



Connecticut Parkinson's Working Group Newsletter

Editor: Stan Wertheimer Stan.wertheimer at gmail.com

Interview Editor: Jeff Lincoln

Distribution: Pam Lincoln, Pat Gerace

Design: Alyssa Morin

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CONTENTS:

Special Edition of the Newsletter	1	Access before Approval — A Right to Take Experimental Drugs?	5
Meeting Times Changed	1	Parkinson's Disease Research in Connecticut: The Vital Role of Clinical Trials Itinerary	6
Introduction to the Participants in the Forum	2	Registration Form	7
What is a Clinical Trial?	4		
First Website on Parkinson's Clinical Trails Unveiled.....	4		
Where to Go to Find Out More	5		

MEETING TIMES CHANGED

The meeting times for the first half of the year are January 13, March 3, and May 19. The January and May meetings will be at the Middlesex Hospital at 10:30, as usual; the March meeting is the Forum on Clinical Trials, and will be at the UConn Health Center in Farmington at 10:30 A.M. If we have any Meetings on the Move dates and times will be announced and you will receive notification by mail.

SPECIAL EDITION OF THE NEWSLETTER

Stan Wertheimer

This is a special edition of the newsletter, although it may look like most of our recent issues; we will address a single topic in several ways, but all articles will have that topic as their focus, or one of their foci. That topic is Clinical Trials. In addition there will be two parts to this edition, this being Part 1; Part 2 will follow in a few weeks.

Some of you have participated in one, or more, over the course of your involvement with PD, but I imagine most have not. It is an alarming statistic that PWP volunteer in fewer numbers for clinical trials (c/t) than most other folks with a chronic disease. One reason may be that many of us believe c/t are too dangerous for one to even consider; another is ignorance of c/t and the lack of an easy way to become more knowledgeable. Before I go any further let me state an obvious fact:

A doctor will use no new drug or procedure for PD legally unless it has proceeded through the clinical trial vetting system.

This is analogous to a person having to get a valid driving license before she can drive a car legally. No license, no driving. No c/t, no drugs or procedures. If this puts c/t in a better perspective for us, good. Other interesting facts about c/t are:

- recruiting people for c/t is extremely expensive;
- recruiting people for c/t is extremely time consuming;
- sometimes people who are borderline acceptable are accepted in a c/t.

The ramifications of this is that there is less money for the research, less time for the research, and, perhaps the worst situation, a person in the c/t suffers irreversible damage because he should have been rejected; this

is not only an unacceptable outcome but one which may keep an excellent remedy from the public. To put the same conclusions in a positive light: If more PWP volunteered for c/t, dollars that are now spent for recruiting would be spent on research; new and beneficial drugs and protocols would come to the market much faster; there would be many fewer negative side effects and people dropping out of the trial. It often happens that a volunteer gets access to a beneficial drug or procedure before it comes to market, a definite personal plus. Also, one is in close contact with research and those doing it, which can only be beneficial for the person when it comes time to select participants in c/t for these.

Do I detect a low rumble coming from somewhere far away as entrenched notions start to tumble and crumble — a sort of crumbling tumbling rumble. It is the rumble of a mind accepting alternative ideas. Listen to it; if it gets louder as you read through the newsletter we will have done our job.

We are not going to try to convince you of any position on c/t, rather to convince you to consider other positions than those you have.

Of course you may already be there, in which case have a good read.

We will present articles on what c/t are, the phases of c/t, the pros and cons of participating, who does them, some actual histories of trials, and much more. It is not a coincidence that CPWG is sponsoring a forum on c/t on March 3 at UConn. We hope that you and others close to you can join the audience. See the announcement and registration form later in this issue.

INTRODUCTION TO THE PARTICIPANTS IN THE FORUM

We will introduce the people you will hear at the Forum; in Part 2 of the newsletter we will have interviews with these same folk that were conducted by Jeff Lincoln.

