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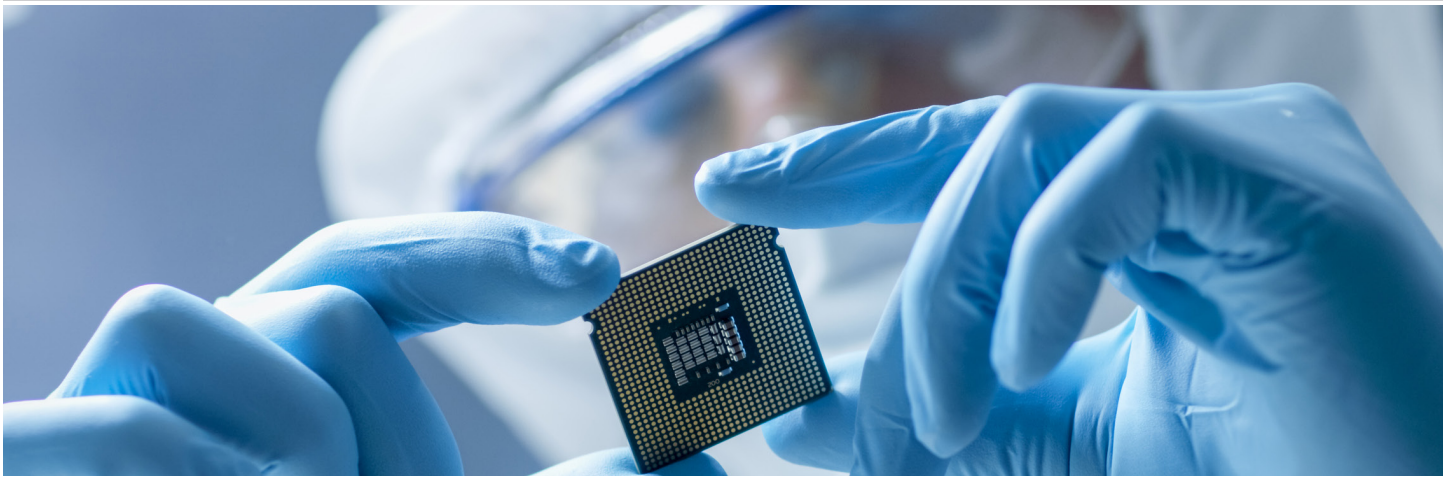

10 FAQs About Blockchain and Life Sciences

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Blockchain is a rapidly emerging technology and has the potential to bring transformative changes to many industries. As more companies become aware of and study this technology, many questions arise. These questions relate to what blockchain technology is, how it works and what about it is so different. Blockchain is often associated with the financial services industry, but it is applicable to all industries. Many people in the life sciences industry have been asking if blockchain is relevant to them and, if so, how is it applicable? This paper addresses these and other frequently asked questions about blockchain technology and its applicability to the life sciences.

1. Is blockchain technology relevant to life sciences?

We believe that blockchain technology has the potential to be as transformative as the internet was, for all industries. The life sciences industry is no exception. Despite being a nascent technology, nearly 70 percent of all life sciences executives surveyed expect to have a blockchain network in production by 2020, according to an IBM Executive Report. Several thought-leading heavyweights have published white papers detailing their views on the applicability of blockchain to life sciences. The following are some high level insights from these papers that point to the tremendous potential for blockchain use in the life sciences industry.

- *"Blockchain: A Catalyst for the Next Wave of Progress in Life Sciences"* by Cognizant

  By applying shared ledgers, smart contracts and powerful encryption technology, pharmaceuticals companies and medical device makers can eliminate costly intermediaries and more effectively ensure security, immutability, transparency, auditability and trust across the value chain.

  This white paper explores how blockchain – the decentralized, distributed ledger infrastructure built around strong cryptography – could power full digital transformation across the life sciences space. It examines key blockchain principles that we believe could be imaginatively applied to areas such as provenance, disintermediation, patient safety, secure data exchange and enhanced productivity to accelerate digital business across the pharmaceuticals and medical devices segments.

