

Parkinson's Disease and PD Genetic Schedule of Activities (Years 0 - 5)

Visit Number	Screening	Baseline (BL)	V02	V04	V05	V06	R06	V08	R08	V10	R10	V12	^b Transition Activities	^h Event Driven Modified Visit	
Assessment	**Timepoint	-60 days	0	6 mths	12 (Y1)	18 mths	24 (Y2)	30 mths	36 (Y3)	42 mths	48 (Y4)	54 mths	60 (Y5)	---	---
Consent Activities															
Documentation of Informed Consent	X	As Needed											X		
Continuing Consent				X		X		X		X		X			
Research Proxy Designation	X	As Needed											X		
Consent to share contact information	X	As Needed											X		
Informed Consent Tracking Log	X	As Needed											X		
General Activities															
Demographics	X													X	
Family History	X													X	
Socio-Economics	X													X	
Physical Examination	X														
Program Assessment		X	X	X	X	X	X	X	X	X	X	X	X		
Vital Signs (Height and Weight BL + Annually)	X	X	X	X	X	X	X	X	X	X	X	X	X		
Review Inclusion/Exclusion Criteria	I	I													
Visit Status	X	X	X	X	X	X	X	X	X	X	X	X	X		
Screen Fail	As Needed													As Needed	
Conclusion of Study Participation			As Needed												
Neurological/Motor Assessments															
Participant Motor Function Questionnaire		P		P		P		P		P		P			
Freezing and Falls		X		X		X		X		X		X			
PD Diagnosis History	I														
Neurological Examination	I			I		I		I		I		I			
Initiation of Dopaminergic Therapy			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		
MDS-UPDRS Part Ib and Part II		P	P	P	P	P	P	P	P	P	P	P	P		
MDS-UPDRS Part III Treatment Determination/Motor Exam/Hoehn & Yahr ^{a,d,e}		I	I	I	I	I	I	I	I	I	I	I	I		
MDS-UPDRS Repeat Part III/Hoehn & Yahr ^{a,d,e}			I	I	I	I		I		I		I			
MDS-UPDRS Part IV ^d			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		
Features of Parkinsonism		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		
Primary Research Diagnosis		I	I	I	I	I	I	I	I	I	I	I	I		
Clinical Global Impression (CGI)		I		I		I		I		I		I			
Clinical Diagnosis		X	X	X	X	X	X	X	X	X	X	X	X		
Non-Motor Assessments															
Olfactory Testing (UPSIT)		P													
REM Sleep Behavior Disorder Screening Questionnaire		P		P		P		P		P		P			

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Epworth Sleepiness Scale			P		P		P		P		P		P		
SCOPA-AUT			P		P		P		P		P		P		
Participant Global Impression (PGI)			P		P		P		P		P		P		
Neuro QoL			P		P		P		P		P		P		
Cognitive Assessments															
Montreal Cognitive Assessment*			X		X		X		X		X		X		
Clock Drawing*			X		X		X		X		X		X		
Lexical Fluency*			X		X		X		X		X		X		
Hopkins Verbal Learning Test-Revised*			X		X		X		X		X		X		
Benton Judgment of Line Orientation*			X		X		X		X		X		X		
Modified Semantic Fluency (Animals only)*			X		X		X		X		X		X		
Letter Number Sequencing*			X		X		X		X		X		X		
Symbol Digit Modalities Test*			X		X		X		X		X		X		
Trail Making Test (A and B)*			X		X		X		X		X		X		
Modified Boston Naming Test*			X		X		X		X		X		X		
Cognitive Change			P	P	P	P	P		P		P		P		
Cognitive Categorization			I		I		I		I		I		I		
Neuropsychological Assessments															
State-Trait Anxiety Inventory for Adults			P		P		P		P		P		P		
Geriatric Depression Scale			P		P		P		P		P		P		
QUIP			P		P		P		P		P		P		
Clinical and Biological Samples															
Clinical Lab blood sample		X													
Research Biosamples (blood + urine)			X	X	X	X	X		X		X		X		
Lumbar puncture			X		X		X		X		X		X		
Skin biopsy ^f			X				X				X			X ^c	
Imaging Activities															
Pregnancy Test (prior to tracer injection), if applicable		X			X		X				X				
Dopamine Imaging		X			X		X				X				
MRI			X		X		X				X				
Safety and General Health															
# Adverse Events		X	X		X		X		X		X		X		
Adverse Event Telephone Assessment		X	X		X		X		X		X		X		
Current Medical Conditions Review		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		
LEDD Concomitant Medication Log		As Needed													
Participation in Other Studies		As Needed													

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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 into EDC

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

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

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