Open Call for Research Proposals

Cycle 3 Call 1

OVERVIEW & GUIDELINES:

CATALYST STUDIES PROGRAM
ENABLING STUDIES PROGRAM
CLINICAL TRIAL PROGRAM
CSEI PROGRAM
CORE FACILITIES PROGRAM

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1.0 Overview

This Open Call for Research Proposals will use BioCanRx's established translational research pipeline approach to fund projects aiming to advance promising cancer biotherapeutics and immunotherapies, and support the adoption of these biotherapeutics into the Canadian healthcare system.

To inform this (and future) Calls for Research Proposals, this past spring we undertook consultations with the Canadian community of researchers, patient partners and individuals with lived experience, cancer charities and advocacy groups, industry partners, and other stakeholders. We also engaged our Research Management Committee, Board of Directors, and Cancer Stakeholder Alliance. These consultations encouraged BioCanRx keep the research scope and breadth of eligible projects broad to ensure we are investing in the most promising innovations.

Call Objectives & Research Scope

Building on this feedback, we are pleased to invite research proposals spanning various topics falling within cancer immunotherapy and biotherapeutic translation. For the purposes of this call, cancer immunotherapy is defined as all therapeutic products that modulate the immune system.

Proposals should aim to address at least one of the following objectives:

1. **Accelerate Cancer Immunotherapy and Biotherapeutic Product Innovations from Bench to Bedside:** Develop and translate promising innovations from proof of concept through to clinical application (i.e. Phase I/II clinical trials).
2. **Address the Clinical, Social, Economic, Regulatory and Policy Elements of these Innovations:** Identify and address the barriers to the adoption and integration of these therapies into clinical practice and Canada's healthcare system.
3. **Support Technology Innovation through Core Facility Activities:** Canadian academic infrastructure and technologies that support the advancement and production of cancer immunotherapies and biotherapeutics.

This call for research proposals includes BioCanRx's five established funding programs:

- **Catalyst Program:** Short-term, early-stage proof-of-concept studies that will advance cancer biotherapeutics development, assessment or clinical translation. Projects may be oriented toward companion technologies or methodologies, or combination therapeutic strategies.
- **Enabling Studies Program:** Prepare and position biotherapeutic products and platforms for clinical testing in patients, including GMP manufacturing and process development. Enabling Studies projects should result in either CTA submission packages or Quality (Chemistry and Manufacturing) packages.
- **Clinical Trials Program:** Phase I/II clinical trials of novel cancer biotherapies that have been substantially developed in Canada.

- **Clinical, Social and Economic Impact (CSEI) Program**: Identify and address the barriers to the adoption and integration of these therapies into clinical practice and Canada's healthcare system.
- **Core Facilities Program:** Manufacturing or research technologies and/or services that support the advancement and production of cancer immunotherapies and biotherapeutics.

2.0 Team Member Eligibility

Funded research team members (i.e., principal investigators) must be based at a Canadian academic or research institution and must be eligible to receive Tri-Agency funding. Further details and requirements are included in the Letter of Intent and Full Application forms.

3.0 Key Dates

- **Call launch**: July 15, 2024
- **Information Session**: July 29, 2024 at 2pm ET – Register Here.
- **Notice of Intent (NOI) to apply**: prior to LOI submission
- **Letter of Intent (LOI) submission deadline**: August 26, 2024
- **Notification of LOI results and invitation to Full Application**: week of October 14, 2024
- **Full application submission deadline**: December 9, 2024
- **Funding award start date**: early March, 2025
- **Public announcement of funding results**: early spring 2025

4.0 Specific Instructions for Each Funding Program

We seek applications fitting within all stages of our translational research project pipeline: Catalyst Studies Program, Enabling Studies Program, Clinical Trials Program, Clinical, Social and Economic Impact (CSEI) Program, and Core Facilities Program.

4.1 Catalyst Studies Program

Specific Program Details At-A-Glance

- Projects are expected to be conducted over 6 months to 2 years
- BioCanRx funding budget request: $500,000
- BioCanRx will fund up to 50% of total project costs
- Catalyst Program projects are technology or product oriented; not fundamental science

The Catalyst Studies Program supports short-term, early-stage projects to conduct critical proof-of-concept studies that will advance cancer biotherapeutics development, assessment or clinical translation. Projects may be oriented toward companion technologies or methodologies, or combination therapeutic strategies. Projects should clearly relate to BioCanRx's mission of *accelerating* the most promising cancer immunotherapies to the clinic to save lives and enable better quality of life. This is **not** a fundamental research discovery grant opportunity. Proposals should clearly situate the product, platform or technology within the translational continuum and provide a realistic plan for transition into the next phase of funding (BioCanRx's Enabling Studies Program), or uptake by other network members, core facilities, partners or stakeholders.

Examples of projects that may be funded by the Catalyst Program call:

- Validation of manufacturing process improvements or companion technologies that may enhance manufacturing or testing of BioCanRx products
- Validation of technologies that may apply to clinical evaluation of BioCanRx products (e.g., imaging, biomarker validation, immunological monitoring)
- Proof-of-concept preclinical studies validating efficacy of combinations of biotherapeutic products.

Examples of projects that are unlikely to be funded by the Catalyst Program:

- Fundamental investigations of cancer cell biology or the tumour ecosystem;

Catalyst projects are expected to be conducted over six months to 2 years with a financial investment from BioCanRx of around $500,000 per project. BioCanRx funding is only intended to contribute to the total cost of the project and, unless a compelling case can be made by the applicant, is capped at 50% of total project costs.

