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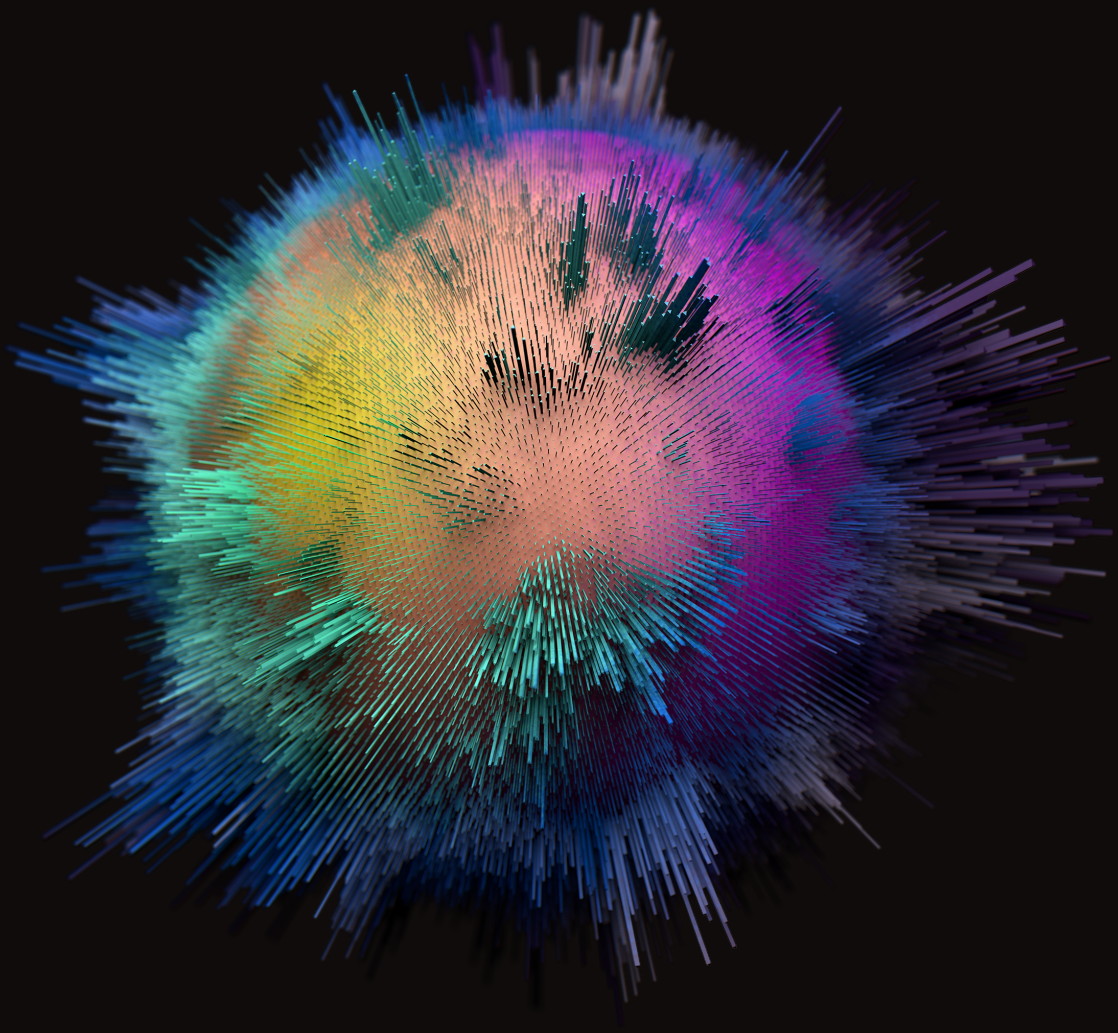

Blockchain opportunities for patient data donation & clinical research

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Introduction

Clinical research is the foundation for medical innovation that can positively impact patient lives. Patients themselves are at the center of the research equation; their medical profile and history are aggregated, analyzed, and curated to understand diseases, make new discoveries, and test research hypotheses. The importance of patient data to clinical researchers cannot be overstated, as research for new drugs can be stagnated due to a lack of availability of medical information to study.

Yet significant barriers exist that inhibit the secure and efficient sharing of patient data:

- Limited accessibility and knowledge of clinical trial (data sharing) opportunities
- Few incentives for patients to share their medical information
- Lack of trust that sensitive medical information will be kept secure
- Lack of digital health record interoperability and ease of aggregating data

The clinical research industry (pharmaceutical firms, research institutions, regulators, etc.) has attempted to implement solutions to address several of these issues, but none have fully succeeded. One such promising yet disruptive technology that has the potential to be the game changer needed to solve these issues is blockchain— a unique technology that holds capabilities to radically reshape industries and change the way information is transacted, stored, and shared.

