PhUSE US Connect 2019

Paper PP03

Achieving Data Integrity in Clinical Trials: Utilizing Blockchain Technology

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ABSTRACT:

In our current digital age, integrity and security of data is of utmost importance and for that huge amount is spent to have a secure system, where breaching or tampering must be checked time by time. This will automatically increase the maintenance cost and need to be constantly on threat alert with more vigilant actions. To have both a better infrastructure with good security feature and to get it cost effectively, we investigate Blockchain technology. For Clinical trials trustworthiness, elimination of fraud and error will elevate its quality of its outcome which can be achieved by this emerging technology. Integrating to clinical trials this technology can benefit more from it and this poster will enumerate how we can utilize and customize it.

INTRODUCTION:

A blockchain is one of the means in which information is recorded into a distributed ledger within a peer to peer network. Here a ledger could be a record of legal documents or a clinical trial data. Each user or member who is connected to the peer will own a copy of the ledger information and will participate in confirming, if there are any updates made in a collective manner. When the update is made it gets addressed in all the ledger copies within the network.

BASIC COMPONENTS OF A BLOCKCHAIN:

Below process chart illustrates the basic components of blockchain. Every component in it is interlinked to each other and are not separable.

DISTRIBUTED LEDGERS: Comprises of blockchain of transactions.

SMART CONTRACT CODE: Captures transactions in code.

NETWORK ARCHITECTURE: Comprises of collection of network, data and processing nodes forming the basic backbone for blockchain. Maintains a consistently updated ledger.

MEMBER ACCESS AND PERMISSION: User identity, transaction certificates and user access permissions are maintained.

NOTIFICATION AND SMART CONTRACT EVENTS: When blockchain operations are performed notifications created.

SYSTEM AND SECURITY MANAGEMENT: Provides platform to create, change, monitor blockchain components and manages user credentials securely.

END USER INTEGRATION WITH BLOCKCHAIN: Bi directional integration with external system.

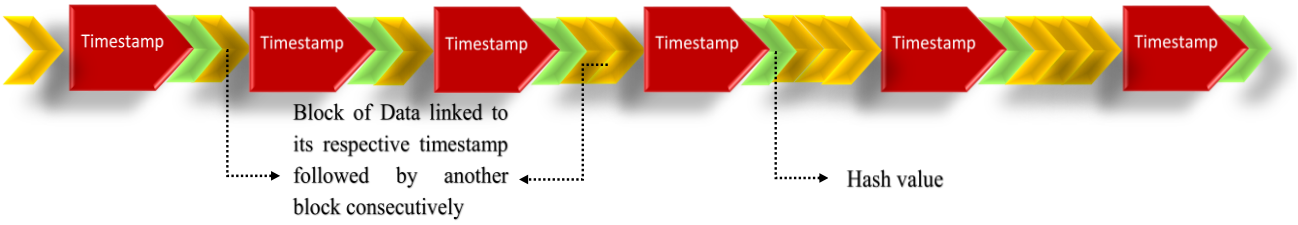
HASH AND TIMESTAMPS:

Following illustration depicts how data converted to hash with timestamp. Each hash holds respective data transacted at the corresponding time. Consecutively similar blocks are linked, and it forms a blockchain.

A hash function is based on a cryptographic mathematical function which turns given data into string of numbers and letters called hash. When consecutive transactions occur, hash is generated for the current transaction along with it previous hash inserted. Therefore, making each entry dependent upon prior entry.

When a small change occurs in a transaction it creates a new hash completely. Respective nodes in the network check and confirm whether a transaction not been changed by verifying the hash. If majority of the nodes in the system confirm the transaction, then its added to the block.

If one tries to change one entry, then they must change hash for all previous entries. This feature makes blockchain more resilient to malicious actions like tampering and corruption of data.



BLOCKCHAIN NETWORK TYPES:

A. Public or Decentralized Blockchain where user will be anonymous, and transactions are copied to every node and participate in transaction confirmation.

B. Consortium or Distributed Blockchain where user won't be anonymous, and transactions are copied to only specific nodes and they participate in transaction confirmation. They can be public or private and vary in their structure and size.

C. Private or Centralized Blockchain where user won't be anonymous, and transactions are copied to only specific nodes and they participate in transaction confirmation.

For having the most secure and transparent blockchain systems public and consortium type networks are preferred. Due to user anonymity in decentralized blockchain it is widely adopted. The major variation with distributed blockchain system is its user non-anonymity, but still user has the control over what to be shared and not to be making it more suited for clinical trials to adopt.

