Review Article

ClinicalPractice

# Collaboration and construction in rehabilitation process management big data using block chain technology


## Abstract

This comprehensive exploration delves into the intersection of block chain technology and the management of medical data, with a particular focus on clinical trials, precision medicine, and the broader healthcare domain. This ongoing project, based at Asia university in Taiwan, seeks to address multiple challenges in the healthcare field. The paper first introduces block chain as a distributed ledger technology that facilitates secure, transparent, and tamper-resistant transactions through decentralized collaboration. It emphasizes the immutability of data once recorded in the block chain and highlights the role of smart contracts in managing digital assets. A key focus is on the potential applications of block chain in the medical field. The authors emphasize the need for secure, time stamped, and immutable medical records, accessible and controllable by individuals across healthcare providers. They discuss the importance of data integration, integrity, privacy, and security in the healthcare domain and propose block chain as an effective solution.


**Keywords: Blockchain, Rehabilitation, Precision medicine, Data integrity, Identity privacy, Big data analytics, IoT**

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## Introduction

This paper provides a concise overview of an ongoing project at Asia university, Taiwan, involving over 30 researchers. The project's focus lies in the development of a block chain platform tailored to the medical domain, with specific applications in clinical trials and precision medicine. Within this scope, we briefly delineate the project's objectives, methodologies, challenges, and system design concepts. The healthcare industry, including clinical trials and precision medicine, confronts unique challenges and opportunities that can be significantly impacted by emerging technologies like block chain. Consequently, this research highlights several key areas of technology challenges and potential research avenues for utilizing block chain in healthcare applications. Furthermore, we outline the methodologies and approaches employed to construct clinical trial and precision medicine applications atop the envisioned block chain platform. These applications aim to support healthcare researchers in tackling critical clinical and precision medical issues while contributing to the enhancement of medical decision-making processes [1]. The ultimate goals of this endeavor are two fold: Firstly, to empower researchers in effectively addressing clinical and precision medical challenges, and secondly, to facilitate research that leads to more cost-effective healthcare solutions. By exploring and integrating diverse datasets encompassing diseases, drugs, and clinical practices, we aspire to drive down healthcare expenses while simultaneously providing superior preventive, curative, and post-treatment care. This endeavor exemplifies the potential of block chain technology to transform rehabilitation process management and improve patient care outcomes.

In the realm of modern technology, block chain stands as a transformative force, revolutionizing the way transactions are conducted and trust is established across the vast landscape of the internet. Unlike traditional systems reliant on central authorities for transaction validation, block chain leverages a distributed and parallel computing mechanism, underpinned by a decentralized ledger. At its core, block chain relies on the principle of trust forged through extensive peer-to-peer collaboration and the execution of smart contract code. This paradigm shift renders centralized intermediaries obsolete in the realm of transaction settlement. Once a transaction is etched into the annals of the block chain's distributed ledger, it becomes immutable and irrefutable. This immutability assures the integrity of recorded transactions, engendering an unparalleled level of trust and transparency in the digital landscape. Crucially, block chain also introduces the concept of smart contracts, which serve as dynamic digital agreements executed automatically by program code. These contracts govern the ownership and management of digital assets, imbuing them with a level of autonomy and security previously unattainable. Within the context of our paper, “Collaboration and construction in rehabilitation process management: Big data using block chain technology,” we delve into the application of block chain in healthcare, particularly in the rehabilitation process. By harnessing the power of block chain, we aim to foster collaboration among stakeholders, enhance efficiency, leverage big data analytics, and contribute to a global transformation in healthcare management. This paper represents a step toward realizing the potential of block chain in revolutionizing rehabilitation process management. Block chain technology has found intriguing use cases within the realm of distributed and parallel computing. For instance, noteworthy examples include FoldingCoin, an initiative stemming from Stanford University, and GridCoin, developed by UC Berkeley. These endeavors have introduced innovative concepts like “Proof of Fold” and “Proof of Research” to assess the computational contributions of block chain nodes [2].

In this unique paradigm, participants allocate their computing resources to support medical research on the block chain network, diverging from the traditional “Proof of work” or “Proof of stake” tasks seen in conventional block chains. UC Berkeley has engineered a dedicated block chain infrastructure to operate GridCoin, while Stanford has integrated FoldingCoin with the Folding at home platform. The latter runs on top of the existing Bitcoin network, boasting a vast network of participant nodes collectively delivering formidable computing power, typically ranging from 80 to 100 petaFLOPS, predominantly for protein folding research. Both FoldingCoin and GridCoin epitomize the potential of block chain in grid computing, underpinning similar block chain-based distributed computing paradigms. Our research endeavors to delve deeper into these concepts, aiming to explore more comprehensive mechanisms for distributed and parallel big data analytics facilitated by block chain networks. This paper offers a concise exploration of various facets and offers valuable insights into the conceptualization of a block chain platform meticulously tailored to meet the intricate technological needs encompassing big data integration, data integrity, secure data storage, safeguarding identity privacy, ensuring data access security, fostering trust in data sharing and collaboration, seamlessly integrating the Internet of Things (IoT), facilitating comprehensive big data analytics, and enabling distributed and parallel computing [3].

