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DIGITAL SYSTEMS & TECHNOLOGY

Blockchain: A Catalyst for the Next Wave of Progress in Life Sciences

By applying shared ledgers, smart contracts and powerful encryption technology, pharmaceuticals companies and medical device makers can eliminate costly intermediaries and more effectively ensure security, immutability, transparency, auditability and trust across the value chain.

June 2017

EXECUTIVE SUMMARY

Progress is the hallmark of advanced civilization. And particularly since the emergence of the Web and mobile devices, technology has functioned as the chief enabler of societal progression.

All industries have been impacted, and in life sciences, the progression has been swift and profound. Take the Internet of Things (IoT), which emerged earlier this decade as a way for consumers to monitor and manage their health and well-being. Today, IoT technologies also enable life sciences organizations to proactively manage their manufacturing processes using smart, connected equipment, reducing maintenance costs and enhancing safety, at scale.

As digital technologies dramatically transform consumer experiences and business capabilities, organizations across industries need to consider whether their structures and operating models impede or enable the pace of change.[1] For many businesses, notions of trade and commerce are still trapped in Victorian grandeur despite increased reliance on IT. Whether it's trade settlements, transfer of property ownership or resolving an insurance claim, complex business processes can take days to complete and require volumes of repetitive, tedious paper-based work.

What all these processes have in common is the need for intermediaries, such as stock exchanges, banks, government agencies or technology platforms, to serve as the trusted middle man between unknown parties and perform record-keeping, chronicling and rule enforcement. The unintended consequence: precious time and money lost creating, maintaining and dealing with intermediaries.

What if technology could provide a mechanism for establishing the mechanisms of trust, immutability, transparency, auditability and security that have traditionally been performed by an intermediary?

This white paper explores how blockchain – the decentralized, distributed ledger infrastructure built around strong cryptography – could power full digital transformation across the life sciences space.[2] It examines key blockchain principles that we believe could be imaginatively applied to areas such as provenance, disintermediation, patient safety, secure data exchange and enhanced productivity to accelerate digital business across the pharmaceuticals and medical devices segments. We also provide guidance on how to identify the best use cases and prepare for blockchain adoption.

DEFINING BLOCKCHAIN

Blockchain is a shared, distributed ledger technology that first emerged as the foundation to the Bitcoin cybercurrency. It offers non-repudiation of transactions that can work with the absence of a trusted intermediary across a peer-to-peer, distributed network. Participants validate transactions and authenticate the ledger without the need for a trusted authority, using public key encryption and consensus protocols. (For more information on how blockchain works, please see our e-book "Demystifying Blockchain.")

In a contemporary business environment, buyers and sellers are brought together via an intermediary such as a stock exchange, settlement agency, electronic trading platform, etc. With blockchain, the intermediary's role shifts to a distributed network on which transactions are resolved and recorded in a shared ledger that functions as the single version of the truth.

The shared ledger stores transactions completed across the network (see Figure 1). Once the entries are recorded in the shared ledger, they cannot be changed. Generally, when a party initiates an addition to the blockchain, "miners" in the network evaluate, verify and agree to the proposed transaction,[3] resulting in its inclusion in the "chain," along with other validated transactions, in the form of a "block." Each block is sequenced with a cryptographic reference to the preceding block, providing the basis for immutability.

Blockchain operates by consensus; unlike relational databases, which are usually owned by the organization providing services, there is no single owner of a transaction. Blockchain networks can be either public (non-permissioned) or private (permissioned). A public blockchain is open to all participants, while private blockchain networks only allow authenticated parties

