



DSCSA & BLOCKCHAIN

Phase 2: Proof of Concept

V.06 – 11/20/17

Dear Potential Study Participant,

The Center for Supply Chain Studies (the Center) is pleased to provide this Charter for: **DSCSA & Blockchain Study Phase 2: Proof of Concept**. This Charter may be updated as the Study progresses and will be re-distributed to all participants, accordingly.

This Study (Phase 2) will demonstrate viability of blockchain solutions using the scenarios, processes and information identified in *DSCSA & Blockchain Study: Phase 1*. Goal is to present these concept variations in the Spring 2018 at influential conferences and education seminars.

The Center hosts and facilitates group-funded *Studies* as a way for the industry to openly exchange ideas and share expertise, supporting our belief that the combination of unique perspectives and viewpoints leads to greater discovery and innovation.

We appreciate feedback and hope you'll join us.

Warmly,

The Center's Study Outreach Team



PHASE 2 - Proof of Concept -

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For Study questions, contact:

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To participate, contact:

Christina Scordia:
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Phone: (215) 771-5885

STUDY OVERVIEW

Goal

Based on the intelligence and findings gleaned from our recent "DSCSA & Blockchain: Phase 1" Study, Phase 2 will develop Proof of Concept variations to demonstrate the *viability* of blockchain solutions for the supply chain.

Background

Phase 1:

We gained valuable insight and useful intelligence from the various simulated ReferenceModels created in our recent exploration of how blockchain technology can address the trust challenges of the Drug Supply Chain Security Act (DSCSA).

Phase 2:

Coming out of the virtual environment in Phase 1, this Study will use real-world conditions (Proof of Concept variations), to verify the data gleaned from the Phase 1 ReferenceModels.

Methodology

Phase 2 will utilize current blockchain and database technologies to create Proof of Concept (PoC) variations that will demonstrate several supply chain processes, such as:

- Governance variations
- Data-persistence variations
- Supply chain capabilities
- Trading partner variations
- Service variations
- Other performance measures

Specifically, the Study Team will create the PoC's as follows:

1. As a group, determine most desirable features for PoC's.
2. Participating industry Team members (or Center) to provide data sets for demonstration.
3. Willing participating technology companies will create the working demos.
4. Participants from industry will provide the rest of the Team with consultation on supply chain processes.

Without bias

Study will be conducted *without bias*. Observations will not represent the operations or solutions of any specific company or organization.



Study Facilitator:

Bob Celeste

Bob's deep understanding and knowledge of the healthcare supply chain, including current standards and technologies, is unparalleled.

His ability to harness his expertise and innovate around the complexities of track & trace implementation, serialization and regulatory compliance has made him a trusted industry partner.

Along with his work with both State and Federal Regulators, Bob is often asked for his insights and opinions by the FDA, State Boards of Pharmacy and other governing organizations. Most recently he was tapped by the USAID and international regulators to advise on the identification and tracking of drugs and medical supplies.

Celeste launched the [Center for Supply Chain Studies](#) in 2015 to continue his practice of utilizing strategic simulations to address the challenges and demands of the supply chain. His expertise extends across many industries, including Pharmaceutical, Consumer Goods, Fresh Foods, Aerospace, Automotive, Specialty Chemicals and others.

Prior to founding the Center, Bob was Sr. Director at GS1 US where he worked with industry on standards-based, item-level traceability and was the lead in developing the first DSCSA implementation guideline.

STUDY DETAILS

Important dates

- Pre-Launch calls began: **November 2nd, 2017**
- Study Launch: **December 2017** (exact date TBD)

Participation fee

"Core Team" participation fee is \$6,500 per company.
(w/unlimited seats for each individual company)

Commitment

Study Team is expected to attend as many weekly calls as possible. In addition, Center will arrange @ 2-3 in-person meetings (dates and locations TBD).

Duration

This Study is expected to last @ 6 months.

Deliverables

Study will produce Proof of Concept variations, White Paper and education materials. Overall goal is to present these concept variations in the Spring 2018 at influential conferences and education seminars.

Recognition

All participating companies will receive:

- Full access to the White Paper
- Acknowledgement of their participation
- Priority consideration and placement in any resulting presentations of the Proof of Concepts

Role of the Center

During a Study, the Center provides:

- Study Facilitation
- Logistical support (scheduling of meetings, etc.)
- Simulation platform & simulation support Team



Anti-trust statement

The Center is committed to full compliance with all 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 the Center facilitator as soon as possible.

Please remember to make your own business decisions.

Thank you.

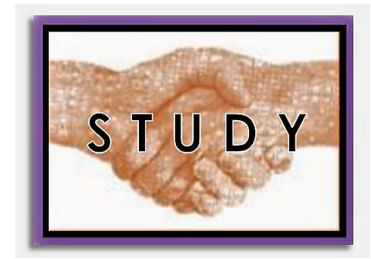
Voting

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.



Online Library

All completed Study materials are archived online in the Center's [Library](#) for future re-use and reference.

Presentation of findings

A list of targeted venues to present the Proof of Concept variations in the Spring of 2018 will be discussed with and agreed-upon by this Study Team.

Group-funding model

Studies are group-funded by Study Team companies. This collaborative model allows stakeholders to share in the costs and more easily bring Study explorations to life.

"Phase 1 Study" in the News

Please **click the article titles below** to see what the media is saying about Phase 1 of this exploration, including why it was initiated and what the Study Team is discovering.

"Could Blockchain Improve Pharma Supply Chain Security?"
PharmTech.com / August 1, 2017

"Blockchain: the technology to make DSCSA work after 2013?"
Pharmaceutical Commerce / July 24, 2017

"Is Blockchain the Solution to Drug Traceability?"
Pharmaceutical Online / July 17, 2017

"Blockchain Reigns at GS1 Connect 2017"
RxTrace / June 26, 2017

What to do next?

1. Read and understand this Charter.
2. Contact **Christina Scordia** (cscordia@C4SCS.org) for a Study Agreement.
3. Sign Agreement and return via email to Christina at email above.





An open industry forum for
study, compliance and education.

Our mission. The Center for Supply Chain Studies opened its doors in 2015 as a nonprofit, vendor-neutral, open industry forum. Through exploration and education, our goal is to assist the pharma supply chain in its efforts to improve efficiencies and streamline compliance.

Partners in discovery. Trusted as forward-thinking thought leaders, we closely monitor the industry and share our insights on emerging technologies and trends with all stakeholders.

Regulatory guidance. With a special focus and expertise on the [Drug Supply Chain Security Act](#), we provide guidance and clarification of government standards and regulations surrounding track & trace implementation, serialization and other aspects of the supply chain.

Group exploration and education. We host group-funded [Studies](#) as a way for the industry to more easily exchange ideas and share expertise – supporting our belief that the diversities in perspectives, viewpoints and experience may lead to greater discovery and innovation.



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