PROTOCOL

Title:	Evaluation of [^{18}F]MNI1008 Imaging across Synucleinopathies Using a High-Resolution Positron Emission Tomography Camera (PPMI MNI1008 PET Imaging)
Sponsor:	The Michael J. Fox Foundation for Parkinson's Research
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PPMI MNI1008 PET Imaging

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1. PURPOSE OF STUDY

The purpose of this single-tracer, Phase 1 clinical study is to evaluate the in-vivo imaging characteristics, safety, and tolerability of the [^{18}F]MNI1008 PET tracer in participants with Parkinson's disease (PD) multiple system atrophy (MSA) and in healthy controls (HC) using a high-resolution Positron Emission Tomography (PET) camera.

[^{18}F]MNI1008 is an investigational PET tracer designed to bind to aggregated α-synuclein (α-syn), a hallmark of PD and related synucleinopathies. The high-resolution PET camera may be particularly valuable in evaluating α-syn PET tracers as it enables signal detection in small regions like the substantia nigra and locus coeruleus affected by α-syn pathology.

This study aims to determine whether [^{18}F]MNI1008 tracer demonstrates favorable brain uptake, distribution, and specific binding in brain regions affected by α-syn pathology in individuals with PD or MSA when compared with healthy controls.

The study will enroll participants in the PD/Prodromal PD and HC cohorts from the Parkinson Progression Marker Initiative (PPMI), a longitudinal study designed to identify biomarkers of disease, to leverage its rich clinical and biological data (Marek et al., 2018; Simuni et al., 2018). (ClinicalTrials.gov Identifier: NCT04477785). The MSA participants will be enrolled from the general population.

Findings from this proof- of-concept study will inform future dosimetry, test-retest and larger multicenter studies if results are promising.

1.1 Primary Objectives

- To characterize brain uptake and signal characteristics of [^{18}F]MNI1008 tracer in Parkinson's disease (PD)/Prodromal PD, multiple system atrophy (MSA) and healthy control (HC) participants.

1.2 Secondary Objectives

Secondary Objectives include:

- To evaluate the safety, tolerability, and feasibility of administering a single intravenous dose of [^{18}F]MNI1008 tracer in PD/Prodromal PD, MSA, and HC participants.
- To determine regional brain uptake and binding patterns associated with α-synuclein pathology.
- To explore potential associations between tracer uptake and clinical measures of disease severity (e.g., MDS-UPDRS, UMSARS, MoCA).
- To explore potential associations between tracer uptake and biological measures of disease

2. STUDY OUTCOMES

2.1 Primary Outcomes

- To compare the imaging outcome measures [Volume of distribution (V_T), Binding potential non-displaceable (BP_{ND}), Standard Uptake Value Ratios (SUVR)] in brain regions from [^{18}F] MNI1008 between PD/Prodromal PD and HC, and MSA and HC participants.

2.2 Secondary Outcomes

- To assess the number and severity of tracer-emergent adverse events following administration of [^{18}F]MNI1008 tracer in human participants.
- To evaluate the regional distribution of [^{18}F]MNI1008 uptake, expressed as SUVR in brain regions typically affected by α-synuclein pathology in PD/Prodromal PD and MSA compared to HC.
- To explore association between [^{18}F]MNI1008 binding and clinical measures of disease severity including motor and cognitive rating scales (e.g., MDS-UPDRS, MoCA, UMSARS).
- To explore associations between [^{18}F]MNI1008 binding measures and biological markers of disease (e.g., CSF α-synuclein seed amplification assay [SAA]), where available.

3. BACKGROUND AND RATIONALE

Misfolded alpha-synuclein (α-syn) aggregates are considered the major pathological hallmark for synucleinopathies such as Parkinson's disease (PD), and multiple system atrophy (MSA) and therefore serves as a potential molecular target (Galvin et al., 2001; Dickson, 1999). The current landscape of α-syn diagnostic tools is limited to biological samples such as cerebrospinal fluid or skin (Gibbons et al., 2024; Kannarkat et al., 2025; Parnetti et al., 2025). Although CSF and other peripheral biomarker tests may allow for α-syn detection, they do not provide information about the regional localization or spatial progression of brain pathology.

Molecular imaging biomarkers have the potential to play a key diagnostic and therapeutic monitoring role in PD and other synucleinopathies. Quantifying α-synuclein deposits *in vivo* – which is not yet possible - offers the potential to understand the pathophysiologic mechanisms contributing to PD, identify synucleinopathies earlier in their course and monitor disease progression, providing a means to measure efficacy of disease-modifying treatments. Therefore, a radiolabeled PET ligand targeting α-synuclein would be a critical tool (Xiang et al., 2025).

The [^{18}F]MNI1008 PET tracer (also known as [^{18}F]RO7196581) is an investigational fluorine-18–labeled radioligand designed to selectively bind aggregated α-synuclein. Preclinical studies have demonstrated high affinity for aggregated α-synuclein, favorable brain penetration, and low off-target binding to amyloid-β and tau species, supporting advancement of [^{18}F]MNI1008 to early human evaluation. Limited proof of concept clinical studies utilizing a standard PET camera have shown equivocal results in PD and HC.

XingImaging, LLC (XI) in New Haven, CT has acquired a state-of-the-art high resolution PET camera called NeuroEXPLORER (NX) manufactured by United Imaging (Li et al., 2024). The NX camera offers substantial technical advancements in the form of high resolution and sensitivity along with automated motion detection. The NX camera permits the visualization of radiotracer binding in smaller nuclei, such as the substantia nigra (Carson et al., 2023; Li et al., 2024; Omidvari et al., 2025). This advancement has the potential to be pivotal in identifying the radiotracers targeting α-synuclein.

This proof-of-concept study will evaluate whether [^{18}F]MNI1008 demonstrates sufficient brain uptake, target engagement, and regional contrast utilizing the high-resolution PET camera to warrant further clinical development.

4. STUDY DESIGN

This is a single-center, open-label clinical study designed to evaluate the imaging characteristics and safety of [^{18}F]MNI1008 in participants with PD/Prodromal PD, MSA, and HC.

