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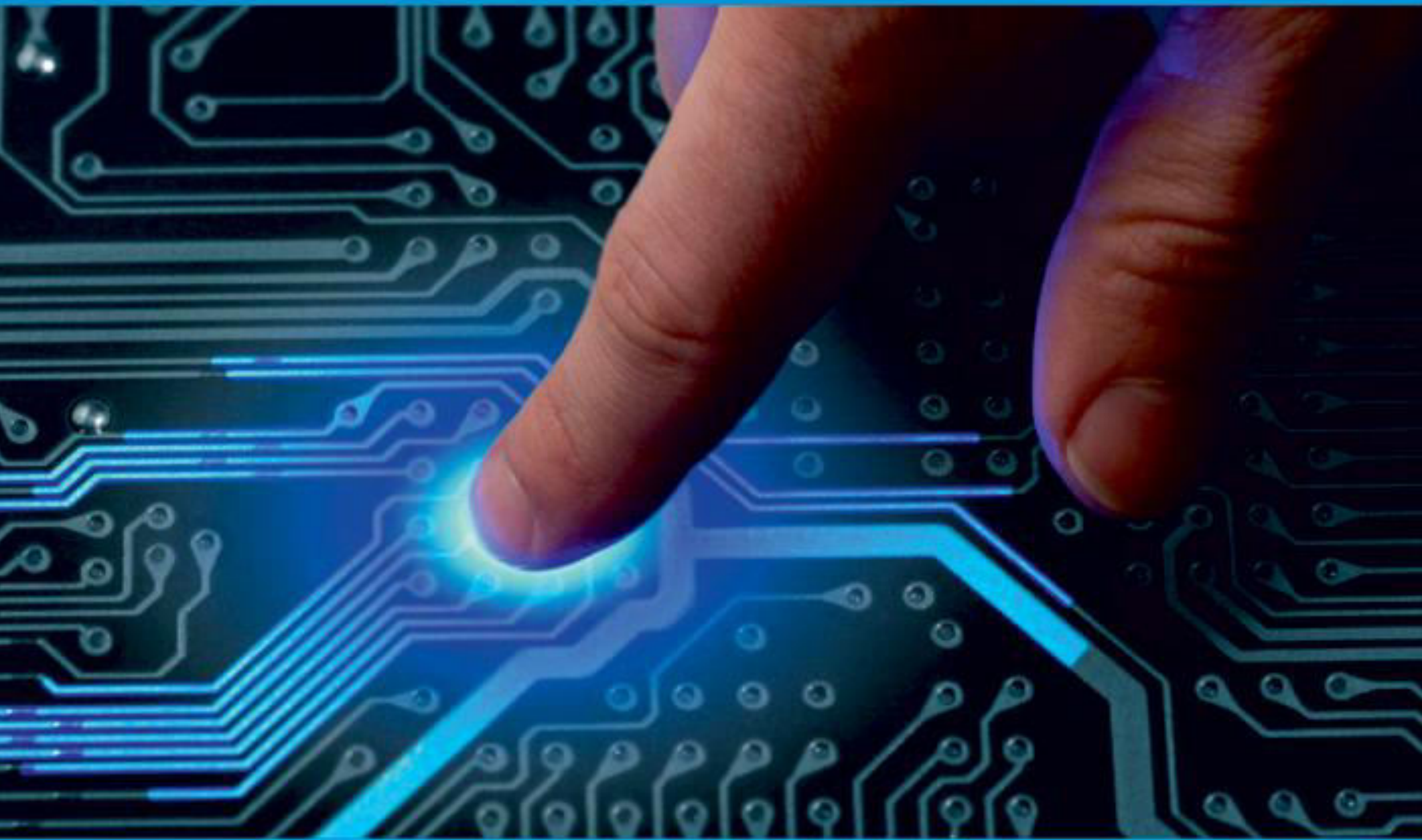

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Counterfeit Drug Tracking System Using Smart Contract

