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PDG DSCSA TI Request Model

This model defines the structure and data definitions for requests for Drug Supply Chain Security Act (DSCSA) Transaction Information (TI) and Ownership Information.

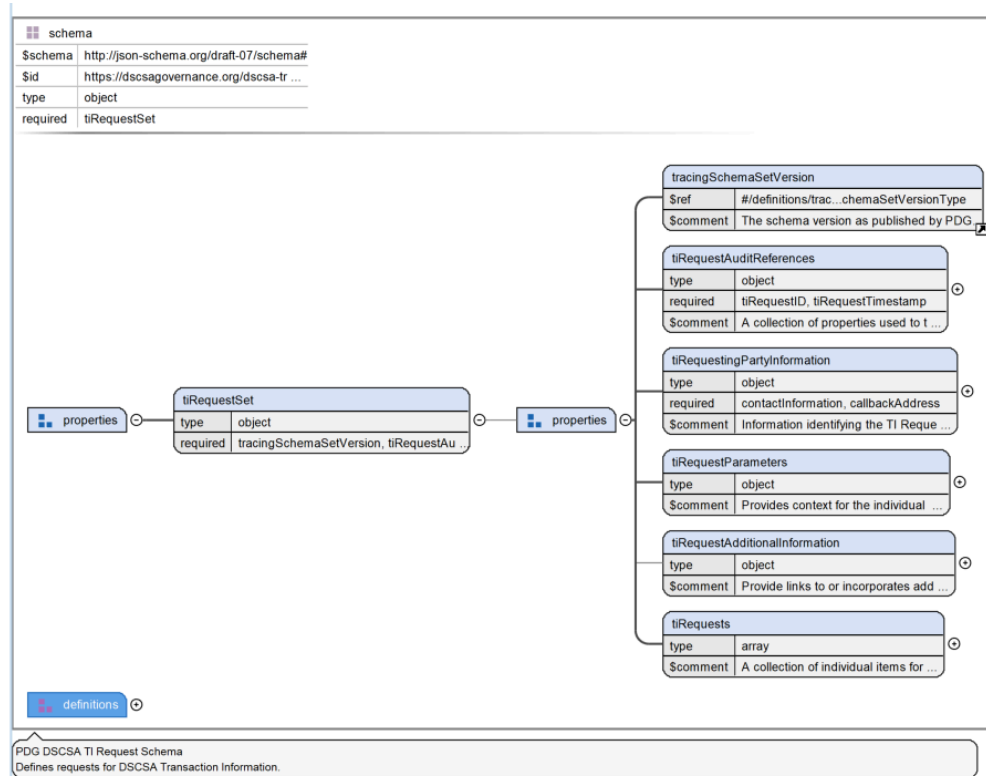


Figure 1 - Top-level data groups of the TI Request message

Model Overview

Title: PDG DSCSA TI Request Model

Description: This document explains a standard format (called a "Model") used to request information about pharmaceutical products under the U.S. Drug Supply Chain Security Act (DSCSA). It defines how requests for Transaction Information (TI) should be structured so that organizations can share details about products efficiently and accurately.

Note: This Model is a structured way to ask for information—it's like a form with specific fields that need to be filled out correctly.

Hierarchy Definition

The Model is organized like a tree, with sections nested inside one another. Below is the structure, numbered to show how everything fits together:

1. **tiRequestSet**

- The main container for the entire request. Everything else lives inside this section.

1.1. **tracingModelSetVersion**

- Specifies the version of the Model being used.

1.2. **tiRequestAuditReferences**

- Tracks details about the request, like its unique ID and timestamp.

1.2.1. **tiRequestID**

1.2.2. **tiRequestTimestamp**

1.2.3. **tiRequesterInvestigationID**

1.3. **tiRequestingPartyInformation**

- Identifies who is making the request.

1.3.1. **dscsaCredentialPresentation**

1.3.2. **contactInformation**

1.3.2.1. **personOrDepartmentName**

1.3.2.2. **organizationName**

1.3.2.3. **contactMethod**

1.3.2.3.1. **phone**

1.3.2.3.2. **email**

1.3.3. **requesterGLN**

1.3.4. **callbackAddress**

1.3.4.1. **apiCallbackAddress**

1.3.4.2. **emailCallbackAddress**

1.4. **tiRequestParameters**

- Explains what information is being requested and why.

