Partnership for DSCSA Governance (PDG) Prospectus 2022 - 2023

This Prospectus provides an overview of the Partnership for DSCSA Governance (PDG), the membership terms, 2022 accomplishments, and strategic outlook going into 2023. All stakeholders continue to be encouraged to participate in PDG. Please review this document carefully in considering your willingness to participate as a member of PDG. Any questions can be directed to PDG staff at admin@dscsagovernance.org. For additional information, visit www.DSCSAgovernance.org.

Contents

PDG Overview

PDG is an independent, balanced, sector-neutral nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA).

PDG's membership includes leading authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the U.S.

For additional information, visit www.DSCSAgovernance.org.

Governance Body Purpose

The ability to gather and use serialization data among trading partners is essential to the effective and efficient implementation of the DSCSA requirements for electronic interoperable verification and tracing. Meeting 2023 interoperability requirements will require a level of cooperation, coordination, and interconnection at the unit level not present today. Stakeholders throughout the supply chain, including FDA, have broadly recognized that governance is critical to the successful implementation of 2023 requirements.

Efficient implementation requires an intentional implementation plan that builds toward a shared vision for 2023 interoperability. As an independent, balanced, and sector-neutral governance body, PDG is best positioned to establish such an implementation plan and will provide certainty and longevity that benefits the effective, efficient implementation of the DSCSA. No individual sector representative can serve as the governing body because they will be, or will be perceived as, inherently biased; PDG is a sector-neutral body with clear rules for engagement. Each trading partner will be committing significant resources to 2023 implementation. The formal structure of PDG, with well-understood, agreed upon rules for governance provides confidence and predictability in the allocation of those resources.

PDG's work is not dependent on any one specific technical vision for how interoperability should be achieved. The specific technical vision to be advanced by PDG will be determined by PDG using its decision-making mechanisms that promote balance, sector-neutrality, and equitability. At a general level, however, PDG will govern interoperable verification and tracing (as required by DSCSA) and practices and processes that impact the integrity and reliability of interoperable verification and tracing.[1] This includes the practices and processes to create, store, and transmit data intended to be exchanged under DSCSA, but excludes internal company processes and practices. Collectively, the technical vision that includes these practices and processes, as well as the technology for accomplishing them, are referred to as the "blueprint for interoperability."

The primary deliverables of PDG in 2022 were the five functional design chapters of the *Foundational Blueprint for 2023 Interoperability*, which provide the functional specifications for how to implement the PDG *Blueprint*. More specifically, the *Blueprint* for interoperability:

- Defines a vision for interoperability (*e.g.*, a model for TI exchange, credentialing, verification, and tracing)
- Defines the use cases, compliance requirements, and business requirements for DSCSA interoperability.
- Identifies standards and/or functional specifications needed for DSCSA interoperability.

The functional design chapters describe the specifications for interoperability, TI exchange, verification, tracing, and credentialing represent one method for achieving the interoperability required by the DSCSA.

Regulators also play an essential role both in helping to define the requirements of the DSCSA and as a potential recipient of information from DSCSA systems and processes. As such, PDG and the FDA have entered into a public-private partnership to advance implementation of the DSCSA. The public-private partnership will facilitate greater collaboration among PDG and its members. As part of this partnership, the FDA actively participates in the Interoperability Committee meetings. However, the FDA will not have input on agenda creation and will not have voting authority. Additional information on

[1] It is acknowledged that other governance activities may take place. First, PDG is intended to govern interoperability among systems and networks. Specific systems and networks and distinct technologies (*e.g.*, blockchain) may require their own governance activities within their own network or system. Second, it is possible that other governance efforts may emerge with the same or overlapping scope and objective. While it is neither possible nor appropriate to restrict the emergence of such effort, multiple divergent approaches could hamper trading partners' ability to be interoperable, as required by the DSCSA. Therefore, PDG strives to develop and advance a vision for interoperability that is inclusive of the views and goals of divergent stakeholders and attracts the broadest possible set of stakeholders.

the general guidelines outlining the public-private partnership are available here.

Who can participate in the governance body?

Full membership in PDG (and therefore decision-making/voting authority) is reserved for authorized manufacturers,[2] repackagers, wholesalers, third-party logistics providers, and dispensers (*i.e.*, "trading partners," as defined in the DSCSA) with legal obligations under the DSCSA. A 14-member Board **elected by the general membership** is responsible for executive management of the governance body, and contracts staff to carry out day-to-day management. [3] PDG **relies heavily on committee and work group activity** to carry out the tactical/substantive work (*e.g.*, creation of a blueprint for interoperability) of the body. Committees and work groups are **open to all general members**. Technical or process experts (*e.g.*, thought leaders, service providers) are encouraged to participate in the Interoperability Committee's Technical Work Group, in which participation is **not limited** to general members. Further, any interested stakeholder may provide recommendations to PDG.

