22nd Annual Symposium

The 22nd Annual Symposium on Etiology, Pathogenesis, and Treatment of PD and Other Movement Disorders was held on Sunday, September 21, 2008 at The Grand America Hotel in Salt Lake City, Utah in association with the ANA meeting. This year the planning committees changed the format somewhat to have complementary keynote presentations on PD and HD with a panel discussion to follow. The audience enjoyed this very much.

Dr. Web Ross delivered his keynote on “Prodromal Features of Parkinson’s Disease in the Honolulu-Asia Aging Study”. Dr. Jane Paulsen followed with a presentation on “Biological and Clinical Markers of Huntington’s Disease before Diagnosis: The PREDICT-HD Study”. A lively panel discussion with audience participation followed to address the challenges involved in early detection and potential treatment of Parkinson’s disease and Huntington’s disease. The panel experts, Dr. Karl Kieburtz and Dr. Carlie Tanner along with Drs. Siderowf and Cha, the committee chairmen, provided excellent information that the audience could use in treating patient’s with PD and HD.

After a short break, the program continued with 6 platform presentations on research regarding Parkinson’s disease and other movement disorders with 2 presentations on late-breaking research in these areas. The audience enjoyed lunch as they attended the poster session where 24 posters were presented.

The award for the best PD abstract went to Dr. Tanya Simuni for her abstract on “Safety and Tolerability of Isradipine, a Dihydropyridine Ca Channel Antagonist, in Patients with Early PD”. The award for the best OMD abstract went to Dr. Raymond Lo for his abstract on “Minimum Incidence of Primary Task-Specific Focal Hand Dystonia”. We congratulate all platform and poster presenters on a job well done. All abstracts have been published in the August issue of Movement Disorders and is available on-line at: http://www3.interscience.wiley.com/journal/121395705/issue.

This program was supported by the following sponsors and contributors: Amicus Therapeutics, Inc., Elan Pharmaceuticals, Inc., EMD Serono, Inc., FP Pharmaceutical Corp., Kyowa Pharmaceutical, Inc., NeuroSearch, Ortho-McNeil Neurologics, Inc., Teva Neuroscience, UCB, Inc., Asubio Pharmaceutica, Inc., Biogen Idec, FoldRx Pharmaceuticals, Inc., Ipsen Pharmaceuticals, Inc., Medtronic Neuromodulation, Valeant Pharmaceuticals North America, Allergan, Inc., and Genentech. This program would not be possible without their generous support.

The Organizing Committees are especially appreciative to the following individuals for their assistance in the preparation of this symposium: Roseanna Battista, Leslie Briner, Donna Moszkowicz, Karen Rabinowitz, Alice Rudolph, Julie Ratzloff of the ANA and Linda Caples of the MDS. The Movement Disorder Society designated this educational activity for a maximum of 3.25 CME credits. CME certificates were issued to 45 physicians claiming credit commensurate with the extent of their participation in the program.

Plans will be underway soon to coordinate next year’s symposium which will be held on Sunday, October 11, 2009 at the Baltimore Marriott Waterfront Hotel in Baltimore, Maryland in association with the ANA annual meeting. Drs. Roger Albin and Jang-Ho Cha, Chairs of the PSG and HSG Symposia Committee, will be in charge this year. Call for Abstracts will be out February/March 2009 and advertised in major journals.
CLINICAL RESEARCH LEARNING INSTITUTE

On July 12th through 14th, 2008, in Glen Cove, New York, a groundbreaking meeting took place that has the potential to improve the clinical trials process for future Parkinson’s disease (PD) treatments. The inaugural Clinical Research Learning Institute, was not a scientific gathering, but an intensive multi-day training designed to provide community leaders who have Parkinson’s with the knowledge and skills necessary to become engaged as effective patient representatives within the clinical research process. PSG was proud to be involved in both the planning and programming of this meeting.

