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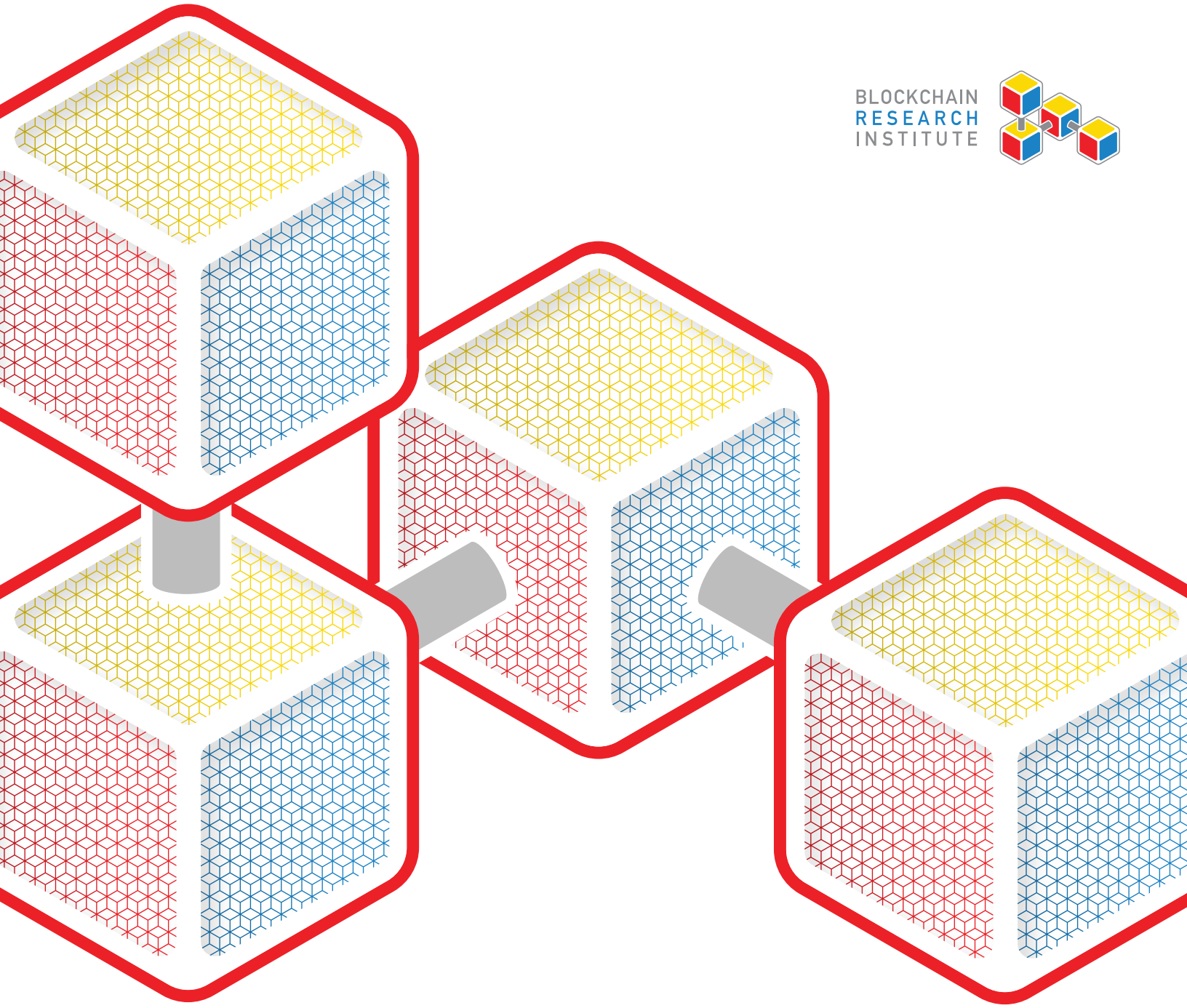

REINVENTING HEALTHCARE ON THE BLOCKCHAIN

Toward a New Era in Precision Medicine

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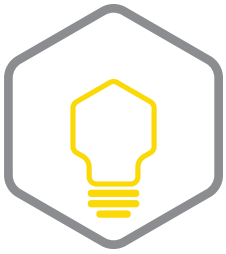
Shivom

January 2018

A BLOCKCHAIN RESEARCH INSTITUTE BIG IDEA WHITEPAPER



Realizing the new promise of the digital economy

In 1994, Don Tapscott coined the phrase, "the digital economy," with his book of that title. It discussed how the Web and the Internet of information would bring important changes in business and society. Today the Internet of value creates profound new possibilities.

In 2017, Don and Alex Tapscott launched the Blockchain Research Institute to help realize the new promise of the digital economy. We research the strategic implications of blockchain technology and produce practical insights to contribute global blockchain knowledge and help our members navigate this revolution.

Our findings, conclusions, and recommendations are initially proprietary to our members and ultimately released to the public in support of our mission. To find out more, please visit www.blockchainresearchinstitute.org.

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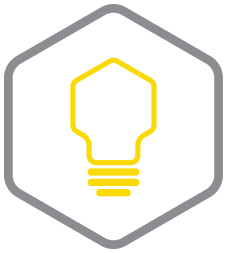

"First, do no harm" is good advice for medical practitioners. The phrase, introduced by 19th century French pathologist, Auguste François Chomel, implies that the solution to a medical problem must not cause undue damage. The US medical system should take this axiom to heart: despite spending the most per capita on healthcare of developed nations, it still scores poorly in key metrics such as life expectancy and infant mortality.

This project outlines how blockchain can lower costs and accelerate research and efficacy while securing patient privacy. The notion of a patient's right to privacy is an ancient one: one of the terms of the Hippocratic Oath has been translated from the Greek to read, "Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private."[1]

When describing the challenge of introducing innovation within large organizations, I often ask audiences, "How could God create the entire universe in only six days?" The answer (at bottom of this page) always gets laughs because it rings true. Executives and innovators alike have experienced the "that's not how we do it here" type of resistance. This project is cognizant of the powerful forces within the healthcare ecosystem that will resist blockchain-powered transformation, and it provides constructive advice on how to push forward.

When assembling the faculty for the Blockchain Research Institute, we recruited people who were not only brilliant thought leaders, but also active practitioners. This dual requirement was particularly important to healthcare research because the status quo is so deeply entrenched.

Axel Schumacher more than met that requirement. Dr. Schumacher has decades of research and development leadership within healthcare and is the author of *Blockchain and Healthcare Strategy Guide*. In addition to his research and writing, Dr. Schumacher and his colleagues at the start-up, Shivom, are building a blockchain-based global genomics and healthcare ecosystem. His optimism for the future of healthcare is contagious.

DON TAPSCOTT
Co-Founder and Executive Chairman
Blockchain Research Institute

Answer: "God didn't have to worry about an installed base."

Idea in brief

- Many global healthcare systems are in crisis because of prohibitive costs, limited access to care, unclear reimbursement models, patient safety and privacy concerns, the slow pace of innovation, data breaches, and varying quality of care. Some countries are reaching the tipping point at which healthcare provisions become unsustainable.

- Blockchain offers a potential solution: it enables us to put the patient at the center of the healthcare ecosystem and increase the security, auditability, and privacy of sensitive health data and interoperability of systems that contain such personal information.

- This distributed ledger instantiates a set of principles—collaboration, openness, and integrity—whereby healthcare providers, hospitals, laboratories and imaging facilities, insurance companies, pharmaceutical firms, pharmacies, medical supply outfits, local public health agencies, national food and drug regulators, global centers for disease control, government lobbyists, medical schools, and professional healthcare associations come together and co-create data with full transparency, public access, and shared control, all for the benefit of the communities they serve.

- Blockchain has been slow to catch on in healthcare; the sector is ripe for disruption. Numerous start-ups are working on applications for genomics and precision medicine and on solutions for patient data management, pharmaceutical provenance, clinical trials, and the administration of healthcare and insurance. These are just the beginning, with potential to reinvent the healthcare ecosystem.

- Blockchain's success depends on whether all stakeholders are willing not only to adopt its technical infrastructure and its core principles but also to participate in healthcare standards development and ongoing governance of blockchain-based healthcare platforms.

Blockchain offers a potential solution: it enables us to put the patient at the center of the healthcare ecosystem and increase the security, auditability, and privacy of sensitive health data.

Introduction

Most global healthcare systems are broken. Healthcare provision must change and insurers, healthcare providers, governments, pharmaceutical companies, and patient support groups, must be prepared to respond and lead. We can use innovative, transformational technology to build a new and improved precision health ecosystem, combining accurate diagnosis and rule-based therapies. One of these is blockchain.

Fixing healthcare: Measuring and responding to a need

To fix most of the global broken healthcare system, we must understand how to measure how our healthcare ecosystems perform. An extensive body of literature explains how to measure and rank performance so that the impact of reforms, such as using blockchain technology, can be assessed.[2] One of the most important factors to consider is how well countries are meeting the critical goal pf maximizing their population's mental and physical health. Most rankings include health infrastructures, availability of preventative care, and responsiveness to the population's expectations.

Measuring stakeholder responsiveness within healthcare

For our purposes, responsiveness refers to the interactions among various stakeholders within the healthcare ecosystem and reflects the client orientation in the delivery of healthcare services. A good healthcare system is affordable: it ensures that poor households are not paying a higher share of their discretionary expenditure on health than wealthier households, and that all people are protected against catastrophic financial losses related to a disease. Global organizations such as the London-based Legatum Institute, the Commonwealth Fund, or the World Health Organization (WHO) are among other scientific and government studies that publish the healthcare rankings annually, by country.

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Most studies show countries ranking high in prosperity also rank among the world's healthiest nations. However, there are exceptions. Among wealthy nations, the underachiever is the United States, which tops the world in per capita healthcare expenditure by some measures. The United States performs exceptionally poorly on population health outcomes such as infant mortality and life expectancy. Insurance premiums and drug prices have skyrocketed, leaving US citizens struggling to access affordable care. In contrast, Switzerland, France, Netherlands, Sweden, Israel, Germany, and Norway are among the healthiest countries, as are the city-states of Luxembourg, Singapore, and Hong Kong.

Linking healthcare ecosystems: The need for interoperability

The responsiveness of a healthcare system relates directly to its level of interoperability, which is the extent to which systems and devices can exchange, interpret, and share data in a format that human users and artificially intelligent machines can understand.

However, many interactions among stakeholders are not computerized, and most systems still leave multiple paper trails per communications between doctors and patients or patients and other healthcare service providers. Although digital solutions such as *electronic health records* (EHRs) do exist, they were not designed to manage multi-institutional medical records across a person's lifecycle. Patients' sensitive health data is often scattered about the healthcare ecosystem. Data are lost, potentially inaccurate, or inaccessible to providers outside a particular silo; they must rekey information into their own data silos.

Blockchain technology is an ideal solution for data management. As a distributed ledger, it tracks and preserves data transmitted from one entity to another. In turn, it addresses such trust issues as patient consent, data ownership, data integrity, and user authentication.

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Establishing trust among stakeholders

A patient-centered, population health-based system should be based on the principle of getting the right information to the patient and members of the patient's healthcare team and transmitting information at the right time in the decision-making process. Most systems fail to meet deadlines because health information systems comprised of insurance, medical, pharmaceutical, and social service organizations are incompatible and complex (Figure 1, next page).

All of these entities need to share patient data to coordinate care successfully. This sharing raises technical, governance, and privacy concerns. When stakeholders seek to cooperate, they need to harmonize all systems so that they interact seamlessly. This task requires daunting changes for organizations in each sector.

Trustworthiness is the crucial feature of blockchain technology. When transactions are executed and settled on a distributed ledger, all parties in the healthcare system need not trust each other; they can trust the ledger. Blockchain combines the openness of the Internet with the security of cryptography to give everyone a faster, safer way to verify key information, shifting the focus from making money for investors to keeping people healthy and curing disease. Unlike classical legacy systems and paper-based alternatives, blockchain is considered immutable, unhackable, and tamper-proof, reducing concerns around fraud by providing a "digital fingerprint" that ensures all parties are indeed who they say they are.

