



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 a 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 of advice satisfactory that questionable topics do not give rise to antitrust problems.
- The Center recognizes the severity of the potential penalties that might be imposed in the event that certain conduct is found to violate the antitrust laws. Should the Center or its cooperative participants be involved in any violation of federal/state antitrust laws, such violation may involve both civil and criminal penalties that may include imprisonment, as well as fines and/or attorney fees.
- This policy statement unequivocally supports the policy of competition served by the antitrust laws. Given this, the Center intends to take all necessary and proper measures to ensure that violations of the antitrust laws do not occur.

Neutral, Non-Profit, 501(c)(6)
Exploration and Education
VirtualPilot™, and ReferenceModel™ Library



[ABOUT](#) [FOLLOW/JOIN A STUDY](#) [STAY CURRENT](#) [TEAM PORTALS](#) [NEWS/EVENTS](#) [TOPICS/A CLOSER LOOK](#) [HEALTHCARE LIBRARY](#) [CONTACT](#)

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.

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 & Blockchain 2

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

The document is titled "Study Charter" and "DSCSA & BLOCKCHAIN VirtualPilot™". It includes a table of contents on the right side with sections like "STUDY BACKGROUND", "The Goal", "Goal of the Study", "Without Data", "The DSCSA in 2013", "2013 Challenges", "Blockchain: Alternate way to establish trust?", "What is Blockchain?", "STUDY LOGISTICS", "Study Duration", "Extending the Study", "Deliverables & Recognition", "Dependencies of Study Team", "Role of the Center", "Healthcare Industry", "Presentation of Findings", "Group Funding Model", and "The Study in the News". It also features contact information for Bob Celeste and Lynette Byrnes, and the Center for Supply Chain Studies logo.

Study Statement of Work

This document is identical to the Study Prospectus but includes a large orange arrow pointing from the Prospectus to this Statement of Work, indicating a transition in the study lifecycle.

Study Charter

This document is identical to the previous two but includes a large orange arrow labeled "Funded" pointing from the Statement of Work to this Charter, and a blue curved arrow labeled "Participant Input" pointing from the Charter back to the Statement of Work, indicating a feedback loop.

Virtual Pilot

Phase I – DSCSA & Blockchain ReferenceModels

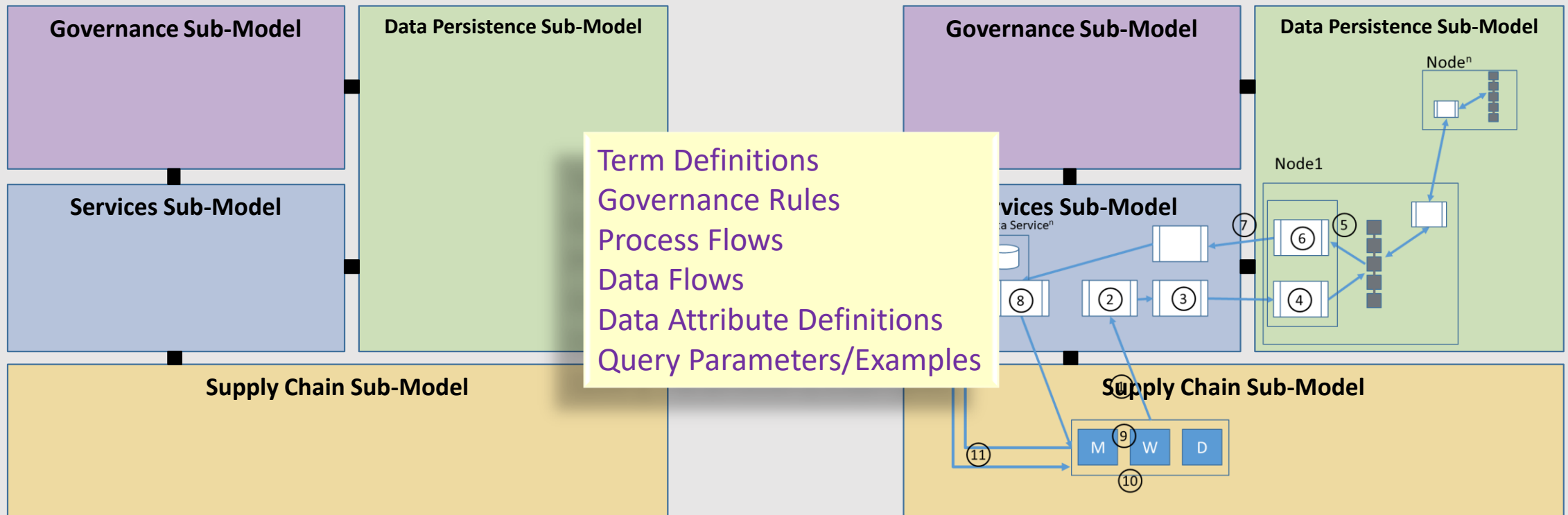
DSCSA – Blockchain Study

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.

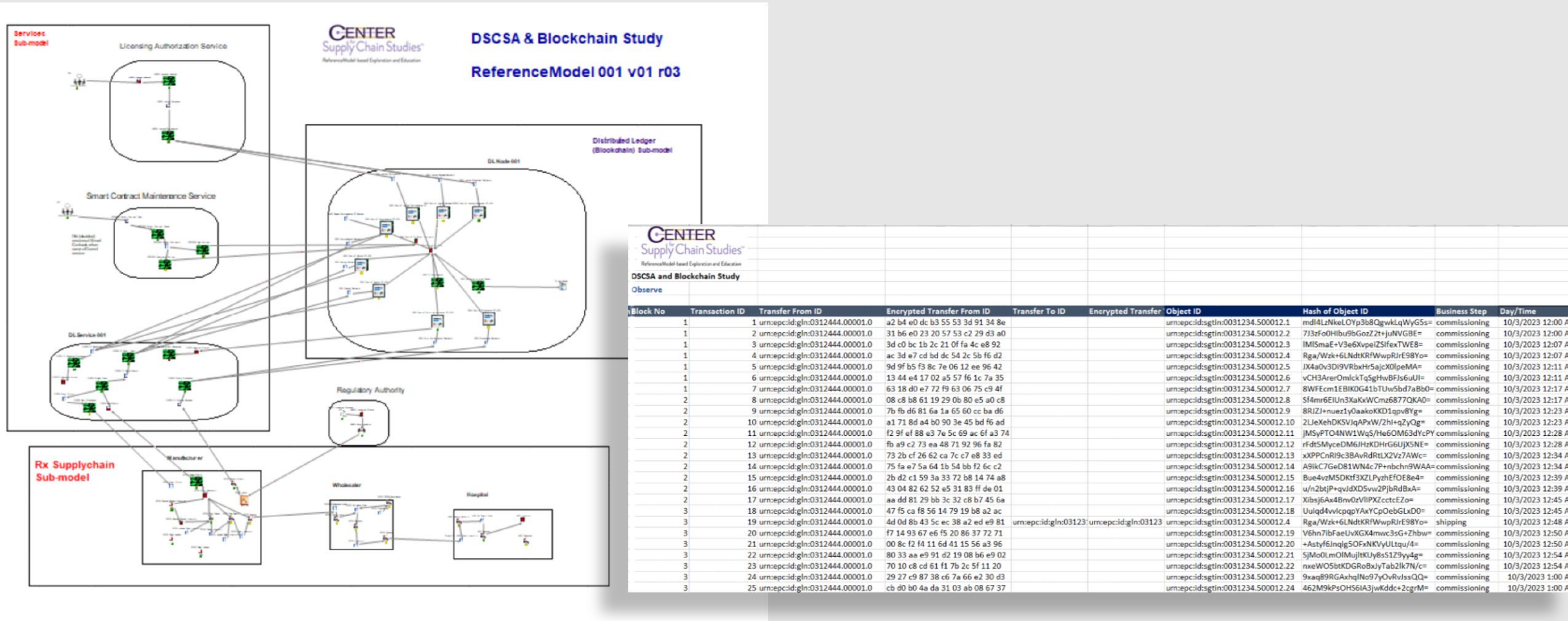
Phase I

Virtual Pilot: DSCSA & Blockchain ReferenceModels



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)

