France

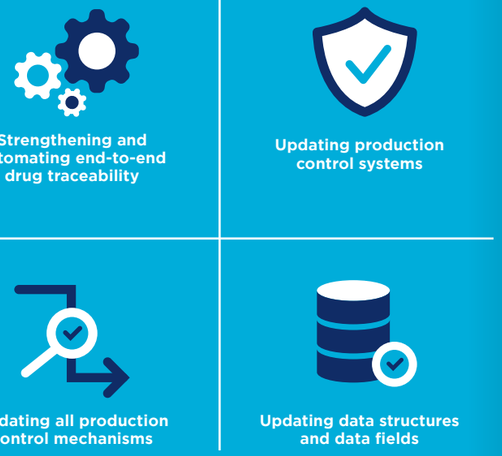
Introducing GS1 standards to the clinical trial supply chain at Creapharm, a Myonex company

Challenge

In the clinical trial industry, drug identification and traceability are essential to ensuring patient safety. However, up until recently, most stakeholders used their own internal tools and proprietary identifiers for tracing investigational products and their locations, as well as for data interchange in clinical trials. As a result, participants had to configure their IT systems to adapt to each solution implemented by each specific Investigational Medicinal Product (IMP) manufacturer.

Approach

When GS1 approved the Identification of Investigational Products in Clinical Trials Application Standard, Creapharm updated its in-house control system to comply. This involved creating new data fields, modifying existing ones and removing obsolete fields. Creapharm also adopted the GS1 DataMatrix® barcode to encode the new data elements, ensuring accurate tracking and efficient data integration across all processes.



Introduction

As a contract packaging and logistics organisation, Creapharm, a Myonex company, partners with pharmaceutical laboratories and biotechnology companies to provide expert support and services, from preclinical/clinical development phases to market launch. This includes worldwide clinical trial supply management and commercial packaging tailored to handle the complexities of advanced therapies.

For 10 years, Creapharm used a proprietary 2D barcode control system on clinical labels to track production steps within its facility. Having now adopted the GS1 standard for the identification of investigational health products – developed as a result of an industry-led working group – Creapharm has enhanced traceability and improved efficiency throughout its clinical trial operations.

Traceability at Creapharm: The journey towards GS1 standards adoption

Back in the 2010s, Creapharm began work on a way to identify the products it needed to package and distribute for clinical trials. While GS1 standards and the GS1 DataMatrix barcode were already being used for barcoding commercial pharmaceuticals, they had not yet been widely adopted by the clinical trials industry. Recognising the benefits, Creapharm chose to implement GS1 standards and barcoding techniques for its clinical trial operations.

Due to the specific requirements for investigational medicinal products and Creapharm's internal processes, the company's in-house control system used proprietary data fields. These fields included a study code, treatment number, packaging level and a period or visit number. Because the resulting 2D barcode was based on proprietary specifications, it could only be used within Creapharm's internal environment and by mutual agreement with its trading partners. Creapharm subsequently recognised that an open and global standard would benefit all stakeholders within its supply chain.

In 2017, Creapharm became an active participant in the GS1 clinical trials group, collaborating with industry partners to develop the GS1 Application Standard for the Identification of Investigational Products in Clinical Trials. In 2019, after a year of efforts by the clinical trials working group, the

new GS1 standard was published. This standard recommends the use of the GS1 DataMatrix barcode for encoding GS1 identifiers including the Global Trade Item Number (GTIN), serial number (treatment number), batch number and clinical trial Protocol ID (study code).

With these predefined and widely understood GS1 data structures, barcode scanning technology and IT systems can capture the necessary information from the GS1 DataMatrix barcode. Any additional data elements present in the barcode can be disregarded if not needed. For Creapharm, the four key data elements in the standard GS1 barcode (GTIN, batch number, serial number and Protocol ID) can be used by all supply chain partners, including clinical trial sites. Additional data elements can be encoded and decoded if necessary. For example, the GS1 functional status identifier can be used with Application Identifier (7021) when detailing the period or visit.

"We always look for standardisation in order to get a simple solution that can apply to most of our clients."

Céline Tinguely,
Operations Director France, Creapharm, a Myonex company

Operational adaptation in three phases

Migrating Creapharm's existing in-house 2D barcode system to the new GS1 application standard for the identification of investigational products, and adopting the GS1 DataMatrix barcode, involved three phases.

Phase one

The first phase involved selecting the appropriate GS1 identifiers to replace Creapharm's internal identifiers. This included the study code, batch number and serial number (treatment number).

This began with the replacement of the existing GS1 Application Identifier for Creapharm's internal study code, Application Identifier (AI) (240), which allows for additional product identification. This field was updated to use the newly created GS1 Application Identifier for Protocol ID (7240).

The identifier used for Creapharm's batch number had historically been a proprietary identifier. This was replaced with the GS1 Application Identifier (10), used for batch identification.

