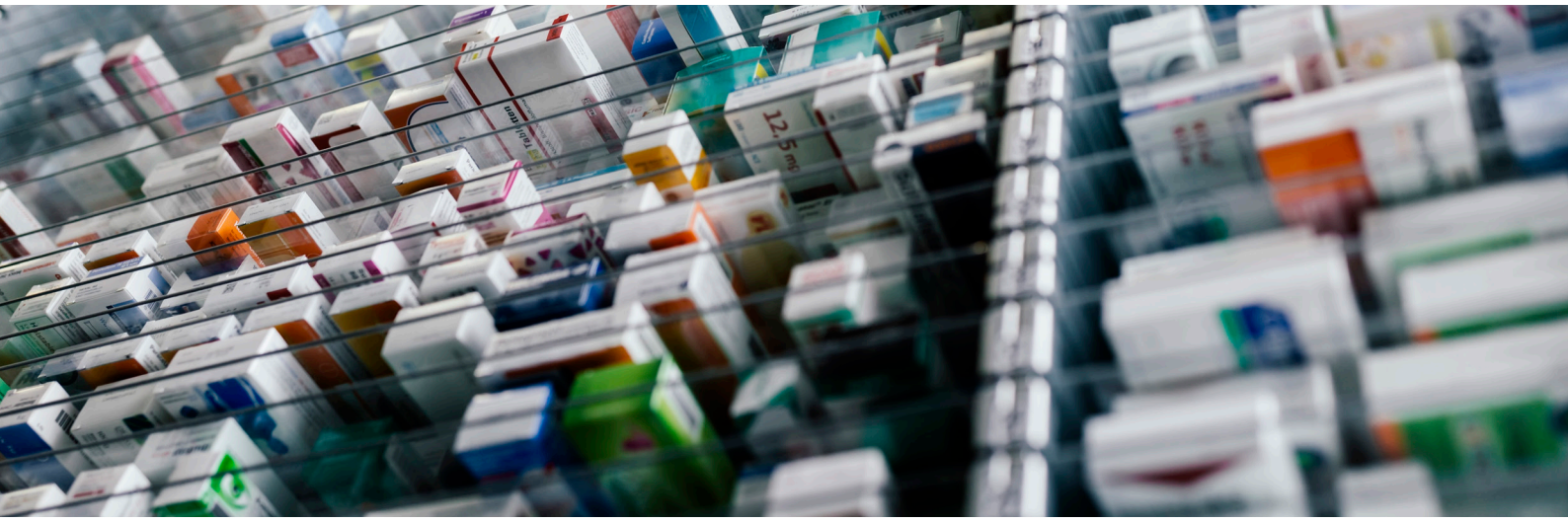
HERBERT SMITH FREEHILLS



Unlocking the Pharma Blockchain

Originally devised for the digital currency Bitcoin, the blockchain or distributed ledger technology (DLT) revolution has expanded to other industries.

Coupled with innovative technologies such as sensor devices and smart contracts, DLT has the potential to positively disrupt every stage of the pharmaceutical lifecycle enabling a truly patient-centric and transparent approach to achieve personalised health.

Blockchain and the drug development process

At the drug development stage, DLT, assisted by electronic data capture, could allow data to be automatically aggregated and distributed among researchers.

Software programmes built on the blockchain can automate the validation of certain steps once pre-determined requirements have been met, for example, allowing patient inclusion once they have consented or enabling data analysis as soon as the database is frozen.[1] Data recorded on the blockchain can then be accessed and verified in real-time by all relevant parties, instead of sitting with one entity (eg contract research organisation) that is responsible for sharing it with other parties (eg sponsors and regulators).

Thus, blockchain could make clinical research more efficient and facilitate seamless collaborations.

At the same time, the decentralised and immutable nature of blockchain would make it virtually impossible to alter or selectively report clinical trial results, which would ensure greater transparency and trust in reported outcomes.

Finally, 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 could support the development of personalised medicine.

