
# Pre-Clinical Acceleration Team Awards (Pre-CATA)

# Request for Applications

# Version 1.0

# October 2023

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# 1. INTRODUCTION

## 1.1 Purpose

This Request for Applications (RFA) is intended to guide investigators applying for an OICR Clinical Translation Pathway (CTP) Pre-Clinical Acceleration Team Award (Pre-CATA), which is focused on supporting preclinical projects focused on clinical biomarker and therapeutic development**.**

For more information on OICR and the CTP, including Clinical Acceleration Team Awards (CATA), please visit our website.

## 1.2 Scope

**Key elements of the Pre-CATA funding program include:**

- Studies that:
  - Advance early cancer detection and intervention
  - Are driven by an unmet medical need, relevant for Ontario cancer patients, with a clear path to the clinic and clinical impact
  - Are collaborative, multi-centre, and where possible, are connected to, and leverage OICR's programs, networks and resources
- Research that is focused on early-stage disease, including:
  - Primary-diagnosed disease: Treatment naïve stage I-III, amenable to definitive therapy
  - Early recurrent disease: Locoregional and oligometastatic recurrence, eligible for first line therapies (systemic, surgical or ablative therapies)

**Projects that are in-scope for biomarker development include:**

- All biomarker development projects after biomarker discovery but prior to clinical trials, as outlined in Figure 1.

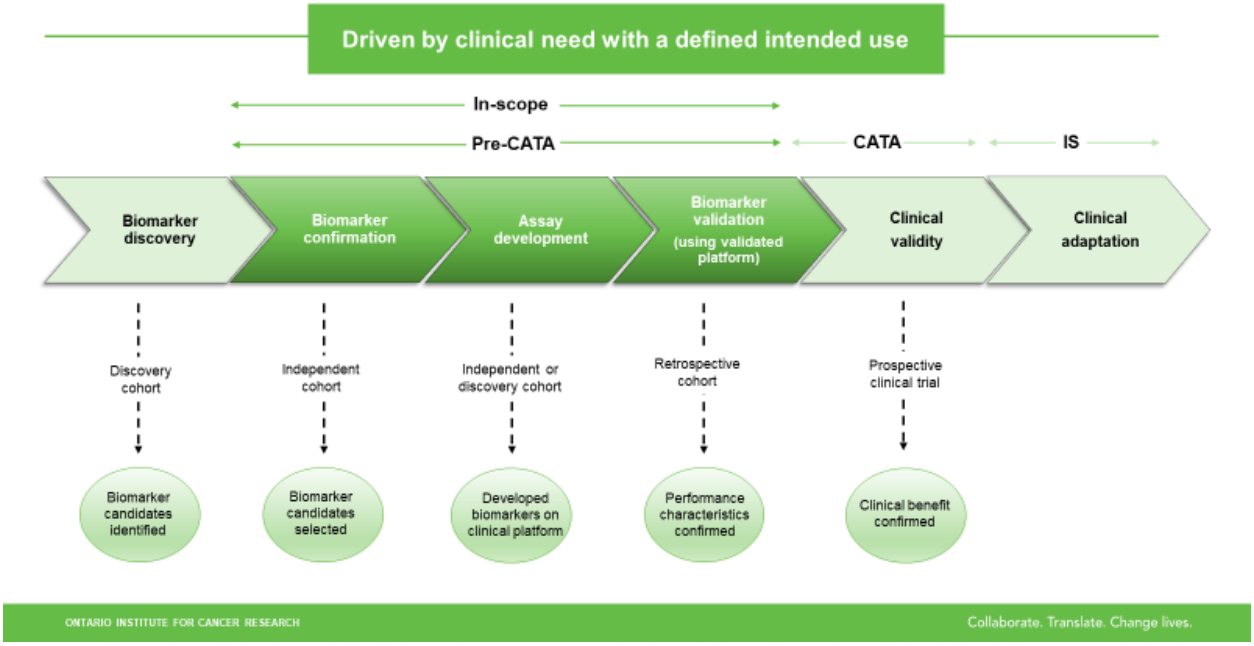


***Figure 1**: Biomarker development phases.*

**Examples of applicable Pre-CATA biomarker development projects may include, but are not limited to:**

- Confirmation of defined biomarkers or biomarker multi-omic signatures using an independent sample cohort from that of the discovery cohort
- Assay development projects to establish analytic metrics for reproducible and clinically relevant measurement of the biomarker:
  - Harmonization projects comparing the analytic parameters of measuring the biomarker(s) on multiple platforms
  - For development of imaging biomarkers, this could include projects for standardizing image processing, acquisition or parameters, or validation of radiomic/machine learning algorithms
- Retrospective biomarker validation projects ('omic', liquid, imaging) for biomarkers for precision oncology (e.g. early cancer detection, diagnosis, prediction of treatment response, improved risk stratification, and improved monitoring)
- Development of defined companion tests to improve clinical management of early-stage cancers with a defined pathway to clinical validation and possible health system adoption.

