Study Prospectus

Center for Supply Chain Studies™

CSCS
CENTER FOR SUPPLY CHAIN STUDIES™

DSCSA & Master Data Management VirtualPilot™

Prospectus V.02

Dear Potential Study Participant,

The Center for Supply Chain Studies is pleased to provide this Study Prospectus of the **DSCSA & Master Data Management (MDM) VirtualPilot™**.

The Study will create a ReferenceModel (or series of models) to demonstrate how product, location and entity master data can be delivered via master data sharing mechanisms that are outside of the DSCSA data stream and accurately brought back together to provide the TI and TH needed for DSCSA purposes.

Along with a ReferenceModel(s), the Study will produce a White Paper and education materials. These materials will be published on the Center's website and may be exhibited at conferences and seminars in the form of a VirtualShowcase™. This Prospectus will be the charter of the Study for the duration of the Study.

The Center for Supply Chain Studies hosts ReferenceModel-based Studies as a way to bring together thought leaders from industry, academia, regulatory and other arenas to examine complex industry issues and explore new ideas and methods for addressing them.

We appreciate feedback on your experience so that we can continue to improve our Studies.

Warmly,

The Study Team,
Center for Supply Chain Studies

DSCSA & Master Data Management VirtualPilot™

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Once you've read the Prospectus, please visit:
www.c4scs.org/dscsa-and-mdm

***Questions*? Call or email:**

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Background

The FDA has just announced a public workshop on DSCSA Pilot Projects (April 5-6, 2016)[1]. The Drug Supply Chain Security Act (DSCSA) requires the transmission of trading partner and product master data for every shipment and possibly each package.

Meanwhile, healthcare providers and trading partners have been pursuing the use of Master Data Management (MDM) techniques for medical devices and also for drug products and transactions.

Currently, few trading partners are able to transact DSCSA information (TI, TH, TS) in varied formats and configurations.

Goal

In an effort to provide thought leadership to the industry, the goal of this Study is to demonstrate how product, location and entity master data can be delivered via master data sharing mechanisms outside of the DSCSA data stream and accurately brought back together to provide the TI and TH needed for DSCSA purposes.

Objectives

The Study seeks to explore potential benefits for trading partners and patients, including:

- *Decrease in risk of data errors*
- *Reduction of data redundancy*
- *Lowering of costs*
- *Improvement of data storage and retrieval accuracy*

Evaluation Criteria

The first phase of the Study will be to determine a set of metrics that the Study Team believes will allow them to assess overall added value to usage of Master Data Management practices in the context of DSCSA requirements. This criteria will also facilitate the development of ReferenceModels and ReferenceModel output.

The Study Team will use the criteria to compare and contrast various facets of the developed ReferenceModels and prioritize the set of uses based on these patient safety and efficiency criteria.

Study Facilitator:

Bob Celeste

Bob's in-depth of knowledge and understanding of the pharmaceutical supply chain, including current standards, regulations and technologies, is unparalleled.

His ability to harness this expertise to innovate around complex challenges has made him a leader and trusted partner to industry in their ongoing efforts to implement serialization, track & trace, and regulations.

For over 20 years, he has used simulation processes in a wide range of industries including banking, pharmaceutical and communications, among others.

Prior to founding the Center for Supply Chain Studies, he was Senior Director for GS1 US working with the healthcare industry on standards-based, item-level traceability.

Bob was the lead in developing the ground-breaking pharmaceutical supply chain simulation model for DSCSA, as well as the comprehensive guideline for how to apply EPCIS in the pharmaceutical supply chain for DSCSA requirements.

Throughout the course of the Study, Bob and the Center will provide ongoing logistical and analytical support. The Center also will guide participants through the creation of a working ReferenceModel(s) to examine relevant industry issues and explore new ways of addressing them.

Scenarios

The Study will follow serialized pharmaceuticals through the supply chain and make use of product location and entry master data available through separate channels and via DSCSA-compliant systems. The Study Team will identify a number of scenarios and variations on scenarios that will be modeled and measured throughout the Study.

The focus of these scenarios may be to better understand the interface between processes, or departments within the hospitals. The Team also may center on a particular process and how it may be affected by DSCSA-marked product and its associated data.

