

BLOCKCHAIN TECHNOLOGY

By Robin Robinson

Pharma is in the pilot stage of using blockchain for its supply chain, but there are many other valuable use cases on the horizon.

Blockchain can be a challenging concept to get your head around, and it's difficult to embrace something you can't understand. That may be why the pharma industry lags behind others in its adoption of the immutable ledger. In fact, a recent survey aimed at assessing blockchain adoption, conducted by Ipsos and sponsored by the Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA), revealed a significant need for more education about blockchain. According to the IEEE report, there exists a considerable need for awareness and education at a baseline level on the benefits and outcomes of the technology. People who are more familiar with blockchain must also be better educated on potential applications beyond compliance. They must have a deeper understanding of the trust in a "trustless" autonomous platform, and understand the role of anonymity in a transparent data-sharing system. These seem to be contradicting paradigms, but once you deep dive into blockchain, it makes sense.

According to our experts, the more people understand the possibilities available through blockchain, the less hesitant the pharma industry will be in getting on board the blockchain train. Several companies have already started.

Pharma companies that have become more blockchain-savvy are starting to explore its potential and many have proof-of-concept pilots already under way, says Susanne Somerville, founder, principal of The LinkLab.

"It's really exciting to see the depth of knowledge grow from even a year ago," she says. "The people who were doubtful before are now asking more positive questions rather than skeptical ones, which is where we were just six months ago."

Ms. Somerville, who is collaborating with tech company Chronicled on the MediLedger Project, says even she was a skeptic not too long ago. "I'll speak for myself," she says. "I was not convinced at the beginning of last year that blockchain was fully feasible for pharma."

The stumbling block for Ms. Somerville was her understanding of bitcoin privacy. (Editor's note: blockchain is the underlying technology that facilitates direct trade of bitcoin cryptocurrency.)

In bitcoin, every person trading is anonymous, but every single bitcoin transaction is public. People with the right knowledge can watch bitcoin being traded from their computers. They can't tell who is doing the trading, but they can follow the bitcoin transaction. This inadvertent transparency is a big red flag for the industry.

"This is a no-go for the pharmaceutical industry," she says. "And I doubted whether we could create a system that allows for data privacy with participants in the same system, without revealing any business intelligence, yet still connect the provenance — the tracking of assets across a supply chain."

However, since then, MediLedger partners have done just that and are piloting a proto-

FAST FACT

OUT OF THREE GROUPS SURVEYED, PHARMACEUTICAL MANUFACTURERS SHOWED THE GREATEST PROPENSITY TO ADVANCE TO THE NEXT STEP OF BLOCKCHAIN TECHNOLOGY IMPLEMENTATION, MOST LIKELY WITHIN TWO YEARS.

Source: IEEE-SA

type system for the registration and verification of medicines on the blockchain, while keeping all business information private from other participants.

"So bit by bit, we're tackling industry needs," Ms. Somerville says. "We've already started a discussion on exception handling, as it is a real issue in the industry."

For example, one wrong package with the wrong serial number can halt the fulfillment of hundreds of packages in its tracks.

"By using the system logic set up in a blockchain solution to validate back to the manufacturer the error that took place and im-



With any potential blockchain solution, the focus is automation and streamlining, and providing companies with control over connected data and with whom they want to share data.

SUSANNE SOMERVILLE
The LinkLab

mediately reconcile it, that product can keep moving,” she says.

US 2013 DSCSA and Blockchain

One of the driving forces for the increased adoption of blockchain is the Drug Supply Chain Safety Act (DSCSA), which will require that all prescription drugs be tracked and traced through the supply chain using an interoperable system by 2023. When the law was written, blockchain didn’t even exist, but it has emerged in the nick of time to provide the industry with a compliance solution. However, some experts see it as the chicken or the egg causality dilemma. The DSCSA gives blockchain the opportunity to prove its worth, and blockchain gives DSCSA the opportunity to prove its purpose.

When asked what impact the DSCSA will have on blockchain adoption, Maria Palombini, director, emerging communities & opportunities development, global business strategy & intelligence, IEEE-Standards Association, suggested the real question is what is the impact blockchain adoption will have on DSCSA compliance?

