

DRUG TRACEABILITY USING BLOCKCHAIN

PROJECT REPORT

Submitted by

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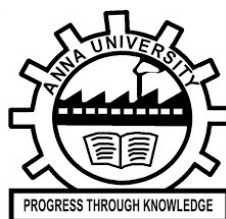
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CHAPTER 1

INTRODUCTION

1.1 PROJECT OVERVIEW

Drug traceability is the process of determining the product's authenticity and originality so that all stakeholders can track and trace transactions at every level of the supply chain. A pharmaceutical supply chain follows an end-to-end process from sourcing the active medication ingredients (source) to manufacturing the final product (medication) distributed and delivered to patients (end-users). It is the primary responsibility of the supply chain members to distribute authentic and high-quality products at the right time as it directly influences the health and safety of patients. The current drug distribution, and delivery systems have grown immensely in scale and complexity. In addition, limited data visibility, lack clear ownership structure, diversity of stakeholders makes transaction verification difficult. The lack of an integrated view of the entire supply chain often requires centralized third-party solutions to collect and validate information.

Pharmaceutical supply chain comprises of several stakeholders (supplier, manufacturer, distributor, retailer, pharmacy, and patient), and product distribution often requires intricate packing, unpacking and repacking process, which makes drug provenance and traceability very complicated. illustrates a high level overview of various stakeholders and their relationship in the pharmaceutical supply chain. There are several factors attributed to the availability of counterfeits in the supply chain, some examples include importing substandard medicines without the approval of regulatory authority, poor manufacturing and storage practices, theft, and infiltration of deficient drugs.

Different technology driven approaches such as bar codes, RFID tags, IoT, serialization, and e-pedigree have been adopted to enhance trust among stakeholders to improve product visibility in the supply chains. However, these solutions are centralized

and have serious limitations when it comes to security, interoperability, privacy, and scalability toward preventing counterfeits in the supply chains. Blockchain technology is a decentralized, distributed ledger system that provides an efficient and trusted solution for product traceability. Blockchain technology powers the crypto currencies and has been applied to variety of industries such as banking, supply chain, energy, commodities trading, healthcare and many businesses involving transaction processing. To deal with the issue of counterfeit drugs, blockchain technology has the potential to provide pragmatic solution for drug traceability and provenance in a secure and immutable manner. counterfeiting of drugs is increasing globally, pharmaceutical companies are adapting blockchain technology to prevent counterfeiting. The supply of medicines is from manufactures to wholesalers, distributors, and pharmacy stores before it is purchased by customers; the counterfeiters come in between this supply chain and thus fake medicines get supplied and distributed. This project is a blockchain-based solution “Drug-chain” to improve on the end the end transparency of the drug in supply chain.

1.2 PURPOSE

Blockchain technology offers several benefits for drug traceability, which is the process of tracking and verifying the authenticity of pharmaceutical products as they move through the supply chain. Here are some key purposes for implementing blockchain in drug traceability:

1. **Immutable Recordkeeping:** Blockchain provides an immutable ledger, meaning once data is recorded, it cannot be altered or tampered with. This ensures that the information about the origin, production, and distribution of drugs remains accurate and trustworthy.
2. **Transparency and Visibility:** Blockchain allows all participants in the supply chain, including manufacturers, distributors, regulators, and consumers, to have real-time access to a transparent and shared ledger. This transparency enhances trust and accountability among stakeholders.
3. **End-to-End Traceability:** Blockchain enables the creation of a complete and unbroken chain of custody for each pharmaceutical product. This means that

every step in the supply chain, from manufacturing to distribution, can be tracked and verified.

4. **Authentication and Verification:** Through unique digital identifiers or serial numbers, each drug package can be associated with a cryptographic token on the blockchain. This allows for instant verification of the authenticity and integrity of a product at any point in the supply chain.
5. **Counterfeit Prevention:** By leveraging blockchain's immutable ledger and cryptographic security features, it becomes extremely difficult for counterfeit drugs to enter the supply chain. Unauthorized alterations or substitutions of genuine products are easily detectable.
6. **Regulatory Compliance:** Blockchain can automate and streamline compliance with regulatory requirements. Smart contracts can be used to enforce predefined rules and trigger actions automatically when certain conditions are met.
7. **Recall Management:** In the event of a product recall, blockchain enables rapid and precise identification of affected batches. This helps minimize the impact on public health and reduces the cost and time associated with recalls.
8. **Efficient Auditing and Reporting:** Traditional auditing processes can be time-consuming and resource-intensive. With blockchain, audit trails are available in real-time, making it easier for regulators and auditors to verify compliance.
9. **Data Security and Privacy:** Blockchain uses advanced cryptographic techniques to secure data. Permissioned blockchains, where only authorized parties have access, can further enhance data privacy and security.
10. **Cost Reduction:** By streamlining processes, reducing paperwork, and minimizing the need for intermediaries, blockchain can lead to cost savings in the pharmaceutical supply chain.
11. **Trust Building:** Implementing blockchain technology in drug traceability builds trust among stakeholders, including consumers. They can have confidence that the products they are using are genuine and safe.

