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PDG Post-Blueprint Strategic Plan

Executive Summary

Publication of the final chapters of the PDG *Blueprint* will mark a significant milestone for PDG. This Strategic Plan outlines the strategy PDG will follow upon *Blueprint* publication to support its adoption throughout the industry and fulfil the PDG mission to *sustain* an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S. The strategy detailed in this document explains how PDG will execute processes to maintain the *Blueprint* and changes to it that are needed, execute a strategy to raise awareness and understanding of the *Blueprint* and encourage and support its adoption, and expand our collaboration with FDA and state regulators to promote consistency across all end users of interoperable DSCSA systems and processes to enhance supply chain security.

Background

PDG was formed in 2019 following more than two years of industry discussion of the need for "industry governance" of DSCSA interoperability. As stated at the time of formation, the need, purpose, and scope of PDG were as follows:

- *Need for an Industry Governing Body*: DSCSA interoperability requires a level of cooperation, coordination, and interconnection at the unit level not previously present, and governance is needed to provide that cooperation and coordination. Efficient implementation of the statute will require an intentional implementation plan, and a forum is needed for development of that plan.
- *Purpose of Governing Body*: Develop a vision for full implementation of DSCSA interoperability and advance commitment to that vision.
- *Scope of Governing Body*: The scope should focus on interoperable verification and tracing (as required by DSCSA), including practices and processes that impact the integrity and reliability of interoperable verification and tracing. Transaction information (TI) exchange should be considered in-scope to the extent it impacts interoperability among trading partners, but business-to-business TI exchange *between* two trading partners is otherwise out of scope.

The design and structure of PDG was developed by numerous industry members across the supply chain over an 18-month period, culminating in an open public workshop for final input and revisions. PDG was specifically designed and structured to provide a balanced, independent, sector-neutral legal entity that could govern DSCSA interoperability within industry. In many ways, PDG can be viewed as a legal entity with a defined mechanism for balanced, sector-neutral industry decision-making, and the ways in which that "shell" can best be used to support interoperability may evolve over time.

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PDG was designed and intended to have a narrow, cross-sector focus. PDG was, and is, not intended to be a trade association. Nor is it intended to engage in lobbying or to act as a consultant to support individual members' DSCSA implementation activities. Rather, PDG is intended to do those things necessary to achieve interoperability (as required by the DSCSA) that no individual trading partner or sector is able or willing to do alone.

As established by the PDG Board of Directors, the organization's mission and vision are as follows.

> ***PDG Mission:*** *PDG is a collaborative forum dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.*
>
> ***PDG Vision:*** *Enhance pharmaceutical supply chain security in the interest of patient safety for generations to come.*

Since formation in 2019, PDG's activities have primarily focused on the development and publication of the *PDG Foundational Blueprint for 2023 Interoperability.* The initial chapter of the *Blueprint* was published in 2021 and established the core business and compliance requirements (i.e., the "what"). Publication of additional chapters setting out the functional requirements (i.e., the "how") is anticipated in the fall of 2022. This document sets out the go-forward strategy for PDG following publication of those additional chapters of the *Blueprint.* For purposes of this document, we refer to PDG's work to publish the *Blueprint* as "Phase I" of PDG's work, and "Phase II" refers to PDGs' go-forward activities following publication of the full *Blueprint.*

The PDG Board of Directors has spent the past year collecting significant input from PDG members to understand the value PDG can provide moving forward in Phase II. PDG hosted a workshop in November 2021 to develop consensus on the governance functions needed to support interoperable verification and tracing, as well as credentialing. Approximately 100 member representatives participated in that workshop, and there was broad consensus that PDG should undertake a governance function to support verification and credentialing. Specifically, members felt that PDG should (1) define common baseline requirements (i.e., conformance criteria); (2) define common baseline process; (3) confirm (or provide for confirmation of) whether the conformance criteria have been met by a given system; (4) ensure consistent interpretation and application of the conformance criteria; and (5) support change management. At the time, the model for interoperable tracing was not mature enough to facilitate a consensus view on governance.

Over the course of 2022, the PDG Board of Directors continued to solicit member input and feedback on the PDG role for Phase II through a detailed set of surveys and focus groups of both General Members and Technical Experts. This process further confirmed the importance and value of an ongoing governance function in Phase II. The recommendations of those surveys and focus groups are directly reflected in this strategy document.

