DSCSA Verification to Improve Product Traceability at FMOL Health System

FDA Pilot Program

Project Pilot Report

2022-12-01

Chris Chandler, PharmD

[Version 1.64]

Reviewed and Approved by:

Chris Chandler	2022-12-01
FMOLHS Pilot Project Coordinator	Date (YYYY-MM-DD)
FDA Consultant	Date (YYYY-MM-DD)

Revision Log

Revision	Date (yyyy-mm-dd)	Description of Changes
00	2019-05-31	Progress Report Month 1
1.1	2019-06-30	Progress Report Month 2
1.2	2019-07-30	Progress Report Month 3
1.3	2019-08-30	Progress Report Month 4
1.4	2019-10-17	Progress Report Month 5
1.5	2019-11-26	Progress Report Month 6
1.6	2020-03-31	Progress Report Month 10
1.62	2020-06-24	Final Report
1.63	2020-07-31	Final Report with detail requested by FDA
1.64	2022-12-01	Final Report with links to latest findings

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I. Executive Summary

- **Goals-** automate the delivery and confirmation the Dispenser has valid T3 for each product received from trading partners to the last mile.

- **Objectives-** capture and achieve perfect order via electronic data interchange (EDI) and automatic identification and data capture (AIDC) for a touch-less process from supplier through pharmacy receiving areas.

- **Processes that will be studied-** validation via DSCSA business rules running in the background of established supply chain practices to compare wholesaler T3 (EDI 856) with the bar code scanning data captured by the Dispenser upon receipt of the shipment. We (FMOL, MCK, CTX) acknowledge the FDA's request for unit-level traceability, however lot and serial numbers are not electronically shared from the Wholesaler to Dispenser at this time.

- **Evaluation methods-** Evaluate the success rate of automatically matching the EDI 856 and barcode scanning data from receipt of the Product. Identify any data, system, or process challenges which limit the ability to automate this process of documentation to meet DSCSA requirement. *For the full intent of DSCSA to improve the recall process via a secondary objective- in future pilots to carry the traceability to the patient record at administration or dispense or final decommission via return or destruction with a mock recall as proof of concept as previously studied by* https://www.gs1.org/docs/healthcare/12h05_Traceability_put_into_praxis_MAGER_BONE_DREES_CHANDLER_eng.pdf
    - From Sep 5-16th 2019 we matched all 1017 lines of T3 (EDI 856) from McKesson at one of our Medical Centers with 994 NDC Receipt scan lines (EDI 861) with a 98% match; 2% (23) T3 lines did not have a receiving scan match due to item mismatch or failed scans resulting in manual receiving via McKesson Connect software program.

- **Proposed start and finish dates of the pilot project-** Testing of the additional invoice field in EDI at McKesson began April 2019 and will be reported to the FDA at the end of each month starting May 31 2019 with a final to our Healthcare Transformation Group Summit at FMOLHS in Oct 2019 https://www.healthcaretransformationgroup.com/summit.

II. Progress Reports- Description of tasks, effort and schedule

Task	Who	Status	Notes
Flow Chart Procedures and EDI	Chris	Complete	Collect process flow diagrams from each partner and combine for FMOLHS 3-way match process flow diagram for EDI verification (see references)
FMOLHS Pharmacy receiving scans to generate 861	All	Complete	• Dispenser account #47768 using McKesson Connect handhelds to generate an 861 receive event • Sync malfunction 7/10 for 7/9 order and 861 output was lost; McKesson suggests using tech support in the future to preserve handheld data
McKesson modify 861 map; format specs to ConsortiEX	McKesson-David	Complete	Initial 856 modifications; final decision use 861 format with specs by 6/6/19 • Add REF segment "IV" qualifier for invoice (example below in references) • ASN invoice# and 856 invoice# match however can have multiple 856 for 1 invoice
ConsortiEX 861 preparation to receive	ConsortiEX-Kate	Complete	ConsortiEX and McKesson EDI teams: • 856 UoM CA=case, change 861 CS to match (810 also uses CS), add invoice # to both • 861 MAN segment is shorter (only 7 digits) vs 856; McKesson logic build to match • Status on the handhelds is "received" or "not received"; use the "received quantity" • 861 receipt logic matches the corresponding 856 line of data based on item #; note the 856 may have the same NDC number appear multiple times
McKesson purchases with alternate T3 supplier for drop ship- alert via 855	McKesson-David	Phase 2	**Problems encountered-Drop shipments** • Drop ships- notification from McKesson via PO or Ack EDI 855 on alternate source for T3 • MPB drop ship T3 from McKesson- corrected/missing T3 for replacement items from McKesson MPB- TBD correct ship date on T3 • Logic built to assume UoM matches the saleable unit • 9/6/19 completed 855 setup and mapping all MPB documents • 9/27/19 remapped 855 as discussed above • 10/14/19 updated 855 map to include the BAK10: DO on MPB items and drop ships