One of the most significant opportunities for blockchain technology is to save costs and time by eliminating redundant intermediaries, those organizations that operate between institutions or people and

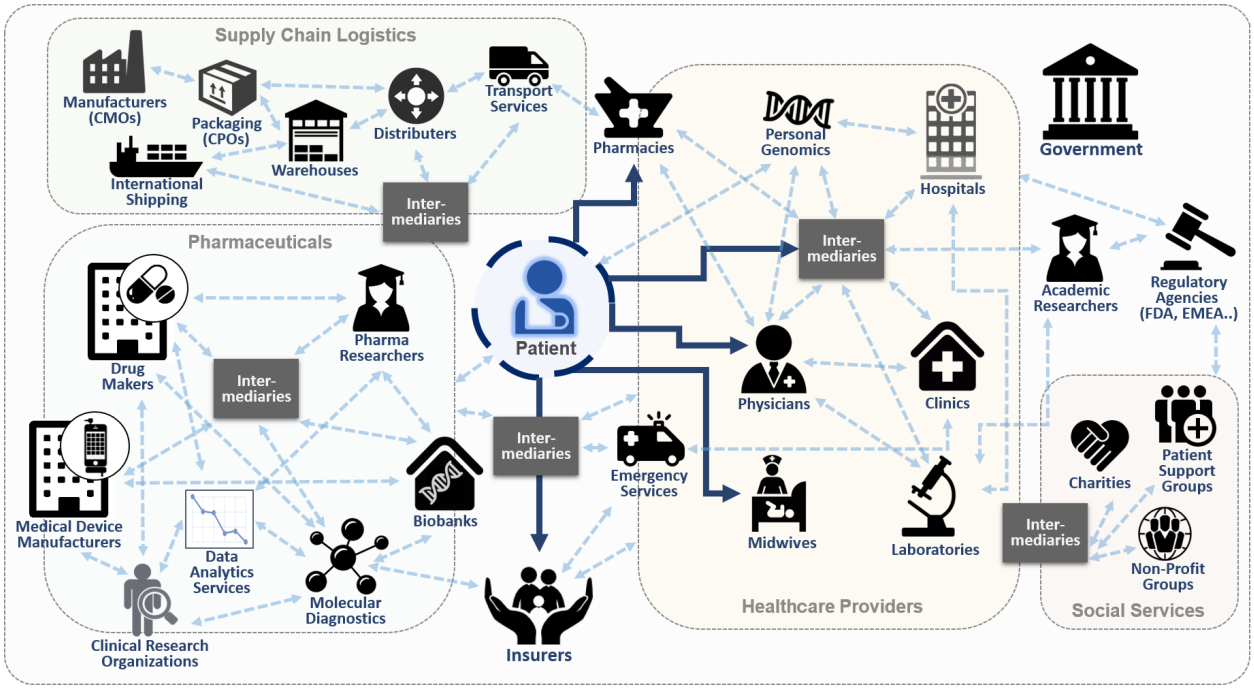
link them together in the healthcare value chain. Some of these are very good for the system, such as *group purchasing organizations* (GPOs), which are buying groups that help reduce transaction costs by negotiating prices on behalf of multiple buyers, thus aggregating demand and leveraging buying power to obtain more favorable pricing for health plans, hospitals, and physician practices.

Conversely, other healthcare intermediaries use exclusionary practices and anticompetitive agreements, which can be detrimental to competition and consumers in the healthcare supply chain.[3] When these intermediaries constrain competition, they affect many stakeholders such as smaller distributors, independent pharmacies, and smaller manufacturers of pharmaceuticals, medical devices, and medical supplies. In most of these cases, the intermediaries' incentives do not include promoting social good and, therefore, add no value to the process.

We have two ways to address this problem: (1) we could vote for legislators who would step in and address these twisted incentives, but that rarely happens against powerful corporate lobbyists, or (2) we could remove the need for these intermediaries altogether.

Figure 1: Value-added chain of the healthcare system

Most healthcare systems are tremendously complex because of extreme heterogeneity in their data, processes, and platforms, with patients and healthcare providers separated by jurisdictions and multiple intermediaries. With blockchain, we could put patients at the center of their care, where every element would align with their needs and keep them healthy. To ensure alignment, participants would store all health data (e.g., lab values, health status and risks, genetics, insurance, imaging, prescriptions) about a patient on a blockchain, and the patient in consultation with a primary care provider could determine who had access to these data.



Because blockchains are decentralized and immutable, counterparties can independently transact and verify the data on a ledger without requiring costly third parties to perform similar tasks. Blockchain will not be the demise of intermediaries; however, it will remove those that add no value. The process of disintermediation requires careful planning.

Addressing roadblocks to reinventing healthcare

Introducing blockchain to our healthcare systems is technically feasible but we have important roadblocks to overcome. As many blockchain innovators are discovering, institutional inertia—comfort with the status quo—is extraordinarily powerful. Many corporate departments and healthcare providers will not give up control of their hierarchical systems and move to peer-to-peer structures. Moreover, most organizations are not prepared for disruptive technology; they are more comfortable with incremental change. Finally, many stakeholders await a strong business case for blockchain adoption—after all, their centralized systems seem to be performing well—whereas many of the new entrants in the blockchain/healthcare market are still working on proofs of concepts, not full-blown business applications. Hospitals, healthcare practices, and insurers have all invested heavily in these database systems and are reluctant to dispense with these systems without understanding the costs of implementing and the impact of integrating blockchain solutions into everyone's job in the healthcare space.

To overcome resistance, leaders should identify the root causes such as lack of awareness of the benefits, the organization's poor response to previous change initiatives, management's lack of visible support and commitment, and employee fear of job loss.

Not all healthcare ecosystems are interested in adopting cheaper, more transparent systems, especially in environments where healthcare is primarily a business and not a service for the greater good. For example, in the United States, executives who run hospitals have MBAs, not MDs. Their goal is to maximize their revenue. From the hospital executives' perspective, every step that a patient takes within the hospital system affects the hospital's bottom line. A 2016 survey of 11 countries by the Commonwealth Fund found that US citizens were far more likely to go without care because it was too expensive.[4] One third of US adults went without recommended care, did not see a doctor when sick, or failed to fill a prescription because of costs.

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There's no incentive for a health industry that is so profitable to innovate. Consumers have no choice but to buy essential services at incredibly high prices. Introducing transparency, empowering patients, and improving healthcare provider responsiveness could help: with actual data about costs relative to prices, healthcare consumers are better positioned to demand change. The challenge for developers is ensuring that those who need the information have ready and safe access. As such, virtually every healthcare stakeholder will need to reengineer its business model.

Deciding when to implement blockchain technology

Most healthcare systems are undergoing a dramatic transformation. Factors such as the emergence of genomics, precision medicine, big data, artificial intelligence, value-based care, increased regulatory oversight, aging populations, and heightened consumer awareness all contribute to complexity, disorganization, and discontinuity of patient care. To ensure patient safety and quality of care while realizing savings, most stakeholders have to build new relationships and must reinvent themselves. Many healthcare stakeholders are just beginning to understand the merits of exploring blockchain, and it is a new concept for the precision medicine ecosystem.

Blockchain offers economic scalability: early adopters can start small. If the organization is profitable and the owners can scale up, the core business prototype can take advantage of all the benefits blockchain offers.

Blockchain offers economic scalability: early adopters can start small. If the organization is profitable and the owners can scale up, the core business prototype can take advantage of all the benefits blockchain offers. Blockchain also has the potential to connect fragmented healthcare systems, generate new insights, and assess the value of care. With many companies already pushing aggressively into this new space, waiting too long might prove disadvantageous. According to Gartner, "Blockchain is still—and will be for the next five to ten years—an innovation trigger, before reaching the peak of inflated expectations."[5]

Some are still cautious. Blockchain data start-up, Tierion, argued that blockchain presents more pitfalls than promises at this early stage. However, its leadership is optimistic about the long-term impact of blockchain. Indeed, the company moved into the healthcare space, joining the Philips Blockchain Lab to explore uses of blockchain technology in healthcare. Forrester advised enterprise CIOs to wait five to ten years before introducing blockchain, in part because of legal restrictions.[6] Why wait so long? When applying game theory—for example, seeing an innovative approach, but being too afraid to consider implementing it because no one else has tried it—we get the opposite of what a thought leader and innovator should do to advance transformation.

Early steps toward implementation

The healthcare industry consists of many different areas in which blockchain solutions would be beneficial; however, each has different dynamics. Investors in the healthcare sector factor in many variables, including trends in demographics, reimbursement, and regional regulation. According to Venture Scanner, funding is going where there is a high need for innovation and a good chance of short-term returns of investment such as:[7]

- Precision medicine ecosystems (or personalized medicine)
- Health insurance and payment
- Disease-specific genetic testing
- Cost-efficient analytic solutions for healthcare providers
- Personalized consumer reports

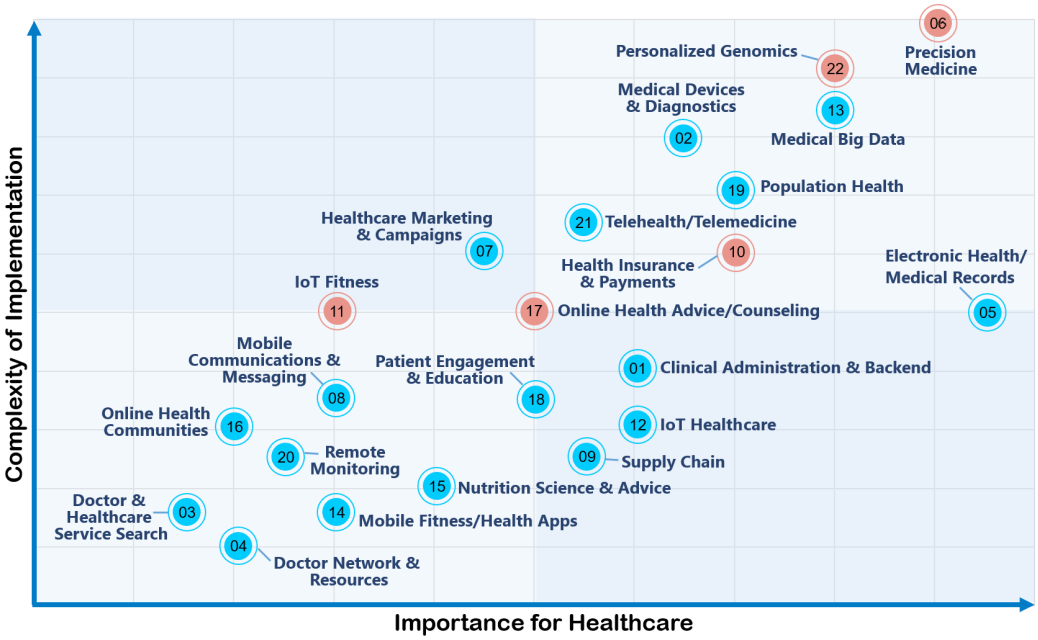
» Online health destinations such as health insurance marketplaces and platforms to manage and automate health benefits, websites that provide symptom checklists, drug information, and health resources

» IoT fitness and wellness solutions such as wearables that track personal fitness stats, monitor heart rate, and sports-specific data collection

To reinvent and reform healthcare, we must focus on the need first (Figure 2). The healthcare industry will likely accept products

Figure 2: Areas of healthcare in dire need of reform

Many sectors of the healthcare ecosystem can benefit from blockchain technology. However, not all are equally easy to implement (points represent a rough estimate based on communication with healthcare providers). To fix a healthcare system with blockchain technology, we must identify areas where system complexities inhibit progress and where we can develop and implement solutions quickly. The red circles denote those areas with the largest flow of venture capital, according to Venture Scanner.



