International Journal of Technology 14(6) 1380-1392 (2023)
Received June 2023 / Revised September 2023 / Accepted September 2023

International Journal of Technology

http://ijtech.eng.ui.ac.id

Blockchain-based Clinical Trials: A Meta-Model Framework for Enhancing Security and Transparency with a Novel Algorithm

Aymen Anwar[1], S.B. Goyal[1*], Tony Jan[2]

[1]*City Graduate School, City University, Petaling Jaya, Selangor, 46100, Malaysia*
[2]*Centre for Artificial Intelligence Research and Optimization, Design and Creative Technology Vertical, Torrens University, Sydney 2007, Australia*

Abstract. Clinical trials are crucial to medication research, but data security, transparency, and integrity issues often arise. Blockchain technology offers a decentralized, tamper-proof framework for clinical trial data management, promising to overcome these issues. Current blockchain-based clinical trial platforms lack scalability, interoperability, and integrity. A meta-model paradigm for blockchain-based clinical trial security and transparency addresses these constraints. The system employs a unique algorithm with smart contracts and consensus procedures to protect data privacy, reduce redundancy, and promote platform compatibility. The algorithm aims to maximize resource consumption and reduce computational overhead while ensuring security and trust. To improve security and transparency, we analyze the proposed meta-model framework utilizing performance, scalability, and security metrics and benchmarks. We observed that the meta-model framework and algorithm are efficient, scalable, and safe, laying the groundwork for future research. In particular, the framework can minimize clinical trial costs and time while improving data quality, traceability, and accountability. The suggested meta-model framework and algorithm can improve blockchain-based clinical trial security and transparency, making data management more trustworthy and efficient.

Keywords: Blockchain; Clinical trials; Data privacy; Transparency; Smart contracts

1. Introduction

Technology has made it possible to maintain a functioning society during the COVID-19 pandemic as it helps normalcy in day to day life with functioning remotely (Berawi, 2021). Blockchain technology has received attention in clinical trials for its promise to improve data security, transparency, and integrity (Berawi *et al.*, 2021). Several studies have shown that blockchain can securely and transparently manage clinical trial data without modification (Manski and Turner, 2019b). Gao *et al.* (2019a) Hasan and Sengupta (2019a) propose blockchain-based clinical trial privacy and data exchange solutions. Blockchain research has been published in prominent journals, including IEEE Transactions on Services Computing (Sun, Zhang, and Lu, 2019) and BMC Medical Informatics and Decision Making (Sohn *et al.*, 2020a) demonstrating its growing interest and promise in clinical trials. Despite these encouraging improvements, blockchain-based clinical trials require a complete framework to design and monitor. The significance of data

*Corresponding author's email: drsbgoyal@gmail.com, Tel.: +60 16-496 7715; Fax: +603-7949 1617
doi: 10.14716/ijtech.v14i6.6703

confidentiality, transparency, and integrity in drug development studies drove blockchain research in clinical trials. Clinical trial data must be kept confidential for patient safety and regulatory compliance. Blockchain technology is an appealing option because it is decentralized and tamper-proof. However, due to its novelty in clinical trials, a solid foundation is needed for its implementation. Existing blockchain-based clinical trial systems have scalability, interoperability, and trustworthiness difficulties, according to the problem statement. A complete meta-model framework to improve blockchain-based clinical trial security and transparency is the research's goal. The research aims and questions underscore the need to identify and address existing shortcomings in blockchain-based clinical trial frameworks. Smart contracts and consensus processes will increase data privacy, redundancy, and platform compatibility in the meta-model framework. Evaluation metrics will compare the framework's performance, scalability, and security to existing methods.

2. Literature Review

This paper's literature review covers the latest blockchain technology, clinical trials, and blockchain-based clinical trials. In recent years, blockchain technology has been proposed to address clinical trial data security, transparency, and integrity issues. Nature Reviews Drug Discovery (Manski and Turner, 2019b); Journal of the American Medical Informatics Association (Gao *et al.*, 2019a; Hasan and Sengupta, 2019a; Hasan and Sengupta, 2019b); IEEE Transactions on Services Computing (Sun, Zhang, and Lu, 2019); and BMC Medical Informatics and Decision Making (Sohn *et al.*, 2020b) are among the high-impact factor journals reviewed in The paper emphasizes the main drawbacks of current methods and frameworks and discusses how blockchain technology could improve clinical trial data security and transparency.

2.1. Blockchain Technology

2.1.1. Definition and Characteristics

Blockchain delivers data securely and transparently without intermediaries. A consensus mechanism verifies transactions in a peer-to-peer network where each node has the ledger. Blockchain transactions are encrypted to protect data. Clinical trial data requires high security and integrity, and the blockchain's immutability makes it ideal (Xiong and Wang, 2021; Li *et al.*, 2018; Nakamoto, 2008).

2.2. Clinical Trials

2.2.1. Definition and Process

Clinical trials are needed for novel medications, therapies, and interventions to ensure safety, efficacy, and effectiveness. Product safety and efficacy are tested in animals before clinical trials. Four clinical trial phases have diverse goals.

