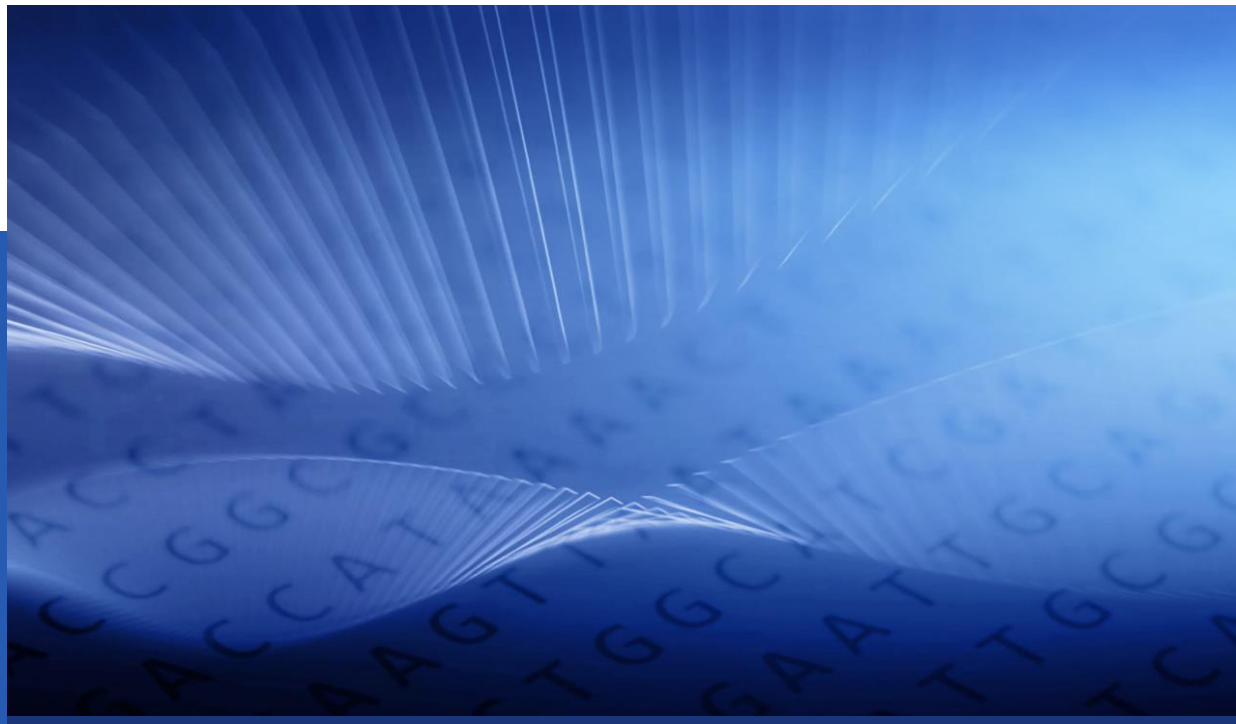
GenomeCanada

GLOBAL CHALLENGES ✦ GENOMIC SOLUTIONS DÉFIS MONDIAUX ✦ SOLUTIONS GÉNOMIQUES



Genomic Applications Partnership Program (GAPP)

