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BLOCKCHAIN TECHNOLOGY IMPROVING THE TRANSPARENCY IN THE CLINICAL TRAILS

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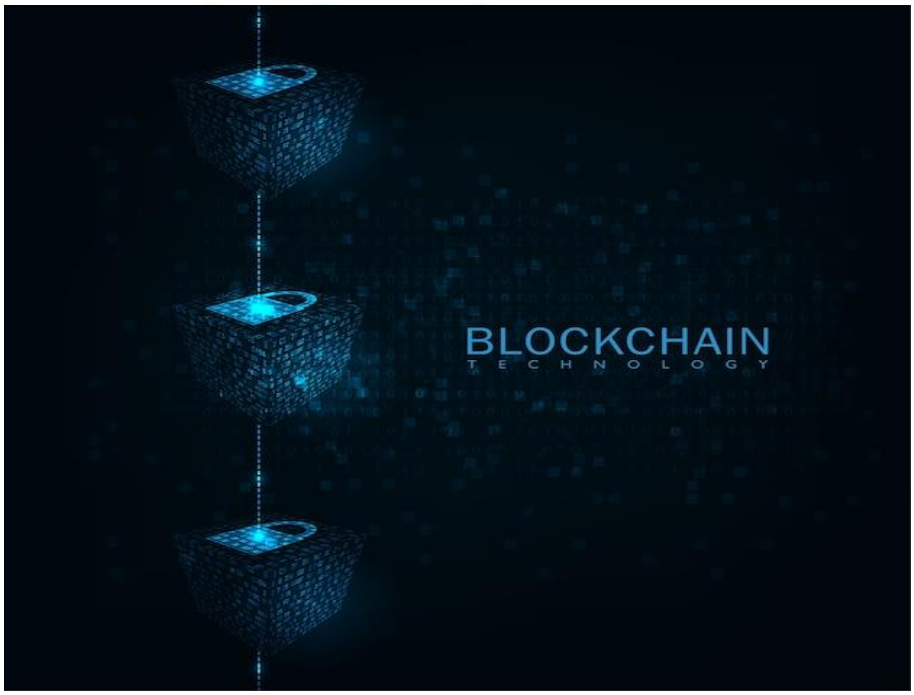
Abstract : Medical records are considered very private because there has been a rising concern and interest in their medical record throughout the last decade. Therefore, blockchain technology in clinical trials enhances the management operations and processing of electronic medical records with information on health patients. In this study, the goal is to investigate what clinical trial benefits of blockchain technology can introduce better synergies among players through transparency. Performed as a literature survey that was evaluated from a review, PubMed, Springer. We expand the definition of collecting out data and documents by embracing smart contacts. As such, we have proposed a blockchain-based approach with myriads of trial contracts based on the trials and patient engagement alongside an umbrella smart contract for conducting topic matching that will automatically recruit patients through means of trialing arrangements. The application of blockchain technology may increase the reliability, safety, and transparency level to edge steadily at reproducibility.



