



The Global Language of Business

Clinical Trial Receiving 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 | Structure changes, class and attributes definition |
| 24-Sep-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Group Revision | |
| 14-Oct-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Updates after community reviews | Add GLN in ReceivingEntity and receivegSiteorDepot description. Change protocolIdentification in protocolID |

| Date of Change | Version | Changed By | Reason for Change | Summary of Change |
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| 29-Oct-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Errata corrige | <p>clinicalTrialReceivingAdviceIdentification, dMESHippingOrderReference, eRPOrderIdentification,, dMESHippingReferenceIdentification wrong secondary class.</p> <p>Rearranged the sequence of lines in GDD report according to BMS writing rules</p> <p>NonCompliantKitInformation: wrong data type and Code List url. Changed from http://apps.gs1.org/GDD/bms/EANCOM/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:4295ChangeReasonDescriptionCode&release=4 to the correct one</p> |
| 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 objective of the Receiving Advice message is to send a notification that the good(s) were received (when compared to the good(s) shipped). There must be a one to one match between the Despatch Advice and Receiving Advice.

This Receiving 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
- 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 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.

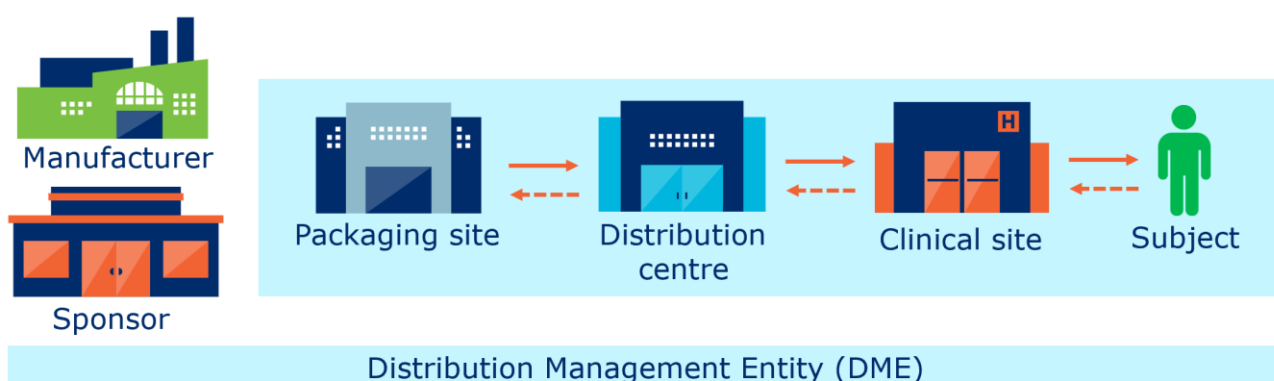


Table 3-1 Roles and responsibilities

| 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

| Performance goals | To ensure confirmation of receipt of goods is sent from the Ship To party to the Shipment Requestor and assessment of shipment integrity is communicated back to the shipment requestor | | | | | | | | | | | | | | | | | | | | | |
|----------------------|--|---|-------|---------------|---|---------------|---|---|---------------|---|--|--------------------|--|---|---------|---|---|---------------|--------------------|---|---------|---|
| Preconditions | Unique identification of locations, trade items and logistics units will be undertaken. Correct identification of sender (Ship To) and receiver (Ship From) are in place. Despatch Advice has been successfully received by the Ship To location. | | | | | | | | | | | | | | | | | | | | | |
| Postconditions | None identified | | | | | | | | | | | | | | | | | | | | | |
