CALL FOR PROPOSALS

CLINICAL, SOCIAL AND ECONOMIC IMPACT IN TRANSLATION OF CANCER BIOTHERAPEUTICS

Demonstrating Value of Cancer Biotherapeutic Products, Platforms, and Companion Technologies

Program Description and Application Guidelines

OVERVIEW

The Biotherapeutics for Cancer Treatment Network (BioCanRx) is a not-for-profit organization with a mission to improve outcomes for cancer patients by accelerating the development of cost-effective and curative biotherapies. BioCanRx has been awarded seed funding of $25 million from the federal government's Networks of Centres of Excellence (NCE) Program, with additional contributions coming from partners in all sectors of the economy.

This call for proposals is open to all investigators located at Canadian institutions eligible to receive peer-reviewed funding from the three federal research granting councils (CIHR, SSHRC, NSERC). If you have questions regarding your eligibility, or that of your institution, please contact Kelley Parato (keparato@biocanrx.com).

BioCanRx provides funding for four research programs (described below), plus a number of core facilities that are accessible to all members of the BioCanRx network. Three of the research programs are directed at therapeutic development and reflect the translational focus of BioCanRx, which organizes its investments into a pipeline-like structure common to the biotechnology industry. The fourth research program funds research into the clinical, social and economic impact of BioCanRx biotherapeutic platforms and technologies. All research programs are targeted at applicants who have already made substantial advances in their basic research programs and are now ready to work in collaborative, multidisciplinary, academic–industry teams to move their discoveries into the clinic in a rational, scientifically well-supported and highly disciplined fashion.

The Catalyst Program

(Funding of approximately $3.5M over five years, supporting a total of 15 to 20 projects)

This program will provide financial support for short-term, collaborative projects that have clear deliverables and will either result in an application to one of the other two BioCanRx programs, or will generate tools or methodologies that may be used by numerous BioCanRx members. Examples of projects that might be funded through this program include: preclinical validation of a new combination of biotherapeutics; or, the development of an innovative manufacturing technology.

The Enabling Studies Program

(Funding of approximately $5.5M over five years, supporting a total of 8 to 10 projects)

This program will provide financial support and resources for GMP manufacturing and process development, GLP assay development and studies required to position biotherapeutic products or platforms for their translation to clinical testing. The anticipated deliverable from these projects will be a Clinical Trial Application (CTA) in Canada.

The Clinical Trial Program

(Funding of approximately $4.0M over five years, supporting a total of 5 to 7 projects)

This program will provide financial support for the clinical evaluation in Canada of novel biotherapeutic products and platforms that have been substantially developed in Canada. The program is focused on clinical trials using biotherapeutics, including but not limited to: oncolytic viruses, immune cell therapies,

and therapeutic antibodies, either as mono-therapies or in combination. The required deliverables include clinical data required to evaluate the case for advancing the therapeutic into later-stage clinical development.

The Clinical, Social and Economic Impact Program

(Funding of approximately $1.5M over five years)

This program is intended to provide financial support for the implementation or application of research methodologies, tools or assets to identify gaps and advance solutions in the uptake of BioCanRx cancer biotherapeutics and companion technologies by receptors, including cancer patients, health-care delivery systems, commercial partners and health-care markets. The anticipated deliverables include data and key findings that: are related to specific projects, platforms or technologies in the BioCanRx research portfolio; assess economic, social, and/or commercial impact; and either informs decisions to advance BioCanRx-funded therapeutics into later-stage clinical development, or adds value to our technologies for their receptors.

Our Research Investment Program

CLINICAL, SOCIAL & ECONOMIC IMPACT PROGRAM

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 from preclinical research to clinical trials. With the ultimate goal of advancing BioCanRx portfolio technologies into the hands of key receptors (including industry partners, patients and health-care systems), BioCanRx is seeking research projects that will assess the value of BioCanRx technologies and platforms, and guide the development plans for each project.

Proposals should apply resources, databases, tools or methodologies to specific products or platforms in the BioCanRx research investment portfolio, and clearly demonstrate the relevance of their anticipated deliverables to the development trajectory and uptake of those products or technologies. Proposals must also clearly demonstrate that necessary inputs or data required for the project are readily available from funded BioCanRx technology project teams, and necessary linkages with collaborators are in place. Teams are expected to be collaborative and multidisciplinary. Teams are also expected to demonstrate their capacity to translate their findings to relevant receptors.

Following consultation with a variety of relevant stakeholders and potential receptors of the current portfolio of BioCanRx technologies in developing this call for proposals, key opportunities for research activities to address the following challenges or research questions include, but are not limited to:

1. Generating and synthesizing high quality preclinical data to better inform the design of high quality clinical trials;
2. Tools for supporting and improving good decision-making in preclinical and clinical development of biotherapeutics;
3. 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;
4. Health technology assessment of biotherapeutics with a particular emphasis on economic analyses and potential impact of new biotherapeutics on health-systems;
5. Navigating the regulatory and IP landscape, particularly considering the complexity of combination biotherapeutic strategies;

Project teams are required to be multidisciplinary and collaborative. Projects should also outline a viable project management plan, including key timelines, milestones and deliverables.

