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Advancing Collaborative, Timely Implementation of DSCSA Interoperability

Overview of PDG Blueprint

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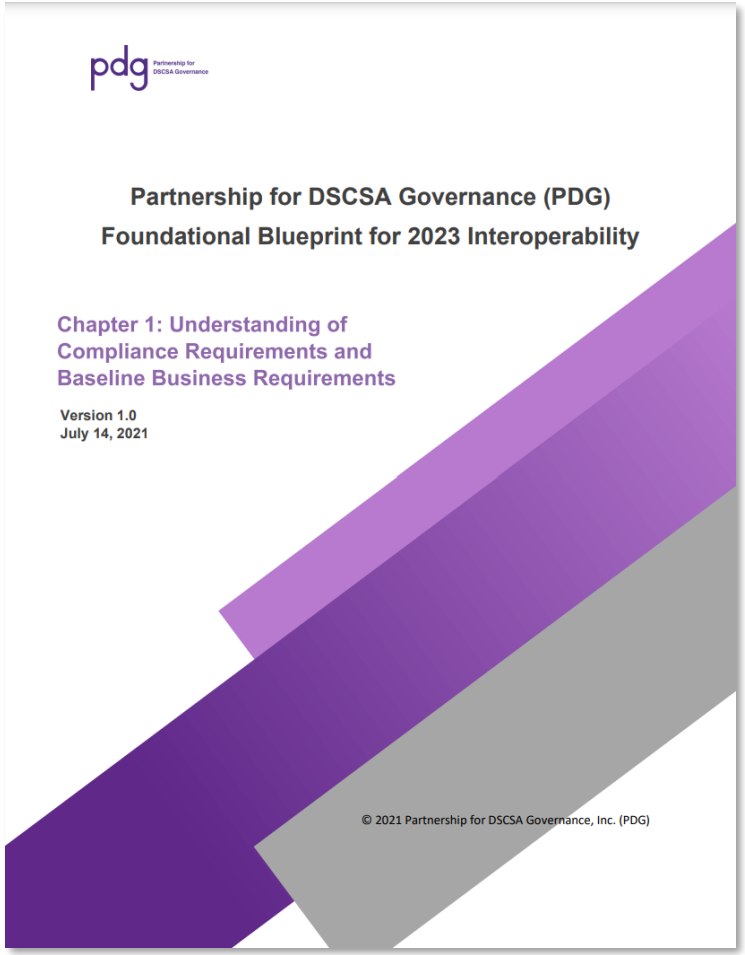
November 18, 2022

PDG Foundational Blueprint for 2023 Interoperability



- Chapter 1 formally approved; focus on compliance and business requirements and recommendations
- Chapters 2-6 coming soon; functional design requirements
- Not legally binding
- 2023 interoperability
- Continued feedback encouraged

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www.DSCSAgovernance.org/Blueprint

Serialized TI Exchange

- “Prior to, or at the time of, each transaction” provide the subsequent owner with TH, TI, and TS
- “Not accept ownership of a product” unless the previous owner provides TH, TI, and a TS
- “Capture” TI, TH, and TS for 6 years

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Serialized TI Exchange: 2023

- TI and TS must be exchanged in secure, interoperable, and electronic manner.
- TI shall include the product identifier at the package level

