

# Block-chain-Based Vaccine Volunteer Records Secure Storage and Service Structure

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**Abstract**— Accurate and complete vaccine volunteer's data are one valuable asset for clinical research institutions. Privacy protection and the safe storage of vaccine volunteer's data are vital concerns during clinical trial services. The advent of block-chain technology fetches an innovative idea to solve this problem. As a hash chain with the features of decentralization, authentication, and resistibility, blockchain-based technology can be used to safely store vaccine volunteer clinical trial data. In this paper, we proposed a safe storage method to control volunteer personal /clinical trial data based on blockchain with storing on cloud. Also, a service structure for sharing data of volunteer's vaccine clinical trials is defined. Further, volunteer blockchain features are defined and examined. The projected storage and distribution method is independent of any third person and no single person has the complete influence to disturb the processing..

**Keywords**- *Clinical Trial data, Vaccine, Block-chain technology Clinical Research Data data sharing, Vaccine data storage, Volunteer Data storage, Clinical research service, Clinical Research institutions*

## 1. INTRODUCTION

Grave novel severe acute respiratory syndrome coronavirus (SARS-CoV-2), COVID-19, has submerged the sphere and produced health and financial challenges. To control the spread of COVID-19, a mechanism is required to enforce physical distancing between people. With the widespread coronavirus disease disrupting the lives of people all over the world globally, the World Health Organisation declared it as a global pandemic. According to WHO as of 7th December 2020 there has been a total of 67,484,167 corona cases of which 1,543,431 deaths cases and 46,682,641 recovered cases and 19,258,095 Currently Infected Patients are recorded as shown in fig 1 and 2[1]. Considering the increasing number of cases, high mortality rate, and multiple peaks of rounds of coronavirus outbreaks adopting certain treatment strategies are an essential requirement. Though there are many different anti-cytokine, antiviral and immunomodulatory agents are been used to manage this disease but as of date no particular drugs have been innovated and declared by the food and drug administration (FDA) or by WHO for corona treatment [2]. This innovation of corona vaccination is a challenge for

researchers and research labs. Many clinical trials and experiments are conducting on large scale by NIH (National Institutes of Health), WHO (World Health Organization), CEPI (Coalition for Epidemic Preparedness Innovations), and many private pharmaceutical companies to accelerate vaccine development.

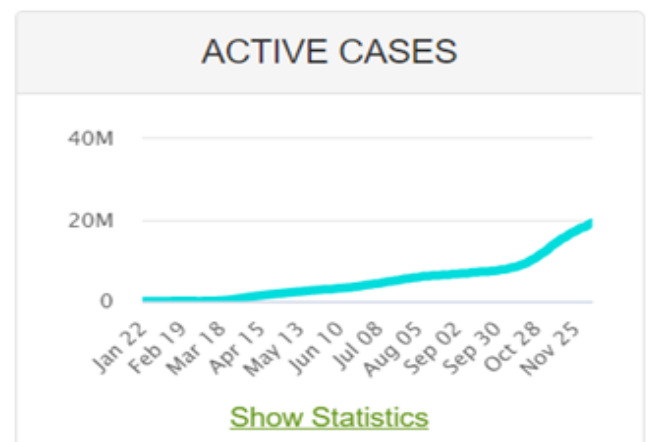


Fig. 1 Represents active cases

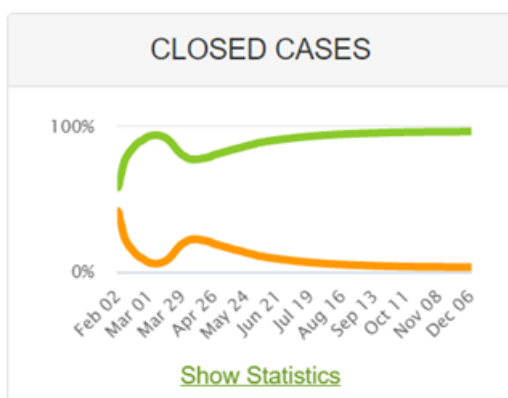


Fig.2 Represents closed cases

On 10th of January, 2020 Chinese researchers published the full RNA genetic sequence of covid-19 from infected patients[3], thereafter many research labs and organizations started working on innovation of vaccines based on MERS and SARS developed the vaccine, by different means including live attenuated virus, inactivated whole COVID-19 virus, adenovirus-based recombinant vector RNA and DNA vaccines [4–6].