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Strategic Focus Areas

Based on the member recommendations and input solicited over the last year, the PDG Board of Directors has identified six strategic areas of focus for Phase II of PDG's work to advance and sustain DSCSA interoperability. Those areas of focus are summarized here, followed by a more detailed strategy and plan for each.

1. **Maintain and update the Blueprint**. PDG will continue to update the Blueprint to ensure it remains in alignment with regulation and industry needs, including change management necessary to support revisions.
2. **Facilitate resolution of implementation issues and problems**. PDG will gather industry intel from organizations that have implemented the *Blueprint* and address implementation challenges that arise.
3. **Provide education related to the *Blueprint***. PDG will execute a communication and education plan to build awareness and understanding of the *Blueprint.*
4. **Encourage Blueprint implementation**. PDG will actively promote and incent stakeholder adoption and implementation of the *Blueprint*.
5. **Maintain and enhance collaboration with FDA & State Boards of Pharmacy**. PDG will solidify and strengthen the public-private partnership (PPP) with the FDA and formalize and expand its collaboration with State Boards of Pharmacy.
6. **Develop Validation Matrices for verification, tracing, and credentialing.** PDG will use the interoperability criteria previously developed for the *Blueprint* and the testing criteria developed by outside organizations to review and adopt validation matrices. PDG will identify testing organizations that agree to execute these matrices for any verification, tracing, or credential testing they perform.

Strategic Focus Areas Detailed Strategy and Plan

1. **Maintain and update the Blueprint**. PDG will continue to update the Blueprint to ensure it remains in alignment with regulation and industry needs.

Throughout the implementation of the *Blueprint*, and as system updates and enhancements are made in the future, changes and additions to the *Blueprint* will be identified. This need has already been experienced in response to Chapter 1 of the *Blueprint*, and PDG has an existing change request process that has generally met the needs for those changes. That process is documented here. PDG will ensure that process is maintained, and improved if needed, to support *Blueprint* updates.

In addition to direct changes to the *Blueprint*, there is also a need for broader industry change management going forward. Interoperability is ultimately being defined through multiple interrelated standards and specifications, such GS1 standards, OCI specifications

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and W3C standards, VRS specifications, and the PDG *Blueprint*. FDA regulation and guidance is also part of this web. Revisions and updates to any one of these standards, specifications, or criteria is likely to have a trickle-down impact on other of the standards and specifications. For example, implementation of the next version of GS1's EPCIS standard may require conforming changes to the PDG Blueprint, VRS specifications, and others. Each organization should retain control over its changes process, but communication, planning, and coordination of sunrise and sunset dates and other change management activities will be critical. As an independent, sector-neutral industry body, PDG is uniquely positioned to facilitate the cross-organization discussion needed to support that change management.

Plan:

- The PDG Board, in consultation with the Interoperability Committee leads, will review the current change request process and identify any necessary revisions needed to support its applicability moving forward. *(Complete)*
- PDG will continue to execute its change request process. *(Ongoing)*
- PDG will promptly convene standards bodies and specification holders to identify and document change management needs. *(Complete)*
- The PDG Board will continue to evaluate and determine its proper role in the broader change management process. *(Complete)*
- It is anticipated that the Committee/WG function will evolve to become more Committee centric with more ad hoc work by the Work Groups. *(Target: 2023 evolution)*

2. **Facilitate resolution of implementation issues and problems**. PDG will gather industry intelligence from organizations that have implemented the *Blueprint* and address implementation challenges that arise.

It should be anticipated that there may be disputes[1] among stakeholders (ATPs or solution providers) as to the appropriate approach to interoperability, and many of those disputes may relate to the *Blueprint*. Such disputes between two or more stakeholders have significant potential to impede interoperability, either by slowing implementation or by driving alternate, non-interoperable approaches. These could be disputes between/among trading partners, disputes between/among solution providers, or disputes between/among trading partners and solution providers. PDG will provide a forum to resolve those disputes through a defined

[1] These "disputes" may not necessarily be contentious. It may be that two parties have differing interpretations/approaches and are largely indifferent to which prevails; rather the need is just for one consistent interpretation/approach.

process. This process will be available to both PDG members and non-PDG members. It is important to note the scope of disputes that PDG will and will not resolve.

