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Blockchain Technology in Clinical Trials

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ABSTRACT

Blockchain technology, known for its secure and transparent record-keeping, has the potential to revolutionize clinical trials by enhancing data integrity, security, and patient consent management. This paper explores the integration of blockchain with machine learning to address current challenges in clinical trials, including data fraud, inefficiency, and compliance violations. We discuss the benefits, such as improved transparency, interoperability, and patient-centricity, as well as the technical and regulatory challenges. The potential applications of blockchain in clinical trials, including data management, patient consent, and compliance with regulatory standards, are examined. The paper concludes with future trends and the potential impact of blockchain technology on the clinical trial landscape.

Keywords: Blockchain Technology, Clinical Trials, Data Integrity, Data Security, Patient Consent.

INTRODUCTION

Over the past few years, the combination of blockchain technology and machine learning has become the center of innovation in addressing a variety of business challenges across multiple industries. We saw a big transformation in fields such as supply chain and financial regulation. In healthcare and life sciences, companies have successfully applied machine learning and data analytics to discover new drugs, support insurance, personalize medicine, and support clinical trials in their drug development. Despite these efforts, the clinical trial remains a task for second-hand companies, with 1098 compliance violations in 2020 alone [1]. On this challenge, we propose to use blockchain technology integrated with machine learning to promote transparency, interoperability, and patient-centricity across the clinical trial lifecycle in small companies so that complex correlation and volume data can be shared more securely among stakeholders. We do not address the legal, regulatory, and adoption challenges. Blockchain is distributed ledger technology that enables tamper-proof record keeping between untrusted stakeholders, and thus provides the potential to reduce fraud by providing permanent traceability in accounting for regulated records in the clinical trial [2].

DEFINITION AND KEY CONCEPTS

The proliferation of blockchain technology in various industries as a beneficial technology currently seems to be inevitable. Indeed, it was first developed in 2008 for cryptocurrencies, still remains well known with cryptocurrency transactions, and covers many other areas of different industries with several potential benefits realized since then. As an industry evolving on data and data sharing, it would not be surprising to see the integration of blockchain technology into the healthcare sector in the long run. It may even be more feasible where it is applied in clinical research, life sciences, and biotechnology-related businesses. Despite the early-stage nature of the emerging blockchain technology in the clinical trial environment, its widespread implementation as a disruptive innovation may bring substantial benefits that cannot easily be underestimated [3].

BENEFITS AND CHALLENGES IN HEALTHCARE

The healthcare system has shown significant interest in blockchain technology. Clinicians and researchers have recognized the potential of blockchain for transforming some aspects of the healthcare industry, especially focused on improving healthcare data security and healthcare data management. In some fields, potential benefits of using blockchain in other industries are emphasized, including privacy and security, transparency and accuracy, speed and cost reduction, and better data and public health management. In

the healthcare industry, many stakeholders will benefit from these advantages, but two critical aspects are essential. One is data security. Different types of health data are extracted, acquired, and handled through various digital systems. Security and privacy are of great concern due to the sensitive nature of this information. It is essential to have robust data security protocols and mechanisms in place, while data exchange must comply with privacy regulations. The lack of proper security policies can harm the reputation and disrupt the general trust in any digital platform. Data errors, unsecured data exchange, and synthesized data difficulties are other potential problems that healthcare stakeholders share and are various sources of inefficiency and expense [4].

CURRENT LANDSCAPE OF CLINICAL TRIALS

Growing public interest in and concern over the ethics, efficacy, and safety of medicine has led to an increased use of the clinical trial model for the study of countless medical treatments and interventions every year. Medical progress through clinical trials has led to a considerable ethical improvement in our ability to offer hope and relief to not only current but also future patients. Tumultuous advances in genetic science (particularly gene sequencing technology) afford medicine a profound transformational capability. Similarly transforming are new uses of technology in clinical trials including, and indeed most significantly, the application of blockchain technology in the realm of clinical trials over the course of the past decade. The further development of this capability into practice could very well prove to be a key tool to enable responsible and scalable growth in an enterprise that is not only very expensive but also initiate a significant improvement in outcomes that would benefit countless numbers of patients [5]. Constitutionally, a U.S. clinical trial has a similar structure and purpose as that of a clinical trial conducted internationally. The overriding purpose is to objectively measure, rather than assume, the efficacy and safety of the use of the product under investigation in terms of an identified indication of need. Clinical trials may be conducted for various purposes including the identification of an alternate dose of a treatment, the identification of an alternate method of administration or patient population group for a treatment, and those trials aiming at the approval of a new product intended to treat an entirely new indication. These trials are long, expensive, and difficult to conduct. They often include numerous challenges associated with dataset accuracy. It is imperative that the Clinical Trials Enterprise continue to evolve and improve beyond existing technologies and methodologies [6].