ConsortiEX 855 preparation to receive	ConsortiEX-Katie	Phase 2	ConsortiEX reviewing specs and sample data
			• 9/10/19 transmit all 855 data (not just drop ships)
			• 10/1/19 855 leave BAK10 field Blank for MPB (blank for all McKesson 855)
			• Software Enhancements- bar code scanning T3 verification:
			  ○ **Auto-match** T3 via Advance Ship Notice EDI 856 or PO Ack EDI 855 (ordered, to include drop ships and alternate suppliers) and generate EDI 861 (pharmacy receiving)
			  ○ **Manual-match** T3 via 856; paper scan auto-upload
			  ○ **Quarantine**- alert receiver of missing T3
			• Push scan of DSCSA Product Identifier, Lot Number, Expiration Date and Serial Number to supplier, inventory system, point-of-care cabinets or EHR
			• Drop shippers not supporting EDI connection- notification (see attached); work with suppliers and FDA on paper or portal only or supplier exemptions

III. Lessons Learned Report (include Interfaces, Dependencies, Risks, Results including unplanned)

FMOLHS

- EDI process flow for FMOLHS 3-way match process differs for accounts payable (Infor format) versus missing product/data exceptions upon receiving with wholesalers requiring additional manual processes.
- EDI 861 can only be generated if the policy is handheld use only. Sync malfunctions do not result in loss of 861 output; calling McKesson tech support preserves handheld data download.
- EDI connections for drop shipment and direct supplier T3 remain inconsistent; we are still not 100% electronic and continue getting paper and/or directed to portals. Also lack a standard listing of products exempted from providing DSCSA T3.

ConsortiEX

- McKesson Plasma & Biologics orders, other Drop Shipments, and Non-McKesson orders need manual verification.
- The matching process required customization to the EDI transactions which needs to be maintained, and also replicated if this was expanded to other trading partners.
- If for any reason the barcode scanner is not used for receiving, even for McKesson Pharma items - the orders need to be manually verified.
- This verification process occurs after the product has been received and accepted into Inventory. The goal is to catch any suspect product/product missing T3s prior to receipt.
- This process does not capture the Lot/Expiration info off the product, so can't be automatically added to the T3 record for search ability.

Future Opportunity- continue for Phase 2 https://info.consortiex.com/fda-epilogue-request-form to develop a comprehensive solution that will:

  - Incorporate 855 Order data and bar code scans to proactively identify drop-shipments
  - Handle all received shipments – not just the ones with electronic EDI records, or just from one trading partner
  - Capture Lot # and Expiration date directly from 2D barcodes on delivered drugs
  - Check for a T3 at the time of receiving, and prevent receiving product that does not already have a valid T3
  - Further insight to a secure supply chain as noted in February 2020 Office of the Inspector General Report *"Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain"* www.oig.hhs.gov/oei/reports/oei-15-17-00460.asp

McKesson

- MPB drop ship process for corrected/missing T3 for replacement items is under development.

