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Pharmaceutical leaders call for the use of GS1 Standards in clinical research

Executive Summary

Clinical trials are carefully designed studies to test the safety and efficacy of medicines in healthy volunteers and patients. At any one time, biopharmaceutical companies are sponsoring tens of thousands of ongoing clinical trials that are conducted with investigators, ranging from the largest research institutions to solitary practitioners.

With the mapping of the human genome and the advent of personalized medicine, clinical trials have become even more complex. Instead of seeking effective treatment for a thousand diseases, the clinical research community is seeking effective treatment for millions of unique patients. Thousands of investigational products—each identified and named in different ways by each pharmaceutical sponsor—are being investigated.

Research pharmacies like the one at the Dana-Farber Cancer Institute (Dana-Farber) face the challenge of managing hundreds of studies across multiple pharmaceutical sponsors, each with its own unique packaging and labeling.

Biopharmaceutical companies take many steps to ensure the safety and integrity of the clinical supply chain that provides investigational products to patients. Investigational products are typically serialized and barcoded; however, to-date there has not been a common method for barcoding among biopharmaceutical companies.

Amgen, Eli Lilly and Company (Eli Lilly), MSD and Pfizer have recognized the value of using standardized barcodes for investigational products. The use of standardized barcodes will help enable more efficient processes at larger institutions such as Dana-Farber that are already using an electronic inventory system with system-generated barcodes to manage investigational products. GS1 Standards will also provide the foundation for technology innovations that can benefit all investigators and ultimately patients.

Rather than create a new standard, Amgen, Eli Lilly, MSD and Pfizer are encouraging the adoption of GS1 Standards for the identification of investigational products and sharing information across the clinical research ecosystem. This will build upon the significant investments to implement GS1 Standards that are already being made across the pharmaceutical industry for approved drugs.

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Research and Opportunity

Developing an innovative medicine is a lengthy and complex process. While great strides are being made in some areas, many unmet medical needs remain. Advances in science and technology—from genomics to Big Data—are enabling a new generation of medications. While ultimately this will lead to more effective treatments and cures, it is adding challenges to the already strained clinical research ecosystem.

"The unraveling of the human genome and the discovery of a myriad of molecular targets has led to the concept of personalized medicine," says Caroline Harvey, research pharmacy manager for the Dana-Farber Cancer Institute in Boston. "In oncology we have gone from a situation where we had little drug-wise to offer patients—either commercially or on the research side—to the exact opposite situation where we have seen so many new drugs being approved."

With research opportunity comes the need to more efficiently manage complicated drug protocols and an increasingly complex supply chain.

Dana-Farber, along with pharmaceutical sponsors Amgen, MSD, Eli Lilly and Pfizer, explored various ways in which the clinical research processes could be simplified and made more efficient. The pharmaceutical sponsors, all of which are retooling manufacturing operations for approved medications to comply with the FDA's Drug Supply Chain Security Act (DSCSA), were quick to recognize that GS1 Standards could be adopted within research to help achieve consistency in how to identify investigational products and provide a foundation for innovation.

> "While all of us (pharmaceutical sponsors) identify our investigational products in a unique and traceable manner, there is a lack of consistency across the industry in exactly how we do this. This lack of standardization makes it harder and more time consuming for clinical sites to receive and dispense products."
>
> **Jodi Smith-Gick**
> Senior Advisor, Product Delivery and Supply, Eli Lilly and Company

Lack of Consistency

Clinical research is a two-way street, in that it can originate with a pharmaceutical sponsor that has developed an investigational product that shows promise in a particular therapeutic realm, or with a research facility like Dana-Farber that initiates a study and reaches out to pharmaceutical sponsors for the investigational products it wishes to include in the research.

