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GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline

A guideline that details the best practice approach to implementation of GS1 standards for electronic messaging in the pharmaceutical clinical trial supply chain.

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1.1	Dec 2020	Tania Snioch & Piergiorgio Licciardello	Work Request 20-102 General revision
1.1.1	Apr 2021	D.Buckley	WR 21-121 & 21-122: terminology errata fixes
1.2	Jun 2023	P. Licciardello	Introduction of references to semantic methodology

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Table of Contents

1 Executive summary

There is no standard for data exchange within the clinical trials environment. Messages are being exchanged between sponsors, carriers, depots, clinical sites and other entities in a heterogeneous way. Lack of a standard for messaging format, structure and content limits exchange between stakeholders. This results in data quality issues and subsequently disruptions in the supply chain.

Data exchange standards are a tool to assist in accelerating getting drugs to market, reducing costs, enabling interoperability and are the foundation for initiatives such as the implementation of the GS1 Global Data Synchronisation Network® (GDSN®).

Given this, it is important to align the standards for data and /information exchange with the direction of other industries, particularly the commercial healthcare supply chain.

2 Benefits of implementation, business opportunity and business needs

There is an industry wide *Identification of Investigational Products in Clinical Trials Application Standard* for the use of GS1 standards for identification and barcoding of the investigational products and kits used in clinical trials. Following the release of this standard, the industry identified the need for a standardised process to electronically exchange data and information to support the clinical trial processes from start to finish.

As a result, the clinical trial community came together to establish this electronic data exchange guideline. This document provides guidance for the exchange of clinical trial data sets for specific messages, the business process and mapping to relevant GS1 standard message formats. This standardisation leverages GS1 Identification Keys such as the Global Trade Item Number® (GTIN®), Global Location Number (GLN) and Serial Shipping Container Code (SSCC).

3 Introduction

3.1 Purpose

This implementation guide is one part of a suite of documents designed to guide readers on WHY and HOW to implement GS1 standards for electronic messaging. This document defines the messages in scope, business-critical data set and relevant business rules. Separate documents contain the detailed technical mappings to GS1 message formats.

3.2 Scope

The scope of this work includes all messages identified in section 4.2 Clinical trial messages. The intent is that messages and processes related to all clinical trials are in scope, including:

- Investigator and manufacturer-sponsored trials.
- Portal and non-Interactive Response Technology (IRT) trials, as well as IRT trials.
- Investigational product movements involving CMO, depot, DC, etc.

The workgroup developing this guideline 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.

4 Business processes and messages

4.1 Business process participants

Figure 4-1 shows the main actors that are involved in the clinical trials processes.

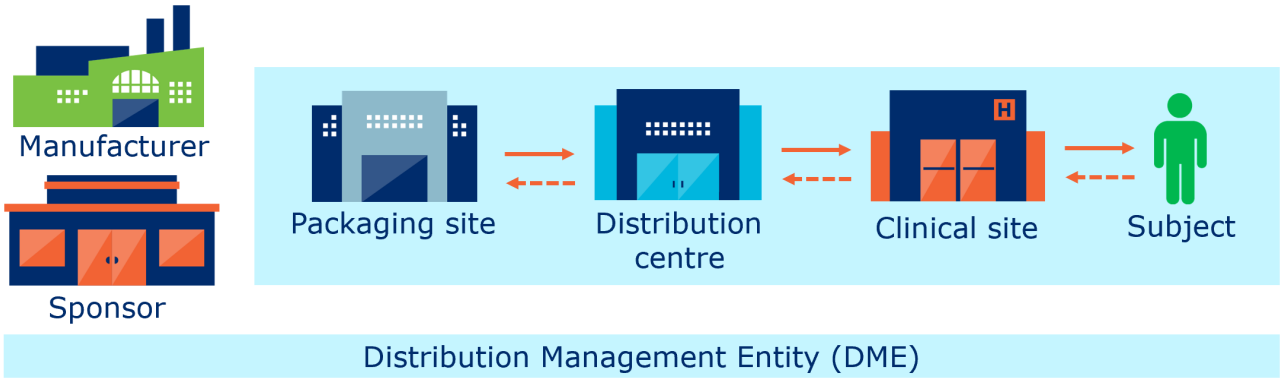

Figure 4-1 Flowchart of actors involved

Table 4-1 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.

4.2 Messaging Sequence Diagram

From sponsor to trial site (a simplified view), the diagram below details the messages in scope for this phase of work and the majority of interactions. This diagram is illustrative only.