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ABSTRACT: Healthcare supply chains are complex structures spanning across multiple organizational and geographical boundaries, providing critical backbone to services vital for everyday life. The inherent complexity of such systems can introduce impurities including inaccurate information, lack of transparency and limited data provenance. Counterfeit drugs is one consequence of such limitations within existing supply chains which not only has serious adverse impact on human health but also causes severe economic loss to the healthcare industry. Consequently, existing studies have emphasized the need for a robust, end-to-end track and trace system for pharmaceutical supply chains. Therein, an end-to-end product tracking system across the pharmaceutical supply chain is paramount to ensuring product safety and eliminating counterfeits. Most existing track and trace systems are centralized leading to data privacy, transparency and authenticity issues in healthcare supply chains. In this article, we present 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. We present the system architecture and detailed algorithms that govern the working principles of our proposed solution. We perform testing and validation, and present cost and security analysis of the system to evaluate its effectiveness to enhance traceability within pharmaceutical supply chains.

KEYWORDS: Blockchain, drug counterfeiting, traceability, healthcare, supply chain, trust, security.

I. 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 mislabeled 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]

II. RELATED WORK

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.

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A. *TRADITIONAL EFFORTS FOR DRUG TRACEABILITY*

Traceability is defined as the ability to access any or all infor- mation relating to the object under consideration, throughout its life cycle, by means of recorded identifications. The object under consideration is referred to as Traceable ResourceUnit (TRU) which is any traceable object within the supply
chain. Traceability objectives are twofold; to track the historyof transactions, and to track the real-time position of the TRU. In this context, a traceability system requires access toinformation 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 mecha-nism for identifying TRUs, a mechanism for documenting the connections between TRUs, and a mechanism for recordingthe attributes of the TRUs [21].

A. *BLOCKCHAIN-BASED SOLUTIONS FOR DRUGTRACEABILITY*

Traditional solutions to achieve traceability within phar-maceutical 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, trans- parency, immutability, provenance and authenticated transac- tion 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. Trans- parency 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.

III. BLOCKCHAIN-BASED DRUG TRACEABILITY SYSTEMFOR PHARMACEUTICAL SUPPLY CHAINS

Figure 2 presents a high-level architecture for the proposed drug traceability system together with the stakeholder and their interactions with the smart contract. The stakehold-ers are envisioned to access the smart contract, decentral-ized storage system and on-chain resources through software devices that have front-end layer denoted by a DApp (Decen-tralized Application) which is connected to the smart con- tract, on-chain resources, and decentralized storage system by an application program interface (API).

Distribution: The next step is the initiation of the distri- bution process, the distributor will pack the drug Lot, and an image of the package will be uploaded to the IPFS which will send a hash to the smart contract. Once this step is completed,the drug Lot packages will be delivered to pharmacies, and this ends the distribution phase.

A. *COMPARISON OF PROPOSED SOLUTION WITHEXISTING SOLUTIONS*

In this section, we present a comparative analysis of the pro- posed solution for traceable supply chain for pharmaceutical drugs with relevant existing solutions. A summary of this analysis is presented in Table 1.The proposed solution is decentralized which is an impor-tant feature as it prevents any single entity from manipu- lating or modifying the data.
Table 2 compares our proposed solution with other blockchain-based solutions.

IV. PROPOSED ALGORITHM

A. *Design Considerations:*

The proposed solution is developed using the Ethereum blockchain platform. Ethereum is a permissionless public blockchain which means it can be accessed by anyone. The smart contract is written in Solidity language, and compiled and tested using Remix IDE. Remix is an online web-based development environment for writing and executing codes for smart contracts, and it also allows the user to debug and test the environment of the Solidity code. The full code[1] has beenmade publicly available.

