



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
VirtualPilot™, and ReferenceModel™ Library



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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.

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.

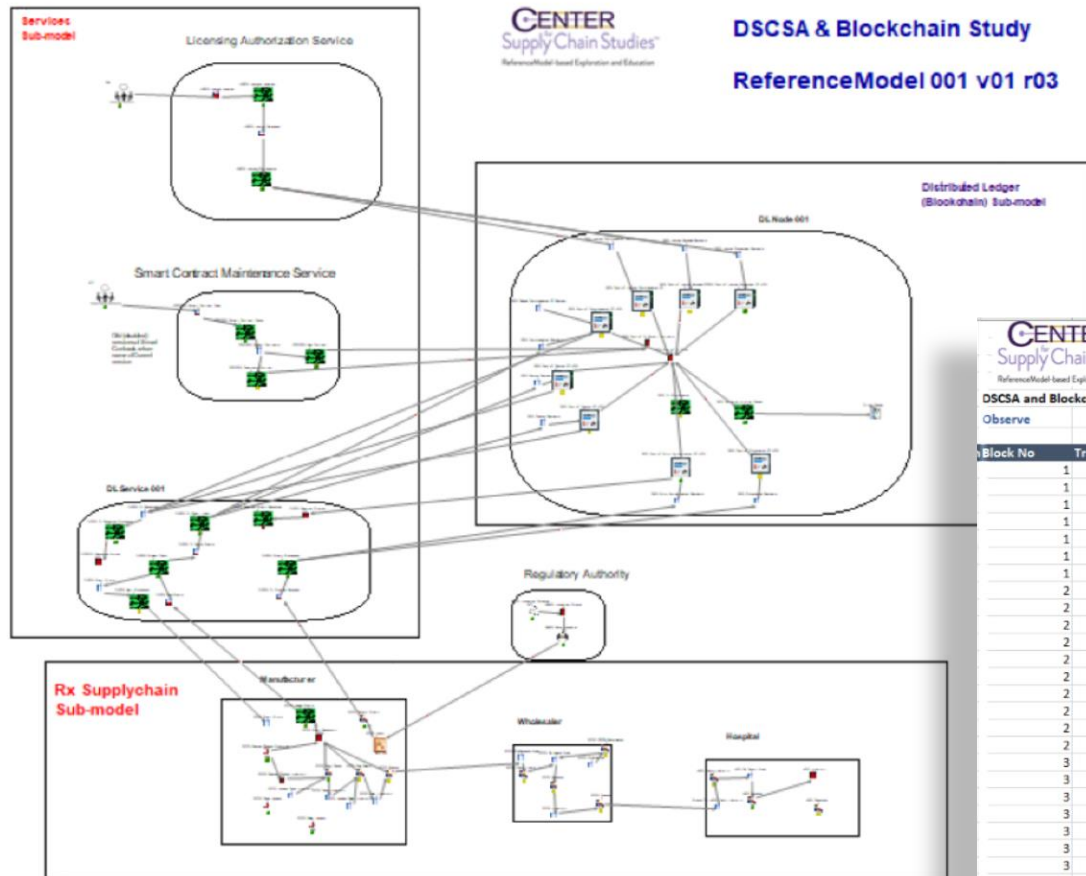


STUDY: DSCSA & Blockchain ²

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

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

CENTER Supply Chain Studies
ReferenceModel based Explanation 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:gln:0312444.00001.0	a2 b4 e0 dc b3 55 53 3d 91 34 8e			urn:epc:id:sgtin:0031234.500012.1	mdl4LzNkeLOyp3b8QgwLqWyG5s=	commissioning	10/3/2023 12:00 AM
1	2	urn:epc:id:gln:0312444.00001.0	31 b6 e0 23 20 57 53 c2 29 d3 a0			urn:epc:id:sgtin:0031234.500012.2	7J3F0f0Hibu9bGozZt+juNVGBE=	commissioning	10/3/2023 12:00 AM
1	3	urn:epc:id:gln:0312444.00001.0	3d c0 bc 1b 2c 21 0f fa 4c e8 92			urn:epc:id:sgtin:0031234.500012.3	IMl5maE+V3e6XpelZSifexTWE8=	commissioning	10/3/2023 12:07 AM
1	4	urn:epc:id:gln:0312444.00001.0	ac 3d e7 cd bd dc 54 2c 5b f6 d2			urn:epc:id:sgtin:0031234.500012.4	Rga/Wzk+6LNdtKRfWwprRrE98Y0=	commissioning	10/3/2023 12:07 AM
1	5	urn:epc:id:gln:0312444.00001.0	9d 9f b5 f3 8c 7e 06 12 ee 96 42			urn:epc:id:sgtin:0031234.500012.5	JX4a0v3Dl9VRbxHr5ajx0lpeMA=	commissioning	10/3/2023 12:11 AM
1	6	urn:epc:id:gln:0312444.00001.0	13 44 e4 17 02 a5 57 f6 1c 7a 35			urn:epc:id:sgtin:0031234.500012.6	vCH3AerOmclckTqSghwBFIs6uUl=	commissioning	10/3/2023 12:11 AM
1	7	urn:epc:id:gln:0312444.00001.0	63 18 d0 e7 72 f9 63 06 75 c9 4f			urn:epc:id:sgtin:0031234.500012.7	8WFcm1EBIKOG41bTU5bd7aBb0=	commissioning	10/3/2023 12:17 AM
2	8	urn:epc:id:gln:0312444.00001.0	08 c8 b8 61 19 29 0b 80 e5 a0 c8			urn:epc:id:sgtin:0031234.500012.8	Sf4mr6EIUn3XaKwCm26877QKA0=	commissioning	10/3/2023 12:17 AM
2	9	urn:epc:id:gln:0312444.00001.0	7b fb d6 81 6a 1a 65 60 cc ba d6			urn:epc:id:sgtin:0031234.500012.9	8RlZl+nuez1y0aakoKKD1qpv8Yg=	commissioning	10/3/2023 12:23 AM
2	10	urn:epc:id:gln:0312444.00001.0	a1 71 8d a4 b0 3e 45 bd f6 ad			urn:epc:id:sgtin:0031234.500012.10	2LJexhDKSVlqAPxW/2hl+qZyQg=	commissioning	10/3/2023 12:23 AM
2	11	urn:epc:id:gln:0312444.00001.0	f2 9f ef 88 e3 7e 5c 69 ac 6f a3 74			urn:epc:id:sgtin:0031234.500012.11	JMSyPT0ANW1WqS/He6OM63dVcPY	commissioning	10/3/2023 12:28 AM
2	12	urn:epc:id:gln:0312444.00001.0	fb a9 c2 73 ea 48 71 92 96 fa 82			urn:epc:id:sgtin:0031234.500012.12	rFd5MyceDM6IHxKDRhG6UJX5NE=	commissioning	10/3/2023 12:28 AM
2	13	urn:epc:id:gln:0312444.00001.0	73 2b cf 26 62 ca 7c c7 e8 33 ed			urn:epc:id:sgtin:0031234.500012.13	xXPCnRl9c3BavRdLxZv7AWIc=	commissioning	10/3/2023 12:34 AM
2	14	urn:epc:id:gln:0312444.00001.0	75 fa e7 5a 64 1b 54 bb f2 6c c2			urn:epc:id:sgtin:0031234.500012.14	ASikC7GeDB1WN4c7P+nbcn9WAA=	commissioning	10/3/2023 12:34 AM
2	15	urn:epc:id:gln:0312444.00001.0	2b d2 c1 59 3a 33 72 b8 14 7a a8			urn:epc:id:sgtin:0031234.500012.15	Bue4vzMSDKrf3XZLPyzhEFOE8e4=	commissioning	10/3/2023 12:39 AM
