PreScouter

Blockchain in Healthcare & Life Sciences

Research Support Service

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Prepared by: **PreScouter**
Charles Wright, PhD I Technical Director
Rakesh Joshi, PhD I Researcher

PRESCOUTER

Intelligence Brief Question

How can blockchain technologies be employed in the life sciences industry?

Blockchain is currently a buzzword across all commercial sectors, from financial services to supply chain management. Blockchain exploded into the public consciousness as the distributed ledger technology (DLT) that acts as the backbone of the digital currency Bitcoin. Fintech quickly recognized the potential of blockchain, with multiple use cases now implemented in areas such as financial transactions and service/product life cycles.

However, within the life sciences sector, the potential use cases of blockchain are not as straightforward, and the rapidly changing landscape of blockchain usage presents a challenge for companies seeking to adopt the technology.

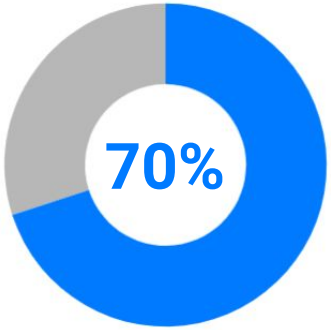
In this Intelligence Brief, we review three broad areas of blockchain deployment that are at various stages of maturity in the healthcare, biopharmaceutical, and medical technology industries.

Table of Contents

Executive Summary

For the life sciences industry, blockchain has the potential to **enhance cross-industry partnerships, integrity and trust** built on consensus, interoperability, tracing, and tracking of entities in a myriad of service and product pipelines. It can also be used to provide **robustness and transparency** across a range of functions, including clinical trials, financial transactions, supply chain management, vouching credentials, and processing claims—just to name a few.

While the potential for blockchain is increasingly recognized, **adoption remains slow** due to various challenges including the technological, cultural, and psychological. In spite of slow adoption, it is predicted that the value added by blockchains will grow to **$176 billion by 2025** including non-financial usages in the life sciences (about 5% of total value) with the improvements to blockchain platforms.



of all life sciences leaders plan to adopt a blockchain network by 2020

The value added by blockchains will grow to

$176B

by 2025

By 2025,

blockchain will add a

$3B value

to the life sciences sector, primarily in supply chain management

Executive Summary

This report reviews the following three broad areas of blockchain deployment, which are at various stages of maturity in the healthcare, biopharmaceutical, and medical technology sectors:

1. **Drug development and supply chain**
2. **Clinical trials management**
3. **Patient-centric usage**

We also enumerate developing use cases of blockchain, from proof-of-concept to real-world blockchain implementations, and identify first movers/early adopters of blockchain, including key collaborations, in the life sciences ecosystem.

Blockchain has great potential to improve upon various activities within the life sciences sector, although it still has a number of challenges when it comes to adoption. The consensus opinion is that changing the mindset of private, public and political leadership for adopting blockchain technology and the requisite change in management is the single greatest hurdle facing blockchain deployment. As the technology matures and early use cases emerge to help mitigate risks, more mainstream adoption is to be expected within the next 5 years, which will enable blockchain technology to bear its fruits in the life sciences ecosystem.

INTRODUCTION

What is a blockchain?

Fundamentally, a blockchain is a growing, real-time list of records (each called a **block**), with each block containing a **timestamp** that cannot be tampered with retroactively. In addition, a block harbors a cryptographic label of the previous and next block in the chain, called a **hash**, which provides provenance—basically authenticating the history of the previous block, thus allowing traceability to the original transaction (called the genesis block). Lastly, a block contains the actual data of a **record**, be it a financial transaction, a multi-party contract, or a drug's batch record.

The blockchain architecture is therefore resistant to the surreptitious modification of data or its provenance. Blockchains are managed by peer-to-peer networks of nodes (servers or even individual computers), which can have open or closed membership, thus providing privacy (without sacrificing consensus) and storage redundancy, all built on a democratic, decentralized system.

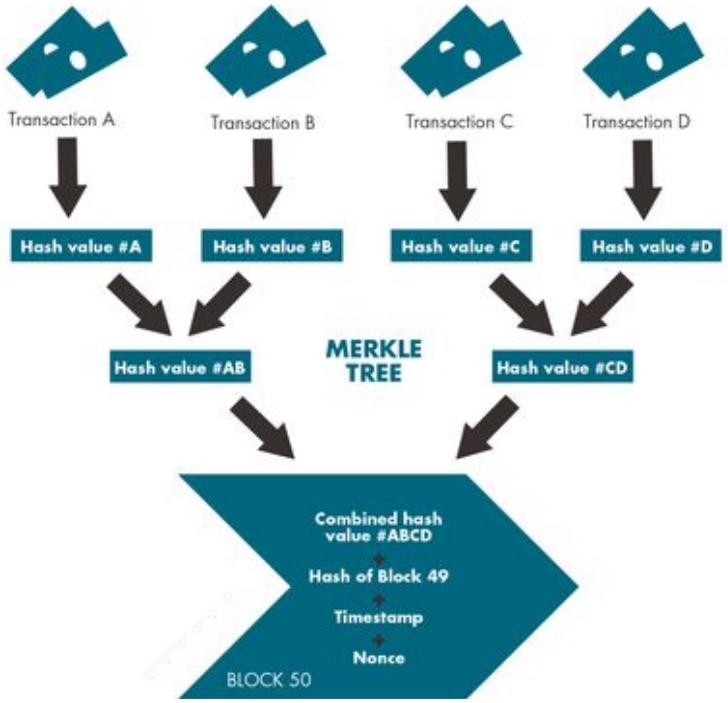


Figure: How the blockchain works (Source Wikipedia)

