

Securing Canada's Health and Economic Future Through Regenerative Medicine

At a time of trade volatility, intense competition for investment, and pressure to reduce strategic dependencies, Canada cannot afford to finance the early stages of innovation only to lose the resulting research discoveries, intellectual property, companies, clinical trials, manufacturing activity, skilled jobs, and tax revenues to other jurisdictions. Nor should Canadian patients wait while therapies developed with Canadian public investment reach foreign markets first. **It is time to accept that modern regulation is a competitive advantage, and an economic imperative.**

Canada has already created the regulatory tools it needs; now it is time to use them. The Advanced Therapeutic Products (ATP) framework was enabled through amendments to the Food and Drugs Act in 2019 to allow tailored, flexible and risk-based requirements for innovative products that do not fit well within conventional drug or device rules. Yet, it has never been fully deployed. Now is the time, so it can be leveraged to support Made-in-Canada innovations, strengthen domestic firms, attract private capital and set in place the opportunity for patient access, while maintaining rigorous standards for safety, efficacy and quality.

For regenerative medicines - including cell and gene therapies, tissue-engineered products and personalized or point-of-care treatments this agility matters. The therapy, manufacturing process, delivery model and evidence plan are deeply interconnected. Forcing products through rigid frameworks designed for conventional drugs or devices can create uncertainty, cost and delay, and this is why Health Canada must begin to actively use the ATP framework.

The window for action is narrowing. Competing jurisdictions are moving quickly to attract novel advanced-therapies and companies, clinical trials, investment, and manufacturing. If Canada's regulatory system continues to be viewed as a barrier, it increases the likelihood that Canadian innovations and their economic benefits will move elsewhere.

Recommendation

Budget 2026 should direct and resource Health Canada to implement Made-in-Canada regulatory prioritization starting with regenerative medicines and other advanced therapeutics. This should include active use of the existing Advanced Therapeutic Products framework where conventional drug or device pathways are not fit for purpose, timely prioritized regulatory engagement and review, and the free single-window concierge service Health Canada originally envisioned.

This should be paired with a fully resourced national Life Sciences Industrial Strategy, including \$75 million over four years for ATIAP, to de-risk Canadian innovations and build the clinical, manufacturing, commercial and workforce pipeline needed to keep more intellectual property, investment, companies and jobs in Canada while giving Canadian patients earlier access to innovations developed here.

One Strategy, Two Complementary Submissions

Canada's life sciences challenge has two sides: promising innovations need help becoming development-ready, and the regulatory system needs sufficient agility and navigability to move novel Canadian products efficiently toward patients. Addressing only one side leaves the job unfinished. As such, the Stem Cell Network is advocating that Budget 2026 provide support on two fronts: Modernizing Canada's regulatory and access system, as detailed in this submission; and resourcing a life sciences industrial strategy supported by a national pipeline-to-production platform described in a second pre-budget submission by partners of the Advanced Therapeutics Industrial Acceleration Partnership (ATIAP). Neither proposal can achieve its full economic impact on its own.

1. MODERNIZE THE REGULATORY ROUTE

Prioritize promising Made-in-Canada innovations, actively use the ATP framework where conventional rules are not fit for purpose, and establish a free single-window concierge service.

2. BUILD THE PIPELINE

The companion ATIAP submission seeks \$75 million over four years for a national pipeline-to-production platform that will de-risk Canadian innovations and early-stage biotech companies so they can attract private capital, manufacture and scale in Canada.

Industrial de-risking without an efficient and predictable Canadian regulatory route will still encourage companies to develop and run clinical trials and manufacture elsewhere. Regulatory modernization without a stronger pipeline of development-ready Canadian innovations will have limited economic impact. Together, ATIAP and a more active ATP framework provide a practical route from Canadian innovation to Canadian delivery.

The Advanced Therapeutics Industrial Acceleration Partnership (ATIAP) is a turnkey response. Four established Canadian organizations (Stem Cell Network, Capital BioVentures, OBIO and CASTL) are ready to partner and integrate their existing capabilities into a single national, milestone-based pipeline. No new institution or infrastructure is required. ATIAP would support the highest-potential Canadian regenerative medicine innovations within academia and biotech through clinical preparation, early trials, manufacturing readiness, commercialization, capital readiness and workforce development. More information about this proposal is available in the ATIAP pre-budget submission.

