Partnership for DSCSA Governance (PDG)
Foundational Blueprint for 2023 Interoperability

Chapter 2: Functional Design

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Chapter 2: Functional Design

The Drug Supply Chain Security Act (DSCSA) is organized around a Chain of Ownership model, which poses a challenge to the industry in architecting an interoperable system in a world where it is natural to be of a mindset of a "Chain of Possession."

By the time the DSCSA was signed into law, leading supply chain stakeholders of the US Pharmaceutical industry had already been hard at work adopting standards, developing component designs, and consenting to a wide range of business and systems changes that collectively contribute to the DSCSA Enhanced Drug Distribution Security (EDDS) network. The DSCSA uses terms such as "processes and procedures necessary ….", "systems and processes", "interoperable", etc. in defining this "interoperable, electronic system". In fact, the EDDS network is a highly decentralized system of systems, where interoperability is accomplished through standardization[1] of data interfaces (messages, events, etc.) and agreement on how trading partners (and their systems) will interpret, manage, and respond to messages and events received from other trading partners or DSCSA authorities.

Existing and new functionality are coming together as the industry adopts and implements components that add to the interoperable EDDS network.

Purpose of the Functional Design Chapters

Elements of the PDG-defined EDDS network have already been specified by the industry, through standards, and by other collaborations and organizations. The PDG functional design described in Chapters 2–6 weaves together those existing designs along with new areas (tracing, credentialing) 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." It is important to note, as also explained in the introduction to this *Blueprint*, that this network is not a legally required method of implementation. The DSCSA expressly permits "alternate methods of compliance."[2] Similarly, PDG membership is not required to adopt or participate in the PDG-defined EDDS network. While PDG, through the work of its members, has defined this network, any DSCSA Authorized Trading Partner, Authorized Trading Partner[3] equivalent or DSCSA authority may choose to adopt or participate in the PDG-defined EDDS network in conformance with the requirements of this *Blueprint*.

Reference standards, guidelines, and specifications may address elements that provide functionality beyond a minimum set. Those elements, although helpful to individual trading partner pairs and for individual trading partners, are not part of the mandatory set of functionalities identified by PDG.

An example of this is "Receiving Events" in the GS1 Implementation Guideline,[4] which are recommended for trading partners to explicitly record the receipt of scanned and inferred items but is not mandatory to be exchanged between trading partners based on a common understanding of the DSCSA.

This chapter provides an overview of the capabilities trading partners (and their supporting systems) SHALL have to participate in the PDG-defined EDDS network effectively. This and the following chapters attempt

[1] Standard defined here as being created and published by a standards organization or published elsewhere and in common use.
[2] FDCA 582(g)(2)(B).
[3] Recognized Trading Partners that do not have State License(s) or FDA registration yet need to participate in the PDG-defined EDDS network.
[4] Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability

to connect the separately designed sub-functions of TI/TS Exchange, product verification, product tracing, and credentialing. These chapters highlight the need for further collaboration to maintain interoperability among publishers of DSCSA architectural component specifications that contribute to the greater PDG-defined EDDS network.

To achieve industry-wide interoperability within the EDDS network, the functional design, functional requirements, and non-functional requirements documented in chapters 3–6 necessarily provide boundaries and limited options for implementations that are considered technically conformant to this PDG-defined EDDS network design. It's important to note that trading partners (and their systems) can be deemed DSCSA compliant without being conformant to the PDG-defined EDDS network design. Conformance to the PDG-defined EDDS network design is meant to ease and enhance interoperability among implementing systems and services.

PDG-defined Interoperable Interactions and Solution-defined Intraoperable Interactions

INTEROPERABILITY is the ability of systems and processes to exchange and use information accurately, efficiently, and consistently among trading partners; it pertains to ***different and multiple*** systems and software applications communicating, exchanging data, processing, and using the information exchanged. INTEROPERABILITY spans **ACROSS** systems.

INTRAOPERABILITY pertains to exchange of data between functional modules/systems that are fundamentally in the ***same system or network*** and generally developed by the ***same vendor***. INTRAOPERABILITY spans **WITHIN** a system.

PDG's scope is to define the interaction rules for **INTEROPERABILITY** and therefore pertain to interactions between systems rather than defining intra-application interactions. However, solution providers must take care that solution-defined intraoperable interactions do not prevent PDG-defined interoperable interactions from occurring. *Figure 1* depicts PDG-defined interoperable interactions between systems and also intraoperable interactions that may occur between trading partners utilizing the same solution.

