



The Global Language of Business

# Shipment Request Business Message Standard (BMS)

*Release 3.6, Ratified, Mar 2023*



## Document Summary

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## Business Requirements Document (BRAD) Reference

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
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



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# Table of Contents

<b>1</b>	<b>Business Domain View</b>	<b>5</b>
1.1	Introduction	5
1.2	References	5
<b>2</b>	<b>Business Context</b>	<b>6</b>
<b>3</b>	<b>Business Transaction View</b>	<b>6</b>
<b>4</b>	<b>Business Information View</b>	<b>8</b>
4.1	Shipment Request	8
4.2	Enumerations (message specific)	13
4.3	Code Lists	13
<b>5</b>	<b>Business Message Examples</b>	<b>13</b>
5.1	Example 1	13
5.2	Example 2	14
<b>6</b>	<b>Implementation Considerations</b>	<b>16</b>
6.1	User Guide	16
6.2	Message Specific Considerations	16
<b>7</b>	<b>Summary of Changes</b>	<b>17</b>
7.1	BMS Release 3.4.2	17
7.2	BMS Release 3.5	17
7.3	BMS Release 3.5.1	17
7.4	BMS Release 3.6	17
<b>8</b>	<b>Appendices</b>	<b>18</b>
<b>9</b>	<b>Acknowledgements</b>	<b>18</b>
9.1.1	Work Group	18
9.1.2	Development Team Members	20

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

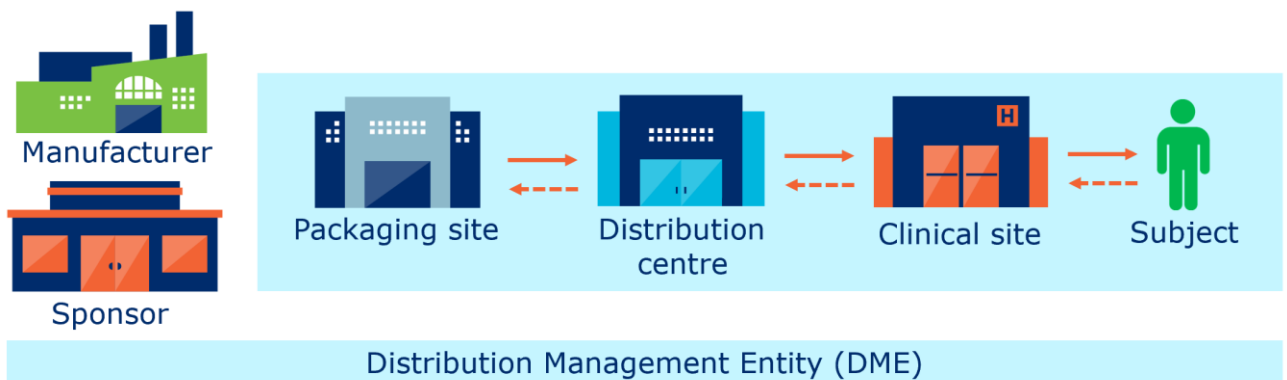
## 2 Business Context

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	<p>Begins when the DME requests that the depot prepare and send a shipment. Continues with...</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #003366; color: white;"> <th style="text-align: center;">Step #</th> <th style="text-align: center;">Actor</th> <th style="text-align: center;">Activity step</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td>Ship From Party</td> <td>Receives request with the list of goods to prepare.</td> </tr> <tr> <td style="text-align: center;">2</td> <td>Trial Site</td> <td>Receives a copy of the request (optional).</td> </tr> <tr> <td style="text-align: center;">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> </tbody> </table> <p>Ends with the acknowledgement of receipt of request to ship.</p>		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	<ol style="list-style-type: none"> <li>1. The sponsor is the ultimate controller of inventory throughout the IP supply chain and determines the appropriate inventory levels at all locations.</li> </ol>													