Up to 15 participants may be enrolled in this study. Approximately, nine participants (approximately 3 PD , 3 MSA, and 3 HC) will be enrolled at first. Based on interim analysis, up to six additional PD (sporadic/genetic/prodromal PD) may be enrolled.

Each participant will receive a single intravenous injection of [^{18}F]MNI1008, followed by PET imaging using the United Imaging NeuroEXPLORER (NX) camera. Image acquisition may extend up to approximately 3- hours post-injection. The NeuroEXPLORER (NX) PET scanner is considered a non-significant risk investigational device. It is a non-invasive imaging system, not an implant, and is not used to diagnose or treat medical conditions.

Arterial and/or venous blood sampling may be performed during imaging to support radiometabolite correction and kinetic modeling, as specified in the Image Acquisition Plan (IAP).

Imaging data will be evaluated to characterize tracer regional uptake and image quality. Safety and tolerability will be assessed throughout participation, including vital signs and adverse event monitoring. As this is an exploratory proof-of-concept study, analyses are primarily descriptive and hypothesis-generating rather than powered for formal hypothesis testing.

The study and all imaging will be conducted at the Institute for Neurodegenerative Disorders (INDD) and XingImaging, LLC in New Haven, CT. The study will enroll PD and HC participants from the ongoing Parkinson's Progression Markers Initiative (PPMI) study. Prodromal PD group with REM sleep behavior disorder and/or hyposmia and genetic PD may also be included into the PD arm of this study. While the MSA (non-PPMI) participants will be enrolled from the general population.

Participants will be comprehensively assessed at Baseline and follow up, if applicable, according to the Schedule of Activities (SOA). Participants will undergo imaging assessments with [^{18}F]MNI1008 and clinical assessments (conducted under the PPMI 002 Clinical study for PPMI participants and per the SOA for non-PPMI participants). Clinical and biological biomarker data already collected under the PPMI parent study may be leveraged for the PD and HC cohorts to minimize participant burden and support analysis of imaging outcomes in relation to clinical measures. Clinical and biological biomarkers will be collected for the MSA cohort according to the schedule of activities (SOA) and will at least include cerebrospinal fluid (CSF) SAA, and amyloid peptides. Plasma biomarkers will include biomarkers such as pTau217 and Neurofilament Light Chain. Data will be collected under uniformly established protocols. Data will be stored and analyzed at designated core facilities.

5. STUDY POPULATION

Approximately 15 participants may be enrolled in this study. The initial target enrollment is approximately 3 PD, 3 HC participants, and 3 MSA participants. An additional of up to 6 PD (sporadic, genetic and/or Prodromal PD) may be included. Prodromal participants with REM sleep behavior disorder and/or hyposmia from the Prodromal PD cohort of PPMI may be included in this study.

The sample size is based on feasibility considerations and is consistent with early-phase exploratory imaging studies intended to evaluate tracer signal characteristics and safety prior to larger confirmatory investigations.

PD/Prodromal PD and HC participants will be enrolled from the ongoing PPMI 002 Clinical study. Leveraging the existing PPMI cohort allows the use of previously collected clinical and biomarker data, thereby minimizing participant burden and ensuring alignment with established study assessments.

The MSA cohort will be enrolled from the general population. Diagnosis of MSA will be confirmed by a movement disorders specialist at the study site according to established Movement Disorder Society diagnostic criteria.

6. RECRUITMENT METHODS

PPMI 002 Clinical study participants who meet preliminary eligibility criteria may be approached during routine PPMI study visits or contacted by study staff via email or phone to assess interest in participation. Interested participants will be provided with detailed information regarding this study and invited to participate voluntarily.

For non-PPMI participants (MSA cohort), IRB-approved recruitment materials, including advertisements and informational flyers, will be used to share information about the study with the public and healthcare community. Recruitment efforts may include digital outreach, local recruitment databases, healthcare referral networks, patient support organizations, and community engagement activities.

All recruitment materials and outreach methods will receive prior IRB approval before implementation.

7. PARTICIPANT ELIGIBILITY

7.1 Inclusion Criteria (all cohorts):

General inclusion criteria include the following:

a) Able and willing to provide informed consent.
b) Ability and willingness to comply with all study procedures and requirements.
c) Demonstrate adequate circulation to both hands as evidenced by Allen's test or Barbeau test (for safe placement of radial arterial lines).
d) Male or Female (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 [^{18}F]MNI1008.
    i. Non-childbearing potential is defined as a female who 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.

Healthy Controls inclusion criteria:

a) Enrolled in the PPMI 002 Clinical study as a healthy control participant
b) Any gender aged 50 to 75 years of age
c) Negative CSF α-synuclein seed amplification assay (α-syn SAA)
d) Movement Disorders Society- Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score of <6 at the last PPMI 002 annual visit
e) Cognitively intact with Montreal Cognitive Assessment (MoCA) ≥26 at the last PPMI 002 annual visit

Parkinson's Disease and Prodromal PD inclusion criteria:

a) Enrolled in the PPMI 002 Clinical study as a Parkinson's disease (PD) participant or a Prodromal PD participant
b) Any gender aged 50 to 80 years of age
c) Positive CSF α-syn SAA
d) Montreal Cognitive Assessment (MoCA) ≥24 at the last PPMI 002 annual visit

Multiple System Atrophy (MSA) inclusion criteria:

a) Any gender aged 50 to 75 years of age
b) Clinically established MSA or Clinically Probable MSA according to the Movement Disorder Society Criteria for the Diagnosis of Multiple System Atrophy (Wenning et al., 2022)
c) Positive CSF α-syn SAA
d) An abnormal DATscan (previously acquired since onset of motor symptoms or at screening) except for suspected MSA-Cerebellar type

