



The Global Language of Business

Inventory Release File Business Message Standard (BMS)

Release 3.6, Ratified, March 2023



Document Summary

Document Item	Current Value
Document Name	Inventory Release File Business Message Standard (BMS)
Document Date	March 2023
Document Version	3.6
Document Issue	1
Document Status	Ratified

Work Request Reference

Date of WR Submission to GSMP:	WR Submitter(s):	Refer to Work Request (WR) Number(s):

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
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



Inventory Release File Business Message Standard (BMS)

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



Disclaimer

GS1®, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **Inventory Release File Business Message Standard (BMS)** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the licencing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organization developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licencing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHERWISE ARISING OUT OF THIS SPECIFICATION. GS1 disclaims all liability for any damages arising from use or misuse of this Standard, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.

GS1 and the GS1 logo are registered trademarks of GS1 AISBL.



Table of Contents

1	Business Domain View	6
1.1	Introduction	6
1.2	References	6
2	Business Context	6
3	Business Transaction View	7
4	Business Information View	9
4.1	Inventory Release File	9
4.2	Enumerations (message specific)	14
4.3	Code Lists	14
5	Business Message Examples	14
5.1	Example 1	14
6	Implementation Considerations	15
6.1	User Guide	15
6.2	Message Specific Considerations	15
7	Summary of Changes	16
7.1	BMS Release 3.4.2	16
7.2	BMS Release 3.5	16
7.3	BMS Release 3.5.1	16
7.4	BMS Release 3.6	16
8	Appendices	16
9	Acknowledgements	16
9.1.1	Work Group	16
9.1.2	Development Team Members	19

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 Request
- 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
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.

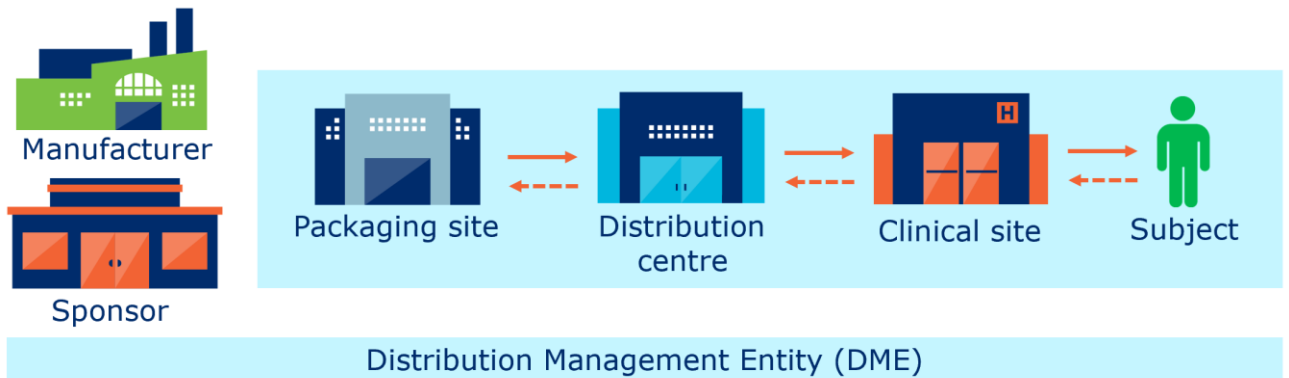


Table 3-1 Roles and responsibilities

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 border="1"> <thead> <tr> <th>Step #</th> <th>Actor</th> <th>Activity step</th> </tr> </thead> <tbody> <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> </tbody> </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)

