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# Medical Management of Blockchain, Patients, and Clinical Studies

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**Abstract**
There are procedures and rules that must be followed throughout clinical examinations and investigation, which is a lengthy, intricate procedure. From the early registration processes, informed consent, clinical data, and the moment at which post-marketing authorisation is granted, and publishing, there are concerns regarding the openness of clinical research data. As a result, persons using authorized medications have had various effects, some of which have been deadly. These impacts are said to appear as fraud, bad conduct, selective reporting, bias, and other things. It has also been challenging to get access to research data from people participating within clinical studies include patients and even academics who could be intrigued by the post-marketing period and pharmacological analyses. Data gathered from reliable sources that highlight the registration-related risks are offered as evidence. A current illustration of how lack of openness has led to a severe problem with opioid usage is a conscious decision and the manner in which clinical study results are publicized considering the usage of blockchain is being considered as a mechanism or framework for clinical research institutions, regulatory and non-regulatory bodies, pharmaceutical associations, medication manufacturers/suppliers, and patients. In order to address the difficulties raised, this article introduces a theoretical model that proposes how blockchain might give a more open and secure solution.

**Keywords**
clinical trials, fraud and misconduct, blockchain, integrity of data, wearables with traceability

## 1. Introduction

The research method of blockchain is identified, and the relation between the method of blockchain and the problem is linked. As the method or framework for clinical research facilities. The methodology will be a blend of exploratory and descriptive research. The epistemological paradigm, primarily with practical knowledge employing pragmatic philosophy and subjectivism approach, will be the finest philosophical method. Authoritarian and rational sources of information will be combined.

It has been more evident in recent years thorough investigations and studies, it has been discovered that making clinical trial data more widely available has several drawbacks, starting with registration and informed permission and continuing through publishing of results and medication administration. Along with worries about the integrity of the whole procedure and the protection of patient data, fraud and misbehavior are also documented. It emphasizes recommendations or requests to enhance openness and security at every stage of the trip, as discussed in some detail in this article. Instead of more rote approaches like patients filling out paperwork when asked or subsequent trips to the clinic, smart medical wearables may now collect data more precisely during trials thanks to significant technical advancements. The advantages of valuable data come with risks to data integrity and challenges in digital forensics, though. Data recording via blockchain is more advantageous. The theoretical model that is used in this article to protect and support all processes throughout the data journey uses blockchain as the mechanism.

The objective of this thesis is to determine how blockchain technology might assist the clinical trial process be faster and less expensive through the interactions of all parties involved. Investigating how blockchain may be used in the clinical trial process, or how technology might assist in taking it to the next level, can provide fresh results on this issue that may be significant for future study between these two-business processes. The objective is to ensure that the conditions of a contract are followed by interacting with computer protocols [1]. Nick Szabo established the notion in 1994 while considering "a computerized transaction protocol ... to fulfil common contractual constraints ... eliminate both deliberate and unintentional exceptions ... to reduce the need for trustworthy intermediates".

## 2. Clinical Trial Transparency and Drug Traceability

Longitudinal data and interoperability are advantageous to patients and providers and improve security and privacy when implemented on systems like blockchain. The potential for research-related businesses to usher in a new age of research to better comprehend the connections between diseases, however, is substantial, and the advantages would be enormous if the data were made widely accessible to researchers, according to Hoffmann's paper [2]. It's not the availability of this wealth of data that is problematic; rather, it's its openness, security, and privacy, which are frequently issues that are complicated by issues of ethics and other factors. But with blockchain, the patient will have a mechanism to "permit" the anonymous sharing of their data, authorizing access to clinical researchers or industry, with the patient as the focus.

