



**Advancing to the Clinic: Preclinical Development Planning for Cancer
Immunotherapies**

June 9-11, 2026

Location: Ottawa, Ontario

Workshop Overview

This multi-day workshop provides a practical introduction to the preclinical development pathway for academic researchers advancing cancer immunotherapies to the clinic. Through expert-led sessions, case studies, and discussion, participants will work through key activities in preclinical development, including early product profiling, safety and efficacy studies, manufacturing and CMC planning, and regulatory requirements for initiating clinical trials.

Participants will leave with an actionable roadmap outlining the preclinical activities, expertise, and planning required to support submission of a Clinical Trial Application (CTA) to Health Canada.

Subject matter experts will facilitate sessions on:

- Overview of Health Canada regulation of investigational products in Canada and components of clinical trial applications
- Preclinical safety and efficacy requirements, including model selection, testing strategies, and GLP expectations
- Manufacturing process development, quality control strategies, and analytical development
- Working with CDMOs and CROs
- Program management for translation, milestone planning, budgeting and preparation for regulatory review
- Preparing and strategizing for engagements with regulators

Learning Objectives:

By the end of this workshop, participants will be able to:

- Assess whether their current data and development plans are aligned with intended clinical application
- Define and apply a Target Product Profile to guide preclinical study design, execution, and regulatory strategy
- Identify gaps in expertise or partnerships and outline next steps for engaging collaborators



- Generate a preclinical development roadmap with key decision points and supporting activities
- Anticipate risks and hurdles in preclinical development and develop risk mitigation strategies

This workshop is intended for academic investigators who are in the early stages of developing a cancer immunotherapy product with the intent to advance it to the clinic. It is ideal for research teams that:

- Have limited or no prior experience in preclinical development,
- Are beginning to plan or conduct preclinical studies, and
- Would benefit from structured guidance and expert input to navigate the translational research process

This workshop closely aligns with projects positioned to apply to BioCanRx's Catalyst or Enabling Studies programs.

Participant Eligibility

- Academic investigators at Canadian institutions who are actively developing a cancer immunotherapy product for clinical application in Canada
- Be able to articulate a translational goal and the need to build or refine their preclinical development strategy, and/or knowledge gaps within their research team
- Priority will be given to BioCanRx-funded research teams, particularly those supported under Catalyst or Enabling Studies programs, as well as research teams intending to apply to BioCanRx's next funding competition
- All team members are expected to attend the full workshop and participate in working sessions.

Research teams are expected to include a small, focused team composed of:

- **1 Principal Investigator**
- **1 Senior research staff/project manager** with responsibility for coordinating preclinical activities (may attend in place of the PI if a strong rationale is provided);
- **1 Trainee (optional)**, where participation is well-aligned with the goals of the workshop and the trainee's role in the project;
- **1 Industry partner (optional)**, where relevant to the stage and needs of the program



Subject Matter Experts:

- TBD

Application Process:

- 1) Research teams submit an application that includes details about:
 - a. Therapy being developed
 - b. Stage of translational development
 - c. Proposed team, including description of expertise and role in the project
 - d. Description of resources available at local institutions
 - e. Anticipated goals of the applicant from attending this workshop
- 2) Organizing Committee will evaluate and select research teams
- 3) BioCanRx will support travel and accommodation for the selected teams

Timeline:

1. Application Deadline: Friday, April 3rd, 2026
2. Applicants Notified: Monday, April 20th, 2026
3. Workshop Delivery – June 9 – 11, 2026

Organizing Committee

- Harold Atkins (Chair), MD, FRCPC, Clinician Scientist, Cancer Therapeutics Program, Ottawa Hospital Research Institute; Attending Physician, Blood & Marrow Transplant Program, The Ottawa Hospital; Associate Professor, Clinical Hematology, University of Ottawa
- Carolina Ilkow, PhD, Senior Scientist, Cancer Research, Ottawa Hospital Research Institute; Associate Professor, Department of Biochemistry, Microbiology and Immunology, University of Ottawa
- Julian Lum, PhD, Distinguished Scientist, BC Cancer, Professor, Biochemistry, Microbiology and Biology, University of Victoria
- Linh Nguyen, PhD, Scientific associate, Campbell Family Cancer Research Institute, Ontario Cancer Institute, University Health Network
- Sandy Pelletier, PhD, Research Associate, Simon Turcotte Lab, Université de Montréal
- Jennifer Quizi, PhD, Director, Virus Manufacturing Facility, Biotherapeutics Manufacturing Centre, Ottawa Hospital Research Institute, Investigator, Cancer Therapeutics Program, Ottawa Hospital Research Institute

BioCanRx

- Erin Bassett, Director, Regulatory Affairs and Policy
- Megan Mahoney, Director, Scientific Affairs and Training Programs
- Julie Jonkhans, Training & Research Manager



Tentative Agenda:

Day 1: Tuesday, June 9th, 2026, 8:30 – 5:00

Module 1: Introduction	
8:30–8:45	Welcome & workshop overview
8:45–9:00	Preclinical Pathway Overview
9:00–9:45	Panel Discussion: Evolving from a discovery research lab to a translational research lab
Module 2: Foundations for Robust Preclinical Programs	
9:45–10:30	Health Canada requirements & CTA fundamentals
10:30-10:45	Break
10:45-11:30	Health Canada requirements & CTA fundamentals cont'd
11:30–12:00	Roundtables
12:00–1:00	Lunch
1:00–2:00	Early trial design strategy
2:00–2:30	Trial design: Case study
2:30–2:45	Break
2:45–3:30	Target Product Profile as a planning tool
3:30–5:00	Working session + office hours
5:30	Networking reception

Day 2: Wednesday, June 10th, 2026, 8:30 – 5:00

Module 3: Preclinical Safety & Efficacy Studies	
8:30–10:00	Preclinical studies for safety & efficacy
10:00–10:30	GLP strategy: Case study
10:30–10:45	Break
10:45–12:00	Working session + office hours
12:00–1:00	Lunch
Module 4: Manufacturing	
1:00–1:30	CMC Foundations
1:30–2:30	Process development
2:30–2:45	Break
2:45–3:45	Developing a quality control plan
3:45–5:00	Working session + office hours

Day 3, Thursday, June 11th, 2026, 8:30 – 12 noon

Module 5: Program Management & Strategy	
8:30–9:30	Common Causes for Delays in Academic Trials
9:30–10:30	Program Management & Preclinical Roadmap Planning
10:30–12:00	Working session + office hours