IV. Resources

- **Submitter**: Chris Chandler , PharmD (FMOLHS Logistics One 12100 Little Cayman Ave Baton Rouge LA 70898 630-815-6183 chris.chandler@fmolhs.org chriscollinschandler@gmail.com William Mosser VP William.mosser@fmolhs.org and Lakisha Bowie Lakisha.bowie@fmolhs.org (FMOLHS 14,000+ employees Logistics One 12100 Little Cayman Ave Baton Rouge LA 70898.

- **Partners** for procurement DSCSA T3 portals for all FMOLHS 20 Pharmacies
    a. ConsortiEX 3rd party DSCSA Service Provider 1000 N Water St Suite 950, Milwaukee WI, 53202; Company Size under 500 employees.
        i. Neal Long (attending FDA Strategy Meeting in-person) neal.long@consortiex.com
        ii. Kate Edwards (attending FDA Strategy Meeting telecon) kate@consortiex.com
    b. McKesson Pharma Wholesale Distributor 6555 Hwy 161, Irving, Texas and the company size is 80,000 employees.
        i. Scott Mooney (attending FDA Strategy Meeting telecon) Scott.Mooney@McKesson.com

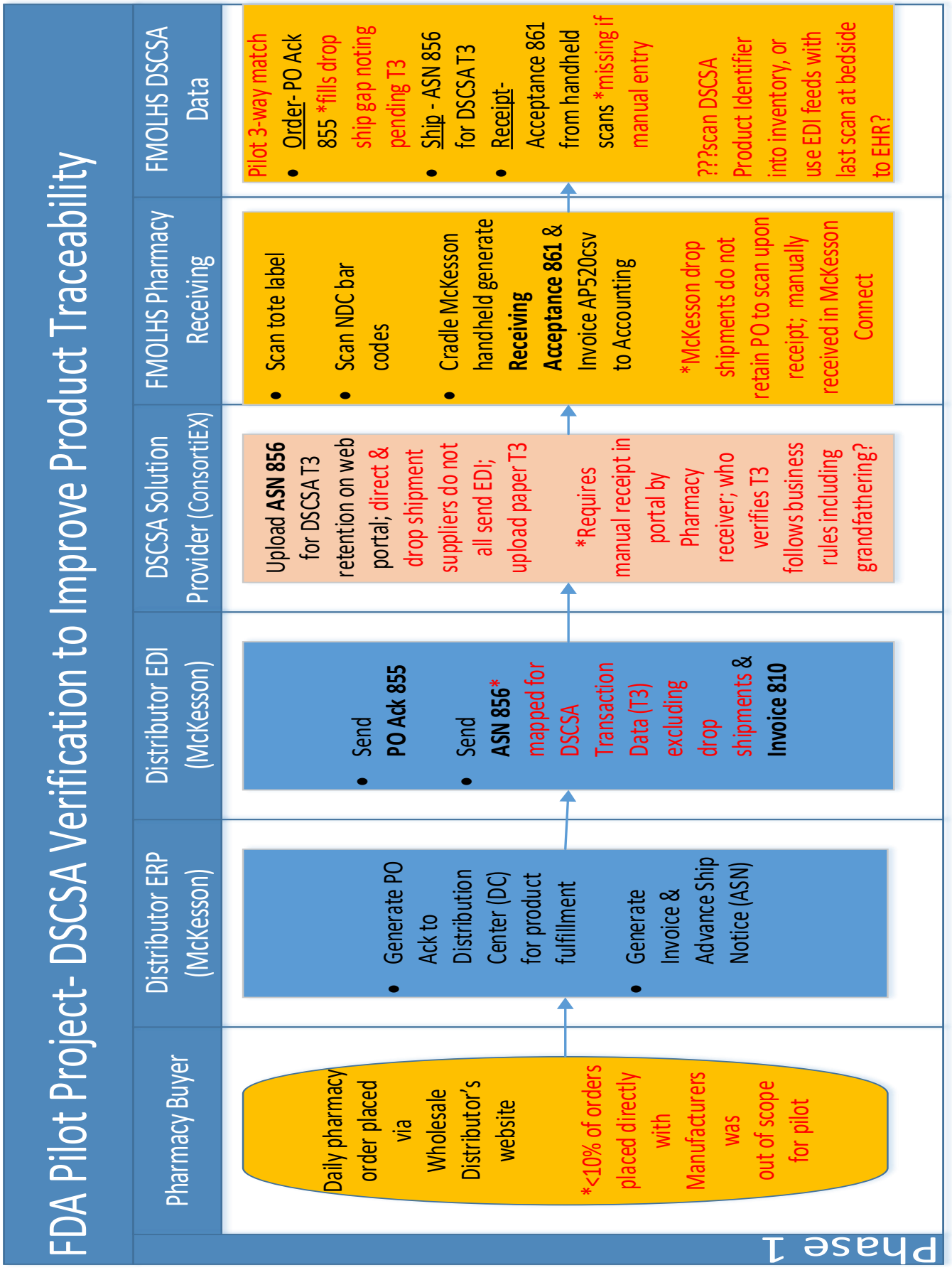
- **Product(s) that will be used in the pilot project and Location(s) where pilot project will be performed** DSCSA T3 for all FMOLHS 20 Pharmacies (Headquarters FMOLHS Logistics One 12100 Little Cayman Ave Baton Rouge LA 70898).

