Revolutionizing Drug Traceability: Implementing Blockchain Technology in Healthcare Supply Chains

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Abstract

The pharmaceutical industry faces persistent challenges in ensuring the authenticity and safety of drugs within the healthcare supply chain. Counterfeit drugs, inefficient traceability systems, and lack of transparency pose significant threats to public health and industry integrity. Therefore, this research explores the implementation of blockchain technology to revolutionize drug traceability in healthcare supply chains. The main aim is to design and implement a blockchain-based drug traceability system, focusing on enhancing transparency, security, and real-time tracking. Key objectives include developing a decentralized ledger for transparent transactions, ensuring data immutability to prevent tampering, and enabling seamless interoperability across the supply chain entities. In addition, it employs a systematic approach, encompassing the analysis of existing traceability systems, the design of a blockchain-based solution, and the development of a prototype for testing and validation. Smart contracts and cryptographic techniques are utilized to secure transactions and ensure the integrity of supply chain data. Further, the introduction of blockchain technology in healthcare supply chain management offers a transformative solution to the longstanding challenges faced by traditional drug traceability systems. By leveraging blockchain's decentralized and immutable ledger, the pharmaceutical industry can establish a transparent, secure, and real-time traceability system, enhancing patient safety and overall supply chain efficiency.

Keywords: Blockchain technology, Supply chain management, Medical Data, Heath care systems, Artificial Intelligence.

1. INTRODUCTION

Healthcare supply chain is a complex network of several independent entities that include raw material suppliers, manufacturer, distributor, pharmacies, hospitals and patients. Tracking supplies through this network is non-trivial due to several factors including lack of information, centralized control and competing behaviour among stakeholders. Such complexity not only results in in-efficiencies such as those highlighted through COVID-19 pandemic [1] but can also aggravate the challenge of mitigating against counterfeit drugs as these can easily permeate the healthcare supply chain. Counterfeit drugs are products deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine product [2], [3]. Such drugs can include medications that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products. Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions [4]. According to the Health Research Funding Organization, up to 30% of the drugs sold in developing countries are counterfeit. Further, a recent study by World Health Organization (WHO) indicated counterfeit drugs as one of the major causes of deaths in developing countries, and in most cases the victims are children [7], [8]. In addition to the adverse impact on human lives, counterfeit drugs also cause significant economic loss to the pharmaceutical industry. In this respect, the annual economic loss to the US pharmaceutical industry due to counterfeit medicine is estimated around $200 billion [9], [10].

A typical drug supply chain distribution process is illustrated in Figure 1. An API supplier is responsible for delivering the raw materials to manufacture drugs approved by a regulatory agency such as the US Food and Drug Administration (US FDA). The manufacturer packages the drugs into a Lot or sends it to a re-packager. The primary distributor receives several Lots of the product and is responsible for transferring them to pharmacies based on product demand or secondary distributors (in case the quantity of Lots is very large) who can transfer these Lots to the pharmacies. Finally, a pharmacy will dispense the drug to patients [11] typically based on a doctor's prescription. Throughout the supply chain, the transfer of drugs is usually facilitated by third party logistic service providers such as UPS or FedEx and in some cases the distributors operate their own fleet of vehicles to transport the products. The primary reason for counterfeit drugs to reach end-user marketplace is due to the complex structure of a healthcare supply chain. Leveraging the complexity of this distribution process, medications can easily pass through with little or no trail of information and verifiable documentation [12]. Consequently, monitoring, effective control and tracking of products in healthcare supply chain is fundamental to combating counterfeits. The importance of drug traceability (track and trace) is increasingly emphasized and mandated by several countries across the world. For example, the U.S. Drug Supply Chain Security Act (DSCSA) has made it mandatory for the pharmaceutical industry to develop an electronic and interoperable system that identifies and tracks prescription drugs as they are distributed across the United States [13]. Similarly, over the last 8 years, China required all the stakeholders involved in the drugs supply chain to record information of individual pharmaceutical products in a specialized IT system whenever drugs are sent to/from their warehouses [14]. Therefore, drug traceability has become an integral part of the pharmaceutical supply chain as it establishes authenticity and aims to track and trace chain of custody of the product across drug supply chain. Blockchain technology has introduced a new model of application development primarily based on the successful implementation of the data structure within the Bitcoin application. The fundamental concept of the blockchain data structure is similar to a linked list i.e., it is shared among all the nodes of the network where each node keeps its local copy of all the blocks (associated with the longest chain) starting from its genesis block [15]. Recently, many real-world applications have been developed in diverse domains, such as the Internet of Things [16], e-Government [17] and e-document management [18]. These applications leverage benefits of blockchain technology due to its self-cryptographic validation structure among transactions (through hashes), and public availability of distributed ledger of transaction-records in a peer-to-peer network. Creating a chain of blocks connected by cryptographic constructs (hashes) makes it very difficult to tamper the records, as it would cost the rework from the genesis to the latest transaction in blocks as illustrated by [19].

