Table 1: Master Protocol Standard Schedule of Activities

All P2P-013 participants will be screened from PPMI. If NSD status and staging were not established prior to P2P-013 screening, it must be done as part of the Master Protocol screening.

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Informed Consent																			
Documentation of Informed Consent	X																		
Research Proxy Designation	X			As needed															
Informed Consent Tracking Log	X	As needed																	
Screening Activities																			
Inclusion /Exclusion Criteria	X	X																	
Screen Fail	As needed																		
General Activities																			
Demographics	X[a]																		
Family History	X[a]																		
Medical History	X[a]																		
Socioeconomics	X[a]																		
Features of REM Behavior Disorder	X[a]																		
Physical Examination	X					X		X				X				X		X	

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Height and Weight[5]	X	X		X	X	X		X		X		X		X		X	X	X	
Vital Signs	X	X		X	X	X		X		X		X		X		X	X	X	
Orthostatic BP	X	X		X	X	X		X		X		X		X		X	X	X	
Neuro/Motor Assessments																			
Participant Motor Function Questionnaire	X[b]				X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Freezing and Falls	X[b]							X				X				X		X	
Neurological Examination	X					X		X				X				X		X	
Initiation of Dopaminergic Therapy			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
MDS-UPDRS Part Ia	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
MDS-UPDRS Part Ib and Part II	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
MDS-UPDRS Part III Treatment Determination/ Motor Exam/Hoehn & Yahr	X	X		X	X	X		X		X		X		X		X	X	X	
MDS-UPDRS Repeat Part III/ Hoehn and Yahr[6]				X	X	X		X		X		X		X		X	X	X	
MDS- UPDRS Part IV[6]				X	X	X		X		X		X		X		X	X	X	
Modified Schwab and England ADL	X				X	X		X		X		X		X		X	X	X	
Features of Parkinsonism	X[b]				X	X		X		X		X		X		X		X	
Other Clinical Features	X[b]				X	X		X		X		X		X		X		X	

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Clinical Diagnosis	X				X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Primary Research Diagnosis	X				X	X		X		X		X		X		X	X	X	
Non-Motor Assessments																			
Olfactory Testing (UPSIT)	X[c]							X				X				X		X	
RBD Screening Questionnaire	X[b]							X				X				X		X	
Epworth Sleepiness Scale	X[b]							X				X				X		X	
SCOPA-AUT	X[b]				X			X		X		X		X		X		X	
Neuro QoL	X[b]							X				X				X		X	
Cognitive and Psychiatric Assessments																			
Montreal Cognitive Assessment	X							X				X				X		X	
Clock Drawing	X[b]							X				X				X		X	
Lexical Fluency	X[b]							X				X				X		X	
Hopkins Verbal Learning Test-Revised	X[b]							X				X				X		X	
Benton Judgment of Line Orientation	X[b]							X				X				X		X	
Modified Semantic Fluency (Animals only)	X[b]							X				X				X		X	
Letter Number Sequencing	X[b]							X				X				X		X	
Symbol Digit Modalities Test	X[b]							X				X				X		X	

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Trail Making Test (A and B)	X[b]							X				X				X		X	
Modified Boston Naming Test	X[b]							X				X				X		X	
Cognitive Change	X				X	X	X	X	X	X	X	X	X	X	X	X		X	
Cognitive Categorization	X				X	X		X		X		X		X		X		X	
State-Trait Anxiety Inventory for Adults	X[b]					X		X		X		X		X		X		X	
Geriatric Depression Scale	X					X		X		X		X		X		X		X	
QUIP	X[b]					X		X		X		X		X		X		X	
Global Function Assessments																			
CGI-S	X[b]	X				X		X		X		X		X		X	X	X	
PGI-S	X[b]	X				X		X		X		X		X		X	X	X	
PDAQ-27	X[b]	X				X		X		X		X		X		X	X	X	
Novel PRO	X	X				X		X		X		X		X		X	X	X	
Digital Assessment																			
Digital Assessment		As needed																	
Safety Assessments																			
Clinical Safety Labs[7]	X			X	X	X		X		X		X		X		X		X	
ECG	X			X				X				X				X		X	
C-SSRS[8]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Biological Sample Collection																			

