



The Global Language of Business

Shipment Notification Business Message Standard (BMS)

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Document Summary

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3-Apr-2020	BMS 3.4.2	Mark Van Eeghem	Initial Draft	Initial Draft
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello	Changes after group revision	Changes to structure and attribute definitions.
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Class diagram update
15-Jan-2021	BMS 3.5 – Issue 1	Miklos Bolyky	BMS Release 3.5	See summary of changes
05-Jan-2022	BMS 3.5.1 – Issue 1	Miklos Bolyky	BMS Release 3.5.1	See summary of changes

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Table of Contents

1	Business Domain View	5
1.1	Introduction	5
1.2	References	5
2	Business Context	6
3	Business Transaction View	6
4	Business Information View	8
4.1	Shipment Notification	8
4.2	Enumerations (message specific)	10
4.3	Code Lists	10
5	Business Message Examples	10
5.1	Example 1	10
6	Implementation Considerations	11
6.1	User Guide	11
6.2	Message Specific Considerations	11
7	Summary of Changes	11
7.1	BMS Release 3.4.2	11
7.2	BMS Release 3.5	11
7.3	BMS Release 3.5.1	11
8	Appendices	11
9	Acknowledgements	12
9.1.1	Work Group	12
9.1.2	Development Team Members	14

1 Business Domain View

1.1 Introduction

- **Purpose**

The Shipment Notification is the acknowledgment of the Shipment Request message. The Shipment Notification should be sent by the recipient once the Shipment Request message is received by the recipient. This Shipment Notification 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 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 guideline detailing 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.

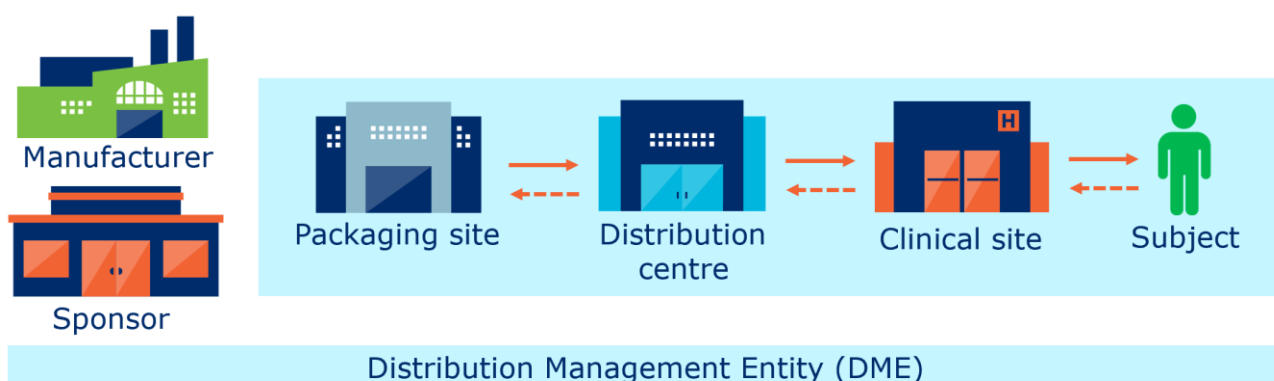


Table 3-1 Roles and responsibilities

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 7.3.2

Performance goals	To ensure an accurate and timely acknowledgement that the shipment request has been received.								
Preconditions	Unique identification of locations, trade items and logistics units will be undertaken. 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><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>Requestor</td><td>Receives the shipment notification.</td></tr></table> <p>Ends when the Requestor provides the shipment notification.</p>			Step #	Actor	Activity step	1	Requestor	Receives the shipment notification.
Step #	Actor	Activity step							
1	Requestor	Receives the shipment notification.							
Alternative scenario	Not applicable								
Related requirements	None identified								
Related rules	None identified								

Activity Diagram(s)