2. LITERATURE SURVEY

We present a critical overview of existing efforts focused at addressing the issue of product traceability in the healthcare supply chain emphasizing solutions proposed for anti-counterfeiting. We have included both blockchain and non-blockchain-based approaches and categorized them accordingly.

A. TRADITIONAL EFFORTS FOR DRUG TRACEABILITY

Traceability is defined as the ability to access any or all information relating to the object under consideration, throughout its life cycle, by means of recorded identifications. The object under consideration is referred to as Traceable Resource Unit (TRU) which is any traceable object within the supply chain. Traceability objectives are twofold; to track the history of transactions, and to track the real-time position of the TRU. In this context, a traceability system requires access to information related to the drug which is the TRU in the supply chain by using different identification techniques to record its identity and distinguish it from other TRUs. The components of a traceability system can be broadly identified by a mechanism for identifying TRUs, a mechanism for documenting the connections between TRUs, and a mechanism for recording the attributes of the TRUs [21].

Existing solutions within supply chain management have traditionally used barcodes and RFID tags as identification techniques, Wireless Sensor Networks (WSN) to capture data, and Electronic Product Code (EPC) to identify, capture, and share product information to facilitate tracking of goods through different stages [22]. In this context, Smart-Track [23] utilizes GS1 standards barcodes containing unique serialized product identifier, Lot production and expiration dates. The information contained in the GS1 barcode is captured across various supply chain processes and used to maintain a continuous log of ownership transfers. As each stakeholder records the possession of the product, an end user (patient) can verify authenticity through central data repository maintained as Global Data Synchronization Network (GDSN) by using a smartphone app. In the downstream supply chain at the warehouse, pharmacy and hospital units can scan the barcode to verify the product and its characteristics. Similarly, Data-Matrix tracking system [24] creates a Data-Matrix for each drug which includes the manufacturer ID, Product ID, Unique ID of the package, the authentication code, and an optional meta-data. This allows the patient to verify the origin of the drug by using the attached Data-Matrix.

More recently Near Field Communication (NFC) tags have been proposed to be used to achieve visibility and authenticity across pharmaceutical supply chain. In this respect, [25] presents an effort to develop a NFC-based system which affords visibility throughout different stages of pharmaceutical supply chain. Each drug is registered and authenticated by using a key value and an NFC tag is attached to it. Similar to the previous two solutions, the user or the patient can verify the authenticity or the origin of the drug by scanning the attached NFC tag using a mobile application.

Corrado et al. [26], Supriya and Djearamane [27], and Jamal et al. [28] have proposed solutions for traceability but they use a centralized database which makes tampering goods information relatively easy and difficult to detect. In addition to that, the use of different types of centralized databases can result in the proposed solutions to have lack of interoperability and scalability.

B. BLOCKCHAIN-BASED SOLUTIONS FOR DRUG TRACEABILITY

Traditional solutions to achieve traceability within pharmaceutical supply chain are typically centralized and lack transparency across participants of the supply chain, which allows the central authority to modify information without notifying other stakeholders. On the other hand, a blockchain based solution offers data security, transparency, immutability, provenance and authenticated transaction records. Blockchain is a decentralized, immutable shared ledger that can be applied to a variety of business settings involving transaction processes. Transparency and traceability are used interchangeably however, they represent very different concepts.

Transparency is usually used when referring to high-level information of a supply chain. For example, product's components, facilities locations, names of suppliers, etc. with the objective to map the whole supply chain. However, traceability is related to granular information where it envisages choosing a specific component to trace, determines common standards to communicate with partners, implements methods to produce and gather accurate data, selects a platform to store traceability data, and determines how to share data on the platform. Although both terms represent different concepts, they rely on each other because accessing granular information requires full understanding of the supply chain.

In this respect, a number of existing approaches leverage cryptographic properties of blockchain to achieve a decentralized, verifiable track and trace system for pharmaceutical drugs. Mettler [32] have discussed the use of blockchain based approach for various issues in healthcare sector with no technical details or specific application. Kurki [33], presented the advantages of blockchain technology in pharmaceutical supply chain. However, similar to [32] only conceptual discussion was provided. Muniandy and Ong Tze Ern [20] proposed a traceability system using Ethereum for anticounterfeiting. The proposed solution employs smart contract however it lacks implementation or evaluation which limits understanding the contribution.

Huang et al. [34] proposed a drug traceability system, Drugledger, which reflects the practical drug transaction logic in the supply chain, and generates both authenticity and privacy of stakeholders' traceability information without losing the resilience of the system. Drugledger completes its workflow based on the expanded UTXO data structure, especially that of package, repackage, and unpackage. However, recent studies such as [35] have highlighted concerns with the use of UTXO data structure with respect to its weakness in programmability, high storage cost, and low state space utilization.

