BLOCKCHAIN: THE CHALLENGES AND OPPORTUNITIES IN HEALTHCARE

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INTRODUCTION

The opportunities to leverage blockchain within the healthcare industry are boundless. This groundbreaking technology allowing the decentralized, secure distribution and sharing of data and transactions across multiple entities, could transform healthcare as we know it today. This whitepaper explores emerging blockchain technology and its opportunities with electronic health records (EHR).

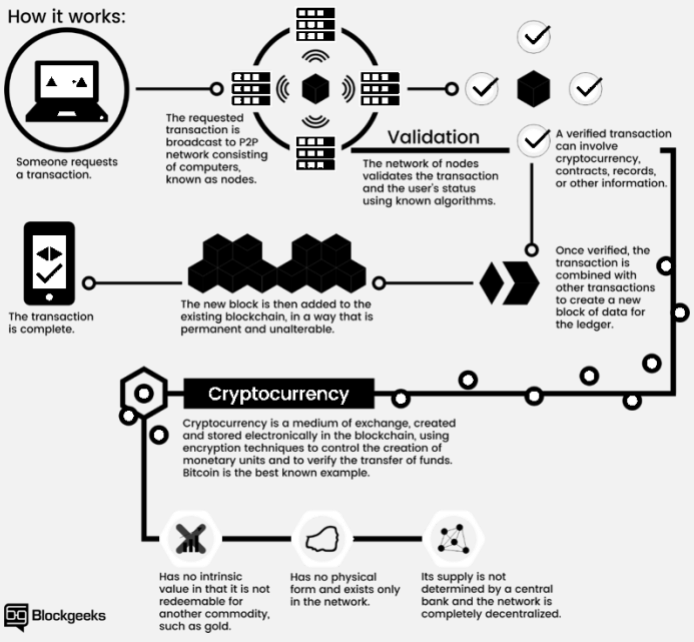
One enticing possibility is securely distributing EHR information across organizations which would optimize the pharmaceutical supply chain, streamline billing and claims management, minimize fraud, and centralize clinical trial and outcomes data to drive innovation; and the list continues.

WHAT IS BLOCKCHAIN?

Blockchain is a decentralized, distributed public ledger of transactions, using an encrypted, structured network of systems to run those transactions, which are recorded chronologically in growing blocks.

Each node (a computer connected to the network) gets a copy of the blockchain, which is downloaded automatically. Blockchain works by using public key cryptography to create an append-only, immutable, time-stamped chain of content blocks, recording transactions across a network of replicated databases that are always in sync. The cryptographic techniques employed allow participants to interact without previous trust or knowledge of the parties. These interactions are verified to enable trust and collaboration between participants while recording an undisputable audit of exchanges. (See Figure 1)

Figure 1: How Blockchain Works



Source: https://blockgeeks.com/guides/what-is-blockchain-

Another component of the Blockchain environment is the smart contract. Smart contracts are a piece of software that serve as an honest broker between entities processing a transaction. The software defines the rules and executes instructions based on those rules as the blockchain transactions are being processed. For example, controlling who receives copies of the transactions, executing other contracts based upon the content of the transaction, storing specific details about the transactions.

Blockchain was originally designed as an accounting technique for Bitcoin, which uses the distributed ledger technology. In that context, blockchain is used to keep track of currency transactions, without any central record-keeping. The record cannot be retroactively altered without altering all of the blocks that come after and without the collusion of the network.

While thinking too deeply about the concept can make the average person's brain hurt, the important thing to remember is that blockchain has enormous security benefits over current database systems in healthcare.

Best known for its original use in financial services technology (FinTech), to manage cryptocurrency transactions, Blockchain more recently has been applied to a broad range of solutions in various industries, many outside of healthcare. These include certifying authorship and ownership of digital art, facilitating job recruitment and searches, innovating in online gaming and gambling, creating transparent supply chains for products in the food industry, driving media and content distribution, creating "digital passports" for individual diamonds in order to fight fraud and money laundering, and even helping entrepreneurs in the cash-heavy cannabis business to establish and maintain their business legitimacy (Mesropyan, 2016).

BLOCKCHAIN IN HEALTHCARE

Healthcare experts are also looking in the direction of blockchain, considering the efficacy and probable challenges of blockchain in data integrity, validation, and transfer of value, without loss or delay on the medical supply chain. Although many in healthcare and other industries are skeptical about this disruptive technology, when rightly deployed, blockchain can be a game changer, and the technology excels when the following conditions are met:

1. Multiple parties generate transactions that change information in a shared repository.
2. Parties must express trust in the validation of transactions.
3. Intermediaries are no longer considered efficient or trustworthy.
4. The system requires enhanced security to ensure the integrity of transactions.

