

Blockchain: A future-proof
enabler of the evolving life
sciences industry paradigm



The life sciences industry is in the middle of a profound transformation driven by stressors such as anemic pipelines, shrinking R&D investments, empowered patients, stricter global regulatory frameworks, low margins rise of generics and biosimilars. Companies are struggling to adapt to this new normal and embrace new patient-centric business models driven by real-world evidence.

The new evolving industry paradigm encompasses solutions to the above-mentioned structural problems and new business models that are now possible due to the advances in technology, genomics and medicine.

This document focuses on exploring how blockchain technology can enable the new industry paradigm with its inherent constructs of immutability, disintermediation, transparency, provenance and security.

The new life sciences paradigm

The new industry paradigm is a locus shift from product centrality to patient centrality. The ecosystem is now being shaped around the patient, caregivers and providers, with players exerting increased scrutiny on the cost vs. benefit of drugs and devices.

One common underlying foundation enabling Patient centrality, value-based care, evidence-based medicine, connected health and precision medicine is patient and real world data

Global regulators are responding to growing calls for patient safety and industry accountability by creating new regulatory frameworks and strengthening existing ones. FDA's Drug Supply Chain Security Act (DSCSA), EMA's Identification

A new industry paradigm is evolving in the life sciences industry characterized by patient centrality, evidence-based medicine and outcome-based reimbursements

of Medicinal Products (IDMP), Falsified Medicines Directive (FMD) and Good Distribution Practices (GDP) are cases in point of increased regulatory rigor.

New business models such as evidence-based therapies, value-based care, outcome-based pricing, personalized medicine, open innovation and crowdsourced clinical trials will be dominant sustainable models.

A common underlying foundation for all the above mentioned new business models is secure collaboration on patient and research data. With advances in genomics and open source tools such as CRISPR, access to large datasets is imperative for any successful large molecule based innovative product.

The ubiquitous data challenge

The new industry paradigm is a locus shift from product centrality to patient centrality. The ecosystem is now being shaped around the patient, caregivers and providers with payers exerting increased scrutiny on the cost vs. benefit of drugs and devices.

Researchers, patients and volunteers are restricted from sharing and donating their data freely. The root of this problem may lie in the common lack of trust around the usage, security and control of such data.

While data democratization is on the rise, acquiring and securing massive amounts of relevant patient, genomic and research data remains a herculean challenge. The distrust

around security, privacy and usage of data is rooted in some of the structural challenges discussed below.

Data ownership and privacy: The world's largest companies continue to build thriving business models and profit from their customers' data and behaviors. Their customers have little or no control over the usage, syndication and privacy of their data.

Sophisticated hackers: Trading customer data has become so profitable that the benefit of illegally selling hacked customer data outweighs the risk of being caught. With advanced technology, smart algorithms and anonymity of the dark web, hackers are becoming sophisticated, prevalent and emboldened.

Data security: The last few years have witnessed several data breaches that exposed millions of customers and patient records. While some of these breaches have been massive, the punitive consequences to the organizations that failed to protect their customers' data are being perceived to be disproportionately light.

Intellectual Property theft: R&D is increasingly being outsourced and collaborative research is emerging as a sustainable trend. In such an environment, it is critical to irrefutably establish IP ownership and protect it from being stolen.

Data forging: Proving authenticity of data is a global problem. It's an undisputed truth that some health insurance claims, certificates, documentation and records are fraudulent.

Blockchain technology can enable the creation of secure collaborative platforms where the data is immutable, transparent, secure and auditable for provenance in real time.

What is blockchain?

Blockchain is a shared book of records (ledger) which allows multiple parties (participants) to record information (digital assets) and control how the information is added onto the ledger. Blockchain enables "value exchange" – be it for currency, patient health records, documentation or any type of ownership of assets. At the heart of it, blockchain allows peer-to-peer exchange in a multi-party ecosystem^[1].

“At its core, Blockchain is nothing more than a special kind of distributed database. This special kind of distributed database features an ecosystem of selected participants, which could include anything from upstream suppliers to downstream consumers, regulators, or other appropriate stakeholders.”