In scope:

- Disputes over interpretation of the Blueprint
- Disputes that can appropriately be resolved through additions/revisions to the *Blueprint* and related PDG documentation
- Major challenges that threaten to undermine interoperable systems and process for verification and tracing even if they are not able to be resolved through the *Blueprint* (*e.g.,* how to manage a drastic uptick in verification volumes that cannot be sustained by current systems)

Out of Scope:

- Purely commercial disputes between software solutions and/or trading partners
- Disputes that cannot appropriately be resolved through additions/revisions to the *Blueprint* or related PDG documentation (other than major challenges that threaten to undermine interoperable systems and process for verification and tracing)

Ambiguities as to whether a particular dispute is in or out of scope for PDG will be resolved by the Board. One key to success in the resolution of issues and problems will be ensuring those involved in such disputes are aware of the PDG process and are inclined to use the PDG process. Clear articulation of this PDG function and education—particularly among solution providers—will be important. PDG will also monitor the environment to identify disputes that may exist. If so identified, PDG will encourage the relevant stakeholders to bring those disputes forward to PDG.

Plan:

- The PDG Board, in consultation with the Interoperability Committee leads, will review the current change request process and determine whether it can accommodate the dispute resolution needs above. The Board will then either revise the change request process to accommodate such dispute resolution or establish a separate dispute resolution process. *(Target: Jan 2023)*
- PDG will develop clear documentation of the dispute resolution process and execute a communications plan to make stakeholders aware of the process and its scope. *(Target: Jan 2023)*
- PDG will execute the defined dispute resolution process. *(Target: Ongoing)*

3. **Provide education related to the *Blueprint***. PDG will execute a communication and education plan to build awareness and understanding of the *Blueprint.*

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The education strategy will have two main components: education of ATPs and education of solution providers (those who develop solutions used by ATPs, which may include ATPs that develop their own solutions).

ATP Education. Individual ATPs hold the regulatory responsibility for DSCSA compliance and interoperability, but that compliance and interoperability is achieved through various systems and solutions. Most often these are purchased third-party solutions, but occasionally they also include "homegrown" solutions developed and operated by an ATP itself. Education efforts targeted at ATPs will seek to build their *general* understanding and comfort with the *Blueprint*. ATPs' general support for the *Blueprint*—particularly their trust and confidence in the process by which it is developed and maintained—is highly important. That said, an individual ATP's disagreement with a few minor components, or even a small number of ATPs' disagreement with the *Blueprint* entirely, is not detrimental to the ultimate goal of the *Blueprint*. Ultimately, what is needed is enough *general* support from a critical mass of ATPs to persuade the developers of DSCSA solutions to follow the *Blueprint*.

If there is adoption and implementation of the *Blueprint* by/through most of the solutions, there will likely be hundreds or thousands of ATPs that "follow" the *Blueprint* by virtue of using solutions that have implemented it, regardless of whether those ATPs have any awareness that they are "following" the Blueprint.

ATP awareness and education efforts will therefore focus on:

1. Expanding general awareness of PDG and the *Blueprint*.
2. Building a general understanding of the independent, sector-neutral, ATP-driven process used to establish the *Blueprint*.
3. Understanding of how the use of solutions that conform to the *Blueprint* improve the efficiency of DSCSA compliance.
4. Providing information on how to engage for more detailed information.

Solution Provider Education. More complete and prescriptive adoption and implementation of the *Blueprint* by solutions[2] is critical. As noted above, ATPs generally rely on solutions to carry out TI exchange and verification, and eventually, tracing. Interoperability is, therefore, dependent on the interoperability of those solutions, and one way to achieve such interoperability of solutions is through conformance of those solutions to the *Blueprint.*

Solutions—via the developers and providers of those solutions—are therefore more of a target for *adoption* and *implementation* of the *Blueprint.* It is important that PDG drive adoption and

2 It is important to note that "solutions" in this instance are narrow and include only those solutions for interoperable TI exchange, verification, tracing, and credentialing. The *Blueprint* is not targeted at every DSCSA-related system, such as an ATP's internal DSCSA repository or similar systems.

implementation of the *Blueprint* by solutions. Of course, that goal is supported by the general support of the ATPs who ultimately purchase (or develop themselves) those solutions.

