The Global Language of Business

Dispensing Advice Business Message Standard (BMS)

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Document Summary

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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	Attributes and class definitions, examples
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
14-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after community revision	Change protocolIdentification in protocolID, add GLN in site description
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Class diagram update
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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Table of Contents

1 Business Domain View

1.1 Introduction

Purpose

The Dispensing Advice is used to communicate information related to the specific Investigational Products (IP) assigned to patients within the trial. This Dispensing Advice 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 Report
- Inventory Report
- Kit Status Change

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 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

Context Category	Value(s)
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.

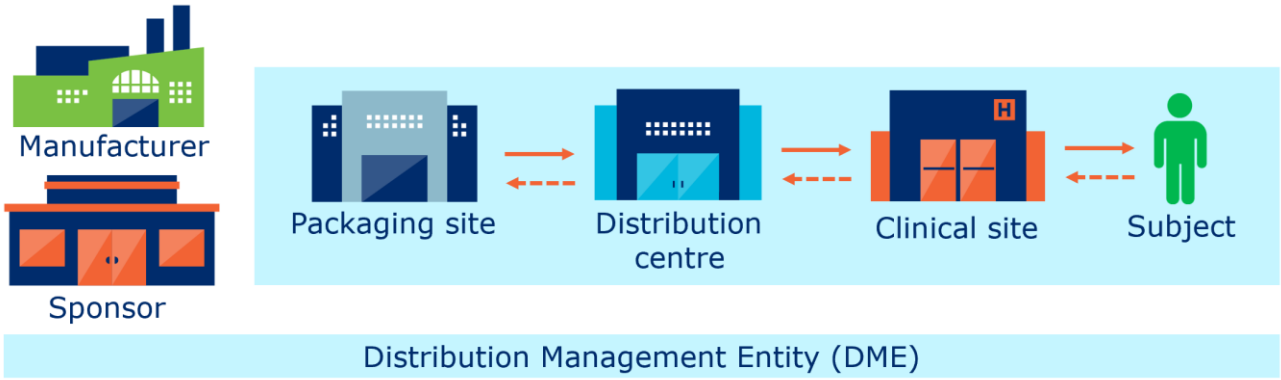


Table 3-1 *Roles and responsibilities*

Role	Responsibility in process
Manufacturer/sponsor	Has overall responsibility for the trial, 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

Below is the use case detailed in *the Guideline*, section 7.10

<table>
<tr><td>Performance goals</td><td>Accurate recording of items to be or that have been dispensed. This will provide accurate use information for planning activities, etc.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units will be undertaken. Correct identification receiver (Ship To/inventory location) are in place.</td></tr>
<tr><td>Postconditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the sponsor sends a communication to the trial site to advise which specific IP kit must be dispensed to a specific patient.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Receiver</td><td>Receives the communication.</td></tr>
</table>
Ends when the receiver takes action to dispense the correct kit to the correct patient.</td></tr>
<tr><td>Alternative Scenario</td><td>Begins when the trial site sends a communication to the sponsor to advise which specific IP kit has been dispensed to a specific patient.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Receiver</td><td>Receives the communication.</td></tr>
</table>
Ends when the receiver takes action to record that dispensing activity in their IT systems.</td></tr>
<tr><td>Related requirements</td><td>If the direction of the dispensing advice message is from trial site to sponsor confirming which drug given to the patient, consider including the staff ID of who did the dispensing.</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

Activity Diagram(s)

