



## ***Policy Brief***

# ***Enhancing Access to CAR T in the Canadian Healthcare System***

January 2025

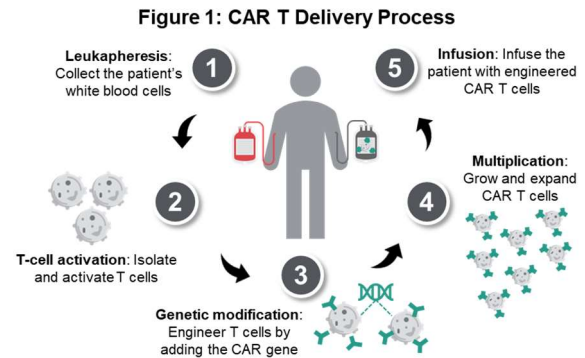
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## Introduction

**CAR T therapy is a revolutionary innovation in personalized medicine that offers hope for people suffering from rare, complex, and potentially lethal conditions.**

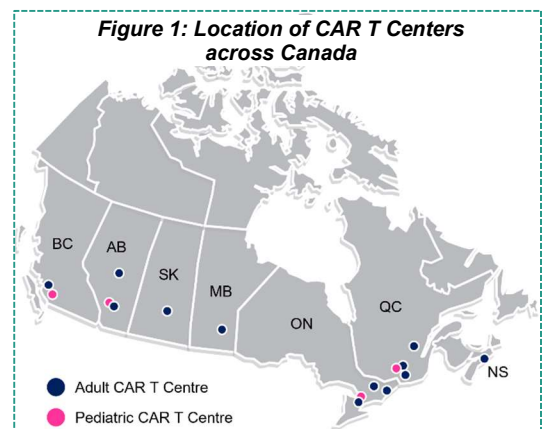
Chimeric Antigen Receptor T-cell (CAR T) therapy leverages the body's own immune system to fight cancer by genetically modifying their T-cells to specifically target and attack cancer cells (Figure 1). To date, CAR T therapies have demonstrated highly effective and durable responses, significantly improving long-term survival. In Canada, several CAR T products are approved, including those for adults with relapsed/refractory Diffuse Large B-Cell Lymphoma (DLBCL) and for pediatric and adult patients with relapsed/refractory B-cell Acute Lymphoblastic Leukemia (B-ALL), offering hope to individuals with few or no remaining treatment options.<sup>1,2,3,4</sup> Indeed, in some cases, clinical studies have shown that CAR T therapies significantly improve overall survival in patients with refractory DLBCL, reducing the risk of death by 27.4%, corresponding to a 38% improvement in overall survival compared to the standard of care.<sup>3</sup>



CAR T therapy has the potential to transform healthcare. Six CAR T products are currently approved for second, third, or fourth-line treatment of several oncology indications in Canada, including DLBCL, B-ALL, follicular lymphoma (FL), mantle cell lymphoma (MCL) and multiple myeloma (MM).<sup>4</sup> Additionally, over 250 novel products are in the clinical development pipeline for blood cancers, solid tumours and autoimmune diseases.<sup>5</sup> Demand for CAR T is expected to rise with approvals of new therapies and new indications of existing ones (e.g. multiple myeloma)<sup>6,7</sup>. These advancements will provide additional treatment options and earlier lines of treatment for hematological cancers (e.g. second line for Large B-Cell Lymphoma)<sup>8</sup>, along with new treatment regimens for solid tumors.<sup>9</sup>

**While CAR T has the potential to improve outcomes for previously untreatable diseases, unlocking the promise of this innovation will require Canadian healthcare systems to think and act strategically.**

As one of the first countries in the world to offer CAR T, Canada has demonstrated early and continued interest in enabling access to this innovative treatment. However, Canada faces the complexity of managing a de-centralised healthcare delivery system, with ten provincial and three territorial systems, and over 1 million residents managed by the federal government (e.g. Indigenous communities, immigrants/refugees, veterans, military and RCMP), leading to variations in healthcare policies and funding, and, ultimately, access to CAR T. Indeed, the need for specialized resources and expertise to deliver CAR T therapy has limited its availability to accredited tertiary centers, primarily located in larger metropolitan areas across Canada (Figure 2). The resulting concentration of these services in select centres, coupled with Canada's vast and diverse geography, creates significant challenges for equitable access. Further, the uneven distribution of CAR T delivery capacity disproportionately affects remote and rural areas with low population density, as well as low-income and Indigenous communities.



