



April 16, 2021

Clinical Translation Pathway

Pre-CATA and CATA Funding Opportunities

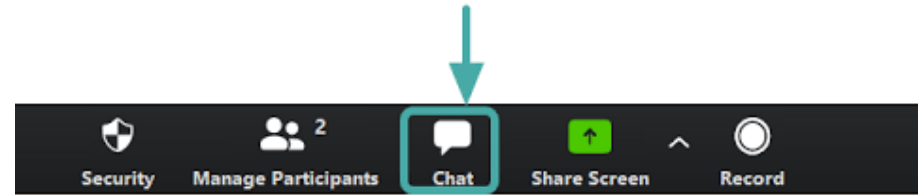
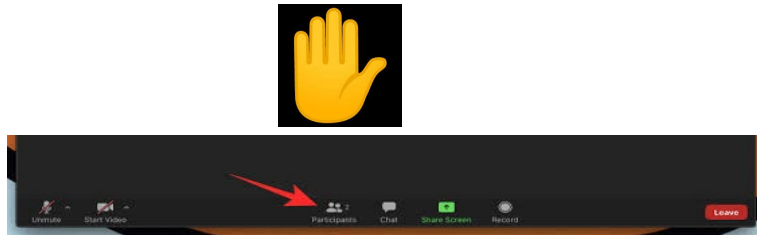


Objectives

- Communicate the goals and focus of the OICR Clinical Translation (CT) theme in the new OICR strategic plan.
- Outline the objectives and scope of Pre-CATA and CATA funding opportunities within CT so scientists understand the 'fit' for their research.
- Provide high level details on the application components and timeline for each of the new funding programs.

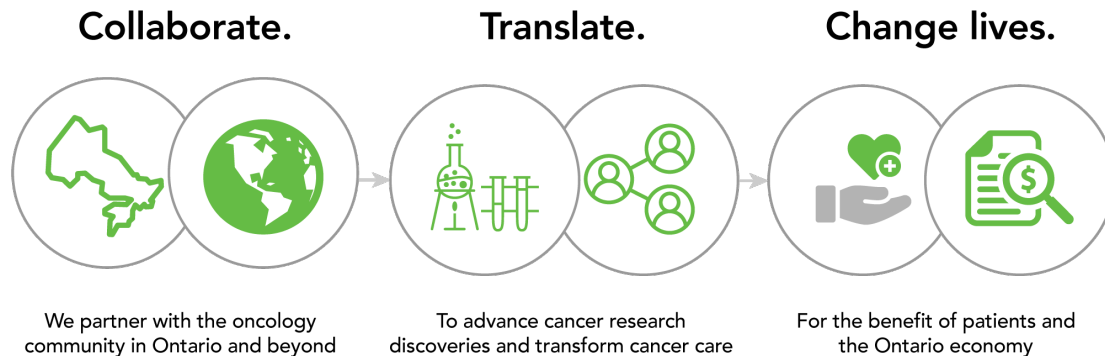
Format

- Presentation: recorded for online posting. Save questions for Q and A.
- Open Q and A period



About OICR

The Ontario Institute for Cancer Research (OICR) mobilizes and reinforces Ontario research excellence in the fight against cancer to benefit patients and produce economic value from cancer discoveries, making Ontario a global leader in cancer research and innovation.