Historically, Catalyst projects have been funded in the range of $80,000-$220,000. To date, BioCanRx has funded 18 Catalyst Studies, with a total investment of $3.12M.

4.2 Enabling Studies Program

Specific Program Details At-A-Glance

- Projects are expected to be conducted over 6 months to 3 years
- BioCanRx funding budget request: $750,000
- BioCanRx will fund up to 50% of total project costs
- Enabling Studies projects provide financial support and resources for activities required to position biotherapeutic products or platforms for their translation to clinical testing, including GMP manufacturing and process development, analytical assay development, and preclinical GLP studies.
- Enabling Studies projects must result in one or both deliverables:
    - CTA submission packages
    - Quality (Chemistry and Manufacturing) packages

The Enabling Studies Program funds work required to prepare and position biotherapeutic products and platforms for clinical testing in patients. It bridges the traditionally difficult-to-fund translation from the laboratory to clinical testing. Projects funded by the Enabling Studies Program are intended to provide critical resources to bridge the funding gap between laboratory discovery and clinical testing of innovations in cancer biotherapeutics, including funding to support GMP manufacturing and process development. Enabling Studies projects should result in either CTA submission packages or Quality (Chemistry and Manufacturing) packages. Projects outlining proof-of-concept or preclinical validation of products or platforms should be directed to the Catalyst Studies Program.

Proposals must outline preclinical scientific rationale for the positioning of the product/platform for clinical testing and highlight the anticipated impact of the innovation within the field. Proposals must clearly situate the proposed product/platform within the translational continuum and provide a realistic plan for transition into clinical testing beyond the end of the Enabling Studies Program funding.

Enabling studies are the most wide-ranging in terms of BioCanRx funded project budgets: historically, projects were funded by BioCanRx from $43,000 to $1.34M over the life of the grant. For the purpose of this call for applications, consider proposing a total BioCanRx-supported budget in the range of $750,000. While there is no maximum grant, BioCanRx funding is targeted to meet around 50% of a project's total cost. The duration of the award is 6 months to 3 years.

To date, BioCanRx has funded 19 Enabling Studies with a total investment of $9.40M.

4.3 Clinical Trials Program

Specific Program Details At-A-Glance

- Projects are expected to be conducted over 1 to 3 years
- BioCanRx funding budget request: up to $1M total
- BioCanRx will fund up to 40% of the total project costs
- Clinical Trial projects must have novel, Canadian content in their approach
- The required deliverables include clinical data required to evaluate the case for advancing the therapeutic into later-stage clinical development.

The Clinical Trials Program provides funds for Phase I/II clinical trials of novel cancer biotherapies that have been substantially developed in Canada. Clinical Trials projects are expected to be high-content, and academically driven. The program is focused on clinical trials using biotherapeutics, including but not limited to: oncolytic viruses and vaccines, cell therapies, and therapeutic antibodies, either as mono-therapies or in combination. Proposals must outline the preclinical scientific rationale for the approach and highlight the anticipated impact within the field. BioCanRx will not fund clinical trials that duplicate technologies already in development within the pharmaceutical industry or that replicate trials for which other academic groups clearly have global

leadership. Such proposals will be subject to administrative triage. The required deliverables include clinical data to evaluate the case for advancing the therapeutic into later-stage clinical development.

Proposals must clearly demonstrate the ability of the assembled team to conduct the clinical trial and the feasibility of the study. Project teams are required to be multidisciplinary and collaborative. This can be demonstrated by integrating BioCanRx core facilities into the project (e.g., for manufacture of the investigational product or analysis of clinical samples) and/or by conducting studies that involve multiple sites. Projects should also outline: a clear project management plan, timelines for patient accrual, and an anticipated end date for clinical data collection and evaluation.

In order to submit a proposal for funding under the BioCanRx Clinical Trial Program, **teams must be ready to have a pre-CTA consultation meeting with Health Canada within three months of the award start date, with an expectation that project teams submit a CTA within the following three months (6 months from award date). Preference will be given to project teams that are within three months of submitting a full CTA at the time of application. Note that BioCanRx will be monitoring the progress of clinical trial initiation closely, will consider modifying the project award, and transferring it to an Enabling Studies project, where applicable.**

Clinical trial project teams may be required by the Research Management Committee (RMC) to collaborate with investigators within the Clinical, Social and Economic Impact (CSEI) program. The CSEI investigators may work with key project team members to prepare an economic and market assessment of the innovation, with the goal of supporting a Phase II clinical trial application and securing additional funding for later stage trials. Any work undertaken by CSEI investigators will be funded separately and need not be included in the project budget.

Historically, Clinical Trial projects have been funded in the range of $400,000-$800,000. For the purpose of this call for proposals, consider proposing a total BioCanRx-supported budget of up to $1M. While there is no maximum grant, BioCanRx funding is targeted to support approximately 40% of a trial's total cost. BioCanRx recognizes that the first contribution toward the cost of a trial is often the most difficult to secure and expects that the validation of the BioCanRx peer-review process should assist in efforts to secure additional partners. Therefore, applications may be made without all funding partners being finalized; however, BioCanRx will only release its funds if, within six months of the date of the award, the project leader provides letters of support from other partners demonstrating that the full costs of the trial have been secured. If needed, the BioCanRx network's management team will assist approved clinical trial projects in securing co-funding partners. The duration of the award is 1 – 3 years.

To date, BioCanRx has funded 12 Clinical Trial projects with a total investment of $7.93M.

