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

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ReferenceModel-based Exploration and Education

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the Study Team

The **"Demonstrating how Master Data Management Can be used in Support of DSCSA Requirements Study"** convened in late 2016. The Team completed its exploration in May of 2017.

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Supporting Partner, *Simulation Software Provider*

The Center would like to express our gratitude to SIMUL8 Corporation for supporting us by providing their simulation software to the Study Team. www.simul8.com

Our mission.

The Center for Supply Chain Studies (the Center) was founded to support industry collaboration and education through community-driven research, discovery and evidence-based information-sharing.

We host "Studies" and assemble Study Teams to address the ever-present challenges and demands that face all stakeholders in the healthcare supply chain. Our relationship with key industry participants, associations, regulatory bodies, academia, solution providers and consultancies aid Study teams to gain critical feedback from industry, regulatory and technology experts.

With a focus on industry exploration and education, Study Teams seek to tap deeper into relevant issues by engaging in closer examination, new understanding, fresh innovation and new possibilities.

Our Studies.

Initiated by the industry, Studies provide participants with an open forum for discussion, free-thinking, closer analysis and access to the insights and perspectives of others, including key thought leaders from industry, universities, regulatory and other arenas.

At the center of each Study lies a set of ReferenceModels™, or verified simulation models, which allow Study participants to "try out" and explore changes to regulations, technology, information and business arrangements. These ReferenceModels serve as virtual pilots and potential blueprints for change. Upon completion of a Study Team's exploration, all findings result in simulated ReferenceModels, White Papers and Education Modules to be published, housed and openly shared on the Center's online educational Resource Library.

The Center encourages suggestions for future Studies from the community for possible research and further exploration.

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The challenge.

Members of the U.S. pharmaceutical supply chain have long established the means to share and store information about the drugs they purchase and sell (Product Master Data) and information about their suppliers and customers (Entity Master Data). They have also established processes to maintain the accuracy of this data for purchasing, delivery and dispensing purposes.

This process, known as **Master Data Management (MDM)**, provides many storage efficiencies and data quality opportunities.

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was signed into law (*Title II of the Drug Quality and Security Act, or DQSA*).

Among other requirements, the DSCSA called for the capturing, sharing and archiving of Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS) by and between trading partners, including certain support entities such as 3PLs[1]. Embedded in the TI and TH data are the same Product and Entity master data that the industry already manages.

In essence, the DSCSA requires the sharing, maintenance and archiving of a second source of master data that the industry already manages.

In essence, the DSCSA required the industry to share, maintain and archive a **second source** of this master data.

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[1] Third Party Logistic companies

The objective.

This Study was established to examine scenarios where consenting trading partners rely on their original source of Product and Entity master data and <u>do not</u> pass the same data in the TI or TH messages and scenarios where trading partners <u>do</u> provide both sources of Product and Entity master data.

This Study was initiated to explore the idea of extending MDM practices to DSCSA Transaction Information (TI) requirements.

The outcome.

The exploration was successful in demonstrating how master data could be redacted from DSCSA Transactions and when needed, be sourced safely from ongoing master data management practices.

The Study showed that significant storage requirements could be reduced for all trading partners in the supply chain. The Study also showed a reduction in processes necessary to quality check the second source (TI) of Product and Entity master data.

Lastly, the Study showed that in certain situations where the delivered drug is needed immediately for a patient (not inventoried for later use) the scenarios where master data is verified prior to ordering provide less opportunity for a delay in the medication's availability for use.

Study was initiated to explore the idea of extending Master Data Management practices to DSCSA information management.

New industry challenges.

The DSCSA specifies that trading partners are to share (via a secure, interoperable, electronic manner) specific information with each other.

Beginning in 2015, that information is identified as "Transaction Information" (TI), Transaction History (TH) and "Transaction Statements" (TS) between immediate trading partners (data attributes are defined in the text of the law).

Beginning in 2023, that information is identified as "Transaction Information" (TI) and "Transaction Statements" (TS) between immediate trading partners (data attributes are defined in the text of the law). Section 203, Enhanced Drug Distribution Security also states the requirement that, *"...the systems and processes necessary to produce the transaction information for each transaction going back to the manufacturer."*

Although there is debate within the industry as to who is to perform the gathering of TI data, the law is clear about the content of the TI. Within the TI data attributes reside Trade Item master data as well as "Entity" master data for both the party transferring ownership and the party taking ownership of the trade item.

In both timeframes, the data is to be kept for six (6) years, or six (6) additional years after the conclusion of an illegitimate drug investigation.

The DSCSA requirement to capture, store and share TI data introduces a second source of Trade Item and Entity master data.

Industry need for further exploration.

The Study Team formed to attempt to demonstrate that current MDM practices can aid in complying with DSCSA requirements.

Most trading partners in the pharma industry currently employ various means to capture and ensure the quality of trade item and trading partner master data (entity and location).

MDM is a well-known method to ensure that this data is accurate and results in high-level quality[2] of static data that can be referenced by day-to-day transactions such as orders, advance ship notices (ASNs), invoices, etc. In these cases, the requirement to capture, store and share TI data – *as defined in the DSCSA law* – introduces a second source of Trade Item and Entity master data.

The need to address MDM uses for DSCSA compliance.

The Study Team formed to attempt to demonstrate that current MDM practices can aid in complying with the requirements of the Drug Supply Chain Security Act.

This was accomplished by showing how product, location and entity master data can be delivered via master data sharing mechanisms *outside of the DSCSA data stream* and accurately be brought back together with a subset of the DSCSA data to provide the full information needed for DSCSA compliance.