- *"Blockchain to Blockchains in Life Sciences and Health Care – What Broader Integration is Making Possible Today"* by Deloitte

  For life sciences and health care, 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 shift from blockchain to blockchains—to networks of networks—is particularly compelling in life sciences and health care where the distinct sectors work together in one broadly interdependent ecosystem.

  A shared network that links medtech and pharma, patients and providers, and plans and payers on the same standard could touch every part of the industry from drug trials to claims adjudication to clinical outcomes.

- *"Demystifying Blockchain for Life Sciences – Blockchain Could Be a Key to Interoperability and Privacy"* by KPMG

  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.

- *"Blockchain Rx: A Cure for Healthcare and Life Sciences?"* by IBM

  For the healthcare and life sciences industries, blockchain is the perfect paradox. These industries operate with overwhelming amounts of data — data which must be shared yet secure, data that is digitized now more than ever, data that belongs to the increasingly empowered patient. By providing faster access to this trusted data, as well as facilitating better collaboration and increased transparency, blockchain can significantly improve and personalize the patient experience. The technology can also help reduce counterfeit medicines, promote more effective research and development, and drive new or optimized business models.

- *"In Blockchain We Trust: Transforming The Life Sciences Supply Chain"* by Accenture

  Blockchain is becoming increasingly relevant to address the perennial challenges of trust and speed in the life sciences supply chain. For example, enabling data driven business decisions in forecasting the flow of goods and having visibility into the origin of materials and inputs has always been difficult, partly due to the technologies involved and partly because suppliers are mistrustful about sharing data they fear will be abused by downstream customers, impacting their ability to price products effectively.

  Blockchain's ability to generate trust and create the right permissions around the sharing of data allows life sciences companies to break through some of those commercial challenges, enabling better traceability. Companies can access the information they want without revealing commercially sensitive data.

2. What is blockchain technology?

Many types of blockchains exist, including public and private and permissioned and permissionless blockchains. At its core, a blockchain is a distributed ledger for recording transaction data and value transfers. A ledger is merely a list of transactions. Traditional paper-based ledgers include consecutive pages, where each line records a transaction. When the page is full, the process repeats on the next page. With many blockchains, each block is like a page. Transactions are verified via a consensus mechanism and written into a block, in a serial, time-stamped manner. When the block is filled, a new block is created. Unlike traditional ledgers, when a block is filled, the system creates a hash value, which is just a random number generated by an algorithm based on the contents of the block. This hash value is then written as the first entry in the new block. This process "chains" blocks together, hence the term "blockchain." If someone ever attempts to change an entry in a prior block, the hash value would no longer match what was written into the subsequent block and that altered block would be deemed invalid. In part, this is how blockchain creates immutable records.

With public blockchains, the ledger is copied to and stored on multiple nodes (or computers) across a network. This results in a distributed system where the data is stored in many locations, and subject to privacy controls, is transparent to all network participants. The system is decentralized because the system itself enforces rules that prevent a single entity from controlling the verification and storage of transaction data. This avoids the "data silos" problem that exists today. With public blockchains, anyone can run a node or view the transaction data. With private blockchains, only users with permission can share and/or view the transaction data. This can help address privacy concerns.

3. What are smart contracts?

Smart contracts are an important and powerful tool enabled by blockchain technology. A smart contract is not necessarily a legal contract. It is self-executing computer code that includes the operational terms of an agreement, between two or more parties, where the terms are written into and executed by the lines of code. The code can be stored across a distributed, decentralized blockchain network. Smart contracts can automatically receive data from various sources (including IoT sensors as described below) and programmatically implement a series of "if-then" rules with little or no human interaction. The way smart

contracts work is that "if" certain conditions (programmed into the smart contract code) exist, "then" the smart contract causes certain action(s) to occur. Smart contracts can be used to automate various processes, but in a very flexible and adaptable way. Smart contracts increase efficiency and reduce costs by removing middlemen who add little value and automating tasks that are typically performed manually. As detailed below, smart contracts can be used in the life sciences industry to automate supply chains and facilitate the tracking and tracing of pharmaceuticals. For more information on smart contracts, see the Chamber of Digital Commerce's white paper on the topic.

