

## ***Equity, Diversity, Inclusion (EDI) Demonstration Project Request for Application Guidelines***

<b>Date Issued:</b>	Monday September 9 <sup>th</sup> , 2024
<b>Closing Date:</b>	Monday October 7 <sup>th</sup> , 2024 at 8 pm EST
<b>Project Period</b>	Nov 1, 2024 to March 31, 2025
<b>E-Submission</b>	<a href="mailto:info@3ctn.ca">info@3ctn.ca</a>
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## 1. Introduction

### 1.1. About the 3CTN Equity, Diversity, Inclusion (EDI) Initiative

In line with our 2022-2027 strategic priorities for improving cancer patient access to clinical trials, a priority for 3CTN is to address barriers to trial accrual and participation among traditionally underrepresented populations across Canada. Many member Cancer Centres have identified and defined milestones and deliverables within their Network agreements focusing on implementation of decentralized clinical trials (DCT) models such as CRAFT<sup>1</sup> as well as integrating other EDI best practices within clinical trial conduct.

To support their success, a comprehensive, overarching [EDI Framework and Toolkit](#) was recently developed through the collaborative efforts of clinical research professionals, people with lived experience from equity-deserving communities, our partners, and sponsors. Resources found within the EDI Toolkit are intended to guide implementation of user-selected priority activities that can be readily sourced according to representative research role, applied setting, and/or target populations intended to benefit from recommended practice changes.

### 1.2. Current Phase: Implementation

This funding opportunity will build on the early successes of CRAFT and the recently launched EDI Framework and Toolkit.

Outcomes of the collective initiatives undertaken by successful site applicants will serve to demonstrate pan-Canadian impacts, inform on opportunities for improvement, and help guide further progress by the Network. Results will be summarized in a manuscript suitable for publication and shared with our stakeholders and partners.

We envision broad adoption of EDI best practices will ultimately create meaningful improvements that enhance equitable access to clinical trials, increase participation from underrepresented populations, and promote greater diversity and inclusiveness within Canada's clinical research community.

## 2. Request for Applications (RFA)

3CTN invites all interested member centres to apply for funding to support cancer centres in the implementation of a project concept, feasibility or pilot and support the assembly of the initial required resources and collaborations necessary for project development and implementation activities.

3CTN is accepting applications under the following two streams:

- Implementation of EDI best practices for cancer clinical trials conduct
- Application of the CRAFT DCT Framework for trial cluster set up activities, including:
  - selection of an open trial candidate and participating satellite centre(s),
  - executing agreements with selected satellites,
  - use of 3CTN CRAFT toolkit elements.

Cancer centres may submit proposals for either new projects or the continuation of existing projects for funding. Applicants are encouraged to collaborate with other Network Cancer Centres, as applicable, and to consider how these projects may lead to future activities beyond this seed funding period.

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<sup>1</sup> [The Canadian Remote Access Framework for Clinical Trial \(CRAFT\)](#) aims to improve trial participation by allowing some trial activities to be conducted at local community healthcare centres under the supervision of a primary cancer centre.

## 2.1. Eligible Applicants

3CTN member cancer centres are eligible to apply. Centres can collaborate with other organizations, including other member centres. The primary applicant will receive funding directly from 3CTN and will be responsible for allocating these funds to collaborators as appropriate.

## 2.2. Project Term

- The term of the award is up to 5 months (November 1, 2024 – March 31, 2025).

## 2.3. Available Funding

- A total of \$250,000 is available.
- Budgets for individual projects applications of up to \$20,000 will be considered for funding.

## 2.4. Eligible Expenses

Direct costs based on project activities such as:

- Salaries and benefits for staff responsible for implementation activities. This may include clinical trials professionals, research assistants, project managers and other highly qualified personnel.
- Patient Partner honoraria
- Educational outreach and communication activities directly related to the project
- Travel expenses directly related to project activities. Travel must be by the most practical and economical methods and adhere to 3CTN travel expense policies.

