

# Opportunities and Challenges for the Pharmaceutical Supply Chain

## Using Digital Ledger Technology

Brennan Bennett

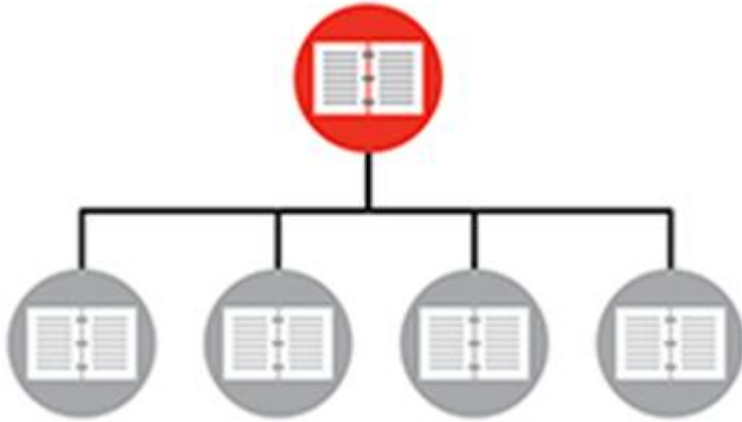
Founder, Blockchain Healthcare Review

# Agenda

- Brief Overview Distributed Ledger Technology
  - Centralized vs. Decentralized ledgers
  - Why DLT for suited for Pharma
  - Key technical features, including smart contracts
- Opportunities
  - Clinical data applications
  - Track and Trace
  - Real time supply chain feedback using IoT
  - Supply chain integrity
- Challenges
  - Identifying data
  - Choosing the right decentralized platform
  - Confidentiality
  - Level of trust in the pharma supply chains
- Importance of Due Diligence

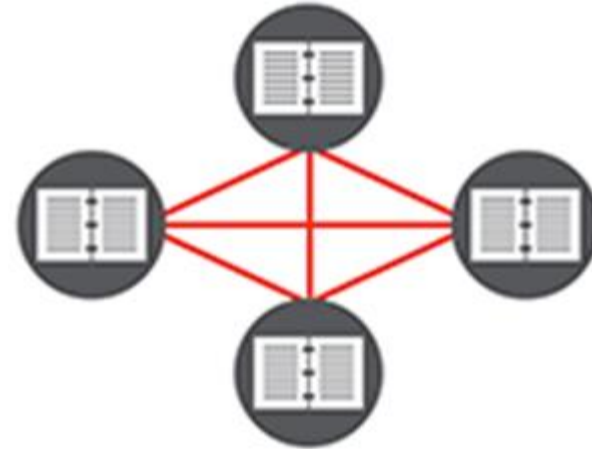
# Distributed Ledger Technology

## Centralized Ledgers



- Traditional systems rely on central authority to generate trust and transfer value
- Participants then undertake duplicative reconciliation with their own systems

## Distributed Ledgers



- Trust comes from the process itself rather than from the status of any 1 player
- Participants validate changes collectively and changes are updated across the network immediately

# Why DLT is Suited for Pharma

## **DLT system integration provides:**

Security

Confirmation

Authorized Visibility

Auditability + Transparency

Distributed Ownership

## **Key usage:**

Drug Safety: integrity of drug manufacturing

Drug Channels: movement of drugs from manufacturer to end consumer

- Manufacturer
- Repackagers
- Dispensers
- Wholesale Distributors
- 3<sup>rd</sup> party logistics

# Opportunities

- Provenance and authenticity of a drug shipments
- Supply chain integrity
- Track and Trace
- Real-time global supply feedback using IoT

# Opportunity: Provenance and Authenticity of Drug Shipments

- Blockchain advantage: MediLedger Project
  - Brought together by Chronicled, Inc. and The LinkLab LLC
  - Also includes Genentech, Pfizer, AmerisourceBergen, and McKesson Corp
- Objectives:
  - To demonstrate compliance with the Drug Supply Chain Security Act (DSCSA)
  - Create an interoperable system in which multiple parties can verify and transfer pharmaceutical products with absolute trust in their authenticity
- Benefits:
  - Entire drug channel, from wholesalers to hospitals could track drug deliveries on a blockchain
  - Opportunity to showcase live POC by the end of 2017