Given that each application domain brings forth its unique circumstances and prerequisites, our research embarks on the design of a versatile block chain platform, commencing with the healthcare sector, specifically focusing on clinical trials and precision medicine. In the healthcare industry, the management of vast volumes of disparate medical records is imperative for delivering enhanced healthcare solutions, expediting the insurance claims process, and fortifying data against the looming threat of cybercrime. Consequently, harnessing the capabilities of block chain technology to forge a secure data-sharing ecosystem founded on trust and collaboration emerges as an enticing and pragmatic approach to address these pressing challenges. The ability to securely capture and store an individual’s complete health history, including every medical visit and related data, on a block chain has the potential to revolutionize personal healthcare. In this block chain-based system, each data event is meticulously time-stamped and rendered immutable, ensuring it remains untampered with. What’s even more promising is the notion that every individual can have control over their own medical data. They can access their records across various healthcare providers and exercise the authority to decide which physicians can access specific portions of their medical history [4].

As the diversity of medical data collected continues to expand, concerns about privacy and data access control are on the rise. In the pursuit of safeguarding patient privacy, the technology underpinning medical data capture and analysis faces significant challenges. Block chain technology, distinguished by its security features, privacy safeguards, distributed architecture, parallel computing capabilities, and robust backup mechanisms, emerges as a promising solution to overcome these challenges. This paper delves into the intricate domain of anonymous identities authentication, underpinned by cutting-edge Zero knowledge technology. This approach serves to address the critical issue of identity privacy. The primary aim is to conceal a patient’s identity within the medical block chain while ensuring that the legitimacy of their identity can be systematically verified. This innovative authentication mechanism is also extendable to the realm of the Internet of Things (IoT), where it can obscure IoT device identities while simultaneously verifying their legitimacy. Furthermore, this technology allows for the granular assignment of permissions for patient data, granting control over who can access specific patient information [5]. Within the IoT environment, similar principles can be applied, enabling IoT devices to determine which applications have access to their sensor data. In sum, the paper explores how block chain technology, combined with sophisticated identity privacy mechanisms, can establish a secure and privacy-centric foundation for the future of healthcare data management and analysis.

In the realm of scientific research, a prevailing issue is the erosion of trust due to the frequent manipulation of data.

To mitigate this problem, we aim to explore and develop an automated block chain mechanism designed to prevent the surreptitious alteration of clinical trial data. This innovation not only acts as a safeguard but also enables researchers to swiftly verify the integrity of data presented in medical journals. Additionally, we delve into the profound potential of block chain smart contracts, which serve as robust tools to enhance the security and privacy of medical data. These smart contracts also facilitate seamless data sharing and collaborative mechanisms within research teams. When data enjoys a foundation of trust and protection, collaboration thrives, and the immense value of shareable and secure Electronic Health Records (EHRs) becomes evident. Drawing insights from IBM's healthcare block chain study report, which estimates substantial savings, particularly in the United States, sharing data across healthcare organizations could potentially save hospitals a staggering USD 93 billion over five years alone [6].

## Literature Review

This paper embarks on a comprehensive exploration of techniques for data sharing and exchange on the block chain. Within the block chain network, various nodes can be organized into distinct groups. Only nodes within authorized groups can access user data based on the user's predefined permissions. Furthermore, we delve into the mechanisms that facilitate the exchange of information across different groups, especially in scenarios where the exchange of Electronic Health Records (EHRs) is paramount across diverse entities and institutions.

This study represents an ambitious endeavor at the convergence of block chain technology and big data, with the overarching goal of seamlessly integrating clinical data and health information records from two prominent institutions, the Chinese Medicine University Hospital and Asia University Hospital in Taiwan, alongside data from the Taiwan national health insurance database. By leveraging block chain for the secure and private storage and management of medical data, this research aims to establish an ecosystem of trust within the healthcare domain. Such trust serves as a foundational element for the creation of a collaborative medical data sharing ecosystem, with the additional benefit of advancing big data analytics for more precise disease prevention [3].

The noteworthy contributions of this paper can be summarized as follows:

**Block chain platform proposal:** We introduce a block chain platform that extends the capabilities of the traditional block chain network to achieve properties conducive to trust-based transactions in the realms of clinical trials and precision medicine. This platform encompasses various design aspects and offers insights into the requisite technology, while addressing the associated challenges.

