COVER PAGE

To: Office of the National Coordinator for Health Information Technology
Karen DeSalvo, National Coordinator for Health Information Technology.
From: Energy Efficient Futures Foundation (E2F2), SOLES, Inc.
Date: Monday, August 8th, 2016
Re: "Blockchain and Its Emerging Role in Healthcare and Health-related Research"

Energy Efficient Futures Foundation (E2F2) and Social Online Liquidity and Exchange Systems, SOLES, Inc., are excited to present to the Department of Health and Human Services our whitepaper on "The Promise of Medicine on the Blockchain". Our team came together to build on a deep knowledge of blockchain technology and our shared professional experience in the healthcare, energy, and home environment sectors.

The future holds so much promise to empower individuals to achieve better health outcomes through the use of blockchains and personal health information. We explore a wealth of ideas about how to apply blockchain technology to the Department's stated goals, with many lively conversations around the potential of blockchain to help improve health in the United States. We've only scratched the surface of our enthusiasm for this project.

Sincerely,

Jason Dispenza, Chairman E2F2, CEO of SOLES, Online Credits Specialist
Christina Garcia, Business Manager of Edge Energy, Blockchain Researcher
Ryan Molecke, CEO of Tectractys, CTO of SOLES, Blockchain Professional
Heather Rae, Healthcare Lead E2F2, Blockchain applications in Healthcare

SOLES - Social Online Liquidity & Exchange Systems, Inc.
E2F2 - Energy Efficient Futures Foundation (a non-profit)

Whitepaper

The Promise of Medicine on the Blockchain

authors:
Jason Dispenza, Chairman E2F2, CEO of SOLES, Online Credits Specialist
Christina Garcia, Business Manager of Edge Energy, Blockchain Researcher
Ryan Molecke, Managing Director E2F2, CTO of SOLES, Blockchain Professional
Heather Rae, Healthcare Lead E2F2, Blockchain applications in Healthcare

Abstract

Healthcare information systems are on the verge of a technological revolution, as powerful systems come online that enable us to store exponentially more patient-data and analyze and navigate this new "big data". Modernizations today involve data input and storage, updating data ownership and access / sharing mechanisms, and even re-engineering key incentives with a focus on patient outcomes and personal responsibility, a goal of the Affordable Care Act. We demonstrate the potential of blockchain technology to upgrade and re-architect healthcare information networks, give patients back the ownership of data that will help incentivize personal responsibility, and provide superior data immutability with state-of-the-art security and sharing mechanisms.

We discuss the goals of the PCORI and NIR, precision medicine, and evaluate the technological landscape before moving into Blockchain as a Healthcare Information Systems and networking upgrade. We show key areas that blockchain technology can impact spanning the healthcare industry, with a focus on medical information systems, data privacy and sharing / interoperability, and underlying incentive models. A section of the paper focuses on current blockchain solutions and the technological horizon, including project scope, budget, and timeline estimates for potential pilot and full-scale programs. A running theme is that blockchains can facilitate doctors to spend more time with patients by alleviating data input, hardening storage layers, and automating privacy and access system and the management of regulatory burdens faced by providers. Blockchain technology promises systems scalability for 21st-century applications in big-data processing, while addressing key incentives to achieve better overall patient outcomes.

I. Project Summary and Impact Statement

Energy Efficient Futures Foundation and Social Online Liquidity & Exchange Systems, Inc., present a whitepaper on the promise and potential of blockchain technology in the medical industry, with critical impact analysis with respect to the stated goals of the Patient-Centered Outcomes Research Institute (PCORI), the Nationwide Interoperability Roadmap (NIR), and President Obama's Precision Medicine Initiative (PMI). This is an exploratory document meant to illuminate core potentials and the relevance blockchain technology to the goals of existing programs. We aim to show how blockchain can enable systemic upgrades to existing information systems and redefine how healthcare professionals interact with and analyze healthcare data. We propose that blockchain mechanisms can enable greater patient ownership of their own data, enable new incentive mechanisms for patient participation towards improved outcomes, and allow sharing of data in a completely secure and modern way. We espouse a sense of urgency in capturing the lost heartbeat of "big data" streams, and the potential for new data-mining techniques to improve the efficiency and efficacy of both diagnostic and therapeutic techniques, to give doctors back the extra minutes with their patients and to make those minutes count.