4.3 Clinical, Social and Economic Impact (CSEI) Program

Specific Program Details At-A-Glance

- Projects are expected to be conducted over 1 to 3 years
- BioCanRx funding budget request: $215,000
- BioCanRx will fund up to 100% of total project costs

The objective of the Clinical, Social and Economic Impact (CSEI) Program is to develop potential solutions to social, legal, ethical, economic or health-systems barriers facing BioCanRx biotherapeutic products and platforms as they progress through the translational pipeline and reach patients in the evolving regulatory and policy landscape. The CSEI program funds projects that identify gaps and advance solutions in the uptake of BioCanRx cancer biotherapeutics and companion technologies by end users, which may include patients, researchers, healthcare providers, regulators, commercial partners, legal experts, payers, and policy makers. CSEI projects are expected to provide deliverables that assess economic, social, and/or commercial impact of cancer biotherapeutics, or inform decisions to advance therapeutics into later-stage clinical development/commercialization.

Projects funded under the CSEI program could address clinical translation, clinical practice or outcomes, patient engagement, regulatory or reimbursement challenges, use of real-world evidence, economic evaluations, intellectual property analyses, or policy development. CSEI proposals should apply resources, databases, tools or methodologies to specific products or platforms that are linked to other BioCanRx project proposals, **or** propose a project that has already engaged key end-users who will implement the outcomes of the project. In all cases, project proposals should clearly demonstrate the relevance of their anticipated deliverables to the development trajectory and uptake of those products or technologies. Teams are expected to demonstrate their capacity to translate their findings to relevant end users.

Key opportunities for research activities to address the following challenges or research questions include, but are not limited to:

1. Tools for establishing good evidence of clinical and other social or economic benefits/outcomes of biotherapeutics for patients, to be used during product development and/or post-market
2. Approaches for meaningful, bi-directional engagement and training of patients, researchers, healthcare providers, policy makers, and other end users, during progression of biotherapeutics through the translational pipeline
3. Projects that address regulatory, policy, economic, and intellectual property-related challenges for progression of Canadian-made biotherapeutics, including low-cost academic products, beyond early clinical trial stages

4. Policy development to support national access to clinical trials for rare cancers and health system adoption pathways
5. Exploration of alternative business models to promote timely and equitable access to novel biotherapeutics and support their market authorization
6. Development of appropriate methodology for the use of early health technology assessment (eHTA) specific to BioCanRx-funded biotherapeutic products and platforms

Historically, CSEI projects have been funded in the range of $100,000-$430,000. For the purposes of this call for proposals, consider proposing a total BioCanRx-supported budget of $215K. The duration of the award is 6 months to 3 years.

To date, BioCanRx has funded 9 CSEI awards with a total investment of $2.13M.

4.4 Core Facilities Program

Specific Program Details At-A-Glance

- BioCanRx funding for 2 years (with possibility of renewal for 3 additional years)
- BioCanRx funding budget request: up to $120,000 per year

Continuing from the previous success of core facility funding, BioCanRx will provide funding for Canadian academic or research institution facilities that offer translational services. Funding from the Core Facilities Program is intended to provide a baseline level of support for core facilities that will be engaged in BioCanRx projects. Previously funded core activities include GMP vector manufacturing and GLP correlative assay development (including immune monitoring) for clinical trials:

- Molecular and Cellular Imaging Core (MCIC), BC Cancer
- Human Immune Testing Suite (HITS), McMaster University
- Biotherapeutics Manufacturing Centre – Virus Manufacturing Facility, Ottawa Hospital Research Institute
- Robert E. Fitzhenry Vector Laboratory, McMaster University
- Immunogenomics Core, University of British Columbia

This call for Core Facility support is open to diverse services that will meet the needs of BioCanRx-funded projects. However, for the purposes of this call, BioCanRx is not seeking to support regulatory, commercialization, or CRO-like services.

Proposals must highlight a management or organizational structure for the facility and demonstrate the track record of the facility in meeting project milestones and deliverables. The Core Facility Program will continue to support the salary of HQP, minor expenses related to ongoing facility maintenance, certification and/or baseline operation for a maximum funding allocation of $120,000 per facility annually. There is an expectation that services offered to BioCanRx-funded projects should be budgeted on a cost recovery basis.

Core facilities will be initially funded for two years. Following year one, Core Facilities will be required to demonstrate current and future engagement with BioCanRx funded projects for continued funding. Facilities with a strong track record after year two may be eligible for renewal of award for an additional three years.

4.5 Core Facility and Research Project Collaborations

BioCanRx has a commitment to leveraging and supporting Canadian academic facilities that support the advancement and production of cancer immunotherapies and biotherapeutics. Applicants seeking Core Facility funding are expected to collaborate with researchers applying to the Catalyst, Enabling Studies, and Clinical Trials programs.

At the time of the Full Application, funding requests for the Core Facility Program must clearly detail the anticipated involvement in BioCanRx projects in the near future. To facilitate this, BioCanRx will provide a summary of Core Facility Program and research program applicants invited to submit a Full Application (subject to consent at the LOI stage). Facility leaders and researchers are expected to collaborate where applicable, and to define the scope of work and anticipated needs.

5.0 General Requirements & Instructions

The following section outlines guidelines and instructions relevant to all research proposal and core facility submissions. Some sections will not be required for Core Facility proposals, and are indicated as such. See section 5.15 for specific requirements for the Core Facilities Program. For specific details, please refer to instructions in the Letter of Intent (LOI) and Full Application (FA) forms, as applicable.

5.1 Project Overview

Required at both LOI and FA stages (with some differences in specific application requirements).

As part of your application, you will be asked to list your project title, lead investigator, projected start date and end date, a lay language project description, summary of relevance and impact, key deliverables, and keywords.

