

## **Glossary: DSCSA Transaction Information (TI) Response Terms (Alphabetical Order)**

This glossary is designed to help non-technical employees understand the key elements involved in a DSCSA TI (Transaction Information) Response.

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### **3911 Incident Number**

*What it is:* An FDA-assigned number for investigations or reported issues.

*Why it matters:* Helps track problem cases.

### **Additional Information (Links or Files)**

*What it is:* Extra documents or links related to the product or request.

*Format:* May be links or encoded files (PDFs, images).

### **Callback email Address**

*What it is:* Where to send follow-ups or exception reports.

*Formats:* May include email or API addresses.

### **Company mailing Address**

*What it is:* The physical address of the company involved in the TI record.

*Why it matters:* Identifies the source or recipient of the drug shipment.

### **Company Name**

*What it is:* The legal name of the company listed in the TI record.

*Why it matters:* Ensures clear identification of supply chain entities.

### **Contact Information**

*What it is:* The name, phone, and/or email of a contact person.

*Why it matters:* Used if there are follow-up questions about the response.

### **Container Size**

*What it is:* The size of the product container (e.g., 100 tablets).

*Why it matters:* Helps verify product and package specifics.

### **Credential Presentation**

*What it is:* A digital credential proving the responder is authorized.

*Why it matters:* Verifies the response comes from a legitimate source.

### **Date of Shipment / Date of Transaction**

*What it is:* When the drug was shipped or sold.

*Why it matters:* Establishes the timeline of ownership.

**Direct Purchase Statement**

*What it is:* Notes if the product was purchased directly from the manufacturer.

*Why it matters:* Helps verify authenticity.

**Dosage Form**

*What it is:* How the drug is administered (e.g., tablet, capsule, injection).

*Why it matters:* Ensures accurate product understanding.

**Drop Ship Indicator**

*What it is:* Shows whether the drug was shipped directly to a third party.

*Why it matters:* Affects who is listed as the buyer and seller.

**Email Callback Address**

*What it is:* The email address where exceptions or questions about the TI response can be sent.

*Why it matters:* Facilitates fast follow-up.

**Expiration Date**

*What it is:* The date after which the drug should not be used.

*Why it matters:* Ensures safety and compliance.

**GTIN (Global Trade Item Number)**

*What it is:* A 14-digit number identifying the product globally.

*Why it matters:* Helps uniquely identify the drug.

**GLN (Global Location Number)**

*What it is:* A 13-digit number identifying the location of a company.

*Why it matters:* Used in the supply chain to identify sender/receiver locations.

**Lot Number**

*What it is:* A batch number used to identify a group of drugs.

*Why it matters:* Important for recalls and tracking production.

**NDC (National Drug Code)**

*What it is:* A unique identifier assigned by the FDA.

*Why it matters:* Required for drug identification in the U.S.

**Number of Containers**

*What it is:* Always "1" for each serialized product unit in a TI response.

*Why it matters:* Indicates package-level tracing.

**Ownership Information**

*What it is:* A list of past owners or the last known owner of the product.

*Why it matters:* Helps verify the drug's movement through the supply chain.

## **Ownership Information Notes**

*What it is:* Additional notes regarding the ownership information provided in a TI Response.

*Why it matters:* The Responder uses it to add context to the ownership information. For example, a returned item was subsequently sold to another customer.

## **PO (Purchase Order) Associated with TI**

*What it is:* A reference to the order tied to the shipment.

*Why it matters:* Helps match the shipment to internal business records.

## **Phone Number**

*What it is:* Contact number for reaching someone about the request or response.

*Why it matters:* Useful for clarifying urgent issues.

## **Product Data**

*What it is:* Details about the drug such as GTIN, name, dosage, and strength.

*Why it matters:* Describes the product in the TI response.

## **Product ID (GTIN or NDC)**

*What it is:* A number identifying the drug product.

*Why it matters:* Tells exactly what drug is being referenced.

## **Production Data**

*What it is:* Includes lot number, serial number, and expiration date.

*Why it matters:* Helps track product origin and integrity.

## **Responder GLN**

*What it is:* The GLN of the company sending the TI response.

*Why it matters:* Identifies the source of the response.

## **Request ID**

*What it is:* The unique number from the original TI request.

*Why it matters:* Ensures the response is tied to the correct request.

## **Request Line Number**

*What it is:* A number identifying a specific item or product in the TI request.

*Why it matters:* Used to match individual requests to their responses.

## **Request Type (Response Type Requested)**

*What it is:* Specifies the information being asked for.

*Options include:* Transaction Info, All Known Owners, or Last Known Owner.

**Response ID**

*What it is:* A unique number that identifies the TI response.

*Why it matters:* Helps match the response to the original request.

**Response Message**

*What it is:* Free-text explanation or notes from the responder.

*Why it matters:* Used when formal data isn't available or to give more context.

**Serial Number**

*What it is:* Unique number printed on the product to track it.

*Why it matters:* Needed to trace individual packages.

**State, City, Postal Code, Country Code**

*What it is:* Part of the company address.

*Why it matters:* Helps precisely locate parties involved in the TI.

**Strength**

*What it is:* The potency of the drug (e.g., 500mg).

*Why it matters:* Ensures proper treatment and product use.

**TI Request Responses**

*What it is:* Contains responses to one or more product tracing requests.

*Why it matters:* Bundles related responses together.

**TI Response**

*What it is:* A message sent in reply to a DSCSA Transaction Information request.

*Why it matters:* Confirms supply chain data about a drug, helping trace its path.

**Tracing Model Set Version**

*What it is:* The version number of the model used to structure the TI response.

*Why it matters:* Ensures all parties use the same format and rules.

**Transaction Information**

*What it is:* Details about a sale or shipment of the drug.

*Includes:* Who sold it, who bought it, dates, and shipment details.

**Transaction Information Notes**

*What it is:* Additional notes regarding the transaction information provided in a TI Response.

