GenomeQuébec

Guidelines and Evaluation Criteria Governing the

Genomics Integration Program

Human Health

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GenomeQuébec

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1. GÉNOME QUÉBEC MISSION AND OBJECTIVES

Génome Québec's mission is to catalyze the development and excellence of genomics research and promote its **integration** and **democratization**. It is a pillar of the Québec bioeconomy and contributes to Québec's influence and its social and sustainable development.

To ensure the development of research excellence in genomics, Génome Québec funds large-scale projects in Québec's priority sectors. The mobilizing effect of these investments helps to maximize socio-economic benefits and establish Québec as a leader in the field of life sciences.

Objectives:
One of the key elements of the Génome Québec strategy for 2018-2023 entails support for genomics research. This translates into ensuring the development of research excellence in genomics by stimulating partnerships with end users and by:

i. Promoting genomics as a tool for economic development in Québec;
ii. Supporting the development of genomics in strategic sectors for Québec;
iii. Optimizing the success rate of Québec in Genome Canada competitions;
iv. Ensuring the emergence of new research teams in genomics;
v. Ensuring the uptake of research results by end users;
vi. Increasing the contribution of external partners (private and international);
vii. Developing emerging sectors with high potential.

2. OVERVIEW

Genomics, the only disruptive technology capable of both saving lives and creating wealth, generates many opportunities and challenges. As industrialized nations continue to focus on the immense potential of this revolutionary technology, Québec has at its disposal the assets it needs to position itself as a global leader of change. If we look to the global environment, we can see that major countries are embracing genomics, particularly as it applies to human health, with many of them adopting national strategies on genomics in medicine. We can also note the unique feature of the Canadian business model in terms of genomics funding. In the last 20 years, Québec has invested over $1 billion through Génome Québec, thus building a critical mass of competitive expertise now capable of serving as a pillar of economic development.

Genomics is not a pipe dream; it offers real deliverables now and a growing number of solutions with major economic potential. It has the capacity to improve our way of doing things by boosting productivity and enhancing quality of life for all. Genomic applications can foster innovation in private corporations and public organizations whether through improved procedures, lower costs, or the launch of new products. It is up to us to use this expertise to create new innovative and lucrative economic opportunities that can bring about the expansion of industrial clusters derived from genomics knowledge.

3. THE GENOMICS INTEGRATION PROGRAM

Within this context, Génome Québec has launched the ***Genomics Integration** (GI)* **Program**, whose aim is to provide our organization with the tools it needs to support the end-user adoption of genomics. The program consists of grants ranging from $50,000 to $200,000 to cover 50% of the funding for partnerships between academic researchers and users capable of implementing and/or commercializing the research results. The funds must be used to develop a **proof of concept** that can be leveraged to secure subsequent funding. The funds can also allow the results of the **proof of concept** to be implemented by the user partner at the end of the project. Projects must deal with human health and include an "omics" technology component – for example, development of new "omics" technology, using artificial intelligence to exploit "omics" data, genetic engineering, synthetic biology, validation of therapeutic targets or biomarkers identified through genomics, etc.

The main program objectives are to:

- Develop applied genomics technologies;
- Foster and facilitate collaborations between the private sector and academia on applied genomics research;
- Stimulate an increase in R&D activities in Québec;
- Prepare and train new scientists to address human resource requirements in the academic, industrial, government, clinical and financial sectors;
- Promote employment and economic growth in Québec by creating attractive and stimulating positions in Québec for researchers who receive education and training at our universities;
- Improve communication between senior management from private corporations and the academic research environment;
- Encourage the implementation of genomics research programs in very young companies, academic research centres, SMEs and larger companies;
- Foster the transfer of technology and knowledge from research to practical applications with significant impact in the health field;
- Promotion of the use of genomics technologies in the Québec healthcare system.

3.1. Eligibility

To be eligible, projects must meet the following criteria:

i. The teams must be composed of at least:
   a. One (1) investigator affiliated with a public research institution in Québec (university, college, or an institution with a research mandate), with adjunct status or equivalent, at a minimum. The researcher may only submit one application per program cycle;
   b. One (1) non-academic organization tasked with implementing or marketing the results, which can include private companies, industrial consortia, non-profit organizations, hospitals, or government departments or organizations, etc.

ii. The non-academic organization must demonstrate its capacity to implement or market the project results. Non-academic organizations have the option of including this demonstration in a use, implementation, or commercialization plan*.

