PharmaChain 3.0: Blockchain Integrated Efficient QR Code Mechanism for Pharmaceutical Supply Chain

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***Abstract*—Because of globalization, many different entities distributed across the locations were able to work together and achieve the availability of services even at remote locations. Supply Chains helped in leveraging such businesses globally with reduced costs and increased efficiency. Pharmaceutical Supply Chain (PSC) is one in which the prescription drugs are moved from the manufacturer to the patient. Providing the right medicine at the right time to the right patient in the right doses coming from the right route is called the five rights of medication. Due to the increased number of participating entities, and interactions between entities and adversaries trying to profit by introducing counterfeit drugs into the supply chain, efficient tracking and tracing mechanism is very much needed in PSC. The current paper proposes an architecture that is integrated with Blockchain, Inter Planetary File System (IPFS) along with QR code technologies to provide a secure QR code mechanism for addressing such tracking and tracing issues in PSC. The proposed model is evaluated for security and efficiency using different metrics.**

***Keywords*—** Pharmaceutical Supply Chain, Blockchain, Remote Monitoring and Control, Distributed Ledger Technology, Secure and Verifiable Log

I. Introduction

Pharmaceutical Supply Chains (PSC) are the backbone of the healthcare sector which facilitates the smooth movement of drugs from the location of manufacturing to the consumers with multiple entities involved in between. Due to the nature of drugs and the large number of entities involved which interact in complex ways during different scenarios, PSCs are complex in nature. This complexity in supply chains introduced obscurity and made it difficult for tracking and tracing of products moving within the supply chain. Counterfeit drugs are more prevalent due to this obscurity caused by the complexity of PSC. Drugs are made up of two components, Active Pharmaceutical Ingredients (API) which are chemical components used to treat a condition and in-active components also called excipients which are mainly used for flavoring, dyeing the product, binding the pill together, and sometimes act as preservatives. Counterfeit drugs are defined as drugs manufactured with incorrect API, fewer doses of API, and no API which doesn't cure the targeted condition of the patient. Some counterfeit drugs are also produced in sub-standard conditions which can be fatal to the consumers in some cases. Adversaries produce such counterfeits and introduce them into the PSC to be benefited monetarily. Detecting and avoiding such counterfeit drugs in complex PSC is very difficult considering the tangled PSC. It is estimated to be 5% of drugs sold worldwide are counterfeits and in some countries percentage of counterfeits can reach as high as 50%. Drug Supply Chain Security Act [1] outlines regulations and procedures which require all the entities participating in PSC like manufacturers, distributors, packagers, wholesalers and pharmacies should be integrated with an electronic system that can help with interoperability along with tracking and tracing the products at lot-level. This lot-level tracing should also provide different transaction information along with history for parties interested which ensures the safety of product consumption. In recent years lot-level tracing is moving towards unit-level tracing for more accurate information and in avoiding costs during recalls. Technologies like 1D-2D barcodes/QR-codes are the most widely used practice to label the lots and keep the transaction histories within the supply chain. Enterprise resource planning systems (ERPs) are used to facilitate generating and recording these unique numerical codes generated and assigned to a lot. Generally, ERPs are centralized and every movement or interaction with the product within the supply chain is recorded on the centralized servers which can be accessed by any participating entities. An adversary who can compromise such centralized systems will be able to introduce counterfeit medicines and can modify the centralized database. Hence, we need a robust mechanism that is secure and should be able to identify the adversaries within the network. In current PSC systems, 1D numeric-only barcodes are widely used among which UPC and EAN are the well-known types. These numerical data encoded will consist of basic information about manufacturer information along with product identification information. These systems make use of centralized UPC/GTIN databases to gather more information about the product. Due to the limited amount of data that can be stored in one-dimensional barcodes, nowadays two-dimensional barcodes are being used which can store large amounts of product information.

