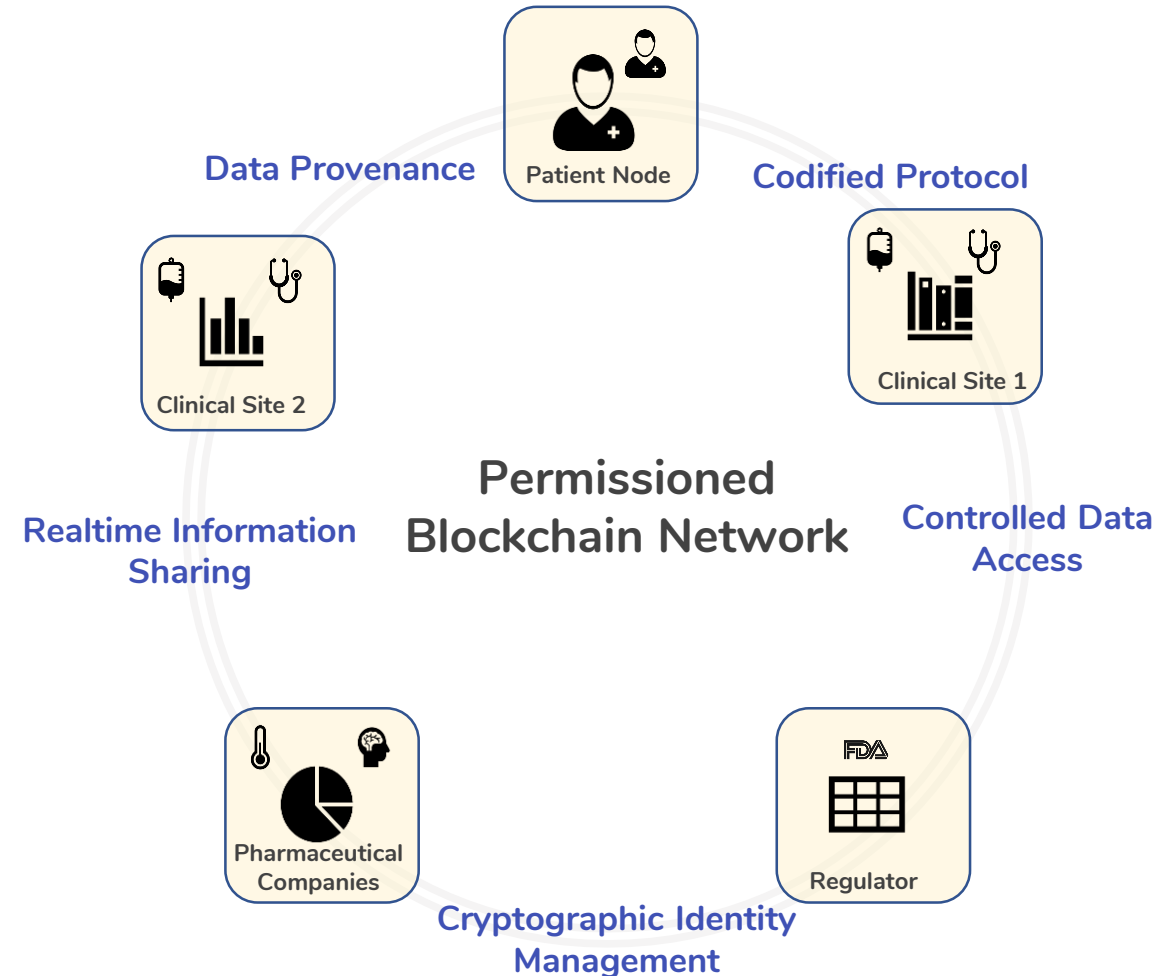
Important Properties w.r.t Clinical Trials