Anatomy of a Blockchain Transaction

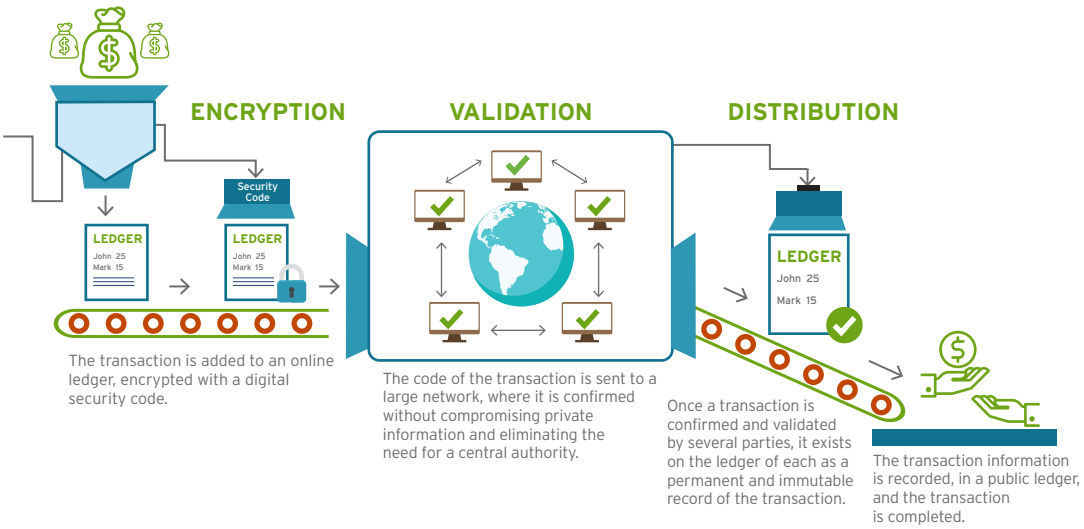

Figure 1

to join and contribute to the chain. Private blockchains are helpful when data sharing is intended only with selected parties.

Blockchain's key elements/principles can be distilled to the following:

- Distributed ledger and single version of the truth with multiple participants.
- Digital signatures for trust and security, provided via public key infrastructure (PKI) encryption.
- Peer network and absence of central authority.

The paradigm shift that blockchain introduces has attracted the interest of governments, academics, start-ups, established businesses and venture capitalists. Gartner has identified blockchain as one of the top 10 strategic technology trends for 2017.[5] The vibrancy of conferences and academic activity add further credence to the transformational impact.

As blockchain gains traction, more evolved offerings have steadily emerged, including Nasdaq's blockchain-based Linq,[6] YES Bank's blockchain-based vendor financing system[7] and BNP Paribas's cross-border B2B payments[8] powered by blockchain technology. All serve to illustrate the enormous potential of digitization and disintermediation, the effects of which are now being felt beyond the boundaries of financial services[9] and into retail, healthcare, manufacturing, utilities and insurance. Interesting experiments include authentication of high-value items such as diamonds, art and wine; storing patients' electronic health records; operating smart energy grids; managing product supply chains, etc.[10]

BLOCKCHAIN IN PHARMACEUTICALS & MEDICAL DEVICES

The world of pharmaceuticals and medical devices is also warming up to the innovative possibilities that blockchain offers. By using blockchain to maintain clinical trial protocols, revisions and patient consent, for example, pharmaceuticals companies can better demonstrate patient safety and transparency. Data from multiple sources, such as genomics, wearables and electronic medical records, can be shared with multiple parties using blockchain's decentralized and secure framework.

Data Governance/Records Management

Given blockchain's built-in cryptography, possibilities abound in the area of records management and data governance. The highly regulated nature of the pharmaceuticals and medical devices businesses and greater reliance on ecosystem partnerships has created a significant burden of documentation and records management.

For example, the contracts between payers and pharmaceuticals organizations could be maintained using blockchain to provide legal authenticity. This is particularly important for value-based healthcare, in which payments are tied to outcomes, as seen in Amgen's agreement with Harvard Pilgrim to connect payments with cholesterol thresholds.[11] All the underlying business rules and processing logic could be automated using blockchain and smart contracts.

Provenance

Provenance refers to the ability to trace origin and ensure the authenticity of the object being traded. Counterfeit drugs continue to pose

Every block added to the blockchain network can be computationally linked to the preceding block, thereby providing immutability.

great challenges to the pharmaceuticals distribution chain. Despite improvements, such as product serialization and e-pedigree – an electronic document that provides data about the history of a particular batch of a drug – the problem of spurious drugs continues to haunt pharmaceuticals.

Using blockchain's inherent capabilities, the provenance of drugs can be tracked back to ensure authenticity. Every block added to the blockchain network can be computationally linked to the preceding block, thereby providing immutability.

