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# Clinical Trial Receiving Advice Business Message Standard (BMS)

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## Document Summary

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## Document Change History

Date of Change	Version	Changed By	Reason for Change	Summary of Change
3-Apr-2020	BMS 3.4.2	Mark Van Eeghem	Initial Draft	Initial Draft
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after group revision	Structure changes, class and attributes definition
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group Revision	
14-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after community reviews	Add GLN in ReceivingEntity and receivegSiteorDepot description. Change protocolIdentification in protocolID

Date of Change	Version	Changed By	Reason for Change	Summary of Change
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	<p>clinicalTrialReceivingAdviceIdentification, dMESHippingOrderReference, eRPOrderIdentification,, dMESHippingReferenceIdentification wrong secondary class.</p> <p>Rearranged the sequence of lines in GDD report according to BMS writing rules</p> <p>NonCompliantKitInformation: wrong data type and Code List url. Changed from <a href="http://apps.gs1.org/GDD/bms/EANCOM/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:4295ChangeReasonDescriptionCode&amp;release=4">http://apps.gs1.org/GDD/bms/EANCOM/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:4295ChangeReasonDescriptionCode&amp;release=4</a> to the correct one</p>
15-Jan-2021	BMS 3.5	Miklos Bolyky	BMS Release 3.5	See summary of changes
05-Jan-2022	BMS 3.5.1	Miklos Bolyky	BMS Release 3.5.1	See summary of changes
01-Mar-2023	BMS 3.6	Miklos Bolyky	BMS Release 3.6	See summary of changes
15-Mar-2025	BMS 3.7	Miklos Bolyky	BMS Release 3.7	See summary of changes



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# 1 Business Domain View

## 1.1 Introduction

### Purpose

The objective of the Receiving Advice message is to send a notification that the good(s) were received (when compared to the good(s) shipped). There must be a one to one match between the Despatch Advice and Receiving Advice.

This Receiving Advice Business Message Standard is one part of a suite of documents designed to provide the detailed technical mappings to GS1 message formats for EDI messages being implemented for Clinical Trials.

The other documents in this suite are:

- Inventory Release
- Shipment Request
- Shipment Notification
- Shipment Confirmation
- Despatch Advice
- Request for Inventory Report
- Inventory Report
- Kit Status Change
- Dispensing Advice

### Scope

The scope of this work includes all messages identified in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#), hereafter called 'the Guideline', section 4.2.

### Considerations

The workgroup that developed this mapping document has ensured that the messages and associated mappings are technology and sponsor agnostic.

It is important that organisations implementing electronic business messaging in line with this guideline undertake an appropriate assessment to ensure that the blinding status of the trial is respected in the messages exchanged.

Messaging communications with transport providers / couriers / carriers are considered out of scope because there are already electronic processes in place and altering them would not add value.

## 1.2 References

Reference Name	Description
<a href="#">GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline</a> ,	The guideline details the business requirement of the clinical trials context, both in terms of process design and data set shared between the actors

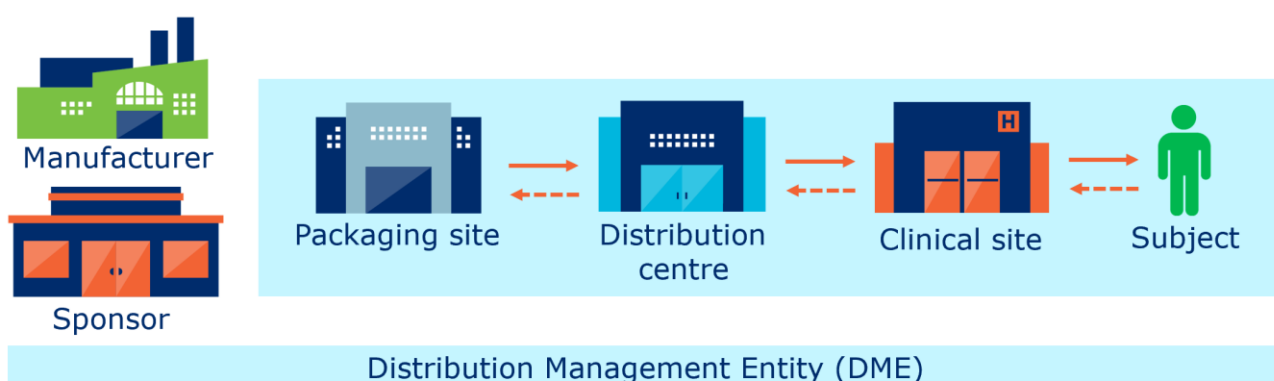
## 2 Business Context

Context Category	Value(s)
Industry	Healthcare, Pharmaceuticals & Medical Devices
Geopolitical	All
Product	All
Process	Clinical Trials
System Capabilities	GS1 System
Official Constraints	None

## 3 Business Transaction View

### Business Process Participants

As detailed in the Guideline, section 4.1, the diagram and table below provide an overview of the main actors involved in the process.



