INTI JOURNAL | eISSN:2600-7320
Vol.2019:35

Implementation of Pharmaceutical Drug Traceability Using Blockchain Technology

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Abstract

The healthcare industry relies heavily on the use of pharmaceutical drugs to treat patients, and acquires said drugs using supply chain management. However, fraud and abuse cases in current healthcare industry are a major problem, costing the industry billions of dollars annually. Furthermore, counterfeit drugs also plague the healthcare industry, which is a major health concern to patients who consume said drugs. To solve these problems, a system is required to trace pharmaceutical drugs as they travel the supply chain, from the provider of the ingredients to produce pharmaceutical drugs, to its consumers. The proposed project will implement blockchain, an emerging technology that enables decentralized storage of data and immutable data. Blockchain stores data in a distributed ledger visible to all participants, which will create transparency in the supply chain, a much-needed change, which are presently very complex and opaque. Blockchain records the transaction details of relevant participants involved in the supply chain process as pharmaceutical drugs move through the supply chain.

Keywords

Supply chain management, pharmaceutical drug, blockchain, traceability

Introduction

Pharmaceutical drugs have been and still are one of the most important components in the healthcare industry used by doctors to diagnose, treat, prevent, and even cure diseases and save human lives (Briggers, 2018). These drugs are designed to combat different types of sicknesses in the human body, ranging from killing or halting the spread of germs in the human body, fighting bacterial infections, to replacing certain chemicals that the human body is unable to produce sufficient amounts without external help of pharmaceutical drugs (Hilmas, 2018).

The factors needed to ensure the effectiveness of these pharmaceutical drugs are the two types of ingredients inside it, which are active ingredients and excipients. Active ingredients are components in a drug that produces a direct effect on the human body to treat symptoms while

International Conference on Innovation and Technopreneurship 2019
Submission: 1 June 2019; Acceptance: 20 June 2019

excipients are other chemically inactive substances used to assist active ingredients in delivering the drug into the human body (Stone, 2019). According to the WHO (World Health Organization), counterfeit drugs are defined as ones whose active ingredients have been replaced with wrong ingredients, does not have any active ingredients, or contains an insufficient amount of active ingredients (Who.int, 2009). This causes the drugs to work differently than expected, or not at all, making it harmful to patients.

Counterfeit pharmaceutical drugs circulate the healthcare industry globally and affects even developed countries, though it is most prominent in developing countries. The problem is relative to how tight the country's legal controls are. In developed countries such as the United States and Europe, WHO estimates that less than one percent of pharmaceutical drugs sold, are counterfeits. However, in developing countries, experts say up to ten percent of pharmaceutical drugs sold are counterfeits (Barrett, 2018).

Counterfeit pharmaceutical drugs take a heavy toll on human lives. According to WHO estimates, counterfeit drugs kill one million people annually (Who.int, 2010). One such example from the year 2008 is the case of contaminated heparin from China which ended up circulating in eleven countries and resulted in eighty-one deaths in the United States alone (Harris, 2008). Another example is from the year 2012 in which the Food and Drug Administration (FDA) discovered counterfeit versions of Avastin, a drug used to treat cancer, contained no active ingredients and was circulating in the United States' drug supply chain (Kuehn, 2013). More recently, there were unapproved pharmaceutical ingredients in dietary supplements (Tucket et al., 2018).

Counterfeit drugs enter supply chains in the healthcare industry through several ways. Firstly, global healthcare supply chains mean that different ingredients that make up a pharmaceutical drug come from various parts of the world, therefore increasing the complexity of the supply chain and making it harder for healthcare institutions to trace the origin of the drug's ingredients. Active and inactive ingredients that make up a drug might originate from suppliers situated in different countries other than the one that distributes the drug (Lazarus, 2018). For example, most pharmaceutical drugs in the United States are made with active ingredients that come from other countries such as China and India (Roberts, 2010). Secondly, the current supply chain is opaque, where processes happening in the supply chain is not visible to all participants in the supply chain. This allows unethical participants in the supply chain to tamper, corrupt, or substitute drugs as they travel the supply chain without the knowledge of other participants (Tampol, 2016).

