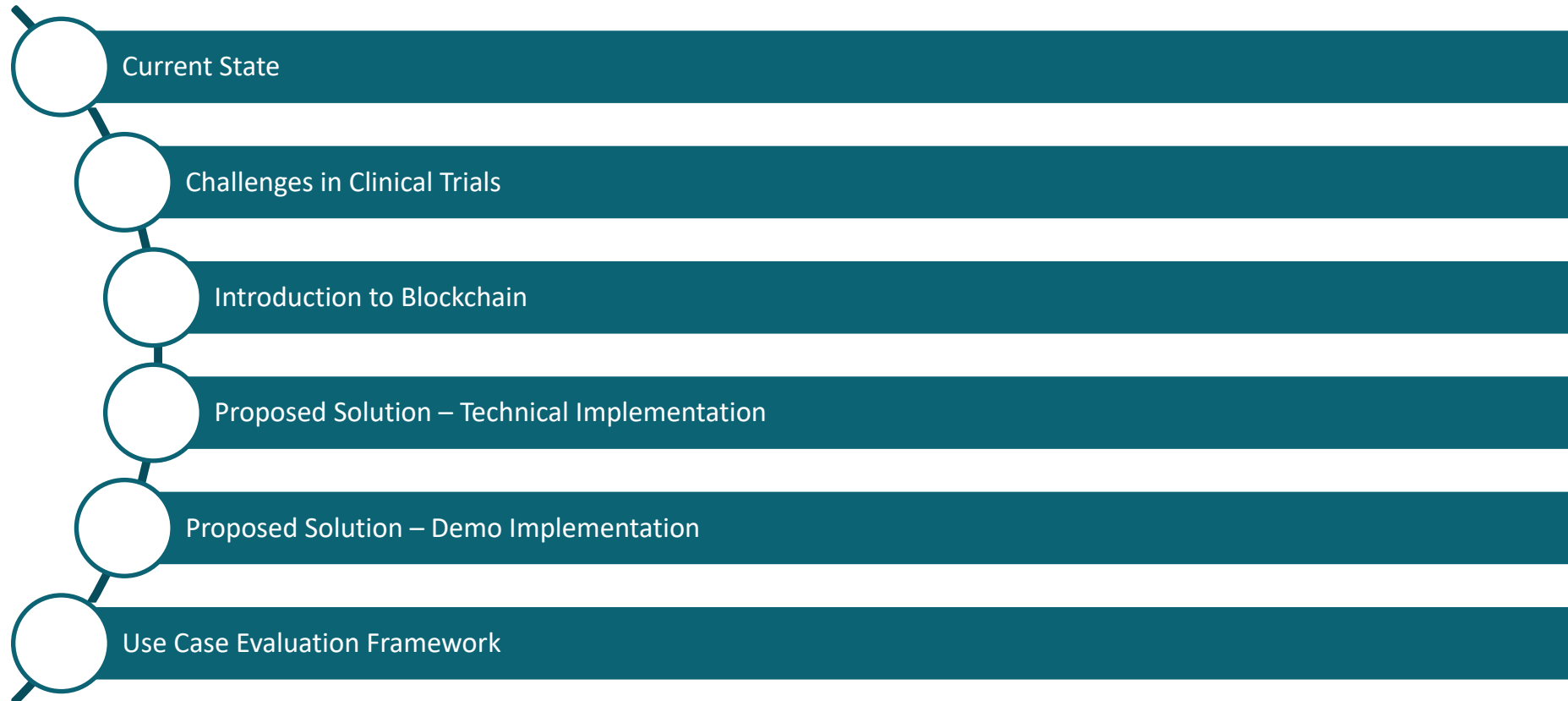


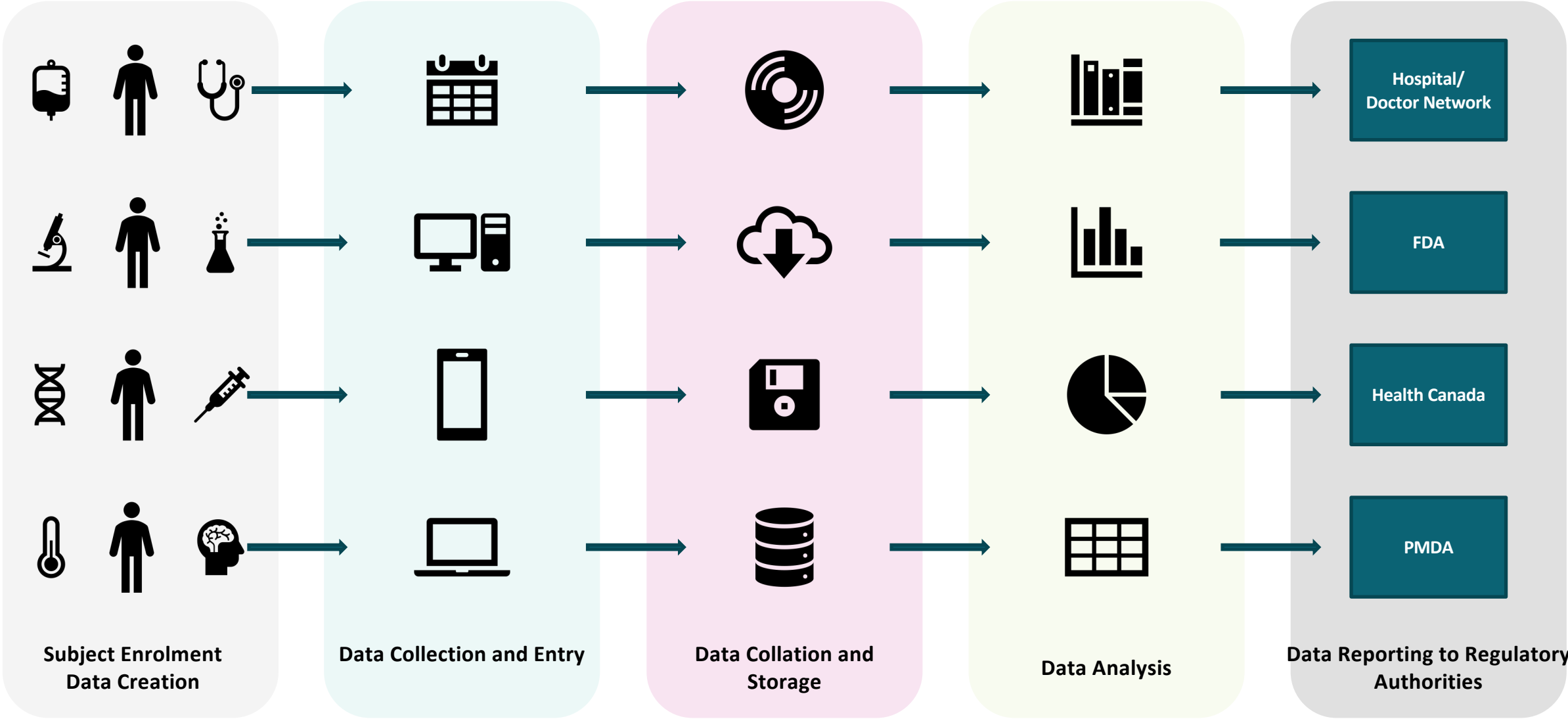
Clinical Trials on Blockchain



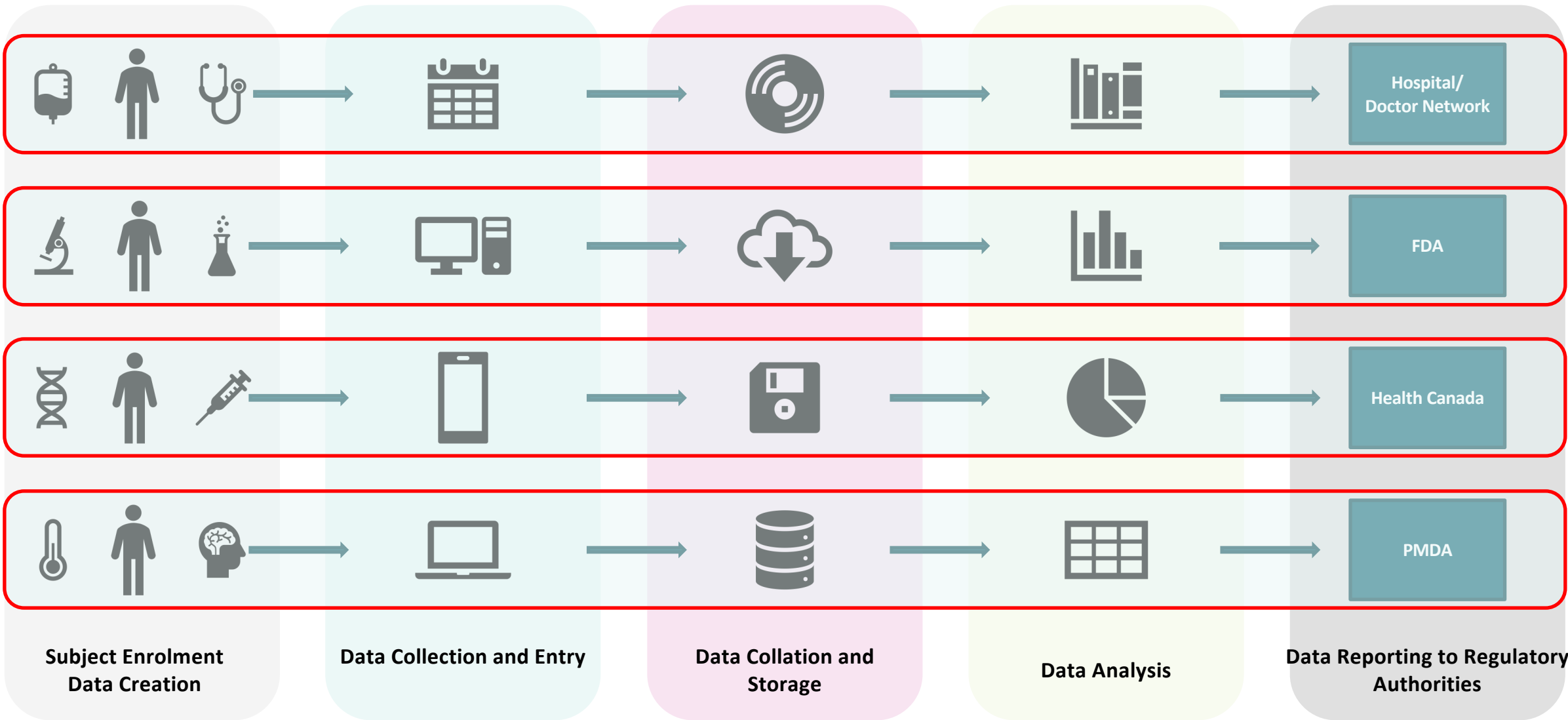
Agenda



Current State



Current State





Challenges in Clinical Trials

1. Data Management
 - Ineffective use of **Real World Data**/Big Data
 - Dynamic **Access Management** of Data
 - **Multiple versions** of data created from variety of sources
 - **Non-aggregation** of Clinical Data
2. Data Sharing & Security
 - Lack of **Collaboration** between Healthcare, Research and Pharmaceutical Industry
 - **Data Sharing** in a controlled manner
3. Subject Enrolment
 - Difficult to **recruit, enrol, and retain** subjects in Clinical Trials
4. Spiralling **Costs** of Clinical Trials
 - Increasing cost of **Compliance – Regulator at the end of chain**
 - Begin from scratch for each trial, little utilization of existing work



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

Blockchain has following properties w.r.t Clinical Trials

- **Immutability**
- **Distributed & Decentralized Database**
 - **Security**
 - **Availability**
- **Transparency**
- **Inbuilt Authentication and Authorization**

Blockchain Database

Hash is a number that is a digital fingerprint of any collection of data

Example - SHA256 hash of "SUBJECT = 110011, SEX = F, AGE = 30"

