



PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research

PPMI News

The newsletter for PPMI participants

Issue 2, Fall 2011

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About PPMI The Parkinson's Progression Markers Initiative (PPMI) is a landmark, five-year international clinical study that aims to find reliable and consistent biomarkers of Parkinson's disease (PD) progression. The study is testing today's most promising biomarker candidates through neuroimaging, the collection of blood, urine, and spinal fluid, and clinical and behavioral tests. Valid measures could allow scientists to predict, objectively diagnose and monitor diseases as well as definitively determine which medications work and which will not. PPMI is sponsored by The Michael J. Fox Foundation for Parkinson's Research and funded by a consortium of industry partners and individual donors. To learn more or volunteer to participate in the study, visit www.michaeljfox.org/PPMI or call (877) 525-PPMI.

PPMI Study Update

Thanks to you, PPMI continues to work toward the goal of identifying biomarkers that reveal the progression of Parkinson's disease – critical to developing disease-modifying treatments that could transform millions of patients' and caregivers' lives.

The PPMI study began in summer 2010 and has continued to expand its presence across the United States and Europe. Nine industry funders, including leading pharmaceutical and biotech companies, have partnered with The Michael J. Fox Foundation to support this work, and researchers and clinicians across the world have begun to analyze the data and biological samples that could unlock clues to the onset and progression of Parkinson's disease.

Here is a bit of what PPMI teams have already accomplished (*All figures as of July 31*): Of 21 planned clinical sites, 19 are now active, with two more in the EU set to begin studies soon. 163 individuals are actively enrolled at PPMI sites, including 92 newly-diagnosed PD participants, and 71 without PD serving as control volunteers. Another 38 volunteers are pending enrollment. PPMI volunteers have already provided the blood, CSF and urine samples and initial testing of PD biomarkers is under way. Additional samples are being stored for future use. These additional samples, along with the data that is being collected in PPMI, are now available to the scientific community at large, to help speed

promising PD biomarker validation efforts worldwide (see What Happens to My Data? p. 3).

"We are encouraged by the early success of our recruiting efforts," said PPMI's principal investigator, Ken Marek, MD, president and senior scientist of the Institute for Neurodegenerative Disorders in New Haven, Connecticut. "While there is still work to do to fill the ranks of study participants, both people with Parkinson's and controls have turned out to support PPMI. Nearly all of our sites are trained and up and running. And now, thanks to the willing volunteers who are participating in the study, scientists across the world dedicated to Parkinson's research will benefit from data and findings that will speed the process of biomarker discovery in PD."

Each PPMI participant has a different reason for signing up, and volunteers have been stepping up to tell their personal stories of involvement. Marc and Karen Jaffe of Cleveland, Ohio were featured on *Fox and Friends* as Marc explained how he gave the gift of PPMI participation to Karen, who has Parkinson's, for their anniversary (see Media Highlights , p. 2).

Coordinator's Corner

Clinical coordinators and site investigators are the heart and soul of any research study, and PPMI is no exception. Meet two of the dedicated professionals whose efforts keep this study going.



Linda Rees: "I'm really impressed with how many...have come forward to participate."

As site coordinator of PPMI at the Parkinson's Institute and Clinical Center in Sunnyvale, California, Linda Rees serves as the main contact for study participants. As an epidemiologist, she explores risk factors in populations such as diet and environmental exposures, and she manages projects within the Institute's brain tissue repository. Rees also conducts the non-physician screening portions of PPMI visits, from processing biologic samples to making assessments of mood, memory, cognition, and behavior.

It is this human interaction within the PPMI study that she truly loves. "PPMI is a time-consuming study with very involved testing," she explains. "Despite this commitment, I'm really impressed with how many patients and potential controls have come forward to participate."

Holly Delgado: "I love that I'm part of PPMI."

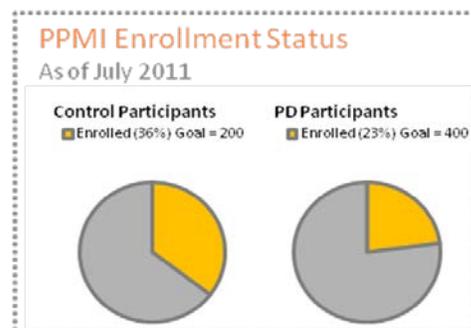
As PPMI site coordinator at the University of South Florida, Holly Delgado RN, BSN (*above*) interacts with both patients and study participants on a daily basis, drawing blood, running EKGs, and administering cognitive tests. She also serves as the liaison between patients and doctors and handles all paperwork for the site's Institutional Review Board and various university committees.

Delgado says that she enjoys the opportunity afforded to her by PPMI to work with participants over long periods of time. "I love that I'm a part of PPMI — it's an exciting study that is very different from the PD drug trials I'm working on," she says. "We're looking for a way to halt disease progression, which will have a tremendous impact on the Parkinson's community."

PPMI Update

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Ultimately, PPMI is about each and every one of our participants and the gift of their commitment. So many of you have compelling stories about why you have chosen to participate, and we'd love to hear your story. Contact the clinical coordinator at your study site and tell them about yourself, and you may be featured in media stories about the study or a future edition of PPMI News!



Where in the World Is PPMI?

Visit michaeljfox.org/PPMI for information on all 21 clinical sites where PPMI is taking place across the United States and Europe.

