Request for Applications

Sharing Big Data for Health Care Innovation:
Advancing the Objectives of the Global Alliance for Genomics and Health

1. Overview

In order for Canada to take full advantage of the advances in DNA sequencing technologies for health care, we need to have the ability to share complex data sets including both genomic and clinical phenotypic data. These data need to be shared across institutional, provincial and national jurisdictional boundaries in order for scientists and clinicians to interrogate disease specific cohorts for validation, statistical significance and disease stratification purposes. There are a number of challenges associated with sharing genomic and clinical data sets including the *ad hoc* use of a range of data formats and technologies in different systems, lack of alignment between approaches to ethics and national legislation across jurisdictions, and the challenges of devising secure systems for controlled sharing of these data.

The Global Alliance for Genomics and Health (Global Alliance; http://genomicsandhealth.org/about-global-alliance) was formed in 2013 to encourage collaboration on the development of innovative solutions to accelerate sharing of genomic and clinical data. The Global Alliance brings together leading international organizations working in health care, biomedical research, disease and patient advocacy, life science, and information technology to create a common strategy using interoperable approaches and initiatives to enable the responsible, secure, and effective sharing of genomic and clinical data.

Canada has played an important role in the development of the Global Alliance and is well-positioned to move forward on a strategy to facilitate the sharing of data for biomedical discovery in Canada and beyond. Canadians are at the forefront of contributions to biomedical discoveries and health care innovation from basic and clinical research to participation in clinical and population studies. Capitalizing on new types of information based on genomics and other sciences linked to clinical characteristics from healthy and diseased individuals will lead to a more comprehensive understanding of health and novel ways to prevent, detect, monitor and treat disease.

2. Objective

Through this "Sharing Big Data for Health Care Innovation: Advancing the Objectives of the Global Alliance for Genomics and Health" competition, Genome Canada and the Canadian Institutes of Health Research (CIHR) aim to support a single pan-Canadian program to develop a comprehensive strategy that will enable the sharing of genomic and clinical datasets across Canada and around the globe in a responsible, secure and effective manner, thereby accelerating progress in health research and improving patient care.

It is expected that the program will leverage existing provincial and national genomic and clinical data sharing efforts and be aligned with international initiatives.

3. Elements of the Canadian Program

In order to meet the objectives of the competition the program must:

- be pan-Canadian, that is, must include applicants from AT LEAST three different provinces/territories;
- involve a broad range of stakeholders, including for example researchers, clinicians, bioinformaticians/computational biologists, GE[3]LS[1] scholars, policy makers, patient/disease groups, and industry;
- support the activities of the Global Alliance and one or more of its working groups (http://genomicsandhealth.org/our-work/working-groups) to ensure interoperability and alignment with international efforts;
- engage with relevant provincial, national and international organizations and initiatives interested in working together to address the challenges of data sharing, many of which may be members of the Global Alliance;
- propose pilot/demonstration projects that validate the utility and possible adoption of the strategy within Canada, as well as a mechanism to identify additional projects as the program develops;
- present an integrated translation plan that engages data stewards and end-users to facilitate the implementation of the program; and,
- have an appropriate management structure.

The program must include activities focused on one or more of the topics being advanced by the Global Alliance, including but not limited to the following:

- development of interoperable guidelines and ethical frameworks for data sharing;
- establishment of data standards and improved methods for analyzing and storing large data sets that can be shared nationally and internationally including application programming interfaces (APIs);
- creation of a technology environment that provides patients, researchers, clinicians and other stakeholders assurance that genomic and clinical data are being accessed, annotated, and interpreted in a secure manner adhering to privacy policies; and/or,
- development of standards for representing phenotypic data and linking it to genotypic information that are in line with international standards in the area.

4. Funding Available and Term

- One pan-Canadian program will be funded.
- There is up to $1.5 million available, with up to $1.0 million from Genome Canada and up to $0.5 million from CIHR.

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[1]The acronym GE[3]LS stands for "Genomics and its Ethical, Environmental, Economic, Legal and Social aspects". However, it should be understood broadly as genomics-related research endeavors and related activities undertaken from the perspective of the social sciences and humanities. Therefore, it is not strictly limited to disciplines that make-up the acronym but rather encompasses all those that rely on quantitative and qualitative methodologies to investigate genomics in society, and help establish a basis to inform applications, practices and policies.

- At least 25% of the requested funding for eligible costs must be obtained through co-funding from other sources (see section 8. below).
- To facilitate engagement with the Global Alliance, certain costs associated with the activities of the Global Alliance and its working groups are eligible (see section 5.1 below).
- Funding will be awarded for a term of up to 3 years.

5. Guidelines for Funding

5.1. Genome Canada Guidelines

Genome Canada's Guidelines for Funding Research Projects
http://www.genomecanada.ca/medias/PDF/en/guidelines-funding-research-projects-june-2014.pdf must be adhered to throughout the competition and post-award management processes.

