



# **Clinical Acceleration Team Awards (CATA)**

## **Request for Applications**

**Version 1.1**

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## 1. INTRODUCTION

### 1.1 Purpose

This document is intended to aid Investigators wishing to apply for a Clinical Acceleration Team Award (CATA) to support **early phase (I-II), prospective, biomarker-rich trials for clinical validation of biomarkers, diagnostics, and therapeutics.**

### 1.2 OICR vision and mission

OICR was established in 2005 to mobilize and reinforce Ontario research excellence in the fight against cancer, realize the local economic value of cancer discoveries, and make Ontario a major global address for cancer research and innovation. As Ontario's facilitator of translational cancer research, OICR brings together researchers, clinicians, patients and caregivers, health system partners, industry, and funders to drive solutions to cancer needs and accelerate the advancement of discoveries to improve cancer prevention, detection, diagnosis, and treatment.

#### Vision

Cancer solved together

#### Mission

Partner with the oncology community to translate cancer research discoveries, transforming cancer care to benefit patients, and strengthening the Ontario economy.

#### Values

Excellence | Innovation | Collaboration | Impact | Responsibility | Community

OICR invests resources in three areas:

1. Strengthening Ontario's capacity to undertake world-class cancer research;
2. Driving collaborative, translational cancer research; and
3. Working with partners to facilitate the advancement, commercialization and adoption of cancer innovations into clinical practice.



**Figure 1: OICR's Research Themes and Enablers**

OICR's research portfolio is grouped under three integrated Themes, as outlined in Figure 1:

- **Adaptive Oncology:** Developing knowledge and approaches to detect and monitor cancer over its life cycle in order to enable precise and proactive clinical management;
- **Clinical Translation:** Advancing Ontario cancer discoveries through early clinical validation, partnering with industry and the health system for downstream development and implementation; and
- **Therapeutic Innovation:** Validating novel cancer drug targets and advancing selective therapeutic candidates to clinical development.

To date, OICR's investments have cultivated a collaborative, world-class cancer research system that has yielded a rich pipeline of discoveries poised for translation and clinical impact. As part of its 2021-2026 Strategic Plan, OICR seeks to capitalize on Ontario strengths and successes to develop and implement transformative, next generation solutions to cancer with a focus on early cancer detection, intervention and monitoring for improved patient management.

### 1.3 Clinical Translation Pathway

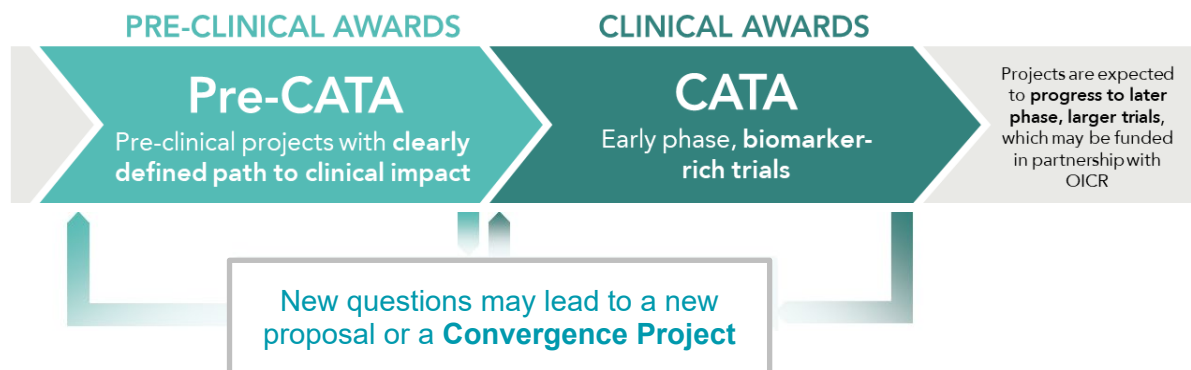
OICR's Clinical Translation (CT) is the translational engine of the Institute, advancing discoveries into clinical testing. It will support the advancement of discoveries through early clinical validation, partnering with patients, industry and the health system for downstream development and implementation. In order to accelerate translational cancer research so that precise, impactful and cost-effective treatments can benefit cancer patients, OICR implemented a new Clinical Translation Pathway (CTP).

The CTP will support practice-changing research in **biomarkers, diagnostics and therapeutics** that will advance early detection and intervention research and have a clear path to the clinic and clinical impact. It will **focus on primary-diagnosed cancer or early recurrent cancers**. The pathway will be fueled by innovations emerging from OICR-supported research and from research originating from across the province. Importantly, it will also support implementation science approaches aimed at the adoption of findings into clinical practice.

The CTP consists of four separate funding streams that support preclinical, clinical, and convergent research. Each funding stream will have its own Request For Applications (RFA). The four funding streams are:

- **Pre-Clinical Acceleration Team Awards (Pre-CATA):** Support pre-clinical projects with a clear path to the clinic, with a focus on development of biomarkers, diagnostics, and therapeutics.
- **Clinical Acceleration Team Awards (CATA):** Support early phase (I-II), prospective, biomarker-rich trials for clinical validation of biomarkers, diagnostics, and therapeutics.
- **Window of Opportunity (WOO) Trials:** Support pre-surgical trials focused on biomarker analysis characterizing the mechanism of action of single or combination agents that modulate the anti-tumour immune response in newly diagnosed, treatment naïve patients.
- **Convergence Projects:** Catalyze transdisciplinary collaborations across OICR and the Ontario research community to seed novel translational opportunities and inform health system changes and policy.

## CLINICAL ACCELERATION TEAM AWARDS (CATA)



**Figure 2.** Progression of Pre-CATA and CATA.

The general principles guiding the CTP theme include:

- Studies are in line with OICR's 2021-2026 Strategic Plan, with a focus on primary diagnosed and early recurrent cancer, improving detection and interventions;
- Research has a clear path to clinical impact:
  - Pre-CATA: Path to a prospective clinical trial.
  - CATA: Path to downstream clinical impact (towards larger trials, with possible adoption by the health system).
- Studies are collaborative, multi-centre, and where possible, are connected to, and leverage OICR's programs, networks and resources;
- Clinical trials are in line with OICR's **Clinical Trial Timeline Targets**.
  - In an effort to ensure that OICR supported trials initiate and complete patient accrual in a timely fashion, benchmarks for OICR supported clinical trials have been developed:
    - *Site activation*: 180 days after funding start, with ethics approval received and site open to accrual; and
    - *First patient accrued*: 60 days after first site activation.
- Studies embrace the principles of:
  - **Patient partnership** in OICR-supported research in order to:
    - Ensure studies meet the needs of the people intended to benefit;
    - Benefit from the integration of patient perspective;
    - Provide insight into how study protocols affect intended participants, removing barriers and reducing burdens, which can improve patient quality of life and help trials meet accrual projections; and
    - Ensure study activities and results are communicated in an accessible way to patients, caregivers and the wider community.
  - **Equality, diversity and inclusion (EDI)** in OICR-supported research in order to:
    - Ensure research serves cancer patients from all communities, in particular those that are historically underrepresented;
    - Foster a more diverse and inclusive research community; and
    - Create an environment where all can thrive and feel included.
- Whenever possible, studies share data arising from CTP funded projects.

## 2. REQUEST FOR APPLICATIONS

This request for applications is specific for investigators wishing to apply for funding support for a **CATA trial**.

