



The Global Language of Business

Shipment Request 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
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group Revision	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Rearranged the line sequence in GDD report according to BMS writing rules, Class diagram corrected, Code list url 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
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 Shipment Request message is used to request the shipment of goods in any of the following scenarios: Serialised directed picking or free picking (blinded, open-label non-serialised or open-label serialised).

This Shipment Request 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 Notification
- Shipment Confirmation
- 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 communication with transport providers/couriers/carriers are 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 document 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.

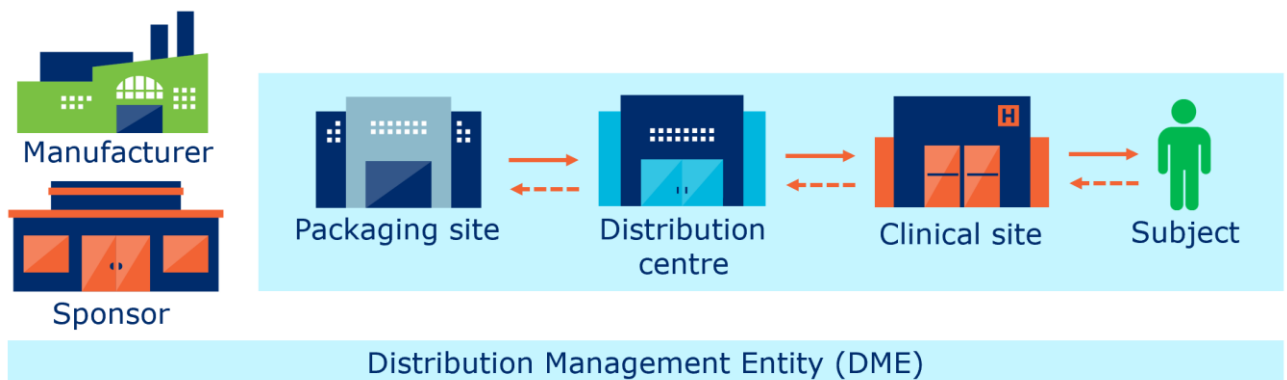


Table 3-1 Roles and responsibilities

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 7.2.2.

Performance goals	To create and deliver appropriate communication to ensure an accurate shipment, as requested by the requestor, to the correct recipient.												
Preconditions	Unique identification of locations, trade items and logistics units.												
Post conditions	None identified												
Scenario	<div>Begins when the DME requests that the depot prepare and send a shipment. Continues with...</div> <table><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>Ship From Party</td><td>Receives request with the list of goods to prepare.</td></tr><tr><td>2</td><td>Trial Site</td><td>Receives a copy of the request (optional).</td></tr><tr><td>3</td><td>Ship from Party</td><td>Provides (optional) shipment acknowledgment (order acknowledgement) that the shipment request has been received. This message does not go to the clinical site.</td></tr></table> <div>Ends with the acknowledgement of receipt of request to ship.</div>	Step #	Actor	Activity step	1	Ship From Party	Receives request with the list of goods to prepare.	2	Trial Site	Receives a copy of the request (optional).	3	Ship from Party	Provides (optional) shipment acknowledgment (order acknowledgement) that the shipment request has been received. This message does not go to the clinical site.
Step #	Actor	Activity step											
1	Ship From Party	Receives request with the list of goods to prepare.											
2	Trial Site	Receives a copy of the request (optional).											
3	Ship from Party	Provides (optional) shipment acknowledgment (order acknowledgement) that the shipment request has been received. This message does not go to the clinical site.											
Alternative scenario	Not applicable												
Related requirements	None identified												
Related rules	<div>1. The sponsor is the ultimate controller of inventory throughout the IP supply chain and determines the appropriate inventory levels at all locations.</div>												

Activity Diagram(s)

Not applicable

Sequence Diagram(s)