The PCORI has a guiding document called the "National Priorities for Research and Research Agenda", which outlines new goals for implementation of the Affordable Care Act, and the core purpose of PCORI. The "Agenda" sets out the goals of helping healthcare providers make better, more informed decisions by improving the quality and relevance of the data they interact with and improving information systems and analysis tools, and identifies priorities and criteria that help PCORI asses new programs for their funding portfolio. The NIR, similarly, is a document focusing on healthcare IT systems, to engage, empower, educate and support a new superior level of quality and personalized care, with the National Coordinator of Healthcare Information systems making a personal call for "equipping every person with a long-term, digital picture of their health over their lifespan". The NIR lays out drivers and ten guiding principles, technical components, and "outcomes" that serve as criteria for evaluating the effectiveness of new programs, and specifically focuses on interoperability of data systems, with mention of data formats regarding ease of parsing, systems scalability, and the "interaction between clinical and administrative electronic health information".

In 2016 the Obama administration unveiled the Precision Medicine Initiative with funding in the congressional budget for programs focused on new tools and innovation in approaches to disease prevention and treatment that take into account patient-specific genes, environments, lifestyles, as opposed to a "one-sized-fits-all" approach. The PMI sets aside funding for building networks for data sharing in research, genome-specific cancer-treatment approaches, and databasing / interoperability system upgrades. These considerations are the driving motivators of our whitepaper, the priorities and criteria that shape our explorations of blockchain and it's potential in healthcare applications.

Blockchain technology holds the promise of being a keystone technology in healthcare information systems, as an immutable, decentralized datastore and notary. Blockchain systems can allow strong privacy controls and access layers on medical record, while enabling simpler sharing of data. One of our key goals is to show how blockchains can be a multiplier on the effectiveness of already-existing systems, how a technological upgrade to some core systems such as the databasing layer and automation of datastreams can "harden" the healthcare information ecosystem. Blockchain tech can provide a robust data-storage and transport network with the extensibility and scalability we need for our healthcare information systems to achieve new levels of improved performance and interoperability under the increasing weight of growing 21st-century healthcare demands. We envision new personal data repositories that will hold exponentially more data about each patient, under the ultimate control of the individual and shared as needed with trusted parties, or anonymously for medical research, and connected to markets and society in new ways. Augmenting existing systems with blockchain components can help free doctors to spend more time with patients and enable more human-friendly interfaces Healthcare IT systems provide, much more valuable automated feedback and powerful new analysis tools, and most importantly, a future with better patient outcomes.

II. Current Initiatives, Goals, and Evaluation of the Current Technology Landscape

The goals of Patient-Centered Outcomes Research Institute (PCORI) are to: substantially increase the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions; speed the implementation and use of patient-centered outcomes research evidence; and influence clinical and health care research funded by others to be more patient-centered.

The “10-Year Vision to Achieve an Interoperable Health IT Infrastructure” established the guiding principles to achieve an interoperable health IT ecosystem and led to creation of the National Interoperability Roadmap (NIR). The NIR’s near term goals are the sending, receiving, finding and using of priority data domains. The priority data domains are clinical to begin with, expanding to cover other types of information, including social determinants of health. The key goals in the NIR are to leverage outcomes-based reimbursement to encourage adoption of electronic health records, a similar goal and mechanism of Meaningful Use. It emphasizes the importance of getting to a level where the person or individual is at the center of a system that can continuously improve care, public health, and science through real-time data access, following these guiding principles: focus on value, be person-centered, protect privacy and security in all aspects of interoperability and respect individual preferences, build a culture of electronic access and use, encourage innovation and competition, build upon the existing health IT infrastructure, one size does not fit all, simplify, maintain modularity, and consider the current environment and support multiple levels of advancement.

