CASE STUDY

Parkinson's disease: multiple ascending dose

An emerging biopharmaceutical company partnered with Fortrea to look at the safety and tolerability of multiple ascending doses (MAD) with an investigational medical product (IMP) on patients with mild to moderate Parkinson's disease (PD). Fortrea was chosen to support this MAD study because of its expertise in investigating the pharmacokinetics and pharmacodynamics of test articles and relationships with Phase I sites with PD expertise. This case study describes the challenges and successes of working with the sponsor to achieve study milestones.

Understanding the challenges

PD is a chronic neurodegenerative disease with no cure, no known cause and no clinically-available test for simple diagnosis. Therefore, to ensure only patients with mild to moderate PD were recruited for the study, it was critical for Fortrea to work diligently to coordinate patient recruitment.

Patients in the study had to be diagnosed with mild to moderate PD based on the unified Parkinson's disease rating scale (UPDRS) Part III 10-30. These PD patients were also required to be stable on a fixed dose of levodopa; PD patients taking other dopamine agents were excluded from the study.

In addition to the challenge of recruiting this specific group of PD patients, Fortrea needed to provide the data monitoring committee (DMC) with timely and accurate data. The DMC chose the timing and levels of dose escalation based on results from patient pharmacokinetics (PK) blood draws and safety data. This required Fortrea to take frequent PK draws and schedule inpatient hospital stays for the study participants.

KEY TAKEAWAYS

- Conducted a multiple ascending dose study on PD patients receiving an investigational drug
- Ensured tight adherence to inclusion criteria—PD patients had to be diagnosed mild to moderate using the UPDRS and stable on a fixed dose of levodopa
- PD patients were closely monitored throughout the study to determine dose escalation
- Collaborative communication helped meet sponsor's milestones and maintain patient safety

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Ensuring data quality and proactive communication

To increase the chances of success of this complex study, Fortrea and the sponsor worked together from the beginning to gain a full understanding of study protocol design. This early engagement helped create strong communication paths throughout the study, ensured that the appropriate patients were recruited and provided accurate data collection throughout the study.

To overcome the challenge of selecting the correct PD patients, Fortrea provided prescreening directives to reduce screening failures and keep PD patients with more severe forms of the disease from being admitted to the study. In addition to the prescreening directives, the team reviewed and verified the UPDRS assessments of each patient accepted to the study. Fortrea also helped the medical team and the site staff ensure that no PD patients taking prohibited medications were accepted to the study.

Successful study leading to further collaboration

From study start-up to the submission of the CSR, Fortrea and the sponsor maintained excellent communication to support successful execution of all study procedures and enable quality data delivery. Fortrea activated study sites and reached first patient in (FPI) on time. Over the course of one year, they recruited 50 patients to the MAD study, staying within budget and meeting the sponsor's milestones.

Fortrea closely managed the DMC to make timely decisions on dose escalation throughout the MAD study to ensure both patient safety and study success. As a result, the sponsor provided positive feedback to Fortrea and anticipates a continued collaboration to support the next milestones in the PD program.

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