# CENTER for Supply Chain Studies™

ReferenceModel-based Exploration and Education

Welcome to the Introductory webinar on the DSCSA and Blockchain Phase II Study.

We will start at 11am EST

# DSCSA and Blockchain Phase II Study

Exploring the use of blockchain technology
within Healthcare

Introduction Briefing
9/21/2017

*How to make the most of the call:*

*Please mute your line if you are in a noisy environment.*

*Please don't put us on hold. Your "hold" music will interrupt the call.*

*Please ask questions and engage as we go along and enjoy the call!*

*Use the chat area if you are finding it difficult breaking into the conversation. Our calls get pretty lively at times☺*

# Antitrust Statement

- The Center for Supply Chain Studies (the Center) is  nonprofit organization that serves as a forum for  free and open discussion of diverse opinions without in any way attempting to encourage or sanction any particular business practice.

- During the course of any Center activity, discussions involving pricing, sales terms, territories, production or other aspects of competition, must be avoided.  In the event any person feels that statements or actions in meetings are headed into such an area, attendees should raise the issue immediately so that further discussion of such matters can be suspended pending receipt advice satisfactory that questionable topics do not give rise to antitrust problems.

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Neutral, Non-Profit, 501(c)(6)
Exploration and Education
VirtualPilotTM, and ReferenceModelTM Library

# DSCSA & Blockchain – Phase II

## From Virtual Pilot – Proof of Concept Pilots



**STUDY: DSCSA & Blockchain**

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: DSCSA & Blockchain2**

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

# Content

- Studies at the Center

- Phase I – DSCSA & Blockchain ReferenceModels

- Phase II – DSCSA & Blockchain Proof of Concepts

- Next Steps

# Studies at the Center

# Studies



**STUDY:** DSCSA & MDM

VirtualPilot was completed in the summer of 2017. The Study Team's White Paper, *"Demonstrating how Master Data Management can be used in support of DSCSA Requirements,"* is available now.

✓

**STUDY:** Blockchain for Cold Chain

Study will incorporate the ability to capture temperature, light and vibration data from the Internet of Things (IoT), and provide data collection solutions for verifying real-time status of supply chain items.

**STUDY:** DSCSA & Blockchain

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.*

# Study Lifecycle

Idea to Publication

# Study Lifecycle
## Prospectus to Charter



Study Prospectus

Study Statement of Work

Funded

Study Charter

Participant Input

Virtual Pilot

# Phase I – DSCSA & Blockchain ReferenceModels

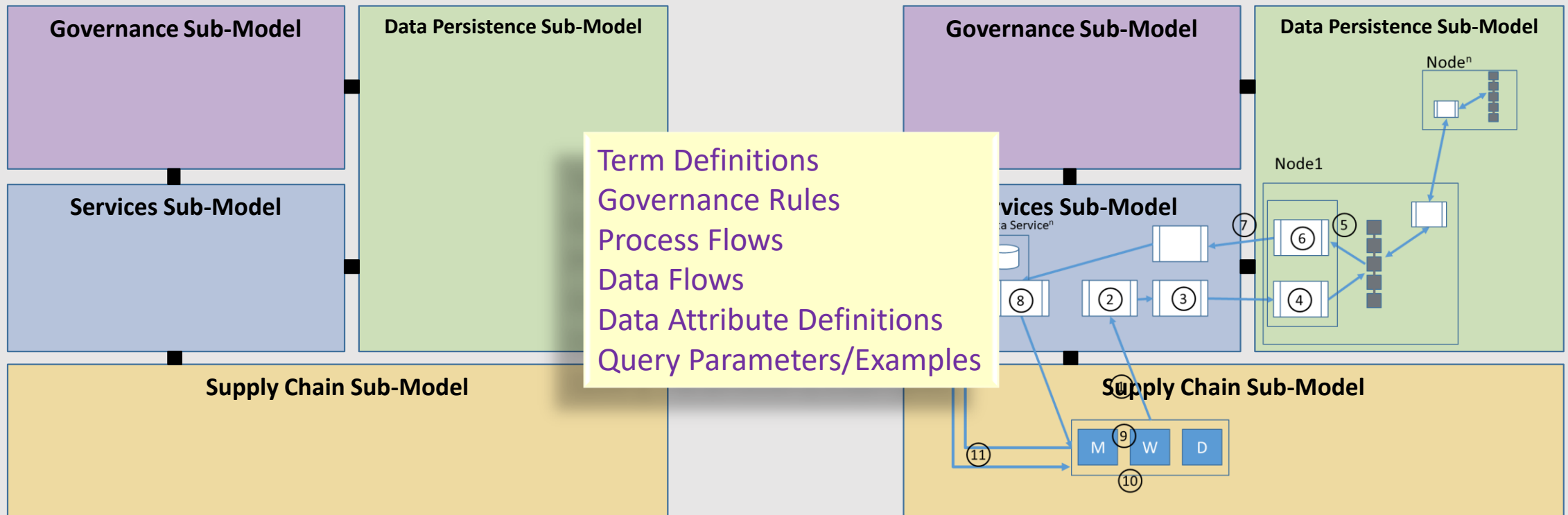# DSCSA – Blockchain Study

Focus: Six unresolved challenges

✓1. Establishing an electronic connection between non-adjacent trading partners.

✓2. Establishing trust between these trading partners.

✓3. Sharing required data without inadvertently exposing proprietary information.

✓4. Reduce the potential activity required of trading partners.

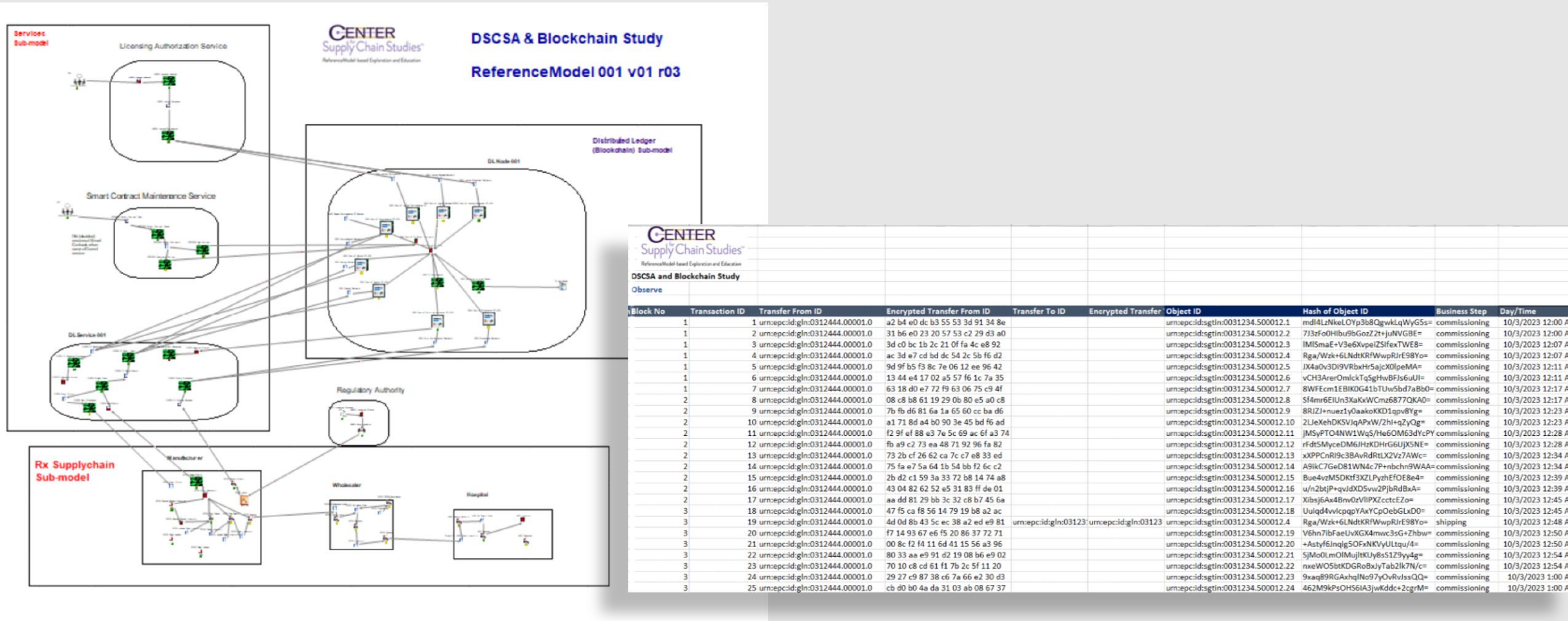✓5. Designing for expansion beyond DSCSA compliance