> "There are about 750 active drug studies at Dana-Farber. In the research pharmacy, a lack of standardization among the different pharmaceutical sponsors translates to each sponsor doing things in a different way and that's a significant challenge as well as a potential medication safety issue."
>
> **Caroline Harvey**
> Research Pharmacy Manager, Dana-Farber Cancer Institute

Yet, the "chain of custody" of investigational products used in the study falls to the research pharmacist or clinical research coordinator who takes possession of all investigational products arriving at the research facility, dispensing them as directed to patients and maintaining robust accountability records. Integral to the research trial are hundreds of pharmaceutical sponsors whose focus is finding new medications that can help the sick and prevent disease.

"While all of us (pharmaceutical sponsors) identify our investigational products in a unique and traceable manner, there is a lack of consistency across the industry in exactly how we do this," says Jodi Smith-Gick, senior advisor, product delivery and supply, Eli Lilly. "This lack of standardization makes it harder and more time consuming for clinical sites to receive and dispense products."

This lack of standardization could impact all research sites that conduct studies for more than one pharmaceutical sponsor. Large research institutions feel this most acutely.

"We have about 1,200 different line items of inventory in our research pharmacy. In fact, we have as many inventory items as our commercial pharmacy and I never thought we would see that," Harvey says. "There are about 750 active drug studies at Dana-Farber. In the research pharmacy, a lack of standardization among the different pharmaceutical sponsors translates to each sponsor doing things in a different way, and that's a significant challenge as well as a potential medication safety issue."

Adding to the complexity are many players in the clinical supply chain such as technology vendors, customs agents, couriers and contract manufacturers that handle the investigational products along the way. Standardizing approaches for identifying investigational products can offer many benefits across the supply chain; however, this can require other important members of the supply chain to adopt these standards in order to realize the greatest benefits.

The explosion in digital technologies is advancing even faster than the increase in the number and complexity of clinical trials. These new technologies—mobile apps, electronic health records, Internet of Things (IoT) sensors, and more—are rapidly being introduced to clinical trials in

order to improve efficiencies and allow clinical data to be collected in new and novel ways. GS1 Standards can provide a foundation necessary to provide interoperability across multiple data platforms.

"If pharmaceutical manufacturers align on a standard, this will allow vendors to develop technology that can be deployed as standardized solutions more broadly," adds Smith-Gick.

> "Normally a site that conducts clinical trials works with multiple companies and runs multiple studies. If they're running studies from ten companies, the research pharmacy may have ten different scanners they need to use."
>
> **Kristen May**
> Director of Clinical Supply Chain, Amgen

Simplify and Accelerate

Pharmaceutical sponsors are shipping investigational products to research sites with different documentation and different serialization methods, requiring the investigator site to log investigational products into their system using manual processes. While many research sites are still using paper-tracking processes, the use of investigational product electronic inventory systems is gaining traction.

At Dana-Farber, this means that when an investigational product is received into its electronic inventory system, a unique, internally generated barcode is created and affixed to each dispensable unit and information that's on the shipping documentation is entered into the system manually.

Pharmaceutical sponsors recognize the challenges faced by clinical sites. "Normally a site that conducts clinical trials works with multiple companies and runs multiple studies. If they're running studies from ten companies, the research pharmacy may have ten different scanners they need to use," says Kristen May, director of clinical supply chain at Amgen.

The numbers also add up on the pharmaceutical side. Large pharmaceutical companies support hundreds of research studies across more than 70 countries around the globe. This impacts tens of thousands of research sites and hundreds of thousands of patients. A single, late-phase study could involve as many as 1,000 investigators, illustrating once again the need for using GS1 Standards in clinical research processes—to simplify and gain greater efficiency.

Pharmaceutical companies can also automate manual processes: "There's a lot of manual data entry and a significant amount of data that's crossing systems. With GS1 Standards, we wouldn't have transcription errors that we typically look for on the backend nor would we spend so much time verifying and validating data," says Jeff England, director of global clinical supply for MSD.

At Dana-Farber, boxes of investigational drugs are currently each identified with the institutional protocol number and a two-dimensional barcode.