1. INTRODUCTION

1.1 CLINICAL TRIALS

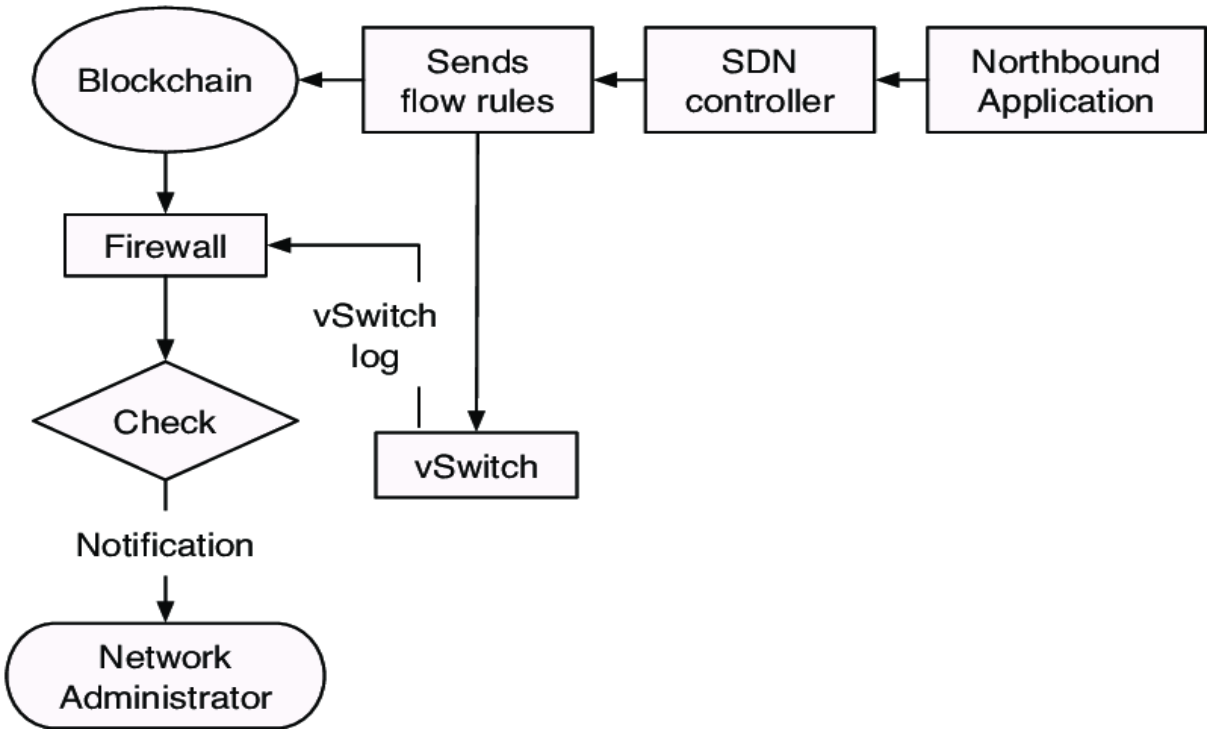
Systematic observational and experimental biomedical studies are performed on human subjects to test new drugs or combinations of drugs or devices or biologics for their safety and therapeutic uses or new approaches to surgery or radiotherapy or procedures to improve the diagnosis of disease and the quality of life of the patients. Clinical trials are research studies that are necessary to evaluate how safe and effective new vaccines and medicines are before they can enter the market.

Each clinical trial is meticulously designed to provide the most information with the least amount of risk, and a protocol, or action plan, is created to accomplish this. This plan describes what will be done in the study, how it will be done, what information will be gathered, and why the various parts of the investigation are required. The protocol also specifies the eligibility requirements for participating in a clinical trial. Some studies require participants to be sick. Some studies seek healthy volunteers or people with specific characteristics such as gender, age, weight, lifestyle/habits, or others. Biomedical clinical trials are divided into four stages: To find a safe dosage range, phase I trials usually test new medications on a small number of participants for the first time. Studies are intended to evaluate the safety of a medication, technology, or procedure; establish the proper dosage range; and identify any potential side effects. Typically, they involve a small number of healthy volunteers (20–100).

Phase II studies are conducted to evaluate the safety and efficacy of a medication. These trials typically involve hundreds of participants (between 100 and 300).

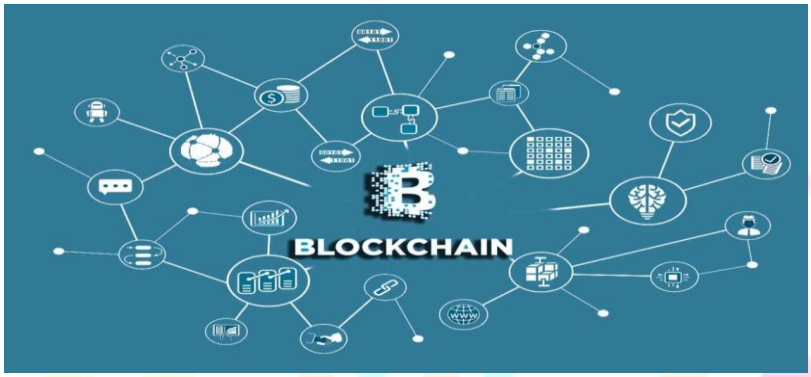
Phase III studies are carried out on larger populations in various regions and countries to confirm the efficacy of a new medical approach and track its benefits as well as any negative effects. After completing Phase III, a regulatory body like the US Food and Drug Administration (FDA) may approve a novel medical strategy or medication.