The potential rewards of blockchain are expected to be great, as evidenced by the fact that in early April 2018 UnitedHealth Group and Humana—two of the largest health insurance providers in the nation and usually industry rivals—announced a joint venture pilot project with Optum, MultiPlan and Quest Diagnostics that aims to improve healthcare data quality using blockchain (Floyd, 2018).

A joint release from the companies stated, "The pilot will examine how sharing data across health care organizations on blockchain technology can improve data accuracy, streamline administration and improve access to care."

The statement also laid out the basic problems the pilot is intended to address: "Today, managed care organizations, health systems, physicians, diagnostic information service providers and other health care stakeholders typically maintain separate copies of health care provider data, which can result in time-intensive and expensive reconciliation processes when differences arise. Industry estimates indicate that $2.1 billion is spent annually across the health care system chasing and maintaining provider data."

EHRs facilitate patient history for planning health care, clinic visitation, and diagnosis. The health care industry faces an urgent need to integrate EHRs in areas of data personalization and patient engagement. This is due in part to the discrepancies and medical fraud that have led to financial loss, deaths, and misdiagnosis in care delivery. By leveraging its unique properties, blockchain assures health stakeholders of authentication, confidentiality, accountability and data sharing—crucial considerations when handling sensitive health information.

BLOCKCHAIN AS A DISRUPTIVE TECHNOLOGY IN HEALTHCARE

In August 2017, the Health Information Management Systems Society (HIMSS) created a work group to examine how this distributed ledger technology could disrupt health IT and change how healthcare operates. The group includes providers, payers, vendors and other interested stakeholders.

In its first blog on the subject, the work group explained a main opportunity of blockchain in healthcare: "The greatest potential of blockchain may be its ability to empower patients to own and gather their own data. In many ways, the promise of blockchain lies outside the current way we think in health IT, serving as a direct challenge to siloed, centralized data approaches." (HIMSS, 2017)

Patient-generated data and patient-reported outcomes are growing areas of interest for providers and leaders in healthcare. In a 2017 survey of nearly 700 healthcare executives, clinical leaders and clinicians conducted for *NEJM Catalyst*, respondents identified what they felt the most useful sources of data are today and what they will be in 5 years. Presently, clinical data was rated highest by far at 92%. At #2 and #3 on the list were cost data at 56% and claims data at 45%. Now go five years in the future.

When asked about what they believed would be the most valuable sources 5 years from now, claims data drops off significantly in value, scoring only 32%, and clinical and cost data will be joined at the top by patient-generated data and genomic data, both scoring 40% (*NEJM Catalyst*, 2017).

This points to an expectation that patients will be increasingly involved in their care very soon. It also indicates that these clinician leaders and executives believe patient-generated data related to conditions, wellness, self-reported outcomes and more will be a valuable source of both clinical and business information. It also envisions a world where information obtained from EHRs, patient biomarkers, medical devices, and patient feedback, will be combined to drive new innovation in care. However, this vision is still out of reach in healthcare today.