1: Scheduling, patient transfers, billing, compliance; **2**: monitoring, detection equipment; **3**: services to search for doctors, healthcare plans, and specialized healthcare; **4**: collaboration platform across hospitals, and social networks that identify and share best practices; **5**: platforms for electronic medical charts, schedules, prescription tracking, and referral letters; **6**: genetic, metabolomics, and epigenetic testing, analytic solutions, patient personalized reports; **7**: healthcare-specific customer relationship management platforms; **8**: secure messaging for doctors, data sharing amongst healthcare professionals; **9**: cold chain logistics, biobanking, drug shipping; **10**: health insurance marketplaces, and platforms to manage and automate health benefits; **11**: healthy eating trackers, exercise tracking wristbands, smartphone-controlled devices; **12**: glucose monitors, sleep trackers, pain relief wearables; **13**: data management, solutions to normalize and link data across different systems, predictive analytics; **14**: fitness apps, mindfulness exercises; **15**: nutrition information, nutraceuticals, lifestyle plans; **16**: online communities that connect patients, and doctors, generalized medical information; **17**: symptom checklists, drug information, and resources on specific issues; **18**: in-hospital multimedia systems, clinical trial recruiting, patient relationship management; **19**: population data management, coordinated care across populations; **20**: services that provide caregivers to senior citizens, alert systems for in-home care; **21**: patients to doctor video conferencing, remote monitoring, remote diagnosis; **22**: pharmacogenomics, direct to customer genomics, ancestry.

and services that support the transition toward a value-driven reimbursement model on national, regional, and local levels because all stakeholders understand their importance. Governments drive other critical areas such as *electronic medical records* (EMR) and population health management, and so progress can be slow. The government gains little for taking risks on programs and achieving program goals but faces substantial criticism and potentially personal loss for failure.

Probably the most accessible markets to conquer fall in the lower right quadrant of Figure 2, clinical administration (e.g., for billing and patient transfer), Internet of Things (IoT) in healthcare (e.g., connected devices such as glucose monitors), and pharmaceutical supply chain (particularly cold chain logistics and drug shipping). The greater the complexity of a project, the greater the effort and the need for collaboration. All entrants into those fields must evaluate the maturity of each potential market to gain insights into strengths, weaknesses, and barriers for a value-based reimbursement model, considering the interoperability aspect.

The healthcare ecosystem supply chain

The healthcare supply chain was the first to consider using blockchain technology to address a range of ailments from counterfeit goods to disputes over ownership. As an industry, the global supply chain is worth over $40 trillion per year, and there are seemingly infinite international laws and regulations governing each step. Many processes are still based on paper transactions, such as bills of lading (detailing merchandise shipment and ownership) and letters of credit (used by banks to guarantee that buyers receive their payments), with auditors or middlemen at each step to add delays, complexity, and cost. To address these inefficiencies and add trust and visibility into the flow of goods and commerce, several companies are beginning to use blockchain technology.

The market for blockchain solutions is already crowded, with start-ups as well as industry giants such as Walmart, IBM, Microsoft, and SAP, all launching efforts to track the movement of goods and information more effectively.

While a few specialized start-ups such as ascribe and Everledger use the blockchain to track single product types, including digital artwork and diamonds respectively, other companies aim to track any product throughout every part of its lifecycle. In these cases, blockchain will create an entirely decentralized network that connects all producers, carriers, banks, traders and other parties of the international trading supply chain. Using decentralized technologies, all communication between these parties will be direct and not pass through a specific central entity or middleman. However, the market for blockchain solutions is already crowded, with some start-ups as well as industry giants such as Walmart, IBM, Microsoft, and SAP launching efforts to better track the movement of goods and information.

Blockchain service providers in supply chain logistics
Catkin, www.catkin.eu
Chronicled, chronicled.com
CargoChain, cargochain.com
Guardtime, guardtime.com
IOTA, iota.org

iSolve, iSolve.com
modum, modum.io
Mojix, www.mojix.com
OTdocs, otdocs.com
Provenance, www.provenance.org
Skuchain, www.skuchain.com
Stratumn, stratumn.com
Synthium Health, www.synthiumhealth.com
The LinkLab, www.thelinklab.com

Blockchain is particularly effective with cold chain logistics and pharmaceutical serialization, especially when combined with smart contracts. This process ensures that contractual rights and obligations, including the terms of payment and delivery of goods and services, are executed automatically by an autonomous system.

The pharmaceutical supply chain: Risks and challenges

Until now, pharmaceutical companies that have benefitted from the old healthcare ecosystem, which brought enormous profits; therefore, they had few incentives to change. As a result, they had grown unresponsive to consumers who, in turn, resented them. Some companies, however, have realized that the business model had to change. Early adopters, Pfizer and Genentech, formed the MediLedger Project, a network that uses blockchain to control pharmaceutical supply chains.

The *pharmaceutical supply chain* is defined as the management of product supply from raw material sourcing to active pharmaceutical ingredient, manufacturing through formulation, packaging, and distribution to the patient. Traceability of supplies throughout an international process is challenging. Under current systems, drug shipments pass through many hands and involve paperwork that people can tamper with. Using distributed ledgers can improve revenue sharing, solve patent issues, trace transfer of assets, and enable proof of work or proof of service. For example, if stakeholders in the blockchain could chart the pharmaceutical supply chain from a batch number and factory of origin all the way to distributor, sale and storage, and adherence, then they could identify issues with greater granularity and speed. If regulators or payers identify a hotspot of patients who have a specific problem with a drug, they could trace the problem back to the batch or administration of drug regimens.

Blockchain is particularly effective with cold chain logistics and pharmaceutical serialization, especially when combined with smart contracts.

Pharmaceutical companies must comply with the guidelines and regulations:

» The European Commission's "Good Distribution Practice of Medicinal Products for Human Use" requires companies to report any deviations, such as cold chain disruptions, humidity, or light conditions to the distributor and the recipient of the affected medicinal products.[8] Companies must adhere to recent changes.

» The US Drug Supply Chain Security Act (DSCSA) outlines steps to build an electronic, interoperable system for identifying and tracing certain prescription drugs during distribution across the United States.[9] This traceability enhances FDA's ability to protect consumers from drugs that might be counterfeit, stolen, contaminated, or otherwise harmful.

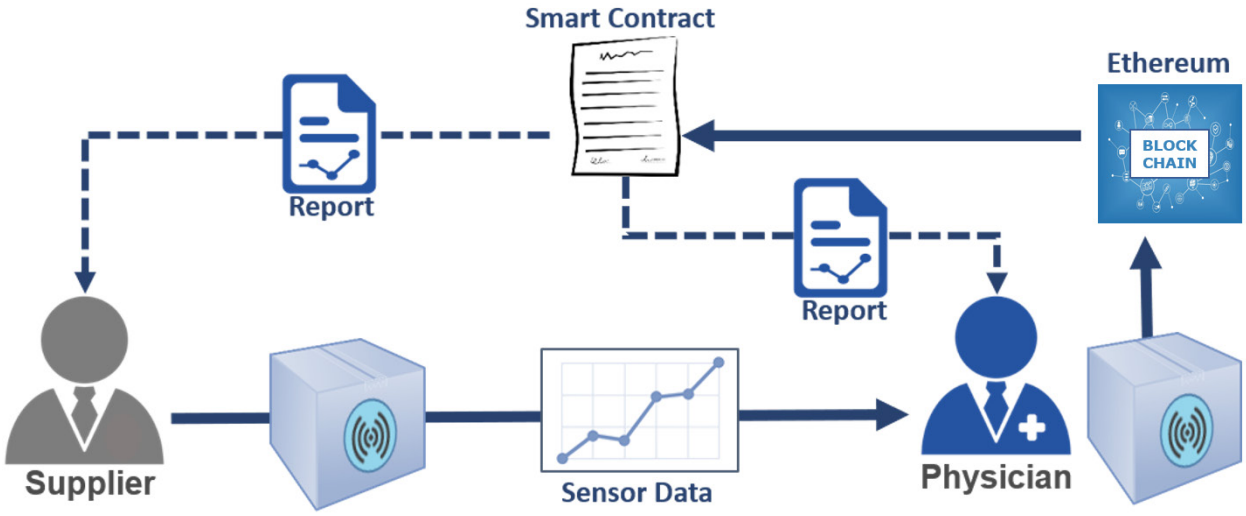
A Swiss start-up, modum, is working on supply chain solutions with its first use case in cold-chain logistics. The company combines sensor devices and blockchain technology to provide data integrity for pharmaceutical logistics under new regulations. Modum's team is developing a blockchain-based temperature tracking system for medicinal products so that distributors can fulfill new requirements for an auditable records of temperatures of products in transit. Users can activate a fully programmable sensor and connect it to a shipment. Upon the shipment's arrival at its destination, sensor data are automatically transferred to the Ethereum blockchain, triggering smart contracts that compare these data against the regulatory or customer requirements. Then the shipment is either released or, if a deviation is detected, then both the sender and the receiver are notified (Figure 3). Modum can apply its technology to any product in transit or throughout the entire supply chain where data collection is required and its integrity is crucial.

Modum's team is developing a blockchain-based temperature tracking system for medicinal products so that distributors can fulfill new requirements for an auditable records of temperatures of products in transit.

What good is a blockchain solution if only one link in the pharmaceutical supply chain is using it or if only one pharmaceutical giant adopts it? Chronicled, a San Francisco-based company, is

Figure 3: Modum's blockchain solution for cold-chain logistics

Modum sensors constantly record environmental conditions on batches of drugs in transport. When the shipment is at its destination and goods change ownership, the collected data is checked against the specific smart contract in the Ethereum blockchain. The contract validates that the transaction meets all the standards set forth by the customer (e.g., no temperature deviations), the customer's clients, or the regulator, and then triggers various actions: notifications to sender and receiver, payment, release of goods, or insurance clauses in case of damaged goods.



producing blockchain systems for these companies. It is crucial to bring together industry partners to design and develop pilots of potential solutions that can meet the GDP and DSCSA legislation, fulfill companies' needs worldwide, and eliminate counterfeit production and distribution. Drug counterfeiting is a widespread problem for pharmaceutical businesses and consumers.

The WHO estimates that up to 10 percent of drugs sold around the world are counterfeit; this might be as high as 50 percent in some countries.

The WHO estimates that up to 10 percent of drugs sold around the world are counterfeit; this might be as high as 50 percent in some countries.[10] Many of these "drugs" might not contain any active ingredients while others contain incorrect quantities of necessary ingredients. If patients take counterfeit drugs, they might experience severe allergic reactions, unexpected side effects, or a worsening of their medical condition, sometimes leading to death. In 2013, over 8,000 patients died over a five-year period in a remote Himalayan hospital because an antibiotic had no active ingredients.[11] In North America and Europe, patients have experienced problems primarily relating to lifestyle drugs, such as Viagra or Cialis, rather than in life-extending medication.

Economic incentives might be spurring the growth in counterfeiting. Also, the ability to sell drugs directly to consumers through purchases over the Internet adds to the problem. Traditionally, to tackle these issues, many countries have implemented pharmaceutical serialization practices, such as recording, authenticating, maintaining, and sharing accurate records of items before dispatch using track and trace technology. However, these programs and regulation depend heavily on local, national laws and standards, and many pharmaceutical companies struggle to identify the best approach to work with serialization.

Blockchain solutions to the pharmaceutical supply chain

The BlockRx Project offers a solution to encourage stakeholder buy-in: invite all stakeholders to participate in a blockchain. This includes series of initiatives by iSolve to verify and enhance the integrity of the drug supply chain and to accelerate new drug development by leveraging the blockchain to support and manage the drug development lifecycle. The idea behind BlockRx is initiating a tracking process that could start with a central authority. For example:

1. A pharmaceutical company that owns the drug IP decides on the participants in its blockchain, such as suppliers, warehouses, quality controls, distributors, and retailers.
2. Once a drug ingredient is manufactured, a notification is broadcast on the blockchain network, and a hash is generated with all the relevant manufacturing details.
3. The hash is printed on the drug package.
4. The drug is delivered to the assigned distributor.
5. The delivery is registered as a transaction: a new hash is generated and linked to the previous hash, containing

further information about the shipment, cold chain control, or distributor details.

