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1 Introduction

This document will be used to coordinate all design decisions be made as part of GS1 XML 3.7 EDI release.

The document contains the list of:

- Work requests originating the changes
- Changes to GS1 XML 3.7 BMS documents

This document is not a formal deliverable, so will not go through any community review or eBallot. Its main purpose is to support the coordinated internal review process in the EDI SMG. The resulting updated BMS documents are the deliverables that will undergo community review and eBallot.

1 Work request & Impact Analysis

WR#	Requirement	Impacted BMS
23-000170	Add the "dangerousgoodsinformation" class to the "warehouse outbound instruction" & "warehouse outbound notification" messages	Warehouse Outbound Instruction and Notification
23-000271	Add "countryKitsReleasedTo" and "doNotShipAfter" to line item level	Clinical Trials Inventory Report
23-000286	Extend the XML schema of the Inventory Release File and Inventory Report messages to support the required data set.	Clinical Trials Inventory Report and Clinical Trials Inventory Release File
23-000292	Update the Shipment Request XML schema	Shipment Request
23-000316	To be able to do that I need the same subset of attributes in both the standards (EANCOM and GS1 XML).	Order
23-000319	In the Request for Inventory Report schema, I request that all fields in the InventoryReportRequestInformation section be optional to allow for more flexibility to request an Inventory Report for the entire protocol if desired.	Clinical Trials Inventory Report



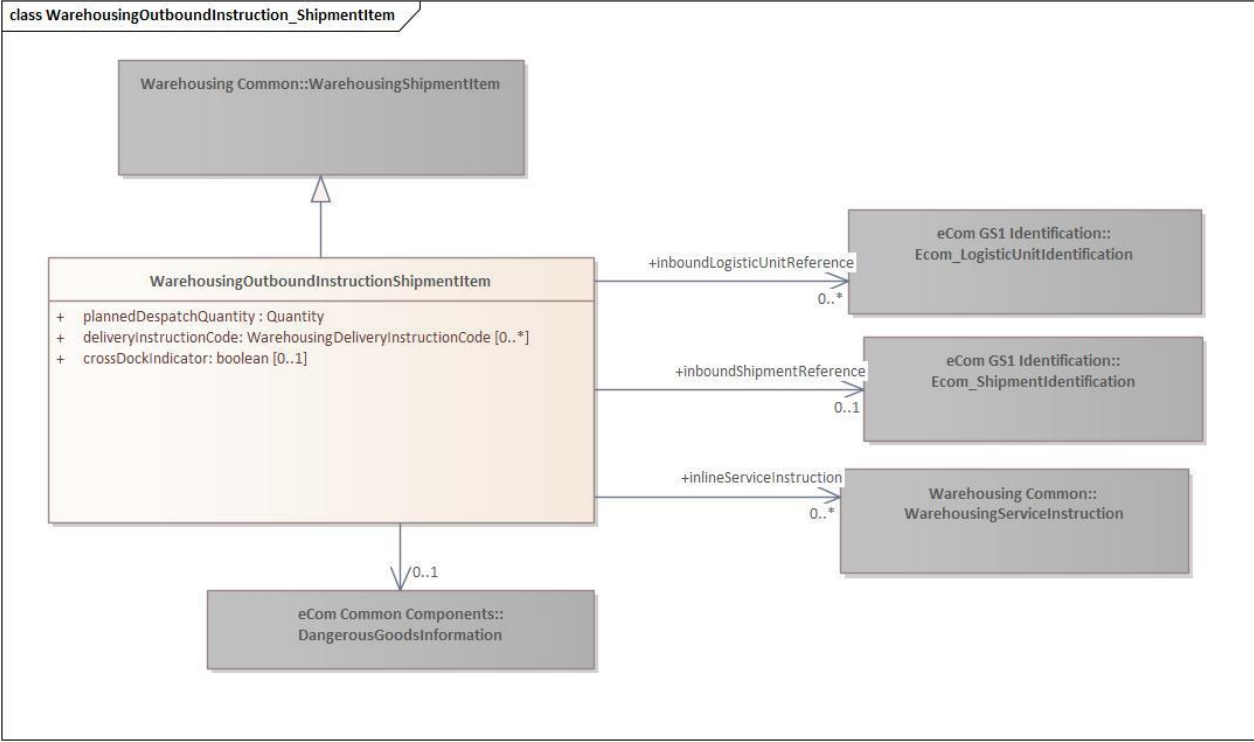
WR#	Requirement	Impacted BMS
23-000350	Request to expand the Inventory Report message to include a field for the Kit's Sequence Number	Clinical Trials Inventory Report
24-000020	The initialOrderNumber field should be changed from Mandatory to Optional because when the attributeStatusCode = REJECTED, the initial order number does not exist	Clinical Trials Shipment Confirmation
24-000030	The Inventory Release File, a field for "doNotShipAfter" was added in Release 3.6 for a new date field. The same field will also be added to the Inventory Report in Release 3.7 via WR-23-000271. The proposal is to add an accompanying field for "doNotShipDays" because the number of days is sometimes preferred over the actual date.	Clinical Trials Inventory Release File
24-000035	The requestedReceivingDateTime field should be changed from Mandatory to Optional because the same field in the Shipment Request is also Optional	Clinical Trials Shipment Confirmation
24-000077	Proposal is to add the segment carrierTrackAndTraceInformation under logisticUnit. This automatically brings it into the warehousing messages (instruction and notification) for inbound goods and outbound goods.	Warehousing messages (inbound instruction and notification and outbound instruction and notification)
24-000186	Proposal to make the sender and receiver fields optional	All Clinical trials messages
24-000208	Request to expand the Inventory Report message to include a field for the Material ID	Clinical Trials Inventory Report
24-000237	Proposal to add Quantity fields at the following levels: 1. ClinicalTrialDespatchAdviceLineItem level to be a quantity of Kits for that specific line item 2. ClinicalTrialDespatchAdvice (header) level to be a quantity of Kits for the entire shipment	Clinical Trials Despatch Advice
24-000251	Add a material master interface to the GS1 Standards for Clinical Trials.	Item Data Notification

WR#	Requirement	Impacted BMS
WR 24-390	Adding TransactionalReferenceTypeCode through the TransactionalGenericReference to the OR message same was as in DA	Order Response
WR 25-152		