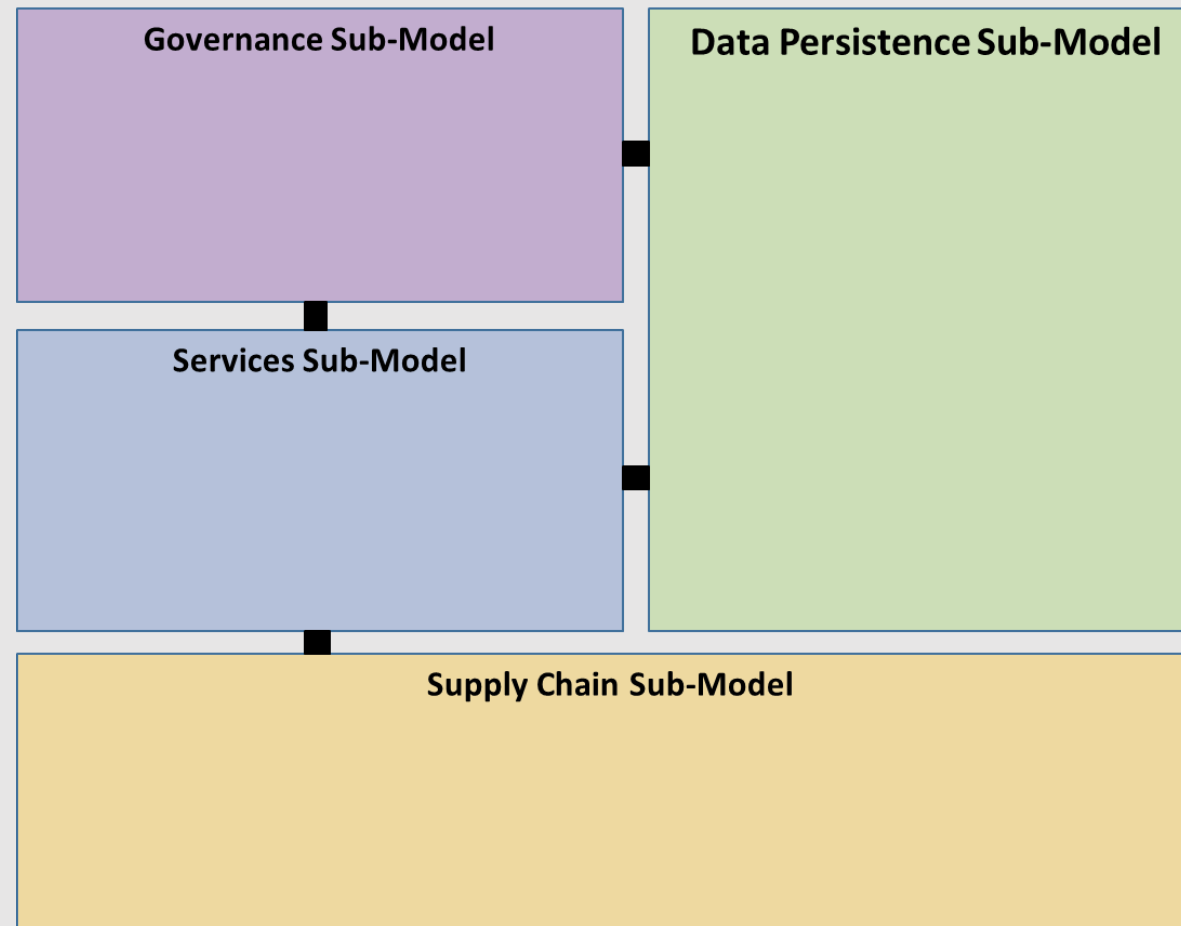
RM008 – Aggregated Model: Blockchain holds chain of Event IDs (Beth's Model)

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

Reference Model Design

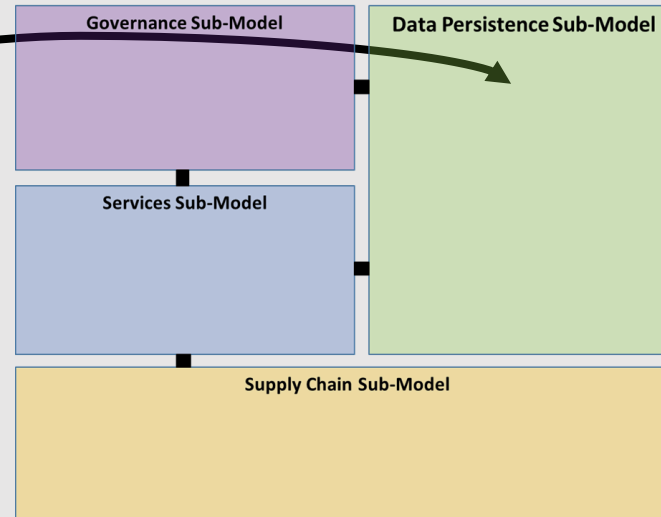
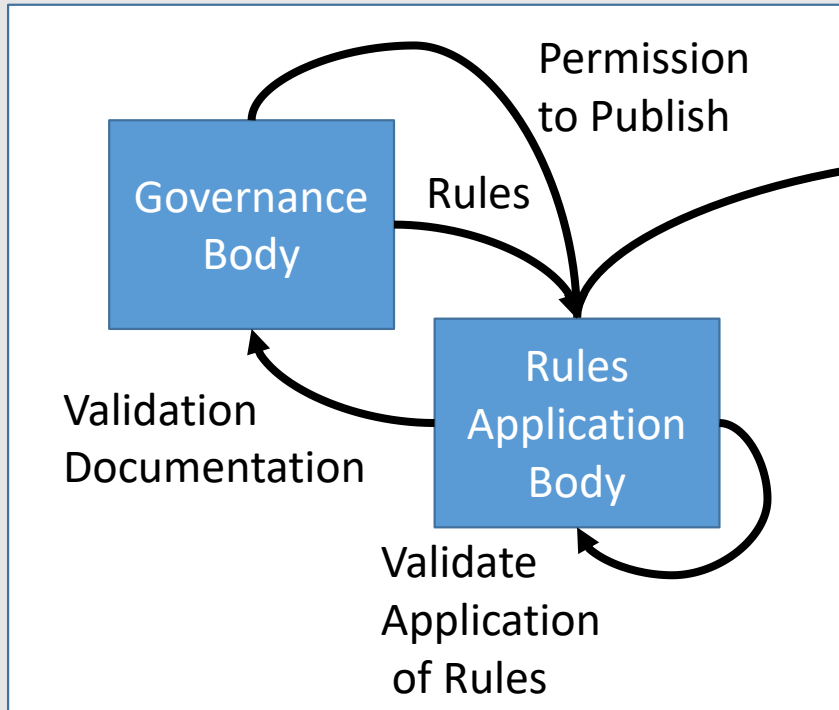
Phase I – DSCSA & Blockchain ReferenceModels

Reference Model Design



ReferenceModel Structure - Governance

ReferenceModel Design: providing a framework for discussions and exploration



Examples of Rules:

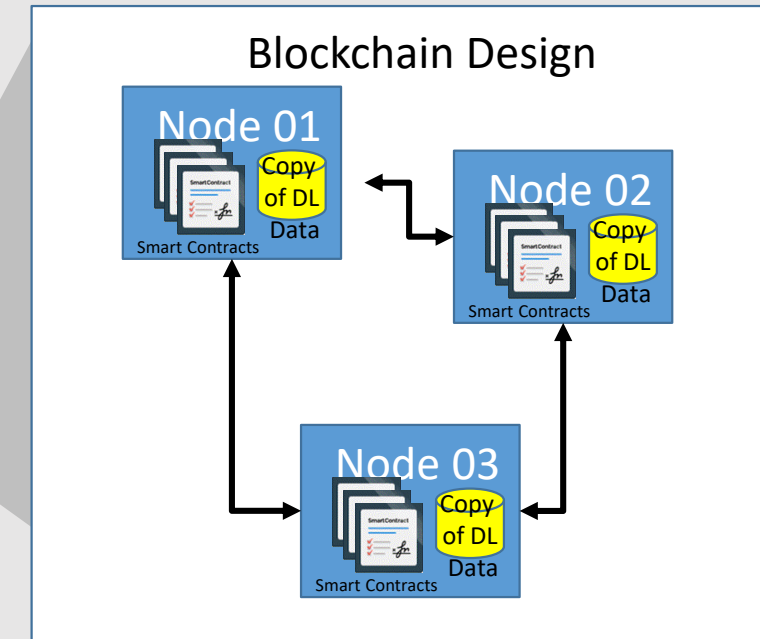
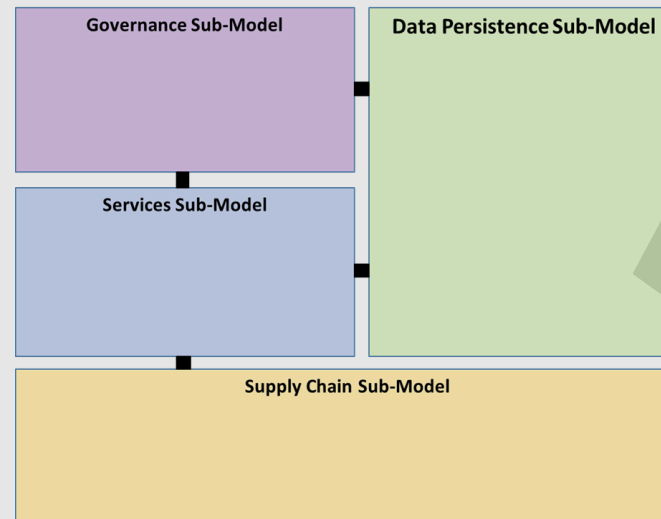
- Properly formatted data (NDC)
- A shipping event cannot be added unless there is a commissioning event.