**Projects that are out-of-scope for biomarker and development include:**

- Discovery projects
- Clinical trials
- Projects for clinical validation and adoption

**Projects that are in-scope for therapeutic development include:**

- Preclinical development of new therapies leading into clinical testing (i.e., preclinical data supporting Phase I-II clinical trials).
  - Therapeutic/pharmacogenomic testing of lead compounds, including theranostic agents destined for the clinic in preclinical animal models and human tumour explants, 3-D cultures or organoids (as part of lead optimization to the clinic)
  - Development of nondrug-based therapeutics including surgical interventions, radiation and other energy modalities, device development for minimally invasive therapeutics and image-guided therapies.

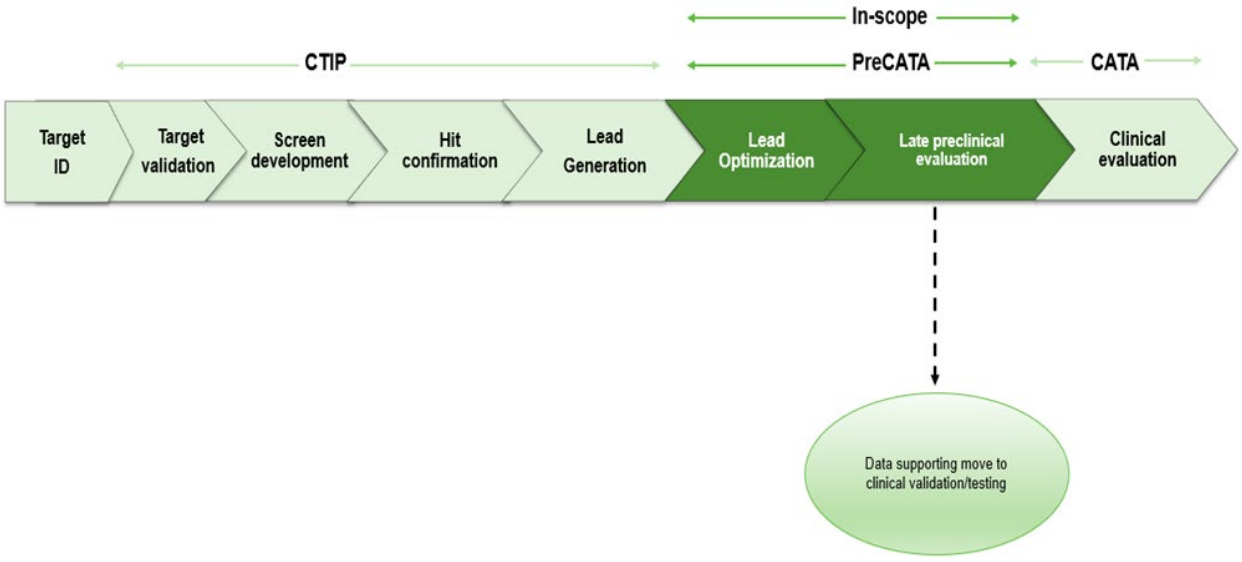


***Figure 2**: Therapeutic development phases.*

**Examples of applicable Pre-CATA therapeutic development projects may include, but are not limited to:**

- Structure Activity Relationship (SAR) strategy from lead optimization to candidate selection
- Use of an existing *in vivo* or *ex vivo* model systems or development of improved model systems to support therapeutic development (including associated biomarkers) prior to clinical testing
- Preclinical assessment of a lead candidate's *in vivo* pharmacokinetics (PK), pharmacodynamics (PD), absorption, distribution, metabolism, excretion (ADME), efficacy and safety
- Device or software prototyping and/or in-phantom validation for pre-clinical development of minimally invasive therapeutics in preparation for clinical trial evaluation.

