DRUG TRACEABILITY

(USING BLOCK CHAIN TECHNOLOGY)

TEAM_ID: NM2023TMID00868

INSTITUTION: UCEK - 5134

DRUG TRACEABILITY

1. INTRODUCTION

The pharmaceutical industry is one of the most regulated industries in the world. The safety and efficacy of drugs are of at most importance to ensure patient safety. However, the supply chain of drugs is complex, and it is challenging to track the movement of drugs from the manufacturer to the end consumer. Counterfeit drugs are a significant concern in the pharmaceutical industry, and they can have serious health implications for consumers.

Blockchain technology has emerged as a promising solution to address the challenges associated with drug traceability. Blockchain is a distributed ledger technology that provides a secure and transparent platform for tracking drug movements. The use of blockchain technology can help to prevent counterfeit drugs from entering the supply chain, thereby ensuring patient safety.

1.1. PROJECT OVERVIEW

A drug traceability project aims to enhance pharmaceutical product tracking and patient safety. It involves unique identifiers, data management, supply chain integration, serialization, data security, and regulatory compliance. The system allows for real-time tracking and verification, helping combat counterfeit drugs and streamline the supply chain. Continuous improvement and cost considerations are key factors in project success.

1.2. PURPOSE

Drug traceability in blockchain technology serves several crucial purposes in the pharmaceutical industry, primarily focusing on enhancing transparency, security, and trust throughout the supply chain. Here are the key purposes of implementing drug traceability in a blockchain:

1. **Anti-Counterfeiting and Product Authenticity:** Blockchain ensures the authenticity of pharmaceutical products, preventing counterfeit medications from entering the supply chain.
2. **Transparency and Trust:** Blockchain enhances transparency and trust among stakeholders by providing a shared and immutable ledger for tracking drug movements.
3. **Real-time Tracking and Tracing**: Blockchain enables real-time tracking and tracing of pharmaceutical products, allowing for rapid responses to recalls and supply chain issues.
4. **Data Integrity and Regulatory Compliance:** Blockchain ensures data integrity and simplifies regulatory compliance, helping pharmaceutical companies meet stringent requirements.
5. **Efficiency and Supply Chain Optimization:** Blockchain streamlines processes, leading to a more efficient pharmaceutical supply chain with potential cost reductions and waste reduction.
6. **Consumer Empowerment and Data Privacy:** Blockchain empowers consumers to verify the authenticity and origin of drugs, while maintaining data privacy and security in the healthcare sector.

2. LITERAURE SURVEY

In recent years, the application of blockchain technology to pharmaceutical drug traceability has emerged as a transformative solution to address critical challenges in the industry. Blockchain's decentralized, immutable, and transparent ledger system offers a promising avenue for ensuring the authenticity of pharmaceutical products and enhancing supply chain security. Research in this domain has underscored the pivotal role of blockchain in combating counterfeit drugs, streamlining supply chain operations, and fostering trust among stakeholders. Case studies and real-world implementations have showcased the practical benefits of blockchain, and they have demonstrated its efficacy in tracking the movement of pharmaceutical products in real-time. Moreover, the technology's potential in meeting stringent regulatory requirements, such as the U.S. Drug Supply Chain Security Act (DSCSA) and the European Union's Falsified Medicines Directive (FMD), has gained prominence in the literature.

However, the literature also reveals ongoing challenges, including scalability issues, adoption barriers, and cost considerations that must be addressed for widespread implementation. Data privacy and consent management in a transparent system, as well as the need for interoperability among diverse stakeholders, have been focal points of discussion. As the field advances, emerging technologies like the Internet of Things (IoT) and artificial intelligence (AI) are anticipated to play significant roles in further optimizing drug traceability in blockchain. In conclusion, the literature survey underscores the substantial potential of blockchain in revolutionizing pharmaceutical traceability, while acknowledging the need for continued research and innovation to overcome the existing hurdles and fully realize the transformative capabilities of this technology in the pharmaceutical industry.

2.1. EXISTING PROBLEM

Existing problems in drug traceability using blockchain include scalability issues for high transaction volumes, complex integration with legacy systems, the challenge of balancing data privacy and transparency, the high implementation costs, the need for widespread user adoption and education, varying regulatory requirements across regions, the potential for single points of failure in data input processes, environmental concerns related to blockchain's energy consumption, the lack of industry standardization, and the possibility of counterfeiters exploiting blockchain's reputation for authenticity, emphasizing the need for careful planning, investment, and collaboration to address these challenges and realize the technology's potential in pharmaceutical traceability.