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[2] See "Perfect Order" document developed by the Strategic Marketplace Initiative
https://smi.memberclicks.net/index.php?option=com_mcform&view=ngforms&id=15598#/

The case for the continued exchange of master data outside of the DSCSA TI.

The U.S. pharmaceutical supply chain is a complex system. It contains many types of trading partners and encompasses a wide array business practices, each with their own method of data exchange. Supply chain partners have established processes to acquire and verify product and entity master data. *(See Figure 1 on next page.)*

Providing trade item and trading partner master data *through a second source*, such as DSCSA TI, is inefficient and is contrary to most process-improvement recommendations (*i.e. Six Sigma, Lean, etc*.).

Adding any additional sources of master data increases the amount of data that must be exchanged and archived for six (6) years and could introduce new error processing steps into each trading partner's environment. Having to support those processes would add cost to the trading partner and supply chain.

Providing product and entity master data through a second source, (such as DSCSA TI), is *inefficient* and *contrary* to most process-improvement recommendations.

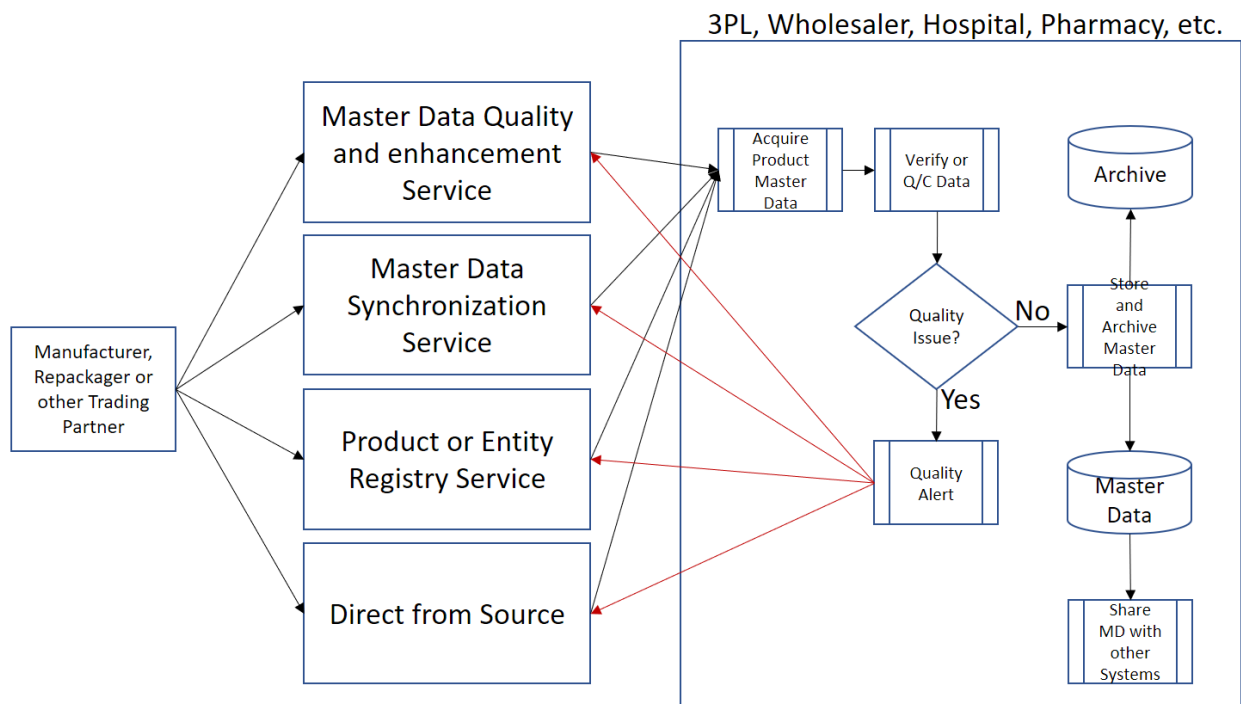**Figure 1** – *Master data transactions already exist in the supply chain.*

Focus of the Study Team.

At the Study's launch, the Team identified **six key areas of concern** worthy of question and exploration and attempted to cause the ReferenceModels to provide data:

1. Could a 2nd set of master data impact supply chain security?

2. Are there efficiencies to be gained by extending MDM practices to DSCSA requirements?

3. Do Master Data Management practices interfere with DSCSA compliance?

4. Are there potential data quality issues associated with multiple sources of trade item or Entity/Location master data?

5. Is there a significant savings in archival space when master data management processes are implemented?

6. In terms of timing, is there an impact on responding to a request to retrieve and report on historical DSCSA data?

Using simulation to visualize the scenario.

To enhance the understanding of complex systems and how changes might *impact* those systems, the Center uses **simulated ReferenceModels™** to visually depict supply chain processes and information flow.

The companies that provided DSCSA transaction or MDM solutions for this Study were interviewed to assure that the nuances of the services were considered in the discussions and models. Each represented solution resulted in a **Monograph** that depicted the solution so that it could replace the generic solution processes of the ReferenceModel.

Building the ReferenceModel.

Step 1:

To demonstrate the benefits and safety of continuing the practice of MDM for DSCSA compliance, the Study Team developed a simple U.S. pharma supply chain ReferenceModel depicting the transition of ownership of drugs from one trading partner to another.

Step 2:

The simulated trading partners in the model included a manufacturer, wholesaler and dispenser. It depicted the movement of trade items, trade item master data, Entity/Location master data, and DSCSA TI.

Step 3:

Next, variations of the initial model were generated to demonstrate trading partners' sourcing-product and entity master data.

