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Document Summary

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Work Request Reference

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Business Requirements Document (BRAD) Reference

| BRAD Title | BRAD Issue Date | BRAD Version |
|------------|-----------------|--------------|
| | | |

Document Change History

| Date of Change | Version | Changed By | Reason for Change | Summary of Change |
|----------------|-----------|--------------------------|------------------------------|---|
| 3-Apr-2020 | BMS 3.4.2 | Mark Van Eeghem | Initial Draft | Initial Draft |
| 10-Aug-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Updates after group revision | Structure changes, classes and attributes definition, examples |
| 24-Sep-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Group revision | |
| 29-Oct-2020 | BMS 3.4.2 | Piergiorgio Licciardello | Errata corrige | protocolOwner is not an association but an attribute. Rearranged the sequence of lines in GDD report according to BMS writing rules. Code list url missing and measurement units code list unnecessary Class diagram updated |
| 15-Jan-2021 | BMS 3.5 | Miklos Bolyky | BMS Release 3.5 | See summary of changes |
| 05-Jan-2022 | BMS 3.5.1 | Miklos Bolyky | BMS Release 3.5.1 | See summary of changes |
| 01-Mar-2023 | BMS 3.6 | Miklos Bolyky | BMS Release 3.6 | See summary of changes |



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Table of Contents

| | | |
|----------|---|-----------|
| 1 | Business Domain View | 6 |
| 1.1 | Introduction | 6 |
| 1.2 | References | 6 |
| 2 | Business Context | 7 |
| 3 | Business Transaction View | 7 |
| 4 | Business Information View | 9 |
| 4.1 | Clinical Trial Inventory Report..... | 9 |
| 4.2 | Enumerations (message specific) | 12 |
| 4.3 | Code Lists | 12 |
| 5 | Business Message Examples | 12 |
| 5.1 | Example 1 | 12 |
| 6 | Implementation Considerations..... | 13 |
| 6.1 | User Guide | 13 |
| 6.2 | Message Specific Considerations | 13 |
| 7 | Summary of Changes | 14 |
| 7.1 | BMS Release 3.4.2 | 14 |
| 7.2 | BMS Release 3.5 | 14 |
| 7.3 | BMS Release 3.5.1 | 14 |
| 7.4 | BMS Release 3.6 | 14 |
| 8 | Appendices | 14 |
| 9 | Acknowledgements..... | 15 |
| 9.1.1 | Work Group | 15 |
| 9.1.2 | Development Team Members | 17 |

1 Business Domain View

1.1 Introduction

Purpose

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.

This Inventory Report Business Message Standard is one part of a suite of documents designed to provide the detailed technical mappings to GS1 message formats for EDI messages being implemented for Clinical Trials.

The other documents in this suite are:

- Inventory Release
- Shipment Request
- Shipment Notification
- Shipment Confirmation
- Despatch Advice
- Receiving Advice
- Request for Inventory
- Kit Status Change
- Dispensing Advice

Scope

The scope of this work includes all messages identified in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#), hereafter called 'the Guideline', section 4.2.

Considerations

The workgroup that developed this mapping document has ensured that the messages and associated mappings are technology and sponsor agnostic.

It is important that organisations implementing electronic business messaging in line with this guideline undertake an appropriate assessment to ensure that the blinding status of the trial is respected in the messages exchanged.

Messaging communications with transport providers / couriers / carriers are considered out of scope because there are already electronic processes in place and altering them would not add value.

1.2 References

| Reference Name | Description |
|--|---|
| GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline , | The guideline details the business requirement of the clinical trials context, both in terms of process design and data set shared between the actors |

2 Business Context

| Context Category | Value(s) |
|----------------------|---|
| Industry | Healthcare, Pharmaceuticals & Medical Devices |
| Geopolitical | All |
| Product | All |
| Process | Clinical Trials |
| System Capabilities | GS1 System |
| Official Constraints | None |

3 Business Transaction View

Business Process Participants

As detailed in *the Guideline*, section 4.1, the diagram and table below provide an overview of the main actors involved in the process.