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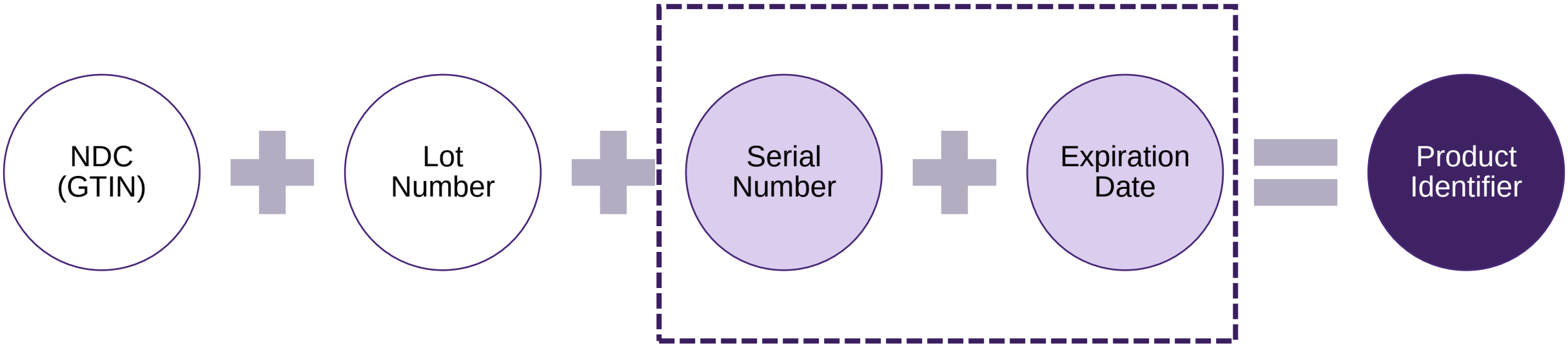
Serialized TI Exchange: 2023



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Serialized TI Exchange

Blueprint

- Standardized TI element formats
- General expectations for accuracy and reliability

Functional Design

- Data push (EPCIS) or data availability (web portals)
- Dropships, 340B, direct ships, etc.
- Misalignment exception resolution

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Interoperable Verification

- Requests for verification **from authorized trading partners** to manufacturer
- Verification of product in requestor's **possession or control**
- Manufacturer **shall respond** within 24 hours
- Response includes **whether** the product identifier **corresponds to the product identifier affixed or imprinted by the manufacturer**

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Interoperable Verification: 2023

- Electronic, interoperable systems and processes
- Verification at the package level (including serial number)

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Interoperable Verification

Blueprint

- Modest enhancements to VRS
- Serial number statuses
- Direct-to-replicate verification

Functional Design

- Extension of VRS to additional use cases
- Addition of contact information
- Role of credentialing

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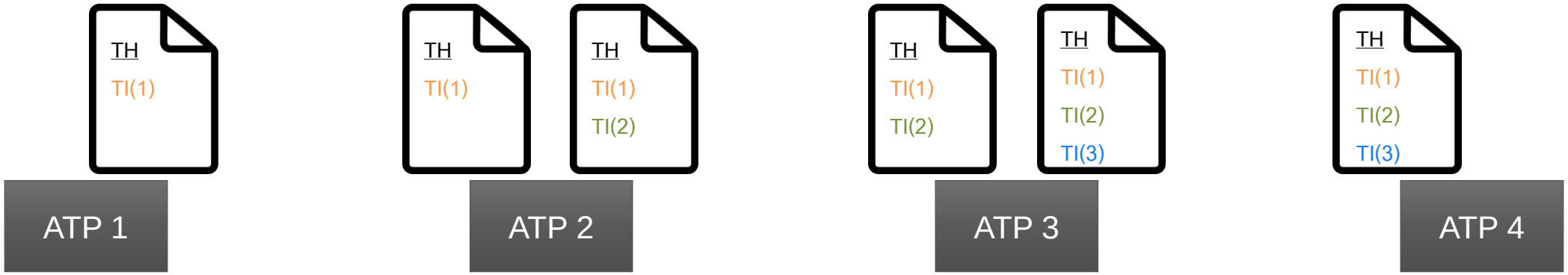
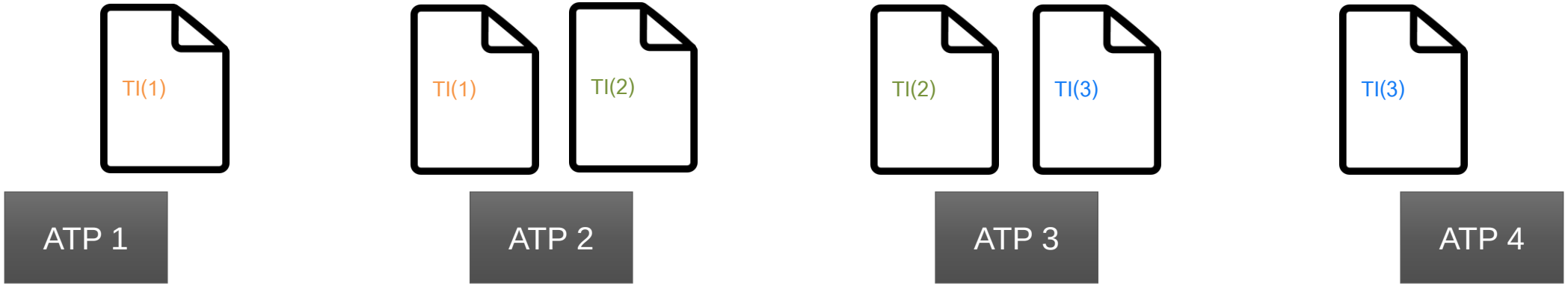
Interoperable Unit Level Tracing