2.2. REFRENCES

1. "Monitoring Supply Chain of Pharmaceutical Drugs Using Blockchain," IEEE. https://ieeexplore.ieee.org/document/9753598

2. "A Blockchain-Based Approach for Drug Traceability in Healthcare," ResearchGate. https://www.researchgate.net/publication/348355196_A_Blockchain-Based_Approach_for_Drug_Traceability_in_Healthcare_Supply_Chain

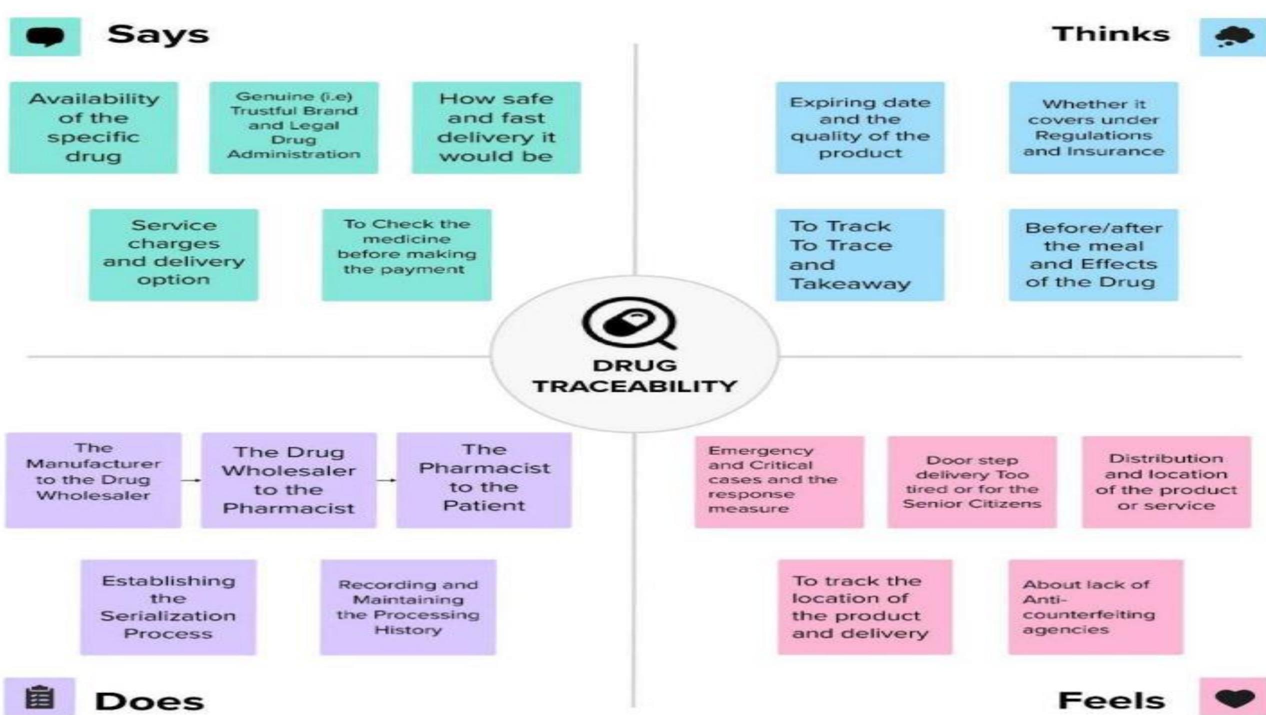
3. "Making Drug Supply Chain Secure Traceable and Efficient: A Blockchain-Based Method," ResearchGate. https://www.researchgate.net/publication/365756958_Making_drug_supply_chain_secure_traceable_and_efficient_a_Blockchain_and_smart_contract_based_implementation

2.3. PROBLEM STATEMENT DEFINITION

The business problem in Drug Traceability Smart Contracts on Ethereum Blockchain revolves around the need to enhance the transparency and security of pharmaceutical supply chains. Counterfeit drugs and substandard medications pose significant risks to public health, and traditional tracking methods are often insufficient. Implementing a smart contract solution on the Ethereum blockchain aims to address this problem by enabling real-time, immutable, and transparent tracking of pharmaceutical products throughout the supply chain, ensuring that consumers receive genuine and safe medications while facilitating regulatory compliance for pharmaceutical companies.