***Separate RFAs are available for investigators seeking funding support for a Pre-CATA project (competition currently open on ReportNet), WOO trial (competition currently open; contact the Director, Clinical Translation for additional information) or a Convergence project (no current competition as of yet; launch date to be confirmed).***

**Key CATA elements include the following:**

- Alignment with CTP principles above;
- Driven by an unmet medical need, relevant for Ontario cancer patients;
- Trials are focused on clinical validation of biomarkers, diagnostics, or therapeutics with a clear path to implementation into the health system;
- Trials are focused in early stage disease, including:
  - *Primary-diagnosed disease*: Treatment naive stage I-III, amenable to definitive therapy and correlative sample collection;
  - *Early recurrent disease*: Locoregional and oligometastatic recurrence, eligible for first line therapies (systemic, surgical or ablative therapies).

**Studies that are **in-scope** include:**

- Clinical validation studies (prospective trials) for:
  - Biomarkers ('omic', liquid, imaging) for early cancer detection, diagnosis, improved risk stratification, prediction to treatment response, and improved monitoring; and
  - Interventions:
    - Therapeutics that intercept, or halt, early cancer progression and early recurrence;
    - Modifications/improvements to standard of care.

**Examples of applicable CATA studies may include, but are not limited to clinical trials testing/validating:**

- Novel therapies (e.g. immunotherapy) with deep biomarker focus;
- Therapies in the neoadjuvant setting;
- Novel combination therapies (e.g. targeted and immunotherapies);
- Improved radiotherapy strategies; and
- Biomarkers, diagnostics or theranostics for improved patient selection, decision making, and improved patient care.

**Studies that are **out-of-scope** include:**

- Phase III and IV studies;
- Observational studies where the main objective is to collect samples from ongoing clinical trials in order to develop annotated bio-specimen repositories for later interrogation; and
- Studies with limited correlative biomarker analysis.

### 2.1 Eligibility

Applicants are eligible to submit a single CATA application as the Principal Investigator (PI) or Co-Principal Investigator (Co-PI). PI/Co-PIs may participate on separate CATA applications as Co-Investigators or Collaborators.



OICR is focused on developing and supporting the next generation of cancer researchers, and strongly encourages applicants to include early career investigators/clinicians as part of the study team.

## 2.2 Term

The start date for funded CATA application is October 1, 2021. The award term is up to **three (3) years**.

## 2.3 Funding available

CATA applications can request up to **\$500,000 per year, inclusive of any eligible overhead** (as per Appendix I), for up to three (3) years. OICR anticipates supporting up to eight CATA trials.

## 2.4 Eligible expenses

Appendix I outlines OICR's guidelines for eligible expenses. It is anticipated that the budget for activities in the first year will be significantly lower than that of other years due to the focus on trial start-up. All study start-up activities will need to be fully justified.

In situations where investigators have leveraged resources of, or a partnership with, existing clinical trial groups or organizations to ensure feasibility of aligning with the OICR Clinical Trial Timeline Targets (see Section 1.3 above), budget line items must be fully justified.

**Funding is contingent upon available funding from the Government of Ontario via the Ministry of Colleges and Universities.**

## 2.5 Deadlines

Notice of Intent submission*:	No later than May 17, 2021
Letter of Intent (LOI) deadline:	May 17, 2021 by 5 p.m. EDT
LOI results communicated:	Week of June 14, 2021
Full application deadline:	August 12, 2021 by 5 p.m. EDT
Notification of results:	End of September 2021

*\*The NOI form must be submitted prior to receiving access to the LOI and will be used for competition planning purposes. Information collected at the NOI stage is **editable** at the LOI stage.*

**Late submissions will not be accepted.**

## 2.6 Application requirements

CATA applications are a three-step process, including a Notice of Intent (NOI), Letter of Intent (LOI), and a full application.

## 2.7 Overview of application requirements using the online submission system

NOIs, LOIs, and full applications are to be submitted online, using OICR's Grant Management System, ReportNet. Potential applicants can view OICR funding opportunities, including this CATA RFA, in ReportNet, by registering for an account. To register, visit <https://oicr.factorial.ca/s/Login.jsp>. Existing ReportNet users should contact the OICR Scientific Secretariat to update their user profile to provide access to the funding opportunities. Once an account has been created, applicants can log into their account to view OICR funding opportunities and the associated RFAs (at the bottom of the screen under 'Funding Opportunities'). Competitions which are currently accepting applications will have a green 'Apply Now' button. Use the 'Apply Now' button to initiate an application.



Applicants and all team members are invited to complete their profiles, including the section on Demographics, within ReportNet to assist the Institute with metric reporting. The OICR Scientific Secretariat is available to help with any questions regarding the online process.

The information below provides an overview of the various sections that make up a CATA application.

## 2.8 Completing a Notice of Intent

The Notice of Intent (NOI) collects basic application information and will be used by OICR for planning purposes. An NOI must be submitted prior to gaining access to the full Letter of Intent (LOI) form. The information provided in the NOI can be updated prior to submitting the LOI. The deadline for submission of the NOI is the same as the deadline for LOI submission, however, applicants are encouraged to submit their NOI as early as possible to assist with planning.

### Application Information

#### *Administrative*

The system will pre-populate the PI's information from their ReportNet user profile. Additional information, outlined below, is to be provided by the applicant(s). Required fields are marked with a red asterisk in the system. Word counts, where applicable, are noted.

- **Title**
  - Once a title for the application has been provided, use the Save Draft button at the bottom of the screen to activate the 'Invite Contacts' function (see below).
- **Invite contacts**
  - Co-PIs, Co-Investigators, Collaborators, and PI Delegate(s) can be added using the 'Invite Contacts' button

**Principal Investigator (PI):** has responsibility for the intellectual direction of the study, the technical and scientific content of the study, the budget and deliverables and milestones of the study, and supervision of members of the research team carrying out the study. If there is more than one PI, the Lead PI (PI) is the individual who initiates the application and should be the PI affiliated with the sponsoring/lead site (host institution). *Co-PIs* can be added subsequently. The PI can submit the application once complete.

**Co-Investigator:** carries out research/clinical activities related to the study. Co-Investigators are not able to submit the application on behalf of the PI(s).

**Collaborator:** is an individual whose role in the proposed activities is to provide specific expertise or access to resources (e.g., access to equipment, reagents, specialized knowledge including techniques and statistical analysis, access to patient populations, patient partners, etc.). Collaborators are not able to submit the application on behalf of the PI(s).

**PI Delegate:** provides an administrative role that can assume the duties of the PI, including editing and submitting the application on behalf of the PI(s).

- Note: **First**, provide a **title**, and then hit '**Save Draft**' in order for the 'Invite Contacts' button to appear;
- All PIs/Co-PIs, Co-Investigators, and/or Collaborators involved in the application **must** be invited;
- Note: Invited contacts will receive an email to join the application. Please advise them to check their junk/spam folders if they do not receive the invitation within 30 minutes. While



not *mandatory*, we encourage all investigators to accept the invitation and complete their profile in the system.

- **Funding start date:** October 1, 2021;
- **Funding end date:** No later than September 30, 2024 and can be earlier depending on the duration of the trial;
- **Application type:** This section lists all possible application types for the Clinical Translation Pathway Theme. Please select '**CATA**'. Only CATA applications will be adjudicated under this RFA;
- **Key words (max. 50 words):** Note that key words may be used for reviewer assignment purposes;
- **Cancer type:** If the cancer type(s) is non-specific, select 'All' at the top of the list. If there is more than one cancer type, select, 'Multiple' at the bottom of the list. If the cancer type(s) is not listed, select 'Other' at the bottom of the list;
- **Lay summary (max. 250 words):** Provide a lay summary, using simple, easy to understand non-technical language of the application. This summary may be shared with external parties for communications and reporting purposes, and with reviewers to identify expertise and potential conflicts of interest.

## 2.9 Completing a Letter of Intent (LOI)

Information provided in the NOI will be carried over to the LOI form and is editable.

