A Blockchain-Based Approach for Drug Traceability in Healthcare Supply Chain

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A BLOCKCHAIN-BASED APPROACH FOR DRUG TRACEABILITY IN HEALTHCARE SUPPLY CHAIN

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ABSTRACT:

Healthcare supply chains are intricate networks that go across several organizational and geographic borders and serve as the structural backbone for many services that are essential to daily living. Such systems' intrinsic complexity makes it possible to add impurities like erroneous data, a lack of transparency, and a weak data provenance. One result of these restrictions within the current supply chains is the production of counterfeit medications, which not only has a substantial negative impact on people's health but also costs the healthcare sector a great deal of money. The necessity for a reliable, end-to-end track and trace system for pharmaceutical supply chains has therefore been highlighted by current research. To ensure product safety and get rid of fakes, the pharmaceutical supply chain needs a comprehensive product tracking system. The majority of current track and trace systems are centralized, which results in data Issues with authenticity, openness, and privacy in healthcare supply networks. In this work, we describe an Ethereum Blockchain-based strategy for effective product traceability in the healthcare supply chain, utilizing smart contracts and decentralized off-chain storage. The smart contract gives a secure, immutable history of transactions to all parties and ensures data provenance. It also does away with the need for middlemen. We outline the system architecture and comprehensive algorithms that underpin the fundamental operations of our suggested solution. We test and validate the system, and then offer a cost and security analysis to determine how well it can improve traceability inside pharmaceutical supply chains.

Keywords: Blockchain, Drug Counterfeiting, Traceability, Healthcare, Supply Chain, Trust, Security.

1. INTRODUCTION

The healthcare supply chain is a complicated web of various distinct businesses ,consisting of Hospitals, Manufacturing companies,Distributors,Raw material supplier, and pharmacies. Tracking commodities within this network is difficult due to a variety of challenges, including a lack of information, centralised administration, and stakeholder competition. Those complexity doesn't lead to inefficiencies like which were revealed during COVID-19 pandemic. Drugs which are made illegally and which are labelled incorrectly on purpose are called counterfeit drugs. These Drugs may be ones that Doesn't contain Adequate quantity of Pharmaceutical ingredients[API],which are of poor quality, contains contaminants, and also may be repacked from the expired drugs. According to the Health Research Funding Agency, up to 30% of medications sold in developing countries are counterfeit. A recent research done by World Health Organisation(WHO) found that using counterfeit drugs is the major cause to underdeveloped nations.

A typical medicine supply chain distribution mechanism is depicted in Figure 1.An API supplier is responsible for delivering the basic materials needed to manufacture pharmaceuticals approved by a regulatory body such as the United States Food and Drug Administration –"US FDA".The producer places the drugs in a lot or sends them to a re-packager.

