

Blockchain: The Chain of Trust and its Potential to Transform Healthcare – Our Point of View

"Use of Blockchain in Health IT and Health-related Research" Ideation Challenge

Office of the National Coordinator for Health Information Technology

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Executive Summary

As it has for centuries, commerce relies on two things: trust and verified identity. Put more simply: What is being exchanged, and who is confirming it? Yet commerce that was once direct and in-person is today conducted mostly online and requires intermediaries such as banks, governments, or other central authorities to verify the identity of each party and establish the needed trust between them. And whenever there are intermediaries there are inefficiencies – decreased speed, increased cost, and sometimes even fraud. Privacy, too, can be affected, and the centralized information stores of the intermediaries can be vulnerable to attacks. The famous 1993 cartoon by Peter Stein in *The New Yorker* sums up the trust limitation that is inherent in online commerce: *"On the Internet, nobody knows you're a dog."* Twenty-three years later, the world is still working to overcome this limitation with a commerce-ready method of validating identity and establishing trust without validation by an intermediary.

Welcome to blockchain, often called the chain of trust. Blockchain technology can support a new generation of transactional applications and streamlined business processes by establishing the trust, accountability, and transparency that are essential to modern commerce. The Internet of Information has been built on protocols such as TCP/IP for machine communication, HTTP for web content, SMTP for email, and FTP for file transfer. Blockchain facilitates trust and validates identity without intermediate third parties, enabling an Internet of Value. What TCP/IP has been for the exchange of information, blockchain can be for the exchange of value. *The Economist* stated it well, calling blockchain "the trust machine" and "the great chain of being sure about things".

As the technology behind the bitcoin digital currency, blockchain's birth is traced to the pseudonymous, unidentified person (or group) known as Satoshi Nakamoto. In recent years blockchain has gained more widespread use in other realms, with a variety of new blockchain-enabled businesses and services entering the market – many with potential to upend established industries. Blockchain technologies can be used to share a ledger of transactions across a business network without control by any

"Over the past two decades, the Internet has revolutionized many aspects of business and society... Yet the basic mechanics of how people and organizations execute transactions... have not been updated for the 21st century. Blockchain could bring to those processes the openness and efficiency we have come to expect in the Internet Era."

—Arvind Krishna Senior VP, IBM Research

single entity. The distributed ledger makes it easier to create cost-efficient commercial relationships where virtually anything of value can be tracked and traded without requiring a central point of control.

Blockchain promises to put privacy and control of data back in the hands of citizens. Trust and integrity will be established without reliance on third-party intermediaries. IBM believes blockchain is an extraordinarily important phenomenon with the potential to transform industries and upend business models. In this paper, we discuss the challenges in the healthcare system and how blockchain can potentially solve them.

Healthcare Challenges and How Blockchain Can Solve Them

The healthcare ecosystem is complex, with multiple stakeholders and intricate, sensitive interactions. This leads to both data security and privacy challenges and operational inefficiencies. Ownership and trusted access to medical information and administrative data is critical, yet the process must be made simpler and less costly.

In healthcare, new research is seeking to apply blockchain's distributed ledger and decentralized database solutions to the critical issues of interoperability, security, record universality, and more. Intriguing uses in other industries are being extended to healthcare, such as extending blockchain's smart contracts to provider network management or connecting myriad medical devices through common, blockchain-enabled systems of information relationships. While technical consensus on a distributed ledger for healthcare has yet to emerge, with debate ongoing regarding scalability, security, and regulatory compliance, blockchain technology and encryption *will* drive innovation in healthcare services and administration.

With blockchain, a business network allows members to exchange items of value through a distributed ledger that each member possesses and whose content is always in sync. Its cost-efficiency and accountability is driven by these key supporting concepts:

- Bit-string cryptography that ensures the integrity of ledger content without violating HIPAA requirements, which have traditionally limited the utility of health data and delayed its use in real time^[16]
- Consensus in which the majority of chain nodes confirm transaction validity
- Smart contracts that authorize and notarize each transaction

Table 1 lists today's most prominent healthcare industry pain points and IBM's views on blockchain's potential impact on them.

Pain Points	Current Challenges	Blockchain's Impact
Interoperability, accessibility, and data integrity	 Providers-payers not accountable for interoperability under Health Information Technology for Economic and Clinical Health (HITECH) Act^[8] 	- Blockchain eliminates data silos and aggregates clinical data from EMRs (whether the Department of Defense, Veteran's Administration, or private vendors) driving seamless interoperability between healthcare systems.
	 Data silos and data complexity limiting interoperability and data sharing Lack of clear data ownership 	 Records are guaranteed to be cryptographically secure, with no possibility of bad actors threatening data integrity.^[10] Outside auditing is made easier.^[5]
	- Inadequate analytic capabilities to support PCOR, precision medicine, and other national healthcare delivery priorities	- Outcomes research and precision medicine initiatives can be better supported; patients can control what data is shared with whom, achieving improved interoperability and increased anonymous data samples.

