Blockchain and Clinical trials

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Maria is an experienced R&D industrial chemist with a PhD in Wine Chemistry. For 15 years she has worked in quality assurance (QA) within various industries including biotechnology (pre-clinical and clinical testing of drugs, and medical devices). She is interested in emerging technologies, particularly blockchain and she is currently undertaking a course in programming. In her role as an auditor, she has identified shortcomings in clinical trials and is advocating for the adoption of blockchain technology as a valuable solution to enhance transparency, security, and efficiency.

Maria has recently launched her business, "The QA Dr", where she can combine her passion for QA with her scientific knowledge, experience, and qualifications as a chemist.

Editors' note: This article is based on the presentation that Maria made at Qualcon 2023

ABSTRACT.
Blockchain is a potentially valuable tool for quality assurance professionals who audit clinical trial information. However, blockchain is perceived as complex and difficult to understand. I want to simplify the concept, and in doing so I hope to make this technology accessible to a wider audience.

KEYWORDS:
Blockchain, clinical trials, zombie trials, peer-to-peer network, public key, private key, hash functions, smart contracts.

BLOCKCHAIN AND CLINICAL TRIALS.

At the Qualcon conference in October 2023, I delivered a concise three-minute presentation that integrated my expertise from first-in-human (FIH) clinical trials and pre-clinical testing of drugs and medical devices with the emerging technology of blockchain. I recognise the potential advantages of blockchain and used this presentation to educate the quality assurance community about its features and capabilities especially for the QA context. In this article, I aim to provide comprehensive information about blockchain technology, its potential significance in clinical trials, and how it can be used for quality assurance purposes.

WHAT IS BLOCKCHAIN?

Blockchain is a technology which has been popularised by cryptocurrency (e.g. Bitcoin). But cryptocurrency is just one of the many potential applications of blockchain technology.

EXPLANATION:
In the world of Quality Assurance, think of a peer-to-peer network like a team of superheroes working together without a central leader. Each member of the team can communicate directly with others, sharing information and making sure everything runs smoothly. The team of experts check and double-check each other's work. In a peer-to-peer network, devices collaborate without relying on a single computer or server. For a Quality Assurance Specialist, this means ensuring that all parts of a system are on the same page, communicating well, and performing at their best. It's like making sure every superhero in the team has their powers working perfectly to save the day!

The revolutionary aspect of blockchain is that it enables the storage and exchange of data on a **peer-to-peer network** in a way that creates an unalterable log of the transactions, thus eliminating the need for a central authority or intermediary.

Importantly, blockchain doesn't rely on trust between individuals but builds trust within the technology itself. Blockchain's transparency and security mean users don't need to trust a third party; they have control over their data and can ensure privacy.

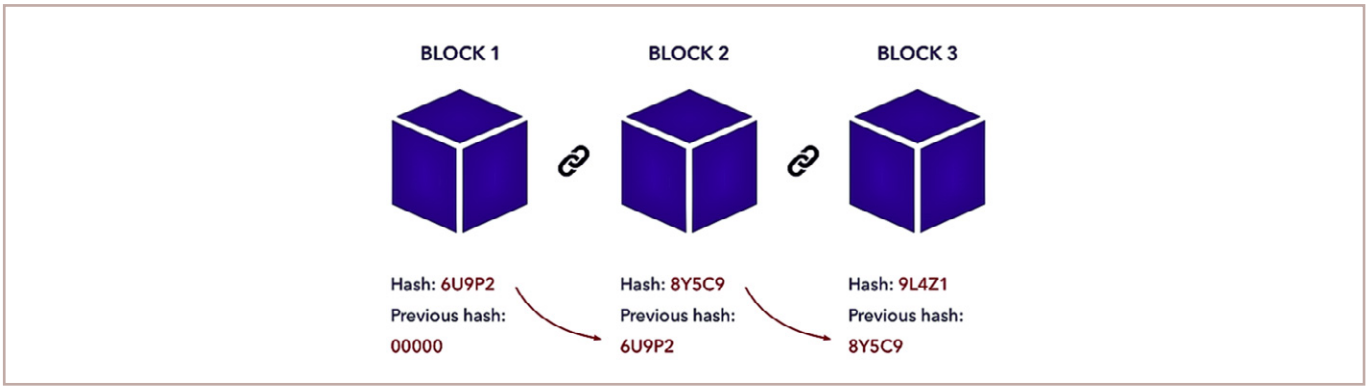

Figure 1: Example of blockchain linking [2]

Through the use of cryptographic hashes (see Figure 1), blockchain organises data into blocks that are securely linked together, forming an unalterable chain [1]. Within each block, valuable information such as transactions, timestamps, and references to preceding blocks are stored. This decentralised approach revolutionizes operations by providing transparency, security, and efficiency in data management [1]. This technology can provide benefits for numerous industries. In the blockchain system, users have a unique key pair consisting of a public key and a private key. The private key is used to sign transactions, while the public key is visible to everyone. The blockchain verifies the keys and ensures privacy of the private key [3]. Nodes validate transactions called blocks for security. Each block has a number and information about previous blocks and transactions. This chain of blocks guarantees data integrity and immutability of each transaction once it has been verified and added.

