Identification of Investigational Products in Clinical Trials Application Standard

Rules about the use of the GS1 keys and attributes for the identification of investigational products in healthcare clinical trial processes, including GTIN management rules and barcoding rules.

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Table of Contents

1 Introduction

This application standard explains how to use the GS1 identification keys and attributes for the identification of investigational products (kits and components) in clinical trial processes from the time of kit assembly, to use, and if necessary, destruction. The document is specifically designed to incorporate best practices using the latest standards and following industry trends. The objective is to ensure that application of the principles in the document help industry stakeholders to introduce solutions to enhance historical, often sub-optimal processes. It should be noted that many of the recommendations in the document are quite specific, and intended to increase the speed of industry adoption towards a globally harmonised outcome.

Clinical trials are used to assess the efficacy of a product that has not yet been finalised for commercial release, and not yet approved by a regulatory body. Several innovative pharmaceutical companies, currently using GS1 standards for commercial supply chain efficiency and accuracy, or to meet regulatory or trading partner requirements, are questioning how to apply GS1 standards to their clinical trials. In addition, clinical trials are mostly conducted at hospital sites, where GS1 standards are increasingly being implemented for patient safety, and process efficiency and accuracy. Hospitals are also starting to question the need to have different processes for identification of commercial versus investigational products.

As a result, whilst recognising the commercial pharmaceutical supply chain is in many ways fundamentally different from the clinical trial supply chain, the recommendations in this document have been drafted to leverage what is appropriate from existing commercial experiences, and to allow for more seamless movement of products between the two environments.

This application standard consists of two main parts:

- The principles, covered in sections *4* & *5*, explain the main business needs and challenges and the way these will be addressed. The principles are not rules, they help to explain the logic behind the rules.
- The rules, covered in sections *6* to *9*, specify how the identification keys, data attributes and data capture standards must be applied.

This application standard will periodically be updated, reflecting the learnings of initial implementations. Please see the page on the website *https://www.gs1.org/healthcare* for more information about GS1's work in healthcare.

For any questions about the practical implementation of this standard, please contact your chosen GS1 Member Organisation via *https://www.gs1.org/contact*.

1.1 Target audience

This standard is intended to be used by all parties involved in clinical trial processes. These include:

- Manufacturers and sponsors
- Packaging sites
- Distributors / 3PLs
- Clinical trial sites
- Regulators
- Patients

1.2 Scope of the standard

The standard addresses the application of GS1 standards for identification and barcoding of finished clinical trial kits and components.

A key enabler will be the ability to unambiguously identify the investigational products and their components used in clinical trial kits across the systems and processes of all stakeholders.

This standard defines the rules, roles and responsibilities for the allocation of GS1 identification keys and the barcoding of investigational products.

1.3 Conventions applied in the standard

1.3.1 References

References to documents, websites etc. are indicated as follows [REFERENCE, paragraph number (optional)]. The list of references with full details is included in section 2.

1.3.2 Rules and recommendations

Rules and recommendations are numbered per section. For example, clause **[4-3]** is the 3rd clause in section 4.

Within this specification, the terms SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, NEED NOT, CAN, and CANNOT are to be interpreted as specified in section 7 of the ISO/IEC Directives, Part 2, edition 7.0 [ISODir2]. When used in this way, these terms will always be shown in ALL CAPS; when these words appear in ordinary typeface they are intended to have their ordinary English meaning.

1.3.3 Format of element strings

The following conventions are applied to indicate the format of GS1 Application Identifiers and data fields.

To indicate the allowed characters:

- N numeric digit
- X any character, see [GENSPECS, figure 7.11 – 1] for the allowed characters.

To indicate the length:

- Nn exact number of digits
- N..n maximum number of digits
- Xn exact number of characters
- X..n maximum number of characters

Examples:

- X3 exactly 3 characters
- N..18 up to 18 numeric digits

To indicate digit / character position:

- X_n
- N_n

Examples:

- N_3 numeric digit on position 3
- X_{16} any character on position 16

2 References

Table 2-1 List of references

REF ID	Document	Author / Year
GENSPECS	*GS1 General Specifications*	GS1, latest
ISODIR2	ISO/IEC Directives part 2; Rules for the structure and drafting of International Standards – 7th edition, 2016	ISO, 2016
GTINMAN	GTIN management rules *http://www.gs1.org/1/gtinrules*	GS1, 2016
GTINHC	GS1 Healthcare GTIN allocation rules *https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf*	GS1, 2015
ARCH	GS1 System Architecture *https://www.gs1.org/docs/architecture/GS1_System_Architecture.pdf*	GS1, 2018
GS1DMX	GS1 DataMatrix Guideline *https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf*	GS1, 2018

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

3.1 Clinical trial concepts

Active product

Contains medicinal product that has a physiological impact on the patient.

Ancillary item / supplies

Additional supplies required for the study, e.g., syringes, pumps, needles etc.

Auxiliary product

A medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational product.

Clinical study

See clinical trial.

Clinical supply pooling

The production of clinical supply finished goods that can be assigned to different protocols.

Clinical trial

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Clinical trial site

The location(s) where trial-related activities are conducted.

Comparator product

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

Commercial label

Label applied to a product licensed to be sold in the commercial supply chain.

Double blind

Study type where patients and care providers are unaware of the patient's medication status.

Drug product

Formulated mixture of the therapeutic in a dosage form.

Investigational Medicinal Product (IMP)

See investigational product.

Investigational Product (IP)

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled

(formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

Investigational Product (IP) label

The label applied to an investigational product.

Investigational Product (IP) kit

A single dispensable unit of investigational product(s) for a specific clinical trial.

Interactive Response Technology (IRT)

Umbrella term that refers to both Interactive Voice Response System (IVRS) and Interactive Web-based Response System (IWRS) – systems used for communication of information during a trial.

Interactive Voice Response System (IVRS)

A tool used by clinical trial sites to receive and enter data via the telephone.

Interactive Web-based Response System (IWRS)

A tool used by clinical trial sites to receive and enter data via web-based applications.

Kit design

The configuration of the clinical trial kit based on its components and dosage of investigational medicinal product (IMP), comparator or placebo to be tested, e.g., 5mg or 5mg placebo.

Kit number / kit ID

The identification (ID) associated with a single investigational product (IP) kit.

Master label text

The master of the text to be included on the kit and component labels, based on the language of choice of the sponsor organisation.

Material ID

The identification (ID) associated with a particular material used in clinical trials.

Open label study

A non-blinded study, where all stakeholders know the investigational product (IP) being tested and administered to each patient.

Placebo product

A product with no active ingredient.

Program

The process of development of an individual medicinal product, which may involve multiple trials.

Protocol ID

The identifier, numeric or alphanumeric, assigned to a specific clinical study. (Protocol ID may also be referred to as Study ID or Trial ID).

Single blind

Study type where patients are not aware if they are taking the investigational product (IP), the comparator, and/or the placebo, as applicable. In contrast to a double blind study, the care provider is aware of the patient's medication status.

Sponsor

An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Study ID

See Protocol ID.

Subject

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control (patient).

Treatment ID

Treatment code assigned to a subject when the subject is randomised to the trial. It is associated with the treatment arm, i.e., active, placebo, or comparator.

Trial ID

See Protocol ID.

Vial

A small container used for holding liquids or powders that are to be reconstituted in a liquid.

3.2 Supply chain concepts

Batch or lot

Quantity of goods or material produced in a single manufacturing run.

Instance

An instance designates an individual manufactured clinical trial product. See also unique identification.

Serial number

A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime.

Primary packaging

Packaging containing the actual investigational product, e.g., syringe, blister, vial, etc.

Secondary packaging

Packaging containing the primary package, e.g., kit box, blister pack, etc.

Distribution centre (DC)

In the context of this standard, the party that distributes investigational products to clinical trial sites.