2 Changes applied to GS1 XML 3.7

2.1 Warehouse Outbound Instruction and Noitification

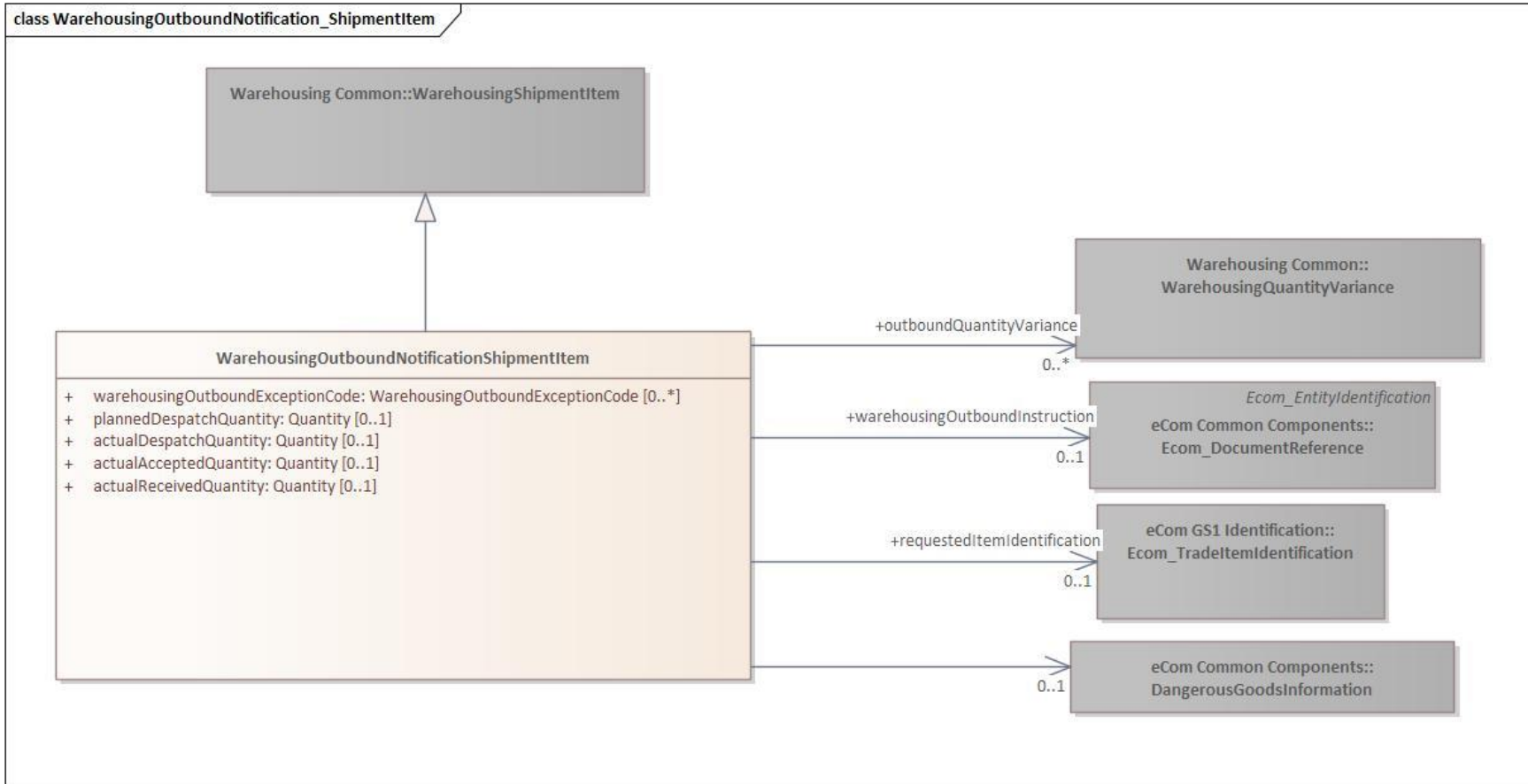
2.1.1 Overview

	Associated CR Number
<p>■ Added new association to ecom:common dangerous goods information to Line item:</p>  <pre> classDiagram class WarehousingOutboundInstructionShipmentItem { +plannedDespatchQuantity : Quantity +deliveryInstructionCode : WarehousingDeliveryInstructionCode [0..*] +crossDockIndicator : boolean [0..1] } class WarehousingCommonShipmentItem class eComGS1IdentificationLogisticUnitIdentification { +inboundLogisticUnitReference } class eComGS1IdentificationShipmentIdentification { +inboundShipmentReference } class WarehousingCommonWarehousingServiceInstruction { +inlineServiceInstruction } class eComCommonComponentsDangerousGoodsInformation { +DangerousGoodsInformation } WarehousingCommonShipmentItem < -- WarehousingOutboundInstructionShipmentItem WarehousingOutboundInstructionShipmentItem --> eComGS1IdentificationLogisticUnitIdentification : +inboundLogisticUnitReference 0..* WarehousingOutboundInstructionShipmentItem --> eComGS1IdentificationShipmentIdentification : +inboundShipmentReference 0..1 WarehousingOutboundInstructionShipmentItem --> WarehousingCommonWarehousingServiceInstruction : +inlineServiceInstruction 0..* WarehousingOutboundInstructionShipmentItem --> eComCommonComponentsDangerousGoodsInformation : 0..1 </pre> <p>The diagram illustrates the new association between the WarehousingOutboundInstructionShipmentItem class and the eCom Common Components::DangerousGoodsInformation class. The WarehousingOutboundInstructionShipmentItem class is a specialization of Warehousing Common::WarehousingShipmentItem. It contains attributes: plannedDespatchQuantity (Quantity), deliveryInstructionCode (WarehousingDeliveryInstructionCode [0..*]), and crossDockIndicator (boolean [0..1]). The new association is represented by a directed line from WarehousingOutboundInstructionShipmentItem to eCom Common Components::DangerousGoodsInformation with a multiplicity of 0..1 at the target end. Other existing associations are shown: WarehousingOutboundInstructionShipmentItem to eCom GS1 Identification::Ecom_LogisticUnitIdentification (multiplicity 0..*), WarehousingOutboundInstructionShipmentItem to eCom GS1 Identification::Ecom_ShipmentIdentification (multiplicity 0..1), and WarehousingOutboundInstructionShipmentItem to Warehousing Common::WarehousingServiceInstruction (multiplicity 0..*).</p>	<p>23-000170</p>

- Added **new association** to ecom:common dangerous goods information to Line item:

Associated
CR
Number

**23-
000170**

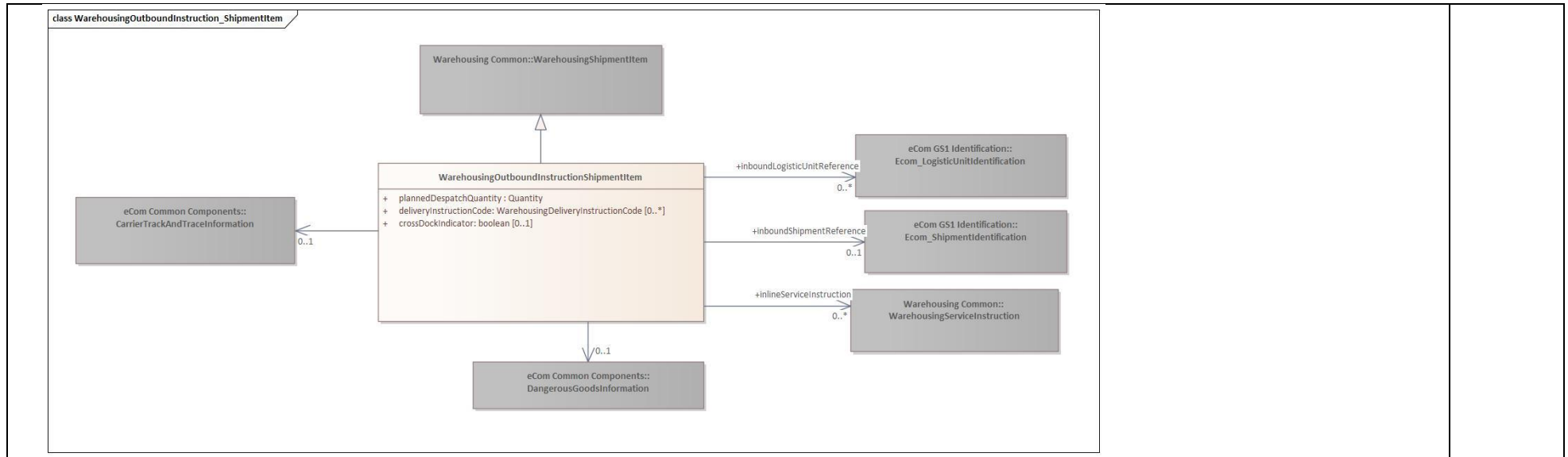




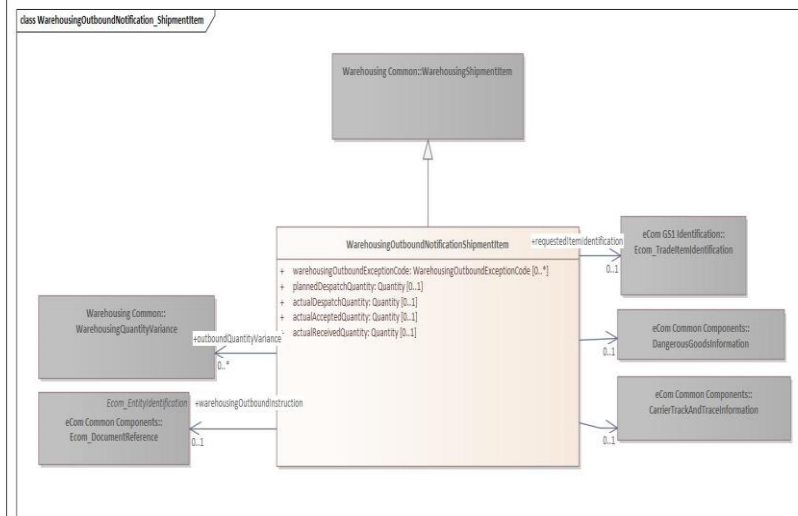
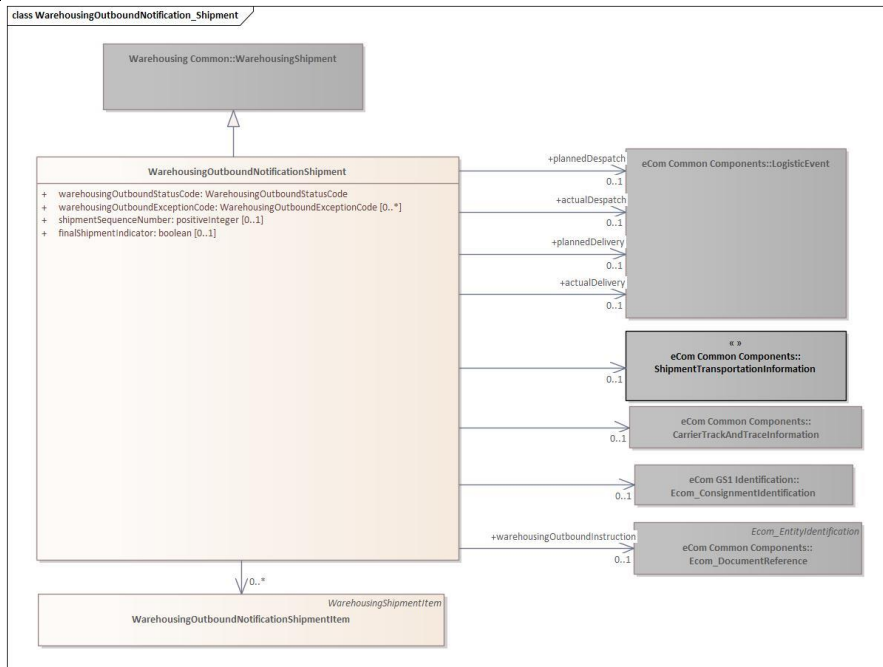
- Added **new association** to ecom:carrierTrackAndTraceInformation to shipment and shipment item level as optional fields.