V. References

- Acronyms
    - EDI Electronic Data Interchange
- FDA Pilot Programhttps://www.federalregister.gov/documents/2019/02/08/2019-01561/pilot-project-program-under-the-drug-supply-chain-security-act-program-announcement
    - **Publication- To ensure that all supply chain members benefit from the information generated by the DSCSA Pilot Project Program, FDA intends to make the following information about each pilot project of the program available to the public in a final program report:** (1) The names and industry sector(s) of the pilot project participant(s); (2) the pilot project's objectives and evaluation methods; (3) the duration of the pilot project; and (4) the key findings and lessons learned from the pilot project. FDA intends to post the information related to the DSCSA Pilot Project Program and the final program report on FDA's website.

    - **Records Retention- Any records generated by a participant while conducting a pilot project should be maintained in accordance with the participant's normal recordkeeping practices**. For pilot projects that involve partnering entities, the partnering entities should decide who is responsible for the records generated in the course of conducting the pilot project. FDA recommends that participants maintain the progress reports and final report for its pilot project for at least 1 year after completion of the pilot project.

- OIG Report *"Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain"* OEI-05-17-00460 February 2020 www.oig.hhs.gov/oei/reports/oei-15-17-00460.asp


FDA Pilot Project- DSCSA Verification to Improve Product Traceability
Phase 1
Pharmacy Buyer
Distributor ERP (McKesson)
Distributor EDI (McKesson)
DSCSA Solution Provider (ConsortiEX)
FMOLHS Pharmacy Receiving
FMOLHS DSCSA Data
Daily pharmacy order placed via Wholesale Distributor's website
*<10% of orders placed directly with Manufacturers was out of scope for pilot
• Generate PO Ack to Distribution Center (DC) for product fulfillment
• Generate Invoice & Advance Ship Notice (ASN)
• Send PO Ack 855
• Send ASN 856* mapped for DSCSA Transaction Data (T3) excluding drop shipments & Invoice 810
Upload ASN 856 for DSCSA T3 retention on web portal; direct & drop shipment suppliers do not all send EDI; upload paper T3
*Requires manual receipt in portal by Pharmacy receiver; who verifies T3 follows business rules including grandfathering?
• Scan tote label
• Scan NDC bar codes
• Cradle McKesson handheld generate Receiving Acceptance 861 & Invoice AP520csv to Accounting
*McKesson drop shipments do not retain PO to scan upon receipt; manually received in McKesson Connect
Pilot 3-way match
• Order- PO Ack 855 *fills drop ship gap noting pending T3
• Ship - ASN 856 for DSCSA T3
• Receipt- Acceptance 861 from handheld scans *missing if manual entry
???scan DSCSA Product Identifier into inventory, or use EDI feeds with last scan at bedside to EHR?

