



GSMP:

General Specifications Change Notification (GSCN)

The Global Language of Business

WR #	GSCN Name	Effective Date
18-087	Clinical trial Protocol ID	27-Mar-2019

Associated Work Request (WR) Number:

18-087

Background:

A new application standard is being developed that explains how to use the GS1 identification keys and attributes for the identification of investigational products in clinical trials, from the time of kit assembly to use, and if necessary, destruction. The mission specific work group has identified the need for a new GS1 Application Identifier, in order to identify the clinical trial study, generally referred to as the protocol ID or protocol number. The new AI will be used as an attribute of the GTIN.

GS1 General Specification Change:

The recommended changes are highlighted in blue, relative to GS1 General Specifications version 18.

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3.2 GS1 Application Identifiers in numerical order

Figure 3.2-1. GS1 Application Identifiers

AI	Data Content	Format (*)	FNC1 required (****)	Data title
7240	Protocol ID	X..20	(FNC1)	PROTOCOL

3.8 GS1 Application Identifiers starting with digit 7

3.8.1 Protocol ID: AI (7240)

The GS1 Application Identifier (7240) indicates that the GS1 Application Identifier data field contains the identifier of a clinical trial protocol. The data is alphanumeric and may include all characters listed in figure [7.11-1](#).

Figure 3.8.1-1. Format of the element string

Application Identifier	Protocol ID
7 2 4 0	X ₁ ————→ variable length —————→X ₂₀

The data transmitted from the barcode reader means that the element string denoting the protocol ID has been captured. As this element string is an attribute of a trade item, it must be processed together with the GTIN of the trade item to which it relates (see section [4.14.2](#)).

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used (see also section [3.2](#)): **PROTOCOL**

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4.14

4.14.2 Mandatory association of element strings

This section defines the element strings that mandate the appearance of another element string on the same physical entity.



Note: This does not necessarily mean that the element strings need to appear in the same data carrier. For example, multiple GS1-128 barcode symbols may be used in combination on a GS1 Logistic Label.

Some explanation on figure 4.14.2-1:

- The table is sorted by AI value, with the AI that is the trigger for the rule displayed in the first column. This means that this table cannot be read in both directions. For example, a rule that states AI (17) must be used together with AI (01), does not imply that AI (01) can only be used together with AI (17), since it can also be used with other AIs.

- Multiple AIs may be listed in the first column, separated by commas. This means that the rule applies to all of the listed AIs (element strings).
- The same AI can occur in the first column multiple times, in different rows. This means that depending on the value of the element string different rules need to be applied.
- When multiple AIs are included in the third column, this is always done with an AND, OR or XOR logical operator between them:
 - AND means that both element strings SHALL appear on the physical entity
 - OR means that one or both of the element strings SHALL appear on the physical entity.
 - XOR means that one of the element strings SHALL appear on the physical entity, and the other element string SHALL NOT.

Figure 4.14.2-1. Mandatory association of element strings

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
7240	Protocol ID	01	The protocol ID SHALL occur in combination with a GTIN.