The Global Language of Business

Clinical Trial Kit Status Change Business Message Standard (BMS)

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Document Summary

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BRAD Title	BRAD Issue Date	BRAD Version

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, classes and attributes definition, examples added
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group review	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	message definition in GDD report missing. Used the one in the purpose. KitStatusChangeInstruction definition missing
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

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Table of Contents

1 Business Domain View

1.1 Introduction

Purpose

The Kit Status Change is designed to convey an instruction to make a change in kit status or to confirm a kit status has changed.

This Kit Status Change File 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
- Receiving Advice
- Request for Inventory Report
- Inventory Report
- 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 developing 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
GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline,	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.

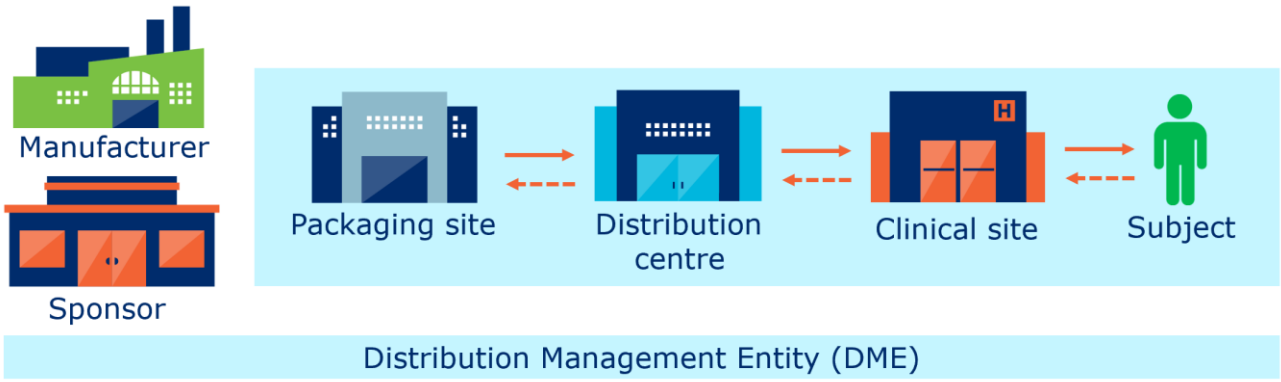


Table 3-1 *Roles and responsibilities*

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.

Use Case Diagram

N/A

Use Case Description

Below is the use case detailed in *the Guideline, section 7.7.2*

<table>
<tr><td>Performance goals</td><td>To ensure useable inventory levels are aligned across the study stakeholders.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units. Correct identification of sender (Ship To) and receiver (Ship From) are in place.</td></tr>
<tr><td>Post conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the sponsor identifies goods in a shipment that need to be put on hold.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Sponsor/trial site/DC</td><td>Advises DC or trial site of the IP kit numbers of the on-hold goods and specifies action to be taken, e.g., destroy, return, hold, etc.</td></tr>
<tr><td>2</td><td>DC/trial site</td><td>Acknowledges advice and acts.</td></tr>
<tr><td>3</td><td>Sponsor</td><td>Advises Ship From of the corrective actions, e.g., ship more IP kits.</td></tr>
</table>
Ends when ship from takes appropriate action.</td></tr>
<tr><td>Alternative scenario</td><td>If it is a DC or site reporting goods to be placed on hold, this would more likely be incident report being, related to temperature issues, for example, flooding, etc.</td></tr>
<tr><td>Related requirements</td><td>The term damaged goods has a QA implication for some organisations ‘Quarantined’ also has a QA implication for some organisations but not others.</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

Activity Diagram(s)