- Biran Behelendrof (Executive Director of Hyperledger Project)

Each member (called node) of the ecosystem holds a copy of a distributed electronic ledger. These ledgers get periodically synced up when new transactions are validated and agreed upon by a majority of the members of the network. This helps in checking against any accidental or malicious data inflow, which can be detrimental to the entire network. This creates a network of records that is nearly impervious to alteration or fraud. Moreover, since each participant is using an identical record, there is no need for any reconciliation. This reduces costs and effort, and accelerates settlement time.

Blockchain technology works on four basic tenets ^[1]:

- **Distributed:** The records of any interaction are logged across all the participants or nodes, a.k.a. distributed ledgers. Since the data is recorded simultaneously on all ledgers, it serves as a single source of truth for all participants. It becomes very difficult or impractical for someone to tamper the data as copies of the source of truth are distributed across, and changing one ledger will not ensure the change of values in all other copies.
- **Ledger:** Adding to the tamper resistance of each record, each action in blockchain is timestamped, generating a sort of complementary anagram of the published data. The resulting code is complex, and its association with the core record is immutable. This makes it impossible to make any changes to the data without losing its linkage to the initial anagram. Timestamping memorializes the data by recording the core data and its anagram across all nodes in the blockchain.
- **Consensus:** Any parties of a blockchain-enabled transaction or contract have agreed in advance to its terms. Based on these terms, blockchain allows the participants to reach a consensus when a record of entry is added into the blockchain. Any record which is changed at a single node

without the shared consensus of all the participants is removed, ensuring a tamper-resistant book of records. A shared consensus complemented with the distributed ledgers establishes trust between participants on the single source of truth for the shared digital asset.

- **Smart contracts:** A smart contract is a business logic embedded in the blockchain network as a computer program. This can be triggered by certain events or by the virtue of interaction with another smart contract. This business logic is agreed upon by all the participating members of the network and hence does not require any third-party intervention.

Key characteristics of blockchain

The new industry paradigm is a locus shift from product centricity to patient centricity. The ecosystem is now being shaped around the patient, caregivers and providers with payers exerting increased scrutiny on the cost vs. benefit of drugs and devices.



Immutability

Blockchain does not allow any modification or deletion of any transaction that has been recorded over the network.



No single point of failure

All the information shared among the participants of the network gets indistinguishably distributed among the participants. This information is verified by all the participants independently. In the event of failure of any or multiple nodes, there is no impact on the working of the blockchain network because of the distributed nature of information.

[1] - The Art of Blockchain: Creating Masterpieces in a New Medium (A Wipro - Forbes Insights report)



Provenance

Records shared on the network are digitally signed (cryptographically) by the participants which gets stored in the block. This block also contains the address (hash) of the previous block and ensures the entire transaction history can be easily audited.



Transparency

Any change done on the blockchain network is visible to all the participating members of the network.



Single source of truth

Any transaction is validated when all the participants give an approval to the transaction. This serves as a single source of truth among the participants.



Authenticity

Data shared over the network can be easily identified by comparing the corresponding signature (hash) of the data, allowing authentic verification.



Automation

Smart contracts lead to automatic settlements of transactions based on completion of certain tasks/milestones and agreed upon business rules.

Type of blockchain networks

There are typically three types of blockchain networks:

- **Public blockchain:** There is no central authority and anyone can join the network and have access to all the rights i.e. read/write/audit. A public blockchain is also called as a permission-less blockchain.
E.g. Bitcoin Blockchain
- **Private blockchain:** There is a central authority in the form of an individual or an organization. The central authority can give certain rights to selected individuals/organizations in the network. A private blockchain is also called as a permissioned blockchain.
E.g. Clinical Trial Management.
- **Consortium blockchain:** To overcome the limitation of a private blockchain i.e. having the sole authority to govern the network, multiple individuals/organizations come together to make the decision in the best interest of the entire network. Such a group is often termed as a consortium. The transactions are validated by multiple stakeholders and thus the risk of having a sole authority is taken away. Consortium blockchain is also permissioned, where the entry and actions of new entrants are decided by the consortia members.
E.g. Provider Data Sharing

Blockchain in life sciences

Research and Development (R&D)

With the advent of open innovation, crowdsourced clinical trials, democratization of data and shrinking R&D funds, companies and researchers are collaborating across the ecosystem including competitors to co-innovate.