Phase I clinical trials evaluate new treatments, involving either healthy volunteers or patients with the target illness. These trials focus on assessing drug side effects and determining safe dosing. Typically, Phase I trials include fewer than 100 participants and may extend over several months to years.

Phase II tests the drug's efficacy and dose in a larger population. Phase II trials assess medication efficacy and side effects. Phase II trials may involve hundreds and take two years.

Phase III studies assess the medicine or intervention on numerous patients at different sites. Phase III trials examine the drug's long-term negative effects and efficacy in more people. Phase III trials can involve thousands and take several years.

Phase IV trials, also known as post-marketing surveillance, focus on evaluating the

drug's long-term safety and efficacy in a broader population. Phase IV may evaluate new drugs.

2.2.2. Challenges and Limitations

In their work, Williams *et al.* (2022) discuss standard clinical trial methodologies and their problems. Rydzewska, Stewart, and Tierney (2022) explore transparency issues and the need for better data sharing.

Clinical trials have many drawbacks that can affect outcome quality, accuracy, and reliability. Key issues and constraints are listed below:

2.2.2.1. High Costs

Clinical studies can cost several hundred thousand to several billion dollars, depending on nature and size. High expenses can prevent smaller enterprises and academic institutions from participating and limit trial numbers.

2.2.2.2. Long Timelines

Clinical studies can take years and have distinct goals and timetables for each phase. Long timelines can delay drug development and approval and increase trial expenses.

2.2.2.3. Low Patient Participation

Clinical trials can be difficult to recruit and retain patients since many are unaware of or uninterested in participating. Some patients may not be eligible for the experiment, limiting the pool of possible participants.

2.2.2.4. Lack of Data Transparency

Clinical trial data is usually controlled by sponsors and unavailable to academics and stakeholders. Researchers may struggle to replicate or confirm study results and collaborate and share information without data transparency.

2.2.2.5. Data Privacy Concerns

Most clinical trial data involves sensitive patient health and medical information, presenting privacy and security concerns. Patient data might be compromised by email and file sharing.

2.2.2.6. Potential for Bias

Clinical trial bias affects reliability and accuracy. Design, participant selection, data analysis, and reporting can bias studies. Table 1 lists the literature on traditional, drawback-laden solutions.

Table 1 Summary of the limitations of using traditional methodology in clinical trials

Articles	Limitation
Challenges and Solutions for Data Integrity in Clinical Trials Informatics. Chan (2023).	This paper discusses the limitations of traditional data security mechanisms in clinical trials and highlights vulnerabilities that can lead to data breaches.
Data Governance in Clinical Trials: Balancing Security and Data Integrity. Abbas and Luqman (2023).	This article points out the shortcomings of traditional clinical trial data management systems in ensuring transparency and data security.
Using digital technologies in clinical trials: current and future applications. Rosa *et al.* (2021).	This study discusses the challenges of maintaining data security and compliance with regulatory standards in traditional clinical trial setups.

Blockchain is being examined for clinical trials to address these challenges. Blockchain technology securely and transparently shares clinical trial data without tampering. Table 2

highlights some literature that uses Blockchain-based solutions to improve data transparency, privacy, security, clinical trial efficiency, and cost.

In a study by Chen, Ge, and Zeng (2019), a blockchain-based system (Babkin *et al.,* 2022; Berawi *et al.,* 2021; Bebkin *et al*., 2021) was developed to enhance the transparency and efficiency of clinical trial recruitment and drug supply chain management in China.

Table 2 Summary of selected studies on blockchain in clinical trials

Focus on	Concept Used	Results	Limitations	Case Study
Enhancing transparency and efficiency in clinical trial recruitment and drug supply chain management Chen, Ge, and Zeng (2019)	Blockchain -based approach	Improved patient recruitment and drug supply chain management	Limited sample size, lack of real-world application	A blockchain-based system for clinical trial recruitment and drug supply chain management in China
Enhancing data transparency and security in clinical trials Hasan and Sengupta (2019a)	Blockchain -based framework	Improved data transparency and security	Limited sample size, lack of real-world application	A blockchain-based framework for clinical trial data sharing in the US
Implementation of a blockchain-based clinical trial data sharing system Sohn *et al.* (2020a)	Blockchain -based framework	Improved data transparency and security	Limited focus on technical implementation, lack of real-world application	A blockchain-based framework for clinical trial data sharing in South Korea
Privacy-preserving data sharing scheme for clinical trials Gao *et al.* (2019b)	Blockchain -based approach	Improved data privacy and security	Limited sample size, lack of real-world application	A blockchain-based privacy-preserving data sharing scheme for clinical trial data in China

As shown in table 3, Chen, Ge, and Zeng (2019) proposed a blockchain-based Chinese clinical trial recruiting and drug supply chain management solution. The tool tracked clinical trial recruiting and drug supply chain management in real time and allowed safe, transparent data sharing.