Handling Patient Sensitive Data

As more medical device activity is enabled by the IoT, the amount of data generated on a consumer's health and lifestyle has dramatically increased. Malicious access to sensitive personal data can cause devastating harm to consumer relationships and grave reputational and financial repercussions to medical device makers. Blockchains can embed rules to control access to sensitive medical data. Patients can specify, for example, that only their family and treating physicians can access their health records.

Disintermediation

An inherent strength of blockchain is that it allows information to be made available to all parties securely, thus obviating the need for an intermediary. Savings in time, cost and agility could make blockchain an ideal candidate for enabling fluid collaboration. In clinical trials, a blockchain network with participants from pharmaceuticals, investigators, trial sites and regulators could be created in which data could be shared securely without any chance of alteration. This would improve patient safety and reduce the need to manage response to regulatory warnings.

Internal Process Management

Enterprises create internal systems and device processes to reconcile transactions between internal systems. For example, pharmaceuticals companies typically use many systems to manage factory operations, such as handling inbound raw materials and processing across product lifecycle stages – finished goods, scrap management, packaging and labeling. Numerous internal systems are created to reconcile and convey a holistic view across such activities. With a blockchain, the need for such artificial reconciliation can be reduced, as transactions across systems can be maintained in a single shared ledger.

Blockchain Challenges

While blockchain's potential to establish transparency, improve trust and reduce reliance on intermediaries is enormous, its limitations are readily apparent. For instance, blockchain technology is relatively new, and its business advantages are unproven. Moreover, implementation tools need to mature with the technology. Simple applications within an organization's transactional boundary that do not require auditing, for example, are better off using plain relational database management systems rather than incurring the computational overhead (and inherent performance hit) of a blockchain-based solution.

A major non-technical challenge is the disruption of cultural notions or mindsets associated with adoption of decentralized ways of working. Enterprises would do well to understand the implementation and adoption challenges prior to investing. To be feasible, a blockchain roadmap should be built on a use case selection framework, as described on page 11.

DOCUMENTING PROOFS OF CONCEPT

We have explored several blockchain proofs of concept (PoC) in the life sciences industry, including the following.

Temperature Excursion

Many pharmaceuticals products – particularly those that are biological in nature – are highly temperature sensitive. For example, a vaccine may be allowed to be no higher than 25°C for only 15 minutes. Since the delivery of a pharmaceuticals product involves multiple partners (i.e., shippers, warehouses and trial sites), it is essential for companies to consistently and securely track temperature excursions across hand-offs.

In this PoC, IoT-enabled temperature loggers are inserted into the batch packages, and a blockchain network is created for all participants (shipper, warehouse provider, etc.). The temperature loggers can transmit temperature excursion data, which is stored on the blockchain, accessible by all network participants. A smart contract is created to implement a rule for stability checks based on temperature excursion data. We used Solidity[12] for smart contract creation, and the PoC was implemented with the Ethereum[13] infrastructure and hosted in an Amazon cloud.

The main advantages of using a blockchain in this scenario include:

- **Smart contracts codify stability checking, making it highly reliable**. The patient is assured of a high level of safety against drug instability or decomposition. Smart contracts compare temperature logger data with stability data previously defined in a batch master. If the temperature logger data values transgress permissible limits, the batch is then marked as expired or invalid.
- **All participants (shippers, warehouse providers, site administrators) have visibility**