Complementary Applications & Linkages Across Projects

Proposal teams can also consider coordination of complementary applications from different BioCanRx funding programs, where applicable. An example could include development of a clinical trial protocol for a novel therapeutic platform via the Enabling Studies program, in tandem with an application to the CSEI program to inform HTA analyses and patient partner participation to embed in the trial design in development.

Where relevant, proposals should maximize the use of Canadian academic or research institution core-like facilities (use of alternate third-party vendors or facilities must be well-justified). See also section 4.5 - Core Facility and Research Program Collaborations.

Important note: Project teams may be required by the Research Management Committee (RMC) to collaborate with the investigators within CSEI program. The CSEI investigators may work with key project team members to prepare an economic and market assessment of the innovation or evaluate regulatory considerations with the goal of supporting a clinical trial application (CTA) and securing additional funding for later stage trials. Any work undertaken by CSEI investigators will be funded separately and need not be included in the project budget.

5.2 Project Team

Required at both LOI and FA stages (with some differences in specific application requirements).

When assembling a team for this call for research proposals, please note that BioCanRx highly values multidisciplinary and functionally collaborative project teams. Applicants should focus on creating project proposals that advance the transition of cancer biotherapeutics and immunotherapy technologies toward clinical testing and evaluation, leverage opportunities to gain translational biological insights from projects in or near the clinical setting, or complement the use of these therapies in clinic.

As part of the LOI, you will be required to list investigators requesting funds. At the time of the FA, you will be required to list all team members. Specific instructions can be found in the application form. If you plan to use core facilities invited to submit a FA, facility leader(s) should be listed as an applicant team member and should receive funding in the proposed budget to conduct the planned work. The core facility services budget should be developed in collaboration with the core facility leader or delegate. See also section 4.5 - Core Facility and Research Program Collaborations.

5.3 Research Proposal

Required at both LOI and FA stages (with some differences in specific application requirements).

See the research program specific elements in the sections above for elements specific to Catalyst Projects, Enabling Studies Projects, Clinical Trial Projects and CSEI Projects, as well as project eligibility and the general guidelines for research proposals falling under this project call. Specific instructions for developing your research proposal are described in the application form.

5.4 Project Management

Required for FA only.

As part of your application, you will be asked to describe how this project will be managed, including details of a dedicated project manager, and to provide a description of the alignment of milestones and deliverables to your proposed timelines. More details can be found in the application form.

5.5 Partnerships

Required at both LOI and FA stages (with some differences in specific application requirements). Note that eligibility criteria and definitions will not change.

5.5.1 General Partner Funding Guidelines

It is critically important to remember that fostering inter-sectoral and multi-institutional partnerships is at the heart of the BioCanRx's programming. Applications that are based on work of a single investigator with little external involvement will be administratively triaged. Applicants should note that, when evaluating proposals, BioCanRx will focus more on the quality of partner engagement rather than the number of partners involved. A letter of support will be far more favourably received if it demonstrates a partner that clearly understands the scope of the project, can describe their specific role within it, and articulates the value they are contributing to the project and receiving from project involvement/participation, as opposed to a letter describing a large discount on a major piece of equipment.

Partnerships with companies, not-for-profit organizations, foundations, charities, research institutions, hospitals, universities, and government bodies are valuable components of project proposals. Please refer to the BioCanRx's **Policy on Industry-Partnered Research** in preparation of your research project concept.

An indication of the status of any Letters of Support and/or Notice of Award will be required at the LOI stage, with signed Letters of Support/and or Notice of Award required for submission at the FA stage.

5.5.2 Specific Partner Funding Guidelines

In your Full Application, you will be required to list each confirmed partner that will support the project, indicate their contribution, provide letters of support/notice of award, and outline whether the contributions are matching or leveraged funds, and cash or in-kind. Please pay critical attention to the requirements of these different types of partner funds and **note that partner contribution requirements outlined in section 4 - Specific Instructions for Each Funding Program section are for matching funds specifically.**

5.5.2.1 Matching and Leveraged Funds (New requirement of BioCanRx's funding process)

***Matched Funds**:* new, incremental contributions (of cash or in-kind) for eligible SSF expenditures, which would not exist in the absence of an SSF award. Eligible sources include non-federal partners or revenues (including donations).

Examples of eligible matched funds:

- Private-sector contributions earmarked to advance specific SSF-funded activities
- Provincial awards to support the advancement of SSF-funded activities or research projects in that province

Please note that matching funding can precede funding of the BioCanRx award start date, assuming that: 1) they are from the same year of the proposed award start date, and 2) they are matched funds that are complementary to a unique element described in your project proposal for which funding from BioCanRx is requested. For example, if you are requesting BioCanRx funding for a novel element (e.g., combination therapy or correlative assays) of an already on-going clinical trial by an industry partner, the industry partner funds will be considered matching funding.

Ineligible to be considered matched funds:

- Leveraged Funds (see definition below)
- Funding from federally-funded entities (e.g., CFI, Digital Research Alliance of Canada, SSF recipients, and organizations primarily funded by the federal government) and from federal departments and agencies
- Funding already used to meet a matching requirement for a federal program

***Leveraged Funds**:* existing investments in the ST&I ecosystem being leveraged to further the objectives of the funded research project. Includes cash or in-kind from federally-funded entities (e.g., CFI, organizations primarily funded by the federal government) and from federal departments and agencies.

