Participation in clinical trials
EXAMPLE CASE

Mr. Jones is a 60 year old man with PD who is a LRRK2 carrier. His gene status has been determined in the course of PPMI participation. Mr. Jones is interested in participating in a clinical trial of a novel agent intended to modify PD, particularly in patients with PD and LRRK2 variants. Can Mr. Jones participate in the clinical trial and remain in PPMI?
PURPOSE: TO PROVIDE GUIDANCE FOR PPMI SUBJECTS WHO MAY WISH TO PARTICIPATE IN OTHER STUDIES

» The PPMI steering committee recognizes that PPMI subjects may consider participation in clinical trials.

» The study protocol allows for participation in other clinical trials, while remaining in PPMI, after one year of follow up within PPMI has been completed.
PPMI DATA MAY BE SHARED WITH CLINICAL TRIAL SPONSORS

» Data collected in PPMI, such as genetic status and dopamine imaging results, may be used in other studies to establish trial eligibility.

» Quantitative PPMI data such as dopamine imaging binding or clinical rating scale scores, may be shared with a study sponsor in lieu of repeating clinical or biomarker assessments with prior agreement of both parties.
CLINICAL TRIAL DATA CAN BE IMPORTED INTO PPMI

» Data from a common source could be used simultaneously by PPMI and another study with prior agreement of both parties. For example, a MDS-UPDRS assessment could be recorded into a clinical source document and then entered into both the Electronic Data Capture system for PPMI and the other study.

» For studies that evaluate novel biomarkers, when possible the other study sponsor should share the biomarker results with PPMI. This data may be made public as part of the PPMI database.
Special attention may be required regarding aspects of PPMI that involve ancillary studies with proprietary materials, such as proprietary wearable sensors.

In such cases, one option is for PPMI subjects to discontinue participation in the ancillary study, but continue participation in the primary PPMI protocol.
POST MORTEM

» Consent to post-mortem examination through the PPMI pathology core should not be affected by participation in another study, and PPMI should remain the primary means for post-mortem examination