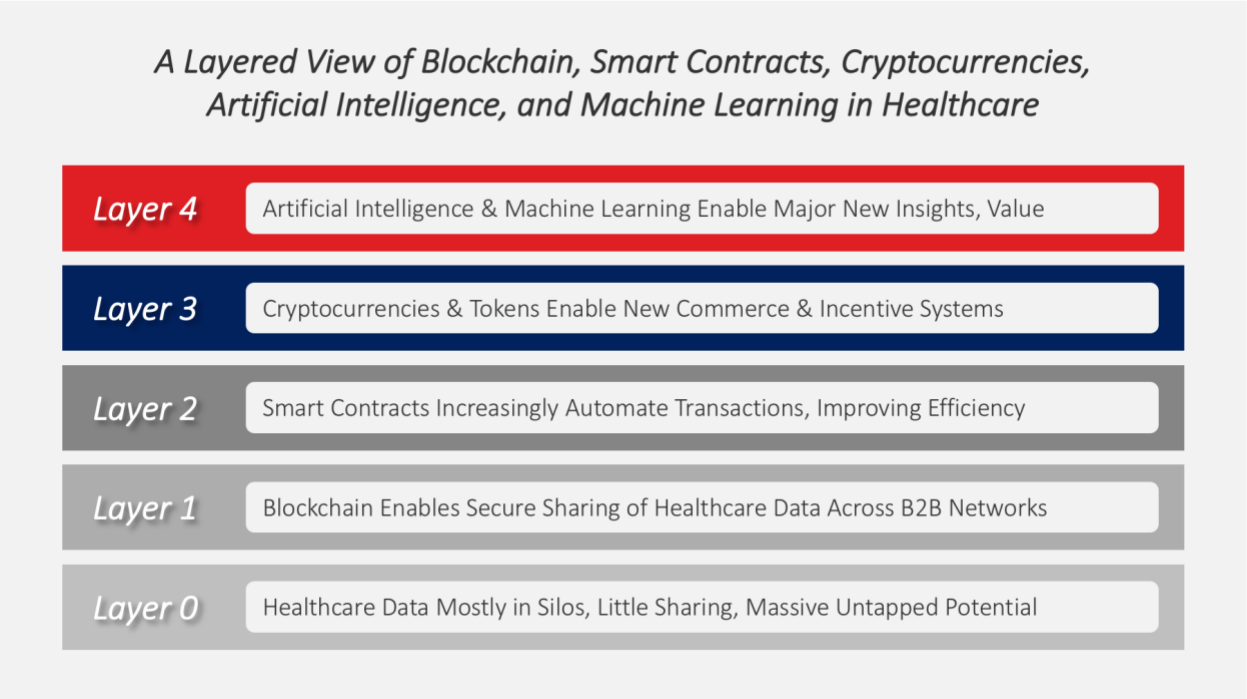
In her analysis of the *NEJM Catalyst* report, Amy Compton-Phillips, MD, Executive Vice President and Chief Clinical Officer for Providence St. Joseph Health System, stated, "For patient data to become more impactful in healthcare, provider organizations will have to figure out how to efficiently obtain, integrate, and share information across disparate systems."

Because this whitepaper series focuses on cybersecurity, it is important to note that, according to a report released by Protenus Breach Barometer, there were a total of 450 health data breaches in 2016, affecting more than 27 million patient records. About 43 percent of these breaches were insider-caused, and 27 percent due to hacking and ransomware (Protenus Inc., 2017). This is one of the many reasons why the healthcare sector should adopt blockchain technology, and why organizations such as Gem Health, a provider of blockchain application platforms for enterprises, have collaborated with Capital One to develop blockchain-based healthcare claims management solutions.

A LAYERED VIEW OF BLOCKCHAIN & ASSOCIATED TECHNOLOGIES

In its second blog in early February 2018 titled, "Healthcare Blockchain – A Path to Success in 2018," HIMSS Blockchain Workgroup members David Houlding, Director of Healthcare Privacy and Security for Intel Health and Life Sciences, and Heather Flannery, CEO of Obesity PPM presented a layered progression of using blockchain in healthcare (See Figure 2).

Figure 2: A Layered View



In explaining where healthcare is presently (Layer 0), the authors wrote: "Today, healthcare data is mostly in silos within enterprises across providers, payers, pharmaceuticals, life sciences, and increasingly also with patients and consumer health organizations. There is massive untapped potential to both improve the quality of patient care and reduce the cost of care with targeted safe sharing of this healthcare data."

In layer 1, blockchain enters the picture, with organizations such as drug and medical device supply chains, health information exchanges, clinical data sharing networks and a range of other healthcare organizations enabled by blockchain to share data in a targeted, secure manner.

In layer 2, smart contracts automate more transactions and execute more code on blockchains rather than on enterprise systems in healthcare organizations, improving efficiencies and patient care and reducing costs.

In layer 3, it is envisioned that cryptocurrencies and tokens might be incorporated for some uses in healthcare, creating new commerce systems and incentives. One example given was patients earning cryptocurrency and tokens for their participation in clinical research, turning this value back into covering their healthcare costs.

In layer 4, artificial intelligence and machine learning help with early and improved disease diagnosis, more precise illness treatment, and improved patient engagement (Houlding. Flannery, 2018).

OPPORTUNITIES FOR BLOCKCHAIN IN HEALTHCARE

Healthcare executives, governments, and the provider community globally are excited about the new possibilities presented by blockchain. However, the industry needs to focus on establishing blockchain consortia to foster community partnerships and create frameworks for future implementation on a massive scale across healthcare use cases.

