

STEADY-PD III STAR



News for STEADY-PD III participants and their families

Volume 1, Issue 1

Winter 2016

Dear STEADY-PD III Participants and Family Members:

Welcome to our first edition of the STEADY-PD III Star newsletter. We are pleased to announce that we have met our enrollment goal and have enrolled 336 participants in the STEADY-PD III study. Recruitment and enrollment are closed.

We would like to extend our warmest thanks and appreciation to all participants, their family members for your dedication and commitment to this important study. It's the cooperative spirit and a commitment to Parkinson Disease research that will lead to better treatments for PD.

Clinical trials are the most important tool we have to gather information and gain a deeper understanding of Parkinson Disease and without your participation this would not be possible.

The value of your participation has become even more important as we are entering the study maintenance phase. It is essential for the success of the study to retain as many participants as possible in the study.

We hope you enjoy reading the newsletter which has been created to bring you up-to-date news on STEADY-PD III and the Parkinson Disease community. We look forward to your continued support in the years ahead. Please let us know your questions and concerns.

Sincerely yours,

Thank You

STUDY OBJECTIVES

Please remember that the goal of this study is to establish efficacy of Isradipine to slow progression of Parkinson Disease (PD) disability as determined by the change in the total UPDRS score in the active treatment arm versus placebo between baseline and 36 months in the medications ON state (approximately 1 hour after first dose of symptomatic therapy, if applicable).

We know that remembering to take the study medication (5mg) twice daily for a long period can be difficult, but your role in the study is crucial to the success of this clinical trial. Taking your study drug as directed is very important to the outcome of the study; we praise you for your time and effort.

**Enrollment Total of
336 Reached**



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Meet the STEADY-PD III Investigators



Tanya Simuni, MD
Northwestern University

- **Arthur C. Nielsen Professor of Neurology**
- **Director, Parkinson's disease and Movement Disorders Center**

Dr. Tanya Simuni graduated with her medical degree from Leningrad Medical School and completed an internship in medicine in Leningrad, Russia. Dr. Simuni subsequently completed an internship in internal medicine at Albert Einstein Medical Center and a neurology residency as well as a clinical neurophysiology fellowship at Temple University in Philadelphia, Pennsylvania.

Dr. Simuni pursued a movement disorders fellowship at the University of Pennsylvania and is board certified in both neurology and clinical neurophysiology.

Dr. Simuni is the lead investigator on a number of different clinical trials and serves on several Steering Committees for National PD clinical trials. In 2008, the Northwestern Medical Foundation honored Dr. Simuni for the Physician Excellence Award in Clinical Leadership.



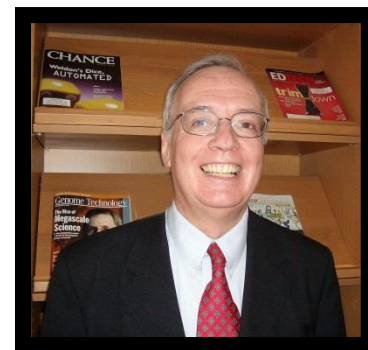
Kevin Biglan, MD, MPH
University of Rochester

- **Professor of Neurology and Associate Chair for Clinical Research**
- **Director, National Parkinson Foundation center of Excellence**

Dr. Biglan is actively involved in clinical trials aimed at identifying therapies that slow progression of Parkinson Disease and Huntington disease. He received his medical degree from Jefferson Medical College in Philadelphia, Pennsylvania.

Dr. Biglan is fellowship trained in movement disorders and provides comprehensive services to individuals with Parkinson's Disease, Huntington's Disease, tremor, dystonia and other movement disorders.

Dr. Biglan has been actively involved in the development of telemedicine for the provision of care in patients with Parkinson disease and for identifying disease modifying therapy in Parkinson's disease and Huntington's disease. He has been at the forefront of establishing the feasibility of telemedicine in Parkinson disease and Huntington disease, the expansion of its use for clinical care, and the validation of clinical trial outcomes assessed via telemedicine



David Oakes, PhD
University of Rochester

- **Professor, Department of Statistics**
- **Department of Biostatistics and Computational Biology**

Dr. Oakes is a Fellow of the American Statistical Association and of the Institute of Mathematical Statistics and an elected member of the International Statistical Institute.

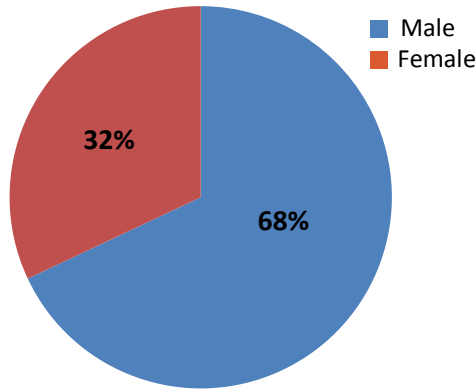
In 1972, Dr. Oakes received his PhD in Statistics at London University. After a period as Assistant Professor of Statistics at Harvard University I returned to London in 1977, he became involved in the design and analysis of epidemiologic studies of cancer and respiratory diseases, and in the education of occupational health professionals.