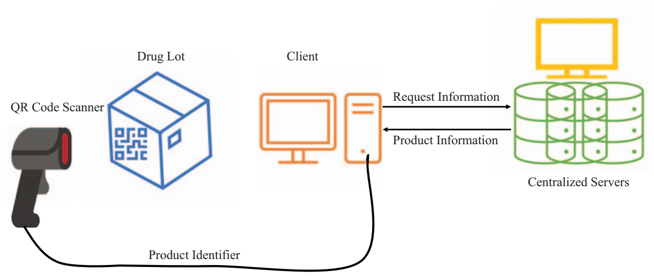

Fig. 1. Working of Typical QR Code Scanner System

The most used 2-D barcode is a QR Code which can hold up to

3Kb of data. There are two types of QR-Codes which include Static QR Codes and dynamic QR codes. Static QR Code as the name suggests data behind it cannot be changed once generated but with dynamic QR codes, the data behind it can be changed any time after the QR code is generated and printed. Along with that flexibility, dynamic QR codes also provide statistics of the code scans and the locations of scans. All this information is stored at the centralized servers which can be accessed by the administrator who generated the codes. A typical QR Code scanner system working is illustrated in Figure 1. Providing better track and trace along with security against manipulation of data is lacking in such centralized systems. One of the recent technologies is blockchain which started as a financial solution and later showed promising applications in different sectors. Some of the features of the blockchain such as immutability, distributed ledger, and P2P network make it a reliable solution to provide better track and trace along with multiple information about the drugs to the consumer while avoiding counterfeits. The current paper proposes a such mechanism that integrated QR codes with blockchain technology to provide a robust solution for tracking and tracing along with drug information.

The rest of the paper is organized in the following sections: Section II provides an overview of prior related research work. Section III discusses the novel features of the proposed PharmaChain 3.0. Section IV presents an architectural overview of the proposed PharmaChain 3.0. Section V discusses the algorithms behind PharmaChain 3.0. Section VI gives an insight into the implementation validation details of the proposed PharmaChain 3.0. Section VII provides the conclusion along with future scope.

II. Related Research

Blockchain even though started as a financial solution to remove the intermediary banking systems, has shown use cases in many other sectors which include smart healthcare [2]–[4], smart agriculture [5]–[7] and many others including redefining the supply chains. Pharmaceutical supply chains that have many problems due to the complexity can also be benefited from using blockchain as a solution.

Modum.io AG proposed in [8] makes use of the sensory tags MAC address and track and trace numbers are embedded in QR Codes for scanning through the phone camera, unlike in our current proposed PharmaChain 3.0 a unique contract address is embedded into the QR Code. Modum.io concentrates on tracking and tracing, but the current paper mainly focuses on integrating the blockchain with QR Codes into the supply chain along with providing a way to include all the drug information accessible to the consumer.

The proposed system in [9] makes use of the QR Codes integrated with blockchain, in this proposed system, all the drug information like drug name, location, timestamp, ingredients, usage of drugs, and side effects are stored on-chain smart contract. Any consumer who wants to access these details, a consumer should send their public key to the manufacturer and in return gets a QR Code with encrypted data. Storing large amounts of information on-chain is not a cost-effective way, unlike in our proposed system PharmaChain 3.0 which uses off-chain storage and avoids the latency during accessing the drug information as it should be publicly available.

A blockchain-based traceability approach which is based on the Ethereum platform is proposed in [10]. This model proposed makes use of smart contracts to track and trace the drug movement within the supply chain however, integrating the drug usage information, another drug-related document, and accessibility to the users is not considered. CryptoCargo proposed in [11] also integrated IoT and Ethereum blockchain systems and make use of smart contracts for better track and tracing along with avoiding the counterfeits in the supply chain but didn't consider QR Code integration and providing easy drug information access to the consumers. Another Ethereum blockchain based solution PharmaChain for tracking and tracing of the drugs in the supply chain and preventing counterfeits is discussed in [12], however Integration of QRCode mechanism with blockchain is not included in the discussion.

Hyperledger Fabric based solutions with chain codes that are similar to smart contracts are proposed in [13]–[15]. They all address the problem of counterfeit detection and avoidance in the drug supply chain however doesn't consider the integration of blockchain into QR Code tracking and also provide the information of drugs.