**24-
000077**





Associated
CR
Number



2.2 Warehousing Inbound Instruction and Notification

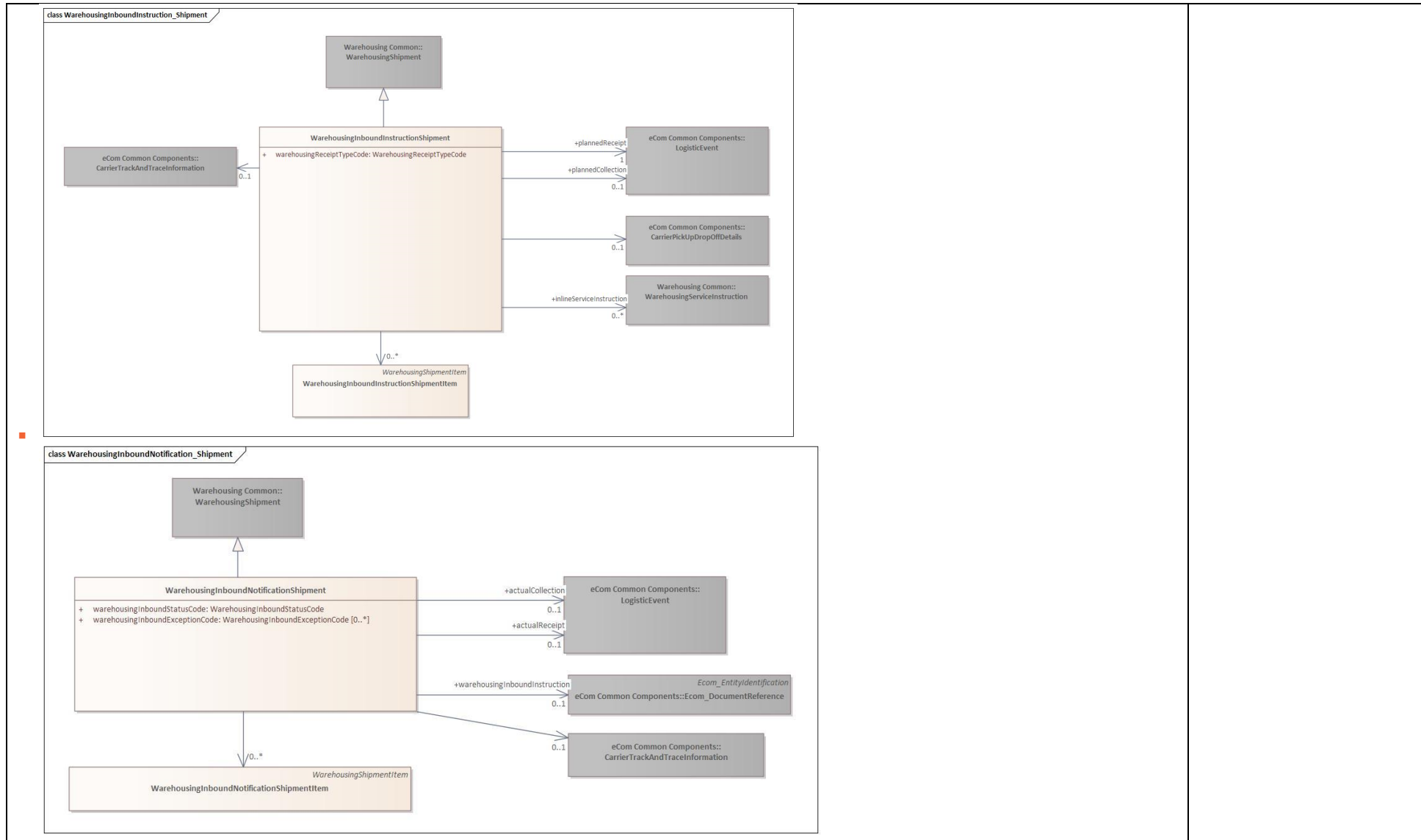
2.2.1 Overview

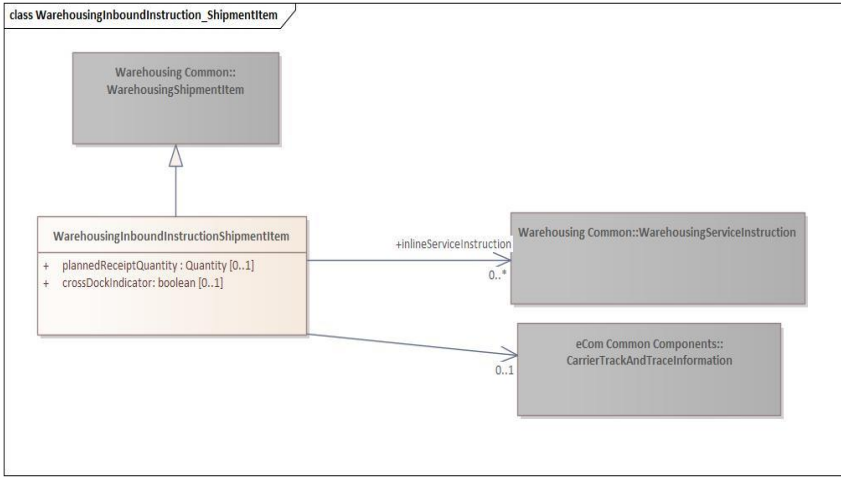
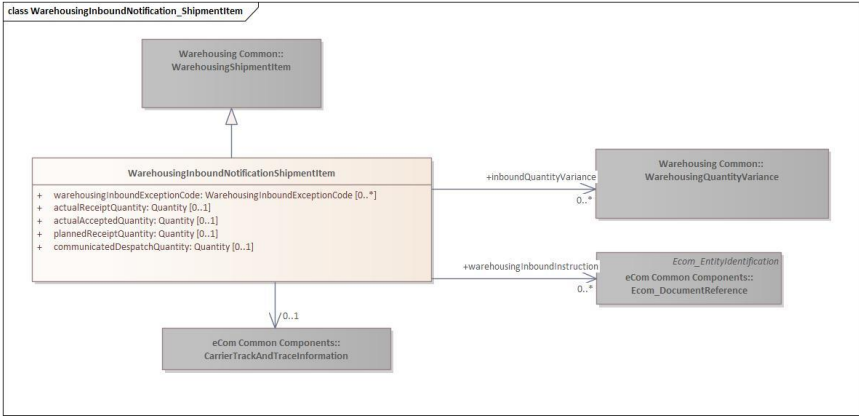


Change	Associated CR Number
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- | | |
|--|------------------|
| ■ Added new association of carrierTrackAndTraceInformation to shipment level as optional fields in both Warehousing Instruction and Notification | 24-000077 |
|--|------------------|



Change	Associated CR Number
<p>■ Added new association of carrierTrackAndTraceInformation to shipment item level in both Warehousing Instruction and Notification.</p> <div data-bbox="185 320 1023 798"> <p>class WarehousingInboundInstruction_ShipmentItem</p>  <pre> classDiagram class WarehousingCommon_WarehousingShipmentItem class WarehousingInboundInstructionShipmentItem { +plannedReceiptQuantity: Quantity [0..1] +crossDockIndicator: boolean [0..1] } class WarehousingCommon_WarehousingServiceInstruction { } class eComCommonComponents_CarrierTrackAndTraceInformation { } WarehousingCommon_WarehousingShipmentItem < -- WarehousingInboundInstructionShipmentItem WarehousingInboundInstructionShipmentItem --> "0..*" WarehousingCommon_WarehousingServiceInstruction : +inlineServiceInstruction WarehousingInboundInstructionShipmentItem --> "0..1" eComCommonComponents_CarrierTrackAndTraceInformation </pre> </div> <p>■</p> <div data-bbox="185 810 1041 1227"> <p>class WarehousingInboundNotification_ShipmentItem</p>  <pre> classDiagram class WarehousingCommon_WarehousingShipmentItem class WarehousingInboundNotificationShipmentItem { +warehousingInboundExceptionCode: WarehousingInboundExceptionCode [0..*] +actualReceiptQuantity: Quantity [0..1] +actualAcceptedQuantity: Quantity [0..1] +plannedReceiptQuantity: Quantity [0..1] +communicatedDespatchQuantity: Quantity [0..1] } class WarehousingCommon_WarehousingQuantityVariance { } class eComEntityIdentification_eComCommonComponents_Ecom_DocumentReference { } class eComCommonComponents_CarrierTrackAndTraceInformation { } WarehousingCommon_WarehousingShipmentItem < -- WarehousingInboundNotificationShipmentItem WarehousingInboundNotificationShipmentItem --> "0..*" WarehousingCommon_WarehousingQuantityVariance : +inboundQuantityVariance WarehousingInboundNotificationShipmentItem --> "0..*" eComEntityIdentification_eComCommonComponents_Ecom_DocumentReference : +warehousingInboundInstruction WarehousingInboundNotificationShipmentItem --> "0..1" eComCommonComponents_CarrierTrackAndTraceInformation </pre> </div>	<p>24-000077</p>

2.3 Order

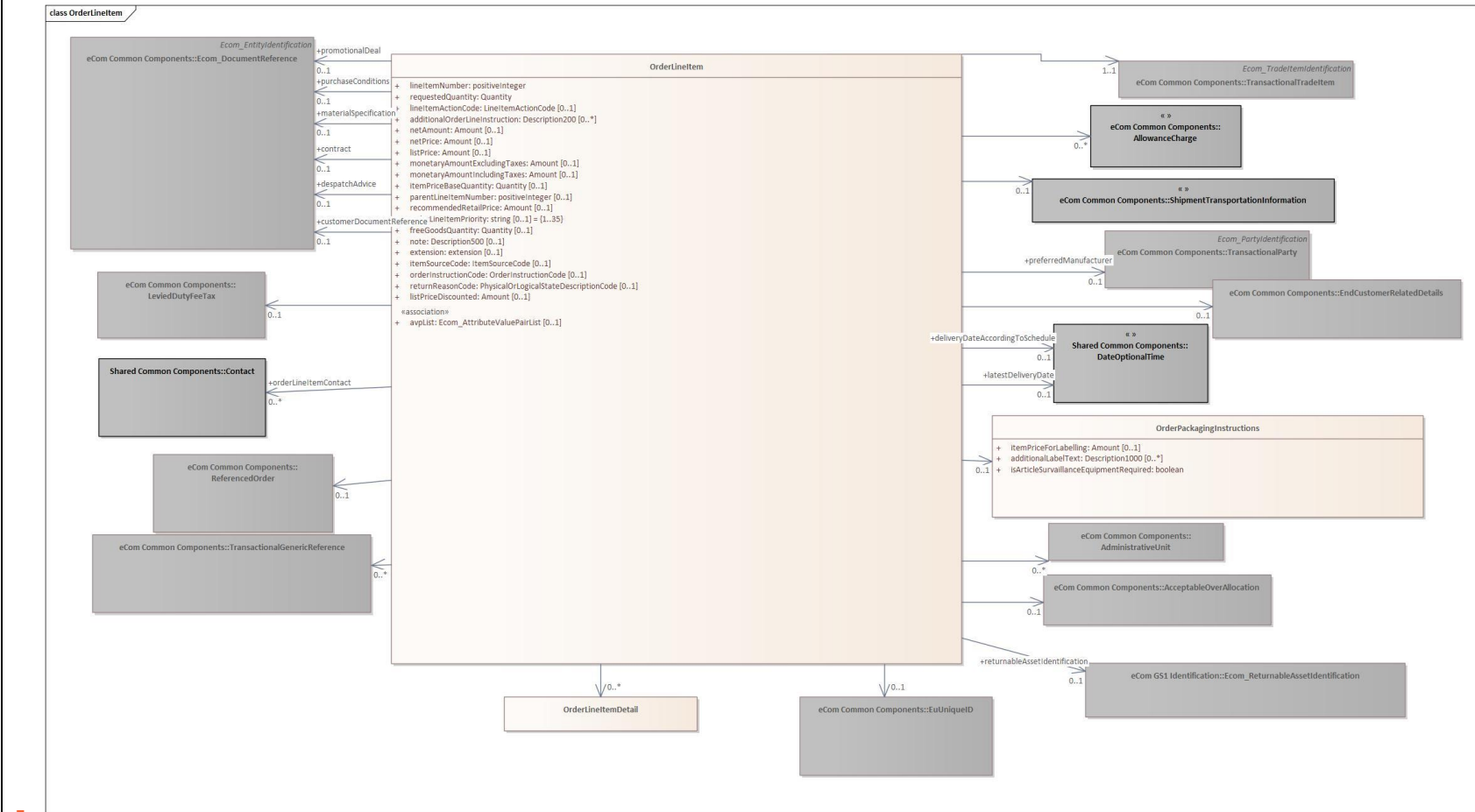
2.3.1 Overview

Change

- Re-used existing class **listPriceDiscounted** to line item
- The attribute is optional and an 'amount' data type

