

Document Summary

Document Item	Current Value
Document Name	Clinical Trial Inventory Report Business Message Standard (BMS)
Document Date	Mar 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
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after group revision	Structure changes, classes and attributes definition, examples
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	protocolOwner is not an association but an attribute. Rearranged the sequence of lines in GDD report according to BMS writing rules. Code list url missing and measurement units code list unnecessary Class diagram updated
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
01-Mar-2023	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 Inventory Report is used to communicate current levels of inventory of items within a given location. In practice, this message has two functions:

- Providing information about where inventory “is” at any point in time.
- A way of communicating back how much inventory each actor has.

This Inventory Report 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
- Request for Inventory
- 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 considered 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.

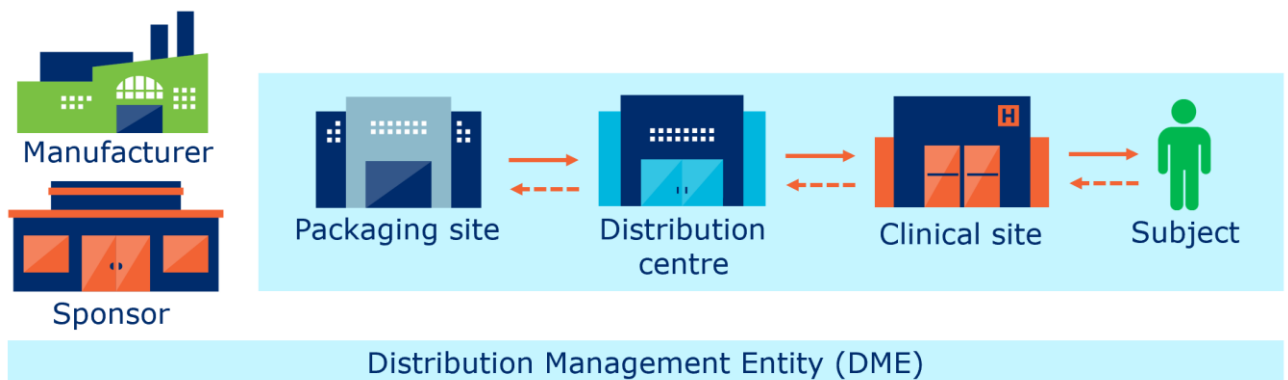


Table 3-1 Roles and responsibilities

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 7.9.2

Performance goals	To ensure that inventory levels are accurate across the clinical trial supply chain.									
Preconditions	Unique identification of locations, trade items and logistics units. Correct identification receiver (Ship To/inventory location) are in place.									
Postconditions	None identified									
Scenario	<p>Begins when the sender/initiator of change (e.g., trial site, CMO, DC) sends a communication to advise of inventory levels.</p> <p>Continues with...</p> <table border="1" data-bbox="550 913 1378 1131"> <thead> <tr> <th>Step #</th> <th>Actor</th> <th>Activity step</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Recipient of advice of change</td> <td>Receives communication and reconciles inventory levels.</td> </tr> <tr> <td>2</td> <td>Sponsor</td> <td>Acknowledges inventory levels.</td> </tr> </tbody> </table> <p>Ends when... This may result in the sponsor acting to ensure stock is replenished to trial site, DC, etc.</p>	Step #	Actor	Activity step	1	Recipient of advice of change	Receives communication and reconciles inventory levels.	2	Sponsor	Acknowledges inventory levels.
Step #	Actor	Activity step								
1	Recipient of advice of change	Receives communication and reconciles inventory levels.								
2	Sponsor	Acknowledges inventory levels.								
Alternative scenario	Not applicable									
Related requirements	None identified									
Related rules	None identified									

Activity Diagram(s)

