Securing Clinical Trial Data Using Private Blockchain Technology

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ABSTRACT

The COVID-19 pandemic placed unprecedented strain on global healthcare systems and exposed several limitations in managing large-scale public health emergencies. The adoption of emerging technologies, however, such as Blockchain, Artificial Intelligence (AI), and Machine Learning (ML), offers opportunities to develop systems that are better suited to help the healthcare system during such challenges. For instance, Blockchain technology can be utilized to secure patient data, Clinical Trial (CT) records, and other sensitive medical information. Among these applications, CTs represent a critical component of drug development and are also one of its most costly and complex stages. Nonetheless, implementing a Blockchain-based CT management system can enhance data traceability, reduce operational costs, and enable efficient record management, assisting regulatory bodies in reviewing and approving drugs more rapidly, enabling faster release of new treatments to the market, and potentially saving lives. Therefore, this study proposes a permissioned private Blockchain-based architecture utilizing Hyperledger Fabric, along with smart contracts within the Hyperledger network, which facilitates secure, transparent, and efficient coordination among all CT stakeholders while maintaining data privacy through controlled access and the use of independent ledgers. Performance analysis of the proposed system, evaluated in terms of throughput, latency, and execution time, indicates that private Blockchain systems demonstrate superior performance relative to public Blockchain implementations.

Keywords-Blockchain technology; clinical trials; consent; healthcare; participants; private Blockchain

I. INTRODUCTION

Clinical Trials (CTs) are scientific studies conducted to evaluate the prevention, diagnosis, and treatment of diseases, performed in multiple phases and involving several key stakeholders, including sponsors, Contract Research Organizations (CROs), CT sites, and regulatory agencies such as the Food and Drug Administration (FDA), investigators, and patients. The global COVID-19 pandemic, which spread to more than 190 countries and caused millions of deaths, accelerated vaccine development and placed enormous pressure on healthcare systems worldwide. Thus, since CTs are considered one of the largest investment elements of vaccine development, regulatory agencies must ensure patient safety while maintaining strict standards for data privacy and integrity throughout the trial process.

However, the involvement of numerous stakeholders increases the complexity of CTs, and the absence of mutual trust among participating entities can further complicate coordination. At the same time, medical information is highly confidential yet extremely valuable for research purposes. A potential solution to these concerns is the implementation of Blockchain technology, which offers a space for storing CT data that detects unauthorized modifications through time-stamped documentation, and the identities of entities accessing the system can be verified [1]. Additionally, decentralizing medical records using Blockchain technology enables secure data sharing while preserving patient anonymity through public-private key encryption mechanisms [2]. Furthermore, Blockchain technology allows designated organizations to access CT data through a secure and scalable infrastructure, thereby reducing problems such as data duplication and inconsistencies that often arise in fragmented conventional trial-management systems [3]. Specifically, the Hyperledger Fabric, a permissioned Blockchain platform, allows network access only to authorized entities and provides features such as private networks, private channels, and smart contracts. These systems operate in controlled environments and, therefore, require less computational power while enabling more efficient verification processes. In a CT environment, dedicated channels can be created for specific trial activities such as participant enrollment, trial monitoring, and data analysis, ensuring that only relevant stakeholders have access to the corresponding data [4].

Furthermore, encrypting and fragmenting confidential CT data and storing them on Blockchain-integrated distributed storage systems offers improved security and potential cost advantages opposed to centralized cloud systems [5]. Smart contracts can also enhance CT management by automating participant incentives, including financial compensation or vouchers, which can improve participant retention and increase transparency in compensation processes [6].

