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Securing Controlled Drug Supply Chains: A Blockchain-Powered Approach for Transparency and Traceability

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Abstract: The advancement in tracking and tracing of controlled substances in today's world requires special attention, particularly concerning their utilization in patient care. Controlled substances, crucial for medical treatment, are vulnerable to many potential risks such as diversion, illicit distribution, illegal use, lack of transparency, and addiction. This possesses critical risks in the event of tracking and tracing of controlled substances. Due to the associated risks with the controlled substances, government has made law enforcement on the production, distribution, and use of these substances. Even with the government control, the current system for monitoring and tracing is susceptible to tampering and data manipulation because of the manual paperwork and human administered tasks. In response to these challenges, this research paper proposes a fresh perspective leveraging blockchain technology for enhanced and efficient tracking and tracing of controlled substances. With the integration of blockchain technology features such as immutable ledger and decentralization, the proposed system aims to provide a secure, transparent, end to end auditable, and efficient platform for recording the movement and provenance of controlled substances across their supply chain. QR code-based authentication provides easy handling of the drug unit throughout the supply chain. Additionally, a decentralized IPFS (Interplanetary File System) is used for storing the images generated throughout the supply chain of the drug unit.

Keywords: Controlled, Consensus, Decentralization, Ethereum, Immutable, IPFS, Ledger, QR code, Smart Contract, Transparency

1. Introduction

Healthcare systems and regulatory bodies across the world have significant obstacles in managing and regulating restricted drugs effectively. Drugs classified as controlled are those that are governed by stringent regulations due to their potential for wrong use, addiction, and associated public health risks. These include stimulants like amphetamines, depressants like cannabis, opioids like methadone and morphine, and hallucinogens like ayahuasca. To mitigate the harmful impacts of wrong use and diversion, it is imperative to ensure the distribution in a secure manner, prescription, and use of these medications.

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According to National Institute of Health (NIH) United States data, over 10.5 million people across all ages have died between year 1999 to 2021 due to overdose involving drugs, including both illicit substances and prescription opioids. Also, according to the UN, trafficking and other illegal drug-related activities present serious economic obstacles, especially in areas where natural resources for these drugs are abundant. Both regional and international economies are impacted by these activities which also contribute to economic instability, environmental damage, and corruption.

However, traditional methods of tracking and tracing controlled substances often suffer from inefficiencies, lack of transparency, and susceptibility to fraud. Centralized databases, manual paper-based ledgers, and fragmented systems contribute to challenges such as data manipulation, limited traceability, and regulatory non-
compliance. These shortcomings undermine the efforts of regulatory bodies to monitor and oversee the movement of controlled substances throughout the supply chain effectively. Also, in various parts of the world where natural resources for cultivation of controlled substances are available alongside limited state presence, many crime groups are involved in illicit production of these controlled substances. This is resulting in the financial and tax related crimes, which in turn affect the economy of that part of the world.

To address the issues identified, blockchain is the technology proposed in this paper. Blockchain provides an immutable ledger that is tamper-proof. To make any changes to the data stored on blockchain more than half of the actors should reach consensus, this ensures all actors have equal rights in the system. Equal distribution of authority points to one more feature of blockchain: decentralization. Additionally, blockchain also provides security and integrity through cryptographic encryption techniques. The blockchain system operates and automates according to the code written in the smart contract, once uploaded on the global blockchain network it is impossible to change the smart contract. For every data entry or modification, a transaction is performed within the system, these transactions can be traced easily, thus providing transparency, auditability, and accountability to all the stakeholders involved in the supply chain.

2. Literature Survey

In reference [1], the authors discuss the challenges faced by the pharmaceutical supply chain due to counterfeit medicines, and propose a system that utilizes a combination of IOT and blockchain. This system helps to track the transportation, prevent theft and contamination, and also provides information on contaminated and counterfeited drugs to validate their authenticity. The IoT (Internet of Things), is used to track the location of the drug lot during the supply chain operations. RFID (Radio Frequency Identification) tags are used on the packaging to detect tampering activities. If the RFID tag is broken, the responsible stakeholder is notified about the opening of the package. Additionally, the methodology uses blockchain for data logging, enhanced traceability, and minimized paperwork.

