NADAR SARASWATHI COLLEGE OF ENGINEERING AND TECHNOLOGY, THENI-625531

A PROJECT STAGE I REPORT ON

”DRUG TRACEABILITY IN HEALTHCARE USING BLOCKCHAIN”

In partial fulfillment for the award of the degree

Of

BACHELOR OF ENGINEERING

IN

COMPUTER SCIENCE AND ENGINEERING

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1.INTRODUCTION

1.1 PROJECT OVERVIEW

Drug traceability system is essentially important for public drug security and busi- ness of pharmaceutical companies, which aims to track or trace where the drug has been and where it has gone along the drug supply chain. Traditional centralized server-client technical solutions have been far from satisfying for their bad performances in data authenticity, privacy, system resilience and flexibility. We have proposed an entirely new blockchain system for drug traceability. This system is more secure and scalable than other alternatives on the market today. In addition, the proposed system is able to effectively prune its storage, resulting in a finally stable and usable blockchain storage solution.

Generally, a drug traceability system should be able to keep track or trace of the drug transaction flow through different stakeholders along the drug supply chain. It should provide reliable information about the flow for stakeholders and patients, especially that of drug production origin for anti counterfeit purposes. Or, at least it could be used to bind the responsibility of drug security to the relevant stakeholders for government regulation. Furthermore, the privacy of traceability data in the system is required to be protected as much as possible, especially that of statistical information (e.g. productivity, quantity of sale, etc.) of drugs that has been passed to the stakeholder. This paper presents the Drug Traceability System, a fully scenario-oriented blockchain system for drug traceability and regulation. It reconstructs the whole service architecture, ensures the authenticity and privacy of traceability data, and meanwhile achieves a finally stable blockchain stor- age with time going by. Algorithms reflecting the practical workflow of the drug supply chain.

1.2 PURPOSE

Blockchain technology ensures an efficient and cost-effective solution that underpins different drug traceability functions and procedures to ascertain proper identification, tracing, tracking, and provenance.

- Execution and owner
- Time
- Location of transmission
- Which stakeholders have involved

The use of blockchain can enhance the security of drug information and combat counterfeit drugs. Counterfeit drugs can affect patients' health directly or indirectly, causing serious health issues and sometimes even death.

2.LITERATURE SURVEY

2.1 EXISTING PROBLEM

In today's world, the healthcare industry relies on extensive supply chains that cross organizational and geographic boundaries. Impurities such as erroneous information, a lack of transparency, and restricted data provenance can be introduced by the intrinsic complexity of such systems. Counterfeit medications are one of the consequences of such constraints in existing supply chains, which not only has a negative impact on human health but also costs the healthcare business a lot of money. A dependable end-to-end track and trace system for pharmaceutical supply chains has thus been emphasized in prior study.An end-to-end pharmaceutical supply chain tracking system is vital to assure product safety and eradicate counterfeits. Most modern track and trace systems in healthcare supply chains are centralized, posing privacy, transparency, and authenticity issues.

2.2 REFERENCES

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2.3 PROBLEM STATEMENT DEFINITION

Drug fraud is a major problem faced by many pharmaceutical companies and, ac- cording to the Health Research Funding Organization, around 10% to 30% of drugs sold in the developing world are fake and, it’s the underground economy is valued at around
$200 billion annually. According to another report by the World Health Organization, around 16% of the counterfeit drugs contain the wrong ingredients. The main issue with such drugs is not that they’re just fake, but it’s mainly about the wrong ingredients that can put the patient’s life in danger.

To stop this fraud in india build and implement drug traceability in healthcare supply chain using block chain.

3.IDEATION & PROPOSED SOLUTION
3.1 EMPATHY MAP CANVAS
IDEATION PHASE & BRAINSTORM

The ideation phase of drug traceability is a critical stage where you explore and generate ideas for implementing a traceability system in the pharmaceutical supply chain using blockchain technology. This phase involves brainstorming, research, and preliminary planning. Here's what you should consider during the ideation phase of drug traceability:

Problem Identification: Begin by identifying the specific problems and challenges within the pharmaceutical supply chain that you want to address. Common issues include counterfeiting, drug diversion, inefficiencies, and a lack of transparency.

Stakeholder Analysis: Understand the various stakeholders involved in the drug supply chain, including manufacturers, distributors, pharmacists, healthcare providers, regulatory authorities, and patients. Identify their needs and concerns.

Technology Assessment: Evaluate the capabilities and limitations of blockchain technology. Consider whether public or private blockchains are more suitable, what consensus mechanisms to use, and which blockchain platforms or frameworks to consider.

Regulatory Compliance: Research the regulatory requirements for pharmaceutical traceability in your region or target markets. Understand how blockchain can help you comply with these regulations.

Use Case Definition: Define the specific use cases for blockchain-based drug traceability. For example, you might focus on product authentication, supply chain visibility, recall management, or patient empowerment. Each use case will have its unique requirements.

Data and Information Flow: Create a flowchart or diagram illustrating how data and information will be recorded, shared, and accessed within the blockchain system.

Consider which data points are critical, such as product details, batch numbers, production dates, and distribution records.

Technical Architecture: Determine the technical architecture of your blockchain-based system. Consider factors like scalability, interoperability with existing systems, and the choice of smart contracts for automating processes.

Partnerships and Collaboration: Explore potential partners and collaborators in the pharmaceutical industry, technology providers, and regulatory agencies. Collaboration is often key to the success of a traceability system.

Cost and Budgeting: Develop a preliminary budget for implementing the system. Consider the costs associated with blockchain development, hardware, software, and ongoing maintenance.

Risk Assessment: Identify potential risks and challenges associated with the implementation of drug traceability using blockchain. This could include technical challenges, regulatory hurdles, and resistance from stakeholders.

Prototyping: Consider building a prototype or proof of concept to demonstrate the feasibility of your proposed system. This can be a valuable tool for securing support and funding.