Faisal et al. [36], proposed a Hyperledger-based solution for drug traceability in the pharmaceutical supply chain. Authors report increase in the performance in terms of throughput and minimizes latency of the proposed system with less utilization of resources, however their solution was not rigorously tested and was implemented in a small-sized network. This effort also highlighted the challenge of achieving scalable solutions with blockchain which has received significant attention in recent literature such as [22]. Similar concerns are valid for the approach adopted by Hulseapple [38] who developed a private blockchain concurrently with the Bitcoin, which is used as a ledger to hash certain data to secure the transactions in chain. Every product has its own permanent record on their blockchain, making it impossible to manipulate with the private keys. The system was designed to protect every stage of product transfer in the supply chain, creating a trustless system of transparency.

In addition to the above, a number of active projects exist which are focused at exploring use of distributed ledger technologies to achieve traceability within pharmaceutical supply chain. For instance, Arsene [39] involves leading companies including IBM, Cisco, Accenture, Intel, Bloomberg, and Block stream where every drug is issued with a timestamp, making it traceable with its origin and manufacturer details. Similarly, MediLedger [40] investigates use of blockchain to provide a solution compliant with the DSCSA regulation to increase interoperability in the industry. Farmatrust project [41] aims to improve traceability in pharmaceutical industry based on Quorum blockchain with future plans to accommodate other platforms such as Ethereum and Hyperledger. The use of Quorum blockchain presents challenges such as lack of transaction ordering of transactions and policy enforcement which limits it widespread use.

3. PROPOSED SYSTEM

This research presents an Ethereum blockchain-based approach leveraging smart contracts and decentralized off-chain storage for efficient product traceability in the healthcare supply chain. The smart contract guarantees data provenance, eliminates the need for intermediaries and provides a secure, immutable history of transactions to all stakeholders. Additionally, the proposed system presents the system architecture and detailed algorithms that govern the working principles of our proposed solution.

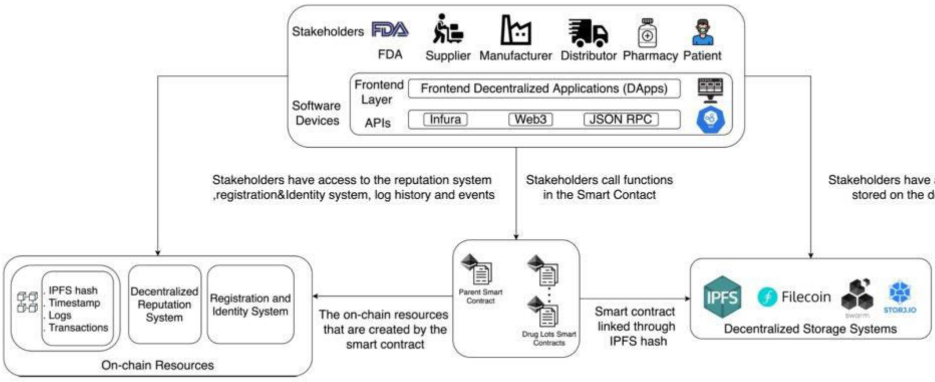


Figure 1: System architecture diagram.

In summary, the project provides a Django-based web interface for users to interact with a blockchain-enabled system managing drug-related data. It covers aspects of user authentication, product management, and tracing updates using Ethereum smart contracts. Here is a more detailed overview:

Step 1 – Blockchain Integration:

- The project leverages the Ethereum blockchain for storing and retrieving drug-related information.
- The web3 library is used to interact with the Ethereum blockchain through a local node (http://127.0.0.1:9545).
- Smart contracts deployed on the Ethereum blockchain are utilized to store and manage data.

Step 2 – Contract Details

- The smart contract details are stored in a JSON file named 'Drug.json'.
- The contract's ABI (Application Binary Interface) is loaded from this file, enabling communication with the deployed contract on the blockchain.

Step 3 – Global Variables:

- Global variables like details, username, contract, and product_name are used to store and share data across different parts of the application.

Step 4 – Views:

- The project consists of several views implemented in Django, each associated with a specific HTML template.
- Views include functionalities like rendering pages ('index', 'Login', 'Register', 'AddProduct'), user login, user registration, and product tracing updates.

Step 5 – User Authentication:

- The project handles user authentication, with a distinction between regular users and an admin user (username: admin, password: admin).
- User login details are verified against the data stored in the Ethereum blockchain.

Step 6 – Product Management:

- Users can add new drug products through the 'AddProduct' view. The product details, including name, price, quantity, description, and an associated image, are stored on the blockchain.

Step 7 – Tracing Updates:

- The project allows users to update tracing information for specific drug products. This includes details such as the drug name, price, quantity, description, image, last update date, and current tracing information.

Step 8 – Security Considerations:

- The project handles user authentication, but security aspects such as password hashing and protection against common web vulnerabilities (e.g., SQL injection, cross-site scripting) are not explicitly addressed in this code snippet. It's important to enhance security features for a production-level application.

Step 9 – User Interface:

- HTML templates (e.g., 'index.html', 'Login.html', 'Register.html') are used to render the user interface for different views.

Step 10 – File Handling:

- The project involves file handling, such as saving and displaying images associated with drug products.