Blockchain & IoT: Temperature Excursion

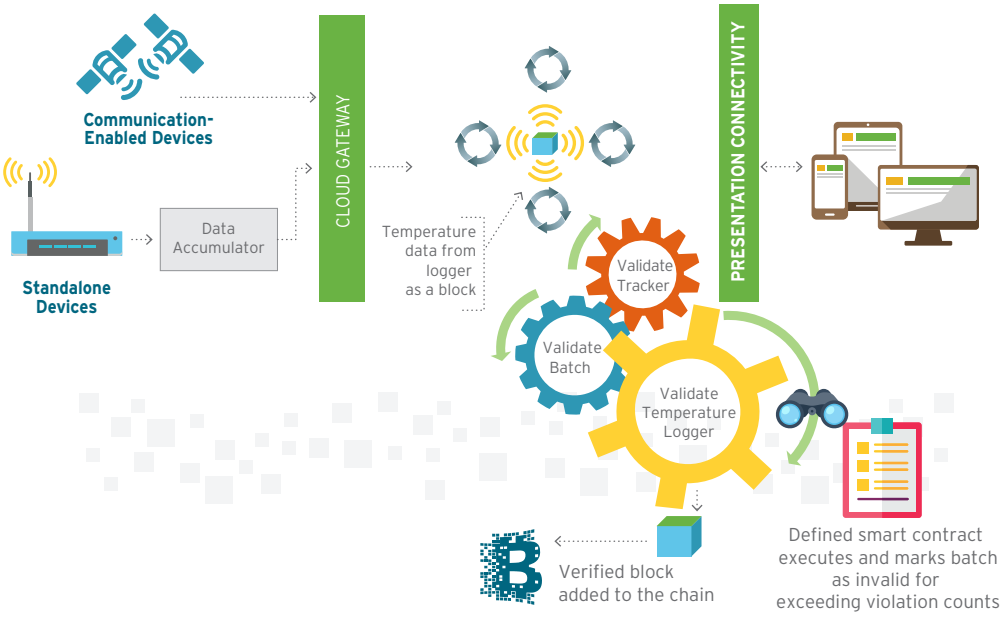

Figure 2

Since the certificates are digitally signed on the blockchain, they are immutable, eliminating the chance of fraud by either the physician or the supplier.

into the product data. Stakeholders share a single version of the truth, thus increasing mutual trust.

- **Manufacturers can be assured their products remain of high quality**. Any batch or product can be traced back to its origin. This ensures that no duplicate product replaces the original one in the supply chain.
- **Regulatory concerns are significantly reduced**. Adverse events due to batch stability cannot occur, as batches are automatically invalidated by the smart contract.

Certificates of Medical Necessity

A certificate of medical necessity (CMN)[14] is a document that helps substantiate that a treating physician has reviewed the patient's condition and determined that services or supplies are medically necessary. Healthcare insurance (for example Medicare) will only pay for services that are medically necessary. For payers, verification of CMN validity is a laborious and error-prone task. Physician intermediation is necessary to ensure the veracity and currency of the CMN. Suppliers need to know the amount of business serviced in the CMN channel. Today, CMNs are filled out manually, and form exchange can be time-consuming, paper-oriented and error-prone.

To substantiate this PoC, we built a sample cloud-powered application, deployed on Amazon Web Services (AWS), using an Ethereum implementation of blockchain with a Solidity smart contract that validates CMNs for adherence to a simple rule: that the CMN should be certified initially and recertified by the physician periodically (see Figure 3). The blockchain network connects patients, physicians and payers.

The workflow is initiated by a patient requesting a CMN, which – when issued by the physician – is embedded with a QR code that identifies the patient on the blockchain. The payer uses the QR

Blockchain & Certificate of Medical Necessity

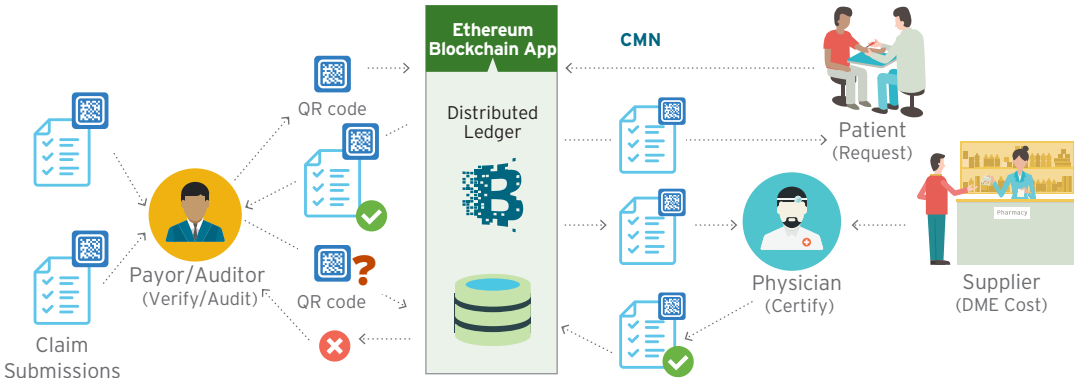

Figure 3

code to scan and relies on the blockchain to verify the validity of the CMN. Since CMNs are digitally signed on the blockchain, they are immutable, eliminating the chance of fraud by either the physician or the supplier. In addition, audit efforts by regulatory bodies are significantly reduced.