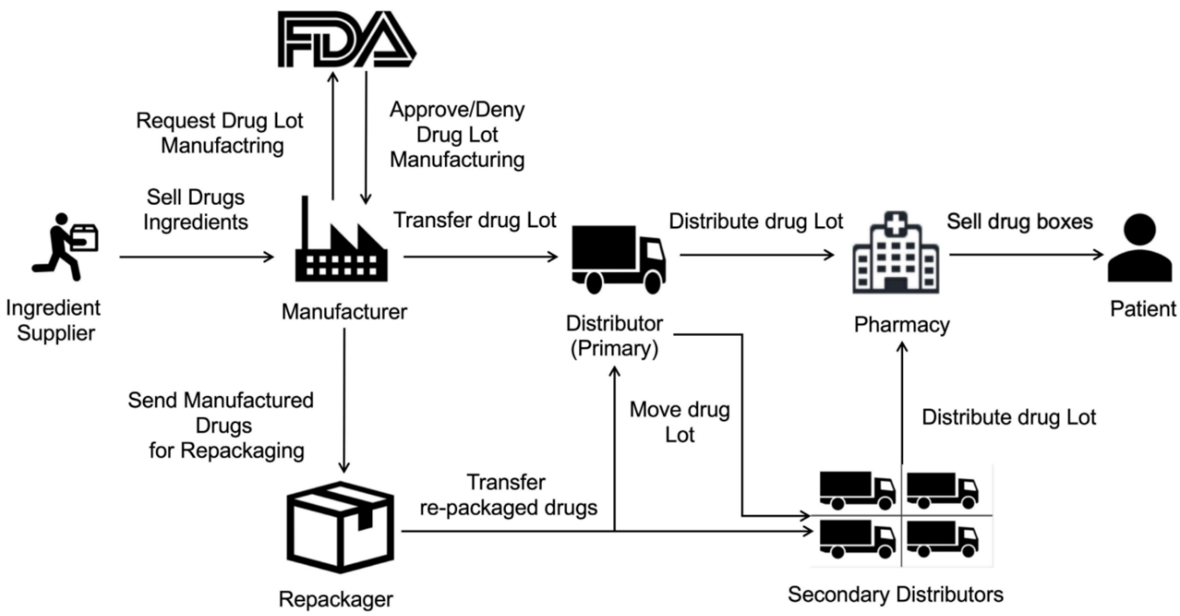

Figure 1. Stakeholders in the drug supply chain and their ties

Demand of customers the primary distributor moves the Lots of product to the pharmacies usual the pharmacist will distribute the drugs to the patients depends upon the doctor's prescription. The Major factor that getting counterfeit drugs to end user market is intricate design of healthcare supply chain. In order to remove counterfeit drugs ,the pharmaceutical supply chain should be effectively monitored ,controlled and tracked.

The introduction of a data format that is shared by all network nodes, enabling self-cryptographic validation and public availability of the distributed ledger of transaction-records, has revolutionised application development thanks to blockchain technology. As a result, numerous practical applications in a variety of fields—including the Internet of Things, e-Government, and electronic document management—have been created. While there are similarities to earlier initiatives, the pharmaceutical supply chain has adopted blockchain-based traceability to prevent tampering with records. This technology gives an end-to-end solution for drug traceability.

The proposed approach for drug traceability in the pharmaceutical supply chain involves identifying and engaging major stakeholders, defining relationships among them, and using smart contracts technology for real-time traceability with push notifications. This is an improvement over previous efforts, which had limitations in terms of stakeholder representation, lack of defined interactions, and manual confirmation of received drugs. The proposed solution also includes a cost and security analysis and can be generalized to other supply chains. Overall, the approach presents a comprehensive application of blockchain technology for drug traceability.

For the pharmaceutical supply chain, we suggest a blockchain-based system that offers data provenance confidentiality, traceability, atomicity, and accessibility for pharmaceutical medications. We create a smart contract that can handle numerous transactions between parties involved in the drug supply chain.

2. MATERIALS AND METHODS

We give a detailed assessment of current initiatives aimed at resolving the problem of product traceability in the pharmaceutical supply chain, placing special emphasis on suggested anti-counterfeiting measures. We've divided them into categories based on whether they use blockchain technology or not.

2.1 CONVENTIONAL APPROACHES TO DRUG TRACEABILITY

Traceability is the ability to access information about a product throughout its lifecycle using recorded identifications. A traceable resource unit (TRU) is any traceable object in the supply chain, such as a drug. Different identification techniques, such as barcodes, RFID tags, and NFC tags, are used to record the identity of the TRU and distinguish it from other objects. Components of a traceability system include mechanisms for identifying TRUs, documenting connections between TRUs, and recording attributes of TRUs. Solutions within supply chain management use barcodes, RFID tags, Wireless Sensor Networks (WSN), and Electronic Product Code (EPC). Smart-Track uses barcodes containing unique serialized product identifiers and lot production and expiration dates to maintain ownership transfer logs. Data-Matrix tracking system creates a Data-Matrix for each drug, which allows patients to verify the drug's origin. NFC tags are used to develop an NFC-based system that provides visibility throughout different stages of the pharmaceutical supply chain. Patients can verify authenticity and origin by scanning the attached NFC tag using a mobile application.

