



The Global Language of Business

Clinical Trial Despatch Advice Business Message Standard (BMS)

Release 3.6, Ratified, Mar 2023



Document Summary

Document Item	Current Value
Document Name	Clinical Trial Despatch Advice 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
09-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group Revision	Changes to the structure, attribute and classes definition, error fixing



Date of Change	Version	Changed By	Reason for Change	Summary of Change
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 dMESHippingReference in dMESHippingReferenceIdentification
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata Corrige	dMESHipmentOrderReference changed to dMESHippingOrderReference. "Quantity" attribute with capital letter, changed to "quantity". ClinicalTrialDespatchAdviceLineItem class definition missing. KitSecurityInformation class definition missing securityTypeCode wrong data type for selected code list storageConditionTypeCode: wrong code list, changed from http://apps.gs1.org/GDD/bms/EANCOM/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:4079HandlingInstructionDescriptionCode&release=2 to the correct one
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 Despatch Advice (also known as the Advanced Shipping Notice) is designed to allow a shipper to provide information about the content of a shipment to a receiver. In the context of a clinical trial, this is advice to the site or depot that they will receive the logistics unit(s) labelled with Serial Shipping Container Code(s). This Dispatch 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
- 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 developing 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.

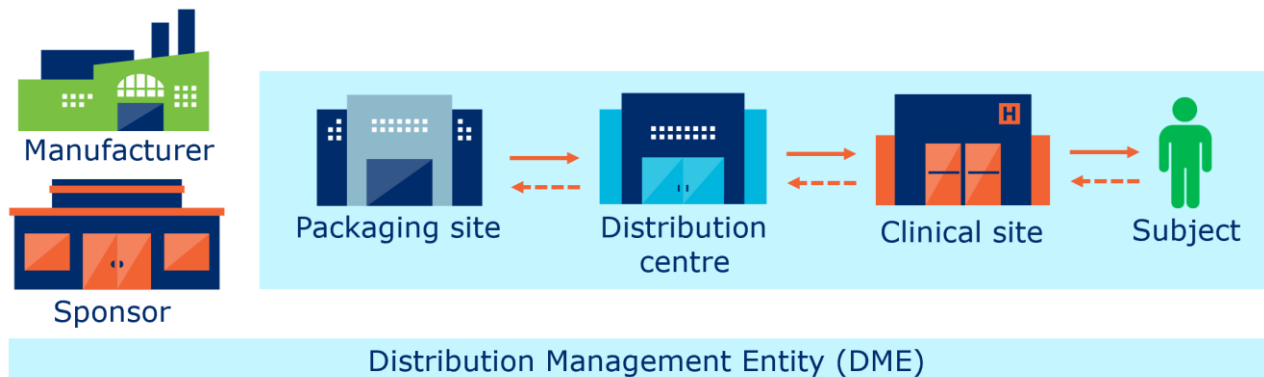


Table 3-1 Roles and responsibilities

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.

Use Case Diagram

N/A

Use Case Description

Below is the use case detailed in *the Guideline*, section 7.5.2.

Performance goals	To ensure an accurate and timely advice of despatch is sent from creation to the recipient of a shipment.															
Preconditions	Unique identification of locations, trade items and logistics units. Correct identification of sender (Ship From) and receiver (Ship To) are in place.															
Postconditions	None identified															
Scenario	<p>Begins when the Ship From party sends an advice of despatch to the Ship To location.</p> <p>In this scenario, the Ship To location is either the ultimate recipient of the goods and will open and use the contents of the logistics units or the DC that will receive and store the goods.</p> <p>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>Ship From</td> <td>Assembles shipment and identifies this as appropriate using logistics unit identifiers (SSCCs).</td> </tr> <tr> <td>2</td> <td>Ship From</td> <td>Creates and sends the despatch advice to Ship To party.</td> </tr> <tr> <td>3</td> <td>Ship To</td> <td>Receives Despatch Advice from the Ship From party.</td> </tr> <tr> <td>4</td> <td>Ship To</td> <td>Checks the delivered goods through scanning the SSCCs or IP Kit IDs</td> </tr> </tbody> </table> <p>Ends when the Ship To party receives the Despatch Advice from the Ship From party.</p>	Step #	Actor	Activity step	1	Ship From	Assembles shipment and identifies this as appropriate using logistics unit identifiers (SSCCs).	2	Ship From	Creates and sends the despatch advice to Ship To party.	3	Ship To	Receives Despatch Advice from the Ship From party.	4	Ship To	Checks the delivered goods through scanning the SSCCs or IP Kit IDs
Step #	Actor	Activity step														
1	Ship From	Assembles shipment and identifies this as appropriate using logistics unit identifiers (SSCCs).														
2	Ship From	Creates and sends the despatch advice to Ship To party.														
3	Ship To	Receives Despatch Advice from the Ship From party.														
4	Ship To	Checks the delivered goods through scanning the SSCCs or IP Kit IDs														
Alternative scenario	None identified															
Related requirements	None identified															