Manufacturer

In the context of this standard, the party responsible for one or more of the following processes:

- production of investigational product
- packaging of investigational product
- labelling of investigational product

Packaging site

In the context of this standard, the location that packages and labels investigational products and investigational product kits.

3.3 GS1 AIDC concepts

Unique identification

Depending on the scope / context the term unique identification may be used to refer to a globally unique identification key for an object class, an instance group or an instance.

- When referring to the object class key, the term class-level ID is used.
- When referring to the instance group key the term lot-level ID is used.
- When referring to the instance key, the term serialised ID is used.

Automatic Identification and Data Capture (AIDC)

A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID. [GENSPECS]

Key

A key is an attribute (or group of attributes) of an entity that serves to uniquely identify that entity, within some specified domain of entities. Often a single attribute is usable as a key, but sometimes a group of attributes is required. In data modelling terminology these are called simple keys and compound keys, respectively.

GS1 identification key

A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit). [GENSPECS]

GS1 ID key issuance and allocation

Issuance is the generation of a GS1 Identification Key based on the format and syntax for that key and on the issuance policy of the managing entity.

Allocation is the association of the issued GS1 Identification Key with an object of the type supported by the GS1 Identification Key in accordance with the GS1 rules.

Different entities may be involved in each process. For example, a computer program could be used to do the issuance and a human could be used to do the allocation. A classic example of this is one where the IT department prepares a spreadsheet of available GTINs (see definition below) for use by the Product Development department. Each GTIN in the spreadsheet is issued, but until Product Development actually has a product for it, it is not considered to be allocated. [GS1 Architecture]

Global Trade Item Number® (GTIN®)

The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit. [GENSPECS]

Identification of an individual Trade Item Piece (ITIP)

The identification scheme used to assign a unique identity to a subordinate element of a trade item (e.g., left and right shoes, suit trousers and jacket, DIY trade item consisting of several physical units), where the subordinate element is not itself a trade item. [GENSPECS (candidate definition to be submitted by CJ)]

GS1 Prefix

A unique string of two or more digits issued by GS1 Global Office and allocated to GS1 Member Organisations to issue GS1 Company Prefixes or allocated to other specific areas. [GENSPECS]

GS1 Company Prefix

A unique string of four to twelve digits used to issue GS1 identification keys. The first digits are a valid GS1 Prefix and the length must be at least one longer than the length of the GS1 Prefix. The GS1 Company Prefix is issued by a GS1 Member Organisation. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes. [GENSPECS]

U.P.C. Company Prefix

A GS1 Company Prefix starting with a zero ('0') becomes a U.P.C. Company Prefix by removing the leading zero. A U.P.C. Company Prefix is used to issue GTIN-12. [GENSPECS]

GS1 Application Identifier

The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.

Human readable interpretation (HRI)

Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation. [GENSPECS]

Non-HRI text

Characters such as letters and numbers that can be read by persons and may or may not be encoded in GS1 AIDC data carriers and are not confined to a structure and format based on GS1 standards (e.g., a date code expressed in a national format that could be used to encode a date field in a GS1 AIDC data carrier, brand owner name, consumer declarations). [GENSPECS]

Data titles

Data titles are the abbreviated descriptions of element strings which are used to support manual interpretation of barcodes. [GENSPECS]

3.4 List of abbreviations

Abbreviation	Full term
AI	GS1 Application Identifier
AIDC	Automatic Identification and Data Capture
DC	Distribution Centre
DPM	Direct Part Marking
GCP	GS1 Company Prefix
GLN	Global Location Number
GSRN	Global Service Relation Number
GTIN	Global Trade Item Number
HRI	Human Readable Interpretation
ID	Identification / Identifier
IMP	Investigational Medicinal Product
IP	Investigational Product
IRT	Interactive Response Technology
ITIP	Identification of individual Trade Item Piece
IVRS	Interactive Voice Response System

Abbreviation	Full term
IWRS	Interactive Web-based Response System
MLT	Master Label Text
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
3PL	Third Party Logistics
UDI	Unique Device Identification
U.P.C.	Universal Product Code

PART I - GENERAL PRINCIPLES

4 Traceability of investigational products

4.1 Introduction to clinical trials

A clinical trial is conducted to investigate the efficacy and safety of treatments, interventions or tests – in preventing, managing or detecting disease or other medical conditions. Clinical trials can compare a new treatment to existing, test different combinations of existing treatments, or even look at other lifestyle factors and their impact on the patient's well-being.

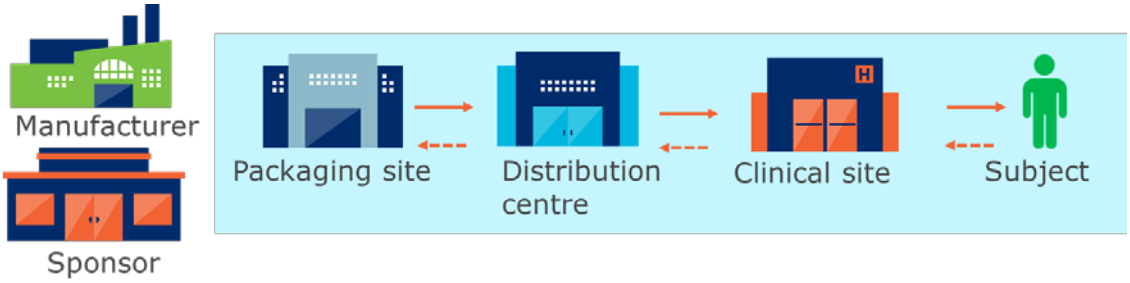
As defined by the World Health Organization (WHO), a clinical trial is '*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*'.

Clinical trials have product identification complexities not seen today in the commercial healthcare supply chain. The uniqueness of an investigational product, which in many cases is only for one patient means this has need to be identified to the instance of the product. In blinded trials the blinded parties should not be able to see from the labelling whether the investigational product is a test article, comparator or placebo. Application of GS1 standards for clinical trials must take these complexities and industry needs into account.

4.2 Business process overview

Figure 4-1 shows the main parties that are involved in clinical trials processes.

Figure 4-1 Stakeholders



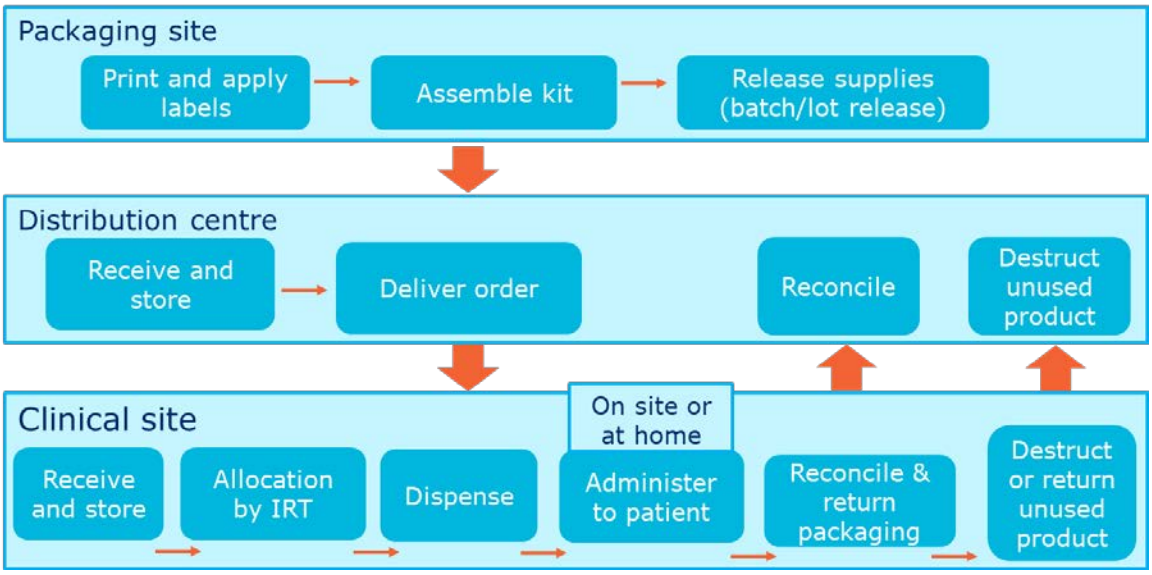
In *Table 4-1* the roles and responsibilities of each party are defined. The solid arrows indicate forward logistics flow and the dotted arrows indicate reverse logistics.

