SU2C Canada-OICR
Cancer Clinical Trials

Canadian Dream Team
Supplementary Funding

Call for Ideas and Full Application Guidelines

9861 Leslie St
Richmond Hill, ON L4B 3Y4
416-797-5366; 905-883-6800 (FAX)
su2ccanada@aacrcanada.ca; www.aacrcanada.ca

CLINICAL TRIALS FUNDING SUPPORT FOR DREAM TEAMS

GUIDELINES

ABOUT ONTARIO INSTITUTE FOR CANCER RESEARCH (OICR)

The Ontario Institute for Cancer Research (OICR) is an innovative, translational research organization, dedicated to research on the prevention, early detection, diagnosis, and treatment of cancer. As a centre of excellence, the OICR moves Ontario to the forefront of discovery and innovation in cancer research and ensures the effective knowledge transfer and commercialization of research findings in order to maximize the health and economic benefits for the people of Ontario.

ABOUT STAND UP TO CANCER CANADA (SU2C Canada)

(Description of SU2C Canada and AACR Canada will be inserted.)

MISSION STATEMENT

Further to the SU2C Canada *Call for Ideas* announced in 2014, OICR is offering a total of $6 million (CAN) in supplementary funds to the two selected SU2C Canada Dream Teams to conduct clinical trials in Ontario (each Dream Team may receive up to $3 million over a 4-year period). In order to receive such funds, applicants must satisfy the requirements of the competition, as outlined in the SU2C Canada Dream Teams Call for Ideas and Program Guidelines and Instructions, as well as any additional requirements put forth in these supplementary guidelines and an ensuing research agreement.

SUPPLEMENTARY FUNDING CRITERIA

1. Financial Contribution: The financial contribution from OICR is available only for clinical activities conducted in Ontario associated with Dream Team projects.
2. Ontario Clinical Trial Lead: A Dream Team member (Dream Team Leader/Co-leader or Dream Team Principal) must be identified who will lead the clinical trial activities in Ontario. The Ontario Clinical Trial Lead must have demonstrated expertise, a track-record in conducting clinical trials and be connected to the Ontario clinical research community. This expertise should be evident in the submitted biographical information. Letters of support from the other clinical trials collaborators in Ontario should confirm the Clinical Trial Lead's commitment to patient accrual.

HOW TO APPLY

Letter of Intent (LOI)

A brief description of the proposed clinical trial activities to be conducted in Ontario should be included within the LOI requested by the SU2C Canada Dream Teams *Call for Ideas*.

Full Proposal

In addition to the twenty-page proposal narrative required for SU2C Canada Dream Teams *Call for Ideas*, a synopsis of the clinical trial protocol (up to 4 pages) and budget must be appended to the application. The summary should succinctly outline the study's objectives and specific aims, study design, study population including inclusion/exclusion criteria, methodology, and statistical assumptions such as early stopping rules. Operational details should also be provided such as: evidence of feasibility of projected patient accrual including number and location of sites, source of drug supply if applicable, regulatory requirements, data management support and data safety monitoring plans, and interim analysis (if applicable). Projected deliverables and milestones must also be stated. Examples include clinical protocol sign-off, clinical trial application submission to Health Canada and approval, research ethics board

submission and approval, study activation meeting(s), site initiation meetings, first patient accrued, quarterly patient accrual targets, last patient accrued, database lock, data analysis, and clinical study report. All Ontario clinical trial activities must be clearly delineated.

USE OF OICR FUNDS

The following expense categories are eligible for OICR funding with the proviso that the expense is realized in the province of Ontario.

Start-up Costs

Eligible start-up costs include clinical protocol preparation, research ethics submission, and Health Canada submission (if applicable).

Fixed Costs

Fixed costs include expenses that are necessary to implement the clinical trial regardless of patient recruitment status (e.g., study coordinator salary, selected external research services, equipment, general & administrative, etc.) Eligible cost of salaries and benefits should be calculated using the employee's actual base salary amount, plus actual payroll benefits (e.g., vacation, medical, dental, etc.). The amount should reflect the proportion of the employee's normal total hours for payroll purposes spent working directly on the clinical trial.

Per-patient Costs

Per-patient costs include expenses that are dependent on patient accrual (e.g., screening costs, patient visit costs, clinical sample collection, site monitoring, etc.). This expense category is to be used to cover patient research costs not deemed to be standard-of-care and specific to the clinical trial. These costs **should not exceed standard OHIP/CMA rates**.

A comprehensive budget is required for all clinical trial activities. A separate budget containing only Ontario specific expenses must be included; this budget must be completed using the OICR SU2C Canada budget template available from proposalCENTRAL.

