



The Global Language of Business

Shipment Confirmation Business Message Standard (BMS)

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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	Revision by the group	Definition of classes and attributes, structure changes, examples, error fixing
24-sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Quantity attribute with capital letter corrected according to modelling writing rules, diagram updated, wrong code list url corrected, kitShipmentInformation class 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	WR 22-343 , WR 22-344

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1 Business Domain View

1.1 Introduction

Purpose

The Shipment Confirmation is sent from the depot back to the DME and confirms that an order will be or has been processed. This message includes many of the order specifics, including the supplies on the order.

This Shipment Confirmation 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
- Despatch Advice
- Receiving 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
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.

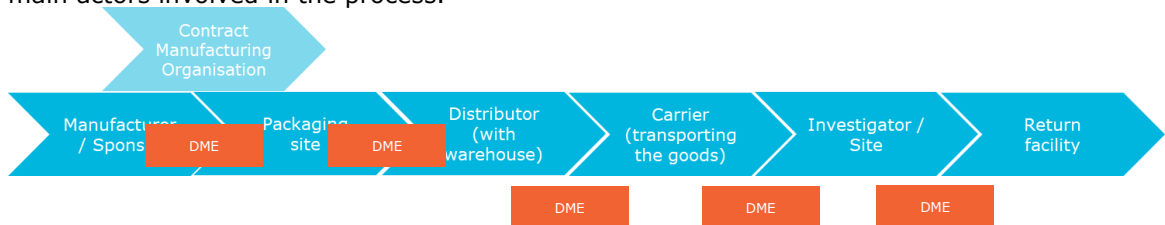


Table 3-1 Roles and responsibilities

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

Performance goals	To ensure accurate and timely advice that the shipment is ready.									
Preconditions	Unique identification of locations, trade items and logistics units. Correct identification of sender (Ship From) and receiver (Ship To) are in place.									
Post conditions	None identified									
Scenario	<p>Begins when the Ship From party sends a notification to the requestor of the shipment request (UC-1).</p> <p>Continues with...</p> <table border="1" data-bbox="552 589 1390 781"> <thead> <tr> <th>Step #</th> <th>Actor</th> <th>Activity step</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Requestor</td> <td>Receives the shipment confirmation.</td> </tr> <tr> <td>2</td> <td>Requestor</td> <td>Records the IP kit numbers in their systems.</td> </tr> </tbody> </table> <p>Ends when the Requestor receives and processes the shipment confirmation into their systems.</p>	Step #	Actor	Activity step	1	Requestor	Receives the shipment confirmation.	2	Requestor	Records the IP kit numbers in their systems.
Step #	Actor	Activity step								
1	Requestor	Receives the shipment confirmation.								
2	Requestor	Records the IP kit numbers in their systems.								
Alternative scenario	Not applicable									
Related requirements	None identified									
Related rules	None identified									

Activity Diagram(s)

Not applicable

Sequence Diagram(s)

