

Welcome to the Webinar!

We will start at 1pm EST



Blockchain your Supply Chain

Exploring the use of blockchain technology
within Healthcare

Introduction Briefing
10/6/2017

This Presentation was underwritten by:



www.delanceyriskpartners.com

Antitrust Statement

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About us.



Pharma industry forum for DSCSA compliance.

The Center for Supply Chain Studies was established in late 2015 a neutral, nonprofit industry exploration and education forum. Trusted as forward-looking thought leaders, we carefully study the implication of these developments in our work to assist the pharmaceutical industry.

We're dedicated to supporting the pharmaceutical supply chain in its ongoing mission to improve efficiencies, increase productivity and streamline Drug Supply Chain Security Act (DSCSA) compliance. We monitor, interpret and clarify industry trends, including legislative and regulatory changes and forecasts.

To this end, we host and facilitate group-funded **VirtualPilot Studies** as a way for thought leaders to come together, exchange ideas and share their expertise.

Content

- Studies at the Center
- Blockchain your Supply Chain – Why the interest in Blockchain
- Current and planned Studies:
 - Phase I – DSCSA & Blockchain ReferenceModels
 - Phase II – DSCSA & Blockchain Proof of Concepts
- Beyond Regulatory Compliance:
 - Blockchain and Cold Chain
- 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 & Blockchain²

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



Study Charter



Funded

Participant Input

Why the interest in Blockchain?

Blockchain your Supply Chain

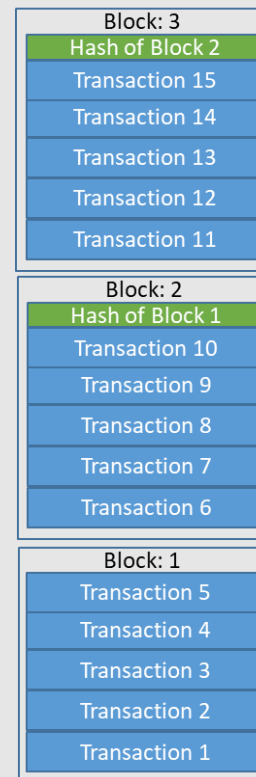
Blockchain your Supply Chain

Why the interest in Blockchain?

Drug Supply Chain Security Act

- Interoperable System
 - 3,500 manufacturers
 - 2,500 Wholesalers
 - 7,500 Hospitals
 - 64,000 Pharmacies
- Trace individual items back to the manufacturer
- Data Confidentiality
 - Don't share confidential data
 - Only share data for items that are owned by the tracing party
- Data immutability
 - Archive and access data for six years

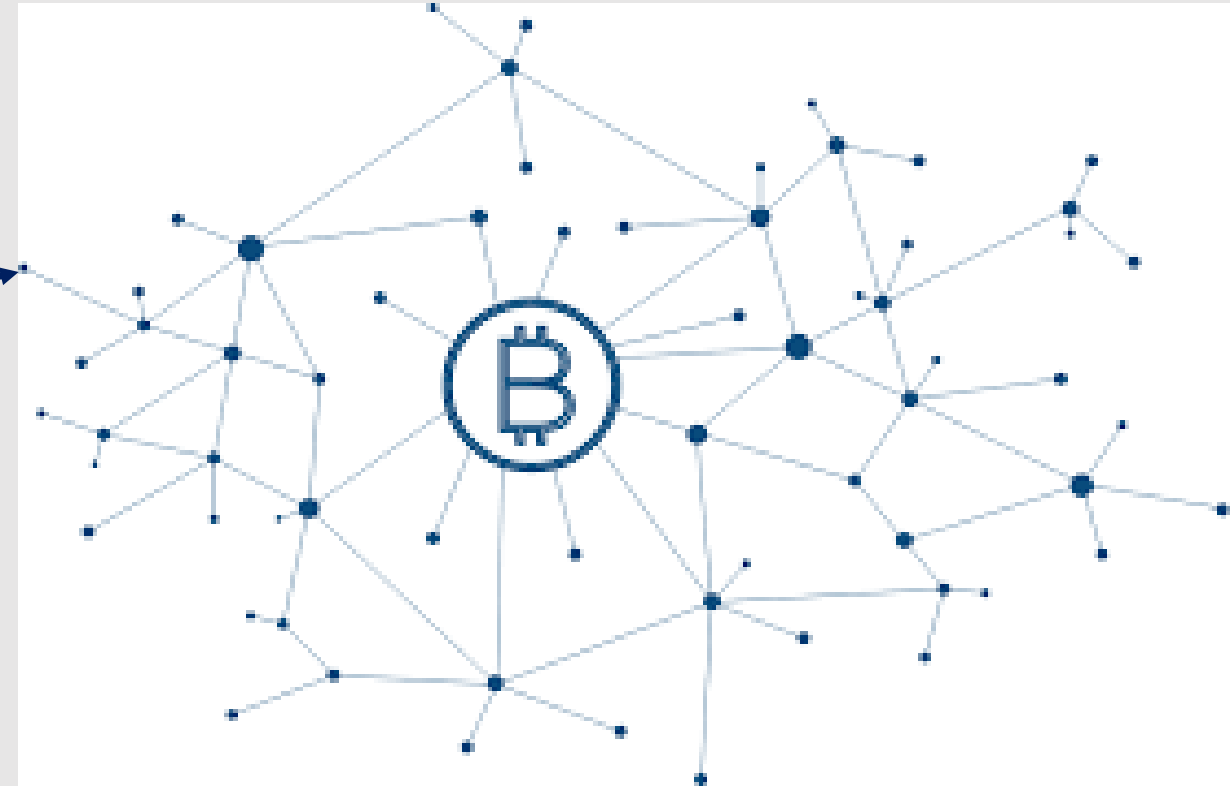
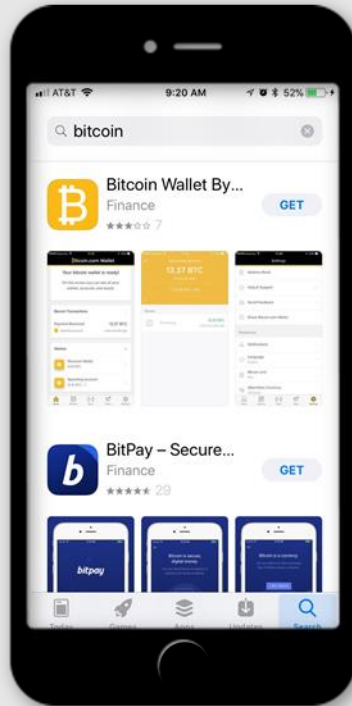
Blockchain Technology



- Secure Transaction Ledger
- Developing Open Standards
- Ease of participation
- Single source of truth (everyone sees the same thing)
 - For info stored in blockchain
 - For info stored off block (via info hash stored on block)
- Eliminate need of a trusted custodian
- Provides a common set of rules executed by all nodes
 - Can be revisioned and audited

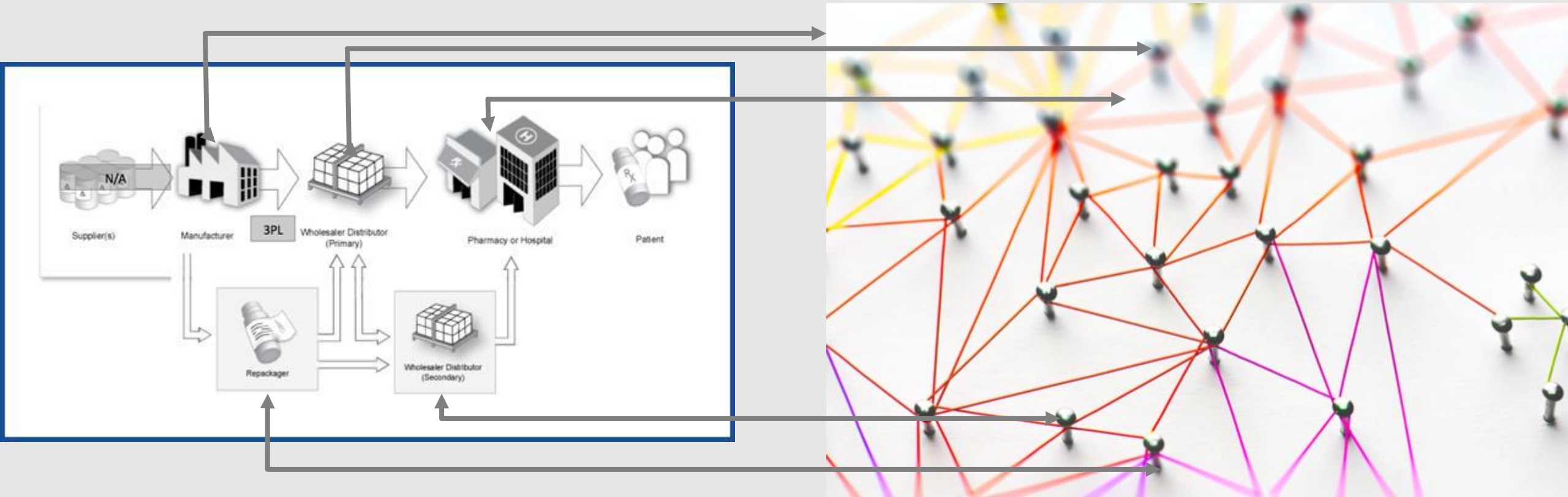
Connectivity

How do you get connected to the most popular Blockchain?



Does connecting to a blockchain connect the Industry?