This was accomplished by using standard MDM processes along with the redaction of master data from shared DSCSA TI data. This included depiction of product and location sourced via MDM processes and through the DSCSA TI (as defined by DSCSA law).

To demonstrate the benefits and safety of continuing the practice of MDM for DSCSA compliance, the Team developed a ReferenceModel to depict the transition of ownership of drugs from one trading partner to another.

ReferenceModel comparisons.

To determine if models were more efficient than others, or allowed for interface at the clinical level (interfered with clinical processes) – all modeled scenarios allowed for a certain amount of introduced errors.

Regarding the amount of data needed to archive, the ReferenceModels showed a certain difference in efficiency.

Can MDM and its attributes be removed from the DSCSA TI data set and be provided through other MDM processes?

New questions arise for MDM processes.

During a May 2016 industry workshop held by the FDA, some stakeholders in the pharma supply chain indicated they take a strict interpretation of DSCSA law regarding *exactly* which data attributes need to be exchanged with each transaction.

In response to this discussion in the workshop and prior knowledge of industry-wide master data management initiatives, this Study was formed to address the question: *Can MDM and its attributes be removed from the DSCSA Transaction Information data set and be provided through other MDM sources?*

The work scope of the Team.

The Team's weekly discussions led to the development of these interactive ReferenceModels and to the realization that master data management *is* an existing practice.

Several levels of "formality" were identified, including catalog sharing, master data alignment and master data synchronization.

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Study findings

What they found.

Following are the Study Team's key findings and conclusions.

1   **Providing master data for DSCSA TI through alternate means would prevent the transmission of inaccurate data that could impact supply chain decisions.**

Contrary to the concern, the ReferenceModels did show that supply chain decisions could be impacted by allowing two, potentially conflicting, versions of product and entity master data *(see Finding 3)*.

2   **MDM is a pre-existing data quality practice within the pharma supply chain. Introducing a *second set* of DSCSA master data could conflict with the primary source of master data.**

Existing master data practices introduce data changes in a controlled environment *prior* to transacting business with supply chain partners. Wholesalers and pharmacies both secure and inspect product data prior to placing information about products into their ordering systems.

The result is that new trade items are not purchased or received until the master data has been verified and transferred to the appropriate systems.

3   **Due to processing and timing differences, the MDM and DSCSA sources of product and entity master data could be out of alignment for periods of time.**

It was noted that it *could* be possible that one source or another might be updated on a different schedule, resulting in an alignment issue. Although there is no requirement in the DSCSA law to match DSCSA master data with pre-existing sources, the ReferenceModel included processes to manage those discrepancies.

The model allows the user to specify how often a discrepancy occurs, as well as vary the length of time that *correcting* the discrepancy would take.

4 Regarding the efficiencies gained by managing and archiving master data only when it changes (rather than with each transaction), the ReferenceModels show that data exchanges by alternate means resulted in approximately:

- **20% savings in Product data** (received & archived)
- **33% savings in Entity/Location data** (received & archived)

Additionally, trading partners also archive the entire incoming message which includes overhead used to identify the message, attributes and message version. Some message architectures (XML, EDI, etc.) result in eight times the volume of the DSCSA data being sent.

5 There was no perceptible difference in retrieving full DSCSA Transaction Information (TI) from an archive where master data was provided by the DSCSA TI or by alternate means.

The Study Team noted this caution: To retrieve the master data as it was known at the time of the DSCSA transaction, **trading partners or their service providers** must establish a master data archiving procedure.

To retrieve the previous TI, a trading partner must first establish an electronic connection with prior trading partners in the supply chain.

What comes next?

For its analysis, The Study Team took a simple, straight-forward "logistics" model into consideration. Minimal exception-handling was modeled or discussed.

Additionally, reverse logistics (*i.e. recalls, returns, withdrawals*) were only nominally discussed and therefore, not modeled.

Impact of a potential 2023 requirement:

To retrieve the previous Transaction Information leading back to the manufacturer (a potential 2023 requirement), a trading partner, or proxy, must first **establish an electronic connection** with those prior trading partners in the supply chain.

Subsequent Study: *Establish electronics connections for DSCSA.*

The Center has established a subsequent Study to provide new insight into **how** and **under what conditions** these electronic connections may be established. The DSCSA and MDM study outcome sets the stage for further exploration by demonstrating MDM practices that lighten the payload of the DSCSA TI.

Subsequent Studies can benefit from and build on the findings of this Study.

conclusions

Certain trading partners (small wholesalers, pharmacies, 3PLs, etc.) may not have access to mature systems that can take advantage of the efficiencies that MDM can offer and may require this data to be passed within the TI. Additionally, as the industry transition period may vary for *"managing serialized product and data,"* there may be a need to provide master data as part of DSCSA TI for some time.

Specifically, this Study showed that:

Trade item and Entity/Location master data can be managed safely, accurately and efficiently <u>outside</u> of the DSCSA TI.

1. **A single set of master data is preferred** to mitigate impacting supply chain security compliance decisions to distribute or dispense a drug.

2. There are **efficiencies to be gained by extending Master Data Management practices to DSCSA** requirements.

3. Master data management practices **do not interfere with DSCSA** requirements and compliance.

4. There are **potential data quality issues** associated with multiple sources of trade item or Entity/Location master data.

5. There is a **significant savings in archival space** when master data management processes are implemented.

6. There is **no significant impact in terms of timing** for responding to a request to retrieve and report on historical DSCSA data.