Table 4-1 Roles and responsibilities

Role	Responsibility in process
Sponsor	Has overall responsibility for the trial
Manufacturer	Produces the investigational product
Packaging site	Packages and labels the investigational product and IP kits
Distribution centre	Distributes the IP kits as needed to the sites
Clinical site	The healthcare provider location where the trial is conducted
Subject	The recipient of the investigational product

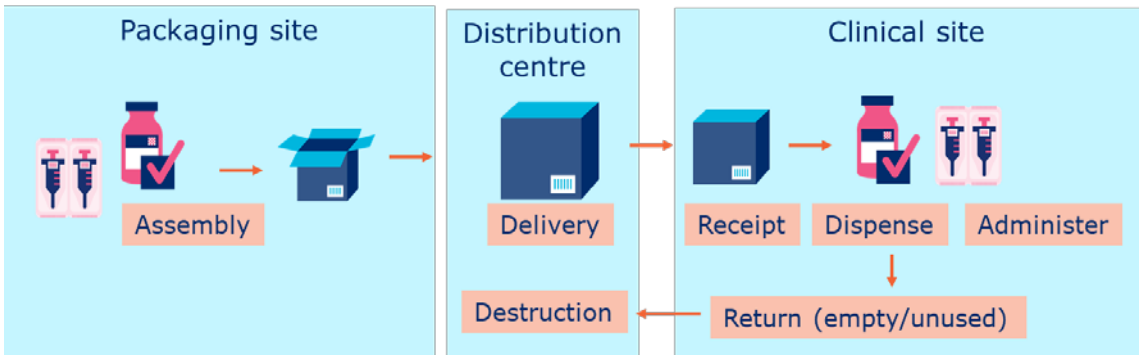
Figure 4-2 and *Figure 4-3* illustrate the physical processes related to the assembly, distribution and use of investigational products in more detail.

Figure 4-2 High-level business process



This diagram shows the main process steps. Some steps may be executed by other parties, e.g., kit assembly may happen at the distribution centre.

Figure 4-3 Physical goods flow



4.3 Need for unique identification, barcoding and traceability

The right medicinal product being administered to the right patient at the right time, via the right route, and in the right dose is a fundamental patient expectation and obligation of the nurses/doctors caring for them – irrespective of whether that product is distributed via a commercial supply chain or as a product subject to a clinical trial.

In the clinical trial context, what happens when product packaging is similar? It might be that the wrong product is picked for distribution to a trial site or even administration to the patient, or it might be that trial participants have similar personal details and could be mistaken for each other. Not often, but sometimes, mistakes happen – to err is human.

The function of scanning a barcode to use the encoded identifier to look up data in a database provides an additional check, a tool, which then can give extra assurance to the patient, the caregiver, the picking and distribution process and ultimately the trial.

The opportunity for benefits from traceability across the clinical trial supply chain from use of a single, standardised approach is significant. Dispatching and receiving products in the absence of standardised identifiers and barcodes leads to manual processes and inefficient double-checking. At some trial sites, site specific identifiers and barcodes are being applied at the point of goods receiving in an effort to try to more accurately manage inventory associated with multiple trials being run concurrently. This duplicates the effort of sponsors who are already identifying their product – but using a solution internal and proprietary to their organisation.

As a result, the case for leveraging a globally standardised approach becomes even more compelling.

4.4 Scope of this application standard

This application standard focuses primarily on the identification and barcoding of investigational products from the time of kit assembly to use and, if necessary, destruction.

Investigational products include active products, comparators and placebos. Besides investigational products, IP kits may also contain auxiliary products and ancillary items.

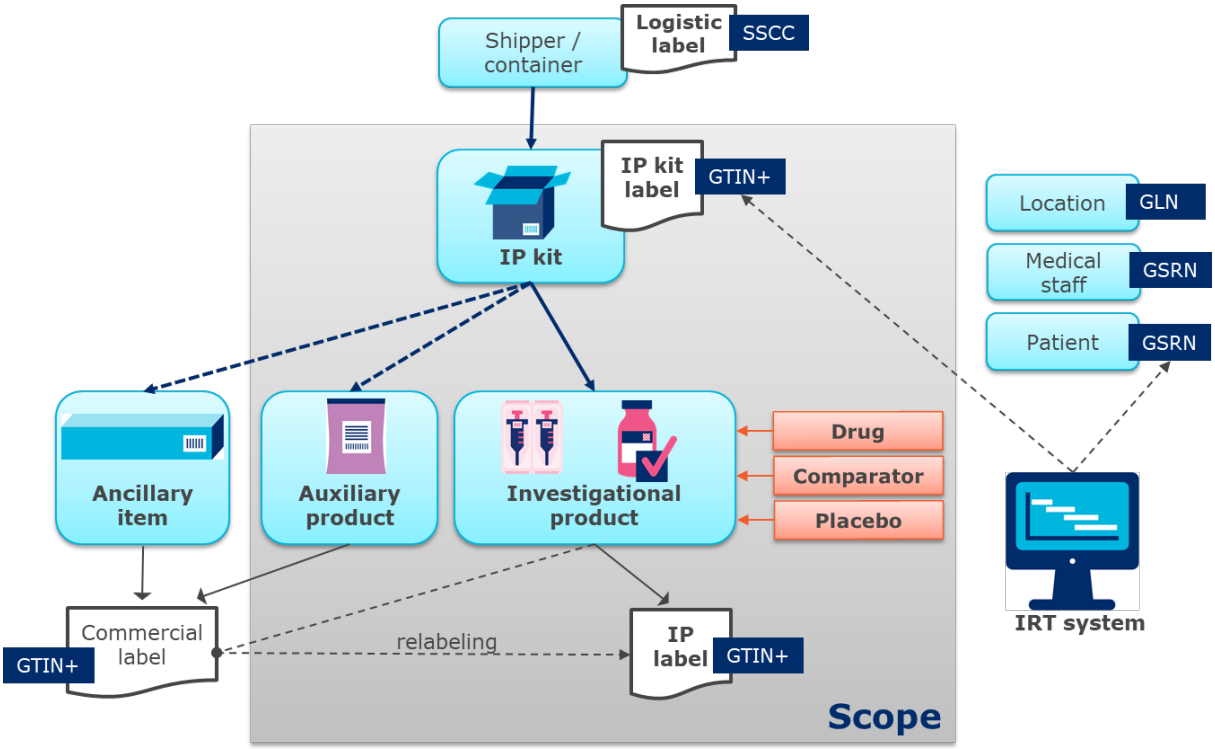
Out of scope:

- Ancillary items, commercial products, mainly medical devices, used in the administration of the investigational product. These are subject to existing regulations and requirements, such as Unique Device Identification (UDI). Information about identification and barcoding commercial healthcare products using GS1 standards can be found in the *AIDC Healthcare Implementation Guideline [REF]*.
- Identification of logistics units using the GS1 Serial Shipping Container Code are likewise discussed in the *AIDC Healthcare Implementation Guideline [REF]*.
- Use of Global Location Numbers (GLNs) to identify parties, locations and entities in healthcare is the subject of the *GLN in Healthcare Implementation Guideline [REF]*.

