



The Global Language of Business

Clinical Trial Request For Inventory Report Business Message Standard (BMS)

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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	Change after workgroup revision	Structure changes, classes and attributes definitions
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
14-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after community revision	
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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
23-Jan-2022	BMS 3.6	Miklos Bolyky	BMS Release 3.6	See summary of changes

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1 Business Domain View

1.1 Introduction

Purpose

The Request for Inventory Report communicates a request for provision of an inventory report, which gives current information about inventory levels. The inventory report request is related to finished products as identified GTINs.

This Request for Inventory 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
- 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 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.

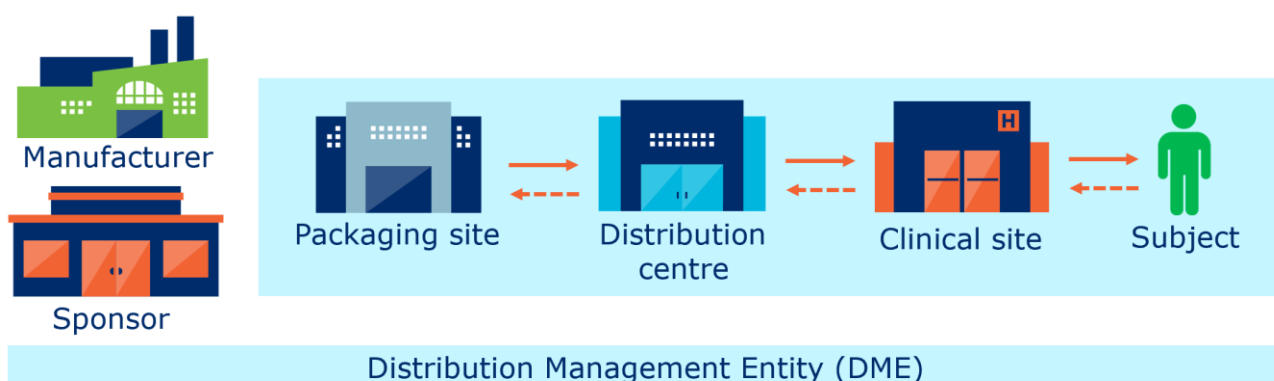


Table 3-1 Roles and responsibilities

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.
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Use Case Diagram

N/A

Use Case Description

Below is the use case detailed in *the Guideline*, section 7.8.

Performance goals	A request to drive the subsequent action of sending an inventory report.						
Preconditions	Unique identification of locations, trade items and logistics units will be undertaken. Correct identification receiver (Ship To/inventory location) are in place.						
Postconditions	None identified						
Scenario	<p>Begins when the sponsor sends a message to ask for inventory levels from across the supply chain.</p> <p>Continues with...</p> <table><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>Receiver</td><td>Receives communication.</td></tr></table> <p>Ends when the Receiver takes action to provide inventory level information.</p>	Step #	Actor	Activity step	1	Receiver	Receives communication.
Step #	Actor	Activity step					
1	Receiver	Receives communication.					
Alternative scenario	Not applicable						
Related requirements	None identified						
Related rules	None identified						

Activity Diagram(s)

