



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	Miklos Bolyky	BMS Release 3.5	See summary of changes



Date of Change	Version	Changed By	Reason for Change	Summary of Change
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 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.

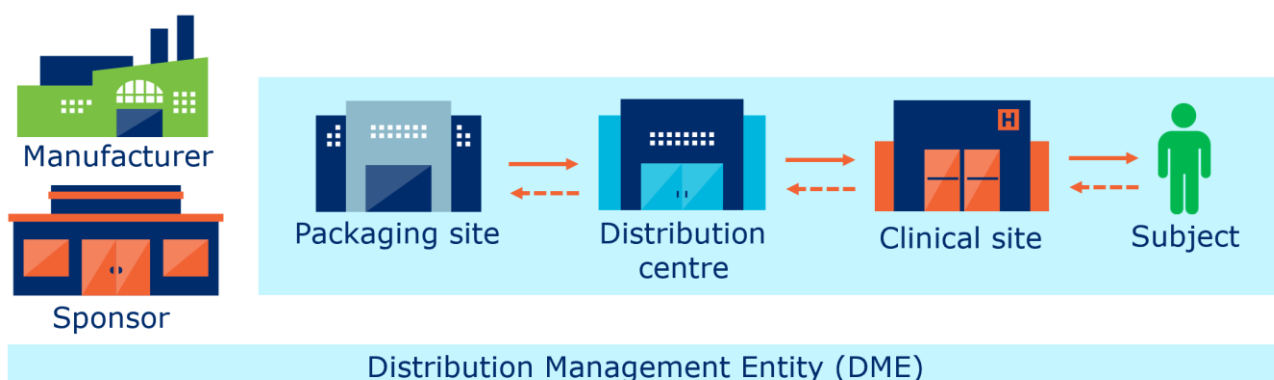


Table 3-1 Roles and responsibilities

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	<p>Begins when the sponsor sends a communication to the DME to advise that inventory can be ordered/requested. Continues with...</p> <table><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>DME</td><td>Receives the communication.</td></tr><tr><td>2</td><td>DME</td><td>Acts to 'release' the inventory in their system and confirms change in stock status (e.g., available to ship).</td></tr></table> <p>Ends when inventory is available for use or shipping to relevant trial locations.</p>	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).
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).								
Alternative scenario	Not applicable									
Related requirements	None identified									
Related rules	None identified									

Activity Diagram(s)

Not applicable

Sequence Diagram(s)

