# Building a bridge: Manufacturing, analytics and trials for translational biomedical researchers

## APPLICATION PROCESS

***Application Deadline: Friday, May 31, 2019*** *Notification of Award: Mid-June, 2019*

*Workshop Dates: Monday, September 30 – Friday, October 4, 2019
Location: University of Ottawa, Faculty of Social Sciences, Ottawa, Ontario*

The application package must be **received by 11:59pm EST, May 31, 2019**. All applications should be directed to Jodi Garner, Senior Manager, Science and Industry Relations, jodi.garner@oirm.ca.

Please direct your questions about the workshop and application process to Megan Mahoney, Manager of HQP Training Programs, memahoney@biocanrx.com, 613-737-8149 (BioCanRx Investigators) or Jodi Garner, Senior Manager, Science and Industry Relations, jodi.garner@oirm.ca, 647-220-3394 (OIRM Investigators).

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 and institution in the header but do not modify the rest of the header. The file name should include the Project Leader’s name (e.g. Smith\_GxP 2019\_Application.pdf).

***Eligibility (BioCanRx)***

We will be accepting applications from currently funded BioCanRx Network Investigators, those applying for funding (have submitted an LOI), or those who had applied to a BioCanRx Catalyst or Enabling award. Attendees must have a biotherapeutic discovery with intended applications for cancer treatment. Note: It is not mandatory that your discovery and associated strategic plan relate to a currently funded BioCanRx-funded project; however, priority will be given to projects currently funded by BioCanRx.

***Eligibility (OIRM)***

We will be accepting applications from both funded and non-funded OIRM Network Investigators. Attendees must have a cell-based discovery with intended applications for clinical treatment. Priority will be given to those teams already receiving OIRM funding or have demonstrated project advancement towards the clinic.

Upon success of your application, you will receive a package with information pertaining to the workshop that will allow you to prepare in advance of the workshop. The information package will also include a reciprocal non-disclosure confidentiality agreement that you will be required to sign as part of acceptance of this award, and prior to attending the workshop.

***Expectations***

The expectation is that by accepting this position, all team members agree to participate in the entirety of the workshop including a presentation of your preclinical plan on the last day of the meeting.

***Evaluation***

Your application will be evaluated with the following criteria in mind:

* Quality of the proposed discovery
* Alignment between the stage of proposed work with the objectives of the workshop
* Fit with BioCanRx’s or OIRM’s research mandates
* Quality and appropriateness of proposed team members attending the workshop. These team members should be integral to the proposed project and whose attendance will directly benefit the proposed project.
* It is not mandatory that your project (discovery) be a currently funded project; however, priority will be given to those projects that are currently funded by either BioCanRx or OIRM.

***Notification, Registration and Reimbursement***

* Applicants will be notified of their application status mid-June 2019.
* Applicants will be required to pay a nominal registration fee of $1000 per team. More details will be circulated with application notifications.
* BioCanRx: Successful applications will have all expenses associated with travel, accommodations and meals paid for by BioCanRx for the project leader, a team member and an HQP to attend.
* OIRM: Successful applications will have a portion of expenses associated with travel, accommodations and meals paid for by OIRM, the remaining expenses are expected to be charged to your Disease Team grant. A full travel policy will be provided to applications upon being accepted to this workshop.

### Section 1: Project Overview

**1.1 Project Title:**

**1.2 Project Leader:**

**1.3 Host Institution:**

### Section 2: Project Team

**2.1 Team Members:** In Table I below, please list the project leader, plus **two (2)** team members, who are integral to the described work that will accompany the project leader. These additional team members can include individuals such as a research clinician collaborator, senior research staff, project managers or research coordinators, and must include one trainee (graduate student or postdoctoral fellow). For each person, provide their name, position, institutional affiliation and email address. Provide two to three sentences that describe the role of each team member in the research project and their respective areas of expertise.

All team members including the project leader (Investigator) must be present in person for the entirety of this workshop.

**CVs:** In a separate PDF, provide a max 2-page CV for each of the members listed in Table I.

#### Table I: Team Members

|  |  |  |
| --- | --- | --- |
| Name | Position and Institution | Phone and Email Address |
| 1. |  |  |
| Role in project and area of expertise: |
| 2. |  |  |
| Role in project and area of expertise: |
| 3. |  |  |
| Role in project and area of expertise: |

### Section 3: Project Description

**3.1 Please describe the discovery to which you will be applying the knowledge gained at the workshop (250 words max)**. *Please note that we will be circulating these descriptions to the Subject Matter Experts, and they will also be included in the program book. The description you include here will be used for adjudication purposes, but if successful, you will be given an opportunity to update your description prior to circulation.*

 **3.2 Please describe in point form, the stage your discovery in terms of translational development (250 words max).**

**3.3 Please indicate the where you are in the translational process:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Discovery \_\_\_ | Pre-CTA meeting scheduled within next 6 months \_\_\_ | Pre-CTA Meeting has taken place \_\_\_ |  Phase I anticipated to start within 6 months \_\_\_ | Phase I initiated \_\_\_ | Phase 2 \_\_\_ |

**3.4 Please indicate the where cell and/or vector manufacturing will occur:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Manufactured by research team \_\_\_ | Manufactured in research institute facility (please specify what facility):  | Contract Manufacturing (please specify):  | Purchase of cells from company (please specify):  | Manufacturing will take place within Canada\_\_\_ | Manufacturing will take place outside of Canada\_\_\_ |

**3.5. In reference to the discovery listed above, please indicate below your grant status:**

**BioCanRx**

|  |  |  |  |
| --- | --- | --- | --- |
| Current holder \_\_\_ | Previous holder \_\_\_ | LOI submitted \_\_\_ |  Applied but not successful \_\_\_ |

**OIRM**

|  |  |  |
| --- | --- | --- |
| Current Disease Team awardee \_\_\_ | Previous Disease Team awardee \_\_\_ | Other (please describe):  |

### Section 4: Anticipated Outcomes

**4.1 Please describe what your goals are for attending this workshop (max 250 words).** In your response, please describe your greatest challenges in moving your technology forward and how this workshop may alleviate these challenges.

**4.2 Please describe how the learning outcomes from this workshop will be disseminated to your team (max 250 words).** Please describe how the information gained through this workshop will be put into practice.

**4.3 Please describe the long-term ambitions of this project (max 250 words).** Please describe the projects sustainability plan and long-term goals.

### Section 5: Institutional Resources

**5.1 Please use table below to indicate (Y/N) which resources you have access to at your or a collaborator’s facility.** Please note that this will facilitate our networking capabilities and will not be used to adjudicate successful applications.

***Table 2. Please check which of the follow you have access to:***

|  |  |  |
| --- | --- | --- |
|  | You (Y/N) | Collaborator (Y/N)If yes, please indicate your collaborator and collaborator institution.  |
| Animal care facility  |  |  |
| Assay Development |  |  |
| Charitable foundations  |  |  |
| Clinical specimen analysis |  |  |
| Clinical trial data management  |  |  |
| Clinical trial design support |  |  |
| Clinicians  |  |  |
| GLP Laboratory  |  |  |
| GMP Laboratory  |  |  |
| Health economist  |  |  |
| Process development space |  |  |
| Regulatory affairs experts  |  |  |
| Statistical methods centre  |  |  |
| Technology transfer office |  |  |

**5.2 Please add any additional comments relating to institutional resources here (250 words max):**