



The Global Language of Business

Shipment Confirmation Business Message Standard (BMS)

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Document Change History

Date of Change	Version	Changed By	Reason for Change	Summary of Change
3-Apr-2020	BMS 3.4.2	Mark Van Eeghem	Initial Draft	Initial Draft
10-Aug-2020	BMS 3.4.2	Piergiorgio Licciardello	Revision by the group	Definition of classes and attributes, structure changes, examples, error fixing
24-sep-2020	BMS 3.4.2	Piergiorgio Licciardello	Group revision	
29-Oct-2020	BMS 3.4.2	Piergiorgio Licciardello	Errata corrige	Quantity attribute with capital letter corrected according to modelling writing rules, diagram updated, wrong code list url corrected, kitShipmentInformation class definition missing
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	WR 22-343 , WR 22-344
15-Mar-2025	BMS 3.7	Miklos Bolyky	BMS Release 3.7	See summary of changes

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1 Business Domain View

1.1 Introduction

Purpose

The Shipment Confirmation is sent from the depot back to the DME and confirms that an order will be or has been processed. This message includes many of the order specifics, including the supplies on the order.

This Shipment Confirmation 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
- Despatch Advice
- Receiving Advice
- Request for Inventory Report
- Inventory Report
- Kit Status Change
- Dispensing Advice

Scope

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

Considerations

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

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

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

1.2 References

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

2 Business Context

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

3 Business Transaction View

Business Process Participants

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

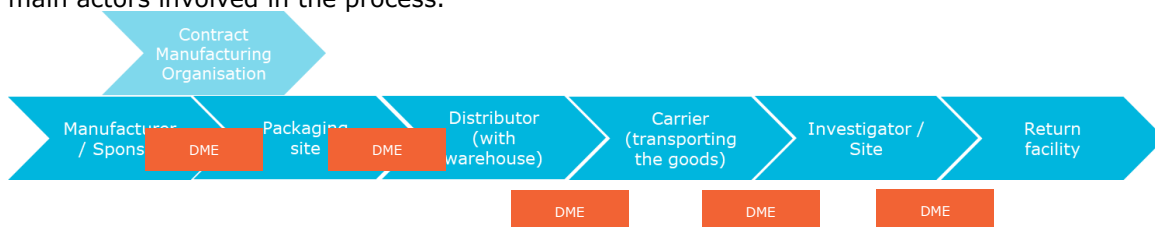


Table 3-1 Roles and responsibilities

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

Use Case Diagram

N/A

Use Case Description

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

Activity Diagram(s)

Not applicable

Sequence Diagram(s)