Companies are also waiting longer into the research projects for solid evidence before filing for expensive patents.

Blockchain provides the required robust IP protection, transparency and verifiability in real time across globally dispersed teams. As each participant uploads their research data onto the chain, it is recorded as immutable time-stamped transactions. At any point of time, it is easy to trace ownership and provenance of the content or portions of the IP to specific entities or individuals. This will enable open collaboration without the fear of IP theft.

Clinical trials

Clinical trials are complex, long and high risk.

Large global studies with multiple trial arms and investigative sites have several CROs, CMOs, Principal Investigators, Clinical Research Associates and healthcare providers collaborating on a daily basis generating massive amounts of clinical and operational data.

Fraud and data tampering can sometime get buried in the volumes of data-skewing safety and efficacy analytics and can be detrimental to the health of the clinical trial and subjects.

How blockchain can help:

- **Tamper-proof data:** With Blockchain, raw data from electronic lab notebooks, instrumentation, lab results etc. can be uploaded in real time to create immutable and verified records. Any fraud patterns can be easily detected with a fraud detection algorithm.

It costs between \$100M to \$ 2B over 10 years to bring a novel product to market through extensive clinical trials. It is imperative that the content/data each player brings to the table and generates as part of the study, is tamper proof.

- **Patient safety:** Any adverse events, contraindications or significant observations are published into blockchain in real time. This can alert other investigators or sites who are experimenting similar scenarios or subject profiles.

Cold chain monitoring

With the rise of biopharma, cold chain logistics is gaining new prominence and focus. Many biotech drugs require temperature-controlled shipping and storage.

Temperature excursions continue to be a major challenge and result in about 20% of spoilage and product wastage. This can cause harm to patients and brief drug shortages where required. A similar scenario exists for drugs that are sensitive to light, humidity, vibration, electromagnetic force etc.

Combining blockchain and IoT technologies, it is possible to measure temperature at a unit of sale level in real time on land, air and sea. This temperature data is uploaded onto blockchain and associated with the batch record of the product.

Any excursion in temperature or any other validated environmental factors are recorded as immutable records and are accessible to all the authorized parties including the patient and regulatory agencies.

The World Health Organization estimates that up to 30% of drugs available in Asia, Africa and Latin America are counterfeits. Average for global counterfeits rises to 10 percent. 100,000 lives per year are lost just in Africa.

Counterfeit drugs

Counterfeiting is a global problem and it no longer affects just the consumer goods industry. It is unquestionable how lucrative the counterfeit drug business is with hefty margins that exceed drug trafficking and carry comparatively low risk.

How blockchain can help?

- Every transaction from drug inception to consumption is recorded on blockchain assuring authenticity and providing traceability in agreement with T3* regulation
- End-to-end traceability of each item will prevent counterfeit drugs getting into the value chain

Inventory management

Inventory management in life sciences falls under the broader umbrella of Good Practices (GxP). Drug and device manufacturers maintain consignment stocks globally and it is critical, both from a regulatory and financial aspect, to be able to account for that inventory at a unit level. With blockchain, it is possible for all the authorized participants to uniquely identify and track the current location and chain of custody of the product at a granular level.

Product expiration

Expired products can be ineffective and even cause harm to the patients. It is critical to be able to identify and dispose expired products to prevent dumpster-diving and reintroduction into the supply chain. Blockchain can track and provide product expiration alerts to the entity with custody of the product. Further, by using blockchain for reverse logistics, products can be tracked until they are disposed of, according to standard operating procedures.



Product recalls

Product recalls are expensive and time-sensitive, requiring quick location and identification of the affected products. Unfortunately, current systems are inadequate or limited for this functionality. Some of it is due to multiple sales channels involved and others due to supply chain complexities.

Blockchain can readily provide location and chain of custody information at a unit level by a simple user search by product, batch, manufacturer etc.

Participants who had handled the recalled products can also be alerted programmatically when the manufacturer broadcasts unique product identifiers from the recalled batch.

This will help with targeted speedy recall improving patient safety, manufacturer's reputation and reduce the overall cost of recall.