Associated CR Number

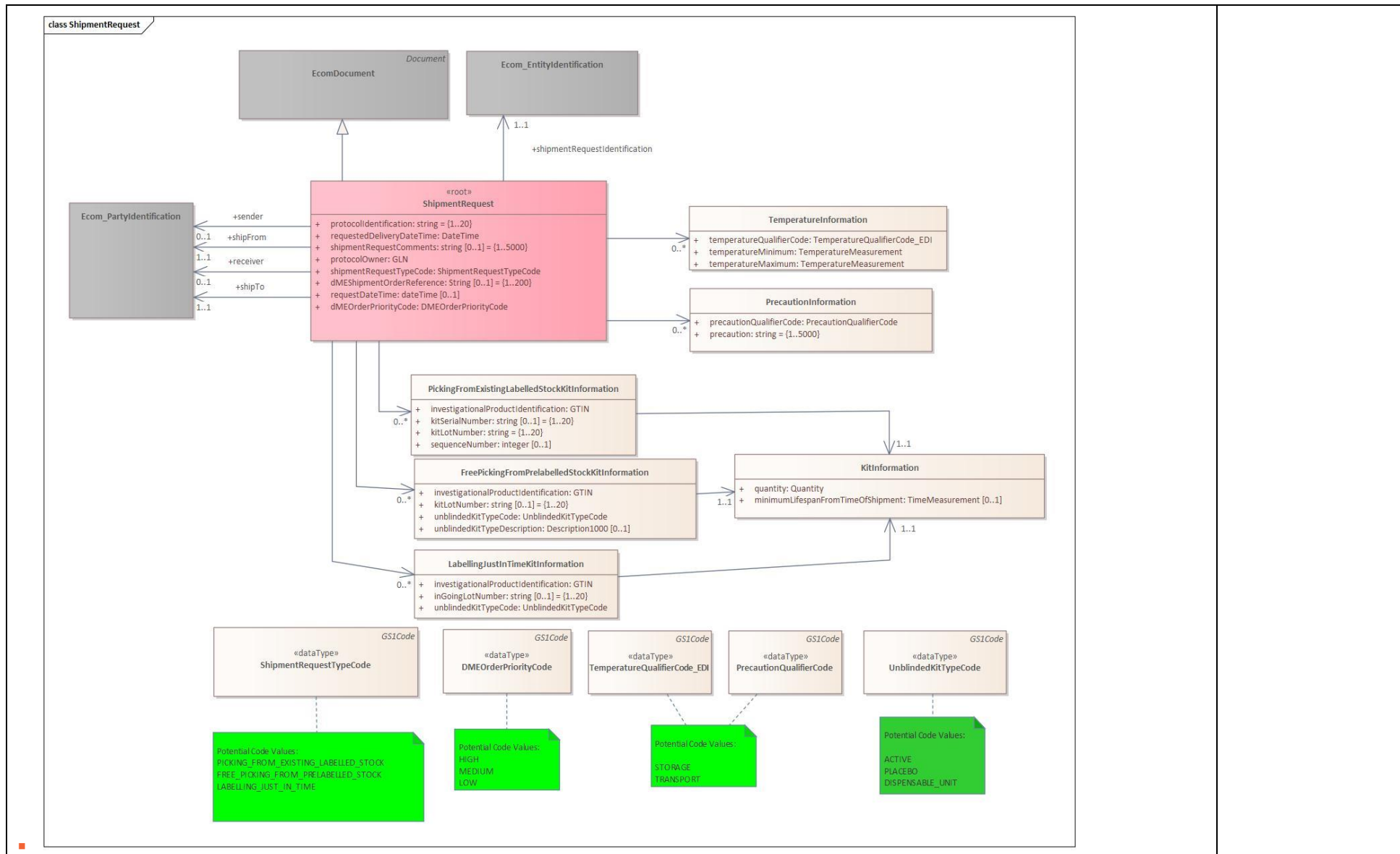
23-000316



2.4 Shipment Request – Clinical Trials

2.4.1 Overview

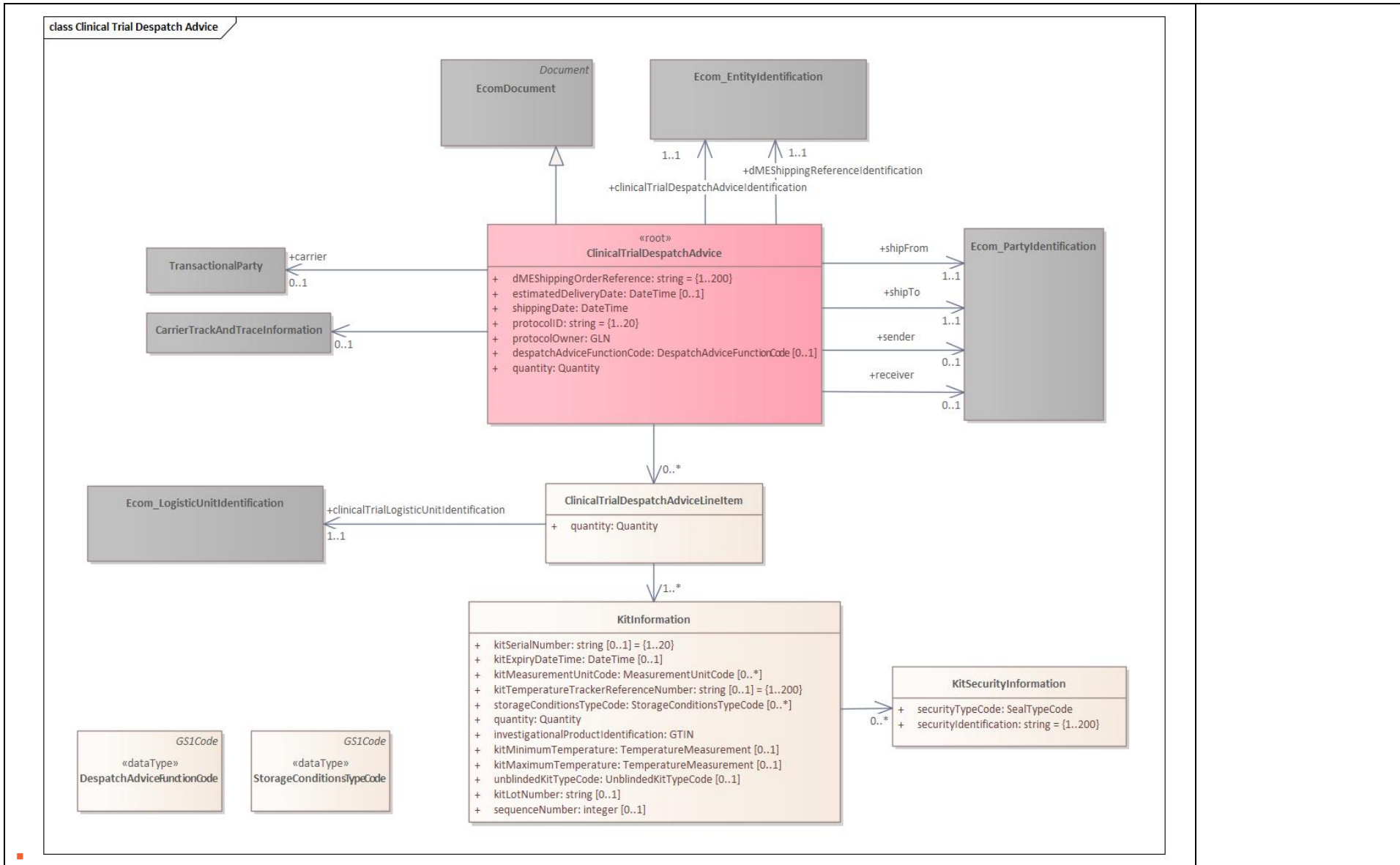
Change	Associated CR Number
■ Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186
■ Added an existing attribute unblindedKitTypeCode to the class freepickingfromprelabelledstock. Added an existing attribute unblindedKitTypeDescription to the class freepickingfromprelabelledstock as an optional description1000 field.	23-000292
■ Changed the cardinality of kitLotNumber from 1..1 to 0..1	23-000292



2.5 Clinical Trial Despatch Advice

2.5.1 Overview

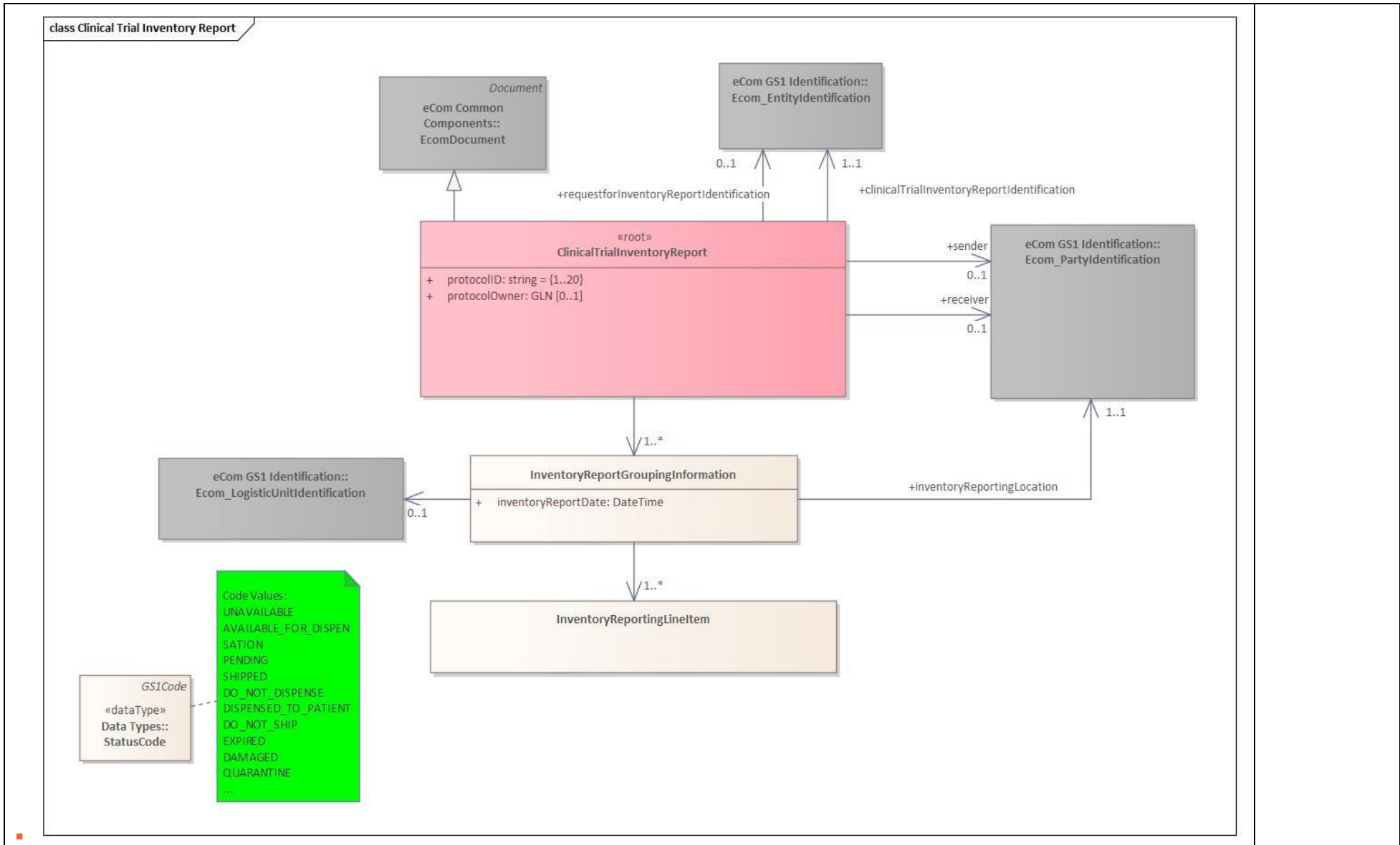
Change	Associated CR Number
■ Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186
■ Added quantity to express the quantity of kits to the line item level and to the shipment level. These quantity fields are mandatory, aligned with the model.	24-000237



