



DSCSA & BLOCKCHAIN VirtualPilot™

V.02 – 1/6/17

Dear Potential Study Participant,

The Center for Supply Chain Studies (the Center) is pleased to provide this Charter for:

DSCSA & Blockchain Study:

Exploring the technology for the U.S. pharma supply chain.

This Charter may be updated as the Study progresses and will be re-distributed to all participants, accordingly.

The Study will create a [ReferenceModel™](#) (or series of models) seeks to explore the potential of applying Blockchain Technology to meet key security and trading partner trust challenges of the Drug Supply Chain Security Act (DSCSA).

Along with ReferenceModel(s), the Study will produce a White Paper and Education materials to be published on the Center's website and may be exhibited at 2017 conferences and seminars in the form of a VirtualShowcase™.

The Center 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 & Blockchain VirtualPilot™

Charter Contents

STUDY BACKGROUND	2
The Goal	2
Goal of the Study.....	2
Without bias.....	2
The DSCSA in 2023	2
2023 Challenges	3
Blockchain: Alternate way to establish trust?	4
What is Blockchain?	4
STUDY LOGISTICS	5
Study Duration.....	5
Extending the Study	5
Deliverables & Recognition.....	5
Expectations of Study Team.....	6
Role of the Center	6
Healthcare Library	6
Presentation of Findings.....	6
Group Funding Model.....	6
This Study in the news.....	6
<i>About the Center</i>	<i>7</i>

Questions? Call or email:

Bob Celeste

215.584.7374

rceleste@C4SCS.org

or

Lynette Byrnes

215.584.7374

lbyrnes@C4SCS.org



ReferenceModel-based Exploration and Education

STUDY BACKGROUND

The Goal

For 2023 DSCSA purposes, **this Study will explore the potential use of blockchain technology as a way to establish trust between trading partners in the U.S. pharma supply chain**, via:

- Providing clear examples of blockchain technology
- Determining if blockchain could work for DSCSA purposes
- Demonstrating a number of blockchain technologies or uses via simulations (ReferenceModels)
- Identifying metrics, such as:
 - Latency
 - Information governance
 - Ad-hoc trust
- Comparing blockchain solutions with other potential solutions
- Providing thought leadership to the Industry on the feasibility of using blockchain technology
- Identifying future phases of Study (e.g. blockchain & authentication at point of dispense, blockchain's use for securing regulatory documents, etc.)

Without bias

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.

The DSCSA in 2023

Effective November 2023, The Drug Supply Chain Security Act (DSCSA) states that companies in the U.S. pharma supply chain will no longer be required to pass Transaction Histories (TH) to their customers, but must have... "...systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer."

Additionally, upon request of an authorized body (i.e. FDA, State Board of Pharmacy, DEA, etc.), all trading partners in the supply chain must:

- **Share "Transaction Information" (TI)** regarding the exchange of pharmaceutical product, and
- **Produce immediate TI & collect and produce all TI data** originating from the drug manufacturer/repackager (via an interoperable electronic system).



Study Facilitator:

Bob Celeste

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

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

As he has done for over 20 years, Mr. Celeste launched the [Center for Supply Chain Studies](#) (the Center) in late 2015 to continue implementation of strategic simulation processes to address the ever-growing challenges and demands that face all stakeholders in the supply chain.

With the launch of the Center's first [ReferenceModel-based Studies](#) that examine the Drug Supply Chain Security Act (DSCSA) as it relates to a variety of subjects, Bob continues to lead the way in industry exploration and education.

Prior to founding the Center, Mr. Celeste was Senior Director at GS1 US where he worked with industry on standards-based, item-level traceability and **was the lead in developing the pharma supply chain simulation model for DSCSA, as well as the comprehensive guideline for how to apply EPCIS for DSCSA requirements.**

With a long history of working with State & Federal regulators, he also is currently working with the FDA on its Pilot Program to explore and evaluate ways to enhance the safety and security of the pharmaceutical supply chain.

