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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 Executive Summary

Currently 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 an heterogenous way, but all are speaking about the same concepts and processes. Not having a dedicated standard for messaging format, structure and content is limiting exchanges between stakeholders and is introducing data quality issues for some stakeholders, which in turn result in interruptions within the supply chain.

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

Given this, it is important the standards for data / information exchange are aligned with the direction other industries, particularly the commercial healthcare supply chain.

2 Benefits of Implementation, Business Opportunity and Business Needs

Today, there is an industry wide *global application standard* for use of GS1 standards for identification and barcoding of the investigational products and investigational product kits used in clinical trials. Following the release of this standard, the industry identified the need for a standardised process to electronically exchange data / information.

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 GTIN (Global Trade Item Number), GLN (Global Location Number) and Serial Shipping Container Code (SSCC).

3 Introduction

3.1 Purpose

This Implementation Guide is one part of a suite of documents designed to provide guidance about WHY and HOW to implement GS1 standards for electronic messaging. This document defines the messages in scope, business critical data set and some 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 5.2. The intent is that messages and processes related to all clinical trials are in scope including:

- Investigator and manufacturer sponsored trials
- Portal and non-IRT trials, as well as IRT trials
- Investigational product movements involving CMO, Depot, DC, etc.

The work group developing this guideline have 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.

It is also important to note that 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.

4 Business processes and messages

4.1 Business process participants

The diagram below provides an overview of the main actors involved in the process for the first phase of work.

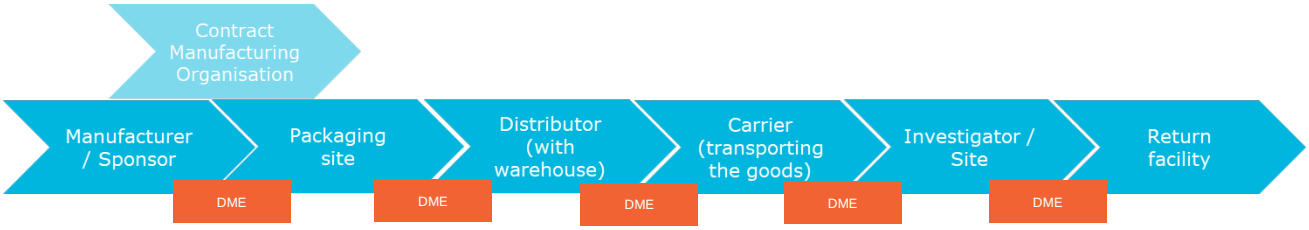


Table 4-1 Roles and responsibilities

Role	Responsibility in process
Manufacturer / Sponsor	Has overall responsibility for the trial, produces the 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 Clinical Trial Messages and their GS1 standards Equivalent

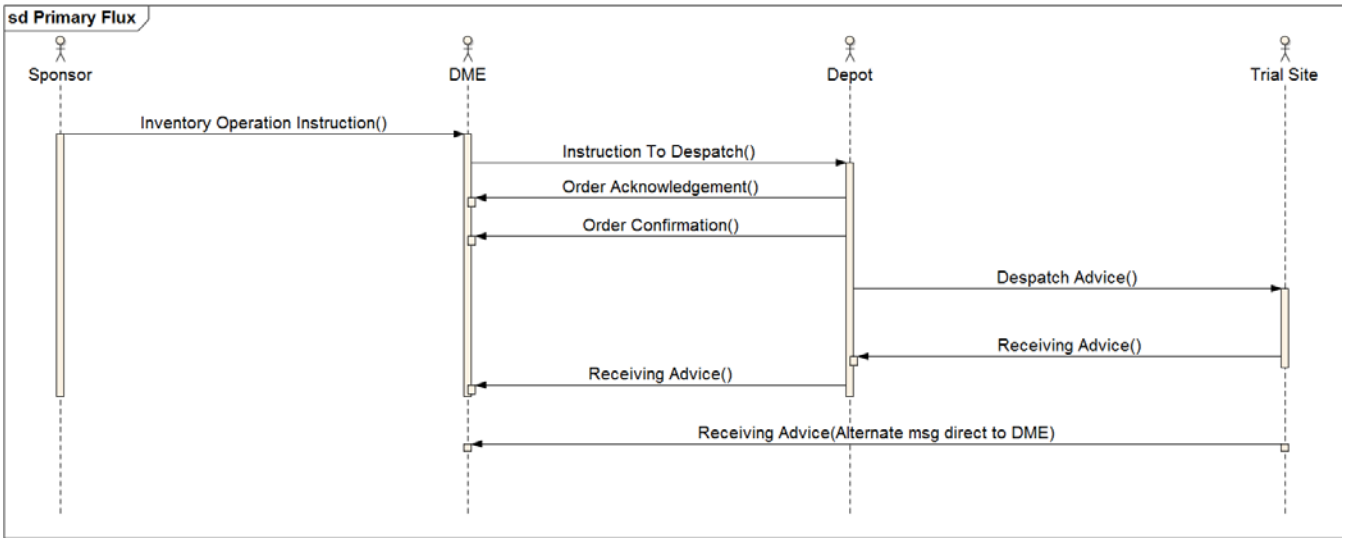
The table below details the agreed clinical trial messages in scope for this guideline and the equivalent name of these messages in the context of GS1 standards.