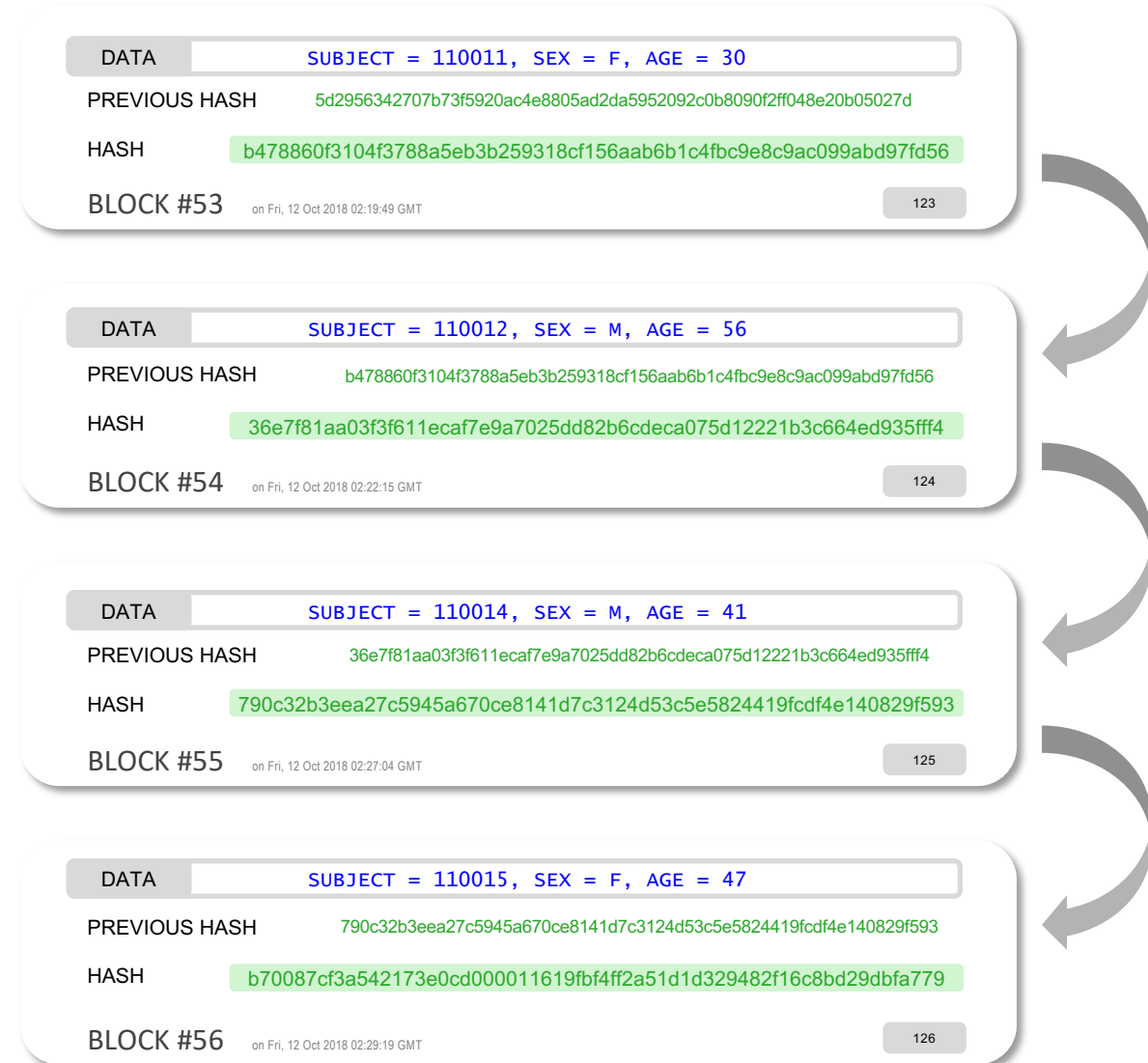
```
library(digest)
data = 'SUBJECT = 110011, SEX = F, AGE = 30'
hash = digest(data, algo = "sha256", serialize=FALSE)
hash

> hash
[1] "b478860f3104f3788a5eb3b259318cf156aab6b1c4fbc9e8c9ac099abd97fd56"
```

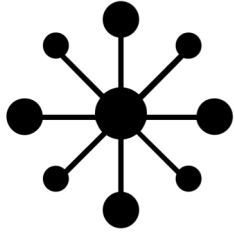
Hash Properties

- Deterministic Output - Same input always gives the same hash output
- Impossible to reverse engineer - Given an output, it is impossible to know the input value without calculating it
- Slightly varying inputs result in wildly different outputs

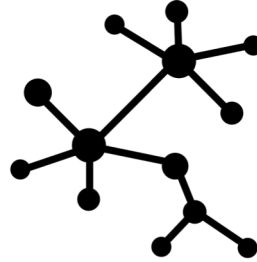
**Current Hash = SHA256 (Current Data
 ,Current Block Number
 ,Timestamp
 ,Previous Block's Hash
 ,Nonce)**



