Partnership for DSCSA Governance

Advancing Collaborative, Timely Implementation of DSCSA Interoperability

Episode 4: Tracing

Webinar Series (Register at https://dscsagovernance.org/blueprint/)

- **Webinar Episode 1: DSCSA Overview, Interoperability, & the Role of ATPs**
  - February 23, 1:00 – 2:00pm ET
  - Register HERE.
- **Webinar Episode 2: TI/TS Exchange**
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- **Webinar Episode 5: Credentialing**
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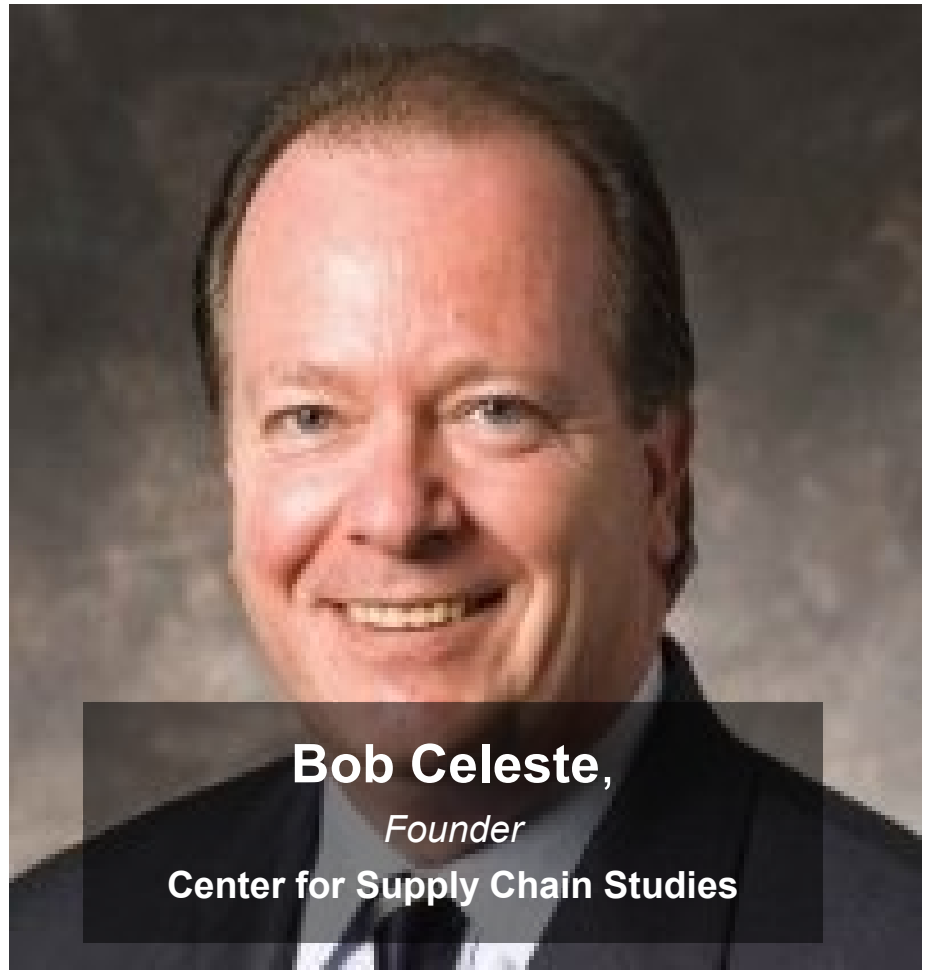
Today's Speakers

Senthil Rajaratnam

Director, Serialization and UDI

Eli Lilly



Bob Celeste,

Founder

Center for Supply Chain Studies

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The Partnership for DSCSA Governance (PDG)

PDG is a collaborative forum and FDA public-private partnership dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.DSCSAgovernance.org

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www.DSCSAgovernance.org/blueprint

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

Chapter 3: DSCSA TI/TS Exchange Functional Design

Version 1.0
February 2, 2023

Interoperable Tracing
PDG Blueprint

To support a sequential request-and-response tracing model, the *Blueprint* defines a standardized protocol for requesting TI information and responding to such requests.

Why It Matters: The standardized protocol provides predictability to authorized trading partners (ATPs) and supports interoperability *between* ATPs while permitting each ATP to define its own *internal* processes.

Key Terminology

Interoperable Tracing is the DSCSA 2023 requirement that trading partners maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a valid request and promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

TI Request Messages provide interoperable information about the requester, the products being traced, the circumstance of the trace, and the kind of information requested to be returned.

TI Response Messages provide interoperable information about the responder, the products traced, and trace endpoints associated with known buyers and sellers for the requester to use in the trace.

Trace Endpoints are the endpoint where TI request and response messages can be submitted, such as an email address or an OpenAPI or DIDComm endpoint.

Five Things to Know

1. **Interoperable tracing is achieved when the ATP or regulatory authority executing the trace sequentially requests and receives relevant TI data from each of the owners of the product.**
2. **ATPs may only trace product as part of a suspect or illegitimate product investigation; regulators may trace on account of a suspect/illegitimate product investigation *or a recall*.**
3. **The *Blueprint* defines a standardized protocol (i.e., message format) for requesting TI and responding with TI to support a trace.**
4. **Each ATP will define their own internal process for evaluating requests, determining whether to respond, and collecting the data to respond.**
5. **Each ATP must determine how they will be able to provide the trace endpoint/contact for each ATP they bought from/sold to.**