Industry message name	Equivalent GS1 standards message name *Hyperlinks for each message to be added*
Inventory release file	Inventory operation instruction
Shipment request	Instruction to despatch
Shipment notification	Order acknowledgement
Shipment confirmation	Order confirmation
Despatch advice / Advanced Shipping Notice	Despatch advice
Proof of Receipt	Receiving advice
Kit status change	Inventory operation instruction OR Inventory report
Request for inventory report	Inventory report request
Issue inventory report	Inventory report
Dispensing advice	Inventory operation instruction

Clinical Trial EDI mapping (link) – *Link will be added once the mapping is complete*

4.3 Messaging Sequence Diagram

From Sponsor to Trial site (a simplified view) detailing the messages in scope for this phase of work and showing the majority of interactions. This is illustrative only.



5 Implementation considerations

It is important to understand that there are some pre-requisites to implementation of GS1 standards for electronic messaging. These include having internal knowledge, capabilities and ensuring foundational aspects have been completed, such as allocation of GS1 Identification Keys. Some initial guidance is provided below. Please note that this is not exhaustive, and each organisation should consider this guidance in line with their current capabilities and levels of GS1 standards implementation.

5.1 Systems capabilities and process considerations

For any implementation of electronic business messaging, it is important to ensure that the data coming from internal systems is complete and accurate. This means that sending and receiving systems will need to have validation / data quality checks before initiating creation of messages otherwise there could be mismatches in data exchange or cancellation of messages which will lead to manual intervention – which is what electronic business messaging is designed to reduce.

5.2 Acknowledgement messages vs processing of messages

When implementing electronic messages, it is important that trading partners are aware of the need for there to be exchange of both a 'technical acknowledgement' by the recipient of the messages received from the sender as well as a response containing meaningful business information. The technical acknowledgement simply serves to indicate that the message has been received and is structurally correct. At the time of sending the technical acknowledgement, the business content within the message has not been processed within the receiver system. This message is purely system generated. Implementation is at the discretion of parties to have separate or combined messages for acknowledgment versus functional response.

There may also be a level of 'functional acknowledgement' which is a message generated by the application receiving the electronic message following checks that the business data contained within the received message meet certain rules, e.g., mandatory fields completed, dates in correct format, etc.

When the receiver system has processed the business content, other electronic messages will be created and sent; to either confirm the accuracy of the content or to identify the errors/issues that exist in the business content. These messages are discussed in more detail 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 & 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

When developing this guideline and the associated detailed message mappings, the assumption has been made that together with the GS1 message standard formats, globally standardised and unique GS1 identification keys will be used as required. This means use of:

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 allocation of Global Location Numbers in healthcare can be found in the *Healthcare GLN Implementation Guide*.
3. GS1 Serial Shipping Container Codes (SSCCs) for identification of logistics units. Information about allocation of SSCCS can be found in the *Healthcare AIDC Implementation Guide*.