6. Once the distributor ships to the retailer, the same process continues and the blockchain grows.
7. Finally, the consumer who buys the drugs at the pharmacy or via the Internet receives the public key on the invoice, which allows the consumer to verify that the medication originated from an authentic manufacturer and hasn't been opened or adulterated.

This process should also work across borders, helping countries work together to share detection technologies, collaborate on a universal database of legitimate pharmaceuticals, and pass international standards. There are other opportunities to connect blockchain technology with measures to counteract the increase in fake drugs on the market, including stronger state licensure supervision of drug suppliers and the use of *radio frequency identification devices* (RFID) to identify original drugs accurately. Whatever approach companies take, the pharmaceutical industry will spend fewer resources on anti-counterfeiting workarounds and regulatory compliance.

The US Center for Supply Chain Studies started a blockchain study bringing together members of the pharmaceutical supply chain, technology companies, and standards and government agencies to explore blockchain's potential in the DSCSA space.[12] The center was established in 2015 as a neutral, nonprofit industry exploration and education forum. Several blockchain projects are planned and interested parties can still join.

Early results from one project indicate that blockchain holds promise in providing a single platform for trading partners to connect system; blockchain could be the missing ingredient in the "interoperable system." The study defines a preliminary solution model that demonstrates a standard set of commands for solutions to interact with the blockchain on behalf of a manufacturer's supply chain customers. This enables large-scale supply chain interoperability and provides a stable market in which solutions can compete and collaborate.

Blockchain can make a considerable impact where sensitive data and/or high volumes of data need to be transferred securely and privately.

Internet of Things healthcare

Blockchain can make a considerable impact where sensitive data and/or high volumes of data need to be transferred securely and privately. That's precisely what the Internet of Things (IoT) needs to do. IoT refers to using electronic devices for capturing or monitoring data, connecting to a private or public cloud, then automatically triggering certain events. IoT has many healthcare applications, from remote monitoring (e.g., fetal monitors), to smart sensors (e.g., temperature monitors or blood glucose level sensors) and medical device integration (e.g., artificial cardiac pacemakers or neural stimulators). The growth of IoT technologies in healthcare will be driven by such factors as the steep rise in the global aging population due to longer life expectancies, the increased demand for health and fitness monitoring solutions, and the prevalence of lifestyle diseases

such as diabetes and obesity. IoT can now accurately analyze a patient's health, identify inefficiencies, and develop patient-specific care plans.

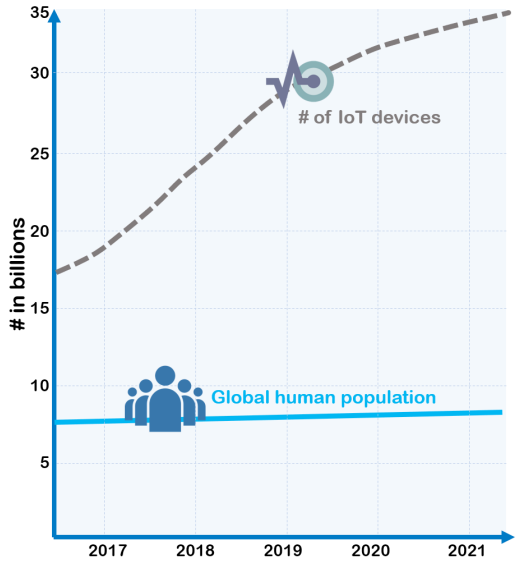
Nevertheless, barriers to adopting wearables in the healthcare sector exist because of concerns surrounding privacy. Most mobility approaches currently do not provide solutions that simultaneously fulfill security needs while enabling mobile access, without causing privacy and usability concerns with end users. Blockchain could support IoT applications by facilitating transaction processing and coordination among interacting devices and downstream analytical processes. For example, blockchain can make it easier to synthesize data from IoT devices for chronic disease management, remote monitoring, or patient-provider communication, enabling fee-for-value systems.

Large information and communications technology companies dominate the IoT market because of its complexity. Such tech giants as Microsoft, Cisco, and IBM control the IoT software and services segment for healthcare, and Apple, Huawei, Siemens, Google, and Samsung are investing significant resources into developing devices that will help bridge the gap between personal fitness tracking and professional healthcare.

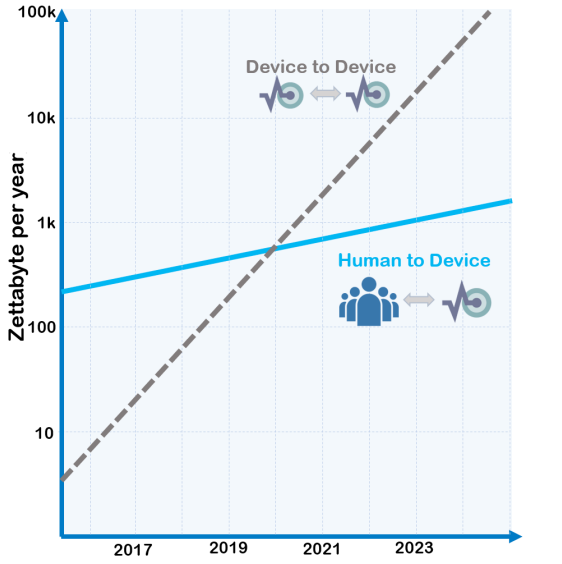
Adopting blockchain solutions in the IoT space can have a significant competitive advantage, for a market that is expected to explode (Figure 4). If we review projections from the leading consulting firms,

Figure 4: How the relationships among people and machines will change

The adoption of small medical devices and IoT applications will produce an unprecedented amount of health data consuming a huge amount of storage space. A zettabyte is a measure of storage capacity two to the 70th power or 10^{21} bytes.



Global population and number of IoT devices



Human-to-device and device-to-device data consumption

Adapted from World Population forecast (Census.gov), International Data Corporation IoT forecast (idc.com).

we can see that gaining market share with blockchain technology can matter enormously. Bain predicts that by 2020 annual revenues in global IoT market could exceed $470 billion for the IoT vendors selling the hardware, software, and comprehensive solutions.[13] BI Intelligence anticipates that the global market for IoT healthcare tech alone will top $400 billion in 2022, while Gartner predicts over 20 billion connected devices will be in use worldwide in 2020.[14]

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With such a vast market, new entrants from the blockchain space are choosing to join existing IoT ecosystems and defining a clear value proposition such as improving the utility of wearables. While adoption levels are rising, the wearables market is driven mainly by consumers who want to quantify personal health metrics. A blockchain could collect information from these mobile applications and through sensors in fitness trackers and other wearables and integrate it through *representational state transfer* (REST) *application programming interfaces* (APIs). RESTful APIs, which are quickly gaining traction in healthcare Bio-IT, are methods of allowing communication between a web-based client and a server through such standards as HTTP, URI, JSON, and XML.

FHIR (pronounced "fire"), for *fast healthcare interoperability resources*, is increasingly supporting interoperability of systems. Created by Health Level Seven International (HL7), a healthcare standards organization, FHIR is a draft standard describing data formats, elements, and an API for exchanging EHRs. The standard facilitates interoperation among legacy healthcare systems so that healthcare providers can share information on such devices as computers, tablets, and smartphones.

Clinical administration

Clinical administration management is the third area where implementation of blockchain is straightforward and solutions can be developed and put in place relatively quickly. A blockchain-based payment process system can improve the efficiency of the hospital revenue cycle, in part, by eliminating the need for intermediaries between hospitals, physicians, insurers, and patients, according to Deloitte.[15] One use might involve enabling patients or insurers to deposit a payment, which would not be released until a predetermined clinical outcome is reached. Also, for hospitals, a blockchain-enabled health information exchange would alleviate security concerns related to data sharing among different providers. Patients would be able to access and share their data and providers would be able to update relevant information with using individual keys.

Representational state transfer application programming interfaces (RESTful APIs) are methods of allowing communication between a web-based client and a server through such standards as HTTP, URI, JSON, and XML.

In September 2017, Black Book Market Research, a full-service healthcare-centric market research and public opinion research company, conducted a survey of 88 healthcare payers and 126 healthcare provider technology executives, managers and IT specialists to deliver comprehensive insights of current and planned enterprise deployment of blockchain solutions.[16] The results demonstrate that the healthcare sector identifies the value in

blockchain, but the lack of technical standards for a still-immature technology is causing regulatory uncertainty. For many people working in the healthcare space, the concept of blockchain is complex. However, the Black Book study found that understanding the healthcare blockchain has developed dramatically, with 29 percent of hospital leaders and 82 percent of health insurance executives having a general knowledge of the technology.

The slow adoption of the technology in hospitals is mainly due to the undetermined cost of such solutions, which makes healthcare providers cautious to set a timeframe or deadline for potential deployment.

Actual breaches and cybersecurity events have boosted readiness significantly, and executive blockchain education has evolved from blockchain 101 to selecting the appropriate healthcare blockchain technology protocols. Sixty-eight percent of payers expected blockchain to be integrated into their systems by the end of 2018, but only 12 percent of provider health organizations and systems have firm plans to implement by then. According to the study, the slow adoption of the technology in hospitals is mainly due to the undetermined cost of such solutions, which makes healthcare providers cautious to set a timeframe or deadline for potential deployment. Black Book respondents who were either deploying or considering implementing blockchain, ranked blockchain companies on their impressions of presentations and offerings to date. Of the vendors named, eleven companies received significant awareness (see box).

Best known blockchain vendors in the healthcare space
BurstIQ, www.burstiq.com
Blockchain Health, blockchainhealth.co
Bloq, bloq.com
Gem, gem.co
Guardtime, guardtime.com
Hashed Health, hashedhealth.com
HealthCombix, www.healthcombix.com
IBM Blockchain, www.ibm.com/blockchain
PokitDok, pokitdok.com
Tierion, tierion.com
YouBase, www.youbase.io

The healthcare industry has been full of disruptions in the last decade, ranging from the explosive growth of medical devices within the Internet of Things to genome editing, and incredible advances in machine learning that could reshape diagnostic medicine. Blockchain might be the next disruptor, addressing industry's biggest challenges, patient data, especially the proverbial holy grail of the medical industry, the elusive EHR.

Interoperability and electronic health records

EHRs are at the core of all data flows. Consequently, they have been a topic of heated discussions in the healthcare industry for

over a decade. Conceptually, EHRs are relatively simple and should not be difficult to design. Each record should contain the patient's consolidated medical history, including all key administrative and clinical data relevant to that person's care under a particular provider, including demographics, progress notes, medications, pharmacogenetic data, vital signs, immunizations, laboratory data, genomic data, and radiology reports.

Health informatics should focus on achieving 100 percent interoperability among healthcare networks and the efficient exchange of EHRs.

However, managing EHRs becomes challenging when the information comes from a variety of sources—providers, insurers, laboratories, and hospitals, each with its own patient records system and a reluctance to share information. As a result, data ownership becomes unclear; and regulations on access, control, and sharing of the information become complicated. Several large US companies failed to develop consolidated and widely accepted EHR systems, including Google Health, the Microsoft HealthVault, the Veterans Information System and Technology Architecture (VISTA).

Challenges to EHRs and data interoperability

For a healthcare system to be responsive, it must be interoperable. In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the transferred information. Data exchange schema and standards should permit data to be shared across clinician, lab, hospital, pharmacy, and patient regardless of the application or application vendor.

Health systems are unable to communicate with each other; time and again, patients have complained about and suffered due to poor information sharing among healthcare providers, sometimes even between departments in the same hospital. According to a 2014 study, only six percent of US healthcare providers could access and exchange information with different EMR systems.[17] Health informatics should focus on achieving 100 percent interoperability among healthcare networks and the efficient exchange of EHRs.

The EHR interoperability problem in Germany

Not only the US healthcare system has serious problems with EHR interoperability; Germany, a country whose healthcare system performs very well in most rankings, is also facing a major infrastructure crisis. When it comes to e-health, many Germans feel as if they are living in the Stone Age. For example, Germany has neither an all-inclusive EHR nor a national patient identifier. Although most physicians use electronic billing and documentation in private practice, only about half of the doctors adopt non-clinical systems, such as online services. Even worse, prescriptions are still on paper, as are referrals and sick notes.

