

# France

## Sanofi uses GS1 standards in clinical trials for significant operational and human health benefits

### Challenge

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe. The global biopharmaceutical company wanted to improve the efficiency of its operational processes related to investigational products that, in turn, would deliver numerous benefits for its healthcare providers and patients.

### Approach

Sanofi worked with its supply chain stakeholders to transition from the use of multiple proprietary barcodes to global GS1 standards. Today, investigational products are uniquely identified with GS1 Global Trade Item Numbers (GTINs) encoded in GS1 DataMatrix barcodes. This standardised approach helps Sanofi's hospitals and trial sites better manage clinical trial activities so that the right investigational product and/or kit goes to the right patient.

**12x**

faster and more efficient distribution of kits when scanning standardised GS1 DataMatrix barcodes

**50%**

reduction in time spent on labelling for increased productivity due to harmonisation and standardisation



Improved accuracy to ensure the right products are in the right kit



More reliable and faster shipments with seamless information sharing

### Introducing Sanofi

Sanofi is dedicated to supporting people through their health challenges. Focused on human health, Sanofi prevents illness with vaccines, and provides innovative treatments to fight pain and ease suffering. Sanofi also stands by the few who suffer from rare diseases and the millions with long-term chronic conditions.

Sanofi's clinical trial kits are designed to use inputs received from end-users of the supply chain, such as patient communities, physicians and hospitals where trials are conducted. As a result, Sanofi transitioned from taking an internal approach of identifying its investigational products and investigational product kits to adopting global standards for unique identification.

Sanofi's goals: Ensure that clinical trials' products are aligned with the relevant needs of patients and healthcare providers, and enhance internal efficiencies in identifying, handling and tracing products within multiple clinical trial protocols.

### Global standards for clinical trials

Sanofi was the leader of an industry working group comprised of 57 organisations that, within

a nine-month period, drove the development of GS1 global standards for the identification and barcoding of investigational products for clinical trials.

Today, the safety of patients remains the main goal and key success indicator for Sanofi, and patient safety will be enhanced through end-to-end traceability and supply chain interoperability—both enabled by global standards.

Why did Sanofi implement global standards for its clinical trials? The aim of Sanofi is continuous improvement on all levels of its operations. The company wanted to improve the efficiency of its internal processes, using a less complex way of generating, identifying and capturing information about investigational products.

As its implementation of global standards moved forward, Sanofi's focus remained on maintaining and enhancing the accuracy of its clinical trial supply chain.

Since 2009 and prior to its implementation of global standards, Sanofi had used internal identifiers and barcodes. This led to the creation of multiple, different DataMatrix formats and the resulting complexity in managing numerous matrices since each barcode required specific processes to be generated and/or captured.

This situation also meant challenges for stakeholders in the supply chain, as they were unable to scan and interpret the different barcodes with their existing IT capabilities. This led to operational inefficiencies that potentially impacted the overall accuracy of information exchanged throughout the supply chain.

Despite Sanofi's intentions to provide the tools that all trial partners needed, Sanofi barcodes were limited to internal use only, leading to limited interoperability with other stakeholders. Sanofi recognised that a single standardised approach was needed.

## Industry collaboration for a common benefit

As Sanofi worked on its vision, other stakeholders in the clinical trials supply chain had come to realise that using internal, proprietary identification and barcode schemas (that were different for each trial) was causing potential confusion for trial sites, hospitals and logistics providers.

Full-scale interoperability enabled by global standards and relevant IT systems across the supply chain would provide multiple benefits for all stakeholders. Clinical trial sponsors could provide enhanced service to both hospitals and patients that, in turn, could more efficiently manage and accurately document the multiple products of their clinical trials, and provide more timely feedback.

*“By speaking a common language, we realised that hospitals could more efficiently manage clinical trials.”*

**Pierre Fernandez-Barbureau,**  
R&D Clinical Supply Chain Operations, Industrial Development, Sanofi



## The implementation process of GS1 standards

### 1 - Standardise the identifier and barcode.

The standardisation of clinical labels and information was a crucial step during the Label & Package Design phase of Sanofi's clinical trial methodology.

Before implementing GS1 standards, Sanofi used seven different DataMatrix formats with seven different formulas. Each DataMatrix format was encoded with data to pilot and direct every single investigational product through its assigned product line in the phase. These formulas had to be rewritten to leverage GS1 standards, including the allocation and encoding of a Global Trade Item Number® (GTIN®) in the GS1 barcode.