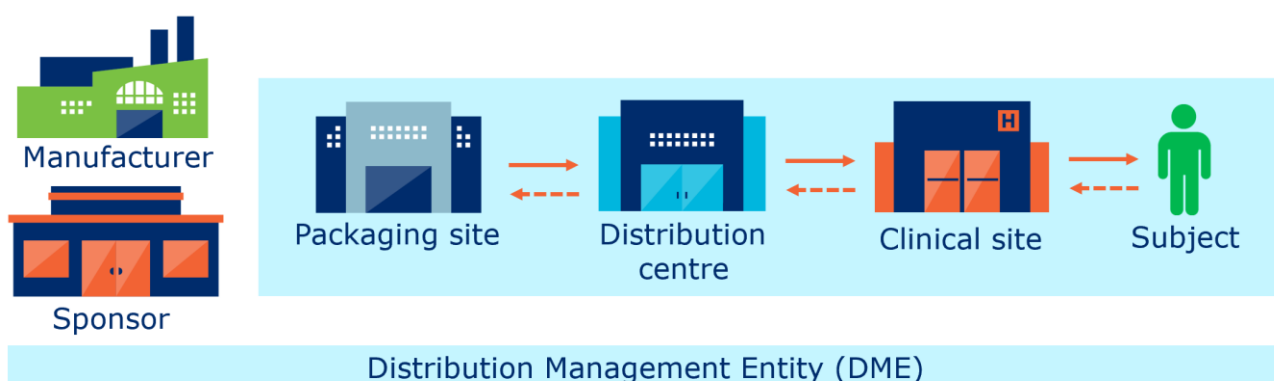


Table 3-1 Roles and responsibilities

| Role | Responsibility in process |
|---|---|
| Manufacturer/sponsor | Has overall responsibility for the trial, and produces the Investigational Product (IP) |
| Contract Manufacturing Organisation (CMO) | Manufactures and may package IP and IP kits at the direction of the manufacturer/sponsor |
| Packaging site | Packages and labels the IP and IP kits |
| Distributor (with warehouse) | Warehouses and distributes the IP kits as needed to the sites |
| Carrier (transporting the goods) | Logistics provider moving the IP kits at the request of other stakeholders |
| Clinical trial site | The healthcare provider location where the trial is conducted and dispensing to the patient typically occurs |
| Return facility | Responsible for receipt of any IP kits returned from trial sites |
| Distribution Management Entity (DME) | A term used to identify the system(s) managing, distribution, and disposition of clinical supplies. In many cases this is the |

| | |
|--|--|
| | interactive technology IRT system, portal, a set of tools or different databases used to share information during a clinical trial, etc. |
|--|--|

Use Case Diagram

N/A

Use Case Description

Below is the use case detailed in *the Guideline*, section 7.9.2

| Performance goals | To ensure that inventory levels are accurate across the clinical trial supply chain. | | | | | | | | | |
|----------------------|---|---|-------|---------------|---|-------------------------------|---|---|---------|--------------------------------|
| Preconditions | Unique identification of locations, trade items and logistics units. Correct identification receiver (Ship To/inventory location) are in place. | | | | | | | | | |
| Postconditions | None identified | | | | | | | | | |
| Scenario | <p>Begins when the sender/initiator of change (e.g., trial site, CMO, DC) sends a communication to advise of inventory levels.</p> <p>Continues with...</p> <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> <p>Ends when... This may result in the sponsor acting to ensure stock is replenished to trial site, DC, etc.</p> | Step # | Actor | Activity step | 1 | Recipient of advice of change | Receives communication and reconciles inventory levels. | 2 | Sponsor | Acknowledges inventory levels. |
| Step # | Actor | Activity step | | | | | | | | |
| 1 | Recipient of advice of change | Receives communication and reconciles inventory levels. | | | | | | | | |
| 2 | Sponsor | Acknowledges inventory levels. | | | | | | | | |
| Alternative scenario | Not applicable | | | | | | | | | |
| Related requirements | None identified | | | | | | | | | |
| Related rules | None identified | | | | | | | | | |

Activity Diagram(s)