What are the benefits to/roles of governance body participants?

General Members

The general membership of PDG has the authority to elect board members, approve budgets, and ratify significant technical documents. General members also have the opportunity to participate in committees, which undertake the tactical/substantive work of PDG, including the creation of a blueprint for interoperability. There are two types of general membership:

1. **Trading Partner Members** – any trading partner (as defined in DSCSA) that is authorized (as defined in DSCSA).
2. **Association Members** – any trade association or society the membership of which consists primarily of trading partners (as defined in the DSCSA), and professional societies representing health care providers.

Upon application for membership, each organization will designate itself as a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider. The designated sector does not need to be the member's primary (e.g., highest revenue, highest volume) sector, but must be a sector in which the organization operates and is subject to related DSCSA requirements.

Board Members

The Board has the authority to set the direction and strategy of the governance body, but the activities of the Board are limited to executive functions of the governance body. The 14 Board seats[4] are held by individuals serving staggered two-year terms in their capacity as a sponsored representative of a specific general member (trading partner or association) (*i.e.*, if the elected individual leaves his/her organization, the individual would not retain the seat). Board seats are allocated as follows:

1. **Four manufacturer/repackager board seats** – open to, and elected by, general members who are manufacturers or repackagers.
2. **Four wholesaler/3PL board seats** – open to, and elected by, general members who are wholesale distributors or 3PLs.
3. **Four dispenser board seats** – open to, and elected by, general members who are dispensers.

---

[2] Contract manufacturing organizations (CMOs) may join PDG as a full member if they are a "manufacturer" (i.e., hold an NDA/ANDA/BLA) and/or are considered a "3PL" as defined in the DSCSA. In instances where a CMO is not considered a manufacturer or 3PL, CMOs may join PDG as Technical Expert members.

[3] A 10-member board was elected for the initial six months of PDG activity (*i.e.*, until April 1, 2020). Appropriate ratios were maintained.

[4] A 10-member board was elected for the initial six months of PDG activity (*i.e.*, until April 1, 2020). Appropriate ratios were maintained.

4. **Two at-large board seats** – open to any **general member** regardless of sector; provided that both at-large seats may not be held by members from the same sector. At-large board members are elected by the full general membership (as opposed to a specific sector).

Committee Members

The Committees within PDG carry out the substantive and technical work of PDG. Three committees have been established: (1) Membership Committee; (2) Finance Committee; and (3) Interoperability Committee. Committees are open to all general members, with the exception of the Finance Committee, which is made up of Board members. The Membership Committee is responsible for the development, recruitment, and retention of membership. The Finance Committee is responsible for financial planning, including the development of an annual budget.

Work Group Members

The Interoperability Committee is responsible for the substantive, tactical, and technical work needed to establish and advance an industry consensus for an interoperable system to meet 2023 DSCSA requirements. As a way of maintaining the Interoperability *Blueprint*, the Interoperability Committee is supported by five (5) work groups that include: (1) Credentialing and User Authentication; (2) Serialized TI/TS Data Exchange; (3) Verification Architecture; (4) Tracing Architecture; and (5) Validation Matrix.

1. **Credentialing and User Authentication Work Group** is responsible for defining the systems and processes by which trading partners/users will demonstrate permission to request and exchange data in the governed environment, including “authorized” status.
2. **Serialized TI/TS Data Exchange Work** Group is responsible for defining any systems and processes and business requirements to support interoperability, and identifying messaging standards needed to enable interoperable electronic verification and tracing.
3. **Verification Architecture Work Group** is responsible for defining systems and processes by which trading partners can implement the requirements to verify products in an interoperable, secure electronic manner.
4. **Tracing Architecture Work Group** is responsible for defining systems and processes by which trading partners can implement the requirements to trace products in an interoperable, secure electronic manner.
5. **Validation Matrix Work Group** is responsible for the development of matrices that solution providers can use to validate to trading partners that their system meets the requirements of the PDG *Blueprint*.

The outputs of these work groups will be synthesized by the Interoperability Committee into what is ultimately a comprehensive vision for interoperability.