* The submission of a use plan, implementation or commercialization plan will be considered as an asset.

This plan can include:
   a. Revenues generated by the commercialization of similar products;
   b. Support from potential clients/end users;
   c. Incubation/training in life science commercialization;
   d. All additional information in support of its implementation/commercialization capacity.

iii. Projects must pertain to human health and include a component derived from genomics technologies. The word "genomics" is meant to be a generic term that encompasses genomics, proteomics, metabolomics, bioinformatics, genetic engineering, synthetic biology and all related "omics" fields.
iv. Projects must meet a significant need of the non-academic partner.
v. Projects must generate socio-economic benefits for Québec: job creation, economic growth in Québec, cost savings for public institutions, impact on society, quality of life, health, etc.
vi. The funds cannot be used for new discoveries. They must be used to establish proof of concept.
vii. The proof of concept could be used as leverage to obtain subsequent funding. If applicants indicate in their application the possibility of obtaining potential funding sources, they must justify their capacity to obtain the necessary funding and the need for the proof of concept. The proof of concept could also allow the user partner to integrate the results of the projects. If so, applicants should detail their ability to incorporate the results of the proof of concept at the end of the project.

Equity, Diversity, and Inclusion (EDI)

Equity, diversity, and inclusion are essential to achieving excellence and the full potential of the research ecosystem. Demonstrating respect for the principles of EDI as set out in the strategy of the Fonds de recherche du Québec as well as the integration of early career researchers (5 years or less) should be considered. For reference: https://frq.gouv.qc.ca/app/uploads/2021/07/frq_strategieedi_en-2.pdf.

3.2. Funds Available, Co-Funding and Term of Projects

Applicants may request grants ranging from $50,000 to $200,000. They must secure co-funding of at least 1:1, for a total budget of $100,000 to $400,000 or more. Sources of co-funding can be the user, namely private companies, industrial consortia, or any other source other than the ministère de l'Économie et de l'Innovation (see section 4.4.1). In-kind contributions are accepted if they are provided in Québec. The duration of projects must be 6 to 24 months. Génome Québec funding can only be paid to the academic partner.

4. APPLICATION AND EVALUATION OF PROPOSALS

4.1. Application process of proposals under the GI Program

Applicants from academic and non-academic organizations interested in submitting proposals under the GI Program can contact Génome Québec (see section 6 for the name of contact) for any questions relating to eligibility. Following the deadline for submitting applications, Génome Québec will determine whether the application meets the eligibility criteria described in these guidelines and can therefore be reviewed by the external evaluation committee. Applications must be submitted to

Integration@genomequebec.com using the form available at the Génome Québec website. There will only be one step in the assessment.
Applications will be assessed by a committee composed of scientific experts, and industry and healthcare representatives. All committee members will be required to sign a confidentiality agreement and report any conflict of interest. The committee will evaluate each application based on the evaluation criteria featured in Appendix A. It will give advice and recommendations to Génome Québec. Once a decision has been made, applicants will be given the result of the evaluation along with a summary of the strengths and weaknesses of their application.

If at any time during the initial review process, an application is found not to meet the general eligibility criteria as defined in Appendix A, Génome Québec WILL NOT submit it for peer review and evaluation.

Génome Québec reserves the right to modify the evaluation process if the complexity of the applications, the volume of application received, or other factors justify it. All modifications will be quickly shared with applicants.

4.2. Eligible costs

Funds can only be used for eligible costs, which are defined as reasonable costs for items that directly support the objectives of the project approved by Génome Québec:

- Salaries and benefits;
- Consumables;
- Services provided by third parties;
- General and administrative fees;
- Equipment.

Project budgets must **NOT** include items for which funding has already been approved from other sources unless the request for funding of these items was specifically made to support activities in the Génome Québec project and meets all other eligibility criteria. Expenses funded through Génome Québec and expenses covered by eligible co-funding must be incurred after the Notice of Award (NOA) to be considered as eligible costs.

Eligible costs are the same as those for Genome Canada projects. A description of the Genome Canada eligible and non-eligible costs can be found in the Guidelines for Funding by Genome Canada.