Not applicable

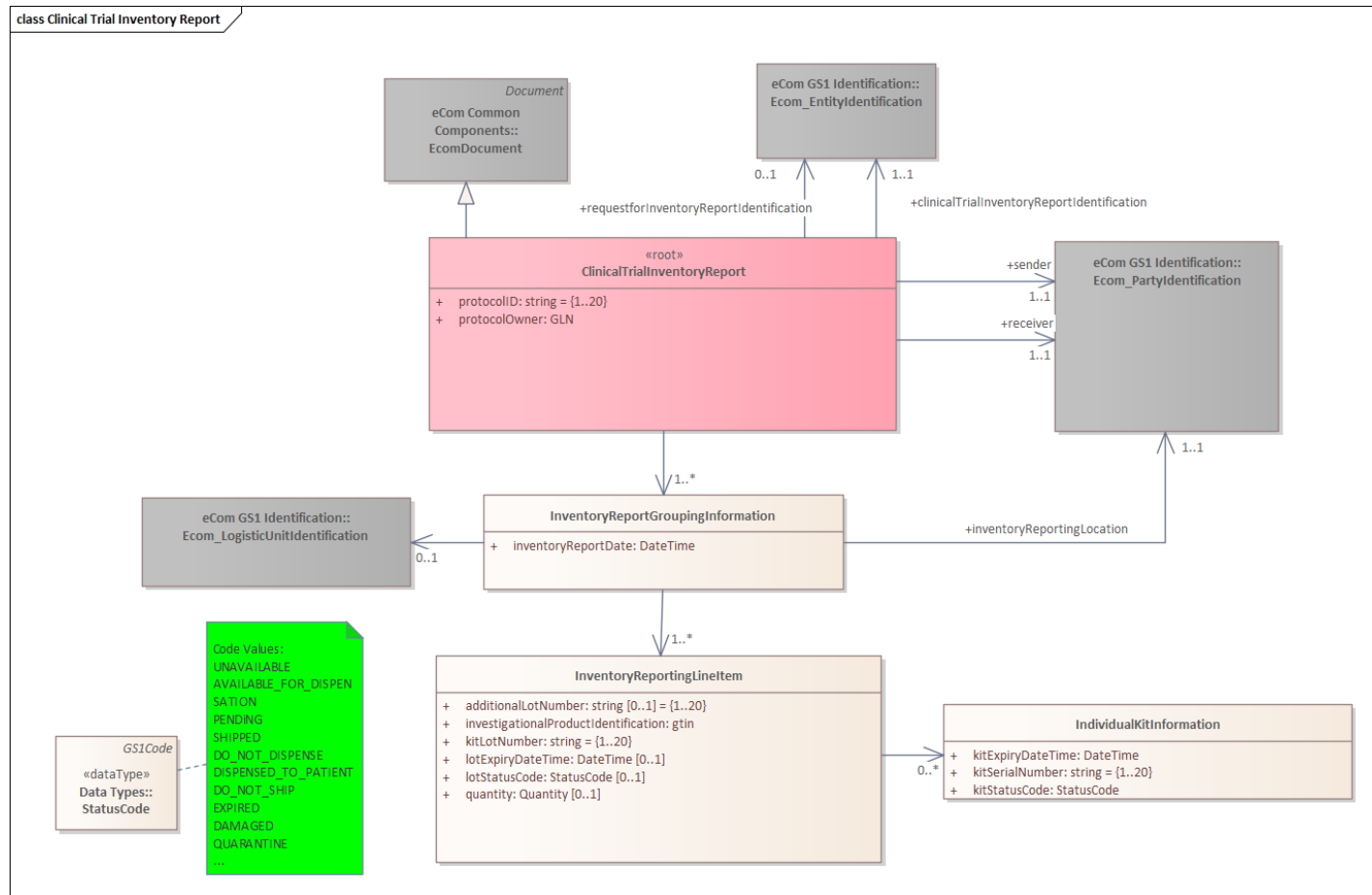
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Clinical Trial Inventory Report

