PPMI DPA-714 PET Imaging Substudy

Adverse Event In-Clinic Assessment

Complete this form at a visit that includes a DPA-714 PET imaging procedure to assess for adverse events.

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

1. Was a DPA-714 PET 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.

PPMI DPA-714 PET Imaging Substudy

Adverse Event Telephone Assessment

Complete this form for the telephone follow up 2-3 business days following a DPA-714 PET imaging procedure to assess for adverse events.

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

1. Was a DPA-714 PET 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.

PPMI DPA-714 PET Imaging Substudy

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either completes study participation, decides to no longer participate in the study/withdraws consent, or has withdrawn/concluded the PPMI Clinical study.

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

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 DPA-714 PET Imaging Study?

   ○ No

   ○ Yes

   ○ Not Applicable

PPMI DPA-714 PET Imaging Substudy

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 019 DPA-714 PET Imaging 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 DPA-714 PET Imaging Substudy

DPA-714 PET Imaging

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

If a PPMI Clinical SPECT Scan was completed prior to DPA-714 Imaging, then DPA-714 Imaging may be completed any time afterwards. However, if DPA-714 Imaging is being completed first, please wait at least 24 hours to complete the PPMI Clinical SPECT Scan.

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

Vital signs measured approximately 5-60 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 ^{18}F-DPA-714 injection: __ __:__ __ (24-hour clock)

Vital signs measured approximately 15-30 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. Was DPA-714 PET imaging scan completed?

   ○ Yes

   ○ No

   If no, please explain:

   _____

   _____

   _____

10. Was a study physician (or designee) present to evaluate the participant prior to discharge?

    ○ Yes

    ○ No

    If no, please explain:

    _____

    _____

    _____

11. Imaging Site:

    ❒ Completed at another PPMI site on behalf of this clinical site

PPMI DPA-714 PET Imaging Substudy

Genetic Testing for TSPO Gene

1. Genetic Testing for TSPO gene polymorphism (rs6971):

   ○ Completed at visit

   ○ Completed using a previously acquired genetic test

   1a. If completed at visit, date of genetic testing: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   1b. If completed at visit, time of genetic testing: __ __:__ __ (24-hour clock)

   1c. If completed previously, date of genetic testing: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

   Genetic testing results should be received prior to assessing baseline Inclusion/Exclusion Criteria.

PPMI DPA-714 PET Imaging 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. A prodromal PD or Healthy participant enrolled in PPMI Clinical protocol, or a PD participant enrolled in PPMI Clinical protocol who has not started symptomatic treatment at time of enrollment or in the first 2 years of participation.

   ○ Yes ○ No

2. Able to provide informed consent.

   ○ Yes ○ No

3. Must have screening genetic testing documenting high binder at the at the known TSPO gene polymorphism (rs6971).

   ○ Yes ○ No

4. Male or Female (Females must meet additional criteria specified below, further defined in protocol, 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-DPA-714.

   b. Females of childbearing potential must not be pregnant, breastfeeding or lactating.

   c. Females of childbearing potential have a negative urine pregnancy test prior to ^{18}F-DPA-714 injection on day of PET scan.

   ○ Yes ○ No

Exclusion Criteria:

1. Exposure to a total effective dose equivalent of 50 mSv for the whole body, which is the annual limit established by the US Code of Federal Regulations, during the past year.

   ○ No ○ Yes

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

   ○ No ○ Yes

PPMI DPA-714 PET Imaging 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 ^{18}F DPA-714 injection for PET scan?

○ Yes ○ No ○ Not Applicable

If no, explain why:

_____

_____

_____

PPMI DPA-714 PET Imaging Substudy

Report of Pregnancy

Note: If a pregnancy was confirmed as occurring within 30 days following DPA-714 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 DPA-714 injection?
   - ○ No
   - ○ Yes
   - ○ Unknown

PPMI DPA-714 PET Imaging Substudy

Screen Fail

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

1. Participant did not enroll in PPMI DPA-714 PET Imaging 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