

# Redefining Regulatory Information Management With Blockchain

## The Opportunity

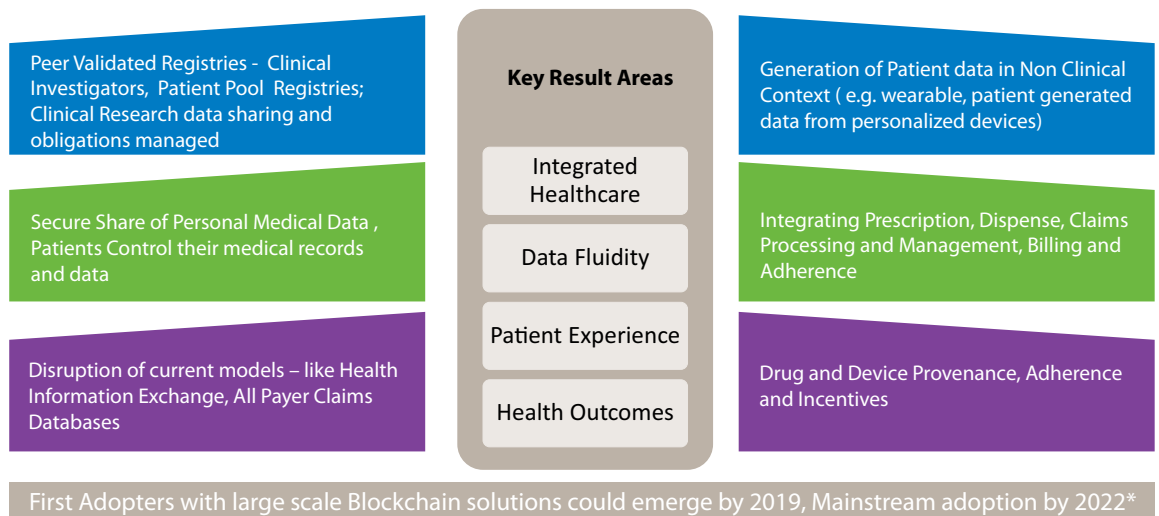
With more consumers demanding a greater say in how their health is managed, life sciences and healthcare companies are increasingly adopting a patient-centric business model. In response to this paradigm shift, enterprises will need to reimagine how they receive regulatory approval for new products while meeting local and global regulatory requirements and gain access to information that can be shared rapidly with the patients and care givers.

Regulatory affairs (RA) is one of the most critical areas within the life sciences domain and is the gateway for acquiring product approvals. Regulatory process are subject to changes and adoption due to the ever changing updates to regulation as well as the new and emerging regulations. This causes several challenges – traceability and global visibility of the process, are the submissions being done as per the current or the earlier regulations, are we current on the latest labelling requirements, and are the products being shipped to that country in conformance with the submission made there in? Equally important is that the entire organization and external consumers (such as clinical research organization (CRO), institutional review board (IRB), patients, and contract manufacturing organization (CMO) in the ecosystem have the most relevant and current data or information sets are the regulatory data like CMC coming from the several stakeholders consistent? This becomes a complicated affair when a globally distributed network of affiliates are responsible for managing a significant volume of critical product information

In this regard, Blockchain could play a vital role. This technology allows companies to gain total ownership of regulatory data while ensuring that it can be securely stored and privately shared with authorized stakeholders. As a decentralized shared ledger that requires cryptographic signatures to access or modify, Blockchain can create a transparent, traceable system of recording transactions across the regulatory data/content aggregation and approval lifecycle.

### The Value Chain Potential

For some time now, the financial services sector has been championing Blockchain adoption. Taking a leaf out of their playbook, many other sectors such as consumer-packaged goods (CPG) are waking up to its potential. The life sciences and healthcare ecosystem is jumping on to the bandwagon. There are several areas within the healthcare value chain that could see a wide application of Blockchain for collective benefit and mutual value outcomes.



\*Source: January 2017 Hyperledger Healthcare Working Group Survey, N=29

Figure 1 : Blockchain in Healthcare

There are four key characteristics of Blockchain that could find relevance in the life sciences domain.