Cybersecurity

Cybersecurity threats are a vital concern for medical device and technology companies. Health systems, drug manufacturers, and suppliers need a secure and trusted health IT ecosystem to manage the healthcare supply chain, data, and patient records. The current growth of connected health devices will be challenging for the Internet of Medical Things (IoMT) as the existing infrastructure will not be able to support the growing IoMT ecosystem. Blockchain is seen as a viable solution to bridge the gaps of device data interoperability while ensuring security and reliability around IoMT use cases. Companies such as Telstra (user biometrics) and Tierion (industrial medical device preventive maintenance) are actively working on these use cases.

Chronic Care Coordination

Inconsistency in care coordination in chronic illness management, commonly called fragmented care, is a common problem throughout healthcare, and has been found to result in suboptimal care and higher costs. In one study, patients of primary care providers with high fragmentation of care had 7% to 9% higher rates of preventable hospitalizations, and an average $4,542 in higher healthcare spending (Frandsen & Joynt, 2015). One example of a chronic condition with challenging care fragmentation problems is managing kidney transplant recipients, who require complicated long-term care that involves several care transitions and hand-offs among multiple providers and specialists (Gill, Wright, Delmonico, & Newell, 2017). With blockchain, the patient's records could be centralized in a care management platform, with care teams of patients and providers working together among separate facilities, exchanging information from different points along that patient's continuum of care, linking hometown primary care providers with distant specialists when needed.

Personalized Healthcare

Consumers are increasingly involved in their medical care delivery. Digital healthcare solutions are enabling this by creating personalized healthcare data, and a sense of consumerism in patients. Patients are beginning to track their symptoms and demand news feeds on related health issues.

Some will change their physicians if they can't access their records. Patients want to know the state of their health before the doctor is called and access the data on their medical history.

The present healthcare system fails to provide this and raises a question on data ownership and the integrity of medical workers. Blockchain, with its peer-to-peer data-sharing networking models, delivers identity management structures with predefined consumer access rules. This will ensure that patients have more control over their health data, and will also enhance patient engagement initiatives. Additionally, it allows for the permanent storage of encrypted patient-generated data on immutable blockchain systems, and this could provide a single, unified view of patient data. As a result, patients will be empowered to share their anonymized personal health data for research selectively and possibly receive incentive payments for doing so from the research entity or some incentive measure from insurers for resulting improvements in health behaviour.

Pharmaceutical Research and Precision Medicine

Blockchain-based, time-stamped permanent records could potentially eliminate the cost of clinical trials and data management and facilitate interoperability and research. Billions of dollars are being wasted on drugs due to non-conformation to consumer genetics or inability to provide a conventional medical solution. Blockchain's security structure could help streamline patient-centric drug development for future targeted therapies by better facilitating the exchange of personalized data and direct health sources for studies or research. The resulting enhancement of collaboration among industry participants, academia, researchers and patients could foster improvements in medical research, and population-based genomic studies to promote precision medicine.

BLOCKCHAIN EHR USE CASE

Blockchain technology will enable data exchange systems that are cryptographically secured and immutable, allowing access to historical and real-time patient data, while eliminating the cost of data reconciliation. The healthcare industry is looking for ways to reconcile medical data in clinics, hospitals, pharma labs, and medical research fields. The emergence of blockchain allows data storage to be efficient as it does not matter the time or place of storage, as such information can always be reconciled.

Blockchain updates every piece of EHR information on an open-source, community-wide trusted ledger, so audits can be transparent and understood by all participants. With blockchain, the EHR reconciles community information, with integrity from the point of data generation to the point of usage (diagnosis, prescription or research), without any human intervention. EHR data is recorded on the blockchain and notifies stakeholders to control the transaction; it shifts the focus of scrutiny from the system to the stakeholders, enabling stakeholders to manage their operations.

Blockchain in EMR features an interface that will simplify patient interaction with records across the health institutions. A patient can access his medical records in Dubai or Berlin as data is on a unified system featuring an enhanced user interface.

John D. Halamka, MD, Andrew Lippman, and Ariel Ekblaw are authors of a whitepaper detailing their MedRec system. In a *Harvard Business Review* article, they explain the concept of using blockchain with EHRs. "The rationale for considering a blockchain in electronic health records is twofold," they wrote. "First, it avoids adding another organization between the patient and the records. It is not a new clearinghouse or 'safe deposit box' for data. The blockchain implies a decentralized control mechanism in which all have an interest, but no one exclusively owns it. This is an architectural change that generalizes past medical records. Second, it adds a consideration to a time-stamped, programmable ledger. That opens the door for intelligent control of record access without having to create custom functionality for each EHR vendor." (Halamka, Lippman, and Ekblaw, 2017)

CHALLENGES WITH BLOCKCHAIN

Several inherent characteristics of the healthcare industry and the way in which EHR technology was historically developed pose a significant challenge for the adoption of blockchain technology.