### LOI proposal (max. 1500 words):

- Describe the rationale and background, outlining the clinical need/question that is being addressed;
- Provide a brief summary of current knowledge relative to the proposed study. Outline how the study adds to the clinical knowledge;
- Provide a brief study synopsis that addresses:
  - Study phase and design: schema as an attachment (see below);
  - Objectives and endpoints;
  - Patient population;
  - Projected sample size and accrual rate;
  - Study timelines including projected ethics approval, study activation, first/last patient, analysis, and study end. Include details in figure/table format as an attachment (see below); and
  - Trial feasibility:
    - How the study will meet the clinical trial timeline of 180 days for site activation;
    - Include information on drug access/availability from pharma. Outline discussions had with pharma.
- Ensure the proposal addresses:
  - Fit: Define how the study is aligned with both the CTP principles and the CATA elements defined above; and
  - Impact: Clearly articulate the path to clinical implementation and how the study can impact cancer patient treatment/management.

### Attachments

The following items should be attached to the application:

- Figures and tables (LOI), in PDF format. Figures and tables can be used to outline study schema, study timeline, and feasibility details (e.g. patient accrual metrics at lead and participating sites); and
- References (LOI), in PDF format.

## 2.10 Completing a full application

Information provided in the NOI and LOI stage will be carried over to the full application form and, with the exception of the *LOI proposal* section, will be editable.

- **Common Scientific Outline:** The applicant must select a primary classification for the research. Secondary and tertiary classifications may also be selected if applicable but **are not required**. CSO codes should reflect the main aim of the research program that is achievable within the lifetime of the award. Coding should NOT include potential or future applications of the research findings. Information on selecting an appropriate code can be found in the [International Cancer Research Partnership \(ICRP\) Coding Guidelines](#).
- **Administrative authority of PI's Host Institution:** Information will be collected for the PI and any Co-PIs.
- **Does this application include a clinical trial?** CATA applications must select 'Yes' and describe the clinical trial as part of the application process.
- **Regulatory requirements:** When applicable, certification requirements may be used in the process of developing funding agreements, should the application be approved for funding. Certificate numbers are not required but are encouraged, if available, for projects being conducted on OICR premises.
- **Equity, Diversity, and Inclusion (EDI) considerations:** Outline how the study will align itself to the principles of EDI outlined in Section 1.3 above, both within the study team and trial participants. Describe how the study will aim to accrue a diverse patient population (where appropriate), including participants from historically underrepresented populations. EDI considerations will be discussed for each application and included in the overall score/recommendation. Feedback on the proposed approach and opportunities for improvement may be provided to applicants.

Several excellent EDI resources have been developed that are available, free of charge, for training and information purposes. OICR requires that teams complete, at a minimum, the CIHR Sex and Gender Training Modules (<https://www.cihr-irsc-igh-isfh.ca/>) in advance of submitting their application.

Among others, OICR supports the EDI resources that have been made available by CIHR (<https://cihr-irsc.gc.ca/e/51709.html>). These resources address many topics, including:

- EDI in research design and practices;
- EDI in the research environment; and
- EDI and research excellence.

Additional resources on including sex and gender in research can be found at: <https://cihr-irsc.gc.ca/e/50836.html>.

### *Research proposal*

- **Scientific summary (max. 500 words).**
- **Lay summary (max. 250 words):** This will be copied over from the LOI submission. *Only edit the summary if substantive updates are necessary.*
- **Proposal (max. 6000 words):** Provide a clinical study proposal, including the information below. Include the listed headings:
  - **Background and rationale (suggested length: 1000 words):** Describe the background and rationale (clinical need/question being addressed) of the study that is based on previously well-designed preclinical and/or clinical research. Provide a brief summary of current knowledge relative to the proposed study. Outline how the study adds to the clinical

knowledge. Describe the study's alignment with OICR and the CATA scope. Clearly outline the clinical impact for cancer patients.

- *Correlative biomarker investigations (suggested length: 300 words)*: Outline the planned biomarker analyses and their significance to the study. Where applicable, describe the expertise and capabilities required for sample collection and biomarker analysis, including OICR's Collaborative Research Resources. For additional information, visit: <https://oicr.on.ca/collaborative-research-resources>.
- *Study synopsis (suggested length: 700 words)*: Provide a brief study synopsis which includes study phase and design, objectives, endpoints (primary, secondary), patient population, main inclusion criteria, and sample size.
- *Statistical analysis plan (suggested length: 300 words)*: Outline the principal features of the eventual statistical analysis of the study data.
- *Team details (suggested length 500 words)*: Identify leadership at lead site and participating sites. Include information on experience of the lead Investigator and clinical teams as they relate to the study.
- *Study initiation and management (suggested length: 1000 words)*:
  - Outline the role of involved teams (lead site, participating sites) with regard to study initiation and management. Describe existing available resources and how they will be used to ensure timely success of the study. Letters of support from committed co-investigators at participating sites must be included as an uploaded document. Letters must attest to the review and approval of the study protocol;
  - Describe the plans to standardize, assure quality of, and monitor adherence to, the clinical protocol and data collection;
  - Describe procedures for data management and data quality control at participating clinical sites;
  - Outline methods for safety monitoring;
  - Describe the communication plans to ensure trial success;
  - Describe the plan to complete data analysis within the proposed period of the award; and
  - Identify potential barriers to trial success and describe possible mitigation plans.

Applicants may wish to refer to resources for best practices or case studies on clinical trials, such as those provided by the Canadian Cancer Clinical Trial Network (<https://3ctn.ca/>) or the Clinical Trials Transformation Initiative (<https://www.ctti-clinicaltrials.org/news/ctti-launches-new-case-study-resource-help-drive-better-more-efficient-clinical-trials>).
- *Recruitment plan (suggested length: 500 words)*: outline the planned monthly patient recruitment rate and demonstrate that the eligible population of patients is available at the participating institutions. Where applicable, describe any competing studies and how they will be managed to ensure success of the current study. Include a description of how the first patient will be accrued within OICR's Clinical Trial Timeline target. Include go-no go decision points for opening additional study sites to ensure patient accrual and timelines are met.
- *Accrual strategy (suggested length: 500 words)*: outline an accrual strategy for patient engagement and retention that will support the recruitment plan. Outline any potential barriers to enrollment and how they would be addressed.
- *Patient partnership (suggested length: 500 words)*: integrating patient perspectives and insight can be transformative to research planning and execution. Provide a patient partnership plan outlining how the study will work to align itself to patient partnership principles outlined in Section 1.3 above. Describe how the study will aim to engage patients at the various stages of trial development and implementation.
  - Patient partnership plan should highlight:

- Information about the patient partner(s) and/or communities that will be engaged (e.g. individual patient partners, caregivers, patient organizations, etc.);
- Role and responsibilities of the patient partner(s) in the study team: Activities can include, but are not limited to, supporting i) protocol design (e.g. potential challenges of protocol design to participating patients, review of all patient-facing materials such as consent forms, accrual strategy, etc.), ii) clinical trial execution (e.g. identifying solutions to potential patient barriers, developing plans to reach patient communities), iii) results reporting (e.g. developing plain language communication material).
- Applicants may wish to refer to resources for best practices in involving patients and the public in research, such as those provided by the Canadian Cancer Clinical Trials Network (<https://3ctn.ca/for-researchers/patient-public-involvement/>) or the Clinical Trials Transformation Initiative (<https://www.ctti-clinicaltrials.org/>).
- Applicants may request assistance on developing patient partnership plans and/or connecting with and recruiting patient partners. Applicants may contact Justin Noble, Patient Partnerships and New Initiatives Lead, at [justin.noble@oicr.on.ca](mailto:justin.noble@oicr.on.ca).
- Successful applicants can work with OICR to refine plans based on recommendations.
- *Study drug plan (suggested length: 100 words)*: detail evidence of access to investigational agent including information of commitment from pharma. This must be reinforced through a Letter of Support from the pharma partner including details of drug access and availability timeline. Include information about drug storage, labelling, and disbursement.
- *Funding (suggested length: 100 words)*: Outline if the trial will be funded entirely by OICR or if co-funded by a partnership. Provide evidence of co-funding through a letter of support, which is to be included as an uploaded document.
- *Path to clinical impact (suggested length: 500 words)*:
  - Outline short (less than five years), medium (five to ten years), and long-term (beyond 10 years) impact;
  - Path to future trials: explain the study's "path to clinical impact" through future, larger clinical trials. Identify prospective partners or granting agencies for leveraged funds;
  - Path to health system adoption: outline the path for how the results of the study can be adopted into Ontario's health system;
  - If applicable, a commercialization plan should be developed in consultation with FACIT Inc., OICR's commercialization partner, and technology transfer offices at relevant institutions to ensure it is consistent with OICR's "Ontario First Policy" (Appendix II). The Ontario First policy requires that reasonable efforts are undertaken to commercialize and manufacture arising intellectual property in Ontario and applicants will contractually agree to consult FACIT Inc. to finalize the commercialization planning, rights and obligations, with an emphasis on Ontario-based development.
- **LOI proposal**: This will be copied over from the LOI submission and is not editable.
- **Data management plan (max. 500 words)**: Applicants must provide a data storage requirements and retention plan, specifying how much data will be generated or transferred into OICR during the course of the trial (as applicable), and the plan for retaining/archiving with the ability to restore the data for the 5-year period following its conclusion. See Appendix III for additional information;
- **Differentiation (max. 250 words)**: Provide a description on what makes this research unique, better and/or disruptive compared to what other researchers are working on in your field (i.e., what is distinguishing about this research that makes it more attractive than other existing or ongoing work by other researchers). Note, this information may be shared with FACIT Inc., should the application be funded.

### Attachments

The following items should be attached to the application:

- Figures and tables, in PDF format
- References, in PDF format
- Deliverables and Milestones (D/Ms), using the provided template, in Excel format.
  - D/Ms must include, but are not limited to:
    - Final protocol completion and approval;
    - Ethics submission and approval;
    - Study activation (at lead and partnering sites);
    - First patient accrued (at lead and partnering sites);
    - Interim analysis (if applicable);
    - Data Safety Monitoring Board meetings;
    - Last patient accrued (at lead and participating sites);
    - Study lock; and
    - Data analysis.
  - *OICR's Clinical Trial Timeline Targets* must be considered when developing proposals and associated deliverable and milestone documents, which will be used by CT staff to track clinical trial timelines and progress. In situations where trials are not progressing towards achievement of deliverable or accruing on target, as evident by bi-annual Clinical Trial Activity Reports and associated D/M updates, the study lead will be expected to meet with CT leadership and outline a plan to ensure study success. If the study continues to encounter issues, OICR can consider closing the study;
    - Applicants are encouraged to visit the Ontario Cancer Research Ethics Board website <https://ocreb.ca/> to understand and prepare for ethics submission requirements and timelines.
  - Where possible, include milestones that specify go/no go decision points;
  - Both deliverables and milestones must be measurable and possess a target date for completion (provide the quarter and fiscal year of projected achievement). These deliverables and milestones will be used to measure research progress.
- Budget
  - Download the budget template provided in the application, complete budget request details (see Appendix I for eligible expenses) and upload the completed budget in Excel format;
  - The total budget, inclusive of overhead for eligible expenses, should represent the OICR contribution. Additional contributions committed from other funding sources or collaborators should be included as co-funding (section provided at the end of the Excel template);
  - Line item descriptions must be brief and **unique\***. The justification should provide a high-level explanation of why the expenses are necessary and how they are calculated;
  - If you need to update your budget after it has been uploaded to the system, please contact the OICR Scientific Secretariat for assistance;
  - The template will automatically calculate overhead at 30 per cent for non-MaRS based institutions. The overhead rate can be adjusted on the 'info and instructions' tab. Please contact the OICR Scientific Secretariat with any questions regarding overhead.  
*\* Line item descriptions must be unique from one another for recognition by the system. If descriptions must be the same, please use a unique identifier/character at the end (1,2,\*,^, etc.)*
- Other
  - *Budget justification*: Provide a high-level justification of the budget requested.
    - The document must outline total costs per expense category. It should summarize the total budget per year;

- The document must highlight all current and pending funding applications, highlighting any overlap with the present application. If applicable, a robust plan must be included for attracting future partners during the funding period.
- *Co-funding letters*: If applicable, provide evidence of co-funding through a letter of support from the funder. Include whether funds are cash vs. in-kind, and whether they are secured vs. expected. Co-funding should also be captured in the Excel budget upload.
- *Curricula Vitae (CVs)*:
  - Compile CVs for the following individuals and submit as a single bookmarked PDF:
    - Principal Investigator and Co-Principal Investigators; and
    - Co-Investigators.
  - CVs can be in any format so long as it addresses education/training, employment, honours and awards, professional affiliations, research funding in the past five years, student/fellow training, and research outputs (e.g., publications, IP, presentations).
- *Lead Principal Investigator's Host Institution commitment letter*
  - A letter from the administrative authority/high-level institutional official (i.e., President or Vice-President, Research) of the Lead Principal Investigator's Host Institution must be submitted;
  - The letter must outline the institutional commitment to facilitate and support the research, assign space and resources, and provide other administrative support for the duration of the proposed research. The letter should describe how the institution maintains accountability for promoting scientific excellence and fiscal responsibility with awarded funds;
  - The letter must declare that the signatories have read and acknowledged OICR's "Ontario First Policy" (Appendix II) and agree to abide by the policy through a funding agreement in the event of a successful application;
  - The letter must declare that the signatories will aim to meet a 45-day turnaround for agreement execution;
  - OICR provides 30 per cent overhead on eligible expenses (Appendix I). If an institution is requesting less overhead, they must confirm this in the commitment letter.
    - Note: Clinical trial expenses are not eligible for overhead.
- *Letters of support*: From i) each site co-investigator involved in the study, confirming their participation and ii) pharma partners, confirming drug supply and leveraged funds (where applicable);
- *Protocol*: Attach a penultimate protocol that has been reviewed and approved by all partner site co-investigators, patient partners and pharma partners (if applicable);
- *Publications*: Upload the top three team publications relating to the study that reviewers should take special note of. Combine all three publications into a single bookmarked, PDF;
- *Study schema*: Provide a diagrammatic representation of the study design, along with corresponding descriptive text; *and*
- *Study timelines*: Provide an overview of study timelines (table or excel format), including, but not limited to, ethics approval, study start-up, first patient accrued, interim analysis (if applicable) and go/no go decision points, last patient accrued, study close, data clean, and analysis.

### 3. REVIEW PROCESS

#### 3.1 LOI review

LOIs will be reviewed by an external review panel which will assess the LOI's fit, clinical impact and feasibility, especially to open the study in line with OICR's Clinical Trial Timeline target. Studies will be reviewed by a primary and secondary reviewer who will provide an overall score and recommendation ('Yes to full application', 'No to full application', or 'Requires discussion'). The review panel will meet to discuss LOIs prior to making a final recommendation.

LOIs that receive a ‘No’ recommendation from both reviewers will be triaged prior to the panel discussion. LOIs that receive a ‘Yes/No’ recommendation or a ‘Discuss’ recommendation will be discussed at the panel meeting. Only applications that are ranked ‘Yes’ by both primary and secondary reviewers, after the panel discussion, will be invited to submit a full application.

