PROJECT REPORT

DRUG TRACEABILITY USING BLOCKCHAIN

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1. INTRODUCTION

1.1. PROJECT OVERVIEW :

The pharmaceutical industry faces numerous challenges related to drug traceability, counterfeiting, and supply chain integrity. These challenges can compromise patient safety and trust in the industry. To address these issues, this project aims to implement a blockchain-based drug traceability system. Blockchain technology offers a secure and immutable ledger that can help track pharmaceutical products throughout their lifecycle, from production to consumption**.**

The project aims to establish a secure and transparent drug traceability system using blockchain technology, enabling stakeholders, including manufacturers, distributors, regulators, and consumers, to track pharmaceutical products throughout their lifecycle. Key features include smart contracts, IoT integration, and user-friendly interfaces. By preventing counterfeit drugs, enhancing patient safety, improving supply chain efficiency, and ensuring regulatory compliance, this system offers significant benefits to the pharmaceutical industry, albeit with challenges such as integration and scalability. Future enhancements may involve AI and expanded industry adoption, making this project a potential game-changer in ensuring drug authenticity and supply chain integrity.

1.2.PURPOSE :

The purpose of drug traceability using blockchain is to enhance the security, transparency, and integrity of the pharmaceutical supply chain. It serves to:

1. **Prevent Counterfeiting:** Blockchain provides an immutable ledger that makes it extremely difficult for counterfeit drugs to enter the market, as the entire history of a drug's journey can be verified.
2. **Improve Patient Safety:** Patients can verify the authenticity and quality of pharmaceutical products, reducing the risk of consuming substandard or harmful medications.
3. **Enhance Supply Chain Efficiency:** Blockchain technology streamlines the tracking of drugs from manufacturing to distribution, improving visibility, reducing errors, and enabling faster recalls when necessary.
4. **Ensure Regulatory Compliance:** Pharmaceutical companies can use blockchain to adhere to industry regulations and provide regulators with real-time access to data for auditing and compliance monitoring.
5. **Minimize Fraud:** Blockchain's security features reduce the risk of fraudulent activities within the supply chain, ensuring trust among stakeholders.

2. LITERATURE SURVEY.

2.1.EXISTING PROBLEMS :

There are several existing problems and challenges associated with implementing drug traceability using blockchain technology:

Achieving widespread adoption of blockchain in the pharmaceutical industry is challenging due to the need for collaboration among various stakeholders, including manufacturers, distributors, and regulators. Overcoming resistance to change and aligning interests can be difficult. Different companies and organizations may use different blockchain platforms or systems, making it necessary to ensure interoperability between these systems for seamless traceability. The pharmaceutical industry is subject to complex and varying

regulations in different regions and countries. Adapting blockchain solutions to meet these regulations while maintaining transparency and traceability can be a significant challenge. Protecting sensitive patient and drug information is crucial. While blockchain is secure, the handling of off-chain data (e.g., patient records) and the management of access control must be carefully addressed to maintain data privacy.

2.2.REFERENCES :

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Fut Gener Comput Syst
(2019)
17.F. Clark
Rise in online pharmacies sees counterfeit drugs go global
The Lancet
(2015).

2.3. PROBLEM STATEMENT AND DEFINITION :

The pharmaceutical industry faces a daunting challenge concerning drug traceability and supply chain integrity. Ensuring the authenticity and safety of pharmaceutical products as they traverse complex global supply chains is a critical concern. Counterfeit drugs, substandard quality, and unauthorized distribution pose significant threats to patient health and the reputation of pharmaceutical companies. To address these issues, there is a growing need for a robust and tamper-proof system that can provide end-to-end traceability of drugs. Blockchain technology has emerged as a promising solution, offering transparency, immutability, and decentralized trust. This project aims to explore and implement a blockchain-based drug traceability system to revolutionize the pharmaceutical supply chain, enhancing patient safety, preventing counterfeiting, and ensuring the integrity of drug distribution. The project seeks to develop a comprehensive problem statement and solution that align with the pharmaceutical industry's evolving needs in an increasingly digital and interconnected world.

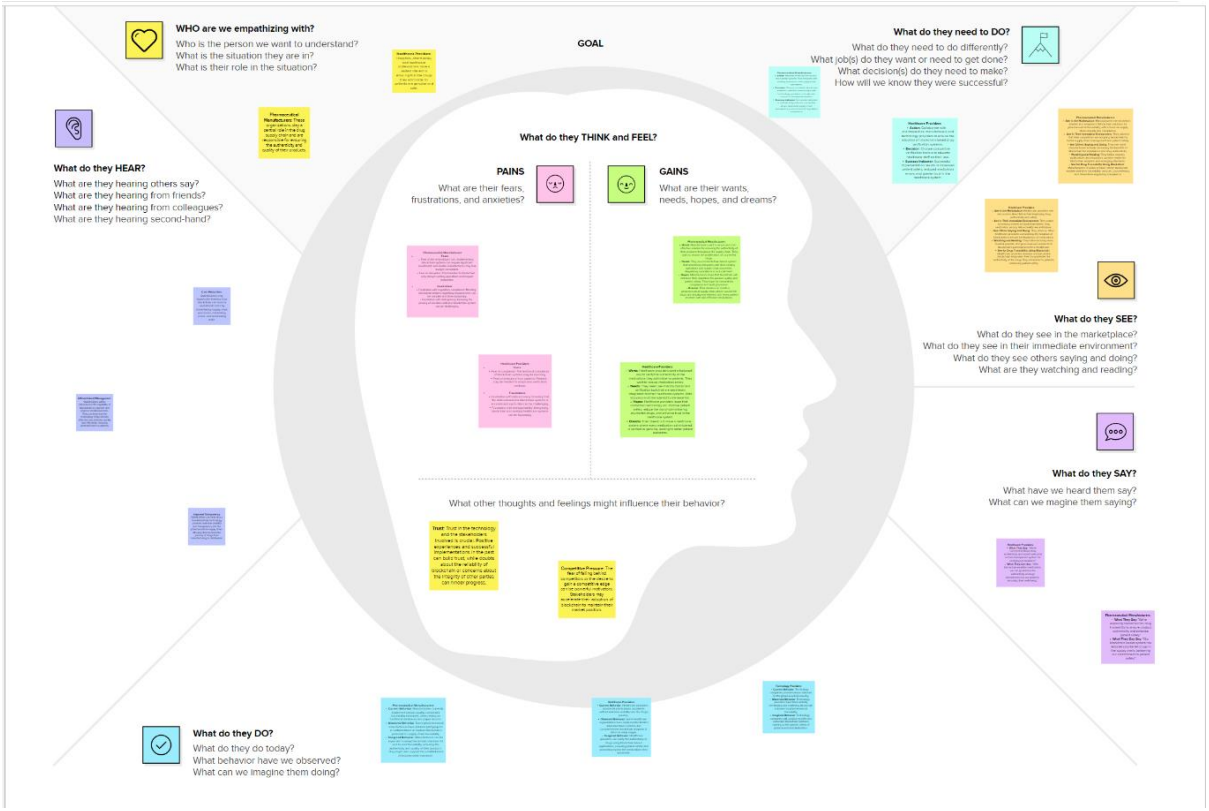
2.3.1.Problem Statement : The pharmaceutical industry grapples with a pressing issue: the proliferation of counterfeit drugs and compromised supply chain security. Counterfeit medications infiltrate the market, jeopardizing patient safety, eroding trust in pharmaceutical products, and causing substantial economic losses. Traditional methods of ensuring drug traceability and authenticity have

