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Blockchain Technology for clinical data sharing

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Meet the Speaker

Kentaro Arai

Title: Statistical Programmer

Organization: Novartis Pharma K.K.

Team activity related to Blockchain

- 2019 - Now: CJUG-SDTM Blockchain team
- 2019 - 2020: JPMA Blockchain task member
- 2020 – 2021: Dell technologies DX acceleration program(Supported by Dell & NAIST)

Events related to Blockchain

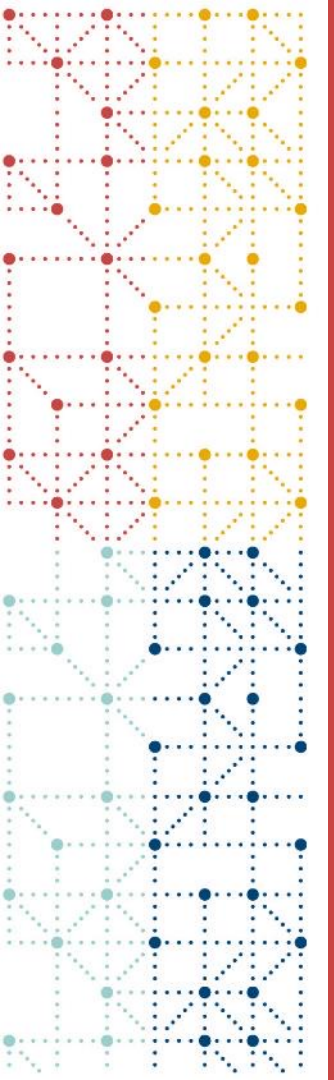
- 2018: Hackathon event sponsored by EMURGO and Tokyo University of Science
- 2019: Hackathon event sponsored by METI (Best award)
- 2020: DX contest sponsored by DELL technologies (Second place)

CJUG-SDTM Blockchain team

- CJUG: CDISC Japan User Group
- Team formed in May 2019 as sub team in CJUG-SDTM
- 7-10 members: Stat programming, Data management, System expert, etc.

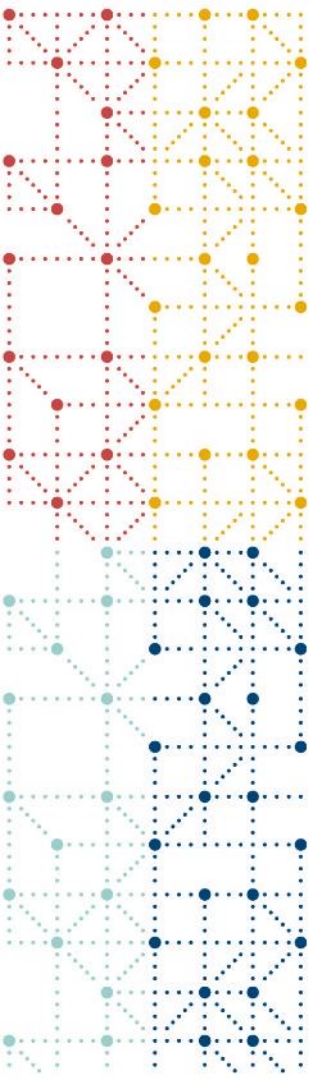
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC and their organization.*
- The author(s) have no real or apparent conflicts of interest to report.



