DSCSA

and the outcomes of studies produced by the

Center for Supply Chain Studies

Bob Celeste, Founder

Content

- Center for Supply Chain Studies

- Studies:
  - DSCSA and Master Data Management Study
  - DSCSA and Blockchain Study

- Q/A

Neutral, Non-Profit, 501(c)(6)
Exploration and Education
VirtualPilotTM, and ReferenceModel^{TM} Library

Studies at the Center

Studies

STUDY: DSCSA & MDM

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STUDY: Blockchain for Cold Chain

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Team is examining the use of blockchain technology as a possible way to address some of the unresolved DSCSA data security issues facing the U.S. pharma industry.

STUDY: Global Pharma Track & Trace

Based on core set of info w/in the blockchain, Study will include international laws & regulations to explore *how to provide data to individual. countries, and how to provision serial and traceability data for their specifications.*
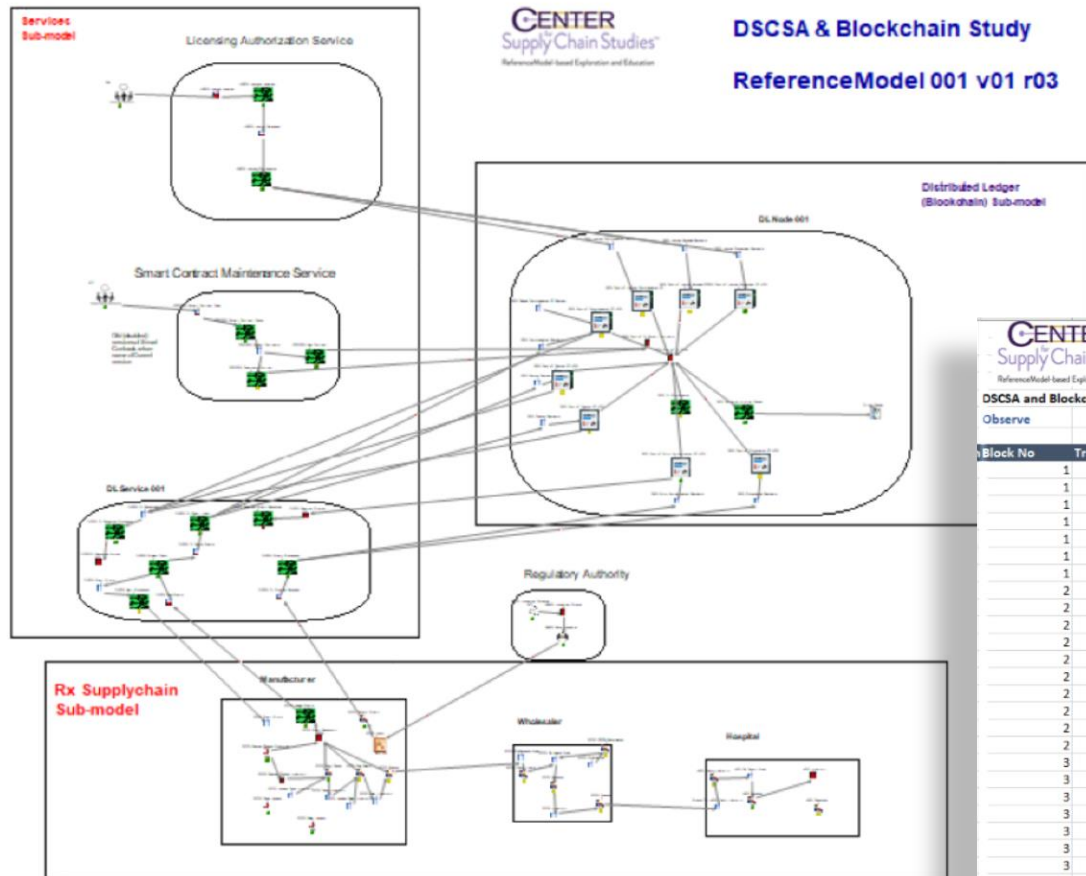
STUDY: DSCSA & Blockchain 2

Phase 2 will apply the scenarios, processes and information flows identified in *DSCSA & Blockchain: Phase 1.*

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ReferenceModels™

Virtual Pilots: Manage complexity and keep discussions in proper context.