*Why it matters:* The Responder uses it to add context to the transaction information. For example, a returned item was subsequently sold to another customer.

**Transaction Statement**

*What it is:* A required DSCSA statement included with the product's info.

*Why it matters:* Legally affirms the product's legitimacy.

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This glossary can be used as part of employee training or kept on-hand for reference when reviewing or creating DSCSA TI Responses.

*End of Glossary*

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# PDG DSCSA TI Response Model

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

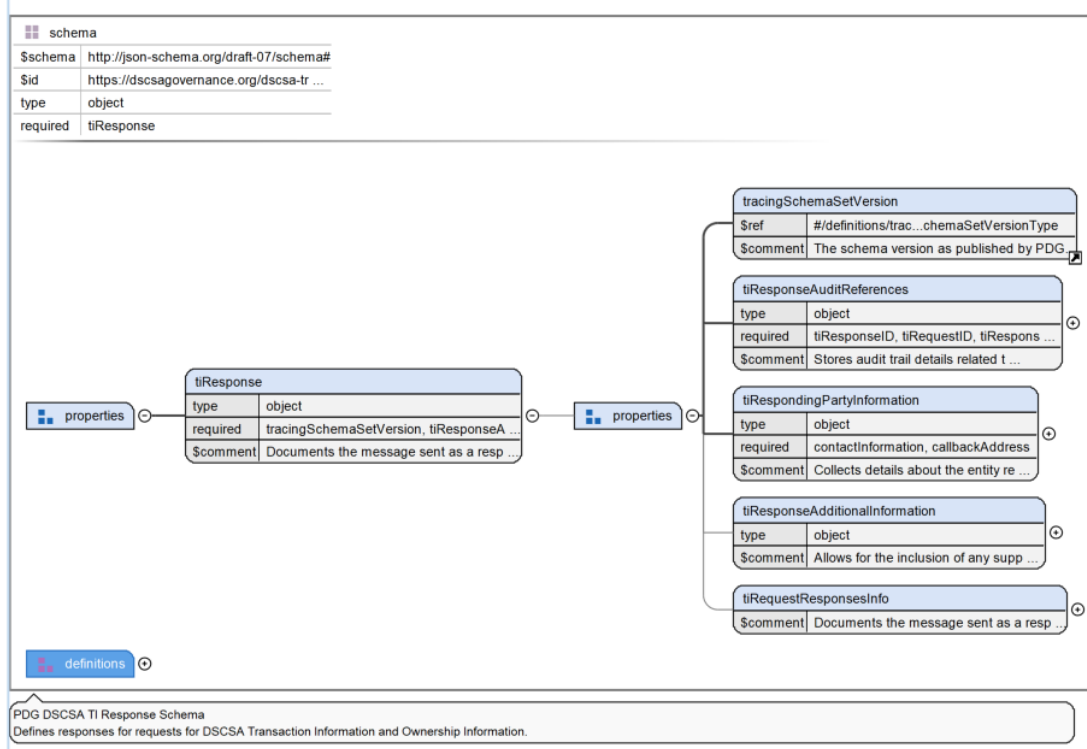


Figure 1 - Top-level data groups of the TI Response message

## 1. Model Overview

**Title:** PDG DSCSA TI Response Model

**Description:** Defines responses for requests for DSCSA Transaction Information and Ownership Information.

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

### 1.1. tiResponse

- **Definition:** Documents the message sent as a response to a trace request set.
- **Required:** Yes

### 1.1.1. tracingModelSetVersion

- **Name:** tracingModelSetVersion
- **Definition:** The model version as published by PDG.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** `^[0-9]{1}.[0-9]{1}.[0-9]{1}$`
- **References<sup>1</sup>:** \$ref: "#/definitions/tracingModelSetVersionType"

### 1.1.2. tiResponseAuditReferences

- **Name:** tiResponseAuditReferences
- **Definition:** Stores audit trail details related to the response.
- **Required:** Yes
- **Data Type:** Object

#### 1.1.2.1. tiResponseID

- **Name:** tiResponseID
- **Definition:** This is a unique ID you have assigned to this message. The receiver of the response can reference this ID in communications.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** UUID format: `^[a-fA-F\d]{8}-[a-fA-F\d]{4}-4[a-fA-F\d]{3}-[89abAB][a-fA-F\d]{3}-[a-fA-F\d]{12}$`
- **References:** \$ref: "#/definitions/uuidType"

#### 1.1.2.2. tiRequestID

- **Name:** tiRequestID
- **Definition:** This is a unique ID provided by the Requester in the TI Request message. Including it in the TI Response allows the Requestor to match responses to their request.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** UUID format: `^[a-fA-F\d]{8}-[a-fA-F\d]{4}-4[a-fA-F\d]{3}-[89abAB][a-fA-F\d]{3}-[a-fA-F\d]{12}$`
- **References:** \$ref: "#/definitions/uuidType"

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<sup>1</sup> See 2. References, Standard Data Types

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### 1.1.2.3. *tiRequesterInvestigationID*

- **Name:** tiRequesterInvestigationID
- **Definition:** This is a unique ID the Requester provided in their TI Request message.
- **Required:** No
- **Data Type:** String
- **References:** \$ref: "#/definitions/investigationIDType"

### 1.1.2.4. *responder3911IncidentNumberList*

- **Name:** responder3911IncidentNumberList
- **Definition:** List of 3911s known by the responder associated with the requested products.
- **Required:** No
- **Data Type:** Array of Strings
- **References:** \$ref: "#/definitions/3911IncidentListType"

### 1.1.2.5. *tiResponseTimestamp*

- **Name:** tiResponseTimestamp
- **Definition:** This is the date and time the response message was created.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** A timestamp to millisecond precision, with an explicit timezone indicator: `^[0-9]{4}-(0[1-9]|1[0-2])-(0[1-9]|1[0-9]|2[0-9]|3[0-1])T(2[0-3]|01)[0-9]:[0-5][0-9]:[0-5][0-9]\.[0-9]{3}(Z|((\+|-)((0[0-9]|1[0-3]):([0-5][0-9])14:00)))`
- **References:** \$ref: "#/definitions/timestampType"