Sanofi used the GS1 Healthcare Barcode Scanner App (HBSA) to ensure the correct string of data was encoded in the GS1 DataMatrix barcode. The HBSA allows users to check if the encoding of data in a certain barcode is compliant with GS1 standards.

### 2 - Enable technologies to encode and decode GS1 barcodes.

Sanofi then needed to ensure its label printers, barcode scanners and other technologies were able to encode and decode GS1 barcodes. The camera controls, which are responsible for the synchronisation of what is scanned from the investigational product label with the visual recognition of labels in the Packaging Operations phase, had to be updated to comply with GS1 standards.

There were also updates made to IT systems and infrastructure, including hardware and equipment for the packaging re-design and accurate reading of the new GS1 DataMatrix. Since barcode scanning is widely used in the Distribution phase of Sanofi's operations, this function was also a key focus.

### 3 - Leverage the new identifiers and barcodes.

Sanofi's priority was to help hospitals and trial sites through the management of their activities at site level to ensure that the right investigational product or investigational product kit went to the right patient. At the same time, Sanofi was aware that various contract manufacturers, contract research organisations, contract packaging organisations, warehousing

providers and logistics providers would need to be able to handle the new GS1 identifiers and barcodes.

As a first step, Sanofi created a document that specifies and explains the content of its new standardised GS1 DataMatrix, and then distributed the document to all stakeholders and partners across the supply chain.

To advance standardisation in the clinical supply chain, Sanofi's vision, as a study sponsor, is to have every stakeholder along the supply chain equipped with barcode readers. With this addition, Sanofi and its stakeholders will be able to fully benefit from the implementation of the new GS1 standard. In short, hospitals and clinical sites can then adopt GS1 standards to identify, capture and use the identification of Investigational kits.

## Successfully transitioning to standards

The implementation of global GS1 identifiers and DataMatrix barcodes meant that Sanofi's current IT systems needed to be able to accurately encode and decode GS1 barcodes. This was not a simple task given the wide range of legacy IT systems in place and IT providers' lack of knowledge regarding the technical structure of GS1 identifiers and barcodes. As such, significant transitional projects included a major systems upgrade as well as educating software providers about how to implement GS1 standards—efforts that proved to offer time savings benefits.

Sanofi is also requiring that its contract manufacturers use the GS1 DataMatrix barcode. This transition is taking some time and effort