Overall, CTs are fundamental to healthcare decision-making, particularly when human subjects are involved, which introduces additional ethical and operational complexities. Clinical Trial Data Management (CTDM) focuses on the collection, cleaning, and management of trial data in accordance with regulatory protocols. However, centralized data storage systems remain vulnerable to manipulation and can compromise data integrity [7]. Concurrently, a growing body of research highlights the application of Blockchain in healthcare for secure patient record sharing, improved interoperability, and increased patient control over personal medical data [8, 9]. Phase III CTs, which involve large numbers of participants, require robust and verifiable data-management platforms, and Blockchain technology provides the immutability and traceability required for such large-scale studies [10]. Blockchain also enables secure peer-to-peer data exchange with traceability while preserving privacy in clinical research environments [11] and is increasingly adopted as a core architectural component in large distributed systems managing heterogeneous and sensitive data [12]. Using cryptographic hashing techniques, data integrity is ensured regardless of data size, since any modification results in a change in the hash value [13]. Hyperledger Fabric further enhances this process by enabling efficient and secure verification mechanisms within a permissioned environment, thereby avoiding excessive computational overhead [14]. The successful adoption of Blockchain technology in other sectors (Figure 1), such as traceable agricultural supply chains, further demonstrates its reliability and applicability to complex ecosystems like CTs [15].

II. RELATED WORK AND RESEARCH GAP

Despite the Blockchain advancements in CTs, existing systems often lack domain-specific endorsement policies, integration with the full CT lifecycle, and mechanisms for machine-learning-assisted verification. Figure 2 illustrates the major challenges associated with CTs and the percentage of reported occurrences.

To address these limitations, this study proposes a private Blockchain architecture tailored for CT environments, embedded with cryptographic validation and performance optimization mechanisms.

A. *Statement of Novelty*

The novelty of the proposed system lies in i) its domain-specific Hyperledger Fabric chain code for CTs, ii) the integration of a real-world dataset comprising 5,000 trial records, iii) the customized endorsement policies for regulatory compliance, and iv) the comparative evaluation against public and private Blockchain platforms with respect to throughput, latency, and execution cost.

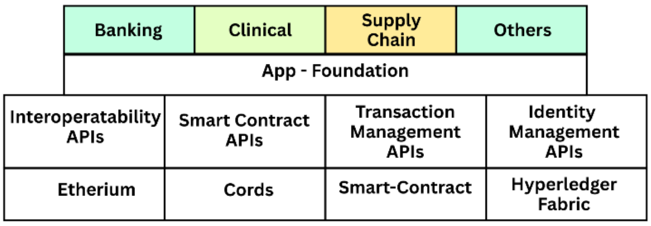

Fig. 1. Applications of Blockchain.

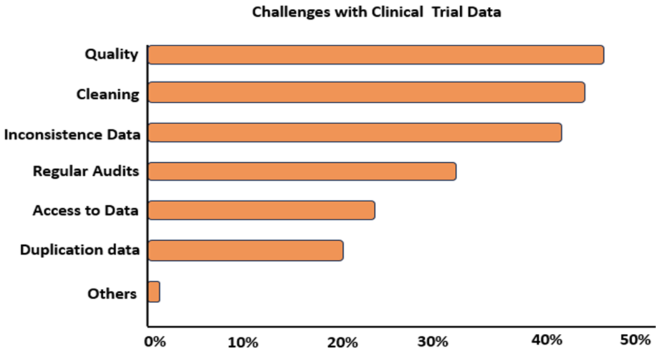

Fig. 2. Challenges with CT data.

The proposed system is capable of resisting malicious attacks and preventing unauthorized manipulation of user information, while business logic operations, such as retrieving data or adding transactions, are executed using smart contracts. These transactions are immutable and fully traceable within the distributed ledger. In addition, all user transactions are recorded in a distributed ledger that includes cryptographic signatures, ensuring protection against data loss because each participant maintains a synchronized copy of the ledger.

III. METHODOLOGY

The proposed system architecture is presented in Figure 3. Each data entry within the system generates a unique cryptographic hash value; thus, even slight tampering with the original data results in a different hash.

In the proposed workflow, sponsors initially provide vaccine samples to the CRO, which distributes them to CT sites. Each distribution event is treated as a Blockchain transaction and recorded in the ledger. The vaccines are then administered to volunteers or patients enrolled in CTs at hospitals and healthcare centers. The CRO monitors the trial and evaluates the effects of the vaccines on participants. Then, the CRO submits the trial results and analyses to the sponsors, while sponsors maintain the results information in a database, and each update is recorded in the ledger as a transaction. Since all transactions are recorded on a single distributed ledger, regulatory agencies such as the FDA can verify the integrity and provenance of the data through traceable records. After performing the necessary background checks and verification procedures, the FDA authorizes the release of vaccines.