Table 1: Healthcare pain points and potential blockchain solutions

Pain Points	Current Challenges	Blockchain's Impact
Privacy and security	 Hacking attacks Confidentiality of protected health information (PHI) Integrity and availability Non-repudiation Trust and access control 	 Security is enhanced through encryption and cryptology. Integrity improves due to peer-to-peer accountability (distributed ledger). Supports data encryption and the management and enforcement of complex permission settings for participants and third parties. Promotes electronic prescriptions and decentralized, trust-based, authenticated data exchange.
Healthcare delivery models and cost	 Fee-for-service versus fee-for-value Managing actuarial risks Excessive costs of managing and maintaining electronic medical record systems^[8] 	 Better risk management is achieved with a more holistic view of healthcare. Fee-for-value is enabled through integration with Internet of Things (IoT). Addresses trade-off between personalized care and operational costs by connecting the ecosystem to universal infrastructure.
Fraud and abuse	 Medical fraud and subrogation Abuse, traceability, and accountability Unnecessary / inadequate care False claims Corruption Improper prescribing (taking advantage of illegible prescriptions) Improper billing 	 Subrogation is simplified thanks to smart contracts (the full role of blockchain in reducing fraud is to be determined). Abuse is reduced through blockchain-enabled traceability and accountability. Fraud is reduced with blockchain-timestamped protocols (prevention and reporting).^[5]
Process and complexity	 Lead time for medical appointments Cycle time to pay claims Benefits verification Pre-authorization 	- Accelerated approval paths result in faster pre-authorization.
Consumer engagement	 Clinical outcomes Utilization management Disease management and public health 	 Outcomes are improved through integration of blockchain, IoT, and cognitive computing. Supports PCOR objectives by improving the quality and relevance of evidence available to help all stakeholders make informed health decisions. With engaged patients owning their data (aggregated from multiple settings: hospital, insurance, lifestyle, wellness, and so on) and controlling with whom to share it, blockchain enables emerging approaches for disease treatment and prevention, including precision medicine.

Table 1: Healthcare pain points and potential blockchain solutions (continued)

Pain Points	Current Challenges	Blockchain's Impact
Procurement and contracting	 Complex contract processing Contract negotiations and execution Hospital supply chain issues 	 Intermediaries are reduced through use of smart contracts (distributed trust). Supply chains are streamlined (smart contracts).
Governance and compliance	 Compliance to regulations such as HIPAA Regulatory requirements for maintaining privacy and security of sensitive data such as PHI^[20] 	 Introduces efficiency and transparency to the heavily siloed healthcare industry by enabling involved parties to use a common blockchain.^[20] Allows health providers to share networks without compromising data privacy, security, or integrity.^[20] Manages patient record lifecycle and streamlines lifecycle of medical bills.^[20]

Table 1: Healthcare pain points and potential blockchain solutions (continued)

IBM believes blockchain can be applied to resolve many of these challenges, including the fundamental issues of security, scalability, interoperability, and privacy (particularly for EMR data).

What Blockchain is Not

Like every technology, blockchain has limitations and is not suited for application to all scenarios. It is not well suited for high performance (millisecond) transactions involving just one participant with no business network involved, or for replicated database replacement. It is not useful as a transaction-processing replacement and is unsuitable for low-value, high-volume transactions.

Scalability is a significant challenge currently, with differences between public and private blockchains. In a public blockchain such as bitcoin, thousands of nodes store copies of the relevant content, forcing a limit on transaction volumes to preserve decentralization. In private blockchains, only nodes with a direct interest in the successful processing of the transactions are running. In addition, blockchains are not ideal for high-frequency trading because of delays introduced by the asynchronous, ad-hoc, peerto-peer nature of the networked blockchain nodes (this can be resolved if, rather than storing complete transactional histories, the blockchain hosts just an ongoing verified representation of the transactions). There are also challenges with throughput capacity and storage limits related to permissions, as well as integration challenges when corporate legacy systems and systems of record are involved.

