Your Imaging Analysis & Operations Experts in Parkinson's Disease Clinical Research

IXICO

IXICO.com

Transforming clinical research in Parkinson's disease

At IXICO, we are committed to enhancing clinical research in Parkinson's disease (PD) through our advanced neuroimaging solutions. With over 20 years of expertise, we utilize cutting-edge technology and a strong scientific network to support the development of investigational therapies.

Our goal is to provide biopharma companies with the technical expertise and confidence needed to navigate the complexities of clinical trials.

IXICO's Parkinson's Disease Expertise

Advancing Precision in PD Imaging

IXICO specializes in PD imaging using advanced imaging biomarkers to quantify markers such as dopamine transporter (DaT) density and brain atrophy. Our AI-driven platform improves the accuracy and efficiency of volumetric measurements. We have supported thousands of brain scans collected through various PD research initiatives, promoting innovation and harmonizing imaging data for better clinical trial outcomes.

Comprehensive Global Imaging Solutions

We offer extensive imaging support with global site management, a regulatory-compliant platform and processes, and timely DaT SPECT eligibility read reports within three days. Our services include centralized radiology reads, PD-specific workflows, advanced analytics, and tailored solutions to meet diverse clinical trial needs, ensuring smooth data collection and analysis.

Reliable Expertise in PD Clinical Trials

IXICO collaborates with leading institutions and initiatives like C-Path CPP and tracer manufacturers such as GE Healthcare. Our expertise ensures high-quality deliverables and successful trial outcomes, making us a dependable partner in advancing PD research and clinical trials.

Collaborative Efforts in Advancing PD Biomarkers

At **IXICO**, we highly value our relationships with academia, industry, and charitable organizations. By working together, we aim to advance treatments for neurological diseases. We are proud to be part of leading scientific groups dedicated to the development of Parkinson's Disease (PD) biomarkers.

Stéphane Lehéricy

Stéphane Lehéricy is Professor of Neuroradiology and Director of the Centre de Neuro-Imagerie de Recherche (CENIR) at Pitié-Salpêtrière Hospital in Paris. His research focuses on imaging of brain structure and function in movement disorders and neurodegenerative diseases. He is a pioneer in neuromelanin-sensitive MRI, having demonstrated its use in visualizing substantia nigra degeneration in Parkinson's disease and advancing automated analysis techniques. As an advisor to IXICO, Prof. Lehéricy supports the translation of neuromelanin imaging into clinical trials, contributing expertise on both the scientific and operational aspects of its implementation.

CPP PARKINSON'S CONSORTIUM

Critical Path in Parkinson's Disease (CPP)

The Critical Path for Parkinson's (CPP) is a global public-private partnership initiated in 2015, involving industry, nonprofit organizations, academic partners, and advisors from the FDA, EMA, NIH, and people living with Parkinson's.

The goal is to accelerate the approval of therapies that improve the lives of people with Parkinson's. IXICO is a key contributor to the CPP Imaging Biomarkers group, which includes several upcoming publications on the use of imaging in Parkinson's disease.

Why Choose IXICO

Choosing IXICO means partnering with a leader in neuroimaging for Parkinson's Disease:

Expertise: Deep knowledge of PD biomarkers and imaging techniques, backed by a proven track record.

Innovation: : Deep knowledge of PD biomarkers and imaging techniques, backed by a proven track record.

Collaboration: Strong ties with academic and industry leaders, fostering a collaborative approach to tackling the challenges of PD research.

For more information on how IXICO can support your imaging analysis needs in clinical trials for Alzheimer's disease, please contact us at **www.ixico.com.**

Key Imaging Biomarkers

In PD research, key imaging biomarkers are essential for screening, eligibility, safety monitoring, and assessing drug efficacy. **Dopamine transporter (DaT) imaging**, particularly using **DaT SPECT**, assesses dopamine transporter density in the brain, aiding in **patient selection** and **trial eligibility.** In addition, our tracer-agnostic PET pipeline supports various tracers for **evaluating treatment efficacy.**

Advanced MRI techniques, such as Diffusion MRI and Free Water analysis, provide insights into white matter changes and neuroinflammation. Our operational excellence includes centralized radiology reads and efficient site management, ensuring high-quality data collection and analysis for successful clinical trials.

Visual & Quantitative Neuroimaging Endpoints in Parkinson's Disease (PD)

Molecular Imaging

SPECT/PET - Dopaminergic function

Importance:
Visualizing dopaminergic activity in the nigrostriatal pathway indicative of Parkinson's disease is a key measure for screening/eligibility

Image Analysis:
Visual read and longitudinal quantitative analysis in the striatum

PET Vesicular monoamine transporter 2 (VMAT2)

Importance:
Plays a key role in dopamine storage and release in nerve cells. Useful in early diagnosis and monitoring progression of PD and other neurodegenerative diseases.

Image Analysis:
Visual read and longitudinal quantitative analysis

PET Glucose FDG

Importance:
Measures glucose metabolism in the brain. Can reveal hypometabolism in specific brain regions.

