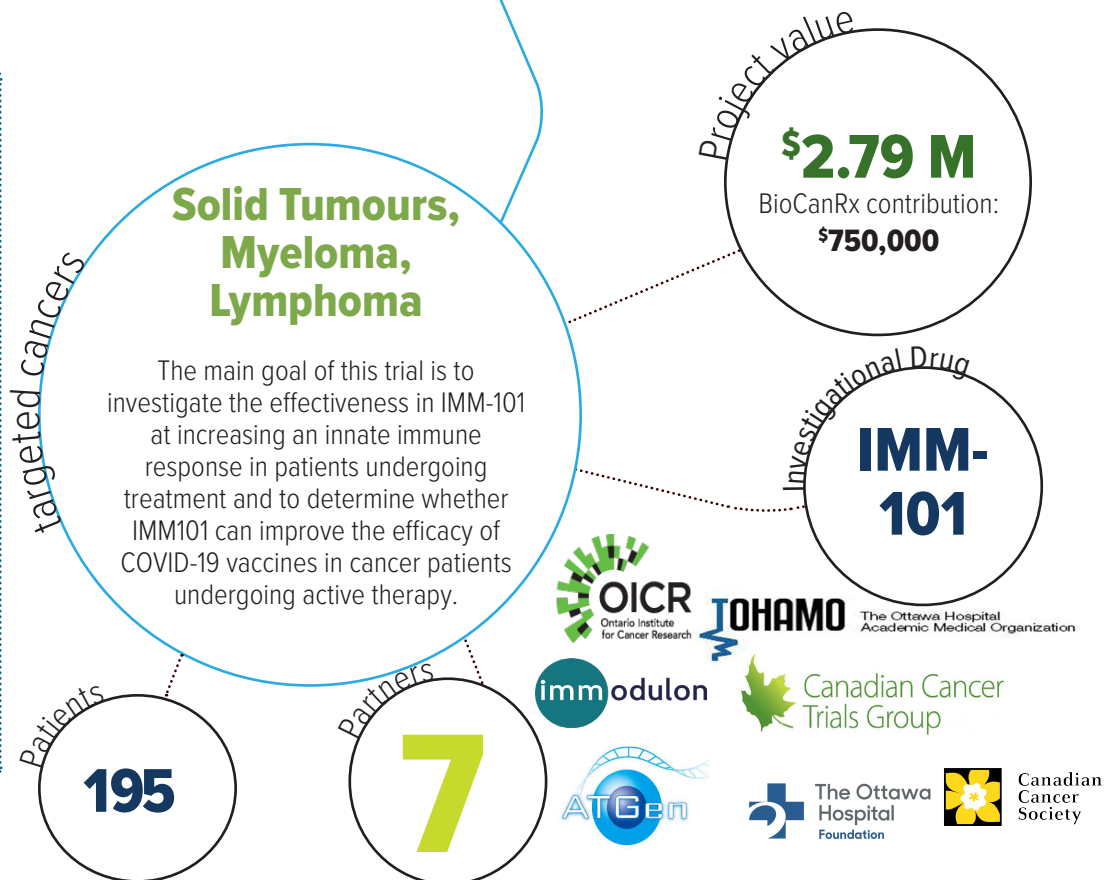


COV-IMMUNO- A randomized phase III trial of immunization with IMM-101 versus observation for the prevention of serious respiratory and COVID-19 related infections in cancer patients at increased risk of exposure

April 1, 2020 - December 31, 2022.

Highlights

- This trial has been developed to address a critical and urgent need to protect cancer patients undergoing active treatment during the COVID-19 pandemic.
- Cancer patients are particularly vulnerable to severe COVID-19 infections because they are both immunocompromised and cannot adhere to strict quarantine as they need to visit the hospital regularly for treatment.
- IMM-101 is a safe, killed, whole cell immunomodulator that has been shown to induce an innate immune response in cancer patients.
- This trial will evaluate the ability of IMM-101 to train the immune system by boosting natural immunity and improving immune response to the COVID-19 vaccine.



About the project

As cancer patients have dysfunctional innate immune responses, they are at higher risk of severe COVID-19 infections, which at best, can result in delays in their treatment of their active cancer, and at worst, an increased incidence of mortality. It is also unclear whether the approved COVID-19 vaccines work as well in patients actively undergoing treatment.

