

The background features a network diagram with white nodes and lines on a light gray gradient. A dark purple trapezoidal shape is positioned in the lower half of the image, containing the text for the episode.

Partnership for DSCSA Governance

**Advancing Collaborative, Timely Implementation
of DSCSA Interoperability**

Episode 3: Verification

Webinar Series (Register at <https://dscsagovernance.org/blueprint/>)

•Webinar Episode 1: DSCSA Overview, Interoperability, & the Role of ATPs

- February 23, 1:00 – 2:00pm ET
- Register [HERE](#).

•Webinar Episode 2: TI/TS Exchange

- March 1, 1:00 – 2:00pm ET
- Register [HERE](#).

•Webinar Episode 3: Verification

- March 9, 1:00 – 2:00pm ET
- Register [HERE](#).

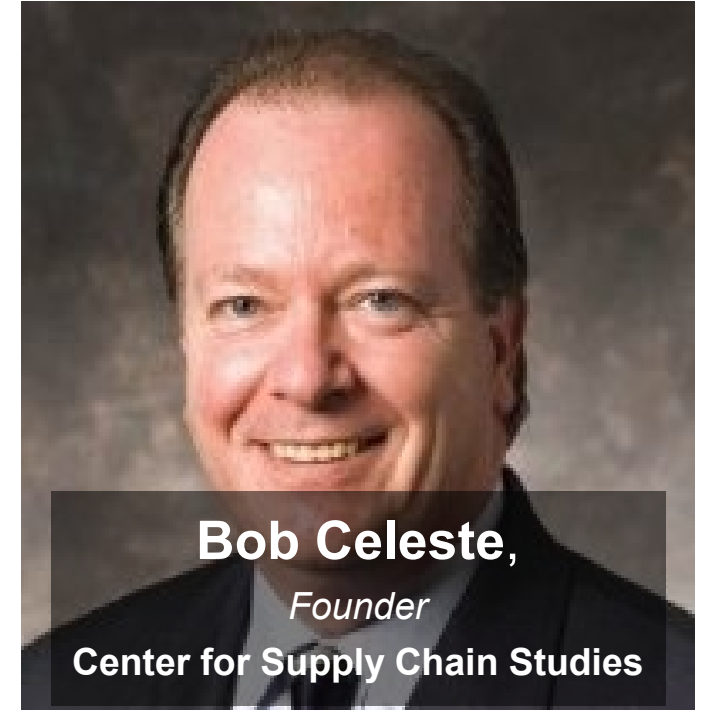
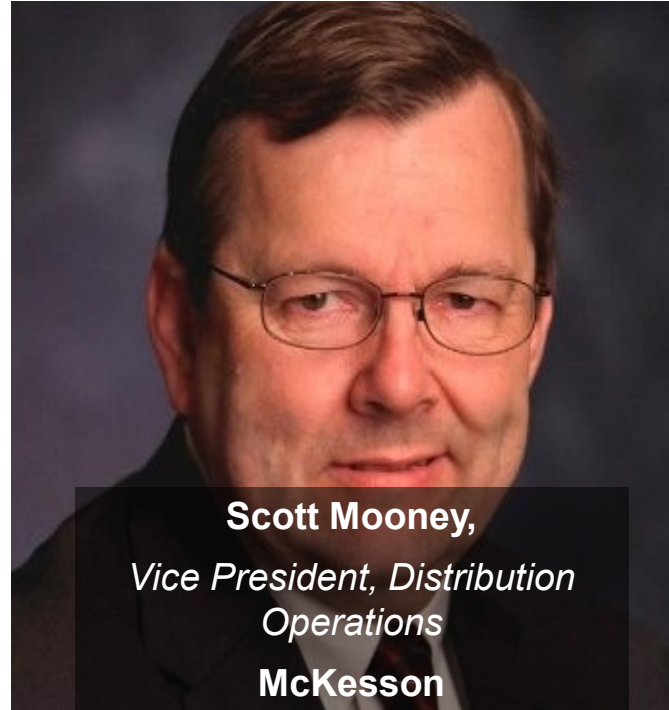
•Webinar Episode 4: Tracing

- March 16, 1:00 – 2:00pm ET
- Register [HERE](#).