Dr. Adam Simmons UCONN Health Center

CAREER HIGHLIGHTS

May 2001 University of Pennsylvania School of Medicine, Philadelphia, PA — Doctor of Medicine

2001–June 2002 MetroHealth Medical Center, Case Western Reserve University, Cleveland

July 2002–June 2006 Beth Israel Deaconess Medical Center, Harvard University, Boston, MA — Neurology Residency (02–05), Movement Disorders Fellowship (05–06)

RESEARCH: EXPERIENCE/INTERESTS

- Research Associate, Applied Neural Control Lab. Explored the effects of deep brain stimulation on the thalamus
- Designed software for the simulation of stimulation with an external electrode
- Designed a virtual thalamic relay neuron using NEURON simulation software



Dr. J. Antonelle de Marcaida

CAREER HIGHLIGHTS

1982-1990 Integrated Bachelor of Science and Doctor of Medicine Program — University of the Philippines College of Medicine

1996-1999 Neurology Residency — University of Connecticut-Hartford Hospital Program

1999-2001 Fellowship, Experimental Therapeutics and Movement Disorders — University of Rochester-Strong Memorial Hospital

RESEARCH: EXPERIENCE/INTERESTS

- Present: Director, Movement Disorders Program Assistant Professor, UCONN School of Medicine
- Publications: Over 20 — mainly Movement Disorders
- Research: Over 20 Clinical Trials
- Presentations: dozens to all different types of audiences



Dr. Mohamed N. Hassan
UCONN and Hartford
Hospital



CAREER HIGHLIGHTS

MB,Ch.B University of Leeds,
U.K. 1973

Board Certified in Neurology at
the University of Ottawa, 1980

Ph.D. in Neuropharmacology —
Columbia University, 1984

Studies in Movement disorders — Columbia University,
1983-1984

RESEARCH: EXPERIENCE/INTERESTS

- Founder/Director of the Ottawa Parkinson's Disease Research Laboratory.
- Initiated the Movement Disorder Clinical and Research Facility, 2000
- Over 25 years clinical experience
- Over 100 publications in Medical and Scientific Journals in Canada, Europe and the USA.

Dr. Danna Jennings
Institute for
Neurodegenerative
Disorders



CAREER HIGHLIGHTS

1988 Oregon Health Sciences
Univ, School of Nursing, BSN

1992 Oregon Health Sciences
Univ, School of Medicine, MD

1992-1993 Internal Medicine
Internship, Boston City Hospital

1993-96 Neurology Resident, Boston University Medical
Center

1995-96 Neurology Chief Resident, BU Medical Center

1996-1998 Movement Disorders Fellow, Columbia
Presbyterian, NY

1998-2001 Asst Professor of Neurology, Yale University

1998-2001 Attending Physician, Dept. of Neurology, Yale

2001-present Research Director, Institute for
Neurodegenerative Disorders

2001-present Research Director, Molecular
NeuroImaging, LLC

RESEARCH: EXPERIENCE/INTERESTS

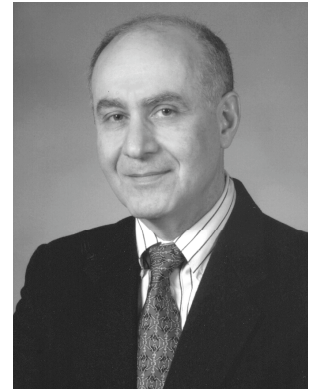
Early diagnosis of Parkinson's disease, Use of brain
imaging in Parkinson's disease

Dr. Bahman Jabbari
Yale University

M.D. — Tehran University
School of Medicine — 1996

Present Position — Professor of
Neurology, Yale University
School of Medicine and Director
of PD and Movement Disorders
Program.

Over 30 years experience with
PD (predates Sinemet)



RESEARCH: EXPERIENCE/INTERESTS

- PD and other movement disorders
- Therapeutic role of Botulinum toxins in clinical
Medicine
- Sleep Medicine
- Epilepsy
- Electrophysiology (EEG, EMG, DBS, VNS)

Present Grants

- Efficacy of Botulinum toxin A (3 studies)
- fMRI in PD patients with Dyskinesias
- Publications: Over 180 Manuscripts and Published
Extract

Dr. John M. Murphy
Associated Neurologists,
P.C. — Danbury, CT



CAREER HIGHLIGHTS

1981 B.S. Fordham University—
Summa Cum Laude #1 in class

May, 1985 Rutgers Medical
School — M.D.