6 Clinical Trial specific considerations

6.1 Handling ancillary and auxiliary items

Generally, 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 and if the clinical trial supplies are managed by a DME (Distribution Management Entity), 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 products preventing 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 *Clinical Trials AIDC 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

In situations where parties wish to exchange electronic messages using GS1 standards (where GTIN is mandatory) for products that don't have a GTIN printed on the pack, a GTIN should be allocated for electronic messaging exchange (and then that GTIN printed in a barcode when packaging presentation is updated).

6.4 Important clinical trial process definitions

When ensuring the correct investigational product kits and products are to be picked for distribution as part of a clinical trial, there are different picking models used by industry stakeholders. The process used in each trial is agreed by trial stakeholders at the start of the trial. Common definitions for these processes are included below.

(1) Serialised directed picking.

When using this picking process, the investigational product kits and investigational products are pre-labelled. The picking process involves using 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. This is the most common form of picking traditionally 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, and then the organisation undertaking the picking (and shipping of the picked goods) selects the appropriate material based on DME provided criteria then 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 GTIN and serialised 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
  - In this case the request from the DME would be for selection of, for example, four investigational product kits.
  - The identification specified to allow picking would be the GTIN and quantity and, as this is an open study with non-serialised picking, there would be no requirement to track the serialised kit IDs meaning that the Order Confirmation would confirm GTIN and quantity information only.
  - It would be 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 with the one difference being that in this model the GTIN and serialised 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. It is important to note that in the case of just in time labelling any entity undertaking labelling will be considered ‘unblinded’.

(4) Shelf life extension or reduction

In a situation where investigational product kits and investigational products are required to have their shelf life extended or reduced, the location in which the inventory is stored will need to physically change the product by applying new labels.

(5) Study pooling

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

7 Messages Description, Use Case & Data Fields

7.1.1 Inventory Release File (Inventory Operation Instruction)

This message is usually used for the initial release of IP kits or other serialised medications to make them visible. The term “release” is considered to mean ‘release for clinical use’. Serialised and non-serialised items should be included in separate messages.

7.1.1.1 Description of the Message Communication

This message is exchanged between the Sponsor and the DME.

7.1.1.2 Example Use Case

<table>
<tr><td>Performance goals</td><td>To ensure that sites, DCs and other locations can release IP kits for use. 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.</td></tr>
<tr><td>Preconditions</td><td>Unique identification of locations, trade items and logistics units will be undertaken.</td></tr>
<tr><td>Post conditions</td><td>None identified</td></tr>
<tr><td>Scenario</td><td>Begins when... 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>Related requirements</td><td></td></tr>
<tr><td>Related rules</td><td>Master data needs to have been shared as a pre-requisite.</td></tr>
</table>

7.1.1.3 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 be included in the header:

- Protocol ID
- Owner of Protocol ID (optional)
- Total Quantity (serialised + non-serialised)

Message content

- Sending entity (GLN)

Serialised items

- Kit serial numbers
- Kit lot number(s)
- Quantity (only total quantity of this item)
- Sequence number
- Medication type ID

Note: Some organisations will blind the Inventory Operations Instructions message and some will not. If the message is blinded, it is because a kit list has previously been shared by the sender and receiver that can be used to decode the kit serial numbers to the correct treatment. However other organisations do not share the kit list up front and therefore depend on the Inventory Operations instructions message as the primary mechanism to both 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.

- Expiry date
- Location of where kits are (GLN)
- Status of item

Non-serialised items (GTIN)

- Lot number(s)
- Quantity (only total quantity of this item)
- Medication type ID
- Expiry date
- Location of where kits are (GLN)
- Status

7.1.2 Shipment request (Instruction to Despatch)

The shipment request is used to request the shipment of goods. This message may be used to communicate the need to ship goods in any of the following scenarios: Serialised directed picking, free picking (blinded, open label non-serialised or open label serialised).

7.1.2.1 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 or packaging organisation or other).