1.4.1. **responseTypeRequested**

1.4.2. **investigationReasonAttestation**

1.4.3. **investigationCircumstances**

1.4.4. **onBehalfOfAuthority**

1.4.4.1. **onBehalfOfAuthorityFlag**

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- 1.4.4.2. **authorityInformation**
 - 1.4.5. **3911IncidentNumberList** (conditional)
 - 1.4.6. **recallDepth** (conditional)
 - 1.4.7. **recallRequestLevel** (conditional)
 - 1.5. **tiRequestAdditionalInformation**

 - Includes extra files or links related to the request.
 - 1.5.1. **additionalInformationLink**
 - 1.5.2. **additionalInformationBase64**
 - 1.6. **tiRequests**

 - Lists the specific products being asked about.
 - 1.6.1. **requestLineNumber**
 - 1.6.2. **productID**
 - 1.6.2.1. **gtin**
 - 1.6.2.2. **ndc**
 - 1.6.3. **serialNumberOrLotNumber**
 - 1.6.3.1. **serialNumber**
 - 1.6.3.2. **lotNumber**
 - 1.6.4. **requestLineNumberAdditionalInformation**
 - 1.6.4.1. **additionalInformationLink**
 - 1.6.4.2. **additionalInformationBase64**
-

2. Field Documentation

Below, each field in the Model is explained in detail. Fields are grouped by their section in the hierarchy, and every piece of information—like whether it's required or what values it can have—is included.

1. tiRequestSet

- **Name:** tiRequestSet
 - **Definition:** The main section that holds all the details of the request for DSCSA Transaction Information.
 - **Required:** Yes
 - **Data Type:** Object (a collection of related fields)
 - **Format (Pattern):** None
 - **Enumerations:** None
 - **References:** Contains all other fields listed below (1.1 to 1.6).
 - **Conditional Logic:** None
-

1.1. tracingModelSetVersion

- **Name:** tracingModelSetVersion
 - **Definition:** The Model version as published by PDG (Pharmaceutical Distribution Group). It tells everyone which version of this "form" is being used.
 - **Required:** Yes
 - **Data Type:** String (text)
 - **Format (Pattern):** Must follow the pattern "X.Y.Z" (e.g., "2.0.0"), where X, Y, and Z are single digits.
 - **Enumerations:** None
 - **References:** Defined in "tracingModelSetVersionType" under Definitions.
 - **Conditional Logic:** None
-

1.2. tiRequestAuditReferences

- **Name:** tiRequestAuditReferences

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- **Definition:** A collection of properties used to track the request and investigation—like a logbook for the message.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains fields 1.2.1 to 1.2.3.
- **Conditional Logic:** None

1.2.1. *tiRequestID*

- **Name:** tiRequestID
- **Definition:** This is a unique ID assigned to this message. The receiver can use this ID when replying or discussing the request.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Must be a UUID (e.g., "123e4567-e89b-12d3-a456-426614174000"), a special format with letters and numbers separated by dashes.
- **Enumerations:** None
- **References:** Defined in "uuidType" under Definitions.
- **Conditional Logic:** None

1.2.2. *tiRequestTimestamp*

- **Name:** tiRequestTimestamp
- **Definition:** This is the date and time the message was created, so everyone knows when the request started.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** A precise timestamp like "2025-02-20T14:30:45.123+00:00", including year, month, day, hour, minute, second, milliseconds, and timezone.
- **Enumerations:** None
- **References:** Defined in "timestampType" under Definitions.

- **Conditional Logic:** None

1.2.3. *tiRequesterInvestigationID*

- **Name:** tiRequesterInvestigationID
 - **Definition:** This is a unique ID the requester assigns to this message, separate from tiRequestID. The receiver can use it to refer to the requester's investigation.
 - **Required:** No
 - **Data Type:** String
 - **Format (Pattern):** No specific pattern, but it's recommended to be unique (e.g., a UUID or a custom code).
 - **Enumerations:** None
 - **References:** Defined in "investigationIDType" under Definitions.
 - **Conditional Logic:** None
-

1.3. tiRequestingPartyInformation

- **Name:** tiRequestingPartyInformation
- **Definition:** Information identifying the person or organization making the TI request.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains fields 1.3.1 to 1.3.4.
- **Conditional Logic:** Must include "contactInformation" and "callbackAddress."

1.3.1. *dscsaCredentialPresentation*

- **Name:** dscsaCredentialPresentation
- **Definition:** The credential proving the requester's identity, like an official ID. It could be an ATP (Authorized Trading Partner), an equivalent, or a DSCSA Authority credential.
- **Required:** No
- **Data Type:** Object

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- **Format (Pattern):** Must be a JWT (a secure text format) for one of the credential types.
- **Enumerations:** None
- **References:** Defined in "dscsaCredentialPresentationType" under Definitions (choose one: ATP, ATP-Equivalent, or Authority).
- **Conditional Logic:** Must pick one credential type if included.