CHAPTER 2

LITERATURE SURVEY

2.1 LITERATURES

The articles published in drug traceability were studied for the project development including:

1. A Blockchain-based approach for Drug Traceability in Healthcare supply chain - Shweta, Shweta M published on International Journal of Creative Research Thoughts on 2022.
2. Blockchain for Drug traceability: Architectures and Open challenges – Mueen Uddin, Khaled Salah, Raja Jayaram, Sasa Pesic, published on Health Informatics Journal on 2021.
3. Using Blockchain for Traceability in the Drug Supply Chain - Jennifer Cristina Molina, Daniela Torres Delgado & Giovanni Tarazona published on Communications in Computer and Information Science book series (CCIS, volume 1027) on 2019.

2.2 EXISTING PROBLEM

There are several existing problems in drug traceability that blockchain technology aims to address

1. **Counterfeit Drugs:** Counterfeit or fake drugs entering the supply chain pose a significant threat to public health. These drugs can contain incorrect ingredients, incorrect dosages, or even harmful substances.
2. **Lack of Transparency:** The current pharmaceutical supply chain often lacks transparency, making it difficult to track the movement of drugs from manufacturer to consumer. This opacity can lead to inefficiencies and difficulties in identifying and addressing issues.

3. **Inefficient Recall Management:** In the event of a product recall, the current systems can be slow and imprecise. It can be challenging to quickly identify affected batches, leading to potential harm to consumers.
4. **Regulatory Compliance Challenges:** Ensuring compliance with regulatory requirements can be complex and resource-intensive. The current processes often involve manual documentation and audits, which can be time-consuming and prone to errors.
5. **Data Integrity and Security:** Data recorded in traditional systems can be susceptible to tampering or unauthorized access. Ensuring the integrity and security of supply chain information is crucial for maintaining trust and reliability.
6. **Fragmented Recordkeeping:** The pharmaceutical supply chain involves multiple parties, including manufacturers, wholesalers, distributors, and pharmacies. Coordinating recordkeeping among these stakeholders can be challenging, leading to discrepancies and inefficiencies.
7. **Manual Verification Processes:** Verifying the authenticity of pharmaceutical products currently relies on manual checks, which can be time-consuming and may not be foolproof.
8. **Lack of Consumer Confidence:** Consumers may lack confidence in the authenticity and safety of the drugs they purchase due to concerns about counterfeit products.
9. **Cost Inefficiencies:** Inefficiencies in the supply chain, such as manual recordkeeping and paperwork, can lead to increased costs for pharmaceutical companies, which may ultimately be passed on to consumers.
10. **Global Supply Chain Complexity:** The pharmaceutical industry operates on a global scale, with products moving across international borders. Coordinating traceability efforts across different countries and regions can be challenging.
11. **Limited Recourse for Victims of Counterfeits:** In cases where counterfeit drugs reach consumers, it can be difficult to trace the origin and hold responsible parties accountable.

Blockchain technology addresses many of these issues by providing a secure, transparent, and immutable ledger that enables end-to-end traceability of pharmaceutical products. It helps to prevent counterfeiting, streamline regulatory compliance, enhance transparency, and improve recall management, ultimately ensuring the safety and integrity of the pharmaceutical supply chain.

2.2 PROBLEM STATEMENT DEFINITION

The current pharmaceutical supply chain faces significant challenges in accurately and efficiently tracking the movement of drugs from manufacturer to consumer. Issues such as counterfeit drugs, lack of transparency, inefficient recall management, and regulatory compliance complexities pose serious threats to public health and safety. Additionally, fragmented recordkeeping and manual verification processes contribute to inefficiencies and hinder the ability to swiftly respond to critical situations. There is a pressing need for a comprehensive and secure system that provides end-to-end traceability, ensures data integrity and security, and builds trust among stakeholders, ultimately safeguarding the integrity of the pharmaceutical supply chain

CHAPTER 3

IDEATION AND PROPOSED SOLUTION

3.1 EMPATHY MAP

An empathy map is a tool used to gain a deeper understanding of a specific user or stakeholder group's thoughts, feelings, needs, and behaviors. In the context of drug traceability using blockchain, here's an empathy map idea:

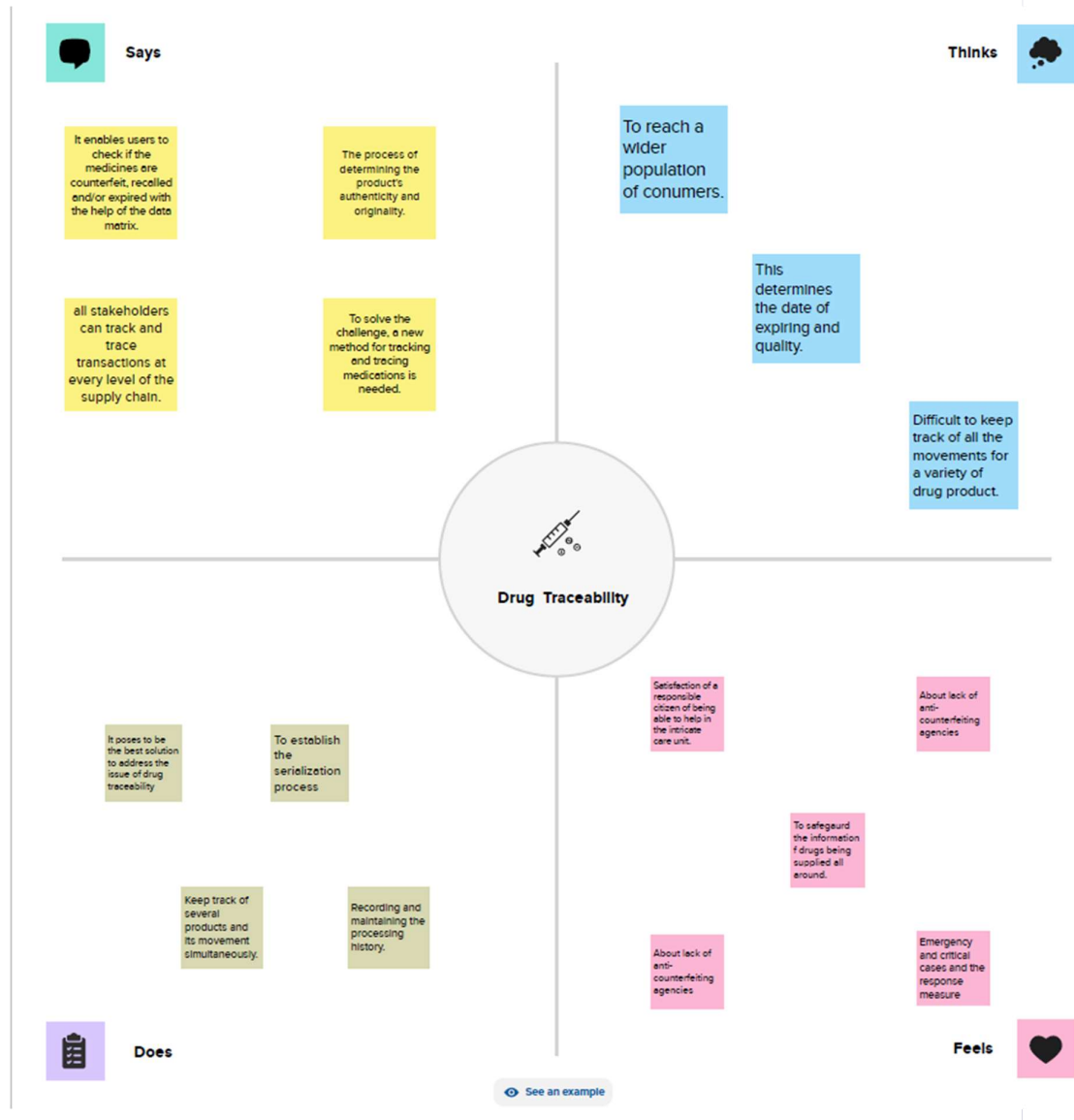


Figure 1: Empathy Map

3.2 BRAINSTORMING AND IDEATION

Brainstorming and ideation are creative processes aimed at generating a wide range of ideas or solutions for a particular problem or challenge. Here's a step-by-step guide to effective brainstorming and ideation.