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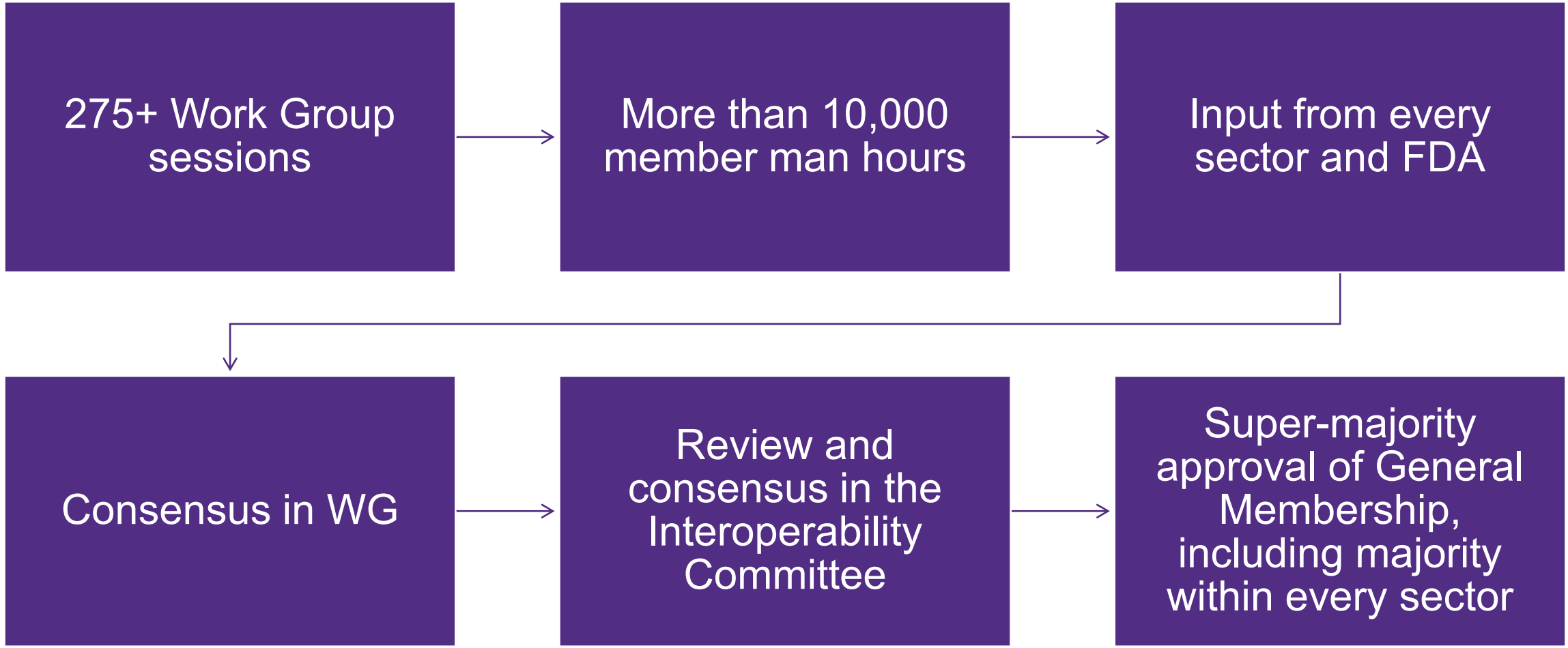

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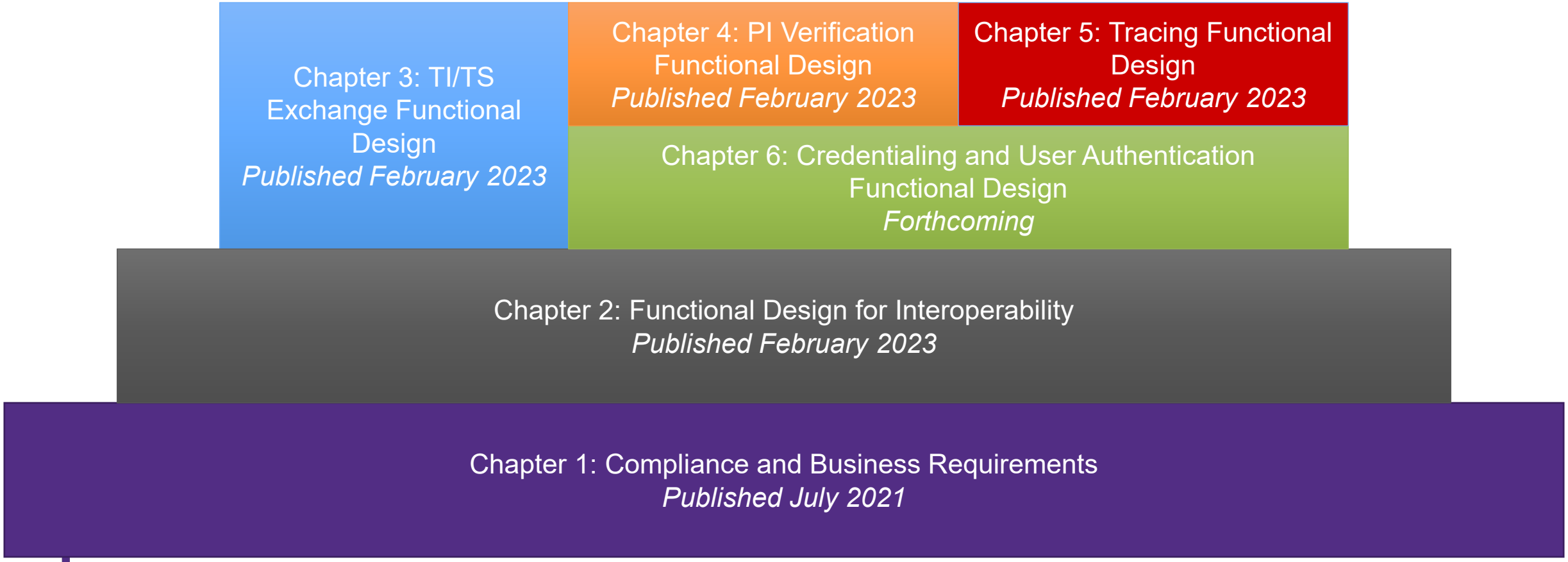

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Key Terminology for this Chapter

- **Interoperable Tracing: T**he DSCSA 2023 requirement that trading partners maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a valid request and promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.
- **TI Request Messages**: These provide interoperable information about the requester, the products being traced, the circumstance of the trace, and the kind of information requested to be returned.
- **TI Response Messages**: These provide interoperable information about the responder, the products traced, and trace endpoints associated with known buyers and sellers for the requester to use in the trace.
- **Trace Endpoints**: Are the endpoint where TI request and response messages can be submitted, such as an email address or an OpenAPI or DIDComm endpoint.

