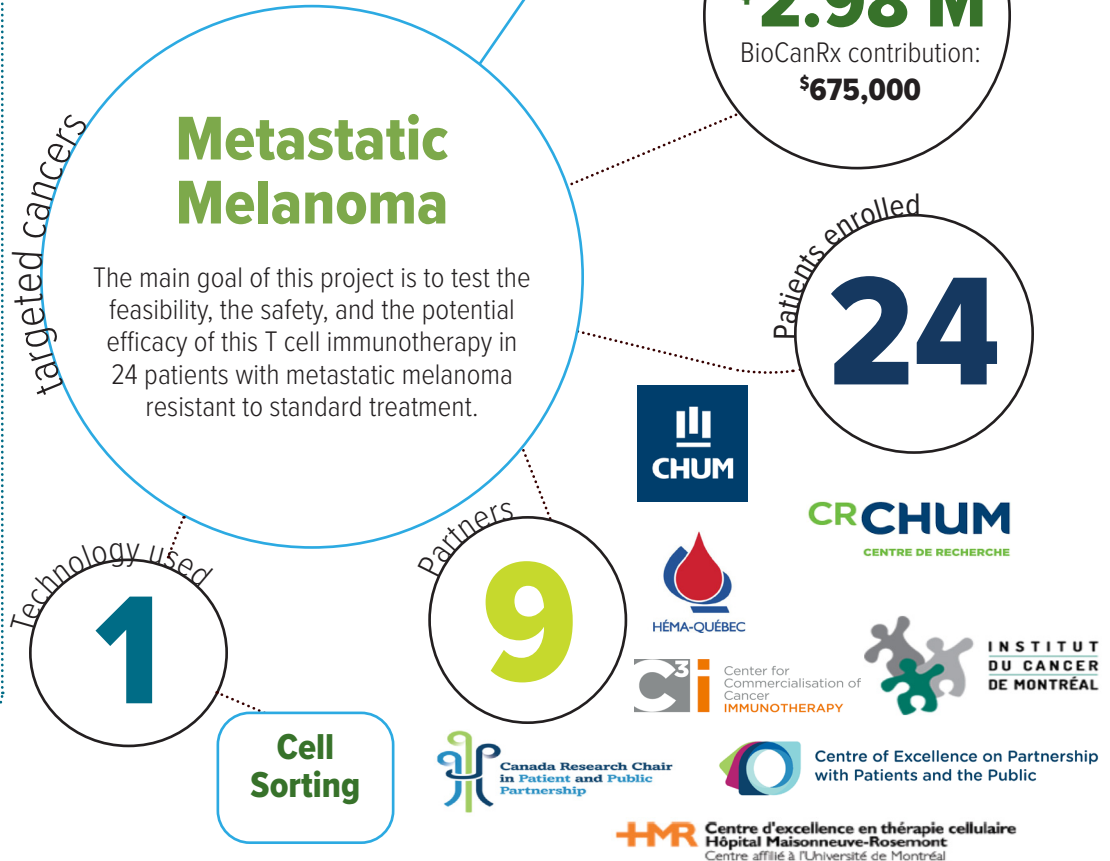


## The Selected Tumor-infiltrating Lymphocyte Against Refractory Melanoma-01 Trial (STAR-M01)

October 1, 2020 - March 31, 2024.

### Highlights

- For the majority of cancer patients, their endogenous anti-tumor T-cell response cannot be sufficiently reinvigorated with just immune checkpoint blocking (ICB) antibodies. As a promising alternative, BioCanRx is emphasizing the development of T cell-based immunotherapies.
- Cell sorting is based on the expression by T cells of a cell surface marker called PD-1, which acts as a "tag" for tumour-reactivity. The researchers have optimized a cell sorting technique and the cell culture conditions to expand sorted T cells into large numbers that can be used for infusion into patients.
- This is likely the first project in Canada that has optimized cell sorting for clinical research, a technology that can be repurposed to enhance T cell products developed by other researchers.



### About the project

The infusion of ex-vivo expanded tumour-infiltrating T lymphocytes (TILs) is a promising approach for the treatment of solid tumour cancers because it addresses the problem of tumour heterogeneity by targeting multiple tumor antigens. An important challenge remains: since bystander (non tumour-reactive) T cells are attracted intratumorally by inflammation, only a small proportion of TILs are tumour-reactive, and standard bulk ex vivo expansion often favors the overgrowth of bystander T cells.