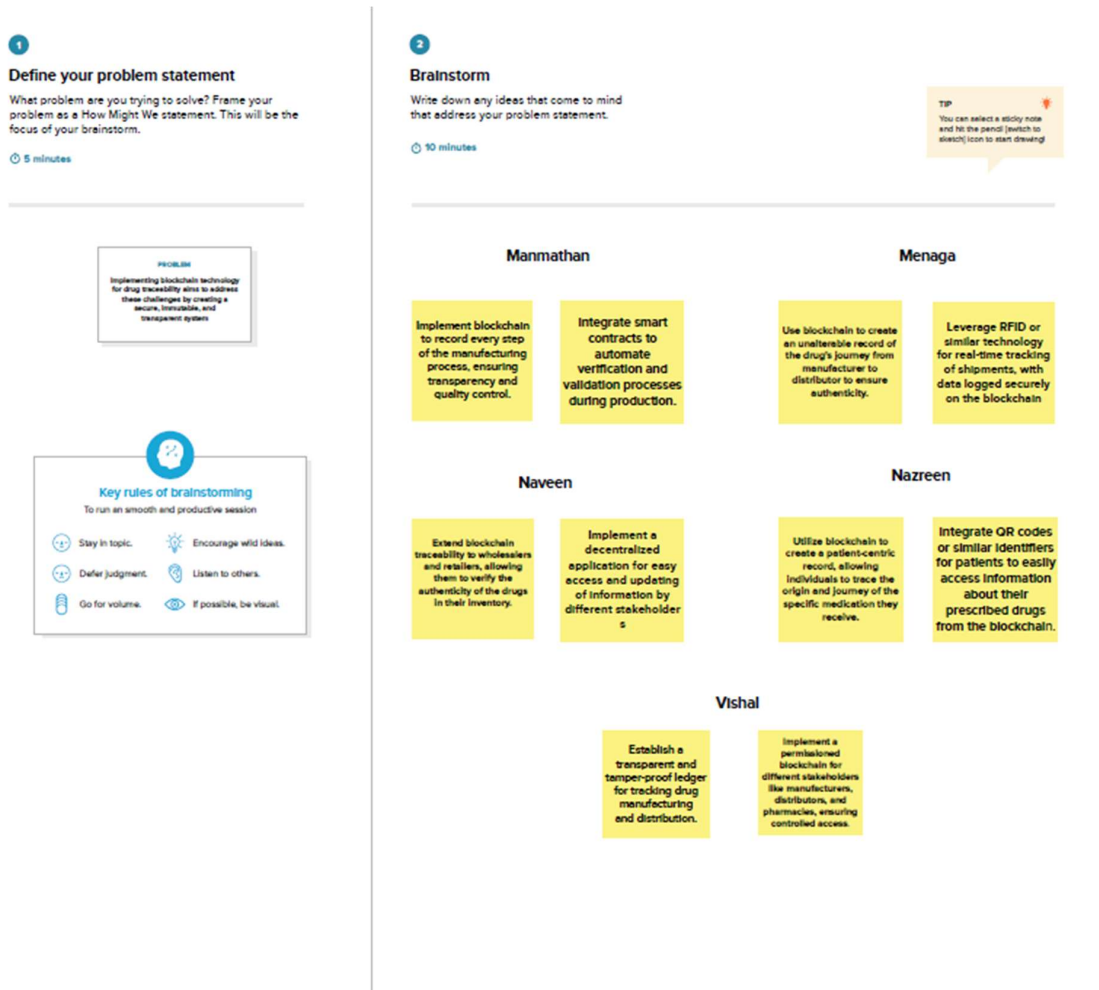


Figure 2: Brainstorming



Figure 2: Ideation Map

CHAPTER 4

PROJECT DESIGN

4.1 SOLUTION ARCHITECTURE

Solution architecture refers to the process of designing and organizing the various components of a system or application to meet specific requirements and objectives. It involves making decisions about the overall structure, technologies, platforms, and interactions between different parts of the solution.

