

Blockchain and the COVID-19 imperative
Working together across the life sciences
industry to realize blockchain's benefits

2021

There is a clear value proposition for blockchain technology within the life sciences industry. Native features of blockchain, or Distributed Ledger Technology (DLT), ensure data integrity, accountability, and traceability to foster an environment of trust throughout the ecosystem's users and contributors. These same concepts – built on layers of integrity and accountability – also serve as the guiding principles of the global life sciences ecosystem.

This clear alignment in principles has resulted in a boom in industry use case exploration and development. Blockchain supports critical life sciences objectives, including transparency, quality, traceability and automation, and delivers value to all ecosystem participants in an increasingly complex supply chain. Before the coronavirus pandemic, the life sciences industry was already devoting resources to mapping blockchain to applications throughout the product lifecycle.

But COVID-19 has galvanized the life sciences industry in a way none could have predicted. For the benefit of global public health, marketplace competitors now have the opportunity to leverage the latest, best-in-class and innovative technologies to support the overall ecosystem and, most notably, the patient. Blockchain is one of the technologies which has the potential to bring transparency and value to the end patient.

Examples of blockchain impact include:



Identify Medical Treatments:

- Clinical trial management
- Clinical trial participants
- Medical research



Medical Supply Chain & Expediting access to patients:

- Track and trace
- eLeaflet/Electronic Product Information (ePI)
- Product verification or digital fingerprinting
- Order to cash



Funding Accountability & Transparency:

- Donation tracking
- Grant management
- Government funding

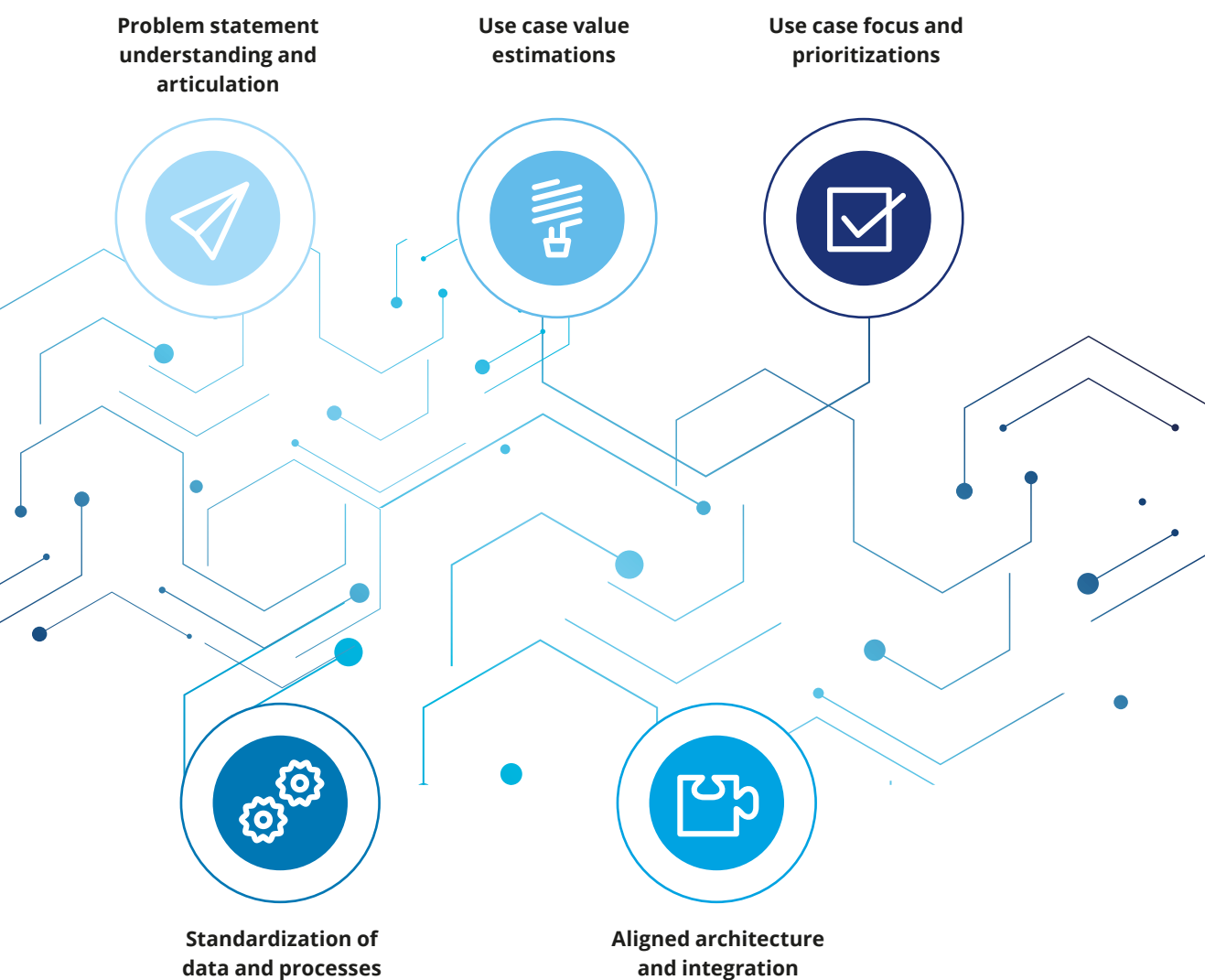


Ecosystem participants need to standardize solutions and scale

Much of the early efforts at mapping potential blockchain use cases to industry pain points have already been completed, resulting in a menu of use case opportunities for industry consideration. But the industry is lagging behind in preparations for coordinated execution of many of these opportunities.

Competing priorities, a lack of ownership, and investment and resource constraints appear to have stood in the way.

To capture these opportunities and realize value, ecosystem participants need to work together as a team to develop and implement:



I. Importance of tailored value propositions

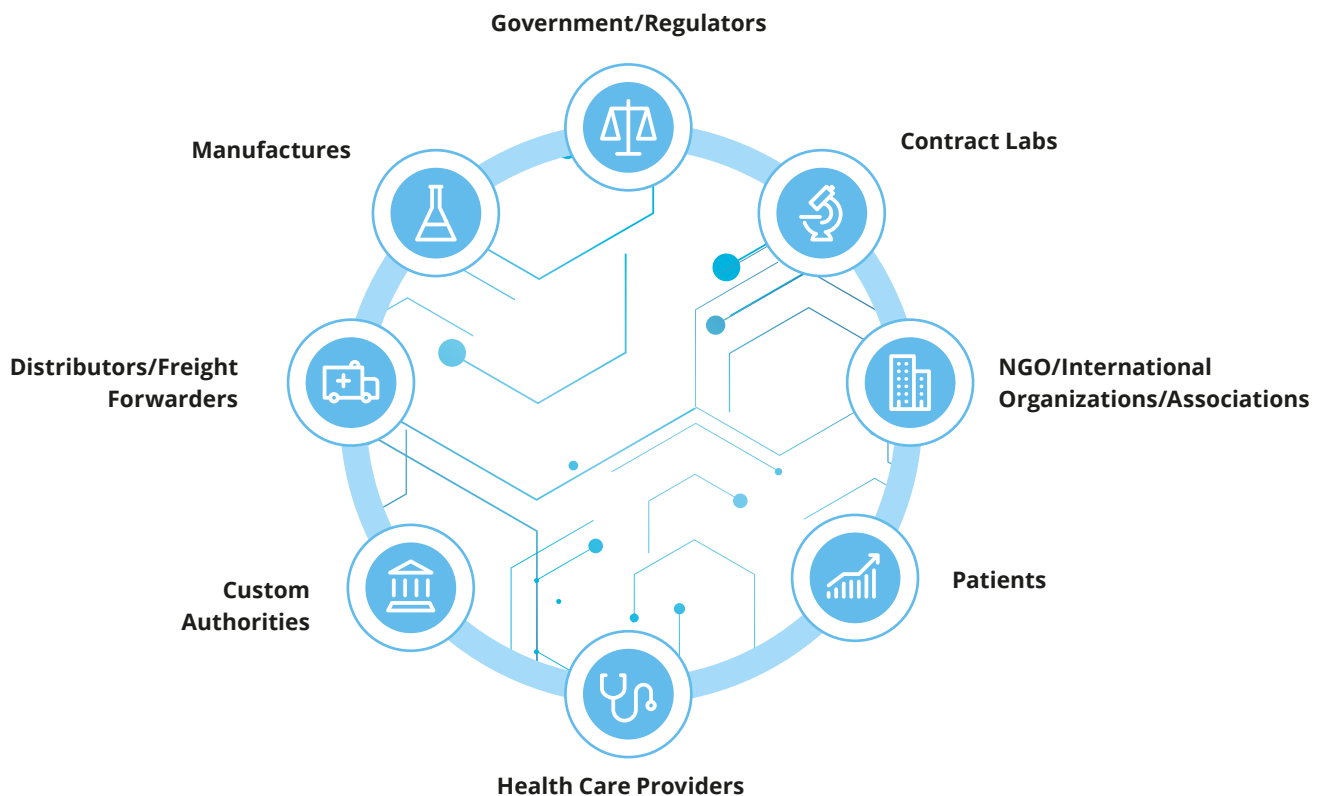
Blockchain has clearly identified use cases but it is an underlying technology. Wider considerations need to be assessed in order to ensure successful implementation. Indeed, what strengthens the power of the blockchain tool is the ecosystem – a network built on collaboration, transparency, and trust. There are multiple players across the ecosystem, some of them primarily observers, checking that