The excitement surrounding blockchain's potential has predominately been focused on financial services; however, the life sciences and health care industry has the potential to be a new frontier for the technology as a novel solution to securely storing and sharing medical information.

In pursuit of exploring how blockchain has the potential to solve patient data challenges, a diverse group of twenty-plus clinical research companies (e.g., major universities, pharmaceutical firms, health tech startups), as well as patients/caregivers and government regulators, came together in November 2017 to ideate blockchain solutions, form working groups for specific topics, and commit to creating real blockchain solutions.[1]

To that end, the purpose of this paper is to:

- Outline the significant trends and issues affecting the organizing and sharing of patient data
- Define what blockchain is and its capabilities for clinical research
- Describe the key blockchain applications ideated from the diverse group of participating organizations
- Predict potential future implications of blockchain in the health care industry
- Spark a call to action from readers who want to contribute to the established blockchain working groups

Data donation trends & issues

Industry actors across the spectrum often operate with a shared goal to provide patients access to improved medicine. Yet, at no other point in history has the patient had more opportunity to shape and influence the health care they receive.

Patients now have unprecedented access to their health data and are actively collecting their own medical information. Laws such as HIPAA and the Affordable Care Act in the United States have codified access for patients to request their health records at any time and mandated that health care providers must provide data in the format in which it is retained (e.g., giving paper copies from a health record captured electronically is not sufficient).[2] This positions patients to be the best aggregators of their medical data – they can aggregate data from each medical center and physician they see that is stored in their electronic health record (EHR), as well as information beyond traditional records such as their fitness data stored on their smart devices or consumer genetic testing information.

This level of access offers tremendous potential. If researchers can harness the data hub that is each singular patient at population scale, then there will be no shortage of medical information that can be analyzed, which could ultimately lead to a more efficient care ecosystem. Moreover, many patients want to donate their data for medical research. According to various surveys, nine-out-of-ten patients with access to their health data are willing to share that data to support research.[3] This figure spans patients at elite medical centers or general patients in the community – on the whole patients want to be part of the solution to solving medical problems. However, there are issues impeding their ability to share their information, including the following:

Limited accessibility and knowledge of clinical research opportunities

There are over 93K registered clinical studies currently being conducted in the United States, and the number of studies has doubled since 2010.[4] A commonality among these clinical studies is the need for patient data and participation. Although investigators and sponsors in a study actively recruit patients, typically it is the patient suffering from diseases that tend to seek out opportunities to participate in research. Their experience can be inconsistent, as patients seek out the advice from their treating physicians who are unlikely to have knowledge of every applicable trial or understand the requirements for participation. Often this treating physician is only aware of studies in which they are participating as an investigator. This lack of accessible information can lead to patient frustration and at times desperation to find research opportunities that could positively affect their lives and the health of others.

Few incentives for sharing information

Donating medical data takes work. Patients need to act as a data aggregator which may include requesting medical information from various physicians and then manually filling out forms or entering data so that the information may be readily analyzed by researchers. This process is often time-consuming, inconvenient, and consequently underutilized. No one is likely to be more


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motivated than a patient suffering from a life-threatening disease to aggregate and share their information in hopes that their action will yield a positive effect for their health. However, the majority of the population lacks an immediate incentive to share their private medical information given the heavy burden involved to aggregate and share today. Lack of incentives for research data sharing slows the generation of evidence, leading to redundant data entry into study databases (with required data monitoring and cleaning) or requiring other ways to acquire and normalize data across different health systems with different data norms and permissions.

Lack of trust in the privacy of patient medical information

Medical information is one of the most intimate forms of data: it can describe a person's identity at a level that reflects one's genealogy, lifestyle, and even future. Medical information can also be a valuable form of data: an electronic health record is now more valuable to a hacker than a credit card number,as these records typically contain names, birth dates, billing information, and medical history.[5] In fact, the average health record sells on the black market for $10, which is multiples higher than a credit card number. [6] Further, even if aggregated and de-identified, trusted health data can sell for significantly more than this amount; identifiable data could be exponentially more valuable. Recent events, such as the data breach of a prominent fitness app where over 150 million user accounts were breached, provide further evidence that hackers are targeting this type of information.[7] The sensitivity and value surrounding medical data has likely contributed to patients lacking trust in medical researchers to protect and secure their information. Patients will typically be hesitant to donate their information if they have any concerns whatsoever that their information could be shared with the wrong party or hacked.