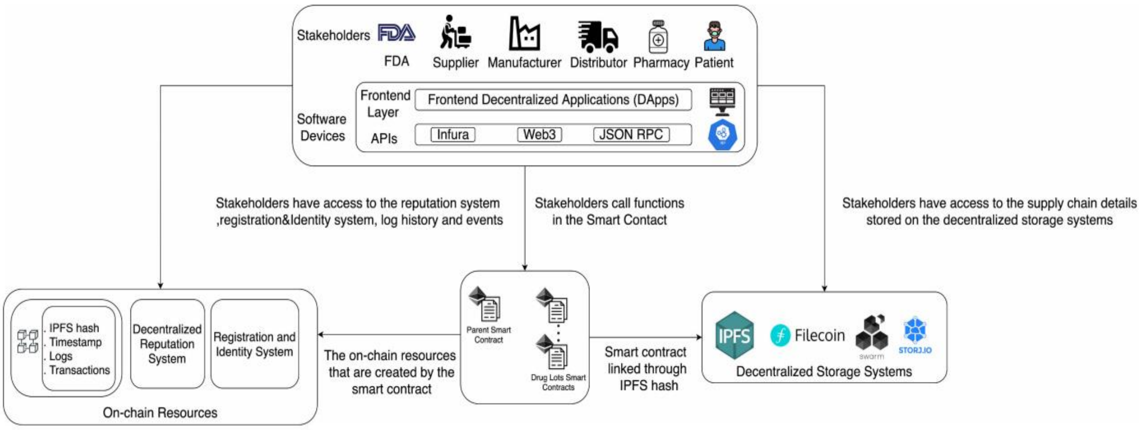

Figure 2. An Architecture for the proposed blockchain-based system for drug supply chain

2.2. BLOCKCHAIN-BASED SOLUTIONS FOR DRUG TRACEABILITY

The conventional, centralised approaches to pharmaceutical supply chain traceability are opaque and permit information alteration without informing other parties. Information security, visibility, immutability, authenticity, and validated transaction records are all features of blockchain-based systems. While they are separate ideas, transparency and traceability depend on one another. Current methods use the cryptographic capabilities of blockchain to create a decentralised, verifiable track and trace system for pharmaceutical products. There have been many ideas, however some of them have restrictions in terms of assessment or usage of certain data formats.