6. Funding the architecture.

# Phase I
## Virtual Pilot: DSCSA & Blockchain ReferenceModels



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

# Phase I

## Virtual Pilot: DSCSA & Blockchain ReferenceModels

# Exploratory ReferenceModels
## ReferenceModel Design Variations

RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events

RM002 – Minimal/Flat Model: Minimal data in BC BizSteps and Dispositions inherited by Items

RM003 - All data in the Blockchain (Master Data, Production Data, Transaction Data)

RM004 - All data in the Blockchain - no restrictions to access (Tom's Model)

RM006 - Blockchain based Discovery Service  (look up the address of EPCIS (TI) repositories)

RM007 - Cloud or Databased Discovery Service (same as RM006 with traditional DB technology)
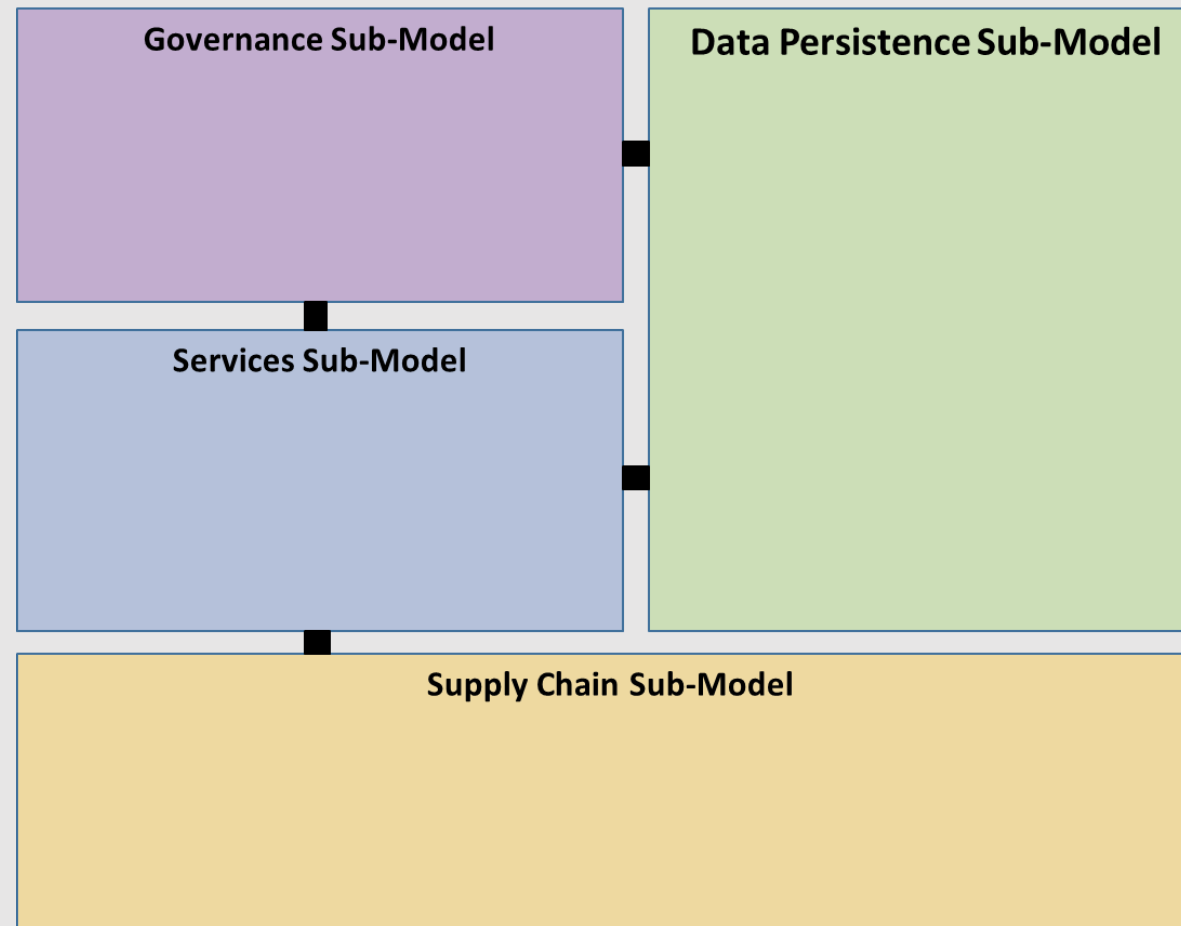
RM008 – Aggregated Model: Blockchain holds chain of Event IDs (Beth's Model)

RM009 – Many Sources Model: Assumes initial implementations on multiple platforms
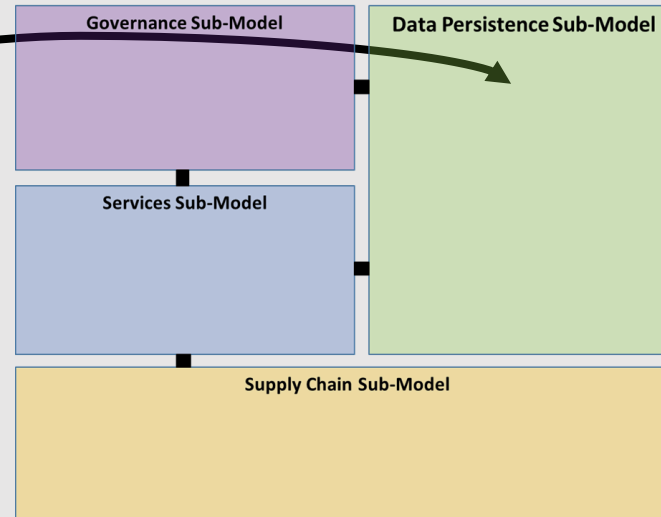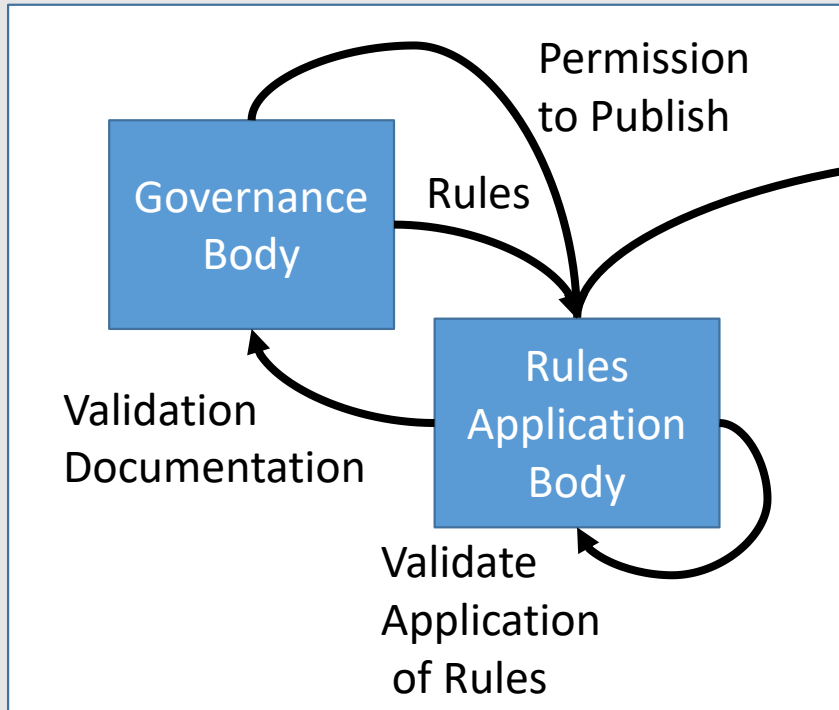
Reference Model Design