Not applicable

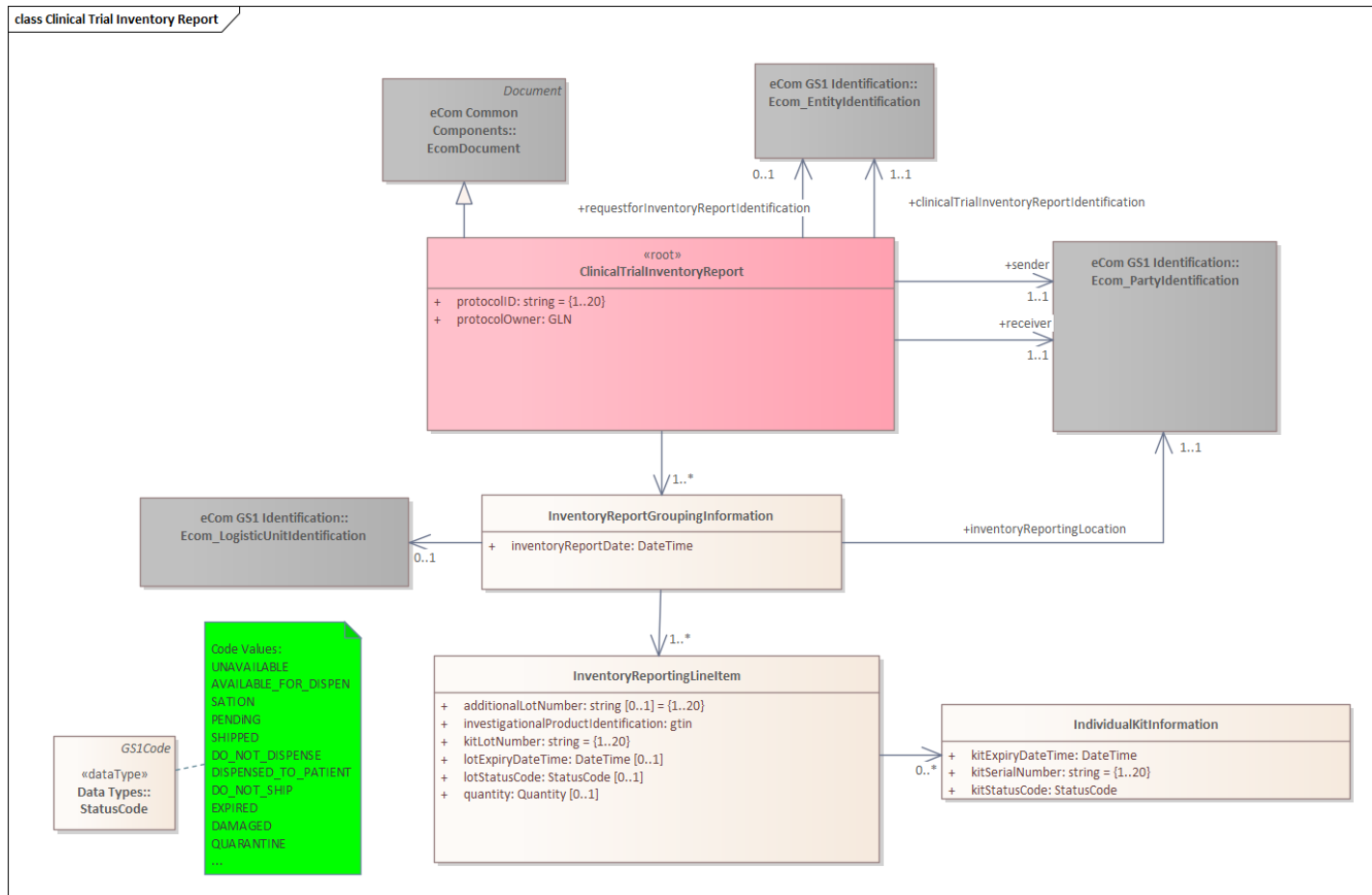
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Clinical Trial Inventory Report