Not applicable

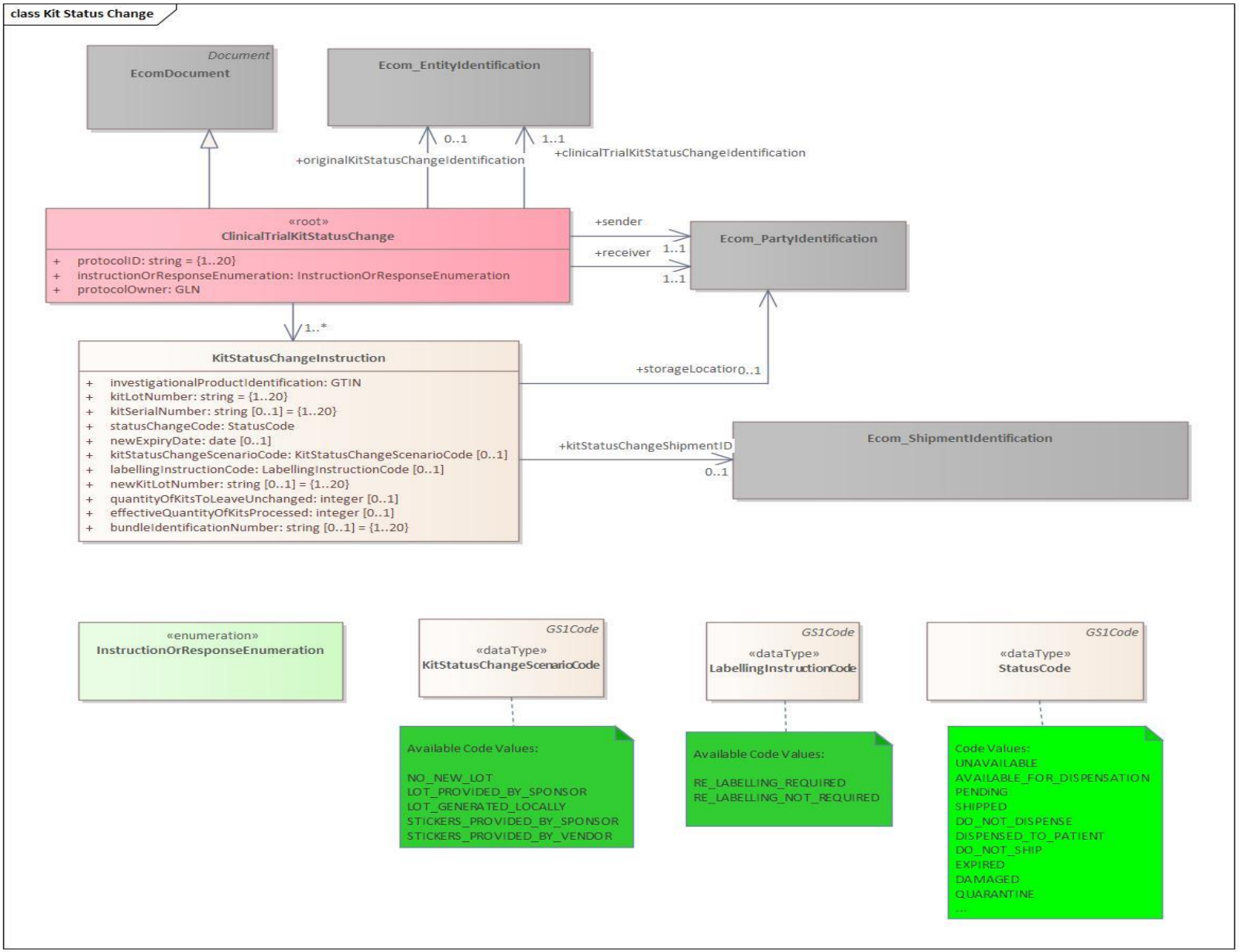
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Clinical Trial Kit Status Change