proven inadequate, as they lack the requisite transparency and security. To address this critical challenge, a comprehensive and technologically advanced solution is required. The current systems are often disjointed, relying on paper-based records and centralized databases susceptible to fraud and errors. It is evident that a modern, blockchain-based approach could bring the much-needed transparency, immutability, and trustworthiness to drug traceability. This project aims to formulate a blockchain-driven solution that aligns with the evolving needs of the pharmaceutical industry, ensuring the secure and transparent tracking of pharmaceutical products from their origin to the hands of patients, ultimately improving public health and regulatory compliance while mitigating the risks associated with counterfeit drugs in the supply chain.

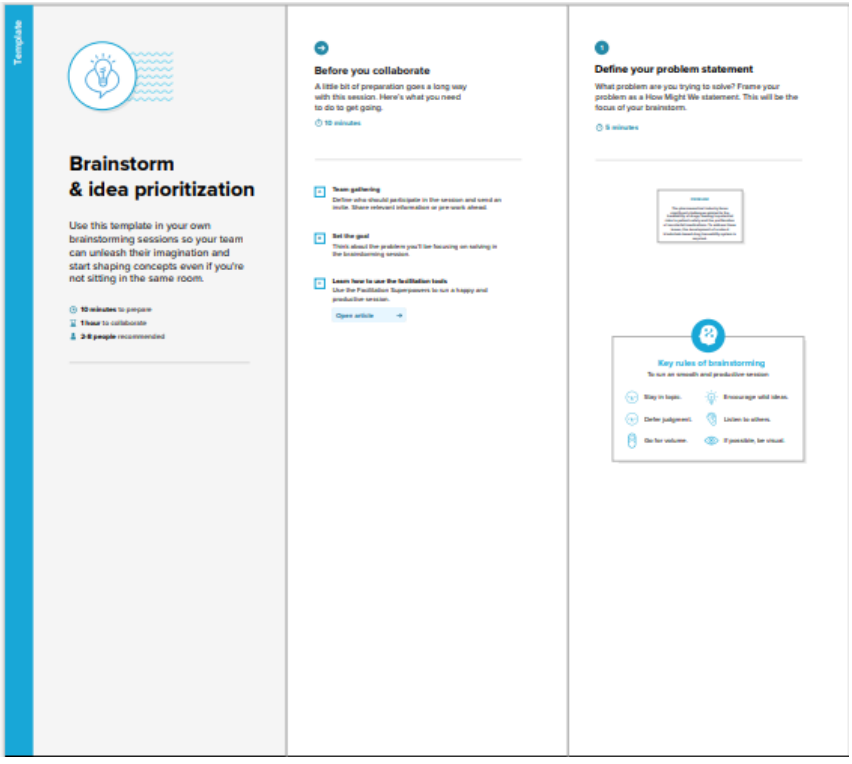
2.3.2.Problem Definition : The pharmaceutical industry faces a critical problem in ensuring the authenticity, safety, and transparency of drug supply chains. The current systems for tracking pharmaceutical products often rely on fragmented, paper-based records and centralized databases that are vulnerable to errors, manipulation, and counterfeiting. As a result, counterfeit drugs infiltrate the market, posing a grave threat to patient health, undermining trust in pharmaceuticals, and causing substantial economic losses. Existing traceability solutions are inadequate in a digital and interconnected world, necessitating a modern approach that can provide end-to-end traceability and tamper-proof records. Blockchain technology presents a promising solution, offering the potential for secure, decentralized, and immutable record-keeping, but the problem lies in effectively implementing this technology in the complex pharmaceutical supply chain. This project seeks to define and address this challenge by developing a blockchain-based system that ensures drug traceability, safeguarding patient well-being, and maintaining the integrity of pharmaceutical products throughout their journey from manufacturer to consumer.

