*Fuzzy Systems and Data Mining IX*
*A.J. Tallón-Ballesteros and R. Beltrán-Barba (Eds.)*

*doi:10.3233/FAIA231094*

# Blockchain Framework for Healthcare Data Management System in Clinical Trials

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**Abstract:** The concept of information management involves the identification and organization of data into distinct sectors, sometimes referred to as silos, in order to anticipate and address future situations. One of the primary obstacles encountered in the administration of clinical trials pertains to the presence of information silos among the several stakeholders involved in the process. The improvement of cooperation and integration may be achieved by processing information in real-time and implementing a comprehensive system. This manuscript evaluates the viability of implementing the blockchain model for auditing clinical trials. It also proposes a blockchain-based solution that has the potential to enhance the overall quality of the practiced solutions and establish sustainable approaches for conducting clinical trials auditing. The suggested model focuses on the development of a grid-based system for organizing the many stages of a clinical trial. This involves creating distinct blocks for each phase and then constructing a complete network of these blocks to be shared across the consortium responsible for managing the trial data. The suggested architecture has substantial potential for enhancing security and adaptability, hence facilitating systematic improvements to information systems in the context of clinical trials.

**Keywords:** Healthcare Data Management System, blockchain, clinical trials, Architecture of Grid Blockchain framework.

## 1. Introduction

Clinical research is pivotal in advancing pharmaceutical accessibility for high-quality healthcare. To uphold research quality, effective clinical training is crucial. Recruiting and retaining subjects in trials significantly impacts study cost and duration. Quality assurance in clinical research is resource-intensive but pivotal for innovative healthcare solutions. Given procedural complexity, optimizing management efficiency is imperative. Ethical and regulatory compliance enhance participant recruitment and trial

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conduct. Subject retention is vital for progress monitoring and generating informative data [1]. Stakeholder involvement bolsters clinical trial infrastructure. Current practices exhibit a concerning 80% lack of reproducibility, attributed to various factors, including human errors and ethical lapses. Inaccuracies in data collection and transcription greatly affect study data integrity, necessitating stricter supervisory protocols. Evaluating data integrity requires expertise in both the business domain and data modeling. This multifaceted effort ensures satisfactory data quality levels in clinical research [2]. Blockchain technology exhibits significant potential for elevating the quality and reproducibility of clinical studies. It offers secure data transmission within academic contexts, ensuring privacy for patient groups. Recently, there has been a surge in recognition of blockchain as a transformative technology, facilitating secure data exchange through a distributed ledger system. This relies on consensus mechanisms for parties with limited mutual trust. Blockchain's robust security and decentralized structure involve collaborative efforts of multiple participants in storing and recording data from various sources. Interconnected nodes enable seamless data transmission through linked blocks, and its transparency allows swift access without third-party involvement [3]. Smart contracts, situated on the blockchain, represent decentralized programs with functionalities such as autonomous execution of an application's logic, verification of predefined operational regulations, and assignment of obligations upon regulation fulfillment [4][5]. Compliance is integral across various aspects of clinical trials, encompassing reporting of animal trial findings, obtaining informed consent, and securing approvals from competent medical authorities. Adhering to Good Clinical Practice (GCP) and the International Conference on Harmonization (ICH) guidelines is vital for effective informed consent management. Recognizing the vulnerability of certain individuals is fundamental to understanding clinical research dynamics [1]. The intensity of clinical trial procedures is amplified by the multitude of trials conducted in diverse research laboratories. Thus, effective management of clinical trial conditions, emphasizing comprehensive and manipulation-resistant information management techniques, is crucial. This approach fosters holistic growth throughout the entire process. The advent of contemporary technology, particularly blockchain models, has significantly transformed information and communication systems in healthcare research. It provides a means to address deficiencies in information management within clinical trials, offering mitigation against fraudulent or mismanaged information [6].

## 2. Related Literature

Clinical trials are initiated when there exists a sound and logical rationale for how a novel testing or treatment modality may result in improved quality of care and treatment outcomes for patients. Before the commencement of clinical trials, tests and treatments are subjected to review in pre-clinical research settings. Human clinical trials are considered relevant for the study only after receiving the necessary authorization. Following this, before to the debut of the market, more examinations are carried out.