We believe blockchain will be a leading technology for achieving a level of true data interoperability that will allow every patient to securely access their electronic health information when and where they need it most, and enable individual health information to be shared securely with providers. We understand that the current landscape has many providers concerned about cybersecurity, and that they may choose not to share data for a variety of reasons beyond technology capabilities including concerns around the increased liability risk of exchanging data, competing technology priorities or a lack of ready trading partners.

This project's mission will empower consumers to improve their health by opening up access to healthcare outcomes, expand data sources and users in the interoperable health IT ecosystem by facilitating the ledgerization of historical data, and provide access and interoperability toolsets to lower costs and increase industry participation in an open access repository and digital contracts platform. A variable range of encryption levels and blockchain architectures is possible to balance efficiency and privacy. Datasets in the blockchains can be designed to be highly encrypted and yet efficient in terms of (1) size stored on disk drives, (2) total energy used to run servers, and also (3) efficient in terms of accessibility by network partners, and datasets can also be securely notarized, timestamped and held by third-parties for later authentication and lookup, to reduce the size of the data needed on-blockchain.

Major industry groups would maintain portfolios and server node-networks serving many blockchain (and/or sidechains) holding data pertinent to their interests. Such subnets would feature data permissions and sharing networks approved by working groups, government agencies, patients and caregivers / practitioners, private payers, employers and public payers for programs like Medicare, Medicaid and TRICARE. One key aspect of blockchain systems is how they can support better stratification across populations of aggregated electronic health information to identify and address health disparities. The proposed system can support massively parallel inputs and can be easily adapted and enhanced in the future to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user.

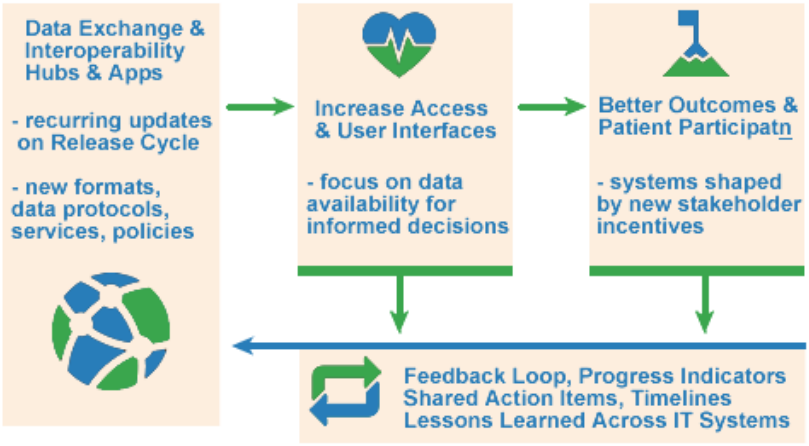

Figure 1. Interoperability Concept Diagram for Progress Feedback Loop

The current medical IT infrastructure is designed for physicians, using advanced technical terminology and processes, and ill-suited for individuals. For example, McKesson Corp. developed PracticeChoice, a cloud-based electronic health records system, to focus on

insurance claim processing and advanced clearinghouse interfaces, with less regard for other practice business needs like patient communications, scheduling and marketing, billing systems functionality, or usability features like notation-entry. MDHQ and eMedicalFusion, server-based EHR systems, developed platforms specifically for concierge, cash-based practices with robust business and patient support features. These are closed systems that do not exchange data from other sources.