**Projects that are out-of-scope for therapeutic development include:**

- All drug or theranostic discovery projects prior to lead optimization
- Projects eligible for Cancer Therapeutics Innovation Pipeline (CTIP) funding
- Clinical trials
- *In-silico* device or algorithm "discovery" without a clear pathway to prototyping or pre-clinical evaluation
- Discovery or *in-vitro* experiments of new non-drug approach (i.e., development of lead compound or cell culture experiments of a nano-particle radiosensitizer)

### 1.3 Eligibility

OICR invites applications from investigators at Ontario academic centres, hospital research institutes or other government research institutions. **OICR funding is only tenable in Ontario. For profit entities are not eligible to receive OICR funding**.

Applicants are eligible to submit a single Pre-CATA application as the Principal Investigator (PI) or Co-Principal Investigator (Co-PI). PI/Co-PIs may participate on separate Pre-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, particularly those from historically under-represented communities, as part of the project team. The inclusion of a patient or supporting individual(s) to the project team is also strongly encouraged. Further, teams should consider the inclusion of a physician and/or a biostatistician for relevant projects.

### 1.4 Term

The funding start date for a funded Pre-CATA application is April 1, 2024. The award term is up to **three (3) years**.

### 1.5 Funding available

Pre-CATA applications can request up to **$250,000 per year, inclusive of any eligible overhead** (as per OICR's Eligible Expenses policy), for up to **three (3) years**. OICR anticipates supporting up to eight Pre-CATA projects.

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

### 1.6 Eligible expenses

Expenses must adhere with OICR's guidelines for eligible expenses. The following expenses are not eligible under this RFA:

- Clinical/health intervention trials.

### 1.7 Deadlines

| | |
|---|---|
| Optional RFA information session (register here): | October 24, 2023 from 10-11 a.m. ET |
| Registration (Letter of Intent) deadline: | November 13, 2023 by 5 p.m. ET |
| Full application deadline: | January 18, 2024 by 5 p.m. ET |
| Anticipated notification of results: | March 2024 |
| Funding to begin: | April 1, 2024 |

**Late submissions will not be accepted.**

## 2 REQUEST FOR APPLICATIONS

### 2.1 Application requirements

**IP, commercialization plan and recipient obligations**

As applicable, the research plan must include a brief, non-confidential description of any project-related IP and any restrictions or third-party rights impacting the IP development in Ontario. It is strongly suggested that this IP and commercialization section of the RFA be reviewed together with institutional Technology Transfer Officers.

**Equity, Diversity and Inclusion**

All OICR-supported research is expected to align with the Institute's principles of Equity, Diversity, and Inclusion (EDI). OICR's Commitment to EDI in Research Statement can be found on our website. OICR is committed to:

- Ensuring our research serves those from all relevant communities, especially those that are historically underrepresented
- Fostering a more diverse and inclusive research community
- Creating a work environment where all can thrive and feel included
- Collecting and analyzing demographic data to better understand the diversity of applicants, funded researchers and project teams in order to identify gaps and develop approaches to address those gaps
- Continuing to evaluate our processes, ask for input, collect data and improve
- Communicating how we will achieve equity, diversity and inclusion
- Sharing best practices and lessons learned to help drive equity, diversity and inclusion across the cancer research community

Refer to OICR's guidelines on Equity, Diversity and Inclusion tactics in research for more details.

**Patient partners**

Patient perspectives and insight can be transformative to research planning, execution and knowledge transfer. Patient partnership in OICR-supported research ensures i) studies meet the needs of the people intended to benefit, and ii) study activities and results are communicated in an accessible way to patients, caregivers and the wider community. All applications must include a patient partnership plan, in which applicants describe how patient partners and stakeholder communities are being, or will be, engaged throughout the life cycle of the project. Applicants are encouraged to involve patient partners as early as possible in the application process, as they can help shape the research question, develop the patient partnership plan, and inform the writing of the lay summary. Teams can explore the resources available on the Patient Partnership page of the OICR website and at their home institutions on how to recruit and involve patient partners and communities into the research process. Members of OICR's Patient and Family Advisory Council (PFAC), or delegates, will participate in the full application review, as well as progress reviews to provide ongoing guidance over the funding term.

**Declaration of Research Assessment**
OICR is a signatory to the San Francisco Declaration of Research Assessment (DORA). As such, we are aligned with DORA principles through our commitment to assess the quality and impact of scientific research through means other than journal impact factors. As part of OICR's commitment to these principles, applicants are asked NOT to include journal impact factors (JIF) or other journal-based metrics in any document submitted as part of the application process.

**Use of Artificial Intelligence**
OICR aligns with the recent statement from CIHR on the use of artificial intelligence (AI) to write grant applications. As with CIHR, OICR expects that applicants will draft proposals and supporting text themselves; use of AI to draft application materials will be considered plagiarism as per the Tri-Agency Framework: Responsible Conduct of Research.