Since coming to Rochester in 1983, Dr. Oakes became deeply involved in clinical trials of treatments for Parkinson's disease and Huntington's disease, and in cardiology. He has worked in cardiology, infectious diseases and pediatrics.

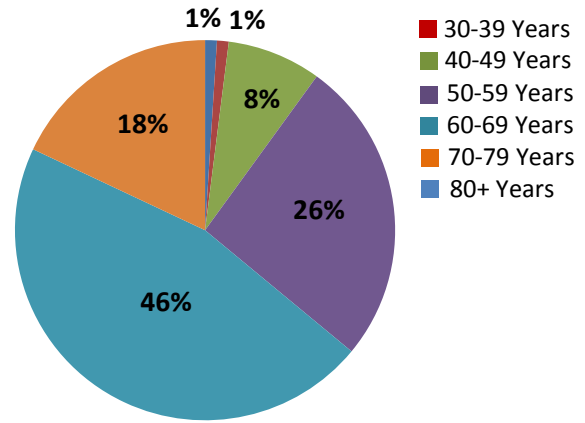
Dr. Oakes has authored or co-authored over 150 publications in medical literature. These publications include methodologic papers in the statistical and biostatistical literature as well as collaborative works.

STEADY-PD III Graphs and Statistics

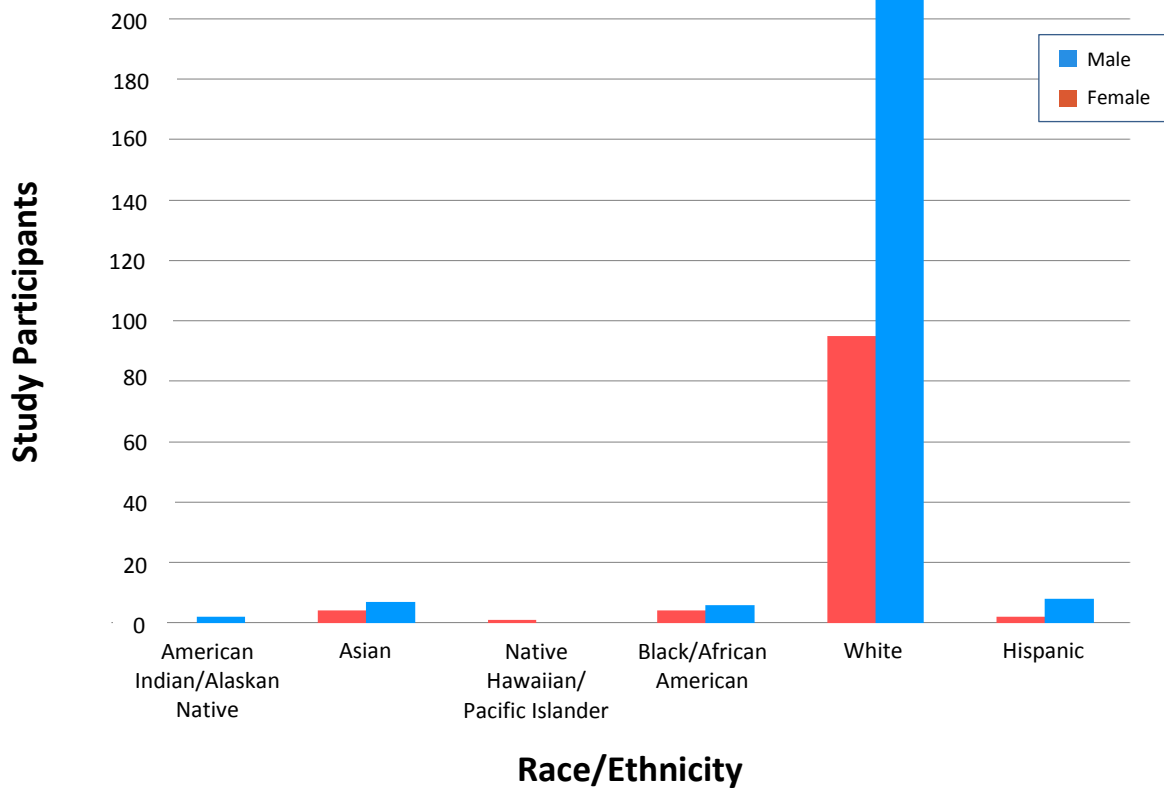
Gender Enrollment



Age Demographics



Racial Demographics of STEADY-PD III



Behind the Scenes..... Some STEADY-PD III Fun Facts

- The Clinical Trials Coordination Center (CTCC) handles project management, data management, and biostatistics for the STEADY-PD III study
- There are over 238 site staff working on the STEADY-PD III study which includes Coordinators, Investigators, Monitors, Regulatory, Labs, and other Clinical support staff
- There is a Data Safety Monitoring Board who monitor the safety of the participants and the trial that meets approximately every 6 months.
- There is a Steering Committee to provide guidance on the trial that consist of 16 members
- The CTCC Project Managers hold STEADY-PD III Site Coordinator Teleconference calls once a month to keep all site staff informed of study updates.
- STEADY-PD III Site Investigators and Coordinators are very experienced and are well trained on the protocol and amendments.
- University of Rochester's Clinical Materials Services Unit (CMSU) is the secondary packaging, labeling and distribution to sites.
- There is a Help Desk available 24 hours a day to assist sites with any Data Management issues.

"I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel." ~ Maya Angelou

STEADY-PD III Participating Sites (57)

| | |
|--|---|
| University of Rochester, NY | CHUM-Hopital Notre-Dame, CANADA |
| Columbia University, NY | University of Utah, UT |
| University of Michigan, MI | Medical College of Wisconsin, WI |
| Rush University Medical, IL | University of California Irvine, CA |
| Oregon Health Science, OR | Cleveland Clinic, OH |
| Toronto Western, CANADA | University of Maryland School of Medicine, MD |
| University of Virginia, VA | LSU Health Science Center Shreveport, LA |
| University of Miami, FL | Pacific Health Research & Education Institute, HI |
| Ottawa Hospital Civic, CANADA | Struthers Parkinson's Center, MN |
| Massachusetts General Hospital, MA | Cleveland Clinic Florida - Weston, FL |
| University of Pennsylvania, PA | Banner Research Institute, AZ |
| University of South Florida, FL | Dartmouth Hitchcock Medical Center, NH |
| Ohio State University, OH | Milton S Hershey Medical Center, PA |
| University of Nebraska, NE | University of Kentucky, KY |
| University of California, San Diego, CA | Medical University of South Carolina, SC |
