

The background features a network diagram with white circular nodes of varying sizes connected by thin white lines. A large, dark purple, irregular shape is positioned in the lower half of the image, serving as a backdrop for the main title. The overall color palette is composed of shades of purple, white, and grey.

# Partnership for DSCSA Governance

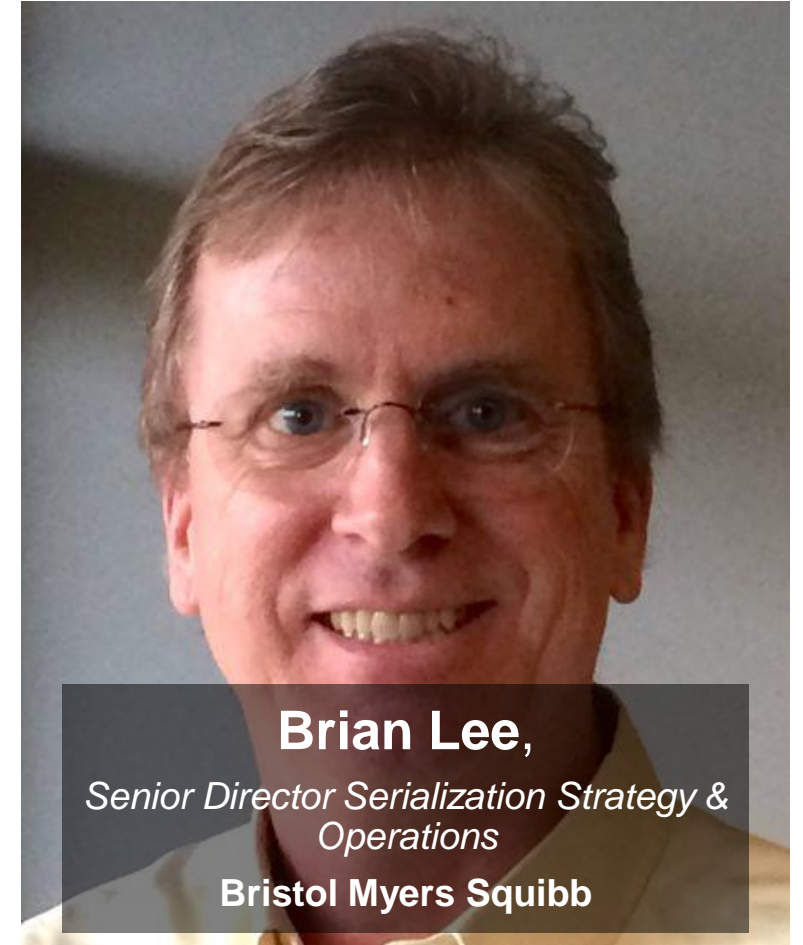
Advancing Collaborative, Timely Implementation  
of DSCSA Interoperability

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

# Webinar Series

- **Webinar Episode 1: DSCSA Overview, Interoperability, & the Role of ATPs**
  - February 23, 1:00 – 2:00pm ET
- **Webinar Episode 2: TI/TS Exchange**
  - March 1, 1:00 – 2:00pm ET
- **Webinar Episode 3: Verification**
  - March 9, 1:00 – 2:00pm ET
- **Webinar Episode 4: Tracing**
  - March 16, 1:00 – 2:00pm ET
- **Webinar Episode 5: Credentialing**
  - March 23, 1:00 – 2:00pm ET

