

IMPLEMENTING CLINICAL BLOCKCHAIN INTEROPERABILITY TO ADDRESS SPECIFIC USE CASES IN PATIENT CARE, PUBLIC HEALTH, AND PHARMACEUTICAL RESEARCH

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“Those who cannot remember the past are condemned to repeat it.” George Santayana 1905

The recent discussion concerning blockchain applicability in healthcare mirrors the conversations surrounding [HL7 and ASTM 1238. \(1986-1991\)](#). HL7 began as a standard for transferring financial ADT (Admit, Discharge, Transfer) data between disparate hospital computer systems. Like HL7, Blockchains roots are also in the financial world of the crypto currency Bitcoin. Prior to any implementation of Blockchain for patient care, entities must recognize the existing drawbacks of the platform, as well as opportunities to proactively incorporate interoperability across multiple competing and cooperating versions of the blockchain.

ASTM 1238 focused on clinical transactions, specifically clinical laboratory orders and results transactions. The difference between HL7 and ASTM 1238² could be seen in the handling of a commonly ordered laboratory test, the Complete Blood Count (CBC). This analogy is similar to the use of the creation of a one line entry found on a blockchain ledger.

Prior to the integration of ASTM 1238, HL7 fundamentally viewed a CBC as a charge transaction which occupied a single line in the general ledger. ASTM 1238 viewed a CBC as an “Order” transaction, with multiple “Result” transactions, White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, etc... attached. The scale and structure of clinical transactions, made it impossible to represent clinical data in HL7 until the standard was merged with ASTM 1238. The HL7 / ASTM 1238 merger was supposed to create a unified and functional view across various hospital and physician computer systems. Instead, certain groups created their own flavors of HL7 which caused the crisis in achieving interoperability that we still have today.

Blockchain, like early HL7, has an underlying purpose of keeping track of financial transactions, (Bitcoin) in what amounts to a simple general ledger transaction. The scale and density of clinical information transactions in healthcare are orders of magnitude more complex than anything ever seen in the current world of bitcoin or Blockchain. The Bitcoin Blockchain also has a fundamental flaw in its lack of consistency for keeping specific transaction time stamps. The fact that a Bitcoin transaction relies on different miners to validate a transaction, and the fact that the transaction can take different paths, causes date and time to be disconnected from the underlying transaction. The clinical blockchain requires a date / timestamp that reflect the date of clinical orders and results for any clinical observations made at labs, hospitals, pharmacies, and physician offices. The bitcoin Blockchain’s lineage and connections to the

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cryptocurrency creation from a 2009 White Paper to a 2016 Platform global sensation are well known

It is only together that we will be able to answer the question of whether blockchains are “as fundamental for forward progress in society as the Magna Carta or the Rosetta Stone” (Swan, 2015, p. viii), whether they are irrevocably bound to the “failed Bitcoin experiment” (Hearn, 2016), or whether the truth lies somewhere in between.³

The total size of the bitcoin Blockchain is approximately 64MB representing all transactions since the currency was first introduced. Each transaction is stored in blocks with a maximum size of 1MB. By comparison, Visa, processes over 2000 transactions per second, and creates approximately 8 Terabytes of data per year. It is clear that healthcare transactions require much more storage than simplistic financial transactions, For instance, a single hospital system, [Beth Israel Deaconess Medical Center \(BIDMC\) generates 20 Terabytes per year for 250,000 patients](#) (80MB per patient record). 19 of the 20TBs are the result of imaging files which can occupy a minimum of 5MB per transaction. Blockchain, as currently configured, could not even accommodate a single transaction from a MRI, performed at a single hospital, because it's limited to a 1MB block size.

In addition to file size limitations, the concept of the blockchain's, “immutable” character will be crushed by the sheer size scale of healthcare records and individual transactions. It is the “append only” structure which gives Blockchain its high trust and confidence scores.