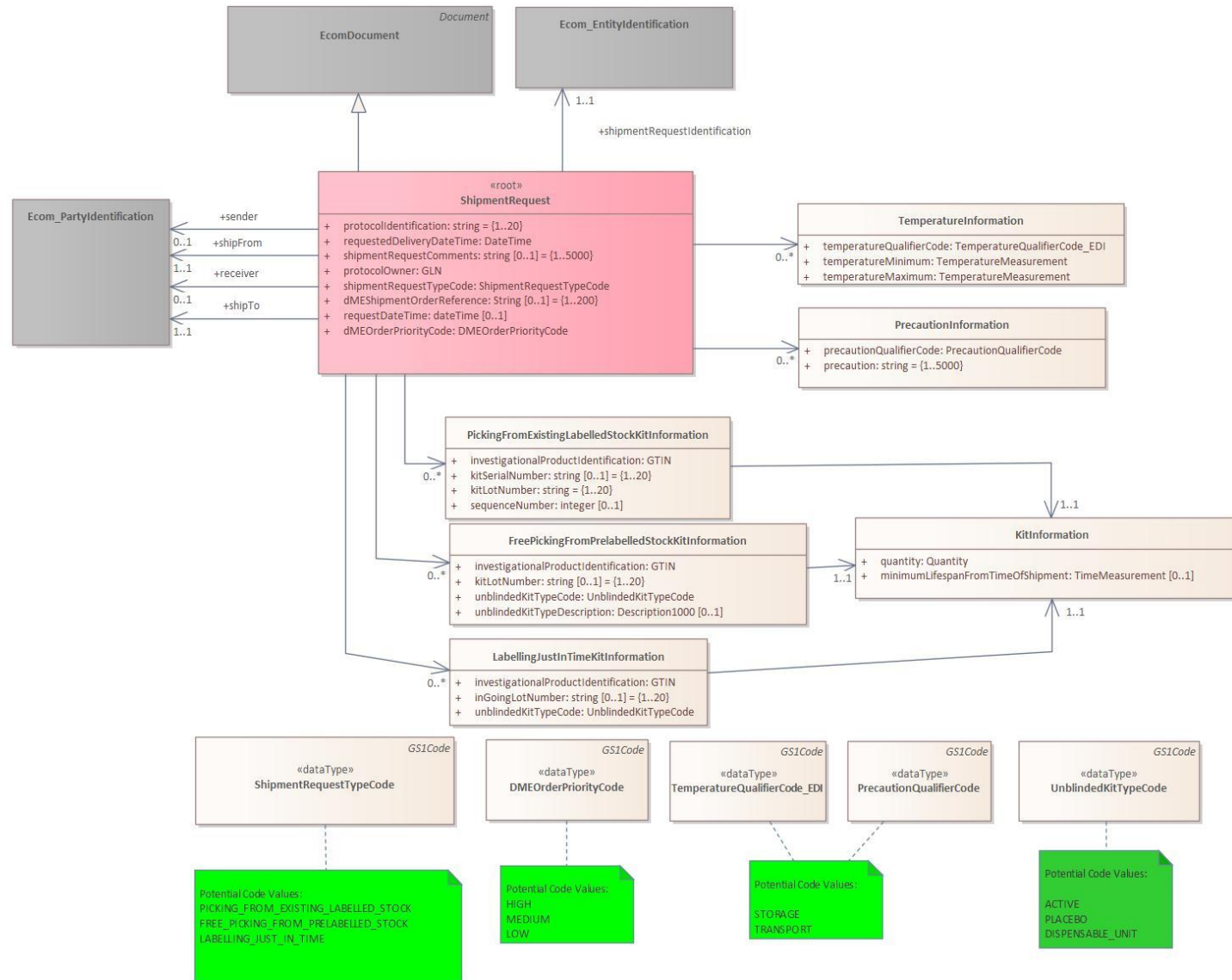
Not applicable

4 Business Information View

4.1 Shipment Request

Class diagram

class ShipmentRequest



Report

The content of the ShipmentRequest class, its structure and component definitions can be accessed in the GS1 Navigator:

[Message Details](#) | [EDI](#) | [Navigator](#) | [GS1](#)