# 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.*

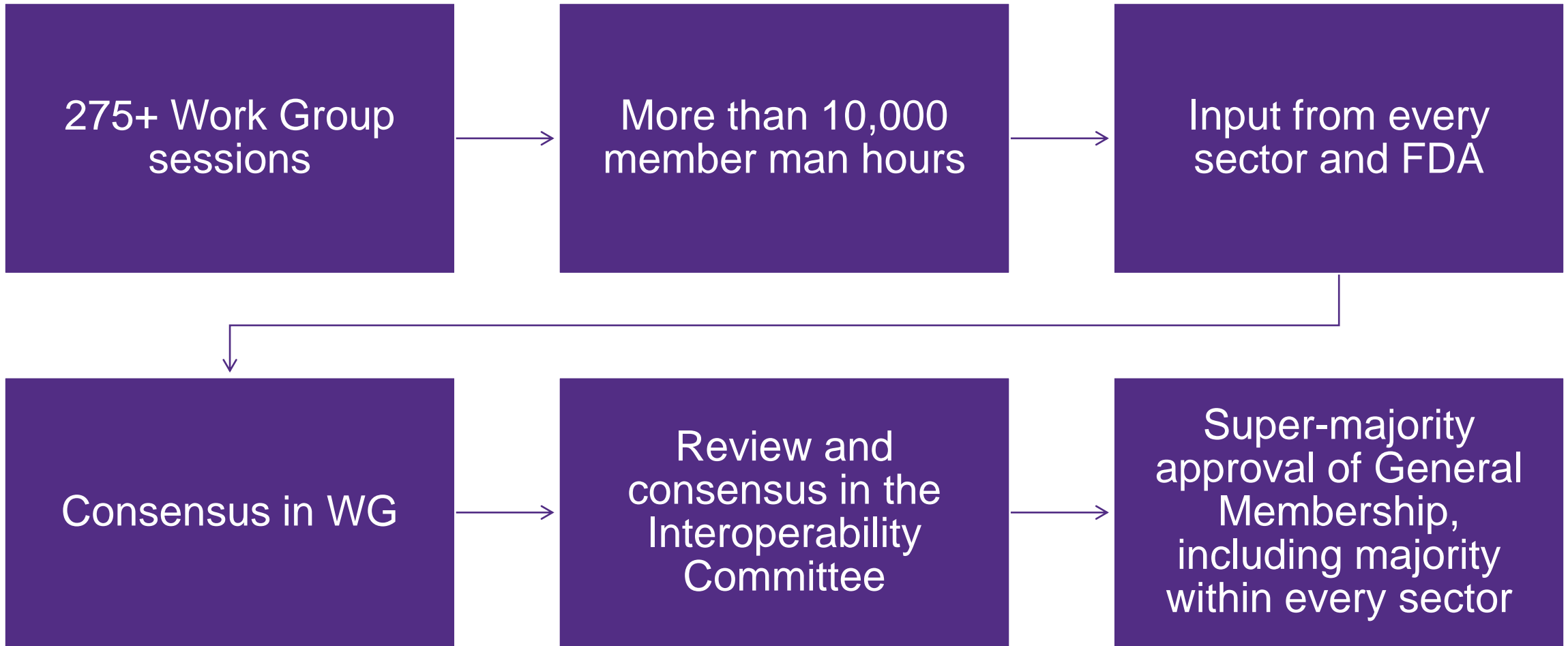
[www.DSCSAgovernance.org](http://www.DSCSAgovernance.org)