Term Definitions
Governance Rules
Process Flows
Data Flows
Data Attribute Definitions
Query Parameters/Examples
Run Data

Study Findings

DSCSA and Master Data Management

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Study Findings
DSCSA and Master Data Management

Typical process for transactions

Order:
- Obtain Supplier information
- Obtain Customer ID
- Obtain Product Information
- Update Ordering System
- Order product by Customer ID and Product ID
- Receive shipping documents

Order fulfillment:
- Obtain Customer information
- Create Customer ID
- Share Product Information
- Obtain Order
- Send Shipping Documents with Customer ID and Product ID

- Send Invoice using Customer ID and Product ID

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Study Findings
DSCSA and Master Data Management

The Issue:

Sec. 582 Requirements

    (b) Manufacturer Requirements.

        (1) Product Tracing.

            (A) In General.

"(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format"

Transaction Information:
- Proprietary or established product name
- Strength
- Dosage Form
- National Drug Code
- Container Size
- Number of Containers
- Lot Number
- Transaction Date
- Shipment Date
- Transfer From:
  - Business Name
  - Address (Street, City, State, Zip)
- Transfer To:
  - Business Name
  - Address (Street, City, State, Zip)

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Types of data in DSCSA Transaction Information

Certain data can be represented by identifiers and held separately from the transaction

Proposed use of Master Data
Reconstructing the "TI"

Proposed use of Master Data
Reconstructing the "TI"

Study Findings

DSCSA and Blockchain

The "interoperable system" of the DSCSA?

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WHAT IS BLOCKCHAIN?

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"YOU NEVER CHANGE THINGS BY FIGHTING THE EXISTING REALITY. TO CHANGE SOMETHING, BUILD A NEW MODEL THAT MAKES THE EXISTING MODEL OBSOLETE."

- BUCKMINSTER FULLER

The Value is in the effort industry is putting into this technology to:

Connect previously unconnected companies, patients and consumers.

WHY IS BLOCKCHAIN INTERESTING?

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WHY IS BLOCKCHAIN INTERESTING?

A blockchain – is a continuously growing list of records, called blocks, which are linked and secured using cryptography.

By design, blockchains are inherently resistant to modification of the data.

[The data is said to be immutable.]

Source: https://en.wikipedia.org/wiki/Blockchain

| Transaction Data |
| Data/Time |
| Trans ID |
| Hash of Prev Block |
| Prev Block ID |
| Block ID |

| Transaction Data |
| Data/Time |
| Trans ID |
| Hash of Prev Block |
| Prev Block ID |
| Block ID |

| Transaction Data |
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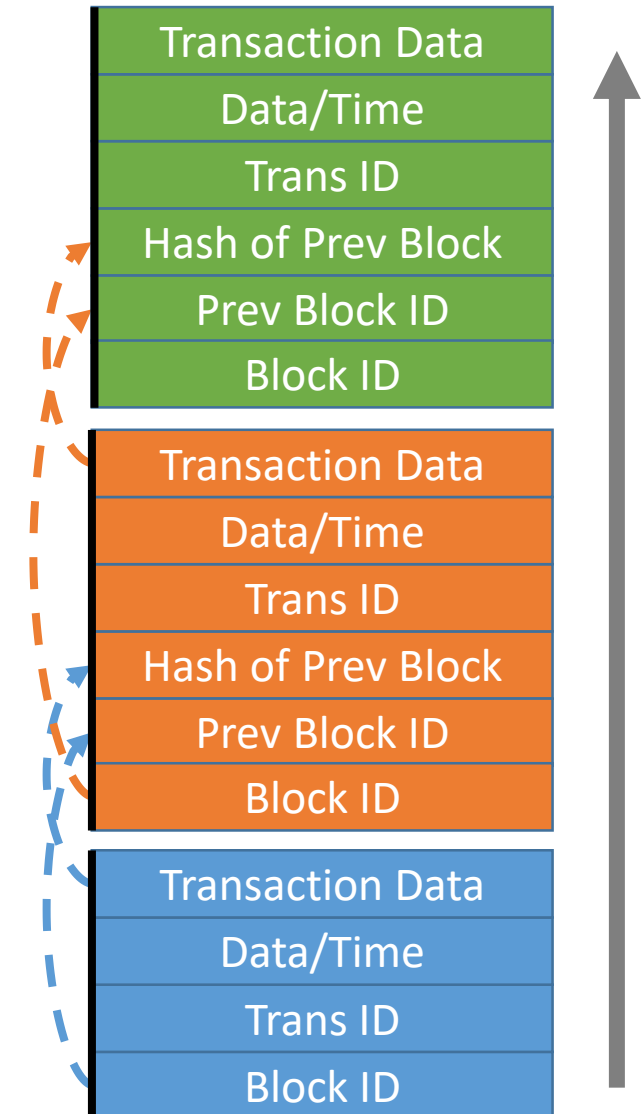
WHY IS BLOCKCHAIN INTERESTING?