Along with creating ReferenceModel(s) that will be housed in the Center's online library, it is possible that the ReferenceModel and other materials will be tailored for relevant conferences and events.

A listing of targeted venues for 2016-2017 will be discussed with this Study Team. Participants in the development of the online version created in this Study will also have the opportunity to participate in the Center's live VirtualShowcase presentations at these events.

Important Note

The ReferenceModel(s) developed in this Study will not represent the operations of any specific company.

The simulated trading partners in the ReferenceModel(s) are generic in nature, but are intended to fairly represent each simulated trading partner's role and behavior in general.

Specific Exclusions from Scope

The supply chain scenarios to be examined in this Study are outlined on this page. It is feasible that, upon completion of this Study, participants may want to initiate future Studies to build on this Study's work to exercise additional scenarios.

(See "Extending the Study" section for further information.)

ReferenceModel™ and Simulation

Very often it is difficult to assess the impact of change on a complex system. Projections of success are often made by taking the area of interest out of context in order to study it without "background noise." Unfortunately, implementations often reveal that some of the background noise created by key processes, information, regulation or interactions really do matter, and the failure to consider and examine them undermines success.

The Center uses a patent-pending simulation software to capture and analyze complex systems in context to that pitfall. Our innovative approach provides a means of verifying processes and information with designated representatives from your organization, and assessing the impact of large or small change(s) to the overall system. The Center extends the functionality of this simulation software to provide key insights on process, information, staff/patient/ customer and financial flow for large systems (e.g., global supply chains) and small systems (e.g., departmental interactions) alike.

This simulated modeling operates as a living system. It can be altered to test any number of ideas, variations or modes of solving real world problems. It enables participants to think freely about and experiment with new ways of solving today's and tomorrow's challenges and explore new opportunities.

Limitations of traditional analysis methods:
Often, traditional means of managing complexity and details blind us to see simple and elegant solutions – impeding advancements and breakthrough thinking. As humans, it is difficult to manage all of the details of large intricate systems while simultaneously analyzing the impact of subtle and not-so-subtle changes to those systems. We are wired to make decisions based on levels of assumptions. Invariably, some of those choices turn out to be inaccurate, undermining our ability to innovate and make key discoveries. Moreover, traditional methods discourage risk-taking and increase the chance that a solution is the product of "group thought."

What you will experience:
A simulated environment is a living system. Components of the simulation representing products, processes, information, human interactions and geographic dimensions react to activity and data that is triggered and created within the simulation. Each component follows a set of rules which dictates its behavior. This allows for an extreme amount of flexibility to develop complex systems that mimic current systems, trial systems or future systems.

Innovation

"If we asked what they wanted, they would have said Faster Horses."
- Henry Ford

"Planning is bringing the future into the present so that you can do something about it now."
- Alan Lakein

"It's really hard to design products by focus groups. A lot of times, people don't know what they want until you show it to them."
- Steve Jobs

A truck was stuck under an overpass, while engineers, police and firefighters struggled over how to free the truck, a little boy walked up and said "why don't you let some air out of the tires?"
- Anonymous

"If the result confirms the hypothesis, you've made a discovery. If the result is contrary to the hypothesis, you've made a discovery."
- Enrico Fermi

A simulated environment will run for a fixed period (representing real time in minutes/hours/days). Once a simulation is stable (i.e., will run for a period of time and produce reasonable results), variations can be introduced to the simulation to determine the best path forward.

During a Study, we break the total duration of the Study into 2-week time periods called **"Sprints"** in which we accomplish a particular task or piece of work.

Figure 1 – Along with the baseline model and end documentation, a Study attempts to create as many working scenario variations as time permits.

The first 2 Sprints are dedicated to developing a baseline model and a set of metrics. The Study Team will use these to compare and contrast variations in terms of effectiveness. The last set of Sprints are reserved for documenting the learnings of the Study Team in the White Paper and Education Modules. The remainder of available Sprints are used to create as many variations or refinements on the scenario(s) as possible.

Sample ReferenceModels:
The ReferenceModels that are output from a Study are in the form of process simulations. While the learnings from a particular simulation can be captured in tables, diagrams and papers, the simulations themselves are interactive computer systems that allow the viewer to interact with the topic at hand, and watch the result of that interaction play out before them.

