APCER LIFE SCIENCES
Together for better health

CASE STUDY

# Bridging the gaps and inconsistencies within a clinical trial program through an expert overlay of medical monitors

**Therapeutic area**: Neurology

**Product type**: Drugs

**Geography**: US, EU, Australia

**Product life cycle stage**: Clinical trial phase 3

## About the Client

The client is an advanced clinical stage drug development company creating the next generation of therapeutics to treat neurodegenerative and other neuroinflammation related disorders.

## Business Challenge

- The pharma company was struggling with the advancement of its large global phase III trial. Eligibility confirmation of screened subjects and ongoing monitoring of randomized subjects were huge challenges for the sponsor.
- Protocol was not designed optimally, leading to subjectivity in patient screening and enrollment. Due to this issue, the sponsor was facing difficulties in resolving site queries for the selection of truly eligible patients.
- There were many data entry errors in different parameters in the eCRF, which took a huge toll on the conduct of the trials to be completed on schedule.

## Overview - Medical Monitoring

Medical monitoring is an essential component of the clinical research process. Medical monitors provide medical expertise and oversight for the entire clinical trial from initial study design through final study close-out. They ensure the clinical integrity of the trial subjects, provide safety accountability for the duration of the study, and provide expert points of reference for both investigative sites and study team members. They are responsible for trial oversight and any safety concerns that might arise from the trials. Medical monitors may be called to assess the inclusion and exclusion criteria of the trial and are also required to have oversight including protocol and site management, if required. They must assure that reported trial data are accurate, complete, and verifiable from the source documents such as electronic case report form (eCRF) and medical records. If not operated per the requirement, there exists a possibility of incurring fines and legal penalties from the regulators.

## Solution

APCER recommended a hybrid approach and deployed a team of experienced medical monitors from India and USA locations:

- The US resources were entrusted with providing coverage to the sites for any urgent medical issues and direct conversation at the sites.
- Indian resources provided support to take care of all other work, including eligibility confirmation, ongoing data monitoring, raising queries to clean the database, and oversight on deviations.
- The team also strongly recommended a protocol amendment to streamline the subject enrollment and assessment of onsite visits.

## Outcome

- APCER's strategy and solution accelerated the trial for recruitment and timely resolved site and clinical research associate (CRA) queries.
- The trial received no objections from the Drug Safety Management Board (DSMB) as recruitment and ongoing visits for the trial were under vigilance of medical monitors.
- Deploying resources from the US helped to resolve real-time site/CRA queries, while Indian resources delivered economic efficiency for work related to medical monitoring that could be completed remotely.
- The clinical trial moved at a faster pace while meeting expected quality standards.

## Our Pharmacovigilance Capabilities - Clinical Trials

- Expertise in **safety services** for global, multi-center clinical trials.
- Expertise in **early-phase dose derivation studies.**
- A dedicated global team of **qualified and experienced medical monitors** mainly physicians.
- Rich experience in **SRC and DSMB meetings** and governance.
- Expertise in **end-to-end medical data review** from eCRFs.

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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