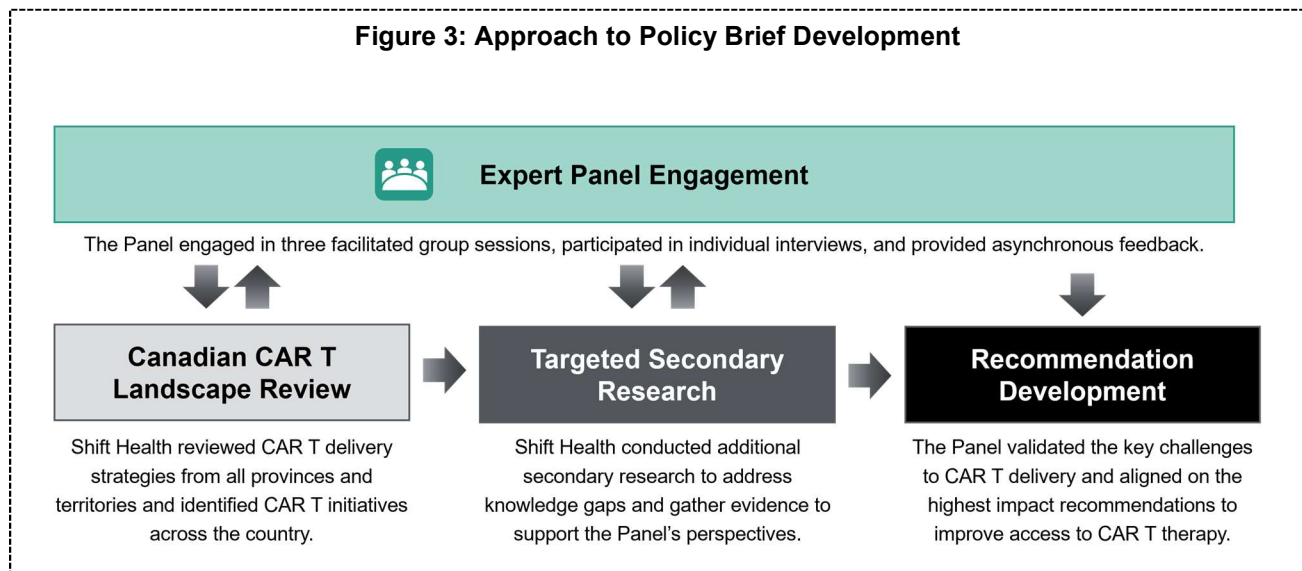
**A strategic approach to improving access to CAR T will enable Canadian healthcare systems to effectively plan for future demand.**

## About This Policy Brief\*

To guide Canadian decision makers in preparing our healthcare systems for the future of CAR T, Shift Health convened an Expert Panel comprised of diverse thought leaders from across the Canadian cancer ecosystem, including healthcare providers, health system administrators, a regulatory expert and a patient advocate, to develop a set of tangible and feasible recommendations for improving access to CAR T in Canada over the next 2-5 years.

Panel Member	Title
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**Figure 3: Approach to Policy Brief Development**



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# Challenges to Expanding CAR T Access in Canada

Recognizing the efforts Canada has already taken to enable access to CAR T, the Expert Panel highlighted five key challenges that must still be addressed to improve implementation and adoption of this therapy.



## Limited Capacity

**1) Delivering CAR T cell therapies is a relatively complex process, requiring specialized healthcare infrastructure, human health resource (HHR) expertise, and coordination for production, distribution, and administration.** Expanding this capacity requires substantial investment of both time and funding in an already resource-constrained healthcare system.



## Patient and Caregiver Burden

**2) Traveling to treatment centres creates a significant burden on patients and caregivers, who often must travel long distances and stay near CAR T facilities for extended periods.** This creates barriers to equitable access and negatively impacts quality of life during treatment. Travel can be particularly costly and burdensome on Canadians living in rural and remote communities, exacerbating inequities in access.



## Physician and Patient Awareness

**3) There is variability in physician and patient awareness of CAR T, particularly in primary care settings, and rural or remote communities.** Differences in awareness about CAR T eligibility, immediate and long-term safety, efficacy, durability, reimbursement and availability across Canada impacts referral rates.