Market Research: Understand the market demand for traceability solutions and gather feedback from potential users. This will help you refine your ideas to better align with market needs.

Legal and Ethical Considerations: Analyze the legal and ethical implications of implementing blockchain-based drug traceability. Consider data privacy, intellectual property, and liability issues.

Scalability and Sustainability: Think about how the system can be scaled as your operations grow and how it will be sustained over the long term.

Feasibility Assessment: Ultimately, assess the feasibility of your ideation. Do the benefits of implementing blockchain-based drug traceability outweigh the costs and challenges?

4.REQUIREMENT ANALYSIS

4.1 FUNCTIONAL REQUIREMENTS

The functional requirements for a system describe what system do.

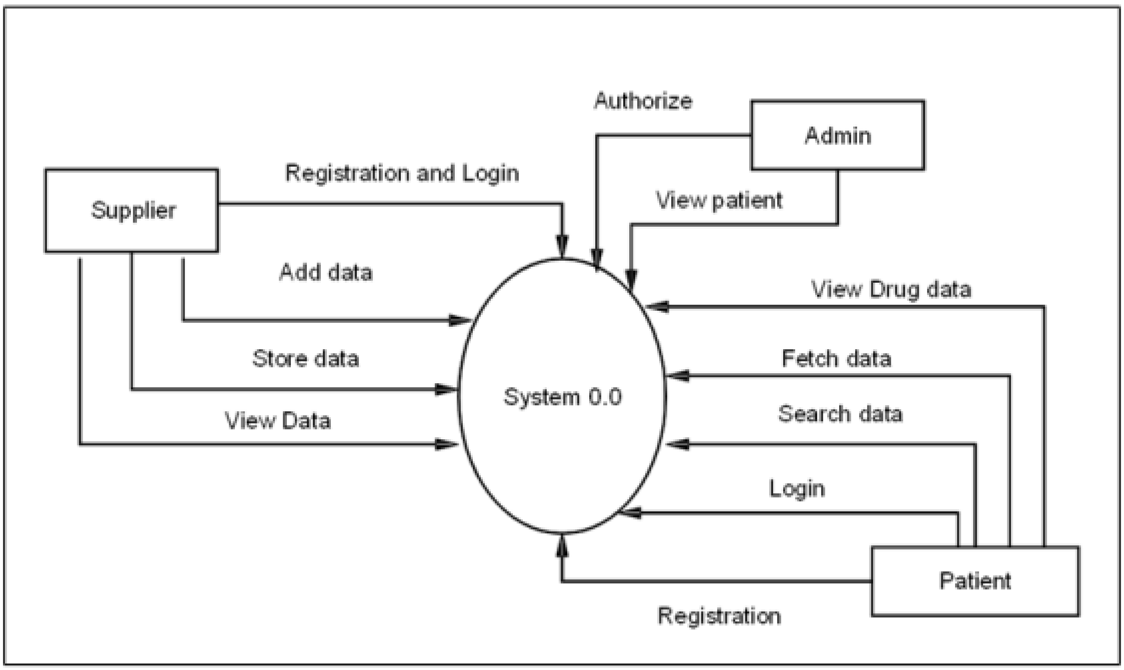
- The developed system should recognize traceability.
- System shall show the error message to the user when given input is not in the required format.
- System must provide the quality of service to user.

4.2 NON-FUNCTIONAL REQUIREMENTS

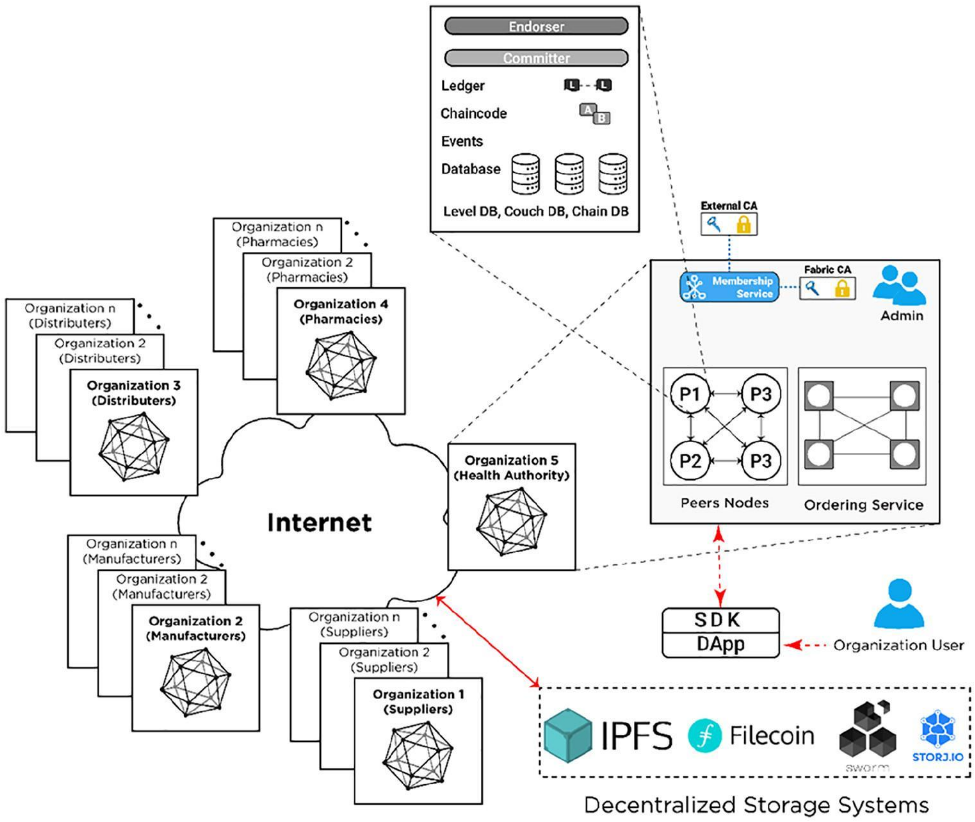
non-functional requirements are not directly related to the functional behavior of the system