1.3.2. *contactInformation*

- **Name:** contactInformation
- **Definition:** Information to help the requester or responder contact each other about the request or response.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Defined in "contactInformationType" under Definitions; contains 1.3.2.1 to 1.3.2.3.
- **Conditional Logic:** Must include all three subfields below.

1.3.2.1. *personOrDepartmentName*

- **Name:** personOrDepartmentName
- **Definition:** The name of the person or department that can be contacted about the request or response.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Defined in "nameValueType" under Definitions.
- **Conditional Logic:** None

1.3.2.2. *organizationName*

- **Name:** organizationName

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- **Definition:** The name of the organization making the request or responding to it.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Defined in "nameValueType" under Definitions.
- **Conditional Logic:** None

1.3.2.3. contactMethod

- **Name:** contactMethod
- **Definition:** A phone number or email address where the requester or responder can be reached.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 1.3.2.3.1 or 1.3.2.3.2 (must include at least one).
- **Conditional Logic:** Must include either "phone" or "email."

1.3.2.3.1. phone

- **Name:** phone
- **Definition:** The phone number of the requester or responder.
- **Required:** No (but must have phone or email)
- **Data Type:** String
- **Format (Pattern):** None (e.g., "123-456-7890" is fine).
- **Enumerations:** None
- **References:** Defined in "phoneType" under Definitions.
- **Conditional Logic:** Optional if "email" is provided.

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1.3.2.3.2. *email*

- **Name:** email
- **Definition:** The email address of the requester or responder.
- **Required:** No (but must have phone or email)
- **Data Type:** String
- **Format (Pattern):** Must be a valid email (e.g., "[name@example.com](#)").
- **Enumerations:** None
- **References:** Defined in "emailType" under Definitions.
- **Conditional Logic:** Optional if "phone" is provided.

1.3.3. *requesterGLN*

- **Name:** requesterGLN
- **Definition:** The GS1 Global Location Number (GLN) of your organization—a unique 13-digit code identifying your location.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Exactly 13 digits (e.g., "1234567890123").
- **Enumerations:** None
- **References:** Defined in "glnType" under Definitions.
- **Conditional Logic:** None

1.3.4. *callbackAddress*

- **Name:** callbackAddress
- **Definition:** The methods and addresses where the responder should send the TI response or where the requester can be contacted about issues.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Defined in "callbackAddressType" under Definitions; contains 1.3.4.1 and 1.3.4.2.

- **Conditional Logic:** Must include "emailCallbackAddress."

1.3.4.1. apiCallbackAddress

- **Name:** apiCallbackAddress
- **Definition:** The web address (URI) where the TI response should be sent electronically.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** A valid URL starting with "http://", "https://", "ws://", "wss://", or "ftp://" (e.g., "<https://example.com/response>").
- **Enumerations:** None
- **References:** Defined in "apiType" under Definitions.
- **Conditional Logic:** Optional if "emailCallbackAddress" is provided.

1.3.4.2. emailCallbackAddress

- **Name:** emailCallbackAddress
- **Definition:** The email address where the TI response should be sent.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Must be a valid email (e.g., "response@example.com").
- **Enumerations:** None
- **References:** Defined in "emailType" under Definitions.
- **Conditional Logic:** None

1.4. tiRequestParameters

- **Name:** tiRequestParameters
- **Definition:** Provides context for the request, including what type of information is needed and why the request is being made.
- **Required:** Yes
- **Data Type:** Object

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- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains fields 1.4.1 to 1.4.7 (some are conditional).
- **Conditional Logic:** Rules apply based on "investigationReasonAttestation" and "onBehalfOfAuthorityFlag" (see below).

1.4.1. *responseTypeRequested*

- **Name:** responseTypeRequested
- **Definition:** The type of information the requester is asking the responder to provide.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:**
 - "Transaction Information"
 - "All Known Owners"
 - "Last Known Owner"
- **References:** None
- **Conditional Logic:** Always required, no matter the investigation reason.

1.4.2. *investigationReasonAttestation*

- **Name:** investigationReasonAttestation
- **Definition:** The reason for initiating this TI request. There are five possible choices, and one must be selected.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:**
 - "Suspect Product Investigation"
 - "Illegitimate Product Investigation"
 - "Recalled Product Investigation"

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- "Compliance Audit"
- "Health Authority Inspection"
- **References:** None
- **Conditional Logic:** Triggers additional fields depending on the choice (see 1.4.5 to 1.4.7).

1.4.3. *investigationCircumstances*

- **Name:** investigationCircumstances
- **Definition:** A short description of the investigation to help the responder decide what to do.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** None
- **Conditional Logic:** Always required.