**Block chain platform architecture:** We outline a comprehensive block chain platform architecture, identifying four new system components and their associated technology challenges. These components include:

**Block chain based parallel computing:** A novel component geared towards devising and exploring parallel computing in the context of big data analytics.

**Block chain application data management:** A crucial element focused on ensuring data integrity, facilitating the integration of diverse medical data, and managing data disparities.

**Verifiable anonymous identity management:** An integral part of the architecture designed to safeguard identity privacy, encompassing IoT devices and secure data access. This component lays the foundation for patient-centric medicine.

**Trust data sharing management:** A vital component aimed at establishing a trustworthy medical data ecosystem that encourages collaborative research.

**Clinical trial and precision medicine:** We delve into the methodologies and approaches pertinent to clinical trials and precision medicine, both of which serve as compelling use cases for the proposed block chain platform. In simple terms, this study embarks on an exciting journey to explore the immense potential of combining block chain and big data in healthcare. We're not just stopping at exploration; we're actively creating innovative platforms and designs to make it happen. Our unwavering commitment lies in ensuring the security and privacy of healthcare data. Our ultimate goal is nothing short of a revolution in how medical data is managed and analyzed. We aspire to foster an environment of trust and collaboration within the medical research community, where data can be shared and used to its fullest potential.

**Here's how the rest of this paper unfolds:**

In section 2, we'll dive into the intricacies of our block chain platform's architecture. We'll outline how it's designed and structured to cater to the unique needs of healthcare.

Section 3 will focus on customizing this block chain platform specifically for precision medicine. We'll explore how it can handle the integration of diverse and often disparate data, accelerate data analysis, and even support general parallel computing through block chain.

In section 4, we'll pivot our attention to the application of the block chain platform in clinical trials. We'll delve into the mechanisms ensuring data integrity and tackle the topic of data sharing, a pivotal aspect of clinical research.

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In essence, this paper is a journey into the future of healthcare data management, where block chain and big data intersect to bring about profound changes. It's a journey aimed at making healthcare more efficient, secure, and collaborative, ultimately benefiting both patients and the entire medical research community [6].

**Block chain platform architecture**

The system architecture of our block chain platform is visually represented in **FIGURE 1**. Our approach involves constructing this platform atop the foundation of a conventional block chain network, capitalizing on its essential components to establish trustworthy transaction capabilities. Within our platform, we've identified four key system components:

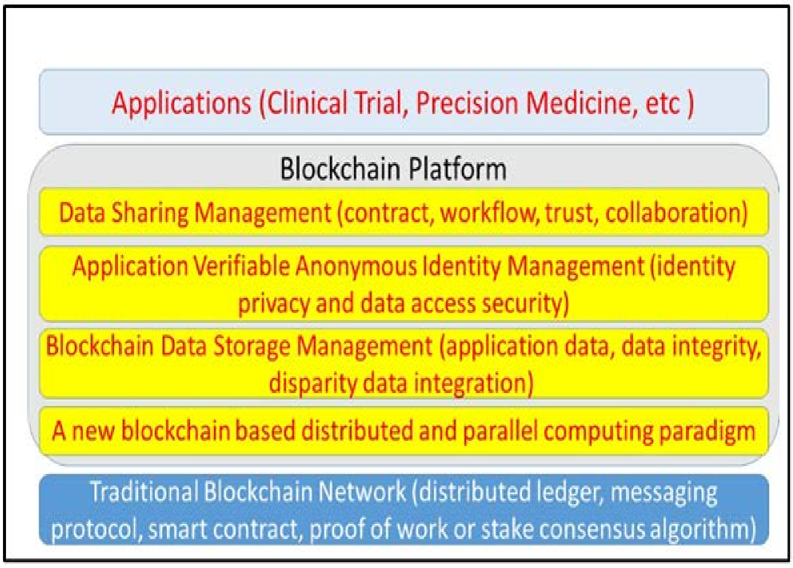


**FIGURE 1. Block chainplatform architecture.**

- **Block chain-based distributed and parallel computing:** This is a novel component that introduces a fresh approach to distributed and parallel computing. It forms the backbone of our platform's capabilities for processing data efficiently and in parallel.
- **Block chain application data management:** This critical component is responsible for the meticulous management of data within our block chain application. It ensures data integrity, facilitates the integration of diverse data sources, and maintains the overall integrity of the data.
- **Verifiable anonymous identity management and secure data access:** This component tackles identity management within the block chain, introducing verifiable anonymity and secure data access. It's instrumental in safeguarding the identities of users while enabling them to access data securely.
- **Trust data sharing management:** Trust is paramount in data sharing, and this component is dedicated to establishing and maintaining trust within our block chain based data sharing ecosystem. It ensures that data can be confidently shared and accessed by authorized parties.