In summary,

For the growing number of stakeholders who desire to manage, process and archive master data as part of their overall data quality program, this Study demonstrates that **trade item and Entity/Location master data can be managed safely, accurately and efficiently <u>outside</u> of the DSCSA Transaction Information.**

glossary of terms

DSCSA	**Drug Supply Chain Security Act** US law defining drug distribution security requirements.
MDM	**Master Data Management** Processes and techniques regarding the identification of static data and processes to keep the data up to date. Emphasizes implementation of one source for master data and referencing the data using standardized identifiers.
Education Module	A "learn at your own pace" tool which summarizes the Study White Paper.
Monograph	An output from the Study. Provides a "deep dive" into a topic of interest in a Study. *(For this Study, Monographs are available on various MDM processes.)*
ReferenceModel™	A simulation of processes and data created by those processes to study the effects of change on complex systems. (For this study, the ReferenceModels simulated the exchange of trade items, master data and DSCSA Transaction Information between a manufacturer, wholesaler and dispenser.)

Product, or Trade Item Master Data

Attributes found in the DSCSA Transaction Information and Existing Trade Item Master Data updates:

/ Proprietary Name
/ Strength
/ Dosage Form
/ Container Size

Entity Master Data

Attributes found in the DSCSA Transaction Information and Existing Entity Master Data updates:

/ <u>Transitioning from (Seller):</u>
- Name
- Street 1
- Street 2
- City
- State
- Zip code

/ <u>Transitioning to (Buyer):</u>
- Name
- Street 1
- Street 2
- City
- State
- Zip code
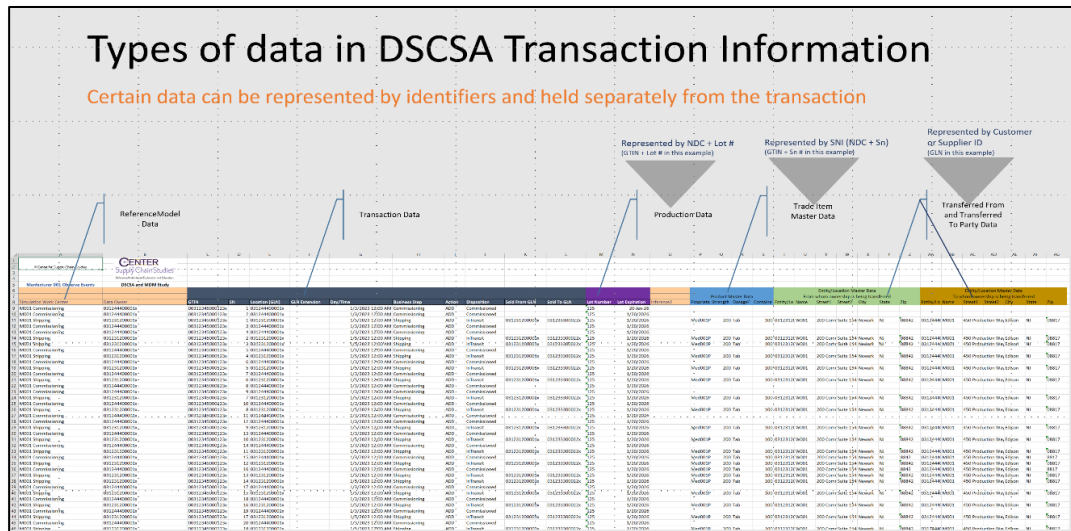
Figure 2 - *DSCSA Transaction Information contains groups of data*
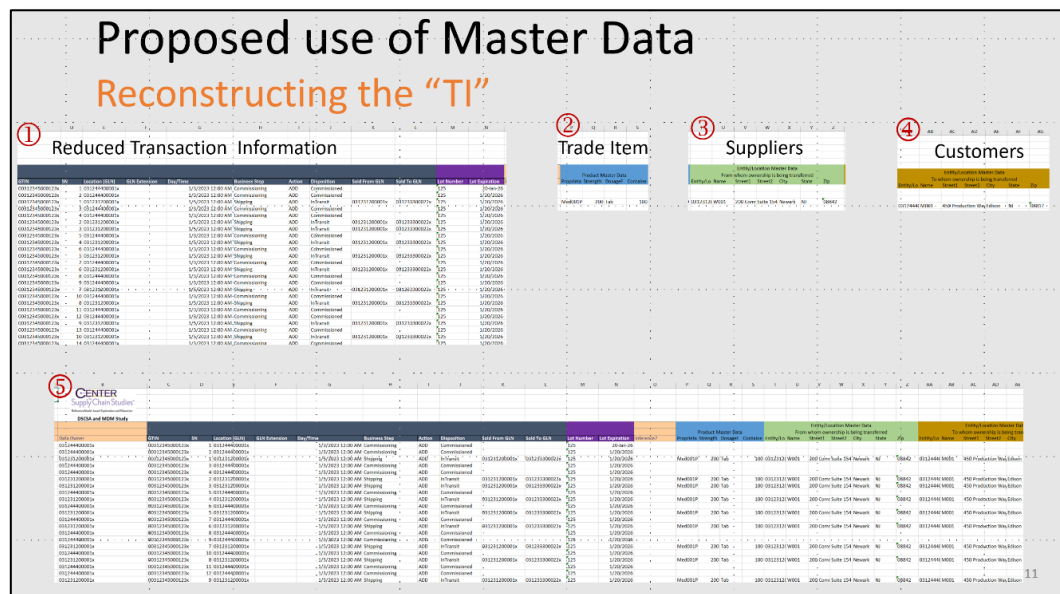
Figure 3 – *Alternate sources (#1-4) can be brought together to provide DSCSA TI (#5)*

Single source of truth.