In 2023, these requests may raise several questions from manufacturers, such as those depicted below:

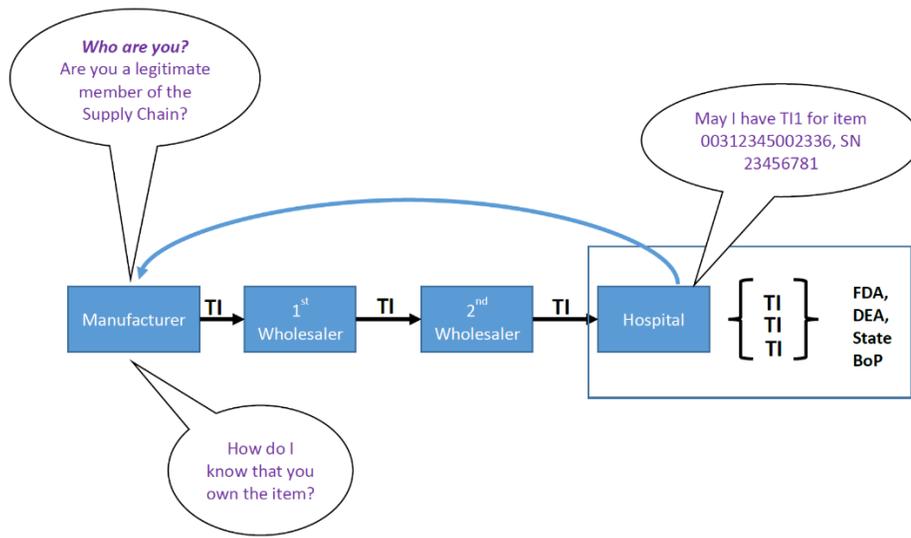


Figure 1 – 2023: Hospital – producing all TIs going back to the Manufacturer

Depending on the product's path through the supply chain, some trading partners may not have the means to properly collect and exchange TIs – leading to security and trust issues. For instance:

- 1) Are the electronic connections in place to **guarantee security**?
- 2) Are all "asking" parties **legitimately licensed** to share the TI?
- 3) Have other trading partners **actually "owned" the product**?

Today, the prevailing thought is to use a large database or central repository with a single point of entry for all parties, providing a measure of organization, consistency and inherent trust.

However, housing data in a centralized location may create complicated data governance issues, as well as leave it vulnerable to hacking or other attacks.

2023 Challenges

In looking at the appeal of blockchain, we will address some major challenges of the DSCSA requirements in 2023, including:

- Distributed environment
- Need to share data, ad-hoc, with unknowns in supply chain
- Lots of data to collect & store
- Current solutions are heavy and expensive (governance & funding)
- Big investment for a single goal (Regulatory compliance)



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.

See Q&A page:

["What is a ReferenceModel?"](#)

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.

Blockchain: An alternative way to establish trust?

As an alternative to a central repository for data...

...what if blockchain could be used for the DSCSA as a way to establish trust between trading partners in the U.S. pharma supply chain?

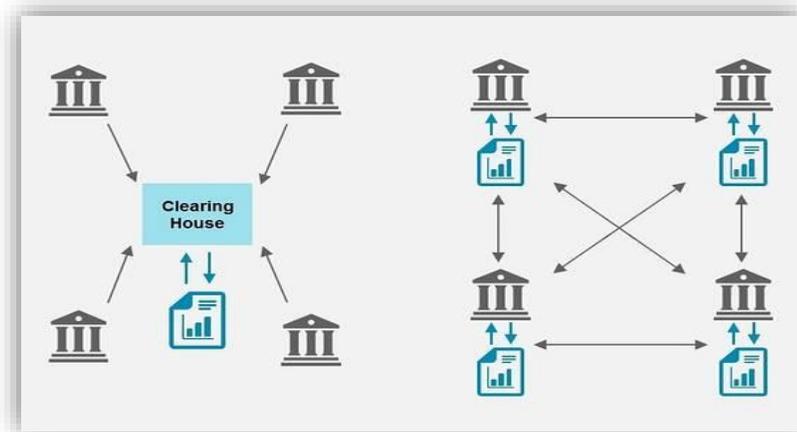


What is Blockchain?

