Breakthrough T1D™

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SUBMISSION TO THE HOUSE OF COMMONS STANDING COMMITTEE ON FINANCE

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Funding the Breakthrough T1D Network for Canada: Strengthening Canada's Capacity to Compete and Lead in Regenerative Medicine

Summary of recommendation

Breakthrough T1D Network for Canada (BTNC)

Recommendation

- That Budget 2026 invests $62 million over five years in the Breakthrough T1D Network for Canada (BTNC).
- This investment would leverage:
  - $25 million from Breakthrough T1D
  - $13 million from industry and research institutions
- Total investment: $100 million, with at least 1:1 matching of federal research funds

Issue

- Canada has a time sensitive opportunity to lead in regenerative medicine as cell and gene therapies move into real-world clinical use.
- Global competitors (U.S., EU, Japan) are coordinating nationally to anchor trials, talent, and commercialization.
- Despite world leading expertise, particularly in type 1 diabetes (T1D), Canada lacks a pan-Canadian coordination mechanism, resulting in the loss of trials, talent, and economic value.

Why type 1 diabetes

- T1D is among the diseases closest to a curative breakthrough in regenerative medicine, with multiple cell-based therapies already in or nearing clinical trials at Canadian sites.
- Canada has performed more insulin producing cell transplants than any other country and has deep clinical expertise in diabetes, transplantation, and trial execution.
- T1D offers clear, measurable outcomes and transferable skills and infrastructure applicable to future advanced therapies.

Expected outcomes (First five years)

- Double the number of curative T1D therapies trialed in Canada.
- Support commercialization of 10+ Canadian innovations.
- Create 120+ high skilled jobs.
- Position Canada as a preferred global destination for regenerative medicine research.

Economic and health impact

Health R&D delivers an estimated 5.75x return on investment.

- A $100 million investment could generate approximately $575 million in economic value.
- Accelerating a T1D cure by just five years could avoid ~$15 billion in health-care costs.

Funding the Breakthrough T1D Network for Canada: Strengthening Canada's capacity to compete and lead in regenerative medicine

Introduction

Canada has a time sensitive opportunity to translate longstanding scientific leadership in regenerative medicine into real therapies, economic growth, and improved health outcomes. Cell and gene therapies are moving rapidly from research toward clinical use, and countries that act decisively are anchoring trials, talent, and investment at home.

This submission sets out a practical, low risk way for Canada to lead: begin where the science is advanced, the clinical base is strong, and results are measurable – type 1 diabetes (T1D) – and use that focus to build durable national capability in regenerative medicine through the **Breakthrough T1D Network for Canada (BTNC).**

Strengthening Canada's capacity to compete and lead in regenerative medicine

Canada is at a pivotal moment in regenerative medicine. Cell and gene therapies are moving into real world clinical use, creating a narrow window to anchor trials, talent, and investment domestically and to build systems to deliver these therapies at scale.

Canada is well positioned to lead the next phase of T1D therapies. However, unlike the United States, the European Union, and Japan, Canada lacks a coordinated, pan-Canadian mechanism to move these therapies efficiently from lab to clinic and into health systems. As a result, trials, talent, and commercialization too often migrate elsewhere. The Breakthrough T1D Network for Canada (BTNC) is designed to close this gap.

BTNC is a federally anchored, public-private partnership that builds durable national capability in regenerative medicine. It uses T1D – one of the most clinically ready areas – as the initial focus to establish a model of coordination and delivery capacity that can demonstrate results quickly and be applied to other advanced therapies over time.

Why regenerative medicine and why now?

Regenerative medicine aims to repair or replace damaged cells and tissues, offering the possibility of cures rather than lifelong disease management. Countries able to support advanced clinical trials, specialized manufacturing, and health-system readiness through coordinated national action are attracting global investment and high-value jobs.

Canada has a unique history in diabetes research, beginning with the discovery of insulin in 1921 and continuing through decades of leadership in cell transplantation, including performing more insulin-producing cell transplants than any other country.

Yet many Canadian discoveries are commercialized elsewhere because the country lacks integrated, end-to-end coordination to translate research into therapies. Without targeted investment, Canada risks missing a generational opportunity to convert scientific leadership into lasting economic benefits.

