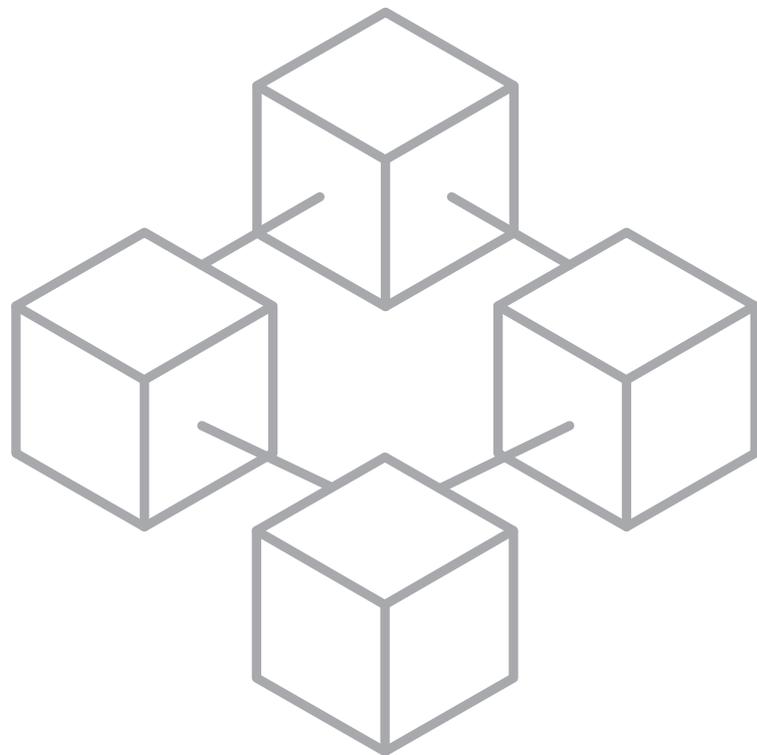


Blockchain for Life Sciences

Primer and Use Cases

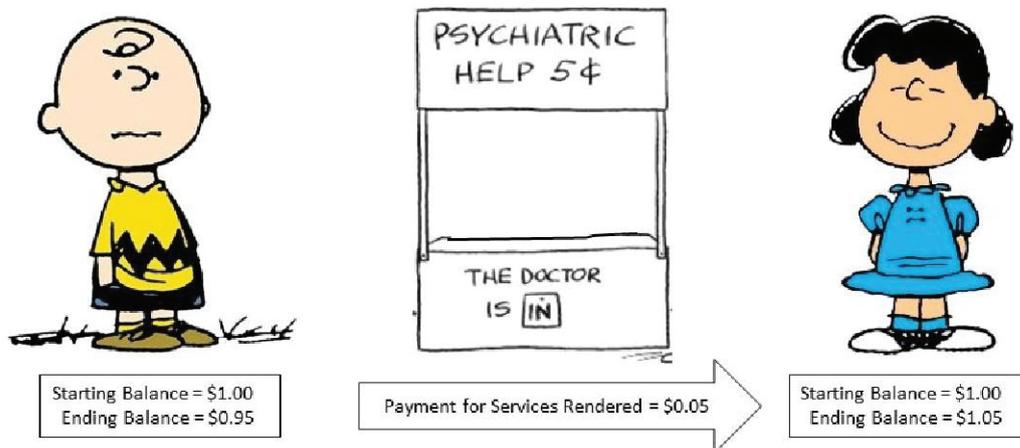


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Introduction and Blockchain Basic Concepts

By now, most people have heard of Bitcoin and Blockchain, but there remains confusion about what these things actually are. Bitcoin is a digital cryptocurrency that enables any parties that wish to engage in financial commerce to do so directly and without a trusted central authority, such as a bank, to serve as an intermediary. Blockchain is the distributed ledger technology underpinning and keeping track of bitcoin transactions. The key, innovative concept behind blockchain is that it enables parties who do not have inherent or proven trust, or even know each other's identity, to do business directly, without an intermediary to enable the necessary trust mechanism.

In traditional financial transactions, banks, credit card companies, PayPal, stock exchanges and governments serve as “trusted intermediaries” to make sure that funds cannot be double spent and once committed, records of transactions cannot be changed or deleted. For example, if Charlie pays Lucy \$0.05 for a service, it’s imperative that Charlie no longer has that \$0.05 and Lucy will have an additional \$0.05 after the transaction has been completed.