5.PROJECT DESIGN

5.1 DATA FLOW DIAGRAMS & USER STORIES



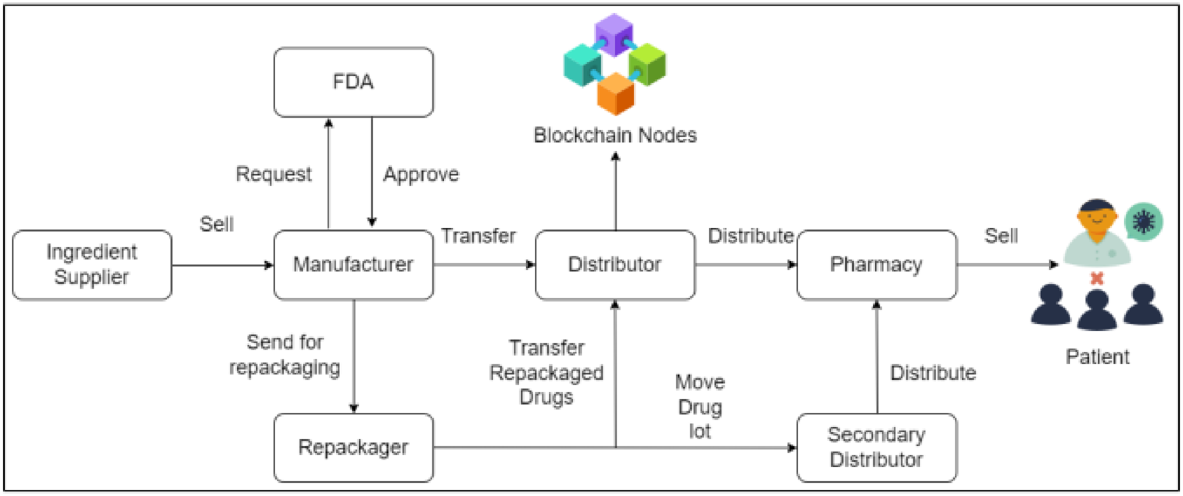
5.2 SOLUTION ARCHITECTURE



6.PROJECT PLANNING AND SCHEDULING

6.1 TECHNICAL ARCHITECTURE

Our method identifies and involves significant stakeholders in the medication sup- ply chain, such as the FDA, suppliers, manufacturers, distributors, pharmacies, and patients, whereas the FDA, suppliers, manufacturers, and wholesalers are the only ones involved. We make a concerted effort to identify and disentangle linkages between stake- holders, on-chain resources, smart contracts, and decentralised storage systems, which is currently lacking. We use smart contracts technology to achieve real-time, seamless traceability with push alerts, reducing the need for human intervention and, as a result, unnecessary delays. Each drug Lot is given its own smart contract, which generates an event whenever there is a change in ownership and sends a list of events to the app user.



6.2 SPRINT PLANNING & ESTIMATION

Sprint planning and estimation in the context of drug traceability involve breaking down the work into manageable tasks, prioritizing them, and estimating the effort required for each task to ensure that the development team can deliver value within a fixed time frame (a sprint). Here's how you can approach sprint planning and estimation for drug traceability:

1.Define Objectives:

Start by understanding the overall objectives of the drug traceability project. These objectives could include regulatory compliance, enhanced security, or improved traceability of pharmaceutical products.

2. Create a Product Backlog:

Develop a product backlog that lists all the features, user stories, and tasks related to drug traceability. These can range from implementing blockchain technology, enhancing data collection, improving reporting, or ensuring serialization of products.

3. Prioritization:

Prioritize the items in the product backlog based on their importance, regulatory requirements, and the value they bring to the drug traceability process. Regulatory compliance tasks often take precedence.

4. Sprint Length:

Decide on the sprint duration. Due to the complexity of drug traceability projects, consider a 3-4 weeks print duration rather than the typical 2-week sprint.

5. Set the Sprint Goal:

Define a clear sprint goal, which could be focused on achieving a specific aspect of traceability, such as implementing a new data capture method, enhancing product serialization, or improving supply chain visibility.

6. User Stories and Tasks:

Break down the prioritized backlog items into user stories and tasks that are small enough to be completed within the sprint. Ensure that each item is well-defined and has acceptance criteria.

7. Estimation:

Estimate the effort required for each user story and task. Common estimation techniques include:

- Story Points: Assign story points to each user story based on its complexity, risk, and effort required.

- Ideal Days: Estimate how many ideal days it will take to complete a task, assuming no interruptions or delays.

T-shirt Sizing: Use sizes like small, medium, large to categorize the complexity of tasks.

8. Team Capacity:

Assess the team's capacity to take on work during the sprint, considering individual team members' availability and any external commitments.

9. Sprint Backlog:

Select user stories and tasks from the product backlog to form the sprint backlog. Ensure that the sum of the estimated effort aligns with the team's capacity.

10. Sprint Planning Meeting:

Conduct a sprint planning meeting with the development team to discuss the sprint goal, user stories, and tasks. Ensure everyone understands the scope and requirements of each item.

11. Daily Standup Meetings:

Hold daily standup meetings during the sprint to track progress, discuss any roadblocks, and adjust the plan as needed to keep the project on track.

12. Sprint Review:

At the end of the sprint, conduct a sprint review to demonstrate the completed work to stakeholders and gather feedback.

13. Sprint Retrospective:

After the sprint review, conduct a retrospective meeting to discuss what went well, what could be improved, and what changes should be made for the next sprint.

14. Adapt and Repeat:

Based on the feedback and insights from the retrospective, adapt your approach for the next sprint and repeat the process.