Membership Dues

Membership dues for 2023 will be reduced by 40% from the 2022 dues. As in 2022, the dues have been established so as to (i) not dis-incent membership by any trading partner, (ii) incent diverse membership, and (iii) incent long-term membership commitment. Accordingly, the membership dues set out below are proposed to be similar (but not identical) among sectors and account for ability-to-pay through three tiers of dues within each sector, based on annual **U.S. pharmaceutical revenue**. A small-business rate is available to trading partners with 25 or fewer full-time employees. A single fee applies to Association Members, and technical expert dues are tiered by number of employees.

	FY 2023 MEMBERSHIP DUES				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**

Tier 1	$ 30,000	$ 30,000	$ 30,000	$ 150	$ 9,000
Tier 2	$ 18,000	$ 18,000	$ 9,000		$4,500
Tier 3	$ 6,000	$ 3,000	$ 1,500		
Small Business	$ 600	$ 600	$ 150		$600

	TIER DEFINITIONS				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	> $10 B	> $10 B	> $10 B	N/A	101+ EEs
Tier 2	$1 B - $10 B	$1 B - $10 B	$1 B - $10 B		26-100 EEs
Tier 3	< $1 B	< $1 B	< $1 B		
Small Business	25 or fewer full-time employees				25 or fewer EEs

Membership dues will cover the period from January 1, 2023, through December 31, 2023. For current members, 2023 membership dues will be invoiced on a schedule that provides flexibility to make payment in late 2022 or early 2023.

2022 Accomplishments

Finalized Chapters 2, 3, 4, 5 and 6 of the PDG *Blueprint*

The *Foundational Blueprint for 2023 Interoperability* is a critical initial framework for implementation of the Drug Supply Chain Security Act (DSCSA)'s 2023 interoperability requirements across the pharmaceutical supply chain and is an important step toward achieving PDG's mission to develop, advance, and sustain an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals.

This document sets forth the PDG-defined compliance requirements and business requirements for 2023 interoperability. Compliance requirements represent characteristics of proposed systems and processes that are necessary to meet the statutory obligations of the DSCSA. Business requirements represent technical characteristics of proposed systems and processes that are operationally necessary to satisfy a compliance requirement. Individual companies' legal interpretations of the specific scope compliance may differ, PDG believes all of the requirements in this document are practically necessary to efficiently achieve interoperability as intended by the DSCSA.

The five functional design chapters build upon the first chapter and provide in great detail how to implement an interoperable system for TI exchange, product identifier verification, tracing, and credentialing. While these chapters represent the best thinking of PDG members, the *Blueprint* does not carry the force of law but serves as an optimal approach to DSCSA implementation.

For additional information on PDG's *Foundational Blueprint for 2023 Interoperability*, please visit: https://dscsagovernance.org/blueprint/.

PDG Interoperability Committee Work Groups

Following the competition of the PDG *Blueprint*, the Interoperability Committee will continue meeting to maintain and update the *Blueprint*, address and resolve implementation challenges, to maintain and enhance collaboration with state and federal regulators, and develop validation matrices for verification, tracing, and credentialing. The work group structure for 2023 will continue on an ad hoc basis to address change requests and questions as they arise. Details on the current and future work of the individual work groups are further outlined below.

- **Credentialing and User Authentication Work Group**. The work group is focused on issues and questions related to the credentialing of ATPs and identity proofing in the existing commercial environment of credentialing organizations.
- Looking ahead, the work group will address any challenge to the credentialing of ATPs or ATP-equivalents, the basis of issuing a credential, and the way in which credentials are issued,
- **Serialized TI/TS Data Exchange Work Group**. The focus of the work group is on determining how EPCIS can be used to convey the 12 elements of TI. Looking ahead, the work group will focus on issues and questions related to functional specifications of TI exchange and processes to facilitate the exchange of TI. The Serialized TI/TS Data Exchange work group will also serve as a single point of contact for interactions with standards development organizations to request and coordinate the development of standards identified by the various work groups.
- **Verification Architecture Work Group**. The work group is working on identifying and resolving data exceptions and will address issues and challenges related to sending or responding to a verification request, including, applying credentials, inadvertent paths for suspect, illegitimate, and recall notifications, and interactive electronically with regulators.
- **Tracing Architecture Work Group**. The work group will remain focused on challenges related to tracing services, including response times, security practices, tracing purpose codes, adjacent trading partner tracing endpoints, internal transfers, broken tracing, and any issue that may arise.
- **Validation Matrix Work Group.** The work group is focused on the development of a validation matrix for each interoperable verification, interoperable tracing, and credentialing. Each validation matrix will crosswalk the compliance and business criteria in the *Blueprint* to the functional criteria in the *Blueprint* to the appropriate testing and acceptance criteria. Where necessary, the work group will define additional testing and acceptance criteria.

