

# Possibility of Process Improvement by Blockchain Technology in Pharmaceutical Industry

CJUG SDTM Blockchain sub-team

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# Agenda

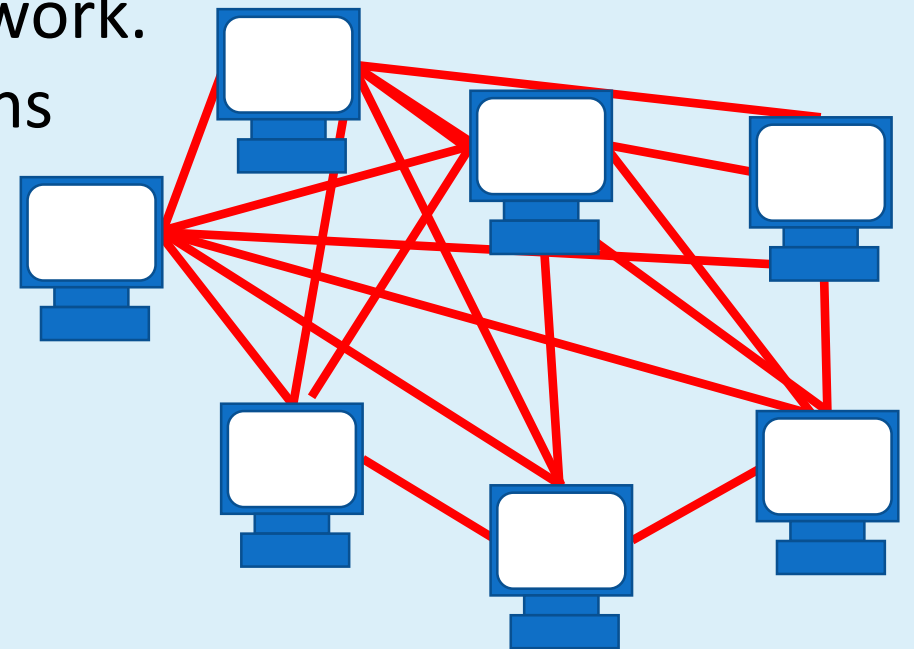
1. Blockchain technology
  - Data structure
  - Smart contract
  - Pros/Cons
2. Use cases of Blockchain in Pharma industry
  - FDA pilot
  - Clinical trial
  - Traceability
3. Proposed idea using Blockchain system
  - Our suggestion
  - System overview
  - Advantage of this system
  - Future outlook