As blockchain technologies develop, many of the initial disadvantages are being eliminated, with further refinements in the blockchain ecosystem and decentralized stack through internet communication, processing (Ethereum is decentralized processing to bridge to corporate systems and assets), and storage and data (BigData, IFS, BigChain DB). For example, BigchainDB fills a gap in the decentralization ecosystem, providing a decentralized database at scale. It is capable of one million writes per second throughput, storing petabytes of data, and sub-second latency.

Blockchain for Healthcare Use Cases

The potential uses of blockchain technology in healthcare are multiple and varied. Here we present a wide-ranging list of prospective healthcare-related use cases that the industry has been debating, followed by a detailed look at three of them:

- Notarization / Identity Verification: Registration of EMR, insurance, and other healthcare records
- Collaborative Crowdsourcing: Open bazaar for services, transparency in pricing, and health property exchange
- Medical Banking: Disintermediating counterparties
- Counterfeit Drug Prevention and Detection: Introduce blockchain-enabled solutions to protect and enhance the pharmaceutical supply chain
- Genomics Research: Accessibility to genetic data secured on blockchain
- Population Health Management: A blockchain-based personal health record (PHR) system measuring consumer outcomes and influencing medical actions (for example, cases of influenza and preventative vaccines)
- Internet of Things and Blockchain: Consumer-generated health data meets IoT wearables through data accessibility and interconnection with health records
- Validation and Payment of Claims: Reduce process time and friction, including compliance with contract terms
- Outcome-Based Payments: Assigns each consumer a unique digital identity with data from blockchain (payers measure metrics for positive outcomes)
- Clinical Trial Results: Improve accountability and transparency in the clinical trial reporting process
- Smart Property: Track provenance and introduce anti-counterfeit measures for healthcare assets
- Real-Time / Contextual Forms of Insurance: Using smart controls, introduce new tools and services for growth, improving fraud detection and pricing, and reducing administrative costs
- **EMR:** Personal health record storage and access administered using blockchain, with user-key permission for doctors and other authorized parties
- Health Research Commons: Aggregated personal medical records, quantified self data commons (DNA bits), genome and connectome files^[27]
- Health Document Notary Services: Proof-of-insurance, test results, prescriptions, status, condition, treatment, physician referrals
- Doctor-Vendor RFP Services: Similar to Uber car services, doctors and health practices bid to supply medical services, possibly using automated bidding over tradenets

Use Case: Healthcare Pre-Authorization Payment Infrastructure

Business Problem / Determining if a given medical expense or event is covered by a member's insurance policy or pre-authorization can be a slow process. Multiple stakeholders are involved (consumer, provider, payer). The amount covered can vary based on the payer-provider relationship (in-network versus out-of-network). Timing is often critical, based on the nature of the patient's medical issue, and pre-authorization must persist through the full revenue cycle, ending with payment to the provider.

Why Blockchain? Blockchain will speed pre-authorization and enable timely treatment of the patient as well as accurate payment to the provider. The goal will be real-time determination of benefits, with the blockchain ledger shared among the stakeholders.

Benefits to Healthcare Stakeholders

Provider (health-related services and medical goods):

- Faster transaction settlement: Improved cash flow
- Accurate pre-authorization: Anticipated payments known earlier in cycle
- Blockchain virtual ledger: Patient data accessible from multiple silos



Payer (private and government insurers and individual payers):

- Proof of member identity: Assurance that proper consumer is treated
- **Faster transaction settlement and lower costs:** Fewer financial intermediaries
- Blockchain immutability: Audits facilitation and better fraud detection
- Blockchain virtual ledger: Less administrative "double record keeping"



Member / Patient:

- Security: Less likelihood of hacking of medical or financial information
- Privacy: Ensure proper application of HIPPA guidelines
- Accurate pre-authorization: Immediate determination of coverage and greater ability to compare options (member pre-authorization portal could provide view into costs, providers, and possibly provider ratings)

Use Case: Counterfeit Drug Prevention and Detection

Business Problem / Counterfeit medicines and other drugs sold to deceptively represent their origin, authenticity, or effectiveness can have a direct impact on consumer care and even provider liability. Whether contaminated, lacking authentic or active ingredients, or labeled at the wrong dose, these "fake medicines" have no place in the marketplace.

In the United States, one current solution is ePedigree, in which drug shipments are tracked, such as through RFID tagging. All movements are logged and include signed certificates that establish a life history of the shipped products, entered in multiple business process systems. In West Africa there is mPedigree, whereby the provider or consumer scratches the package to reveal a code that they send to a toll-free telephone number and receive a return text message confirming whether or not the product is genuine.

Why Blockchain?