Strengths

1. The system enables continuous tracking of pharmaceutical items during the supply chain operations.
2. Blockchain's decentralized and immutable nature provides a high level of security, minimizing the issue of falsified medicines entering into the market. Each transaction recorded on the blockchain is tamper-proof, which increases trust.
3. As this method uses RFID technology, the responsible stakeholder will be easily notified if someone tries to dismantle or try counterfeiting the drugs.
4. Use of IOT allows real time monitoring and location tracking.
5. Temperature and humidity of drugs can also be monitored using IOT sensors.

Limitations

1. As these methodologies involve three technologies, IOT, Blockchain and RFID, it will be difficult to integrate all the three and make sure they work properly in relation to each other.
2. The adoption of IoT devices and blockchain technology may incur substantial upfront costs for pharmaceutical companies. This includes the expense of purchasing and deploying IoT sensors.
3. Resistance to adopting new technologies and processes within the pharmaceutical industry may hinder the widespread adoption of IoT-based solutions.
4. The pharmaceutical industry is subject to strict regulatory requirements governing the storage, handling, and distribution of drugs. Implementing IoT-based solutions must comply with regulatory standards.

The authors in literature [2] suggested the use of machine learning for categorizing medication movement transactions based on the risk of diversion. Two datasets were obtained from diverse health information technology systems by ten inpatient hospitals specializing in acute care spread across four distinct health systems. These data collections underwent processes such as consolidation, normalization, classification, and sampling to create an integrated data collection suitable for analytics. Iterative application of supervised machine learning techniques was conducted on the initial data available to educate the algorithms for classifying medicine movement activities into high or low risk categories for diverting.

Strengths

1. The system is really good at identifying drug theft, with a success rate of 96.3%.
2. It can quickly spot cases of drug diversion, helping healthcare teams to act sooner.
3. Users found the system made their investigations quicker and more effective.

Limitations

1. If the information used to teach the system is not diverse enough, it might not work well in different situations.
2. There's a risk that the system might reflect existing biases in the data it was trained on, which could affect fairness, especially in healthcare settings.
3. Keeping the system up-to-date and working smoothly might be tricky, especially for smaller healthcare organizations. Regular updates and adjustments are needed.

3. Proposed System

The proposed system utilizes an Ethereum-based blockchain to record data generated throughout the entire supply chain of controlled drugs and substances. An actor represents the entity using the system, and participation is required for data logging, though tracking remains possible even if the actor is not formally part of the system. A unique QR code is generated for every drug unit manufactured, facilitating easy identification as needed. The "QR code API" serves as the free API for generating QR codes, and "instascan.js" is the library employed for scanning these codes. Image data generated is stored using the "Pinata" IPFS service, offering a decentralized storage solution for blockchain-based systems. Wherever state change occurs the geographic coordinates of that location are automatically logged into the system using the JavaScript geolocation API.

The system consists of five actors: the regulating authority, manufacturer, hospital, doctor, and nurse. The regulating authority is a government body which verifies the manufacturers and hospitals and incorporates them into the system using their Ethereum ID's. The system consists of five modules "Manufacturer," "Hospital," "Doctor," "Nurse," and "Tracking".

4. Working

Manufacturer:

1. After manufacturing, the manufacturer inputs drug details, including drug name, manufacturing date, expiry date, quantity, the hospital's ID for which the drug is manufactured, and the manufacturer's ID (retrieved automatically from the Ethereum wallet being used). All these details are then hashed using the SHA256 algorithm to create a unique ID for the drug unit. Subsequently, a QR code is generated using the unique ID, which can be downloaded for further use. Once the drug information is logged into the system, the state for that drug is set to 'Manufactured,' and the manufacturer affixes the QR code onto the drug unit.
2. As the drug unit becomes ready for dispatch the manufacturer should scan the QR code on the drug unit and change its state to "In-Transit".
3. Additionally, the manufacturer should upload the photographic proof of the drug unit which is ready for dispatch.

Hospital:

1. The hospital has the capability to add the doctor and nursing staff as actors to the system after verification.
2. On delivery of the drug unit to the hospital the hospital should scan the QR code and change the state to "Delivered".
3. Additionally, the hospital should upload the photographic proof of delivery to the system.

Doctor:

1. The doctor can prescribe drug to the patient by providing information such as patient name, age, gender, dose, doctor's ID (retrieved automatically from the Ethereum wallet being used) and, the drug ID (obtained by scanning the QR code). If enough drug quantity is available with the hospital the drug will be prescribed to the patient and the state for that particular unit will be changed to "Prescribed".