•Webinar Episode 5: Credentialing

- March 23, 1:00 – 2:00pm ET
- Register [HERE](#).

Today's Speakers



The Partnership for DSCSA Governance (PDG)

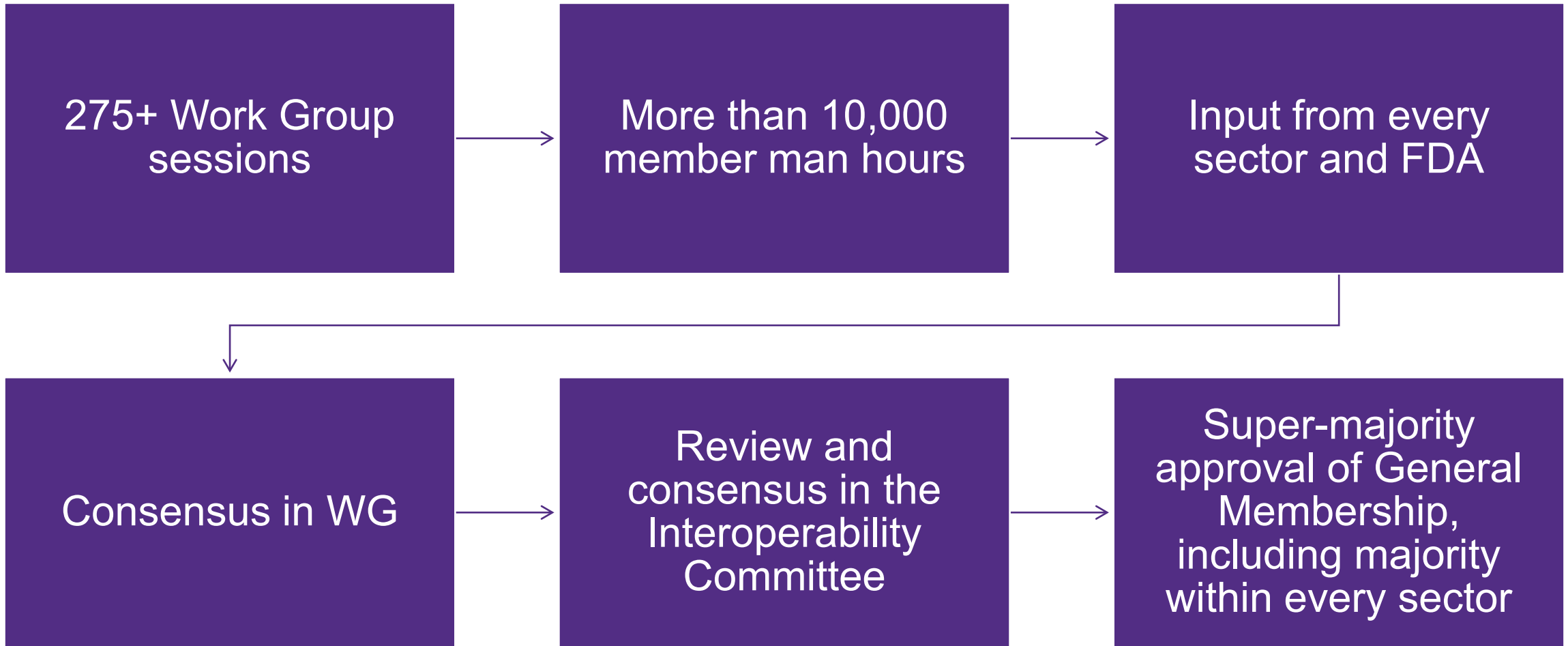
PDG is a collaborative forum and FDA public-private partnership dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.DSCSAgovernance.org

