

Abstract:

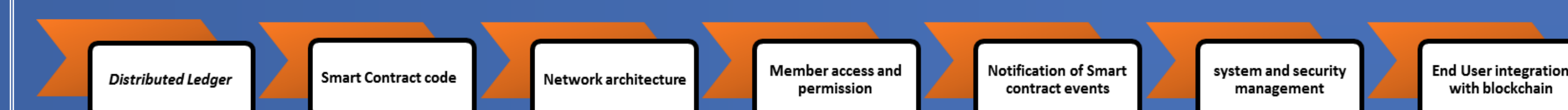
In our current digital age, integrity and security of data is of utmost importance and for that huge amount is spent to have a secure system, where breaching or tampering must be checked time by time. This will automatically increase the maintenance cost and need to be constantly on threat alert with 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.

What is a Blockchain ?

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.

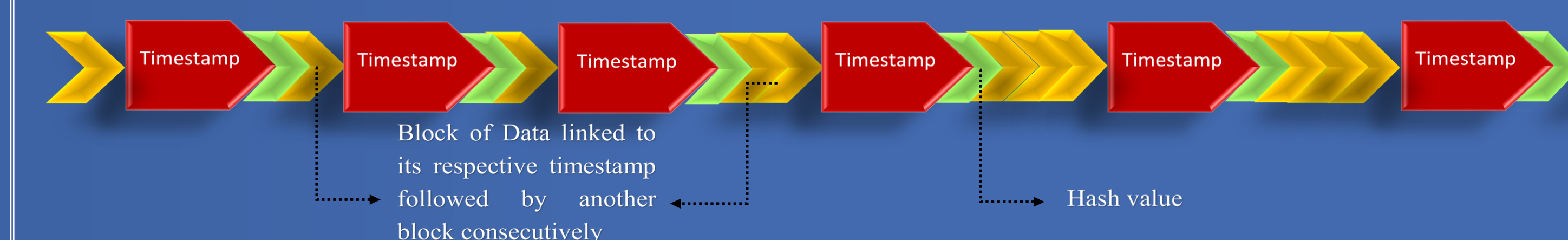
Basic components of a blockchain:

Below process chart illustrates the basic components of blockchain .