III. Novel Contributions

A. Problems Addressed in Current Paper

Problems addressed in existing ERP systems are:

- Removing centralized authorities to enhance the security of the supply chain.
- Increasing the response times of the tracking and tracing system by hosting data on the P2P network.
- Consumer accessibility of drug information can be increased significantly.
- Data security and integrity are maintained by eliminating adversaries in the Supply Chain Network.
- Drug information along with track and trace logs can be maintained with a single QR code mechanism.
- End-to-end transparency is provided to increase consumer confidence.
- Fragmentation of drug information at multiple data sources in supply chain network.

B. Novel Solutions Proposed

Below are novel solutions proposed in current PharmaChain 3.0:

- P2P network and consensus-based updates used in PharmaChain 3.0 remove the centralized entities and need for centralized databases for retrieving drug information.
- Shared ledger proposed in PharmaChain 3.0 provides high availability of data providing low latency for data retrieval.
- With the proposed QR Code integrated with the Blockchain mechanism, various drug information along with track and trace information can be stored in a single place and can be accessed using a single QR Code scan.
- Due to the immutability nature of blockchain, various threats like data security and unauthorized modifications are eliminated.
- Track and trace the medicines movement within the supply chain and information about approvals, retailers, wholesalers, drug usage instructions, Warnings, Side effects, etc. is stored and accessed using a single QR Code, providing transparency to consumers.

IV. Architectural Overview of Proposed PharmaChain 3.0

An architectural overview of the proposed PharmaChain 3.0 is shown in Figure 2. The main components of the proposed PharmaChain 3.0 consist of: Entities of the PSC which consist of different participants responsible for moving the drugs from manufacturing units to patients. The manufacturer is responsible for undertaking the research and production of new generic or brand name drugs. Drugs move from manufacturing units in lots to distributors/wholesalers and then to retailers. Retailers send the drugs to different pharmacies and healthcare units from which patients can access the medicines. The manufacturer is also responsible for creating the unique identity in the form of QR codes and assigning them to each drug lot manufactured. In the proposed PharmaChain 3.0, whenever a new drug lot is created the parent smart contract is called and creates a new lot smart contract. The manufacturer then uploads the drug information and usage instructions document to the InterPlanetary File System (IPFS). Hash returned from IPFS is updated to the newly created lot smart contract and the contract address is embedded into a QR code and used to label the new lot created.

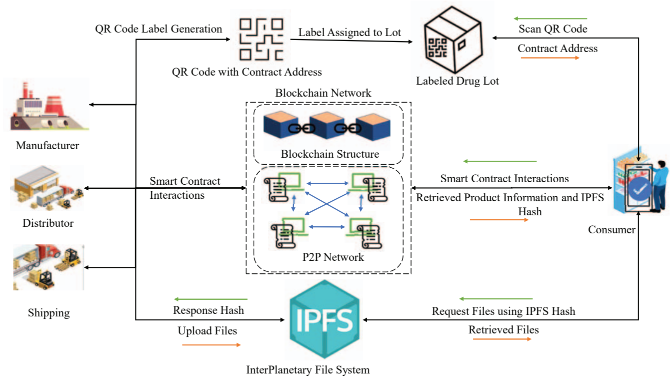

Fig. 2. Architectural Overview of Proposed PharmaChain 3.0

The blockchain layer consists of the P2P nodes which are managed by different entities participating in the PSC. Proposed PharmaChain 3.0 makes use of the Ethereum platform as a blockchain network. Ethereum currently uses Proof-of-Stake (PoS) consensus in which the miner is chosen based on the staking coin age eliminating the hard computational problems that are power consuming. The Ethereum environment is analogous to a single computer (Ethereum Virtual Machine) and all the peers in the network agree upon the current state of the EVM. Changes in the state of the EVM are tracked and records are kept at each node. Ethereum also facilitates smart contracts which are pieces of self-executing code that run when certain conditions are met. Proposed PharmaChain 3.0 makes use of these smart contracts to store and retrieve information about the drug lots and IPFS hashes pointing to the drug information and usage files stored.