- **Immutable**
- Public or **Permissioned**



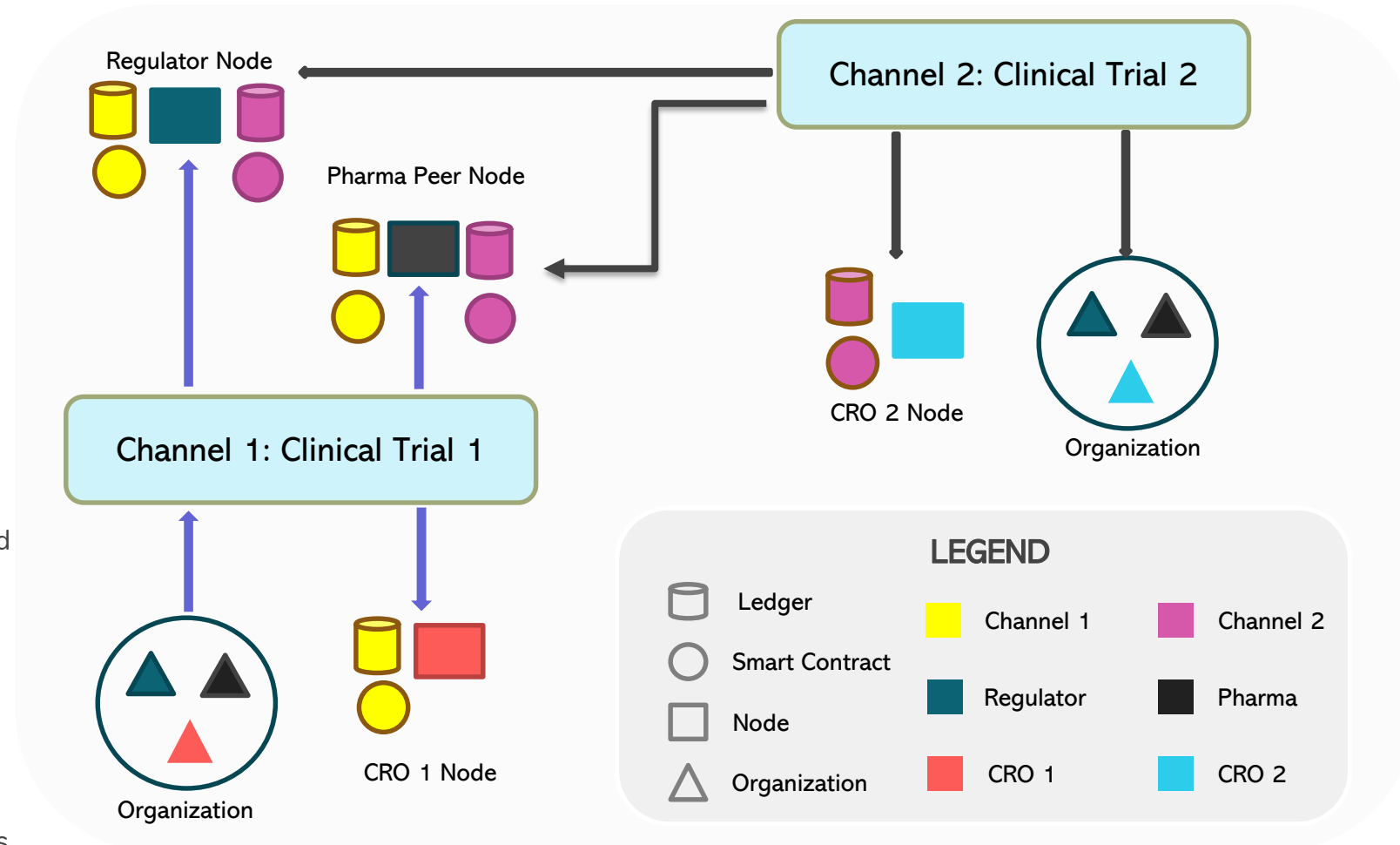
Proposed Solution – Technical Implementation

- All stakeholders - Pharma companies, CROs, Regulators, Subjects - participate in a Permissioned Blockchain network
- Data sharing, and the clinical trial execution take place in a distributed manner with programmable Smart Contracts based on the Clinical Trial Protocol,
- All Stakeholders run their own version of Smart Contract that updates their own local version of the ledger (i.e. Blockchain Database)
- The organization nodes remain in sync through consensus algorithm

