PPMI FD4 Tracer Substudy

Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a FD4 imaging procedure to assess for adverse events.

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

1. Was a FD4 imaging scan conducted at this visit?
   - ○ No
   - ○ Yes

1a. If Yes, were adverse events assessed following the procedure?
   - ○ No
   - ○ Yes

i. If No, please explain:

_____

_____

_____

ii. If Yes, were any adverse events observed?
   - ○ No
   - ○ Yes

If question 1.a.ii is “Yes”, document information on the Adverse Event Log.

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Adverse Event Telephone Assessment

Complete this form for the telephone follow up 1-3 business days following a FD4 imaging procedure to assess for adverse events.

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

1. Was a FD4 imaging scan conducted at this visit?
   - ○ No
   - ○ Yes

2. Was contact made during this telephone call?
   - ○ No
   - ○ Yes

   2a. If no, indicate the reason:
   - ○ Phone disconnected/number no longer in service
   - ○ Messages for participant were not returned
   - ○ Participant moved/unable to locate
   - ○ Other, specify: _____

3. Were any adverse events reported by the participant?
   - ○ No
   - ○ Yes

If question 3 is "Yes", new adverse event(s) should be documented on the Adverse Event Log.

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Conclusion of Study Participation

The *Conclusion of Study Participation* form should be completed when a participant either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study.

1. Date of conclusion of participation: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

2. Select a reason for conclusion of study participation:
   - ○ Completed study per protocol
   - ○ Transportation/Travel issues (ex: logistics or travel, moved away from study site)
   - ○ Burden of study procedures (other than travel)
   - ○ Family, care-partner, or social issues (such as work/job obligations)
   - ○ Non-compliance with study procedures
   - ○ Adverse event
   - ○ Decline in health
   - ○ Lost to follow up
   - ○ Other, please specify:

     _____

     _____

     _____

     _____

3. Did increasing PD disability contribute to the decision to withdraw from the PPMI FD4 Tracer Study?
   - ○ No
   - ○ Yes
   - ○ Not Applicable

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Documentation of Informed Consent

Form instructions: Document date participant signed consent as the "Assessment Date" below.

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

1. Informed consent was discussed with participant and/or legally authorized representative for the PPMI 032 FD4 Tracer Study. Participant and/or legally authorized representative was given adequate time to read the informed consent, the opportunity to ask questions and consent was obtained prior to any study procedures being performed.

   ○ No ○ Yes

Monitor responsibilities

- Verify site process for obtaining informed consent is adequate according to 21 CFR 56.109(c) and 28 (21 CFR 50.27).
- Current approved ICF(s) version(s) are signed.
- Informed consent was obtained by person authorized on site delegation log.

PPMI FD4 Substudy

FD4 Imaging

Note: Women of childbearing potential must have a negative urine pregnancy test result prior to the imaging scan.

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

Vital Signs Measured Approximately 30 Minutes Prior to Injection

1. Was a study physician present to evaluate the participant prior to injection?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

2. Time vital signs measured prior to injection: __ __:__ __ (24-hour clock)

   To be taken after participant has been supine for 1-3 minutes:

3. Supine blood pressure: _____ / _____ mmHg (systolic/diastolic)
4. Supine heart rate: _____ beats per minute

5. Time of FD4 injection: __ __:__ __ (24-hour clock)

Vital Signs Measured Approximately 15 Minutes Post-Injection

6. Time vital signs measured after injection: __ __:__ __ (24-hour clock)

   To be taken after participant has been supine for 1-3 minutes:

7. Supine blood pressure: _____ / _____ mmHg (systolic/diastolic)
8. Supine heart rate: _____ beats per minute

9. Which enantiomer was received?
   ○ [^{18}F]FD4-R (XI-0002)
   ○ [^{18}F]FD4-S (XI-0004)

10. Was FD4 NeuroEXPLORER imaging scan completed?
    ○ Yes
    ○ No
    If no, please explain:
    _____
    _____
    _____

11. Was FD4 Conventional PET imaging scan completed?
    ○ Yes
    ○ No
    If no, please explain:
    _____
    _____
    _____

12. Was a study physician (or designee) present to evaluate the participant prior to discharge?
    ○ Yes
    ○ No
    If no, please explain:
    _____
    _____
    _____

PPMI FD4 Tracer Substudy

Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF for this substudy.

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

Inclusion Criteria:

1. Ability to comply with the study procedures.

   ○ Yes ○ No

2. Written informed consent from the participant.

   ○ Yes ○ No

3. Male or Female 40 years of age and older (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]FD4.

      - 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).
      - 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.

   ○ Yes ○ No

Inclusion Criteria – Healthy Control only:

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

   ○ Yes ○ No

Inclusion Criteria – Parkinson's Disease and Prodromal only:

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

   ○ 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. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine, within 6 months of Baseline Visit.

   ○ No ○ Yes

3. 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

4. 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

PPMI FD4 Tracer Substudy

Pregnancy Test

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

B. Is participant a female of childbearing potential?

○ Yes ○ No

1. If female of childbearing potential, was urine pregnancy test performed?

○ Yes ○ No

If no, explain why:

_____

_____

_____

1a. If pregnancy test performed, is the participant pregnant?

○ Yes ○ No

1b. Was the pregnancy test result confirmed prior to FD4 injection for PET scan?

○ Yes ○ No ○ Not Applicable

If no, explain why:

_____

_____

_____

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Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following FD4 injection, document this in the database within 24 hours of notification.

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

1. This is a report of pregnancy for which person?
   - ○ Female participant
   - ○ Female partner of participant

2. Is the pregnancy confirmed as occurring within 30 days following the FD4 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown

PPMI FD4 Tracer Substudy

Screen Fail

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

1. Participant did not enroll in PPMI FD4 Tracer substudy due to:
   - ○ Eligibility Criteria
   - ○ Participant declined participation prior to completing baseline visit

   1a. Please select the reason for declining:
   - ○ Risks of Protocol
   - ○ Confidentiality issues
   - ○ Protocol too time intensive
   - ○ Changed mind about lumbar puncture
   - ○ Travel requirements
   - ○ Family or caregiver/informant advised declining
   - ○ Physician (other than Site Investigator) advised declining
   - ○ Enrolled in other study
   - ○ No longer interested
   - ○ Other