Regulatory compliance requirements

To protect patient safety, regulatory agencies are implementing supply chain security frameworks. Once implemented it will require manufacturers, re-packagers, wholesale distributors and dispensers to comply.



DSCSA requirement	Blockchain applicability
Trade with authorized trading partners only	<ul style="list-style-type: none"> • Only authorized trading partners can be provided access to the blockchain network to transact • Trading partners with valid license by the jurisdiction authority will be active and allowed to transact
Serialize product with unique identifier and transact only with serialized product	<ul style="list-style-type: none"> • Blockchain can be programmed to allow transactions on products that are compliant with serialization requirements.
Provide T3* information in electronic format to trading partners and regulators upon request	<ul style="list-style-type: none"> • T3* information of all transactions will be available as immutable records and can be accessed by unique product identifier, manufacturer, batch number etc. • The location and chain of custody of every product transacted on blockchain can be easily identified in real time enabling quarantine and investigation • As T3* information of the original shipment of a returned product is already available on blockchain, it can be easily verified against the returned products that are intended for resale
Quarantine and investigate suspected products at a package level	
Identify and remove suspected products and notify FDA and trading partners	
Respond to verification request from trading partners within 24 hours	
Verify unique product identification at a unit level for returned products intended for resale	
Participate in package level traceability system by November 2023	<ul style="list-style-type: none"> • Blockchain provides a futuristic secure mechanism to comply with this requirement
Partner proprietary information should be kept intact	<ul style="list-style-type: none"> • Blockchain will exchange information without compromising on identity and confidentiality with required authorization and verification

Case studies

Pharma Cold Chain - A Wipro innovation for one of the world's leading biopharmaceutical companies

A Digital Supply Chain & Anti-Counterfeiting Solution built on IoT, Blockchain and Cloud technologies

The solution involves creating an industry framework that secures the supply chain and prevents cold chain wastage by generating geospatial alerts in real-time in the event of a temperature excursion or counterfeiting attempt. The data of shipment and any anomalies during the shipment are recorded on a private permissioned blockchain network.

This platform helps in the minimization of drug spoilage during shipment, which in turn results in improving patient safety. It gives an immutable audit trail across the supply chain that helps in identifying any counterfeiting attempts, thereby reducing losses for the organization from the sale of counterfeit products.

Pharmaceutical Track and Trace - A Wipro solution developed for one of the world's leading pharmaceutical companies

A pharma track and trace solution built on IoT and blockchain technologies

Our Proof of Concept (PoC) brings the pharmaceutical company, distributors, customs, wholesalers and retailers on a common blockchain platform to track and trace the

provenance of international drug shipments. Another key aspect of this project is to ensure that all compliance documentation required at each stage of the supply chain is made available proactively through blockchain.

The solution provides real-time visibility into the status of pharmaceutical drugs shipments, better inventory reconciliation, on-demand document & compliance check, and improved collaboration amongst multiple parties.

Lab to Launch - A Wipro solution developed for one of the world's leading pharmaceutical companies

A blockchain-based solution enabling collaboration across global teams in a pharmaceutical drug launch lifecycle

A new drug launch consists of multiple, complex and interdependent processes within an organization. These processes include government approvals, internal corporate approvals, ground team mobilization as well as the entire supply chain enablement. This entire process spans over 3-5 years. Our PoC brings together corporate, marketing, finance, internal regulatory teams, medical teams and supply chain teams on a common blockchain collaboration platform. In the overall set of activities, multiple internal and external approvals and certifications are recorded on blockchain.

Speed, accuracy and auditability of information are very critical during these processes. Blockchain enables seamless, transparent and proactive information exchange between all stakeholders.

About blockchain at Wipro

Wipro is a partner of choice for our clients across industries in driving Blockchain innovation. We achieve this through our industry recognized strategic advisory and consulting services combined with a strong portfolio of industry solutions and patents developed in our center of excellence. We constantly invest in creating a

strong Blockchain community and developing talent for building deep technology expertise across multiple leading Blockchain platforms. We have a comprehensive Blockchain ecosystem of technology partners, industry and regulatory bodies and academia to deliver value to our clients by driving enterprise-grade production Blockchain networks.

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