Related rules	<ol style="list-style-type: none">1. The majority of the time the Ship To party is the trial site but may also be the DC.2. It is advised to send a despatch advice to the trial site and also from the packaging site/CMO to the first warehouse in the distribution process.3. If kits that are nominated in the shipment request cannot be shipped, then the shipment request must be cancelled.4. If pallets are created for shipping, this is the point where these are confirmed to the Requestor (sponsor).5. In the case of just in time labelling or free picking, it is at this point where the IP kit numbers are confirmed to the Requestor (sponsor).
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Activity Diagram(s)

Not applicable

Sequence Diagram(s)

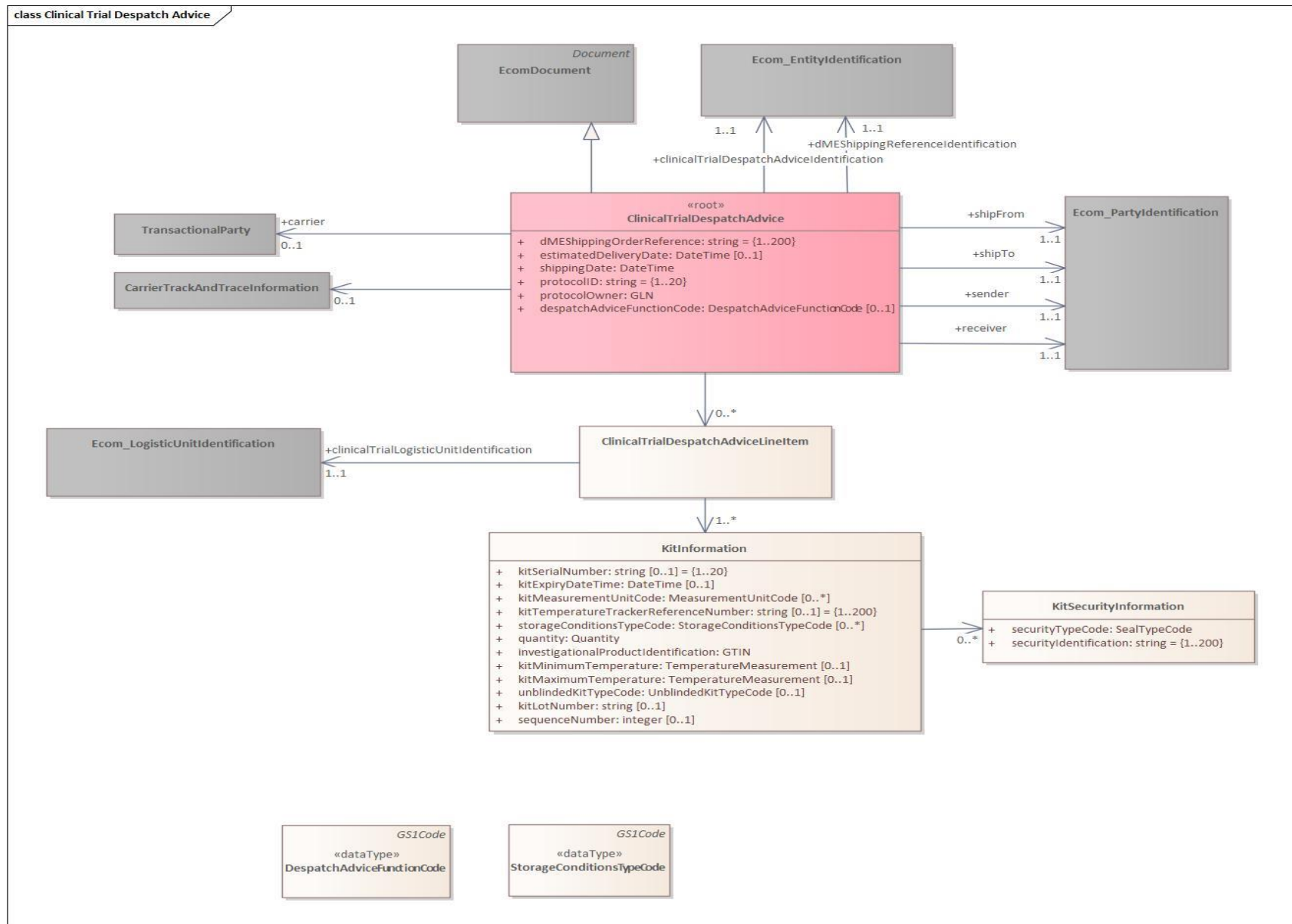
Not applicable



4 Business Information View

4.1 Clinical Trial Despatch Advice

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ClinicalTrialDespatchAdvice				The despatch advice (also known as the Advanced Shipping Notice) is designed to allow a shipper to provide information about the content of a shipment to a receiver. In a clinical trials context, this is advice to the site or depot that they will receive the logistics unit(s) labelled with Serial Shipping Container Codes(s). It is important to note that there could have more than one Despatch Advice per Instruction to Despatch.	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	clinicalTrialDespatchAdviceIdentification	Ecom_EntityIdentification	1..1	The identification of the dispatch advice message	
ASSOCIATION	dMESHippingReferenceIdentification	Ecom_EntityIdentification	1..1	The shipping number assigned by the DME to the shipment	
ASSOCIATION	shipFrom	Ecom_PartyIdentification	1..1	The physical location from where the goods are shipped	
ASSOCIATION	shipTo	Ecom_PartyIdentification	1..1	The physical location where good are shipped to	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The organization generating the Despatch Advice	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The organization receiving the Despatch Advice	
ASSOCIATION	carrier	Ecom_TransactionalParty	0..1	Uniquely identifies the party who transports the shipment.	WR 22-347
ASSOCIATION		Ecom_CarrierTrackAndTraceInformation	0..1	Tracking and tracing information about the package, provided by the carrier.	WR 22-347