Enhancing the role of the public in the clinical research enterprise, a strategic imperative of the National Institutes of Health, is becoming more widely recognized as a critical variable in building public trust in and support for research, as well as reducing barriers in moving research from bench to bedside. The Clinical Research Learning Institute (CRLI) – developed and implemented by the Parkinson’s Disease Foundation – aims to prepare people with Parkinson’s to engage in such activities as: educating the broader community about the importance of clinical research; providing research investigators and sponsors with input on the design; implementation and evaluation of clinical trials; providing input to federal agencies on clinical study oversight and approval; and serving on local Institutional Review Boards (IRBs) and Data Safety Monitoring Boards (DSMBs).

“I was very impressed by the interest demonstrated by CRLI participants in learning more about clinical trials in PD. They all took the exercises and information presented very seriously, and I think gained some essential skills to take to their respective communities,” said Joohi Jimenez-Shahed. Joohi was joined on the CRLI planning committee by Aviva Abosh, Maureen Cook, Christine Hunter, Patricia Kavanagh, Irene Hegeman Richard, Mickie Welsh and Lin Zhang, as well as eight people with Parkinson’s (PWP).

PWP’s in attendance were not the only beneficiaries of the formal sessions at the CRLI. “The presentation from which I gained the most was that of Mike McDermott (Analysis and Evaluation of Clinical Research). He presented statistics in a way that was very useful and understandable. In the context of the PSG, I think all coordinators, especially the newer ones, would benefit immensely. Who knew a statistician could have a sense of humor!” stated Christine Hunter. Other PSG members who provided their expertise as faculty included: Mark Stacy (Parkinson’s Disease and Clinical Research); Bernard Ravina (Clinical Research 101); Scott Kim (Ethical Controversies in PD Research); Mickie Welsh (The Rights and Responsibilities of Clinical Research Participants); Maureen Cook (Deciding to Participate in Clinical Research); and Joohi Jimenez-Shahed, Christine Hunter and Karen Marder (Current Issues in Clinical Research).

When the CRLI concluded, all those who participated—people with Parkinson’s, faculty, planning committee members and PDF staff—left with new knowledge, perspectives and excitement about working together in the future. “My fondest memory of the CRLI (process) was the opportunity to bring together a significant group of people with Parkinson’s and those of us who work to serve them. Though I do this on a daily basis, it is more of a one to one experience. The intensity of the Learning Institute environment provided all of us with the opportunity to truly share our experiences and knowledge with each other. I feel that the length and breadth of the course provided true learning and growth for all who participated,” recalled Mickie Welsh. This sentiment was echoed by Patricia Kavanagh, “I think the Clinical Research Learning Institute bridged the gap between physician/researcher and patient/subject/advocate/caregiver better than any other event I have been part of – it was a real advance.“

PDF is working closely with CRLI graduates as they identify opportunities to become engaged in the clinical research process and will be monitoring the impact of this new program. For more information, please contact Ronnie Todaro, MPH, Director of National Programs at the Parkinson’s Disease Foundation, at rtodaro@pdf.org or (800) 457-6676.

Please see more pictures on page 7.
Study Updates

APLIED
by Karen Hodgeman
A new PSG study, APLIED (A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Three Doses of Aplindore MR (1, 3, and 6mg BID) in Patients with Early PD is recruiting subjects to participate. APLIED is being conducted to evaluate safety, efficacy and tolerability of aplindore in the treatment of early-stage PD. Aplindore is a new dopamine receptor partial agonist. The study will also look at how aplindore affects mood, thinking and memory, behavior, impulse control and daytime sleepiness. Men and women who are at least 30 years old and who have been diagnosed with PD within the last 5 years are invited to participate.

Approximately 42 sites within the U.S. will enroll roughly 5 subjects per site. A total of 168 subjects are expected to be enrolled. The study is sponsored by Neurogen Corp and is led by Ira Shoulson and Karen Marder.

SURE-PD
by Alice Rudolph
SURE-PD (Safety of URate Elevation in Parkinson’s Disease) held its Orientation Meeting September 7-9. The protocol and data forms funded by the Michael J. Fox Foundation are being finalized, and we anticipate FDA and IRB approval to distribute study materials at the end of December and begin enrolling in January.