Examples of leveraged funds:

- Existing NSERC, SSHRC or CIHR projects with work that will be complimentary to the SSF activities
- The rental value of CFI-funded equipment that is essential to the delivery of SSF activities
- Projects funded in collaboration with other SSF-supported recipients

5.5.2.2 In-kind contributions: The guidelines for calculating the value of in-kind contributions must align with following guidelines outlined here (and in accordance with the SSF Guidelines):
In-kind contributions are defined as cash-equivalent goods or services that represent an incremental expense that would not otherwise be incurred, and which would have to be paid for with cash if not provided.

In-kind contributions:

- Must be relevant and central to the activities of the project proposal.
- Must be eligible expenses as per the Project Proposal Guidelines; and
- Cannot have been used to fulfill the matching requirements of other federal programs.

In-kind Calculation table

The table below is a non-exhaustive list of in-kind contributions, with an indication of how to calculate their value. If in doubt about a particular item, please contact us.

Category	Acceptable valuation method	Not acceptable
Access to unique databases	Incremental cost of access	Cost of developing or maintaining database
Analytical and other services	Internal cost of services	Commercial cost of access
Equipment	Donated (used) - Fair market value - Company book value Donated (new) - Selling price to most favored customer (if stock item) - Cost of manufacture (if one of a kind) Loaned - Rental equivalent based on depreciation - Rental equivalent to highest-volume rate	List price or discounted list price Rental equivalents exceeding accepted values had the equipment been donated or sold Development costs
Hospitality	Cost	Alcoholic refreshments
Materials	- Unit cost of production for commercial products - Selling price to most favoured customer - Price for internal transfers - Cost of production of prototypes and samples	Development costs
Intellectual property	Fair market value of licensing and royalties	Cost of maintenance and litigation Licensing fees paid to partners

Category	Acceptable valuation method	Not acceptable
Professional and technical service contracts	Cost	
Salaries (General)	Actual salary cost (including benefits)	Salary overheads, external charge-out or consultant rates, cost of benefits outside the average market range.
Salaries (Academic researcher)	Actual costs to the institution for release time from teaching duties (e.g., the cost of hiring a sessional instructor for course release may be counted).	Academic faculty salaries
Salaries (Clinicians)	Portion of their salary for time devoted to working on SSF projects that are additional to their routine (including teaching or service work) activities	Remuneration already received for teaching or service work
Student stipends	Cost of the stipend equivalent to the portion of their time working on SSF work	The portion of time dedicated to non-SSF work
Software	- Most-favoured-customer cost for 1 licence per software package - Cost of equivalent commercial product (where donated software is not commercially available) - Cost of training and support (at the university/college site) for software by industrial partner personnel	Development costs
Travel costs	Travel and accommodation costs (generally aligned with the National Joint Council's Travel Directive or similar institutional directive)	
Use of facilities	- Cost of access to the facility - Internal rates for use of specialized equipment - Internal rates for value of lost production, resulting from downtime	

5.6 Research Budget

Required at both LOI and FA stages (with some differences in specific application requirements).

5.6.1 Research Funding Mechanism (New Requirements to BioCanRx's funding process)

As you are considering your budget, please note that as per the Strategic Science Fund requirements, funded projects **will NOT be granted no cost project extensions beyond the original award date**, and any unspent funds at the term of the award will be required to be returned to the Government of Canada. To prevent this from occurring, we expect that funded investigators aim to draw down their funds on a fiscal basis (e.g., April 1, 2025 – March 31, 2026).

When developing your budget, please consider these requirements and their implications regarding project feasibility, plans on the use of BioCanRx versus partner funding, and project timelines. These factors will be critically evaluated by the RMC and by BioCanRx administration.

At the LOI stage, only a high-level budget summary will be required. In the FA, you will be asked to provide a detailed budget breakdown along with a budget justification that is aligned with your proposed Milestones and Deliverables. You will also be asked to include quotes in support of your proposed budget. Project proposals with unrealistic budgets will be triaged by BioCanRx.

5.6.2 Guidelines

- To develop your budget, please use the Budget Template (to be linked in application form)
- Refer to the specific project funding type descriptions above for specific information regarding project duration maximums, budgetary envelopes and partnered matched fund expectations.
- Your BioCanRx budget should include **eligible** costs only (see definitions below); partners may provide matched or leveraged non SSF-eligible partner contributions.
- The budget will require you to outline partner **matching** and **leveraged** funds for **cash** and **in-kind** contributions (see definitions below).
- **Important note:** Only **MATCHING** funds contribute to the expected partner matching requirements of total project costs outlined in the section 4.0 - Specific Instructions for Each Funding Program section above (e.g., 50% of total project cost).
- **CSEI Projects:** CSEI projects do not require partner matched funding as a requirement; however we ask that you please describe partners and partner contributions toward this project.
- Note that this budget template is developed to parallel SSF requirements for BioCanRx financial reporting. This requires investigators to outline the aforementioned budgetary considerations across the following types of expenditures: 1) Research, 2) Mobilization of Knowledge/Technology Transfer, and 3) Networking.

5.6.3 Details of Project Expenditures

5.6.3.1 Eligible Activities & Costs

Research includes expenses related to:

- Incremental research costs, including salaries of researchers and research staff, related costs of students, highly qualified personnel (HQP), trainees
- Material and supplies
- Patient partner compensation
- Professional and technical services
- Equipment (except for Major Research Equipment, as described under *Ineligible Expenditures*); scientific collections; costs of computer hardware or software (except where the scale of costs fall within the mandate of the Digital Research Alliance of Canada); information databases
- Operations of core research facilities
- Direct cost of knowledge creation
- Research-related travel and accommodation costs**

Mobilization of knowledge or technology transfer includes expenses related to:

- Incremental knowledge mobilization and technology transfer costs, including salaries of staff, related costs of students, highly-qualified personnel (HQP, trainees)
- Policy development
- Tool development and evaluation
- Intellectual property protection

Networking includes expenses related to:

- Incremental networking costs, including salaries of staff, related costs of students, highly-qualified personnel (HQP, trainees)
- Seminars and workshops
- Networking meetings
- Conferences**
- Communications.