Investment strategy and exceptions to Genome Canada's *Guidelines for Funding*

December 1, 2017

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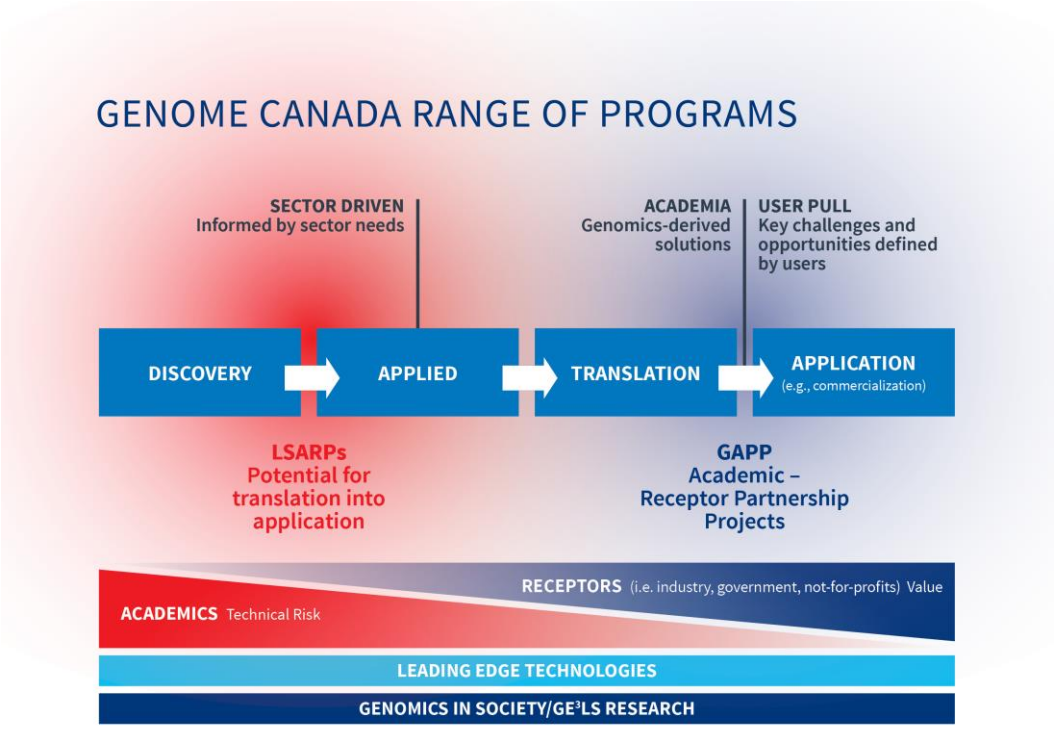
1. GAPP Overview

Genome Canada is a catalyst for the development and application of genomics[1] knowledge and technology for the benefit of Canadians, with emphasis on strategically important sectors (human health, agriculture, fisheries, forestry, energy, mining, and environment). Genome Canada and the regional Genome Centres have made significant investments in large-scale genomics research and leading-edge technologies, making Canada globally competitive in the field of genomics. We are now increasing our efforts to promote the translation of Canadian genomics discoveries, inventions and capabilities into valuable innovations.

The Genomic Applications Partnership Program (GAPP) represents a key element in Genome Canada's strategic plan – funding downstream research and development (R&D) projects that address real world opportunities and challenges identified by industry, government, not-for-profits and other "Receptors" of genomics knowledge and technologies. GAPP projects are collaborations between academic researchers and Receptor organizations. The projects are co-funded by Receptors and other stakeholders and have the potential to generate significant social and/or economic benefits for Canada.



[1] The term genomics is defined here as the comprehensive study, using high throughput technologies, of the genetic information of a cell or organism and its functions. The definition also includes related disciplines such as bioinformatics, epigenomics, metabolomics, metagenomics, nutrigenomics, pharmacogenomics, proteomics and transcriptomics.

2. GAPP Goal and Objectives

The goal of GAPP is to increase and accelerate the positive social and economic impact of Canada's genomics R&D capacity. Working towards this goal, the objectives of GAPP are to:

1. Accelerate the application of Canadian genomics–derived and genomics-enabling solutions to real-world opportunities and challenges defined by industry and public sector receptors.
2. Channel Canada's genomics capacity into sustainable innovations that benefit Canadians.
3. Enhance the value of Canadian genomics technologies, de-risking and incentivizing follow-on investment from industry and other partners.
4. Foster mutually beneficial collaboration and knowledge exchange between Canadian academia and technology receptors.

3. Project Eligibility

To be eligible for GAPP funding, projects must:

- develop and apply a genomics-derived or genomics-enabling tool, product or process to an opportunity or challenge clearly defined by the Receptor(s);
- focus on late stage R&D that will position the innovation for near term implementation / commercialization;
- be co-led by an Academic and a Receptor organization in partnership, with active and necessary roles for both (see Section 5 for GAPP project partner definitions); and,
- have the potential to generate significant social and/or economic benefits for Canadian stakeholders (see Section 6 for description of benefits to Canada).