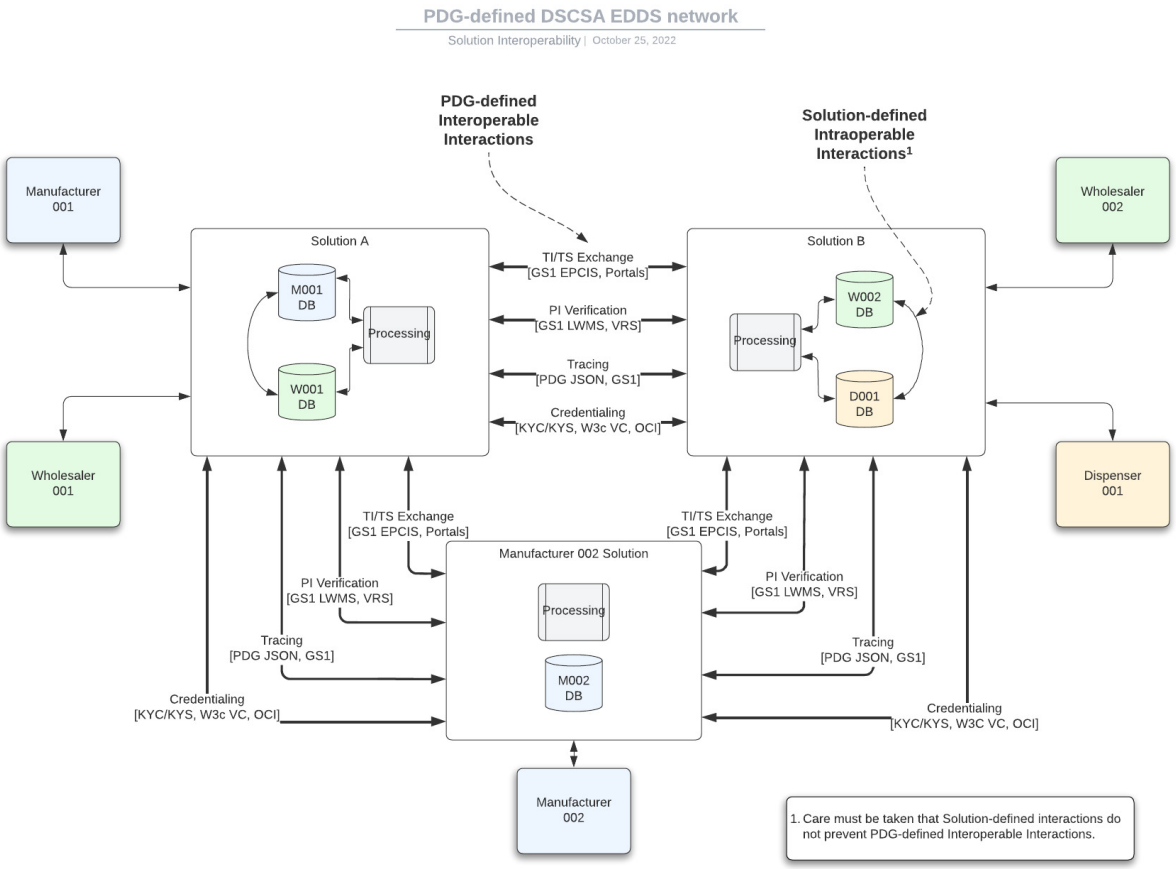

Figure 1- Interoperable and Intraoperable Interactions

This blueprint documents the business and technical requirements and functional design or architecture of the PDG-defined EDDS network. Adherents to the PDG-defined EDDS network architecture have expectations that their solutions and those of other participants use the PDG-defined architecture, interactions, and processes as designed. The architecture specifies, either directly or by reference to external specifications, standards and guidelines of authoring bodies, data attribute forms and definitions, message structures and rules, checks and verifications of message content, audit records requirements, etc.

Using the *Figure 1* illustration

> **Example 1:** The PDG architecture for TI/TS exchange relies on the GS1 EPCIS event architecture as specified by the GS1 EPCIS standard and the GS1 US implementation guideline for DSCSA. Solution providers may have an agreement with users of their solution that in the case of a transfer of product between trading partners who both use the same solution, the solution may transfer the TI/TS information within the solution using an internal method other than EPCIS events. This means that raw EPCIS events may not be available to the two trading partners and methods other than those specified in the GS1 Standards are used to check, process, and archive the interaction. An external audit of a series of interactions may result in referencing the PDG architecture (referencing the EPCIS guidelines and standards) and the solution providers' documented processes, checks, and record structures.

Example 2: OCI specifies certain audit records to be maintained by the Issuer, Wallet, VRS provider, and Trace provider. Trading partners can expect that those records will be available to them in the case of an audit (internally or externally). Should a solution or network come to an agreement with their participants to have a different mechanism intra-solution or intra-network, that will cause different records to be available for audit, and the trading partner participants must account for that in their SOPs.