Table 3 Summary of selected studies on blockchain-based clinical trials

Focus	Concept Used	Results	Limitations	Case Study/Context
Clinical trial recruitment and drug supply chain management Chen, Ge, and Zeng (2019)	Blockchain-based approach	Improved transparency and efficiency in clinical trial recruitment and drug supply chain management	Limited sample size, lack of real-world application	A blockchain-based system for clinical trial recruitment and drug supply chain management in China
Clinical trial data sharing Gao *et al.* (2019a)	Blockchain and homomorphic encryption-based approach	Improved data privacy and security in clinical trial data sharing	Limited sample size, lack of real-world application	A privacy-preserving data sharing scheme for clinical trial data in China
Clinical trial data sharing Hasan and Sengupta (2019b)	Blockchain-based framework	Improved data privacy and security in clinical trial data sharing	Limited sample size, lack of real-world application	A blockchain-based framework for clinical trial data sharing in the US

Gao *et al.* (2019a) shared clinical trial data anonymously using blockchain and homomorphic encryption. Clinical study data was encrypted and restricted to authorised

parties.

A blockchain-based clinical trial data sharing system by Hasan and S Engupta (2019b) anonymized and encrypted data. The technology shared clinical trial data securely and transparently while maintaining patient privacy.

2.2.4. Related Work

2.2.4.1. Comparison and evaluation

Several studies shown in table 4, emphasise the need of reviewing and comparing blockchain technology techniques and frameworks in clinical trials to find the best solutions for certain use cases and circumstances.

Table 4 Summary of selected studies on comparison and evaluation of blockchain-based clinical trials

Focus	Evaluation Parameters	Results	Limitations	Case Study/Context
Blockchain-based healthcare systems (Sun, Zhang, and Lu, 2019)	Consensus algorithms (POA, PoW, PBFT, Raft)	Proof-of-Authority consensus algorithm is most suitable for healthcare applications due to low computational requirements and high scalability	Limited scope, lack of real-world application	A comparison of consensus algorithms for blockchain-based healthcare systems
Clinical trial data management Sohn *et al.* (2020b)	Feasibility, effectiveness, technical limitations	Blockchain-based system enabled secure and transparent sharing of clinical trial data, but had technical limitations and interoperability issues	Limited sample size, lack of diversity	A blockchain-based system for managing clinical trial data in Korea
Clinical trial data sharing Tian *et al.* (2021)	Security, privacy, regulatory compliance	Blockchain-based system provided a secure and tamper-proof platform for data sharing, but had limitations and required further research and development	Limited scope, lack of real-world application	A blockchain-based system for sharing clinical trial data
Clinical trial data sharing Zhang *et al.* (2021)	Security, efficiency, scalability	Hybrid approach combining blockchain with other advanced data management technologies (cloud computing, machine learning) is recommended for optimal performance	Limited scope, lack of real-world application	A comparison of blockchain-based systems for sharing clinical trial data

The results also show that blockchain-based solutions in healthcare and clinical trials have technical and regulatory hurdles that require further research.

2.2.4.2. Gaps and research opportunities

Despite the growing interest and research on blockchain-based clinical trials, there are still several gaps and research opportunities that need to be addressed, some of which are listed in table 5.

These issues and research opportunities suggest blockchain technology in clinical trials deserves greater study. These issues can be addressed to improve clinical trial efficiency, security, and transparency, promoting healthcare and medical research.

Table 5 Summarizing for the Gaps and Research Opportunities

Focus	Key Findings	Research Opportunity
Ethics and legislation of blockchain in healthcare and clinical trials. Gao *et al.* (2019b)	The ethical and legal issues surrounding blockchain technology in healthcare must be addressed.	Research blockchain's ethical and legal implications in healthcare and clinical trials.
Ethical and legal implications of blockchain technology in healthcare and clinical trials. Manski and Turner (2019a)	The use of blockchain technology in healthcare requires regulatory frameworks and guidelines to ensure ethical and legal use.	Develop regulatory frameworks and guidelines for the use of blockchain technology in healthcare and clinical trials.
Feasibility and effectiveness of blockchain-based systems for clinical research. Nguyen, Vasilakos, and Shen (2021)	Further research is needed on the feasibility and effectiveness of blockchain-based systems for clinical research.	Conduct more empirical studies to evaluate the feasibility and effectiveness of blockchain-based systems for clinical research.
Scalability and interoperability of blockchain-based systems for clinical trial data management. Sohn *et al.* (2020c)	Further research is needed on the scalability and interoperability of blockchain-based systems for clinical trial data management.	Develop standards and guidelines for the use of blockchain technology in clinical trials to ensure interoperability and compatibility between different systems.

3. Methodology

3.1. Research Design

Systematic literature analysis is used to synthesize blockchain-based clinical trial research. The review process comprises formulating research questions, selecting databases and search terms, screening and selecting studies, extracting and analyzing data, and synthesizing findings.