Typically, a GAPP project involves either advancing a genomics technology that is emerging from Academic research, or applying a solution (genomic or otherwise) derived from Academic research and expertise to add value to a Receptor product, tool or process. In the latter case, either the solution or the Receptor technology (but not necessarily both) must have a clear basis in genomics.

GAPP is not intended to fund:

- discovery research;
- commercial launches;
- projects led by industry with an academic in a supporting or service role; or,
- projects or project components (e.g., certain types of clinical trials) that would normally be funded solely by the Receptor.

4. Funds Available, Co-funding and Term

Applicants can request up to 1/3 of the project budget from Genome Canada, from a minimum contribution of $100,000 to a maximum of $2 million. The remaining project funding must be secured from other eligible sources, with at least 1/3 provided by the Receptor(s) (see Appendix 2).

The duration of GAPP projects should be a minimum of one year to a maximum of three years, but may be shorter or longer if justified.

5. Project Partners

Each GAPP project must be co-led by an eligible Academic researcher and a senior representative of a Receptor organization (see below and Genome Canada's *Guidelines for Funding*). The project partnership must leverage the expertise and resources of each partner, and their respective roles and responsibilities must be clearly defined in the submission. Collectively, the project team should have experience with projects involving translational R&D for commercial and/or public service applications.

5.1. Academics

An Academic is defined as a researcher who is a faculty member of a Canadian university or affiliated, non-commercial entity, such as hospitals and research institutes. Researchers in not-for-profit corporations and registered charities may qualify as Academics for the purposes of GAPP if their organization has an explicit research mandate.

5.2. Receptors

A Receptor is defined as an organization that intends to put the resulting innovation into practice (in internal operations, by commercialization, or otherwise making it available to its ultimate users). Eligible Receptors include:

- companies (private / public, Canadian / foreign-owned);
- industry consortia;
- government departments and agencies (federal, provincial and municipal);
- healthcare organizations; and,
- not-for-profit organizations.

Small or start-up companies that have a clear business model and credible indication of traction in their industry are eligible Receptors. Companies that are owned by or employ the Academic Project Leader must demonstrate that they have their own business office and staff, physically separated from the Academic's laboratory and independently governed (e.g., by a dedicated executive team and Board of Directors).

5.3 Project Roles

In GAPP projects, both the Academic and the Receptor must play integral roles in planning, leading and executing the project, and be jointly responsible for major project decisions.

The Academic is expected to jointly develop the project plan (with the Receptor), provide critical scientific/technical expertise and direction, and administer project funds. The Receptor is expected to co-develop the project plan (with the Academic), provide technical expertise and direction for technology implementation, manage regulatory issues, and lead commercialization efforts (if applicable). Each Receptor representative is responsible for administering any project activities and associated costs taking place within their organizations. The Receptor(s) must have access to the expertise and resources to contribute substantially to the project from both a technical and commercial perspective, and to exploit the project outputs for the social and/or economic benefit of Canada.

In projects with more than one Receptor, the group must appoint one Receptor Project Leader to represent all Receptors.

6. Social and/or Economic Benefits to Canada

Evaluation of GAPP proposals includes an assessment of the social and/or economic benefits for Canadian stakeholders that could be realized if the project substantially achieves its objectives. The potential benefits should be well defined, quantifiable, and significant within the context of the project. Examples of benefits sought in GAPP projects include, but are not limited to:

- business growth and international competitiveness;
- improved health and safety;
- food security;
- environmental protection;
- public cost savings;
- effective public policy;
- economic development;
- investment attraction; or,
- other tangible benefits.

When appropriate and feasible, project teams are expected to take reasonable steps to maximize the benefits of the project and its central innovation at a national level. For example, project teams developing technologies intended to be offered in a public service setting should have plans to make their innovations available to interested entities across Canada after the project is completed.

GAPP project teams are expected to consider and, where feasible, address through research and/or stakeholder engagement, the societal concerns and barriers that may impact the advancement and implementation of the project's resulting innovations.