Today



2023



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Interoperable Tracing

Blueprint

- 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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Initiation of a Trace

[Requirements-Trac-002 to -004] define the legal authority to request that tracing systems and process be executed.

Suspect Product

- To support the investigation of a suspect product
- May be initiated by an **ATP** *involved in the investigation* of the suspect product at issue
- May be initiated by a **Regulator**

Illegitimate Product

- To support the investigation of an illegitimate product
- May be initiated by an **ATP** *involved in investigation* of the illegitimate product at issue
- May be initiated by a **Regulator**

Recall

- On account of a recall
- May only be initiated by a **Regulator**

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Initiation of a Trace

[Requirement-Trac-004] Any use of systems and processes for tracing for use cases other than those for suspect product, illegitimate product, or recall is a matter of commercial business practice that shall be left to, and would require agreement by, the relevant ATPs.

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Speed of Tracing

[Requirement-Trac-016] The systems and processes for Tracing shall be configurable to enable Responding ATPs the optionality to respond in a rapid automated manner or to manually review the request and respond within one business day.

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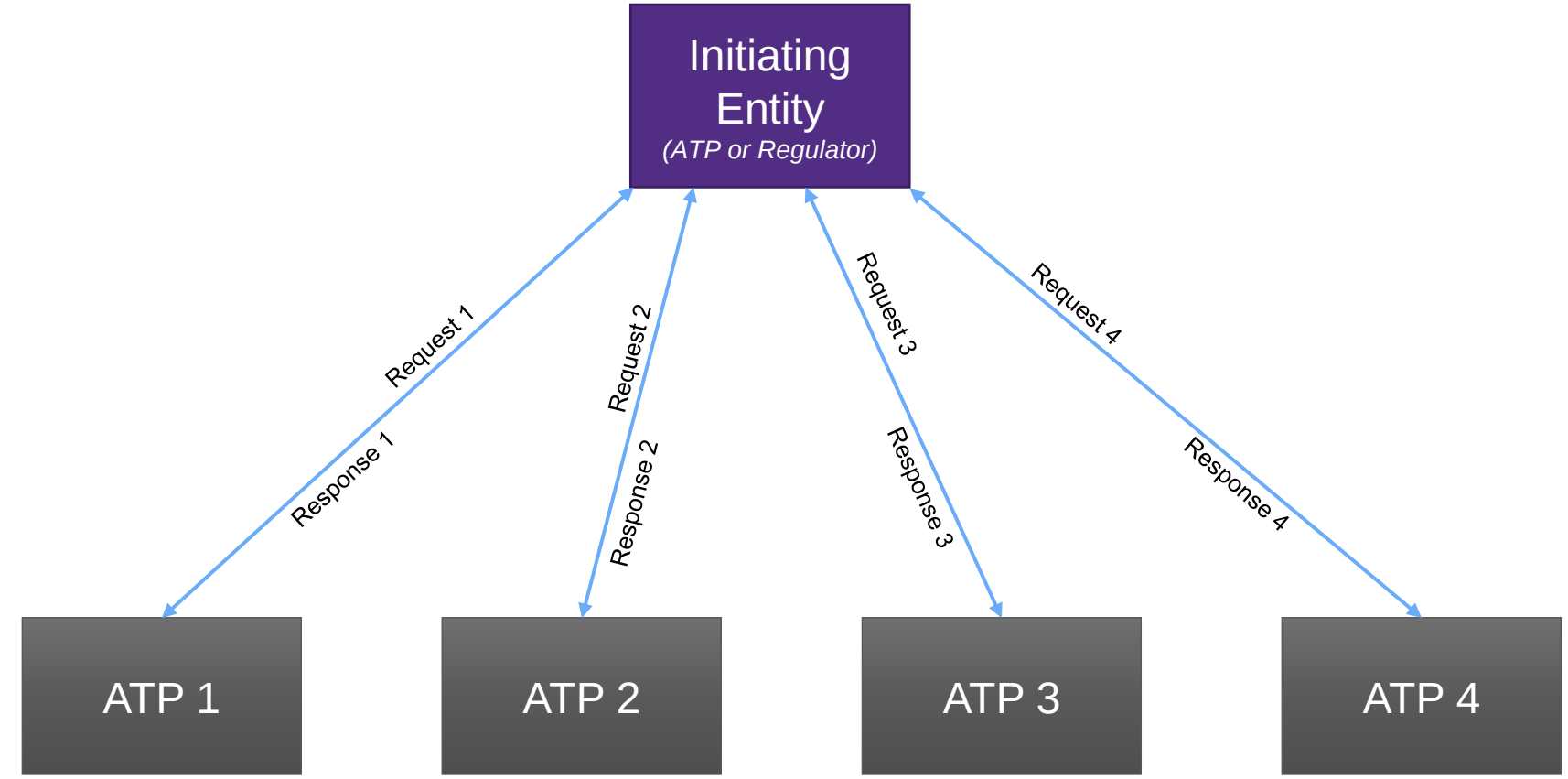
Interoperable Tracing

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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Credentialing

Blueprint