PDG recommends trading partners work with their solution provider(s) to understand when PDG-defined interoperable interactions and solution-defined intraoperable interactions are used. These discussions may inform the trading partner's operation and compliance SOPs.

Terminology

Term/Acronym	Definition	Notes
ATP	A Trading Partner (as defined in the glossary) that is also authorized (as defined in the glossary).	Authorized Trading Partner. The DSCSA and FDA guidances define certain entities as being "Authorized" and "Trading Partners". For the purposes of this document, we consider the following entity types as ATPs (as defined in the DSCSA): • Manufacturers • Repackagers • Wholesale Distributors (Wholesalers) • Third Party Logistics Providers (3PLs) • Dispensers
ATP Equivalent	The DSCSA provides definitions of ATPs. However, Trading Partners exist that do not meet the strict requirements for "authorization" but still need access to the network. PDG defines these entities as "ATP Equivalent". Examples are the Veterans Administration (VA), Department of Defense (DOD), etc.	
DSCSA Authorities	In addition to the FDA (the Secretary), the DSCSA refers to other Federal or State officials as having authority in the context of the DSCSA. PDG refers to these entities collectively as "DSCSA Authorities".	
PDG-defined EDDS network	A collection of industry systems that achieve interoperability through conformance to the PDG Blueprint.	

Standards, Specifications, and Guidelines

Industry, standards bodies, associations, and other organizations have published various standards, guidelines, and specifications detailing key components of the EDDS network. The following chapters address those sub-functions and the elements that PDG membership identifies as mandatory within the scope of the PDG-defined EDDS network.

Agreement on Identifiers

A key factor for the interoperability of the EDDS network is the use of standardized identifiers. For the PDG-defined EDDS network design, standardized identifiers allow trading partners (and their systems) to hold a common understanding of an entity, location, product, or logistics unit. They allow the industry to associate common sets of attributes to define those identifiers and alleviate having to rely on matching changeable attributes such as names or addresses.

For the purposes of this PDG-defined EDDS network design, the following identifiers are used to promote standardization, simplify design, enhance reconciliation and verification, and mitigate confusion in the supply chain.

Identifiers

1. **Global Location Number (GLN):** GS1 Standard Identifier, required to identify trading partners in the transfer of ownership exchange of product. Also required if location data is provided (Ship To).
2. **Global Trade Item Number (GTIN):** GS1 Standard identifier, required for identifying drug packages and homogeneous cases of drug packages.
3. **National Drug Code (NDC):** FDA identifier, required by DSCSA Statute, identifies the drug and its package size. For pharmaceuticals in the US, NDCs are often encoded within the GTIN[5].
4. **Serialized Shipping Container Code (SSCC):** GS1 Standard identifier, required for identifying logistics units such as heterogeneous cases and totes.
5. **Decentralized Identifier (DID):** W3C Standard identifier, required for enabling verifiable, decentralized digital identity supporting digital Identity and Access Management capability.

Identifiers used in conjunction with the above Identifiers.

1. **Lot:** GS1 Standard attribute. When combined with a GTIN (GTIN + Lot) or NDC (NDC + Lot), identifies a finished product production batch. GTIN + Lot can identify all packages within a Lot and all Cases within a Lot.
2. **Serial Number (Sn):** GS1 Standard attribute. When combined with a GTIN (GTIN + Sn) identifies a specific instance of a drug package or homogeneous case. When combined with an NDC (NDC + Sn), identifies an individual drug package and[6] also might simultaneously identify a homogeneous case.

[5] See chapter "4.1 Relationship between NDC – GTIN – SGTIN" of the Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability. We recognize that the NDC in its standalone form is not typically included in the human-readable or machine-readable portion of the product identifier, and we do not intend to suggest that the NDC should or SHALL be included in the product identifier in its standalone form.

[6] The GTIN can differentiate between a drug package and a drug case of the same drug packages, manufacturers and repackagers do not have to ensure serial number uniqueness between packages and cases. If a manufacturer or repackager uses the same serial number sequence for packages and cases of the same product, it is possible that a package and case could have identical NDC + Sn paired identifiers.

Capabilities

To comply with the DSCSA, each trading partner must develop and maintain certain business and system capabilities to enable them to be effective and reliable participants in the PDG-defined EDDS network. Trading partners depend on each other to have acquired these capabilities and be ready to respond to interactions within the PDG-defined EDDS network.

Figure 2 illustrates the capabilities, components, and participant types PDG-defined EDDS network participants are dependent on. Capability components in red identify areas where functions of the EDDS network enable a component and its parent capability.