7.1.2.2 Example Use Case

Performance goals	To create and deliver appropriate communications to ensure an accurate shipment, as requested by the requestor, to the correct recipient.
Preconditions	Unique identification of locations, trade items and logistics units will be undertaken.
Post conditions	None identified

<table>
<tr><td>Scenario</td><td>Begins when... 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 acknowledgment (order acknowledgement) that the shipment request has been received. This message does not go to the clinical site.</td></tr>
</table>
Ends when... Acknowledgement of receipt of request to ship.</td></tr>
<tr><td>Related rules</td><td>1. The sponsor is the ultimate controller of inventory throughout the IP supply chain and determines the appropriate inventory levels at all locations.</td></tr>
</table>

7.1.2.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID
- Goods receiving Site ID (GLN) (depot or site)
- Date of request
- Requested delivery date
- Comments i.e. free text, e.g. priorities or other special request
- Message type, i.e. blinded shipment serial number specified, free picking, re-supply, site to site transfer,
  - There is a list of options for this field
- DME Order Reference ID
- Storage conditions (temperature, also used to enable the DC to set the temperature tracker) or storage precautions (e.g., protect from light, protect from UV, keep in shade, protect from sun)

Message Content

- By document type:

Document type: picking from existing labelled stock

- GTIN
- Serial Number
- Quantity
- Minimum lifespan (shelf life) - optional
- Lot Number

Document type: Free picking from pre-labelled stock

- Unblinded Item number (master item number describing the kit) / dispensing unit / unblinded GTIN
- Unblinded packaged lot /batch number – of the labelled stock (to segregate active or placebo)
- Quantity
- Minimum lifespan (shelf life) - optional

Document type: Labelling just in time

- Unblinded Item number (master item number describing the kit) / dispensing unit / unblinded GTIN
- Quantity
- Minimum lifespan (shelf life) - optional
- In-going lot number - optional

7.1.3 Shipment notification (Order acknowledgement)

Shipment Notification is the acknowledgment of the Shipment Request message. It should be sent by the recipient as soon as possible once the Shipment Request message is received by the recipient. It is an important hand-shake between the 2 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.

7.1.3.1 Description of the Message Communication

Messages are sent between the Depot and the DME.

7.1.3.2 Example Use Case

<table>
<tr><td>Performance goals</td><td>To ensure an accurate and timely advice that the shipment is ready.</td></tr>
<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... 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>
<tr><td>2</td><td>Requestor</td><td>Records the IP kit numbers in their systems.</td></tr>
</table>
Ends when... Requestor acknowledges shipment notification.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>If pallets are created for shipping, this is the point where these are confirmed to the Requestor (sponsor).
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>
<tr><td>Related rules</td><td></td></tr>
</table>

7.1.3.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Initial Order Number (group to decide what this is and definition. Not an EDI header)
- Protocol ID
- Response message

7.1.4 Shipment Confirmation (Order Confirmation)

Shipment confirmation is the detailed message from the depot back to the DME that confirms that an order will be/ or has been processed along with much of the specifics about the order including the supplies on the order. As noted above, this message sometimes comes chronologically later than the Shipment Notification message because of the time needed for 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.

7.1.4.1 Description of the Message Communication

Messages are sent between the Depot and the DME.

7.1.4.2 Example Use Case

<table>
<tr><td>Performance goals</td><td>To ensure an accurate and timely advice that the shipment is ready.</td></tr>
<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... Ship From party sends a notification to the requestor of the shipment request (UC-1).
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<tr><td>1</td><td>Requestor</td><td>Receives the shipment notification.</td></tr>
<tr><td>2</td><td>Requestor</td><td>Records the IP kit numbers in their systems.</td></tr>
</table>
Ends when... Requestor acknowledges shipment notification.</td></tr>
<tr><td>Alternative scenario</td><td>Not applicable</td></tr>
<tr><td>Related requirements</td><td>If pallets are created for shipping, this is the point where these are confirmed to the Requestor (sponsor).
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>
<tr><td>Related rules</td><td></td></tr>
</table>

7.1.4.3 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 be included in the header:

- Initial Order Number
- Shipping order number
- Protocol ID
- Receiver GLN
- Sending GLN
- Requested order date
- Requested receive date

Message Content

- GTIN of kit
- Quantity
- Error handling code (example; not enough stock)

7.1.5 Despatch advice / Advanced Shipping Notice (ASN)

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.