The third identifier – the serial number – replaced the treatment number that was initially integrated into Creapharm's 2D barcode. Creapharm continues to use the GS1 Application Identifier for a serial number using AI (21).

The changes made in phase one, specifically the transition from internal IDs to standardised GS1 identifiers, affected the creation of product labels. This required procedural changes for managing new and existing labels. As a subcontractor, Creapharm had to revalidate label templates with its clients. Packaging and distribution software was also reconfigured to allow the retrieval of information used for internal business controls and capturing traceability information.

Phase two

Phase two involved updating a specific existing field within Creapharm's label template to meet the requirement for a period/visit identifier. Previously, Creapharm used the GS1 Application Identifier for internal company information, AI (91), before transitioning to the GS1-defined identifier for functional status, AI (7012).

Once Creapharm had determined a suite of standards to implement using appropriate GS1 identifiers, it was able to modify and update its label creation and packaging software and adapt its business procedures accordingly.

Phase three

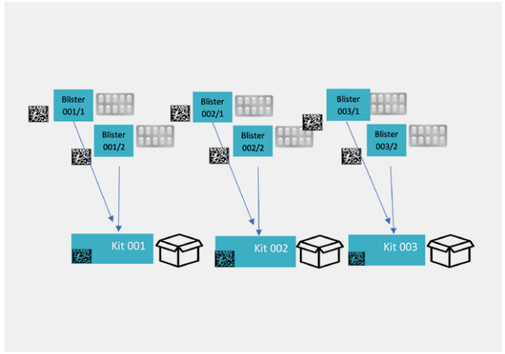
The third and final phase of Creapharm's migration to GS1 standards involved removing and replacing the existing identifiers used for period/visit and packaging level from its systems and label designs.

Identifiers	GS1 standard	Before adapting to the GS1 standard (Creapharm)	Intermediate situation - adaptation to GS1 standard (Creapharm)	Penultimate situation - adaptation to GS1 standard (Creapharm)	Final situation - adaptation to GS1 standard	Format	FNC1 required
AI 01	**Global Trade Item Number (GTIN)**	**Global Trade Item Number (GTIN)**	**Global Trade Item Number (GTIN)**	**Global Trade Item Number (GTIN)**	**Global Trade Item Number (GTIN)**	N2+N14	
AI 10	**Batch or lot number**		**Batch or lot number**	**Batch or lot number**	**Batch or lot number**	N2+X..20	(FNC1)
AI 17	*Expiration date (YYMMDD)*	*Expiration date (YYMMDD)*	*Expiration date (YYMMDD)*	*Expiration date (YYMMDD)*	*Expiration date (YYMMDD)*	N2+N6	
AI 21	**Serial number**		**Serial number**	**Serial number**	**Serial number**	N2+X..20	(FNC1)
AI 230	***Not GS1 identifier***	**Batch or lot number**					
AI 240	*Additional product identification assigned by the manufacturer*	**Protocol ID**				N3+X..30	(FNC1)
AI 250	*Secondary serial number*	*Packaging level identifier (necessary for step controls)*	*Packaging level identifier (necessary for step controls)*	*Packaging level identifier (necessary for step controls)*	~~*Packaging level identifier (necessary for step controls)*~~	N3+X..30	(FNC1)
AI 91	*Company internal information*	*Period or Visit*	*Period or Visit*			N2+X..90	(FNC1)
AI 7021	*Functional status*			*Period or Visit*	~~*Period or Visit*~~	N4+X..20	(FNC1)
AI 7240	**Protocol ID**		**Protocol ID**	**Protocol ID**	**Protocol ID**	X..20	(FNC1)

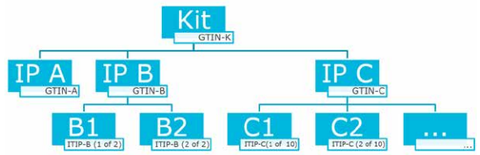
Mandatory
Optional

- Period/visit refers to successive periods of time during which treatments of different nature or dosage are taken successively. This was a two-digit field in Creapharm's original barcode, and has now been updated to use the GS1 AI (7021).
- Packaging level was initially used to allow the capture of packaging steps when assembling or grouping several elements within the production process. It will soon use the GS1 AI (250).

The following diagram illustrates an example of three treatment packs (kits) numbered from 001 to 003. Each kit contains two blister packs, which are numbered sequentially based on the kit number (for example, 001/1, 001/2 and so on).



Use of the GTIN using AI (01), and identification of an individual trade item piece (ITIP) using AI (8006) to control production steps, will be implemented as part of Creapharm's future enhancements.



Following the changes made in phase three, Creapharm will update its label creation and packaging software to reflect the new GS1 data identifiers. This update will allow the use of the GTIN and, where appropriate, ITIP for sub-elements that constitute a treatment unit. The use of the period/visit and packaging level identifiers will subsequently be discontinued.