2	16	urn:epc:id:gln:0312444.00001.0	43 04 82 62 52 e5 31 83 ff de 01			urn:epc:id:sgtin:0031234.500012.16	u/n2btjP+qvdXDSvwwZPjbrDBA=	commissioning	10/3/2023 12:39 AM
2	17	urn:epc:id:gln:0312444.00001.0	aa dd 81 29 bb 3c 32 c8 b7 45 6a			urn:epc:id:sgtin:0031234.500012.17	XlBsj6Ax48Bnv0zVlIPXZcctcEzo=	commissioning	10/3/2023 12:45 AM
2	18	urn:epc:id:gln:0312444.00001.0	47 f5 ca f8 56 14 79 19 b8 a2 ac			urn:epc:id:sgtin:0031234.500012.18	Uuiq4vvlcpqpyAYXcP0ebGLxDO=	commissioning	10/3/2023 12:45 AM
2	19	urn:epc:id:gln:0312444.00001.0	4d 0d 8b 43 5c ec 38 a2 ed e9 81	urn:epc:id:gln:031234.500012.13	urn:epc:id:gln:031234.500012.13	urn:epc:id:sgtin:0031234.500012.19	Rga/Wzk+6LNdtKRfWwprRrE98Y0=	shipping	10/3/2023 12:48 AM
3	20	urn:epc:id:gln:0312444.00001.0	f7 14 93 67 e6 f5 20 86 37 72 71			urn:epc:id:sgtin:0031234.500012.20	V6hn7ibFaeUvXGX4mwc3sG+ZhbW=	commissioning	10/3/2023 12:50 AM
3	21	urn:epc:id:gln:0312444.00001.0	00 8c f2 f4 11 6d 41 15 56 a3 96			urn:epc:id:sgtin:0031234.500012.21	+Astyf6lnqjSOFxNKVYUtlqu/4=	commissioning	10/3/2023 12:50 AM
3	22	urn:epc:id:gln:0312444.00001.0	80 33 aa e9 91 d2 19 08 b6 e9 02			urn:epc:id:sgtin:0031234.500012.22	SjM0lOmIujltKJy8s51Z9yy4g=	commissioning	10/3/2023 12:54 AM
3	23	urn:epc:id:gln:0312444.00001.0	70 10 c8 cd 61 f1 7b 2c 5f 11 20			urn:epc:id:sgtin:0031234.500012.23	nueW05bKDGroBxlyTab2lk7N/c=	commissioning	10/3/2023 12:54 AM
3	24	urn:epc:id:gln:0312444.00001.0	29 27 c9 87 38 c6 7a 66 e2 30 43			urn:epc:id:sgtin:0031234.500012.24	9xa89R9AxhqlN9y7OvRvssQQe=	commissioning	10/3/2023 1:00 AM
3	25	urn:epc:id:gln:0312444.00001.0	cb d0 b0 4a da 31 03 ab 08 67 37			urn:epc:id:sgtin:0031234.500012.25	462M9KpSOHS6IA3jwKddc+2cgrM=	commissioning	10/3/2023 1:00 AM

Study Findings

DSCSA and Master Data Management

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**

Study Findings

DSCSA and Master Data Management

The Issue:

Sec. 582 Requirements

(b) Manufacturer Requirements.

(1) Product Tracing.

(A) In General.

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)

“(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”

Types of data in DSCSA Transaction Information

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

The diagram illustrates the mapping of various data types to specific fields in a DSCSA transaction spreadsheet:

- ReferenceModel Data:** Points to columns A through F of the spreadsheet header.
- Transaction Data:** Points to columns G through N of the spreadsheet header.
- Production Data:** Points to columns O and P of the spreadsheet header, labeled as "Represented by NDC + Lot # (GTIN + Lot # in this example)".
- Trade Item Master Data:** Points to columns Q through R of the spreadsheet header, labeled as "Represented by SNI (NDC + Sn) (GTIN + Sn # in this example)".
- Transferred From and Transferred To Party Data:** Points to columns S through V of the spreadsheet header, labeled as "Represented by Customer ID or Supplier ID (GLN in this example)".

