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Blockchain in Electronic Health Records (EHR) – A Distant Future, but a Step in the Right Direction

FutureBridge

In the healthcare industry, there are growing incidences of patient mortality due to the decisions made on fragmented and inaccessible data. Moreover, the prevalence of a data breach in the traditional EHR system is also on the rise. Blockchain technology is inherently immutable and distributed in nature. This is motivating the private and public players, including healthcare agencies across the globe, to mull over the possibility of leveraging blockchain technology as a potential solution to the problems of existing EHR systems.

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Executive Summary

Traditional EHR system has been plagued with issues, such as lack of interoperability and privacy, data inaccessibility, and data incoherence. According to the Journal of American Medical Association, in the past seven years, the number of annual health data breaches have increased by 70% to 344. Moreover, 75% of these breached, lost, or stolen records are due to 'hacking' or 'IT incident.' Researchers at John Hopkins University have concluded 'medical errors' to be the third leading cause of death in the USA. Blockchain technology has emerged as a savior of the traditional EHR system. Many companies have already started experimenting and developing platforms using the blockchain technology that can improve data accessibility, interoperability and privacy. They are either in the form of a standalone EHR platform or an aggregator of records existing in different EHR systems. However, most of these companies are still in their pilot phase. High implementation cost, absence of regulations, and integration of already existing pile of data are the major hurdles in the implementation of blockchain technology in the EHR systems. Nevertheless, the participation of big EHR players can bolster the implementation and adoption rate of the technology.

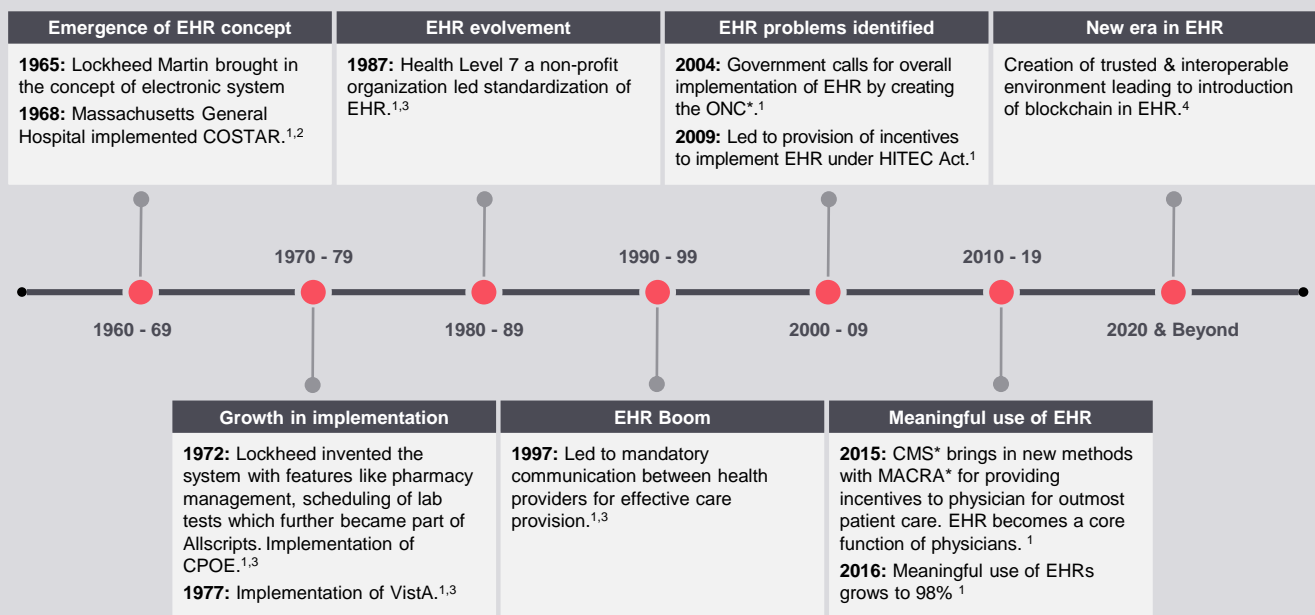# Electronic Health Record Systems – A digital ledger

EHR is a digital version of a patient's record consisting of medical history, treatment plans, laboratory and test results. Dated back to 1960s, EHR was introduced to maintain all the healthcare information in an electronic format. Before the introduction of EHR, the healthcare information was recorded on paper and bound together as a book. In 1972, Lockheed Corporation developed an electronic system, called the 'clinical information system,' to record all the healthcare-related data. Since then, the evolution of EHR began, and efforts were made to further develop the EHR into a more secure, reliable, and effective tool for maintaining healthcare information. *Exhibit 1* describes the developmental timeline of EHR. The cost of EHR was too high in the early years of its introduction that led to its slow adoption amongst the healthcare providers and organizations. With the advancements in the technology, i.e., the emergence of web-based software, EHR was eventually affordable to implement. The government also made rules and regulations that encouraged the adoption of EHR. Starting from 2015, penalties were implemented on healthcare providers and organizations with no initiatives towards EHR adoption in the United States[5].