Phase IV studies are conducted, and there is a need for additional testing in a large population over a longer timeframe. Studies are carried out following the marketing of new medicines, gadgets, or processes.

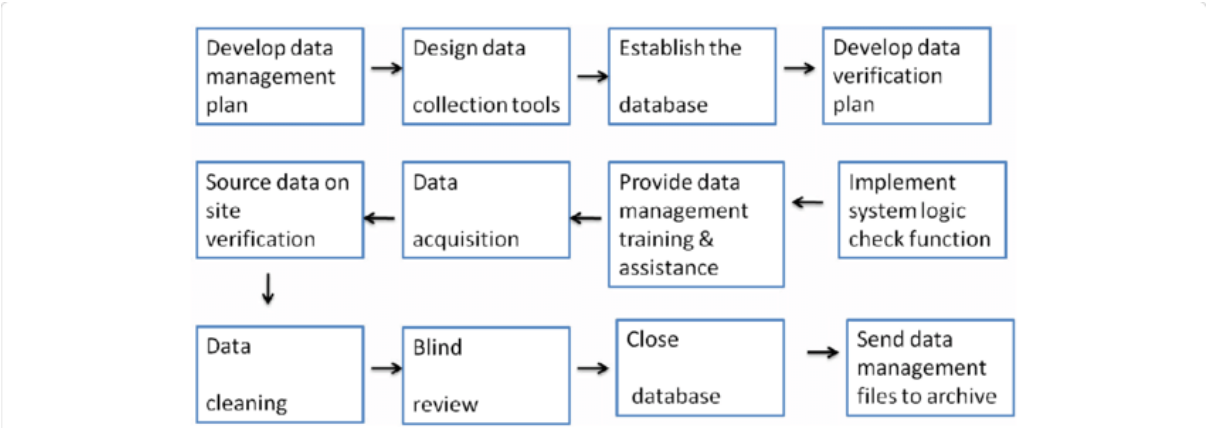


1.2 BLOCKCHAIN

Blockchain research began in 1990, but it was not implemented until 2009. In 2008, an anonymous developer Satoshi Nakamoto created Bitcoin using blockchain technology, and it was only after that cryptocurrency began to boom around the world. The properties of blockchain technologies, such as data transparency and traceability, have sparked a wave of reformation in the traditional healthcare organization, including health data sharing and patient follow-up via transaction traceability [1].



A blockchain is distributed ledger technology (DLT) made up of an expanding list of data, known as blocks, that are safely connected using encryption. A timestamp, transaction information, and a cryptographic hash of the previous block are included in each block. They effectively create a chain. Each block links to the blocks before it because each block includes information about the block before it. Blockchain transactions are therefore irreversible in the sense that, once they are recorded, the data in any given block cannot be changed retrospectively without changing all succeeding blocks. For usage as a public distributed ledger, blockchains are often administered using peer-to-peer (P2P) computer networks, where nodes collectively abide by a consensus algorithm protocol to add and validate new transactions [2]. Blockchain technology has the potential to transform the way every industry manages its information and data, as well as financial services. Blockchain technology provides new tools for digital authentication and authorization that eliminate the need for many centralized administrators. As a result, it makes it possible to establish new digital relationships. Blockchain in clinical trials stores electronic medical records that can be accessed and updated using biometrics, allowing for the democratization of patient data and reducing the burden of transferring records between providers.



1.3 CURRENT ISSUES IN CLINICAL TRIAL AND HOW BLOCKCHAIN TECHNOLOGY WORKS

Clinical trials necessitate patient consent. Today, the way patients receive information is heavily reliant on the staff on-site, specifically their knowledge, access to the right documents, and ability to explain them. As a result, patients are less motivated to complete the trial or consent to further sampling or testing of samples because they do not fully understand the study's information details and their rights and responsibilities. This can raise the cost of a sponsor delaying marketing approval due to regulatory concerns about consent or limiting long onsite patient consultations.

