

IXICO's Precision Neuroimaging in a Global Phase 1 Parkinson's Disease Clinical Trial

2025



Introduction

Parkinson's Disease (PD) is a progressive neurodegenerative disorder that affects millions worldwide. As the search for effective treatments intensifies, imaging biomarkers have emerged as critical tools for tracking disease progression and evaluating therapeutic efficacy. This case study highlights IXICO's role in managing a complex, multi-site clinical trial focused on advanced neuroimaging in PD. The study leveraged IXICO's expertise in imaging science, data management, and regulatory compliance to ensure high-quality, reproducible results.



Objectives

The primary objective of the study was to utilize advanced imaging modalities—specifically MRI and DaTScan—to assess biomarkers associated with Parkinson's Disease. These biomarkers were intended to support clinical endpoints related to disease progression, patient eligibility, and treatment safety.

Identify and validate imaging biomarkers that correlate with PD progression.

Deploy advanced imaging modalities to assess biomarkers associated with PD.

Ensure consistent and high-quality imaging data across multiple clinical sites.

Support regulatory submissions with robust, quantifiable imaging endpoints.

Facilitate centralized image analysis and reporting for clinical decision-making.

Maintain scientific and operational integrity throughout the study lifecycle.



Method of Execution

This long-term study spanned approximately 6 years. It involved over 250 participants across more than 220 clinical sites located throughout Europe and North America. IXICO's execution strategy was built on a foundation of rigorous planning, robust technology, and scientific leadership.

Project Setup Services

Study Setup:

A dedicated project team was formed to oversee the study from initiation to close-out. IXICO established a centralized document and record management system, created a project-specific risk register, and developed a comprehensive communication and escalation plan. A remote kick-off meeting aligned all stakeholders, clarified expectations, and laid the groundwork for smooth execution. This early-stage planning was essential to prevent delays, ensure compliance, and uphold scientific standards.

Site Management: We provided technical and operational support to sites, resolved data queries, and reported site performance. Ongoing management of sites by IXICO's Site Management Team included providing technical and operational support, resolving data queries, and reporting site performance. The team ensured that sites adhered to image acquisition procedures and maintained high-quality data collection. Direct communication was maintained with sites, and any issues were escalated as per the communication plan.

Data Management and Reporting



Data Handling

IXICO implemented a secure and scalable data management framework to handle imaging data from all sites. Each dataset underwent automated and manual quality control checks. Discrepancies were flagged and resolved using the IXIR™ platform, which enabled real-time communication and tracking. Data transfer agreements governed the secure exchange of data with sponsors and third parties, and all endpoint data was reviewed for integrity before release.



Data Transfer

We transferred image data and endpoint data to the sponsor or designated third parties in accordance with defined specifications and agreements. This included interim and final data transfers, ensuring that all data was securely and accurately transmitted. IXICO defined the specifications, format, and process for transferring image data in DICOM format to/from Sponsor/third party from/to IXICO.

Data transfer agreements (DTAs) were established to govern the secure and compliant exchange of data with sponsors and third parties. Interim and final data transfers were conducted according to these agreements, with all endpoint data reviewed for integrity and plausibility before release. A final study report summarized the imaging methods, endpoints, and results, providing a comprehensive overview without statistical interpretation.

Centralized radiology reads were conducted to evaluate subject eligibility and safety based on MRI and DaTScan images. Neuroradiologists underwent study-specific training and followed standardized workflows documented in Reader Manuals. Quantitative analysis and review of DaT-SPECT scan biomarkers were used to verify that the imaging data was of sufficient quality to be included in the study's statistical analysis, ensuring that the imaging data met the study's scientific and regulatory requirements.



Imaging Analysis Services

Centralized radiology reads were performed to assess subject eligibility and safety. Neuroradiologists received study-specific training and followed standardized workflows. DaTSPECT scans underwent quantitative analysis to support endpoint quality control. IXICO maintained a standard turnaround time (TAT) of 5 days for image reads, with an expedited option of 3 days for urgent cases.



Imaging Review

We prepared an imaging charter, conducted site qualification, and provided training. An imaging charter was prepared using IXICO's standard template, detailing imaging methods, timepoints, endpoints, and objectives. This charter ensured that imaging data contributed effectively to the study objectives. Site qualification and training were conducted to ensure consistency and quality in data collection. The charter described how the imaging data contributed to the study objectives, roles and responsibilities of key personnel, and methods for image analysis.



Radiology Reads

We performed central radiology reads for MRI and DaT scans, including eligibility and safety assessments. Central radiology reads were performed for MRI and DaT scans, assessing subject eligibility and safety. Neuroradiologists underwent study-specific training to ensure accurate and consistent reads. The Reader Manual described training requirements, read workflows, and reporting processes. Upon receipt of a complete imaging dataset of sufficient quality, IXICO returned reads within 5 working days.



Technology Services

IXICO Platform configuration

The IXI Platform was configured to manage data uploads, QC workflows, and endpoint analysis. It provided GCP- and 21 CFR Part 11-compliant data handling and included a Sponsor Medical Monitor Module for secure access and oversight. Training and access control ensured that all users could interact with the system effectively and securely.

Our platform to manage imaging data and workflows which was configured to meet study requirements, including data formats, imaging visit schedules, QC and analysis workflows, and user access privileges. The system provided end-to-end data management and storage compliant with regulatory standards. Configuration and validation of the system ensured that it met the specific needs of the trial. IXICO's platform provided GCP and 21 CFR Part 11 compliant end-to-end data management and storage of clinical imaging data.

It also included a Sponsor Medical Monitor Module, which allowed designated sponsor personnel to access and review imaging data securely. Training and access control were provided to ensure effective use of the system.

Scientific Study Leadership



Scientific Oversight

Scientific oversight was provided by IXICO's biomarker scientists and neuroimaging experts, supported by the wider Science Team. This leadership ensured that imaging protocols were scientifically robust and that advanced techniques—such as 3D pseudo-continuous arterial spin labeling (3DpCASL) perfusion imaging—were implemented effectively. 3DpCASL is a non-invasive MRI technique used to measure cerebral blood flow, offering valuable insights into brain perfusion without the need for contrast agents. Its application in the study enabled sensitive detection of functional changes in brain regions relevant to the disease under investigation. The team also offered ongoing consultancy and troubleshooting throughout the clinical trial, ensuring scientific integrity and regulatory compliance across all imaging endpoints.

This included training site staff, ensuring high-quality data collection, and providing scientific input on imaging methods and endpoints. The team ensured that the study adhered to scientific and regulatory standards. Scientific consultancy included enabling advanced imaging protocols and providing scientific study leadership and oversight for the duration of the project. The team also provided consultancy for advanced imaging setups, such as 3D pseudo-continuous arterial spin labelling (3DpCASL), ensuring that cutting-edge techniques were implemented effectively.



Results

The study successfully collected and analyzed high-quality imaging data across a large and diverse network of clinical sites. All imaging endpoints were met, and data were transferred to the sponsor in accordance with regulatory and contractual requirements. The final report summarized imaging methods, QC outcomes, and endpoint results, providing a strong foundation for future clinical and regulatory decisions.

Conclusion

This Parkinson's Disease imaging study demonstrates the power of combining scientific rigor with operational precision. IXICO's end-to-end management—from site setup to final reporting—enabled the successful execution of a complex, multi-national trial. With approximately 250 subjects, over 220 sites, and a 6-year duration, the study exemplifies IXICO's capability to deliver reliable, high-quality imaging data at scale.



Interested in partnering with IXICO for your next imaging study?

Visit www.ixico.com or contact us to learn how we can support your clinical development goals.