### *2.1. Stages of Clinical Trials*

According to the criteria set out by the Good Clinical Practice (GCP), it is essential to conduct clinical trials in accordance with the prescribed therapies. Clinical trials are conducted to evaluate the safety of a certain medicine or treatment modality for individuals. Broadly speaking, the stages involved in clinical trials pertaining to novel medicinal treatments include:

- Phase 0: involves a minimal dosage of a medication administered to a limited cohort of human subjects, aiming to understand pharmacokinetics, metabolism, and effects within the human body.
- Phase 1: centers on identifying a suitable drug-induced composition with minimal adverse effects, establishing safety thresholds. Phase II follows for a more specific patient group evaluation.
- Phase II: involves closely monitoring patients within a broader participant base, lacking comprehensive comparison with existing medications. Efficacious drugs proceed to Phase III.
- Phase III: entails comparing the novel drug with standard-of-care medications on a larger sample size for comprehensive analysis. Randomization ensures unbiased participant distribution. FDA approval precedes widespread usage.
- Phase IV: involves large-scale testing post-FDA approval, providing deeper insights into drug performance, effectiveness, and potential adverse effects, both short-term and long-term.

The phases of clinical trials are of paramount relevance in managing situations related to clinical research. The use of this approach facilitates the thorough evaluation of novel medications and therapies, ensuring their safety and efficacy prior to their approval for use among the general population. However, it is important to take into account the contextual circumstances in which historical records indicate instances of compromised clinical trials or manipulation of results at various stages. Any discrepancies in the approval process could potentially have significant consequences on the efficacy of a drug in meeting the specific needs of patients [7].

### *2.2. Conditions of Clinical Trials in Silos*

The text highlights the extensive ongoing research in therapeutic approvals worldwide, with regulatory bodies like the FDA expediting approval rates. The focus of clinical research is to streamline the clinical development process, ensuring safety and compliance with regulations. While technology integration has enhanced operational efficiency, there remain fundamental gaps. Electronic Data Capture (EDC) software in the 1990s revolutionized data collection. Randomization and Supplies Management (RTSM) systems have since evolved, aiding biostatisticians and clinical supplies managers. A global standard for drug safety reporting was established, a pivotal functional milestone. However, the fragmented nature of existing solutions leads to overlapping and isolated systems, resulting in challenges like data redundancy and consistency issues. Within pharmaceutical research labs and CROs, electronic data capture (EDC) systems and research supply tracking management (RSTM) systems are crucial for data collection and supplies management. Additionally, the pharmaco-vigilance (PV) system monitors adverse events during clinical trials. Despite functional responsibilities in siloed systems, redundancy and inconsistency in generated reports persist. To enhance operational efficiency, there's a call to address integration challenges and implement a unified, cloud-based clinical trial management system. The integration of blockchain technologies is proposed as a significant advancement, emphasizing effective coordination of shared functionalities for all major stakeholders involved [8].

### *2.3. The Effect of Blockchain in Addressing Silos*

The presence of data silos in information technology presents a persistent challenge, hindering seamless data sharing within organizations. Despite technological advancements, implementing an enterprise systems strategy remains a significant obstacle. These robust silos adversely affect organizational efficiency, influencing broader industrial ecosystems. Addressing this issue requires overcoming barriers in data politics, compliance, data architecture foresight, research culture, enterprise solutions, service agreements, standards, and underlying schemas. Distributing data among network participants enhances transparency and establishes a practical framework for collection, shifting data ownership to consumers. While valuable, blockchain technology necessitates careful consideration of stakeholder access amidst silo challenges. Rigorous examination is crucial, as not all information can be entirely public and alternative methods may lack enforceable requirements. Blockchain systems, with their primary focus on transactions, may have limitations in accommodating metadata conditions. The inflexible structure of schemas may impede adaptability. [9].

