

By Denise Myshko



# The Blockchain Movement

The pharmaceutical industry is actively exploring blockchain technology — a digital ledger system for records and log transactions — for a number of uses. Experts discuss applications for the industry.

**B**lockchain, the underlying technology behind bitcoin and other cryptocurrencies, is being explored with greater depth throughout the health and life-sciences ecosystem. A September 2018 report by the Pistoia Alliance found that 60% of those surveyed in the pharmaceutical and life-sciences industries were using or experimenting with blockchain technologies in 2018, compared with 22% in 2017.

“Blockchain is a great way to keep track of information,” says Mark Treshock, global blockchain leader, HCLS, IBM. “Blockchain allows parties, whether they’re business partners or competitors or even adversaries, to have both elements of privacy and transparency infused into their business at the same time.”

Blockchain, he says, allows all parties to have a central ledger of transactions. A blockchain is a list of records, called blocks, which are linked using cryptography. Each block contains a cryptographic hash of the previous block, a timestamp, or transaction data. While information can be added, it cannot be copied or deleted.

For the biopharmaceutical industry, blockchain has the potential to enhance collaboration, trust, interoperability, traceability, and auditability across a range of functions, such as clinical trials, supply chain management, financial transactions, credentialing, and claims processing.

The attribute of blockchain that’s very important for pharmaceutical companies is that it is immutable, Mr. Treshock says. “Once the information is recorded in a blockchain, it can’t be altered, which is not necessarily the case with a traditional database. The immutability also helps prevent fraud or diversion.”

Blockchain adoption throughout the industry is increasing. According to a Deloitte survey, the number of life-sciences and healthcare orga-

nizations that said they planned to deploy blockchain last year (35%) outpaced similar outlooks from other industries.

One of the factors that makes blockchain so appealing is that in the United States, manufacturers will have to comply with the Drug Supply Chain Security Act (DSCA), says David Colombo, advisory director, at KPMG. “There is no centralized system in America, similar to the systems that have been set up in other countries that require serialization and traceability,” he says.

The DSCA, enacted by Congress in November 2013, which is set to go into effect in 2023, outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Mr. Colombo says what makes blockchain intriguing is that the pharma distribution space has a lot of actors involved. Most pharma manufacturers contract their distribution to a third-party logistics provider and the products get sold to a national distribution center of a wholesaler and are then distributed to a regional center.

“There are reverse logistics providers that are involved, as well,” he says. “Because blockchain can’t be altered or modified, there’s a benefit when compared with a technology that only tracks data between two parties.”

He says the requirements outlined in the DSCA could be met using a central database in the cloud, but that isn’t as powerful and there are questions about who governs and owns that cloud, as well as who administers the platform. “A database in the cloud doesn’t provide the same degree of freedom that blockchain would, insofar as stakeholders can have their own copy of the shared visible data for use within their own enterprises,” he says. “This is what makes blockchain compelling.”

Having a tamper-proof record provides a bit more security since everybody is seeing the same information simultaneously, Mr. Colombo says. “It certainly provides security in that there is an immutable audit trail and one can see what’s happened. The pilot programs we’re working on are private blockchains that have permissions, which are designed to be secure against malicious transactions.”

### Blockchain for the Supply Chain

Blockchain is one of many technologies being considered for product tracing and verification. Food and Drug Administration officials say the agency is open to considering all viable technologies and methods through



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**MARK TRESHOCK**  
IBM

the DSCSA Pilot Project Program. In February 2019, the FDA launched a new pilot project in which participants representing the drug supply chain — manufacturers, repackagers, and other stakeholders — can pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States to ensure suspect and illegitimate products do not enter the supply chain. Eligible entities may apply to participate in the program.

The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements. The program will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information.

The FDA will share the new approaches through this program with the broader drug supply chain community on the agency’s website. The goal is to ensure that all parties can be apprised of the program’s progress and take advantage of any shared learning.

In May 2019, Pfizer, McKesson, and AmerisourceBergen joined the MediLedger Project Contracting and Chargebacks working group, which is a working in parallel to the ongoing DSCSA working group. MediLedger is an initiative of Chronicled, a technology company that builds blockchain-powered ecosystems and supply chain solutions. They join Genentech and AbbVie, which are already working on the MediLedger project.

Chronicled is finalizing a protocol to improve the complex process of chargebacks; the goal is to begin testing the protocol in the third quarter of 2019. MediLedger’s protocol aims to eliminate friction by connecting the disparate parties on a common network as well as automating the contract reconciliation and chargeback processes.

In another pilot announced in June 2019, Merck, IBM, KPMG, and Wal-Mart are creating a shared permissioned blockchain network that allows real-time monitoring of products.

### Challenges of Implementing Blockchain in Healthcare

- ▶ **Scalability.** Many of the processes for blockchain would require more scalability and balance between permissionless blockchains, which offer more computing power, and permissioned ones, which offer faster processing.
- ▶ **Standardization.** To foster greater efficiency and performance, organizations can consider implementing governance to control what type of data may be written into a blockchain.
- ▶ **Incentives.** Blockchain participants should determine technical, financial, and business incentives that could encourage organizations to adopt the technology and lend their computing power.
- ▶ **Cost.** Organizations need to determine their costs for operating a blockchain.
- ▶ **Regulatory.** While a blockchain solution could address the HIPAA privacy rule in part by separating and encrypting Phase I/II data, regulatory bodies should consider deep collaboration with the industry to facilitate adoption.