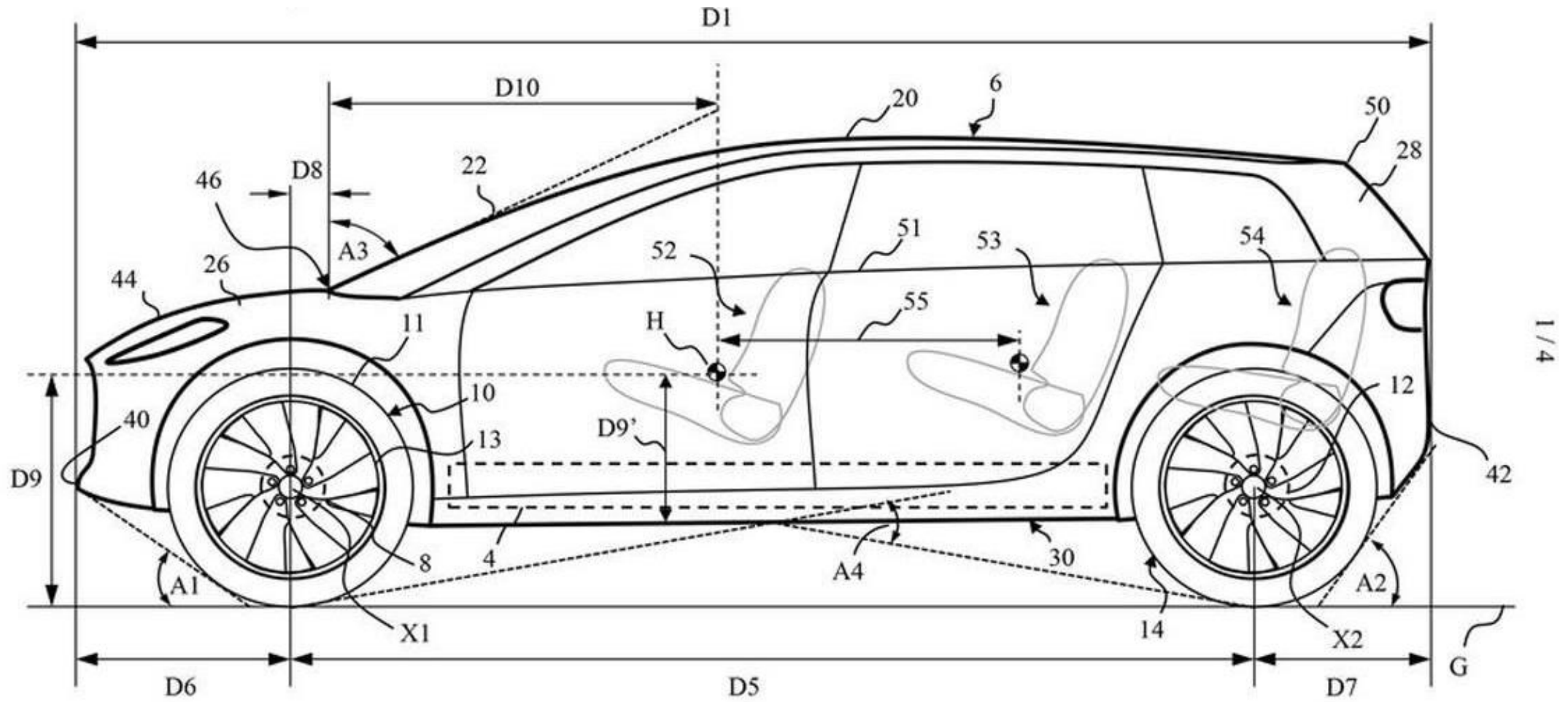
# Membership

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









1 / 4



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*

## Change Control Request

mm / dd / yyyy



Name

Organization

Document Version (e.g., Version 1.0)

Are you a PDG member?

☐ Yes

☐ No

Change Request Type:

# DSCSA Public Private Partnership

- Public Private Partnerships (PPPs)
- DSCSA PPP - FDA and the Partnership for DSCSA Governance (PDG) engagement

<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-public-private-partnership>

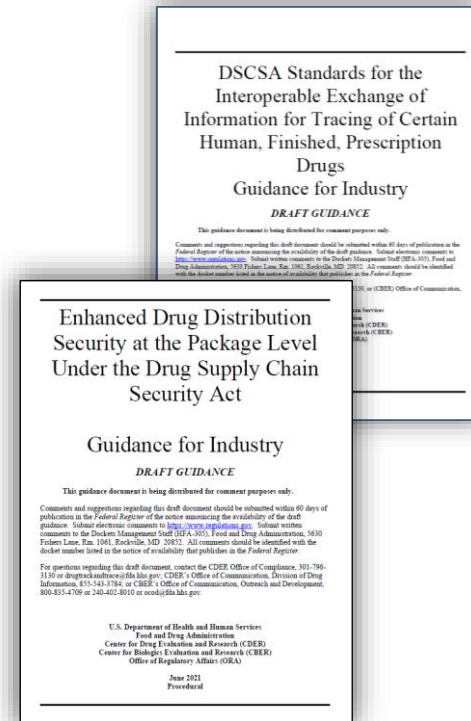
# DSCSA Implementation

**2023+**

## Enhanced Drug Distribution Security Requirements

- All electronic
- Enhanced product tracing at the package level (i.e., includes product identifier)
- Enhanced verification