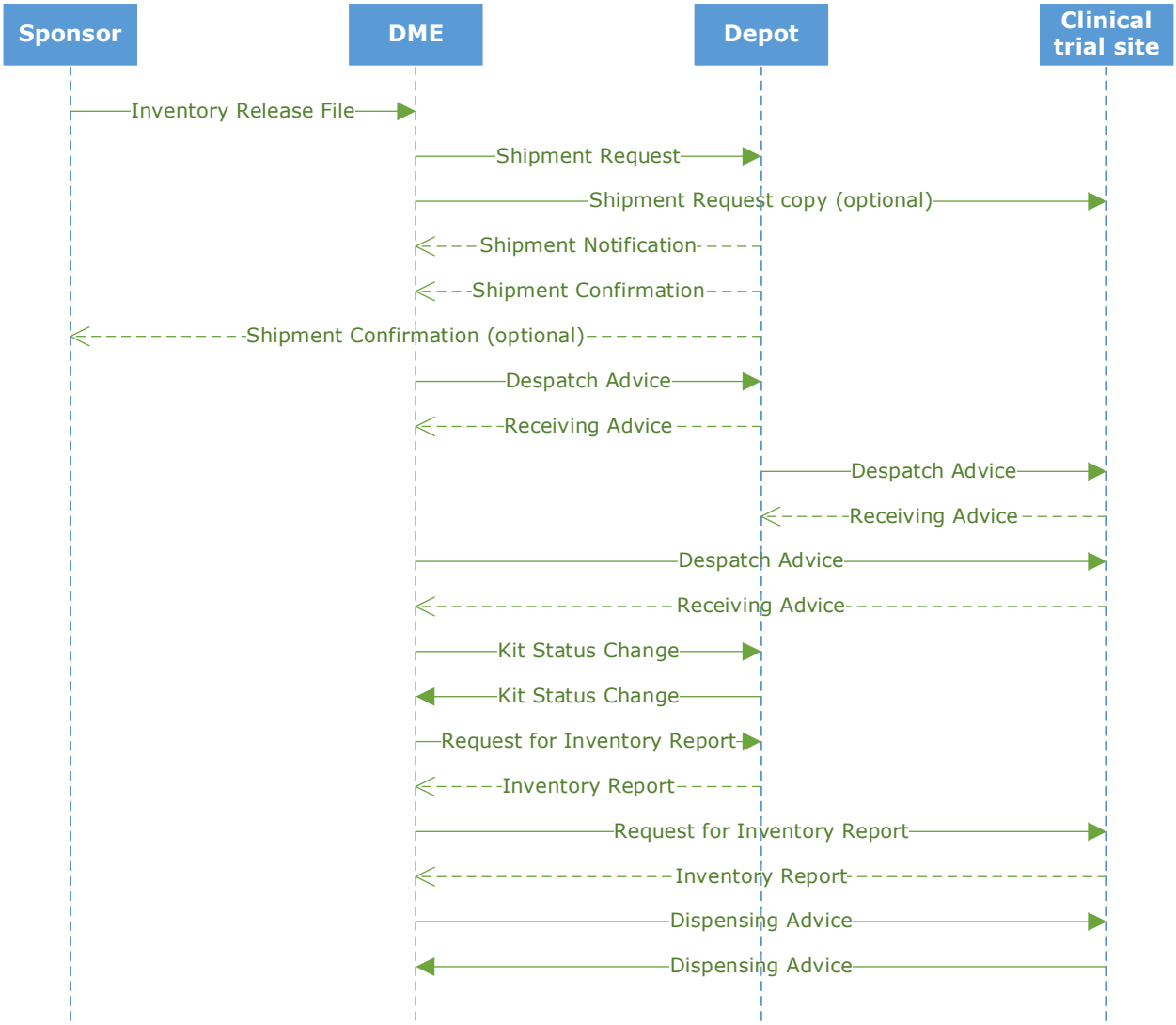

Figure 4-2 Messages in scope

5 Implementation considerations

There are some pre-requisites to implementation of GS1 standards for electronic messaging. These pre-requisites include internal knowledge and capabilities and completion of foundational aspects, such as allocation of GS1 Identification Keys.

The pre-requisites discussed in this chapter are not exhaustive. Each organisation should consider this guidance in line with its current capabilities and levels of GS1 standards implementation.

5.1 Systems capabilities and process considerations

Data coming from internal systems must be complete and accurate. Sending and receiving systems must have validation/data quality checks before initiating the creation of messages. Without quality checks, there could be mismatches in data exchange or cancellation of messages, which will lead to manual intervention. Electronic business messaging is designed to reduce precisely that.

5.2 Acknowledgement messages versus processing of messages

When implementing an electronic exchange between business partners, there are different levels of feedback a receiving party can provide to the sender.

The first and simplest one is the "technical acknowledgement" that is nothing more than a feedback message informing the sender that the message has been received. This doesn't means that the message has been correctly processed and provides no info about the correctness of the content.

After checking the message in terms of business rules, mandatory fields, content format, etc., a "functional acknowledgement" can be, eventually, generated by the receiving system.

When the message has been processed, another response message can be generated to either confirm the accuracy of the content or to identify the errors/issues that exist in the business content.

The set of messages that can be exchanged among business partners are detailed in this document.

5.3 Unique identification of messages

The message guidelines have been developed so that every file generated (technical, functional acknowledgement or business response) has a unique identifier to help facilitate the order in which it should be processed, i.e. a date and time stamp. The location of this message identification is shown within the detailed message mappings (complimentary documents to this guideline).

5.4 Use of GS1 identification keys

Together with the GS1 message standard formats, the following globally standardised and unique GS1 identification keys must be used:

1. GS1 Global Trade Item Numbers (GTINs) for identification of the investigational product kits, investigational products, and other products. The GS1 *global application standard* details how to allocate GTINs for investigational products.
2. GS1 Global Location Numbers (GLNs) to identify physical locations, functional and legal entities. More information about the allocation of Global Location Numbers in healthcare is in the *Healthcare GLN Implementation Guide*.
3. GS1 Serial Shipping Container Codes (SSCCs) for identification of logistics units. Information about the allocation of SSCCS is in the *Healthcare AIDC Implementation Guide*.