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ClinicalTrialKitStatusChange				The Kit Status Change is designed to convey an instruction to make a change in kit status or to confirm a kit status has changed.	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	clinicalTrialKitStatusChangeIdentification	Ecom_EntityIdentification	1..1	The identification of the Status Change message	
ASSOCIATION	originalKitStatusChangeIdentification	Ecom_EntityIdentification	0..1	The identification of the original Kit status change instruction when generating a response message	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The entity sending the message, i.e. DME vendor or third-party depot system	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The entity receiving the message	
ASSOCIATION		KitStatusChangeInstruction	1..*	Kit status change instructions	
ATTRIBUTE	protocolID	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the protocol sponsor	
ATTRIBUTE	instructionOrResponseEnumeration	InstructionOrResponseEnumeration	1..1	The type of message, i.e instruction to change or response to a change request	
KitStatusChangeInstruction					
ASSOCIATION	storageLocation	Ecom_PartyIdentification	0..1	The physical site where the kit is stored	WR 22-354
ASSOCIATION	kitStatusChangeShipmentID	Ecom_ShipmentIdentification	0..1	The identification of the shipment used on the stickers applied on the medication kits	WR 22-354
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	1..1	The lot number of the kit subject to the change	{1..20}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	kitSerialNumber	string	0..1	The serial number of the kit subject to the change.	{1..20}
ATTRIBUTE	statusChangeCode	StatusCode	1..1	The new status of the kit after the change	
ATTRIBUTE	newExpiryDate	Date	0..1	The new expiry date assigned after the shelf life modification	WR 22-354
ATTRIBUTE	kitStatusChangeScenarioCode	KitStatusChangeScenarioCode	0..1	The code specifying the type of application scenario the message is referred to	WR 22-354
ATTRIBUTE	labellingInstructionCode	LabellingInstructionCode	0..1	The code identifying if the relabelling is needed and who is in charge of the process	WR 22-354
ATTRIBUTE	newKitLotNumber	String	0..1	The new identification eventually assigned to a lot as a result of the shelf life modification	{1..20} WR 22-354
ATTRIBUTE	quantityOfKitsToLeaveUnchanged	integer	0..1	The quantity of medication kits in the stock that should not be subject to change requested	WR 22-354
ATTRIBUTE	effectiveQuantityOfKitsProcessed	Integer	0..1	The quantity of medication kits to which the requested change has been applied	WR 22-354
ATTRIBUTE	bundleIdentificationNumber	String	0..1	The identification of a bundle	{1..20} WR 22-354

Note: Reference Shared Common Library Business Message (BMS) Release 3.6 and eCom Domain Common Library Business Message (BMS) Release 3.6 for all common information.

4.2 Enumerations (message specific)

Class	Codelist	Values
ClinicalTrialKitStatusChange	InstructionOrResponseEnumeration	https://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:InstructionOrResponseEnumeration

4.3 Code Lists

Class	Codelist	GDD Link
KitStatusChangeInstruction	StatusCode	
KitStatusChangeInstruction	KitStatusChangeScenarioCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:KitStatusChangeScenarioCode
KitStatusChangeInstruction	LabellingInstructionCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:LabellingInstructionCode

Note: Refer to the Global Data Dictionary (GDD) for the code values.

5 Business Message Examples

5.1 Examples

Example 1: The DME requiring a clinical site a status change on a specific batch

Example 2: The clinical site respond to the DME confirming the change

Party Information

GS1 Global Location Number	Party Type
9520000000028	DME
9520000000127	Organization receiving the request
9520000000004	Sponsor
9520000000127	Location

Message Example 1

Attribute	Value
kitStatusChange	
clinicalTrialKitStatusChangeIdentification	
entityIdentification	121
sender	
GLN	9520000000028
receiver	
GLN	9520000000127
protocolID	PROT1

Attribute	Value
protocolOwner	9520000000004
instructionOrResponseEnumeration	INSTRUCTION
KitStatusChangeInstruction	
storageLocation	
GLN	9520000000127
investigationalProductIdentification	9520000000530
kitLotNumber	L001
kitSerialNumber	0001
statusChangeCode	DO_NOT_DISPENSE