Today, EHR eliminates the need for medical data to be stored on paper and provide superior quality patient care. Below are the benefits of EHR for the healthcare

industry:

- **Minimizing medical error** by avoiding illegible handwriting and incomplete data on the prescriptions and lab results

- **Cost reduction** in terms of decreased paperwork and manpower for managing medical records

- **Effective communication and coordination** between healthcare providers through instant sharing of medical records

EXHIBIT 1: Developmental Timeline of EHR

Emergence of EHR concept	EHR evolvement	EHR problems identified	New era in EHR
1965: Lockheed Martin brought in the concept of electronic system **1968:** Massachusetts General Hospital implemented COSTAR.[1,2]	**1987:** Health Level 7 a non-profit organization led standardization of EHR.[1,3]	**2004:** Government calls for overall implementation of EHR by creating the ONC*.[1] **2009:** Led to provision of incentives to implement EHR under HITEC Act.[1]	Creation of trusted & interoperable environment leading to introduction of blockchain in EHR.[4]

1970 - 79   1990 - 99   2010 - 19

1960 - 69   1980 - 89   2000 - 09   2020 & Beyond

Growth in implementation	EHR Boom	Meaningful use of EHR
1972: Lockheed invented the system with features like pharmacy management, scheduling of lab tests which further became part of Allscripts. Implementation of CPOE.[1,3] **1977:** Implementation of VistA.[1,3]	**1997:** Led to mandatory communication between health providers for effective care provision.[1,3]	**2015:** CMS* brings in new methods with MACRA* for providing incentives to physician for outmost patient care. EHR becomes a core function of physicians. [1] **2016:** Meaningful use of EHRs grows to 98% [1]

Abbreviations:

COSTAR - Computer Stored Ambulatory Record
CPOE - Computerized Physician Order Entry
ONC - Office of the National Coordinator for Health Information Technology
HITEC - Health Information Technology for Economic and Clinical Health
CMS - Centre for Medicare & Medicaid Services
**MACRA** - Medicare Access and CHIP Reauthorization Act of 2015

Challenges with the EHR system

No system can be devoid of challenges. Similarly, even the EHR system, in spite of having a lot of associated benefits, is plagued with some key issues like - Inaccessibility, Interoperability, Data incoherence, Privacy, etc.

Consider a scenario in *Exhibit 2*. It represents a typical patient journey where a Patient visits Provider I on 1st January 2018. The Provider I diagnoses the patient and records the diagnosis and treatment regime in its own institutional EHR Y. Unhappy with the treatment provided by Provider I, the patient decides to visit Provider II on 1st January 2019. Provider II wants to understand the patient's history to prescribe a new line of treatment. As the patient's history was recorded in EHR Y, it remains inaccessible to Provider II.

"Among individuals who visited a health care provider within the past year, over one-third experienced at least one gap in information exchange"

– **Office of the National Coordinator** – 'Trends in Consumer Access and Use of Electronic Health Information' report
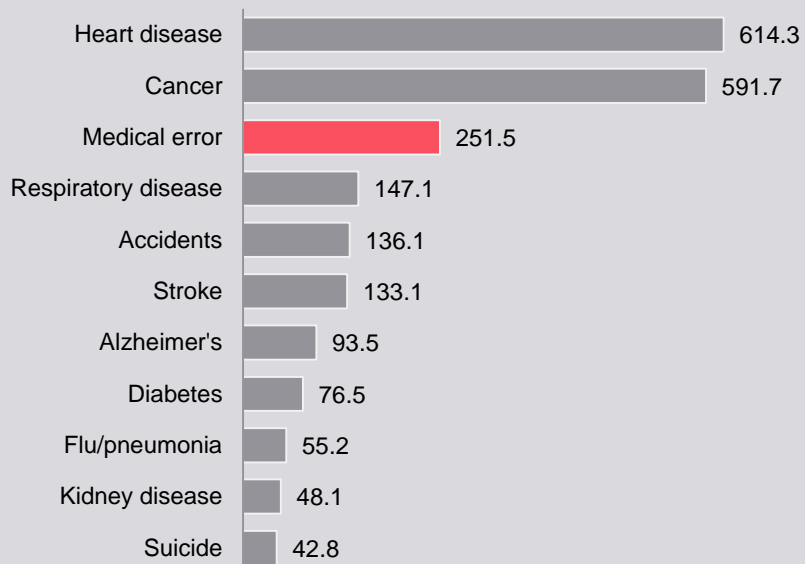
EXHIBIT 2: Patient Journey
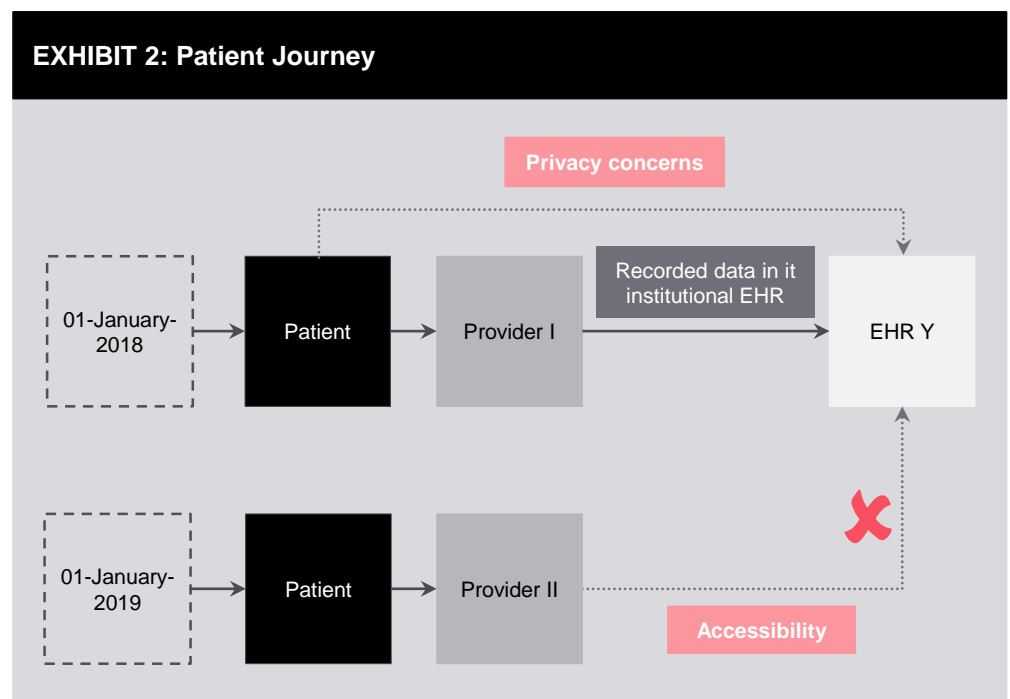
- **Accessibility/Interoperability:** Since most institutions are using their own EHR system, a patient record is stored in a silo, which leads to the issue of data incoherence. Moreover, their unwillingness to share their EHR data with other institutions and absence of any mechanism with which one EHR system can talk to another EHR system (Interoperability) have led to the issue of inaccessibility to patient records. This leads to a medical decision being made on limited available data. A research carried out by John Hopkins University *(Exhibit 3)* highlights the number of deaths in the USA in the year 2016 due to medical errors. It can be clearly seen that medical errors which can be due to inaccessibility to patient data are the third leading cause of death in the USA.