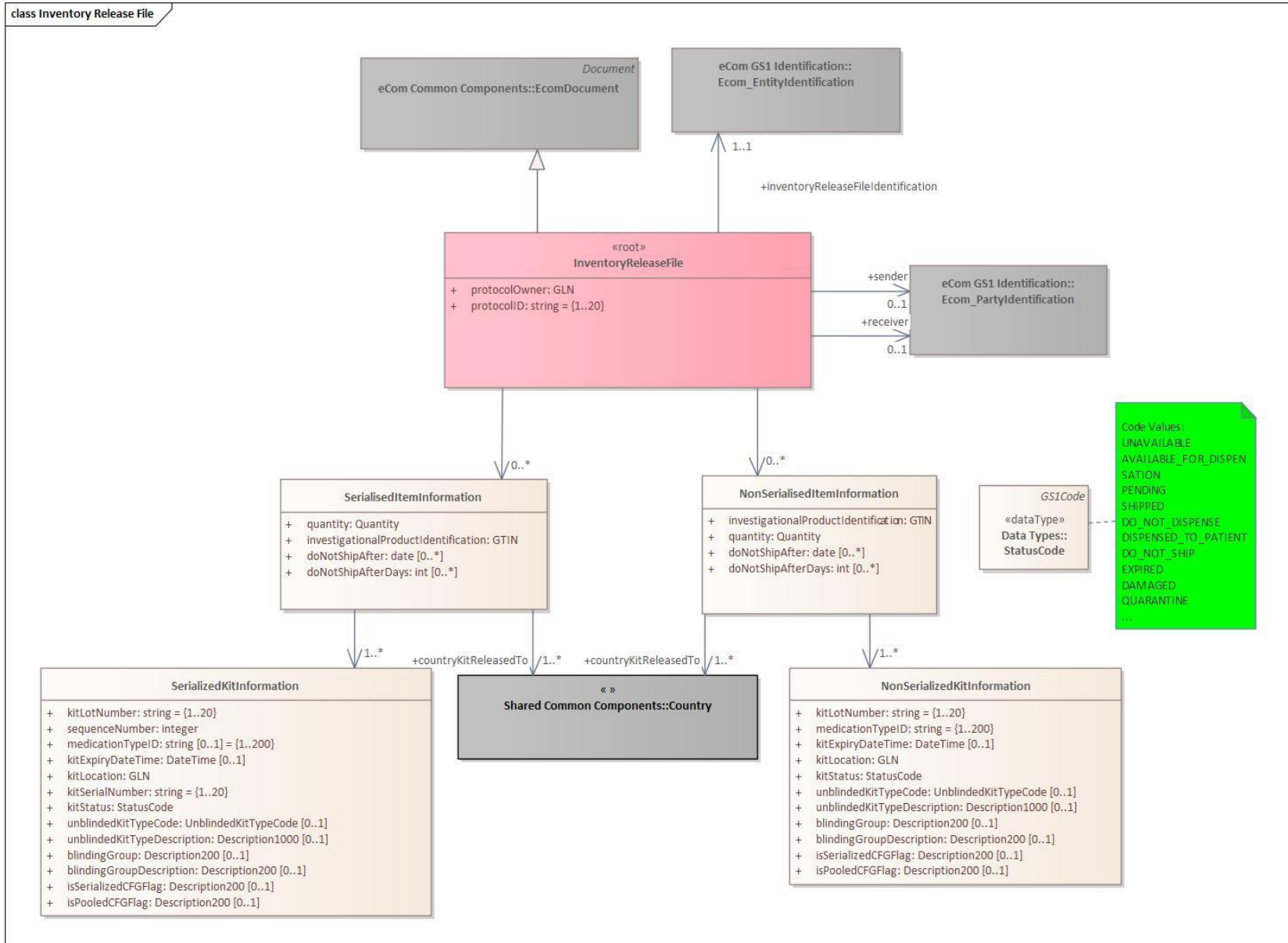
Not applicable



4 Business Information View

4.1 Inventory Release File

Class diagram





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

[Navigator link](#)

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	0..1	The generator of the message, usually the sponsor	
ASSOCIATION	receiver	Ecom_PartyIdentification	0..1	The receiver of the message, usually the DME	
ASSOCIATION		SerializedItemInformation	0..*	The set of attributes applicable to a serialised kit	
ASSOCIATION		NonSerializedItemInformation	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	
SerializedItemInformation					
ASSOCIATION		SerializedKitInformation	1..*	The data set identifying a serialized kit	
ASSOCIATION	countryKitReleasedTo	Shared_common_components_country	1..*	The code identifying the country for which the inventory of investigational product is released	WR 21-545
ATTRIBUTE	investigationalProductIdentification	GTIN	1..1	The GTIN of the investigational product	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ATTRIBUTE	doNotShipAfter	Date	0.. *	The date of the ultimate limit for the shipment	WR-22-355
ATTRIBUTE	doNotShipAfter Days	int	0.. *	The ultimate limit for the shipment expressed in days	WR-24-000030
SerializedKitInformation					
ATTRIBUTE	kitLotNumber	string	1..1	The lot number identifying a group of investigational products	{1..20}
ATTRIBUTE	kitSerialNumber	string	1..1	The serial number of the kit	{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	
ATTRIBUTE	unblindedKitTypeCode	ct_common_unblinded KitTypeCodeType	0..1	The code identifying the type of unblinded medication kit to be shipped.	WR-23-000286
ATTRIBUTE	unblindedKitTypeDescription	Description200	0..1	A description field expressing the type of the unblinded kit.	WR-23-000286
ATTRIBUTE	blindingGroup	Description200	0..1	A field expressing the blinding group type	WR-23-000286
ATTRIBUTE	blindingGroupDescription	Description200	0..1	A field expressing the description of the blinding group.	WR-23-000286
ATTRIBUTE	isSerializedCFGFlag	Description200	0..1	A flag indicating if the investigational product is serialized	WR-23-000286
ATTRIBUTE	isPooledCFGFlag	Description200	0..1	A flag indicating if the investigational product is pooled for multiple protocols	WR-23-000286