Hospitals and physicians no longer control personal health data, and they possess only a subset of data relevant to a person's health. Institutional systems do not include home environment, self-testing, food journals, health apps and myriad personalized data. Precision medicine (similar in its approach to functional medicine) adds complexity to systems interoperability. Traditional insurance generally does not cover precision/functional medicine laboratory testing (organic acid, IgG/IgM/IgE inflammation, genetic SNP, hair mineral, micro/macro nutrient tests, for examples). It may be purchased directly by the individual outside the conventional medical insurance paradigm. It is not accounted for in the interoperable network of practitioner-derived data, but it could be part of the deep health history, as part of a repository owned and managed by the individual.

Real-time biometric data is a useful predictor of health outcomes, but its collection generates *zettabytes* of data. These systems were not designed for APIs from other sources. They are not designed to capture real-time data, like historical variability of heart beat, blood sugar, and hormones.

HITECH and HIPAA challenge hospitals, insurance payors, and other healthcare institutions to comply with electronic personal health information (ePHI) security protections. HHS recently settled its largest data protection violation, fining an Illinois hospital $5.55 million for failure to prevent security breaches. Covered entities are expected to implement physical, technical, and administrative security measures sufficient to reduce the risks to ePHI in all physical locations and on all portable devices to a reasonable and appropriate level. They are to engage in a comprehensive risk analysis and risk management to ensure that individuals' ePHI is secure. Healthcare records are more valuable on the black market than credit card records because their data elements, such as birth dates, addresses and Social Security numbers can't be readily changed, like credit cards. Insurance payers that connect disparate systems (point of sale, PHI) without a secure architecture risk exposure. HHS keeps a record of data breaches; two of the largest hacks were of Anthem in 2015 and Banner Health in June 2016. The HHS "wall of shame" is evidence of the lack of security of ePHI.

III. Blockchain as a Healthcare Information Systems and Networking Upgrade

The use of Merkle Trees to securely timestamp entries in a ledger with secure consensus protocols, what we now think of as "blockchain" or "distributed hash-chain ledger" technology, represents a culmination of decades of progress in computer science and

cryptography, a new apex in secure data storage, and it introduced us to the completely new economic niche of digitally tokenized asset classes. Playing on these strengths, the key areas that blockchain can positively impact on an intersect with the goals of the PCORI, NIR, and PMI initiatives are:

1) Data Storage: blockchains provide data immutability in a decentralized node network, with the option of either storing the data directly in the blockchain or notarizing a record stored in a third-party system. Multiple blockchains and sidechains can be used to provide clean separation of data by class or type, node operators are stakeholders in given datasets.

2) Data Access & Analysis: privacy and sharing can be provided by encrypting datasets with varying numbers of key-holders, using "hierarchically deterministic" data addressing schemes. Patients will gain greater control their own data, and learn to take more responsibility over it. The future brings "big-data", blockchains will help us to collect exponentially more data and analyze it in completely new ways, whereas current systems "lose" data.

3) Interoperability & Dataflow: Blockchains can act as highly connected and automated repository systems, with standards and protocols defining data read/write, notary, and sharing, and adaptable user-interfaces. Connections can be forged to outside industries and emerging / real-time markets more easily with blockchain technology.

4) Personal Healthcare Repositories: A sidechain just for one person, containing a person's healthcare data via references to entries in other chains, might include curated content from the patient themselves. As we change the incentives of the stakeholders and systems designers, the character and nature of healthcare databases will change, to become more personal, social, and living.

5) Roles & Incentive Systems: Blockchains can complement emergent changes in support roles, and provide better service via clearer and redefined incentive models. Links to real-time market systems and tokenizations of healthcare credits can promote accurate and competitive pricing.

In diagnostics and research, blockchain can offer some distinct advantages over classical information systems. Notably, a shift is occurring in the early 21st-century towards systems that can store and process exponentially larger datasets than were ever imagined possible before, "big data". In medicine, this shift will manifest as an increased capacity to capture many types of personal and real-time datasets that were "lost" in classic systems, an invaluable archive for the new fields of precision medicine and big-data analysis techniques. In preventative care and diagnostics, blockchains may offer new avenues for uncovering geo-statistical and environmental health trends, as complementary industries affecting environmental health can tie in relevant data such as home-performance and air quality. Automated diagnostic tools may be able to detect early indicator symptoms, provide warnings

or suggestions for relevant medical tests, or flag input as relevant to larger datasets being monitored by research efforts.