- Requirements to confirm ATP status
- Requirements to confirm identity

Functional Design

- Digital verifiable credentials as one way to efficiently manage credentialing

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ATP Proof

- Requirements specific to each sector
- License/registration confirmed against the source-of-truth
- One valid license/registration per corporate entity
- Wholesalers/3PLs complying with FDA reporting requirement
- License/registration routinely re-confirmed

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ATP Proof

If a license/registration is confirmed today, for how long can you rely on today's confirmation?

Where there are not regulator systems and process to push changes in licensure/registration status

Weekly re-confirmation

Where there are regulator systems and process to push changes in licensure/registration status

Upon expiry of the current license/registration

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Identity Proof

Level 2

Functional Design

Requirement: Tracing requests and responses must contain the standardized PDG data elements.

Transport mechanism to meet requirement:

1. Structured email (*outside PDG EDDS)*
2. **Email with JSON attachment** (*inside PDG EDDS, at least near-term)*
3. **B2B/API connection** (*inside PDG EDDS; optimal future state)*

Requirement: Identity and ATP status must be validated according to the criteria in Ch. 1. of the PDG Blueprint.

Method to meet requirement:

1. **Individual company process** (e.g., existing KYC/KYS process, manual check, phone call) (*inside PDG EDDS, at least near-term)*
2. **OCI-conforming verifiable credential** (*inside PDG EDDS; optimal future state)*

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