Solution provider awareness and education efforts will therefore focus on:

1. Expanding awareness and understanding of PDG and *Blueprint.*
2. Ensuring an understanding of the *Blueprint* development process and the value proposition for adherence to it.
3. Supporting complete and accurate understanding of the *Blueprint.*
4. Providing information on how to engage for more detailed information.

Plan:

- Develop and execute communication, education, and awareness plan surrounding publication of additional *Blueprint* chapters. *(Dec 2022 to Jan 2023)*
  - Publish and rollout new chapters
    - Website, email communications, and distribution through associations
  - Build awareness
    - Social media campaign
    - Amplifying articles/op-eds
    - FDA/State acknowledgement
  - Educate
    - Webinar(s)
    - Short video summaries for social media use
    - Supporting documents/summaries/FAQs
    - Participation/presentation at key industry events
- Execute ATP communication, education, and awareness plan to support *Blueprint* awareness and the objectives above. *(Dec 2022 to Nov 2023)*
- Execute solution provider communication, education, and awareness plan to support *Blueprint* adherence and the objectives above. *(Dec 2022 to Nov 2023)*

4. **Encourage Blueprint implementation**. PDG will actively promote and incent stakeholder adoption and implementation of the *Blueprint*.

PDG will execute a strategy to encourage implementation and adherence to the *Blueprint*. As noted above, this activity will primarily focus on solution providers (including ATPs who develop their own solutions for TI exchange, verification, tracing, and credentialing), but they will ultimately be incented to adhere to the *Blueprint* if their user-ATPs encourage or insist upon adherence. Accordingly, PDG will focus on two main activities: (1) engaging ATPs to encourage solution provider adoption and adherence to the *Blueprint*, and (2) engaging solution providers

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to understand their intent to adopt and adhere to the *Blueprint* and concerns they may have with adoption and adherence.

Plan:

- Develop messaging and materials that highlight the value proposition for adoption of the *Blueprint* and why ATPs expect adoption. *(Target: Jan 2023)*
- Engage solution providers one-on-one to understand their intention to adhere (or not adhere) to the *Blueprint* and surface any concerns or challenges *(Target: Q1 2023)*

5. **Maintain and enhance collaboration with FDA & State Boards of Pharmacy**. PDG strengthen the public-private partnership (PPP) with the FDA and formalize and expand its collaboration with State Boards of Pharmacy.

Successful implementation of interoperable traceability under the DSCSA requires collaboration and alignment among three critical stakeholder groups: authorized trading partners, the providers of technical solutions to achieve interoperable traceability, and regulators (Federal and State). PDG is well-position to serve as the common forum for collaboration among those stakeholder groups, and it will enhance its collaboration with regulators to achieve interoperability.

With regard to the FDA, the PPP provides a mechanism for direct collaboration with the Agency, but a more open, interactive dialogue is needed. PDG will work with the FDA PPP coordinator to identify and establish additional approaches, structures, or methods that will enable more dialogue.

State regulators are also beginning to more actively engage in the DSCSA implementation. The National Association of Boards of Pharmacy (NABP) is actively facilitating that dialogue and engagement among the various states. So long as NABP continues to act as a convener of the States, PDG will continue to enhance its interaction with NABP as a method of coordination with the States.

With regard to both FDA and the States, it will be important that PDG continue to engage those regulators in their capacity as end users of the interoperable system. PDG will continue to avoid direct advocacy or other efforts to shape regulators' approaches to compliance. Instead, we will continue to work with the regulators to design and achieve interoperable traceability.

