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CENTER FOR SUPPLY CHAIN STUDIES™

"DSCSA & Master Data Management" VirtualPilot™

definition

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.

The FDA Pilot Program represents a unique opportunity to demonstrate the use of MDM techniques in context with the DSCSA requirements.

Currently, few trading partners are able to transact DSCSA information (TI, TH, TS) in varied formats and configurations. This Study (or VirtualPilot[2]) has been initiated 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.

Additionally, this VirtualPilot 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*

deliverables

This VirtualPilot will produce a ReferenceModel, White Paper and education materials. This content will be published on the Center's website and may be exhibited at upcoming 2016-2017 conferences and seminars.

current phase

| Definition | **FORMATION** | Scheduling | Execution | Delivery | Closed |

[1] *More detailed information can be found on the FDA's website as well as in the Federal Register Notice,* ***Agency/Docket Number FDA-2016-N-0407.***

[2] *A* ***VirtualPilot™*** *is computer-based simulation modeling that allows companies to analyze many scenarios at a fraction of the time and cost of a typical pilot, resulting in a blueprint for real-world piloting or implementation.*

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