LOIs will be ranked based on the average overall score provided by reviewers. If the number and quality of LOIs received far surpasses the number of applications that can reasonably be reviewed at the full application stage, then a cutoff score may also be used to triage applications.

CATA LOIs will be reviewed in parallel with Pre-CATA LOI submissions by the same review panel. The concurrent reviews will allow OICR to ensure that the two programs are diverse, but complementary, and align with OICR’s strategic priorities.

## 3.2 Full application review process

### 3.2.1 Administrative review

An administrative review will be completed by the OICR Scientific Secretariat in order to assess the submission for conformity with these guidelines. Relevant points from the administrative review will be shared with the PI.

### 3.2.2 Review panel

Full applications will be reviewed by a review panel, which will be composed of:

- Clinical Translation – Scientific Advisory Committee (CT-SAC) members; and
- Members with expertise in oncology, biomarker/therapeutic development and clinical validation, and the conduct of clinical trials including statisticians.

CATA applications will be reviewed in parallel with Pre-CATA submissions by the same review panel. The concurrent reviews will allow OICR to ensure that the two programs are diverse, but complimentary, and align with OICR’s strategic priorities.

### 3.2.3 Patient and Family Advisory Council

Full applications will be shared with OICR’s PFAC, who will review application materials and provide written feedback to the review panel in advance of the full application review meeting. As deemed appropriate by the review panel, PFAC feedback may be provided to applicants as part of the Scientific Officer report that will be provided to teams following the review meeting.

### 3.2.4 Reviewer reports

Reviewers will receive applications approximately three (3) weeks before the reviewer report deadline and will be tasked with providing a brief report and preliminary score for their assigned studies using the following criteria:

- Relevance;
- Excellence;
- Potential for impact/path to clinical impact;
- Feasibility; and
- Leadership, team, and collaboration.

Reviewers will also provide an overall score for the application which will reflect the proposal as a whole and is not an average or sum of the scores for the above criteria. The overall score may be used for ranking applications, if deemed appropriate by the review panel Co-Chairs.



Reports will be submitted online using OICR's ReportNet system. Anonymized reviewer reports will be circulated to the review panel in preparation for the review meeting.

### 3.2.5 Preparation teleconference

If deemed appropriate by the Co-Chairs, a teleconference will be organized prior to the review meeting to discuss any questions/feedback which will be provided to applicants ahead of the review meeting. Applicants will need to provide written responses within two (2) business days, which will be circulated to the panel in advance of the meeting. Late responses will not be accepted.

### 3.2.6 Review meeting

A review meeting will be organized and include the review panel, PFAC, and CT-SAC members, and representatives from OICR. For information on evaluation criteria and scoring, see Appendix IV.

Depending on application pressure, and with the approval of the review panel Co-Chairs, applications may be ranked by overall score prior to the review meeting so that only the top applications in contention for funding will be discussed. The review panel will have an opportunity to review the rankings in advance of the meeting, and, if appropriate, revise the order.

The meeting will be moderated by the review panel Co-Chairs with support from OICR's Scientific Secretariat. Co-Chairs will invite the primary reviewer and secondary reviewers to provide their feedback and will oversee a discussion of the application by the review panel. Following open discussion, reviewers will be provided with an opportunity to revise their initial scores and comments and will be asked to provide a final overall score. The panel will then recommend a consensus score by which the application will be ranked. Highly ranked applications, which are deemed meritorious for funding, will be recommended for approval to the CT-SAC by the review panel. Upon receipt of the Pre-CATA and CATA funding recommendations from the review panel Co-Chairs, the CT-SAC will make an overall strategic recommendation across both award types and provide a final funding recommendation to OICR and its Board.

## 4. NOTIFICATION OF DECISION

A meeting report summarizing the review discussion and recommendation will be prepared by a Scientific Officer (SO) and distributed to applicants, along with anonymized reviewer reports, as part of the Notification of Decision (NOD) from OICR.

OICR intends to provide NOD letters to all applicants by the end of September 2021. Applications recommended for funding by the CT SAC will receive a Notice of Award outlining next steps in order to accept the award and establish a funding agreement.

## 5. ESTABLISHMENT OF AGREEMENTS

Following approval of the study, OICR will establish a funding agreement with the Host Institution of the Lead PI. The agreement will cover the general principles regarding the conduct of research activities, eligible research expenses, terms and conditions regarding the disbursement of funds, agreements with third-party funders, financial and progress reporting, PI/Co-PI covenants, intellectual property (IP), commercialization, publications, and communication policies. In addition, OICR will establish a commercialization framework, which will require the recipient and OICR to set up an IP co-management plan, where applicable.

Subsequently, the Host Institution is expected to enter into sub-agreements with other institutions involved in the CATA trial. The OICR agreement with the Host Institution will outline obligations



and conditions that the Host Institution is expected to include in its sub-agreements with other institutions.

## 6. REPORTING REQUIREMENTS

### 6.1 Financial and operational status reporting

The following schedule (Table 1) will be used for financial and operational status reporting. Note that the deadlines indicated are moved to the next business day if they fall on a non-working day. A quarterly reporting template and instructions will be available on the OICR online financial reporting system, CaAwardNet.

Financial Officers of the Lead Institution will be required to provide quarterly updates on budget versus actual expenditures as per the table below. When reporting on the operational status of a trial, an explanation of variances of greater than  $\pm 15$  per cent and mitigation plans to address the budget gaps should be provided.

**Table 1: Financial and operational status reporting**

Period covered	Responsible party and action	
	Financial Officer	PI at Lead Institution (or designate)
Q1 Apr-Jun	Quarterly financial report: <i>Due July 31</i>	Review and submit quarterly financial and operational status report: <i>Due Aug. 15</i>
Q2 Jul-Sep	Quarterly financial report: <i>Due October 31</i>	Review and submit quarterly financial and operational status report: <i>Due Nov. 15</i>
Q3 Oct-Dec	Quarterly financial report: <i>Due January 31</i>	Review and submit quarterly financial operational status report: <i>Due Feb. 15</i>
Q4 Jan-Mar	Quarterly financial report: <i>Due April 30</i>	Review and submit quarterly financial operational status report: <i>Due May 15</i>
Q1-Q4 Apr-Mar	Annual fiscal year financial report: <i>Due May 31</i>	N/A

### 6.2 Progress/Key Performance Indicator (KPI) Reporting

All trials will be included in the reporting process as required by the Government of Ontario according to the schedule below (Table 2). Note that the deadlines indicated are moved to the next business day if they fall on a non-working day.

**Table 2: Progress/KPI Reporting**

Period covered	PI at Lead Institution (or designate)
Q1-Q2 Apr-Sep	Provide status updates on D/Ms, study timelines, patient accrual, etc. to CT leadership: <i>Due November 15</i>
Q3-Q4 Oct-Mar	Provide status updates on D/Ms, study timelines, patient accrual, etc. to CT leadership: <i>Due May 15</i>
Q1-Q4 Apr-Mar	Provide quantitative KPIs using ReportNet (OICR's online KPI reporting system): <i>Due April 30</i>

### 6.3 Communication with OICR

The obligations of the investigators to advise OICR of anticipated public dissemination, publications, and media announcements will be outlined in the research agreement.



## **7. ACKNOWLEDGEMENT AND RECOGNITION OF SUPPORT**

All investigators and the recipient institutions must acknowledge and credit the contribution/support, in whole or part, of OICR and the Government of Ontario to the trial in any promotional material, including, without limitation, scientific publications of whatever nature or kind, and in any communication materials or publications supported by OICR funding by referencing the trial with 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.”

## **8. CONTACT INFORMATION**

Email: [scientificsecretariat@oicr.on.ca](mailto:scientificsecretariat@oicr.on.ca).