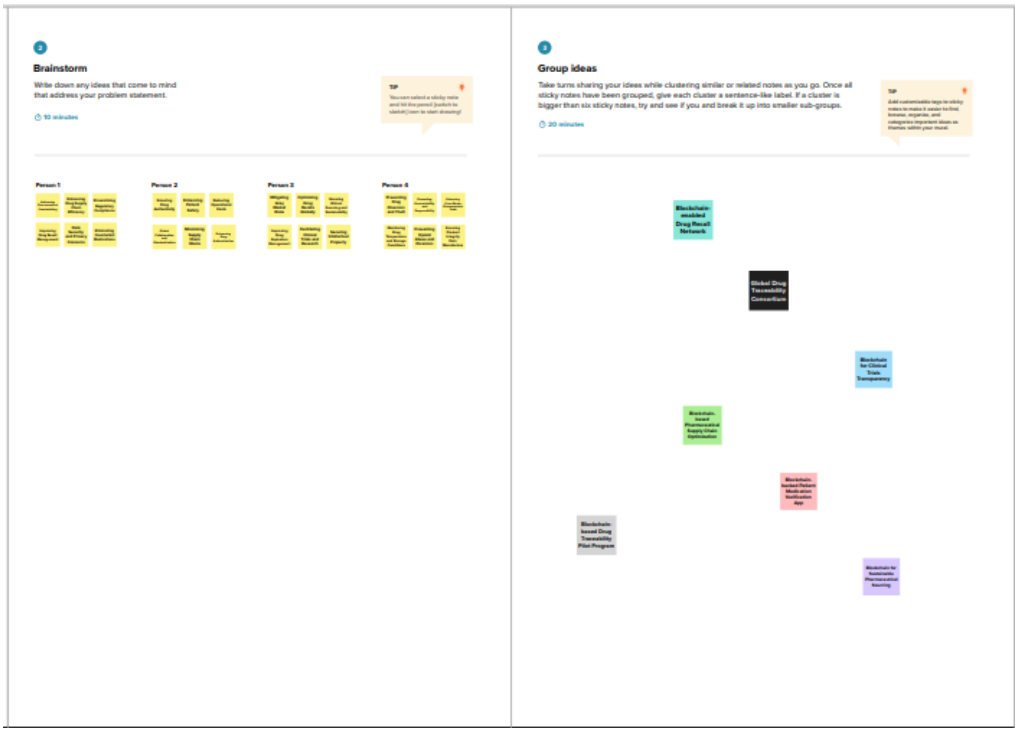
3. IDEATION AND PROPOSED SOLUTION

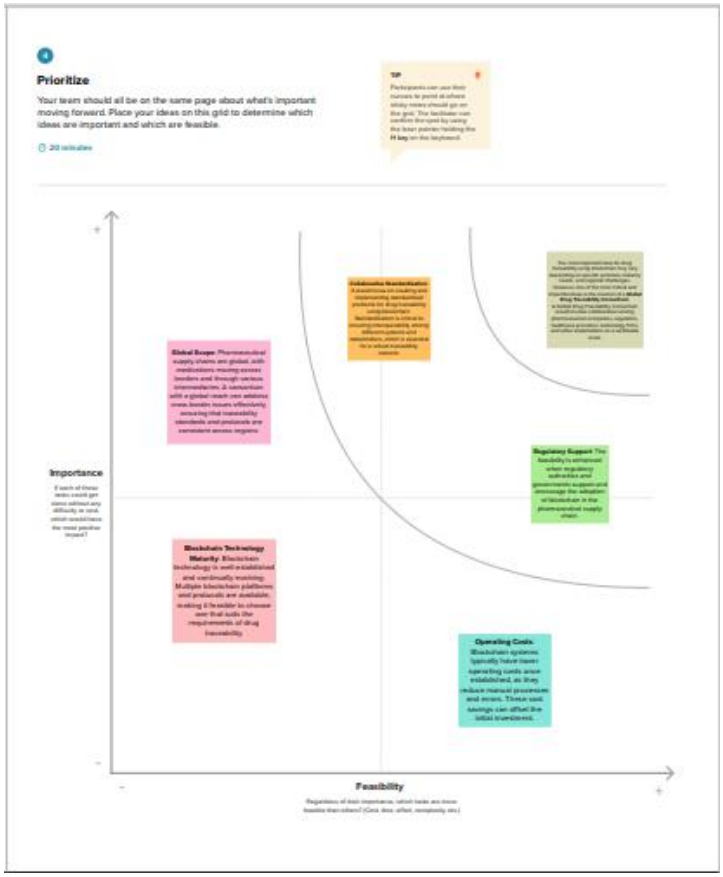
3.1.Empathy Map Canvas:



3.2.Ideation and Brainstorming :




2
Brainstorm
Write down any ideas that come to mind that address your problem statement.
10 minutes
TIP
Person 1
Person 2
Person 3
Person 4
3
Group ideas
Take turns sharing your ideas while clustering similar or related notes as you go. Once all sticky notes have been grouped, give each cluster a sentence-like label. If a cluster is bigger than six sticky notes, try and see if you and break it up into smaller sub-groups.
20 minutes
TIP
Blockchain-enabled Drug Recall Network
Global Drug Traceability Consortium
Blockchain for Clinical Trials Transparency
Blockchain-based Pharmaceutical Supply Chain Optimization
Blockchain-based Patient Medication Verification App
Blockchain-based Drug Traceability Pilot Program
Blockchain for Sustainable Pharmaceutical Sourcing


4
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
Importance
Feasibility
Global Scope: Pharmaceutical supply chains are global, with medications moving across borders and through various intermediaries. A consortium with a global reach can address cross-border issues effectively, ensuring that traceability standards and protocols are consistent across regions.
Collaborative Standardization: A consortium can leading and implementing standardized protocols for drug traceability using blockchain. Standardization is critical to ensuring interoperability among different systems and stakeholders, which is essential for a robust traceability network.
Regulatory Support: The feasibility is enhanced when regulatory authorities and governments support and encourage the adoption of blockchain in the pharmaceutical supply chain.
Blockchain Technology Maturity: Blockchain technology is well-established and continually evolving. Multiple blockchain platforms and protocols are available, making it feasible to choose one that suits the requirements of drug traceability.
Operating Costs: Blockchain systems typically have lower operating costs once established, as they reduce manual processes and errors. These cost savings can offset the initial investment.

4. REQUIREMENT ANALYSIS :

4.1. Functional Requirements

1. **User registration with verification processes :** Secure authentication methods for all stakeholders, such as manufacturers, distributors, regulators, and consumers.
2. **Product Data Entry:** Capability for manufacturers to input comprehensive product data, including batch numbers, manufacturing dates, expiration dates, and unique identifiers.Support for linking product information to specific blockchain transactions.
3. **Blockchain Infrastructure:** Creation and maintenance of a secure and scalable blockchain network. Implementation of a suitable consensus mechanism for pharmaceutical use cases, ensuring transaction validation and data integrity.
4. **Smart Contracts:** Development and deployment of smart contracts to manage data creation, transfer, and verification. Automation of processes for regulatory compliance and supply chain events.
5. **User Interfaces:** User-friendly interfaces for manufacturers, distributors, regulators, and consumers. Accessibility via web applications, mobile apps, or other suitable platforms.
6. **IoT Integration:** Integration with IoT devices for real-time monitoring of environmental conditions (e.g., temperature, humidity) during drug transportation and storage. Storing IoT data on the blockchain to ensure supply chain integrity.
7. **Regulatory Compliance:** Ensuring the system complies with pharmaceutical regulations and standards in different regions. Facilitating audits and inspections by regulatory authorities.

8. **Scalability and Performance:** Ensuring the system can handle a large number of transactions as the network grows. Implementing measures to maintain system performance under high transaction loads.
9. **Integration with Existing Systems:** Compatibility with existing pharmaceutical and supply chain management systems to facilitate smooth data exchange.
10. **Notification and Alerts:** Providing timely notifications and alerts for stakeholders regarding critical supply chain events, product recalls, or compliance issues.