Adjacent and non-adjacent trading partners



Virtual Pilot

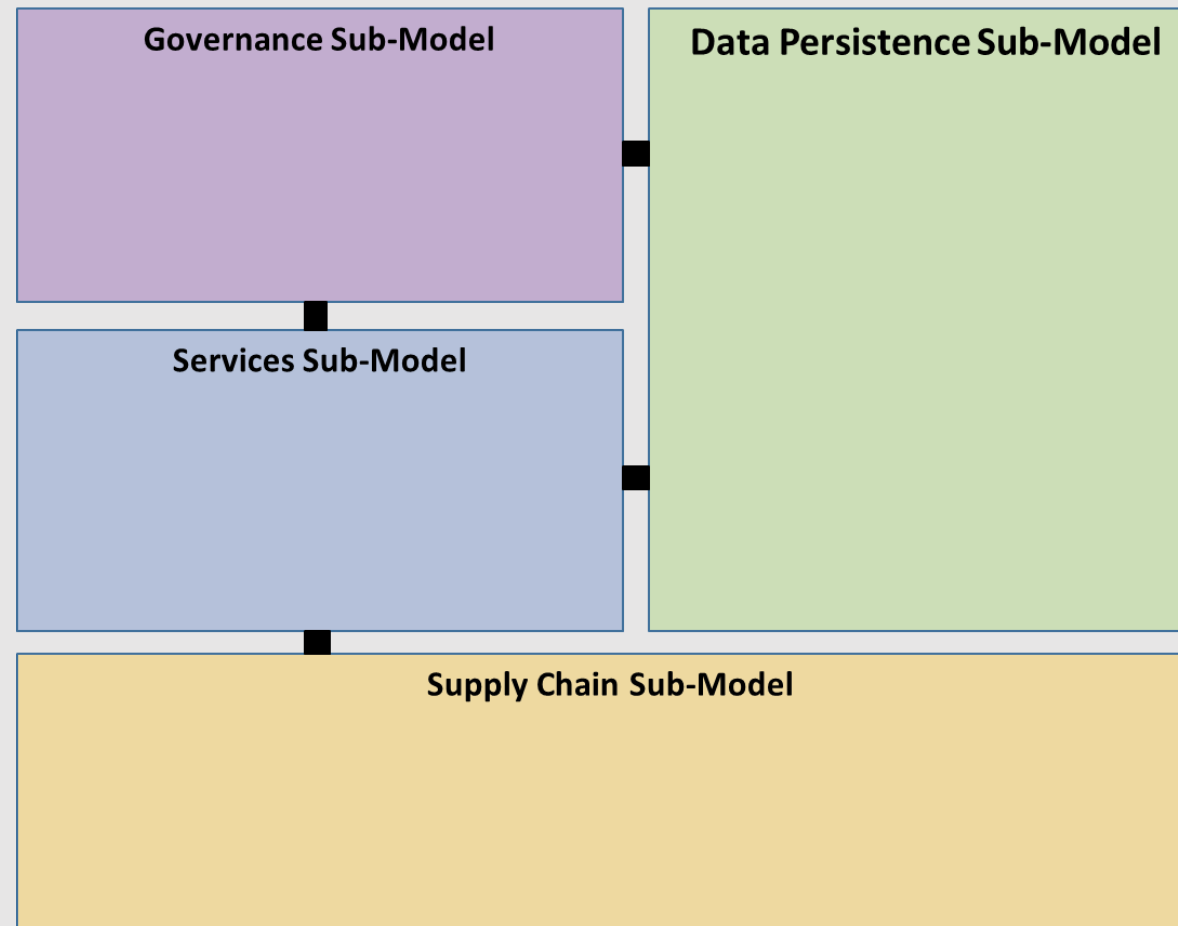
Phase I – DSCSA & Blockchain ReferenceModels

DSCSA – Blockchain Study

Focus: Six unresolved challenges

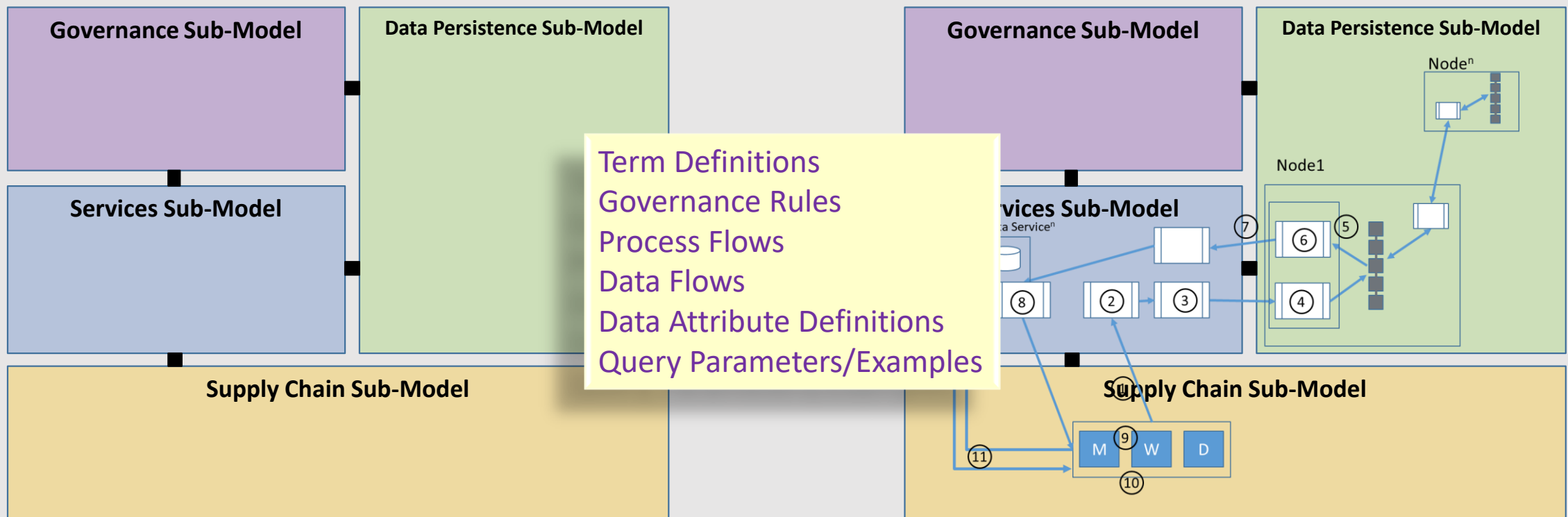
- ✓ 1. Establishing an electronic connection between non-adjacent trading partners.
- ✓ 2. Establishing trust between these trading partners.
- ✓ 3. Sharing required data without inadvertently exposing proprietary information.
- ✓ 4. Reduce the potential activity required of trading partners.
- ✓ 5. Designing for expansion beyond DSCSA compliance
- 6. Funding the architecture.

