The attached Prospectus details the structure and membership terms of the Partnership for DSCSA Governance (PDG), an industry governance body to support interoperability as required by the Drug Supply Chain Security Act (DSCSA). It has been developed collaboratively and launched by dozens of stakeholders throughout the supply chain.

All stakeholders are encouraged to participate in PDG. A diversity of members (sectors, sizes, business models) is expressly desired. Please review the attached document carefully in considering your willingness to participate as a member of PDG. Any questions can be directed to PDG Executive Director, Eric Marshall at Eric.Marshall@leavittpartners.com.

Interested stakeholders should complete a membership application and return the application to Eric.Marshall@leavittpartners.com. All membership applications will be reviewed and approved by the Membership Committee, and application approval will trigger the invoicing process. Upon acceptance of membership, member representatives can indicate their interest in committee participation.

OVERVIEW

Partnership for DSCSA Governance (PDG)

Various stakeholders have worked in recent months to launch a balanced, sector-neutral governance body to support the interoperable electronic tracing of pharmaceuticals, as required by the Drug Supply Chain Security Act (DSCSA). This document is intended to provide stakeholders with the information necessary to evaluate their interest and willingness to formally participate in those governance activities through formal membership in the Partnership for DSCSA Governance (PDG).

What is the purpose of the governance body?

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. Phase II interoperability 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 Phase II interoperability.

Efficient implementation requires an intentional implementation plan that builds toward a shared vision for Phase II interoperability. As an independent, balanced, and sector-neutral governance body, PDG will be 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 will 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 Phase II implementation. The formal structure of PDG, with well-understood, agreed upon rules for governance will provide confidence and predictability in the allocation of those resources.

Formation and operation of PDG 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 within the first year is this blueprint for interoperability, the establishment of which will help to further define the scope of governance moving forward. More specifically, it is expected that the blueprint for interoperability will:

- Define a database architecture (*e.g.*, centralized, semi-centralized, distributed) for DSCSA interoperability.
- Define necessary governance body activities (*e.g.*, whether the body will issue best practices or will identify technical specifications to support interoperability).
- Define the vision for interoperability (*e.g.*, a model for credentialing tracing services, establishment of technical systems to support interoperability)
- Define the use cases and business requirements for DSCSA interoperability.
- Identify standards and/or functional specifications needed for DSCSA interoperability.

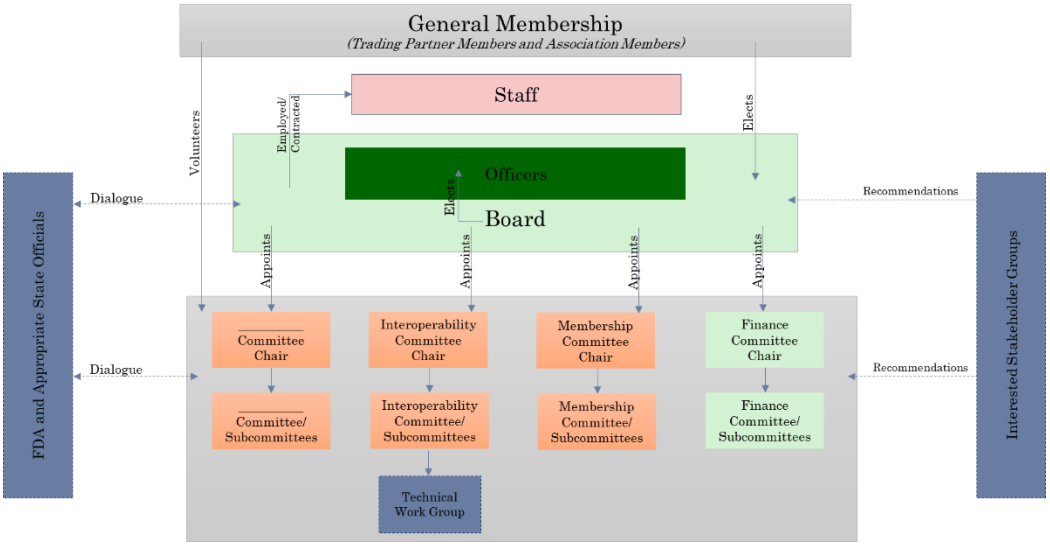
[1] It is acknowledged that other governance activities may take place. First, PDG is intended to govern interoperability among systems and networks. Specific systems and networks and distinct technologies (*e.g.*, blockchain) may require their own governance activities within their own network or system. 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.