Class diagram





GDD report

| Content | Attribute / Role | Datatype / Secondary class | Multiplicity | Definition | Constraints |
|---|--|------------------------------------|--------------|---|-------------|
| ClinicalTrialInventoryReport | | | | | |
| ASSOCIATION | GENERALIZATION | EcomDocument | 1..1 | The inventory report is used to communicate current levels of inventory for the requested items within a given location | |
| ASSOCIATION | clinicalTrialInventoryReportIdentification | Ecom_EntityIdentification | 1..1 | The identification of the inventory report message | |
| ASSOCIATION | requestForInventoryReportIdentification | Ecom_EntityIdentification | 0..1 | The reference to the request that generated the inventory | |
| ASSOCIATION | sender | Ecom_PartyIdentification | 1..1 | The generator of the message, usually the DME or the third-party depot | |
| ASSOCIATION | Receiver | Ecom_PartyIdentification | 1..1 | The issuer of the request of the inventory report | |
| ASSOCIATION | | InventoryReportGroupingInformation | 1..* | The information about the inventory status | |
| ATTRIBUTE | protocolOwner | GLN | 1..1 | The sponsor of the clinical trial / protocol | |
| ATTRIBUTE | protocolID | string | 1..1 | The identification of the protocol | {1..20} |
| InventoryReportGroupingInformation | | | | | |
| ASSOCIATION | inventoryReportingLocation | Ecom_PartyIdentification | 1..1 | The GLN of the location where the kits are stored | |
| ASSOCIATION | | Ecom_LogisticUnitIdentification | 0..1 | Identification of the logistic unit (SSCC) | |
| ASSOCIATION | | InventoryReportingLineItem | 1..* | The report detail at item level | |
| ATTRIBUTE | inventoryReportDate | DateTime | 1..1 | The date to which the stock refers | |
| InventoryReportingLineItem | | | | | |

| Content | Attribute / Role | Datatype / Secondary class | Multiplicity | Definition | Constraints |
|---------------------------------|--------------------------------------|----------------------------|--------------|--|-------------|
| ASSOCIATION | | IndividualKitInformation | 0..* | Specific information related to the single kits | |
| ATTRIBUTE | investigationalProductIdentification | gtin | 1..1 | The GTIN of the investigational product | |
| ATTRIBUTE | kitLotNumber | string | 1..1 | The lot number the kits are belonging | {1..20} |
| ATTRIBUTE | additionalLotNumber | string | 0..1 | Additional identification internal to the supplier | {1..20} |
| ATTRIBUTE | quantity | Quantity | 0..1 | The quantity of kits | |
| ATTRIBUTE | lotStatusCode | StatusCode | 0..1 | The inventory status referred to the lot | |
| ATTRIBUTE | lotExpiryDateTime | DateTime | 0..1 | The expiry date of the lot | |
| IndividualKitInformation | | | | | |
| ATTRIBUTE | kitSerialNumber | string | 1..1 | The serial number of the Kit | {1..20} |
| ATTRIBUTE | kitStatusCode | StatusCode | 1..1 | The inventory status of the specific kit | |
| ATTRIBUTE | kitExpiryDateTime | DateTime | 1..1 | The expiry date of the kit | |



Note: Reference Shared Common Library Business Message (BMS) Release 3.6 and eCom Domain Common Library Business Message (BMS) Release 3.6 for all common information.

4.2 Enumerations (message specific)

Not applicable.

4.3 Code Lists

| Class | Codelist | GDD Link |
|----------------------------|------------|---|
| InventoryReportingLineItem | StatusCode | http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:StatusCode |
| IndividualKitInformation | StatusCode | http://apps.gs1.org/GDD/Pages/clDetails.aspx?semanticURN=urn:gs1:gdd:cl:StatusCode |



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

5 Business Message Examples

5.1 Example 1

Party Information

| GS1 Global Location Number | Party Type |
|----------------------------|--|
| 9520000000004 | Sponsor |
| 9520000000127 | Sender - Organization in charge of the stock |
| 9520000000011 | Receiver – requestor of the inventory report |
| 9520000000028 | Kit Location |