First, in healthcare, the lack of structures to collect, share, and analyse information results in a lack of interoperability. Existing systems are managed in an off-line architecture, with centralized, local databases, whereas blockchain technology is decentralized and in the cloud. Moving healthcare systems in this direction and implementing the blockchain technology will not be possible without first having an efficient EHR system capable of facilitating collaboration and interoperability among medical and scientific communities

Smart contracts encrypt patient data, and permissions are sometimes taken to access this information. Data will be digitally signed, and medical workers would need access to this data in cases where the patient cannot give it. For example, unconscious patients, whose privacy is respected, will need their health history for patient-centric prescriptions. This would require the patient to entrust his or her key with someone else, creating a security gap.

In 2016, MIT Media Lab and Beth Israel Deaconess Medical Center released a white paper entitled "A Case Study for Blockchain in Healthcare: 'MedRec' Prototype for Electronic Health Records and Medical Research Data." The prototype uses smart contracts to demonstrate how principles of decentralization and blockchain architectures could contribute to secure, interoperable EHR systems (Ekblaw, Azaria, Halamka, and Lippman, 2016).

In the whitepaper, the authors noted a primary challenge: “EHRs were never designed to manage multi-institutional, lifetime medical records. Patients leave data scattered across various organizations as life events take them away from one provider's data silo and into another. In doing so, they lose easy access to past data, as the provider, not the patient, generally retains primary stewardship (either through explicit legal means in over 21 states, or through default arrangements in the process of providing care). Through the HIPAA Privacy Rule, providers can take up to 60 days to respond (not necessarily to comply) to a request for updating or removing a record that was erroneously added. Beyond the time delay, record maintenance can prove quite challenging to initiate as patients are rarely encouraged and seldom enabled to review their full record. Patients thus interact with records in a fractured manner that reflects the nature of how these records are managed.”

The authors also cite interoperability challenges among various provider and hospital systems, resulting in a lack of coordinated data management and exchange, and ultimately, fragmented health records. Economic incentives encouraging health information blocking were also mentioned as a barrier.

There are many technical challenges. How will data be migrated from the EHR to the blockchain, given that both technologies are different? The existing healthcare ledger is undistributed, making it unready for wide-scale integration or development. Technically, this entails minimizing the data that needs replication–for example, a patient who is going back for the same prescription–as blockchain functions within the same ledger instead of among different clinic administrators. Also, how will you seamlessly change the contract semantics once the schema is in operation?

As with many new technologies, the most resistant hurdles are the people who will use it or be affected by it. It is important that health consumers and medical workers be part of the innovations from start to finish. Blockchain should be implemented gradually, to test the response of the users at every stage.

Healthcare policymakers should consider collaboration with industry players to understand and facilitate the growth of the ecosystem within the bounds of the existing regulatory framework and new administration policy objectives. Considerations may include the implication of the distributed storage nature of the blockchain, who has ownership of records (and when does ownership change), and how access is granted using the blockchain.

The following are some questions that are emerging in healthcare regarding blockchain:

- Is blockchain suitable for healthcare and how can it be implemented?
- How long will primary stakeholders agree on blockchain entrance into the system?
- Are there organizational or government structures that must be formed for a development of blockchain when it comes to EHR integration?
- Is there a blockchain quality standard for user experience and health outcomes?

- Can the concerns of stakeholders be balanced within the blockchain implementation?
- Blockchain has no central regulation. How will the system overcome the present social, central and across boundaries / barriers to implementation?
- Are there challenges in data ownership and EHR analytics?
- How do we align different terminologies within devices, hospitals and across the industry so EHR integration can be completed more efficiently and more often?
- How will the system make patients, and not health records, the focal point?

EHRS & STAKEHOLDER CONCERNS

The Centers for Medicare and Medicaid Services (CMS) describes the EHR as "an electronic version of a patient's medical history, which is maintained by the provider over time, and may include all of the essential administrative clinical data." It can also include data relevant to that person's care under a particular vendor, including demographics, challenges, medications, medical history, immunizations, laboratory data, and reports.