ReferenceModel Data		Transaction Data							Production Data		Trade Item Master Data		Transferred From and Transferred To Party Data																													
Manufacturer	Observe Events	GTIN	SN	Location (GLN)	GLN Extension	Day/Time	Business Step	Action	Disposition	Sold From GLN	Sold To GLN	Lot Number	Lot Expiration	Product Master Data	Entity/Location Master Data (From whom ownership is being transferred)				Entity/Location Master Data (To whom ownership is being transferred)																							
Proprieta	Strength	Dosage#	Contain	Entity/Lo Name	Street1	Street2	City	State	Zip	Entity/Lo Name	Street1	Street2	City	State	Zip																											
8	Simulation Work Center	03124440001x	00312345000123x	1 03124440001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	20-Jan-26																													
9	M001 Commissioning	03124440001x	00312345000123x	2 03124440001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026																													
10	M001 Commissioning	03124440001x	00312345000123x	1 031231200001x		1/3/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026	Med001P	200 Tab	100	0312312x	W001	200	Comr Suite 154	Newark	NJ	08842	0312444x	M001	450	Production Way	Edison	NJ	08817												

Proposed use of Master Data

Reconstructing the "TI"

1

Suppliers						
Entity/Location Master Data From whom ownership is being transferred						
Entity/Lo Name	Street1	Street2	City	State	Zip	
0312312W001	200	Comr Suite 154	Newark	NJ	08842	

2

Customers						
Entity/Location Master Data To whom ownership is being transferred						
Entity/Lo Name	Street1	Street2	City	State	Zip	
0312444M001	450	Production Way	Edison	NJ	08817	

3

Trade Item			
Product Master Data Proprieta Strength DosageF Containe			
Med001P	200	Tab	100

4

Reduced Transaction Information													
GTIN	SN	Location (GLN)	GLN Extension	Day/Time	Business Step	Action	Disposition	Sold From GLN	Sold To GLN	Lot Number	Lot Expiration		
00312345000123x	1	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	20-Jan-26		
00312345000123x	2	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	1	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	3	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	4	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	2	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	3	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	5	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	4	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	6	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	5	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	7	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	6	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	8	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	9	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	7	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	10	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	8	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	11	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	12	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	9	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	13	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		
00312345000123x	10	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		
00312345000123x	14	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026		

5

DSCSA and MDM Study																
Data Owner	GTIN	SN	Location (GLN)	GLN Extension	Day/Time	Business Step	Action	Disposition	Sold From GLN	Sold To GLN	Lot Number	Lot Expiration	Inference?	Product Master Data Proprieta Strength DosageF Containe	Entity/Location Master Data From whom ownership is being transferred Entity/Lo Name Street1 Street2 City State Zip	Entity/Location Master Data To whom ownership is being tran Entity/Lo Name Street1 Street2 City
031244400001x	00312345000123x	1	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	20-Jan-26				
031244400001x	00312345000123x	2	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	1	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	3	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031244400001x	00312345000123x	4	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	2	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031231200001x	00312345000123x	3	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	5	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	4	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	6	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	5	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	7	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	6	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	8	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031244400001x	00312345000123x	9	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	7	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	10	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	8	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	11	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	12	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison
031244400001x	00312345000123x	13	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031244400001x	00312345000123x	12	031244400001x		1/3/2023 12:00 AM	Commissioning	ADD	Commissioned			125	1/20/2026				
031231200001x	00312345000123x	9	031231200001x		1/5/2023 12:00 AM	Shipping	ADD	InTransit	031231200001x	031233300022x	125	1/20/2026		Med001P 200 Tab	100 0312312W001 200 Comr Suite 154 Newark NJ 08842	0312444M001 450 Production Way Edison

Proposed use of Master Data Reconstructing the “TI”

1

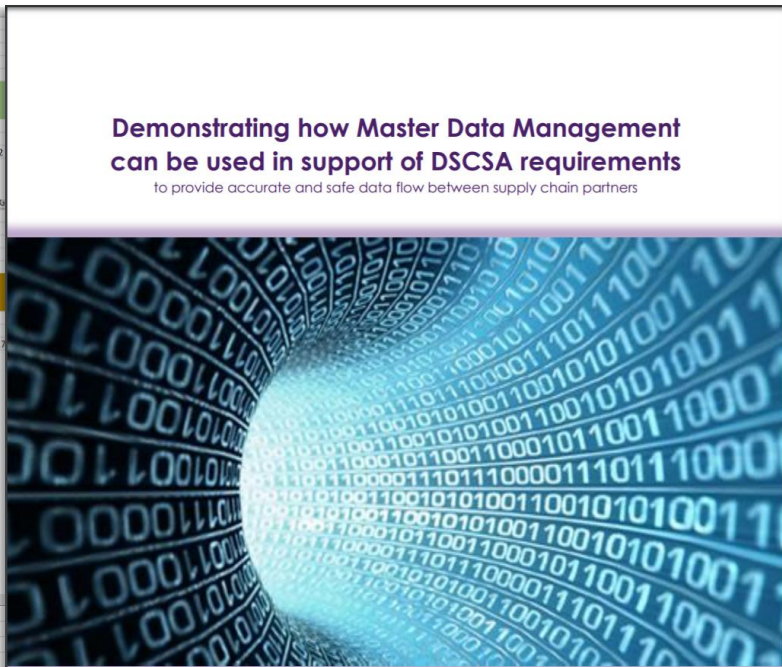
Suppliers						
Entity/Location Master Data From whom ownership is being transferred						
Entity/Lo. Name	Street1	Street2	City	State	Zip	
0312312(W001	200 Comr Suite 154	Newark	NJ		08842	

2

Customers						
Entity/Location Master Data To whom ownership is being transferred						
Entity/Lo. Name	Street1	Street2	City	State	Zip	
0312444(M001	450 Production Way	Edison	NJ		08817	

3

Trade Item		
Product Master Data Proprietary Strength Dosage# Containe		
Med	Strength	Container
Med001P	200 Tab	100



**Demonstrating how Master Data Management
can be used in support of DSCSA requirements**
to provide accurate and safe data flow between supply chain partners

A White Paper for Stakeholders in the Pharmaceutical Supply Chain



5

CENTER
Supply Chain StudiesSM
ReferenceModel-based Exploration and Education
DSCSA and MDM Study