Agenda

1. Overview of Blockchain technology
   - Background
   - Elemental technologies and Mechanism of Blockchain
   - Topics in Pharma
2. PoC conducted by CJUG Blockchain team
   - Related technologies: IPFS, ABE
   - Overview of PoC

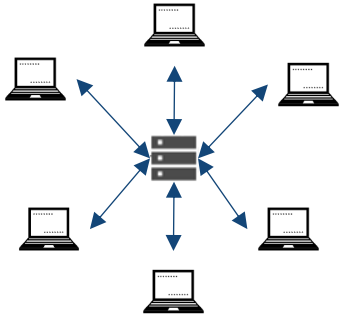


Overview of Blockchain technology

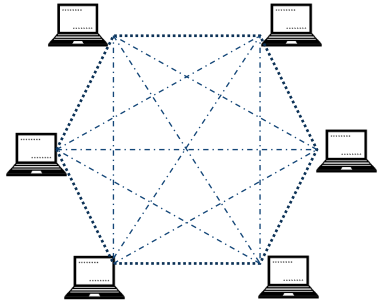
- Background
- Elemental technologies and Mechanism of Blockchain
- Topics in Pharma

What is Blockchain?

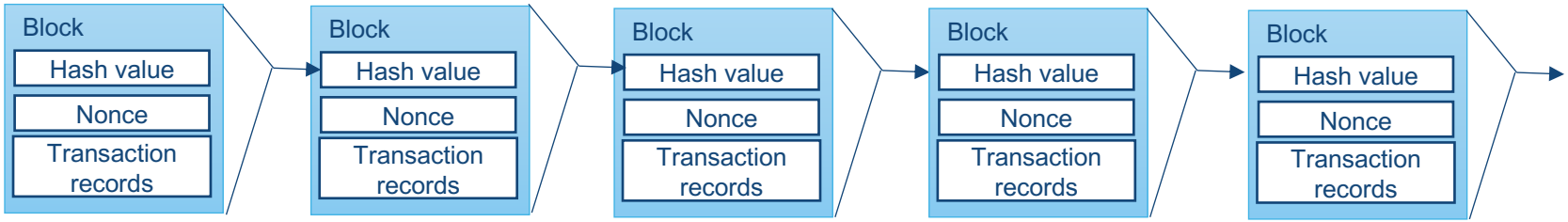
Centralized system



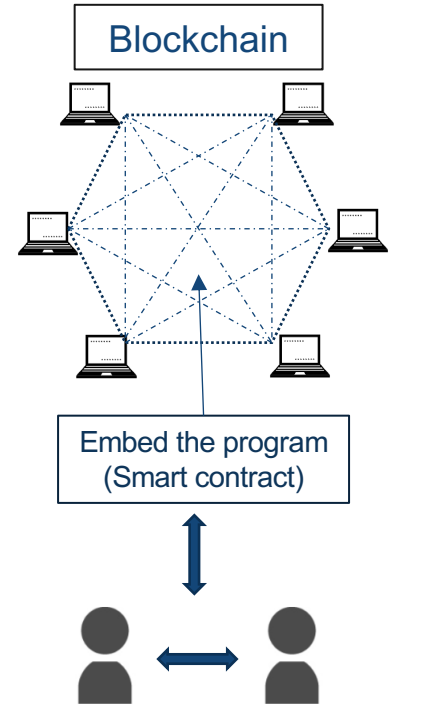
Blockchain-based system



- Core technology of Bitcoin
- Core technology of Web3, NFTs, DAO etc.
- P2P based decentralized system
- Store the right data in the block by consensus algorism
- PoC is ongoing in Pharma industry