****Travel and Accommodation Costs:** Costs must be aligned with the National Joint Council's Travel Directive or similar institutional directive. For guidelines on the calculation of in-kind contributions, refer to the Government of Canada's *Directive on Travel, Hospitality, Conference and Event Expenditures*.

5.6.3.2 Ineligible expenditures include the following:

- Indirect institutional costs
- Flat-rate charges for overhead costs (indirect costs)
- Principal investigator salaries
- Costs associated with the construction of, or major renovation to building and structures

- The purchase or lease of land
- Alcoholic refreshments
- The acquisition of major research equipment
- Costs associated with the lobbying of federal officials or public office holders (including by hiring outside firms or consultants)

5.7 Future Product/Platform Innovation Development Trajectory

Required for FA only.

A key objective of BioCanRx funding is to accelerate the translation of cancer biotherapeutic innovations from the laboratory through to early phase clinical evaluation, with the ultimate goal of providing access of products and platform innovations to Canadian cancer patients.

In this section of your application, you will be asked to outline the anticipated next steps in clinical and/or commercial development of the product(s) and/or platform(s) in the proposed study. For CSEI projects, please address the impact of the work on policy and practice, including how the project deliverables will be adopted by end users to address barriers to uptake of BioCanRx biotherapeutic products and platforms. Detailed instructions are outlined in the application form.

5.8 Knowledge Sharing, Technology Transfer, and Networking

Required for FA only.

It is expected that project leaders will share data and/or research deliverables arising from their projects with other network investigators in a timely fashion, whenever possible. In this section of the application, you will be asked to outline how this project will be networked with other prospective BioCanRx projects and network investigators.

5.9 Patient Partnerships

Required for FA only.

BioCanRx research is enhanced by the involvement of patient partners, and therefore the engagement of patients in the development of projects is a mandatory requirement for all funded projects. Patient partners should be engaged as early as possible in the development of a research project, as they provide a valuable patient perspective that will enhance the patient experience.

You will not be required to indicate patient partners at the Letter of Intent stage. As part of your full application, you will be required to name *at least* one patient partner, provide their contact information, and provide a description of their level of engagement and their role in the project. We strongly encourage engagement of prospective patient partners at the LOI stage where possible.

If your project is related to an outcome that you do not believe would not benefit from patient engagement at this stage, please email Laurie Cameron (lcameron@biocanrx.com) as soon as possible to discuss. Note that we envision this representing a *very small* cohort of applicants.

Resources:
To assist BioCanRx researchers in finding patient partners, we have invested annually over the past several years in the Learning Institute. This program runs in collaboration with the Summit for Cancer Immunotherapy and has been a great success in preparing patients to participate in research. If you require assistance in finding a patient partner for your research project, please reach out to Laurie Cameron.

BioCanRx has supported patient engagement projects, including GO-CART and the MARVEL program - both led by Drs. Dean Fergusson and Manoj Lalu and the OHRI Blueprint Translational Research Group. The outputs of GO-CART and MARVEL projects are incorporated into two of their websites on patient engagement and resources (https://www.ohri.ca/blueprint/patient-engagement), and patient engagement tools specifically for preclinical researchers (https://labpartners.ca/). We encourage you to review these resources.

For further examples of meaningful involvement of patients in research, please consult SPOR - Patient Engagement Framework

5.10 Training Highly Qualified Personnel

Required for FA only.

As part of your Full Application, you will be asked to briefly describe the unique nature of the training environment provided by your team and the role of HQP in the realization of your proposed project.

5.11 Equity, Diversity, and Inclusion

Required for FA only.

For two years, BioCanRx has been the proud recipient of Diversio's DEI Certification L1 and the IDEAL Bioscience Employer (Powered by BioTalent Canada). You can refer to our BioCanRx Statement on EDI policies and practices in our Network Governance, Research, and Activities here.

As part of your Full Application, you will be asked to include a plan that describes project Equity, Diversity, and Inclusion (EDI) considerations regarding: 1) a description of your team, 2) challenges that exist in your research field (e.g., barriers and impact on research related to EDI), and 3) steps that your project team is taking to ensure diversity.

5.12 Intellectual Property

Required for FA only.

Please note that while questions surrounding IP will not be addressed at the Letter of Intent stage, they are a requirement of the Full Application and should be reviewed and planned for accordingly.

Representation of Intellectual Property (New Funding Requirement)

Funded investigators must:

- Indicate that they own the Background IP or hold sufficient rights to the Background IP to permit the research project to be carried out and the Foreground IP to be exploited (i.e., practiced or commercialized).
- Indicate that no person or entity has alleged that the Background IP, or the use thereof by the funded investigator, infringes or misappropriates third party Intellectual Property Rights.
- Indicate that, to the best of the funded investigator's knowledge, no third-party Intellectual Property Rights will be infringed in carrying out a BioCanRx-funded research project.
- Indicate that funded investigators shall take appropriate steps to protect Foreground IP and enforce rights to the Foreground IP.

Intellectual Property (IP): all inventions, whether or not patented or patentable, all proprietary technical information, whether or not constituting trade secrets, and all copyrightable works, industrial designs, integrated circuit topographies, and trademarks, whether or not registered or registerable.