A vast amount of data is generated during the course of a clinical trial held by the sponsor, which is required by regulatory authorities all over the world before a new medical product can be brought to market. During a clinical trial, the investigator collects data from the subjects at regular intervals, such as vital signs, changes in symptoms, and serious adverse reactions caused by the trial drug [3]. Clinical trials, in general, necessitate collaboration among various stakeholders, including sponsors, regulatory bodies, clinical sites, and, most importantly, clinical trial participants [4]. This is a lengthy process that has become increasingly complex, data-heavy, and fragmented, resulting in increased costs and patient access to new medicines being delayed.

The accessibility of patient data is a major issue in clinical trials. An Investigator must be able to locate individuals for specific studies. However, with current technologies, data is dispersed across multiple proprietary systems that are frequently independent and incompatible with one another, making it extremely difficult to recruit individuals for trials. To make matters worse, even if investigators do find enough patients to begin an effective clinical trial, the quality of patients for that specific treatment or medical condition may still be an issue, resulting in an inaccurate study with false positive or false negative data. Blockchain technology can help to prevent this.

Using a blockchain-based system allows you to look at records years later and know that the data held in that block of the chain is complete and unaltered. This is especially important in regulatory processes or when conducting cause-and-effect analyses to resolve issues. Furthermore, blockchain systems have the advantage of being used decentralized. In practice, this means that in the future, clinical trials could be conducted in a patient's home while maintaining strong governance mechanisms. This also levels the playing field, as you should be able to achieve the same results whether you are in rural Africa, India, or Latin America, or a major hospital in New York, Paris, or London.

Three of the biggest pharmaceutical conglomerates – Pfizer, Amgen, and Sanofi – are working together to develop a practical approach to applying blockchain technology in clinical trials, from storing safe data to speeding up clinical trials and ultimately lowering drug development costs [5]. To ensure that society's evolving medical demands are effectively supplied, a consistent and effective flow of medical advances is essential. Drug development expenses are increasing, according to ongoing studies, by an average of 10.5% per year [6]

1.4 DECENTARILIZATION

Decentralization simply means that no one power has sole authority over the data or its processing. This is possible in the context of blockchain because the data is dispersed, or held at each node in the network rather than just one. Decentralized clinical trials are not conducted at a single central location; instead, they may take place in multiple locations or make use of connected technologies to allow participants and researchers to submit reports online while still adhering to general scientific and regulatory guidelines. One of the main strategies used to ensure the continuation of clinical research during the epidemic is trial decentralization. As a result, numerous additional remote options, such as electronically submitted patient-reported outcomes (ePRO), have gained popularity. These methods not only generate enormous amounts of data, much like a normal trial does but also call for strong governance because, frequently, participants may not attend routine face-to-face follow-ups with medical specialists [7].

1.5 SMART CONTRACT IN CLINICAL TRIAL

A cryptographer named Nick Szabo first put out the notion of encoding contracts in computer code in 1994. A computer code-based contract between two parties is known as a smart contract. These are maintained on a public database and cannot be changed because they are based on blockchain. A smart contract's transactions can be sent automatically and without the assistance of a third party because they are processed by the blockchain. When the conditions of the contract are fulfilled and no third party is present, transactions can only occur.

Smart contracts are used in the health system to record and safely transfer data. EncrypGen and others use smart contracts in the medical industry. This is an application that uses smart contracts to securely transfer patient data with no third-party access. Patients are in charge of their data in this manner. Researchers must pay to use patient data. Furthermore, the patient must decide whether or not to sell it to them.