The benefit of blockchain for researchers is the data's immutability, which means that the data can be trusted not to alter, according to Hoffmann's paper [2], who makes the fascinating point that patients desire this control in addition to having their data be helpful. In the field of research, the idea that data may be trusted more is significant. If legacy concerns are examined, it is clear that clinical trials are vulnerable to numerous fraud and mistake incidents that compromise the entire process and threaten the validity of the conducted study. Point out that there are problems with reproducibility (misconduct and fraud), and in an ideal world. It would be desirable to provide research organizations with a secure data exchange platform as well as a mechanism to ensure anonymity, perhaps utilizing blockchain. The blockchain argument is further backed by study of Asha and Nirmala [3], who claim that it "allows for the capture, sharing, and care of data", and that it may be a greater step toward transparency and improving confidence in the scientific community.

The following are some advantages and reasons to take into consideration from the research on the use of blockchain in clinical research:

- Chronological order – the right event order may be tracked so that time order logic can be used;
- Data integrity – along with concerns of embellishment, data fabrication is as near as it can go to being abolished;
- A traceable system – with the help of the timestamp, and a duplicate of each transaction is preserved on file at each node, reducing the risk of data manipulation and boosting trust.

## 3. Blockchain-Based Theoretical Model to Protect Intelligence Trials in Clinical Research

Trying to solve the problems with healthcare data security and openness has proven difficult. Nevertheless, recent developments in blockchain deployment which were discussed in the prior sector, now provide a tool or way to help with the data journey throughout, giving the benefits of blockchain. The clinical research institutes, regulatory and non-regulatory agencies, the pharmaceutical sector, medication manufacturers/suppliers, and most crucially, the patients, are all proposed to be connected via a trustless blockchain architecture in Figure 1.

Ethereum has been mentioned as a possible form of blockchain since it is already widely used in healthcare applications as well as the fact that its processing times for transactions are well-known to be fast. But it can also be adaptable to other types of blockchain for future studies or pilot projects. Given that users will require invitations to access information during authentication is required, it will also be a permissioned framework.

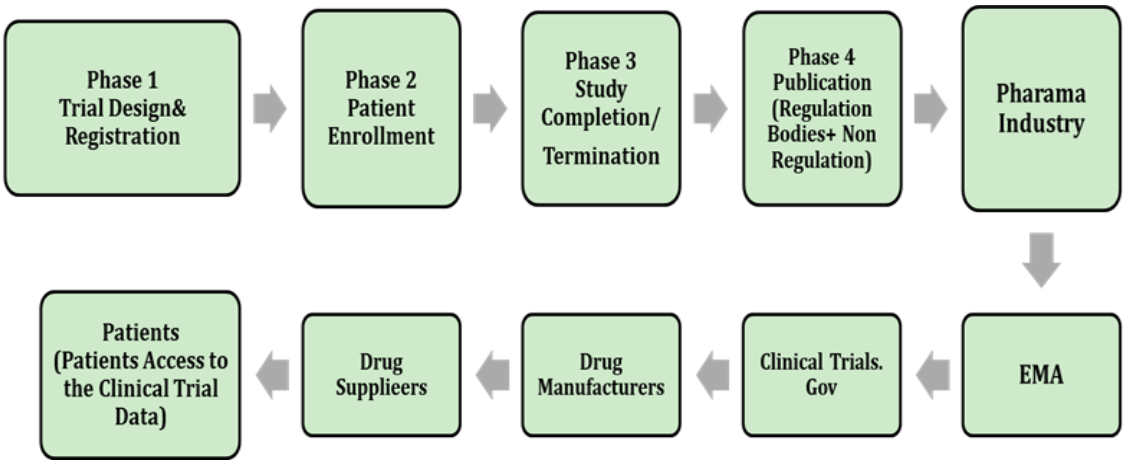


Fig. 1. Theoretical concept for enhancing clinical research procedures utilizing blockchain technology

## 4. Addressing an Issues with Blockchain

The clinical data journey is described in this section. And to demonstrate the theoretical blockchain paradigm, how blockchain increases the openness and enhances clinical and patient data security. All transactions and interactions that are documented, time-stamped, and done in a manner that is consistent with the law that assures integrity may be authenticated, sanity-checked, and verified using blockchain as a layer throughout the whole clinical trial process. The chain is made up of several components, each of which might encounter the mentioned problems.