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ShipmentRequest					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	The shipment request is used to request the shipment of goods. This message may be used to communicate the need to ship goods in any of the following scenarios: Serialised directed picking, free picking (blinded, open label non-serialised or open label serialised).	
ASSOCIATION	shipmentRequestIdentification	Ecom_EntityIdentification	1..1	The Unique identifier of the document	
ASSOCIATION	sender	Ecom_PartyIdentification	0..1	The generator of the message, the Distributor Management Entity or Third-party Depot	
ASSOCIATION	receiver	Ecom_PartyIdentification	0..1	The identification of the depot in charge of the shipment	
ASSOCIATION	shipFrom	Ecom_PartyIdentification	1..1	The GLN of the site from where the goods are shipped	
ASSOCIATION	shipTo	Ecom_PartyIdentification	1..1	The identification of the site where the goods are shipped to	
ASSOCIATION		TemperatureInformation	0..*	The temperature requirements for transport / storage	
ASSOCIATION		PrecautionInformation	0..*	The precaution description for transport / storage	
ASSOCIATION		PickingFromExistingLabelledStockKitInformation	0..*	The set of information applicable to the use case of picking from existing labelled stock	
ASSOCIATION		FreePickingFromPrelabelledStockKitInformation	0..*	The set of information applicable to the use case of free picking from existing labelled stock	
ASSOCIATION		LabellingJustInTimeKitInformation	0..*	The set of information applicable the use case of just in time labelling	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	dMESHipmentOrderReference	String	0..1	The reference number assigned by the DME to the shipment order	
ATTRIBUTE	protocolIdentification	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the Sponsor	
ATTRIBUTE	requestDateTime	DateTime		The date / time of the request	
ATTRIBUTE	requestedDeliveryDateTime	DateTime	1..1	The requested date / time for delivery	
ATTRIBUTE	shipmentRequestComments	string	0..1	Free text for special instructions or requests	{1..5000}
ATTRIBUTE	shipmentRequestTypeCode	ShipmentRequestType Code	1..1	The type of shipment requested	
TemperatureInformation					
ATTRIBUTE	temperatureQualifierCode	TemperatureQualifierCode	1..1	The context of application of the temperature information	
ATTRIBUTE	temperatureMinimum	TemperatureMeasurement	1..1	The minimum temperature allowed	
ATTRIBUTE	temperatureMaximum	TemperatureMeasurement	1..1	The maximum temperature allowed	
PrecautionInformation					
ATTRIBUTE	precautionQualifierCode	PrecautionQualifierCode	1..1	The context of application of the precaution instructions	
ATTRIBUTE	precaution	string	1..1	The precaution description	{1..5000}
PickingFromExistingLabelledStockKitInformation					
ASSOCIATION		KitInformation	1..1		
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	kitSerialNumber	string	0..1	The specific serial number of the kit ordered	{1..20}
ATTRIBUTE	kitLotNumber	string	1..1	The lot number identifying a group of investigational products	{1..20}
ATTRIBUTE	sequenceNumber	Int	0..1	The sequential number that is assigned to each patient kit during production for the purpose of identifying the kits during manufacture, and coordination of storage and distribution.	WR 22-343
FreePickingFromPr elabelledStockKitIn formation					
ASSOCIATION		KitInformation	1..1		
ATTRIBUTE	investigationalP roductIdentifica tion	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	0..1	The lot number identifying a group of labelled investigational products	{1..20}
ATTRIBUTE	unblindedKitTyp eCode	UnblindedKitTypeCode	0..1	The code identifying the type of unblinded medication kit to be shipped.	WR 23-000292
ATTRIBUTE	unblindedKitTyp eDescription	Description1000	0..1	A description field expressing the type of the unblinded kit.	WR 23-000292
LabellingJustInTim eKitInformation					
ASSOCIATION		KitInformation	1..1		
ATTRIBUTE	investigationalP roductIdentifica tion	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	inGoingLotNum ber	string	0..1	The original lot number assigned by the manufacturer to a not labeled kit component	{1..20}
ATTRIBUTE	unblindedKitTyp eCode	UnblindedKitTypeCode	1..1	The code identifying the type of unblinded medication kit to be shipped.	WR 22-342
Kitinformation					
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	minimumLifespanFromTimeOfShipment	TimeMeasurement	0..1	The minimum lifespan of the kit from the date of shipment	

4.2 Enumerations (message specific)

Not applicable.

4.3 Code Lists

Class	Codelist	Navigator Link
ShipmentRequest	ShipmentRequestTypeCode	CodeList Details EDI Navigator GS1
ShipmentRequest	DMEOrderPriorityCode	CodeList Details EDI Navigator GS1
TemperatureInformation	TemperatureQualifierCode	CodeList Details EDI Navigator GS1
PrecautionInformation	PrecautionQualifierCode	CodeList Details EDI Navigator GS1
LabellingJustInTimeKitInformation	UnblindedKitTypeCode	TBC



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

5 Business Message Examples

5.1 Example 1

Below is an example of a shipment request for a free picking.