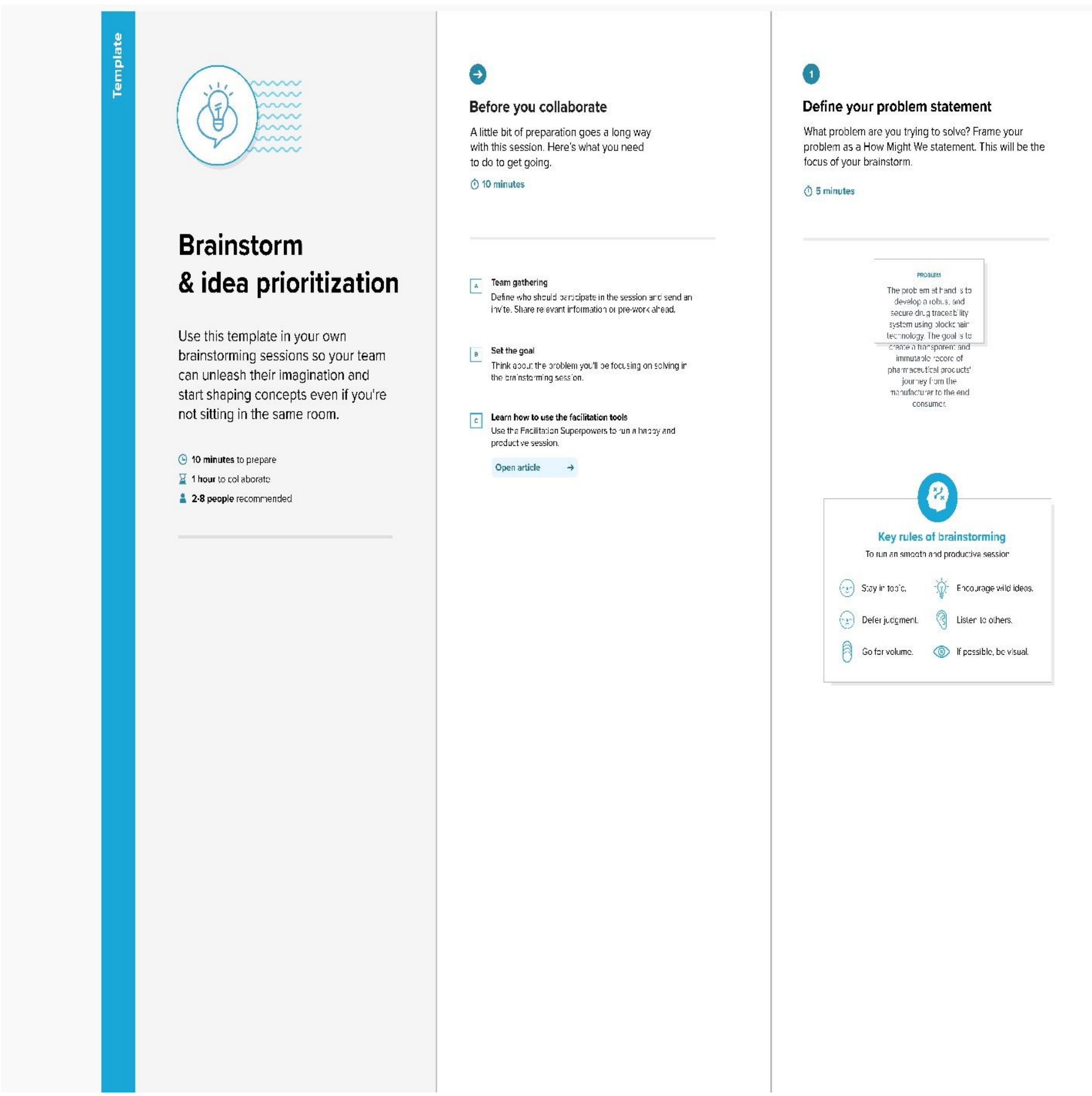
3.IDEATION & PROPOSED SOLUTION

3.1. EMPATHY MAP CANVAS

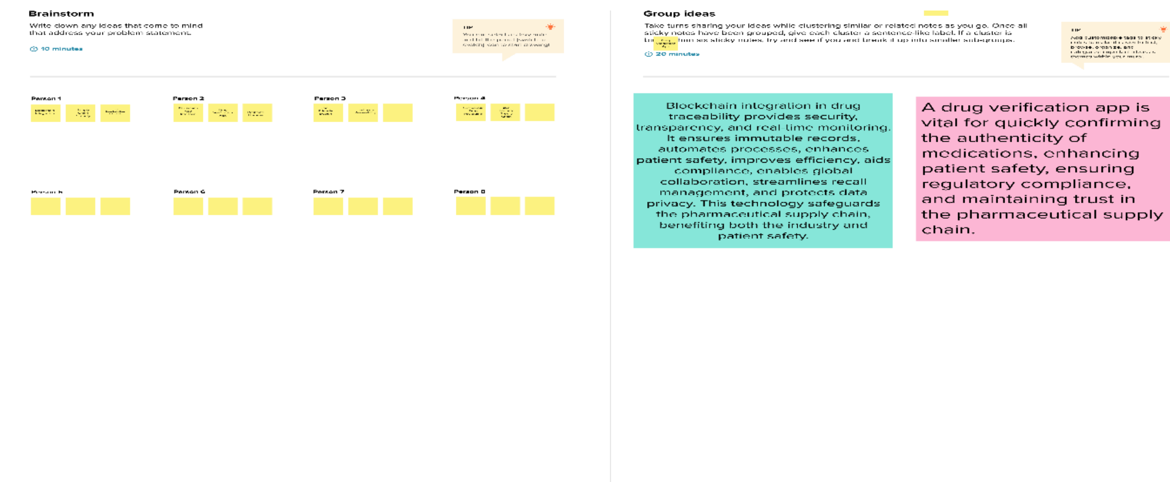


3.2. IDEATION & BRAINSTROMING

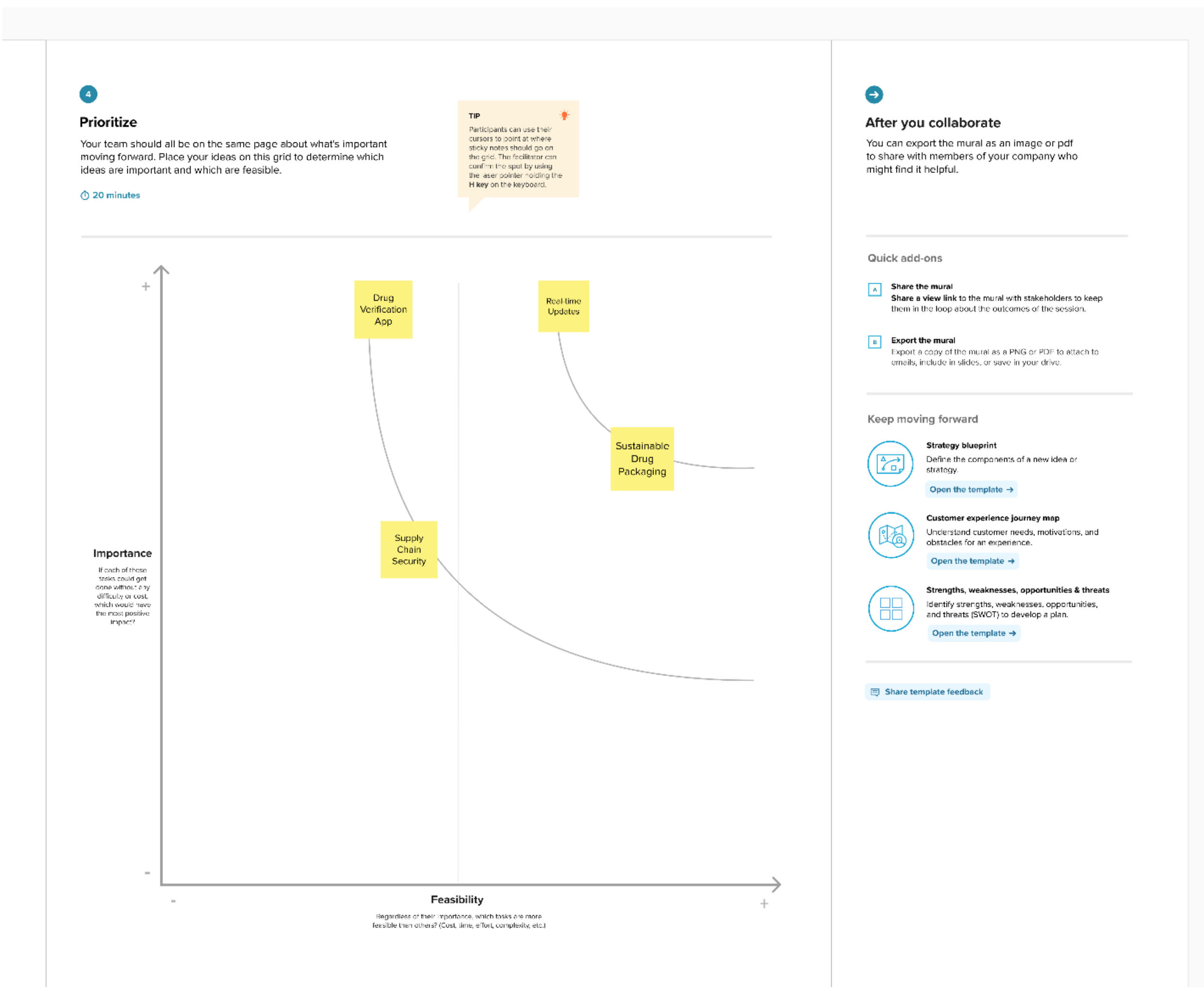
STEP-1:



STEP-2


Brainstorm
Group ideas
Blockchain integration in drug traceability provides security, transparency, and real time monitoring. It ensures immutable records, automates processes, enhances patient safety, improves efficiency, aids compliance, enables global collaboration, streamlines recall management, and protects data privacy. This technology safeguards the pharmaceutical supply chain, benefiting both the industry and patient safety.
A drug verification app is vital for quickly confirming the authenticity of medications, enhancing patient safety, ensuring regulatory compliance, and maintaining trust in the pharmaceutical supply chain.

STEP-3:


Prioritize
Your team should all be on the same page about what's important moving forward. Place your ideas on this grid to determine which ideas are important and which are feasible.
20 minutes
TIP
Drug Verification App
Real-time Updates
Sustainable Drug Packaging
Supply Chain Security
Importance
Feasibility
After you collaborate
You can export the mural as an image or pdf to share with members of your company who might find it helpful.
Quick add-ons
Share the mural
Export the mural
Keep moving forward
Strategy blueprint
Open the template
Customer experience journey map
Open the template
Strengths, weaknesses, opportunities & threats
Identify strengths, weaknesses, opportunities, and threats (SWOT) to develop a plan.
Open the template
Share template feedback

4. REQUIREMENT ANALYSIS

4.1. FUNCTIONAL REQUIREMENTS

Functional requirements for drug traceability using blockchain can vary depending on the specific use case and the stakeholders involved. Here are some key functional requirements:

1. Data Security and Privacy:

Ensure secure storage and transmission of sensitive pharmaceutical data. Implement encryption and access controls to protect data from unauthorized access.

