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CASE STUDY

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How clinical trial design impacts the supply chain

A pharmaceutical manufacturer established a head-to-head study comparing the safety and efficacy of Product A and Product B (the competitor's product) for diabetic peripheral neuropathic pain (DPNP). The study was conducted in 15 countries in the EU and other countries outside the U.S.

The Challenge

Study randomization was 1:1:1:1, with patients taking doses in the morning and evening:

- Group 1 dosed with Product A only
- Group 4 dosed with Product B only
- Group 2 starts with Product A and adds Product B
- Group 3 starts with Product B and adds Product A

Patients could opt to reduce the dose at any visit; however, dose escalation was required at visits five and six. Patients could also elect early discontinuation at any time.

There were five basic packages— Morning, Evening, Dose Reduction Morning, Dose Reduction Evening and Week 2 taper packages. Materials were packaged in 4 x 9 inch blister cards. Over encapsulation was required for Product B, along with development of a matching placebo.

The Solution

The original plans called for the use of 40 distinct blister cards to manage all of the dose increases, decreases, tapering, morning and evening designations and to blind either Product A or Product B. Through careful planning, the team was able to reduce the number of blister cards by 80% to just eight base cards. Color coding and distinct labels were used to denote morning, evening, dose reduction and Week 2 taper doses.

The initial supply was planned to support about 50,000 cards. However, the packager could package only 10,000 cards to start the study due to higher priorities. Resupply was needed for dating on the bulk drug.

The team worked with Clinical Operations to refine the enrollment plan and win strict agreement to adhere to the plan until more material could be packaged. The team also calculated the most needed packages to start the study. This meant enough material to complete Study Period Two. Clinical also had to agree to potentially using the maximum visit window for all patients if new material was not available prior to Study Period Three.

Outcomes

Enrollment began more slowly than expected, which allowed the supply to last longer than anticipated. The second resupply was also limited to 10,000 cards because of competing priorities and capacity issues at the packager.

Now, however, the demand for supplies had to be spread across the entire study and was not isolated to packaging material for Study Period Two. A third resupply with dating to last to the end of the study was packaged much sooner than expected; from initial to final, there were three supplies in about eight months.

Lessons learned: Further reduction of package types could have been achieved had Regulatory and Country contacts been willing to allow the IRT to play a role in denoting the packages. For example, instead of labeling packages as either “morning” or “evening”, a sticker could have included both words. Then the IRT could have told the study coordinator at the point of assignment what the package actually was—i.e. “This is a morning package; please mark it ‘morning’.”

Additionally, better alignment on priorities between Material and Clinical would have permitted work to begin earlier on material needed to support the trial. This would have eliminated the need to expedite small packaging runs and limit trial enrollment.

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