2.6 Clinical trial Inventory Report

2.6.1 Overview

Change	Associated CR Number
<ul style="list-style-type: none"> Changed the cardinality of sender and receiver from 1..1 to 0..1 	24-000186
<ul style="list-style-type: none"> Re-used and added countryKitReleasedTo and doNotShipAfter to line item as optional 0..unbounded 	23-000271
<ul style="list-style-type: none"> Added new attributes to line item: unblindedKitTypeCode (optional , type code) unblindedKitTypeDescription (optional description1000) , blindingGroup (optional description200) , blindingGroupDescription (optional description200), isSerializedCFGFlag (optional description200) , isPooledCFGFlag (optional description200) 	23-000286
<ul style="list-style-type: none"> Changed the cardinality of GLN in root level and GTIN in line level from 1..1 to 0..1 	23-000319
<ul style="list-style-type: none"> Added a new attribute doNotShipAfterDays to the line level as 0..unbounded 	24-000030
<ul style="list-style-type: none"> Added a new attribute clinicalTrialMaterialID to line item level as an optional string with {1..20} 	24-000208

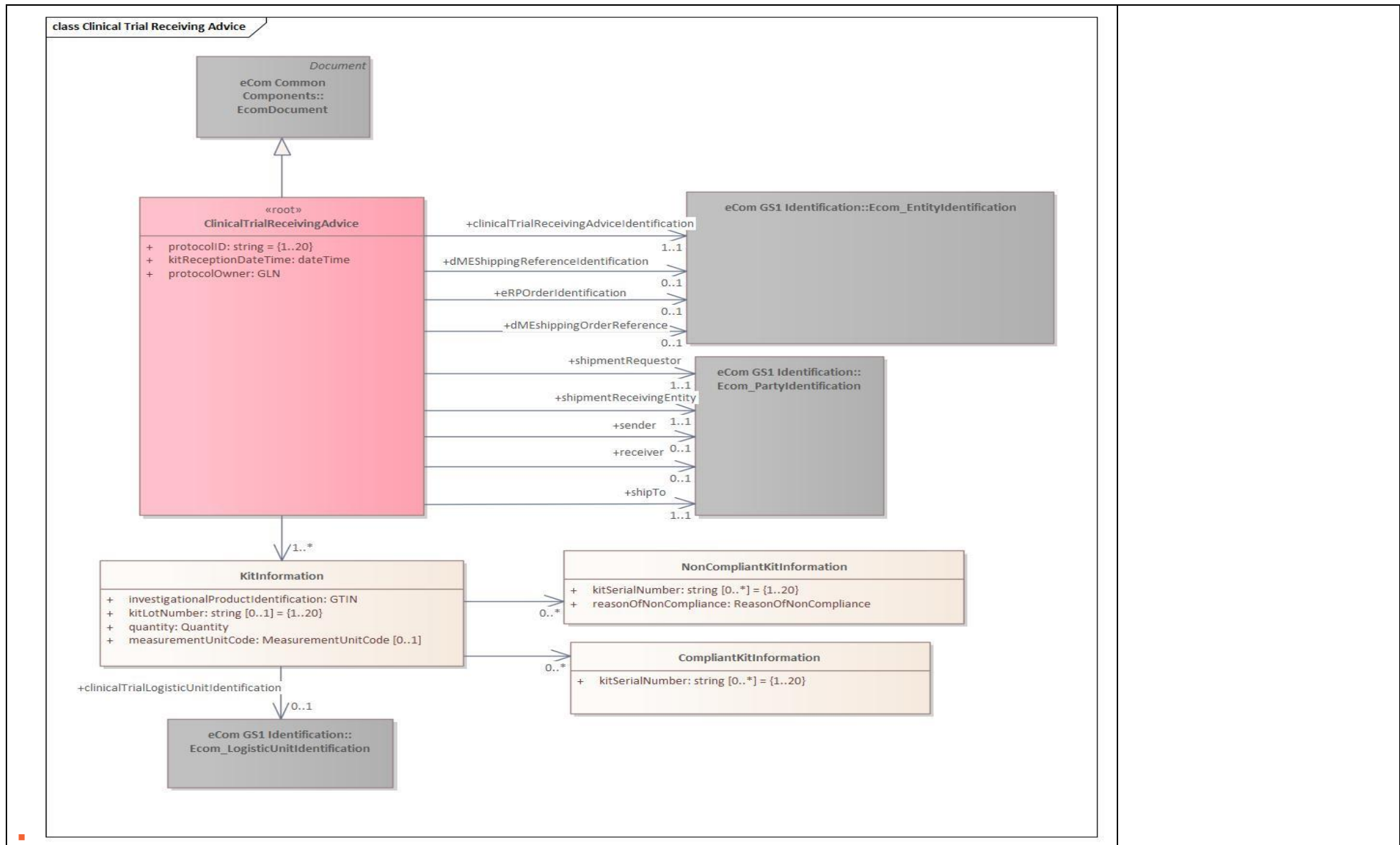


Change	Associated CR Number
<div> <div>class InventoryReportingLineItem</div> <div> <div>InventoryReportingLineItem</div> <div> + investigationalProductIdentification: GTIN [0..1] + kitLotNumber: string = {1..20} + additionalLotNumber: string [0..1] = {1..20} + quantity: Quantity [0..1] + doNotShipAfter: date [0..*] + clinicalTrialMaterialID: string [0..1] = {1..20} + lotStatusCode: StatusCode [0..1] + lotExpiryDateTime: DateTime [0..1] + unblindedKitTypeCode: UnblindedKitTypeCode [0..1] + unblindedKitTypeDescription: Description1000 [0..1] + blindingGroup: Description200 [0..1] + blindingGroupDescription: Description200 [0..1] + isSerializedCFGFlag: Description200 [0..1] + isPooledCFGFlag: Description200 [0..1] + doNotShipAfterDays: int [0..*] </div> </div> </div> <div> <div>IndividualKitInformation</div> <div> + kitSerialNumber: string = {1..20} + kitStatusCode: StatusCode + kitExpiryDateTime: DateTime + sequenceNumber: integer [0..1] </div> </div> <div> <div>« »</div> <div>Shared Common Components::Country</div> </div> <div> +countryKitReleasedTo </div> <div> 0..* </div> <div> 0..* </div>	

2.7 Clinical Trial Receiving Advice

2.7.1 Overview

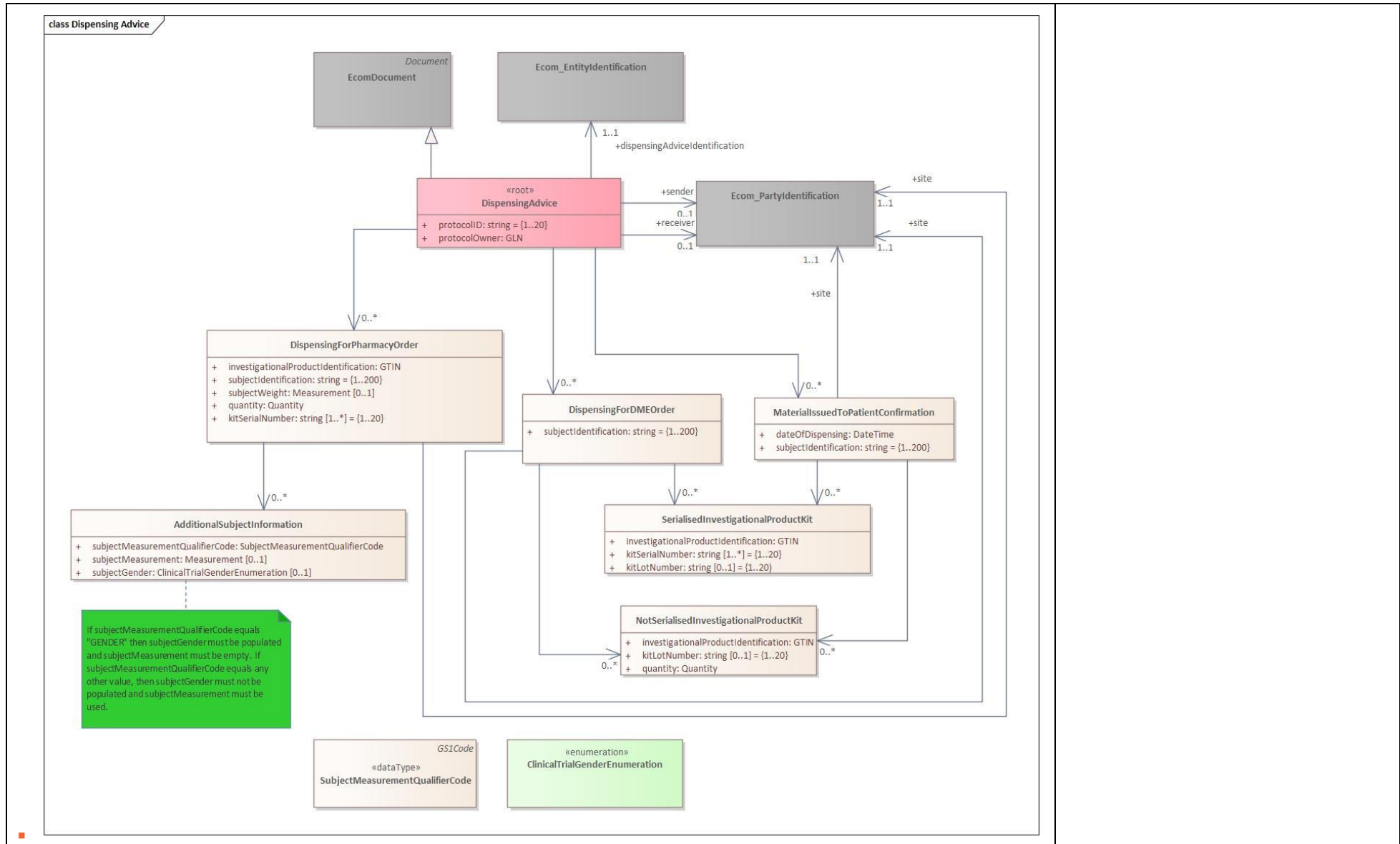
Change	Associated CR Number
<ul style="list-style-type: none"> Changed the cardinality of sender and receiver from 1..1 to 0..1 	24-000186