Interoperable Unit Level Tracing

"(k) SUNSET.—The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act:

"(1) The provision and receipt of transaction history under this section.

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Interoperable Unit Level Tracing

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

Section 582, as added by section 202, is amended by adding at the end the following:

"(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

"(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

. . .

"(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

"(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

"(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

"(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

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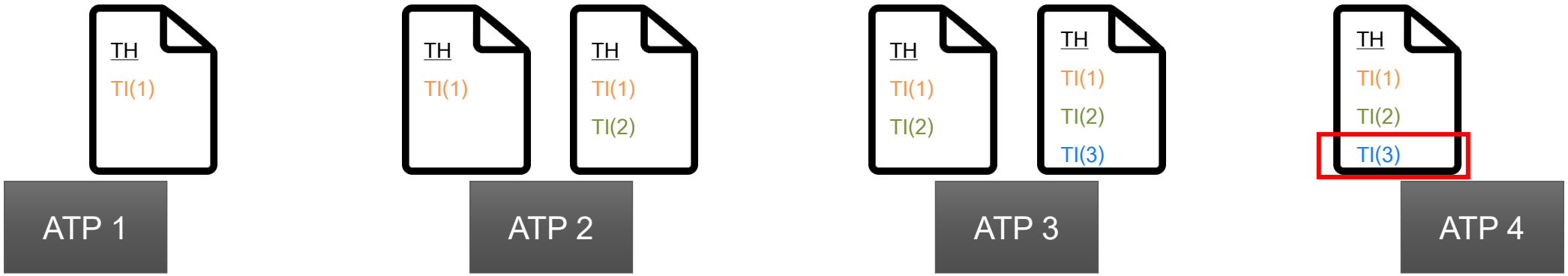
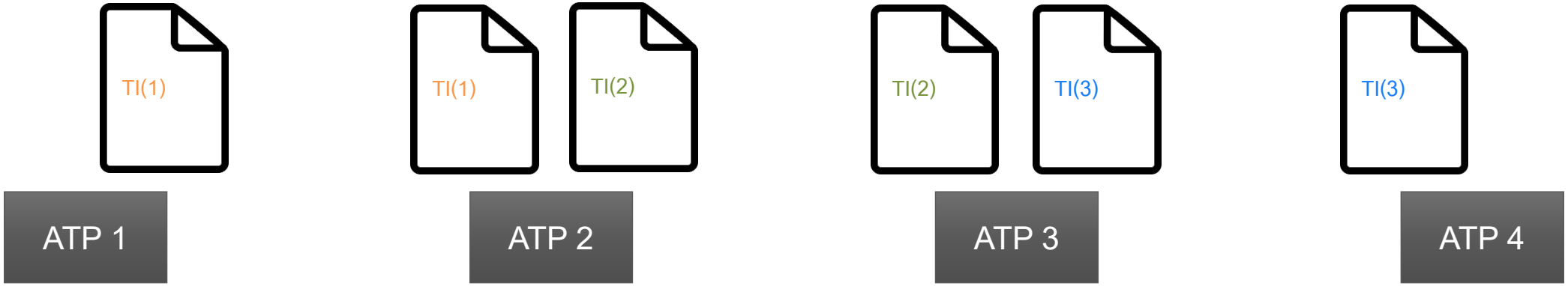
Interoperable Unit Level Tracing Timeline

Today



2023



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Interoperable Tracing Foundations

Blueprint Ch. 1

- Who can trace for what purposes
- What information can be requested
- How fast is tracing performed

Functional Design

- General request-response model
- Request-response message protocol
- Role of credentialing

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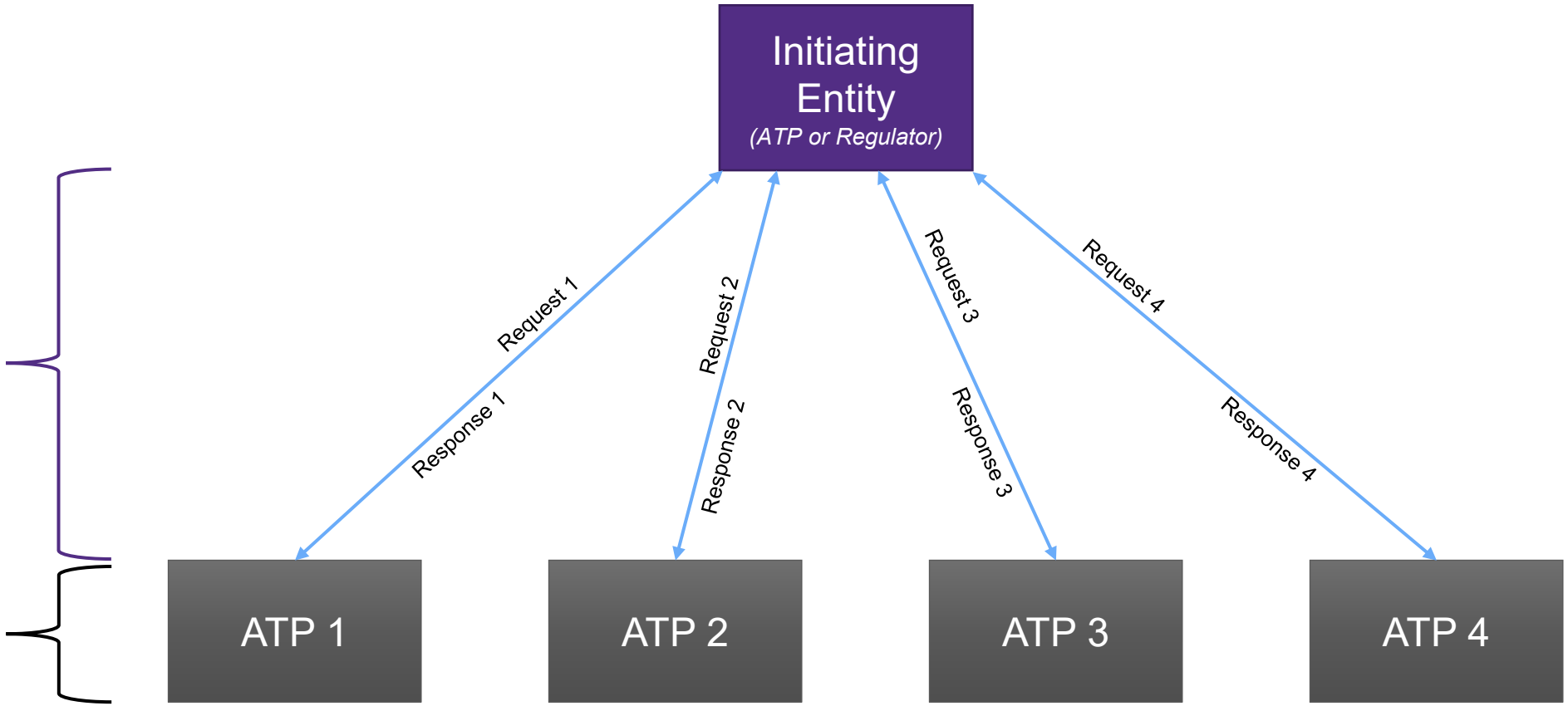
Interoperable Tracing Model