PDG Membership

Upon the formation of PDG, the founding members were focused on ensuring that membership recruitment would enable PDG to achieve the principles that engagement of all trading partner sectors of the pharmaceutical supply chain is critical to achieving supply chain security and improving patient safety. PDG has been successful in recruiting 68 members that includes all trading partners sectors within the pharmaceutical supply chain. These members include 17 manufacturers/repackagers; 10 wholesalers/3PLs; 12 dispensers; 27 technical experts, and 2 liaisons. While dispenser participation is still needed, the Board has been successful in recruiting several small dispensers to participate in Interoperability Committee discussions. These small dispensers are participating in a non-voting technical capacity. Importantly, the Board of Directors continues to work through initiatives aimed at increasing dispenser membership within PDG.

PDG Role in Governance

The role of PDG has been to ensure the execution of its mission to develop, advance, and sustain an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the United States. With the business requirements, functional design, and conformance criteria finalized, the role and structure of PDG for 2023 and beyond is a governance role to sustain

interoperability.

Looking Ahead: 2023

The 2023 activities will focus on the Interoperability Committee work group activity while continuing to address and resolve implementation challenges and meet the needs of PDG membership and industry. Based on the member recommendations and input solicited over 2022, PDG has identified six strategic areas of focus, which are described in detail in the PDG Post-*Blueprint* Strategic Plan, to advance and sustain DSCSA interoperability.

These six focus areas are:

1. Maintain and update the *Blueprint*.
2. Facilitate resolution of implementation issues and problems.
3. Provide education related to the *Blueprint*.
4. Encourage *Blueprint* implementation.
5. Maintain and enhance collaboration with FDA & State Boards of Pharmacy.
6. Develop Validation Matrices for verification, tracing, and credentialing.

Aside from the work groups, significant progress continues to be made coalescing around an overall model for governance and interoperability. That model will solidify PDG's governance role at the highest level by leveraging the existing commercial environment and bringing coordination and alignment to the interoperability functions within that environment. Continued work on this model will be a critical component of the remaining year's work and will drive the long-term role, structure, and function of PDG as an organization.

Appendix B

FY 2023 Budget

The membership dues structure was developed to provide sufficient funding for the following budget. Importantly, and as further noted above, we view 2023 as a transitional year to significantly lighter maintenance efforts in 2024 and beyond. To that end, while PDG will remain quite active in 2023 with an emphasis on education, awareness, and adoption of the *Blueprint,* its workload will be meaningfully reduced compared to years prior. The FY 2023 target budget outlined below may need to be reduced/revised/revisited based on actual FY23 revenue.

Spend Category	Target FY23 Budget	Notes & Assumptions
Administration	-	
Management Fees (Staff)	$250,000	Executive Director role, POC for administrative functions, basic PPP engagement, respond to member inquires, represent the organization, board support, general member support
Meeting Space	$10,000	Cost of reserving meeting space.
Technology/Equipment	$1,000	Office space, technology, and equipment, required for meetings.
Accounting (Internal)	$20,000	Invoicing, Dues Collection, and Vendor Payments
Travel	$15,000	Travel to off-site meetings, conferences and conference fees where applicable to present on PDG and recruit membership. (5 Trips @ 3k / Trip)
Membership Management Tool	$10,000	Collaboration platform/tool to manage committees, boards, voting, and documentation.
Consultants/SMEs	-	
PM Consultant	0	Project management of technical deliverables.
Technical Support Consultant	$75,000	Technical support for the interoperable committee and work groups. Responsible for development of technical documentation and deliverables.
External Fees	-	
Accounting (external)	$5,000	Fees to handle external tax filings and external audits.

Legal	$42,000	External Council - Covers review of SOPs and documents, antitrust advice, general corporate support, attendance of Board meetings, etc.
Insurance	$20,000	Insurance for PDG/Board Members
Marketing	-	
Website Development	$2,000	Initial Website registration and Development
Marketing and Recruitment Services	$50,000	Expenses to socialize and elevate PDG awareness and engagement
Educational Services	$250,000	Educate stakeholders on PDG and its work and incentivize Blueprint adoption
Other	-	
Transition Planning	0	Expenses needed to transition PDG to its, currently TBD future state; may include legal fees, insurance, permanent staff search and recruiting, creation of partnerships, etc.
Contingency	0	To be drawn from prior year's surplus
Total Budget	**$750,000**	