FOLLOWING FIGURES DEPICT BASIC STRUCTURE OF THE BLOCKCHAIN NETWORKS UTILIZED:

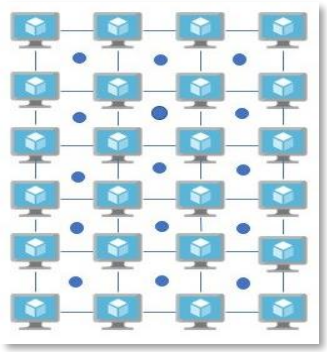


Figure A. Public or Decentralized Blockchain

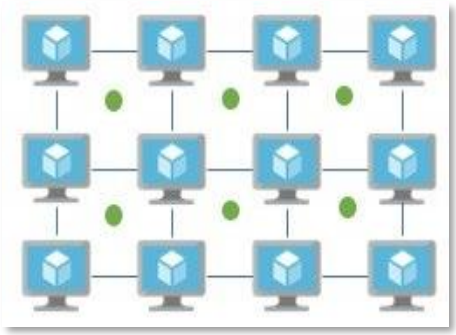


Figure B. Consortium or Distributed

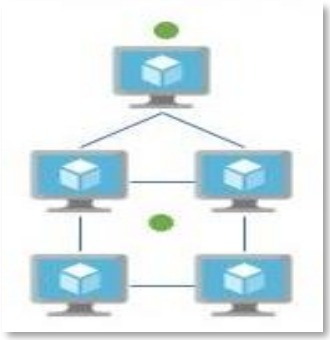


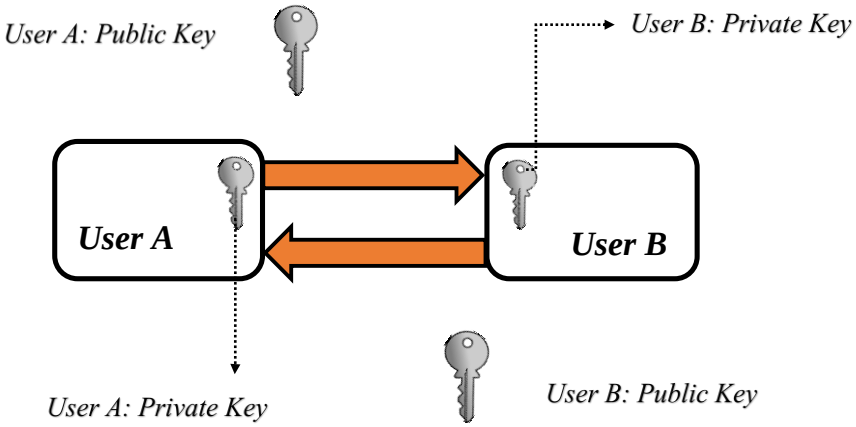
Figure C. Private or Centralized Blockchain

PUBLIC AND PRIVATE HASH KEYS:

For performing transactions via blockchain, public and private key hash is required. For a user there will be a set of hash keys where one will be public key which is used most like a user id and the other will be private key which is more of a password. Hence while performing transactions via blockchain these two keys enable a user to encrypt and decrypt information.

Cryptographic algorithms are utilized to create public/private keys. One of the prominent algorithms used is ECDSA (Elliptic Curve Digital Signature Algorithm). Private key generated through this algorithm by a user will be a secret number only known to that person. Public key will be the corresponding number related to the private key and doesn't require to be kept as secret. A public key can be deduced from its respective private key, but a private key can't be deduced in same manner from its respective public key.

To determine if the signature for a transaction is genuine one can use public key. Whereas the signature in blockchain is more of a number which proves a transaction signing operation occurred. This signature part is mathematically generated from a fixed length hash (hash algorithm converting given randomly chosen large data into a hash with definite length) which is to be signed along with its respective private key.



NEED FOR BLOCKCHAIN IN CLINICAL TRIALS?

It provides specific subjects or patients to have control over who should access their medical information stored in the ledger, by so privacy is maintained at their own discretion. And due to the decentralized nature of the network utilized by blockchain, data stored are pointedly more secure and less susceptible towards malicious actions when compared to current systems. Main features of blockchain which elevates it for utilization for clinical trials is its invulnerability and maintaining authenticity of data.

BLOCKCHAIN IN CLINICAL TRIALS FOR SMART CONTRACT:

- Blockchain incorporated patient enrolment process can collect patient consent with more authenticity and securely. It can avoid misconducts in patient enrolment such as where patient is not made aware of the adverse effects of the trial drug taken and taking consent without the knowledge of patient.

- Patients who enter enrolment process will be given a public and private key to access the protocol with consent. Once they are gone through the protocol and if they are eligible to participate can confirm their consent to move forth else if they don't meet the criteria can drop off. This action by the patient will be encrypted with their respective private key and will be recorded in the ledger within the blockchain network they use.

- Further when this information is sent to investigators, sponsors and IRB, they also need to have a public and private key to access it. Those patients who have signed the smart contract will be moved to next phase.