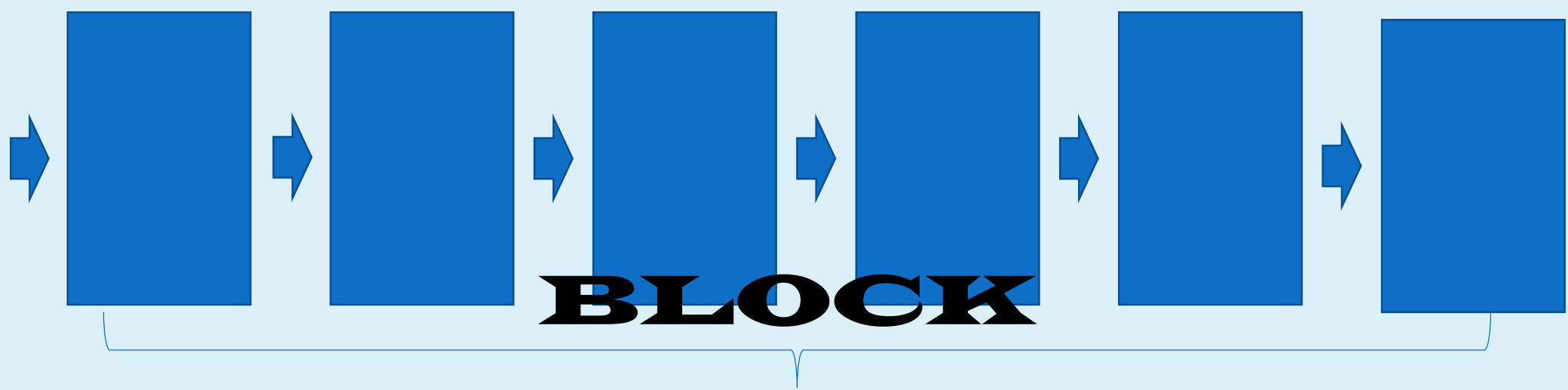
# 1. Blockchain technology

# Data structure

- Blockchain is a distributed ledger technology.
- Transaction histories spread through P2P network.
- Blockchain network users verify all transactions
- Transactions are recorded in blocks.
- Each block has a hash value of the previous block and blocks are connected like a chain.

Connected by P2P (peer-to-peer) network





## Contents of data in a block

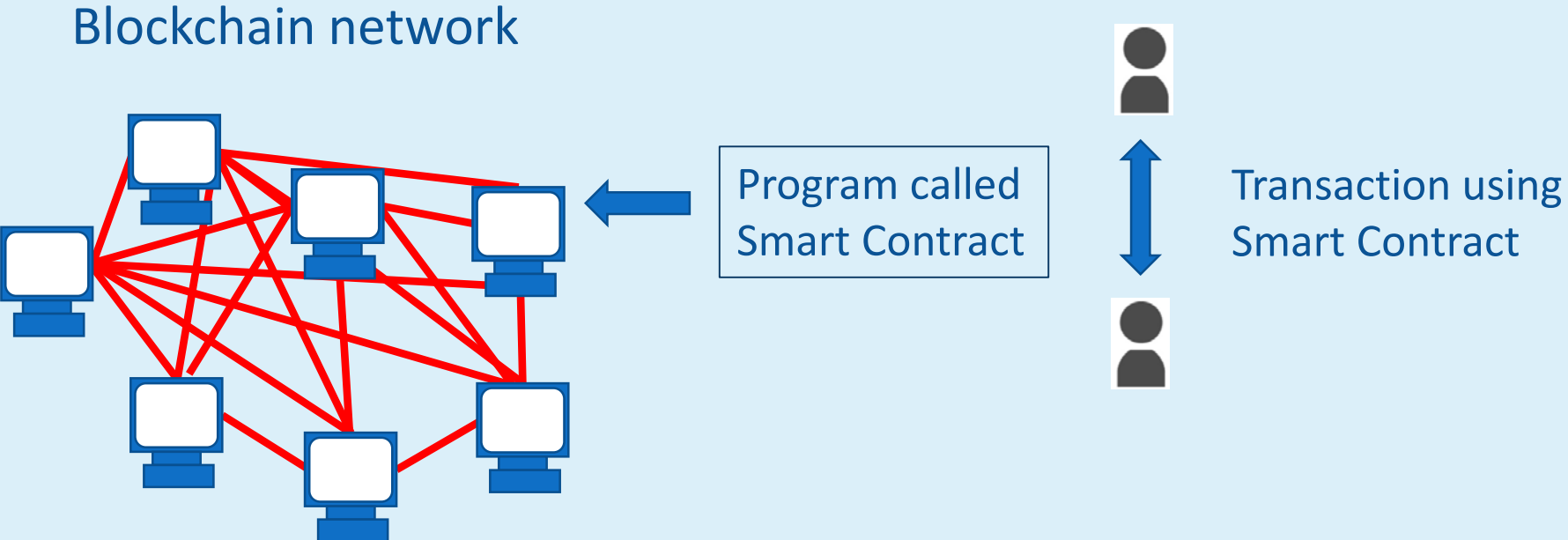
- Transaction data
- Hash value of the transaction data of the previous block
- NONCE: The value to adjust hash value to meet the condition (Need huge calculation to find NONCE)

### ***Is it possible to alter transaction data in the Block?***

**If data in the Block is updated, it will generate different hash value. Therefore, it is practically difficult to rewrite all the hash values of the subsequent blocks.**