Some stakeholders are skeptical about the value of electronic health cards. They are concerned that health data will be stored centrally, not directly on the card and could offer a single entry-point for

hackers. Consequently, medical associations and health insurance companies are now speculating about the end of the electronic health card. Tests have shown that these cards are not practical and already technologically outdated. Some insurers started developing their own digital platform; however, these new platforms are making the digital healthcare landscape increasingly fragmented, which is the worst thing that can happen to a healthcare ecosystem. The dispute over the design and feasibility of the electronic health card is likely to persist for many years.

In 2002, the German government decided to modernize the statutory health insurance, including the implementation of an electronic health card. However, the companies involved in this project failed to deliver a working solution, mostly due to complicated data protection regulations. Consequently, in 2015, the Federal Cabinet passed a bill for secure digital communication and healthcare applications, which provided concrete deadlines for implementing a nationwide, technically mature telematics infrastructure for interconnecting patients, doctors, hospitals, and health insurance companies.[18]

However, the implementation did not go ahead as planned. Too many stakeholders took part in the development, a scenario that led to the technical requirements changing over 150 times. Thus, despite many years of development and a staggering 1.9 billion euros, the current card holds only the patient name, address, date of birth, illnesses, health insurance number and insurance status, as well as a photograph of the cardholder; it does not store data such as known allergies, patients' specific medication plans, implants or previous diseases, as had been planned. In addition, it is not intended to store other critical health data, such as information garnered from medical devices, or genomic-, proteomic- or metabolomic data that can be used to improve precision medicine.

The danger of fraudulent practices

Fraudulent healthcare claims are also an increasing burden on many healthcare systems. Generally, healthcare frauds are not obvious and thus difficult to detect. They often originate from the inside of an organization. Typical examples of healthcare fraud techniques include:

Fraudulent healthcare claims are an increasing burden on many healthcare systems.

- Providers who bill for services not provided.
- Doctors who administer tests or conduct procedures not medically necessary.
- Administrators who practice multiple-billing.
- Healthcare providers who charge more than peers for the same services.
- Researchers who modify clinical trial or research study data.
- Policy holders who allow others to use their healthcare cards.

The danger of cyberattacks

More high-profile cyberattacks have hit companies in recent years, such as Quest Diagnostics, which provides diagnostic services to millions of Americans each year and health insurance giant Anthem, the second largest health insurer in America. The attackers gained unauthorized access to Anthem's IT system and obtained the names, birthdays, medical IDs, social security numbers, street addresses, email addresses and employment information, including income data of 78.8 million customers. According to Protenus, a company that monitors health data breaches in the United States, on average, there are daily, costly breaches in healthcare systems, with the majority (59.2%) of breached patient records—230,044 records (for January 2017)—are attributed to insider incidents.[19]

Where interoperability shows promise

Healthcare organizations still aren't doing enough to protect themselves or their customers from cyberattacks.

Despite regulations like the Health Insurance Portability and Accountability Act (HIPAA), healthcare organizations still aren't doing enough to protect themselves or their customers from such cyberattacks; those companies must take steps now to prevent future incidents. One step forward could be the decentralization of health and research and development data via blockchain technology. In this scenario, patients will control their own data through a patient-centric EHR blockchain—a network of computers that stores identical encrypted medical records that protects patients' privacy against corruption because encrypted duplicates are permanently stored on the network.

We might need new rules and guidelines to help healthcare professionals understand how HIPAA and EU regulations would potentially apply to blockchain technology. Client information would need to remain secure through any data transfer process, even across regulatory borders. Although 100 percent crime prevention is impossible, using blockchain would allow for the possibility of gaining full detection, accountability, and audibility across highly complex systems.

Beth Israel Deaconess Medical Center took the first step toward the necessary physical, technical, and administrative safeguards to make all processes possible. A teaching hospital of Harvard Medical School in Boston, the center made blockchain technology a working reality by implementing a system called MedRec, a platform for managing medical records that uses the Ethereum blockchain, a decentralized platform that supports applications that run exactly as programmed without possibility of downtime, censorship, fraud, or third-party interference.

In addition, Amazon is developing an EHR blockchain via its stealth team, named 1492.[20] With the aggregation of a critical mass of patient EHRs in the AWS blockchain, Amazon can mine these significant data stores with deep learning tools to identify disease patterns, aging trends, and efficient treatment models more quickly. Furthermore, it can potentially sell or make available anonymized

patient data to researchers studying aging demographics, disease prevention, and public health issues.

Estonia was the first country to implement a blockchain into its electronic healthcare record system with the collaboration of Guardtime, a local team of over 150 cryptographers, developers and security architects, using their *keyless signature infrastructure* (KSI). Governments should learn from Estonia's example. This small Baltic country continues to be one of the most digitally advanced, using blockchain to keep citizens' data safe. Guardtime was one of the very first companies to leverage blockchain technology in the EHR-space.

Governments should learn from Estonia's example. This small Baltic country continues to be one of the most digitally advanced, using blockchain to keep citizens' data safe.

So far, mostly start-ups have followed, typically in the early stages of platform development, such as Medibond, which seeks to improve interaction between the biggest healthcare industrial players to help provide services more efficiently and securely to end users. On its platform, a trinary multisignature sign-off from all parties (insurance, pharmacies, doctors) is required for the dispensation of any data to third parties.

Another start-up, Medicalchain, is looking to give users of the platform full access and control over their EHRs, enabling them to license their EHRs to pharmaceutical companies for research. When used in conjunction with Medicalchain's conditional permissioned access system, users will be able to set parameters on what information is available and how long companies may access it. Similarly, E-Nome, an Australian private company, developed a system based on blockchain and encrypted database technology that empowers consumers to control their medical history on their smartphone. The system allows consumers to share their data anonymously to participate and assist in medical research.

Google's health-tech subsidiary, DeepMind Health, is also piloting what it calls the "verifiable data audit" using a digital ledger "that automatically records every interaction with patient data in a cryptographically verifiable manner. … Any changes to, or access of, the data would be visible."[21] The ledger will be append-only, so that once a record of data usage is added, it cannot be erased. Moreover, like traditional blockchain solutions, the ledger will allow third parties to verify that nobody has tampered with any of the entries. The company's data audit system uses a mathematical function called a Merkle tree, which allows a relatively small record to represent the entire history of the data, yet instantly shows any attempt to rewrite history.

DeepMind Health's solution has also attracted criticism because of the difficulty of distinguishing between uses of data for care and research. Patient groups criticized the overly broad data sharing agreements, raising fears that the data sharing mechanism has the potential to give DeepMind, and thus Google, too much power over regulators and patients. DeepMind Health tried creating a board of independent reviewers for the DeepMind Health platform to address criticism; however, only transparency and better control of the data can build genuine trust in the long term.

For EHR interoperability, all stakeholders must adopt certain governance and trust principles, create business agreements, and use highly detailed guides for implementing standards.

Blockchain companies involved in medical/health record management

BurstIQ, www.burstiq.com
DeepMind Health, deepmind.com
E-Nome, enome.io
Gem, gem.co
Guardtime, guardtime.com
HealthHeart, www.healthheart.io
Labchain, www.labchain.nl
Medicalchain, medicalchain.com/en
MediBond, medibond.io
Minthealth, minthealth.io
Patientory, patientory.com
Solve.care, solve.care
YouBase, www.youbase.io

Interoperability standards

For EHR interoperability, all stakeholders must adopt certain governance and trust principles, create business agreements, and use highly detailed guides for implementing standards. Tackling these issues requires both a multistakeholder approach and strong incentives. This is often a problem. Many stakeholders in the healthcare industry do not have a proper motivation. Many sellers of items or services can keep customers they might otherwise lose if they make it difficult to move data to another vendor's system. Similarly, healthcare providers can keep lucrative patients they might otherwise lose if they make it cumbersome and expensive to transfer a medical record to a new provider.

Patients and policymakers have the clearest and strongest interest in promoting interoperability. It is up to them to push for robust, cross-vendor interoperability in the healthcare ecosystem. In highly competitive markets, providers might turn the other way even when the cost and complexity of interoperability are reduced. Starting such processes anew with blockchain technology has enormous potential, but stakeholders must avoid the implementation mistakes of other industries from the start. Blockchain enthusiasts should seek to leverage existing standards that support clinical data capture and exchange (Figure 5, next page).

An advantage of using FHIR is that it can transfer specific bits of healthcare information—a word or code, not a whole record—from one place (e.g., the physician) to another (e.g., billing) so that healthcare workers need not sort through volumes of extraneous data to find what they need quickly. Communities of developers and researchers such as the Global Alliance for Genomics and Health (GA4GH) are supporting and developing FHIR for the exchange of health data. GA4GH is driving projects to build out the information infrastructure (forms, term lists, information models).

These projects will help us to understand the terminology, and we need new information models to describe a clinical phenotype and support clinical care and research. Representing these data as FHIR

resources with standard terminologies such as *human phenotype ontology* (HPO) and *systematized nomenclature of medicine—clinical terms* (SNOMED CT) will enable interoperability in the health system and help data analytics in research. HPO aims to provide a standardized vocabulary of phenotypic abnormalities in human disease. SNOMED CT is a comprehensive, multilingual clinical healthcare terminology to encode the meanings used in health information and support the active clinical recording of data.

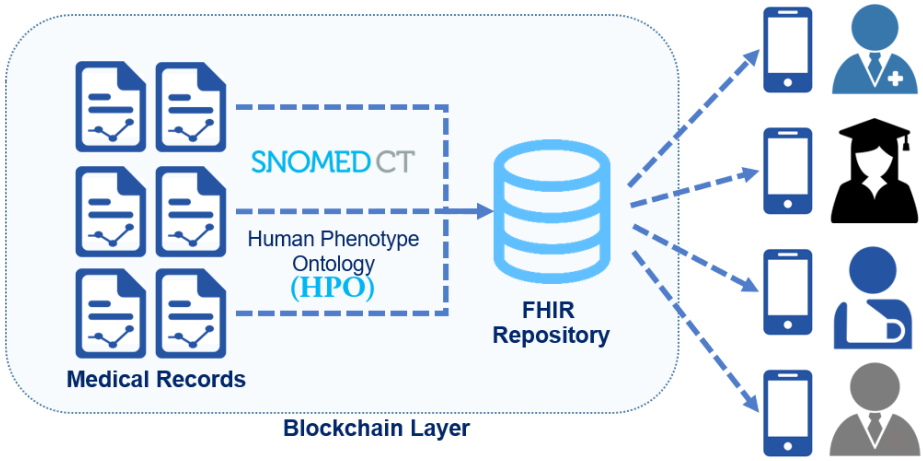
While most established players in the EHR-ecosystem make their own systems, third-party developers could connect all the information through open APIs. This environment heralds an excellent opportunity for start-ups and smaller companies to enter the market. Tech giants embrace many new technologies such as nanotechnology, self-driving cars, artificial intelligence, and virtual reality. Blockchain presents one of the most substantial non-corporate start-up opportunities to further interoperability.

Strategies to move healthcare verticals forward

Using blockchain to revolutionize healthcare presents a unique opportunity to simplify a process overburdened by complexity. With industry-wide collaboration, stakeholders can share the cost burden of basic research tasks.

Figure 5: The need for standards development and adoption

In healthcare, standards provide a common language and set of expectations that enable interoperability among systems and devices. New platforms based on blockchain technology need to adopt standards. Vendors and communities that develop new EHR platforms should use the HL7 FHIR standard so that users could transfer healthcare information over standard APIs.



Collaborations in the blockchain space

We have many successful examples of precompetitive collaborations in which stakeholders had the right incentives for working together for mutual benefit such as the Biomarkers Consortium, launched by the FDA and pharmaceutical and biotechnology companies with the goal of developing biomarkers for diagnosis and treatment of diseases, or the Innovative Medicines Initiative, initiated by the European Federation of Pharmaceutical Industry Associations (EFPIA) and the European Commission.[22] Let's look at two such collaborations, Hashed Health and the Hyperledger Healthcare Working Group.