A blockchain is typically managed by a peer-to-peer network collectively adhering to a protocol for validating new blocks.
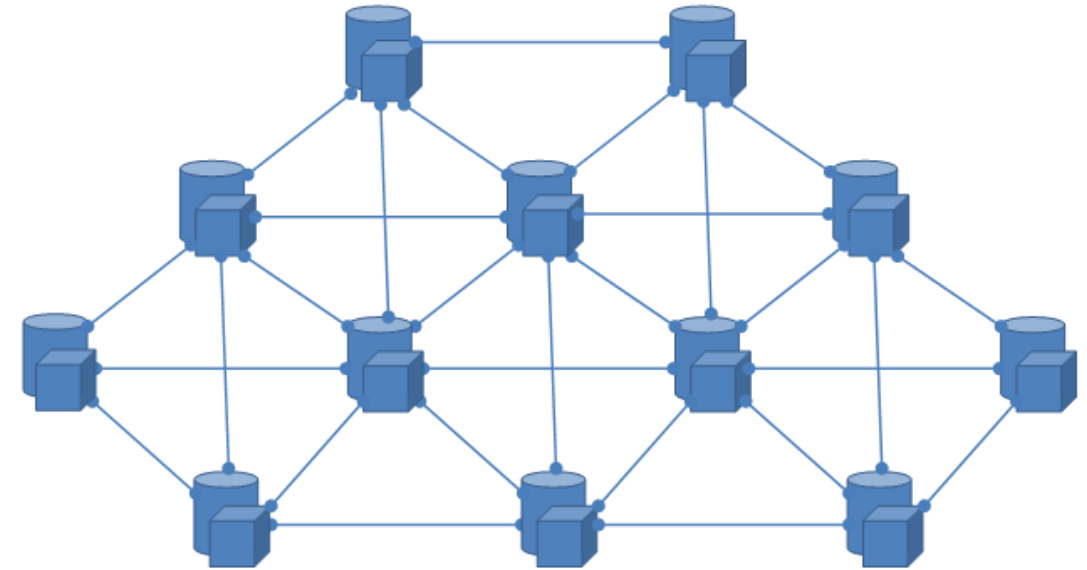
Decentralized
nodes are only connected to peers

Source: https://en.wikipedia.org/wiki/Blockchain

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Study Findings

DSCSA and Blockchain

The interoperable system of the DSCSA?