Party Information

GS1 Global Location Number	Party Type
9520000000011	Sender - DME
9520000000028	Receiver - Depot
9520000000004	protocolOwner - Ssponsor
9520000000127	Delivery point

Message Example 1

Attribute	Value
ShipmentRequest	
shipmentRequestIdentification	
entityIdentification	1
sender	
GLN	9520000000011
receiver	
GLN	9520000000028
shipFrom	
GLN	9520000000028
shipTo	
GLN	9520000000127
protocolID	PROT1
protocoOwner	9520000000004

Attribute	Value
requestDateTime	2020-03-23T00:00:00.000
requestedDeliveryDateTime	2020-03-27T09:00:00.000+02:00
shipmentRequestComments	KEEP DRY
shipmentRequestTypeCode	FREE_PICKING
TemperatureInformation	
temperatureQualifierCode	TRANSPORT
temperatureMinimum	
value	10
temperatureMeasurementUnitCode	CEL
temperatureMaximum	
value	15
temperatureMeasurementUnitCode	CEL
PrecautionInformation	
precautionQualifierCode	TRANSPORT
precaution	DO NOT STACK
FreePickingFromPrelabelledStockKitInformation	
Kitinformation	
quantity	
quantity	1
measurementUnitCode	H87
minimumLifespanFromTimeOfShipment	30
investigationalProductIdentification	9520000000530
kitLotNumber	L001

5.2 Example 2

Below is an example of a shipment request for a picking from existing labelled stock

Party Information

GS1 Global Location Number	Party Type
9520000000011	Sender - DME
9520000000028	Receiver - Depot
9520000000004	protocolOwner - Ssponsor
9520000000127	Delivery point

Message Example 2

Attribute	Value
ShipmentRequest	
shipmentRequestIdentification	
entityIdentification	1
sender	
GLN	9520000000011

Attribute	Value
receiver	
GLN	9520000000028
shipFrom	
GLN	9520000000028
shipTo	
GLN	9520000000127
protocolID	PROT1
protocoOwner	9520000000004
requestDateTime	2020-03-23T00:00:00.000
requestedDeliveryDateTime	2020-03-27T09:00:00.000+02:00
shipmentRequestComments	KEEP DRY
shipmentRequestTypeCode	FREE_PICKING
TemperatureInformation	
temperatureQualifierCode	TRANSPORT
temperatureMinimum	
value	10
temperatureMeasurementUnitCode	CEL
temperatureMaximum	
value	15
temperatureMeasurementUnitCode	CEL
PrecautionInformation	
precautionQualifierCode	TRANSPORT
precaution	DO NOT STACK
PickingFromExistingLabelledStockKitInformation	
Kitinformation	
quantity	
quantity	1
measurementUnitCode	H87
minimumLifespanFromTimeOfShipment	30
investigationalProductIdentification	95200000000530
kitSerialNumber	123454
kitLotNumber	L001