| Scenario | <p>Begins when the Ship To party must send an advice of receipt to the Ship From location. In this scenario, the Ship To location is either the ultimate recipient of the goods that will open and use the contents of the logistics units or the DC which will receive and store the goods.</p> <p>Continues with...</p> <table><tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr><tr><td>1</td><td>Ship To Party</td><td>Receives shipment and reconciles content of the physical shipment vs the Despatch Advice.</td></tr><tr><td>2</td><td>Ship To Party</td><td>Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor.</td></tr><tr><td></td><td>Shipment Requestor</td><td></td></tr><tr><td>3</td><td>Sponsor</td><td>Receives the receiving advice from the Ship To party.</td></tr><tr><td>4</td><td>Ship To Party</td><td>Updates inventory.</td></tr><tr><td>5</td><td>Sponsor</td><td>(Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site.</td></tr></table> <p>Ends when the oods can be used.</p> | Step # | Actor | Activity step | 1 | Ship To Party | Receives shipment and reconciles content of the physical shipment vs the Despatch Advice. | 2 | Ship To Party | Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor. | | Shipment Requestor | | 3 | Sponsor | Receives the receiving advice from the Ship To party. | 4 | Ship To Party | Updates inventory. | 5 | Sponsor | (Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site. |
| Step # | Actor | Activity step | | | | | | | | | | | | | | | | | | | | |
| 1 | Ship To Party | Receives shipment and reconciles content of the physical shipment vs the Despatch Advice. | | | | | | | | | | | | | | | | | | | | |
| 2 | Ship To Party | Creates and sends Receiving Advice, including discrepancies, any visible quality issues, etc, to the sponsor. | | | | | | | | | | | | | | | | | | | | |
| | Shipment Requestor | | | | | | | | | | | | | | | | | | | | | |
| 3 | Sponsor | Receives the receiving advice from the Ship To party. | | | | | | | | | | | | | | | | | | | | |
| 4 | Ship To Party | Updates inventory. | | | | | | | | | | | | | | | | | | | | |
| 5 | Sponsor | (Optional step) Enables 'use' or 'dispensed' of the goods upon confirmation of receipt at the receiving site. | | | | | | | | | | | | | | | | | | | | |
| Alternative scenario | None identified | | | | | | | | | | | | | | | | | | | | | |
| Related requirements | Inventory status and quality will be reported using the receiving advice, including any damaged or missing goods – compared to the original shipment. | | | | | | | | | | | | | | | | | | | | | |

| | |
|---------------|--|
| Related rules | <ol style="list-style-type: none"> 1. The Ship To party may be either the distributor or trial site depending on where the necessary inventory is to be shipped. 2. One Receiving Advice will be sent by the Ship To location to each Ship From location. 3. Upon notification of any discrepancies, investigation of root cause occurs. Part or all of the contents of the shipment will be held in an 'unreleased state' until the investigation is complete. 4. A combination of sponsor ID, study ID and order ID will uniquely identify the message. 5. Each receiving system will determine how to handle the status of the supplies, e.g., available to dispense, quarantined or inventory management issue (quantity, wrong item, missing item, damaged item, etc). 6. In all cases the sponsor is the receiver of the Receiving Advice. |
|---------------|--|

Activity Diagram(s)