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DSCSA and Blockchain Study
Established a Framework for discussing complexity
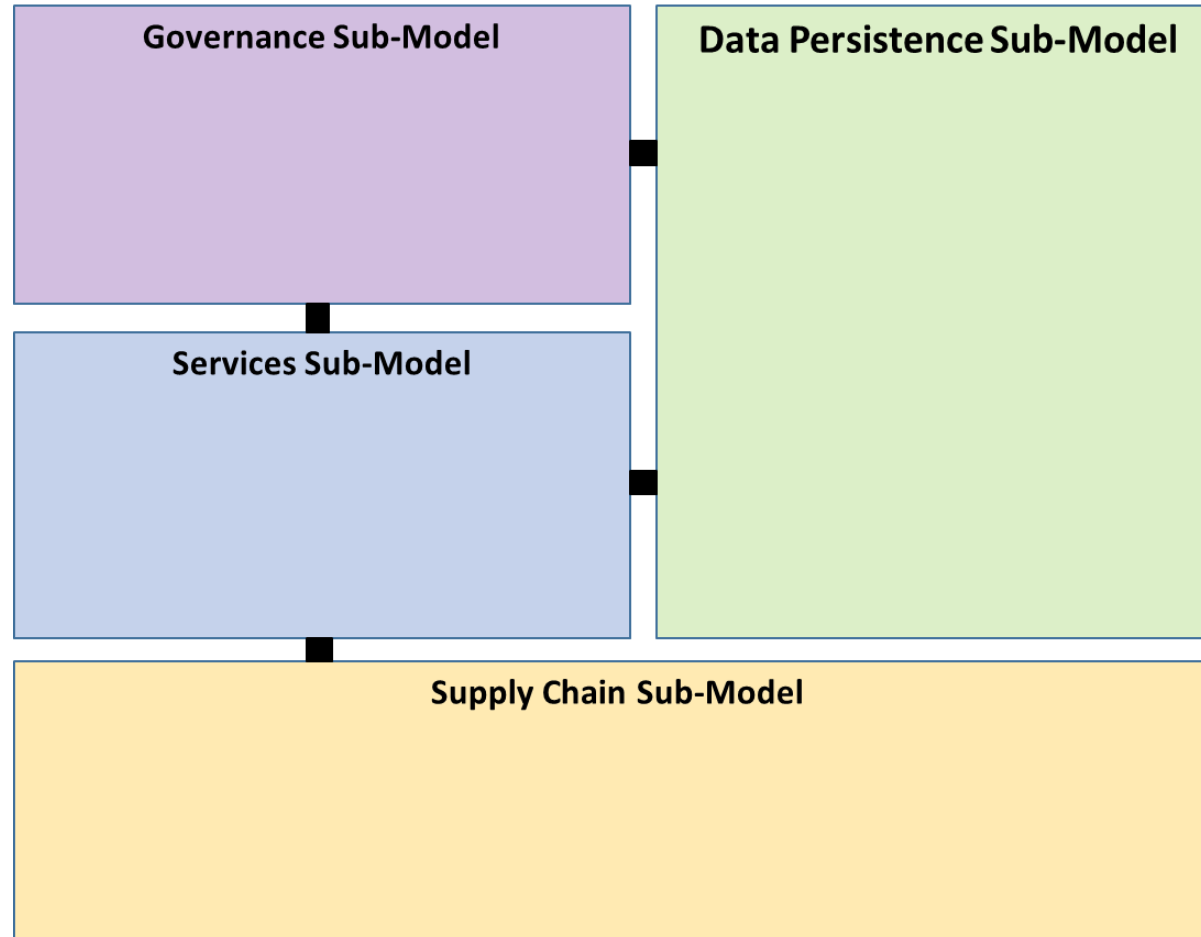
Study Findings
Distributed Data and Distributed Governance

