

A Comprehensive Blockchain Framework for (COVID-19)Vaccine Program Registration, Supply Chain and Side Effects

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Abstract— The history of mankind witnessed a lot of pandemics throughout its years. Many of which caused fatalities and created severe consequences socially and economically. The latest example is the COVID-19 pandemic that got the world into a heated race to contain by developing immunization vaccines. Many of the vaccines came into production in record time which raises questions about their side effects. Also, since vaccines are sensitive medical products, they require continuous cold supply chain monitoring and tracking. It is clear how vital it is to link any occurring side effects to their causes to determine whether it is a manufacturing problem or a supply chain management issue. Additionally, and to properly establish this link, an effective beneficiaries' registration process is required. Therefore, it is necessary to establish a comprehensive system that combines vaccines cold supply chain management solution with side-effects follow-up data and individuals registration records. To achieve these goals, the technology of blockchain was selected to develop a framework for the vaccines program. Blockchain is known as the architecture behind cryptocurrencies, however, it proved its reliability and effectiveness in different use cases. Blockchain special characteristics were the reason behind adopting it to establish a blockchain-based platform for vaccines cold supply chain associated with traceable side-effects information records combined with beneficiaries registration data. The connection between the three parts of our system framework is important to achieving the utmost benefits out of the vaccine program in terms of compliance with standard measures and its link to side-effects and beneficiaries metadata.

Keywords—COVID-19, vaccine, blockchain, smart contract, cold supply chain, side effects

I. INTRODUCTION

Coronavirus SARS-CoV-2 is a type of virus that was identified in 2019 and caused a global pandemic called COVID-19. It took the lives of millions of people around the world as well as caused lasting health issues in some who have survived the illness. Its infectious nature resulted in a rapid spread within communities. Globally, as of the 25th of March 2022, there have been 476,374,234 confirmed cases of COVID-19, including 6,108,976 deaths [1]. This put a huge burden on health systems in all countries nevertheless created economic and social crises with deep and persisting impacts. Its sudden origination and spread took the world by surprise and the efforts to contain it were massive. A heated race between pharmaceutical companies supported by some governments and pressured by public demand started to produce immunization vaccines [2]. The concentrated efforts resulted in several COVID-19 vaccines which have been authorized for emergency use by WHO and most governments were as of the 17th of March 2022, a total of 10,925,055,390 vaccine doses have been globally administered [1].

Vaccination programs are in progress in most countries around the world, however, multiple aspects should be considered by governments and health authorities to guarantee the success of the COVID-19 vaccination schemes. Firstly, as vaccines have special and critical requirements in terms of storage temperature, operational procedures during administration and validity among other aspects, a trusted and transparent end-to-end cold supply chain system is required to ensure proper vaccine stock distribution and storage management following strict temperature control [3, 4]. Temperature monitoring during the whole cold supply chain including chemical raw material supplying, production process, vaccine storage, distribution and transportation is a real challenge that requires proper solution since any temperature fluctuation above or below the recommended thresholds set by the World Health Organization might render vaccines usability [5]. Secondly, the record speed at which the vaccines were developed created concerns among the public and health practitioners about vaccines' probable undesirable side effects and their causes. These side effects if were of concerning figures and nature might slow down or even cease vaccination of a certain type. It is important to associate any side effect with its source whether it is a manufacturing issue or a supply chain mishandling. Furthermore, and in order to be able to properly link witnessed side effects with individuals and as vaccines are usually administered to a huge number of beneficiaries, a well-organized registration process is required. Based on the above discussion, it is vital to develop a comprehensive system that provides an efficient solution to combine and manage vaccines cold supply chain, potential side-effects information and beneficiaries' health records.

