# CALL FOR PROPOSALS

## CLINICAL TRIAL PROGRAM*Clinical Evaluation of Innovative Cancer Biotherapeutics*

### Application Form for Full Application

### *Full Application Deadline:*

The application package must be delivered by email to applications@biocanrx.com and must be received by 11:59 am ET, on the deadline in advance of the next scheduled RMC meeting (see [Apply for funding](http://www.biocanrx.com/apply-for-funding/) on the BioCanRx website).

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).

### Document 1

Please complete the Application Form in single-spaced type, Times New Roman or Arial (minimum 11 pt font), with one-inch margins. Please enter the project leader’s name in the header but do not modify the rest of the header. You may delete the specific section instructions but do not delete section headings. The file name should include the Project Leader’s name (e.g. Bell\_CT\_Application.pdf).

### Section 1: Project Overview

**Project Title:**

**Project Leader:** Identify one network investigator who will be responsible for overseeing management of the project, including allocation of project budgets and progress reporting to BioCanRx. Also indicate the host institution.

**Requested Period of Support:** (dd/mm/yyyy) to (dd/mm/yyyy): Pick a period that most accurately reflects the expected time over which the project will be conducted, and the milestones and deliverables (outlined in Section 3) achieved. Projects will be able to request “no-cost” extensions from the Research Management Committee where circumstances warrant.

**Project Description**: Using **lay language** only, and in no more than 250 words, describe the current unmet clinical need to which the proposed project applies, and make the case for BioCanRx to fund it. Note: This description may be posted on the BioCanRx website, and used in BioCanRx communications material targeted at potential donors or partners.

**Relevance and Impact:** In no more than 250 words, highlight the anticipated impact of this clinical trial project within the cancer biotherapeutics scientific community, focusing particularly on what is unique and how the project is relevant to the BioCanRx mission.

**Key Deliverables:** Identify key project deliverables (a bulleted list with one or two sentences detailing each deliverable).

### Section 2: Project Team & Roles

**Team Members:** In Table I below, list all proposed investigators involved in the project, including Principal Investigators (PIs) requesting BioCanRx funding, co-investigators not requesting BioCanRx funding, and collaborators (international collaborators, industry collaborators, project stakeholders) not funded by BioCanRx. For each person, provide their name, position, institutional affiliation and email address. Do not include trainees and personnel. **Note that for Clinical Trial projects, inclusion of biostatistics expertise is expected.**

**CVs:** In a separate PDF (**Document 2)**, provide a Canadian Common CV (CCV) in the CIHR, NSERC or SSHRC format for all Principal investigators and co-investigators listed in Table I. Do not submit CVs online, instead print CCVs in PDF format and assemble into one PDF file.

#### Table I: Project Investigators

Indicate Principal Investigators (PIs) participating in the project, including collaborators not funded by BioCanRx. In the “Portion of total working time committed to project” input value as either hours/week OR %.  Be sure to include the appropriate unit.

|  |  |  |
| --- | --- | --- |
| **Principal Investigator & Institution** | **Role in Project/Expertise** | **Portion of total working time committed to project** (hrs/week or %; be sure to include the appropriate unit) |
| Principal investigators (receiving BioCanRx funds) |
| Name, position, institution, email address |  |  |
|  |  |  |
|  |  |  |
| Co-Investigators (not receiving BioCanRx funds) |
| Name, position, institution, email address |  |  |
|  |  |  |
|  |  |  |
| Industry collaborators |
| Name, position, institution, email address |  |  |
|  |  |  |
|  |  |  |
| International collaborators |
| Name, position, institution, email address |  |  |
|  |  |  |
|  |  |  |
| Project stakeholders |
| Name, position, institution, email address |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

### Section 3: Research Proposal

In six (6) pages maximum, including figures and tables but excluding references:

1. Describe the background, rationale and objectives of the clinical trial project.
2. Outline the study design and describe the use/expectations of BioCanRx core facilities, if applicable.
3. Detail the anticipated key milestones for each of the funded years and the key deliverables anticipated by the end of the funding period, including an anticipated patient accrual schedule. **Note that feasibility of study completion and likelihood of projected accrual will be rigorously reviewed by the Research Management Committee.**
4. Highlight the international competitiveness and innovative nature of the proposed project. Also provide comment on potential clinical and/or commercial impact of the proposed project.
5. Describe the team and infrastructure supporting the project; articulate why the team has the necessary expertise and resources to conduct the proposed trial and, where relevant, describe the role of partners in achieving the project goals.
6. References may be added to a maximum of two (2) pages.

### Section 4: Partnerships

Please read application guidelines section on Partnerships carefully before completing this section.