Therapeutics and outcomes-monitoring are both fields that face radical makeovers as medical information storage expands from a shallow sea of hand-taken notes and filed paperwork into a deep ocean of digitized recordings of drug, allergy, incident histories, analog datastreams, even genealogical records and personalized video or holographic entries might adorn the historical records of our future ancestors. Environmental, dietary, and geo-statistical data patterns will emerge, leading to the most effective treatments among variational factors. Automated therapeutics systems may help medical "coach" personnel prepare reports from patient interviews, alert to prescription drug interactions or allergies, even provide automated appointment and medication and nutritional compound reminder systems.

Blockchain can enable complete strong privacy for medical data, controlled by a single key-holder with absolute privacy for that single entity. In a more real-world scenario, key-holding systems will incorporate multiple-signing or "multi-sig" data protection, as illustrated in Fig. 2., below. All stakeholders may hold keys and share subsets of data, including certification and auditing authorities, administrative / financial personnel. Stakeholders also operate nodes in the decentralized node network for their own access and to ensure data redundancy. Third-party data-storage service (or even patients running sidechain nodes themselves) will hold much, if not most of the analog datastreams and data-heavy personal entries, and these will simply be notarized in the more public or widely-used chains, providing timestamping that can prove ownership, existence, and authenticity of the data as of a given date in the past. Mechanisms for allowing data to be publicly or privately searched for medical research and diagnostics can also be automated, via publishing channels to designated sidechains.

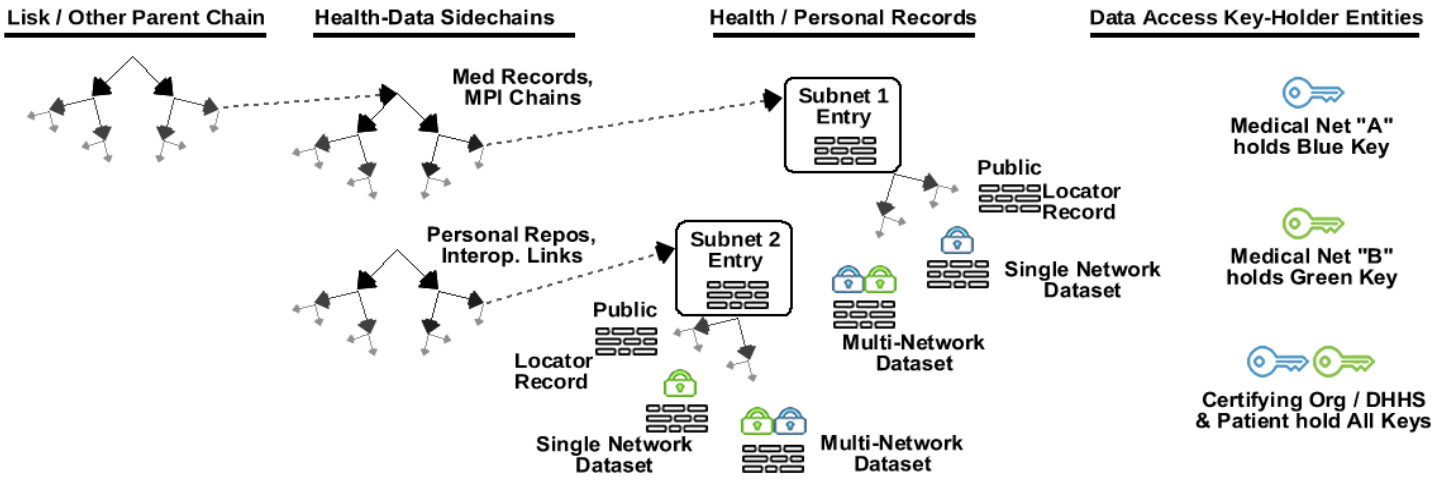

Figure 2. Sidechain Data Structure with Hierarchical Permissions and Access Sharing