Reference Model Design



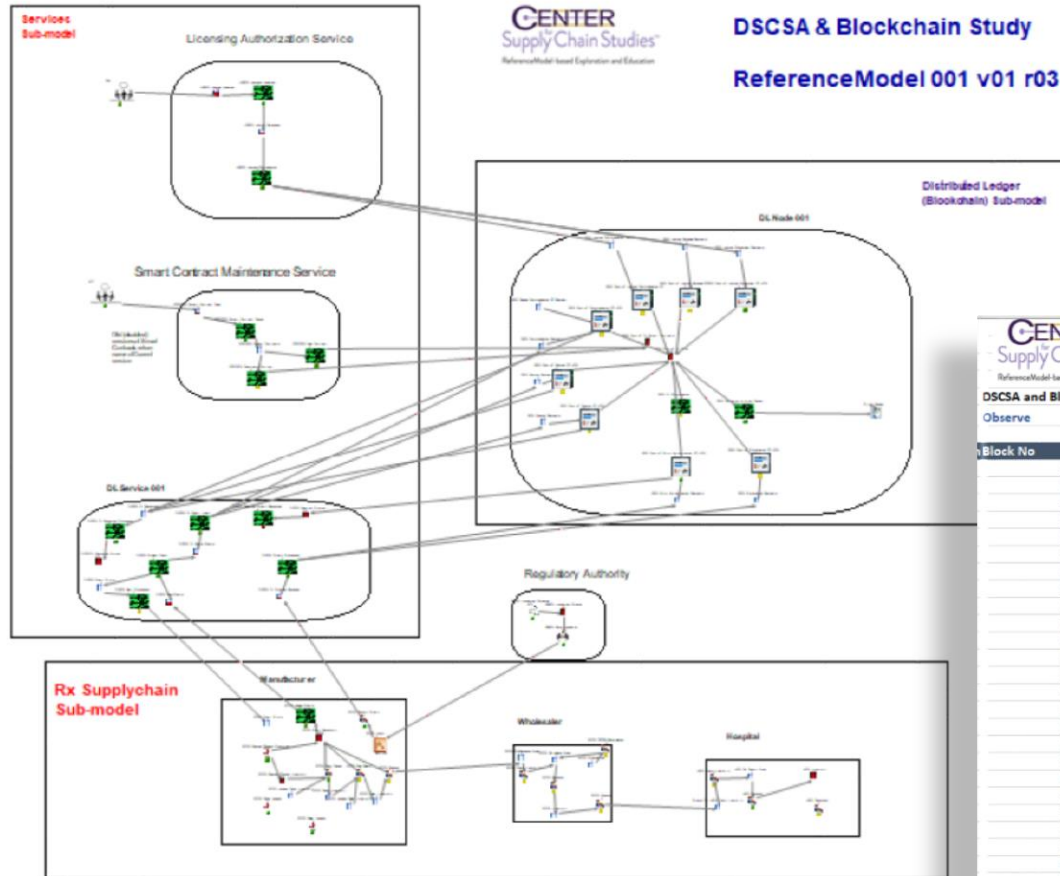
Phase I

Virtual Pilot: DSCSA & Blockchain ReferenceModels



Phase I

Virtual Pilot: DSCSA & Blockchain ReferenceModels

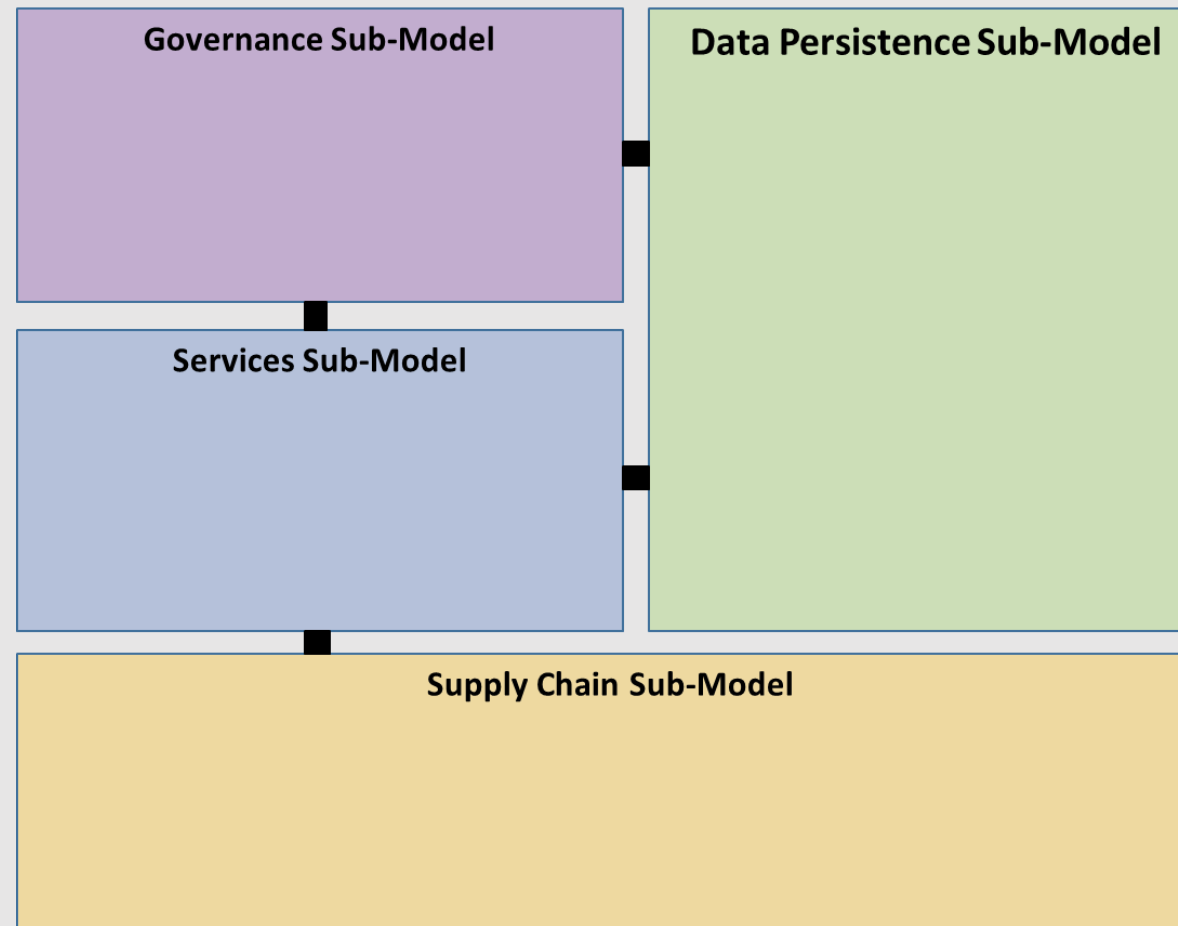


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1	2 urn:epcid:gl:n:0312444.00001.0	31 b6 e0 23 20 57 53 c2 29 43 a0				urn:epcid:sgtin:0031234.500012.2	7J3f0dHibur9bGosz2t+juNVGBE=	commissioning	10/3/2023 12:00 AM
1	3 urn:epcid:gl:n:0312444.00001.0	3d c0 bc 1b 2c 21 0f fa 4c e8 92				urn:epcid:sgtin:0031234.500012.3	lMISmaE+V3e6XvpeIZSifexTWE8=	commissioning	10/3/2023 12:07 AM
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Reference Model Design

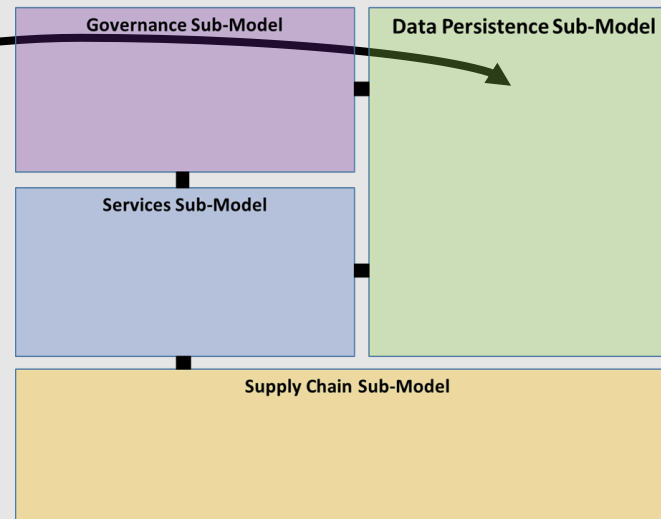
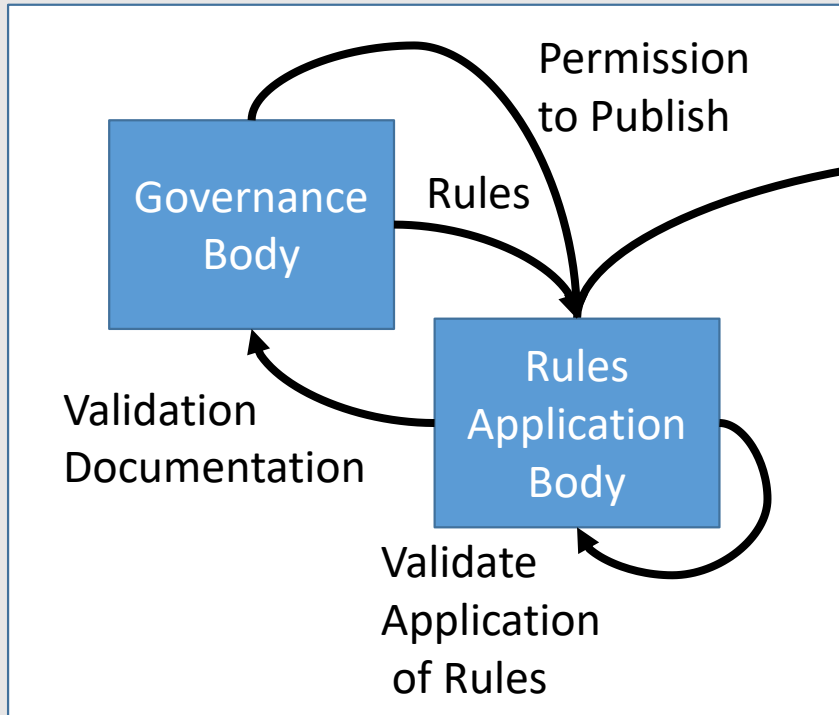
Phase I – DSCSA & Blockchain ReferenceModels

Reference Model Design



ReferenceModel Structure - Governance

ReferenceModel Design: providing a framework for discussions and exploration



Examples of Rules:

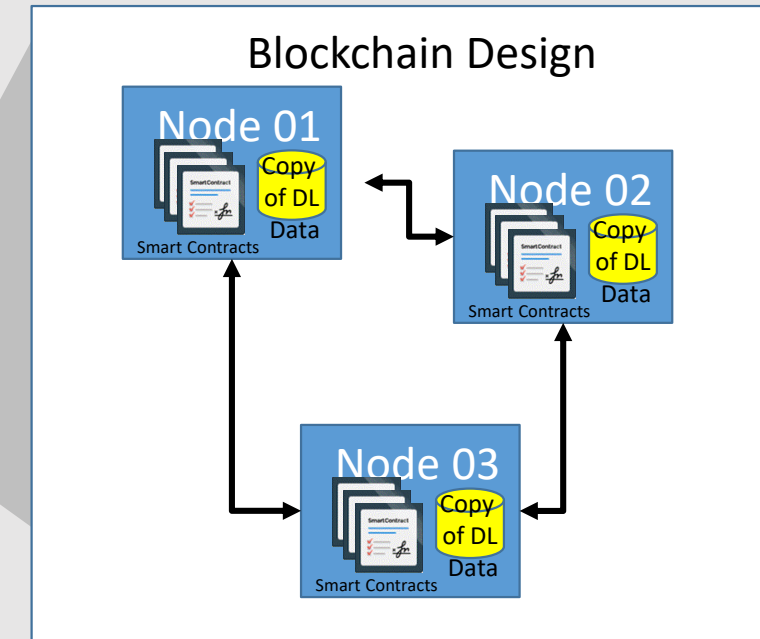
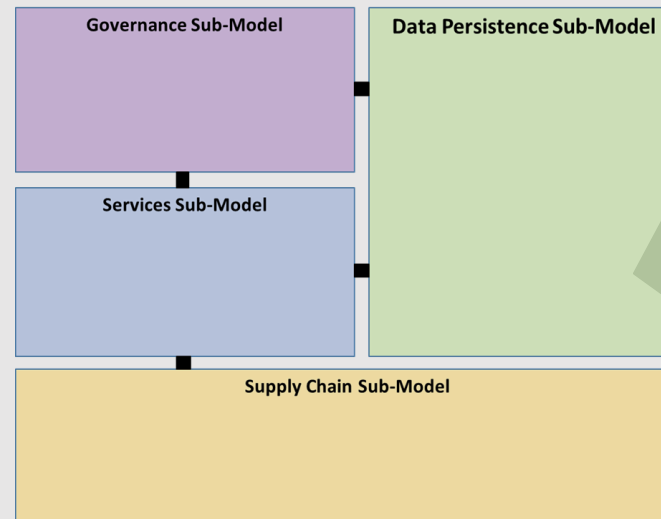
- Properly formatted data (NDC)
- A shipping event cannot be added unless there is a commissioning event.

Rule Types:

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

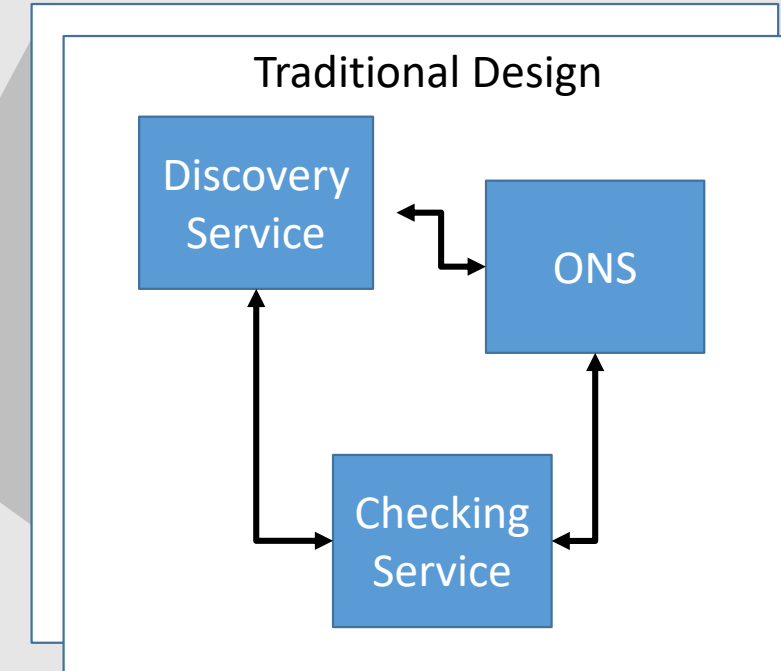
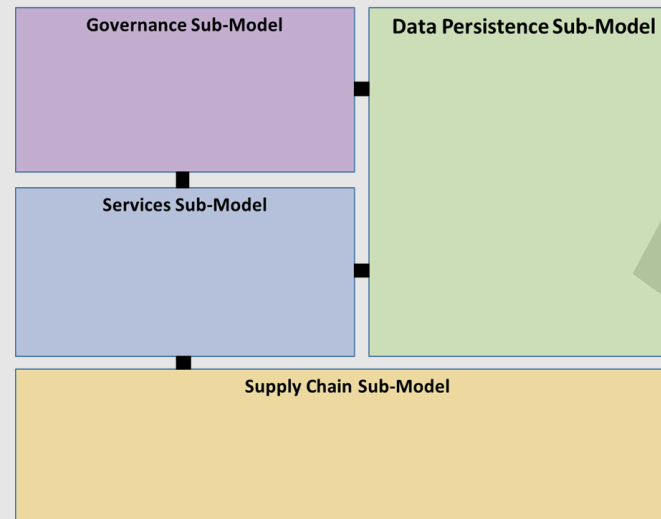
ReferenceModel Structure - Blockchain