To achieve the above goal, a powerful and reliable technology should be used to establish such a solution. The revolutionary blockchain technology is adopted in this research due to its characteristics of decentralization, security, transparency, automation, traceability, privacy, reliability and robustness [6, 7]. Blockchain is proposed to establish a platform for vaccines cold supply chain that is connected to a traceable side-effects information mechanism combined with reliable registration records. Establishing information sharing and data connection between the three elements of the intended solution is extremely important to harvest the maximum possible benefits from the vaccine program by ensuring vaccines safety and compliance with standard measures as well as linking any symptoms with individuals' metadata to provide a better insight on the cause and whether it is related to distribution conditions or manufacturing issues. Our proposed blockchain framework shall support automated operations using smart contracts. Also, the cold supply chain smart contract monitoring and tracking operations will be fulfilled through integration with temperature sensors via

blockchain oracles to ensure captured temperature data authenticity.

It is noted that the researches in the field of adopting blockchain in dealing with COVID-19 implications and the immunization vaccines are in the early stages due to the sudden and recent spread of the pandemic on one hand and the record time in which the vaccines were developed on the other. Thus, there is a wide area for new ideas and researches in this field.

The implementation of this research will contribute to the body of knowledge in the following ways:

- Provide secured, tamper-proof, authenticated, transparent yet private personal and health records of vaccinated individuals.
- Support an automated, immutable, authenticated registration service for new individuals who want to get the vaccine.
- Provide a transparent, traceable, authenticated and secured vaccines cold supply chain management platform where temperature and expiry date among other safety parameters are monitored and tracked.
- Provide an authenticated reporting system for health and safety violations during any stage of the vaccine's cold supply chain.
- Support a secured, authenticated vaccine side-effect database to exchange expertise about the vaccine's effectiveness and deal with any spreading symptoms.

Our work is important since the COVID-19 pandemic is far from being over with new variants continuously appearing in different places around the world. This implies that the vaccination programs will not only continue and expand but rather become part of the basic vaccination requirements in healthcare systems. Also, our solution is not only applicable to the COVID-19 vaccines but rather to any vaccine program since efficient individuals registration, vaccine monitoring, tracking, as well as vaccine side effect follow-up are necessary to achieve the desired health protection and benefits.

The rest of this paper is organized as follows: Section II demonstrates blockchain features and applications while Section III reviews the literature for researches adopting blockchain in addressing COVID-19 issues. Section IV proposes our solution framework for a comprehensive COVID-19 vaccine program platform. Section V and finally the conclusion provided in section VI.

II. BLOCKCHAIN CHARACTERISTICS AND IMPLEMENTATIONS

Blockchain is an emerging technology that is considered one of the hottest and most intriguing ones in the global business and science seen nowadays [8]. It is well known as the technology behind cryptocurrencies such as Bitcoin which is increasingly gaining confidence in worldwide economies. Today, Bitcoin and other cryptocurrencies are accepted as a form of payment by many businesses [9]. However, blockchain goes far beyond establishing the infrastructure of the cryptocurrency market. It is identified by governments, global organizations and investors to reshape many industries and disrupt different economic sectors [8]. It is anticipated that blockchain will challenge the way technology serves society and economy as well as open the door for new value creation for human civilization [10].

Blockchain is a secured platform for storing and verifying information in a decentralized and permanent matter [11]. Once a data transaction is added to the blockchain, it cannot be altered, making blockchain an immutable record of previous activities [12]. Transactions in a blockchain do not have to contain only financial records of cryptocurrency transfer of ownership but they rather may include data about anything that can be digitally represented and this is where the power of blockchain lies. It could be implemented in unlimited fields other than cryptocurrency with the same level of efficiency, reliability and distinguishing features of decentralization, elimination of third parties, and the ability to support irreversible transactions [13]. Presently, blockchain is successfully implemented in many areas such as digital identity, real estate, voting, insurance [11], healthcare, distributed cloud storage, Internet of Things [14, 15], finance and banking, digital assets management [16], logistics [17] and others. Moreover, blockchain has been implemented in sustainability, climate change to build carbon emission trading automated systems such as in the researches by [18, 19].

Additionally, blockchain is the enabler of smart contracts which are the digital representation of real-world contracts. Smart contracts add a customization layer to the basic blockchain network in the form of binding enforceable agreements between entities [20]. Smart contracts are capable of handling beneficiaries' registration process, cold supply chain management activities, and storing and sharing vaccines' reported side effects, all without intermediaries or third parties. They also provide the security needed for personal and operational data in a superior manner to traditional systems [21].