## 1.1.3. *tiRespondingPartyInformation*

- **Name:** tiRespondingPartyInformation
- **Definition:** Collects details about the entity responding to the trace request.
- **Required:** Yes
- **Data Type:** Object

### 1.1.3.1. *dscsaCredentialPresentation*

- **Name:** dscsaCredentialPresentation
- **Definition:** The ATP, ATP-Equivalent or DSCSA Authority credential.
- **Required:** No
- **Data Type:** Object
- **References:** \$ref: "#/definitions/dscsaCredentialPresentationType"
- **Conditional Logic:** One of dscsaATPCredentialPresentation, dscsaATP-EquivalentCredentialPresentation, or dscsaAuthorityPresentation must be present.

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### 1.1.3.2. *contactInformation*

- **Name:** contactInformation
- **Definition:** Information to aid the Requester or Responder in contacting the other party in regard to the Request or Response.
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/contactInformationType"

### 1.1.3.3. *responderGLN*

- **Name:** responderGLN
- **Definition:** The GS1 Global Location Number of your organization.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Must be 13 digits long: `^\d{13}$`
- **References:** \$ref: "#/definitions/glnType"

### 1.1.3.4. *callbackAddress*

- **Name:** callbackAddress
- **Definition:** The methods and addresses where the responder is to send the TI Response message or where the requester can contact to send exception information.
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/callbackAddressType"

### 1.1.4. *tiResponseAdditionalInformation*

- **Name:** tiResponseAdditionalInformation
- **Definition:** Allows for the inclusion of any supplementary information regarding the response.
- **Required:** No
- **Data Type:** Object

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### 1.1.4.1. *additionalInformationLink*

- **Name:** additionalInformationLink
- **Definition:** Lists the addresses to documents or files that are related to this response.
- **Required:** No
- **Data Type:** Array of Strings (URI format)
- **References:** \$ref: "#/definitions/additionalInformationLinkType"

### 1.1.4.2. *additionalInformationBase64*

- **Name:** additionalInformationBase64
- **Definition:** Encodes (in Base 64) document or files that are relevant to this request.
- **Required:** No
- **Data Type:** Array of Strings (Base64 encoding)
- **References:** \$ref: "#/definitions/additionalInformationBase64Type"

## 1.1.5. tiRequestResponsesInfo

- **Name:** tiRequestResponsesInfo
- **Definition:** Documents the message sent as a response to the trace request set.
- **Required:** No
- **Data Type:** Object

### 1.1.5.1. *tiRequestResponses*

- **Name:** tiRequestResponses
- **Definition:** Documents the message sent as a response to the trace request.
- **Required:** Yes (one of tiRequestResponses or responseMessage must be present)
- **Data Type:** Array of Objects

#### 1.1.5.1.1. *individualRequest*

- **Name:** individualRequest
- **Definition:** A TI request message may contain a number of individual requests for TI on individual drug packages or Lots (DSCSA Authorities only). Each individual request may result in many responses.
- **Required:** Yes
- **Data Type:** Object

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### 1.1.5.1.1.1. requestLineNumber

- **Name:** requestLineNumber
- **Definition:** Not specified in model comments, inferred as line identification for the request.
- **Required:** Yes
- **Data Type:** Number

### 1.1.5.1.1.2. productID

- **Name:** productID
- **Definition:** Not specified in model comments, inferred as identifier for the product.
- **Required:** Yes
- **Data Type:** Object

### 1.1.5.1.1.2.1. gtin

- **Name:** gtin
- **Definition:** The GS1 Global Trade Item Number (GTIN) identifying the product. Conditional based on Product ID choice (GTIN or NDC).
- **Required:** Yes (if ndc is not provided)
- **Data Type:** String
- **Format (Pattern):** Must be 14 digits long: `^\d{14}$`
- **References:** \$ref: "#/definitions/gtinType"

### 1.1.5.1.1.2.2. ndc

- **Name:** ndc
- **Definition:** The FDA National Drug Code. Conditional based on Request Product ID choice (GTIN or NDC).
- **Required:** Yes (if gtin is not provided)
- **Data Type:** String
- **Format (Pattern):** One of the following formats:
  - 4-4-2: `^[0-9]{4}-[0-9]{4}-[0-9]{2}$`
  - 5-3-2: `^[0-9]{5}-[0-9]{3}-[0-9]{2}$`
  - 5-4-1: `^[0-9]{5}-[0-9]{4}-[0-9]{1}$`
  - 6-4-2 (future): `^[0-9]{6}-[0-9]{4}-[0-9]{2}$`
- **References:** \$ref: "#/definitions/ndcType"

### 1.1.5.1.1.3. serialNumberOrLotNumber

- **Name:** serialNumberOrLotNumber
- **Definition:** Not specified in model comments, inferred as either serial or lot number for product tracking.
- **Required:** Yes



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- **Data Type:** Object

### 1.1.5.1.1.3.1. serialNumber

- **Name:** serialNumber
- **Definition:** Not specified in model comments, inferred as the unique serial number of the product.
- **Required:** Yes (if lotNumber is not provided)
- **Data Type:** String
- **Format (Pattern):** Length between 1 and 20 characters
- **References:** \$ref: "#/definitions/serialNumberType"

### 1.1.5.1.1.3.2. lotNumber

- **Name:** lotNumber
- **Definition:** The Lot number assigned by the Manufacturer or Repackager found in the original Transaction Information.
- **Required:** Yes (if serialNumber is not provided)
- **Data Type:** String
- **Format (Pattern):** Length between 1 and 20 characters
- **References:** \$ref: "#/definitions/lotNumberType"

