Cancer Therapeutics Innovation Pipeline

Request for Applications
Early Validation and Early Accelerator project proposals

Version 1.1

June 2022

Table of contents

1. INTRODUCTION

1.1. Purpose

This document is intended to aid Investigators wishing to apply for a Cancer Therapeutics Innovation Pipeline (CTIP) award to support the translation of Ontario discoveries into therapeutic assets with the potential for improving the lives of cancer patients.

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.

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 of new treatments, diagnostics and biomarkers thus fostering precision medicine for cancer patients; and
- **Therapeutic Innovation**: Validating novel cancer drug targets and advancing selective therapeutic candidates to clinical development.

In addition to collaborative research conducted under these Themes, OICR enables world-class translational cancer research in Ontario through:

1. Talent Mobilization activities focused on recruiting, developing, and engaging outstanding Ontario cancer researchers and clinician-scientists.
2. The Collaborative Research Resources that provide access to cutting-edge research tools, high-quality validated assays, databases, expertise, resources, and infrastructure.
3. Implementation Science, which supports activities that promote the uptake of evidence-based practice and research into regular use by policymakers and healthcare providers.

OICR supports Intellectual Property (IP) development and commercialization through our strategic partnership with FACIT, which invests in and builds local companies to accelerate commercialization of Ontario cancer discoveries to patients, attracts investment and industry partners, and creates and retains private sector jobs in Ontario. The scale of OICR's investment in FACIT facilitates commercialization by addressing a critical gap.

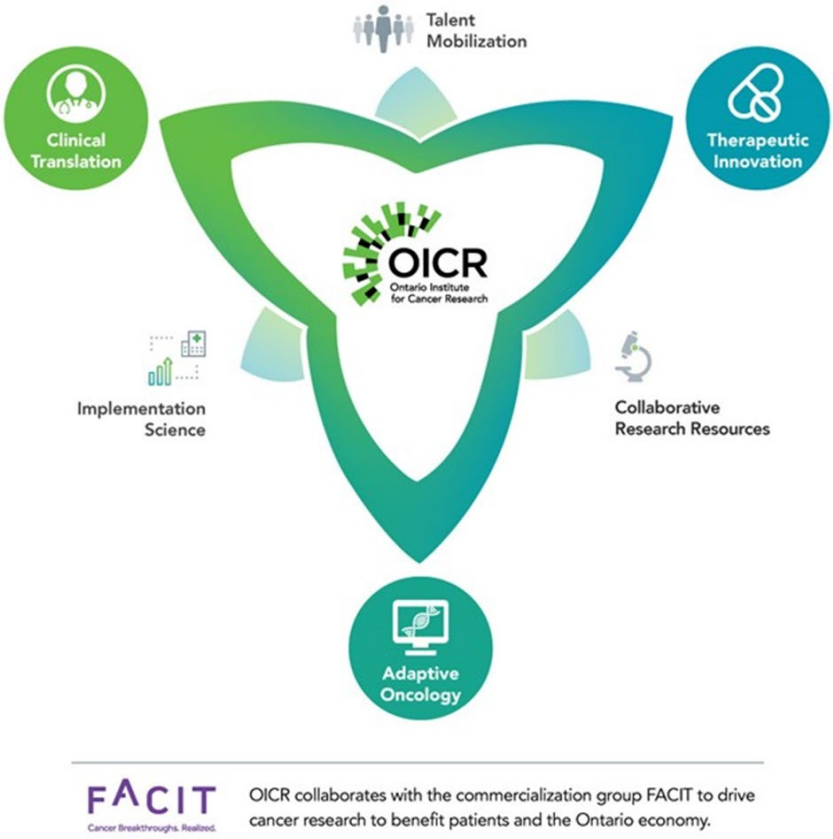


Figure 1: *OICR's Research Themes and Enablers*

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 the development of precision medicine biomarkers for patient monitoring for improved clinical management.

1.3. Cancer Therapeutics Innovation Pipeline (CTIP)

In 2017, OICR established the CTIP Program to capitalize on Ontario's expertise in cancer biology and drug discovery. Its aim is to create a pipeline of validated cancer targets and First-in-Class (FiC) or Best-in-Class (BiC), novel, selective lead molecules (small molecules or biologics) that will attract partnerships and/or investment for further preclinical and clinical development. To generate a sustainable pipeline, CTIP will support projects that aim to provide increasing evidence of target validation and disease association using data from knowledge bases, functional assays, and drug screening in relevant *in vitro* and *in vivo* models of the cancer type of interest.

CTIP funds projects in four stages of preclinical drug discovery as shown in Figure 2:

- **NEW Early Validation (EV) projects:** Deliver robust translational evidence that a Target-of-Interest (TOI) is associated with a specific cancer type(s) based on data from knowledge bases and from studies demonstrating that perturbation of the TOI in relevant cell-based models produces anti-cancer effects sufficient to trigger a drug discovery campaign;
- **Early Accelerator (EA) projects**: Deliver a validated primary assay to enable initial screening of molecules against a defined target;
- **Late Accelerator (LA) projects**: Focus on screening, using validated primary, secondary, and orthogonal assays and deliver confirmed Hit[1] molecules against a defined target supported by evidence of disease association. A confirmed Hit molecule should possess features that support its potential to become a Lead[2] molecule; and
- **Lead Generation (LG) projects**: Deliver high-quality Lead molecules (small or large), with demonstrated *in vivo* efficacy, ideally accompanied by pharmacodynamic and/or efficacy biomarkers, and markers of resistance (where applicable), that correlate with target modulation. Lead molecule profiles should be sufficiently mature to attract partnership/investment for further development and ultimately commercialization. In addition, a clear path for development of defined biomarkers to guide patient selection is required together with a Target Product Profile (TPP[3]).

[1]A minimal definition of a Hit is a molecule series with an understood Structure-Activity Relationship (SAR) and selectivity profile in relevant *in vitro* models.
[2]A minimal definition of a Lead is a molecule series with an understood SAR and selectivity profile in pharmacologically relevant *in vivo* models.
[3]A TPP outlines the desired profile or characteristics of a drug that is aimed at a particular disease. In addition, a TPP states the intended use, target populations and other desired attributes of a drug, including safety and efficacy-related characteristics.

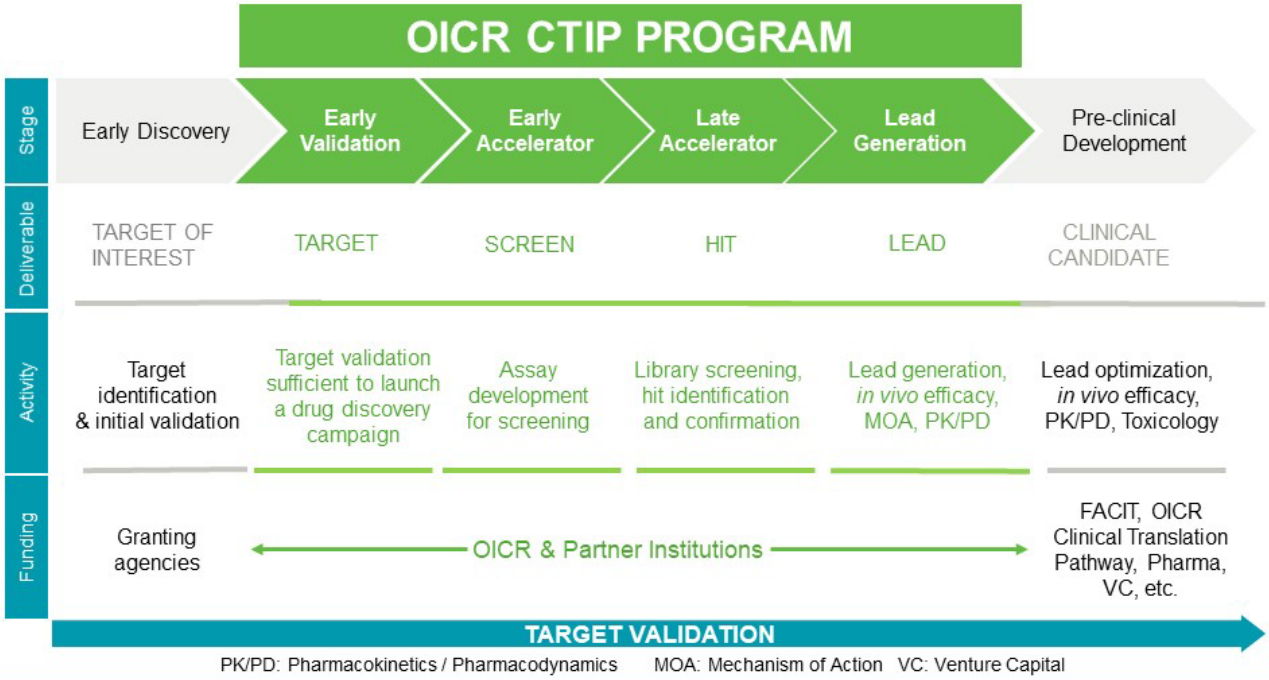


***Figure 2**: The Cancer Therapeutics Innovation Pipeline: Stages, deliverables, major activities and funding sources.*

A project can enter at any stage and can advance across stages as deliverables are met based on a go/no go decision aligned with industry standards. Expert and strict stage-gated strategic

and scientific review is provided by the Therapeutics Pipeline Advisory Committee (TPAC), a group of highly qualified academic and industry experts with years of experience in drug discovery, systems biology, and clinical trials.