ReferenceModel Design: providing a framework for discussions and exploration



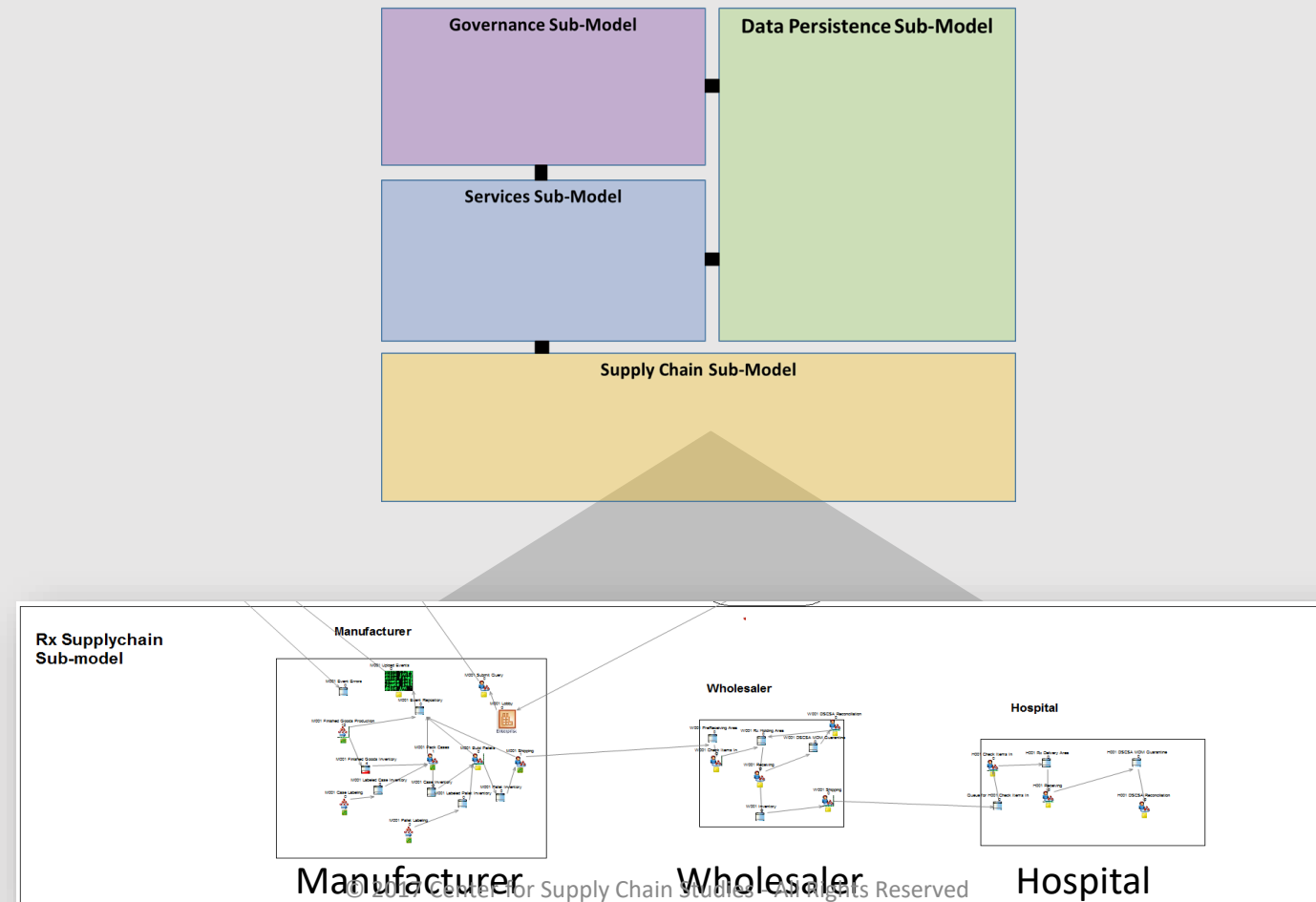
ReferenceModel Structure - Traditional

ReferenceModel Design: providing a framework for discussions and exploration



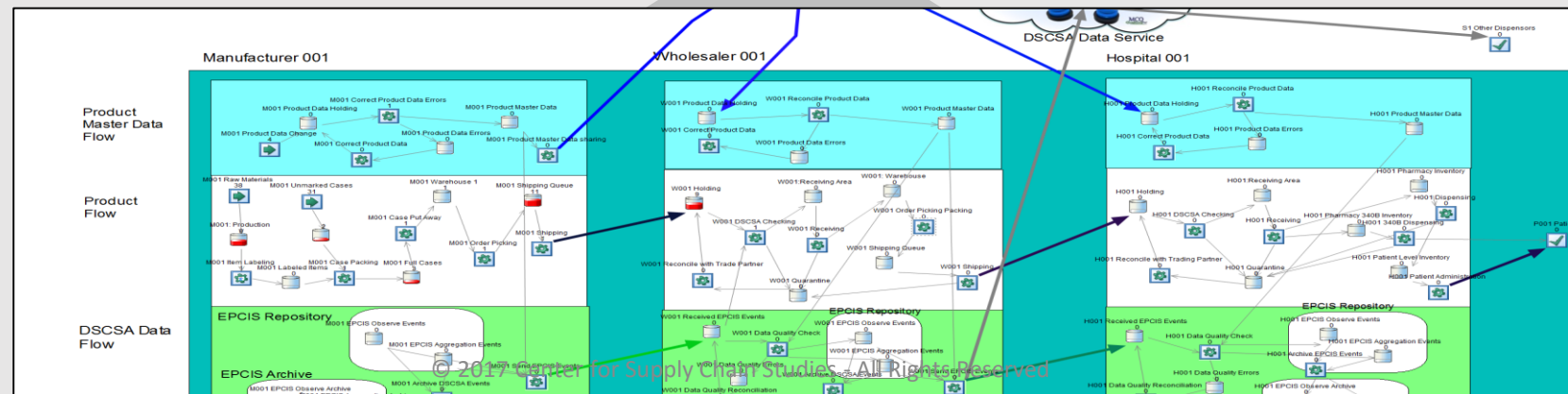
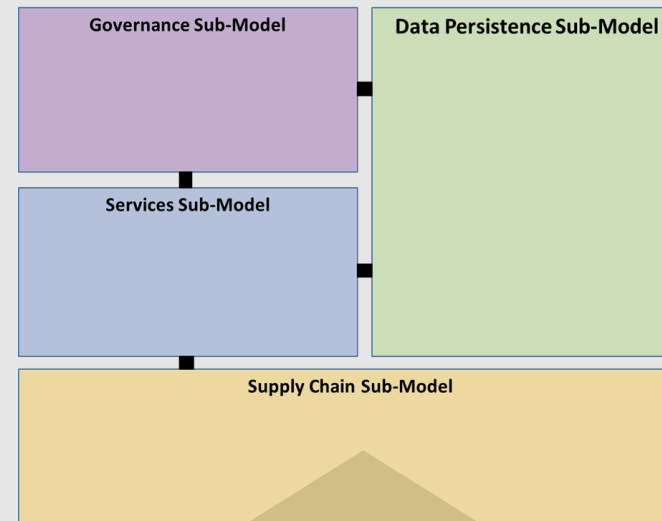
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



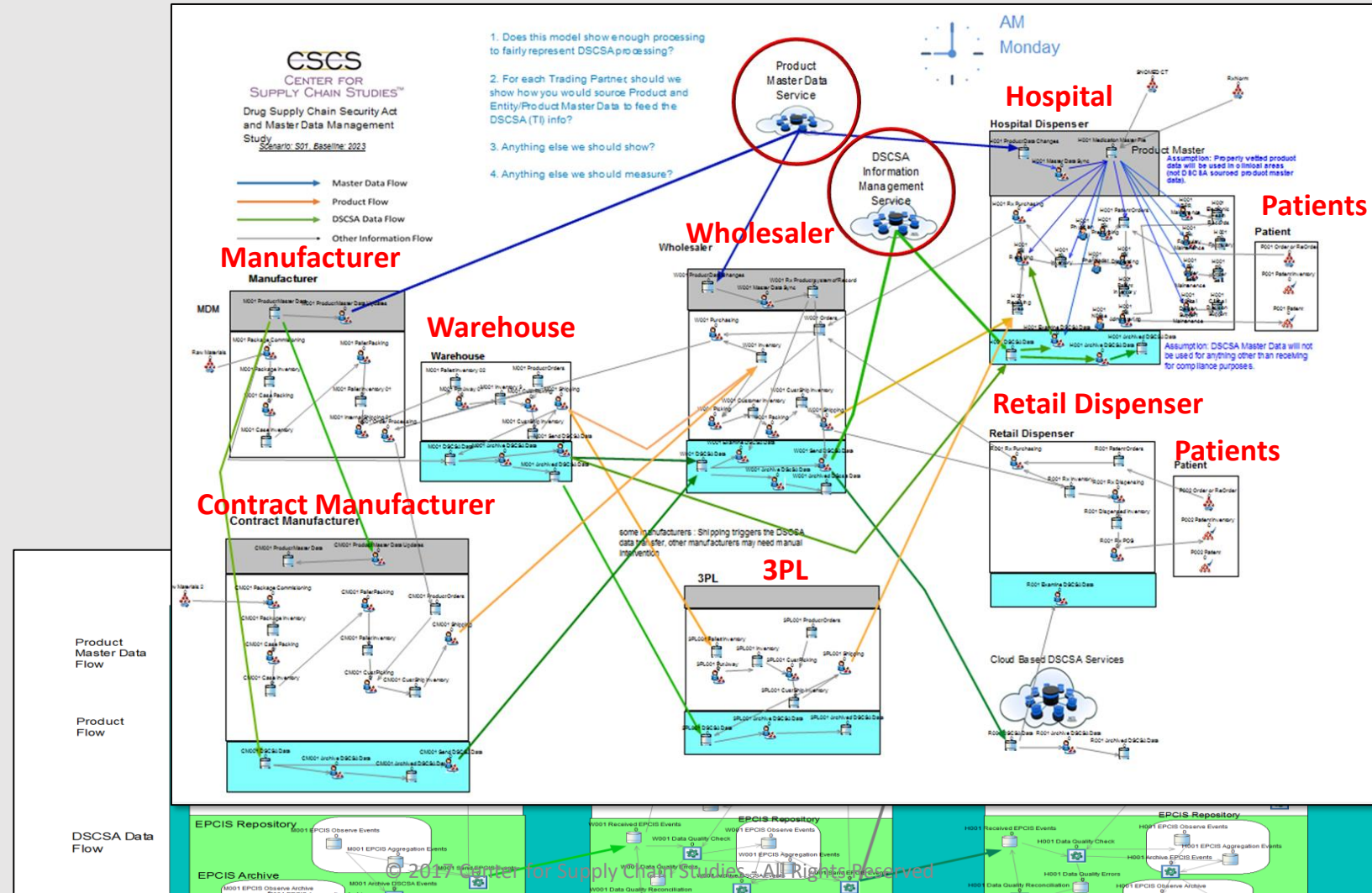
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