## 9. APPENDIX I: ELIGIBLE EXPENSES

Eligible expenses are actual expenses necessary for the completion of the approved Deliverables, subject to the terms and conditions of the Agreement and the guidelines in this Schedule, and subject to review and approval by OICR. Unspent funds must be returned to OICR upon request by OICR. It is expected that the Recipient will withhold payment of expenses should it become known that any OICR, institutional, provincial, and/or federal regulations and/or policies have been breached.

Funding for the Projects/Sub-Projects is provided by the Government of Ontario through the Ministry of Colleges and Universities. **Awarded funds will be solely disbursed to and administered by Eligible Institutions in Ontario. Further, with the exception of budget items classified as external research services, eligible expenses may only be incurred in the province of Ontario.** Allocation of funds to institutions outside of Ontario is allowable only when the studies outlined cannot be performed in whole at eligible Ontario institutions. Justification for such an allowance must be provided to and approved by OICR in advance of the investigator utilizing OICR funds for such a purpose.

Expenditures are actual outlays that can be documented through invoices or receipts. Expenses must support and be essential to carry out the activities described in the approved proposal for funding. Evidence of payment must be maintained for audit purposes.

In-kind expenses may include the contribution of goods, services, labour, fixed assets, or other such items that would otherwise have been provided and paid for in order to carry out the Projects/Sub-Projects. In-kind expenses are not reimbursable.

Eligible expenses are described in the categories below. Expenses of the Projects/Sub-Projects, which are not described in the categories below, require written approval by OICR. Pre-award budget questions should be submitted to the OICR Scientific Secretariat at [ScientificSecretariat@oicr.on.ca](mailto:ScientificSecretariat@oicr.on.ca). Post-award budget questions should be addressed to OICR Research Operations at [ResearchOps@oicr.on.ca](mailto:ResearchOps@oicr.on.ca).

Table 3 outlines eligible expense categories and specifies which are eligible for overhead.

**Table 3: Eligible expenses**

Expense category	Eligible for overhead?
Salaries and benefits	Yes
Laboratory consumables (wet or dry lab)	Yes
External research services	No
Internal charge-back for laboratory services	No
Equipment, information technology (IT) support services and software	No
Dissemination of research results	No
Educational outreach activities	No
Hospitality	No
Training and professional development	No
Travel	No
Commercialization activities	No
Audit costs	No
General office and administrative costs	No
Clinical/health intervention trial costs	No
<b>NOTE: All expenses incurred at OICR are NOT eligible for overhead</b>	

Expense category	Eligible for overhead?
<p><b>NOTE: Overhead is <i>NOT</i> provided for personnel awards, including the <i>OICR Investigator Award Program</i></b></p>	

### Direct research expenses

**Stipends, salaries and benefits:** Eligible expenses include the stipends or salaries and benefits for those staff responsible for supporting the conduct of the funded proposal, including research assistants and associates, technicians, statisticians, informaticians, support staff, postdoctoral fellows, students, project and program managers, study coordinators, and other highly qualified personnel. Applicable stipend levels for students are those used by the institution in which the research will be carried out. While benefits for postdoctoral fellows, research assistants, technicians, and support staff are eligible, stipends and student training awards are not to include allowances for CPP, Employment Insurance, health taxes, or any extra fringe benefits.

The eligible cost of salaries and benefits should be calculated using the employee's actual base salary amount, plus actual payroll benefits (vacation, medical, dental, etc.). The amount to be charged should reflect the proportion of the employee's normal total hours for payroll purposes spent working directly on the Projects/Sub-Projects. The host institution is required to maintain time sheets or other appropriate records for all personnel working directly on the Projects/Sub-Projects.

Staff and trainee hiring should align with the Equity, Diversity, and Inclusion (EDI) principles of the host institution and, when requested, meet the criteria outlined in the Request for Applications (RFA).

Provision of salary increases should reflect applicable host institution guidelines.

Discretionary severance and separation packages are not eligible expenses.

Funds cannot be used to cover the salaries of applicants, including Principal Investigators and Co-Investigators. The exception being the ***OICR Investigator Awards Program***, where the salary of the Principal Investigator is an Eligible Expense. The OICR Investigator Awards Program does **not** provide overhead.

Salaries and benefits **are eligible** for overhead.

**Laboratory consumables:** Expenditures are permitted on the actual cost of research materials, laboratory materials and supplies necessary for the Projects/Sub-Projects. Procurement should be in accordance with the policies of the host institution and occur in a commercially reasonable manner in order to achieve value for money.

Costs related to animal expenses are only eligible as a laboratory consumable in cases where the institution does not operate an internal facility that provides animal purchasing and husbandry, and the lab maintains the animals themselves. Costs related to animals housed and cared for in institutional or other facilities should be classified as an external research service or internal charge-back, as appropriate (see below).

Laboratory consumables **are eligible** for overhead.

**External research services:** Contracted services related to the Projects/Sub-Projects provided and invoiced by other research groups, platforms or companies are eligible. To be eligible, fees for use of services or equipment must be consistent with fees charged to all institutional users in

accordance with a published schedule. The service provider will issue an itemized purchase order/invoice that will include the full cost of the services rendered (e.g., labour, consumables, sample handling, etc.). The services must be free from any intellectual property (IP) restrictions or restrictions on use of data. Service providers do not need to be located in Ontario, but whenever possible, Ontario-based service providers, with the capability to provide the required capacity, quality, timeliness, and value of the service, should be selected.

External research services **are not eligible** for overhead.

**Internal charge-back:** Funds for laboratory and/or technical services provided within an institution.

Internal charge-back amounts **are not eligible** for overhead.

**Equipment, information technology (IT) support services, data retention, and software:** Eligible expenses include research equipment and components, IT support services, data retention, software, and licenses required for the Projects/Sub-Projects (beyond what is typically provided by the host institution), as listed in the Application, and agreed upon with OICR. Data retention charges are capped at five per cent of the direct, annual award value and are eligible over the term of the award only. Requests in excess of five per cent may be considered with appropriate justification. The plan for data retention over the term, and beyond (as required by the specific RFA) must be detailed within the application. Costs for equipment maintenance and service contracts, training of staff operating equipment/software, travel costs to visit manufacturers to select major equipment purchases, transportation costs for purchased equipment, and extended warranty for equipment are eligible. Since the approved budget may reflect changes from the Application, these should be confirmed with the Senior Director, Research Operations. Procurement must be in accordance with the policies of the host institution and should occur in a commercially reasonable manner to achieve value for money. Note that equipment costs exceeding \$25,000 per item require appropriate justification and prior approval from the OICR President and Scientific Director and/or Deputy Director.

Equipment purchased with OICR funding will belong to the host institution. The host institution is responsible for the proper functioning and maintenance of research equipment purchased using OICR funds. Final disposition of research equipment will be the responsibility of the host institution. However, no OICR-purchased equipment should be sold within five (5) years of its acquisition without written approval from the OICR President and Scientific Director and/or Deputy Director.

Should the equipment no longer be required during the funding period, OICR reserves the right to relocate it at OICR's expense.

Equipment, IT support services, data retention, and software **are not eligible** for overhead.

**Dissemination of research results:** Expenses associated with the dissemination of research results and/or knowledge translation strategies, including publication costs directly related to the funded proposal, as well as costs to ensure open access of research results (up to a maximum of \$10,000 per year, or five per cent of the overall budget (excluding overhead) per year, whichever is less), are eligible.

Dissemination of research results costs **are not eligible** for overhead.

**Educational outreach activities:** Expenses associated with educational outreach activities/workshops for the general public, students, stakeholders, and peer groups are eligible.