### *2.4. The Impact of Fragmented Processes and Silos on Clinical Trials*

This study emphasizes the need for a collaborative framework to enhance clinical trial management within companies, supported by empirical evidence. The Veeva 2019 Unified Clinical Operations Survey highlights the industry's urgency to prioritize sharing capabilities among sponsors, contract research organizations (CROs), and stakeholders. Integration across multiple tiers is crucial for sustained, effective collaboration. Manual processes pose a significant risk of incomplete or incongruous information dissemination. Reluctance to share arises from prioritizing core responsibilities, including patient care, precise data collection, and regulatory compliance. Survey results indicate concerns about streamlining information exchange, eliminating manual procedures, enhancing collaboration, ensuring consistency, and bolstering oversight throughout trials. Integration and reporting processes face impediments due to existing gaps and silos in healthcare systems. The incorporation of blockchain technologies alongside a comprehensive system holds potential to mitigate these challenges. Given substantial stakeholder involvement and the extensive processing of numerous clinical trials, establishing a comprehensive system is imperative. This envisioned system aims to provide timely updates, support improved research conditions, streamline communication, and enhance reporting efficiency. Blockchain technology facilitates instantaneous data exchange and reinforces data governance, fostering a unified framework for information dissemination during clinical trials. [10].

## 3. Methodology Overview

The concept of blockchain may be defined as a digital framework that encompasses a shared and unchangeable ledger. This framework aims to guarantee a high degree of traceability, durability, and general effectiveness in managing data among various parties involved. The use of blockchain technology was first launched inside cryptocurrency systems. However, over time, this solution has been pragmatically adopted across several industrial sectors. In the healthcare industry, research findings consistently demonstrate the considerable efficacy of using blockchain-based solutions, which can make a holistic difference to the system.

### *3.1. Blockchain Framework Architecture for the Healthcare Sector*

The architecture of blockchain may be described as a decentralized system in contrast to the conventional centralized database. In this distributed system, data is exchanged in real-time across several computers or database systems referred to as "nodes." Each node inside the group has an identical copy of the transactional information [11]. The blocks are interconnected via the use of digital signatures represented by random letters in the form of a hash. This process results in the formation of a chain that represents a comprehensive record of transactions, hence enhancing resistance against tampering. Reference [12] have been provided one of the primary advantages of using blockchain technology is its emphasis on security. This is achieved by the use of sophisticated encryption techniques, which instill confidence, acceptance, and approval among participant nodes while dealing with data blocks [12]. This architectural design leads to increased decentralization of data systems, whereby a single source of information is shared across all nodes. Consequently, this fosters more confidence and unanimity among the participating nodes. In an alternate dimension, the blockchain system may be managed via two distinct approaches: public sharing, which allows for widespread access, and a private system that restricts access to a certain group of stakeholders [13]. The blockchain systems that may be managed inside the system include the use of many computers as an essential component of the network, the implementation of smart contracts among the involved parties, and the integration of a unified system [14]. Figure 1 illustrates the foundational architecture used as the framework for creating the suggested solution. This approach entails the conditional acceptance of blocks and the subsequent recording of transaction links to establish a chain. The primary benefit of implementing such a system is in its ability to provide a comprehensive verification framework, hence reducing discrepancies in reports and enhancing the general efficiency of reporting and communication among members.

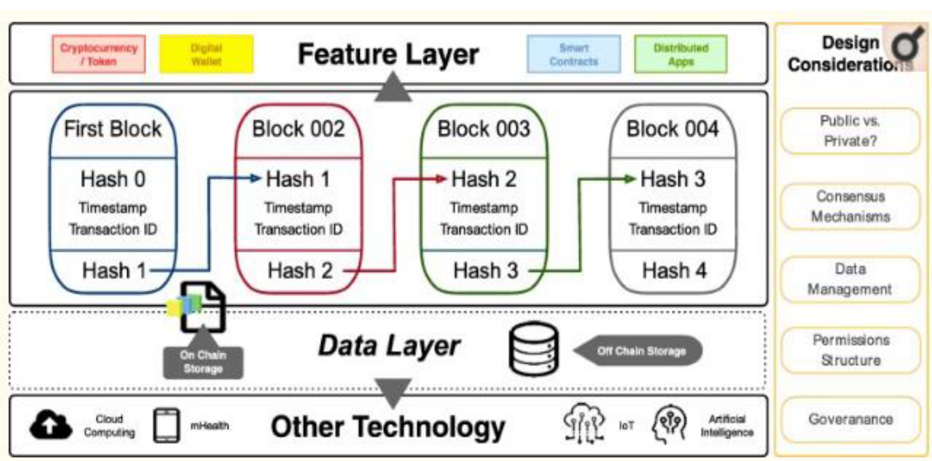


**Figure 1:** Blockchain Layer

### 3.2. Fundamentals of the Framework

The process flow governing the integration of blockchain-based systems within the context of clinical trials is delineated by a set of regulatory principles, as illustrated in Figure 2. These regulatory precepts are considered pragmatically advantageous in the context of deploying a blockchain-based solution for overseeing the entirety of clinical trial processes.