4. What are crypto currencies and tokens?

A cryptocurrency is a digital currency that uses cryptography for security and for which transactions are typically recorded to a blockchain. Crypto tokens can be a digital currency, but can be programmed to include additional functionality, such as ownership of title, voting rights, distribution rights, and other functionality. Recordation of ownership of currencies and tokens occurs via a blockchain. Typically this is implemented using public key/private key encryption. The "keys" are long strings of numbers and letters linked through the mathematical encryption algorithm that was used to create them. The public key (comparable to a bank account number) serves as the address which is disclosed to others and to which others may send currencies and tokens. The private key (comparable to an ATM PIN) is meant to be a guarded secret, and only used to authorize transfers or transmissions associated with the currencies or tokens. Crypto currencies and tokens can be bought and sold (or traded) via exchanges and can be transferred in a peer-to peer manner. Transfers can occur via a software "wallet," which is associated with a user or device, has a unique alphanumeric identifier and can transfer and receive crypto currencies and tokens. One use for crypto currencies is to facilitate a payment mechanism on a blockchain network. Tokens can have many uses. For example, a token can be used to represent title to some object and transfer of the token can effect transfer of title to that object.

5. What is the Internet of Things (IoT)?

The IoT is a network of sensor-enabled devices that can collect data, communicate via the internet or other networks, and, if programmed to do so, execute transactions or take other actions based on a predetermined set of conditions. As an example, an IoT sensor can be located on a container of pharmaceuticals and the sensor can generate real-time location data for that container. In a more sophisticated example, the sensor data can be provided as input to a smart contract such that when the data indicates and validates that a container was delivered by party A to party B, the smart contract can be programmed to transfer title to Party B and trigger a payment to Party A.

6. What are some of the key advantages of blockchain technology?

Some of the many advantages of blockchain technology are that it is:

- **Immutable** – hashing the block contents and "chaining" the blocks, by writing the hash to the next block, renders the recorded data immutable

- **Distributed** – storing copies of the ledger on multiple nodes, under control of multiple entities, avoids data silos and single points of failure

- **Decentralized** – validating the transactions via a trusted consensus mechanism avoids the need to rely on and trust any single (central) authority

- **Transparent** – subject to privacy controls, the data on a blockchain is visible to all parties, which for example, can create greater end-to-end transparency in supply chains

- **Secure** – using digital signatures via public key infrastructure (PKI) encryption provides state of the art security

- **Automated** – using smart contracts to automatically enforce business rules enables a greater level of automation

- **Cost-effective** – eliminating unnecessary middlemen who add little if any value; eliminating manual processes; and reducing fraud can all reduce operational costs and increase efficiency

- **Auditable** – storing the verified transaction data in a serial, time-stamped, immutable manner facilitates auditing and regulatory reporting

7. How can blockchain technology be used with the drug supply chain?

Blockchain technology can be very effective for ensuring integrity in the drug supply chain, including "provenance" and the concepts of "tracking and tracing."

Provenance refers to the place of origin or a record of ownership used as a guide to authenticity or quality. In the context of life sciences, this relates to the complex challenges of effectively tracking the origin of a product (e.g., a pharmaceutical) from raw materials, to the finished product and delivery to the consumer. The drug production and distribution supply chain involves various players, including manufacturers, distributors, wholesalers, and pharmacies. Each of these players has an interest in knowing the true source of a drug and may desire to track its distribution. Yet, this is difficult to accomplish with traditional technologies and business models. Despite current efforts to document chain of custody, the fragmentation of systems opens them to potential fraud. According to Interpol, roughly 1 million people die from counterfeit drugs each year. By utilizing blockchain technology, every transaction in the supply chain can be accurately traced, from origin to distributor, ensuring the delivery of the intended product.