These four components collectively form the core of our block chain platform, working in harmony to deliver a secure, efficient, and trustworthy environment for handling and sharing medical data.

Within our block chain platform, the novel block chain parallel computing component takes center stage. This component ventures into uncharted territory by introducing a fresh approach to distributed and parallel computing. Its primary purpose is to develop and explore a new paradigm for distributed and parallel computing specifically tailored for conducting extensive big data analytics. In the landscape of parallel computing, several established paradigms have gained prominence. These include Hadoop computing, grid computing, and cloud computing.

Furthermore, there's a hybrid computing paradigm that combines the elasticity characteristic of cloud computing with the distributed nature of grid computing, often involving supercomputer grids [7].

Our block chain parallel computing component aims to forge a path beyond these existing paradigms, devising a new approach tailored to the unique demands of big data analytics within the block chain context. In statistical calculations and inference, having knowledge of the distribution function is often essential. In cases where this function is unknown, generating the distribution of samples can be achieved through a process known as permutation. However, when dealing with large sample sizes, conducting random sample permutations becomes an exceptionally time-consuming task.

For instance, consider the commonly used statistical method known as the independent sample t-test. This method is employed to determine whether the expected values of two population characteristics are equal. When assessing whether a difference exists in the mean values of two groups, the independent sample t-test is a valuable analytical tool. It involves comparing the mean values derived from the dependent variable, which represents different attributes (or groups) within the independent variable [7]. Generating this distribution can be accomplished by employing a random reordering process. In our research, we intend to explore the mechanism of harnessing block chain technology to facilitate the generation of random sample permutations, particularly for handling large and complex datasets. This innovation has the potential to significantly streamline statistical analysis processes, particularly when dealing with extensive datasets in the realm of big data.

In essence, our quest for a deeper understanding of stroke and its management necessitates a holistic approach that encompasses not only medical history but also the myriad factors that shape an individual's health and recovery journey, from genetics to environmental influences. The most common genome research initiatives involve genetic variables such as gene expression, SNP, and miRNA. In general, stroke research must incorporate disparate sources of huge data, such as macrocosmic epidemiology and microscopic genetics. The study of stroke prediction, treatment, and rehabilitation after stroke has aimed to personalise stroke therapy and provide personalised medical care.

**Blockchain platform for precision medicine**

Combining clinical stroke datasets is a significant hurdle in advancing stroke prevention and researching the connections between new stroke treatments and other illnesses, such as cancer. To address this challenge, we are working on creating a medical block chain. This block chain will house data from the stroke clinic medical data library at the Chinese Medical University Hospital (CMUH) in Taiwan and the Taiwan health insurance database. Our primary focus is on tackling two key technical challenges:

- Seamlessly integrating a variety of medical data.
- Developing a new approach to distributed and parallel computing within the block chain context, with the goal of advancing our capabilities for handling extensive data analytics.
- In essence, our aim is to use block chain technology to unify clinical stroke data, enabling more comprehensive research and a deeper understanding of the relationship between stroke treatments and other medical conditions [7].

This aims to develop a precision medical application use case with a block chain platform to deliver more accurate stroke sickness prevention, treatment, and care. **FIGURE 2** depicts the system architecture. NCBI PubMed is a valuable repository of biomedical research, housing a vast collection of approximately 24 million articles. In our research, we initially turn to NCBI PubMed's Biomedical Literature Library as a primary source of literature. We then employ semantic computation and text exploration techniques to delve into these articles, analyzing the semantic similarities present within the literature. Through this process, we create two essential health knowledge databases: One dedicated to medical questions under investigation, and the other focused on analytics methods and the knowledge generated from them. The medical question database records the specific inquiries being explored, while the analytics knowledge database documents the outcomes and the methodologies, approaches, and analytical tools employed to attain those outcomes [5].