1.4. CTIP projects

Understanding the role of a target in the pathophysiology of disease is repeatedly cited as the most critical factor in predicting the therapeutic value of modulating the activity of a putative target. During a drug discovery and development campaign, there is an absolute need to continually interrogate a target in the context of its biological function within a pathway(s) using functional assays, systems biology informatic tools and drug screening in increasingly complex *in vitro* and *in vivo* models that recapitulate the phenotype, genotype and systems of the cancer type of interest. The generation of robust evidence of target validation and disease association, and a reasonably clear ultimate target clinical indication(s), are essential requirements of projects that enter and continue in the CTIP portfolio. These parameters will be assessed together with feasibility, safety, and strategic considerations in the evaluation of a proposal's suitability for CTIP funding (Appendix I).

With advances in science and technologies such as informatics, multi-omics (genome, epigenome, transcriptome, proteome, metabolome, microbiome, etc.), artificial intelligence, disease modelling, and nanotechnologies, CTIP projects are expected to couple traditional target validation/disease association and screening approaches with state-of-the-art strategies such as querying of multi-omic and functional knowledge bases, selective perturbation of targets using genomic tools, pharmacogenomic screening, patient-derived 3D or organoid modelling, biomarker identification, and machine learning-inspired drug hunting, to name a few. Furthermore, it is increasingly apparent that the experiences of patients and their families/friends bring much value to disease knowledge creation and to the conversation as to how their health should be managed.

It therefore follows that the establishment of a drug discovery team should involve a collaboration of talent from different branches of science that includes, but is not limited to, biologists, chemists, biochemists, protein scientists, bioinformaticians, systems biologists, pharmacologists, biomarker experts, functional genomics experts, artificial intelligence scientists, imaging scientists, clinicians who regularly treat patients with the cancer of interest, and data scientists. Furthermore, teams should endeavour to capture the voice of the cancer patient and their support in the design of their drug discovery campaign.

Applicants are encouraged to reach out to the research community, preferably within the province of Ontario, as well as to the Collaborative Research Resources (CRR) offered by OICR. CRR helps to enable research in Ontario by providing expertise, advice and access to research services on a cost-recovery basis. Researchers can benefit from OICR's high-end technology infrastructure, world-leading research knowledge, high-quality services and support. In addition, OICR funds major research initiatives in Clinical Translation and Adaptive Oncology and teams are encouraged to seek collaborations with investigators in these areas as they may be able to assist in buttressing the therapeutic target hypothesis and potentially contribute complementary expertise towards the achievement of CTIP deliverables, such as robust target validation.

In the event that a contract research organization (CRO) with the desired expertise, experience, model system(s), and track record of quality is available to conduct experiments efficiently and with rigour, or to generate high-quality reagents, the CTIP program will consider funding of such

work. In this regard, OICR's Drug Discovery Program will work with the project team in the coordination and establishment of agreements with CROs.

Although this **RFA is limited to EV and EA applications only**, since successful projects have the potential to advance through the CTIP pipeline, the four stages of EV, EA, LA, and LG are described herein.

1.4.1. EV projects – Target-of-Interest to Target: Translational target validation and disease association

The goal of an EV project is to deliver robust translational evidence that a TOI is associated to a specific cancer type based on data from knowledge bases and from studies demonstrating that perturbation of the TOI in relevant cell-based models produces anti-cancer effects sufficient to trigger a drug discovery campaign.

Prerequisites: Entry into the EV stage requires demonstrable evidence of disease association to the cancer of interest, which **at a minimum** should include supportive data from:

1. Queries of multi-omics (genome, epigenome, transcriptome, proteome, metabolome, microbiome, etc.) and functional knowledge bases to ascertain the relevancy of the TOI in the cancer of interest as well as other cancer types; and
2. Application of systems biology tools to:
   a) reveal redundancies and crosstalk within pathways, and identify associated pathway molecules that when perturbed, would be expected to result in phenocopying the effects of modulating the TOI;
   b) identify potential correlative biomarkers and anti-targets; and
   c) expose any known potential off-target effects on molecules of similar molecular structure.
3. Perturbation (e.g., knockout/knockdown) of the TOI derived from the literature or generated in the applicants' laboratory which provides evidence for the relevance of the target in cancer. Building upon these preliminary results will form the core of the EV proposal in order to achieve the deliverables stated below.

Deliverables of an EV project: Demonstration that perturbation of the TOI in relevant cell-based models (including patient-derived lines whenever possible) or higher order systems using genomic (e.g., knockout/knockdown or upregulation/overexpression) and/or tool compounds supports target validation and disease association. At the end of the EV stage, there must be sufficient translational evidence to trigger a drug discovery campaign.

The project team should strive to replicate literature-sourced evidence within their own laboratories. Furthermore,

- Efforts must be made to demonstrate the effects in several cell lines which differentially express the target at the protein level and in a normal cell line control;
- The evidence must include results from control experiments using inactive or unrelated vectors;
- In knockdown or knockout experiments, rescue data supportive of target function is highly desirable; and
- Pharmacologic or genetic manipulation of cell-based models used to mimic the conditions seen in human cancers (e.g., a specific protein or marker of stress) must be at levels that correlate with human data.

If feasible, development and validation of a tool compound to be used to interrogate the TOI can be included in the EV research plan. In addition, evidence from more complex 3D culture systems

or existing animal models (from the applicant's own laboratory, another academic laboratory, or a CRO) is desirable.

It is highly recommended that EV applicants identify a bioinformatics or systems biology collaborator or consultant to participate in the project. In addition, EV applicants are strongly encouraged to solicit the advice of a clinician in the relevant disease area to begin to define the target clinical indication(s) and the corresponding patient population.

Funding: EV projects will be funded up to $150,000 per year for a maximum of two (2) years.

1.4.2. EA projects – Target to Screen: Primary screen development

The goal of an EA project is to deliver a validated primary assay to enable initial screening of molecules against a defined target.

Prerequisites: Entry into the EA stage requires translational target validation and disease association evidence as described in the EV stage above.

Deliverables of an EA project: A validated primary screening assay is the ultimate deliverable of an EA project. Performance of a small, focused screen using the primary assay to ascertain the feasibility of scale-up is highly recommended during the EA stage. The application of machine learning and artificial intelligence-inspired drug discovery and disease modelling would enhance the value of an EA proposal.

Funding: EA projects will be funded up to $150,000 for a maximum of one (1) year.

It is highly recommended that EA applicants identify a bioinformatics or systems biology collaborator or consultant to participate in the project. In addition, EA applicants are strongly encouraged to solicit the advice of a clinician in the relevant disease area to begin to define the target clinical indication(s) and the corresponding patient population.

1.4.3. LA projects – Screen to Hit: Hit generation

At this time, OICR is not inviting applications for LA projects.

The goal of a LA project is to deliver confirmed Hit molecules against a defined target using validated primary, secondary, and orthogonal assays for screening.

Prerequisites: Entry into the LA stage requires translational target validation and disease association evidence as described in the EV and EA stages above. The availability of a validated primary assay for screening of molecules against a defined target is mandatory.