Membership

Accenture • Advasur, LLC • American Pharmacists Association (APhA) • AmerisourceBergen • Apotex Corp. • Association for Accessible Medicines (AAM) • AstraZeneca • Bayer U.S., LLC • Be4ward Ltd • Biocon Pharma • Blue Link ERP • Bristol Myers Squibb • Cardinal Health • Cleveland Clinic • ConsortiEX, Inc. • CVS Health • DirectTrust • Eli Lilly and Company • Emergent BioSolutions, LLC • Endo Pharmaceuticals • Eversana Life Science Services, LLC • Excellis Health Solutions • E2E VISIBILITY, Inc. • Gateway Checker • Geisinger Health • Genentech • Gilead Sciences, Inc. • GS1 US (Liaison Member) • Harmony Biosciences Holdings, Inc. • Healthcare Distribution Alliance (HDA) • Hercules Pharmaceuticals, Inc. • InfiniTrak, LLC Inmar, Inc. • International Warehouse Logistics Association (IWLA) • Johnson & Johnson Services, Inc. • Kaiser Permanente • LedgerDomain • Legisym, LLC • LSPediA Inc. • McKesson Corporation • Medline Industries • Meijer Pharmacy • Movilitas Consulting, LLC • National Association of Boards of Pharmacy (NABP) National Community Pharmacists Association (NCPA) • National Council for Prescription Drug Programs (NCPDP) (Liaison Member) • Navitas Life Sciences • Novo Nordisk, Inc. • Optel Group • OrderInsite, LLC • Pfizer, Inc. • Pharmaceutical Research and Manufacturers of America (PhRMA) • Providence Health Technologies, LLC • rfxcel Corporation • Sanofi • SAP SE • Second Generation LTD • SerialLab • Spherity • Systech TraceLink Inc. • TrackTraceRx • Two Labs • UNC Health • Upsher-Smith Laboratories, LLC • Uptown Pharmacy • Vantage Solutions • VeV Scientific, Inc • Walgreen Co. • Walmart Inc. • XATP





Chapter 3: TI/TS
Exchange Functional
Design
Published February 2023

Chapter 4: PI Verification
Functional Design
Published February 2023

Chapter 5: Tracing Functional
Design
Published February 2023

Chapter 6: Credentialing and User Authentication
Functional Design
Forthcoming

Chapter 2: Functional Design for Interoperability
Published February 2023

Chapter 1: Compliance and Business Requirements
Published July 2021



Product Identifier Verification

vs.

Verification Systems

“(28) VERIFICATION OR VERIFY.—The term ‘verification’ or ‘verify’ means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

Manufacturers, “upon receiving a request for verification **from an authorized** repackager, wholesale distributor, or dispenser that is **in possession or control** of a product such person believes to be manufactured by such manufacturer, a **manufacturer shall**, not later than **24 hours** after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, **notify** the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer.”

**Verification in
Suspect Product
Investigation**

**Saleable Return
Verification**

Beginning November 27, 2023, the following interoperable, electronic systems and processes are required under 582(g)(1)(C):

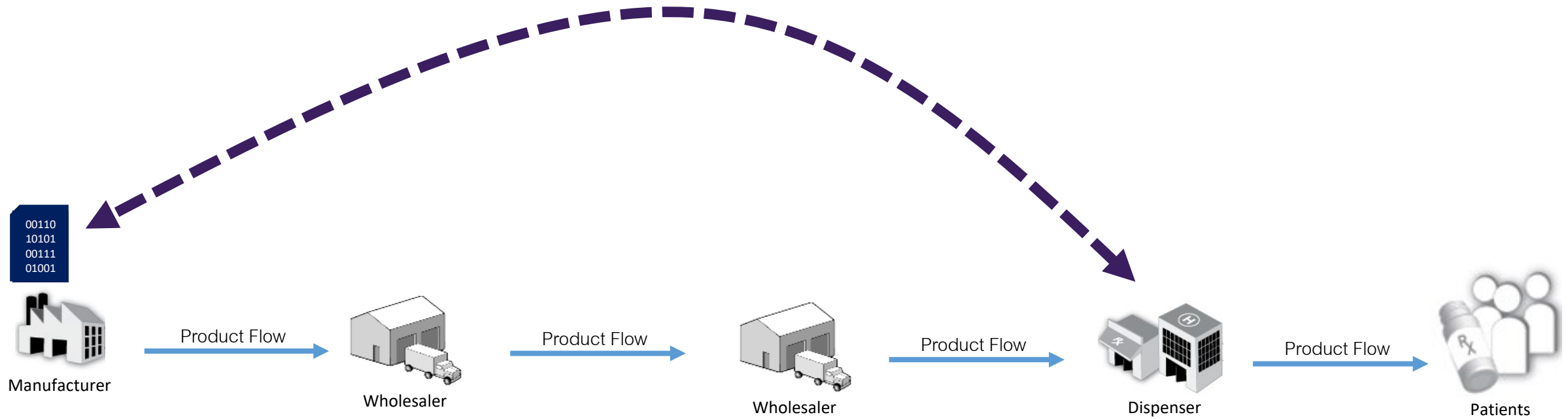
- “Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to [the DSCSA].”