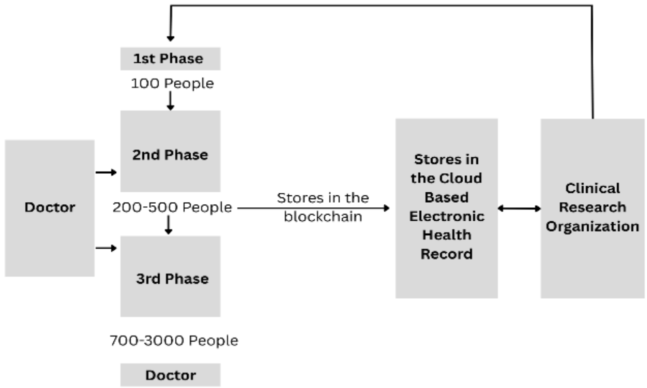

Fig. 3. Proposed Blockchain architecture.

A. Phase 1: Data Acquisition and Standardization

CT data generated at clinical sites are collected by authorized CROs. Before submission to the Blockchain system, the data are validated for schema consistency, missing values, and compliance with CT protocols.

B. Phase 2: Cryptographic Hashing and Off-Chain Storage

Each CT record is cryptographically hashed using the SHA-256 algorithm. The original dataset is stored in a secure off-chain repository, while only the hash digest and metadata are recorded on-chain, reducing storage overhead while preserving integrity.

C. Phase 3: Smart Contract Execution

Smart contracts (chaincode) implemented in Hyperledger Fabric enforce several operational rules, including:

- Role-based access control for stakeholders (sponsors, CROs, FDA).
- Endorsement policies.
- Duplicate submission prevention.

Only authorized CROs are permitted to perform write operations on the Blockchain ledger.

D. Phase 4: Consensus and Ledger Commit

Transactions undergo endorsement, ordering, and validation before being immutably committed to the distributed ledger.

E. Phase 5: Regulatory Verification and Audit

Regulatory authorities independently recompute hashes from sampled off-chain data and verify integrity against Blockchain-stored hashes.

This phased methodology ensures transparency, non-repudiation, and regulatory compliance throughout the CT lifecycle.

Below we present Algorithm 1 and 2, which showcase how the timestamped Blockchain-based update mechanism operates and how the system verifies the integrity of sampled CT data by recomputing its cryptographic hash and comparing it with the Blockchain-stored hash, respectively. Algorithm 2 also confirms block authenticity, chaincode correctness, endorsement signatures, and ledger consistency to detect possible tampering.

```
Algorithm 1: Blockchain-based Update Mechanism for CT Data
Input:
CT_Data – CT dataset received from CRO in a standardized and validated structure.
Output:
Immutable ledger entry comprising (Dh, timestamp, metadata).
      Algorithm 1: Update_CT_Data_On_Blockchain(CT_Data)
BEGIN
    Step 1: Data Acquisition
        Receive CT_Data in the predefined standardized format.
    Step 2: Hash Generation
        Dh ← SHA-256(CT_Data)
    Step 3: Ledger Duplicate Verification
        IF Dh exists in the Blockchain ledger THEN
            TERMINATE process (No update required; duplicate/unchanged dataset).
        END IF
    Step 4: Transaction Formation
        Construct transaction proposal (TP) embedding:
            Dh, timestamp, and relevant metadata
    Step 5: Authentication and Endorsement
        Authenticate TP using Membership Service Provider (MSP)
        Endorse TP in accordance with the prescribed endorsement policy
    Step 6: Ordering, Validation, and Commit
        Submit TP to the ordering service
        Validate TP through consensus protocol
        Commit validated TP as a new block in the ledger
    Step 7: Final Record
```

```
        Store (Dh, timestamp, metadata)
within the newly appended block
END
```

```
Algorithm 2: Federated Verification of CT
Data Integrity by Regulatory Authority
Input:
Rd — Randomly extracted data instance from
the local CT database
Dh — Corresponding stored hash retrieved
from Blockchain ledger
Output:
Integrity validation outcome (Valid or
Tampered).
Algorithm 2: Verify_CT_Data_Integrity (Rd,
Dh)
BEGIN
    Step 1: Sample Selection Select Rd
from the secure local database repository.
Step 2: Hash Recalculation
        Rh ← SHA-256(Rd)
    Step 3: Integrity Verification
        IF Rh = Dh THEN
            Report "Data Valid — No
Evidence of Modification"
        ELSE
       Report "Data Invalid — Potential
Tampering Detected"
        END IF
    Step 4: Extended Blockchain Validation
        Authenticate block origin through
MSP-issued credentials
        Validate integrity of chain code
execution logic
        Confirm endorsement signatures
from authorized peers
        Verify ordering and commit history
consistency with ledger state
END
```