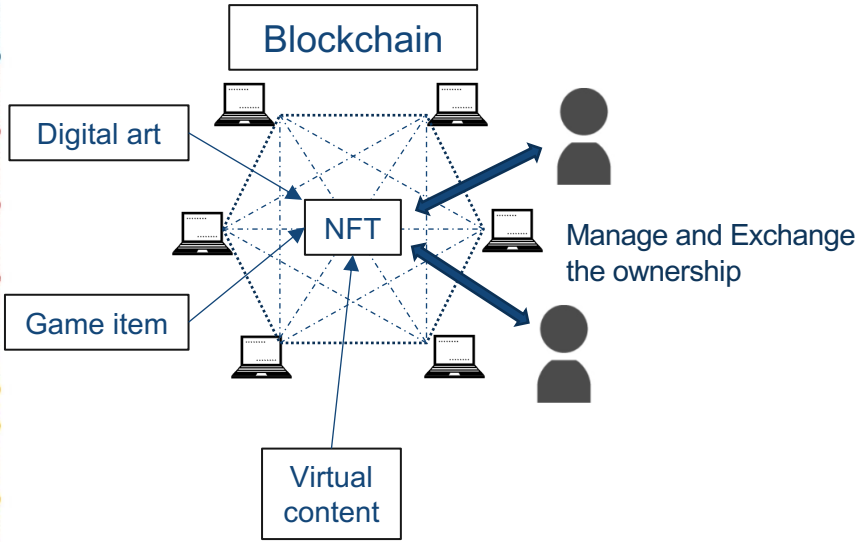
Smart contract



Transaction using Smart Contract

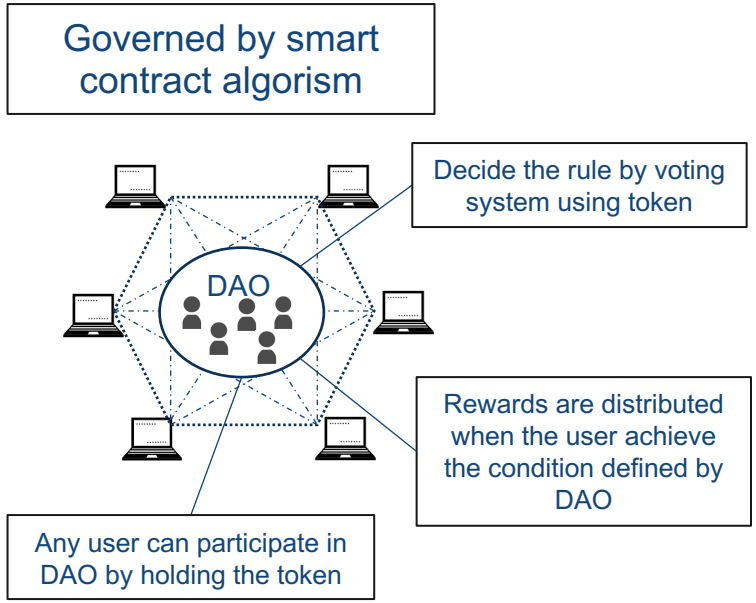
- Programs can be embedded on the blockchain
- Transactions are verified and recorded on the blockchain
- Automated transactions are possible without administrator
- Reduction of system usage fees and intermediary fees are expected
- Once a smart contract program is deployed on the blockchain, it cannot be modified
- Not suitable for transactions that require flexible exchange

NFT: Non-Fungible Token



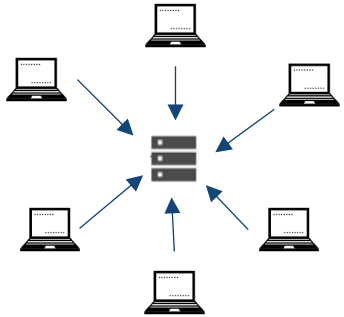
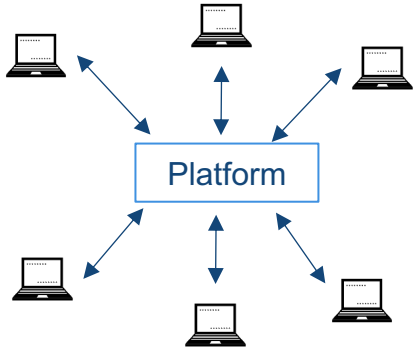
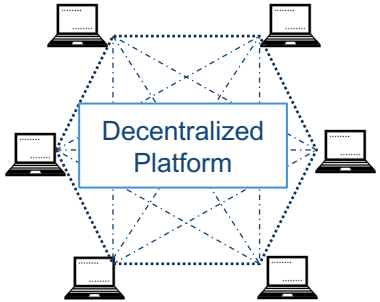
- Tokenized digital content on the blockchain
- Manage the ownership for various digital content such as art, music, and virtual items
- NFT cannot be duplicated because managed by Blockchain
- Monetization is also possible through NFT transactions

