



The Global Language of Business

Inventory Release File Business Message Standard (BMS)

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3-Apr-2020	BMS 3.4.2	Mark Van Eeghem	Initial Draft	Initial Draft
3-Jun-2020	BMS 3.4.2	Piergiorgio Licciardello	Error fixing and draft definition	Change of cardinality for some attributes, ProtocolID added, draft definition included
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello, Tania Snioch, Elisa Zwaneveld	Error fixing and draft definition	Language corrections and attributes definition updates, examples inclusion
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Final Group review	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Quantity attribute name with capital letter, Cardinality missing in sender and receiver, rearranged the order of lines in GDD report according to BMS writing rules, Attribute ProtocolID changed to protocolID according to standard writing rules. Code list url missing. Class diagram updated, non-serialized information class definition missing
15-Jan-2021	BMS 3.5 – Issue 1	Miklos Bolyky	BMS Release 3.5	See summary of changes



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05-Jan-2022	BMS 3.5.1 – Issue 1	Miklos Bolyky	BMS Release 3.5.1	See summary of changes

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1 Business Domain View

1.1 Introduction

Purpose

The Inventory Release File is used for the initial release of IP kits or other serialised medication and to communicate this to stakeholders. The term 'release' means 'release for clinical use'.

This Inventory Release File 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:

- Shipment RequestShipment 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 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

Context Category	Value(s)
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.

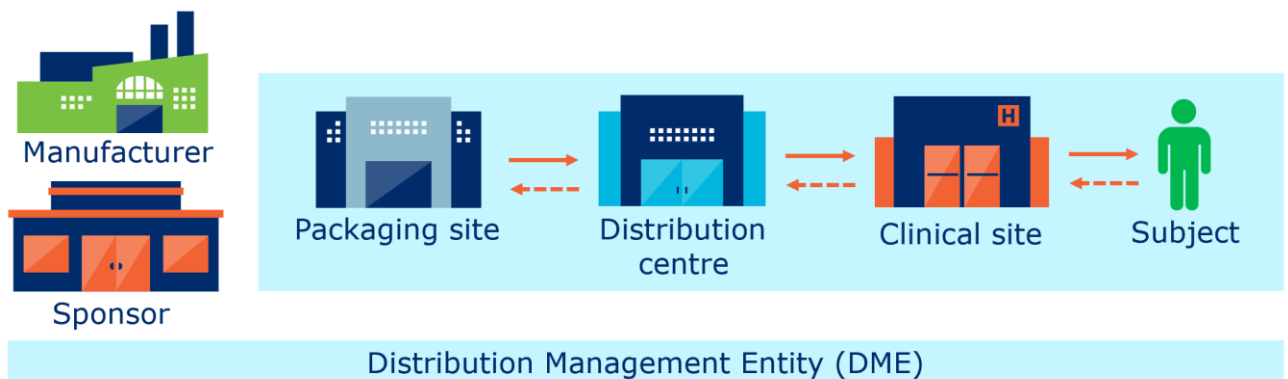


Table 3-1 Roles and responsibilities

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

This message is typically exchanged between the sponsor and the DME, but can be used by any entity in the supply chain who needs to transmit or receive it.

Below is the use case detailed in *the Guideline*, section 7.1.2.

Performance goals	To ensure that clinical trial sites, DCs and other locations can release IP kits for use.		
Preconditions	Unique identification of locations, trade items and logistics units. Master data is shared.		
Postconditions	None identified		
Scenario	Begins when the sponsor sends a communication to the DME to advise that inventory can be ordered/requested. Continues with...		
	Step #	Actor	Activity step
	1	DME	Receives the communication.
	2	DME	Acts to 'release' the inventory in their system and confirms change in stock status (e.g., available to ship).
	Ends when inventory is available for use or shipping to relevant trial locations.		
Alternative scenario	Not applicable		
Related requirements	None identified		
Related rules	None identified		

Activity Diagram(s)