### 1.1.5.1.1.4. responseTypeRequested

- **Name:** responseTypeRequested
- **Definition:** Not specified in model comments, inferred as the type of response information requested.
- **Required:** Yes
- **Data Type:** String
- **Enumerations:**
  - "Transaction Information"
  - "All Known Owners"
  - "Last Known Owner"

### 1.1.5.1.2. responsesToRequest

- **Name:** responsesToRequest
- **Definition:** This object holds response to a particular request (identified by line number).
- **Required:** Yes (if requestLineNumberMessage is not provided)
- **Data Type:** Object

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### 1.1.5.1.2.1. *transactionInformationResponses*

- **Name:** transactionInformationResponses
- **Definition:** If the Requester requested Transaction Information, the Responder provides the Transaction Information in this section.
- **Required:** Conditional (required if responseTypeRequested is "Transaction Information")
- **Data Type:** Array of Objects
- **References:** \$ref: "#/definitions/transactionInformationResponses"

### 1.1.5.1.2.2. *ownershipInformationResponses*

- **Name:** ownershipInformationResponses
- **Definition:** If the Requester requested all known owners or last known owners, the Responder provides one or more owner information and shipment dates (to sequence the ownership).
- **Required:** Conditional (required if responseTypeRequested is "All Known Owners" or "Last Known Owner")
- **Data Type:** Array of Objects
- **References:** \$ref: "#/definitions/ownershipInformationResponses"

### 1.1.5.1.3. *requestLineNumberMessage*

- **Name:** requestLineNumberMessage
- **Definition:** This is a free form text where the Responder can add relevant information about the line number request.
- **Required:** Yes (if responsesToRequest is not provided)
- **Data Type:** Object
- **References:** \$ref: "#/definitions/requestResponseMessageType"

### 1.1.5.1.4. *responseLineNumberAdditionalInformation*

- **Name:** responseLineNumberAdditionalInformation
- **Definition:** Provide links to or incorporates additional documents.
- **Required:** No
- **Data Type:** Object

#### 1.1.5.1.4.1. *additionalInformationLink*

- **Name:** additionalInformationLink
- **Definition:** Lists the addresses to documents or files that are related to this request.
- **Required:** No
- **Data Type:** Array of Strings (URI format)
- **References:** \$ref: "#/definitions/additionalInformationLinkType"

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### 1.1.5.1.4.2. *additionalInformationBase64*

- **Name:** additionalInformationBase64
- **Definition:** Encodes (in Base 64) document or files that are relevant to this request.
- **Required:** No
- **Data Type:** Array of Strings (Base64 encoding)
- **References:** \$ref: "#/definitions/additionalInformationBase64Type"

### 1.1.5.2. *responseMessage*

- **Name:** responseMessage
  - **Definition:** Free form text regarding the trace request set.
  - **Required:** Yes (if tiRequestResponses is not provided)
  - **Data Type:** Object
  - **References:** \$ref: "#/definitions/responseMessageType"
-

## 2. Definitions, Standard Data Types

### 2.1. 3911IncidentListType

- **Name:** 3911IncidentListType
- **Definition:** List of 3911 Incident number(s) are provided if assigned. The 3911 Incident Number(s) assigned by the FDA associated with the investigation. Responders provide 3911 Incident Number(s) they know and do not repeat 3911 Incident Number(s) that the Requester may have included in the TI Request.
- **Required:** No
- **Data Type:** Array of Strings
- **Minimum Items:** 0

### 2.2. addressType

- **Name:** addressType
- **Definition:** Standard postal address information.
- **Required:** Yes (all subfields)
- **Data Type:** Object

#### 2.2.1. streetAddress

- **Name:** streetAddress
- **Required:** Yes
- **Data Type:** String
- **Default:** Empty string ("")
- **Examples:** ["21 2nd Street"]

#### 2.2.2. city

- **Name:** city
- **Required:** Yes
- **Data Type:** String
- **Default:** Empty string ("")
- **Examples:** ["New York"]

### 2.2.3. state

- **Name:** state
- **Required:** Yes
- **Data Type:** String
- **Default:** Empty string ("")
- **Examples:** ["NY"]

### 2.2.4. postalCode

- **Name:** postalCode
- **Required:** Yes
- **Data Type:** String
- **Default:** Empty string ("")
- **Examples:** ["10021-3100"]

### 2.2.5. countryCode

- **Name:** countryCode
- **Definition:** The country using the standard two-letter abbreviation specified in ISO 3166-1 Alpha-2 list of 2-letter country codes.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Exactly two characters long
- **Examples:** ["US"]

## 2.3. additionalInformationBase64Type

- **Name:** additionalInformationBase64Type
- **Definition:** This property can hold base64 encoded data of various image and document formats (e.g., PNG, JPG, PDF).
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Base64 encoded string
- **Content Encoding:** base64

## 2.4. additionalInformationLinkType

- **Name:** additionalInformationLinkType
- **Definition:** Not explicitly defined but inferred as a link to additional information.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** URI format

## 2.5. apiType

- **Name:** apiType
- **Definition:** Not explicitly defined but inferred as an API endpoint.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** URI format with a pattern for web protocols:  
`^(https?|wss?|ftp)://[^\s/$. ?#].[^\\s]*$`

## 2.6. callbackAddressType

- **Name:** callbackAddressType
- **Definition:** The methods and addresses where the responder is to send the TI Response message or where the requester can contact to send exception information.
- **Required:** Yes (for emailCallbackAddress)
- **Data Type:** Object

### 2.6.1. apiCallbackAddress

- **Name:** apiCallbackAddress
- **Definition:** The URI address where the Requester can alert the Responder of Exceptions found in the TI Response (possible future use).
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** URI format
- **References:** \$ref: "#/definitions/apiType"

### 2.6.2. emailCallbackAddress

- **Name:** emailCallbackAddress
- **Definition:** The email address where the Requester can alert the Responder of Exceptions found in the TI Response.

- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Email format
- **References:** \$ref: "#/definitions/emailType"

## 2.7. companyInformationType

- **Name:** companyInformationType
- **Definition:** 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.
- **Required:** Yes (all subfields)
- **Data Type:** Object

### 2.7.1. gln

- **Name:** gln
- **Definition:** The GS1 Global Location Number (GLN) as recorded in the TI record. See Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Must be 13 digits long: `^\d{13}$`
- **References:** \$ref: "#/definitions/glnType"

### 2.7.2. companyName

- **Name:** companyName
- **Definition:** Not explicitly defined but inferred as the name of the company.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/nameValueType"

### 2.7.3. companyAddress

- **Name:** companyAddress
- **Definition:** Not explicitly defined but inferred as the address of the company.
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/addressType"

#### 2.7.4. tiRequestConnectivityInformation

- **Name:** tiRequestConnectivityInformation
  - **Definition:** Not explicitly defined but inferred as information on how to connect for TI requests.
  - **Required:** Yes
  - **Data Type:** Object
  - **References:** \$ref: "#/definitions/connectivityInformationType"
- 

### 2.8. connectivityInformationType

- **Name:** connectivityInformationType
- **Definition:** Not explicitly defined but inferred as information for connecting to a company.
- **Required:** Yes
- **Data Type:** Object

#### 2.8.1. connectivityMethod

- **Name:** connectivityMethod
- **Definition:** Includes Connectivity options by email or URI or both.
- **Required:** Yes
- **Data Type:** Object

##### 2.8.1.1. emailConnectivity

- **Name:** emailConnectivity
- **Definition:** Not explicitly defined but inferred as an email address for connectivity.
- **Required:** Either emailConnectivity or uriConnectivity must be present.
- **Data Type:** String
- **Format (Pattern):** Email format
- **References:** \$ref: "#/definitions/emailType"

##### 2.8.1.2. uriConnectivity

- **Name:** uriConnectivity
- **Definition:** Not explicitly defined but inferred as a URI for connectivity.
- **Required:** Either emailConnectivity or uriConnectivity must be present.
- **Data Type:** String
- **Format (Pattern):** URI format
- **References:** \$ref: "#/definitions/uriType"



## 2.9. contactInformationType

- **Name:** contactInformationType
- **Definition:** Information to aid the Requester or Responder in contacting the other party in regard to the Request or Response.
- **Required:** Yes (all subfields)
- **Data Type:** Object

### 2.9.1. personOrDepartmentName

- **Name:** personOrDepartmentName
- **Definition:** Part of contactInformation. The person or Department that can be contacted regarding the Request or Response.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/nameValueType"

### 2.9.2. organizationName

- **Name:** organizationName
- **Definition:** Name of organization requesting TI or responding to a request.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/nameValueType"

### 2.9.3. contactMethod

- **Name:** contactMethod
- **Definition:** Phone number or email address that the Requester or Responder can be contacted with.
- **Required:** Yes
- **Data Type:** Object

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### 2.9.3.1. phone

- **Name:** phone
- **Definition:** The phone number of the Requester or Responder.
- **Required:** Either phone or email must be present.
- **Data Type:** String
- **References:** \$ref: "#/definitions/phoneType"

### 2.9.3.2. email

- **Name:** email
- **Definition:** Not explicitly defined but inferred as the email address for contact.
- **Required:** Either phone or email must be present.
- **Data Type:** String
- **Format (Pattern):** Email format
- **References:** \$ref: "#/definitions/emailType"

## 2.10. dateType

- **Name:** dateType
- **Definition:** Not explicitly defined but inferred as a date format for specific use.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Must be 6 digits long: `^\d{6}$`

## 2.11. directPurchaseStatementType

- **Name:** directPurchaseStatementType
- **Definition:** The direct purchase statement as recorded in the TI.
- **Required:** No
- **Data Type:** String

## 2.12. dropShipIndicatorType

- **Name:** dropShipIndicatorType
- **Definition:** True if this TI was the result of a drop shipment, False if not.
- **Required:** No
- **Data Type:** Boolean
- **Enumerations:**
  - true
  - false

- **Default:** false

## 2.13. drugNameType

- **Name:** drugNameType
- **Definition:** Not explicitly defined but inferred as the name of the drug.
- **Required:** No
- **ata Type:** String

## 2.14. dscsaCredentialPresentationType

- **Name:** dscsaCredentialPresentationType
- **Definition:** Requester or Responder signed presentation of an ATP, ATP-Equivalent or DSCSA Authority credential. See latest OCI Model Version.
- **Required:** No (but one of the subfields must be present)
- **Data Type:** Object

### 2.14.1. dscsaATPCredentialPresentation

- **Name:** dscsaATPCredentialPresentation
- **Definition:** Not explicitly defined but inferred as a credential presentation for ATP.
- **Required:** One of dscsaATPCredentialPresentation, dscsaATP-EquivalentCredentialPresentation, or dscsaAuthorityPresentation must be present.
- **Data Type:** String
- **Format (Pattern):** JWT format

### 2.14.2. dscsaATP-EquivalentCredentialPresentation

- **Name:** dscsaATP-EquivalentCredentialPresentation
- **Definition:** Not explicitly defined but inferred as a credential presentation for ATP-Equivalent.
- **Required:** One of dscsaATPCredentialPresentation, dscsaATP-EquivalentCredentialPresentation, or dscsaAuthorityPresentation must be present.
- **Data Type:** String
- **Format (Pattern):** JWT format

### 2.14.3. dscsaAuthorityPresentation

- **Name:** dscsaAuthorityPresentation
- **Definition:** Not explicitly defined but inferred as a credential presentation for DSCSA Authority.
- **Required:** One of dscsaATPCredentialPresentation, dscsaATP-EquivalentCredentialPresentation, or dscsaAuthorityPresentation must be present.
- **Data Type:** String
- **Format (Pattern):** JWT format

### 2.15. emailType

- **Name:** emailType
- **Definition:** Not explicitly defined but inferred as an email address format.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Email format