DAO: Decentralized Autonomous Organization



- Guarantees transparency and reliability as managed by program
- Tasks run under decentralized system without administrator

Web3.0

Centralized		Decentralized
Web1.0 (1990~200x)	Web2.0 (200x~2020)	Web3.0 (2021~)
		
Read the contents Ex.) Simple web page	Social media and user-generated content Ex.) SNS	- Blockchain based decentralized system. - Manage the ownership of data. - Exchange the value Ex.) NFT, DAO, DeFI, Dapps

Pros/Cons of Blockchain

Pros

- Tamper resistance
  - If data is altered, different hash value will be generated.
  - Huge calculation or consensus process is required if data is altered.
- Benefit of decentralization
  - System down resistance
  - Intermediary institution is not required
- Transparency
  - All transactions are open and can be traced

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

Recent topic in Pharma

- Clinical trial using Blockchain based EDC system
  - ➢ Tamper-resistance check function
  - ➢ Function to guarantee compliance with procedures by smart contract
  - ➢ NFT of clinical data for future secondary use

Reference: https://jrct.niph.go.jp/en-latest-detail/jRCT1030220258

- A major pharmaceutical company released a roadmap for web3

Reference: https://note.chugai-pharm.co.jp/n/nbd1b39eaab4b

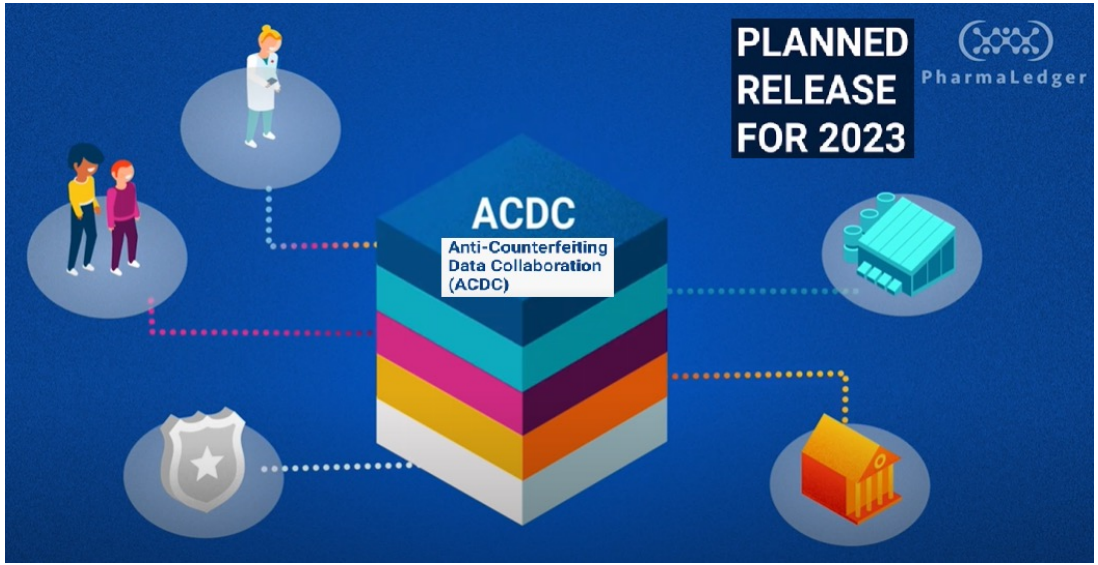
- NFT platform for personal healthcare data