Not applicable

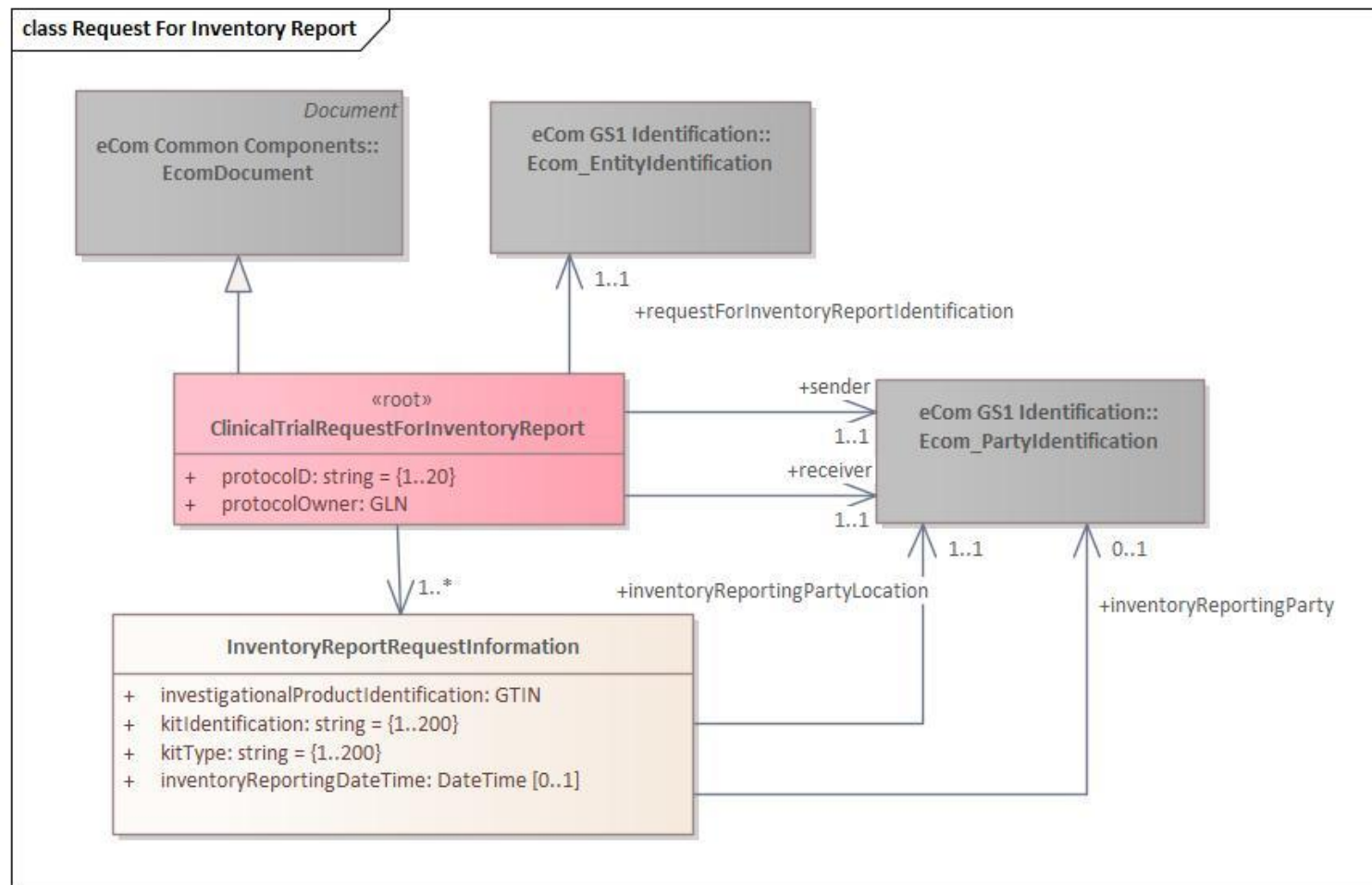
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Clinical Trial Request For Inventory Report

Class diagram





Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ClinicalTrialRequestForInventory Report				The Request for Inventory Report communicates a request for provision of an inventory report, which gives current information about inventory levels. The inventory report request is related to finished products as identified GTINs.	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	requestForInventoryReportIdentification	Ecom_EntityIdentification	1..1	The unique identification of the inventory request	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The sender of the request, usually the sponsor or the DME	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The organization in charge of the physical sites where items are located	
ASSOCIATION		InventoryReportRequestInformation	1..*	The set of parameters necessary to identify the items for which the inventory is requested	
ATTRIBUTE	protocolID	string	1..1	The unique identifier of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the sponsor of the protocol	
InventoryReportRequestInformation					
ASSOCIATION	inventoryReportingPartyLocation	Ecom_PartyIdentification	1..1	The GLN of the physical location for which the inventory is requested	
ASSOCIATION	inventoryReportingParty	Ecom_PartyIdentification	0..1	The GLN of the entity reporting the inventory when different from the receiver of the request in the header	
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	kitIdentification	string	1..1	The identification of the kit (usually serial+GTIN or protocol number)	{1..200}
ATTRIBUTE	kitType	string	1..1	The medication type (ACTIVE, PLACEBO)	{1..200}
ATTRIBUTE	inventoryReportingDateTime	DateTime	0..1	The reference date of the requested inventory	