In the existing solutions, there is still a central authority that can be compromised and documents that can be faked. The ePedigree solution is already close to a blockchain solution. If it can be modified with blockchainenabled anti-tampering capabilities during manufacturing, the supply and dispensation system could make drug counterfeiting a non-issue.

Benefits to Healthcare Stakeholders

Consumer:

- Authenticity: Ensures drugs originate from the true manufacturer
- Tampering: Prevents addition of substances after manufacture
- Efficacy: Ensures proper ingredients in the proper doses



Government agencies:

- **Better detection:** Addresses priority of identifying counterfeit medicines early in the chain, with improved anti-tampering, and less expense (current measures based on electronic documentation, SMS and GSM networks, and so on)
- **Improved reputations:** Governments where counterfeit drugs originate, or are suspected to originate, want statistics to counter that perception



Pharmaceutical industry:

- **Cost savings:** Big Pharma expends a lot of resources on anti-counterfeiting workarounds and regulatory compliance; this will be reduced or eliminated if drug authenticity can be assured at manufacture, delivery, and eventual consumption

Use Case: Clinical Trial Results

Business Problem / The US Food and Drug Administration requires all publicly-funded clinical trial labs to submit their data on human subjects to designated public repositories. Some repositories of the National Institutes of Health allow trial data to be deposited at ClinicalTrials.gov and using research data-sharing services such as figshare.

Today, few research groups follow through correctly on this requirement, especially in the case of negative data. And the groups that do upload their data often fail to maintain it over the long-term, eventually leading t missing information.

WhyBlockchain can provide additional accountability and transparency to the
clinical trial reporting process. The data itself can be deposited anywhere while
the blockchain stores the links to pertinent clinical trials. All trials associated
with a published study can be curated within individual blocks and published
on the blockchain.

Further, the service can be made available as a subscription for research labs where partner institutions maintain dedicated project pages listing past and current trials. This adds transparency and offers research groups the opportunity to easily upload links to the negative data for addition to the blockchain (the links have the added advantage of being timestamped). With over 30,000 trials published annually and rising, manual outcome verification is simply not possible^[5]. On a blockchain, the curated links and blocks could even be entered into a rewards program to promote publishing as much complete trial data as possible.

Benefits to Healthcare Stakeholders

Researchers and medical publications

- **Trial-related searches:** Researchers will be able to search for a trial -related transaction on the blockchain, confirm when it occurred, and verify the authenticity of the original protocol by generating identical public and private keys (blockchain provides an immutable record of existence, integrity, and ownership)
- **Precision medicine:** Blockchain-based individual clinical data enables the Precision Medicine Initiative in which researchers, providers, and patients work together to develop individualized care

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Food and drug regulators

- **Protection of trial participants:** Timely and improved submission of human clinical trial data will help protect the participants and provide reliable historical information to future trial subjects

IBM's Investment In Blockchain

IBM is a founding member of the Linux Foundation's Hyperledger Project and has been a leading voice in developing collaborative open standards for distributed ledgers and smart contracts. Here are some of our current blockchain initiatives:



- **IBM Blockchain on Bluemix** – Developers can create and test a blockchain on the cloud using our Bluemix platform-as-a-service offering.



IBM Bluemix

- **IBM Bluemix garages for blockchain** Participants can connect with our own experts and each other to find new ways to apply blockchains in business.
- Blockchain on IBM z Systems We're building a "blockchain made for business" by putting blockchain hooks and features in z Systems mainframes.
- **IBM Watson Cognitive Platform** We're out to merge blockchain with Watson cognitive computing tools to build an even more powerful technology.

More information on IBM's commitment to Blockchain can be found at www.ibm.com/blockchain.

Conclusion

Blockchain will play an increasingly significant role in healthcare IT and bring beneficial disruption and new efficiencies to every stakeholder in the ecosystem. It is vitally important that healthcare organizations understand and explore blockchain technology today to ensure they are ready for the changes sure to come tomorrow. Where does the approach work and where does it not? From these efforts, the best ideas will emerge and gaps in specifications, technology, and governance will be identified. The result will be a new generation of powerful, blockchain-based applications that will shape the next era of business, including healthcare.

For blockchain to fulfill its potential, it must be based on open technology standards to assure the compatibility and interoperability of systems. IBM is committed to helping make blockchain real for business, and we will put the same force behind our efforts that we did in working to mainstream Linux, Eclipse, Java, Spark, and other open source technologies. Only with openness will blockchain be widely adopted and flourish with innovation.

IBM is grateful for the opportunity to participate in the Ideation Challenge and looks forward to presenting our point of view at the upcoming, industry-wide "Blockchain & Healthcare Workshop" co-hosted by The Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology.

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