propharma

case study

NDA medical writing

challenge

- A Midwest-based pharmaceutical client needed medical writing and biometric support for a 505(b)(2) New Drug Application (NDA). The client had little NDA filing experience and needed an experienced team to develop a filing strategy, complete programming and statistical analysis, and author CTD and other documents.
- Strategic differences in utilizing literature for supporting information.
- Competitor scheduled to file similar product in the same indication in the same time-frame.
- Statistical sub-analyses in flux.
- Timelines tied to corporate goals.

solution

- Our experts created a submission strategy approved by FDA that allowed for a 2-part submission approach.
- We deployed 10+ team members to write and quality review Modules 2 and 5. In addition, literature strategy to support 2 key areas of the submission was developed and included a separate team of scientists and medical reviewers who reviewed over 1000+ literature publications that were summarized in the submission.
- Our team also aided the client's biometrics team with programming and statistical input, creating ad-hoc tables and analyses as requested by the client's senior management. The client also requested label development and narrative writing support as the project progressed.

results

- Our team was able to complete the first part of the submission 1.5 weeks ahead of schedule.
- The second part of the submission was completed on time and accepted for review by the agency without issues.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

www.ProPharmaGroup.com
Info@ProPharmaGroup.com