Rule Types:

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

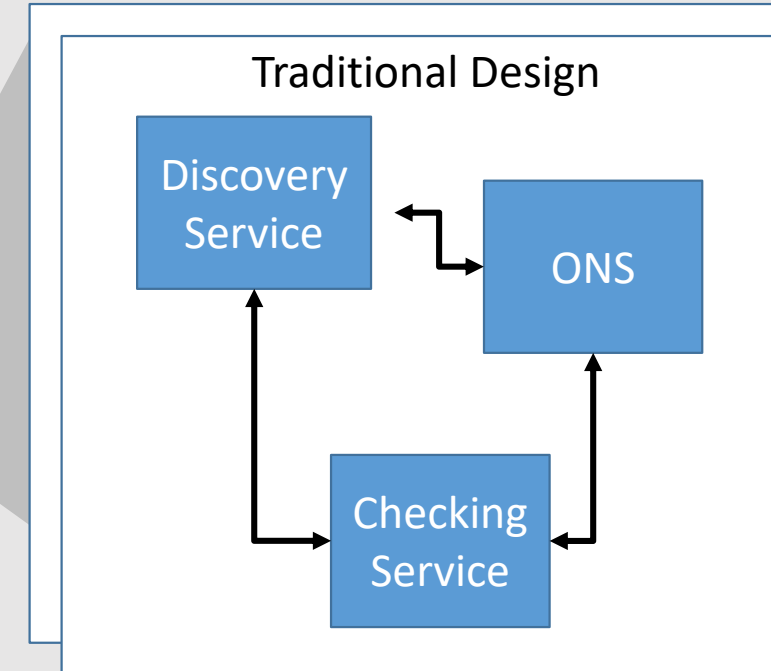
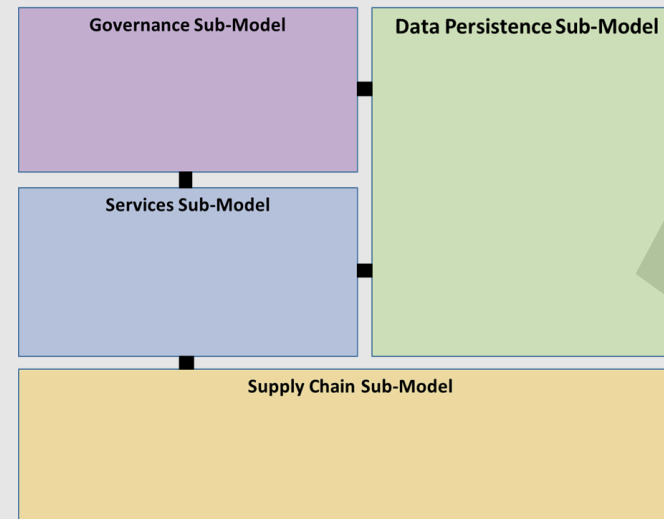
ReferenceModel Structure - Blockchain

ReferenceModel Design: providing a framework for discussions and exploration



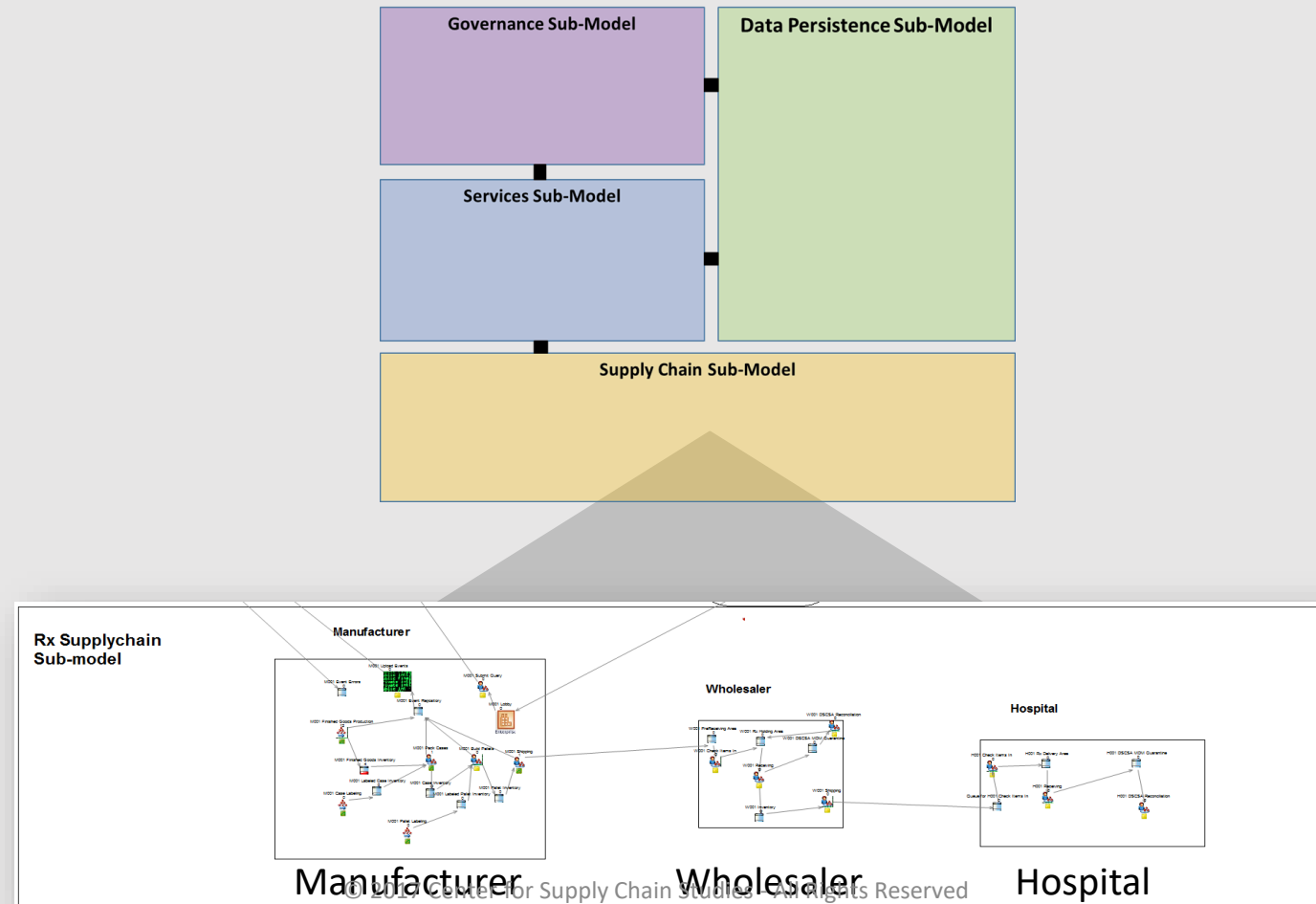
ReferenceModel Structure - Traditional

ReferenceModel Design: providing a framework for discussions and exploration



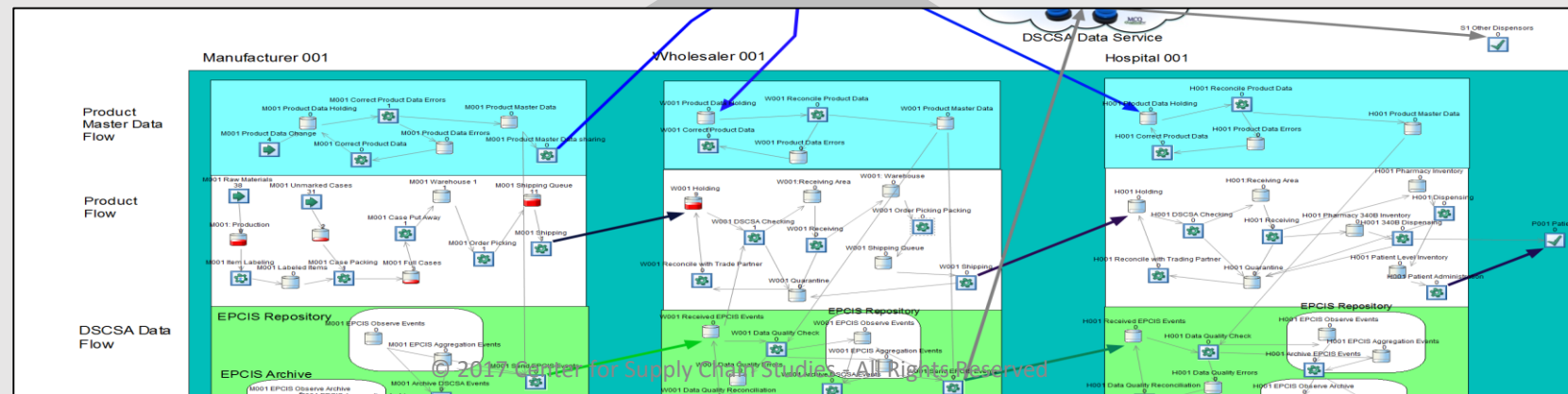
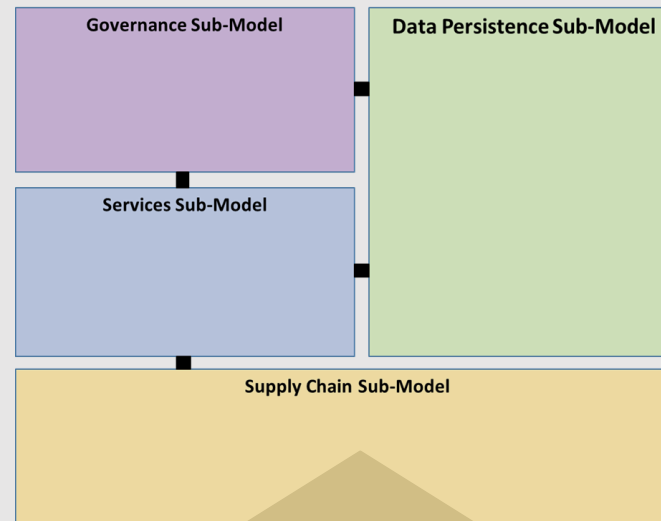
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