F. Experimental Setup and Computational Environment

All experiments were conducted using the following configuration:

1) Hardware and Software

- Hardware: Intel Core i7 processor, 16 GB Random Access Memory (RAM).
- Operating System: Ubuntu 20.04 LTS.
- Blockchain Framework: Hyperledger Fabric v2.2.

2) Network Configuration

To estimate the performance and the usefulness of a private Blockchain solution for safeguarding CT resources, we implemented a custom Hyperledger Fabric network. The network is based on Hyperledger Fabric v2.2 and consists of six peer nodes distributed across three organizations. A single communication channel handles all CT transactions, governed by a majority endorsement policy requiring at least two of the three organizations to approve each transaction. The smart contracts (chaincode) were developed in Node.js and deployed across the network. The Blockchain employs the SHA-256 hashing-algorithm, with a maximum block size of 500 KB and a transaction timeout threshold of 30 seconds. This configuration is optimized to ensure high throughput, low latency, and fast execution while maintaining security and auditability. Python-based preprocessing libraries were used for tokenization, lemmatization, and other data-cleaning tasks.

3) Dataset

CT data were collected from the ClinicalTrials.gov website using its public Application Programming Interface (API). More information regarding the dataset is presented in the Data Availability section. The dataset includes 5,000 CT entries recorded between January 2020 and December 2023. The fields retained for this study are: Key-Outcome-Measures, Marginal-Outcome-Measures, Supplementary-Outcome-Measures, Age, and Brief Summary. The data underwent extensive preprocessing, which involved removing duplicate records using unique trial identifiers, excluding trials with missing or empty outcome fields, standardizing age formats, and cleaning the text data through tokenization, stop-word removal, lowercasing, and lemmatization. Additionally, semantically similar outcome labels were harmonized to ensure consistency.

4) Pseudocode

The pseudocode implementation on the Hyperledger Fabric network is:

```
Class Clinical Research Contract extends
Contract
    Method initLedger (ctx)
        Print "Initializing Ledger"
        Initialize an empty array of data
        For each record in data
            Convert record to JSON string
            Store the JSON string in the
ledger with the record's ID as the key
            Print "Added data with ID:
record.ID}"
    Method to create Research Data (ctx,
id, data)
        Call research Data Exists (ctx,
id) to check if data with the given ID
already exists
        If data with the given ID exists
            Throw an error "The data with
ID {id} already exists"
Parse the input data from JSON string to
object
       Create a new research Data object
with ID and parsed data
Convert research Data object to JSON
string
      Store the JSON string in the ledger
with the given ID as      the key
  Method read Research Data (ctx, id)
```

```
    Get the JSON string of data from the
ledger by the given ID
    If no data is found or data is empty
       Throw an error "The data with ID
{id} does not exist"
  Return the JSON string of data
  Method research Data Exists (ctx, id)
    Get the JSON string of data from the
ledger by the given ID
        Return true if data exists and is
not empty, otherwise return false
```

IV. RESULTS AND ANALYSIS

A. *Performance Analysis*

Recent studies on Blockchain-based CT systems consistently report that permissioned platforms, such as Hyperledger Fabric, offer superior throughput, lower latency, and greater governance flexibility than Ethereum-based deployments, making them technically preferable for regulated healthcare workflows [1, 11, 14, 16, 17-19]. However, a more meaningful comparison for real-world adoption lies between Blockchain-enabled architectures and traditional centralized CT databases, rather than between public and private Blockchains.

