Blockchain for a Robust and Efficient Supply Chain

The life sciences supply chain has struggled with balancing risk, costs, and integrity in the collaborative aspect of its ecosystem. This imbalance can become more acute with the advent of personalized medicine as the supply chain is transitioning from one supply chain being executed hundred times to hundreds of supply chains executed simultaneously. The inherent transparency, reliability, auditability, and capacity for disintermediation, holds a lot of promise for the life sciences supply chain in the current context as well as in the future.

The supply chain has a three-flow dimension – physical flow, financial flow, and the information flow from the n-tier supplier to the pharmaceutical company to various distribution centers and partners, and then finally reaching the patient via the hospital or pharmacy.

Blockchain technology has the ability to address all three dimensions to address collaboration, cost optimization, and risk management. This technology allows companies to gain total access of the end-to-end supply chain data while ensuring that it can be securely stored and privately shared with authorized stakeholders. As a decentralized shared ledger that requires cryptographic signatures for access and modification, the blockchain can create a transparent, traceable system of recording transactions across the product life cycle.

While there are a number of applications of this technology across the supply chain, the industry appears to be focused on the following:

- **Supply Chain Security** – Driven by the need to control and eliminate counterfeit drugs in the marketplace, supply chain security has gained paramount importance. Coupled with serialization and Track-n-Trace features, there is a need to share and exchange information across a vast ecosystem. With regulatory agencies across the industry issuing new mandates to boost the integrity of pharmaceutical supply chains and eliminate fake drugs, blockchain technology could offer an industry-wide solution for supply chain security

- **Drug Tracking and Provenance** – New-age drug distribution has grown immensely in scale and complexity. Product traceability from the point of origin of raw materials/ingredients across the manufacturing sites, and then to larger healthcare ecosystems can piggy back on the blockchain to create an immutable global batch traceability, making it easier to respond to product recalls, holds, and new releases in the market

- **Cold Chain** – It is forecasted that 26 out of the top 50 pharmaceutical products will be in the cold chain. With new regulations, the entire pharmaceutical product portfolio has been deemed as temperature sensitive. Current supply chains lack instantaneous, continuous, and transparent access to end-to-end cold chain data. This results in regulatory non-compliance, inability to take timely corrective actions, increased liability, loss of product and potentially, life. Blockchain could be the solution to trust the efficacy of the drugs, at the point of dosing

- **Transforming Developing/Emerging Markets** - In developing nations, the market is fragmented and comprises several hundred companies. Such small companies are beset by cash flow problems as the more financially stronger customers are on end for more than 90-day payments for delivered medicines or devices. Big Pharma, on the other end, seeks shorter credit periods, hence the small players are risk averse. Tracking the drugs on a blockchain for transaction legitimacy and authenticity could make it easier for small and mid-sized players to access credit easily as well reduce the overall turnover time

- **Trade Finance on Blockchain** - There are several points in the trading process which causes the delays in shipments and payments. For trading across borders, around 40% of the shipments get delayed due to custom clearances. The use of blockchain and smart contracts will automate the execution of business logic and bring a tremendous amount of efficiency to trade finance.

In our point of view the application of blockchain technology in life sciences can be categorized into five buckets– chain of custody, data sharing, financial supply chain, collaboration and patient engagement. It is worthwhile looking at use cases using these as the lenses of focus. The top areas within supply chain can be as that given in Figure 1 below:

Figure 1: Top 7 Applications of Blockchain in Healthcare and Pharmaceutical Supply Chains

Life Sciences Use Cases

With the increasing importance of blockchain technology in clinical supply chains, it is imperative to be aware of its use cases within the life sciences domain:

1. Secure Product Transfer

Imagined as a system to track the movements of drugs and medical devices, using blockchain and smart contracts, coupled with the use of smart IoT edge devices, cloud ecosystems, from the point of manufacture to the point of dispense or dosage, establishes a clear chain of custody and related obligations. Blockchain will be implemented as a shared ledger for all the ecosystem participants to track and trace at unit-level drug or device in order to overcome the multiple nodes of risk, disruption and dispute. Issues of provenance, point of obligations transfer, end-to-end view will be eliminated. Cross-border transparency may persist in different forms along with shipment document permutations and combinations.

