The Parkinson’s Progression Markers Initiative (PPMI)

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Senior Scientist,
Institute for Neurodegenerative Disorders
PD patient vignette

- 67 yo right headed WF in excellent general health
- History
  - 6 month history of poor tennis play
  - Note 1-2 years – mild constipation
  - 2 months intermittent R UE tremor while reading the newspaper, or if in stressful situation
- Exam
  - Mild R UE resting tremor
  - Reduced R arm swing
- PD DIAGNOSIS – 1 MONTH AGO

- “IF THE SYMPTOMS REMAIN AS THEY ARE NOW – I COULD DEAL WITH THIS”
# Neuroprotection studies

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<td>PROUD – PRAMIPEXOLE</td>
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Rationale for PPMI:
Challenges of disease-modifying trials

• Disease modifying PD therapeutics remain a major unmet need

• A major obstacle to current phase 2/3 neuroprotection studies is the lack of biomarkers for
  – Disease mechanism
  – Drug mechanism
  – Dosage determination
  – Study eligibility
  – Stratification into PD sub-types
  – Correlation with clinical signals

• Biomarkers would potentially shorten study duration, reduce study sample size, limit study costs.
Developing the Parkinson’s Progression Markers Initiative

Academic, industry, government, foundation, patient constituencies worked to develop the PPMI study - process driven by the MJFF through its SAB and its unique ability to convene the interested groups.

Specific Data Set
- Appropriate population (early stage PD and controls)
- Clinical (motor/non-motor) and imaging data
- Corresponding biologic samples (DNA, blood, CSF)

Standardization
- Uniform acquisition of data and samples
- Uniform storage of data and samples
- Strict quality control/quality assurance

Access/Sharing
- Data available to research community → data mining, hypothesis generation & testing
- Samples available for studies
PPMI Overview

- PPMI is an observational multi-center study to assess progression of clinical features, imaging and biologic biomarkers in Parkinson’s patients and healthy controls.
- PPMI is a study to establish PD progression biomarkers – not a treatment trial.

- Intensive, comprehensive project for subjects, sites, investigators.
- Established study instruments complemented by novel technologies. Flexibility in incorporating new technologies and new studies.
- Openness to provide data to community.
- Set standards for biomarker collections and image acquisition.
- Biological samples will be used for verification of promising biomarkers.
- Sponsor – MJFF// Support from Pfizer, GE healthcare.
## PPMI Study Details: Synopsis

| Study population | ▪ 400 *de novo* PD subjects (newly diagnosed and unmedicated)  
▪ 200 age- and gender-matched healthy controls  
▪ Subjects will be followed for a minimum of 3 years and a maximum of 5 years |
|---|---|
| Assessments/ Clinical data collection | ▪ Motor assessments  
▪ Neuropsychiatric/cognitive testing  
▪ Olfaction  
▪ DaTSCAN imaging, MRI |
| Biologic collection/ | ▪ DNA collected at screening  
▪ Serum and plasma collected at each visit; urine collected annually  
▪ CSF collected at baseline, 6mo, 12mo and then annually  
▪ Samples aliquotted and stored in central biorepository |
| Initial Verification studies | ▪ Lead biologic candidates to be tested:  
▪ Alpha-synuclein (CSF)  
▪ DJ-1 (CSF and blood)  
▪ Urate (blood)  
▪ Abeta 1-42 (CSF)  
▪ Total tau, Phospho-tau (p-181) (CSF) |
| PD treatment | ▪ *De novo* for ~6 months  
▪ Can participate in other clinical trials (including interventional trials) after 12 months |
# PPMI SC and Study Cores

<table>
<thead>
<tr>
<th>Steering Committee</th>
<th>PI-K Marek, A Siderowf, C Scherzer, D Jennings, K Kieburtz, W Poewe, B Mollenhauer, C Tanner, B Ravina (core leaders, MJFF, ISAB)</th>
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</thead>
</table>
| Clinical Coordination Core | ▪ University of Rochester’s Clinical Trials Coordination Center  
• PI: Karl Kieburtz |
| Imaging Core | ▪ Institute for Neurodegenerative Disorders  
• PI: John Seibyl |
| Statistics Core | ▪ University of Iowa  
• PI: Chris Coffey |
| Bioinformatics Core | ▪ Laboratory of Neuroimaging (LONI) at UCLA  
• PI: Arthur Toga |
| BioRepository | ▪ Coriell/BioRep  
• PI: Alison Ansbach, Pasquale De Blasio, Michele Piovella |
| Bioanalytics Core | ▪ University of Pennsylvania  
• PI: John Trojanowski, Les Shaw |
| Genetics Core | ▪ National Institute on Aging/NIH  
• PI: Andy Singleton |
| ISAB | ▪ Kim Gallagher/GE Healthcare  
• Thomas Comery/Pfizer |
| MJ FOX PPMI | ▪ Sohini Chowdhury, Mark Frasier, Claire Meunier, Jamie Eberling, Todd Sherer |
# PPMI Clinical Sites