Background Intellectual Property (Background IP): any pre-existing Intellectual Property that is developed prior to, or independent of, the project but is necessary to carry out the funded project.

Foreground Intellectual Property (Foreground IP): any Intellectual Property conceived, produced, developed or reduced to practice in carrying out the Project by the Recipient.

As part of this Strategic Science Fund requirement for Representation of Intellectual Property, in your application, we will ask you to: 1) describe your Background IP (if any), 2) to list your patent applications and granted patents as they pertain to the funding proposal innovation(s) (if any), 3) and if using others' IP, describe relevant licenses to conduct these research activities.

5.13 Research Security

Researchers applying to funding must be aware of the Government of Canada's recommendations and guidelines for research security, data management, and privacy. In addition, investigators should be aware of their Institutional policies and practices as they relate to research security and research partnerships.

Resources of best practices to mitigate potential research security risks can be found the Safeguarding your Research portal, and Safeguarding Science workshops. **At the time of award**, funded researchers will be required to complete an Attestation for Research Aiming to Advance Sensitive Technology Research Areas, and you may be required to provide further information on Research Security Best Practices.

5.14 Open Access and Research Data Management

Funded investigators must ensure compliance and alignment with the federal Tri-Agency Open Access Policy on Publications and the Research Data Management Policy. The funded investigator should adopt **Open Science principles** that maximize the value of all research activities, including by making negative research findings accessible where possible.

These policies should be considered when developing your section on Knowledge Sharing, Technology Transfer & Networking activities described above in your full application (if applicable).

5.15 Core Facilities Specific Requirements and Instructions

Both Letters of Intent and Full Applications to the Core Facilities Program have some specific requirements to consider when crafting an application.

Common sections across all applications:	**Sections unique to Core Facilities applications:**
At the LOI stage: • Project Overview *At the FA stage:* • Project Overview • Project Team • Project Management • Budget and budget justification • Knowledge Sharing, Technology Transfer and Networking • Training Highly Qualified Personnel • Equity, Diversity, and Inclusion • Intellectual Property	*At the LOI stage:* • Activity Summary *At the FA stage:* • Activity and Performance • Projected Activity – including linkages with other BioCanRx projects • Impact of Planned/Potential Facility Upgrades • Facility Publications (past 12 months)

Activity, Performance, and Impact sections are meant to evaluate the activity and capacity of the facility in the 12 months prior to and 12 months following the start of the requested period of support. You will be required to provide details about ongoing and upcoming projects supported by the facility and outline partner involvement.

6.0 Letter of Intent Evaluation Criteria

6.1 Evaluation Criteria for LOI Submissions

- Relevance to the Open Call for Proposals objectives and BioCanRx mandate
- Scientific excellence, creativity and innovation, in an international context
- Tangible deliverables that are achievable in terms of scope, expertise and resources
- Clear proposed objectives and hypothesis and sound research methodology
- Multidisciplinary and collaborative nature of the proposed funded investigators
- Alignment of project goals to the BioCanRx specific research program (i.e., Catalyst, Enabling, Clinical Trial, CSEI, Core)

6.2 Program Specific Evaluation Criteria (assessed at both LOI and Full Application Stages)

6.2.1 Catalyst Studies Program

Our Research Management Committee will evaluate **Catalyst Studies** projects for:

- A demonstration of how they are *accelerating* the most promising cancer biotherapeutics and immunotherapies to the clinic. This is **not** a fundamental research discovery grant opportunity, and should be translationally driven in nature.

6.2.2 Enabling Studies Program

Our Research Management Committee will evaluate **Enabling Studies** projects for:

- A project whose outcome is a trial that we would fund through the Clinical Trials Program
- Critical experiments that will lead to a clinical trial application (CTA) and bolster its chances of approval by Health Canada

6.2.3 Clinical Trial Program

Our Research Management Committee will evaluate **Clinical Trial** projects for:

- Canadian innovation that is an integral element of the trial's approach
- Therapies with a reasonable expectation that the healthcare system will pay for them if a trial succeeds at Phase III
- Criteria are met with respect to pre-CTA consultation meetings and CTA submission timelines

6.2.4 Clinical, Social and Economic Impact (CSEI) Program

Our Research Management Committee will evaluate **CSEI** projects for:

- Likeliness that project deliverables will be adopted by end users to address barriers to uptake of products and platforms fitting with BioCanRx's mandate to have meaningful impact
- Degree to which the project addresses critical gaps in policy or practice

- Strength of linkage(s) to other proposed BioCanRx projects for this funding call **or** strength of engagement with ultimate end-users of the CSEI project outputs and deliverables

6.2.5 Core Facilities Program

Our Research Management Committee will evaluate **Core Facilities** proposals for:

- Track record of the core facility
- Alignment of the core facility to anticipated needs of BioCanRx-funded projects
- Accessibility and capacity to BioCanRx investigators
- How BioCanRx funding will play a role in future, projected activity (i.e, how this investment will facilitate ongoing operations of the Core Facility)

7.0 Full Application Evaluation Criteria

BioCanRx's Research Management Committee will evaluate Full Application submissions to make funding recommendations, which include recommendations for conditional funding contingent on project proposal revisions.

