Partnership for DSCSA Governance (PDG) Prospectus 2021 - 2022

This Prospectus provides an overview of the Partnership for DSCSA Governance (PDG), the membership terms, 2021 accomplishments, and strategic outlook going into 2022. 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 deliverable of PDG in 2021 was the *Foundational Blueprint for 2021 Interoperability*, the publication of which will help to further define the scope of governance moving forward. 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.

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.

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[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.

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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 are used to 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 aiding in the development and completion of the Interoperability Blueprint, the Interoperability Committee is supported by four (4) work groups that include: (1) Credentialing and User Authentication; (2) Serialized TI/TS Data Exchange; (3) Verification Architecture; and (4) Tracing Architecture.

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 product 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 product in an interoperable, secure electronic manner.

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

Membership Dues

Membership dues for 2022 will remain unchanged from 2021. As in 2021, 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 2022 MEMBERSHIP DUES				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	$ 50,000	$ 50,000	$ 50,000	$ 250	$ 15,000

Tier 2	$ 30,000	$ 30,000	$ 15,000		$7,500
Tier 3	$ 10,000	$ 5,000	$ 2,500		
Small Business	$ 1,000	$ 1,000	$ 250		$1,000

	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, 2022 through December 31, 2022. For current members, 2022 membership dues will be invoiced on a schedule that provides flexibility to make payment in late 2021 or early 2022.

2021 Accomplishments

Finalized Chapter 1 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. 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 FDA DSCSA Pilot Project, the Interoperability Committee has been successful in moving into a work group structure and will continue to do so for the remainder of 2021 and throughout 2022. The work groups are heavily engaged and focused on defining, drafting, and publishing functional specifications and conformance criteria. Detail on the current and future work of the individual work groups is further outlined below.

- **Credentialing and User Authentication Work Group**. The work group is focused on developing a framework for the Credentialing of ATP status. To this end, the work group has organized and aligned on an overall model for ensuring both ATP credentialing and identity proofing are consistent with a consensus framework, while also maintaining and leveraging the existing commercial environment of credentialing organizations.
- Looking ahead, the work group will focus on (1) credentialing regulators, (2) the basis on which credentials will be issued, and (3) the way in which credentials will be issued, exchanged, and trusted. Those frameworks will incorporate solutions to critical issues, such as delegation of credentials to an ATP's service providers and third parties and the challenges of M&A activity and divestitures.
- **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 functional specifications, including the functional design of use cases, which will become part of the Blueprint, and propagating an extended expiration date through the supply chain and within company operations. Importantly, 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 exception specifications, applying credentials, inadvertent paths for suspect, illegitimate, and recall notifications, and interactive electronically with regulators.
- **Tracing Architecture Work Group**. The work group is focused on defining and documenting the minimum capabilities for accredited tracing services (response times, security practices, tracing purpose codes, etc.). Looking ahead, the work group will focus on adjacent trading partner tracing endpoints, internal transfers, and broken tracing.

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 71 members that includes all trading partners sectors within the pharmaceutical supply chain. These members include 21 manufacturers/repackagers; 9 wholesalers/3PLs; 10 dispensers; and 31 technical experts. 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. It is expected that when the remaining business requirements, function design, and conformance criteria are finalized, the role and structure of PDG will need to shift to a governance role to sustain interoperability. During 2022, PDG will more comprehensively define the need of a governance function to support credentialing, verification, and tracing and, if needed, whether PDG is best positioned to provide that governance function.

Looking Ahead: 2021 – 2022

The remainder of 2021 activities will focus on the Interoperability Committee work group activity while continuing to progress toward publication of additional chapters of the *Foundational Blueprint* that

define functional design and conformance criteria for (1) credentialing services/methods for demonstrating ATP status and identity (*i.e.*, authorization), (2) serialized TI exchange (3) verification services, and (4) tracing services, including the review and escalation of those frameworks through the Interoperability Committee, Board, and General Membership. Additional organizational efforts will focus on raising awareness of the PDG activity and socializing the expected release of the Vision for 2023, as well as continued recruitment of additional members.

Looking toward 2022, PDG will build on the success of 2021 through focus on several areas:

1. Finalizing the functional design and conformance criteria for Serialized TI Exchange, Verification, Tracing, and Credentialing in 2021;
2. Promote, building awareness of, and aligning to/support for the PDG vision for 2023 interoperability among trading partners, solution providers, and regulators;
3. Collaboration with standards bodies and other similar stakeholders to fill gaps identified through the PDG *Foundational Blueprint*;
4. Execution, pursuant to a plan, on PDG technical implementation items identified in the *Foundational Blueprint*;
5. Transitioning the PDG organizational structure, as necessary, to fill the industry governance role needed to advance and sustain the *Foundational Blueprint*;
6. Establishing and executing process for escalation of issues identified by those impacted by the PDG vision;
7. Developing and advancing testing and onboarding plans; and
8. Monitoring industry progress toward the *Foundational Blueprint*.

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 2022 Budget

The membership dues structure was developed to provide sufficient funding for the following budget. Importantly, and as further noted above, dues will remain flat for FY 2022. The FY 2022 target budget outlined below may need to be reduced/revised/revisited based on actual FY22 revenue.

Spend Category	Target FY22 Budget	Notes & Assumptions
Administration	-	
Management Fees (Staff)	$600,000	Fees associated with performing the administrative tasks with running PDG.
Meeting Space	$20,000	Cost of reserving meeting space.
Technology/Equipment	$10,000	Office space, technology, and equipment, required for meetings.
Accounting (Internal)	$50,000	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	This will fund project management of interoperable committee and support of related deliverables.
Technical Support Consultant	$150,000	Technical/Regulatory support for the interoperable committee. Responsible for development of technical documentation and deliverables.
External Fees	-	
Accounting (external)	$15,000	Fees to handle external tax filings and external audits.

Legal	$75,000	External Council - Covers review of SOPs and documents, antitrust advice, general corporate support, etc., but does not contemplate legal counsel in every meeting.
Insurance	$20,000	Insurance for PDG/Board Members
Insurance [pdg accrediting]	0	Included in the event that PDG is the accrediting body vs. contracting it out (i.e., GS1 EPCIS Badging Model).
Marketing	-	
Website Development	$2,000	Initial Website registration and Development
Marketing and Recruitment Services	$10,000	Specific Fees for recruiting new members
Educational Services	$25,000	Educational Materials and Communication (Webinars, etc.).
Other	-	
Transition Planning	$200,000	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	$100,000	General Surplus of Revenue less % Fee
Total Budget	**$1,302,000**	