Many business process improvement methodologies (Deming, Six Sigma, Lean, etc.) promote the removal of waste from systems and processes. Waste can come in the form of redundant information or processes. A concern with the DSCSA law is that it represents a second source of Product and Entity master data and processes that manage that data.

Current Master Data Management techniques can reduce product and entity data to a single source, thereby reducing potential conflicting data within an organization.
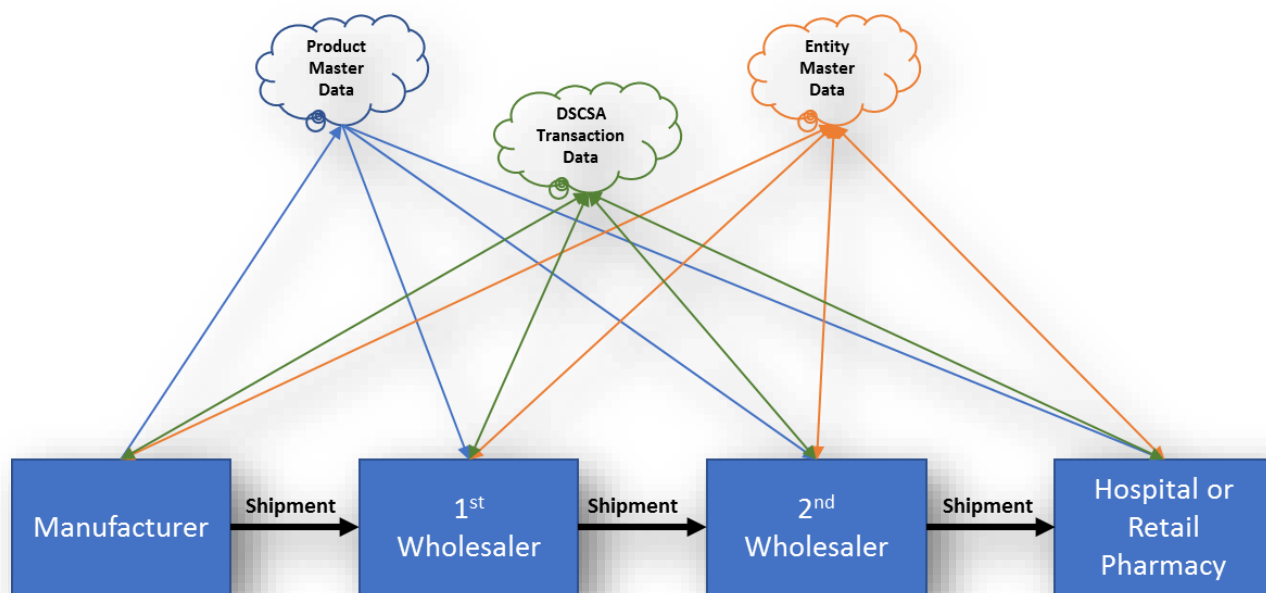
Figure 4 - *Example of Master data acquired from separate from DSCSA data.*

A matter of timing.

Master Data Management techniques provide for the exchanging, cleansing and updating of master data prior to ordering product; while a change to master data acquired though the DSCSA TI, TH and TS is received at the time of shipment – giving the recipient less time to respond to those changes.

Errors in DSCSA data can cause delays in processing the shipment.

For wholesalers and 3PLs, this could impact tight outbound shipment windows.

For healthcare providers, this could impact patient care and medication availability.

Therefore, there is **less chance of disturbance to daily operations** if the management of master data revisions (through controlled processes) is conducted **prior to ordering**.

Two ReferenceModels.

The Study Team created and compared two (2) ReferenceModels that depicted random changes to master data:

Model #1 (RM001)
This model passed master data **between trading partners** through the DSCSA TI data.

Model #2 (RM002)
This model passed master data **through separate processes prior to ordering** the product.

