IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Blockchain Innovations for Pharmaceuticals and Healthcare

By **Tim Sandle**

Aug 6, 2019 4:00 am EDT

Introduction

Blockchain in the full-blown sense has yet to be accepted by pharmaceutical regulators; however, the U.S. FDA agreed in 20198 to a pilot study. This blog posts looks at what blockchain is and how it might work in the context of pharmaceuticals and healthcare. This post also looks at areas where blockchain can be directed and what advantages it can deliver to pharma. Of these different applications, avoiding the falsification of medicines is probably the most important.

While blockchain as yet to take-off fully in the pharma world, across other industries (such as food and shipping) it is regarded as one of the most disruptive technologies within the digital transformation paradigm, introducing greater security and transparency to economic transactions. As soon as it become accepted by pharmaceutical regulators, it will change the industry permanently - passing information from A to B in a fully automated and safe manner.

What is blockchain?

Blockchain is based on digital technology and it is a form of software that provides a digital ledger system for records and log transactions, by grouping them into chronologically ordered blocks (1). This makes it ideal for tracking supplies and ensuring that required storage conditions have been achieved and that goods have not been tampered with. The “blocks” on the blockchain are made up of digital pieces of information, which store information about transactions, say the date, time, and transaction price. Blocks also store information about who is participating in transactions, and information that distinguishes the block from other blocks. The system is designed to provide transparency and security.

Sometimes there is confusion between blockchain and tokens like Bitcoin. Bitcoin is powered by a blockchain, but not all blockchains utilize Bitcoin; and many blockchains do not use any cryptocurrency or token at all. Where tokens are used, these vary significantly depending on the type of blockchain or distributed ledger (2).

Blockchains can also provide real-time information. The blockchain enables the transmission of data and information to all users of the supply chain network on a real-time basis. This means that when goods move from point A to point B, all of those in the supply chain are made aware at the same time. Should a change occur, such as a switch to a different distributor every actor is made aware and the system can be configured so that each party would need to agree such a change.

As things currently stand, full-blown blockchain is not yet permitted be used in the pharmaceutical industry to label actual drug products, by any major regulator. However, the digital ledger technology is being implemented in moderated forms, such as a two-dimensional barcoding system. The technology is then used to authenticate containers throughout the supply chain. In the near future, many pharmaceutical manufacturers hope that blockchain will be accepted as the primary tool to enable stronger

serialization. The primary purpose of serialization is to prevent fraud (through reducing opportunities for counterfeit medicines to enter the supply chain) and to enhance patient safety.

Serialization becomes mandatory for both the U.S. and Europe by the end of 2019. Serialization will generate massive amounts of data for global companies that will need to be retained for many years to meet compliance requirements. This places additional strain on information management systems and will itself drive further investment into digital technologies and adds momentum for the adoption of blockchain.

Blockchain holds the potential to end the falsification of medicines

Counterfeit medicines are a problem around the world, with many producers of false medicines attempting to illegitimate drugs from pharmaceutical companies. Concerns with falsified medicines extend to where drugs which are targeted at those who are seriously ill. These types of medicines may be contaminated, or they can contain the wrong ingredient or no active ingredient at all. Alternatively, the drugs may have the right active ingredient but at the wrong dose. Through any of these combinations, adulterated medicines may harm the patient or exert no beneficial effect at all. The rise in counterfeit medicines is linked to a general increase in the number of people using the Internet to purchase commodities and this includes those using the Internet to self-diagnose and self-prescribe. This practice can lead to people purchasing ineffective medicines; medicines that normally require a prescription; or purchasing what they think are legitimate medicines, but which are in fact fake.

For many years regulators, such as the U.S. Food and Drug Administration (FDA), Health Canada and the European Medicines Agency have taken measures to prevent counterfeit medicines from entering the drug supply chain. One such example of a practice designed to reduce counterfeiting is by implementing product serialization and a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain, as discussed above.