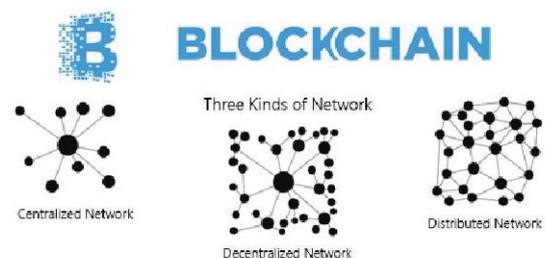


Blockchain technology serves to ensure that the record of this transfer of funds between Charlie and Lucy, regardless of whether they know or trust each other, is logged and cannot be changed or deleted, thereby disintermediating the need for a third-party to execute and journal the transaction record. It is able to do this by utilizing cryptography, mathematical calculation and networked computing power in an innovative way and with the following characteristics:

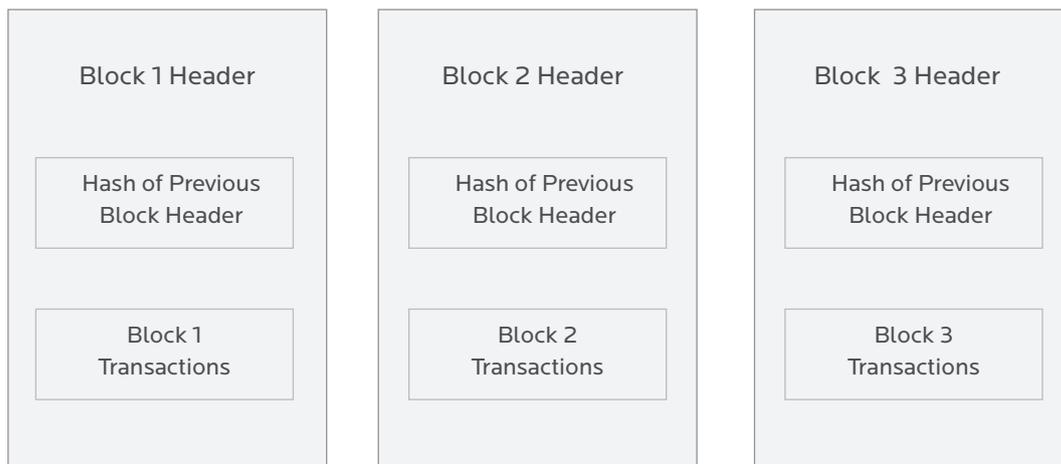
...it is a **Distributed Ledger**, so it has no single point of failure

...it is a **shared — and continually reconciled — record of transactions**. It’s not a true “database”, but it’s sometimes referred to as such

...it is **hosted by scores of distributed computers simultaneously**, so its data is accessible to anyone on the internet, or in a private blockchain, to all of the member computers (called “nodes”) on that blockchain



...it is **immutable and incorruptible** due to the innovation that each transaction “block”, which contains the details of one or more transactions, contains a cryptographic “hash” value of the preceding block. So, all blocks on the blockchain are interrelated and if a block is deleted, or changed, it renders all subsequent blocks invalid. Since this value is arrived at via a computationally intensive mathematical calculation and the chain is replicated to millions of computers several times per hour, it is virtually impossible to make a nefarious change to a block and recalculate the values of all subsequent blocks without detection. This enables trust to be established by consensus, rather than by intermediaries.



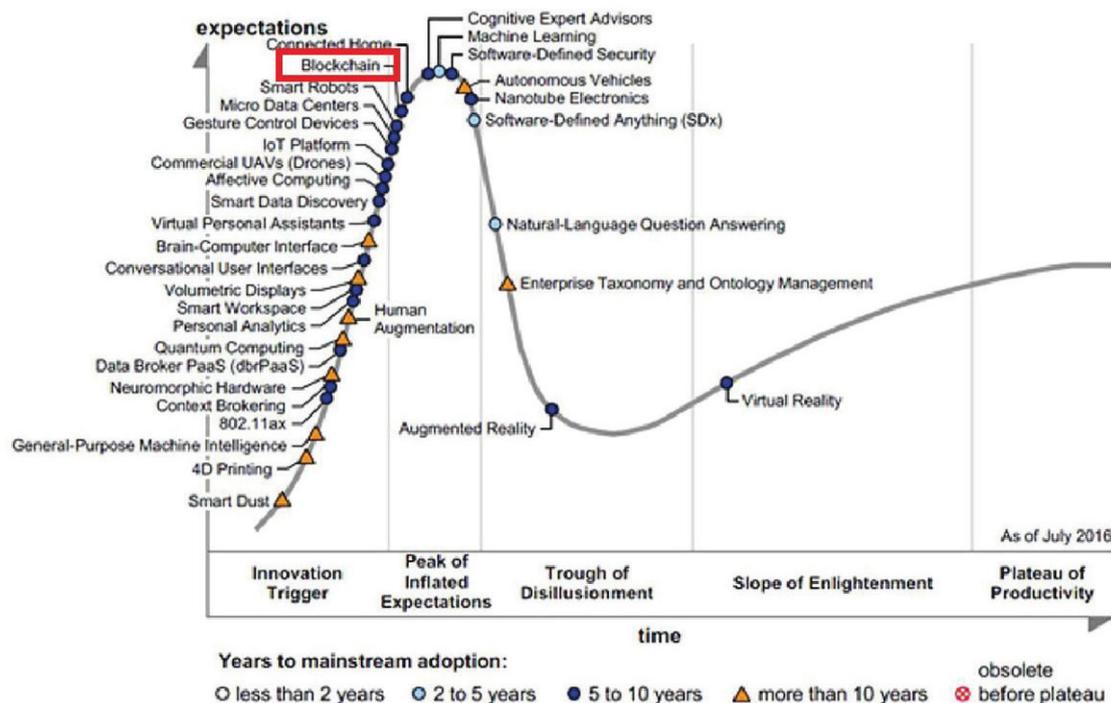
...it includes **Smart Contracts**, which are code that automate rules and agreements to automatically execute when specific conditions are met. Since its inception around 2009, bitcoin and other digital peer-to-peer currency transaction journaling has been the primary use for blockchain technology, but that is changing rapidly, as many new and existing companies are creating new business models to address the potential uses of this technology to remove friction, cost and latency from business transactions.