Reviewers must also abstain from the use of AI when drafting their feedback and must never copy/paste applications (or excerpts) into AI platforms as doing so will constitute a breach in confidentiality.

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

Pre-CATA applications are a two-step process, including a registration and a full application. Registrations and full applications are to be submitted online using ReportNet, OICR's online system for managing grants and awards. Refer to OICR's guidelines on using ReportNet.

Uploaded files must be in 11-point Arial font with single spacing and one-inch margins.

## 2.3 Completing a registration

The registration process uses ReportNet's Letter of Intent (LOI) form and collects relevant information that will be used to ensure that the full application review panel has the necessary expertise and experience to adjudicate the applications. The registration process is non-competitive, but must be completed and submitted prior to the registration deadline in order to obtain access to the full application form. The 'Research scope' section of the registration is intended to assist applicants in assessing whether their proposal is within scope for the Pre-CATA competition. Applicants should carefully consider their responses prior to submission, and are encouraged to reach out to OICR with questions. The information provided in the registration will be available to the review panel as part of the full application submission.

Applicants will receive access to the full application form within one business day of registration submission.

**Application Information**
*Administrative*
The system will pre-populate the PI's information from their ReportNet profile. Applicants will not be able to submit a registration without first completing their user profile, including the demographic questions. To complete, click on the initial of your first name at the top right of your screen, and select, "User profile". Then, select "More..." on the left hand panel and complete all fields with a red asterisk.

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.

- **Application type:** This section lists all possible application types for the CTP theme. Please select '**Pre-CATA**'. Only Pre-CATA applications will be adjudicated under this RFA.

- **Project 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). The project title may be shared with external parties and should be considered non-confidential.
- **Invite contacts**
  - Co-PIs, Co-Investigators, Collaborators, Patient Partners and a PI Delegate(s) can be added using the '**Invite Contacts**' button. **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. 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.
- **Research scope:** Provide responses to the questions to outline how the project aligns with the scope for this funding opportunity to ensure eligibility.
- **Funding start date:** Enter a funding start date for the application, no earlier than April 1, 2024.
- **Funding end date:** Enter a funding end date for the application no later than March 31, 2027.
- **Key words (max. 50 words)**
- **Cancer type**
- **Lay summary (max. 500 words):** The lay summary should explain complex research ideas in simple terms and plain language that can be easily understood by non-scientists at the high school graduate level. This is unlike a scientific abstract, which is written for subject peers. The lay summary will be used by reviewers and patient partners during the review process. If funded, it may be used to communicate your research to the public and funders. The applicants are strongly advised to engage a patient partner to co-write or review the lay summary.

  - An overview of each of the following topics is recommended, as applicable:
  - Background/context to the research
  - Description of the current standard of care
  - Research question or problem to be solved
  - Thorough description of proposed research/method(s)
  - Potential benefit to patients/impact on the field.

  Bullet points are acceptable to highlight key points. Please use plain English while avoiding acronyms, scientific jargon and technical, field-specific terms unless a short explanation is added. Short sentences with easy sentence constructions are advisable.

  The lay summary may be shared with external parties for communications and reporting purposes, and with reviewers to identify potential conflicts of interest. The lay summary should be considered non-confidential.

### 2.4 Completing a full application

Information provided in the registration stage will be carried over to the full application form and will be editable. Only applicants who have submitted a registration by the deadline will be provided with access to the full application form.

The following information will be required for a full application:

- **Common Scientific Outline**
- **Administrative authority of PI's Host Institution**
- **Does this application include a clinical trial?** Pre-CATA applications must select 'No'.
- **Regulatory requirements**

- **Equity, Diversity, and Inclusion (EDI) (max 500 words):** Outline how the project will align itself to the principles of EDI outlined in Section 2.1 above, with regard to the project team, knowledge users (such as patients, clinicians and other healthcare professionals, health technology assessment agencies, and health policy decision makers) and the conduct of the study. At minimum, teams should:
  - Describe how the project will draw samples and/or patients from diverse populations (where appropriate), specifically historically underrepresented populations. If this is not possible, please explain.
  - Describe whether the project may be of particular benefit to any historically underrepresented groups, and what those benefits may be.
  - Include specific, actionable and measurable and time-bound tactics and address multiple areas wherever possible (e.g., outline tactics relating to both research team recruitment and dissemination of results).
  - Note that stating the team is currently diverse, that the team will follow the EDI policies of their institution, or that the institution serves a diverse patient population does not satisfy the requirement for an EDI plan.