Governance Sub-Model

Data Persistence Sub-Model

Services Sub-Model

Supply Chain Sub-Model

Manufacturer

Wholesaler

Dispenser

Decentralized

nodes are only connected to peers

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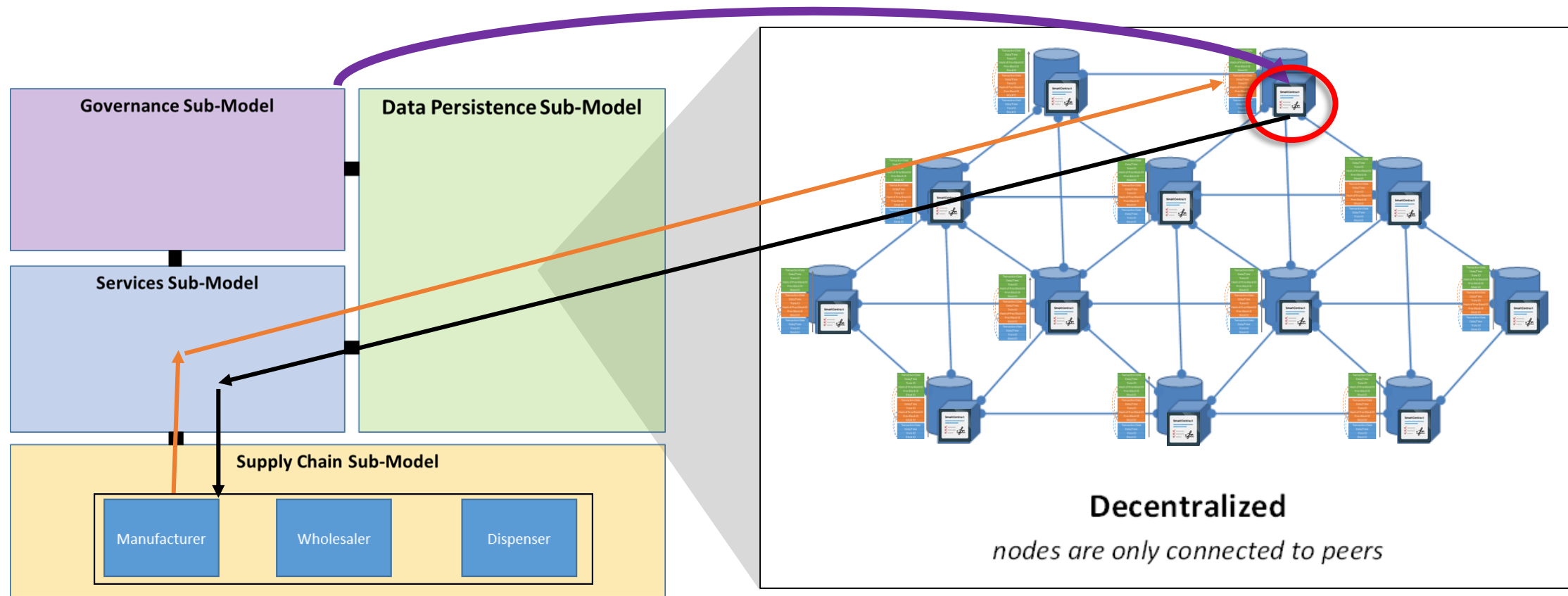
Study Findings
Study found two methods for sharing data

RM001 – Minimal Model: Minimal data in Blockchain.

RM006 - Blockchain based Discovery Service (look up data repositories)