7. Intellectual Property

Genome Canada does not take an ownership stake in any IP that may be generated as a result of a funded project but, for projects in which significant IP is an expected outcome, GAPP funding is conditional on a legally binding agreement between the project partners regarding IP that is consistent with Genome Canada's IP Policy. The agreement must address, at a minimum:

- rights to use 'background' IP required for the project;
- ownership of, and rights to license, new ('foreground') IP generated by the project;
- management of new IP (such as filing and prosecution expenses, maintenance, licensing); and,
- responsibility and/or liability for patent litigation.

Applicants are advised to contact their regional Genome Centre for guidance on IP policies and guidelines.

8. Application Process

GAPP project proposals are reviewed in two stages, as follows:

8.1. Expression of Interest (EOI) / Project Pitch

The EOI is a summary of the proposed project and its value proposition. EOIs are screened by an internal Genome Canada committee to determine eligibility for GAPP. Applicants will normally be informed within one week whether or not their application is eligible to advance to the first review stage – EOI / Project Pitch.

Project leaders with eligible EOIs will be invited to "pitch" their project via teleconference to a panel of external industry and technical experts convened by Genome Canada. The Pitch consists of a presentation, with accompanying slides, that describes in further detail the scientific rationale, economic case, and potential social and/or economic value of the proposed innovation. The presentation is followed by a question and answer period between the reviewers and the project leaders.

The expert panel reviews the information obtained through the EOI and accompanying Pitch and, based on the criteria set out in Appendix 1, recommends to Genome Canada whether or not the proposal should advance to the Supplementary Proposal stage. A conditional decision may also be rendered, whereby a proposal may advance if certain follow-up questions are answered to the satisfaction of the review panel and Genome Canada. Genome Canada notifies the Regional Genome Centres of the decision, normally, within one week after the Pitch, and provides feedback from the external reviewers.

8.2. Supplementary Proposal

The Supplementary Proposal provides a more thorough description of several sections of the EOI, including a detailed explanation of the technical aspects, project plan and budget. Applicants are also expected to address any concerns about the project pointed out in the EOI / Pitch feedback. Supplementary Proposals are reviewed by the same external experts that reviewed the EOI / Pitch, plus additional experts if deemed necessary, and by the Genome Canada Core Evaluation Team (CET). The CET is also provided with the EOI and EOI / Pitch reviews.

The CET consists of external professionals with extensive experience in industrial R&D, technology implementation and commercialization, public policy, IP, investment and other relevant areas. The CET assesses all GAPP projects and expert reviews to provide additional viewpoints and consistency across project reviews, and is involved in the ongoing oversight of GAPP funded projects (see Appendix 2). The CET provides recommendations on project funding (new and ongoing) to Genome Canada's Board of Directors, who have final authority for funding decisions.

All reviewers and CET members engaged by Genome Canada are signatories to confidentiality and conflict of interest agreements with Genome Canada to ensure that information is kept in strict confidence and that reviewers are not biased by conflicting professional obligations or financial considerations.

9. Contacts

All documentation and information related to proposal submissions and follow-up must be submitted to Genome Canada through a regional Genome Centre. Please contact your regional Genome Centre (https://www.genomecanada.ca/en/about-us/genome-centres) with any questions you have about the program and application process.

Appendix 1. GAPP Proposal Review Criteria

1.1 Expression of Interest (EOI) / Pitch Review Criteria

Social and/or Economic Benefits to Canada

- There is a clear value proposition for the innovation with sufficient consideration of market potential, alternatives and competitors (if any) to support claims of unmet need or opportunity for a new entrant.
- The potential (direct and indirect) benefits of the innovation after implementation are quantifiable, significant (to the Canadian stakeholders), and likely to be realized, in large part, within 3 to 5 years after project completion.
- The steps and conditions required to realize the potential benefits of the innovation are well-defined and realistic (regardless of the level of involvement of the project participants at that stage).