1.4.4. *onBehalfOfAuthority*

- **Name:** onBehalfOfAuthority
- **Definition:** Indicates if this request is made on behalf of an authority (like the FDA), with contact details if so.
- **Required:** No
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 1.4.4.1 and 1.4.4.2.
- **Conditional Logic:** If "onBehalfOfAuthorityFlag" is "true," then "authorityInformation" is required.

1.4.4.1. *onBehalfOfAuthorityFlag*

- **Name:** onBehalfOfAuthorityFlag

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- **Definition:** Indicates that this request is made on behalf of an authority. Defaults to "false" if not specified.
- **Required:** No
- **Data Type:** Boolean (true or false)
- **Format (Pattern):** None
- **Enumerations:**
 - true
 - false
- **References:** Defined in "onBehalfOfAuthorityType" under Definitions.
- **Conditional Logic:** If "true," then "authorityInformation" must be included.

1.4.4.2. authorityInformation

- **Name:** authorityInformation
- **Definition:** Contact details for the authority making the request. Responders can use this to reach out directly.
- **Required:** No (but yes if "onBehalfOfAuthorityFlag" is true)
- **Data Type:** Object
- **Format (Pattern):** Same as "contactInformation" (see 1.3.2).
- **Enumerations:** None
- **References:** Defined in "contactInformationType" under Definitions.
- **Conditional Logic:** Required only if "onBehalfOfAuthorityFlag" is "true."

1.4.5. 3911IncidentNumberList (Conditional)

- **Name:** 3911IncidentNumberList
- **Definition:** List of 3911 Incident number(s) assigned by the FDA related to the investigation. Responders add any they know without repeating the requester's numbers.
- **Required:** No
- **Data Type:** Array (list of strings)
- **Format (Pattern):** None
- **Enumerations:** None

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- **References:** Defined in "3911IncidentListType" under Definitions.
- **Conditional Logic:**
 - Included only if "investigationReasonAttestation" is "Illegitimate Product Investigation."
 - Not allowed for other reasons.

1.4.6. *recallDepth* (Conditional)

- **Name:** recallDepth
- **Definition:** Used to limit unnecessary returns during a recall by specifying how far down the supply chain the recall applies.
- **Required:** Yes (if "Recalled Product Investigation")
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:**
 - "Wholesale Distributor"
 - "Pharmacy"
 - "Patient"
- **References:** Defined in "recallDepthType" under Definitions.
- **Conditional Logic:**
 - Required only if "investigationReasonAttestation" is "Recalled Product Investigation."
 - Not allowed for other reasons.

1.4.7. *recallRequestLevel* (Conditional)

- **Name:** recallRequestLevel
- **Definition:** Specifies whether the recall applies to individual serial numbers or entire lots.
- **Required:** Yes (if "Recalled Product Investigation")
- **Data Type:** String
- **Format (Pattern):** None
- **Enumerations:**

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- "Serial Number"
 - "Lot Number"
 - **References:** None
 - **Conditional Logic:**
 - Required only if "investigationReasonAttestation" is "Recalled Product Investigation."
 - Not allowed for other reasons.
-

1.5. tiRequestAdditionalInformation

- **Name:** tiRequestAdditionalInformation
- **Definition:** Provides links to or includes extra documents related to the request.
- **Required:** No
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 1.5.1 and 1.5.2.
- **Conditional Logic:** None

1.5.1. additionalInformationLink

- **Name:** additionalInformationLink
- **Definition:** Lists the web addresses (URLs) to documents or files related to this request.
- **Required:** No
- **Data Type:** Array (list of strings)
- **Format (Pattern):** Each item must be a valid URL (e.g., "<https://example.com/doc.pdf>").
- **Enumerations:** None
- **References:** Defined in "additionalInformationLinkType" under Definitions.
- **Conditional Logic:** None

1.5.2. *additionalInformationBase64*

- **Name:** additionalInformationBase64
 - **Definition:** Encodes documents or files (like PDFs or images) in Base64 format—a way to turn files into text so they can be included directly in the request.
 - **Required:** No
 - **Data Type:** Array (list of strings)
 - **Format (Pattern):** Base64 encoded text (e.g., "data:image/png;base64,iVBORw0KGgo...").
 - **Enumerations:** None
 - **References:** Defined in "additionalInformationBase64Type" under Definitions.
 - **Conditional Logic:** None
-

1.6. tiRequests

- **Name:** tiRequests
- **Definition:** A collection of individual items (products) for which transaction or ownership information is being requested.
- **Required:** Yes
- **Data Type:** Array (list of objects)
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Each item contains fields 1.6.1 to 1.6.4.
- **Conditional Logic:** Must include at least one item.