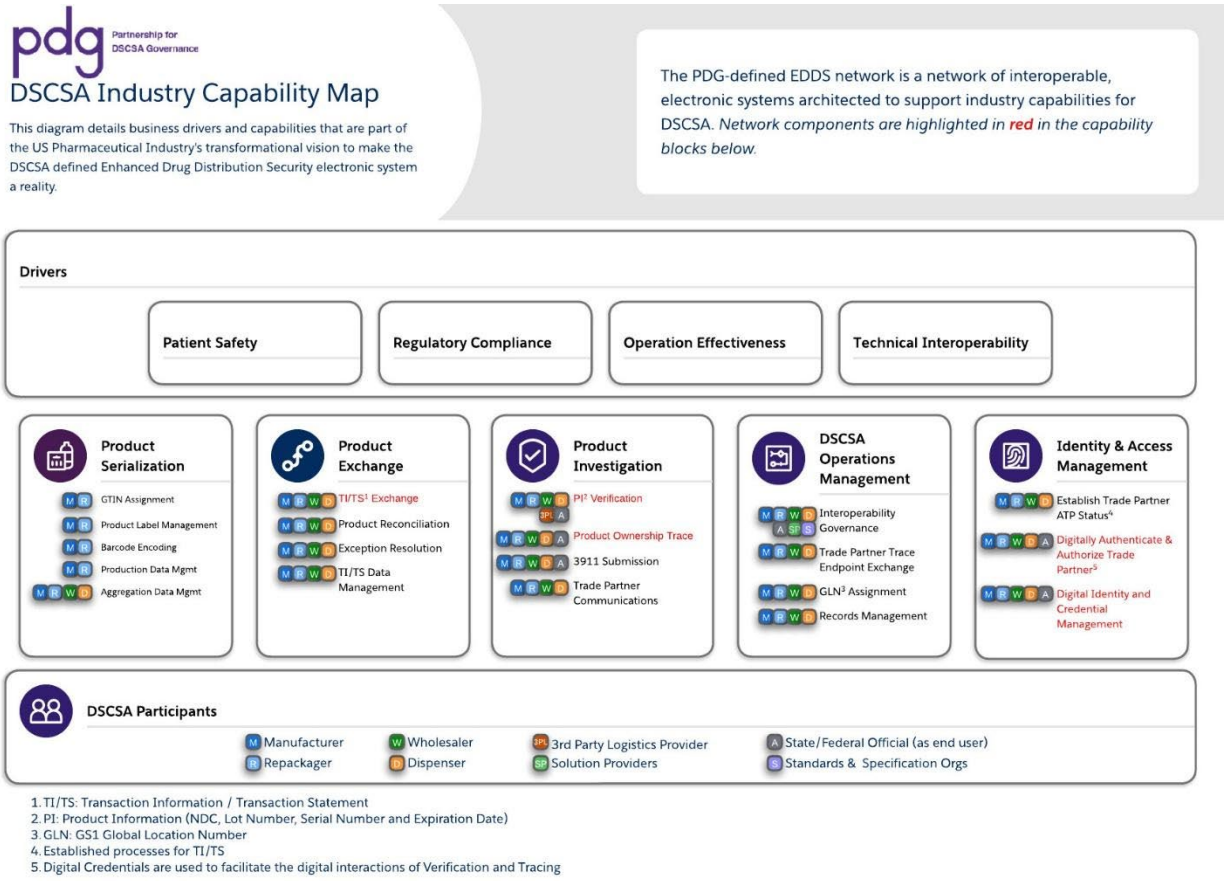

Figure 2 - Business and System Capabilities map

Table 1 illustrates the four main functional areas of the PDG-defined EDDS network and their relationship to business or systems capabilities. An EDDS function may enable a participant's capability and an EDDS function may be dependent on a participant having a capability. Key takeaways from the table are:

1. The extent to which trading partners depend on each other to develop DSCSA-enabling capabilities.
2. The many ways in which the PDG-defined EDDS network is useful in enabling those capabilities.
3. Certain functions of the PDG-defined EDDS network are named similarly to a sub-capability; these functions were purposely architected to support the sub-capability and its parent capability.

Table 1 - Relationship between participant capabilities and PDG-defined EDDS network functions

	TI/TS Exchange	PI Verification	TI Tracing	Credentialing
Product Serialization				
• GTIN Assignment	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	
• Product Label Management	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	
• Barcode Encoding	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	
• Production Data Management	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	
• Aggregation Data Management	Network function *depends* on Capability		Network function *depends* on Capability	
Product Exchange				
• TI/TS Exchange	Network function *enables* Capability[7]	Network function *enables* Capability[8]	Network function *depends* on Capability	
• Product Reconciliation	Network function *enables* Capability			
• Exception Resolution	Network function *enables* Capability	Network function *enables* Capability		
• TI/TS Data Management	Network function *enables* Capability	Network function *enables* Capability[9]	Network function *depends* on Capability	
Product Investigation				
• Product Information Verification	Network function *enables* Capability[10]	Network function *enables* Capability[11]		Network function *enables* Capability
• Product Ownership Trace	Network function *enables* Capability	Network function *enables* Capability	Network function *enables* Capability[12]	Network function *enables* Capability