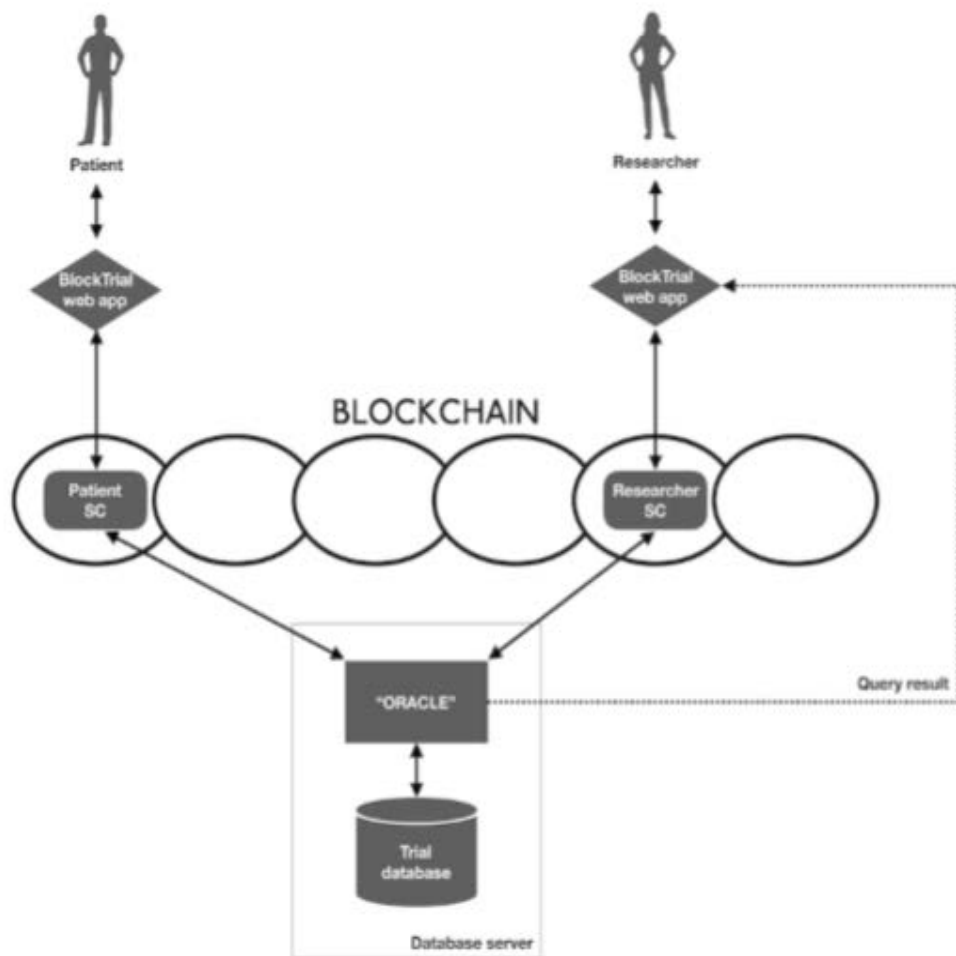
# Smart Contract

A program distributed in a Blockchain network is automatically executed when condition is met, and results will be given and recorded.





**Figure 2.** The BlockTrial structure—patients and researchers interact with BlockTrial through the Web-based BlockTrial App. SC: Smart Contract.



**This study presents a proof-of-concept Blockchain-enabled clinical trials data management solution that enables the interaction of patients and researchers engaged in clinical research.**

**Textbox 1.** Smart contract methods.

**Patient Smart Contract**

- addPatient: Registers a patient for the study and sets access permissions
- editPermissions: Changes a patient's access permissions
- getPeople: Gets the set of patients registered for the study

**Researcher Smart Contract**

- addQuery: Submits a new query to the blockchain
- addQueryResult: Places a hash of a query result on the blockchain
- getQueries: Retrieves waiting queries from the blockchain
- getUnsolvedCount: Retrieves the number of waiting queries from the blockchain

# Advantages of Blockchain

- Tampering data is extremely difficult
  - If data tampering is performed, hash value of subsequent block have to be adjusted and that will be huge calculation.
- Benefit of decentralized system
  - There is no central governance/control. And system will not be down even if some nodes of a network are down due to a cyber attack or failure, it is still possible to maintain data and keep the infrastructure running.