What are the most important benefits, difficulties, and solutions that blockchain may offer to the clinical trial process? Having a compliance system where data from clinical management is immediately transmitted to the research file, created by doctors and others who will use the system, is a significant benefit. A method for analysing the clinical trial process [4] proposes a five-step procedure for improving and identifying the benefits and drawbacks of processes, mostly in clinical trials. He mentioned the first two processes as creating and mapping the process, identifying the important points, workflow, and crucial decision points. The second stage is to examine the map-derived procedure. In this example, the analysis was carried out by comparing the findings with the interviews and localizing the challenges they encountered in their real-life experiences. There are several benefits to employing technology. In this study, the hashing method ensures that if any block is modified, the entire blockchain is rendered invalid. A centralized database allows you to create, edit, and delete items, whereas blockchain allows you to just create, read, and attend, resulting in more consistent and accurate data.

## 5. Phases of Clinical Research and Testing

A better way of life for many individuals may be accommodated by clinical research, which also helps to enable new treatments, enhance patient outcomes, and develop procedures. Clinical studies are important to determine how therapies will affect patients, if they can be deemed safe, and whether they may help move medicine toward a prevention-based approach. Trials, a technique used to carry out research, are what create the testing process. There is a lot of confidence throughout the procedure, although across several of the phases, Kim-Kwang Raymond Choo et al. claim that it is vulnerable to data that is inaccurately portrayed and only contains a tiny percentage of the study provided in published articles [5].

The procedure is quite confident, but there are different places along the journey where it is vulnerable to data that is not properly represented, and only includes a small portion of the study contained in published papers, according to this paper [5]. Smart contracts that provide a time ordering stamp can be used to record clinical research data on the blockchain, including information on the study's objectives, patient consents, and registration details. The patient must assent to any modification changes to the study, and this permission must be documented in the same way.

Because modifications to any trial procedure might have an effect on the patient, this is a crucial point that will be covered in more detail in the data analysis sections that follow. The patient should have

provided consent before moving forward with any substantial changes. The vast difference in reported results compared to the data analysis given from the collected raw data shows differences to the original Protocol setups.

There are several instances in which data from Phase III trials is not publicized after investigations are finished, and this can continue for a number of years: include oseltamivir, paroxetine, pregabalin, gabapentin, and zanamivir, with oseltamivir being the most often used [6]. If data gathering were a necessary necessity and all data, even unsuccessful trials, were secured into the blockchain paradigm, this might be avoided. Researchers, doctors, and patients all suffer as a result of cherry-picking or selective reporting of findings.

## 6. Medical Trials for Smart Wearable Gadgets

Data collection used to be a manual procedure that could be managed by asking trial participants questions before the emergence of intelligent wearable technologies. Given that it is dependent on memory and experience and is susceptible to the patient's prejudice perception, this may not produce the most accurate findings. Another issue is how these data records are stored, which raises concerns about privacy and security.

The unpredictable nature of collecting correct data or the requirement to plug devices into computers has been removed by more recent developments in smart health wearable devices (IoMT). There are many different types and applications for these devices, including activity trackers, pacemakers, monitoring, etc. Without any extra practical demands on trial participants, data may be sent to researchers in real time. The authentication component of the data capture, upload, and synchronization process uses blockchain and cloud technology. The blockchain allows for the storage and connection of all linked patient data in a timestamp-ordered way, along with connections to patient healthcare records.

This provides 100 percent correctness in terms of chronological ordering and may be applied to a number of smart contracts as trial-related checkpoints. Additionally, it addresses the problems associated with data silos caused by the possibility of cyber security breaches. A crucial factor in this is compatibility. In their presentation on integrating blockchain with medical wearables [7], describe a related procedure.