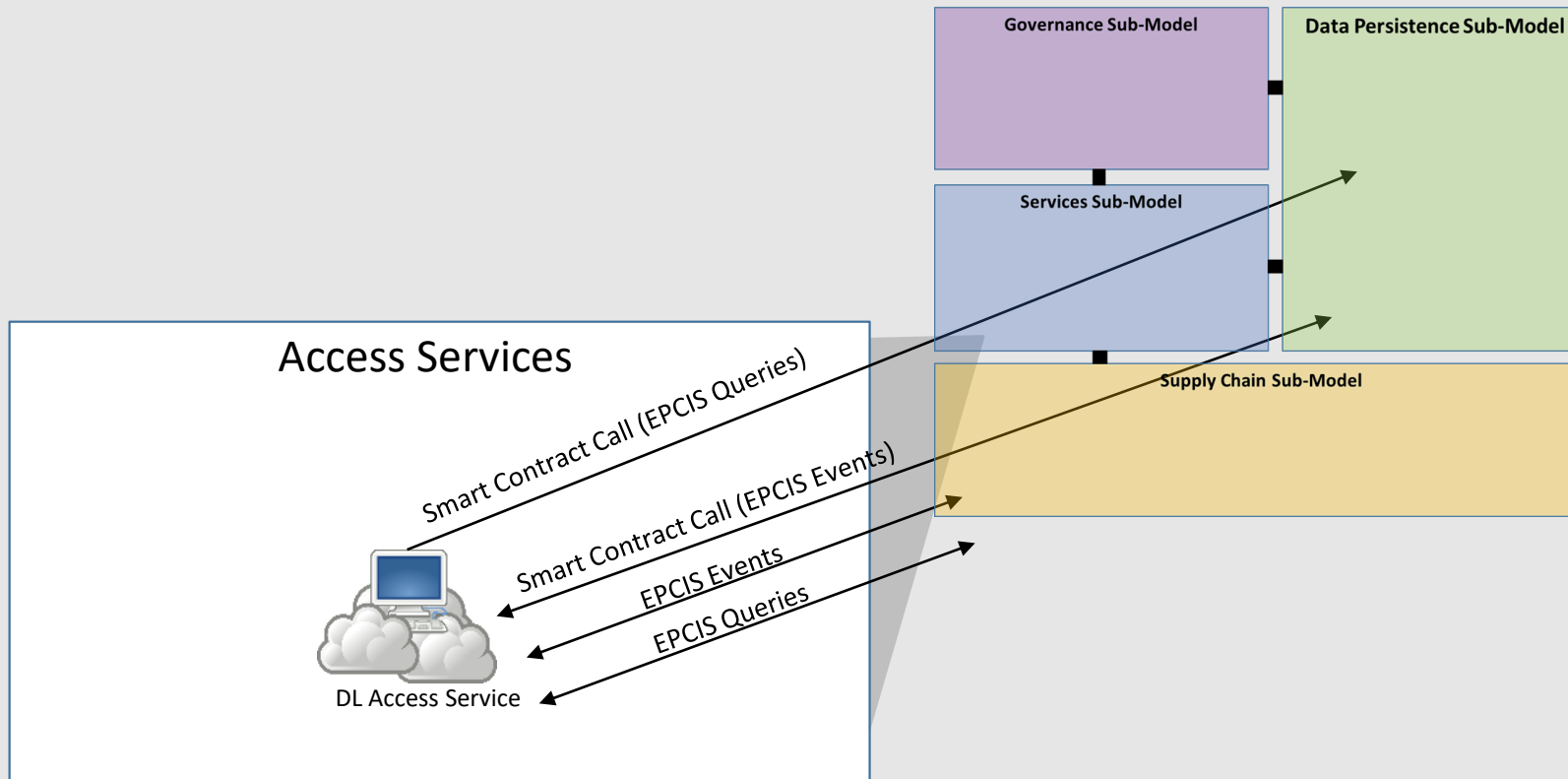
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



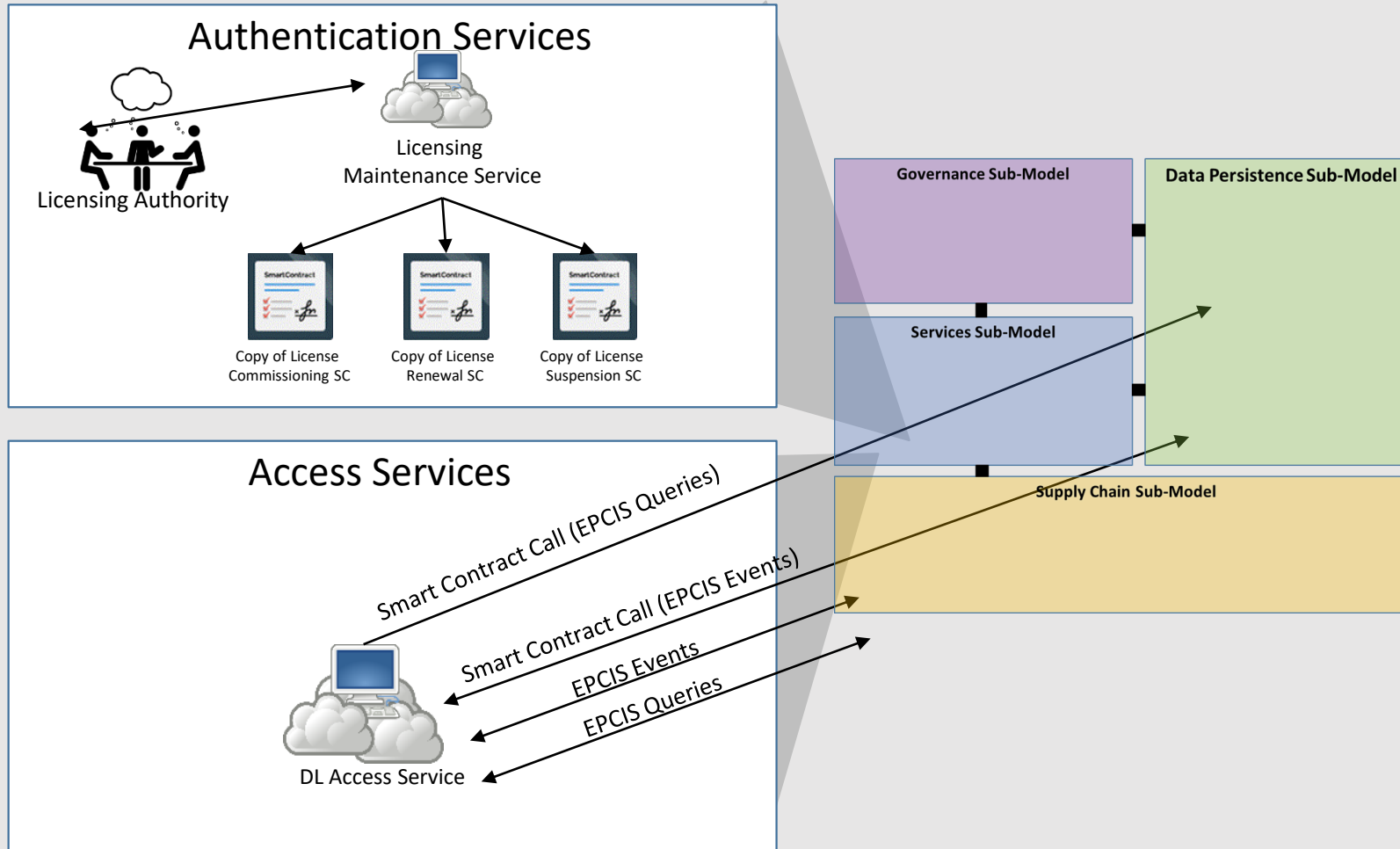
ReferenceModel Structure – Services

ReferenceModel Design: providing a framework for discussions and exploration



ReferenceModel Structure – Services

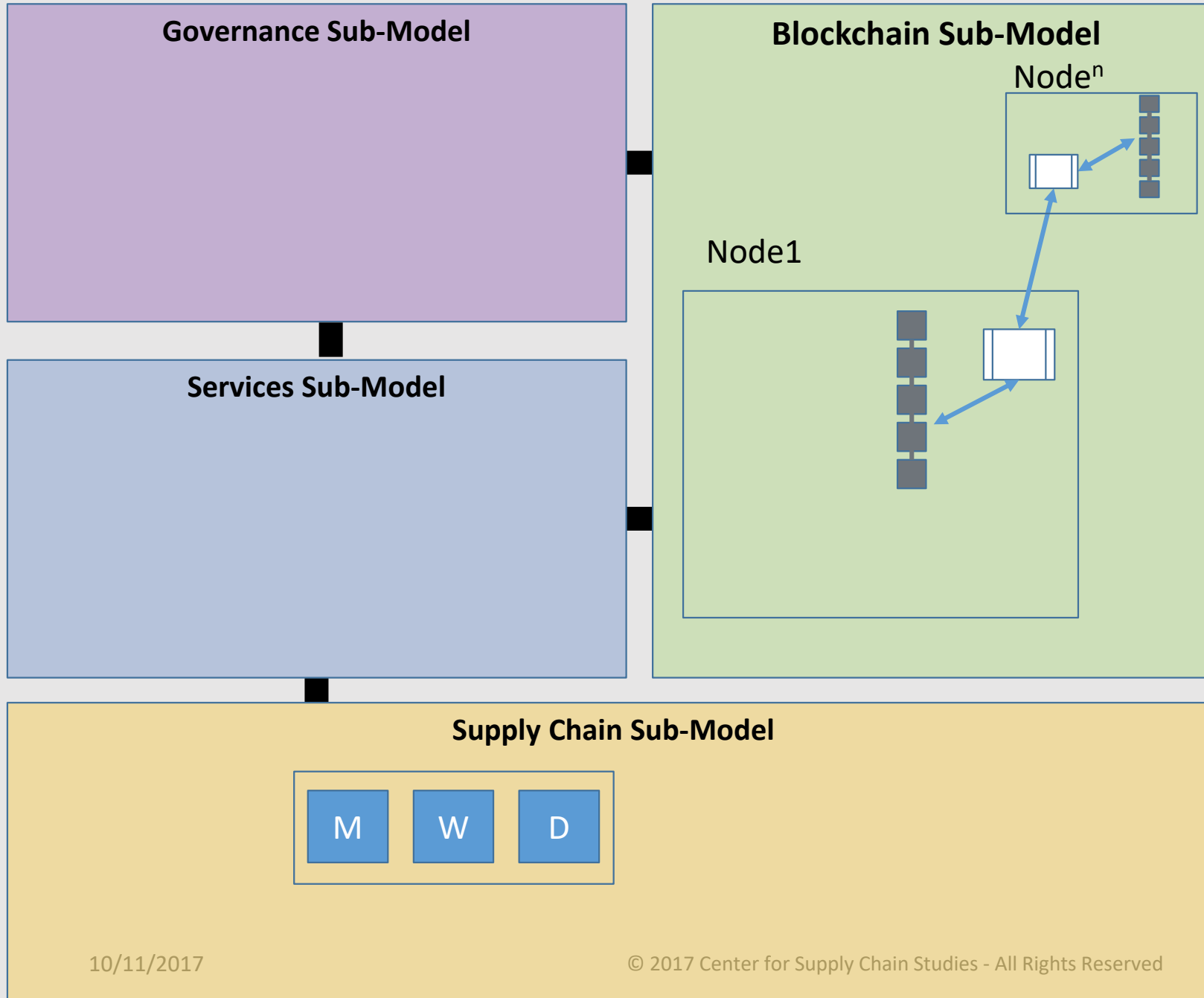
ReferenceModel Design: providing a framework for discussions and exploration



RM001 – Minimal Model: Minimal data in Blockchain.

