ALMAC

Partnering to Advance Human Health

Case study

Agility and expertise combine to overcome late stage design issues in comparator study

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There are multiple points of a clinical trial's route-map where the success of the study can be derailed. When it comes to sourcing comparator products to effectively assess an Investigational Product's (IP) performance against the current standard of care, there's a lot that can go wrong.

For instance, the current global supply shortages in particular therapeutic areas can drive-up procurement costs and supply complexity, by forcing sponsors to source product from multiple suppliers and regions. Likewise, if comparator drugs are unexpectedly discontinued, sponsors may be faced with leaving patients in limbo while they update and resubmit the Clinical Trial Authorisation (CTA) to relevant regulatory bodies.

Regardless of the specific cause, if appropriate and timely interventions are not made, the effect of comparator supply and availability issues are typically the same. Processes are inhibited, timelines are delayed and vital study milestones missed, IP is wasted due to expiration, costs are incurred due to the inevitable need to rework materials, potential revenue is lost as a result of delayed trial completion and – most significantly – patients' access to often vital medication is left hanging in the balance.

The challenges

Delays in comparator supply and over encapsulation

These were the risks facing one pharma company embarking upon a phase III trial, involving over 1000 patients at approximately 100 sites, spread across two continents with pressure to deliver against an aggressive timeline with little capacity for delay.

The clinical protocol was complex and included a variation of drugs with different storage and handling requirements. To facilitate blinding criteria, multiple products needed to be over-encapsulated before being packaged within wallets and labelled.

The comparator was to be supplied by the sponsor ahead of the production schedule. Manufacturing activities had already started, based upon enrolment forecasts developed by Almac's supply chain management team, with the blister tooling generated and the wallet card design agreed based on a pre-supplied specification.

However, unforeseen manufacturer delays meant that the sample comparator product didn't arrive until packaging activity was about to commence. Upon inspection, it was discovered that the comparator supplied via the sponsor was too large to be over encapsulated. The largest capsule suitable for human consumption (DBAAA) wouldn't 'click' into place around the tablet, creating serious GMP compliance concerns.

The Almac solution

New, right-fit comparator located within just one week

If an alternative comparator couldn't be found, the sponsor would need to delay treatment schedules: increasing the risk of negatively impacting patients and missing vital study milestones. The success of the study, along with the treatment plans of patients, relied upon quickly finding a alternative product that would fit inside DBAAA.

Needing to find a quick, compliant, and cost-effective resolution, the sponsor turned to Almac and its 30 years experiencing in comparator supply for thousands of clinical trials around the world.

Almac was already working in partnership with the company to provide a full range of supply chain management services, from intelligent forecasting and analytical testing to clinical packaging strategy and label design. The Almac team harnessed their in-depth knowledge of the study's unique requirements and drew upon the company's network of reliable comparator drug suppliers and wholesalers across global markets, to source an alternative comparator.

After reviewing multiple options, Almac located a new comparator product from a different market that would fit the preferred shell. Almac also supported the sponsor to make the necessary amendments to the Clinical Trial Application (CTA) and Simplified Investigational Medicinal Product Dossier (sIMPD) to avoid any study delays and ensure regulatory approval and compliance.

Following approval of the new comparator, Almac recalibrated the tooling equipment, and rescheduled primary and secondary production to avoid any study delays.

The results

Sponsor protects patients and meets ambitious study milestones

Thanks to Almac's intervention and ability to source and procure a suitable alternative product, potential delays were minimised, along with the associated time and cost of having to re-submit the study for CTA approval. As a result, packaging and clinical supply activities were completed on target, the risk of negative patient impact was removed and the trial's ambitious, commercially focused timelines were able to continue uninterrupted.

Throughout the process, Almac provided the sponsor with full visibility via product tracking. Almac's partnership ethos also came into play with daily communication between its clinical supply experts and the sponsor's project leaders; facilitating a transparent and collaborative approach to comparator supply issues and problem solving.

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