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The blockchain revolution and what it means for pharma



Shaun McVicar, Global Head of Pharmaceuticals, and Solicitor Marine Giral, of law firm Herbert Smith Freehills, delve into the much-talked about technology, which looks set to be a game-changer in the handling and exchange of data.

Originally devised for the digital currency Bitcoin, the blockchain revolution has expanded to other industries. Coupled with innovative technologies such as Internet of Things (IoT) devices and smart contracts, blockchain is likely to disrupt and has the potential to benefit every stage of the pharmaceutical lifecycle.

Blockchain in drug discovery and development

Blockchain has the potential to considerably reduce drug development costs, alleviate inefficiencies and improve clinical research quality. The development of interoperable and secured blockchain platforms to collect and exchange healthcare data such as the one developed by IBM Watson Health and the FDA increases the number and quality of participants potentially available to be recruited for clinical trials.

Existing electronic health records are currently scattered amongst different healthcare providers using different (and generally non-interoperable) systems. For example, in Boston alone, 26 different systems are used for maintaining electronic medical records. Blockchain could record the generation of any data by a prescription, imaging scan, diagnosis test or monitoring device in a systematic way on a distributed database. Patients could then more efficiently access their medical/genomics data and reliably share that data with health providers or researchers, with no

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need to rely on a third party. Trial recruiters could then reach out directly to patients if their data qualifies them for a particular study. As blockchain ledgers are both mirrored and decentralised, there is not one single point of failure, which protects data integrity.

Blockchain can also be used to streamline patient consent collection and minimise documentation error or fraud. Participants could be assigned private keys linked to their digital signature. Blockchain could then record each step of the patient consent in a standardised, time-stamped and immutable way. It can also facilitate more efficient research collaborations. Data recorded on decentralised ledgers can be accessed and verified in real-time by all relevant parties, instead of sitting with one entity responsible for sharing it with other interested parties.

Computer protocols (so-called “smart contracts”) built on the blockchain can automate the validation of certain steps once pre-determined requirements have been met, leading to greater efficiencies. For instance, they could automatically allow patient inclusion once (but only if) consent is obtained, or prompt data analysis as soon as (but not before) the database is frozen. They can also be linked, for example, to clinical trial protocol revisions or updates, necessarily generating patient consent renewals. With the development of data driven artificial intelligence, increasingly complex decision could be automated, and implemented without delay.

Blockchain transactions are immutable, which makes it virtually impossible to alter or selectively report clinical trial results and could ensure greater transparency and trust in reported outcomes.

Blockchain and intellectual property

Companies could use blockchain to record exactly when digital content was created or when a step in the drug discovery and development process occurred, for example by recording and distributing electronic laboratory notebooks. Time-stamped records could alleviate concerns associated with sharing research data prior to publication or patent filing and could also be used by companies in priority disputes.

Companies that need to share trade secret and other trusted information with collaborators can do so using private and permissioned blockchain platforms, which offer fine-grained access control over transaction details. The combined features of encryption, decentralisation and immutability protect data integrity and ensure that confidential information cannot be shared outside the network of authenticated and authorised users without the consensus of the entire network. Blockchain can therefore enhance non-disclosure agreements. In the event of a breach, the time-stamped record will help establish that a business held a particular concept or information at a specific time.

Blockchain can help companies manage their intellectual property by serving as an immutable, accurate and transparent record of the complete chain of ownership (including any licence or assignment).

Blockchain and the supply chain

Pharmaceutical products are routinely monitored throughout the supply chain. However, as each participant in the supply chain is independent, generally maintaining its own records, tracking

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problems at any particular point can be difficult. However, blockchain's key functionalities make it a powerful tool to secure and optimise the supply chain.

Coupled with smart devices, blockchain can be used to track and trace products in the supply chain, ensuring that they have not been tampered with and if they are, instantly recognising it. IoT sensors linked with the blockchain could record any change in key product characteristics (such as temperature). A smart contract could then assess those attributes against the contract specifications and automatically implement actions within the supply chain in case of departure. For example, a batch of products could be instantly recalled, marked to be offloaded from transport, or a payment made, suspended or cancelled.

The surging cost of counterfeiting has led to the introduction of stricter drug traceability rules in Europe and the US, requiring, notably, that the industry adopt interoperable systems or harmonised databases to track drugs across the supply chain. This creates many challenges for companies, who are required to exchange information securely, and compatibly with other organisations' applications and serialisation architectures.

With its key features (a decentralised, immutable and secure record of transactions), blockchain could be the answer. In fact, the industry is already working on blockchain solutions for the supply chain. In the US, leading drug manufacturers including Roche and Pfizer are collaborating with distributors and tech companies on the MediLedger Project, an interoperable blockchain solution for the supply chain. In Europe, a consortium of nine big pharmaceuticals companies led by Novartis is developing a blockchain network called the Innovative Medicine Initiative Blockchain Enabled Healthcare Program.

By maintaining a record of the chain of custody, blockchain can enhance visibility over a company's products and its other assets. It has been reported that drug shortages cost US hospitals about \$230 million each year. Adopting a blockchain solution could, by optimising inventory management, result in huge savings and efficiencies.