Plan:

- FDA
  - Seek more express PPP language on PDG website in advance of *Blueprint* publication *(Ongoing discussion with FDA)*

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- Request joint meeting with the FDA PPP Coordinator and PPP Lead to better understand the boundaries of the PPP *(Ongoing discussion with FDA)*
- Identify and implement structural changes that would facilitate more open dialogue *(Ongoing discussion with FDA)*
- Ensure continuity of FDA relationship, and expand engagement, beyond current PPP Lead *(Ongoing discussion with FDA)*

- States
  - Evaluate and pursue an ongoing direct State regulator forum within PDG building off the June 2022 Tabletop Pilot and Workshop *(Target: Dec 2022 to Jan 2023)*
  - Evaluate the possible inclusion of NABP in substantive work similar to FDA *(Dec 2022)*
  - Discuss and develop better understanding of the boundaries of collaboration with NABP *(Dec 2022)*

6. **Develop a Validation Matrix for verification, tracing, and credentialing.** PDG will use the interoperability criteria previously developed for the *Blueprint* and the testing criteria developed by outside organizations to review and adopt validation matrices. PDG will identify testing organizations that agree to execute these validation matrices for any verification, tracing, or credential testing they perform.

The *Blueprint* sets out the agreed upon PDG requirements and recommendations for achieving DSCSA interoperability. While each ATP has the regulatory obligation to be interoperable, as noted above, this is generally achieved through technology solutions or systems. This creates a need for a controlled mechanism to enable ATPs to efficiently ensure their compliance is achieved through the solutions that are utilized. While reliance on technology systems to meet regulatory obligations is not a novel concept, the DSCSA requirement for interoperability does present a unique need because, in the multi-solution environment that exists, no individual ATP can achieve interoperability independently.

Take, for example, interoperable verification required by the DSCSA. Assume Manufacturer A uses Solution 1 to receive and respond to verification requests. Assume Dispenser B uses Solution 2 to make verification requests. For Manufacturer A and Dispenser B to achieve interoperable verification, Solution 1 and Solution 2 must be interoperable; however, Manufacturer A has no ability to *independently* ensure Solution 2 is interoperable, and Dispenser B has no ability to *independently* ensure Solution 1 is interoperable. Ultimately, the role governance can play is to fill that gap and provide a mechanism ATPs can use to ensure control over interoperability at the solution network-level. This mechanism is reflected in the **graphic below** with ATPs on the left and solutions on the right. It is important to note here that

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DSCSA solutions include both commercially available third-party solutions and "homegrown" solutions that are developed (or custom implemented) by an individual ATP.

PDG will support interoperability by providing validation matrices for third-party testing organizations to use to reliably test and certify the conformance of solutions to PDG's interoperability criteria for verification, credentialing, and tracing. The development of these matrices has the follow four elements:

A. Through the *Blueprint* process, PDG has developed and published **interoperability criteria** for verification, tracing, and credentialing in the form of both business/compliance requirements and functional design criteria, which will be used as the functional specifications and will be approved by PDG trading partners.
B. **Testing criteria** for verification has been developed by the VRS task force, and the testing criteria for credentialing has been defined by OCI. The testing criteria for tracing has not yet been defined, and there is an open question for continued development as to where and how that should occur.
C. PDG will develop a **validation matrix** for verification, tracing, and credentialing, which will match the business and functional specifications of the Blueprint to the testing criteria and explain how a solution can demonstrate those criteria. The groups developing the testing criteria and seeking PDG ratification will be asked to populate the matrix with their testing criteria, then the testing criteria and validation matrix will be reviewed and ratified/approved (or disapproved) by PDG General Members. An example of the matrix that would be provided to the groups developing the testing criteria is as follows:

Validation Matrix

Bus/Compliance Req	Functional Req	Test Script	Pass/Fail
Requirement-Trac-015: A request for Tracing and the outputs of systems and processes for Tracing shall be treated as confidential by all ATPs, and (i) shall only be used for purposes of supporting a suspect or illegitimate product investigation or recall, as relevant, and (ii) shall only be made available to individuals within the ATP who have a specific need to for the information.	**Trace-FR-005:** A TI Request Must indicate a single investigation type (Suspect, Illegitimate or Recall), or compliance audit		

D. PDG will **identify testing organizations** that agree to execute the validation matrix for any testing they perform with regard to verification, credentialing, and/or tracing.