  Refer to OICR's guidelines on Equity, Diversity and Inclusion tactics in research for more details.

  EDI plans will be evaluated for each application and the evaluation counted in the overall score/recommendation. Feedback on the proposed approach and opportunities for improvement will be provided to applicants. Progress towards meeting objectives of the EDI plan will be evaluated as part of progress reviews.

  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
  - EDI and research excellence

    Additional resources on including sex and gender in research, which can be applied to including other demographic factors, can be found at: https://cihr-irsc.gc.ca/e/50836.html.

## Research proposal

- **Scientific summary (max. 500 words)**
- **Lay summary (max. 500 words):** This will be copied over from the LOI submission. At the full application stage, the lay summary must be reviewed by the patient partner.
- **Research plan (max. 6000 words.** Label file name: Request ID_Research Plan and upload as a PDF. Figures, tables and reference can be included at the end of the proposal and do not count towards the page limit): Provide a research plan, including the information below. Include the listed headings:
  - *Background and rationale (approximately 1000 words)*: Describe the background and rationale (clinical need/question being addressed) of the project. Provide a summary of current knowledge in the field and outline how this project will add to that knowledge. Describe the project's alignment with OICR and Pre-CATA research emphases and clearly outline the clinical impact for cancer patients.

- *Research plan (approximately 3000 words):* Provide a detailed description of the biomarker or therapeutic development plan including the approach/methodology that will be employed. Outline the principal features of the statistical analysis of the project data. A flow diagram of the biomarker or therapeutic development plan must be included as an attachment (see below) that reflects the methodology outlined in this section. Ensure that the description and the diagram outlines past methodology, research outputs, and a clear path towards clinical testing. Also, indicate if the progress of the project at any point in the project's lifecycle will be wholly dependent on the availability of a drug, therapeutic agent, antibody, IP etc. from a third party or industry partner. The research plan should address the following questions, as appropriate:
  - *Biomarker development:*
    - Biomarker: Why has this/these biomarker(s) been chosen for study? Provide evidence that the (clinical) utility of measuring the biomarker(s) will address an unmet clinical need. In cases where a biomarker is already available to address the clinical utility question described above, describe the potential value-added in terms of analytic metrics or cost of the biomarker chosen for study.
    - Assay: Why this assay and how will it be developed, optimized, and validated in second cohorts? Can the assay be used with samples of low quantity?
    - Samples: Are the samples of high-quality, well-characterized and of sufficient quantity to carry out the development process? Are all sample types relevant to the project included in the analysis, or are only convenience samples being assessed? 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.
  - *Therapeutic development – Drug based therapeutic development:*
    - Is there strong evidence supporting the hypothesis that modulating or targeting (in the case of theranostics) the biological target will produce a desirable outcome for the intended disease indication?
    - Are there structure activity relationships within the lead series that indicate that further optimization is possible?
    - Are validated primary, secondary and selectivity assays available for driving SAR studies?
    - Are there proposed biomarkers for patient selection? In the case of theranostics are there identified diagnostic and therapeutic pairs?
    - Do lead and clinical candidate molecules meet the Target Product Profile criteria with respect to *in vitro* and *in vivo* biological activity, physicochemical properties, PK, ADME properties, and safety profile appropriate for the intended clinical use (i.e., the disease indication, patient population, delivery mode, treatment duration, and treatment regimen) and anticipated clinical outcomes?
    - Is there freedom to operate and a path for generating novel intellectual property?
    - Do lead and clinical candidate molecules possess differentiation from competitor molecules to offer an opportunity for the development of a first-in class or best-in-class drug?
  - *Therapeutic development – Non-drug based therapeutic development*
    - Is there a clear clinical need and biologic rationale for the non-drug approach being developed?
    - Has the device/approach been sufficiently developed to the point of physical device prototyping and or evaluation in-phantom or pre-clinical (animal) models?

- Is there a clear path towards deployment of the technology in a clinical trial? Have Health Canada and REB concerns been considered in terms of future movement of the technique into clinical trials?
- Is there freedom to operate and a path for generating novel intellectual property?