## 2.5. Ineligible Expenses

- Indirect costs or overhead
- Salaries and benefits of the 3CTN Principal Investigator
- The costs of construction, the refurbishing of laboratories or clinical trial offices

## 2.6. Application Requirements

Applicants must complete the 'EDI Demonstration Projects Application Form' and provide:

- Project title
- Project summary
- Goals and objectives of the project
- Implementation plan
- Project timelines and milestones
- Project deliverables and measures of success to demonstrate project impact
- Anticipated challenges/risk management plan
- Patient and community engagement plan
- Proposed budget

In addition, if applying for the CRAFT stream, applicants must also provide:

- A description of the trial cluster, comprising 1 or more satellite centres cluster.
- A signed (.pdf) letter of support from each participating satellite institution.
- A candidate interventional cancer clinical study that is currently open to accrual and is expected to remain open for the next fiscal year.
- A letter of acknowledgement from the study sponsor, indicating support for the proposed application of the CRAFT model.

Progress will be evaluated throughout the study period to identify opportunities to improve current 3CTN EDI strategies and existing resources. After the funding period, we aim to share our learnings from the EDI Demonstration Projects and disseminate the results.

## 2.7. Patient Engagement Plan

Embedding Patient Partners in research activities is a priority for 3CTN. Applicants must include a patient and community engagement plan in their application, outlining how patient and community input will be integrated throughout the project. Applicants are encouraged to consult and engage with Patient Partners for their project. For support in identifying a Patient Partner, contact 3CTN.

## 2.8. Expectations of Participating Applicants

- Participate in 3CTN's project evaluation plan: report on progress to completion of project deliverables and financials quarterly or more frequently as required for 3CTN funder updates.
- Financial reporting as of the end of the funding period (**March 31, 2025**).
- Contribute to knowledge exchange activities to share back results to the Network.

## 2.9. Application Submission

Completed applications must be submitted by **Monday, October 7<sup>th</sup>, 2024, at 8 pm EST (5 pm PST)** to [info@3CTN.ca](mailto:info@3CTN.ca). The application must include:

- Completed 'EDI Demonstration Projects Application Form 2024'.
- Signed (.pdf) letters of support from the Institution's Administrative Authority at the applicant's site.
- For CRAFT Stream, signed (.pdf) letters of support from participating institutions' Administrative Authority:
  - each proposed satellite
  - study sponsor

## 2.10. Questions about Demonstration Project and this RFA

3CTN welcomes questions and requests for clarification throughout the RFA response period until Friday September 27<sup>th</sup>, 2024, at 3 pm EST (12 pm PST). Questions and requests must be submitted to [info@3CTN.ca](mailto:info@3CTN.ca).

At 3CTN's discretion, any responses that could be helpful to all respondents will be anonymized and shared in the [Equity, Diversity and Inclusion section](#) of the 3CTN website.

If you require that your question and response be kept confidential, please state this with your question. Before providing our response, 3CTN will advise whether confidentiality can be maintained, and provide the opportunity to withdraw the question if confidentiality is required.

## 3. Selection and Agreement Process

### 3.1. Response Evaluation Process

RFA responses will be evaluated by a panel of non-conflicted individuals comprised of the EDI Demonstration Project Steering Committee, patient partners and external expert advisors.

Responses will be reviewed by panel members independently and scored for each section (see Appendix A for reviewer scoring criteria). Cumulative scores will be used to rank the responses by the evaluation

panel, who will meet to review and discuss individual and overall scoring results and ensure there is diversity in the selected centres and projects. Feedback will be provided back to the applicant. The final selection of projects will be approved by 3CTN's Management Committee. Successful entrants will be notified by email.

### **3.2. Notice of Award Letter**

Successful applicants will receive a Notice of Award letter during the week of Oct 28<sup>th</sup>, 2024. The intended start date for the projects is **Nov 1, 2024**.