The Bitcoin Blockchain derives trust and confidence from the consensual agreement of multiple nodes agreeing that the Blockchain is correct. If more than 50% of the network nodes agree that a Blockchain is correct, the transaction is approved. This node concept is critical to the Bitcoin blockchain's success, and the creation of trust among unknown actors. If a single group controls, more than 50% of the network nodes, confidence and trust are lost due to the potential for a single point of failure or tampering. The size of healthcare records will increase the storage and processing requirements at each network node, which will have a net effect of increasing node operating costs thus, ultimately decreasing the number of nodes to a point where trust and confidence could be called into question.

In a relatively short period of time, it will become apparent that only a handful of corporations (IBM, Microsoft, Dell, Amazon, Google, etc...), national clinical laboratories, pharmaceuticals, the government, health systems, insurance companies, and universities will have the storage capability, resources, infrastructure, and raw processing power to accommodate real time terabyte and even petabyte transaction volume. This small number of nodes has the potential to defeat the credibility of blockchains reliance on hundreds / thousands of nodes to engender trust.

In addition to creating large file sizes when a relatively small “edit” transaction occurs, immutability also has social implications on privacy. For instance, the UK based Open Data Institute has found: [for people that have made a transition to a new gender⁴](#) ; they may have a

³ Open Data Institute. Applying Blockchain Technology in Global Data Infrastructure. 2016

⁴ Open Data Institute. Applying Blockchain Technology in Global Data Infrastructure 2016.

legal right for previous data to be altered to ensure it is interpreted according to their new gender, immutability would prevent this right.

As of [July 11, 2016](#), [over 700 cryptocurrencies](#) have been recorded, each with their own flavor of Blockchain. [Investment in Blockchain technology will grow to over \\$1 billion](#), a 200% increase from 2015. [IBM, Microsoft](#), Philips, Accenture, Deloitte and other Fortune 500 corporations have set up Blockchain Groups in their respective organizations, each bringing a new twist to the Blockchain discussion. [IBM and Microsoft are already seen as diverging in their approaches](#) to Blockchain development, even though the product offerings are based upon open source projects. Healthcare is already in the midst of a monumental centralized database interoperability morass, and it will take leadership to prevent the situation from becoming worse with ill-conceived Blockchain in healthcare implementations.

It is critical to the future of interoperability in healthcare that we look thoughtfully at the opportunities presented by Blockchain. We must avoid the oversimplification of any implementation in healthcare as shown an August 3, 2016 article published in Health Data Management.

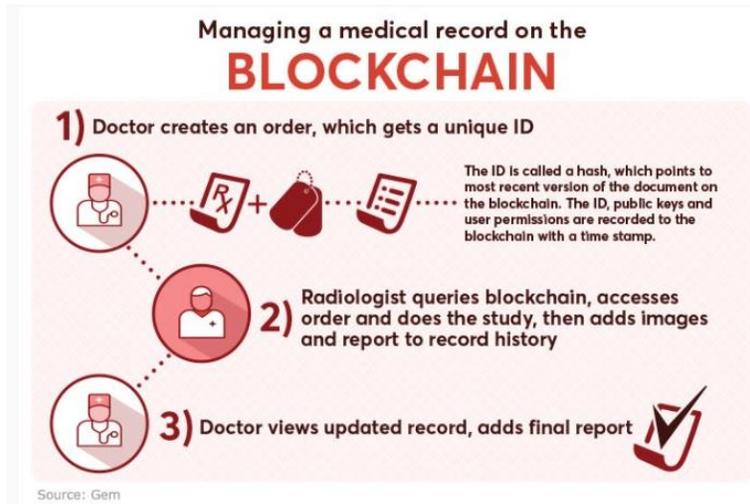


Figure 1 Simplified Blockchain EHR Workflow

In fact, the idea that a radiologist would query a Blockchain is analogous to a physician searching IP address to locate a patient. Blockchain provides a layer that supports the secure access to information about transactions. In fact, an application queried the actual Blockchain, the result would look like the screen below, which would be nonsensical to a physician.