2.8 Dispensing Advice – Clinical Trials

2.8.1 Overview

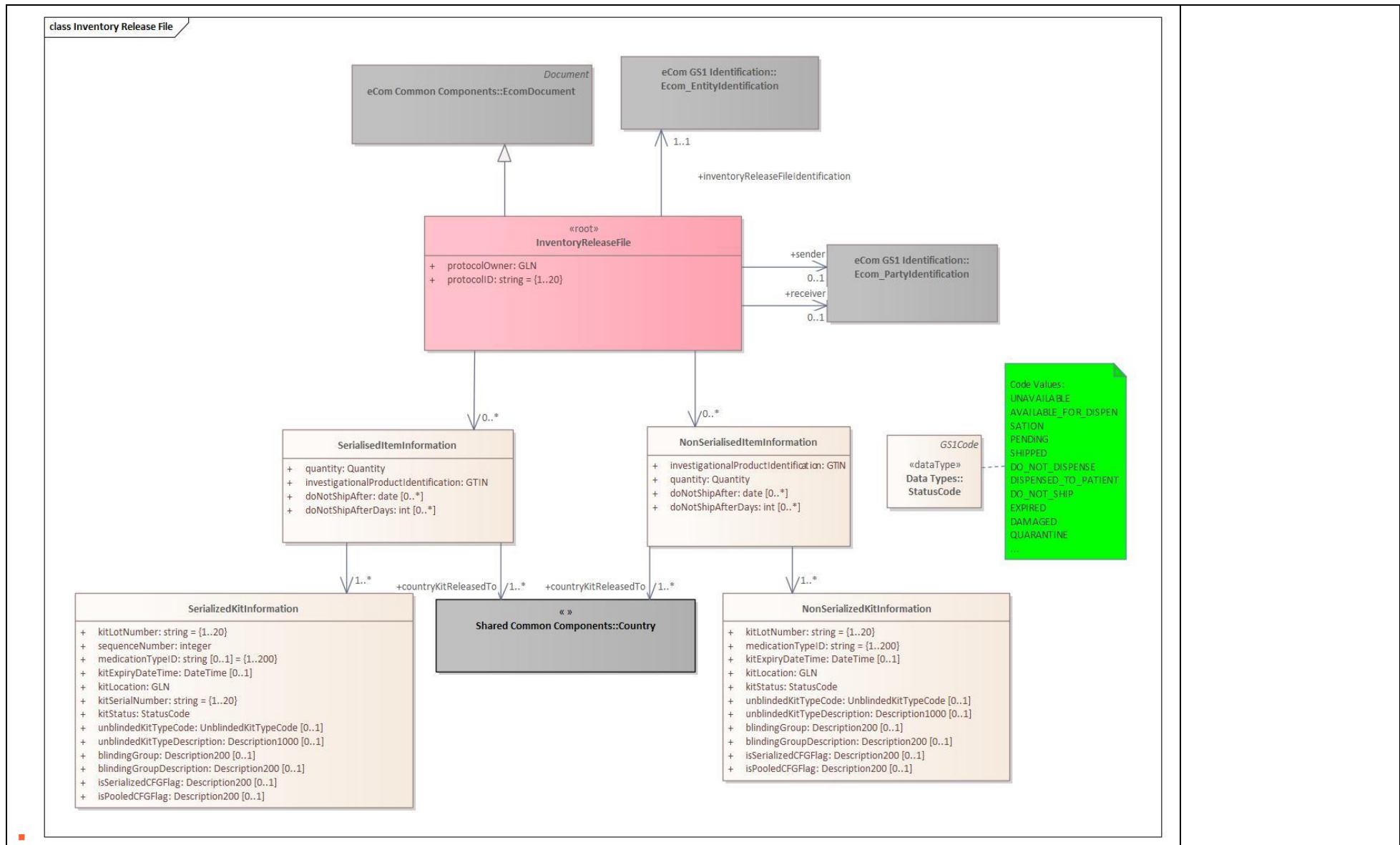
Change	Associated CR Number
■ Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186



2.9 Inventory Release File – Clinical Trials

2.9.1 Overview

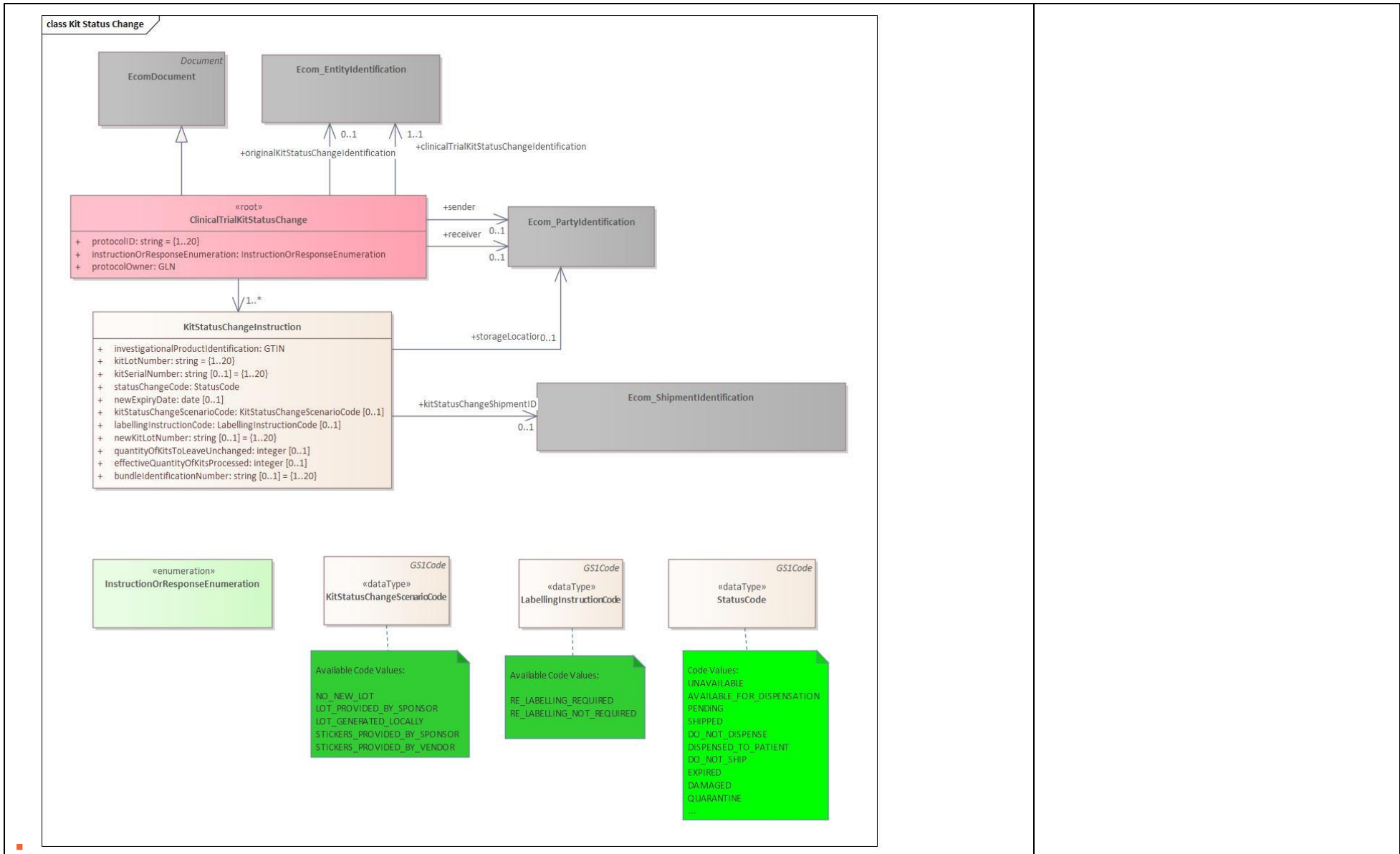
Change	Associated CR Number
<ul style="list-style-type: none">Added new attributes to Serialized/Non Serialized kit information: unblindedKitTypeCode (optional , type code) unblindedKitTypeDescription (optional description1000) , blindingGroup (optional description200) , blindingGroupDescription (optional description200), isSerializedCFGFlag (optional description200) , isPooledCFGFlag (optional description200)	23-000286
<ul style="list-style-type: none">Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186
<ul style="list-style-type: none">Added a new attribute doNotShipAfterDays to the Serialized/Non Serialized kit information class, as 0..unbounded changed the cardinality of doNotShipAfter to 0..unbounded	24-000030



2.10 Kit Status Change – Clinical Trials

2.10.1 Overview

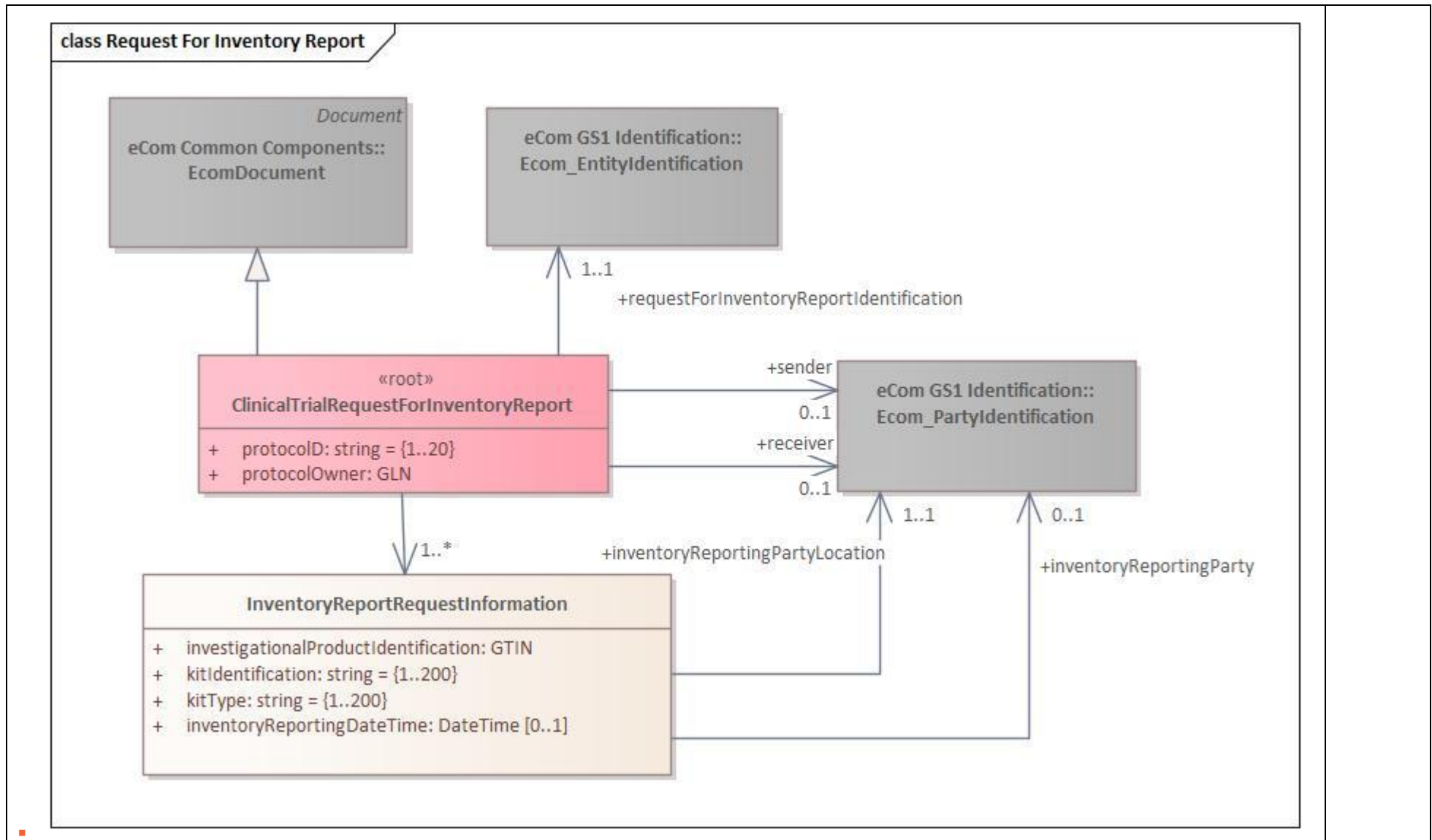
Change	Associated CR Number
■ Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186