“If blockchain can prove it can deliver the management, distribution, and security of serialized data with all its partners, while maintaining compliance and deterring the growth of counterfeit medicine, then its future could be a great one in the healthcare ecosystem,” she says. “I find the entrance of an emerging technology such as blockchain and the introduction of an aggressive 10-year old policy guideline somewhat perfect timing.”

Achieving DSCSA compliance through blockchain is possible in two significant ways, Ms. Palombini says.

The purpose of the DSCSA is to track the distribution of medicine through the complex network of the pharmaceutical supply chain with the end goal of delivering security.

“Blockchain not only offers the ability to track but also to trace, which is a key combatant in the counterfeit epidemic and unregulated Internet pharmacy epidemic,” she says.

Secondly, blockchain is a tool that offers the key trading partners the ability to comply with critical points of the DSCSA guidelines especially in the area of collaboration with trusted partners through data sharing, and the ability to electronically track all the transactions to verify that it was not tampered.

“It is important to remember that blockchain is the tool that can amplify the outcomes of policies such as DSCSA with its ability to both track and trace,” Ms. Palombini says. “Each unique data point on the blockchain is immutable, can be verified by all permissioned users as every transaction is replicated in every block, while retaining anonymity and controlling different levels of access.”

Blockchain Along the Drug Lifecycle

Hong Kong-based Caywon Pharmaceutical Group, a drug product developer led by former pharma IP attorneys and drug development experts, seeks to accelerate the translation of biomedical advances into innovative products through distributed partnering. To that end, Caywon is actively researching and developing blockchain applications in healthcare. It has recently partnered with Crowd Machine, an advanced distributed computer, to create a decentralized global pharmaceutical products development and commercialization platform to realize this vision.

This makes it the first international pharmaceutical company to adopt Crowd Machine as the key enabling technology to power its Pharma 4.0 digital transformation initiative.

One area of great interest is to thwart counterfeiting. A blockchain supply chain records and tracks price, date, location, quality, certification, and other relevant information to more effectively manage the supply chain. The availability of this information within blockchain can increase traceability of material supply chain, lower losses from counterfeit and gray market, improve visibility and compliance over outsourced contract manufacturing, and potentially enhance an organization’s position as a leader in responsible manufacturing.

The MediLedger Project

Two companies — Chronicled, a technology company leveraging blockchain and The LinkLab, a supply chain consulting firm — have created a joint venture that will explore and develop blockchain solutions for the pharmaceutical industry. The project has formed a working group of pharmaceutical industry leaders, which include Genentech, Pfizer, Amersource-Bergen, and McKesson Corp. The working group defined the industry requirements for a blockchain pilot. The group has built a prototype system for the registration and verification of medicines using blockchain, while keeping all business information private from other participants. The next effort will be focused on developing business models and operating requirements.

The project is primarily aimed at demonstrating compliance with the Drug Supply Chain Security Act (DSCSA), using innovative capabilities found with blockchain technology to track and trace prescription medicines. The project seeks to demonstrate the ability to prevent counterfeit medicines from entering the supply chain. The DSCSA requires the industry to adopt an interoperable system to manage records of ownership and transfer of prescription drugs in the United States, and MediLedger members strongly believe that blockchain technology could be best suited to do this.

Beyond the DSCSA, MediLedger participants hope to use their system to fundamentally move the industry forward in improving drug security and preventing the production and trafficking of counterfeit and illicit drugs globally.

Source: mediledger.com

“The most important thing to remember about blockchain is that it’s a highly secure and immutable record of assets,” says Dr. Matthew Lee, VP of innovations, Caywon Pharmaceutical Group. “When you consider these characteristics for tackling counterfeiting, it’s clear how useful this technology would be.”

