Did the subject ever take any non-study PD medications?

[ ]  Yes (Follow instructions below)

[ ]  No

[ ]  Unknown

Please record all PD medications the subject has ever taken (including PD medications the subject has taken while participating in the study). Enter each dose change on a new line. All other medications (i.e., non-PD medications) should be recorded on the Non-PD Medications Log.

## PD Medication Class Reference

Parkinson’s Disease-Medication Class Reference.

Class Reference Table

| Levodopa | Dopamine agonists | MAO-B inhibitors | COMT inhibitors | Antiglutamat agents | Anticholinergics | Other, specify |
| --- | --- | --- | --- | --- | --- | --- |

## PD Medication Name Reference

Parkinson's Disease Medication Name Reference

Name Reference Table

| 1 Alpha-Dihydroergocryptine | Budipine | L-Dopa Methylester | Lisuride | Pramipexole | Selegiine standard oral |
| --- | --- | --- | --- | --- | --- |
| Amantadine | Cabergoline | L-Dopa Slow Release | Mematine | Rasagiline | Selegiline patch |
| Apomorphine | Entacapone | L-Dopa Soluble | Pergolide | Ropinirole | Selegiline sublingual |
| Bromocriptine | L-Dopa Duel Release | L-Dopa Standard | Piribedil | Rotigotine | Tolcapone |

## Parkinson's Disease Medication Log.

Medication Log Table

| Line # | Medication Class | Medication Name (Trade or generic name) | Maximum Dose (Specify units) | Estimated Total Duration of Exposure (Check units) | Medication Use Ongoing? | If Applicable, Reason for Discontinuation |
| --- | --- | --- | --- | --- | --- | --- |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  \*Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  \*Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  [[1]](#footnote-1)Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  [[2]](#footnote-2)Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  [[3]](#footnote-3)Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  [[4]](#footnote-4)Side Effect:[ ]  Other: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | [ ]  Years[ ]  Months[ ]  Weeks[ ]  Days | [ ]  Yes[ ]  No[ ]  Unknown | [ ]  Lack of efficacy[ ]  [[5]](#footnote-5)Side Effect:[ ]  Other: |

Side Effects Table

| AA = Motor offs (including wearing off and sudden off) | DD = Cognitive impairment – not dementia | GG = Autonomic dysfunction | JJ = ICD (including Gambling, Hypersexuality, Binge eating, Shopping) | MM=Dopamine agonist withdrawal |
| --- | --- | --- | --- | --- |
| BB = Dyskinesia | EE= Non-motor offs, specify: | HH= Daytime sleep abnormalities | KK=Punding | OT = Other important side effects, specify |
| CC = Hallucination/psychosis | FF - Behavioral disturbances specify: | II = Nighttime sleep abnormalities | LL=Dopadysregulation syndrome |  |

## General Instructions

The Parkinson’s disease medication log provides information about current non-study PD medications the participant/ subject has taken in his/her lifetime. Study PD medications should not be listed on this CRF.

The PD Medication Log was created as an alternative to the Prior and Concomitant Medication CDEs that are available under the General CDE Data Standards. For example, in a PD population, patients may be able to recall ‘duration’ with greater accuracy than they can recall specific medication start and stop dates.

Important note: Three of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all Parkinson’s disease clinical studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The majority of the data elements on the CRF have the following instructions:

History can be obtained from participant/ subject, family member, friend, or chart/ medical record. In some studies it may be possible to ask the subject/ participant or a family member to bring in the pill bottles for all current medications.

Medication name – Please refer to the PD Medication Name Reference Chart. Additionally, please include the genric name or trade name of the medication.

Side effects – Please refer to the Common Side Effects chart for the codes of the possible side effects experienced from PD medications. Only capture the side effects code on this form. Specifics of the side effect (i.e., Severity, Relatedness, Outcome, etc) should be recorded on the General Adverse Events form if they occur during the study.

There are no other specific instructions for the data elements not already included on the CRF.

1. Common Side Effects [↑](#footnote-ref-1)
2. Common Side Effects [↑](#footnote-ref-2)
3. Common Side Effects [↑](#footnote-ref-3)
4. Common Side Effects [↑](#footnote-ref-4)
5. Common Side Effects from Medication [↑](#footnote-ref-5)