Nurse:

1. The nurse can scan the QR code on the drug unit and change the state to "Consumed" or "Disposed" based on the actual usage.
2. Additionally, the nurse should upload the photograph proof of the actual action performed into the system.

Tracking:

1. Tracking is possible at any stage of the supply chain. The actor can simply scan the QR code or manually enter the drug ID to retrieve drug information such as the current state, patient ID (if prescribed), manufacturer's ID, hospital's ID, doctor's ID, nurse's ID, drug name, quantity, manufacturing date, expiry date and prescribed dosage. The geographic coordinates of the location where a state change occurred can also be tracked.

5. Pseudocodes

Add a new actor

```
if (msg.sender == regulator)
    {
        if (actorType == "manufacturer")
        {
          if (manufacturer ID does not exist in the system)
          {
            Add new manufacturer's ID
          }
        }

        if (actorType == "hospital")
          {
            if (hospital ID does not exist in the system)
              {
                Add new hospital's ID
              }
          }
      }
if (msg.sender == hospital)
      {
        if (actorType == "doctor")
        {
    if (doctor ID does not exist in the list of the calling
        hospital)
    {
      Add the new doctor ID to that particular hospital's list
    }
  }
if(actorType == "nurse")
  {
    if (nurse ID does not exist in the list of the calling hospital)
    {
      Add the new nurse ID to that particular hospital's list
    }
  }
}
```

Add a new drug

```
if (msg.sender == manufacturer)
{
    1. Input: manufacturerID, drugName, MFG.date, EXP.date,
       quantity, hospitalID.
```

```
        2. Concatenate all values to a string.
        3. Hash the string to create a unique ID for the drug unit.
        4. Add the new drug ID to the system.
        5. Send the hashed string to the QR code generator API.
        6. Download the QR code received.
}
```

Upload image

```
1. Scan the QR code to obtain drugID.
2. Take the image as input.
3. Upload the image to "Pinata" IPFS storage.
4. Receive the unique access key for that image from "Pinata".

   if (msg.sender == manufacturer)
     {
imgList[drugID].manuImage=access-key;
     }
   if (msg.sender == hospital)
     {
imgList[drugID].deliveredImage=access-key;
     }

   if (msg.sender == nurse)
     {
imgList[drugID].finalImage=access-key;
     }
```

Add patient

```
 if (msg.sender == doctor)
      {
            1.Input: patientName, patientAge, gender, drugDose.

            2. Scan the QR code to obtain drugID.

            3.Concatenate the input data along with the doctor's ID and drugID into a string.

        if (required quantity <= available quantity)
        {
            4. Hash the string using SHA256 to create a unique patient ID.

            5. Add the patient to the system.

            6. The drug state will change to "prescribed" so log the coordinates using geolocation API.

        }
     else{
          Show error "Desired quantity not available"
        }
  }
```

Update drug state

```
1. Scan QR code to obtain drugID.
       if (drugID exists)
       {
           if (msg.sender == manufacturer && state == "Manufactured")
           {
               Update state to "In-transit" and log the coordinates
           }

           if (msg.sender == hospital && state == "In-transit" &&msg.sender's ID matches with the hospital ID assigned to the drug)
           {
               Update state to "Delivered", update the hospital inventory, and log the coordinates
           }

           if (msg.sender == nurse && state == "Delivered")
           {
               if (Drug is used)
                   {
                       Update state to "Consumed" and log the coordinates
                   }

       if (Drug expires before use)
           {
               Update state to "Disposed" and log the coordinates
           }
     }
           }
else{
        Show error "DrugID not found"
       }
```

Tracking

```
1. Scan QR code to obtain drugID.

     if(drugID exists)
      {
         2. Retrieve images corresponding with the drugID from the IPFS.
         3. Output: current status, patientID, drugName, manufacturer's ID, hospital's ID, doctor's ID, nurse's ID, MFG. date, EXP. date, quantity supplied, quantity used, geographic coordinates of every location where state change occurred, the images associated with the drug unit.
      }
```