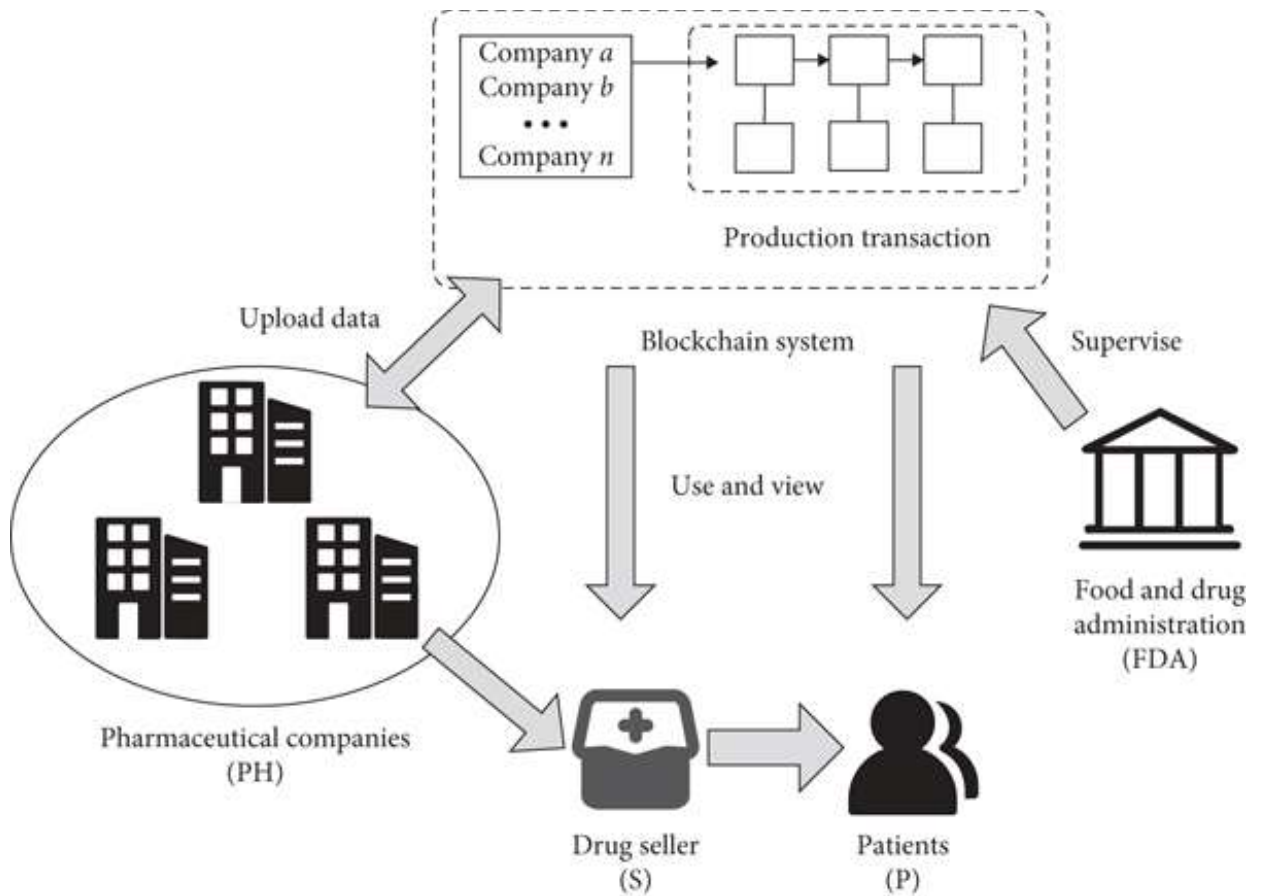


Figure 3: Solution Architecture for the problem

4.2 DATA FLOW DIAGRAM

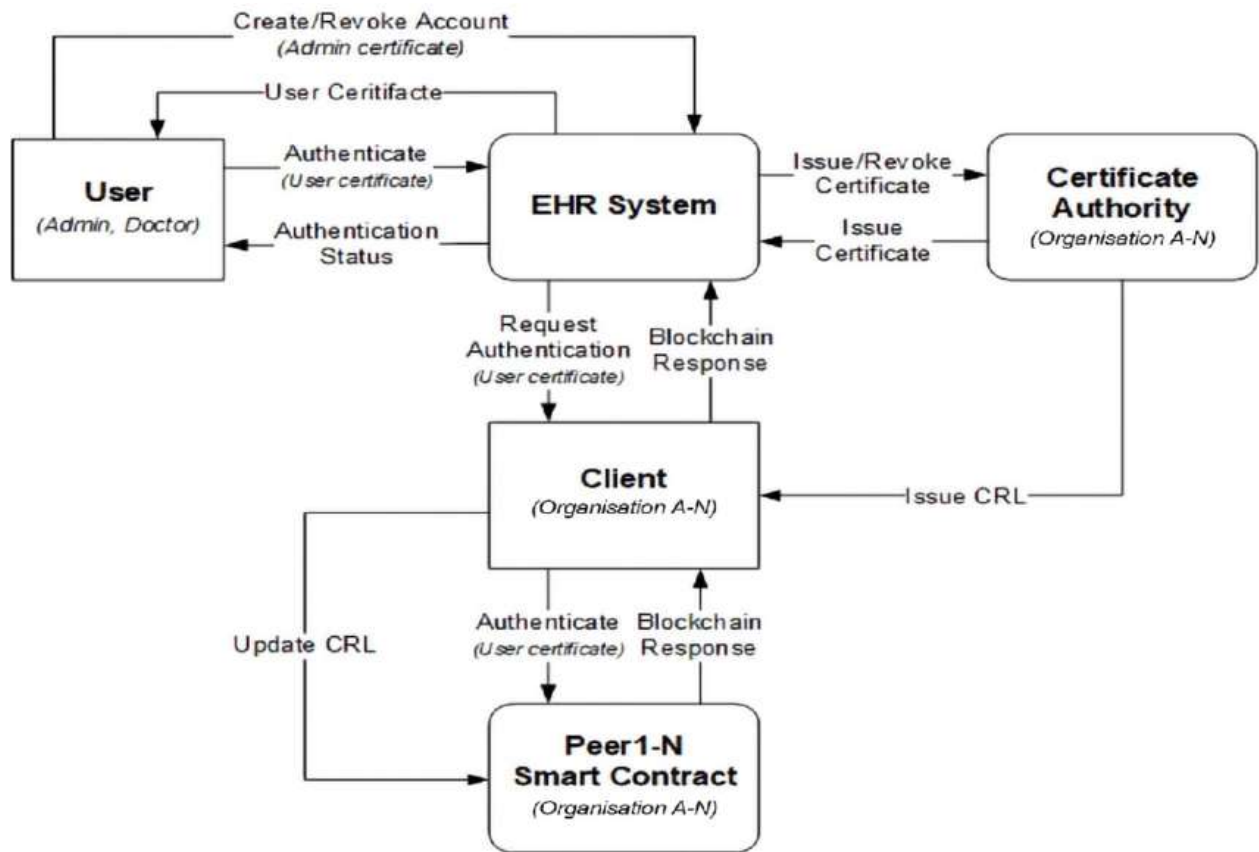


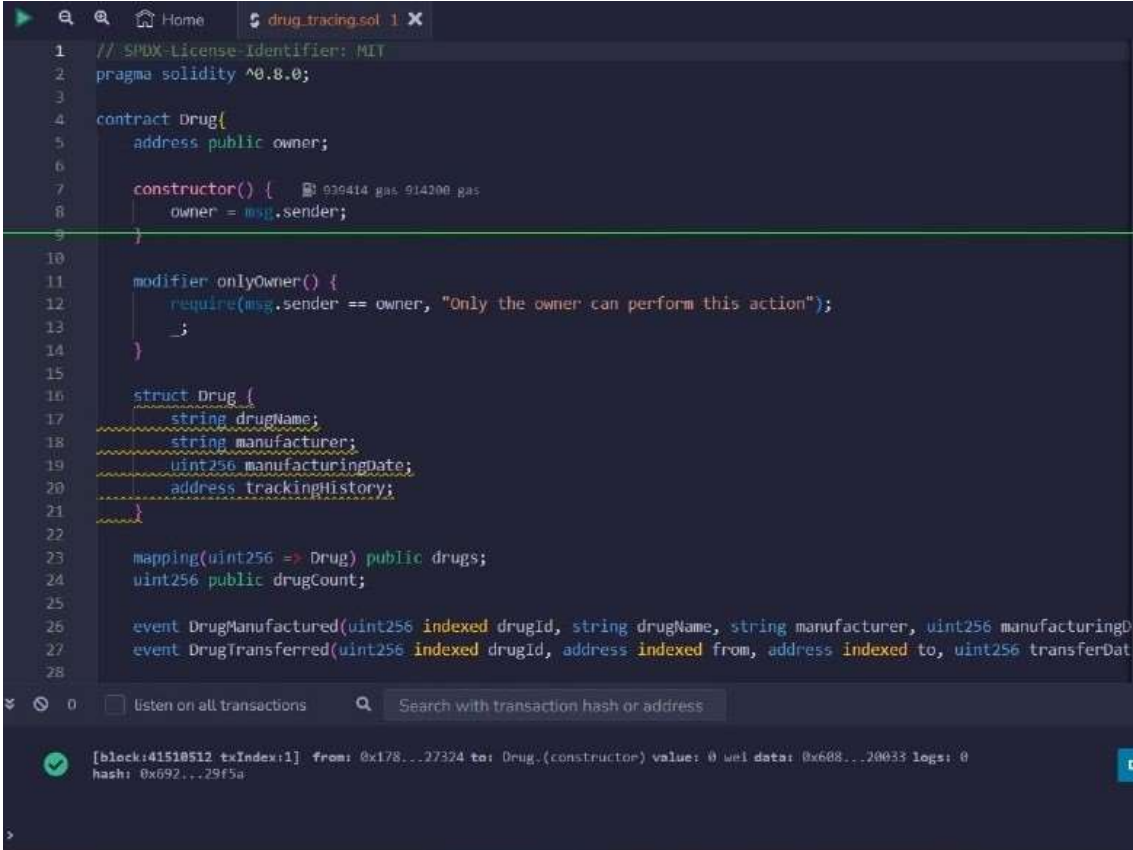
Figure 4: Data flow diagram

CHAPTER 5

CODING AND SOLUTIONING

5.1 CODE

Solidity is a programming language specifically designed for writing smart contracts on the Ethereum blockchain platform.



```

1 // SPDX-License-Identifier: MIT
2 pragma solidity ^0.8.0;
3
4 contract Drug{
5     address public owner;
6
7     constructor() {
8         owner = msg.sender;
9     }
10
11     modifier onlyOwner() {
12         require(msg.sender == owner, "Only the owner can perform this action");
13         _;
14     }
15
16     struct Drug {
17         string drugName;
18         string manufacturer;
19         uint256 manufacturingDate;
20         address trackingHistory;
21     }
22
23     mapping(uint256 => Drug) public drugs;
24     uint256 public drugCount;
25
26     event DrugManufactured(uint256 indexed drugId, string drugName, string manufacturer, uint256 manufacturingDate);
27     event DrugTransferred(uint256 indexed drugId, address indexed from, address indexed to, uint256 transferDate);
28

```

The screenshot shows a code editor with a dark theme. The code is a Solidity smart contract named 'Drug'. It includes a pragma statement for Solidity version ^0.8.0, a constructor that sets the owner to the sender, a modifier 'onlyOwner' that checks if the sender is the owner, a 'Drug' struct with fields for drugName, manufacturer, manufacturingDate, and trackingHistory, a mapping 'drugs' from uint256 to Drug, a public variable 'drugCount' of type uint256, and two events: 'DrugManufactured' and 'DrugTransferred'. The bottom of the editor shows a transaction log for block 41510512, transaction index 1, from address 0x178...27324 to the Drug contract, with a value of 0 wei and data 0x608...20033. The logs are empty.