Technical		Monetary	
Block Time	30 Aug 2015 18:23 (15 hours ago)	Transaction Count	2
Confirmations	2634	Avg. Transaction Value	5,190,072,415,000,000,000 ether
Hash	0xf72d21aa7c0616674f199ee6a1e390b70ddb17f556420a1879da77f5164b48	Total Transaction Value	10,380,144,830,000,000,000 ether
Miner	0x0ded3da479d0be8eeec52a76644d34e3c177f7	Gas Limit	3,141,592
Chain	Main	Gas Used	42,000
Difficulty	7.00 TH	Avg. Gas Price	57,298,184,887 (Gwei)
Size	764 B	Total Gas Income	2,409,043,796,854,000 (finney)
Extra	0xd783010100844765746887676312e342e32856c6996a7578	Block Reward (excl. uncles)	5,000,000,000,000,000 ether
Show details			
Transactions			
Date	From	To	Value Tx Hash
30 Aug 2015 18:23	0xc517a1ce7f630dc7ebd59e97fb80f5eac21e	0x32be343b94f860124dc4fee278fcbcd38c102d88	5,121,228,610,000,000,000 0x21eb7...
30 Aug 2015 18:23	0xe7523f78ae9ed81dc7b2a9ca718ba3776c142e	0x32be343b94f860124dc4fee278fcbcd38c102d88	5,258,916,220,000,000,000 0xf5682...

Figure 2 Ethereum Tradeblock Explorer information would be useless in clinical care

Recently, Ethereum, a provider of a cryptocurrency with a Blockchain that supports “smart contracts,” made a decision to upgrade the ‘software’ with additional capabilities in what is known as a “hard fork.” As reported in the [August 1, 2016 Wall Street Journal, the hard fork, caused the Ethereum community to be cleaved](#) into 2 camps. One camp representing about 85% of miners that went with the upgrade, and a second group that stayed with the classic version of Ethereum Blockchain (ETC). If this scenario were played out in a healthcare system, it would be analogous to 15% of all patient records suddenly becoming unavailable. For instance, if a group of hospitals under a forward thinking CIO decided to go with the upgrade, while, local pharmacies, and clinical reference laboratories decided to stick with what was working, physicians would be left with an incomplete view of their patients medical history.

The *ONC Shared Nationwide Interoperability Roadmap* recognizes that healthcare is determined by multiple groups, some of which are outside of the normal clinical care settings and the sphere of influence of HHS.

Most determinants of health status are social and are influenced by actions and encounters that occur outside traditional institutional health care delivery settings, such as in employment, retail, education and other settings.

This paper recognizes that there will be multiple “flavors” of Blockchain deployed in various settings in the United States. These flavors will include multiple forms of ownership, governance and openness. Interoperability amongst various Blockchain “flavors” must be paramount consideration for any ONC recommendation. In virtually every deployment of Blockchain in hospital, clinical laboratory, pharmaceutical research, public welfare, clinical analyzer, utilizing flavors, from IBM, Microsoft, Deloitte, and others, interoperability must be guaranteed at a fundamental level.

PREVENTING ANOTHER THERANOS USE CASE

The [controversy surrounding Clinical Laboratory vendor Theranos demonstrates the need for transparency in laboratory testing](#). One version of the Blockchain would create identification and maintenance tracking for all blood, urine, other bodily fluids, and for cellular and genetic analyzers used by clinical and genomic laboratories. The July 31, 2016, American Association for Clinical Chemistry (AACC), Convention in Philadelphia brought together over 20,000 laboratory professionals from around the world. The Laboratory Analyzer “flavor” of the Clinical Blockchain would allow for the tracking of all Point of Care Technologies that monitor blood, DNA and other medically significant sensor / analyzer information. Major medical device companies such as Abbott, Ortho, Sysmex, Roche, Streck, Binding Site, Med Test, Hologic, Becton Dickinson, Siemens, and others would benefit from participating in a Clinical Blockchain. If Theranos, had been involved in providing end to end transparency (from analyzer to lab test report), patients, doctors, regulators, and the laboratory industry would have discovered Theranos was not using its in-house “Edison” analyzers to perform routine clinical laboratory tests. Theranos was able to cover-up the truth for over 2 years resulting in potential harm to patients, and the closing of its California laboratory.