information is visible, others adding data throughout the product lifecycle.

The benefits will vary by stakeholder across the ecosystem. Therefore, when approaching different stakeholders, the value proposition needs to be clearly tailored and defined. To galvanize adoption it is critical when approaching government organizations and regulators that the use case application and the solution offered are explained effectively.

The Fourth Industrial Revolution has triggered a renaissance in what is possible for physical and digital technologies through tools such as analytics, artificial intelligence (AI), the internet of things (IoT), and blockchain. However, in many cases, governments have not yet had the opportunity to adopt laws and regulations that build quality assurance, transparency and trust into the new solutions.

Figure 1: Illustrative LSHC Blockchain Ecosystem



Proactive and meaningful collaboration

As mentioned above, the power of blockchain is amplified as ecosystem participants broaden their adoption of the technology. While a single pharmaceutical manufacturer can ensure memorialized data within a blockchain on its own, it is less likely to achieve critical acceptance from more skeptical external stakeholders, including government regulators.

DLT adoption should therefore be approached by ecosystem players from an industry perspective, to increase the speed of adoption and minimize duplicated efforts. Regulatory issues can more easily be addressed through a unified industry effort, rather than company-specific solutions. To achieve regulatory acceptance, simplicity is best. Offering

slightly differentiated solutions within the same industry may generate confusion.

Example of Industry Collaboration

PharmaLedger

In January 2020, the PharmaLedger project, a public-private partnership sponsored by the Innovative Medicines Initiative (IMI), was launched to connect the healthcare value chain using blockchain technology¹.

This three-year project aims to strengthen IMI's efforts to accelerate innovation in healthcare through the creation of a trusted blockchain-based framework across supply chain, clinical trials and health data management². It brings together 12 global pharma companies and 17 public and private entities to support the design and adoption of a blockchain-based platform in the life sciences and healthcare spaces.

