

Biotherapeutics for Cancer Treatment – BioCanRx

Canada's Immunotherapy Network Transforming the Future of Cancer Treatment

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Executive Summary

Closing the Gap Between Discovery and Delivery: BioCanRx as a National Translational Engine

Canada is a global leader in cancer research, producing high-impact publications and contributing significantly to scientific discove . Yet, despite this excellence in basic science, only 4% of cancer immunotherapy clinical trials conducted in Canada are based on Canadian innovations. This disconnect is largely the result of a critical and persistent underinvestment in translational research—the phase that moves promising discoveries from the lab to the clinic.

BioCanRx was created in 2015 under the Networks of Centres of Excellence (NCE) program to address this exact gap. As Canada's only national, not-forprofit network focused on the development of immunotherapies for cancer, BioCanRx has become a case study in how targeted translational funding and infrastructure can convert world-class research into life-saving treatments, while simultaneously building domestic biomanufacturing capacity and contributing to the innovation economy.

The Translational Challenge: Canada's Innovation Bottleneck

Canada currently spends approximately \$500 million annually on cancer research, with roughly 70% of those funds allocated to early-stage, basic science. Only about 0.3% is directed toward the type of translational work needed to prepare a treatment for a clinical trial such as process development, regulatory filing, and GMP manufacturing. As a result, the country suffers from a "valley of death" that prevents high-potential discoveries from progressing. Compared to peer nations such as the U.S., U.K., and EU, which have built robust translational ecosystems (e.g., NCATS, NIHR, EATRIS), Canada remains under-equipped to develop, test, and commercialize its own biomedical innovations.

This lack of investment undermines Canada's ability to realize returns—both economic and therapeutic—on its early-stage research investments. In short, Canada remains a high-performing discovery engine, but continues to function as a late stage clinical trial branch plant for foreign-developed therapies. BioCanRx is actively changing this paradigm.

BioCanRx: An Integrated Model for Translational Success

Operating across the full translational continuum, BioCanRx supports projects from proof-of-concept through to early clinical trials. The network does this through three core funding streams:

- Catalyst Program (TRL 3–4): Supporting promising preclinical research
- Enabling Studies (TRL 5–6): Advancing regulatory and manufacturing readiness
- Clinical Trials Program (TRL 7–8): Launching made-in-Canada trials

These programs are reinforced by the **Clinical, Social and Economic Impact (CSEI)** program, which provides support for early health technology assessment and patient-informed clinical trial protocol development, and by funding for core facilities specializing in GMP biomanufacturing, viral vector production, and immune monitoring. BioCanRx's investment decisions are guided by an international Research Management Committee to ensure alignment with global standards in this highly competitive field.

2015-2024 Highlights:

- 12 Canadian-developed clinical trials launched, treating over 400 patients
- 34 novel therapies advanced targeting 40 cancer indications
- 8 spinouts created, including Virica Biotech and others
- 675 HQP trained, many now working in biomanufacturing, clinical trial design, and regulatory science
- \$109.5M in partner contributions leveraged from a \$40M NCE investment, 66% of which is from industry
- Despite launching in 2015, 42% of made-in-Canada immuno-oncology clinical trials are directly attributable to the BioCanRx translational research program

Driving Systemic Change and Economic Impact

The BioCanRx model also addresses broader systemic barriers identified in national assessments, including lack of interdisciplinary collaboration, underutilized infrastructure, and weak links between academia, government, and industry. Through its national network of 202 partners—including researchers, clinicians, industry players, and patient advocates—BioCanRx fosters collaboration across sectors.

In doing so, BioCanRx supports the objectives of Canada's **Biomanufacturing and Life Sciences Strategy** (**BLSS**) by advancing new therapies, building GMP capacity, and creating a skilled talent pipeline. The development of the **Canadian-Led Immunotherapies in Cancer (CLIC)** platform, which enables decentralized CAR-T manufacturing, exemplifies the model's potential for equitable access and sustainable innovation.

Strategic Path Forward (2024–2029)

Now operating under the **Strategic Science Fund (SSF)**, with \$38 million in renewed federal support, BioCanRx is poised to:

- Expand GMP CAR-T and TIL biomanufacturing capacity across Canada
- Launch additional first-in-human clinical trials
- Increase Canada's share of globally competitive immunotherapy IP
- Drive adoption of Canadian therapies through regulatory and health systems engagement

100% of Canadian Institutes of Health Research (CIHR) funded made-in-Canada oncology immunotherapy trials originated in BioCanRx's portfolio

This record illustrates BioCanRx's role in de-risking early-stage assets, enabling them to attract downstream funding and partnerships. For example, CIHR's Clinical Trial Fund investments of \$6.2M in two CAR-T trials would not have been possible without prior BioCanRx support for regulatory and manufacturing work. And all CIHR funded made-in-Canada oncology clinical trials stem from the BioCanRx program demonstrating the importance of integrated translational research support to get to the finish line.



Partner Funding by Source

These goals align with national priorities in cancer care, pandemic preparedness, and economic resilience. By investing in translational infrastructure and aligning policy, program, and funding mechanisms, Canada can scale the BioCanRx model across disease areas.

Conclusion: The Case for Translational Investment

BioCanRx is more than a funding program—it is a national translational engine. The network has demonstrated that with the right model, Canada can transform high-impact science into homegrown therapies that save lives, generate economic return, and strengthen health system capacity. The BioCanRx experience highlights what is possible when translational research is recognized, resourced, and coordinated. Continued support for this model is essential to ensure that Canadian discoveries lead to Canadian cures.

"Even if the cancer comes back, this has given me precious time, and I know the research will help many others. It has given me a fighting chance."

Diagnosed with acute lymphoblastic leukemia in January 2020, and after struggling through various treatments and a recurrence of her cancer in 2021, Camille Leahy found hope – and a new lease on life. Thanks to the treatment she received in a BioCanRx funded chimeric antigen receptor-modi ed T cells (CAR-T) clinical trial in Ottawa, Leahy had a complete response – with no more cancer detected in her blood.



BioCanRx 2015-2024 Impact to Date



BioCanRx - 2015 to 2024

Mission – Accelerating to the clinic the most promising cancer immunotherapies designed to save lives and enable a better quality of life.

Vision – Turning all cancers into curable diseases.

More Than the Sum of its Parts: The BioCanRx Ecosystem

Since 2015, BioCanRx has built an extensive network of scientists, clinicians, academic institutions, NGOs and industry partners dedicated to transforming all cancers into curable diseases through immunotherapy. Our network is built on collaboration, encouraging connection and cooperation across all disciplines involved in immunotherapy and life sciences research to accelerate the development of cutting-edge immunooncology therapies. By investing in the translation, manufacture, and adoption of cancer immunotherapies, and facilitating the inter-disciplinary connections required for success, our entire network is working to bring world-class technologies from the research lab to clinical trials, leveraging existing Canadian infrastructure leveraging existing Canadian infrastructure investments.



This approach has been able to address national challenges in both developing homegrown discoveries and adopting international innovations. As a collective, our mission has been to accelerate the most promising cancer immunotherapies to the clinic, saving and enhancing the lives of people living with cancer. We are working together with our partners, integrating and coordinating research investments, infrastructure, skills training, patient engagement, and partnerships to swiftly deliver novel, made-in-Canada immunotherapies to patients. Thanks to funding from the NCE program, between 2015 and 2023 our tailor-made approach to translational cancer immunotherapy established a high-performing program delivering curative therapies. Today, we are able to address critical health system needs by bolstering translational research capacity within our borders, and are capturing the value of Canada's early-stage cancer research investments while benefiting Canadian cancer patients. To build a strong network, the Networks of Centres of Excellence (NCE) program identified fiv evaluation criteria around which BioCanRx programming, and our network, have been built.

Research	Training and HQP		
Funding projects aimed at advancing novel therapies towards the clinic and providing support to access critical infrastructure to rapidly move these forward.	Training the next generation of immunotherapy researchers and addressing knowledge gaps in clinical translational research by providing targeted training and development in clinical translation and biomanufacturing.		
Network and Partnerships	Knowledge and Technology Exchange and Exploitation		
Developing a cultivated, comprehensive, collaborative network that encompass academic, industrial, governmental, and non-profit sectors and capable of advancing cancer biotherapeutics from laboratory discoveries to clinical applications that can be rapidly translated into tangible healthcare benefits.	Accelerates the clinical development of novel immunotherapies using a staged pipeline system that yields tangible results and attract investment by other partners.		

Providing leadership and direction to BioCanRx and our network to ensure that we remain on target with respect to our strategic plan, make the best decisions regarding our investments and research objectives and commitment to the NCE mandate.

Management and Governance

While the BioCanRx Network was launched with NCE funding in 2015 and subsequently extended for a second, reduced three-year term, the announcement of the NCE program's sunsetting in 2018 encouraged BioCanRx to identify new funding support. This led to our application to the new and highly competitive Strategic Science Fund (SSF). While waiting for the announcement of a successful application from the SSF (announced in late 2023), BioCanRx continued operations under a no-cost extension in Cycle 2 through FY 2023-2024, when SSF funding of \$38M for 2024-2029 was confirmed.



While BioCanRx has faced challenges in the last years, the strength of our incredible network of scientists and clinicians, academic institutions, industry, government organizations, charities and patient groups, not-for-profits and highly qualified personnel (the next generation of cancer immunotherapy researchers) allowed us to continue to move forward with one vision – to cure and enhance the quality of life of those living with cancer. Our shared outcomes and successes are testament to the value of our approach to supporting translational research, to building collaborative connections and to sharing resources, knowledge and know-how to advance immunotherapies for cancer and to the potential for this approach to be applied across the life sciences sector in Canada.

Research – Advancing Therapeutic Development

Since its inception, BioCanRx has provided financial support and aligned ey infrastructure resources to its network of researchers and partners, resulting in the successful advancement of 34 novel therapeutics and approaches targeting 40 cancer indications through it's translational pipeline, including hard-to-treat and refractory cancers. As of March 31, 2024, BioCanRx supported members of our network as they have advanced these therapies and treated over 400 patients in 12 clinical trials, evaluating the safety and efficacy of these novel therapeutics

From 2015 to 2023, BioCanRx has invested in novel approaches and therapeutic targets to modulate the immune system to fight cancer. This has included, but not been limited to, cellular therapies, antibodies and antibody-like molecules, and oncolytic viruses & vaccines targeting a number of targets. The network has also invested in projects to accelerate the outputs of translational research and maximize efficiency of the portfolio: manufacturing processes, early health technology assessment (HTA), patient engagement and clinical trial protocol design – all contributing to supporting a thriving translational research ecosystem in immunotherapy for the treatment of cancer.