KEY STAKEHOLDERS AND PROCESSES

In traditional clinical trials, there are several key stakeholders in the trial conduct, oversight and settings, including, but not limited to: the patient(s), the patient's caregivers, the investigator(s), the study coordinators and staff, the institutional review board (IRB) and subject matter experts (SMEs), the regulatory agencies, the trial sponsor, the contract research organization (CRO), the data technology provider, the biosample laboratory or biostatistician, the data review committee, the steering committee, the safety assessment committee, the clinical events classification (CEC), etc. They are involved across the various stages and during the conduct of a clinical trial. These stakeholders also perform many different tasks within the organization. The key functions in a clinical trial usually involve: design, protocol development, sponsor oversight, study initiation, site selection, site resources, patient recruitment, patient consent and communication plan, on-site monitoring, off-site monitoring, adverse event reporting, central lab, regulatory submitting, warehousing and blinding, statistical programming and dummy data, medical reviewer, central desktop review committee, clinical site close-out, trial reporting and disclosure, etc [7]. Each stakeholder may use different methods to identify their best options pertaining to recruitment, biomarker achievement, regulatory changes or protocol amendment, trial closure, patient retention, and other related issues. These results and discussions delivered by the stakeholders may then impact medical progress and result in expensive clinical trials that may save time, obtain access to health-related benefits, and ensure that safety issues are properly identified and addressed, etc. These results and discussions derived by the individual stakeholders may then be evaluated from their measurements before they can be adequately exposed, tracked, discussed, and appropriate comments can be advised. In addition, the generated data and oro, in order, organized, where the stakeholders' input will influence and direct the entire process, so monitoring the trail input is not the only critical factor. It is, however, currently the most difficult, time-consuming, and objective task to accomplish in clinical research, which usually can comply with the needs for quality monitoring or automated controlled trial requirement [8].

ISSUES AND LIMITATIONS

Despite the potential for accelerating and streamlining clinical trial processes, there are several challenges at the operation, technical, and security and privacy levels. The technical limitations are highly associated with blockchain scalability, exposure to malicious attacks, and the stability of privacy mechanisms. Depending on which consensus protocol was used and the network's status, the time for a transaction to

be recorded in a blockchain is slow. To be specific, Ethereum and Bitcoin have a capacity of 15 and 7 transactions per second, respectively. Many patients, devices, and health records both generate and demand a large amount of data. The low throughput poses a major challenge for blockchain to accommodate the increasing volume of demands. Most importantly, the consensus protocol brings wasteful and specialized power usage with a big impending environmental burden [9]. Blockchain adopts a peer consensus validation mechanism to judge if a transaction is legal. Hence, only honest nodes are encouraged to participate in this process and all peers can view all transactions. It has a structure that is not controlled by anyone, is not opaque, and cannot be corrupted. It ensures the integrity of all records as they have been validated and stored. Thanks to similar features, health data can be fully open by the patient, biopharmaceutical company, and the development process disclosed in a highly transparent manner. Despite protection from the above technical limits, the patient's health status and promotion behaviors can be merged to register more details in the transaction. Given that patients' privacy is exposed to others, the patient's attributes and transaction process are at risk. Due to these attributes, we cannot fully confirm if patients are at risk as long as their privacy is not guaranteed [10].