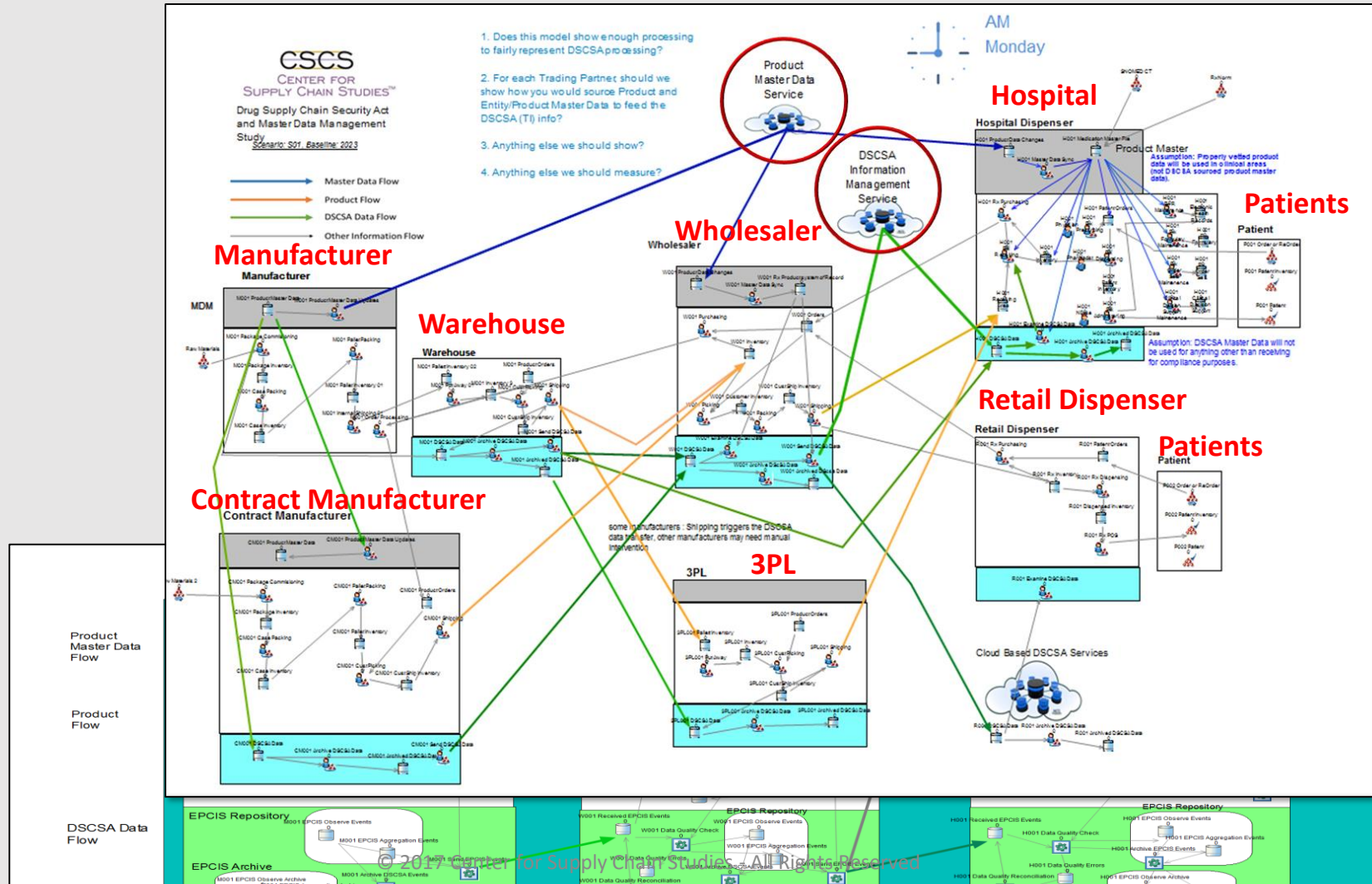
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