Not applicable

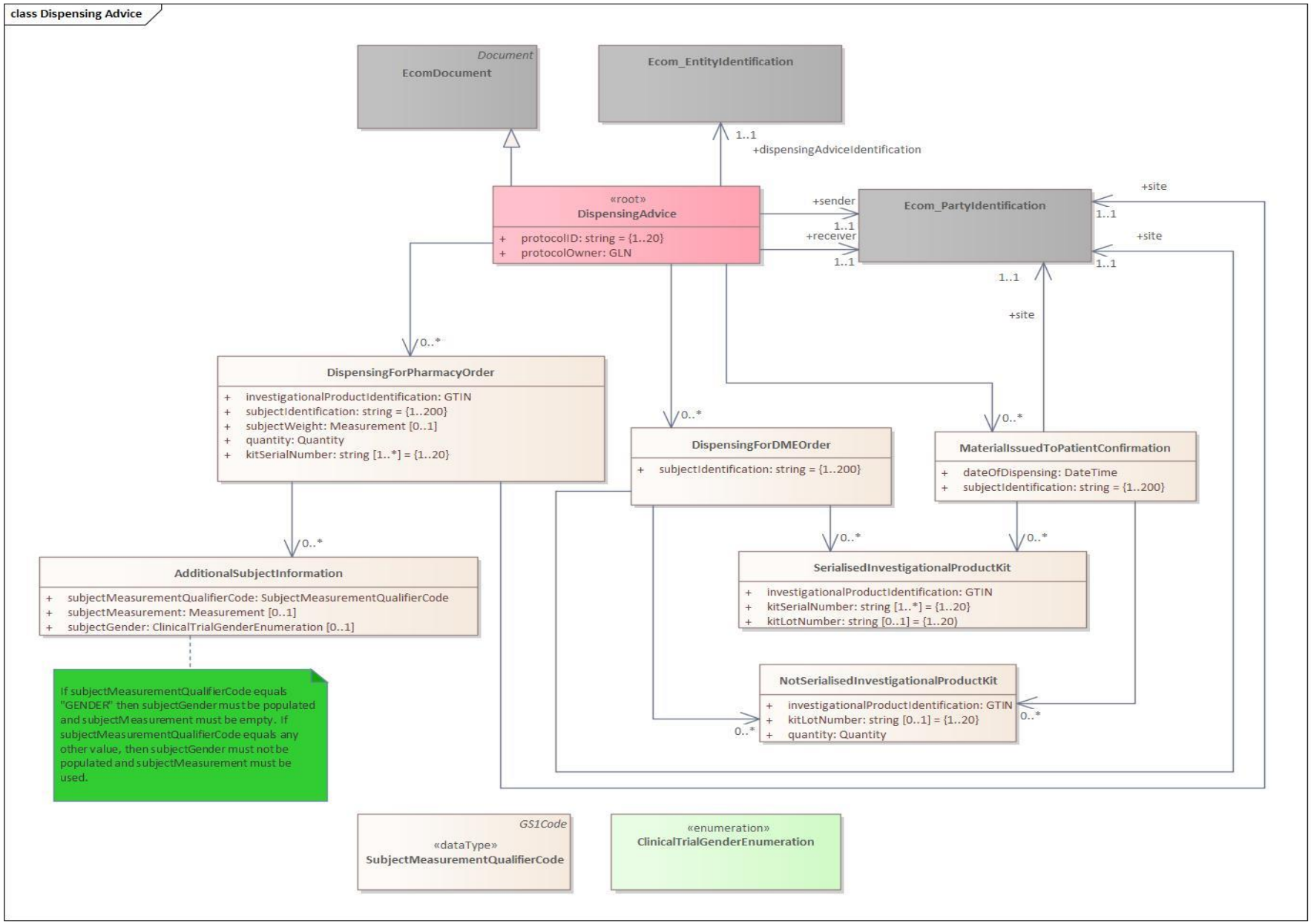
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Dispensing Advice

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
DispensingAdvice				The Dispensing Advice is used to communicate information related to the specific IPs assigned to patients within the trial	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	dispensingAdviceIdentification	Ecom_EntityIdentification	1..1	The identification of the dispensing advice message	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The entity sending the dispensing instruction or the information about the dispensing execution	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The entity receiving the dispensing instructions or the dispensing execution information	
ASSOCIATION		DispensingForPharmacyOrder	0..*	Dispensing instructions for the use case where clinical pharmacy identifies the quantity and materials dispensed	
ASSOCIATION		DispensingForDMEOrder	0..*	Dispensing instructions for the use case where the DME dictates the quantity and materials dispensed	
ASSOCIATION		MaterialIssuedtoPatientConfirmation	0..*	The detail of dispensed kits	
ATTRIBUTE	protocolID	string	1..1	The identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the owner of the protocol	
DispensingForPharmacyOrder					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ASSOCIATION		AdditionaSubjectInformation	0..*		WR 22-350
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	1..*	The serial number of the kit	{1..20}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}
ATTRIBUTE	subjectWeight	Measurement	0..1	The weight of the patient	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of IP to dispense to the patient	
AdditionalSubjectInformation					WR 22-350
ATTRIBUTE	subjectMeasurementQualifierCode	SubjectMEasurementQualifierCode	1..1	The code specifying the type of measurement provided	WR 22-350
ATTRIBUTE	subjectMeasurement	Measurement	0..1	The value of the measurement related to the patient	WR 22-350
ATTRIBUTE	subjectGender	ClinicalTrialGenderEnumeration	0..1	The gender of the patient	WR 22-350
DispensingForDMEOrder					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ASSOCIATION		SerialisedInvestigationalProductKit	0..*	Set of information identifying the serialized kits to dispense	
ASSOCIATION		NotSerialisedInvestigationalProductKit	0..*	Set of information identifying the non-serialized kits to dispense	
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}
MaterialIssuedtoPatientConfirmation					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ASSOCIATION		SerialisedInvestigationalProductKit	0..*	Set of information identifying the serialized kits to dispense	
ASSOCIATION		NotSerialisedInvestigationalProductKit	0..*	Set of information identifying the non-serialized kits to dispense	
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	dateOfDispensing	DateTime	1..1	The date when the kits have been dispensed to the patient	
SerialisedInvestigationalProductKit					
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	1..*	The serial number of the kit	{1..20}
ATTRIBUTE	kitLotNumber	string	0..1	The batch/lot number of the kit	{1..20}
NotSerialisedInvestigationalProductKit					
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	0..1	The batch/lot number of the kit	{1..20}
ATTRIBUTE	quantity	Quantity	1..1	The quantity of IP dispensed / to dispense	