Technical Aspects / Project Plan

- The project objectives are clear, quantifiable and achievable within the proposed timeline.
- There is a clear scientific rationale for the proposed approach, targeted performance of the innovation, and desired outcomes based on previous work, data, literature and/or other credible references.
- The major tools and methods to be employed in the project are appropriate and reasonably well-established in the field.

Commercialization/Implementation Plan

- The pathway to implementation and/or commercialization of the innovation is clear, realistic, and accounts for likely hurdles to adoption (legal, regulatory, social, economic, logistical, etc.).
- There is a viable model for funding the final development, launch and ongoing use of the innovation in the market or in public service after project completion (regardless of the level of involvement of the project participants at that stage).
- There are no significant IP barriers to developing and implementing the innovation and there is a clear plan to protect newly generated IP such that Canadian stakeholders are fairly compensated.

Management

- The Academic Leader and key scientific personnel are well qualified and experienced in the project field, based on credentials, past projects, publications and other considerations.
- The Receptor has the capacity to contribute significant knowledge and technical support to the project, and to use the innovation to create significant value.
- The Academic Leader and Receptor (and other project team members) each have appropriate and necessary roles in the project, including involvement in project leadership, contribution of specific knowledge and resources, and execution of certain activities.

1.2 Supplementary Proposal Review Criteria

Technical Aspects / Project Plan

- The project objectives and deliverables are clear, quantifiable and achievable within the proposed timeline.
- The project plan is sufficiently detailed and logical, with well-defined go/no-go milestones that recognize and mitigate technical risks.
- There is a clear scientific rationale for the proposed approach, targeted performance of the innovation, and desired outcomes based on previous work, data, literature and/or other credible references.
- The major tools and methods to be employed in the project are appropriate and reasonably well-established in the field.
- The team has the technical expertise and ability to carry out the work proposed.
- The facilities, equipment and services to be employed in the project are appropriate for the proposed activities.

Commercialization/Implementation Plan

- The pathway to commercialization and/or implementation of the innovation is clear, realistic, and accounts for likely hurdles to adoption (legal, regulatory, social, economic, logistical, etc.).
- There is a clear value proposition for the innovation with sufficient consideration of market potential, alternatives and competitors (if any) to support claims of unmet need or opportunity for a new entrant.
- There is a viable model for funding the final development, launch and ongoing use of the innovation in the market or in public service after the project (regardless of the level of involvement of the project participants at that stage).
- There are no significant IP barriers to developing and implementing the innovation and there is a clear plan to protect newly generated IP such that Canadian stakeholders are fairly compensated.
- The plan for sharing data and resources within the project and externally is appropriate and complies with Genome Canada's policies on Data Release and Sharing.

Financial Aspects

- The proposed budget is reasonable considering the anticipated level of effort and deliverables, and typical costs for the proposed expense categories and activities.
- The proposal provides reasonable assurance that expenditures from a funded project will be closely and critically monitored.
- The Receptor(s) is (are) providing at least 1/3 of the total project budget.
- The proposed co-funding plan is well-documented, eligible and feasible.
- The proposed co-funding (cash and in-kind) is integrated with and directly supports the objectives of the project.
- It is expected that all co-funding will be secured at the time of release of Genome Canada funds.
- The valuation of the in-kind contributions appears reasonable.

Appendix 2. Exceptions to Genome Canada's *Guidelines for Funding*

Genome Canada's *Guidelines for Funding* must be adhered to throughout the competition and post-award management processes. Specific guidelines for projects funded under the GAPP differ from the *Guidelines for Funding* as specified in this Appendix 2.

2.1 Data Release and Sharing Policies

Genome Canada's policies regarding Data Release and Resource Sharing, and Access to Research Publications are referred to in Section 2.2 of the *Guidelines for Funding*. GAPP funding is conditional upon Project Leaders agreeing to comply with these policies, and GAPP applicants must provide a Data Release and Resource Sharing Plan as part of their Supplementary Proposal. The Genome Canada policies recognize the importance of maintaining the confidentiality of commercially valuable information and seek a balance between openness and protection of Canadian economic interests.