OICR's research blueprint

OUR INTEGRATED RESEARCH THEMES

Clinical Translation

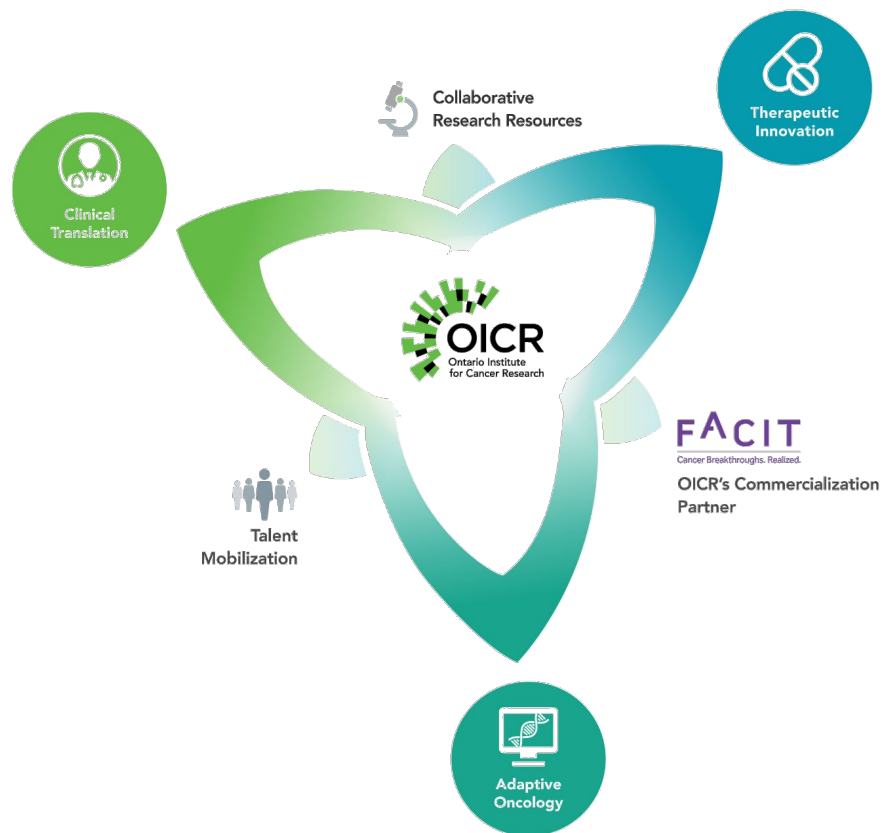
Advance Ontario cancer discoveries through early clinical validation, partnering with industry and the health system for downstream development and implementation

Therapeutic Innovation

Validate novel cancer drug targets and advance selective therapeutic candidates to clinical development

Adaptive Oncology

Develop knowledge & approaches to monitor cancer over its lifecycle in order to enable precise and proactive clinical management



Clinical Translation 2021-2026

Goal: to advance cancer discoveries **through to early clinical validation**, partnering with patients, industry and the health system for development and implementation.



Components

Research Initiative

- Clinical Translation Pathway (CTP): supports the **development and validation** of practice-changing diagnostics, decision-making tools and therapeutics through clinical testing towards health system implementation. Support is through ***four funding streams***:
 - i. Pre-Clinical Acceleration Team Award (Pre-CATA)
 - ii. Clinical Acceleration Team Award (CATA)
 - iii. Window of Opportunity (WOO) Trial Award
 - iv. Convergence Projects Award

Research Platforms and Networks

- Ontario Health Study: CanPath
- Ontario Cancer Research Ethics Board
- Canadian Clinical Trials Network



CTP principles

- Aligned with OICR's 2021-2026 Strategic Plan:
 - Focus on primary diagnosed and early recurrent cancer;
 - Improved disease detection and interventions.
- Studies have a clear path to clinical impact;
 - Pre-CATA: not pure discovery, path to clinical trial;
 - CATA: “recruitment ready”, accrual within 8 months, path to downstream clinical impact.
- Collaborative, multi-centre, and where possible, leverage OICR programs, networks and resources;
- Studies embrace the principles of Patient Partnership and EDI.