6 Clinical trial specific considerations

There are important considerations to take into account when implementing EDI for clinical trials.

6.1 Handling ancillary and auxiliary items

It is by agreement between the parties involved in a clinical trial whether to exchange information about ancillary and auxiliary items via the electronic messaging guidelines discussed within this document. To align with industry best practice electronic messaging is recommended. If a DME (Distribution Management Entity) manages the clinical trial supplies, then ancillary and auxiliary items should be managed as per the messages defined in this guideline.

If the items have been allocated a GTIN and serial number those data elements must be used in the electronic messages (if electronic messaging is implemented).

6.2 Understanding serialisation for clinical trials and serialisation of commercial items

More than 70 countries have regulations, government requirements or trading partner requirements driving implementation of GS1 standards for identification of commercial medicinal products and medical devices. A significant proportion of these are driving implementation of serialisation – often for unique instance identification for medical devices and for medicinal productsso as to prevent counterfeit items entering the supply chain.

This means that many of the ancillary, auxiliary or comparator products entering the clinical trial supply chain (and discussed in these electronic messages) will already carry GTINs and serial numbers. If these products (in line with the *Application StandardIdentification of Investigational Products in Clinical Trials Application Standard*) are to maintain their commercial presentation (commercial label) these GTINs and serial numbers will be used in the electronic messages exchanged. If however, these products are to be defined in a clinical presentation, they will be re-labelled with appropriate GTINs and serial numbers as defined by the trial sponsor.

6.3 Clinical trials already in progress - Products without GTINs

For products that don't have a GTIN printed on the packaging, a GTIN should be allocated for electronic messaging exchange purpose. The GTIN needs to be printed on the packaging when the packaging is updated.

6.4 Important clinical trial process definitions

There are different models for picking investigational product kits and products . Trial stakeholders agree on the process at the start of each trial. Common definitions for these processes are below.

(1) Serialised directed picking

During the serialised directed picking process, the investigational product kits and investigational products are pre-labelled. The picking process involves using the GTIN, quantity and serial number for identification of the items to be picked and this can be facilitated by scanning the GS1 barcodes applied to the items. Serialized directed picking is the most common form of picking used in the clinical trial environment.

(2) Free picking

The process of free picking allows the Distribution Management Entity (DME) to specify the general criteria relating to the kits to ship. The organisation undertaking the picking (and shipping of the picked goods) selects the appropriate material based on DME provided criteria and responds to the DME with the kit numbers that have been sent. There are several free picking configurations, including:

- Blinded
  - The GTIN, quantity and order treatment type (arm of the study) are specified for picking. There is an option to also include the minimum expiry (use period).
  - The picker communicates back the kit ID using the Order Confirmation message as defined in this guideline.
  - The Order Confirmation message would be exchanged between the DME and the unblinded depot/DC/CMO.
- Open-label non-serialised
  - The request from the DME will be for selection of, for example, four investigational product kits.
  - The identification to allow picking is the GTIN and the quantity. There will be no requirement to track the kit IDs. This means that the Order Confirmation will confirm the GTIN and the quantity information only.

- It is optional for the DME to specify minimum lifespan specified (use period) of the kits to be selected.

- Open-label serialised
  - This picking process is almost identical to open-label non-serialised picking. The difference is that in this model the kit IDs are communicated from the picking location to the DME via the Order Confirmation message.

(3) Just in time labelling

Free picking is also used in trials that leverage just in time or on-demand labelling. In the case of just in time labelling any entity undertaking labelling will be considered 'unblinded'.

(4) Shelf-life extension or reduction

When investigational product kits and investigational products are required to have their shelf life extended or reduced, the organisation storing the inventory will need to physically change the product by applying new labels.

(5) Study pooling

The concept of study pooling is accounted for in the messages contained within this guideline. As a result, in some electronic messages protocol number is considered mandatory and in other messages it is considered optional.

7 Messages description, use case & data fields

7.1 Inventory Release File

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'. Serialised and non-serialised items are included in separate messages.

7.1.1 Description of the message communication

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.

7.1.2 Example use case

<table>
<tr><td>Performance goals</td><td>To ensure that clinical trial sites, DCs and other locations can release IP kits for use.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units.
Master data is shared.</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 DME to advise that inventory can be ordered/requested. Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<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>
</table>
Ends when inventory is available for use or shipping to relevant trial locations.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
</table>

Related requirements	None identified
Related rules	None identified

7.1.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	BDTG00000953
Business document receiver party information	BDTG00000954
Clinical trial protocol owner party information	BDTG00000961
Clinical trial protocol identification	BDT00000960

Message content

Serialised items

Note: Some organisations will blind the Inventory Operations Instructions message. When the message is blinded, it is because a kit list has previously been shared between the sender and receiver that can be used to decode the kit serial numbers to the correct treatment. Organisations that do not share the kit list upfront depend on the Inventory Operations instructions message to share which inventory has been released and in the case of blinded medication, the decode of serial kit number to treatment arm. Therefore, this field is optional in the message depending on the technique chosen by the parties involved.