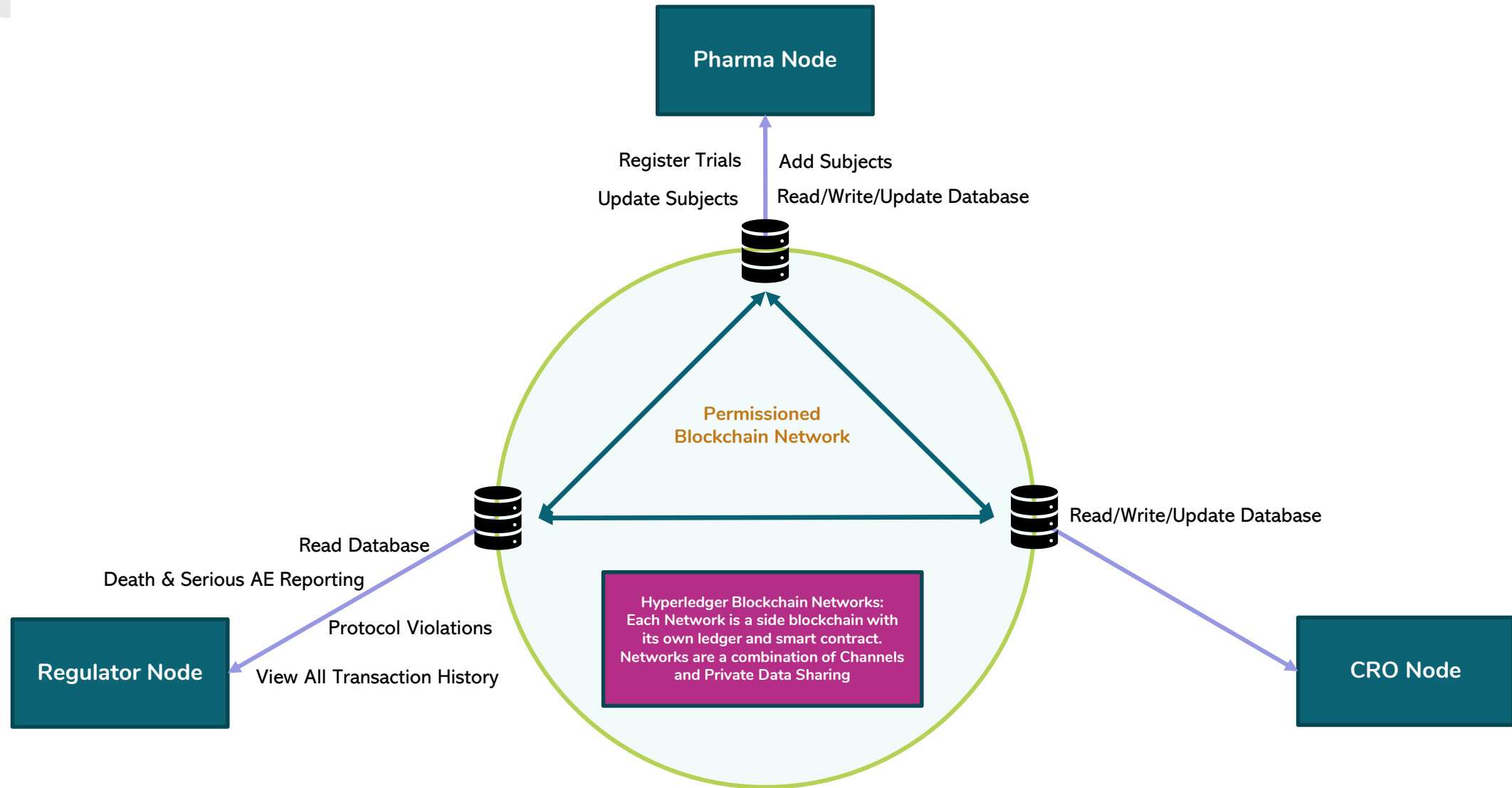


Key Components example

- Pharmaceutical Company is running 2 trials - Clinical Trial 1 and Clinical Trial 2
- Each trial has its own channel – Channel 1 for Trial 1 and Channel 2 for Trial 2
- CRO 1 is a participant in Trial 1/Channel 1 and CRO 2 is participant in Trial 2/Channel 2
- Regulator is part of both the Channel 1/2
- Data for Trial 1 will be only shared across Channel 1 participants - CRO 1, Regulator and Pharmaceutical Company and Data for Trial 2 will only be shared across Channel 2 participants i.e. CRO 2, Regulator and Pharmaceutical Company
- All the data associated with a Channel is stored in the Ledger
- Each Channel maps to one Ledger
- Each Organization that is part of the Channel maintains its own copy of shared ledger for the channel



Proposed Solution – Demo Implementation





Blockchain Application - Data Management

Challenges

- Multiple versions of data created from variety of sources – leads to **duplication**
- **Non-aggregation** of Clinical Data – difficult to access
- **Data Verification** through multi party channels

Why Blockchain?