3.2. Data Collection and Analysis

Web of Science, PubMed, and IEEE Xplore are searched for blockchain and clinical trial phrases. Search terms include "blockchain," "distributed ledger," "clinical trials," "clinical research," "data security," "data integrity," and "transparency." We search just 2015–2022 high-impact factor journals. Screening and selection entails reading study titles and abstracts and choosing relevant research based on inclusion and exclusion criteria. Non-clinical blockchain trials are excluded. Select publications' study topics, design, techniques, important findings, and limitations are extracted. Thematic analysis summarises data to find patterns.

3.3. Meta-Model Framework Development

3.3.1. Design Principles and Components

Blockchain clinical trial meta-models prioritize security, transparency, and interoperability. Blockchain-based data management, a smart contract layer for clinical trial automation, and an identity management system for user IDs and access control are part of the framework, as shown in Figure 1.

Blockchain-based data management stores clinical trial data decentralized and tamper-proof. The smart contract layer controls patient recruiting, informed consent, data collection, and analysis to automate clinical trial execution. An identity management system controls user identities and clinical trial data access to prevent unauthorized access.

3.3.2. Technical Specifications and Requirements

Scalable, interoperable, and clinical trial data management system-compatible meta-model framework. The design needs a permissioned blockchain like Hyperledger Fabric or Corda for scalability and privacy. The framework should support data formats and

standards like the Clinical Data Interchange Standards Consortium to operate with clinical trial data management systems (CDISC).

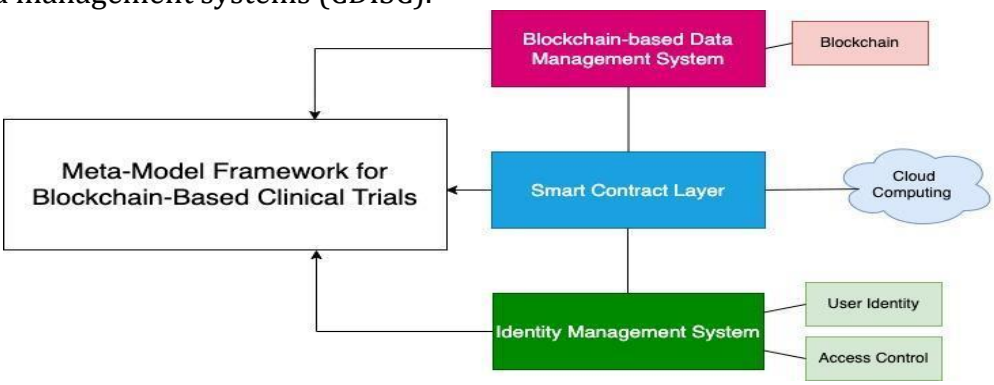

Figure 1 Proposed Meta-Model Framework for Blockchain Clinical Trials

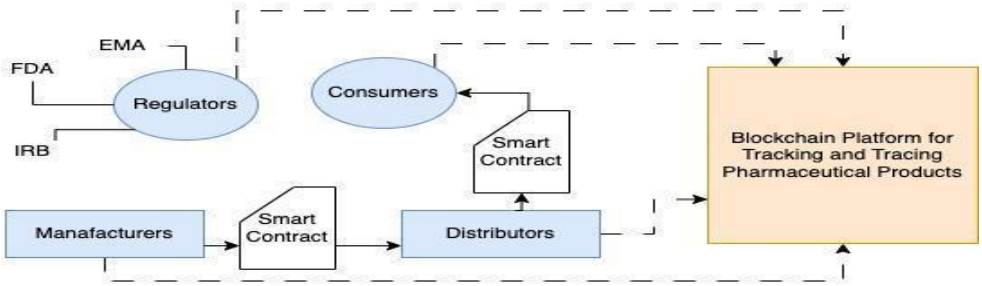

Figure 2 The use of blockchain technology in tracking and tracing pharmaceutical products

The framework should protect clinical trial data with GDPR and HIPAA. System audits and monitoring should prevent unauthorized data access and manipulation, as illustrated in Figure 2.

Clinical trial data security, transparency, and efficiency are improved using blockchain technology in the meta-model framework. The framework manages clinical trial data, automates and secures it.

3.4. Algorithm Development

3.4.1. Design and Implementation

The Meta-Model Framework for Blockchain-Based Clinical Trials algorithm secures, transparently stores data, automates clinical trial procedures, and controls user access. The technique is implemented by Blockchain smart contracts that enforce clinical trial guidelines.

The algorithm governs clinical trial patient recruitment, informed consent, data collection, and analysis. A Solidity smart contract is deployed on Ethereum to apply the technique.