Hashed Health is a healthcare innovation firm leading the design, development, and productive use of blockchain and distributed ledger technologies. It partners with public and private sector clients to develop solutions for health delivery challenges.

Hashed Health

Hashed Health is a healthcare innovation firm leading the design, development, and productive use of blockchain and distributed ledger technologies. It partners with public and private sector clients to develop solutions for health delivery challenges. Hashed Health's mission is to create new, shared value systems for individuals and communities of health through a variety of enterprise and consumer-focused projects. To empower its consortium members, Hashed Health provides value-added services including product management, product development, regulatory guidance, and technology support services for blockchain solutions and blockchain networks. Its healthcare experts help members launch new industry level solutions and expose them to existing networks so they can actively explore, pilot, or use existing solutions. Hashed Health educates members, organizes multi-sector proofs of concepts (POCs), and navigates regulatory hurdles by, developing technology, supporting technical standards, and providing blockchain/distributed ledger network support.

Members can join workgroups focused on specific business problems such as security, revenue cycle, payments, supply chain and pharma, consumerism, and legal. Workgroups meet regularly to learn, collaborate, and advance opportunities. One consortium member, Accenture, is a global management consulting and professional services company. Accenture focuses on developing industry use cases for distributed ledger technologies and identifies opportunities where organizations can implement solutions at scale. Another member, Change Healthcare, is one of the largest independent healthcare IT companies in the United States. It joined the consortium to help advance blockchain innovation and distributed transactional protocols in healthcare.

Hyperledger Healthcare Working Group

In December 2015, the Linux Foundation started Hyperledger, an umbrella project of open source blockchains and related tools, to support the collaborative development of blockchain-based distributed ledgers. The project intends to build an open platform that met the demands of users in various industries and to simplify business processes.

The project working group will host and foster technical and business-level conversations about appropriate applications for blockchain technology in the healthcare industry.

Large companies interested in blockchain technology are predominantly collected in the Hyperledger consortium. Premium members include Intel, Airbus, Baidu, Fujitsu, Cisco, Daimler, SAP, and American Express. Members are cross-sectoral, including leaders in finance, banking, IoT, supply chain, manufacturing, and healthcare. Among the members interested in healthcare applications are Microsoft, Huawei, and IBM, one of the founding members of the Hyperledger Project. The project interests healthcare organizations because of its dedicated healthcare working group, which will host and foster technical and business-level conversations about appropriate applications for blockchain technology in the healthcare industry.

Hyperledger Fabric

Hyperledger Fabric is a framework (initially contributed by Digital Asset and IBM) that leverages container technology to host smart contracts called *chaincode* that make up the system's application logic. Intended as a foundation for developing applications or solutions with a modular architecture, Hyperledger Fabric allows components, such as consensus and membership services, to be plug-and-play.

Hyperledger Quilt

In October 2017, Hyperledger announced its latest project, Hyperledger Quilt, offering another potential framework for organizations to develop their healthcare blockchain solution. Quilt is an implementation of the Interledger protocol (ILP). ILP is primarily a payment protocol and routes and shares data across different digital ledgers. It also isolates senders and receivers, protecting them from centralized transaction failure. Quilt has a critical function in a world where thousands of new blockchains are developed at a rapid pace. The Quilt framework is a ledger interoperability system for Hyperledger projects that will connect compatible and complete transactions regardless of the Hyperledger framework an organization uses to build its blockchain solution.

PokitDok

PokitDok used the Hyperledger framework to create one of the first healthcare solutions. Its API platform facilitates the integration of healthcare business data at scale. The company offers five types of solutions: clearinghouse (X12), private label marketplace, scheduling, identity management, and payment optimization. All of the data, regardless of where they originate, are maintained and verified across an encrypted, distributed network that uses the Hyperledger Sawtooth blockchain, a modular platform for building, deploying, and running distributed ledgers.

ScriptDrop

Another start-up that uses the Hyperledger framework is ScriptDrop. The company has built a blockchain that enables two services that

interact with the patient: (1) prescription delivery and medication reminders, and (2) adherence tokens that patients can use as cash discounts on co-pays to incentivize them to interact with this network. Hyperledger Quilt is developed in Java and provides libraries and reference implementations of core Interledger components. In time, it will provide ledger integrations for other Hyperledger projects.

"We are considering tracking all of our products from manufacturing to the end users."

ARMIN FURTWÄNGLER
Global Senior Medical Director
Boehringer Ingelheim Pharma

Collaborations with big pharmaceutical companies

While established players, particularly big pharmaceutical companies, are typically the healthcare players, their current rate of innovation is too slow to keep up with all the new players entering this field. This is particularly true in the areas of new technology capabilities, piloting and launching new products, and overcoming legacy mind-sets and functional silos. Large tech companies like Amazon, Google, Baidu, Tencent, and Apple have not only the resources to enter the healthcare market but also a vast expertise in sensing and responding to customers' needs, something often lacking in the pharmaceutical sector.

Already, some experts argue that Amazon will be the winner in the race to dominate healthcare.[23] Amazon and other tech giants can leverage massive cloud and AI capabilities and have extensive experience with non-regulated customer-centric services and products in a most competitive environment. Almost all drug manufacturers need to increase the efficiency of drug development because the current model of operating addresses neither the growing demands for innovative drugs nor the increasing cost. It's time for big pharma companies to move into the blockchain space.

Among the innovators predicting the future of big pharmaceutical companies, is Dr. Armin Furtwängler, the global senior medical director of healthcare innovation of Boehringer Ingelheim Pharma, an international research-driven company and one of the world's 20 leading pharmaceutical firms. He has carefully considered how pharmaceutical companies can leverage blockchain to adapt and compete with the healthcare newcomers who are ready to transform the multi trillion-dollar part of the economy.[24]

Dr. med. Armin Furtwängler, global senior medical director of healthcare innovation, Boehringer Ingelheim Pharma, and co-founder of the Blockchain for Healthcare Expert Circle.

Dr. Armin Furtwängler © 2017 Axel Schumacher. Photograph used with subject's permission.

Axel Schumacher: Armin, what are the main blockchain areas that you and your colleagues in the pharmaceutical industry are examining?

Armin Furtwängler: What we discuss at Boehringer Ingelheim Pharma and with other pharma companies in a consortium are the "low hanging fruits" in the blockchain space, particularly the supply chain for pharma. We are considering tracking all of our products from manufacturing to the end users, especially if you have detailed requirements such as cold-chain, where you have sensors to control the temperature; such as keeping the product below a specific threshold. Ultimately, what we in this international blockchain consortium (an expert circle of pharmaceutical companies

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and technology providers) are trying to establish (our "moonshot idea"), is a way to enable patients to share their data using blockchain technology. These data can be genomic data, data stored in electronic health records or other health data, with clear rules, how to use this information; for example, who will be granted access to which part and level of detail of the data, and how and where it should be stored? Finally, the use of blockchain technology could also lead to a completely new reimbursement system and strategy, where the patients could get rid of all the intermediaries, whether this is a wholesaler, pharmacies or even —in the future—physicians. This will empower patients to directly interact with their respective and personally chosen healthcare providers.

Axel: Are you developing your own solutions in-house, or are you working with external service providers to build your blockchain platforms?

Armin: Both. We have several on-going projects, where we are working internally with our IT colleagues and data scientists. Partly, we also share the efforts with collaborators, such as the Fraunhofer Institute [a German research organization with 69 institutes spread throughout Germany, each focusing on different fields of applied science], and with the group of Prof. Dr. Philipp Sandner, head of the Blockchain Center at the Frankfurt School of Finance and Management. In addition, we initiated a pharma and technology consortium, the "Blockchain for Healthcare Expert Circle," initially in Germany, Switzerland, and Austria, but also long-term across and at a later stage beyond Europe. Furthermore, one of our consortium partners, Merck KGaA, already joined the Ethereum Enterprise Alliance in May 2017, and several other pharmaceutical companies will likely join soon as well (potentially Pfizer, Boehringer Ingelheim, and others).

Axel: What should be done by the blockchain enthusiasts to push the traditionally slow moving pharmaceutical community to adopt blockchain solutions faster?

Armin: This is mainly a communication problem, related to some negative perceptions around the only blockchain use case, cryptocurrencies, of which a majority of people are aware at this point in time. I am facing this problem with many conservative management colleagues who have heard about blockchain only in connection with virtual money such as bitcoin, ether, XRP, dash, and others. Those cryptocurrencies are primarily associated with money laundering, the darknet, and all their unwanted associations; therefore, they have a bad reputation. If we want to include blockchain technology in the very sensitive personal healthcare environment, we have to establish and work jointly toward a level of trust into blockchain technology and its potential future use cases.

Axel: Is this distrust of blockchain in the healthcare space a general problem or is it particularly evident in Europe?

"The most prominent opportunities are certainly regarding electronic health records, where blockchain can democratize healthcare to a certain extent and give power back to the patients."

ARMIN FURTWÄNGLER
Global Senior Medical Director
Boehringer Ingelheim Pharma

Armin: It is certainly a European problem, with Germany probably the worst, especially when it comes to data protection and adapting to new technologies. Also, pharmaceutical companies are still suffering from a bad reputation, even though they have delivered innovative medications for the past 150 years. Whether blockchain solutions developed by IBM, Microsoft, Google, or governments are more trustworthy than those designed by the pharma industry remains to be seen. Developing new blockchain solutions should probably be tried not by single blockchain companies (such as Healthcoin, Gem, or others) but in a multistakeholder approach, where we create a new ecosystem of information and communication technology providers, pharam, and computer and software companies all coming together to build something trustworthy.

Axel: What about governments? Can they have a role in this process to bring blockchain and healthcare together?

Armin: Yes, particularly in certain healthcare ecosystems such as the Baltic regions and in more autocratic countries like Russia or China, which has made bold moves in blockchain technology. Even in large countries such as India, the government could have vested interest in establishing blockchain solutions in the healthcare system.

Axel: Besides supply chain, where do you see practical approaches for the pharmaceutical companies to invest?

Armin: The most prominent opportunities are certainly regarding electronic health records, where blockchain can democratize healthcare to a certain extent and give power back to the patients. There are huge discussions and controversies over "who owns the data," such as genomics. Who will have access to those individual data sets? The employer, the government, or a research institution on the academic side? Those questions should be for the customer (the patient) to decide!

Axel: But in many countries, electronic health records are heavily regulated by the government, and innovations have failed miserably. This lack of progress cannot be a technological problem.

"Mistakes happen because stakeholders cannot agree."

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Global Senior Medical Director
Boehringer Ingelheim Pharma

Armin: Mistakes happen because stakeholders cannot agree. Everybody wants to be part of the decision process; data is the new currency. Health data will be especially valuable in the future; but so far, the patients do not see a single cent of that money or any other incentive. Nevertheless, the healthcare ecosystem is changing, and new legislation or regulations might be introduced, partly under the pressure of new technologies such as blockchain, artificial intelligence, machine learning, and other digitization efforts.

Axel: Do you expect that pharma companies will still play a significant role in it or do you fear that you will be overrun by new players in the healthcare market, such as Google or Amazon, who aggressively move into the healthcare space?

Armin: There is no time to lose, or rather to get up to speed! Amazon, for sure, is a key player, Apple as well and, of course, Chinese players such as Tencent or Baidu and many others. Those data giants will all enter the lucrative healthcare industry with new business models that are going to dematerialize, demonetize, and democratize today's system. Many pharma stakeholders in North America and Europe do not have them on their radar, yet.

At Shivom, people can share their genomic and health data with researchers; in exchange, the company either sponsors the sequencing effort or directly compensates the data owner with tokens.

Blockchain will change the pharmaceutical business model in two areas: (1) patient care and (2) value-based care. For example, for patients who decide to participate in a clinical trial, it is complex and requires weighing the pros and cons of potential medical benefit versus the unidentified risks of side effects. They also must consider the time, effort, and commitment needed to comply with the study protocol. If there is an incentive for participation, the outcome of the decision might be more favorable.

One incentive might be to offer patients the opportunity to become owners of their data and of the research and development efforts for their trial. Having a process based on blockchain technology could provide value for patients by making the all of the patient data for the transparent. Patients can then monetize their data, for example, by anonymously selling controlled access to their health data to pharmaceutical companies.

