



Pharma Enabled Blockchain Platform

FDA Pilot Overview

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Intro

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FDA Pilot Overview



MediLedger Pilot Objectives

The FDA requested pilots of the Drug Supply Chain Security Act (DSCSA) requirements related to the interoperable, electronic tracing of products at the package level that go into effect in 2023.

Model supply chain events

Attempt to model serialized data exchanges for prescription drugs using a blockchain/ledger-based system.

Define what's possible

Explore questions about the technology's viability:

- system performance
- IT architecture
- adoption challenges

Determine how errors can be managed

Important to solutions to meet DSCSA 2023 will be the ability to manage error conditions that will proliferate when transactions are at the serial number level.

Pilot as an academic exercise

The MediLedger pilot was not a commercial endeavor. The objective was to show what the industry thought about blockchain solutions for complying with DSCSA in 2023.

MediLedger FDA Pilot Report - Published February, 2020

Cross-industry effort to evaluate blockchain as a solution to DSCSA 2023 track and trace requirements

Manufacturers



AMGEN

Genentech
A Member of the Roche Group



GILEAD

hikma.

Dermira^o

Lilly



Wholesalers

MCKESSON



AmerisourceBergen[®]



CardinalHealth



VAXSERVE[®]
A SANOFI PASTEUR COMPANY

Dispensers

MAXOR[®]
NATIONAL PHARMACY SERVICES COMPANY

Walmart*

Walgreens

Others



FedEx



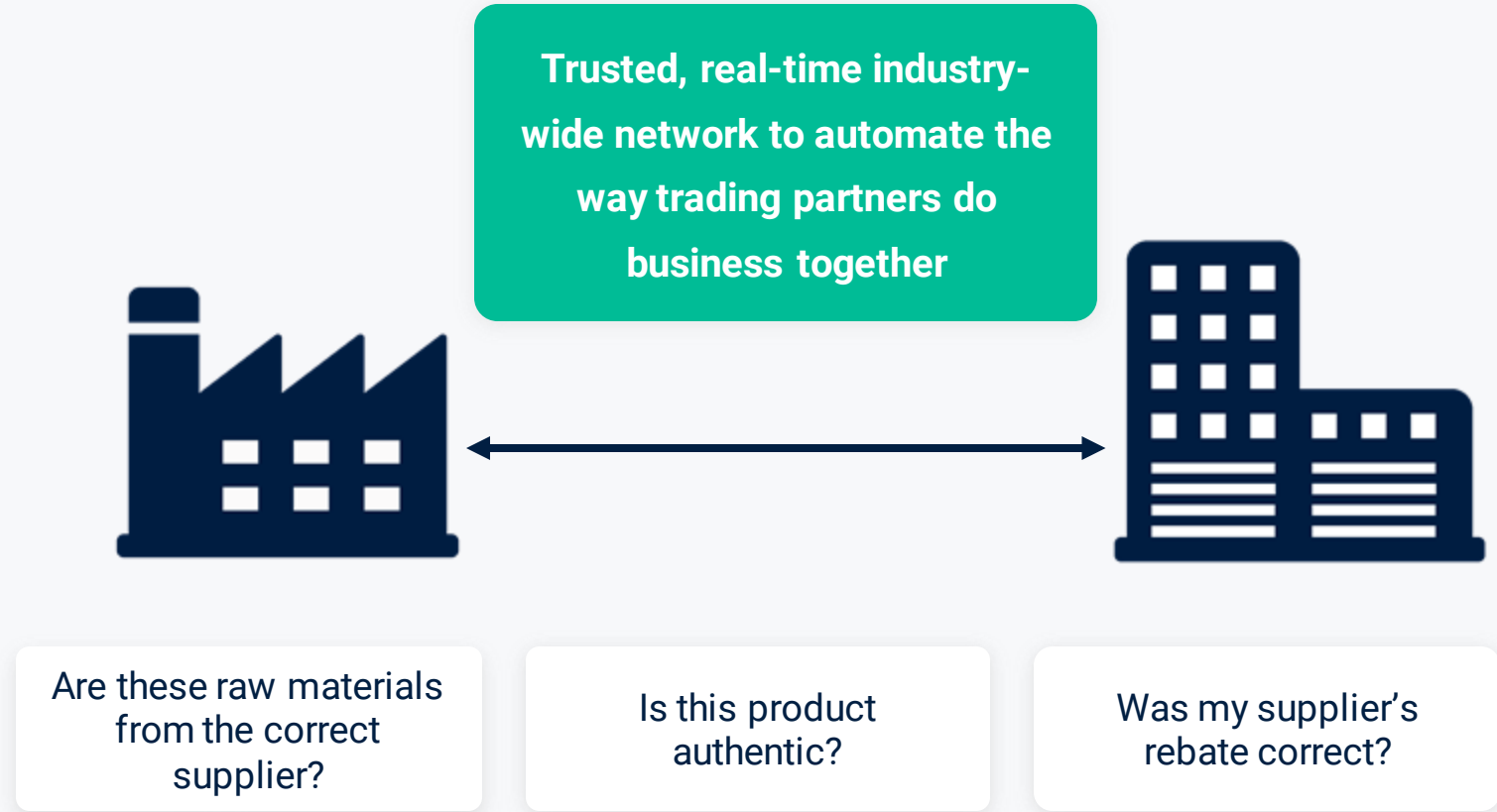
CENTER
Supply Chain Studies[™]

