Full Biometrics Support

A pharmaceutical company with Clinical and Regulatory departments — but no in-house Biometrics department — needed post-submission support for their first NDA one month after filing. They had lost confidence in their CRO and approached PharmaStat and one of our partners for statistics and regulatory expertise to cover the review period.

The review resulted in requests for additional information to support an alternate labeling claim. The company decided to run a small study to address the reviewers' concerns. They called upon PharmaStat to work with in-house Clinical staff to review the literature, identify endpoints, design the study, and write the protocol.

PharmaStat worked closely with a CRO to rapidly produce high quality data for this time-sensitive project. By the end of the project, PharmaStat and our partner had collaborated to provide services that included regulatory strategy, vendor support, CDISC modeling, and statistical reporting. The collaboration was a success; the labeling claim was addressed and the NDA was approved.