- **Privacy:** The data that is stored in respective EHR systems is owned by the institution, and hence patient has minimal control on his/her data. This brings us to the second issue with the traditional EHR system, i.e., Data privacy.

Blockchain technology can address these challenges to make the current EHR platforms completely anonymized, encrypted, and accessible systems.

EXHIBIT 3: Deaths in United States, 2016

(figures in '000s)

Heart disease	614.3
Cancer	591.7
Medical error	251.5
Respiratory disease	147.1
Accidents	136.1
Stroke	133.1
Alzheimer's	93.5
Diabetes	76.5
Flu/pneumonia	55.2
Kidney disease	48.1
Suicide	42.8

Johns Hopkins University researchers estimate that medical error is now the third leading cause of death.

Source: National Center for Health Statistics, BMU

# Blockchain Technology – A digital, distributed and immutable ledger

The blockchain is an incorruptible, back-linked ledger of encrypted records that is completely open to anyone. Each block contains a set of information (a transaction or an interaction) and all such blocks - linked to a particular identity - forms a chain. Once the information is saved into the block and added to the blockchain, it can neither be recreated nor destroyed. The concept was first outlined in 1991 by Stuart Haber and W. Scott Stornetta with an objective to implement a system intended to timestamp digital documents that are tamper-proof. In 2009, Satoshi Nakamoto introduced the first real-world application of blockchain technology through Bitcoin.

"Blockchain technology will fundamentally change how payers and providers share claims information, how provider data is updated and matriculated through a network, how a patient's medical records are shared and updated as she moves through the care continuum, how population health data is aggregated and analyzed, how clinical trial data is recorded, and how prescription drugs are tracked and monitored through the supply chain"
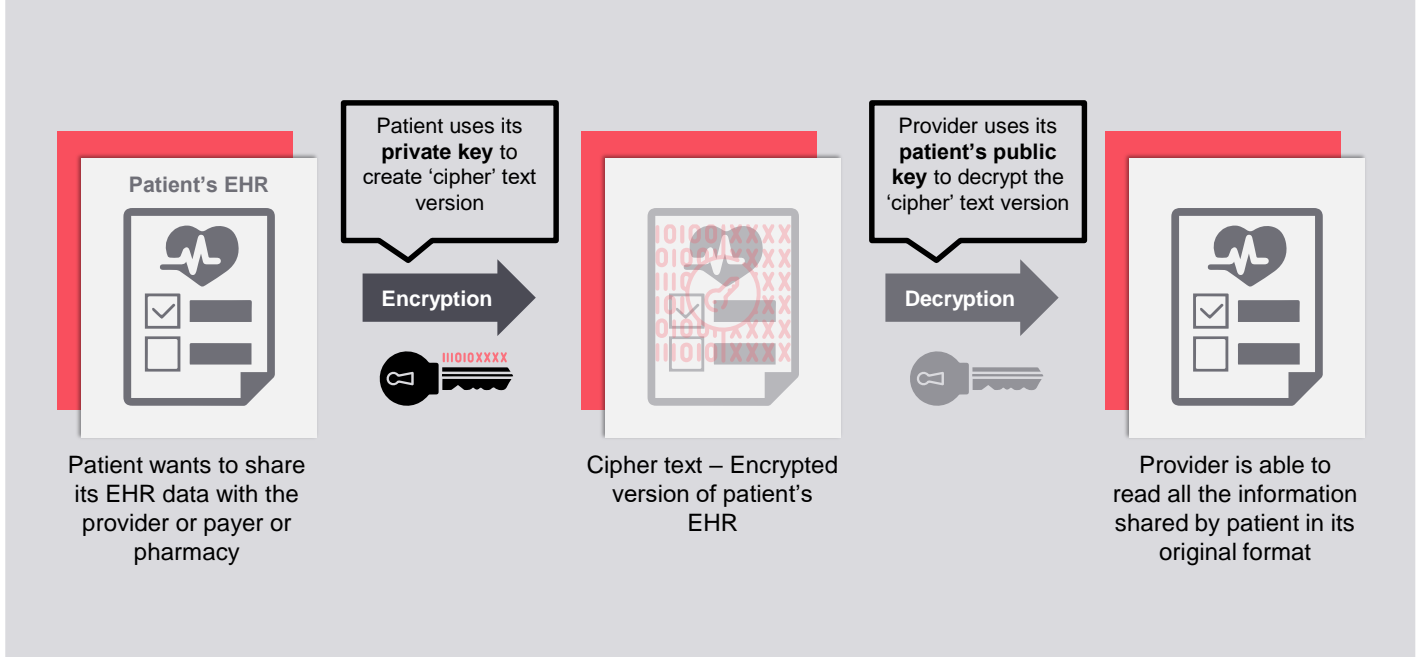
– **Peter Nichol**