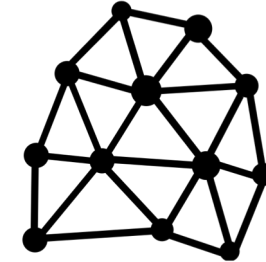
Public vs Permissioned Blockchain



Private and Centralized
Current Systems



Private and Decentralized
(Permissioned Blockchain)
Hyperledger, Quorum

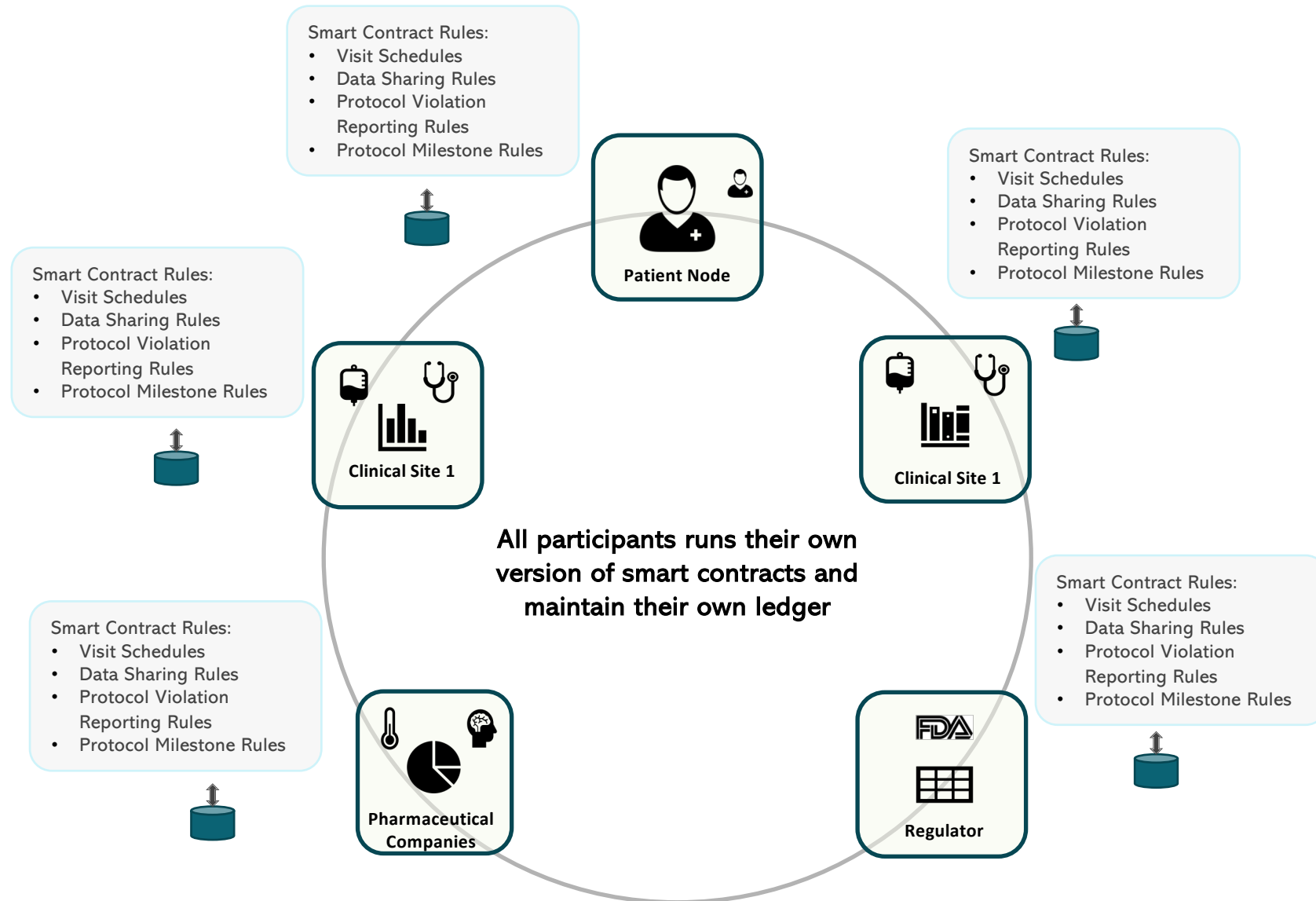


Public and Decentralized
(Public Blockchain)
Bitcoin, Ethereum

	Permissioned Blockchain	Public Blockchain
Who can access ?	Only authorized users and organizations can access	Anyone can access
Where is the data stored ?	On proprietary systems under control of each company	Public Nodes. Anyone can run a node
Compliance	Possible to achieve Compliance with Healthcare Data Standards	Not Possible
What is it used for ?	Enterprise Level Systems	Public Access Systems
How to think about ?	Intranet	Internet