4.2. Non Functional Requirements :

1. **Data Privacy:** Ensure that sensitive drug traceability data is securely stored and transmitted. Compliance with data protection regulations such as GDPR should be assured.

2**. Authentication and Authorization:** Implement robust user authentication and authorization mechanisms to control access to the blockchain system.

3. **Throughput:** Define the desired transactions per second (TPS) and ensure the blockchain network can handle the expected load.

4. **Latency:** Specify acceptable response times for various transactions and queries.

5. **High Availability:** Ensure the blockchain network is highly available, with minimal downtime for maintenance and upgrades.

6**. Fault Tolerance:** Design the system to withstand node failures or network disruptions without losing critical data.

7. **Real-time Monitoring:** Implement real-time monitoring of the blockchain network and associated systems to detect and respond to issues promptly.

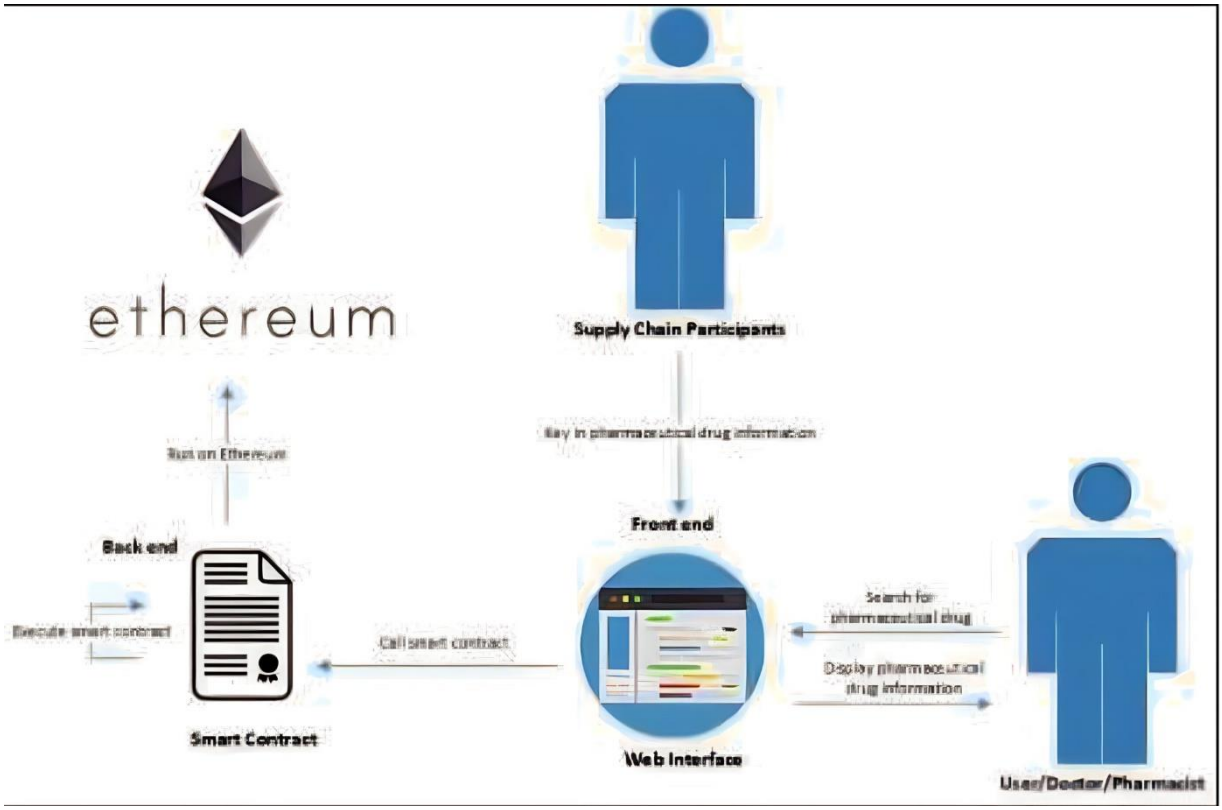
8. **Reporting and Analytics:** Provide tools for generating reports and analytics to gain insights from traceability data.

9. **Energy Efficiency:** Minimize energy consumption, especially in blockchain networks that rely on proof-of-work (PoW) consensus mechanisms.

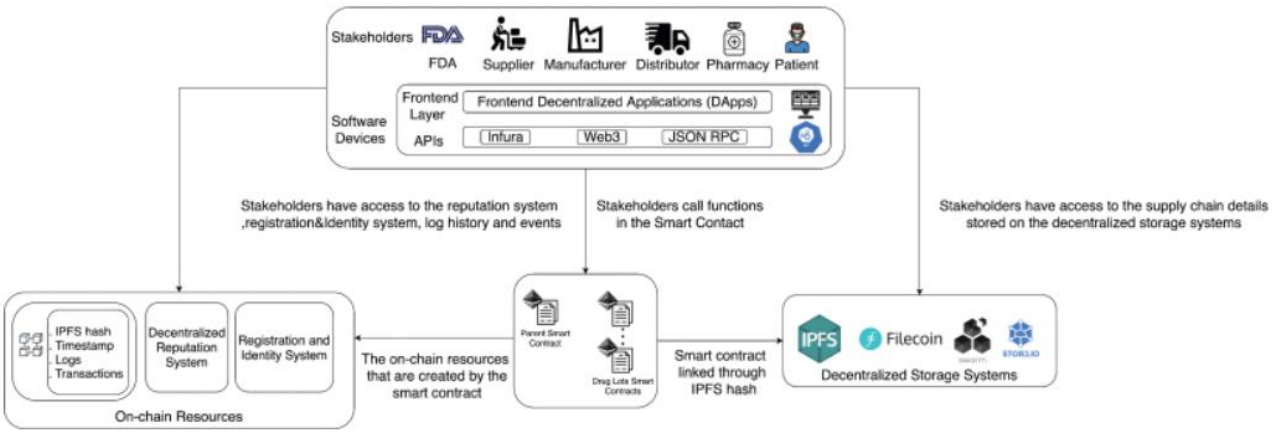
10. **Data Localization:** Ensure compliance with data localization laws and regulations that dictate where certain data can be stored and processed.