Blockchain is a relatively new technology for providing a secure and transparent way to digitally track the ownership of assets.

According to Steven Norton (from *The Wall street Journal*, CIO
Explainer: ["What is Blockchain?"](#) Published Feb 2, 2016):

"Known by many as the technology underpinning the bitcoin digital currency, blockchain has acquired a new identity in the enterprise. At a time when companies face new challenges in data management and security, it's emerging as a way to let companies make and verify transactions on a network instantaneously without a central authority."



A distributed ledger, right, is a network that records ownership through a shared registry OLIVER WYMAN

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 Center representative as soon as possible.

Please remember to make your own business decisions.

Thank you.

The Appeal of Blockchain

- **Distributed environment** – but no central authority
- **Anonymous** – anyone can participate at any time
- **Ease of connection** – single point of entry (*don't need to know everyone*)
- **TRUSTED & SAFE**
- **Self-funded** – generates income for parties that perform necessary services
- **Diversity of technology** - could be used for other challenges, including recalls, legal documents, clinical trials, etc.

STUDY LOGISTICS:

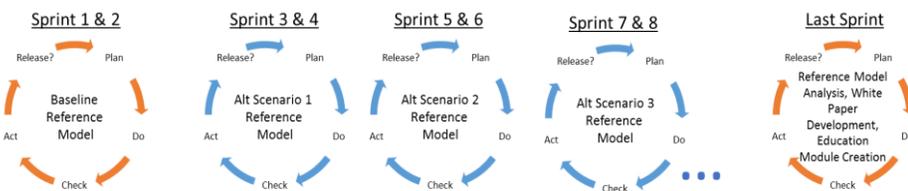


Duration of Study

The Study is currently scheduled to commence with a **Team Call on January 27, 2017** (scheduling for the first in-person meeting will be discussed on this call).

This Study is expected to last @ 6 months.

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.



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.

Extending the Study

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.

Deliverables & Recognition

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(s) that may be initiated to exhibit the ReferenceModel at industry conferences.

What to do next?

1. Read and understand this Charter.
2. Please call with any questions.
3. Sign and return Study Agreement to:
Lynette Byrnes
(lbyrnes@C4SCS.org)
4. **For more payment options** (via credit card, partial payments, etc.), visit:
www.c4scs.org/studypayment/

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.

Expectations of Study Team

It is essential that the Study stay on schedule. This means that company-assigned participants are expected to attend certain Study meetings and calls, provide timely feedback and preferences, and review material within the timeline defined in the Study Schedule (*to be prepared shortly*).



Role of the Center

During a Study, the Center for Supply Chain Studies provides:

- Study Facilitation
- Logistical support (scheduling of meetings, etc.)
- Simulation Platform & Simulation Support Team
- Expert Analysis and Marketing/Communications support

Healthcare Library

All ReferenceModels are retained in the Center's online *Healthcare Library* for future reference and re-use.

Presentation of Findings

A list of targeted venues for 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.

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.

This Study in the news...

Please click the link below to read about this Study, including why it was initiated and the overall mission.

(From **RxTrace Online**, published Dec. 5, 2016).

"Could Blockchain Technology Be Used for DSCSA Compliance?"

<https://www.rxtrace.com/2016/12/could-blockchain-technology-be-used-for-dscsa-compliance.html/#respond>

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



ReferenceModel-based Exploration and Education

The Center for Supply Chain Studies was established in late 2015 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 [Healthcare 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.

www.C4SCS.org