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Research Samples (blood and urine)	X[c]	X[13]				X		X				X				X		X	
Lumbar Puncture	X[c]							X				X				X		X[14]	
Skin Biopsy	X[c]							X				X				X		X[14]	
Imaging Activities																			
Pregnancy Test[7]	X							X				X				X		X	
DAT SPECT	X[b]							X				X				X		X[12]	
MRI[9]	X[b]							X				X				X		X[14]	
CT Scan[10]	X																		
Medications																			
Concomitant Medications Review	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
LEDD Concomitant Medication Log			As needed																
Randomization																			
Randomization	X	X																	
Adverse Events (AEs)																			
AE Assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
AE Telephone Assessment[11]	X							X				X				X		X	
Current Medical Conditions Review	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Report of Pregnancy	As needed																		
Other Assessments																			

Activity	MP Screening	Baseline	W2	W4	W12	W24	W36	W48	W60	W72	W84	W96[2]/ ET	W108	W120	W132	W144	Initiation of Dopaminergic Tx[3]	End of RSSP Treatment	End of RSSP Treatment Safety Call[4]
	Clinic	Clinic	Phone	Clinic	Clinic	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Tele[1]	Clinic	Tele[1]	PPMI Annual Visit	Clinic	Clinic	Phone
Window (days)	-90 to -1	0	3±	7±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	14±	3±
Study Completion Form			As needed																
Procedures for PD Log			As needed																
Participation in Other Studies	As needed																		
Visit Status	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Note: If any screening assessment indicated above was not completed as part of PPMI Clinical (e.g., the participant was identified from myPPMI or other remote platform), it must be completed as part of the P2P-013 Master Protocol screening visit.

a. Data will be pulled in from PPMI Clinical, if available, and must be verified during the screening visit by the clinical site.

b. Data from these assessments will be pulled in from participant's last annual PPMI Clinical visit if the assessment was performed < 6 months prior to the Master Protocol screening visit. In case of re-screening for the Master Protocol, the participant does not need to repeat these assessments if performed < 6 months prior to the Master Protocol re-screening visit.

c. Data from these assessments will be pulled in from participant's last annual PPMI Clinical visit if the assessment was successfully performed < 12 months prior to the Master Protocol screening visit. In case of re-screening for the Master Protocol, the participant does not need to repeat these assessments if performed < 12 months prior to the Master Protocol re-screening visit.

1. Tele (video if possible) visits may be converted into in-person clinic visits as necessary at the discretion of the site investigator. If converted into in-person visits, vital signs (including orthostatic blood pressure) and clinical safety laboratory samples should be collected.
2. The end of treatment is defined when the last participant randomized to an RSSP completes their Week 96 visit for the assigned RSSP or until 96 weeks have passed since randomization (if terminated early). All consented participants will remain active in the RSSP for a maximum of 144 weeks or until the last participant has had the opportunity to complete the Week 96 visit (whichever occurs first).
3. This visit should be scheduled prior to the initiation of dopaminergic therapy. If this visit occurs < 90 days from the next annual in-clinic visit, replace this visit with the next PPMI annual in-clinic visit and follow the SOA accordingly.
4. End of RSSP Treatment Safety Call is performed 30 days (±3 days) after completion/ withdrawal from RSSP unless specified otherwise in the RSSP.
5. Height is only collected at the screening visit. Weight will be collected at all indicated visits.
6. The MDS-UPDRS Repeat Part III /Hoehn and Yahr and MDS-UPDRS Part IV will be performed only if the participant has initiated dopaminergic therapy (levodopa or dopamine agonists). When OFF testing is required, it is preferred that the OFF exam be performed first. OFF testing should occur at least 6 hours post last dose of dopaminergic medication.

7. Clinical Safety Labs: See Appendix 3 for specific analytes. HIV serology, HBV serology, Hep C antibody, and Urine Drug Screen performed at Screening only. Collect samples as outlined in the laboratory manual; Collect Screening blood samples after other requisite tests for eligibility have been completed. For women of childbearing potential, perform serum pregnancy test (HCG) at Screening; perform urine pregnancy test or (serum if required by the site) prior to injection of DaTscan and at all other indicated visits.
8. At the screening visit, use the C-SSRS baseline/screening version of the form. At all other visits, use the C-SSRS Since Last Visit version of the form.
9. An MRI is not required if completion of the MRI is not possible for a safety or medical reason.
10. CT Scan is optional and can be performed if required by the site for pre-LP imaging.
11. AE Telephone Assessment is performed 2-3 business days after a skin biopsy, DAT SPECT, and lumbar puncture.
12. Repeat DATSPECT if last DATSPECT was collected ≥ 6 months prior to the End of RSSP Treatment visit.
13. Collect research samples if not completed at Screening.
14. To be completed only if done ≥12 months before this time point.

Abbreviations: ET = Early Termination; MP = Master Protocol; Tx = Therapy; W = Week

See Section 5.1 for a description of the Parkinson Progression Marker Initiative (PPMI) Clinical study