



P³G – 10 years of toolbuilding: From the population biobank to the clinic



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ARTICLE INFO

Article history:

Received 9 January 2014

Received in revised form 19 February 2014

Accepted 2 April 2014

Keywords:

Biobank

Catalogue

Ethics

Harmonization

Law

Tool

ABSTRACT

Over the past ten years, the Public Population Project in Genomics and Society (“P³G”) has grown as a consortium. It has expanded its range of services and resources to adapt to the ever-evolving needs of the research community. From its outset – when P³G first tackled the building of biobanks as resources as well as data cataloguing and harmonization for data integration – to its new mission and vision, it has continually developed the tools for the conceptualization and design of population biobanks from their inception to their use to their closure. In so doing, P³G has become key in fostering research infrastructures to facilitate transition to the clinic. The consortium has become a crucial stakeholder in the international scientific, ethical, legal, and social research communities.

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1. Introduction

The Public Population Project in Genomics and Society (P³G), established in 2004, is a non-profit international consortium focusing on genomics and biobanking. Originally, P³G served four different but complementary population genomics research projects: CARTaGENE (Quebec); GenomEUtwin (FP5 (EC) project involving 8 countries); Estonia's genome project (Estonia); and the U.K. Biobank (U.K.). Dedicated to the development and management of multi-disciplinary research infrastructures, it sought to facilitate translational research via tools for prospective harmonization.

P³G quickly established itself as a key resource for biobanking (in particular, for large cohort biobanking), and for the genomics research community at large. The importance of P³G was illustrated in a major paper in the *European Journal of Human Genetics*, in which the consortium and its early achievements were introduced and discussed (Knoppers et al., 2008). For instance, at the time of its inception, one of the major issues with which genomic researchers had to contend was the disparities in the type and quantity of data available (Collins et al., 2003). This was compounded by the fact that both policy compatibility between studies and the ability to compare and use data (e.g. socioeconomic status, behaviours, diet, lifestyle, etc.) were lacking, thus limiting statistical significance (Burton et al., 2009). P³G began to address the harmonization of questionnaires (Fortier et al., 2010), the issues surrounding population data and access (Fortin et al., 2011), as well as the need for templates that could be used to prospectively ensure the future interoperability of large biobanks (Wallace et al., 2009).

Through the years, P³G's mission has been to lead, catalyse, and coordinate international efforts and expertise relating to policy and data harmonization for studies, biobanks, research databases and other health and social research infrastructures, in order to improve the health of individuals and populations. P³G's tools, support and network help the international research community to use health and social data for health care strategies aimed at disease prevention and tailored treatments. Finally, P³G is committed to:

- maintaining a global vision of the scientific, technical, ethical, legal, social environmental, economic and behavioural issues;
- promoting pre-competitive data sharing whilst respecting all applicable legal and ethical obligations; and
- supporting and enabling wide access to research tools and expertise.

P³G comprises over 450 individual and institutional members. It was founded on a common shared philosophy of data harmonization and sharing under a common ethical framework, as expressed in a Charter of Principles:

Charter of Principles (adopted by P³G Board of Directors: March 23, 2007)
P³G aspires to the highest standards of ethical comportment and research integrity. The fundamental principles that underpin its activities are:

- Promotion of the common good: P³G will optimise the benefits of collaborative research for the benefit of all.
- Responsibility: Protection of the interests of all affected stakeholders including families, groups, populations, researchers and research sponsors is the highest priority. Every effort will be made to respond to the concerns of stakeholders in a timely and appropriate manner.
- Mutual respect: The development and sustainability of P³G is based on responsibility, collaboration, co-operation, trust and mutual respect for others, which

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includes recognition of cultural diversity and the scientific specificity of the projects involved.

- Accountability: All standards, processes and procedures will be transparent and clear, developed on the basis of consensus, and aim to create best practice in the networking of population genomics resources.
- Proportionality: All research materials (such as data and samples) must be protected to the highest standards of privacy and propriety, whilst at the same time allowing and promoting the free exchange of ideas, datasharing and openness for the benefit of all.

In Phase I (2004–2012), the goal of P³G was to ensure the future interoperability of large population cohorts by providing expertise and fostering interoperability. Now in Phase II (2013–), the focus of P³G is on access and use of genomic research and clinical databases, so as to move towards genomic medicine and address the issues that arise during this translation.

2. P³G Phase I (2004–2012) – fostering interoperability of large population cohorts

At the outset, P³G created five International Working Groups (IWGs) on:

- 1) socio-demographic health;
- 2) physical/physiological/biochemical measurements;
- 3) storage, logistics and security;
- 4) governance and ethical clearance; and
- 5) public engagement.