4.3. Non-eligible costs for Génome Québec

The following expenses are not eligible under Génome Québec criteria:

i. Salaries (or bonuses) for the principal investigator and co-applicants;
ii. Costs of entertainment, hospitality and gifts, such as the cost of regular interactions with colleagues from the institution and personnel meetings;
iii. Costs associated with staff awards and recognition;
iv. Education-related costs, such as thesis preparation, tuition and course fees;
v. Costs involved in the preparation of teaching material;

vi. Costs of basic services, such as heat, lighting, water, compressed air, distilled water, vacuums and janitorial services supplied to all laboratories in a research facility;
vii. Insurance costs for buildings and equipment;
viii. Costs associated with regulatory compliance, including ethical review, biohazard or radiation safety, environmental assessments or provincial or municipal regulations and by-laws;
ix. Monthly parking fees for vehicles, unless specifically required for field work;
x. Sales taxes to which an exemption or rebate applies;
xi. Costs of moving a lab;
xii. Costs related to alcoholic beverages;
xiii. Expenses of incorporation and legal fees associated with a new or spin-off company.

4.4. Co-funding

The complete application must include all documentation related to the secured co-funding. The co-funding must be at least equal to the contribution made by Génome Québec (minimum of 1:1). Here are examples of documentation required:

i. Written confirmation, such as a letter of commitment from the co-funding source;
ii. If the co-funding is from industry, documentation supporting the organization's financial viability and its ability to fulfil its co-funding commitment (e.g., statement of cash flow, most recent audited financial statement, press release announcing significant new funding);
iii. If the co-funding is from a funding agency, in addition to the above, a copy of the first page of the application, a project summary, detailed budget and notice of award (if applicable). Please note that the documentation must clearly demonstrate that the funding will be used for eligible costs included in the project budget approved by Génome Québec;
iv. For in-kind contributions: clear rationale and calculation of how the value of the contribution was determined, including documentation to certify the contribution (e.g., price lists, etc.). All in-kind contributions must be auditable by external experts.

4.4.1. Eligible co-funding sources

Génome Québec will accept the following potential co-funding sources, which can be Canadian or foreign, as long as the expenses are incurred in Québec:

i. Institutional funds, trust funds or foundations;
ii. Private companies and industrial consortia;
iii. Departments and agencies of the federal government, including the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), Social Sciences and Humanities Research Council (SSHRC) and tri-agency programs (e.g., Networks of Centres of Excellence);
iv. Departments and agencies of the provincial and municipal governments are eligible, with the exception of the ministère de l'Économie et de l'Innovation;
v. Firms and corporations;
vi. Non-profit organizations;
vii. Individuals;
viii. Venture capital or other investment funds;
ix. Cash contributions as co-funding are preferred. However, in-kind contributions, defined as non-cash contributions that can be given a cash value, may be considered as co-funding if:
    a. The value can be reasonably determined and supported by documentation;

b. The value of the contribution is based upon the fair market value of a tangible item and sufficient justification is provided. Supplier discounts are one example. However, institutional discounts generally offered to medical establishments or research facilities are not eligible as co-funding.

4.4.2. Non-eligible sources of co-funding

i. The value of previously existing intellectual property (IP) transferred to a project is NOT considered eligible co-funding;
ii. Co-funding not associated with proof of concept.

5. ADMINISTRATION

5.1. Conditions of release of Génome Québec funds

The following are the minimum requirements to allow for the disbursement of funds by Génome Québec:

i. Signed agreement between Génome Québec, the academic institution and the researchers that establishes the resolution of major areas, such as contributions, funding terms, termination policy, financial policies, etc.
ii. Approved budget, updated objectives and milestones in accordance with the recommendations of the Génome Québec review panel;
iii. Appropriate certification for proposals involving research with human subjects, human stem cells, animals, biohazards, radioactive materials or possible effects on the environment.

5.2. Project readiness

All applicants must demonstrate that they will be able to meet all conditions of the release of Génome Québec funds within three (3) months from notification of approval (see section 5.1 on Conditions of release of Génome Québec funds). **Génome Québec reserves the right to withdraw its funding for any approved project that is not ready to receive the funding or for which signed agreements as described in 5.1.i, have not been secured, within three months from notification of approval**.

5.3. Management of funding

The Génome Québec funds will be transferred to the academic institution once all the conditions listed in section 5.1 have been met. Two instalments will be made. The first 90% of the funds will be released upon receiving the signed agreements. The remaining 10% will be released once the final reports have been provided, and a strategic exit meeting has been held, no later than 3 months following project completion.

The final reports must describe at minimum the accomplishments of the project. They must include a final financial report – for which a template will be provided by Génome Québec – that must reconcile actual expenses to budgeted amounts, proof of the co-funding received for the project and the current state of any concrete outputs developed as a result of Génome Québec funding.