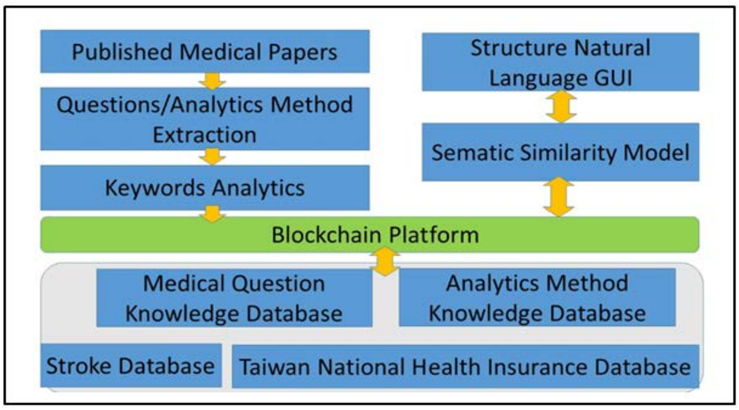


**FIGURE 2. Block chain platform for precision medicine.**

To ensure secure data access and management, both of these databases will be integrated with and governed by block chain technology. We are also in the process of developing a user interface that utilizes structural natural language queries. This interface leverages a semantic similarity model to analyze the resemblance between structural natural language queries and metadata associated with the problem knowledge database and the analytics method knowledge database. This enables us to provide precise answers and analytical methods to users, enhancing the accessibility and utility of this wealth of health knowledge. In this particular use case, block chain serves as the central management and integration hub for four distinct datasets. Two of these datasets originate from medical practice sources, specifically the stroke clinic medical data library dataset from CMUH and the Taiwan Health Insurance Database dataset. The remaining two datasets are derived from literature analytics: One comprising a medical question database, and the other containing knowledge generated through analytics [7].

It's important to note that these four datasets possess their own unique data structures, relationships, data access security policies, read/write throughput requirements, and real-time versus offline processing characteristics. These variations in dataset properties present intriguing variables that we aim to investigate and understand better. Our focus lies in exploring the mechanisms through which the block chain platform can effectively store and manage these diverse datasets, considering their distinct characteristics and demands.

**Integration complexity of disparity medical big data sets**

Typically, we evaluate a large dataset based on four essential properties known as the "4Vs": Volume (referring to the sheer amount of data), variety (indicating the diversity of data types and sources), veracity (relating to data trustworthiness), and velocity (referring to the speed at which data is generated and processed). Medical data, without a doubt, exhibits all four of these 4V properties. Moreover, the value of medical data, often considered the fifth "V," is self-evident, as it can save lives. Big data, characterized by its sheer volume, data trustworthiness, data frequency, data complexity, and data structure, poses significant challenges to traditional database and computing systems. These conventional systems struggle to effectively store, compute, process, and analyze this vast amount of data, let alone transform it into actionable knowledge [1].

In the case of Taiwan's national health insurance data, it primarily follows a structured data format. However, hospital treatment records encompass a mix of structured information, semi-structured Electronic Medical Records (EMR), and unstructured data formats like nuclear resonance imaging and computer tomography. Integrating these various data sources, particularly Taiwan's national health insurance healthcare databases with hospital records, is crucial. Such integration allows for a comprehensive analysis of an individual's disease prevention and healthcare treatment, providing a more holistic understanding of their health. With the advancement of medical technology and the widespread adoption of personal healthcare-related wearable IoT devices, the spectrum of medical data has grown significantly. However, this expansion of medical data comes hand-in-hand with heightened concerns about privacy. Meeting the demand for computing and storage technologies that can effectively capture and integrate this diverse range of medical data while safeguarding patient privacy and data security has become a challenging task [5].

In the course of analyzing a specific research question in the medical field, a substantial volume of diverse medical data must be processed. This involves tasks such as sampling, filtering, and aggregation before the data can be presented to analysis tools. Ideally, researchers should have the flexibility to write their own analytical program code using various programming languages and diverse underlying datasets with arbitrary data structures. Additionally, it would be highly efficient if this analytical code could be designed to run in parallel computing environments. However, achieving this often requires extensive cross-domain knowledge and expertise, especially in the complex realm of biomedical research [7]. As a result, many studies resort to using open-source or commercially available analytical tools that may not inherently support parallel processing. Most of these tools, like SAS, typically require data in a SQL-like database structure as their default input format. Consequently, regardless of the original raw data sources, there is often a need to transform the filtered data into a SQL-like structure to meet the requirements of these analysis tools (**FIGURE 3**).