2. Unique Identification and Serialization:

Assign unique identifiers (e.g., serial numbers, QR codes) to each drug unit. Record these identifiers on the blockchain for traceability.

3. Provenance Tracking and Transaction Recording:

Track the complete journey of a drug product through manufacturing and distribution. Record each supply chain transaction on the blockchain.

4. Timestamping and Chronological Record:

Include timestamps for each transaction to establish a chronological record. Ensure accurate time and date records for traceability.

5. Authentication and Verification Mechanisms:

Provide methods for authenticating and verifying drug products at each supply chain point. Enable stakeholders to verify the legitimacy of pharmaceuticals using the blockchain.

6. Regulatory Compliance and Standards:

Ensure compliance with relevant pharmaceutical regulations and industry standards (e.g., DSCSA, FMD). Align the system with GS1 standards for product identification.

7. User-Friendly Interfaces and Reporting:

Develop user-friendly interfaces for easy interaction with the blockchain system. Implement auditing and reporting tools for compliance and quality control.

8. Scalability, Consensus, and Immutable Ledger:

Design the blockchain system to handle growing transaction volumes as the supply chain expands. Choose an appropriate consensus mechanism and make the ledger immutable to maintain transparency and trust.

4.2. NON-FUNCTIONAL REQUIREMENTS

Non-functional requirements for drug traceability in blockchain encompass aspects of the system's performance, security, scalability, and usability. Here are non-functional requirements:

1. Performance and Scalability:

Ensure the system can handle a high volume of transactions efficiently. Maintain low latency and high throughput to accommodate growing data loads.

2. Security and Privacy:

Implement robust security measures to protect sensitive pharmaceutical data. Ensure data privacy and access controls to prevent unauthorized access.

3. Reliability and Availability:

Maintain high system availability to minimize downtime. Implement redundancy and failover mechanisms to ensure reliability.

4. Auditability and Compliance:

Support auditing requirements with easily accessible traceability records. Ensure compliance with relevant regulatory standards and industry best practices.

5. Interoperability and Integration:

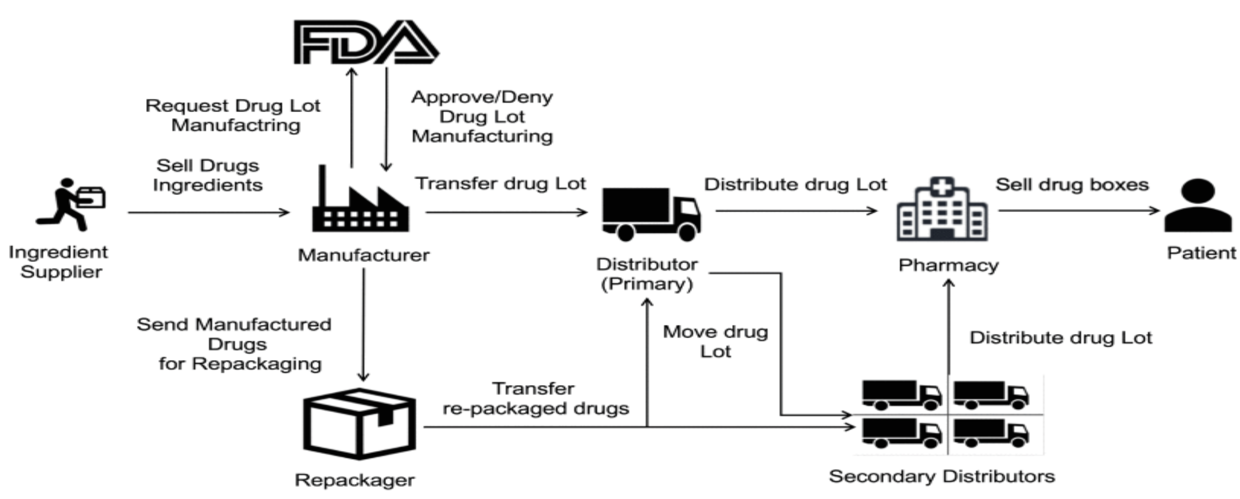
Ensure seamless integration with existing supply chain systems and standards. Facilitate data exchange and communication between different stakeholders.