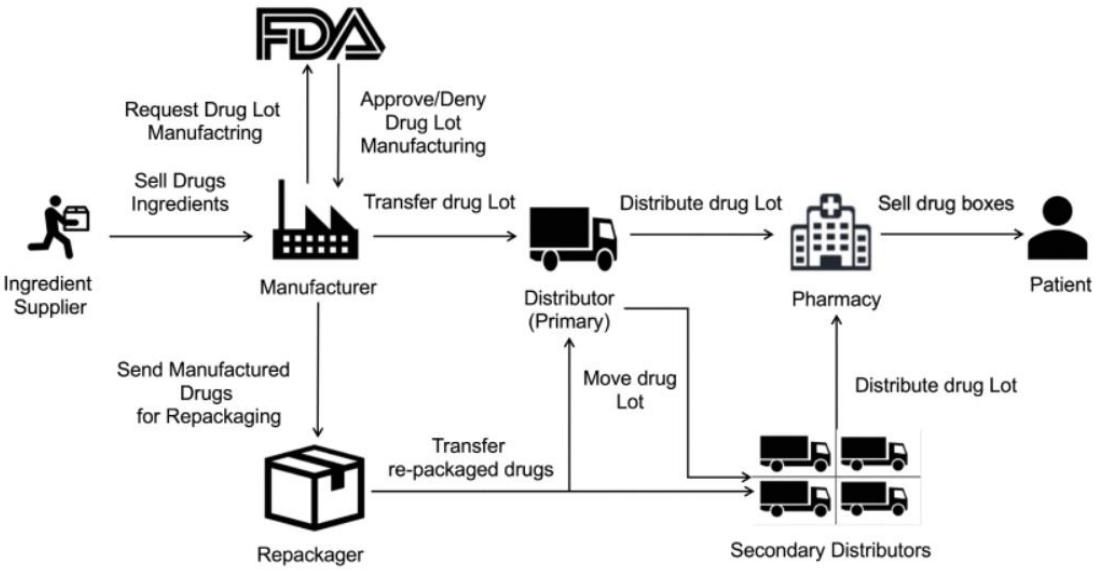
5. PROJECT DESIGN :

5.1. Solution Architecture



5.2. Technical Architecture





6. TESTING AND VALIDATION :

In order to asses the smart contracts developed via Ethereum, Remix IDE in-browser developing and testing environment was used to test and validate different functions. The scenarios involved three different participants and their corresponding Ethereum Addresses.

We further present the transactions and logs of the smart contract's functions below.

- **lotDetails:** In this function, it was tested whether the current owner of the smart contract is able to add the details of a newly manufactured Lot such as the Lot name, Lot price, number of boxes within the Lot, and the price of each box.

- **grantSale:** The grantSale function has a simple task yet it's very important, it basically notifies all the entities that the manufactured Lot is currently for sale.

- **buyLot:** In this function, Participant2 is used to buy the Lot from Participant1. Participant1 has specified the correct amount of ether to transfer and the successful execution of the function.

- **buyBox:** This function deals with transactions related to purchase of specific number of boxes from the Lot (usually happens between a patient and the pharmacy). The price of the boxes has been selected arbitrarily and they may not be logical but the purpose here is to confirm that the execution of the functions properly.

6.1. Discussion And Validation :

Drug traceability using blockchain is a promising solution that addresses critical issues in the pharmaceutical industry. Blockchain technology provides a transparent and immutable ledger that can track the movement of drugs throughout the supply chain.

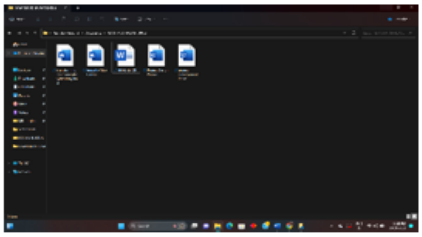
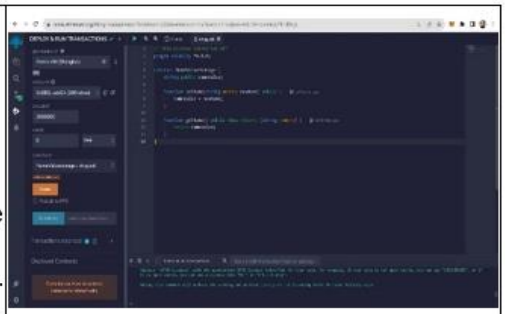
1. **Improved Transparency and Trust:** Blockchain provides a tamper-resistant ledger of transactions, making it easier to verify the authenticity and origin of pharmaceutical products. This builds trust among consumers and regulators.
2. **Enhanced Security and Data Integrity:** Data stored on the blockchain is highly secure and immutable, reducing the risk of counterfeit drugs and data manipulation.
3. **Reduced Counterfeit Drugs:** Counterfeit drugs are a significant problem in the pharmaceutical industry. Blockchain can help track a drug's journey from manufacturer to consumer, making it difficult for counterfeit drugs to enter the supply chain.
4. **Efficient Recall Management:** In case of a product recall, blockchain enables swift and precise tracking of affected batches, reducing the scope of recalls and minimizing potential harm to consumers.
5. **Regulatory Compliance:** Blockchain can facilitate compliance with regulations like the Drug Supply Chain Security Act (DSCSA) in the United States and similar regulations worldwide.

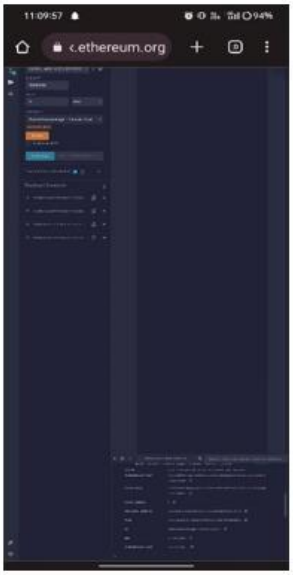
6.2. Challenges and validation :

1. **Integration with Existing Systems:** Validating the feasibility of integrating blockchain into existing pharmaceutical supply chain systems without disrupting operations is a challenge. It's important to ensure compatibility and minimize disruption during implementation.