The main advantages of using a blockchain in this scenario include:

- **Near-real-time determination of validity**. This significantly reduces processing time.
- **Transparency, traceability and security**. Transactions and related data are immutable and visible to all participants
- **Automated triggers and processes**. Smart contracts provide the foundation for digitization and automation for business processes. Logic can be embedded to automatically trigger payment on successful verification.
- **Paperless processing and elimination of inappropriate claims**. Blockchain rules are indelible, and fraudulent claims can be easily checked, reducing manual audit efforts.

Trusted Data Sharing

Industry acceptance is gaining momentum for open internal data storage for product development, clinical trial assessment and other imaginative applications. Successful experiments such as Apple ResearchKit[15] and HealthData.gov[16] have served to accelerate this trend.

We built a sample application, deployed on the Microsoft Azure cloud, using a MultiChain[17] implementation of blockchain. A blockchain network is created with publishers (i.e., a pharmaceuticals or medical device company that wishes to open data access) and researchers (those who wish to consume data for research purposes). Researchers query for available data, and once the dataset of interest is located, they download it. An entry is made in a blockchain for tracking. Researchers can reference the blockchain data while publishing their findings, lending authenticity and repeatability of their findings (see Figure 4).

The main advantages of using a blockchain in this scenario include:

- **Security:** The main attraction is the tamper-proof nature of blockchain. Once uploaded for

Clinical Data Sharing via Blockchain

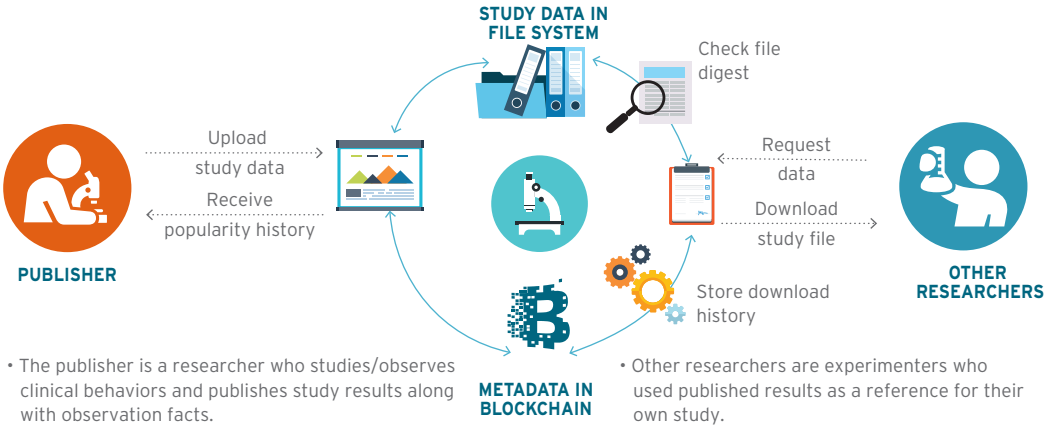

Figure 4

sharing, the data cannot be modified, ensuring participants of its veracity.

- **Collaboration:** When participants join the blockchain network, they can collaborate more quickly and smoothly.
- **Productivity:** Data sharing is faster between clinical research and analysis departments because of the secure access facilitated by blockchain.

Drug Provenance

Is there a better way for patients and consumers to verify the authenticity and source of a drug? Drug production and distribution involves many participants, including manufacturers, distributors, wholesalers and pharmacies. Each participant in the distribution chain is typically interested in knowing the true source of the drug and track distribution. A blockchain-based solution can help build such trust in products and their supply chain.

To illustrate this concept, we created a sample application (hosted on the Amazon AWS cloud) based on a MultiChain implementation of a blockchain, which allows manufacturers to record drug batches as blockchain transactions tagged with a QR code revealing batch details. The drug batch details are immutable once confirmed on the blockchain. All downstream participants can trust a drug batch based on the scanned QR code and also use the same data to track further distribution (see Figure 5).