According to the vaccine study, one group of volunteers are monitored under experimental vaccine whereas another group will be monitored without vaccine over some time and then the comparison is made as a result to find out the vaccination effectiveness and safety. But now in this challenging situation of covid-19 pandemic vaccine study is conducted by giving the experimental vaccine to healthy volunteers and then they are exposed to the organism causing the disease to monitor the effectiveness of the vaccine. However, some significant ethical guidelines are to be followed by scientists, research labs, research ethics committees, stockholders, funders, government agencies, regulators, and policy-maker in negotiations regarding SARS-CoV-2.

Safety of participants as coronavirus vaccination volunteers is an important condition for the study of ethical challenges acceptability. Vaccination volunteer participation and selection must be intended as a high level of confidentiality and confidence regarding the safety of volunteers in terms of health and identity information. This process includes gathering and analyzing confidential patient information, disseminate information, and publish anonymous information to those organizations with a lawful basis to process it.

The information is collected by individuals who signed up as vaccine volunteers. Potentially eligible participants are categorized and vaccine on trails for the specific study. This confidential data include name, age, geographic location area, country, sex, and health-related

questions. This will allow the researchers to contact the participants to discuss their taking part in a trial and if so, to obtain their further permission to take part in the trial.

Complete and accurate information is a valuable asset for patients. Secure storage and privacy protection of volunteer's medical data are crucial subjects during the research study. With the innovation of blockchain technology, the privacy and security of volunteer's medical data protection are ensured. In blockchain technology, the sensitive information is shared as a decentralized ledger on the blockchain network. The hash chain attributes of blockchain technology are verifiability, decentralized, distributed, and immutable, which has vital characteristics for vaccine volunteer's data protection. Blockchain application and research are actively exploring options to tap into blockchain such as smart contracts [7].

The contribution of this paper is as follows. The "motivation" section of this paper discusses the importance of vaccination study, different vaccination under innovation, volunteer's information dashboard, and features of blockchain in comparison with traditional systems for data storage. The next section defines "vaccine volunteer service structure based on blockchain technology to protect the information of vaccine volunteer" than the research proceeds with an analysis of structure in the next section. The "Conclusion" section summarizes the paper and discusses future work.

## 2. MOTIVATION

### 2.1 Importance of vaccination study:

A vaccine study is a potential and effective method of the clinical trial for preventing the spread of infectious diseases; these studies are carried out to determine whether a vaccine is effective and can prevent people from ailing with diseases without causing serious side effects. Every single vaccination is processed with multiple stages. Due to covid-19 emergency National Institutes of Health and Food and Drug Administration, and national health agencies -- usually the Centres for Disease Control and Prevention -- will agree to expedite the process. As covid-19 is a global pandemic, the vaccine development process has been fast-tracked which aims to make available to the world as soon as possible [18].

Previously vaccines were developed with a series of steps that can take many years. But now due to corona breakout urgent need for covid-19 vaccine has to be developed. Scientific collaborations and extraordinary financial investments are changing how vaccines are developed. This means that some of the steps in the development process and research are taking place simultaneously while maintaining safety and strict clinical

standards. The recent COVID-19 outbreak emphasized the requisite for a more refined healthcare system and real-time data analytics in the pandemic mitigation process [20].

**2.2 Different vaccination under innovation:**

A large scale of research is being conducted to achieve an efficient vaccine for covid-19 as shown in table-1.

Vaccines are an important countermeasure immediately needed to control the pandemic. The uncertain surety and effectiveness without any side effects are the concern of the new vaccine platform. Vaccine trials are done on healthy volunteers in the age group 18-65 years, with diverse geographic areas, racial and ethnic backgrounds, genders, and ages excluding pregnant women, elderly people, and

children. Several vaccines are under development which includes live attenuated vaccine, deoxyribonucleic acid (DNA) vaccine, viral vector-based vaccine, subunit vaccine; virus-like particles based vaccine, and inactivated whole-virus vaccine [8].

Vaccine innovation for Coronavirus is an extremely difficult procedure involving viral genomic studies, vaccine design, identification of target for vaccine, manufacturing, distribution, storage and, preclinical efficacy, and clinical safety studies. Global collaboration and the high levels of efforts at this scale are exceptional. Vaccine development for COVID-19 seems to be very challenging due to the special nature of this novel virus [19].