2. **Scalability:** As the pharmaceutical supply chain generates a vast amount of data, blockchain networks need to be scalable to handle the volume of transactions and data. Ensure that the chosen blockchain platform can meet these scalability requirements.
3. **Data Privacy and Security:** While blockchain offers strong security, ensuring that sensitive patient and drug information remains private is crucial. This requires robust encryption and access controls.
4. **Interoperability:** The pharmaceutical supply chain involves a multitude of stakeholders and systems. Ensuring that all parties can participate and interact with the blockchain network is vital. Industry standards can help address this challenge.
5. **Cost and Infrastructure:** Implementing and maintaining a blockchain network involves costs, including hardware, software, and operational expenses. A cost-benefit analysis is needed to validate the investment.
6. **Regulatory Compliance:** Different countries have varying regulations for the pharmaceutical industry. Validation includes ensuring the blockchain system meets the legal requirements of all regions involved.
7. **User Adoption:** Validating the willingness of stakeholders to adopt the blockchain solution is essential. Proper training and user-friendly interfaces can help with user acceptance.

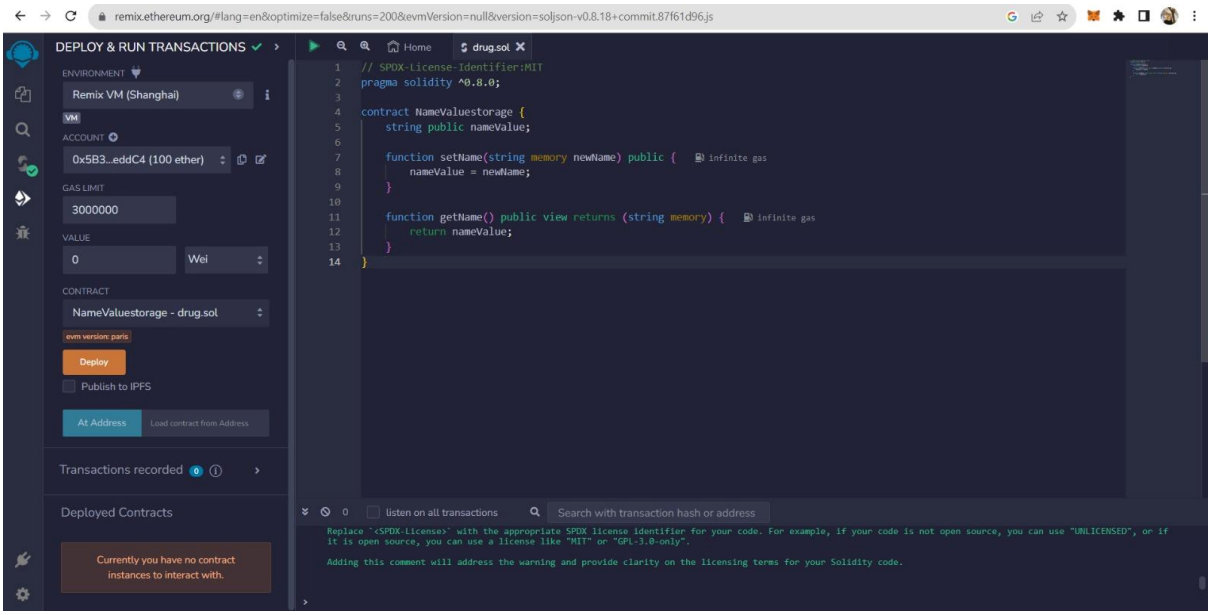
7. PERFOMANCE TESTING :

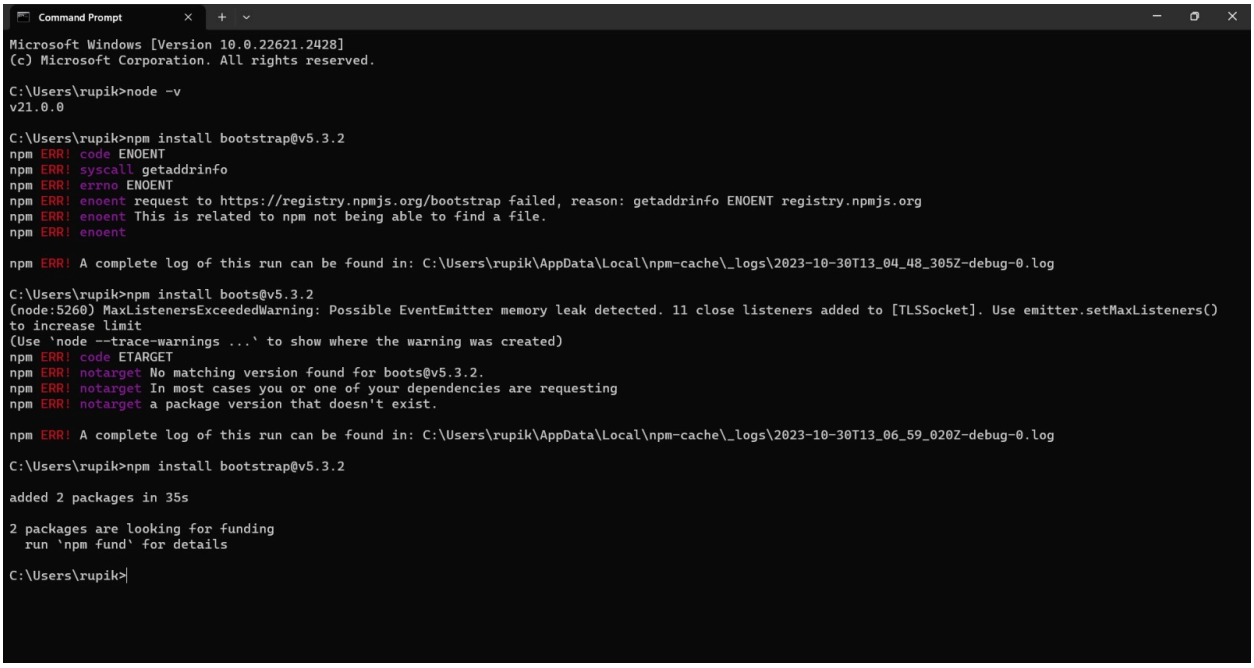
S.No.	Parameter	Values	Screenshot
1.	Information gathering	Setup all the Prerequisite:	
2.	Extract the zip files	Open to vs code	
3.	Remix Ide platform exploring	Deploy the smart contract code Deploy and run the transaction. By selecting the environment - inject the MetaMask.	