In Cycle 1, Dr. Turcotte and team were funded through the Catalyst [Study Program](#) to enhance TIL efficacy by selecting tumor-infiltrating T cells expressing PD-1, that act as a "tag" for tumor-reactive T cells. To do this, the team optimized the use of a clinical-compliant flow cytometry cell sorter to select reactive TILs from tumors prior to ex vivo expansion.

The STAR-M01 is a prospective, open-label, two-cohort, non-randomized, single center phase 1b study in stage IIIC unresectable or stage IV metastatic melanoma patients refractory to PD-1 immune checkpoint blockade. The primary objective of this trial is to test the feasibility, the safety, and the potential efficacy of this T cell immunotherapy after lymphodepletion and with intravenous IL-2, in 24 melanoma patients.

Additionally, enrolled patients will have the option to participate in a patient-led support group to help them understand and communicate with others about what to expect from anti-tumour T-cell transfusion immunotherapy.



# Project Team Members



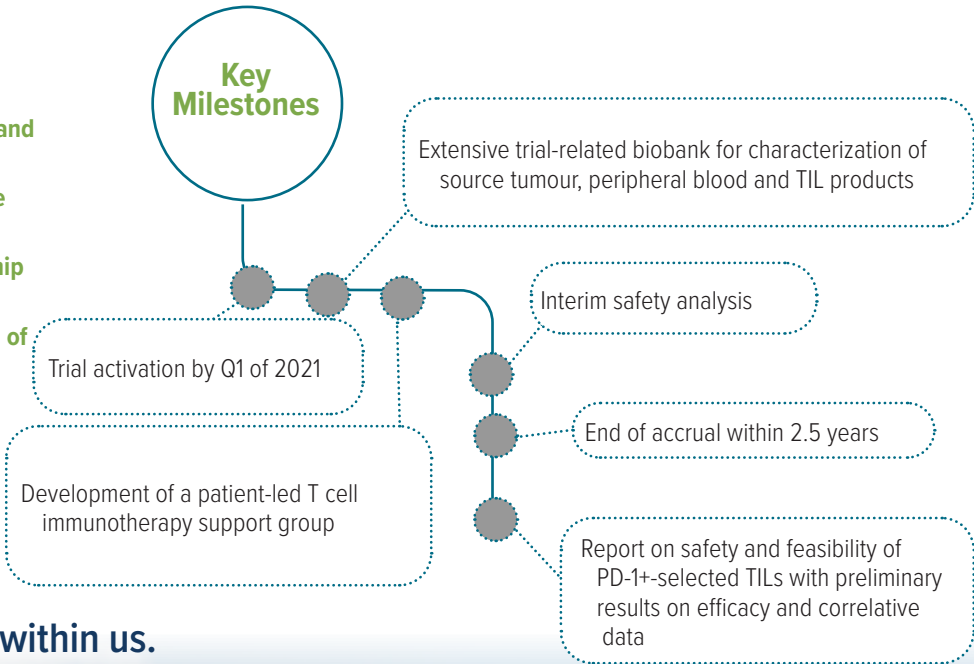
**Vancouver**  
 BC Cancer - Deeley Research Centre  
 Dr. Brad Nelson

**Montréal**  
 Centre Hospitalier de l'Université de Montréal  
 Dr. Simon Turcotte  
 Dr. Rahima Jamal  
 Dr. Réjean Lapointe  
 Centre d'excellence en thérapie cellulaire (CETC)  
 Dr. Jean-Sebastien Delisle

## Partners - \$2.3 M

- Centre de Recherche du Centre Hospitalier de l'Université de Montréal / Centre Hospitalier de l'Université de Montréal
- Institut du cancer de Montréal
- Héma-Québec
- Canada Research Chair in Patient and Public Partnership
- Centre d'Excellence en Thérapie Cellulaire
- Centre of Excellence on Partnership with Patients and the Public
- C3i (Centre for Commercialization of Cancer Immunotherapy)

**Facility Utilization:**  
 Molecular & Cellular Immunology Core (MCIC)  
 BC Cancer Deeley Research Centre



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



**BioCanRx**  
 Canada's Immunotherapy Network  
 Le réseau canadien d'immunothérapie