  - *Team details and project management (approximately 500 words)*: Provide an overview of the team's organizational structure and describe the expertise and experience of the Principal Investigator/Co-Principal Investigators and capabilities of the team to execute the proposed research plan. Further, outline the role of team members with regards to research plan management. Teams are encouraged to include a biostatistician as a member of the team or have access to statistical support. Describe existing available resources and how they will be used to ensure the timely success of the project. Describe the plan to complete data analysis within the proposed period of the award. Identify potential barriers to the research plan success and describe possible mitigation plans.
  - *Funding (approximately 100 words):* Outline if the project will be funded entirely by OICR or if co-funded by a partnership. If applicable, provide evidence of co-funding through a letter of support, which is to be included as an uploaded document.
  - *Path to testing in a clinical trial (approximately 500 words)*:Outline the project's path to testing in a clinical trial. Identify prospective partners or granting agencies for leveraged funds. Surmise a potential timeline for clinical application and impact.
  - *IP, commercialization plan and recipient obligations (approximately 500 words):* Highlight possible commercial applications for this project. As applicable, include a brief non-confidential description of any project-related IP, and any restrictions or third-party rights impacting the IP development in Ontario. See section 2.1 for more details.

- **Patient partnership plan (500 words):** Patient perspectives and insight can be transformative to research planning and execution. Applicants should address how patient partners and/or communities will be partnered with throughout the life cycle of the project. This section must be written as a stand-alone piece, assuming that readers may not have read the application research proposal. It should be written in clear, easy to understand, lay language understandable to a high school graduate. It should include the patient partner name(s), the organization or entity from which they were sourced, how they will be engaged, examples of the specific contributions they will be asked to make, and support of the specific deliverables and milestones. OICR encourages all teams to provide compensation to patient partners to recognize their expertise and contribution.

### Additional information

- **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 project (as applicable), and the plan for retaining/archiving with the ability to restore the data for the five-year period following its conclusion. See data sharing, open access and retention for more details.
- **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 work). This information may be shared with FACIT, OICR's commercialization partner, should the proposal be funded.

### Attachments

The following items should be attached to the application:

- **Deliverables and Milestones** (D/Ms), using the Excel template provided in ReportNet (Label file name: Request ID_DM and upload as an Excel file on ReportNet)

- Deliverables are pre-defined outputs or outcomes that describe what success looks like for the project. When achieved, deliverables must provide meaningful impact towards achieving the goal of the proposal. Milestones are points in the research plan that facilitate measurement of progress towards the achievement of the deliverable. These deliverables and milestones will be used to measure research progress during progress updates.
- Specify high-level deliverables that are projected to be achieved during the funding term.
- For each deliverable, specify at least two associated milestones. Milestones will be monitored to assess progress towards achievement of the deliverable. **Include milestones that specify go/no go decision points** whenever applicable.
- Both deliverables and milestones must be measurable and possess a target date for completion (provide the quarter and fiscal year of projected achievement).
- Include deliverables and milestones for the EDI and Patient Partnership plans.

- **Budget,** using the Excel template provided in ReportNet (Label file name: Request ID_Budget and upload as an Excel file on ReportNet)
  - Download the budget template provided in the application and complete budget request details. Expenses must adhere with OICR's guidelines for eligible expenses. The following expenses are not eligible under this RFA:
    - Clinical/health intervention trials
  - The template will automatically calculate overhead at thirty per cent (30%) for overhead eligible expenses for non-MaRS based institutions. The overhead rate can be adjusted on the 'info and instructions' tab. Please contact the Scientific Secretariat with any questions regarding overhead. Overhead must be accounted for in the budget requested which cannot exceed the maximum amounts stated in section 1.5.
- **Budget justification:** Label file name: Request ID_Budget justification and upload as a PDF on ReportNet. 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** (optional; Label file name: Request ID_Co-funding. Combine all co-funding letters as one bookmarked PDF and upload on ReportNet)**:** 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):**
  - Label file name: Request ID_CVs. Combine CVs for the following individuals as one bookmarked PDF and upload on ReportNet.:
    - 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).
- **Host institution attestation** (Label file name: Request ID_HI attestation. Combine all attestations as one bookmarked PDF and upload on ReportNet)): Using the PDF form provided, the applicant must obtain the signature of the institutional administrative authority attesting to the terms outlined in the form. Additional forms must also be signed and uploaded from the Host Institution of any Co-PIs. If the host institution for a PI or Co-PI is OICR, an attestation form from OICR is not required.
- **Publications** (Label file name: Request ID_Publications. Combine all publications as one bookmarked PDF and upload on ReportNet)**:** Upload the top three team publications relating to the project that reviewers should take special note of.