[7] Function purposely architected to support this capability
[8] For Direct-to-Replicate verification use cases only
[9] For Direct-to-Replicate verification use cases only
[10] For Direct-to-Replicate verification use cases only
[11] Function purposely architected to support this capability
[12] Function purposely architected to support this capability

	TI/TS Exchange	PI Verification	TI Tracing	Credentialing
• 3911 Submission	Network function *enables* Capability	Network function *enables* Capability	Network function enables Capability[13]	
• Trade Partner Communications	Network function *enables* Capability	Network function *enables* Capability	Network function *enables* Capability	
DSCSA Operations Management				
• Interoperability Governance	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability
• Trade Partner Trace Endpoint Provisioning			Network function *depends* on Capability	Network function enables Capability[14]
• GLN Assignment	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	
• Records Management	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability
Identity and Access Management				
• Establish Trade Partner ATP status	Network function *depends* on Capability	Network function *depends* on Capability	Network function *depends* on Capability	Network function *enables* Capability[15]
• Digitally Authenticate & Authorize Trade Partner		Network function *depends* on Capability	Network function *depends* on Capability	Network function *enables* Capability[16]
• Digital Identity & Credential Management		Network function *depends* on Capability	Network function *depends* on Capability	Network function *enables* Capability[17]

Capability Definitions

Product Serialization

GTIN Assignment

The GS1 Global Trade Item Number (GTIN) is a required product identifier for pharmaceutical packages and homogeneous cases. It is also a requirement for encoding product barcodes and for identifying products in EPCIS events used for TI/TS Exchange.

Product Label Management

Manufacturers and Repackagers are responsible for providing clear, legible product labels. Downstream trading partners depend on both the human and machine-readable elements printed on the product labels.

Barcode Encoding

With the advent of serialized products including the GTIN/NDC, Lot Number, Expiration Date, and Serial Number, downstream partners depend on legible barcodes meeting the GS1 standards and HDA guidelines.

[13] Investigation of a suspect investigation may trigger a 3911 submission
[14] Some solutions may use a W3C Standard DID Document to share the trading partner's trace endpoint
[15] Established trading partner process enable this capability for TI/TS Exchange interactions
[16] Function purposely architected to support this capability
[17] Function purposely architected to support this capability

Production Data Management

In addition to GTIN with embedded NDC, production-specific data (Lot Number, Expiration Date, and Serial Number) is needed for TI/TS Exchange, product verification, and tracing processes. In addition, the requirements for records retention[18] emphasize the importance of organizing and managing production data associated with transactions.

Aggregation Data Management

The draft guidance Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act[19] defines Aggregation as "*the process of building a relationship between unique identifiers assigned to packaging containers. For example, a parent-child relationship would exist between the product identifiers for a package or group of packages (the child or children) that are contained in a homogeneous case (the parent).*" As a business necessity, all trading partners rely on inference (defined in latest FDA EDDS Guidance as "the practice of examining or using information for a higher level of packaging to infer information about the lower level(s) of packaging and its contents—for example, inferring information about individual packages from information about a sealed homogeneous case") at some point in their processes to mitigate opening sealed cases and totes, instead relying on data collected and shared by the entity that packed the cases or totes.

Product Exchange

TI/TS Exchange

A function of the PDG-defined EDDS network is detailed in Chapter 3. The functionality and information are necessary to provide TI/TS information to a trading partner either through using GS1 EPCIS events or the supplier solution portal.

Product Reconciliation

Although trading partners rely on inference for smooth and timely processing of product management, Chapter 1 requirements Requirement-Ser-028 and -029 require trading partners to reconcile the product physically received against the TI/TS digital data they have received from their supplier. Trading partners include reconciliation into existing operations to manage products efficiently and securely.

Exception Resolution

Data and product movement errors happen. When they do, trading partners rely on guidelines and standard operating procedures to understand and resolve misalignment exceptions with their trading partners.

TI/TS Data Management

The records retention requirements of the DSCSA mean that trading partners SHALL plan for managing their TI/TS data in a manner where it is secure and accessible for verification and tracing needs.

Product Investigation

PI Verification

This function of the PDG-defined EDDS network is defined in Chapter 4. The DSCSA requires products SHALL be verified in several situations and that manufacturers and repackagers SHALL respond to verification requests from authorized trading partners.

