

PPMI NX PI-2620 Tau Imaging Substudy

Inclusion/Exclusion Criteria

All inclusion criteria must be marked “Yes” and all exclusion criteria must be marked “No” before proceeding to enrollment.

Note: For inclusion criteria, the participant must meet general inclusion criteria and the criteria for their specific disease group only (Healthy Control or PD).

A. Assessment Date: ____ / ____ / ____ (mm/dd/yyyy)

Inclusion Criteria:

General inclusion criteria include the following:

1. Ability to comply with the study procedures and attend follow-up visits.
☐ Yes ☐ No
2. Written informed consent from the participant or legal guardian.
☐ Yes ☐ No
3. Male or Female between 45 years and 85 years of age (Females must meet additional criteria specified below, as applicable)
 - a) Females must be of non-childbearing potential or using a highly effective method of birth control 14 days prior to until at least 24 hours after injection of [18F]PI-2620 or DaTscan.
 - i. Non-childbearing potential is defined as a female that must be either postmenopausal (no menses for at least 12 months prior to PET scan) or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy).
 - ii. Highly effective method of birth control is defined as practicing at least one of the following: A birth control method that results in a less than 1% per year failure rate when used consistently and correctly, such as oral contraceptives for at least 3 months prior to injection, an intrauterine device (IUD) for at least 2 months prior to injection, or barrier methods, e.g., diaphragm or combination condom and spermicide. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) is not acceptable.
 - b) Females of childbearing potential must not be pregnant, breastfeeding or lactating, or planning pregnancy during the duration of the study.
 - c) Non PPMI participant females of childbearing potential must have a negative serum pregnancy test at Screening and all females of childbearing potential must have negative urine pregnancy test prior to [18F]PI-2620 injection on day of Baseline PET scan.
 - d) Non PPMI participant females of childbearing potential must have a negative urine pregnancy test prior to Screening Visit DaTscan injection.
☐ Yes ☐ No

Healthy Controls only:

4. Enrolled in the PPMI study as a healthy subject.

☐ Yes ☐ No

Parkinson's disease only:

5. Enrolled in the PPMI study as a sporadic PD or LRRK2 PD participant.

☐ Yes ☐ No

6. Known CSF alpha synuclein seeding amplification assay status.

☐ Yes ☐ No

7. Known Plasma phosphorylated Tau217 status.

☐ Yes ☐ No

Exclusion Criteria:

1. Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.

☐ No ☐ Yes

2. For those receiving Screening DaTscan:

- Received any of the following medications that could interfere with the imaging and unwilling or medically unable to hold them for five half-lives before SPECT imaging: alpha methyl dopa, methylphenidate, amphetamine derivatives or modafinil, bupropion, phentermine, phencyclidine, fentanyl, or medication commonly considered to interfere with loflupane binding per standard clinical practice.

☐ No ☐ Yes

3. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine, within 6 months of Screening Visit for non-PPMI participants or within 6 months of Baseline Visit for PPMI participants.

☐ No ☐ Yes

4. Any structural abnormality or finding on previously obtained or screening brain MRI suggestive of clinically significant neurological disorders other than the diseases of interest (in the opinion of the investigator).

☐ No ☐ Yes

5. Any other reason that in the opinion of the investigator, including abnormal labs, that could interfere with the safety with radiotracer injection, would render the participant unsuitable for the study enrollment.

☐ No ☐ Yes