Reference: https://aimedis.com/exchange

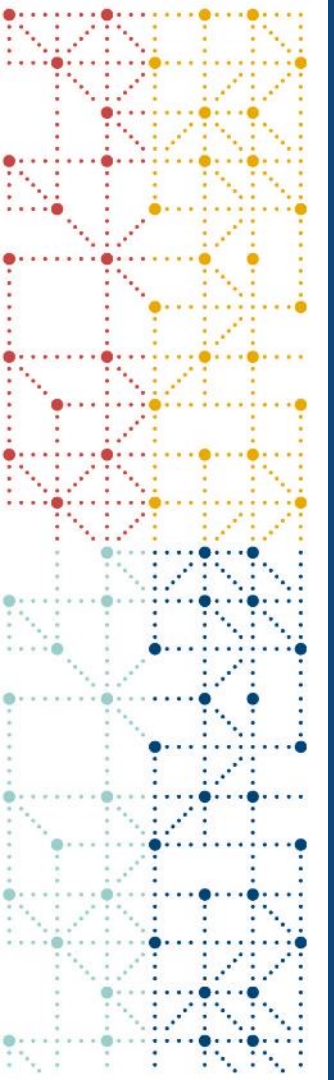
Recent topic in Pharma

PharmaLedger (2020-2023)

- Health data
  - Personalized Medicine
  - Clinical Trial Recruitment
- Clinical Trials
  - Medical Device IOT
  - eConcent
- Supply chain
  - Clinical Supply Traceability
  - Finished Goods Traceability
  - eLeaflet ePI
  - Anti-Counterfeiting



Reference: https://pharmaledger.eu/



PoC conducted by CJUG Blockchain team

- Related technologies: IPFS, ABE
- Overview of PoC

Team members

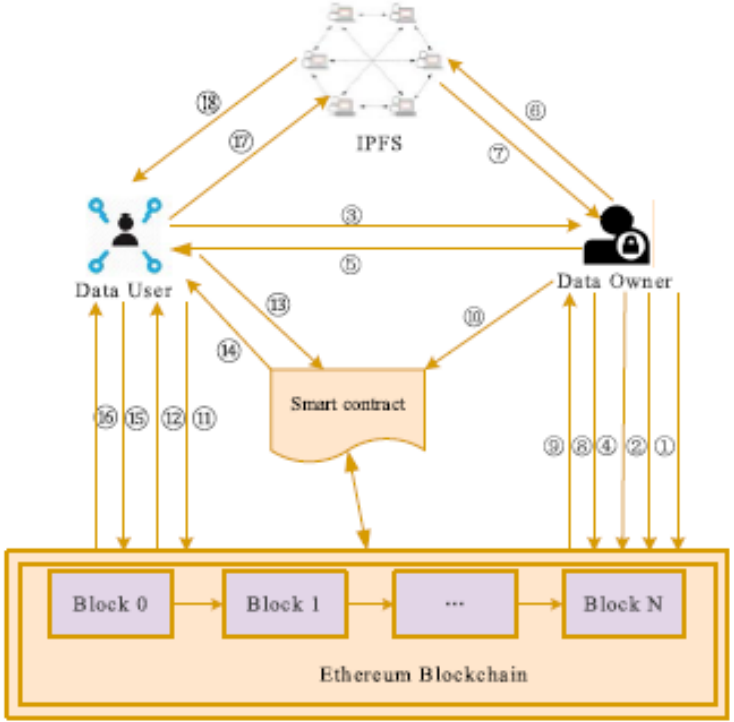
- CJUG-SDTM Blockchain team (5~8 members)

- Dell Technologies (Oct 2020 – Oct 2021)
  - Facilitator
  - Technical support
- Nara Institute of Science and Technology (Oct 2020 – Oct 2021)
  - Technical support

Theme of investigation

- Investigate the effective use of Blockchain in Pharma industry
  - ➢Explore effective use of Blockchain in clinical data sharing
  - ➢PoC for access control of clinical data using Blockchain

Referred concept: IPFS × Blockchain × ABE



Rerefence: S. Wang *et al.*: Blockchain-Based Framework for Data Sharing With Fine-Grained Access Control