Conventional centralized systems rely heavily on trusted intermediaries, manual audits, and repeated data reconciliation across sponsors, CROs, and regulators, resulting in high operational and compliance costs [11, 16]. In contrast, the proposed private Fabric-based system, which employs hash-only on-chain storage with off-chain data repositories, introduces limited computational overhead while substantially reducing audit, verification, and reconciliation effort.

The comparison between the Ethereum-based system and the proposed system in terms of throughput, execution time, and latency under fixed computational conditions is presented in Tables I-III, while the corresponding visualization of this data is presented in Figures 4-6, respectively. Throughput refers to the amount of information transmitted from one location to another per unit time, execution time refers to the duration required to complete a transaction, and latency is the time delay between the initiation and completion of a transaction.

Experimental evaluation on 5,000 real CT records shows that the proposed system achieves faster execution, lower latency, and higher throughput than baseline Ethereum implementations, while enabling automated regulatory verification through immutable audit trails reported in the present study. These results indicate that, although Blockchain introduces additional infrastructure costs compared to centralized databases, the net cost is offset by reduced operational delays, improved trust, and elimination of post-hoc compliance overhead, supporting the economic viability of permissioned Blockchain adoption for large-scale CTs [14, 17, 19].

B. *Comparison of Previous Studies*

To contextualize the potential of Hyperledger Fabric, a comparative analysis against other platforms, namely Corda, Quorum, MultiChain, and a traditional MongoDB with Express database, is conducted based on transaction speed and throughput, as summarized in Table IV.

As shown, when compared to a traditional database system such as MongoDB with Express, Hyperledger Fabric exhibits higher transaction latency (i.e., lower transaction speed) but lower throughput than the database baseline. However, this performance gap is expected, as traditional databases are optimized for high-speed data processing, whereas Blockchain systems prioritize security, decentralization, and trust.

TABLE I. THROUGHPUT VALUES

No. of Transactions	Throughput in Ethereum (TPS)	Throughput in Hyperledger Fabric Platform (TPS)
1	4.65	10.56
5	15.65	34.56
10	28.23	68.45
50	32.45	178.47
100	38.58	300.9
500	36.4	275.34
1,000	34.76	258.86
5,000	28.98	183.23
10,000	20.67	160.26

Transactions Per Second (TPS).

TABLE II. EXECUTION TIME VALUES

No. of Transactions	Time Taken in Ethereum (s)	Time Taken in Hyperledger Fabric Platform (s)
1	0.2	0.1
5	0.25	0.11
10	0.35	0.12
50	1.6	0.2
100	2.65	0.34
500	13.23	1.72
1,000	30.04	2.78
5,000	230.78	26.6
10,000	489.67	60.54

TABLE III. LATENCY VALUES

No. of Transactions	Time Taken in Ethereum (s)	Time Taken in Hyperledger Fabric Platform (s)
1	0.23	0.08
5	0.24	0.1
10	0.25	0.11
50	1.68	0.14
100	2.16	0.18
500	13.65	0.89
1,000	26.78	1.98
5,000	267.89	20.45
10,000	485.12	35.78

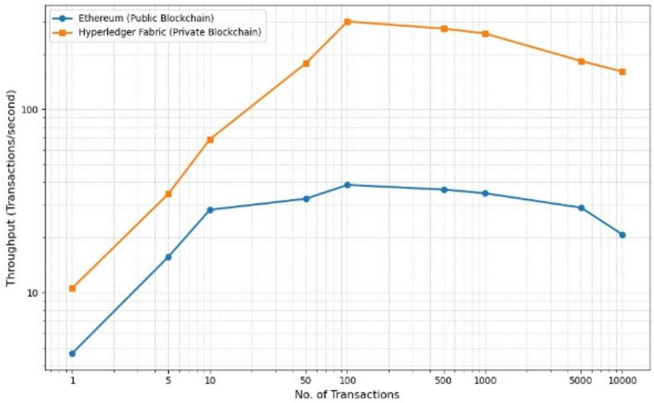

Fig. 4. Average throughput.

In contrast, when compared to other private Blockchain platforms (Corda, Quorum, and MultiChain), Hyperledger Fabric demonstrates a more favorable balance. Specifically, it achieves significantly higher throughput (3000 TPS) while maintaining moderate transaction speed, outperforming these platforms in terms of scalability. This indicates that Hyperledger Fabric is better suited for applications requiring high transaction volumes with controlled access, such as CT data management.