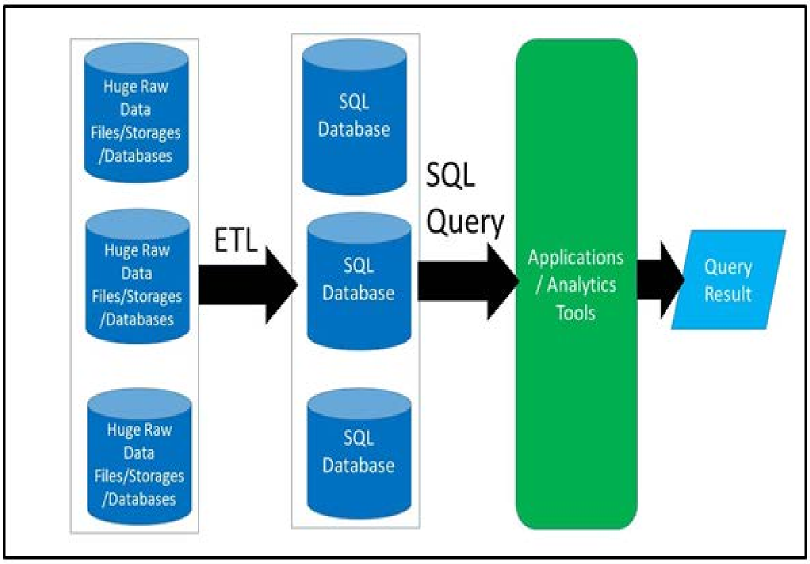


**FIGURE 3. Traditional medical data analytics model.**

Traditionally, handling medical data for research purposes often involves creating a unique data ETL (extraction, transfer, and load) process for each SQL database associated with an individual medical research question. In many cases, this proves to be an immensely challenging and costly endeavor, primarily due to the nature of big data sets and the stringent security compliance requirements associated with medical data. To streamline this process and make it more efficient, we are exploring a virtual mapping data analytics model, as depicted in **FIGURE** 4. In this model, for each medical research question, we establish a virtual SQL database. This database is logically defined based on the researcher's specified requirements, but it doesn't involve the actual copying and storage of real data. Instead, the original medical raw data remains securely stored at its original location to comply with HIPPA requirements [3].

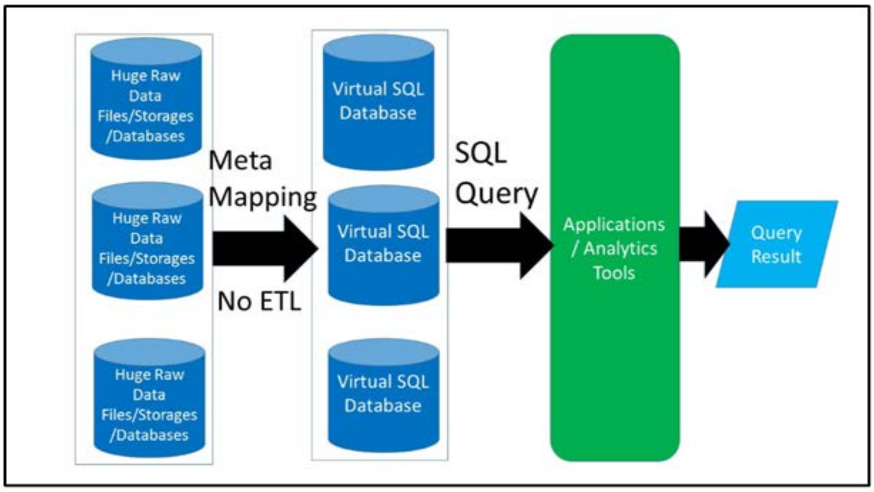


**FIGURE 4. Virtual mapping data analytics model.**

The virtual SQL database stores metadata mappings that link the logical schema to the physical medical data. This setup allows researchers to modify the schema as needed, and the virtual SQL database becomes available immediately after such modifications. Importantly, analytics tools operate seamlessly on this virtual SQL database, with no distinction from a real one. As a result, researchers can run their analytics application code without any modifications or rewrites. This feature is particularly valuable because researchers often need to make frequent schema modifications during their study, which can be a significant source of frustration for IT teams. Furthermore, deploying the SQL queries in a Hadoop environment enables parallel execution, enhancing efficiency. For instance, Hive already supports virtual mapping SQL for HBase, making this approach even more powerful and versatile. In the virtual mapping data analytics model, we will study the technique for integrating Hadoop infrastructure into the block chain platform to ensure data privacy and security.

## Block chain for clinical trial

**Data integrity issue in clinical trial:** In the realm of scientific research, there is a growing concern about the erosion of trust due to data manipulation. The pharmaceutical industry is driven by the desire to bring new drugs to market, and researchers are equally eager to validate positive findings. Clinical trials not only serve to assess the efficacy of new medications but also play a critical role in identifying potential side effects, weighing the benefits against the risks. Since 2007, regulatory bodies in the United States have mandated that all clinical trials involving recruited subjects must be registered in the publicly accessible database ClinicalTrials.gov. Despite these mandates for transparency and open access to trial protocols and data, the issue of maintaining data integrity in clinical trials persists. An alarming revelation from projects like COMPare [7], which monitors clinical trials, indicates that only a small fraction of trials (13 percent in one study) reported results accurately. It's worth noting that ClinicalTrials.gov sees nearly 20,000 registrations per year, suggesting that the problem of data integrity may be even more extensive than what has been uncovered.