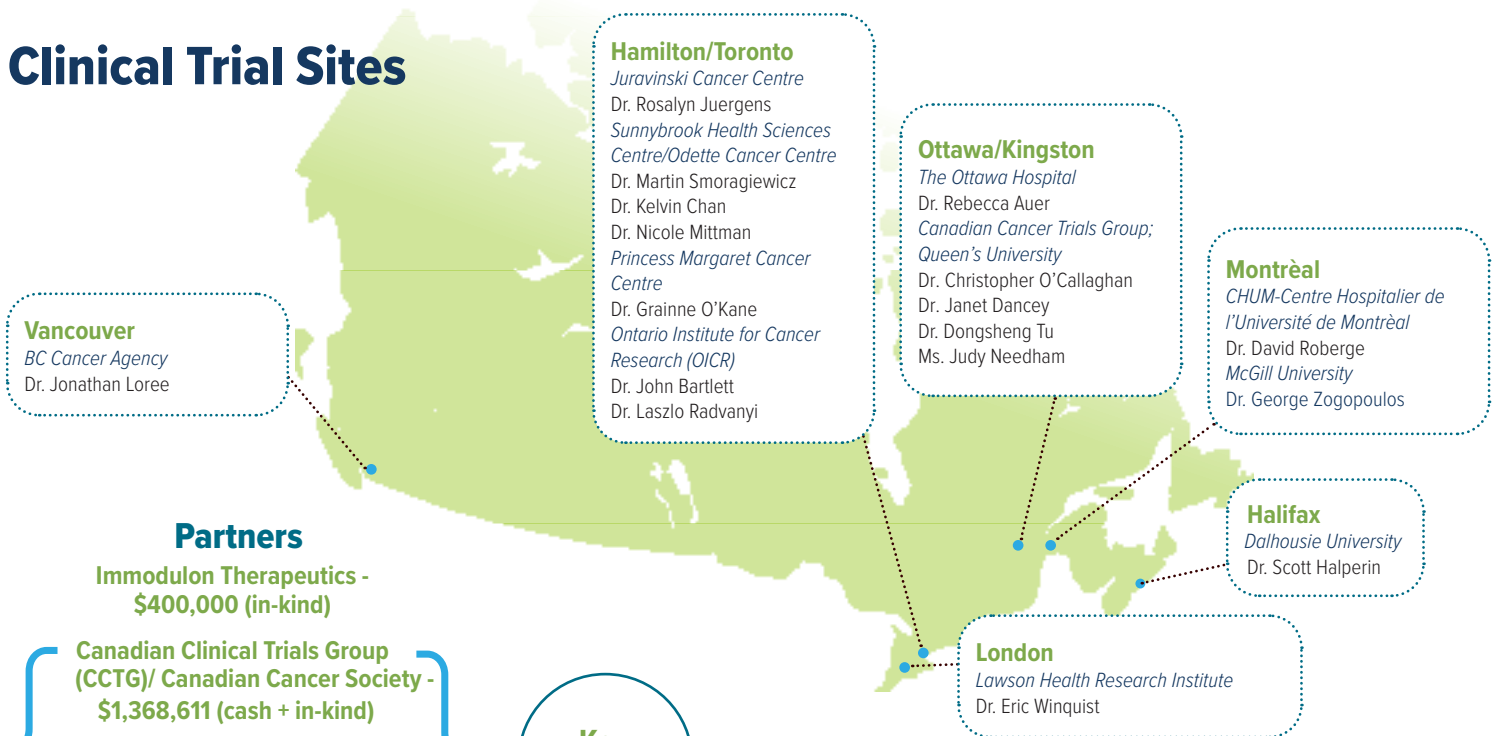
Stimulation of the innate immune system (known as “trained immunity”) is a promising approach to optimizing the innate to adaptive transition for many infections, including COVID-19. This principle has been shown in the past with recipients of the tuberculosis vaccine, known as BCG, demonstrating an increased resistance to multiple other infections due to a parallel, non-specific stimulation of their innate immunity. While BCG vaccination is being tested in healthcare workers against COVID-19 infection in multiple clinical trials around the globe, because it is composed of a live (but modified) bacteria, its use is contraindicated in patients with a weakened immune system, such as cancer patients.

In contrast, IMM-101, the investigational drug for this trial, is a whole cell immunomodulator that is safe to use in cancer patients because the bacteria has been killed. IMM-101 (Immodulon Therapeutics) is a systemic immune modulator containing a suspension of heat-killed whole cell Mycobacterium obuense, an environmental, harmless saprophyte. Given that it is NOT a live vaccine, it is being developed as an anti-cancer therapy, based on the same rationale of trained immunity, but against cancer cells. IMM-101 has been shown to induce an innate immune response in cancer patients of equal or greater magnitude to that reported with BCG treatment.

The purpose of this trial is to examine 1) IMM-101 impacts on the overall innate immune response/”immune training” of patients with cancer undergoing active treatment 2) the immune response to the COVID-19 vaccines in cancer patients on active therapy, 3) whether IMM-101 can improve the immune response of the COVID-19 vaccines or other vaccines, especially patients on immunosuppressive therapies.



Clinical Trial Sites



Partners

Immodulon Therapeutics -
\$400,000 (in-kind)

Canadian Clinical Trials Group (CCTG)/ Canadian Cancer Society -
\$1,368,611 (cash + in-kind)

Ontario Institute for Cancer Research (OICR) - \$100,000 (in-kind)

The Ottawa Hospital Academic Medical Organization - \$96,000

ATGen - \$44,550 (in-kind)

The Ottawa Hospital Foundation - \$25,000

Key Milestones

November 30, 2020
• Patient accrual completed

June 30, 2020
• Anticipated start date

November 30, 2021
• Patient follow-up completed

January 1, 2022
• Final report issued

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

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