Not applicable

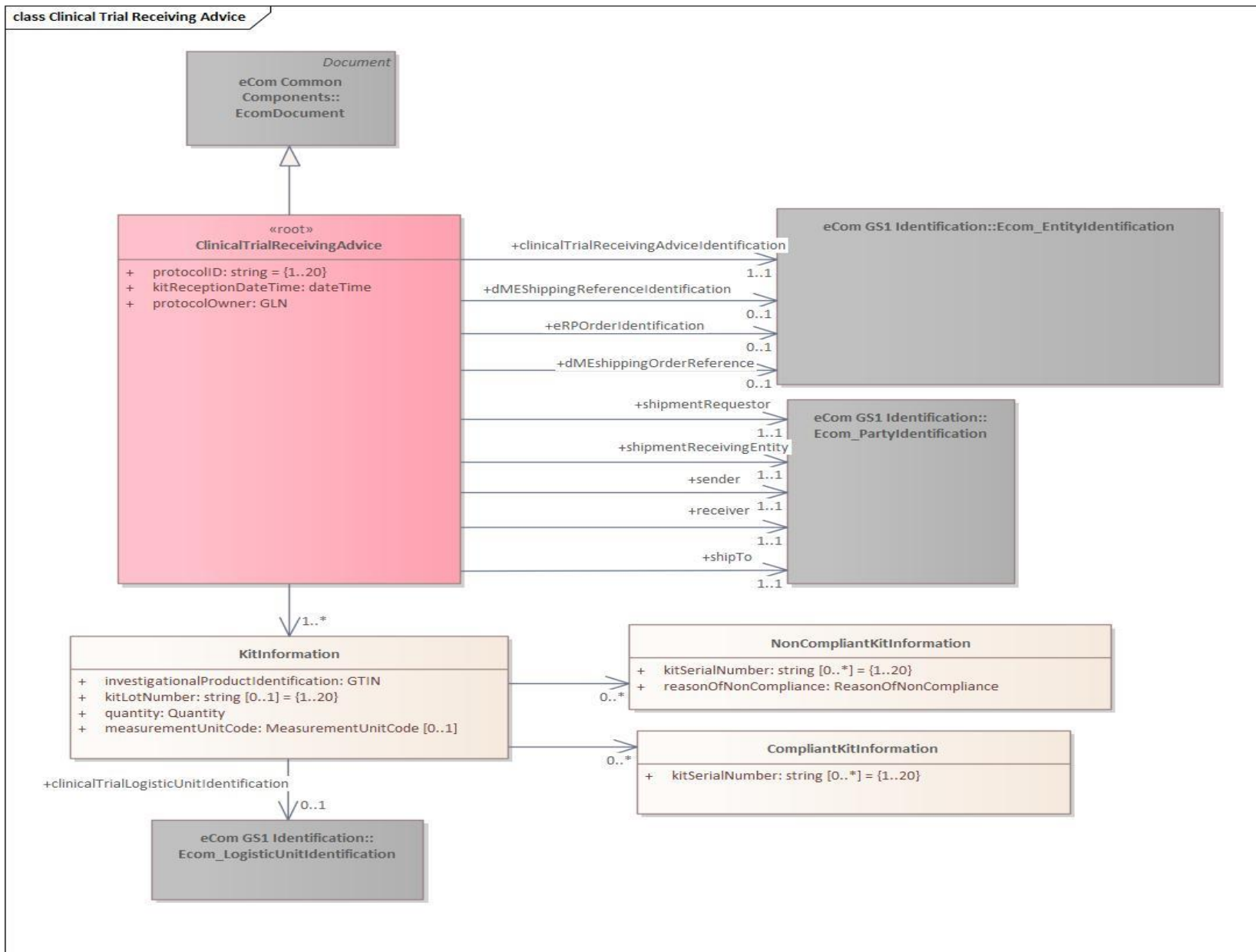
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Clinical Trial Receiving Advice

Class diagram





Global Data Dictionary (GDD) report

| Content | Attribute / Role | Datatype / Secondary class | Multiplicity | Definition | Constraints |
|-------------------------------------|--|----------------------------|--------------|---|-------------|
| ClinicalTrialReceivingAdvice | | | | This message is sent from the receiver of the shipment (e.g. trial site) to the creator the shipment request (e.g. the DME) to confirm the goods received | |
| ASSOCIATION | GENERALIZATION | EcomDocument | 1..1 | | |
| ASSOCIATION | clinicalTrialReceivingAdviceIdentification | Ecom_EntityIdentification | 1..1 | The identification of the Receiving Advice message | |
| ASSOCIATION | sender | Ecom_PartyIdentification | 1..1 | The sender of the message | |
| ASSOCIATION | receiver | Ecom_PartyIdentification | 1..1 | The receiver of the message | |
| ASSOCIATION | shipmentRequestor | Ecom_PartyIdentification | 1..1 | The GLN of the requestor of the shipment, i.e. DME vendor or third-party depot system | |
| ASSOCIATION | shipmentReceivingEntity | Ecom_PartyIdentification | 1..1 | The GLN of the entity receiving the shipment | |
| ASSOCIATION | | KitInformation | 1..* | Information related to the kits received | |
| ASSOCIATION | dMESHippingOrderReference | Ecom_EntityIdentification | 0..1 | The reference to the DME order number | |
| ASSOCIATION | ERPOrderIdentification | Ecom_EntityIdentification | 0..1 | Internal receiving site ERP reference to the shipment order | |
| ASSOCIATION | dMESHippingReferenceIdentification | Ecom_EntityIdentification | 0..1 | The reference to the DME shipping number | |
| ATTRIBUTE | kitReceptionDateTime | DateTime | 1..1 | The date / time of the reception of the items | |
| ATTRIBUTE | protocolID | string | 1..1 | The unique identification of the protocol | {1..20} |
| ATTRIBUTE | protocolOwner | GLN | 1..1 | The identification of the protocol sponsor | |
| ASSOCIATION | shipTo | Ecom_PartyIdentification | 1..1 | The GLN of the physical location where the goods are received | |
| KitInformation | | | | | |
| ASSOCIATION | | NonCompliantKitInformation | 0..* | Information about non-compliant kits | |