# Phase I – DSCSA & Blockchain ReferenceModels

# Reference Model Design

# ReferenceModel Structure - Governance

## ReferenceModel Design: providing a framework for discussions and exploration
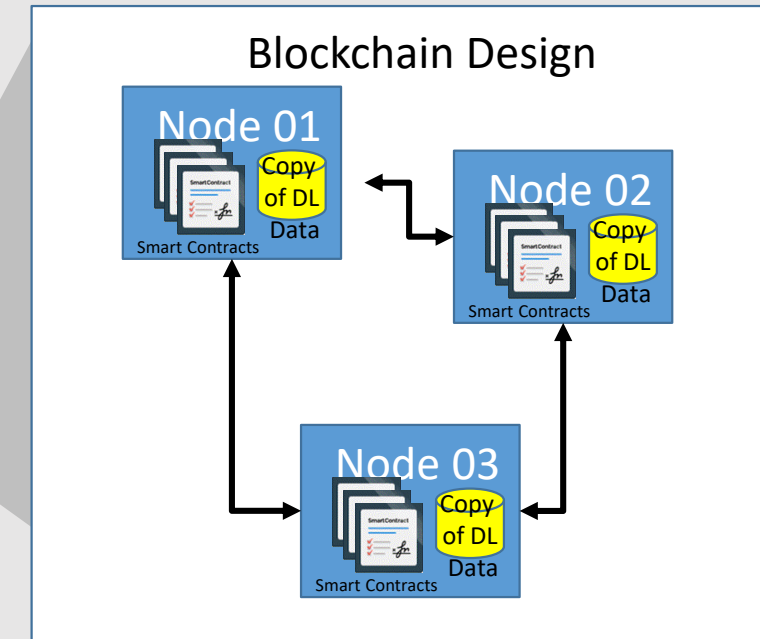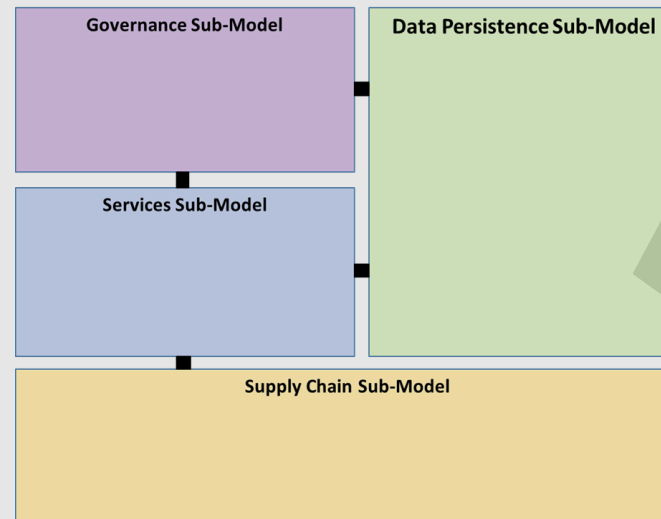


**Examples of Rules:**
- Properly formatted data (NDC)
- A shipping event cannot be added unless there is a commissioning event.

**Rule Types:**
1. DSCSA Rules (Chain of Ownership)
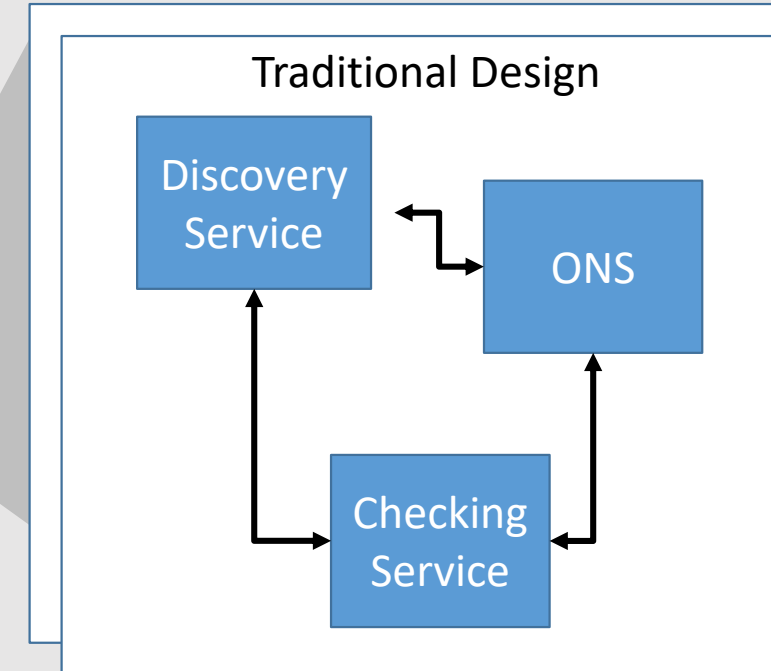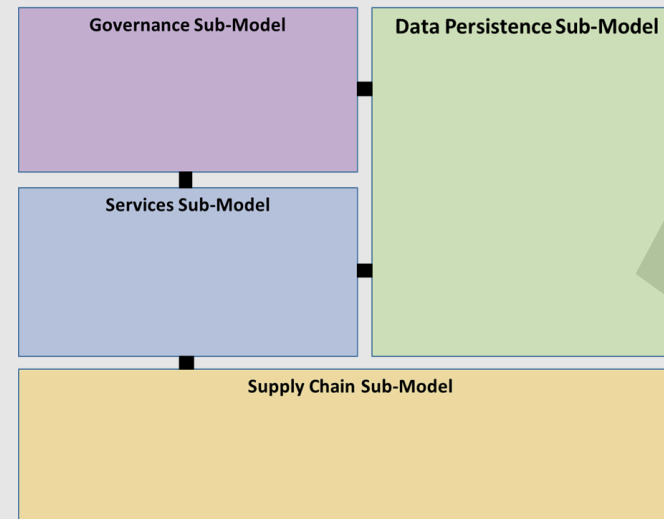2. Business Practice (industry) Rules
3. Rules between Trading Partners

# ReferenceModel Structure - Blockchain

## ReferenceModel Design: providing a framework for discussions and exploration
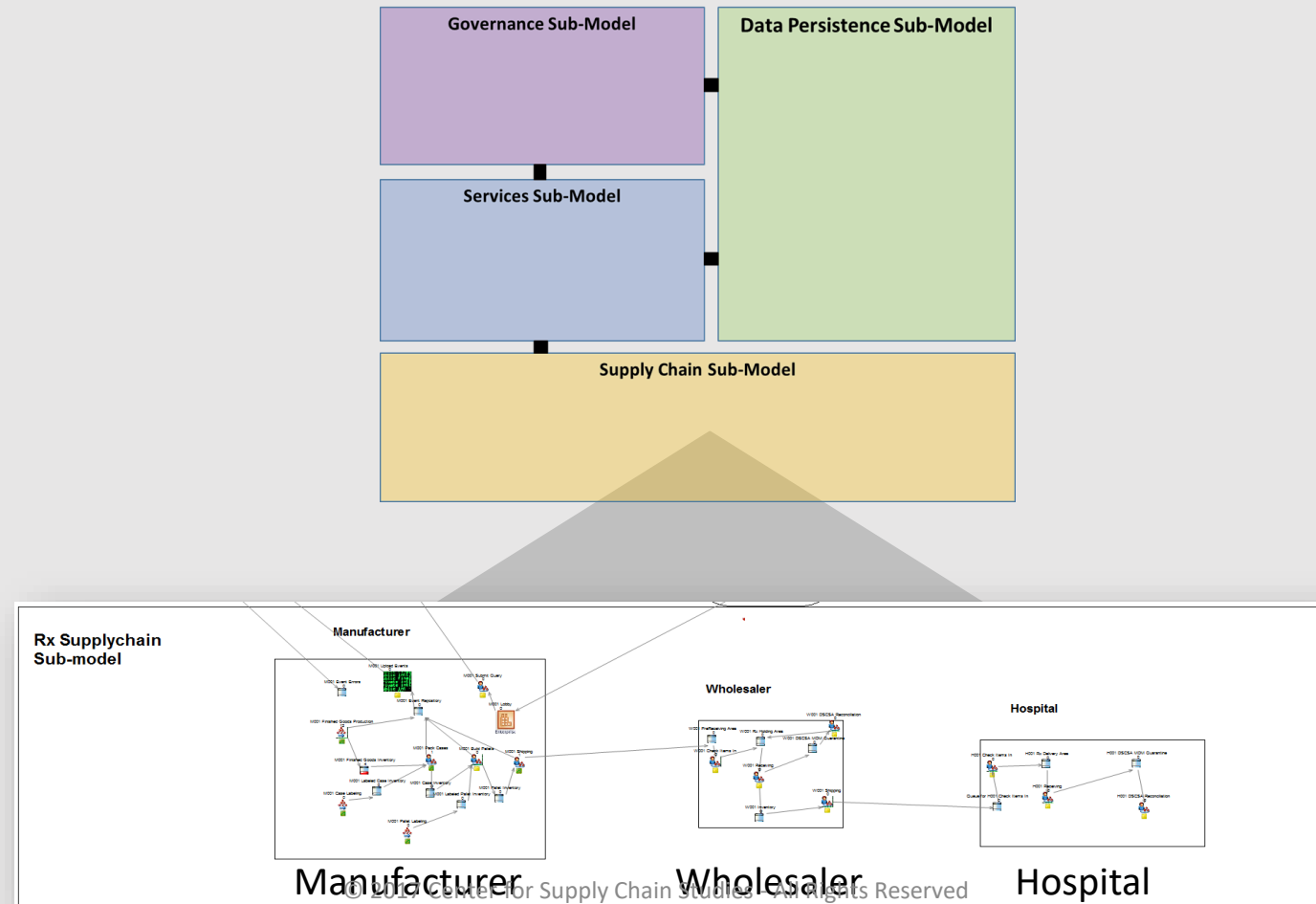
# ReferenceModel Structure - Traditional