National Medical Honor Society

1986-1988 Resident in
Neurology, UMDNJ-New Jersey Medical School,
University Hospital, Newark, NJ

1988-1989 Chief Resident in Neurology, UMDNJ-New
Jersey Medical School, University Hospital, Newark, NJ

RESEARCH: EXPERIENCE/INTERESTS

Over 12 years of various administrative positions at
Danbury Hospital. Lead to: Chairman of the Board of
Directors, Danbury Hospital and Danbury Health Systems,
Inc.

WHAT IS A CLINICAL TRIAL?

(This definition is from The Open Door Clinic <http://www.opendoorclinic.org/introduction.htm>)

Clinical: Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

Clinical trial: A clinical trial is a research study designed to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

Phase 1 trial: a closely monitored clinical trial of a drug or vaccine conducted in a small number of healthy volunteers. A Phase 1 trial is designed to determine the vaccine's safety in humans, its metabolism and pharmacologic actions, and side effects associated with increasing doses.

This was published by the NPF on their website.

FIRST WEBSITE ON PARKINSON'S CLINICAL TRIALS UNVEILED

Collaboration between Voluntary Groups, Industry and Government Marks Launch of Website Devoted to Parkinson's Clinical Research

A new website dedicated to PD clinical trials was launched, marking a novel collaboration between voluntary patient groups, private foundations, government and industry, www.PDtrials.org.

The website is being launched under the banner of a public awareness initiative known as Advancing PD Therapies (APT), a community-wide project designed to accelerate the development of new treatments for PD by increasing awareness and participation of PD patients in clinical research. Seven leading PD groups, in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), lead APT. The patient-centered website will act as a central gateway for information on industry and government sponsored clinical trials.

The concept of APT grew from patients themselves. An online grassroots network of people with PD known as the PD Pipeline Project highlighted concerns about a growing disparity between the number of new therapies that will soon be moving into clinical trials and the number of PD patients who are volunteering

Phase 2 trials: controlled clinical study of a drug or vaccine to identify common short-term side effects and risks associated with the drug and to collect some information on its effectiveness against the disease being studied. Phase 2 trials enroll some volunteers who have the same characteristics as persons who would be enrolled in an efficacy (Phase 3) trial of a drug or vaccine. Phase 2 trials enroll up to several hundred participants and have more than one arm.

Phase 3 trials: expanded controlled and uncontrolled trials conducted after preliminary evidence suggesting effectiveness of the drug at an optimally selected dose and schedule has been obtained. Phase 3 trials are also intended to gather additional information about safety needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 trials usually include several hundred to several thousand volunteers.

Phase 4 trials: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

to take part in them. This disparity could result in severe delays in the availability of new treatments that offer relief for the nearly 1.5 million Americans who suffer from PD. Currently an estimated 5,000 people with Parkinson's are participating in clinical research — far short of the 10,000-15,000 participants that researchers anticipate they will need to efficiently conduct clinical studies over the next two to three years.

The new website will work to address this issue by improving access to information on Parkinson's clinical trials and by providing a tool for patient and physician audiences to identify trials that are actively seeking patients. The site will also help to educate patient communities on the value of clinical research.

Key features of the website include:

- Providing a one-stop gateway for patient and medical communities to access information about Parkinson's clinical research.
- Helping potential participants identify trials that are open by type and by geographic location (e.g. within 50 miles of the patient's zip code).

- Encouraging visitors to sign-up to receive e-mail updates when new trials are added.
- Making available print materials including a new patient education brochure: Parkinson's Clinical Research: A guide to understanding how you can play a part in moving Parkinson's research forward that can be ordered either online or through a recorded campaign phone line (888) 823-8889.

The following organizations have pledged to unite to support the effort: the American Parkinson Disease Association, the Michael J. Fox Foundation for Parkinson's Research, the National Parkinson Foundation, the Parkinson's Action Network, the Parkinson Alliance and WE MOVE. The coalition is being coordinated by and staffed by the PD Foundation.

WHERE TO GO TO FIND OUT MORE

PDtrials.org (see previous article) where you'll find up-to-date information on PD clinical trials currently enrolling participants in the U.S. by symptom and location, as well as the latest news and views on what's happening in the world of Parkinson's trials. This is the website of the "PDtrials campaign" (you can enter the quote enclosed phrase to find out more), an initiative of the major Parkinson's patient voluntary groups to accelerate the development of new treatments for the disease.

ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. The information provided on ClinicalTrials.gov should be used in conjunction with advice from health care professionals. Before searching, you may want to learn more about clinical trials.

<http://www.centerwatch.com/> (CenterWatch Clinical Trials Listing Service) You can use this site to find a wealth of information about clinical research, including listings of more than 41,000 active industry and government-sponsored clinical trials, as well as new drug therapies in research and those recently approved by the FDA. It is designed to be an open resource for patients interested in participating in clinical trials and for research professionals.

ACCESS BEFORE APPROVAL — A RIGHT TO TAKE EXPERIMENTAL DRUGS?

Susan Okie, M.D.

A surprising court decision this past May has advanced an effort to allow terminally ill people to purchase experimental drugs after initial safety testing but before they have been shown to work. A three-judge panel of the U.S. Court of Appeals for the D.C. Circuit was considering a lawsuit by the Abigail Alliance, a patient-advocacy group, against the Food and Drug Administration (FDA). Two members of the panel ruled that patients with life-threatening and otherwise untreatable diseases have a constitutional right to seek experimental treatments for which efficacy is not yet established and that the government cannot interfere unless it proves it has a "compelling interest." The suit was sent back to a lower court, which had dismissed it. The dissenting judge, Thomas Griffith, wrote that "there is no evidence in this Nation's history and traditions of a right to access experimental drugs."

The pre rogative asserted by the FDA — to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access . . . impinges upon an individual liberty deeply rooted in our Nation's history and tradition of self-preservation.

— D.C. Circuit Judge Judith Rogers

I have serious doubt about how a court can know, as a matter of constitutional law, that the lesser of two evils will be achieved by providing all terminally ill patients access to all Phase I experimental drugs, given the risks these drugs present.

— D.C. Circuit Judge Thomas Griffith

To read the entire article: Volume 355:437-440, August 3, 2006 Number 5

PART 2 OF THIS NEWSLETTER WILL BE SENT TO YOU WITHIN TWO WEEKS.

PARKINSON'S DISEASE RESEARCH IN CONNECTICUT: THE VITAL ROLE OF CLINICAL TRIALS

March 3, 2007 at the UCONN Health Center — Keller Auditorium — Farmington, CT

Organized by: The Connecticut Parkinson's Working Group

In Collaboration with: PDtrials.org — Parkinson's Disease Foundation

Hosted by: UCONN Health Center

PROGRAM:

9:30–10:30 am: Registration sign-in and coffee/tea with assorted muffins/breads/bagels

10:30–10:45 am: Welcome and Introduction

Stan Wertheimer: Co-Director Connecticut Parkinson's Working Group

Dr. J. Antonelle deMarcaida: Eastern Connecticut Neurology Specialists, Manchester

Dr. Adam Simmons: Department of Neurology, UCONN Health Center, Farmington

Veronica L.Todaro: PDtrials.org — Parkinson's Disease Foundation

10:45–12:25 pm: Forum Presentations

Dr. Mohammed N. Hassan: Department of Neurology, UCONN Health Center, Farmington

Dr. Bahman Jabbari: Department of Neurology, Yale University, New Haven

Dr. Danna Jennings: Institute for Neurodegenerative Disorders, New Haven

Dr. John Murphy: Associated Neurologists, Danbury

12:25 pm — Closing and Recognitions

12:30 pm — Refreshments and Socializing

— PRE-REGISTRATION IS REQUIRED — FREE ADMISSION — SPACE IS LIMITED —

Please tear off registration form, provide required information, mail completed form to:

CPWG

c/o Patricia Sullivan
94 East Ridge Rd
Middletown, CT 06457

Space is allotted on a "first come" basis.

CONNECTICUT PARKINSON'S WORKING GROUP

132 HIGHWOODS DRIVE
GUILFORD CT 06437

DISCLAIMER:

*Articles in this newsletter are for information only.
Any questions of treatment should be discussed with your physician.*

Write your Representatives in Congress!

Christopher Dodd

Russell Senate Office Building
Washington, D.C. 20510

Joseph Lieberman

Hart Senate Office Building
Washington, D.C. 20510

Please note 1 or more e-mail addresses of members have been edited to make them invisible to spam search engines by changing "@" to " at " in the address. To use the e-mail address, swap the " at " for "@".