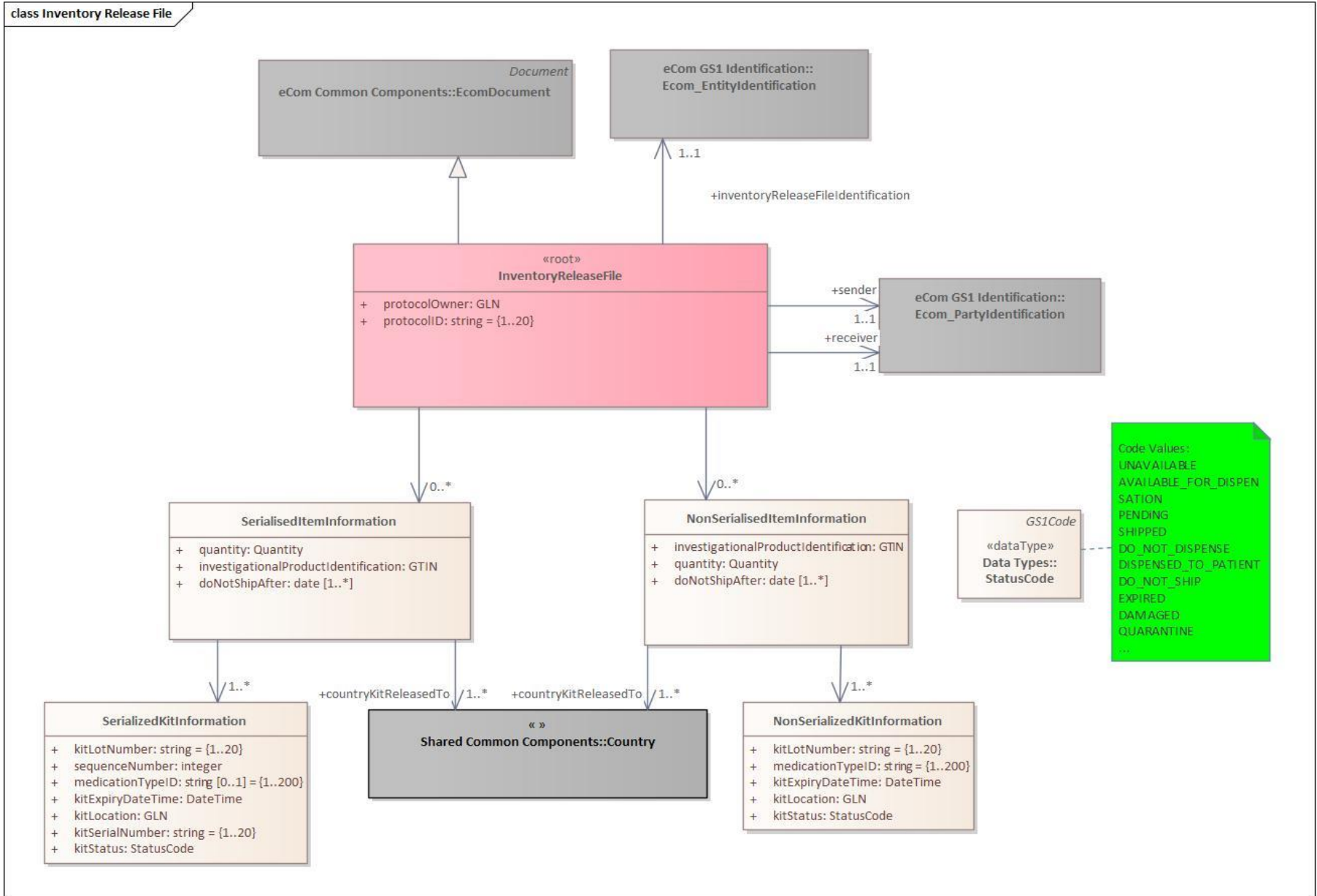
Not applicable



4 Business Information View

4.1 Inventory Release File

Class diagram





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	
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	
ATTRIBUTE	kitSerialNumber	string	1..1	The serial number of the kit	{1..20}
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	doNotShipAfter	Date	1..*	The date of the ultimate limit for the shipment	WR 22-355
SerializedKitInformation					
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	
ATTRIBUTE	doNotShipAfter	Date	1..*	The date of the ultimate limit for the shipment	WR 22-355
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}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
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 3.6 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
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