Step 11 – Date Handling:

- The 'datetime' library is used to capture and display dates, including the last update date for products.

Proposed methodology

In order for a country to achieve progress, it is essential to establish a well-functioning and accurate pharmaceutical system. Drugs have a significant impact, and it is crucial to ensure the quality and accurate tracking of their progress, such as whether they are currently being produced, transported, or processed. In this study, the author utilizes Blockchain technology to establish reliable traceability in the management of drug supply chains. Current supply chain management systems rely on centralized servers. If these servers go down, traceability becomes difficult. Additionally, if the centralized server is hacked, there is no way to recover or extract details of the hacking incident.

Many enterprises are shifting their applications to Blockchain in response to the drawbacks of centralized servers. Blockchain is a decentralized system where data is stored across numerous interconnected nodes. It incorporates inherent features for data encryption and verification. Blockchain stores data across numerous nodes, ensuring that if one node fails, traceable information may still be retrieved from the remaining functioning nodes. One additional benefit of Blockchain is its ability to verify data. In Blockchain, each piece of data is stored as a block or transaction and is linked to a unique hash code. Before storing a new block, Blockchain verifies the hashcode of each block. If any block's data is altered, the hashcode will not match, causing the verification to fail and the alteration to be detected.

This project facilitates numerous user roles, including an Admin (manufacturer), supplier, pharmacy, and normal users. Users can sign up and log in to access tracking details for specific drugs. In order to execute this Drug products tracing project, we have utilized the Blockchain Ethereum platform in conjunction with the Truffle environment. To store and retrieve data within the Blockchain, it is necessary to develop SOLIDITY code (also known as a Smart Contract) that includes functions for data storage and retrieval. In order to execute this project, we have formulated the following Solidity code.

4. RESULTS AND DISCUSSION

This project implements a Django application for blockchain-based system for tracking and managing drug-related information. Here is an overview of the implementation:

1. Imported Libraries:

- The necessary Django modules such as render, RequestContext, HttpResponse, and messages are imported.
- External libraries like pymysql, web3 (for interacting with Ethereum blockchain), os, and json are imported.

2. Global Variables:

- details and username are declared as global variables.
- contract and product_name are declared as global variables.

3. Blockchain Connection and Contract Initialization:

- The code includes functions (readDetails, saveDataBlockChain, updateQuantityBlock) to interact with an Ethereum blockchain. It connects to a local Ethereum node (http://127.0.0.1:9545) and initializes a contract using the web3 library.

4. Index View: The index view renders the 'index.html' template.

5. Login, Register, AddProduct Views: Similar to the 'index' view, these views render their respective HTML templates.

6. UpdateTracingAction and UpdateTracing Views: These views handle the updating of tracing information for a product. UpdateTracingAction is triggered by a form submission in 'AddTracing.html', and UpdateTracing displays a table of products for tracing updates.

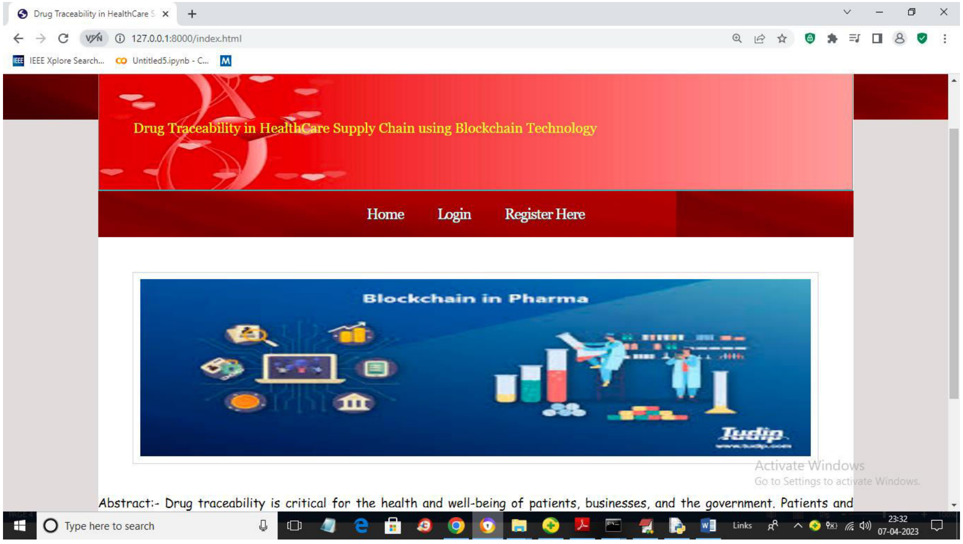
7. AddTracingAction View: Handles the form submission for updating tracing information. It reads the existing details, modifies the relevant record, and updates the blockchain.

8. AddProductAction View: Handles the form submission for adding a new product. It saves the product details to the blockchain.