Standardized request/response messaging protocol to enable interoperability company-by-company automation, as desired.

Company-by-company process to review request and determine how to respond.



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Importance of Endpoints

Each trading partner (ATP and ATP-Equivalent) shall exchange their preferred trace method and trace endpoint where TI Request messages can be submitted.

Initially during the proof-of-concept or proof-of technology phase(s), it is thought that email addresses will be used as trace endpoints to exchange standardized TI Request and TI Response messages.

As the trace ecosystem enters the production phase, the PDG-defined EDDS network will move to OpenAPI or DIDComm to exchange messages securely and privately.

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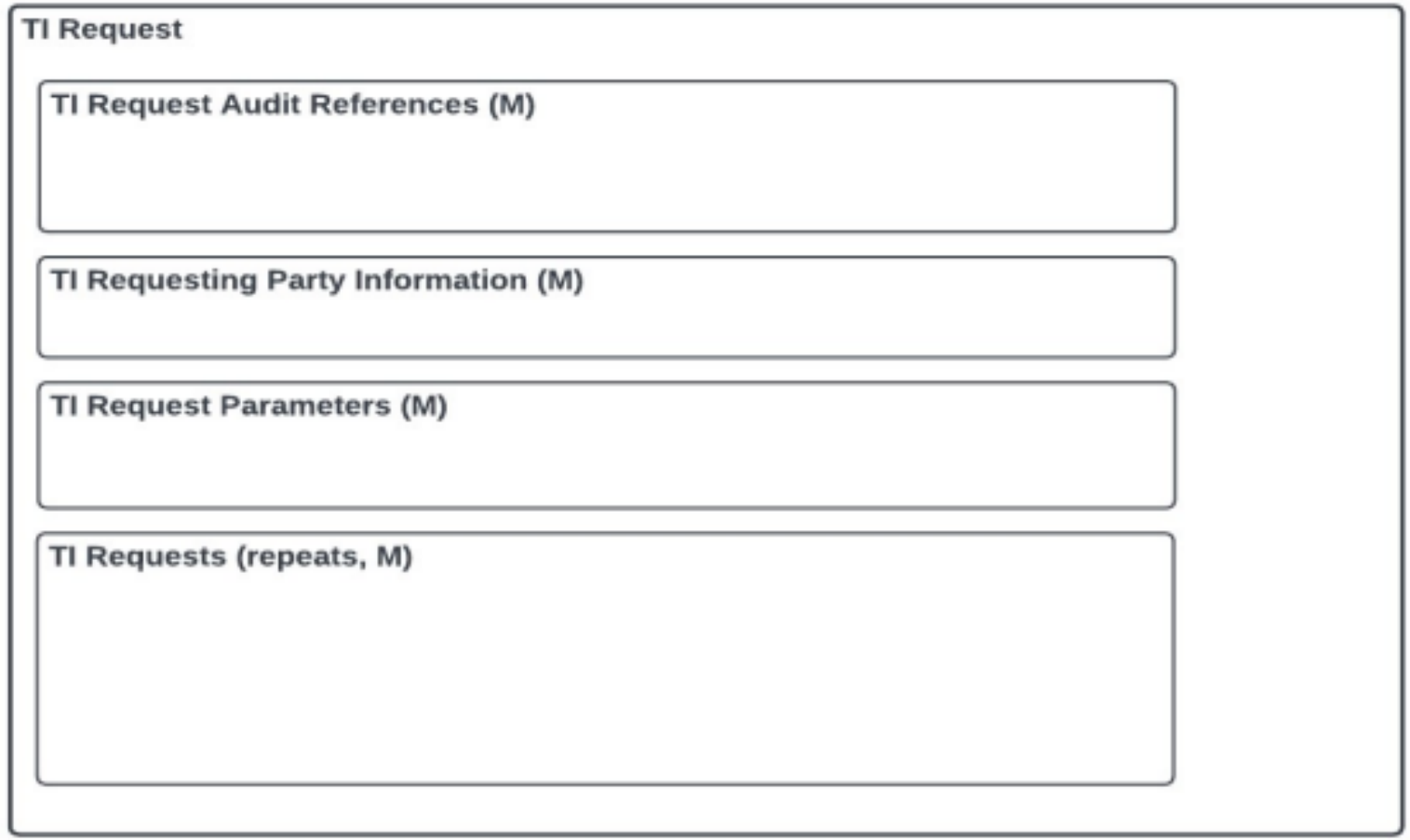
High Level Tracing Request Message