Educational outreach activities costs **are not eligible** for overhead.

**Hospitality:** When directly related to the funded Projects/Sub-Projects, hospitality costs (non-alcoholic beverages and meals) for the purpose of essential communications between the awardee and other individuals involved in the Projects/Sub-Projects, are eligible. The purchase of alcohol and entertainment is not eligible.

Hospitality costs **are not eligible** for overhead.

**Training and professional development:** Expenses for scientific staff training and/or professional development (e.g., novel techniques, specialized courses and membership fees in professional associations or scientific societies) related to the execution of the Projects/Sub-Projects are eligible. Training and professional development must be carried out in accordance with the host institution's policies.

Training and professional development costs **are not eligible** for overhead.

**Travel costs:** Expenses for Project/Sub-Project-related travel (including accommodation) are eligible and are capped at five per cent of direct research expenses per year. Travel must always be by the most practical and economical method. When air or rail are the most practical and economical methods, only the cost of an economy class seat will be reimbursed by OICR funds, and the Recipient must maintain appropriate records of travel expenses and their purpose.

Travel costs are not limited to travel within Ontario.

Travel costs **are not eligible** for overhead.

**Commercialization activities:** Expenses related to intellectual property protection are eligible. Costs for securing external expertise for the preparation of a commercialization plan or for patent filings are capped at \$10,000 per Project/Sub-Project (\$5,000 if it is part of a contract with another academic institution, a business development office, a private consultant, or equivalent).

Commercialization activities **are not eligible** for overhead.

**Audit costs:** The Ontario Government can audit OICR and any of its funded programs at any time during the award, with a forty-eight (48) hour advance notice and at the expense of the Government of Ontario. OICR may audit the research programs annually and/or at the end of the term.

Recipients of financial contributions may be requested to submit an independent auditor's certificate with their year-end financial report.

Audit costs **are not eligible** for overhead.

**General office and administrative costs:** Expenses directly related to office expenses and communications necessary for the successful completion of the Projects/Sub-Projects are eligible and capped at three per cent of direct research expenses per year.

General office and administrative costs **are not eligible** for overhead.

**Clinical/health intervention trials:** Trial costs fall under two categories:

1. **Fixed costs:** Costs that are necessary to implement the trial regardless of patient recruitment status, which may include, but are not limited to:
  - a. *Trial start-up costs* (e.g., protocol development, investigator meetings, Research Ethics

- Board costs, site initiation costs, etc.);
- b. *Central trial management and site monitoring*; and
  - c. *Data management and statistical support*.
2. **Per-case funding costs:** Costs that are dependent on patient accrual, which include, but are not limited to:
- a. *Study coordinator salary and benefits*;
  - b. *Screening costs*;
  - c. *Patient visit costs*: physical exams, blood test, imaging assessments, etc.;
  - d. *Clinical sample collection and processing*; and
  - e. *Correlative laboratory analyses* (e.g., immune correlates, gene panels, etc.)

Per-case funding costs should not exceed standard Ontario Health Insurance Plan/Canadian Medical Association rates if rates have been published. Details of each type of assessment will be required in the budget justification for per-case funding costs.

Clinical/health intervention trial costs **are not eligible** for overhead.

### Cost recovery

Although cost recovery is a form of revenue, and not an expense, it may be reported as part of the budget to demonstrate that recoveries are part of the plan to cover all true expenses to ensure that the project or program does not exceed the OICR-approved budget.

Cost recovery **is not eligible** for overhead.

### Overhead/indirect costs

Overhead (also known as indirect costs) will be automatically calculated in CaAwardNet, OICR's financial tracking tool. OICR will provide up to 30 per cent with respect to eligible direct research expenses of the approved proposal to cover institutional overhead. The total amount of the OICR award that can be allocated for overhead will be listed in the Agreement.

When changes to funded research activities result in a reallocation of funds between projects/sites or expense categories, the resulting calculations of overhead will require adjustments.

Overhead costs are:

- The facility or infrastructure costs required to perform research, and typically include costs associated with maintaining, renovating, and operating physical facilities (e.g., heating, lighting, maintenance, insurance), project administration costs (e.g., accounting), expenses associated with regulatory requirements and accreditation, and technology transfer offices and support facilities (e.g., libraries and computing facilities); and
- Calculated based on overhead-eligible expense categories as detailed above.

The allowable budget listed in the Request for Applications (RFA), or program guidelines (as applicable) is inclusive of overhead costs. Overhead must be accounted for in the allowable budget.

**NOTE: Overhead is *NOT* provided for projects funded through the OICR Investigator Award Program, consistent with other salary award programs.**

The host institution will not be eligible for reimbursement of overhead costs for the Projects/Sub-Projects from any other Government of Ontario funds.

If an overhead amount of less than 30 percent is requested, this must be detailed in the host institution Letter of Support as part of the proposal submission process.



### Placeholder budget

When eligible as per the RFA/Guidelines, a placeholder budget for future research activities (up to a maximum of 15 per cent of the total budget including overhead costs) will be allowed at the time of submission.

A placeholder budget **is not eligible** for CTP RFAs.

### Non-eligible expenses

The items below are not eligible for OICR funding:

- Salaries and benefits of the PIs, Co-PIs, etc. (with the exception of the Investigator Awards Program which will pay the salary and benefits for the awardee);
- Insurance for equipment;
- Benefits for trainees (i.e., undergraduate and graduate students). Note that benefits for postdoctoral fellows are an allowable cost and should be in accordance with the host institution's policy; and
- Funding for any project where there is significant scientific overlap (e.g., the research objective and design are identical or very closely related) with a project currently funded through other sources.

### Deviation from proposed activities and/or budget

A significant deviation (as assessed by the PI(s) in consultation with the Heads of Adaptive Oncology, Clinical Translation or Therapeutic Innovation) in a project's anticipated deliverables/milestones and/or end date can be the result of significant delays (i.e., more than six months) in recruitment of qualified personnel, regulatory approvals, recruitment of patients, availability of supplies/drugs, or inter-institutional transfer of funds/activities due to enhanced collaborative activities. In such instances, the PI must provide an explanation for the change/delay, and formally request budget amendments/transfers or extensions, providing justification for all changes. Such changes will require a budget and agreement amendment. Any resulting budget amendment should be reported to OICR. Minor variances/shifts can be reported through quarterly reports and may not require changes to contractual obligations.

### Reallocation of budget

Up to 15 per cent of the total budget may be reallocated between previously approved projects without OICR's prior approval.

Reallocation of more than 15 per cent of the total budget will require express written permission of OICR's Deputy Director and relevant Head.

Any resulting changes will require an amendment to the agreement and a corresponding budget amendment.

### Carryover funds and no-cost extensions (NCE)

Budget monitoring must be carried out to ensure that funds allocated for a given fiscal year are utilized, as OICR does not have the ability to allow carryover of funds into the subsequent fiscal year. Host institutions are also strongly encouraged to utilize the funds for the fiscal year for which they are intended.

An NCE may be granted in exceptional cases with prior approval from OICR's Deputy Director or Senior Director, Research Operations. Application for an NCE must be made in writing and supported by appropriate justification.



## 10. APPENDIX II: “ONTARIO FIRST” POLICY

In order to promote the commercialization and public availability of inventions made in Ontario by Ontario industry and, to ensure that Ontario businesses obtain sufficient opportunity to commercialize provincially-supported inventions, the Host Institution agrees that the following options to commercialize the arising intellectual property (IP) will be considered:

- An existing organization in Ontario with receptor capacity;
- An expansion of an existing company in Ontario;
- The formation of a new company in Ontario;
- Joint ventures or strategic alliances with a company in Ontario;
- Co-manufacturing involving a company in Ontario;
- Cross-licensing or co-development with a company in Ontario; establishment of a new subsidiary in Ontario (R&D, manufacturing, sales, marketing, distribution); and
- Development and/or production in Ontario by a foreign company.