These guidelines are publicly available at https://www.gs1.org/healthcare/standards

Global standards for patient and medical staff (caregiver) identification are specified in *ISO TS 18530 Health Informatics -- Automatic identification and data capture marking and labelling -- Subject of care and individual provider identification [REF]*.

Figure 4-4 Scope of the application standard



5 IP identification and barcoding principles

5.1 Identification levels

A critical question is at what level investigational products need to be identified. GS1 distinguishes three identification levels:

1. Class level: The identifier links to attributes that apply to all instances of the investigational product.
2. Batch/lot level: The identifier links to attributes that apply to all instances within a single batch or lot of the investigational product, but the attributes may vary between different batches/lots.
3. Instance level: The identifier links to attributes that apply to a single instance of the investigational product, but the attributes which may vary between different instances, even within the same batch/lot.

GS1 identification keys enable these levels of identification. For clinical trials it has been decided to follow the GTIN-based approach that is followed for commercial pharmaceutical products and medical devices. The GTIN is a class-level identifier. To enable batch/lot level identification, the GTIN needs to be combined with a batch/lot ID. To enable instance level identification, the GTIN needs to be combined with a serial ID. These options are illustrated in *Table 5-1*.

Table 5-1 Overview of identification keys

key attribute(s)	key type	supported level of identification
GTIN	simple key	Class level
GTIN + serial ID	compound key	Class and instance level
GTIN + serial ID + batch/lot ID	compound key	Class, instance and batch/lot level

For traceability of investigational products in both open and blinded trials, batch/lot and instance level identification are applied.

GTIN-based identification is a new concept in the clinical trial space, although companies apply their own internal article numbers to the various types of investigational products.

Instead, the protocol ID that identifies the trial is used as the key to all elements of the trial – which instances of product are used, the protocols for use, number of subjects to participate, distribution processes, etc.

Adding the GTIN as a globally unique identifier will offer two important benefits:

- It will make the identification of the kit and its components globally unique, as batch/lot and serial ID will be associated with this globally unique identifier.
- It will provide interoperability and consistency of identification structures, with systems that also manage commercial pharmaceutical product flows, such ERP (Enterprise Resource Planning) and WMS (Warehouse Management System) and pharmacy-inventory systems. This means investigational products will be able to be more easily introduced into existing commercial supply chains without clinical trial sites needing to re-label product as occurs today.

The Protocol ID remains the identifier of the trial itself and is an attribute of all investigational products that are used in the trial. Other information about the trial, such as the protocols for use, the number of subjects participating, and distribution processes will be cross-referred to the Protocol ID.

Note: In case of clinical supply pooling, the protocol number is not assigned at the time finished goods labelling is completed. The GTIN-based identifier will help to ensure precise identification of the produced IP kits, and enable to link it to the protocol ID at a later stage.

Figure 5-1 Introduction of the GTIN enables globally unique (non-internal) identification

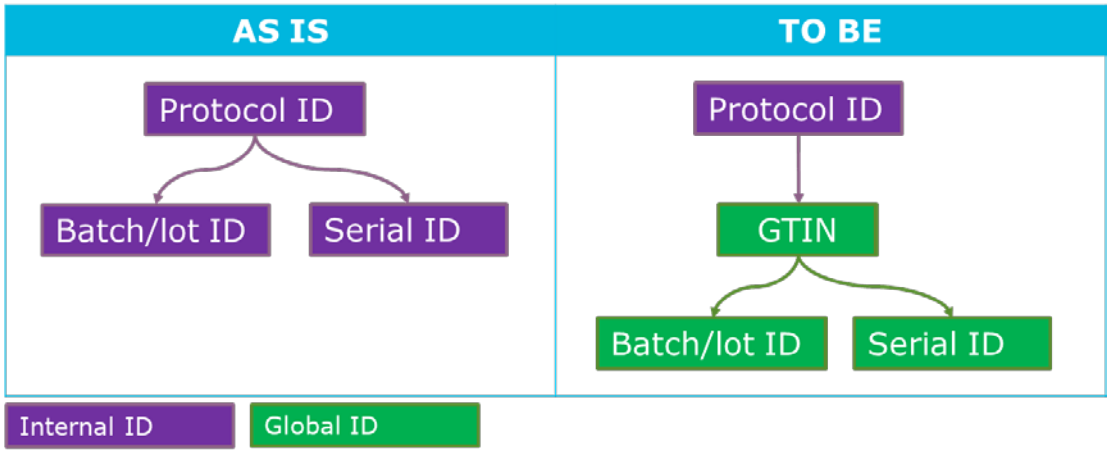
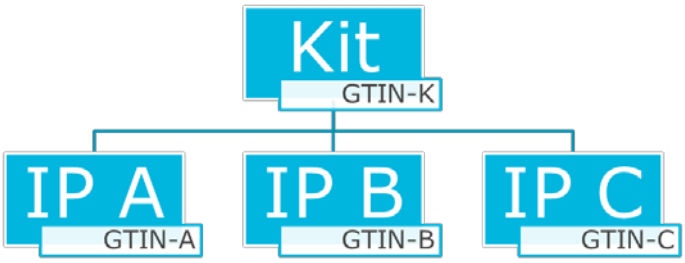


Figure 5-1 illustrates a business centric approach to the current situation (As Is) where identification of the trial kit is based on internal data, in the absence of global standards. This diagram assumes the presence of a Protocol ID. The future situation (To Be) illustrates the change from local internal data to globally aligned and standardised data as facilitated by introduction of the GTIN.

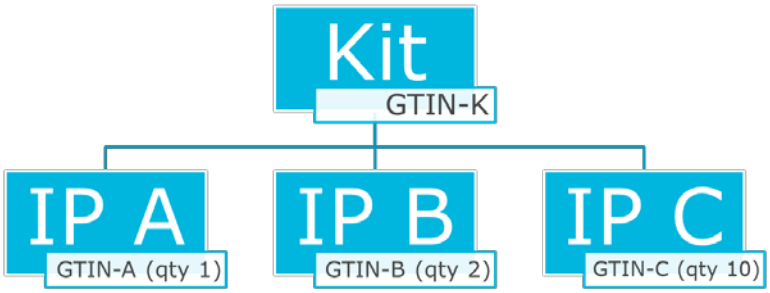
5.2 Identification of IP kits and their contents

IP kits as well as the products contained in the kits need to be identified. In the GS1 system of standards this is accomplished by creating hierarchical relationships between GTINs.

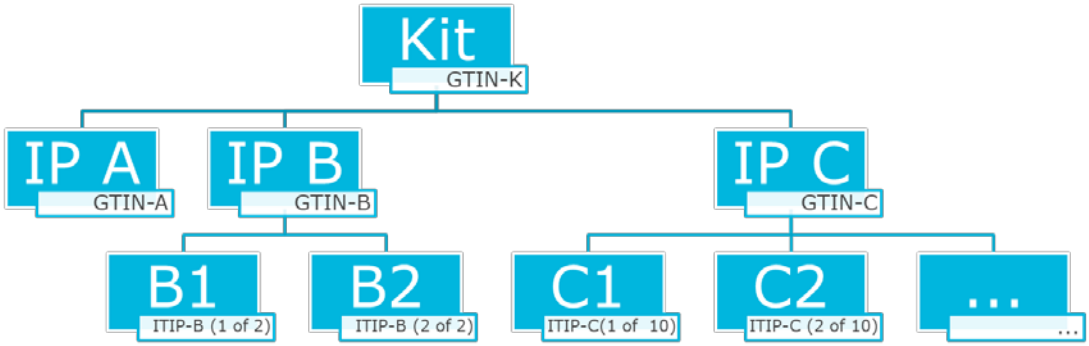
Figure 5-2 Identification of kit and contained investigational products (IPs)



Often, multiple quantities of the same product will be present in the kit. These quantities can be specified in the product hierarchy:



If there is a need for precise control of sequence and count quantity during kit assembly and dosing, each of the contained pieces of the investigational product can be specified individually. For this purpose, a special variant of the GTIN called Identification of an Individual Trade Item Piece (ITIP) can be applied:



5.3 Optional attributes

Key attributes — the GTIN, batch/lot ID and serial ID — point to related data attributes. Such attributes will often reside in databases, and be shared electronically between supply chain partners.