Sprint planning and estimation for drug traceability projects are essential to ensure that the development efforts are well-organized, focused, and can deliver the required traceability features and compliance within the designated time frame.

6.3 SPRINT DELIVERY SCHEDULE

Creating a sprint delivery schedule for a drug traceability project involves planning and organizing the work to ensure that specific features or tasks are delivered within each sprint. Here's how you can set up a sprint delivery schedule for drug traceability:

Define the Overall Project Timeline:

Start by determining the total project duration and identifying any fixed deadlines or milestones. For instance, consider regulatory compliance deadlines or product launch dates.

Break Down the Work:

Divide the overall drug traceability project into manageable components, such as modules or features, based on your project scope and requirements.

Prioritize Features and Modules:

Prioritize the features or modules based on their importance, regulatory requirements, and dependencies. Ensure that the most critical aspects are addressed first.

Select Sprint Length:

Decide on the sprint length. As previously mentioned, sprints in drug traceability projects may be longer (3-4 weeks) due to the complexity of the work.

Create Sprint Backlogs:

For each sprint, create a sprint backlog by selecting the prioritized features or tasks that can be completed within that sprint.

Estimation and Capacity Planning:

Estimate the effort required for the items in the sprint backlog, and ensure that the estimated effort aligns with the team's capacity for the sprint.

Schedule Sprint Start Dates:

Set the start dates for each sprint. Ensure that these dates align with the overall project timeline.

Sprint Delivery Schedule:

Create a sprint delivery schedule that outlines which features or modules will be delivered in each sprint. Be realistic about what can be accomplished in each sprint, taking into account the complexity of the work and the team's capacity.

Adjust for Dependencies:

Consider dependencies between features or tasks. Ensure that prerequisites are completed in earlier sprints to support the work in later sprints.

Communication and Reporting:

Communicate the sprint delivery schedule to the team and stakeholders. Regularly report progress against the schedule during sprint reviews and other project meetings.

Iterative Development:

Keep in mind that software development, especially in complex projects like drug traceability, is often an iterative process. You may need to revisit and adjust the schedule as the project progresses and new insights are gained.

Continuous Monitoring and Adaptation:

Continuously monitor progress and adapt the sprint delivery schedule as needed. If unforeseen challenges or changes in requirements arise, be prepared to make adjustments to maintain project alignment with goals and deadlines.

Final Delivery and Testing:

Plan for a final sprint or phase dedicated to thorough testing, quality assurance, and validation to ensure that the drug traceability system meets all regulatory and project requirements.

Deployment and Go-Live:

After successful testing, plan for the deployment of the drug traceability system, making it operational and ready for use.

Post-Implementation Support:

Consider post-implementation support and ongoing maintenance as part of your project schedule, as this is crucial in maintaining the integrity of the drug traceability system.

A well-structured sprint delivery schedule ensures that your drug traceability project progresses in a controlled and organized manner, with a clear plan for delivering features, meeting deadlines, and maintaining regulatory compliance.

7.CODING & SCHEDULING

7.1 Feature

1 1. Smart Contract (Solidity): Develop a Solidity smart contract to manage user registration and verification. Include functions for user registration, email verification, and account activation.

2. Front-end (React): Create a user registration form in your React app using HTML and CSS. Implement a form submission handler in JavaScript. Connect Metamask to the app to facilitate user registration. Send a transaction to the Ethereum network to register the user on the smart contract.

3. Verification Email (JavaScript and JSON): Generate a unique verification token and store it in a JSON file or the blockchain. Send a verification email with the token using JavaScript.

4. Account Activation: Create an activation endpoint in your smart contract. Implement account activation in your React app by interacting with the smart contract. Verify the user's token from the verification email. User Registration and Verification

7.2 Feature

1 Extend your smart contract to allow users to submit documents. Include functions to upload documents and record document details

2. Front-end (React): Add a document submission form to your React app using HTML Create a file input field and a form to gather document details. Implement a file upload handler using JavaScript. Use Metamask to send transactions for document submission.

3. Document Storage (Solidity and Ethereum): Store document data on the Ethereum blockchain or IPFS. Record document references in your smart contract.

4. User Access: Implement user authentication to ensure that only authorized users can access their submitted documents. Use Metamask for user authentication when accessing documents. Document Submission and Storage

7.3 Database Schema

In this context, the schema should accommodate user registration, document submission, and other relevant data. For user registration, the schema includes tables for user details, login credentials, and account verification information. Document submission requires a separate table to store document metadata and references. Each table will have primary and foreign keys to establish relationships and maintain data integrity. The schema design also considers security measures and access controls. It outlines how data is structured, stored, and retrieved, facilitating efficient and secure data management. In a relational database, like PostgreSQL or MySQL, tables are used to represent these entities, while in a NoSQL database, such as MongoDB, collections serve a similar purpose.

8. PERFORMANCE TESTING

8.1 Performance

Performance testing of drug traceability challenges can include:

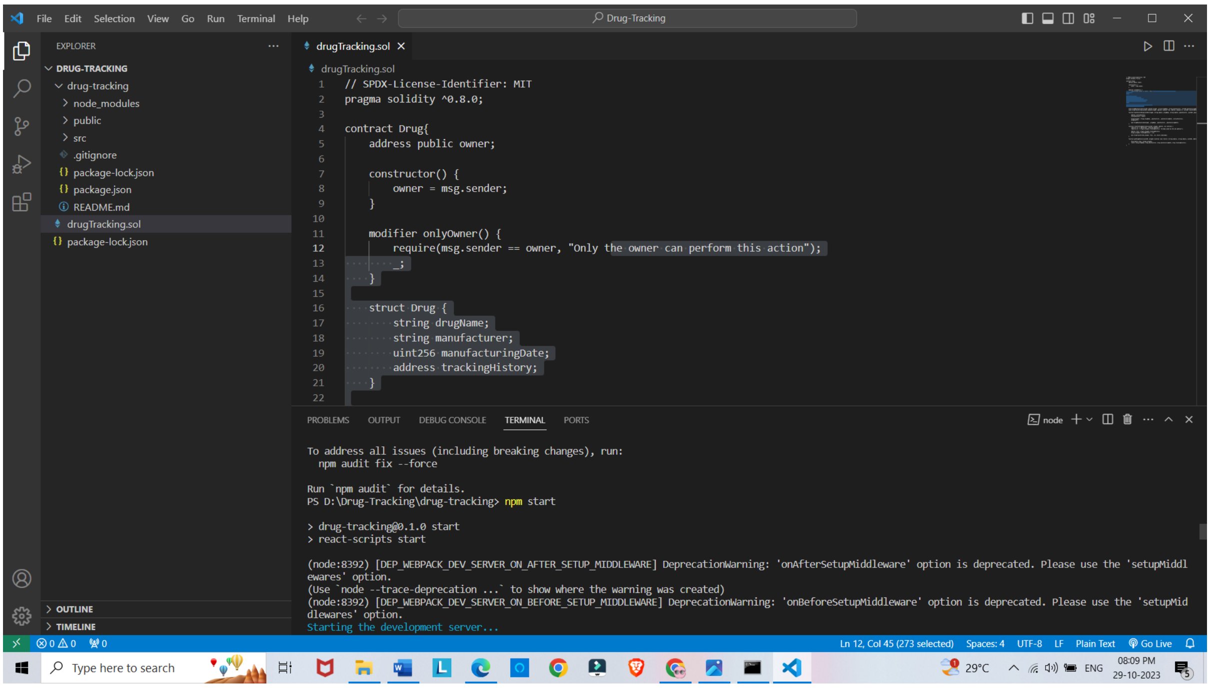
Aligning firms to enable improved health status through the provision of medicines

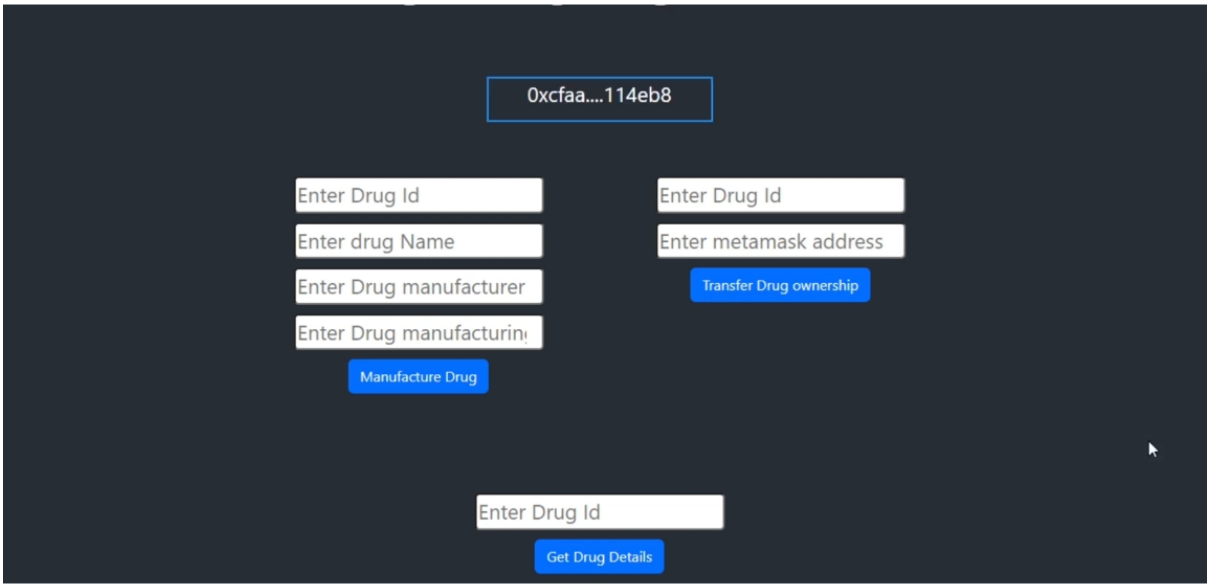
Creating socio-technical systems

Metrics Response Time: Throughput: Concurrency: Error Rate: Resource Utilization: Performance testing involves the measurement and analysis of various performance metrics to assess a system's behavior and identify areas for improvement. Here are some common performance metrics used in performance testing: The time taken for a system to respond to a user request. It's a critical metric for assessing user experience and system responsiveness. The number of transactions or requests processed by the system in a unit of time. It indicates the system's capacity to handle a load and is often measured in requests per second (RPS). The number of users or processes interacting with the system simultaneously. Measuring concurrency helps evaluate how well the system manages multiple simultaneous requests. The percentage of failed transactions or requests during testing. A high error rate may indicate performance issues or system instability. Monitoring the utilization of system resources like CPU, memory, disk, and network bandwidth. High resource utilization can lead to performance bottlenecks. CPU Utilization: Memory Usage: Network Latency: Page Load Time: Transaction Response Time: Hit Rate: Database Query Time: Transaction Success Rate: Server and Network Errors: The percentage of CPU capacity used during testing. High CPU utilization can lead to system slowdowns. Monitoring memory consumption helps identify memory leaks and inefficient memory management. The delay in data transmission between the client and the server. High network latency can affect response times. Relevant for web applications, this metric measures the time it takes to load a web page, including all its resources (HTML, CSS, images, scripts). Specific to database systems, it measures the time it takes for a database transaction to complete. In caching systems, this metric indicates the percentage of requests served from cache, reducing the load on the backend. The time taken to execute database queries, important for applications heavily reliant on database operations. The percentage of successfully completed transactions or operations during testing. The number and type of server and network errors encountered during testing

9.RESULTS

9.1 OUTPUT SCREENSHOTS





10.ADVANTAGES & DISADVANTAGES

ADVANTAGES

Drug traceability offers several significant advantages, primarily in the pharmaceutical and healthcare industries. These advantages contribute to the safety, security, and efficiency of the drug supply chain and patient care. Here are some key benefits of drug traceability:

Enhanced Patient Safety:

One of the primary advantages of drug traceability is the improved safety of patients. Traceability ensures that pharmaceutical products are genuine and have not been tampered with, reducing the risk of counterfeit or substandard drugs reaching consumers.