Not applicable

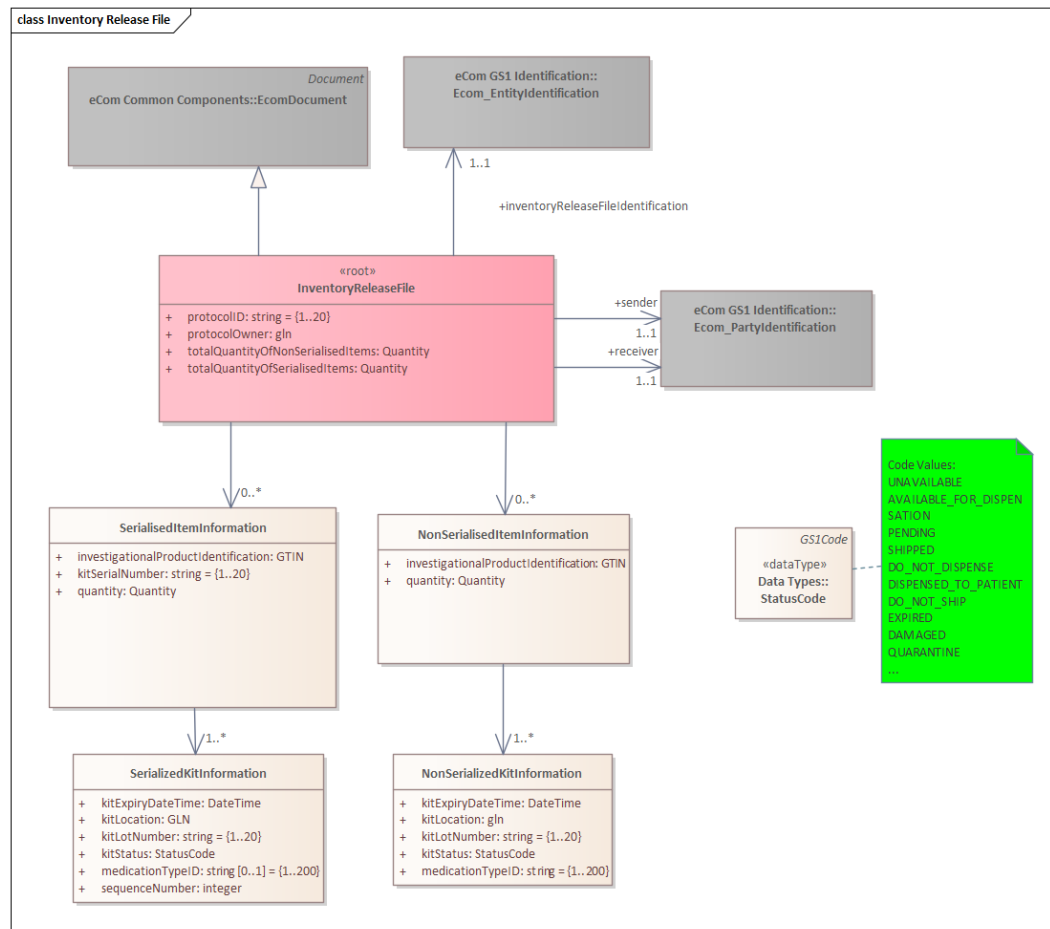
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Inventory Release File

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
InventoryReleaseFile					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	The Inventory release message is used for the initial release for clinical use of investigational product kits or other serialised medications to make them visible. Serialised and non-serialised items should be included in separate messages	
ASSOCIATION	inventoryReleaseFileIdentification	Ecom_EntityIdentification	1..1	The unique identifier of the document	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The generator of the message, usually the sponsor	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The receiver of the message, usually the DME	
ASSOCIATION		SerialisedItemInformation	0..*	The set of attributes applicable to a serialised kit	
ASSOCIATION		NonSerialisedItemInformation	0..*	The set of attributes applicable to a non-serialized kit	
ATTRIBUTE	protocolID	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identifier of the sponsor of the protocol	
SerialisedItemInformation					
ASSOCIATION		SerializedKitInformation	1..*	The data set identifying a serialized kit	
ATTRIBUTE	investigationalProductIdentification	GTIN	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	1..1	The serial number of the kit	{1..20}
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
SerializedKitInformation					

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	1..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	
ATTRIBUTE	medicationTypeID	String	0..1	The type of the medication kit	{1..200}
ATTRIBUTE	kitExpiryDateTime	DateTime	0..1	The expiry date of the kit	
ATTRIBUTE	kitLocation	gln	1..1	The location where the kits are available	
ATTRIBUTE	kitStatus	StatusCode	1..1	The status of the kit	
NonSerializedItemInformation					
ATTRIBUTE	investigationalProductIdentification	GTIN	1..1	The GTIN of the investigational product	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ASSOCIATION		NonSerializedKitInformation	1..*	The data set identifying a non-serialized kit	
NonserializedKitInformation					
ATTRIBUTE	kitLotNumber	string	1..1	The lot number identifying a group of investigational products	{1..20}
ATTRIBUTE	medicationTypeID	String	1..1	The type of the medication kit	{1..200}
ATTRIBUTE	kitExpiryDateTime	DateTime	0..1	The expiry date of the batch	
ATTRIBUTE	kitLocation	gln	1..1	The location where the kits are available	
ATTRIBUTE	kitStatus	StatusCode	1..1	The status of the kit	



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
SerialisedItemInformation	StatusCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:StatusCode
NonSerialisedItemInformation	StatusCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:StatusCode



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 serialised item inventory release.