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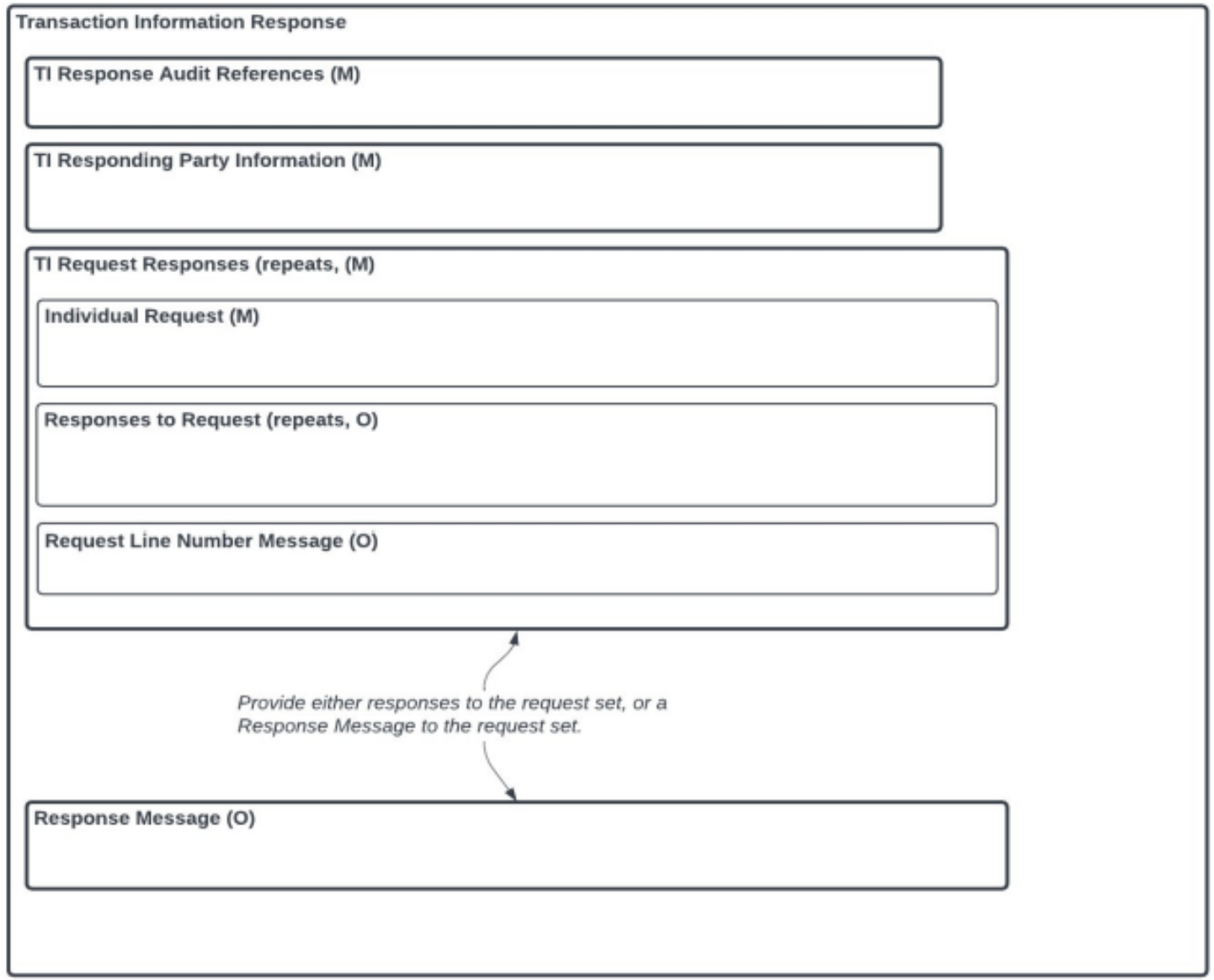
High Level Tracing Response Message



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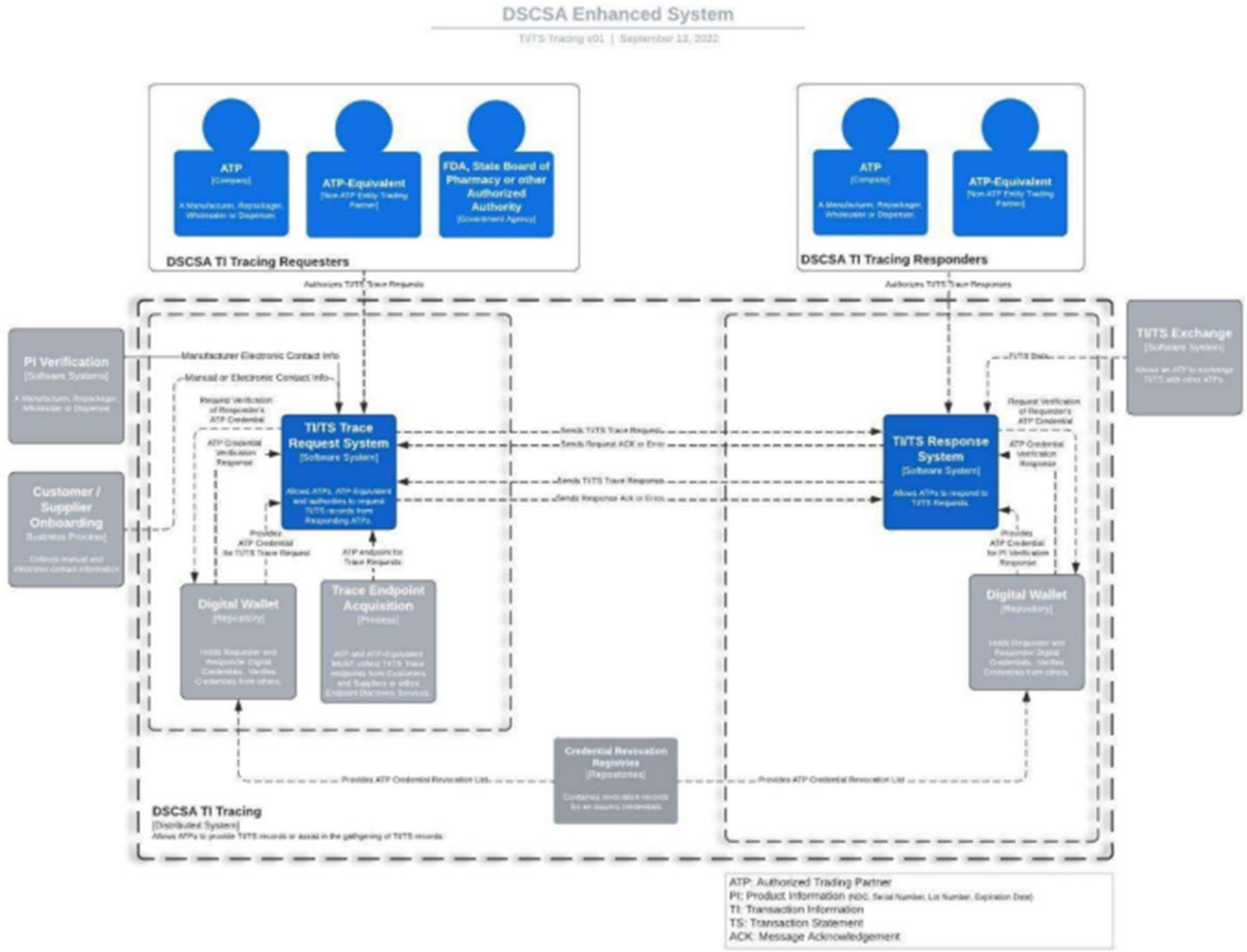
Detailed Protocol