- **Research plan flow diagram** (Label file name: Request ID_Flow diagram and upload as a PDF on ReportNet)**:** Provide a diagrammatic representation (flow diagram) of the biomarker/therapeutic research plan (as described above).
- **Letters of support** (optional. (Label file name: Request ID_LOS. Combine all letters of support as one bookmarked PDF and upload on ReportNet)): A maximum of three letters from key stakeholders, partners, etc. can be attached to outline support for the application. Patient testimonials/letters of support, while not required, are encouraged.

Once you have completed all required fields, select the green '*Submit*' button at the bottom of the screen.

# 3 REVIEW PROCESS

## 3.1 Administrative review

An administrative review may 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 Review panel

Full applications, including information submitted as part of the registration process will be reviewed by an external panel consisting of members with expertise in oncology, biomarker/therapeutic development and clinical validation. The panel's mandate will be to evaluate the merits of the applications. Panel members will be assigned to applications as primary, secondary or tertiary reviewers and will provide a brief preliminary report outlining their feedback on the proposal, based on the evaluation criteria in Appendix I.

## 3.3 Patient and Family Advisory Council (PFAC)

Applications will be shared with the OICR PFAC, or their delegates, who will review applications and provide written feedback to the review panel in advance of the full application review meeting. PFAC feedback will be provided to applicants as part of the Scientific Officer report that will be provided to teams following the review meeting.

## 3.4 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 projects using the following criteria (see Appendix I for additional information):

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

Reviewers will also provide an overall score for the application as a whole. The overall score may be used for ranking applications, if deemed appropriate by the review panel Chair. Reviewers will also be asked to indicate whether the proposal should be in contention for funding and evaluated further at the review meeting (Yes, No or Undecided). Applications that receive a 'No' from all three assigned reviewers may not be discussed further at the review meeting.

## 3.5 Preparation teleconference

If deemed appropriate by the Chair, 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.

### 3.6 Review meeting

Depending on application pressure, and with the approval of the review panel Chair, 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 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 Chair with support from OICR's Scientific Secretariat and will include representatives from OICR and PFAC. The Chair will invite the three assigned 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 OICR leadership and OICR's Board of Directors.

### 3.7 Notification of decision

A meeting report summarizing the review discussion and recommendation for each application 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 March 2024. Funding will start on April 1, 2024 for successful applicants. Applications recommended for funding will receive a Notice of Award outlining next steps in order to accept the award and establish a funding agreement.

## 4 ESTABLISHMENT OF AGREEMENTS

Following approval of the proposal, OICR will establish a funding agreement with the Host Institution of the Lead PI and Partner Institutions (if applicable). 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.

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

## 5 REPORTING REQUIREMENTS

### 5.1 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

project, an explanation of variances of greater than ±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<br>April-June | Quarterly financial report<br>Due: July 31 | Review and submit quarterly financial and operational status report<br>Due: July 31 |
| Q2<br>July-September | Quarterly financial report<br>Due: October 31 | Review and submit quarterly financial and operational status report<br>Due: October 31 |
| Q3<br>October-December | Quarterly financial report<br>Due: January 31 | Review and submit quarterly financial operational status report<br>Due: January 31 |
| Q4<br>January-March | Quarterly financial report<br>Due: April 30 | Review and submit financial and operational status report<br>Due: April 30 |
| Q1-Q4<br>April-March | Annual fiscal year financial report: Due May 31 | N/A |

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

All projects will be included in OICR's annual reporting process, as required by the Ministry of Colleges and Universities 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<br>Apr-Sep | Complete the CT Progress Report on ReportNet. The report will be reviewed by the CT Progress Review Committee and the PI will be provided with feedback and suggestions: *Due October 31* |
| Q3-Q4<br>Oct-Mar | Complete the CT Progress Report on ReportNet. The report will be reviewed by the CT Progress Review Committee and the PI will be provided with feedback and suggestions: *Due April 30* |
| Q1-Q4<br>Apr-Mar | Provide quantitative KPIs using ReportNet: *Due April 30* |

## 6 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 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 projects/subprojects 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. The views expressed in the publication are the views of the authors and do not necessarily reflect those of the Government of Ontario”.

## 8 CONTACT INFORMATION

For any questions, please refer to the FAQ page before contacting the OICR Scientific Secretariat office (ScientificSecretariat@oicr.on.ca).

