

Chapter 9

A Concrete Way to Develop Clinical Research in a Fair Way to the Users / Patients Using Blockchain Technology

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ABSTRACT

Blockchain is being explored as a potential solution to many problems in areas other than the one created initially: cryptocurrency. Blockchain technology allows the authenticity of data, security in transactions, and privacy without the need for a third party. For that main reason, one of the growing interests concerns its application in healthcare, namely in clinical research. Multiple pain points of clinical research might benefit from the implementation of blockchain technology. This chapter shows some examples in which this technology is already implemented, identifying the advantages of its use. One of those advantages is clinical research, with the possibility of the patients managing their own clinical data and being properly rewarded for that. Research about clinical data monetization for patients is currently limited, and this chapter also proposes a hypothetical scenario of health data monetization workflow.

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INTRODUCTION

Generically, it is widely established that Science is made of reliable data. Unfortunately, over the past years, there is a tendency for an increase in research misconduct, data fraud, and lack of transparency. (Benchoufi et al., 2017, 2019; Gupta, 2013). Inevitably, this tendency can disrupt one of the essential characteristics of clinical research: trust. Combining the incorruptibility of blockchain technology with clinical research might be a powerful tool to re-establish trust in clinical data. Moreover, the introduction of this technology may allow patients to possess their clinical data and decide to share it in exchange for a token representing some benefit. This study describes a way to develop clinical research in a fair way to patients using blockchain technology. This chapter also discusses the main advantages of blockchain-based technologies in clinical research and the challenges of their implementation. On the other hand, it explores data monetization to benefit the patient using smart contracts. Pros and challenges of blockchain implementation in clinical trials for the patient and the healthcare industries and society were also discussed.

BLOCKCHAIN TECHNOLOGY OVERVIEW

In October 2008, Satoshi Nakamoto introduced a peer-to-peer electronic cash system: The Bitcoin (Nakamoto, 2008). He/she proposed a way to make transactions between two parties without the need of going through a financial institution. Nakamoto realized that digital signatures would not solve the need of a trusted third part to avoid double-spending transactions. The solution proposed was a peer-to-peer network. Timestamps transactions hashed and saved on an ongoing chain former a record of data that can no longer be edited or removed (Nakamoto, 2008). Although it was been explored in other systems, to date, cryptocurrencies are still the most commonly recognized use of blockchain technology. This technology have been described in several ways, the most generally accepted is: a peer-to-peer (P2P) distributed ledger technology (Laure A. Linn, 2016). This means that blockchain works as a system where each member in the network (node) stores an identical copy of the ledger. Each node gives their contribution on the collective process of validation and certification of the data recorded. The advantage of this decentralised P2P architecture is the lack of a central server to guarantee trust. When happens to occur a record of a digital transaction it has to be evaluated through algorithms by each member of the distributed network. The update of a new transaction on a shared ledger occurs only if the majority of the members vote as a valid process. When a consensus is reached all the other nodes updated themselves and that information can no longer be edited or deleted.

The security of the process is guarantee through the usage of cryptographic keys and signatures. Privacy is protected in the blockchain using a system of a key pair for each member: a public key and a private key. Zhuang and colleagues refer to the private key as a signature and a public key as a bank account. To understand how this key pair works, a new transaction by an user might be considered. All the other members of the blockchain can see the public key of that user, but it keeps the private key hidden. Although the private key is not accessible, it is possible to check if the public key and the signed private key of the transaction match. If they not match the transaction will be voted down by the users and discarded. (Yan Zhuang et al., 2019) In addition, to being digitally signed the information contained in the transaction is encrypted to guarantee authenticity and accuracy. Transactions are stored into blocks that are added in a chronological order to a chain. Each block contains a unique code called hash. It

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