Message Example 1

| Attribute | Value |
|---|--------------------|
| ClinicalTrialInventoryReport | |
| clinicalTrialInventoryReportIdentification | |
| entityIdentification | 1 |
| requestForInventoryReportIdentification | |
| entityIdentification | 10 |
| sender | |
| GLN | 9520000000127 |
| receiver | |
| GLN | 9520000000011 |
| protocolOwner | 9520000000004 |
| protocolID | PROT1 |
| InventoryReportGroupingInformation | |
| InventoryReportingLocation | |
| GLN | 9520000000028 |
| clinicalTrialLogisticUnitIdentification | |
| SSCC | 952000000000000125 |

| Attribute | Value |
|--------------------------------------|-------------------------|
| inventoryReportingDateTime | 2020-08-22T00:00:00.000 |
| InventoryReportingLineItem | |
| investigationalProductIdentification | 9520000000530 |
| kitLotNumber | LOT001 |
| additionalLotNumber | BTCHAK38 |
| quantity | |
| quantity | 1 |
| measurementUnitCode | H87 |
| lotStatusCode | DO_NOT_DISPENSE |
| lotExpiryDateTime | 2020-10-22T00:00:00.000 |

6 Implementation Considerations

6.1 User Guide

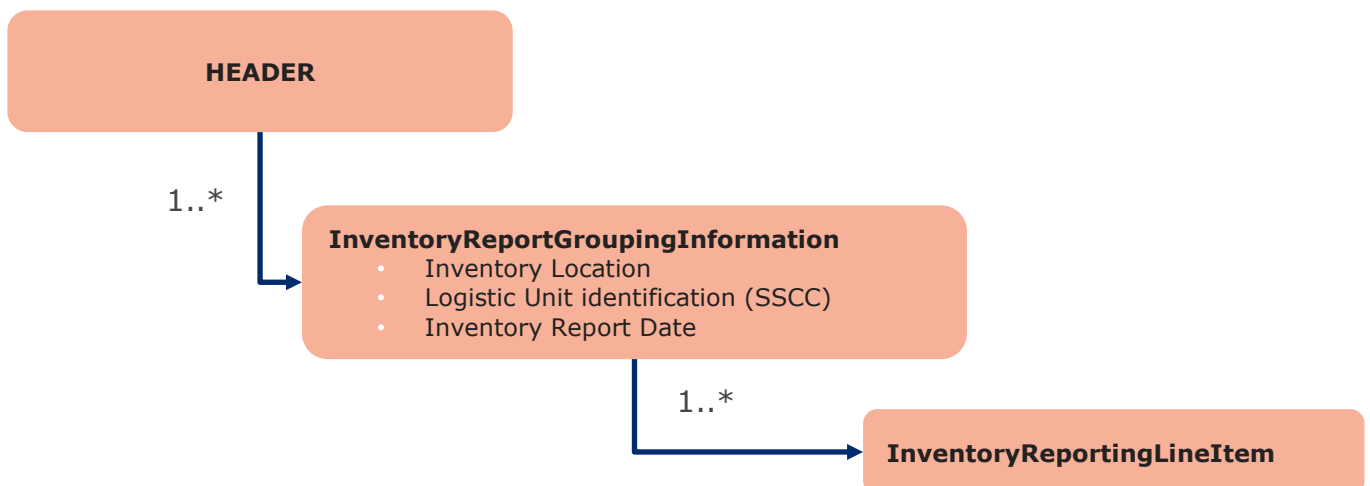
All implementation considerations are discussed in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#).