- Block chain Design Type: The proposed system incorporates a private blockchain framework, characterized by constrained participation and a clearly defined permission structure governing data dissemination.
- Data sharing and access: The management of data adheres to specific privacy and legal stipulations, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR). Determination regarding the scope of data sharing amongst participants and the storage locus of data whether on chain, off chain, or on a side-chain coupled with a prescribed permission model, is contingent upon the nodes.
- Block chain Governance: Central to the operational efficacy of the blockchain is its governance framework, constituting a pivotal facet. This encompasses the decision-making process involving the nodes, users, and peers. The delineation of the validation protocol for blocks and the establishment of a procedural framework for approvals are mandated to be determined by the consortium, in strict adherence to the regulatory guidelines delineated by the Food and Drug Administration (FDA) pertaining to the clinical trial milieu.
- System Enhancement: The administration of clinical trial solutions is advised to be executed through the application of smart contracts, a measure that serves to mitigate the potential for data tampering or manipulation amongst principal stakeholders. These smart contracts are pertinent to the validation of outcomes by duly authorized entities, particularly within the ambit of collaborations between pharmaceutical enterprises and Contract Research Organization (CRO) entities. Additionally, these contracts encompass the procedure for obtaining informed consent from individuals participating in human clinical investigations.

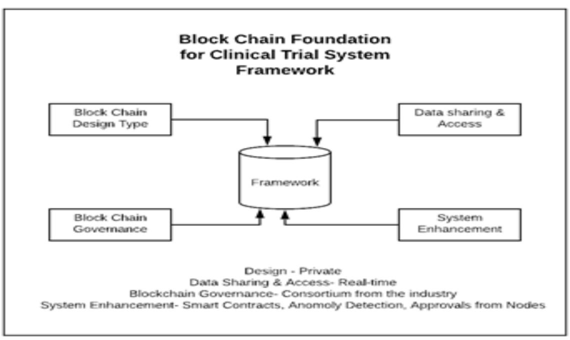


**Figure 2:** Proposed solution's blockchain framework.

### *3.3. Adopting the Blockchain Framework Method*

Table 1 outlines the operational procedure and proposed architecture for deploying a blockchain framework in enterprises conducting clinical trials. The block architecture, as depicted in Figure 3, is fundamental for validating information within the blockchain system. For instance, the successful completion of the pre-clinical trial block is a prerequisite for forming the phase-1 grid. This grid represents a cohesive entity composed of a series of blocks, referred to as a superblock structure. In a hypothetical scenario, collaboration among stakeholders (CRO, sponsoring company, competent authority, and trial participants) could lead to the establishment of 20 blocks in Phase-1. These interconnected blocks form a comprehensive superblock grid. The creation of the second grid block is contingent upon the production of all requisite blocks in Phase-1, as regulated by the consortium overseeing the framework's structure and data collection.

**Table 1:** Architectural Framework of Blockchain for Entities Engaged in Clinical Trial Operations.

| Details | A description |
|---|---|
| System Adapted | The integration of a clinical trial system based on blockchain technology. |
| Objective | To effectively tackle the problem of manipulation and inconsistencies in the given data and its reporting. Improve the reliability of the information architecture and data obtained from the system. |
| Expected Outcome | Improved and systematic methodology for the comprehensive documentation of clinical research, including pre-clinical trials as well as the five distinct phases of clinical trials. The implementation of real-time information exchange across authorities has the potential to enhance the overall result. |
| Network | A distributed peer-to-peer (P2P) network. A Peer-to-Peer network is a decentralized system in which data is distributed and shared among all stakeholders involved in the exchange of information. |
| Stakeholders | The pharmaceutical sector involves various entities like the FDA, CROs, medication manufacturers, and regulatory bodies. This system comprises multiple stakeholders acting as users, with their information systems functioning as nodes. |
| Approval Structure | The approval of the blocks relies on endorsement from key user networks like the FDA and local competent authorities. The approval framework for specific clinical trials may undergo periodic decision-making by the consortium. |
| Block | The topics discussed include compliance reports, the filing of research reports, the use of smart contracts, the dissemination of anomaly information, and the acquisition of informed permission from study participants. |

The proposed block's grid established by including numerous integral blocks inside each grid unit. The process flow phases that are essential for the process may be seen in Figure 4.

