Note: This is a template form. Please consider whether your study needs to collect additional data (e.g., exact timing for PRN medications) and if additional data are required add fields to this template or capture them on a separate form.

Did the subject take any medications before or during the study? (days):

Yes (Follow instructions below)

No

Unknown

In the table below please record all non-Parkinson’s Disease medications the participant/subject was taking at the time of the protocol-specified period indicated above. These can include prescription medications, over the counter drugs, vitamins, supplements, minerals, complementary/alternative medications etc.

Table 1: Non-Parkinson’s Disease medications

| Line # | Medication Name (Trade or generic name) | Total Daily Dose or PRN Dose (with units) | Start Date (M M/D D/Y Y Y Y) | End Date (M M/D D/Y Y Y Y) | Medication Use Ongoing? | \*PRN Med? | If PRN, Average Frequency (with units e.g., times per month) | Indication |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No  Unknown | Yes  No  Unknown | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No  Unknown | Yes  No  Unknown | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No  Unknown | Yes  No  Unknown | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No  Unknown | Yes  No  Unknown | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Yes  No  Unknown | Yes  No  Unknown | Data to be filled in by site | Data to be filled in by site |

\* “PRN Med?” asks whether the medication is taken on an as needed basis. NO should be answered for chronic medications that are taken on a regular basis.

General Instructions

The non-Parkinson’s disease medication log provides information about non-PD medications the participant/ subject was taking prior to or during the study. Collecting non-PD medications taken prior to the study in a defined time window is important when there may be potential interactions with the study intervention. Thus, a potential subject may need to stop a medication prior to starting the study intervention (washout period). The study exclusion criteria may identify drugs that cannot be taken during the study and so prior medications are identified to determine whether an individual may be eligible for the study.

Important note: None 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). All 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 non-PD medications.

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