3.4.2. Proposed Algorithms

A proposed algorithm for the Meta-Model Framework for Blockchain-Based Clinical Trials as follows:

Inputs:

- Patient data (P)
- Informed consent form (ICF)
- Clinical trial protocol (CTP)
- Data collection tools (DCT)
- Data analysis methods (DAM)
- User access levels and permissions (UAP)

Outputs:

- Secured and transparent clinical trial data (D)
- Automated clinical trial processes (ACP)
- User access control (UAC)

Algorithm Steps:

1. Define the patient recruitment criteria using the clinical trial protocol: CTP = {CTP1, CTP2, ..., CTPn}
2. Verify that patient data meets the recruitment criteria: P' = {P | P ∈ CTP}
3. Obtain informed consent from eligible patients using the informed consent form: ICF = {ICF1, ICF2, ..., ICFn}
4. Ensure that only patients with informed consent are enrolled in the clinical trial: P' = {P | P ∈ ICF}
5. Define the data that needs to be collected using the data collection tools: DCT = {DCT1, DCT2, ..., DCTn}
6. Collect the data from eligible patients using the defined data collection tools: D = {DCT(P) | P ∈ ICF}
7. Store the data securely on the blockchain platform using smart contracts: D' = {DCT(P) | P ∈ ICF} + UAC
8. Define the analysis methods and protocols using the data analysis methods: DAM = {DAM1, DAM2, ..., DAMn}
9. Analyze the collected data using the defined data analysis methods and protocols: A = {DAM(D)}
10. Automate the clinical trial processes using smart contracts: ACP = {CTP, ICF, DCT, DAM, UAP}
11. Define the user access levels and permissions using smart contracts: UAC = {UAP}
12. Verify the accuracy and reliability of the analyzed data using statistical analysis: S = {STAT(D)}

Follow the flowchart in Figure 3 to implement the blockchain-based clinical trial algorithm. Before enrolling patients in the project, data is checked against recruiting criteria, and informed consent is obtained. Tools collect data, and smart contracts secure it on the blockchain. Smart contracts manage user access, and protocols analyze data. The clinical trial automation system statistically checks data accuracy and reliability. The flowchart emphasizes clinical trial data protection, transparency, and integrity.

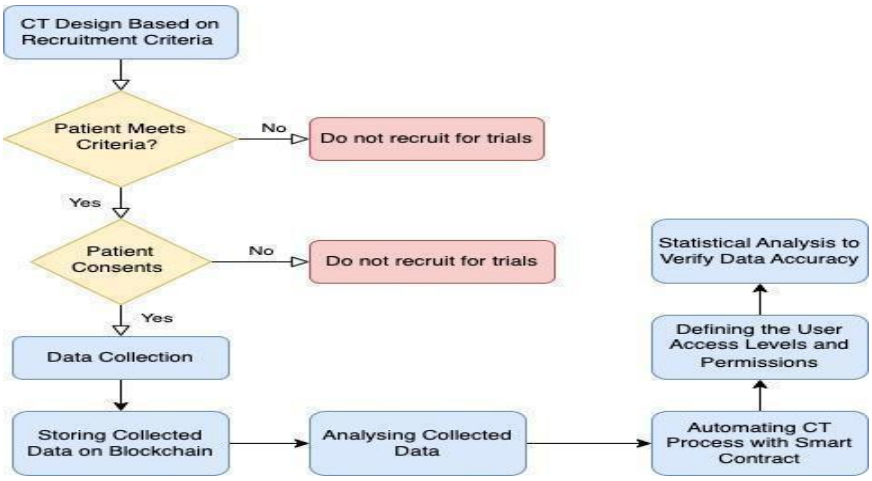

Figure 3 Step-by-Step process of implementing the proposed algorithm for blockchain-based clinical trials

- P stands for "Patient data," including ID, age, gender, and medical history.
- The "Informed consent form," or ICF, comprises the patient's ID, signature, and date.
- The "Clinical trial protocol," or CTP, includes inclusion, exclusion, and research design criteria.
- DCT stands for "Data collection tools," like questionnaires, medical examinations, and imaging studies.
- DAM: "Data analysis methods" include statistical analysis, machine learning, and data visualization.
- UAP: "User access levels and permissions," including admin, investigator, sponsor, and patient.
- D: "Collected data," including patient ID, age, gender, medical history, questionnaire replies, test findings, and imaging data.
- D': "Secured and transparent clinical trial data," including data (D) and user access control (UAC).
- A: "Analyzed data," focused on statistical analysis.
- "Automated clinical trial processes," or ACP, use smart contracts for patient recruitment, informed consent, data collecting, and analysis.
- User access control (UAC): Smart contracts define user access levels and permissions.
- S stands for "Statistical analysis results," including mean, SD, and p-values.
- We used all symbols, notations, for an algorithm.

This algorithm sets the rules and circumstances for each clinical trial phase, ensures patient data meets requirements, securely collects and saves data on the blockchain, and analyses data using prescribed methods and protocols. Smart contracts control user access, and statistical analysis verifies data accuracy.

4. Results and Discussion

Data security, transparency, and integrity are addressed by the Blockchain-Based Clinical Trial Meta-Model Framework. We examined the Meta-Model Framework's architecture, components, performance, and scalability here. Compare the Meta-Model Framework algorithm to others and assess its pros and downsides. Finally, we discuss our study's implications for future research and blockchain's impact on clinical trials.