ASSOCIATION		ClinicalTrialDespatchAdviceLineItem	0..*	Despatch Advice line item	
ATTRIBUTE	dMESHippingOrderReference	string	1..1	The reference to the shipment order	{1..200}
ATTRIBUTE	protocolID	String	1..1	The protocol identification	{1..20}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the Sponsor of the protocol	
ATTRIBUTE	estimatedDeliveryDate	DateTime	0..1	The estimated date / time of the goods delivery	
ATTRIBUTE	shippingDate	DateTime	1..1	The date / time of the effective shipment	
ATTRIBUTE	despatchAdviceFunctionCode	DespatchAdviceFunctionCode	0..1	The code identifying the expected function of the message	WR-22-349
ClinicalTrialDespatchAdviceLineItem					
ASSOCIATION	clinicalTrialLogisticUnitIdentification	Ecom_LogisticUnitIdentification	1..1	The unique identification of the logistic unit shipped	
ASSOCIATION		KitInformation	1..*	The set of information related to a Kit	
KitInformation					
ASSOCIATION		KitSecurityInformation	0..*	Kit security information	
ATTRIBUTE	investigationalProductIdentification	GTIN	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	0..1	The serial number of the kit	{1..20}
ATTRIBUTE	kitExpiryDateTime	DateTime	0..1	The expiry date of the kit	
ATTRIBUTE	kitMeasurementUnitCode	MeasurementUnitCode	0..*	The measurement unit applicable to the kit	
ATTRIBUTE	kitTemperatureTrackerReferenceNumber	string	0..1	The identification of the temperature tracker	{1..200}
ATTRIBUTE	kitMinimumTemperature	TemperatureMeasurement	0..1	The minimum temperature allowed according to the storage instructions	
ATTRIBUTE	kitMaximumTemperature	TemperatureMeasurement	0..1	The maximum temperature allowed according to the storage instructions	
ATTRIBUTE	storageConditionsTypeCode	StorageConditionsTypeCode	0..*	The code representing the storage instructions for the kit	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	unblindedKitType	UnblindedKitTypeCode	0..1	The code identifying the type of unblinded medication kit to be shipped	WR-22-384
ATTRIBUTE	kitLotNumber	string	0..1	The lot number of the medication kits	WR-22-384
ATTRIBUTE	sequenceNumber	integer	0..1	The sequential number that is assigned to each patient kit during production.	WR-22-343
KitSecurityInformation					
ATTRIBUTE	securityTypeCode	SealTypeCode	1..1	The type of security seal applied	
ATTRIBUTE	securityIdentification	string	1..1	The identification of the security seal applied	{1..200}