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Data Attributes

Attribute	Definition	Type	Notes	TI Request Message	TI Response Message
3911IncidentNumber	The 3911 Incident Number assigned by the FDA	String		✓	
apiCallbackAddress	The URI address where the TI Response is to be sent.	String		✓	
callbackAddress	The method and address the responder is to send the TI Response message	Object	Includes Any of: - apiCallbackAddress - emailCallbackAddress	✓	
companyInformation	Information identifying a company recorded in the TI and their connectivity information (used by the Requester to submit a TI Request to them). This can be the seller, buyer or drop ship buyer.	Object	Includes: - gln - companyName - companyAddress - tiRequestConnectivityInformation		✓
contactInformation	Information to aid the Requester or Responder in contacting the other party in regard to the Request or Response.	Object	Includes: - personOrDepartmentName - organizationName - phone - email	✓	✓
contactMethod	Phone number or email address that the Requester or Responder can be contacted with.	String		✓	✓

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JSON Option

JSON Schema for TI Request Message (Draft v13)


```
{
  "$schema": "http://json-schema.org/draft-07/schema#",
  "$id": "https://c4scs.org/pdg/Draft/1.0.0/pdgdscsatirequestschema.json",
  "title": "PDG DSCSA TI Request Schema",
  "description": "Defines requests for DSCSA Transaction Information.",
  "type": "object",
  "properties": {
    "tiRequestSet": {
      "properties": {
        "tiRequestAuditReferences": {
          "type": "object",
          "properties": {
            "tiRequestID": {"$ref": "#/definitions/uuidType"},
            "tiRequestTimestamp": {"$ref": "#/definitions/timestampType"}
          },
          "required": [
            "tiRequestID",
            "tiRequestTimestamp"
          ]
        },
        "tiRequestingPartyInformation": {