Sample 861:

ISA*00* *00* *01*177667227 *ZZ*CONSORTIEX *190620*1126*U*00401*200170067*0*P*>~
GS*RC*177667227*CONSORTIEX*20190620*1126*200001307*X*004010~
ST*861*0001~
BRA*127S370400*20190509*06*1~
REF*IV*7133611253~
DTM*050*20190509~
PRF*rhino ~
N1*SU*MCKESSON~
N1*ST**91*320552~
RCD*1*2*EA~
SN1**2*EA~
LIN*1*VC*3484417*ND*50580064601*UP*30045064660~
MAN*CA*5911715~
CTT*1~
SE*13*0001~
GE*1*200001307~
IEA*1*200170067~

Sample 855:

ISA*00* *00* *01*177667227 *ZZ*CONSORTIEX *191001*0740*U*00401*200884923*0*P*/~
GS*PR*177667227*CONSORTIEX*20191001*0740*200000147*X*004010~
ST*855*0001~
BAK*06*AC*093019DS1 *20190930*****20190930*DO~
N1*ST*OUR LADY OF LOURDES RMC*91*477618~
N3*4801 AMBASSADOR CAFFERY~
N4*LAFAYETTE*LA*70508~
N1*SE*MCKESSON*1*177667227~
N1*BY*OUR LADY OF LOURDES RMC*11*FO2601741~
PO1*1*1*EA*1995**VC*1713379*ND*09978000199~
PID*F****APLIGRAF 3IN UN DS 1UNIT~
ACK*IA*1*EA****VC*1713379*ND*09978000199~
CTT*1~
SE*12*0001~
GE*1*200000147~
IEA*1*200884923~

Missing EDI

Mfr/Supplier Name	EDI?	ITEMS
AGAMATRIX INC		
ALEXION PHARMA DS MPB		
ALLERGAN PHARMACEUTICAL	N	BOTOX, DEXAMETHASONE IMPLANT
ASTRAZENECA / MCK SP/MPB		
BAXALTA US INC DS MPB		
BAXTER MD		
BTG INTERNATIONAL INC MPB		
ELI LILLY / MCK SP / MPB		
ENDO PHARMACEUTICALS	N	VALRUBICIN, HISTRELIN IMPLANT
ER SQUIBB / MCK SP / MPB		
GE HEALTHCARE		
GENENTECH/MCK SP/MPB		
GENZYME A SANOFI CO		
GENZYME CORP DS MPB		
GORDON LABORATORIES		
GSK / MCK SP MPB		
HOPE PHARMACEUTICALS	N	SODIUM THIOSULFATE
ICS/BIOGEN/TYSABRI DIRECT		
ICS/MILLENNIUM DIRECT		
JANSSEN / MCK SP / MPB		
JOM PHARM/MCK SP/MPB		
LLORENS PHARMACEUTICALS I		
MEDISCA INC		
MERCK / MCK SP / MPB		
MERCK SHARP & DOHME	N	ALVIMOPAN, ZOSTER VACCINE, MMR VACCINE, VARICELLA VACCINE
MERZ NORTH AMERICA		
NOVARTIS PA /MCK SP/ MPB		
OTSUKA AMERICA PHARM	N	TOLVAPTAN
PACIRA PHARMACEUTICALS IN		
PAR PHARM / STERILE PROD	N	DANTROLENE
PFIZER INC		
PIERRE FABRE	N	PROPRANOLOL
PIRAMAL CRITICAL CARE DS	N	BACLOFEN
SAFECOR HEALTH LLC	N	NIMODIPINE
SAOL THERAPEUTICS INC		
SEATTLE GENETICS DS MPB		
TERSERA THERAPEUTICS LLC	N	GOSERELIN
THERACOM/SHIRE/ELAP/VPRIV	N	VELAGLUCERASE

*we anticipate this list changing over time, refer to https://info.consortiex.com/fda-epilogue-request-form