# Disadvantages of Blockchain

- Scalability
  - As blocks are generated at specific time interval, transaction amount is limited. E.g.) In case of Bitcoin, several transactions /second
- Capacity
  - There is an upper limit of amount of data each block can store, thus not possible to store large amount data.
- Privacy
  - Because everyone can see all transactions, confidential data cannot be uploaded and handled in a public network.

# Pros/Cons of Blockchain technology

## Pros

- Tampering data is difficult
  - Encrypted data (hash value) is irreversible.
  - If data is altered, different hash value will be generated.
  - Huge calculation is required if data is altered.
- Benefit of decentralization
  - If some nodes of a network is down, system can be still running and data is kept as usual.

## Cons

- Scalability
  - Limit of data block can store.
  - Limit of generating blocks at time
  - Thus transactions amount is limited
- Privacy
  - Transactions can be seen by all
- Capacity
  - Not suitable to store large data

## 2. Use cases of Blockchain in the Pharma industry

# FDA pilot projects

- In 2017, formal intent to study blockchain technology:
  - Partner: IBM Watson Health,
  - Explore how data (e.g. electronic medical records, clinical trials, and wearables) could be better shared and stored
  - Leverage the large volumes of diverse data in today's biomedical and healthcare industries
  - Define a secure, efficient, and scalable exchange of health data using blockchain technology.
- In 2018, a pilot project has been started:
  - Partners: Four major hospitals, Booz Allen Hamilton (consulting firm)
  - Purpose: Evaluate how blockchain technology could be implemented to facilitate the secure sharing of information among the FDA, health care providers, and hospitals

## Details of pilot projects

- Enable real-time exchange of patient-level data within the network for in 2017/2018
  - Partners: Booz AllenHamilton
  - Using RAPID(Application for Portable Interactive Devices)

**They developed a purpose-built solution based on hospital privacy and security requirements that leverages a collection of strong cryptographic algorithms to enable user and group based secret sharing.**

### Overcoming Cons of Blockchain technology

- ✓ Privacy  
-> **Facilitating additional layers of encryption that enforce privacy of content embedded within transaction data**
- ✓ Capacity  
-> **Using IFPS decentralized filesystem that deploy alongside blockchain nodes to enable storage of very large files**

