



PARKINSON STUDY GROUP

The Parkinson Study Group (PSG) is a non-profit group of physicians and other health care providers from medical centers in the United States, Canada, and Puerto Rico. PSG members are experienced in the care of Parkinson patients and dedicated to clinical research of Parkinson disease, including both motor and non-motor aspects of the illness. The PSG was formed in 1986, prompted by the recognition that clinical research in Parkinson disease (PD) required the participation of large numbers of research participants under the cooperative care of skilled and experienced research physicians. **The PSG mission is to advance knowledge about the cause, disease progression and treatment of PD and related disorders.** The PSG is committed to:

- Democratic governance of its organization and activities
- Open communication on any potential conflicts of interest of the group and members
- Open communication within the scientific and patient communities
- Ensuring all research results are available to the public through peer-reviewed publication

The PSG has carried out more than 35 multi-center cooperative therapeutic research studies since 1986. Beginning with the NIH-sponsored DATATOP (Deprenyl and Tocopheral Antioxidative Therapy of Parkinsonism) clinical trial, investigators have examined the symptomatic and neuroprotective effects of experimental interventions in PD. The PSG partners with pharmaceutical companies and the NIH in bringing new drugs for PD to the market. Results from PSG studies of pramipexole, entacapone, rotigotine and rasagiline have contributed to FDA approval.

All PSG research studies (over 250 abstracts and journal articles) have been published in internationally recognized peer-reviewed journals in an effort to make all research results available to the public.

Topic-based Working Groups generate research ideas and develop proposals that are internally reviewed by the PSG Scientific Review Committee before outside funding is sought. Since their inception in 2006, the working groups have generated a dozen proposals for review, half of which have been approved to become a PSG study.

The PSG is governed by a Constitution and Bylaws and an elected Executive Committee that is primarily responsible for the direction and oversight of its research projects and activities. The PSG Executive Committee oversees all of the PSG study-specific Steering Committees, the Scientific Review Committee, the Mentoring Committee, the Nominating Committee, the Credentials Committee, the Publications Committee, the Standards Committee, the Study Budget Committee, and the Symposia Committee as well as the Working Groups. The PSG includes more than **600 investigators, coordinators and scientists from approximately 120 PSG sites located throughout the United States and Canada.** Site investigators go through a credentialing process and coordinators are reviewed to ensure that they are highly qualified to conduct clinical trials. Sites are selected for participation in PSG trials based on their experience and past performance.

PSG members are collaborators who have a lot of intellectual capital. What sets the PSG apart from the standard CRO is: (1) the respect it has in government (NIH funding) and industry; (2) its world-class expertise in the care of PD patients; (3) an infrastructure of state-of-the-art data management, study coordination, and biostatistical expertise, all of which is PD-specific; and (4) an impressive collection of “thought leaders” who are at the forefront of clinical research and trial design. The sponsor has an opportunity to contribute to publications and benefit by the dissemination of information relevant to their market. The stability of the group, sophistication of sites, ability to recruit, and additional opportunities to be involved in the organization are the strengths of the PSG.

Contact information: The PSG central operating office is located at the University of Rochester in Rochester, New York. The central office contact is Donna Moszkowicz at 585-273-2862. More information as well as a complete list of PSG publications can be found on the PSG web site at: www.parkinson-study-group.org.