Governance

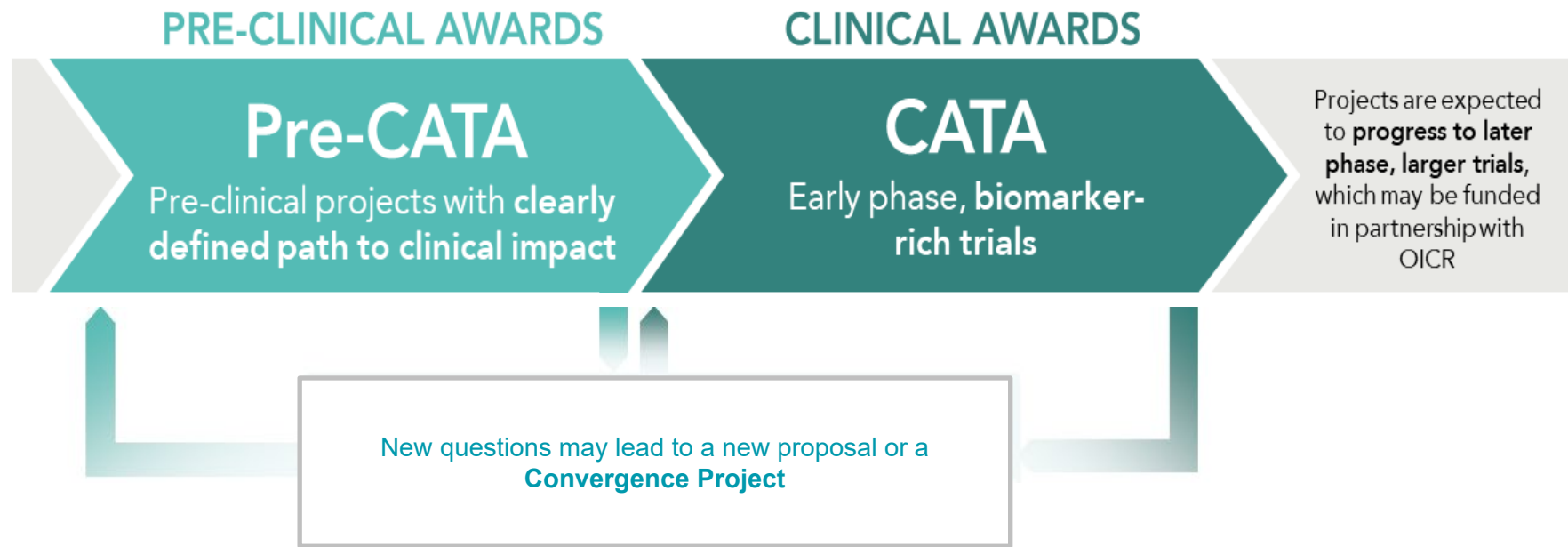
OICR Leadership

- Steven Gallinger: Clinical Translation Pathway
- Christine Williams, OICR Deputy Director: Clinical Translation Networks

Scientific Advisory Committee

- Provide scientific, strategic and funding recommendations;
- Monitor progress (biannual progress reports) and advance recommendations for underperforming projects and trials:
 - Modification of project plan or timelines;
 - Reduction in funding support;
 - Discontinuation of projects/trials not meeting milestones.

CLINICAL ACCELERATION TEAM AWARDS (CATA)



Pre-CATA

Focus	Stage/disease condition	In scope	Out of scope	Funding
Biomarker development	<ul style="list-style-type: none"> • <u>Primary-diagnosed disease</u>: treatment naive stage I-III, amenable to definitive therapy. • <u>Early recurrent disease</u>: locoregional and oligometastatic recurrence, eligible for first line therapies (systemic, surgical or ablative therapies). 	<p>All biomarker development studies after biomarker discovery but prior to prospective clinical trials</p>	<ul style="list-style-type: none"> • Basic science including biomarker and target discovery. • Therapeutic development activities supported by OICR's Therapeutic Intervention 	<ul style="list-style-type: none"> • 3-year awards • \$250K/yr. (inclusive of OH) • Start: Oct 2021 • Future: 2023
Therapeutic development		<ul style="list-style-type: none"> • Late pre-clinical development of new therapies leading into clinical testing (data supporting impending clinical trials). 		

Biomarker development

Driven by clinical need with a defined intended use

In- scope

PreCATA

CATA

**Biomarker
Discovery**

**Biomarker
confirmation**

Assay development

**Biomarker
validation
(using clinically
validated platform)**

Clinical validity

Clinical use

Discovery
cohort

Independent
cohort

Independent or
discovery cohort

Retrospective
cohort
(Level 2
evidence)

"Prospective"
-retrospective cohort
(Level 1 evidence)

Prospective
Clinical Trial
(Level 1 evidence)