Another issue that blockchain can address is how to safely store and preserve the enormous increase that is projected for healthcare wearables and the data that goes with them via Wireless Body Area Networks (WBAN). Healthcare is a main target for cybercriminals and data breaches, as was previously indicated, raising this worry. Considering that most data from health wearables increasingly being seen as a target for cyberattacks, there is a larger chance of more data being hacked if alternative technologies like blockchain are not taken into consideration. Although the General Data Protection Regulation (GDPR) mandates that notice be given at the very least 72 hours after a breach occurs, the patient is the most vulnerable party in this cycle since they have no control, access to, or awareness of where the data is stored or whether a breach has occurred. But if security was neglected, this is of little use to the patient. Blockchain serves as the foundational underpinning for every link in the trial chain, and wearable technology is a substantial contribution to the body of evidence.

## 7. State of The Art

The CIA triangle (Confidentiality, Integrity and Availability) is seriously threatened by the existing storage practices for healthcare data. Despite the fact that the development of healthcare technology has greatly benefited everyone, it is a serious worry and is related to the flow of data from clinical research. Wearables, machines, medications, etc. that help provide better and more focused healthcare also mean that the amount of data generated by these things will grow rapidly, necessitating the development of increasingly complex methods to safeguard healthcare data. Additionally, more openness is needed to safeguard patients from identity theft and other potential victimization that typically accompanies data breaches and its worst impacts. This extensive data breach across businesses is seen in Figure 2 below, but it is abundantly obvious that healthcare has experienced the greatest number of intrusions.

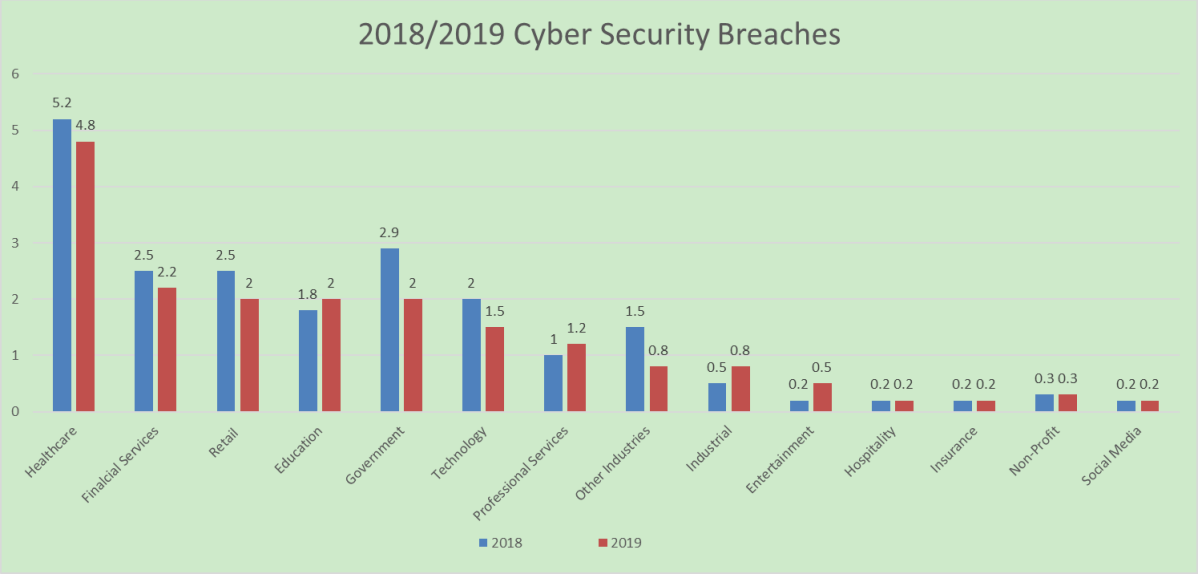


Fig. 2. Industry comparison of cyber security breaches in 2018 and 2019 (Breachlevelindex.com data for 2023)

Gemalto is a company that proactively monitors global data breaches across many sectors by compiling and aggregating them on Breachlevelindex.com. The report's inclusion of information about the origin of the weblink data source makes it possible to confirm that it is a reliable source of quantitative data with high-quality information.