7.1 General Evaluation Criteria

- Relevance to the Open Call for Proposals objectives and BioCanRx mandate
- Scientific excellence, creativity and innovation, in an international context
- Potential for benefit to Canada in terms of clinical, social, and/or economic benefit
- Clearly articulated expected impact that aligns with project proposal elements
- Multidisciplinary and collaborative proposed team and research
- Team members' demonstrated scholarly contributions, academic excellence, and alignment with project activities
- The extent to which the team has demonstrated engagement of patients in the development and planned activities of the project
- Commitment and level of involvement of partners, or potential for new partner engagement
- Feasibility of the research proposal, and of the access to required resources and expertise
- Clear project management plan (milestones and deliverables, timeline, human and financial resources)
- Appropriate budget and budget justification relevant to the proposed project and that takes SSF funding stipulations into consideration (e.g., no opportunities for project no cost extensions)
- Equity, diversity and inclusion will be evaluated based on: overall completeness of the EDI plan in addressing all required components, feasibility, and potential impact of the EDI plan on creating a more equitable and inclusive research environment
- Proposed project provides unique training opportunities for HQP to fuel innovative biotherapeutics discovery and translation into clinical deliverables

Note that Core Facilities proposals will not be evaluated for involvement of patient partners, commitment and involvement of partners, or any other sections that are not included in the Core Facilities Program application forms. Refer to section 5.15 and 6.2.5 for details on core-specific requirements and evaluation criteria.

7.2 Program Specific Evaluation Criteria

See section 6.2.

8.0 Reporting Expectations

Funded project leaders will be required to submit formal progress reports to the BioCanRx Research Management Committee (RMC) every six months and may be asked to present to the RMC. The review is intended to provide ongoing advice that will maximize the project's chances of success. However, BioCanRx reserves the right to reduce or cancel a project budget, with an appropriate lead time, if the project is clearly not meeting its milestones and deliverables, or providing the anticipated value to BioCanRx products or technology platforms. When meeting with the RMC, project leaders may also request reallocation or changes in budget, as circumstance warrants.

Please note that future interim and annual progress reporting for funded projects will be completed using an online grant management system.

9.0 Criteria for the Release of Approved Funding

All applications will be subject to review and recommendation by the BioCanRx's Research Management Committee at both the Letter of Intent and Full Application stages. All project investments must be approved by the BioCanRx Board of Directors. Following Board approval, the following conditions must be fulfilled if funding is to be released to the project:

All Project Types

- ❑ Execute and return the BioCanRx Acceptance of Award
- ❑ Executed BioCanRx's funding agreement by funded researchers and their research institution's appropriate signatories
- ❑ Completion by funded investigators of the Attestation for Research Aiming to Advance Sensitive Technology Research Areas, and may be required to provide further information Research Security Best Practices
- ❑ You may be required to provide a revised budget and/or project timelines and milestones and deliverables contingent on specific recommendations by the RMC

Additional requirements for Clinical Trial Projects

- ❑ Provide BioCanRx with a copy of Health Canada approval for the trial (upon execution)
- ❑ Provide BioCanRx with a copy of notice of REB approval for the trial (upon execution)
- ❑ Provide BioCanRx with a copy of the trial budget submitted to the REB (upon execution)
- ❑ Provide BioCanRx with letters of support from partners showing that the full costs of the trial have been secured, and required leverage obtained (as requested by BioCanRx administration)
- ❑ Provide BioCanRx with confirmation that adequate liability measures/insurance are in place for the study (as requested by BioCanRx administration)

Unless a further extension is granted by the BioCanRx Board of Directors, if these conditions have not been met within six months of the notice of award date, the award will be cancelled.

10.0 Application & Submission Process

Step 1. Notice of Intent (NOI). The NOI is for administrative purposes only. Please send a brief email with the **Subject: Open Call – Notice of Intent [lead investigator surname]** noting your intention to apply to applications@biocanrx.com.

Please indicate the following:

1) project lead
2) funding program for which you will be applying (Catalyst, Enabling Studies, Clinical Trial, CSEI, and/or Core Facility)
3) draft project title (if known)
4) 3-5 keywords

A NOI must be submitted prior to gaining access to the LOI form. The deadline for submission of the NOI is the same as the deadline for LOI submission, however, applicants are encouraged to submit their NOI as early as possible.

Step 2. Letter of Intent (LOI). The LOI stage is your opportunity to assemble a multi-disciplinary team and propose a research project to BioCanRx's Research Management Committee (RMC). The RMC will evaluate LOIs based on their alignment with BioCanRx's research mandate and eligibility within one of the established funding programs (Catalyst, Enabling Studies, Clinical Trials, CSEI, and Core Facilities). This call is open to all investigators located at Canadian institutions eligible to receive peer-reviewed funding from the federal research-granting councils (CIHR, SSHRC, NSERC).

How to submit your LOI: Further instructions will be provided in response to the Notice of Intent.

Step 3. Invitation to the Full Application. Following review by BioCanRx's Research Management Committee, successful LOIs will be invited to submit a Full Application and will receive further instructions on how to apply.

Step 4. Full Application Submission. Full application submissions will also be reviewed by BioCanRx's Research Management Committee. Instructions on how to submit your FA will be provided at the time of invitation.

Information Session

On **Monday July 29, 2024 at 2pm ET**, BioCanRx will host an information session on this Open Call for Research Proposals. You can register here. This information session will be recorded and made available here: https://biocanrx.com/research/research-program/open-call-2024

11.0 Confidentiality and COI Statement

All proposals submitted to BioCanRx will be kept confidential; all reviewers of submitted material will have signed a Confidentiality Agreement and Conflict of Interest declaration with BioCanRx.

12.0 Contact Information

Please direct questions about the program and application process to Dr. Julie Jonkhans, Manager of Training and Research (jjonkhans@biocanrx.com) or Dr. Stéphanie Michaud, BioCanRx President and Chief Executive Officer (smichaud@biocanrx.com).