Deliverables of a LA project: To deliver confirmed Hit molecules, the project must establish an integrated testing cascade consisting of primary, secondary, and orthogonal assays focused on demonstrating target binding, target engagement, and pharmacodynamic and efficacy effects in cell-based models (including patient-derived lines whenever available) coupled with medium-to-high-throughput screening for Hits. LA projects should consider, when appropriate, the incorporation of more complex biological systems than cell lines (e.g., 3D cultures, organoids) to further validate target-drug effectiveness and identify any off-target effects as well as potential toxicities. Depending on the target and the competitive landscape, initial *in vivo* data may be required by TPAC during the LA stage.

Funding: LA projects will be funded up to $500,000 per year for a maximum of two (2) years.

LA applicants should have a bioinformatics or systems biology collaborator or consultant on the project team. In addition, the project team must engage a clinician in the relevant disease area to define the target clinical indication(s) and the corresponding patient population.

Eligible EV, EA and LA project activities:

EV, EA and LA projects can include the following activities so long as they represent components of an integrated testing cascade that leads to a target with sufficient translational evidence of disease association (for an EV project), a validated primary assay to enable screening against a defined target (for an EA project) or confirmed Hit molecules against a defined target (for an LA project):

- Functional genomic screens (e.g., knockdown or knockout experiments using RNA interference or CRISPR) and/or pharmacological knockdown using a tool compound;
- Medium-to-high-throughput screens for large and/or small molecules;
- Development and validation of biochemical and cell-based target engagement or modulation assays for screening and orthogonal target validation. Cell-based assays should clearly demonstrate whether perturbation of the target by leading molecules induces the death of cancer cells or only arrests cell proliferation;
- Testing of patient-derived cell lines and 3D systems (spheroids or organoids);
- Structure-activity relationship (SAR) assessments to define minimum pharmacophores that demonstrate potential for further optimization;
- X-ray structure generation;
- Cross-target and cross-species selectivity assessments;
- Characterization of *in vitro* pharmacokinetic properties (absorption, distribution, metabolism, excretion, ADME) and toxicology;
- Computational approaches (e.g., virtual screening, machine learning, AI-inspired drug hunting and modelling);
- *In vivo* pharmacokinetics for representative molecules; and
- Assessment of the viability of candidate Hit molecules to support an LG effort.

1.4.4. LG projects – Hit to Lead: Lead molecules with demonstrated *in vivo* efficacy

At this time, OICR is not inviting applications for LG projects.

The goal of an LG project is to deliver high-quality Lead molecules (small and/or large), with demonstrated *in vivo* efficacy, ideally accompanied by a pharmacodynamic and/or efficacy biomarkers, and markers of resistance (where applicable), that correlates with target modulation. Lead molecule profiles should be sufficiently mature to attract partnership/investment for further development and ultimately commercialization. To achieve this goal, the project must describe an integrated testing cascade of experiments which advances confirmed Hits into quality Lead series, coupling efficacy with target modulation. There must be an emphasis on establishing a connection between *in vitro, ex vivo* and *in vivo* assays, and biomarker modulation (or other surrogate measure of efficacy). Applications for the LG stage must fulfill the prerequisites for EA and LA projects as described above and must have confirmed Hit molecules to a defined target. In addition, LG proposals will require a preliminary biomarker plan and possible biomarkers for patient selection for drug therapy.

Prerequisites: Entry into the LG stage requires translational target validation and disease association evidence as described in the EV, EA and LA stages above. The availability of

confirmed Hit molecules against a defined target using validated primary, secondary, and orthogonal assays for screening is mandatory.

Deliverables of a LG project: To deliver high-quality Lead molecules, the project must establish an integrated testing cascade of experiments which advances confirmed Hits into quality Lead series, coupling efficacy with target modulation. It is critical that a connection between *in vitro* and *in vivo* assays, and biomarker modulation (pharmacodynamic and efficacy biomarkers, as well as markers of resistance as applicable), that translates to the human cancer of interest are demonstrated during this stage.

LG research plans must contain:

- a well-articulated hypothesis for modulation of the target as a treatment for the cancer type in the intended patient population;
- a preliminary biomarker plan and possible biomarkers for patient selection for drug therapy. Pharmacogenomic screening to identify and validate pharmacodynamic and efficacy biomarkers, as well as potential safety liabilities in response to drug treatment is highly desirable; and
- a Target Product Profile (TPP) which summarizes the desired characteristics of the therapeutic asset, clinical development goals regarding safety and efficacy, and strategic elements that would confer a competitive advantage on the asset. MaRS has developed some excellent resources to help develop a TPP scheme, which can be accessed at https://learn.marsdd.com/article/defining-your-target-product-profile-therapeutics/.

Funding: LG projects will be funded up to $1,000,000 per year for a maximum of two (2) years. It is recognized that some LG projects may require funding in excess of what OICR can provide to achieve the Lead molecule series deliverable. In such situations, applicants will need to identify leveraged funding or describe a plan to secure additional support from OICR or an external partner(s) during the funding period. Co-funding may be particularly important during the latter stages of an LG project when costs exceed OICR support, prompting the need to secure funds from other academic centres (e.g., host institution) or commercial partners, including FACIT Inc., OICR's commercialization partner, based on commercial interest in the Lead molecule.

LG applicants must have a bioinformatics or systems biology collaborator or consultant on the project team. In addition, the LG project team must have a clinician in the relevant disease area to define the target clinical indication(s) and the corresponding patient population.

Eligible LG project activities:

Projects entering the LG stage will possess Hit molecules characterized by a range of supporting evidence as described in the EV, EA and LA stages. LG projects should include, but are not limited to, the following activities:

- SAR studies exhibiting a sufficiently broad dynamic range that would allow for optimization in potency, selectivity and safety, within chemical space where there is legal freedom to operate and the opportunity to generate intellectual property (IP);
- Experiments demonstrating differentiation in the context of the expected therapy in the target patient population (e.g., mechanism of action studies);
- Protein engineering studies (for large molecule therapeutics);
- Cell line generation and biophysical characterization for large molecule therapeutics;
- Bioavailability studies using the intended route(s) of administration;
- Pharmacodynamic (PD) and efficacy animal model development;

- Dose ranging PD, PK and efficacy studies;
- *In vivo* proof of concept or efficacy in a relevant biological system (animal model species) that will be used for margin of safety calculations; and
- Assessment of the viability of candidate Lead molecules to support a Lead Optimization effort.

2. REQUEST FOR APPLICATIONS

This Request for Applications (RFA) is specific for investigators wishing to apply for funding support for an EV or EA project. Submissions for LA and LG projects will not be considered under this RFA.

2.1. Eligibility

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

Investigators are eligible to participate on and submit multiple CTIP submissions via this RFA.

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 funding term start date for a funded CTIP application is December 1, 2022.

- The award term for **EV projects** is up to two (2) years (December 1, 2022 – November 30, 2024); and
- The award term for **EA projects** is up to one (1) year (December 1, 2022 - November 30, 2023).

2.3. Funding available

EV projects will be funded up to $150,000 per year, **inclusive of overhead,** for a maximum of two (2) years.

EA projects will be funded up to $150,000, **inclusive of overhead**, for a maximum of one (1) year.

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

2.4. Eligible expenses

Appendix II outlines OICR's guidelines for eligible expenses. CTIP funding is intended to provide support to cover salaries and benefits of research personnel over the funded term. Other expenses, including consumables, external research services, etc. are also eligible. Budgets should include thirty per cent overhead on eligible direct research expenses to cover institutional overhead (Appendix II). Overhead must be accounted for in the budget requested which cannot exceed the maximum amounts stated in section 2.3.

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

2.5. Deadlines

CTIP applications are a three-step, competitive process, including an NOI, a LOI and full application.

Information session*:	June 30, 2022, 2-3 p.m. ET
Notice of Intent (NOI) submission**:	No later than July 14, 2022 by 5 p.m. ET
Letter of Intent (LOI) deadline:	July 14, 2022 by 5 p.m. ET
LOI results communicated:	The week of August 22, 2022
Applicants invited to submit questions to TPAC:	Until August 31, 2022
Full application deadline:	October 5, 2022 by 5 p.m. ET
Notification of results:	December 2022
Funding start date:	December 1, 2022

**Register here. This session will be recorded and posted on OICR's funding opportunities website.*
***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

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

2.6. Application requirements

IP, commercialization plan and recipient obligations

If invited to submit a full application, 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. No commercialization plan is required for an EV, EA or LA application beyond a description of the use of proceeds for the proposed project. It is strongly suggested that this IP and commercialization section of the RFA be reviewed together with institutional Technology Transfer Officers.