### **3.3. Contractual Agreement**

Successful applicants will be required to enter into a contractual agreement with the Ontario Institute for Cancer Research (OICR), as the legal entity for 3CTN. An amendment to the existing 3CTN-Centre Agreement will include project description, eligible expenses, performance measures and reporting requirements.

## **4. Accompanying Documents & Resources**

- EDI Demonstration Project Application Form 2024
- [EDI Framework and Toolkit](#)
- [CRAFT Position Paper and Toolkit](#)

## APPENDIX A

### Application Review and Scoring Guide

#### Section 1: Project Summary (0 - 3 points)

Applicants are asked to provide a summary of the project and describe the goals and objectives of the project during the funding period. For the CRAFT stream, supplementary information was submitted regarding the selection of the satellite site.

##### Evaluation for CRAFT projects:

**1 point:** The rationale for selecting the location is insufficient, with minimal details about the location, local population, clinical trial experience, local services, or infrastructure. The rationale does not demonstrate suitability, feasibility or anticipated impact.

**2 points:** The rationale includes relevant information but requires additional details to ensure suitability, feasibility and/or impact of including the satellite location.

**3 points:** The rationale is thorough and well-detailed, providing information about the appropriateness of the satellite location(s), appropriateness for inclusion in the proposed trial cluster.

##### Evaluation for other EDI projects:

**1 point:** The project shows limited alignment with EDI priorities. The goals and objectives are vague, and it is uncertain whether meaningful outcomes will be achieved within the funding period.

**2 points:** The project demonstrates alignment with EDI priorities, with moderately clear goals and objectives. The project appears feasible but requires further refinement.

**3 points:** The project strongly aligns with EDI priorities, with well-defined goals and objectives. The project is clear and realistic, ensuring success within the funding period.

#### Section 2: Implementation Plan (0 - 3 points)

Applicants are asked to provide a summary of the implementation plan for their project. Review and assess the feasibility of the implementation plan. For the CRAFT stream, supplementary information was submitted regarding the suitability of the proposed candidate trial, research assessment and involvement at satellite site.

##### Evaluation for CRAFT projects:

**1 point:** The trial selection would be feasible overall but there is significant risk of adverse trial outcomes or project delays (e.g. proposed trial cluster setup, management or satellite location responsibilities). The feasibility of offering the study at the satellite site has been partly assessed. It is not entirely clear how the scope of trial activities can be carried out at the satellite site.

**2 points:** The trial selection is generally feasible but presents notable risks or challenges, such as potential issues with trial outcomes, project delays, or alignment with the proposed level of oversight and satellite capabilities. The feasibility of offering the study at the satellite site is well-understood and there is a plan to provide most or all the trial activities at the satellite site. Assessments should not be penalized when specialized equipment or resources are required.

**3 points:** The trial selected would be a reasonable, appropriate, feasible option for the proposed level of oversight at each satellite; trial cluster setup and management plan are sound. There is a strong plan to implement and provide oversight for trial activities at the satellite site.

### **Evaluation for other EDI projects:**

**1 point:** The implementation plan is unclear and lacks sufficient details, raising feasibility concerns.

**2 points:** The implementation plan is generally clear but has some concerns that may require refinement for successful execution.

**3 points:** The implementation plan is well-defined and feasible within the proposed timeframe.

### **Section 3: Project Milestones and Timelines (0 - 2 points)**

Applicants are asked to provide a project timeline with key milestones for the proposed project. Review and assess the feasibility of the milestones.

#### **Evaluation:**

**1 point:** Some milestones are missing or require further clarification/refinement to better ensure project feasibility can be determined.

**2 points:** Milestones are complete and generally well-defined.

### **Section 4: Project Deliverables and Measures of Success (0 - 5 points)**

Applicants are asked to define project deliverables and appropriate measures that will help determine the success and impact of each deliverable. Wherever necessary, an explanation of how applicable outcomes will be measured should be provided.

#### **Evaluation:**

**1 point:** Expected deliverables are missing, requires further clarification or refinement to enable appropriate measurement of success and intended impacts.