IPFS is another major component in the proposed PharmaChain 3.0, IPFS is a distributed file-sharing protocol that allows devices across the P2P network to view and download shared files. Protocols like HTTP, and HTTPS are location addressable, the resources pointed by this URL point to a location where the file, webpage, etc. are available. location addressable protocols allow duplication of data while IPFS is content addressable and removes duplication of the same data. The address of every file shared on IPFS is given a unique address based on the hash of the file's content. Currently, IPFS makes use of SHA-256 hashing which outputs a 256-bit output by digesting the content of the file.

The client layer consists of a client program that takes the contract address from the QR code attached and interacts with the smart contract to fetch details of the manufacturer, retailer, and pharmacy through which the drug has moved in the supply chain and along with that the IPFS hash of the files related to the medicine stored on IPFS. Once these details are queried, File content can be fetched by interacting with the IPFS network. This gives complete details of the medicine to the patient to verify it's not a counterfeit and also all the instructions about the usage.

V. Proposed Algorithms for PharmaChain 3.0

Steps involved in generating blockchain-integrated QR Code and assigning it to each lot along with sending shipment updates by entities are clearly shown in Algorithm 1. Initially, when a new lot of drugs are manufactured, the manufacturer sends a call to the parent smart contract and creates a new lot smart contract specific to the newly created lot. Once the lot smart contract is created, the drug information files are added to the IPFS storage and returned IPFS hashes for each individual file are updated to the smart contract in-memory array. Once the IPFS hashes are updated the manufacturer information is also appended and the lot contract address is embedded into the QR Code. This unique QR Code generated is then allotted to the new lot generated. When shipment moves within the supply chain, each entity will scan the QR code and get the lot contract address information and the smart contract is updated with the entity information at the which the product is reached. This helps in keeping the trail of drugs in the supply chain.

Algorithm 1 Data Upload and QR Code Generation Algorithm for Proposed PharmaChain 3.0

Input: Newly manufactured drug lot information files, shipping updates by entities in supply chain.

Output: Unique QR Code specific for newly manufactured lot and Immutable ledger of shipment updates.

Phase 1 – QR Code Generation

procedure QR Code Generation
  for Each Drug Lot Manufactured **do**
    Lot specific contract is created by calling parent contract
    Contract$_{lot}$ ← Contract$_{partent}$.createNewLotContract()
    Manufacturer uploads all required information about medicine on to IPFS system
    for Each Data File **do**
      Upload each individual file on IPFS
      IPFSHash$_{file}$ ← IPFS.add(File)
      Returned hash is then updated in the newly created drug lot smart contract
      Contract$_{lot}$.addIPFSHash(IPFSHash$_{file}$)
    end for
    Create a QR Code with newly created lot contract address information
    QRCode.embed(Contract$_{lot}$ Address)
    Generated QR Code is assigned to the newly created drug lot
  end for
end procedure

Phase 2 – Track and Trace Updates

procedure Track and Trace Updates
  for Each Shipment Update in Supply Chain **do**
    Entity scans the QR Code to retrieve the lot contract address
    Contract$_{lot}$ ← QRCodeScan()
    New transaction is generated and contract call is done to update the information of lot
    Newly generated transaction will be added to the unconfirmed transaction pool
    Group of unconfirmed transaction will be picked by miner and a new block is created after performing consensus
    New block is added at each and every node participating in the network creating immutable ledger of trail of ownership data
  end for
end procedure

The client program at the end user is used to retrieve the drug information and to verify the authenticity of the product by checking the trail of drugs within the supply chain. Clear steps involved

Algorithm 2 Algorithm for Drug Information Access and Authenticity Verification of Drug in Proposed PharmaChain 3.0