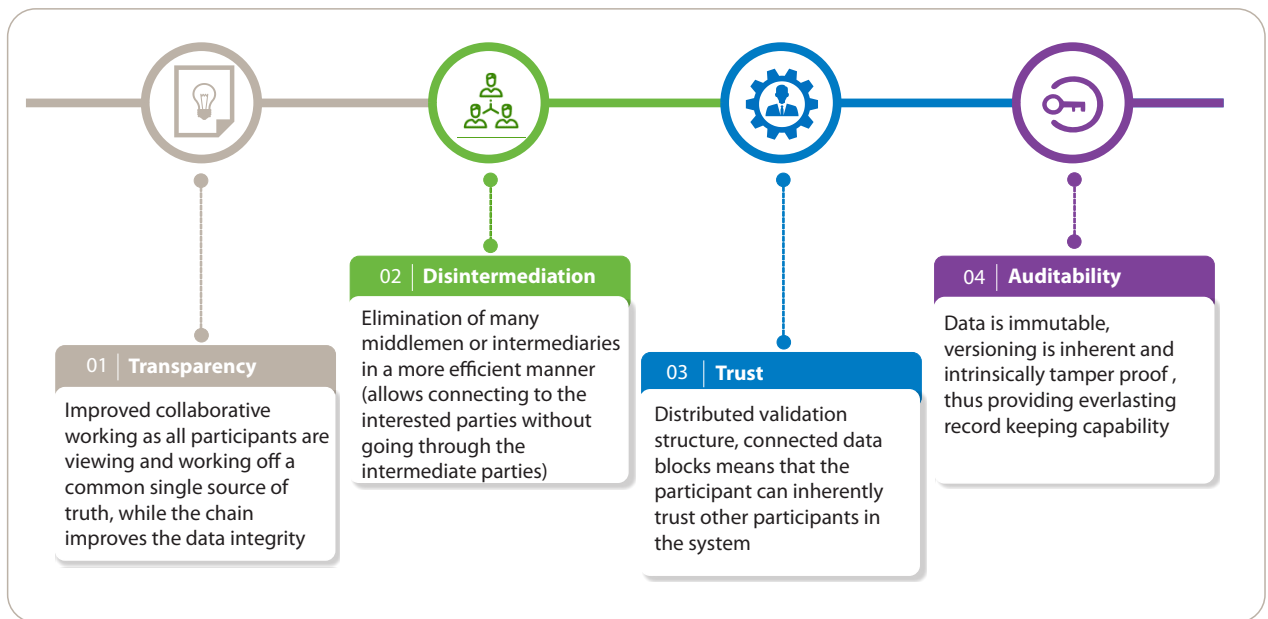


Figure 2: Blockchain Features Relevant to Life Sciences

## Blockchain Application In Pharma

Some areas where Blockchain can be deployed to streamline processes are as below.

### IDMP Management

With identification of medicinal products (IDMP) emerging as the new global standard for managing healthcare product data, the case for adopting blockchain grows stronger. Information required for meeting IDMP standards flows in from multiple processes including clinical trials, manufacturing, and labeling, among others. As such, process owners have to meaningfully integrate the myriad systems where this information is stored and converge it into a single source of truth for building the IDMP data model.

For example, a pharma company and the country’s regulatory body can operate their own distinct Blockchains in parallel with a public Blockchain accessible to the general population. Once the pharma company publishes a product’s data on their Blockchain, it is replicated at the nodes maintained by regulators. The data from the regulator’s node is combined with the pharma company’s data block to create a single source of truth. This can be used to submit clinical trial application forms, market authorization requests, patient label summary Information or even summary of product

characteristics (SmPC). Part of this information can then be released on the public Blockchain node and made accessible for cross-border product compatibility and identification, and other similar scenarios.

While each entity operates on their own Blockchain or a common one, the information available can be trusted and used for rapid dissemination. Based on its inherent quality, it can automate and simplify processes such as reconciling product recall data.