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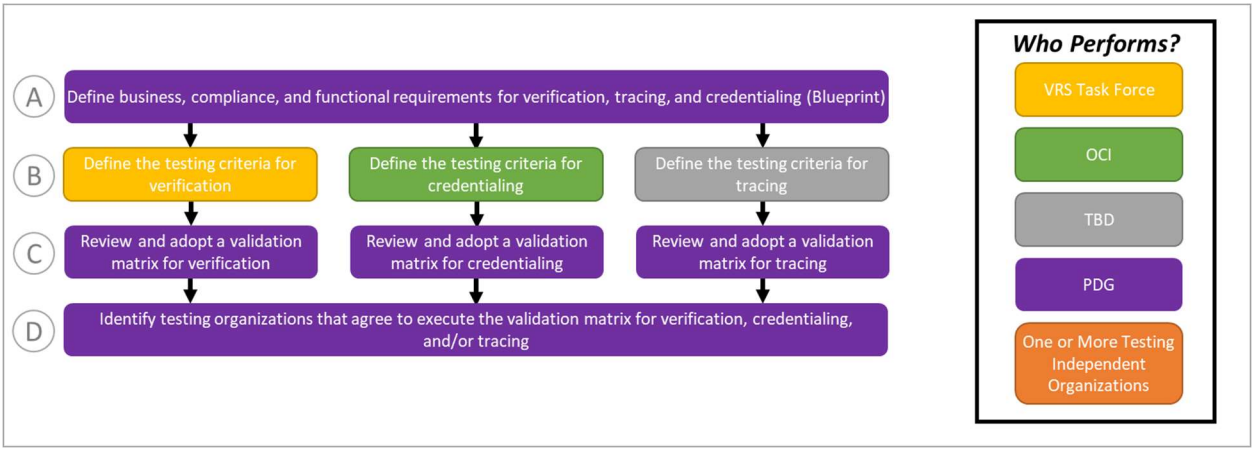

This structure will create an environment that minimizes PDG's direct role, including resource commitment and liability risk, in the testing or certification of solutions while maintaining ATP control—via PDG's review and adoption of each matrix—over the criteria to which solutions are held and creating transparency as to whether those criteria are being met. For an individual solution to go through the testing and certification process, which will occur outside of PDG, the solution provider will bear the cost of testing its solution.

Plan:

- Define the business, compliance and functional requirements for verification, tracing, and credentialing (*Completed by PDG)*
- Develop the testing criteria for verification *(Completed by VRS Task force)*
- Develop the testing criteria for credentialing *(Completed by OCI)*
- Identify organization responsible for developing the testing criteria for tracing *(Target: Q1 2023)*
- Review and adopt validation matrices for verification, credentialing, and tracing *(Target: Q2 2023)*
- Engage testing organizations to encourage their engagement. *(Target: Dec 2022)*
- Develop summary document that explains to all stakeholders (ATPs, solution providers, etc.) this testing environment and PDG's role. *(Target: Jan 2023)*

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Organizational Structure

At this time, the strategy above does not necessitate significant changes to PDG's organizational structure (*e.g.*, membership categories, voting structures, member rights and responsibilities). The Board will continue to monitor and evaluate any changes that may become necessary or valuable.

The role and structure of the various work groups will evolve in light of the strategy above. First, upon completion of the Blueprint, the current work groups within the Interoperability Committee (TI Exchange Work Group, Verification Work Group, Tracing Work Group, and Credentialing Work Group) will all move to an ad hoc meeting cadence. While each of those work groups will remain in place, they will only meet as needed to address specific issues, primarily through the change request process. It is anticipated that each work group will only need to meet a few times each year. This shift will put greater emphasis on the role of the Interoperability Committee. Second, a new Validation Matrix Work Group will be established under the Interoperability Committee to undertake the validation matrix development and review activities outlined in item 6 of the strategy above. This Work Group will meet regularly through the first two to three quarters of 2023.

Financial Plan

The completion of the *Blueprint* will represent a milestone moment for PDG, and it will also mark the completion of a significant piece of PDG's workload. The strategy above represents a substantial amount of work for PDG but also a significant reduction in workload relative to prior years. For that reason, we anticipate meaningful budget reductions (through the annual budget process) over the course of 2023 and 2024 to get more sustainable levels of funding. At this time, revenue streams outside of membership dues are not foreseen, but the Board will continue to monitor and evaluate those opportunities.

Summary

This Strategic Plan will capitalize on the good work of PDG's membership over the last three years and support the adoption and continued value of the PDG *Blueprint.* Execution of this Plan will help PDG achieve its mission to develop, advance, and sustain an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.