In addition to providing transparency for test results reporting, the Laboratory Analyzer Clinical Blockchain will include reporting of maintenance schedules for individual devices, certification of technicians, reference ranges, and even reagents. Elements of the analyzer Clinical Blockchain could be integrated into other Clinical Blockchains, or provide interoperability with other “flavors” via a clinical Blockchain 2-way peg that is described below.

Clinical Reference Laboratories such as Quest, LabCorp, RML, ARUP, Mayo Medical Laboratories, Bio-Reference Laboratories, 23 And Me, Alere, and others could participate in the Laboratory Analyzer Clinical Blockchain. The Clinical Blockchain could also integrate the CDC and the Public Health Laboratories involved in responses to Ebola, Zika, Salmonella, and bioterrorism.

In addition to tracking clinical laboratory and analyzer information, blockchains will be utilized to aggregate all medication information for a given patient including **Express Scripts**, CVS Health (formerly **CVS Caremark**) and United Health/OptumRx, Walgreens and other retail pharmacies. In short, any item with an NDC Code will be tracked on the Clinical Blockchain.

THE CLINICAL BLOCKCHAIN

As mentioned above, the Clinical Blockchain implemented in various industries, environments, and settings touching healthcare, should have a foundation of interoperability. The Bitcoin Blockchain was not designed for large data sets and the requirement for instantaneous time sensitive reporting found in healthcare and patient records. In [October 2014, Adam Back of Blockstream authored a White Paper](#) titled “Enabling Blockchain Innovations with Pegged Sidechains.” This white paper is not yet two years old, and yet it has influenced virtually every innovation in Blockchain to date. In [October 2015, 5 cryptocurrency vendors announced interoperability with Bitcoin and Blockstream](#) through the use of sidechains. It is noteworthy, that the creation of sidechains appears to not be an initial intention of the Bitcoin Blockchain. Backward interoperability to the bitcoin Blockchain is based upon the use of the OP_RETURN text field located on the Bitcoin Blockchain.

The Clinical Blockchain incorporates interoperability with bitcoin to provide patients the ultimate ability and opportunity to transfer records to a globally recognized standard. Patients will have access to their own records and have the ability to add messages that will be displayed on the Clinical Blockchain. In certain circumstances, patients may choose to store their records on other platforms. The Clinical Blockchain will have the ability to transfer data between other blockchains based upon Ethereum and Bitcoin. Furthermore, any files referenced in sidechains attached to the blockchain should have the ability to be displayed and /or stored in a browser based Clinical Blockchain viewer, including [Microsoft’s Health Vault](#), [Health Bank](#), and/or innovative vendors such as [LifeSpeed](#). The Clinical Blockchain will also provide additional messaging information to future telemedicine platforms such as those proposed by [Apples recent telehealth platform patent](#).



Figure 3 Blockchains will come in multiple "flavors" but Interoperability will be maintained in the Clinical Blockchain through Pegged Sidechains

In addition to the Clinical Laboratory / Analyzer Blockchain, other “flavors” could include a Public Health Blockchain (Nutrition, Food, and other Social Determinants), Health System Blockchain including all Pharmacy Drugs, Insurance Clinical Blockchain, and Research Clinical Blockchain.

Patient voices should be heard throughout every instance of Blockchain interoperability. The presentation of patient messages in the Blockchain and associated sidechains are important for documentation of 2-way communication with healthcare providers. In addition to patient messaging, each “flavor” of Blockchain should incorporate third party organizations representing patient constituents as part of any permissioned / private Blockchain group or consortium. To guarantee patient advocacy input, the Clinical Blockchain should include consideration of advocates such as Dave deBronkart (aka @epatientDave), Dana Lewis (creator of the first artificial pancreas @danamlewis) and Regina Holliday (@ReginaHolliday). There are many other voices that consistently advocate for patients including physicians, healthcare entities and associations, most notably the Society for Participatory Medicine. In addition to patients organizations that have supported patients should be involved in any “federation” of groups implementing a Blockchain locally, regionally or nationally. CDC, NIH, American Diabetes Association and Doctors Without Borders should also be considered. As these systems, including the Clinical Blockchain, are put in place, we cannot underestimate their influence and importance, especially in this age of Social Media. Ideally, a clinical Blockchain dashboard will identify the voting patterns of permissioned participants to provide an audit trail on the effectiveness of the clinical Blockchain and the “voting patterns” of permissioned members.

