



The Global Language of Business

Clinical Trials Common Business Message Standard

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1 Business domain view

1.1 Introduction

Purpose

This document defines components that are determined to be foundational to the Clinical Trials domain within GS1.

The other documents in the Clinical Trials suite are:

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

1.2 References

Reference name	Description

2 Business context

Context category	Value(s)
Industry	Healthcare, Pharmaceuticals & Medical Devices
Geopolitical	All

Context category	Value(s)
Product	All
Process	Clinical Trials
System capabilities	GS1 System
Official constraints	None

3 Business transaction view

Not applicable

4 Business Information View

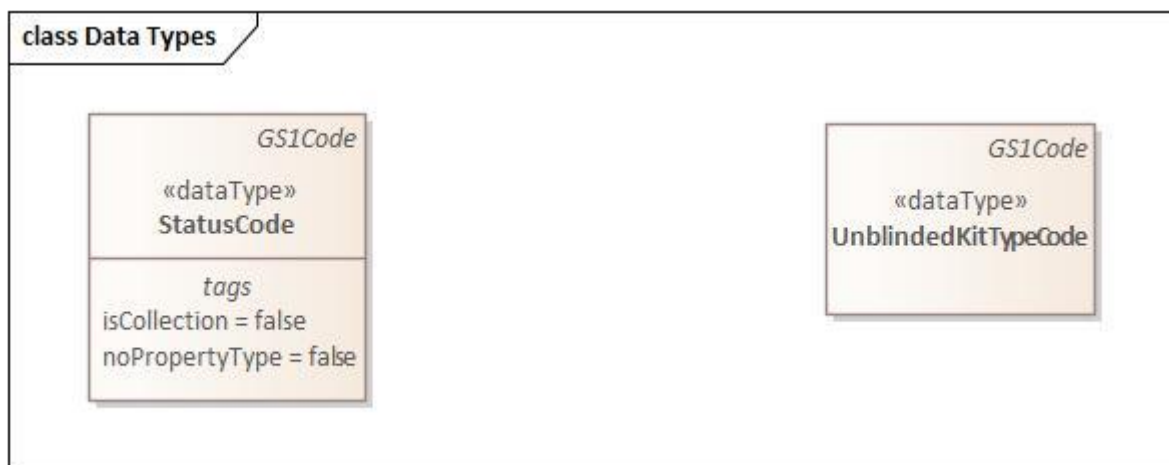
4.1 Business Data Types

4.1.1 Codes

Class Diagram



Note: Please note that all codes in the diagrams below are generalizations of "GS1Code" as indicated by the text in *italics* at the top right hand side of the classes.



Content	Attribute / Role	Datatype / Secondaryclass	Multiplicity	Definition	Requirements
StatusCode					
Generalization		GS1Code			
UnblindedKitTypeCode					
Generalization		GS1Code			

4.2 Components

(Insert class diagrams here)

4.3 Code lists



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

Class	Code list	Referenced in
	statusCode	TBC

Class	Code list	Referenced in
	unblindedKitTypeCode	TBC

5 Business Message example

Not Applicable

6 Implementation considerations

Not applicable

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 3.7

Change	Associated CR Number
▪ Initial release for architectural consistency	

8 Appendices

Not applicable

9 Acknowledgement

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