Biomarker
candidates
identified

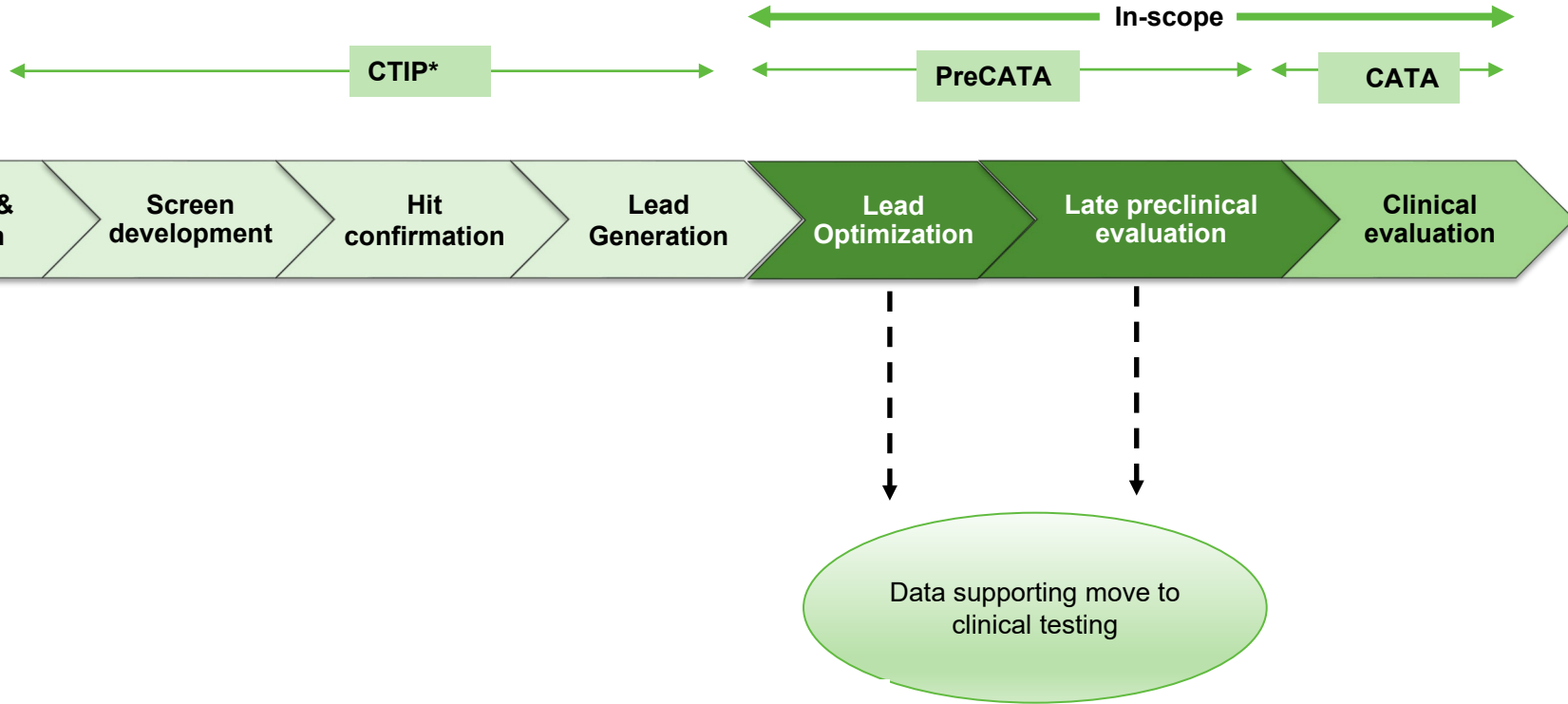
Biomarker
candidates
selected

Assay on
clinical platform

Biomarker
characteristics
confirmed

Clinical benefit
confirmed

Therapeutic development



CTIP*

- Cancer Therapeutics Innovation Pipeline
- Funding program in Therapeutic Innovation
- <https://oicr.on.ca/research-portfolio/cancer-therapeutics-innovation-pipeline/>

CATA

Focus	Stage/disease condition	In-scope	Funding
Phase I-II, early stage disease	<ul style="list-style-type: none"> • <u>Primary-diagnosed disease</u>: treatment naive stage I-III, amenable to definitive therapy and correlative sample collection. • <u>Early recurrent disease</u>: locoregional and oligometastatic recurrence, eligible for first line therapies (systemic, surgical or ablative therapies). 	<ul style="list-style-type: none"> • Prospective clinical validation trials: <ul style="list-style-type: none"> • Biomarkers ('omic', liquid, imaging) for early cancer detection, diagnosis, improved risk stratification, prediction to treatment response, and improved monitoring. • Interventions: <ul style="list-style-type: none"> • Therapeutics that intercept early cancer progression and early recurrence. • Modifications/improvements to standard of care. 	<ul style="list-style-type: none"> • 3-year awards • \$500K/yr. max (OH not eligible on trials) • Start: Oct 2021 • Future: 2023

CATA: out of scope

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

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

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

2021 RFA timelines: PreCATA & CATA

Letter of Intent

Full
Application

Final funding
Recommendations

Award Notice

Deadline: May 10

Review: Mid June

Evaluation criteria:

- Fit
- Potential for impact
- Feasibility

Deadline: August 12

Review: Early September

Evaluation criteria:

- Relevance;
- Excellence;
- Potential for impact;
- Feasibility/trial readiness;
- Leadership, team, collaborations.

CT-SAC: late September

- Receive funding recommendations (ranked list) from review panel.
- Will make an overall strategic/financial funding recommendation across both funding types.

End of September



LOI components: PreCATA and CATA

- 1500 words;
- Background and rationale;
- Clinical need/question being addressed;
- Alignment with CTP principles and funding stream (Fit);
- Pathway to clinical implementation (Impact);
- Research plan/trial synopsis (Feasibility);
- Recruitment readiness (Feasibility - CATA):
 - Credible plan for first patient accrued (within first 8 months);
 - Pharma (drug) and site engagement.