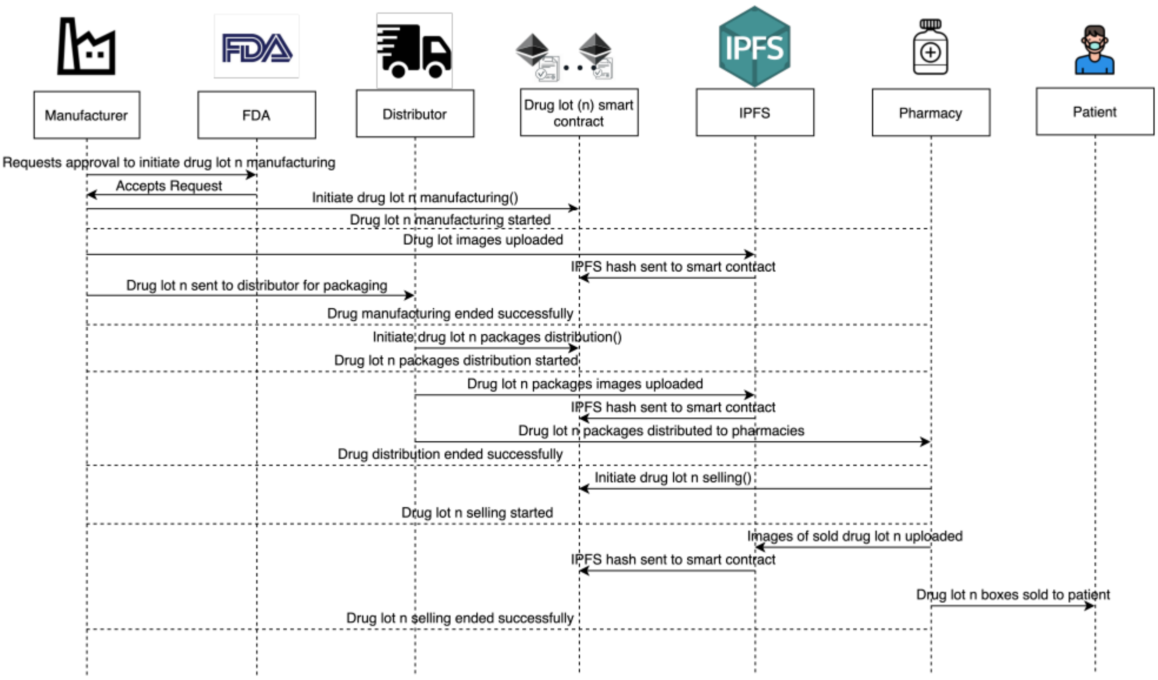

Figure 3. Sequence Diagram displaying interactions between the Smart Contract's involved elements

Faisal et al. proposed a Hyperledger-based solution for drug traceability, but it was not rigorously tested and was implemented in a small-sized network. Hulse apple developed a private blockchain concurrent with Bitcoin to protect every stage of product transfer in the supply chain. Active projects include Arsene, MediLedger, and Farmatrust, which explore the use of distributed ledger technologies to achieve traceability within the pharmaceutical supply chain. These projects face challenges such as lack of transaction ordering and policy enforcement.

2.3. A PHARMACEUTICAL TRACEABILITY SYSTEM BASED ON BLOCKCHAIN FOR DRUG SUPPLY CHAINS

Figure 2 shows an Architecture for the proposed blockchain-based system together with the stakeholder and their interactions with the smart contract. The proposed system for pharmaceutical traceability involves stakeholders accessing a smart contract, decentralized storage system, and on-chain resources through a DApp connected to an API such as Infura, Web3, and JSON RPC. Stakeholders interact with the smart contract to initiate pre-authorized function calls, access data files through the decentralized storage system, and obtain information such as logs, IPFS hashes, and transactions through the on-chain resources.

The use of decentralized storage systems, such as IPFS, is a key feature of blockchain-based supply chain solutions. These systems offer a cost-effective way to store large amounts of data securely, while maintaining the integrity of the stored data. The Ethereum smart contract is the central component of the system, responsible for managing the different functions of the stakeholders and tracking the history of transactions. The on-chain resources store logs and events created by the smart contract, allowing for easy tracking and tracing. The registration and identity system is also an on-chain resource, providing a way to associate the Ethereum address of the different participants with human-readable text in a decentralized manner. Overall, this system provides a transparent and secure solution for tracking the supply chain of pharmaceuticals, improving the safety and efficacy of these products.

The final phase involves the patient purchasing the drug from the pharmacy. The patient will use the DApp to scan the drug Lot package, which will initiate a request to the smart contract to access the IPFS to retrieve the associated drug Lot images and information leaflets. The DApp will then display the retrieved information to the patient, who can verify the authenticity of the drug before consuming it. In case the drug is found to be counterfeit, the patient can notify the authorities, and the supply chain history can be used to trace the source of the counterfeit drug.

Overall, the proposed system provides a secure and reliable solution for tracking the supply chain of drugs and ensuring the authenticity of drugs by using blockchain technology, smart contracts, and decentralized storage. The system can be used by different stakeholders, including regulatory agencies, manufacturers, distributors, pharmacies, and patients, to access information about the drug and its history in the supply chain. Correct, the final step in the sequence diagram involves the pharmacy initiating the sale of the drug Lot box to the patient, which is declared to all participants in the supply chain. The image of the sold drug package is then uploaded to the IPFS, and a hash is sent by the IPFS to the smart contract, allowing authorized participants to access the information later. Once the drug

Lot box is sold to the patient, this concludes the selling phase of the drug Lot, and all transactions are stored for future reference by supply chain participants. This ensures that the authenticity and validity of the products in the supply chain can be verified through a sequence of events that have been tracked and recorded by the proposed system

Table 1. Comparison between our proposed solution and the non-blockchain solutions

	Smart-Track	Data-Matrix Tracking System	NFC	Proposed Solution
Decentralized	No	No	No	Yes
Resilience	No	No	No	Yes
Integrity	No	No	No	Yes
Tracking and Tracing	Yes	Yes	Yes	Yes
Security	No	No	No	Yes
Transparency	No	No	No	Yes

2.3.1. COMPARISON OF PROPOSED SOLUTION WITH EXISTING SOLUTIONS

The proposed solution for traceable supply chain for pharmaceutical drugs is compared to existing solutions in a comparative analysis presented in Table 1. The proposed solution offers decentralization, resilience, data integrity and security through blockchain technology. Transparency of transactions is ensured and all solutions in Table 1 have the track and trace feature, but decentralized storage, integrity and transparency are also important for a trustworthy system.