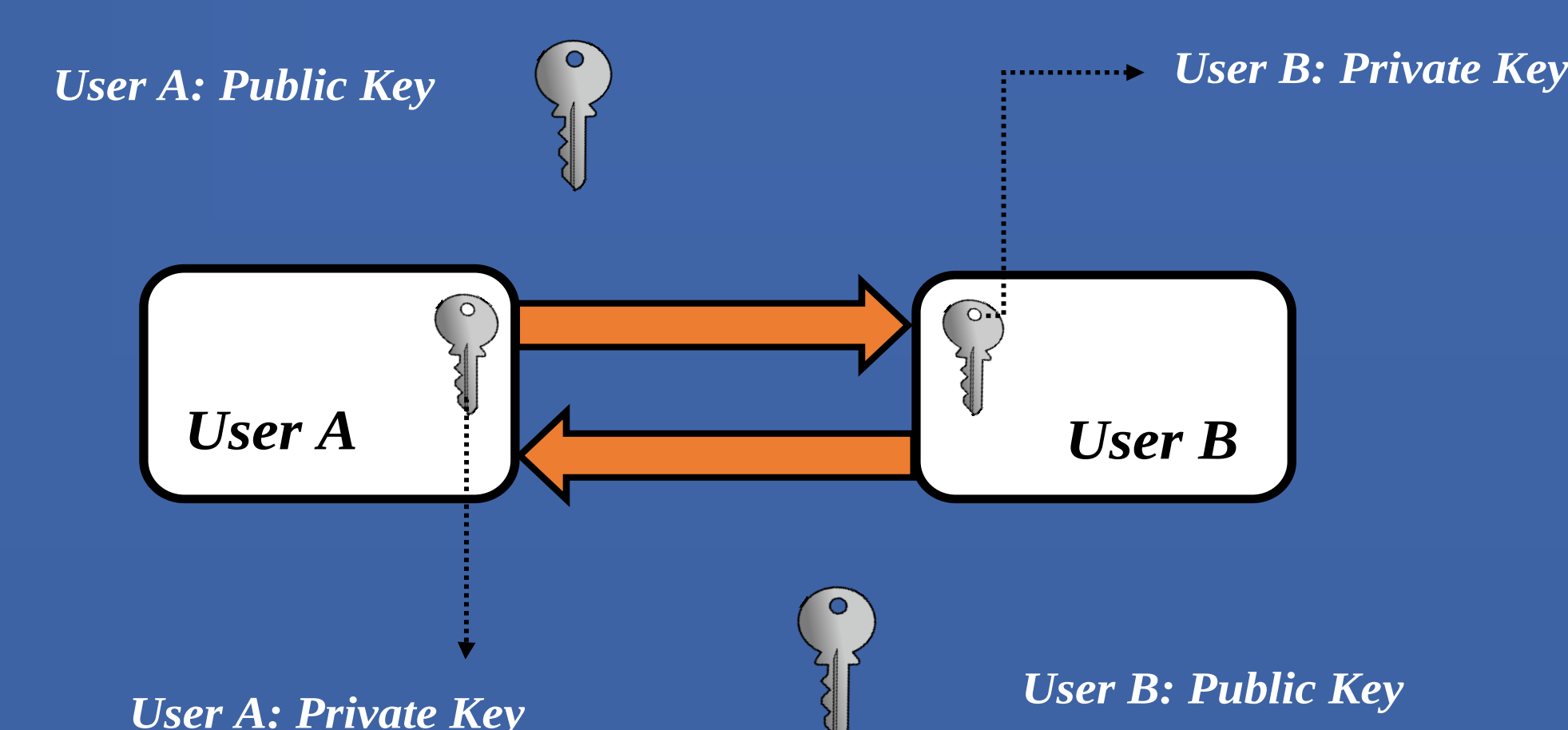
Data Blocks and Timestamps:

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.



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.



Blockchain network types:

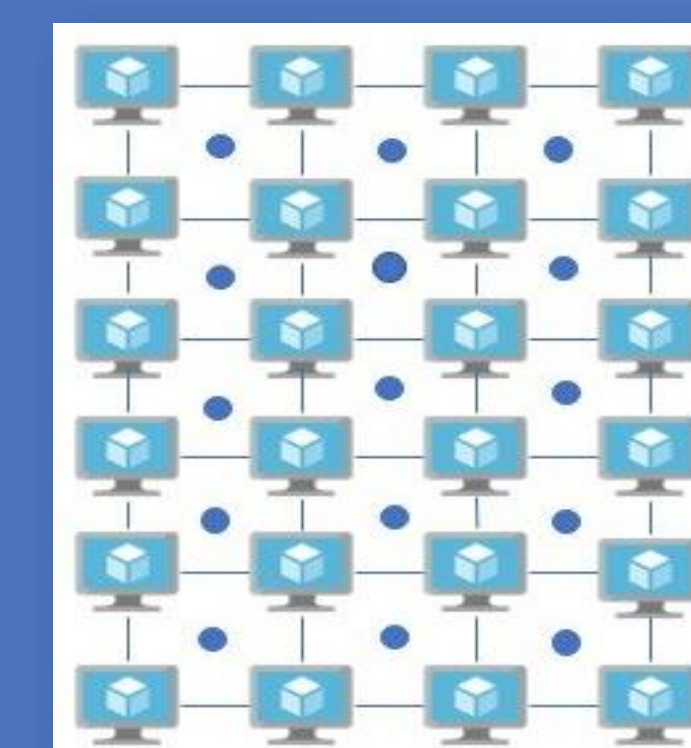


Figure A. Public or Decentralized Blockchain

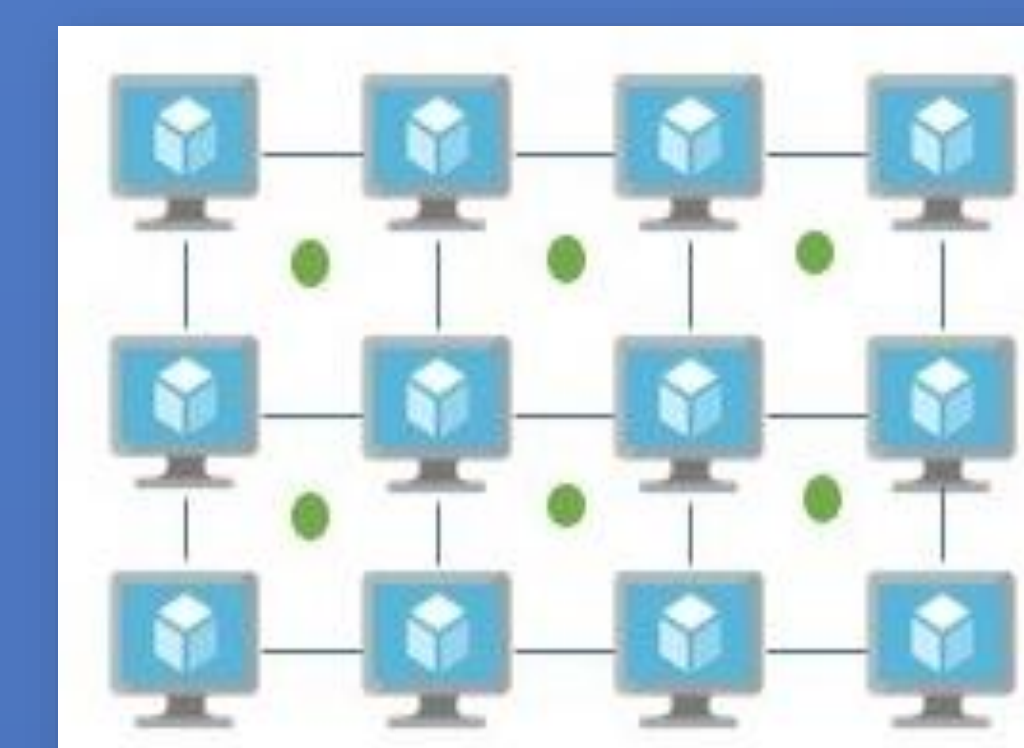


Figure B. Consortium or Distributed Blockchain

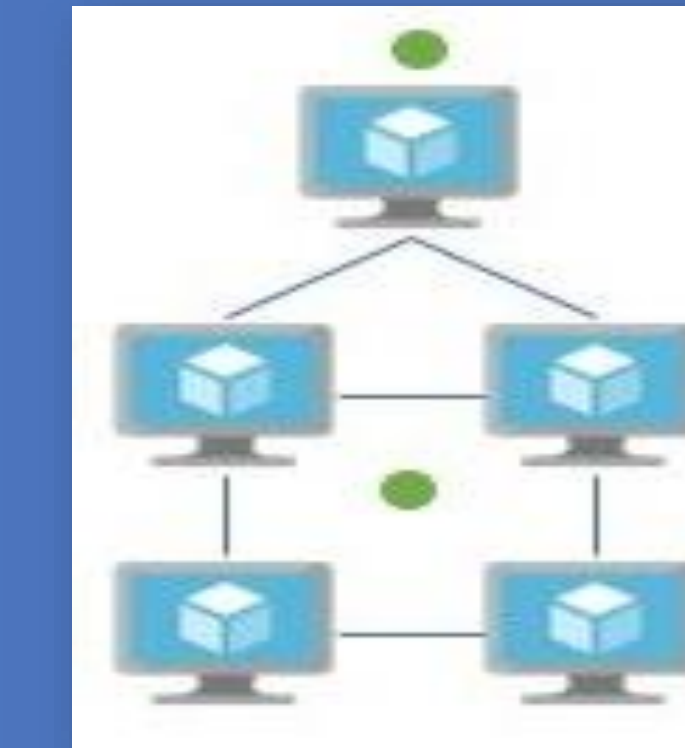


Figure C. Private or Centralized Blockchain

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 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:

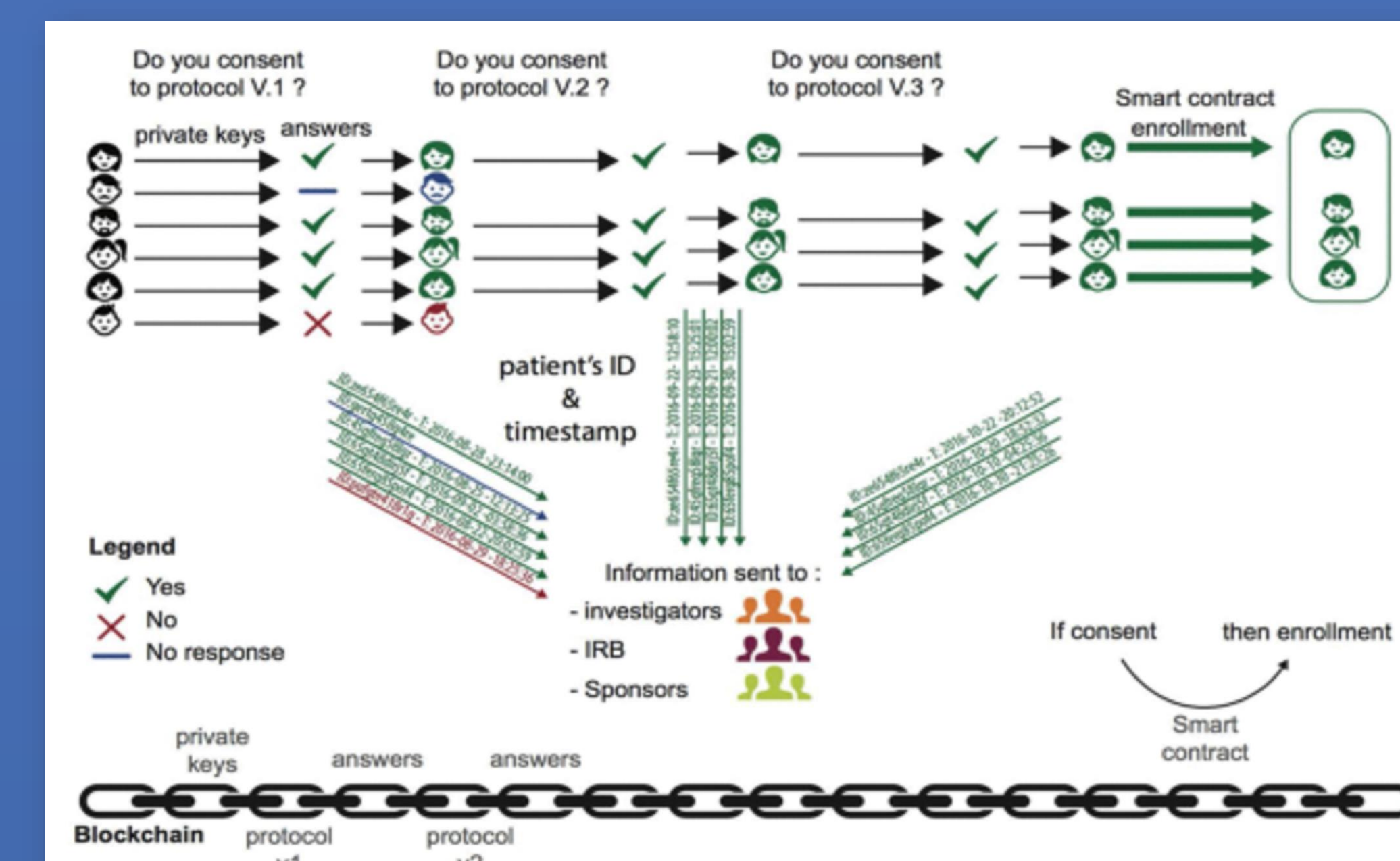


Figure D. Blockchain workflow for consent collection

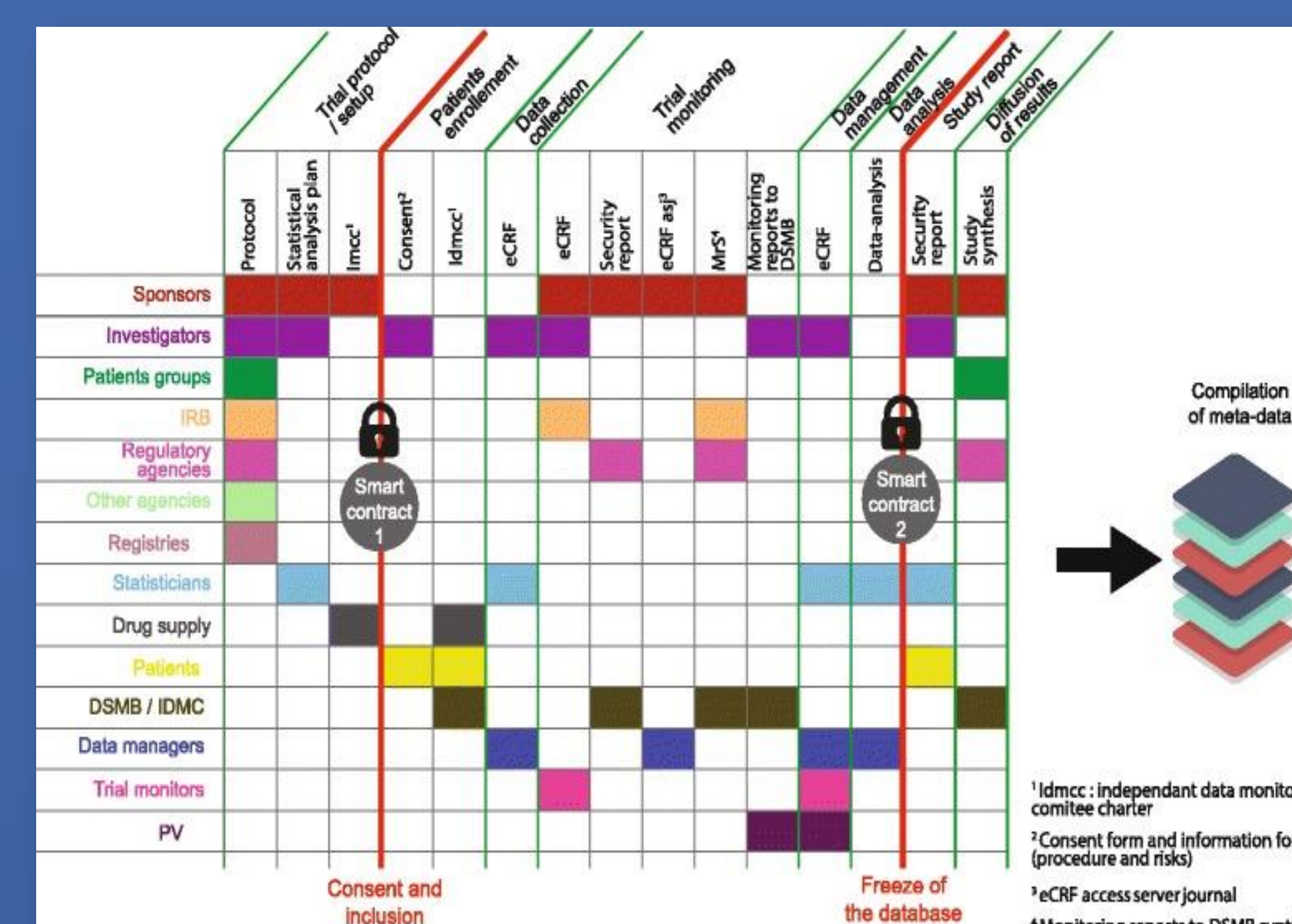


Figure E. Blockchain workflow for complete Clinical trial

Benefits and Scope of use in Clinical Trials:

- ❖ 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.

References:

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