APPLICATIONS OF BLOCKCHAIN IN CLINICAL TRIALS

The increasing application of blockchain innovation in healthcare has led to over 200 research works on blockchain innovation in the field of healthcare between 2016-2017, and the number keeps increasing as seen through continuous monitoring of the most reputable research indexing databases. The following applications summarize the use of blockchain in healthcare: patient-centered data management and exchange, secure data sharing protocols, source verification for accessing controlled substances, IoT security for medical devices, clinical trials, decentralized access to electronic health records, supply chain management, smart public health surveillance, decentralized insurance services, health research information and access through tokens, electromedical equipment counterfeiting, donor incentives, personal health wallet, health data analysis, blockchain as a service, consent of the data manager, decentralized genomic data sharing, IoT healthcare, secured health record storage. These applications are similar in line with the opportunities that were identified by the authors [11]. In particular, the application of blockchain technology within the context of clinical trials is reported to have a significant impact on the process of recruitment, randomization, conduction, compliance, and managing, as well as monitoring the data generated from clinical trials. The use of blockchain technology in clinical trials serves as a potential game-changer in various stages of conducting clinical research with significant benefits from better data management to enhanced speed, authenticity, and compliance. With the advent of blockchain technology within the context of clinical trials, the major hurdles in clinical trial conduction like data anomalies, reliability, monitoring & compliance, and other bottlenecks are overcome in the clinical trial as blockchain has the potential to address the data security, privacy, transparency, and data sharing bottlenecks of the clinical trials process. The applications are modifications of the existing blockchain framework or are the newly designed ones. These clinical trial applications of blockchain are titles of the proposed blockchain model in the healthcare sector. From the sections, we get to know that existing blockchain infrastructures could have a broken consensus which is exploited or combined with mathematical formulas.

DATA INTEGRITY AND SECURITY

Data integrity and security are two of the principal challenges while using CRF data in a clinical trial because of the way data is currently moving through different systems and processes. According to the FDA, computerized systems used in clinical investigations should permit the establishment of levels of access and a system for documenting these levels. Secure access control includes password protection, user list, and read/write access. Security is a key feature of blockchain and is the reason why it is used in blockchain-based cryptocurrencies. Thanks to blockchain technology in clinical trials, a more robust security is offered, both for CRF data and continuous supply chain in clinical trials. The distributed nature solves the potential security issues in blockchain by using advanced cryptography. Data is protected by being stored on different nodes (computers) and controlled through a different consensus mechanism. A consensus mechanism is more difficult to attack than a single point. Currently, databases are stored on a single server, presenting a single point of attack. MongoDB, an open-source document database currently popular with developers and used in a number of mobile applications, has suffered from repeated ransomware attacks. Consensus mechanisms based on blockchain technology use advanced cryptography to validate the accuracy and integrity of the pending transactions and maintain this in a way that is more consistently incorruptible than in any traditional system [12].

PATIENT CONSENT AND PRIVACY

Implementing patient consent and privacy on the blockchain could prevent problems in obtaining permission to use medical data for clinical research. Current medical data permission rules are complex, involve multiple parties, are data location dependent, and are sensitive to patient privacy. Patient consent is very important in health information science. These rules dictate how health data, such as medical images, genetic information, and drug records, can be accessed and processed. The rules vary based on the data's privacy context and the clinical trial goal. Different parties in the medical data consent model agree on the consent rules. However, an open blockchain implementation can offer a transparent overview of the consent processes that are important to health information. Therefore, using blockchain technology in patient consent, privacy, and access will improve healthcare institutions' confidence in the methods used. Blockchain will prevent authentication issues and tracing when data exchanges are performed. Using blockchain technology and its smart contracts, patients could automate the process to allow researchers access to medical information. Software entities may need access to health data to guarantee patient-controlled permission. Without a blockchain, software entities need to have significant trust. Central authorities, lawyers, and institutions could be left out. Patients remain in control of their consent data and can access it at any time. At the same time, the organization that puts data on the blockchain and the software entity that wants to access it have a record of the transaction for legal purposes, secured with a time-stamped encryption. However, the cost of obtaining an on-chain consent is not practical. The overhead of an on-chain consent is related to the cost of the blockchain service and the certification performance. Each certificate request's access time cannot exceed a protected period. The healthcare institution has the infrastructure to respond to requests within the timeframe. Healthcare institutions with stricter latency requirements require specialized deployment planning since they must have actual control over the data and charging a fortune. The healthcare organization can put encrypted consent on the blockchain. Suppose a patient gives software entities access through the same blockchain. In that case, the organization can provide the software entity with encrypted data and consent, all of which are in their control. In data encryption and consolidation, healthcare institutions could leverage the greatest degree of control [5].