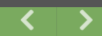
Full Application components: Pre-CATA

- Proposal (6000 words):
 - Background, rationale;
 - Clinical need/question being addressed;
 - Research execution plan;
 - Team details;
 - Study management;
 - Path to the clinic/future CATA.
- Budget: full budget, including leveraged funds, if available (e.g. pharma, other grants);
- Deliverables and milestones;
- Letters of support.

Full Application components: CATA

- Proposal (6000 words):
 - Background, rationale;
 - Clinical need/question being addressed;
 - Correlative biomarker investigations;
 - Study synopsis, schema, statistical plan;
 - Recruitment plan, accrual strategy;
 - Team, study management details;
 - Patient Partnership plan;
 - Study drug plan;
 - Path to clinical impact.
- Budget: full budget, including leveraged funds, if applicable (e.g. pharma, other grants).
- Deliverables and milestones: final protocol, ethics approval, site activation, 1st & last patient.
- **Protocol: reviewed and approved by partner site co-investigators, pharma and patient partners.**
- **Letters of support: pharma partner (drug supply, leveraged funds if applicable), participating site(s) co-investigators (patient population, study team commitment).**

0 of 0



#	Request ID	Project Title	Activity Type	Assigned	Due Date
No Results Found					

Funding Opportunities

1-2 of 2



#	Opportunity	Opportunity Details	Open Date	Close Date	
1	2021 Pre-Clinical Acceleration Team Awards (Pre-CATA) Funding Opportunity	This request for applications is specific for investigators wishing to apply for funding support for Pre-CATA Projects (pre-clinical projects with a clear path to the clinic, with a focus on pre-clinical development of biomarkers, diagnostics and therapeutics). Pre-CATA_RFA_v1_0_April_2021.pdf	08/04/2021	10/05/2021 17:00	Apply Now
2	2021 Clinical Acceleration Team Awards (CATA) Funding Opportunity	This request for applications is specific for investigators wishing to apply for funding support for CATA Trials (early phase (I-II), prospective, biomarker-rich trials for clinical validation of biomarkers, diagnostics and therapeutics). CATA_RFA_v1_0_April_2021.pdf	08/04/2021	10/05/2021 17:00	Apply Now

Submitting a Notice of Intent

Complete required fields and select “Submit & Continue to LOI”



P.CTP.603

2021 Pre-Clinical Acceleration Team Awards (Pre-CATA) Funding Opportunity

* Principal Investigator name

Kelly Gmail Battistuzzi

Principal Investigator email address

kelly.battistuzzi@gmail.com

* Principal Investigator institution

Sample Organization

* Principal Investigator institution address

111 Address Lane Suite 123
City, Alberta H0H 0H0
Canada

Before inviting others to contribute to your application, complete the 'Project title' field and select "Save Draft".
Once the Project title is populated, the Invite Contacts button will become visible.

Click the button below to invite Investigators and Collaborators to your application. The 'Pending Invitations' list will be populated once invitations have been sent and 'Save Draft' is selected.

Investigators

Full Name	Email	Institution	Role
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* Title

Save Draft

Submit & Continue to LOI

Withdraw


Deadline
No later than May 10






Submitting a Letter of Intent

Applications in progress can be found under “Applications & Renewals”

COLLABORATE. TRANSLATE. CHANGE LIVES.


Applications & Renewals

 IN PROGRESS (1)  UNDER REVIEW (0)  COMPLETED (0)

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#	Project ID	Opportunity Name	Project Title	Application Type	Status	Modified Date		
1	P.CTP.603	2021 Pre-Clinical Acceleration Team Awards (Pre-CATA) Funding Opportunity	Test	Clinical Translation Pathway	Draft LOI	14/04/2021 14:51		

Reports & Extensions

 IN PROGRESS (0)  UNDER REVIEW (0)  COMPLETE (0)

						0 of 0	 
#	Request ID	Project Title	Activity Type	Assigned	Due Date		

Submitting a Letter of Intent

Complete required fields and select “Submit LOI”

P.CTP.603

* Lay summary

This summary may be shared with external parties for communications and reporting purposes, and with reviewers to identify expertise and potential conflicts of interest.

Test

249 words left

* LOI proposal

1500 words left

▼ Attachments

* Figures and tables (LOI)



* References (LOI)



Save Draft

☒ Submit LOI

Withdraw

Deadline
May 10 by 5 p.m.
EDT

Questions?



Funding provided by the
Government of Ontario.