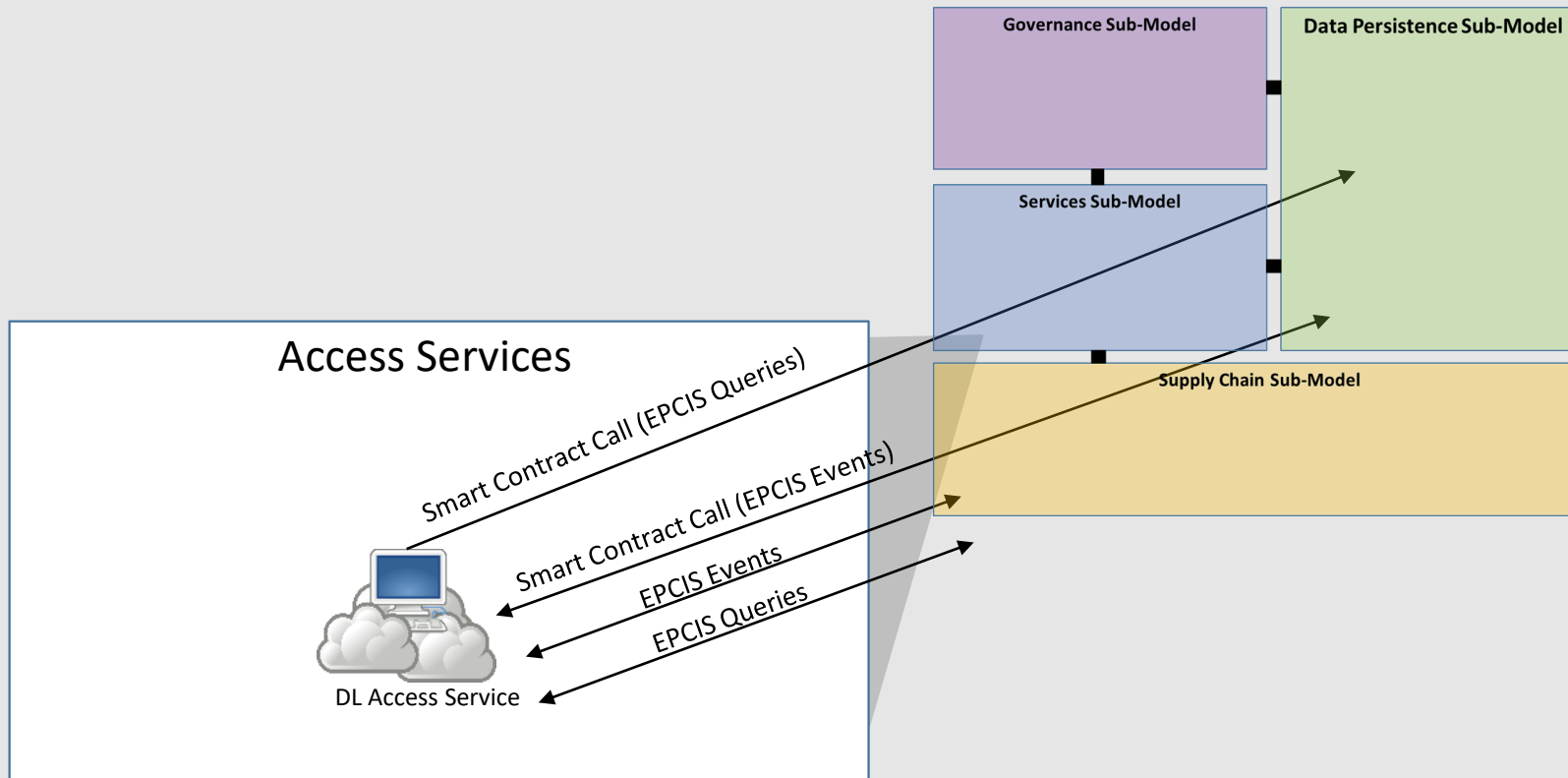
ReferenceModel Structure – Supply Chain

ReferenceModel Design: providing a framework for discussions and exploration



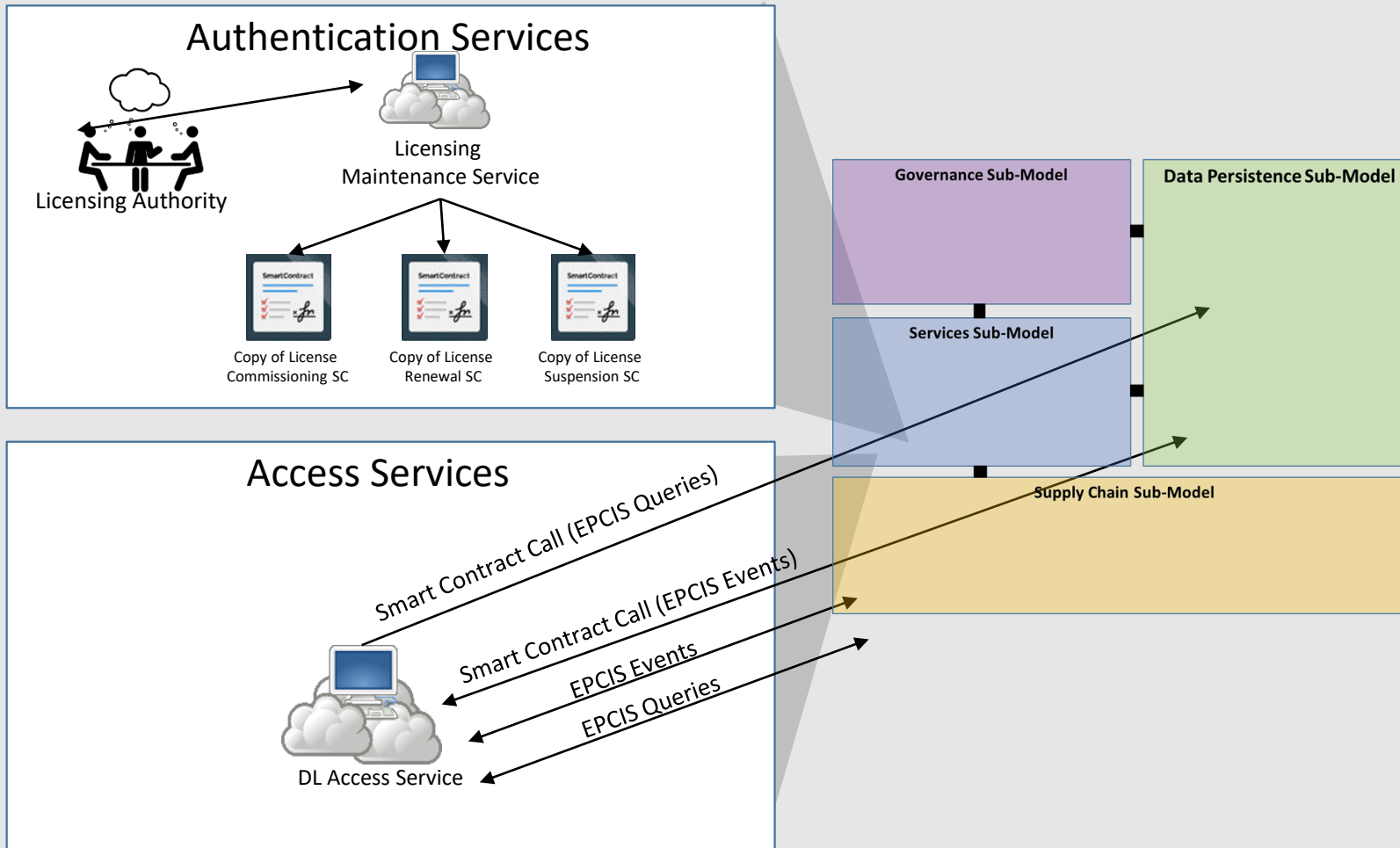
ReferenceModel Structure – Services

ReferenceModel Design: providing a framework for discussions and exploration



ReferenceModel Structure – Services

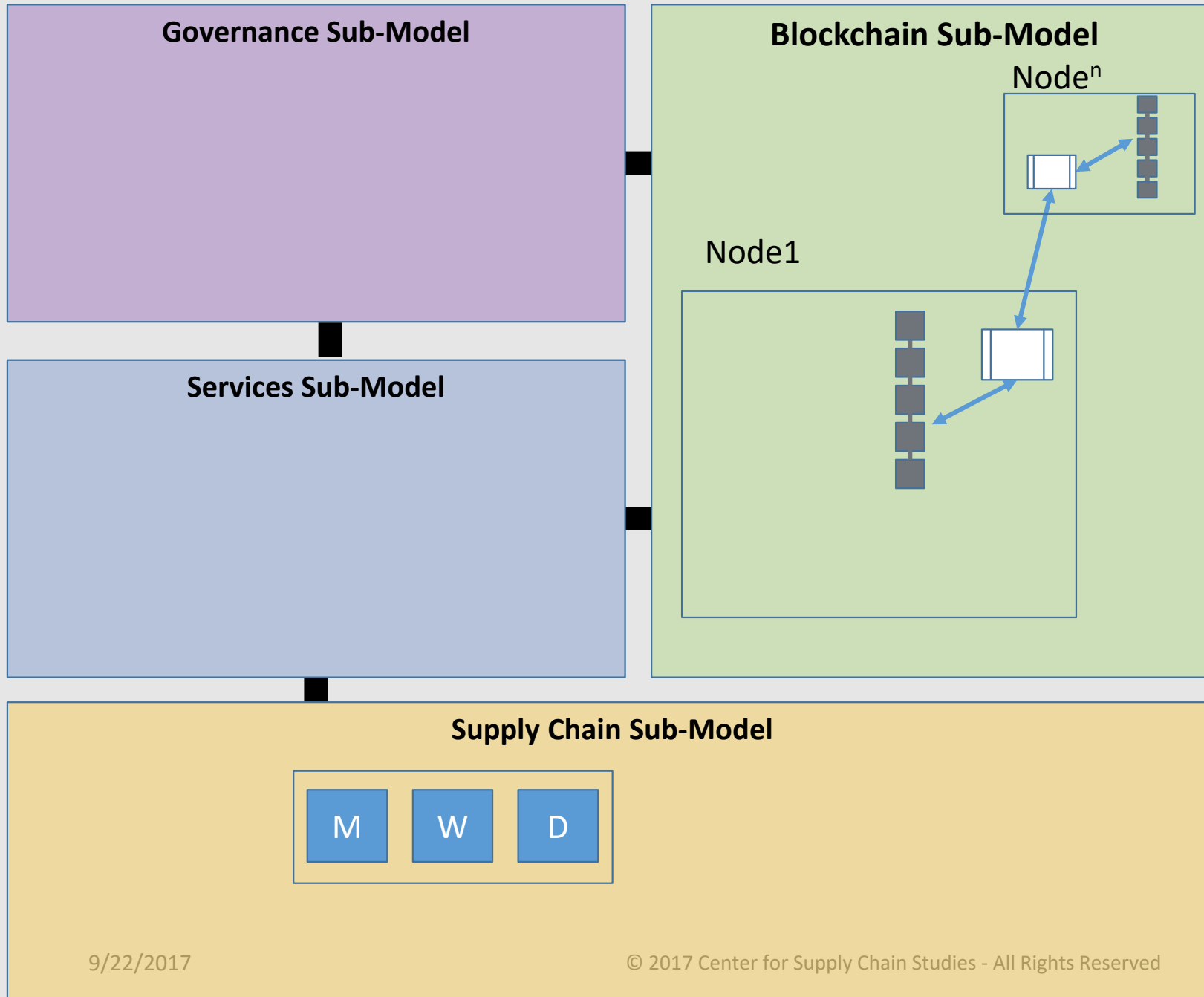
ReferenceModel Design: providing a framework for discussions and exploration



RM001 – Minimal Model: Minimal data in Blockchain.

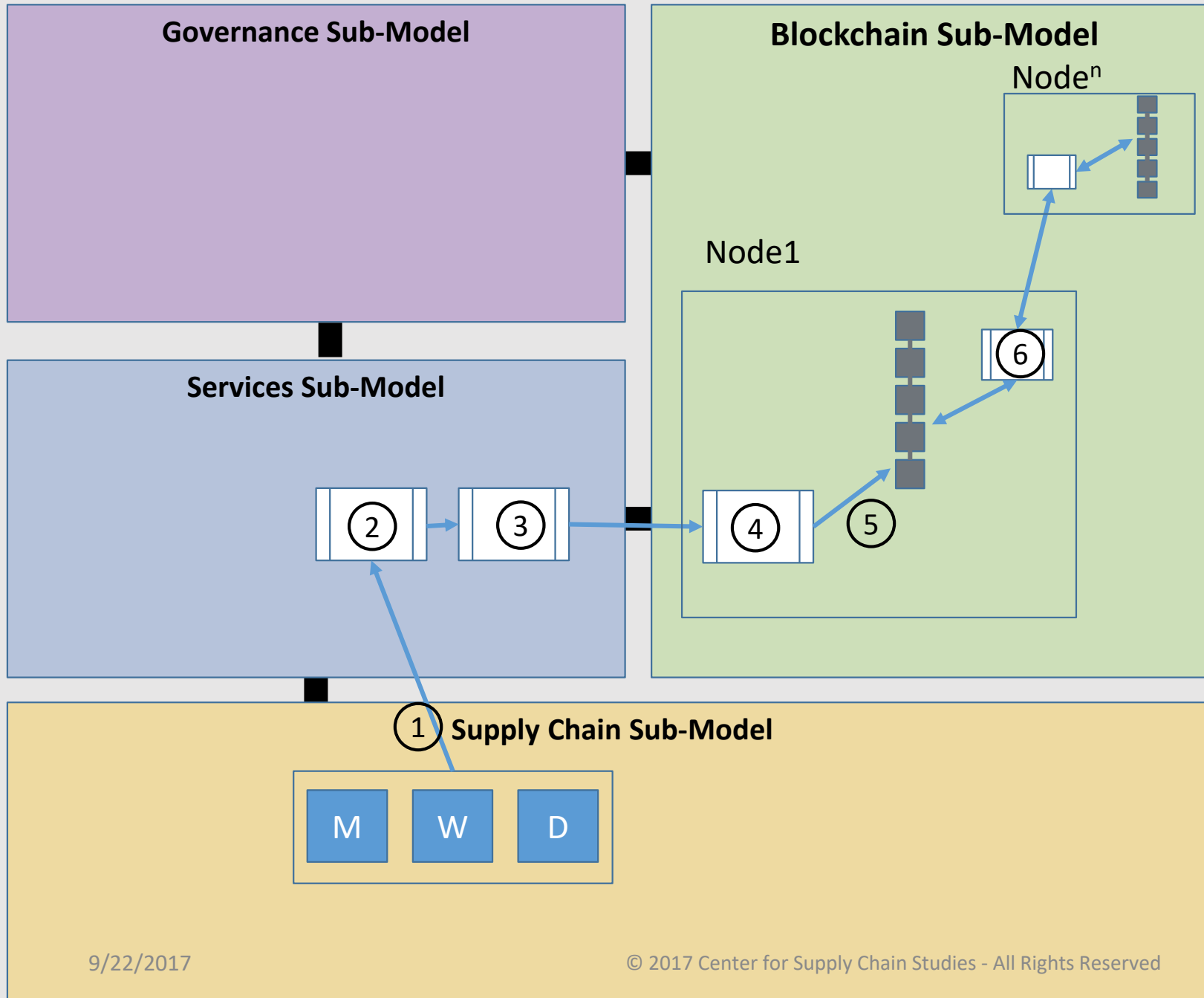
Phase I – DSCSA & Blockchain ReferenceModels