A high-level perspective of the blockchain network shows that the ledger and the smart contract together make up its core. By asking the REST API to carry out actions on the blockchain network, external applications can activate a smart contract. The transaction log, which permanently stores the history of every transaction ever made in the blockchain, and the global state, which keeps track of these states' most recent values, are the two separate parts of the ledger that the smart contract programmatically accesses. It can carry out operations on the states kept in the world state or run queries on the transaction log's transaction records [8]. A smart contract is software that stores rules for negotiating agreement terms automatically verifies fulfillment and then executes the agreed terms. Because smart contracts eliminate the need for a third party when establishing business relationships. The parties to an agreement can transact directly with each other, which is the primary reason why large enterprises are shifting to smart contracts.

Smart contracts are designed and implemented within blockchains and therefore they inherit some of the blockchain properties the most prominent ones include:

1. They are immutable, which means they can never be changed and no one can tamper with or violate the contract.

2. They are distributed, which means that the contract's outcome is validated by everyone in the network, just like any other transaction on the blockchain. This distribution makes it impossible for an attacker to force control to release any information because all participants would easily detect such an attempt and have the power to mark it as invalid, protecting the contract's integrity.

1.6 ELECTRONIC MEDICAL RECORD

The official patient file that is created digitally in ambulatory, hospital, and clinical trial settings is called an electronic medical record, or EMR. An EMR may include information on billing, vital signs, laboratory test results, vaccination status, demographics, medical history, medication and allergy information, laboratory test findings, audiological images, and vital signs. Electronic Medical Records (EMRs) are far more useful than paper records because they enable doctors to thoroughly chronicle all patient data across time. Here are five fundamental elements of an EMR that fall under the purview of HIPAA compliance.

Progress note entry: Medics utilizing EMRs use a note entry tool to record information about their patient's conditions, symptoms, appearance, and other details. This is similar to how nurses and doctors write notes on paper in their patients' charts. By use of surveys or email alerts, several electronic medical records even enable patients to enter their symptoms in advance.

Data module input system: In addition to taking notes during patient talks, a full EMR enables doctors to record dictation, upload scans of documents and photos, and retrieve data from EKGs, CT scans, and other sources. An input system would be necessary for doctors to have a comprehensive understanding of their patients' health.

Patient call log: This should include all pertinent phone calls and discussions that take place between doctors and their patients. Additionally, in the event of an audit, this log need to be accessible for retrieval and examination. An IT staff should provide instructions on how to set up and utilize a call log system compliantly.

Prescription management system: One of the most crucial elements of any prescription management system is the ability to input a patient's allergies and any medications they are currently taking. This helps guarantee that no adverse reactions occur. Prescriptions should be sent straight to the pharmacy for the patient to pick up, including new and refills.

Backup system- Backup and disaster recovery plans are essential for any virtual (or even non-virtual) system containing large amounts of sensitive information. The backup system in your EMR should be able to store all data offsite, keeping it secure and accessible when and if needed

2. METHODOLOGY

A review of the literature was conducted using a combination of keywords related to blockchain, clinical trials, data transparency, smart contracts, EMR, benefits, and current clinical trial issues in electronic bibliographic databases of published research such as PubMed, Springer, and Science Direct. A quality assessment of the literature was performed on the six papers chosen. We also used Google Scholar to find original research articles. We used Google Scholar's structured search function to search for "blockchain" AND "clinical trials" or "data transparency in clinical trials."

Health-related terms were derived and chosen from published literature. The next step was to screen the papers for relevance after retrieving them from the databases using our search protocol. Some of the papers returned by our search protocol had nothing to do

with blockchain in clinical trials and were thus removed. The following stage of the screening process involved reading the abstracts of the selected papers. This procedure entailed extracting keywords from the abstracts. The paper was divided into categories based on the keywords.

RESULTS AND DISCUSSION

The use of blockchain technology in clinical trials will improve data security, data management, and analysis. Because of its decentralization, immutability, transparency, and traceability, blockchain is a viable technology that can improve healthcare data sharing and storing systems. Nonetheless, many healthcare organizations are hesitant to adopt blockchain technology due to threats such as security and authorization issues, interoperability issues, and a lack of technical skills in blockchain technology. Because healthcare data is sensitive and requires real-time processing, especially in emergencies, we must carefully select the type of consensus algorithm, working platform, and blockchain type.

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