## Data Sharing

**4) There are challenges in data sharing and interoperability among healthcare systems in Canada.** Federal, Provincial and Territorial privacy laws and confidentiality policies lead to the development of cumbersome data-sharing agreements between referring and treatment centres. This can hinder timely data exchange and reduce the efficiency of CAR T referrals, care plans, research, product development and capacity planning.



## Coverage and Reimbursement

**5) The relatively high up front costs associated with CAR T and its implementation, combined with payer uncertainty about its durability and long-term safety, have led to restrictive policies and reimbursement challenges.** These costs significantly impact Canada's ability to expand delivery capacity, creating barriers to widespread adoption and accessibility, especially when patients must travel to another province to receive treatment.

Provincial and territorial policymakers must work closely with each other, the federal government, patient and clinical networks, national organizations and industry to address these challenges and ensure that the transformative potential of CAR T therapy can be fully realized for people living with cancer in Canada.

## Expert Panel Recommendations



**Recommendation 1: Increase the capacity to deliver CAR T in Canada** through targeted investments, optimizing resource utilization, expanding scope of existing cancer centres and enhancing industry support to upskill HHR.

**Taking a strategic approach to growing treatment centre capacity represents an important and feasible opportunity to improve CAR T delivery in Canada.**

The safe and effective delivery of CAR T therapy and associated follow-up care requires specialized healthcare infrastructure and skilled human resources that are generally only available at select accredited tertiary care facilities. By making targeted investments and optimizing the use of existing healthcare resources, capacity can be expanded to meet current and future demand for CAR T.

Planning for this expansion in capacity is a critical but relatively complex process, requiring a deep understanding of needs at both the hospital and system levels, along with strategic investments in sustainable growth. Since CAR T therapies can only be administered at manufacturer-approved accredited centres, its delivery and follow-up care demand highly specialized resources and equipment, along with extensive HHR training and upskilling. For instance, clinical cell therapy lab technicians require 6-12 months of training post-hire, necessitating significant investment in both human capital and infrastructure. This scarcity of required resources, compounded by a general shortage of HHR in Canada, further emphasizes the need for additional training initiatives to upskill existing personnel for CAR T delivery. Furthermore, given the relatively high costs of CAR T therapies, it is crucial to ensure that plans for capacity expansion accurately reflect current and anticipated patient demand and corresponding operational needs to maximize the return on this investment.

**Based on this rationale, the Panel recommends the following high-priority actions to grow CAR T capacity in Canada.**

1. **Make Targeted Investments in Expanding CAR T Capacity and Upskilling HHR:** Invest strategically in expanding CAR T delivery capacity, taking into consideration infrastructure and HHR training needs, projected future patient demand for CAR T across Canada, current capabilities of existing or prospective CAR T centres, as well as potential impacts on other cancer care and general healthcare services.
2. **Optimize Resources at Existing CAR T Treatment Centres:** Defining specific tiers of service for tertiary care centres equipped to deliver CAR T and regional cancer centres that could absorb responsibility for all, but the most complex cancer treatment and care, would allow tertiary CAR T centres to maximize their capacity to deliver CAR T and other highly specialized care.
3. **Expand the Scope of Existing Stem Cell Transplant Centres:** Enabling more centers that currently perform autologous stem cell transplants to also deliver CAR T procedures would enhance CAR T delivery capacity without creating net new treatment centres. Additionally, equipping all cancer centres (regional and tertiary) to operate at the upper limit of service delivery and staff scope of practice would help further increase CAR T capacity.

4. **Enhance Industry Support to Upskill HHR:** Recognizing the expertise of commercial CAR T manufacturers in delivering specialized training programs, increased industry investment in training could greatly expand the number of healthcare professionals equipped to deliver CAR T therapy and provide long-term follow-up care.

### Anticipated Outcomes of Recommendation 1

*Increasing the capacity to deliver CAR T through targeted investments, optimizing resource utilization, expanding scope of existing cancer centres and enhancing industry support to upskill HHR will improve access to CAR T in Canada by:*

- ◆ Improving utilization of specialized resources needed for CAR T
- ◆ Alleviating the burden on existing tertiary centres to increase capacity for CAR T
- ◆ Expanding the pool of HHR with specialized skills to deliver CAR T, including nurses, apheresis staff, clinical cell therapy lab technicians



**Recommendation 2: Expand support for patients and caregivers** by addressing travel costs and other treatment expenses through strategic funding, enhanced inter-provincial agreements and stronger industry collaboration.

