Chapter 34
Data Security in Clinical Trials Using Blockchain Technology

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ABSTRACT

Blockchain technology in a clinical trial setting is a valuable asset due to decentralization, immutability, transparency, and traceability features. For this chapter, a literature review was conducted to map the current utilization of blockchain systems in clinical trials, particularly data security managing systems and their characteristics, such as applicability, interests of use, limitations, and issues. The advantages of data security are producing a more transparent and tamper-proof clinical trial by providing accurate, validated data, therefore producing a more reliable and credible clinical trial. On the other hand, data integrity is a critical issue since data obtained from trials are not instantly made public to all participants. Work needs to be done to establish the significant implications in security data when applying blockchain technology in a real-world clinical trial setting and generalized conditions of use to establish its security.

INTRODUCTION

Since its discovery, Blockchain is emerging as an innovative technology to provide data transactions and storage in an effective, secure, and timely manner system. This technology has been applied to many sectors of activity, potentializing its features and improving processes and business mindsets.

The health sector is no exception, and many uses of this technology have been reported. Blockchain's full applicability in healthcare is still underway, and many optimizations are needed to be made, not only from a technology development perspective but also concerns about ethical and data protection regulation are raised and need improvement.

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It is considered essential to mention that the interest in the applicability of blockchain systems in the healthcare sector has been increasing since 2016. More specifically, the number of published articles related to Blockchain in the Pubmed bibliographic database has increased drastically in 2018 (only five studies were published in 2016 and only 16 in 2017), reflecting the potential and growing interest of these systems in the healthcare sector (Mackey et al., 2019). Only 4% of these studies were related to clinical trials, and 32% were related to healthcare data (Mackey et al., 2019).

Particularly in clinical trials, this technology is yet to reach its full potential. Nevertheless, considering the dimension and complexity of a clinical trial network and process interlined, blockchain technology might improve data sharing, management, and access to all key players. However, identifying the risks and threats of applying this technology in such an environment is still amiss, and work needs to be done to establish them in a realistic scenario setting.

Therefore, the purpose of this chapter is to map the current use of blockchain systems in clinical trials, particularly data security managing systems, and its characteristics, such as applicability, interests of use, limitations, and issues, as reported throughout the literature review.

BACKGROUND

Although variations of term have been used before, Blockchain came around in 2008 when this technology was created by Satoshi Nakamoto to support and securely record Bitcoin cryptocurrency transactions (Meunier, 2018; Monrat et al., 2019). Since then, the interest in this technology has increased and soon was applied into other areas of interested such as government, manufacturing, finance, healthcare and distribution (Monrat et al., 2019).

Blockchain is an advanced data structure, designed for storing and sharing information, composed by a growing chain of blocks organized by chronological order (Agbo et al., 2019)(S Chen, Hannah et al., 2019). Each block stores information with digital signatures in a decentralized and distributed network, it allows to record a transaction by binding different blocks connected with chains (S Chen, Hannah et al., 2019) (Abu-elezz et al., 2020) (Monrat et al., 2019). This transaction is validated by a consent algorithm, and therefore, needs no third-party validation to complete an action. The chain continues to grow as new transactions are built and blocks are added into it (Omar, Jayaraman, Salah, Yaqoob, et al., 2020).

Unlike traditional methods, blockchain enables peer-to-peer transfer of digital assets without any intermediaries. All the transactions occur in a decentralized manner that eliminates the requirement for any intermediaries to validate and verify the transactions. Every transaction is regulated by the participants who store and share the information throughout the private key: an unique and individual signature linked to each transaction recorded (S Chen, Hannah et al., 2019).

The digitalization era is reaching almost every industry and is expected that the Distribution Ledger Technology, where technologies such as blockchain, artificial intelligence and Internet of Things are inserted, to reach a market value of $60.7 billion by 2024 (Smetanin et al., 2020).

The features of blockchain, include (Hussien et al., 2019):

- Decentralization, access of information through third parties with multiple copies in multiple locations;
- Consent, the consensus algorithm created controls the access and distribution within a network;
- Immutability: once the information has entered a blockchain no longer can be changed or altered; a