Since the ultimate goal of this program is to support translation of new cancer therapies to the clinical setting, the creation and protection of IP that will make drug candidates attractive to potential licensing and commercialization partners is a significant consideration in prioritizing projects for funding. CTIP is structured so that the awardee Host Institution(s) retains background IP rights. In line with the provincial government's "Ontario First" mandate (see Appendix III), which requires that reasonable efforts are undertaken to commercialize and manufacture a project's arising IP in Ontario, applicants will contractually agree to oversight by FACIT Inc., OICR's commercialization partner, to finalize the commercialization planning, rights, and obligations, with an emphasis on Ontario-based development.

Award agreements will include an Option for FACIT to act as the commercial agent for any arising IP. In order to balance academic commercialization freedom and to be in line with other similar programs, the Option will be restricted to the period during the EV, EA or LA project and a three-month period following the completion of the project. Further, should an LA project evolve into a LG project, OICR funding of EV, EA and LA research activities will be added to any investments made by OICR during the LG stage in the determination of OICR's total contributions to the project.

Patient partners
Patient perspectives and insight can be transformative to research planning and execution. Applicants should address how patient partners and communities are being, or could be, engaged throughout the life cycle of the proposal. Throughout the funding period, and as early as possible, applicants are encouraged to contact Cassandra Bergwerff (Cassandra.Bergwerff@oicr.on.ca), Lead, Patient Partnership & Equity, Diversity and Inclusion, to explore how to better involve patient partners and communities into the research process. OICR's Patient and Family Advisory Council (PFAC) may participate in the funding request and progress reviews to provide ongoing guidance over the funding term.

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 the OICR website. OICR is committed to:

- Ensuring our research serves those from all communities, in particular those that are historically underrepresented;
- Fostering a more diverse and inclusive research community;
- Creating an 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; and
- Sharing best practices and lessons learned to help drive equity, diversity and inclusion across the cancer research community.

OICR is committed to embracing the concepts of equity, diversity and inclusion (EDI) in our research design, practice, personnel support mechanisms, and training. It is mandatory for all ReportNet users to answer a series of demographic questions to assist the Institute with metric reporting. The questions are similar to those asked on the Canada Research Chairs Program Self-Identification Form, based on the current standards used by Statistics Canada in the Census. If an applicant prefers not to self-identify and/or provide the requested information, they may select "Prefer not to answer" for any or all the questions. Self-identification or the decision to withhold self-identification information will not be used as part of the review process for funding applications. Opting to answer or not answer these questions will not impact the applicant's chances of receiving funding from OICR, now or in the future, and responses will not be shared as part of the review process. To update your profile in ReportNet, click on the initial of your first name at the top right-hand corner of the screen, and select 'User Profile'. Complete the questions under 'Demographics' and click Save. Responses to the demographics questions may be changed in the user's profile at any time.

2.7. Overview of application requirements using the online submission system

NOIs, LOIs and full applications are to be submitted using ReportNet, OICR's online system for managing grants and awards.

Applicants who have not used ReportNet before must register by visiting https://oicr.factorial.ca/s_Login.jsp and selecting 'Register' under 'New User?'. Once an account has been created, applicants can login to their account to view OICR funding opportunities and the associated RFAs (at the bottom of the screen under 'Funding Opportunities').

Applicants who have used ReportNet before can login to their account at https://oicr.factorial.ca/s_Login.jsp. If after logging in you see the screen in Figure 3 below, click on the 'list' icon on the menu at the top right-hand side of your screen and select 'Applicant' from the dropdown menu. If you do not see this option, please contact the OICR Scientific Secretariat office at ScientificSecretariat@oicr.on.ca.

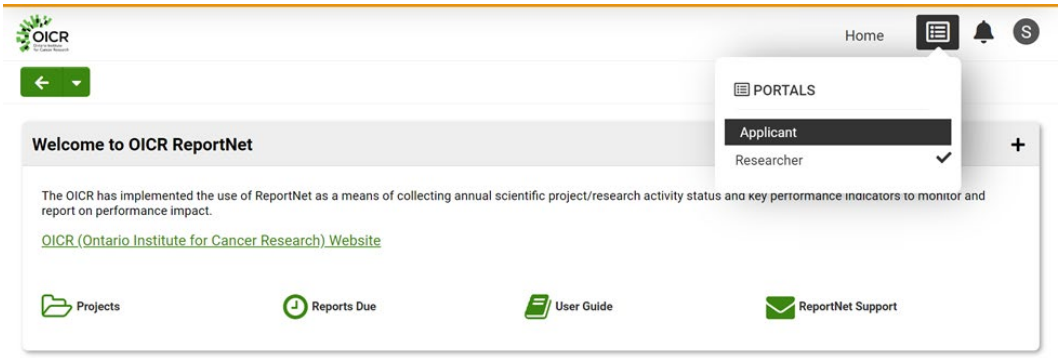


Figure 3: *How to toggle to the Applicant portal to apply for funding opportunities*

Completing fields in ReportNet
Open text fields in ReportNet accept plain text only, meaning that any text formatting (bold, italic or underlined font, bulleted lists, etc.) will not be accepted. For file uploads, please use 11-point Arial font, single spacing and one-inch margins.

Contact information
The OICR Scientific Secretariat (ScientificSecretariat@oicr.on.ca) is available to help with any questions regarding the online submission process.

2.7.1. Completing a Notice of Intent

The 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 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 and to ensure sufficient time to complete the LOI by the deadline.

Application information

The system will pre-populate the PI's information from their ReportNet profile. PIs must attest that they have completed the Demographics questions in their ReportNet profile. To update your profile in ReportNet, click on the initial of your first name at the top right-hand corner of the screen, and select 'User Profile'. Complete the questions under "Demographics' and click Save.

Additional information, outlined below, is to be provided by the applicant(s). Required fields are marked with a red asterisk in ReportNet. Word counts, where applicable, are noted.

- **What project category are you applying for?** Only EV or EA projects are eligible under this RFA; select the appropriate category for your proposal;
- **Title:** Once a title for your 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 a PI Delegate(s) can be added using the '**Invite Contacts**' button:

  Principal Investigator (PI): Has responsibility for the intellectual direction of the project, as well as the technical and scientific content, the budget, deliverables and milestones, and supervision of members of the research team carrying out the activities of the project. If there is more than one PI, the PI is the individual who initiates the application and Co-PIs can be added subsequently. The PI can submit the application once complete (Co-PIs are not able to submit the application on behalf of the named PI).

  Co-Investigator: Carries out research activities related to the project. Co-Investigators are not able to submit the application on behalf of the PI(s).

  Collaborator: 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/advocates 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: You must first provide a project title and hit 'Save draft' for the 'Invite contacts' button to appear;
- All PIs/Co-PIs, Co-Investigators, and/or Collaborators involved in the application **must** be invited;
- Note: Before inviting contacts to your application, contact them to confirm if they have a ReportNet account, and if so, which email address they are registered with. Please use their registered email address when inviting them to your application. 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 create their profile in the system. If you wish to remove an invited contact from your application, click on 'Invite contacts' and select the 'x' button at the end of the applicable contact's row. If you wish to change their role on your application (i.e., from collaborator to Co-Investigator), you may remove them as an invited contact, and then re-add them in the new role. If you have any questions, please contact the OICR Scientific Secretariat (ScientificSecretariat@oicr.on.ca).

- **Start date:** Enter a funding start date for the application, no earlier than December 1, 2022;
- **End date:** Enter a funding end date for the application. EV projects can be a maximum of two (2) years; EA projects can be a maximum of one (1) year;
- **Application type:** Indicate whether this is an initial application for this proposal or a re-application.
  - **Note:** If '*Re-application*' is selected, additional information will be requested at the full application stage, including a requirement to upload the Scientific Officer and reviewer reports from the initial application.
- **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.

Once you have completed all required fields, select the green '*Submit and Continue to LOI*' button at the bottom of the screen. You will immediately be provided with access to the LOI form.

2.7.2. Completing a Letter of Intent

Information provided in the NOI will be carried over to the LOI form and is editable. The *'Contacts'* will also be editable at this stage.