Lack of electronic medical information interoperability

A patient's medical information can be scattered across medical centers, physicians, health plans and others. Often these health care organizations store this data in different digital formats and EHR systems, which can make the task to aggregate and analyze patient data on common terms very difficult and can result in inconsistent formats in the way data holders may make health data available to patients. The lack of continuity that surrounds medical data and EHRs is a major concern for patients. For example, Carolina Drummond, a cancer survivor and advocate for her own care, points out that "we have learned to be our [own] best advocates" because patients are forced to collate data and search for answers themselves. Carolina, like many patients, has experienced incorrect diagnoses and depends on the data she collects to deepen her search for an accurate answer on her own. Her struggle is embodied in a small yellow notebook she carries with her to every appointment.

There have been major nonprofit projects, such as the FHIR protocol (fast health care interoperability resources) that seek to improve the interoperability of medical information, but these projects are still in the development stage and recommendations have not been universally adopted.[8]

The need for a game changer

Traditional solutions and technologies have not been able to completely solve these issues, leaving patients in a position where they face challenges taking advantage of their own medical information to accelerate new cures. A game changer is needed.

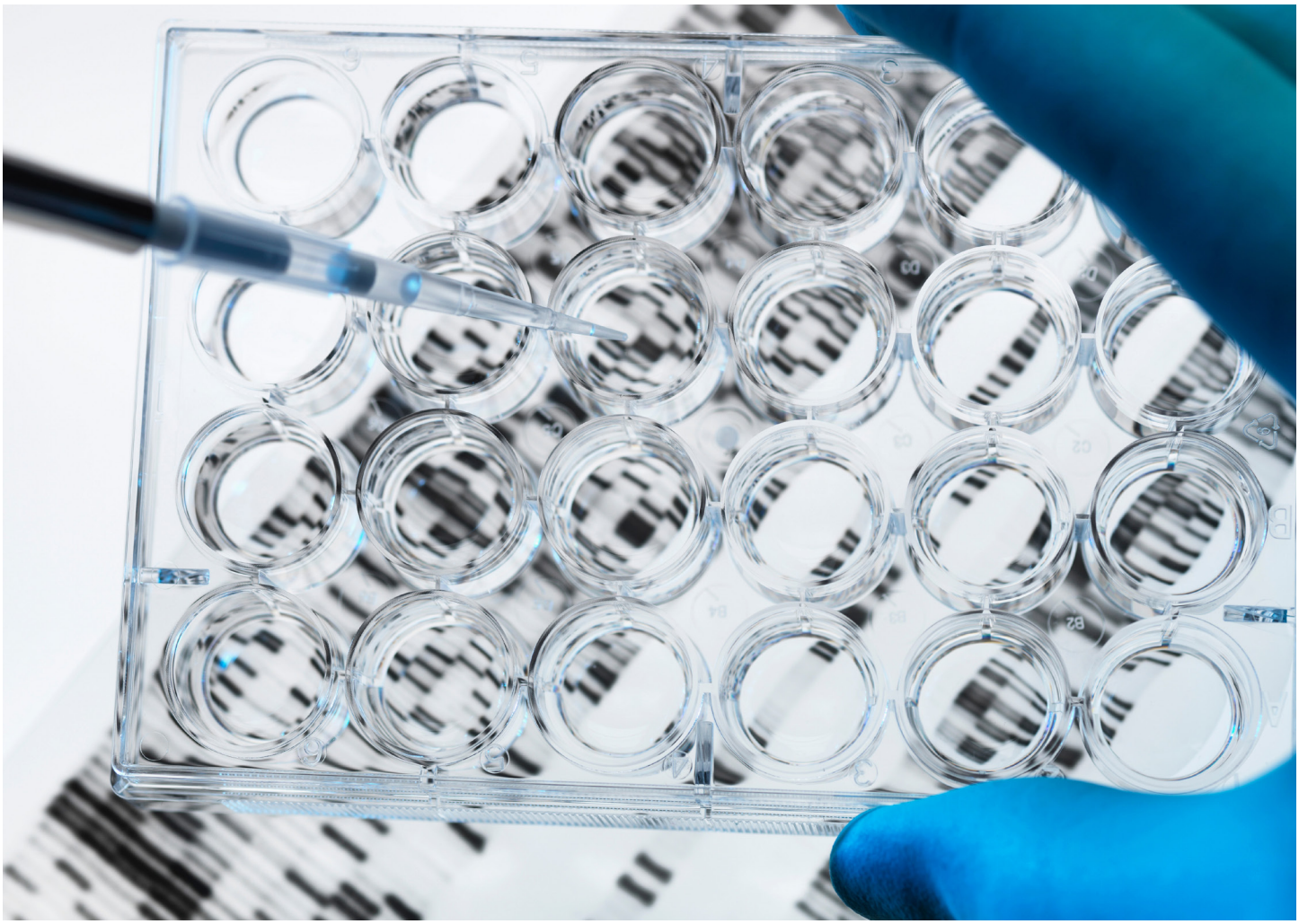
Blockchain: The potential game changer

Blockchain provides a way for information to be recorded and shared through a peer-to-peer community.

In this community, each member maintains his or her own copy of the information and all members must validate any updates collectively through a consensus process to validate transactions and events stored in the repository.

Blockchain has evolved from capturing cryptocurrency transactions (e.g., bitcoin) where entries are financial transactions, to a medium that can enable decentralized information sharing and application operations. In this new evolution, information on the blockchain can represent contracts, assets, records, transactions, identities, or practically anything else that can be described in digital form. At its core, blockchain provides a specific set of capabilities: transparency, trust, disintermediation, auditability, and smart contracts:

- **Transparency:** Data stored on the blockchain is available to all approved participants – creating a single source of truth
- **Trust:** Data are linked among tamper-proof blocks and is distributed across multiple participants – enabling trust between participants who don't need to know one another
- **Disintermediation:** By creating an ecosystem of trust, the blockchain can fulfill the roles of existing intermediaries
- **Auditability:** Data on the blockchain is everlasting and difficult to change – creating an extensive audit trail
- **Smart contracts:** Digitally encoded contracts / rules that autonomously and consistently execute on t he blockchain – providing new methods to agree to terms and validate transaction requirements



With the advent of these novel blockchain capabilities, the health care industry has started to take the technology seriously. The market for blockchain startup funding has reached epic proportions as over $1.6B in capital was raised in 2017 through initial coin offerings, with numerous health care startups successfully acquiring funds.[9]