The nature of healthcare forces the use of private / permissioned blockchains with the ability to have an “off ramp” to a public Blockchain such as Bitcoin or Ethereum. People who enter the healthcare system and provider healthcare services are not anonymous. In many cases, the Clinical Blockchain will have characteristics of a private intranet or virtual private network, with Blockchain features.

ETHEREUM – BITCOIN INTEROPERABILITY, SMART CONTRACTS, AND THE 2-WAY SIDECHAIN PEG

Since, [Adam Back’s white paper regarding sidechains and there functionality in Blockchain enhanced capabilities](#) there has been a movement towards incorporating smart contracts and increasing interoperability. As discussed above, the reason for the Ethereum “hard fork” was to enhance the functionality of “smart contracts.” Smart contracts provide computer coded language that executes specific instructions based upon programmed conditions. Proposed

MIPS / MACRA rules require physicians' to gather information on Population Health. One of the first areas of focus is in physician Diabetes Management programs. ONC and NIST can help physicians in this task by integrating a Clinical Blockchain with a smart contract that evaluates Hemoglobin A1C reported by a Clinical Laboratory / Analyzer Blockchain. By incorporating a smart contract rule, patients with elevated Hemoglobin A1c can be evaluated on a proactive basis.

[RootStock is only a few months old, but has captured the imagination of the entire Blockchain ecosystem](#) in its innovative use of sidechains and drive chains to create Blockchain interoperability between Ethereum and Bitcoin blockchains.

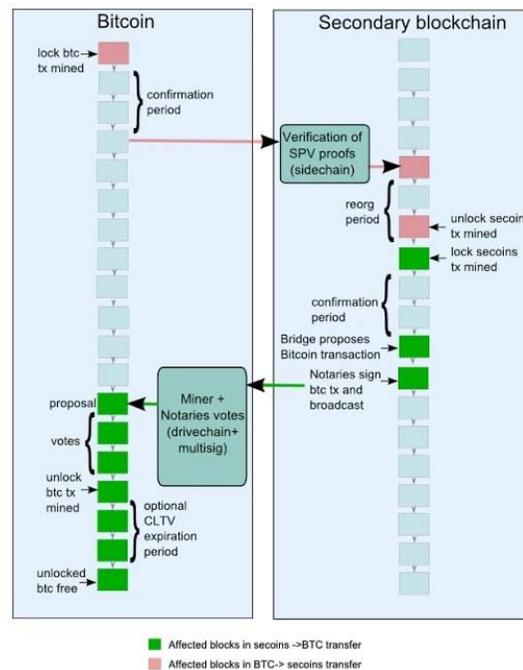


Figure 4 RootStock 2 Way Sidechain Peg provides a model for Clinical Blockchain Interoperability

The RootStock 2 Way Peg identified above provides an important model for interoperability in Ethereum – Bitcoin – RootStock Blockchains. [On August 3, 2016 RootStock led a coalition of 25 respected companies](#) to create an interoperable federation. RootStocks interoperability and its recent announcement has the potential to turn the Blockchain ecosystem on its head. The Clinical Blockchain integrates components of the RootStock peg (ie: compatibility with the bitcoin Blockchain)⁵ and adds specific functions required for any effective implementation of a Clinical Blockchain. The Clinical Blockchain requires additional functionality not yet considered by any Bitcoin, Ethereum or Rootstock Blockchain. Unlike the requirements of cryptocurrencies, the Clinical Blockchain requires a transition from a Parent – Child relationship, access to patient records on the Blockchain, and extraction of existing records to create an entirely new Blockchain. Similarly, Caregiver, or a fiduciary access must be provided to trusted friends and family of elderly, sick, or disabled. The parent / guardian /

⁵ Compatibility is limited to information maintained in sidechains.

caregiver will also have the right to add information to the immutable Blockchain in the form of messaging. Furthermore, the parent may require physician, hospital, and patient caregiver, friend, or family member access to the patient record / Blockchain. At present, there is no version or iteration of Blockchain that accounts for a parent child relationship or a child caregiver relationship. In fact, this type of relationship is antithetical to the existence of any cryptocurrency. [athenahealth recently stated that 21%](#) of all portal activity are for parents checking on children.