By taking this holistic approach to supporting translational research, we have been able to ensure projects advance more effectively and efficiently: BioCanRx's track record and research outcomes have demonstrated the success of this approach.

BioCanRx's Translational Pipeline – A Pragmatic Ecosystem Approach

In addition to building a strong member and partner network, BioCanRx utilizes a pragmatic approach that has provided funding to projects across the translational continuum, from pre-clinical studies (Catalyst program and Enabling Studies program) to clinical application (Clinical Trials program). These programs reflect various stages of pre-clinical to clinical development such as: proof of concept, pre-clinical development, process development and manufacturing, and clinical trials. This pragmatic pipeline approach allows BioCanRx to continue investing in projects that demonstrate scientific promise as they move along the translational continnum (e.g., from an enabling study to clinical trial), and also invest in new projects entering at any point in the pipeline.

Underpinning these efforts is our Clinical, Social, and Economic Impact (CSEI) program and Core Facilities program. The CSEI program provides the network with the interdisciplinary support and knowledge required to address social, legal, ethical, economic, and healthsystem challenges encountered by biotherapeutic technologies, including early health technology assessments (HTA), as they advance from pre-clinical research to clinical trials and eventual integration into the healthcare system. Projects are further supported by investments in Core Facilities that enhance translational research by providing highly specialized and necessary expertise and services to support funded project teams.

This approach to funding immunotherapy development within the BioCanRx network has been highly successful and is supported by an international Research Management Committee (RMC) and also informed by our Cancer Stakeholder Alliance – both of which provide insights and expertise to shape our investment focus. The RMC ensures BioCanRx research investments are sound, innovative, benchmarked against international initiatives, and have the potential for commercialization and adoption in the Canadian health system. Our Cancer Stakeholder Alliance (CSA), a consortium of more than 50 cancer charities and NGOs, shapes patient engagement in network activities informs research program priorities related to patient access to innovative therapies and future health system adoption (e.g., highlighting the need for early HTA research for CAR T cell therapy). Lastly, the provision of preclinical to clinical development training in at specific points along the translational continuum ensures alignment of the project team with the regulatory dossier requirements of Health Canada, increasing the efficiency of our research investments and representing a pragmatic ecosystem approach to translation.

The Pipeline Approach – BioCanRx Projects – 2015-2023

Working together, our network members are helping to bridge the translational research gap and turn lab discoveries into novel and potentially curative immunotherapies for the treatment of cancer. We collaborate, coordinate and share interdisciplinary knowledge that allows research to be carried out as efficiently as possible, leveraging existing investments in the Canadian landscape. As a network, we have focused on five areas of translational research, each of which contributes to transforming laboratory ideas into clinical products that can be tested in cancer patients.



Catalyst Program

Supports short-term early-stage projects that can advance to the next stage in a research pipeline and generate scientific tools and methods that can be used by other network researchers

Enabling Studies

Funds work required to prepare and position biotherapeutic products and platforms for clinical testing and patients

Clinical Trials

Provides funds for clinical trials of novel cancer biotherapeutics or innovative combination approaches. The trial must be collaborative, including multiple sites using our core facilities in other networked institutions in other member institutions, if applicable.

Clinical, Social, and Economic Impact Program

Supports the development of potential solutions to social, legal, ethical, economic, or health systems barriers facing BioCanRx biotherapeutic products and platforms as they progress through the translational pipeline from preclinical research to clinical trials.

Core Facilities

Within the network, we are able to provide operational funding to facilities across the country that support bioengineering and GMP biomanufacturing. Core facilities within the network also develop tests and conduct monitoring to better understand the biology of what these treatments are doing for patients

Network Projects

From 2015 through 2023, BioCanRx network researchers led 61 projects – all supported through funding from BioCanRx and all of which will contribute to developing potentially curative immunotherapies for the treatment of

cancer and making these available to Canadian patients. A complete list of the projects funded can be found in Appendix A.



Significant Research Impacts and the Researchers Behind Them

CAR T cells (Chimeric Antigen Receptor T cells) are a groundbreaking cancer treatment, some currently marketed, and others used in clinical trials around the world, which involves extracting a patient's immune cells, genetically modifying them to target the patient's tumor, and returning them in large numbers to attack cancer cells. This adoptive cell transfer has shown dramatic results in some patients, particularly those with advanced blood cancers like acute lymphoblastic leukemia (ALL) and lymphoma.

While this therapeutic approach is in use in a number of countries including the United States and China, altering a patient's own T cells requires substantial infrastructure and expertise. This had traditionally limited accessibility and affordability for Canadians looking to obtain this treatment as we have historically lacked the infrastructure and support for translational research to manufacture CAR T in Canada. In fact, compared to the USA and many other countries, Canada has fewer CAR T clinical trials, and access to the marketed CAR T therapies varies across provinces due to varying reimbursement approaches in our provincial health systems, leading to Canadians having to travel to the USA and having to pay between \$1-2M to access the therapy, even in a clinical trial.

Since its inception, our network of researchers, clinicians and partners has recognized that onboarding biomanufacturing capacity in Canada was critical to supporting bench to bedside translational research. To ultimately expand access to novel therapies such as CAR T cell therapy in Canada, we as a country had to onboard a biomanufacturing process. In 2017, BioCanRx started a cross-country "made-in-Canada" CAR T biomanufacturing and clinical trial program known as Canadian-Led Immunotherapy for Cancer (CLIC) and by 2019, members of our network were treating blood cancer patients who otherwise would have no access to this innovative cancer treatment, such as Camille Leahy and Owen Snyder, due to the 25-year age cutoff for the commercially available therapy at the time. This success is a testament to the leadership of researchers across our network including Drs. John Bell, Natasha Kekre and Jennifer Quizi of the Ottawa Hospital Research Institute (OHRI), Brad Nelson (BC Cancer Agency), Robert Holt (BC Cancer Agency), and Kevin Hay (now University of Calgary) and many others whose scientific collaboration has been pivotal in making CAR T cell therapies accessible to patients across Canada.

"This "Made-in-Canada CAR T" platform program uses a GMPenabled manufacturing device to produce a cell therapy dose in 7 to 10 days and has already been used for more than 50 patients at less than a tenth of the cost of a commercial product."

- Innovative Genomics Institute

The influence of the research being done across the BioCanRx network extends well beyond CAR T cells as our programs are agnostic to the type of immunotherapy development we support as long as these are used to modulate the immune system to treat cancer.

Our approach, and the projects we have supported, have demonstrated success. Among the projects in our portfolio are 34 therapeutics that have been advanced towards the clinic, among them a pioneering use of **exosomes** to attack and destroy cancer from within. Led by Dr. Carolina Ilkow, a Senior Scientist in the Cancer Therapeutics Program at the Ottawa Hospital Research Institute and an Associate Professor at the University of Ottawa, the use of exosomes - often referred to as the body's natural "Fed-Ex system"—to deliver targeted messages to immune cells, has shown significant promise in preclinical studies, demonstrating the potential to treat a wide range of cancers by harnessing the body's own cellular communication network.

In addition to supporting therapeutic development, we have invested in the facilities and services critical to enabling translational research, for example GMP viral vector manufacturing and fill/finish, to enhance their product offerings and ensure their longer-term sustainability. Thanks to BioCanRx's leadership, particularly the efforts of Dr John Bell, Canada has fortified its position in biomanufacturing, ensuring a home-grown supply of these vital components and services.

Impact on the performance of our oncology health research ecosystem: A clear demonstration of the impact of the work of the network is our ability to support home-grown innovation all the way to a clinical trial. From 2002 – 2022, 36 or 4% of immune-oncology clinical trials in Canada were based on our Canadian innovations. Of these, 42% are directly attributable to work being done by members of the network and the funding, support and pipeline approach of the BioCanRx translational program, and this, since only 2015. This is a substantial improvement from our inception in 2015 when less than 1% of immune-oncology clinical trials in Canada were based on Canadian innovation. A pragmatic approach, and targeted investment that is tailored-made for Canada can result in large scale impact for both our patients and our economy.



Highlights – BioCanRx Funded Projects

All of the projects supported by BioCanRx are contributing to innovation in cancer immunotherapy, growing capacity in our life-sciences sector and bene tting patients in Canada.

Catalyst Program (O ered only in Cycle 1)

Dr. Michel Duval (CHU Sainte-Justine)



Dr. Michel Duval was funded through the Catalyst program in Cycle 1 to develop an innovative cell-based immunotherapy based on a specific type of stimulation of the innate immune system that could be applicable to several types of leukemia and

solid cancers. Coined *Therapeutic Inducers of Natural Killer Cell Killing* (ThINKK), Dr. Duval and his team

established the optimal dosage (number of cells) and therapeutic schedule (frequency and number of treatments) of injections for his ThINKK therapy. This project continued in BioCanRx's project pipeline as an Enabling Study project funded in Cycle 2 to support GMP manufacturing and trial initiation of this technology. Dr. Duval's next step is to imminently open a Phase I clinical trial assessing the feasibility and safety of ThINKK adoptive transfers in patients with leukemia or neuroblastoma undergoing allogeneic hemopoietic stem cell therapy (HSCT).

Enabling Study

Jean-Simon Diallo (Ottawa Hospital Research Institute)



Dr. Jean-Simon Diallo's team has developed small molecules termed "viral sensitizers" (VSE-Lenti ") that boost the production and efficiency of lentiviruses. Today, VSE-Lenti is produced commercially by Virica, a company Diallo founded in 2018. BioCanRx has been

an integral part of this spin-out, first investing in Dr. Diallo's Enabling Study Project to develop analytical assays and regulatory compliance packages for viral sensitizer technology commercialization. The goal of this project was to generate a laboratory process that enables the increased manufacture of clinical-grade material suitable for Canadian clinical trials, ultimately increasing Canadian cancer patients' access to next generation immunotherapies.

Since then, Virica received a grant for \$790K from the Ontario Together Fund to "expand its bioprocessing facilities and increase its capacity to scale up viral medicines and vaccine production". The company has attracted significant follow-on investments and is establishing new partnerships with international contract manufacturing organizations and is considered a jewel in the crown of the Ottawa life sciences ecosystem.