Shivom is one pharmaceutical company in the blockchain space that practices this principle. At Shivom, people can share their genomic and health data with researchers; in exchange, the company either sponsors the sequencing effort or directly compensates the data owner with tokens, which patients can use to pay for other health and wellbeing apps and services. This business model is based on shared value, which opens new opportunities for observing wide-reaching patterns in drug development while preserving patient privacy and control and lowering the overhead associated with traditional clinical trials. In this model, blockchain technology enables a new market to emerge between data producer and data consumer. It empowers both researchers and patients who can decide how much and which metadata to release.

Value-based healthcare delivery is a framework for restructuring healthcare systems around the globe. Distributed ledger platforms offer a once-in-a-generation opportunity to reshape the fundamental infrastructure in healthcare by embedding rational economics into health processes.

As pharmaceutical companies move toward value-based healthcare, the delivery model of hospitals, physicians, and drug manufacturers will shift so that healthcare providers receive payment based on patient health outcomes. According to Harvard Business School Professor Michael Porter, value-based healthcare delivery is a framework for restructuring healthcare systems around the globe. Distributed ledger platforms offer a once-in-a-generation opportunity to reshape the fundamental infrastructure in healthcare by embedding rational economics into health processes. Porter proposed

following patients' medical condition over the full episode of care and introduced a value-based strategic agenda that crosses many areas of the health sector.[25]

As pharmaceutical companies look to transform their traditional business models and rethink the value chain, they must also restructure their product and service offerings. To restructure, they need partners to help navigate a far more complex market. They could even leverage blockchain technology to become health information companies, IT vendors, and disease management organizations themselves.

Collaborations with innovators beyond blockchain

While blockchain has been described as one of the most innovative technologies of recent decades, this technology is still in its infancy with issues that have yet to be resolved, such as how to scale blockchain technology or how to solve incompatibility issues with existing IT systems. In some rare instances, the absolute immutability of the blockchain might be a hurdle standing in the way of its adoption. Another obstacle might be potential regulatory restrictions in light of the new European Union's General Data Protection Regulation regarding consumer data privacy and ownership rights, or the US Fair Credit Reporting Act, among others.

Such regulatory frameworks might require a mechanism by which personal data can be redacted or censored, which is not possible on an incontrovertible platform. As a consequence, in specific circumstances, we might need an editing capability to accommodate an imperfect world where human error or unexpected events require flexibility. We also have insufficient data standards, interoperability bottlenecks, and some concerns about security. However, the evolution of the technology is rapid with adaptions of the Bitcoin blockchain, including new distributed ledger concepts, some specifically designed for machine-to-machine interactions such as the IOTA tangle.

IOTA tangle

Technological innovations succeed when each new product is relatively more efficient and effective than its predecessor.

Technological innovations succeed when each new product is relatively more efficient and effective than its predecessor. The classical blockchain framework is not ideal for machine-to-machine transactions, which will be increasingly important for mobile health applications and wearables. New blockchain-like protocols specifically designed for IoT will open new fields in digital health. For example, using current blockchain technology, a stakeholder must pay a fee to make a transaction. Consequently, transferring a tiny amount of data, a so-called micropayment makes no sense if there is a fee many times larger than the value of the data.

One innovation that could ease this bottleneck is the *tangle*, a microtransaction distributed ledger. The main developer of the tangle ecosystem is the IOTA Foundation, a nonprofit quickly

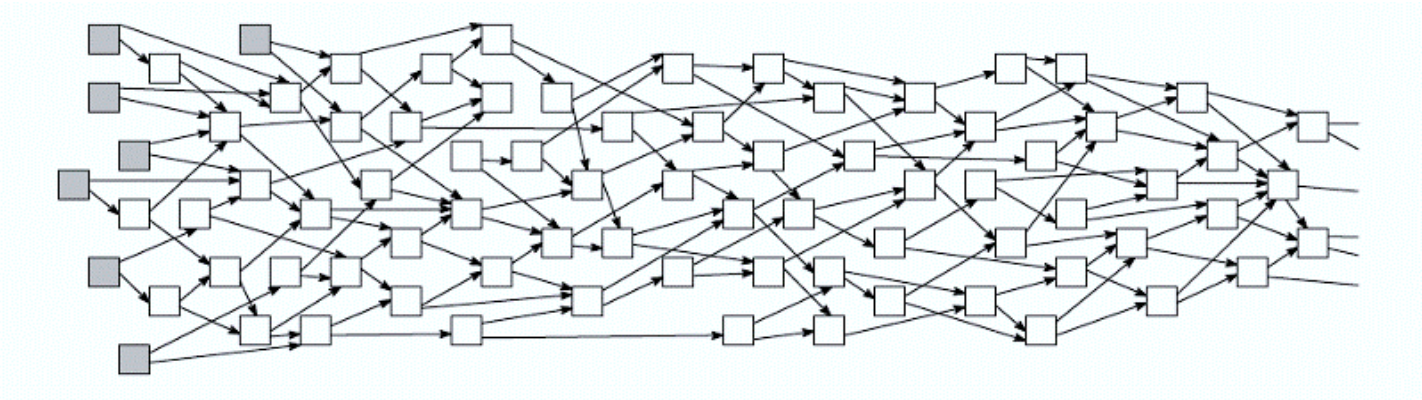
gaining recognition. Its quantum-proof ledger protocol, IOTA, settles transactions with zero fees so that devices can not only trade exact amounts of resources on demand but also store and verify data from sensors and data loggers securely on the ledger. With this new blockless distributed ledger, consensus is an intrinsic part of the system.

How does IOTA tangle work?

Instead of the global blockchain, there is a *directed acyclic graph* (DAG) for storing transactions. In networking parlance, a graph is a collection of nodes and edges, where each node corresponds to an object and each edge represents a connection between two objects. In a directed graph, the connection flows in one direction. *Acyclic* means without cycles: the graph neither contains nor represents a cycle. Nodes conduct transactions, which constitute the site set of the tangle (Figure 6). To send an IOTA transaction, a user's device must confirm two other transactions on the tangle. To confirm these two transactions, any digital device (e.g., laptop or smartphone) performs low difficulty puzzles. In IOTA, the user and validator are no longer decoupled. The transaction removes the data-mining requirement and the risk of centralization of validation. Since there is no pool of miners to validate blocks of transactions, there are no transaction fees.

Figure 6: The IOTA tangle

The tangle, a *directed acyclic graph*, represents a collection of nodes. It allows connectivity among nodes without circular edging. It is a network where each node is linked to others in one direction only ("directed"), and users never end up where they started ("acyclic"). Like a blockchain, a tangle is a distributed database that relies on a consensus and validation mechanism. However, in the IOTA tangle, users and validators are the same. To issue a transaction on the tangle, users must approve other transactions, thereby contributing to the network's security.



The Tangle © 2017 Serguei Popov, IOTA.org. Used with permission.

Why IOTA for healthcare applications?

Although IOTA is uniquely suited for the Internet of Things, the tangle enables a variety of use cases that involve secure data transmission. True micro- and even nanotransactions provide developers with a new set of tools for building applications in both IoT and the Web. Because of these tools, business models that have been inaccessible due to prohibitive transaction fees are now possible. IOTA's unique tangle architecture provides several options to transfer data, making it possible to establish secure and authenticated communication channels between devices and entities. All data transferred through IOTA is fully authenticated and tamper-proof, making attacks impossible.

IOTA's unique tangle architecture provides several options to transfer data, making it possible to establish secure and authenticated communication channels between devices and entities.

When we reflect on data security in healthcare, we should consider:

- Data privacy: the data are encrypted and secure
- Data integrity: protection against fraud and tampering
- Cyberterrorism: malicious attacks could destroy a healthcare infrastructure
- Critical problems that demand secure solutions

IOTA is helpful in all of these areas. First, IOTA has an integrated quantum-resistant algorithm, the Winternitz One-Time Signature Scheme. This protection is necessary for the long term as quantum computing will end encryption as we know it. The Winternitz hash is known as a post-quantum signature because the cryptographic algorithm is thought to be secure against a quantum computer attack. Second, IOTA's proof-of-work mechanism works differently from traditional blockchains in that IOTA prevents spam and Sybil-attacks, wherein reputation system is subverted by forging identities in peer-to-peer networks. Also, with a growing number of smart medical devices, there will be more data traffic, and all this information must be encrypted. IOTA uses a system called *masked authenticated messaging* (MAM) to secure and encrypt entire data streams. Only authorized parties will be able to read and reconstruct the stream.

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IOTA solves data integrity issues by storing the data in a distributed and trustless fashion among the nodes in the network, making it auditable. No one can alter the original data without the other nodes of the network noticing that the data are incompatible with their copy. There is no reason to store the whole dataset in the tangle; only the hashes must be stored. Hashes are the equivalent of biometrics for data; if content is changed, the hash will change. IOTA guards against malware and ransomware attacks such as the one in May 2017 that encrypted computers and demanded users pay money to restore access in corporations across the world—including hospitals, England's National Health Service, and Merck, one of the largest drug manufacturers in the States. The malware program, WannaCrypt, locked doctors and nurses out of patients' records and included a countdown clock that threatened to destroy the affected files after a few days unless the organizations paid. IOTA assures data integrity.

Additional features of the tangle architecture include its infinite scalability, which is hard to implement with blockchains such as Bitcoin and Ethereum. Since each transaction requires the sender to verify two other transactions on the tangle, more transactions can be confirmed with zero cost as the number of users increases. So IOTA scales proportionally to the number of transactions (Figure 7).

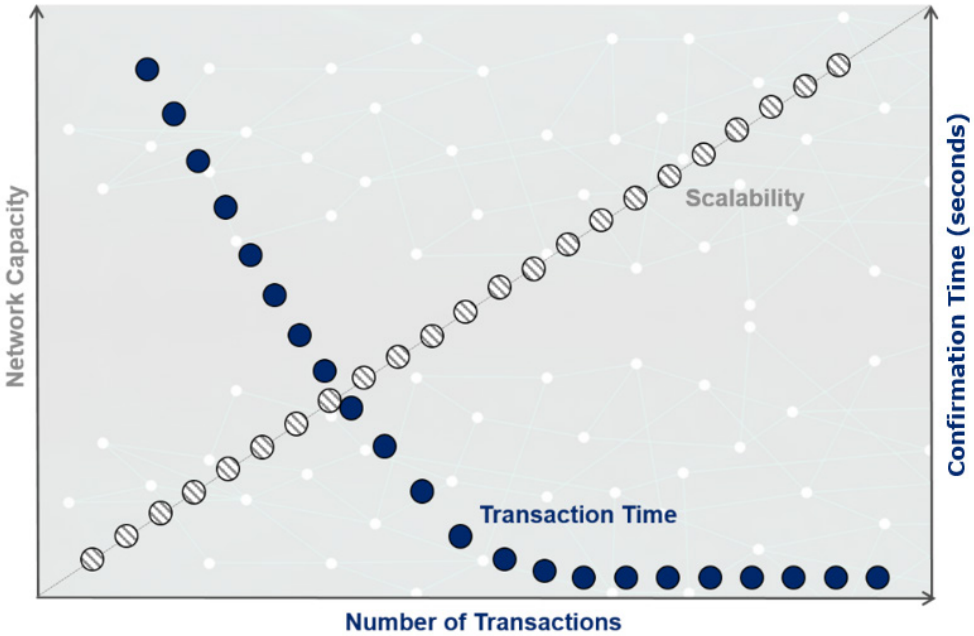
How to get involved with IOTA?

The IOTA Foundation is responsible for developing and maintaining the core open source protocol of IOTA. There are already several healthcare projects in development. The foundation, registered in Germany as an official nonprofit organization, is trying to extend IOTA's utility, open IOTA to anyone who wants to build on top of the IOTA network and support the hardware development. For example, a project called Jinn is a new type of microprocessor designed for IoT.