Both models experienced master data changes. However, due to the timing of *when the changes were recognized*, RM001 experienced delays in receiving the product into inventory.
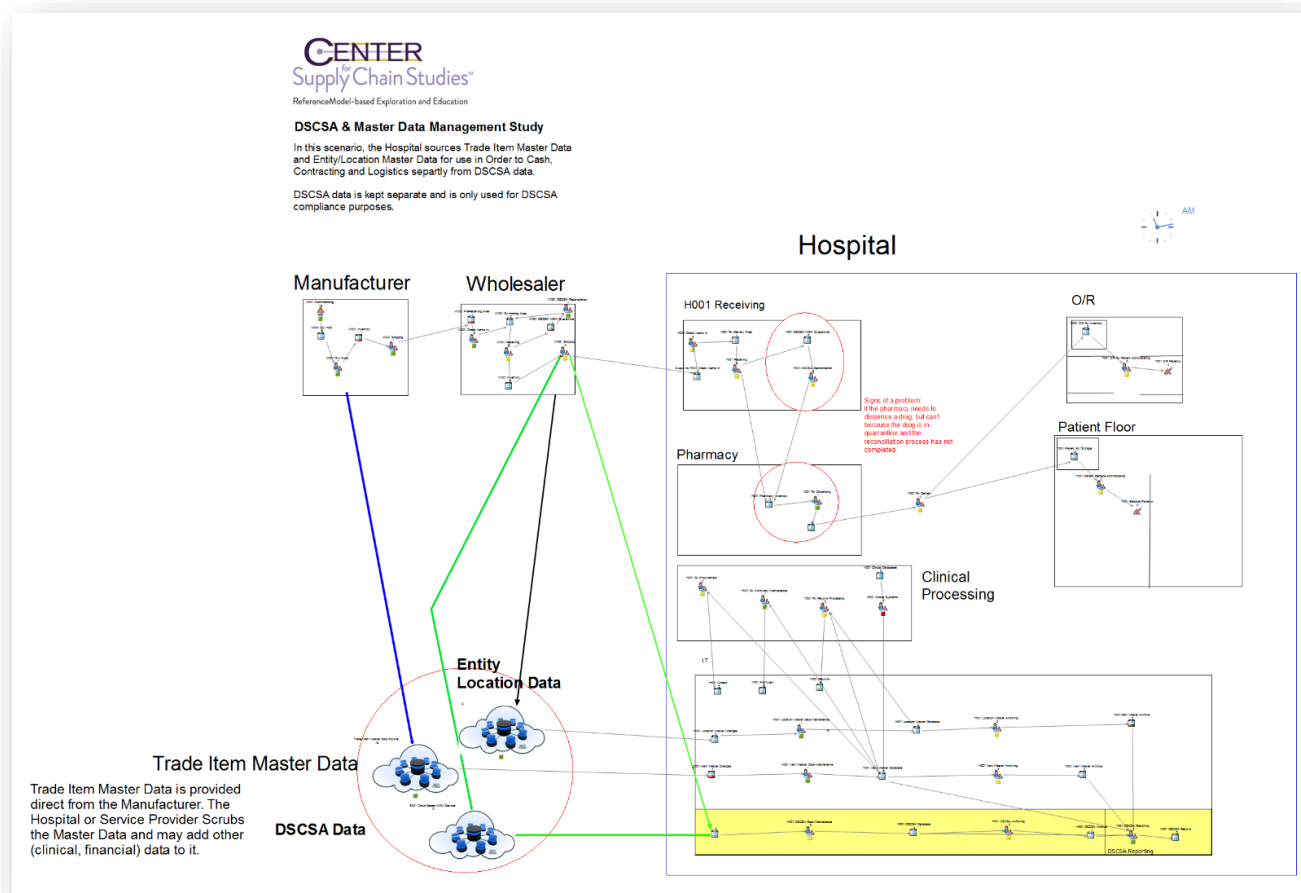
Figure 5 - *ReferenceModel depicting effect of Master Data Changes*

Existing ways to acquire master data.

Trading partners have several choices in acquiring master data, ranging from <u>sophisticated synchronization</u> services (where updates are immediately communicated), to services that <u>enhance basic product data with clinical, storage and transport attributes</u>, as well as simple <u>catalog files</u> shared between suppliers and buyers.
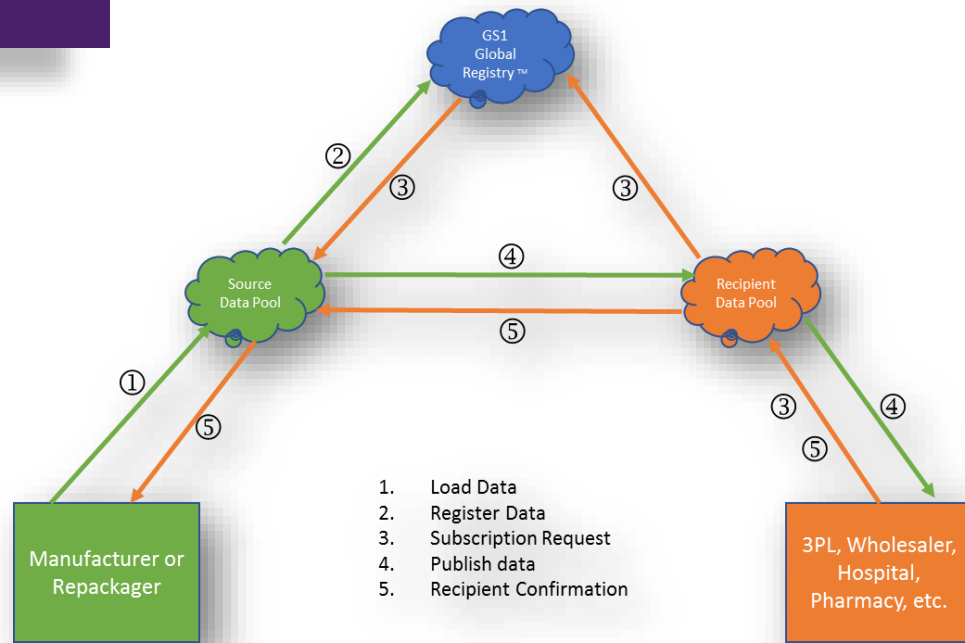
1. Load Data
2. Register Data
3. Subscription Request
4. Publish data
5. Recipient Confirmation