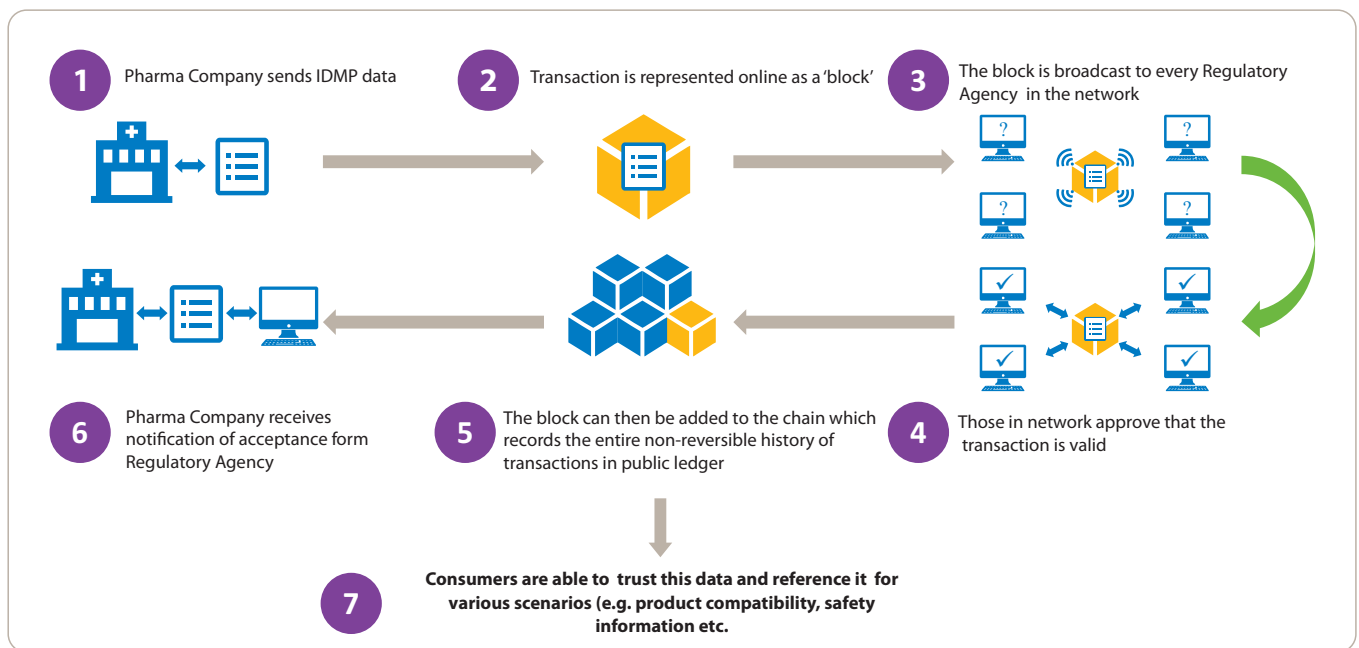


Figure 3: Simplified Illustrative Scenario for IDMP Data Management

### Marketing Authorization

Another potential Blockchain application in the regulatory space is the marketing authorization process. In the SEA / ASEAN regions, it is most likely that the pharmaceutical company is selling the same drug product with slight differences in labelling. However, change of the drug product would warrant re-submission of the marketing authorization request and fresh approvals. In many cases, the manufacturing location is different from the country of sale, and high number of licenses leads to an increase in the supply chain nodes.

Consider an example of a Foreign Medical Device Company seeking to sell in Country X. Country X mandates that the Foreign Company cannot sell directly to the Medical Institution or Care Providers. They can do so only through a marketing

authorization holder who holds the certification and is responsible for distribution of products. But in order to sell the product physically in the country there has to be other Licensed Entities – Import License Holders and the Retail License Holder. We consider all the parties to be different in this situation. Hence, each party's application is dependent upon a regulatory approval of the others to realize the business value. Blockchain-based process or application could bring in efficiencies, timely notification, and action thereof for the affiliates to manage the regulatory aspects effectively with the ability to cut down the total cycle time.