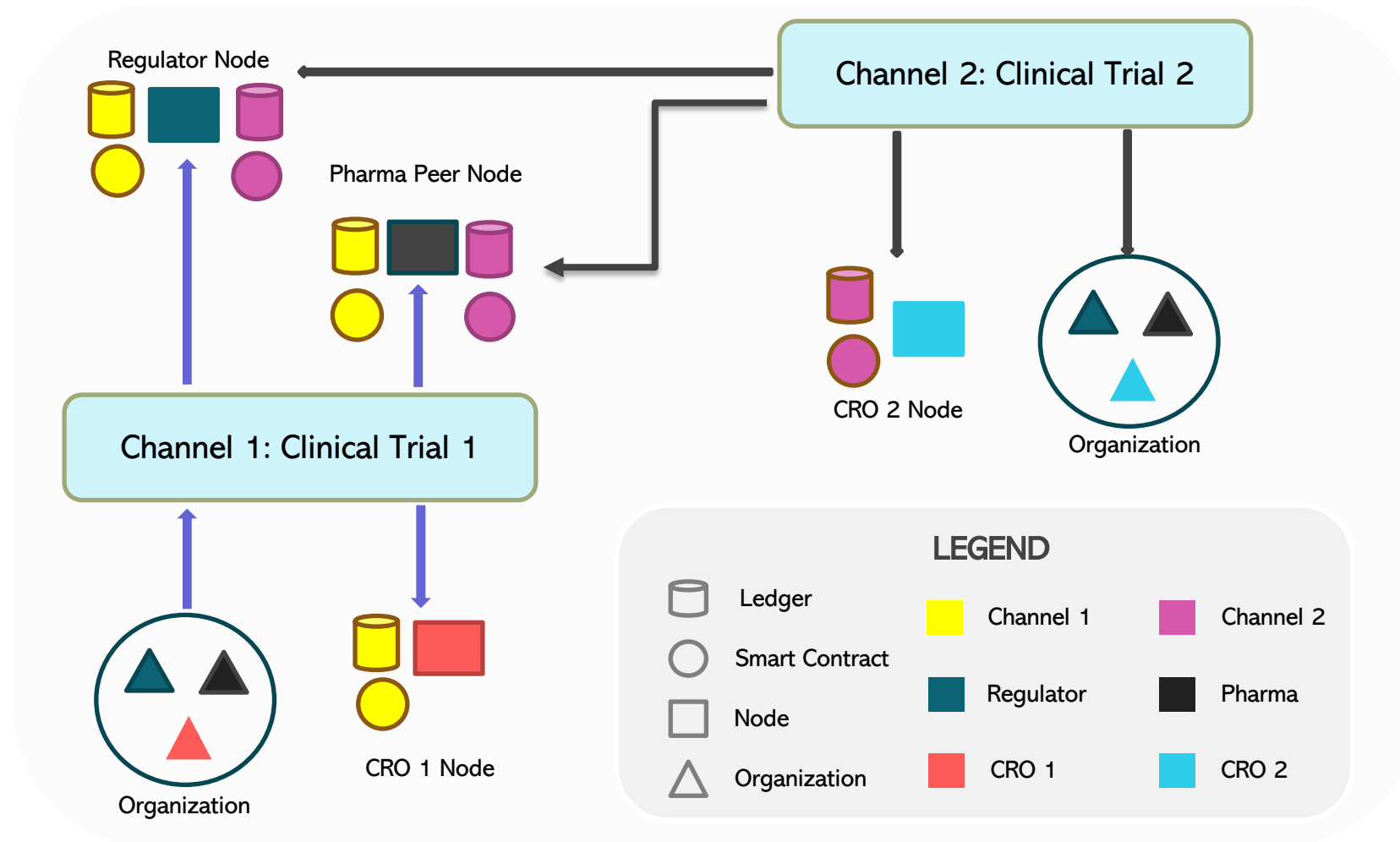
Proposed Solution – Technical Implementation

