

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

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.

\$364,441















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

is difference is a superior

Engineered CAR-T cells

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 healthcare 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 evidenceinformed 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.



Project Investigators Ottawa Ottawa Hospital Research Institute. The Ottawa Hospital, University of Ottawa Dr. Dean Fergusson Dr. Manoj Lalu Dr. Natasha Kekre Dr. Justin Presseau Vancouver Dr. Kednapa Thavorn Simon Fraser University, Dr. Harry Atkins University of British Colombia, Vancouver General Hospital, Canada's Michael Smith Genome Sciences Centre, BC Cancer Agency Dr. Robert Holt Dr. Raewyn Broady Kev **Outputs Partners BC** Cancer Agency (in-kind) **Health Canada (in-kind)** Integrated Knowledge Translation Preclinical and Clinical Systematic University of Manitoba (in-kind) Reviews **Canadian Blood and Marrow Transplant Group – University of Calgary (in-kind)** Knowledge Translation (Interviews) Knowledge Translation (Survey) Leukemia & Lymphoma Society of Canada (in-kind) Early Economic Evaluation **Ottawa Methods Centre (OHRI)** \$50,000 (in-kind) 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.