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Clinical markers

- Cognition
- Behavioral
  - Depression
  - Apathy
  - Anxiety
  - ICD
- Autonomic
  - Constipation
  - Bladder
  - Sexual
  - Cardiac
- Olfaction
- Sleep - RBD
- Skin
- Motor analysis
- Speech

Biomarkers for PD

- Imaging – Phenotomics
  - SPECT/PET-Dopamine - DAT, F-Dopa, VMAT2
  - SPECT/PET-non-dopamine
    - FDG, MIBG, NE, 5HT, Nicotine, Ach, PBR, Amyloid, α-synuclein
  - MRI – DTI, volumetrics
  - Nigral Ultrasound

- Biologics – Blood/CSF/Urine
  - Alpha-synuclein, DJ1, Urate, Tau, β-Amyloid

- ‘Omics’ –
  - RNA profiling

- Genetics
  - Synuclein, LRRK2
  - Parkin DJ-1, Pink1
PPMI – Pushing back Diagnosis

Eligibility for PD - Possible PD + DAT deficit
# Identification of biomarker candidates for inclusion is critical to PPMI

*The Biomarkers Taskforce identifies/prepares promising candidates for verification*

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<td><strong>Markers for which there is</strong></td>
<td>• Markers for which there is some evidence for a disease association</td>
<td>• Putative markers with weak data correlating to PD</td>
<td>• Minimal data available</td>
</tr>
<tr>
<td><strong>some evidence for a disease</strong></td>
<td>• Preliminary data around the detection of the marker in a biochemical assay exist</td>
<td>• Standardized assays exist → straightforward to study in PD subjects</td>
<td>• Relationship to PD hypotheses and mechanisms of disease exist</td>
</tr>
<tr>
<td><strong>association</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preliminary data around the</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>detection of the marker in a</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>biochemical assay exist</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Candidates</strong></td>
<td>• Alpha-synuclein</td>
<td>• Cytokines</td>
<td>• ST13</td>
</tr>
<tr>
<td></td>
<td>• DJ-1</td>
<td>• Glutamine/Glutamate</td>
<td>• J. Zhang’s panel of proteins from proteomics</td>
</tr>
<tr>
<td></td>
<td>• Urate</td>
<td>• Total Tau and Phospho-Tau (p-181) and Abeta 1-42 species (INNO-BIA AlzBio3 assay)</td>
<td>• Glutathione</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 8-OHdG</td>
</tr>
</tbody>
</table>
Data Input

Acquisition → Repository

Imaging Acquisition

Clinical Acquisition

Biological Acquisition

Imaging Core (IND)
- Quality Control
- Image Pre-processing

Clinical Core (CTCC)
- Quality Control
- Study Management

Sample Repository (Coriell)
- Sample Storage

Data Transfer & Validation

PD@LONI

- Public Information
- Publications
- Investigator Resources
- Data Sharing Tools
- Data Access

Play a Part in Parkinson's Research
Data Output

Repository ➔ Investigators

PD@LONI

Web Interface
Queries
Requests
Downloads

Database
Clinical Data
Image Data
Sample Inventory

Data
Requests

Inventory
Requests

Scientific Investigators

Samples via mail

Sample Repository (Coriell)
Sample Storage
www.ppmi-info.org

- Portal for PPMI data
- Portal for PPMI samples through the biologic resource committee
- PPMI – study documents and SOPs available
- PPMI study progress
- Recruitment and retention tool
PPMI - Standardization/Training

- Biologics - Collection/Aliquoting/Shipping/Storage
- Imaging - Acquisition/QC/analysis/backup
- UPDRS - MDS UPDRS certification
- Neuropsych/Neurobehavioral
- CSF collection
- Data entry
PPMI Key Features

- Subject recruitment eligibility includes DAT imaging status
- Comprehensive longitudinal biomarker and imaging assessments
- Longitudinal CSF acquisition in all study subjects
- Standardization of all data acquisition
- All data merged into PPMI database and data and biologic samples rapidly available to scientific community via PPMI website www. PPMI-info.org
- Flexibility to incorporate novel biomarker candidates – ongoing biologic and imaging task forces to seek new candidates
- Public private partnership in pre-competitive space.
PPMI requires a Partnership

• Expertise and experience in PD, trial design/operation, statistics and biomarkers
• Communication and coordination

- Intellectual leadership
- Validate project relevance
- Clinical trial design/operations expertise
- Financial leadership

- Neutral intellectual leadership
- Strategic project management
- Coordinate fundraising
- “Fox Effect” impacts recruiting

- Provides valuable intellectual input and resources; ADNI model has proven successful

- PD expertise/Clinical study experience
- Experience with assessment tools
- Access to subject population

- Subject enthusiasm, engagement and commitment to PPMI critical for success

PPMI

SC/Cores

MJFF

Clinical Sites

Study Subjects

Industry Partners

NIH
PPMI - Current Status/Timeline

- Study launched June 2010
- All US sites recruiting by mid Nov.
- All EU sites recruiting by mid Feb
- All SOPs complete
- Database operational
- Web site live
- 11 subjects consented