CASE STUDY

Regulatory and recruitment expertise expedites clinical trial timelines for neurology clinical study

Client: Pharma
Therapeutic area: Neurology
Phase: III
Patients: 120
Geography: Europe
Duration: 7 years

Challenge:

When a pharmaceutical company completed a successful phase II study for the treatment of severe tardive dyskinesia, they were keen to progress into a phase III study.

The international study included 337 patients, of which the sponsor wanted 120 patients from European sites. The sponsor needed an experienced CRO with a strong European presence to complete the study successfully.

Solution:

MONIPOL reviewed the proposed protocol and worked with the sponsor to finalize several elements of the clinical trial. **Our company** advised the sponsor on the selection of sites and utilized a network of referral sites to meet targets – saving the sponsor up to one month of start-up time.

Working with the chosen sites in Poland, Hungary, Germany, Czech Republic, and Slovakia, **our company** project managed the trial and exceeded recruitment targets with 120 patients enrolled.
MONIPOL's services included:

- Developing comprehensive patient recruitment and retention.
- Strong site collaboration and motivation, including identifying obstacles specific to each site and developing possible solutions.
- Taking care of daily contact with sites and close relationships.

Result:

MONIPOL team managed the trial from start to finish, providing preparation of trial documents, site management, regulatory services, and contract management. Close cooperation between the sponsor and the sites allowed the study targets to be met and completed successfully on time and within budget. Armed with positive data and results from the trial, the sponsor was able to engage with the FDA and start another trial with **Us.**