Director, Research & Development, IT Portfolio Management Company, Regeneron Pharmaceuticals, Inc.

EXHIBIT 4: Blockchain process in EHR platforms
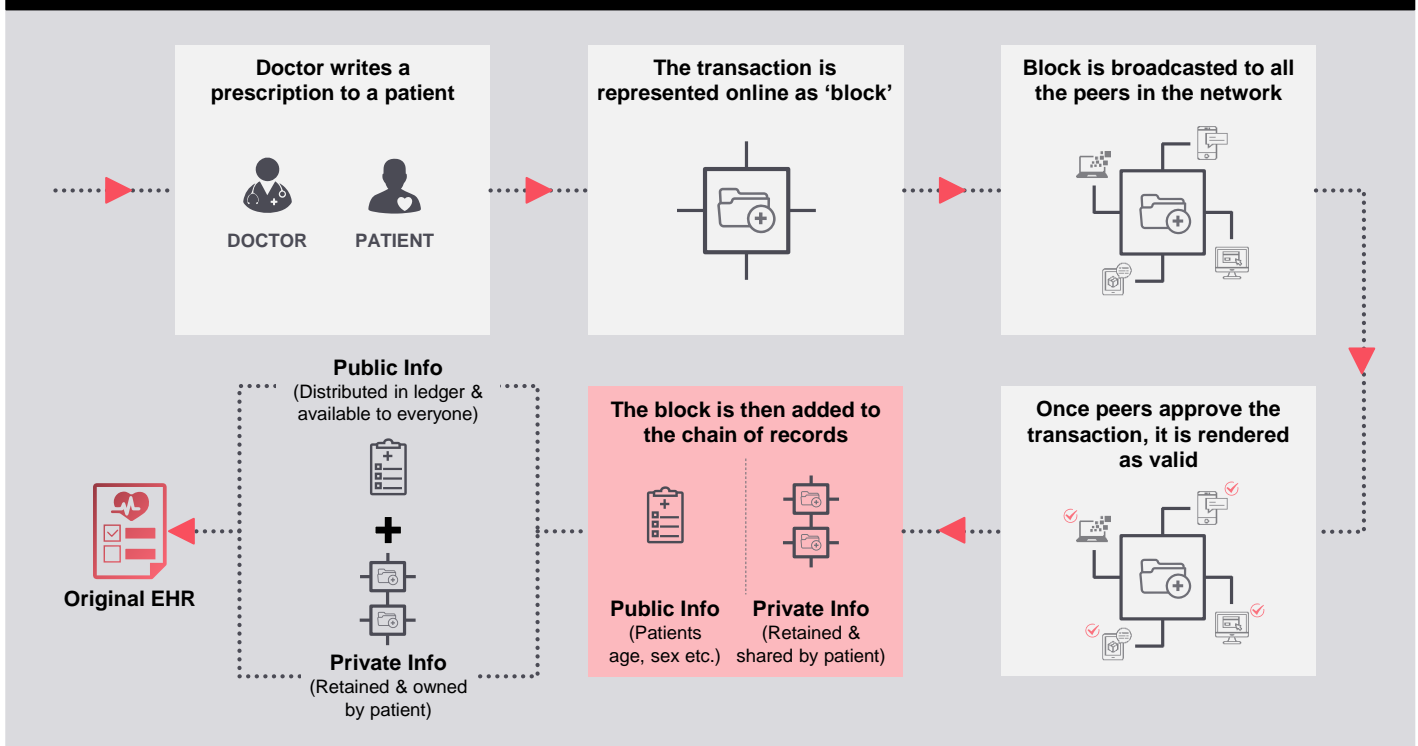
It is a decentralized system that uses a peer-to-peer network for the chain management. All users on the blockchain are nodes (peers) administering their own blockchains. Consensus mechanism (Peer-to-peer or P2P network) is implemented in the blockchain to ensure that no editing can be done without the consensus from all the concerned peers. When a new block is created, it is sent to everyone on the network. Peers create a consensus which is an agreement for authentication of that block. Peers ensure that the new block added is tamper-proof and only after authentication added to their blockchains.

