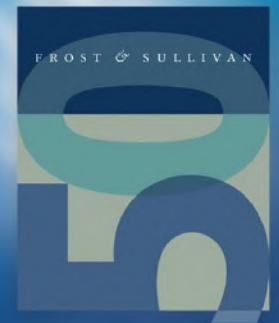# Why Healthcare Industry Should Care About Blockchain?

**Blockchain Application Potential with Multiple Healthcare Stakeholders
[Medical Device | Pharma/Biopharma | Health Insurance]**

**Frost Prospective –
Growth Opportunities for Blockchain
in Healthcare**

What is Blockchain to a Medical Device Company? (1/2)

Blockchain could provide significant cost savings by streamlining the secure tracking and management of billions of medical devices and medical assets

Key challenges with existing technology/systems (Examples of failure)

Business Need:
- As per the UDI mandate, medical device OEMs are accountable to ensure complete traceability for their devices.
- **Example:** Medical device for medication administration such as infusion pumps and anesthesia device are produced with the help of several subcontractors and often operate on 3rd party software or IT systems. In case of any malfunction in medication administration or error in warning systems, the regulatory agencies (such as FDA) usually takes action to find out who is responsible.

Current Industry Challenge:
- Current inventory and device identity management systems are not efficient or reliable (lack trust) to register and track the point of failure and accountability.
- In case of any such deficit or malfunction medical device OEM must prove that they are not responsible for the mistakes. Or else, they are liable to pay hefty fines, recall devices, and even have to stop future commercialization.

Medical Device OEMs' Strategic Priority

Compliance with UDI Requirements

Image Source: http://www.1ohww.org/fda-address-cybersecurity-medical-devices/

If all production and on-going usage or maintenance relevant data are recorded in a Blockchain, its immutable and trusted workflow with a "single source of truth" would empower the medical device OEM with complete traceability (both pre and post marketing) and evidence on accountability for any malfunction in a device.

Role of Blockchain?

Blockchain Key Benefits
- Unique identifiers for medical devices or assets on blockchain
- Autonomous monitoring and preventive maintenance of medical devices
- Promote Internet of Medical Things (IoMT) applications and smart contracts to automate device life cycle management

UDI - Unique Device Identification

What is Blockchain to a Medical Device Company? (2/2)

Due to privacy and security issues, medical device manufacturers only have 20%–30% of their IoT medical devices connected in the hospital.

Key challenges with existing technology/systems (Examples of failure)

Business Need:
- Like any other IT systems, a majority of connected medical devices with embedded software and supporting infrastructure are susceptible to cybersecurity threats.
- **Example:** In 2015, it was reported that the Symbiq medication infusion pump was vulnerable to hacking. FDA also reported findings of cybersecurity vulnerabilities in St. Jude Medical heart devices in 2017.

Current Industry Challenge:
- With growing number of connected devices, the potential for hacking any medical device, whether it is connected to a network or not, is a problem that must be taken seriously by device OEMs.
- FDA last year emphasized on this issues and has published a new guidance documenting post-market management of cybersecurity in medical devices.
- Considering the risk associated with cybersecurity attacks, medical device OEMs cannot ignore the current FDA Cybersecurity guidance and should proactively invest in cutting edge security technologies.

Medical Device OEMs Strategic Priority

Pre & Post Market management of Cybersecurity in medical devices

Role of Blockchain?

- Blockchain-based distributed network consensus with cryptography techniques would provide additional layer of trust to minimize cybersecurity threats for medical device and embedded IT systems.
- Blockchain systems could also provide more reliable and secure strategy for medical device identity management to promote IoMT applications and smart contracts to automate device life cycle management.

Blockchain Key Benefits

- Medical device data integration and security - Helps in streamlining the secure tracking and management of billions of medical devices, wearables, and medical assets, providing significant cost savings.
- Encryption and permanent storage of device-generated health data with access control and smart contact features.
- Blockchain would also help to improve patient privacy by proving secure and selective access to patient-generated health data.