PSG trials to date with citations for primary publications where applicable

	STUDY NAME	N	Sponsored by
1	DATATOP (Deprenyl & Tocopherol Antioxidative Therapy Of PD) Effects of tocopherol and deprenyl on the progression of disability in early Parkinson's disease. <i>N Engl J Med</i> 1993;328:176-183.	800	NIH (NINDS)
2	START-UP (Short Term Assessment of RO-196327 Tolerability in Untreated Parkinsonism) A controlled trial of lazabemide (RO19-6327) in untreated Parkinson's disease. <i>Ann Neurol</i> 1993;33:350-356.	201	Hoffman-LaRoche, Inc.
3	START-LE (Short Term Assessment of RO-196327 Tolerability-Levodopa Exposed) A controlled trial of lazabemide (RO19-6327) in levodopa- treated Parkinson's disease. <i>Arch Neurol</i> 1994;51:342-347.	137	Hoffman-LaRoche, Inc.
4	DATE (DATatop Extension) Impact of deprenyl and tocopherol treatment on Parkinson's disease in DATATOP subjects not requiring levodopa. <i>Ann Neurol</i> 1996;39:29-36. Impact of deprenyl and tocopherol treatment on Parkinson's disease in DATATOP patients requiring levodopa. <i>Ann Neurol</i> 1996;39:37-45.	560	Somerset Pharmaceuticals, Inc.
5	ROADS (RO-196327 Assessment and Dose Finding Study) Effect of lazabemide on the progression of disability in early Parkinson's disease. <i>Ann Neurol</i> 1996;40:99-107.	321	Hoffmann-LaRoche, Inc.
6	BLIND-DATE (BLINDED DATatop Extension) Impact of sustained deprenyl (selegiline) in levodopa-treated Parkinson's disease: a randomized placebo-controlled extension of the deprenyl and tocopherol antioxidative therapy of parkinsonism trial. <i>Ann Neurol</i> 2002;51(5):604-12.	369	Somerset Pharmaceuticals, Inc.
7	STEP-UP (Safety, Tolerability and Efficacy of Pramipexole in Untreated Parkinsonism) Safety and efficacy of pramipexole in early Parkinson disease: A randomized dose-ranging study. <i>JAMA</i> 1997;278:125-130.	264	The Upjohn Company
8	DATE-MATE (Caregiving study of spouses of DATATOP subjects) Living with a person who has Parkinson's disease: The spouse's perspective by stage of disease. <i>Mov Disord</i> 1998;13:20-28.	321	Med Res Fd of Oregon, APDA
9	DOPASCAN (Phase II Study of the Sensitivity and Specificity of DOPASCAN™ Injection) A multicenter assessment of dopamine transporter imaging with DOPASCAN/SPECT in parkinsonism. <i>Neurology</i> 2000;55:1540-1547.	96	Guilford Pharmaceuticals, Inc.
10	SEESAW (Safety Efficacy of Entacapone Study Assessing Wearing Off) Entacapone improves motor fluctuations in levodopa-treated Parkinson's disease patients. <i>Ann Neurol</i> 1997;42:747-755.	205	Orion-Farmos, Inc.
11	PSYCLOPS (PSYchosis and CLOzapine in Parkinson'S Disease) Low Dose Clozapine for the treatment of drug-induced psychosis in Parkinson's disease. <i>N Engl J Med</i> 1999;340:757-763.	60	FDA, Orphan Drug Division
12	CALM-PD (Study of Pramipexole and Carbidopa-Levodopa in the TreatMent of PD) Pramipexole vs levodopa as initial treatment for Parkinson disease: A randomized controlled trial. <i>JAMA</i> 2000;284:1931-1938.	301	Pharmacia & Upjohn, Inc.
13	PRIME (PRamipexole In Minorities Efficacy) Pramipexole in levodopa-treated Parkinson disease patients of African, Asian and Hispanic heritage. <i>Clinical Neuropharmacology</i> 2007;30(2):72-85	144	Pharmacia & Upjohn, Inc.
14	RAMP (Remacemide As Monotherapy in Parkinson's Disease) A multicenter randomized controlled trial of remacemide hydrochloride as monotherapy for PD. <i>Neurology</i> , 2000;54:1583-1588.	200	Astra Merck Inc.
15	SPIRAL (Pharmacokinetic Interactions between Remacemide & Levodopa) The impact of remacemide hydrochloride on levodopa concentrations in Parkinson's disease. <i>Clin Neuropharmacol</i> 1999;22:220-225.	16	Astra Merck Inc.
16	REAL (REmacemide as Adjunct to Levodopa) A randomized, controlled trial of remacemide for motor fluctuations in Parkinson's disease. <i>Neurology</i> 2001;56:455-462.	279	Astra Merck Inc.