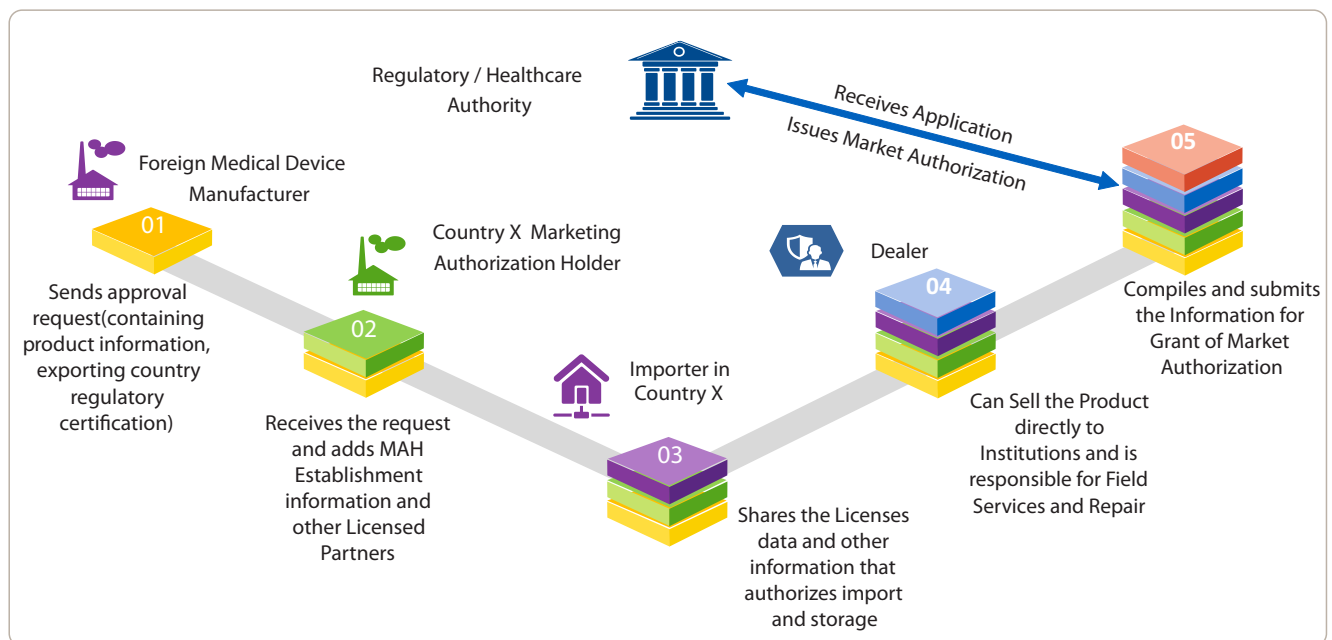


Figure 4: Market Authorization Application- Medical Devices

## Streamlining The Regulatory Process With Blockchain

To sum up, Blockchain deployment can streamline the regulatory affairs by:

- Ensuring an effective chain of custody for the information and data set while providing individualized updates but preserving the data integrity and relevance.
- Ensuring that the product-related data being shared across the ecosystem is consistent, most current over a distributed ledger model.

- c) Improving collaboration between the data generators, approvers, and consumers for a more real-time, auditable, and traceable content while providing the flexibility to operate independently.

With respect to managing regulatory activities, a Blockchain-based solution exhibits immense potential and can, in fact, double up as regulatory information management (RIM) platform for the enterprise. It will allow regional affiliates to easily update the localized and country-specific information in real time, making the validation and stakeholder communication process redundant. This will ensure integrity, validity, and complete accessibility to regulatory information for any medical product.

Therefore, Blockchain adoption can provide a faster time-to-approve since data sets are available with end-to-end traceability of data travelling across the entire regulatory value chain. The entire flow of information can be easily traced or relied upon for taking regulatory actions such as recalling products or issuing statutory warnings. Blockchain can act as the backbone for a global harmonized regulatory landscape at a much lower Total Cost of Compliance and improved stakeholder centricity.

## About The Author

Yezhuvath Vinesh Balakrishnan  
Yezhuvath Vinesh Balakrishnan is currently working with the life sciences business unit at TCS, leading some of the key initiatives in the areas of Blockchain and IDMP. He has over 26 years of experience in supply chain management, manufacturing, process excellence, and IT management across pharmaceutical and chemical industries. He combines process orientation and analytical abilities with an in-depth understanding of technology to conceptualize innovative solutions. As part of the Centre of Excellence, he is involved in strategy & consulting, optimization, practice management as well as product/service development. An alumni of Birla Institute of Technology and Science (BITS Pilani), Vinesh holds a graduate degree in Chemical Engineering and a postgraduate degree in Mathematics.

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