7.2 Exclusion Criteria (all cohorts):

a) Clinical evidence of other non-synucleinopathy neurodegenerative diseases, such as Alzheimer's disease
b) Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.
c) Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine, within 6 months of Baseline Visit.
d) Any structural abnormality or finding on MRI Brain previously acquired since onset of motor symptoms or obtained at screening, suggestive of clinically significant neurological disorders other than the diseases of interest (in the opinion of the investigator).
e) Currently being treated with and unable to hold antiplatelets (other than low dose aspirin up to 100mg/day) or anticoagulants that might preclude safe attempt of a lumbar puncture, if applicable.
f) Condition that precludes the safe performance of routine lumbar puncture, if applicable, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant and uncorrected coagulopathy or thrombocytopenia.
g) 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.
h) Conditions or medications that preclude safe performance of imaging procedures (e.g., MRI or DaTscan), including severe claustrophobia, MRI-incompatible metal implants, or hypersensitivity to imaging agents.
i) Known hypersensitivity to DaTscan or iodine-containing compounds. Participants with iodine sensitivity may be evaluated to proceed with imaging without iodine premedication at the investigator's discretion.
j) Use of medications known to interfere with DaTscan imaging (e.g., bupropion, amphetamines, methylphenidate, modafinil, alpha-methyldopa), unless the participant is willing and medically able to discontinue the medication for at least 5 half-lives or for specified duration per investigator's judgement prior to imaging.Contraindications to arterial line placement, including but not limited to a history of bleeding disorders, recent significant blood donation, or inability to safely hold anticoagulant or antiplatelet medications, as determined by the investigator.

8. OBTAINING INFORMED CONSENT

As part of the consenting process, each potential participant will be explained the procedures and requirements of the study, together with any potential hazards/risks, and the freedom to withdraw from participation in the study at any time. The consent process will take place in a space that allows for privacy and confidentiality and should allow for enough time for the individual to consider participation and ask any questions. Consent will be obtained by the study Investigator or delegated study staff, as applicable. Each participant will sign such an informed consent to document agreement to participate in the study, as well as to document HIPAA authorization. The signed informed consent will be uploaded to a secure portal for remote monitoring, if possible.

It is the responsibility of the Investigator (or as delegated to the person obtaining consent) to make sure that the participant understands what she/he is agreeing to, and that written informed consent is obtained before the participant is involved in any protocol-defined procedures. Each participant will be provided with a copy of the consent form.

9. PARTICIPANT ID ASSIGNMENT

All PPMI participants will use their assigned PPMI 002 study ID. The PPMI Participant ID number will be used to identify a participant on all study-related documentation (e.g., clinical database, imaging data). Non-PPMI participants will be assigned a study ID using internal protocol, which will be used to identify the participant across all study documents, including clinical and imaging data.

10. STUDY PROCEDURES

The study visits may occur over a period of more than one day due to the complexity of visits and resources required at the site. The date each assessment is completed will be documented in source records and the EDC, allowing visit windows to be confirmed regardless of whether procedures span multiple days.

10.1 Screening Visit (Non-PPMI participants Only):

Refer to the Schedule of Activities (see Appendix) for the activities to be conducted at the Screening visit.

After providing informed consent for the [^{18}F]MNI1008 PET imaging study, non-PPMI participants will complete the clinical assessments and screening procedures outlined in the SOA. Due to the complexity of these procedures, Screening may occur over multiple days. Out of window visits can be accommodated for reasonable reasons and will not be considered as protocol deviations.

The Screening period may extend up to 8 weeks prior to the Baseline visit. Out-of-window Screening assessments may be permitted for reasonable scheduling or participant-burden considerations and will be documented in source but not considered protocol deviations.

10.2 Baseline Visit

Refer to the Schedule of Activities (see Appendix) for the activities to be conducted at the Baseline visit.

<u>PPMI (PD & HC) Participants</u>

Refer to the Schedule of Activities (see Appendix) for the activities to be conducted at the Baseline visit.

Eligible participants consented for the PPMI 002 Clinical study interested in completing additional scans under this study will be asked to complete the [^{18}F]MNI1008 PET imaging consent and complete any additional assessments as part of the study.

Once the Investigator determines that all eligibility criteria have been met, the participant may be considered enrolled in the [^{18}F]MNI1008 PET study. The study activities are anticipated to take

about 3-5 hours. The [^{18}F]MNI1008 PET imaging visit may be combined with the PPMI 002 Clinical visit when feasible. If not combined, the [^{18}F]MNI1008 PET visit may occur within ±45 days of the most recent PPMI 002 Clinical study annual visit. An out-of-window visit will be noted in the source document but will not be considered as a protocol deviation.

Non-PPMI (MSA) participants

Once all Screening activities for this protocol have been completed and the Investigator determines that all eligibility criteria have been met, the participant may be considered enrolled in the [^{18}F]MNI1008 PET study. Participants will complete the clinical protocol activities as outlined in the schedule of activities for the Baseline visit. Given the complexity of the procedures, the visit could occur over more than one day. The study activities are anticipated to take 6-8 hours.

10.3 Withdrawal from the Study

If a participant withdraws from the study, the study team will complete the Conclusion of Participation case report form (CRF) under the last completed visit, with the withdrawal reason.

11. CLINICAL ASSESSMENTS

PPMI (PD & HC) Participants

For PPMI participants, all applicable clinical assessments required for study participation are performed under the PPMI 002 Clinical study and will not be duplicated for this study. These PPMI 002 clinical study assessments (e.g., motor, cognitive, and other standardized clinical measures) will be used to support clinical characterization and exploratory analyses in the [^{18}F]MNI1008 PET study.

Non-PPMI (MSA) Participants

For non-PPMI participants, all clinical assessments outlined in the SOA will be completed as part of this protocol. Information collected from these assessments will be combined with the imaging data and any additional information collected for this study.

For non-PPMI participants, cerebrospinal fluid (CSF) testing will be performed as part of the lumbar puncture (LP) procedure. Routine CSF laboratory analyses will be processed at the local laboratory and will include CSF protein, glucose, and cell count with differential. CSF send-out analyses will include a tau profile, amyloid peptides, and a-synuclein seed amplification assay.

12. SAFETY ASSESSMENTS

Screening Safety Assessments

PPMI (PD & HC) Participants

For PPMI participants, all routine clinical safety laboratory tests required for study participation are conducted under the PPMI 002 Clinical study and will not be duplicated for this study.

Non-PPMI (MSA) Participants

For non-PPMI participants, all screening safety assessments will be completed at the Screening visit according to the SOA. The screening safety assessments will include complete blood count (CBC), comprehensive metabolic panel (CMP), urinalysis, coagulation labs, serum or urine pregnancy test for females of childbearing potential.