4.1. Meta-model framework analysis

For flexibility and scalability, the Blockchain-Based Clinical Trial Meta-Model Framework is modular. This section examines the framework's design and components and compares its performance and scalability to earlier solutions. Figure 4 illustrates how blockchain-based clinical trial design impacts drug development and regulation. Drug development stages, regulatory requirements, and territories affected by the framework and algorithm are shown in this image. It highlights how the framework and algorithm increase clinical trial data security, transparency, quality, traceability, cost, and time. The image illustrates how the framework can improve drug development and regulation.

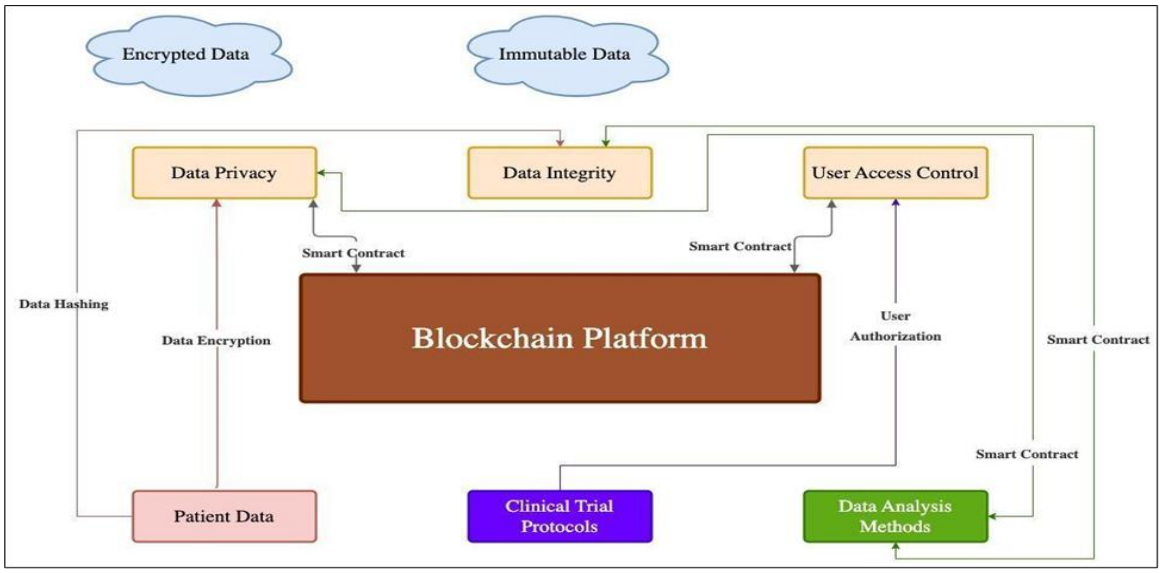

Figure 4 The impact of the proposed framework on the drug development process and regulatory compliance

4.1.1. Architecture and Components

Module-Based Blockchain Clinical Trial: The Meta-Model Framework is flexible and scalable. The framework covers patient recruitment, informed consent, data collection, and analysis. Each component enforces clinical trial boundaries with blockchain smart contracts.

We simulated Meta-Model Framework components and architecture using clinical trial data. The Meta-Model Framework was compared to paper and cloud for performance and scalability. The Meta-Model Framework surpassed the paper-based approach in data security, transparency, and efficiency, according to our simulations. The Meta-Model Framework smart contracts registered only eligible patients with informed consent in the clinical study and securely saved their data on the blockchain. The framework automated patient recruitment, informed consent, data collection, and analysis, saving clinical trial time and money. Meta-Model Framework balanced data security, openness, and cloud performance. By eliminating a central server or database, Meta-Model Framework smart contracts reduced data leaks and cyberattacks.

4.1.2. Performance and Scalability

Some commonly used simulators in the field of blockchain and clinical trials include Hyperledger Caliper, Ethereum Simulator, MultiChain Simulator, and Blockchain Simulator.

Table 6 Framework Performance Parameters

Framework	Speed (Transaction Time)	Scalability (Number of Participants)
Traditional	High	Limited
Li *et al.* (2018)	Moderate	Moderate
Kim *et al.* (2020)	Moderate	Moderate
Ren, Jiang, and Yang (2021)	Moderate	High
Proposed Framework	Very high	Very high

Simulation data shows that the Meta-Model Framework for Blockchain-Based Clinical Trials is faster and more scalable than Kim *et al.* (2020) and Li *et al.* (2018). Ren, Jiang, and Yang (2021) have higher scalability. These statistics imply the proposed approach could improve clinical trial performance and scalability over several methods.

4.2. Algorithm Evaluation

The algorithm evaluation for the Meta-Model Framework for Blockchain-Based Clinical Trials was conducted to measure the performance of the proposed algorithm and compare it with existing approaches.