Key Terminology for this Chapter

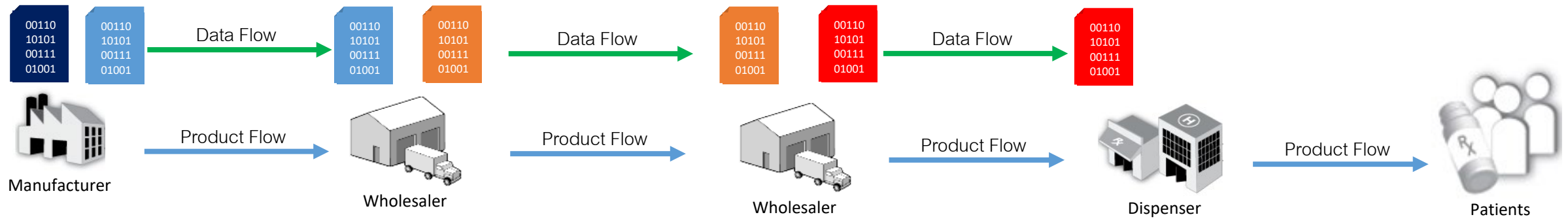
- **Interoperable Verification:** The DSCSA 2023 requirement that trading partners be able to verify a product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner.
- **Direct-to-Source Verification:** Is the process by which a product identifier is verified against commissioning-level data generated and maintained by the manufacturer or re-packager.
- **Direct-to-Replicate Verification:** Is the process by which a product identifier is verified against a replicate of the commissioning-level data generated by and received from the manufacturer or re-packager of the product.
- **VRS:** Is the verification router service, an existing method of performing direct-to-source verification developed by an industry work group facilitated by the Healthcare Distribution Alliance (HDA).

Within the PDG-defined Enhanced Drug Distribution Security System (EDDS) network, PI Verifications are executed as either a PI Verification Request and Response interaction between Requester and Responder or by using TI/TS records received directly from the Manufacturer or Re-packager (in certain circumstances).

Direct-to-Source



Direct-to-Replicate



Direct-to-Replicate

Appropriate only when all of the following conditions are met:

1. The trading partner performing the verification purchased the package directly from the manufacturer/repackager.
2. The trading partner performing the verification uses commissioning-level data provided directly by the manufacturer/repackager.
3. The trading partner performing the verification does so only for product in their ownership and possession.
4. The verification is not for investigation of a suspect/illegitimate product nor for exceptions processing.
5. The trading partner performing the verification and the manufacturer/repackager utilize processes to exchange known SN statuses.

TI Exchange Methods

PDG-Defined EDDS Network

***Direct-to-Source:
VRS***

***Direct-to-Source:
LWMS***

Direct-to-Replicate
(In certain circumstances)

Alternate Methods

E.g., Individual
manufacturer site, email

Interoperable Verification: Serial Number Statuses

Verification
must reflect
known status
of the sGTIN

Necessarily known:

- Expired
- Recalled
- Subject to a 3911

May be known or unknown:

- Damaged
- Destroyed
- Consumed

PDG-Initiated Enhancements to PI Verification

- Confirmation of ATP status
- Attestation to possession or control
- Request Contact Information
- Request Types
 - Saleable Return
 - Suspect/Illegitimate
 - Requester contact information
 - Exceptions Processing
 - Other Status Check