Starting in 2016-2017, we've seen blockchain start to emerge from the realm of technical novelty into mainstream corporate strategic planning. It holds the promise of reducing latency from all kinds of financial transactions, reducing or eliminating fees from intermediaries and opening up commerce opportunities to individuals and companies that previously lacked the resources to pay an intermediary to manage the transactional records. Opportunities for new business models likely will be created and all industries that rely on intermediaries will be disrupted.

It is not, however, a likely replacement for all corporate information technology systems, such as ERP. Blockchain technology has specific strengths and weaknesses that make it good for applications that require management of ledgers of transactions between multiple parties that may not have established trust and need to have an agreed-upon record of immutable data that they can trust. For business processes within an enterprise, there is generally established trust through corporate policies, secure access control and a general level of familiarity and shared responsibility for the data. In this case, traditional business applications and databases are generally the best tools. Blockchain weaknesses do need to be understood. For example, there is time required to create new blocks on the chain, due to the computational complexity of the hashing problems involved. It takes about 10 minutes for each new bitcoin block to be added, for instance. The required computing power also makes it an expensive and energy intensive technology.

Blockchain in the Pharmaceutical Industry

As a global information technology solutions and services partner of leading medical device and pharmaceutical multinationals, Birlasoft is committed to being a leader in bringing appropriate technologies to bear to best address the needs of our customers. As such, we have been tracking the evolution of blockchain technology from its beginnings as a niche novelty through to its emergence today as a technically and commercially viable basis for innovative business solutions.



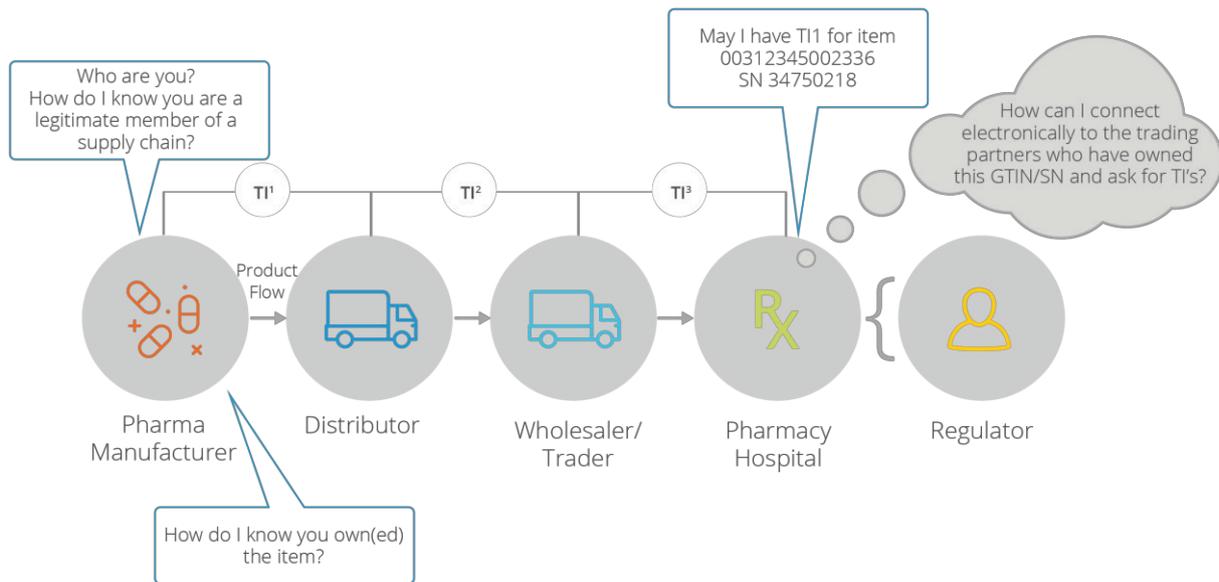
Source: Gartner (July 2016)