Blockchain could be the answer to stem the tide and for this reason the U.S. FDA are interested. In theory, with a pharmaceutical blockchain it would be impossible to tamper with a medicine or to swap legitimate medicines with fake medicines. In addition, someone purchasing a medicine would be able to assess where the medicine came from (that is, did it come from a bona fide manufacturer?) According to the FDA, blockchain will enable the "use of innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the U.S. to ensure suspect and illegitimate products do not enter the supply chain." (3) The concept of blockchain also fits with the current focus on data integrity.

Blockchain for healthcare

Blockchain applications are being introduced more freely into health care than with pharma, due to the different regulatory landscape. Blockchain can decentralize the storage and authentication of information, allocating it across a "distributive ledger" amongst the participants. This means that all participants, or "nodes," on the designated blockchain have a complete copy of the information. Information is no longer stored in a single data warehouse or repository but across all nodes on the blockchain and each transaction or change to the information is a new "block" along the chain.

This distributive ledger offers an alternative means for health care providers to backup and access information because it is nearly impossible for all nodes to suffer simultaneous data loss. This also provides increased confidence in data accuracy as each blockchain node has an updated copy of the ledger and, first, previous "blocks" along on the chain are never deleted, only replaced by a new "block"; and, second, new blocks must be added to the chain through appropriate and approved protocols. A verified piece of data forms a block which then has to be added to the chain. To do this, blockchain users have to use their respective keys and powerful computing systems to run algorithms that solve very complex mathematical problems. When a problem is solved, the block is added to the chain and the data it contains exists on the network forever, meaning that it cannot be altered or removed.

Several startups are pioneering blockchain technology into the health and pharmaceuticals market. The types of applications stretch from medical record interoperability; data security; patient or supplier reimbursement; and drug management. Also, some big technology players are working on blockchain technologies for healthcare. For instance, IBM Watson has entered into an agreement with the U.S. Food and Drug Administration to assess whether blockchain technologies can better secure share patient data (4). This will start with oncology data in the form of electronic medical records, clinical trials, genomic data, and health data from mobile devices, wearables and the Internet of Things.

Examples of healthcare applications include (5):

- Portable patient records: Blockchain can add portability to patient data. This means a patient's health record becomes

electronic and it can be moved across health institutions. Blockchain technology allows for new records, be they visits of images, to be added. All of the data is then visible to the patient and to any other institution granted access.

- Medical claims process: Blockchain applications for healthcare and supply chain management can extend to the medical claims process, and also with providing technology for patients, providers, and insurers to view a patient's health timeline in real-time in a secure manner.
- Digital patient records: Some technologies are seeking to integrate health data with the health cards that citizens carry and also to add stronger data integrity and security to the health records process.
- Tracking organ donations: Blockchain can also be applied to tracking of a range of products including pharmaceuticals, blood, and human organs. These products are critical to human health and they often have a tight time expiry and they need to be kept at low temperatures (cold chain management). This makes safely tracking each step something of great importance.

Blockchain can also assist with precision medicine. The technology combines several advantages at the same time, such as being ideal for the storage and sharing of genomic data components. Primarily blockchain offers an additional level of security and trust, as data cannot be revised or tampered with which is particularly crucial for the highly regulated medical field. Also, blockchain can help enable layers of privacy, ensuring that identities are kept private, and users' information is not easily accessible. Additionally, it allows the user to retain data ownership, and control, such that only the necessary information about the user is disclosed and disclosure is done under the user's control (6).

Blockchain can also help connect stakeholders, eliminating some unwanted middlemen that increase costs in healthcare systems. The technology also helps to operate across borders so that users can operate everywhere, reaching underserved markets such as transitional countries like India, Brazil, Turkey, or the Middle East. All of this can be accomplished with decentralization of information (data is not stored in one centralized database), so blockchain offers no single hacker access point. With the help of smart contracts, blockchain allows for real-time transactions to occur automatically via pre-defined agreements.

Blockchain and medicine

Blockchain can also assist with medicine and global healthcare efforts, according to Pharmaceutical Microbiology Resources (7). As an example, Kamari, a project building an ecosystem of mobile gaming and lotteries with existing licenses in over seven African countries, has partnered with Kinect, a blockchain-based health technology platform focused on advancing the United Nations Sustainable Development Goals (SDGs), to fund and promote new HIV testing programs in countries across the African continent. Kinect has also operated in Mumbai, India for the last four months with its blockchain enabled electronic health record and patient incentivisation system working seamlessly to improve patient treatment programs.