Figure 6 - *Synchronization Service Example*
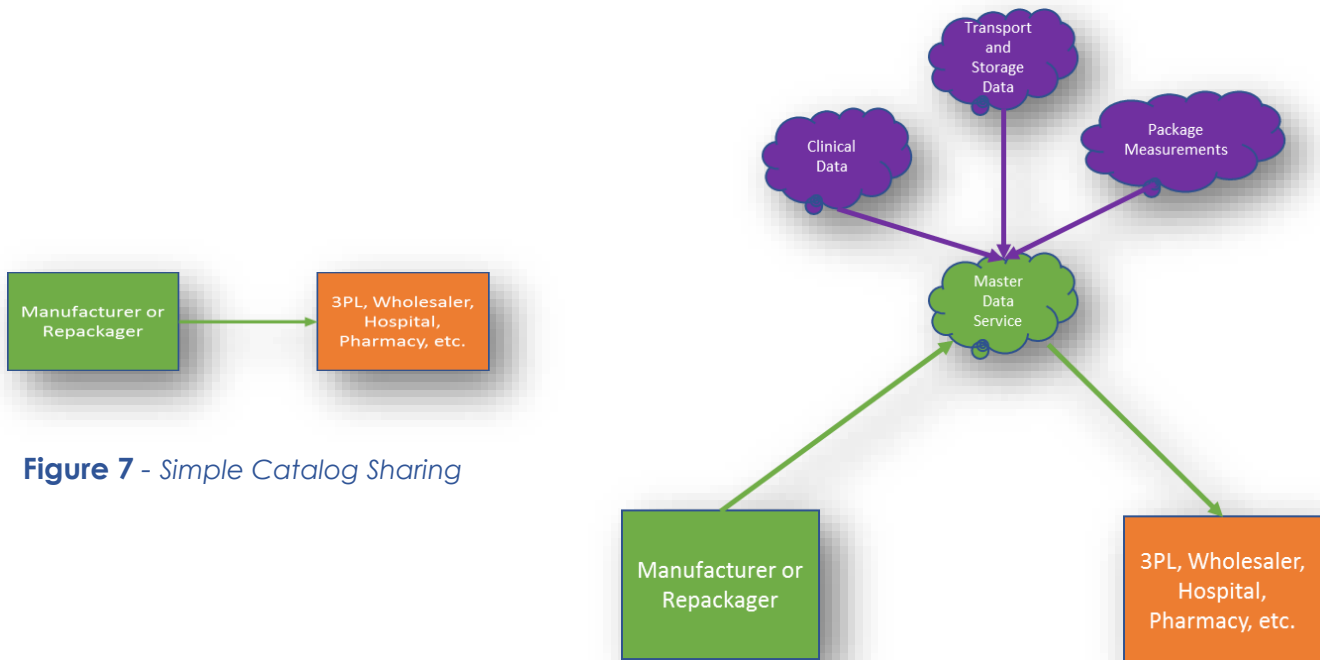
Figure 7 - *Simple Catalog Sharing*

Figure 8 - *Enhanced Master Data Services*

ReferenceModels^{TM}

Throughout the Study, ReferenceModels (verified simulations) were run to ascertain the likely savings that might be available to trading partners who establish Master Data Management processes.

Savings varies by mix of product being shipped. Large homogeneous product shipments can take advantage of the shared product master data by only recording it a single time for a shipment; whereas, heterogeneous product shipments and a mix of products from different manufacturer Lots could result in additional, duplicate Product Master Data being passed.

In addition, trading partners often archive not only the raw data that is stored in databases, but also the TI, TH, TS data as it was originally received along with it's necessary overhead (XML in the case of a GS1 EPCIS transaction).

For the purposes of this Study, ReferenceModels (verified supply chain and information flow simulations) were built based on the following:

1. **DSCSA baseline:** all DSCSA data within one document

2. **Industry baseline:** GS1 US DSCSA and Track & Trace Guideline (www.gs1us.org/industries/healthcare/standards-in-use/dscsa/implementation-guideline) – minimizing duplication by placing product and entity master data in the XML header of the EPCIS Event

3. **Traditional, low-tech:** acquiring product and entity master data from suppliers directly

4. **MDM Service Providers:** who cleanse, correct and enhance the base data

5. **GS1 MDM tools:** Acquiring product data from the Global Data Synchronization Network (GDSN) and entity master data from the GGS1 US GLN Registry

6. **HDA-Item Repository:** Acquiring product data from the HDA Item Repository

Figure 9 - *DSCSA Baseline - All data in single document*

Figure 10 - *Industry Baseline - GS1 US Guideline*
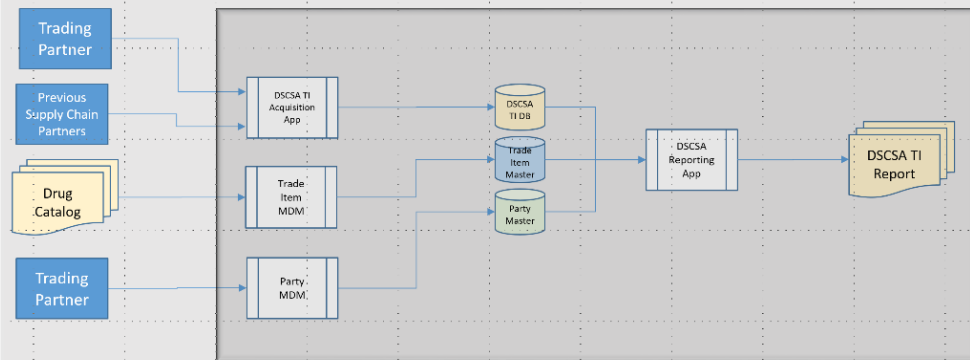
Figure 11 - *Low Tech: acquisition direct from trading partners*

