

Biomarker Network

International Studies

Working Group

New Orleans, PA April, 2013

Within Country Biomarker Issues

- Sample collection protocols – feasibility, pros/cons, other issues?
 - DBS vs. Venous
 - Point-of-Contact
 - Other non-blood
 - Lung Fx
 - BP
 - BMI/WHR
 - Performance – e.g., cognitive and physical Fx

Within Country Biomarker Issues (cont'd)

- Laboratories
 - Initiation evaluation (e.g., validation of assays)
 - On-going oversight - Quality control (over time)
- Sample storage (over time)
- Reporting issues – what information should/ can be reported back to participants
 - Non-genetic
 - Genetic?

Harmonization Issues: Between Country Comparisons

- Equilibration between laboratories
 - NIH HIV centralized laboratory infrastructure for “clinical trials network”
 - Smaller scale options?
 - Centralized vs. decentralized?
 - Developing algorithms for cross-laboratory equilibration
 - Maintaining overtime?

Group Discussion

- Common & unique issues faced by various of the different international studies?
 - Build on morning study-specific information
 - “issues” they face relating to biomarker data collection
- Going forward - How best to address common “issues”
 - Infrastructure?
 - Other needs

Main Steps for Establishing New DBS-Based Assays

- Training of laboratory personnel
- Securing equipment for the assays
- Obtaining test reagents and supplies
- Assay validation: including pre-test with validation samples
- Ongoing quality control during testing of study samples

More Lessons Learned

- Need to conduct well-designed pre-test and ongoing monitoring to ensure data quality for DBS-based assays
- Good pre-test and quality control rely on availability of adequate validation samples, which requires infrastructure, expertise, and funding typically beyond what studies can do individually
- Maintain ongoing and timely communication with the laboratories that conduct DBS-based assays is crucial, but may be challenging

Major Questions Remain

- No current specific criteria defining acceptable assay quality and between-laboratory variability
 - How good is good enough (or how bad is not good enough)?
- In addition to good pre-test and quality control for each individual study, how can we compare DBS-based results across different surveys/countries?
 - Need for macro-level infrastructure
 - Laboratories for most surveys are operational for only a short period of time
- What are the other support/services USC/UCLA Biodemography Center may be able to provide?

Group Discussion

- Commonalities & unique issues faced by various of the different international studies?
- Future Priorities? How can we collaboratively move the field forward?
 - What needs to be developed?
 - What infrastructure would be optimal?

Future Directions “next steps”/priorities

- Your Ideas?