Why type 1 diabetes is the right starting point

T1D is among the conditions closest to a curative breakthrough. It is an autoimmune disease in which the body destroys the insulin producing cells needed to convert food into usable energy. People with T1D currently require lifelong insulin injections, a significant daily burden. Restoring insulin production would fundamentally change care.

Multiple cell-based approaches to restore insulin production are already in, or approaching, clinical trials, including trials at Canadian sites. This makes T1D an ideal starting point for a national regenerative medicine effort. T1D offers clear advantages as a first use case:

- **Proven Canadian clinical foundation:** Canada has deep, hands on experience in insulin producing cell transplantation and immune management in T1D, giving Canadian sites a head start in trial design, patient selection, and safety oversight.
- **Biological and clinical fit:** T1D involves the loss of a single, well-defined cell type (insulin producing beta cells). Replacing these cells addresses a key impact of this disease, making T1D especially well-suited to regenerative approaches compared with multi-tissue or poorly defined conditions.
- **Clear, measurable outcomes:** Success in T1D can be assessed quickly and objectively (e.g., insulin independence, C-peptide production, hypoglycemia reduction), enabling faster learning, derisking, and decision-making than many other regenerative indications.
- **Transferable capability building:** The challenges addressed in T1D – including cell sourcing, immune protection, manufacturing quality, regulatory approval, and clinical delivery – are the same core challenges Canada must master for future regenerative therapies.

While BTNC would focus on T1D initially, it is not about a single disease. It is about building durable national capability in regenerative medicine, using T1D as a clinically ready demonstration.

The burden of type 1 diabetes in Canada

The discovery of insulin transformed T1D from a fatal disease into a chronic condition. More than a century later, it remains a serious, life altering disease. The 300,000 Canadians living with T1D make an estimated 180 additional health related decisions each day and face elevated risks of severe hypoglycemia, kidney failure, cardiovascular disease, vision loss, and reduced life expectancy.

T1D also places a significant burden on Canada's health-care system, accounting for more than $3 billion annually in health-care costs. The number of Canadians living with T1D is projected to grow substantially by 2040, increasing this burden in the absence of new therapies. A cure remains urgently needed.

A unique moment for breakthroughs in T1D

After decades of research, much of it supported by the federal government through the Canadian Institutes of Health Research and the Stem Cell Network, in partnership with Breakthrough T1D, curative therapies for T1D are now within reach. Multiple approaches to restoring insulin producing cells are advancing rapidly, including:

- **Vertex Pharmaceuticals**, testing a stem cell derived therapy that has enabled many trial participants to resume endogenous insulin production.
- **CRISPR Therapeutics**, developing gene edited insulin producing cells designed to evade immune attack.
- **Encellin**, testing an implantable device for insulin producing cells in clinical trials in Toronto and Montréal.
- **Sernova**, a Canadian company advancing a cell pouch approach for insulin producing cell transplantation.

Trials for these and other therapies are underway or in planning at Canadian research centres. Strategic investment now can prevent talent loss, accelerate progress, and help ensure Canada captures the scientific, economic, and health benefits.

The solution: The Breakthrough T1D Network for Canada

The Breakthrough T1D Network for Canada (BTNC) is a federally anchored, public/private partnership designed to build national capability in regenerative medicine. It is not a new institute or facility. Rather, it is a coordinated, pan-Canadian approach that organizes, funds, and actively manages work across the country under a single, accountable framework, ensuring discoveries translate into commercialized therapies for Canadians.

What BTNC enables that would not otherwise happen is deliberate national coordination at scale

BTNC uses Breakthrough T1D's established, milestone driven peer review processes to advance projects with the strongest scientific and clinical potential, while reallocating resources away from efforts unlikely to translate. This enables Canada to lead in areas of strength rather than follow pathways set elsewhere.

BTNC extends beyond research funding by strengthening pathways to commercialization, which may include working with established Canadian partners such as the Centre for Commercialization of Regenerative Medicine (CCRM), the Biosciences Research Infrastructure Fund (BRIF), and Breakthrough T1D's T1D Fund. This ensures successful projects are supported to become commercialization-ready therapies capable of attracting follow-on investment and delivering real world impact.