Data Owner	GTIN	SN	Location (GLN)	GLN Extension	Day/Time	Busi
031244400001x	00312345000123x	1	031244400001x		1/3/2023 12:00 AM	Com
031244400001x	00312345000123x	2	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	1	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	3	031244400001x		1/3/2023 12:00 AM	Com
031244400001x	00312345000123x	4	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	2	031231200001x		1/5/2023 12:00 AM	Ship
031231200001x	00312345000123x	3	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	5	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	4	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	6	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	5	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	7	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	6	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	8	031244400001x		1/3/2023 12:00 AM	Com
031244400001x	00312345000123x	9	031244400001x		1/3/2023 12:00 AM	Com
031231200001x	00312345000123x	7	031231200001x		1/5/2023 12:00 AM	Ship
031244400001x	00312345000123x	10	031244400001x		1/3/2023 12:00 AM	Commissioning
031231200001x	00312345000123x	8	031231200001x		1/5/2023 12:00 AM	Shipping
031244400001x	00312345000123x	11	031244400001x		1/3/2023 12:00 AM	Commissioning
031244400001x	00312345000123x	12	031244400001x		1/3/2023 12:00 AM	Commissioning
031231200001x	00312345000123x	9	031231200001x		1/5/2023 12:00 AM	Shipping

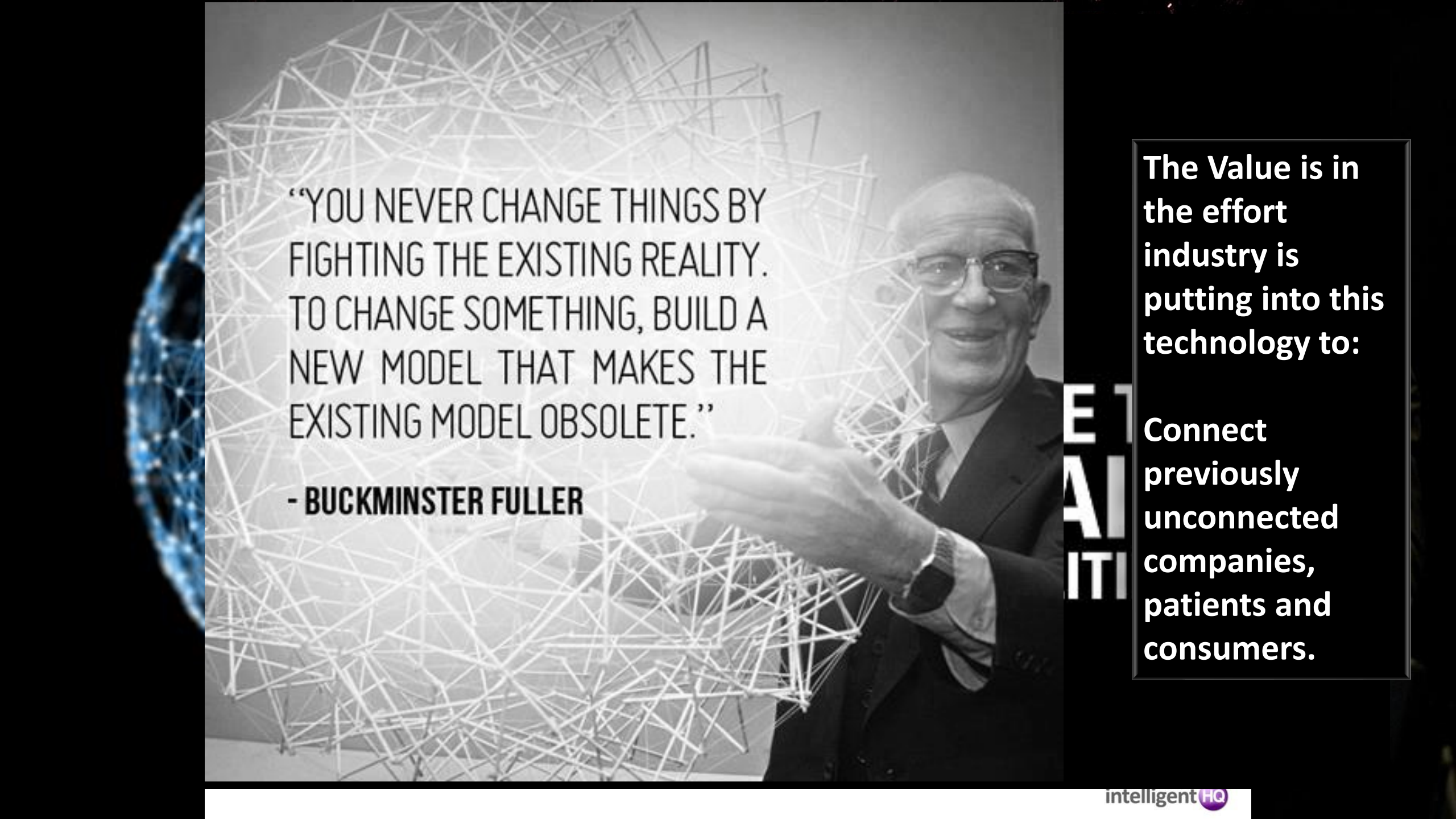
Condition	Sold From GLN	Sold To GLN	Lot Number	Lot Expiration	Entity/Location Master Data From whom ownership is being transferred				Entity/Location Master Data To whom ownership is being transferred					
					Entity/Lo. Name	Street1	Street2	City	State	Zip	Entity/Lo. Name	Street1	Street2	City
Commissioned			125	20-Jan-26										
Commissioned			125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Commissioned			125	1/20/2026										
Commissioned			125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Commissioned			125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Commissioned			125	1/20/2026										
Commissioned			125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Commissioned			125	1/20/2026										
Commissioned			125	1/20/2026										
Lot	031231200001x	031233300022x	125	1/20/2026										
Commissioned			125	1/20/2026										
Commissioned			125	1/20/2026										

Study Findings

DSCSA and Blockchain

The “interoperable system” of the DSCSA?

WHAT IS BLOCKCHAIN?



“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?

