The difference is in the data.™

Adaptability of the MMS NDA Approach

CHALLENGE

The sponsor program was behind schedule, with two ongoing Phase 3 studies that were at risk in terms of data quality and timeline delays. The delays in the Phase 3 program would impact their development plan, including commitments to a New Drug Application (NDA) filing. The sponsor team was lean, with limited time for vendor oversight and limited experience with NDAs.

MMS SOLUTION

MMS provided data management, statistics, clinical programming, and medical writing support for the two ongoing pivotal trials. Keeping the end in mind – a successful NDA data package – the team quickly moved from study-level to submission-level support, responsible for the NDA submission and post submission activities. Expertise and familiarity with the Phase 3 program was carried forward; MMS proactively considered items for discussion with the US Food & Drug Administration (FDA), strategies for data pooling, and analyses best suited to support agency approval. MMS established a regulatory submission core team to lead all submissions activities, and leads were divided between efficacy and safety – two teams across all functional areas. MMS worked to ensure efficiency was maximized, including programs developed at the study level for statistical analyses and results were used as the foundation for submission activities.

"Close collaboration between sponsor and MMS resulted in a successful submission and approval within 5 months."

OUTCOME

The NDA was successfully submitted on time to the FDA. MMS was requested to provide post submission support, and a rapid response team was assigned and remained available as queries came in from the FDA. The team was very familiar with the pivotal and integrated study analyses, and all responses were addressed within the timeframe requested by the agency. The sponsor had a successful AdComm. The close collaboration between sponsor and MMS teams resulted in a successful submission and approval within five months.