Current uses of blockchain technology include manufacturing and industrial internet of things (IoT), food supply chains and agri-food networks with quality assurance [4], [5], [6], [7], [8] and [9] as well as banking, share transactions and property titles.

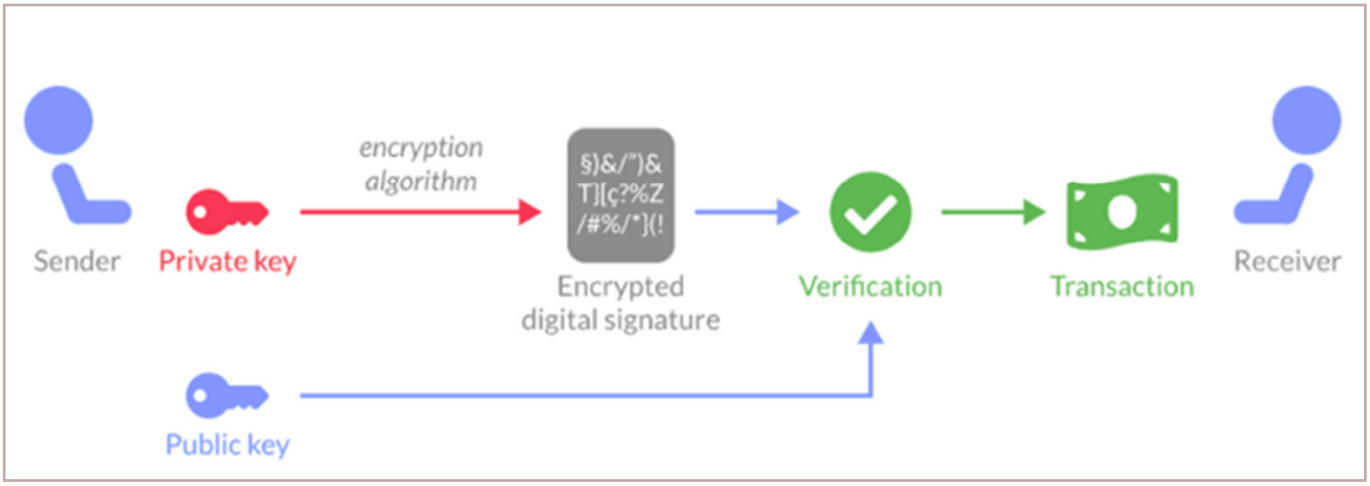

Figure 2: Private and public keys used in blockchain technology [3]

So why not include clinical trials? Implementing blockchain in clinical trials could revolutionise modern clinical research and address key challenges [10], [11].

TOO MANY BAD CLINICAL TRIALS.

John Carlisle, an anaesthetist and editor of the scientific publication, Anesthesia, analysed 526 manuscripts from 2017

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to 2020 [12]. From the individual participant data for 153 trials, Carlisle judged that 44% (73) of these trials contained flawed data: impossible statistics, incorrect calculations or duplicated numbers or figures, for example. When Carlisle couldn't access a trial's raw data, only aggregated information, he found that 1% (six out of the remaining 373 manuscripts) had false data. A total of 43 manuscripts were considered "zombie trials" that should have been retracted (Figure 3). These included data from Chinese, South Korean, Indian, Japanese, and Egyptian trials. These findings highlight the need for strong research practices and quality control in the scientific community.

Figure 3: John Carlisle coined the term "zombie trials" in his paper "False individual patient data and zombie randomised controlled trials submitted to Anaesthesia" [12].

BLOCKCHAIN USES IN CLINICAL TRIALS.

Clinical trial data is crucial for validating new medicines and medical devices. The Food and Drug Administration (FDA) and Therapeutics Goods Administration (TGA) manage approvals in the US and Australia respectively. Regulatory authorities have found that processes to ensure the quality of clinical trials are frequently inadequate, and clinical trial records are often erroneous or incomplete, which puts the interpretability of trials at risk and may risk patient safety.