**Table 3-1** Roles and responsibilities

Role	Responsibility in process
Manufacturer/sponsor	Has overall responsibility for the trial, and produces the Investigational Product (IP)
Contract Manufacturing Organisation (CMO)	Manufactures and may package IP and IP kits at the direction of the manufacturer/sponsor
Packaging site	Packages and labels the IP and IP kits
Distributor (with warehouse)	Warehouses and distributes the IP kits as needed to the sites
Carrier (transporting the goods)	Logistics provider moving the IP kits at the request of other stakeholders
Clinical trial site	The healthcare provider location where the trial is conducted and dispensing to the patient typically occurs
Return facility	Responsible for receipt of any IP kits returned from trial sites
Distribution Management Entity (DME)	A term used to identify the system(s) managing, distribution, and disposition of clinical supplies. In many cases this is the interactive

	technology IRT system, portal, a set of tools or different databases used to share information during a clinical trial, etc.
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## Use Case Diagram

N/A

## Use Case Description

Performance goals	To ensure confirmation of receipt of goods is sent from the Ship To party to the Shipment Requestor and assessment of shipment integrity is communicated back to the shipment requestor																					
Preconditions	Unique identification of locations, trade items and logistics units will be undertaken. Correct identification of sender (Ship To) and receiver (Ship From) are in place. Despatch Advice has been successfully received by the Ship To location.																					
Postconditions	None identified																					
Scenario	<p>Begins when the Ship To party must send an advice of receipt to the Ship From location. In this scenario, the Ship To location is either the ultimate recipient of the goods that will open and use the contents of the logistics units or the DC which will receive and store the goods.</p> <p>Continues with...</p> <table><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>Ship To Party</td><td>Receives shipment and reconciles content of the physical shipment vs the Despatch Advice.</td></tr><tr><td>2</td><td>Ship To Party</td><td>Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor.</td></tr><tr><td></td><td>Shipment Requestor</td><td></td></tr><tr><td>3</td><td>Sponsor</td><td>Receives the receiving advice from the Ship To party.</td></tr><tr><td>4</td><td>Ship To Party</td><td>Updates inventory.</td></tr><tr><td>5</td><td>Sponsor</td><td>(Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site.</td></tr></table> <p>Ends when the oods can be used.</p>	Step #	Actor	Activity step	1	Ship To Party	Receives shipment and reconciles content of the physical shipment vs the Despatch Advice.	2	Ship To Party	Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor.		Shipment Requestor		3	Sponsor	Receives the receiving advice from the Ship To party.	4	Ship To Party	Updates inventory.	5	Sponsor	(Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site.
Step #	Actor	Activity step																				
1	Ship To Party	Receives shipment and reconciles content of the physical shipment vs the Despatch Advice.																				
2	Ship To Party	Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor.																				
	Shipment Requestor																					
3	Sponsor	Receives the receiving advice from the Ship To party.																				
4	Ship To Party	Updates inventory.																				
5	Sponsor	(Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site.																				
Alternative scenario	None identified																					
Related requirements	Inventory status and quality will be reported using the receiving advice, including any damaged or missing goods – compared to the original shipment.																					

Related rules	<ol style="list-style-type: none"> <li>1. The Ship To party may be either the distributor or trial site depending on where the necessary inventory is to be shipped.</li> <li>2. One Receiving Advice will be sent by the Ship To location to each Ship From location.</li> <li>3. Upon notification of any discrepancies, investigation of root cause occurs. Part or all of the contents of the shipment will be held in an 'unreleased state' until the investigation is complete.</li> <li>4. A combination of sponsor ID, study ID and order ID will uniquely identify the message.</li> <li>5. Each receiving system will determine how to handle the status of the supplies, e.g., available to dispense, quarantined or inventory management issue (quantity, wrong item, missing item, damaged item, etc).</li> <li>6. In all cases the sponsor is the receiver of the Receiving Advice.</li> </ol>
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### Activity Diagram(s)