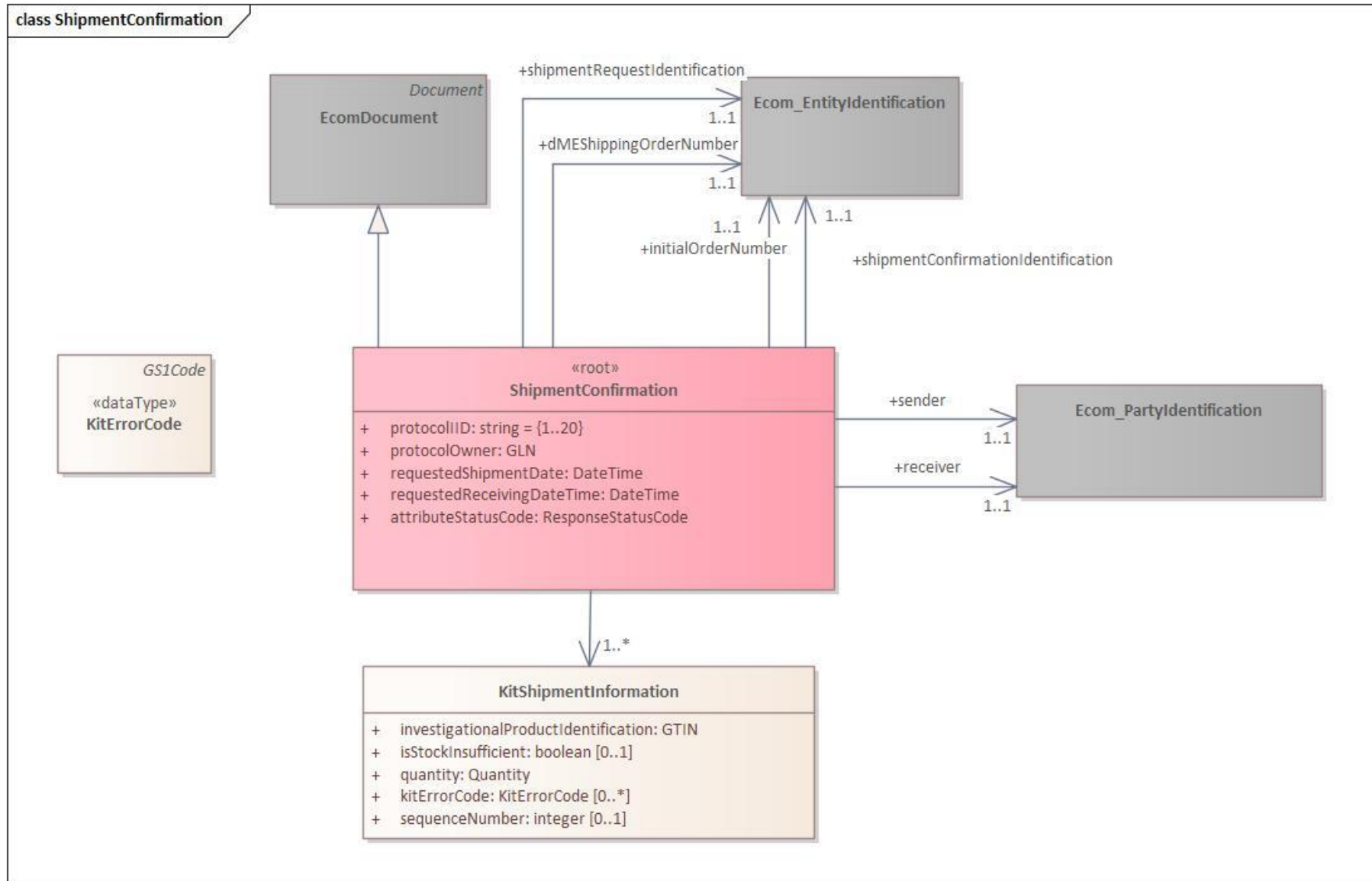
Not applicable



4 Business Information View

4.1 Shipment Confirmation

Class diagram





Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ShipmentConfirmation					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	The detailed message from the depot back to the DME that confirms that an order will be/ or has been processed.	
ASSOCIATION	shipmentConfirmationIdentification	Ecom_EntityIdentification	1..1	The identification of the EDI Shipment Notification message	
ASSOCIATION	shipmentRequestIdentification	Ecom_EntityIdentification	1..1	The reference to the request originating the shipment	
ASSOCIATION	dMESHippingOrderNumber	Ecom_EntityIdentification	1..1	The DME order number	
ASSOCIATION	initialOrderNumber	Ecom_EntityIdentification	1..1	The first order number originating the shipment process in case of multiple partial shipments	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The entity in charge of the shipment	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The entity generating the referred shipment request	
ASSOCIATION		KitShipmentInformation	1..*	Kit shipment information	
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	requestedShipmentDate	DateTime	1..1	Shipping date/time confirmation	
ATTRIBUTE	requestedReceivingDateTime	DateTime	1..1	The expected delivery date / time	
ATTRIBUTE	attributeStatusCode	ResponseStatusCode	1..1		WR-22-344
KitShipmentInformation					



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	isStockInsufficient	boolean	0..1	A flag indicating if the stock is enough to fulfill the requested shipment	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ATTRIBUTE	kitErrorCode	KitErrorCode	0..*	The code identifying an eventual error. Possible values in code list http://apps.gs1.org/GDD/bms/EANCOM/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:c/4295ChangeReasonDescriptionCode&release=4	
ATTRIBUTE	sequenceNumber	Integer	0..1		WR 22-343



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)

Not applicable.