6. Proposed System Architecture

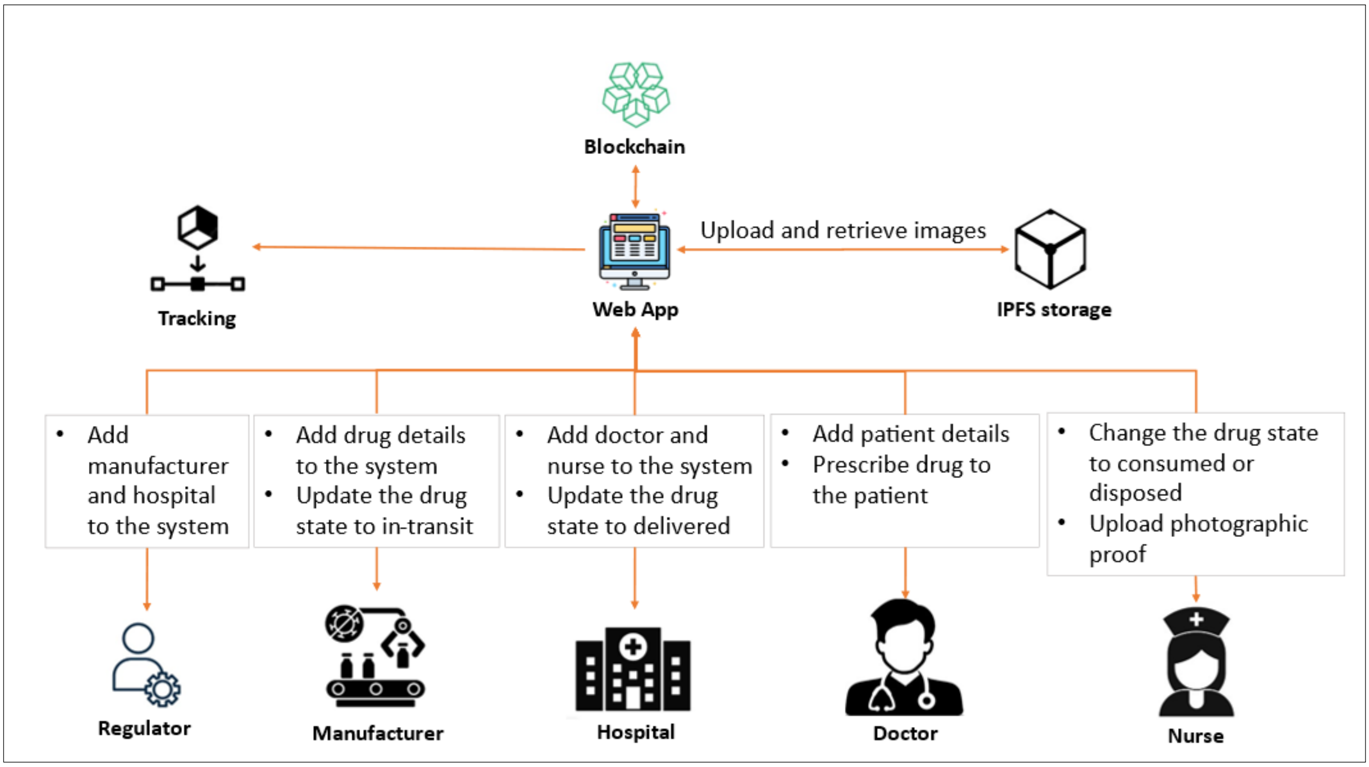

Fig. 1. System Architecture

7. Dashboard Screenshots

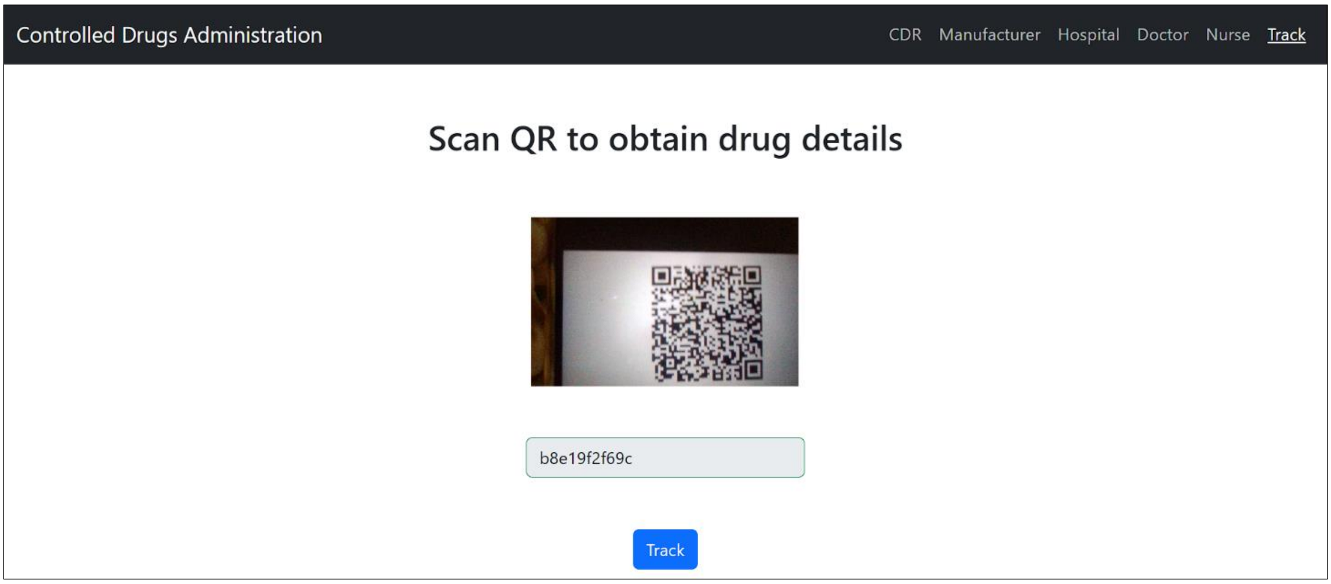

Fig. 2. Scanning the QR code to track the drug unit

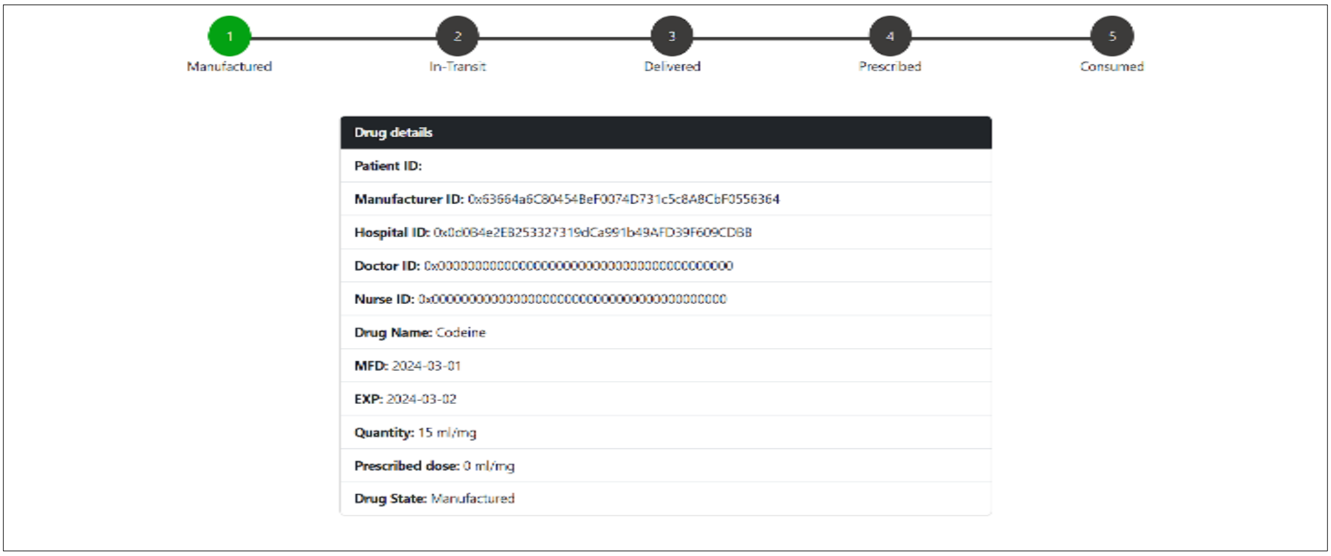

Fig. 3. Drug unit in "Manufactured" state

Fig. 4. The latitude and longitude at each state

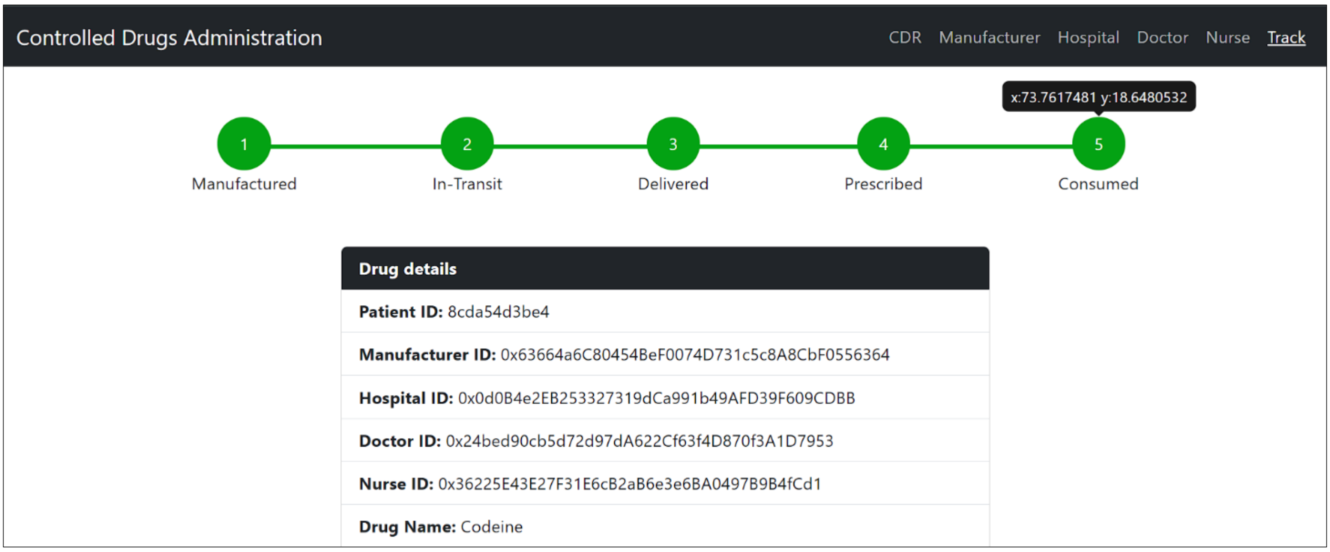

Fig. 5. Drug was prescribed to a patient and consumed

Fig. 6. Images available for drug unit were retrieved from IPFS and displayed on the dashboard

8. Issues addressed by the proposed system

- **Human error and fraud:** The pen-paper [14] based methods and digital methods where humans are involved for data entry are suspectable to errors and frauds, the proposed system uses smart-contracts that automate the critical data logging activities.
- **Misuse of authoritative power in centralized systems:** The proposed system is completely decentralized; every actor has similar authoritative power. Domination by a single entity is not possible.