The strategic exit meeting will consist of a virtual discussion with representatives of Génome Québec and will help orient the teams' transition from a proof of concept towards development for commercialization or implementation.

5.4. Accountability and Reporting

Génome Québec must meet the evaluation, auditing, responsibility and accountability requirements stipulated by the ministère de l'Économie et de l'Innovation, including information that allows Génome Québec to evaluate the ongoing performance of projects and their related activities. It is the responsibility of funded researchers to participate in this process and provide the necessary information on the project's performance and progress as required by Génome Québec. As part of its responsibilities, Génome Québec will implement mechanisms to evaluate, on an ongoing basis, the performance and productivity of funded projects in order to determine whether funding must be continued, reduced, suspended or withdrawn. These mechanisms include the final report and the closing strategy meeting, as well as any other form of review that is deemed necessary.

6. GÉNOME QUÉBEC CONTACT

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APPENDIX A – EVALUATION CRITERIA

To ensure that the objectives of Génome Québec are met, proposals are assessed based on the following: level of need for the genomics technology by users; scientific excellence, project's potential to secure subsequent funding through its proof of concept; commercialization or implementation potential of the project; and socio-economic impact for Québec. The descriptors following each criterion are not all-inclusive.

A) Broad criteria of eligibility

1. Project is directed towards applied genomics or related research areas (proteomics, metabolomics, bioinformatics, genetic engineering, synthetic biology, etc.);
2. Project has the potential to have a major impact on human health;
3. Presence of a user and academic partner as principal investigators and degree of involvement of both partners;
4. Project is carried out in Québec.

B) Need for genomics-based innovation

1. Capacity of genomics to solve user issue;
2. Genomics-based innovation results in significant improvement compared to other possible solutions.

C) Scientific criteria

1. Scientific excellence of the proposed research as affirmed by peer review; particularly the extent to which the proposed research will increase the outcomes of genomics or proteomics research;
2. Feasibility of the milestones and the critical path table, proposed objectives and goals;
3. Quality of the scientific environment in which the work will be done.

D) Next steps in the process of use, implementation, or commercialization

Application will be evaluated according to one of the following two avenues:
a) Potential to obtain subsequent funding

1. Identification of subsequent funding source(s);
2. Demonstration of project eligibility;
3. Demonstration of the need for proof of concept, for example, to meet eligibility criteria or prior assessment;
4. Description of the leverage effect of the proposed GI Program project, for example, by including a financial plan of subsequent steps, including public and private funding sources.

b) Potential for technology integration by the user

1. Description of the integration of results by the user;
2. Demonstration of the integration of project results;
3. Demonstration of the need for a proof of concept for the user;
4. Description of the anticipated impact of the proof of concept on the user.

E) Commercialization/implementation plan

The path towards the commercialization or implementation of the innovation is realistic and clearly defined:

1. The steps to be taken are grounded in a proven business model;
2. The proposed approach is feasible based on a realistic schedule;
3. The sources of funding in support of this approach are identified and realistic;
4. The legal, social, economic, logistic, etc. barriers are identified and a strategy to minimize their impact is described.

F) Social and/or economic benefits

1. The quality of the plan for the transfer, dissemination, use, implementation or commercialization (as appropriate) of the expected results of the proposed research;
2. Demonstration of how the research results will contribute to job creation and economic growth in Québec and their impact on society, quality of life, health and the environment, including the creation of new policies in these areas;
3. Expected outcomes are quantified and realistic.

G) Project management and expertise of project leaders

The quality and experience of the applicants affiliated with the proposal: the appropriateness of the training and/or track record of the applicant(s) for the proposed research, in particular, prior contributions to public-private collaborative research; the importance and originality of the recent productivity of the applicant(s); and the level of confidence in the ability of the applicant(s) to do the work proposed.

H) Financial criteria

1. Budget and financial control processes
    a. The budgeted costs meet the definition of Eligible Costs (section 4.2);
    b. The budgeted costs are aligned with the proposed research plan and activities; the relationship between the proposed costs and potential benefits of the research proposed is evident;
    c. The budgeted costs of the project are reasonable.

2. Co-funding
    a. The proposed co-funding plan complies with the Eligible co-funding guidelines provided in section 4.4;
    b. The supporting documentation is made available, which may include a letter of commitment or signed agreements by co-funding sources, quotes from suppliers, grant applications to other funding agencies or confirmation of grants received;
    c. The demonstrated relationship between the proposed co-funding and the objectives of the project.