Table-1 various vaccines under innovation for covid-19

Developed Vaccine	Description of Vaccine
CoronaVac Vaccine	Developed by Sinovac Life Sciences Co. Ltd.
AZD1222 Vaccine	Developed by Oxford University and has been licensed to British pharmaceutical company AstraZeneca
mRNA-1273 Vaccine	Developed by Moderna (Massachusetts, United States) along with researchers at the National Institute of Allergy and Infectious Diseases and Biomedical Advanced Research and Development Authority
Ad5-nCoV Vaccine	developed by CanSino Biologics (Tianjin, China) company in collaboration with the Beijing Institute of Biotechnology in the Academy of Military Medical Sciences.
BNT162 Vaccine	developed by BioNTech (Germany) in collaboration with Fosun Pharmaceuticals (Shanghai, China) and Pfizer(Canada) through “Project Lightspeed”.
New Crown COVID-19 Vaccine	developed by Sinopharm (China) in collaboration with the Wuhan Institute of Biological Products
Sputnik V Vaccine	developed by the Gamaleya National Research Centre of Epidemiology and Microbiology (Moscow, Russia)
Covaxin Vaccine	developed by Bharat Biotech (India) in collaboration with the Thomas Jefferson University of Philadelphia, Indian Council of Medical Research (ICMR), and National Institute of Virology (Pune, India).
Re-purposed vaccines for COVID-19	Several randomized controlled trials are being conducted on the potential effect of BCG vaccine, measles vaccine, and oral polio vaccines in managing COVID-19
Novavax’s NVX-CoV2373	a clinical trial of NVX-CoV2373 initiated in Australia

**3. CORONAVIRUS VACCINE VOLUNTEER’S INFORMATION DASHBOARD**

Research and development in the stream of vaccines are found out the efficient vaccine. For this purpose, the researcher requires and requests people to take Table-2 defines the information collected regarding volunteers.

part in their study voluntarily to find out the best vaccine. NIHR National institute for health research agrees with the volunteer for the study of vaccination by permitting to take trail vaccine. Information collected by NHS is shown in table-2 and data displayed on the dashboard.



Column	Description	Values
Age group	Current age based on the date of birth the volunteer entered when completing the volunteering process	All Male Female
Gender	Gender registered at birth, based on the details the volunteer entered when completing the volunteering process	All 18-39 40-59 60-79 80+
Ethnicity	Ethnicity, based on the details the volunteer entered when completing the volunteering process	All Another ethnic group Asian or Asian British Black, African, Black British, or the Caribbean Mixed or multiple ethnic groups Not known Prefer not to say White

#### 4. FEATURES OF BLOCKCHAIN IN COMPARISON WITH TRADITIONAL SYSTEMS FOR SECURE DATA STORAGE

Key-aggregate cryptosystem (KAC) and Attribute-based encryption (ABE) are usually used cryptographic techniques for data sharing in cloud storage. When compared to KAC and ABE, the blockchain system is the tamper-proof, distributed, and centralized network on which data privacy and protection are maintained as defined in table-3. KAC and ABE are dependent on trusted third party but the blockchain is independent. Well organized electronic

corona vaccination volunteer’s information system can be generated using the blockchain-based distributed system for storing data which can’t be tampered with and falsified. The decentralized structure of the blockchain allows the volunteer’s information to be updated in real-time at each network node participating in the data storage, securely collecting and storing data and permanently storing it on the cloud server, which reduces the risks of sensitive information loss in the research lab or medical centers, and increases the security and credibility of the medical data.

Table-3 Features of blockchain in Comparison with the ABE, the KAC

Technology	Reliance on trusted third parties	Tamper resistance	Privacy protection	Secure Storage	Control of medical records
ABE	√	√	√	√	Partial
KAC	√	√	√	√	Partial
blockchain	X	√	√	√	Complete

#### 4.1 Blockchain-based Clinical Research data storage and service

The opportunity of participating BC and healthcare has been a subject of examination taken by various investigators as evident from works and surveys. The volunteer’s data storage system uses blockchain and cloud technology to attain secure storage and sharing for vaccine clinical trials. The volunteer’s blockchain architecture is shown in Fig. 1. Clinical Research includes

NIH(National Institute H)/Research Labs / Coalition for pandemic preparedness innovations(CEPI), volunteers and third-party organizations (such as medical information service platform, Private Pharmaceutical companies, stakeholders, government, etc.) are three leading types of transaction forms in this blockchain. NIH(National Institute H)/Research Labs / Coalition for pandemic preparedness innovations(CEPI) is liable for the volunteer’s prior medical

tests complying with the guidelines layout and producing their **vaccine** clinical trials records.