Product Ownership Trace

The DSCSA specifies information retention (TI/TS Exchange) and retrieval (Tracing) on a chain-of-ownership (as opposed to a chain-of-custody) basis. This requires trading partners to have the capability of exchanging and tracing products reflecting the change of ownership. Tracing supports

[18] The requirements of six years after the transaction and six years after an investigation could result in a twelve-year retention period.
[19] Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act, 86 Fed. Reg. 30053 (proposed June 4, 2021), https://www.regulations.gov/document/FDA-2020-D-2024-0001.

Suspect, Illegitimate, and Recall investigations as well as compliance audits. Within the PDG-defined EDDS network, this function is referred to as "Interoperable Tracing"[20].

3911 Submission

Trading partners who have declared a product "illegitimate" SHALL, among other things, file Form 3911 with the FDA.

Trading Partner Communications

It has been the learning of the PDG community, that communications between trading partners help avoid and resolve errors. As well-designed as the EDDS network functionality is, supply chain processes are complex, and the human element is needed for unexpected situations. Direct communications between trading partners are required to keep good products moving through the supply chain.

DSCSA Operations Management

Interoperability Governance

The PDG-defined EDDS network contains many elements that may change over time. It is important that network-wide interoperability be planned for and coordinated across contributing entities.

Trading Partner Trace Endpoint Provisioning

This function of the PDG-defined EDDS network is defined in Chapter 6. Electronically tracing product ownership among adjacent and non-adjacent trading partners is a unique requirement of the DSCSA. Successful electronic tracing requires trading partners to have knowledge of their trading partners' trace endpoints. Trace endpoints of entities identified in DSCSA Transaction Information data sets are included in TI Responses to allow Requesters to continue their tracing activity by sending TI Requests to the trace endpoint of another trading partner(s) identified in the TI.

GLN Assignment

The GS1 Global Location Number (GLN) is a required trading partner identifier of EPCIS, which standardizes TI/TS Exchange events.

Records Management

The DSCSA requires trading partners to retain TI/TS data and investigation data (suspect or illegitimate product and recalled product). In addition, there may be other related data that may be needed to clarify certain ownership transfers such as returns, destruction, dispensing, and internal transfers.

Identity and Access Management

The DSCSA requires that trading partners[21] only transact with other trading partners that are authorized[22]. For this discussion, this means establishing the identity of the trading partner and that they hold the proper registrations or licenses to do business as claimed. This determination is colloquially known as establishing ATP status, although the PDG-defined EDDS network includes ATP-Equivalent and DSCSA Authority organizations as well.[23]

Established ATP Status of Trading Partners

For TI/TS Exchange: Trading partners may rely on their established processes to establish the identity and ATP or ATP-Equivalent status of each other.

Digitally Authenticate and Authorize Participants

For electronic Product Information Verification and Tracing, Digital credentials mitigate against delays in the authentication and authorization process by digitally verifying the identity and status (ATP, ATP-

[20] See Chapter 5, Tracing for more information
[21] See Chapter 1 Glossary for a definition
[22] See Chapter 1 Glossary for a definition
[23] See Chapter 6, Credentialing for additional information on this

Equivalent, or DSCSA Authority) of participants interacting in the network. The following capabilities enable this digital feature of the PDG-defined EDDS network. Entities participating in PI Verification and TI tracing over the PDG-defined EDDS network can utilize (where present) these credentials to make decisions (automated through system rule configuration and/or manually through review processes) as to whether to respond to a request or accept a response.

Credential Verification

This function of the PDG-defined EDDS network is defined in Chapter 6. The PDG-defined EDDS network relies on this capability to verify that a conformant issuer issued each credential, the entity providing the credential is identified in the credential, the credential has not been tampered with, and the credential has not expired or been revoked (reflecting a change of status of the underlying registration or license used as proof in the credential acquisition process).

Digital Identity and Credential Management

The PDG-defined EDDS network is a highly distributed network of systems. PI Verification and TI tracing in this network are enhanced by participating entities maintaining an Identity Credential (provides authentication) and Authorization Credentials (ATP Credential, ATP-Equivalent Credential, or DSCSA Authority Credential).

Credential Issuance

Perform the necessary identity verification of the entity, achieving a NIST IAL2 (Identity Assurance Level2) and verifying the entity's ATP, ATP-Equivalent, or DSCSA Authority status as defined in Chapter 6, Credentials.

Credential Acquisition

Credentials are a mechanism used to fulfill the "Authorized Trading Partner" requirements of the DSCSA and Chapter 1 for the purposes of verifications and tracing. The process of acquiring credentials for use in the PDG-defined EDDS network is defined in Chapter 6.

Credential Monitoring

Periodic monitoring of evidence presented in the Credential Issuance process as defined in Chapter 6, credentialing.