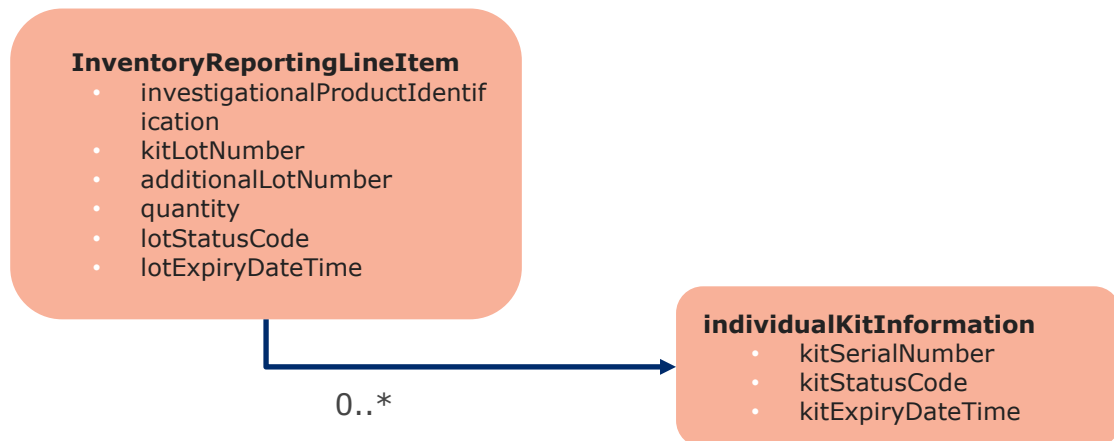
6.2 Message Specific Considerations

The body of the Inventory Report can express two different levels of detail.

The first level is referred to a bath / lot, so the report can provide to the requestor the status and total inventory for every specific lot

It is also possible to have another detail level, providing the status at single serial level





7 Summary of Changes

Any change in the GS1 standards is done based on the Work Request (WR) submitted by the GS1 User Companies or Member Organisations. All Work Requests are documented in the Work Request system available on the GS1 website: <http://wr.gs1.org>. The system is accessible to registered users. New visitors need to register first, to be able to access it. WRs can be searched by the number referenced in tables below, see: Search Work Requests. The number starts with the two last digits of the year when it was submitted, followed by the consecutive number within that year.



Note: WRs submitted earlier than February 2012 should be searched in Old Change Requests.

7.1 BMS Release 3.4.2

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.

7.2 BMS Release 3.5

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.

7.3 BMS Release 3.5.1

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.

7.4 BMS Release 3.6

No work requests. Indirect changes due to upgrade to new Shared and eCom Common libraries.
Errata fixed in one of the type name.

8 Appendices

Not Applicable

9 Acknowledgements

9.1.1 Work Group

| Function | Name | Company / organisation |
|------------------|------------------------------------|--|
| WG chair | Olivia Chauvel (Chair) | CH Victor Dupouy |
| WG chair | Pierre Fernandez-Barbureau (Chair) | SANOFI |
| WG chair | Hans von Steiger (Chair) | Pfizer |
| WG member | Jean-Michel Descoutures | International Hospital Federation (IHF) |
| WG member | Feargal Mc Groarty | St. James's Hospital |
| WG member | Vincent Puglia | endpoint clinical |
| WG member | Mike Meakin | DHL |
| WG member | Sylvain Alberola | SANOFI |
| WG member | Céline Bordes-Terrier | CREAPHARM |
| WG member | Giedré Bracaité | F. Hoffmann-La Roche Ltd. |
| WG member | Doris Cadart | SANOFI |
| WG member | Pedro Carvalho | Ipsen |
| WG member | Robert Giguere | AbbVie |
| WG member | Nicolas Gryspeert | F. Hoffmann-La Roche Ltd. |
| WG member | Michael Hoefling | Boehringer Ingelheim Pharma GmbH & Co.KG |
| WG member | Richard Hwang | Pfizer |
| WG member | Marco Inserra | CSL Behring GmbH |
| WG member | Jason James | Bristol-Myers Squibb |
| WG member | Matthias Kallmeyer | Boehringer Ingelheim Pharma GmbH & Co.KG |
| WG member | Nicolas Le Rudlier | CREAPHARM |
| WG member | Yann Montcourt | Ipsen |
| WG member | Barry Moore | GlaxoSmithKline |
| WG member | Marianne Perdrijat | DBV TECHNOLOGIES |
| WG member | Amy Rupp | CSL Behring GmbH |
| WG member | Amanda Scott | Biogen |
| WG member | Jodi Smith-Gick | Eli Lilly and Company |
| WG member | Richard Austin | PAREXEL International GmbH |
| WG member | Nick Bobrinskoy | nCoup, Inc. |
| WG member | Arpad Boldis | Deloitte |
| WG member | Robert Celeste | Center for Supply Chain Studies |
| WG member | Dilip Daswani | Qliktag Software (formally Zeebric LLC) |
| WG member | Andreas Geissler | PAREXEL International GmbH |
| WG member | Mark Hanly | Almac Clinical Technologies |
| WG member | Mike Hutton | Almac Clinical Technologies |
| WG member | Kelly Knowles | Bracket Global |
| WG member | Jitendra Kumar | Thermo Fisher Scientific |