### 2.16. glnType

- **Name:** glnType
- **Definition:** The GS1 Global Location Number (GLN) as recorded in the TI record. See Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Must be 13 digits long: `^\d{13}$`

### 2.17. gtinType

- **Name:** gtinType
- **Definition:** The GS1 Global Trade Item Number (GTIN) identifying the product. See Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability. Conditional based on Product ID choice (GTIN or NDC).
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Must be 14 digits long: `^\d{14}$`

## 2.18. investigationIDType

- **Name:** investigationIDType
- **Definition:** Identifier created by Requester to group and archive requests and their associated responses. Recommend for Requester to assign unique identifier and consider use of UUID or unique key combinations of RequestID + CaseID + Requester.
- **Required:** No
- **Data Type:** String

## 2.19. lotNumberType

- **Name:** lotNumberType
- **Definition:** The Lot number assigned by the Manufacturer or Repackager found in the original Transaction Information.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Length between 1 and 20 characters

## 2.20. nameValueType

- **Name:** nameValueType
- **Definition:** Not explicitly defined but inferred as any name or value type string.
- **Required:** No
- **Data Type:** String

## 2.21. ndcType

- **Name:** ndcType
- **Definition:** The FDA National Drug Code. Conditional based on Request Product ID choice (GTIN or NDC).
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** One of the following formats:
  - 4-4-2: `^[0-9]{4}-[0-9]{4}-[0-9]{2}$`
  - 5-3-2: `^[0-9]{5}-[0-9]{3}-[0-9]{2}$`
  - 5-4-1: `^[0-9]{5}-[0-9]{4}-[0-9]{1}$`
  - 6-4-2 (future): `^[0-9]{6}-[0-9]{4}-[0-9]{2}$`

## 2.22. ownershipInformationResponses

- **Name:** ownershipInformationResponses
- **Definition:** Not explicitly defined but inferred as responses containing ownership information.
- **Required:** No
- **Data Type:** Array of Objects
- **Minimum Items:** 1

### 2.22.1. gtin

- **Name:** gtin
- **Definition:** As per gtinType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/gtinType"

### 2.22.2. ndc

- **Name:** ndc
- **Definition:** As per ndcType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/ndcType"

### 2.22.3. serialNumber

- **Name:** serialNumber
- **Definition:** As per serialNumberType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/serialNumberType"

### 2.22.4. knownOwnerInformation

- **Name:** knownOwnerInformation
- **Definition:** Information identifying the company recorded in the TI and their connectivity information (used by the Requester to submit a TI Request to them).
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/companyInformationType"

### 2.22.5. ownerInformationNotes

- **Name:** ownerInformationNotes
- **Definition:** Used by the Responder to provide additional context to the ownership information provided.
- **Required:** No
- **Data Type:** String

### 2.23. phoneType

- **Name:** phoneType
- **Definition:** The phone number of the Requester or Responder.
- **Required:** No
- **Data Type:** String

### 2.24. productContainerSizeType

- **Name:** productContainerSizeType
- **Definition:** The containerSize of the drug as recorded in the TI.
- **Required:** No
- **Data Type:** Number
- **Minimum:** 1

### 2.25. productDataType

- **Name:** productDataType
- **Definition:** Information about the drug product as recorded in the TI.
- **Required:** No
- **Data Type:** Object

#### 2.25.1. gtin

- **Name:** gtin
- **Definition:** As per gtinType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/gtinType"

### 2.25.2. ndc

- **Name:** ndc
- **Definition:** As per ndcType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/ndcType"

### 2.25.3. drugName

- **Name:** drugName
- **Definition:** The name of the drug as recorded in the TI record.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/productNameType"

### 2.25.4. strength

- **Name:** strength
- **Definition:** Not explicitly defined but inferred as the strength of the drug.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/productStrengthType"

### 2.25.5. dosageForm

- **Name:** dosageForm
- **Definition:** The dosage form of the drug as recorded in the TI.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/productDosageFormType"

### 2.25.6. containerSize

- **Name:** containerSize
- **Definition:** The containerSize of the drug as recorded in the TI.
- **Required:** Yes
- **Data Type:** Number
- **References:** \$ref: "#/definitions/productContainerSizeType"



### 2.25.7. numberOfContainers

- **Name:** numberOfContainers
- **Definition:** As the response is at an individual SNI level, this attribute is always "1".
- **Required:** Yes
- **Data Type:** Number
- **References:** \$ref: "#/definitions/productNumberOfContainersType"

### 2.26. productDosageFormType

- **Name:** productDosageFormType
- **Definition:** Not explicitly defined but inferred as the form in which the drug is administered.
- **Required:** No
- **Data Type:** String

### 2.27. productNameType

- **Name:** productNameType
- **Definition:** Not explicitly defined but inferred as the name of the product.
- **Required:** No
- **Data Type:** String
- **References:** \$ref: "#/definitions/nameValueType"

### 2.28. productNumberOfContainersType

- **Name:** productNumberOfContainersType
- **Definition:** Not explicitly defined but inferred as the number of containers for the product.
- **Required:** No
- **Data Type:** Number
- **Minimum:** 1

### 2.29. productProductionDataType

- **Name:** productProductionDataType
- **Definition:** Not explicitly defined but inferred as data related to the production of the product.
- **Required:** No
- **Data Type:** Object

#### 2.29.1. lotNumber

- **Name:** lotNumber

- **Definition:** As per lotNumberType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/lotNumberType"

### 2.29.2. serialNumber

- **Name:** serialNumber
- **Definition:** As per serialNumberType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/serialNumberType"

### 2.29.3. expirationDate

- **Name:** expirationDate
- **Definition:** Not explicitly defined but inferred as the expiration date of the product.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** Must be 6 digits long: `^\d{6}$`
- **References:** \$ref: "#/definitions/dateType"

## 2.30. productStrengthType

- **Name:** productStrengthType
- **Definition:** Not explicitly defined but inferred as the strength or concentration of the drug.
- **Required:** No
- **Data Type:** String