Study-Specific Imaging Day Safety Assessments (Applies to All Participants)
On the day of [^{18}F]MNI1008 tracer administration, all participants (PPMI and non-PPMI) will undergo study-specific pre- and post-imaging safety assessments as outlined in the SOA and Image Acquisition Plan (IAP).

Study-specific safety assessments on the imaging day will include the following:

Vital Sign Assessments
- Pre-injection vital signs [completed within 5-60 minutes prior to injection]
- Post-injection vital signs [completed 30 min +/-5 min post injection]
- Post-imaging vital signs [completed within 30 min after completion of imaging scan]

Electrocardiogram (ECG)
A 12-lead ECG will be performed pre and post injection as outlined in the SOA at pre-defined time point;
- Pre-injection ECG will be completed 5-60 minutes prior to injection.
- Post-injection ECG will be completed within 30 minutes after completion of imaging scan.

Safety Laboratory Testing
Following safety laboratory testing will be completed pre and post injection as outlined in the SOA
- Complete Blood Count (CBC)
- Comprehensive Metabolic Panel (CMP)
- Urinalysis

Pre-injection safety labs can be drawn any time on the day of the imaging prior to injection.
Post-injection safety labs will be drawn within 30 minutes after completion of imaging scan.

For women of childbearing potential, a urine pregnancy test must be performed on the day of [^{18}F]MNI1008 injection and confirmed negative prior to administration of the tracer.

Radiometabolite Sampling (For analysis and imaging data interpretation)
Blood samples for radiometabolite analysis may be collected at specified timepoints before, during and/or after PET acquisition to allow for radiometabolite correction/kinetic modeling to inform the imaging data. This will be completed in accordance with the Image Acquisition Plan (IAP). The blood samples will either be collected via an arterial line or a venous line to inform the imaging data.

An arterial catheter will be inserted in the radial artery by a trained physician and arterial sampling will be collected where possible for scheduled PET scan. A local anesthetic (lidocaine 1% or 2%) can be used to reduce discomfort associated with insertion of the catheter. If arterial sampling cannot be completed for any reason per investigator, an intravenous line may be used for metabolite sampling where applicable.

Up to 100ml of blood may be collected for radiometabolite sampling.

Total Blood Volume
Combined blood draws for safety labs and radiometabolite sampling will total approximately **120 -140 mL** per participant per tracer administration.

13. [^{18}F]MNI1008 PET IMAGING

The radiotracer, [^{18}F]MNI1008, will be produced and distributed by XingImaging. Each participant will receive a single intravenous (IV) dose of ≤8 mCi [^{18}F]MNI1008, administered prior to PET imaging.

All participants will undergo [^{18}F]MNI1008 PET imaging using the NeuroEXPLORER (NX) camera. The NX PET scanner is a non-invasive investigational imaging device and does not present a significant risk to participants.

Because [^{18}F]MNI1008 imaging is investigational, imaging results will not be used for diagnostic or clinical decision-making. Participants will be monitored for adverse events during the imaging visit. A safety follow-up will be conducted by phone (or in person) 2–3 business days after injection to assess adverse events. All adverse events will be documented in the EDC and reported to the IRB, Radiation Safety Committee, FDA, and Sponsor as applicable.

The imaging procedures are summarized below and fully detailed in the IAP.

13.1 [^{18}F]MNI1008 Imaging Procedures

- All women of childbearing potential must have a urine pregnancy test prior to injection of [^{18}F]MNI1008. The result must be confirmed as negative prior to proceeding with the injection. Pregnant and lactating individuals are excluded from the study.
- An IV catheter line for radiotracer administration and an arterial or 2nd IV line for kinetic modeling/metabolite sampling will be inserted in accordance with IAP.
- Participants will receive a single IV administration of ≤8mCi of [^{18}F]MNI1008.
- Participants will undergo PET image acquisition using the NX camera for up to 3 hours following [^{18}F]MNI1008 injection, in accordance with the Image Acquisition Plan (IAP).
- Study-specific safety assessments (CBC, CMP, urinalysis, and ECG) will be completed before and after tracer administration upon completion of the imaging for all participants. Pre- and post-injection safety evaluations will be completed as outlined in the SOA.
- Blood samples for kinetic modeling/radiometabolite correction (approximately 100 mL) may be collected from all participants (PPMI and non-PPMI) during imaging at time points specified in the IAP.
- Vital signs (supine heart rate and supine blood pressure) will be assessed
    - approximately 5-60 minutes prior to tracer administration,
    - repeated within 30 minutes (±5 minutes) after injection,
    - repeated again within 30 minutes after completion of imaging.

  Any clinically significant changes will be reviewed by the Investigator prior to discharge.
- Participants will be monitored for at least 30 minutes post completion of imaging before being discharged.
- Safety and tolerability will be assessed throughout the imaging visit. Adverse events will be recorded in the adverse events log in the EDC database.

- XingImaging will be responsible for imaging site training, oversight of imaging procedures including metabolite analysis, data quality, and data analysis. The data and quality assurance procedures to be employed in this study are described in the IAP.

14. CONCOMITANT MEDICATIONS

Concomitant medications, including over the counter (OTC), dietary supplements (e.g., herbal remedies) or prescriptions, are permitted except as restricted by the PPMI 002 Clinical study for PPMI participants. . This includes medications known to be associated with drug-induced parkinsonism which are not allowed for 6 months prior to screening for the PPMI 002 clinical study and for the duration of the study (dopamine receptor blockers, metoclopramide, and reserpine). All concomitant medications reported at the time of the [^{18}F]MNI1008 PET Imaging visit are recorded on the study medication log in the respective clinical databases.

Certain medications are known to interfere with DaTscan imaging, such as alpha-methyldopa, bupropion, methylphenidate, modafinil, amphetamine derivatives and other CNS stimulants. Participants taking such medications may be required to temporarily hold them prior to imaging, if medically safe to do so. The appropriate washout period (e.g., at least 5 half-lives) will be determined by the investigator.

15. PARTICIPATION IN CLINICAL TRIALS

It is preferred that participants do not participate in any investigational clinical trials of study drugs during participation in this study, particularly those targeting alpha synuclein. The investigator will document the study drug dosage, if applicable, and, if unknown, will report on the identity of any study drug and the dosage after it is unmasked.