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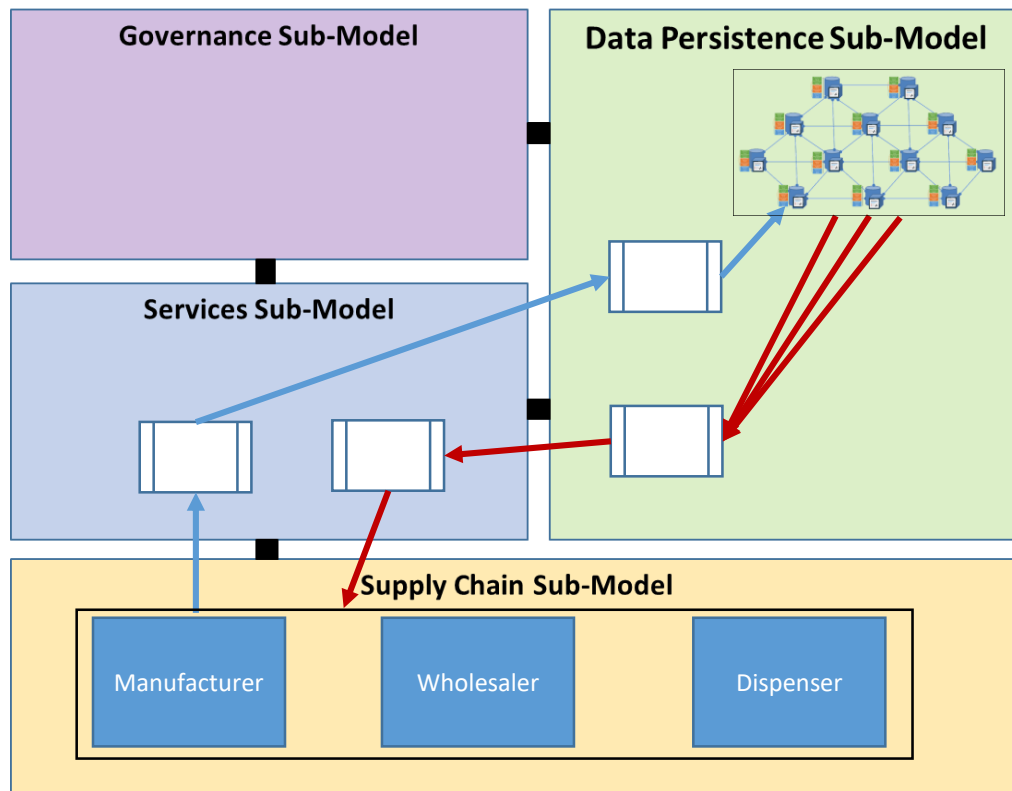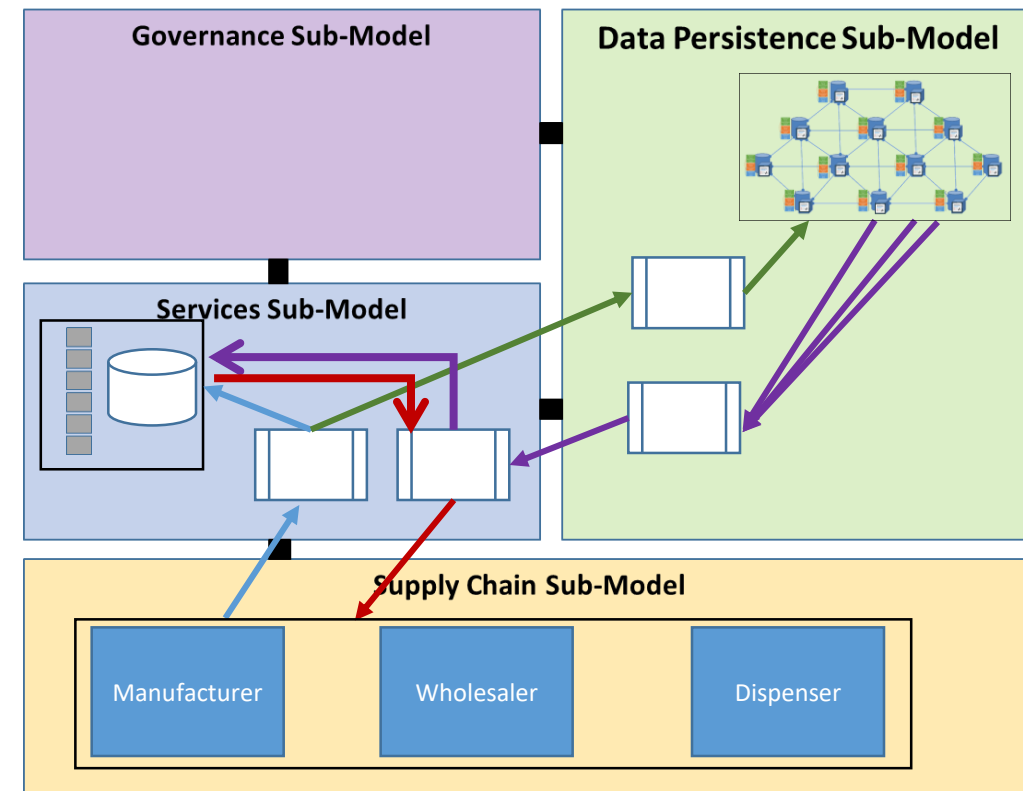
Study Findings

How Do we handle the Transaction Statement?

Is the act of posting transactions the statement, or do we pass certain data?

RM001 – Minimal Model: Minimal data in Blockchain.