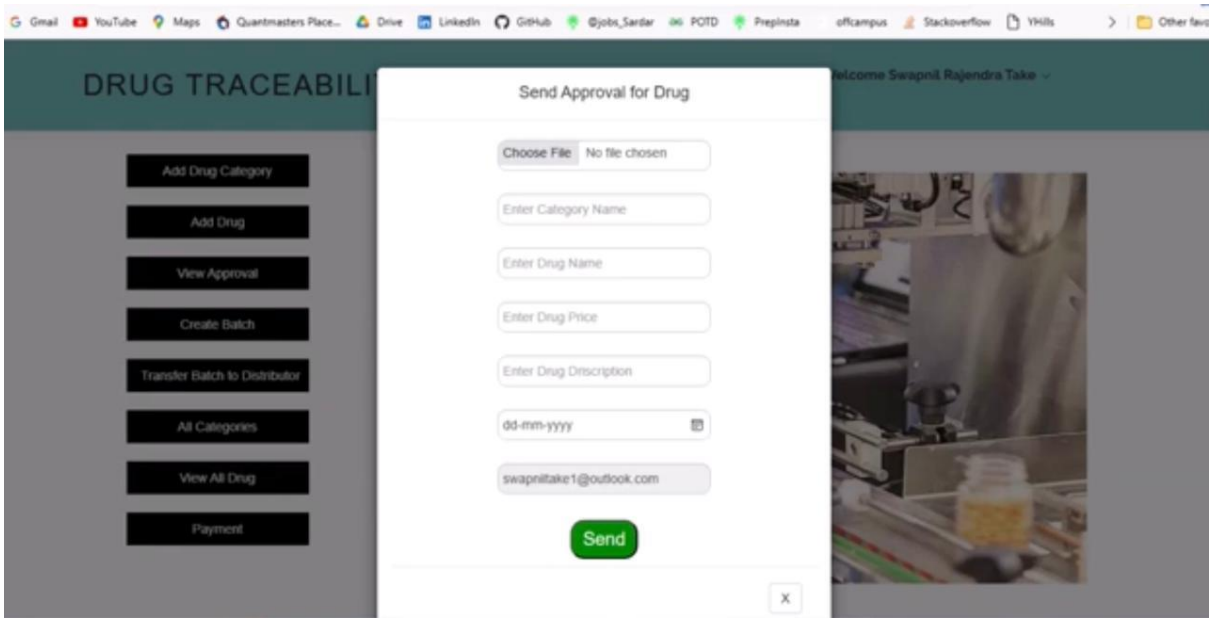
4	Open file explorer	Open the extracted file and click on the folder. Open src and search for utiles. Open cmd enter commands 1.npm install 2.npm bootstrap 3. npm start	
5.	{LOCALHOST IP ADDRESS	copy the address and open it to chrome so you can see the front end of your project.	

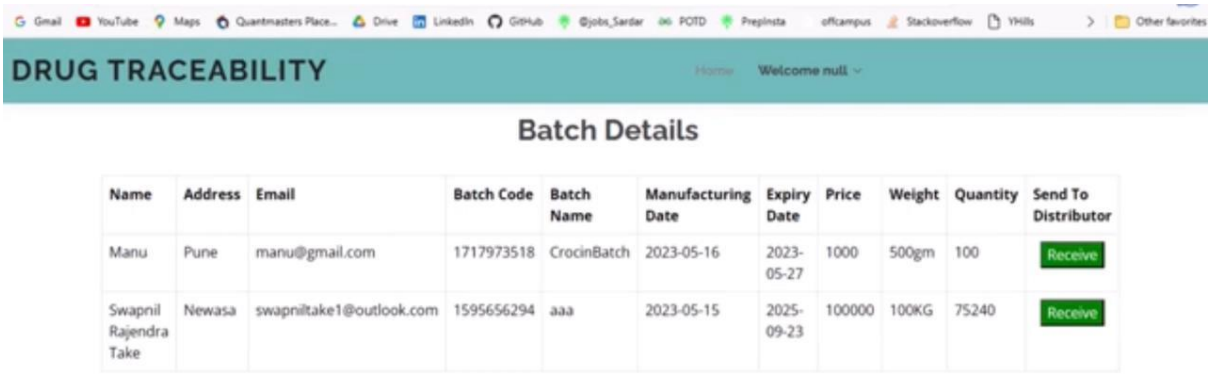
8. RESULTS :

8.1. Output Screenshot :

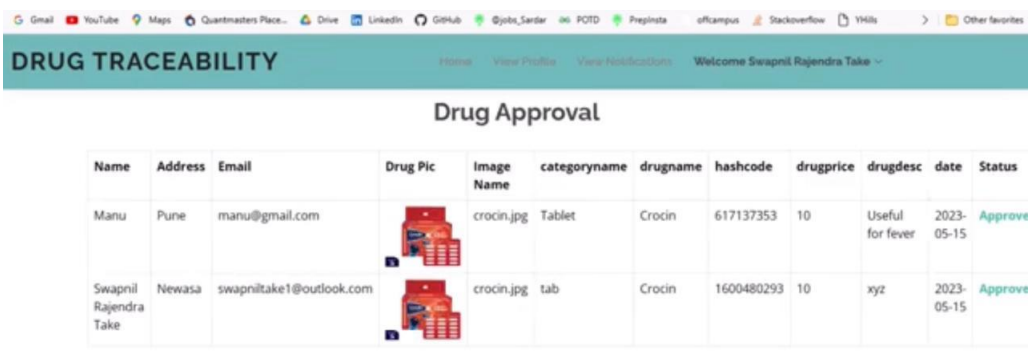








Name	Address	Email	Batch Code	Batch Name	Manufacturing Date	Expiry Date	Price	Weight	Quantity	Send To Distributor
Manu	Pune	manu@gmail.com	1717973518	CrocinBatch	2023-05-16	2023-05-27	1000	500gm	100	Receive
Swapnil Rajendra Take	Newasa	swapniltake1@outlook.com	1595656294	aaa	2023-05-15	2025-09-23	100000	100KG	75240	Receive



Name	Address	Email	Drug Pic	Image Name	categoryname	drugname	hashcode	drugprice	drugdesc	date	Status
Manu	Pune	manu@gmail.com		crocin.jpg	Tablet	Crocin	617137353	10	Useful for fever	2023-05-15	Approve
Swapnil Rajendra Take	Newasa	swapniltake1@outlook.com		crocin.jpg	tab	Crocin	1600480293	10	xyz	2023-05-15	Approve