QE3
by Rory Doolan
The QE3 study team has been working diligently to initiate participating sites in preparation for delivery of study drug in December. Enrollment is poised to begin early 2009. The objective of this study is to evaluate the safety and effectiveness of high dosages of CoQ (2400 mg and 1200 mg vs placebo) in slowing clinical decline in patients with early PD. Participants, who will be followed every 4 months over a 16 month period, must be diagnosed with PD within the last 5 years and not yet receiving dopaminergic therapy.

PramiBID
by Alice Rudolph
On September 25th the final subject visit was conducted for PramiBID (A randomized, double-blind, active 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). We congratulate and send our appreciation to the investigators, coordinators, and data entry and regulatory documents staff at the 40 sites that screened/enrolled 311 subjects. We anticipate locking the database and beginning the analysis in the next few weeks.

PROGENI
by Cheryl Halter
At the annual PSG meeting in May of 2008 Dr. Tatiana Foroud from Indiana University invited all PSG investigators and coordinators not participating in other genetic studies to join the PROGENI study. She is pleased to announce the addition of 6 new and 4 returning PSG sites into the study. The enrollment criteria for the PROGENI study have been expanded to include any individual with PD who also has at least one first degree relative (parent, sibling, child) with PD. These expanded criteria have resulted in a boost in recruitment, with the study having already completed 1742 Study Visits, with an additional 40 visits being scheduled. Dr. Foroud is pleased to announce that the study has published several new manuscripts. Results from analyses reviewing depression in PD and the role of glucocerebrosidase (GBA) were recently accepted for publication. In addition, the PROGENI study has recently completed a genewide association study in conjunction with Dr. Richard Myers, the leader of the GenePD Study. Results of these analyses were recently published. The study continues to perform analyses to identify novel genes contributing to the risk for PD.

PostCEPT, PROBE and LABS-PD
by Emily Flagg
PostCEPT (A Longitudinal Observational Follow-up of the PRECEPT Study Cohort) is continuing into the second year of follow up visits. In addition to the clinical data that are being collected, sites have submitted over 380 DNA samples to the NINDS Human Genetics DNA and Cell Line Repository at Coriell Institute for Medical Research, which will catalogued at Coriell and made available to other researchers. Subjects are also continuing to be imaged by the team at the Institute for Neurodegenerative Disorders in New Haven, CT as continued follow up to the imaging they received in the PRECEPT study.

PROBE (Blood α-Synuclein, Gene Expression, and Smell Testing as Diagnostic and Prognostic Biomarkers in Parkinson’s Disease) is in the final stages of recruitment and enrollment, with an anticipated completion by end of year 2008. We have enrolled a total of 102 PD, 27 MSA, 26 PSP and 47 Healthy Control subjects. Analyses of the biomarker research labs are planned to take place over the first quarter of 2009.

LABS-PD (Longitudinal and Biomarker Study in PD) is being established as an umbrella project to reflect the broader biomarker objectives and longitudinal design of the expanding cohorts contributing to this study (PostCEPT, PROBE, FOUND, as well as future cohorts like QE3). LABS-PD represents an ongoing longitudinal study aimed at providing researchers with prospectively accrued and de-identified clinical and imaging data that can be correlated with publicly accessible biological material (eg, DNA already obtained) and shared data pertaining to the natural history of early PD.
My overarching goal is to improve the lives of patients with Parkinson’s disease (PD) using multidisciplinary, translational research. The privilege of being a clinician involved in all aspects of PD care (from diagnosis to surgical treatment) has given me a broad perspective on the complexity of the disease, and an appreciation of the disabling cognitive and behavioral aspects of PD. Clinician-scientists, with their unique combination of clinical acumen and understanding of scientific principles, have a central role in translational research in generating the research questions, building multidisciplinary teams to collaboratively develop methods for assessment and treatment, and interpreting the results in the clinical context. Throughout my career, I have aspired to be a clinician-scientist.