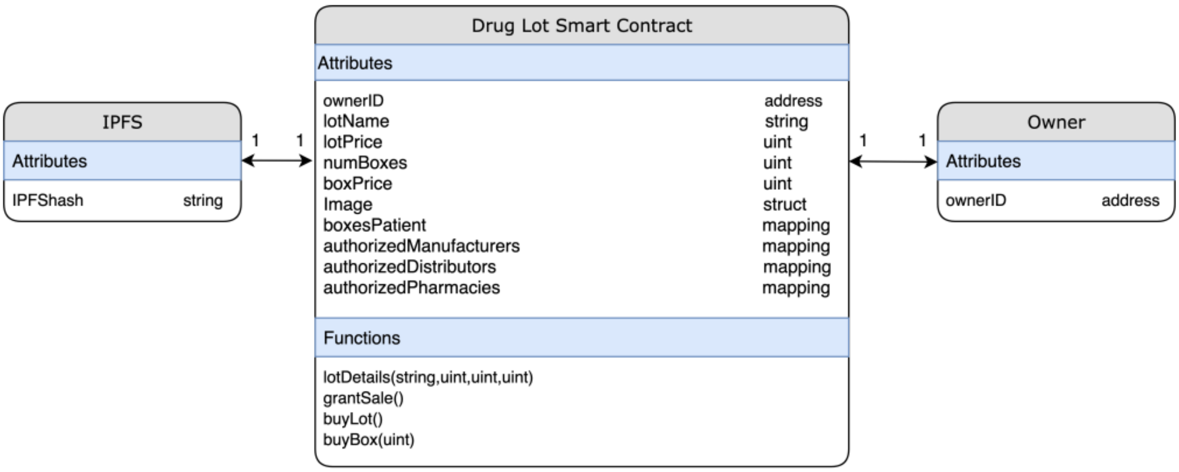

Figure 4. Entity relationship diagram

Table 2. Comparison between our proposed solution and other blockchain-based solutions

	Our Solution	Huang et al [34]	Faisal et al [32]
Blockchain Platform	Ethereum	Bitcoin	Hyperledger-Fabric
Mode of Operation	Public Permissioned	Public Permissioned	Private Permissioned
Currency	Ether	BTC	None
Off-Chain Data Storage	Yes	No	No
Programmable Module	Smart Contract	None	Docker Container

Table 2 compares the proposed Ethereum-based solution with other blockchain-based solutions. Our solution and one other operate in public permissioned mode, while the third operates in private permissioned mode. Our solution uses Ether as the currency, while the other two use BTC or no currency. Our solution allows for off-chain data storage, while the other two store all data on-chain. Our solution and one other have programmable modules, while the third does not.

2.4. IMPLEMENTATION OF PROPOSED TRACEABILITY SYSTEM

The Ethereum blockchain platform is utilised in the creation of the suggested fix. Because Ethereum is a permissionless public blockchain, anybody may access it.Solidity is used to write the smart contract, which is then tested and assembled using the Remix IDE. Remix is an online web-based development environment that enables users to write and execute smart contract code as well as debug and test the Solidity code's environment. The complete code1 has been made available to the public.

2.4.1.IMPLEMENTATION DETAILS :

The manufacturer deploys a smart contract with drug Lot details and triggers an event for all supply chain participants. New participants can access the events and track the history of the Lot. The manufacturer can upload an image of the Lot to IPFS for visual inspection. Before sale, the manufacturer announces availability and interested participants access a specialized function to buy. Once sold, an event declares the new owner. FDA approval is not implemented in the smart contract.