Clinical Trial

Aly-Khan Lalani



The CYTOSHRINK clinical trial was an innovative, interdisciplinary study investigating whether combining systemic immunotherapy with highly precise, targeted radiation could improve outcomes for patients with metastatic kidney cancer. Led by Dr. Aly-Khan Lalani (McMaster University), this trial was among the first randomized controlled studies to assess this combination in this patient population. It represents an important advancement in cancer treatment, leveraging immunotherapy—now the standard of care for metastatic kidney cancer—with radiation therapy, an approach gaining renewed interest due to emerging evidence of its effectiveness, paving the way for improved treatment strategies. The trial expanded beyond its initial site in Hamilton to include London, Toronto, Ottawa, Kitchener, Edmonton, Montreal, and internationally to Australia, ultimately enrolling 67 patients. Its success was made possible through BioCanRx funding and a \$774,000 industry partnership with Bristol-Myers Squibb, highlighting the strength of academic-industry collaboration and a shared investment in advancing innovative cancer therapies.

Beyond evaluating treatment efficacy, the trial incorporated biomarker research to investigate potential correlations between patient responses and biological indicators. A key aspect of this work was the integration of the BioCanRx-funded Human Immune Testing Suite (HITS) at McMaster, along with microbiome analyses, which enabled in-depth analyses of patient samples collected at different stages of treatment. Researchers examined how changes in the microbiome might influence immunotherapy responses, with the goal of better predicting and enhancing treatment outcomes.

"This really is team science," says Dr. Lalani. "It really does, like they say, take a village to raise a clinical trial. We are grateful to patients, their families and the trial investigators for their support".

Clinical Social Economic Impact (CSEI) Program

Dr. Dean Fergusson (OHRI)



Funded in Cycle 2, Dr. Dean Fergusson (OHRI) and colleagues were funded via a CSEI project grant to expand the knowledge of who, when, and at what dose individuals best respond to CAR T therapy, as we know that there is a significant heterogeneity in individuals who see improvement versus those that do not. In a first-of-its-kind analysis for CAR T cell therapies, Dr. Fergusson's team examined individual patient data from individual records of more than 2,400 patients who participated in more than 102 clinical trials. The analyses identified important characteristics which may be impacting the efficacy of CAR T cell therapy for individuals with blood cancers. These data have been integrated into clinical trials falling under the CLIC program and have been recently <u>published</u> in the open access journal BMC Systematic Reviews.

Core Facilities Program

Molecular and Cellular Immunology Core

The Molecular and Cellular Immunology Core (MCIC) is a 1,000 sq. ft. full-service facility specializing in advanced molecular and histological services. Thanks to BioCanRx's investment in staff and infrastructure development, the MCIC has significantly expanded its capacity and impact, and established itself as a leading center in Canada for cell- and tissue-based immune analyses. Prior to this support, the facility accommodated approximately 10 academic collaborations annually, primarily focused on complex immune monitoring studies. Today, it supports 50-60 projects per year, serving both academic and industry collaborations at the national and international level. These projects range from preclinical to clinical studies, such as biomarker discovery and investigations into immune cell activity in clinical trial samples. The MCIC's comprehensive services include basic tissue processing, tissue microarray construction, and the development and analysis of complex multicolor immunofluorescent panels relevant to human cancer immunology and immunotherapy.

Funding the big discoveries is rewarding. Infrastructure such as BioCanRx's core facilities is less glamorous. Infrastructure support such as that available via the BioCanRx Core Facility program is less glamorous. Without these facilities, though, the big discoveries would take much longer, be much costlier and, possibly, wouldn't be made at all. The relatively small investments BioCanRx is making in Canadian core facilities are poised to generate big payoffs for Canadians.

The MCIC has contributed to numerous BioCanRxfunded projects, including extensive support for CLIC-01 (CD19 CAR) and CLIC-02 (CD22 CAR) clinical trials. Its efforts have resulted in 40 publications and the facility has seen a notable increase in collaborations with Canadian biotechnology companies. In addition to investing in translational research, BioCanRx – working with network members, partners, governments and institutions – has been instrumental in developing the structures and facilities needed to advance therapeutic development in Canada.

Investing in Pan-Canadian Cooperation and Core Facilities to build up our Translational Ecosystem for Self-Sufficien



GMP Manufacturing

Early in our mandate, BioCanRx and our network members identified the critical need for Good Manufacturing Practices (GMP) biomanufacturing to not only support but also help to deliver on a successful translational research program. Recognizing the inefficiency of sending GMP-grade viral products to the USA for fill and finish (the act of putting a GMP-grade product into a bottle), BioCanRx worked with network partners and collaborated with the National Research Council (NRC) to onboard this capability at the Alberta Cell Therapy Manufacturing (ACTM) facility in Alberta. This strategic investment not only ensured that clinicalgrade biotherapeutics could be produced and vialed in Canada, but also attracted a \$5 million follow-on investment from the province. As a result, the ACTM now provides fill-finish services to network members and the broader Canadian research community on an ongoing basis, thus helping to reduce the cost and time involved in the production of GMP-compliant products for early-phase clinical trials and enabling this essential service within our own borders. Facilities like the ACTM and the Ottawa Hospital Research Institute (OHRI) – both network members – are pivotal to the success of BioCanRx, offering advanced technologies and resources to researchers, and playing a key role in developing new biotherapeutics.





Core Facilities

Advanced imaging and analytics technologies within these core facilities offer critical insights into the mechanisms of action and efficacy of new treatments. This has led to breakthroughs in understanding cancer therapies, further solidifying the BioCanRx network's leadership in the translation, manufacture and adoption of cancer immunotherapies.

The benefits to the facilities themselves are noteworthy. The funding and support provided by BioCanRx has not only allowed them to demonstrate their capacity to provide services, allowing them to attract further investment and both academic and commercial users of their facilities, ensuring that they can continue to support translational research in the long term.

CLICing into Place: A Made-in-Canada Success Story

Canada's first homegrown CAR T-cell therapy is a landmark achievement in Canadian science and innovation—demonstrating how strategic investment, collaborative research, and translational infrastructure can drive world-class breakthroughs in cancer treatment.

CAR T-cell therapy is a personalized form of immunotherapy that engineers a patient's own immune cells to recognize and kill cancer. While these therapies have revolutionized care for certain blood cancers, access in Canada was limited to commercially available treatments developed outside the country—often at high cost and with constrained availability.

In 2016, recognizing this critical gap, BioCanRx network leaders launched an ambitious project to build a fully Canadian CAR T therapy platform, gathering the requisite expertise around CLIC.

This initiative brought together leading Canadian scientists, clinicians, cell manufacturing experts, and patient partners to develop a made-in-Canada solution from discovery to clinical delivery – and utilized the Enabling Studies, CSEI and Clinical Trial programs to achieve this outcome:

Key milestones in the timeline include:

2017: BioCanRx funds the initial projects, one laying the groundwork for a Canadian CAR T manufacturing (Enabling Studies project, PI Holt) and clinical pipeline and the second to produce a patient-informed clinical trial protocol (CSEI project GO-CART, PI Lalu).

- 2018: BioCanRx funds a project examining implementation of CAR T in health care system.
- 2019: Health Canada approves the first madein-Canada CAR T clinical trial application (CLIC-01), making it the first such trial fully designed, manufactured, and led in Canada. BioCanRx alongside partners invests in this clinical trial.
- 2020: The team establishes the core scientific and translational capabilities required to support clinical trials, and invests in expanding cell manufacturing to other sites across the country.
- 2022: CLIC-01 clinical trial results demonstrate safety and promising outcomes in patients with relapsed/ refractory blood cancers.
- 2022 and beyond: Building on this success, new CAR Ts are proposed by BioCanRx clinicians and scientist that use this manufacturing know-how to produce novel CAR cells applicable to other disease indications and exploring how to make Canadianmade CAR T therapies more accessible across the country.

This made-in-Canada CAR T platform is a powerful example of translational research in action. It showcases how BioCanRx's model—fostering collaboration across disciplines and sectors—can turn research discoveries into real-world treatments. More than just a scientific success, the program reflects Canada's capacity to lead in cell and gene therapy innovation, while ensuring equitable, sustainable access for patients. A made-in-Canada solution.



Training: Developing Highly Qualified Personnel (HQP)

Recognizing the need to support our network as it grows, BioCanRx has been committed to the training and development of Highly Qualified Personnel (HQP). With its members and partner organizations, BioCanRx has established a variety of training programs designed to cultivate a new generation of experts equipped with the skills and knowledge essential for advancing cancer therapies from the laboratory bench to clinical applications.

These programs not only enhance technical competencies but also instill a comprehensive

understanding of the broader implications

of their work, fostering a well-rounded and

immunotherapy across Canada. To date, more

than 675 HQP have benefitted from training – through BioCanRx, with our member researchers

impactful cadre of professionals ready to support innovation and excellence in

and through our partners. Many of these have gone on to successful careers in academia, industry, and healthcare, significantly contributing to advancements in cancer research and treatment and, in many cases, becoming part of our expanded BioCanRx network.



Building Excellence in Translational Research and Comprehensive Hands-on Training



BioCanRx's approach to training is comprehensive, addressing the entire drug development continuum and offering opportunities that range from internships to targeted workshops. This includes programs that build translational research excellence by providing the next generation of researchers with hands-on experience working closely with seasoned researchers from across the network. Programs include undergraduate internships, lab exchanges, and travel awards, which collectively support the academic and professional growth of HQP while introducing them to the research being led by network members. The hands-on training immerses trainees in the latest translational research, enabling them to work closely with experienced scientists on cutting-edge biotherapeutics, allowing the benefit of learning from experienced Network members. This direct engagement is crucial for developing both the technical expertise and practical experience necessary for translating groundbreaking research.

Research and learning extends beyond BioCanRx's mandate of cancer immunotherapy and biotherapeutics to include cancer-related research or policy-related work. Recognizing the need for interdisciplinary expertise for success in translational research, this could include participation in projects aiming to find solutions to social, legal, ethical, economic or health-systems barriers relating to cancer and patient care, including those with an

Indigenous-oriented framework, such as Indigenous traditional knowledge to study cancer, or to develop strategies to improve cancer care of Indigenous people.

In addition to hands-on training, BioCanRx is committed to supporting skill development in translational research, and offers numerous workshops, seminars, and networking events. These activities not only support the development of the skills needed to engage in translational research, but also cultivate networks amongst the ecosystem to support collaboration and innovation.

Lastly, the Preclinical Program Development Workshop, a unique 5-day intensive event designed to equip

research teams with the tools and strategies needed to develop robust preclinical programs for biotherapeutic discoveries. The workshop featured in-depth talks by subject matter experts from academia, industry, government, and patient advocacy organizations, offering valuable insights into key areas such as QA/QC, assay development, program management, regulatory processes, and business development.