NOTIFICATION OF AWARDS

Should a Dream Team meet the supplementary funding criteria, the Ontario Clinical Trial Lead will be informed in writing by a notification of award (NOA) letter. The NOA will announce the maximum grant award and provide a description of any adjustments to the budget. Notification to other clinical trials collaborators in Ontario will be the responsibility of the Ontario clinical trial lead.

ESTABLISHMENT OF AN AGREEMENT

A research agreement will be executed between OICR and the Ontario Clinical Trial Lead's institution (Recipient Institution). The agreement will cover general principles regarding the conduct of clinical trial activities, eligible expenses, terms and conditions regarding the disbursement of funds, progress reporting, and publication and communication policies. The Recipient Institution must serve as the administrator of OICR's financial contribution and enter into subcontracts with institutions of collaborating clinical trialists in Ontario (if applicable). Assurances that such contractual agreements are executed will be required prior to disbursement of funds.

DISBURSEMENT OF FUNDS

OICR's financial contribution will commence upon successful execution of the Dream Team research agreement, and the agreement between OICR and the Recipient Institution. Initial disbursement will include funds sufficient for clinical trial start-up, first quarter fixed costs, and ten per cent (10%) of the projected total "per-patient" budget. Subsequent disbursements are subject to receipt of bi-annual progress reports.

Subsequent disbursement of funds for fixed costs will occur quarterly, whereas subsequent per-patient costs will be based on patient accrual performance and future projections. The Ontario Clinical Trial Lead will be responsible for conveying the anticipated accrual projection numbers and per-patient costs to OICR in bi-annual reports.

MONITORING OF RESEARCH PROGRESS

The AACR International-Canada and funders of the SU2C Canada Dream Teams, including OICR, will develop a consolidated reporting mechanism and progress report template which will be set out in the research agreement. Progress reports are a tool to ensure that the Dream Team is meeting its predefined deliverables and milestones. The reports can also be used to specify revised or new deliverables and milestones, as dictated by actual findings and as approved by SU2C Canada Scientific Advisory Committee (CSAC). Ontario clinical trials activity reports are to be submitted twice a year to OICR and the AACR International-Canada. The reports are intended to highlight the Ontario-based accomplishments of the reporting period and a projection of what will be accomplished during the remainder of the year.

Progress will be monitored against agreed upon deliverables and milestones. Special attention will be given to evaluate progress towards attainment of projected Ontario patient recruitment. Reports should provide details of attainment of clinical trial milestones (e.g., FTE hires, ethics approval, site initiation, recruitment activity, etc.), impediments to attainment of milestones (if applicable), and mechanisms to redirect milestones back on track to meet target dates. OICR may withhold release of any future financial contribution until reports have been filed and approved.

COMPLIANCE AND RESEARCH INTEGRITY

Recipients of OICR financial contributions shall be in compliance with all applicable laws, regulations, and government orders that affect the conduct of clinical trials in Ontario. Studies involving human subjects must be conducted in accordance with all applicable policies governing the protection of human subjects of medical research, including, without limitation, Tri-council Policy Statement (TCPS 2), International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated guideline, the Declaration of Helsinki, Health Canada: Therapeutic Products Directorate, provincial policies, OICR policies, investigators' institutional policies, and research ethics board approvals.

The Recipient Institution must take full responsibility for the conduct of work being funded by OICR. Recipient Institutions must agree to ensure compliance with all applicable laws and regulations, full ethical review and surveillance, compliance with accepted biohazard and animal care regulations, and full financial accounting and control, including appropriate record retention practices. Moreover, Recipient Institutions must agree to enforce policies for governing research integrity and intellectual

property. Through sub-agreements, they will ensure that Ontario institutions that are collaborating on Ontario clinical trials (if applicable) abide with applicable laws and regulations.

Recipient Institutions must also agree to investigate any charges of scientific misconduct, and to impose appropriate sanctions. OICR requires that all institutions that have investigated allegations of scientific misconduct provide a report to OICR of the allegations made, results of any investigation, and any actions taken in response to the investigation.

PUBLICATIONS AND ACKNOWLEDGEMENT OF SUPPORT

In addition to the acknowledgement of support from SU2C Canada and other funders, as outlined in Dream Team Call for Ideas and Program Guidelines and Instructions, recipients of OICR financial contributions will acknowledge and credit the contribution, in whole or in part, of OICR and the Government of Ontario in any promotional material, including, without limitation, scientific publications of whatever nature or kind, by setting out in any communications materials or publications referencing the Dream Team projects, the following statement: "This study was conducted with the support of the Ontario Institute for Cancer Research through funding provided by the Government of Ontario."

INQUIRIES

Inquiries about the OICR's Dream Team supplementary funding guidelines, eligibility requirements, and application materials can be directed to the AACR International-Canada at:

Phone: 416-797-5366
E-mail: su2ccanada@aacrcanada.ca