MediLedger

How it could work

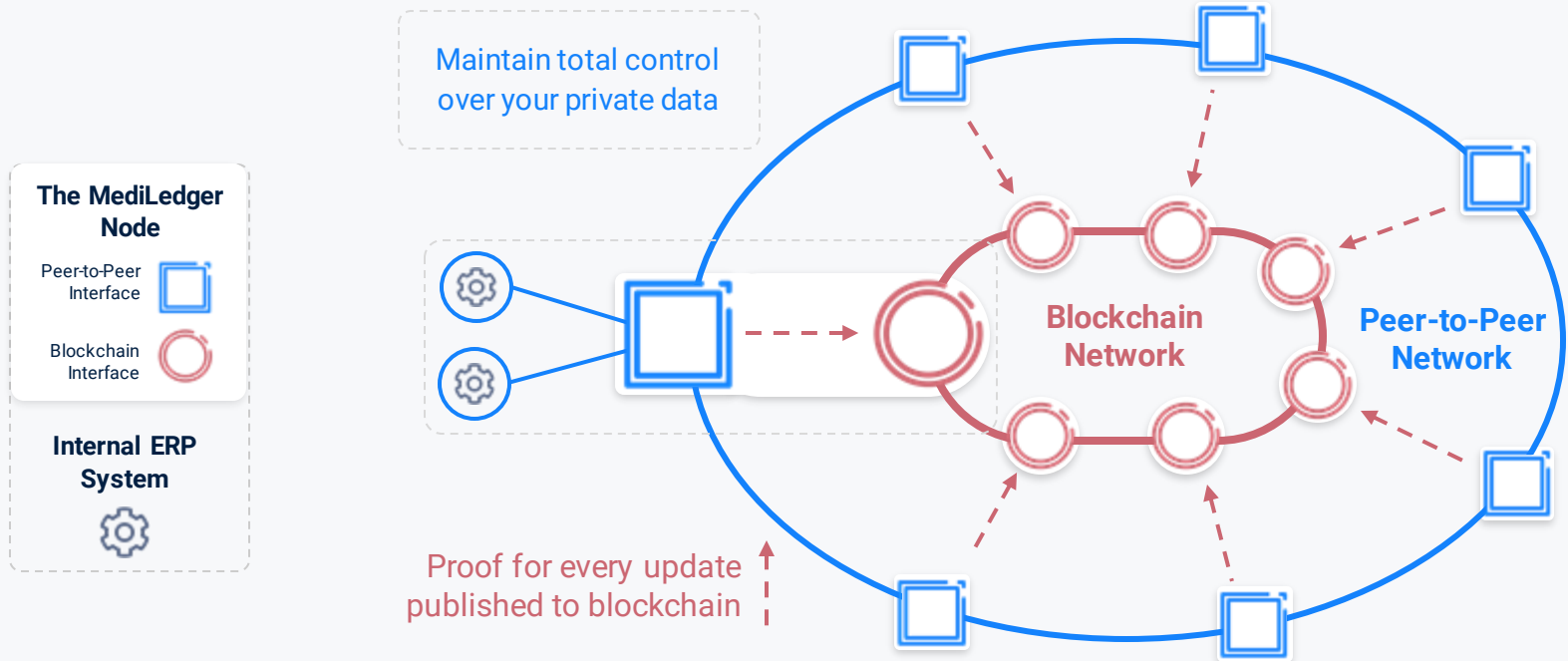


MediLedger Basics



The MediLedger Network

A secure, decentralized, peer-to-peer messaging network and blockchain network become the backbone for solutions between trading partners



MediLedger Conclusions



Pilot Conclusions

Chain of custody and provenance can be assured

Business rules for each transaction can be enforced by blockchain smart contracts in real time, while keeping each company's data 100% private

Additional supply chain benefits for participants

Trust established by a blockchain network can be leveraged to flag suspicious product and automate exception handling.

Strong adoption required

Long-term success will require strong participation and adoption from all segments of the supply chain.
(manufacturers, wholesalers, dispensers, service providers, etc...)

Interoperability standards are required

Without appropriate standards, it is unlikely that disparate track and trace systems can be interoperable.

Thank you!

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