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)

Class	Codelist	Values
AdditionalSubjectInformation	subjectGender	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:ClinicalTrialsGenderEnumeration

4.3 Code Lists

Class	Codelist	GDD Link
AdditionalSubjectInformation	subjectMeasurementQualifierCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:SubjectMeasurementQualifierCode Note: If subjectMeasurementQualifierCode equals "GENDER" then subjectGender must be populated and subjectMeasurement must be empty. If subjectMeasurementQualifierCode equals any other value, then subjectGender must not be populated and subjectMeasurement must be used.

Note: Refer to the Global Data Dictionary (GDD) for the code values.

5 Business Message Examples

5.1 Example 1

This example maps the use case "scenario 1" as defined in the section 7.10.3 of the message implementation guideline. The message 1 maps the dispensing instructions from DME to clinical pharmacy and the message 2 is the dispensing confirmation from clinical pharmacy to DME

Party Information

GS1 Global Location Number	Party Type
9520000000011	Sender of dispensing instructions DME
9520000000028	Organisation receiving the instructions
9520000000004	Protocol sponsor
9520000000127	Clinical Pharmacy location

Message Example 1

Attribute	Value
DispensingAdvice	
dispensingAdviceIdentification	
entityIdentification	3
sender	
GLN	9520000000011
receiver	
GLN	9520000000028

Attribute	Value
protocolID	PROT1
protocolOwner	9520000000004
DispensingForPharmacyOrder	
site	
GLN	9520000000127
investigationalProductIdentification	9520000000530
kitSerialNumber	1243
subjectIdentification	M254
subjectWeight	85
quantity	
quantity	1
measurementUnitCode	H87

Message Example 2

Attribute	Value
DispensingAdvice	
dispensingAdviceIdentification	
entityIdentification	5
sender	
GLN	9520000000028
receiver	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004
MaterialIssuedtoPatientConfirmation	
site	
GLN	9520000000127
subjectIdentification	M254
dateOfDispensing	2020-08-14T00:00:00.000

6 Implementation Considerations

6.1 User Guide

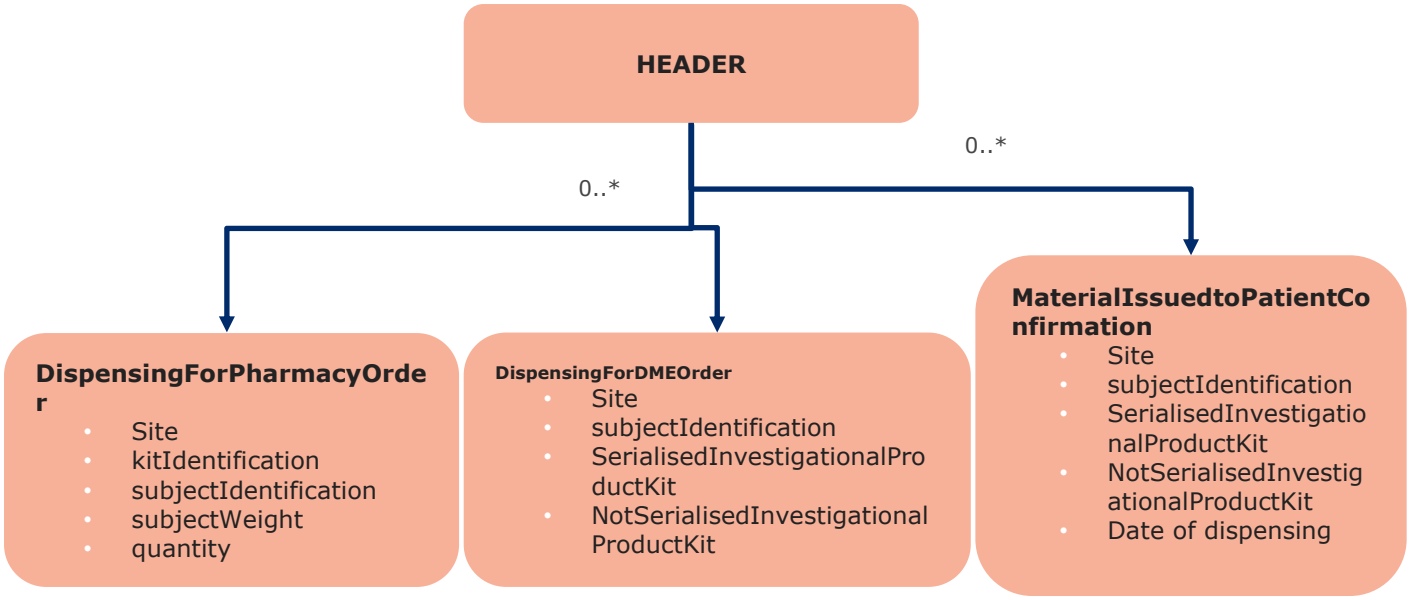
All implementation considerations are discussed in *the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline*.