EXHIBIT 5: Public and private keys in blockchain

Patient's EHR

Patient uses its **private key** to create 'cipher' text version

Encryption

Patient wants to share its EHR data with the provider or payer or pharmacy

Cipher text – Encrypted version of patient's EHR

Provider uses its **patient's public key** to decrypt the 'cipher' text version

Decryption

Provider is able to read all the information shared by patient in its original format

However, due to a large amount of data generated in the healthcare domain, each block can store only access links to the data. As the access links are saved, the block generates a hash which is similar to a fingerprint or unique identification code; it identifies the block and all its content. Thus, every block has its own hash, and when a new block is added into the chain, it is also given the hash of the previous block. In this way each block has a hash of its own and the hash of the previous block, this leads to the blockchain system cryptographically secure. The chain of the block thus created has two keys to it – public and private key. Public Key is visible to all the stakeholders, but the Private Key is retained with the patient, and he/she can use it to provide access to the other stakeholder wishing to view/edit/download the patient EHR. This renders the patient to be in complete control of his/her data and also solves the issue of inaccessibility faced by the traditional EHR system.

"Blockchain for healthcare is very early in its life cycle, but it has the potential to standardize secure data exchange in a less burdensome way than previous approaches"

– **John D. Halamka**
MD, chief information officer,
Beth Israel Deaconess Medical Center Boston

Implementation of Blockchain in EHR – Possible solution, but currently at a nascent stage

In order to implement blockchain-based EHR, all the existing EHR systems and other record keeping systems need to encrypt and transfer the data to a public blockchain platform. The transaction would be secured with a digital signature from the transferor to trace the source and the patient's blockchain ID as a transaction receipt. Once the documents are transferred and stored in the blockchain, patients are then able to use a web-based or mobile application to view/download their blockchain contents and manage access to individual parties.

> "According to the new study published by CB insights, we are currently in a stage where blockchain is used only by closed consortia & pilot projects. Patient-driven systems with master health records and control over access rights appears to be a long term plan"

There are three possible solutions to link an existing EHR's view/download/transmit function to a blockchain-based EHR. The table below gives a head-to-head comparison of the proposed solutions:

Solutions	Solution 1	Solution 2	Solution 3
Ownership	EHR vendors	Blockchain platform owners	Patients
Description	Implement blockchain client within their EHR application	Configure platforms to handle the communication protocols like REST, SOAP APIs, etc.	Manually transmit the existing and newer documents to the blockchain based EHR platform while continuing to receive information through existing systems
Impact	Health information will automatically get transferred to the blockchain based EHR	EHR vendors can directly send the patient information to the blockchain based EHR platform	Simplest solution and works on least common denominator module
Challenge	Difficult to convince EHR vendors to implement it without any incentive or regulation	It will convert a simple electronic transaction ledger to a complex platform which will increase the burden on the platform and slow it down	Heavily dependent on patients as it requires them to put an additional effort to upload the data which in the worst-case scenario might lead to incomplete records if they fail to transmit the information

Use Cases – Standalone EHR platforms and aggregators

CASE 1: Medicalchain platform - An EHR platform that uses blockchain technology to ensure safety, transparency, and privacy[6]