16. RISKS TO PARTICIPANTS

16.1 Imaging Radiation Exposure

The radiation exposure from [^{18}F]MNI1008 is expected to be within FDA guidelines.
Prior to [^{18}F]MNI1008 injection, each participant's cumulative radiation exposure will be reviewed according to local imaging radiation exposure guidelines to ensure it remains within allowable limits.

The estimated whole-body effective radiation dose from administration of up to 8 mCi of [^{18}F]MNI1008, including attenuation correction CT, is approximately 9–10 mSv, which is comparable to approximately 3 years of natural background radiation while living in the United States.

For PPMI (PD & HC) participants, this cumulative review will also include radiation exposure from imaging procedures performed under the PPMI 002 Clinical study, such as DaTscan.

For non-PPMI participants (MSA cohort), cumulative radiation exposure will include any imaging performed for this protocol in addition to the radiation from [^{18}F]MNI1008 PET imaging.

The estimated cumulative effective radiation dose from [^{18}F]MODAG-009 PET imaging, including attenuation correction CT, and DaTscan is estimated to be approximately 13-14 mSv, considered equivalent to ~4 years of natural background radiation while living in the United States.

The site's Radiation Safety Officer (RSO) or designated reviewer will confirm that each participant's cumulative exposure is within institutional and federal research radiation guidelines prior to administering [^{18}F]MNI1008.

16.2 Risks Specific to [^{18}F]MNI1008

[^{18}F]MNI1008 is an investigational imaging agent that will be used at low mass dose with minimal potential pharmacological risks. To date limited clinical studies have been performed which have shown a favorable safety profile for this tracer. However, because [^{18}F]MNI1008 is in the very early stages of clinical investigation, participants receiving [^{18}F]MNI1008 for injection will be monitored closely by means of adverse event reporting and vital signs.

The potential for drug-drug interactions is presently unknown. There is no data on the effects of [^{18}F]MNI1008 in human prenatal development. For this reason, fertile females must avoid becoming pregnant and must use adequate contraceptive methods 14 days prior to until at least 24 hours after injection of [^{18}F]MNI1008. [^{18}F]MNI1008 injection must not be administered to females who are pregnant or lactating. Males with female partners of childbearing potential must use adequate contraceptive methods and male participants should refrain from donating sperm until 90 days after injection of [^{18}F]MNI1008.

16.3 Blood Sampling

Risks associated with venous blood draw include pain and bruising at the site where the blood is taken. Sometimes people can feel lightheaded or even faint after having blood drawn. Very rarely, blood draw can lead to nerve damage.

The total amount of blood collected during study participation, including safety laboratory assessments and radiometabolite sampling, will remain within acceptable limits for research participation.

16.4 Risks Associated with Blood Sampling and Arterial Catheterization

Risks associated with venipuncture include pain, bruising, bleeding, lightheadedness, fainting, infection, and rarely nerve injury.

In addition, placement of a radial arterial catheter for repeated blood sampling carries additional risks. These include pain at the insertion site, bruising, hematoma, bleeding, infection, arterial spasm, thrombosis (clot formation), temporary reduction in blood flow to the hand, and very rarely, ischemia or nerve injury. Prior to arterial catheter placement, circulation to the hand will be assessed using Allen's or Barbeau test to reduce the risk of complications. After catheter removal, pressure will be applied to the site to minimize bleeding and vascular complications.

16.5 MRI

Participants should notify the study doctor if they suffer from claustrophobia or become anxious while in the magnetic resonance scanner. The investigator may prescribe or coordinate with

participant's medical team regarding the use of peri procedural anxiolytic, if indicated. There may be loud noises such as knocking or hammering that occur while the MRI is being conducted.

Participants should also inform the study doctor if they have a pacemaker or metal implants (screws, plates or clips) because this may preclude MR evaluation. Participant may experience bodily discomfort or pain by lying flat on MRI table. Participants with contraindications to MRI (e.g., certain implanted metal devices or severe claustrophobia) will not undergo MRI procedures.

16.6 DaTscan Imaging

DaTscan imaging, when performed, will utilize a standard clinically approved dose of I-123 ioflupane (approximately 3–5 mCi). DaTscan is administered at radiotracer doses and is not expected to have any pharmacological or toxicological effects. DaTscan binds to the dopamine and serotonin transporter. At pharmacologic doses DaTscan might be expected to have stimulant-like effects and affect cardiovascular responses. However, in the proposed study the estimated mass dose of DaTscan is very low (<30/pmol kg). More than 500,000 doses of the radiotracer have been administered to human participants and DaTscan is an FDA approved procedure.

Iodine: Prior to each injection, participants will be pretreated with Lugol's (or similar) solution, 10 drops of a saturated solution of potassium iodide, to reduce thyroid uptake of the radioactive agent. Participants may experience a metallic or bitter taste in their mouths from the iodine. Participants with allergies to iodine might get itching, a rash, bloating, severe blood pressure changes (shock), and death if given iodine. Participants who are allergic to iodine may be imaged without Lugol's or if available may be administered potassium perchlorate rather than Lugol's.

16.7 Lumbar Puncture

The most common risks of a lumbar puncture are pain at the procedure site and a temporary headache usually due to a small amount of CSF leakage around the needle insertion site. The headache is usually mild and self-resolves in a few days. Lying flat, drinking water and caffeinated drinks, and analgesics can relieve the headache. In rare instances of severe headache, participants may be referred for blood patch procedure. Apart from the common risks, there is a slight risk of infection because the needle breaks the skin's surface, providing a possible portal of entry for bacteria. A temporary numbness to the legs or lower back pain may be experienced. There is a small risk of bleeding in the spinal canal. Participants will have blood drawn prior to procedure to test for coagulopathies.

16.8 Risks Specific to Clinical assessments

The clinical assessments will be conducted in a private room. Participants may be asked to move to the examination table or sit in a chair. The neurological exam will also include assessments of walking. These assessments pose a very small risk of fall or inconvenience. The study staff are highly trained and have worked with elderly population and with individuals with neurodegenerative diseases. The study team will use appropriate measures to minimize any potential adverse event related to these assessments. Cognitive assessments will require participants to perform cognitive tasks with use of paper and pencil. The assessments may make some of the participants feel uncomfortable. The study staff will make participants as comfortable as possible. Participants will be informed that they do not have to answer any questions they choose not to answer. Completing all the assessments may lead to physical, mental, or emotional

fatigue. Study staff can space out assessments to minimize these effects if needed. Participants will be informed that they can take breaks anytime.