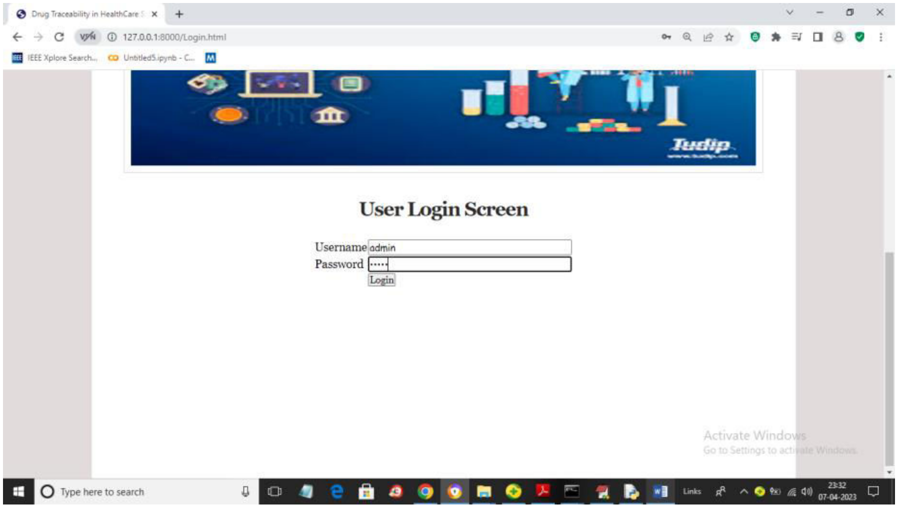
9. Signup View: Handles user registration. Checks for existing usernames and stores new user data in the blockchain.

10. UserLogin View: Handles user login. If the user is the admin, they are redirected to 'AdminScreen.html'; otherwise, regular users are directed to 'UserScreen.html'.