ReferenceModel Design: providing a framework for discussions and exploration

# ReferenceModel Structure – Supply Chain

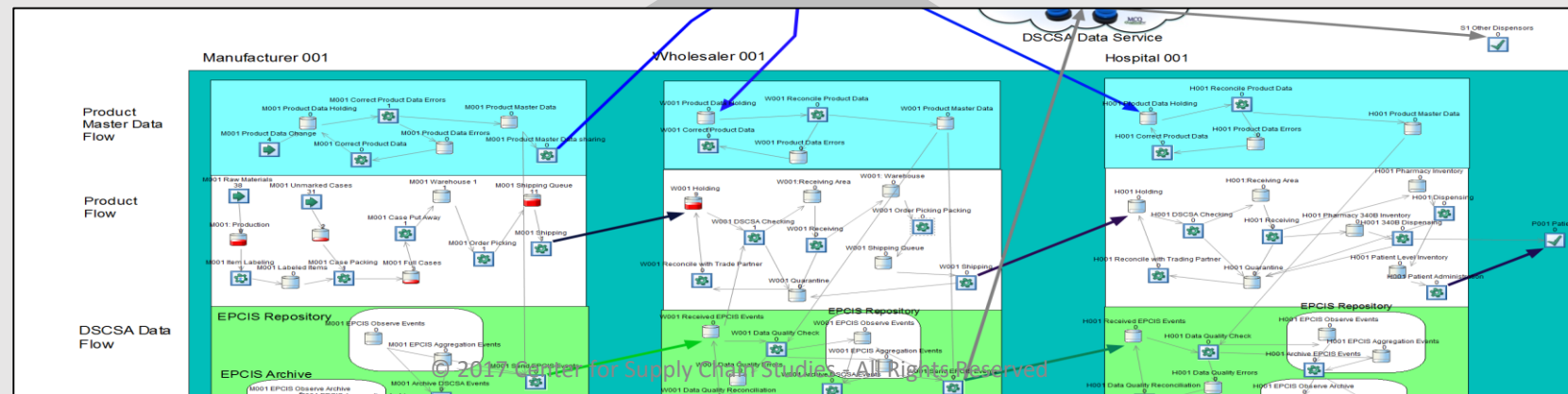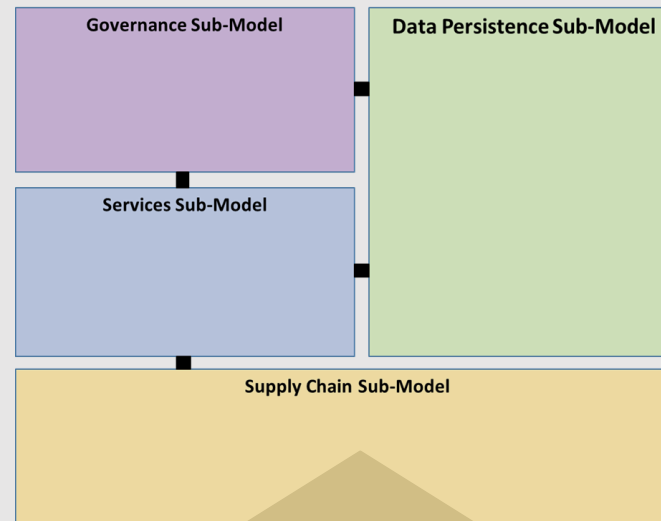## ReferenceModel Design: providing a framework for discussions and exploration