# Opportunity: Supply Chain Integrity

- Blockchain advantage: asset registration
  - Every time an asset is registered or verified on a blockchain, a distributed "nodes" come to a consensus, making it nearly impossible to tamper with event logs without detection
- Objectives:
  - Vouch for the provenance and authenticity of a drug shipment each step of the distribution process using a distributed network
- Benefits:
  - Stop a flow of stolen or counterfeit pills entering the supply chain
  - Ability to tokenize assets

# Opportunity: Track and Trace

- Blockchain advantage: Traceability
  - Would allow multiple, non-adjacent trading partners need to exchange data
- Objectives:
  - Provide data confidentiality and security while still allowing for flexibility in sharing data
- Benefits:
  - DSCSA compliance



# Opportunity: Real Time Global Supply Chain Feedback Using IoT

- Blockchain advantage: smart contracts
  - Feature software on a blockchain that defines agreement terms and execution and could, reduce costs, prevent fraud, and improve connectivity to the Internet of Things (IoT)
- Objectives:
  - Identifying all of the potential trusted partners, existing systems and processes, and requirements for data transfer
- Benefits
  - Full track and trace
  - Theft/brand protection

# Challenges

- Identifying data
- Choosing the right decentralized platform
- Confidentiality
- Level of trust in the pharma supply chain

# Challenge: Identifying Data

- Primary challenges:
  - Identifying what data to collect, the format, and the level of analysis to be completed before channel partners receive it
  - Clinical data transfer in the context of supply chains, such as applications touching patient data, or even tracing back product dispensing to end users for recalls, is a tricky issue.
- How blockchain can help
  - For 2017, blockchain implementation for the pharma supply chain should be limited to traceability of product
  - Groundwork for full end-to-end solutions for post-market surveillance

# Challenge: Choosing the right decentralized platform

- Primary challenges: range of blockchain technologies available
  - The pharmaceutical industry ships thousands of units per day, so startups are coming to the market that claim to offer scalability, which would be useful to pharma in the future.
- How blockchain can help:
  - Hybrid platforms enable functionalities from both public and permission DLT networks
  - Once the scalability questions are addressed, distributors will have to decide whether they can play in multiple blockchains.
  - Since regulations put the emphasis on manufacturers, small-to mid-sized distributors and contract manufacturing organizations (CMOs) are at risk because they may not have the means to work in multiple blockchains. The cost for serialization is already prohibitive for these suppliers

# Challenge: Confidentiality

- Primary challenges: multiple, non-adjacent trading partners need to exchange data
  - Ensure that proprietary information is not shared or inadvertently disclosed as part of a distributed ledger visible to more than a bilateral relationship
- How blockchain can help:
  - One of the most innovative underlying technical underlying features of DLT is confidentiality
  - Each entity within the blockchain network transacts with a generated address, which does not need to reveal to others the real identity of the user. This allows a certain amount of privacy on all transactions.
  - Only authorized personnel would have access to the identity of the users.

# Challenge: Level of Trust in the Pharma supply chain

- Particularly between manufacturers and distributors, in terms of running a proof-of-concept (POC).
  - Typically, these firms are at odds with each other, and often the distributor makes money from the data it collects.
- How blockchain can help:
  - Increase awareness and education about what blockchain can do
  - The fact that data shared in a blockchain can be limited on a permissions basis and can also be limited to simply verifying that a product came from the person who it was supposed to come from (not including any other proprietary data, such as pricing, shipping volumes, or underlining supplier networks).

# Importance of Due Diligence

## ■ Mistakes in Enterprise Blockchain Projects

1. Don't assume leading platforms will be dominant tomorrow
2. Confusing a foundation level protocol with a complete business solution
3. Viewing blockchain as a purely database storage mechanism
4. Failure to incorporate a learning process
5. Assuming smart contract technology is a solved problem

\* Source: Gartner

# Contact Information

Brenan Bennett, Founder, Blockchain Healthcare Review



- Twitter: [@BlockchainHIT](https://twitter.com/BlockchainHIT)
- Web: <http://blockchainhealthcarereview.com>
- Email: [bbennett@blockchainhealthcarereview.com](mailto:bbennett@blockchainhealthcarereview.com)