

Frequently Asked Questions

What is CCRM? CCRM is a Canadian-led, global public-private partnership that brings together key stakeholders, gap-filling expertise and infrastructure, targeted funding and a highly trained ecosystem to accelerate the development and commercialization of regenerative medicines.

What is regenerative medicine? Regenerative medicine, including cell and gene therapy, harnesses the power of (stem) cells, biomaterials, molecules and genetic modification to repair, regenerate or replace diseased cells, tissues and organs. It has the promise to treat, manage and perhaps cure some of the most devastating and costly diseases in the world today.

What is commercialization? Commercialization is the process of bringing a new product to market.

Why aren't there more regenerative medicine therapies for patients?

Many potentially life-changing cell and gene therapies, and regenerative medicine-based treatments, never reach patients because of several factors that impede commercialization. For example, the science is complex, clinical trials are risky, manufacturing is costly, and demand for clean rooms can outstrip capacity with therapeutics developers having to wait months to initiate new manufacturing projects. In addition, expertise is limited, talent is scarce, regulations are uncertain, and early-stage investment is lacking. These factors create the commercialization gap.

How can CCRM solve this problem?

CCRM aims to bridge the commercialization gap by focusing on key bottlenecks and establishing an optimal ecosystem for industrialization made up of gap-filling infrastructure and networks of scientists, engineers, entrepreneurs, academic institutions, industry partners and investors. CCRM's subsidiary, OmniaBio Inc., is also playing a role in addressing manufacturing capacity challenges.

What is OmniaBio Inc.?

OmniaBio is a contract development and manufacturing organization (CDMO) producing gene-modified cell therapies and viral vectors, compliant with Good Manufacturing Practices (GMP) standards. OmniaBio was established in 2022. Once it is fully operational, it will add a sixfold increase to CCRM's manufacturing capacity, enabling manufacturing from the pre-clinical to commercial scale. Benefitting from CCRM's 10-plus years of expertise, OmniaBio is built upon leadership in induced pluripotent stem cells, immunotherapy and lentiviral vectors.

Currently under construction, its commercial-scale manufacturing site will anchor a biomanufacturing centre of excellence and will open with late clinical phase and commercial capacity in 2024 in a site totalling approximately 100,000 square feet. This facility was made possible with support from the Government of Ontario's Invest Ontario fund, and private investment from Medipost, a leading biotechnology company and global player in cell therapy. Once complete, OmniaBio will be the largest facility of its kind in Canada focused on cell and gene therapies. OmniaBio is located at McMaster Innovation Park, approximately one hour from the U.S. border. Find out more at omniabio.com.

Who are the members of CCRM's Industry Network?

CCRM's Industry Network represents all aspects of the regenerative medicine industry: pharmaceuticals, devices, reagents, tools, biomaterials and cell therapies. These companies utilize CCRM's translational platforms to address real-life bottlenecks in their companies. The companies are listed [on our website](#).

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Who makes up CCRM's academic network?

Ontario has one of the largest populations of stem cell scientists in the world, with over 175 labs operating in the province. These scientists reside in CCRM's Founding Institutions, including the University of Toronto, University Health Network, The Hospital for Sick Children and Ottawa Hospital Research Institute, as well as Associate Institutions, including McMaster University and Mount Sinai Hospital, and represent a significant proportion of all regenerative medicine research activity in Ontario. CCRM also engages leading institutions and companies from around the world.

Where does CCRM's funding come from?

In 2011, CCRM received CA\$15M (all figures are Canadian) in federal seed funding from the federal government's Networks of Centres of Excellence (NCE) program. In 2016, GE Healthcare committed \$20M to establish a Centre for Advanced Therapeutic Cell Technologies (CATCT). This amount was matched with \$20M from the Federal Economic Development Agency for Southern Ontario. CCRM's Centre for Cell and Vector Production was built in partnership with the University Health Network. CCRM has also received funding through its fee-for-service work, the University of Toronto's Medicine by Design, academic institutions, industry, and the Province of Ontario. In 2018, CCRM received another \$15M in funding from the NCE program. Cytiva, formerly GE Healthcare Life Sciences, announced its renewed commitment to CATCT in 2020. CCRM's NCE funding has now ended, as the organization has benefited from the maximum funding allowable. Having graduated from the NCE program, CCRM has successfully transitioned to sustainability through contract services and work it does for OmniaBio Inc., company creation and company exits, and investments.

How does CCRM support the launch and growth of new companies?

CCRM Enterprises Inc., CCRM's venture investment arm, was created to distinguish its for-profit commercial and investment endeavours. CCRM Enterprises catalyzes new company innovation and investment in regenerative medicine by pulling together all the necessary components to vet, de-risk and develop high-potential, early-stage ventures as they scale up along the development and commercialization pathway. The goal of CCRM Enterprises is to address gaps in the Canadian investment ecosystem. With extensive deal sourcing capability, supported by "wet" diligence through CCRM's technical teams, CCRM Enterprises can then progress these technologies, enabled by CCRM's strengths in manufacturing and technology development. Companies in CCRM Enterprises' portfolio also benefit from access to the Good Manufacturing Practices facility at CCRM. Through CCRM Enterprises, CCRM has supported the launch and growth of 17 companies, including two that CCRM has exited from, which have gone on to raise more than \$1B.

In addition, in December 2023, CCRM announced a strategic alliance with Medicine by Design. Together, the two organizations represent an end-to-end perspective of the bench-to-bedside process — from research and discovery, to company development, to manufacturing, to bringing the therapy to market.

How is CCRM supporting the regenerative medicine ecosystem with training?

As the cell and gene therapy market grows, the industry needs qualified, skilled personnel to manufacture and produce cell and gene therapies following Good Manufacturing Practices. Recognizing the gap in highly qualified personnel, in 2021 CCRM and CellCAN launched the Canadian Advanced Therapies Training Institute (CATTI). By combining their strengths, CCRM and CellCAN, through CATTI, are growing the industry's manufacturing capabilities by offering specialized training to accelerate the market readiness of the workforce. Visit catti.ca for more information.

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