Supporting Skills Development in Patient Engagement for HQP and Immunotherapy Research for Patients and Caregivers

Patient engagement is a cornerstone of BioCanRx's translational research approach, and requires the development of skills in plain language communication and the implementation of best practices for inclusive capacity building. The Learning Institute fosters these skills as well as the commitment to integrating patient perspectives into research. Its inclusion in the annual Summit for Cancer Immunotherapy (Summit4CI) exemplifies this approach through its bi-directional learning model, where patients and academic trainees are paired as "buddies" to share their unique expertise on cancer immunotherapy research. By working together to explain plenary sessions in plain English, this initiative ensures that scientific content is accessible to a wider audience, including patients, fostering a deeper connection between research and community impact.

"Following this experience, I better appreciate why this change is upon us. The research teams cannot fully understand the point of view of a patient through a statistic or a survey. The impact of their voices and stories is more significant than what the numbers could tell us; we just have to listen."

> 2023 Learning Institute HQP Participant

90% of HQP graduates secure relevant employment, creating a skilled workforce crucial to Canada's economic and social development and driving advancements in cancer research, biomanufacturing, and healthcare.



Building a Talent Pipeline in Canada – For Today and Tomorrow

Cultivating Biomanufacturing Expertise

Along with each of BioCanRx's biomanufacturing initiative, comes access to sought-after and unique training opportunities. BioCanRx has implemented several strategic initiatives to create an academic-toindustry pipeline that addresses the significant skills gap in biomanufacturing that exists in Canada today. **CanPRIME** is a great example and is the first of its kind hands-on biomanufacturing training program.

Algonquin College Micro-Credential GMP Training:

Developed closely with BioCanRx senior staff and Algonquin College, 'GMP Knowledge and Principles' was the first of its kind 7-week course where students identified and reviewed standards and specific cases and learned how to use and apply GMP requirements, as well as quality management systems (QMS) and good documentation practices (GDP).

S mitacs

CanPRIME 2.0: In 2022, the second iteration of the CanPRIME program – developed by OHRI in concert with BioCanRx and supported by Mitacs - was launched to support the POC cell therapy network, to onboard five new CanPRIME training sites at GMP facilities in British Columbia, Alberta, Manitoba, Saskatchewan, and Ontario, building upon the highly successful CanPRIME1.0 program based at the Biotherapeutics and Manufacturing Centre of the OHRI. This competitive program offers college and university students eight months of paid hands-on training at one of the above mentioned GMP facilities, providing students with the opportunity to gain a functional understanding and practical application of GMP principles in a biomanufacturing environment. CanPRIME 2.0 creates a pipeline of HQP with essential biomanufacturing skills, uniquely preparing individuals for careers in industry, academia, government and non-profits, ensuring they are GMP-ready and highly employable.

"As a student finishing my studies, preparing to enter the professional world was a daunting task. With partnerships like CanPRIME bridging the gap, those dream jobs I've heard about suddenly became more real than ever."

– Reuben Benedict,
 Past CanPRIME Intern



Indigenous Student Summer Internships

The BioCanRx network is committed to diversity and inclusion at all levels. Inclusion is exemplified by the Indigenous Student Summer Internship Program – an initiative that offers Indigenous undergraduate students impactful research or policy experience in cancer-related projects at partner post-secondary institutions across Canada. The program not only provides hands-on experience but also fosters networking and mentorship opportunities, and has earned BioCanRx an award from Diversio for its replicability and expansion potential.

The success and expansion of this program has been made possible through the support of ecosystem partners. Sponsorship from the Ontario Institute for Cancer Research and Canadian Cancer Society has allowed expansion of the number of internships, while the Canadian Partnership Against Cancer has offered students the



opportunity to work in cancer policy, broadening the program's scope. Indspire, through its Rivers to Success program, has further enriched the experience by providing one-on-one and group guidance and mentorship from Indigenous peers and role models, helping participants stay grounded as they prepare to take the next steps on their personal path to success. Our partnership and collaboration with Indspire has been critical to the success of this program.



Canadian Société Cancer canadienne Society du cancer





"The BioCanRx Indigenous Summer Studentship has allowed me to engage in hands-on cancer immunotherapy research that I cannot imagine partaking in through any other means. Over the past four months, I conducted research with the overall goal of assessing CD19 CAR T cell activation following CRISPR-Cas9 mediated gene editing, which I can confidently say I would have never done without the help of BioCanRx. This summer has been invaluable, and their continued efforts to improve

our understanding of research through various workshops and seminars have been incredible."

- Alexandria McRorie, Mahoney Lab, University of Calgary

Developing the next generations – Let's Talk Science

An innovative aspect of BioCanRx's training program is its partnership with Let's Talk Science, an awardwinning national organization that supports career awareness and education across the research continuum. BioCanRx's participation in the organization's Let's Talk Cancer symposiums, career awareness events, and engagement with Indigenous and rural communities is helping to inform and inspire the next generations of cancer researchers.

To date more almost 15,000 high school students – including 2,156



Indigenous students - have engaged with programming at over 450 events and activities through our partnership.

Networking and Partnerships

The BioCanRx network is the result of cultivated, comprehensive collaborations that encompass academic, industrial, governmental, and non-profit sectors. These partnerships are the cornerstone of the BioCanRx mission to advance cancer biotherapeutics from laboratory discoveries to clinical applications, ensuring that these advancements are rapidly translated into tangible healthcare benefits, ultimately improving patient outcomes across the country.

We have built a substantial and diverse ecosystem of partners who recognize the value offered by the network as observed by the significant value of investment and number of partners. Through a rigorous selection process supported by international experts, we are able to identify and fund those projects with the best opportunity for positive outcomes and those which will enhance and support the development of immunotherapies within the Canadian cancer research ecosystem. Our derisking approach works: as projects advance towards the clinic, partner investment increases, confirming the validity of approach in our project selection.

The BioCanRx Cancer Stakeholder Alliance (CSA)

A core part of our network, the CSA is a consortium of charities and non-government organizations committed to the **inclusion** of the experience and perspective of cancer patients, their families and the concerned public in BioCanRx activities and projects, and the **accessibility** of BioCanRx research information to cancer patients, their families and the concerned public. Within the CSA, we have developed a two-way learning program between researchers and patients, the Learning Institute, a model internationally recognized by the European Society for Gene and Cell Therapy.

To date, the activities of the BioCanRx Cancer Stakeholder Alliance has resulted in a **9-fold increase** in patient collaboration in BioCanRx research projects, and a new generation of researchers trained in patient engagement and collaboration.

Collaborative Foundation

At the heart of the BioCanRx network's success are its partnerships with the scientists and clinicians within our academic institutions from across the country; without these, BioCanRx could not advance our mission. There are key partnerships with both provincial and federal public sector organizations, cancer charities, and industry partners. These collaborations facilitate every aspect of the biotherapeutic translational continuum, from technology development and research design to knowledge mobilization and the preparation of new technologies for adoption in the healthcare system. This holistic, multifaceted partnership strategy ensures that our varied partners benefit from our research investments aligned to their objectives while always keeping in mind the ultimate stakeholder and partner: Canada's cancer patients.



Significant artnership Achievements

Clinical Trials and Financial Impact: One of the most notable outcomes of BioCanRx's partnerships and the work of our network members has been the substantial increase in clinical trials in Canada that are based on home-grown innovation. These trials are a direct result of strategic investments in translational research and our network's ability to attract additional funding from industry partners, provinces, charities and NGOs and importantly, the Government of Canada. These collaborative efforts have enabled BioCanRx to work strategically and collectively to address complex challenges in cancer therapy and help accelerate the

18 Biotherapeutics for Cancer Treatment – BioCanRx, 2015 - 2024

development of new treatments, ensuring that Canadian patients benefit from cutting-edge treatments.

To date, BioCanRx-funded projects have secured \$109.49 million across 202 partners have led to the formation of eight spin-out companies, illustrating the significant economic impact of these partnerships. This leveraged funding has been a direct result of our successful model for supporting translational research. Funding is crucial for sustaining the network's activities and ensuring continued advancements in cancer immunotherapy. Partnership Diversity: BioCanRx's diversity of partnerships is a significant achievement. Harnessing the strengths of leading academic institutions, industry partners, government, and non-profit organizations, these collaborations foster innovation, provide essential funding and technical expertise, and ensure that BioCanRx is able to accelerate the development and commercialization of new biotherapeutics and enhance patient outcomes nationwide, aligned to the desired outcomes of sectoral partners.

- Academic Institutions: BioCanRx collaborates with leading academic institutions across Canada, fostering innovation through access to extensive knowledge, expertise, and research infrastructure. These partnerships are crucial for conducting cuttingedge research, training highly qualified personnel (HQP) while providing highly specialized tools and services via specialized facilities (i.e. Core Facilities).
- Industry: Close collaboration with industry partners is essential for the development and commercialization of new biotherapeutics. These partnerships provide critical funding and technical expertise, which are vital for bringing new therapies to market, in addition to the contribution of experimental and approved drug products.

Government and Non-Pro t Organizations:

Partnering with government agencies and non-profit organizations supports research initiatives, raises public awareness, and advocates for policies that promote cancer research and treatment. This holistic approach ensures comprehensive support for cancer therapy development and implementation, allowing us to examine new approaches of delivering drugs to the Canadian health care system. Our collaborations with science-based federal departments such as the NRC had enabled synergies between the government, non-profit, and academia.



Rapid Mobilization and Pivot – Drawing on the Network and Partnerships to Protect Vulnerable Cancer Patients during COVID

For people with cancer, COVID-19 posed a triple threat. First, their immune systems are suppressed, both by the cancer itself and potentially by treatments, making them more vulnerable to severe illness from the virus. Second, isolation—a key tool to prevent infection—is difficult due to frequent hospital visits for treatment. Third, despite progress in COVID-19 vaccine development, there was no certainty these vaccines would work for cancer patients. Dr. Rebecca Auer sought to protect them using IMM-101 and knew she had to act quickly.

COV-IMMUNO: A randomized, phase III trial of vaccination with IMM-101 versus observation for the prevention of severe COVID-19 related infections in cancer patients at increased risk of exposure



Dr. Auer was able to call on network colleagues and partners to bring together a large, interdisciplinary team able to collaborate effectively and move swiftly towards clinical trial. Starting in late March, funding and drug product were secured from multisectoral partners and developed a trial protocol. By June, the protocol for testing IMM-101—an immune booster used in some cancer therapies—was submitted to Health Canada and received approval for clinical trial within *6 weeks*. By September, *just six months* from the initial concept, the trial was recruiting patients, offering hope in a time of great uncertainty and a clinical trial protocol, developed.