GS1 Standards: A Clear Choice

- GS1 Standards are global and can help enable processes to work better and efficiently across country borders and the world.
- Healthcare systems in more than 65 countries and regions are implementing GS1 Standards—in Australia, Brazil, Europe, Japan, Korea, New Zealand, Saudi Arabia, UK, United Arab Emirates, U.S. and many more.[1]
- More than 60 leading healthcare organizations have endorsed "the adoption of GS1 Standards for healthcare on a global basis."[2]
- GS1 Standards are already accepted by 65 regulations and government health organizations like the NHS and U.S. Food and Drug Administration.[3]
- GS1 collaborates with standards development organizations: ISO (International Organization for Standardization), CEN (European Committee for Standardization) and the JIC (Joint Initiative Council), which is a group of organizations that work to ensure interoperability between their standards.

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Jeff England
Director of Global Clinical Supply, MSD

Standards as a Common Language

All of these clinical challenges spell the need for a common language to be used by all stakeholders in the clinical research process. This common language can be based on a foundation of GS1 Standards—the same language that is being implemented throughout commercial healthcare.

The majority of pharmaceutical sponsors are either using or moving to the use of a common digital language based on GS1 Standards for identifying their commercial products. Throughout the industry, GS1 Standards have been adopted for increased patient safety, supply chain security and efficiency, traceability and accurate data synchronization in the commercial supply chain.

But in the realm of research, these same manufacturers have not yet embraced GS1 Standards for the investigational products destined for clinical trials.

Pfizer's Moorman and his peers argue the time has come: "Why can't we have a common pharma format for barcodes? It doesn't make sense to create a new format when a GS1 Standard already exists. We should move towards GS1 Standards throughout."

And because compliance with the DSCSA is already well underway industry-wide, it would seem an ideal time to add the clinical research investigational products to the standardization effort.

"In clinical research the types of things that are in the GS1 Standards—lot number, vial number, expiry dates—those are things that we've always been required to track. It's interesting to see that standards governing the commercial realm are now requiring the same level of traceability," Harvey says.

Moorman asserts that part of the attraction is the extensibility of GS1 Standards' use. Each new use of standards leads to more ways in which to gain operational efficiencies, pointing to the electronic exchange of information, such as the Advance Shipping Notice (ASN) that would be useful in a clinical setting. Mobile technology also holds promise, using smartphones as a way to directly provide patients with information once they return home, such as dosing regimens or dietary restrictions.