Figure 4 shows the relationship between entities and the smart contract. The smart contract is deployed using attributes such as owner ID, lot Name, lot Price, and Image. Authorized entities are mapped for accessing specific functions, and the manufacturer can upload images to IPFS using the lot Details function. The IPFS and smart contract have a 1:1 relationship, and events are emitted and stored on the blockchain to trace the origin of the drug Lot.

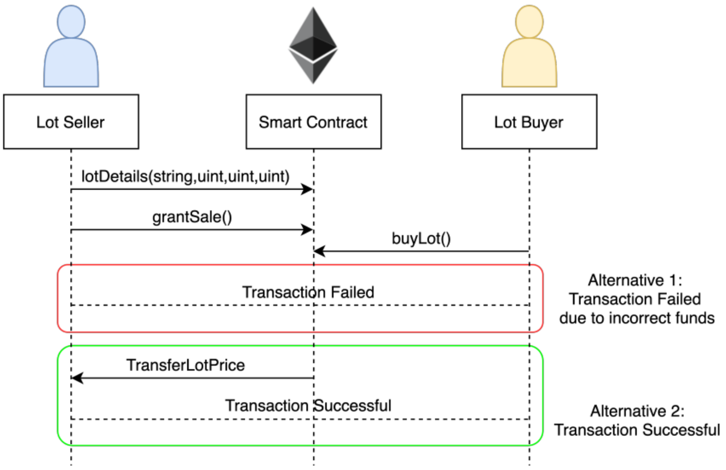

Figure 5. Function calls and events for two different scenarios for Lot sale

The scenario in Figure 5 shows a buyer attempting to buy a Lot from a seller. The seller adds Lot details and announces the sale to all participants. The buyer executes the buy Lot function with requirements that they should not have the same address as the Lot owner and have sufficient funds to buy the Lot. If the funds match the price, the transaction is successful, and funds are transferred to the buyer.

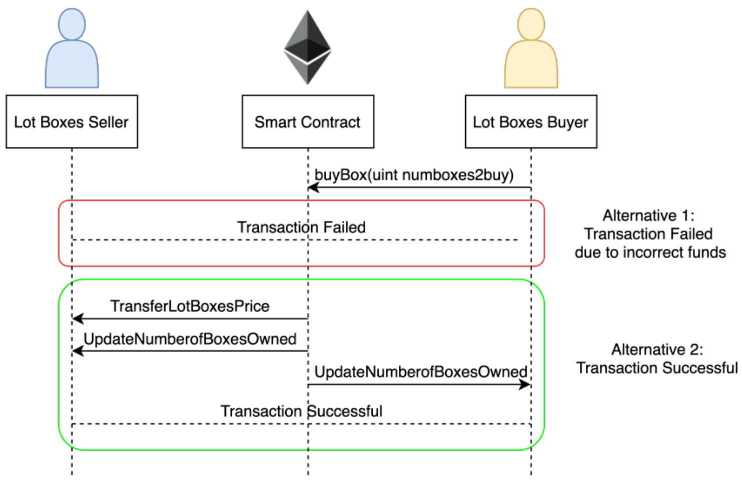

Figure 6. Function calls and events for two different scenarios for lot boxes sale

The text discusses a scenario depicted in Figure 6 where a buyer specifies the number of boxes to purchase from a Lot. The buyer executes the buy Box function with the required number of boxes, and if the transferred amount matches the price of the requested boxes, the transaction is considered successful, and the boxes' price is transferred to the seller. The number of boxes owned by both entities is updated according to the quantity purchased. Additionally, the text mentions the presence of various algorithms for different functions in the proposed solution.

Creating a Lot: Algorithm 1 describes how to make a Lot. The operations are presented together with the data to the smart contract that they need. Only when the caller's address matches the owner ID's address does the function really run. The caller will be able to modify the fields in Algorithm 1 if access is given to them. The two events will change the status as stated in Algorithm 1 after all fields have been updated.

Grant Lot Sale: The drug's grant lot sale is described in algorithm 2.This algorithm can only be activated if the caller is the ownerID holder, and it is responsible for delivering an event informing all participants that the Lot is presently up for sale.