User scans the QR Code to get the lot contract address
$\text{Contract}_{lot} \leftarrow \text{QRCodeScan()}$
IPFS hashes are retrieved from the lot contract call
$\text{IPFSHashes}_{file} \leftarrow \text{Contract}_{lot}.\text{getHashes()}$
for Each IPFS hash **do**
    Retrieve each information file
    $\text{FileData} \leftarrow \text{IPFS.get}(\text{IPFSHash}_{file})$
end for
To verify authenticity, check the entities information updated in the smart contract
$\text{TrailInformation} \leftarrow \text{Contract}_{lot}.\text{getTrailInfromation()}$
Authenticity of product can be checked along with all required drug information can be accessed.

are shown in Algorithm 2. The user who wants to retrieve the drug information and check the authenticity of the product scans the product QR Code and gets the lot contract address. Once the lot contract address is obtained, IPFS hashes of the uploaded drug information files are retrieved. With the help of hashes, the data uploaded is accessed from the IPFS distributed storage system. To check the authenticity of the product, the trail information stored in the lot smart contract is retrieved and all the entities through which the drug has been passed are verified.

VI. Implementation and Validation

A. Implementation

As multiple different entities are involved in the supply chain, Role Based Access Control mechanism is implemented using smart contracts. Roles smart contract designed has the capability of creating, adding, and renouncing different roles to different Externally Owned Accounts (EOA). Manufacturer, Distributor, Retailer, and consumer are the different roles created and assigned in the implemented prototype of PharmaChain 3.0. This ensures the entities update only the corresponding information about the drug, like the manufacturer can only update or add information about the manufacturer of the drug, and similarly, only the manufacturer, Distributor, Retailer, or 3PL logistic operations can only add the files to IPFS, not the consumer or any other adversaries to introduce misinformation into the chain. RBAC model developed in the proposed PharmaChain 3.0 is clearly shown in Figure 3. As it can be seen a different contract is designed for adding and managing different roles in the network. Each role smart contract has the function add the bearer to a specific role or renounce the access which is controlled by the modifiers in the smart contract. LotFactoryContract which generates a unique lot contract for each newly manufactured lot can be clearly seen in the class diagram represented in Figure 4.

Ethereum platform is used for implementing the prototype of PharmaChain 3.0, a local ganache blockchain that generates 10 test accounts with 100 test ETH for performing transactions has been set up for PharmaChain 3.0 prototype. The designed prototype ran locally to avoid the cost of transactions in the mainnet as the local blockchain functionality of smart contracts can be tested using test ether which doesn't have any monetary value. This local blockchain Ganache simulates the behavior of the mainnet accurately to verify the functionality of the decentralized applications (DApps) designed. Below Table I shows the address and the roles assigned to those addresses.

Interplanetary File System (IPFS) is used for providing distributed storage of large amounts of data which include drug information,

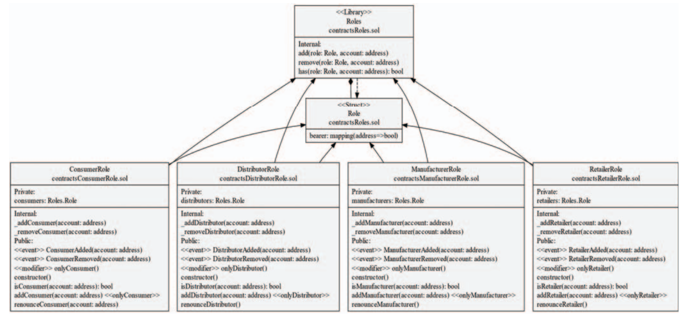

Fig. 3. Class Diagram Representing Role Based Access Control Mechanism Implemented in Proposed PharmaChain 3.0