## 2.31. requestResponseMessageType

- **Name:** requestResponseMessageType
- **Definition:** Not explicitly defined but inferred as messages related to requests and responses.
- **Required:** No
- **Data Type:** Object

### 2.31.1. requestResponseMessageCode

- **Name:** requestResponseMessageCode

- **Definition:** Not explicitly defined but inferred as a code for the message type.
- **Required:** Yes
- **Data Type:** String
- **Enumerations:**
  - "RM-001" (Credential verification failed)
  - "RM-002" (Request parameter error)
  - "RM-003" (Compliance audit Request Received)
  - "RM-004" (Request model verification failed)
- **References:** \$ref: "#/definitions/requestResponseMessageCodeType"

### 2.31.2. requestResponseItemMessageDescription

- **Name:** requestResponseItemMessageDescription
- **Definition:** Not explicitly defined but inferred as descriptive text for the message code.
- **Required:** Yes
- **Data Type:** String
- **Maximum Length:** 250 characters

### 2.32. requestResponseMessageCodeType

- **Name:** requestResponseMessageCodeType
- **Definition:** Enumeration of message codes for request responses.
- **Required:** No
- **Data Type:** String
- **Enumerations:**
  - "RM-001" (Credential verification failed)
  - "RM-002" (Request parameter error)
  - "RM-003" (Compliance audit Request Received)
  - "RM-004" (Request model verification failed)

### 2.33. requestResponseItemMessageCodeType

- **Name:** requestResponseItemMessageCodeType
- **Definition:** Enumeration of message codes specific to line items in requests.
- **Required:** No
- **Data Type:** String
- **Enumerations:**
  - "RL-001" (Request Closed)
  - "RL-002" (No TI found for the Request)
  - "RL-003" (Response Delayed)
  - "RL-004" (Request addressed via your supplied Contact Information)

- "RL-005" (Request GTIN, NDC, Lot Number or Serial Number not formatted correctly)
- "RL-006" (Response includes an Intracompany Transfer)

## 2.34. responseMessageType

- **Name:** responseMessageType
- **Definition:** Not explicitly defined but inferred as messages related to responses.
- **Required:** No
- **Data Type:** Object

### 2.34.1. responseMessageCode

- **Name:** responseMessageCode
- **Definition:** As per requestResponseMessageCodeType.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/requestResponseMessageCodeType"

### 2.34.2. responseMessageDescription

- **Name:** responseMessageDescription
- **Definition:** Not explicitly defined but inferred as descriptive text for the response message code.
- **Required:** Yes
- **Data Type:** String
- **Maximum Length:** 250 characters

## 2.35. serialNumberType

- **Name:** serialNumberType
- **Definition:** Not explicitly defined but inferred as the unique serial number of an item.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** Length between 1 and 20 characters

## 2.36. timestampType

- **Name:** timestampType
- **Definition:** A timestamp to millisecond precision, with an explicit timezone indicator (+/- hh:mm) relative to UTC.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** `^[0-9]{4}-(0[1-9]|1[0-2])-(0[1-9]|1[0-9]|2[0-9]|3[0-1])T(2[0-3]|01)[0-9]:[0-5][0-9]:[0-5][0-9]\.[0-9]{3}(Z|(\+|‑)((0[0-9]|1[0-3]):([0-5][0-9])|14:00)))`

## 2.37. tracingModelSetVersionType

- **Name:** tracingModelSetVersionType
- **Definition:** Tracing Request and Response Model Set Version. The tracing request and tracing response model are versioned together to ensure alignment.
- **Required:** No
- **Data Type:** String
- **Default:** "2.0.0"
- **Format (Pattern):** Matches versions like 'x.x.x': `^[0-9]{1}\.[0-9]{1}\.[0-9]{1}$`

## 2.38. transactionInformationResponses

- **Name:** transactionInformationResponses
- **Definition:** Not explicitly defined but inferred as responses containing transaction information.
- **Required:** No
- **Data Type:** Array of Objects
- **Minimum Items:** 1

### 2.38.1. transactionInformationData

- **Name:** transactionInformationData
- **Definition:** Not explicitly defined but inferred as detailed data of a transaction.
- **Required:** Yes
- **Data Type:** Object

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### 2.38.1.1. *productData*

- **Name:** productData
- **Definition:** Information about the drug product as recorded in the TI.
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/productDataType"

### 2.38.1.2. *productProductionData*

- **Name:** productProductionData
- **Definition:** Not explicitly defined but inferred as production details of the product.
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/productProductionDataType"

### 2.38.1.3. *ownershipFromInformation*

- **Name:** ownershipFromInformation
- **Definition:** Information identifying the Transfer From party recorded in the TI and their connectivity information (used by the Requester to submit a TI Request to them).
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/companyInformationType"

### 2.38.1.4. *ownershipToInformation*

- **Name:** ownershipToInformation
- **Definition:** Information identifying the Transfer To party recorded in the TI and their connectivity information (used by the Requester to submit a TI Request to them).
- **Required:** Yes
- **Data Type:** Object
- **References:** \$ref: "#/definitions/companyInformationType"

### 2.38.1.5. *dropShipInfo*

- **Name:** dropShipInfo
- **Definition:** Not explicitly defined but inferred as information related to drop shipments.
- **Required:** No
- **Data Type:** Object

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### 2.38.1.5.1. dropShipIndicator

- **Name:** dropShipIndicator
- **Definition:** True if this TI was the result of a drop shipment, False if not.
- **Required:** No
- **Data Type:** Boolean
- **Default:** false
- **Enumerations:**
  - true
  - false
- **References:** \$ref: "#/definitions/dropShipIndicatorType"

### 2.38.1.5.2. dropShipToInformation

- **Name:** dropShipToInformation
- **Definition:** Information identifying the Ship To party recorded in the TI if this was a drop ship transaction and their connectivity information (used by the Requester to submit a TI Request to them).
- **Required:** Conditional (required if dropShipIndicator is true)
- **Data Type:** Object
- **References:** \$ref: "#/definitions/companyInformationType"

