



Parkinson's Disease Trial Training Needs

Situation: A Phase III Global Study Relies on Subjective Patient Self-Report

For their Phase III global study of Parkinson's Disease, the sponsor was concerned that both patients and investigators would not intuitively report symptoms consistently or accurately and would require proper instruction. As is the case in many Parkinson's Disease clinical trials, a patient diary was selected as the primary efficacy endpoint.

Challenge: Need for Consistent and Accurate Reporting

Parkinson's Disease is a troublesome condition that is difficult to treat. When evaluating new compounds, inconsistent reporting from both patients and clinicians can be impediments to the analysis of a drug's efficacy.

Solution: Patient and Investigator Education for Parkinson's Disease

UBC developed a two-pronged education video that addressed the needs of both the patient and clinician. The complimentary curriculum encompassed accurate identification and reporting of symptoms and a discussion of the effects of both drugs and placebo on Parkinson's patients.

The Patient and Caregiver Education video clearly described how patients should report the three main disease states – “off”, “on” and “on with dyskinesias” – which was supported by extensive examples of patients across various levels of severity and transitioning from one state to another. The goal of the education video was to ensure patients understood critical study terms and definitions so they might accurately complete the patient diaries. This video was used as a part of the patient education kit which study subjects could return to reference throughout the trial.

The Investigator Training Video expanded on the patient examples in the patient education video adding footage of patients being administered the Unified Parkinson's Disease Rating Scale (UPDRS). The goal of the investigator training video was to promote standardization across sites by promoting a consistent set of definitions and standardizing the administration and scoring of the UPDRS.

This curriculum, presented by Dr. Joseph Friedman, Clinical Professor of Neurology from Brown University, and Dr. Stephen Gollomp, Clinical Professor of Neurology at Thomas Jefferson University, would be highly beneficial in a variety of settings where an understanding of Parkinson's Disease is required including clinical research, patient care and patient outreach.

UBC At-a-Glance

- 1,000 employees
- 30% of employees hold advanced science degrees
- 10% hold PhDs
- > 90% client retention rates
- < 10% employee turnover
- 2,000+ peer-reviewed publications
- 365,000 patients
- 82,000 study sites
- 3,000 clinical protocols
- 20,000 investigators trained in 60 countries

Technologies

- Interactive voice response systems (IVRS)
- Interactive web response systems (IWRS)
- Dynamic randomization
- Electronic data capture (EDC)
- Electronic patient diaries
- Adaptive trial design and consulting
- Client portals
- Web-based learning management system
- Searchable databases: MetaHub, RaterHub, Site Database

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