Figure 5: Solidity code

```

28
29 function manufactureDrug(uint256 drugId, string memory _drugName, string memory _manufacturer, uint256 _manufacturingDate)
30
31     address initialHistory;
32     initialHistory = owner;
33
34     drugs[drugId] = Drug(_drugName, _manufacturer, _manufacturingDate, initialHistory);
35     drugCount++;
36
37     emit DrugManufactured(drugId, _drugName, _manufacturer, _manufacturingDate);
38 }
39
40 function transferDrugOwnership(uint256 _drugId, address _to) external {
41     require(_to != address(0), "Invalid address");
42     require(_to != drugs[_drugId].trackingHistory, "Already owned by the new address");
43
44     address from = drugs[_drugId].trackingHistory;
45     drugs[_drugId].trackingHistory = _to;
46
47     emit DrugTransferred(_drugId, from, _to, block.timestamp);
48 }
49
50 function getDrugDetails(uint256 _drugId) external view returns (string memory, string memory, uint256, address) {
51
52     Drug memory drug = drugs[_drugId];
53     return (drug.drugName, drug.manufacturer, drug.manufacturingDate, drug.trackingHistory);
54 }
55 }

```

Figure 6: Solidity Code 2

The screenshot displays the Remix IDE interface for deploying a Solidity contract. The left sidebar, titled 'DEPLOY & RUN TRANSACTIONS', shows the following configuration:

- ENVIRONMENT:** Injected Provider - MetaMask
- ACCOUNT:** 0x178...27324 (0.39734869498409217 ether)
- GAS LIMIT:** 3000000
- VALUE:** 0 Wei
- CONTRACT:** Drug - drug_tracing.sol
- Buttons:** Deploy, Publish to IPFS, At Address, Load contract from Address
- Transactions recorded:** 1
- Deployed Contracts:** DRUG AT 0x533...37830 (BLOCKCHAIN)

The main editor shows the Solidity code for the 'Drug' contract, which includes a constructor, a modifier, a struct, a mapping, and two events.

```

1 // SPDX-License-Identifier: MIT
2 pragma solidity ^0.8.0;
3
4 contract Drug{
5     address public owner;
6
7     constructor() {
8         owner = msg.sender;
9     }
10
11     modifier onlyOwner() {
12         require(msg.sender == owner, "Only the owner can perform this action");
13         _;
14     }
15
16     struct Drug {
17         string drugName;
18         string manufacturer;
19         uint256 manufacturingDate;
20         address trackingHistory;
21     }
22
23     mapping(uint256 => Drug) public drugs;
24     uint256 public drugCount;
25
26     event DrugManufactured(uint256 indexed drugId, string drugName, string manufacturer, uint256 manufacturingDate);
27     event DrugTransferred(uint256 indexed drugId, address indexed from, address indexed to, uint256 transferDate);
28 }

```

The bottom panel shows the deployment status: [block:41518512 txIndex:1] from: 0x178...27324 to: Drug.(constructor) value: 0 wei data: 0x608...20033 logs: 0 hash: 0x692...29f5a.

Figure 7: Deployment of contract using REMIX

CHAPTER 6

RESULT

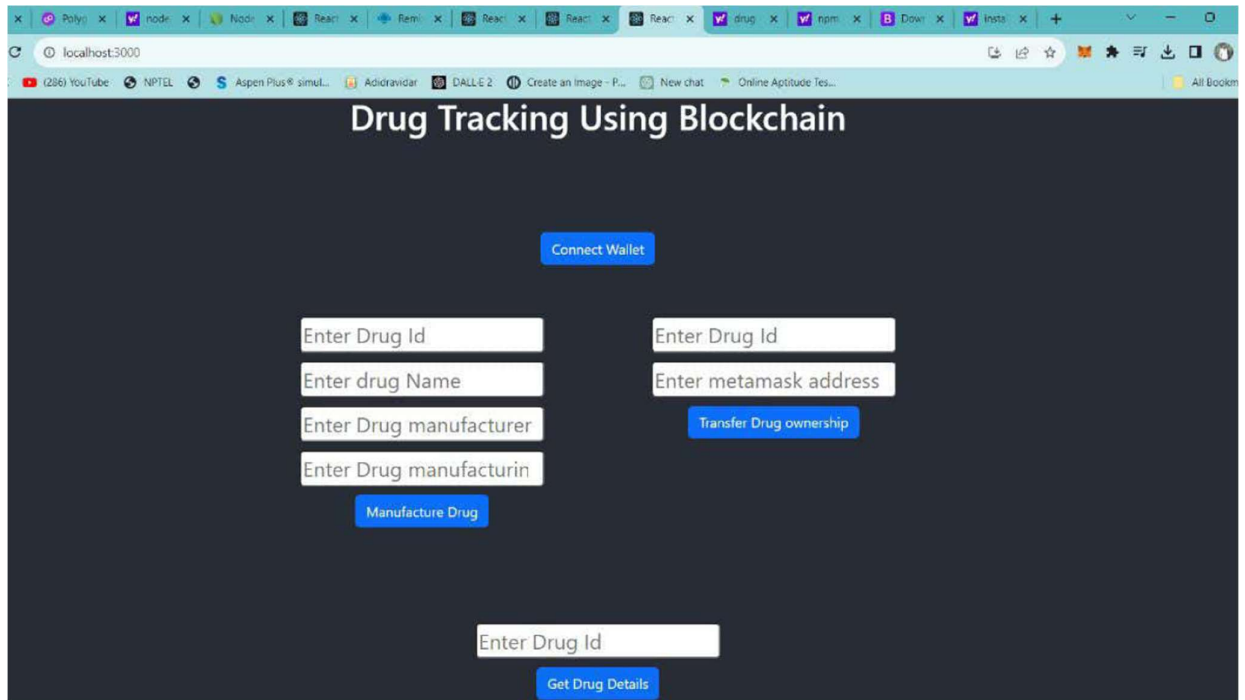


Figure 8: Project Frontend

CHAPTER 7

ADVANTAGES AND DISADVANTAGES

7.1 ADVANTAGES

1. Increased safety:

Traceability can help to identify and remove counterfeit and substandard medications from the supply chain. This can help to protect patients from serious health risks.