Phase I – DSCSA & Blockchain ReferenceModels

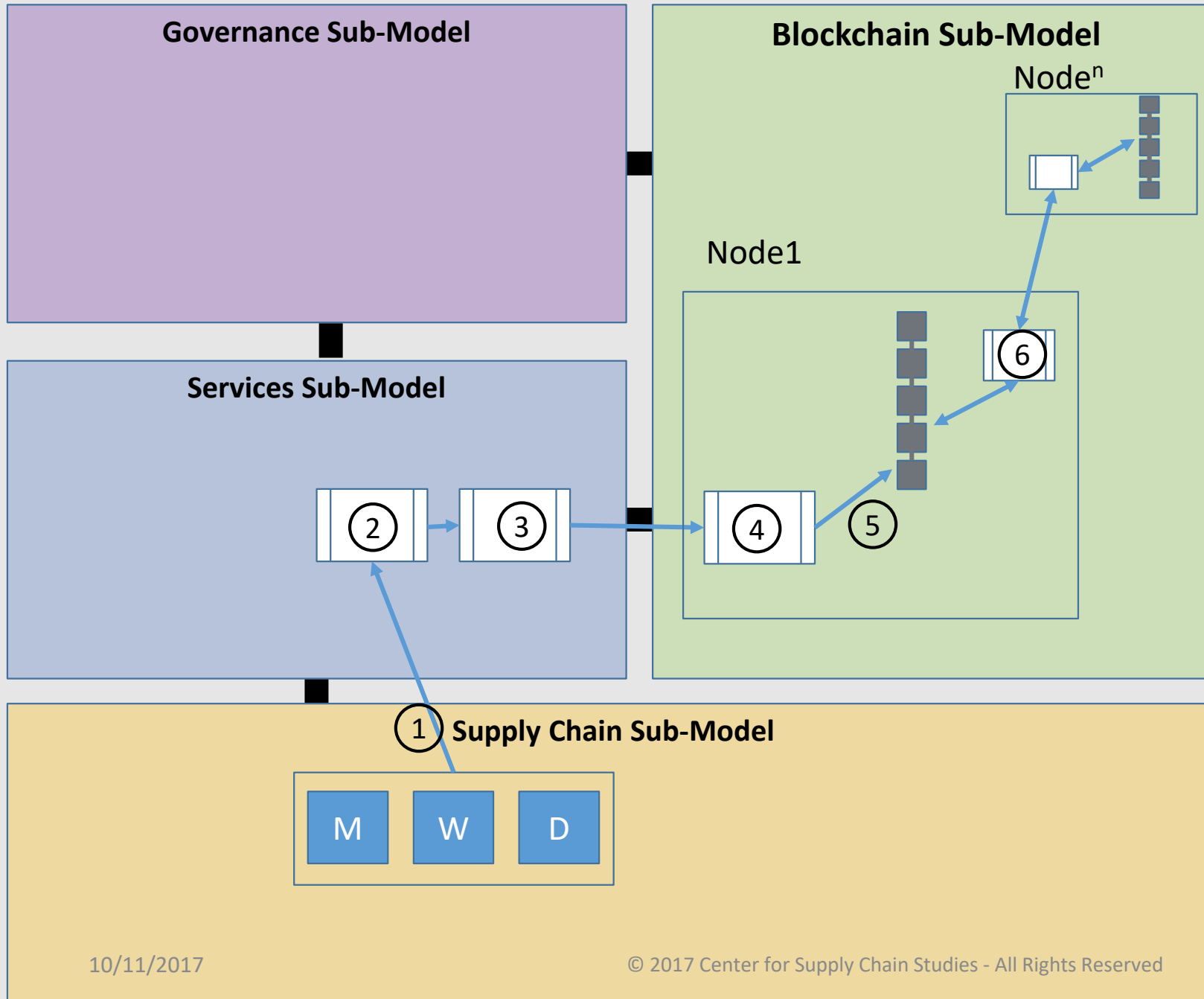
RM001 – Minimal Model: Minimal data in Blockchain. Includes Aggregation Events



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



Contributing Event Data

BC Events:

- Commissioning (Object)
- Packing
- Shipping

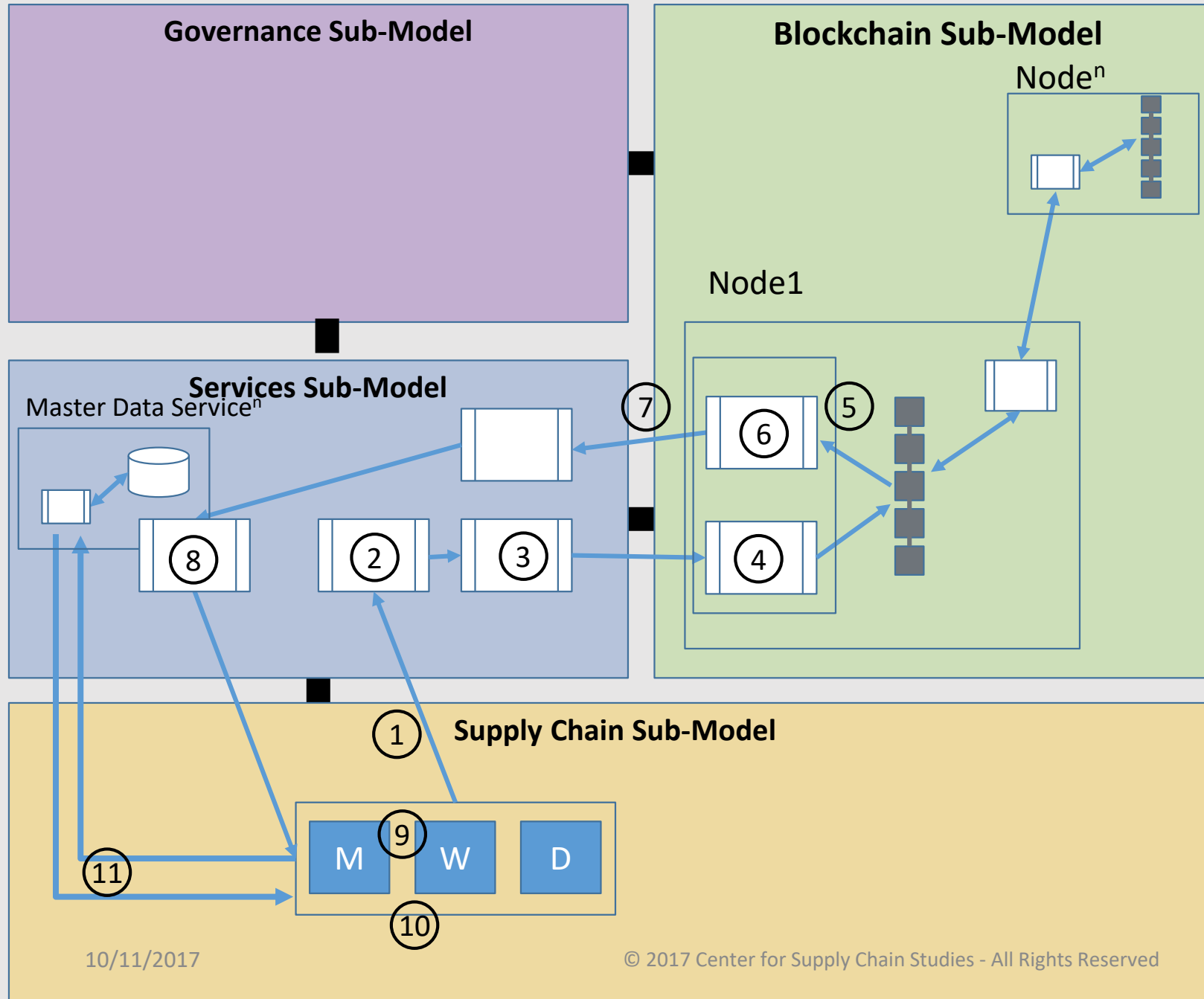
BC Item Hierarchy:

- 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

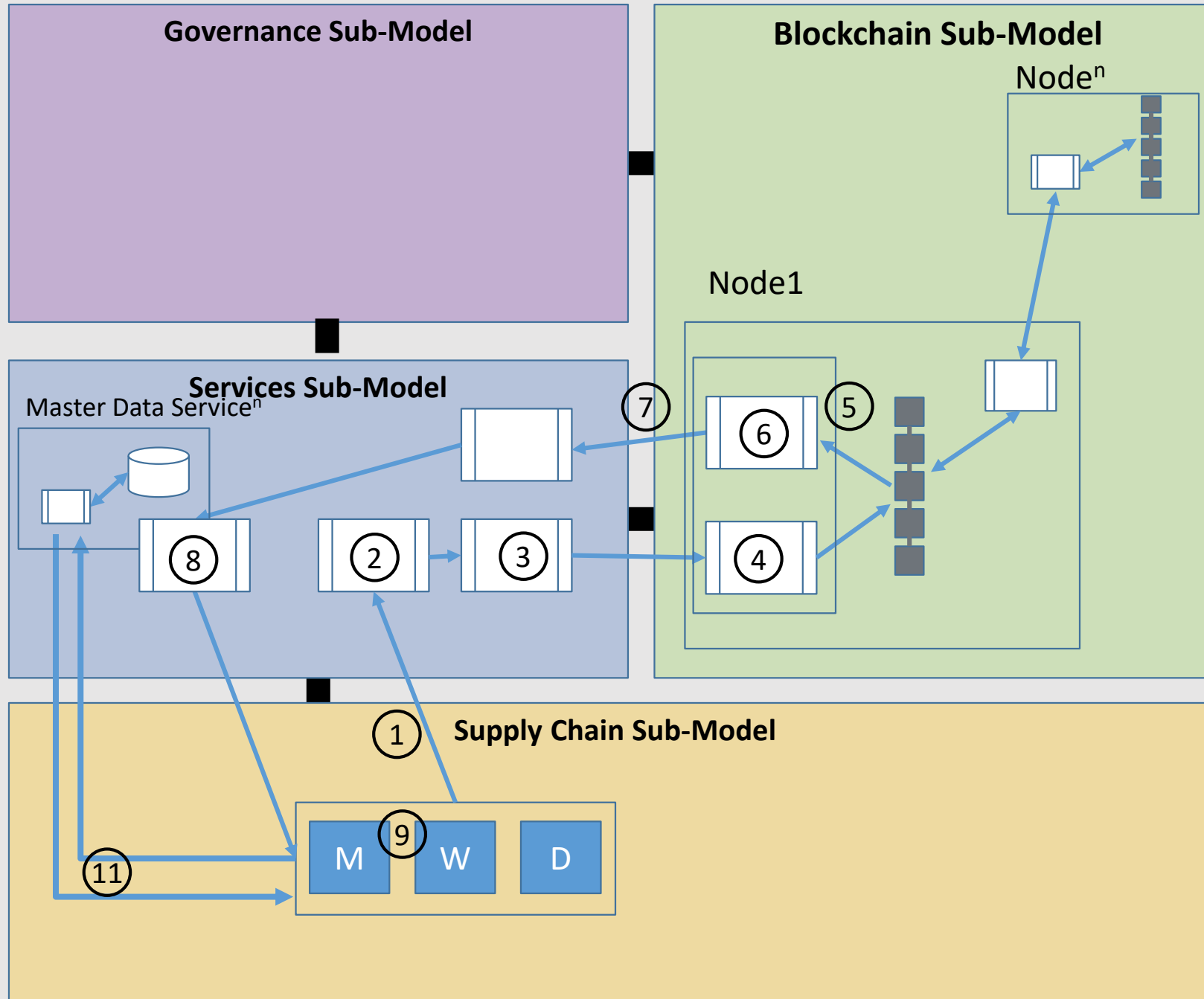
BC Item Hierarchy:

- 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



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).
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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

Where is data stored?