VirtualPilot™:

Simulation modeling that allows companies to analyze situations at a fraction of the cost of a typical pilot. VirtualPilots also provide the ability and freedom to test a variety of scenarios that are often too risky for live pilot testing; resulting in a blueprint for real-world piloting and/or implementation

ReferenceModel™:

A simulation model that fairly represents a real-world or projected scenario and can be used to visually demonstrate a finding, point of view or just to educate on a topic. Some ReferenceModels may also serve as baselines for future discovery or experimentation.

VirtualShowcase™:

A ReferenceModel that has been further developed (including a companion Guide) to lead the viewer through a demonstration of the ReferenceModel. Showcases typically focus on a limited portion of a ReferenceModel for a specific audience.

A sample ReferenceModel can be viewed on the Center's website (www.c4scs.org/hc-reference-models). The video demonstrates the basics of a simulation that, once completed, verified and accepted by industry, will be published as a ReferenceModel for a particular process, information or financial flow. The generic model could then be altered to reflect a company's particular environment to assess alternatives and predict outcome of actual implementation of changes to process flow, information flow, financial flow or business practice.

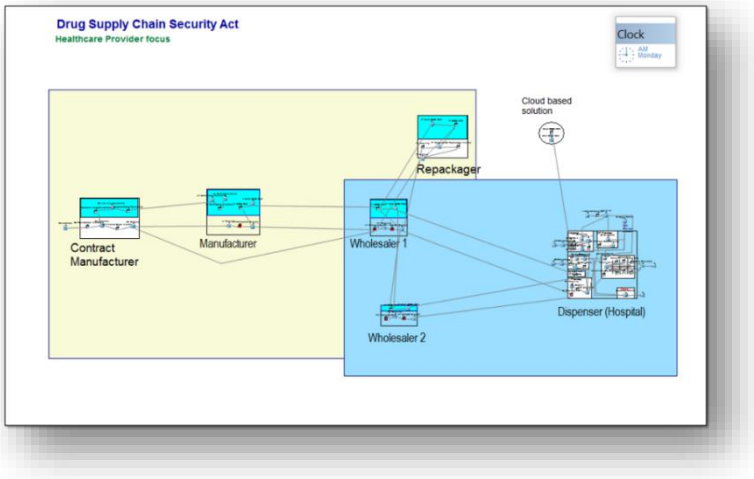

Figure 2- Sample ReferenceModel™ - Healthcare Provider Focus

The ReferenceModel Library

All ReferenceModels are retained in the Center's *Library of Collaborative Supply Chain Studies* for future reference and re-use.

Deliverables

The goal of this Study is to examine the benefits of utilizing serialized barcodes on medication and DSCSA data in the hospital setting. The Study will enable participants to gain knowledge about observable issues and challenges, to understand their major responsibilities as defined in the law, and connect with the companies that provide products and services necessary to implement. To support the express intention to share the knowledge gained with industry, this Study will produce a ReferenceModel and White Paper, both of which will be published openly and made available to industry on the Center for Supply Chain Studies (CSCS) website and other venues upon completion of the Study.

ReferenceModel(s)[1]:

This model will depict the movement of pharmaceutical product through a simulated supply chain pursuant to the Study's "High-Level Requirements." The model will show the movement of product and the information that must precede or accompany the medication.

Note

This Study will not produce standards, guidelines or comments to any regulatory body. However, output from this Study will be made available to organizations that perform those tasks.

Publishing Results

It is probable that the Study findings documented in the White Paper may have potential value to other organizations including trade associations, standards bodies, etc.

In such cases, the White Paper will be presented to those organizations for review, consideration and publication (with appropriate attribution to CSCS and Study participants).

[1] *See ReferenceModels and Simulation section for more information on this key component of the Study.*

The published ReferenceModel(s) decided upon by the participants will demonstrate key learnings from the Study, as well as present various approaches that were explored and evaluated for the collection and exchange of information to support regulatory requirements. Additionally, the model(s) will provide viewable and downloadable access to data output from the simulated scenarios.

The Center for Supply Chain Studies will publish and maintain this ReferenceModel(s) on its website. It also may be presented at other venues (*with appropriate attribution to CSCS and Study participants*).