As such, there is a need to have a system to track the pharmaceutical drugs from manufacturing to supplying, in the supply chain. Therefore, to ensure traceability in supply chain process, the authors have studied how to trace pharmaceutical drugs in a supply chain system using blockchain technology. The authors conducted testing to ensure the effectiveness and traceability of the newly designed supply chain system.

Methodology

To identify the needs and requirement of this system, the authors gathered data via questionnaire and interview. 54 respondents participated in the questionnaire using Google Form, a majority of the respondents were between the ages of 18-24 years old and are currently studying. A little more than half of the respondents were men while the rest were women. For the interview, one doctor and one pharmacist gave their responses.

Based on the responses from the respondents, the authors identified functional and non-functional requirements of the system. The functional requirements identified were search function, enter, store and display drug details. Drug details include ingredients used, origin of location, manufacturing environment and conditions, and companies involved. There is a need to enable different users to control different features of the system using their own accounts. Ultimately, the stored information needs to be secure and unaltered using Blockchain technology.

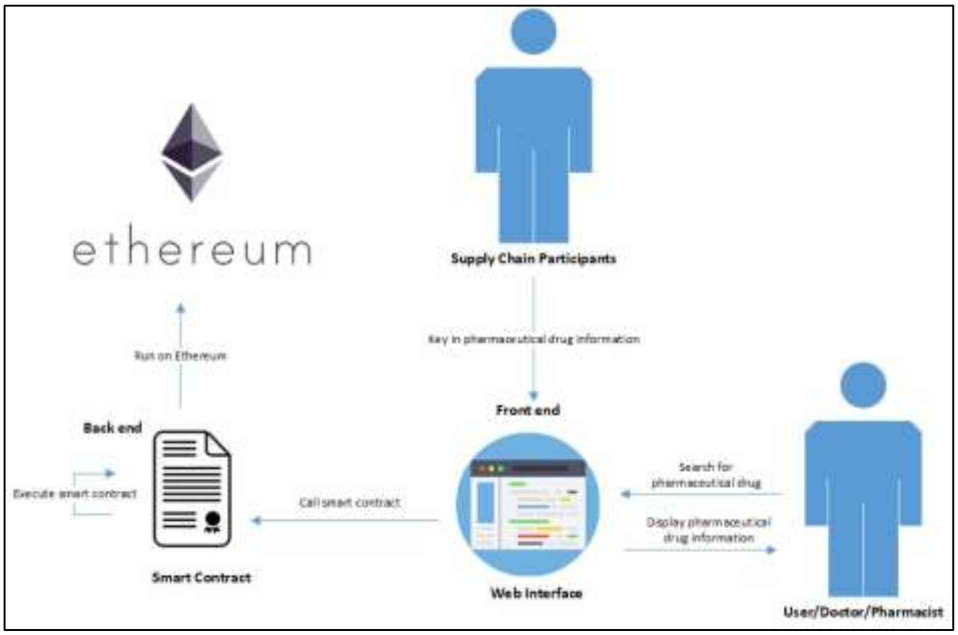

Figure 1. Architectural design of blockchain for pharmaceutical drug

Figure 1 shows the architectural design applied in the proposed system. The Blockchain uses Smart Contract to make the necessary transactions and the Blockchain runs on Etherium. A smart contract is a special account or code consisting of functions and data that usually provides application binary interfaces (ABIs) that can be executed by sending a transaction from an account or a message from another contract (Zhang, 2018). There is a website created for supply chain participants that include supplier, manufacturer and wholesaler. These participants need to login to add on details. However, any user including doctors and pharmacists could view details of the drug, without logging in.

All coding done throughout this project uses HTML, Bootstrap, JavaScript, and Solidity, and Visual Studio as its IDE (Integrated Development Environment). Firstly, the application checks on the installation of MetaMask. MetaMask allows running of Ethereum dApps in a browser. Without MetaMask, users would have to run a full Ethereum node. Before a supply chain participant can access the web page to key in details of a particular pharmaceutical drug, they have to sign in to their MetaMask account. Therefore, the application should ensure that the participant's web browser has the MetaMask extension installed. Before participants have access to the application's functions, they first have to sign in to their account. Consequently, when the participant accesses the page to key in information, the application will prompt a MetaMask account login window for them to sign in to their account.