Not applicable

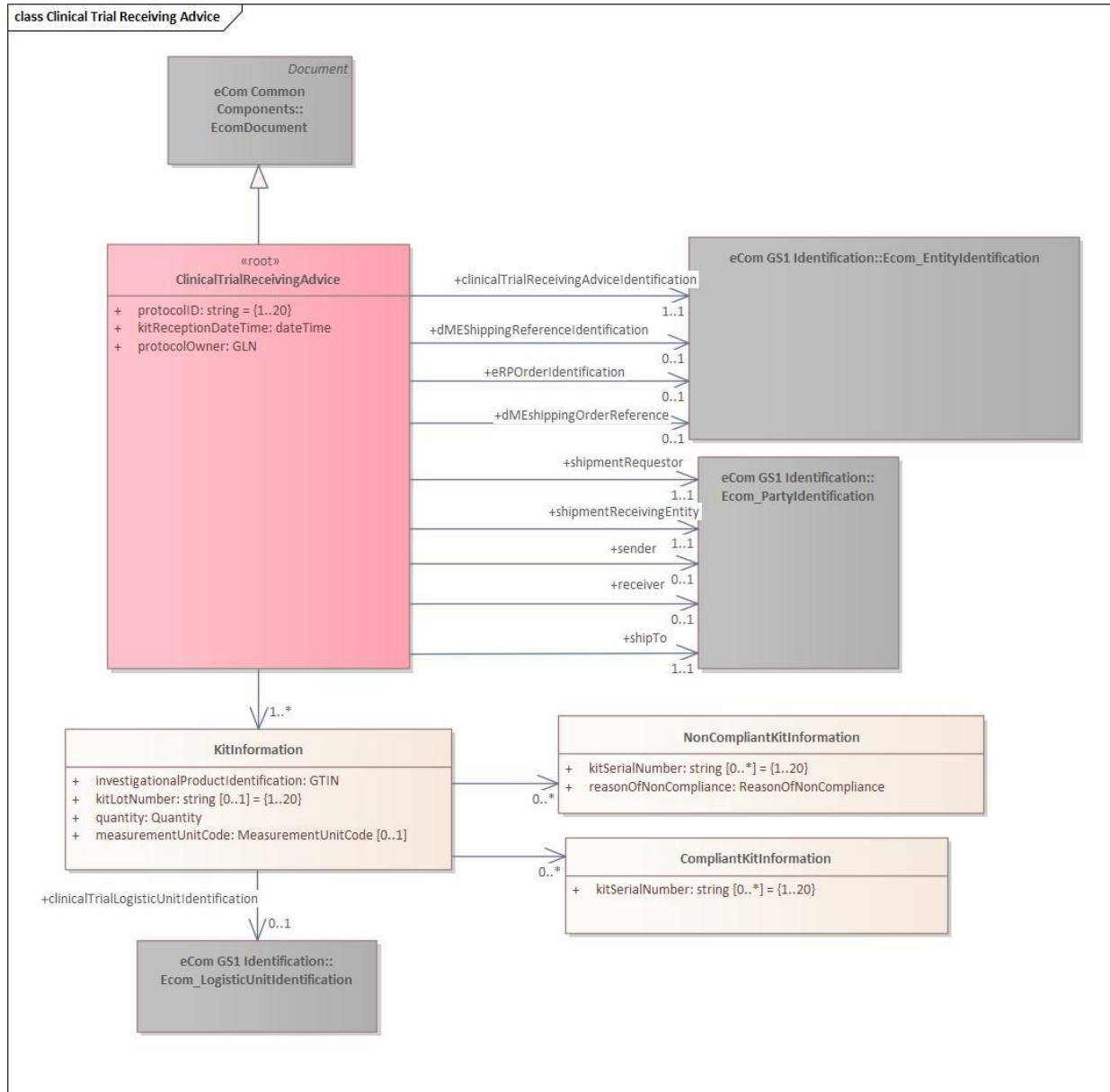
### Sequence Diagram(s)

Not applicable

## **4 Business Information View**

### **4.1 Clinical Trial Receiving Advice**

#### **Class diagram**



## Report

The content of the ClinicalTrialReceivingAdvice class, its structure and component definitions can be accessed in the GS1 Navigator: [Navigator link](#)

