ABSTRACT

After following SAS® blogs and other social media outlets that correspond to the latest pharmaceutical trends, the words "blockchain" and "bitcoin" have been prevalent. How are any of these words associated with healthcare and patient data? Like other programmers working in the pharma industry, my curiosity grew beyond just procs and data steps. Many can agree that the credibility of clinical outputs can be undermined by a plethora of common issues including incomplete, missing, or inaccurate data. After multiple layers of data manipulation, how is it certain that what is being submitted to publications is an undistorted version of the benefits and risks of these drugs? This paper will give the audience a glimpse of how blockchain technology, whose implementation is cryptographically validated by a network, has enough potential and momentum to emerge into the healthcare industry and stick around for quite some time.

INTRODUCTION

HISTORY

Blockchain technology is one of the greatest innovations of the century. The impact on various sectors such as finance, education, and healthcare seeps into the curious minds of all. The history dates to the early 1990s, when the concept for electronic notaries came into fruition. Stuart Haber and W. Scott Stornetta envisioned timestamped digital documents without the fortuitous event of backdating. Though Haber and Stornetta created the concept, it was not until 2008's financial crisis did people challenge the idea of a centralized bank, thus jumpstarting Satoshi Nakamoto to develop the first application of the digital ledger technology. This peer-to-peer cash system “Bitcoin” then played a large role in popularizing blockchains.

WHAT IS IT?

A blockchain is a distributed ledger that records transactions across a decentralized network. Blockchain networks can be on a public platform where anyone may maintain the ledger (ie Wikipedia), or other types like private, hybrids, or a consortium. Because clinical trial data contains Personally Identifiable Information that is protected by regulations and laws, it makes sense that a private platform with vetted participants maintain the ledger and make decisions to accept or reject new blocks.

The imperative power of this technology is the ability to distribute information across individual computers. A blockchain database is not held in a single location, which could be hacked and infiltrated, but rather hosted by thousands of computers at once. The underlying desire to validate and authenticate data in a decentralized network builds the foundation for these blocks.
**HOW BLOCKCHAIN WORKS**

In Figure 1, each block contains: data, a unique hash identifier, and the hash of the previous block. Block C and Block B are linked because Block C has the hash of Block B. Any subsequent blocks will carry the previous hash, thus giving the chain a link. The first block will not have a previous hash assigned because it is the very first block – this is called the genesis block.

Altering any of the contents in the block will change the unique hash identifier. In Figure 2, tampering with Block B’s data causes the hash to change, in turn unlinking subsequent blocks from the chain. The following blocks are considered invalid. Every block will then need to be recalculated. Since modern technology is powerful enough to create blocks in seconds, blockchain users have found a way to mitigate interferences. A “Proof-of-Work” mechanism allows the block calculation to slow down – to about 10 minutes per block. This “Proof-of-Work” makes tampering very tedious because if one block is tampered with, all the following blocks will need to go through this process. Solving the algorithm uses a high level of computational power. Miners are responsible for completing the mathematical algorithm to confirm transactions and produce new blocks.

Most importantly, because blockchain technology is on a peer-to-peer network, every user receives a full copy of the blockchain. When a new block is created, a copy of the new block is distributed to each member of the network. Each member will verify it and a consensus will decide on accepting or rejecting the new block. If accepted, each member adds the new block to his/her own blockchain.
To successfully tamper with the blockchain, you need to tamper with all blocks in the chain, rebuild the proof-of-work and take control of over 50% of the peer to peer network.

**USE IN HEALTHCARE**

Healthcare technologies are at the forefront of advancement. So why is obtaining data – your own health data that you are entitled to – like squeezing out dried up toothpaste? Imagine obtaining a longitudinal assessment of a person’s health journey from birth. Anyone who attempts to do so will be the laughing stock of the year. Why? The inefficiencies in the medical space is embarrassing. Data may be entered into the system in error, or people may move and switch primary providers who do not use an identical platform. Furthermore, many privacy laws and regulations prevent healthcare data from being safely shared and capably distributed by providers to individuals.

In recent months, there is a spotlight on startups specializing in blockchain technology for handling healthcare data. For example, consumers do not appreciate the meticulous efforts that go into the distribution of prescription drugs. In a society where instant gratification plays a large role in consumers’ lives, people are subject to wait in line at the pharmacy, only to wait for the pharmacist to verify a prescription that they receive regularly. These startups strive to use blockchain technology to highlight predictive medical care, in part by analyzing patient health history and evolving patterns to audit prescription and medication usage. Allowing doctors, pharmacies and patients to coexist in a platform to exchange information freely and securely.

In the pharmaceutical industry, where data originates from multiple sources, clinical trial data suffers the same fate. Programmers consistently face incomplete, missing or inaccurate data. The process that follows the crackdown of data issues is expensive, time-consuming and stressful. Blockchain technology is the opportunity to increase patient trust and reduce inefficiencies in data sharing. The mechanism delivers real-time, transparent, auditable clinical research data in the peer-to-peer network. Each step in a clinical trial is time-stamped at a major milestone such as: screening, enrollment, trial monitoring, and data reporting. Reliable data reduces waste, which in turn minimizes reporting errors and any post data capture manipulation.
PROS VS CONS

- Easy audit trail
- Transparency
- Accurate data
- Immutable
- Faster transactions
- Trusting the blockchain vs manual data entry, data cleaning and repetition of work

- Requires training since this is new to the pharma industry
- Shaky future if not adopted well
- Must be well regulated with Good Clinical Practice, HIPAA, etc
- May need to hire a third party with blockchain expertise

Display 1. Pros and Cons of using blockchain technology in healthcare

Though the technology exists, it does not mean it won’t come with risks. Most companies do not have enough talent in blockchain programming, let alone have a full-time team building the network. Hiring a third party to handle data is expensive and understanding which ones to choose from is frustrating. Additionally, the third party must be regulated by Good Clinical Practices and privacy laws. Not to mention understanding the ins and outs of blockchain technology is cumbersome and time-consuming so the implementation could take years.

The good news is, all data is accessible and audit trails manageable. Backdating is essentially nonexistent and putting trust in a blockchain to hold valuable information is relieving.

CONCLUSION

With the imminent popularity of blockchain and its usage, this technology bolsters validity and transparency, which ultimately gives programmers the best gift of all time – clean and accurate data. Now that more industries are implementing this technology, the widespread demand is forthcoming. Will the pharma industry jump on this bandwagon and ride it out to sunset? Or will we sit back and let it mull over and see what happens? Though the adoption may come with obstacles, the plethora of benefits outweigh them. There is no better time than the present to start handling healthcare data more responsibly. Let’s all put our pitchforks down and pick up a block instead.
REFERENCES


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