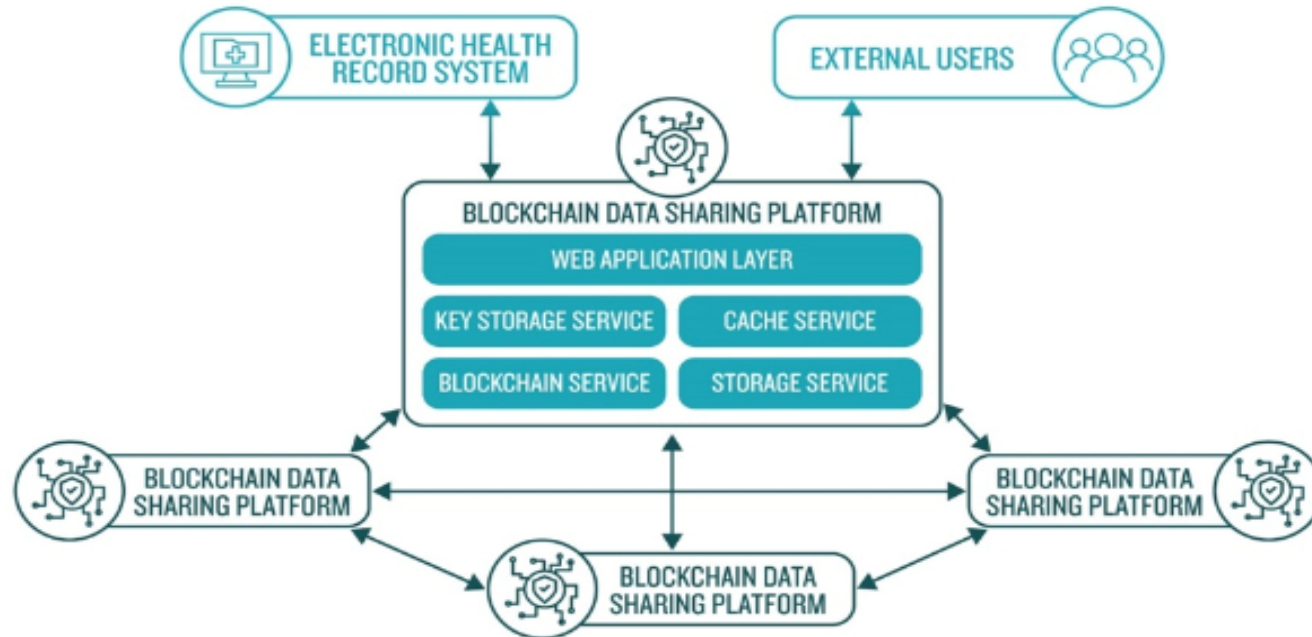
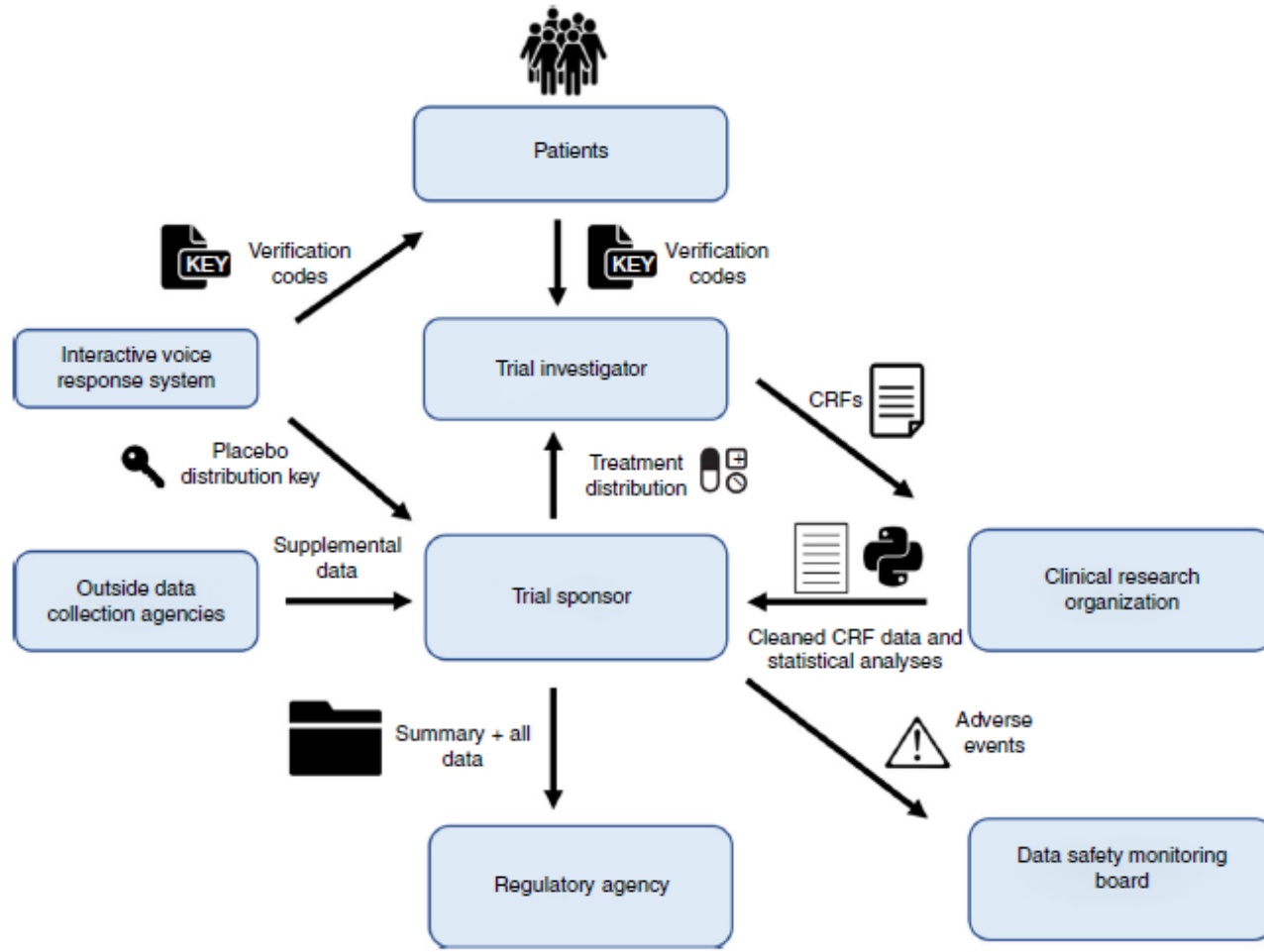


