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BLOCKCHAIN: THE NEXT BIG DISRUPTOR IN CLINICAL TRIALS?

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The digital revolution is driving change across all industries. With its ability to increase transparency and trust between parties, the recent innovation called blockchain has the potential to significantly disrupt the clinical trials industry.

Blockchain was invented in 2008 with the creation of the cryptocurrency known as bitcoin.[1] Finance was the first sector to utilize this new technology, which helped foster trust and transparency in financial transactions.

As blockchain technology has steadily matured, its potential to reduce costs, increase efficiency, and improve trust have made it attractive to other industries as well: A recent study from IBM, for example, revealed that 16% of health care executives had solid plans to implement a commercial blockchain solution this year, while 56% expected to do so by 2020.[2]

BLOCKCHAIN TECHNOLOGY, DEFINED

Blockchain technology uses a distributed computer network to create a digital ledger or database that stores time-stamped transaction records. Each server or node in the network verifies each data entry, and every node archives all transactions that have been recorded to the network.

Transaction data stored in a blockchain cannot be stolen or hacked, since it is not kept in a central repository; the data is distributed across dozens or even thousands of geographically dispersed nodes. The distributed nature of the network, time-stamped records, and verification requirements ensure that the stored data remains intact and immutable, since it is write once and read only.

By utilizing established cryptographic techniques to allow "trustless" peer-to-peer interactions between network participants, blockchain enables effective collaboration and an immutable audit trail. Participants can store, exchange, and view information in the database without the need for preexisting trust between parties. In fact, trust is coded into the blockchain protocol via a complex cryptographic algorithm. Rather than relying on a centralized, trusted third party to facilitate transactions, blockchain technology effectively eliminates the need for the "middleman," thereby reducing costs.

Blockchain is not a substitute for an enterprise database that is optimized for high-volume data and instantaneous access within a single organization. Instead, blockchain solutions are ideal for data records that are meant to be shared across a network of partners where transparency and collaboration are important.

BLOCKCHAIN TECHNOLOGY IN CLINICAL TRIALS

Researchers face numerous challenges concerning trust and transparency in clinical data. The enormous amounts of data generated in clinical trials, along with trends toward globalization and increasing regulatory constraints, are outstripping the ability of legacy data-management platforms to manage the competing needs of data sharing, patient privacy, and data integrity. The dearth of platforms that are both secure and transparent enough for effective, trustworthy data distribution is having detrimental effects on many aspects of clinical research.

Reproducibility, regulatory approval, data integrity, data sharing, privacy concerns, and patient enrollment are significant challenges for modern clinical trials. How could blockchain technologies help?

Patient recruitment

The traditional method of recruiting patients at investigative sites is less than ideal. Some estimates calculate that patient enrollment takes up 30% of the time required to conduct a clinical trial, with some sites never enrolling even a single patient.[3] Blockchain databases have the potential to dramatically improve the recruitment process. A blockchain-enabled solution could share patient information with pharmaceutical or contract research organizations (CROs) without divulging the patient's identity; this could provide more information about potential participants who are likely to be motivated to join a study.[4]

Medical data sharing and privacy

Unfortunately, most clinical trials results are not reported, and investigators often do not share their study results.[5] In fact, around 90% of trials on ClinicalTrials.gov currently lack results.[6] This creates knowledge gaps for researchers and safety issues for patients. Blockchain technology could create a secure tracking system for any data generated from patient-physician interactions. Blockchain anonymity allows electronic health record (EHR) data to be stored

BLOCKCHAIN IS IDEAL FOR DATA RECORDS THAT ARE SHARED ACROSS A NETWORK WHERE TRANSPARENCY AND COLLABORATION ARE IMPORTANT

and shared transparently, yet still maintain patient privacy. This could free enormous amounts of data for clinical research, and open clinical trials to secondary or meta-analysis.[7]

Data integrity

Good quality data from clinical trials requires security, proper content (metadata), and an immutable audit trail. Blockchain data integrity is ensured by cryptographic validation of each interaction or transaction. When there is a data integrity issue in a blockchain, it is possible to immediately identify where and when the problem happened, along with the last person to touch the data. These immutable, time-stamped records could reduce fraud and error in clinical trial records by eliminating the potential for outcome switching, selective reporting, and data snooping.

Protocol and traceability of consent

In clinical research, tracking patient consent for the approved protocol (including revisions) is an important aspect of good clinical practice compliance. According to the US Food and Drug Administration (FDA), nearly 10% of studies have issues related to patient consent, including unapproved forms, failure to obtain written informed consent, invalid consent documents, and failures to obtain reconsent to a revised protocol.[8]

In a recent proof-of-concept study,[4,9] researchers from the University of Paris and Columbia University applied cryptographic validation to transactions related to patient consent and the clinical research protocol for a fake experimental study. Each patient consent was time-stamped on the blockchain, as were consent renewals for protocol revisions. The resulting master data collection traced each consent to a version of the revised protocol. The result was a cryptographic representation of the real consent and protocol document data that can be verified on the web.

Blockchain as a service

Organizations looking to utilize blockchain technology to record, track, and share clinical data securely must first decide how to build the application. Public blockchains have thousands of computer nodes distributed randomly worldwide to verify and archive the records. Private blockchains distribute nodes only among stakeholders, who can then access the data-management solution that is built on the network.

To reduce the time and cost associated with building a private blockchain network, consortia are working to develop and adapt blockchain technologies for health care. One such group, Hashed Health (a collection of health care companies) provides value-added technology support services for blockchain solutions.[10]

Other companies have created private blockchains that are anchored to a public blockchain. Tierion, for example, has created an application programming interface that anchors data to the bitcoin public blockchain and provides a cryptographically verifiable audit trail for each record. This technology provides seamless data and process tracking.[11–12]

DELIVERING TRANSPARENCY WITH PRIVACY

From a global perspective, applying blockchain technologies to clinical research has wide-ranging promise and promotes data integrity while increasing the availability of granular patient information. Health care companies and regulatory agencies alike are excited about these new possibilities; both the FDA and Centers for Disease Control have announced partnerships with IBM to pilot blockchain technology for patient data exchange and medical data management solutions.[13–14] Ultimately, blockchain technologies offer the possibility to not only further clinical research, but to improve patient safety while bolstering data privacy. ‹›

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