FOOD STAMPS / SNAP BENEFITS AS SOCIAL DETERMINANT IN HEALTH USE CASE

In [July 2016, The Financial Times reported, that the British Government](#) is already testing a system based upon using the Blockchain for unemployment and disability benefits.

“Claimants are using an app on their phones through which they are receiving and spending their benefit payments,” David Freud, the welfare reform minister, told a payments conference last week. “With their consent, their transactions are being recorded on a distributed ledger to support their financial management.”⁶

As referenced in the 2015 *ONC Interoperability Roadmap*, social determinants of health will need to be connected to the patients’ health status. Physicians currently monitor carboxyhemoglobin as an indicator of a patient’s level of smoking. As part of a smoking cessation program, a smart contract on the clinical Blockchain could identify normal blood carboxyhemoglobin (COhb) as reported by a clinical reference lab from the Laboratory Analyzer Blockchain and execute a request to increase an incentive benefit controlled by a “private / permissioned” USDA Clinical Blockchain. The clinical Blockchain will track the specific “chain of custody” from iStat Analyzer (Accriva, Radiometer, etc..) to patient test results report, which triggers the smart contract with the USDA to distribute an incentive. Both the physician and the patient are notified of the disbursement. Similar use cases could be implemented for patients with diabetes, and obesity.

The Food Stamp program now represents over \$78 billion in annual spending. Every year, there are various threats to completely cut or dramatically decrease the program. By linking Food Stamps to specific health outcomes, [Stanford Researchers have found that 144,000 people per year could be saved from obesity](#) complications through food stamp incentive and modification programs. Furthermore, by linking nutrition to the health status of the patient, and their family, draconian cuts in food subsidies may be avoided. Additional incentives can be entered based upon patient entry of self-reported information relating to weight, blood pressure, pulse, and diet. In fact, as retail grocery and/or pharmacy data are added, clinicians will have a significantly greater holistic insight into the patients’ health status, and better information to make clinical decisions in concert with the patient and care team members.

⁶ Financial Times. Use of Bitcoin Tech to Pay UK Benefits Sparks Privacy Concerns. July 11, 2016.

PATIENT – PHYSICIAN MESSAGING ON THE CLINICAL BLOCKCHAIN

At present, the vast majority of communications between healthcare providers and patients is in one direction, from physician to patient. Blockchain will ensure a 2-way stream of communication exists. There are obvious positive results from capturing messages from patients and storing these messages on an immutable Blockchain. Patients and providers will be required to thoughtfully consider this type of messaging and its implications on promoting quality care and better communications.