Within the health care industry, there are many examples of blockchain implementations, including: Estonia's health initiative that has onboarded 1 million citizens onto a blockchain based health record system,[10] the State of Illinois' provider project that is storing physician licenses on a blockchain,[11] and pharmaceutical supply chain consortia formed by many of the world's largest firms (e.g., Pfizer, Merck).[12]

How blockchain can help solve the data donation issues

Due to its capabilities, blockchain may offer a solution to more easily aggregate health data in a secure, trusted, automated, and error-free way. A solution which enforces rules, privacy, and regulations in a mutually agreed upon manner, resulting in a smart-contract between patient and health care stakeholders can be an important enabler to clinical research. This can allow patients to more easily aggregate their data from different sources and share what they choose to with their physicians and researchers. All this puts the patient in the driver seat of health and well-being, rather than being along for the ride.

This new blockchain enabled paradigm can significantly impact the existing data donation issues (see table next page).

Data donation issues and how blockchain can help	
Accessibility and knowledge of clinical research opportunities	A blockchain shared among patients, pharmaceutical firms, academic research institutions, medical providers, and government regulators can act as the source of truth for clinical research opportunities, whereby patients can submit their medical information and search for applicable clinical research opportunities that match their medical profile.
Incentives for sharing information	The blockchain can help incentivize sharing of information through immediate transparency into clinical study results and crypto-tokens. As an example, through the blockchain, researchers can incentivize patients to participate by publishing the results of studies on the blockchain and distributing them to patient participants – so that patients can better understand how their information was used and the results that were achieved. Moreover, blockchain crypto-tokens (e.g., similar to digital currencies) can be awarded to patients who donate and share information in clinical studies, allowing opportunities such as copay relief or other use of currency.
Privacy of patient medical information	Patient information on the blockchain can be de-identified and permissioned through smart contracts so that only trusted viewers of the data can associate a record on the blockchain that contains medical information (e.g., history of illnesses, vitals, demographics) with the underlying individual who donated the information. This can allow researchers to analyze a rich set of de-identified information and then request access from the underlying individual to use their information for studies.
Interoperability of electronic medical information	Blockchain platforms are uniquely positioned to facilitate interoperability by creating a level playing field among data contributors where there is no single owner of information, where all participants can maintain their own copies of the data, and where the underlying patient can maintain their identity. Although this blockchain would require standards and agreements from various stakeholders, its distributed nature and capabilities (e.g., smart contracts that autonomously and consistently execute rules) can better facilitate widescale adoption among groups that do not inherently share information with one another when compared to other traditional technologies.