The main advantages of using blockchain in this scenario include:

- **The true source of the drug can be irrefutably proved.** Manufactured batches are recorded on a blockchain as a single source of truth available to all participants.
- **A single tracking identifier is established via a QR code across the distribution chain.** Each participant buys or sells the drug post-verification using the QR code returned by the blockchain.
- **Patient safety is ensured as spurious drugs cannot enter the distribution chain.** Each participant in a blockchain can verify the drug before it is purchased and after it is received.

Drug Provenance via Blockchain

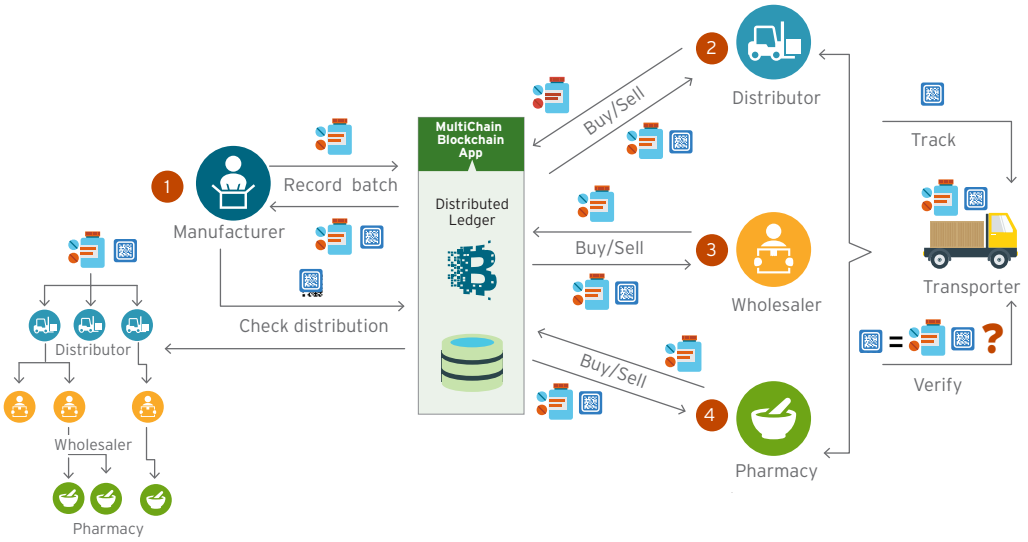

Figure 5

Blockchain is deeply technical in nature and requires non-trivial computing infrastructure changes. It also introduces potential performance tradeoffs and, to some degree, suffers from a lack of commonly accepted standards.

LOOKING AHEAD

Blockchain is an emerging distributed ledger, shared computing infrastructure that is expected to take a few years to reach mainstream acceptance. The shift is not just technological; its implications extend across legal, cultural and social parameters. Blockchain in many ways disrupts, if not dismantles, the very edifices used historically to create and reinforce trust – both internally and with external parties (business partners and consumers).

We see blockchain as a necessary step forward, and life sciences companies must prepare for the change across all dimensions, including business strategy, internal and external cultural shifts and building or acquiring the necessary operational and technical capabilities. To do this, we suggest the following.

Sow the Seed

Organizations should consider seeding a core set of passionate evangelists for exploring blockchain possibilities. The team should be staffed with business- and technology-savvy individuals who can promote the necessary cultural shifts and serve as agents of change. Business and technology teams should help identify potential use cases for exploring, gaining hands-on experience, coming up with innovative ideas for experimentation and collaborating with partners. Business leaders need a point of view on how they see blockchain impacting their business processes and key tactical and strategic areas for focus.

Identify the Right Use Case

A well-thought-out framework is needed to identify appropriate blockchain use cases (see Figure 6, next page). Considerations include:

- Does the use case provide value for stakeholders to demonstrate blockchain power?
- Does it lend itself to live deployment?
- Could this problem be solved using contemporary technologies?

Keep Pulse on Emerging Ecosystem

Blockchain technology is developing rapidly, from infrastructure platforms (R3[18] and Hyperledger[19]) to immutable storage (Bigchain DB[20]) and decentralized storage (IPFS,[21] Storj[22]). It is important to develop a well-informed view of the relative strengths and limitations of each of these emerging networks. Selecting the right technology for the use case at hand is a critical step and should only be considered after the business requirements are understood. Too often, platform providers pressure firms into overlooking this critical step.

