

## Parkinson’s Disease Version 2.0 NINDS CDE Project Imaging Subgroup Summary

Imaging data is widely used in Parkinson’s disease (PD) clinical research studies both to understand normal brain function and to detect and monitor brain disease in living patients. Imaging tools are increasingly utilized to inform disease diagnosis, longitudinally monitor disease progression, and identify disease pathology prior to clinical symptoms in ‘at risk groups.’ The Imaging Subgroup focused on developing CDEs for those PET, SPECT, and MR imaging and spectroscopy tools with sufficient data to support their use in clinical studies. Our goal is to provide the data to enable investigators to assess the methods of acquisition of the imaging data for each imaging tool and modality. This strategy will allow investigators to utilize these CDEs to customize their analyses based on their expertise, the study question, and the study cohort.

The Imaging Subgroup reviewed and updated two CRFs, Magnetic Resonance Imaging and Spectroscopy and PET-SPECT Localization, and a guidance document, Imaging Guidance for CDE Use. The v1.0 recommendations included an additional separate MR CRF however, all the elements overlapped with the version that included spectroscopy. In v1.0 the parameters did not accurately capture the information that needed to be acquired for the type of imaging. Subgroup members were assigned portions of the two CRFs to review and divided each CRF by imaging parameters, sequences, and specific tracers.

The subgroup updated the guidance document to focus on data collection for more exploratory imaging methods, information that cuts across modalities, data acquisition methods, targets, quality assurance, analysis/processing, and diagnostic information. This document also expands on the information on MRI and Spectroscopy and PET-SPECT Localization CRFs.

Imaging tools are generally applicable to most people, but they may be more relevant to some groups than others. For example, evaluation of amyloid imaging is more relevant to those with cognitive impairment. The Imaging Subgroup did not focus on recommendations specific to subpopulations within PD. Imaging in PD is essential at all stages of disease and can be used to target disease subsets defined by disease pathology, molecular biomarkers, and clinical symptoms. Imaging tools can also be used to identify people who are at a higher risk for PD.

### Summary of Recommendations

CRF/Guidance Document Name	Subdomain	Classification
Magnetic Resonance Imaging and Spectroscopy	Imaging Diagnostics	Supplemental – Highly Recommended
PET-SPECT Localization	Imaging Diagnostics	Supplemental – Highly Recommended; Supplemental
Imaging Guidance for CDE Use	Imaging Diagnostics	N/A

Certain imaging modalities may be more dependent on the medication state of the participant than others.

The subgroup recommendations do not address multi-center studies and compatibility issues across sites if different cameras/methods are used. Optical imaging and other new and more exploratory MRI methods were not included in detail and could be added in the future.