WCG CLINSPHERE™ TOTAL FEASIBILITY

WCG Delivers 300+ Site Evaluations in Less Than 10 Days

Driving Faster Start-Up and Smarter Decisions for a Phase III MDD Trial

A mid-sized biopharmaceutical company specializing in investigating treatments for neurological, neuroendocrine, and neuropsychiatric disorders partnered with WCG on a Five Study Phase II Program in Major Depressive Disorder (MDD).

After reported success in the Phase II program, the client transitioned into Phase III with five protocols in the same indication across more than 20 countries. This presented obstacles and challenges in terms of site selection and ensuring the right sites were being selected for these protocols.

With WCG's ClinSphere™ Total Feasibility solution, the client was able to make informed decisions based on comprehensive site evaluations.

THE CHALLENGE

The biopharmaceutical company's Phase III MDD program involved five individual protocols in the same indication across multiple countries. One of these protocols was an open-label extension (OLE) study, and available sites were limited due to the large number of studies being conducted across the program. Furthermore, the client wanted to confirm the quality of the sites they were getting from their CRO list.

The client sought to understand current rater training and performance at a site, a critical factor contributing to the endpoints of their trials. This included the ability to conduct assessments accurately and interpret answers correctly to minimize issues and errors. This was a key interest for the client in their protocols.

WCG and the client had discussions around site evaluation and their keen interest regarding the rater information.

SOLUTION

As a result of this conversation, WCG completed a 10-site evaluation leveraging the Total Feasibility solution. WCG was able to provide insightful data to the biopharmaceutical company on which sites had trained raters on multiple scales. The client decided to move forward with a full evaluation of all of the pre-identified sites to do a thorough assessment for all sites being proposed on the Phase III program.

To equip the client to focus on and select the best-fit sites for their study and accelerate start-up, WCG evaluated and prioritized more than 300 sites in less than two weeks, providing expert insights, including:

36% of the investigators on the list did not have MDD trial experience in the last five years.

15% of the investigators had not had any clinical trial experience in the last five years.

13% of the investigators received an overall grade of "D" for their performance or lack of performance over the last five years.

WCG's proprietary investigator grading algorithm provides a directional perspective on investigator quality relative to peers within the indication with the validated variables of enrollment rates, experience, reselection rates, protocol deviation rates, and regulatory flags. In general, grades A/B are investigators who have above average performance in the positive variables and are without significant findings in the negative variables. Grades C/D are investigators with either insufficient evidence of good enrollment performance and experience, or those with significant findings in protocol deviation and regulatory flags.

Included in the client's evaluation were metrics and an overall score for one investigator that was provided by the sponsor that was found to be a grade "D" by WCG. Shortly after this information was provided to the client, this investigator was issued a warning letter from the FDA for significant violations.

This valuable information helped the client identify which sites to consider and which ones to avoid for their study.

"Please send our thanks to your team for providing this to us before the end of the week!!! We appreciate all the hard work and dedication the WCG team has put forth in this program."

—NBI Director, Clinical Operations

OUTCOME

After the success of the biopharmaceutical company's Phase II program, WCG's early involvement in Phase III prior to final site selection was crucial. WCG was able to use their existing library of scales and provided historical data on rater training to better inform site selection, saving time and meeting the needs of the client's Phase III program.

The WCG team's ability to deliver the robust site evaluation in less than 10 days was critical for the client's regulatory submission timeline, as they needed to submit their site list to the EU in under 30 days.

The client was very pleased with WCG's rapid and proficient efforts. The client appreciated the valuable insight provided for their study, which enabled informed decisions and delivered ahead of contract signature to meet tight time constraints.

CONCLUSION

WCG's Total Feasibility solution helped the mid-sized biopharmaceutical company validate the sites that were best fit for their study and reduce the risk of selecting lower performing sites that were not familiar with the multiple scales being utilized in the trials.

WCG strives to partner with clients to identify challenges and provide solutions customized to their needs to support study success.

Learn more about WCG ClinSphere™ Total Feasibility ›