Focused Solutions Lead to Accelerated Recruitment and Efficient Database Lock: Neuroscience Case Study

A multi-national pharmaceutical company needed to conduct a Phase II study for a new molecule for major depressive disorder. Midway through the study, the client deemed it a pivotal trial since the outcome would determine their long-term investment in the drug.

Understanding the Challenge

- Difficult recruitment and high screen failure rates due to strict protocol inclusion/ exclusion criteria
- Revised, compressed timelines from original target dates
- Expedited database lock

Meeting and Exceeding Expectations

Proactively working with the client, we created several custom solutions that maximized recruitment and accelerated database lock. First, using our proprietary clinical trial knowledgebase, Xcellerate®, our knowledge of the competitive environment and available sites, and our close collaboration with the client, we were able to increase the number of participating investigator sites from 45 to 79. In the United States alone, we doubled the number of investigator sites in less than nine months. In addition, the average start-up time for add-on sites was only seven weeks from feasibility/site selection.

To help increase recruitment and overcome barriers, we held motivational visits with targeted physician investigators. These face-to-face meetings included client scientists teaming up with Covance physicians, clinical research associates and project managers to realign budgets, discuss science and share ideas to improve overall performance. Next, we conducted intensive investigator training on MADRS assessment techniques that reduced both inter-rater assessment variability and screen failure rate. In addition, we conducted a global web and local advertising campaign to maximize study awareness and interest. Database mining and referral networks were also established to increase the accessible pool of patients. Finally, in Japan, we proactively worked with the regulatory authorities to translate the protocol, followed a reporting process that met regulatory requirements and demonstrated an appropriate level of communication for local study management. Monthly calls were instituted between Covance, our client and our client's local affiliate to ensure precision delivery.

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All these solutions supporting recruitment made the following results real:

- Fifty percent increase in enrollment in just three months
- Last Patient In was three months ahead of the original timeline and two weeks ahead of the compressed schedule

Once we hit our targeted enrollment, it was critical to drive database lock as efficiently as possible. We were relentless in our desire to clean and enter available data in all countries except Japan, whose data would be available six weeks later. Gantt charts were updated weekly that set expectations and corresponding achievements and detailed site activity to facilitate rapid query management and resolution of outstanding issues. In addition, we increased the frequency of vendor transfers and medical review of data to eliminate backlogs and to facilitate data cleaning. Finally, we held weekly team meetings to proactively update our client on progress, to strategize and to make timely resource adjustments. This relentless approach led to a reduction in aged queries as well as a reduction in the data query resolution turn-around time. In the end, by efficiently and effectively using the time between "rest of world" Last Patient Out and Japanese Last Patient Out, the Covance team achieved database lock in just over two weeks, a significant gain over the standard six weeks.

Learn more about our neuroscience drug development solutions at **www.covance.com/neuroscience**

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