



Enabling Cell Manufacturing and Regulatory Compliance for CLIC-02: A Phase I Clinical Trial of a Novel Made-In-Canada CD22-Specific CAR-T Cell Product

Project duration: 2025-3-9 to 2027-3-31



About the project:

Patients with aggressive B-cell leukemias and lymphomas that are resistant to standard therapies have a dismal outcome, with survival measured in months. Chimeric antigen receptor (CAR) T cell therapy targeting CD19, a marker on these cancers, has proven highly effective for treating such patients and has recently become standard of care. Unfortunately, however, 50-60% of patients show resistance to CD19 CAR-T cell therapy. To help such patients, the team leveraged BioCanRx support to develop a new CAR-T cell product targeting a different B-cell marker called CD22. They recently opened a phase I clinical trial to evaluate this new CD22 CAR-T cell product in leukemia and lymphoma patients at seven clinical sites across Canada.

BioCanRx will now support costs assosicated with: (1) manufacturing CD22 CAR-T cells for 24 adult and pediatric leukemia and lymphoma patients; (2) performing essential regulatory procedures to meet Health Canada requirements; and (3) developing essential assays to measure CAR-T cell safety and potency. This trial offers an urgently needed new treatment option for Canadian patients while substantially increasing the size and global impact of our CAR-T cell consortium.

Research

Virus Manufacturing

Cell Manufacturing

Clinical Trial Site

Industry Collaborator

Core Facility (research services)

Core Facility (research services)

Patient/Focumental

Research:

BC Cancer, Vancouver, BC Dr. Kevin Hay, Dr. Robert Holt, Miruna Bala, Dr. Hannah Cherniawsky, Dr. Kevin Song

Research and Clinical Site:

BC Children's Hospital, Vancouver, BC Dr. Amanda Li

Clinical Site:

Vancouver General Hospital, Vancouver, BC Dr. Hannah Cherniawsky, Dr. Kevin Song **C**

Cell Manufacturing:

BC Cancer, Victoria, BC Dr. Julie Nielsen

Research:

BC Cancer, Victoria, BC Dr. Brad Nelson

Research and Clinical Site:

Arthur J.E. Child Comprehensive Cancer Centre, Calgary, AB Dr. Robert Puckrin

Alberta Children's Hospital, Calgary, AB Dr. Victor Lewis



Research and Clinical Site: The Hospital for Sick Children, Toronto, ON

Dr. Joerg Krueger

Princess Margaret Cancer Centre, Toronto, ON Dr. John Kuruvilla

Research:

National Research Council, Ottawa, ON Dr. Scott McComb, Dr. Risini Weeratna

Research and Clinical Site:

The Ottawa Hospital, Ottawa, ON Dr. Natasha Kekre, Dr. Harry Atkins

Partners:

BC Cancer Foundation

CIHR

Total Pledged Partner Contribution: \$2,976,410 Total Pledged Matched Contributions: \$749,308 Total Leveraged Partner Contributions: \$2,227,102



- 2. Development and implementation of an Aseptic Process Simulation (APS) protocol
- 3. Development and qualification of optimized Quality Control assays



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