



The Global Language of Business

Dispensing Advice Business Message Standard (BMS)

Release 3.5.1, Draft, Jan 2022



Document Summary

Document Item	Current Value
Document Name	Dispensing Advice Business Message Standard (BMS)
Document Date	Jan 2022
Document Version	3.5.1
Document Issue	1
Document Status	Draft

Work Request Reference

Date of WR Submission to GSMP:	WR Submitter(s):	Refer to Work Request (WR) Number(s):

Business Requirements Document (BRAD) Reference

BRAD Title	BRAD Issue Date	BRAD Version

Document Change History

Date of Change	Version	Changed By	Reason for Change	Summary of Change
3-Apr-2020	BMS 3.4.2	Mark Van Eeghem	Initial Draft	Initial Draft
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after group revision	Attributes and class definitions, examples
24-Sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
14-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Updates after community revision	Change protocolIdentification in protocolID, add GLN in site description
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Class diagram update
15-Jan-2021	BMS 3.5 – Issue 1	Miklos Bolyky	BMS Release 3.5	See summary of changes
05-Jan-2022	BMS 3.5.1 – Issue 1	Miklos Bolyky	BMS Release 3.5.1	See summary of changes

Disclaimer

GS1®, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **Dispensing Advice Business Message Standard (BMS)** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the licencing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organization developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licencing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHERWISE ARISING OUT OF THIS SPECIFICATION. GS1 disclaims all liability for any damages arising from use or misuse of this Standard, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.

GS1 and the GS1 logo are registered trademarks of GS1 AISBL.

Table of Contents

1	Business Domain View	5
1.1	Introduction	5
1.2	References	5
2	Business Context	5
3	Business Transaction View	6
4	Business Information View	8
4.1	Dispensing Advice	8
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	15
7.3	BMS Release 3.5.1	15
8	Appendices	15
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 Dispensing Advice is used to communicate information related to the specific Investigational Products (IP) assigned to patients within the trial. This Dispensing Advice Business Message Standard is one part of a suite of documents designed to provide the detailed technical mappings to GS1 message formats for EDI messages being implemented for Clinical Trials.

The other documents in this suite are:

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

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 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

Context Category	Value(s)
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.

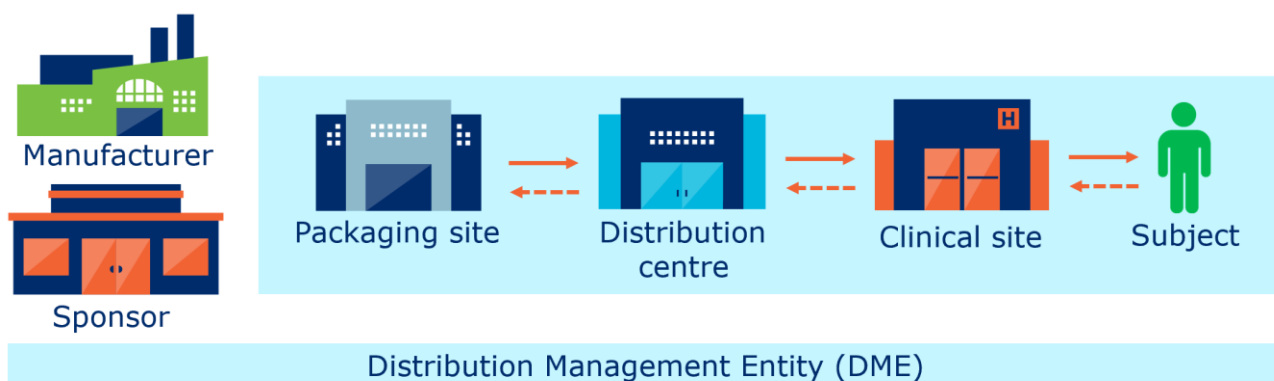


Table 3-1 Roles and responsibilities

Role	Responsibility in process
Manufacturer/sponsor	Has overall responsibility for the trial, 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 7.10