Existing electronic health records are currently scattered amongst different healthcare providers using different (and often non-interoperable) systems.[2] A patient-centric/patient-controlled blockchain could record any data generated by a doctor's prescription, an imaging scan, a

pharmacist's dispensation, a genetic test, or a monitoring device. This would enable patients to easily access their medical/genomics data and reliably share that data with health providers, or use it to participate in studies, with no need to rely on third party service.

Blockchain and intellectual property

DLT could record exactly when (digital) content was created or a step in the discovery process occurred (eg by recording and distributing electronic laboratory notebooks). This time-stamped record could alleviate concerns associated with sharing research data prior to publication and could also be used by companies in patent applications/ priority disputes.

DLT 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).

Companies can also rely on DLT to record, encrypt and protect their trade secrets and other confidential information. DLT can serve as a tool to manage and enhance non-disclosure or confidentiality agreements. In the event of a breach, the time-stamped record can help establish that a business had a particular concept or information at a specific time.

Blockchain and the supply chain

Coupled with smart sensors, DLT can track products on the supply chain and protect the integrity of key product information (characteristics or chain of custody). This could help control quality, fight counterfeiting and manage inventories.

With the surging cost of counterfeiting and introduction of stricter drug traceability requirements in Europe, the US and other jurisdictions, it is no surprise to see pharmaceutical and technology companies competing or collaborating to develop DLT based solutions for the supply chain.

The world's largest counterfeit market

With sales ranging from €150 billion to €200 billion per year, it is estimated that ten percent of medicines supplied globally are counterfeits. While developing markets are most affected, counterfeiters are now using digital channels to penetrate developed countries.

In response, an increasing number of countries across the world have been initiating or reinforcing anti-counterfeiting legislation.

The US Drug Supply Chain Security Act requires that the pharmaceutical industry adopt an 'interoperable system' to track and trace prescription drugs across the supply chain by 2023. In Europe, companies have been required to place unique identifiers and tampering devices on individual packs of prescription medicine since January 2013. More recently, Regulation 2016/161, which comes into effect on 9 February 2019, has introduced standard labelling requirements relying on barcoding and database technologies being harmonised across member states, manufacturers and distributors.

Blockchain solution for the supply chain

Since September 2017, a group of leading drug manufacturers and distributors (including Roche, Pfizer, AmerisourceBergen and McKesson) have been working with Chronicled, a technology company, and the LinkLab, a life sciences supply chain consultancy, on the MediLedger Project, an interoperable blockchain solution.

Another interesting solution developed by the start-up Modum.io relies on IoT sensor devices monitoring the temperature of each parcel during the shipment. The data is then transferred to a blockchain where a smart contract (running on Ethereum Virtual Machine) assesses the product attributes against the specifications/requirements and prompts actions within a supply chain.

[1] The position paper 'Blockchain technology for improving clinical research quality', available here, outlines the documentation that can be stored safely and securely in a DLT and processes that could be automated.

[2] In Boston alone, 26 different systems are used for electronic medical records.

[3] General Data Protection Regulation 2016/679 (GDPR), article 16. Australian Privacy Principles (APP), Principle 13.

[4] GDPR article 17. While there is no equivalent 'right to be forgotten' under Australian or US law, the GDPR applies to any company that processes or stores the personal data or any person residing in Europe, regardless of where the company is located (GDPR, article 3). Further, in certain states such as Victoria, data controllers must erase or de-identify personal health data which they no longer need (Victorian Health Records Act, Health Privacy Principle 4.5).

[5] GDPR article 17(3).

[6] See for example, the TGA's page on Qualified person responsible for pharmacovigilance.

Pharma has long sought to maximise the resources that can be channelled directly to meeting unmet medical need by focussing their efforts in the twin areas of improved efficiency and in increased personalisation and efficacy.

Blockchain and pharmacovigilance

Once the drug is on the market, DLT has the potential to help companies comply with their extensive monitoring and reporting obligations by making it easier to collect, track and share information on (suspected) adverse events. Companies that outsource their pharmacovigilance activities can directly access and verify any information recorded on the blockchain. Further, the use of blockchain could guarantee that reported adverse event data have not been altered and can be trusted. Finally, because DLT can be used to track and trace products, it will make it easier for companies to target recalls.