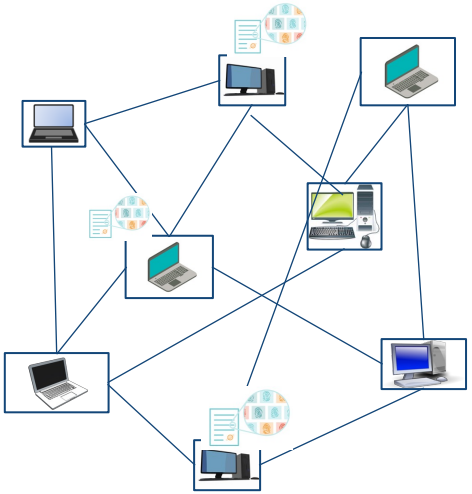
- IPFS(Interplanetary File System): P2P based distributed database
- Access control by the combination of smart contract and ABE*(Attribute-based encryption)

*ABE: Multiple decryption keys can be created for one encryption key according to attributes

Only the data owner can control the access right

IPFS: InterPlanetary File System

The data are store in P2P based system



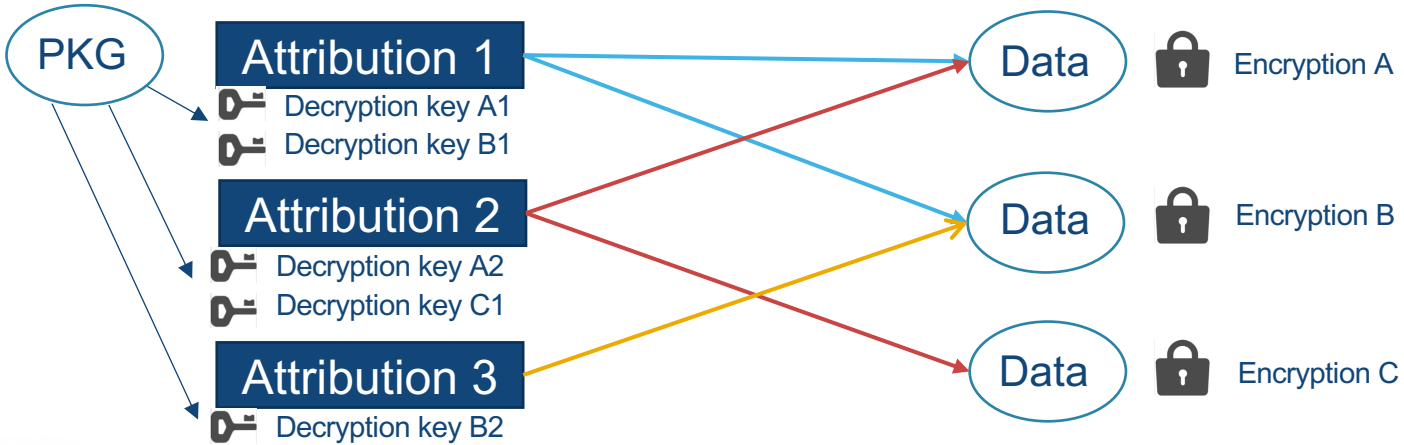
Hash value is used for the data location

Condition for access
- The data is stored in any of the nodes
- Hash value information is available