Media Highlights: Parkinson's Awareness Month

During Parkinson's Awareness Month this past April, Marc and Karen Jaffe of Cleveland, Ohio, appeared on "Fox and Friends" to share the story of her PD diagnosis, and the decision he made to enroll in PPMI. Check out this segment on our YouTube channel at:

<http://www.youtube.com/user/michaeljfox#p/u/32/YLaYGRciiYE>.



A Message from PPMI's Lead Investigator

Thanks to your participation, study sites across the U.S. and Europe are sharing critical data for PD research.

I want to extend my gratitude to the growing community of PPMI volunteers and PPMI site study teams for all their efforts to move the PPMI study forward. We have successfully established a centralized database and specimen repository that are providing wide access to critical scientific information for Parkinson's researchers who share the goal of finding biomarkers of PD.

One of PPMI's primary aims is to establish an infrastructure that both allows and promotes scientific collaboration, through the initiative's Web-based portal. This teamwork is already in action: At our annual investigators' meeting in May, together we accessed the initial data collected by study sites in real time. It was inspiring to see what we have already accomplished and exciting to consider how much more we can do by working together.

Now that most of the study sites are active, we have also begun to consider additional testing and assessments in the form of ancillary studies that can be added to PPMI to further leverage the data and samples being collected. Two such studies have already been proposed, and we continue to consider others. (Read about one approved

study, which measures PD motor characteristics with a home-based device, on p. 4).

PPMI works because of you, the study's volunteers. Reaching the goal of finding biomarkers for disease progression depends on the continued long-term follow-up of all study volunteers. We are impressed with those who give so much time and energy to these efforts. We are inspired by the selflessness and vision of each of you who are participating with a common goal of moving forward Parkinson's disease research.

We continue to recruit PPMI participants across the United States and in Europe. Our goal is to enroll 400 people who are newly diagnosed with PD, and 200 controls. If you know someone who might want to participate in PPMI, encourage them to visit www.michaeljfox.org/PPMI to learn more about our study and find the site nearest them.

Thank you for your continued involvement in PPMI. We look forward to sharing more news of our progress as the study advances toward our shared goal of a Parkinson's biomarker.

-Ken Marek, MD

Featured FAQ:

What Happens to My Data?

In the last issue, we talked about how the samples you contribute to PPMI, like blood and cerebral spinal fluid, are processed. As a PPMI participant, you also know to expect other tests and assessments when you report to the clinic: like reciting the alphabet backwards and filling out surveys. So what happens to all of this data being collected?

First, researchers enter the data they have compiled from these tests and assessments into an online database. Your profile is de-identified so that your name and other personal information is not publicly available. The study database is then made available to the scientific community at large where PD researchers from around the world who have requested access and who have been verified can take advantage of this dataset for use in their own studies.

Scientists using PPMI resources agree up front to report back to the initiative with any findings and to share new data in the study database, enabling future researchers to build on their work. This unique, collaborative design can help the most promising biomarker validation studies get started faster so that therapeutic breakthroughs can sooner impact patients' lives.

"I love that I'm a part of PPMI."

"We're looking for a way to halt disease progression, which will have a tremendous impact on the Parkinson's community."

*-Holly Delgado, PPMI site coordinator
University of South Florida*

Ancillary Studies Highlight the Flexible Model of PPMI

One study is searching to more accurately measure the severity of PD through a finger tapping dexterity device

PPMI offers scientists the flexibility to propose ancillary studies involving PPMI participants to add new study assessments that expand on the study data in a meaningful way. One such ancillary study, funded by the Kinetics Foundation in partnership with The Michael J. Fox Foundation, seeks to measure the impact of a computer-based device and how it might help to better measure specific motor characteristics of PD.

The study is called TAP-PD, and it will be offered at three PPMI sites. It will test dexterity through finger tapping and peg transfer exercises meant to gauge speed and reaction time. Participants at the three sites will have the opportunity to opt into this study, but will not be required to do so.

“The principal goal of PPMI is to develop biomarkers that measure PD progression more effectively,” said Andrew Siderowf, MD, the investigator leading the TAP-PD study and an Investigator for PPMI at the University of Pennsylvania Medical Center. “Currently, we aim to accomplish this by taking samples of proteins in the blood, through surveys, and by clinical tests. The TAP-PD study tests a device that may be another way to do this, as a non-invasive and easy to operate assessment tool.”

“Past studies have found that the device used in TAP-PD is a feasible way for people

with Parkinson’s to take a proactive role in assessing PD progression,” said James McNames, PhD, an investigator funded by the Kinetics Foundation to investigate the efficacy of dexterity testing devices like OPDM, the one used in the TAP-PD study. In a previous study, the computer-based device being used in TAP-PD was tested by individuals in their home environments and found to successfully detect changes in Parkinsonian motor function.

“Not only is OPDM easy to use, we’ve noted that it actually helps motivate people to participate,” said McNames.

Together, MJFF and Kinetics are committed to thinking out of the box about new ways to speed progress toward a cure. TAP-PD is one such way to do so.

Be PPMI Proud! Visit www.michaeljfox.org/Proud to download a “PPMI Proud” badge that can be displayed on a personal Web site or blog. It’s a great way to spread the word about PPMI and encourage others to get involved.



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