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
KitInformation	StorageConditionsTypeCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:StorageConditionTypeCode
KitInformation	MeasurementUnitCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:MeasurementUnitCode&release=1
KitSecurityInformation	SealTypeCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:SealTypeCode&release=1
KitInformation	UnblindedKitTypeCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:UnblindedKitTypeCode
Root	DespatchAdviceFunctionCode	http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:DespatchAdviceFunctionCode



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
9520000000028	Sender
9520000000011	Receiver
9520000000004	Sponsor
9520000000127	Ship To
9520000000152	Ship From

Message Example 1

Attribute	Value
DespatchAdvice	
<i>clinicalTrialDespatchAdviceIdentification</i>	
entityIdentification	345
<i>dMESHippingReference</i>	
entityIdentification	133
<i>sender</i>	
GLN	9520000000028
<i>receiver</i>	
GLN	9520000000011
<i>ShipFrom</i>	
GLN	9520000000152

Attribute	Value
ShipTo	
GLN	9520000000127
dMESHippingOrderNumber	13
protocolID	PROT1
protocolOwner	9520000000004
estimatedDelivery Date	2020-03-27T00:00:00.000
shippingDate	2020-03-23T09:00:00.000+02:00
ClinicalTrialDespatchAdviceLineItem	
clinicalTrialLogisticUnitIdentification	
SSCC	9520000000000000125
kitInformation	
investigationalProductIdentification	95200000000530
kitSerialNumber	1243
kitExpiryDateTime	2021-01-20T00:00:00.000
kitMeasurementUnitCode	H87
kitTemperatureTrackerReferenceNumber	XDTR456
kitMinimumTemperature	
TemperatureMeasurement	10
kitMaximumTemperature	
TemperatureMeasurement	25
storageConditionTypeCode	1
KitSecurityInformation	
securityTypeCode	1
securityIdentification	PFISR-346-TZ
quantity	
quantity	1
measurementUnitCode	H87