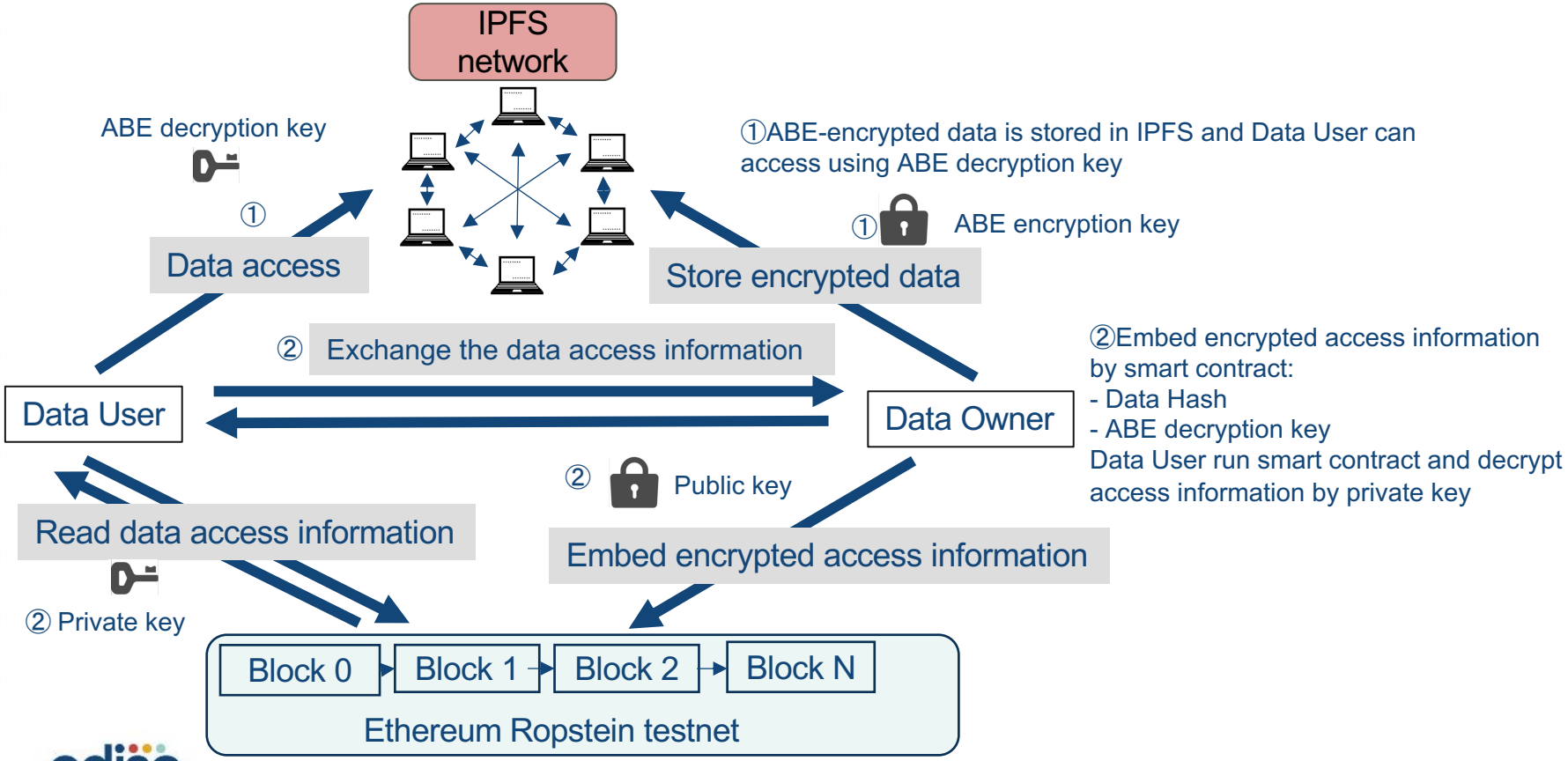
- In case of large data such as clinical data, data can be stored by dividing it among nodes.
- Advantage: Tamper resistance, System down resistance, Censorship resistance