### 2.38.1.6. poAssociatedWithTI

- **Name:** poAssociatedWithTI
- **Definition:** The purchase order number as recorded in the TI.
- **Required:** No
- **Data Type:** String

### 2.38.1.7. transactionStatement

- **Name:** transactionStatement
- **Definition:** Not explicitly defined but inferred as a statement regarding the transaction.
- **Required:** Yes
- **Data Type:** String
- **References:** \$ref: "#/definitions/transactionStatementType"

### 2.38.1.8. directPurchaseStatement

- **Name:** directPurchaseStatement
- **Definition:** The direct purchase statement as recorded in the TI.
- **Required:** No
- **Data Type:** String

- **References:** \$ref: "#/definitions/directPurchaseStatementType"

#### *2.38.1.9. dateOfShipment*

- **Name:** dateOfShipment
- **Definition:** Will only have a Shipment Date if Shipment date was greater than 24 hours from the transaction.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** As per timestampType
- **References:** \$ref: "#/definitions/timestampType"

#### *2.38.1.10. dateOfTransaction*

- **Name:** dateOfTransaction
- **Definition:** Not explicitly defined but inferred as the date when the transaction occurred.
- **Required:** Yes
- **Data Type:** String
- **Format (Pattern):** As per timestampType
- **References:** \$ref: "#/definitions/timestampType"

#### *2.38.1.11. transactionInformationNotes*

- **Name:** transactionInformationNotes
- **Definition:** Used by the Responder to provide additional context to the Transaction Information provided.
- **Required:** No
- **Data Type:** String

### **2.39. transactionStatementType**

- **Name:** transactionStatementType
- **Definition:** Not explicitly defined but inferred as a statement about the transaction.
- **Required:** No
- **Data Type:** String



## 2.40. uriType

- **Name:** uriType
- **Definition:** Not explicitly defined but inferred as any URI reference.
- **Required:** No
- **Data Type:** String
- **Format (Pattern):** URI reference format

## 2.41. uuidType

- **Name:** uuidType
  - **Definition:** Universally Unique Identifier (UUID).
  - **Required:** No
  - **Data Type:** String
  - **Format (Pattern):** UUID format: `^[a-fA-F\d]{8}-[a-fA-F\d]{4}-4[a-fA-F\d]{3}-[89abAB][a-fA-F\d]{3}-[a-fA-F\d]{12}$`
-

# Conditional Logic and Validation

## 1. tiResponse

- **Required Fields:**
  - tracingModelSetVersion
  - tiResponseAuditReferences
  - tiRespondingPartyInformation

## 2. tiResponseAuditReferences

- **Required Fields:**
  - tiResponseID
  - tiRequestID
  - tiResponseTimestamp

## 3. tiRespondingPartyInformation

- **Required Fields:**
  - contactInformation
  - callbackAddress

## 4. tiRequestResponsesInfo

- **OneOf Logic:** Either tiRequestResponses or responseMessage must be present.

### 4.1. tiRequestResponses

- **Structure:** An array where each item represents a response to an individual request.
- **Conditional Logic within Each Item:**
  - Each individualRequest must include:
    - requestLineNumber
    - productID (with either gtin or ndc)
    - serialNumberOrLotNumber (with either serialNumber or lotNumber)
    - responseTypeRequested
  - responsesToRequest and requestLineNumberMessage are mutually exclusive; one must be present:
    - If responseTypeRequested is "Transaction Information", transactionInformationResponses must be present in responsesToRequest.

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- If responseTypeRequested is "All Known Owners" or "Last Known Owner", ownershipInformationResponses must be present in responsesToRequest.

### 4.2. responseMessage

- **Required Fields:**
  - responseMessageCode
  - responseMessageDescription

## 5. Definitions

### 5.1. dropShipInfo

- **Conditional Logic:**
  - If dropShipIndicator is false, dropShipToInformation must not be provided.
  - If dropShipIndicator is true, dropShipToInformation must be provided.

### 5.2. connectivityMethod

- **AnyOf Logic:** Must include either emailConnectivity or uriConnectivity.

### 5.3. contactMethod

- **AnyOf Logic:** Must include either phone or email.

### 5.4. dscsaCredentialPresentationType

- **OneOf Logic:** One of dscsaATPCredentialPresentation, dscsaATP-EquivalentCredentialPresentation, or dscsaAuthorityPresentation must be present.

### 5.5. productID

- **OneOf Logic:** Either gtin or ndc must be provided, but not both.

### 5.6. serialNumberOrLotNumber

- **OneOf Logic:** Either serialNumber or lotNumber must be provided, but not both.

### 5.7. ndcType

- **OneOf Logic:** The ndc must match one of the specified formats (4-4-2, 5-3-2, 5-4-1, or 6-4-2).

## 6. Validation Patterns

- Various fields have specific patterns for validation:

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- uuidType for UUID validation.
- timestampType for date-time validation with UTC offset.
- glnType, gtinType, lotNumberType, serialNumberType, etc., for length and content validations.

## 7. Enumeration

- Enumerated values are used for:
  - responseTypeRequested in individualRequest
  - requestResponseMessageCodeType
  - requestResponseItemMessageCodeType
  - dropShipIndicatorType

## Summary

This model employs several logical constructs to ensure data integrity and appropriate responses:

- **Required Fields:** Ensures essential information is always provided.
- **Conditional Requirements:** Adjusts what data is necessary based on other field values (e.g., drop shipping).
- **Mutual Exclusivity:** Ensures only one of two options is chosen (e.g., responsesToRequest vs. requestLineNumberMessage).
- **Format and Pattern Validation:** Checks for correct numbers, dates, and identifiers formats.
- **Enumerations:** Limits the possible values for specific fields to predefined options.

This structure helps maintain consistency and accuracy in the responses to DSCSA transaction and ownership information requests.