When clinical trials are prone to errors or manipulation, patient care suffers, with far-reaching consequences. Block chain technology offers a promising avenue to restore trust and reduce suspicion regarding reported data. As clinical trials become more reliable and transparent through block chain based verification, it enhances the precision of big data analyses reliant on clinical trial data. Ultimately, this improved accuracy has the potential to save more lives. Notably, early adopters like Carlisle published a clinical trial protocol using block chain, while recent research by Greg Irving and John Holden has demonstrated that block chain serves as a cost-effective and independent verification method for ensuring the integrity of scientific research data. Block chain technology has the potential to play a pivotal role in restoring trust in scientific research, particularly in the context of clinical trials. By capturing the entire lifecycle of clinical trials, including the development and time stamping of trial protocols, block chain can expose practices like "outcome switching," which can introduce randomness into reported data rather than reflecting genuine results [7].

Complete transparency of all trial data can act as a deterrent for those who might be inclined to selectively report only favorable outcomes. However, it's important to note that there are instances when keeping clinical trial protocols confidential is necessary due to research and commercial sensitivities. Here, block chain can ensure that trial data is recorded in real-time while maintaining protocol secrecy. Data integrity can be subsequently verified without exposing the trial details to competitors before public release. A block chain-recorded clinical trial dataset holds immense value in medical research. Clinical trials often involve a limited number of test subjects, which may not fully represent the broader population. As a result, certain treatment effects and side effects might not be fully discovered during the trial phase. Trustworthy trial data can be integrated with patient outcome data post-drug approval. These combined datasets, spanning both pre and post-approval phases, offer insights into the real and long-term effects of the drug. Clinical trial records on the block chain serve as a valuable resource for trusted medical data.

**Block chain for peer verifiable clinical trials:** We aim to develop a mechanism using block chain to prevent any hidden alterations or manipulations in clinical trial outcomes. Block chain technology is a cost-effective and widely accepted tool that can enhance the transparency and reliability of scientific research. It allows researchers to quickly validate the accuracy of results reported in medical journals and can even automate this process, enabling peer verification of clinical trials. Furthermore, we will delve into the application of block chain smart contracts to streamline the clinical trial process and enhance data sharing and collaboration among research teams. This study will leverage smart contracts to establish a block chain platform that facilitates seamless data sharing and collaborative workflows in clinical trials.

To enable public data sharing and collaboration, it's crucial to have a mechanism for recording and enforcing data ownership. This ensures that when others use the data, they can properly credit the owner, or the owner can explore potential monetization opportunities. Our aim is to establish a robust and trustworthy data ecosystem that benefits the entire research community. We will explore various solutions to address data ownership challenges. When data can be trusted, and privacy is safeguarded, it paves the way for seamless sharing and collaboration among stakeholders. To mitigate the risk of pharmaceutical companies and researchers manipulating data, Greg Irving, a researcher and medical doctor at the University of Cambridge, devised a block chain based system. This system documents and independently validates ongoing clinical trials. The details of this study have been published by Greg Irving and co-author John Holden in the F1000 study. Greg Irving developed a Proof of Concept (POC) using a research protocol on the ClinicalTrials.gov website. This approach ensures that once clinical trials are initiated, pharmaceutical companies or researchers cannot deviate from the agreed-upon trial parameters or modify previously approved agreements to manipulate the test results.

Here's the method employed by Greg Irving:

- Begin by preparing a clinical trial raw file that contains the protocol and all prospective plan analysis files.
- Ensure the document is in a non-proprietary format, such as an unformatted text file or LaTeX format.
- Calculate the SHA256 hash value of the document and convert it into a Bitcoin key.
- Import this key into a Bitcoin wallet and generate a transaction to its corresponding public address.

By following these steps, a public key can be generated for any unformatted text file containing a clinical trial protocol. If the newly generated public key matches the one stored in the block chain, it serves as proof of the file's existence with a timestamp. Additionally, it verifies that the document has remained unaltered, as any modification to the document would result in a different SHA256 hash value and, consequently, a different public key. This method ensures the integrity and authenticity of clinical trial documents.

**Block chain platform for clinical trial:** The development of clinical trials faces two major challenges: Ensuring data integrity and establishing trust in data sharing. To address these challenges, we are working on the creation of a block chain platform that will focus on achieving

- Peer-verifiable data integrity.
- Facilitating data sharing and trust collaboration.

Our collaboration with the National Institutes of Health (NIH) in the USA involves leveraging their Integrated Biomedical Informatics System (IBIS) for collecting clinical trial data. Our goal is to integrate this block chain platform with IBIS to provide peer-verifiable data integrity and support collaborative data sharing within clinical trials, establishing a practical use case for block chain technology in this context. You can see the system architecture in **FIGURE 5**. While Greg Irving's block chain Proof of Concept (POC) for clinical trials exclusively utilizes the Bitcoin block chain distributed ledger to demonstrate data integrity, it's important to note that block chain technology offers another crucial feature: smart contracts. Currently underutilized in clinical trials, smart contracts are software programs that can execute actions on a block chain. They have the capability to read other contracts, make decisions, and execute further contracts. We intend to explore the application of smart contracts to ensure the data integrity of clinical trials and eliminate the potential for human manipulation [7].