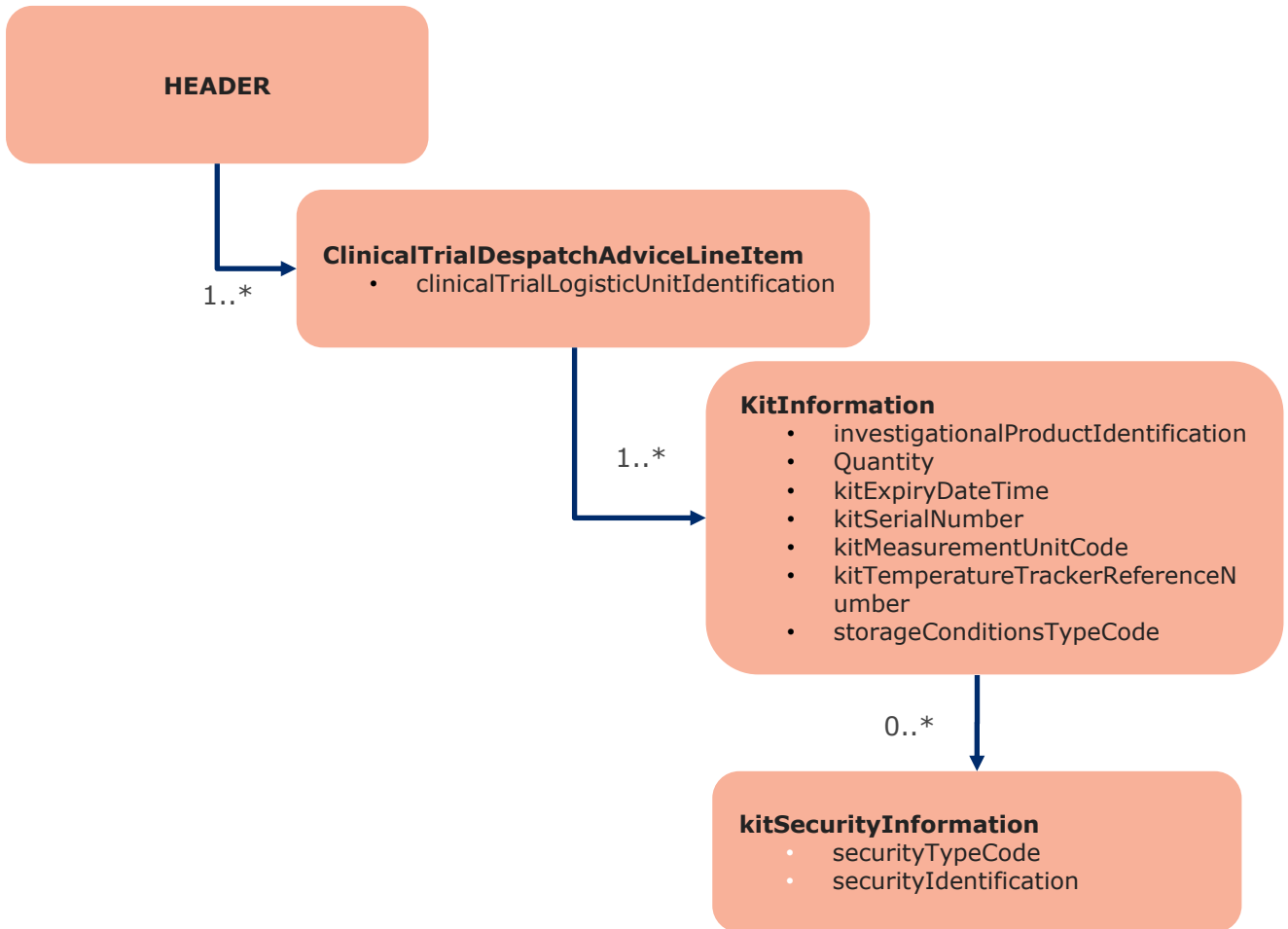
6 Implementation Considerations

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 detail section of the message is created as a set of logistics units. For every logistic unit the content, in terms of lots and / or serial number is specified. For every kit there's the possibility to include one or more security seal numbers and the seals type.



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"> draft 	

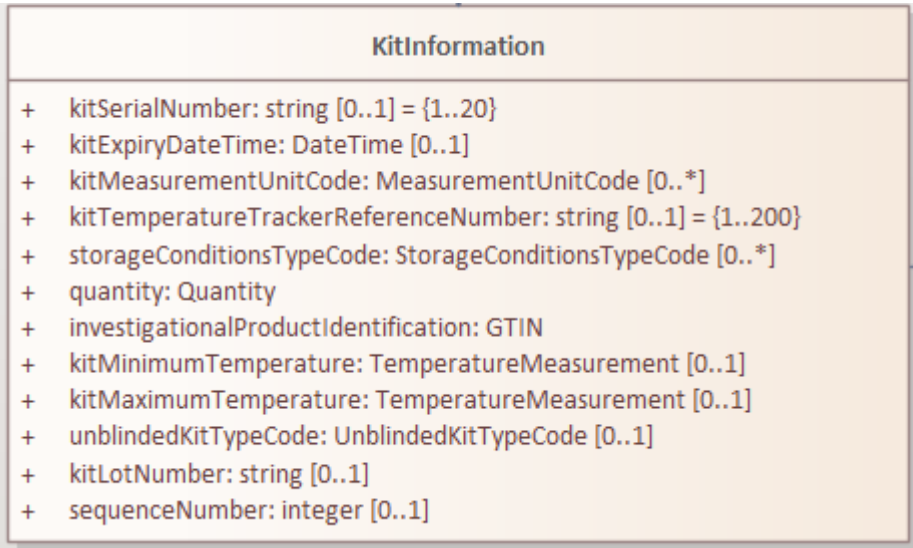
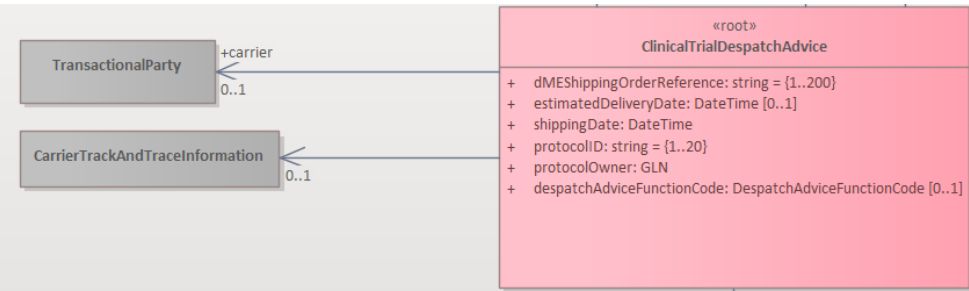
7.2 BMS Release 3.5