I am currently the principal investigator of two federally funded translational, multidisciplinary research studies on driving safety and effects of aerobic exercise on cognition and function in PD. Upon my return to the Neurology Department at the University of Iowa, where I had done my neurology residency and movement disorders fellowship with Dr. Rodnitzky, I joined the Neuroergonomics team (Drs. Matthew Rizzo-behavioral neurologist, Steve Anderson-neuropsychologist, Jeffrey Dawson-biostatistician) in 2001. A University of Iowa Carver College of Medicine/College of Public Health New Investigator Research Award enabled us to conduct a pilot study and paved the way for an R01 award from the NINDS to study driving impairment in PD. In this longitudinal study, we use a battery of measures covering different aspects of PD in addition to experimental drives in an instrumented vehicle on the road and in a driving simulator and state driving records to determine the associations of different aspects of PD with driving performance and outcomes. We are finding that cognitive and visual dysfunction has a prominent contribution to reduced driving performance and safety in PD.

My interest in aerobic exercise and PD started as a complete serendipity in 2005. I heard a talk by Dr. Arthur Kramer (Beckman Institute, University of Illinois, Urbana-Champaign) during a symposium on Geriatric Mobility. He reported that a modest improvement in cardiac fitness using a brisk walking program improved executive functions and visuospatial abilities in normal sedentary elderly, accompanied by changes in biologic markers, brain function, and structure. I introduced myself and proposed collaboration to use similar paradigms in PD, as executive and visual dysfunction can be disabling even in early PD. In a cross-sectional pilot study, we found that various cognitive functions were associated with cardiac fitness independent of age, education, and motor severity of PD. We have recently been funded by the Merit Review Program of the Rehabilitation Research and Development Service, US Dept of Veterans Affairs to study effects of different aerobic exercise programs on cognition in PD in a Phase I/II trial using neuropsychologic measures, biomarkers, and functional and volumetric MRI.

The Parkinson Study Group (PSG) embodies all the tenets of multidisciplinary, translational research and is a great organization for a clinician-scientist to flourish. The pioneers of the PSG represent great role models to emulate for junior clinician-scientists. There is a lot to learn from the structural organization of PSG to establish successful translational research enterprise. New committees and working groups were established under Karl’s and Karen’s leadership, which institutionalized PSG’s commitment to foster junior faculty development, to promote investigator initiated research by a rigorous review process and grant support for data mining of its powerful clinical trial databases. I have been fortunate to participate in this effort by being a member of the Scientific Review Committee and a co-chair of the Cognition/Behavior Working Group.

I have been leading the project on the incidence and predictors of dementia (Dr. McDermott statistical co-PI, Drs. John Growdon, Karen Marder, and other members of the Working Group) and depression (also with contributions from Drs. Laura Marsh and Daniel Weintraub) in the DATATOP study, funded by a data mining grant by the Parkinson’s Disease Foundation. In addition to confirming known predictors, we have found potential novel risk factors for dementia such as early bulbar function and autonomic dysfunction. I presented our data on dementia at the 2008 PSG meeting and at the Derek Denny-Brown Symposium at the 2008 annual meeting of the American Neurological Association. I am very excited to coordinate the effort to organize the Second Annual Clifford W. Shults Symposium: Cognitive & Psychiatric Aspects of Parkinson’s Disease for the 2009 PSG meeting in San Diego. I hope that this symposium will further enhance the awareness about the cognitive and behavioral aspects of PD, increase their incorporation into outcome measures, and lead to new PSG clinical trials in this field.