Improved Product Quality:

Traceability systems enable manufacturers to monitor and control the entire production and distribution process. This leads to better quality control, minimizing the chances of defective or contaminated products entering the market.

Faster and More Accurate Recalls:

In the event of a product recall or quality issue, traceability allows for the rapid identification and withdrawal of affected products, minimizing health risks and reducing costs associated with recalls.

Regulatory Compliance:

Many countries have implemented strict regulations that require pharmaceutical companies to maintain drug traceability records. Complying with these regulations not only helps avoid legal issues but also fosters public trust in the pharmaceutical industry.

Supply Chain Transparency:

Traceability systems provide transparency into the entire supply chain, from manufacturing to distribution. This transparency helps identify inefficiencies, reduce errors, and ensure that products reach their intended destinations.

Counterfeit Drug Prevention:

Drug traceability helps prevent the circulation of counterfeit drugs by verifying the authenticity of products throughout the supply chain. Consumers can also use traceability information to confirm the legitimacy of the drugs they purchase.

Easier Serialization:

Serialization, which involves assigning unique codes or serial numbers to each drug package, is a key component of traceability. This method aids in tracking individual product units, reducing the risk of theft and tampering.

Efficient Inventory Management:

Traceability systems provide real-time information about product inventory levels and locations. This helps manufacturers and distributors manage their inventory more efficiently, reducing costs and minimizing waste.

Reduction in Medication Errors:

Traceability systems can be used in healthcare settings to match patients with the correct medications, reducing the risk of medication errors and improving patient safety.

Data for Continuous Improvement:

The data collected through traceability systems can be used for analysis, allowing companies to identify areas for improvement in the supply chain, production processes, and product distribution.

Improved Decision-Making:

Access to data and insights from traceability systems empowers organizations to make informed decisions, optimize processes, and respond quickly to emerging challenges and opportunities.

Public Trust and Brand Reputation:

Implementing traceability measures demonstrates a commitment to product safety and quality, which can enhance a company's brand reputation and instill trust in consumers and healthcare professionals.

In summary, drug traceability is a crucial component of the pharmaceutical industry that provides multiple benefits, including improved patient safety, regulatory compliance, supply chain efficiency, and the prevention of counterfeit drugs. These advantages collectively contribute to the integrity and reliability of the drug supply chain and the healthcare system as a whole.

DISADVANTAGES

While drug traceability offers numerous advantages, there are also some potential disadvantages and challenges associated with its implementation. It's important to consider these drawbacks to make informed decisions about how to implement and manage drug traceability systems. Here are some disadvantages of drug traceability:

Implementation Costs:

Developing and deploying a comprehensive drug traceability system can be expensive. Costs can include acquiring and installing the necessary technology, software, and infrastructure, as well as training personnel to use the system.

Operational Costs:

Maintaining and operating a traceability system requires ongoing investments in technology, personnel, and data management. This can add to the operational costs for pharmaceutical companies and healthcare providers.

Complexity:

Implementing and managing a traceability system can be complex, especially in large and complex supply chains. Ensuring data accuracy, security, and interoperability with other systems can be challenging.

Interoperability Issues:

Different organizations in the supply chain may use different traceability systems or standards, leading to compatibility and interoperability challenges. This can hinder seamless data sharing and communication.

Data Privacy and Security Concerns:

Traceability systems involve sensitive data about pharmaceutical products, patients, and supply chain partners. Protecting this data from breaches or unauthorized access is a significant concern.

Data Entry Errors:

The accuracy of the data entered into traceability systems is crucial. Human errors in data entry can lead to inaccuracies that may compromise the traceability of drugs.

Resistance to Change:

Implementing traceability systems often requires changes in processes and workflows. Resistance to these changes from employees and partners can hinder adoption and implementation.

Resource Requirements:

Maintaining and supporting a traceability system requires dedicated resources, both in terms of personnel and financial investments. Smaller organizations may find it more challenging to allocate these resources.

Regulatory Compliance Burden:

While regulatory compliance is a benefit of drug traceability, it can also be a disadvantage, especially for smaller companies. Complying with evolving regulations and reporting requirements can be burdensome.

Impact on Small Businesses:

Smaller pharmaceutical manufacturers and distributors may find it more difficult to invest in and implement traceability systems, potentially putting them at a disadvantage compared to larger competitors.

Global Harmonization Challenges:

Achieving global harmonization in drug traceability standards and regulations can be challenging, leading to discrepancies and complexities for organizations operating in multiple regions.

Potential for System Failures:

Like any technology-based system, drug traceability systems are susceptible to technical failures, including system crashes, data corruption, or data loss. These failures can disrupt operations and lead to errors in traceability.

While these disadvantages exist, many organizations and governments still see the benefits of drug traceability as outweighing the drawbacks. They work to address these issues through continuous improvement and collaboration to make drug traceability systems more effective and efficient.

11.CONCLUSION

We have investigated the challenge of drug traceability within pharmaceutical sup- ply 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.