IV. Current Blockchain Solutions and the Technology Horizon

Blockchain technology represents a culmination of decades of theoretical breakthroughs in computer science and cryptography, with historical roots tracing back to Diffie-Hellman secure communications, Turing machines, mathematical "hashing", and computer science, specifically Merkle-tree "binary tree" data structures. Early experiments in using hash functions for securing financial transactions were described and implemented by innovators such as David Chaum, with his eCash, Wei Dai, with b-money, and Nick Szabo, with bit gold. It wasn't until a project with a murky originator with the pseudonym Satoshi Nakamoto, called Bitcoin, started gaining traction that cryptocurrency started to become a household term. Since then, almost a decade has passed, many shallow copycats have come and gone, a few semi-clones with interesting features added have survived, like namecoin, litecoin, peercoin, and a new breed of re-engineered blockchain technologies called "blockchain 2.0", such as Ethereum, Bitshares and Lisk came out within the last few years, and they hold the promise of real innovation. Indeed, this budding tech niche has proven itself as not only disruptive in the financial tech industry, but as having the potential to fundamentally change how we think of data storage, the value of data, digital contracts, even the delivery of applications, and how people interact with "tokenized" data systems.

There are several factors to consider when choosing the best blockchain system for the purposes of implementing the priorities of the PCORI, NIR, and PMI, and all are not built equal. SOLES and E2F2 have evaluated a dozen blockchain systems and startup groups in terms of 1) consensus mechanism, 2) smart contract and/or decentralized application abilities, 3) on-chain & off-chain data storage mechanisms, 4) difficulty of getting a minimum viable (MVP) product demo running with each tech "stack" and API. Bitcoin and Ethereum both run on the "Nakamoto" proof-of-work consensus, where energy is burned to solve a computational task and the network controls the distribution of the underlying crypto-currency asset tokens, whereas systems like Ripple, BitShares, LISK are all "permissioned" blockchains on a Byzantine Fault Tolerance (BFT) consensus mechanism. BFT systems can much more energy efficient because they don't rely on proof-of-work, and in BFT systems, share / asset token supply is controlled by a trusted issuing organization instead of by an algorithm. Smart contracts are algorithmic logic that can be run directly from code stored in the blockchain, and they can execute the terms of digitized contracts controlling based on pre-determined sources of outside input called "oracles". Decentralized apps are like websites or smart-device apps, but instead of being served by web-servers, they are served by blockchain nodes, they can enable transactions, notarizations, data-input and signing. At this time, E2F2 and SOLES are interfacing with the LISK team, a newer blockchain startup based in Berlin, that we see as most promising according the criteria listed above.

One of the most important considerations in blockchain engineering is the idea that the architecture and integrity of a tokenized, decentralized node-network is largely be dictated by the system stakeholders and their underlying incentives. In permissioned systems, it is often termed "decentralized", where a group of tens or hundreds of pre-approved node operators

come together to run a network, as opposed to truly "peer-to-peer", where there is truly public blockchain in the sense that anyone can just become a node and see all the data in the blockchain/s without any prior approval. Hospitals may become node operators for several blockchains, each storing different aspects of patient and administrative data. Insurance companies might become node operators in blockchains holding medical financing info, even participating in credit systems for preventative care and healthy living rewards systems.