Some of the use cases in these industries, and others, where blockchain may enable business process improvements include:

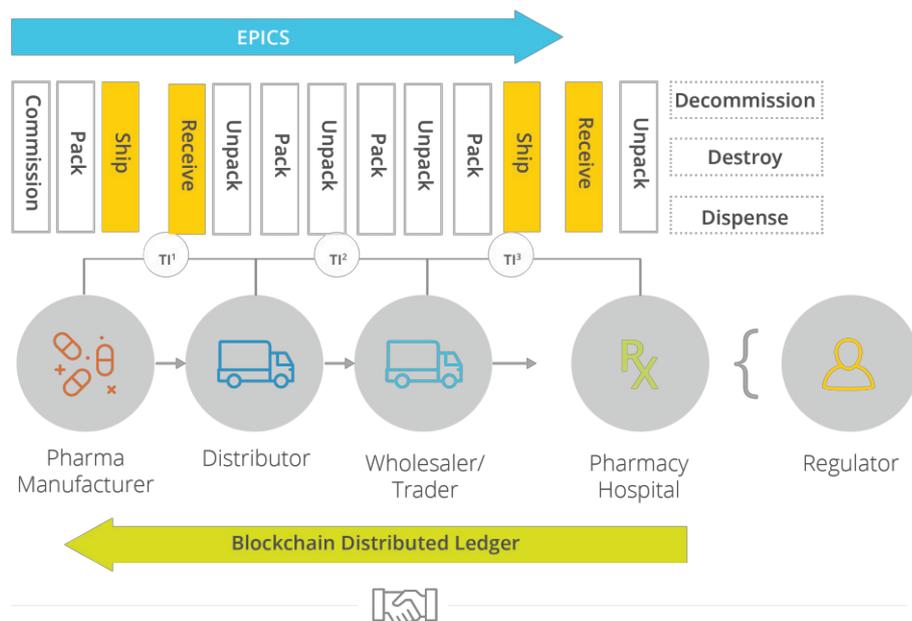
- Electronic Health Records
- IDN: Integrated Delivery Network for medical devices
- Clinical Trial Management: Providing trust in trial results reporting
- The Sharing Economy: Using the blockchain to create a peer-to-peer eBay
- Corporate Governance: Enabling organizational decision-making to happen on the blockchain
- File Storage: Inter Planetary File System (IPFS) distributes data throughout the network to protect files from getting hacked or lost
- Internet of Things (IoT): Utilizing smart contracts make the automation of remote system management possible
- Identity Management:: e.g. Netki, Peer Ledger, Sovrin, UPort, Shocard
- Supply Chain Auditing:
 - Revenue / Chargeback Management in Pharma and Med Dev industries
 - Pharmaceutical product tracking and tracing in compliance with the US Drug Supply Chain Security Act (DSCSA) and other global regulatory mandates.

Specifically to the last item, Birlasoft has invested in funding the non-profit Center for Supply Chain Studies DSCSA Feasibility Study that has run throughout most of 2017 and into early 2018. Collaborating with the top global pharmaceutical manufacturers and wholesalers on study team, Birlasoft is helping to evaluate the applicability of blockchain technology to address the DSCSA's mandate for industry to implement an "electronic, interoperable system to trace products at the package-level by 2023".

Although most pharmaceutical companies have taken at least some steps toward addressing the product mass-serialization requirements in the DSCSA and other global regulatory mandates by implementing established IT systems from TraceLink, rfxCel, SAP, Oracle and other software providers. However, the question of how to best communicate the track and trace data electronically and interoperably across the distribution chain, in a secure and immutable manner with business partners and with regulatory agencies that do not have the necessary level of trust remains a challenge.



Various approaches have been explored for how to exchange, retrieve and assemble the data recording a drug product's provenance through the legitimate supply chain from manufacturer, through the distribution chain to the point of dispensation.



Combined with the GS1 EPCIS (Electronic Product Code Information System) standard as a common "language" for describing supply chain events for serialized items, the blockchain-based distributed ledger holds promise as an enabling technology upon which to build these capabilities

Conclusion

Blockchain holds promise as a foundational enabler for business process innovation and the creation of new business models. However, many details need to be sorted out including which data should be on the “chain” vs held in private company databases and how the model would be funded before we can determine if blockchain is a viable technology approach to address pharmaceutical track and trace needs.

As an information technology partner to leading pharmaceutical and medical device companies, Birlasoft is committed to providing our customers with the best solutions to enable their digital transformation journeys. As such, Birlasoft’s investment in blockchain has progressed through to developing of requisite skills needed to create, implement and integrate blockchain solutions and development of proof of concept working models for various industry needs.



RESOURCES

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