"The most difficult challenge for this implementation was, without a doubt, the change of identifier enabling production control. This change has an impact not only on the labels, but also on the IT tools used for control. In our case, it is essential to master the impact of this change on the different levels of control. The IT control engine needs to be completely rethought so that the packaging level identifier, made up of the product identifier/ packaging levels, can disappear, to be replaced by the GTIN/ITIP duo."

Nicolas Le Rudulier,
Head of Innovations and Group Synergy Development & IT, Creapharm, a Myonex company

Making customers aware of measurable benefits

Big pharma is now embracing the move to GS1 standards alongside middle-sized pharma businesses, healthcare institutions and biotech companies. Ongoing support and guidance will be essential to this transition.

Throughout the update to Creapharm's internal tools, teams worked with long-standing customers to integrate the new GS1 standard into their products. New Creapharm customers receive specialist support to adopt GS1 standards in their product identification systems.

As a result of this initiative, Creapharm has increased its customers' awareness of the GS1 system of standards and the GS1 DataMatrix barcode, and provided them with a clear path towards GS1 standards adoption. In the meantime, Creapharm continues to integrate the GS1 DataMatrix barcode on all packaging that is produced.

For Creapharm, the use of GS1 standards and the GS1 DataMatrix barcode provides operational benefits such as:

- Control of production and distribution steps.
- Elimination of data re-entry.
- Traceability throughout the supply chain.

Beyond operations, general advantages are clear for all stakeholders:

- Supplier interoperability.
- Access to an ecosystem of tools based on the GS1 standard.
- Updated software equipped to meet business needs.
- Reduction in the number of software solutions needing to be managed by investigational centres.
- Implementation of personalised services and support solutions based on treatment identification for patients or professionals.

"Thanks to the GS1 DataMatrix barcode standard, we are all speaking the same language. This interoperability is a real advantage: each link in the chain is able to identify each treatment on a unit basis and get the data in its own IT system. This foundation stone is going to make exchanges easier between the supply chain stakeholders and the product final users (investigational sites and patients)."

Nicolas Le Rudulier,
Head of Innovations and Group Synergy Development & IT, Creapharm, a Myonex company

Next steps

Creapharm will continue supporting customers in the integration of GS1 standards and the use of the GS1 DataMatrix barcode, promoting the advantages of adopting a truly global standard. The Creapharm team is also looking to implement the GS1 eXtensible Markup Language (XML) standard for Electronic Data Interchange (EDI) to facilitate internet-based messaging between IT systems used by various stakeholders in the pharmaceutical supply chain. Once adopted by Interactive Web Response Systems (IWRSs) in the clinical trial sector, the new GS1 standard for the identification of investigational products should facilitate and secure information exchanges in use cases such as randomisation and inventory management in clinical trials. These objectives form part of Creapharm's approach to continuous business improvement.

Conclusion

By implementing GS1 standards and the GS1 DataMatrix barcode, Creapharm has automated controls in its clinical packaging and distribution processes, allowing staff to be redeployed to other crucial business activities.

Product traceability has been made possible throughout the packaging process by enabling essential information to be captured in the GS1 DataMatrix barcode and decoded, resulting in accurate tracking and verification of products. Automated production controls have been implemented in the assembly of patient kits, ensuring that components are arranged precisely.

In logistics operations, GS1 standards allow for reliable data integration without manual re-entry. In addition, reception operations, shipping preparation and the management of returns at the end of clinical studies are all automatically controlled, minimising manual data entry/re-entry and reducing errors.

GS1 standards ensure a global harmonisation in investigational product identification for patients, investigational centres, the study sponsor and its partners. Thanks to the implementation of GS1 standards, Creapharm has optimised its supply chain and packaging operations, ensuring that each supply chain partner can easily interpret and use the information being shared.

About the author

Nicolas Le Rudulier
Head of Innovations and Group Synergy Development & IT, Creapharm, a Myonex company

Nicolas Le Rudulier, postgraduate in Biotechnology, began his career at Creapharm in 2001 as a logistics manager. Today, he manages structuring projects for Creapharm, a Myonex company.

As Head of IT and Logistics at Creapharm Clinical Supplies for 10 years, and an expert in the international supply chain, his background enabled him to assess the needs related to the traceability of products throughout the supply chain, from clinical trials of products manufacturing to their destruction at the end of the study. Nicolas Le Rudulier has accompanied technical developments related to traceability and production controls of investigational products, and in particular, the implementation of the GS1 DataMatrix.

About the organisation

Creapharm, a Myonex company

Creapharm, a Myonex company, offers capabilities and flexibility to serve pharmaceutical and biotech companies in both clinical and commercial stages, including companies managing advanced therapies.

Beyond decades of experience in clinical trial supply management, we provide strong expertise in cold chain management and recently developed ultra-cold solutions to handle biologicals and Advanced Therapy Medicinal Product (ATMP) supply chains. For marketed health products, we offer expert commercial packaging services.

Myonex is established throughout Europe (France, Germany and Denmark), in the UK and in the US.

www.creapharm.com