- Better execution of clinical trials through **codification** of trial execution rules in smart contracts
- **Immutability**

Opportunities

- **Improve clinical trial operations**, through reduced fraud, faster audits, and fewer protocol violations
- Reduced Costs



Blockchain Application - Data Sharing

Challenges

- Data Sharing in a controlled manner - lack of collaboration between Healthcare, Research and Pharmaceutical Industry
- Dynamic Access Management of Data
- Increasing cost of Compliance-**Regulator at the end of chain**

Why Blockchain?

- Distributed & Decentralized Database
 - Security
- **Controlled Data Sharing:** Only authorized organizations can join the network, patient data is never exposed to wider public, ensuring patient privacy

Opportunities

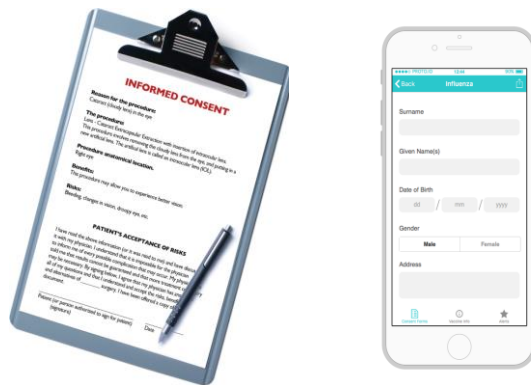
- **Enable data sharing** across hospitals, pharmaceutical companies, regulators, and patients
- Potentially faster approvals

Blockchain Application - Informed Consent

Informed Consent – Paper + Electronic

Paper based Informed Consent is non-interactive. Manual tracking and storage of paper documents needed to achieve compliance.

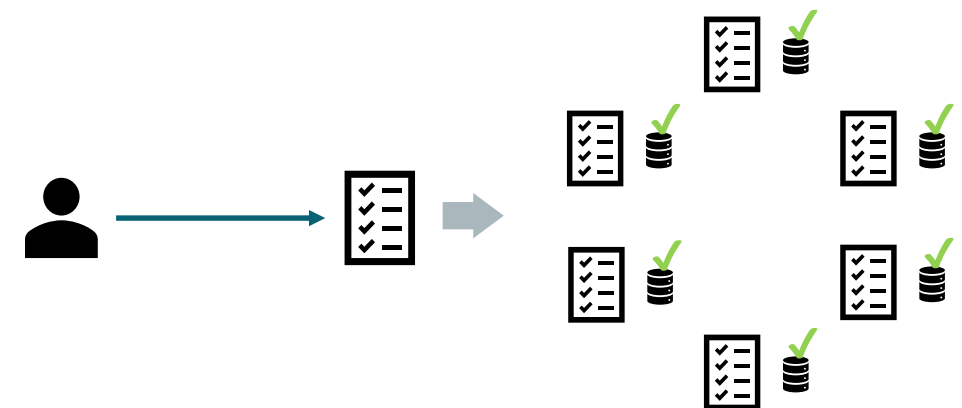
eConsent – Interactive, significant improvement over paper based consent. However, regulatory compliance still need to be met



Cryptographic eConsent on Blockchain

Blockchain stores an immutable record of informed consent obtained via any means- paper, eSignature, audio or video

A cryptographic hash of informed consent digitally signed by the patient is distributed across blockchain network ensures compliance and transparency





So What?

Blockchain streamlines clinical trials by digitizing and automating compliance, which enables following sample (non-exhaustive) use cases

Build Trust with Regulator for Phase 2/3 Studies

Clinical trial protocol is codified using smart contracts. For instance, smart contracts can ensure identification and sharing of clinical trial protocol violations as they occur.

Build Trust with Payer for Health Economics/ Phase 4 Studies

Data is shared in real time across the network. Any changes/updates are logged enabling real time audits, and data provenance thereby building a trustless system.

Improve Pharmacovigilance and Compliance

Enable real time sharing of pharmacovigilance and patient reported Adverse Events with regulator and other stakeholders.

Make Supply Chain more compliant

Logistic, Pharmaceutical, Regulatory and Administrative participants on same platform receiving real time data on state and movement of clinical trial drugs streamlines regulatory and administrative approval.



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