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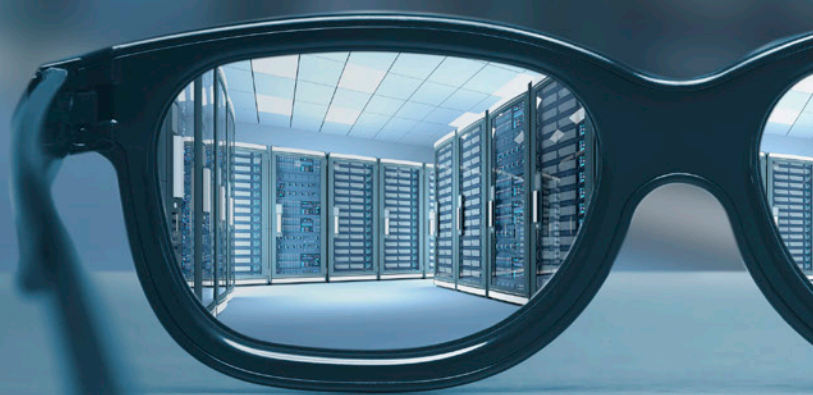
Demystifying blockchain for life sciences

Blockchain could be a key to interoperability and privacy



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Life sciences has two problems with data.

The first is the sheer volume. From electronic health records to patient claims to unstructured data from wearables, protected health information (PHI) has reached historic levels. And the growth of Big Data in all industries shows no signs of slowing. According to IDC, global data will grow to a trillion gigabytes by 2025, and this year the world will generate more data than in the previous 5,000 years.[1] The problem is, of all the world's data, less than one percent is actually being put to use.[2] And the General Data Protection Regulation (GDPR) is upping the ante on data privacy, which will make it even more difficult to share and derive value from protected data.

The second problem is the impending need for interoperability across trading partners as product is distributed from the manufacturer to its distributor and finally to dispensers. The final phase of the Drug Supply Chain Security Act (DSCSA) mandates the interoperable exchange of serialized product data across all supply chain participants allowing for product tracking if and as needed— by 2023. Every unit and case of product will be encoded with an individual serial number along with the product's Global Trade Item Number (GTIN), lot number and expiration date, all of which must be accessible and unalterable by all parties along a product's chain of ownership.

These are two disparate data problems that, in our view, may be at least partially addressed by one solution. That solution is blockchain.

1 D. Reinsel, J. Gantz, J. Rydning (2017). Data age 2025: The evolution of data to life critical, IDC.

2 D. Reinsel, J. Gantz, J. Rydning (2017). Data age 2025: The evolution of data to life critical, IDC.

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The technology

Blockchain is open source software where digital units (of money or data) are organized into a series of chronologically grouped transactions, or blocks, which are digitally signed. The technology behind the solution is cryptography (consensus methods, digital signatures, encryption, hash values), coding, and networking technologies, which are managed by sophisticated mathematical algorithms. Although these technologies should be familiar to most IT professionals, the magic is in the combination.

You might associate blockchain with its precursor, bitcoin. However, blockchain is not synonymous with bitcoin, and many of bitcoin's shortcomings have been overcome. Here's one way to look at it: Blockchain is like a shared Excel file, hosted by no one. Or in more technical language: Blockchain is a distributed ledger technology where transactions are recorded and stored with incomparable security.

The proposition

Why is this so important for life sciences? The free and secure flow of data – between individuals in an organization and between the organization and third parties – is the lifeblood of the industry. However, since much of this data is either protected health information (PHI) or intellectual property (IP), it cannot be shared indiscriminately or privacy could be compromised and cyber criminals could wreak havoc.

Blockchain allows organizations to provide access to secured content selectively in a trusted and controlled mechanism. At the same time, they can prevent copying or destruction of data and record "one version of the truth" that can be cryptographically proven to be correct.

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Why the urgency?

While some believe that full blockchain adoption is still a decade away, there are some realities in life sciences that have dramatically accelerated this timeline.

Supply chain transparency

Even before the DSCSA's mandate for interoperability, pharmaceutical manufacturers faced four increasing challenges that drive the need to take supply chain management to the next level.

1. Cost pressures

2. Expanded quality requirements

3. Increasing complexity in the regulatory environment

4. Demand for greater access and speed

Existing solutions are limited in scope due to lack of transparency and integration with external business partners, as well as inaccuracies resulting from disparate data standards. With the DSCSA requirement, organizations are now feeling the urgency to revamp their approaches to supply chain data management.

In our view and that of many of our life sciences clients, blockchain may be ideally suited to solve some of these problems. The technology has the potential to support the traceability and visibility of drugs from the time of packaging until dispensed or destroyed. Recording the movement of a drug between parties as ownership changes allows stakeholders to validate a product's authenticity via its digital identity.

Specifically, when using a blockchain, drugs are logged as digital assets during the serialization process at the manufacturing plant. These goods are then tracked throughout the supply chain as they progress from manufacturers, to distributors, to retailers, and, ultimately, to customers. Evolving product information and locations are logged onto the blockchain and accessed by authorized parties through a dashboard. In the event of a product recall, all affected products can be traced back to the manufacturer and relevant parties can be alerted.