The next section surveys the literature for articles related to our research topic.

III. LITERATURE REVIEW

One of blockchain's main implementation field that is related to our research is supply chain. Blockchain is used to track products' origin and distribution flow and exchange information needed to manage the supply chain [22]. Generally, tracking and monitoring products in any supply chain are achieved using different purpose sensors such as moisture, movement, temperature, sound, optical, chemical/gas where the information gets collected and exchanged. The existing method for sensors data exchange is through the internet in what is called the Internet of Things (IoT) technology [22]. However, with the emergence of blockchain and its implementation in the field of supply chain, the connection to sensing devices is evolved to a different level where IoT devices are integrated with smart contracts to inject the data readings into the supply chain management blockchain-based platform as proposed by [23]. Good insight and analysis on the potential of blockchain solutions in making supply chain transparent and traceable were provided by [24]. Researchers outlined how IoT and smart contracts support such solutions, especially for cold chain scenarios. Practically, multiple researchers applied blockchain in supply chain such as the study by [25] which implemented blockchain precisely in the agricultural supply chain where blockchain smart contract was developed and integrated with IoT to efficiently and securely monitor shipments providing trusted and transparent information. Also, [26] suggested a blockchain-based system to authenticate the origin and of food items. The proposed platform is suitable to manage cold

supply chain where IoT devices provide food data such as storage temperature, environment humidity, and GPS data.

Surveying the literature, a limited number of studies were found related to the COVID-19 pandemic where most of them are of theoretical and conceptual basis such as the study by [27] which gauged the applicability of blockchain as an enabling technology to combat COVID-19 and identified potential use cases. Also, a review paper by [28] investigated blockchain usage in supporting health actions to limit the spread of COVID-19, especially in the area of contact tracing and vaccine passports. A further step into structural design, a research by [29] discussed the adoption of blockchain for combating COVID-19 and presented three blockchain-based systems to address health issues caused by the disease such as contact tracing, medical supplies handling, immunity passport, logistic monitoring of vaccines and identity management. However, the research only proposed systems designs and did not develop any practical smart contracts. Also, patients' and healthcare providers' identity management using blockchain was tackled by another research by [30] to provide authenticated, transparent and secured sharing of information across eHealth domains. Furthermore, another article by [31] tackled COVID-19 health records data sharing and privacy by proposing a blockchain-based zero-knowledge proof (BZKP) model utilizing IoT. The design supports patients' privacy and ensures their consent on health data sharing while maintaining the required availability.

Looking at practical and smart contract development researches, a paper by [32] concentrated on improving the efficiency, security and privacy of Electronic Health Records (EHR) sharing systems by developing a permissioned Blockchain and smart contract using Hyperledger Besu. Another research by [33] integrated complex event processing with blockchain creating a system called CEPchain. The research goal was to simplify blockchain functionality by hiding implementation details and supporting efficient smart contract deployment. The authors used vaccine delivery in cold chain as an evaluation case study which showed a successful deployment of a smart contract without requiring experts on event processing and smart contract languages. However, the research model assumed one pharmaceutical company, one distributor and one hospital which is not comprehensive. Also, it only considered temperature monitoring without including other health and safety factors such as lots validity. Furthermore, it did not cover the vaccines beneficiaries' registration process or the side effects information records of taking the vaccine.

Another study by [34] developed a "vaccine blockchain" system combining blockchain and machine learning technologies to support vaccine traceability and handle vaccine expiration and record fraud. The use of machine learning was to provide recommendations to practitioners and recipients in order to choose better vaccines. However, neither temperature monitoring and cold supply chain management were tackled in the research nor vaccines beneficiaries registration and side effects.