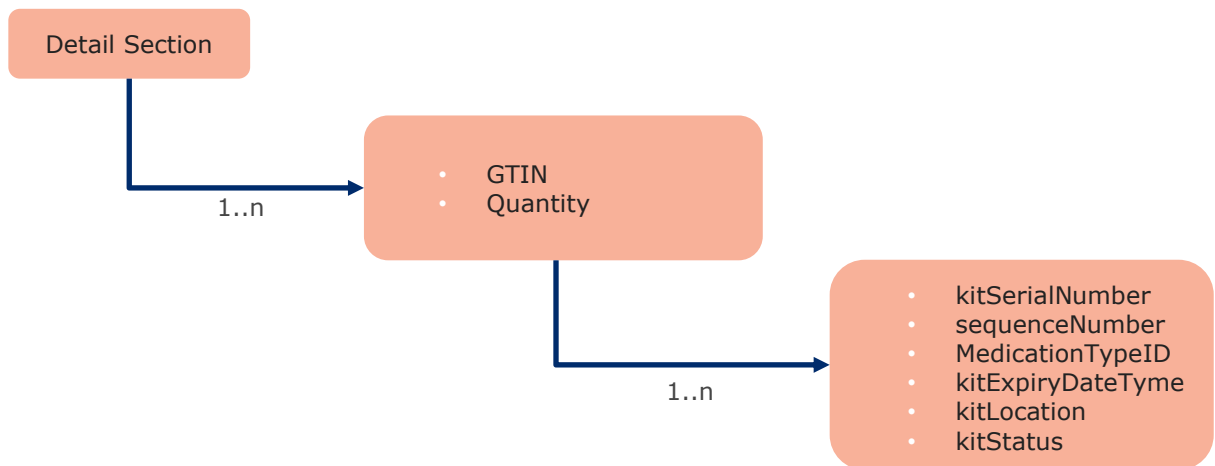
6.1 User Guide

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

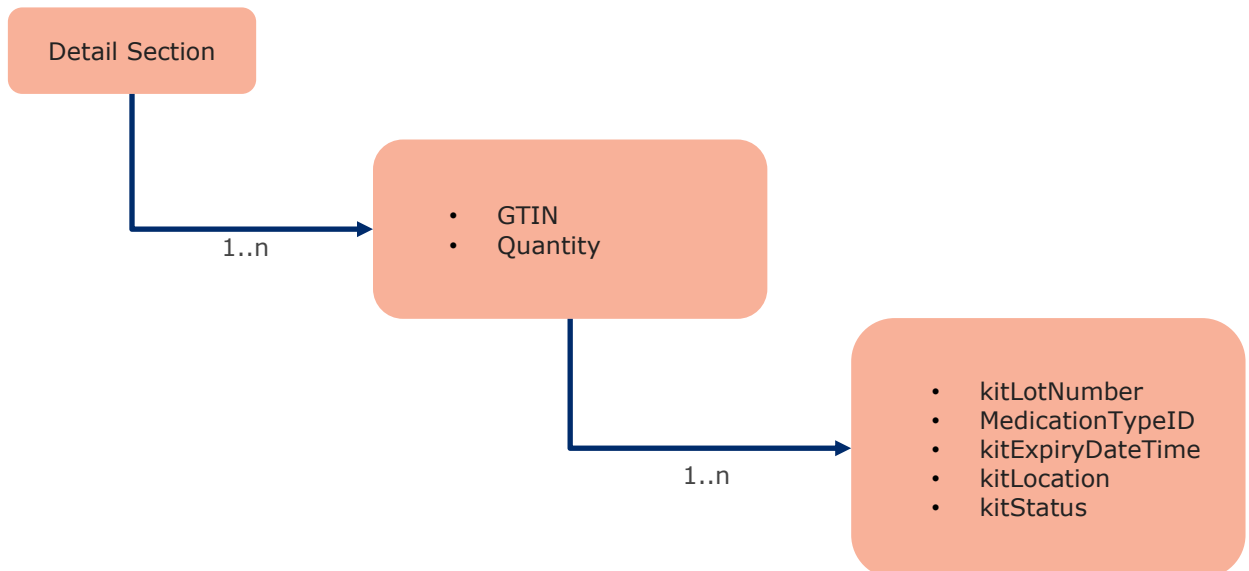
6.2 Message Specific Considerations

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
<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

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

Function	Name	Company / organisation
WG chair	Olivia Chauvel (Chair)	CH Victor Dupouy
WG chair	Pierre Fernandez-Barbureau (Chair)	SANOFI
WG chair	Hans von Steiger (Chair)	Pfizer