- The transaction is recorded inside the block.
- The provided or compliant standard format of reporting shall include the transaction information as clinical trials information.
- Each block that is successfully added to the blockchain will possess a hash value, which will be included into subsequent blocks, therefore establishing the link chain.
- The signature of each block is predetermined and should not be modified after agreement is reached among the participating nodes.

- Once a clinical trial phase receives approval, each subsequent phase will be structured as a grid consisting of numerous subset blocks.
- In the subsequent grid, the preceding grid block will be transformed into the feed, while the data will be collected as a super grid block.

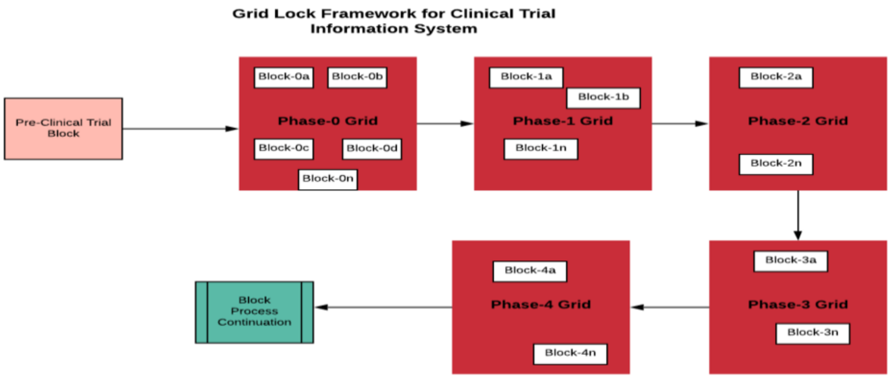


**Figure 3:** Architecture of Grid Block

- The ongoing use of corresponding sets of blocks in the creation process is expected to result in an enhancement of system development.
- The use of a ranking system will be employed to determine the requisite number of consensuses necessary to get permission for the effective connection of the block.

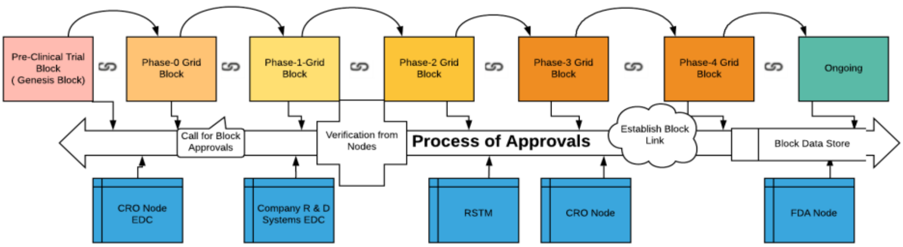


**Figure 4:** Comprehensive Framework Outlook

If any modifications are made to a single block inside the grid, it would result in a cascade effect on all blocks dispersed throughout the grids. As a result, any endeavor to engage in data tampering is rendered impracticable. Thus, with regard to the security paradigm of the system, it is evident that the model exhibits a heightened degree of resilience, predicated on the specific category of block and the requisite number of consensuses for its approval.

## 4. Conclusion

In conclusion, the rise in clinical trials and research volume, along with pending approvals across various organizations, emphasizes the need for an improved collaborative information and transaction processing system. These systems are pivotal for governance and consistency in clinical trial processes. Current corporate models exhibit fragmentation with isolated systems, leading to redundant efforts and data. Operating in isolated compartments further exacerbates inconsistencies. Considering the potential of blockchain solutions, this paper introduces a novel framework for clinical trials in healthcare based on a grid structure and blocks, aimed at enhancing the auditing process. The study suggests future research avenues, including consensus protocols, block size, and interval impacts on blockchain performance, as well as integrating the framework into existing clinical trial systems for practicality assessment in real-world scenarios.

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