Only a few researches of interest that address COVID-19 vaccines cold supply chain were found in the literature such as the one conducted by [35]. The authors developed a blockchain-based solution for managing vaccines' distribution and delivery using smart contracts. However, the research did not propose authentication methods for integrating temperature sensors with smart contracts and

injecting readings. Also, the research only discussed vaccines cold supply chain while beneficiaries registration platform and vaccines side effects information records were not covered in the research. Another article by [36] developed blockchain solution using smart contracts to support data integrity of individuals' registration for vaccination, monitor and track vaccines distribution conditions against the safe handling rules and provide a transparent and tamper-proof solution for the beneficiary's side effects self-reporting. However, the proposed solution did not cover the supplied raw chemical material chain within the vaccine cold supply chain and only included the vaccines storage and distribution network. Also, the authors proposed that the blockchain platform would be deployed by vaccine manufacturers which is not a particle practice in terms of supply chain complexity management. Additionally, the authors did not include data authentication method necessary to validate temperature sensors data and inject it into the blockchain. Lastly, the self-reporting method is found to be inefficient and should be replaced with health authority follow-up.

In summary, there are many shortcomings to current research on the applications of blockchain to manage vaccination programs such as:

- Most studies covered theoretical aspects or suggested design structures without technical or practical implementations.
- Researches proposed partial solutions where they covered only the supply chain management system or even part of it, or beneficiaries registration process, or side effects follow up.
- The only study that tackled vaccines' side effects proposed a self-reporting method that is not initiated or supervised by health authorities which is less effective.
- External data authentication methods were not suggested by any research to connect temperature sensors or any monitoring device to the blockchain which is a huge shortcoming since any input data should be verified before being injected into a blockchain.

The next section proposes our comprehensive blockchain framework for (covid-19) vaccine beneficiaries administration, cold supply chain and potential side effects.

IV. PROPOSED COMPREHENSIVE BLOCKCHAIN-BASED VACCINE PROGRAM FRAMEWORK

Our proposed research covers major aspects that control the success of vaccine programs which have never been addressed by any previous research. The solution as shown in Fig. 1, is a blockchain-based platform utilizing smart contracts and IoT. It enables governmental and health authorities to manage, administer and handle previous and future vaccine beneficiaries' registration process and after vaccination side-effects in a secured, authenticated, transparent and traceable manner. Collecting information about vaccines' side-effects in a secured, trusted and reliable method in combination with reliable and authenticated beneficiaries registration records is extremely important in improving the manufacturing of vaccines and preparing the health care system for treating