Medicalchain uses blockchain technology to securely store health records. The different stakeholders, such as doctors, hospitals, laboratories, pharmacists, and health insurers, can request permission to access a patient's record to serve their purpose and record transactions on the distributed ledger.
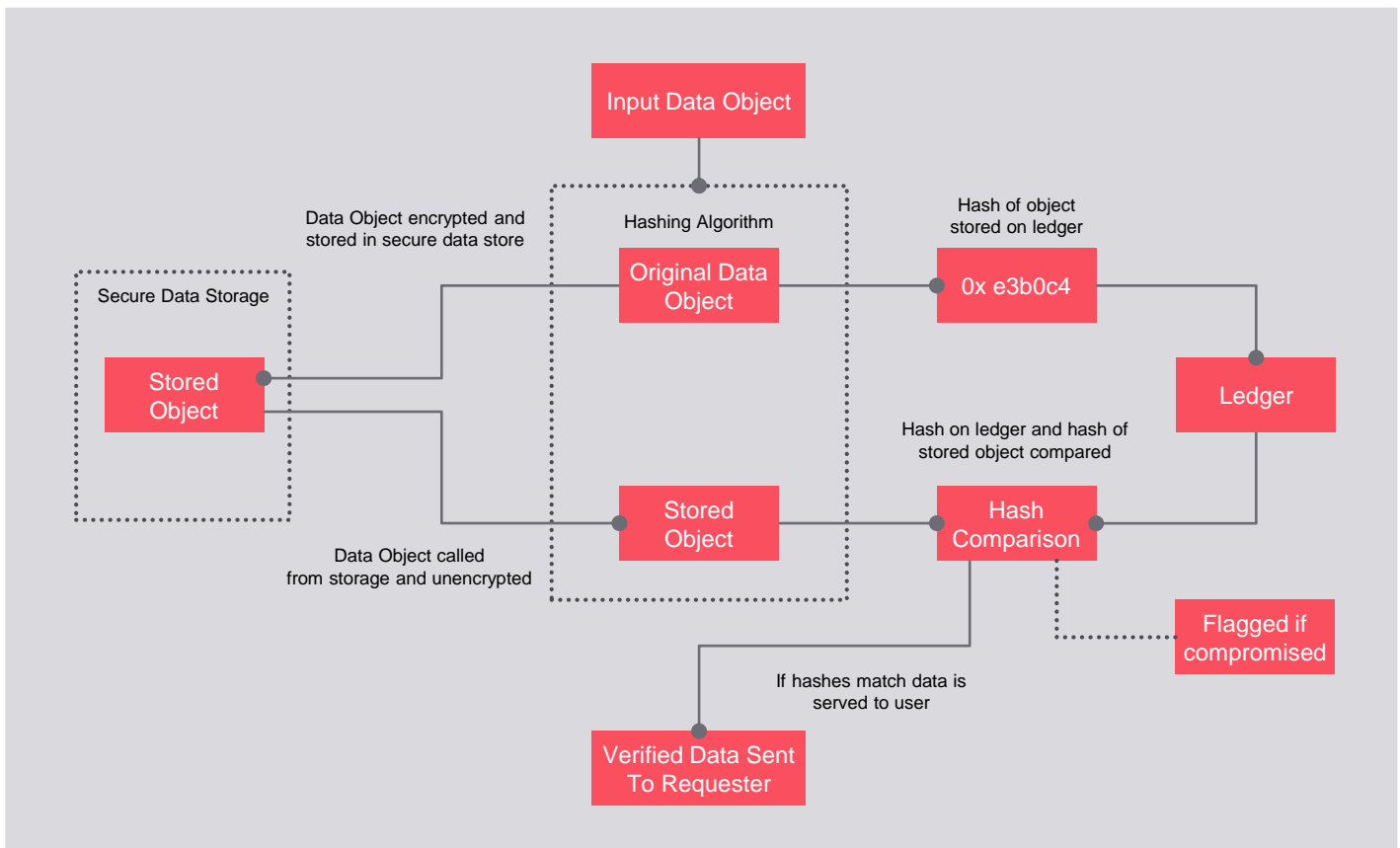
Medicalchain is built using a dual blockchain structure:

- The first blockchain – controls access to health records and is built using permission-based Hyperledger Fabric, which is controlled using hyper-ledger modeling and access control languages. This helps it to deliver a high degree of confidentiality, resilience, flexibility, and scalability.

- The second blockchain – Smart Contracts - is powered by an ERC20 token on Ethereum (a digital platform having thousands of computers hosting Ethereum network) that automates and validates activities like billing & insurance in a secure and transparent manner, thereby saving time & cost.

CASE 2: Patientory – A peer-to-peer EMR record improving the accessibility of health records[7]

