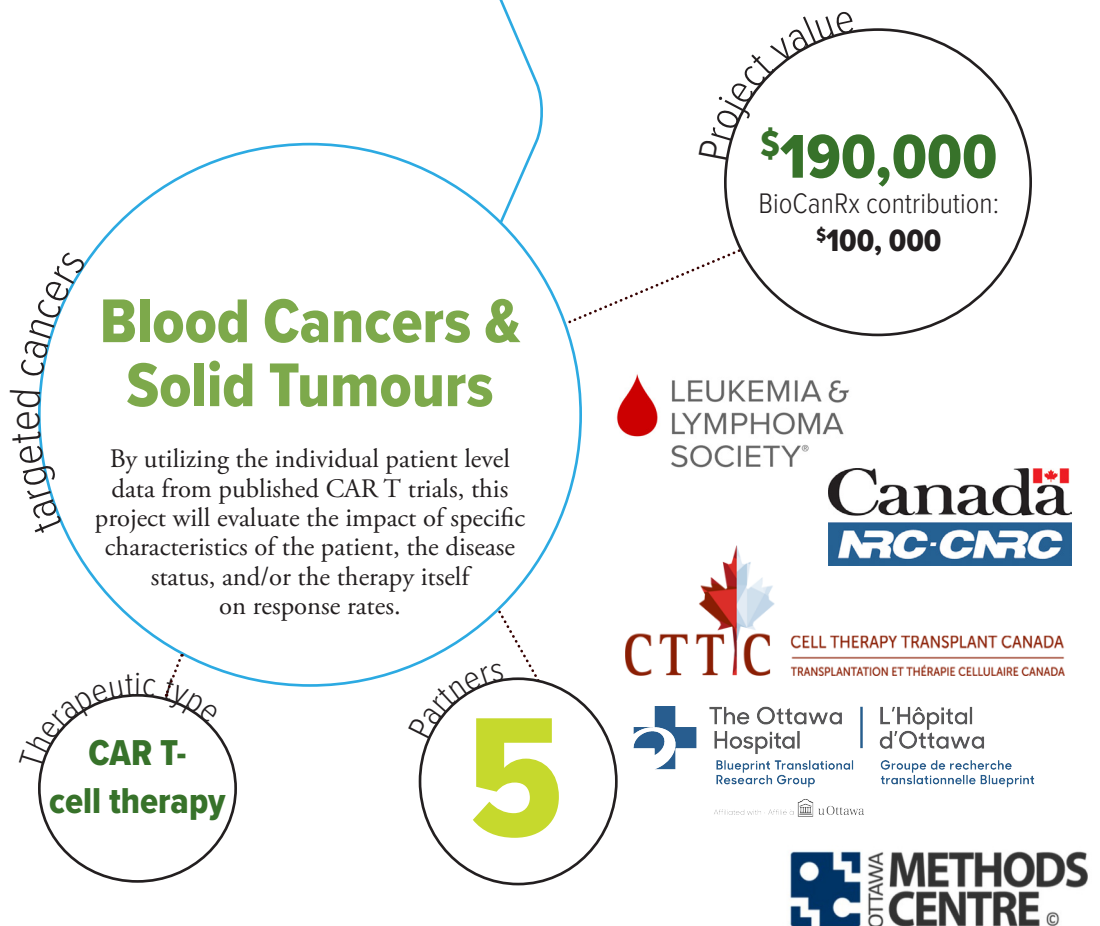


Identifying Effect Modifiers of CAR T-Cell Therapeutic Efficacy

July 1, 2020 - June 30, 2021.

Highlights

- The heterogeneity seen in efficacy both between and within clinical trials has been a detriment to the advancement of the field of CAR T-cell therapy.
- Using individual patient data, as opposed to data aggregated at the study level, improves the ability to identify important characteristics which may be impacting the efficacy of CAR T-cell therapy.
- Individual patient data meta-analyses have demonstrated the ability to help shape and inform clinical trial design, an important and relevant feature in the fast-moving field of CAR T-cell therapy.
- Given the safety concerns and the cost currently surrounding CAR T therapy, it is important that the right group of patients be properly identified and treated safely.



About the project

Chimeric antigen receptor T-cell therapy is a promising new treatment option for patients with relapsed or refractory blood cancers. Although small clinical trials of CAR T-cells have been conducted and demonstrated exciting results, potential issues with safety, efficacy, and economic viability have been identified. The researchers' recent review of published CAR T-cell trials ([funded by BioCanRx](#)) demonstrated that the therapy can be extremely effective in some people and not others. The reasons for this difference remain unclear but emerging evidence suggests that specific characteristics about either the people (for example biological sex or age), disease status or of the therapy itself (dose, for example), can lead to differences in efficacy between patients.

By utilizing the individual patient level data from each of the published trials, this project will evaluate the impact of these characteristics on response rates. This powerful approach is known as an individual patient data systematic review and metaanalysis. At the same time, the project will provide an updated review of all CAR T-cell trials in blood and solid tumor cancer patients. This will help clinicians and decision-makers optimize CAR T-cell therapy for patients, and help inform the design of future clinical trials and interventions that may demonstrate better efficacy. Identifying characteristics that may act as modifiers of CAR T-cell efficacy is of paramount importance and can help shape future clinical trials in the field. Results from this project have the potential to not only impact future BioCanRx projects, but CAR T-cell projects around the world. The ultimate goal is to create better and safer outcomes for patients undergoing CAR T-cell therapy.



Project Team Members



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Ottawa Methods Centre - \$50,000

Cell Therapy Transplant Canada - \$10,000 (in-kind)

Leukemia & Lymphoma Society of Canada - \$10,000 (in-kind)

BLUEPRINT Translational Research Group - \$10,000 (in-kind)

National Research Council (NRC) - \$10,000 (in-kind)

Key Milestones

Protocol Refinement: All listed investigators will be involved in the protocol refinement process.

Literature search: All listed investigators will be involved in the protocol refinement process.

Level 2 screening: The principal investigators will be involved at this stage, providing oversight and mentorship to the HQP performing screening.

Manuscript revision and preparation: All listed investigators will be involved in the manuscript preparation and revision stage.

Level 1 screening: The principal investigators will be involved at this stage, providing oversight and mentorship to the HQP performing the screening.

IPD extraction: The principal investigators will be involved at this stage, providing oversight and mentorship to the HQP performing the data extraction.

Data analysis: All listed investigators will be involved in the data analysis and interpretation stage.

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

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