1.6.1. *requestLineNumber*

- **Name:** requestLineNumber

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- **Definition:** Identifies an individual request within the set—like a line number on a list.
- **Required:** Yes
- **Data Type:** Number
- **Format (Pattern):** Any number (e.g., 1, 2, 3).
- **Enumerations:** None
- **References:** None
- **Conditional Logic:** None

1.6.2. *productID*

- **Name:** productID
- **Definition:** Identifies the product using either a Global Trade Item Number (GTIN) or National Drug Code (NDC).
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 1.6.2.1 or 1.6.2.2 (must choose one).

- **Conditional Logic:** Must include either "gtin" or "ndc."

1.6.2.1. gtin

- **Name:** gtin
- **Definition:** The GS1 Global Trade Item Number (GTIN) identifying the product—a 14-digit code. See the GS1 guideline for DSCSA traceability.
- **Required:** No (but must have gtin or ndc)
- **Data Type:** String
- **Format (Pattern):** Exactly 14 digits (e.g., "01234567890123").
- **Enumerations:** None
- **References:** Defined in "gtinType" under Definitions.
- **Conditional Logic:** Required if "ndc" is not used.

1.6.2.2. ndc

- **Name:** ndc
- **Definition:** The FDA National Drug Code—a unique code for the product.
- **Required:** No (but must have gtin or ndc)

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- **Data Type:** String
- **Format (Pattern):** One of these formats:
 - 4-4-2 (e.g., "1234-5678-90")
 - 5-3-2 (e.g., "12345-678-90")
 - 5-4-1 (e.g., "12345-6789-0")
 - 6-4-2 (e.g., "123456-7890-12")
- **Enumerations:** None
- **References:** Defined in "ndcType" under Definitions.
- **Conditional Logic:** Required if "gtin" is not used.

1.6.3. *serialNumberOrLotNumber*

- **Name:** serialNumberOrLotNumber
- **Definition:** Specifies either a serial number or lot number for the product. Serial numbers identify individual items; lot numbers identify batches. Be aware that lot-based requests might return a lot of data.
- **Required:** Yes
- **Data Type:** Object

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- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 1.6.3.1 or 1.6.3.2 (must choose one).
- **Conditional Logic:** Must include either "serialNumber" or "lotNumber."

1.6.3.1. serialNumber

- **Name:** serialNumber
- **Definition:** A unique or random number that, with the GTIN, identifies a specific item (like a case or package).
- **Required:** No (but must have serialNumber or lotNumber)
- **Data Type:** String
- **Format (Pattern):** 1 to 20 characters (e.g., "SN12345").
- **Enumerations:** None
- **References:** Defined in "serialNumberType" under Definitions.
- **Conditional Logic:** Required if "lotNumber" is not used.

1.6.3.2. lotNumber

- **Name:** lotNumber

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- **Definition:** The lot number assigned by the manufacturer or repackager, found in the original transaction information.
- **Required:** No (but must have serialNumber or lotNumber)
- **Data Type:** String
- **Format (Pattern):** 1 to 20 characters (e.g., "LOT123").
- **Enumerations:** None
- **References:** Defined in "lotNumberType" under Definitions.
- **Conditional Logic:** Required if "serialNumber" is not used.

1.6.4. *requestLineNumberAdditionalInformation*

- **Name:** requestLineNumberAdditionalInformation
- **Definition:** Lists file names or links to files related to this specific request line.
- **Required:** No
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None

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- **References:** Contains 1.6.4.1 and 1.6.4.2.
- **Conditional Logic:** None

1.6.4.1. additionalInformationLink

- **Name:** additionalInformationLink
- **Definition:** Lists web addresses (URLs) to documents or files related to this request line.
- **Required:** No
- **Data Type:** Array (list of strings)
- **Format (Pattern):** Each item must be a valid URL (e.g., "<https://example.com/line1.pdf>").
- **Enumerations:** None
- **References:** Defined in "additionalInformationLinkType" under Definitions.
- **Conditional Logic:** None

1.6.4.2. additionalInformationBase64

- **Name:** additionalInformationBase64
- **Definition:** Encodes documents or files related to this request line in Base64 format (text version of files).
- **Required:** No

- **Data Type:** Array (list of strings)
 - **Format (Pattern):** Base64 encoded text (e.g., "data:application/pdf;base64,JVBERi0xLj...").
 - **Enumerations:** None
 - **References:** Defined in "additionalInformationBase64Type" under Definitions.
 - **Conditional Logic:** None
-

3. Additional Notes

- **Definitions Section:** The Model includes a "definitions" area that sets rules for common field types (like UUIDs, timestamps, or GTINs). These are referenced throughout the documentation to keep things consistent.
- **Conditional Logic Summary:**
 - For "investigationReasonAttestation":
 - "Recalled Product Investigation" requires "recallDepth" and "recallRequestLevel."
 - "Illegitimate Product Investigation" allows "3911IncidentNumberList."
 - Other reasons don't use these extra fields.
-

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- For "onBehalfOfAuthority": If the flag is "true," "authorityInformation" is mandatory.
- **** Completeness:**** Every field, including nested ones, has been documented with all required details.