Patientory is a cybersecurity blockchain-based distributed application that provides access to users to their health data. It is like a bridge that connects siloed, centralized medical, and health record-keeping systems. They create smart contracts that can be executed in relation to the medical and patient care continuum cycle. Their system aggregates data from EMRs like Epic, Cerner, Allscripts and Meditech, and other health-related database systems. Patientory's mobile app allows patients to create an individual profile. On this profile, they store their medical information on a secure, HIPAA-compliant blockchain platform, which enables them to connect with care providers as well as other patients who have similar health issues or concerns. This allows patients greater control over their overall health across multiple care teams, both inside and outside the hospital.
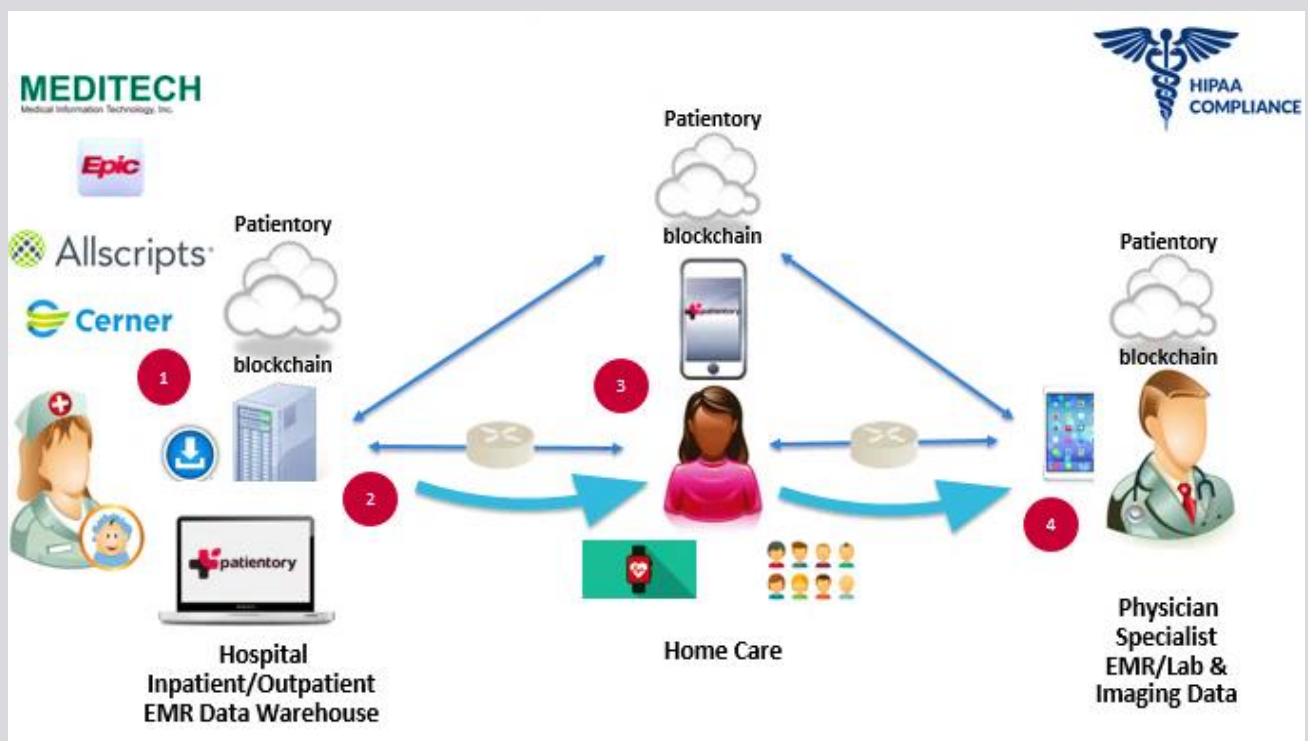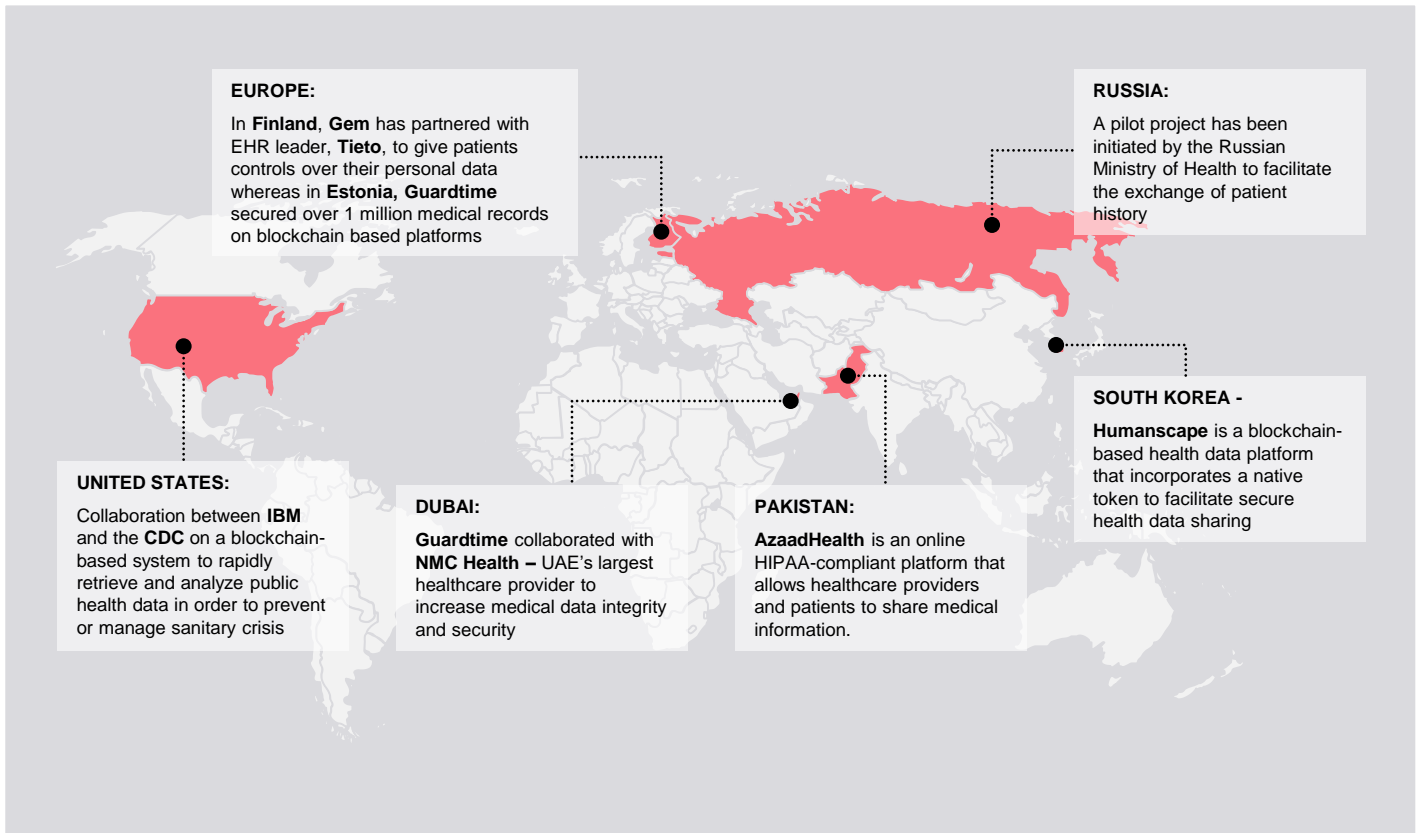

Image source: Patientory investor presentation deck

CASE 3: Guardtime Announces EPIC Systems Integration, Targets US Health Care Interoperability[8]

Guardtime's integration attempts to provide seamless and automated interoperability by integrating into robust commercial EHR systems, such as Epic Systems, providing a mechanism to link data across disparate systems and authoritative boundaries without the need to trust intermediaries.