RM006 - Blockchain based Discovery Service (look up data repositories)

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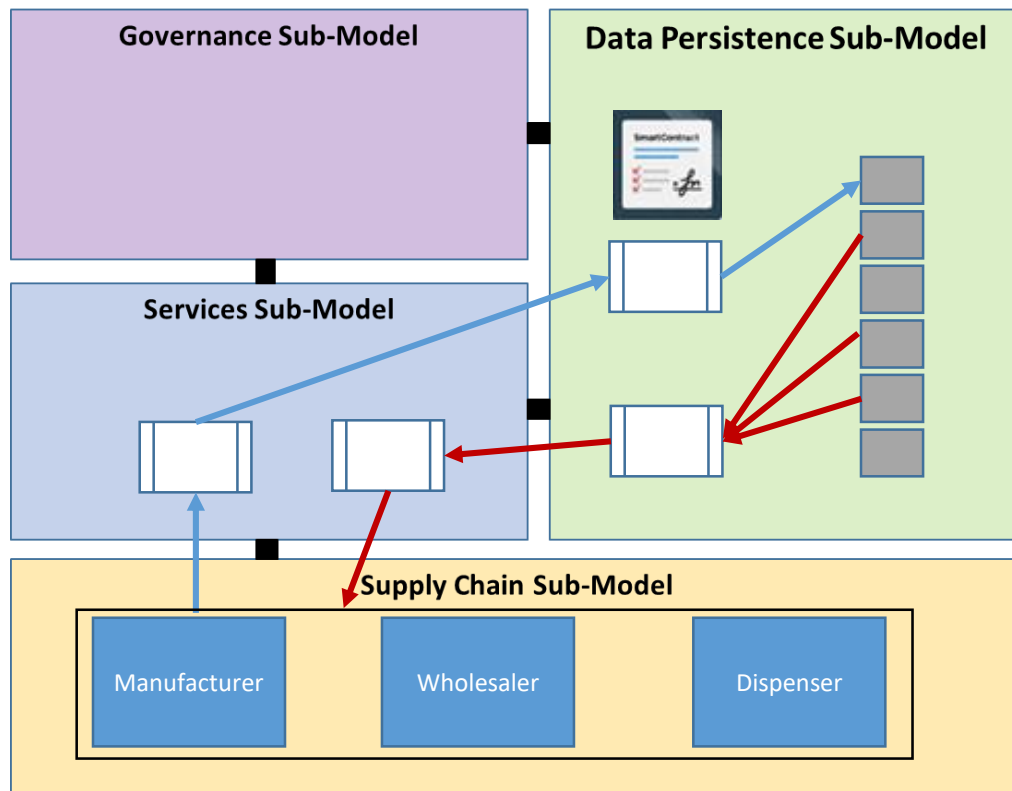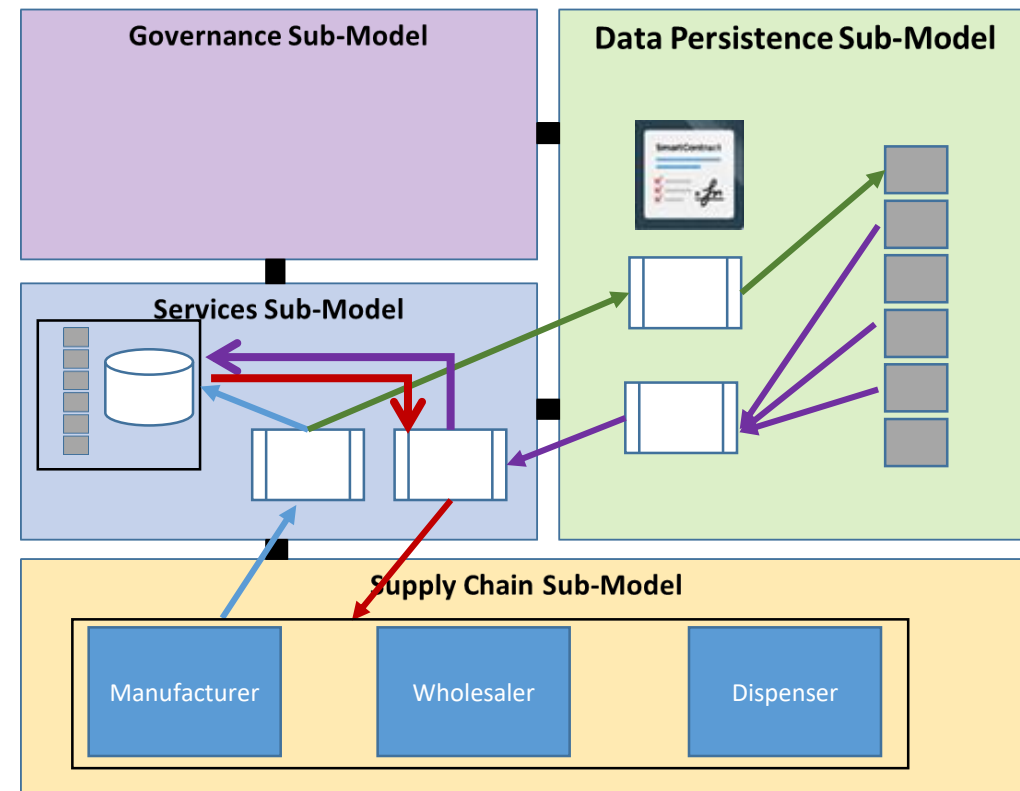
Study Findings