The Research Management Committee (RMC) may recommend projects, products or platform technologies that should be the subject of CSEI projects. The RMC will evaluate the progress of CSEI projects in terms of meeting milestones and deliverables, and will also review the added value provided by the information arising from the various assessment activities or deliverables.

Eligible expenses

Eligible expenses under the Clinical, Social and Economic Impact Program are identical to those defined under CIHR guidelines (see http://www.cihr-irsc.gc.ca/e/805.html). At this time, equipment purchase is not an allowable use of BioCanRx funds. Funds awarded may be used to pay for services of third party vendors for specialty/custom materials and services, or for services beyond the capacity of BioCanRx core facilities and network investigators. These expenses must be well justified.

Budget and partnerships

It is critically important to remember that fostering inter-sectoral and multi-institutional partnerships is at the heart of the NCE Program. 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 on the quality of partner engagement and/or the potential opportunity for partner engagement with the proposed project. Please refer to the BioCanRx Policy on Industry-Partnered Research (see https://biocanrx.com/wp-content/uploads/2017/08/3.3a-BioCanRx-Policy-on-Industry-Sponsored-Research-3-1.pdf) in preparation of your application.

Applicants should also be aware that BioCanRx is **not** overly concerned about their ability to demonstrate that partner dollars being pledged to the project are uniquely attributable to the BioCanRx investment; so, partnership already secured for other grants **may** be eligible. What is important to BioCanRx is that its funding be used to align all of these investments toward a common goal — that the BioCanRx funding brings together project funding for a greater impact than otherwise possible. If applicants are repurposing earlier investments to their BioCanRx project, they require updated letters of support from their partners that speak specifically to this BioCanRx project and confirm that the partners are comfortable with their investments being directed in this manner.

Please note that if applicants plan to use BioCanRx Core Facilities in the conduct of their proposed research (see https://biocanrx.com/research/core-facilities), the 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 budget should be developed in collaboration with the Core Facility leader or delegate.

Project management and reporting expectations

Every application must identify a **single** investigator to act as project leader. The project leader is accountable to BioCanRx for the preparation of all project team reports and for overall project progress.

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 in person 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.

Knowledge sharing

In keeping with the collaborative nature of the BioCanRx network and the investment of the NCE Program in creating and fostering networks, it is expected that project leaders will share data or other research outputs arising from their projects with other network investigators in a timely fashion, whenever possible.

Evaluation criteria

The BioCanRx Research Management Committee will evaluate applications to the Clinical, Social and Economic Impact Program according to:

- Relevance to the BioCanRx mandate;
- Relevance to barriers in the translation of BioCanRx technologies into clinical testing and/or uptake by relevant receptors;
- Scientific excellence, creativity and innovation, in an international context;
- Feasibility of the study and of the access to required resources and expertise;

- Multidisciplinary and collaborative aspect of the proposed team and research;
- Commitment and level of involvement of partners, or potential for new partner engagement;
- Clear project management plan (milestones and deliverables, timeline, human and financial resources);
- Appropriate budget justification; and
- Track record of the applicants.

Criteria for release of approved project funding

All applications will be subject to review and recommendation by the BioCanRx's Research Management Committee. 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:

- ❑ Execute and return the BioCanRx Letter of Award; and
- ❑ Ensure your research institution has executed BioCanRx Network Agreement, and all investigators and project personnel have signed Appendix A to the Network Agreement.

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

APPLICATION PROCESS

To be eligible to apply, the applicant must employed by a Canadian research institution and be eligible to receive research funds from CIHR, SSHRC or NSERC. For this competition, the applicant must also be named on the original BioCanRx application.

The application package must be delivered by email to applications@biocanrx.com and must be received by 11:59 am ET, by the specified deadline in advance of a BioCanRx RMC meeting.

Please direct questions about the program and application process to Kelley Parato, BioCanRx Director, Scientific Affairs (keparato@biocanrx.com; 613-739-6595) or Stéphanie Michaud, BioCanRx President and Chief Executive Officer) (smichaud@biocanrx.com; 613-739-6202).

A complete application includes:

Document 1: Application form: A single PDF file that includes the completed application form, in single spaced type, Times New Roman or Arial (minimum 11 pt font), with 1 inch margins. Please enter the project leader's name in the header. The file name should include the project leader's name (e.g., Bell_CSEI_Application.pdf).

Document 2: Personnel: A single PDF file including a Canadian Common CV (CCV) in CIHR, NSERC or SSHRC format for each network investigator requesting BioCanRx funding. Do not include collaborator or trainee CVs. You should include selected publications relevant to the current application, but do not exceed one page. Do not submit your CCV online, instead print the CCV as a PDF file. The file name should include the project leader's name (e.g., Bell_CVs.pdf).

Document 3: Partners: A single PDF file that includes letters from eligible partners. The file name should include the project leader's name (e.g., Bell_PartnerLetters.pdf).

Document 4: Budget: A single Excel file, detailing the total project cost, and a breakdown of use of BioCanRx and partner funding. For BioCanRx funds, budget expenditures should follow CIHR guidelines.

Budget justifications are included in Section 6 of the application form. The file name should include the project leader's name (e.g., Bell_Budget.xls).

Document 5: Appendix (optional): A single PDF file containing any vendor contracts or service quotes in support of the budget request, as applicable. The file name should include the project leader's name (e.g., Bell_Appendix.pdf).