6. Usability and User Experience:

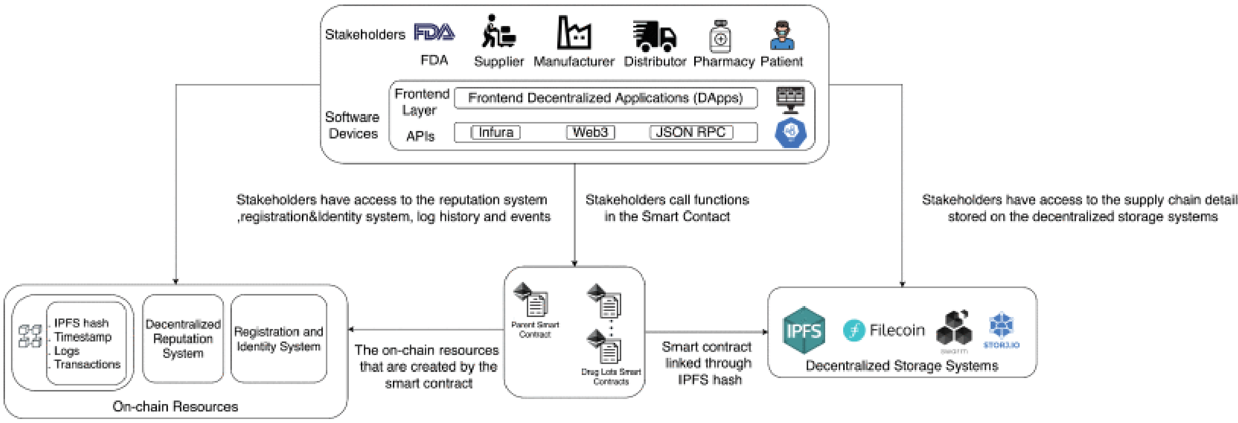
Provide user-friendly interfaces for stakeholders to interact with the blockchain system. Ensure an intuitive user experience for tasks such as verification and data entry.

5. PROJECT DESIGN

5.1. DATA FLOW DIAGRAM & USER STORIES



5.3. SOLUTION ARCHITECTURE



6. PROJECT PLANNING & SCHEDULING

6.1. TECHNICAL ARCHITECTURE

1. Blockchain Network Selection:

Choose the appropriate blockchain type (e.g., public, private, consortium) and underlying technology (e.g., Ethereum, Hyperledger) based on supply chain requirements and privacy considerations.

2. Smart Contracts and Logic:

Develop smart contracts to automate traceability processes, defining how data is created, transferred, and verified in the supply chain.

3. Data Structure and Encryption:

Define the structure for recording drug product data on the blockchain, and implement encryption to secure sensitive information.

4. User Interfaces and Integration:

Create user-friendly interfaces for stakeholders to interact with the system, including identity management and external integration with existing supply chain systems.

5. Scalability and Compliance:

Design for scalability as the supply chain grows, and ensure the system complies with pharmaceutical regulations and reporting requirements.

6.2. SPRINT PLANNING AND ESTIMATION

SPRINT NUMBER	SPRINT FOCUS	DURATION (WEEKS)	GOALS AND TASKS
Sprint 1	Blockchain Architecture design	2	Research and design blockchain architecture. Define data structures and encryption methods. Select a suitable blockchain platform.
Sprint 2	Drug registration and verification	3	Develop smart contracts for voter registration. Implement identity verification mechanisms. Create a user-friendly registration interface
Sprint 3	Supply chain process	3	Integrate blockchain into the tracing and supply chain process. Develop smart contracts for supply chain and recording. Implement real-time drug tracking and verification.
Sprint 4	Ethereum Setup and Smart Contract Design	2	Set up Ethereum development environment with Visual Studio Code. Design the core smart contracts for secure voting on the blockchain. Develop initial smart contract drafts.

Sprint 5	MetaMask Integration and Identity Verification	3	Integrate MetaMask for Ethereum wallet functionality in the voting application. Implement identity verification mechanisms using MetaMask's features. Develop the user interface for interacting with MetaMask.
Sprint 6	Deployment & Final Optimization	2	Deploy the drug traceability in a controlled environment. Conduct final testing, validation, and performance optimization. Prepare for live implementation and ongoing system monitoring.

6.3. SPRINT DELIVERY SCHEDULE:

SPRINT NUMBER	SPRINT FOCUS
SPRINT 1	Blockchain Architecture Design
SPRINT 2	Drug registration on blockchain
SPRINT 3	Blockchain-Based Verification
SPRINT 4	User-Friendly Interface
SPRINT 5	Security and Privacy Features Accessibility Enhancements
SPRINT 6	Quality Assurance, Deployment and Final Testing

7. CODING & SOLUTIONING

7.1. FEATURE 1

OWNERSHIP CONTROL WITH MODIFIER “onlyowner”:

The use of the “**onlyOwner”** modifier is a crucial feature in this smart contract. This modifier restricts access to specific functions to only the owner of the contract. Here's how it works:

CODE:

```
modifier onlyOwner() {
    require(msg.sender == owner, "Only the owner can perform this action");
    _;
}
```

The modifier checks whether the sender of a transaction (msg.sender) is the same as the contract's owner. If it's not, the function call is halted with an error message.

This feature ensures that critical functions, such as creating a new drug (manufactureDrug), can only be executed by the owner, typically representing the pharmaceutical company or a trusted entity. This control prevents unauthorized actors from tampering with the core functionality of the contract.

7.2. FEATURE 2

Drug Transfer and Tracking History:

The **“transferDrugOwnership”** function and the concept of "tracking history" are significant features related to the traceability of drugs:

CODE:

```
function transferDrugOwnership(uint256 _drugId, address _to) external {
    require(_to != address(0), "Invalid address");
    require(_to != drugs[_drugId].trackingHistory, "Already owned by the new address");


    address from = drugs[_drugId].trackingHistory;
    drugs[_drugId].trackingHistory = _to;


    emit DrugTransferred(_drugId, from, _to, block.timestamp);
}
```

Ownership Transfer: This function allows the current owner of a drug to transfer ownership to a new address (‘_to’). This action is essential for tracing the movement of drugs within the supply chain.