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



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



Contributing Event Data

BC Events:

- Commissioning (Object)
- Packing
- Shipping

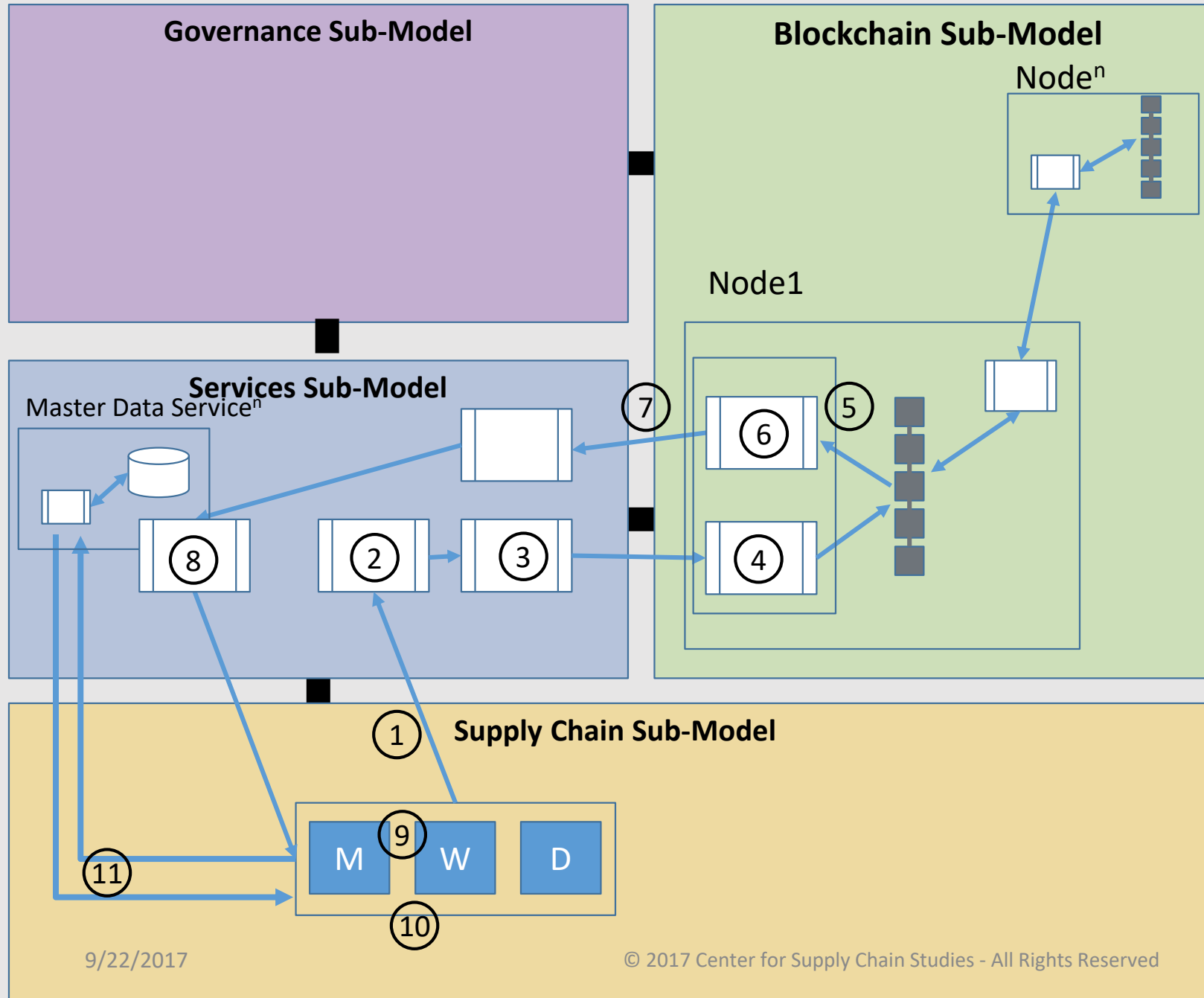
BC Item Hierarchy:

- 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

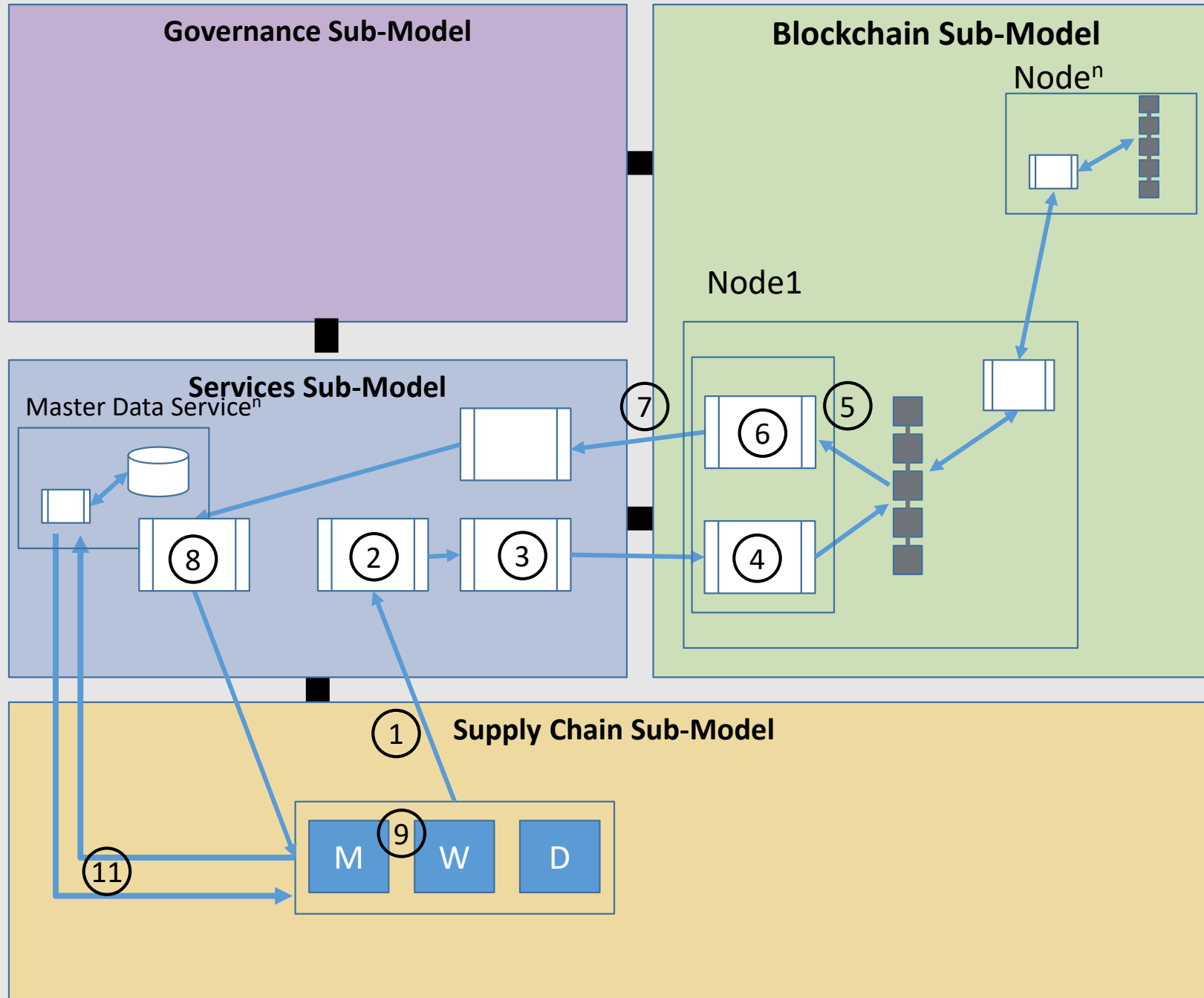
BC Item Hierarchy:

- 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).
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