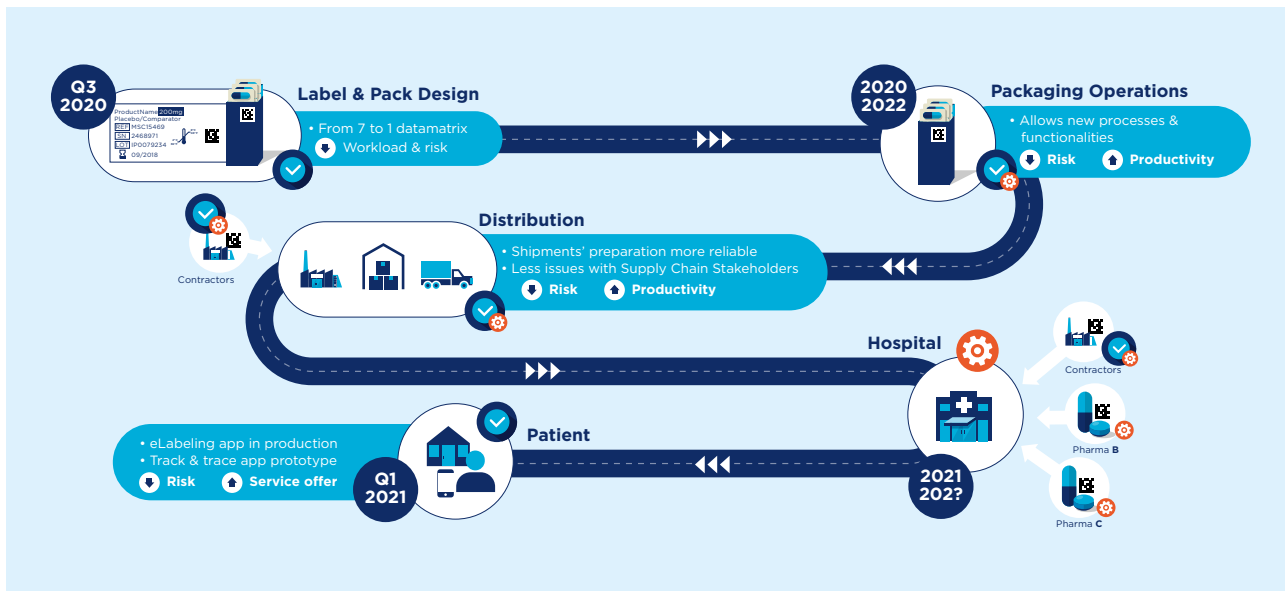


Figure 1: Sanofi implementation timeline and outcomes

since the manufacturers' IT systems need to be updated to accommodate the change to standards. At the same time, both Sanofi and the contract manufacturers realise the major benefits of investing in and adopting this standardised approach.

## Giving patients access to investigational product information

As a top priority, Sanofi wanted to help patients use smart applications to scan GS1 barcodes easily and then share the scanned data with Sanofi. This could provide patients with stable home delivery of products and enhanced guidelines on how to use those products. Sanofi's E-product information application was developed

by solution provider, ClickTag. Now, a patient can simply scan the GS1 DataMatrix barcode on the product's e-label and the application retrieves digital information about the products while simultaneously helping Sanofi track and trace the product in the process. As of August 2021, the e-label app is being used for 4-6 trials with plans to use it for all trials, starting in 2022.

## Operational benefits for Sanofi

GS1 standards are now being used throughout all operational phases at Sanofi, increasing efficiencies and reducing time and risks. And with a standardised structure for the GS1 DataMatrix barcode, Sanofi needs less support from IT, reducing its reliance on and time spent with IT resources.

In the label and package design phase, the time needed for processes has been cut by 50%, significantly reducing workload and improving overall productivity. This productivity hike due to harmonisation and standardisation efforts has improved Sanofi's ability to ensure the investigational products in a box are the right ones.

With its contract manufacturers using GS1 DataMatrix barcodes to label investigational kits, Sanofi also expects to realise significant time savings and operational efficiencies in its own distribution process. It will no longer need separate distribution processes to accommodate non-standardised and standardised barcode labels. Rather, Sanofi will be able to use a single, automated distribution process with no manual intervention.

GS1 standards have helped Sanofi with the re-modelling of its distribution and shipment management processes, which ensures standardised identification of products throughout the supply chain. Sanofi anticipates that the benefits associated with this standardised approach will enable its depots (3PLs) to streamline their processes and help ensure that the right kits get to the right healthcare providers.

Prior to the standardised approach, with multiple barcodes, Sanofi found it was time-consuming to scan and retrieve information based on all the formats.

The company also discovered how disruptive the manual preparation of kits could be.

When preparing 250 kits, it took two people working 2.5 hours compared to less than 10 minutes required when scanning standardised DataMatrix barcodes.

In short, the distribution process is now more efficient, resulting in more reliable and faster shipment preparation, as well as the seamless sharing and exchange of information across the supply chain.

## Looking forward

Sanofi sees that the identification of investigational products and their kits is just the beginning in the overall transformation of its clinical trial operations. Currently, the company is engaging vendors to implement GS1 EDI (electronic data interchange aligned with GS1 standards) to guarantee an optimised flow of business data by "speaking with one common language."

Sanofi will start to implement just-in-time labelling that will allow sponsors and vendors to request labelling for a specific country. This late-stage customisation effort is expected to reduce product wastage, increase the efficiency of distributions, and maximise the usage of products with short expiration dates.

All of these benefits—for Sanofi, its hospitals and patients—are a result of leveraging global GS1 standards.

### About the author



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Pierre Fernandez-Barbureau enables and coordinates the development of next-generation clinical supply chain technologies, taking into consideration new regulations and pharma trends. While remaining patient and clinical-site oriented, he is focused on continuous improvement and operations optimisation.

Previously, Mr. Fernandez-Barbureau held several positions in Clinical Supply Chain and IT departments in France and US, as Domain Leader in Technology and Innovation areas. He joined Sanofi in 2004 as IT Project Manager bringing more than five years of expertise and project management experience at Cap Gemini Ernst & Young. Mr. Fernandez-Barbureau holds a Master of Information Technology, Computer Science and Management.

### About the organisation



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