| Content | Attribute / Role | Datatype / Secondary class | Multiplicity | Definition | Constraints |
|----------------------------|---|---------------------------------|--------------|---|-------------|
| ASSOCIATION | | CompliantKitInformation | 0..1 | Information about compliant kits | WR-22-351 |
| ASSOCIATION | clinicalTrialLogisticUnitIdentification | Ecom_LogisticUnitIdentification | 0..1 | The identification (SSCC) of the logistic unit | |
| ATTRIBUTE | investigationalProductIdentification | gtin | 1..1 | The GTIN of the investigational product | |
| ATTRIBUTE | kitLotNumber | string | 0..1 | The kit lot / batch number received | {1..20} |
| ATTRIBUTE | quantity | Quantity | 1..1 | The quantity of kits | |
| ATTRIBUTE | measurementUnitCode | MeasurementUnitCode | 0..1 | Unit of measure for the content for bulk drugs, i.e. KG or count of pills | |
| NonCompliantKitInformation | | | | | |
| ATTRIBUTE | kitSerialNumber | string | 0..* | The serial number of the non-compliant kit | {1..20} |
| ATTRIBUTE | reasonOfNonCompliance | ReasonOfNonCompliance | 1..1 | The non-compliance code | |
| CompliantKitInformation | | | | | |
| ATTRIBUTE | kitSerialNumber | string | 1..* | The serial number of the compliant kit | WR-22-351 |



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 | MeasurementUnitCode | http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:MeasurementUnitCode&release=1 |
| NonCompliantKitInformation | ReasonOfNonCompliance | http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:ReasonOfNonCompliance |
| | | |



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 |
|----------------------------|----------------------|
| 9520000000011 | ShipmentRequestor |
| 9520000000028 | ReceivingEntity |
| 9520000000004 | Sponsor |
| 9520000000127 | receivingSiteOrDepot |

Message Example 1

| Attribute | Value |
|---|-------------------------------|
| ReceivingAdvice | |
| clinicalTrialReceivingAdviceIdentification | |
| entityIdentification | 12 |
| dMESHippingOrderReference | 13 |
| eRPOrderIdentification | |
| entityIdentification | 332 |
| dMESHippingReference | |
| entityIdentification | 133 |
| shipmentRequestor | |
| GLN | 9520000000011 |
| shipmentReceivingEntity | |
| GLN | 9520000000028 |
| kitReceptionDateTime | 2020-03-27T12:54:00.000+02:00 |
| protocolID | PROT1 |
| protocolOwner | 9520000000004 |

| Attribute | Value |
|--|--------------------|
| shipTo | |
| GLN | 9520000000127 |
| kitInformation | |
| clinicalTrialLogisticUnitIdentification | |
| SSCC | 952000000000000125 |
| investigationalProductIdentification | 95200000000530 |
| kitLotNumber | LOT1 |
| quantity | |
| quantity | 1 |
| measurementUnitCode | H87 |
| kitMeasurementUnitCode | H87 |
| nonCompliantKitInformation | |
| kitSerialNumber | 1243 |
| reasonOfNonCopliance | BA |