### Activity Diagram(s)

Not applicable

### Sequence Diagram(s)

Not applicable



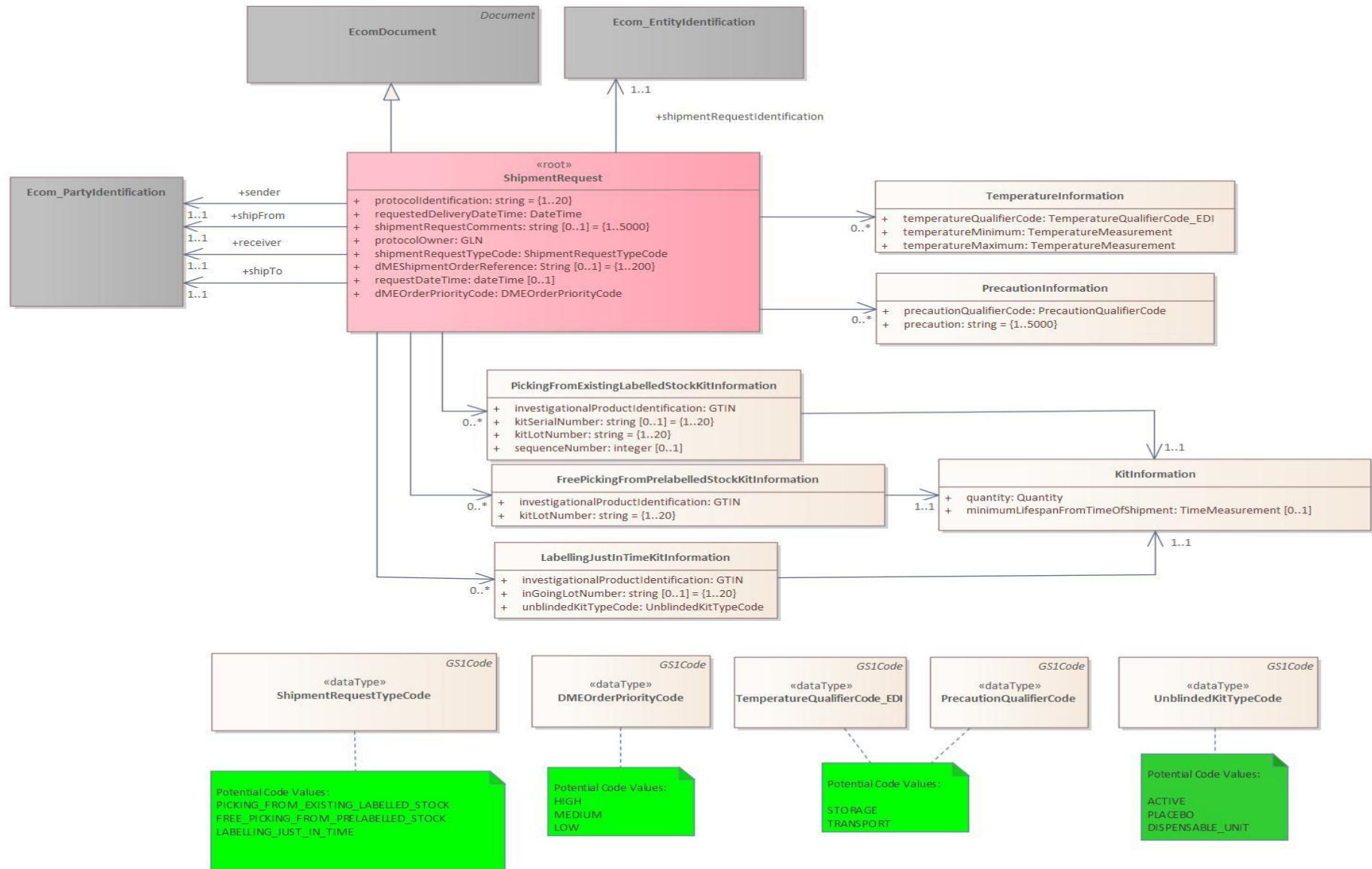
## **4 Business Information View**

### **4.1 Shipment Request**

**Class diagram**



class ShipmentRequest



**Global Data Dictionary (GDD) report**

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
<b>ShipmentRequest</b>					
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	1..1	The generator of the message, the Distributor Management Entity or Third-party Depot	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..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	
ATTRIBUTE	dMESHipmentOrderReference	String	0..1	The reference number assigned by the DME to the shipment order	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
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	ShipmentRequestTypeCode	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	
ATTRIBUTE	kitSerialNumber	string	0..1	The specific serial number of the kit ordered	{1..20}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
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
FreePickingFromPrelabelledStockKitInformation					
ASSOCIATION		KitInformation	1..1		
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	1..1	The lot number identifying a group of labelled investigational products	{1..20}
LabellingJustInTimeKitInformation					
ASSOCIATION		KitInformation	1..1		
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	inGoingLotNumber	string	0..1	The original lot number assigned by the manufacturer to a not labeled kit component	{1..20}
ATTRIBUTE	unblindedKitTypeCode	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	
ATTRIBUTE	minimumLifespanFromTimeOfShipment	TimeMeasurement	0..1	The minimum lifespan of the kit from the date of shipment	



**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
ShipmentRequest	ShipmentRequestTypeCode	<a href="http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:ShipmentRequestTypeCode">http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:ShipmentRequestTypeCode</a>
ShipmentRequest	DMEOrderPriorityCode	<a href="http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:DMEOrderPriorityCode">http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:DMEOrderPriorityCode</a>