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

It is also important that the following are 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 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 dispatch 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.

7.1.5.1 Description of the Message Communication

This message is communicated from the organisation creating the shipment to the organisation destined to receive the shipment.

7.1.5.2 Example Use Case

Performance goals	To ensure an accurate and timely advice of despatch is sent from create to the recipient of a shipment.

<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... Ship From party must send an 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... Ship To party receives Despatch Advice from the Ship From party.</td></tr>
<tr><td>Related requirements</td><td></td></tr>
<tr><td>Related rules</td><td>1. The majority of the time the Ship To party is the trial site but may 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.</td></tr>
</table>

7.1.5.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID
- DME Shipping reference
- Order number for the shipment
- Estimated delivery date
- Shipping Date

Message Content

- Ship to GLN (physical shipment)
- Ship from GLN (physical shipment)
- SSCC number(s)

- Serial numbers / kit numbers (if items are serialised); consider this as optional as there may be cases where communicating only the quantity and date of estimated arrival is necessary
- Expiry Date (optional, only if the expiry date is on the label and not present in the GS1 DataMatrix)
- Unit of measure (if applicable), to give the site /DC direction about how to measure inventory back to the sender if in bulk
- Temperature tracker reference number (if applicable)
- Other security ID, e.g., anti-tamper seal number
- Special storage conditions (e.g. cold storage)
- Quantity

7.1.6 Receiving advice (Proof of receipt / Consignment receipt)

The objective of this message is to send notification that the goods(s) were received (when compared onto the good(s) shipped). It is important that there be a one to one match between the despatch advice and receiving advice.

7.1.6.1 Description of the Message Communication

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.

7.1.6.2 Example Use Case

Performance goals	To ensure a 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.
Post conditions	None identified

<table>
<tr><td>Scenario</td><td>Begins when... 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... Goods can be used.</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 sponsor is the receiver of the receiving advice.</td></tr>
</table>

7.1.6.3 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 be included in the header:

- Shipment Requestor GLN, i.e. DME vendor or third-party depot system (the name can change but the GLN is the base needed when sending and receiving EDI messages)
- Receiving entity GLN
- Protocol ID
- Shipping Order number (or ERP order number of the depot sending the shipment)
- DME shipment reference ID (check above)

Message Content

- GTIN
- GLN of receiving site or depot
- Date of reception
- Lot/batch number (whilst considering the blinded status of the trial)
- SSCC (optional)
- Total quantity – quantity of any individual unit, line item quantity
- Unit of measure - for shipping bulk drugs between sites (how is the content measured e.g., kg or count of pills)
- Serial number / kit number of any physically damaged items

In the case of ancillary or auxiliary product, these could be part of the same shipment (and could be serialised).

7.1.7 Kit status change (Inventory operation instruction and Inventory report)

This message 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, temp issues while stored

7.1.7.1 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.

7.1.7.2 Example Use Case

Performance goals	To ensure useable inventory levels are aligned across the study stakeholders.
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.
Post conditions	None identified

<table>
<tr><td>Scenario</td><td>Begins when... 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></td></tr>
</table>

7.1.7.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system (optional)
- Receiving entity GLN (optional)
- Protocol ID

Message Content

- GTIN
- Lot Number
- Serial Number / Kit Number
- New Status as per a defined code list (i.e. unavailable, available for dispensation, pending, shipped, do not dispense, dispensed to patient, do not ship, expired, damaged, quarantine, etc, etc)
- Storage location (depot or site) GLN
- DME GLN (optional)

7.1.8 Request for inventory report (inventory report request)

This message is used to communicate 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.

7.1.8.1 Description of the Message Communication

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

7.1.8.2 Example Use Case

<table>
<tr><th>Use case ID</th><th>UC-7a</th></tr>
<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... Receiver takes action to provide inventory level information.</td></tr>
<tr><td>Related requirements</td><td>None noted</td></tr>
<tr><td>Related rules</td><td>None noted</td></tr>
</table>

7.1.8.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID

Message Content

- Inventory reporting party location (GLN)
- Inventory reporting party (GLN)
- Which GTIN(s) – kit type or kit ID
- Inventory period (optional) (start period & end period of time in which the inventory is made)

7.1.9 Issue inventory report (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.

It is important to note that depending on the granularity at which inventory needs to be tracked, reporting may be made 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 report should only include Company X’s inventory not another organisations inventory.