Patient Focused

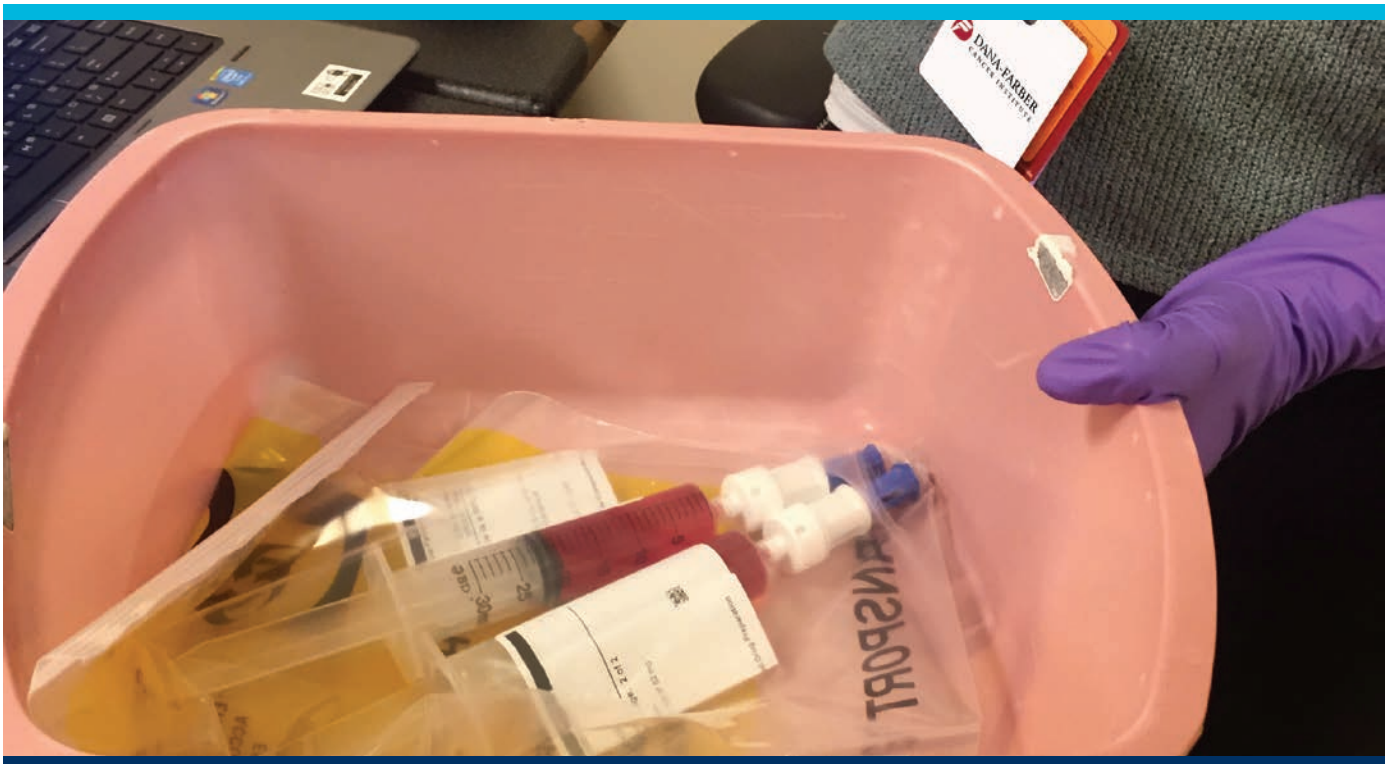
While the Dana-Farber research pharmacy has been using internally generated barcodes for investigational products for almost ten years, this is not a standard approach among research sites, which can include community hospitals and private office practices. There, too, the advantages of using GS1 Standards—accuracy, efficiency, process familiarity and safety—become an across-the-board benefit that extends throughout the medical community, including to the patients themselves.

"If we harmonize our operations on standards, we are not just benefiting the drug industry or the research community, but all the doctors, hospitals and other healthcare facilities that scan barcodes," May says. "It doesn't make sense to use different codes. It shouldn't matter if it's a clinical product or a commercial product. They should be able to follow the same approach to identify a product."

England adds, "We're driving toward a consistent enterprise model across clinical and commercial supply to ensure the highest level of control and efficiency in the management of our products. Investigational drugs shouldn't be treated differently than commercial drugs, just because they're part of a clinical trial."

"Pfizer is putting a stake in the ground saying that we are committed to using GS1 Standards for clinical research. We hope others in the industry will commit to making this a priority. It's for the common good."

Michael Moorman
Global Clinical Supply System Lead, Pfizer



GS1 Standards will enhance patient safety by using barcode scanning technology to ensure that the correct drug is used during the drug preparation process.

"Pfizer is putting a stake in the ground saying that we are committed to using GS1 Standards for clinical research," Moorman says. "We hope others in the industry will commit to making this a priority. It's for the common good."

Amgen's May strongly agrees: "The logistics around product management is not where we should be competing. We should be competing on the basis of science, not on technology advancements that can serve society."

"Not every research site will use GS1 Standards," says Smith-Gick with Eli Lilly. "But, if they do or want to, it's important that we (pharmaceutical sponsors) adopt one set of standards across the industry—one barcoding practice, one labeling approach—so that clinical research sites that choose to can take advantage of using GS1 Standards for more efficient processes."

"Once we standardize data, a big benefit is the work progresses faster and is more reliable, data is compiled quicker, accelerating our submissions to the regulatory agencies. Yet, in the end, it's the patients who will benefit the most—something that we all get behind."