TemperatureInformation	TemperatureQualifierCode	<a href="http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:TemperatureQualifierCode">http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:TemperatureQualifierCode</a>
PrecautionInformation	PrecautionQualifierCode	<a href="http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:PrecautionQualifierCode">http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:PrecautionQualifierCode</a>
LabellingJustInTimeKitInformation	UnblindedKitTypeCode	<a href="http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:UnblindedKitTypeCode">http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:UnblindedKitTypeCode</a>



**Note:** Refer to the Global Data Dictionary (GDD) 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
<b>ShipmentRequest</b>	
<b>shipmentRequestIdentification</b>	
entityIdentification	1
<b>sender</b>	
GLN	9520000000011
<b>receiver</b>	
GLN	9520000000028
<b>shipFrom</b>	
GLN	9520000000028
<b>shipTo</b>	
GLN	9520000000127

Attribute	Value
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
<b>TemperatureInformation</b>	
temperatureQualifierCode	TRANSPORT
<b>temperatureMinimum</b>	
value	10
temperatureMeasurementUnitCode	CEL
<b>temperatureMaximum</b>	
value	15
temperatureMeasurementUnitCode	CEL
<b>PrecautionInformation</b>	
precautionQualifierCode	TRANSPORT
precaution	DO NOT STACK
<b>FreePickingFromPrelabelledStockKitInformation</b>	
<b>Kitinformation</b>	
<b>quantity</b>	
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
<b>ShipmentRequest</b>	
<b>shipmentRequestIdentification</b>	
entityIdentification	1



Attribute	Value
<b>sender</b>	
GLN	9520000000011
<b>receiver</b>	
GLN	9520000000028
<b>shipFrom</b>	
GLN	9520000000028
<b>shipTo</b>	
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
<b>TemperatureInformation</b>	
temperatureQualifierCode	TRANSPORT
<b>temperatureMinimum</b>	
value	10
temperatureMeasurementUnitCode	CEL
<b>temperatureMaximum</b>	
value	15
temperatureMeasurementUnitCode	CEL
<b>PrecautionInformation</b>	
precautionQualifierCode	TRANSPORT
precaution	DO NOT STACK
<b>PickingFromExistingLabelledStockKitInformation</b>	
<b>Kitinformation</b>	
<b>quantity</b>	
quantity	1
measurementUnitCode	H87
minimumLifespanFromTimeOfShipment	30
investigationalProductIdentification	9520000000530
kitSerialNumber	123454
kitLotNumber	L001

