A new standard for investigational products

A global standard by the industry...
resulting from an industry-led working group

... for the industry

Applicable to blinded and unblinded trials

Global Trade Item Number (GTIN) for unambiguous identification of investigational products and their components

No requirement to include expiration date within barcodes

Respects space constraints of labelling small kit components

Scope of work

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. Where identification of items outside of this scope, locations, patients or caregivers is required, reference is made to relevant existing GS1 standards.

Example of a product with a GS1 DataMatrix barcode

Across-the-board benefits

Benefits for suppliers
• Data compiled quicker
• Full supply chain traceability enabled
• Fewer transcription errors on the backend
• Less time spent verifying and validating data

Benefits for clinical trial sites
• Saves time
• Improves inventory management
• Limits need for internal relabelling and transcriptions
• Easy to adopt processes that leverage the barcodes

Benefits for patients
Most importantly, adopting GS1 standards adds an element of trust at all levels of the supply chain – a trust that ultimately extends to the patients themselves.