11. ViewTracing View: Displays a table of drug products with their tracing information.

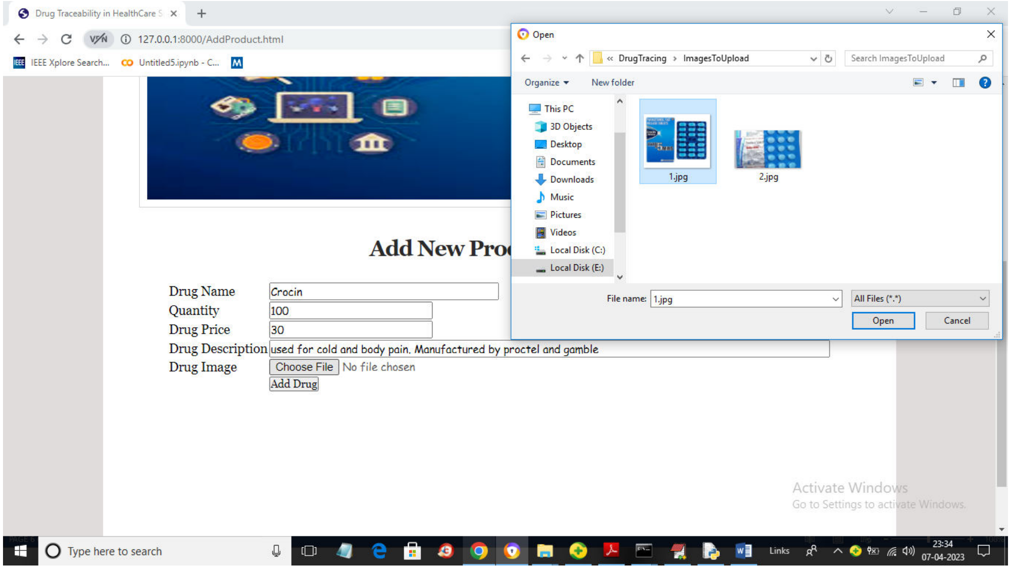


In above screen click on ‘Login’ link and login as admin

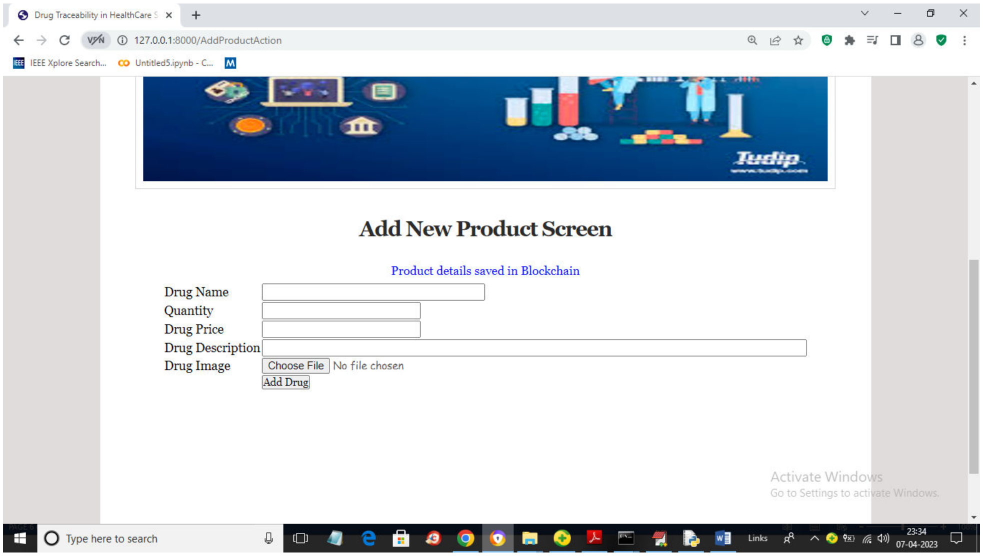


In above screen admin is login and after login will get below output

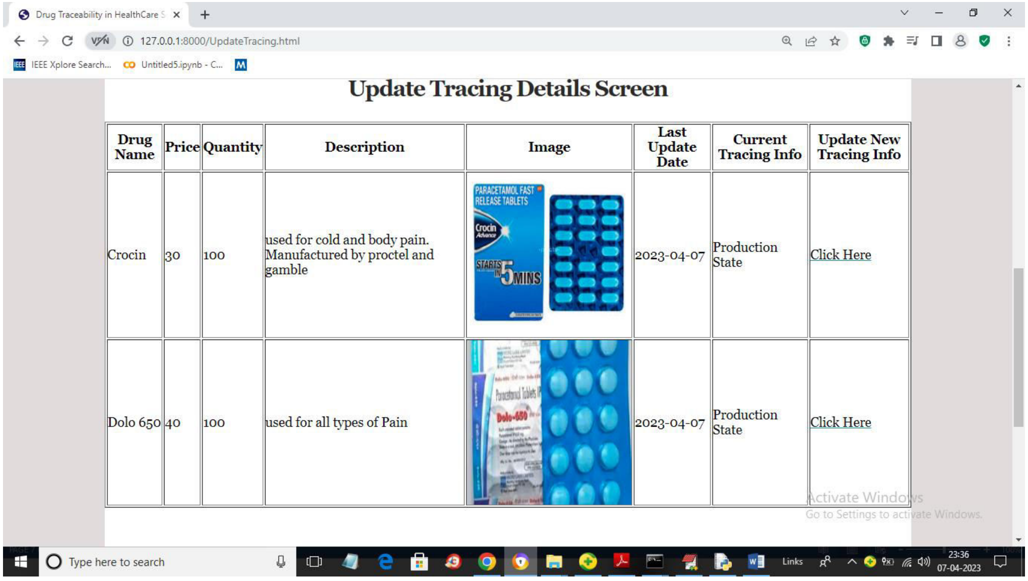
In above screen admin can click on ‘Add New Drug’ link to add new product details



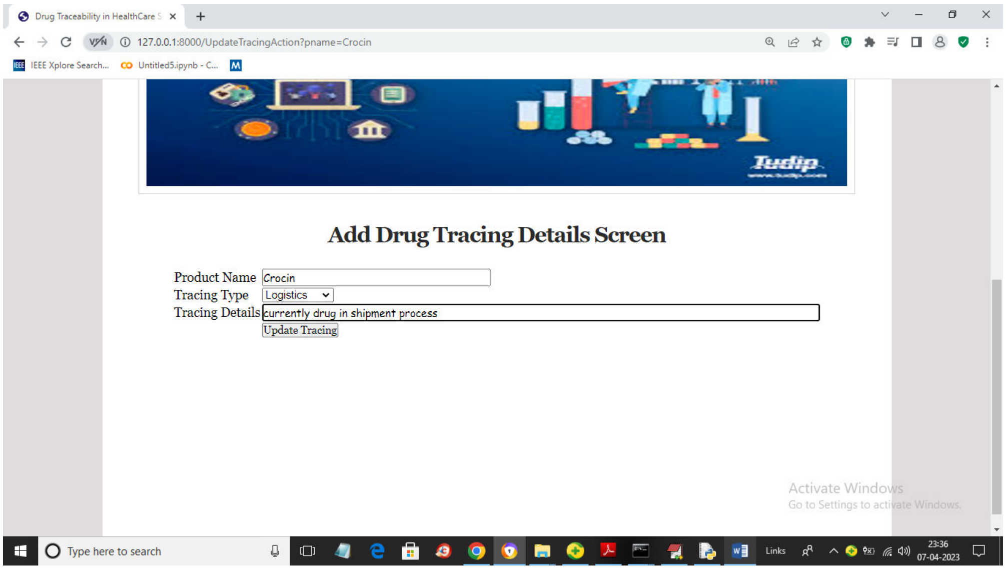
In above screen admin will add all Drug details and then upload image and then press 'Add Drug' button to get below output