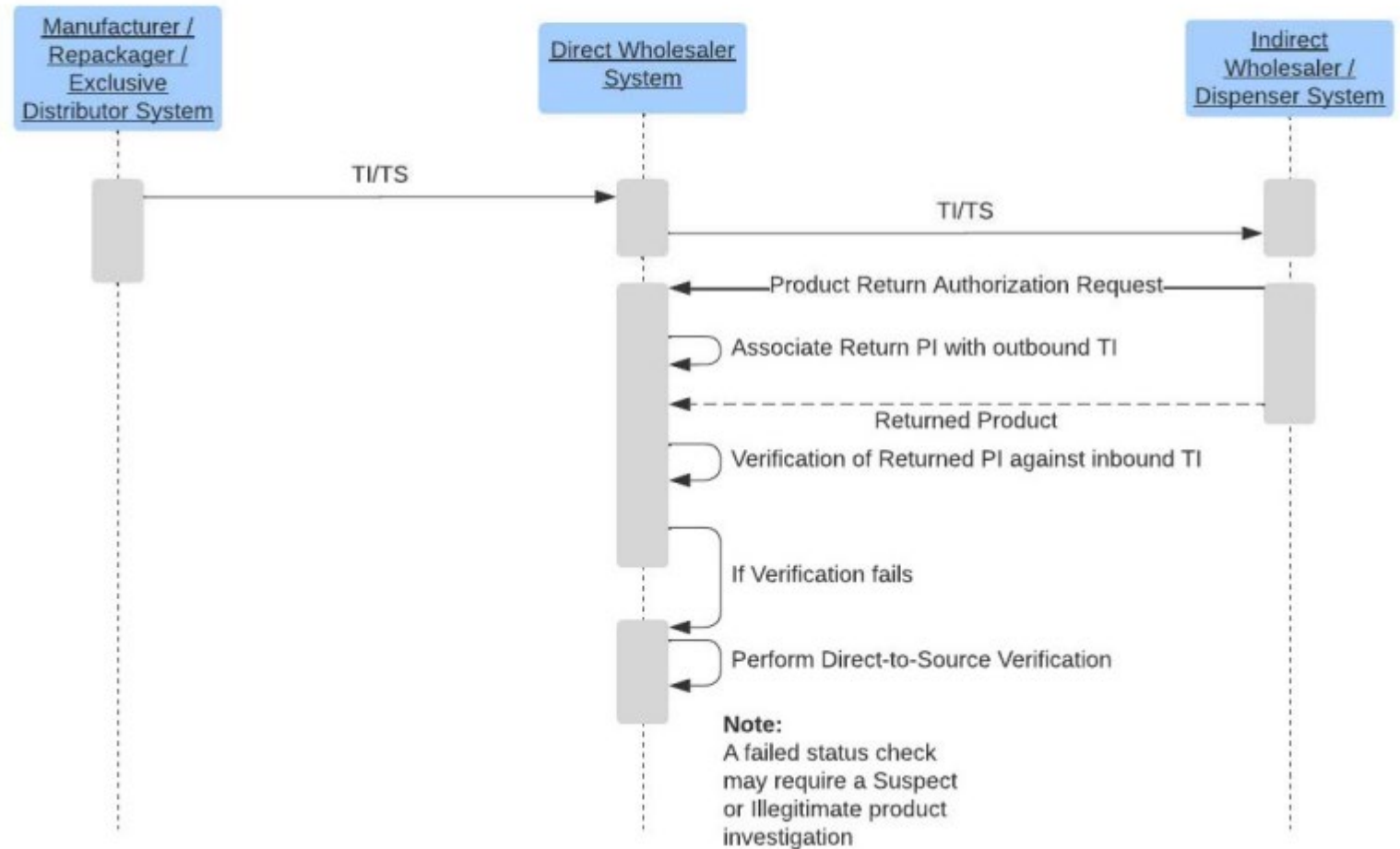
Illustrative PI Verification Choreographies