9. ADVANTAGES AND DISADVANTAGES :

9.1. Advantages :

1. **Enhanced Transparency:** Blockchain provides a transparent and immutable ledger that records the complete history of a drug's journey from manufacturer to consumer. This transparency builds trust among stakeholders, including consumers, regulators, and manufacturers.
2. **Immutable Records:** Once data is recorded on the blockchain, it cannot be altered or deleted. This ensures the integrity of drug traceability records, making it nearly impossible to tamper with or counterfeit information.
3. **Reduced Counterfeit Drugs:** Counterfeit drugs are a serious issue in the pharmaceutical industry. Blockchain helps combat this problem by ensuring that each drug's origin and authenticity can be verified at every step of the supply chain.
4. **Improved Product Recall Management:** In the event of a product recall, blockchain enables rapid and accurate tracking of affected batches. This can minimize the scope of recalls, reduce costs, and protect consumers from potentially harmful products.
5. **Streamlined Supply Chain:** Real-time tracking and traceability in the supply chain lead to more efficient inventory management, reduced waste, and lower operational costs. This efficiency benefits both manufacturers and consumers.
6. **Regulatory Compliance:** Many countries have regulations in place to ensure the authenticity and safety of pharmaceutical products. Blockchain technology can facilitate compliance with these regulations by providing an auditable and transparent record of each drug's journey.

9.2. Disadvantages :

While using blockchain for drug traceability offers numerous advantages, it also comes with certain disadvantages and challenges that should be considered. Here are some of the key disadvantages of drug traceability using blockchain:

1. **Complexity and Integration Challenges:** Implementing a blockchain system in an existing supply chain can be complex and require significant changes to existing processes and systems. Integrating blockchain with legacy systems can be challenging.
2. **Scalability Issues:** As the number of transactions and data on the blockchain increases, scalability becomes a concern. Some blockchain platforms may struggle to handle the high transaction volume of the pharmaceutical supply chain, leading to potential performance issues.
3. **Costs and Resource Intensity:** Implementing and maintaining a blockchain network can be expensive. It requires investments in hardware, software, and skilled personnel. Additionally, the energy consumption of some blockchain networks, particularly those using proof-of-work consensus mechanisms, can be high.
4. **Privacy Concerns:** While blockchain offers robust security, it may not be sufficient to protect sensitive patient and drug information. Additional privacy measures are often required to ensure compliance with data protection regulations.
5. **Interoperability Challenges:** Ensuring that all stakeholders in the supply chain can participate and interact with the blockchain network can be complex. Achieving interoperability with various systems and participants is crucial.
6. **Regulatory Uncertainty:** The regulatory environment for blockchain in the pharmaceutical industry is still evolving. Changes in regulations can impact the implementation and use of blockchain for drug traceability.

10. CONCLUSION :

In this article, we have investigated the challenge of drug traceability within pharmaceutical supply chains highlighting its significance especially to protect against counterfeit drugs. We have developed and evaluated a blockchain-based solution for the pharmaceutical supply chain to track and trace drugs in a decentralized manner. Specifically, our proposed solution leverages cryptographic fundamentals underlying blockchain technology to achieve tamper-proof logs of events within the supply chain and utilizes smart contracts within Ethereum blockchain to achieve automated recording of events that are accessible to all participating stakeholders.

We have demonstrated that our proposed solution is cost efficient in terms of the amount of gas spent in executing the different functions that are triggered within the smart contract. Moreover, the conducted security analysis has shown that our proposed solution achieves protection against malicious attempts targeting is integrity, availability and non-repudiation of transaction data which is critical in a complex multi-party settings such as the pharmaceutical supply chain.

We continue our efforts to enhance the efficiency of pharmaceutical supply chains and envision to focus on extending the proposed system to achieve end to end transparency and verifiability of drugs use as future work.

11. FUTURE SCOPE :

The future scope of drug traceability using blockchain technology is highly promising and offers substantial advancements for the pharmaceutical industry. As blockchain continues to mature and gain acceptance, it will likely play a pivotal role in ensuring the authenticity, safety, and transparency of pharmaceutical products. This technology will facilitate a seamless, end-to-end

traceability system that not only combats counterfeit drugs but also optimizes supply chain processes. Moreover, the integration of IoT devices and sensors with blockchain will enable real-time monitoring of temperature and other environmental conditions, enhancing the quality control of pharmaceuticals. As regulatory bodies worldwide increasingly emphasize traceability and data integrity, blockchain's immutable ledger will become a standard tool for compliance. Looking ahead, we can expect further innovation in blockchain-based solutions, fostering collaboration between stakeholders, ensuring patient safety, and bolstering trust within the pharmaceutical supply chain. This technology will likely be instrumental in addressing emerging challenges and opportunities, making the future of drug traceability more secure, efficient, and accountable.

12. APPENDIX :

12.1. Source Code :

```
pragma solidity ^0.8.0;
contract DrugTraceability {
   address public owner;
 struct Drug {
       string name;
       string batchNumber;
       uint256 manufacturingDate;
       address manufacturer;
       address distributor;
       address retailer;
       address consumer;
   }
    Drug[] public drugs;
```

```
    event DrugCreated(uint256 indexed drugId, string name, string batchNumber);
    event DrugTransferred(uint256 indexed drugId, address from, address to);

     constructor() {
        owner = msg.sender;
    }

    modifier onlyOwner() {
        require(msg.sender == owner, "Only the owner can perform this action.");
        _;
    }
     function createDrug(string memory _name, string memory _batchNumber) public onlyOwner {
        drugs.push(Drug({
            name: _name,
            batchNumber: _batchNumber,
            manufacturingDate: block.timestamp,
            manufacturer: msg.sender,
            distributor: address(0),
            retailer: address(0),
            consumer: address(0)
        }));

        uint256 drugId = drugs.length - 1;
        emit DrugCreated(drugId, _name, _batchNumber);
    }

    function transferDrug(uint256 _drugId, address _to) public {
        require(_drugId < drugs.length, "Invalid drug ID.");
```

```
        require(drugs[_drugId].manufacturer == msg.sender, "Only the manufacturer can transfer.");
        require(_to != address(0) && _to != msg.sender, "Invalid recipient address.");


        if (drugs[_drugId].distributor == address(0)) {
            drugs[_drugId].distributor = _to;
        } else if (drugs[_drugId].retailer == address(0)) {
            drugs[_drugId].retailer = _to;
        } else {
            drugs[_drugId].consumer = _to;
        }

          emit DrugTransferred(_drugId, msg.sender, _to);

    }

}
```

13. Github and Project Demo Link :

Github link : https://github.com/rupikaramanan/NM2023TMID01628

Video Link : https://drive.google.com/file/d/1clTJ0IRVZCQFXU6kCWDf4_bsvmxV1Hja/view?usp=drivesdk