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Serial number	BDT00000121
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Kit sequence number	BDT00000963
Medication kit type	BDT00000964
Expiration date	BDT00000057
Kit location information	BDTG00000962
Medication kit status type code	BDTG00000966

Non-serialised items

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Medication kit type	BDT00000964
Expiration date	BDT00000057
Kit location information	BDTG00000962
Medication kit status type code	BDTG00000966

7.2 Shipment Request

The Shipment Request is used to request the shipment of goods in any of the following scenarios: Serialised directed picking or free picking (blinded, open-label non-serialised or open-label serialised).

7.2.1 Description of the message communication

This message is sent between the DME and the depot (which may be a warehouse, 3rd party logistics facility, contract manufacturing, packaging organisation or other).

7.2.2 Example use case

<table>
<tr><td>Performance goals</td><td>To create and deliver appropriate communication to ensure an accurate shipment, as requested by the requestor, to the correct recipient.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the DME requests that the depot prepare and send a shipment.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Ship From Party</td><td>Receives request with the list of goods to prepare.</td></tr>
<tr><td>2</td><td>Trial Site</td><td>Receives a copy of the request (optional).</td></tr>
<tr><td>3</td><td>Ship from Party</td><td>Provides (optional) shipment acknowledgement (order acknowledgement) that the shipment request has been received. This message does not go to the clinical site.</td></tr>
</table>
Ends with the acknowledgement of receipt of request to ship.</td></tr>
</table>

Alternative scenario	Not applicable
Related requirements	None identified
Related rules	1. The sponsor is the ultimate controller of inventory throughout the IP supply chain and determines the appropriate inventory levels at all locations.

7.2.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Business document identification information	*BDTG00000480*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*
Kit minimum temperature information	*BDTG00000950*
Kit maximum temperature information	*BDTG00000952*
Precaution description	*BDT00000979*
Precaution qualifier code	*BDTG00000978*
Referenced distribution management entity shipping order information	*BDTG00000959*
Requested delivery date time	*BDTG00000291*
Ship from party information	*BDTG00000310*
Ship to party information	*BDTG00000311*
Shipment request date	*BDT00000971*
Shipment request comments	*BDT00000972*
Shipment request type code	*BDTG00000974*
Temperature qualifier code	*BDTG00000976*

Message Content

By document type:

Document type: picking from existing labelled stock for both serialised and open-label studies

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Minimum lifespan from shipment	BDTG00000981
Serial number	BDT00000121

Document type: Free picking from pre-labelled stock (kit is already packaged and labelled)

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Minimum lifespan from shipment	BDTG00000981

Document type: Labelling just in time (where the kit is not pre-assembled)

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Kit component original lot number	BDT00000892
Medication kit quantity	BDTG00000968
Minimum lifespan from shipment	BDTG00000981

7.3 Shipment Notification

The Shipment Notification is the acknowledgement of the Shipment Request message. The Shipment Notification should be sent by the recipient once the Shipment Request message is received by the recipient. It is an important hand-shake between the sender (DME) and receiver (depot) in the clinical supply chain. Its purpose is to confirm the Shipment Request has been received without any transmission delays, corruption, data integrity, broken business rules or any other such undesirable effects.

7.3.1 Description of the message communication

Messages are sent between the depot and the DME.

7.3.2 Example use case

Performance goals	To ensure an accurate and timely acknowledgement that the shipment request has been received.

<table>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units will be undertaken. Correct identification of sender (Ship From) and receiver (Ship To) are in place.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the Ship From party sends a notification to the requestor of the shipment request (UC-1).
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Requestor</td><td>Receives the shipment notification.</td></tr>
</table>
Ends when the Requestor provides the shipment notification.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>None identified</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

7.3.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*
Referenced shipment request information	*BDTG00000982*

7.4 Shipment Confirmation

The Shipment Confirmation is sent from the depot back to the DME and confirms that an order will be or has been processed. This message includes many of the order specifics, including the supplies on the order. This message comes later than the Shipment Notification message because of the time needed for the processing of the supplies (e.g., in the case of JIT, the supplies that will be sent for the order may not be known until after they have been labelled). This message may also be shared with the sponsor.

7.4.1 Description of the message communication

Messages are sent between the depot and the DME.

7.4.2 Example use Case

Performance goals	To ensure accurate and timely advice that the shipment is ready.

<table>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units. Correct identification of sender (Ship From) and receiver (Ship To) are in place.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the Ship From party sends a notification to the requestor of the shipment request .
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Requestor</td><td>Receives the shipment confirmation.</td></tr>
<tr><td>2</td><td>Requestor</td><td>Records the IP kit numbers in their systems.</td></tr>
</table>
Ends when... Requestor receives and processes the shipment confirmation into their systems.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>None identified</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

7.4.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*
Referenced distribution management entity shipping order information	*BDTG00000959*
Referenced initial order number information	*BDTG00000983*
Referenced shipment request information	*BDTG00000982*
Requested delivery date time	*BDTG00000291*

Message Content

Business Term	SDD-ID
Clinical trial product identification information	*BDTG00000947*
Lot number	*BDT00000090*

Business Term	SDD-ID
Medication kit quantity	BDTG00000968
Reason for non compliance code	BDTG00000984
Sufficient stock indicator	BDT00000985

7.5 Despatch Advice

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). There can be more than one Despatch Advice per Instruction to Despatch.