- **Has this work been published/patented?** (max. 100 words) If *'Yes'* is selected, you will need to describe how the proposal builds upon the published/patented work;
- **Target and/or pathway** (max. 25 words): Indicate the target or pathway that will be explored in this proposal;
- **Molecule type**: Select from the options provided;
- **Target class** (max. 25 words): Indicate the target class that will be investigated in this proposal;
- **Cancer type:** Pre-populated from NOI stage (editable);
- **Lay summary** (max. 350 words)**:** The lay summary should explain complex research ideas in simple terms and plain language that can be easily understood by non-specialists. 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); and
  - 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.
- **Scientific summary** (max. 350 words): Provide an executive summary of the proposal;
- **Research plan – LOI** (max. 1500 words, excluding figures, tables and references. Label file name: Request ID[1]–Research Plan_LOI and upload as a PDF). Using the following headings, address the items below **(bulleted lists are strongly encouraged where appropriate**):
  - **Target validation and disease association**
    - Define the project hypothesis, specifying the desired mechanism of modulation (e.g., inhibitor, agonist, etc.) and the intended modality (e.g., small molecule, biologic, etc.);
    - Provide bioinformatics and systems biology queries of relevant knowledge bases (e.g., DepMap, TCGA, cBioPortal, MalaCards, etc.) showing clear disease indication association and/or target dependency of the disease area;
    - Describe the target's function and interactions with other players in the pathway(s);
    - Provide the scientific and clinical evidence supporting prosecution of the target for the treatment of the cancer type in the intended patient population. This must contain the minimal requirements for portfolio entry as described in section 1.4; and

[1] Your project's Request ID can be located on your application in ReportNet and is in the format: P.CTIP.###

- Describe gaps or uncertainties related to target validation and disease association, and research plans to address these.

- **Safety**
  - Describe any known or potential toxicology considerations and plans to monitor these liabilities;
  - Provide data on published knockout models indicating safety and little or no off-target effects; and
  - Describe any known or suspected toxicity with other previously developed drugs hitting the same pathway of the proposed target.
- **Feasibility**
  - Describe the primary screening assay(s) that the team plans to validate (for EA proposal) or has validated (for LA proposal) and the status and performance of the assay(s);
  - Provide information on the resources available to the applicant to support target enablement and primary screen development (e.g., recombinant target protein, cell lines including patient-derived lines, controls, etc.);
  - Describe all secondary and orthogonal assays (e.g., target engagement, selectivity, cell-based, etc.) to be used for confirming Hit molecules (LA stage deliverable) and the status and performance of the assays;
  - Provide information on the resources available to the applicant to support development of all secondary and orthogonal assays;
  - Describe the chemical collections to be used for primary screening;
  - Describe the Hit (for LA proposal) or Lead (for LG proposal) generation strategy and the tools needed to execute on that strategy (e.g., crystal structure or homology models, medicinal chemistry or biologics-based approaches);
  - Specify the biomarkers (pharmacodynamic, efficacy, and/or resistance) to be measured and if they have been validated or a plan to address validation;
  - Describe the team composition and collaborations, planned or in place, and the expertise that will be contributed to the project by each PI and collaborator; and
  - Separately upload a testing cascade. The testing cascade must not exceed one page. Refer to Appendix IV for an example.
- **Strategic considerations**
  - Describe the unmet clinical need, identifying the current standard of care for the disease indication, and its limitations;
  - Describe the competitive landscape and the differentiation features of the proposed therapeutic approach;
  - Describe issues with contemporary efforts with the same or related target including reasons for successes or failures based on biologic, pharmacologic or toxicity concerns; and
  - Indicate if molecules identified from this effort have the potential to be FiC or BiC potential.

- **LOI uploads**: The following items should be attached to the LOI:
  - **Figures, tables and references** (max. of six figures and tables). Label file name: Request ID_Figures tables ref_LOI, and upload as a PDF; and
  - **Testing cascade – LOI** (must not exceed one page; refer to Appendix IV. Label file name: Request ID_Testing cascade_LOI, and upload as a PDF).

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

2.7.3. Completing a full application

Information provided at the NOI and LOI stage will be carried over to the full application form and, with the exception of '*Research plan - LOI*', will be editable. Only LOI applicants invited to submit a full application following the LOI review will be provided with access to the full application form.

Applicants invited to submit a full application will have an opportunity to send inquiries to TPAC, via email to ScientificSecretariat@oicr.on.ca, until August 31, 2022. The Scientific Secretariat will coordinate responses from TPAC and return to applicants in a timely fashion.

Applicant information

PI attestation: The PI submitting the application must agree to the statement on research integrity prior to submission of a full application.

Administrative authority contact information

Information will be collected for the PI and any Co-PIs. The administrative authority is an individual who can legally bind the institution. Typically, a Vice President of Research, or similar.

Project details

- Re-application - Response to reviewer feedback: If you are submitting your proposal as a re-application, complete this section and indicate what modifications have been made as a result of the critiques. If you choose not to address reviewer feedback, the application will be reviewed as an initial application; and
- SO and reviewer reports from the initial application: If you are submitting your proposal as a re-application, upload the Scientific Officer and reviewer reports from the initial application.

EDI considerations

Applicants should outline how the research team and proposal will align with the principles of EDI. EDI considerations will be discussed during the review process. Feedback regarding the appropriateness of the approach(es) being undertaken, including areas where the team is doing well, 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. **The Lead PI will have to attest to the completion of these training modules prior to submission.**

Among others, OICR supports 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)

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 for projects being conducted at OICR.

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 project 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.

Research proposal

Research plan – Full application (max. 5000 words. Label file name: Request ID–Research Plan_Full and upload as a PDF): Using the headings indicated, provide details on the proposed research. The research plan must **expand** upon the content provided at the LOI stage (black bullets below) as well as address the additional full application requirements (blue bullets below).

- **Target validation and disease association**
  - Define the project hypothesis specifying the desired mechanism of modulation (e.g., inhibitor, agonist, etc.) and the intended modality (e.g., small molecule, biologic, etc.);
  - Provide bioinformatics and systems biology queries of relevant knowledge bases (e.g., DepMap, TCGA, cBioPortal, MalaCards, etc.) showing clear disease indication association and/or target dependency of the disease area;
  - Describe the target's function and interactions with other players in the pathway(s);
  - Provide the scientific and clinical evidence supporting prosecution of the target for the treatment of the cancer type in the intended patient population. This must contain the minimal requirements for portfolio entry as described in section 1.4;
  - Describe gaps or uncertainties related to target validation and disease association, and research plans to address these;
  - Describe the intended route of administration; and
  - Describe the mechanism of action and related pathway pharmacology.
- **Safety**
  - Describe any known or potential toxicology considerations and plans to monitor these liabilities;
  - Provide data on published knockout models indicating safety and little or no off-target effects; and
  - Describe any known or suspected toxicity with other previously developed drugs hitting the same pathway of the proposed target.
- **Feasibility**
  - Describe the primary screening assay(s) that the team plans to validate (for EA proposal) or has validated (for LA proposal) and the status and performance of the assay(s);
  - Provide information on the resources available to the applicant to support target enablement and primary screen development (e.g., recombinant target protein, cell lines including patient-derived lines, controls, etc.);
  - Describe all secondary and orthogonal assays (e.g., target engagement, selectivity, cell-based, etc.) to be used for confirming Hit molecules (LA stage deliverable) and the status and performance of the assays;
  - Provide information on the resources available to the applicant to support development of all secondary and orthogonal assays;

- Describe the chemical collections to be used for primary screening;
- Describe the Hit (for LA proposal) or Lead (for LG proposal) generation strategy and the tools needed to execute on that strategy (e.g., crystal structure or homology models, medicinal chemistry approaches);
- Specify the biomarkers (pharmacodynamic, efficacy, and/or resistance) to be measured and if they have been validated or a plan to address validation;
- Describe the team composition and collaborations, planned or in place, and the expertise that will be contributed to the project by each PI and collaborator; and
- Separately upload a testing cascade. The testing cascade must not exceed one page. Refer to Appendix IV for an example;
- Describe plans to address issues associated with primary, secondary, and orthogonal assay development including the acquisition of key assay components and reagents;
- Specify any interactions with OICR's Collaborative Research Resources or other research areas under OICR's Clinical Translation and Adaptive Oncology themes;
- Describe the desired selectivity profile, including any intentional polypharmacology; and
- Summarize host/partner institution facilities and resources available to support research execution.