In practice, BTNC would:

- Select and actively manage a national portfolio of T1D cell therapy trials and trial enabling projects.
- Coordinate trial start-up and execution across sites, reducing delays and duplication.
- Support shared protocols, workforce training, and knowledge sharing for complex cell therapy trials.

- Engage industry partners to support scale-up and commercialization, increasing the likelihood discoveries are retained in Canada.

T1D is the initial focus, but BTNC is designed as durable national infrastructure for advanced therapy development, not a one-time research grant.

What BTNC enables Canada to do

Through a network of leading institutions, BTNC would:

- Accelerate clinical trials and position Canada as a preferred destination for global regenerative medicine research.
- Build a skilled workforce in cell therapy, clinical translation, and advanced manufacturing.
- Reduce risk and duplication through coordinated trial management and shared resources.
- Strengthen the life sciences economy by attracting investment and supporting commercialization of Canadian discoveries.

In its first five years, BTNC is designed to double the number of T1D cure therapies trialed in Canada, support the commercialization of at least ten academic discoveries, and create more than 120 highly skilled jobs.

Investment model

BTNC would be supported by a $100 million investment over five years:

- $62 million — Government of Canada
- $25 million — Breakthrough T1D
- $13 million — Industry and research institutions

All federal funds directed to research funding through the BTNC would be matched at least 1:1 by partners, maximizing the impact of public investment. The public-private partnership model aligns incentives, shares risk and leverages private and philanthropic capital.

Health research and development is a strong economic driver. According to Statistics Canada, $3.2 billion in health R&D spending generated $18.4 billion in GDP in 2022 – a return of approximately 5.75 times the initial investment.[i] Applying this ratio suggests a $100 million investment in BTNC could generate roughly $575 million in economic value over five years.

Over the longer term, successful therapies could also reduce health-care costs. If this initiative accelerated a cure for everyone with T1D by just five years, it could avoid approximately $15 billion in health-care costs across Canada.[ii]

Why Breakthrough T1D

Breakthrough T1D brings scientific credibility, execution capability, and proven stewardship of public funds. For more than five decades, it has funded and actively managed research from discovery through clinical trials and early commercialization, investing over $3 billion globally in T1D research and helping bring automated insulin delivery systems into routine care.

Breakthrough T1D has partnered with the Government of Canada on research investments for more than fifteen years, supporting over 20 clinical trials nationwide. These partnerships exceeded targets for trials supported, leverage achieved, and jobs created.

All investments are subject to rigorous independent peer review, strong conflict of interest policies, milestone based decision-making, and regular scientific and financial oversight. Grant policies align with TriCouncil standards and governance includes independent Board and Finance & Audit Committee oversight. A national community of people living with T1D, clinicians, and researchers further strengthens outcomes by supporting trial participation and readiness for clinical adoption.

BTNC is an additive to CIHR, Stem Cell Network, and ISED programs. It focuses on the "last-mile" gaps that often prevent discoveries from becoming therapies, offering speed, flexibility, end-to-end enablement, and global leverage with Canadian control.

The benefits of BTNC would accrue nationally. Only the federal government can catalyze a coordinated, pan-Canadian effort of this scale and signal to global investors that Canada is serious about leading in regenerative medicine.

The cost of inaction

Without coordinated investment, Canada risks losing trials, talent, and commercialization to other jurisdictions. Canada discovered insulin, yet the global insulin industry – worth more than $40 billion annually – is dominated by companies outside the country. Regenerative medicine offers a chance to capture both health and economic value from Canadian innovation.

Conclusion: A practical path to national leadership

Canada can advance regenerative medicine without sacrificing prudence. By starting with T1D, where the science is advanced, outcomes are measurable, and clinical expertise is strong, the federal government can make a focused investment that delivers near-term results while building long-term national capability. BTNC provides a disciplined, co-funded, and accountable mechanism to retain the benefits of Canadian innovation and position Canada to lead.

With global competitors moving quickly to anchor trials and commercialization, delay risks losing a generational opportunity.

Breakthrough T1D urges the Standing Committee on Finance to recommend a $62 million investment over five years in Budget 2026 to support BTNC, leveraging matching funds. This investment will generate near-term impact and establish durable national infrastructure for regenerative medicine.

[i] Statistics Canada (2022), Economic footprint of health R&D in Canada
[ii] Health Canada (2024), Diabetes cost estimates