Function	Name	Company / organisation
WG member	Jean-Michel Descoutures	International Hospital Federation (IHF)
WG member	Feargal Mc Groarty	St. James's Hospital
WG member	Vincent Puglia	endpoint clinical
WG member	Mike Meakin	DHL
WG member	Sylvain Alberola	SANOFI
WG member	Céline Bordes-Terrier	CREAPHARM
WG member	Giedré Bracaité	F. Hoffmann-La Roche Ltd.
WG member	Doris Cadart	SANOFI
WG member	Pedro Carvalho	Ipsen
WG member	Robert Giguere	AbbVie
WG member	Nicolas Gryspeert	F. Hoffmann-La Roche Ltd.
WG member	Michael Hoefling	Boehringer Ingelheim Pharma GmbH & Co.KG
WG member	Richard Hwang	Pfizer
WG member	Marco Inserra	CSL Behring GmbH
WG member	Jason James	Bristol-Myers Squibb
WG member	Matthias Kallmeyer	Boehringer Ingelheim Pharma GmbH & Co.KG
WG member	Nicolas Le Rudlier	CREAPHARM
WG member	Yann Montcourt	Ipsen
WG member	Barry Moore	GlaxoSmithKline
WG member	Marianne Perdrijat	DBV TECHNOLOGIES
WG member	Amy Rupp	CSL Behring GmbH
WG member	Amanda Scott	Biogen
WG member	Jodi Smith-Gick	Eli Lilly and Company
WG member	Richard Austin	PAREXEL International GmbH
WG member	Nick Bobrinskoy	nCoup, Inc.
WG member	Arpad Boldis	Deloitte
WG member	Robert Celeste	Center for Supply Chain Studies
WG member	Dilip Daswani	Qliktag Software (formally Zeebric LLC)
WG member	Andreas Geissler	PAREXEL International GmbH
WG member	Mark Hanly	Almac Clinical Technologies
WG member	Mike Hutton	Almac Clinical Technologies
WG member	Kelly Knowles	Bracket Global
WG member	Jitendra Kumar	Thermo Fisher Scientific
WG member	Cherish Lallone	McCreadie Group
WG member	Charlotte Meuldermans	Deloitte
WG member	Fabiana Monaco	PAREXEL International GmbH
WG member	Josef Preishuber-Pflügl	CISC Semiconductor GmbH
WG member	Theodora Sarver	Almac Clinical Technologies



Function	Name	Company / organisation
WG member	Michael schlesselman	McCreadie Group
WG member	Colette Thorold	PAREXEL International GmbH
WG member	Elizabeth Waldorf	TraceLink
WG member	Stefan Zietze	PAREXEL International GmbH
WG member	Andrea Zobel	PAREXEL International GmbH
WG member	Shreenidhi Bharadwaj	Syndigo
WG member	Tony Zhang	Syndigo
WG member	Richard Perkins	eClinical Forum
WG member	Olivier Mary	COLCA Medical & Scientific
WG member	Poppy Abeto Kiese	GS1 Austria
WG member	Andrea Arozamena	GS1 Mexico
WG member	Mahdi Barati	GS1 Iran
WG member	Jiraporn Chalermjirarat	GS1 Thailand
WG member	Shawn Chen	GS1 Thailand
WG member	Mignone Cheng	GS1 Hong Kong, China
WG member	Luiz Costa	GS1 Brasil
WG member	Sandra Couto	GS1 Canada
WG member	Jesper Kervin Franke	GS1 Denmark
WG member	Stefan Gathmann	GS1 Ireland
WG member	Nicole Golestani	GS1 Canada
WG member	Rami Habbal	GS1 UAE
WG member	Michaela Hähn	GS1 Germany
WG member	Christine Horvath-Hanko	GS1 Hungary
WG member	Anna Klapper	GS1 Germany
WG member	Catherine Koetz	GS1 Australia
WG member	Anne-Claire Krid	GS1 France
WG member	Camille Labeaune	GS1 France
WG member	Ildikó Lieber	GS1 Hungary
WG member	Valerie Marchand	GS1 France
WG member	Adrien Molines	GS1 France
WG member	Zubair Nazir	GS1 Canada
WG member	Alice Nguyen	GS1 Vietnam
WG member	James Perng	GS1 Chinese Taipei
WG member	James Perng	GS1 Chinese Taipei
WG member	Paul Reid	GS1 UK
WG member	Sylvia Reingardt	GS1 Germany
WG member	Sue Schmid	GS1 Australia
WG member	Julian Sin	GS1 Hong Kong, China
WG member	Mig Smith	GS1 UK
WG member	Peter Sturtevant	GS1 US
WG member	Flora Sue	GS1 China



Function	Name	Company / organisation
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 Keddie	GS1 Global Office
WG member	Neil Piper	GS1 Global Office
WG member	Greg Rowe	GS1 Global Office
WG member	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