| Function | Name | Company / organisation |
|------------------|-------------------------|-----------------------------|
| WG member | Cherish Lallone | McCreadie Group |
| WG member | Charlotte Meuldermans | Deloitte |
| WG member | Fabiana Monaco | PAREXEL International GmbH |
| WG member | Josef Preishuber-Pflügl | CISC Semiconductor GmbH |
| WG member | Theodora Sarver | Almac Clinical Technologies |
| WG member | Michael schlesselman | McCreadie Group |
| WG member | Colette Thorold | PAREXEL International GmbH |
| WG member | Elizabeth Waldorf | TraceLink |
| WG member | Stefan Zietze | PAREXEL International GmbH |
| WG member | Andrea Zobel | PAREXEL International GmbH |
| WG member | Shreenidhi Bharadwaj | Syndigo |
| WG member | Tony Zhang | Syndigo |
| WG member | Richard Perkins | eClinical Forum |
| WG member | Olivier Mary | COLCA Medical & Scientific |
| WG member | Poppy Abeto Kiese | GS1 Austria |
| WG member | Andrea Arozamena | GS1 Mexico |
| WG member | Mahdi Barati | GS1 Iran |
| WG member | Jiraporn Chalermjirarat | GS1 Thailand |
| WG member | Shawn Chen | GS1 Thailand |
| WG member | Mignone Cheng | GS1 Hong Kong, China |
| WG member | Luiz Costa | GS1 Brasil |
| WG member | Sandra Couto | GS1 Canada |
| WG member | Jesper Kervin Franke | GS1 Denmark |
| WG member | Stefan Gathmann | GS1 Ireland |
| WG member | Nicole Golestani | GS1 Canada |
| WG member | Rami Habbal | GS1 UAE |
| WG member | Michaela Hähn | GS1 Germany |
| WG member | Christine Horvath-Hanko | GS1 Hungary |
| WG member | Anna Klapper | GS1 Germany |
| WG member | Catherine Koetz | GS1 Australia |
| WG member | Anne-Claire Krid | GS1 France |
| WG member | Camille Labeaune | GS1 France |
| WG member | Ildikó Lieber | GS1 Hungary |
| WG member | Valerie Marchand | GS1 France |
| WG member | Adrien Molines | GS1 France |
| WG member | Zubair Nazir | GS1 Canada |
| WG member | Alice Nguyen | GS1 Vietnam |
| WG member | James Perng | GS1 Chinese Taipei |
| WG member | James Perng | GS1 Chinese Taipei |
| WG member | Paul Reid | GS1 UK |
| WG member | Sylvia Reingardt | GS1 Germany |

| Function | Name | Company / organisation |
|------------------|-------------------|------------------------|
| WG member | Sue Schmid | GS1 Australia |
| WG member | Julian Sin | GS1 Hong Kong, China |
| WG member | Mig Smith | GS1 UK |
| WG member | Peter Sturtevant | GS1 US |
| WG member | Flora Sue | GS1 China |
| WG member | Sarah Torrance | GS1 UK |
| WG member | Koichi Uemura | GS1 Japan |
| WG member | Amber Walls | GS1 US |
| WG member | Connie Wong | GS1 Canada |
| WG member | Pete Alvarez | GS1 Global Office |
| WG member | Jean-Luc Champion | GS1 Global Office |
| WG member | Steven Keddle | GS1 Global Office |
| WG member | Neil Piper | GS1 Global Office |
| WG member | Greg Rowe | GS1 Global Office |
| WG member | Tania Snioch | GS1 Global Office |

9.1.2 Development Team Members

| Function | Name | Organisation |
|----------------------------|-----------------|-------------------|
| GSMP Process Lead | David Buckley | GS1 Global Office |
| Technical Development Lead | Miklos Bolyky | GS1 Global Office |
| Peer Review | Mark Van Eeghem | GS1 Global Office |