2.11 Request For Inventory Report - Clinical Trials

2.11.1 Overview

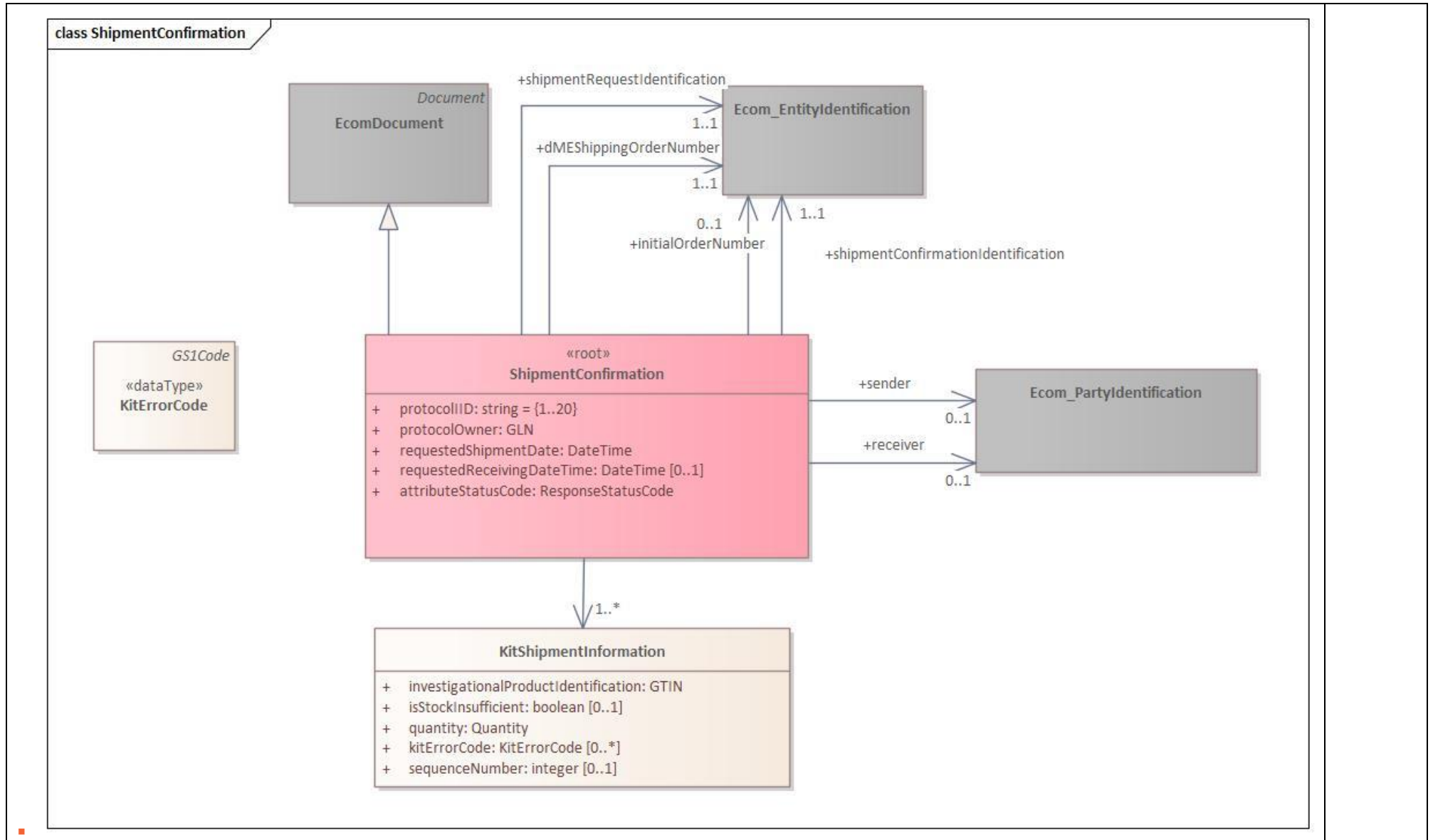
Change	Associated CR Number
<ul style="list-style-type: none">Changed the cardinality of sender and receiver from 1..1 to 0..1	24-000186



2.12 Shipment Confirmation – Clinical Trials

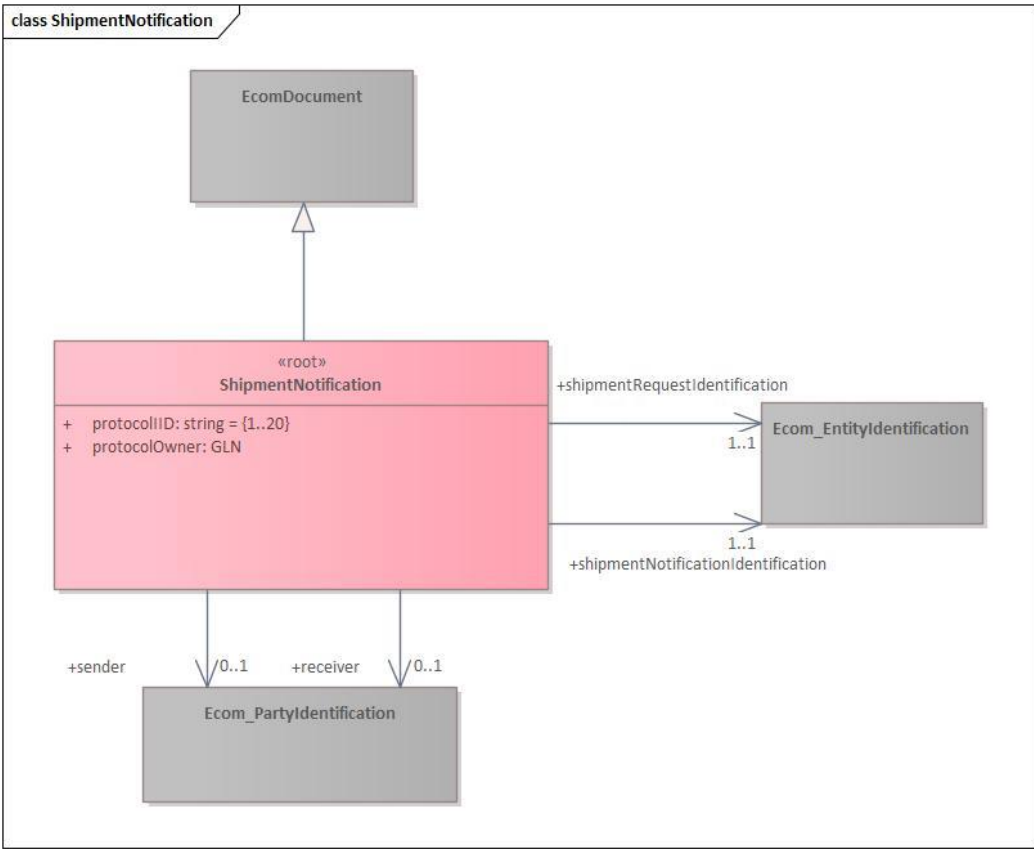
2.12.1 Overview

Change	Associate d CR Number
■ Changed the cardinality of sender and receiver from 1..1 to 0..1	24- 000186
■ Changed the cardinality of initialOrderNumber from 1..1 to 0..1	24- 000020
■ Changed the canrdinality of requestedReceivingDateTime from 1..1 to 0..1	24- 000035



2.13 Shipment Notification – Clinical Trials

2.13.1 Overview

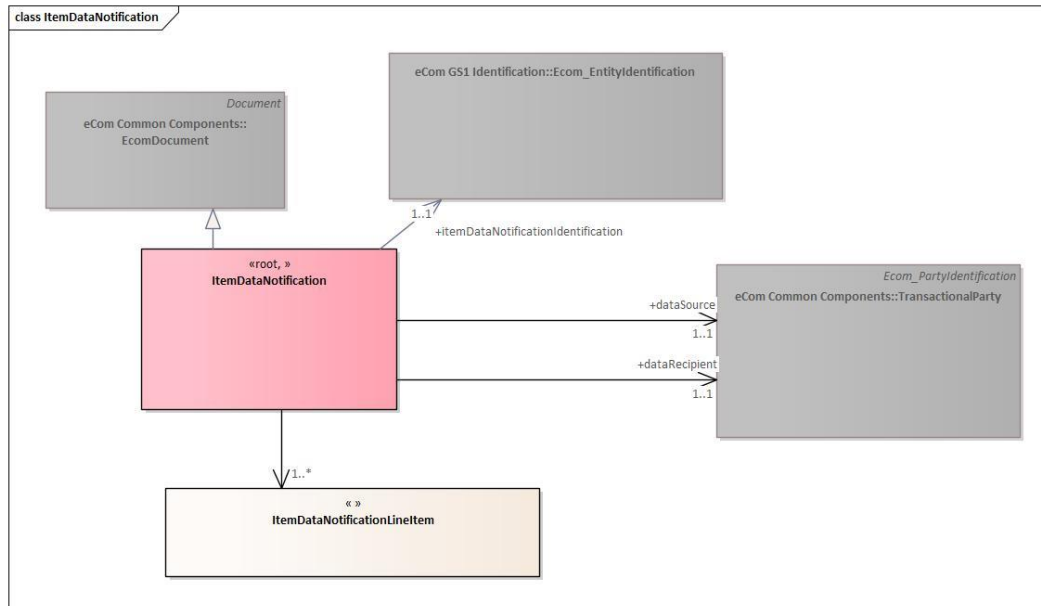
Change	Associated CR Number
<ul style="list-style-type: none"> Changed the cardinality of sender and receiver from 1..1 to 0..1 	24-000186
<div> <div>class ShipmentNotification</div>  <pre> classDiagram class ShipmentNotification { +protocolID: string = {1..20} +protocolOwner: GLN } class EcomDocument class Ecom_EntityIdentification class Ecom_PartyIdentification ShipmentNotification < -- EcomDocument ShipmentNotification --> Ecom_EntityIdentification : +shipmentRequestIdentification 1..1 ShipmentNotification --> Ecom_EntityIdentification : +shipmentNotificationIdentification 1..1 ShipmentNotification --> Ecom_PartyIdentification : +sender 0..1 ShipmentNotification --> Ecom_PartyIdentification : +receiver 0..1 </pre> <p>The diagram shows the ShipmentNotification class structure. It is a root class (pink box) that inherits from EcomDocument (grey box). It has two attributes: protocolID (string, 1..20) and protocolOwner (GLN). It has two associations with Ecom_EntityIdentification (grey box): shipmentRequestIdentification (1..1) and shipmentNotificationIdentification (1..1). It also has two associations with Ecom_PartyIdentification (grey box): sender (0..1) and receiver (0..1).</p> </div>	