What is Blockchain to a Pharma/Biopharma Company? (1/2)

Blockchain-based chain-of-custody log to track each step of supply chain can save $200 Billion within the Pharmaceuticals industry

Key challenges with existing technology/systems (Examples of failure)

Business Need:
- The drug supply chain has become increasingly complex with ever increasing threats for counterfeiting, cargo theft, and importation of unapproved or substandard drugs
- **Example:** Pharmaceuticals companies incur an estimated annual loss of $200 billion due to counterfeit drugs globally. About 30% of the drugs sold in developing regions such as Africa, Latin America and parts of Asia are considered counterfeit. On an average, medicines worth $33.5 million are stolen in cargo theft each year in European markets.

Current Industry Challenge:
- To ensure drug supply chain provenance, serialization policy will be a global requirement by 2018. Majority of Global health authorities such as US FDA, EU, China (CFDA) and Brazil (RDC 54) will have some form of serialization requirement mandates for drug supply to protect patient safety and ensure product integrity.
- However, lack of robustness and standardization issues with existing serialization or track and trace systems creates critical concern for drug manufacturers.

Pharma/ Biopharma Strategic Priority

Drug Supply Chain Integrity and Serialization Compliance Requirements

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- Unique properties of Blockchain systems such as chain-of-custody log will empower drug manufacturers to track each step of the supply chain by individual raw martial/drug level.
- Blockchain would also help in automating the serialization and geo-tagging process across value chain activities such as production, development, and testing by manufacturing facilities.

Role of Blockchain?

Blockchain Key Benefits
- Ensure data integrity and improve drug traceability across the supply chain; check drug counterfeiting to reduce industry losses
- Optimize overall marketing efforts and workflows
- Help implementing Medication adherence and incentive management programs more efficiently for value-based care paradigm

Helps in driving unprecedented collaboration between participants and researchers to drive innovation in medical research for concepts such as precision medicine and population health research

Business Need:
- Failure or fraudulent reporting of clinical trial results creates crucial safety issues for patients, and knowledge gaps for healthcare stakeholders and policy-makers.
- **Example:** About 50% of all clinical trials go unreported, and investigators often fail to share their study results.
- Furthermore, unjustified cost of trial-and-error medicine makes it imperative for precision medicine.
- **Example:** Based on research estimates, about $300 billion is wasted each year on drugs which do not work in people or results in getting dangerous side effects.

Current Industry Challenge:
- Pharma companies are facing increasing pressure to prove the value of their medicines. This necessitate the drug industry to shift from blockbuster to a patient-centric drug development models for future precision medicine practice.
- However, personalized health data being the 'Holi Grail' for precision medicine practice, it is not unique to some of the prevailing challenges involving health data interoperability, privacy, and ownership.
- There is a critical need for pharma companies to explore how Blockchain technology could provide an additional layer of trust and security to potentially eliminate the burden and cost of clinical trials data reconciliation, facilitate interoperability, and research commons models.

Pharma/ Biopharma Strategic Priority

Clinical Trial Integrity and Population Health Research

- Blockchain-based time-stamped immutable records would bring integrity and provenance around clinical trials protocols, data trails and results.
- Blockchain trusted systems would also help in driving unprecedented collaboration to drive innovation in medical research for concepts such as precision medicine and population health research

Role of Blockchain?

Blockchain Key Benefits
- Help in making clinical trial patient recruitment process more targeted and efficient
- Promote Research commons and remunerative models for data sharing and crowdsourcing-based research models
- Addresses the issues of outcome switching, data snooping, and selective reporting

What is Blockchain to a Health Insurance Company?

About 6% of all medical claims are denied due to incomplete or incorrect information. The blockchain system could automate the claim process and dispel administration layers to reduce transaction costs and frauds.

Key challenges with existing technology/systems (Examples of failure)

Business Need:

- Rising healthcare costs to unsustainable levels globally is shifting the industry from fee-per-service to value-based reimbursement models. However, current inefficiencies with billing related activities (BIR) and medical claims frauds are creating critical challenges for payers and insurance companies.