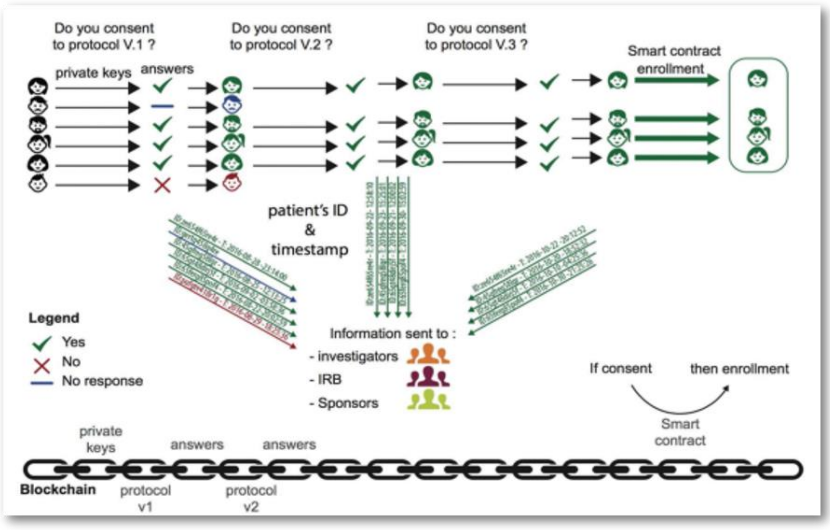


Figure D. Blockchain workflow for consent collection

- When protocol gets updated, concerned patients who have already enrolled will be updated of this and they can provide their consent respectively.

- All these activities will be recorded and timestamped in a sequential manner, right from the start of getting the initial protocol to consenting to the updated protocol, making it blocks of data interlinked based on the time they got passed.

- This data can't be tamped or corrupted as the user will be made aware of it and again data is distributed throughout the network making it easier to retrieve the actual one.

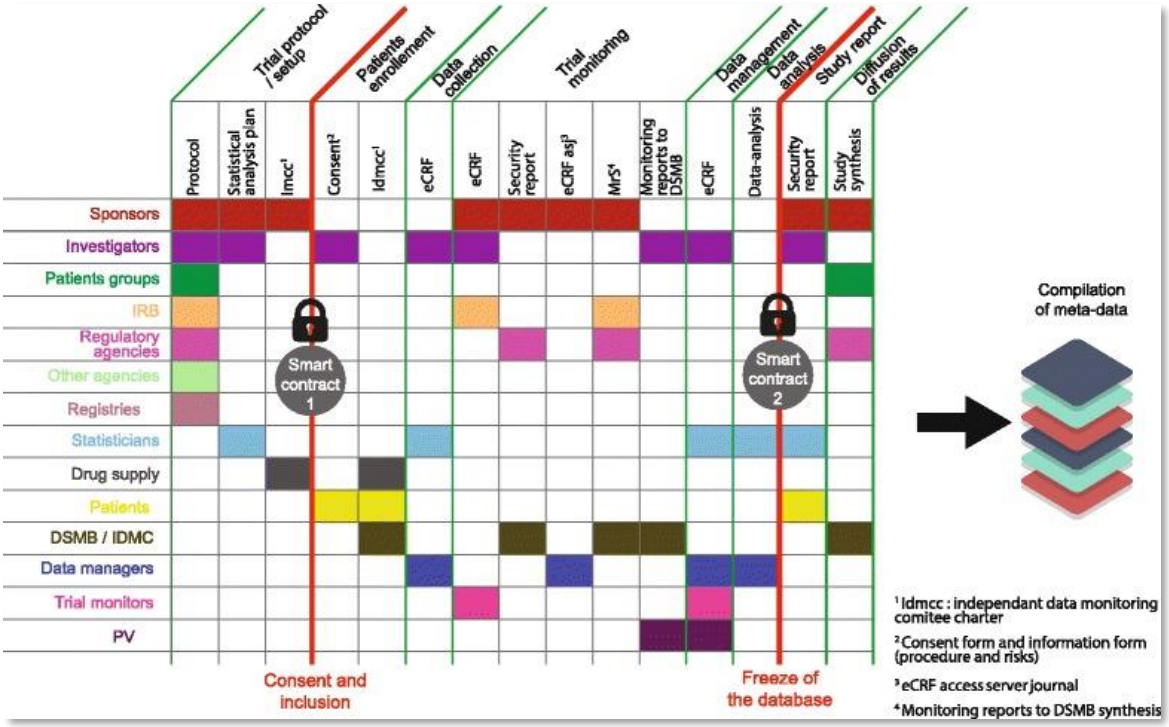


Figure E. Blockchain workflow for complete

OTHER BENEFITS:

- Can be utilized to stream line trial data collection for each phase with proper traceability of data.
- One can't change the source data captured as desired or in intent to fit the protocol end points, as all of them are recorded with tamper proof timestamps.
- Patient can easily have control over their consent and their medical records by their own discretion.
- The person in charge of site monitoring can have controlled access to study data and medical records.
- In the clinical trials for the safety of the patient there will be proper accountability and transparency in reporting process.
- A secure platform for data submission with real time record for every submission done.
- There won't be need of centralised server or a third-party management system for data management and data ownership.
- Cost spent on security systems for clinical trial data can be minimized as the security of the data gets shared among the trial participants.
- For reviewers and readers, access to clinical trial data can be provided by scientific publications or pharmaceutical company based on the requirement and request.

CONCLUSION:

As an emerging technology blockchain has its own challenges which are to be addressed while incorporating it to clinical trials. The benefits of utilizing it will increase data integrity with an invulnerable system containing all of trial data. Moving forward there will be a drastic shift towards blockchain technology for its core features provided in a cost-efficient manner. The proof of concept working models developed to demonstrate its properties have shown good results which indeed paves way for wider use of this technology in clinical trials.

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