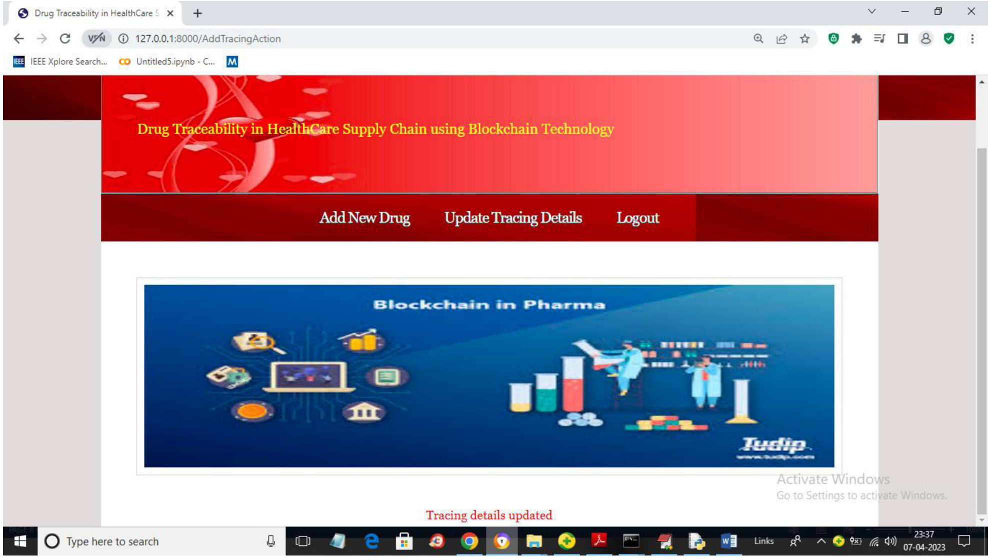
In above screen in blue colour text we can see Drug details added. Similarly you can add any number of drugs to Blockchain. now click on 'Update Tracing Details' link to get below output



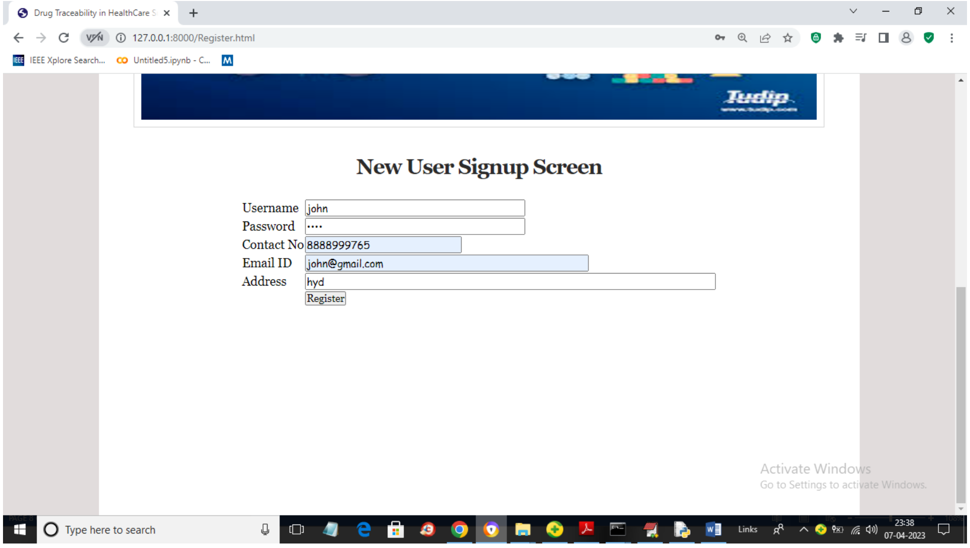
In above screen admin can view all Drug details and to update tracing details from current state, admin will click on ‘Click Here’ link to get below screen



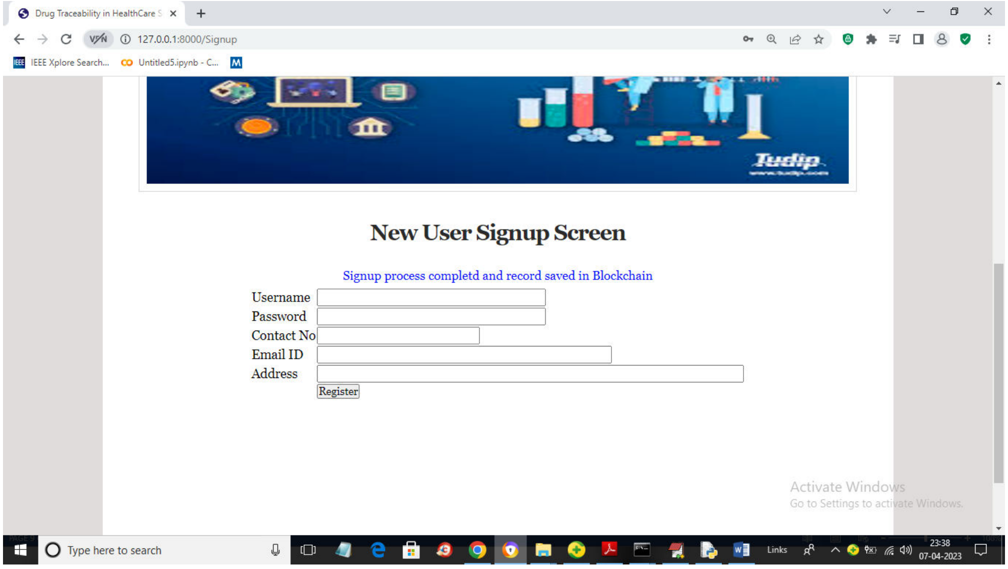
In above screen admin will select Tracing Type and then enter current tracing details and press button to store current tracing data to Blockchain and get below output



