BioCanRx
Biotherapeutics for Cancer Treatment
Biothérapies pour le traitement du cancer

Clinical, Social and Economic Impact Program

Getting better Outcomes with Chimeric Antigen Receptor T-cell therapy (GO–CART): A BioCanRx Research Excelerator to Safely and Effectively Translate CAR-T Cell Therapy for Hematological Malignancies

Jan. 17, 2017 to Dec. 30, 2018

Highlights

- A unique world-class translational research platform
- Creates a clinical trial protocol that is better than any previously designed cellular therapy trial in the CAR-T arena using stakeholder engagement throughout the process

targeted cancers

Hematologic malignancies (blood cancers)

It is this project's goal that GO-CART will produce the most evidence-informed trial protocol for any first-in-human trial conducted to date, directly address challenges facing first-in-human trials, and ultimately accelerate the translation of potentially transformative therapy.

Biotherapeutics

Engineered CAR-T cells

Project value

$414,119

BioCanRx contribution:
$364,119

Partners

6

C B M T G
CANADIAN BLOOD AND MARROW TRANSPLANT GROUP
SOCIÉTÉ CANADIENNE DE GREFFE DE CELLULES SOUCHES HÉMATOPOÏÉTIQUES

OTTAWA **METHODS CENTRE**

LEUKEMIA & LYMPHOMA SOCIETY OF CANADA
fighting blood cancers

UNIVERSITY OF MANITOBA
EST. 1877

Health Canada   Santé Canada

BC Cancer Agency
CARE & RESEARCH
An agency of the Provincial Health Services Authority

About the project

The vast majority of early phase clinical trials fail due to feasibility (e.g. patient recruitment), safety, or efficacy concerns. Although only a small number of clinical trials of CAR-T cells have been done, potential issues with safety, efficacy, and economic viability have already been identified. To avoid these pitfalls, the GO-CART Excelerator program will help BioCanRx scientist effectively use CAR-T cells in Canada, a new treatment process for blood cancers.

This project team, led by Dr. Lalu, will address these concerns to formulate a trial protocol that will be feasible, safe, effective, and economical. Experts drawn from different disciplines are coming together to create a "team-science" approach. First, they will perform comprehensive reviews of existing preclinical and clinical studies of CAR-T cells to help them understand how beneficial CAR-T cells may be and identify gaps in their knowledge. Then, they will perform knowledge translation stakeholder engagement studies with patients and clinicians to identify values/preferences for an early

phase clinical trial of CAR-T cells. They will go on to perform an economic evaluation to ensure they develop a therapy that is feasible for our health-care system. Finally, they will conduct studies of eligible patients to make sure that the criteria to enter their planned trial will allow enough patients to participate.

The multi-disciplinary team believes this pilot project will provide a template for future therapeutics to be evaluated and trials to be designed in an evidence-informed manner. This will accelerate safe and effective bench-to-bedside translation while providing a documented and transparent process. By addresses issues that most first-in-human/early phase trials encounter, this platform will offer a structured method to evaluate available data and design an evidence informed trial protocol for CAR-T cell therapy of hematologic malignancies.

Key investigators

Project lead:
Dr. Manoj **Lalu**

Principal Investigator:
Dr. Dean **Fergusson**

The Ottawa Hospital
L'Hôpital d'Ottawa

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

uOttawa

Project Investigators

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University of British Colombia,
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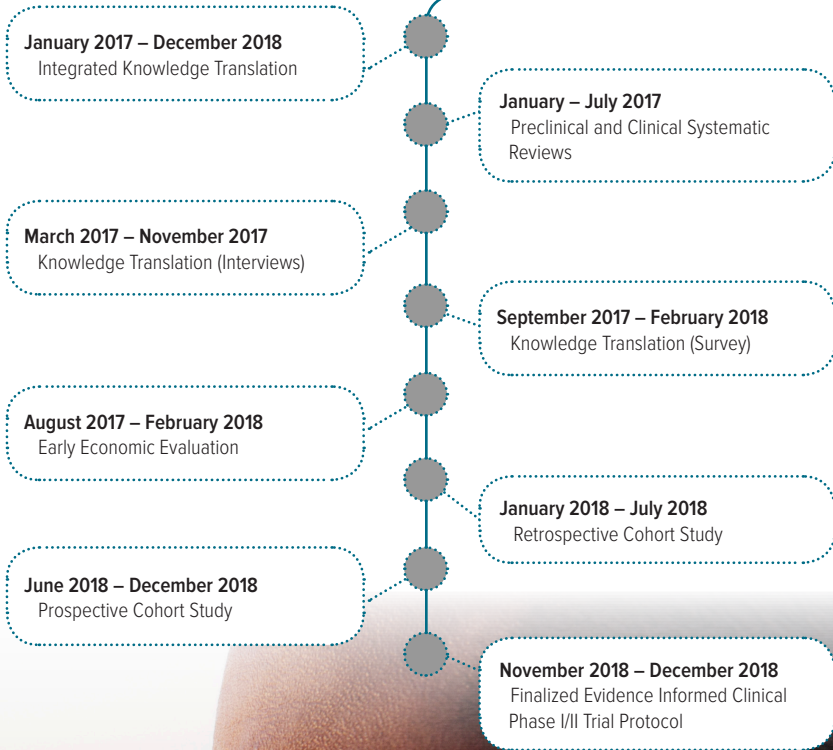## Partners

BC Cancer Agency (in-kind)

Health Canada (in-kind)

University of Manitoba (in-kind)

Canadian Blood and Marrow Transplant Group – University of Calgary (in-kind)

Leukemia & Lymphoma Society of Canada (in-kind)

Ottawa Methods Centre (OHRI) $50,000 (in-kind)

Key Milestones

January 2017 – December 2018
Integrated Knowledge Translation

January – July 2017
Preclinical and Clinical Systematic Reviews

March 2017 – November 2017
Knowledge Translation (Interviews)

September 2017 – February 2018
Knowledge Translation (Survey)

August 2017 – February 2018
Early Economic Evaluation

January 2018 – July 2018
Retrospective Cohort Study

June 2018 – December 2018
Prospective Cohort Study

November 2018 – December 2018
Finalized Evidence Informed Clinical Phase I/II Trial Protocol

The power to kill cancer lies within us.
Let's tell our bodies how.

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