Class diagram





GDD report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ClinicalTrialInventoryReport					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	The inventory report is used to communicate current levels of inventory for the requested items within a given location	
ASSOCIATION	clinicalTrialInventoryReportIdentification	Ecom_EntityIdentification	1..1	The identification of the inventory report message	
ASSOCIATION	requestForInventoryReportIdentification	Ecom_EntityIdentification	0..1	The reference to the request that generated the inventory	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The generator of the message, usually the DME or the third-party depot	
ASSOCIATION	Receiver	Ecom_PartyIdentification	1..1	The issuer of the request of the inventory report	
ASSOCIATION		InventoryReportingInformation	1..*	The information about the inventory status	
ATTRIBUTE	protocolOwner	GLN	1..1	The sponsor of the clinical trial / protocol	
ATTRIBUTE	protocolID	string	1..1	The identification of the protocol	{1..20}
InventoryReportGroupingInformation					
ASSOCIATION	inventoryReportingLocation	Ecom_PartyIdentification	1..1	The GLN of the location where the kits are stored	
ASSOCIATION		Ecom_LogisticUnitIdentification	0..1	Identification of the logistic unit (SSCC)	
ASSOCIATION		InventoryReportingLineItem	1..*	The report detail at item level	
ATTRIBUTE	inventoryReportDate	DateTime	1..1	The date to which the stock refers	
InventoryReportingLineItem					



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ASSOCIATION		IndividualKitInformation	0..*	Specific information related to the single kits	
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	1..1	The lot number the kits are belonging	{1..20}
ATTRIBUTE	additionalLotNumber	string	0..1	Additional identification internal to the supplier	{1..20}
ATTRIBUTE	quantity	Quantity	0..1	The quantity of kits	
ATTRIBUTE	lotStatusCode	StatusCode	0..1	The inventory status referred to the lot	
ATTRIBUTE	lotExpiryDateTime	DateTime	0..1	The expiry date of the lot	
IndividualKitInformation					
ATTRIBUTE	kitSerialNumber	string	1..1	The serial number of the Kit	{1..20}
ATTRIBUTE	kitStatusCode	StatusCode	1..1	The inventory status of the specific kit	
ATTRIBUTE	kitExpiryDateTime	DateTime	1..1	The expiry date 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
InventoryReportingLineItem	StatusCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:S
IndividualKitInformation	StatusCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:S



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
9520000000127	Sender - Organization in charge of the stock
9520000000011	Receiver - requestor of the inventory report
9520000000028	Kit Location

Message Example 1

Attribute	Value
ClinicalTrialInventoryReport	
<i>clinicalTrialInventoryReportIdentification</i>	
entityIdentification	1
<i>requestForInventoryReportIdentification</i>	
entityIdentification	10
<i>sender</i>	
GLN	9520000000127
<i>receiver</i>	
GLN	9520000000011
protocolOwner	9520000000004
protocolID	PROT1
InventoryReportGroupingInformation	
<i>InventoryReportingLocation</i>	
GLN	9520000000028
<i>clinicalTrialLogisticUnitIdentification</i>	
SSCC	95200000000000125

Attribute	Value
inventoryReportingDateTime	2020-08-22T00:00:00.000
InventoryReportingLineItem	
investigationalProductIdentification	9520000000530
kitLotNumber	LOT001
additionalLotNumber	BTCHAK38
quantity	
quantity	1
measurementUnitCode	H87
lotStatusCode	DO_NOT_DISPENSE
lotExpiryDateTime	2020-10-22T00:00:00.000