16.9 Unknown Risks

In addition to the known risks listed above, the imaging procedures in this study may cause unknown risks to the participant, or a developing embryo or fetus or possible risks to the future offspring of male participants. Confirmation of negative pregnancy test is required for participation in the study. All female participants are encouraged to use reliable form of contraception 14 days prior to until at least 24 hours after injection of the radiotracer. All male participants are encouraged to use reliable form of contraception and refrain from donating sperm for 90 days post injection.

The device (NX PET camera) is not an implant, is not used to support or sustain human life, is not used for a purpose of substantial importance in diagnosing, curing, mitigating, or treating disease or preventing impairment of human health, and does not otherwise present a potential for serious risk to the health, safety, or welfare of participants.

17. POTENTIAL BENEFITS TO PARTICIPANTS

There are no direct anticipated benefits to study participants from this study. However, new information may be generated by the study that will support better understanding of the disease characteristics and potential development of better treatments for Parkinson's disease and multiple system atrophy.

18. COSTS FOR PARTICIPATION

All research travel, assessments and tests will be provided with no cost to the study participant.

19. PAYMENT FOR PARTICIPATION

All participants will receive a stipend for completing specific steps under this study protocol, as per their cohort.

The stipend schedule will be as follows:

- Completing a screening visit: $100 (applicable only to non-PPMI participants)
- Completing a baseline PET scan visit: $200
- Completing a venous sampling for radiometabolite analysis: $100
- Completing an arterial sampling for radiometabolite analysis/kinetic modeling: $200

20. PARTICIPANT WITHDRAWALS

Study participants will be informed during the consent process that they have the right to withdraw from the study at any time without prejudice and may be withdrawn at the Site Investigator's or Sponsor's discretion at any time. PPMI participants who withdraw may remain in the main PPMI 002 Clinical study. Non-PPMI participants who withdraw can continue to participate in other studies at the site, if they are already doing so. Withdrawal from the study will not impact any participant's interaction with the study team or participation in any other ongoing studies at the site. Any information that has already been collected prior to the study participant's withdrawal will not be removed.

21. ADVERSE EVENTS

21.1 Adverse Event Reporting Requirements

Site investigators and coordinators will be instructed to assess for adverse events at the study visit when [^{18}F]MNI1008 PET imaging is conducted (or other study procedures like DaTscan, and LP, if applicable), as well as by telephone (or in person) 2 to 3 business days following such activity as outlined in the SOA. Adverse experiences, whether observed by the investigator, or elicited from or volunteered by the participant, should be recorded on the Adverse Event Log. Events occurring outside of the study procedure adverse event reporting period defined above do not require documentation for study purposes (i.e., will not be listed on the Adverse Event Log).

Any adverse event ongoing at the 2 to 3 business day reporting period should be followed until resolution or stabilization. Adverse events reported following a premature withdrawal or conclusion of participation visit should be followed not more than 30 days from [^{18}F]MNI1008 PET imaging, DaTscan imaging, and/or LP.

Adverse events will be reported by the site as required by the site's Institutional Review/Ethics Board and to the Radiation Safety Committee, as applicable.

21.2 Serious Adverse Event Reporting Requirements

Serious adverse events pertaining to [^{18}F]MNI1008 PET imaging, DaTscan Imaging, and LP will be reported as follows:

a) Any serious and unexpected adverse event occurring within 48 hours following [^{18}F]MNI1008 or DaTscan injection, and LP, regardless of relatedness to study procedures or investigational agent, will be documented on the Adverse Event Log within the EDC and reported by the site-to-site management core (SMC), using the PPMI 037 MNI1008 SAE Report Form.

b) The SMC will notify the appropriate responsible person(s) to report any serious and unexpected adverse events to the respective Health Authority as soon as possible, but no later than within 15 calendar days of first being notified of the event, as well as additional regulatory and Sponsor entities per respective reporting requirements.

c) The Investigator will comply with his/her local Institutional/Independent Review Board (IRB)/Ethics Board, and Radiation Safety Committee (as applicable), regarding the reporting of adverse experiences.

21.3 Adverse Event Definitions

Adverse Events (AE)

An AE is any undesirable experience occurring to a participant during study participation, whether or not considered related to the study procedure.

Serious Adverse Event (SAE)
An SAE is an AE that is fatal or life-threatening, or results in hospitalization, prolongation of hospitalization, persistent or significant disability/incapacity, or a congenital anomaly/birth defect. A life-threatening AE is an AE that, in the view of the investigator, places the participant at immediate risk of death from the reaction, as it occurred. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Inpatient admission in the absence of a precipitating, treatment emergent, clinical adverse event does not require immediate reporting. For example:

- Admission for treatment of a pre-existing condition not associated with the development of a new adverse event.
- Social admission (e.g., participant has no place to sleep).
- Protocol specific admission during a clinical study (e.g., for a procedure required by another study protocol).
- Optional admission not associated with a precipitating clinical adverse event (e.g., for elective cosmetic surgery).

Inpatient admission does not include the following:

- Emergency Room/Accident and Emergency/Casualty Department visits
- Outpatient/same day/ambulatory procedures
- Observation/short stay units
- Rehabilitation facilities
- Hospice facilities
- Respite care (e.g., caregiver relief)
- Skilled nursing facilities
- Nursing homes
- Custodial care facilities

Unexpected Adverse Event
For FDA reporting purposes, an unexpected AE is an AE not previously reported or an AE that occurs with specificity, severity or frequency that is not consistent with the current investigator's brochure.

21.4 Assessing Relationship of Adverse Events

The assessment of the relationship of an AE to the imaging procedure is a clinical decision based on all available information at the time the event is being documented. The following definitions of the relationship between the AE (including SAEs) and the study procedure should be considered:

- Unrelated - No possible relationship
  The temporal relationship between study procedure and the adverse event onset/course is unreasonable or incompatible, or a causal relationship to study procedure is implausible.