Potential Blockchain Uses in Life Sciences

1

ACADEMIC GRANT TRACKING:

A blockchain that integrates and updates research data, expenses, personnel data etc. in real-time for the duration of a grant

2

OPEN SOURCE DISTRIBUTED REPOSITORIES FOR LARGE-SCALE "-OMICS" LIFE SCIENCES DATA:

A blockchain to update life sciences "omics" data , such as mass spectrometry data on patient blood samples in real-time

3

FINANCIAL META-TRANSACTIONS BETWEEN STAKEHOLDERS:

A blockchain to track secondary monetary transactions linked to a major transaction like a discount for a bulk drug purchase

4

HEALTH CARE PROFESSIONAL (HCP) CREDENTIALING:

A blockchain to track the credentials of health care professionals across siloed health education and hospital systems

5

INTELLECTUAL PROPERTY (IP) MANAGEMENT:

Blockchaining IP that results from a clinical trial in real-time therefore saving time and streamlining patent filing procedures

6

CONSENT MANAGEMENT BEYOND PATIENT-HCPS:

Blockchaining consent management between a clinical trial subject and a clinical trial recruiter/manager

Early Adopters & Key Players

Patient-Focused Access to Medical Records

PHILIPS BLOCKCHAIN LAB FIRST TO JOIN GEM HEALTH NETWORK

A collaboration between Philips Blockchain Lab, an R&D development center of healthcare giant Philips, and Gem intends to leverage blockchain based on Ethereum to address the balance between patient-centric care and transactional efficiency by creating an ecosystem connected to a universal data infrastructure.

DELOITTE, SNS BANK NV & RADBOUD UMC'S *RESHAPE CENTER* DEVELOPS PRESCRYPT

The *Prescrypt* blockchain developed by this collaboration attempts to give patients ownership and access control of their medical records and also allows providers to prescribe drugs on the same blockchain.

WORLD'S FIRST BLOCKCHAIN-SUPPORTED PERSONAL CARE RECORD PLATFORM

The collaboration's *MyPCR* platform provides 30 million UK National Health Services patients access to their medical data on their smartphones. The platform ensures medical data provenance and integrity, GDPR-adherent patient data management and automated verification of medication usage

THE PATIENT CONTROL AND CONSENT BLOCKCHAIN INITIATIVE

This proof-of-concept patient control and consent blockchain initiative aims to overcome the challenges of fragmented health data that resides in public and private health provider siloes. Initial efforts are focused on the release of data for research purposes with patient consent.

Early Adopters & Key Players

HCP-Focused Access to Medical Records

KEYLESS SIGNATURE INFRASTRUCTURE (KSI) TECHNOLOGY

Stakeholders integrated a blockchain with existing databases to provide increased security, transparency, auditability and governance for electronic systems and lifecycle management of patient records.

MEDREC: BLOCKCHAIN IN HEALTHCARE

Partnered on a Ethereum-based prototype of private blockchain that tracks medication data views and changes to prescription. It incentivizes the "miners", medical researchers and HCPs, with access to medical records of patients who have given consent.

TAMPER-PROOF DATA MANAGEMENT FOR MEDICAL RECORDS

The partnership will use Factom's blockchain to secure medical records and enable audit trials for the medical records ecosystem of HealthNautica (who has now been acquired by CHANGE Healthcare).

Early Adopters & Key Players

Clinical Trials (Left) | Supply Chain (Right)

COLLABORATION TO INTEGRATE BLOCKCHAIN TECHNOLOGY INTO CLINICAL TRIALS

The partnership is integrating blockchain into clinical trials management to ensure secure data management without sacrificing patient empowerment.

MEDILEDGER PROJECT: AN OPEN AND DECENTRALIZED NETWORK FOR THE PHARMACEUTICAL SUPPLY CHAIN

MediLedger brings together pharmaceutical manufacturers and distributors to track and trace regulations and improve supply chain performance.

PHARMACEUTICAL BLOCKCHAIN PILOT

The partnership between IBM and the US Food and Drug Administration wants to use blockchain to identify, track, and trace prescription medicines and vaccines distributed throughout the country.