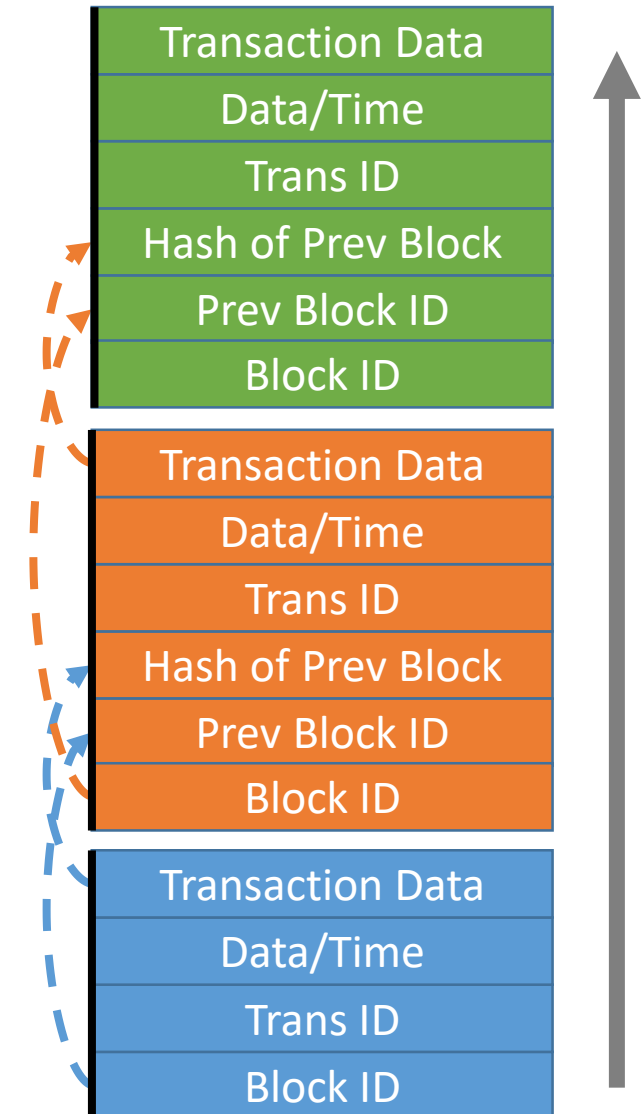
WHY IS BLOCKCHAIN INTERESTING?

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.

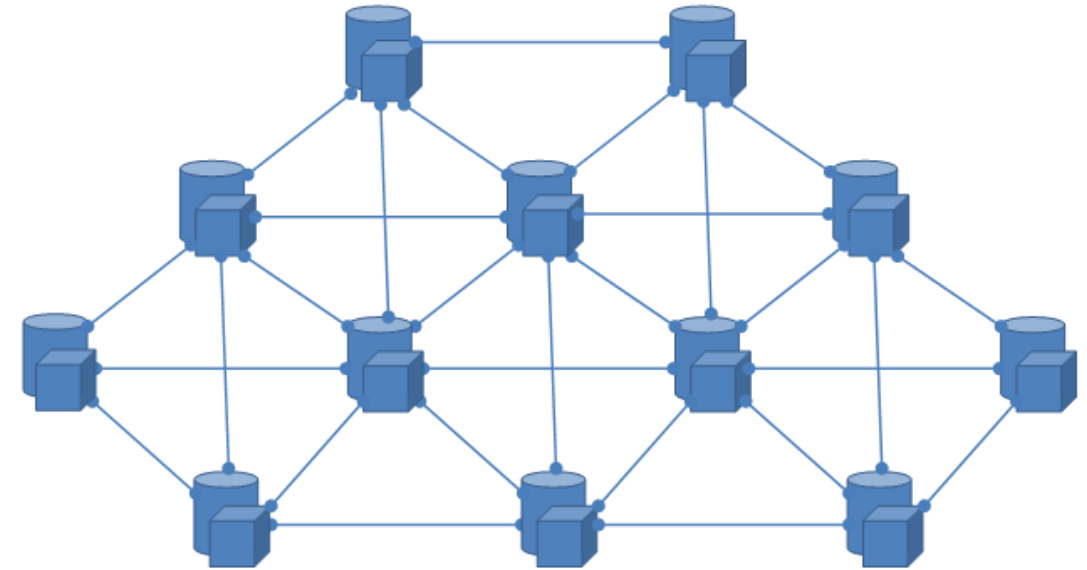
[The data is said to be immutable.]

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



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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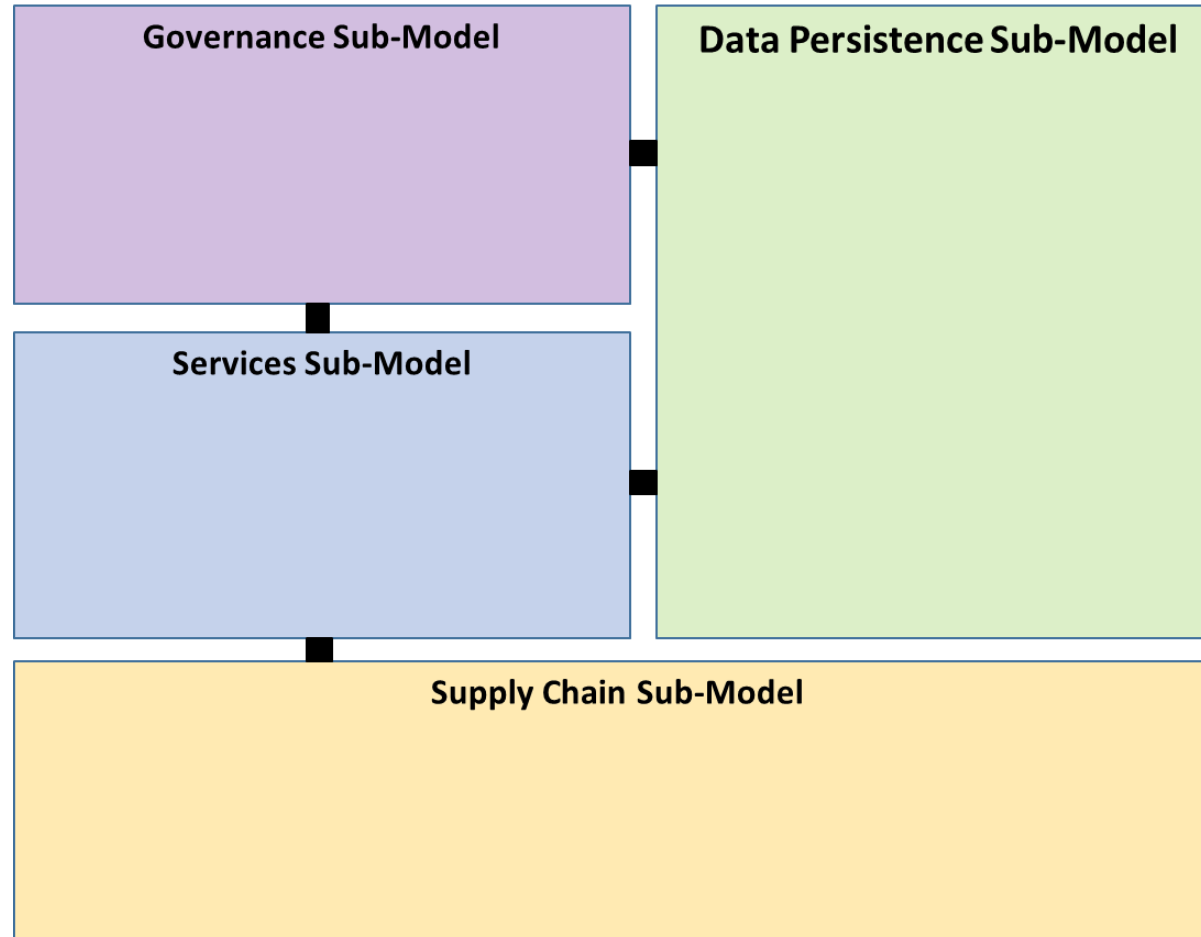
Study Findings