- **Strategic considerations**
  - Describe the unmet clinical need, identifying the current standard of care for the disease indication, and its limitations;
  - Describe the competitive landscape and the differentiation features of the proposed therapeutic approach;
  - Describe issues with contemporary efforts with the same or related target including reasons for successes or failures based on biologic, pharmacologic or toxicity concerns;
  - Indicate if molecules identified from this effort have the potential to be FiC or BiC potential;
  - 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 (see section 2.6);
  - Describe patient selection opportunities;
  - Provide an estimate of the size of the target patient population; and
  - Describe any known or anticipated hurdles associated with regulatory approval, adoption of the therapeutic by patients or clinicians, and reimbursement of the medicine.

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 work). This information may be shared with FACIT Inc., OICR's commercialization partner, should the proposal be funded; and
- **Data management plan** (max. 500 words): Applicants must provide a data sharing and access plan, as well as a data storage requirements and retention plan, specifying how much data will be generated or transferred into OICR (if applicable) during the course of the project, and the plan for retaining/archiving with the ability to restore the data for the five-year period following its conclusion. See Appendix V for additional information.

Attachments

The following items should be attached to the application:

- Figures, tables and references (max. of 12 figures and tables). Label file name: Request ID_Figures tables ref_Full, and upload as a PDF;

- Testing cascade – Full application (must not exceed one page; refer to Appendix IV. Label file name: Request ID_Testing Cascade_Full, and upload as a PDF);
- Host institution commitment letter (label file name: Request ID_HI letter, and upload as a PDF): 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. Importantly, the letters must declare that the signatories have read and acknowledged the provincial government's "Ontario First" mandate (Appendix III) and agree to abide by the related terms through a funding agreement in the event of a successful application. Letters should also be included from the Host Institution of any Co-PIs;
- Deliverables and milestones, using the Excel template provided (Label file name: Request ID_DM, and upload as an Excel file)
    - 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; and
    - Both deliverables and milestones must be measurable and possess a target date for completion (provide the quarter and fiscal year of projected achievement).
- Budget, using the Excel template provided (Label file name: Request ID_Budget, and upload as an Excel file)
    - Download the budget template provided in the application and complete budget request details (see Appendix II for eligible expenses); and
    - The template will automatically calculate overhead at 30 per cent for overhead eligible expenses (see Appendix II) 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 2.3.**
- CVs
    - Compile CVs (**abbreviated CVs are encouraged**) for the following individuals (label file name: Request ID_CVs, and upload as a single, bookmarked PDF):
        - PIs and Co-PIs; 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; and
        - Research outputs (e.g., publications, IP, presentations, etc.)
- Other
    - Include a list of all current and pending funding applications, highlighting any overlap with the present application (label file name: Request ID_Funding apps, and upload as a PDF); and

- Co-funding letters, if applicable (label file name: Request ID_Co-funding letter, and upload as a single, bookmarked PDF): 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 template. 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 template.

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

3. REVIEW PROCESS

3.1. LOI review

LOIs will be reviewed by TPAC, and *ad hoc* experts, if required, along the four themes of target validation/disease association, safety, feasibility and strategic considerations (Appendix I).

Reviewers will provide feedback and an overall recommendation ('Yes to full application', 'No to full application', or 'Requires discussion').

LOIs that receive a 'No' recommendation from both reviewers may be triaged prior to the panel discussion. Only applications that are ranked 'Yes' by both primary and secondary reviewers, after the panel discussion will be invited to submit a full application.

If the number and quality of LOIs received far surpasses the number of applications that can reasonably be reviewed at the full application stage, TPAC will be asked to score proposals in order to establish a cut-off that will be used to triage applications.

3.2. Full application review

Administrative review

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

External peer review

Review panel

Full applications will be reviewed by a panel consisting of TPAC and *ad hoc* experts, if required. The panel's mandate will be to evaluate the merits of the applications. Panel members will be assigned to applications as primary and secondary reviewers and will provide a brief preliminary report outlining their feedback on the proposal.

Patient and Family Advisory Council (PFAC)

Applications may be shared with the OICR PFAC, or their delegates, who will review application materials and may 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 (SO) report that will be provided to teams following the review meeting.

Reviewer reports

Reviewers will be tasked with providing a brief report for their assigned projects using the following criteria (see Appendix I for additional information):

- Target validation/disease association;
- Safety;
- Feasibility; and
- Strategic considerations.

Reviewers will also provide scores for each criterion and 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 full application review meeting (Yes, No or Undecided). Applications that receive a 'No' from both reviewers may not be discussed further at the review meeting.

Review meeting

Depending on application pressure, and with the approval of the TPAC Chair, applications may be ranked by overall score prior to the review meeting so that only the top applications in contention for funding are 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 TPAC Chair with support from OICR's Scientific Secretariat and will include representatives from OICR and PFAC (if appropriate). Following open discussion, the panel will recommend a consensus overall 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.

3.3. Notification of Decision

A meeting report summarizing the review discussion and recommendation for each application will be prepared by an 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 early December 2022. Funding will be retroactive to December 1, 2022 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, 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.

Note that delays in execution of research agreements may impact OICR's ability to disburse funds. **Funding is contingent upon available funding from the Government of Ontario via the Ministry of Colleges and Universities.**

5. REPORTING REQUIREMENTS

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 April-June	Quarterly financial report Due: July 31	Review and submit quarterly financial and operational status report Due: August 15
Q2 July-September	Quarterly financial report Due: October 31	Review and submit quarterly financial and operational status report Due: November 15
Q3 October-December	Quarterly financial report Due: January 31	Review and submit quarterly financial operational status report Due: February 15
Q4 January-March	Quarterly financial report Due: April 30	Review and submit financial and operational status report Due: May 15
Q1-Q4 April-March	Annual fiscal year financial report: Due May 31	N/A

Progress and 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**: Reporting requirements*

Report	Period covered	Due date	Person(s) responsible	Action
Progress update	Q1-Q2	Q3	PIs/Co-PIs	Provide status updates on Deliverables and Milestones (D/M), progress update to TPAC
Progress update	Q3-Q4	Q1	PIs/Co-PIs	Provide status updates on D/Ms, progress update to TPAC
KPI report	Fiscal year: April-March	April 30 of the subsequent fiscal year	PIs/Co-PIs	Provide quantitative KPIs using ReportNet (OICR's online submission system)

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 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).

9. APPENDIX I: EVALUATION RUBRIC AND SCORING CRITERIA

LOIs and full applications will be assessed by the Therapeutics Pipeline Advisory Committee (TPAC) using an evaluation rubric developed along four themes of inquiry:

- Target validation/disease association;
- Safety;
- Feasibility; and
- Strategic considerations.

The rubric below is meant to provide *guidance* for discussion and feedback to the teams. If additional guidance is required, reviewers should reach out to the Scientific Secretariat for assistance. The application will be discussed and evaluated against the listed criteria, where applicable.

Table 3: *Evaluation rubric for CTIP proposals*

Target validation/disease association	Safety	Feasibility	Strategic considerations
Human disease altered by drugs hitting target and/or target pathway from Phase II, III or post-marketing decision clinical trial data	Toxicity liabilities can be tracked and are manageable	Relevant *in vivo* models with and efficacy endpoints	Clinical need
Promising Phase I-IIa clinical trial data with other drugs hitting the target and/or target pathway or similar biology	Toxicity profile of known ligands understood	Relevant *in vivo* models with pharmacodynamic endpoints	Clinical delivery
Biomarker for target dependence understood in the disease	Toxicity liabilities in genetically modified animals is understood	Relevant organoid-based assays with relevant endpoints	Target patient population
Preclinical, dose-dependent efficacy modeling predictive of human efficacy, with human genetic evidence	Toxicity liabilities of the pathway, anti-targets and isoforms understood	Relevant patient-derived cell-based assays with relevant endpoints	Market opportunity
Intervention at target in pathway using selective tool compounds demonstrates preclinical efficacy	Toxicity assays are available and affordable for the stage	Relevant cell-based assays (immortalized cell lines) with relevant endpoints	Differentiation: First-in-class or Best-in-class potential
Transgenic or knockout animals have disease phenotype	Toxicity liabilities can be measured reproducibly	Biomarker(s) identified and validated	Competitive landscape and history of successful or unsuccessful targeting of the major pathway or organelle under question