By recording the source of manufactured

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Pharma Blockchain Benefits

Blockchain offers pharma the opportunity to manage a legacy platform problem: the ability to evenly balance the dilemma of data privacy and sharing within a tamper-proof environment. Blockchain has proven this in its application with bitcoin as the management system for the peer-to-peer digital currency where it can account and make apparent all the transactions while retaining user anonymity. Therefore, this innate ability can deliver many benefits to the pharmaceutical industry, including to:

1. Enhance patient safety and care by enabling data sharing throughout the healthcare ecosystem
2. Enable true collaboration among trusted trading partners without sacrificing IP or data privacy in exchange for data sharing
3. Optimize critical processes throughout the pharmaceutical value chain — R&D, clinical trials, and supply chain
4. Achieve compliance with regulatory authorities as it relates to patient data privacy, partner collaboration, ethics, and supply chain security
5. Apply and achieve policy guidelines as it relates to combatting counterfeit medicine and unregulated Internet pharmacies
6. Create a transparent yet private and secure two-way data highway between pharma and patients
7. Create an inclusive patient and qualified patient engagement/recruitment program that will lead to more efficiency and patient safety throughout clinical trials

Source: Maria Palombini, IEEE-SA

drugs, as well as the different parties involved in their development and production, regulators and buyers can quickly trace the source of a drug and sort the authentic ones from the counterfeits.

"It's true to say that secure Internet of Things technology, which ensures the data being used are true and haven't been tampered with at the point of record, is an important



In the world of blockchain, utilizing the valuable data trapped in silos could open new doors of opportunities for disease prevention, drug development, treatments, and clinical research without sacrificing patient privacy.

MARIA PALOMBINI
IEEE-SA

component and these two advances could work to completely eradicate counterfeiting," he says.

Dr. Lee expects blockchain applications will also be used to improve efficiency for smart contracts and increase security and streamline EHRs.

"Virtually any area where important data are recorded by humans could be improved by blockchain," he says. "For counterfeit drugs, that means eradicating the fraud that exists at all levels. However, for other areas of life sciences, one of the benefits of blockchain could be to remove duplication of work when entering patient details into a database. We're already starting to see this occur with the use of blockchain-enabled electronic health records."

Another important area of blockchain technology that can be used across the life sciences is the area of smart contracts. These coded contracts are self-executing when certain events occur and could not only be used across complex supply chains to increase efficiency but also to reduce paperwork that patients need to fill in to receive and pay for treatment.

Once blockchain becomes universally adopted, there will be many ways to use it to improve the drug development process, says Ms. Palombini.

"In an ideal world, blockchain could offer the capability of tracking a compound (with an assigned unique identifier) developed at the bench level through to distribution," she says. "However, we may be many years away before



When considering how effective blockchain can be for tackling counterfeiting, it's clear it can be a game changer.

DR. MATTHEW LEE
Caywon Pharmaceutical Group

we realize this opportunity but the capability is promising."

So, in the current environment, companies should focus on applying the technology to parts of the enterprise that can improve the whole lifecycle. For example, blockchain can have a viable and positive impact on the drug development lifecycle in the area of the supply chain (raw materials and commercialization), clinical trials, and research/genetics.

"If we can get these critical areas fully operational with blockchain and with positive intended outcomes, the entire drug development lifecycle would be optimized and more secure," Ms. Palombini says.

Ms. Somerville has seen movement within pharma toward pure finance use cases, as well as clinical trials and facilitating payer reimbursement.

Use of blockchain within the payer and provider space could verify information automatically, leading to faster and more accurate claims payments. Tracking patient outcomes and patient databases is also a viable use case.

"I know of companies that are working on patient outcomes with the drugs that are only paid for upon positive use; there are so many exciting possibilities with this technology," she says. "In any potential blockchain solution, the focus is automation and streamlining, and providing companies with control over connected data and to whom they want to share the information with."

Defining Blockchain

Of all the videos, articles, diagrams, and slide presentations accessed in search of an easily understood definition of blockchain, there were a few resources that were able to lay it out in terms even non-techies can understand. Author Bernard Marr wrote one in a Forbes article last year, another is from a Deloitte Insights article posted on its website, and a third is a TedTalk presented by Richie Etwaru. I hope they help bring some clarity.

Bernard Marr: A Complete Beginner's Guide to Blockchain, Jan. 24, 2017, Forbes

A blockchain is a distributed database, meaning that the storage devices for the database are not all connected to a common processor. It maintains a growing list of ordered records, called blocks. Each block has a timestamp and a link to a previous block.

Cryptography ensures that users can only edit the parts of the blockchain that they "own" by possessing the private keys necessary to write to the file. It also ensures that everyone's copy of the distributed blockchain is kept in synch.