Strengths of BioCanRx Partnerships

Resource Optimization: BioCanRx has leveraged Canadian research infrastructure investments in support of its translational research program. This collaborative approach benefits the projects and facilities, allowing the latter to demonstrate their value to the Canadian life science ecosystem and maintaining them in a state of readiness for the sector.



Building a Point-of-Care Network

After collaborating at a conference in 2016, BioCanRx network investigators in Ottawa, Vancouver and Victoria began developing the safe and efficient production of CAR T therapy treatment in Canada using a madein-Canada point-of-care (POC) method – closed and automated CAR T cell manufacturing equipment to fully capitalize on the advantages of automation. The therapeutic product that was developed, was fully made in Canada – with the clinical-grade plasmids developed in the GLP lab of Dr. Robert Holt at BC Cancer, the GMP lentiviral vector manufactured at the Biotherapeutics Manufacturing Centre at the Ottawa Hospital Research Institute, and the final GMP cell product manufactured at Dr. Brad Nelson's facility at BC Cancer in Victoria. The network's leadership in developing this approach to CAR T cell manufacturing also means that different GMP facilities across Canada and the world can also benefit from this network approach and know-how to manufacture their own products. Using NCE funds, investments were made to expand this manufacturing across the country to work in a networked fashion. This decentralized approach is different from the centralized model shown in the figure below, benefitting our country's geography while also allowing for the build-up of manufacturing capacity in the case that a site is not able to manufacture. The onboarding of three additional sites (Winnipeg, MB, Toronto, ON and Ottawa, ON) is ongoing and will contribute to the production of existing and novel made-in-Canada products.



Knowledge and Technology Exchange and Exploitation (KTEE)

BioCanRx has significantly contributed to the commercialization of biotherapeutics and the transfer of knowledge, impacting the biotechnology landscape in Canada and enhancing cancer treatments. The organization has been instrumental in ensuring that the ideas and innovations generated within supported within the network are appropriately derisked to enable a rapid go/no-go decision point by Canadian receptors. This has led to practical applications and innovations in cancer treatment, benefiting not only BioCanRx researchers but also the entire biotechnology industry in Canada and ultimately, patients seeking access to innovative therapeutics via clinical trials in Canada.

In addition, network members and BioCanRx staff have actively participated in consultations that have informed the Canadian Trials Fund and the Biomanufacturing and Life Sciences Strategy. Leadership and members have provided input and feedback that has helped shape current practices and policies and continue to work to influence future life sciences investment strategy to ensure it recognizes the importance of funding translational research.

Effective KTEE: Harnessing the ower of Collaboration

BioCanRx leadership has supported the onboarding of new technologies and services through strategic partnerships with entities such as the Alberta Cell Therapy Manufacturing (ACTM), the Ottawa Hospital Research Institute (OHRI) BMC, and the National Research Council (NRC). These facilities are pivotal in producing clinical grade biotherapeutics, ensuring high-quality standards and rapid delivery to patients. By galvanizing critical core facility infrastructure and providing network investigators and partner companies seamless access to the tools they need, BioCanRx has significantly accelerated the translation of research discoveries into clinical applications, and reinforced the critical role played by these facilities in advancing an asset towards the clinic by supporting the generation of fulsome regulatory dossiers.

By establishing a point-of-care network across the country and encouraging knowledge sharing, our researchers have worked collaboratively to share standard operating procedures (SOPs) allowing all groups to onboard manufacturing more easily and efficiently. This has been critical to establishing the infrastructure and processes needed to build our immunotherapy for cancer translational research network Transformative Impact through Commercialization: The outcome of leveraging this robust infrastructure and investing in preclinical to clinical development has led to numerous commercialization success stories at BioCanRx. Using the network's support, scientists, clinicians and academic institutions have successfully supported the development and commercialization of several innovative therapies and technologies, including an exosome-based cancer vaccine platform and viral sensitizer technology and Bispecific T-cell engager (BiTE).

in Canada and to our ability to develop and deliver novel therapeutics to Canadians. In fact, to date there have been 45 documented exchanges of SOPs, technology and expertise and BioCanRx funding of the Point of Care network has resulted in the development and sharing of 86 SOPs to onboard new facilities for manufacturing CD19 CAR T cells. An excellent example of the knowledge transfer is Denmark who are currently using both the CLIC 1901 lentiviral vector and have benefitted from receiving all related SOPs from the Canadian CLIC program to launch their own made-in-Denmark program – based on the construct from Canada.

Shared expertise and access to facilities across Canadian labs for our network — a practice that is not typical in other countries, where competition is the norm. International experts on Research Management Committee and Board of Directors share global best practices, ensuring Canada's competitiveness in immunotherapy. 319 researcher
collaborations, trained
675 personnel, and
partnered with 52 NGOs,
40 industry partners, and
53 cancer stakeholder
organizations

Development of a Virally Programmed Exosome-based Cancer Vaccine Platform

July 1, 2020 – March 31, 2025



Oncolytic or "cancer-killing viruses" are an exciting class of anticancer therapeutic agents not only due to their specific predilection to kill cancer cells but also because these tumour-combating viruses can "wake up" the patient's immune system to fight the tumour. This team is developing a novel, virus-programmed exosome platform which has the potential to transform the application of immunotherapy.

Today, the research IP from this project is being leveraged by Esphera Synbio to continue developing bespoke cancer immunotherapies using their



proprietary engineered exosome-based platform for improved vaccine efficacy.

Bispeci c T-cell engager antibodies targeting CD133+ brain tumor-initiating cells: A novel immunotherapy for recurrent glioblastoma

Oct 14, 2016 - Sept 30, 2019



Glioblastoma (GBM) is the most common primary adult brain tumor and is typically highly aggressive, infiltrative and resistant to standard therapies. Even with surgery, standard chemotherapy with temozolomide (TMZ), and radiation, tumor re-growth

(or recurrence) and patient relapse and fatal outcomes are inevitable.

Dr. Singh and Dr. Moffat combined their expertise in human GBM biology and clinically relevant patientderived stem cell models of brain tumors, and human synthetic antibody engineering technologies, to develop effective immunotherapies to target recurrent GBM.

Their research – in preclinical animal models, published in Nature Medicine on Aug. 2, 2024, has offered new hope for potential treatments for patients with recurrent glioblastoma and could be applied to other invasive brain cancers.

In 2018, Dr. Singh and Dr. Moffatt co-founded Empirica Therapeutics to further develop their therapeutic approach with the aim of bringing it to patients and eventually improving chances of survival for those with untreatable cancers. In 2020, the company was purchased for an undisclosed sum by Century Therapeutics which formed a new company Century Therapeutics Canada to be based at the McMaster Innovation Park in Hamilton, Ontario. These advancements hold the potential to revolutionize cancer treatment by providing more targeted and effective therapies.





In addition to these technological advancements, researchers supported by BioCanRx have successfully founded several spin-out companies, such as Esphera SynBio (exosome-based platform) and Virica Biotech (viral sensitizer technology). By leveraging BioCanRx funding and expertise, these companies are developing pioneering therapies and products. These innovations have garnered significant follow-on investments and have substantially expanded Canada's biotechnology landscape, underscoring the network's pivotal role in fostering cutting-edge research and supporting commercialization by investing in development to derisk an asset.

SPINOUT COMPANIES



(Empirica Therapeutics Inc Acquired by Century Therapeutics)

Virica Biotech – Building Efficiency and Cost

Savings in Manufacturing

Dr. Jean-Simon Diallo (OHRI/ University of Ottawa)'s <u>viral</u> <u>sensitizer technology</u> funded through BioCanRx's Catalyst and



Enabling programs led to the spin-out company <u>Virica</u> <u>Biotech</u>. Their proprietary and pioneering viral sensitizer technology has significant manufacturing value in terms of increased yield and better margins of virus-based therapeutics. From viral medicines manufacturing to anticancer therapy, Virica is working to address unmet needs in production and development to positively change human health.

Virica Biotech benefited from a timely BioCanRx investment to develop tools that decrease the cost of manufacturing vaccines and biotherapeutics.

Virica's innovations have significantly enhanced the efficiency of biomanufacturing, an activity that is critical to Canada's ability to respond to the next pandemic and reduce the cost of producing life-saving therapeutics. This is a clear example of how strategic translational research funding is benefitting both the health of Canadians and our economy.

ESPHERA SynBio – From a Project to a Platform

Just as FedEx delivers countless parcels to different addresses and with different contents, Dr Carolina Ilkow and her team have found that exosomes can go to any number of specific targets. Even more



promising, however, is the ability to change the contents of the exosome, the material that is being delivered to the various addresses. Today, Dr. Ilkow and her team can embed in the exosomes tiny pieces of RNA that act as immune checkpoint inhibitors to inhibit the growth of cells in the tumour, as well as toxins that can directly attack the cancer cells – moving forward from their initial BioCanRx funded research to develop a platform that could change the way immunotherapies are delivered.

By building up their patent portfolio, and raising the money required to support the commercialization of their platform, the Esphera SynBio team has been able to work to address manufacturing requirements, determining appropriate dosing to ensure the exosome can efficiently penetrate the tumour and how to place the desired therapeutic cargo into the exosome.

From one BioCanRx Enabling grant, Illkow and her colleagues are opening a whole new avenue for delivering immunotherapies in a cost-effective and potentially transformative manner – an exciting outcome!

Social Innovations, Policy Development and Publications

Between 2015 and 2024, BioCanRx members produced 1,196 research publications, with many appearing in journals such as Science, Translational Medicine and Nature Genetics.

BioCanRx also shares its expertise with policymakers and the public to benefit Canada's healthcare landscape, for example through Annual Public Forums and engagements with the Parliament of Canada. The network actively participates in events that provide a platform for discussing the latest developments in cancer immunotherapy and addressing barriers to patient access. Demonstrating the government's recognition of BioCanRx's expertise and leadership, Drs. John Bell and Stephanie Michaud have been repeatedly invited to testify before the Parliamentary Science and Research (SRSR) Committee. Their contributions to the Biomanufacturing and Life underscore BioCanRx's achievement in helping shape national strategies for scientific innovation and patient advocacy.