The consortium aims to leverage blockchain to:

Enhance compliance with standards and regulations

Combat counterfeit medicines and medical supplies

Simplify compliance with Drug Supply Chain Security Act (DSCSA)



1. PharmaLedger, "Press Release", <https://pharmaledger.eu/press>, accessed July 20, 2021.
2. Innovative Medicines Initiative, "PharmaLedger", <https://www.imi.europa.eu/projects-results/project-factsheets/pharmaledger>, accessed July 20, 2021.
3. PharmaLedger, "Press Release", <https://pharmaledger.eu/press>, accessed July 20, 2021.
4. Innovative Medicines Initiative, "PharmaLedger". <https://www.imi.europa.eu/projects-results/project-factsheets/pharmaledger>, accessed July 20, 2021.
5. Technovative Solutions Limited, "PharmaLedger", <https://technovativesolutions.co.uk/pharmaledger/>, accessed July 20, 2021

Example

PharmaLedger Use Case - ePI – Electronic Product Information Use Case

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“Product information leaflets are found in every package and offer valuable information to both healthcare practitioners and patients, such as information on product ingredients, how to report adverse effects, how to take medicines safely, etc. These leaflets are closely regulated and require constant updates during the lifecycle of the product. There are many issues with the existing processes and usage of paper leaflets:

- Readability of print
- Updates are not instant as they are linked to production (which may limit availability)
- Cost to produce
- Environmental impact

PharmaLedger vision for ePI

Switch from paper to digital ePI leaflets.

Leverage blockchain technology to:

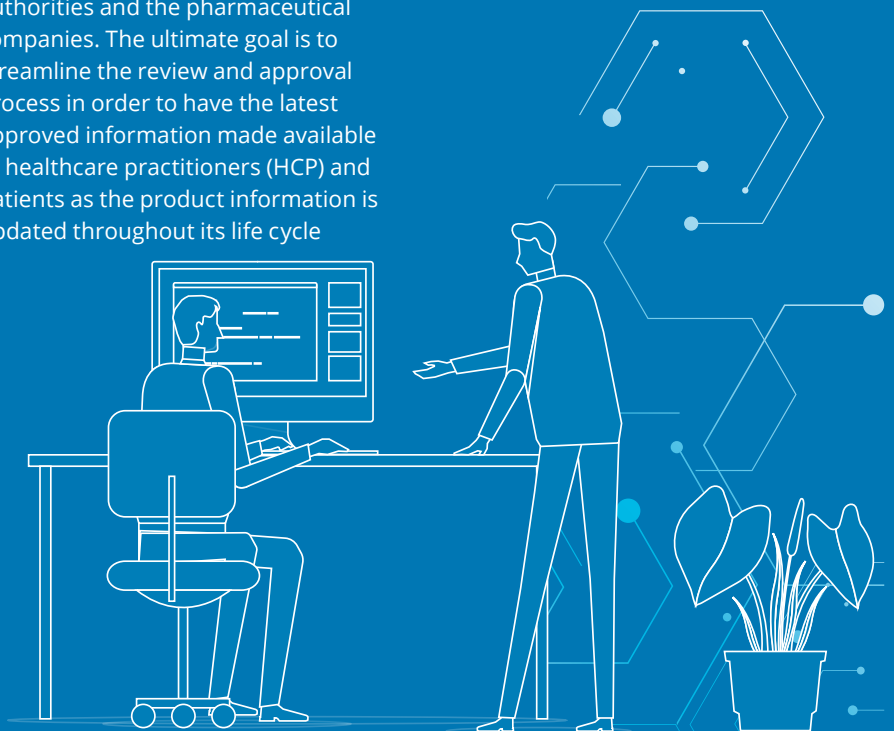
- Enable trusted transactions between multiple entities

- Enable trusted and secure content
- Allow interoperability with other digitally enabled services and systems

Additionally, the ePI use case aims to create a transactional infrastructure to connect all players involved. An example is the review and approval and dissemination component:

- The review and approval component enhances trust and brings efficiencies to the interactions between the health authorities and the pharmaceutical companies. The ultimate goal is to streamline the review and approval process in order to have the latest approved information made available to healthcare practitioners (HCP) and patients as the product information is updated throughout its life cycle