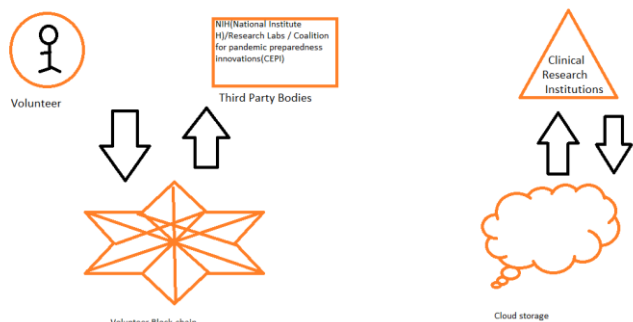


Figure 3 Architecture of Volunteer Block-chain

Volunteers can have possession of their private (excluding **vaccine** clinical trials) records. The third-party interventions can provide few services, for example, NIH(National Institute H)/Research Labs / Coalition for pandemic preparedness innovations(CEPI) endorsement, appointment, and registration. The permissions for these three kinds of transaction forms are shown in Table 1. Securing volunteer’s **vaccine** clinical trials data and granting access control for basic private data are the foremost transactions in the volunteer block-chain[23]. It would be ideal to save all

**vaccine** clinical trials data of volunteers on the block-chain, but due to valuable bounds such as rate, storage capacity, due to that key information of volunteer’s trials data and transaction accounts are noted on the block-chain. Huge Volunteer’ vaccine clinical trials /personal data must be encrypted and kept separate from the block-chain. In our proposed approach, these volunteer vaccine clinical trial data are warehoused in the cloud under the chain. To gain access control over data is determined by approval; as well different transaction units have dissimilar access control consents. In the volunteer block-chain, the correct usage of basic personal data (excludes vaccine clinical trials data) is controlled by the volunteer. The volunteer block-chain is answerable for producing construction blocks. The recently produced blocks by system nodes are first validated and then further added to the foremost chain to form stable protection of the transaction volunteer data. The timestamp is used to confirm the blocks follow the scheduling link in the volunteer block-chain. The vaccine clinical trial data in the volunteer block-chain have not meddled through the hash function, and self-authentication can be extended with public-key encryption[24]. The combinations of these technologies certify volunteer block-chain safety and security. In the volunteer block-chain, the main functions are the release, preservation, and sharing of volunteer’s data.

Table 4 Granting Permission from three types of units

Permissions	Volunteer s	NIH /Research Labs / (CEPI), appointment & registration	Third-party organizations
Read/write	Yes	Yes	Yes
Read other Volunteer data	Get permission from the data owner.	By default no such permission. In Emergency or critical condition access without the owner's permission. In general with the consent from the owner.	By default no such permission access with the consent from the owner.
Write on other Volunteer data	By default no such permission access with the consent from the owner.	By default no such permission access with the consent from the owner.	By default no such permission access with the consent from the owner.

**Volunteer data publication:** When a volunteer pay visits for vaccine clinical trials, the concerned physician produces clinical trials data or check-up reports for the volunteer. When the volunteer’s medical records are produced, the

doctor produces the digest and hash of the health records and writes them to the blockchain after validation with the issuer’s reserved key. At the same phase, the **vaccine** clinical trials are encoded with a help of a

symmetric key also the encryption key of the trial records encrypted with the volunteer's public key. Both of these are sent to the volunteer together.

**Vaccine clinical trials data storage:** After receiving the data from the clinical research institution, the volunteer confirms the institution's signature, then routines its private key to decrypt the **vaccine** clinical trials record encryption key, the original based with volunteer's trials records and the sign, also at that time generates a new encryption key to stock the **vaccine** clinical trials data records with its signature in the cloud storage[10].