2. Field Documentation

Below, each definition is explained in detail. These are the building blocks used in the main Model, so each entry includes its name, purpose, rules, and any specific formats or options.

These definitions are like templates that the main Model uses to make sure data is entered correctly. For example, every time a phone number is needed, it follows the "phoneType" rules.

1. 3911IncidentListType

- **Name:** 3911IncidentListType
- **Definition:** List of 3911 Incident number(s) provided if assigned. These are numbers the FDA gives to track investigations. Responders add any they know without repeating numbers the requester already listed.
- **Required:** No (depends on where it's used)
- **Data Type:** Array (a list of text entries)
- **Format (Pattern):** None (just a list of text, e.g., ["INC123", "INC456"])
- **Enumerations:** None

- **References:** Used in "tiRequestParameters" for "3911IncidentNumberList."
 - **Conditional Logic:** Can be empty (minimum 0 items).
-

2. additionalInformationBase64Type

- **Name:** additionalInformationBase64Type
 - **Definition:** This property can hold Base64 encoded data of various image and document formats (e.g., PNG, JPG, PDF)—a way to turn files into text for inclusion in the request.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** Base64 encoded text (e.g., "data:image/png;base64,iVBORw0KGgo...")
 - **Enumerations:** None
 - **References:** Used in "additionalInformationBase64" fields.
 - **Conditional Logic:** None
-

3. additionalInformationLinkType

- **Name:** additionalInformationLinkType

- **Definition:** A web address (URL) pointing to a document or file related to the request.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** Must be a valid URL (e.g., "<https://example.com/doc.pdf>")
 - **Enumerations:** None
 - **References:** Used in "additionalInformationLink" fields.
 - **Conditional Logic:** None
-

4. apiType

- **Name:** apiType
- **Definition:** A web address (URI) for sending or receiving information electronically, like where a response should go.
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** Must start with "http://", "https://", "ws://", "wss://", or "ftp://" (e.g., "<https://example.com/api>")

- **Enumerations:** None
 - **References:** Used in "apiCallbackAddress."
 - **Conditional Logic:** None
-

5. callbackAddressType

- **Name:** callbackAddressType
- **Definition:** The methods and addresses where the responder sends the TI response or where the requester can be contacted about issues.
- **Required:** Yes (when used, must include "emailCallbackAddress")
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Used in "callbackAddress"; contains 5.1 and 5.2.
- **Conditional Logic:** Must include "emailCallbackAddress."

5.1. apiCallbackAddress

- **Name:** apiCallbackAddress

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- **Definition:** The web address (URI) where the TI response should be sent electronically.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** See "apiType" (e.g., "<https://example.com/response>")
- **Enumerations:** None
- **References:** Defined in "apiType."
- **Conditional Logic:** Optional if "emailCallbackAddress" is provided.

5.2. *emailCallbackAddress*

- **Name:** emailCallbackAddress
- **Definition:** The email address where the TI response should be sent.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** See "emailType" (e.g., "response@example.com")
- **Enumerations:** None
- **References:** Defined in "emailType."

- **Conditional Logic:** None
-

6. contactInformationType

- **Name:** contactInformationType
- **Definition:** Information to help the requester or responder contact each other about the request or response.
- **Required:** Yes (when used)
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Used in "contactInformation" and "authorityInformation"; contains 6.1 to 6.3.
- **Conditional Logic:** Must include all three subfields below.

6.1. personOrDepartmentName

- **Name:** personOrDepartmentName
- **Definition:** The person or department that can be contacted regarding the request or response.

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- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** See "nameValueType" (e.g., "John Doe" or "Quality Dept")
- **Enumerations:** None
- **References:** Defined in "nameValueType."
- **Conditional Logic:** None

6.2. *organizationName*

- **Name:** organizationName
- **Definition:** Name of the organization requesting TI or responding to a request.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** See "nameValueType" (e.g., "PharmaCorp")
- **Enumerations:** None
- **References:** Defined in "nameValueType."
- **Conditional Logic:** None

6.3. contactMethod

- **Name:** contactMethod
- **Definition:** Phone number or email address that the requester or responder can be contacted with.
- **Required:** Yes
- **Data Type:** Object
- **Format (Pattern):** None
- **Enumerations:** None
- **References:** Contains 6.3.1 or 6.3.2 (must include at least one).
- **Conditional Logic:** Must include either "phone" or "email."