Ownership Validation: The function includes validation to ensure that the provided target address (‘_to’) is valid and different from the current tracking history. This prevents transferring ownership to an invalid or the same address.

Tracking History: The code uses the “trackingHistory” field in the “Drug” struct to maintain a historical record of the ownership and movement of each drug. The “transferDrugOwnership” function updates the tracking history, allowing anyone to trace the entire ownership history of a drug from its creation.

Event Logging: The function emits the “DrugTransferred” event, which logs the transfer of ownership, including details about the sender (‘from’), recipient (‘_to’), and the timestamp of the transfer. These events provide a transparent and auditable history of drug ownership changes.

8.PERFORMANCE TESTING

8.1. PERFORMANCE METRICS

1. Gas Efficiency:

Measure the gas consumption of contract functions. Optimizing gas usage can reduce transaction costs and improve cost-effectiveness.

2. Transaction Throughput:

Evaluate how many transactions the contract can process per second. Understanding its capacity for handling concurrent transactions is crucial for scalability.

3. Latency:

Monitor the time it takes for transactions to be confirmed on the blockchain. Low latency is essential for real-time applications.

4. Scalability:

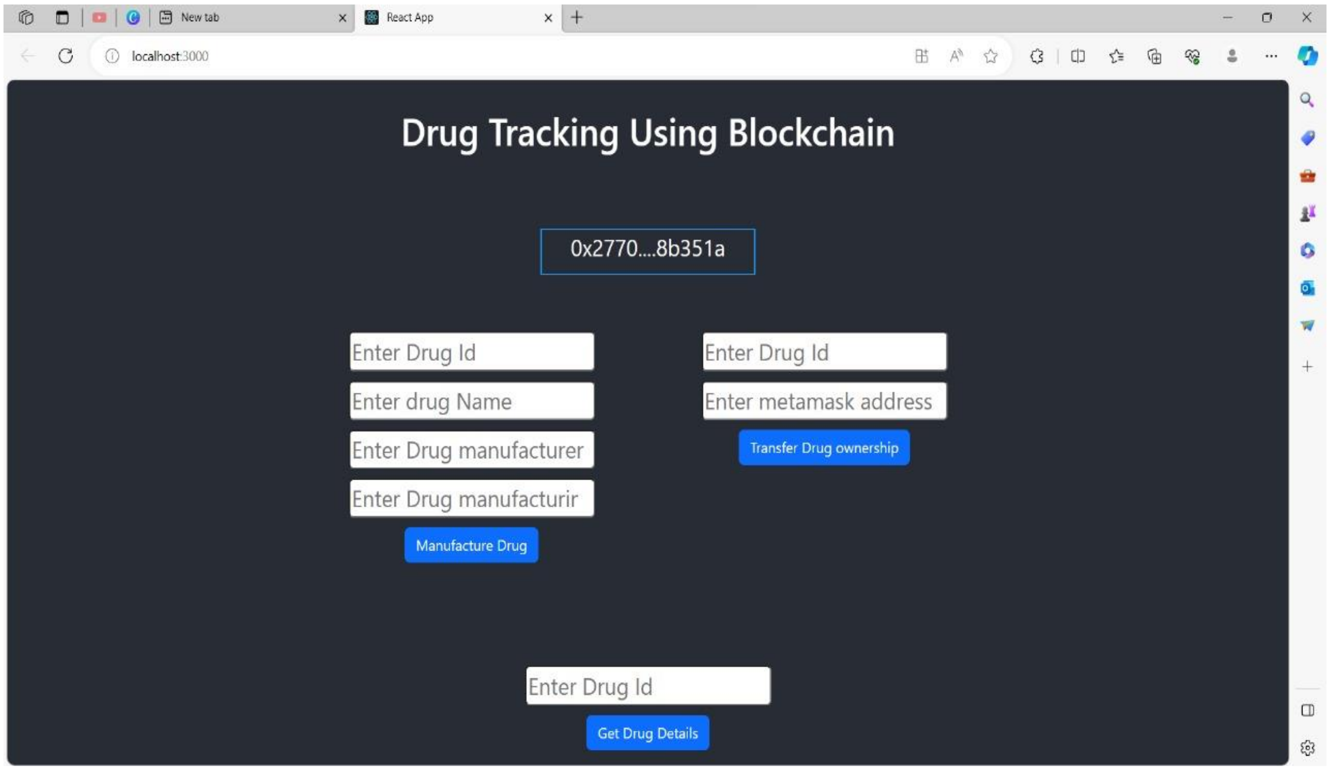
Assess how well the contract performs as the volume of data and user activity increases. A scalable contract can handle growing demand efficiently.

5. Data Storage Efficiency:

Optimize data storage to reduce costs associated with storing large amounts of data on the blockchain. Efficient storage practices can enhance performance and cost-effectiveness.