Many major players have recognized the role blockchain technology may play in addressing these issues. As IBM has noted, "Blockchain is an ideal solution for the business problem of tracking and tracing pharmaceuticals, as it provides increased trust through consensus, provenance and supply chain immutability." According to Deloitte, "An estimated 10–30 percent of the drugs sold in developing countries are counterfeit. Blockchain could potentially help companies maintain drug traceability from inception to consumption in adherence with 'trace and track' regulations. End-to-end traceability could help prevent serial number duplication, keep original drug unit changes unaltered, and validate the receipt of a drug." According to Accenture:

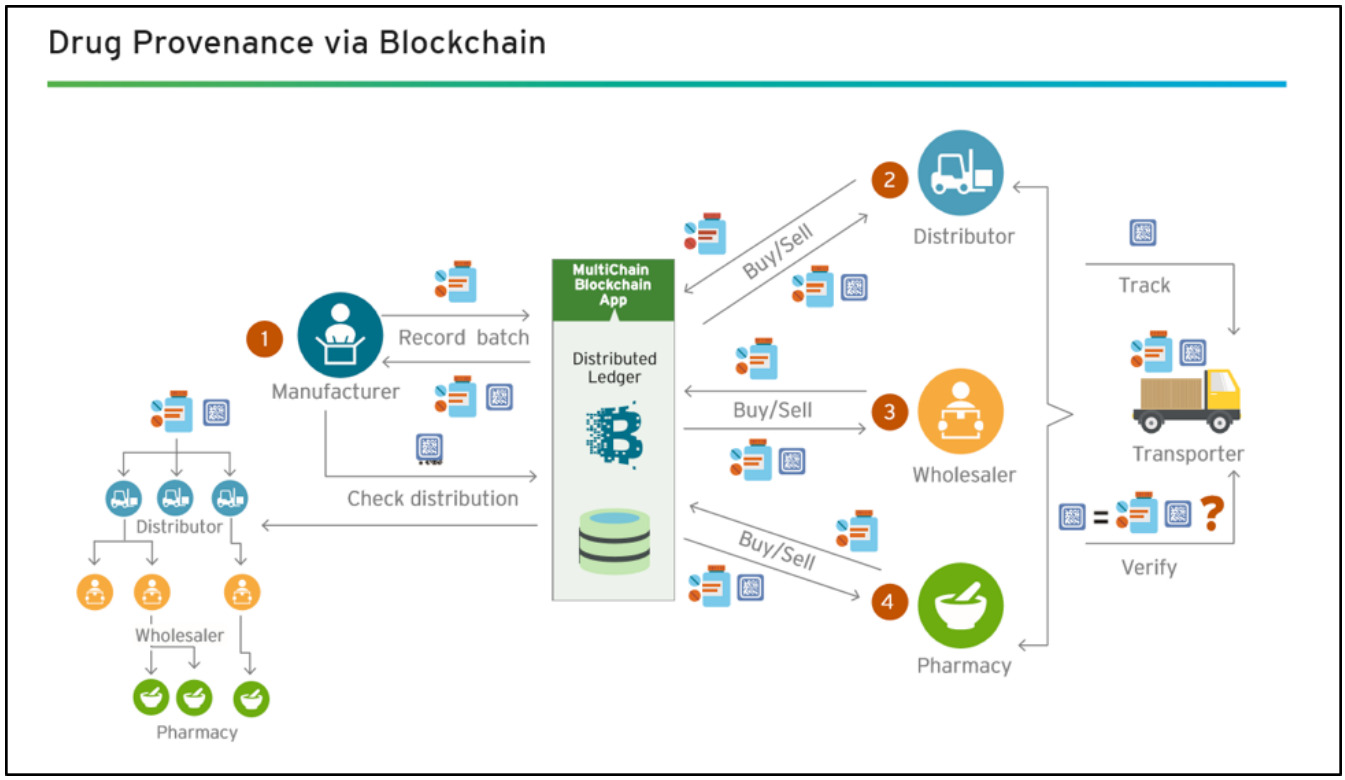
> For the last two decades, regulators across the globe have been implementing requirements for unique product identification to deliver greater security of finished products through the supply chain.