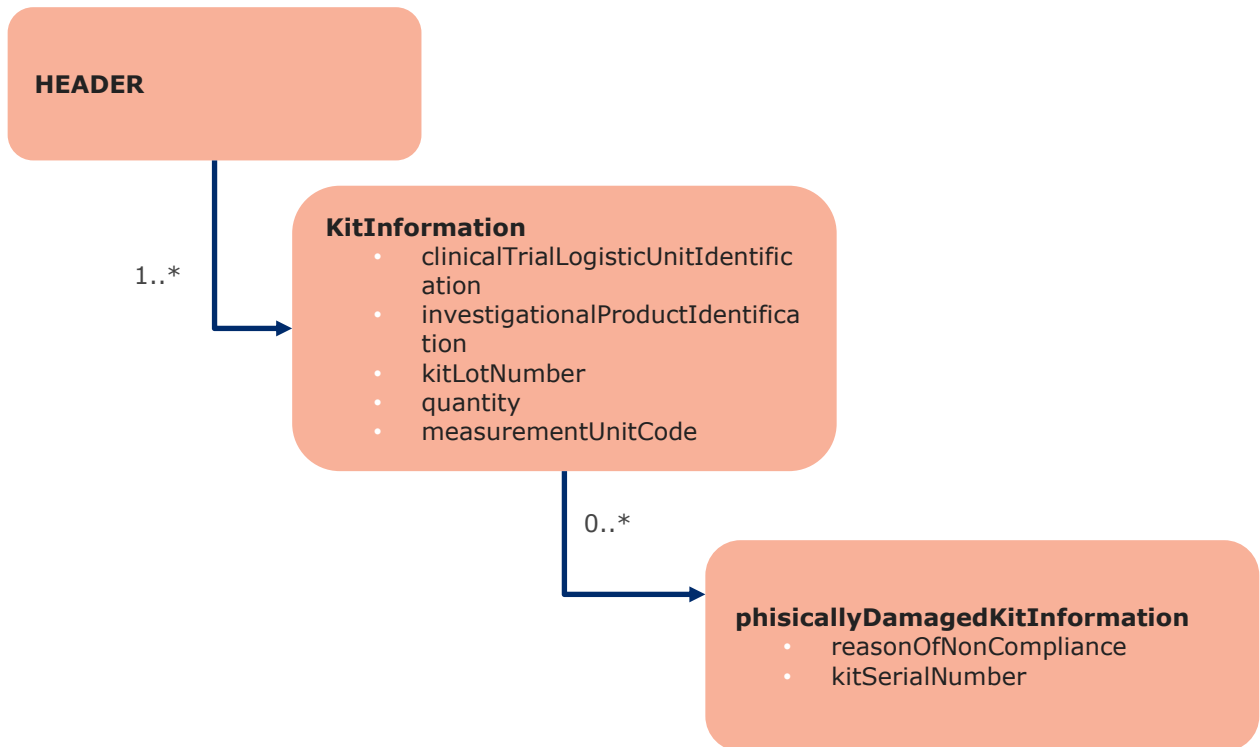
6 Implementation Considerations

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 Receiving Advice section provides the list of logistic units and lots received. For every logistic unit there's the possibility to specify a list of non-compliant serials.



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 | Associate d CR Number |
|---|-----------------------------|
| <ul style="list-style-type: none"> Created new class CompliantKitInformation created new association from KitInformation to CompliantKitInformation Added existing attribute kitSerialNumber in CompliantKitInformation class with cardinality 0..* | WR-22-351 |
| <ul style="list-style-type: none"> Fixed errata kitSerialNumber attribute in bms from 1..1 to 0..* cardinality to be consistent with the xsd and model | |
| <ul style="list-style-type: none"> Fixed errata reasonForNonCompliance spelling error in model and schema fixed. | |

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

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