Target validation/disease association	Safety	Feasibility	Strategic considerations
Data implicating target in disease state pathogenesis and/or demonstrated pharmacology in pathway		Selectivity assays (target class and target-specific isoforms) with no undue risk that required recombinant proteins or protein complex cannot be synthesized	Freedom to operate
Pharmaceutical intervention at the target unproven but suggestive research		Availability of computational expertise	Regulatory considerations
Transgenic or knockout (including shRNA or CRISPR *in vivo* models) animals demonstrate linkage to physiology and/or disease		Availability of crystal structure or homology model	Reimbursement
Loss or gain of function in patient-derived organoids shows disease phenotype		Feasibility of structure-based drug design	
Loss or gain of function in patient-derived cell-based assay shows disease phenotype		Confirmatory/binding assays	
Target function linked to pathway which is abnormal in the disease based on cell biology research		Biochemical inhibition assays	
Loss (e.g., shRNA, CRISPR, partially selective tool compounds) or gain (e.g., overexpression) of function phenotype in immortalized cell lines		Feasibility of protein complex assembly suitable for screening	
Target function linked to disease progression and/or poor prognosis		Availability/feasibility of key screening reagents (e.g., target, recombinant proteins, functional domains, inactive constructs, selectivity reagents, etc.)	
Target tissue distribution known		Availability of chemical collections for screening	
New therapeutic hypothesis or disease association of target by clinical genetics (e.g., mutation, amplification, translocation)		Team composition and collaborations	
Disease hypothesis based on pathway or related protein biology			

Full applications for CTIP projects will receive scores for each theme outlined in the evaluation rubric above (Table 3), as well as an overall score for the project. The final overall score will be used to rank projects for funding consideration. Scores will be assigned as outlined in Table 4.

Table 4: *Scoring*

Overall impact	Score	Description
High	8	Excellent with no weaknesses identified
	7	Excellent with minor weaknesses identified
Medium	6	Very good with minor weaknesses identified
	5	Very good with moderate weaknesses identified
	4	Good with moderate weaknesses identified
Low	3	Fair with moderate weaknesses identified
	2	Poor with moderate to major weaknesses identified
	1	Poor with major weaknesses identified

10. APPENDIX II: 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/Clinical Trials 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/Clinical Trials. In-kind expenses are not reimbursable.

Eligible Expenses are described in the categories below. Expenses of the Projects/Sub-Projects/Clinical Trials, 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. Post-award budget questions should be addressed to OICR Research Operations at ResearchOps@oicr.on.ca.

Table 5 outlines Eligible Expense categories and specifies which are eligible for overhead.

Table 5: 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 and communication 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
***NOTE**: All expenses incurred at OICR are NOT eligible for overhead*	
NOTE:** Overhead is NOT provided for personnel awards, including the **OICR Investigator Award Program	

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).

Only Project/Sub-Project staff salaries and benefits that are not funded by monies received from any other grants from either the Government of Ontario or Government of Canada are Eligible Expenses.

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 exceptions being the ***OICR Investigator Awards Program***, where the salary of the Principal Investigator is an Eligible Expense, and postdoctoral fellows who are listed as co-applicants on an application for funding. 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 (5%) of the annual award value and are eligible over the term of the award only. Requests in excess of five per cent (5%) 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 in order 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 Executive Vice President, Head of Implementation Science.

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 Executive Vice President, Head of Implementation Science.

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

Fees for use of equipment owned by the host institution are not Eligible Expenses, unless such fees are charged to all institutional users based on a published schedule.

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 (5%) 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 and communication activities directly related to the Projects/Sub-Projects: Expenses associated with educational outreach activities/workshops for the general public, students, stakeholders and peer groups, marketing and communication services and materials, website hosting/development, online application forms, and other knowledge materials, directly related to the Projects/Sub-Projects, 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), and networking initiatives/events (e.g., workshops, seminars, meetings), 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 (5%) 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. Audit costs may be included in a funding application as Eligible Expenses.

Recipients of financial contributions may be requested to submit an independent auditor's certificate with their year-end financial report. Such costs may be included in a funding application as Eligible Expenses.

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 (3%) of direct research expenses per year. Telecommunications expenses (e.g., telephone, internet, mail, courier) are eligible only if such costs are not already covered by the Recipient.

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

Overhead/indirect costs

Overhead (also known as indirect costs) will be automatically calculated in CaAwardNet, OICR's financial tracking tool. Overhead is not eligible for OICR-based expenses. OICR will provide up to thirty per cent (30%) 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. Overhead is NOT provided for expenses that will be incurred at OICR.

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 thirty per cent (30%) 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 fifteen per cent [15%] of the total budget including overhead costs) will be allowed at the time of submission.

Non-eligible expenses

As stated earlier in this Schedule D, expenses of the Projects/Sub-Projects/Clinical Trials, which are not described in the categories above, require written approval by OICR. Without limiting the foregoing, 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, and salaries for co-applicants who are not independent researchers*);
- Insurance for equipment;
- Benefits for trainees (i.e., undergraduate and graduate students). Note that benefits for undergraduate coop students and postdoctoral fellows are an allowable cost and should be in accordance with the host institution's policy;
- Rent, maintenance, and leasehold/facility infrastructure improvements;
- Bonuses;
- 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; and
- Any project costs that are funded, will be funded, or reimbursed by any third party, ministry, agency, or organization of the Government of Ontario.

*An independent researcher is an individual who:

- Is autonomous regarding their research activities; and

- Has an academic or research appointment which:
  - Must commence by the effective date of funding; and
  - Allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees (if applicable, as per their institution's policy), and to publish the research results; and
  - Obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with OICR funding.

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.

**In instances where the Head is also a recipient of OICR funding, the deviation should also be discussed with the Senior Director, Research Operations.*

Reallocation of budget

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

Reallocation of more than fifteen per cent (15%) of the total budget will require express written permission of OICR's Executive Vice President, Head of Implementation Science 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 Executive Vice President, Head of Implementation Science or Senior Director, Research Operations. Application for an NCE must be made in writing and supported by appropriate justification.

11. APPENDIX III: "ONTARIO FIRST" MANDATE

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 OICR's commercialization agent or assignee 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.

12. APPENDIX IV: TESTING CASCADE

The images in Appendix IV (Figures 4, 5 and 6) are the property of the Ontario Institute for Cancer Research.