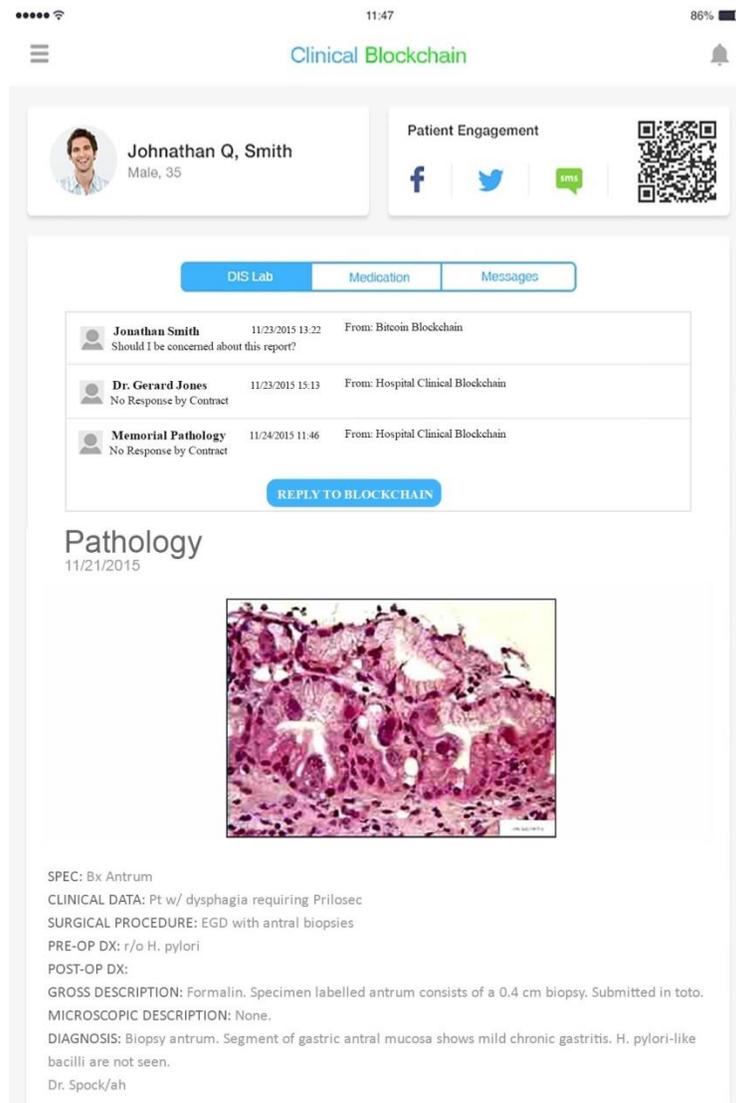


Figure 5: Patients and Physicians will have access to the encrypted Patient Record and Messaging on the Clinical Blockchain.

Every entity, physician, hospital, pharmacy, and laboratory, connected with any specific patient report will have opt-in access to the clinical Blockchain (with permission). There may be a requirement to focus a single point of contact for patients to interact with their physicians by implementing smart contracts that respond to patient messages. It is also possible that secure

patient physician messaging platforms may write a copy of the messaging interactions to the Blockchain.

PHARMACEUTICAL / RESEARCH CLINICAL BLOCKCHAIN USE CASE

Blockchain represents an interesting opportunity for research organizations in numerous ways. One of the most significant aspects of blockchains impact on research is the tracking and publication of intellectual property (not the subject of this whitepaper). Unlike the healthcare, pharmacy, laboratory / analyzer, blockchains described above, the Pharmaceutical Clinical Blockchain will have an anonymous representation of information of a patient's clinical information. The research organization will post a request for a "smart contract" identifying the conditions for inclusion in a clinical trial. Patients with the appropriate clinical trial or research diagnosis and conditions, including lab results and prescribed medications will have the ability to respond directly to the pharmaceutical company, and CRO (Clinical Research Organization ie: Quintiles, Parexel, Mayo Clinic, University of Pennsylvania, Duke Clinical Research Institute, Stanford, NIH, etc...)

IMPLEMENTING THE INTEROPERABLE CLINICAL BLOCKCHAIN

The current state of limited interoperability in the US should not prevent the ultimate implementation of a Clinical Blockchain. Off the shelf solutions are available for vendors to create [PDF file representations of electronic medical records](#). An ideal representation of the patient files would be an encrypted file that includes metadata in HL7 format for each patient. Trust is added to the system by inviting patient advocacy groups into the private / permissioned Clinical Blockchain. Although, a minority votes on the Blockchain, the representation of patients and the audit trails on real-time voting will force larger permissioned participants to recognize the voice of the smaller participants.

Work is performed by Clinical Blockchain permissioned participants comparing all previous entries into the Blockchain as well as pointers to encrypted file locations referenced on the sidechains. The Clinical Blockchain maintains primary accounts and sub accounts for parents and children and relationships for family caregivers. Any changes to these relationships would require a supermajority vote of permissioned Clinical Blockchain participants. No matter what vendor, governance model or "flavor" of Blockchain is selected we must insure that interoperability is integrated at the heart of the Clinical Blockchain.

"Won't Get Fooled Again" The Who, June 25, 1971