Not applicable

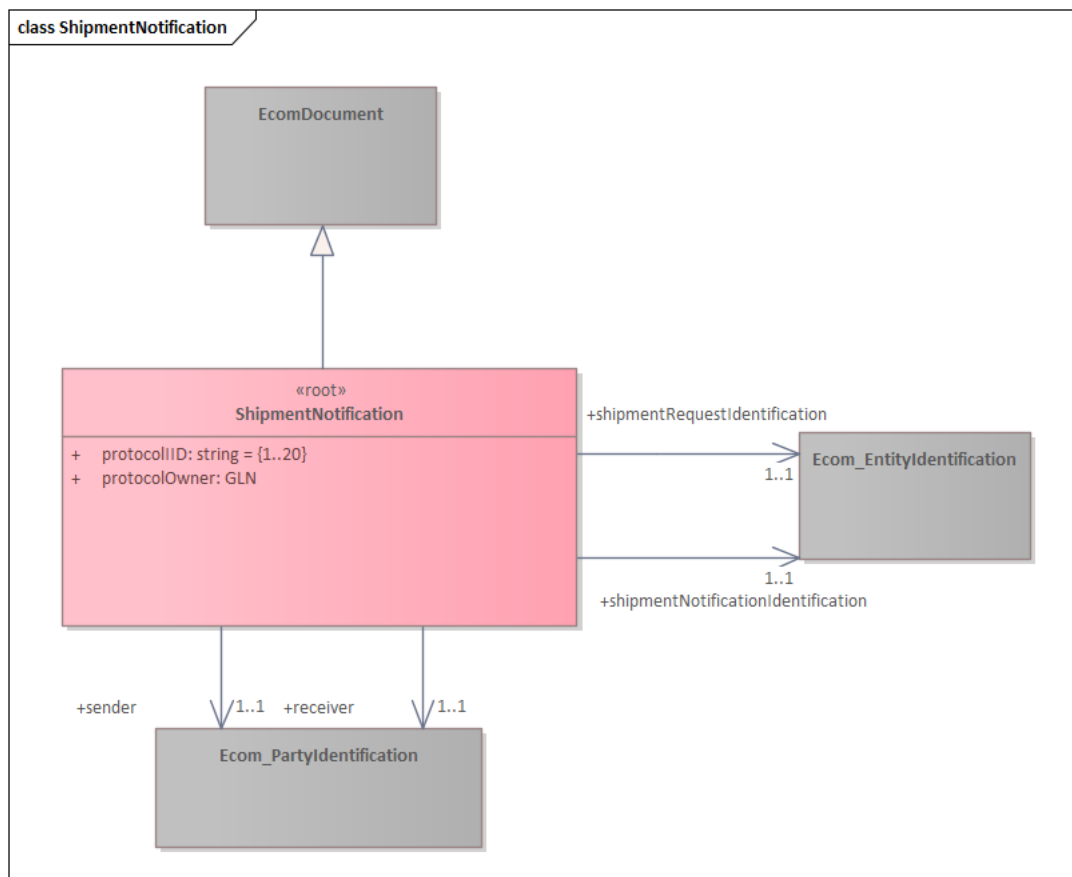
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Shipment Notification

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ShipmentNotification					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	Shipment Notification is the acknowledgment of the Shipment Request message. It should be sent by the recipient as soon as possible once the Shipment Request message is received by the recipient.	
ASSOCIATION	shipmentNotificationIdentification	Ecom_EntityIdentification	1..1	The identification of the Shipment Notification message	
ASSOCIATION	shipmentRequestIdentification	Ecom_EntityIdentification	1..1	The reference to the request originating the shipment	
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	
ATTRIBUTE	protocolID	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The protocol sponsor	



Note: Reference Shared Common Library Business Message (BMS) Release 3.5.1 and eCom Domain Common Library Business Message (BMS) Release 3.5.1 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

Below is an example of acknowledgement that the shipment request has been received.

Party Information

GS1 Global Location Number	Party Type
9520000000028	sender
9520000000011	receiver
9520000000004	Protocol owner

Message Example 1

Attribute	Value
ShipmentNotification	
<i>shipmentNotificationIdentification</i>	
entityIdentification	12
<i>shipmentRequestIdentification</i>	
entityIdentification	523
<i>sender</i>	
GLN	9520000000028
<i>receiver</i>	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004

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

Any message specific considerations are discussed in the above guideline.

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.

8 Appendices

Not Applicable

9 Acknowledgements

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