



GenomeCanada



GenomeQuébec



December 15, 2003

THE U.K. BIOBANK



eesti geenivaramu

Cart@gene

GENOM EU IWIN



Mission

The U.K. Biobank, CARTaGENE (Canada) as well as the Estonian Genome Project and GenomEUtwin research projects have agreed to develop common areas of interest over the next several years, and accomplish the following mission:

Creating P3G, a resource, service and infrastructure for existing and future partners involved in large-scale population genetics projects.

While it is recognized that specific projects will have differences in terms of study design, governance, outcomes, it is expected that there will be many common elements (such as phenotypes, genetic tests, consent issues) that can be shared in order to augment the knowledge created by these projects. Ultimately, P3G will include shared population genomics data, according to ethical and legal norms, and foster international collaboration and public access.

Through such data, researchers around the world are seeking to understand the role of genetic variants in comprehending human biological diversity and the genetic and non-genetic factors affecting common diseases, in order to improve health care policies and practices.



Partner Projects

GenomEUtwin

Study 800,000 twin pairs from a collaborative European pool of registries through a combination of genetic, epidemiology and phenotype data for common diseases

Estonian Genome Project

Collect data from up to one million participants into a database, including health status, genomic DNA, plasma and genealogical data

UK Biobank

Obtain samples from 500,000 volunteers in order to appraise the effects of genetic and environmental factors on the risk of common multifactorial diseases

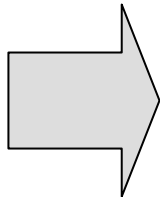
CARTaGENE

Obtain personal, medical and sociological data and biological samples from 60,000 to 65,000 random participants for the study of normal genetic variation

P3G Objectives

Mutual Areas of Interest

- Harmonization, where possible
- Prioritization of phenotypes collected
- Compatible data
- Protecting ethical standards
- Security measures for data protection
- Clarity in benefit sharing
- Support transfer of knowledge and technology to other researchers
- International leadership in ethics
- Evaluation and validation of results on health and disease



Objectives

- To connect the international leading public population genomics projects for the creation of open, public and accessible genomic data
- To provide necessary coordination, harmonization and standardization so that sharing genomic data, where possible, will foster international collaboration, advance science and maximize public health benefits
- To develop common understanding of the socio-ethical and legal issues
- To foster a deeper understanding of the relative contribution of genetic and non-genetic determinants to health and disease, as well as,
- To transfer this knowledge to the international community so as to optimize benefits for public health care worldwide

P3G Working Groups

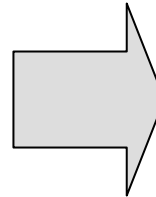
**Socio-demographic/health
questionnaires**

**Physical/physiological/
biological/biochemical
measurements**

**Storage, genotyping,
logistics and security**

Public engagement

**Governance/ethical
clearance/
commercialization**



Strategy of Working Groups

Discuss key areas of interest

Determine areas of
divergence/convergence
across the four projects

Discuss possibilities for
standardization/harmonization

Define emerging issues

Next steps

Progress of Working Groups

	Socio-demographic/health Questionnaires	Physical/physiological/biological/biochemical measurements
Leader	Andres Mestpalu	Leena Peltonen
Some Highlights	<ul style="list-style-type: none"> • Harmonization, where possible, on content of questionnaires • Validating questionnaires • Possibility of forming subgroups of participants • Pooling data vs. meta-analysis • Use of macro-environmental indicators 	<p>Created subgroups for various aspects of collaboration</p> <ul style="list-style-type: none"> • Comparison table on study design etc. • Phenotype questionnaires (health related) with criteria • Physical traits • SOPs with biological samples • Biochemical measures



Progress of Working Groups

	Storage, genotyping, logistics and security	Public Engagement
Leader	Thomas Hudson	Alan Doyle
Some Highlights	<p>Compared methods of:</p> <ul style="list-style-type: none">• DNA storage• Non-DNA storage• Logistics and security of data <p>Standards required for:</p> <ul style="list-style-type: none">• Quality of DNA samples• Biological markers• Coding, security and formats for data sharing	<p>Possible areas for convergence:</p> <ul style="list-style-type: none">• Harmonizing international message• Communication among projects about successful PR initiatives• Promotion of P3G as an international project to give credibility and commit the public• Opportunities of international approach to media coverage• Advantages of developing international best practices

Leader

Governance/ethical clearance/commercialization

Bartha Maria Knoppers

Some Highlights

Minimal thresholds of ethical acceptance across projects in the areas of:

- Recruitment and consent
- Feedback to participants and right to withdraw
- Confidentiality and security
- Transfer of data
- Governance
- Sharing of benefits
- IP issues