12.FUTURE SCOPE

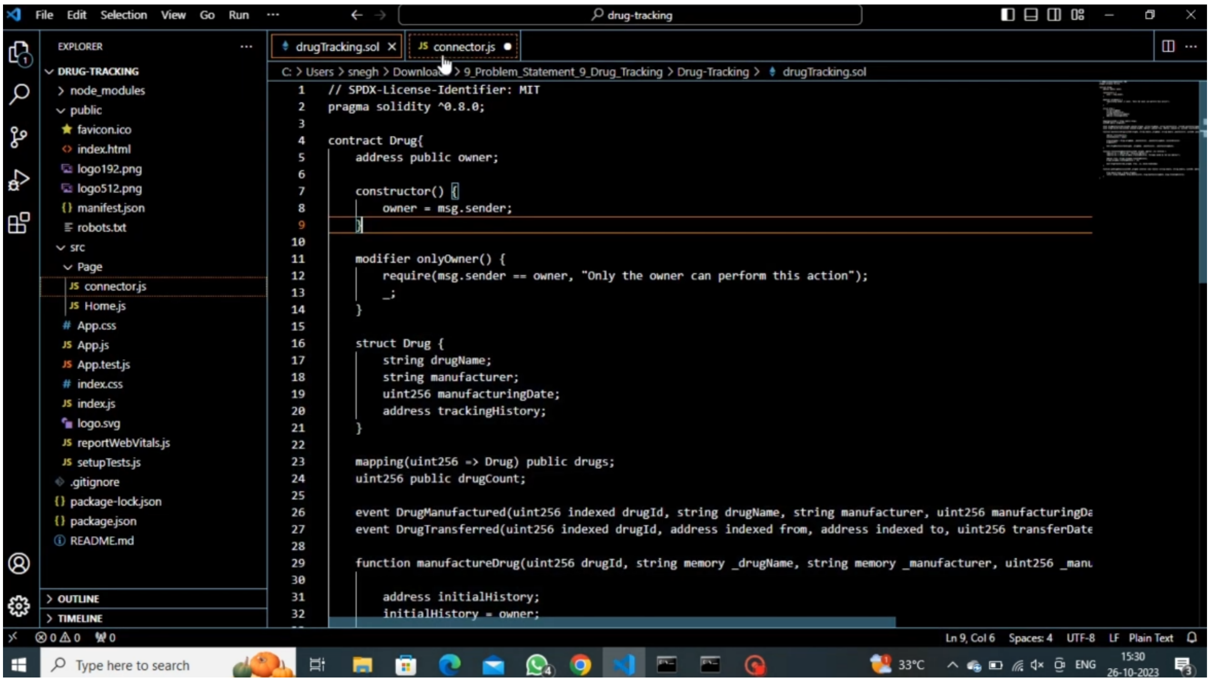
- The future scope of drug traceability is expected to continue evolving and expanding as technology and regulatory requirements advance. Several key trends and areas of development can be identified in the ongoing evolution of drug traceability:
- Blockchain Technology
- Serialization and Unique Identifiers
- Global Harmonization
- IoT and Sensor Integration
- Real-time Monitoring
- Artificial Intelligence (AI) and Machine Learning
- Mobile Apps and Patient Engagement
- Regulatory Evolution
- Data Standardization
- Integration with Healthcare Systems
- Sustainability and Environmental Concerns
- Blockchain in Clinical Trials
- Supply Chain Efficiency
- New Methods of Authentication