**Vaccine clinical trials data sharing:** The practice privileges of the **vaccine** clinical trials records are entirely organized by the associated clinical research institution, and can authorize the vaccine volunteer, third-party assistance to gain access about of his/her trial records through the entree control tool as well can pull out institution approval at any moment. The whereabouts, practice privileges, and date of cessation of the shared data in the cloud storage including the decryption key of the volunteer and third-party assistance inscribe into the block-chain, and cloud storage administration will set the right of entry control program [9].

## 5. A VACCINE VOLUNTEERS SERVICE STRUCTURE FOR SHARING CLINICAL RESEARCH TRIALS DATA

Conventionally, clinical research preserves volunteer's data [11]. The vaccine clinical trials data sharing is one crucial stride to create a smarter health system and expand the health services quality. It can help volunteers to become active contributors [12, 13], advance service class [14], and give healthier sanctions for volunteers and medical doctors [15].

Blockchain technology is here as a helping hand to all clinical research, volunteers, also to all provision benefactors rapidly and firmly verify consents for free sharing and gain data access[16 17]. With the help of this blockchain technology, vaccine clinical trial records can be gained rapidly and precisely, and volunteers will obtain a healthier check. Consequently, here is the proposed framework for vaccine clinical trials record sharing and to gain control access established on the blockchain technology. Figure 2 summarizes the procedure of this proposed framework.

**(1) Privatization of vaccine clinical trials:** First, individually volunteer has a smart digital library includes personal health data. The storing and gaining access to the digital archive is based on blockchain technology, and each volunteer has access control privileges of their personal

data. Availability and protection of data can be appropriately and quickly combined into the vaccine experiment data of clinical research. The regulation of various records enables the sharing of information among clinical research, volunteers and service providers. Second, personal vaccine clinical trial management rights are completely controlled by the clinical research institutions. A service provider requests the institutions to access and collect personal vaccine clinical trials data when the required by service provider. The institution may authorize the service provider to access part of volunteer records and can withdraw the service provider's rights at any time.

**(2) Private vaccine clinical trials records application data :** This is very much valued. There are vaccine clinical trial applications for these records which are not only used for analysis but also can be required for other reasons such as WHO reports or for further experiments by other Clinical research institutions. Blockchain-based private vaccine clinical trials data applications can offer a volunteer medicinal info facility devoid of violating confidentiality fears[25][26].

## 6. SYSTEM ANALYSIS

The features of the vaccine Volunteer blockchain are the system launch in which volunteers have their own complete private medicinal info, the storage and sharing of their vaccine clinical trials data among volunteers, clinical research, and third-party organizations in the organization that is benign and trustworthy. The perfect features of the volunteer blockchain comprise volunteer possession, storing safety, and confidentiality guard, tamper-resistant, and appropriate inter-operability. The volunteer blockchain delivers a decentralized way to store and cope with personal medical records. This method break-downs the data of old-style health data systems, authorizing clinical research to focus on their candidate's vaccine clinical trials data distributed in different locations (second and third party). A clinical research institution gets complete access to volunteer trial records, unlike others who have to request information access. The volunteer can also pull out their consent at any interval before injecting the vaccine. Records storing safety is a vital distinction of volunteer blockchain. The protected medical data is analyzed from three parts of volunteer information, information generation, and data reception. The vaccine candidate information on vaccine clinical trials data, for example, store address, the hash value, and authorization of vaccine clinical trials data are recorded onto blocks. This vaccine candidate information is visible (without identity) but cannot be altered. Using hash algorithms to process information produced by clinical research, the hash value is signed, and



the vaccine candidate's record and sign are used to encrypt the volunteer's public key. These records are kept in the cloud storage under the blockchain. The volunteer gets the hash and sign of medical institutions' records by decrypting the cipher-text with his private key. Then, the new record is encrypted and added to the existing record. These tools ensure the authenticity of clinical research sources, the security of medical records diffusion and storage. Volunteers are now contributing to connections on the

blockchain namelessly for confidentiality guard. Vaccine candidate's trial records are encrypted and kept in cloud storage beneath the chain. No individual is unable to decrypt the original info of the volunteer data without the clinical research institute's encryption key. Consequently, it is impossible to get any actual records about the Vaccine candidate from the open data of the medical chain, so guarding the confidentiality of the volunteer.