As set out in the policies, applicants may request an exemption from data sharing requirements. Exemptions will normally be confirmed early on in the application process upon mutual understanding of the nature of the data and information in question.

2.2 Eligible Project Expenses

Eligible and ineligible expenses in Genome Canada funded projects are listed and described in Section 4 of the *Guidelines for Funding*.

Exceptions under the GAPP to the eligible expenses listed in the *Guidelines*:

- Project budgets can include individual equipment items with costs less than or equal to $50,000 per item. Requests for more expensive equipment will be assessed on a case-by-case basis and will only be considered eligible expenses if the equipment is specific to the project, crucial to its success, and cannot reasonably be funded by other sources or accessed by other means.
- The collective use of Genome Canada funds for equipment cannot exceed ten percent (10%) of the approved Genome Canada funding, regardless of the total amount of equipment expenses allowed. Any eligible equipment expenses in excess of this limit must be covered by other approved funding sources.
- Costs associated with downstream product development, such as formulation, kit or primary package design, and protocol development and validation, may be eligible and will be assessed on a case-by-case basis.
- Costs associated with sales and marketing activities, such as sales training, marketing strategy development, detail aids, and promotional and educational events, are generally not eligible.

2.3 Co-funding Requirements

Genome Canada's general guidelines regarding co-funding are in Section 5 of the *Guidelines for Funding*.

Additional co-funding requirements under the GAPP:

- Genome Canada will invest up to 1/3 of the funds required to cover eligible project costs; the remaining 2/3 must be secured from other eligible sources with at least 1/3 provided by the Receptor(s). The co-funding provided by the Receptor(s) may be derived from their own resources or from funds provided to the Receptor(s) by another source.
- All co-funding must be secured before funds can be released to the project. The Genome Centres, working with the applicants, are responsible for securing co-funding.
- In exceptional circumstances, e.g., when the Receptor is a small start-up company, it is allowable to confirm Receptor co-funding year-by-year, as long as all co-funding for the first year is secured and a well-developed and feasible plan for securing the remaining co-funding is in place at the time of release of Genome Canada funds to the project.

2.4 Co-funding Sources

Eligible co-funding sources are listed in Section 5.1 of the *Guidelines for Funding*.

Additional eligible co-funding sources for GAPP projects include the following:

- Canadian Centres of Excellence for Commercialization and Research (CECRs)
- Canadian Business-led Networks of Centres of Excellence (BL-NCEs)

2.5 Project Administration

2.5.1 Conditions for Release of Genome Canada Funds

Genome Canada's guidelines regarding the conditions for release of Genome Canada funds to a project are in Section 6.2 of the *Guidelines for Funding.*

Additional conditions that must be met by GAPP projects prior to the release of Genome Canada funds:

- An IP term sheet, legally binding and signed by all concerned parties must be provided, or IP terms must be provided as part of a broader, legally binding agreement executed by all concerned parties.
- 100% of the co-funding (received or committed) for the project must be confirmed, unless otherwise specified by Genome Canada. Genome Canada reserves the right to withdraw its funding for any approved project that does not meet this requirement or if there is a substantial change in a project's co-funding status.

2.5.2 Management of Funding and Project Reporting

Genome Canada's requirements regarding the management of project funds and project reporting are described in Section 6.3 of the *Guidelines for Funding*.

Additional requirements for managing funds and reporting on projects under the GAPP:

- Funded projects must submit to their lead Genome Centre on a periodic (generally, semi-annual) basis, information and data as prescribed by the Centre and the Genome Canada in terms of timing, format and content, which will allow for the on-going assessment and

monitoring of their performance. Some projects may be required to report quarterly if deemed necessary by Genome Canada.

- For projects in which the investment from Genome Canada is less than $1 million and there is no go/no-go gate in that reporting period, Genome Canada will review the progress report and provide feedback to the project via the Genome Centre. For projects where the investment by Genome Canada is greater than $1 million or for any project where there is a go/no-go milestone during that reporting period, the progress reports will be forwarded to the Core Evaluation Team (CET). The CET will make recommendations to Genome Canada regarding whether funding should be continued, modified or cancelled for those projects.