Patients themselves will become node operators, themselves or served by dedicated node-operator companies, to safeguard personal blockchain records including all of their own records, histories, charts, genealogy, and even personal blogs, video, holographic entries, social media, personal and business finances, even dating and voting data might be linked. Personal healthcare records may be just one class of blockchains in new world populated by blockchains for all sorts of other related data, which may be invaluable for big-data and patient-specific analysis, such as property ratings / construction / building performance, dietary and environmental data, geo-specific data related to travel, relationship / career / mood trends, financial/economic data, and socio-cultural contributions may all contribute to people's health and treatment outcomes in ways traditional medicine could never discover.

The privacy mechanisms of blockchain technology are so absolute that the must be implemented careful, so that lost keys don't permanently lock records or give rise to unanswerable malicious attack vectors. Key certification authorities will likely hold at least one master key for personal healthcare records of most types, where patients, doctors & clinics, hospitals & provider networks, insurance and remittance companies all might hold keys in multi-sig permission as indicated in Figure 2. This also allows the key certification authorities to maintain and publish "identity" chains holding the data about certified contractors, auditors, practitioners, and then the these chains can be used to automatically verify signatures attached to data in other chains for authenticity. This is called "cross-chain" certificate verification and may allow for digital signing of prescriptions or authorizations for medical procedures, for example.

Smart contracts have the ability to look up data within the blockchains, and do simple computational tasks like hash or signature verifications, while decentralized autonomous organizations (DAOs) are special forms of smart-contracts that can also send / receive and take action upon messages sent amongst themselves, like neurons in a digital brain, reacting to data stimuli on the blockchains. Just this month we have a report of IBM's Watson AI system diagnosing a woman with a rare cancer and recommending a much more successful treatment regiment after comparing her genome and medical history to that of thousands of other patients. We see such smart diagnostic and trend-spotting tools as a major boon to doctors of the 21st-century, and we posit that blockchains will be a keystone technology enabling humanity to collect, store, integrate, and navigate the new oceans of data we find before us.

A budget estimation for simple blockchain exploratory pilot programs might include budgeting for basic systems design and testing phases, healthcare and hospital

ledgerizations (on-ramping), software user-interface design and market-testing, filesystems interoperability work, each of these might rightly cost $200-$300k. A full-scale rollout would have a much lower per-hospital or per-clinic cost for software / hardware and point-of-sale systems rollouts, but would also require personnel training, patient training, node server setups and systems admins for the node servers. Full hospital / big insurance company rollouts for blockchain tech may come with a price tag in the millions of dollars per hospital, and may essentially represent a foreign system integration for insurance companies. This is likely to be a gradual process but we do envision that blockchain tech has a large potential as a systemic upgrade and modernization opportunity that can retain on the investment with great gains in understanding illness, prevention, diagnostics, effective treatments as judged by long-term positive outcomes, and as a baseline data-collection system for patient-specific and precision-medicine techniques.

V. Summary and Thanks

This paper is meant as a brief exploration and summation of promise of blockchain technology to upgrade and re-architect healthcare information networks, build better systems based on revamped incentive and usage models, and give patients back the ownership of data to help incentivize personal responsibility. Blockchains can provide superior data immutability with state-of-the-art security and sharing mechanisms, even smart utilities, scalable and adaptable interoperability layers. The PCORI, NIR, and PMI initiatives should all consider further investigation and grant-funding for collaborative efforts to explore this new and exciting new technology for it's potential as an infrastructure / IT and credits / payments systems upgrade. Most importantly, we think this whitepaper challenge and Blockchain Workshop is a great way for the sponsoring organizations and the healthcare industry to learn about blockchain and how it can be used to achieve better patient outcomes.

E2F2 and SOLES, Inc. thank the Office of the National Coordinator for Health Information Technology and the Department of Health and Human Services for sponsoring this whitepaper challenge. We believe our team has the relevant experience to speak smartly and succinctly on the topic of "Blockchain and Its Emerging Role in Healthcare and Health-related Research" at the NIST Blockchain & Healthcare Workshop, and even to help sponsor pilot programs and rollouts in the future. We'd love the opportunity to stay involved and offer input as a collaborator with any grant awardees under this competition also.