4.3 Code Lists

Class	Codelist	GDD Link
KitShipmentInformation	KitErrorCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:KitErrorCode
ShipmentConfirmation (root)	attributeStatusCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:ResponseStatus



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

5 Business Message Examples

5.1 Example 1

Party Information

GS1 Global Location Number	Party Type
9520000000028	Sender - Depot
9520000000011	Receiver - DME
9520000000004	protocolOwner - Sponsor

Message Example 1

Attribute	Value
ShipmentConfirmation	
shipmentConfirmationIdentification	
entityIdentification	115
shipmentRequestIdentification	
entityIdentification	1
dMESHippingOrderNumber	
entityIdentification	13
initialOrderNumber	
entityIdentification	134
sender	
GLN	9520000000028
receiver	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004

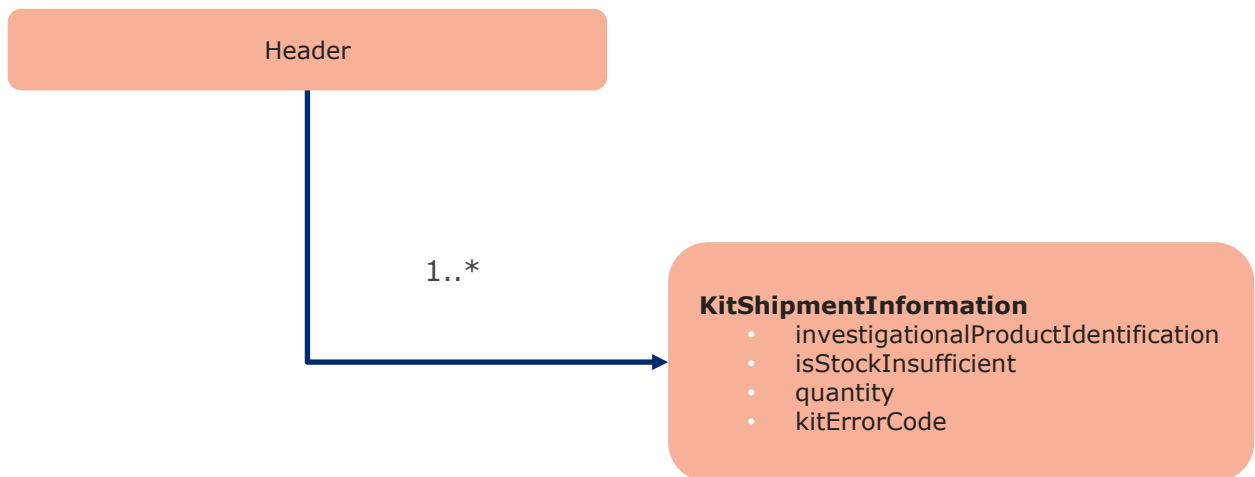
Attribute	Value
requestedShipmentDate	2020-03-26T00:00:00.000
requesteReceivingDateTime	2020-03-27T09:00:00.000+02:00
KitShipmentInformation	
investigationalProductIdentification	9520000000530
isStockInsufficient	Y
quantity	
quantity	0
kitErrorCode	WR

6 Implementation Considerations

6.1 User Guide

6.2 Message Specific Considerations

The message has only a simple detail loop with the detail of confirmed items and the reason codes for eventual unavailability of kits



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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> New attribute sequenceNumber added to KitShipmentInformation class which is an integer with cardinality 0..1 <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">KitShipmentInformation</p> <hr/> <ul style="list-style-type: none"> + investigationalProductIdentification: GTIN + isStockInsufficient: boolean [0..1] + quantity: Quantity + kitErrorCode: KitErrorCode [0..*] + sequenceNumber: integer [0..1] </div>	WR – 22-343
<ul style="list-style-type: none"> New Code added to ShipmentConfirmation class (root) attributeStatusCode <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">«root» ShipmentConfirmation</p> <hr/> <ul style="list-style-type: none"> + protocolIID: string = {1..20} + protocolOwner: GLN + requestedShipmentDate: DateTime + requestedReceivingDateTime: DateTime + attributeStatusCode: ResponseStatusCode </div>	WR 22-344

8 Appendices

Not Applicable

9 Acknowledgements

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Technical Development Lead	Miklos Bolyky	GS1 Global Office
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