These requirements have the aspiration to eliminate counterfeit and diverted products, ultimately contributing to increased patient safety. Like provenance, one of the major challenges with track and trace is the effective exchange of data across the ecosystem of partners – from the pharmaceutical manufacturers, to wholesale distributors, to dispensers. With the use of blockchain, supply chain partners can more effectively and securely share data across the supply chain and, eventually, with the end patient.

A significant business opportunity exists in using blockchain with serialization capabilities for the recall process. Recall notification, once injected into the blockchain, can initiate communication and alert messages to all affected parties (manufacturers, distributors, dispensers and eventually patients). All parties can track and verify the recalled product, minimizing the time it takes to dispose of the recalled products, reducing risk and costs.

Enacted in 2013, the Drug Supply Chain Security Act (DSCSA) outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States in an effort to enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The DSCSA is just another motivating force for life sciences companies to embrace blockchain technology in an effort to provide secure, immutable histories for drugs in the supply chain.

The following image illustrates an example of a blockchain-based drug provenance system:



* Figure 5 from "Blockchain: A Catalyst for the Next Wave of Progress in Life Sciences" by Cognizant.

8. What role can IoT play in Blockchain?

An oft-cited example of how IoT sensors can be used in this context relates to cold chain logistics (i.e., a temperature-controlled supply chain). An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range, for example, for delivery of certain drugs or biologic material. The pharmaceutical industry expects to spend nearly $17 billion by 2020 on cold chain management. The use of blockchain and IoT can efficiently create secure documentation of storage temperatures along the entire supply chain.

In its white paper, Cognizant explains a proof of concept (PoC) using IoT and blockchain to tackle this issue. The white paper states:

> Many pharmaceuticals products – particularly those that are biological in nature – are highly temperature sensitive. For example, a vaccine may be allowed to be no higher than 25°C for only 15 minutes. Since the delivery of a pharmaceuticals product involves multiple partners (i.e., shippers, warehouses and trial sites), it is essential for companies to consistently and securely track temperature excursions across hand-offs.
>
> In this PoC, IoT-enabled temperature loggers are inserted into the batch packages, and a blockchain network is created for all participants (shipper, warehouse provider, etc.). The temperature loggers can transmit temperature excursion data, which is stored on the blockchain, accessible by all network participants. A smart contract is created to implement a rule for stability checks based on temperature excursion data.

Advantages resulting from the application of blockchain technology in this scenario would include the highly reliable nature of stability checks that are automatically performed per smart contracts, the ability to provide all participants with the information they need, the assurance manufacturers have that the product that is delivered is of high quality, and the reduction of regulatory concerns as smart contracts may automatically invalidate non-compliant batches.

IBM has also addressed the use of blockchain technology to address cold chain storage in a white paper, which also includes a link to a video that explains how IBM Blockchain technology and an SAP IoT solution may work together to make the pharmaceutical cold chain more transparent.

DHL and Accenture also are developing a blockchain-based serialization system to better track and verify the validity of drugs through the supply chain. A joint report by these companies highlights how blockchain can transform logistics in a variety of industries, with a special focus on the life sciences and pharmaceutical industries.

9. How can blockchain technology be used in clinical trials?

Blockchain technology has an array of potential applications related to clinical trials. In fact, an entire clinical trial may be managed on one or more blockchains. In many clinical trials, the coordination and communication among the various stakeholders in the clinical trial can be inefficient. Blockchain technology can provide a means for all parties to a clinical trial to communicate, safely share data, and interact, all without comprising PHI. Additionally, research and other information (such as informed consent) may be recorded on the blockchain, cryptographically secured, and provided to the appropriate parties in compliance with protocols established at the outset of the clinical trial. This would allow for the seamless access to data in a secure and efficient manner.