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B. *Description of the Proposed Algorithm:*

The manufacturer will first deploy the smart contract in which details of the manufactured drug Lot will be defined, declared and an event will be triggered and announced toall participants in the supply chain. In case new participants are added to the network, they will have access to the events since they are permanently stored on the ledger and therefore they can track and trace the history of any manufactured drug Lot. The manufacturer also has the option of uploading an image of the Lot to the IPFS so that it can be accessed by participating entities to visually inspect the drug Lot

Step 1 **Creating a Lot**: Algorithm 1 explains the steps in cre- ating a Lot. The inputs to the smart contract needed by the functions are shown with their descriptions. Thefunction executes only if the address of the caller isthe same as the address of the *ownerID*. If the caller is granted access, he/she will have the authority to update the fields in Algorithm 1.

Step 2 **Grant Lot Sale**: The algorithm 2 describes Granting Lot Sale of the drug. This algorithm is responsible for sending an event alerting all participants that the Lot is currently available for sale, and can only be triggered if the caller is the *ownerID* holder.

Step 3 **Buying Lot**: Algorithm 3 describes the transactions between the buyer and the seller of the drug Lot. It requires the caller of the function (buyer) to not have the same address as seller (to ensures Lot owner doesn't buy his own Lot) and requires the transferred amount tobe exactly equal to the Lot price. Once both requirements are fulfilled, the sale amount will be transferred to the seller. eq. (3)

II. ALGORITHM

Algorithm 1 Creating a Lot in Smart Contract

Input: lotName, lotPrice, numBoxes, boxPrice, IPFShash,Caller, OwnerID
Output: An event declaring that the Lot has been manufac-tured
An event declaring that the image of the Lot has beenuploaded

Data:
lotName: is the name of the Lot
lotPrice: is the specified price of the Lot
numBoxes: is the total number of boxes within a Lot*boxPrice*: is the price of each box within a Lot *IPFShash*: is the IPFS hash of the Lot image
ownerID: is the Ethereum address of the owner of the Lotinitialization;
if *Caller* == *ownerID* **then**Update *lotName* Update *lotPrice* Update *numBoxes*
Update *boxPrice*
Add *IPFShash*
Emit an event declaring that the Lot has been manufac-tured
Emit an event declaring that the Lot image has beenuploaded to the IPFS server

else
Revert contract state and show an error.

Algorithm 2 Granting Lot Sale

Output: An event declaring that the Lot is for saleinitialization;
if *Caller* == *ownerID* **then**
Emit an event stating that the Lot is up for sale

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else
Revert contract state and show an error.

Algorithm 3 Buying Lot

Input: ownerID, Buyer, Seller, Transferred Amount, lotPrice
Output: An event declaring that the Lot has been sold
Data: *ownerID*: The Ethereum address of the current Lot owner
Buyer: The Ethereum Address of the buyer
Seller: The Ethereum Address of the Seller
Transferred Amount: The amount transferred to the function
lotPrice: The price of the Lotinitialization;
if *Buyer* /= *Seller* ∧ *TransferredAmount* = *lotPrice* **then**
Transfer the price of the Lot to the seller
Update ownerID by replacing the seller Ethereum addressto the buyer Ethereum Address
Emit an event declaring that the Lot has been sold

else
Revert contract state and show an error

V. SIMULATION RESULTS

The proposed work in this article demonstrates how blockchain technology can be applied for drug traceabilityin a pharmaceutical supply chain. Although the functions inthe smart contract were defined in a way that fits the pharma- ceutical supply chain specifically, it can be easily extended toother types of supply chains [47].
The main difference between the pharmaceutical supply chain and any other supply chain is the products/items that are being shipped, distributed, and sold and the way they are han- dled throughout the process. For example, some pharmaceu- tical drugs require very specific conditions like temperature and humidity while they are being transferred from a point toanother whereas a spare part supply chain for example wouldhave very different conditions. Since live tracking is out of the scope of this article, tracing the origin of a product/item regardless of its type will be very similar because it only requires the scanning of a unique identification code which is attached to the product/item and the DApp will handlethe rest. The only difference might occur in the way unique identifications are generated for the products/items which does not hinder the process.
Figure 2 can be used as a reference to discuss the gen- eralized application of the proposed solution in a different supply chain. Based on the specific supply chain application, for example, food, spare parts or other application the stake-holders of the supply chain and their role needs modification. Moreover, the use of a decentralized storage system might not be needed in cases where there is no necessity to store and access large data files from off-chain. Finally, the on-chain resources can be modified according to the needs of the pro- posed application, for example, a reputation system, paymentand funds transfer setup might not be needed. In such cases the on chain storage will be more than adequate to retain thetransaction logs amid stakeholders.