And our work to build awareness and understanding of translational research and immunotherapy for cancer extends beyond policy and academia. Our members are regularly published in national and international publications and in media features.



Technical publications have also been critical to knowledge sharingacross the network. Not only is our network committe to advancing immunotherapy for cancer research, but it is also building up our capacity by sharing knowhow and Standard Operating Procedures (SOPs) ensuring that once a process is established, in can be initiated elsewhere enabling research to be accelerated.

BioCanRx was recognized by Nobel Laureate Dr. Jennifer Doudna's Innovative Genomics Institute (IGI) in a report addressing the future of genetic therapies. The report highlights BioCanRx's leadership in the development of «Made-in-Canada CAR T» cells—a network led, government-backed initiative that leverages pointof-care (POC) manufacturing infrastructure across multiple provinces. BioCanRx's collaborative efforts in support of POC have led to significant cost reductions in CAR T therapy production, making it more accessible and affordable. This recognition from a leading global genomics institute underscores BioCanRx's contributions to cutting-edge cancer treatment and its influence on the international stage.



Publication Spotlight

BioCanRx investigators publish regularly in leading journals, contributing to advancements in immunotherapy. Below are examples of some of our investigator's most cited publications, demonstrating the novelty and impact:

Key in

A novel chimeric antigen receptor containing a JAK–STAT signaling domain mediates superior antitumor effects Yuki Kagoya, Shinya Tanaka, Tingxi Guo, Mark Anczurowski, Chung-Hsi Wang, Kayoko Saso, Marcus O Butler, Mark D Minden & Naoto Hirano

Nature Medicine (2018) 552 Citations

BioCanRx CSEI Project: Getting better Outcomes with Chimeric Antigen receptor T-cell therapy (GO-CART)



BioCanRx Enabling Study: Capacity Building for Chimeric Antigen Receptor (CAR)-modified T cell Therapies in Canada

Project lead:

Dr. Naoto

Hirano

Margaret Cancer



Risks and Benefits of Chimeric Antigen Receptor T-Cell (CAR-T) Therapy in Cancer:

BioCanRx Catalyst Program:

T cell therapy for cancer

New generation chimeric antigen

receptors for improved adoptive

A Systematic Review and Meta-Analysis

Emma J M Grigor, Dean Fergusson, Natasha Kekre, Joshua Montroy, Harold Atkins, Matthew D Seftel, Mads Daugaard, Justin Presseau, Kednapa Thavorn, Brian Hutton, Robert A Holt, Manoj M Lalu

Transfusion Medicine Reviews (2019) 195 Citations

The chimeric TAC receptor coopts the T cell receptor yielding robust anti-tumor activity without toxicity

Christopher W. Helsen, Joanne A. Hammill, Vivian W. C. Lau, Kenneth A. Mwawasi, Arya Afsahi, Ksenia Bezverbnaya, Lisa Newhook, Danielle L. Hayes, Craig Aarts, Bojana Bojovic, Galina F. Denisova, Jacek M. Kwiecien, Ian Brain, Heather Derocher, Katy Milne, Brad H. Nelson & Jonathan L. Bramson

Nature Communications (2018) 123 Citations BioCanRx Catalyst Program: Validation and manufacturing of anti-BCMA-TACT cells for the treatment of Multiple Myeloma



Enhancing National and International Visibility

As part of our mission to growing cancer immunotherapy research capacity in Canada, the BioCanRx network has been committed to increased visibility of our members, their work and our collaborative accomplishments both at home and around the world. This has been achieved through a variety of activities – involving individual members, partner organizations and with the engagement of patients and patient advocacy groups since the inception of the network in 2015.

BioCanRx has actively engaged with the Parliament of Canada to advocate for cancer immunotherapy research and its effective approach to translational research on behalf of, and with, its network members and partners. Presentations before the Parliamentary Standing Committee on Science & Research by key BioCanRx representatives, such as BioCanRx Founder Dr. John Bell and BioCanRx President and CEO Dr. Stéphanie Michaud, have highlighted the network's achievements and future goals - building awareness and support for continued funding of our unique approach to supporting translational research. These high-level engagements have brought attention to and awareness of the work being done across our network and underscored BioCanRx's role in shaping national policies and promoting cancer research. By directly interfacing with policymakers, BioCanRx has been able to not only raises awareness about the critical importance of cancer immunotherapy but also ensure sustained support for its innovative research initiatives.

Our growing reputation and influence have also been recognized internationally. Notably, the work of our network was highlighted in the book Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective (Second Edition), part of the Advances in Experimental Medicine and Biology series. BioCanRx was acknowledged for our pivotal role in developing, manufacturing, and clinically testing new immunotherapies that promise to be more effective, affordable, and safe than conventional cancer treatments. The book also highlighted BioCanRx's collaboration with key partners such as CADTH and Health Ontario, our contributions to CAR T biomanufacturing in Canada, and our innovative point-of-care manufacturing network. This unsolicited recognition underscores BioCanRx's leadership, the incredible work of our members and partners and the impact we are having both locally and on a global scale.

An excellent example of the growing reputation and regard for the work of the BioCanRx network is in Denmark's use of both the CLIC 1901 lentiviral vector and all related SOPs developed by the Canadian CLIC program to launch their own made-in-Denmark program, treating both adult and pediatric cancer patients.



8 conferences 300+ attendees each year

Featured Keynote Speakers:

Dr. Laurence Zitvogel, Paris-Saclay University Dr. Carl June - June Lab Dr. Len Seymour - University of Oxford Dr. Crystal MacKall - Stanford

Finally, a cornerstone of BioCanRx's efforts to strengthen our network and visibility is our annual scientific conference, the Summit for Cancer Immunotherapy. This event is a testament to BioCanRx's dedication to fostering collaboration and knowledge exchange on a national and international scale. Each year since 2016 the Summit has brought together scientists, clinicians, trainees, patients, government officials, and industry representatives from across Canada to discuss emerging science and patient engagement. By creating a dynamic platform for interaction and collaboration, the Summit enhances the network's research and outreach efforts and serves as a catalyst for new connections and partnerships, driving forward our mission and amplifying our collective impact on cancer research and patient care.

Through these strategic initiatives—strengthening patient and caregiver engagement, advocating at the national policy level, and fostering collaborative networks— BioCanRx is not only enhancing our national and international visibility but also reinforcing our position as a leader in cancer immunotherapy research.

Patient Engagement and Public Outreach

Patient engagement and public outreach are central to the BioCanRx mission, forming the cornerstone of a multifaceted approach to advancing cancer immunotherapy.

Through our network's Cancer Stakeholder Alliance (CSA), BioCanRx integrates invaluable patient and caregiver perspectives into research priorities, ensuring that the work is aligned with the real-world needs and experiences of those affected by cancer. Initially composed of 14 members, the CSA has expanded to 53 members, including various non-profit organizations and an independent member, focused on cancer indications, patient support, and advocacy. Strategic advice

and action plans developed by the CSA are instrumental in ensuring that our research remains patient-centered and impactful, aligning with the network's mission to address real-world cancer challenges. The inclusion of diverse groups and voices in our CSA also reflect our commitment to diversity and inclusion – ensuring all perspectives are considered in developing our research programs.

Furthermore, our CSA supports initiatives like our award-winning Learning Institute and public forums – parts of our Summit for Cancer Immunotherapy. These platforms provide patients with opportunities to interact directly with researchers, allowing them to contribute to the scientific discourse and feel empowered in the fight against cancer.

Bringing together leaders from oncology patient communities, Principal Investigators of BioCanRx projects, and members of our HQP, the Learning Institute encourages engagement in interactive and collaborative knowledge exchange activities at the annual Summit for Cancer Immunotherapy. Patient participants have gone on to serve on our working groups and on the CSA itself – helping to shape the focus of our work and providing invaluable insights to our network.

Moreover, BioCanRx extends its engagement efforts to the younger generation through a strategic partnership with Let's Talk Science. This collaboration focuses on promoting cancer immunotherapy topics to youth, particularly in schools with predominantly Indigenous students. By expanding outreach and educational efforts, BioCanRx fosters trust in science and addresses prevalent misinformation. This initiative not only enhances scientific literacy but also inspires a new



generation to participate in and advocate for innovative cancer research.

In essence, BioCanRx's commitment to patient engagement and public outreach creates a dynamic ecosystem where patients, caregivers, youth, and scientists come together to drive progress in cancer immunotherapy. By integrating diverse perspectives and promoting education, we are not only advancing scientific knowledge but also building a supportive and informed community dedicated to overcoming cancer.

In 2019 The European Society for Gene and Cell Therapy presented Dr. John Bell with the inaugural Public and Patient Engagement Award for work including the Learning Institute



Making Patient Partnerships A Reality in Very Early Phase Clinical TriaLs (MARVEL)

October 1, 2020 - April 1, 2023



Patient engagement in early phase clinical trials holds great promise for impact. However, very few clinical trials report on the involvement of patients as partners. This unique project encompassed clinical programs at various development

stages (late-stage development programs, and trials that are enrolling or about to enroll). Publications describing the resulting frameworks and processes, evaluations, and comparisons across trials, help to advance the field of patient engagement; in turn this can inspire other researchers within the cancer biotherapeutics scientific community to engage patients.

Lalu and his team established partnerships with five collaborating teams: three clinical trials, the BioCanRx Cancer Stakeholder Alliance, and the Ontario Institute for Cancer Research (OICR). They successfully onboarded patients to two trials and partnered with a third trial. Patients co-developed guides to improve the experience of trial participants and patient partners. With further support from CIHR, SCN, and Ontario SPOR Support Unit, they launched labpartners.ca, a comprehensive suite of information and resources for meaningful patient engagement.



Management of the Network



The BioCanRx network benefits from an established and robust governance and management framework, characterized by effective leadership, strategic planning, and a dedication to inclusivity and excellence. This cohesive structure ensures that BioCanRx remains a leader in cancer immunotherapy research and development.

Providing guidance to the network is a Board of Directors, providing strategic direction, financial oversight, and performance monitoring. The board members, renowned for their expertise in leadership, business management, and scientific rigour, are instrumental in guiding the network towards achieving its strategic objectives. The Board provides leadership and direction to ensure the network remains on target with respect to our strategic plan and mandate.

Research Management Committee (RMC)

Critical to our strong governance and the success of our network is our RMC which includes international experts who benchmark the network's research against leading global efforts in immune oncology. This committee rigorously evaluates research proposals, ensuring they meet the highest standards of scientific excellence and potential impact.

