

Blockchain for the Cold Chain

Blockchain for the Cold Chain

Managing sensor data

V.02 – 11/20/17

Dear Potential Study Participant,

The Center for Supply Chain Studies (the Center) is pleased to provide this Charter for our **Blockchain for the Cold Chain VirtualPilot** that will examine use of blockchain technology to capture and disseminate cold chain sensor data.

The Study will generate simulated ReferenceModels, White Paper and education materials.

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.

Trusted by the industry as forward-thinking thought leaders, we carefully examine and help clarify the implications of regulatory changes and forecasts, as well as monitor new technologies, processes and other industry trends that may impact the pharmaceutical supply chain.

We hope you'll join us.

Warmly,

The Center Study Outreach Team

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For Study questions, contact:

Bob Celeste: rceleste@C4SCS.org
Lynette Byrnes: lbyrnes@C4SCS.org

To participate, contact:

Christina Scordia:
Email: cscordia@C4SCS.org
Phone: (215) 771-5885



STUDY OVERVIEW

Goal

The Study Team will examine the use of blockchain technology to capture and disseminate cold chain sensor data.

Background

We gained valuable insight and useful intelligence from the ReferenceModels created in our recent "DSCSA & Blockchain" Study. By leveraging some of these findings, we seek to examine the possible benefits of applying blockchain technology to the cold chain.

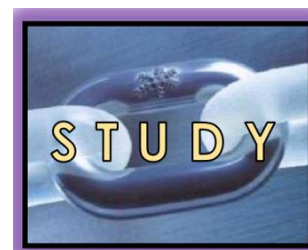
Although most of our simulated models are based on solid dose medications, they can be adjusted for this Study to examine cold chain processes, data and other scenarios.

Methodology

- ◉ Identify/define a common set of cold chain data criteria
- ◉ Demonstrate the movement, use and trading partner reaction to temperature sensor and other measures (*i.e. humidity, vibration, light, etc.*)
- ◉ Explore various sensor inputs and how they can be incorporated (*i.e. data loggers, online sensors, binary indicators, etc.*)
- ◉ Test different process flows, data sets and responses/alerts
- ◉ Investigate new connectivity opportunities that may aid in the availability of sensor data (*i.e. cell phones, Bluetooth*)
- ◉ Produce cold chain sensor data capture & sharing models

Without bias

Study will be conducted *without bias*. The final observations will not represent the operations or solutions of any specific company or participating 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 14th, 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 ReferenceModels, White Paper and education materials to be published on the Center's website.

Recognition

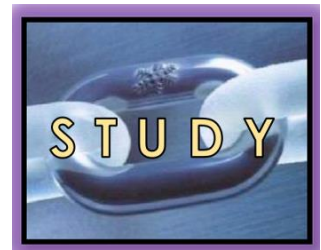
All participating companies will receive:

- Full access to the White Paper
- Participants will have special access to all ReferenceModel scenarios developed during this Study.
- Acknowledgement of their participation

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?"

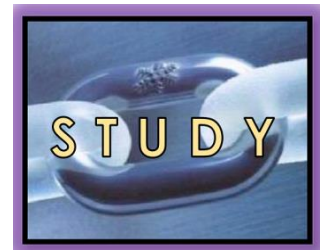
Pharmaceutical Commerce / July 24, 2017

"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.

The Center acknowledges SIMUL8 Corporation
Provider of Study Simulation Software

SIMUL8

www.simul8.com



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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