Purchasing Lot: Algorithm 3 details the exchanges that take place between the purchaser and the vendor of the medicine Lot. In order to prevent Lot Owner from Purchasing His Own Lot, it is necessary for the buyer (caller) of the function to not reside at the same location as the seller and for the transferred money to be exactly equal to the Lot Price. The selling proceeds will be given to the seller after both conditions have been met.The ownerID will also be updated. The sale of the Lot will then be announced and the information on the new owner updated through an event. The fact that the smart contract may only be used by trustworthy parties is crucial to keep in mind. Consequently, the buyer may be confident that when a Lot is officially sold, the seller is trusted and the Lot will be delivered.

Algorithm 1: Creating a Lot in Smart Contract

Input: lotName, lotPrice, numBoxes, boxPrice, IPFShash, Caller, OwnerID

Output: Event indicating the Lot has been created and its image has been uploaded

Data:

lotName: Name of the Lot

lotPrice: Specified price of the Lot

numBoxes: Total number of boxes within a Lot

boxPrice: Price of each box within a Lot

IPFShash: IPFS hash of the Lot image

ownerID: Ethereum address of the Lot owner

initialization;

if Caller == ownerID then

Update lotName

Update lotPrice

Update numBoxes

Update boxPrice

Add IPFShash

Emit an event indicating the Lot has been created

Emit an event indicating the Lot image has been uploaded to the IPFS server

else

Revert contract state and display an error.

Algorithm 2: Granting Lot Sale

Output: Event declaring that the Lot is for sale

initialization;

if Caller == ownerID then

Emit an event stating that the Lot is up for sale

else

Revert contract state and display an error.

Algorithm 3: Purchasing Lot

Input: currentOwnerID, Buyer, Seller, Payment Amount, Lot Price

Output: A notification that the Lothas been sold

Data:

currentOwnerID: The Ethereum address of the current Lotowner

Buyer: The Ethereum Address of the buyer

Seller: The Ethereum Address of the Seller

Payment Amount: The amount paid for the function

Lot Price: The price of the property

Initialization:

if Buyer ≠ Seller and Payment Amount = Lot Price then

Transfer the Lot price to the seller

Update current OwnerID with the buyer's Ethereum address

Notify that the Lot has been sold

else

Revert to previous contract state and show an error.

2.4.2.TRACEABILITY ANALYSIS OF THE PROPOSED SOLUTION

This subsection describes the process for verifying the authenticity of drug Lots using a smart contract designed specifically for each Lot, with a unique Ethereum address generated for each one. To make it easier to access the Ethereum address, a QR code is used, which can be scanned with smartphones. An Ethereum QR code generator is used to map the Ethereum address to a unique QR code that will always map to that address when scanned. The QR code is attached to the drug Lot and can be scanned by patients to verify its authenticity. The verification process involves scanning the QR code using a DApp that interacts with the Ethereum node via web3j and JSON-RPC to retrieve the smart contract events stored on the ledger. The Ethereum node serves as a gateway, allowing users to access the ledger without the need to set up their own Ethereum node.