White Paper:

The Study will produce a White Paper documenting the findings of the Study, as well as any recommendations or best practices the participants feel would be valuable. Upon completion of the Study, CSCS will openly publish the White Paper on its website. It is expected that this White Paper may also be presented at other venues (*with proper attribution to CSCS and Study participants*).

The Role of the Center for Supply Chain Studies

The Center brings together some of the foremost experts across industry, regulatory, supply chain, technology, and standards arenas to serve industry efforts and to openly publish educational and explorational materials in an open forum. At various stages in the process, these experts will be invited to participate in Studies to provide their unique perspective to the participants.

Combining expertise and knowledge with a unique supply chain simulation process, the Center creates an exciting, innovative business experience that accelerates the process of learning, discovery and decision-making, and increases the value of community collaboration.

For this Study, CSCS will facilitate the work by providing (as needed):

Simulation Platform[2]:

Using simulation software and an online component as a method for examining supply chain scenarios provides insight into product, information, patient/staff/customer and financial flow. The Center provides hosting space and an archiving facility for all Study artifacts.

Important Announcement

The Center for Supply Chain Studies is committed to complying fully with antitrust laws.

We ask and expect everyone participating in this Study to please refrain from discussing prices, margins, discounts, suppliers, timing of price changes, marketing or product plans, or other competitively sensitive topics.

If you have concerns about the propriety nature of any discussion, please inform a CSCS representative as soon as possible.

Please remember to make your own business decisions.

Thank you.

[2] *See the "ReferenceModels and Simulation" section for more information on this key component of the Study.*

Simulation Support Team:
Includes technical and coding expertise to develop ReferenceModel(s) and simulate all scenarios; supply chain expertise to support participants in designing the model(s); regulatory advisor to identify and assess relevant regulations; and standards expertise to guide the application and use of global visibility standards.

Analysis & Communications Support:
Includes analysis expertise to support development of model(s) and identification/evaluation of alternatives to be simulated; strategic writer to work with Study participants in articulating key insights to write and design the Study's White Paper; as well as marketing support to promote the work of the Study.

Logistical Support:
Includes meeting and call facilitation; dial-in and web meeting facilities; and coordination of physical on-site meetings (e.g., scheduling; planning; etc.) if desired by participants.*

** Travel, food, and lodging are at the participant's expense. In addition, there may be an additional charge for physical meeting costs.*

Expectations of Study Participants

For participating companies to realize maximum benefits from a Study, it is essential that the Study stay on schedule. This means that company-assigned participants are expected to attend Study meetings and calls, provide timely feedback and preferences, and review material within the timeline defined in the Study Schedule in the official Study Charter.

At the completion of this Study, the Facilitator will mark any open items in the activity log as "held." If time permits, these items will be addressed. If not, these items may be considered for a follow-up Study.

What to do next?

1. Read and understand this Prospectus.
2. Choose a way to participate via Convener, Underwriter, Scholarship or Invited Guest. *(See page 10.)*
3. Request a Study Agreement.
4. Sign and return Study Agreement.

Voting

At times, there may be a need to vote on whether to move to the next phase of the Study, or to include or exclude contents discussed in Study calls or meetings.

A Study participant or Facilitator may request a vote on a resolution. Each participating organization has one (1) vote.

Decisions will be decided by simple majority, and a quorum of 50% of the Study's participants is mandatory.

Voting shall be by voice, show of hands or ballot.

Preliminary Study Schedule

The Study start date and schedule will be set upon reaching 100% funding. The Center's staff will set the actual dates and socialize with the Study Team prior to the start of the Study.

The following is the generic Study schedule. The actual schedule will be set 2 weeks prior to the start date.

Milestone	Date
Kickoff	
ID Trading Partners & Key Events	
Viewer Interaction	
Participant Product/Service Info Due	
ReferenceModel Draft	
Final ReferenceModel	
ReferenceModel Guide Draft	
ReferenceModel and Guide published online	

Extending the Study

This Study will run for a fixed period of time detailed in the Study Schedule. Based on the discovery and experimentation aspects, it is feasible that there could remain issues or avenues of thought that all or some Study Team members would like to pursue.

In that event, the current Study Team will continue through to conclusion (White Paper finalization, ReferenceModel finish work and publication, etc.) and a second Study Sprint will be proposed based on the new areas of interest.