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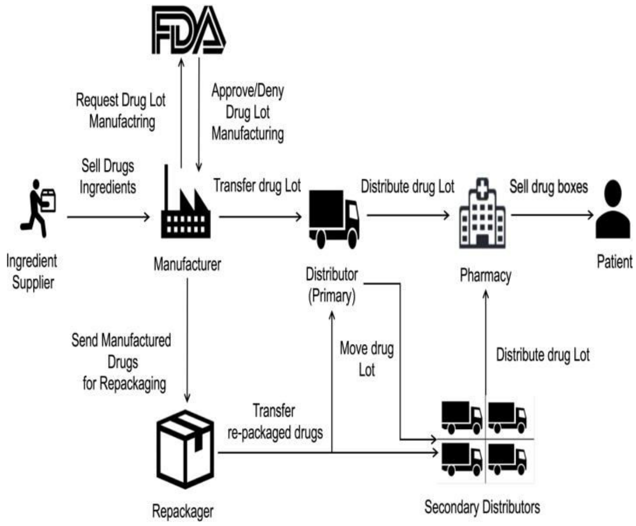

FIGURE 1. Drug supply chain stakeholders and their relationships.

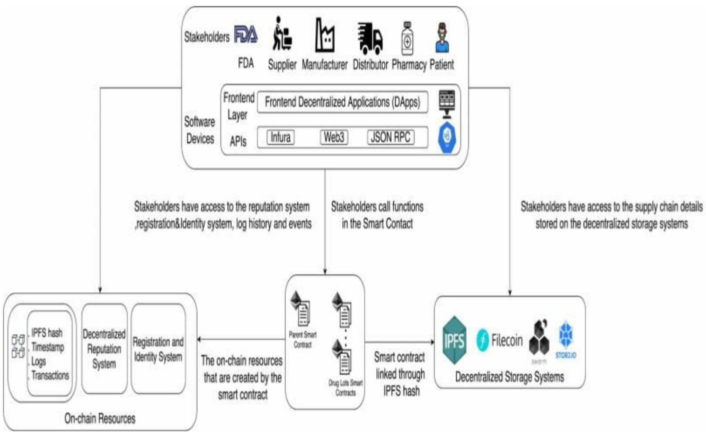

FIGURE 2. A high-level architecture for the proposed blockchain-based system for pharmaceutical supply chain.

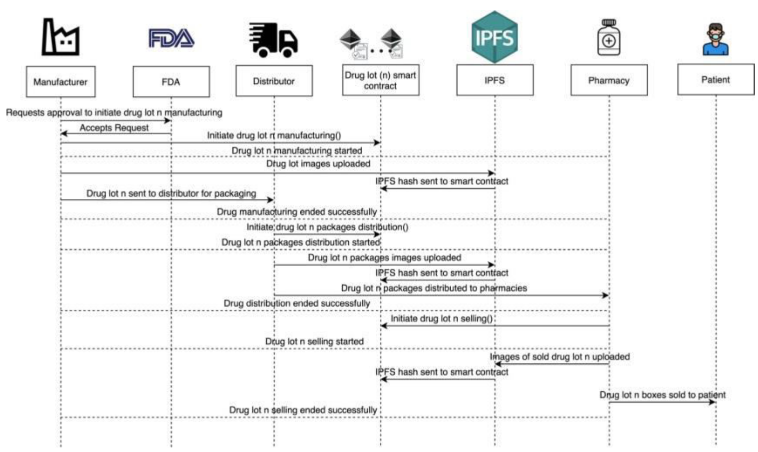

FIGURE 3. Sequence Diagram showing interactions among the participating entities of the smart contract.