**3 points:** Defined deliverables are generally complete and appropriately considered to support impactful change; minor clarification or refinements would improve intended impacts and/or better assure successes can be measured.

**5 points:** Deliverables are clearly defined, are expected to support impactful changes of practice and enable clear measurement of success.

### **Section 5: Risk Management (0 - 2 points)**

Applicants are asked to describe, assess, and mitigate any anticipated risks for their proposed project or study. An assessment scheme for risk probability (unlikely, even, likely) and impact (low, moderate, high) is provided.

This scoring guide aims to reward proactive solutions that increase clinical trial competencies at the site through mentorship, collaboration and/or long-term solutions.

**Evaluation:** Assign an overall score based on assessment of the following two components:

a) Risk Assessment

The application provides a comprehensive and reasonable assessment of the probability and impact for all identified risks.

b) Risk Mitigation Strategy

Proposed strategies address the cited risk and are preventive and sustainable where possible.

**1 point:** The risk assessment provides an inadequate consideration of reasonable risks and/or mitigation strategies are insufficient for addressing the identified risks.

**2 points:** The risk assessment provides a thorough consideration of foreseeable risks, with appropriate mitigation strategies that suitably address identified risks.

## Section 6: Patient and Community Engagement Plan (0 - 3 points)

Reviewers will assess the patient and community engagement strategy, focusing on meaningful engagement and involvement during the development and execution of the proposed project. Strong applications will demonstrate how the project incorporates patient voices and views and how learnings will be shared back to the community.

### Evaluation:

**1 point:** Minimal engagement, patient partners and community members are informed about the project but not actively engaged throughout the project activities. Plan for sharing back learnings to community is minimal or unclear.

**2 points:** Moderate engagement from patient partners and community members. The project outlines a strategy to gather input from members and incorporate their feedback into the project. There is a plan for sharing back learnings, but approach requires further clarification and refinements.

**3 points:** Strong engagement, patient partners and community members are actively participating in decision-making with their recommendations playing a key role in shaping the project. The project includes a robust plan for sharing back learnings to community, ensures knowledge gained will be effectively disseminated.

## Section 7: Budget (0 - 2 points)

Applicants were asked to provide a breakdown of the proposed expenditures and how the seed funding will be allocated.

### Evaluation:

**1 point:** The budget breakdown is incomplete or provides insufficient detail on how seed funding will be utilized. Refinements are required for the budget breakdown.

**2 points:** The budget is reasonably detailed and clear, with a well-justified breakdown of how seed funding will be used. The allocation of funds is appropriate and directly supports the project's start-up and initial needs.



## Application Status:

Each application will receive scores for each section outlined in the review guide, as well as an overall score for the project (Table 1). The final overall score will be used to rank projects for funding consideration. The review panel will convene to discuss overall scoring results and make final decisions on the applications (Table 2).

**Table 1:** Scoring

Scoring Outcome	Description
<b>Low</b> (0 – 8)	Poor to fair with moderate to major weaknesses.
<b>Medium</b> (9 – 14)	Good to very good with moderate to minor weaknesses.
<b>High</b> (15 – 20)	Excellent with minor to no weaknesses.

**Table 2:** Funding Decision

Decision	Explanation
<b>Approved</b> (15 or above)	The application meets all the evaluation criteria. It demonstrates strong alignment with 3CTN's EDI objectives, includes a clear and feasible plan, and is highly likely to achieve its intended outcomes. No significant revisions or adjustments are needed.
<b>Conditional Approval</b> (9 or above)	The application demonstrates a strong alignment with 3CTN's EDI objectives and meets most of the criteria set out in the RFA. Revisions or additional information are required in some areas before it can be fully approved. Once revisions are made, the application will be considered approved.
<b>Rejected</b> (≤ 8)	The application does not meet the necessary criteria and/or contains major issues that prevent it from being considered for funding. The plan may lack feasibility, alignment with objectives, or sufficient detail. Significant changes would be required for future consideration.

**Maximum Total Score for proposal = 20 points**