Direct-to-Replicate

PI Verification

PDG | December 12, 2022

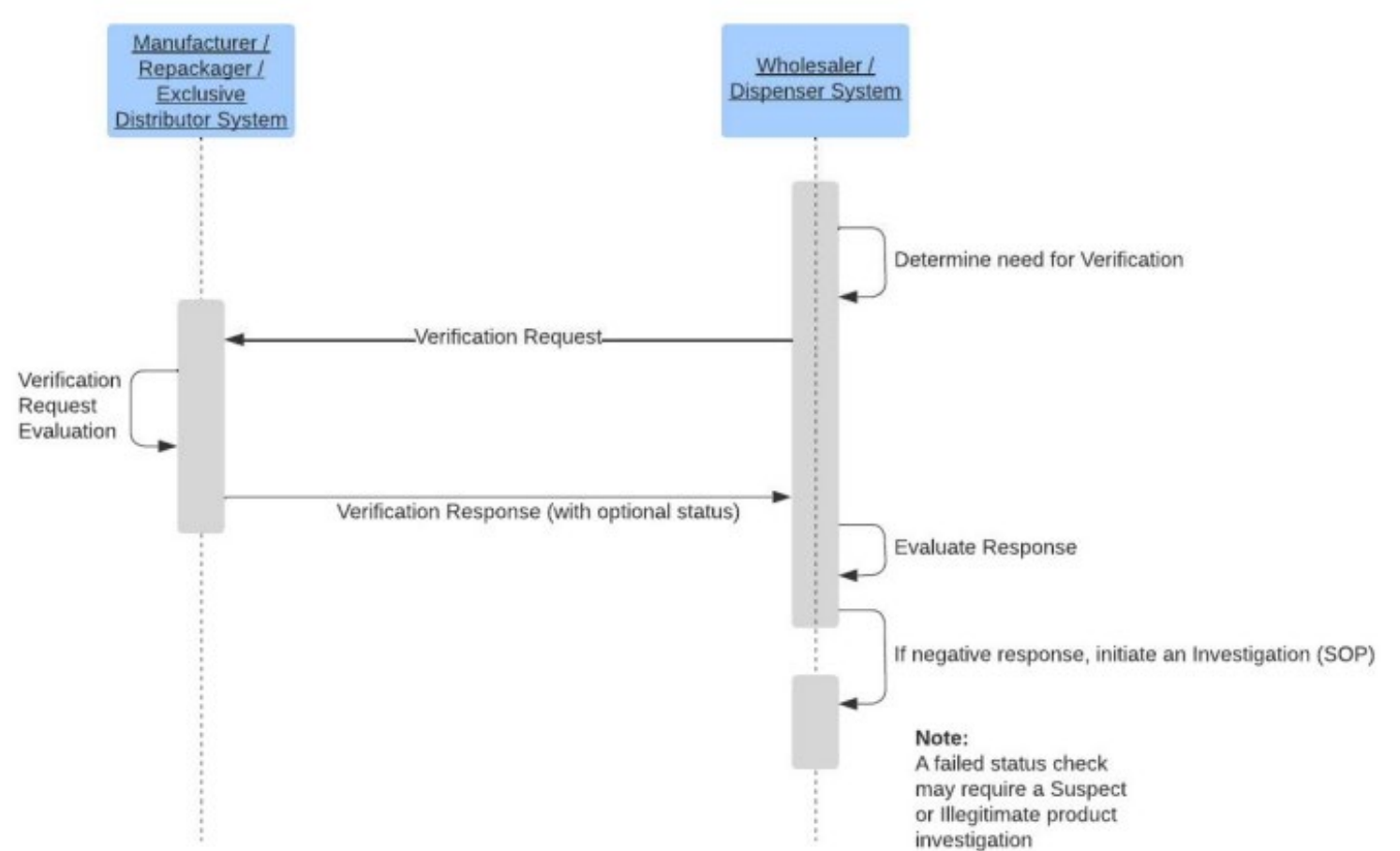
