

P3G International Working Group 4: Epidemiology and Biostatistics

Summary of activities undertaken since formation of IWG4 in 2006 to May 2007

The goals of IWG4 are:

- To promote the harmonization of biobanks in epidemiologic design, conduct, analysis, reporting and synthesis of information
- To collaborate with other groups attempting similar biobank harmonization efforts (e.g. EU PHOEBE)
- To integrate P3G activities more closely with those of HuGENet network of networks.

The Mode of Operation of IWG4 is to:

- Work closely with IWG1
- Identify needs for a strong epidemiologic and biostatistical foundation of biobanks
- Develop focused topic specific workshops
- Develop outcome reports, tools, guidelines
- Make tools widely available through P3G Observatory and closer linkages with HuGENet
- Work with IWG2 to develop IT solutions
- Develop appropriate research agenda/cores

The next section summarizes progress in relation to the needs, activities and products identified so far.

1. *Making the case for international biobank harmonization:* The Group felt that a manuscript on this would be important in fostering the inclusiveness of P3G to the greatest extent possible. One paper has been completed, and two are in development.
2. *Development of catalogue of key elements of biobanks:* This is seen as particularly valuable in assisting prospective harmonization. Requirements of the catalogue include:
 - Structured information format, with use of structured ontology approach (and we plan that this will be consistent with other catalogues being developed in P3G)
 - Link to other web sources.

The catalogue is in development. We plan to run a test annotation of samples. The group agreed that this activity would be a new CORE.

3. *Assessing measurements of non-genetic factors (e.g. environment, nutrition):* A prospective harmonization workshop was held in Edinburgh in November 2006. This resulted in a draft generic dataset. A 3-day meeting is being planned for Fall 2007, with input from experts on specific disease areas (respiratory; musculoskeletal; mental health; autoimmune disease; infection; neurology) and on environment, SES, well-being and social networks. The group agreed that this activity would be a new CORE.
4. *Developing calibration studies:* A CORE proposal was submitted in April 2007. There was discussion as to how best to take forward in the May 2007 meeting. As noted in the proposal, there will be a need for a link with IWG1.
5. *Assessing biobank design, data structure and analysis:* A workshop was held in Stockholm in March 2007. This reached the conclusion that the Genestat website (<http://www.meb.ki.se/genestat/genestat.htm>) would be a good basis on which to build this work. A paper is in preparation. The Group noted the need to link with IWG2. The group agreed that this activity would be a new CORE.
6. *Assessing measurement of disease outcomes and intermediate phenotype:* A CORE proposal for work with HuGENet networks and other experts to integrate outcome specific guidance was submitted in April 2007. There was discussion as to how best to take forward in the May 2007 meeting. As noted in the proposal, there will be a need for a close link with the prospective harmonisation activities.
7. *Biobanking manual:* This would provide documentation of norms, standards and guidelines across all biobanking domains. Plans for its development form part of the ASSIST proposal (submitted). The group agreed that this activity would be a new CORE.
8. *Promulgating guidelines for joint analysis and integration of data from biobanks:* We plan to disseminate the HuGENet handbook (<http://www.hugenet.ca/>) through the P3G Observatory soon. Feedback is sought from P3G members as they make use of this.
9. *Developing guidelines for reporting of biobank based studies:* The STREGA (Strengthening the REporting of Genetic Association studies) workshop was held in June 2006. Guidelines from that workshop, in which some P3G members took part, and which extend the STROBE guidelines are being finalized (a third draft manuscript is being commented on by participants as of June 2007).
10. *Enriching P3G Observatory with tools from HuGENet networks:* In addition to the reporting guidelines, guidance on the assessment of cumulative evidence on genetic associations, about which a workshop was held in November 2006 in Venice, is being finalized.