DSCSA and Blockchain

The interoperable system of the DSCSA?

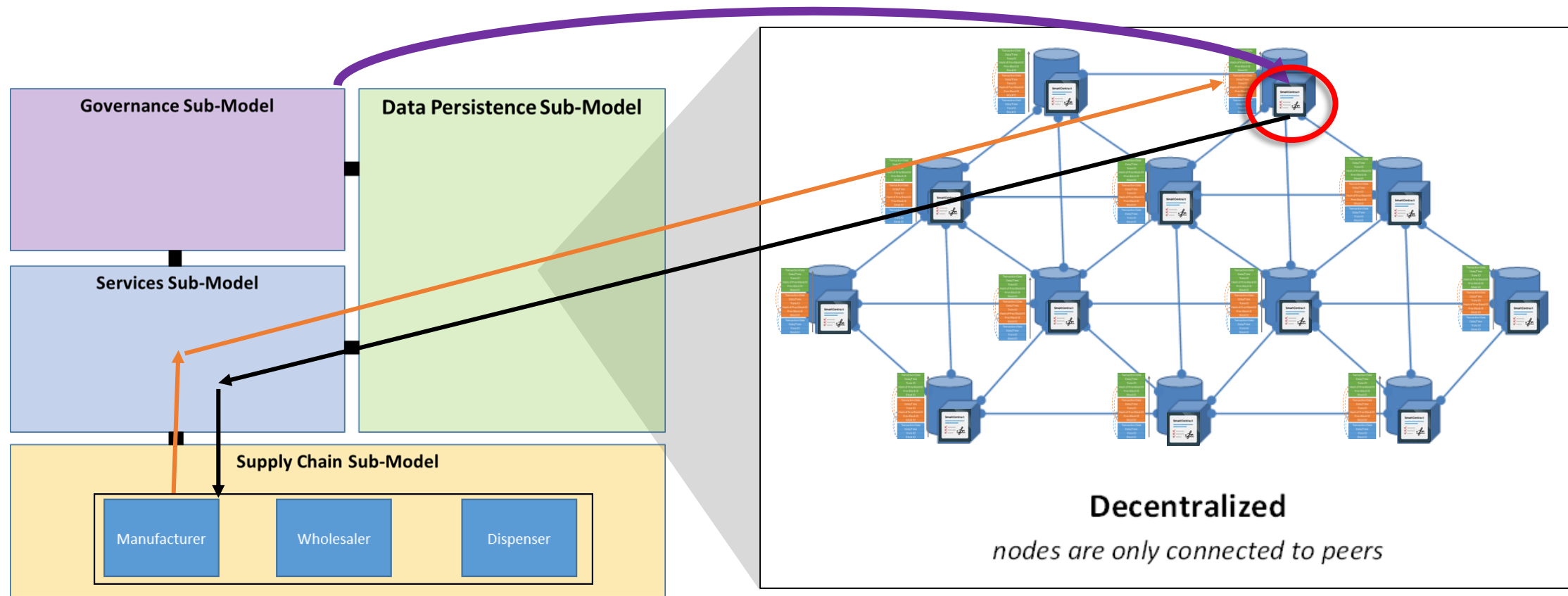
DSCSA and Blockchain Study

Established a Framework for discussing complexity



Study Findings

Distributed Data and Distributed Governance



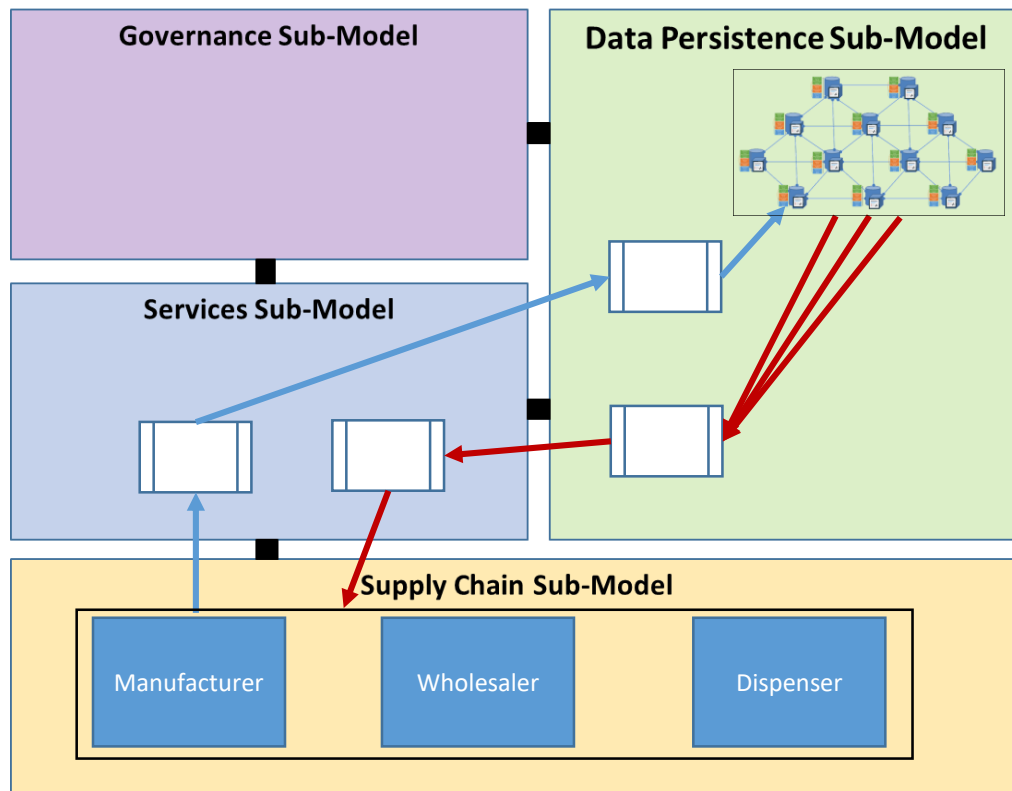