The centralization of CAR T therapy in select tertiary care facilities, while necessary for its safe and effective delivery, creates significant access barriers for patients, necessitating comprehensive support for both patients and caregivers to overcome challenges related to travel, accommodation, and extended care coordination.

Canada's vast geography and numerous remote regions make it challenging to provide highly specialized care locally for every individual, necessitating a centralized CAR T therapy delivery model that, while ensuring quality and safety, creates access barriers for some cancer patients living far from tertiary care centers. The centralization of CAR T delivery forces many individuals living with cancer and their caregivers to travel outside of their regional cancer care centres for extended periods, creating financial barriers, including the costs of transportation and accommodation, as well as the potential for job loss or extended periods away from work, all of which challenge equitable access to CAR T.

There is also a need to enhance existing industry and public-private initiatives to increase funding for travel and accommodation for people undergoing treatment and their caregivers. Additionally, modifying inter-provincial agreements to facilitate better payment systems for out-of-province treatments, could improve access and enable more eligible people with cancer to utilize existing CAR T capacity in Canada.

**Based on this rationale, the panel recommends the following high-priority actions to expand support for patients and caregivers:**

1. **Launch Strategic Funding Initiatives:** Develop a strategic and coordinated approach to provide funding for patient and caregiver travel and other expenses associated with CAR T treatment through public-private

initiatives. Actively engaging patients and caregivers during the design of these initiatives will provide them an opportunity to share insights related to travel time, proximity to care and out-of-pocket costs.

2. **Enhance Inter-provincial Agreements:** Optimize inter-provincial agreements to minimize out-of-pocket expenses for patients and caregivers, and to maximize equitable access for all Canadians.
3. **Strengthen Industry Support Programs:** Building on the efforts already made by industry, further enhance industry support to patients and caregivers that address gaps in government support programs and policies.

### Anticipated Outcomes of Recommendation 2

*Expanding support for patients and caregivers by addressing travel costs and other treatment expenses through strategic funding, enhanced inter-provincial agreements, and stronger industry collaboration could significantly improve CAR T delivery in Canada by:*

- ◆ Ensuring patients and caregivers do not experience significant out-of-pocket costs to access CAR T to alleviate financial burden
- ◆ Enhancing equitable access to CAR T regardless of geographic location or socio-economic status
- ◆ Leveraging industry expertise to fill gaps in patient and caregiver burden



**Recommendation 3: Improve physician and patient awareness of CAR T** through increased education by leveraging professional networks and developing educational programs to improve awareness.

**Inconsistent awareness of CAR T among referring physicians and patients highlights the potential value-add of additional education that will support more widespread and equitable CAR T uptake and delivery across Canada.**

Physician awareness of current CAR T eligibility, safety, efficacy, durability, reimbursement and availability varies significantly across Canada. This disparity in knowledge is further complicated by the referral process, which involves cumbersome paperwork that can be especially challenging to navigate for physicians who infrequently encounter people eligible for CAR T treatment. As a result, this complexity can impede timely referrals for potentially eligible patients, ultimately delaying their access to CAR T therapy. While industry-supported educational initiatives have provided valuable product-specific information, there remains an opportunity to further enhance our approach to education. By offering generalized core content, we can improve overall awareness and understanding of CAR T therapy among referring physicians, patients, and caregivers. Expanding the reach of these educational programs to both referring physicians and patients is crucial, as it will help ensure that all potentially eligible people with cancer are presented with CAR T as a possible treatment option, regardless of their place of residence.

**Based on this rationale, the panel recommends the following high-priority actions to help educate patients and physicians on current clinical practices and Canadian specific policies and reimbursement of CAR T:**

1. **Improve Patient Education and Awareness:** Develop educational programs and communication opportunities to enhance knowledge and improve awareness of the benefits, risks, reimbursement, and availability of CAR T among people living with cancer, empowering them to make informed decisions about their treatment journey.
2. **Create Targeted Educational Programs for Physicians and other Staff at Referral Centres:** Leveraging professional networks and developing targeted educational initiatives through existing organizations with a mandate to promote awareness, such as Cell Therapy Transplant Canada (CTTC), and provincially-developed programs would significantly enhance awareness of recent advances in CAR T therapy, eligibility criteria, and the referral process among referring physicians<sup>10,11,12,13,14</sup>, particularly those outside metropolitan centers, thereby increasing CAR T acceptance, uptake, and ensuring timely referrals.