The best practice recommendation is that sending of the Despatch Advice is considered mandatory given its benefit in providing advanced notification of shipment to locations receiving stock.

The following shall be considered when implementing the Despatch Advice between partners:

- There must be one Despatch Advice per shipment, even if the shipment contains multiple logistics units.
- Parties exchanging the Despatch Advice must agree if they will accept a partial shipment or not.
- In the case of items that have different temperature storage requirements (e.g., ambient medication compared with cold chain), there could be a single instruction to dispatch, a single Despatch Advice, but with the items subject to different temperatures in different containers (to maintain those temps).
- The message content must conform to the type of trial (open, single blind, double blind) within the despatch advice.

7.5.1 Description of the message communication

The Despatch Advice is communicated from the organisation creating the shipment to the organisation destined to receive the shipment.

7.5.2 Example use case

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.
Post-conditions	None identified

<table>
<tr><td>Scenario</td><td>Begins when the Ship From party sends a advice of despatch to the Ship To location.

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.

Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<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>
</table>
Ends when the Ship To party receives the Despatch Advice from the Ship From party.</td></tr>
<tr><td>Alternative scenario</td><td>None identified</td></tr>
<tr><td>Related requirements</td><td>None identified</td></tr>
<tr><td>Related rules</td><td>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).</td></tr>
</table>

7.5.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Actual ship date time	*BDT00000455*
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Business document identification information	*BDTG00000480*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*
Estimated delivery date time	*BDT00000457*

Business Term	SDD-ID
Referenced distribution management entity shipping information	BDTG00000958
Referenced distribution management entity shipping order information	BDTG00000959
Requested delivery date time	BDTG00000291
Ship from party information	BDTG00000310
Ship to party information	BDTG00000311

Message Content

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Expiration date	BDT00000057
Kit minimum temperature information	BDTG00000950
Kit maximum temperature information	BDTG00000952
Kit measurement unit code	BDTG00000955
Kit security seal type code	BDTG00000945
Logistic unit identification information	BDTG00000859
Lot number	BDT00000090
Despatched quantity	BDTG00000869
Serial number	BDT00000121
Storage conditions type code	BDTG00000957
Security seal identification	BDT00000946
Temperature tracker identification	BDT00000954

7.6 Receiving Advice

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.

7.6.1 Description of the message communication

This message is sent from the receiver of the shipment (e.g., trial site) to the creator of the shipment request (e.g., the DME) to confirm the goods received.

7.6.2 Example use case

<table>
<tr><td>Performance goals</td><td>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.</td></tr>
<tr><td>Preconditions</td><td>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.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>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.
Continues with...
<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>
Ends when the goods can be used.</td></tr>
<tr><td>Alternative scenario</td><td>None identified</td></tr>
<tr><td>Related requirements</td><td>Inventory status and quality will be reported using the receiving advice, including any damaged or missing goods – compared to the original shipment.</td></tr>
<tr><td>Related rules</td><td>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.</td></tr>
</table>

7.6.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	BDTG00000953
Business document receiver party information	BDTG00000954
Clinical trial protocol owner party information	BDTG00000961
Clinical trial protocol identification	BDT00000960
Medication kit reception date time	BDT00000988
Referenced distribution management entity shipping information	BDTG00000958
Referenced distribution management entity shipping order information	BDTG00000959
Referenced system order identification	BDTG00000960
Shipment receiving party information	BDTG00000990
Shipment requestor party information	BDTG00000989
Ship to party information	BDTG00000311

Message Content

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Kit measurement unit code	BDTG00000955
Logistic unit identification information	BDTG00000859
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Serial number	BDT00000121
Reason for non compliance code	BDTG00000984

7.7 Kit Status Change

The Kit Status Change is designed to convey an instruction to make a change in kit status or to confirm a kit status has changed.

There are two messages that can be used in this situation:

- "Inventory operation instruction" – to advise that a kit status change is to occur; and also to provide an immediate response for each item.
- "Inventory report" – to provide a response in batch (e.g., daily or weekly). This would only be used for the inventory that was requested to be changed.

Note: Guidance of when this message should be used and not be used:

- This message does not only apply to medication that is in a shipment but also to kits already at a DC where a need to change the status is identified e.g., relabelling or temperature issues while stored.

7.7.1 Description of the message communication

This message is bi-directional, i.e., the DME can tell the depot to change the status of the kit; but also the depot can tell the DME to change the status of the kit.