However, in some cases it can be valuable to include some of these attributes on the IP kit label and/or investigational product label. The following optional attribute for inclusion in the barcode has been identified:

- Expiration date (use by date): This can help to prevent errors for some kinds of products. Note: In some situations, the expiration date can be extended during the trial, which could require relabelling of the products.

Note: Attributes in support of other business processes may be included. See [GENSPECS] for an overview of GS1 Application Identifiers.

5.4 Barcoded and human readable data

Product labels are applied on IP kits and investigational products. For the purpose of application of this standard (i.e., introduction of globally standardised identification and barcodes for IP kits and IP product labels), GS1 distinguishes two main types of standardised label data:

1. Data included in barcoded format (symbology)
2. Data included in human readable format (called Human Readable Interpretation (HRI) Text)

Note: Text on the label that is not related to the encoded data in the barcode is not considered by this application standard.

GS1 DataMatrix

For IP kits and IP products, GS1 DataMatrix is the selected barcode symbology, due to its compact size, adoption in other healthcare supply chains, available tools, robustness in the case of damage, etc.

GS1 Application Identifiers

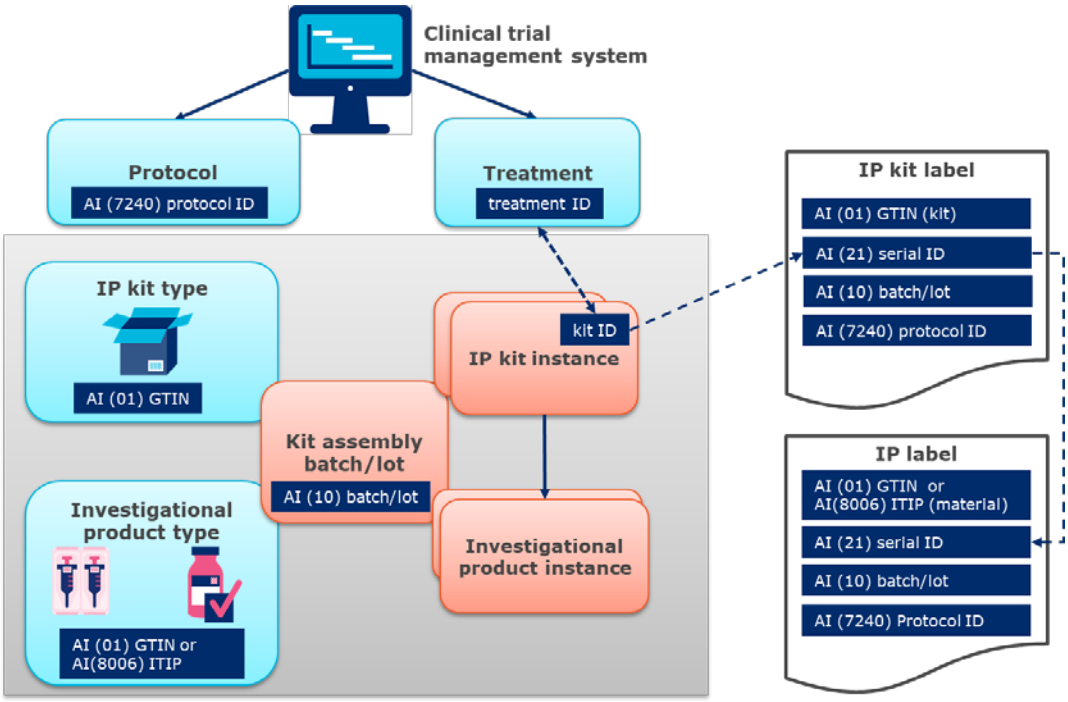
GS1 Application Identifiers enable the structured encoding of data elements in barcodes. Each GS1 Application Identifier also has an associated data title, which is used to support the manual interpretation of barcoded data.

Figure 5-3 shows the main GS1 Application Identifiers for the different levels of identification discussed in this application standard. To the left the corresponding business terms are included. This diagram is designed to be a quick reference to illustrate the identification levels and concepts, see section 9 for the definitions of the GS1 Application Identifiers.

Important: As per the foundational principles of the GS1 standards across all industry sectors and applications, GS1 Application Identifiers (7240) Protocol ID, AI (21) Serial ID, and

AI (10) Batch/lot ID cannot be included in a barcode without the presence of AI (01) GTIN or AI (8006) ITIP. See section 9 and the *GS1 General Specifications* for the rules on the association of GS1 Application Identifiers.

Figure 5-3 GS1 Application Identifiers and corresponding clinical trial terms



It is important to note that the serial number is equivalent to the Kit ID and will be associated with Treatment IDs, where applicable.

Human readable information

It is the best practice recommendation that all information encoded in a barcode should also be represented as human readable information on the product label.

5.5 Standard identification and barcode related data that needs to be present on the label

Note: These principles are intended for global use. Other attributes may be mandated to comply with local regulatory or legal requirements.

Since the space on labels is limited, the following principles define the data elements that need to be present at a minimum.

Kit label

- AI (01) GTIN (barcoded and human readable)
- AI (10) Batch / lot ID (barcoded and human readable)
- If applicable: AI (21) Serial ID (barcoded and human readable)
- AI (7240) Protocol ID (human readable, if possible also barcoded)

Product label

- AI (01) GTIN or AI (8006) ITIP (barcoded, if possible also human readable)

- AI (10) Batch / lot ID (barcoded and human readable)
- If applicable: AI (21) Serial ID (barcoded and human readable)
- AI (7240) Protocol ID (human readable, if possible also barcoded)

Other attributes, such as the expiration date, may be included as well.

Figure 5-4 illustrates these key principles.

Figure 5-4 Standard data that needs to be present on the label

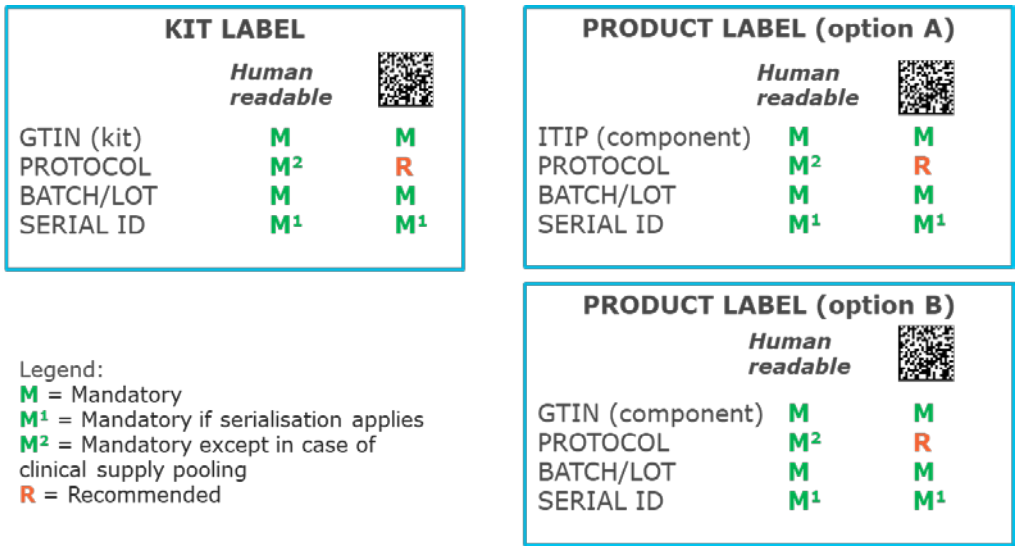


Figure 5-4 represents the best practice use of GS1 identification and barcoding for clinical trial kit and product labels. All information encoded in the barcode should be represented on the label in human readable format.