Other examples of blockchain initiatives taken up by different countries: [9,10,11]

EUROPE:

In **Finland**, **Gem** has partnered with EHR leader, **Tieto**, to give patients controls over their personal data whereas in **Estonia**, **Guardtime** secured over 1 million medical records on blockchain based platforms

RUSSIA:

A pilot project has been initiated by the Russian Ministry of Health to facilitate the exchange of patient history

UNITED STATES:

Collaboration between **IBM** and the **CDC** on a blockchain-based system to rapidly retrieve and analyze public health data in order to prevent or manage sanitary crisis

DUBAI:

Guardtime collaborated with **NMC Health –** UAE's largest healthcare provider to increase medical data integrity and security

PAKISTAN:

AzaadHealth is an online HIPAA-compliant platform that allows healthcare providers and patients to share medical information.

SOUTH KOREA -

Humanscape is a blockchain-based health data platform that incorporates a native token to facilitate secure health data sharing

Impact of Blockchain in EHR – Blockchain-based EHR, a clean winner

Parameter	Traditional EHR system	Blockchain-based EHR system
Data Storage	In silo on individual EHR system	Decentralized & distributed
Information sharing & Interoperability	A provider has to manually extract and share the data	Data is available to all the stakeholders
Data ownership, privacy & access control	EHR system owner	Patient
Data update	Manipulation of back-dated records allowed	Append-only system. No manipulations allowed
Data coherence	No standardized field structure. Individual EHR has its own defined fields	Standardized fields across all the systems
Security	Can be easily hacked	Hacking is nearly impossible unless the patient's private key is lost or stolen

Challenges in Implementing Blockchain

CHALLENGES	POSSIBLE SOLUTIONS
DATA MANAGEMENT — EHR links a patient's data to hospitals, labs and insurers resulting in a huge amount of data that needs to be stored and shared using the blockchain. This requires a robust blockchain design that can handle such a large amount of data	Data can be stored off-chain and the summary of clinical data and access links to the data are saved on the blockchain. For example, radiology report to be saved on the blockchain instead of DICOM images.
SECURE STORAGE OF PATIENT'S PRIVATE KEY — The data on a blockchain is stored in such a manner that it can only be accessed using the patient's private key. This ensures that only patients have the right to provide access to their medical history. Although the private key has to be stored somewhere to link to the patient's identity, in case of any leak of patient's private key, entire medical history can be accessed leading to catastrophe.	A dedicated secure platform is needed for identity management i.e. patient identities corresponding to their private keys must be stored in a fail-safe database. Another solution can be the implementation of a private blockchain that gives control of the entire data to a single entity or an organization.
HIGH COST — The initial cost of adoption of blockchain technology in EHR is quite high. This makes healthcare providers and organizations unwilling to invest in expensive software dedicated to run blockchain technology.	Stakeholders can be demonstrated with the long-term benefits which may outweigh the initial setup cost and encourage them to adopt the blockchain technology
ABSENCE OF REGULATIONS — In the present scenario, there are no regulations for blockchain which is making it overlap with many other existing healthcare regulations. E.g. though blockchain can solve many of the problems within the healthcare system that HIPAA was designed for, the mathematical encryption, however, conflicts with HIPAA privacy rule. Similarly issues like the signing of Business Associates Agreements (BAA) – which implements technical safeguards to protect information – remains a grey area in the era of blockchain as the data is distributed and not stored in one central location.	Alternatively, to comply with HIPAA, smart contracts can be enforced to all the healthcare providers and organizations employing blockchain technology. A smart contract is a computer protocol version of the fraud-tolerant agreement between patient and healthcare provider. Organizations need to seek consent from the patients in order to use their medical history for research purpose. Failing to do so, the contract may serve as an exhibit in court.

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Conclusion – Participation of big players can lead to a faster implementation

Electronic Health Records (EHR) promises reduced medical errors and costs with improved patient safety and outcomes by utilizing better access to patient data. Quick access to comprehensive health records to a specific condition and medical history of the patient helps the physician to provide better diagnosis and treatment, resulting in a better and cost-effective outcome. However, different healthcare stakeholders use different EHR systems, thereby making fragmented patient data difficult for utilization. EHR systems remain an easy target for hackers due to poor security protocol at different healthcare facilities.

Blockchain technology is capable of making patient data readily accessible to authorized users with data security by being averse to hacking and ransomware attacks and providing a distributed ledger technology, which also helps in reducing the overall time and costs in the longer run. But the medical information is very large for blockchain storage, and there are no regulations for the use of it in the healthcare industry. Moreover, the one-time implementation cost of blockchain technology is very high. However, there are few successful startups in the market that have launched EHR platforms using blockchain technology and have overcome these existing challenges. It will be interesting to witness big players like Allscripts, Epic Systems, Cerner, et al., leveraging the technology and ensuring its success in the healthcare industry, eventually benefitting all the stakeholders and the society at large.

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