If reasonable efforts to grant licenses to potential licensees to commercialize and manufacture the arising IP substantially in Ontario are unsuccessful, then the Host Institution agrees that the Lead will be responsible for documenting the rationale and circumstances that led to any proposed decision or step to pursue commercialization/exploitation by a non-Ontario company, including an account of the benefits to Ontario for review by an IP Commercialization Committee prior to finalizing the decision or step. The documentation will be forwarded to OICR.

## 11. APPENDIX III: DATA RETENSION, SHARING AND OPEN ACCESS

Applicants agree to adhere to the Global Alliance for Genomics and Health's [Framework for Responsible Sharing of Genomic and Health-Related Data](#). The Framework interprets the right of all people to share in the benefits of scientific progress and its applications as being the duty of data producers and users to engage in responsible scientific inquiry and to access and share genomic and health-related data across the translation continuum, from basic research through practical applications. It recognizes the rights of data producers and users to be recognized for their contributions to research, balanced by the rights of those who donate their data. In addition to being founded on the right of all citizens in all countries to the benefits of the advancements of science, and on the right of attribution of scientists, it also reinforces the right of scientific freedom.

Recipients of OICR funding are required to retain original data sets arising from OICR-funded research for a minimum of five (5) years after the end of the research project as defined by the research agreement or Notice of Award. This applies to all data, whether published or not. Applicants must provide a data retention plan, specifying how data generated will be stored during the course of the project and for the 5-year period after its conclusion. If needed, applicants can request funds to support this data retention requirement, however, charges are capped at five (5) per cent of the direct, annual award value and are eligible over the term of the award only. For clarity, data retention costs must be accounted for within the allowable budget and is not in addition to the budget requested to conduct the project.

OICR promotes the GA4GH framework related to the deposition of publication-related data in openly accessible databases. OICR funding recipients are required to deposit bioinformatics, atomic, molecular coordinate data and source code for software into the appropriate public database, as already required by most journals, immediately upon publication of research results (e.g., deposition of nucleic acid sequences into GenBank, and source code into a publicly accessible FTP or web server).

OICR strongly supports unrestricted access to research outputs and aligns with the [Tri-Agency Open Access policy on Publications](#). Funding agreements for successful applicants will include the expectation for adherence to Open Access principles.

## 12. APPENDIX IV: EVALUATION CRITERIA AND SCORING

Applications will be reviewed using the following evaluation criteria:

- Relevance;
- Excellence;
- Potential for impact/path to clinical impact;
- Feasibility; and
- Leadership, team, and collaboration.

Table 4 provides a description of each criterion. The merit of each study will be evaluated against the listed criteria, where applicable.

Table 4: Evaluation criteria
<p><b>Relevance</b></p> <p>The study:</p> <ul style="list-style-type: none"> <li>• Is in line with the OICR's strategic plan, the principles of the Clinical Translation Pathway and elements of the CATA RFA;</li> <li>• Addresses a specific, well-defined, clinical priority/question for early cancer patients and/or the Ontario health care system;</li> <li>• Current state of knowledge relative to the proposed study is included; and</li> <li>• Is driven by a strong hypothesis that rests on sufficient evidence.</li> </ul>
<p><b>Excellence</b></p> <ul style="list-style-type: none"> <li>• Study design is appropriate to answer the question(s) posed, with a cohesive plan that will lead to meaningful results;</li> <li>• The outcomes, and their measures, are clearly described and appropriate to the hypothesis;</li> <li>• Statistical justification is provided to support the hypothesis and study design; and</li> <li>• Potential pitfalls and possible mitigation plans are provided and appropriate.</li> </ul>
<p><b>Impact</b></p> <ul style="list-style-type: none"> <li>• Management and/or treatment of cancer patients will be improved if the study is successful;</li> <li>• The study clearly articulates a clear path to impact, including future larger trials and health system adoption;</li> <li>• The proposed study will have a transformative impact on clinical practice, benefitting Ontario patients, practitioners and/or users of the health care system; and</li> <li>• The EDI and Patient Partnership plan are appropriate to support the impact of the study. The EDI plan takes into consideration how to accrue a diverse patient population, including participants from historically underrepresented populations. The Patient Partnership plan takes into consideration the integration of patient partners so that the study meets the needs of the people intended to benefit.</li> </ul>
<p><b>Feasibility (trial readiness)</b></p> <ul style="list-style-type: none"> <li>• Proposed study is feasible, within the term of the award, with potential for success;</li> <li>• Study team has access to appropriate facilities and resources to ensure study success;</li> <li>• The application provides strong evidence that the study is poised to meet the OICR Clinical Trial Timeline Targets (open to accrual 180 days after award start; first patient 60 days later);</li> <li>• The deliverables and milestones are attainable within the specified timeline. They are appropriately defined to allow the monitoring of progress against goals and objectives. Appropriate Go/no-go decision points are outlined;</li> <li>• The budget is fully justified and appropriate to support the study; and</li> <li>• Although not to be considered when scoring, the Patient Partnership plan is clearly articulated and, as written, can contribute positively to study feasibility.</li> </ul>

**Table 4: Evaluation criteria**

**Leadership, team, and collaboration**

- The team, and its leadership, have the necessary range of disciplines and experience necessary to conduct the study;
- The trial leadership is recognized in the cancer research community and have appropriate qualifications, experience, and record of publications;
- The trial leadership has led or contributed to research that has resulted in improvements in clinical practice;
- The team engages collaboratively with investigators with complementary expertise. There is a strong level of provincial participation, and where appropriately OICR;
- Opportunities for early career investigators/trainees are supported;
- The Patient Partnership plan clearly articulates the role of all integrated patient partners; and
- The approach for alignment with the principles of EDI within the study team is clearly articulated.

Table 5 will be used for scoring.

**Table 5: Scoring**

Score	Descriptor	Additional guidance
4.7-5.0	<b>Excellent with no weaknesses identified</b>	Exceptionally strong with essentially no weaknesses. The trial excels in most or all criteria. Any shortcomings are minimal. Proposed trial has a very high potential for transformative impact on clinical practice and has a very clear path to completion with sufficient funding.
4.2-4.6	<b>Excellent with minor weaknesses identified</b>	Very strong with only some minor weaknesses. The trial excels in many criteria and reasonably addresses all others. Certain improvements are possible. Proposed trial has a high potential for transformative impact on clinical practice and has a clear path to completion with sufficient funding.
3.6-4.1	<b>Very good with minor weaknesses identified</b>	Some strengths but also some weaknesses. The trial excels in some criteria and reasonably addresses all others. Minor revisions are required. Proposed trial has a moderate probability for impact on clinical practice and has a reasonably clear path to completion with sufficient funding.
3.0-3.5	<b>Very good with moderate weaknesses identified</b>	Some strengths but also some moderate weaknesses. The trial excels in some criteria and reasonably addresses all others. Major revisions are required. Proposed trial has a moderate probability for impact on clinical practice and has a reasonably clear path to completion with sufficient funding.
2.4-2.9	<b>Good with moderate weaknesses identified</b>	Some strengths but with at least one major weakness. The trial broadly addresses criteria, but revisions required are too significant to overcome. Proposed trial has a moderate to low probability for impact on clinical practice, and the path to completion is missing or not feasible.
<b>Below 2.4</b>	<b>Unsatisfactory</b>	Very few strengths and numerous major weaknesses. The trial fails to meet most of the criteria and/or has serious inherent flaws or gaps. Proposed trial has a low probability for impact on clinical practice. The proposed trial should not be funded.