- 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

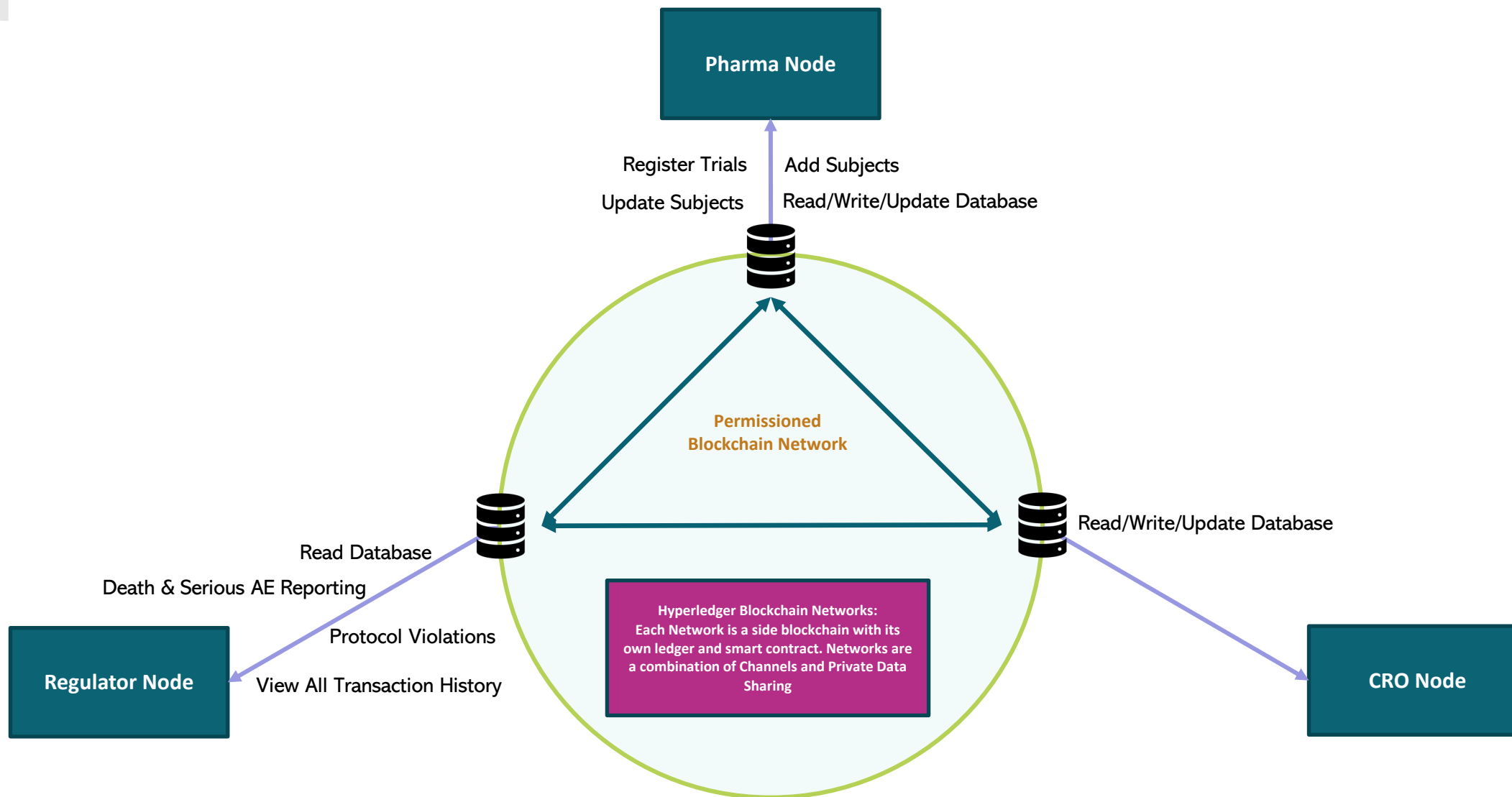




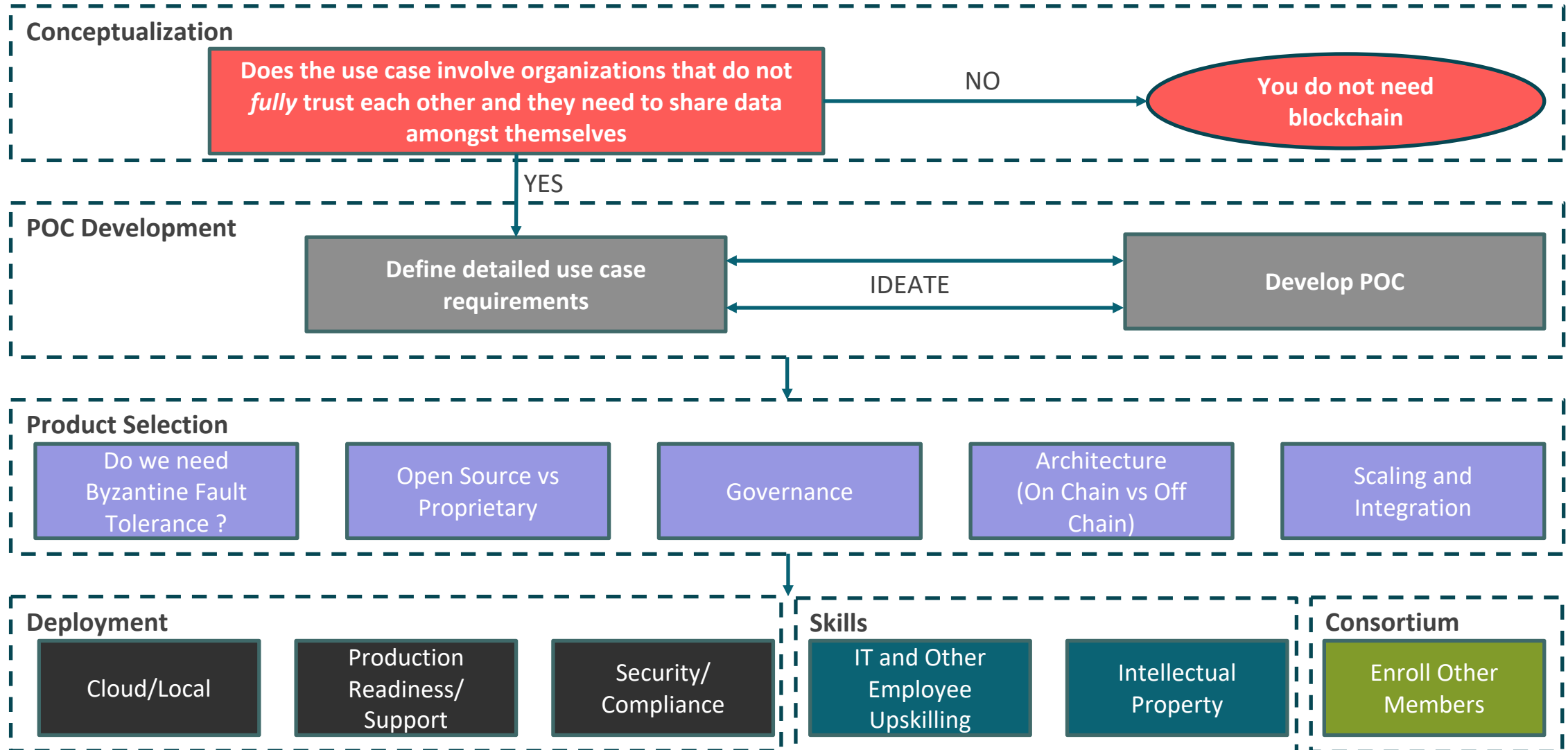
Key Components

- **Organization Nodes** - Business entity - Pharmaceutical company, Regulator, Hospital, CRO - that participates in the network
- **Channel** - Private Blockchain Networks that organizations can create amongst themselves. Data is shared only within a channel.
- **Transaction History** - historical log of all the transactions on the network
- **World State** - current state of ledger
- **Smart Contracts** - piece of code that executes within a Channel and define the logic of clinical. Each channel is linked to a Smart Contract trials
- **Proposal** - proposal is created when a node requests data to be added to the ledger

Proposed Solution – Demo Implementation



Use Case Evaluation Framework





Thank You



contact@lyfescience.com



(+1) 519 702 2334



(+91) 98 11 88 0002