7.1.9.1 Description of the Message Communication

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

7.1.9.2 Example Use Case

<table>
<tr><th>Use case ID</th><th>UC-7b</th></tr>
<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 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 Sender / Initiator of change (e.g., trial site, CMO, DC, etc) 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>Related requirements</td><td></td></tr>
<tr><td>Related rules</td><td>None noted</td></tr>
</table>

7.1.9.3 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 be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID
- Sponsor GLN

Message Content

- Inventory reporting location GLN (depot / site)
- Kit type ID (unblinded type of medication) - GTIN
- Lot Number
- Inventory reporting quantity (for non-serialised items) or list of unique Kit IDs
- Unit of measure (open label bulk) – in the case of dispensing
- Status
- Expiry date of kits

- 'Other' Lot Number – supplier internal code
- Date of inventory report

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 would be 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.

7.1.10 Dispensing advice (Inventory Operation Instruction)

The inventory operation instruction is used to communicate information related to the specific IPs assigned to patients within the trial. Three scenarios have been identified as examples of dispensing:

- At the time of patient screening, the inventory operation instruction 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.

7.1.10.1 Description of the Message Communication

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

7.1.10.2 Example Use Case

<table>
<tr><th>Use case ID</th><th>UC-8</th></tr>
<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... Receiver takes action to dispense the correct kit to the correct patient.</td></tr>
</table>

<table>
<tr><th>Use case ID</th><th>UC-8</th></tr>
<tr><td>Alternative Scenario</td><td>Begins when… the trial site sends a communication to the sponsor to advise which specific IP kit has been dispensed to a specific patient.

Continues with.
<table>
<tr><th>Step #</th><th>Actor</th><th>Activity step</th></tr>
<tr><td>1</td><td>Receiver</td><td>Receives the communication.</td></tr>
</table>
Ends when… the Receiver takes action to record that dispensing activity in their IT systems.</td></tr>
<tr><td>Related requirements</td><td>If the direction of the dispensing advice message is from trial site to sponsor confirming which drug given to patient, consider including the staff ID of who did the dispensing.</td></tr>
<tr><td>Related rules</td><td>None noted</td></tr>
</table>

7.1.10.3 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 be included in the header:

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

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID

Message Content

- Kit ID (Serial Number + GTIN)
- GLN of site
- Subject / Patient ID
- Subject / patient weight
- Quantity of IP (could be number of vials or volume)

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

Fields recommended to be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID

Message Content

- Site GLN
- Patient ID
- Serialised IP kits
  - GTIN
  - Kit ID (serial number(s) (if serialised inventory) mandatory

- Batch (most of the time will not have the batch indicated)
- Not serialised IP kits
  - GTIN
  - Batch (provided most of the time)
  - Quantity (if not serialised inventory)

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

Fields recommended to be included in the header:

- Sending entity GLN, i.e. DME vendor or third-party depot system
- Receiving entity GLN
- Protocol ID

Message Content

- Date of dispensing
- Site GLN
- Patient ID
- Serialised – confirm serial number has been used
  - GTIN
  - Kit ID (serial number(s) (if serialised inventory) mandatory
- Not serialised
  - GTIN
  - Batch (provided most of the time)
  - Quantity (if not serialised inventory)

8 Glossary

For the purposes of this document the following terms and definitions apply. Please refer to the *GS1 Glossary* for the full version.

8.1 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.

Term	Definition/concept
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.
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.
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 ID	The identifier, numeric or alphanumeric, assigned to a specific clinical study. (Protocol ID may also be referred to as Study ID or Trial ID).
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 ID	See Protocol ID.
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.

Term	Definition/concept
Trial ID	See Protocol ID.
Vial	A small container used for holding liquids or powders that are to be reconstituted in a liquid.

8.2 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.
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.