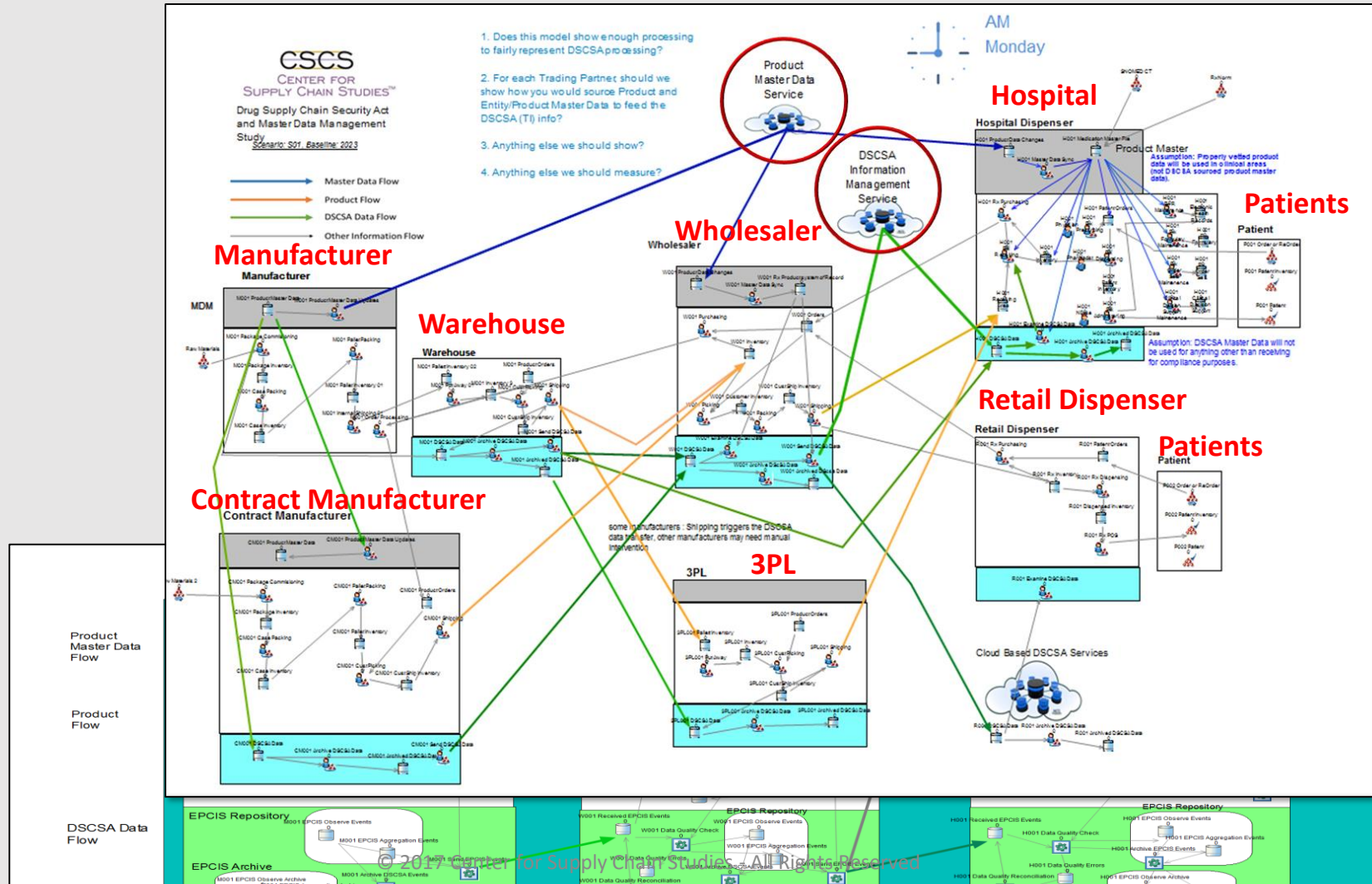
# ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration
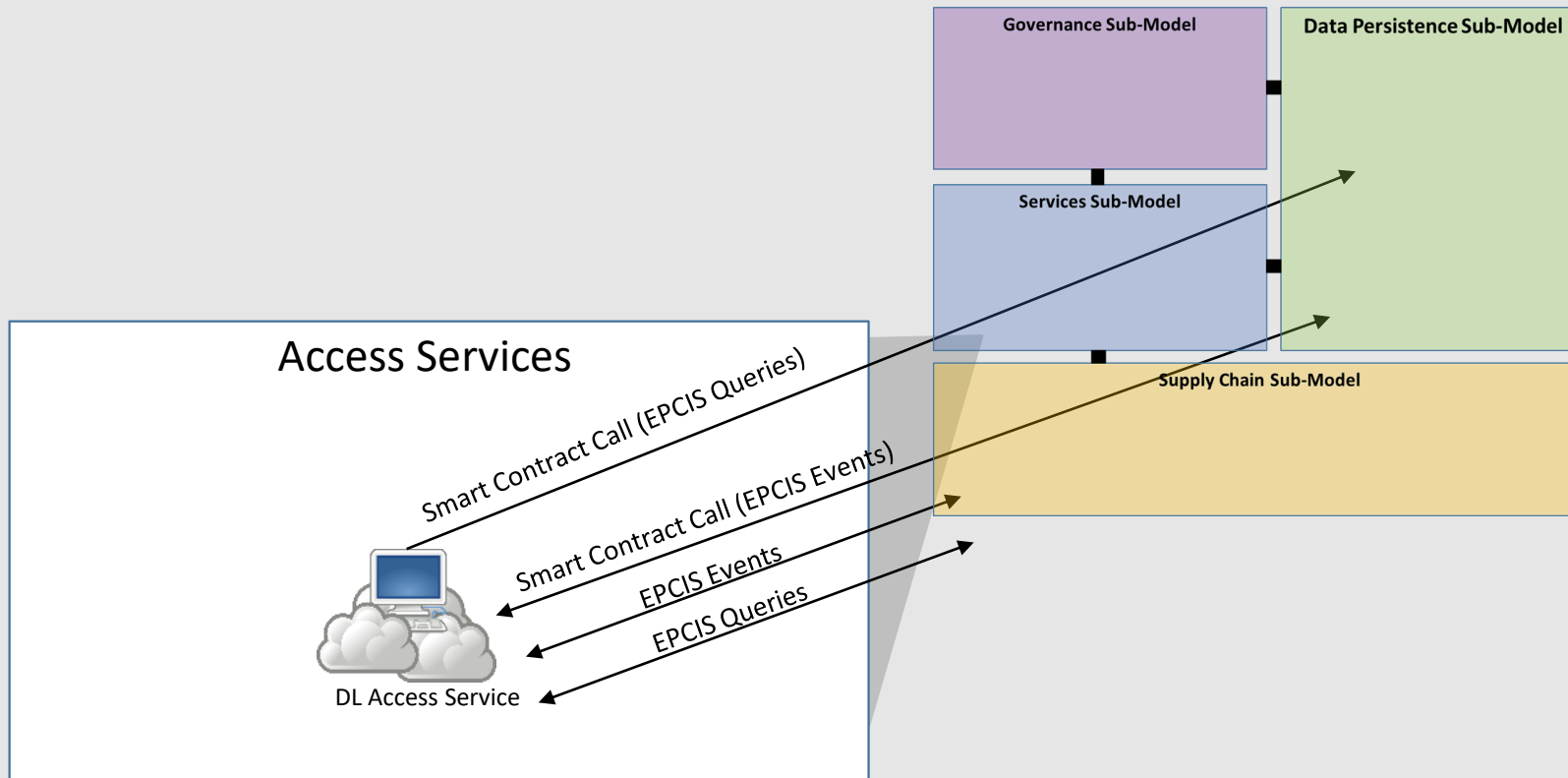
# ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration
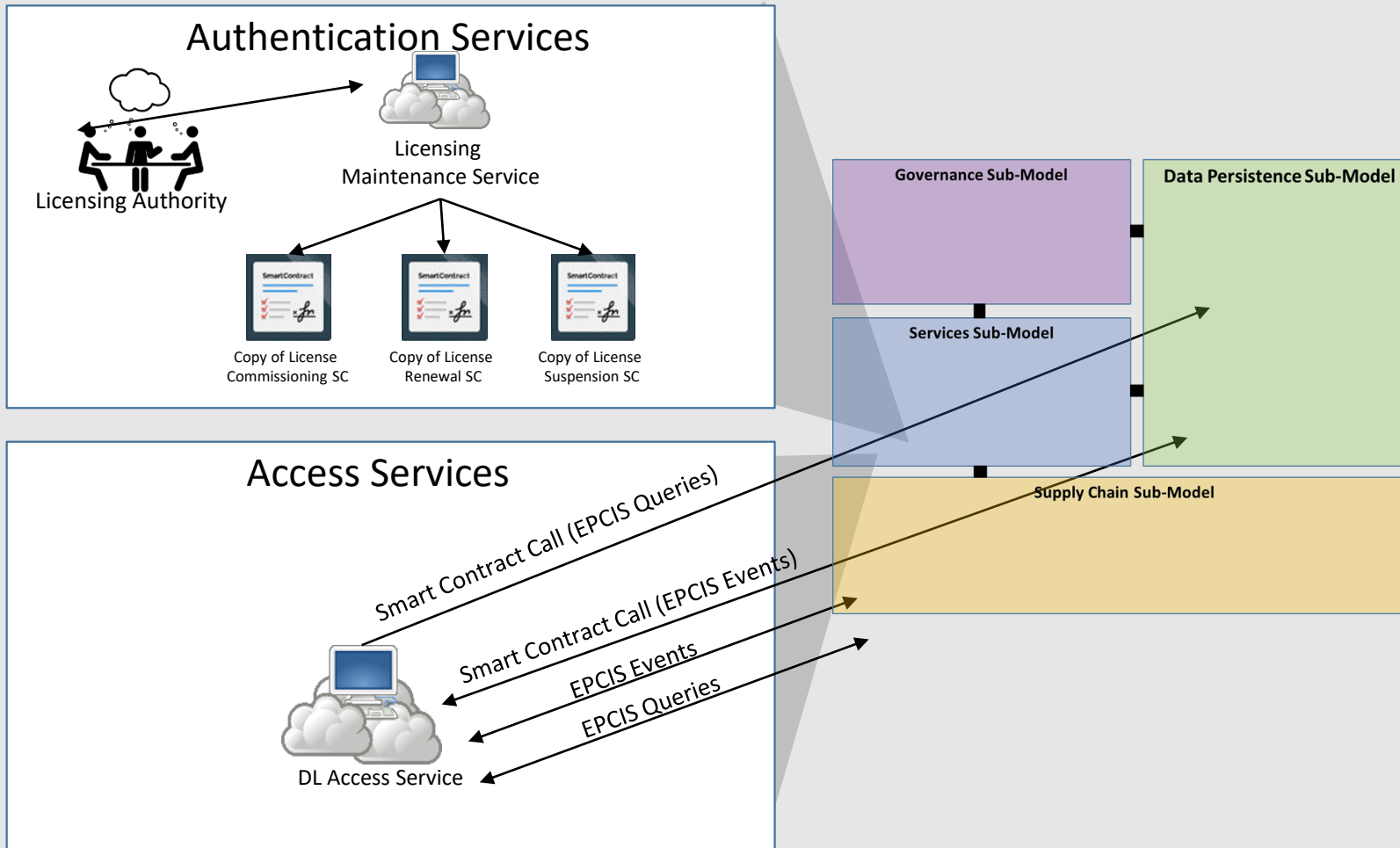
# ReferenceModel Structure – Services