6 Implementation Considerations

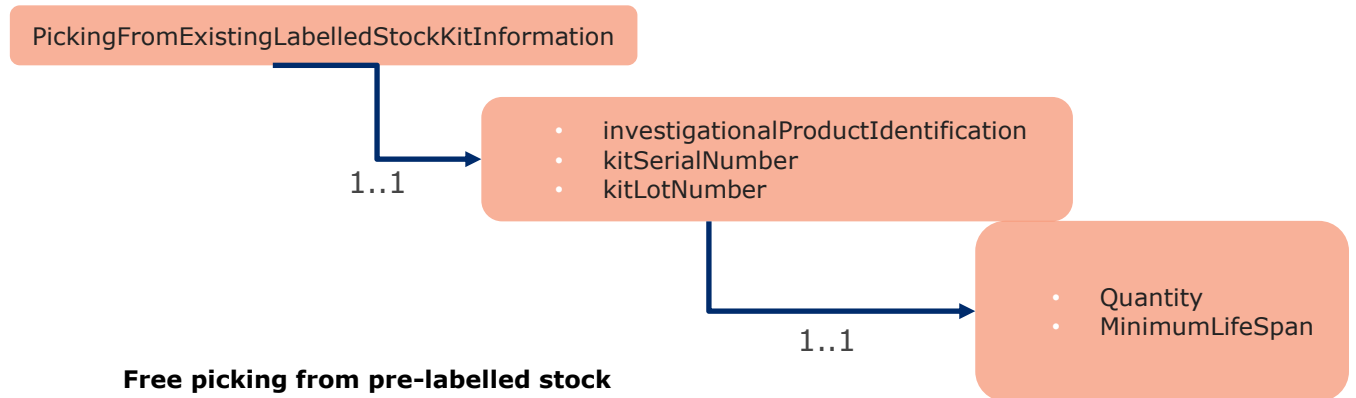
6.1 User Guide

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

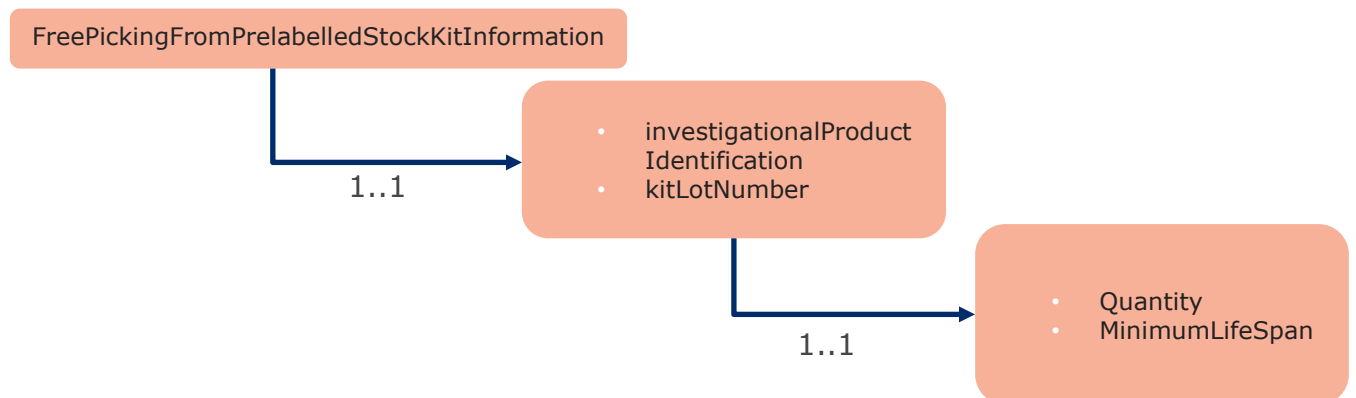
6.2 Message Specific Considerations

The Shipment Request message is designed to map three different kind of picking. The structure of the message and the data set required are different, depending on the specific use case.