Companies adopting IOTA are primarily from fintech and automotive sectors. Over 30 major corporations—Bosch, Cisco, Innogy, Microsoft, Canonical/Ubuntu, SAP, UBS, and one of the world's largest automotive manufacturers—are developing prototypes on the tangle platform. Although the healthcare industry is behind other industries, the IOTA team is catalyzing collaboration across public and private healthcare research and innovation stakeholders such as Norway Health Tech, the Norwegian University of Science of Technology,

Figure 7: IOTA tangle scales proportionally

The greater the number of transactions conducted on the IOTA tangle, the faster the verification of those transactions. Since the tangle requires each initiator of a transaction to verify two other transactions, the tangle can process more transactions as the number of users initiating them increases.



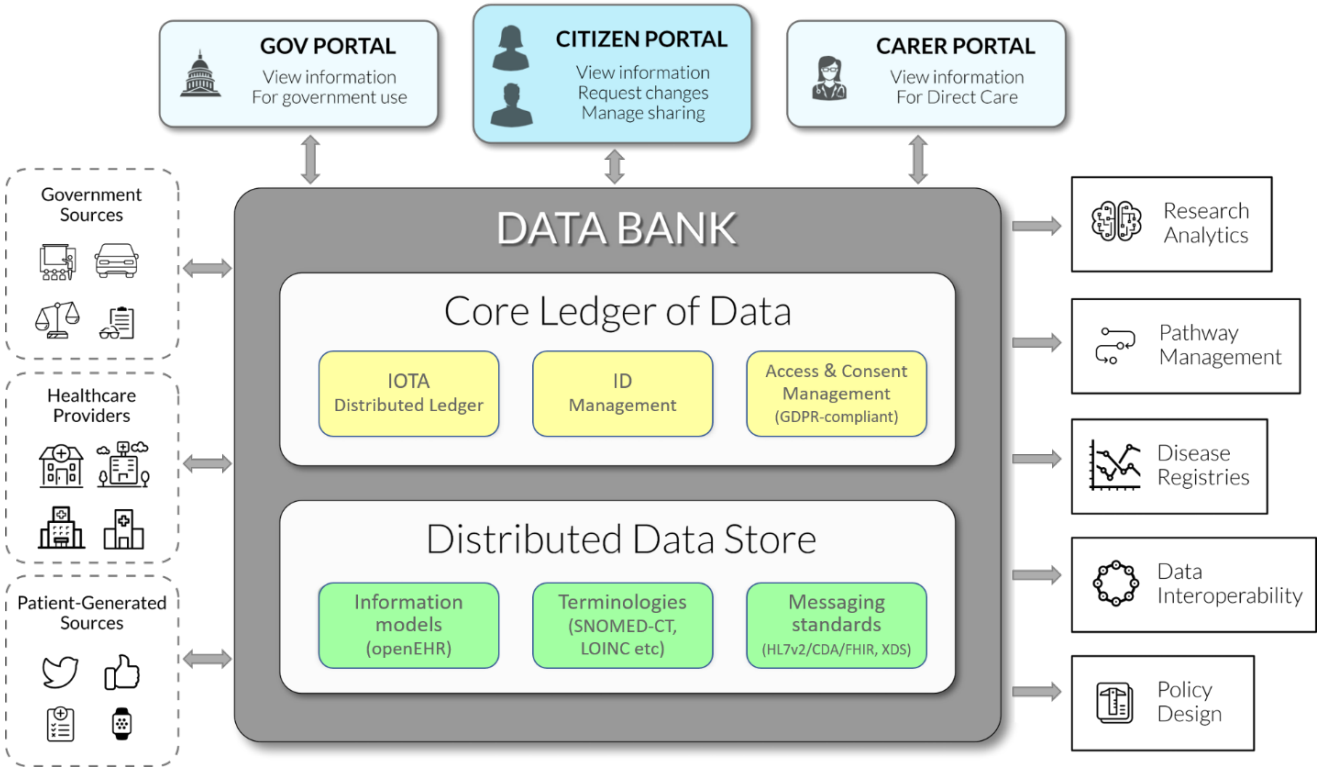
the Norwegian Centre for E-health Research, and the Oslo Cancer Cluster.[26] IOTA will also foster cross-silo knowledge sharing among industries and geographies, starting with Northern Europe.

The IOTA Foundation provides developers access to the IOTA sandbox tools, utilities and environment for experimenting (Figure 8). IOTA is open source so that anyone can participate in its development.

The IOTA founders have also recognized opportunities arising from using the technology in healthcare start-ups. They have started to develop their own applications to address the issue of connected healthcare, particularly data integrity and the security of sensitive data, data provenance and event logging, and easy ID management for data access. Work has commenced on the initial proof of concept in healthcare—namely, remote monitoring of chemotherapy patients using IoT devices—to track factors such as blood pressure, pulse, weight, temperature, blood glucose, genetics, activity levels, diet, directly from the patient's home. The general premise is that all the biometrics data (in the form of hashes) can be put onto the IOTA ledger so that users can automatically check if the raw data have

Figure 8: High-level schematic of the proposed IOTA "MyData" sandbox

This sandbox is a system to aggregate medical data and make it available for sharing and secondary. IOTA worked closely with local regulators to ensure its acceptability. Beyond e-health, IOTA's MyData ambition and sandbox proposals cover personal data in areas such as finance, mobility, energy, and retail.



Source: Navin Ramachandran, University College London Hospitals, co-founder of OpenCancer.net, and member of the IOTA Foundation.

been corrupted. These data are directly encrypted from connected devices in real time so that no one can intercept it. It uses a new form of cryptographic protocol that leverages randomness and the asymmetric cost of computation versus memory. This framework allows otherwise inaccessible data from millions of people to be securely leveraged, protecting the privacy of the all individuals.

The ultimate goal is to provide the best in healthcare for the individual, with blockchain technology increasing the speed in which precision medicine is implemented at a lower cost.

The distributed ledger revolution has just begun with the majority of use cases yet to be conceived. Developers will invent even more solutions by using IOTA's next generation ledger. At the time of writing, we have no way of running a private tangle; however, the IOTA Foundation is currently establishing a framework with a set of tools that will enable stakeholders to run their own tangles. These ledgers will not fully replace blockchain; rather, they will add to the current blockchain ecosystem by acting as oracles for smart contract platforms such as Ethereum and Rootstock. There are also non-blockchain solutions such as Apache Kafka, a geospatial distributed event sourcing system.

Conclusions and recommendations

Healthcare is on the cusp of a major paradigm shift. Blockchain can be indispensable in building a global precision-medicine ecosystem that optimally connects patients, clinicians, and researchers, and lower cost. Blockchain will improve such key areas as artificial intelligence-based diagnostics, big data analytics, data security, data sharing, health information exchange, identification of counterfeit drugs, interoperability of systems, patient engagement, research and development processes, and vertical business models.

The ultimate goal is to provide the best in healthcare for the individual, with blockchain technology increasing the speed in which precision medicine is implemented at a lower cost. Leaders and advocates of each stakeholder group in the ecosystem can take the following bold steps to expedite this important shift.

- **Join or form precompetitive blockchain consortia**. The time to establish precompetitive blockchain consortia is now. Participate in Hashed Health or Hyperledger healthcare working group, where the Hyperledger framework is constantly evolving. Although early blockchain consortia are operational, there are challenges in forming and propagating such collaborations, particularly among different types of stakeholders' interests. For example, varying levels of support for new collaborators make for an uneven playing field.

- **Be mindful of incentives and intellectual property.** To improve collaborations, consider open-source projects, IP-free zones, and patients or nonprofit steering committees.

The healthcare community must identify and train more software developers and engineers who understand how to build blockchain-based products and services that comply with healthcare regulations.

Different stakeholders, such as academics, industry, not-for-profit organizations, and regulators often need different incentives to participate. Participants might inadvertently share trade secrets or disagree on how to allow IP-developed collaborations. To minimize IP conflict, participants might need to channel all work and IP through the blockchain consortium, and then directly license IP from the consortium.

Collaborate with start-ups in the blockchain space. As blockchain organizations collaborate with start-ups, they should encourage sharing research and development costs with companies such as BurstIQ, Blockchain Health, Bloq, Gem, Guardtime, Shivom, Tierion, or YouBase among others. Such collaborations might allow blockchain companies to expand their client base in public and private sectors.

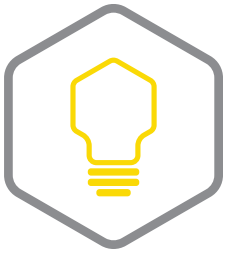
Hire blockchain-ready talent and cultivate blockchain know-how. The healthcare community must identify and train more software developers and engineers who understand how to build blockchain-based products and services that comply with healthcare regulations.

Persuade large stakeholders resistant to change of the benefits of blockchain. Big pharmaceutical companies are entrenched in the healthcare supply chain, yet they have not completely embraced the value-based, decentralized model of blockchain technology as a healthcare solution. Big pharma companies should consider leveraging blockchain to become health information companies, IT vendors, and/or disease management organizations.

Invest in a significant education campaign. Because stakeholders want to see results quickly, they need to understand why and how blockchain will be useful. Provide examples of where and how blockchain has succeeded in other industries. Explain how implementing a new system will save time, protect their data, and allow them to connect easily with others in the entire healthcare network.

Pursue relationships with technological innovators beyond blockchain. With the advent of new, blockless, non-fee based microtransaction system such as the IOTA tangle, there are new opportunities to collaborate with the next generation of data transmission in the healthcare industry.

Participate in health data alliances. The Global Alliance for Genomics and Health (GA4GH) offers a community for FHIR developers and researchers in exchange for health data. These developers are driving projects developing the information infrastructure (forms, term lists, information models) to support the capture or sharing of information.



About the Blockchain Research Institute

Co-founded in 2017 by Don and Alex Tapscott, the Blockchain Research Institute is a knowledge network organized to help realize the new promise of the digital economy. It builds on their yearlong investigation of distributed ledger technology, which culminated in the publication of their critically acclaimed book, *Blockchain Revolution* (Portfolio|Penguin).

Our syndicated research program, which is funded by major corporations and government agencies, aims to fill a large gap in the global understanding of blockchain technology and its strategic implications for business, government, and society.

Our global team of blockchain experts is dedicated to exploring, understanding, documenting, and informing leaders of the market opportunities and implementation challenges of this nascent technology.

Research areas include financial services, manufacturing, retail, energy and resources, technology, media, telecommunications, healthcare, and government as well as the management of organizations, the transformation of the corporation, and the regulation of innovation. We also explore blockchain's potential role in the Internet of Things, robotics and autonomous machines, artificial intelligence, and other emerging technologies.

Our findings are initially proprietary to our members and are ultimately released under a Creative Commons license to help achieve our mission. To find out more, please visit www.blockchainresearchinstitute.org.

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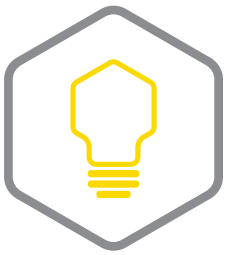

About the author

Axel Schumacher has over 20 years of research and development leadership experience in genomics, epigenetics, Bio-IT, aging and longevity. He is the author of "Blockchain and Healthcare Strategy Guide," the standard blockchain compendium for the healthcare industry. Axel has a documented track record as scientist, inventor, and business leader in academic, clinical, and pharmaceutical environments. He is also experienced in exploring strategic opportunities in the fields of precision medicine, multi-omics, blockchain, digital health, and genomics data analytics. He is a valued thought leader and strategic consultant, evidenced by an excellent publication record in leading scientific journals, and regular requests to write book chapters, white papers, and editorials from esteemed content providers. Axel works on translating scientific discoveries into practical applications to help understand, treat, and prevent complex disorders, but also to promote cutting-edge technologies that might transform healthcare and the way we age. In his spare time, he actively supports human rights efforts to improve global democratization, economic development, and conflict resolution, with a focus on evidence-based education and secularism. Axel holds a Ph.D. in Human Genetics from the University of Cologne/Germany.

Disclosures

Axel Schumacher is co-founder and CEO of Shivom, a company that builds a global genomics and healthcare ecosystem on the blockchain.

Notes

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