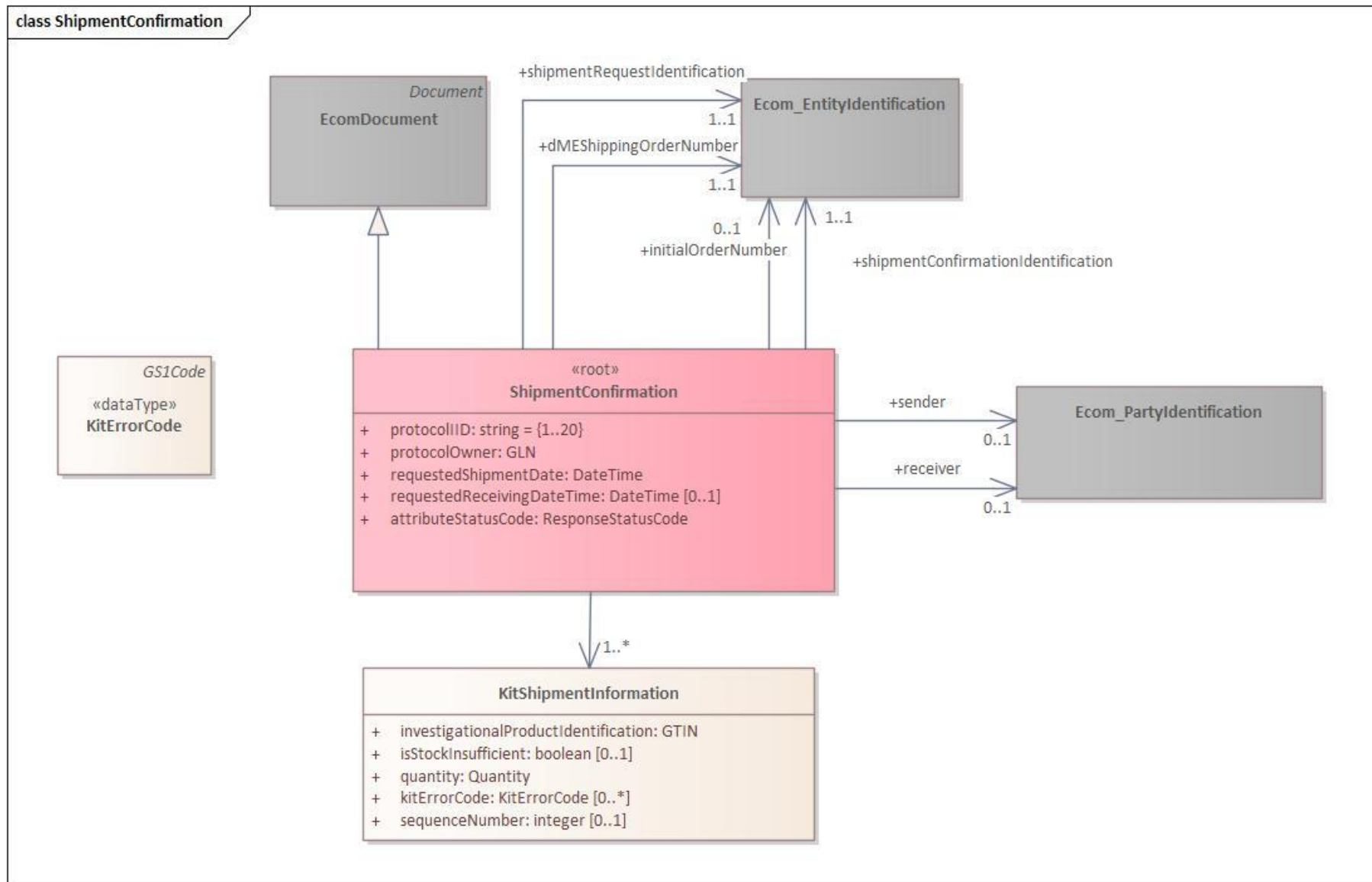
Not applicable



4 Business Information View

4.1 Shipment Confirmation

Class diagram



The content of the ShipmentConfirmation class, its structure and component definitions can be accessed in the GS1 Navigator:

[Navigator link](#)

Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
ShipmentConfirmation					
ASSOCIATION	GENERALIZATION	EcomDocument	1..1	The detailed message from the depot back to the DME that confirms that an order will be/ or has been processed.	
ASSOCIATION	shipmentConfirmationIdentification	Ecom_EntityIdentification	1..1	The identification of the EDI Shipment Notification message	
ASSOCIATION	shipmentRequestIdentification	Ecom_EntityIdentification	1..1	The reference to the request originating the shipment	
ASSOCIATION	dMESHippingOrderNumber	Ecom_EntityIdentification	1..1	The DME order number	
ASSOCIATION	initialOrderNumber	Ecom_EntityIdentification	0..1	The first order number originating the shipment process in case of multiple partial shipments	
ASSOCIATION	sender	Ecom_PartyIdentification	0..1	The entity in charge of the shipment	
ASSOCIATION	receiver	Ecom_PartyIdentification	0..1	The entity generating the referred shipment request	
ASSOCIATION		KitShipmentInformation	1..*	Kit shipment information	
ATTRIBUTE	protocolID	string	1..1	The unique identification of the protocol	{1..20}
ATTRIBUTE	protocolOwner	GLN	1..1	The identification of the protocol sponsor	
ATTRIBUTE	requestedShipmentDate	DateTime	1..1	Shipping date/time confirmation	
ATTRIBUTE	requestedReceivingDateTime	DateTime	0..1	The expected delivery date / time	
ATTRIBUTE	attributeStatusCode	ResponseStatusCode	1..1		WR-22-344



Content	Attribute / Role	Datatype / Secondary class	Multiplicity	Definition	Constraints
KitShipmentInformation					
ATTRIBUTE	investigationalProductIdentification	gtin	1..1	The GTIN of the investigational product	
ATTRIBUTE	isStockInsufficient	boolean	0..1	A flag indicating if the stock is enough to fulfil the requested shipment	
ATTRIBUTE	quantity	Quantity	1..1	The quantity of kits	
ATTRIBUTE	kitErrorCode	KitErrorCode	0..*	The code identifying an eventual error. Possible values in code list: navigator link	
ATTRIBUTE	sequenceNumber	Integer	0..1		WR 22-343

4.2 Enumerations (message specific)

Not applicable.

4.3 Code Lists

Class	Codelist	Navigator Link
KitShipmentInformation	KitErrorCode	navigator link
ShipmentConfirmation (root)	attributeStatusCode	Navigator link



Note: Refer to the GS1 Navigator (Navigator) for the code values.

5 Business Message Examples

5.1 Example 1

Party Information

GS1 Global Location Number	Party Type
9520000000028	Sender - Depot
9520000000011	Receiver - DME
9520000000004	protocolOwner - Sponsor

Message Example 1

Attribute	Value
ShipmentConfirmation	
shipmentConfirmationIdentification	
entityIdentification	115
shipmentRequestIdentification	
entityIdentification	1
dMESHippingOrderNumber	
entityIdentification	13
initialOrderNumber	
entityIdentification	134
sender	
GLN	9520000000028
receiver	
GLN	9520000000011
protocolID	PROT1
protocolOwner	9520000000004