Early Adopters & Key Players
Others

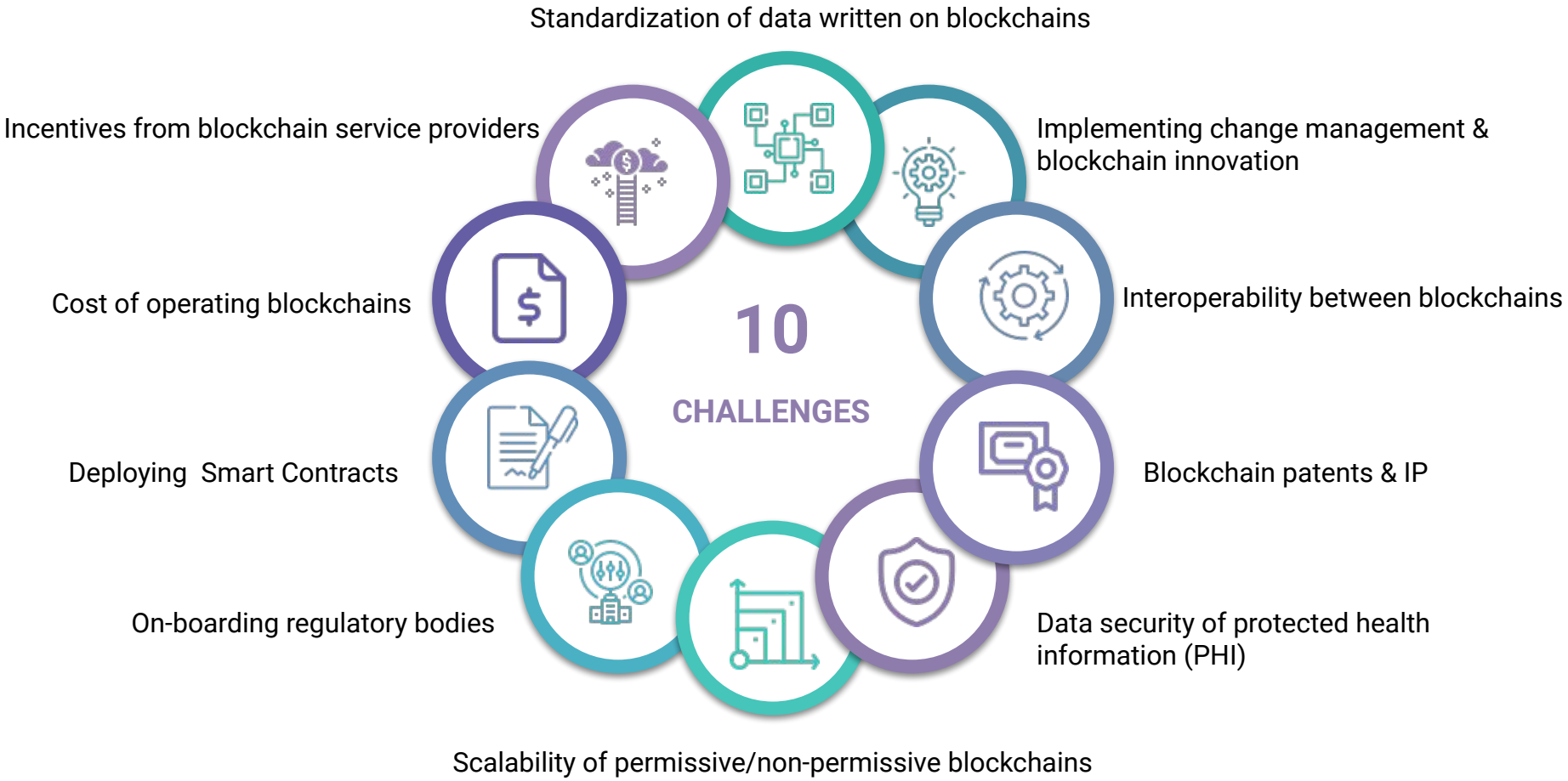
US GOVERNMENT LAUNCHES "BLOCKCHAIN IN HEALTHCARE" CHALLENGE

Proposals explored how blockchain technology can advance industry interoperability needs, including patient-centric outcomes research, the Precision Medicine Initiative, and delivery system reform.

POKITDOK'S HEALTHCARE API

A collaboration that will allow the PillPack pharmacy customers on Medicare plans to understand prescription costs, insurance and changes using Pokitdok's Healthcare API and Dokchain DLT.

Main Challenges to Adoption of Blockchain in Healthcare



DRUG MANUFACTURING & SUPPLY CHAIN MANAGEMENT

Potential Advantages

Nearly all reports published over the past three years, from Deloitte to IBM, have identified the drug development and supply chain management as sectors where blockchain could have the biggest impact in the life sciences.

Reports suggest blockchain will add value by:

- offsetting waste
- avoiding protocol failure
- enhancing real-time product-tracking
- ensuring traceability for regulatory authority auditing and fighting counterfeiting

For life sciences, blockchain could have the largest impact in the drug development and supply chain management sectors.

From keeping meticulous batch records of active pharmaceutical ingredients (APIs) in the manufacturing process to easily recalling bad batches of drugs after adverse reports, blockchain provides a potential solution.

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1. Here's Why Blockchains Will Change the World, *Fortune*
2. The Future of Blockchain in 8 Charts. *Raconteur*
3. Deloitte Blockchain Survey 2017
4. In Blockchain We Trust: Transforming the Life Sciences Supply Chain.
5. The Drug Supply Chain Security Act, USFDA
6. Blockchain to Blockchains in life sciences and healthcare: what broader integration is making possible today.

Uses: Validating Authenticity

Blockchain technology can be very effective for ensuring integrity in the drug supply chain, including **provenance** and **tracking and tracing**, two key areas that are under the purview of authorities such as the FDA, which has oversight through the Drug Supply Chain Security Act.

Provenance *defines the origin and/or ownership of an entity, either a service but more usually a product like a drug, which attests to the authenticity or quality of that entity.*

Tracking and tracing *defines an unbroken chain of records of each step a drug undergoes in its lifecycle, from APIs used to manufacture it to its prescription/sale or disposal by a pharmacy.*

Current methodologies that permit this are fragmented due to data silos and can lead to human errors as well as fraud. In the life sciences, provenance can be for a raw material, APIs, a medical device, or even data, like a batch record or a test result from another source, within a complex supply chain. For example, a pharmaceutical supply chain can include manufacturers, distributors, wholesalers and pharmacies. Each link in the chain requires validation of the entity's provenance and the ability to track and trace it.

The pharmaceutical supply chain

Uses: Validating Authenticity

Problems can arise when the chain is broken. Drug counterfeiting is an important case in point. An Interpol report estimates roughly 1 million people die from counterfeit drugs each year, and a report from Deloitte estimates that 10–30% of drugs in developing countries are counterfeit. Unfortunately, some of these countries are also where API and generic drugs are manufactured, which then make their way to the rest of the world.