ABE: Attribute-Based Encryption

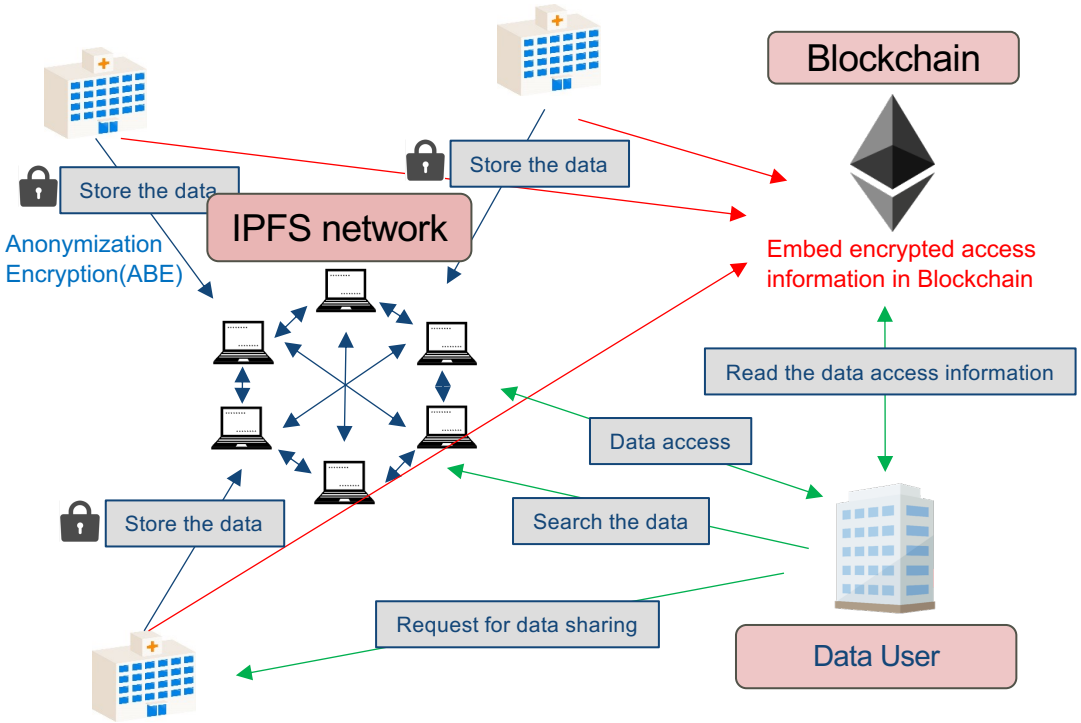
- Multiple decryption keys can be created for one encryption key according to attributes
- Institution of PKG (private key generator) and data server are separated
- In case of normal ABE system, PKG can access to all data, but this can be solved by combining IPFS and Blockchain



PoC : IPFS × Blockchain × ABE



Expected use case



- Consortium type should be used
- Decentralized management system will be possible
- Only the data owner can manage the access right

Expected advantage of Blockchain × IPFS × ABE system

- Mechanism of data access control
  - Only data Owner can manage the access control in consortium network
  - Trustless system (Don't need to trust third party)
- Advantages of IPFS
  - Tamper resistance
  - System down resistance
  - Server load distribution
  - Censorship resistance
- Transparency and tamper resistance of transaction history by recorded in Blockchain
- Possibility of cost down

Challenges to feasibility

- Only encryption is not enough in terms of personal information protection
- Further evaluation of ABE encryption is needed
- Unification of data standards is needed

Summary of PoC

- It was confirmed that a series of assumed flows could be constructed
  - Storing and retrieving data to and from IPFS
  - Writing and retrieving access information to Blockchain
  - Encryption/decryption with public encryption and ABE encryption
- Future plan
  - Construction and verification of a system with a detailed flow
  - Verification of encryption reliability
  - Verification of expected operation cost
  - Verification of operational feasibility with large data (ex. encryption of large data)
  - Investigation of a method to manage data by linking it to individual patients

Key takeaways

- Blockchain technology
  - Decentralized system
  - Advantages and disadvantages should be considered when applying
  - Some PoC have been done in Pharma industry
- Result of PoC
  - Only Data Owner can manage the access rights
  - Further PoC is needed

Thank You!