Figure 12 - *Acquiring Master Data from Service providers*
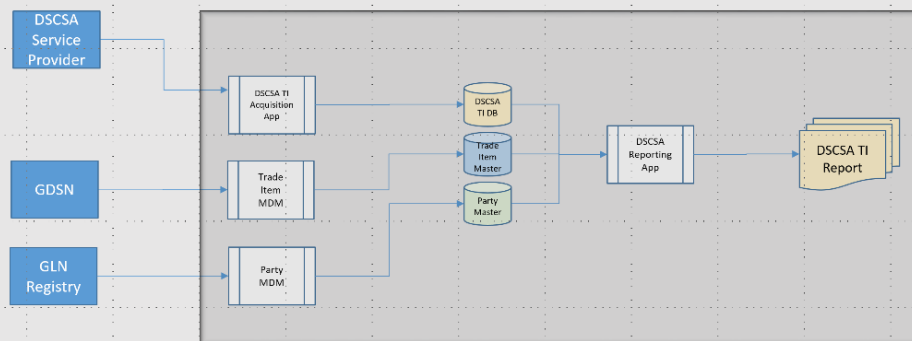
Figure 13 - GS1 GDSN and GLN Registry
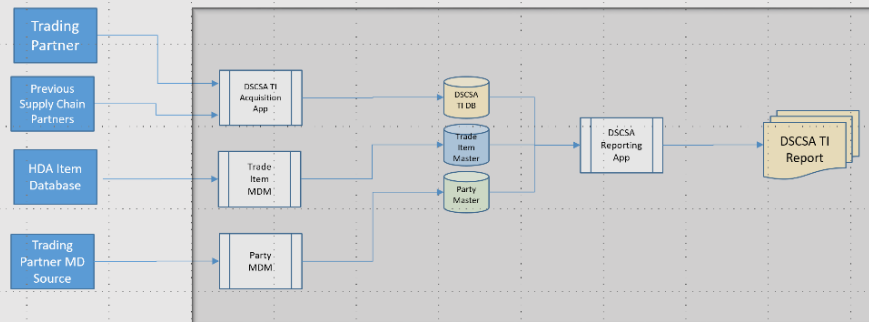
Figure 14 - *Product Data acquisition from the HDA Item Repository*

What the Team saw.

The following are observations made from the data created from the ReferenceModels.

Although individual trading partner experience may vary widely due to product shipment mix and size, these observations provide some insight as to the magnitude of potential savings available to companies who adopt Master Data Management techniques.

- Product Master Data makes up 20% of DSCSA TI data.
- Product Data should never change (would trigger a new NDC or GTIN to be assigned).
- Entity Master Data makes up 33% of DSCSA TI data.
- EPCIS XML overhead can be as much as eight (8) times the volume of contained DSCSA Data

Master Data (Product and Party) accounts for 53% of "TI" data required.

By implementing MDM techniques, trading partners could manage 53% less data per SKU per shipment (2015-2023) and 53% less data per each **instance** of a SKU per shipment.

Wholesalers would save twice as much information to manage as they have both inbound and outbound shipments.

Figure 15 - *Significant storage savings may be attributed to MDM techniques*

Data Type	Attribute	Length	Data Type Length	Master Data Management Model					
				Baseline	GS1 US Guideline	Traditional / Low Tech MDM	MDM Services	GS1 MDM Tools	HDA Item Repository & GS1 US Guideline
Transaction & EPCIS Attributes	Date/Time	23	109	1 per item in shipment	1 per shipment	1 per shipment	1 per shipment	1 per shipment	1 per shipment
	Business Step	20							
	Action	20							
	Disposition	20							
	Transferred From	13							
	Transferred To	13							
Production	Lot #	20	28	1 per SKU	1 per SKU	1 per SKU	1 per SKU	1 per SKU	1 per SKU
	Expiration Date	8							
Item Instance ID	Serial #	20	34	1 per item in shipment	1 per item in shipment	1 per item in shipment	1 per item in shipment	1 per item in shipment	1 per item in shipment
	GTIN (NDC)	14							
Product Master Data	Proprietary Name	100	160	1 per item in shipment	1 per SKU	1 per product lifetime	1 per product lifetime	1 per product lifetime	1 per SKU
	Strength/UOM	20							
	Dosage Form/UOM	20							
	Container Size/UOM	20							
Transfer From Entity Master Data	GLN	13	444	1 per item in shipment	1 per shipment	1 per supplier lifetime	1 per supplier lifetime	1 per supplier lifetime	1 per shipment
	GLN Ext	20							
	Name	100							
	Street 1	100							
	Street 2	100							
	City	100							
	State	2							
	Zip	9							
Transfer To Entity Master Data	GLN	13	444	1 per item in shipment	1 per shipment	1 per self lifetime	1 per self lifetime	1 per self lifetime	1 per shipment
	GLN Ext	20							
	Name	100							
	Street 1	100							
	Street 2	100							
	City	100							
	State	2							
	Zip	9							

Figure 16 - *DSCSA "TI" attributes (not including EPCIS XML overhead)*

EPCIS XML Overhead (1 item shipped, based on examples in GS1 US DSCSA & GS1 Standards Guideline)				
DSCSA Data Type	EventType	Total Characters (Min)	DSCSA Data Characters	Overhead (times as much data)
Product Master Data, Production Data	Commissioning	1856	192	9.7
Aggregation Data	Packing	741	126	5.9
Transfer From Master Data, Transfer To Master Data, Transaction Data	Shipping	2623	306	8.6
	AVG Total:	5220	624	8.4
Manufacturer or Dispenser:		5220	624	8.4
Wholesalers (x2: Received & Sent):		10440	1248	8.4

Figure 17 - *Companies may store the received transaction (includes XML overhead).*

DSCSA Law

A copy of the law as well as FDA guidance's and timelines can be found at:

https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm

Study Archives

All materials created for the *"Demonstrating how Master Data Management Can be used in Support of DSCSA Requirements" Study* can be found at:

https://www.c4scs.org/dscsa-and-mdm-study

Archived materials include:

- ReferenceModels
- White paper
- DSCSA Data Sharing and Monographs
- Education Models