Direct to Replicate Verification



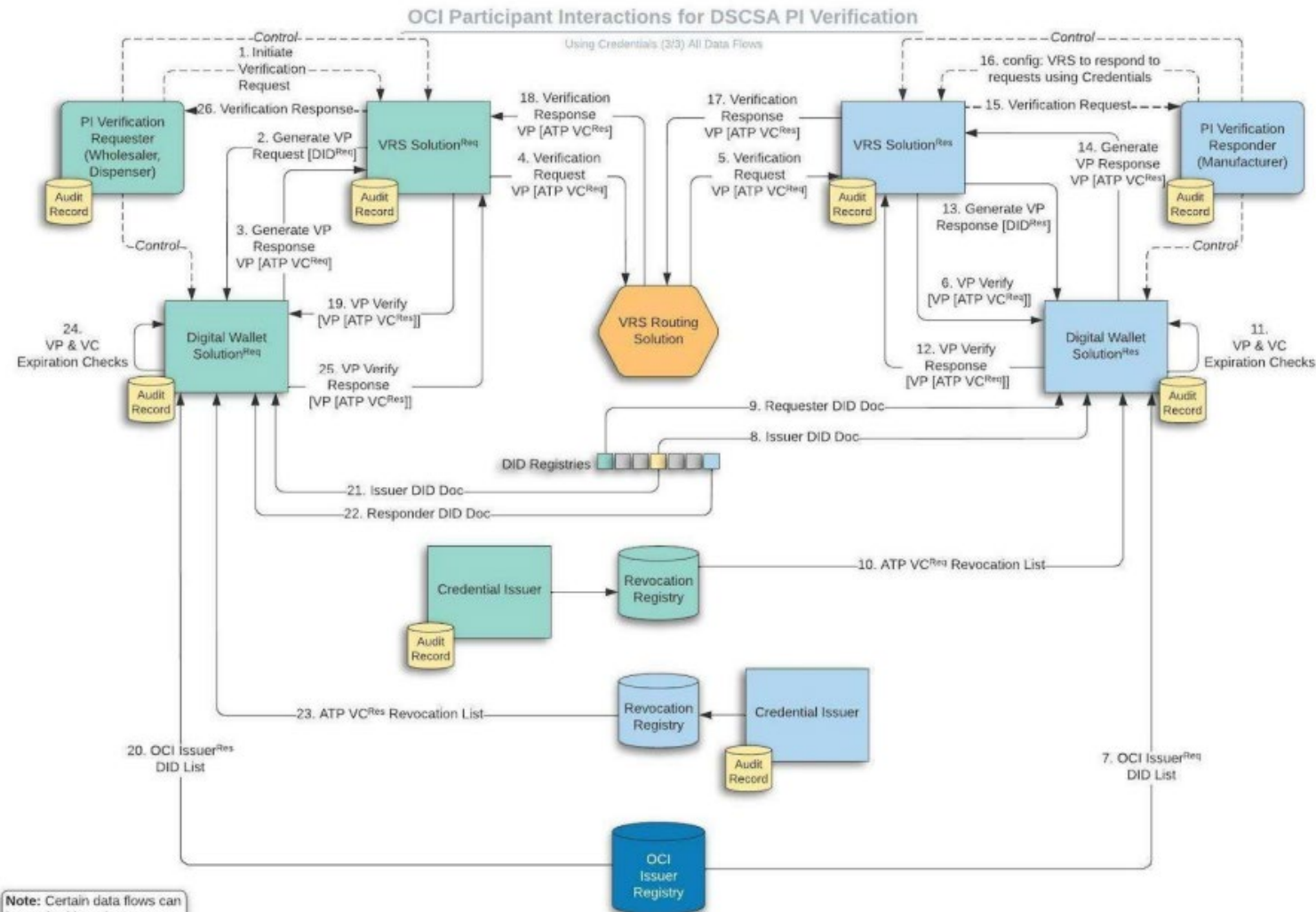
Illustrative PI Verification Choreographies