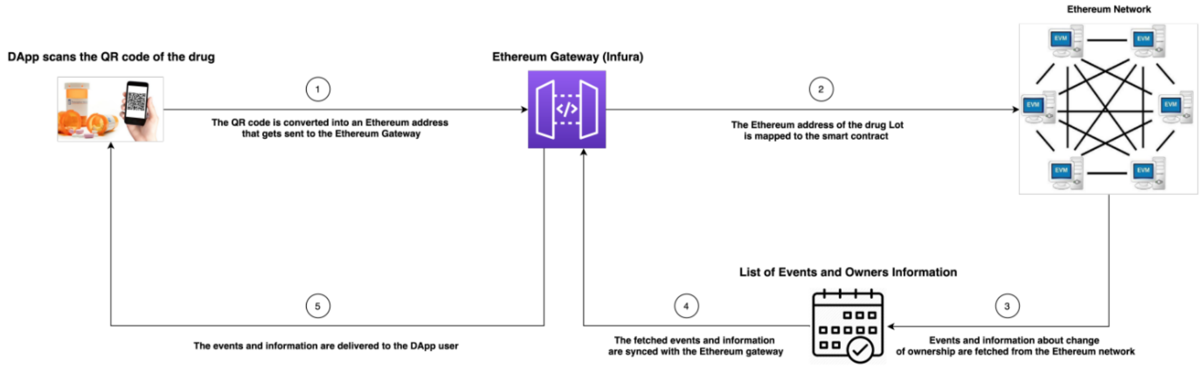

Figure 7. Application use case of the proposed blockchain-based solution

This section describes how a service user can verify the authenticity of a drug Lot using the event filtering feature of the Ethereum blockchain, which allows them to access stored events and confirm if the drug is authentic. Various events are used, such as lotSold to confirm legal sale, lotSale to verify pricing, imageuploaded to view product images, lotManufactured to check manufacturer Ethereum address, and newOwner to view original owner Ethereum address. The Ethereum network ensures authenticity by distributing information among participating nodes, with each node having an immutable replica of the ledger. The requested events and information are fetched from the network and synced with the Ethereum gateway (Infura) before being displayed to the user. This application demonstrates the effectiveness of automating the drug tracking process using the Ethereum blockchain's features.

3. RESULTS AND DISCUSSIONS

Remix IDE's in-browser development and testing environment was utilised to test and validate various features of the smart contracts created with Ethereum.As seen in Table 3, there were three distinct players in the scenarios, each with a matching Ethereum Address.Here, we also display the functionality of the smart contract's transactions and logs.

Table 3. The Ethereum address of each participant in the testing scenario

	Ethereum Address
Participant1	0xCA35b7d915458EF540aDe6068dFe2F44E8fa733c
Participant2	0x14723A09ACff6D2A60DcdF7aA4AFf308FDDC160C
Participant3	0x4B0897b0513fdC7C541B6d9D7E929C4e5364D2dB

IotDetails: It was tried in this function to see if the owner of the smart contract at the time could add information about a recently made Lot, including the Lot name, Lot price, the number of boxes in the Lot, and the price of each box.The function's successful execution is indicated, and related logs and events are shown.

GrantSale: This function's straightforward but crucial duty is to inform all entities that the produced Lot is presently up for sale.an effective performance of the function.

BuyLot: In this method, Participant2 purchases the Lot from Participant1 (Table 3 displays the associated Ethereum address).Participant 1 correctly estimated the quantity of ether transfer and ensured that the function was carried out.

BuyBox: This feature handles business involving the purchase of a certain quantity of boxes from the Lot (usually happens between a patient and the pharmacy).Suppose this process is carried out successfully, and Participant3 buys 50 cartons from Participant2.Although the cost of the boxes was chosen at random and may not make sense, the goal is to ensure that the functions are being carried out as intended.

This paper deals the difference between the pharmaceutical supply chain and other supply chains due to the nature of the products being shipped. The article notes that live tracking is out of scope but tracing the origin of a product is similar, requiring scanning a unique identification code attached to the product, which the DApp handles. The article suggests that the generation of unique identifications for products may be the only difference between tracing the origin of pharmaceuticals and other products.

Integrity, accountability, authorisation, availability, and non-repudiation are regarded to be major security goals in the proposed blockchain-based solution for the healthcare supply chain. Also, our system is resistant to popular threats like distributed denial of service and man-in-the-middle (MITM) (DDoS).

Test Results: All the test cases mentioned above passed successfully. No defects encountered.

IV. CONCLUSION

In this paper, we discuss the challenge of drug traceability within pharmaceutical supply chains and proposes a blockchain-based solution to track and trace drugs in a decentralized manner. The proposed solution uses blockchain technology to achieve tamper-proof logs of events and utilizes smart contracts within Ethereum blockchain to achieve automated recording of events that are accessible to all participating stakeholders. The solution is cost-efficient and offers protection against malicious attempts targeting its integrity, availability, and non-repudiation of transaction data. The authors envision future work to extend the proposed system to achieve end-to-end transparency and verifiability of drugs use.

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COMPETING INTERESTS

The authors declare no conflict of interest.

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Authors' contributions

We conceived the presented idea also developed the theory and performed the computations. We also verified the analytical methods and provided guidance. All authors discussed the results and contributed to the final manuscript. A. Anusha madam also provided valuable guidance with her expertise.

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