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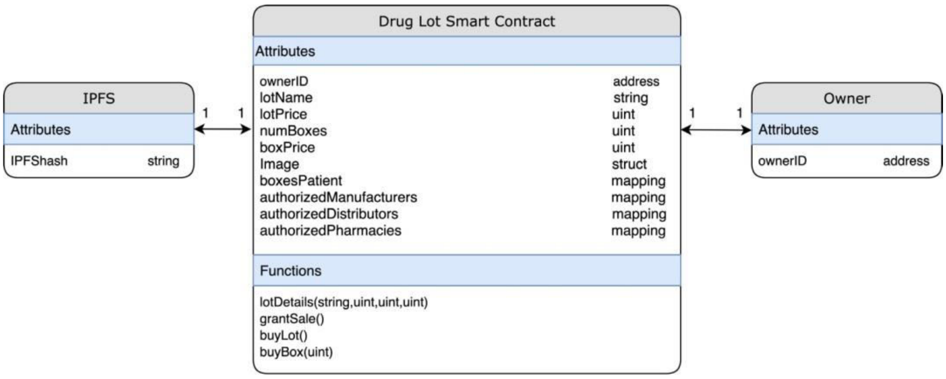

FIGURE 4. Entity Relationship Diagram.

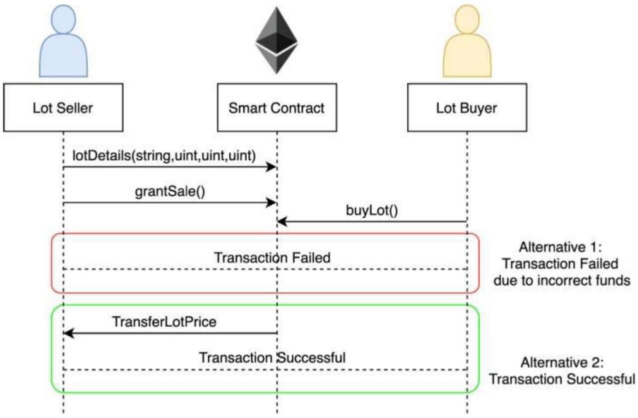

FIGURE 5. Function calls and events for two different scenarios for Lotsale.

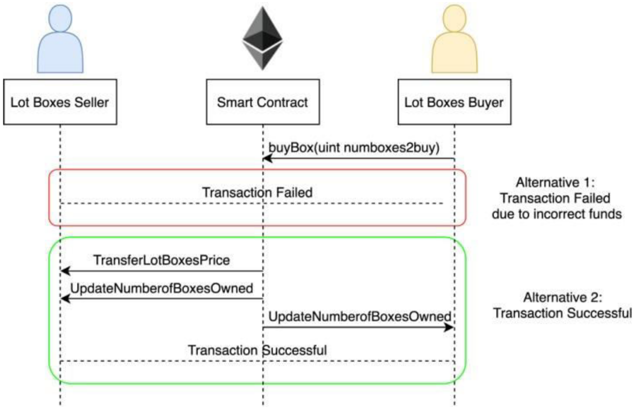

FIGURE 6. Function calls and events for two different scenarios for lotboxes sale.

VI. CONCLUSION AND FUTURE WORK

There are many stages in supply chain management which can be exploited and thus it becomes important to secure them to avoid counterfeit products. Malfunctioning can take place in the system which cannot be even tracked using the current architecture. Thus, technology like Blockchain can be used to provide security to the system, thus improving overall efficiency of the system.

IoT devices can be introduced at some stages to automate the system and thus increase its efficiency. Globally Recognized Avatars (GRAvatars) can be used to replace QR-codes to perform the task of scanning in a more secure way.

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BIOGRAPHY

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