          "type": "object",
          "required": [
            "contactInformation",
            "callbackAddress"
          ],
          "properties": {
            "dscsaCredentialPresentation": {"$ref": "#/definitions/dscsaCredentialPresentationType"},
            "contactInformation": {"$ref": "#/definitions/contactInformationType"},
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```


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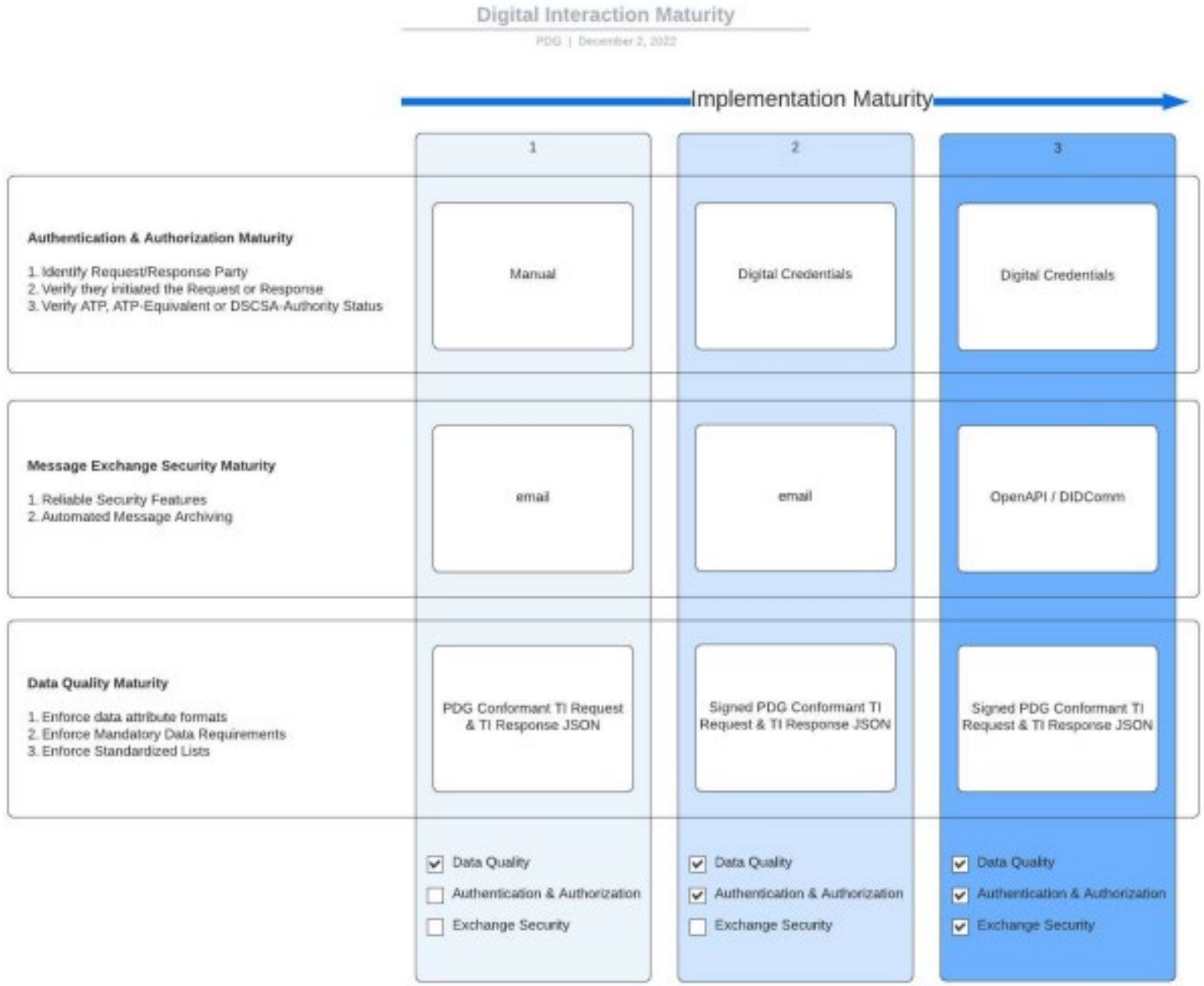
The Implementation Roadmap



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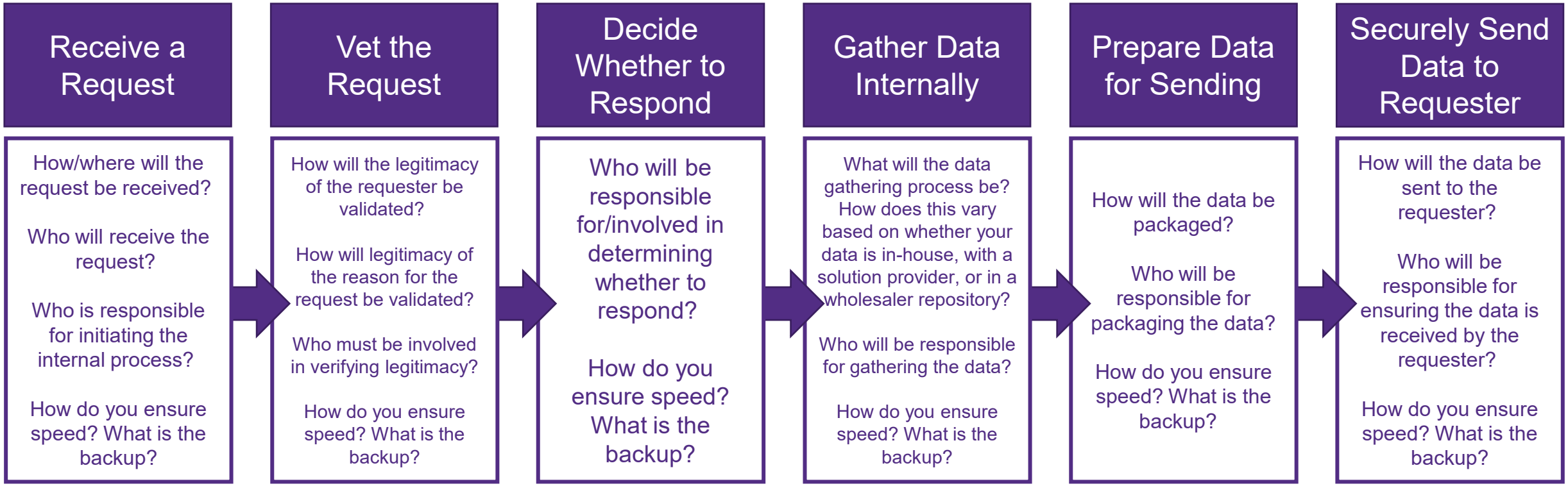
Responding to a Tracing Request



To what extent do internal business, legal compliance, and data security teams need to be involved in each step?

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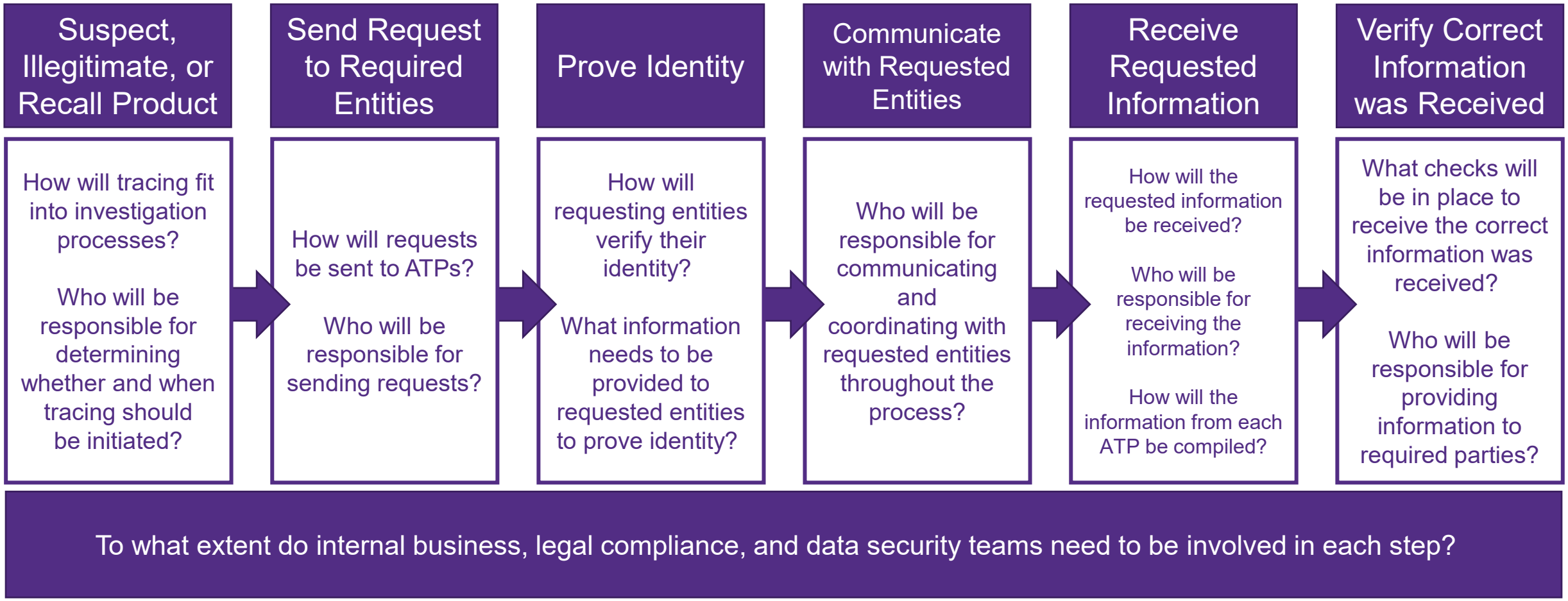
Initiating a Tracing Request



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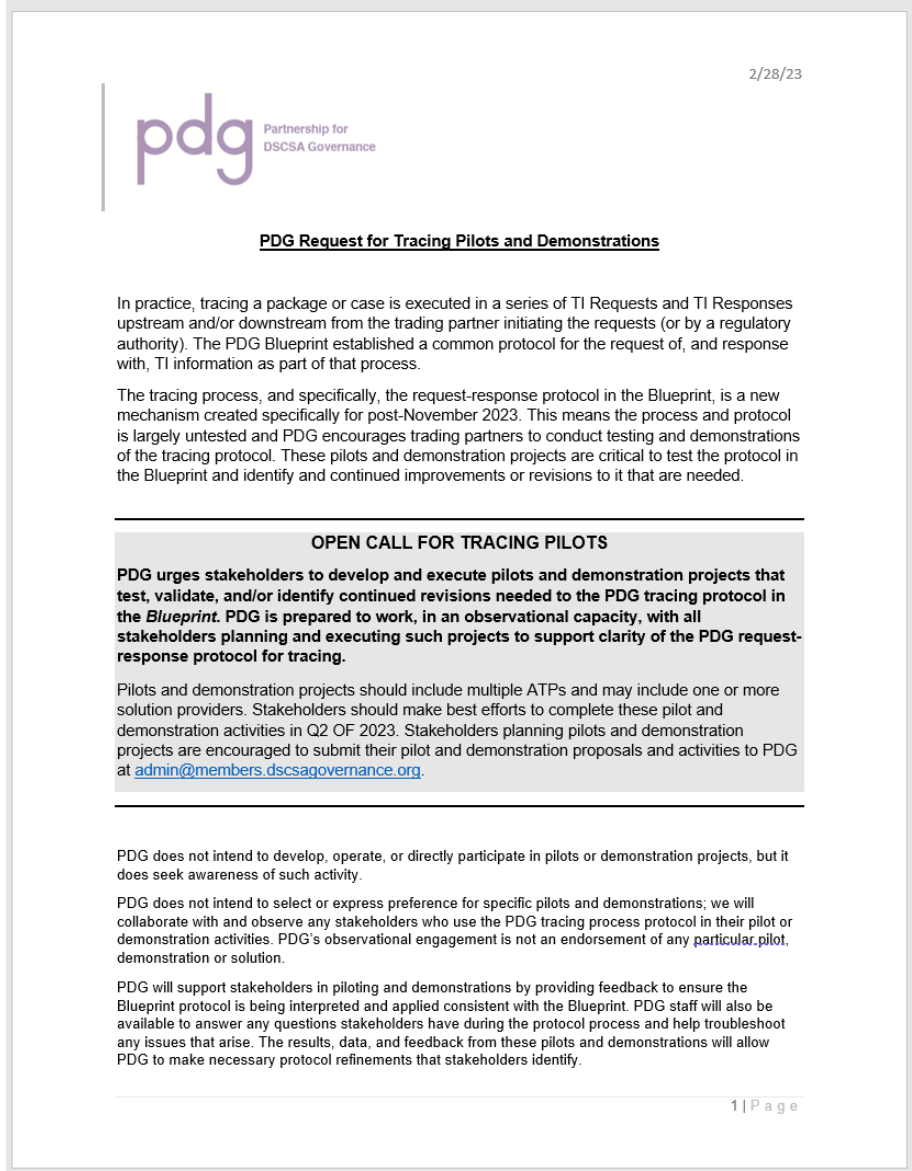
Call for Pilots and Demonstrations



2/28/23

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PDG Request for Tracing Pilots and Demonstrations

In practice, tracing a package or case is executed in a series of TI Requests and TI Responses upstream and/or downstream from the trading partner initiating the requests (or by a regulatory authority). The PDG Blueprint established a common protocol for the request of, and response with, TI information as part of that process.

The tracing process, and specifically, the request-response protocol in the Blueprint, is a new mechanism created specifically for post-November 2023. This means the process and protocol is largely untested and PDG encourages trading partners to conduct testing and demonstrations of the tracing protocol. These pilots and demonstration projects are critical to test the protocol in the Blueprint and identify and continued improvements or revisions to it that are needed.