Not only does the RMC make funding recommendations, but it also provides continued evaluation, advice and guidance through a project's lifespan. Projects are regularly assessed for progress and outcomes, and, where necessary, the RMC is able to offer recommendations to improve on the likelihood of success.

The RMC's independence and expertise have been recognized as exemplary by the NCE Monitoring Committee as 'enabling peer-review based on international standards of excellence and providing access to markets, technologies and know-how in Europe and the US'.

Our board and committee structure ensures that appropriate policy and financial decisions are made and implemented effectively and have resulted in our rapid success in funding pipelines and advancing cancer immunotherapy research while also supporting notable achievements in patient engagement and training of HQP.

Strategic and Operational Planning

BioCanRx's management team is responsible for the meticulous planning and execution of the network's operations and initiatives. Since its inception in 2015, BioCanRx has demonstrated exceptional efficiency in transitioning basic discoveries through various stages to clinical trials. This is facilitated by a project management approach that ensures timely, budget-conscious, and high-quality completion of research projects, clinical trials, and training programs. Complementing this strategic foresight is BioCanRx's adept allocation of financial, and human resources. The management team employs rigorous research planning and budgeting mechanisms to ensure resources are used efficiently and effectively. These practices are continuously refined, allowing BioCanRx to adapt to the evolving landscape of cancer research and maintain its position at the forefront of innovation.

Current Board of Directors



Russell Williams, Chair, Board of Directors



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Antonia Palmer Co-Founder at Ac2orn: Advocacy for Canadian Childhood Oncology Research Network



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BioCanRx Research Management Committee – 2023-2024



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Dr. Alan Melcher Professor University of Leeds



Dr. Guy Ungerechts Deputy Director of the Medical Oncology Department at the Heidelberg University Hospital and National Center for Tumor Diseases (NCT) Heidelberg



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Dr. Cliona Rooney Texas Children's Cancer & Hematology Center Professor, Baylor College of Medicine



Dr. Bruce Seet Head of Medical Affairs (Canada) Novavax



Dr. Len Seymour Professor University of Oxford

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	Μ		Μ			Members:		
А	А		В		Dr. Ro	b Coffin		
А	A B			Dr. Chris Klebanoff				
А		А	В		Dr. Grant McFadden			
А	A A			Michael Mee				
Dr.	А	В			Dr. Alan Melcher			
	А	В			Dr. Nic	cole Onetto		
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Commitment to Equity, Diversity, and Inclusion (EDI)

Work led by the BioCanRx network has been at the forefront of contributions to social innovation and effective public policy across the life sciences. The BioCanRx network's Equity, Diversity, and Inclusion (EDI) Action Plan has garnered recognition from Diversio and we were named a BioTalent Canada I.D.E.A.L. Bioscience Employer in 2023-2024. Our initiatives ensure that research outcomes are socially impactful, addressing ethical challenges and promoting inclusivity in cancer treatment development.

As an organization and network, BioCanRx is committed to implementing EDI practices to enhance research excellence and inclusivity. The EDI Action Plan, based on recommendations from Diversio and guidance from the EDI Board Committee, includes:

- Standard Code of Conduct & Zero Tolerance Policy
- Indigenous Summer Student Internship Program
- Allyship and Unconscious Bias Training
- Developing a sponsorship program for marginalized HQP
- Multi-Network Safe Environment Initiative (HearU) for reporting incidents of harassment and discrimination

To ensure sustained progress, the EDI Committee diligently monitors and reports on the implementation of the EDI Action Plan. This committee, comprising members of the Board of Directors and external experts in EDI, ensures that BioCanRx remains at the forefront of promoting diversity and inclusion within the scientific community.

While BioCanRx recognizes that challenges remain in achieving the full participation of equity-seeking groups (including women, visible minorities, Indigenous peoples, people with diverse gender identities, and people with visible and invisible disabilities) in science careers, the EDI Action Plan has led to significant recognition from organizations like Diversio and BioTalent, highlighting the network's commitment to inclusivity and excellence.



BioCanRx has been Diversio Certified since 2021 and our Indigenous Student Summer Internship Program was recognized as a Top 20 EDI Initiative in 2022.



BioCanRx was named an I.D.E.A.L. Bioscience Employer[™] for 2023-2024 by BioTalent Canada. A commitment to inclusion, diversity, equity, and accessibility is not just a moral imperative but a strategic advantage in the bio-economy. The I.D.E.A.L. Bioscience Employer[™] Recognition Program is a BioTalent Canada initiative dedicated to celebrating organizations at the forefront of fostering Inclusion, Diversity, Equity, and Accessibility (IDEA) within the dynamic Canadian bio-economy.

Looking Forward

The network's future plans are ambitious and forwardthinking, focused on leveraging new technologies, expanding global collaborations, and addressing health disparities. These initiatives will ensure that BioCanRx remains at the forefront of cancer research, driving innovation and improving patient outcomes. BioCanRx is the sole national, science-based, not-forprofit organization in Canada dedicated to developing immunotherapies towards clinical trials. This translational pipeline program enables the progression of Canadian innovations from bench to bedside.



BioCanRx Project Pipeline Investment Model. Funded BioCanRx projects can enter or exit the pipeline at different stages from proof of-concept and preclinical development (Catalyst Program, Enabling Studies Program; TRL 2-7) to clinical development (Phase 1-3; TRL 7-8). All funded projects must have a clear path to the clinic. Under the CSEI Program, we provide funding to further advance the forward path of these projects to inform clinical practice and health decision making, dissemination and adoption, evidence- informed changes in policy and programs, and community engagement. BioCanRx also provides funding support for essential Core and Biomanufacturing Facilities thatF are engaged in our projects, which are not already receiving facility staff or maintenance support within the budgets of those BioCanRx projects. TRL; technology readiness level.

Investing in health research is crucial for Canada's future. To maximize impact, Canada must adopt an ecosystem approach, funding the entire health research continuum, including translational research. Failure to do so hampers Canada's ability to respond to future pandemics and capitalize on discoveries for Canadians' benefit. BioCanRx benefits from the excellent research outputs funded by Canadian cancer early-stage research funders, highlighting the need for continuous health research funding. The BioCanRx network plays a unique role in translating novel immunotherapies for cancer treatment, an area where Canada has not strategically invested. Translational research projects are resource-intensive, requiring coordination, expertise, and continuous funding. Support for these activities is essential as they deliver homegrown discoveries to Canadian patients, serving as a beacon of hope to cancer patients and tangible results to those affected by cancer. Working collaboratively, we have shown that this is possible, benefiting patients and boosting Canada's innovation performance and economy.

Appendix A: Researchers in the BioCanRx Network

Catalyst Projects (CAT)

CAT1

\$200,000

Naoto Hirano Adoptive transfer of T cells redirected by a high affinity antitumor T-cell receptor (TCR)

CAT2 \$200,239

David Stojdl Selecting a Clinical Candidate Oncolytic Rhabdovirus Vaccine Targeting CMV for Glioblastoma

CAT3

\$107,500

Jonathan Bramson, Raja Ghosh Development of a Bioreactor System to Automate T-Cell Manufacturing

CAT4

\$220,230 John Babcock, Brad Nelson

Novel Anti-Tumour Antibodies Isolated from Cancer Patient Immune B cell Repertoires

CAT5

\$220,230

Rebecca Auer, Jean Simon Diallo, Dean Fergusson A cancer vaccine composed of autologous tumour cells infected with an IL12 expressing Rhabdovirus

CAT6 \$200,000

Jonathan Bramson, Jean-Sebastien Delisle

Validation and Manufacturing of anti-BCMA-TACT cells for the treatment of multiple Myeloma

CAT7

\$200,000 Naoto Hirano

Molecularly constructed numerous CAR genes targeting antigens found on solid cancers

CAT8

\$209,804 Natasha Kekre

A personalized strategy employing virus-infected leukemia cell vaccine (ILCV) may provide a new tool in the treatment of leukemia

CAT9

\$199,996 Francois Bernard, Julian Lum, Andrew Minchinton

Targeted RadioLigand (tRL) and checkpoint blockade for metastatic castrate resistant prostate cancer

CAT10 \$200,000

Jason Moffat, Sheila Singh Bispecific T-cell engager antibodies targeting CD133+ brain tumorinitiating cells

CAT11 \$133.111

Robert Holt, Simon Turcotte Recombinant TCRs and peptide-MHC

antibodies to target KRAS hotspot mutations in pancreatic cancer

CAT12 \$200,000

Jason Moffat, Sachdev Sidhu

Pre-clinical validation of anti-SIRPa antibodies anti-tumor efficacy through immuno-modulation of macrophages

CAT13 \$200,000

Jean Simon Diallo, Guy Ungerechts Scalable Vector Manufacturing Enhancement Using Viral Sensitizer

CAT14

\$78,996

Carolina likow, Gary Levy, Barbara Vanderhyden Evaluation of FGL2 as a therapeutic target in ovarian cancer sensitizer

CAT15

\$199,500 Robert Rottapel

Targeting the Relaxin Autocrine Loop in High Grade Serous Ovarian Cancer using RLN2 Neutralizing Monoclonal Antibodies as a Therapeutic Strategy

CAT16 \$98,650

Karen Rossman

In vivo genome-wide CRISPR/ Cas9 screen to identify genes that limit curative checkpoint blockade immunotherapy in triple negative breast cancer

CAT17 \$100,000

Jean Simon Diallo

Evaluating and optimizing the immune response to our novel prime-boost vaccination regimen consisting of priming with anti-DEC205 and boosting with oncolytic vectors encoding ovalbumin (OVA) in immunocompetent mice

CAT18

\$214,890 Michel Duval

Activated plasmacytoid dendritic cells (pDC) to prevent leukemia development in humanized mice

CAT19 \$207,867

Jean-Sebastien Delisle, Robert Holt, Rahima Jamal, Rejean Lapointe, Simon Turcotte

Improving adoptive cell transfer immunotherapy with clinical-grade cell sorting of tumor-reactive T cells infiltrating solid tumors

Enabling Projects

ES1

\$462,264 John Bell, Brian Lichty, Andrea McCart

couples anti-cancer T cell responses with the targeting of human papilloma virus oncoproteins E6 and E7 for HPV associated cancers

ES2

\$263,181

Denis-Claude Roy, Yonghong Wan

Combining Oncoloytic Vaccine Therapy with Adoptive Cell Therapy to Target Cancers Expressing MAGE-A3

ES3 \$741,473

Byram Bridle, Brian Lichty, Jason Moffat

New canine melanoma vaccine: induce a sufficient number of tumourspecific T cells to determine the impact of anti-PDL1 therapy on T cell quantity and function