## 6 Implementation Considerations

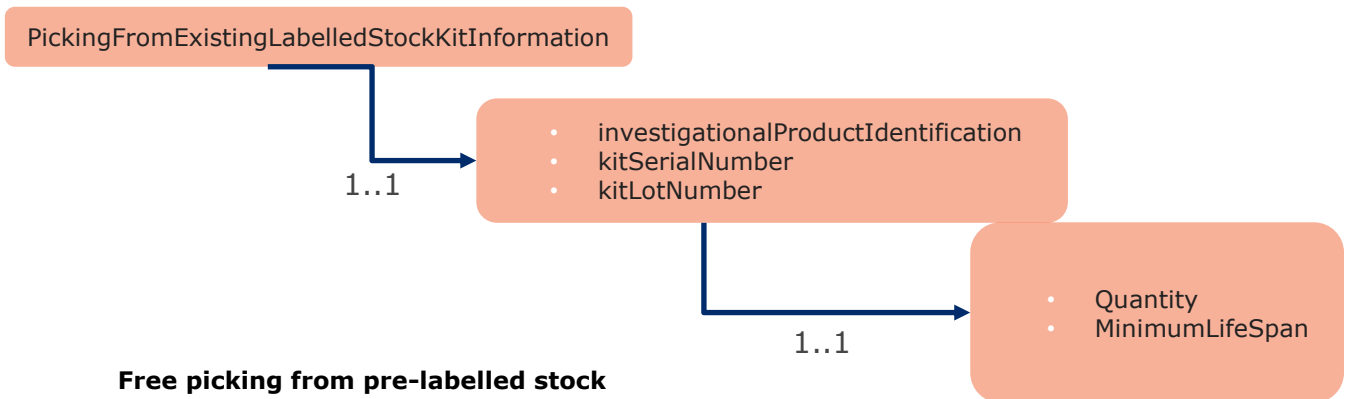
### 6.1 User Guide

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

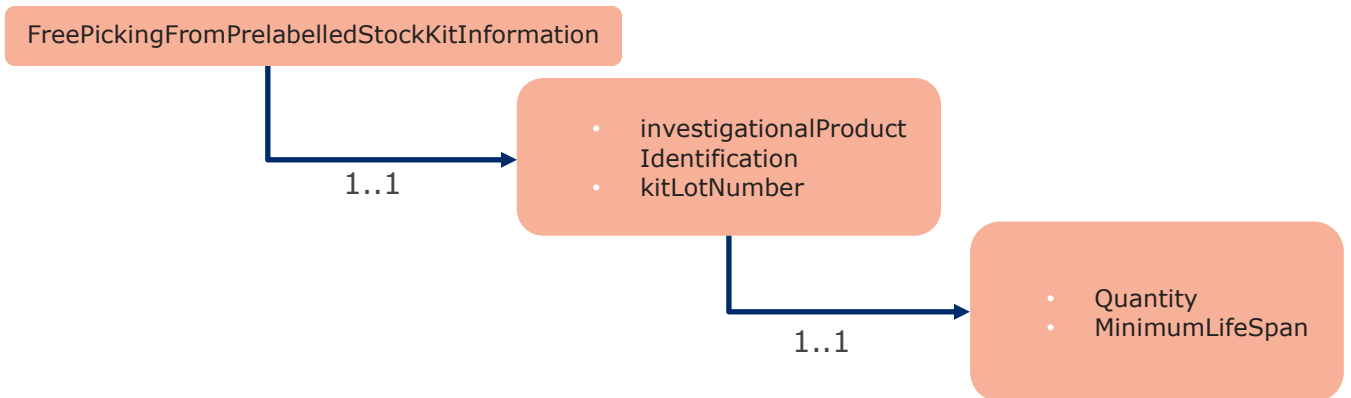
### 6.2 Message Specific Considerations

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.