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

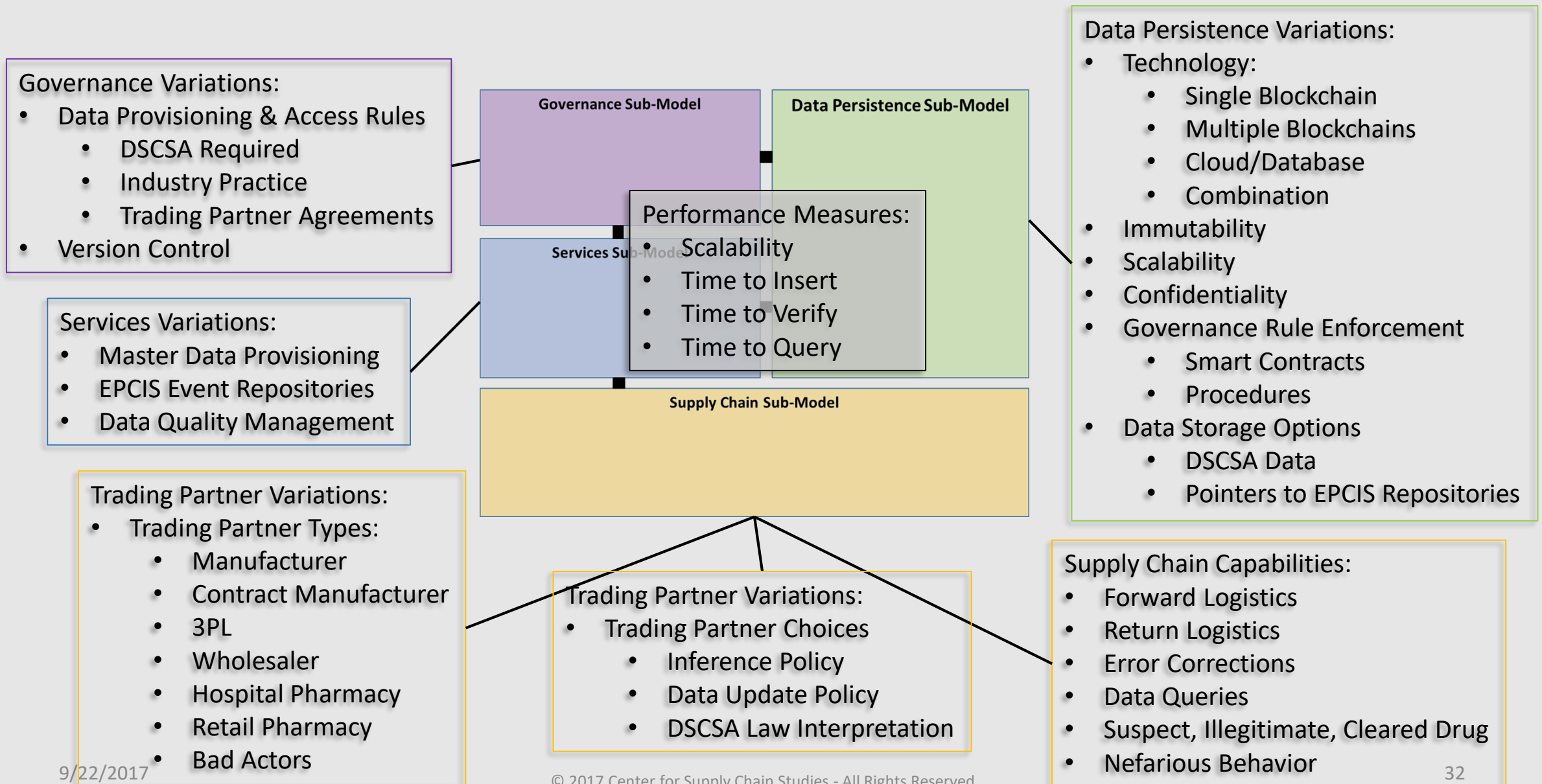
Concept:

- 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

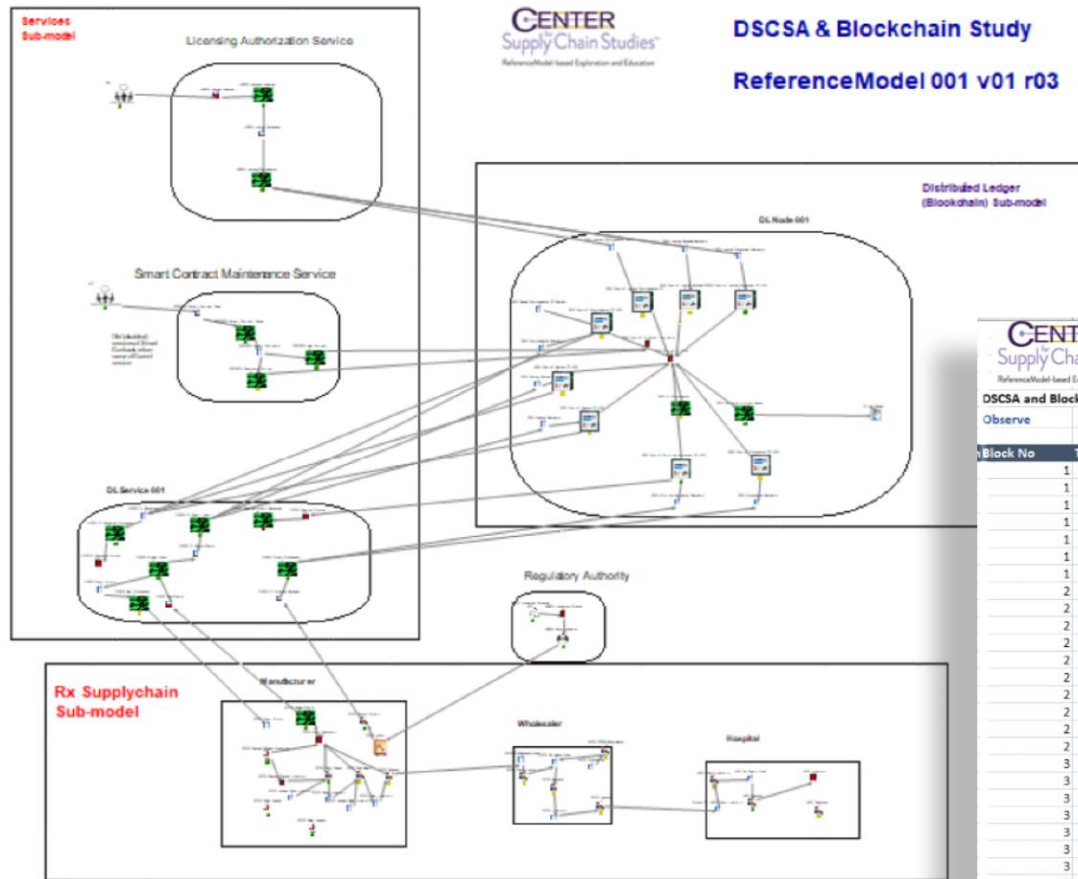
Proof of Concept Options



POC Support

ReferenceModel Documentation and POC Data

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



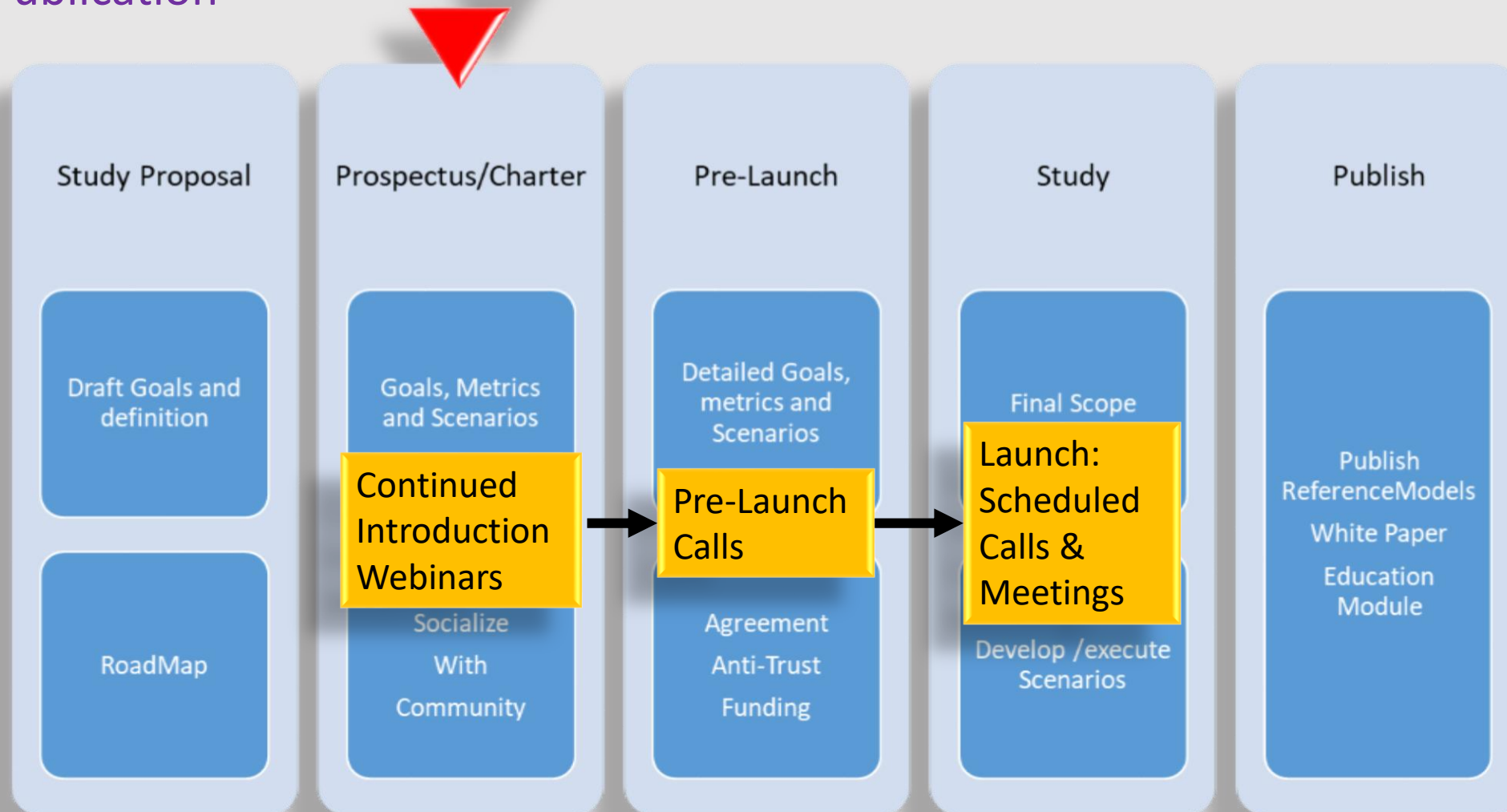
CENTER Supply Chain Studies
ReferenceModel based Exploration and Education
DSCSA and Blockchain Study
Observe