**Section 582(g)(1)  
of the FD&C Act  
Effective  
11/27/2023**



## FDA DSCSA-related Guidances for Industry

<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies>

# Today

Several-hundred-thousand lots  
tracked by TI and TH

~4.5 Billion Units  
Traced by TI

***10,000 – 20,000  
times as many  
instances  
recorded***

8-10 Billion  
Transactions



16-20 Billion  
Instances of TI



Years or Record  
Retention



100 Billion  
Instances of TI



# Today

ATP 1



ATP 2

# November 27, 2023

ATP 1

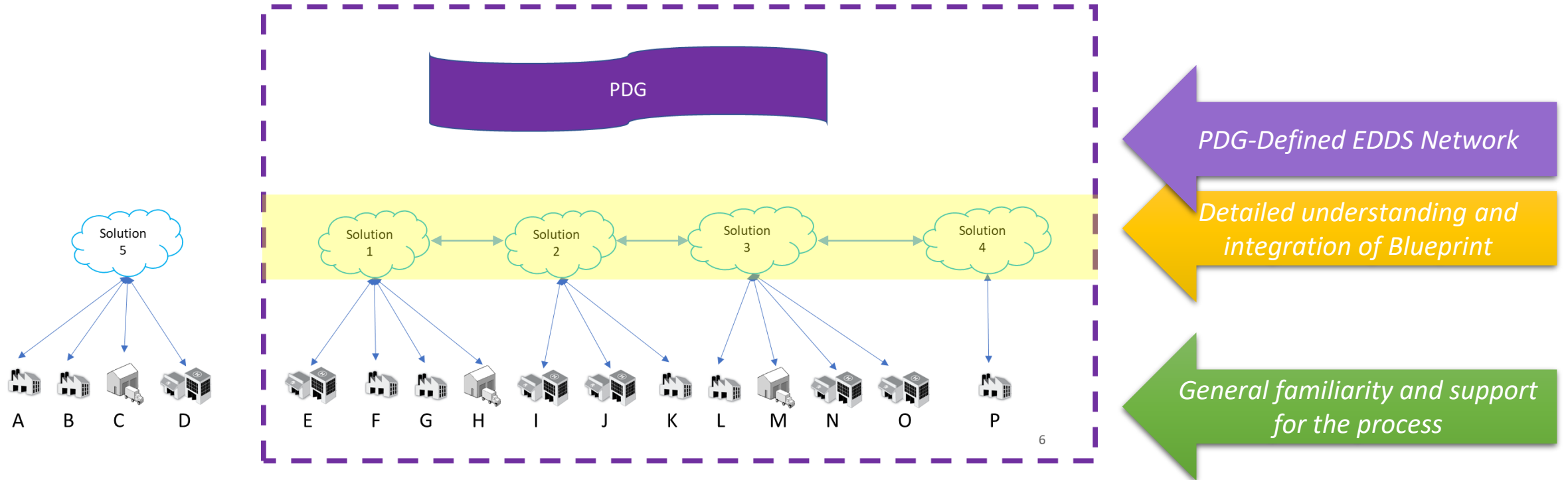


ATP 2

ATP 3



# PDG-Defined EDDS Network



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

Chapter 4: PI Verification  
Functional Design  
*Published February 2023*

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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*

# Five things to know about the Blueprint



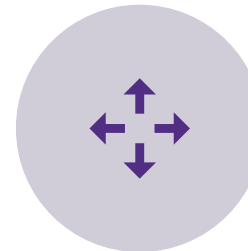
The Blueprint incorporates, by reference, standards and the work of other stakeholder groups wherever possible.



The Blueprint defines compliance, business, and functional requirements for (i) TI Exchange, (ii) verification, (iii) tracing, and (iv) credentialing.



While conformance to the Blueprint is not a legal or regulatory requirement, it does represent the best thinking of the industry's leading organizations.



The Blueprint does not call for the development of shared industry infrastructure; rather, it is built on the assumption of a distributed data architecture.



All trading partners should be familiar with the Blueprint, but implementation of it will occur at the solution-level.

## Chapter 2: Functional Design

The PDG functional design described in Chapters 2–6 weaves together existing designs along with new areas (e.g., tracing) and defines what PDG views as the optimal functional design that meets the compliance and business requirements defined in Chapter 1.