Some of the solution features are as follows:

- Triple accounting model– leveraged to reduce financial reconciliations– contracts, call offs, and settlements
- IoT integration for seamless events tracking– effective temperature data management or route management
- Secure Box Concept– applicable for VMI, Smart Cabinets, or authorized access (e.g. Field Rep can only open) using a key issued by blockchain). Hash key is used to lock and unlock boxes or cabinets (provide for secured access)

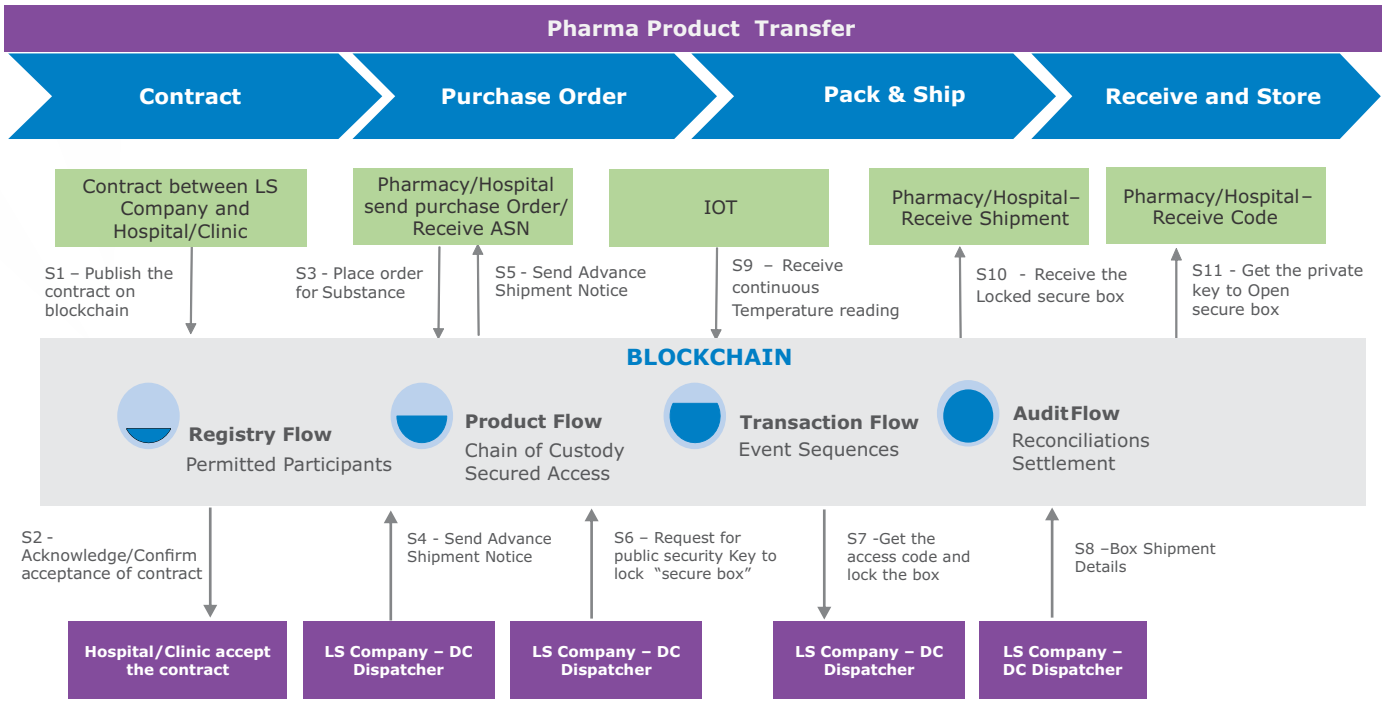

Figure2: Secure Product Transfer

- Automated Smart Contract to trigger action – such as a device with a specific serial number status update as restricted for sale due to insufficient prior documentation (e.g. Sterilization Certificate not issued)

2. Surgical Implant Field Tracking

Surgical implant field tracking is imagined as a system to track the movement of devices from the point of scheduled surgery to the return of material and billing as well as long term anonymized tracking of the patient. It will improve the visibility, verification, and validation of the implant, backed by related accessories and instruments leveraging distributed ledgers, decentralization, authentication, and proof of ownership. A chronological ledger will assist in reaching a consensus on supplied products that each recipient agrees on, and acceptance of the implant with the ownership is established and recorded authoritatively through the blockchain. Automated reconciliation triggered through smart contracts will reduce reconciliation and audit schedules.

