

HOW TO GET INVOLVED IN PSG CLINICAL TRIALS

PSG resources for multicenter trials and the QE3 Experience

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PSG Clinical Trials Overview

- Any PSG member (voting or associate) can propose a study
 - See “Procedures for Review of New Study Proposals”, PSG website
- Applications are reviewed by the Scientific Review Committee and final decisions are made by the Executive Committee
- PI and Co-PI (different institutions) are appointed by the chair, and approved by Executive Committee
- A Steering Committee is appointed by the PI and Co-PI
- All studies use a PSG-credentialed Coordination Center and a PSG-credentialed Biostatistics center

PSG ongoing studies

- Ongoing studies include:
 - QE3: Effects of coenzyme Q10 in Parkinson's Disease - Phase III (NINDS-funded)
 - SURE-PD: Safety and ability to elevate urate in early Parkinson's disease (MJFF-funded)
 - STEADY PD: Safety, tolerability and efficacy assessment by Dynacirc CR for PD (MJFF and Dixon Foundation-funded)
 - SPIN PD: Spectroscopy in Parkinson Disease Diagnosis (Molecular Biometrics Inc-funded)
 - FOUND: Follow up of persons with neurologic disease

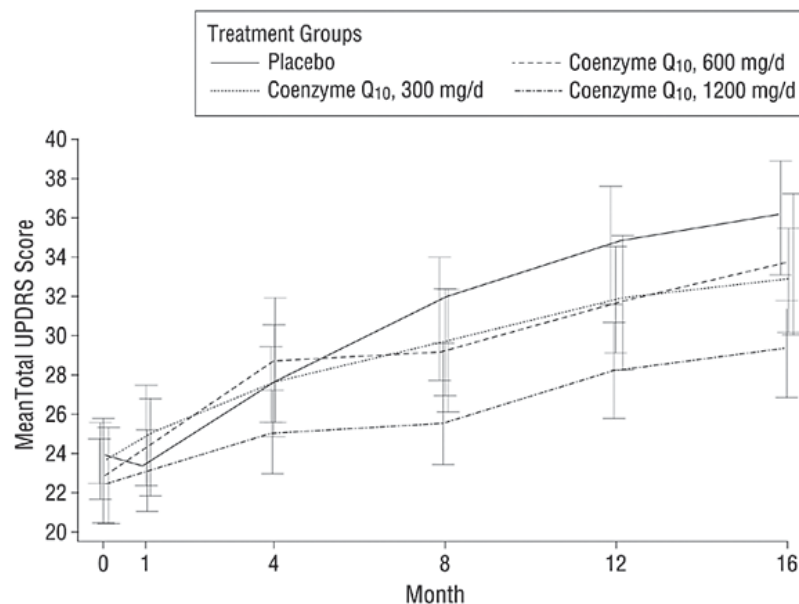
The QE3 Trial - An Overview

- Multi-center randomised double blind placebo-controlled clinical trial of high dose coenzyme Q10 in early PD (n=600)
- Intervention based upon QE2, a phase II clinical trial in early PD (n=80)
- NINDS funding (U01)
- PIs: M. Flint Beal

David Oakes

Co-PI: Ira Shoulson

Shults et al. Arch. Neurol (2002) 59:1541-1549

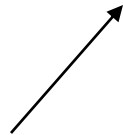


The QE3 Team: A Partial View

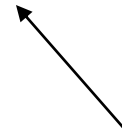
PIs, Steering Committee, Medical Monitor



67 sites (US/Canada)
Investigators/coordinators



Investigators: Ancillary studies



Investigators: Future data mining studies

1. Getting involved as a site investigator/coordinator

- QE3 has sixty-seven PSG sites in US and Canada
- Chosen based upon site interest form, location, site history, specific advantages of new sites
- Training: investigators meetings (including in-person meetings at PSG), teleconferences, webcasts
- Site-specific efforts have included minority recruitment efforts with competitive funding based upon each site's proposals (PDF/NIH)

PSG resources

- PSG-credentialed Coordination Center and Biostatistics Center
- Credentialing/oversight ensuring proper guidance for all investigators
- Guidance from seasoned PD investigators/coordinators within the network of clinical trial sites
- Rigorous training and follow up

2. Getting involved as an ancillary study investigator

- Ancillary studies for QE3 include:
 - Blood sample collection for biomarker studies (MJFF)
 - Effect of CoQ10 on MR spectroscopic indices of cerebral metabolism (Dana Foundation)
 - Sleep study
 - FOUND
- Ancillary sites chosen based upon site interest forms and location

PSG Resources

- Network of potential co-investigators
 - Clinical
 - Scientific
- Support for protocol development
 - Scientific Review Committee
 - Mentoring Committee
 - PSG Working groups

3. Getting involved in the working groups - a new PSG resource

- PSG working groups
 - Biomarkers
 - Classic motor
 - Cognitive and non-motor
 - Epidemiology and Genetics
 - Neurosurgical
 - Other non-motor

Membership is open to all within the PSG

PSG working groups

- Developed as area-specific “think tanks” to
 - Aid in developing new study protocols
 - Bring together investigators with overlapping interests
 - Foster collaborations
 - Aid in developing policies and recommendations
 - Interact with SRC, Mentoring Committee, other working groups