The data is measured in terms of documents that have been lost or stolen, the sort of breach, its origin, and its classification into industrial sectors. Gemalto utilizes a rating methodology to evaluate the danger associated with the incident. The risk impact is therefore graded using the following scale:

- 1–2.9 (minimum)
- 3–4.9 (middle)
- 5–6.9 (crucial)
- 7–8.9 (serious)
- 9–10 (devastating)

Table 1 provides a breakdown of the various categories as well as the whole raw data sets that were taken from Healthitsecurity.com. Fifteen million patient records were breached during 503 healthcare data breaches in 2018, nearly triple the amount of reported incidents from the previous year, according to the Protenus 2019 Breach Barometer.

Table 1. Breakdown of 473 healthcare breaches of 2023

| **Source of breach** | **Breach volume** |
|---|---|
| Malicious outsider | 322 |
| Malicious insider | 68 |
| Accidental loss | 82 |
| Hacktivist | 1 |
| **Type of breach** | **Breach volume** |
| Identity theft | 414 |
| Nuisance | 19 |
| Account access | 18 |
| Existential data | 11 |
| Financial access | 8 |
| Financial loss | 3 |

Analysis and comparison of the locations where the most common breach types and sources occur are important as well. Identity theft, the most serious type of breach, and the breach's source are

dangerously. The quantitative analysis makes it quite evident that identity theft is the main goal, which is consistent with the fact that the attack is being planned by an evil foreigner. There may be a need for continued training programs, stronger defenses, etc. since alternative sources of breach, including unintentional loss, are growing. Even if it is a must, there should be a more direct way to aid in patient protection when data are compromised, which presents a compelling argument for blockchain use. Since it is generally known that malicious attackers targeted the healthcare sector, as will be shown in the next section, identity theft is the main cause for worry.

## 8. Conclusions and Future Research Proposals

The purpose of managerial implication is to discover whether it is feasible to incorporate blockchain technology, the healthcare industry, more especially into the clinical trials process. As a result, the investigation will uncover a new conclusion or evaluation highlighting the problems and prospects for this technology, using a combination of inductive and deductive reasoning to obtain a suitable assessment from evidence. It will be inductive at times during the investigation, as the goal is to get a definitive conclusion.

With its time stamp, temporal ordering, smart contracts, and immutability, blockchain technology is revolutionizing the world, the clinical trials theoretical model discussed in this paper offers a fascinating demonstration of how to make healthcare data more visible, how to improve privacy, and how to maximize blockchain technology. In addition to the advantages previously mentioned, it raises extremely important issues and questions about the possible harm brought on by prejudice, selective reporting, misbehavior, and fraud. As the example data analysis tends to imply, there now appear to be numerous holes in the clinical process. As demonstrated by the example of opioid usage, blockchain may streamline these procedures, create a fair framework, restore confidence, and lessen the problems mentioned. The research method of blockchain is identified. A patient may notice a variety of fatally harmful problems. In order to create a more reliable framework focused on blockchain, the theoretical paradigm for clinical trials was explored, in the paper provides a fascinating illustration ways to make healthcare data more accessible and improve privacy, and learn how to leverage blockchain technology. It does this through the use of a time stamp, temporal ordering, smart contracts, and immutability.

The objective of this thesis is that the primary properties of smart contracts are as follows [8]. The initial stage for the researchers is to investigate the research aim, hazards, and inconveniences of the trial. Then, gather all of this material for approval by board members and physicians, while also establishing a point of contact to convey information regarding the experiment (concerns and advantages) as required. While doing so, it is critical to get study funding.

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