Performance goals	Accurate recording of items to be or that have been dispensed. This will provide accurate use information for planning activities, etc.						
Preconditions	Unique identification of locations, trade items and logistics units will be undertaken. Correct identification receiver (Ship To/inventory location) are in place.						
Postconditions	None identified						
Scenario	<p>Begins when the sponsor sends a communication to the trial site to advise which specific IP kit must be dispensed to a specific patient.</p> <p>Continues with...</p> <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> <p>Ends when the receiver takes action to dispense the correct kit to the correct patient.</p>	Step #	Actor	Activity step	1	Receiver	Receives the communication.
Step #	Actor	Activity step					
1	Receiver	Receives the communication.					
Alternative Scenario	<p>Begins when the trial site sends a communication to the sponsor to advise which specific IP kit has been dispensed to a specific patient.</p> <p>Continues with...</p> <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> <p>Ends when the receiver takes action to record that dispensing activity in their IT systems.</p>	Step #	Actor	Activity step	1	Receiver	Receives the communication.
Step #	Actor	Activity step					
1	Receiver	Receives the communication.					
Related requirements	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.						
Related rules	None identified						

Activity Diagram(s)

Not applicable

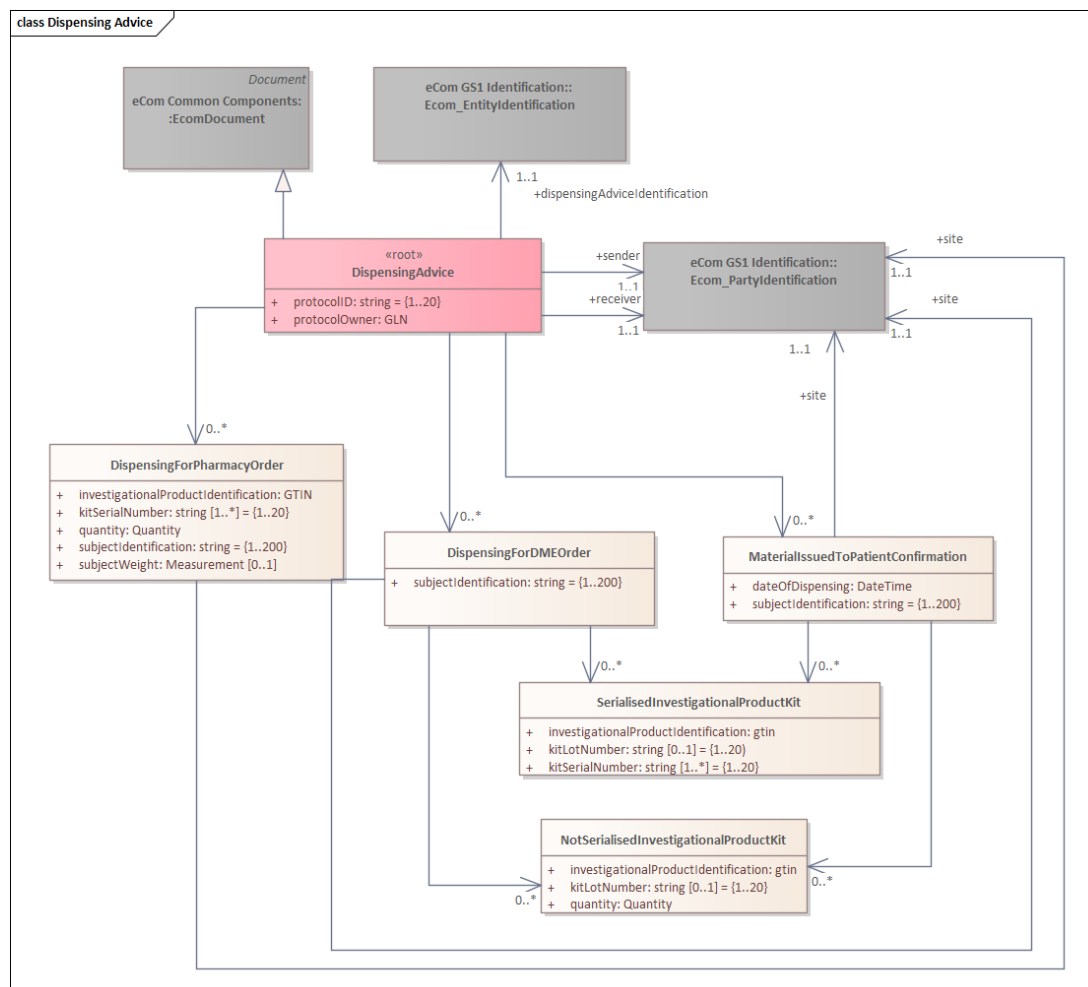
Sequence Diagram(s)