6.3.1. phone

- **Name:** phone
- **Definition:** The phone number of the requester or responder.
- **Required:** No (but must have phone or email)
- **Data Type:** String

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- **Format (Pattern):** See "phoneType" (e.g., "123-456-7890")
- **Enumerations:** None
- **References:** Defined in "phoneType."
- **Conditional Logic:** Optional if "email" is provided.

6.3.2. email

- **Name:** email
- **Definition:** The email address of the requester or responder.
- **Required:** No (but must have phone or email)
- **Data Type:** String
- **Format (Pattern):** See "emailType" (e.g., "[contact@example.com](#)")
- **Enumerations:** None
- **References:** Defined in "emailType."
- **Conditional Logic:** Optional if "phone" is provided.

7. drugNameType

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- **Name:** drugNameType
- **Definition:** A simple text field for the name of a drug (not used directly in the Model but available for reference).
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** None (e.g., "Aspirin")
- **Enumerations:** None
- **References:** Not directly used in the Model.
- **Conditional Logic:** None

8. dscsaCredentialPresentationType

- **Name:** dscsaCredentialPresentationType
- **Definition:** A credential proving identity, like an official ID. It can be an ATP (Authorized Trading Partner), an equivalent, or a DSCSA Authority credential.
- **Required:** Yes (when used)
- **Data Type:** Object
- **Format (Pattern):** Must be a JWT (a secure text format) for one of the types below.

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- **Enumerations:** None
- **References:** Used in "dscsaCredentialPresentation"; contains 8.1 to 8.3 (must choose one).
- **Conditional Logic:** Must pick one of the three subfields.

8.1. dscsaATPCredentialPresentation

- **Name:** dscsaATPCredentialPresentation
- **Definition:** A W3C standard verifiable credential following the OCI DSCSA ATP specification—an official ID for authorized partners.
- **Required:** No (but must pick one credential)
- **Data Type:** String
- **Format (Pattern):** JWT format (e.g., "eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...")
- **Enumerations:** None
- **References:** Part of "dscsaCredentialPresentationType."
- **Conditional Logic:** Required if not using the other two options.

8.2. dscsaATP-EquivalentCredentialPresentation

- **Name:** dscsaATP-EquivalentCredentialPresentation

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- **Definition:** A W3C standard verifiable credential following the OCI DSCSA ATP Equivalent specification—similar to ATP but for equivalents.
- **Required:** No (but must pick one credential)
- **Data Type:** String
- **Format (Pattern):** JWT format
- **Enumerations:** None
- **References:** Part of "dscsaCredentialPresentationType."
- **Conditional Logic:** Required if not using the other two options.

8.3. *dscsaAuthorityCredentialPresentation*

- **Name:** dscsaAuthorityCredentialPresentation
- **Definition:** A W3C standard verifiable credential following the OCI DSCSA Authority specification—for authorities like the FDA.
- **Required:** No (but must pick one credential)
- **Data Type:** String
- **Format (Pattern):** JWT format
- **Enumerations:** None

- **References:** Part of "dscsaCredentialPresentationType."
 - **Conditional Logic:** Required if not using the other two options.
-

9. emailType

- **Name:** emailType
 - **Definition:** A standard email address format.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** Must be a valid email (e.g., "[name@example.com](#)")
 - **Enumerations:** None
 - **References:** Used in "email" and "emailCallbackAddress."
 - **Conditional Logic:** None
-

10. glnType

- **Name:** glnType

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- **Definition:** The GS1 Global Location Number (GLN)—a 13-digit code identifying a location, as recorded in the TI record. See the GS1 guideline for DSCSA traceability.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** Exactly 13 digits (e.g., "1234567890123")
 - **Enumerations:** None
 - **References:** Used in "requesterGLN."
 - **Conditional Logic:** None
-

11. gtinType

- **Name:** gtinType
- **Definition:** The GS1 Global Trade Item Number (GTIN)—a 14-digit code identifying a product.
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** Exactly 14 digits (e.g., "01234567890123")
- **Enumerations:** None

- **References:** Used in "gtin" under "productID."
 - **Conditional Logic:** None
-

12. investigationIDType

- **Name:** investigationIDType
 - **Definition:** An identifier created by the requester to group and archive requests and responses. It's recommended to be unique, like a UUID or a combination of IDs.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** None (e.g., "INV-001" or a UUID)
 - **Enumerations:** None
 - **References:** Used in "tiRequesterInvestigationID."
 - **Conditional Logic:** None
-

13. lotNumberType

- **Name:** lotNumberType

- **Definition:** The lot number assigned by the manufacturer or repackager, found in the original transaction information—a code for a batch of products.
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** 1 to 20 characters (e.g., "LOT123")
 - **Enumerations:** None
 - **References:** Used in "lotNumber" under "serialNumberOrLotNumber."
 - **Conditional Logic:** None
-

14. nameValueType

- **Name:** nameValueType
- **Definition:** A simple text field for names (like a person, department, or organization).
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** None (e.g., "Jane Smith" or "Acme Inc.")