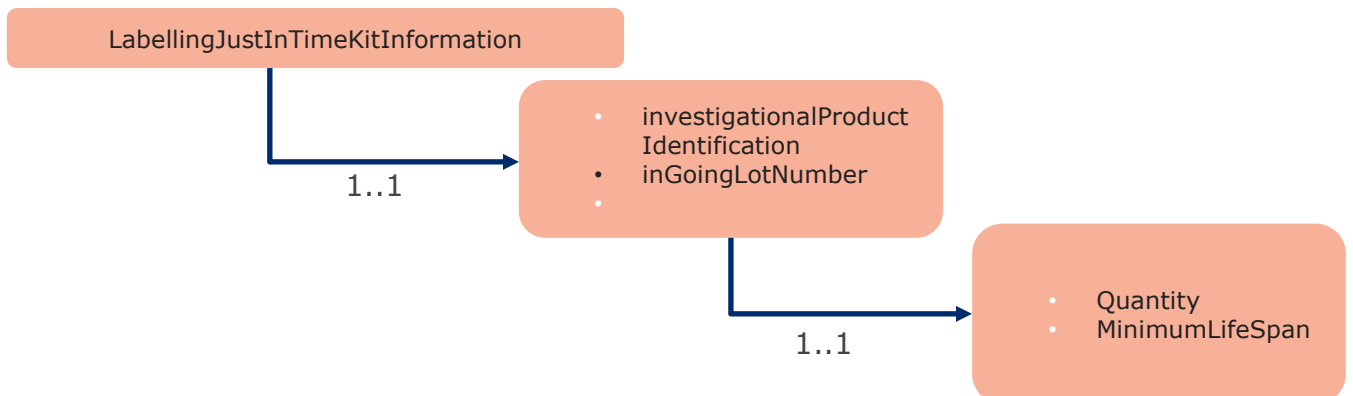
#### Picking from existing labelled stock



#### 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"> <li>Initial Draft</li> </ul>	

### 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"> <li>New attribute <b>unblindedKitTypeCode</b> added to LabellingJustInTimeKitInformation class which is a codelist with cardinality 1..1</li> </ul> <div style="border: 1px solid #ccc; padding: 5px; margin: 5px 0;"> <p style="text-align: center; margin: 0;"><b>LabellingJustInTimeKitInformation</b></p> <ul style="list-style-type: none"> <li>+ investigationalProductIdentification: GTIN</li> <li>+ inGoingLotNumber: string [0..1] = {1..20}</li> <li>+ unblindedKitTypeCode: UnblindedKitTypeCode</li> </ul> </div>	WR 22-342
<ul style="list-style-type: none"> <li>New attribute <b>sequenceNumber</b> added to PickingFromExistingLabelledStockKitInformation class which is an integer with a cardinality 0..1</li> </ul> <div style="border: 1px solid #ccc; padding: 5px; margin: 5px 0;"> <p style="text-align: center; margin: 0;"><b>PickingFromExistingLabelledStockKitInformation</b></p> <ul style="list-style-type: none"> <li>+ investigationalProductIdentification: GTIN</li> <li>+ kitSerialNumber: string [0..1] = {1..20}</li> <li>+ kitLotNumber: string = {1..20}</li> <li>+ sequenceNumber: integer [0..1]</li> </ul> </div>	WR-22-343