17	DARE (Dyskinesia And Remacemide Effects) Evaluation of dyskinesias in a pilot, randomized, placebo-controlled trial of remacemide in advanced Parkinson disease. <i>Arch Neurol</i> 2001;58:1660-1668.	40	Astra Merck Inc.
18	TEMPO (Rasagiline Mesylate (TVP-1012) in Early Monotherapy for PD Outpatients) A controlled, randomized, delayed-start study of rasagiline in early Parkinson's disease. <i>Arch Neurol</i> 2004;61:561-566.	404	Teva Pharmaceutical Industries
19	ELLDOPA (Earlier vs. Later L-DOPA in Parkinson's Disease) Levodopa and the progression of Parkinson's disease. <i>N Engl J Med</i> 2004;351:2498-2508.	361	NIH (NINDS)
20	TEST-PD/RETEST-PD (Tolerability & Efficacy of SIB-1508Y Therapy) Randomized placebo-controlled study of the nicotine agonist SIB-1508Y in Parkinson disease. <i>Neurology</i> 2006;66:408-410.	32/45	SIBIA Neurosciences, Inc.
21	QE2 (Coenzyme Q10 Evaluation-2) Effects of coenzyme Q10 in early Parkinson disease: Evidence of slowing of the functional decline. <i>Arch Neurol</i> 2002;59:1541-1550.	80	NIH (NINDS)
22	PROGENI (Parkinson's Research: The Organized GENetics Initiative) Linkage stratification and mutation analysis at the <i>parkin</i> locus identifies mutation positive Parkinson's disease families. <i>J Med Genet</i> 2002;39:489-492.	900	NIH (NINDS)
23	PATCH I (Parkinson's Dis Transdermal Clinical Trial Helping to Assess SPM-962 TDS) A controlled trial of rotigotine monotherapy in early Parkinson's disease. <i>Arch Neurol</i> 2003;60:1721-1728.	242	Schwarz Pharmaceuticals
24	RAPID (Comparing TV-1203/Carbidopa Tablets with Levodopa/Carbidopa (LD/CD) Tablets) in Advanced PD Patients with Motor Fluctuations A randomized controlled trial of etilevodopa in patients with Parkinson disease who have motor fluctuations. <i>Arch Neurol</i> 2006;63:210-216.	327	Teva Pharmaceutical Industries
25	PRESTO (Parkinson's Rasagiline: Efficacy, Safety in Treatment of "Off") A randomized placebo-controlled trial of rasagiline in levodopa-treated Parkinson's disease patients with motor fluctuations. <i>Arch Neurol</i> 2005;62:241-248.	472	Teva Pharmaceutical Industries
26	POETRY (Parkinson's Dis On EsTrogen Replacement in the Menopause Years)	30	Newman Philanthropic Fund, Wyeth & Novartis
27	FOUND (FOLLOW-Up of Persons with Neurologic Diseases)	450+	Parkinson's Disease Foundation
28	CONCEPT (CONtrolled Evaluate Pharmacokinetics, Tolerability, Safety CEP-1347) The safety and tolerability of a mixed lineage kinase inhibitor (CEP-1347) in PD. <i>Neurology</i> 2004;62:330-332.	30	Cephalon, Inc. & Lundbeck
29	CEPCIT (Evaluate Effect of CEP-1347 on [123] b-CIT uptake in SPECT Imaging)	8	Cephalon, Inc. & Lundbeck
30	PRECEPT (Parkinson Research Examination of CEP-1347 Trial) Mixed lineage kinase inhibitor CEP-1347 fails to delay disability in early Parkinson disease. <i>Neurology</i> 2007;69:1480-1490.	806	Cephalon and H. Lundbeck
31	QE3 (Effects of Coenzyme Q10 in Parkinson's Disease – Phase 3)	600	NIH (NINDS)
32	PostCEPT (A Longitudinal Observational Follow-up of the PRECEPT Study Cohort)	575	NIH (NINDS); Cephalon; Lundbeck
33	PROBE (Blood α-Synuclein, Gene Expression, and Smell Testing as Diagnostic and Prognostic Biomarkers in Parkinson's Disease)	100	U.S. Department of Defense
34	PramiBID (A randomized, double-blind, active (pramipexole 0.5 mg tid) and placebo controlled, efficacy study of pramipexole, given 0.5 mg and 0.75 mg bid over a 12-week treatment phase in early PD patients) – publication is in press. Twice-daily, low-dose Pramipexole in early PD: A randomized, placebo-controlled trial. <i>Mov Disord</i> 2010; DOI: wileyonlinelibrary.com. DOI: 10.1002/mds.23396	311	Boehringer Ingelheim
35	SURE-PD (Safety and Ability to Elevate Urate in Early Parkinson's Disease)	90	Michael J. Fox Foundation
36	STEADY-PD (Safety, Tolerability, and Efficacy Assessment of Dynacirc CR for PD)	100	Michael J. Fox Foundation
37	SPIN-PD (Spectroscopy in Parkinson Disease Diagnosis)	500	Molecular Biometrics, Inc.

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