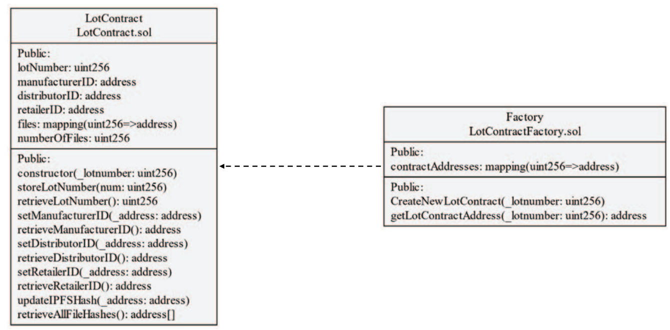

Fig. 4. Class Diagram Representing Lot Contract Factory Implemented in Proposed PharmaChain 3.0

drug usage instructions, and side effects information. All these files are hashed and stored in the file system, IPFS prevents storing of the same file multiple times as content identifiers (CID) are unique hashes generated from the content of files. Distributed Hash Tables (DHT) are used for content routing in IPFS which makes use of these hash keys to peer holding the requested data as values. User Interface is designed by using react.js and web3.js to interact with smart contracts.

B. Results and Validation

Lot contract factory deployment can be seen in Figure 6.a. 5. To test the proposed mechanism of PharmaChain 3.0, a test drug lot is generated and the corresponding transaction is shown in Figure 6.b. 5. For a newly manufactured lot, the created unique contract address is "0x1EcbFd5Edb3747927033Aa893416e4aD01DF0c6E" generated automatically by the lot contract factory smart contract. This unique contract address is embedded into the QR code label as shown in Figure 6 which will be attached newly manufactured lot.

The designed UI Prototype and operations are shown in Figure 7. Figure 8.a. shows the home page which will take the unique QR code contents of the lot which is the lot contract address. Figure 8.b. shows the verification of drug trail within the supply chain and fetching the file hashes which are uploaded to the IPFS. Publicly accessible COVID-19 instruction documents are used for a test run and are uploaded to the IPFS and hashes updated to the lot smart contract are retrieved successfully. Table II shows the IPFS Content IDs of the uploaded documents.

1) Security Analysis: Security analysis is performed on the proposed PharmaChain 3.0 to check the feasibility and adaptability of the system in real-world pharmaceutical supply chains.

Threat 1: Counterfeit Drugs introduced into the supply chain by a malicious entity

TABLE I
TEST ACCOUNTS AND ASSIGNED ROLES IN IMPLEMENTED PHARMACHAIN 3.0

Externally Owned Address	Role Assigned
0xc7Ad775244bbd65E433e6 AE170AF5D43757dDF2C	Manufacturer
0xf27BA403Fc1512C633605 349445334325d58F2A2	Distributor
0x69526EC0A74e93CA0fDaC 03aa4195EDfad8d5a48	Retailer

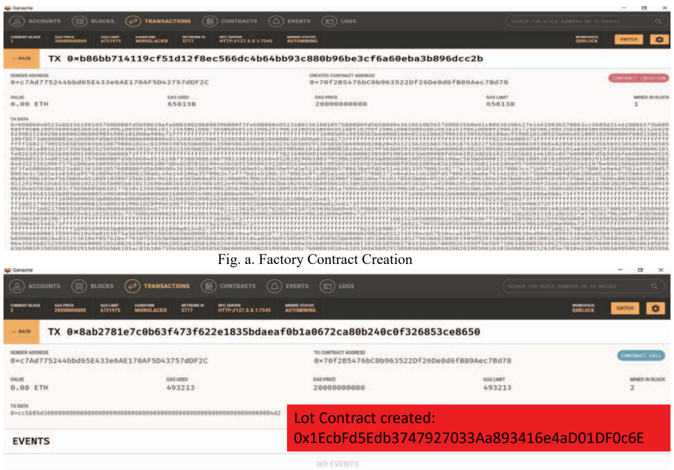

Fig. a. Factory Contract Creation

Fig. b. New Lot Contract Creation Transaction

Fig. 5. Lot Contract Factory Smart Contract Deployment and New Lot Creation Transaction