Source: Deloitte

The proposed network is intended to help reduce the time needed to track and trace inventory; allow timely retrieval of reliable distribution information; increase accuracy of data shared among network members; and help determine the integrity of products in the distribution chain, including whether products are kept at the correct temperature.

A spokesperson from Merck says the goal of the pilot is to develop a trusted and verifiable supply chain that establishes interoperability from manufacturer to the point of dispense and connect the channel with each stakeholder’s independent system of record.

Beyond this pilot, Merck will continue to discuss with others how blockchain might solve a business problem or unlock new opportunities based on purpose.

IBM’s Mr. Treshock says the blockchain in use today tracks the provenance of food in the United States. The Merck and Wal-Mart pilot aims to leverage that same blockchain for the supply chain in pharmaceuticals.

“The actual mechanics of tracking how food moves through the supply chain is very

similar to tracking how drugs move as well, he says. “The life-sciences industry and the food industry have similar concerns as to how data is shared among competitors within the supply chain. The food industry has solved many of these trust issues, so we’re going to take this model as a starting point and modify it. Food and drugs will never coexist or be comingled on the same blockchain. We’re simply going to take those assets and use them as a starting place.”

KPMG’s Mr. Colombo says the pilot program with the FDA is evaluating private and permission-based blockchains versus a public anonymous blockchain, which is what cryptocurrencies, such as bitcoin use. “We’re trying to provide more intelligence and functionality with the data and transactions that are posted to the blockchain and then replicate the information across the various ledgers,” he says.

Mr. Colombo says this pilot aims to demonstrate how blockchain technology can be used to satisfy the interoperability requirements of the DSCSA.

“To meet the requirements, every time pharmaceutical products are sold from one company to another the individual serialized data needs to be provided to that downstream customer and it needs to propagate throughout as the product is physically distributed,” he says. “This level of data sharing has never been required in the past, and one of our goals is to show how blockchain technology can be used to achieve this purpose.”

Additionally, Mr. Colombo says, the pilot aims to demonstrate how product recalls can be facilitated using blockchain technology. “We want to see how much of a product is still with a manufacturer and the distribution center, how much has been sold to distributors, how much has been sold downstream to dispensing pharmacies, and how much has been dispensed,” he says.

Lastly, he says, the companies want to learn what’s involved with onboarding the organization to a blockchain solution, what’s the impact to an organization, and what is the impact on the processes, policies, or procedures that companies have in place.

Mr. Colombo says the pilot was executed from August through September with a final report due to the FDA at the end of October.

This pilot, he says, is being done in parallel with a broader initiative launched in March 2019 by IBM and KPMG to establish a pharmaceutical utility network that would be blockchain-based. “We’re reaching out to

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**RONAN FOX**  
ICON



industry stakeholders to establish a blockchain-based platform that would be able to be used for not only compliance with the DSCSA but for other use cases.”

Mr. Colombo says the biggest challenge of both programs has been addressing the needs of multiple stakeholders, including manufacturers, wholesale distributors, dispensers, third-party logistics providers, and contract manufacturers. “Each stakeholder has different views, different operating models, and different goals and objectives,” Mr. Colombo says. “One of the challenges is coalescing and defining what the functional requirements of the application need to be to get everyone on the same page. The challenges are less around the technical coding and the technology itself and more around getting buy-in and alignment on the priorities and the approach.”

### Blockchain in Clinical Trials

Industry leaders say within pharmaceutical R&D, there is a use case for blockchain. “Clinical trials are changing,” Mr. Treshock says. “They’re becoming much more dispersed, and they’re becoming much more digitally enabled. Trial participants can be spread all over the world, potentially interacting with different types of research organizations. Blockchain has the potential to enable clinical trials to become much more powerful and to underpin a broader digitally enabled process.”

Blockchain pilot programs in R&D have already begun. For example, in February Boehringer Ingelheim Canada and IBM Canada announced a first-of-its-kind collaboration to explore the use of blockchain technology in clinical trials in Canada.

The companies aim to test whether using blockchain technology in clinical trials can provide a decentralized framework that enables data integrity, provenance, transparency, and patient empowerment as well as automation of processes, ultimately improving trial quality and patient safety at reduced cost.



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**DAVID COLOMBO**  
KPMG

Ronan Fox, VP, applied digital solutions at ICON, says because blockchain is an enabling technology that underpins distributors’ data, this makes it an attractive option for clinical research. “Blockchain is in its very nature an enabler of a virtual trial where patients, providers of services to patients, and the investigators are disbursed around the globe,” he says. “The automation provided by blockchain gives transparency, allowing multiple parties to gain consensus on transactions and activities and to use the information in a real-time environment. Additionally, they can trust that the data they are seeing is real, valid, up-to-date, and accurate.”

Mr. Fox says as blockchain becomes more widely understood, new use cases will emerge. “The pharma industry can leverage blockchain in logistics operations within the clinical research environment, including how investigator payments and even contract negotiations and signings are handled.”

He adds for blockchain to be successful, there needs to be education around the technology.

ICON, Mr. Fox says, is investigating the use of blockchain to satisfy regulatory requirements in future trials. “We want to make sure we are relieving some of the burden on sites while making sure that the regulation is satisfied.” **PV**

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