Not applicable

4 Business Information View

4.1 Dispensing Advice

Class diagram



Global Data Dictionary (GDD) report

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
DispensingAdvice				The Dispensing Advice is used to communicate information related to the specific IPs assigned to patients within the trial	
ASSOCIATION	GENERALIZATION	EcomDocument	1..1		
ASSOCIATION	dispensingAdviceIdentification	Ecom_EntityIdentification	1..1	The identification of the dispensing advice message	
ASSOCIATION	sender	Ecom_PartyIdentification	1..1	The entity sending the dispensing instruction or the information about the dispensing execution	
ASSOCIATION	receiver	Ecom_PartyIdentification	1..1	The entity receiving the dispensing instructions or the dispensing execution information	
ASSOCIATION		DispensingForPharmacyOrder	0..*	Dispensing instructions for the use case where clinical pharmacy identifies the quantity and materials dispensed	
ASSOCIATION		DispensingForDMEOrder	0..*	Dispensing instructions for the use case where the DME dictates the quantity and materials dispensed	
ASSOCIATION		MaterialIssuedtoPatientConfirmation	0..*	The detail of dispensed kits	
ATTRIBUTE	protocolID	string	1..1	The identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the owner of the protocol	
DispensingForPharmacyOrder					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	1..*	The serial number of the kit	{1..20}
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ATTRIBUTE	subjectWeight	Measurement	0..1	The weight of the patient	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of IP to dispense to the patient	
DispensingForDM EOrder					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ASSOCIATION		SerialisedInvestigationalProductKit	0..*	Set of information identifying the serialized kits to dispense	
ASSOCIATION		NotSerialisedInvestigationalProductKit	0..*	Set of information identifying the non-serialized kits to dispense	
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}
MaterialIssuedto PatientConfirmation					
ASSOCIATION	site	Ecom_PartyIdentification	1..1	The GLN of the site where the kits are dispensed	
ASSOCIATION		SerialisedInvestigationalProductKit	0..*	Set of information identifying the serialized kits to dispense	
ASSOCIATION		NotSerialisedInvestigationalProductKit	0..*	Set of information identifying the non-serialized kits to dispense	
ATTRIBUTE	subjectIdentification	string	1..1	The identification of the patient	{1..200}
ATTRIBUTE	dateOfDispensing	DateTime	1..1	The date when the kits have been dispensed to the patient	
SerialisedInvestigationalProductKit					
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitSerialNumber	string	1..*	The serial number of the kit	{1..20}
ATTRIBUTE	kitLotNumber	string	0..1	The batch/lot number of the kit	{1..20}

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
NotSerialisedInvestigationalProductKit					
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	kitLotNumber	string	0..1	The batch/lot number of the kit	{1..20}
ATTRIBUTE	quantity	Quantity	1..1	The quantity of IP dispensed / to dispense	



Note: Reference Shared Common Library Business Message (BMS) Release 3.5.1 and eCom Domain Common Library Business Message (BMS) Release 3.5.1 for all common information.

4.2 Enumerations (message specific)

Not applicable.

4.3 Code Lists

Class	Codelist	GDD Link



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

5 Business Message Examples

5.1 Example 1

This example maps the use case "scenario 1" as defined in the section 7.10.3 of the message implementation guideline. The message 1 maps the dispensing instructions from DME to clinical pharmacy and the message 2 is the dispensing confirmation from clinical pharmacy to DME

Party Information

GS1 Global Location Number	Party Type
9520000000011	Sender of dispensing instructions DME
9520000000028	Organisation receiving the instructions
9520000000004	Protocol sponsor
9520000000127	Clinical Pharmacy location

Message Example 1

Attribute	Value
DispensingAdvice	
<i>dispensingAdviceIdentification</i>	
entityIdentification	3
<i>sender</i>	
GLN	9520000000011
<i>receiver</i>	
GLN	9520000000028
protocolID	PROT1
protocolOwner	9520000000004
DispensingForPharmacyOrder	
<i>site</i>	
GLN	9520000000127
investigationalProductIdentification	9520000000530