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- **Enumerations:** None
 - **References:** Used in "personOrDepartmentName" and "organizationName."
 - **Conditional Logic:** None
-

15. ndcType

- **Name:** ndcType
- **Definition:** The FDA National Drug Code—a unique code for a drug product. It depends on whether GTIN or NDC is chosen for the product ID.
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** One of these formats:
 - 4-4-2 (e.g., "1234-5678-90")
 - 5-3-2 (e.g., "12345-678-90")
 - 5-4-1 (e.g., "12345-6789-0")
 - 6-4-2 (e.g., "123456-7890-12")
- **Enumerations:** None

- **References:** Used in "ndc" under "productID."
- **Conditional Logic:** None

16. onBehalfOfAuthorityType

- **Name:** onBehalfOfAuthorityType
- **Definition:** Indicates if the request is made on behalf of an authority (e.g., FDA). The responder might use this to contact the authority directly. Defaults to "false" if not specified.
- **Required:** No (depends on where it's used)
- **Data Type:** Boolean (true or false)
- **Format (Pattern):** None
- **Enumerations:**
 - true
 - false
- **References:** Used in "onBehalfOfAuthorityFlag."
- **Conditional Logic:** None

17. phoneType

- **Name:** phoneType
- **Definition:** The phone number of the requester or responder.
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** None (e.g., "123-456-7890")
- **Enumerations:** None
- **References:** Used in "phone" under "contactMethod."
- **Conditional Logic:** None

18. recallDepthType

- **Name:** recallDepthType
- **Definition:** Specifies how far down the supply chain a recall applies, to avoid unnecessary returns.
- **Required:** No (depends on where it's used)

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- **Data Type:** String
 - **Format (Pattern):** None
 - **Enumerations:**
 - "Wholesale Distributor"
 - "Pharmacy"
 - "Patient"
 - **References:** Used in "recallDepth" under "tiRequestParameters."
 - **Conditional Logic:** None
-

19. serialNumberType

- **Name:** serialNumberType
- **Definition:** A unique or random number that, with the GTIN, identifies a specific item (like a case or package).
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** 1 to 20 characters (e.g., "SN12345")

- **Enumerations:** None
- **References:** Used in "serialNumber" under "serialNumberOrLotNumber."
- **Conditional Logic:** None

20. timestampType

- **Name:** timestampType
- **Definition:** A timestamp with millisecond precision and an explicit timezone (e.g., +00:00 for UTC), showing when something happened.
- **Required:** No (depends on where it's used)
- **Data Type:** String
- **Format (Pattern):** Like "2025-02-20T14:30:45.123+00:00" (year-month-day T hour:minute:second.milliseconds +timezone)
- **Enumerations:** None
- **References:** Used in "tiRequestTimestamp."
- **Conditional Logic:** None

21. tracingModelSetVersionType

- **Name:** tracingModelSetVersionType
 - **Definition:** The version of the tracing request and response Model, ensuring they match. Defaults to "2.0.0."
 - **Required:** No (depends on where it's used)
 - **Data Type:** String
 - **Format (Pattern):** Must be "X.Y.Z" (e.g., "2.0.0"), where X, Y, Z are single digits
 - **Enumerations:** None
 - **References:** Used in "tracingModelSetVersion."
 - **Conditional Logic:** None
-

22. uuidType

- **Name:** uuidType
- **Definition:** A Universally Unique Identifier (UUID)—a special code to ensure no two things have the same ID.
- **Required:** No (depends on where it's used)
- **Data Type:** String

- **Format (Pattern):** Like "123e4567-e89b-12d3-a456-426614174000" (letters and numbers with dashes)
 - **Enumerations:** None
 - **References:** Used in "tiRequestID."
 - **Conditional Logic:** None
-

3. Additional Notes

- **Purpose of Definitions:** These definitions are like templates that the main Model uses to make sure data is entered correctly. For example, every time a phone number is needed, it follows the "phoneType" rules.
- **Completeness:** Every definition has been documented, including nested fields, with all required details.
- **References:** Each definition lists where it's used in the main Model (if applicable), helping users see the connections.