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
NonSerializedItemInformation					
ATTRIBUTE	investigationalProductIdentification	GTIN	1..1	The GTIN of the investigational product	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ATTRIBUTE	doNotShipAfter	Date	0.. *	The date of the ultimate limit for the shipment	WR 22-355
ATTRIBUTE	doNotShipAfterDays	int	0.. *	The ultimate limit for the shipment expressed in days	WR-24-000030
ASSOCIATION		NonSerializedKitInformation	1..*	The data set identifying a non-serialized kit	
ASSOCIATION	countryKitReleasedTo	Shared_common_components_country	1..*	The code identifying the country for which the inventory of investigational product is released	WR 21-545
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	
ATTRIBUTE	unblindedKitTypeCode	ct_common_unblindedKitTypeCodeType	0..1	The code identifying the type of unblinded medication kit to be shipped.	WR-23-000286
ATTRIBUTE	unblindedKitTypeDescription	Description200	0..1	A description field expressing the type of the unblinded kit.	WR-23-000286
ATTRIBUTE	blindingGroup	Description200	0..1	A field expressing the blinding group type	WR-23-000286
ATTRIBUTE	blindingGroupDescription	Description200	0..1	A field expressing the description of the blinding group.	WR-23-000286



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	isSerializedCFG Flag	Description200	0..1	A flag indicating if the investigational product is serialized	WR-23-000286
ATTRIBUTE	isPooledCFGFlag	Description200	0..1	A flag indicating if the investigational product is pooled for multiple protocols	WR-23-000286

4.2 Enumerations (message specific)

Not applicable

4.3 Code Lists

Class	Codelist	Navigator Link
SerialisedItemInformation	StatusCode	TBC
NonSerialisedItemInformation	StatusCode	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 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	
<i>inventoryReleaseFileIdentification</i>	
entityIdentification	567
<i>sender</i>	
GLN	9520000000004
<i>receiver</i>	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004
SerialisedItemInformation	
investigationalProductIdentification	9520000000530
<i>Quantity</i>	
quantity	1
measurementUnitCode	H87
SerialisedKitInformation	
kitSerialNumber	0001
kitLotNumber	L001
medicationTypeID	PLACEBO