Jeff England
Director of Global Clinical Supply, MSD

Something to Get Behind

Amgen, Eli Lilly, MSD and Pfizer suggest that their peers work with their organizations' teams responsible for implementing GS1 Standards on the commercial side to learn how to leverage and build synergies on the clinical side.

Pharmaceutical sponsors will need to take steps to implement the changes in packaging and ERP systems to create and manage Global Trade Item Numbers (GTINs) and possibly convert to two-dimensional GS1 DataMatrix barcodes.

"Transitioning to GS1 Standards will take time, yet a commitment to start and move in that direction is needed. As foundational standards are put into place, we can then work together to leverage the information-sharing power enabled by these standards," explains Moorman. "It's time to lay the foundation of GS1 Standards today to support clinical research and tomorrow's breakthrough cures."

For more information on GS1 Standards in healthcare, visit www.gs1us.org/industries/healthcare.

GS1 Standards At-a-Glance: Uniquely Identifying Investigational Products

The GS1 Global Trade Item Number® or GTIN® is a GS1 Standard that uniquely identifies a product and information about that product (e.g., manufacturer of the product).

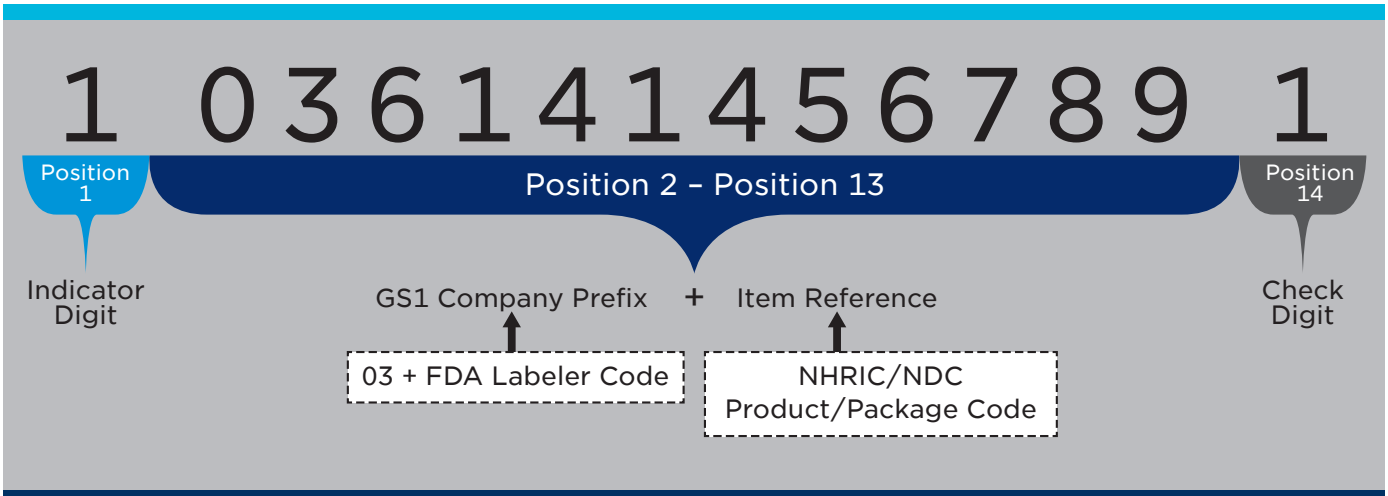
Part of the GTIN includes the GS1 Company Prefix, which identifies the manufacturer, and the Item Reference, which uniquely identifies the product from the perspective of a consumer. When a serial number is added to the GTIN, it identifies the specific package that will be dispensed to the patient.

The GTIN and serial number are encoded in a barcode and applied to the product's packaging. Members of the clinical research team or others in the supply chain could easily identify a specific container of an investigational product and access information about it by reading the container's barcode via a simple scan.

GS1 Standards provide the needed flexibility to "start small" and then extend their use to other parts of a process. With this in mind, pharmaceutical sponsors could start by identifying each container of investigational product with a GTIN and serial number encoded in a GS1 DataMatrix barcode.