The data titles as shown above and detailed in sections *8.4* and *9.1*, have been standardised to ensure common understanding across the supply chain of the data elements used.

There is recognition that space is limited on labels, so it is important to note that these elements do not need to be located together, as long as they are present. In the case of product labels with space limitations, preference should be given to human readable representation of those elements necessary for identification of the product by all users across the supply chain.

In the case of clinical supply pooling, it is recognised that the protocol ID may not be able to be included on the label.

PART II - RULES

6 Identification rules

6.1 Identification keys

Note: See section 9 for the data formats of the keys.

6.2 GTIN

[6-1] The GTIN SHALL be assigned in accordance with the general GTIN management rules as defined in [GTIN-MAN] and [GTIN-HC] and the sector specific rules as defined in section 7 of this standard.

[6-2] A GTIN allocated to an investigational product SHALL never be reused.

6.3 Batch/lot ID

[6-3] The batch/lot ID in combination with the GTIN SHALL be unique.

[6-4] The attributes identified with the GTIN + batch/lot ID SHALL correspond to a group of investigational products that were assembled as part of the same packaging batch/lot.

6.4 Serial ID

[6-5] The serial ID in combination with the GTIN SHALL be unique.

[6-6] The serial ID in combination with the protocol ID SHALL be unique. In the case of pooled supply, the serial ID needs to be unique across protocols that are part of the same program.

6.5 ITIP

[6-7] For the identification of pieces of investigational products, a special variant of the GTIN called the Identification of an Individual Trade Item Piece (ITIP) MAY be applied, for better control of kit assembly and dosing sequence (see section 5 for more background).

[6-8] The GTIN contained in the ITIP SHALL follow the identification rules (section 6.2) and GTIN management rules (section 7).

6.6 GS1 Company Prefix (GCP)

The GS1 Company Prefix is included at the beginning of the GS1 identification keys and so establishes global uniqueness (see section 9 for more information).

[6-9] The GS1 Company Prefix SHALL be only be used to issue keys by or on behalf of the company that is the licensee of the GS1 Company Prefix, in accordance with the key allocation rules specified in *GENSPECS section 4 Application rules and management practices*.

[6-10] When the ownership or legal structure of the company that assigned the key changes, for example due to a merger, acquisition, split or spin-off, the responsibility for the GS1 Company Prefixes SHALL be re-arranged according to the rules in *GENSPECS section 1.6 Allocation*.

7 GTIN management rules

These rules explain the way GTINs need to be assigned to investigational products, in support of catalogue, and order and inventory management purposes. These rules will also be included on the GTIN management page.

7.1 GTIN assignment responsibilities (based on trial design)

[7-1] GTIN SHALL be assigned by either the sponsor or manufacturer, following the logic as specified in *Table 7-1*.

Note: If a sponsor applies any labels or makes changes to an existing label applied to a commercial product this product then becomes an investigational product. In this case, the sponsor of the trial is solely responsible for the data contained in the barcode label, including GTIN allocation.

Table 7-1 GTIN assignment responsibilities

	Sponsor (1)	Brand owner of the drug	Product (2)	Product Packaging	Sponsor allocated GTIN required?(3)
1	Industry sponsor	Sponsor	Investigational medicinal	Clinical	Y
2	Academic / University	3rd party	Investigational medicinal	Clinical	Y (4)
3	Academic / University	3rd party	Investigational medicinal - bulk	Clinical	Y
4	Academic / University	3rd party	Commercial - packaged	Clinical	Y
5	Academic / University	3rd party	Commercial - bulk	Clinical	Y
6	Academic / University	3rd party	Commercial	Commercial	N
7	Industry sponsor	Sponsor	Commercial	Clinical	Y
8	Industry sponsor	3rd party	Commercial	Commercial	N
9	Industry sponsor	3rd party	Commercial	Clinical	Y
10	Industry sponsor	Sponsor	Commercial	Commercial	N

The table shows ten different situations that can occur in practice. For each of the situation the last column indicates whether a GTIN needs to be allocated by the sponsor or whether the GTIN as present on the commercial label may be used.

Notes:

(1) When considering GTIN allocation, contract research organisations (CROs) are not considered as the sponsor and therefore do not allocate GTINs to investigational products. From a regulatory perspective, CROs may be considered a sponsor in certain countries.

(2) Saline for reconstitution is often considered an investigational product. However, it may not always be relabelled, in which case it is an exception to the logic specified in table.

(3) In all scenarios in this table GTINs are used for identification of investigational products and kits. This column indicates if the GTIN used is to be allocated by the sponsor (Y in this column) or if the existing GTIN already on the product is to be used (N in this column).

(4) The product is packaged by the brand owner to the specification of the academic/university.

7.2 Adding a new investigational product

[7-2] When IP kits and investigational products are created for a new trial / protocol new GTINs SHALL be assigned for the products that will be used in the trial. Generally, the GTINs will be unique to one study, in case of clinical supply pooling the GTINs MAY relate to multiple protocols.

[7-3] Different GTINs SHALL be used for the identification of the IP kit and for the IP components contained in the kit.

Examples:

- *Kit with 3 syringes and 3 vials*

[7-4] When multiple IP kits with different kit designs are used in the trial, each IP kit SHALL be assigned a different GTIN. Generally, each kit with a different master label text (MLT) is assigned a separate GTIN. Exception: Active and Placebo products used in double blinded trials (see rule [7-6]).

Examples:

- *Kits with different dosage, different form, different administration instructions.*

[7-5] Each different IP component type contained in the kit SHALL get a different GTIN or ITIP. Exception: Active and placebo products used in double blinded trials (see rule [7-6]).

Examples:

- *Kit containing a bottle and a syringe. Generally, each IP product with a different master label text (MLT) is assigned a separate GTIN.*

[7-6] In case of (single or double) blinded trials, the same GTIN or ITIP SHALL be used for different IPs which are blinded against each other as part of the trial design. In that case, the batch/lot or serial ID will be relied on for identification of the different IPs.

7.3 Changing an existing investigational product

[7-7] When the GTIN of an existing investigational product is changed, newly produced instances SHALL be marked with the new GTIN. The GTINs as marked on already produced items MAY remain the same.

[7-8] When the formulation of an existing investigational product is changed a new GTIN SHALL be assigned on kit and component level.

Examples:

- *Change of strength / potency*

[7-9] When the functionality or presentation of an existing investigational product is changed a new GTIN SHALL be assigned on kit and component level.

Examples:

- *Prefilled syringe --> syringe is placed in device*

[7-10] When the net content of an existing investigational product is changed a new GTIN SHALL be assigned on kit and component level.

Examples:

- *10 ml vial --> filled with 4.5 ml and changed to 5 ml*

[7-11] When the dimensions of an existing investigational product are changed, while the net content stays the same, the GTIN MAY remain the same.

Examples:

- Size of bottle in kit changes, but quantity stays the same

- Size of kit changes, contained components stay the same

[7-12] When the sponsor of the trial for an existing investigational product changes a new GTIN SHALL be assigned.

[7-13] When a language or region-specific text is added to or removed from the package or booklet of an existing investigational product the GTIN MAY stay the same.
Rationale: Language and market release are sometimes not known at the time of labelling, and are controlled at batch/lot level, meaning there is no need to control this by GTIN.