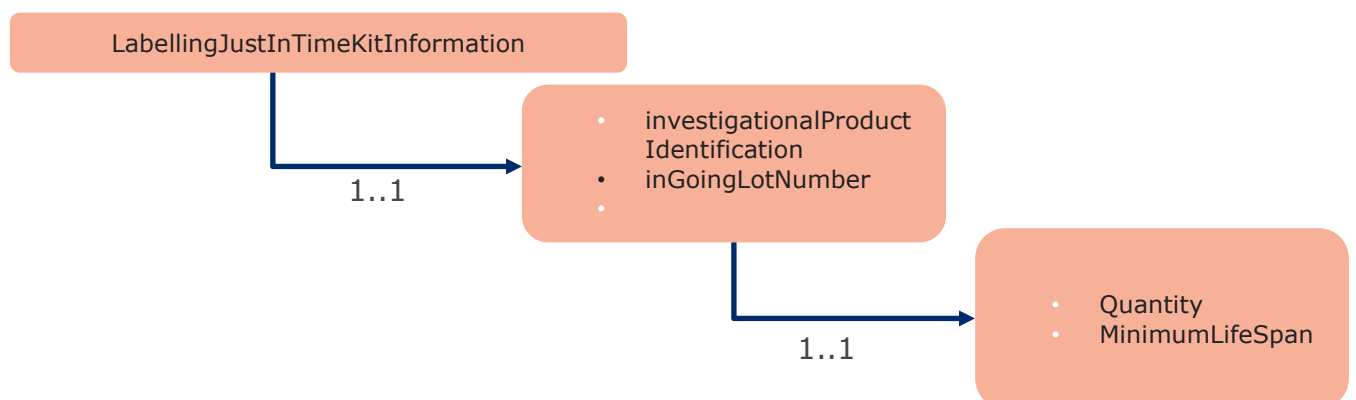
Picking from existing labelled stock



Free picking from pre-labelled stock



Labelling Just in Time



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 unblindedKitTypeCode added to LabellingJustInTimeKitInformation class which is a codelist with cardinality 1..1 <div data-bbox="317 1254 948 1469"> <p>LabellingJustInTimeKitInformation</p> <ul style="list-style-type: none"> + investigationalProductIdentification: GTIN + inGoingLotNumber: string [0..1] = {1..20} + unblindedKitTypeCode: UnblindedKitTypeCode </div>	WR 22-342
<ul style="list-style-type: none"> New attribute sequenceNumber added to PickingFromExistingLabelledStockKitInformation class which is an integer with a cardinality 0..1 <div data-bbox="317 1568 1010 1812"> <p>PickingFromExistingLabelledStockKitInformation</p> <ul style="list-style-type: none"> + investigationalProductIdentification: GTIN + kitSerialNumber: string [0..1] = {1..20} + kitLotNumber: string = {1..20} + sequenceNumber: integer [0..1] </div>	WR-22-343

7.5 BMS Release 3.7

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"> Added an existing attribute unblindedKitTypeCode to the class freepickingfromprelabelledstock. 	23-000292
<ul style="list-style-type: none"> Added an existing attribute unblindedKitTypeDescription to the class freepickingfromprelabelledstock as an optional description1000 field. 	23-000292
<ul style="list-style-type: none"> Changed the cardinality of kitLotNumber from 1..1 to 0..1 	23-000292
<pre> classDiagram class ShipmentRequest { +protocolIdentification: string [1..20] +requestedDeliveryDateTime: DateTime +shipmentRequestComments: string [0..1] [1..5000] +protocolOwner: GLN +shipmentRequestTypeCode: ShipmentRequestTypeCode +dMEShipmentOrderReference: string [0..1] [1..200] +requestDateTime: DateTime [0..1] +dMEOrderPriorityCode: DMEOrderPriorityCode } class EcomDocument { } class Ecom_EntityIdentification { } class Ecom_PartyIdentification { } class TemperatureInformation { +temperatureQualifierCode: TemperatureQualifierCode EDI +temperatureMinimum: TemperatureMeasurement +temperatureMaximum: TemperatureMeasurement } class PrecautionInformation { +precautionQualifierCode: PrecautionQualifierCode +precaution: string [1..5000] } class PickingFromExistingLabelledStockKitInformation { +investigationalProductIdentification: GTIN +kitSerialNumber: string [0..1] [1..20] +kitLotNumber: string [1..20] +sequenceNumber: integer [0..1] } class FreePickingFromPrelabelledStockKitInformation { +investigationalProductIdentification: GTIN +kitLotNumber: string [0..1] [1..20] +unblindedKitTypeCode: UnblindedKitTypeCode +unblindedKitTypeDescription: Description1000 [0..1] } class LabellingJustInTimeKitInformation { +investigationalProductIdentification: GTIN +incomingLotNumber: string [0..1] [1..20] +unblindedKitTypeCode: UnblindedKitTypeCode } class ShipmentRequestTypeCode { } class DMEOrderPriorityCode { } class TemperatureQualifierCode EDI { } class PrecautionQualifierCode { } class UnblindedKitTypeCode { } ShipmentRequest -- > EcomDocument ShipmentRequest -- > Ecom_EntityIdentification ShipmentRequest -- > Ecom_PartyIdentification ShipmentRequest -- "0..1" -- "0..1" Ecom_PartyIdentification : +sender ShipmentRequest -- "0..1" -- "0..1" Ecom_PartyIdentification : +shipFrom ShipmentRequest -- "0..1" -- "0..1" Ecom_PartyIdentification : +receiver ShipmentRequest -- "0..1" -- "0..1" Ecom_PartyIdentification : +shipTo ShipmentRequest -- "0..1" -- "0..1" Ecom_PartyIdentification : +shipTo ShipmentRequest -- "0..1" -- "0..1" TemperatureInformation ShipmentRequest -- "0..1" -- "0..1" PrecautionInformation ShipmentRequest -- "0..1" -- "0..1" PickingFromExistingLabelledStockKitInformation ShipmentRequest -- "0..1" -- "0..1" FreePickingFromPrelabelledStockKitInformation ShipmentRequest -- "0..1" -- "0..1" LabellingJustInTimeKitInformation ShipmentRequestTypeCode -- > ShipmentRequest DMEOrderPriorityCode -- > ShipmentRequest TemperatureQualifierCode EDI -- > ShipmentRequest PrecautionQualifierCode -- > ShipmentRequest UnblindedKitTypeCode -- > ShipmentRequest </pre>	