Overcoming (legal) challenges

With its many opportunities, the development of DLT also presents unique challenges.

Protecting sensitive information

Because their transactions often involve sensitive health and commercial information, pharmaceutical companies are more likely to use private and permissioned blockchains in which participants are pre-approved and well defined.

This type of blockchain offers fine-grained access control over transaction details, thus enhancing privacy. However they are less transparent than permissionless and public blockchains, and because they are not as decentralised, it has been argued they could be easier to tamper with.

Personal data protection regimes

In the case of personal data, the immutable nature of blockchain is hard to conciliate with data protection regimes that provide that data subjects have the right to request that their data be corrected[3] and erased.[4]

It is worth noting however, that the right of erasure generally does not apply if processing is necessary for scientific research purpose.[5] 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 could be to encrypt the data on the chain and delete the key if a data subject requests that the data be deleted.

Liability

Currently, key decisions such as whether to report an adverse event, or release or recall a batch are made by specifically designated qualified persons who are legally responsible for these decisions.[6] Automation makes it less clear who will be responsible if a smart contract inadequately (or fails to) prompts an action. Careful consideration will be needed when writing self-executing codes or so called smart contracts.

Protecting DLT solutions

Companies that develop DLT solutions also need to consider how to protect their interests in the technology itself. Like other subjects involving software, blockchain solutions may be patentable. Requirements vary depending on the jurisdiction but generally, there must be a technical solution or contribution to a technical problem. Alternatively, companies could protect blockchain related innovations as copyright or trade secrets.

Looking ahead

Pharma has long sought to maximise the resources that can be channelled directly to meeting unmet medical need by focussing their efforts in the twin areas of improved efficiency and in increased personalisation and efficacy. Developing and adopting DLT could fast-track that ambition.

To hear more from us on this topic, please subscribe for updates here or at www.hsf.com/futureofpharma

Key contacts

Shaun McVicar
Partner, IP Dispute Resolution
Global Sector Co-Lead Partner, Pharmaceuticals
T +61 3 9288 1587
shaun.mcvicar@hsf.com

Marine Giral
Graduate
Herbert Smith Freehills
T +61 3 9288 1496
marine.giral@hsf.com

HERBERTSMITHFREEHILLS.COM

BANGKOK
Herbert Smith Freehills (Thailand) Ltd

BEIJING
Herbert Smith Freehills LLP
Beijing Representative Office (UK)

BELFAST
Herbert Smith Freehills LLP

BERLIN
Herbert Smith Freehills Germany LLP

BRISBANE
Herbert Smith Freehills

BRUSSELS
Herbert Smith Freehills LLP

DUBAI
Herbert Smith Freehills LLP

DÜSSELDORF
Herbert Smith Freehills Germany LLP

FRANKFURT
Herbert Smith Freehills Germany LLP

HONG KONG
Herbert Smith Freehills

JAKARTA
Hiswara Bunjamin and Tandjung
Herbert Smith Freehills LLP associated firm

JOHANNESBURG
Herbert Smith Freehills South Africa LLP

KUALA LUMPUR
Herbert Smith Freehills LLP
LLP0010119-FGN

LONDON
Herbert Smith Freehills LLP

MADRID
Herbert Smith Freehills Spain LLP

MELBOURNE
Herbert Smith Freehills

MILAN
Studio Legale Associato in association with
Herbert Smith Freehills LLP

MOSCOW
Herbert Smith Freehills CIS LLP

NEW YORK
Herbert Smith Freehills New York LLP

PARIS
Herbert Smith Freehills Paris LLP

PERTH
Herbert Smith Freehills

RIYADH
The Law Office of Nasser Al-Hamdan
Herbert Smith Freehills LLP associated firm

SEOUL
Herbert Smith Freehills LLP
Foreign Legal Consultant Office

SHANGHAI
Herbert Smith Freehills LLP
Shanghai Representative Office (UK)

SINGAPORE
Herbert Smith Freehills LLP

SYDNEY
Herbert Smith Freehills

TOKYO
Herbert Smith Freehills