2.14 Item Data Notification

2.14.1 Overview

Change	Associate d CR Number
<ul style="list-style-type: none">Added a new class clinicalTrialsItemDataNotificationLineItemDetails to ItemDataNotificationLineItem as optional.	24-000251
<ul style="list-style-type: none">Added the following new attributes to the clinicalTrialsItemDataNotificationLineItemDetails class: clinicalTrialMaterialID as an optional string with {1..20} length. protocolID re-used as an optional string with {1..20} length. protocolOwner re-used as an optional GLN. clinicalTrialAuthorityAuthorizationNumber as an optional string with {1..20} length. iMPTtypeDefinition as an optional description200 field. blindedKitDescription as an optional description200. unblindedKitDescription as an optional description200. blindingGroupDescription as an optional description200. clinicalTrialShippingConditionGrouping as an optional description200.	24-000251

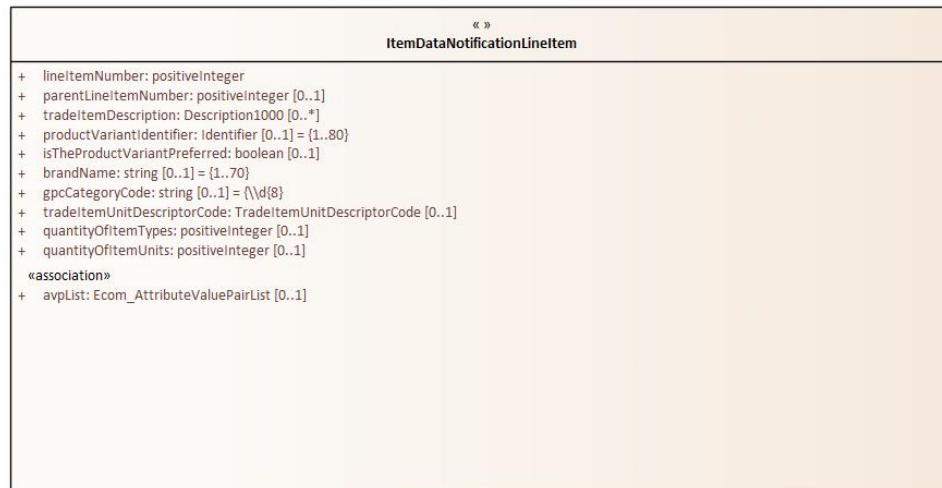
Change

Associate
d CR
Number


Change

Associate
d CR
Number

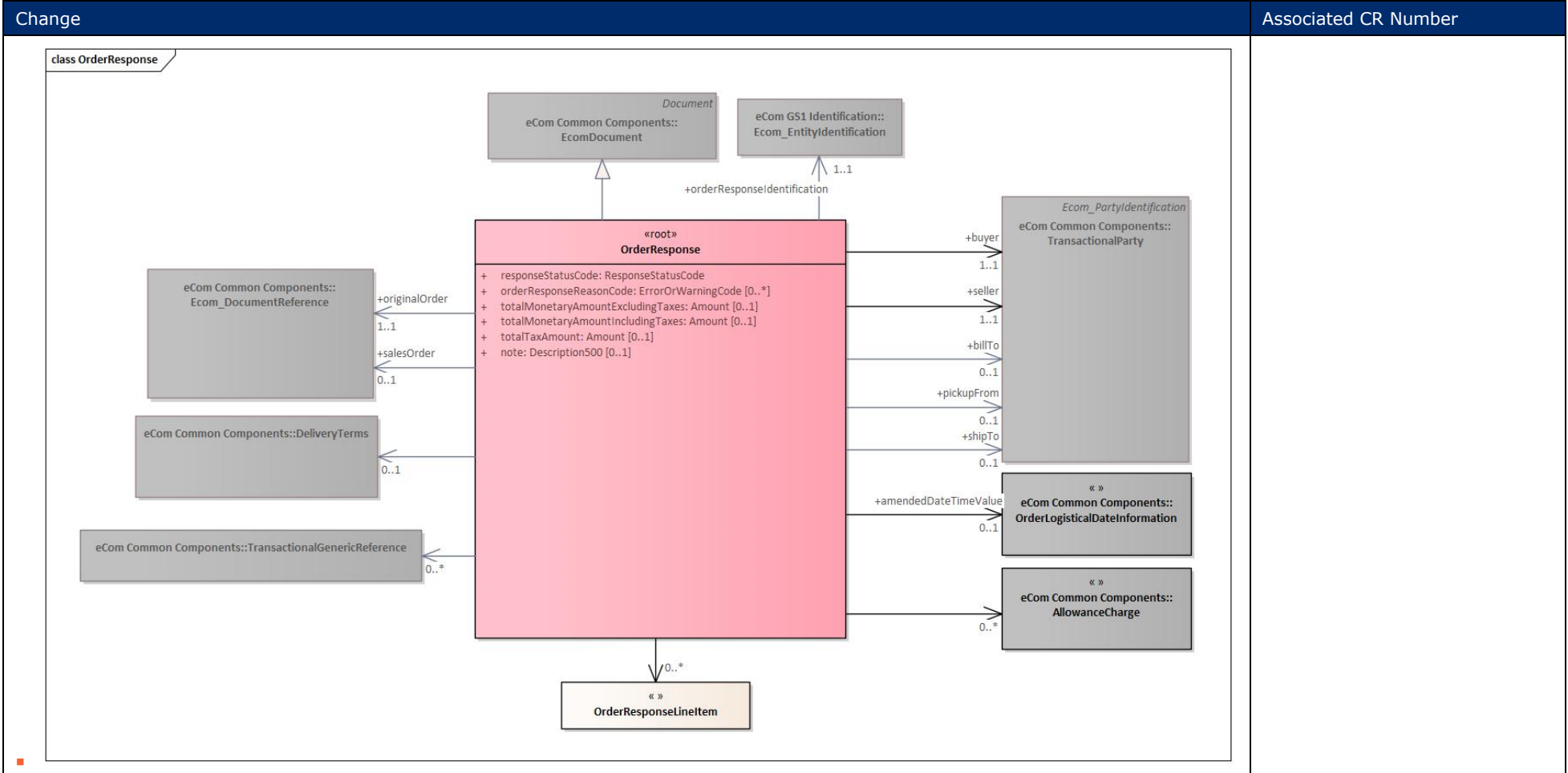
class ItemDataNotificationLineItem



2.15 Order Response

2.15.1 Overview

Change	Associated CR Number
■ Adding TransactionalGenericReference association to root class with 0..* cardinality	WR 24-390

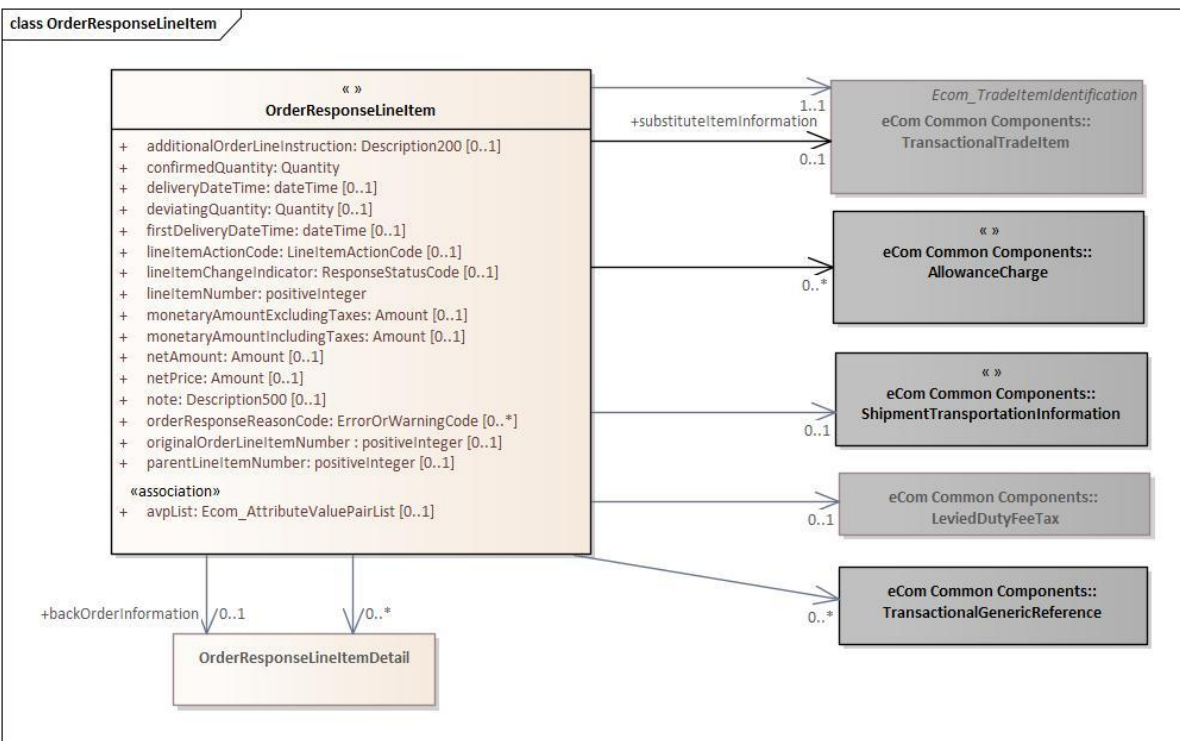


3 Changes applied to GS1 XML 3.7.1

3.1 Order Response message

3.1.1 Overview

- Added **new association** to ecom:common **TransactionalGenericReference** to Line item as optional (0..*):


Associated
CR Number

**WR 25-
152**

