

Summary of the National Institute of Neurological Disorders and Stroke Parkinson's Disease Biomarkers Program Consortium Meeting September 22, 2014 Bethesda MD

On September 22, 2014, representatives from non-government organizations, NINDS staff and Principal Investigators (PIs), and clinical and data management experts from each project sponsored under the National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's Disease Biomarkers Program (PDBP) gathered to discuss progress over the last twelve months and future plans for the consortium. A summary of the meeting discussion is given below.

Overview of Performance - Year 2

Progress across all sites

- Collectively 44 papers have been published and a consortium manuscript is near completion
- At least 4 new biomarkers have been nominated
- At least 6 existing biomarkers have been further tested or refined
- Preparing for NeuroX chip array genotyping of samples
- Periodic statistical analysis on biorepository data to help correct for site-to-site variability

Site Recruitment and Biospecimen Collection

- Over 1000 subjects have been recruited: As of September 11, 2014, a total of **1073** subjects have been enrolled across the 7 actively recruiting sites. This represents 73% of the PDBP recruitment goal.
- The PDBP biospecimen collection housed at the NINDS Repository continues to expand: As of September 11, 2014, 1021 DNA samples, 1690 RNA samples, 1376 whole blood samples, 1377 plasma samples, 1257 serum samples and 311 CSF samples have been collected.
- A total of 21,233 clinical data forms have been entered into the PDBP Data Management Resource (DMR)

PDBP Data Management Resource (DMR)

- Requests for biospecimens can now be placed via the DMR 'Order Manager' for review by the established PDBP Biospecimen Resource Access Committee (BRAC)



- Legacy data from 3 sites have been mapped to DMR form structures and is searchable using the Query tool

Resources for Participants

- Launch of PDBP newsletter ([click here](#))
- Interview with Dr. Paul Zimmet, a retired dentist and very first PD patient recruited at the Johns Hopkins University site. Dr. Zimmet shared his thoughts about improving recruitment of PD patients in research studies (<http://blog.ninds.nih.gov/>)

Acknowledgements

Alice Chen-Plotkin (University of Pennsylvania), Dwight German (University of Texas Southwestern): PDBP Steering Committee Chairs

Looking Forward to Year 3 - Suggestions from the meeting

PDBP:

- Increase awareness of the resource
- Create more opportunities for partnerships between investigators with PD expertise and technology/platform biomarker investigators
- Further differentiate PPMI from PDBP to help the community understand differences between the two studies and the cohort of PD patients represented (this also relates to PDBP DMR recommendations)
- Encourage larger scale biomarker discovery studies. In other words, support biomarker discovery studies that use > 10-20 samples for discovery
- Report cognitive outcome measures – e.g. MCI. The PDBP steering committee will need to determine if current neuropsychology data is sufficient to make this determination, or if additional clinical assessments would be necessary.
- Set up a meeting with PIs using the Somalogic platform and Somalogic science staff. The cost per sample for this platform is expensive so understanding the stability/instability and issues arising when comparing studies that have used the platform at various time points is essential. Also, understanding how to report data and aptamer representation in the PDBP DMR is required before data can be broadly shared.
- Distribution of NeuroX genotype data to consortium members - Andy Singleton's group will work with PDBP consortium members to identify key variants (30 to 40) as well as additional criteria e.g. overall risk score, PCs, etc. to report to PDBP consortium members prior to final dataset release. Andy Singleton's group will work with PDBP consortium members on genotype/phenotype data analysis.



- Explore next phase of global PDBP sample analysis: 1) list of current analytes to measure; 2) measure of dopamine and dopamine agonists

PDBP DMR:

- Provide webinar for Query and Order Manager that can be referenced online. Use a case example to help investigators work through the options available for data selection and filtering.
- Provide PDBP Operations team support for first-time PDBP DMR users. Some hand holding might be needed.
- Identify what metadata is needed for biological data collected from biomarker platforms, e.g. define experiment, samples used, date performed, platform used etc.
- Identify common reports that will be useful to the research community – define criteria to be included in these reports. A PDBP consortium data group will be assembled to assist in this effort and also provide additional feedback for the DMR and identification of scope going forward.
- Create a data table for all baseline participants focused on inclusion/exclusion criteria (case/control), demographics (age, gender, ethnicity), neurological exam (diagnosis and age at diagnosis), MDS-UPDRS scores, and medications summary. Circulate this list to the PDBP steering committee to ensure that everything is captured. The idea is to help the community better understand the data available in the PDBP DMR.
- Global data dump is still a requested function for the DMR. All data in one file.
- Create 2 data files: 1) aggregate data (this could also feed into monthly reports) and 2) individual level data

PDBP Biorepository :

- Consider commencing urine collection across PDBP sites (based on data presented by Andy West). A protocol needs to be developed with the PDBP steering committee in collaboration with the NINDS Repository staff.
- Consider including reticulocyte counts in the blood work analysis (based on data from Clemens Scherzer's study).

PDBP BRAC:

- PDBP consortium member access to biosamples: develop a FastTrack system, where biosamples are available to consortium members to extend the number of samples available for analysis of biomarkers/platforms that were peer-reviewed in their grant applications (U01/U18) for PDBP. Expediting requests should be considered when additional biosample requests are within the same scope/specific aims of the peer reviewed grant.