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

6 Implementation Considerations

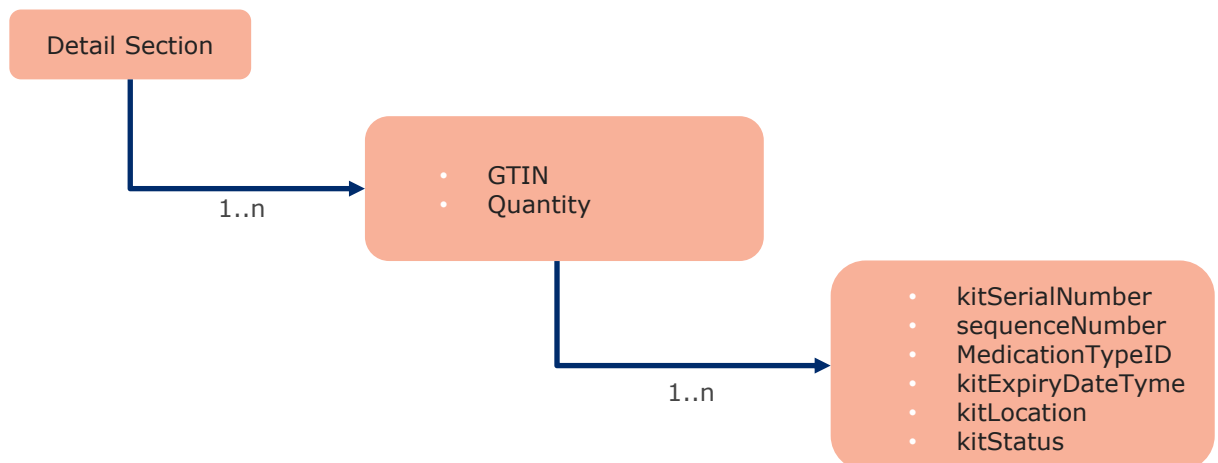
6.1 User Guide

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

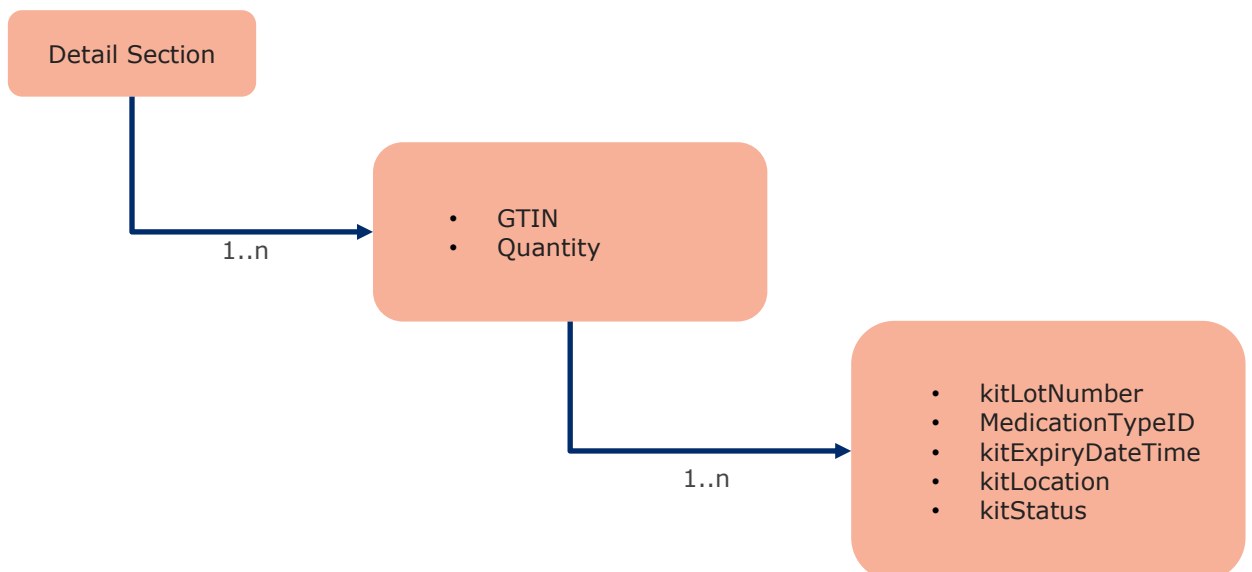
6.2 Message Specific Considerations

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
<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"> Created new association: countryKitReleasedTo from SerializedItemInformation to Shared common components Country with the cardinality of 1..* countryKitReleasedTo from NonSerializedItemInformation to Shared common components Country with the cardinality of 1..* 	WR 21-545
<ul style="list-style-type: none"> Created new attribute doNotShipAfter which is a date with a cardinality of 1..* in SerializedItemInformation and NonSerializedItemInformation classes. 	WR 22-355

7.5 BMS Release 3.7

Change	Associated CR Number
<ul style="list-style-type: none"> Added new attributes to Serialized/Non Serialized kit information: unblindedKitTypeCode (optional , type code) unblindedKitTypeDescription (optional description1000) , blindingGroup (optional description200) , blindingGroupDescription (optional description200), isSerializedCFGFlag (optional description200) , isPooledCFGFlag (optional description200) 	WR-23-000286
<ul style="list-style-type: none"> Changed the cardinality of sender and receiver from 1..1 to 0..1 	WR-24-000186
<ul style="list-style-type: none"> Added a new attribute doNotShipAfterDays to the Serialized/Non Serialized kit information class, as 0..unbounded 	WR-24-000030
<ul style="list-style-type: none"> Fixed errata in BMS – kitLotNumber placement in Report 	

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

Function	Name	Company / organisation
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WG member	Mig Smith	GS1 UK
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 Keddle	GS1 Global Office
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Peer Review	Mark Van Eeghem	GS1 Global Office