- **Single point of failure:** Centralized systems often use a single server for operations and storage. If the server fails the complete system has to face down time. Whereas, the proposed system is distributed across all the nodes who are part of the system. The system continues to operate even in case of node failures.
- **Cost effectiveness, integration and, migration:** Systems which use technologies such as machine learning, IOT, etc. are difficult to integrate with the current healthcare supply chains, require high expertise, and heavy infrastructure investments. However, adapting blockchain does not require high quality infrastructure, the blockchain already exists, the users just need to write the smart contract for their use case and host it on the network that is readily available. The new generation of web, that is "web3.0" is based on the concept of blockchain and decentralization, the migration is already happening, so migration is not an issue either.
- **Transparency and accountability:** No technology can provide the level of transparency that blockchain does. Every operation that modifies data requires gas/fees in the form of money (Ethers for Ethereum). Each transaction is recorded on the ledger and cannot be hidden. This increases accountability.
- **Security and data integrity:** The proposed system uses cryptographic encryptions to maintain data integrity. Robust logic is implemented in the smart contract for authorization and authentication of users.

9. Conclusion

Robust administration of controlled substances is one of the major issues in the society due the risks such as addiction and misuse. Currently, traditional paper-based ledgers and centralized storage systems are utilized for administration of such substances. These systems are prone to human error, fraud, and unreliability. The system proposed, utilizing blockchain technology offers features like immutability, decentralization, transparency, auditability and, accountability for the administration of controlled substances. The proposed system also has potential applications in other domains where a chain of events is present, and a lot of data is generated, such as tracking government documents, and managing the diamond supply chain, etc.

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