[7-14] When one of the components of an existing investigational product kit is substituted with a different component, the GTIN of the kit MAY remain the same, provided that the function of the component doesn't change.
Note: The component will have a different GTIN (e.g., from a different supplier).

Examples:

- *Substitute one dosing syringe in a kit for a different dosing syringe and the two are equivalent in function. The syringes are not identical but have the same function.*

[7-15] .When the manufacturing organisation or material supplier for an existing investigational product changes the GTIN SHALL remain the same, provided that it does not lead to other changes (formulation, functionality, etc.).

Examples:

- *Change the manufacturer of a bottle but the specifications for the bottle don't change.*

8 Barcoding rules

8.1 Introduction

Information marked on objects comes in two basic forms:

1. Information to be used by people.
2. Information designed for data capture by a machine.

Barcodes are machine readable and are a secure and efficient method for conveying structured data, while text and graphics allow people general access to basic information at any point in the supply chain and serve as fall-back positions for unreadable AIDC data. Both methods often co-exist.

Figure 8-1 lists the labelling scenarios that are supported in this standard. The rules for each scenario are defined in the next paragraphs.

Figure 8-1 Overview of labelling scenarios

Labeling of investigational products	Product label (primary packaging)
	Marking directly on product (DPM)
Labeling of IP kits	Kit label (secondary packaging)

8.2 Data content

On IP kits:

[8-1] The GTIN SHALL be present in barcoded form and in human readable form. (Please refer to rule 7-6 to understand how GTINs are assigned to ensure maintenance of blinding of a trial).

[8-2] The protocol ID SHALL be present in human readable form, and SHOULD be present in barcoded form. Exception: In case of clinical supply pooling the protocol ID will not be assigned at the time of production, and added on the label later on.

[8-3] The batch/lot ID SHALL be present in barcoded and human readable form.

[8-4] When serialisation is applied, the serial ID SHALL be present in barcoded and human readable form.

[8-5] Additional attributes such as the expiration date MAY be included in barcoded and/or human readable form.

On investigational products the same rules apply except for rule 8-1, which is replaced with the following rule:

[8-6] The ITIP or GTIN SHALL be present in barcoded form and in human readable form.

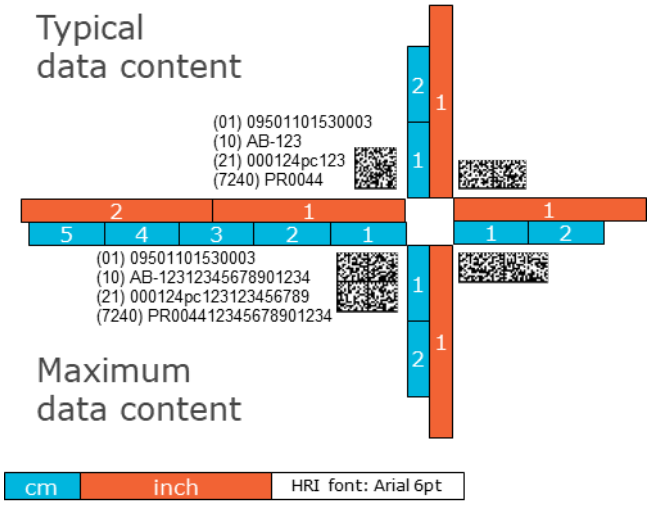
8.3 Barcodes

[8-7] The GS1 DataMatrix barcode SHALL be used for the barcoding of investigational products and IP kits.

8.3.1 Symbol size

[8-8] GS1 DataMatrix SHALL follow the dimensions as defined in symbol specification table 8 [GENSPECS].

Figure 8-2 Symbol size variability depending on the amount of data encoded (image not to scale)



8.3.2 Symbol placement rules

[8-9] The symbol can be placed on the clinical label or can be independent of the clinical label and placed directly on the kit or component, i.e., directly marked on carton or bottle. The location will depend on the product type and its destination.

8.4 Human readable data

HRI (human readable interpretation) text, which represents all the information encoded within the GS1 DataMatrix symbol, serves as back-up information in case the barcode cannot be scanned.

Printing the GS1 DataMatrix symbol and all associated HRI may not always be possible, for example due to space limitations. In such situations non-HRI text, which represents other text (not confined to a standard format), may be used.

Figure 8-3, *Figure 8-4* & *Figure 8-5* illustrate some of the possible scenarios. It is important to note that non-HRI text may be also included elsewhere on the label or packaging, while HRI text needs to be presented adjacent to the GS1 DataMatrix symbol.

Figure 8-3 HRI only
data elements preceded by GS1 Application Identifier

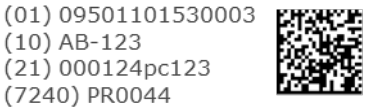


Figure 8-4 HRI only
data elements preceded by data title and GS1 Application Identifier

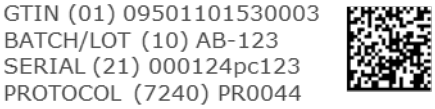
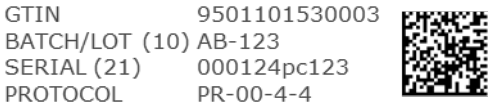


Figure 8-5 Combination of HRI and non-HRI text
HRI text preceded by data title and AI, non-HRI text preceded by data title only



8.4.1 HRI

[8-10] Barcodes SHOULD have HRI adjacent to the symbol. [GENSPECS section 4.14]. Brackets (parentheses) SHALL be printed around each AI but these SHALL not be encoded in the barcode. See *Figure 8-1* and *Figure 8-2*.

[8-11] A clearly legible font SHALL be used (e.g., OCR-B as defined in ISO 1073-2) and the character set as defined in section *9.3*. Reasonable alternative type fonts and character sizes are acceptable provided the interpretation is clearly legible.

[8-12] In case there is not sufficient space HRI MAY be omitted. In that case non-HRI text SHOULD be present.

8.4.2 Non-HRI text

[8-13] For each included data field representing a barcoded data element the GS1 data title related to the AI (see section *9.1*) SHALL be included. See *Figure 8-2* and *Figure 8-3*.

[8-14] Data titles SHOULD follow the format as specified in the 'GS1 General Specifications', in particular they should be presented in UPPERCASE when indicated.

[8-15] A clearly legible font SHALL be used (e.g., OCR-B as defined in ISO 1073-2). Reasonable alternative type fonts and character sizes are acceptable provided the interpretation is clearly legible.

[8-16] If data represented in the non-HRI text does not match the HRI, then only a data title may be used. The AI SHALL NOT be printed. See *Figure 8-3* GTIN and PROTOCOL.

9 Technical standards

9.1 GS1 data formats

9.1.1 GTIN

In this standard three GTIN formats can be applied: GTIN-12, GTIN-13 and GTIN-14 (see *Figure 9-1*).

[9-1] IP kits and investigational products SHALL be identified with a GTIN-12 or GTIN-13 or GTIN-14.

[9-2] If the GTIN-14 is used to identify a grouping of identical trade items, the GTIN-14 SHALL be based on the GTIN-12 or GTIN-13 of the contained trade item. See *GS1 General Specifications section 2* for more information.

Figure 9-1 Overview of GTIN formats

	GS1 Company Prefix →								← Item reference					Check digit
(GTIN-13)		N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}
(GTIN-14)	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}
	U.P.C. Company Prefix →								← Item reference					Check digit
(GTIN-12)			N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}

[Part of figure taken from GENSPECS]

Note: The GS1 Company Prefix (GCP) is a string of 4 to 12 digits. Depending on the GCP length this provides users with a basic numbering capacity of 100,000,000 items (GCP of 4 digits, item reference of 8 digits) to 1 item (GCP of 12 digits, item reference of 0 digits). Companies may license multiple company prefixes if necessary, so even with non-reuse of GTINs they will have sufficient numbering capacity.