Phase I – Exploratory 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)

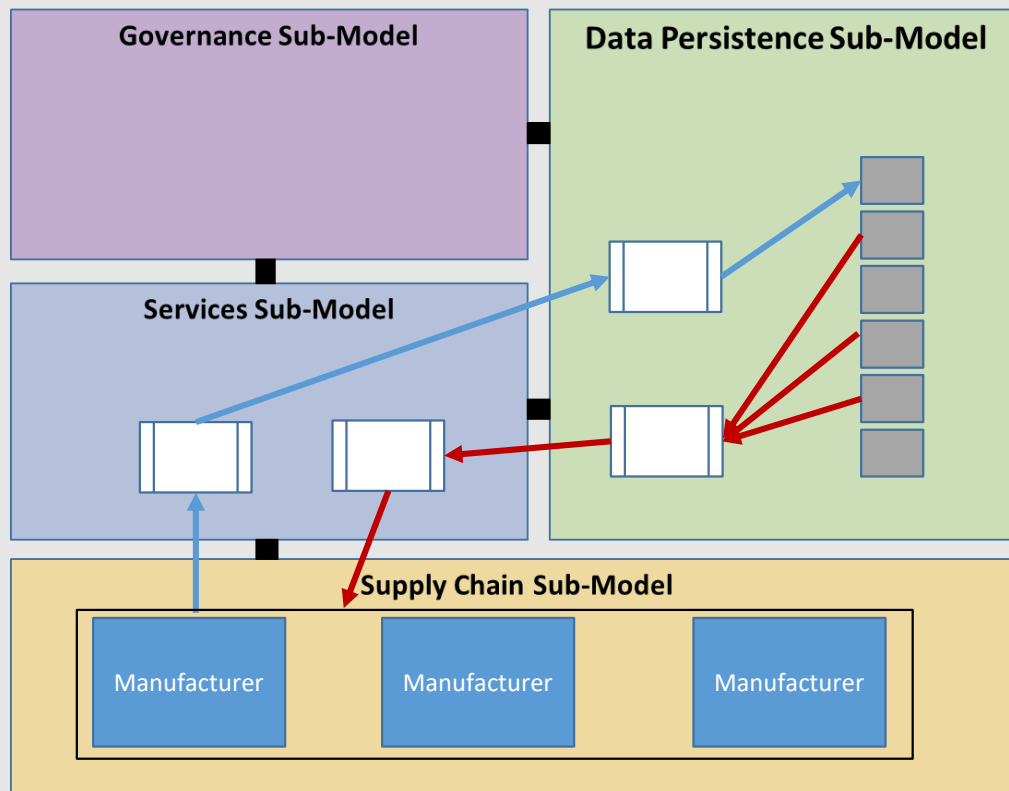
RM008 – Aggregated Model: Blockchain holds chain of Event IDs (Beth's Model)

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

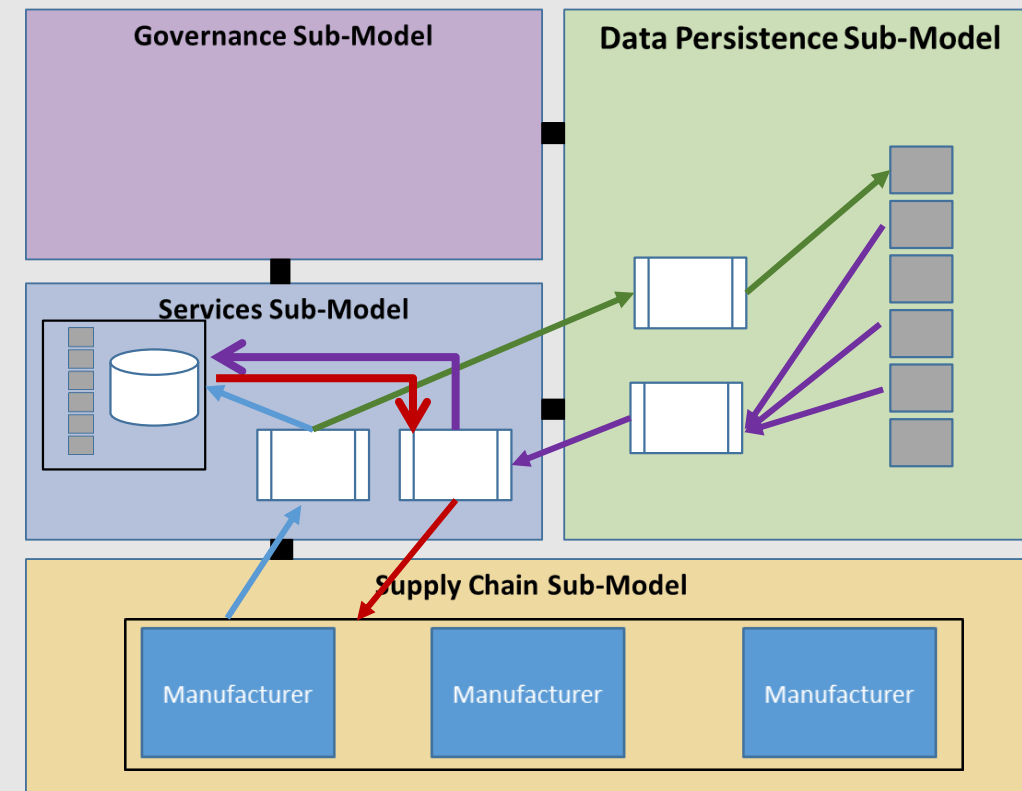
Exploratory ReferenceModels

ReferenceModel Design Variations

RM001 – Minimal Model: Minimal data in Blockchain.



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



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

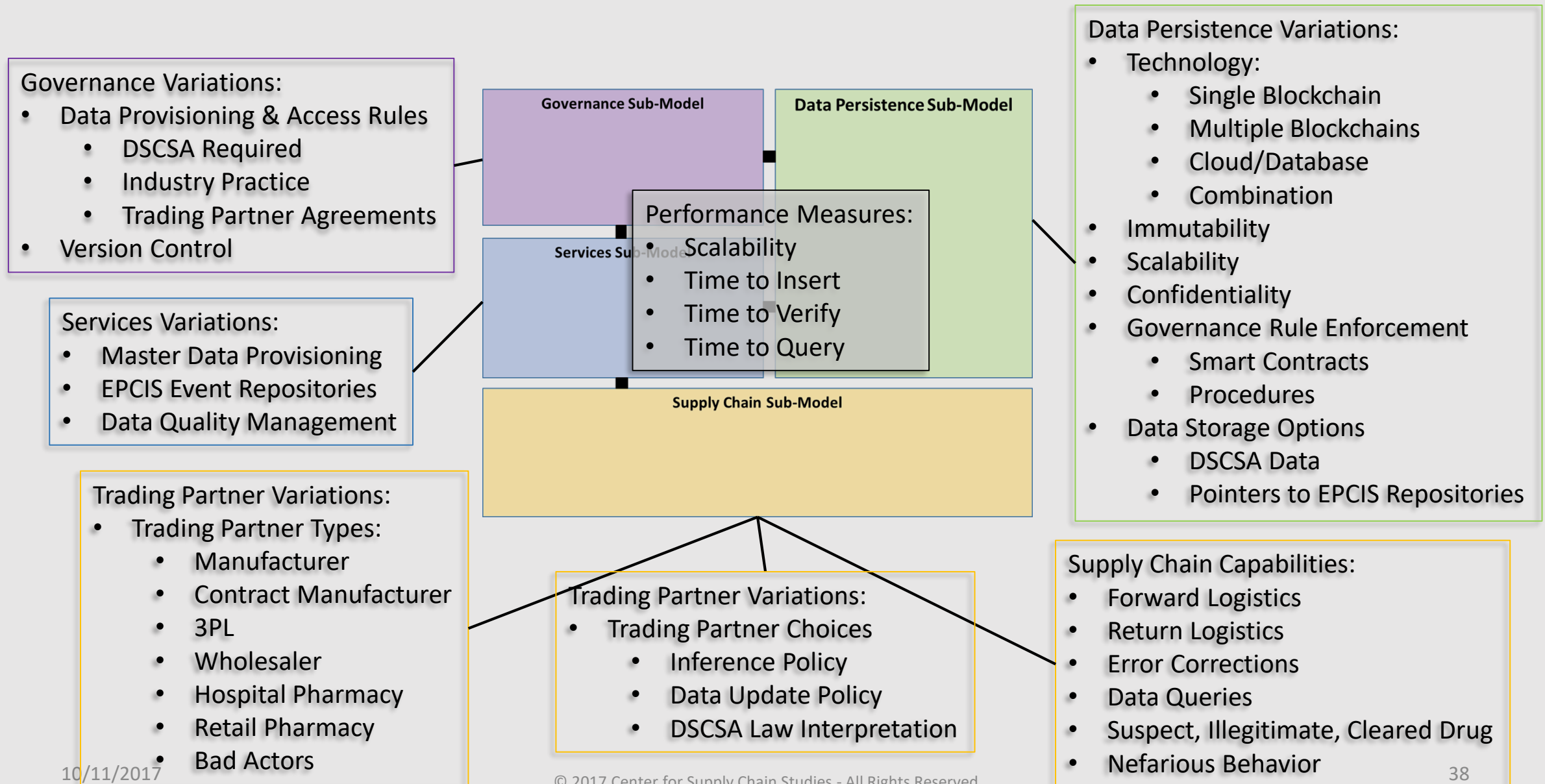
Concept:

- 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

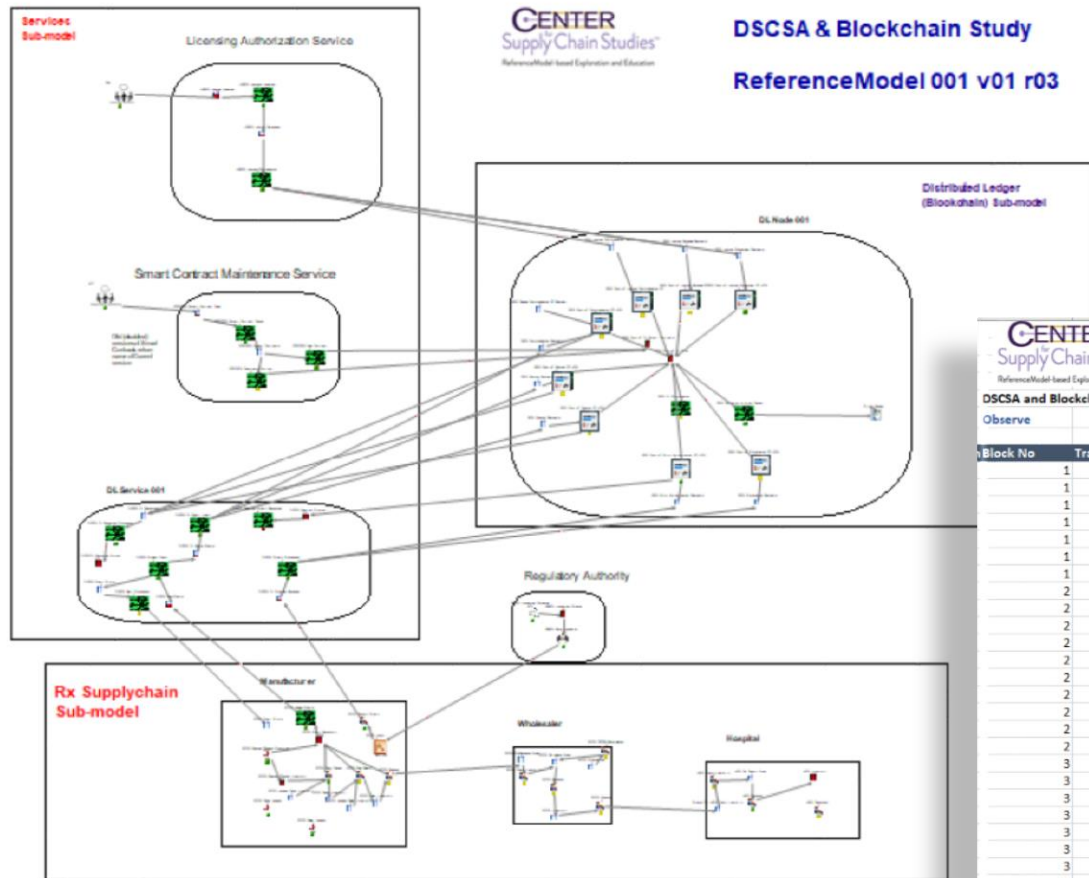
Proof of Concept Options



POC Support

ReferenceModel Documentation and POC Data

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



Block No	Transaction ID	Transfer From ID	Encrypted Transfer From ID	Transfer To ID	Encrypted Transfer	Object ID	Hash of Object ID	Business Step	Day/Time
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1	2 urn:epc:gid:0312444.00001.0	31 b6 e0 23 20 57 53 c2 29 43 a0				urn:epc:gid:0312444.00001.0	7J3fo0Hibub9GoszZt+juNVGBE=	commissioning	10/3/2023 12:00 AM
1	3 urn:epc:gid:0312444.00001.0	3d c0 bc 1b 2c 21 0f fa 4c e8 92				urn:epc:gid:0312444.00001.0	lMISmaE+V3e6XvpeZSifexTWE8=	commissioning	10/3/2023 12:07 AM
1	4 urn:epc:gid:0312444.00001.0	ac 3d e7 cd bd dc 54 2c 5b f6 d2				urn:epc:gid:0312444.00001.0	Rga/Wzk+6LNdKRfWwpRJRtE98Y=	commissioning	10/3/2023 12:07 AM
1	5 urn:epc:gid:0312444.00001.0	9d 9f b5 f3 8c 7e 06 12 ee 96 42				urn:epc:gid:0312444.00001.0	JX4a0v3Di9VRbxHr5ajcX0lpeMA=	commissioning	10/3/2023 12:11 AM
1	6 urn:epc:gid:0312444.00001.0	13 44 e4 17 02 a5 57 f6 1c 7a 35				urn:epc:gid:0312444.00001.0	vCH3ArerOmlckTqSgHwBFJs6uUl=	commissioning	10/3/2023 12:11 AM
1	7 urn:epc:gid:0312444.00001.0	63 18 d0 e7 72 f9 63 06 75 c9 4f				urn:epc:gid:0312444.00001.0	8WFEom1EBIKOG41bTUw5bd7aBb=	commissioning	10/3/2023 12:17 AM
2	8 urn:epc:gid:0312444.00001.0	08 c8 b8 61 19 29 0b 80 e5 a0 c8				urn:epc:gid:0312444.00001.0	Sf4mr6EUn3XaKxWcmz6877QKA=	commissioning	10/3/2023 12:17 AM
2	9 urn:epc:gid:0312444.00001.0	7b fb d6 81 6a 1a 65 60 cc ba d6				urn:epc:gid:0312444.00001.0	8RIZ1+nue21y0aakoKKD1qpv8Yg=	commissioning	10/3/2023 12:23 AM
2	10 urn:epc:gid:0312444.00001.0	a1 71 8d a4 b0 90 3e 45 bd f6 ad				urn:epc:gid:0312444.00001.0	2LleXehDKSVIqAPxW/2hl+qZy/Qg=	commissioning	10/3/2023 12:23 AM
2	11 urn:epc:gid:0312444.00001.0	12 9f ef 88 e3 7e 5c 69 ac 6f a3 74				urn:epc:gid:0312444.00001.0	JMSyPTO4NW1WqS/He6OM63dYcPY	commissioning	10/3/2023 12:28 AM
2	12 urn:epc:gid:0312444.00001.0	fb a9 c2 73 ea 48 71 92 96 fa 82				urn:epc:gid:0312444.00001.0	rfd5MyceDM6lHxKHrG6UJX5NE=	commissioning	10/3/2023 12:28 AM
2	13 urn:epc:gid:0312444.00001.0	73 2b cf 26 62 ca 7c c7 e8 33 ed				urn:epc:gid:0312444.00001.0	xxPPCnRl9c3BAvRdRtLX2Vz7AWC=	commissioning	10/3/2023 12:34 AM
2	14 urn:epc:gid:0312444.00001.0	75 fa e7 5a 64 1b 54 bb f2 6c c2				urn:epc:gid:0312444.00001.0	A9ikC7GeD81WN4c7P+nbcn9WAA=	commissioning	10/3/2023 12:34 AM
2	15 urn:epc:gid:0312444.00001.0	2b d2 c1 59 3a 33 72 b8 14 74 a8				urn:epc:gid:0312444.00001.0	Bue4vzMSDKtf3XZLPyzhf0E8e4=	commissioning	10/3/2023 12:39 AM
2	16 urn:epc:gid:0312444.00001.0	43 04 82 62 52 e5 31 83 ff de 01				urn:epc:gid:0312444.00001.0	u/n2btJP+qvjdXDSvu2PjRdBxA=	commissioning	10/3/2023 12:39 AM
2	17 urn:epc:gid:0312444.00001.0	aa dd 81 29 bb 3c 32 c8 b7 45 6a				urn:epc:gid:0312444.00001.0	Xibsj6A48nv0zVlIPXZcctcZox=	commissioning	10/3/2023 12:45 AM
3	18 urn:epc:gid:0312444.00001.0	47 f5 ca 58 f6 14 79 19 b8 a2 ac				urn:epc:gid:0312444.00001.0	Uulq44vclcpqYAxYcPobGLxDO=	commissioning	10/3/2023 12:45 AM
3	19 urn:epc:gid:0312444.00001.0	4d 0d 8b 43 5c ec 38 a2 ed e9 81		urn:epc:gid:03123:urn:epc:gid:03123		urn:epc:gid:0312444.00001.0	Rga/Wzk+6LNdKRfWwpRJRtE98Y=	shipping	10/3/2023 12:48 AM
3	20 urn:epc:gid:0312444.00001.0	f7 14 93 67 e6 f5 20 86 37 72 71				urn:epc:gid:0312444.00001.0	V6hn7ibfaeUvXG4mwc3G+ZhbW=	commissioning	10/3/2023 12:50 AM
3	21 urn:epc:gid:0312444.00001.0	00 8c f2 f4 11 6d 41 15 56 a3 96				urn:epc:gid:0312444.00001.0	+Astyf6Inqig5OFxNKVYUtlq/4=	commissioning	10/3/2023 12:50 AM
3	22 urn:epc:gid:0312444.00001.0	80 33 aa e9 91 d2 19 08 b6 e9 02				urn:epc:gid:0312444.00001.0	SjMo0lOmImltKuy8s51Z9yy4g=	commissioning	10/3/2023 12:54 AM
3	23 urn:epc:gid:0312444.00001.0	70 10 c8 cd 61 f1 7b 2c 5f 11 20				urn:epc:gid:0312444.00001.0	nxeW05hKDGroBxlyTab2lk7N/c=	commissioning	10/3/2023 12:54 AM
3	24 urn:epc:gid:0312444.00001.0	29 27 c9 87 38 ce 7a 66 e2 30 d3				urn:epc:gid:0312444.00001.0	9xag8R9cAashqN97yOvRvJssQQ=	commissioning	10/3/2023 1:00 AM
3	25 urn:epc:gid:0312444.00001.0	cb d0 b0 4a da 31 03 ab 08 67 37				urn:epc:gid:0312444.00001.0	46ZM9kPsOH56IA3jwKddc+2cgrM=	commissioning	10/3/2023 1:00 AM

Virtual Pilot – managing sensor data

Blockchain for Cold Chain Study

Blockchain for Cold Chain Study

Exploring the use of blockchain to support sensor data sharing

Concept:

- Define or identify a common set of cold chain (temp sensor) data
- Demonstrate the movement, use and trading partner reaction to temp data (and possibly other sensor data)
- Explore whether blockchain technology provides benefits
- Explore different sensor inputs (data loggers, online sensors, binary indicators, etc.) and how they might be incorporated
- Create a simulated environment (ReferenceModels) to test the creation and transfer of temperature data
- Initiate pilots based on the ReferenceModels

What's Next

Study Lifecycle

Idea to Publication



Discussion / Questions

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 Track & Trace



STUDY: DSCSA & Blockchain²

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



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