- Identify any infrastructure that may be 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. FDA has acknowledged the importance of governance and has shown a willingness to engage in dialogue regarding the method by which FDA will engage with PDG. FDA has called for governance at public meetings, has attended an industry workshop where industry members discussed the specifics of governance, and has accepted into the official FDA Pilot Program an application for a governance pilot that is being conducted by PDG. The pilot accepted by FDA is specifically intended to determine and refine methods of regular engagement between the governing body and FDA. FDA's engagement with PDG will provide valuable feedback on governance activities and should help the governance body be assured its activities and plans are consistent with regulators' expectations.

Who can participate in the governance body?

Full membership in PDG (and therefore decision-making/voting authority) is reserved for authorized manufacturers, 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 may hire or contract staff to carry out day-to-day management. [2] PDG **relies heavily on committee activity** to carry out the tactical/substantive work (*e.g.*, creation of a blueprint for interoperability) of the body. Committees 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. This structure is detailed in the graphic below.



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

OVERVIEW

Partnership for DSCSA Governance (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[3] 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.
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

Committees are used to carry out the substantive and technical work of PDG. Three initial committees were established: a Membership Committee, a Finance Committee, and an 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.

Members of the Technical Work Group

The Interoperability Committee is responsible for substantive, tactical, and technical work needed to establish a blueprint for interoperability. The Interoperability Committee also has a Technical Work Group

[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.

in which both general members and non-member thought leaders, such as service providers and other experts, can participate. The Work Group meets regularly to ensure service providers and other technical experts have continuity of information and early awareness of, and input to, the blueprint for interoperability. The Work Group also serves an advisory function making recommendations to the Interoperability Committee on technical matters (*e.g.*, recommendations on reasonably expected response times).

What is the cost of membership in the governance body?

Projecting the long-term funding model for PDG is very difficult given that the technical blueprint for interoperability is not currently known and will be established by PDG over the course of 2020. During this first year of operation, while the blueprint for interoperability is being developed, the governance body will be funded by membership dues.

Beyond the first year of operation, the funding will be highly dependent on the specific blueprint PDG pursues. For example, the cost of operating PDG will be relatively low if it simply develops a set of high-level best-practices documents, but the cost will be relatively high if PDG determines that significant shared asset or services (*e.g.*, databases, registries) are needed to achieve interoperability. Such assets or services would, however, open the possibility for funding streams other than membership dues. While this will need to be determined—*and approved*—by the membership, it is expected that long-term membership dues will use a similar *structure* to the initial year's dues, even if the amounts vary or supplemental revenue streams are established.

Membership dues for 2020 were established so as to (i) not dis-incent membership by any trading partner, (ii) incent early, 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 by through three tiers of dues within each sector, based on annual U.S. pharmaceutical revenue. In addition, a small-business rate is available to trading partners with 25 or fewer full-time employees. A single fee applies to Association Members as well as technical experts in the technical work group.

	ANNUAL MEMBERSHIP DUES				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	$ 50,000	$ 50,000	$ 50,000	$ 10,000	$ 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

Initial membership dues will cover the period from commencement of membership through December 31, 2020. It is generally expected that annual membership dues will be paid in full at the beginning of the year.

The budget supported by these dues rates is detailed in Appendix A.

When was the governance body formed?