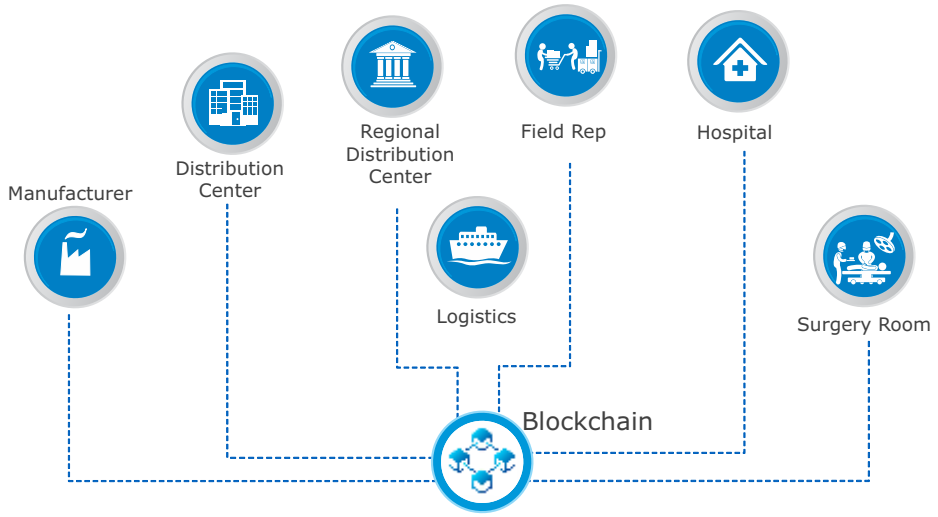

Figure 3 : Surgical Implant Tracking

3. Contract and Revenue Management

Contract and revenue management is imagined as an industry lever distributed ledger system. With a plethora of players in this ecosystem, a considerable amount of time is spent in collecting, collating, verifying, and submitting various information and claims to different parties– examples like chargeback, promotional Medicaid among other come to mind. Distributed ledgers along with smart contracts and the underlying ability for all the players to trust the data within provides an ample scope to completely reimagine and provide significant savings in the healthcare ecosystem.

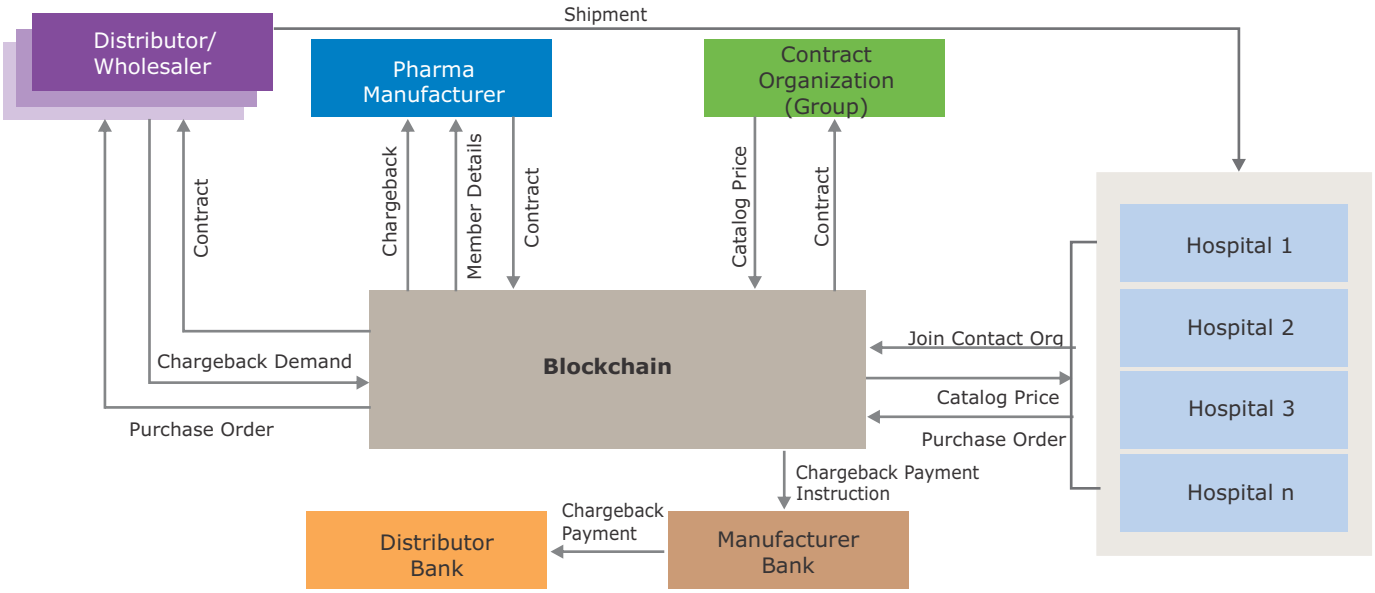

Figure 4 : Contract and Revenue Management

4. Clinical Trial Supplies – The clinical supply chain an ideal candidate for blockchain-based Business 4.0 disruption. TCS views the clinical supply chain on blockchain as ubiquitous "disruptive and transformative" applications. Data provenance that is required for business or regulatory reasons can be recorded in a secure, immutable, and auditable manner.