It must also be noted that blockchain is deeply technical in nature and requires non-trivial computing infrastructure changes. It also introduces potential performance tradeoffs and, to some degree, suffers from a lack of commonly accepted standards.

Stay Abreast of Regulatory Thinking

Most regulatory bodies are struggling to keep up with blockchain's accelerating trajectory but remain cautiously optimistic of how the tech-

How to Evaluate Use Cases

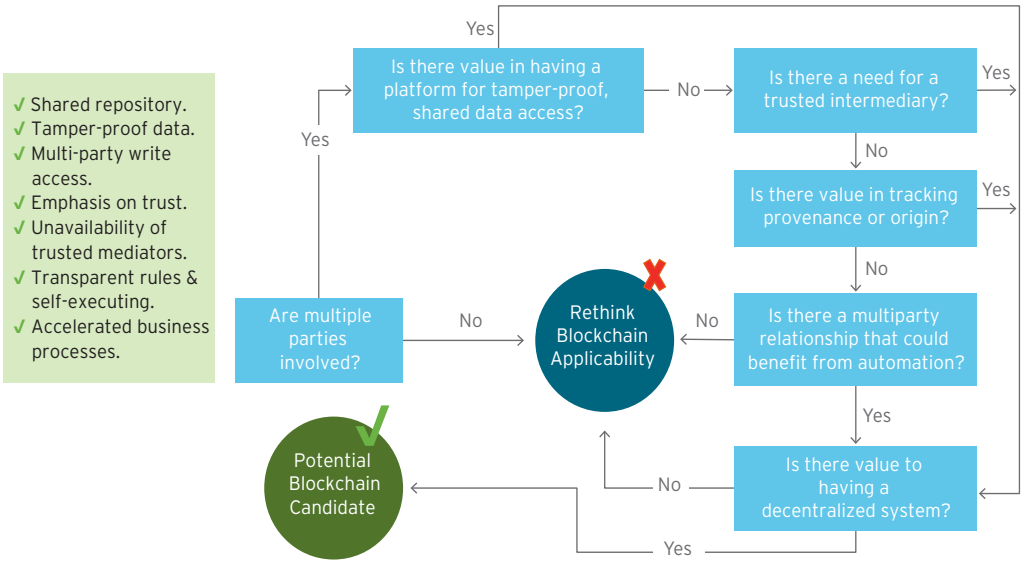

Figure 6

nology will influence markets. They are focused primarily on building task forces and working groups. The technology itself is not under scrutiny; however, many standing regulations were not written with the concept of shared infrastructure and decentralization in mind. This is akin to how sales-tax laws are being rewritten with the steady advance of e-commerce.

We encourage clients to keep abreast of early regulatory thinking; one approach is to participate in the Chamber of Digital Commerce, the world's largest blockchain trade association. Organizations can also connect with regulatory agencies when conducting pilots as a form of two-way education.

Collaborate or Risk Irrelevance

Many application areas require collaborative relationships to reveal blockchain's true potential. Keeping this insight in mind from the start can make it easier for organizations to inculcate fresh blockchain thinking. By looking across the value chain from the consumer perspective, organizations can begin exploring innovative offerings.

An example could be creating a medical devices ledger with device manufacturers, consumers, service organizations and insurance providers as participants. If life sciences organizations operate only within their enterprise boundaries, such impactful offerings will not materialize. Moreover, they will be left out of emerging collaboration networks. Cultivating ecosystems will help unlock the true power of blockchain across the value chain.

We recommend that pharmaceuticals and medical devices firms start preparing now for blockchain by equipping themselves with technical capabilities, effecting cultural shifts in their organization and cultivating ecosystem collaborations that keep customers central to the value proposition. As blockchain dissolves inter- and intra-enterprise boundaries, an accelerated pace of digital business will be available to life sciences companies that are willing to experiment and harness blockchain's potential for ushering in greater data transparency in clinical trials, enable secure data sharing, accelerate process improvement, and automate rule execution across the value chain.

FOOTNOTES

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