Pfizer

Using barcodes to support efficient clinical trials

Challenge

To run a clinical trial for a potential new medicine is to confront a challenging and very precise distribution process. Ensuring every healthcare site involved in the trial receives the right products for the right patients – including placebos, or perhaps several different doses of the active ingredient being investigated – is complicated. There is then the further issue of clinicians being certain that the right patient is being administered the right product. Getting all this correct is crucial to successfully running trials, which are in turn crucial to testing new medicines that could improve treatment options for patients. A clinical trial is a highly controlled environment, and an incorrect shipment or the wrong drug going to the wrong patient could ultimately impact the integrity of outcomes and patient safety.

Approach

To help support meeting the challenges of the distribution process, Pfizer has introduced a single GS1 standard barcode to all its clinical trial products. In the first instance, this is helping those at Pfizer's packaging and distribution centres to ensure the right products go to the right sites in the right quantities. But, in the longer term, those at the company envisage the same barcode will also be used by hospitals to help with the administration of clinical trials – and even by the patients taking part in trials, who could perhaps scan the code to access information such as dosing instructions and storage conditions.

So much information, so little space

Testing one new drug in a clinical trial actually involves testing several products. There may be a placebo as a control, enabling investigators to understand whether the active drug is making a difference or improvements. In later phase trials there may be several different doses of the active ingredient being tested, to understand what amount makes the optimal difference in comparison to an existing treatment.

All this means that there is a lot of information that needs to be included on product labels for clinical trials. "It's not like designing artwork for commercial supplies," stresses Nicola Barnes, Senior Director Global Clinical Supply at Pfizer.

"For commercial supplies, you've got six sides of a carton – all of this landscape on which you can put information. The challenge in clinical supply packaging is we usually have quite a limited label landscape. We're trying to accommodate multiple languages to give us diversity of countries to which we can provide our clinical trial material. All the country-specific regulatory requirements have to fit onto the label, as well as the protocol information, the storage conditions, drug product information, administration instructions, expiry date, and our unique packaging reference number."

Encoding some of this information in barcodes seems like a natural solution, but until relatively recently the company was struggling to find space to accommodate sometimes multiple barcodes on clinical trials packages.

That changed when there was a decision to move to GS1 barcodes, enabling just one such code to appear on the package. When scanned, the barcode provides the protocol number, serial number, package lot or batch number, and a Global Trade Item Number (GTIN) – a unique number which identifies a product and is the 'key' to which other information is linked.

What that means is that those working in Pfizer's distribution centres can scan the barcode to make sure they are selecting the right product and right batch to the right trial site. It makes the first step in clinical trials both safer and more efficient.

Taking the time to get it right

Those at the company say the process to implement the codes has been a careful and gradual one. "There's been a lot of preparatory work around getting ready to use GS1 on our labels," explains Nicola.

That has included upgrading Pfizer's labelling software to support the use of GS1 standards, and encouraging partners to do the same.

"There was a growing awareness about GS1 among our booklet label suppliers and our vendors who do packaging and labelling for us. And to implement GSI barcodes, I needed to provide them with information on what we were trying to achieve and how we could incorporate GS1 into the label designs without distracting from the regulatory information required for clinical labels."

For staff in Pfizer, meanwhile, there was the need to find ways to manage and track the GTINs being used for clinical trials. With commercially sold products, it's possible to simply have one GTIN which identifies a particular product in a particular strength and potentially for one or multiple markets.

But with blinded clinical trials – in which patients do not know if they are receiving the actual drug or a placebo or a comparator – enormous care needs to be taken to ensure the GTIN does not identify which is the drug, the comparator or the placebo.

"That means that for every packaging configuration we create, we are allocating a unique GTIN," says Nicola. "For a blinded trial we have a unique GTIN which is the same for all of the treatments packaged in that batch, to maintain the blind."

"For open-label supplies, again, we create a unique GTIN for each open-labelled product."

"In both blinded and open product and packaging configurations, the GTIN can be reused if the same configuration is packaged again for a re-supply." confirms Nicolas.

For now, these GTINs assigned are managed via a validated spreadsheet. But in the longer term, we will generate and manage GTINs within the company's enterprise resource planning (ERP) software. This should make the whole process much simpler.

An evolving picture

That is far from the only way in which those at the company see the barcoding project developing. "We didn't just put these GS1 barcodes on our clinical trials products just because we wanted our packagers to have one barcode to process at the packaging site," says Hans Von Steiger, Group Leader in Clinical Supply Chain management. "We really did it with a much broader vision."

That vision encompasses healthcare sites making use of the barcodes as well. "We want to make sure that managing the flow of materials and then dispensing to patients is as easy as possible for these very busy caregivers," says Hans.

Scanning a barcode to automatically check the clinical trial product is the right one for a patient – and to record when and where it was administered – could be a big contribution to this. It would also make it much easier to manage a site's clinical trial inventory; ensuring they had sufficient quantities of the right products at the right times.

In time there might also be the potential to share information with patients via barcodes. "The patient could scan it and it would display a message saying: 'Now please take one of these and hit confirm when you have', or give them reminders as to when doses are due. We could then keep track of compliance in an electronic patient diary."

The simple act of moving to one barcode also helps here. "We have more space to display the other key information on the label more prominently, which helps the site and the patients read the information more readily," says Nicola. "With a single use barcode it's also easier for all those who 'touch' the product, to know which barcode to scan, as opposed to having multiple barcodes and attempting to scan the incorrect barcode."

In the future, it's possible that patients will be able to scan the codes to get detailed information. For now, though, Hans argues the most important step is for pharmaceutical companies to simply make a start with using GS1 barcodes for clinical trials. "The first step is to standardise the barcode," he says. "The second step is that our software solution providers can start building and programming software so that we can take advantage of the barcodes."

About the authors

Nicola Barnes
Senior Director Global Clinical Supply, Pfizer

Nicola Barnes is senior director global clinical supply, Pfizer. Nicola has over 25 years of experience in the industry leading clinical supply packaging and labelling operations. Nicola has developed processes and published guidance documents for Pfizer to define the requisition, design and production of IMP labels for clinical supplies. She is also a subject matter expert in clinical supply packaging design and supply strategies and has implemented new capability including the utility of 3D printing and CAD technology to advance packaging design. Nicola holds a bachelor of science degree in pharmaceutical science and a master's degree in industrial pharmaceutical science.

Hans von Steiger
Group Leader Clinical Supply Chain Management, Pfizer

Hans von Steiger started his pharmaceutical career at Procter & Gamble as a drug product formulator in the product and process development division. He moved on to Pfizer in 1996 supporting R&D solid dose manufacturing and clinical drug product outsourcing. Hans is now in Pfizer's global clinical supply chain management, responsible for a team of supply chain leads overseeing clinical supply strategy. Hans graduated from Rutgers College of Engineering with a degree in chemical engineering.

About the organisation

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