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
<b>ClinicalTrialReceivingAdvice</b>				This message is sent from the receiver of the shipment (e.g. trial site) to the creator the shipment request (e.g. the DME) to confirm the goods received	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	clinicalTrialReceivingAdviceIdentification	Ecom_EntityIdentification	1..1	The identification of the Receiving Advice message	
ASSOCIATION	sender	Ecom_PartyIdentification	0..1	The sender of the message	
ASSOCIATION	receiver	Ecom_PartyIdentification	0..1	The receiver of the message	
ASSOCIATION	shipmentRequestor	Ecom_PartyIdentification	1..1	The GLN of the requestor of the shipment, i.e. DME vendor or third-party depot system	
ASSOCIATION	shipmentReceivingEntity	Ecom_PartyIdentification	1..1	The GLN of the entity receiving the shipment	
ASSOCIATION		KitInformation	1..*	Information related to the kits received	
ASSOCIATION	dMESHippingOrderReference	Ecom_EntityIdentification	0..1	The reference to the DME order number	
ASSOCIATION	ERPOrderIdentification	Ecom_EntityIdentification	0..1	Internal receiving site ERP reference to the shipment order	
ASSOCIATION	dMESHippingReferenceIdentification	Ecom_EntityIdentification	0..1	The reference to the DME shipping number	
ATTRIBUTE	kitReceptionDateTime	DateTime	1..1	The date / time of the reception of the items	
ATTRIBUTE	protocolID	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the protocol sponsor	
ASSOCIATION	shipTo	Ecom_PartyIdentification	1..1	The GLN of the physical location where the goods are received	

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
KitInformation					
ASSOCIATION		NonCompliantKitInformation	0..*	Information about non-compliant kits	
ASSOCIATION		CompliantKitInformation	0..1	Information about compliant kits	WR-22-351
ASSOCIATION	clinicalTrialLogisticUnitIdentification	Ecom_LogisticUnitIdentification	0..1	The identification (SSCC) of the logistic unit	
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	0..1	The kit lot / batch number received	{1..20}
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ATTRIBUTE	measurementUnitCode	MeasurementUnitCode	0..1	Unit of measure for the content for bulk drugs, i.e. KG or count of pills	
NonCompliantKitInformation					
ATTRIBUTE	kitSerialNumber	string	0..*	The serial number of the non-compliant kit	{1..20}
ATTRIBUTE	reasonOfNonCompliance	ReasonOfNonCompliance	1..1	The non-compliance code	
CompliantKitInformation					
ATTRIBUTE	kitSerialNumber	string	1..*	The serial number of the compliant kit	WR-22-351

## 4.2 Enumerations (message specific)

Not applicable

## 4.3 Code Lists

Class	Codelist	Navigator Link
KitInformation	MeasurementUnitCode	<a href="https://navigator.gs1.org/edi/codelist-details?name=MeasurementUnitCode">https://navigator.gs1.org/edi/codelist-details?name=MeasurementUnitCode</a>
NonCompliantKitInformation	ReasonOfNonCompliance	<a href="https://navigator.gs1.org/edi/codelist-details?name=ReasonOfNonCompliance">https://navigator.gs1.org/edi/codelist-details?name=ReasonOfNonCompliance</a>



**Note:** Refer to the GS1 Navigator (Navigator) for the code values.

# 5 Business Message Examples

## 5.1 Example 1

### Party Information

GS1 Global Location Number	Party Type
9520000000011	ShipmentRequestor
9520000000028	ReceivingEntity
9520000000004	Sponsor
9520000000127	receivingSiteOrDepot

### Message Example 1

Attribute	Value
<b>ReceivingAdvice</b>	
<b><i>clinicalTrialReceivingAdviceIdentification</i></b>	
entityIdentification	12
dMESHippingOrderReference	13
<b><i>eRPOrderIdentification</i></b>	
entityIdentification	332
<b><i>dMESHippingReference</i></b>	
entityIdentification	133
<b><i>shipmentRequestor</i></b>	
GLN	9520000000011
<b><i>shipmentReceivingEntity</i></b>	
GLN	9520000000028
kitReceptionDateTime	2020-03-27T12:54:00.000+02:00
protocolID	PROT1
protocolOwner	9520000000004
<b><i>shipTo</i></b>	
GLN	9520000000127

Attribute	Value
<b>kitInformation</b>	
<b>clinicalTrialLogisticUnitIdentification</b>	
SSCC	952000000000000125
investigationalProductIdentification	95200000000530
kitLotNumber	LOT1
<b>quantity</b>	
quantity	1
measurementUnitCode	H87
kitMeasurementUnitCode	H87
<b>nonCompliantKitInformation</b>	
kitSerialNumber	1243
reasonOfNonCopliance	BA