Clinical trial management

Over the last decade, clinical trials have seen an exponential increase in the number of trial sites, size of subject pools, and number of clinical investigators per study. The global expansion of the industry has also increased the usage of intermediaries like clinical research organizations (CROs) and contract manufacturing organizations (CMOs). The sheer quantity of new interactions has resulted in inefficient partner coordination, substandard patient retention and the inability to effectively detect misconduct.

Blockchain could provide a forum for all parties involved in a clinical trial to manage this complexity, safely share data and collaborate, without compromising PHI. Specifically, pre-specified trial start and endpoints can be entered onto the blockchain for CROs to use. Changes to the protocol are not allowed or accepted by other participants. And clinical research outcomes can be recorded on the chain so that results can be evaluated in near real time.

Whether it is preferable to use public or private, permissioned blockchain for clinical trials is a sticky question that the industry must evaluate. On the one hand, public blockchain allows automated regulatory filings, streamlined trial participant consent and transparency of patient therapy protocols. On the other hand, permissioned blockchain would allow organizations to better manage risks to intellectual property and PHI. Whichever route organizations take, blockchain is poised to be the means for sharing clinical trial data among pharmaceutical companies, CROs and regulators in the future.

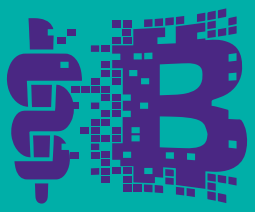
Ultimately, the goal is to use blockchain to rethink the filing of drug and device applications to the FDA. Currently, industry leaders are participating in consortiums and syndicates to develop the evidence needed to convince the FDA of the viability of blockchain for clinical trials. Even further into the future, if organizations can use blockchain to track which exact product goes to which patient, they may gain unprecedented visibility into long-term patient outcomes and insight into whether efficacy is consistent across manufacturers and distributors in different parts of the world.

Other applications

Secure connected devices: Adoption of intelligent medical devices, wearables, bio sensors, digital twins and other connected devices creates continuous sensitive data streams. When these data streams are compromised, it can cause life-threatening situations. Distributed ledger technologies like blockchain may serve as the basis of security mechanisms that include time-stamped audit trails to verify and validate the authenticity of data streams.

Digital business models: The availability of data and advanced analytics to harvest insights can supercharge life sciences companies' efforts to identify new revenue streams and opportunities. Distributed ledger technologies have the potential to provide an open and trust-enabled framework for these efforts, while creating transaction visibility and a platform for cognitive intelligence and automation capabilities.

Blockchain design considerations



The most important design considerations for blockchain are authenticity, provenance and smart contracts:

Authenticity. It is critical for life sciences to be able to verify the authenticity of an individual or product's digital identity. Blockchain allows digital identities to be tracked and prevents malicious misrepresentation of identity at the same time as anonymizing identities.

Provenance. It is hard to overstate the importance for life sciences of recording and proving the existence and ownership of a drug or medical device as it journeys through the supply chain. The same could be said for patient data as it traverses through the clinical trial process. Blockchain enables provenance, allowing pharmaceutical companies to validate therapeutic products during these critical processes.

Smart contracts. The life sciences industry needs to execute and validate transactions beyond the boundaries of individual organizations. Blockchain-enabled smart contracts use immutable code logic to automate execution of actions based on authenticated events. Specific applications include automated rebate payments based on where a product is in the supply chain, clinical research payments based on milestones and e-consent.

What to do next

While the journey to blockchain adoption may seem complex, there has been an explosion of investment and vendor startups that is broadening the scope of choices available to organizations. Life sciences organizations need to develop roadmaps and strategies for blockchain that are tied to clear business benefits, as well as a solid vision of the technologies needed to quickly harvest the benefits.

Four broad phases of an organization's blockchain roadmap are:

1. Begin with an adoption strategy that explores value potential across the business model.
2. Develop *fast fail* proofs of concept for specific areas to quickly prove the potential to realize value.
3. Utilize proofs of concept to learn the implications of blockchain for the organization and lay out the necessary architectural vision including on-chain and off-chain capabilities.
4. Consider other digital technologies such as mobile, smart devices, big data and analytics, intelligent automation, and cognitive analytics, which together with blockchain can open up strategic possibilities.

The future

Right now, the entire life sciences industry is laser-focused on using blockchain to meet the requirements of the DSCSA for interoperability between manufacturers and partners as goods move through the supply chain. According to a leading pharmaceutical manufacturer, the next step after that will be interoperability of the blockchains themselves. At that point, the technology will become a commodity that will generate the next stream of value. Value will include phenomena like *side chains* containing related drug content, e.g., product information and inserts, and *off-chains* housing unique product information and value-added services organizations want to keep confidential.

Further, while supply chain and clinical trials have an immediacy, applications of blockchain that touch the patient are believed by many in the industry to be at least several years out. For example, blockchain will eventually play a major role in clinical data sharing to cure disease and develop treatments, *beyond the pill* services for customers, smart prescriptions, and smart payments.

What can KPMG offer?

KPMG's distributed ledger technology capabilities and perspectives include a global distributed ledger services team, a *Lighthouse* team of data scientists, a market-leading strategy practice, and industry-specific professionals. KPMG provides the following services to clients:

— Strategy development

— Business case reviews and validation

— Customized use case development

— Proof of concept and prototypes

— Business and technical evaluation and selection

— Production systems development

— Education and change management

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