Barcode format

[9-3] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (01) GTIN SHALL be used. Exception: If the ITIP is used for the identification of individual trade item pieces, the rules in section *9.1.4* apply.

[9-4] When encoding a GTIN-12 two leading zeroes SHALL be added, and when encoding a GTIN-13 one leading zero SHALL be added. (see *Figure 9-2*)

Figure 9-2 GTIN formats in AI (01)

	Application Identifier	Global Trade Item Number (GTIN)													
		GS1 Company Prefix →									← Item reference				Check digit
(GTIN-12)	0 1	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
(GTIN-13)	0 1	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}
(GTIN-14)	0 1	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

[Part of figure taken from GENSPECS]

Non-HRI format

[9-5] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GTIN**

9.1.2 Serial ID

Barcode format

[9-6] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (21) Serial number SHALL be used. The AI (21) indicates that the data field contains a serial number. The data is alphanumeric and may include all characters contained in character set 82 (see 9.3).

Figure 9.1.2-1. Format of the element string

Application Identifier	Serial number
2 1	X_1 ——— variable length ———› X_{20}

[source: GENSPECS]

[9-7] AI (21) Serial number SHALL be used in combination with AI (01) GTIN or AI (8006) ITIP.

Non-HRI format

[9-8] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **SERIAL**

9.1.3 Batch/lot ID

Barcode format

[9-9] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (10) SHALL be used.

AI (10) indicates that the data field contains a batch or lot number. The data is alphanumeric and may include all characters contained in character set 82 (see section 9.3).

Figure 9.1.3-1. Format of the element string

Application Identifier	Batch or lot number
1 0	X_1 ———› variable length ———›X_{20}

[source: GENSPECS]

[9-10] AI (10) Batch or lot number SHALL be used in combination with AI (01) GTIN or AI (8006) ITIP.

Non-HRI format

[9-11] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **BATCH/LOT**

9.1.4 ITIP

The ITIP consists of:

- GTIN: the GTIN for the complete trade item (investigational product).
- The piece number, which identifies an individual piece of the trade item.
- The total count, which provides the total number of individual pieces of the trade item.

Barcode format

[9-12] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (8006) SHALL be used.

Figure 9.1.4-1. Format of the element string

GS1 Application Identifier	Global Trade Item Number (GTIN)	Piece number	Total count
8 0 0 6	N_1 N_2 N_3 ..... N_{12} N_{13} N_{14}	N_{15} N_{16}	N_{17} N_{18}

Non-HRI format

[9-13] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **ITIP**

9.1.5 Expiration date

The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary to specify the day, the field must be filled with two zeros.

Note: When it is not necessary to specify the day (the day field is filled with two zeros), the resultant data string SHALL be interpreted as the last day of the noted month including any adjustment for leap years (e.g., “130200” is “2013 February 28”, “160200” is “2016 February 29”, etc.).

Barcode format

[9-14] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (17) SHALL be used.

Figure 9.1.5-1. Format of the element string

GS1 Application Identifier	Expiration date		
	Year	Month	Day
1 7	N_1 N_2	N_3 N_4	N_5 N_6

Non-HRI format

[9-15] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **EXPIRY**

9.1.6 Clinical Trial Protocol ID

[9-16] When represented in a GS1 DataMatrix barcode, GS1 Application Identifier (7240) SHALL be used.

AI (7240) indicates that the data field contains the identifier of a clinical trial protocol. The data is alphanumeric and may include all characters contained in character set 82 (see section 9.3).

Figure 9.1.6-1. Format of the element string

Application Identifier	Protocol ID
7 2 4 0	X_1 ——————› variable length ——————› X_{20}

[9-17] AI (7240) Protocol ID SHALL be used in combination with AI (01) GTIN or AI (8006) ITIP.

Non-HRI format

[9-18] When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **PROTOCOL**

9.2 GS1 DataMatrix

Fragments taken from [GENSPECS]:

GS1 DataMatrix is a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.

Data Matrix ISO version ECC 200 is the only version that supports GS1 system data structures, including Function 1 Symbol Character. The ECC 200 version of Data Matrix uses Reed-Solomon error correction, and this feature helps correct for partially damaged symbols.

Some of the production processes that are used to produce GS1 DataMatrix symbols are as follows:

- Direct part marking, such as is done by dot peening on items, such as automotive, aircraft metal parts, medical instruments, and surgical implants.
- Laser or chemically etched parts with low contrast or light marked elements on a dark background (e.g., circuit boards and electronic components, medical instruments, surgical implants).
- High-speed ink jet printed parts and components where the marked dots cannot form a scannable linear symbol.

GS1 DataMatrix symbols are read by two-dimensional imaging scanners or vision systems. Most other scanners that are not two-dimensional imagers cannot read GS1 DataMatrix.

Note: See the GS1 DataMatrix Guideline [GS1DMX] for technical guidance for implementers.

9.3 Character set 82

Table 9-1 lists the characters that are allowed for use in the GS1 Application Identifiers (AI) referenced in this application standard.

Table 9-1 GS1 AI encodable character set 82

Graphic symbol	Name	Coded representation	Graphic symbol	Name	Coded representation
!	Exclamation mark	2/1	M	Capital letter M	4/13
"	Quotation mark	2/2	N	Capital letter N	4/14
%	Percent sign	2/5	O	Capital letter O	4/15
&	Ampersand	2/6	P	Capital letter P	5/0
'	Apostrophe	2/7	Q	Capital letter Q	5/1
(	Left parenthesis	2/8	R	Capital letter R	5/2
)	Right parenthesis	2/9	S	Capital letter S	5/3
*	Asterisk	2/10	T	Capital letter T	5/4
+	Plus sign	2/11	U	Capital letter U	5/5
,	Comma	2/12	V	Capital letter V	5/6
-	Hyphen/Minus	2/13	W	Capital letter W	5/7
.	Full stop	2/14	X	Capital letter X	5/8
/	Solidus	2/15	Y	Capital letter Y	5/9
0	Digit zero	3/0	Z	Capital letter Z	5/10
1	Digit one	3/1	_	Low line	5/15
2	Digit two	3/2	a	Small letter a	6/1
3	Digit three	3/3	b	Small letter b	6/2
4	Digit four	3/4	c	Small letter c	6/3
5	Digit five	3/5	d	Small letter d	6/4

Graphic symbol	Name	Coded representation	Graphic symbol	Name	Coded representation
6	Digit six	3/6	e	Small letter e	6/5
7	Digit seven	3/7	f	Small letter f	6/6
8	Digit eight	3/8	g	Small letter g	6/7
9	Digit nine	3/9	h	Small letter h	6/8
:	Colon	3/10	i	Small letter i	6/9
;	Semicolon	3/11	j	Small letter j	6/10
<	Less-than sign	3/12	k	Small letter k	6/11
=	Equals sign	3/13	l	Small letter l	6/12
>	Greater-than sign	3/14	m	Small letter m	6/13
?	Question mark	3/15	n	Small letter n	6/14
A	Capital letter A	4/1	o	Small letter o	6/15
B	Capital letter B	4/2	p	Small letter p	7/0
C	Capital letter C	4/3	q	Small letter q	7/1
D	Capital letter D	4/4	r	Small letter r	7/2
E	Capital letter E	4/5	s	Small letter s	7/3
F	Capital letter F	4/6	t	Small letter t	7/4
G	Capital letter G	4/7	u	Small letter u	7/5
H	Capital letter H	4/8	v	Small letter v	7/6
I	Capital letter I	4/9	w	Small letter w	7/7
J	Capital letter J	4/10	x	Small letter x	7/8
K	Capital letter K	4/11	y	Small letter y	7/9
L	Capital letter L	4/12	z	Small letter z	7/10

Table taken from [GENSPECS]