7.7.2 Example use case

<table>
<tr><td>Performance goals</td><td>To ensure useable inventory levels are aligned across the study stakeholders.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units. Correct identification of sender (Ship To) and receiver (Ship From) are in place.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the Sponsor identifies goods in a shipment that need to be put on hold.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Sponsor/trial site/DC</td><td>Advises DC or trial site of the IP kit numbers of the on-hold goods and specifies action to be taken, e.g., destroy, return, hold, etc.</td></tr>
<tr><td>2</td><td>DC/trial site</td><td>Acknowledges advice and acts.</td></tr>
<tr><td>3</td><td>Sponsor</td><td>Advises Ship From of the corrective actions, e.g., ship more IP kits.</td></tr>
</table>
Ends when ship from takes appropriate action.</td></tr>
<tr><td>Alternative scenario</td><td>If it is a DC or site reporting goods to be placed on hold, this would more likely be incident report being, related to temperature issues, for example, flooding, etc.</td></tr>
<tr><td>Related requirements</td><td>The term damaged goods has a QA implication for some organisations. ‘Quarantined’ also has a QA implication for some organisations but not others.</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

7.7.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	BDTG00000953
Business document receiver party information	BDTG00000954
Clinical trial protocol owner party information	BDTG00000961
Clinical trial protocol identification	BDT00000960

Business Term	SDD-ID
Referenced original kit status change information	BDTG00000993

Message Content

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Kit location information	BDTG00000962
Lot number	BDT00000090
Medication kit status type code	BDTG00000966
Serial number	BDT00000121

7.8 Request for Inventory Report

The Request for Inventory Report communicates a request for provision of an inventory report, which gives current information about inventory levels. The inventory report request is related to finished products as identified GTINs.

7.8.1 Description of the message communication

This message is communicated from the DME to the location in which inventory is stored.

7.8.2 Example use case

<table>
<tr><td>Performance goals</td><td>A request to drive the subsequent action of sending an inventory report.</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>Post conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the sponsor sends a message to ask for inventory levels from across the supply chain.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Receiver</td><td>Receives communication.</td></tr>
</table>
Ends when the Receiver takes action to provide inventory level information.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>None noted</td></tr>
<tr><td>Related rules</td><td>None noted</td></tr>
</table>

7.8.3 Business-critical data fields included

The following are some of the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields recommended to include in the header:

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*

Message Content

Business Term	SDD-ID
Clinical trial product identification information	*BDTG00000947*
Inventory reporting date time	*BDT00000991*
Inventory reporting party information	*BDTG00000986*
Kit location information	*BDTG00000962*
Medication kit identification information	*BDTG00000996*
Medication kit type	*BDT00000964*

7.9 Inventory Report

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.

Depending on the granularity at which inventory needs to be tracked, reporting may be at GTIN (trade item) or SSCC (logistics unit) level, batch/lot level or serial number level. The level of reporting may vary for IPs and IP kits when compared to ancillary or auxiliary items. In some cases, hierarchical levels of reporting may occur.

This message should only return inventory that belongs to the requestor, e.g., company X would like to have the status of all inventory at GLN1, so the report should only include Company X's inventory not another organisation's inventory.

7.9.1 Description of the message communication

This message is communicated between the location in which inventory is stored and the DME.

7.9.2 Example Use Case

<table>
<tr><td>Performance goals</td><td>To ensure that inventory levels are accurate across the clinical trial supply chain.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units. Correct identification receiver (Ship To/inventory location) are in place.</td></tr>
<tr><td>Post-conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when the sender/initiator of change (e.g., trial site, CMO, DC) sends a communication to advise of inventory levels.
Continues with...
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<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>
</table>
Ends when... This may result in the sponsor acting to ensure stock is replenished to trial site, DC, etc.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>None identified</td></tr>
<tr><td>Related rules</td><td>None identified</td></tr>
</table>

7.9.3 Business-critical data fields included

The following are some of the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

The assumption is that this is an unblinded message as the rights to see the unblinding or not is within the DME.

Fields recommended to include in the header:

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*
Referenced request for inventory report information	*BDTG00000992*

Message Content

Business Term	SDD-ID
Additional lot number	*BDT00001003*

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Expiration date	BDT00000057
Inventory reporting date time	BDT00000991
Kit location information	BDTG00000962
Lot number	BDT00000090
Medication kit quantity	BDTG00000968
Medication kit status type code	BDTG00000966

Where the two parties involved in a trial agree, an additional level of granularity can be provided, for example using the customer container number (a number allocated to a grouping of kits for management of inventory during shipping). This is not a common practice; however, a number of sponsors and depots use such internal numbers. In line with the GS1 Healthcare GTIN Allocation Rules best practice is to replace this internal customer container number with a globally unique GTIN for the container of stock (which has set parameters). It is important to note that the SSCC is different to the customer container number.

7.10 Dispensing Advice

The Dispensing Advice is used to communicate information related to the specific Investigational Products assigned to patients within the trial. There are three scenarios:

- At the time of patient screening, the Dispensing Advice can be used to communicate the dosing weight at the time of patient screening. This is applicable for example in oncology studies where compounding is required to prepare the medications for patient dispensing.
- For a DME to advise a trial site that a specific kit is available and assigned to a specific patient.
- For a trial site to advise a DME that a specific kit has been dispensed to a specific patient.

7.10.1 Description of the message communication

The communication is bi-directional between the trial site and the DME.

7.10.2 Example use case

<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>Post-conditions</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>
</table>

<table>
<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>

7.10.3 Business-critical data fields included

The following are the business-critical data fields included in the message. Note that structural fields (e.g., unique message identifier) are not listed, however, these will be provided in the full mapping specifications).

