

New packaging strategy optimises supplies and prevents break in enrolment

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Decisions made early in the clinical trial plan—such as randomisation scheme and package design—can have major implications on the success of a trial, particularly if they leave little room to accommodate changing trial conditions.

For one client, slower-than expected enrolment created a product expiry issue that threatened the continuation of the trial.

By turning to Almac's Clinical Services Supply Chain Management (SCM) team for expert help in creating a fresh forecast and a new packaging strategy, the crisis was averted.

The business challenge

Looming drug shortage and a wasteful packaging strategy

The sponsor of a women's health trial had succeeded in enrolling just over half of its target number of patients when it foresaw a major problem: the existing drug supplies would be reaching their expiration date before new supplies would be available.

The sponsor had developed its own supply plan for the complex trial (which involved two patient cohorts and multiple treatment arms in each) and was following a block randomisation scheme. Upon randomisation, each patient received a kit containing 13 wallet cards—enough to last through the year-long dosing scheme. This approach had the potential to create unnecessary wastage if 1) a patient were to drop out of the trial early and 2) if the product expired mid-way through the patient's treatment, in which case, it would have to be replaced with another year's supply.

That second possibility became a reality when enrolment was slower than anticipated and existing supplies were due to expire before they could be used. At that point, the trial had enrolled 1,100 patients—800 of whom were still dosing and would have to be provided with replacement Investigational Medicinal Product (IMP).

To make matters worse, the product was in short supply and would take months to replenish the stock. Meanwhile, the trial still needed to enrol another 700 subjects to reach its target randomisation.

- How could the existing supplies be stretched to accommodate existing and new patients?
- Would there be enough IMP to finish the trial?

The Almac solution:

A new, dual packaging strategy

Recognising that it needed help, the sponsor sought Almac Clinical Services' supply chain expertise in forecasting, packaging, labelling, and distribution and the help of another vendor for Interactive Response Technology (IRT) support. As a first step, Almac worked with the IRT provider and the sponsor's Clinical Research Organisation (CRO) to gather all existing patient data across all treatment groups. Almac then developed a material forecast, and the IRT was used to execute a dispensing schedule that would match the protocol, accommodating both existing and new patients.

Because drug supplies were running so low, Almac immediately recommended a new packaging strategy that would take advantage of kits on hand while avoiding future wastage.

The solution entailed:

- Reworking all of the 13-wallet kits, breaking them down into individual wallet packs each containing a 28-day supply. They were relabelled with unique, blinded medication numbers that were logged into the IRT.
- Taking advantage of the four-to-six week patient screening cycle to label and ship the individual wallet packs to sites to support future enrolment.
- Instructing sites to continue drawing down their inventory of existing 13-wallet kits by providing them to patients currently in the screening process, upon their randomisation (most sites' inventory had the expiry dating to support this).
- Arranging for enrolled patients to return their expiring kits during their next regularly scheduled visit when they would be given a single, 28-day wallet pack, which would be resupplied on subsequent visits. The IRT was programmed to calculate when these visits would take place and to send drug orders as needed.
- Sending a small buffer stock of individual wallet packs to sites to cover unexpected patient visits. The product production schedule was then adjusted based on the forecast, and the Almac Clinical Services team continued packaging and releasing the new single-wallet kits as needed to sustain the trial.



The client results:

Enrolment proceeds without interruption

Before Almac stepped in, the trial was in jeopardy of coming to a halt when supplies ran out.

The hold on enrolment could have lasted months while the new production batch was being prepared, disrupting dosing and jeopardising the study.

As it was, Almac's team of experienced professionals worked with other key vendors under very tight time constraints to avoid disaster. Thanks to Almac's intervention, the trial was completed successfully; no patients were lost due to drug shortages.

In fact supplies were sufficient to dose every patient on schedule, and no new patient randomisations were delayed.

The sponsor continues to partner with the Almac Supply Chain Management Team.

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