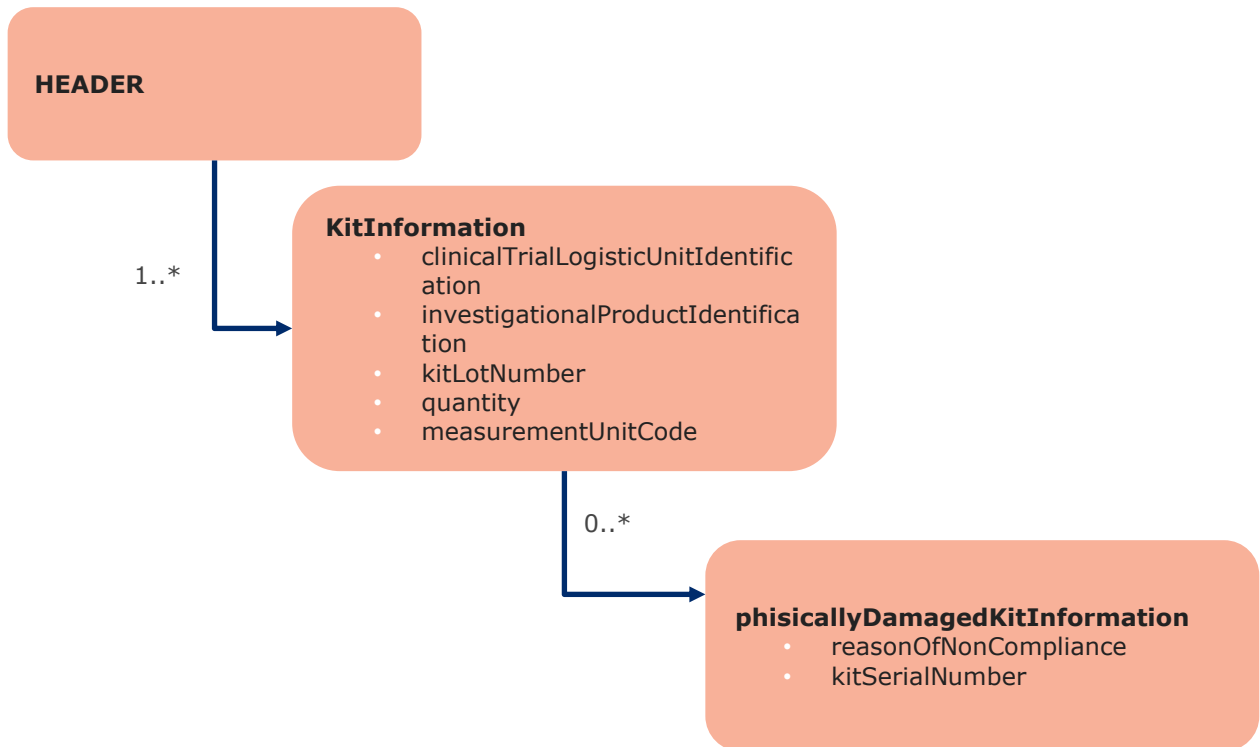
## 6 Implementation Considerations

### 6.1 User Guide

All implementation considerations are discussed in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#).

## 6.2 Message Specific Considerations

The detail section of the Receiving Advice section provides the list of logistic units and lots received. For every logistic unit there's the possibility to specify a list of non-compliant serials.



## 7 Summary of Changes

Any change in the GS1 standards is done based on the Work Request (WR) submitted by the GS1 User Companies or Member Organisations. All Work Requests are documented in the Work Request system available on the GS1 website: <http://wr.gs1.org>. The system is accessible to registered users. New visitors need to register first, to be able to access it. WRs can be searched by the number referenced in tables below, see: Search Work Requests. The number starts with the two last digits of the year when it was submitted, followed by the consecutive number within that year.



**Note:** WRs submitted earlier than February 2012 should be searched in Old Change Requests.

### 7.1 BMS Release 3.4.2

Change	Associated CR Number
Initial Draft	

### 7.2 BMS Release 3.5

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.

## 7.3 BMS Release 3.5.1

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.

## 7.4 BMS Release 3.6

Change	Associate d CR Number
<ul style="list-style-type: none"> <li>Created new class <b>CompliantKitInformation</b> created new association from KitInformation to CompliantKitInformation Added existing attribute kitSerialNumber in CompliantKitInformation class with cardinality 0..*</li> </ul>	WR-22-351
<ul style="list-style-type: none"> <li>Fixed errata <b>kitSerialNumber</b> attribute in bms from 1..1 to 0..* cardinality to be consistent with the xsd and model</li> </ul>	
<ul style="list-style-type: none"> <li>Fixed errata <b>reasonForNonCompliance</b> spelling error in model and schema fixed.</li> </ul>	

## 7.5 BMS Release 3.7

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

# 8 Appendices

Not Applicable

# 9 Acknowledgements

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