- **Example:** An estimated 5%–10% of healthcare costs are fraudulent and in the United States alone, Medicare frauds incurred about $30 million in losses during 2016. Moreover, an estimated 15%–20% of healthcare spending and processing costs are associated with BIR activities.

Current Industry Challenge:

- Technology is playing a pivotal role in shifting the healthcare industry's focus from volume to value-based reimbursement models.

- Inefficiencies and lack of trust or integrity around current Claims Adjudication and Billing Management solutions make it critical for insurance and payers community to explore the potential of blockchain technology in addressing these inefficiencies to reduce transaction costs and frauds.

Health Insurance Industry Strategic Priority

Minimizing Insurance Notarization and Medical Billing frauds

- Blockchain technology could significantly improve inefficiencies in BIR activities; help reduce administrative cost and time for providers and payers by eliminating middlemen or intermediaries.
- Blockchain network consensus with smart contrasting features would help in maintaining a benefits database, determining patient insurance for self-execution as per pre-programmed terms and conditions.

Role of Blockchain?

Blockchain Key Benefits

- Reduce cost related to commission, sales, and operations
- Automate underwriting, policy insurance and other BIR activities
- Improved claimant and beneficiary KYC process
- Promote pay for outcomes and incentive-based behavioral health programs
- Promote peer-to-peer insurance models: (for example, Peer-evaluated and peer-adjudicated health claims)

Blockchain Application Potential with Multiple Healthcare Stakeholders

Pharma and health insurance payers are expected to be the early adopters for blockchain systems compared to other healthcare industry stakeholders.

Blockchain Benefit for Healthcare Stakeholders

Physicians / Care Providers
- Complete view of individual health history with longitudinal health records
- Improve clinical care coordination—help physicians in effective management of emergency medical situations
- Greater collaboration with research communities
- Safe streamlining of EHR information—transfer relevant patient data from one provider to another

Pharma / Clinical Research
- Increase drug supply chain provenance; check drugs counterfeiting
- Managing IP and R&D asset transactions on blockchain
- Optimize overall marketing efforts and reduce leakages
- Access to anonymized, medical metadata
- Clinical trial integrity and provenance of data trails

Hospitals and ACOs
- Eliminate the burden and cost of data reconciliation, resulting in seamless health data exchange across health systems
- Facilitate care coordination for population health management
- Improve revenue cycle management (RCM) and reduce payment disputes/frauds
- Promote value-based care platforms: Pay for outcomes with smart contracts
- Optimize utilization for healthcare capacity and resources

