September 20, 2022

Clinical Translation

Innovation to Implementation (I2I) Funding Opportunity



Objectives of the I2I information session

- Present an overview of OICR and the Clinical Translation (CT) theme.
- Outline the objectives and scope of I2I funding stream so scientists understand the 'fit' for their research.
- Provide high level details on the application components and timeline.
- Discuss how to apply on ReportNet.
- Answer questions from the audience.

Information Session Agenda

Time	Agenda	Presenter
11:00am - 11:10am	 Introduction Overview of OICR and the CT research theme CT goals, governance, program and awards 	Steven Gallinger Head, Clinical Translation and Co-Lead, PanCuRx
11:10am - 11:20am	 I2I funding stream Key elements and objectives Funding available In-scope vs out-of-scope projects RFA timeline and review process Application requirements 	Christine Williams Executive Vice President and Head of Implementation Science
11:20am - 11:30am	 Implementing Equity Diversity & Inclusion and Patient Partnership in research 	Cassandra Bergwerff Lead, Patient Partnership & EDI
11:30am - 11:40am	Using OICR's ReportNet to apply for I2I competition	Jessica Sullivan Associate Director, Scientific Secretariat
11:40am - 11:55am	Q&A Session	All
11:55am - 12:00pm	Closing remarks	Sola Dokun Program Manager, Clinical Translation

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.



We partner with the oncology community in Ontario and beyond

To advance cancer research discoveries and transform cancer care

For the benefit of patients and the Ontario economy

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





OICR collaborates with the commercialization group FACIT to drive cancer research to benefit patients and the Ontario economy.

OICR goals:

- Advance early detection and intervention research
- Drive the translation and commercialization of cancer innovations in Ontario.

CT goals:

• Support the advancement of cancer discoveries (*internal* & *external to OICR*), through **to early clinical validation**, <u>partnering</u> with patients, industry and the health system for development and implementation.

Governance

CT Leadership

- Steven Gallinger, Head, Clinical Translation and Co-Lead, PanCuRx
- Christine Williams, Executive Vice President and Head of Implementation Science
- Glenn Bauman, Clinical Lead, Clinical Translation
- Teresa Petrocelli, Director, Clinical Translation

Program, Initiatives and Networks: towards health system implementation

- Clinical Translation Pathway (CTP) PreCATA/CATA: Drive the advancement of diagnostics, decision-making tools and therapeutics through → to clinical validation.
- Window of Opportunity Network: Provincial community of engaged partners focused on supporting novel immune modulatory therapeutics and identification of novel biomarkers through brief trials that use the window of time prior to surgery.
- **PanCuRx:** International initiative aimed at generating new knowledge about genetics and biologic subsets of pancreatic cancer, mechanisms of tumorigenesis and precision medicine options.
- Innovation to Implementation (I2I): Move research/innovations from experimental phase towards health policy or health system implementation.

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Program, Initiatives and Networks: towards health system implementation

- Canadian Cancer Clinical Trials Network (3CTN): Aimed at improving the lives of cancer patients and those at risk for cancer by addressing challenges in the academic cancer clinical trial enterprise and improving the efficiency and quality of cancer clinical trials in Canada.
- Ontario Cancer Research Ethics Board (OCREB): An innovative, oncology-specialized Research Ethics Board serving hospitals in Ontario that conduct cancer clinical trials.
- Ontario Health Study (OHS): Canada's largest population-based, precision medicine health cohort study that serves as a platform for investigating the environmental, lifestyle, clinical and genetic factors associated with risks of chronic diseases.

OICR introduced Implementation Science as a priority



"...the scientific study of methods and strategies that facilitate the **uptake of evidence-based practice and research into regular use** by practitioners and policymakers." -University of Washington

How do we get 'what works' to the people that need it?

Fund evidence gaps: support projects that have identified critical data needed to overcome barriers to uptake of research into policy or care

New Innovation to Implementation (I2I) RFA

Influence policy: work with stakeholders and government partners to provide policy solutions to facilitate the evaluation and adoption of new research (innovation pathway, Ministry of Health)

- **Build bridges:** e.g., new OICR/Queen's 'Implementation Lab' to test biomarker assays and optimize test parameters, performance and bioinformatics requirements in order to standardize the introduction of new biomarker tests to Ontario clinical laboratories.
- **Knowledge translation:** synthesize, disseminate, exchange and apply knowledge related to research to broad audiences to influence decision-making (patients, public, researchers, clinicians, policy-makers)

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Key elements of I2I

- Alignment with OICR's 2021-2026 Strategic Plan
- Supports the development of evidence or processes to move the existing innovation/research findings significantly further by partners/stakeholders outside the original development team towards health policy or health system implementation.
- Embraces the principles of Patient Partnership and Equality, diversity and inclusion (EDI).

I2I funding stream

Objectives

- To support research projects needed to overcome implementation bottlenecks and provide optimal approaches to accelerate the uptake and sustainability of research outputs in population health, cancer screening and clinical settings.
- To support efforts to synthesize, disseminate, exchange and apply knowledge related to research in order to build on and use that knowledge to improve high-quality decision making to support health, the healthcare system or healthcare delivery.