Fields to include in the header:

Scenario 1 – Patient dispensing order in which clinical pharmacy identifies the quantity of material issued to the patient

Business Term	SDD-ID
Business document sender party information	*BDTG00000953*
Business document receiver party information	*BDTG00000954*
Clinical trial protocol owner party information	*BDTG00000961*
Clinical trial protocol identification	*BDT00000960*

Message Content

Business Term	SDD-ID
Clinical trial product identification information	*BDTG00000947*
Dispensing location information	*BDTG00001001*
Medication kit quantity	*BDT00000968*
Patient identification information	*BDTG00000998*
Patient weight information	*BDTG00001000*
Serial number	*BDT00000121*

Scenario 2 – Patient dispensing order in which DME dictates specific material issued to the patient

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	BDTG00000953
Business document receiver party information	BDTG00000954
Clinical trial protocol owner party information	BDTG00000961
Clinical trial protocol identification	BDT00000960

Message Content

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Dispensing location information	BDTG00001001
Lot number	BDT00000090
Medication kit quantity *only non serialised	BDT00000968
Patient identification information	BDTG00000998
Serial number *only serialised kits	BDT00000121

Scenario 3 – Message confirming material requested in dispensing order had been issued to the patient

Fields to include in the header:

Business Term	SDD-ID
Business document sender party information	BDTG00000953
Business document receiver party information	BDTG00000954
Clinical trial protocol owner party information	BDTG00000961
Clinical trial protocol identification	BDT00000960

Message Content

Business Term	SDD-ID
Clinical trial product identification information	BDTG00000947
Dispensing date time	BDT00001002
Dispensing location information	BDTG00001001
Lot number	BDT00000090
Medication kit quantity *only non serialised	BDT00000968

Business Term	SDD-ID
Patient identification information	BDTG00000998
Serial number *only serialised kits	BDT00000121

8 Glossary

For the purpose of this document, the following terms and definitions apply. Please refer to the GS1 Glossary and to the EDI Semantic Data Dictionary for the full version and the complete set of attributes, like business rules, code lists and examples, applicable to each term.

8.1 Business-critical data fields

These are the business-critical data fields mentioned in this Implementation Guideline.

Field name	Field description	SDD-ID
Actual ship date time	The date (and optional time) when the goods were shipped.	BDT00000455
Additional lot number	The additional identification number for a lot consisting of products produced within different production batches.	BDT00001003
Business document identification information	The information specifying the identification details of the business document.	BDTG00000480
Business document receiver party information	The information specifying the details of the party receiving a business document	BDTG00000954
Business document sender party information	The information specifying the details of the party sending a business document	BDTG00000953
Clinical trial protocol identification	The information specifying the clinical trial study protocol identification	BDT00000960
Clinical trial product identification information	The information specifying the Global Trade Identification number, GTIN, of a clinical trial product	BDTG00000947
Clinical trial protocol owner party information	The information specifying details of the party sponsoring the clinical trial	BDTG00000961
Despatched quantity	The number of units shipped of the order unit or associated item.	BDTG00000869
Dispensing date time	The date when the kits have been dispensed to the patient	BDT00001002
Dispensing location information	The information specifying the details of the location where the kits are dispensed	BDTG00001001
Estimated delivery date time	The date and optional time when the goods is estimated to be delivered.	BDT00000457
Expiration date	The date after which the product should not be used or consumed.	BDT00000057
Inventory reporting date time	The date and optional time the inventory is referred to.	BDT00000991
Inventory reporting party information	The information specifying the details of the party reporting the inventory	BDTG00000986
Kit component original lot number	The original lot number assigned by the manufacturer to a not labeled kit component	BDT00000892
Kit location information	The information specifying details of a location where the kits are available.	BDTG00000962
Kit minimum temperature information	The information on the minimum temperature allowed according to the handling	BDTG00000950
Kit maximum temperature information	The information on the maximum temperature allowed according to the handling	BDTG00000952

	instructions	
Kit measurement unit code	The code specifying the unit of measure applicable to the medication kit	BDTG00000955
Kit security seal type code	The code identifying the type of seal used on the kit.	BDTG00000945
Kit sequence number	The sequential number that is assigned to each patient kit during production.	BDT00000963
Logistic unit identification information	The information specifying the identification details of a logistic unit.	BDTG00000859
Lot number	The identification number for a lot consisting of products produced within different production batches.	BDT00000090
Medication kit quantity	The quantity of medication kits and/or dispensable units	BDT00000968
Medication kit reception date time	The date and optional time when the items were received	BDT00000988
Medication kit status type code	The code specifying the status of a medication kit	BDTG00000966
Medication kit type	The information specifying the type of medication kit	BDT00000964
Minimum lifespan from shipment	The minimum lifespan of an item from the date of shipment	BDTG00000981
Patient identification information	The information specifying the details of the patient	BDTG00000998
Patient weight information	The weight of the patient	BDTG00001000
Precaution description	The text containing the description of the precaution to be applied	BDT00000979
Precaution qualifier code	The code specifying the context of application of precaution information	BDTG00000978
Reason for non compliance code	The code identifying the reason for non compliance	BDTG00000984
Referenced distribution management entity shipping information	The information specifying the reference to the distribution management entitiy's, DME, shipping identification	BDTG00000958
Referenced distribution management entity shipping order information	The information specifying the reference to the DME shipping order identification	BDTG00000959
Referenced initial order number information	The initial order number originating the shipment process	BDTG00000983
Referenced original kit status change information	The information specifying the reference to the original kit status change request identification	BDTG00000993
Referenced request for inventory report information	The information specifying the details of the request generating the inventory report	BDTG00000992
Referenced shipment request information	The information specifying the details of a reference to the shipment request	BDTG00000982
Requested delivery date time	The date and optional time when the ordered trade items are requested to be delivered.	BDTG00000291
Security seal identification	The identification of the security seal applied.	BDT00000946
Serial number	The serial number assigned to an individual instance of a specific identified product or trade item to make an instance of a product or trade item unique.	BDT00000121
Shipment receiving party information	The information specifying the details of the shipment receiving party	BDTG00000990
Shipment requestor party information	The information specifying the details of the party requesting the shipment	BDTG00000989

