CASE STUDY · CENTRAL NERVOUS SYSTEM

Parkinson's Trial With DaT-SPECT Imaging

40 sites · DaT-SPECT, 3T MRI · Striatal binding ratios

Challenge

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. Quantitative striatal binding ratios derived from DaT-SPECT imaging served both as an enrollment screening tool and as a longitudinal biomarker in this Parkinson's disease trial. Yet differences in imaging systems and reconstruction practice across 40 sites introduced variability into the measurements used for both purposes. Without harmonization, apparent differences in binding ratios risked reflecting scanner characteristics rather than underlying biology, undermining screening accuracy and biomarker reliability alike.

Screening accuracy carried particular weight. Patients with insufficient dopaminergic deficit could be enrolled inappropriately, while eligible patients could be excluded if technical variability distorted binding ratios. Longitudinal assessment required equally careful control, since changes in reconstruction, camera performance or acquisition timing could create apparent biomarker change unrelated to disease progression or treatment effect. The sponsor required harmonized quantitative DaT-SPECT, timely screening assessment and sustained comparability across follow-up, with screening decisions resting on interpretable visual and quantitative findings rather than binding ratios considered in isolation, and every reported result retaining a documented relationship to its source images, reconstruction parameters and processing history. A quantitative binding ratio is interpretable only within its acquisition and reconstruction context. Harmonization reduces a technical alternative explanation for apparent differences, without making imaging biomarkers direct substitutes for clinical progression measures.

Intrinsic Imaging’s Solution

Intrinsic Imaging qualified every site through phantom imaging, characterizing each system's quantitative performance before subjects were scanned, and aligned reconstruction parameters across platforms to maximize comparability. Our team developed acquisition and reconstruction guidance for each imaging platform, reviewed every submission for adherence to protocol requirements and returned prompt feedback when technical issues could affect quantitative results.

Central review combined quantitative striatal binding ratio measurement with standardized visual interpretation, so that enrollment decisions and longitudinal assessments each drew on consistent, controlled methodology regardless of the acquiring site. Central readers were trained on standardized visual interpretation, while quantitative analysis followed a defined methodology for binding ratio measurement. Quantitative results were reviewed for plausibility before release, and discrepancies between visual interpretation and binding ratio measurements were investigated under a defined procedure, so that eligibility decisions rested on reliable imaging information rather than unexamined numerical outputs.

Our team monitored sites for equipment and software changes throughout the study, requiring requalification where needed to preserve comparability over time. Site qualification procedures, reconstruction guidance and analysis conventions were tested across a diverse network of imaging systems and documented so that the sponsor could carry consistent DaT-SPECT methodology into subsequent Parkinson's disease studies, supporting interpretation of biomarker findings across trial phases and imaging platforms.

Intrinsic Imaging’s Results

- 40 sites harmonized through phantom-based qualification and aligned reconstruction parameters, reducing cross-site signal variation in quantitative striatal binding ratios across imaging platforms
- Accurate imaging-based enrollment screening, with standardized visual interpretation and quantitative binding ratio measurements reconciled under a defined procedure before each eligibility decision was released
- Reliable longitudinal biomarker data, with site requalification after any camera, software or reconstruction change preserving measurement comparability across the full follow-up period
- Qualification, reconstruction and analysis conventions documented for reuse, allowing consistent DaT-SPECT methodology to extend across the sponsor's later-phase Parkinson's disease program and imaging platforms

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Read the full study online: https://intrinsicimaging.com/case-studies/cns-parkinsons

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging’s team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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