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"> SequenceNumber added as new attribute to kitInformation class with cardinality 0..1 	WR-22-343
<ul style="list-style-type: none"> 3 new attributes added to kitInformation class all with cardinality 0..1 unblindedKitTypeCode kitLotNumber sequenceNumber <div data-bbox="320 969 1238 1514" data-label="Diagram">  <pre> classDiagram class KitInformation { + kitSerialNumber: string [0..1] = {1..20} + kitExpiryDateTime: DateTime [0..1] + kitMeasurementUnitCode: MeasurementUnitCode [0..*] + kitTemperatureTrackerReferenceNumber: string [0..1] = {1..200} + storageConditionsTypeCode: StorageConditionsTypeCode [0..*] + quantity: Quantity + investigationalProductIdentification: GTIN + kitMinimumTemperature: TemperatureMeasurement [0..1] + kitMaximumTemperature: TemperatureMeasurement [0..1] + unblindedKitTypeCode: UnblindedKitTypeCode [0..1] + kitLotNumber: string [0..1] + sequenceNumber: integer [0..1] } </pre> </div>	WR-22-348
<ul style="list-style-type: none"> 2 new associations added to root class, both with cardinality 0..1 carrier carrierTrackAndTraceInformation <div data-bbox="320 1632 1294 1921" data-label="Diagram">  <pre> classDiagram class root["«root» ClinicalTrialDespatchAdvice"] { + dMESHippingOrderReference: string = {1..200} + estimatedDeliveryDate: DateTime [0..1] + shippingDate: DateTime + protocolID: string = {1..20} + protocolOwner: GLN + despatchAdviceFunctionCode: DespatchAdviceFunctionCode [0..1] } class TransactionalParty class CarrierTrackAndTraceInformation root --> TransactionalParty : +carrier 0..1 root --> CarrierTrackAndTraceInformation : 0..1 </pre> </div>	WR-22-347

Change	Associated CR Number
<p> ■ despatchAdviceFunctionCode added as a new type code to root class with a cardinality of 0..1 </p> <div style="border: 1px solid black; background-color: #f8d7da; padding: 10px; margin: 10px 0;"> <p style="text-align: center;">«root»</p> <p style="text-align: center;">ClinicalTrialDespatchAdvice</p> <hr/> <ul style="list-style-type: none"> + dMESHippingOrderReference: string = {1..200} + estimatedDeliveryDate: DateTime [0..1] + shippingDate: DateTime + protocolID: string = {1..20} + protocolOwner: GLN + despatchAdviceFunctionCode: DespatchAdviceFunctionCode [0..1] </div>	WR-22-349

8 Appendices

Not Applicable

9 Acknowledgements

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WG chair	Hans von Steiger (Chair)	Pfizer
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WG member	Andreas Geissler	PAREXEL International GmbH
WG member	Mark Hanly	Almac Clinical Technologies
WG member	Mike Hutton	Almac Clinical Technologies
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WG member	Jitendra Kumar	Thermo Fisher Scientific
WG member	Cherish Lallone	McCreadie Group
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WG member	Elizabeth Waldorf	TraceLink
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WG member	Tony Zhang	Syndigo
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WG member	Sue Schmid	GS1 Australia
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WG member	Mig Smith	GS1 UK
WG member	Peter Sturtevant	GS1 US
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WG member	Koichi Uemura	GS1 Japan
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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
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Function	Name	Organisation
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Function	Name	Organisation
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Peer Review	Piergiorgio Licciardello	GS1 Global Office