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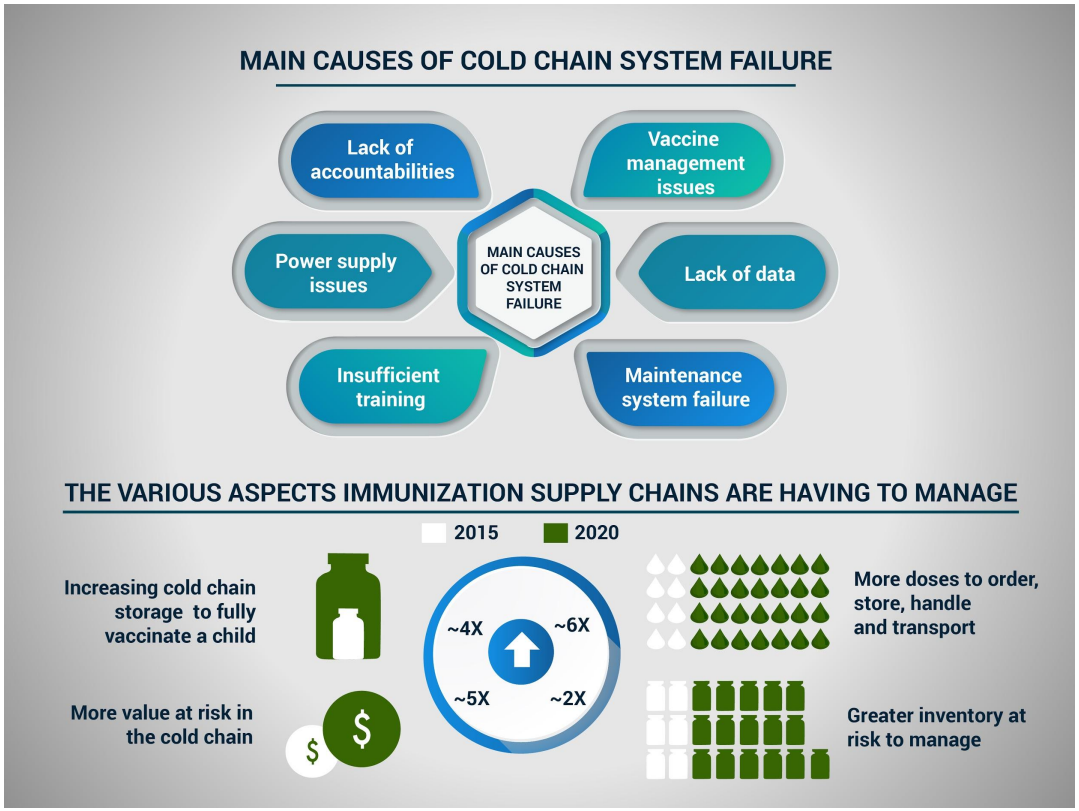
A blockchain for the **entire drug/API lifecycle**, where each step of the manufacturing and supply chain process would be treated as a block or series of blocks, would provide oversight. This would guarantee provenance of the incoming material as well as have a timestamp for the outgoing material at any stage of the drug/manufacturing lifecycle process.

Uses: Tracking Errors in Transportation & Storage

A consensus has been reached that blockchain technology may address the issues of fraud as well as innocent human errors. For example, a proof of concept from Accenture is that of tracking of **environment-sensitive drugs**, like vaccines, which are temperature-sensitive (require a cold chain). This specific use case is referred to as "temperature excursion" tracking.

Vaccines are stored and transported in a narrow temperature window. However, inappropriate global storage and transportation activities can cause loss of the entire vaccine batch's efficiency if adherence to stringent temperature windows is ignored.



Uses: Tracking Errors in Transportation & Storage

Using **internet-of-things (IoT) principles**, each vaccine batch can be embedded with temperature sensors, wirelessly connected to a control center and put on a blockchain platform for tracking and real-time reporting. This blockchain system can help manage a vaccine supply chain efficiently with oversight over bad batches of vaccines. In December 2018, UNICEF, the world's largest procurer and distributor of vaccines, decided to explore blockchain-based supply chain tracking solutions by investing in six startups, who each received a $100K investment from the UNICEF Innovate Fund.

The six emerging blockchain startups selected by UNICEF for a $100K investment

Two other specific areas within a supply chain ecosystem in the pharma/medtech industry that can take advantage of smart contract-based blockchains are:

1. internal process management to track processes and changes within a supply system, and
2. adverse event reporting between consortiums of drug development players.

CLINICAL TRIAL MANAGEMENT

Advantages of Blockchains In Clinical Trials

A clinical trial is a complex activity that includes patients, sponsors, drug providers, investigators, HCPs, and various government regulators. Importantly, sensitive data, including patients' medical records and the trial's outcomes, must remain private. The trial protocol itself has to be immutable and transparent. However, the entire process has to be conducted in a transparent manner for all participants, with strict protocols to be followed, in order to trust the results of the clinical study. Moreover, secure communication between professionals from different fields and multiple sites can be inefficient and can easily compromise protected health information (PHI) in a clinical study.

Blockchain technologies in clinical trials allow for immutability, scalability, traceability and varied permissive levels for data access.

Clinical trials therefore are perfect for the blockchain technology, or interoperating blockchains, which allows for immutability, scalability, traceability and varied permissive levels for data access. A blockchain provides the required shared communications and security framework for all this to be accomplished.