## APPENDIX I: EVALUATION CRITERIA AND SCORING

Applications will be reviewed using the following evaluation criteria:

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

**Table 3** provides a description of each criterion. The merit of each project will be evaluated against the listed criteria, where applicable.

| **Table 3 Evaluation criteria** |
|---|
| **Relevance**<br>The project**:**<br>● Is in line with the OICR's strategic plan, the principles of the Clinical Translation Pathway and elements of the Pre-CATA RFA<br>● Addresses a specific, well-defined, clinical priority/question for early cancer patients and/or the Ontario health care system<br>● Current state of knowledge relative to the proposed project is included<br>● Is driven by a strong hypothesis that rests on sufficient evidence |
| **Excellence**<br>● The proposed research is innovative and of international calibre.<br>● Research design is appropriate to answer the question(s) posed, with a cohesive plan that will lead to meaningful results.<br>● Goals and objectives are well defined and attainable.<br>● Statistical justification is provided to support the hypothesis and project design.<br>● Potential pitfalls and possible mitigation plans are provided and appropriate. |
| **Impact**<br>● The proposed research will have a transformative impact on clinical practice, benefitting Ontario patients, practitioners and/or users of the health care system.<br>● The research tests an innovation/asset/intervention with health economic and/or commercialization potential for Ontario.<br>● The application articulates a clear path to impact, including a path to testing in prospective clinical trials.<br>● The EDI and Patient Partnership plans are appropriate to support the impact of the project. Among other items, the EDI plan takes into consideration using samples from diverse populations, specifically historically underrepresented populations, and the consideration of sex and gender (if feasible). The Patient Partnership plan takes into consideration the integration of patient partners so that the project meets the needs of the people intended to benefit. |
| **Feasibility**<br>● The proposed research is feasible, within the term of the award, with potential for success.<br>● The project team has access to appropriate facilities and resources to ensure project success. |

| Table 3 Evaluation criteria |
|---|
| ● 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.<br>● A plan for biospecimen acquisition (if applicable) and/or a description of the existing biospecimen resource to be utilized is included. Where an existing biorepository is to be accessed, confirmation of support for the research is included by the "owner" of the specimens.<br>● The budget is fully justified and appropriate to support the project. |
| **Leadership, team, and collaboration**<br>● The team, and its leadership, have the necessary range of disciplines and experience necessary to conduct the project.<br>● The project leadership is recognized in the cancer research community and have appropriate qualifications, experience, and record of publications.<br>● The project leadership has led or contributed to research that has resulted in improvements in clinical practice.<br>● The team engages collaboratively with investigators with complementary expertise. There is a strong level of provincial participation, and where appropriate, OICR's program's/networks/resources.<br>● Opportunities for early career investigators/trainees are supported.<br>● The Patient Partnership plan clearly articulates the role of all integrated patient partners.<br>● The approach for alignment with the principles of EDI within the project team is clearly articulated. |

**Table 4** will be used for scoring.

| Table 4: Scoring | | |
|---|---|---|
| **Score** | **Descriptor** | **Additional guidance** |
| **4.7-5.0** | **Excellent with no weaknesses identified** | Exceptionally strong with essentially no weaknesses. The project excels in most or all criteria. Any shortcomings are minimal. Proposed research 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** | **Excellent with minor weaknesses identified** | Very strong with only some minor weaknesses. The project excels in many criteria and reasonably addresses all others. Certain improvements are possible. Proposed research has a high potential for transformative impact on clinical practice and has a clear path to completion with sufficient funding. |
| **3.6-4.1** | **Very good with minor weaknesses identified** | Some strengths but also some weaknesses. The project excels in some criteria and reasonably addresses all others. Minor revisions are required. Proposed research has a moderate probability for impact on clinical practice and has a reasonably clear path to completion with sufficient funding. |
| **3.0-3.5** | **Very good with moderate** | Some strengths but also some moderate weaknesses. The project excels in some criteria and reasonably addresses all others. Major revisions are required. Proposed research has a moderate |

| Table 4: Scoring | | |
|---|---|---|
| **Score** | **Descriptor** | **Additional guidance** |
| | **weaknesses identified** | probability for impact on clinical practice and has a reasonably clear path to completion with sufficient funding. |
| **2.4-2.9** | **Good with moderate weaknesses identified** | Some strengths but with at least one major weakness. The project broadly addresses criteria, but revisions required are too significant to overcome. Proposed research has a moderate to low probability for impact on clinical practice, and the path to completion is missing or not feasible. |
| **Below 2.4** | **Unsatisfactory** | Very few strengths and numerous major weaknesses. The project fails to meet most of the criteria and/or has serious inherent flaws or gaps. Proposed research has a low probability for impact on clinical practice. The proposed project should not be funded. |