There are benefits of tracking medicine, providing drug provenance information, and securely collecting patient-level data under the HIPAA or other compliance laws. However, this isn't the only way by which blockchain technology can make a difference in the clinical supply chain. Secure boxes with digital locks can be used for safer shipping. Such boxes can only be opened by digital keys issued by the blockchain which ensures authorized access by say, doctors and nurses.

An industry-wide deployment of the technology can usher in regulatory changes in the blockchain. Once these changes gain the industry consensus, they can be implemented through smart contracts or automated drug reconciliation through triple accounting-based shared 'records of trust.' This can enable adherence and integration with the IoT, and will consequently drive accountability as well as faster reconciliation.

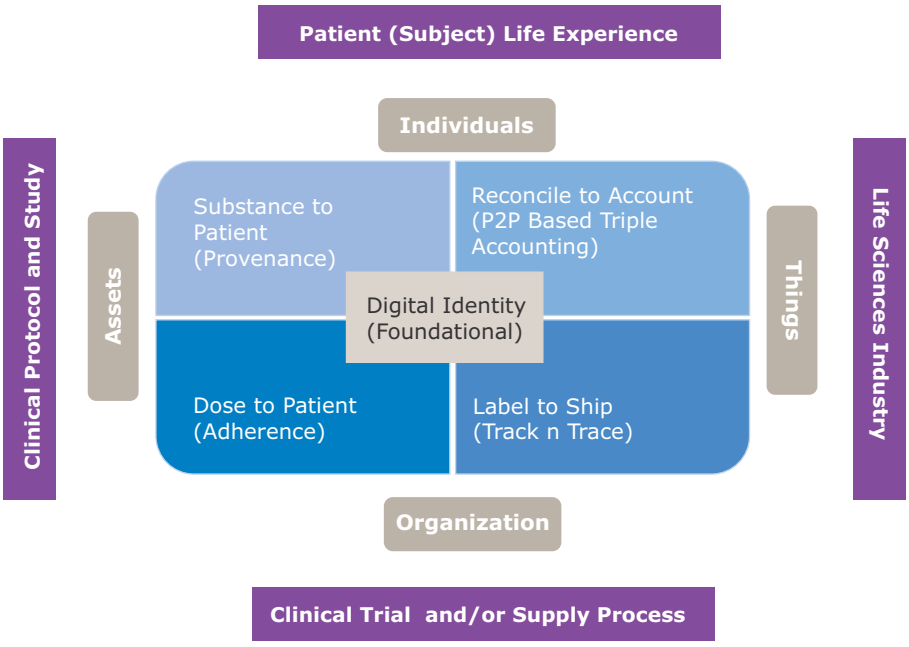

Figure 5: Clinical Trial Supply Chain 4.0 - Secure, Agile, Automated and on the Cloud

Unlike other technologies, blockchain has the potential to address the operational and business challenges at the efficiency level, transform business processes, and create a

disruptive business model. Pharmaceutical enterprises today are still at a nascent stage as far as embracing the technology is concerned. While they seek to have a clearer understanding of the blockchain capabilities that are relevant to the level of transformation desired and have a solid understanding of the blockchain ecosystem, the potential impact of the technology on the target operating or business models is tremendous. It is possible to bring in steep changes, transforming the business and operating models, instill unwavering trust in lifesaving pharmaceutical products and give patients greater command to administer the clinical trial data through blockchain technology. As digitization of the supply chain increases and end-to-end processes begin to encompass external partners, blockchain technology can become the backbone of the multi-enterprise supply chain network while offering a great degree of enterprise independence simultaneously.

About The Author

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Yezhuvath Vinesh Balakrishnan works with the Tata Consultancy Services (TCS) Life Sciences unit, focusing on supply chain management. He has over 22 years of experience in supply chain management, manufacturing, process excellence, and IT management across the pharmaceutical and chemical industries. He combines process orientation and analytical abilities with an in-depth understanding of technology to develop IT solutions that drive productivity, efficiency, and governance in the life sciences supply chain and manufacturing domains. Vinesh is actively involved in numerous supply chain and outsourcing transformation initiatives, and has helped conceptualize and develop innovative solutions, and enabled process optimization. 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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