

Parkinson's Disease and PD Genetic Schedule of Activities (Years 6+)

Visit Number	R12	V13	R13	V14	R14	V15	R15	V16	R16	V17	R17	V18	R18	V19	R19	Annual	Remote	^b Transition Activities	^u Event Driven Modified Visit	
Assessment	**Timepoint	66 mths	72 (Y6)	78 mths	84 (Y7)	90 mths	96 (Y8)	102 mths	108 (Y9)	114 mth	120 (Y10)	126 mths	132 (Y11)	138 mths	144 (Y12)	150 mths	156+ (Y13+)	162 mths+	---	--
<i>Consent Activities</i>																				
Documentation of Informed Consent	As Needed																	X		
Continuing Consent		X		X		X		X		X		X		X		X				
Consent to share contact information	As Needed																			
Research Proxy Designation	As Needed																			
Informed Consent Tracking Log	As Needed																			
<i>General Activities</i>																				
Demographics																			X	
Family History																			X	
Socio-Economics																			X	
Program Assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Vital Signs + Height and Weight		X		X		X		X		X		X		X		X				
Visit Status	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Screen Fail																			As Needed	
Conclusion of Study Participation	As Needed																			
<i>Neurological/Motor Assessments</i>																				
Participant Motor Function Questionnaire		P		P		P		P		P		P		P		P				
Freezing and Falls		X		X		X		X		X		X		X		X				
Neurological Examination		I		I		I		I		I		I		I		I				
Initiation of Dopaminergic Therapy	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
MDS-UPDRS Part Ia	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
MDS-UPDRS Part Ib and Part II	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
MDS-UPDRS Part III Treatment Determination/Motor Exam/Hoehn & Yahr ^{a,d,c}	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
MDS-UPDRS Repeat Part III/Hoehn & Yahr ^{a,d,c}		I		I		I		I		I		I		I		I				
MDS-UPDRS Part IV ^d	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Modified Schwab & England ADL	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Features of Parkinsonism	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Other Clinical Features	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Primary Research Diagnosis	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I		
Clinical Global Impression (CGI)		I		I		I		I		I		I		I		I				
Clinical Diagnosis	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
<i>Non-Motor Assessments</i>																				
REM Sleep Behavior Disorder Screening Questionnaire		P		P		P		P		P		P		P		P				
Epworth Sleepiness Scale		P		P		P		P		P		P		P		P				
SCOPA-AUT		P		P		P		P		P		P		P		P				
Participant Global Impression (PGI)		P		P		P		P		P		P		P		P				
Neuro QoL		P		P		P		P		P		P		P		P				
<i>Cognitive Assessments</i>																				
Montreal Cognitive Assessment*		X		X		X		X		X		X		X		X				
Clock Drawing*		X		X		X		X		X		X		X		X				
Lexical Fluency*		X		X		X		X		X		X		X		X				
Hopkins Verbal Learning Test-Revised*		X		X		X		X		X		X		X		X				
Benton Judgment of Line Orientation*		X		X		X		X		X		X		X		X				
Modified Semantic Fluency (Animals only)*		X		X		X		X		X		X		X		X				
Letter Number Sequencing*		X		X		X		X		X		X		X		X				
Symbol Digit Modalities Test*		X		X		X		X		X		X		X		X				
Trail Making Test (A and B)*		X		X		X		X		X		X		X		X				
Modified Boston Naming Test*		X		X		X		X		X		X		X		X				

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Cognitive Change			P		P		P		P		P		P		P		P			
Cognitive Categorization			I		I		I		I		I		I		I		I			
Neuropsychological Assessments																				
State-Trait Anxiety Inventory for Adults			P		P		P		P		P		P		P		P			
Geriatric Depression Scale			P		P		P		P		P		P		P		P			
QUIP			P		P		P		P		P		P		P		P			
Clinical and Biological Samples																				
Research Biosamples (blood + urine)			X		X		X		X		X		X		X		X			
Lumbar puncture					X				X				X				X			
Skin biopsy ^f																			X ^c	
Safety and General Health																				
[#] Adverse Events					X				X				X				X			
Adverse Event Telephone Assessment					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		
Concomitant Medication Review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Participation in Other Studies		As Needed																		
LEDD Concomitant Medication Log		As Needed																		
Surgery for PD Log		As Needed																		
Report of Pregnancy		As Needed																		

I = Investigator (or trained designee) completed assessment

P = Participant completed assessment

X = Investigator or Coordinator completed assessment (or as otherwise delegated)

R0X Visits are conducted remotely (e.g., video, audio)

a = rigidity and postural stability not assessed for Out of Clinic or Remote "R" visits; Part III and Hoehn & Yahr not done if phone/audio only

b = Transition Activities completed for all previously enrolled participants transitioning into new database at first visit only

c = Previously enrolled participants transitioning to new database may be asked to have skin biopsy. If not done at first visit, may be conducted at a subsequent in person visit.

d = Investigator or Coordinator may complete treatment and timing information.

e = If the participant is on levodopa, dopamine agonists, or has had DBS, the MDS-UPDRS Part III should be performed in the OFF and ON state.

f = Skin biopsy will be conducted at participating sites

H = see protocol section 11 for modification of visit schedule due to New Clinical Diagnosis, Need for PD Therapy or withdrawal from study

*Completed on paper source first, and then scores entered in to EDC.

**Window of +45 days either side of Target Visit Date

Adverse events collected only day of and 2-3 business days post LP and skin biopsy per protocol.

As needed assessments can be located under the Event Driven category in EDC