### Anticipated Outcomes of Recommendation 3

*Providing education to increase awareness among referring physicians and patients about CAR T could improve patient outcomes in Canada by:*

- ◆ Increasing CAR T referrals and the number of eligible individuals presented with CAR T as a treatment option
- ◆ Enabling more people living with cancer to access potentially curative CAR T therapy



**Recommendation 4: Enhance CAR T data collection by increasing support for the national CTTC registry and educating people receiving cancer treatment about data security and utility to encourage consent.**

**Better consolidation and cross-provincial standardization of CAR T patient data is needed to support research, facilitate development and implementation of innovative contracting models and ultimately improve access and patient outcomes.**

Access to treatment and patient outcome data is a critical tool for researchers and clinicians to analyze trends, such as demographics and access equity, as well as to refine technologies and improve care in many disease areas, including oncology. Comprehensive data collection and monitoring is also particularly important when considering innovative contracting models linked to patient volumes and/or outcomes, which have the potential to reduce up-front treatment costs but are difficult to implement effectively without robust data systems.

While Canada has a national Cell Therapy Transplant Canada (CTTC) registry, it would greatly benefit from additional support and enhancements to its database to consolidate and standardize data across provinces and maximize its utility.



Further, it's important to note that people undergoing cancer treatment are often understandably concerned about data privacy and may be unaware of available risk mitigation measures and/or the potential value of their health data to improving cancer care. Addressing these concerns is crucial, especially in light of Health Canada's Forward Regulatory Plan<sup>15</sup>, which acknowledges the need for regulatory reform, including greater integration of real-world evidence to streamline and adapt regulatory pathways for advanced therapies such as CAR T.

**Based on this rationale, the panel recommends the following high-priority actions to help Canada optimize the collection and analysis of data on the utilization, real-world safety and efficacy of CAR T:**

1. **Increase Support for the National CTTC Registry:** Further expanding existing industry and public initiatives to fund and support the expansion and maintenance of the CTTC registry, which in partnership with the Center for International Blood and Marrow Transplant Research (CIBMTR) collects CAR T and transplant utilization and outcomes data, will help centralize and standardize CAR T data in Canada. Additionally, addressing data privacy issues and improving technology to streamline data collection will further enhance access and maximize applications for its use.
2. **Education for Individuals Undergoing Cancer Treatment:** Helping people undergoing cancer treatment understand how their anonymized health data can be used to improve cancer care, while protecting data security and privacy, could lead to increased acceptance, consent and ultimately more comprehensive CAR T data collection and sharing.

#### Anticipated Outcomes of Recommendation 4

*Improving CAR T data collection by supporting the national CTTC registry and educating people receiving cancer treatment about data security and utility to encourage consent could improve CAR T delivery in Canada by:*

- ◆ Enabling comprehensive tracking of patient data and health outcomes
- ◆ Facilitating more effective use of innovative contracting models linked to real-world outcomes
- ◆ Improving the ability to understand patient demographics and evaluate CAR T access and equity across Canada
- ◆ Providing patient data and real-world evidence to support post market regulatory and health technology assessment (HTA) processes for advanced therapies like CAR T



**Recommendation 5: Optimize the cost-efficiency of CAR T for patients and payers** by adopting innovative contracting models and exploring the potential benefits of “made-in-Canada” CAR T.

**CAR T's higher up-front infrastructure costs and relatively sophisticated delivery process can significantly impact healthcare budgets.**

Like many leading-edge cancer treatments, commercial CAR T initially carries substantial costs due to the necessary upfront investments in specialized infrastructure and comparatively complex delivery process. While these factors can strain healthcare budgets, the long-term value of CAR T in improving patient outcomes and potentially reducing future treatment needs and associated costs necessitates measures to enhance

affordability and return on investment. To address this challenge, Canada should investigate and employ innovative contracting models such as outcome-based agreements, warranties, subscription models, installment payments, and coverage with evidence development. These approaches aim to balance long-term data generation with the comparatively high upfront costs of CAR T and adopting similar reimbursement strategies could potentially lead to cost-efficiencies for Canada.