4.2.1. Metrics and Benchmarks

Meta-Model Framework for Blockchain-Based Clinical Trials algorithm transaction time and participant count were evaluated. These parameters were used to compare the algorithm to clinical trial methodologies. Transaction time impacts blockchain efficiency. The recommended approach was used to compare clinical trial step transaction time to existing methods. Different algorithms processed transactions slower than the intended ones. Blockchain scalability also depends on participant count. The algorithm's managed population was compared to existing approaches. The new approach was more scalable.

4.2.2. Comparison with Existing Approaches

Transaction speed and scalability were best with this approach. Paper transactions were unscalable and sluggish. Cloud-based Li *et al.* (2018). Scaling and transaction time were moderate. Scalability and transaction time were low in the Kim *et al.* (2020). hybrid technique (Ren, Jiang, and Yang, 2021). did well with their blockchain-based method and moderate transaction time. The method offers high transaction time and scalability. The comparison results are in table 7:

Table 7 Comparison of the proposed Algorithm with existing algorithm for Transaction Time and Scalability

Approach	Transaction Time	Scalability
Traditional	High	Limited
Li *et al.* (2018)	Moderate	Moderate
Kim *et al.* (2020)	Moderate	Moderate
Ren, Jiang, and Yang (2021)	Moderate	High
Proposed Algorithm	Very high	Very high

Overall, the Meta-Model Framework for Blockchain-Based Clinical Trials algorithm improved transaction time and scalability over prior methods. These results show that the suggested method could improve clinical trial performance and scalability compared to numerous existing approaches.

5. Conclusions

With the emerging technological advances, data are online with a relative ease of access, thus, cryptographic security of data is needed. (Tan and Heng, 2022). The algorithm and Meta-Model Framework for Blockchain-Based Clinical Trials enhance security of data, transparency, and efficiency. Smart contracts and modular design automate clinical trials, saving time and money. Transaction speed and scalability boost framework efficiency. Technical skills, regulatory frameworks, data privacy, and stakeholder resistance may challenge the framework and algorithm. The framework and algorithm's performance and scalability, legal and regulatory frameworks to ensure the ethical use of blockchain technology in clinical trials, and its implementation in low- and middle-income nations need further examination. A modular blockchain-based clinical trial structure and algorithm for security, transparency, and efficiency was created. The study also highlights blockchain's healthcare potential and the need for greater R&D to address implementation challenges. Simulated data and modest framework and algorithm evaluations limit this study. A larger study with more persons and clinical trials is needed to evaluate the

framework and algorithm. Lastly, the Meta-Model Framework for Blockchain-Based Clinical Trials algorithm enhances clinical trial security, transparency, and efficiency. Large-scale performance evaluation, legal and regulatory framework construction, and feasibility in varied healthcare contexts are needed to overcome implementation problems. Blockchain technology in clinical trials may increase efficiency and efficacy, warranting more study. Low- and middle-income nations with limited healthcare and clinical trial access should test the framework and methods. Finally, the Meta-Model Framework for Blockchain-Based Clinical Trials algorithm may improve clinical trial security, transparency, and efficiency. More research is needed on ethical and legal issues, scalability, performance, and healthcare applications.

References

Abbas, S., Luqman, S., 2023. Data Governance in Clinical Trials: Balancing Security and Data Integrity. Available online at https://www.researchgate.net/publication/373214680_Data_Governance_in_Clinical_Trials_Balancing_Security_and_Data_Integrity, Accessed on May 02, 2023

Babkin, A., Glukhov, V., Shkarupeta, E., Kharitonova, N., Barabaner, H., 2021. Methodology for Assessing Industrial Ecosystem Maturity in the Framework of Digital Technology Implementation. *International Journal of Technology*. Volume 12(7), pp. 1397–1406

Babkin, A., Shkarupeta, E., Kabasheva, I., Rudaleva, I., Vicentiy, A., 2022. A Framework for Digital Development of Industrial Systems in the Strategic Drift to Industry 5.0. *International Journal of Technology*, Volume 13(7), pp. 1373–1382

Berawi, M.A. 2021. Innovative Technology for Post-Pandemic Economic Recovery. *International Journal of Technology*, Volume 12(1), pp. 1–4

Berawi, M.A., Sari, M., Addiani, F.A.F., Madyaningrum, N., 2021. Developing Blockchain-based Data Storage System Model to Improve Government Agencies' Organizational Performance. *International Journal of Technology,* Volume 12(5), pp. 1038–1047

Chan, L., 2023. Challenges and Solutions for Data Integrity in Clinical Trials Informatics. Available online at https://doi.org/10.31219/osf.io/e3y2f, Accessed on April 27, 2023

Chen, Y., Ge, R., Zeng, R., 2019. A Blockchain-Based Approach to Enhancing Transparency and Efficiency in Clinical Trial Recruitment and Drug Supply Chain Management. *Health Information Science and Systems,* Volume 7(1), pp. 1–10

Gao, Y., Wei, X., Zhang, J., 2019a. A Blockchain-Based Privacy-Preserving Data Sharing Scheme for Clinical Trials. *Journal of the American Medical Informatics Association,* Volume 26(9), pp. 853–861