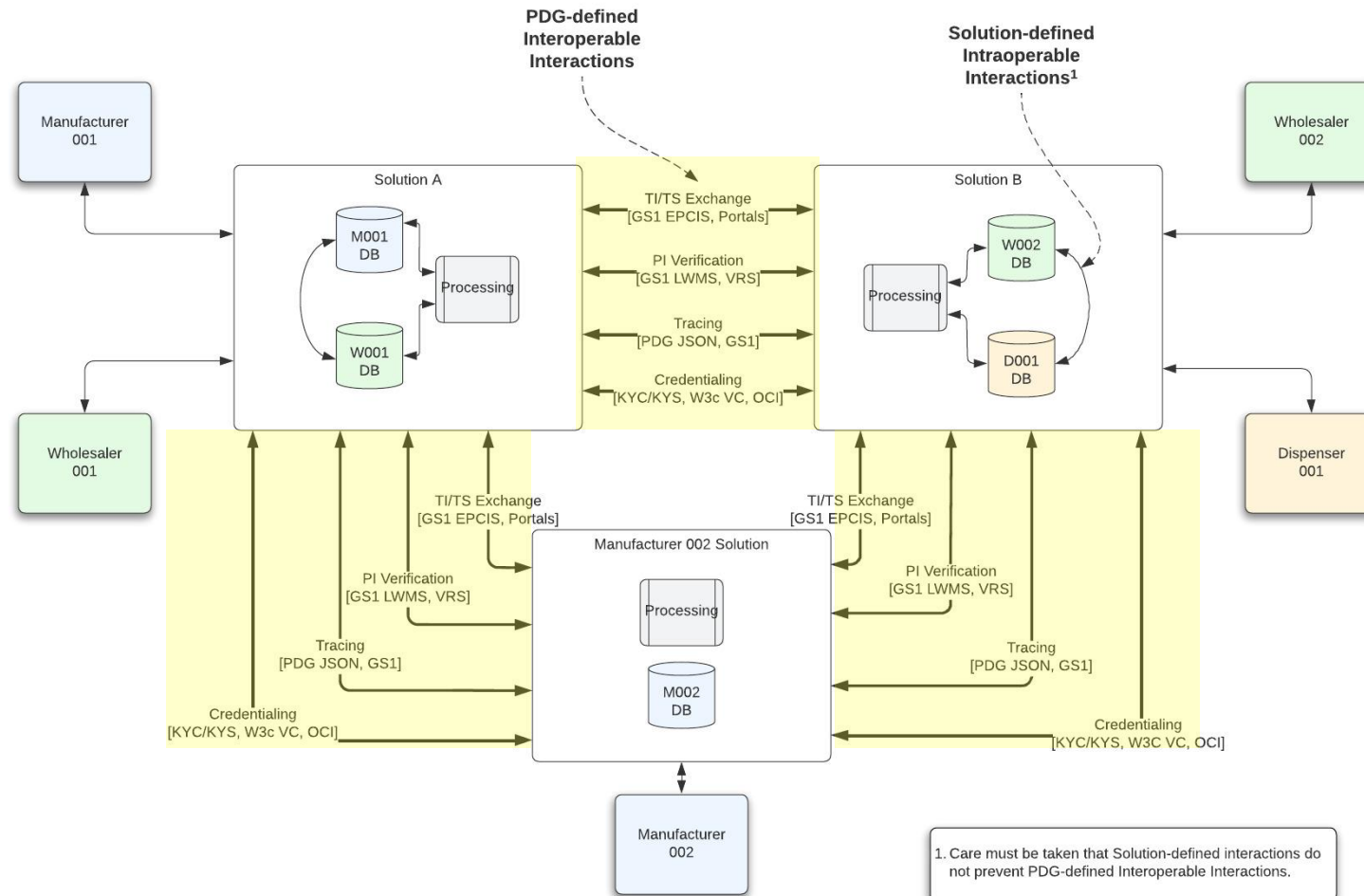
We refer to this PDG-defined set of functional designs as the **PDG-Defined EDDS network**.



# Chapter 2: Functional Design

## PDG-defined DSCSA EDDS network

Solution Interoperability | October 25, 2022



# Ch. 3: Serialized TI Exchange

## Blueprint Ch. 1

- Standardized TI element formats
- General expectations for accuracy and reliability

## Ch. 3 Functional Design

- Data push (EPCIS) or data availability (web portals)
- Dropships, 340B, direct ships, etc.
- Misalignment exception resolution

# Ch. 4: Interoperable Verification

## Blueprint Ch. 1

- Modest enhancements to VRS
- Serial number statuses
- Direct-to-replicate verification

## Ch. 4 Functional Design

- Extension of VRS to additional use cases
- Addition of contact information
- Addition of possession confirmation
- Role of credentialing

# Ch. 5: Interoperable Tracing

## Blueprint Ch. 1

- Who can trace for what purposes
- What information can be requested
- How fast is tracing performed

## Ch. 5 Functional Design

- General request-response model
- Request-response message protocol
- Role of credentialing

# Ch. 6: Credentialing

## Blueprint Ch. 1

- Requirements to confirm ATP status
- Requirements to confirm identity

## Ch. 6 Functional Design

- Digital verifiable credentials as one way to efficiently manage credentialing



**Questions?**



# More Information



For additional information and to join:

Visit [www.DSCSAgovernance.org](http://www.DSCSAgovernance.org)

Email [admin@members.dscsagovernance.org](mailto:admin@members.dscsagovernance.org)