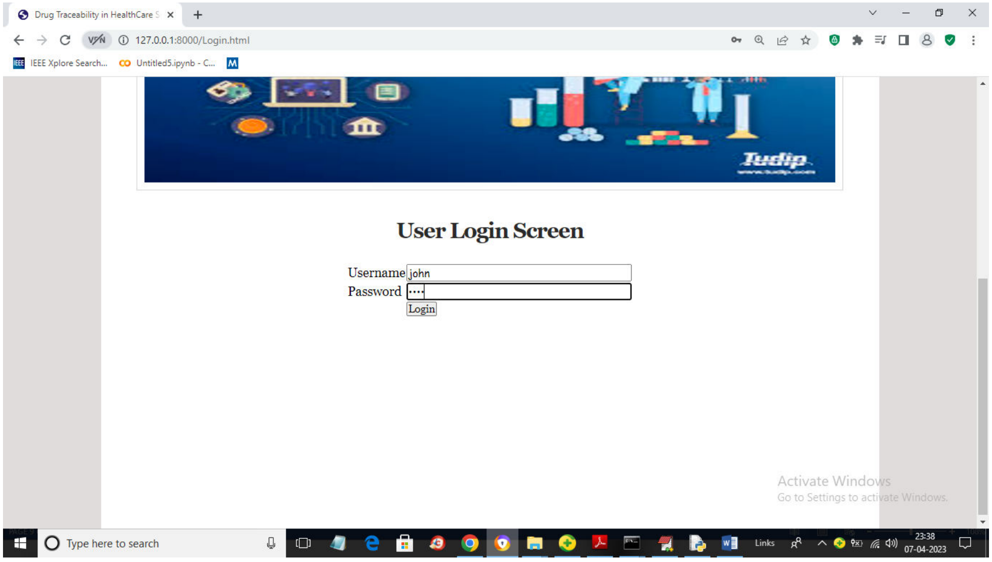
In above screen in red colour text we can see tracing details updated and all users can view this updated trace details. Now logout and signup new user



In above screen user is entering signup details and then press button to store user data to Blockchain and get below output

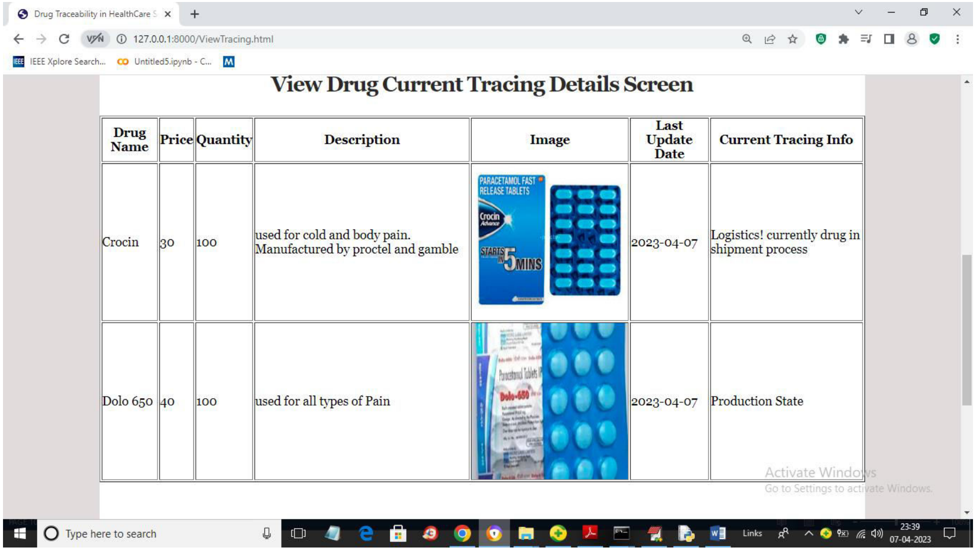


In above screen in blue colour text we can see User details saved in Blockchain and now click on 'Login' link to login as user



In above screen user is login and after login will get below output

In above screen user can click on 'View Drug & Tracing Details' link to get all product details



View Drug Current Tracing Details Screen

Drug Name	Price	Quantity	Description	Image	Last Update Date	Current Tracing Info
Crocin	30	100	used for cold and body pain. Manufactured by proctel and gamble		2023-04-07	Logistics! currently drug in shipment process
Dolo 650	40	100	used for all types of Pain		2023-04-07	Production State

In above screen user can view all product details and in last column user can see current tracing data for each Drug. So by using this application any user can know current tracing and manufacture details of any Drug

5. 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.

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