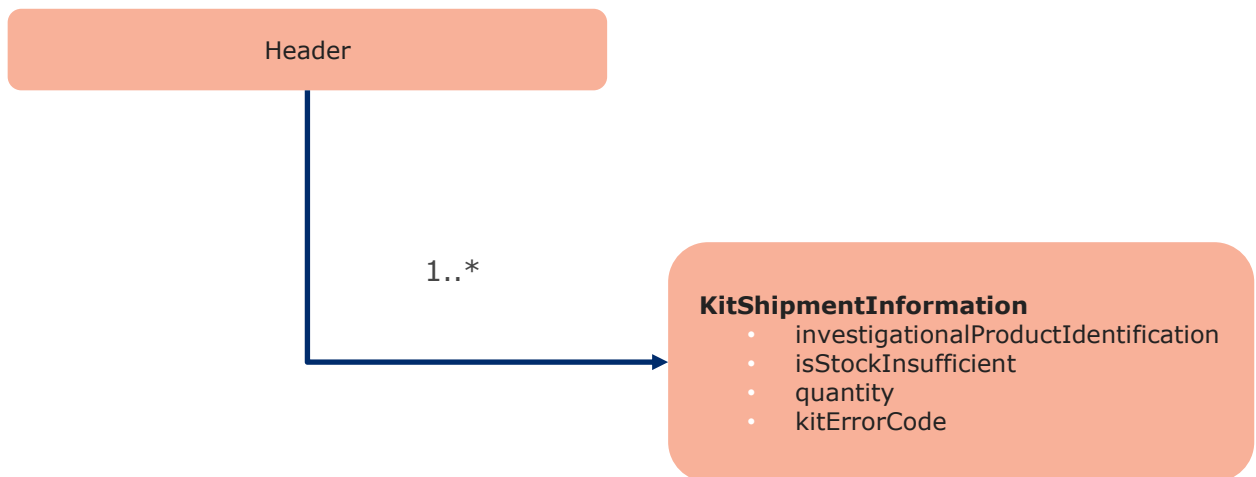
Attribute	Value
requestedShipmentDate	2020-03-26T00:00:00.000
requesteReceivingDateTime	2020-03-27T09:00:00.000+02:00
KitShipmentInformation	
investigationalProductIdentification	9520000000530
isStockInsufficient	Y
quantity	
quantity	0
kitErrorCode	WR

6 Implementation Considerations

6.1 User Guide

6.2 Message Specific Considerations

The message has only a simple detail loop with the detail of confirmed items and the reason codes for eventual unavailability of kits



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 	


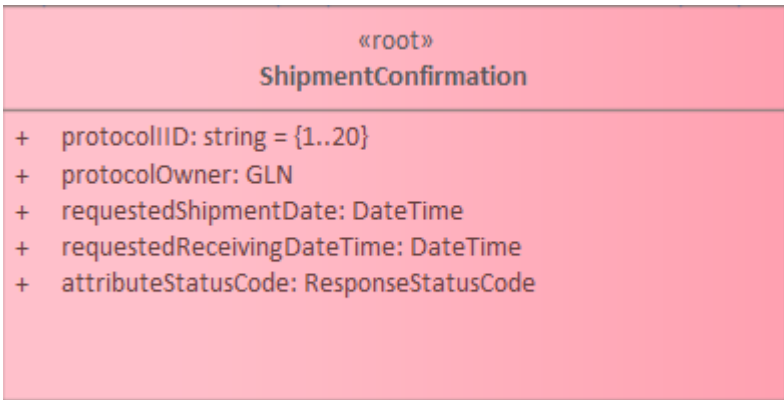
7.2 BMS Release 3.5

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.

7.4 BMS Release 3.6

Change	Associated CR Number
<ul style="list-style-type: none"> New attribute sequenceNumber added to KitShipmentInformation class which is an integer with cardinality 0..1 <div data-bbox="316 1030 1061 1317" data-label="Diagram">  <pre> classDiagram class KitShipmentInformation { + investigationalProductIdentification: GTIN + isStockInsufficient: boolean [0..1] + quantity: Quantity + kitErrorCode: KitErrorCode [0..*] + sequenceNumber: integer [0..1] } </pre> </div>	WR – 22-343
<ul style="list-style-type: none"> New Code added to ShipmentConfirmation class (root) attributeStatusCode <div data-bbox="316 1388 1104 1787" data-label="Diagram">  <pre> classDiagram class ShipmentConfirmation { <<root>> + protocolIID: string = {1..20} + protocolOwner: GLN + requestedShipmentDate: DateTime + requestedReceivingDateTime: DateTime + attributeStatusCode: ResponseStatusCode } </pre> </div>	WR 22-344

7.5 BMS Release 3.7

Change	Associated CR Number
<ul style="list-style-type: none"> Changed the cardinality of sender and receiver from 1..1 to 0..1 	WR-24-000186

Change	Associated CR Number
■ Changed the cardinality of initialOrderNumber from 1..1 to 0..1	WR-24-000020
■ Changed the cardinality of requestedReceivingDateTime from 1..1 to 0..1	WR-24-000035

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

Function	Name	Company / organisation
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	Preedee Chenhansa	Tenthpin
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 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