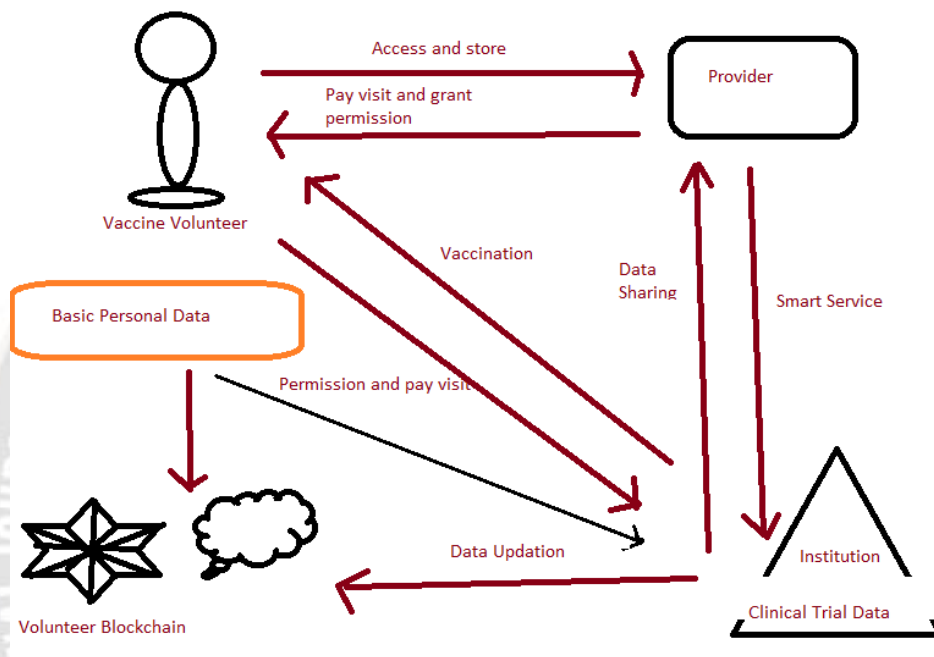


Figure.4 Structure of Vaccine volunteer service based on blockchain technology

The control right is in the fingers of the clinical research institution. clinical research institutions can allow some trial info about Volunteers to a unit and can cancel their access control privileges at any stint. Clinical Research data is agreed on the blockchain by time. For each block clasps a hash of the earlier block and records unable to alter with the minute they are inscribed into the blockchain. The hash of the Clinical Research data is stored in the volunteer blockchain [27][28]. Any alteration to the plain text will change its hash value to which confirms that the Clinical Research data cannot be amended. The volunteer blockchain will visibly provide info on when, where, and for what determination the Clinical Research trail information was used. Access to all vaccine candidate's records on the volunteer blockchain is controlled by the institution, which stops malevolent access to volunteer's information from the source. Joined Clinical Research data can be used comprehensively for biomedical or behavioral research at Clinical Research institutions and facilities from third-party assistances[29].

## 7. CONCLUSION

A vaccine study is a potential and effective method of the clinical trial for preventing the spread of infectious diseases; these studies are carried out to determine whether a vaccine is effective and can prevent people from ailing with diseases without causing serious side effects. Every single vaccination is processed with multiple stages. Research and development in the stream of vaccines are to found out the efficient vaccine. For this purpose, the researcher requires and requests people to take part in their study voluntarily to find out the best vaccine. NIHR National institute for health research agrees with the volunteer for the study of vaccination by permitting to take trail vaccine. Information collected by NHS and data displayed on the dashboard. Complete and accurate information is a valuable asset for patients. Secure storage and privacy protection of volunteer's medical data are crucial subjects during the research study. The distribution and claim of vaccine volunteers are vibrant for smart medication. Conversely, clinical trial data are shared in different a body, which leads

to data being distributed. The period in-between, saving, sharing, and implying clinical research data is vital in conditions where safety and confidentiality are assured. The block-chain is observed as a repository stock chain in each process that might be confirmed, responsible, and indisputable. Such essential features make it a possible answer for clinical research data systems that alarms both sharing and vaccine volunteers' confidentiality. Consequently, the storage method and service structure based on the block-chain technology are projected for saving, distribution, and using clinical research data in this paper. In the prospects, a volunteer block-chain network linking vaccination and clinical research institutions as probably be built. Crucial vaccination data can move securely, suitably, and cost governable in the volunteer block-chain network. Additional application situations based on volunteer block-chain networks are therefore established.

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