Funding available

• Maximum of \$100,000 per year, inclusive of overhead, for a maximum of two years. (April 1, 2023 – March 31, 2025).

Projects that are in-scope include:

- Projects that facilitate movement of research-generated knowledge to actual application of such knowledge in population health, screening or clinical practice settings.
- Studies that enable engagement of new users, including patients, along the translational continuum in order to advance the research into clinical settings.
- Projects that adapt a research tool for use in cancer prevention, clinical settings or clinical trials.
- Studies that conduct economic analysis or generate real-world evidence required to inform adoption of research into policy or routine health care.
- Studies evaluating the comparative real-world clinical- and cost-effectiveness of interventions.
- KT activities (e.g., generation of policy papers, workshops, meta-analysis) that will advance the adoption of research into policy or routine healthcare.

Projects that are out-of-scope include:

• Foundational or early discovery research.

Eligibility

- Investigators at Ontario academic centres, hospital research institutes or other government research institutions.
- Funding is only tenable in Ontario. For-profit entities are not eligible to receive OICR funding.
- There is no limit to the number of applications investigators are eligible to submit as PI or Co-PI.
- OICR is focused on supporting the next generation of cancer researchers, and strongly encourages applicants to include early career investigators/clinicians as part of the project team. Further, teams should consider the inclusion of a biostatistician for relevant projects.

Examples of currently funded projects

- Ontario Implementation Laboratory: Pathway to Standardization of Molecular Assays
- Modeling Endgame Policies to Inform Cancer Prevention in Ontario and Canada
- Expanding remote support for toxicity management to high-risk populations receiving systemic cancer therapy
- Developing a health economic modeling framework to evaluate the cost-effectiveness of novel therapies for metastatic lung cancer
- Lifecycle Health Technology Re-Assessment of Innovative Cancer Therapies: The Case of Chimeric Antigen Receptor T-cell (CAR T) Therapy

RFA timeline and review process



Application requirements

Letter of Intent (LOI)

- Collects information to assess fit to the I2I funding call. Abstract (250 words)
 - Background
 - Description of how the project will generate real-world knowledge and/or engage new partners.
 - Description of how the innovation will be moved towards clinical application or adoption into the healthcare system/policy; and
 - Discussion of the expected impact.

Deadline: Oct 13

Application requirements

Full Application (if invited)

Proposal (2000 words)

- Background and rationale
- Execution plan and deliverables
- Expected clinical impact.
- Path to implementation
 - Description of how the project will facilitate movement of knowledge to actual application of such knowledge in clinical practice settings and/or engage new users.
 - If applicable, description how the KT activities will raise knowledge users' awareness of research findings and facilitate the application of those findings.
- Patient and/or partner engagement plan

Other components

- Budget
- Co-funding letters
- Lead PI's Host Institution commitment letter
- Commercialization plan
- Project team

Deadline: Jan 19

SEPTEMBER 20, 2022

Ontario Institute for Cancer Research

Implementing Equity, Diversity & Inclusion and Patient Partnership in research



Section I Equity, Diversity, and Inclusion

Innovation to Implementation and EDI

I2I embraces the principles of equity, diversity and inclusion (EDI) in OICR-supported research in order to:

- Ensure research serves cancer patients from all relevant communities, especially those that are historically underrepresented
- Foster a more diverse and inclusive research community
- Create an environment where all can thrive and feel included

Importance of EDI in research

Review > BMB Rep. 2018 Apr;51(4):167-173. doi: 10.5483/bmbrep.2018.51.4.034.

Sex as an important biological variable in biomedical research

Suk Kyeong Lee 1

Affiliations + expand PMID: 29429452 PMCID: PMC5933211 DOI: 10.5483/bmbrep.2018.51.4.034

- Principals of EDI are important for conducting good research, as can be seen in many examples where they were lacking.
- 1997-2000, U.S. FDA suspended 10 prescription drugs producing severe adverse effects on the market.
 - **8/10** drugs caused greater health risks in women
 - Male biases (i.e.,
 - underrepresentation of females) in basic, preclinical, and clinical research were the main reason for the problem.

Considerations for your EDI plan

- Outline how the project will align itself to the principles of EDI within the project team, knowledge users and project participants.
- Describe how the project will include a diverse patient population, including participants from historically underrepresented populations, or explain why this is not applicable.
- Describe whether the project may be of particular benefit to any historically underrepresented groups, and what those benefits may be.
- Include specific and actionable tactics and address multiple areas wherever possible (e.g., outline tactics relating to both research team recruitment and dissemination of results).