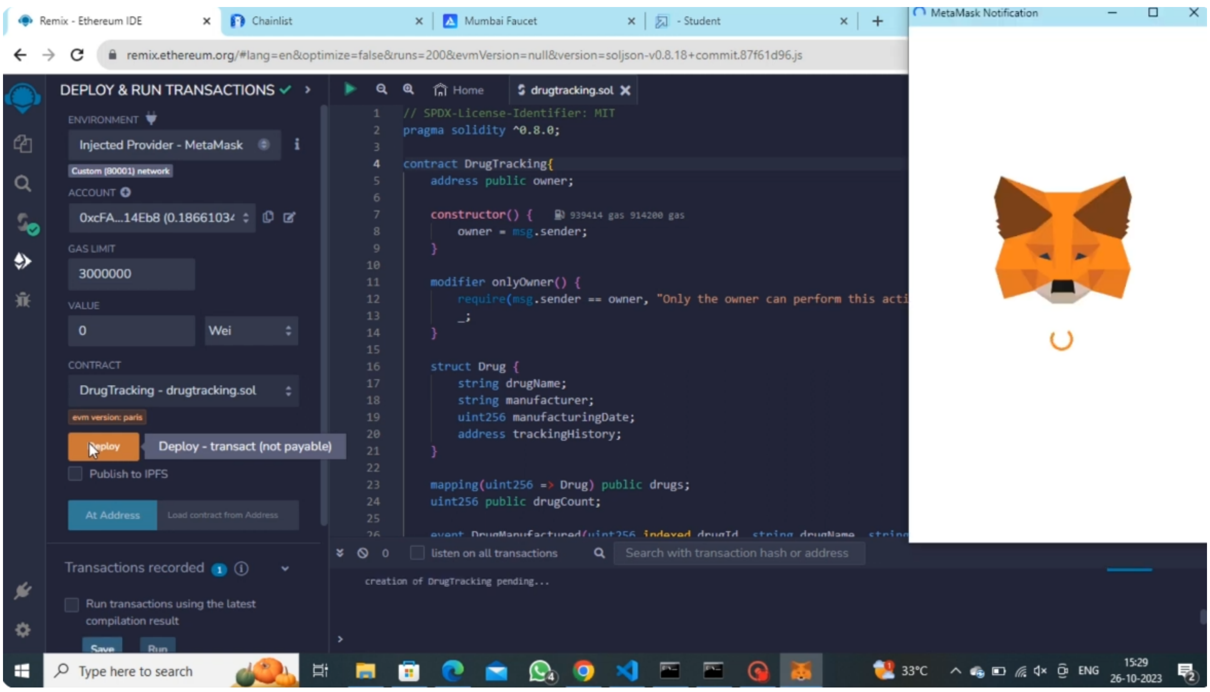
APPLICATIONS

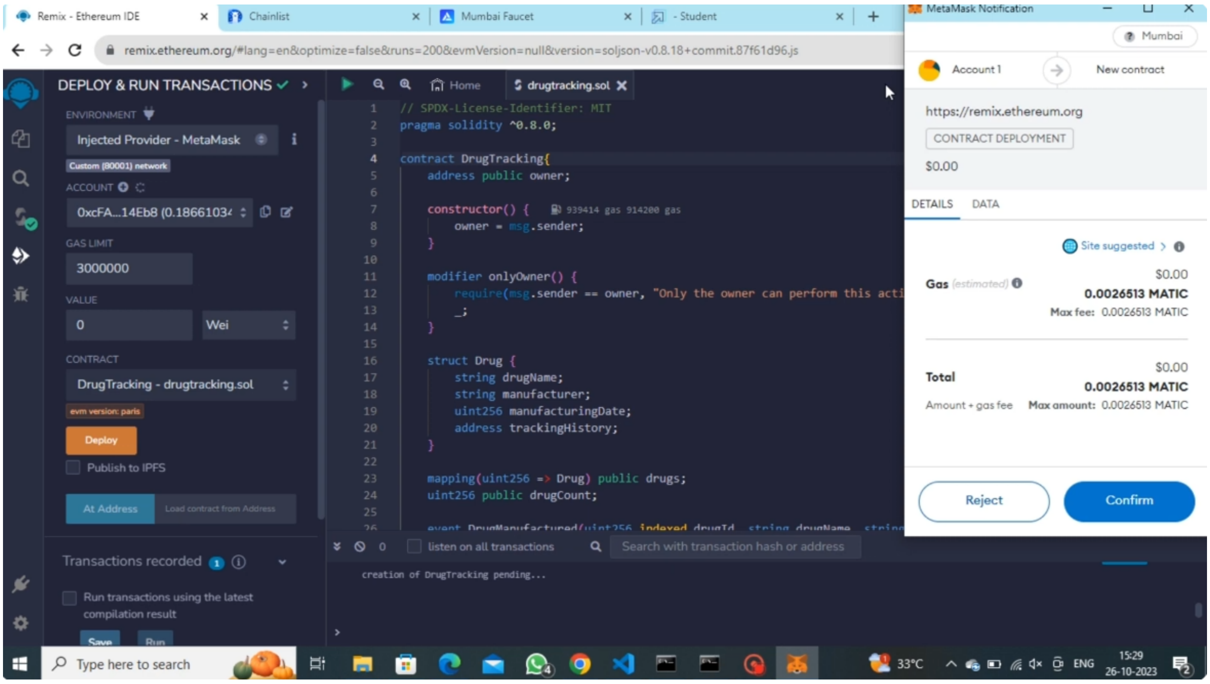
- Medical Application
- Healthcare Application

13. APPENDIX

SourceCodeFrontend-VScode



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DrugTracking - drugtracking.sol
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Reject
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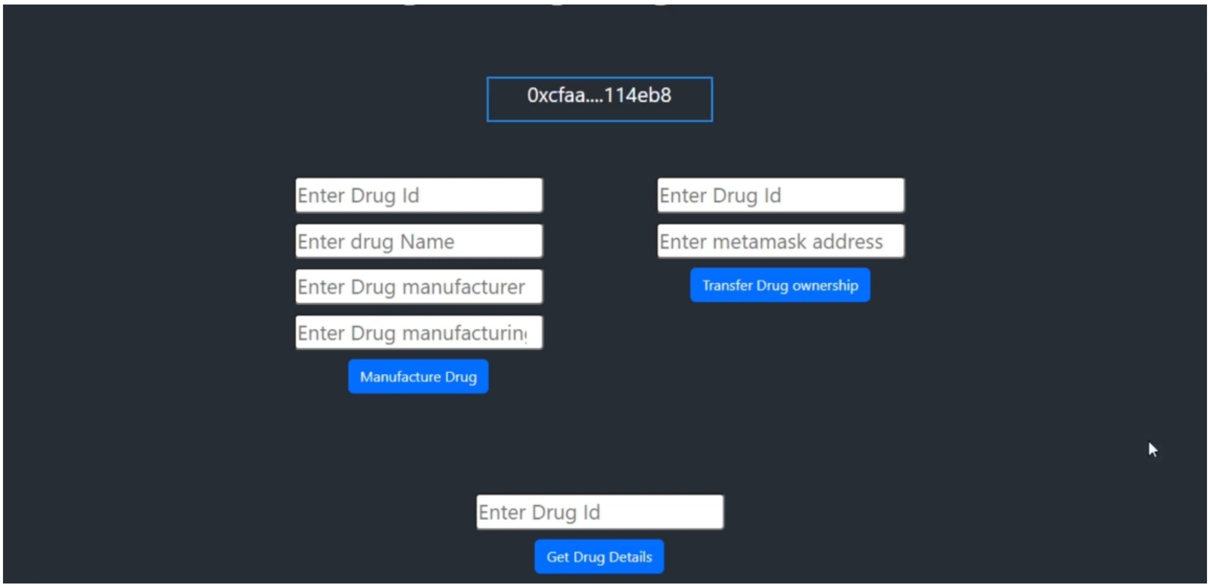
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Enter Drug Id
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Manufacture Drug
Enter Drug Id
Enter metamask address
Transfer Drug ownership
Enter Drug Id
Get Drug Details

GitHub & Project Demo Link

Github Repository Link:

https://github.com/Harini-882/nm-drug-traceability

Demo link:

https://drive.google.com/file/d/1Q5s1JeGFtmdzQfYIvOiOEZghZmknc4dX/view?usp=drive_lin
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