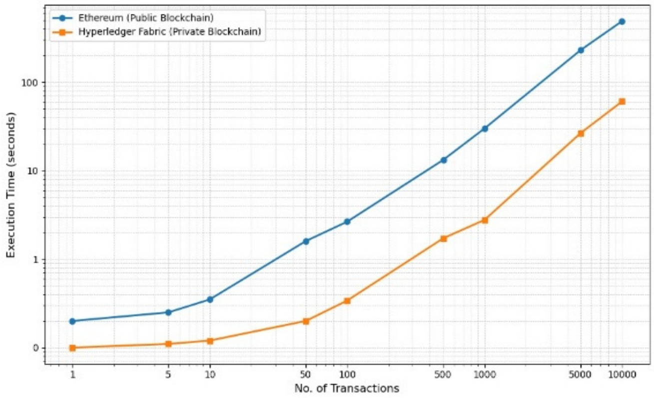

Fig. 5. Execution time.

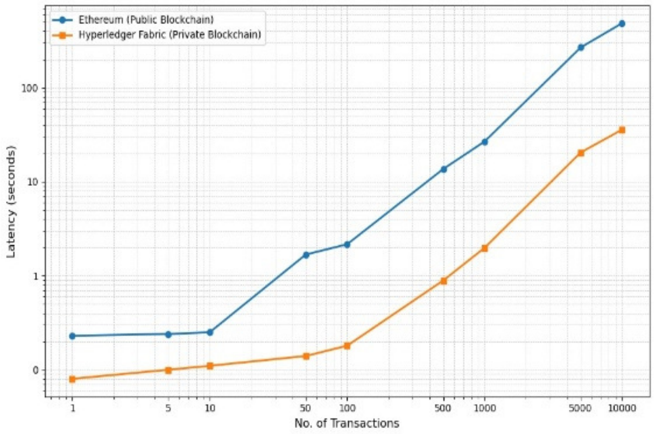

Fig. 6. Latency.

TABLE IV. PERFORMANCE COMPARISON OF HYPERLEDGER FABRIC WITH OTHER PRIVATE BLOCK CHAINS & TRADITIONAL DATABASE

Technology	**Transaction Speed (TPS)**	**Throughput (TPS)**	**Ref.**
Corda	1000	50	[20]
Quorum	800	60	[21]
MultiChain	1200	40	[22]
MongoDB + Express	200	5000	[23]
Hyperledger Fabric	300	3000	[24]

V. CONCLUSION

This study addresses the limitations of traditional centralized Clinical Trial (CT) management systems, which often suffer from inefficiencies, high operational costs, limited transparency, and risks to data integrity. To overcome these challenges, a permissioned private Blockchain architecture is proposed to enable secure, transparent, and efficient coordination among CT stakeholders while preserving data privacy through controlled access mechanisms.

The proposed framework leverages the immutability of Blockchain and the automation capabilities of smart contracts to enforce workflows, prevent data tampering, and improve system reliability. The framework supports faster regulatory review processes, reduces the drug and vaccine development lifecycle, and improves overall CT efficiency by enabling trusted data sharing and auditable records.

The primary contribution of this work lies in demonstrating a scalable, cost-effective, and regulatory-compliant private Blockchain solution applicable to real-world clinical environments. It provides a practical alternative to both public Blockchain systems and centralized databases. Future work will focus on extending the framework with digital consent mechanisms, cross-chain regulatory auditability, large-scale validation, and the integration of fairness-aware analytics.

DATA AVAILABILITY

CT records were obtained from the public repository (https://ClinicalTrials.gov) using its official API v2, including key parameters such as trial identifiers (NCT ID), study details, recruitment status, interventions, outcomes, eligibility criteria, and study design information. Each CT is associated with a unique identifier (CT ID). The subset of CT IDs used for storage within the Blockchain network is available at the provided repository link [25]. Each record is submitted as a transaction to the Hyperledger Fabric network, where it is hashed using SHA-256 and stored immutably on the Blockchain, ensuring data integrity and traceability.

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