Enabling Realtime Information Sharing and Streamlining Clinical Trials Using Blockchain

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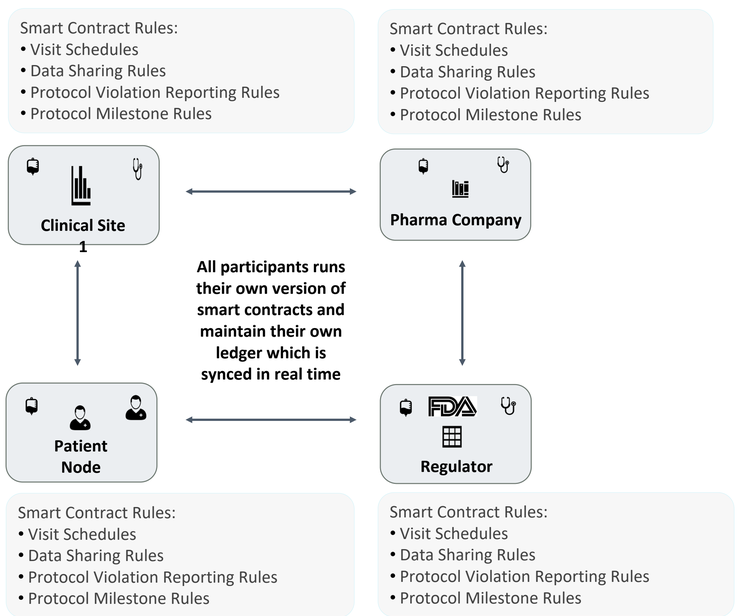
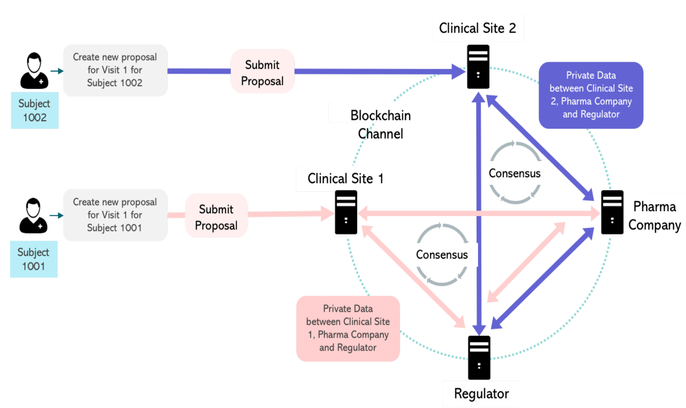
ABSTRACT

During the clinical trials, regulators access the data at the end of the process. Due to current processes and technological capabilities, it is not possible to enable “real time” information sharing during clinical trials. The paper describes a novel approach through which clinical trial workflow can be optimized using Blockchain technology. The paper describes a blockchain network in which Patients, Pharmaceutical Companies, CROs, Regulators, and other pre-approved entities participate and share data. As soon as the clinical data is entered it is shared across the network enabling true “real time” information sharing. Additionally, distributed ledger and consensus algorithms ensure that the compliance and audit process for clinical trials can be digitized. Finally the paper introduces smart contracts that can enable codification of clinical protocol rules into software code thereby automating the processes in clinical trial operations. Permissioned blockchain (in which data is shared in a controlled manner between pre approved entities) can fundamentally transform the clinical trials by reducing redundancies, improving compliance, as well as enabling real time and faster access to information. The paper presents a use case where blockchain is perfectly suited to improve clinical trial execution

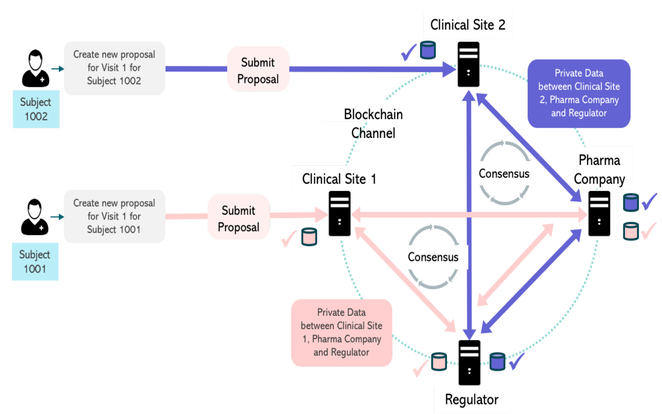
INTRODUCTION TO BLOCKCHAIN TRIALS



SAMPLE IMPLEMENTATION



Proposal creation stage – For each new data entry request, a proposal is created which is validated and confirmed by participating nodes of the sub network (Clinical Site 2, Regulator and Pharma Company for Subject 1002) (Clinical Site 1, Regulator and Pharma Company for Subject 1001)



Consensus State: Once confirmed, data is synced across respective nodes for the sub networks (Subject 1001 is synced across Clinical Site 1, Pharma Company and Regulator) (Subject 1002 is synced across Clinical Site 2, Pharma Company and Regulator)

IMPLEMENTATION DETAILS

Consider sample clinical trial with following participants –

- Pharmaceutical Company; Regulator; Clinical Site 1; Clinical Site 2

Following are the sequence of events:

Step 1: Subject 1001 visits Clinical Site 1 and Subject 1002 visits Clinical Site 2.

Step 2: Clinical Sites collect data for the subjects for the particular visit.

Step 3: Both the sites create separate proposal to add data to the respective ledgers for respective Subjects (Site 1 for Subject 1001, Site 2 for Subject 1002).

Step 4: For each sub network, organization nodes within their network reach a consensus over the current state of the ledger as well as the validity of the proposal. Once the consensus is reached, they update the ledger state with the data defined in the proposal. The data is only synced with the organization nodes of the sub network.

Subject 1001 is synced with Pharma Ledger, Regulator Ledger, and the Clinical Site 1 Ledger, whereas the Subject 1002 is synced with Pharma Ledger, Regulator Ledger, and Clinical Site 2 Ledger.

REAL TIME INFORMATION SHARING

Blockchain enables realtime information sharing. As soon as any data entry is made (for instance a new visit for the patient) , the data is independently added on each database for each entity (such as pharma company, regulator) thereby enabling real time information sharing for all data that is generated anytime for clinical trials.

Through analytical/visualization tools build on top of the data, regulators, and other regulated entities can get real time insights into clinical trial and the datasets

CODIFICATION OF STUDY PROTOCOL

Rules of clinical trial protocols can be embedded into software codes (smart contracts) thereby improving operations

For instance, if CRO/pharma company add data for a patient, smart contract will validate whether patient has provided cryptographic informed consent, if not, a protocol violation will be recorded across all the nodes i.e. on all databases for all entities (regulator, pharma, CRO)

PHARMACOVIGILANCE

Integration with patient reported adverse event, and other systems to ensure pharmacovigilance reports are shared in real time across the network between pharmaceutical companies, other patient/healthcare stakeholders, and regulators

DATA PROVENANCE

Blockchain is an append only database which enables provenance and decentralized audit trails.

For instance, consider a scenario where a visit record for a patient is created. However later on the visit record is updated. The decentralized blockchain database will store both the records and the complete audit trail is visible and shared in real time across the network participants