Image Analysis:
Visual read and longitudinal quantitative analysis

Magnetic Resonance Imaging (MRI)

Structural MRI

Importance:
Assesses structural changes in the brain

Imaging Analysis:
Cross-sectional and longitudinal volumetric analysis to measure brain atrophy in key regions including the striatum and thalamus

Arterial Spin Labelling (ASL) MRI

Importance:
Measures tissue perfusion (cerebral blood flow (CBF)

Imaging Analysis:
Quantitative Regional CBF measurements.

Iron deposition sensitive MRI (SWI, QSM)

Importance:
Provides insights into iron deposition in key regions expanded SWI and QSM

Imaging Analysis:
Visual and quantitative methods to assess altered iron deposition

Diffusion MRI

Importance:
Evaluates white and grey matter tissue microstructural integrity and connectivity.

Imaging Analysis:
Diffusion Tensor Imaging (DTI) Analysis: Assesses microstructural integrity of grey and white matter tissue

Structural Connectivity: Measures loss of white matter pathways.

Neurite Orientation Dispersion and Density Imaging (NODDI): Multi-compartment model to provides detailed microstructural integrity.

Free Water Analysis: Quantifies changes in intra- and extra-cellular water.

Neuromelanin sensitive MRI (NM)

Importance:
Measures the neuromelanin content of neuromelanin containing neurons known to degenerate in Parkinson's disease

Imaging Analysis:
Cross sectional and longitudinal quantitative metrics (volumes and contrast to noise ratios) in key NM rich regions such as the Substantia Nigra

Functional MRI (fMRI)

Importance:
Measures altered functional connectivity patterns during resting state (rs-fMRI) and task-based (tb-fMRI) imaging.

Imaging Analysis:
Quantitative metrics in key ROIs including the Parkinson's disease related pattern (PDRP).

Centralised radiology reading services in Parkinson's Disease (PD)

Central Radiology Reads

Importance: Conducted by our expert neuroradiologists and nuclear medicine physicians, ensuring rigorous evaluation of imaging data.

Service: Includes centralized MRI eligibility and safety reads, DaT SPECT, and PET reads tailored to specific tracers.

Study-Specific Training

Importance: Ensures that all personnel are well-versed in the specific requirements and protocols of each study.

Service: Provides comprehensive training for study teams to maintain consistency and quality in imaging assessments.

Gene Therapy-Specific Workflows and Read Reports

Importance:ailored workflows and reports to meet the unique needs of gene therapy trials.

Service: Customized read paradigms and detailed reporting to support gene therapy research.

Robust Discordance Resolution Workflow:

Service: A well-defined process to address discrepancies between local and central reads, minimizing delays in trial enrolment

Tailored Radiological read solutions:

Service: Customizable read reports and reading paradigms to meet the specific needs of each clinical trial, such as single, dual, consensus or adjudication workflows.

Key Imaging Biomarkers in PD

Eligibility	SPECT/PET Visual Read MRI Visual Read
Stratification	Visual Read of MRI for differential diagnosis of Parkinsonian Syndromes
Efficacy	SPECT/PET/ MRI quantification
Safety Monitoring	Presence, number, and location of new or changed findings MRI Visual Read above

IXICO

Advanced Analytics and Technology

Our advanced analytics capabilities are designed to enhance trial outcomes:

AI-Driven Analysis: We employ sophisticated AI pipelines for quantifying imaging endpoints, ensuring rapid and accurate results.

TrialTracker™ Platform: A GCP and 21 CFR compliant infrastructure that centralizes imaging data, streamlining the workflow from image acquisition to reporting.

Quantitative Analysis: Provides accurate and consistent measurements for imaging biomarkers essential to PD research. This includes DaT SPECT striatal binding ratios (SBR), FDG and AV-133 PET standardized uptake value ratios (SUVRs), and MRI quantification, supporting the evaluation of longitudinal changes in key regions of interest.

Comprehensive Imaging Support

End-to-End Services: IXICO delivers complete clinical imaging support for neurological diseases, collaborating with specialty biotech firms, CROs, and top pharmaceutical companies.

Global Site Support: Our extensive network of sites across multiple countries ensures that we can efficiently manage and support clinical trials worldwide. We have the operational capacity to onboard and manage 100s of sites, facilitating seamless data collection and analysis across diverse geographies.

PD Tracer Management: Ensures the availability and appropriate use of radiotracers critical to PD research. This includes managing supply contracts for DaTSCAN and providing expert consultancy support for the use of other PET and SPECT tracers to support ongoing and future research initiatives.

Experience in Parkinsonian Disorders

IXICO brings deep expertise in neurodegenerative diseases beyond Huntington's, with a strong history supporting clinical research in Parkinsonian disorders.

Our imaging and analytics capabilities have been applied across multiple therapeutic indications, including:

Parkinson's Disease (PD)

Progressive Supranuclear Palsy (PSP)

Multiple System Atrophy (MSA)

We have supported clinical trials from Phase I through Phase III, providing end-to-end imaging services including protocol development, site qualification, data acquisition, and advanced analysis. Our work includes:

Early-phase biomarker exploration using advanced MRI and PET modalities.

Late-phase efficacy trials, supporting regulatory submissions with validated imaging endpoints.

Post-hoc data re-analysis, leveraging our AI-driven platform to extract new insights from legacy datasets.

Our operational infrastructure and scientific leadership enable us to deliver high-quality imaging data across global sites, ensuring consistency and reproducibility in complex imaging endpoints, multicenter studies.

IXICO

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