Furthermore, the relatively high costs of delivering CAR T therapy could potentially be reduced over the long term if Canada established a domestic or "made-in-Canada" CAR T development and manufacturing ecosystem. This approach, coupled with public investment in open-ended CAR T research, development, and manufacturing technologies, would not only contribute to the growing body of scientific knowledge but also support Canadian innovation in this critical field.

**Based on this rationale, the panel recommends the following high-priority actions to help Canada optimize the cost-efficiency of CAR T for patients and payers:**

1. **Innovative Contracting Models:** Expand adoption of innovative contracting models that link healthcare spending to real-world treatment efficacy. These models should incorporate mechanisms to cap direct drug costs and leverage strategic partnerships with private sector entities and/or NGOs to facilitate more effective price negotiations.
2. **"Made-in-Canada" CAR T:** Expand current studies (e.g. BioCanRx's investigation into the cost effectiveness of Canadian-made CAR T)<sup>16</sup> and initiate new studies to comprehensively assess the benefits and challenges of "made-in-Canada" and/or point-of-care CAR T manufacturing. Clearly defining these opportunities will provide a strong data-driven foundation to secure federal and provincial funding support to advance Canadian research and innovation in developing "made-in-Canada" CAR T products, including funding for academic clinical trial costs and the commercialization of these innovations.

### Anticipated Outcomes of Recommendation 5

***Adopting innovative contracting models and exploring the potential for "Made-in-Canada" CAR T could optimize the cost-efficiency of CAR T for patients and payers by:***

- ◆ Reducing the financial burden on healthcare systems by aligning payments with treatment success
- ◆ Driving continuous improvements in CAR T research towards better patient outcomes by linking reimbursement to therapy effectiveness
- ◆ Realizing operational and/or cost efficiencies over the long term
- ◆ Further strengthening Canadian life sciences research and innovation






## Conclusion

By implementing the Panel's recommendations, Canadian decision makers will not only be poised to meet the imminent expected surge in demand for CAR T therapy, but will also pave the way for a future where every eligible Canadian facing cancer has access to this groundbreaking, life-changing treatment. The recommendations in this policy brief are aligned with the recent collective agreement amongst Canada's Premiers to increase the speed of access to life-saving oncology drugs (such as those approved under Project Orbis) and call for collaboration among all stakeholders to close access gaps and improve healthcare outcomes across Canada.<sup>17,18</sup> Canada must make thoughtful investments and optimize existing resources through coordinated federal and provincial initiatives to maximize the benefits of CAR T for people living with cancer.

### Key Challenges

	<b>Limited Capacity</b>
	<b>Patient and Caregiver Burden</b>
	<b>Physician and Patient Awareness</b>
	<b>Data Sharing</b>
	<b>Coverage and Reimbursement</b>

### Recommendations

	<b>Recommendation 1: Increase the capacity to deliver CAR T in Canada</b> through targeted investments, optimizing resource utilization, expanding scope of existing cancer centres and enhancing industry support to upskill HHR.
	<b>Recommendation 2: Expand support for patients and caregivers</b> by addressing travel costs and other treatment expenses through strategic funding, enhanced inter-provincial agreements and stronger industry collaboration.
	<b>Recommendation 3: Improve physician and patient awareness of CAR T</b> through increased education by leveraging professional networks and developing educational programs to improve awareness.
	<b>Recommendation 4: Enhance CAR T data collection</b> by increasing support for the national CTTC registry and educating people receiving cancer treatment about data security and utility to encourage consent.
	<b>Recommendation 5: Optimize the cost-efficiency of CAR T for patients and payers</b> by adopting innovative contracting models and exploring the potential benefits of "made-in-Canada" CAR T.

**CAR T is changing the face of cancer treatment in Canada, offering potentially curative outcomes for people living with cancer. Federal, provincial, and territorial healthcare systems must collaborate with each other, with patient and clinical networks, with industry and the research community, and with relevant national organizations to strengthen Canada's readiness to deliver CAR T, improve equitable access to this life saving therapy and ultimately ensure that all eligible people living with cancer can achieve their best possible outcome.**

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