For the supply chain participants, the application will check the MetaMask account. The smart contract is programmed with set account IDs for specific roles such as supplier, manufacturer and wholesaler. Therefore, based on the account IDs set in the smart contract for specific roles, the application will identify the participants, and grant access for specific tasks to specific participants.

For the application to function, the MetaMask and the smart contract must be on the same network. To ensure the user is on the correct blockchain network, the web application will check the network that MetaMask is currently on, and if it does not match the correct network, it will prompt the user to switch networks.

When the user enters the drug ID of a pharmaceutical drug, the application will first check whether the drug ID exists on the blockchain. If it does, all information about the drug ID entered previously by the supply chain participants is retrieved from the blockchain and then displayed in the web application. It not, the user will be notified that the drug ID entered does not exist.
When generating a new ingredient bulk, drug batch, or individual drug, the participant will specify the number of items to generate. The amount to be generated is obtained using JavaScript and the IDs will be generated using a *for-loop* which loops the number of times as specified. In the loop, there will be a *do-while* loop to check if the ingredient bulk ID generated matches with any of the bulk IDs already stored in the blockchain. If there is, a new ID is generated. This is to prevent any duplicate IDs from being stored. A MetaMask transaction confirmation window will then pop up for the user to confirm this transaction. Once the transaction is confirmed the smart contract will run the function to store the array of generated IDs into the blockchain, otherwise the transaction is rejected and nothing happens.

When a supply chain participant wants to transfer ingredient bulks or individual drugs, a table with the list of IDs that have been received but not been transferred will be retrieved from the blockchain and presented based on the 'isMoved' and 'isReceived' Boolean values of the particular ID.

To transfer any ingredient bulk or individual drug, the supply chain participant will select the IDs to transfer from the table displaying all available IDs. Upon clicking the button to transfer, the IDs will be stored into an array in JavaScript and passed to the smart contract to change each

Boolean value of the ID's 'isMoved' to true. The application will then refresh the webpage to show only IDs of items whose 'isMoved' value is still false.

When a supply chain participant wants to view the ingredient bulk IDs or individual drug IDs transferred to them and acknowledge to the sender that they have received the particular items, a table with a list of transferred IDs will be displayed after being retrieved from the blockchain through the smart contract.

To acknowledge receiving an ingredient bulk or individual drug, the supply chain participant will choose the items by ticking them in the checkboxes associated with the IDs, presented in a table. The selected IDs will be stored into an array and passed to the smart contract to run and mark the 'isReceived' Boolean value as true. The webpage when refreshed reflects the changes accordingly.

When the account in MetaMask is changed to a different account, the application detects the change as it constantly checks the current account at different time intervals, and if the current account no longer matches the account ID that was retrieved and stored in a temporary variable, the web application will refresh and store the updated account ID.
Consequently, each change made is stored in the blockchain. Deleting or editing data is not possible. Instead, to make any changes, only appending data is possible. This supports transparency to enable users to trace back the origin of a drug, and to check if there were any alterations made.

Results and Discussion

The application was tested and it showed greater transparency in identifying the supplier, manufacturer or wholesaler of a specific drug. The use of blockchain enhances the security of drug information and inadvertently combats counterfeit drugs. This improvement is by the traceability provided by blockchain technology.

Pharmaceutical drug consumers now have a means to trace the supply chain information of pharmaceutical drugs that they consume or purchase, and can rest easy knowing that the pharmaceutical drugs are authentic as they know the drug information are unaltered and accurate. However, one feature of blockchain is that a participant cannot delete data. This means that there is no room for errors. Other than that, there are monetary costs to write data to blockchain. Testing of the current system was only on local host. Therefore, the deployment of such a system on an actual server needs further investigation.

Conclusion

The developed system is functional and meets the project objectives. Even so, there is room for improvement for its features and functions. The developed system needs real time deployment and testing.

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