## ReferenceModel Design: providing a framework for discussions and exploration
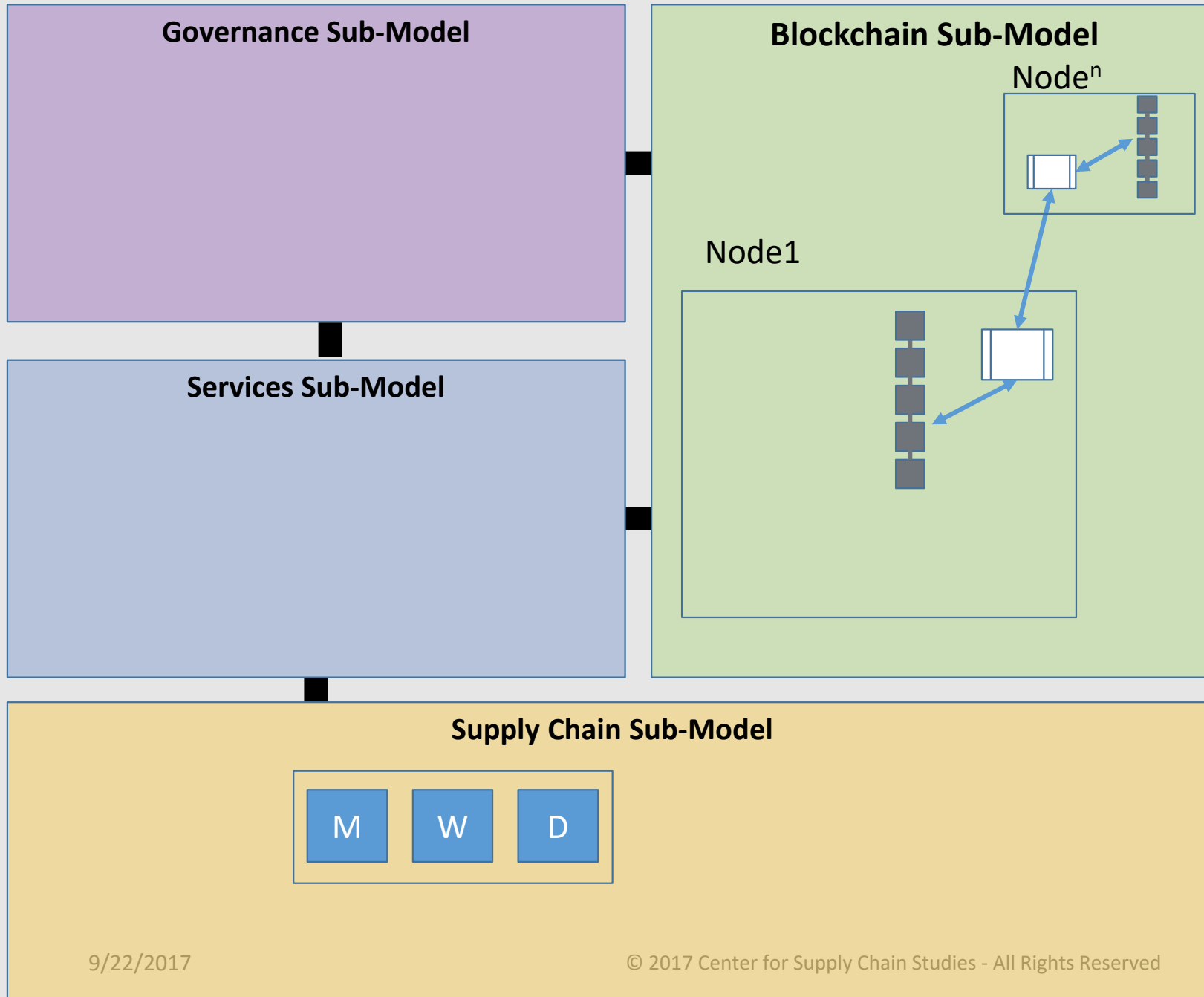
# ReferenceModel Structure – Services

## ReferenceModel Design: providing a framework for discussions and exploration

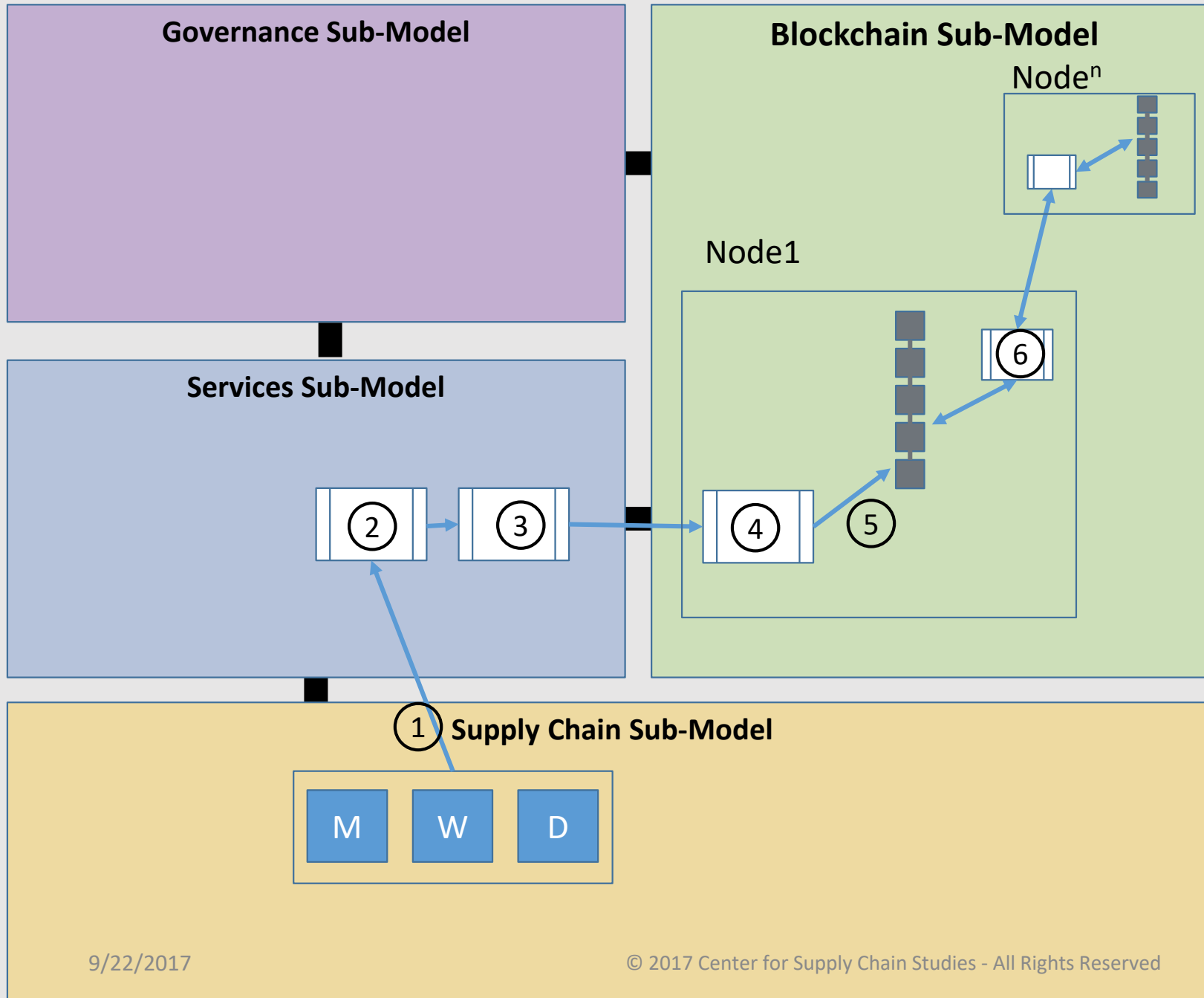**RM001 –** Minimal Model: Minimal data in Blockchain.