- The Dissemination component ensures that the patient or HCP only gets approved and trusted information in addition to built-in anti-counterfeit checks, potential recall messages, etc. There is no need to have an individual app for each manufacturer, nor an app for specific countries around the world. The ultimate goal is to allow the patient to have a solution that allows them to access all the required information for their medicines⁶⁷



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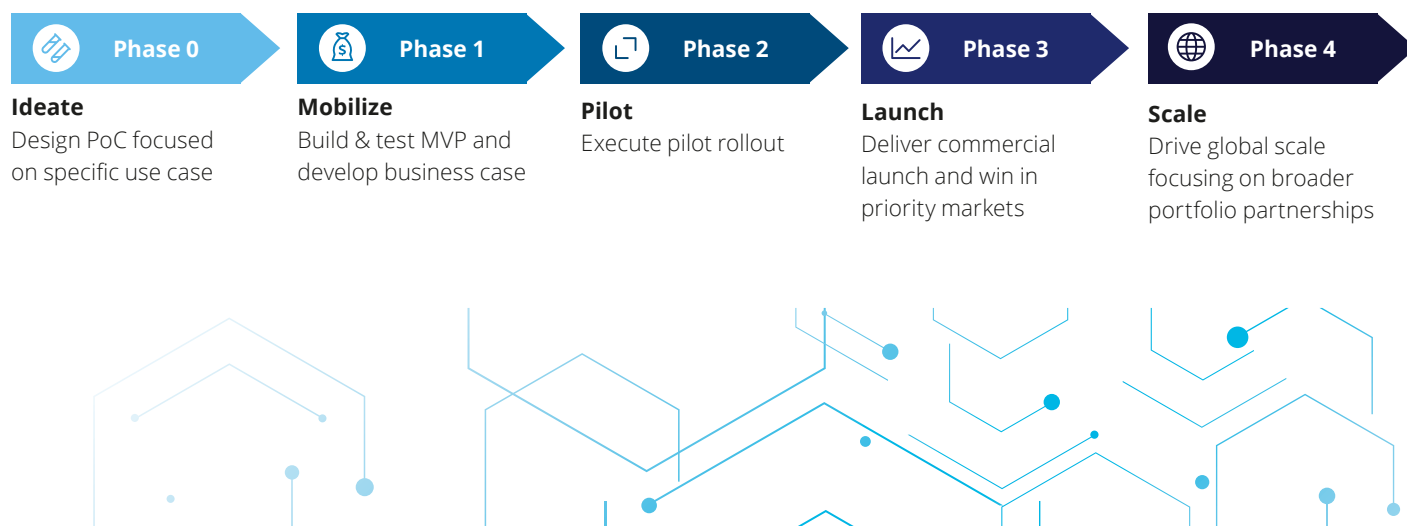
6. PharmaLedger's ePI – Electronic Product Information Use Case, “PharmaLedger”, <https://pharmaledger.eu/news/3-pharmaledgers-epi-electronic-product-information-use-case/>, accessed July 20, 2021.

Moving faster together, as an industry

Multiple platforms and consortiums already exist for discussion and ideation within the life sciences community, and these fora frequently include blockchain in their agendas.

"The governance structure of a consortium has four key elements:

- Decision-making authority
- Legal entity structures & risk
- Funding and revenue-sharing
- Identification and ownership of intellectual property.⁷"



Call to action – ecosystem participants:

- **Assess your use case** – confirm your value-added and joint-value to the ecosystem
 - **Review existing use cases in the ecosystem** – if use cases are complementary, reach out and partner together early
 - **Let down barriers** – be willing to share data, cooperate and partner within the ecosystem – see other ecosystem participants as collaborators, not competitors
 - **(Re-)educate yourself** on consortium missions, roadmaps, and existing participants
 - **Standardize solutions** – work together to standardize single use cases to enable efficient scaling globally
 - **Commit to the journey** – the solution will not be instantaneous; scaling takes time
- Current circumstances demand industry cohesion and collaboration like never before. Having faced the COVID-19 pandemic, the world's pharmaceutical manufacturers and stakeholders should seize the opportunity to build momentum for initiatives that can speed up access to COVID-19 vaccines. There are also additional follow-on benefits in a post-COVID environment. Embracing blockchain technology and its underlying benefits represents just such an opportunity, creating value for the industry ecosystem far beyond the immediate pandemic.