Benefits

Working Groups

Socio-demographic/health questionnaires

Physical/physiological/biological/biochemical measurements

Storage, genotyping, logistics and security

Public engagement

Governance/ethical clearance/commercialization

P3G Benefits

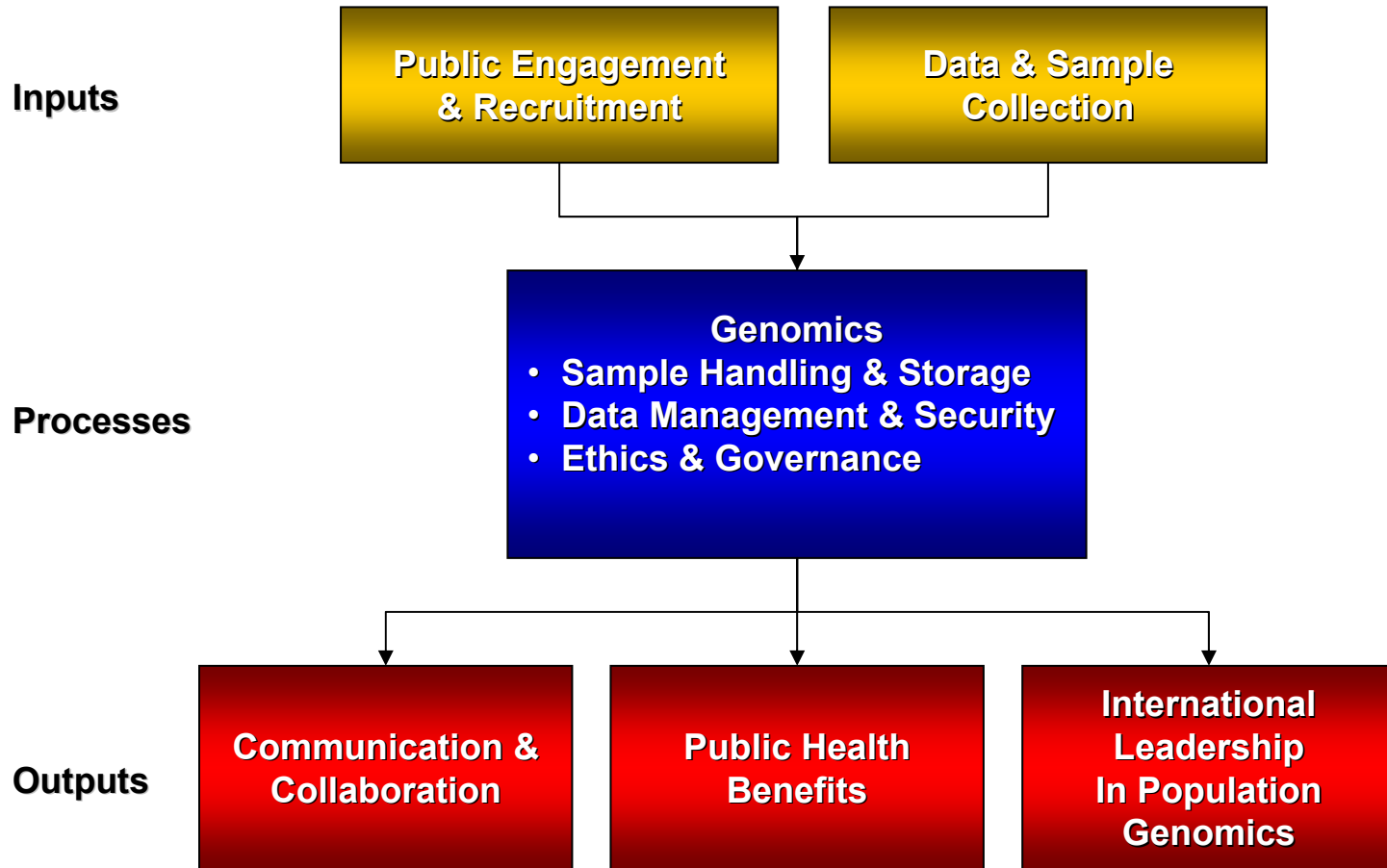
Open access to certain shared data
Increased statistical power
Opportunities for validation
Harmonization for future data sharing
Fostering international research

International communication
Shared experiences/methodology
Harmonization of strategy
Increased public trust
International perspectives

International modelling of core elements of consent/security/confidentiality
International standardized approaches re: conflict of interest
Ethical clearance strategies
Shared IP/benefit/sharing principles



P3G Scientific Program





P3G Progress to Date

- **London Meeting of the Founders (February, 2003)**
- **Montreal Meeting (July, 2003)**
 - P3G workshop organized by Genome Canada/Genome Quebec and the Centre de recherché en droit public (Public Law Research Center); Working Groups were set up to address key issues
- **Canadian Partnerships Meeting in Montreal (August, 2003)**
- **EU 6th Framework Programme Coordinated Action Application**
 - Several P3G participants in the EU 6th Framework application
- **Ongoing communication with potential partners**
 - Sweden, Spain, US, UNESCO, HUGO, OECD, Council of Europe
- **International Conference Calls (November- December, 2003)**
 - Between P3G partners resulted in the drafting of a Memorandum of Understanding for discussion
- **Agreement between founding scientific partners to sign a MOU (December 14, 2003)**

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