Applications

- A study by Cognizant highlighted that by using a blockchain to maintain subject consent, trial protocol(s), revisions/deviations, and adverse event reporting, a sponsor can demonstrate their commitment to patient privacy and safety, transparency in the conduction of the trial and the integrity of the trial's result to regulatory bodies. Furthermore, using a blockchain for communication and secure data sharing between various participants, especially those in multi-site trials, will **decrease regulatory warnings** on data integrity and security.
- A similar report by Deloitte on clinical trial management suggests that a potential subject's **cloud-based "health passport"** can use blockchain to search for relevant clinical trials, registration, patient consent and the actual participation. The same blockchain, or an interoperable blockchain, can then track patient sample collection, tracking, usage and analysis throughout the trial until the endpoint of the study is reached.
- A report by KPMG also suggests that since contract research organizations (CROs) are involved in clinical trials, **prescribed milestones and protocols embedded in a blockchain** by the sponsors and HCPs will not be altered by third-parties whose help is required conducting the trial, but not necessarily for the study design.

Use Cases

Using a blockchain allows monitoring of the entire clinical trial ecosystem, including patient health status, milestones met, and any protocol deviations—all in real time. Recognizing this potential in early 2019, Boehringer Ingelheim and IBM announced a partnership to explore blockchains in clinical trials in Canada. The partnership aims to use IBM's blockchain prowess and Boehringer Ingelheim's leadership in clinical testing to explore whether blockchain in clinical trials could provide a decentralized framework that assures patient consent, data provenance, process automation and transparency in protocol changes, without sacrificing trial quality and patient safety.

Triall, with its technology partner Sphereon, is developing several modular applications for improving auditability and operational efficiency in clinical trials. These applications run on Factom's blockchain infrastructure. The consortium's beta-version of its *Verial* application, a clinical document management solution, is being used in a Phase II clinical trial and is touted as the world's first clinical trial in production on a blockchain. The solution allows users to authenticate the integrity of documents after trial registration and allows audit of a document's evolution as the clinical trial progresses.

Challenges

Two challenges currently facing the use of blockchains in clinical trials are:

1) The permissive level of a blockchain:

Patient privacy issues and the intellectual property of trial sponsors are of paramount concern in any clinical trial. Not all participants in a clinical trial need to be privy to either sets of data. Choosing a data permissive level for a member, or a group of "nodes", is a major challenge in deploying blockchain to a clinical trial.

2) The adoption of blockchain technology by regulatory bodies:

The other challenge is how regulatory agencies such as the FDA can approve and use data generated and saved using blockchain technology. The endpoint of a clinical trial is usually to get approval for a drug or a medical device that enhances patient care, or even what course a treatment should take, a process usually approved by key opinion leaders, such as leadership and practitioners on a HCP association. Convincing and helping these governing bodies to deploy blockchain-based platforms for a clinical trial is proving a challenge due to technological, work culture and psychological barriers.

References:

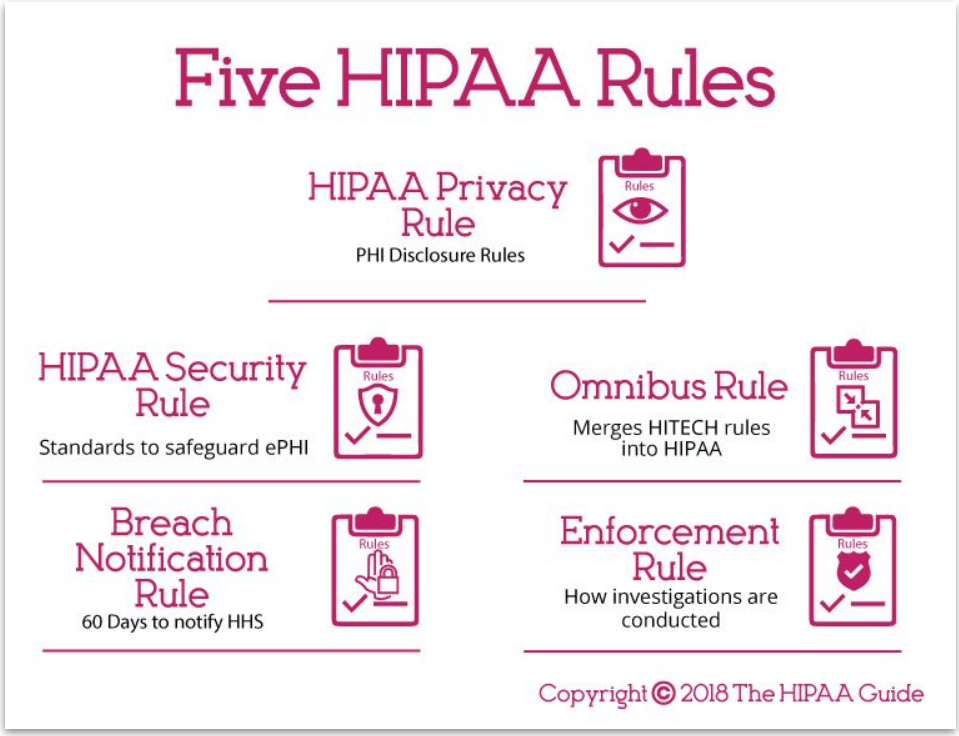
1. Healthcare rallies for blockchains: Keeping patients at the center
2. Team Medicine: How life sciences can win with blockchain
3. Blockchain to Blockchains in life sciences and healthcare: what broader integration is making possible today
4. Demystifying Blockchain for life sciences

PATIENT-CENTRIC USAGE

Patient Consent

Individuals, including patients, have more say over the privacy and usage of their personal and medical data than ever before, due to the digital revolution and new legislations that are being implemented. Privacy and usage protections are being offered by legislations governing protected patient health information (PHI) such as the Health Insurance Portability and Accountability Act (HIPAA) in the US and the broader protections offered by legislations like the EU's General Data Protection Regulation (GDPR) on personal data.