6.2 Message Specific Considerations

The structure of the Dispensing Advice is multifunctional, depending on the direction of the message and the function.

The DME can generate two kind of dispensing instructions, mapping two scenarios, and the structure of the detail section changes.

The dispensing confirmation maps a third possible structure applicable in the flow from clinical pharmacy to DME



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	

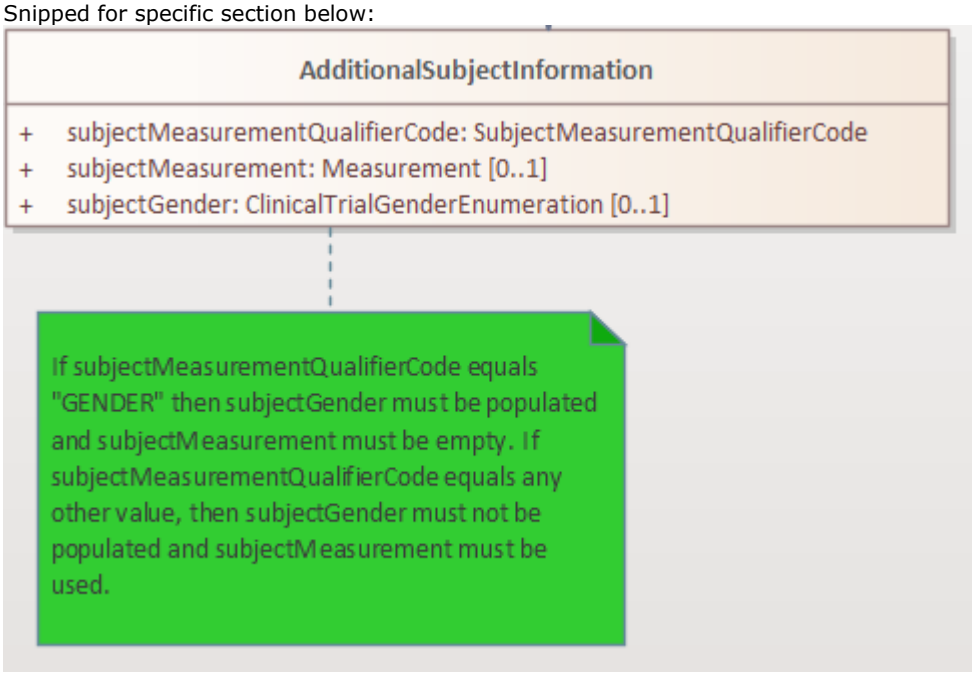
7.2 BMS Release 3.5

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.

7.4 BMS Release 3.6

Change	Associated CR Number
▪ New class **AdditionalSubjectInformation** created New association from DispensingForPharmaOrder to AdditionalSubjectInformation created	WR-22-350
▪ New codelist **subjectMeasurementQualifierCode** added to new class. new measurement **subjectMeasurement** which has cardinality 0..1 added to new class. new enumeration added **subjectGender** to new class with cardinality 0..1	WR-22-350
▪ Snipped for specific section below: 	WR-22-350

8 Appendices

Not Applicable

9 Acknowledgements

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