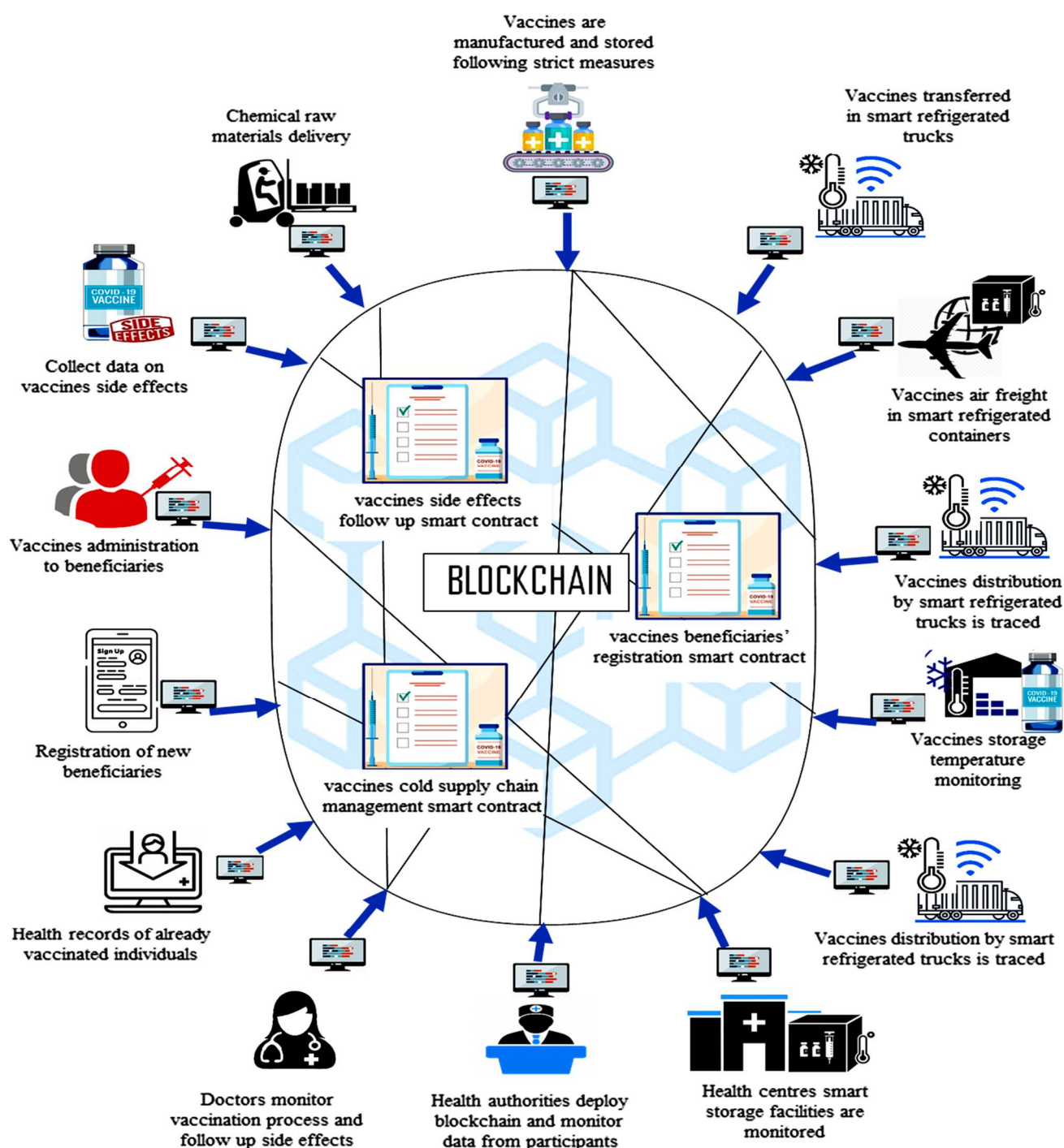


Fig. 1. The proposed blockchain solution for the vaccination program

patients' symptoms. Also, the solution provides a complete, transparent, secured, trusted monitoring and tracking system for different vaccines cold chain pharmaceutical products starting from the raw material supplier, including manufacturer processes all the way to covering the storage and distribution network, while following safety regulations and manufacturing restrictions related to temperature, expiration and any other restrictions specified by pharmaceutical companies or government health authorities. Since vaccine monitoring and tracking within cold supply chain are performed using sensors, blockchain oracles are used for data authentication and injection. To elucidate the oracle concept, smart contracts cannot pull data from IoT devices such as temperature sensors. For blockchain and smart contracts to

integrate with IoT sensors to form a monitoring and tracking platform, an oracle is used to validate the data obtained from the temperature sensor and injected into a smart contract residing on a blockchain. Therefore, building a blockchain system requires ensuring that the data collected by temperature sensors or any IoT devices are authentic and not tampered with bearing in mind that once data is inserted in the immutable blockchain, it cannot be corrected or modified [37].

the cold supply chain part of the platform is also deployed and initiated by authorities in collaboration with vaccine manufacturers. It is important to note that while cold supply chain management helps in optimizing the distribution and storage processes in alignment with the rules and conditions

set by authorities, the link between beneficiaries, their side effects and cold supply chain shall help in identifying whether the cause of any symptom is due to violation of lots storage and transfer conditions or manufacturing issues.

V. FRAMEWORK IMPLEMENTATION AND DISCUSSION

We intend to implement this platform using Ethereum blockchain and its test network. Ethereum is a decentralized, open-source blockchain and the biggest smart contract platform in the world. Its native cryptocurrency is Ether which is amongst cryptocurrencies, the second only to Bitcoin in market capitalization. Ethers are used to complete transactions on the blockchain. every transaction using an Ether cryptocurrency must be verified and recorded as an additional new block on that coin's unique blockchain. The Ethereum blockchain stores more than transaction records for Ether currency. It enables software development of decentralized economic and social applications, called decentralized applications (dApps) by creating smart contracts codes that are stored in Ethereum transactions just like currency transfer records. Therefore, smart contracts algorithms inherit the same distinguishing features of cryptocurrency financial transactions. Ethereum is well known for its robustness and reliability making it our choice to implement our sensitive and important research [38]. Ethereum's specially designed language is called "Solidity". It supports a wide range of functionalities used to write smart contract codes. Solidity is an object-oriented, high-level programming language and is the primary code language currently used for implementing smart contracts [39] [40].

