AKEURA

Case Study

Neuroscience

Delivering Early Enrollment Against Aggressive Timelines in a Phase II Parkinson's Disease Study

A biotech sponsor initiated a Phase II study of inhaled apomorphine (AZ-009), an investigational, on-demand therapy designed to rapidly reverse OFF episodes in Parkinson's disease, which happen when symptoms return as medication wears off. The final protocol came with a hard target tied to broader program timelines: first patient consent within eight weeks. The clock started immediately.

The Study

CONTRIBUTION
Comprehensive, multi-functional delivery for a Phase II study

DESIGN
Multicenter, randomized, double-blind, placebo-controlled study

PATIENT POPULATION
Patients with established Parkinson's disease experiencing daily OFF episodes

GEOGRAPHY
United States

SCALE
~50 planned patients across ~20 sites

The Challenge

OFF episodes are unpredictable and self-reported, so this study depended on patients who could reliably recognize and communicate when an episode started. That's a smaller, more variable pool than in most chronic disease studies, and sites had to find those patients fast.

The hybrid design added another layer. Patients titrated in clinic, then dosed themselves at home, so they had to be trained, compliant, and confident managing treatment on their own. Keeping protocol adherence consistent across both settings took tight coordination between investigators, monitors, and patients. And because protocol revisions were still being finalized, start-up had to move forward before the eight-week clock even began.

The Approach

A focused, site-centric delivery model got sites active and patients identified fast, without cutting corners on patient readiness or protocol compliance.

Strategic Site Selection

We prioritized investigators with Parkinson's experience and pre-identified patients, then built strong CRA-site relationships that kept responses fast and collaboration close.

Accelerated Start-Up

Start-up began before the protocol was final, with site-specific kickoffs and streamlined activation keeping delays to a minimum.

Recruitment Enablement

Sites began identifying patients as soon as SIVs were scheduled, with early OFF-episode assessments flagging enrollment-ready candidates.

Coordinated Oversight

Close tracking against key milestones and consistent communication across sponsor, sites, and internal teams kept everyone aligned as timelines evolved.

The Impact

- **4 sites activated within 8 weeks of final protocol**
- **3 informed consents secured in the same 8-week window, exceeding the sponsor's first-consent goal**

> *They brought creative ideas to the project, were proactive throughout, and led by an experienced team... The result was not only meeting the corporate goal but securing three ICFs within the aggressive timeline.*

The Difference

Direct Access to Deep Expertise

Specialists who know Parkinson's endpoints, raters, and patients knew which investigators could find OFF-episode patients fast.

Relationships That Deliver

1,500+ specialist neuro sites already know our people. They pick up when we call, so four sites went live in eight weeks.

Tough Gets Us Going

With the protocol still in revision, we didn't wait. Quality held through every change, including early termination.

Looking to accelerate study start-up and early enrollment?

Contact us at info@akeura.com to discuss how we can support your next study.