6 Implementation Considerations

6.1 User Guide

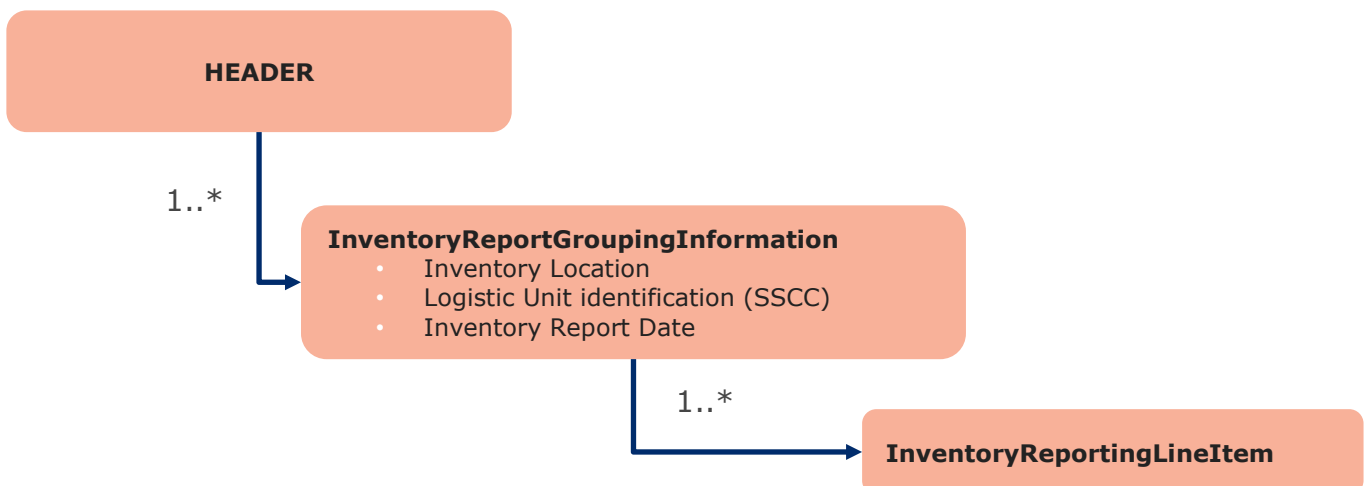
All implementation considerations are discussed in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#).

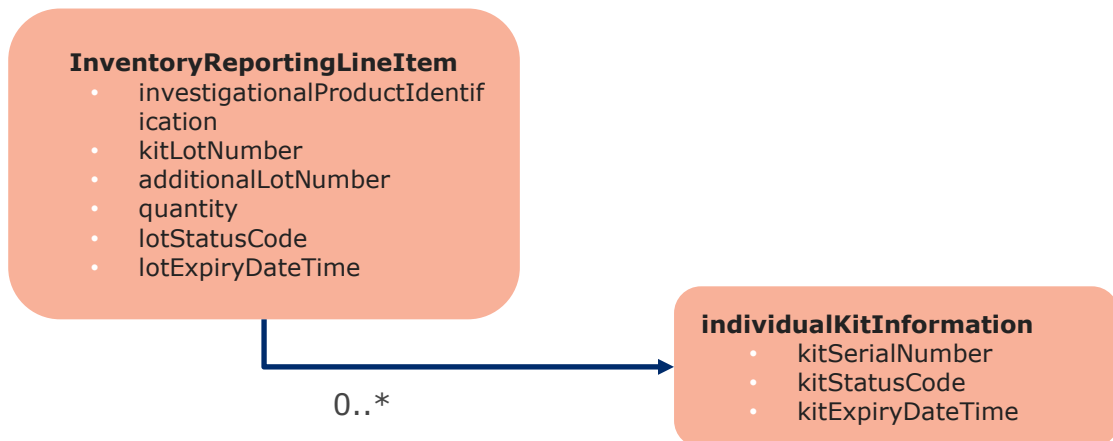
6.2 Message Specific Considerations

The body of the Inventory Report can express two different levels of detail.

The first level is referred to a bath / lot, so the report can provide to the requestor the status and total inventory for every specific lot


It is also possible to have another detail level, providing the status at single serial level





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

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

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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WG member	Greg Rowe	GS1 Global Office
WG member	Tania Snioch	GS1 Global Office

9.1.2 Development Team Members

Function	Name	Organisation
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Technical Development Lead	Miklos Bolyky	GS1 Global Office
Peer Review	Mark Van Eeghem	GS1 Global Office