Figure 1. An illustration of the system architecture of our blockchain solution

# Clinical Trial



**Fig. 1** The idealized clinical trial network in the context of a blockchain-based record system. The various transactions (along each arrow) and key participants (boxed) within a clinical trial are shown

By using the actual clinical trials data from a previously completed major clinical study, they showed that data entry, storage, and adverse event reporting can be performed in a more robust and secure manner, which could withstand attacks from both other people in the network and infrastructure damage at the storage level.

## Overcoming Cons of Blockchain technology

- ✓ Scalability  
-> Not be overcome, but indicating scalability is possible via growing cloud storage capabilities
- ✓ Privacy  
-> Encryption through a password based key derivation function is offered
- ✓ Capacity  
-> Not be overcome, but indicating data storage of the blockchain will be accomplished by duplicating and distributing the chain to physically separate machines and data warehouses to be managed by the regulator



# Traceability of drug supply chain

## **IBM, Walmart, KPMG, Merck build Blockchain for drug supply chain**

- Proof-of-concept of a Blockchain network partnering with the US FDA (Food and Drug Administration).
- The purpose is to support development of a Blockchain network that enables FDA and companies involved in drug supply chain to identify and track prescribed drugs.
- The proposed Blockchain network addresses challenges of the current supply chain, reduces inventory tracking time, and improves the accuracy of data shared between companies in the supply network.

Reference: (Gagliardi, 2019)

3. Proposed idea using Blockchain system by  
CJUG-SDTM Blockchain subteam

# Background

- There are some existing systems for Clinical Data Sharing but privacy protection is not enough
- Even if we anonymize, the risk for identifying personal information still remains
- The patients have no access to information where/when/how their data are used
- Currently patients cannot reject secondary use of their data under the way of anonymization