Message Example 2

Attribute	Value
kitStatusChange	
clinicalTrialKitStatusChangeIdentification	
entityIdentification	154
originalKitStatusChangeIdentification	
entityIdentification	121
sender	
GLN	9520000000127
receiver	
GLN	9520000000028
protocolID	PROT1
protocolOwner	9520000000004
instructionOrResponseEnumeration	RESPONSE
KitStatusChangeInstruction	
storageLocation	
GLN	9520000000127
investigationalProductIdentification	9520000000530
kitLotNumber	L001
kitSerialNumber	0001
statusChangeCode	DO_NOT_DISPENSE

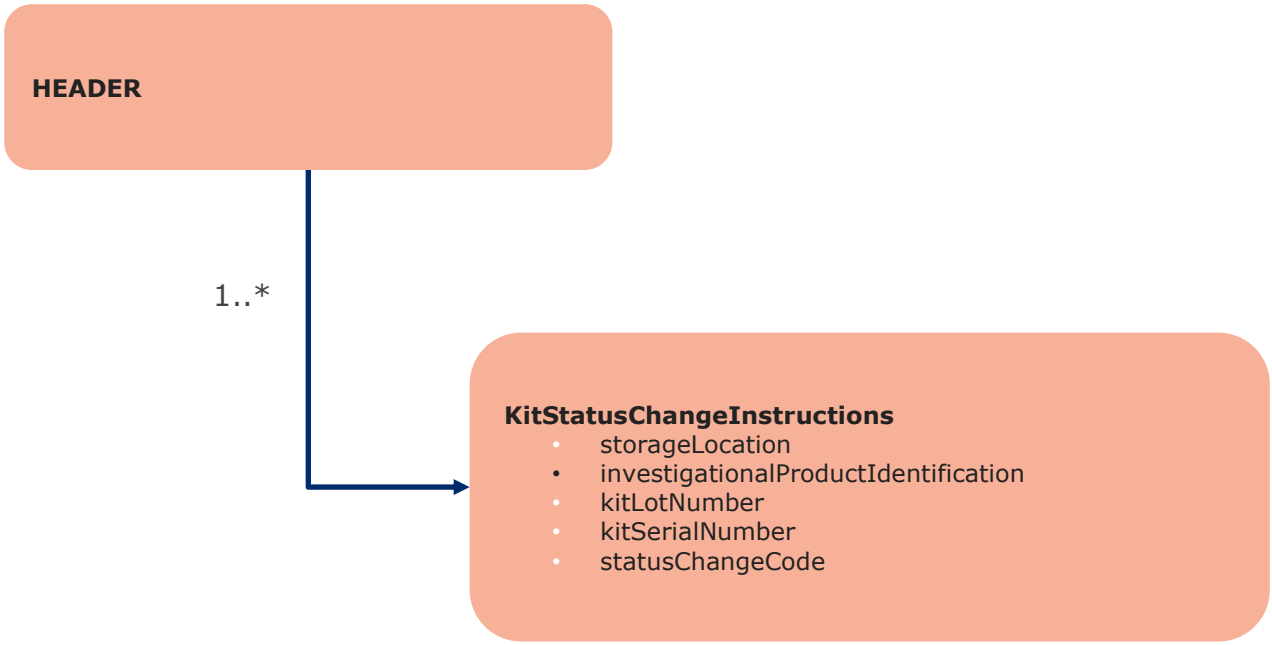
6 Implementation Considerations

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 Kit Status Change message provide a list of batch/lot numbers and, eventually, serial numbers. If the message type is INSTRUCTION, the statusChangeCode represents the requested status. If the message is a RESPONSE, the statusChangeCode represents the actual status of the kits after the execution of the request