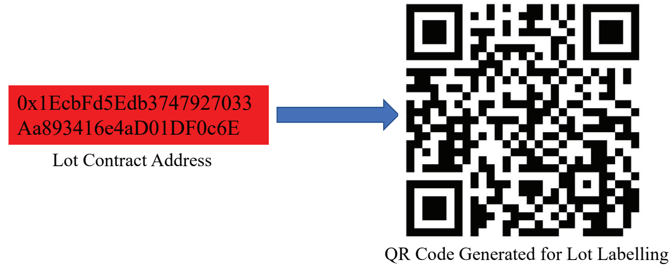

Fig. 6. New Lot Contract Address Converted to QR Code for Labeling

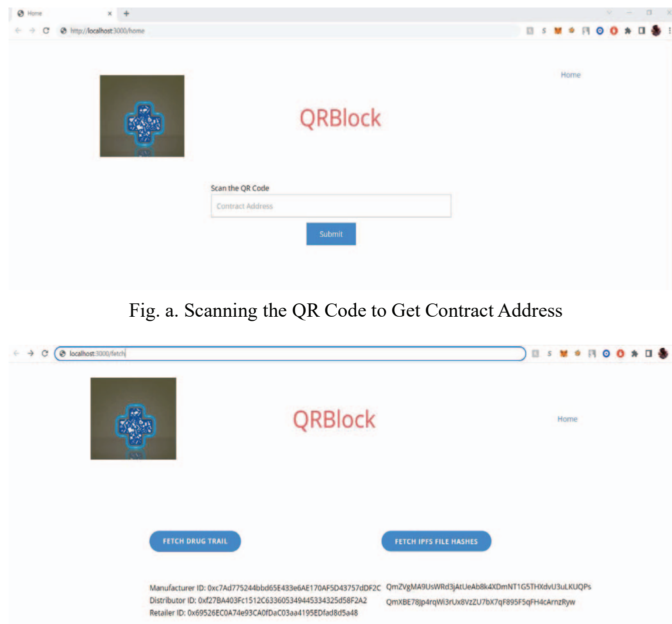

Fig. a. Scanning the QR Code to Get Contract Address

Fig. b. Fetching Drug Trail and IPFS Hashes

Fig. 7. Verifying the Drug Trail and Retrieving IPFS Hashes

Solution: Each transaction generated in the proposed PharmaChain 3.0 has to be signed by the private key of the entity before sending it to the blockchain. RBAC mechanism implemented in the proposed PharmaChain 3.0 also ensures only the entities with assigned privileges will be able to perform the smart contract calls, hence discarding the malicious transactions. Along with these, distributed ledger in the blockchain will make it easy to find the fake data introduced and eliminate the counterfeits.

Threat 2: Data Integrity Attacks to manipulate data within the network

Solution: Proposed PharmaChain 3.0 makes use of distributed shared ledger, each entity node participating in the network will have its own copy of the ledger, and any modifications done by any of the malicious entities or the attacker will corrupt the entire chain. Hence, the immutability feature of the blockchain helps in maintaining the data integrity.

2) Timing and Cost Analysis: To perform timing and cost analysis, each smart contract interaction is performed 10 times and average of the gas cost and time taken to include transaction in block is considered. The results from the analysis can be seen in Figure 8 for transaction times and Figure 9 for cost. From the timing analysis, average time taken is measured to be 16.8 sec which is acceptable in pharmaceutical supply chain tracking and tracing compared to current ERP systems. From the cost analysis it can be seen, average cost is measured to be 0.86$ which will be a little overhead on the cost but both timing and cost can be improved by adapting a private blockchain with nodes managed by the entities participating the network instead of using public blockchain as there will be no miner fee and other transactions blocking the network bandwidth.

3) Comparative Analysis for Proposed PharmaChain 3.0: A comparative analysis is performed between the proposed PharmaChain 3.0 and some of the models proposed in related research articles. Comparative analysis is shown in Table III, comparing to other proposed models current solution PharmaChain 3.0 considers easy integration of QR Code with blockchain technology and also investigates usage of distributed storage system IPFS for storing and accessing large amount of drug related information. Both track and trace along with drug related information can be accessed through the same QR code ensuring counterfeit-free and safe drug reaching consumer.

