Catalent clinical supply

CASE STUDY
Clinical Supply Management

Executive Summary

A small sized pharmaceutical company was approaching the final phases of a large phase III global multiple treatment arm oncology study that involved comparator drug. The study criteria required the client to provide study medication to patients active at the conclusion of the study until the drug would be commercially available, when it could then be prescribed to patients continuing treatment. This necessitated patients to continue with drug assignment visits through at least the following 11 months. With the challenge of assuring continuous supply of drug treatment available to meet study needs, the client called upon Catalent Clinical Supplies Management (CSM) to support the study during this final phase to ensure that no patient would be without ongoing treatment.

The Challenge

The study involved 450 evaluable patients across, 62 sites and 8 countries. At the outset, the client felt confident that their recently completed re-supply packaging run would meet the drug requirements for the remainder of the drug assignment period of the study. The design of the study protocol directed that as certain drug adverse events occurred or designated end points were met, patients would either be discontinued from the study or switch to a new treatment arm and continue in the study. This would result in a fluctuation and uncertainty of not only the number of active patients in the study but also the number of patients on a particular treatment arm. Each treatment arm had a different kit type. Additionally, the comparator drug was expensive with a minimum of a 12 week lead-time to procure, and complete a new packaging run for re-supply. Additional time would also be required to complete re-supply drug shipments to the depots and ensure release in time for patient need.

The Catalent Solution

The Catalent Clinical Supply Manager initiated data gathering, which included unblinded patient visit information along with Site and Depot inventory numbers contained within the Interactive response system (IRT) used in the study. This information was accumulated and customized into a report which reflected the number of active patients in the study, current treatment assignment, projected remaining drug assignment visits, and the average discontinuation rate. Running study projections against the current Site and Depot inventory of each treatment arm determined an accurate forecast of remaining drug treatment quantities required to meet patient drug assignment visits for the remainder of the study. As the client was blind, the ability for Catalent to forecast in an unblinded manner, whilst still ensuring that they remained blind to the detail of the analysis was invaluable.

Conclusion

Employing clinical supply management tools and experience, the Catalent Clinical Supply Manager was able to provide the client with clear evidence from the analysis of actual and projected information which defended the necessity of an additional packaging campaign in order to meet drug requirements to study end. In addition, Catalent was able to identify appropriate timing, size and destination of shipments to ensure supplies were optimized. The amount of comparator drug required was assessed to ensure that the order was placed in sufficient time.

Without this intervention by Catalent's experienced Clinical Supply Manager, the study would have experienced serious drug supply issues and potential "Out of Stock" situations with patients not being able to continue their treatment. The required packaging and shipments were managed in a controlled manner with re-forecasting during these late stages ensuring that kits were provided to the right site in the optimal quantity at the right time. Moreover, an assessment of unused patient kits following drug accountability revealed a minimal amount of unused patient kits of 12%. This was less than a third of what the client had experienced in earlier studies. The client was extremely appreciative of Catalent's achievement in these results.