Extend to additional Value?

Is the act of posting transactions the statement, or do we pass certain data?

RM001 – Minimal Model: Minimal data in Blockchain.
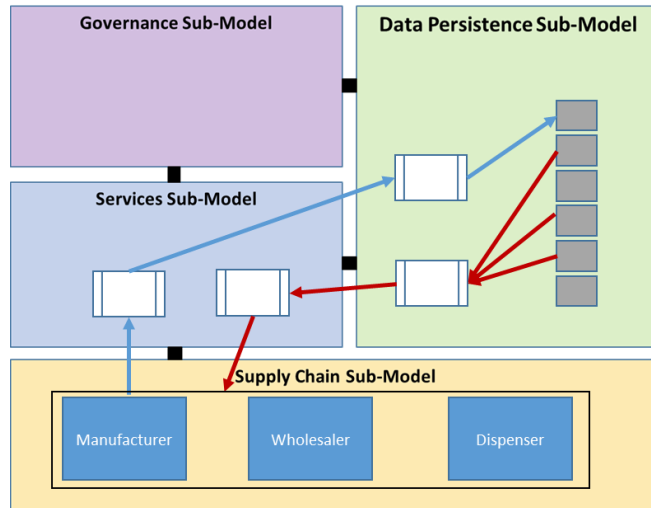
Global Identification and Traceability Requirements

Temperature sensor data for cold chain products

Returns Reconciliation

Enhanced Product Data for Clinicians

Enhanced Product Use Data for Manufacturers

Clinical Trials

RM006 - Blockchain based Discovery Service (look up data repositories)

Questions?

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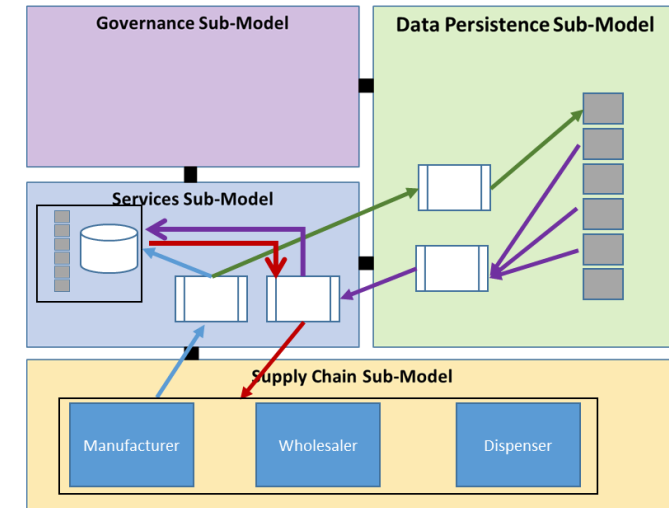
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