VII. CONCLUSION AND FUTURE RESEARCH

This paper presents a novel solution to use the Blockchain Enabled QR Code mechanism for efficient track and trace along with providing the drug information to the consumer. This ensures the right medicines reach the consumer instead of counterfeits and increase consumer confidence. Proposed PharmaChain 3.0 also provides a novel idea of embedding the smart contract addresses as the QR codes which will increase the accessibility of the tamper-proof information provided by the single source of truth from the blockchain ledger. Proposed PharmaChain 3.0 also addresses the issue of uploading large data drug information files onto the blockchain by introducing an IPFS distributed storage system. An efficient Role Based Access Control Mechanism is also implemented to avoid unintended updates to the drug lot by other entities in the network. A proof of concept is implemented and tested for functionality along with evaluating the

TABLE II
UPLOADED FILE AND IPFS HASHES IN IMPLEMENTED PROTOTYPE OF PHARMACHAIN 3.0

File Name	Content ID
Clinical Guidance Summary	QmZVgMA9UsWRd3jAtUeAb8k4XDmNT1G5THXdvU3uLKUQPs
Summary interim clinical considerations	QmXBE78Jp4rqWi3rUx8VzZU7bX7qF895F5qFH4cArnzRyw

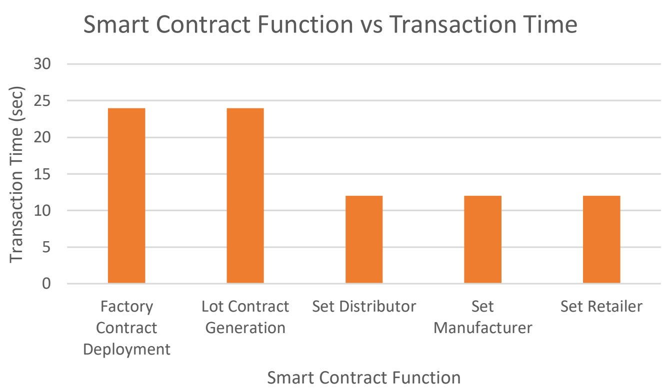

Fig. 8. Smart Contract Function Transaction Times in Implemented Pharma-Chain 3.0

built prototype for security, adaptability and reliability. Results from the analysis have shown that the proposed PharmaChain 3.0 is a feasible solution for efficient Blockchain Integrated QR Code labeling to increase the efficiency of the pharmaceutical supply chain and ensure counterfeit-free drugs in the supply chain. In future work, a mechanism to avoid the duplication of the QRCodes will be included and make the GUI more user-friendly.

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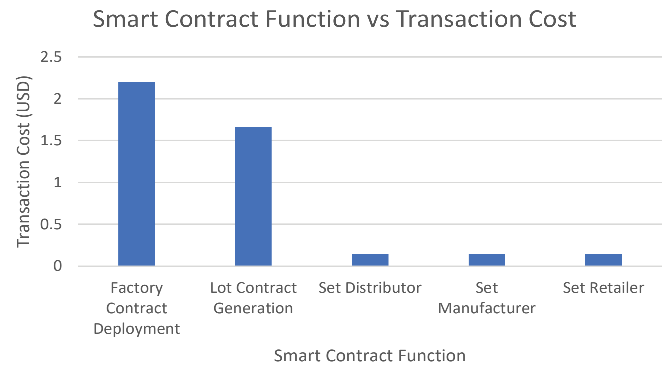

Fig. 9. Smart Contract Function Transaction Costs in Implemented Pharma-Chain 3.0

TABLE III
COMPARISON OF PROPOSED PHARMACHAIN 3.0 WITH EXISTING SOLUTIONS

Parameter	Crypto Cargo [11]	Pharma Chain [12]	Kumar et.al. [9]	Current Solution(Pharma Chain 3.0)
Blockchain	Ethereum	Ethereum	NA	Ethereum
Consensus Mechanism	Proof of Work (PoW)	Proof of Authority (PoA)	NA	Proof of Stake (PoS)
Less computational needs	No	Yes	NA	Yes
Openness	Public	Private	NA	Private
QR Code Integrated	No	No	Yes	Yes
Storage	On-chain and cloud	On-chain and cloud	On-chain	On-chain and off-chain
Handling large data	No	No	No	Yes

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