Shipment request comments	The text containing special instructions or requests related to the requested shipment	BDT00000972
Shipment request date	The date when the shipment request has been generated	BDT00000971
Shipment request type code	The code identifying the type of shipment requested	BDTG00000974
Ship from party information	The information specifying the location from which goods are shipped.	BDTG00000310
Ship to party information	The information specifying the location to which goods are shipped.	BDTG00000311
Storage conditions type code	The code specifying the storage conditions	BDTG00000957
Sufficient stock indicator	A flag indicating if the stock is enought to fullfill the requested shipment	BDT00000985
Temperature qualifier code	The code specifying the context of application of temperature information	BDTG00000976
Temperature tracker identification	The identification of the temperature tracker.	BDT00000954

8.2 Clinical trial concepts

Term	Definition/concept
Active product	Contains medicinal product that has a physiological impact on the patient.
Ancillary item/supplies	Additional supplies required for the study, e.g., syringes, pumps, needles etc.
Auxiliary product	A medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational product.
Clinical study	See clinical trial.
Clinical supply pooling	The production of clinical supply finished goods that can be assigned to different protocols.
Clinical trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Clinical trial site	The location(s) where trial-related activities are conducted.
Comparator product	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.
Commercial label	Label applied to a product licensed to be sold in the commercial supply chain.
Distribution Management Entity (DME)/Interactive Response Technology (IRT)	Umbrella term that refers to both Interactive Voice Response System (IVRS) and Interactive Web-based Response System (IWRS) – systems used for communication of information during a trial.
Double blind	Study type where patients and care providers are unaware of the patient's medication status.
Drug product	Formulated mixture of the therapeutic in a dosage form.
Investigational Medicinal Product (IMP)	See investigational product.
Investigational Product (IP)	A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.
Investigational Product (IP) label	The label applied to an investigational product.

Term	Definition/concept
Investigational Product (IP) kit	A single dispensable unit of investigational product(s) for a specific clinical trial.
Interactive Voice Response System (IVRS)	A tool used by clinical trial sites to receive and enter data via the telephone.
Interactive Web-based Response System (IWRS)	A tool used by clinical trial sites to receive and enter data via web-based applications.
Kit design	The configuration of the clinical trial kit based on its components and dosage of investigational medicinal product (IMP), comparator or placebo to be tested, e.g., 5mg or 5mg placebo.
Kit number/kit ID	The identification (ID) associated with a single investigational product (IP) kit. Consists of GTIN + serial number +/or protocol number.
Master label text	The master of the text to be included on the kit and component labels, based on the language of choice of the sponsor organisation.
Material ID	The identification (ID) associated with a particular material used in clinical trials.
Medical Type ID	Lowest level shippable item that will be uniquely identified for a clinical trial shipment and dispensable to the patient.
Minimum Life Span	Minimum expected residual duration of the good. The residual duration is the time interval from the date of receipt of shipment and the expiry date
Open-label study	A non-blinded study, where all stakeholders know the investigational product (IP) being tested and administered to each patient.
Placebo product	A product with no active ingredient.
Program	The process of development of an individual medicinal product, which may involve multiple trials.
Protocol Number	The identifier, numeric or alphanumeric, assigned to a specific clinical study. (Protocol Number may also be referred to as Study Number or Trial Number).
Single-blind	Study type where patients are not aware if they are taking the investigational product (IP), the comparator, and/or the placebo, as applicable. In contrast to a double-blind study, the care provider is aware of the patient's medication status.
Sponsor	An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Study Number	See Protocol Number.
Subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control (patient).
Treatment ID	Treatment code assigned to a subject when the subject is randomised to the trial. It is associated with the treatment arm, i.e., active, placebo, or comparator.
Trial Number	See Protocol Number.
Vial	A small container used for holding liquids or powders that are to be reconstituted in a liquid.

8.3 Supply chain concepts

Term	Definition/concept
Batch or lot	Quantity of goods or material produced in a single manufacturing run.
Instance	An instance designates an individual manufactured clinical trial product. See also unique identification.
Serial number	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime.
Primary packaging	Packaging containing the actual investigational product, e.g., syringe, blister, vial, etc.
Secondary packaging	Packaging containing the primary package, e.g., kit box, blister pack, etc.

Term	Definition/concept
Distribution centre (DC)	In the context of this standard, the party that distributes investigational products to clinical trial sites.
Manufacturer	In the context of this standard, the party responsible for one or more of the following processes: ▪ production of investigational product ▪ packaging of investigational product ▪ labelling of investigational product
Packaging site	In the context of this standard, the location that packages and labels investigational products and investigational product kits.