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	

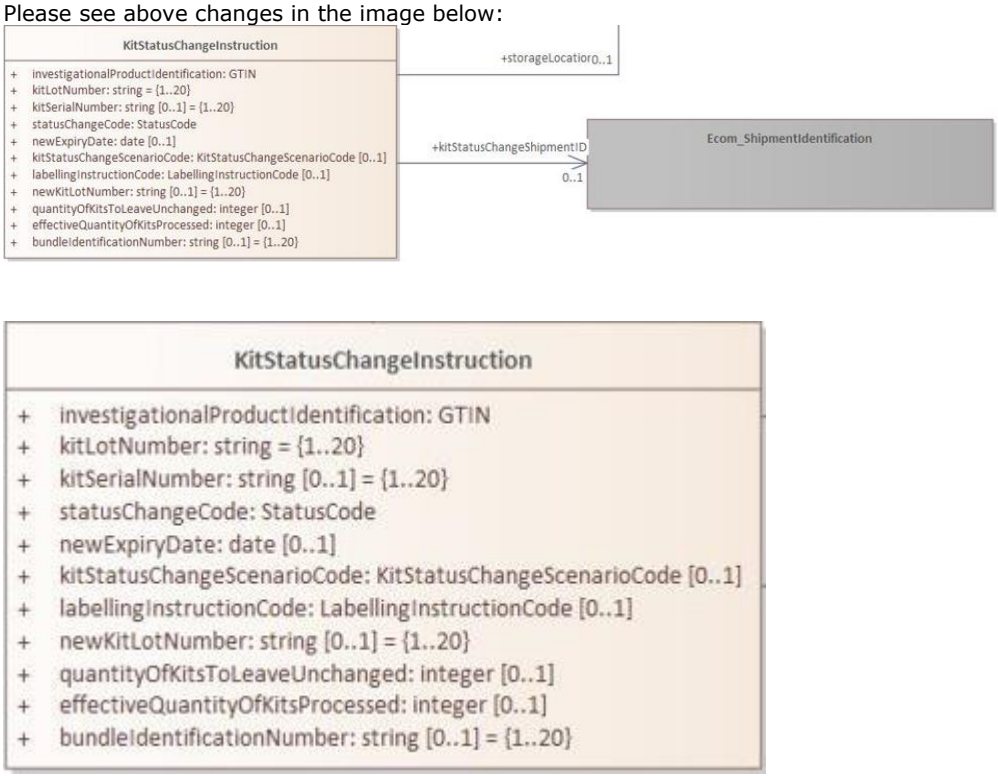
7.2 BMS Release 3.5

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	Associated CR Number
▪ **newExpiryDate** added as a new attribute to KitStatusChangeInstruction class with cardinality 0..1	WR 22-354
▪ **kitStatusChangeScenarioCode** added as a new codelist to KitstatusChangeInstruction class with cardinality of 0..1 , see CodeList section for potential values	WR 22-354
▪ **labellingInstructionCode** added as a new codelist to KitstatusChangeInstruction class with cardinality of 0..1 , see CodeList section for potential values	WR 22-354
▪ **newKitLotNumber** added as a new attribute to KitStatusChangeInstruction class with cardinality 0..1	WR 22-354
▪ **quantityOfKitsToLeaveUnchanged** integer added as a new attribute to KitStatusChangeInstruction class with cardinality 0..1	WR 22-354
▪ **effectiveQuantityOfKitsProcessed** integer added as a new attribute to KitStatusChangeInstruction class with cardinality 0..1	WR 22-354
▪ **bundleIdentificationNumber** added as a new attribute as a string to KitStatusChangeInstruction class with cardinality 0..1	WR 22-354
▪ **storageLocation** association cardinality change from 1..1 to 0..1	WR 22-354
▪ new association introduced to Ecom_ShipmentIdentification, named as **kitStatusChangeShipmentID**	WR 22-354
▪ Please see above changes in the image below: 	WR 22-354

8 Appendices

Not Applicable

9 Acknowledgements

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