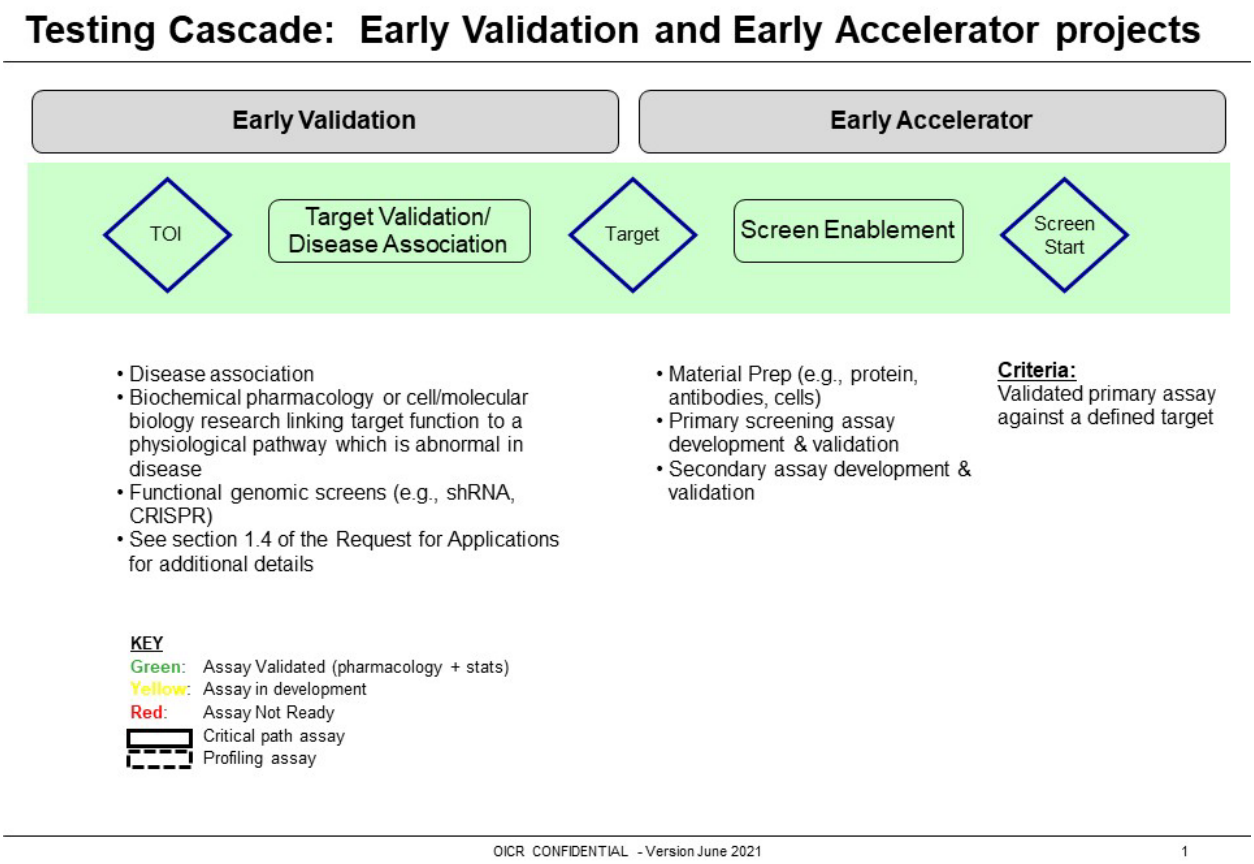
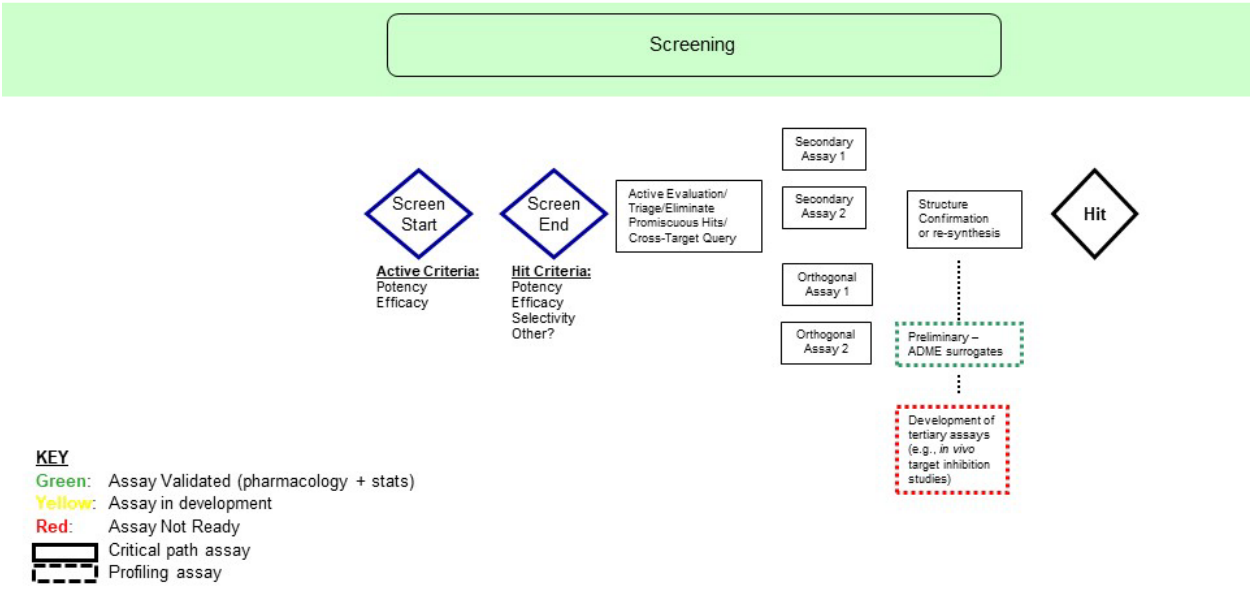


Figure 4: *Testing cascade for Early Validation and Early Accelerator projects*

- The testing cascade should identify which assays are completely validated (in green boxes), in progress (yellow boxes), or required (red boxes);
- Critical path assays should be in solid boxes, profiling assays in dotted boxes; and
- Statistical validation data (both inter- and intra-assay) should be listed and documented in a supporting document.

Testing Cascade: Late Accelerator Project (Screen → Hit)

This RFA is limited to Early Validation and Early Accelerator project proposals only. This slide is shown for awareness.



OICR CONFIDENTIAL - Version June 2021 2

Figure 5: *Testing cascade for Late Accelerator projects*

- The testing cascade should identify which assays are completely validated (in green boxes), in progress (yellow boxes), or required (red boxes);
- Critical path assays should be in solid boxes, profiling assays in dotted boxes; and
- Statistical validation data (both inter- and intra-assay) should be listed and documented in a supporting document.

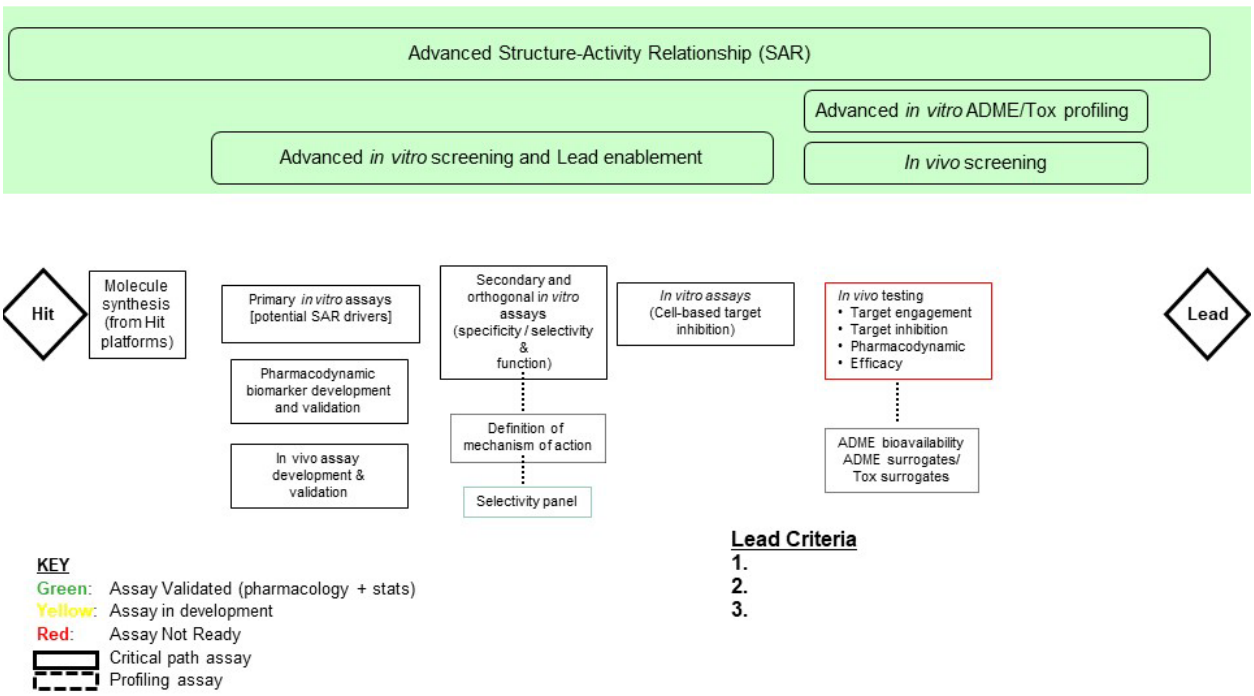


Figure 6: *Testing cascade for Lead Generation projects*

- The testing cascade should identify which assays are completely validated (in green boxes), in progress (yellow boxes), or required (red boxes);
- Critical path assays should be in solid boxes, profiling assays in dotted boxes; and
- Statistical validation data (both inter- and intra-assay) should be listed and documented in a supporting document.

13. APPENDIX V: DATA SHARING, OPEN ACCESS AND RETENTION

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.

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. Applicants must provide a data sharing and accessibility plan, specifying how data generated by the OICR-funded research will be shared and how the research community can access the data.

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 five-year period after its conclusion. If needed, applicants can request funds to support this data retention requirement, however, charges are capped at five (5) percent 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 are not in addition to the budget requested to conduct the project.