In Canada, Boehringer Ingelheim and IBM [13] are working together to test whether blockchain technology can provide a decentralised framework for clinical trials that enables data integrity, provenance, transparency, patient empowerment, and process automation.

The opportunity in leveraging blockchain technology lies in increasing trust and transparency among all stakeholders, especially when it comes to patient consent and data management. To address consent collection issues in clinical trials, blockchain technology can be used to timestamp and secure each patient's consent. The data is **hashed** for integrity, and its existence can be verified on a public website.

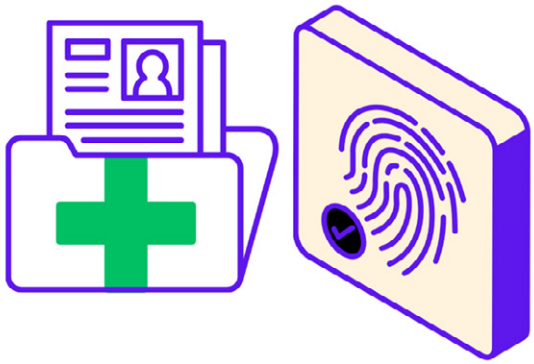
EXPLANATION:

Take a QA professional overseeing the integrity of patient data. Hash functions play a crucial role in maintaining the security and authenticity of this sensitive information.

When data is collected during a clinical trial, especially patient records, it undergoes hashing before storage. Each piece of information, like a patient's medical history or test results, is transformed into a unique digital fingerprint ('hash') using a hash function. This hash is then stored in the system.

If a QA professional needs to verify the integrity of the data, they don't have to examine the entire patient record. Instead, they can compare the hash of the stored data with the newly generated hash. If the two hashes match, it ensures the data's consistency and authenticity without exposing the actual patient details. This helps maintain privacy and security, crucial aspects in the healthcare and clinical trial domain.

Hash functions, in this scenario, act as a secure and efficient way to ensure that the clinical trial data remains unchanged and trustworthy, providing a robust layer of security for patient confidentiality and data integrity.



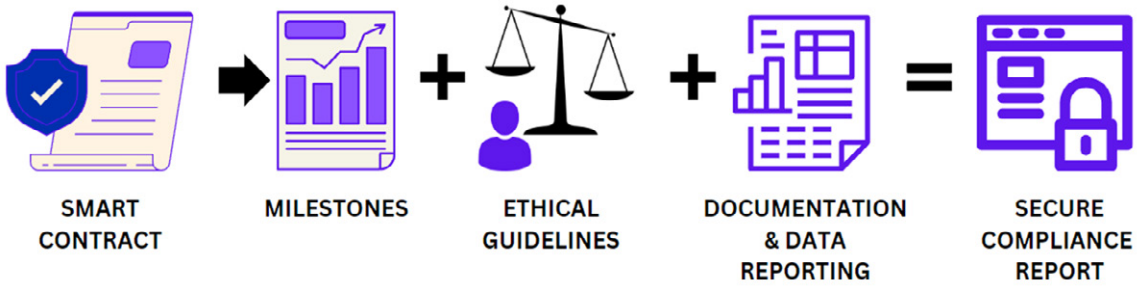
Smart contracts are digital agreements that run on blockchain technology. Use of smart contracts makes sure that trial participation and data collection or sharing is done with valid consent, reducing administrative errors, providing transparency, and increasing trust.

EXPLANATION:

As an example, take a smart contract designed to automate the auditing process for a clinical trial. The terms of the contract could include milestones and criteria that need to be met for the trial to be considered compliant with regulatory standards. These milestones might involve the timely submission of documentation, adherence to ethical guidelines, and the accuracy of data reporting.

Once the clinical trial progresses, the smart contract continually checks these predefined conditions. If the trial meets the milestones, the smart contract could automatically generate an audit report, detailing the compliance status. This report is then securely stored on the blockchain, ensuring transparency and immutability.

In this way, smart contracts streamline the auditing process, reducing manual efforts, minimising the risk of errors, and providing a transparent and tamper-resistant record of the trial's compliance history.



So, what's required next for blockchain to be adopted in the clinical trial industry? Various stakeholders within the blockchain need to collaborate to establish best practices and standards for implementing blockchain technology for clinical trials. There's a need to assure privacy and security, which will make patients willing to share their medical information. Consequently, the development of guidelines will be instrumental in driving innovation and advancement in the field of clinical research.

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