PDG-defined EDDS Network Interoperability

Figure 3 shows the Standards, Guidelines, Specifications, and other published artifacts that impact the architecture and interoperability of the PDG-defined EDDS network. Some standards, specifications, and guidelines are dependent on others and the introduction of changes (especially mandatory elements) may affect how other functions are architected. Lastly, it is recognized that each publishing organization has processes in place to manage changes to its standards, guidelines, and specifications. Coordination between these organizations may mitigate delays that affect the industry's ability to efficiently develop, test, and deploy systems based on these standards, guidelines, and specifications.

As these artifacts are managed by several organizations, PDG believes routinized communication and collaboration among these organizations is a critical element to maintaining interoperability in the future. Areas of discussion should include:

- What is each group currently working on related to DSCSA?
- What changes are each group considering/expecting that may affect others' work?
- Are there potential problems on the horizon that will pose challenges to interoperability?
- Are there projects/issues that should be handed off from one group to another?
- Are there important milestones that each group should have on their calendars?

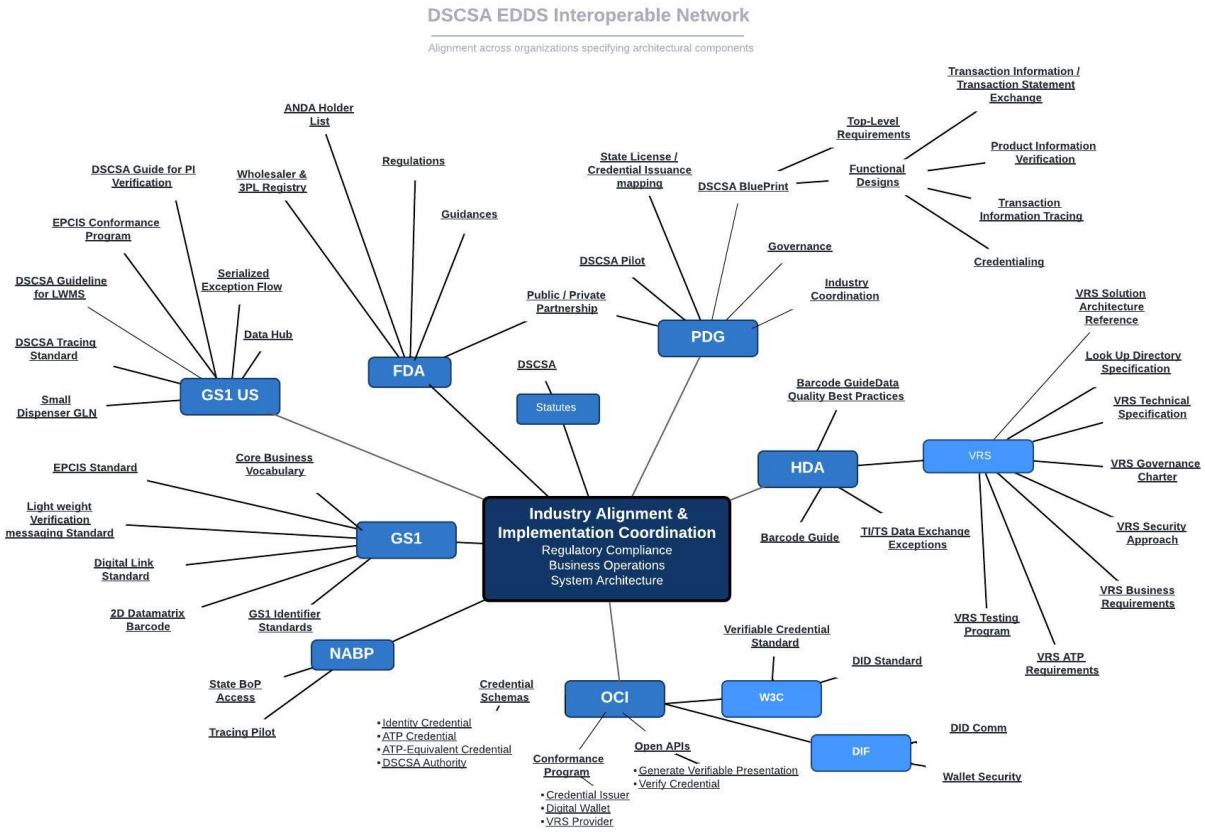

Figure 3 - Standards and Specifications supporting the PDG-defined EDDS network

PDG-defined EDDS network Functional Overview

The Enhanced Drug Distribution Security System (EDDS network) supports trading partner enhanced capability requirements defined in the DSCSA[24]. As defined in Chapter 1 of this blueprint, this generalized and distributed network provides functionality in four main areas:

1. Transaction Information and Transaction Statement (TI/TS) Exchange
2. Product Identifier (PI) Verification
3. Transaction Information and Transaction Statement Tracing
4. Identity and Authorized Trading Partner Credential acquisition, usage, and management

Figure 4 depicts high-level interactions between an Authorized Trading Partner and these network functions. Records retention is called out in *Figure 4* as the DSCSA requires all trading partners to retain records from TI/TS exchanged as well as investigations for six years after the transaction or conclusion of an investigation.