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
1	1	urn:epc:id:gl:0312444.00001.0	a2 b4 e0 dc b3 55 53 3d 91 34 8e			urn:epc:id:sgtin:0031234.500012.1	md14LzNkeLOyp3b8QgwkLqWyg5s=	commissioning	10/3/2023 12:00 AM
1	2	urn:epc:id:gl:0312444.00001.0	31 b6 e0 23 20 57 53 c2 29 d3 a0			urn:epc:id:sgtin:0031234.500012.2	7J3fodHlbu9bGozZt+juNVGBE=	commissioning	10/3/2023 12:00 AM
1	3	urn:epc:id:gl:0312444.00001.0	3d c0 bc 1b 2c 21 0f fa 4c e8 92			urn:epc:id:sgtin:0031234.500012.3	lMISmaE+V3e6XvpeiZSifexTWfE8=	commissioning	10/3/2023 12:07 AM
1	4	urn:epc:id:gl:0312444.00001.0	ac 3d e7 cd bd dc 54 2c 5b f6 d2			urn:epc:id:sgtin:0031234.500012.4	Rga/Wzk+6LNdtKRfWwpRJRtE98Yc=	commissioning	10/3/2023 12:07 AM
1	5	urn:epc:id:gl:0312444.00001.0	9d 9f b5 f3 8c 7e 06 12 ee 96 42			urn:epc:id:sgtin:0031234.500012.5	JX4a0v3Di9VRbxHr5ajcX0lpeMA=	commissioning	10/3/2023 12:11 AM
1	6	urn:epc:id:gl:0312444.00001.0	13 44 e4 17 02 a5 57 f6 1c 7a 35			urn:epc:id:sgtin:0031234.500012.6	vCH3ArerOmckTqSgHwBFj6uUl=	commissioning	10/3/2023 12:11 AM
1	7	urn:epc:id:gl:0312444.00001.0	63 18 d0 e7 72 f9 63 06 75 c9 4f			urn:epc:id:sgtin:0031234.500012.7	8WFEm1EBIKOG41bTUw5bd7aBb=	commissioning	10/3/2023 12:17 AM
2	8	urn:epc:id:gl:0312444.00001.0	08 c8 b8 61 19 29 0b 80 e5 a0 c8			urn:epc:id:sgtin:0031234.500012.8	Sf4mr6EUn3XakKwCmz6877QKA0=	commissioning	10/3/2023 12:17 AM
2	9	urn:epc:id:gl:0312444.00001.0	7b fb d6 81 6a 1a 65 60 cc ba d6			urn:epc:id:sgtin:0031234.500012.9	8RIZI+nue21y0aakoKKD1qpv8Yg=	commissioning	10/3/2023 12:23 AM
2	10	urn:epc:id:gl:0312444.00001.0	a1 71 8d a4 b0 90 3e 45 bd f6 ad			urn:epc:id:sgtin:0031234.500012.10	2LlXehDKSVlqApXW/2h1+qZyQg=	commissioning	10/3/2023 12:23 AM
2	11	urn:epc:id:gl:0312444.00001.0	f2 9f ef 88 e3 7e 5c 69 ac 6f a3 74			urn:epc:id:sgtin:0031234.500012.11	jMSyPTOANW1WqS/He6OM63dYcPY	commissioning	10/3/2023 12:28 AM
2	12	urn:epc:id:gl:0312444.00001.0	fb a9 c2 73 ea 48 71 92 96 fa 82			urn:epc:id:sgtin:0031234.500012.12	rfd5MycDm6JHxKHrG6UJX5NE=	commissioning	10/3/2023 12:28 AM
2	13	urn:epc:id:gl:0312444.00001.0	73 2b cf 26 62 ca 7c c7 e8 33 ed			urn:epc:id:sgtin:0031234.500012.13	xxPPCnRl9c3BAvRdRtLX2Vz7AWc=	commissioning	10/3/2023 12:34 AM
2	14	urn:epc:id:gl:0312444.00001.0	75 fa e7 5a 64 1b 54 bb f2 6c c2			urn:epc:id:sgtin:0031234.500012.14	A9rkC7GeD81WN4c7P+nbchn9WAA=	commissioning	10/3/2023 12:34 AM
2	15	urn:epc:id:gl:0312444.00001.0	2b d2 c1 59 3a 33 72 b8 14 7a a8			urn:epc:id:sgtin:0031234.500012.15	Bue4vzMSDKtf3XZLPyzhEFOE8e4=	commissioning	10/3/2023 12:39 AM
2	16	urn:epc:id:gl:0312444.00001.0	43 04 82 62 52 e5 31 83 ff de 01			urn:epc:id:sgtin:0031234.500012.16	u/n2btJP+qvjdXD5vvZPjbrdBxA=	commissioning	10/3/2023 12:39 AM
2	17	urn:epc:id:gl:0312444.00001.0	aa dd 81 29 bb 3c 32 c8 b7 45 6a			urn:epc:id:sgtin:0031234.500012.17	Xlbtj64v48nv0zVlIPXZcctcEz=	commissioning	10/3/2023 12:45 AM
3	18	urn:epc:id:gl:0312444.00001.0	47 f5 ca f8 56 14 79 19 b8 a2 ac			urn:epc:id:sgtin:0031234.500012.18	Uulq4vvcppqYAvYcPoebGLxDO=	commissioning	10/3/2023 12:45 AM
3	19	urn:epc:id:gl:0312444.00001.0	4d 0d 8b 43 5c ec 38 a2 ed e9 81	urn:epc:id:gl:03123:urn:epc:id:gl:03123	urn:epc:id:gl:03123:urn:epc:id:gl:03123	urn:epc:id:sgtin:0031234.500012.19	Rga/Wzk+6LNdtKRfWwpRJRtE98Yc=	shipping	10/3/2023 12:48 AM
3	20	urn:epc:id:gl:0312444.00001.0	f7 14 93 67 e6 f5 20 86 37 72 71			urn:epc:id:sgtin:0031234.500012.20	V6hn7ibfaeUvXG4mwc3Sg+Zhbv=	commissioning	10/3/2023 12:50 AM
3	21	urn:epc:id:gl:0312444.00001.0	00 8c f2 f4 11 6d 41 15 56 a3 96			urn:epc:id:sgtin:0031234.500012.21	+Asyf6Inqj5OFxNKVvYUlltu/4=	commissioning	10/3/2023 12:50 AM
3	22	urn:epc:id:gl:0312444.00001.0	80 33 aa e9 91 d2 19 08 b6 e9 02			urn:epc:id:sgtin:0031234.500012.22	SjM0tOm0MjltKuY8s51Z9yy4g=	commissioning	10/3/2023 12:54 AM
3	23	urn:epc:id:gl:0312444.00001.0	70 10 c8 cd 61 f7 7b 2c 5f 11 20			urn:epc:id:sgtin:0031234.500012.23	nxeW05btKDGroBxlyTab2k7N/c=	commissioning	10/3/2023 12:54 AM
3	24	urn:epc:id:gl:0312444.00001.0	29 27 c9 87 38 c6 7a 66 e2 30 d3			urn:epc:id:sgtin:0031234.500012.24	9xaq89GAsahqN97yOvRlssQlQ=	commissioning	10/3/2023 1:00 AM
3	25	urn:epc:id:gl:0312444.00001.0	cb d0 b0 4a da 31 03 ab 08 67 37			urn:epc:id:sgtin:0031234.500012.25	46ZM9kPsOHS6IA3jwKddc+2cgrM=	commissioning	10/3/2023 1:00 AM

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 & Blockchain 2

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

Contact Information

125 North Lincoln Avenue
Suite 200
Newtown, PA 18940 USA

Bob Celeste

T: +1 609.947.2720

E: rceleste@C4SCS.org

www.C4SCS.org

Connect with :  



CENTER
Supply for Chain Studies™
ReferenceModel-based Exploration and Education

[ABOUT](#) [FOLLOW/JOIN A STUDY](#) [STAY CURRENT](#) [TEAM PORTALS](#) [NEWS/EVENTS](#) [TOPICS/A CLOSER LOOK](#) [HEALTHCARE LIBRARY](#) [CONTACT](#)

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.

The Center acknowledges SIMUL8 Corporation
Provider of Study Simulation Software

SIMUL8

www.simul8.com