OPEN CALL FOR TRACING PILOTS

PDG urges stakeholders to develop and execute pilots and demonstration projects that test, validate, and/or identify continued revisions needed to the PDG tracing protocol in the *Blueprint.* PDG is prepared to work, in an observational capacity, with all stakeholders planning and executing such projects to support clarity of the PDG request-response protocol for tracing.

Pilots and demonstration projects should include multiple ATPs and may include one or more solution providers. Stakeholders should make best efforts to complete these pilot and demonstration activities in Q2 OF 2023. Stakeholders planning pilots and demonstration projects are encouraged to submit their pilot and demonstration proposals and activities to PDG at admin@members.dscsagovernance.org.

PDG does not intend to develop, operate, or directly participate in pilots or demonstration projects, but it does seek awareness of such activity.

PDG does not intend to select or express preference for specific pilots and demonstrations; we will collaborate with and observe any stakeholders who use the PDG tracing process protocol in their pilot or demonstration activities. PDG's observational engagement is not an endorsement of any particular pilot, demonstration or solution.

PDG will support stakeholders in piloting and demonstrations by providing feedback to ensure the Blueprint protocol is being interpreted and applied consistent with the Blueprint. PDG staff will also be available to answer any questions stakeholders have during the protocol process and help troubleshoot any issues that arise. The results, data, and feedback from these pilots and demonstrations will allow PDG to make necessary protocol refinements that stakeholders identify.

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Questions?

More Information

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