



CASE STUDY

Large Global Phase III Clinical Trial in Metastatic Colorectal Carcinoma (mCRC)

Patient enrollment completed 3 months ahead of schedule and database lock 3.5 months ahead of schedule



Large Global Phase III Clinical Trial in Metastatic Colorectal Carcinoma (mCRC) Case Study

Patient enrollment completed 3 months ahead of schedule and database lock 3.5 months ahead of schedule



SITUATION

UBC successfully managed a large global phase III clinical trial in patients with mCRC refractory to standard chemotherapies. The target was to randomize 800 patients in an 18-month period. The trial ran in 113 sites, across 13 countries. This was a full service contract, with UBC being responsible for all activities related to study execution and analysis.



CHALLENGES

- The accelerated patient enrollment resulted in several challenges:
 - Rapid flow of data to be verified, reviewed, and cleaned
 - Limited drug supply availability
 - Aggressive timeline changes in subsequent milestones i.e. database lock



SOLUTIONS

UBC successfully overcame the above challenges with the following strategic solutions:

- Flexible resource strategy to accommodate adjusted timelines, enabling increased monitoring visit frequency
- Streamlined communication and close collaboration between physicians, UBC, and the sponsor to rapidly clean data and close queries
- Using local in-house experts within each country to support the regulatory and ethics/IRB submissions related to limited drug supply and the need for expiration extension re-labelling



RESULTS

The attention to detail in project management, led by UBC's industry experts, resulted in the sponsor gaining approval for the product in U.S. and Europe ahead of schedule.

UBC provides exemplary stage II-IV and patient-support services, focused on safety, access, and value for the biopharmaceutical industry.

To learn more about our services and solutions, please visit ubc.com or email us at contact@ubc.com.