2. Improved security:

Traceability can help to track and trace medications throughout the supply chain, which can help to deter theft and diversion.

3. Increased compliance:

Traceability can help pharmaceutical companies to comply with regulations. This can help to protect their businesses from fines and penalties.

4. Enhanced efficiency:

Traceability can help to improve the efficiency of the pharmaceutical supply chain. This can lead to lower costs and shorter lead times. These technologies can go hand-in-hand with automated inventory management systems to bolster efficiency at busy health systems.

7.2 DISADVANTAGES

1. Immutability:

Blockchains are immutable where any information appended to the ledger cannot be altered or removed. While this can be beneficial for data integrity, it presents a major challenge, there is no way to correct inaccuracies on a blockchain because they are immutable.

For example: the operators conducting the physical tasks in the drug supply chain can still make errors when recording information to the ledger.

2. Data Privacy:

Although immutability is considered one of the main advantages of blockchains, it can be in conflict with emerging laws that address information storage issues.

For example: the General Data Protection Regulation (GDPR) in Europe requires that organizations accurately control where and how data is stored because the person it is collected from have the right to modify or delete it any time, and if actions are not taken according to their requests, the organization can be liable to heavy fines.

3. Interoperability:

Blockchain networks other than Ethereum work in their own unique way which leads to interoperability issues where the different blockchains are not able to communicate with each other.

CHAPTER 8

CONCLUSION

In the realm of pharmaceuticals, the implementation of blockchain technology has ushered in a new era of transparency, accountability, and security. Our exploration into drug traceability using blockchain has illuminated the transformative potential of this innovative solution. As we conclude this report, several key insights and outcomes underscore the significance of adopting blockchain for drug traceability.

Enhanced Transparency and Trust:

Blockchain technology provides an immutable and transparent ledger, ensuring that every transaction and movement of pharmaceuticals is recorded in a secure and unchangeable manner. This heightened transparency cultivates trust among stakeholders, including manufacturers, distributors, healthcare providers, and most importantly, patients. The ability to access real-time, trustworthy information about the origin and journey of drugs instills confidence in the pharmaceutical supply chain.

Efficient and Accurate Tracking:

By leveraging blockchain, the pharmaceutical industry can now accurately trace the entire lifecycle of drugs, from manufacturing to distribution and consumption. The decentralized nature of blockchain eliminates the need for intermediaries, reducing the risk of errors, fraud, and counterfeit products. Real-time tracking ensures that stakeholders can pinpoint the location of pharmaceuticals at any given moment, enabling swift responses to recalls, minimizing losses, and ensuring timely deliveries.

Mitigating Counterfeit Drugs:

Counterfeit drugs pose a significant threat to public health, making it imperative to combat their proliferation. Blockchain's tamper-proof nature makes it exceedingly difficult for counterfeiters to infiltrate the supply chain. By utilizing unique identifiers and secure digital records, blockchain empowers consumers and regulatory authorities to authenticate the legitimacy of pharmaceutical products. This proactive approach not only safeguards patients but also upholds the integrity of the pharmaceutical industry.

Compliance and Regulatory Advancements:

Blockchain technology facilitates adherence to regulatory requirements and compliance standards. Smart contracts embedded within the blockchain can automate compliance processes, ensuring that pharmaceutical products meet the necessary quality, safety, and documentation standards. By streamlining regulatory procedures, blockchain minimizes bureaucratic hurdles, expedites approvals, and enhances overall industry efficiency.

Future Prospects and Continuous Innovation:

The implementation of blockchain for drug traceability represents a pivotal moment in the evolution of the pharmaceutical sector. As technology continues to advance, further innovations such as Internet of Things (IoT) integration, artificial intelligence (AI) analytics, and machine learning (ML) algorithms will enhance the capabilities of blockchain-based traceability systems. These advancements promise even greater efficiency, accuracy, and intelligence in managing the pharmaceutical supply chain.

In conclusion, the adoption of blockchain technology in drug traceability is not merely a technological upgrade but a paradigm shift in ensuring the safety, authenticity, and reliability of pharmaceutical products. As we move forward, collaboration among industry stakeholders, policymakers, and technologists will be essential in realizing the full potential of blockchain, transforming the pharmaceutical supply chain into a model of integrity, security, and accountability. The journey towards a safer and more transparent pharmaceutical industry has begun, and blockchain is guiding us toward that brighter future.