Direct-to-Source

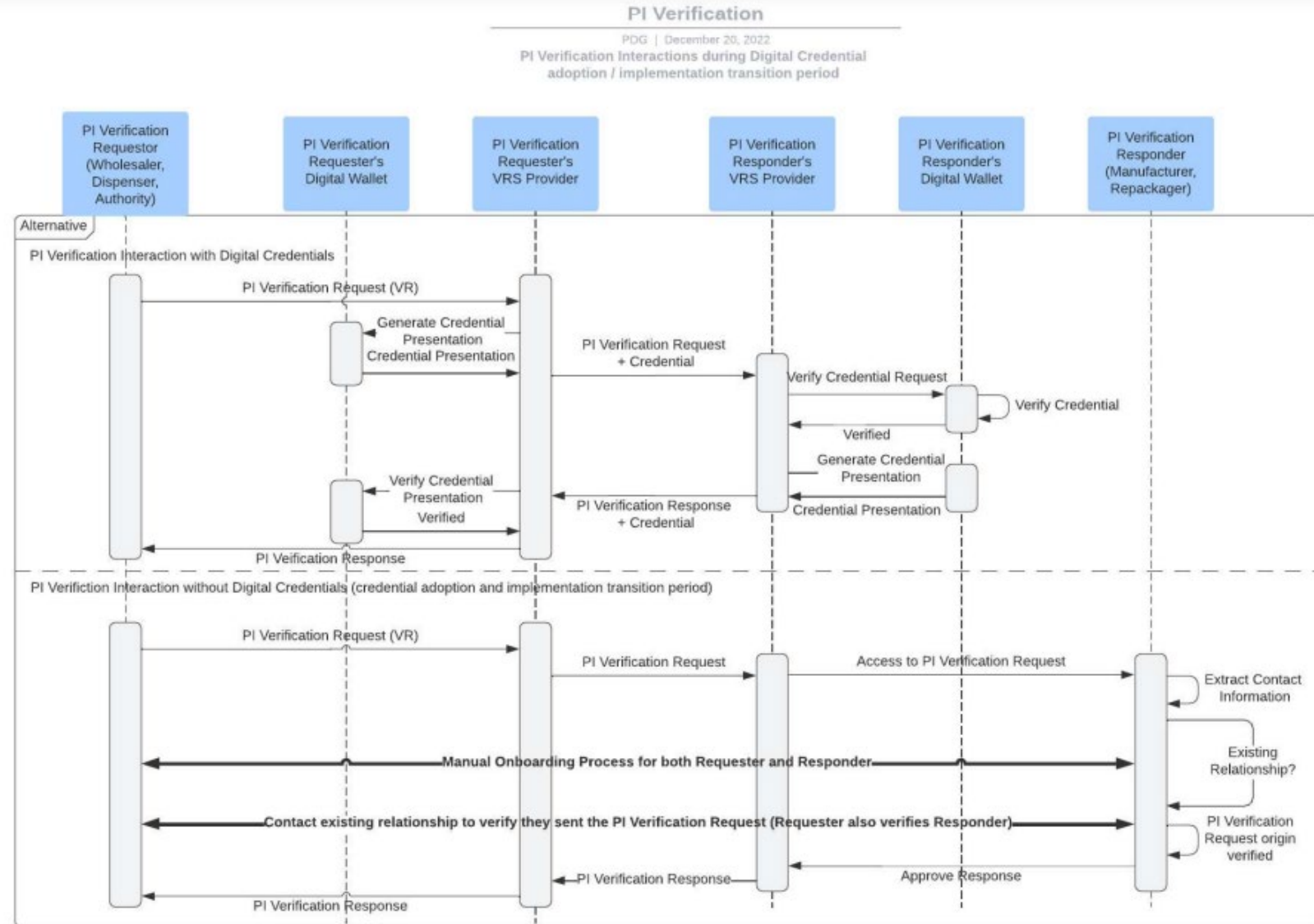
Direct to Source Verification



Using Verifiable Credentials for PI Verification Interactions



PI Verification Interactions with Digital Credentials and Transition Period



Webinar Series (Register at <https://dscsagovernance.org/blueprint/>)

•Webinar Episode 1: DSCSA Overview, Interoperability, & the Role of ATPs

- February 23, 1:00 – 2:00pm ET
- Register [HERE.](#)

•Webinar Episode 2: TI/TS Exchange

- March 1, 1:00 – 2:00pm ET
- Register [HERE.](#)

•Webinar Episode 3: Verification

- March 9, 1:00 – 2:00pm ET
- Register [HERE.](#)

•Webinar Episode 4: Tracing

- March 16, 1:00 – 2:00pm ET
- Register [HERE.](#)

•Webinar Episode 5: Credentialing

- March 23, 1:00 – 2:00pm ET
- Register [HERE.](#)



Questions?

More Information



For additional information and to join:

Visit www.DSCSAgovernance.org

Email admin@members.dscsagovernance.org