PDG was officially incorporated on October 4, 2019, and the initial 10-member board was officially seated on November 13, 2019. The following is a full list of key formation milestones:

October 4, 2019	Entity Officially Incorporated
October 14, 2019	Governance Body Kick-Off Meeting
October 15 – October 30, 2019	Board Elections
November 13, 2019	Board Officially Seated; Entity Officially Named the Partnership for DSCSA Governance (PDG)
November 21, 2019	Board Meeting; Committee Chairs Appointed
December 12, 2019	Board Meeting
December 13, 2019	PDG Membership & Prospects Meeting
December 16, 2019	Public Rollout of PDG
January 2020	Committee Activity Commences

There are several key milestones that must be reached and deliverables that must be created within the first year of PDG operations. These milestones include:

- Complete FDA pilot – Target date: April 2020
- Approve a business plan – Target date: July 2020
- Establish a high-level blueprint for interoperability – Target date: September 2020

A more detailed overview of milestones for the first year is included in Appendix B.

OVERVIEW

Partnership for DSCSA Governance (PDG)

What is the value of PDG?

The risk to trading partners from a void of governance is that systems and networks for DSCSA compliance will emerge and evolve without the foresight and coordination needed to ensure interoperability of those systems and networks, as required by DSCSA. Membership in PDG will support operation of an independent, balanced, sector-neutral mechanism to ensure the development of an effective, efficient path to DSCSA interoperability, and it will afford members the opportunity to shape the blueprint and thereby minimize the impact of interoperability on their business.

Draft Budget

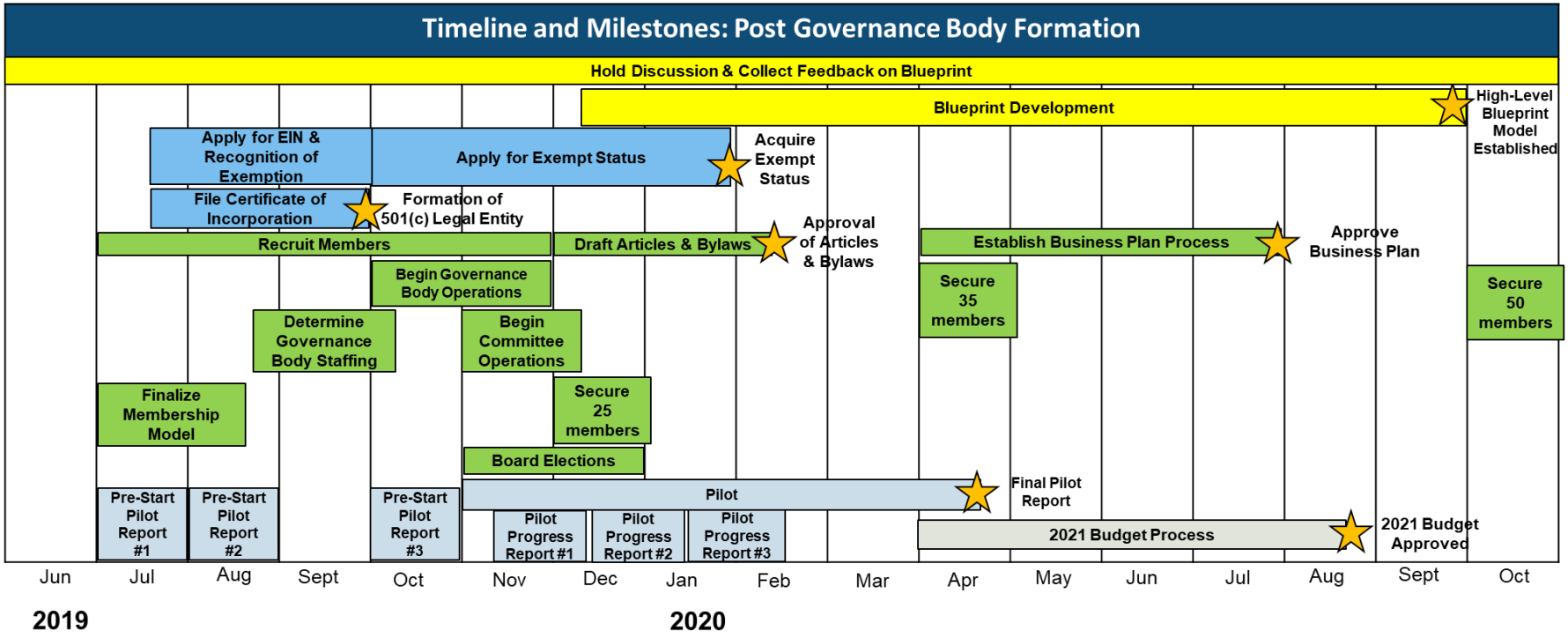
The membership dues structure was developed to provide sufficient funding for the following budget. As noted, the budget beyond the first year is unknown and could fluctuate significantly depending on the technical blueprint for interoperability that is developed by the governance body. Accordingly, the budget below for Years 2 and 3 should be used only as a point of reference subject to significant potential fluctuations.