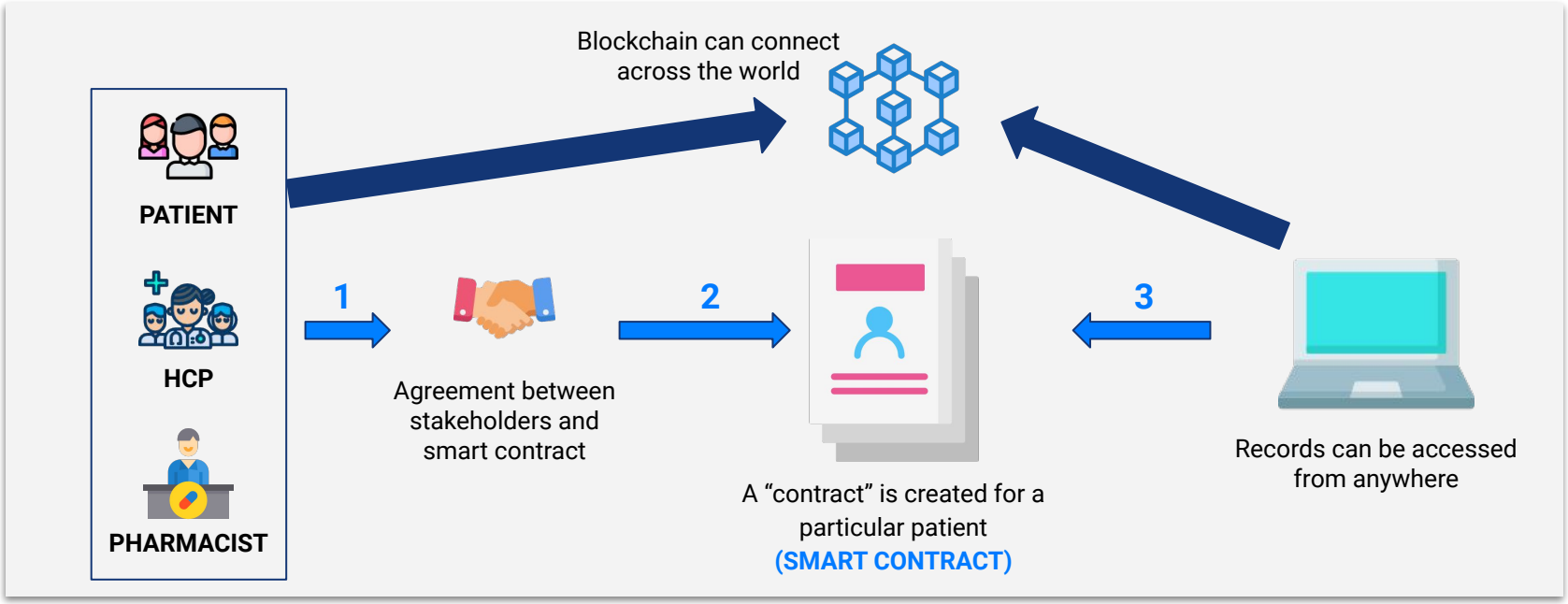
However, personal and health data need to be distributed to various HCPs, from doctors to insurance providers for efficient care. Currently, few health systems have the means by which to release only select sections of personal medical data.



Source: [The HIPAA Guide]