Ergun Y. Uc is an Associate Professor of Neurology at Carver College of Medicine, University of Iowa, VA Medical Center in Iowa City. Dr. Uc has been a PSG member since 2000.
Credentials Committee

The Credentials Committee has credentialed 22 new investigators to the PSG from February to October of this year, 3 new sites 2 of which are representing new states to the PSG. We welcome the following investigators and coordinators:

James Boyd, MD, U of Vermont, Burlington, VT
Murray, P. Andrews, A. Wilson, coordinators
Edward Burton, MBChB, MD, U of Pittsburgh, PA
Larry Ivance, coordinator

New Sites:
Anwar Ahmed, MD, The Cleveland Clinic, Ohio Patricia St. Marie, coordinator
Lauren Seeberger, MD, Elks Rehab Hosp, Idaho Lisa Vogt-Feusi, coordinator

Scientific Review Committee

The Scientific Review Committee reviewed 8 proposals submitted in response to the RFP of August 15, 2008. Dr. Robert Hauser's proposal on “Determination of Minimally Clinically Important Change in Early and Advanced PD” was funded. Dr. Alberto Ascherio’s proposal on “Urate-related genes and PD progression” was approved as a PSG study and funding has been obtained by NIH/NINDS. The committee also was busy with fast-tracked reviews for the APLIED and LABS-PD studies.

We also want to congratulate Andrew Siderowf and the Genetics/Environmental Risk Working Group for obtaining funding from the National Parkinson’s Foundation for their research proposal entitled “Impact of commonly-prescribed medications on PD progression”.

Mentoring Committee

The PSG is requesting proposals for the Mentored Clinical Research Award (MCRA). Deadline for submissions is March 27, 2009. The MCRA is an annual award program funded by a grant from the Parkinson’s Disease Foundation to the PSG. This year funding is available for two awards of $75,000 each. The purpose of this grant is to support a new investigator for a 1 year project in patient oriented research in PD or other parkinsonian disorders under the mentorship of an experienced investigator with the goal of making this individual an independent researcher. Please visit the PSG web site for further information.

Standing Committees

A Repository Committee is being formed to address the use, storage and continuing ability to use irreplaceable repositories (data, DNA, CSF, etc). The current list of standing committees and members serving is posted on the PSG web site.
Calendar of Events

April 27, 2009
PSG MENTORING COMMITTEE NEW INVESTIGATORS FORUM, at AAN Annual Meeting, Seattle, Washington. Invitations and registration information will be sent out soon. Contact Roseanna Battista for more information at: roseanna.battista@ctcc.rochester.edu.

May 27-29, 2009
PSG 21st ANNUAL MEETING, Coronado Island Marriott Resort, Coronado, CA (San Diego). Invitations and registration information will be sent out to members and invited guests in April 2009. Contact Donna Moszkowicz for more information at: donna.moszkowicz@ctcc.rochester.edu.

October 11, 2009
23rd ANNUAL PD/OMD SYMPOSIUM, at ANA Annual Meeting, Baltimore, Maryland. Call for Abstracts to be out February/March 2009. Contact Roseanna Battista for more information at: roseanna.battista@ctcc.rochester.edu.

September 28-October 1, 2010
WORLD PARKINSON CONGRESS, Glasgow, Scotland. Learn more at: www.worldpdcongress.org or contact Elizabeth “Eli” Pollard, Congress Manager, at info@worldcongress.org. PSG is proud to be an organizational partner of this event.

Comments? Questions?

Please let us know...your comments and questions will be kept confidential. We also welcome your feedback on the newsletter and your ideas for topics for future newsletters.

Please send all correspondence to Roseanna Battista, roseanna.battista@ctcc.rochester.edu or contact Karl Kieburtz at karl.kieburtz@ctcc.rochester.edu or Karen Marder at ksm1@columbia.edu.

Wishing you all a happy and healthy Holiday Season and New Year!
Pictures from the Clinical Research Learning Institute, July 2008

Lin Zhang, MD, PhD and Jim Doria

Scott Kim, MD, PhD and Celeste Stoddard

Maureen Cook, RN, BSN and Lin Zhang, MD, PhD

Neil Davis and Bernard Ravina, MD

Tony DeCamp, Ken Cater and Christine Hunter, RN, CCRC

Patricia Kavanagh, MD, Michael O'Leary and Linda Cooper-O'Leary