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

Function	Name	Company / organisation
WG chair	Olivia Chauvel (Chair)	CH Victor Dupouy

Function	Name	Company / organisation
WG chair	Pierre Fernandez-Barbureau (Chair)	SANOFI
WG chair	Hans von Steiger (Chair)	Pfizer
WG member	Jean-Michel Descoutures	International Hospital Federation (IHF)
WG member	Feargal Mc Groarty	St. James's Hospital
WG member	Vincent Puglia	endpoint clinical
WG member	Mike Meakin	DHL
WG member	Sylvain Alberola	SANOFI
WG member	Céline Bordes-Terrier	CREAPHARM
WG member	Giedré Bracaité	F. Hoffmann-La Roche Ltd.
WG member	Doris Cadart	SANOFI
WG member	Pedro Carvalho	Ipsen
WG member	Robert Giguere	AbbVie
WG member	Nicolas Gryspeert	F. Hoffmann-La Roche Ltd.
WG member	Michael Hoefling	Boehringer Ingelheim Pharma GmbH & Co.KG
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WG member	Marco Inserra	CSL Behring GmbH
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WG member	Arpad Boldis	Deloitte
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WG member	Andreas Geissler	PAREXEL International GmbH
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WG member	Mike Hutton	Almac Clinical Technologies
WG member	Kelly Knowles	Bracket Global
WG member	Jitendra Kumar	Thermo Fisher Scientific
WG member	Cherish Lallone	McCreadie Group
WG member	Charlotte Meuldermans	Deloitte
WG member	Fabiana Monaco	PAREXEL International GmbH
WG member	Josef Preishuber-Pflügl	CISC Semiconductor GmbH

Function	Name	Company / organisation
WG member	Theodora Sarver	Almac Clinical Technologies
WG member	Michael schlesselman	McCreadie Group
WG member	Colette Thorold	PAREXEL International GmbH
WG member	Elizabeth Waldorf	TraceLink
WG member	Stefan Zietze	PAREXEL International GmbH
WG member	Andrea Zobel	PAREXEL International GmbH
WG member	Shreenidhi Bharadwaj	Syndigo
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WG member	Camille Labeaune	GS1 France
WG member	Ildikó Lieber	GS1 Hungary
WG member	Valerie Marchand	GS1 France
WG member	Adrien Molines	GS1 France
WG member	Zubair Nazir	GS1 Canada
WG member	Alice Nguyen	GS1 Vietnam
WG member	James Perng	GS1 Chinese Taipei
WG member	James Perng	GS1 Chinese Taipei
WG member	Paul Reid	GS1 UK
WG member	Sylvia Reingardt	GS1 Germany
WG member	Sue Schmid	GS1 Australia
WG member	Julian Sin	GS1 Hong Kong, China
WG member	Mig Smith	GS1 UK

Function	Name	Company / organisation
WG member	Peter Sturtevant	GS1 US
WG member	Flora Sue	GS1 China
WG member	Sarah Torrance	GS1 UK
WG member	Koichi Uemura	GS1 Japan
WG member	Amber Walls	GS1 US
WG member	Connie Wong	GS1 Canada
WG member	Pete Alvarez	GS1 Global Office
WG member	Jean-Luc Champion	GS1 Global Office
WG member	Steven Keddie	GS1 Global Office
WG member	Neil Piper	GS1 Global Office
WG member	Greg Rowe	GS1 Global Office
WG member	Tania Snioch	GS1 Global Office

9.1.2 Development Team Members

Function	Name	Organisation
GSMP Process Lead	David Buckley	GS1 Global Office
Technical Development Lead	Miklos Bolyky	GS1 Global Office
Peer Review	Mark Van Eeghem	GS1 Global Office