ES4

\$299,875

Claude Perreault, Denis-Claude Roy Targeting of immune cells to specific minor histocompatibility antigens (MiHAs)

ES5

\$43,500 Gregory Dekaban, Sowmya Viswanathan

In vivo human therapeutic cell tracking using a [19F]perfluorocarbon cellular MRI contrast agent

ES6 \$275,659

Megan Levings, Lori West

Transition of protocol for the isolation and expansion of T-regulatory cells (Tregs) from discarded human thymus from the research lab to a clinically-applicable GMP protocol

ES7

\$353,044 Brad Nelson

Adoptive T Cell Therapy Targeting Patient-Specific Driver Mutations in Lymphoma

ES8

\$744,996 Uri Tabori

Development of predictive companion biomarkers and therapeutic monitoring for hypermutant cancers to immune checkpoint inhibition

ES9

\$1,344,376 Robert Holt, John Bell, John Webb, Natasha Kekre Capacity Building for Chimeric Antigen Receptor (CAR)-modified T cell therapies in Canada

ES10

\$226,054 David Evans Oncolytic vaccinia virus for bladder cancer

ES11

\$675,000 James Koropatnick Advanced Preclinical Development of AVID200

ES12

\$375,000 John Bell, Jean-Simon Diallo Development of a Novel, Phase 1-Ready, Viro-Immunotherapeutic Oncovac

ES13 \$200,000

David Stojdl Selecting a Clinical Candidate Oncolytic Rhabdovirus Vaccine Targeting CMV for Glioblastoma

ES14

\$685,000 Carolina Ilkow, John Bell, Brian Lichty Development of a virally programmed exosome-based cancer vaccine platform

ES15

\$450,000

Kevin Hay, Brad Nelson, Robert Holt Enabling a Phase I/II multicenter CT of a novel single domain (sd)CD22specific camelid-derived(CAR) T-cell therapy

ES16

\$476,000 Robert Holt, Simon Turcotte

Recombinant TCRs to target KRAS hotspot mutations in pancreatic cancer

ES17

\$499,809 Jean-Simon Diallo, Christopher Boddy, Jeff Smith Development of Supporting Analytical Assays and Regulatory Compliance Package for Viral Sensitizer Technology Scott McComb, Kevin HayCommercialization

ES18

\$495,000 Michel Duval

First in human THINKK adoptive immunotherapy to prevent leukemia and neuroblastoma relapse: GMPmanufacturing and Phase I clinical trial initiation

ES19 \$500,000

Scott McComb, Kevin Hay Clinical Trial Enabling Studies for Multi-targeted Chimeric Antigen Receptor Therapeutics for the treatment of B-Cell Malignancies

ES20

\$125,000

Doug Mahoney, Jennifer Quizi CLIC-GPNMB41bbζ: Personalized CAR-T cell therapy for a patient with a rare sarcoma

ES21

\$367,250

Marcus Butler Manufacturing Process Development for Metabolically Reprogrammed

Tumor-Infiltrating Lymphocytes

ES22

\$732,783

JS Diallo, Marcus Boddy

Advancing GMP-Compliant Lentiviral Vector Manufacturing Enhancers for Cost-Effective Production of Anti-Cancer Cell Therapies

ES23

\$749,901 Caroline Ilkow, John Bell, Jennifer Quizi

Accelerating the Clinical Translation of a Virally Programmed Exosome-Based Cancer Vaccine

ES24 \$750.000

Megan Levings, Kevin Hay CTA submission for TITAN-01 (Thymic Treg Immune Therapy AgaiNst GVHD)

ES25

\$766,997 Jennifer Quizi, JS Delisle, Johnathan Bramson Enabling studies for a first-in-human clinical trial of BCMA-directed TAC-T cells

Clinical Trials (CT)

CT1

\$100,000 Kelvin Chan, Petros Pechlivanoglou, Tom Kouroukis, Christine Chen, Pierre Villeneuve Assessing the Real-World Clinical and Economical Outcomes of Emerging Innovative Technologies in Oncology: The Cases of Biosimilars and CAR T-cells

CT2

\$534,381

Naoto Hirano, Pamela Ohashi Evaluative Adoptive Cell Therapy to Treat Ovarian Cancer Using TILS Conditions with Dendritic Cells

CT3 \$498,640

Natasha Kekre, Christopher Paige Phase I study of autologous acute myelogenous leukemia (AML) cells containing lentivirus engineering expression of IL-12

CT4 \$498,640

\$496,640

Natasha Kekre, Christopher Paige Phase I study of autologous acute myelogenous leukemia (AML) cells containing lentivirus engineering expression of IL-12

CT5

\$796,397

Claude Perreault, Denis-Claude Roy Phase I clinical trial of Anti-

Minor Histocompatibility Antigen Immunotherapy: Broadening the scope of Application for Precision Therapeutics

CT6 \$733,977

Jonathan Bramson, Glenwood Goss, Robert Holt, Bryan Lo, Brad Nelson, Harmanjatinder Sekhon Interrogation of Biomarkers in Patient Samples from a Phase Ib Trial of the Immune Checkpoint Inhibitor, Avelumab, in Combination with SMAC Mimetic Debio1143

CT7 \$500.000

Marcus Butler

Phase Ib trial of pembrolizumab administered following adoptive cell therapy- A multiple cohort study; The ACTIVATE (Adoptive Cell Therapy InVigorated to Augment Tumor Eradication) Trial

CT8 \$400,000

Natasha Kekre

Canadian-Led Immunotherapies in Cancer: CLIC-1901 for the Treatment of Patients with Relapsed/Refractory CD19 Positive Hematologic Malignancies (CLIC-01 Study)

CT9 \$749

\$749,998 Rebecca Auer,

Christopher O'Callaghan

IC.8 COV-IMMUNO - A randomized, phase III trial of vaccination with IMM-101 versus observation for the prevention of severe respiratory and COVID-19 related infections in cancer patients at increased risk of exposure

CT10

\$750,000 Simon Turcotte

Adjuvant dual selected Tumor Infiltrating Lymphocytes for (4) ColoRectal cancer Liver Metastases trial (aTIL4CRLM)

CT11 \$544,482

Aly-Khan Lalani, Jonathan Bramson, Michael Surette

Phase II CYTOSHRINK trial: Cytoreductive Stereotactic Hypofractionated Radiotherapy with Combination Ipilimumab and Nivolumab for Metastatic Kidney Cancer

CT12 \$749.960

Denis-Claude Roy

An interventional, open-label, nonrandomized dose-escalation Phase I multicenter clinical trial of multi-peptide anti-minor histocompatibility antigen immunotherapy for the prevention of relapse in patients with high-risk malignancy eligible for matched related ASCT

CT13 \$997,463

Doug Mahoney

A Phase I Study of GCAR1, a Chimeric Antigen Receptor (CAR) T-Cell Therapy for Patients with Selected Relapsed / Refractory GPNMB-Expressing Solid Tumors

Clinical, Social, and Economic Impact Projects (CSEI)

CSEI1 \$431,262

Dean Fergusson, Jonathan Kimmelman, Chris McCabe Improving the Quality of Judgment in Cancer Therapeutics Development

CSEI2

\$346,390 Tania Bubela, Jean-Sebastien Delisle, Chris McCabe Improving the Quality of Judgment in Cancer Therapeutics Development

CSEI3

\$196,093 Kelly Cobey, Dean Fergusson, Manoj Lalu, Justin Presseau Translational Cancer Immunotherapeutics: Improving the Design, Analysis, and Reporting of Preclinical Studies

CSEI4

\$364,441 Dean Fergusson, Natasha Kekre, Manoj Lalu, Justin Presseau, Kednapa Thavorn Getting better Outcomes with Chimeric Antigen Receptor TCell therapy (GO-CART)

CSEI5

\$100,000 William Wong Developing System-level Policy Model for regenerative medicine and cell therapy in Oncology

CSEI6

\$100,058 Dean Fergusson Identifying effect modifiers for CAR-T cell therapeutic efficacy

CSEI7 \$394,967

Manoj Lalu, Dean Fergusson, Justin Presseau MARVEL: Making Patient Partnerships A Reality in Very Early Phase Clinical Trials: Development of a Patient Engagement Platform

CSEI8

\$100,000

Kednapa Thavorn Using real-world data and iterative economic evaluation to prioritize resource allocation for care and research in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia

CSEI9

\$100,000

Kelvin Chan, Petros Pechlivanoglou, Tom Kouroukis, Christine Chen, Pierre Villeneuve

Assessing the Real-World Clinical and Economical Outcomes of Emerging Innovative Technologies in Oncology: The Cases of Biosimilars and CAR T-cells

CSEI10 \$215,594

Dean Fergusson, Manoj Lalu Excelerating tumor-infiltrating lymphocytes (TIL) as a treatment for melanoma (TIL-ME)

Appendix B: Partnerships

HOST INSTITUTE/ ÉTABLISSEMENT HÔTE

The Ottawa Hospital Research Institute













INTERNATIONAL















MAYO CLINIC

Icahn School of Medicine at Mount Sinai













RS1



Memorial Sloan Kettering Cancer Center

National Institutes of Health







Universidade de São Paulo







NOT-FOR-PROFIT PARTNERS AND CANCER STAKEHOLDER ALLIANCE MEMBERS: PARTENAIRES CARITATIFS ET MEMBRES D'ALLIANCE DES INTERVENANTS CONTRE LE CANCER :

BREAST CANCER SOCIETY of Canada ²⁰ LA SOCIÉTÉ DU CANCER DU SEIN du Canada ²¹

15







Center for Commercialisation of Cancer IMMUNOTHERAPY



CANADIAN CANCER STATE RÉSEAU CANADIEN DES SURVIVOR NETWORK

CCRAN Colorectal Caster Resource 5 Actus Manager Actus Manager Actus Caster Actu



Childhood Cancer Canada







Canadian Breast Cancer Network Réseau canadien du cancer du sein



CellCAN



CANADIAN NEUROENDOCRINE TUMOUR SOCIETY

CNE







CBCN RCCS





Craig's Cause







Société de recherche sur le cancer

Cancer Research Society





Centre of Excellence on Partnership with Patients and the Public



Priorité Cancer

CANCER COLORECTAL COLORECTAL CANCER CANADA

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Save your skin



















ThéCell: Réseau de thérapie cellulaire, tissulaire et génique du Québec

ell











BioCanRx Headquarters

Siège social de BioCanRx

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