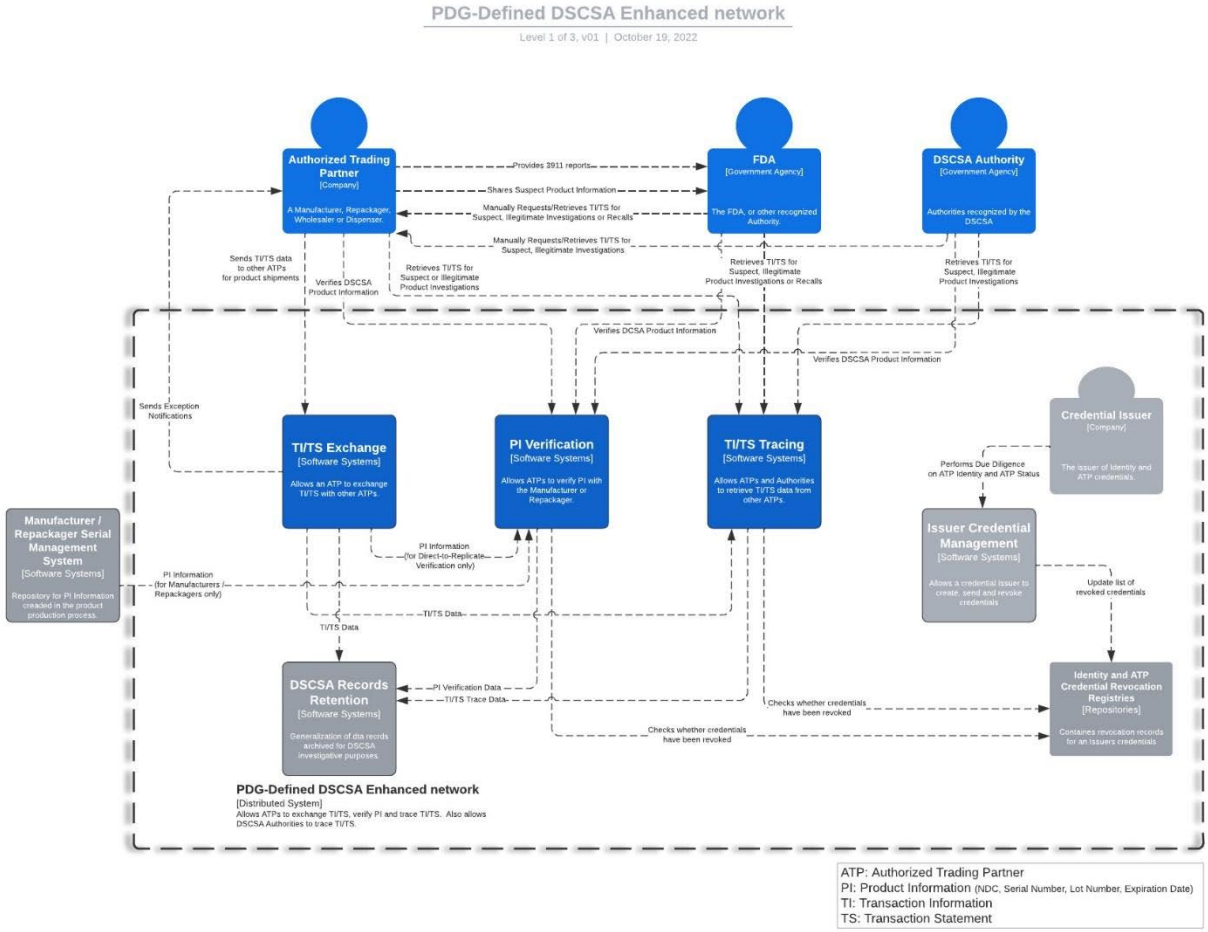

Figure 4 - PDG-Defined EDDS Network Overview

[24] Defined throughout the DSCSA statute and especially in Sec. 203. Enhanced Drug Distribution Security.

Functional Requirements

ID	Issue
EDDS-FR-001	Solutions SHALL not prevent PDG-defined interoperable interactions from occurring. Overall data capture and format, processing, and checks SHALL be maintained such that investigations and audits are able to be carried out through and between systems.

Change Control

Date of Change	Section	Description of Change	Approved By
Version 1.2			
		No changes from prior version	