Attribute	Value
kitSerialNumber	1243
subjectIdentification	M254
subjectWeight	85
quantity	
quantity	1
measurementUnitCode	H87

Message Example 2

Attribute	Value
DispensingAdvice	
dispensingAdviceIdentification	
entityIdentification	5
sender	
GLN	9520000000028
receiver	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004
MaterialIssuedtoPatientConfirmation	
site	
GLN	9520000000127
subjectIdentification	M254
dateOfDispensing	2020-08-14T00:00:00.000

6 Implementation Considerations

6.1 User Guide

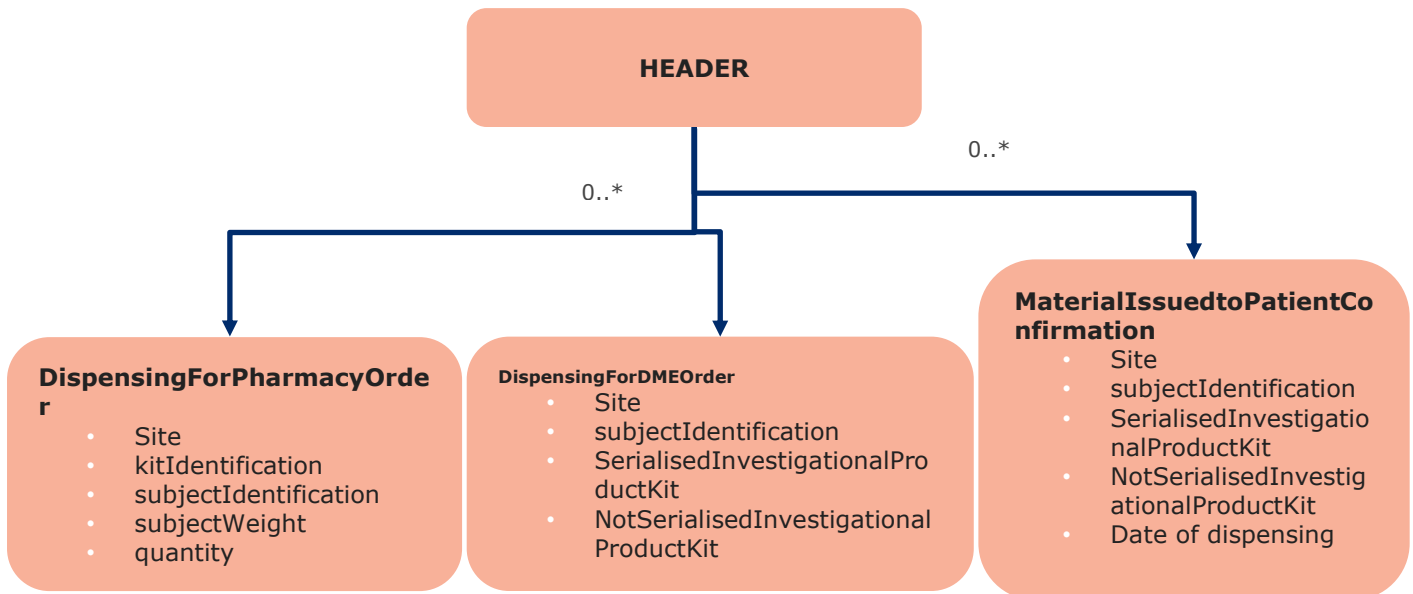
All implementation considerations are discussed in [the GS1 Pharmaceutical Clinical Trial Electronic Messaging Standard Implementation Guideline](#).

6.2 Message Specific Considerations

The structure of the Dispensing Advice is multifunctional, depending on the direction of the message and the function.

The DME can generate two kind of dispensing instructions, mapping two scenarios, and the structure of the detail section changes.

The dispensing confirmation maps a third possible structure applicable in the flow from clinical pharmacy to DME



7 Summary of Changes

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



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

7.1 BMS Release 3.4.2

Change	Associated CR Number
<ul style="list-style-type: none"> Initial Draft 	

7.2 BMS Release 3.5

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

7.3 BMS Release 3.5.1

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

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

Function	Name	Company / organisation
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
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

Function	Name	Company / organisation
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
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 Keddie	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