All following Study Sprints can have access to the current Study's artifacts to build upon.

Formation of a Study

Each Study is brought together by a group of companies or healthcare providers. They share in funding which allows for model variations, Study Facilitation, ReferenceModel and White Paper creation and publication, as well as online maintenance of ReferenceModel.

Group Funding Model

Studies are funded by Study Team companies. This group-funded model allows stakeholders to participate in a Study and have access to Study materials at a fraction of the cost of a whole Study. The Center also provides Scholarships to individuals, companies and healthcare providers who may not be able to contribute full funding.

All participating companies will receive:

- Access to the White Paper
- Acknowledgement of their contribution in the White Paper, ReferenceModel Library, and ReferenceModel Guide
- Priority consideration and placement in any resulting VirtualShowcase [3] that may be initiated to exhibit the ReferenceModel at industry conferences.

Funding Contribution for this Study

*The funding level for this 6-month study is **$5,000**.*

Companies committing to fund a Study will be invoiced prior to the start date. Access to Study meetings, calls and artifacts will be given to company participants once Study invoices are paid.

Ways to participate in a Study…

CONVENER:

Companies that come together to initiate and define the parameters of a Study. This group typically has the most interest in seeing the Study produce meaningful, actionable results. They also may be the subject of the Study and provide access to their facilities & operations to the Study Team.

UNDERWRITER:

Stakeholders who provide funding and other support for the Study. Because Studies are based on a group-funded model, each company provides a small percentage of the full funding needed. They have full access to all key learnings, ReferenceModels, White Papers and final educational materials. They may also sponsor Scholarships

SCHOLARSHIP RECIPIENT:

In an effort to gain access to certain Subject Matter Experts (SMEs) or to ensure the participation of key supply chain participants who may be unable to contribute financially, the Center has developed a Scholarship program where other organizations can fund scholarships for those SMEs and organizations.

INVITED GUEST:

The Center may also extend "Invited Guest" status to Subject Matter Experts (SMEs) who the Team deems necessary or beneficial to the successful outcome of a Study.

[3] *The online ReferenceModel can be accessed by Study participants to demonstrate and educate on key learnings of the Study. The ReferenceModel may later be tailored to the needs of specific conferences, seminars or other events to further share learnings of the Study.*

Participation and Recognition:

This Study will have its own page on the Center for Supply Chain Studies website and will result in the publication of a White Paper and ReferenceModel(s).

By offering several ways to participate *(via Convener, Underwriter, Scholarships, or Invited Guest)*, our goal is to enable companies to fairly initiate, partake in and benefit from Studies, and ensure that the overall value of a Study stands on its own.

Funding Period:

The funding period will run for 4 weeks.

The Study schedule (TBD), is based on attaining 100% funding. If at the end of this period the Study fails to achieve 100% funding, the participating companies shall decide whether to increase their financial support, reduce scope or cancel the Study.

If a Study achieves more than 100% funding, the Center will use the additional subsidies to produce additional ReferenceModels or variations, and may increase the number of industry experts and invited guests to participate.

Charter Revision Record

Version	Date	Change
Release V.02	TBD	Initial drafting of the Prospectus
	TBD	Prospectus becomes Charter

Current Level of Interest

Through our series of informational Study webinars and ongoing open-forum discussions with the healthcare supply chain, the Industry has expressed a great deal of interest in this Study.

To monitor the status of this Study or for an overview of all CSCS Studies currently in the Formation Phase, please visit:

www.c4scs.rg/studies-for-2016

Welcome to the Center for Supply Chain Studies.

The Center for Supply Chain Studies was established as a neutral, nonprofit, open forum with one overall mission: "*to improve supply chain efficiencies, enhance practices and improve overall patient and consumer safety through industry collaboration, exploration and education.*"

The Center hosts "Studies" as a way to bring together the foremost experts and thought leaders from industry, academia, regulatory and other arenas to take a closer look at the complex issues facing today's supply chains.

Studies are initiated by the industry and result in the publication and dissemination of resourceful evidence-based content to be housed in the Center's "*Reference & Education*" Library.

Combining expertise with the Center's ReferenceModel-based exploration and education approach creates an exciting, innovative business experience that accelerates the process of learning, discovery and decision-making, and increases the value of community collaboration and exploration.

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