# Phase I – DSCSA & Blockchain ReferenceModels

# RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events

CENTER
Supply Chain Studies™
ReferenceModel-based Exploration and Education

### Governance Sub-Model

### Services Sub-Model

### Blockchain Sub-Model

Node$^n$

Node1

### Supply Chain Sub-Model

M   W   D

**Blockchain Data:**
- Commissioning:
  - Block Number
  - Transaction ID
  - Entity ID (encrypt)
  - Lot Number
  - Expiration Date
  - Object ID List (hashs)
  - EventTimestamp
  - BCTransactionTimestamp
- Shipping:
  - Block Number
  - Transaction ID
  - Transfer from (encrypted)
  - Transfer to (encrypted)
  - Object ID (hash of EPC)
  - BizStep
  - EventTimestamp
  - BCTransactionTimestamp
- Aggregation:
  - Block Number
  - Transaction ID
  - Parent Object ID (encrypted)
  - Children Object ID List (each encrypted
  - BizStep (packing)
  - EventTimestamp
  - BCTransactionTimestamp

# RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events



**Governance Sub-Model**

**Blockchain Sub-Model**

$Node^n$

Node1

**Services Sub-Model**

**Supply Chain Sub-Model**

M    W    D

## Contributing Event Data

**BC Events:**
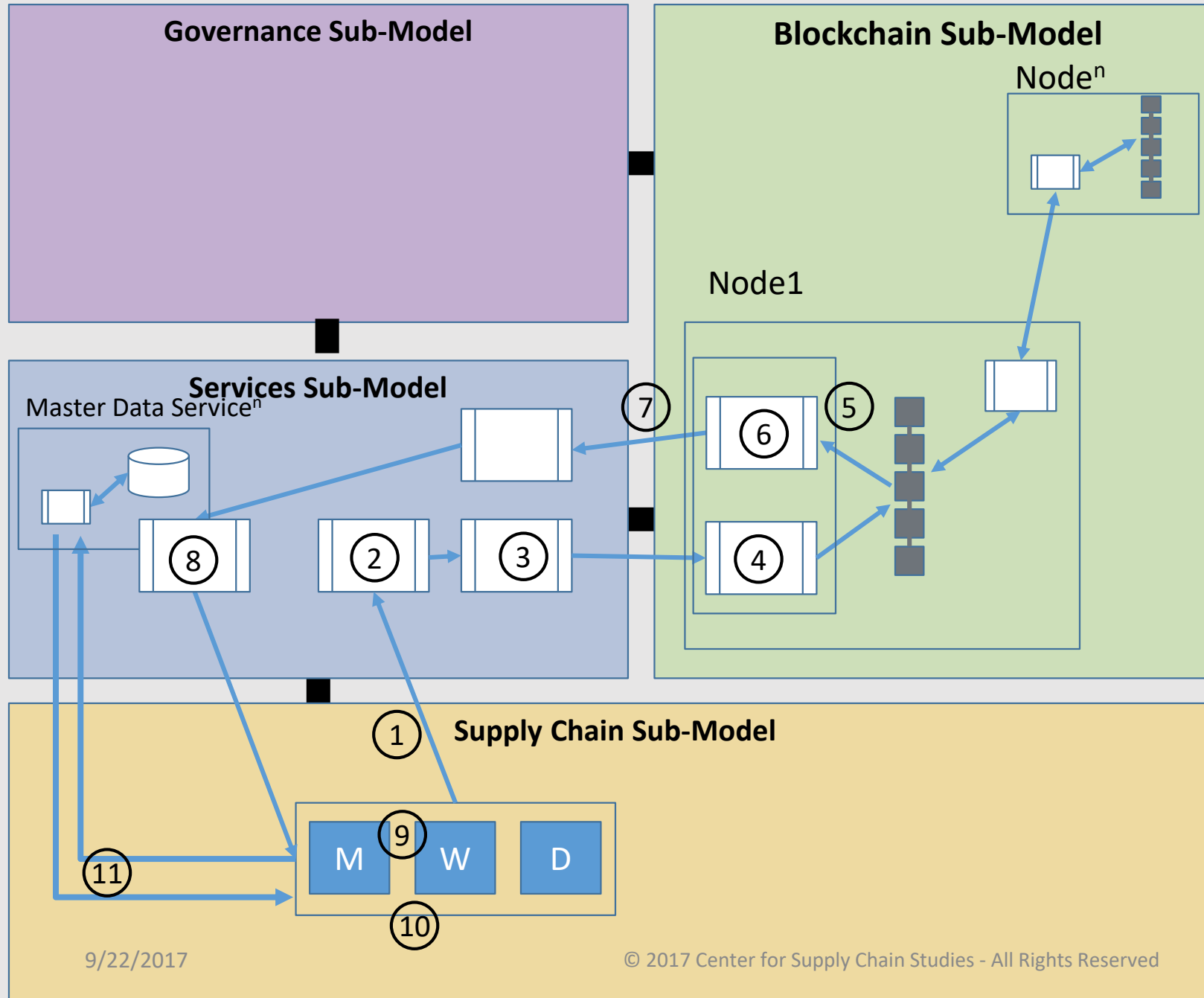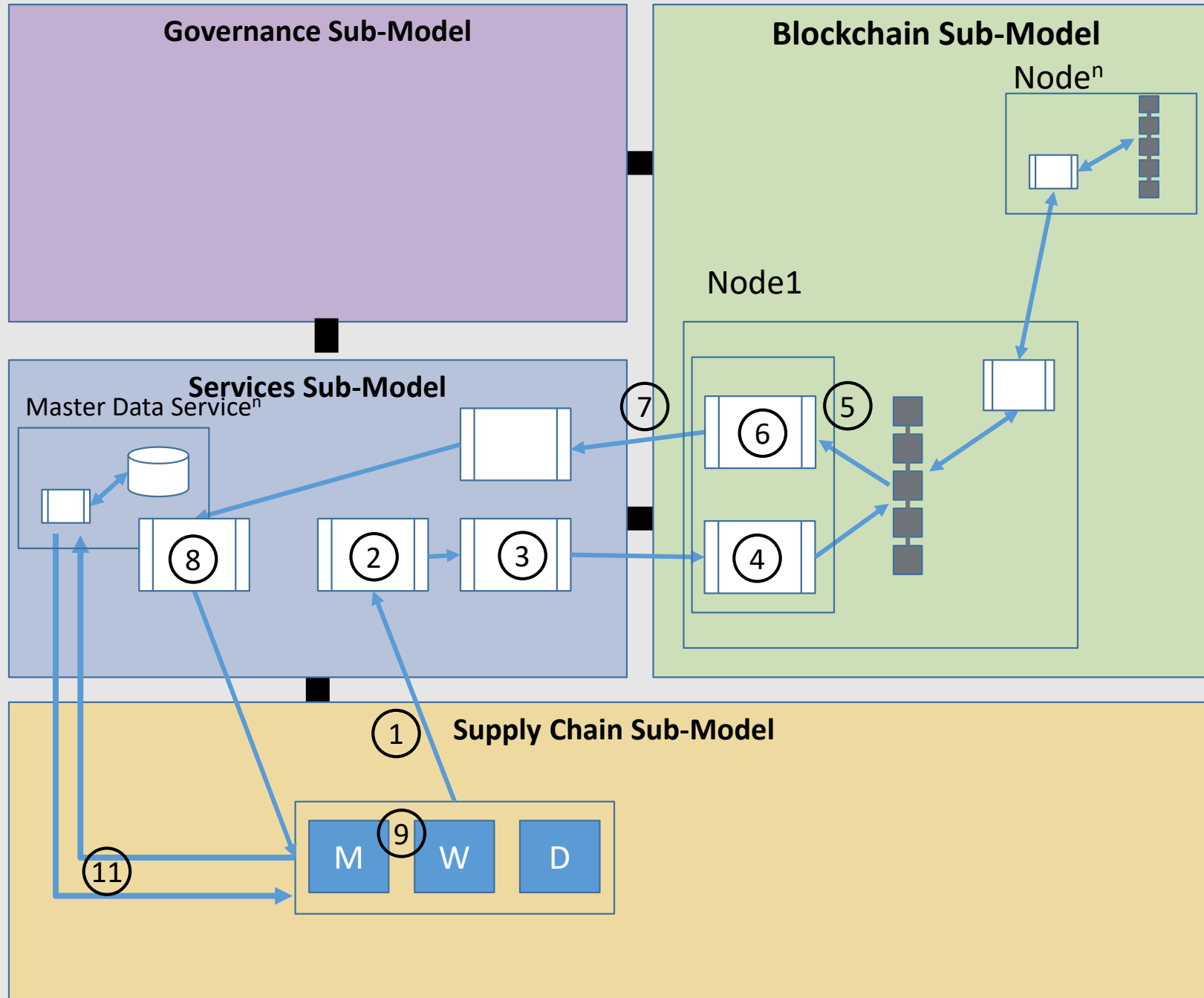- Commissioning (Object)
- Packing
- Shipping

**BC Item Hierarchy:**
- Item
- Case / Tote
- Pallet

Steps: ① ② ③

1. Trading Partner sends EPCIS Event to Service (this could be done within a Service application).
2. Service performs data quality checks (returns error alert if failed).
3. Services calls appropriate SmartContract, supplying attributes as call parameters.
4. SmartContract performs data checks (returns error alert if failed).
5. SmartContract applies data to blockchain.
6. Blockchain Nodes validate transaction and synchronize data.

# RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events



## Querying for Event Data

**BC Events:**
- Commissioning
- Packing
- Shipping

**BC Item Hierarchy:**
- Item
- Case / Tote
- Pallet

Steps: ① ② ③

1. Trading Partner sends EPCIS Query Event to Service (this could be done within a Service application).
2. Service performs data quality checks (returns error alert if failed).
3. Services calls appropriate SmartContract, supplying attributes as call parameters.
4. SmartContract performs data checks (returns error alert if failed).
5. SmartContract retrieves all Events associated with the query parameters.
6. SmartContract determines if Trading Partner had contributed an Event to each series of Events for the queried Object
7. SmartContract returns all Events allowed by rules (contributed event and prior)
8. Service formats returned data into EPCIS Event(s) and returns to Trading Partner
9. Trading Partner Associates Event data with Master Data
10. Trading Partner retrieves missing Master Data (non-adjacent Trading Partner Master Data) from Service

# RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events



**Governance Sub-Model**

**Blockchain Sub-Model**

$Node^n$

$Node1$

**Services Sub-Model**

Master Data $Service^n$

**Supply Chain Sub-Model**

M   W   D

## Querying for Event Data

**BC Events:**
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Demonstrating solutions based on Phase I ReferenceModels

# Phase II – DSCSA & Blockchain Proof of Concept

# Proof of Concept

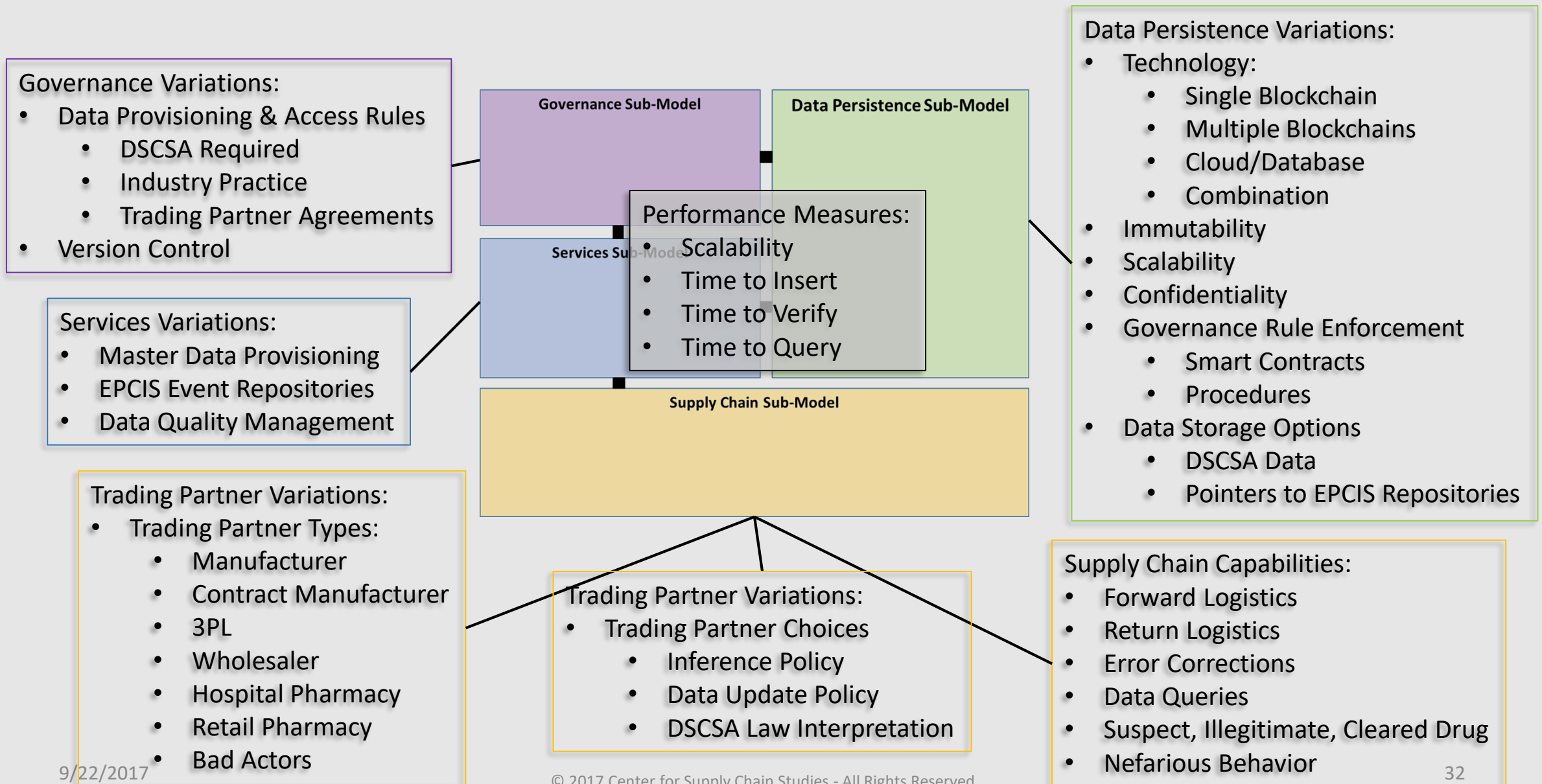Demonstrating Architecture Features and Supply Chain Process Support

Concept:
- Participants determine the set of features that are most desirable for PoC
- Matching of technology and industry companies for PoC set
- Willing technology companies create a working demonstration
- Industry or Center provides data sets for demonstrations
- Industry provides consultation on supply chain processes
- PoCs are free to demonstrate value added processes

Timing:
- Fall 2017:
  - Study organization
  - Feature set selection
  - PoC participant pairing
- Winter 2017 - 2018:
  - PoC development
- April 2018
  - 2 day event to demonstrate, explore and discuss PoCs

# Proof of Concept Options

**Governance Variations:**
- Data Provisioning & Access Rules
  - DSCSA Required
  - Industry Practice
  - Trading Partner Agreements
- Version Control

**Services Variations:**
- Master Data Provisioning
- EPCIS Event Repositories
- Data Quality Management

**Trading Partner Variations:**
- Trading Partner Types:
  - Manufacturer
  - Contract Manufacturer
  - 3PL
  - Wholesaler
  - Hospital Pharmacy
  - Retail Pharmacy
  - Bad Actors

**Governance Sub-Model**

**Data Persistence Sub-Model**

**Services Sub-Model**

**Performance Measures:**
- Scalability
- Time to Insert
- Time to Verify
- Time to Query

**Supply Chain Sub-Model**

**Data Persistence Variations:**
- Technology:
  - Single Blockchain
  - Multiple Blockchains
  - Cloud/Database
  - Combination
- Immutability
- Scalability
- Confidentiality
- Governance Rule Enforcement
  - Smart Contracts
  - Procedures
- Data Storage Options
  - DSCSA Data
  - Pointers to EPCIS Repositories

**Trading Partner Variations:**
- Trading Partner Choices
  - Inference Policy
  - Data Update Policy
  - DSCSA Law Interpretation

**Supply Chain Capabilities:**
- Forward Logistics
- Return Logistics
- Error Corrections
- Data Queries
- Suspect, Illegitimate, Cleared Drug
- Nefarious Behavior

# POC Support

## ReferenceModel Documentation and POC Data



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

# What's Next

# Study Lifecycle

Idea to Publication



| Study Proposal | Prospectus/Charter | Pre-Launch | Study | Publish |
|---|---|---|---|---|
| Draft Goals and definition | Goals, Metrics and Scenarios | Detailed Goals, metrics and Scenarios | Final Scope | Publish ReferenceModels |
| | **Continued Introduction Webinars** | **Pre-Launch Calls** | **Launch: Scheduled Calls & Meetings** | White Paper |
| | | | | Education Module |
| RoadMap | Socialize With Community | Agreement Anti-Trust Funding | Develop /execute Scenarios | |

# Discussion / Questions

# Studies



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**STUDY**: Global Track & Trace

**STUDY:** DSCSA & Blockchain 2

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

# Contact Information

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