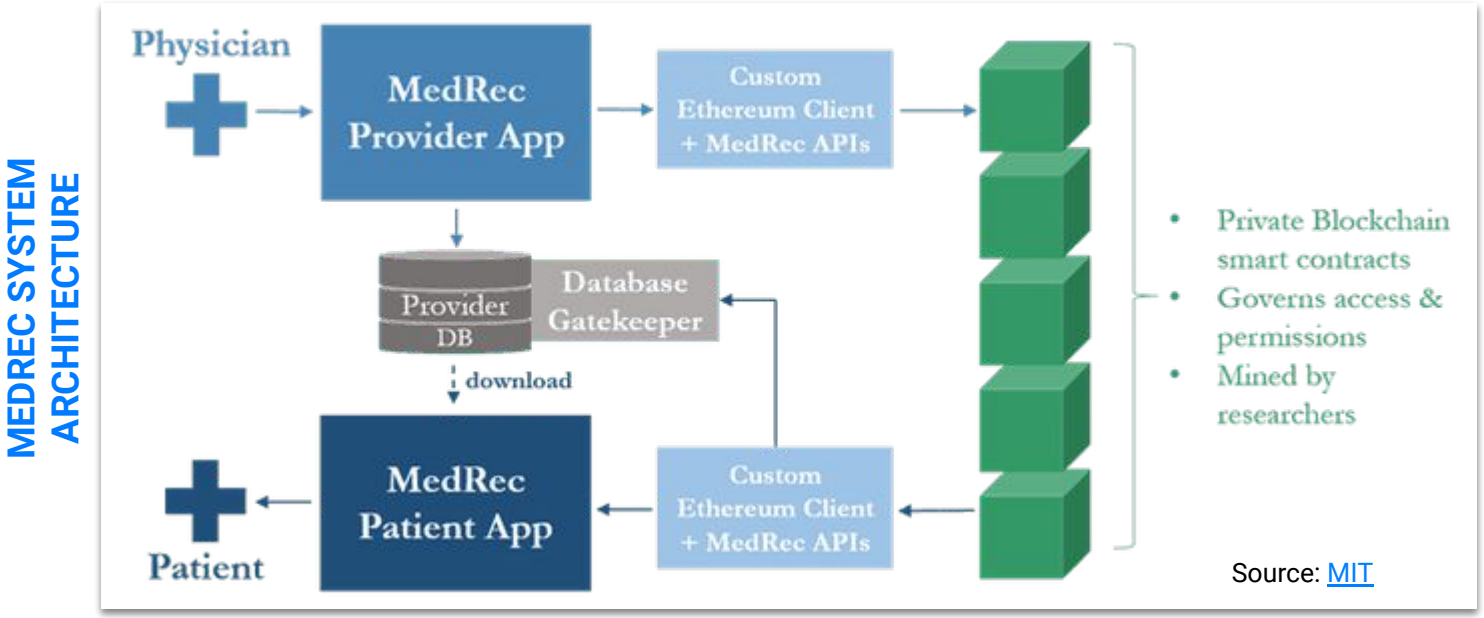
Patient Consent

Individuals should be able to consent to disclosing only sections of their health records while remaining confident that their privacy isn't being violated. Blockchain-based “smart contracts” are enabling this. Smart contracts are not legal contracts per se, but rather algorithms that are triggered into action when a certain condition is met, using “if-then” logic built into blockchains. These smart contract blockchains can access patient consent forms and the release permissions they contain. HCPs can thus access and identify which patients and data are eligible for a service or product, or what data can be used for inclusion in a study from a specific patient. In addition, the blockchain provides the the patient immutable proof of a record access event and its details.



Patient Consent

Several endeavors have targeted using blockchains for patient consent for enhanced services. **Guardtime's collaboration with the Estonian eHealth Services** is a use case in point. The blockchain is GDPR-adherent, showcasing the melding of data privacy, distribution and trust by all parties dealing with medical records. Similarly, the **MedRec program**, spearheaded by MIT, is a robust example of large-scale deployment of a proof-of-concept blockchain for patient consent, one that works across over 20 e-health record platforms currently used in the Greater Boston area. The MedRec program highlights the interoperability offered by blockchain for siloed patient data.



Patient Record Management

Blockchains can go beyond providing flexibility for patient consent and medical data dissemination. Electronic health records (EHRs) are becoming globally prevalent, and can themselves be harbored on a blockchain, hence allowing the same advantages of a blockchain to the currently siloed and fragmented patient medical data that is held by various HCPs, health systems, pharmacies, and insurance providers.

This centralization will make secure accessing of medical data, with a patient's consent, easier and trackable, with robust checks and balances against privacy infringement via unconsented usage by members of the blockchain.

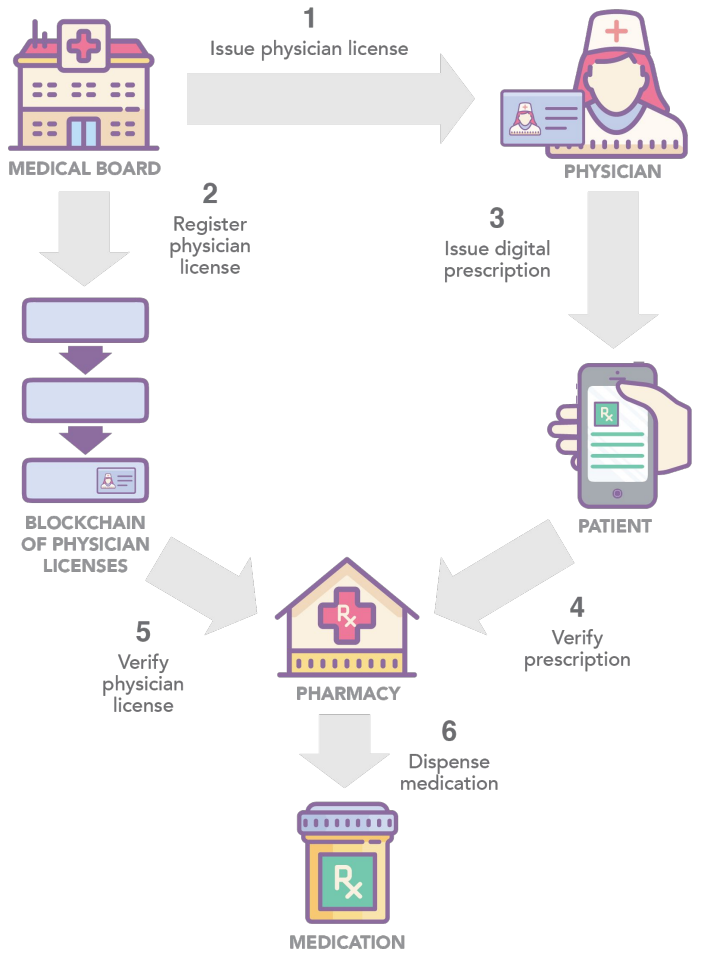
The UK National Health Service (NHS), along with Guardtime, has taken the necessary steps to move 30 million patient records in its national medical registry onto a blockchain. This myPCR platform seeks to make patient records accessible to 30 million patients from their smartphones and to patient-approved parties. It is specifically designed not only for patients' access and privacy rights to their data under the GDPR legislation in Europe, but also for medical adherence tracking.

The MyPCR platform will help improve medication adherence in the UK, with potential savings of over GBP 800M (USD 1B).