1. In the Table II below (adding lines as necessary), list each confirmed partner that will support the proposed clinical trial project. Detail the amount ($) and nature of support provided. It is expected that each project will secure 60% of total project funds from partners, although not all of this funding needs to be secured at the time of submission. **Please note that the three federal granting councils (CIHR, NSERC and SSHRC), other NCEs, CFI and Genome Canada are not eligible partners for the purpose of this competition.** For projects that were included in the submission to the NCE, partner letters need not be updated if the scope of the project remains substantially unchanged. However, they should still be listed in the table below and copies included in **Document 3**.
2. In a separate PDF (**Document 3**), provide signed letters of support on the letterhead of eligible partners detailing the extent of their support toward the proposed project. The letter should be addressed to BioCanRx and should include the name of the project leader, the title of the project and any conditions placed on the funding.
3. Conflict of Interest Declaration: Where a researcher has a financial interest (as defined by NCE Conflict of Interest Guidelines) in a partner, the potential conflict of interest should be declared to provide transparency to the review process.
4. Please refer to the BioCanRx Policy on Industry-Partnered Research in preparation of your application.

#### Table II: Partners

|  |  |  |
| --- | --- | --- |
| Name of Partner | Value of Contribution ($CAD) | Cash/In-Kind (detail) |
| 1. |  |  |
| Role in Project:Potential Conflict of Interest? |
| 2.  |  |  |
| Role in Project:Potential Conflict of Interest? |
| 3. |  |  |
| Role in Project:Potential Conflict of Interest? |
| 4. |  |  |
| Role in Project:Potential Conflict of Interest? |

### Section 5: Future Product/Platform Development Trajectory

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 delivering products and platforms for commercialization, and market access to cancer patients. In **two (2) pages maximum**, describe the anticipated next steps in clinical and/or commercial development of the product(s) and/or platform(s) in the proposed study. Describe the intellectual property status of the technology, and include a realistic assessment of the likelihood of industry partner engagement and the role of prospective partners in future development of your product/platform. Also describe future clinical trials planned featuring the described technology, and discuss any additional partners from other sectors (NGO, consortia) that might be required to realize these clinical development goals.

### Section 6: Training Highly Qualified Personnel

In half a page, describe the unique nature of the training environment provided and the role of trainees in the realization of the proposed project. Detail the types of highly qualified personnel (HQP) to be trained in areas including but not limited to: academia, clinical coordination, clinical oncology, bioethics, clinical epidemiology, statistics, commercialization, health economics, intellectual property, technology assessment, GMP manufacturing, GLP practices, clinical site education.

### Section 7: Budget

Please complete the budget template provided (**Document 4** of the Application Package) and provide justification to the budget below. A major concern of BioCanRx is to ensure that all clinical trial costs will be covered from all sources. Therefore, applicants must indicate the proposed allocation of BioCanRx and partner funds against the expenses of the proposed clinical trial. Total partner funds in the budget should be reflected in the text of the accompanying partner letter. Note that BioCanRx eligible expenses are identical to those of CIHR. However, equipment purchase is not an allowable use of BioCanRx funds at this time. CIHR guidelines can be found at <http://www.cihr-irsc.gc.ca/e/805.html>.

**Projects that propose unrealistic budgets will be triaged by BioCanRx's network office and will not be reviewed by the Research Management Committee.**

Include in the budget personnel (cost including salary and benefits) that will be hired for the project with BioCanRx funding but do not include the costs of inter-laboratory exchange of personnel as these costs can be obtained from the Network office by other means. Also include in the budget, expenses to be incurred while using a BioCanRx Core Facility in the conduct of the proposed research, if applicable.

**Justification:** Provide budget justification (**no page limit**) referring to budget items by noting the Excel spreadsheet row number relevant to the item.

**Proactive disclosure:** According to NCE guidelines, “Applicants must provide a statement of other sources of funding with their application, demonstrating that there is no duplication of funding for the same research. However, when research programs are supported by multiple sources, the additional benefits of NCE support must be well explained and justified”.

Please use the space below following the budget justification narrative (**no page limit**) to disclose any potential or perceived overlap in your current or pending funding applications as set forth in the Common CV.

In a separate **Document 5** (single PDF file), please append any vendor quotes or service contracts in support of the funding request.

### Section 8: Project Management and Networking

Please read project management section of application guidelines carefully before completing this section.

**Schematic of Project Plan:** In **one page (maximum)**, provide a workflow diagram that illustrates the key steps, milestones and deliverables described in the research plan, and the investigators involved in each step.

**Project Manager:** A project of this magnitude will require a dedicated project manager. Funding for a project manager is an eligible expense and may be included in your budget. In **half a** **page (maximum)**, describe how you envisage using a project manager to accomplish the project goals. If you have a project manager in mind, please include their free-form CV (2 pages maximum) at the end of Section 8; if you do not, describe the skills/attributes you would seek in a project manager recruit.

**Networking:** In **half a** **page (maximum)**, describe specifically how this project will be networked with other BioCanRx projects and network investigators (e.g., workshops, lab exchanges, web-based communications, hosting clinical trial investigators at your trial site). Note that, once approved, project teams will have access to funds to organize team meetings, site exchanges of HQP and workshops. Therefore there is no need to identify these costs within the project budget, but you need to describe these activities in this section.