



CASE STUDY

PRAHEALTHSCIENCES

PRA'S UNIQUE MODEL LEADS TO CLIENT SATISFACTION

Project Team Uses Innovation and Flexibility to Overcome Challenges





PRA'S TEAMWORK DEMONSTRATES VISION

Recruitment Strategies Pay Off in Epilepsy Trials

STUDY DESCRIPTION

A randomized, multi-center, double-blind study to compare the efficacy and safety of Study Drug A and Study Drug B as monotherapy in newly diagnosed partial epilepsy

PRIMARY ENDPOINT

Compare the efficacy and safety of Study Drug A and Study Drug B as monotherapy in newly diagnosed partial epilepsy

PRA SERVICES

Full Service

INDICATION

Epilepsy

DRUG CLASS

Chemical Entity

STUDY PHASE

III

BUSINESS SEGMENT

Product Registration

STUDY DURATION

67
MONTHS

NO. OF CLINICAL SITES

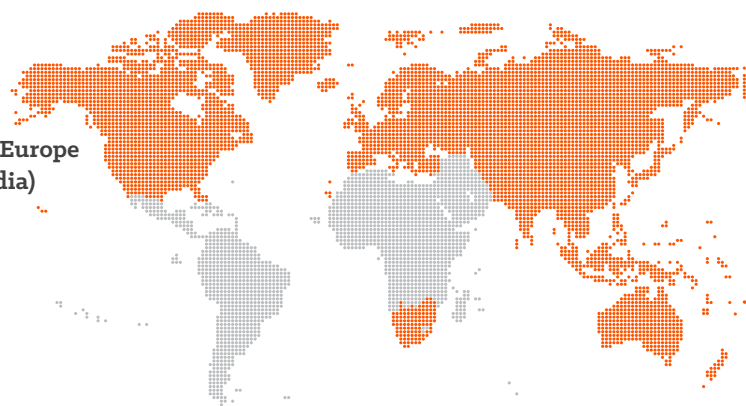
173

PATIENT POPULATION

582
epileptic patients;
150 in India

REGIONS

South Africa
Western Europe
Central and Eastern Europe
Asia Pacific (incl. India)



SITUATION

A large pharmaceutical client selected PRA to conduct 2 Phase III epilepsy studies in India, Eastern and Western Europe, and Australia. PRA's project teams surpassed recruitment goals and achieved timely site activations despite administrative delays and tough competition for volunteers.



CHALLENGES

PRA's project teams tackled numerous enrollment and site activation challenges. For example, the client requested 10 study sites with a recruitment goal of 100 patients in Mumbai, India — a city where CROs often have difficulty recruiting members of the population for clinical studies. In addition, Western Europe hosted a high concentration of epilepsy studies, which slowed subject recruitment, and it offered a scarce population of patients who had not been pre-treated (despite having experienced 2 seizures).

The major obstacle to achieving timely site activations was obtaining the client's insurance documentation required for certifications. Some countries (eg, Russia and Ukraine) have strict requirements about how the policies should be worded, which can delay study start-up times.



SOLUTIONS

PRA accomplished the highly successful enrollment thanks to our strategic alliances with Good Clinical Practice (GCP)-trained investigators throughout India. PRA has forged strong relationships with sites and investigators in both smaller and major metropolitan cities, such as Delhi, Chennai, Kolkata, Hyderabad, Bangalore, and Mumbai. Our ability to achieve record enrollment in India was due to our investigator networks throughout the country, first-hand knowledge of the region, and dedicated project teams.

To bolster enrollment in Western Europe, we recruited sites that specialized in treating patients recently diagnosed with epilepsy. In other cases, we used referral sites.

We relied on a few success factors to overcome the initial insurance certification delays and to meet site activation milestones. For example, the project managers ensured team members had manageable workloads, which was valuable in maintaining enthusiasm and avoiding team burnout. Another important team “asset” in the smooth transition was the stability of the core team. Since most staff members were assigned to both studies, they were able to ensure consistent support for sites and minimize the learning curve for the follow-up study.

While the original study’s recruitment timelines were shifted due to the various delays for approvals, the team kept the client apprised of changes and avoided communication lapses. Recruitment calls made to investigator sites were comprehensively documented to provide an in-depth understanding of the enrollment environment.



RESULTS

PRA’s Mumbai team enrolled 150 patients, far exceeding the protocol’s original target of 100 patients. Our teams also achieved on-time site activation for both studies. Several on-site audits conducted by the client and PRA resulted in no critical observations.

The following factors contributed to PRA’s enrollment and site activation successes:

- Solid networking with investigators throughout India and first-hand knowledge of the region
- Strategic planning to account for delays with insurance certifications
- “Load balancing” of the team’s workload to avoid burnout and maintain morale
- Focusing on patients recently diagnosed with epilepsy, as well as referral sites to bolster recruitment
- Resourcing stable, dedicated project teams

PRA Health Sciences conducts comprehensive Phase I-IV biopharmaceutical drug development.

To learn more about our solutions, please visit us at prahs.com
or email us at prahealthsciences@prahs.com.