Prescription Sharing & Longitudinal Patient Care

Another potential use case for a blockchain will be the ability to track a patient's prescription usage by the patient, HCPs, pharmacies, and insurance providers on a blockchain. The *Prescrypt* project, spearheaded by Deloitte and its collaborators in the Netherlands, is an example of "blockchaining" a chronic illness patient's drug prescriptions for secure communication, usage tracking and analysis for increasing treatment efficacy by health providers.

A recent report by Deloitte identified the possibility of using patient EHRs to track the entire history of a patient. This would potentially allow tracking an individual's health from infancy to old age; more specifically, the responses to specific health treatments. This would increase the value of a specific treatment to the overall long-term longitudinal care of a patient.



An example of a use case flow of Veres's Verifiable Prescription blockchain-based platform.
Source: Veres.io

Personalized Medicine

The nascent field of personalized medicine, with includes the use of a patient's genomic, proteomic and other high-throughput data to tailor a regimen specific to that patient, is an important paradigm shift in the delivery of healthcare. It is especially gaining ground in the treatments of cancers, which have unique signatures and progression in each individual. CAR-T cell therapy and other similar advanced cell and gene therapies involve the use of the patient's own DNA and cells that are re-engineered and put back into the patient. However, such treatments raise questions on how to track steps in a personalized treatment regimen as well as manage data ownership and security related to a patient's DNA and tissue. **Zenome** and **DNATix** are two examples of companies capitalizing and facilitating personalized healthcare by using blockchain technology.

zenome

Zenome is a decentralized peer-to-peer network constructed for the secure trading of genomic data. With Zenome, users can sell their genetic data to the companies interested in buying.

DNATIX

DNATix is a genetics and blockchain company, building the infrastructure for the world's genetic blockchain ecosystem. It is the first company to successfully transfer a genetic sequence over the Ethereum Blockchain, and the first to transfer a complete chromosome.

Data Security of Medical Devices/Wearable Techs

With the rise of the internet of medical things (IoMT), where various devices like pacemakers and portable/wearable health monitors are linked by wireless/bluetooth technology, the privacy and security of data exchange between medical devices, HCPs and other providers is crucial. Having IoMT devices platformed on blockchain technology will allow encrypted data privacy and security beyond what currently exists.

Another use case under development is the tracking of medical device through blockchain-based manufacturing, supply chain management, and adverse event reporting. One such example of a medical device company using blockchain technology to track medical devices is the SOOM application from 121Nexus.The mobile application allows a smartphone to scan barcodes on a medical device to provide immutable and real-time data on a product. A user can scan their individual devices to see if there has been a recall, access instructions for use and maintenance, and find other relevant safety and regulatory information.

Patient Claims & Billings

Another patient-oriented use of blockchain is the claims and billings process between an individual and an HCP or an insurance provider. Some claims may not be automatically covered by a healthcare provider or an insurer, a high-frequency event for certain procedures in most countries, especially the U.S. This can cause delays in legitimate processing of claims but also opens the doors to fraudulent claims and billings.

A Tech Trends estimate from Deloitte estimates direct healthcare fraud at USD $4B, from over-billing, billing for services not performed and outright fraudulent claims. Other reports that take into account incidental costs used to fight fraud puts it at a higher value (USD $272B).

NEXT STEPS

Next Steps

THESE ARE SOME POSSIBILITIES THAT PRESCOUTER CAN OFFER FOR CONTINUATION OF OUR RELATIONSHIP:

PERIODIC TRACKING OF NEW DEVELOPMENTS: quarterly/biyearly scouting on any novel technologies related to the topic of interest.

OUTREACH to companies or research groups for detailed anonymous interviews.

Engagement with **SUBJECT MATTER EXPERTS** to receive an expert opinion.

Engaging with a **CONTRACT RESEARCH ORGANIZATION** for building a prototype, testing an equipment or any other related research service.

CONFERENCE SUPPORT: PreScouter can attend conferences of interest on your behalf.

WRITING ARTICLE: PreScouter can write technical or more public facing articles on your behalf.

For any requests, we welcome your additional questions and custom building a solution for you.

About the Authors

Charles Wright, PhD

Managing Director, Healthcare & Life Sciences

Charles is a Senior Project Architect and Managing Director of the Healthcare & Life Sciences Practice at PreScouter. He is responsible for ensuring that our clients' innovation needs in this space are being addressed by overseeing PreScouter's teams of Advanced Degree Researchers. He has managed projects covering all stages of innovation in the biomedical space, from emerging academic research through preclinical and clinical development of therapeutics and medical devices, to implementations of products in clinical settings. As an academic, he developed integrated microscopy–computational systems for high-precision quantification of the behavior of individual bacterial cells. Charles graduated with a BA in Physics, Molecular and Cellular Biology, and Spanish from Vanderbilt University, then earned his PhD in Biophysical Sciences from the University of Chicago before working as a Postdoctoral Scholar at Purdue University.

About the Authors

Rakesh Joshi, PhD

York University

Rakesh is a life sciences professional with a passion for data-driven analytics and discovery. Rakesh earned his PhD is Biochemistry from Purdue University. Currently, he is enrolled in the Schulich School of Business at York University diving deeper into machine learning/artificial intelligence and technology-driven strategic planning & management.

About PreScouter

PRESCOUTER PROVIDES CUSTOMIZED RESEARCH AND ANALYSIS

PreScouter helps clients gain competitive advantage by providing customized global research. We act as an extension to your in-house research and business data teams in order to provide you with a holistic view of trends, technologies, and markets.

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