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Study Findings

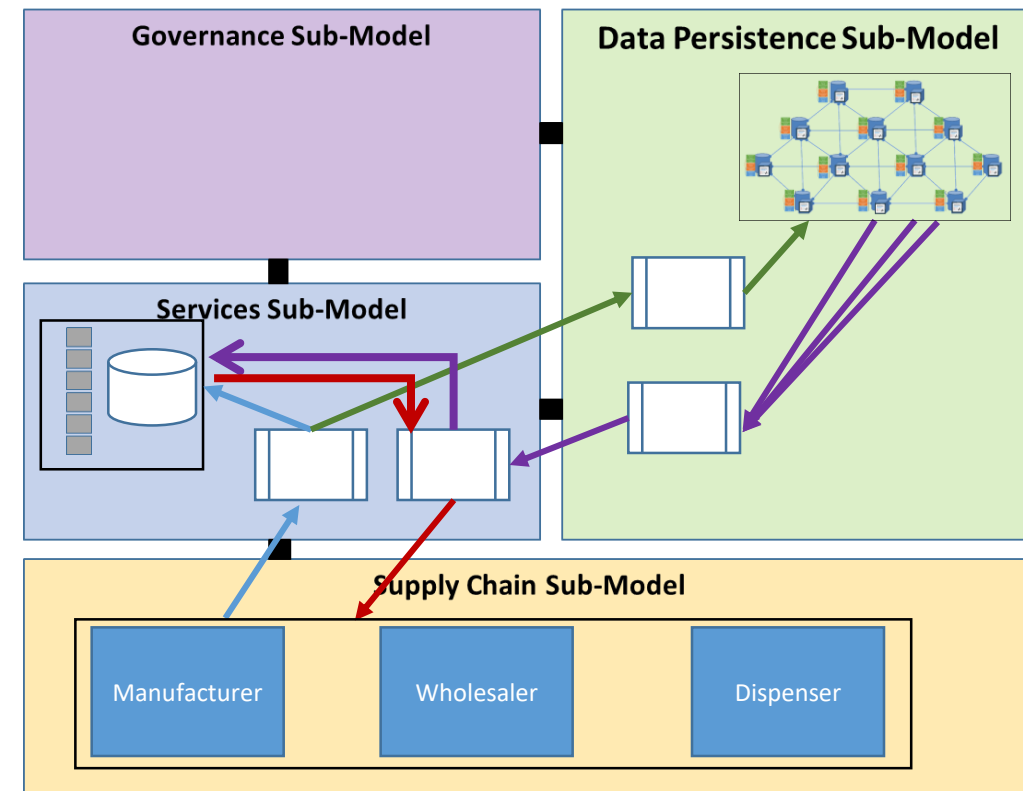
Study found two methods for sharing data

Each has different Data Governance and Secure Supply Chain Implications

RM001 – Minimal Model: Minimal data in Blockchain.