REGULATORY CONSIDERATIONS

While Bitcoin has had a great deal of success, much of that has come from the fact that it is not widely regulated. However, many of the other proposed uses for the blockchain involve money that is highly regulated. Exchange of various types of securities, voting/business entity actions, and various types of interactions with government or industry regulators are firmly within the worlds of securities and other financial regulation. If the proposals for expansion of the blockchain are to have real success, we believe that the hopes of anonymity and weak regulation are unachievable. By analogy, the internet, which runs on top of the TCP/IP protocol, does not specify DNS settings. Rather, that delegation of governance to ICANN opens it to regulation by many different countries. The result being that most websites enforce geographic restrictions to avoid falling under policies that could turn it over to a country with less freedom-respecting laws. Technology that changes the relationships among parties will influence real-world legal structure and policies. The hope that changes could happen, leading to decentralized regulation, needs to be balanced against the reality of public choice influencing regulation of relationships affected by such technology. The public and financial costs of assuming no regulation are likely to be extremely high [13].

COMPLIANCE AND DATA STANDARDS

Despite strict data quality and GxP regulations, data collected in research to date have not always been unbiased or subject to standardization, and it is also questionable whether the data have actually been used for decision-making in clinical practice. To promote the collection of high-quality and meaningful data, transparency, convenience, and standardization of the exchanges and transactions of information are required, and this has led to the current strictness of data quality regulations. In addition, much standardization in the form of data exchange operation has been achieved through EDC, and things have advanced to the extent that, in most cases, the structure and content of case report forms can now be decided in a standardized fashion supported by industry bodies [14]. Due to the immutability of data in blockchain operations, the ability to tamper with and falsify data is significantly reduced. In addition, by publishing research data on data infrastructure utilizing blockchain, we are making data highly transparent, convenient, and standardized, and we are able to contribute to real-world research, medical practice, and evidence-based healthcare. In this context, the actual method of preparation of data on a clinical trial service using blockchain will vary according to the scale and purpose of the clinical trial, and whether or not EDC operations are to be commercialized, but it is considered practical to prepare data for

national research according to the data standards of the PMDA or FDA. Furthermore, as government data standards, knowledge regarding governments' acceptance of datasets and data structure and contents will make data generally available and promote the spread and convenience of the trial service, these are expected to contribute to the acceptance of data infrastructure supporting national research globally.

FUTURE TRENDS AND POTENTIAL IMPACT

In addition to serving as a real-time decentralized database that can be operated and validated by all stakeholders, blockchain technology is also expected to have a significant impact in the area of real-world data, which are valuable supplements for real-world evidence. Real-world data are generated not within the framework of randomized trials but in real-world routine clinical practice. The possible impact of blockchain in this field would be, but not limited to, the following [15]. The first important impact is to improve data completeness, including the integrity and accuracy of patient identification, event capture rate, and follow-up. The second impact is to enhance the data quality by adding outside-in data such as electronic health records and laboratory reports, which is essential for all stakeholders including researchers, sponsors, regulators, and the authorized third party. Utilize smart contracts to increase the data quantity and authenticity [16]. The third impact will be to tackle challenges that arise with distributed ledger data, e.g., the non-standardized local jurisdiction, through creating an updatable decentralized data audit for data management and reaching consensus among the clinical sites, sponsors, and regulators through setting contract rules and customized permissions. In conclusion, blockchain as a concept provides a secure, available, and extremely resilient way of storing data. Its confirming leader can make data immutable, non-repudiate, and untampered, and this slightly solves the problems in clinical trials and improves data completeness. Furthermore, it provides pointers and records of data rather than storing the data itself, which helps to solve the challenges brought by large amounts of data. With the increasing demand and application of blockchain technology in recent years, we believe that its potential in the clinical field deserves further research in data management in the future [17].

CONCLUSION

The integration of blockchain technology in clinical trials presents a promising solution to many persistent challenges, including data integrity, security, and compliance. By providing a decentralized, tamper-proof record-keeping system, blockchain can enhance the transparency and efficiency of clinical trials. This technology, combined with machine learning, has the potential to improve patient-centricity and facilitate secure data sharing among stakeholders. However, significant challenges remain, particularly in terms of scalability, privacy, and regulatory compliance. Despite these obstacles, the future of blockchain in clinical trials looks promising, with potential applications extending beyond data management to encompass comprehensive healthcare solutions. Continued research and development are essential to fully realize the benefits of blockchain technology in clinical trials and healthcare at large.

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