| Washington University, MO | Michigan State University, MI |
| Johns Hopkins University, MD | University of Nevada School of Medicine, NV |
| University of Calgary, CANADA | University of Texas Houston Medical School, TX |
| Emory University, GA | Weill Medical College of Cornell University, NY |
| Institute for Neurodegenerative Disorders, CT | University of Minnesota, MN |
| Albany Medical College, NY | Centre Hospitalier Affilie, CANADA |
| The Centre for Addition and Mental Health, CANADA | Eastern Connecticut Neurology Specialists, CT |
| Boston University Medical Center, MA | Health Quest Kingston, NY |
| North Shore LJJ Health System, NY | Booth Gardner Parkinson's Care Center, WA |
| University of Alabama Birmingham, AL | Sentara Neurology Specialists, VA |
| The Parkinson's Movement Disorder Institute, CA | Atlantic Neuroscience Institute, NJ |
| University of California San Francisco, CA | University of Alberta Hospital, CANADA |
| Northwestern University, IL | Rocky Mountain Movement Disorders Center, CO |
| University of Cincinnati, OH | |

PSG

PARKINSON STUDY GROUP

What is the Parkinson Study Group (PSG)?

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 experienced in the care of Parkinson patients and dedicated to clinical research of Parkinson disease. 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 patients (subjects) under the cooperative care of skilled and experienced research physicians.

The PSG aims to advance knowledge about the cause(s), disease progression and treatment of PD and related disorders.

The PSG is committed to:

- Open communication within the scientific community;
- Ensuring research is peer reviewed by other health care providers prior to publication and that all research results are available to the public;
- Revealing potential conflicts of interest of the group and each PSG member and;
- Democratic governance of its organizations and activities.

Useful Links for Your Computer

National Institute of Neurological Disorders and Stroke (NINDS):

<http://www.ninds.nih.gov> http://www.ninds.nih.gov/disorders/clinical_trials/NCT02168842.htm

National Institute of Health Clinical Trials:

www.clinicaltrials.gov

The Movement Disorder Society:

<http://www.movementdisorders.org/MDS.htm>

Parkinson's Disease Foundation (PDF):

www.pdf.org

PDF Parkinson's Advocates Research PAIR:

www.pdf.org/pair

The Michael J. Fox Foundation:

www.michaeljfox.org

National Parkinson Foundation:

www.parkinson.org

Parkinson's Action Network:

<http://www.parkinsonsaction.org>

Parkinson Study Group:

www.parkinson-study-group.org/

World Federation of Neurology:

www.wfneurology.org/

If you would like a topic presented in the next STEADY-PD III newsletter, notify your site coordinator. We will do our best to provide this information. All submissions will be anonymous and your privacy will be protected.