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



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
9520000000004	Sponsor
9520000000011	Sender - DME
9520000000127	Receiver - Organization receiving the request
9520000000028	Kit Location

Message Example 1

Attribute	Value
ClinicalTrialRequestForInventoryReport	
requestForInventoryReportIdentification	
entityIdentification	10
sender	
GLN	9520000000011
receiver	
GLN	9520000000127
protocolID	PROT1
protocolOwner	9520000000004
InventoryReportRequestInformation	
InventoryReportingPartyLocation	
GLN	9520000000028
investigationalProductIdentification	9520000000530
kitIdentification	9520000000280001
kitType	PLACEBO

Attribute	Value
inventoryReportingDateTime	2020-08-22T00:00:00.000

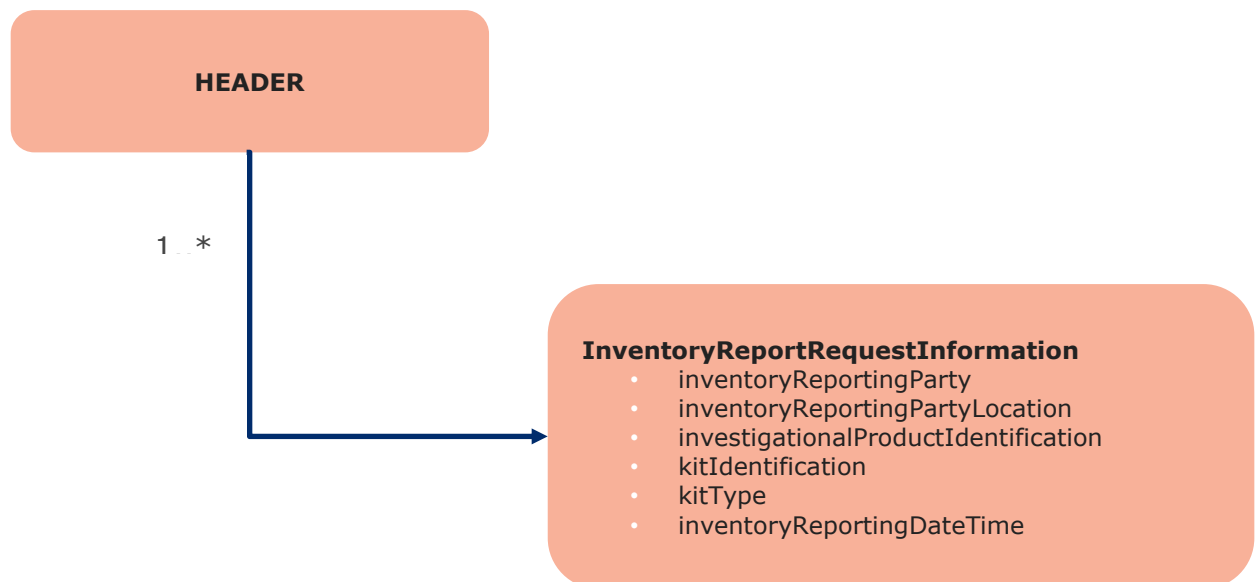
6 Implementation Considerations

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 message includes the list of the specific kits for which the inventory status is required



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

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

8 Appendices

Not Applicable

9 Acknowledgements

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