Considerations for your EDI plan

- Outline how the project will align itself to the principles of EDI within the project team, knowledge users and project participants.
- Describe how the project will include a diverse patient population, including participants from historically underrepresented populations.
- Describe whether the project may be of particular benefit to any historically underrepresented groups, and what those benefits may be.
- Include specific and actionable tactics and address multiple areas wherever possible (e.g., outline tactics relating to both research team recruitment and dissemination of results).
 - As a starting point, refer to OICR's guide to Equity, Diversity and Inclusion tactics in research

Example tactics

Area	Tactic
Research team recruitment	Establish a policy/procedure to ensure that career leaves of absence are fairly considered in the recruitment and selection processes.
Training and development opportunities for the research team	Establish procedures/policies for distributing training and development opportunities associated with the grant to team members (conferences, publications, networking, etc.).

Example tactics

Area	Tactic
Study participant recruitment	Consider the different forms of support required (e.g., financial, logistical, cultural, linguistic) to ensure that the individuals or communities involved in the research are able to meaningfully participate in it.
Analysis of results	Where applicable, take into account sex, gender, race and ethnicity considerations and disaggregate by identity factors to determine differences between groups.
Dissemination of results	Include plain language summary in addition to technical reporting of results.

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Resources available

- Visit the links in the RFA
- Review the list of EDI tactics in research
- Email me at cbergwerff@oicr.on.ca



Equity, diversity and inclusion resources

EDI in research design and practices

- 1. Resources on integrating sex and gender in health research
- 2. Fairness and Equity in Research Participation (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Chapter 4)
- 3. Guide for Applicants: Considering Equity, Diversity and Inclusion in your Application NSERC [PDF (190 KB) external link]
- 4. Why sex and gender need to be considered in COVID-19 research

EDI in the research environment

- 1. Equity, Diversity and Inclusion: A Best Practices Guide for Recruitment, Hiring and Retention Canada Research Chair
- 2. Dimensions: Equity, Diversity and Inclusion Canada
- 3. Gender Summit Report: Toward a New Normal [PDF (2.43 MB) external link]
- 4. Guide for Applicants: Considering Equity, Diversity and Inclusion in your Application NSERC [PDF (190 KB) external link.]
- 5. New Frontiers in Research Fund Best Practices Guide in EDI
- 6. Supporting Women in Research: Policies, Programs and Initiatives Undertaken by Public Research Funding Agencies, [PDF (6.24 MB).- external link]
- 7. Universities Canada Equity, Diversity and Inclusion (Principles and Action Plan)

Section II Patient Partnership

Benefits of patient partnership in research

Partnering with patients can:

- ensure proposed studies are meaningful and impactful to the people intended to benefit
- give researchers and other healthcare stakeholders access to insights from the patient experience
- help to gather, analyze and interpret patient data to support patient-oriented studies
- improve knowledge mobilization by acting as a "translator" in between the researcher and the public
- create knowledge and expertise among patient partners which can be leveraged for future projects

Considerations for your patient partnership plan

- Applicants should address how patient partners and communities are being, or could be, partnered with throughout the life cycle of the project.
- This section must be written as a stand-alone piece and in clear, easy to understand, lay language understandable to a high school graduate.
- Members of OICR Patient and Family Advisory Council (PFAC) will participate in application reviews with a focus on the patient partnership plan.
- Patient partners will participate in the review of progress reports with a focus on the execution of the patient partnership plan.

Spectrum of engagement for research

	INCREASING STAKEHOLDER INFLUENCE ON THE RESEARCH						
	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER		
STAKEHOLDER PARTICIPATION GOAL	Researchers provide stakeholders with balanced and objective information to assist them in understanding the research.	Researchers obtain stakeholder feedback on the research.	Researchers work directly with stakeholders to ensure that stakeholder concerns and aspirations are consistently understood and considered in the research.	Researchers partner with stakeholders for salient aspects of the research.	Researchers assist stakeholders in conducting their own research.		
PROMISE MADE TO STAKEHOLDERS BY RESEARCHERS	We will keep you informed.	We will keep you informed, listen to and acknowledge your concerns and aspirations and provide feedback on how your input influenced the research.	We will work with you to ensure your concerns and aspirations are directly reflected in the research and we will provide feedback on how your input influenced the research.	We will look to you for advice and innovation in designing and conducting the research and incorporate your advice and recommendations to the maximum extent possible.	We will provide advice and assistance as requested in line with your decisions for designing and conducting your research, as well as for implementing the findings.		

Recommendations

- Focus on opportunities that have a real impact in both directions (research/researchers and the patient partners).
- Consider the "touch points" where patient partner involvement makes an impact.
 - Ask patient partner(s) what they think are the important points.
- Consider how to recruit patient partners and engage them as early as possible.
 - Your home institution may have patient partners already.
 - Patient organizations specific to your area of study.
 - Can engage the organization or seek out patient partner members to act as patient partners for your study.
 - o OICR can help recruit patient partners from its patient community.

Recommendations

- Meaningful engagement takes time and effort but creates significant benefits for all parties.
- Provide the resources and support needed to make partnership successful for everyone involved.
 - Onboarding and training
 - Compensation
- There are no "minimum" or "required" elements to patient partnership because each project is different.



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