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

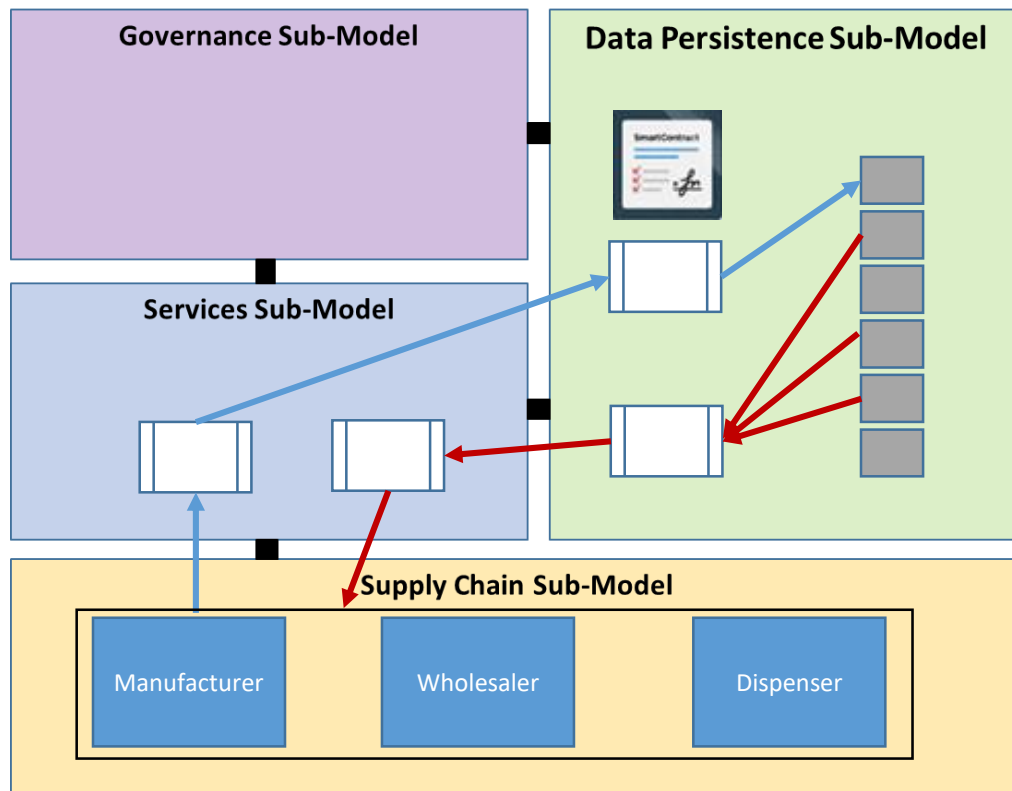


Study Findings

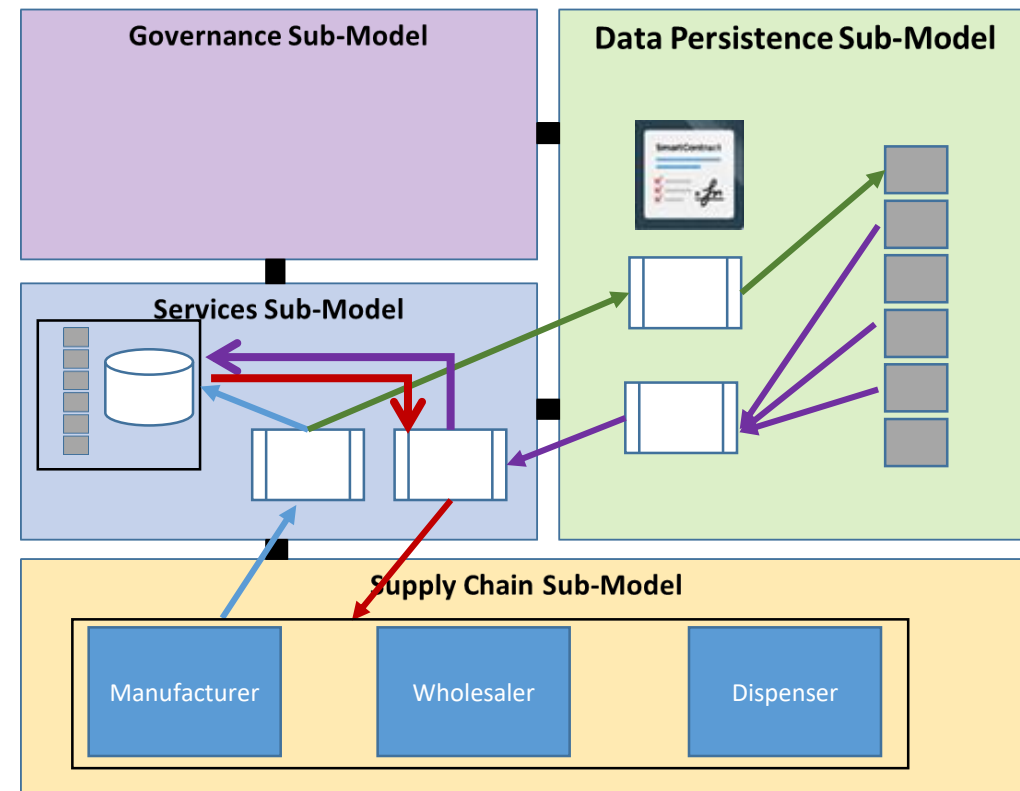
How Do we handle the Transaction Statement?

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)

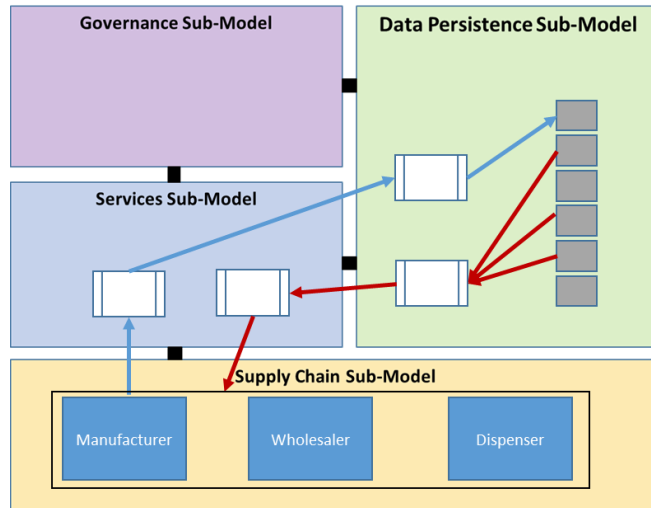


Study Findings

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

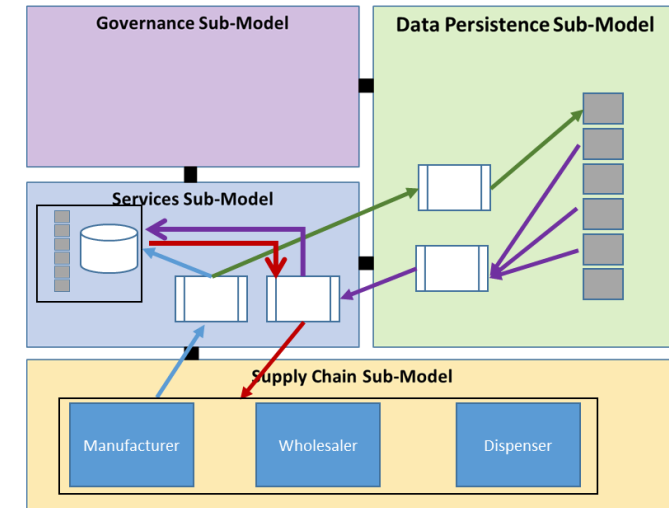
Returns Reconciliation

Enhanced Product Data for Clinicians

Enhanced Product Use Data for Manufacturers

Clinical Trials

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



Questions?

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*.

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