For commercial products in the U.S., the National Drug Code (NDC) is utilized for the Item Reference. For investigational products, since there is no NDC assigned, pharmaceutical sponsors would need to determine what to use as an Item Reference and how to manage this within their systems. For blinded dispensable units, the Item Reference could be a Packaging Control Number or other equivalent number.

A major benefit of using GS1 Standards comes from the power inherent in sharing the information. The pharmaceutical industry, either directly or through third-party providers, is investing in infrastructure to facilitate information sharing that will be necessary to comply with the DSCSA and analogous national standards. Therefore, this infrastructure could be leveraged in the future for sharing information about investigational products.



The figure above illustrates how the GTIN-14 is recommended to be used to identify commercial pharmaceutical products in the U.S., incorporating the National Drug Code (NDC). The GTIN-14 can also be adapted for investigational products. Since there is not an NDC assigned for investigational products, pharmaceutical sponsors will need to determine what to use as an Item Reference and how to manage this within their systems. For blinded dispensable units, the Item Reference could be a Packaging Control Number or other equivalent number.

About the Companies

About Amgen

Amgen is deeply rooted in science and innovation to transform new ideas and discoveries into medicines for patients with serious illnesses. Amgen believes in a "biology first" approach, using cutting-edge science and technology to study the subtlest biological mechanisms in search of therapies that will improve the lives of those who suffer from serious diseases. Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. A pioneer in biotechnology since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies. www.amgen.com

About Dana-Farber Cancer Institute

The mission of Dana-Farber Cancer Institute is to provide expert, compassionate care to children and adults with cancer while advancing the understanding, diagnosis, treatment, cure, and prevention of cancer and related diseases. As an affiliate of Harvard Medical School and a Comprehensive Cancer Center designated by the National Cancer Institute, the Institute also provides training for new generations of physicians and scientists, designs programs that promote public health particularly among high-risk and underserved populations, and disseminates innovative patient therapies and scientific discoveries to target communities across the United States and throughout the world. www.danafarber.org

About Eli Lilly and Company

Eli Lilly and Company was founded in 1876 by Colonel Eli Lilly, a man committed to creating high-quality medicines that met real needs, during an era of unreliable elixirs peddled by questionable characters. His charge to the generations of employees who have followed was: "Take what you find here and make it better and better." More than 140 years later, Eli Lilly and Company remains committed to his vision through every aspect of its business and the people it serves starting with those who take the medicines, and extending to health care professionals, employees and the communities in which it lives. www.lilly.com

About MSD

For over a century, MSD has been a global health care leader working to help the world be well. MSD is known as Merck in the United States and Canada. Through its prescription medicines, vaccines, biologic therapies, and animal health products, the company works with customers and operates in more than 140 countries to deliver innovative health solutions. To demonstrate its commitment to increasing access to health care, it has implemented far-reaching policies, programs and partnerships. www.msd.com

About Pfizer

Pfizer applies science and its global resources to bring therapies to people that extend and significantly improve their lives. Striving to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products, Pfizer's global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. For more than 150 years, Pfizer has worked to make a difference. www.pfizer.com

Automated box-picker within commercial drug storage unit at Dana-Farber.

Automated storage unit at Dana-Farber for investigational products, which are stored separately from commercial drugs.

About GS1 US

GS1 US®, a member of GS1® global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). **www.gs1us.org**

1 "Strength in unity: The promise of global standards in healthcare," McKinsey, https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

2 "The healthcare stakeholders expressed their strong support in the adoption of GS1 as the global standard best suited for their industry," GS1 website, http://www.gs1.org/sites/default/files/docs/healthcare/endorsement_paper-hd.pdf

3 "Strength in unity: The promise of global standards in healthcare," McKinsey, page 69, https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

All information contained in this paper, unless otherwise noted, has been provided by Amgen, Dana-Farber, Eli Lilly, MSD and Pfizer.

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