- Unlikely - Not reasonably related, although a causal relationship cannot be ruled out.

While the temporal relationship between study procedure and the adverse event onset/course does not preclude causality, there is a clear alternate cause that is more likely to have caused the adverse event than the study procedure.

- Possible - Causal relationship is uncertain
  The temporal relationship between study procedure and the adverse event onset/course is reasonable or unknown, and while other potential causes may not exist, a causal relationship to the study procedure does not appear probable.

- Probable - High degree of certainty for causal relationship
  The temporal relationship between study procedure and the adverse event onset/course is reasonable and other causes have been eliminated or are unlikely.

- Definite - Causal relationship is certain
  The temporal relationship between study procedure and the adverse event onset/course is reasonable and other causes have been eliminated.

21.5 Assessing Intensity/Severity of Adverse Events

In addition to assessing the relationship of the adverse event to the study procedure, an assessment is required of the intensity (severity) of the event. The following classifications should be used:

- *Mild:*
  A mild AE is an AE, usually transient in nature and generally not interfering with normal activities.
- *Moderate:*
  A moderate AE is an AE that is sufficiently discomforting to interfere with normal activities.
- *Severe:*
  A severe AE is an AE that incapacitates the participant and prevents normal activities. Note that a severe event is not necessarily a serious event. Nor must a serious event necessarily be severe.

21.6 Study Stopping Criteria

In the event of a serious adverse event (SAE) that is determined by the Investigator and Sponsor to be related to administration of [^{18}F]MNI1008, enrollment and further administration of [^{18}F]MNI1008 will be temporarily suspended. The study team will conduct a review of the SAE to determine causality and assess participant safety prior to resuming study procedures or additional tracer administrations. Any decision to restart study enrollment and administration of [^{18}F]MNI1008 will be made collaboratively by the Principal Investigator, Sponsor, and as appropriate, regulatory authorities.

Progression to subsequent study phases (dosimetry, test–retest, and clinical validation studies) will be contingent upon completion of a Sponsor-led safety and data review confirming acceptable tolerability, image quality, and tracer performance in the PoC study. Each phase will require separate IRB/IEC and regulatory authorization prior to activation.

22. STUDY MONITORING AND SITE MANAGEMENT

The Institute for Neurodegenerative Disorders and XingImaging have the responsibility to monitor all procedures for safety, GCP, and regulatory compliance. The study site will be managed and overseen in an ongoing manner by the PPMI Site Management Core to verify:

a) The rights and well-being of human participants are protected.
b) The reported study data are accurate, complete, and attributable.
c) The conduct of the study follows the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

23. PRIVACY AND CONFIDENTIALITY

Privacy of participants will be protected in that each person will have the option to voluntarily choose whether to participate in this study. It is the responsibility of the site Investigator to consider the participant's privacy and confidentiality when completing study visits and related protocol activities.

The Site Investigator must assure that the confidentiality of participants, including their personal identity and personal medical information, will be maintained at all times. As a U.S. site, there is additional confidentiality obligations to study participants under the Health Insurance Portability and Accountability Act (HIPAA), as applicable. Participants will be identified by participant ID numbers on data forms and other study materials. For PPMI participants, the PPMI assigned ID number will be utilized. For non-PPMI participants, unique study assigned ID will be utilized.

The Site Investigator will permit the study monitor or designated SMC representative to review signed informed consent(s) and that portion of the participant's medical record that is directly related to the study (or provide certified copies of source documentation upon request). This shall include all study relevant documentation, including participant medical history to verify eligibility, laboratory test result reports, admission/discharge summaries for hospital admissions occurring while the participant is in the study, if applicable, and autopsy reports for deaths occurring during the study (when available). In addition, electronic document storage will be maintained within the Florence electronic trial master file for both PPMI and Non-PPMI participants. Identifiable participant information may be stored within this system, which has been validated and deemed compatible with 21 CFR Part 11 requirements. Only study staff requiring access to related study documentation will have permission to view identifiable information.

24. DATA SHARING AND STORAGE FOR FUTURE USE

Data collected for this study will be maintained and stored indefinitely at the study Cores on secure, password-protected systems. All study information (data and samples) will be accessed only by those who require access as pertains to the individual's role in the study. All organizations responsible for data storage and review will observe the highest precautions to ensure data integrity and security.

Data collected for this study for PPMI participants may be transferred and shared across participating PPMI Cores including the Clinical Trials Statistical and Data Management Core (CTSDMC) at the University of Iowa, Indiana University PPMI Cores (Indianapolis, IN), the Site Management Core (SMC) and Data Systems and Technology Operations at the Institute for

Neurodegenerative Disorders (New Haven, CT) for conducting operations and analyses as pertains to the study including, but not limited to, enrollment, compliance, and study outcomes. Additionally, data collected for this study for PPMI participants may be shared with select study partners, including Roche, owner of the [^{18}F]MNI1008 radiotracer. All PPMI data will be incorporated into the PPMI database to create a fully harmonized PPMI database.

The data for non-PPMI participants may be shared with the study teams/cores including, the Institute for Neurodegenerative Disorders (New Haven, CT), XingImaging (New Haven, CT), the Michael J. Fox Foundation for Parkinson's Research (New York, NY), and select study partners, Roche, solely as necessary to support study conduct, data analysis, and regulatory obligations.

Data obtained during the conduct of this study will be transferred to secure data repositories designated by the study Cores for long-term storage and research use. PPMI participant data will be sent to the Laboratory of Neuro Imaging (LONI) in Los Angeles, California to be stored indefinitely for research purposes. De-identified research data may be made available to qualified researchers in accordance with applicable PPMI data access procedures and data use agreements. All personally identifiable information will be removed before data are shared outside the study team.