Patients/Consumers
- Increases patients' control over their personal health data
- Direct payment of incentive and health tokens toward positive and healthy behavior (HSN/Health Wallets)
- Promote concepts such as Quantified-self and DIY Health
- Price transparency for drug and healthcare services
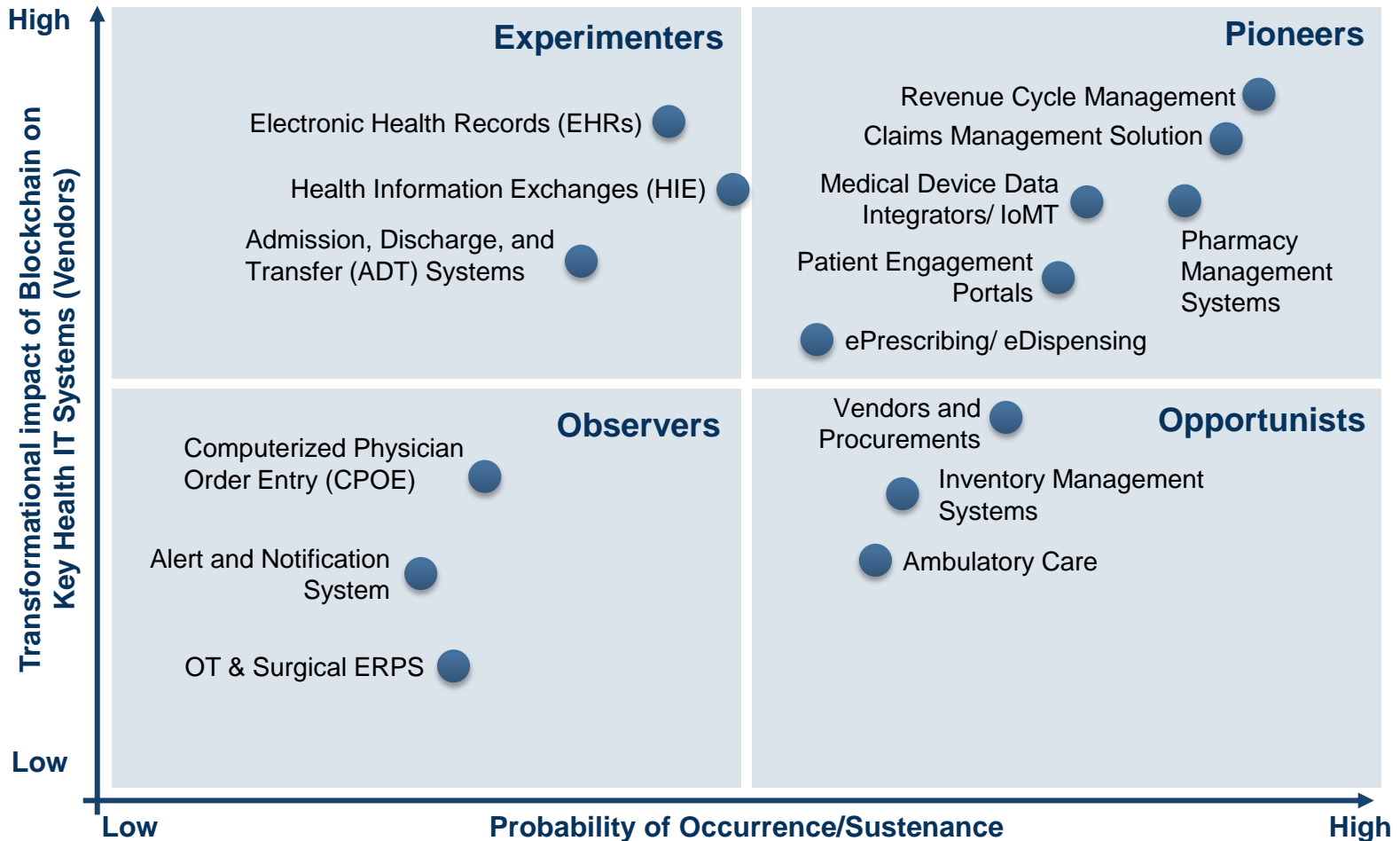- Share data for research commons under remunerative models

Government and Payers
- Increase collaborations across government-driven services
- Pooled real-time population risk
- Improve inefficiencies in billing and insurance-related (BIR) activities
- Smart contrasts to maintain a benefits database to determine patient insurance and premiums

Blockchain Technology—Impact on Key Health IT Systems and Vendors

Blockchain solutions are expected to have immediate implications for RCM and claim management HIT vendors; could potentially replace claims clearinghouses and decrease the need for prior authorization.

Blockchain Impact on HIT Systems: Threat Mitigation Strategy/Challenge Impact Assessment Grid, Global, 2017–2025

Y-axis: Transformational impact of Blockchain on Key Health IT Systems (Vendors) — Low to High

X-axis: Probability of Occurrence/Sustenance — Low to High

Experimenters (top-left):
- Electronic Health Records (EHRs)
- Health Information Exchanges (HIE)
- Admission, Discharge, and Transfer (ADT) Systems

Pioneers (top-right):
- Revenue Cycle Management
- Claims Management Solution
- Medical Device Data Integrators/ IoMT
- Patient Engagement Portals
- Pharmacy Management Systems
- ePrescribing/ eDispensing

Observers (bottom-left):
- Computerized Physician Order Entry (CPOE)
- Alert and Notification System
- OT & Surgical ERPS

Opportunists (bottom-right):
- Vendors and Procurements
- Inventory Management Systems
- Ambulatory Care

Note: The list of HIT systems is not exhaustive and captures those that would be the most affected by blockchain technology.

FROST & SULLIVAN