Imagine a digital medical record: each entry is a block. It has a timestamp, the

date and time when the record was created. And by design, that entry cannot be changed retroactively, because we want the record of diagnosis, treatment, etc. to be clear and unmodified. Only the doctor, who has one private key, and the patient, who has the other, can access the information, and then information is only shared when one of those users shares his or her private key with a third party — say, a hospital or specialist. This describes a blockchain for that medical database.

Deloitte Insights: Building the Trust Economy

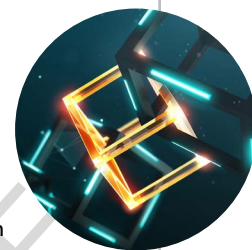
with Blockchain Simply put, blockchain is a distributed ledger that provides a way for information to be recorded and shared by a community. In this community, each member maintains his or her own copy of the information, and all members must validate any updates collectively. The information could represent transactions, contracts, assets, identities, or practically anything else that can be described in digital form. Entries are permanent, transparent, and searchable, which makes it possible for community members to view transaction histories. Each update is a new block

added to the end of the chain.

A protocol manages how new edits or entries are initiated, validated, recorded, and distributed. Crucially, privacy can also be selectively enforced, allowing varying degrees of anonymity or protection of sensitive information beyond those who have explicitly been given access. With blockchain, cryptology replaces third-party intermediaries as the keeper of trust, with all blockchain participants running algorithms to certify the integrity of the whole.

Richie Etwaru, Chief Digital Officer, IQVIA,

discusses the opportunity and implications of blockchain as a paradigm to slow/close the expanding trust gap in commerce. He unpacks blockchain to a level of simplicity to be consumed by those that are just starting to understand and explore the paradigm. He lays out a current state of commerce, suggesting that every company is currently at risk of being disrupted or incurring severe strain from a blockchain version of itself. To view, visit: <https://www.youtube.com/watch?v=k53LUZxUF50>



Blockchain-based EHR Solutions Benefit Pharma

In the healthcare space, there is a concerted effort to focus on care coordination and EHR access across the care continuum. Blockchain's ability to use time stamping to authenticate changes to a dataset is ideal for managing EHR data. While the benefit to healthcare systems include ensuring data integrity and protection of patient privacy, blockchain EHR solutions can also have a positive outcome for pharma.

According to Ms. Palombini, there are two obstacles that can be easily met through a blockchain-based EHR.

"Patient engagement, recruitment, and retention would be completely disrupted in a good way," she says. "Imagine a program where sponsors of clinical trials can query every validated patient record on a blockchain based on specifications around the design protocol."

Patients would retain complete anonymity while controlling their right to be first queried

and second choosing to participate in the clinical trial. In addition to making their health record available, they would also have their trial participation data reflected back into their health record so it is accessible to those who have been granted permission, by the patient, to access it.

"This would all be feasible with a blockchain-based EHR system," Ms. Palombini says. "And this would effectively close the disconnect between clinical research and medical treatment."

In today's medical practice there are millions of data points held in silo systems controlled by doctors, health facilities, labs, etc. In addition, with digital innovation of medical IoTs/health wearables and AI there is a new flood of data that sits in another silo database system.

"In the world of blockchain, 'putting this data to work' where it can be shared and applied could unlock new doors to opportunities to prevent disease, accelerate drug development, advance new treatments, and improve

clinical research without sacrificing patient privacy," Ms. Palombini says.

Such a system can reduce duplicated work, eliminate fraud, and make the process of giving and receiving care more efficient, Dr. Lee says.

Blockchain-based EHR solutions could assuage patients' fears of lack of privacy, as they are not only highly secure but could be shared autonomously.

According to the EEEI report, efforts to use blockchain and technologies that it enables, such as smart contracts, in pharma are at an earlier stage, but there is a growing recognition that the decentralized platform could offer benefits, allowing supply chain partners to share and verify data in a secure IT environment that is difficult to hack into.

Most executives surveyed said they are actively exploring use of blockchain in their supply operations. Some have advanced these efforts to the proof-of-concept stage, while roughly 20% are currently involved in a pilot study of the technology. ^{PV}