9. RESULTS

9.1. OUTPUT SCREENSHOTS



10. ADVANTAGES & DISADVANTAGES

ADVANTAGES:

1. Enhanced Transparency and Traceability:

Blockchain creates an immutable and transparent ledger of drug-related data. Every step in the supply chain, is recorded, providing complete traceability. This transparency reduces the risk of counterfeit drugs entering the market**.**

2. Improved Data Integrity:

Blockchain's immutability ensures that once data is recorded, it cannot be altered or deleted. This feature prevents data tampering and fraud. The data recorded on the blockchain is accurate and reliable.

3. Reduced Counterfeiting:

Counterfeit drugs pose a significant threat to public health. Blockchain allows for real-time tracking of pharmaceuticals, making it extremely difficult for counterfeit products to enter the supply chain undetected. This protects consumers and the reputation of pharmaceutical companies.

DISADVANTAGES:

1. Complex Implementation:

Integrating blockchain into existing pharmaceutical supply chain systems can be complex and costly. It may require significant changes to existing processes, and not all stakeholders may be technologically ready to adopt blockchain.

2. Scalability Issues:

As more data is added to the blockchain, scalability can become a concern. Public blockchains, in particular, may face limitations in terms of the number of transactions and data storage.

3. High Operational Costs:

Running a blockchain network can be expensive. The cost of transactions and smart contract deployment may be prohibitive for smaller pharmaceutical companies or organizations in resource-constrained regions.

4. Privacy and Data Protection:

Storing sensitive drug-related information on a public blockchain may raise privacy concerns. While blockchain data is pseudonymous, some stakeholders may prefer more stringent privacy measures, which can be challenging to implement on a public blockchain.

11. CONCLUSION

In conclusion, blockchain technology has immense potential to revolutionize drug traceability in the pharmaceutical industry. Its ability to provide a secure and transparent platform for tracking drug movements can help to prevent counterfeit drugs from entering the supply chain, thereby ensuring patient safety. The research papers discussed in this report provide valuable insights into how blockchain technology can be leveraged for drug traceability. Further research is needed to explore how blockchain technology can be integrated into existing supply chain management systems.

12. FUTURE SCOPE

The future scope of drug traceability using blockchain includes enhanced supply chain transparency, improved patient safety, and streamlined regulatory compliance. Blockchain can significantly reduce drug counterfeiting, enable efficient pharmaceutical recall management, and facilitate automation through smart contracts. Integration with IoT and AI will further enhance traceability, and global collaboration among stakeholders can ensure a secure, real-time data sharing ecosystem. Additionally, blockchain ensures data security and privacy while supporting research and development processes. Challenges like regulatory hurdles and industry-wide adoption need to be addressed, but the technology has the potential to revolutionize drug traceability and safety.

13. APPENDIX

SOURCE CODE

```
// SPDX-License-Identifier: MIT
pragma solidity ^0.8.0;

contract Drug{
    address public owner;

    constructor() {
        owner = msg.sender;
    }

    modifier onlyOwner() {
        require(msg.sender == owner, "Only the owner can perform this
action");
        _;
    }

    struct Drug {
        string drugName;
        string manufacturer;
        uint256 manufacturingDate;
        address trackingHistory;
```

```
    }
    mapping(uint256 => Drug) public drugs;
    uint256 public drugCount;

    event DrugManufactured(uint256 indexed drugId, string drugName, 
string manufacturer, uint256 manufacturingDate);
    event DrugTransferred(uint256 indexed drugId, address indexed from, 
address indexed to, uint256 transferDate);

    function manufactureDrug(uint256 drugId, string memory 
_drugName, string memory _manufacturer, uint256 
_manufacturingDate) external onlyOwner {

        address initialHistory;
        initialHistory = owner;

        drugs[drugId] = Drug(_drugName, _manufacturer, 
_manufacturingDate, initialHistory);
        drugCount++;

        emit DrugManufactured(drugId, _drugName, _manufacturer, 
_manufacturingDate);
    }
```

```
    function transferDrugOwnership(uint256 _drugId, address _to) external {
        require(_to != address(0), "Invalid address");
        require(_to != drugs[_drugId].trackingHistory, "Already owned by the new address");

        address from = drugs[_drugId].trackingHistory;
        drugs[_drugId].trackingHistory = _to;

        emit DrugTransferred(_drugId, from, _to, block.timestamp);
    }

    function getDrugDetails(uint256 _drugId) external view returns (string memory, string memory, uint256, address) {

        Drug memory drug = drugs[_drugId];
        return (drug.drugName, drug.manufacturer, drug.manufacturingDate, drug.trackingHistory);
    }
}
```

ZIP File Link: https://drive.google.com/file/d/1Nn29sCblJXkgpnQI2vEpnbjc256WGmEU/view?usp=sharing

GITHUB & PROJECT DEMO LINK

GitHub link:

https://github.com/VARSHINI0710/DRUG-TRACEABILITY.git

Project Demo link:

https://drive.google.com/file/d/16RDF8ceg_BKsnDFjXEwN9FMfTed0qpAW/view?usp=sharing