Some other examples of how blockchain can be used in clinical trials is as follows.

Cognizant's white paper suggests:

- By using blockchain to maintain clinical trial protocols, revisions and patient consent, for example, pharmaceuticals companies can better demonstrate patient safety and transparency. Data from multiple sources, such as genomics, wearables and electronic medical records, can be shared with multiple parties using blockchain's decentralized and secure framework.

- In clinical trials, a blockchain network with participants from pharmaceuticals, investigators, trial sites and regulators could be created in which data could be shared securely without any chance of alteration. This would improve patient safety and reduce the need to manage response to regulatory warnings.

According to Deloitte:

- In clinical trials, blockchain could be a common frame of reference for an entire ecosystem of solutions that may improve participation and processes and ultimately lead to better health outcomes, with patients, investigators, managers, and doctors all touching different parts of the same ledger. A person's cloud-based "health passport" could use blockchain to carry consistent information securely across the entire process of searching for relevant trials, matching criteria and registering, documenting consent, and participation. The same unbroken information chain could then support trial functions such as sample collection, tracking, and analysis. Many of the current systems used to track clinical trial samples and document proper storage, transport, and handling leverage spreadsheets that are hard to read or automate. Blockchain could help the data follow the samples, promoting more efficiency in the process and greater confidence in the results.

KPMG suggests:

- 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.

10. What are some legal issues to consider with life sciences use of blockchain technology?

The life sciences industry is heavily regulated. These issues do not go away with blockchain, but regulatory compliance may be facilitated, as mentioned above. However, there are some other legal issues that are relevant when using blockchain technology.

Smart Contracts

Structuring smart contracts in a way that ensures enforceability will be important. Often, there will be a separate legal agreement between the parties in addition to the smart contract code. This is similar to online services such as auto bill pay, where a user agrees to terms of service and the computer code actually implements the transaction. Other issues governing the smart contract (e.g., governing law, warranties, dispute resolution, etc.) may be addressed in a standard contract. Supply chain smart contracts are more complex and sophisticated. They typically require agreement among all of the ecosystem partners on allowed transactions, data sharing and visibility, payments and other issues. Smart contracts can be self-enforcing in that they can implement in code certain actions to happen upon the default by a party. But what if the result is not what the parties intended? Often smart contracts are dependent on one or more data sources (often referred to as oracles). The parties may wish to contractually deal with scenarios where the data is bad or the smart contract code does not actually execute what the parties intended. International law and jurisdictional issues also may come into play. Many other issues will arise with smart contracts. A number of projects are underway to develop smart contract templates to address these and other issues.

Data Privacy

The use of blockchain and smart contracts will create some interesting legal issues. Due to HIPPA, the storage of PHI on a public, permissionless blockchain will be challenging. Storing such data on a private blockchain or “off-chain” with a system that communicates with a public blockchain may offer one solution. Structuring the interoperability and associated agreements will be key to keeping this legal.

Patents

As with any new technology or new application of existing technology, patents will play a role. There has been a surge in patent filings for blockchain-related technology. For an overview on patentable aspects of blockchain technology please see our recent papers on Patent Strategies for Cryptocurrencies and Blockchain Technology and Drafting Effective Blockchain Patents.

These are just a few of the legal issues that will arise as blockchain applications are rolled out in the life sciences industry. As with many new technologies, particularly as applied to regulated industries, new legal issues are sure to arise. To stay abreast of these legal issues, sign up for Sheppard Mullin's Blockchain and Digital Currency blog Law of the Ledger.

Conclusion

The KPMG white paper does a nice job of putting into context where things are now and where they may be heading with blockchain and life sciences. KPMG states:

> 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.
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> 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.

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