Party Information

GS1 Global Location Number	Party Type
9520000000004	Sender – Sponsor
9520000000011	Receiver – DME
9520000000028	Kit Location

Message Example 1

Attribute	Value
InventoryReleaseFile	
inventoryReleaseFileIdentification	
entityIdentification	567
sender	
GLN	9520000000004
receiver	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004
SerialisedItemInformation	
investigationalProductIdentification	9520000000530
Quantity	
quantity	1
measurementUnitCode	H87
SerialisedKitInformation	
kitSerialNumber	0001
kitLotNumber	L001

Attribute	Value
medicationTypeID	PLACEBO
kitExpiryDateTime	2020-03-22T00:00:00.000
kitLocation	9520000000028
kitStatus	AVAILABLE_FOR_DISPENSATION

6 Implementation Considerations

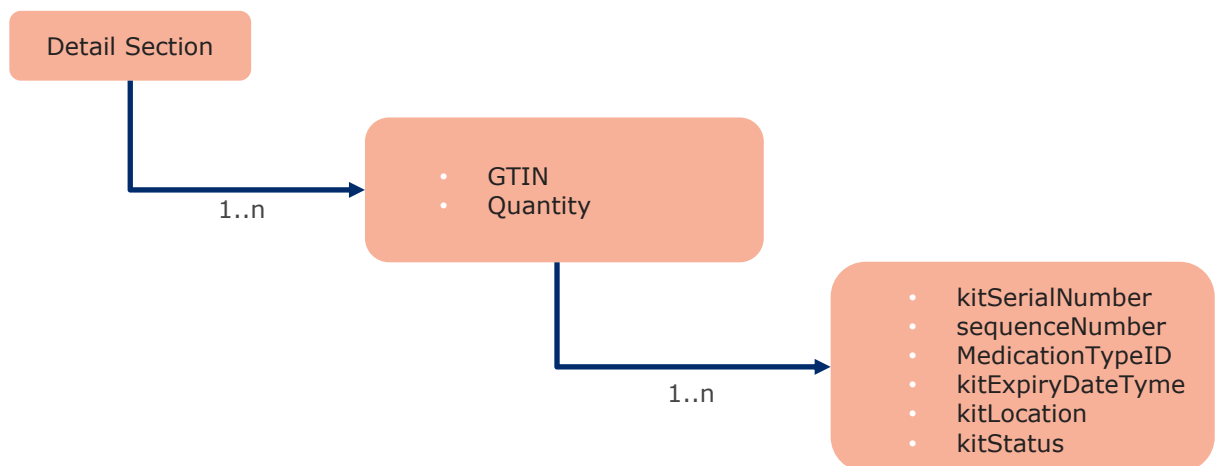
6.1 User Guide

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

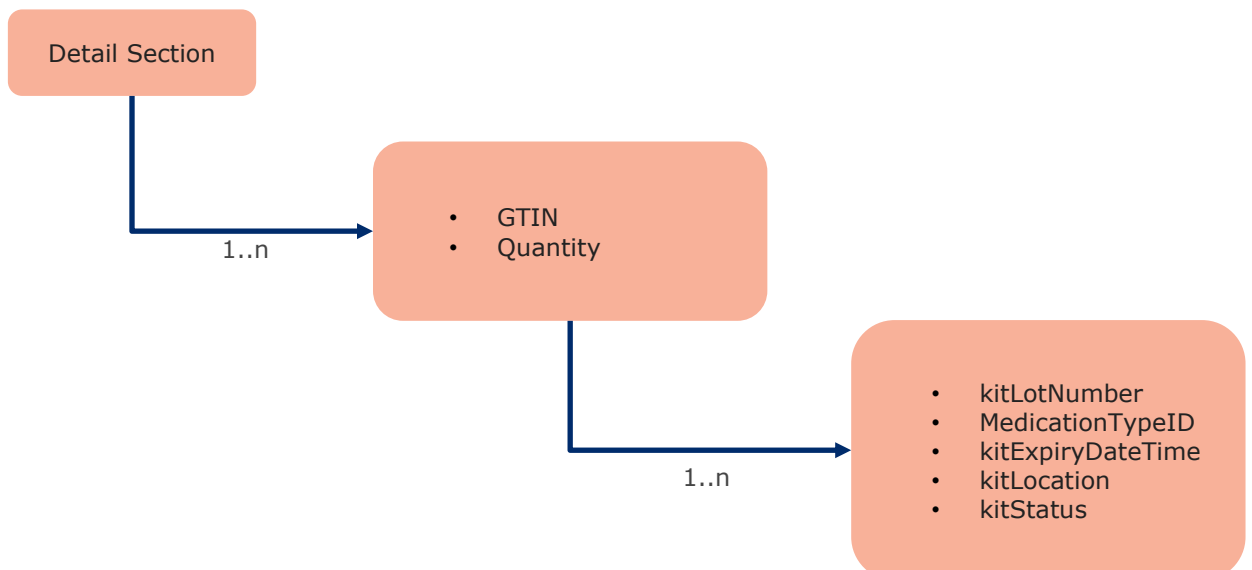
6.2 Message Specific Considerations

The message maps two different use cases, serialized and not serialized items. The structure of the detail loop, and so the information shared, changes according to the specific use case.

Serialized items:



Not Serialized items:



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.

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

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