The IWGs focused on the similarities and differences amongst projects; key areas of collaboration; emerging issues; next steps; and harmonization. In order to keep the community informed of their progress, the results of the IWG's findings were discussed and presented to the membership at regular meetings.

One of P³G's first major achievements was the creation of the Observatory. The P³G Observatory was launched at a meeting in Salt Lake City in October 2005. Its main objectives were to provide support tools for researchers in the harmonization, development, and implementation of epidemiological and genomic studies; to disseminate scientific and technical information developed and collected by P³G Cores and IWGs; and to make feasible the comparison and sharing of information and data between studies. The P³G Observatory quickly became a valuable tool amongst the biobanking community; not only did it contain information from worldwide, large population-based biobanks (>10,000 participants) (such that the number of cohorts listed soon amounted to over 160), but also the information gathered was also made readily available as cohorts emerged. This effectively ensured a large degree of prospective harmonization and interoperability.

The P³G Catalogues in the Observatory comprised a wide range of study descriptions, and many of them also linked to questionnaires, physical/cognitive measurements, DNA analysis, etc. The Catalogues provided access to both standard and detailed information on population projects in genomics; facilitated the selection of projects by specific criteria (study design, number of cases, etc.), and expedited the generation of synthesis tables.

Through compiling such information, disparities between cohorts, the accumulated data, and different variables became readily apparent. In response, P³G sought to harmonize such variables by developing tools that would ease the integration of data across biological studies (Fortier et al., 2010). In point of fact, one of these tools, DataSHaPER, demonstrated that harmonization was possible (Fortier et al., 2011) by retrospectively assessing 53 cohorts from 21 countries, which resulted in a harmonization rate of 62% of essential variables. This made possible the “virtual” aggregation of 6.9 million individuals on any of the 148 variables, thereby creating the necessary statistical significance (power).

In short, the P³G Observatory provided the community with the resources, tools and know-how to perfect data management and improve methods of transfer and sharing. This result was consonant with P³G's main objective – the creation of open, public and accessible datasets. P³G's emphasis on transparency and collaboration not only enabled its members (and any other entity that abided by its policies, and used its tools) to enjoy horizontal access to data, but also legitimized the works of P³G.

P³G became a much sought-after resource for establishing ground rules and policies for the worldwide biobanking community. For instance, several tools were developed by P³G and its partners to facilitate the development of population research projects, including model frameworks for the governance of biobanks, generic models of consent forms or information pamphlets, and core elements and clauses for samples and data access agreements (www.p3g.org/resources/biobank-toolkit, accessed 24 Sept. 2013).

These endeavours enabled P³G members to keep abreast of new development, and to respond to community-based needs. P³G subsequently engaged in the conceptualization and publication of statements. For example, P³G prepared the principles for the elaboration of a data sharing code of conduct (Knoppers et al., 2011), and a policy statement framing the return of research results and incidental findings particular to population studies (Knoppers et al., 2012).

On the international scene, P³G quickly established itself as a major player, able to address issues and needs. For instance, P³G proposed a roadmap for biobanks to enhance data pooling, so as to ease and accelerate international collaborations (Harris et al., 2012).

3. Phase II (2013–) – promoting access and use of research and clinical databases

P³G developed as a fluid and flexible organisation, able to modify its trajectory and adapt according to the needs of its community. In order to better serve the research community, P³G prepared Phase II in 2012. As P³G had already built a foundation for biobanks, it soon began to address the needs arising from the usage of and access to biobanks. This shift necessitated major changes in the focus, mission and structure of P³G. Thus, P³G changed its name to Public Population Project in Genomics and Society to better reflect the societal aims of the consortium, and its optimization of access to and use of population studies. P³G also broadened its mission to include social science databases and linkage with administrative and personal health records and databases, for incorporation into societal health systems the creation of diverse research programmes with distinct platforms and a new suite of tools.

3.1. Mission

In early 2012, P³G began to prepare Phase II, having achieved the critical mass needed to become the principal international body for the harmonization of public population studies in genomics and society. Structural changes and new tools were needed to meet the challenge of optimising the use of and access to biobanks and cohort studies, together with a new emphasis on integrating social science, administration, and clinical data.

3.2. Structure

P³G remains governed by its Assembly of Members, and operates pursuant to its Board of Directors as a non-profit international consortium. The Board is itself composed of a Finance Sub-Committee and a Member's Sub-Committee. Scientific guidance is provided by an International Steering Committee (ISC), and the P³G's secretariat works in collaboration with three research programmes to promote the realisation of research endeavours for the benefit of the entire research community (www.p3g.org/about-p3g/glance – accessed 24 Sept. 2013).

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