DSCSA & Blockchain: Phase 2
Proof-of-concept pilots

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Supply Chain Studies™
ReferenceModel-based Exploration and Education

YELLOW TEAM PILOT

- Authentag
- Accenture

"Beyond Compliance: DLT Lessons Learned & Optimization Potential for the Supply Chain"

Overview

This PoC demonstrates how an immutable chain of custody and granularity of ownership can reshape logistics. Team discusses current advances enabled by FDA led GS1 GTIN and PI labeled unique identification and demonstrate full 'creation to end use traceability through all parties in the supply and use network and analyzes current usage of FDA Regulated GS1 GTIN + PI uniquely labeled traceability and how full traceability is already being used for more than just FDA compliance. Real examples then illustrate why a distributed ledger and blockchain are necessary and suitable as part of a traceability solution for pharma.

Team's vision

An open source, community owned and community governed digital ledger that manages transactions and traceability for all actors within the pharma community, whilst providing isolated data protection and multi-party contracts that can adapt overtime with regulatory and business needs.

Pilot will demo:

Full traceability of any standard (including GS1) using uniquely labeled items and how this practice is presently altering the way supply networks are managed. Team demonstrates how a chain of custody is created and how the DSCSA regulations already provide for serial, isolated control of that history. Pilot also shows how full data isolation and protection is maintained, with usable data that is always within the confines of the signing counterparties.

Target audience

This PoC is for any interested party that wants to see an existing use of full traceability for product and patient protection, regulatory compliance and financial benefit. It requires no prior technical knowledge as it uses real-life examples to illustrate the reasons distributed ledger technology is a viable solution to fulfill the aims of DSCSA while still conforming to Antitrust regulations.

DSCSA focus

- Open source: Release to open source the technical, functional and protocol specifications for the pharma community to comply to the DSCSA by connecting through a commonly held distributed ledger, performing full traceability while maintaining discrete, protected data pools.
- Necessary Technical Services: Build, or commission the building of, the technical services necessary for the distributed ledger to function, including a financial service that will distribute revenues from use of smart contracts on the distributed ledger to those technical service providers, financial backers of the Distributed Ledger Community and the creators of smart contracts used on the Ledger.
- Access: Designate audit services companies to control access to the community.
- Competence: Designate technical audit services companies to ensure technical competence to join the community.
- Implementation: Designate implementation service providers technically competent to assist members who wish to join the community.

Governance structure

- <u>IP:</u> Protecting the intellectual property of smart contract creators and facilitating the payment for smart contracts created for use on the distributed ledger.

- <u>Competitive environment:</u> Allowing the community to replace any of the above community services with suitable alternatives at will.

- <u>Innovation:</u> Allowing for the adoption of new Smart Contracts to address all parts of pharmaceutical track, trace, inventory management, and financing.

Technical features

Pilot demonstrates a system that is currently blockchain agnostic as it uses the pre-requisite technological building blocks to be serviced by any underlying immutable ledger technology that can deliver the speed and transaction volumes needed for full-scale multi-purpose implementation.

<u>Full adoption comes in 7 phases (build, operate, transfer)</u>:

- Phase 1 – Cloud-based instance for testing and integration (allows internal verified returns)

- Phase 2 – Multiple instances that can be cloud or enterprise-hosted, depending on the need of community member (allows internal verified returns)

- Phase 3 – Opening up of routing layer to allow externally verified returns (i.e. build or commission your own connections with the community)

- Phase 4 – Community technical services fully functional

- Phase 5 – Validated Smart Contracts other than verified returns allowed (traceability, tax, invoicing, etc.)

- Phase 6 – Governance and voting structure trial period

- Phase 7 – Hand-over of governance control from Track.one to community