25. ANALYSIS PLAN

Given this is an exploratory study, no formal sample estimates are provided. The analysis will be primarily descriptive. The analysis pathways will include, but not be limited to :

- Determination of [^{18}F]MNI1008 SUVR in brain regions in all participants to assess tracer binding across study cohorts. SUVR will be calculated as the ratio of SUV in each region of interest to SUV in the appropriate reference region. The optimal time window may be determined based on tracer kinetic characteristics observed in the dynamic data.
- Analysis of variance (ANOVA) on a voxel-wise level with group (PD vs MSA vs HC) as the main factor to evaluate potential differences in tracer uptake.
- Association between [^{18}F]MNI1008 binding and clinical measures [e.g. MDS-UPDRS, MoCA, UMSARS] will be assessed using correlation analyses.
- Association between [^{18}F]MNI1008 binding and biological measures [e.g. CSF α-synuclein seed amplification, and other biomarker assays] will be assessed using correlation analyses. Determination of incidence and severity of tracer emergent adverse events using descriptive analyses.

26. REFERENCES

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27. Appendix 1 PPMI Participants [^{18}F]MNI1008 PET Imaging Schedule of Activities

Visit Number	Baseline (BL)**
Assessments	
Informed Consent Documentation	X
Informed Consent Tracking Log	X
Inclusion/Exclusion Criteria	I
Urine Pregnancy Test (prior to tracer injection), if applicable[a]	X
Screen Fail	As Needed
Conclusion of Study Participation	As Needed
Arterial Catheter Placement and Arterial Blood Sampling[b]	X
Radiometabolite Venous Blood Sampling[b]	X
Vital Signs[c]	X
Safety Laboratory Tests[d]	X
ECG[e]	X
[^{18}F]MNI1008 PET Imaging injection	X
[^{18}F]MNI1008 PET Imaging	X
[#] Adverse Event In-Clinic Assessment	X
Adverse Event Telephone Assessment	X
Report of Pregnancy	As Needed

**Window of +45 days either side of the PPMI 002 Target Visit Date
I = Investigator (or trained designee) completed assessment
X = Investigator or Coordinator completed assessment (or as otherwise delegated)
a = Urine pregnancy test required for women for childbearing potential. Must be completed on the day of [^{18}F]MNI1008 injection and confirmed negative prior to administering tracer.
b= Blood samples for radiometabolite correction/kinetic modeling may be collected during imaging at time points defined in the IAP
c = Vital signs (supine heart rate and supine blood pressure) will be assessed approximately 5-60 minutes prior to [^{18}F]MNI1008 administration. Vitals signs will be repeated 30 minutes (± 5 minutes) post [^{18}F] MNI1008 -injection. and within 30 minutes post completion of imaging. While on camera, body temperature will only be taken pre- and post-scan, not during imaging, to avoid head movement.
d = Safety labs (CBC, CMP, and urinalysis) will be completed before and after [^{18}F]MNI1008 injection as specified in the protocol and/or IAP. Pre-injection safety labs can be drawn any time on the day of the imaging prior to injection. Post-injection safety labs will be drawn within 30 minutes after completion of imaging scan.
e= ECG will be completed 5-60 minutes prior to [^{18}F]MNI1008 injection and 30 minutes after completion of imaging scan.
# Adverse events will be collected on the day of [^{18}F]MNI1008 imaging during the visit and again via telephone 2–3 business days following injection.

28. Appendix 2 Non-PPMI Participants [^{18}F]MNI1008 PET Imaging Schedule of Activities

Visit Number	Screening (SC)	Baseline (BL)
Assessments	**Up to - 8 weeks**	**0**
Documentation of Informed Consent	X	
Inclusion/Exclusion Criteria	I	I
Demographics	X	
Medical History and Concomitant Medications Review	X	
Screening vital signs, ECG, and safety labs[a]	X	
Physical exam	I	
Full Neurological Exam	I	
MoCA		X
Unified Multiple System Atrophy Rating Scale		I
MDS-UPDRS (III)[b]		I
Lumbar Puncture[c]	X	
Plasma Biomarkers		X
Screening DaTscan, if applicable	X	
Screening MRI Brain, if applicable	X	
Serum or Urine Pregnancy Test (prior to tracer injection), if applicable[d]	X	X
Imaging Screen Fail	As Needed	
Conclusion of Study Participation	As Needed	
Arterial Catheter Placement and Arterial Blood Sampling[e]		X
Radiometabolite Venous Blood Sampling[e]		X
Vital Signs[f]		X
Safety Laboratory Tests[g]		X
ECG[h]		X
[^{18}F]MNI1008 PET Imaging injection		X
[^{18}F]MNI1008 PET Imaging		X
[#] Adverse Event In-Clinic Assessment		X
Adverse Event Telephone Assessment		X
Report of Pregnancy	As Needed	

I = Investigator (or trained designee) completed assessment
X = Investigator or Coordinator completed assessment (or as otherwise delegated)
a = Screening safety laboratory tests will include CBC, CMP, coagulation labs, and urinalysis.

b = MDS-UPDRS III must be performed in the defined “OFF” state, which is achieved by withholding Levodopa (and other short-acting dopaminergic medications, if applicable) for at least 10 hours prior to the examination
c = CSF routine labs include CSF protein, glucose, and cell count with differential (processed locally). CSF send-out assays include tau profile, amyloid peptides, and α-synuclein seed amplification assay.
d = Required for women of childbearing potential. A serum or urine pregnancy test must be completed at Screening, and a urine pregnancy test must be performed prior to the injection of [^{18}F]MNI1008 (or DaTscan, if applicable) and confirmed negative on the day of administration.
e= Blood samples for radiometabolite correction/kinetic modeling may be collected during imaging at time points defined in the IAP
f = Vital signs (supine heart rate and supine blood pressure) will be assessed approximately 5-60 minutes prior to [^{18}F]MNI1008 administration and repeated within 30 minutes (± 5 minutes) post [^{18}F] MNI1008 -injection, and within 30 minutes post completion of imaging. While on camera, body temperature will only be taken pre- and post-scan, not during imaging, to avoid head movement.
g = Safety labs (CBC, CMP, and urinalysis) will be completed before and after [^{18}F]MNI1008 injection as specified in the protocol and/or IAP. Pre-injection safety labs can be drawn any time on the day of the imaging prior to injection. Post-injection safety labs will be drawn within 30 minutes after completion of imaging scan.
h= ECG will be completed 5-60 minutes prior to [^{18}F]MNI1008 injection before and 30 minutes after completion of imaging scan
# Adverse events will be collected on the day of [^{18}F]MNI1008 imaging and again via telephone 2–3 business days following injection.