7. Blockchain consortium governance Considerations on consortia models, standards, and roles, "Deloitte", <https://www2.deloitte.com/us/en/pages/consulting/articles/blockchain-consortium-governance-considerations-models-standards.html>, accessed September 7, 2021

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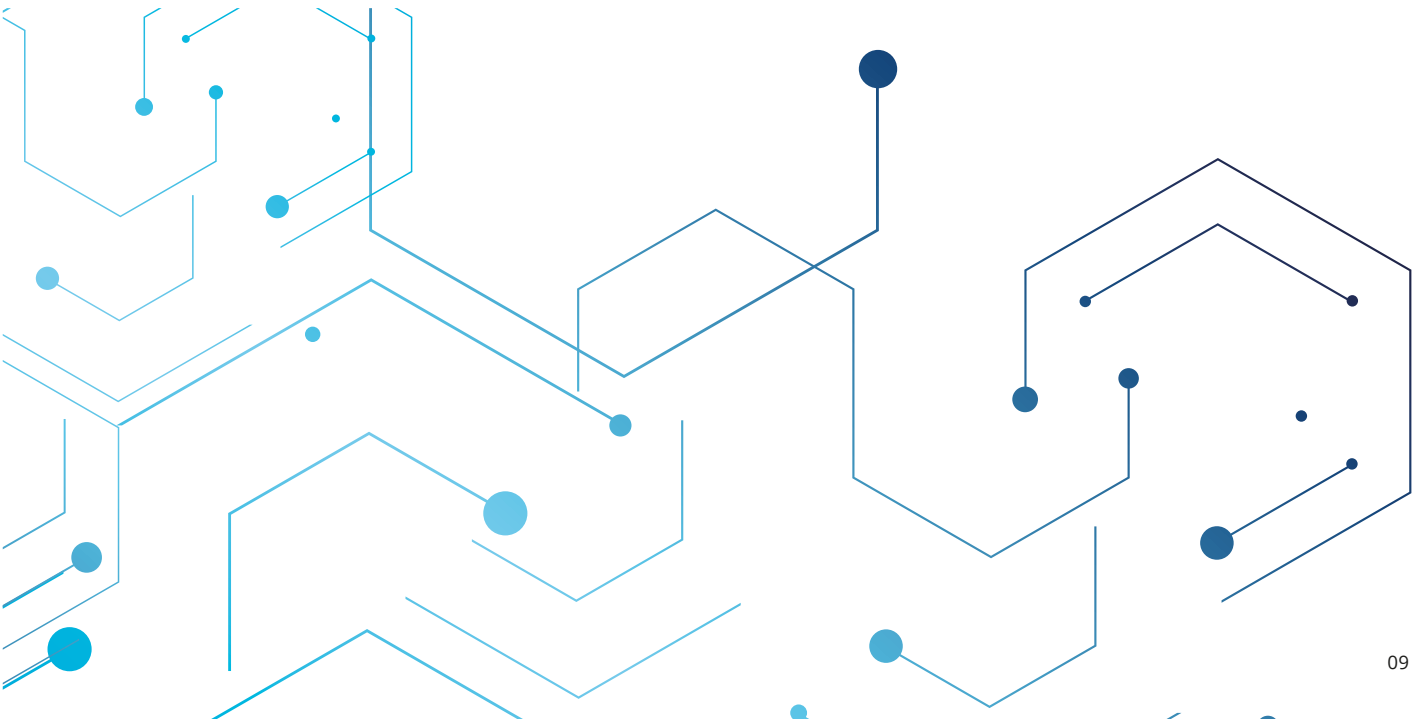
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