



Global Standards Management Process

# CLINICAL TRIALS

## Mission-specific work group

Call to Action



## Background

While barcodes are more and more commonly used throughout clinical trial supply processes, in the majority they are designed by individual companies for their own internal use. They are often inconsistent in the format and structure of the data encoded, and not useful to anyone apart from the organisation who originally printed the barcode.

Investigational medicinal products are often designed to be administered to a single specific patient without the knowledge of the patient or caregiver of whether the patient received that investigational product or a comparator. In other cases, the caregiver has awareness of whether the patient received the investigational product or comparator, but not the patient.

There is significant crossover of commercial product into clinical trials environments, for example commercial product being used as a comparator in a particular trial. In addition, late stage investigational product is regularly introduced into commercial supply chains.

As a result, representatives from the pharmaceutical industry have requested development of a guideline that details best practice application of GS1 standards in clinical trial processes.

## Objectives

The Mission-Specific Work Group (MSWG) will gather the community and expertise needed **to complete development of a guideline to define the best practice identification and barcoding approach** that could be used for investigational medicinal products and associated aspects of the clinical trial environment, including patient, caregiver and location identification.

## Benefits

The outputs of this group will:

- **Facilitate implementation of a universal format** and type of identification across all clinical trial sponsors which would eliminate the need for clinical sites to manage different, and sometimes duplicate, identification and barcode formats from different sponsors, or alternatively invent their own type and format for identification and barcoding.
- **Enable a consistent approach** for both commercial and investigational products which move into the other's environment.
- **Help to prevent 're-identification' of patients and caregivers** who are active in both clinical trials and traditional healthcare environments.

- **Lay the foundations** for more effective and accurate traceability of clinical trials products, as well as best practice supply chain business processes.

## The issue at hand

If no action is taken, clinical trials stakeholders will continue to work with company-specific solutions unable to be used by their trading partners and collaborators across the supply chain. As reliance on barcodes grows, more and more company-specific solutions will be propagated, leading to increased inefficiency, risk and possible confusion.

As indicated by the many clinical trial organisations who have approached GS1, this is not appropriate in any modern supply process, particularly one dealing with some of the most advanced medicinal products with the potential to transform health care as we know it today.

Please [join this group](#) to help facilitate use of global standards for unique identification and barcoding across clinical trials supply processes.

## Who should join this work group?

**Clinical trial process experts, healthcare sector stakeholders impacted by clinical trials and GS1 Member Organisation staff,** who can:

- Provide insights into current supply chain visibility practices;
- Work towards consensus around a common approach;
- Communicate this consensus within their own organisation.

## How will the work group operate?

This work group will follow GS1's improved standards development process:

- **Propose and validate business needs**— analyse business needs from industry input as described in the work order and collect additional feedback to ensure that industry objectives as defined in the work request are met.
- **Develop guidelines**— industry experts will draft a guideline and present it to industry for confirmation and approval.
- **Ratify and publish**— guidelines are approved by the standards development community, ratified by GS1 governance bodies and published.

## Next Steps

1. Join the work group: <https://www.gs1.org/standards-development-work-groups#CLINICAL>
2. Register for and attend by phone the group's kick-off meeting on Wednesday, 18<sup>th</sup> April, 08:00 (EST) – 14:00 (CET) – 21:00 (JST)

The GSMP is a community-based forum for businesses facing similar problems to work together and develop standards-based solutions to address them. Active GSMP participants represent industries ranging from retail and consumer goods to fresh foods, healthcare, transport and logistics, government and more—a healthy mix of business and technical people from nearly 60 countries.



## Help or questions? Please contact:

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