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. 31, 2019

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.

Project value: **$414,441**
BioCanRx contribution: **$364,441**

Biotherapeutics: **Engineered CAR T cells**

Partners: **6**

CBMTG Canadian Blood and Marrow Transplant Group
Ottawa Methods Centre
Leukemia & Lymphoma Society of Canada – fighting blood cancers
University of Manitoba
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 pre-clinical 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 addressing 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
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Project Investigators

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Partners

BC Cancer Agency

Health Canada

University of Manitoba

Canadian Blood and Marrow Transplant Group – University of Calgary

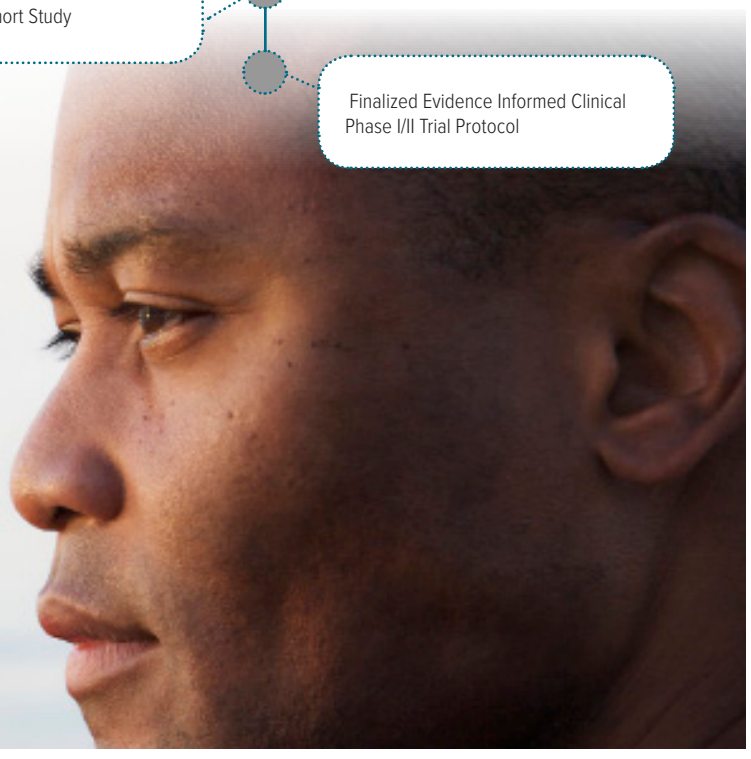
Leukemia & Lymphoma Society of Canada

Ottawa Methods Centre

Key Outputs

- Integrated Knowledge Translation
- Preclinical and Clinical Systematic Reviews
- Knowledge Translation (Interviews)
- Knowledge Translation (Survey)
- Early Economic Evaluation
- Retrospective Cohort Study
- Prospective Cohort Study
- 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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