Blockchain and pharmacovigilance

Once a drug is on the market, blockchain has the potential to help companies with their extensive pharmacovigilance obligations and better address the growing expectations of increasingly vigilant regulators and the uncompromising public. Blockchain can be used to collect, record and maintain pharmacovigilance data in a systematic and standardised way across departments and sites, while blockchain-based smart contracts can help ensure timely and accurate reporting; for example, any report of adverse drug reaction could trigger the execution of an automatic notification to the person(s) or entity(ies) responsible for case processing within a pharmaceutical company. Where certain parameters are met, such as the severity of the reaction, they could also automatically populate pharmacovigilance reports and send them to the relevant authorities.

The immutable nature of blockchain ensures that reported adverse event data cannot be altered, and thus can be trusted by regulators and consumers. It also makes it easier for companies' pharmacovigilance systems to be audited and will help streamline compliance operations.

By maintaining a real-time record of the chain of custody, blockchain also enables companies to target recalls or alert specific (groups of) patients. In a test conducted in the food industry by

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Blockchain can also support companies that outsource their pharmacovigilance activities or enter into safety data exchange agreements with third parties. By enabling sponsors to directly access and verify any information recorded by safety services providers, blockchain removes the transactional friction and expense caused by the need to verify or undertake costly inspections. Safety data exchange agreements and other pharmacovigilance agreements running on the blockchain could be (at least partially) automated, facilitating enforcement of the parties' obligations.

Overcoming challenges

With its many opportunities, the development of blockchain technologies also presents unique challenges for the pharmaceutical industry. To fully realise the potential benefits, pharmaceutical companies must customise blockchain solutions that comply with their extensive regulatory obligations and can be trusted by regulators and other stakeholders in the industry.

Erasing or correcting data

In regard to personal data, the immutable nature of blockchain appears contradictory with the requirements under the General Data Protection Regulation (GDPR) and other data protection regimes that data subjects have the right to request that their individual data be corrected or erased. Relevantly, the GDPR applies to any company that processes or stores the personal data of any person residing in Europe, regardless of where the company is located.

The right of erasure generally does not apply if processing is necessary for scientific research purpose. This would arguably include data collected during clinical trials that cannot be removed from the dataset without changing the statistical trial outcome. When companies cannot rely on this exemption, one solution might to encrypt the data on the chain and delete the key if a data subject requests that the data be deleted. However, resolving the tension between the GDPR and the very nature of blockchain would take some careful thought.

Enforcing smart contracts

Smart contracts can effectively facilitate or force compliance with contract obligations, and streamline contract management. They are not, however, legally binding agreements and companies will need to make sure they are encompassed within legal arrangements which include dispute resolution provisions. Further, with nodes potentially located anywhere in the blockchain, the decentralised nature of blockchain can pose a number of jurisdictional issues which will need to be considered and resolved.

Liability

Currently, key decisions such as whether to report an adverse event or to release or recall a batch are made by designated qualified persons within a Pharma organisation who are legally responsible for these decisions.

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Automation makes it less clear who will be responsible for these decisions. Careful consideration will be needed when writing self-executing codes, and a legal agreement will need to provide a dispute resolution mechanism or other course of action should the smart contract inadequately prompt or fail to prompt an action.

Implementation of appropriate pharmacovigilance procedures often requires clear accountability. Blockchain and smart contracts may challenge this.

Protecting blockchain solutions

Companies that develop blockchain solutions also need to consider how to protect their interests in the technology itself. Of course, protecting IP in their products is second nature to pharmaceutical companies, but blockchain will not be. Inventive blockchain solutions could be protected by a patent giving the right to the inventor/patent holder to exclude others from making, using, selling or importing the solution within a specified territory, for a certain time.

Over the past few years, the number of patent applications filed for blockchain technology has been on the rise. Most so called 'blockchain patents' are filed in the financial services sector, however patents have been granted in other areas including supply chain monitoring and prescription drugs tracking.

Not every blockchain solution can be patented. Blockchain is, in essence, a software based technology, and so the patentability rules applicable to software inventions apply. Requirements vary depending on the jurisdiction, but generally, blockchain must provide a technical solution to a technical problem to be patentable. It cannot be a mere 'abstract idea' or business method. Specifications will need to be carefully drafted and focus on technical and distributed ledger features, such as protocols for smart contracts or consensus, or security aspects such as encryption, real time transactions or the detection of malicious events in a blockchain, instead of the transaction's features.

Alternatively, companies could protect their solutions as trade secrets. Trade secret protection is available for commercially valuable and undisclosed information, whether or not this information constitutes a patentable invention. This would require, however, an ongoing investment to maintain secrecy.

Copyright could also protect the source codes of blockchain computer programs from unauthorised copying or use. However, a program's functionalities and language do not constitute a form of expression of that program, and thus are not protected by copyright.

Regardless of the type of protection, pharmaceutical companies will need to consider the impact of collaborations with the tech industry when developing blockchain solutions. Issues such as intellectual property ownership and the scope of trade secret protection will need to be addressed in software development or collaboration agreements.

Pharma has long sought to maximise the resources that can be channeled directly to meet unmet medical needs by focusing its efforts in the twin areas of improved efficiency and safety. Developing and adopting blockchain solutions, while not without challenge holds out huge promise to fast-track that ambition.

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