Draft Budget				
	Year 1	**Year 2**	**Year 3**	*Notes & Assumptions*
Staff	$ 700,000	$ 875,000	$ 875,000	*For Year 1, this assumes an Executive Director at $300k and two staff at $200k each (fully loaded). These could be direct hires or outsourced FTEs.*
Consultants/SMEs	$ 500,000	$ 625,000	$ 781,250	*This will fund issue-specific technical experts to support development of a blueprint for interoperability, and includes their travel.*
Accounting	$ 75,000	$ 56,250	$ 56,250	*This assumes payroll support from any consultant that provides the staffing.*
Legal	$ 150,000	$ 112,500	$ 84,375	*Covers review of SOPs and documents, antitrust advice, general corporate support, etc., but does not contemplate legal counsel in every meeting.*
Facilities/Equipment	$ 50,000	$ 62,500	$ 78,125	*Office space, technology, and equipment, recognizing much of this is offloaded if staff are outsourced.*
PR and Communications	$ 50,000	$ 62,500	$ 78,125	*Website, marketing materials, educational materials, etc.*
Recruiting/education/ membership services	$ 75,000	$ 93,750	$ 70,313	*Membership recruitment and general industry educational activities.*
Travel	$ 50,000	$ 62,500	$ 78,125	*20 trips at $2500 per trip, assuming approximately 6 industry functions and 12-14 recruiting/member visits.*
Meetings	$ 100,000	$ 100,000	$ 75,000	*Cost of space and support for membership and committee meetings, assuming such is not provided by outsourced staff.*
Insurance	$ 15,000	$ 15,000	$ 15,000	*General business liability and D&O insurance.*
Total Budget	**$ 1,765,000**	**$ 2,065,000**	**$ 2,191,563**	

The dues structure will support the above budget based on the following targeted number of members (52 trading partners, 6 association, and 14 technical experts). It is recognized that it will take time to reach or exceed these targets. Therefore, formation of the governance body would be initiated upon commitment from half of the targeted number of members and the budget will be managed fluidly over the course of the year to scale up to the budgeted levels as the full targeted number of members are added.

	Targeted Number of Members				
	Manufacturers	**Wholesalers**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	12	3	4	6	10
Tier 2	7	2	8		
Tier 3	3	2	6		
Small Business	0	0	5		
Total	22	7	23	6	10

Appendix B


Timeline and Milestones: Post Governance Body Formation
Hold Discussion & Collect Feedback on Blueprint
Blueprint Development
High-Level Blueprint Model Established
Apply for EIN & Recognition of Exemption
Apply for Exempt Status
Acquire Exempt Status
File Certificate of Incorporation
Formation of 501(c) Legal Entity
Recruit Members
Draft Articles & Bylaws
Approval of Articles & Bylaws
Establish Business Plan Process
Approve Business Plan
Begin Governance Body Operations
Secure 35 members
Secure 50 members
Determine Governance Body Staffing
Begin Committee Operations
Finalize Membership Model
Secure 25 members
Board Elections
Pre-Start Pilot Report #1
Pre-Start Pilot Report #2
Pre-Start Pilot Report #3
Pilot
Final Pilot Report
Pilot Progress Report #1
Pilot Progress Report #2
Pilot Progress Report #3
2021 Budget Process
2021 Budget Approved
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