Blockchain application to the EHR addresses three major issues:

- Fragmented, slow access to medical data
- System interoperability; patient agency
- Enhanced data quality and measure for medical research

There are many primary and secondary stakeholders in EHR integration and implementation. These include clinicians, patients, hospitals, insurers, public health agencies, accreditation agencies, medical researchers, technology vendors, pharmaceutical manufacturers, biotech research firms, and medical device manufacturers. Because of the complexity of full integration of the EHR, many of these stakeholders' expectations have not been met. Stakeholders are recognizing the social and business importance of efficiently managing patient records, and therefore are looking for adaptable and cost-effective approaches to deploy EHR by integrating blockchain technology.

Other concerns are that the EHR provides only a snapshot of what the stakeholders want—it doesn't give detailed descriptions for diagnosis, prescriptions, and prognosis of a patient. Consider this simple example with prescriptions: Say that one medical record shows a patient takes aspirin and Tylenol, and maybe Lipitor. It doesn't essentially tell the doctor what the patient is taking right now. But with blockchain, each prescription is like a deposit, and when a doctor suspends a medication, he makes a withdrawal.

As patients are increasingly engaged in healthcare and are reporting health status and outcomes of clinical care into the EHR, privacy concerns drive patients' intention to participate in managing, contributing to, and using it. Computerization of health records raises safety issues for patients who are concerned that typographical errors can lead to dispensing wrong prescriptions. Further, patients expect the EHR to be easy to use so they can view their test results, track health status, and enhance their personalized EHR by including physical exercise information.

IN SUMMARY

As the volume of patient data grows, providers are increasingly concerned about the security, privacy, and accuracy of patient data. Organizational issues such as incompatible EHR data standards are a concern because of delays in sharing data with other providers. For purveyors of EHRs, concerns include accuracy, security, and irretrievability of large-scale patient data.

The integration of blockchain in healthcare has the potential to standardize secure data exchange in a less burdensome way, compared to the traditional approaches. Summarily, Blockchain will achieve these three things:

- **Create a trusted decision-making environment** – For example, using the blockchain-based system called MedRec, patients can authorize new members of their private, secure EMR community to approve changes, and govern sharing between their different providers. This means providers can add a new record associated with a particular patient, and patients can authorize sharing of records between providers. There is prioritization of usability in all user-provider relationships, and this will provide a single database to check for any updates to patients' medical history. Besides improving patient agency and control over data sharing, this practice may help to remove one of the biggest barriers to medical decision-making, that is, data trust at the point of care
- **Enabling patient-centered interoperability** - By capturing patient agreement statements in a complete blockchain, healthcare professionals and others involved in the care cycle can trust those statements and act upon them accordingly. Also, patients can add consent reports at any point in their care journey – confident that the blockchain will hold them securely. Healthcare experts can act upon directives, and the systems used can interpret them as access control points established by the patient or designated party.
- **Supporting the progress of accountable care and quality metrics** - The ability to impeccably monitor blockchain platforms in which the benefits can be redeemed with ease provides the necessary avenue for providers and patients to keenly engage in symbiosis. In contrast, if one or more participants tend to misbehave, penalties can also be levied with similar ease. This accountability will prompt a paradigm shift in the participants' mind-sets from incident to wholeness.

In our next whitepaper, we will explore cyber extortion within the healthcare industry and how the greatest perpetrators of cyber extortion may be within your own organization.

ABOUT THE AUTHOR

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As Principal, David leads Divurgent's strategic information technology and cybersecurity projects and a diverse portfolio in each area. With over 40 years of IT experience, over 20 of those years are in healthcare, David leverages his multi-industry experience to provide new perspectives on the use of information technology within a healthcare setting.

With expertise ranging from establishing IT organization from the ground up, optimizing EHR platforms, managing large-scale, complex technology projects, applying data-driven analytics, to leveraging clinical data to improve clinical processes and quality of care and establishing security processes, procedures, and policies.

David has held numerous positions including CIO, Information Security Officer, Program Manager, Project Manager, and Director of Applications, where he's been able to apply his years of dynamic experience in information technology and apply innovation solutions to today's top-of-mind IT challenges. When David is part of the consulting team, an organization gets more than just the knowledge and expertise to complete his assignment, they also get access to an experienced IT executive that can and will provide other value add expertise and guidance to the organization.

While David's healthcare experience spans multiple ambulatory and acute care settings, he has a strong focus in pediatric facilities.

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