Taking a different subject within medicine, with drug development reproducibility of clinical research studies has been an issue for quite some time. Using blockchain technology can combine privacy with secure, decentralized tracking of all data and lead to more robust and reproducible clinical trials. Blockchain may also lead to more people volunteering to participate in clinical trials; using blockchain could help address the concern that some people have of their data being compromised while participating in a clinical trial. If more people are comfortable with providing data, then life-changing therapies can be advanced more quickly.

Blockchain and science publishing

Blockchain can also assist with science publishing. For example, with the platform DEIP, which enables scientists to publish immediately – all papers are open to public once submitted to the platform (8). The papers are peer reviewed by other members of DEIP, scientists in the corresponding disciplines, who are incentivized to do it after publishing. DEIP also offers publishers a monetization model, enabling them to become fully open access (now only about 25% of the research knowledge is such) and to stop charging any fees – either from researchers, or from their institutions. This model can easily be adopted by reputable journals.

Blockchain and business efficiency

Another reason why pharmaceutical companies are interested in blockchain is to drive business efficiencies. Blockchains bring cost-efficiencies to value exchange and information sharing by removing middlemen or counterparts who profit from information asymmetry. They can also support the digitization of assets, opening access to market opportunities by eliminating physical boundaries and enabling fractional participation in financial transactions. Furthermore, blockchains make it possible to

share data transparently across ecosystems in which counterparties implicitly or loosely trust each other. All participants have permissioned views to the same transaction audit trail (changes to data or financial transactions) so mistakes or fraud can be prevented. Additionally, blockchains remove siloed information so that participants benefit from single-record keeping—that is, they do not re-enter the same information multiple times, resulting in wasted efforts and data inconsistencies.

Blockchain provides enhanced security

Blockchain also provides enhanced security for distributors. The technology is very secure, providing mathematical algorithms in combination with a peer-to-peer consensus network to create an immutable ledger of transactions that is nearly impossible to crack. The technology also introduces authenticity through the use of private keys, and it is transparent by offering independent verification of each transaction stored on the digital ledger.

Summary

Blockchain is making waves in healthcare and it has the potential to irreversibly change pharma, assuming that the U.S. FDA gives their backing after the pilot program is finished. The advantages are multifaceted: decentralized ledgers and blockchains could offer robust cybersecurity solutions for healthcare data, secure pharma and medical device supply chains, offering a solution to the requirements of data integrity and a means of minimizing counterfeit products from reaching patients and consumers.

References

1. Swan, M. (2015) Blockchain: Blueprint for a New Economy, O'Reilly Media, Inc., Beijing, China, pp1-6
2. Chen, Y. (2017) Blockchain tokens and the potential democratization of entrepreneurship and innovation, Business Horizons, 61 (4): 567-575
3. FDA (2019) FDA takes new steps to adopt more modern technologies for improving the security of the drug supply chain through innovations that improve tracking and tracing of medicines, see: https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-... (accessed 3rd August 2019)
4. IBM ‘Blockchain in Healthcare’ at: https://www.ibm.com/blogs/blockchain/category/blockchain-in-healthcare/ (accessed 4th August 2019)
5. MobiHealthNews ‘How and why startups are using blockchain to tackle healthcare hurdles’ at: https://www.mobihealthnews.com/content/how-and-why-startups-are-using-bl... (accessed 3rd August 2019)
6. Frost & Sullivan report ‘Role of Blockchain in Precision Medicine: Challenges, Opportunities, and Solutions’ at: https://ww2.frost.com/wp-content/uploads/2018/03/Edited_Frost_Prospectiv... (accessed 2nd August 2019)
7. Sandle, T. (2019) ‘Kamari and Kinect Partner to Fund HIV Testing Programs in Africa’ at: https://www.pharmamicroresources.com/2019/06/kamari-and-kinect-partner-t... (accessed 4th August 2019)
8. DEIP at: https://deip.world/ (accessed 4th Augusts 2019)