Developing and testing the platform smart contracts shall be performed using Remix IDE (Integrated Development Environment) which is an online web-based development environment for smart contracts where codes are compiled, developed, executed and debugged in a fast development cycle. Remix IDE is an open-source web and desktop application that supports a rich set of plugins with intuitive GUIs [41].

Additionally, to check the results of platform operations, each on-chain transaction can be viewed, checked and validated on the Etherscan open exploring tool. Etherscan is selected since it is the most important real-time analysis service provider for Ethereum blockchain simulation and network statistics such as information about the entity that created a transaction, the executed data calls and the cost of transaction in the form of consumed units. Also, it does not need registration and no payment is required [42].

Temperature sensors wiring and connection shall be done using node-red which is an IoT network for programming IoT and feeding the information into a blockchain [43]. As per the authentication method required for temperature sensors readings verification and injection, a blockchain oracle service is going to be adopted and utilized. Multiple oracle options exist in the blockchain industry such as "Provable" which is one of the most secure platforms. Provable is a state-of-the-art oracle service used for designing the safest data transport layer for blockchain existing in the market today [44, 45].

The data required to develop the intended solution shall be collected from different sources and be adequate to design the logic of the blockchain system that will be used as the basis for smart contract coding and development as per the following steps:

- First, we should identify what is the data required to build the system such as vaccines safety measures, manufacturing conditions, supply chain elements, beneficiaries registration process, potential dangerous symptoms. The required data shall be obtained from the literature review as well as from enterprises' reports, related case studies, vaccine manufacturers and health authorities.
- Secondly, the blockchain logic should be developed for the three main processes included in our suggested platform which are: beneficiaries registration process, cold supply chain monitoring and tracking process and vaccines side-effects information record process.
- The next stage involves translating the built logic into smart contracts code using REMIX -IDE and exploring the simulation results using Etherscan.
- The feedback of the simulation should be used to upgrade and validate the smart contracts to achieve the feasibility level.
- Lastly, the smart contracts shall be finalized by transferring them from the REMIX testing environment and launching them on the real Ethereum blockchain network.

VI. CONCLUSION AND FUTURE WORK

The world regularly faces different pandemics that threaten human lives and degrades social and economic status. This situation occurred recently when the COVID-19 pandemic suddenly spread around the globe causing fatalities and disturbing health care systems. Different vaccines were developed in record time by pharmaceutical companies to combat the pandemic. It is well known that vaccines are sensitive medical products that require close and thorough monitoring and tracking of their cold supply chain where temperature and expiration date are among many safety measures to be aligned with. Also, COVID-19 vaccines' future side effects are uncertain yet in terms of cause and severity. It is important to associate any side effect with its source whether it is a manufacturing issue or a supply chain mishandling. Furthermore, and in order to be able to properly link witnessed side effects with individuals and as vaccines are usually administered to a huge number of beneficiaries, a well-organized registration process is required. Therefore, it is vital to develop a comprehensive system to support COVID-19 vaccine programs. Blockchain is adopted in this research to establish a blockchain-based platform for vaccines cold supply chain that is connected to a traceable side-effects information mechanism combined with reliable registration records. Establishing information sharing and data connection between the three elements of the intended solution is extremely important to harvest the maximum possible benefits from the vaccine program by ensuring vaccines safety and compliance with standard measures as well as linking any symptoms with individuals' metadata to provide a better insight on the cause and whether it is related to distribution conditions or manufacturing issues. As a future work, a practical smart contract-based implementation of the designed framework is intended. This shall represent the next practical phase that creates a blockchain platform. Also, the smart contract development process will be associated with a performance, security and cost analysis to validate the functionality of the blockchain solution.

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