5.1.1. Exceptions to the Guidelines

Since the main objective of this program is the development of a comprehensive strategy that will enable the sharing of genomic and clinical datasets rather than a traditional research-based project, exceptions to the Guidelines specific to this RFA include:
- Integrated GE^{3}LS: An integrated GE^{3}LS research component is not required, though GE^{3}LS scholars should be engaged in the program.
- Project Managers: A dedicated Project Manager is not necessarily required but is an eligible expense.
- Research Oversight Committee: A Research Oversight Committee (ROC) is not required.

5.2. CIHR Guidelines

In addition, in order to receive funds from CIHR, their guidelines must be followed. See the CIHR Funding Opportunity (anticipated to be available shortly) for a complete listing of all CIHR guidelines and policies.

6. Application Process

Applicants are required to apply for funding through their regional Genome Centre. The application process is comprised of two steps: Registration and Full Application.

6.1. Registration

A brief Registration outlining the vision of the teams will be used to provide early information on elements such as, who is applying and what they are planning to do. Registrations will be posted on the funders' websites to help identify potential synergies between applications and help teams explore any interest in engaging with one another. The registrations will allow for screening for eligibility by the Genome Centres and facilitate the early selection of reviewers for the peer review process.

6.2. Full Application

Full Applications will be reviewed by a panel of experts to assess the effectiveness of the proposed strategy to advance the objectives of the Global Alliance and for overall excellence as determined by the review criteria. The top ranked application will be funded.

Full applications must address the review criteria as well as the specific requirements of the program as outlined in Section 3, above. The application form, including a budget template, will be made available through Genome Canada.

Genome Canada may adjust the evaluation process where warranted by the complexity of the proposals or other relevant factors. Any adjustments will be rapidly communicated through Genome Canada's website and through the Genome Centres.

7. Competition Timeline

> **Requests for support of projects must be submitted to Genome Canada through a Genome Centre. The competition timeline outlined below includes both Genome Canada and Genome Centre deadlines. Please contact your Genome Centre for further information on their process and internal deadline dates.**

Week of November 24, 2014	Launch of competition
December 1, 2014	Webinar to bring interested stakeholders together to discuss the Program
January 15, 2015	Registration due date - Genome Centres
January 19, 2015	Eligible registrations submitted to Genome Canada
February 16, 2015	Deadline for Full Applications to Genome Centre
March 16, 2015	Deadline for Full Applications to Genome Canada
Early April, 2015	Review
Late April, 2015	Decisions by Funders (anticipated)
Early May, 2015	Notification of Decision

8. Co-Funding

At least 25% of the requested funding for eligible costs must be obtained through co-funding from other sources. The Genome Centres, working with the applicants, are responsible for securing co-funding. Co-funding for this competition must be for activities that are an integral part of the approved project and must be for eligible costs specifically requested in the Genome Canada budget form in order to be considered as an eligible co-funding source. See the Guidelines for Funding Research Projects http://www.genomecanada.ca/medias/PDF/en/guidelines-funding-research-projects-june-2014.pdf for more details.

Appendix 1. Evaluation Criteria

The applications will be reviewed by an expert panel to identify the proposals that best respond to the RFA.

1. Program

- To what extent does the program advance the objectives of the Global Alliance?

- To what extent does the program build upon existing provincial, national and international genomic and clinical data sharing efforts, as well as link to existing international activities, including those of the members of the Global Alliance?

- To what extent does the program lead to the development of systems and tools that will allow Canadian clinicians and researchers to share genomic and clinical data?

- How realistic are the goals of the program, given the projected resources and timelines?

- To what extent does the program demonstrate the potential for translation to the data stewards and end-users identified?

- How appropriate are the methods and approaches proposed in terms of the overall goals of the program?

- To what extent do the proposed pilot/demonstration projects align with the proposed strategy and support the objectives of the Global Alliance?

- How appropriate are the methods and approaches proposed for the pilot/demonstration projects?

- How appropriate is the mechanism to develop new pilot/demonstration projects?

- How appropriate is the expertise and track record of the team in terms of realizing the goals of the program?

- How well will the different types of expertise on the team be integrated into the program?

2. Benefits

- How significant are the anticipated benefits described?

- How strong is the plan for knowledge translation and development of benefits, i.e., how well does the plan explain the next steps of how the deliverables from the program will be transferred, disseminated, used, and/or applied?

3. Management and Finance

3.1. Management plans and expertise
- How well does the management plan cover project governance, accountabilities of personnel and finance, and processes for decision-making?

- How realistic is the project schedule given the likely need to "ramp-up" activities at the front end?

- To what extent do the project leaders have experience in managing similar projects?

3.2. Budget and expenditure controls
- How reasonable is the proposed budget in terms of the anticipated level of effort and deliverables?

- To what extent are the budget and proposed expenditures well-documented and eligible per the guidelines?

- To what extent does the proposal provide assurance that expenditures from a funded project would be closely and critically monitored?