Clinical trial data can be efficiently and securely linked and stored on the block chain platform through the implementation of streamlined and automated contract designs. This approach will enable future medical researchers to promptly store their data and verify the accuracy of their reports using smart contracts. Our research will delve deeply into the utilization of block chain smart contracts to investigate and enhance data integrity throughout the clinical trial process. Additionally, we aim to establish mechanisms that promote data sharing and trust-based collaboration among research teams (**FIGURE 5**).

**Verifibale identity privacy and secure data access**

**Verifiable anonymous identity privacy:** The transparency of transaction data stored in the block chain ledger poses a significant privacy risk, as it allows anyone to access this data, potentially compromising user privacy. Even when block chain user identities are encrypted, research has shown that a substantial portion of users' real identities can still be uncovered through extensive big data analysis involving other internet data sources. This privacy concern becomes particularly critical for applications such as banking, where both transparency and privacy are essential but often conflicting requirements. Our research will focus on developing mechanisms that enable block chain to simultaneously ensure user identity anonymity and data confidentiality. Various types of user identification authentication methods exist, including pass-through authentication, biometric authentication, and identity verification based on public key cryptography algorithms. These methods can be chosen based on the specific security requirements and computational capabilities of different devices or systems [7].

## Discussion

In traditional authentication processes, user account information is often transmitted in clear text to the server, making it vulnerable to eavesdropping, especially in public network environments. With the increasing prevalence of smartphones and IoT applications, safeguarding identity privacy and data security has become even more critical. Our research aims to address these challenges and enhance the privacy and security of block chain based systems. Anonymity's identity verification technology offers a novel approach by replacing a user's fixed identity with a dynamic identity identification code, thus ensuring user anonymity. Additionally, zero-knowledge proofs technology plays a crucial role in anonymous authentication. Zero-knowledge proofs were first proposed by Goldwasser and other scholars in 1985, and they leverage cryptographic techniques to verify the correctness of a statement without revealing any valuable information to the verifier. This property makes zero-knowledge proofs highly resistant to replay attacks [8]. Furthermore, since the verifier lacks the user's credentials, attackers cannot gain control of the server by posing as a user. Our research aims to explore the integration of block chain platforms with zero knowledge technology to achieve anonymous identity authentication for block chain users. This approach allows us to conceal a patient's identity on a medical block chain while still validating the legitimacy of their identity. In IoT block chain applications, it can similarly be employed to hide the identity of IoT devices while verifying their legitimacy.

**Secure data access:** Data access control within the medical block chain context is of paramount importance, demanding intricate and adaptable policies. For instance, to facilitate communication and collaboration between patients' healthcare providers and healthcare groups like physicians for disease prevention and treatment, healthcare providers might need to share a patient's healthcare information. However, as patient data is inherently private, the block chain system's access control architecture must be capable of verifying the user's identity, even when an anonymous identity is employed. Furthermore, the system's access control policy should exhibit flexibility, permitting users to create customized data access policies that dictate who, when, and what can be viewed within individual medical records. When authorized by the patient, other users can lawfully access their medical data.

To advance patient-centric healthcare, patients should have the authority to grant healthcare providers the ability to permit other individuals to access their medical data, guided by the patient-created access control policy [9-12]. This policy can encompass more than mere access or denial; it can involve setting access durations, specifying which specific pieces of information can be accessed, and allowing patients to manage data sharing. Patients can assign access permissions, determine who can query the data, monitor data access history, and modify permissions as needed. Block chain serves as a protective fortress for personal medical data, ensuring privacy and security while placing control squarely in the hands of individuals. Data sharing only transpires once trust is firmly established, fostering the concept of collaborative utilization of personal medical data [13-15].

Our research will delve into the development of mechanisms that enable patient-centric access control, empowering individuals to define distinct permissions for their medical data. Additionally, these mechanisms will extend to IoT devices, allowing them to grant or deny applications access to sensor data based on user-defined permissions. We will also explore various techniques for data exchange on block chain networks [16-18]. Nodes within the block chain can be categorized into groups, with access to user data contingent on the permissions set by the user. This setup enables the secure exchange of information across different groups, a particularly crucial aspect when dealing with data like electronic medical records that may need to be shared between distinct entities [19].

## Conclusion

This paper provides a concise overview of a block chain platform's scope, approach, challenges, and system design, primarily focused on the medical field, with a particular emphasis on clinical trials and precision medicine. This ongoing project is currently being conducted at Asia University in Taiwan. The paper delves into various technology challenges, potential research areas, and approaches under consideration. Moreover, it discusses the methodologies and approaches being explored for clinical trials and precision medicine, both of which serve as vital use cases for the proposed block chain platform.

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