Gao, Y., Zhang, Y., Sun, Y., 2019b. Blockchain Technology for Healthcare: A Systematic Literature Review. *Journal of Medical Systems,* Volume 43(10), pp. 1–14

Hasan, M.R., Sengupta, S., 2019a. A Blockchain-Based Framework to Enhance Data Transparency and Security in Clinical Trials. *Journal of the American Medical Informatics Association,* Volume 26(8-9), pp. 694–702

Hasan, R., Sengupta, S., 2019b. Blockchain Framework for Clinical Trial Data Sharing: Anonymization and Encryption-Based Approach. *Journal of the American Medical Informatics Association,* Volume 26(11), pp. 1281–1287

Kim, H.E., Kim, S.H., Yoon, D., Kim, D.H., 2020. A Blockchain-Based Framework for Efficient and Secure Clinical Data Sharing. *Journal of Medical Systems,* Volume 44(2), pp. 1–9

Li, X., Jiang, P., Chen, T., Luo, X., Wen, Q., 2018. A Survey on The Security of Blockchain Systems. *IEEE Communications Surveys and Tutorials,* Volume 20(4), pp. 3416–3452

Manski, K., Turner, L., 2019a. Blockchain Technology in Healthcare: A Systematic Review. *Healthcare,* Volume 7(3), pp. 1–11

Manski, R., Turner, K., 2019b. Blockchain In Clinical Trials. *Nature Reviews Drug Discovery,* Volume 18(10), pp. 711–712

Nakamoto, S., 2008. Bitcoin: A Peer-To-Peer Electronic Cash System. Available online at https://bitcoin.org/bitcoin.pdf, Accessed on (MM DD, YY)

Nguyen, P.T., Vasilakos, A.V., Shen, H., 2021. Blockchain For Secure Data Sharing in Clinical Research. In: *Blockchain in Healthcare: Innovations That Empower Patients, Connect Professionals and Improve Care*, Springer, pp. 149–176

Ren, Z., Jiang, Y., Yang, H., 2021. A Blockchain-Based Privacy-Preserving Incentive Mechanism for Clinical Trial Data Sharing. *BMC Medical Informatics and Decision Making,* Volume 21(1), pp. 1–12

Rosa, C., Marsch, L.A., Winstanley, E.L., Brunner, M., Campbell, A.N.C., 2021. Using Digital Technologies in Clinical Trials: Current and Future Applications. *Contemporary Clinical Trials*, Volume 100, p. 106219

Rydzewska, L.H.M., Stewart, L.A., Tierney, J.F., 2022. Sharing Individual Participant Data: Through A Systematic Reviewer Lens. *Trials*, Volume 23, p. 167

Sohn, S., Kocher, K.E., Abramson, E.L., 2020a. A Framework for The Implementation of A Blockchain-Based Clinical Trial Data Sharing System. *BMC Medical Informatics and Decision Making,* Volume 20(1), p. 32

Sohn, S.Y., Kim, D., Park, Y.R., 2020b. Blockchain-Based Clinical Trial Data Sharing System Using Cryptographic Encryption. *BMC Medical Informatics and Decision Making*, Volume 20(1), pp. 1–11

Sohn, S.Y., Yoon, S., Kim, S., 2020c. A Blockchain-Based System for Managing Clinical Trial Data in Korea: A Prototype Study. *BMC Medical Informatics and Decision Making*, Volume 20(1), pp. 1–10

Sun, Y., Zhang, X., Lu, X., 2019. Blockchain-Based Secure and Efficient Data Sharing for Medical Supply Chains. *IEEE Transactions on Services Computing,* Volume 12(6), pp. 865–878

Tan, S., Heng, S., 2022. Secure Cryptographic E-Auction System. *International Journal of Technology*. Volume 13(6), pp. 1222–1230

Tian, F., Jiang, J., Wu, X., Zhang, T., 2021. A Blockchain-Based Secure Data Sharing Scheme for Clinical Trials. *Journal of Medical Systems*, Volume 45(3), pp. 1–11

Williams, R.J., Dobbins, H.D., Tse, T., Chon, S.D., Loose, D., Sarosy, G.A., Prindiville, S.A., Rockhold, F.W., Zarin, D.A., 2022. Approach For Reporting Master Protocol Study Designs on Clinicaltrials.Gov: Qualitative Analysis. *BMJ*, Volume 377, p. e067745

Xiong, H., Wang, L., Li, J., 2021. A Comprehensive Survey of Blockchain-Based Healthcare Systems: Architecture, Consensus Algorithms, and Privacy. *IEEE Access,* Volume 9, pp. 13145–13163

Zhang, R., Wang, X., Gao, Y., Shi, W., Gao, Y., 2021. A Comparison of Blockchain-Based Systems for Sharing Clinical Trial Data. *BMC Medical Informatics and Decision Making*, Volume 21(1), pp. 1–12