## 8 Appendices

Not Applicable

## 9 Acknowledgements

### 9.1.1 Work Group

Function	Name	Company / organisation
<b>WG chair</b>	Olivia Chauvel (Chair)	CH Victor Dupouy
<b>WG chair</b>	Pierre Fernandez-Barbureau (Chair)	SANOFI
<b>WG chair</b>	Hans von Steiger (Chair)	Pfizer
<b>WG member</b>	Jean-Michel Descoutures	International Hospital Federation (IHF)
<b>WG member</b>	Feargal Mc Groarty	St. James's Hospital
<b>WG member</b>	Vincent Puglia	endpoint clinical
<b>WG member</b>	Mike Meakin	DHL
<b>WG member</b>	Sylvain Alberola	SANOFI
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<b>WG member</b>	Doris Cadart	SANOFI
<b>WG member</b>	Pedro Carvalho	Ipsen
<b>WG member</b>	Robert Giguere	AbbVie
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<b>WG member</b>	Michael Hoefling	Boehringer Ingelheim Pharma GmbH & Co.KG
<b>WG member</b>	Richard Hwang	Pfizer
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<b>WG member</b>	Jason James	Bristol-Myers Squibb
<b>WG member</b>	Matthias Kallmeyer	Boehringer Ingelheim Pharma GmbH & Co.KG
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<b>WG member</b>	Robert Celeste	Center for Supply Chain Studies
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<b>WG member</b>	Andreas Geissler	PAREXEL International GmbH
<b>WG member</b>	Mark Hanly	Almac Clinical Technologies

Function	Name	Company / organisation
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<b>WG member</b>	Kelly Knowles	Bracket Global
<b>WG member</b>	Jitendra Kumar	Thermo Fisher Scientific
<b>WG member</b>	Cherish Lallone	McCreadie Group
<b>WG member</b>	Charlotte Meuldermans	Deloitte
<b>WG member</b>	Fabiana Monaco	PAREXEL International GmbH
<b>WG member</b>	Josef Preishuber-Pflügl	CISC Semiconductor GmbH
<b>WG member</b>	Theodora Sarver	Almac Clinical Technologies
<b>WG member</b>	Michael schlesselman	McCreadie Group
<b>WG member</b>	Colette Thorold	PAREXEL International GmbH
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<b>WG member</b>	Jiraporn Chalermjirarat	GS1 Thailand
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<b>WG member</b>	Jesper Kervin Franke	GS1 Denmark
<b>WG member</b>	Stefan Gathmann	GS1 Ireland
<b>WG member</b>	Nicole Golestani	GS1 Canada
<b>WG member</b>	Rami Habbal	GS1 UAE
<b>WG member</b>	Michaela Hähn	GS1 Germany
<b>WG member</b>	Christine Horvath-Hanko	GS1 Hungary
<b>WG member</b>	Anna Klapper	GS1 Germany
<b>WG member</b>	Catherine Koetz	GS1 Australia
<b>WG member</b>	Anne-Claire Krid	GS1 France
<b>WG member</b>	Camille Labeaune	GS1 France
<b>WG member</b>	Ildikó Lieber	GS1 Hungary
<b>WG member</b>	Valerie Marchand	GS1 France
<b>WG member</b>	Adrien Molines	GS1 France
<b>WG member</b>	Zubair Nazir	GS1 Canada
<b>WG member</b>	Alice Nguyen	GS1 Vietnam
<b>WG member</b>	James Perng	GS1 Chinese Taipei

Function	Name	Company / organisation
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<b>WG member</b>	Paul Reid	GS1 UK
<b>WG member</b>	Sylvia Reingardt	GS1 Germany
<b>WG member</b>	Sue Schmid	GS1 Australia
<b>WG member</b>	Julian Sin	GS1 Hong Kong, China
<b>WG member</b>	Mig Smith	GS1 UK
<b>WG member</b>	Peter Sturtevant	GS1 US
<b>WG member</b>	Flora Sue	GS1 China
<b>WG member</b>	Sarah Torrance	GS1 UK
<b>WG member</b>	Koichi Uemura	GS1 Japan
<b>WG member</b>	Amber Walls	GS1 US
<b>WG member</b>	Connie Wong	GS1 Canada
<b>WG member</b>	Pete Alvarez	GS1 Global Office
<b>WG member</b>	Jean-Luc Champion	GS1 Global Office
<b>WG member</b>	Steven Keddie	GS1 Global Office
<b>WG member</b>	Neil Piper	GS1 Global Office
<b>WG member</b>	Greg Rowe	GS1 Global Office
<b>WG member</b>	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