# Existing data sharing platforms

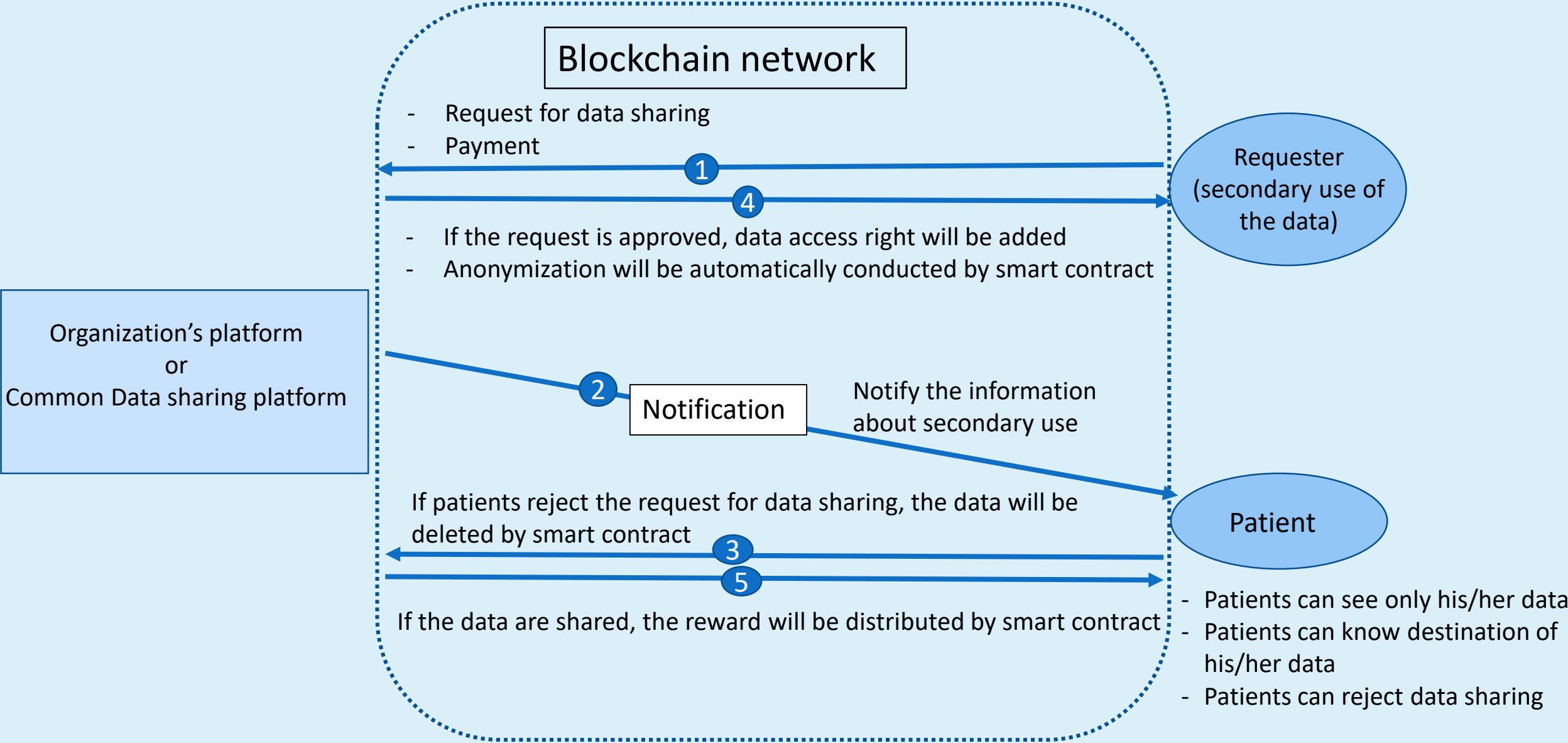
- [ClinicalStudyDataRequest.com](https://clinicalstudydatarequest.com)
- Project Data Sphere
- ImmPort
- FreeBIRD
- Vivli
- The platform created by individual Pharmaceutical company

All systems cannot protect personal information completely and an improvement is necessary

# Our suggestion

- Get an agreement for secondary use of data in the beginning of clinical trial
- Manage data access rights using Blockchain
- Develop the system which records and visualizes where SDTM data is shared in Blockchain and enables patients to know destination of data
- Develop the system which enables patients to reject data sharing by smart contract function in Blockchain
- Develop the system which automatically execute payments to patients by smart contract function in Blockchain

# Data flow after sharing in Blockchain network



# Advantage of using Blockchain

- Blockchain can trace destination of data sharing, and transaction records cannot be altered
- Blockchain can manage transactions among multiple platforms
- Distribution of payments and management of access rights will be executed by smart contract

# Innovation by this new system

- Improvement of the way to protect personal information
  - Patients can access to information where/when/how their data are used
  - Patients can reject data sharing any time
- Decentralized transaction management
  - Requester can directly connect to providers of data, and transaction records will be verified publicly
- Rewards to patients for secondary use of data



# Future outlook

- Create detailed specification to develop this system
- Create a prototype
- Test prototype using simulated data
- Collect errors/problems and fix them to apply for actual data

# Key takeaways

- Blockchain technology is expected to be applied to some processes in Pharma industry.
- Understanding Pros/Cons of Blockchain is important to apply.
- The team is planning to develop clinical trial data sharing system using Blockchain.

# References

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Thank you for attending!  
Any questions?