From blockchain hypothesis to action

On November 1, 2017, a blockchain workshop was held at Pfizer's Research Center in Cambridge, where over 50 individuals across 20 companies, and patients took part in an all-day session to understand issues inherent to patient data donation and ideate blockchain applications.

The group discussed numerous blockchain applications and then voted on the most impactful ideas that could serve as the foundation for future development. The following sections contain the key blockchain applications that were prioritized by the working groups and will be pursued over the coming months. As such, today these proposed applications are at their starting points and will evolve and grow as the teams work on them.

"Enabling patients a place to store and share their information through the trusted blockchain network would empower the patient to seek out clinical research opportunities or even develop their own networks of support groups to help one another with similar diseases. "

Clinical supply chain

Imagine a world where investigational drug product can be tracked by supply chain managers, clinical sites, and patients in an inter-operable Amazon-esque user experience that provides a fully auditable and transparent system. Where all stakeholders are allowed to have direct access to a trusted source of validated data, thereby ensuring quality and accountability throughout the end to end supply chain. This is the clinical supply chain enabled by blockchain.

In this new construct, blockchain would be used to connect disparate groups, systems and internet of things (IoT) devices involved in the chain of custody of drugs. The blockchain would be a critical component to store the clinical supply chain information to act as the single source of truth between all of the parties involved (manufacturers, CROs, distribution vendors, sites, patients, study teams etc.). The blockchain will help bring transparency to this ecosystem and help all parties better track and understand the status of investigational drugs from API (active pharmaceutical ingredients) to the patient.

Health information exchange

Imagine a world where all members of the health care ecosystem (across health plans, providers, academia, pharmaceutical firms, and patients) could be connected on a single health care information exchange built on blockchain; where all players know the rules of operation and can freely exchange information digitally between one or more parties through smart contracts.

Developing such a network would require a consortium between regulators and health care players to develop technology agnostic standards, policies, and governance to accelerate adoption of blockchain and promote knowledge sharing.

Longitudinal view of the patient

Imagine a world where patients can own their own data, share it, store it, and choose who has access to it. This would require extensive interoperability between the myriad of existing systems and parties and the development of a shared blockchain ledger that could act as the middleman between the different source systems and store patient data that is donated..

Enabling patients a place to store and share their information through the trusted blockchain network would empower the patient to seek out clinical research opportunities or even develop their own networks of support groups to help one another with similar diseases.

Patient incentivization

Imagine a world where patients have full control and understanding of how their data is used, where patients are compensated to maintain accurate and up to date health information. Where patients selectively contribute their data to research programs in disease areas that are of substantial personal significance.

Players in the health care industry can benefit greatly from more diverse and comprehensive datasets, while patients contribute directly to medical breakthroughs that impact themselves, their families, and communities. Blockchain can be a mechanism to enable this objective to understand who has requested access to their data, who has permission to view it, and potential token based compensation for when they share data in a clinical study.

A look to the future

To help the health care industry address its challenges, a game changer is needed, and blockchain has the potential to be the answer we've all been waiting for.

With blockchain as the foundational technology to improve data sharing and bring patients to the center of their own health care, there are immense impacts that blockchain could have on the future:

- Will blockchain be an enabler for advanced artificial intelligence models and algorithms that can leverage enormous clinical data sets stored on the blockchain to perform deep learning to generate new insights?
- Will blockchain bring about the age of digital clinical trials, where patients can remotely send in their samples, with each touchpoint being tracked on the blockchain, and have immediate visibility into study results without ever having to leave their home?
- Will blockchain – alongside data standards – be the connector between patient smart devices (e.g., wearables, biometric patches) and researchers / health providers where personalized recommendations can be directed towards patients to positively change their behavior?
- Will data itself become democratized, where large scale medical data brokers lose control and power over medical data?
- Will blockchain bring about new profit sharing models where patients are compensated for providing and maintaining their medical data?
- Will blockchain help realize government backed initiatives such as the MyHealthEData initiative[13] or the other data democratization initiatives?[14]
- Will blockchain ultimately help realize P4 medicine (Predictive, Preventative, Personalized, Participatory). Realization of P4 medicine can help move the current reactive medicine environment to a proactive one where medical predictions can be made before symptoms arise?

There is no way to know at this point if blockchain will fulfill all its promises or potential. Yet, to move it forward in a meaningful way, it requires leaders across commercial companies, government regulators, and patients to participate in building the future.

Endnotes

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