



## Symptomatic Therapy (ST) Visits

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### Summary

PPMI subjects with Parkinson's disease (PD) may not have initiated PD therapy or medications/s at the time of enrollment into the PPMI study. Additionally some of the Prodromal (unaffected with a reported PD risk factor) or the SWEDD subjects may initiate a PD medication/s during the course of the study. When a PPMI site becomes aware that an enrolled PPMI subject will be initiating the use of PD medication, either in advance of a pending study visit or at the time of a scheduled visit, a Symptomatic Therapy (ST) visit should be conducted **prior to** the subject starting PD medications. The ST visit will (in most instances) replace the current visit (if this occurs at the time of the visit) or the next planned study visit.

If a subject is unable to return to the PPMI site for an ST visit prior to starting PD medication, the next study visit is completed per the regular visit schedule. If the subject is starting PD medication and is able to complete a study visit prior to initiation of PD medication/s an ST visit should be conducted.

### Method for ST visits:

The initiation of PD medication is reported to the PPMI clinical core and documented on the appropriate source worksheet.

The visit replacement schedule is followed per the PPMI Protocol. The PPMI visit replacement standard for an ST visit is outlined below:

#### **For de novo PD (idiopathic), SWEDD, or Prodromal Subjects initiating PD Medication for the first time:**

- **Before Visit 01 (3 Months):** The ST visit assessments are completed per protocol. Visit 01 is replaced by the ST Visit and the subject continues the regular visit schedule at Visit 02 (6 months) assessments.
- **At Visit 01 (3 months) or prior to Visit 02 (6 months):** The ST visit assessments are completed per protocol. Visit 02 is replaced by the ST Visit and the subject returned to the regular visit schedule for Visit 03 (9 months) assessments.





- **At Visit 02 (6 months) or prior to Visit 03 (9 months):** The ST visit assessments are completed per protocol. Visit 03 is replaced by the ST Visit and the subject will return to the regular visit schedule for Visit 04 assessments.
- **At Visit 03 (9 months) or prior to Visit 04 (12 months):** The ST visit assessments are completed per protocol. Visit 04 is replaced by the ST Visit and the subject will return to the regular visit schedule for Visit 05 (18 months) assessments.
- **At Visit 04 (12 months):** The ST visit assessments are completed per protocol. . The subject will return to the regular visit schedule for Visit 05 (18 months) assessments.
- **After Visit 04 (12 months):** If an ST visit was conducted within 3 months prior to the next visit's Target Date, or as part of that next regularly scheduled study visit, the ST visit replaced that visit. The subject then continued to follow the Visit Window Schedule. If the subject returned outside of the 3 month window prior to the next visit, conduct the ST visit. The subject returned again for the next regular study visit per protocol.

**Genetic Cohort Subjects (PD or Unaffected Mutation Carriers) initiating PD Medication:**

- **At or prior to Visit 02 (6 months):** The ST visit assessments are completed per protocol.. Visit 02 is replaced by the ST Visit and the subject returned to the regular visit schedule for Visit 04 assessments.
- **After Visit 2 (6 months) but Prior to Visit 04 (12 months):** The ST visit assessments are completed per protocol. Visit 04 is replaced by the ST Visit and the subject returned to the regular visit schedule for Visit 05 assessments.
- **At Visit 04 (12 months):** The ST visit assessments are completed per protocol.. The subject returned to the regular visit schedule for Visit 05 (18 months) assessments.
- **After Visit 04 (12 months):** If an ST visit is conducted within 3 months prior to the next visit's Target Date, or as part of that next regularly scheduled study visit, the ST visit replaced that visit. The subject then continued following the Visit Window Schedule. If the subject returned outside of the 3 month window prior to the next visit, the ST visit was conducted. The subject returned for the next regular study visit per the PPMI Protocol.

ST visits are not required for all subjects in the cohort indicated above. For subjects that require an ST visit, this will be completed only once, at the time of initiation of a PD medication.





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For a list of ST visit assessments completed as part of an ST visit refer to section 5 of the PPMI protocol. For a listing of subjects who have completed an ST visit and the corresponding visit that was replaced by the ST Visit, please refer to the PPMI database as part of the ST Visit Table.

### References

PPMI Protocol [www.PPMIinfo-org](http://www.PPMIinfo-org)

### About the Authors

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