Made-in-Canada Prioritization for Advanced Therapeutics

Regenerative medicine is a major driver of the advanced-therapeutics field and includes stem cell-based therapies, cell and gene therapies, and tissue-engineered products. Many are unlike conventional medicines: they may be living, personalized, manufactured in small batches or at the point of care, administered only once, delivered through specialized hospitals, or intended for very small patient populations. Alternatively, they may be manufactured in large batches to address a chronic disease or illness and offered for wide marketing to other jurisdictions.

Other unique features include:

- **Product and process can be inseparable.** Changes in manufacturing can change the therapy itself.
- **Evidence can look different.** Small populations, durability questions and long-term follow-up often require lifecycle evidence strategies.
- **Delivery can be part of the product.** Specialized sites, diagnostics, logistics, trained teams and monitoring may be essential to safe use.
- **Commercial models are not always possible.** Scientifically viable therapies for rare or ultra-rare conditions may not support conventional development economics.

In 2025 and 2026, the Stem Cell Network hosted national workshops on advancing regenerative medicine therapies to the clinic and market. Both workshops reached the same conclusion across large- and small-population use cases: Canada has strong science and many of the necessary tools, but the path from innovation through regulation, manufacturing, reimbursement and adoption remains fragmented.

The Economic Cost of Fragmentation

6% → 4%

Canada's share of global clinical-trial activity

\$2.5B

Estimated annual clinical-trial expenditures forgone, with about 20,000 associated jobs.

76%

Share of investors that are international in later-stage Canadian life-sciences financings above \$50M.

Source: Government of Canada, Pharmaceutical and Life Sciences Sector Task Force report (2026), as summarized in SCN's pre-budget submission.

Further, the global regenerative medicine market is valued at approximately \$50–60B USD and is projected to reach roughly \$150B USD by the mid-2030s. North America accounts for the largest share of this market, creating a significant opportunity for Canada.

If Canada captures between 5–10% of the North American market, it could generate between \$7–15B annually in economic activity, anchoring high-value jobs, biomanufacturing capacity, and long-term productivity growth. To achieve this growth requires regulatory, assessment and adoption systems that are transparent, timely, flexible and ready to adopt the future of medicine.

Activate the ATP Framework Canada Already Has

In 2019, Parliament amended the Food and Drugs Act to create authorities for Advanced Therapeutic Products. Health Canada describes ATPs as products that are so unique, complex and distinct that they face a significant barrier under existing regulations. The framework allows Health Canada to establish tailored authorization requirements, apply terms and conditions, and adapt requirements over time as evidence and experience develop. Unfortunately, the framework and pathway have not been adequately deployed or used as originally envisioned.

THE POLICY SHIFT REQUIRED

Move ATP from a rarely deployed regulatory option to an actively considered tool for Canadian regenerative medicines that require agility and flexibility due to their design and unique needs.

Canada is not starting from ground zero. Health Canada has ATP authorities, aligned regulatory/HTA review mechanisms, clinical-trial modernization initiatives and international reliance tools. CDA-AMC and pCPA are also developing faster, more flexible access mechanisms. The policy task is therefore not to build a new system. It is to connect and use the capabilities Canada has already financed for the benefit of Canadian innovations and companies.

Commit to Made-in-Canada Prioritization: A Driver of Health and Economic Growth

Prioritizing Made-in-Canada health innovations within Canada's regulatory system, starting with advanced therapeutics, would strengthen our nation's life sciences sector and deliver a return on public investment in research and innovation.

Canada invests billions of taxpayer dollars in research, talent, infrastructure and commercialization support, yet too often the resulting technologies, companies, clinical trials and economic and health benefits migrate elsewhere before reaching Canadian patients. A clear regulatory prioritization approach for Canadian-derived innovations, with early engagement, coordinated guidance and timely, prioritized review, would help promising technologies move more efficiently from Canadian laboratories and companies into clinical development and the domestic market.

This would reduce uncertainty for innovators and investors, enhance Canada's appeal as a place to build and scale life sciences companies, and help retain intellectual property, highly skilled jobs, manufacturing activity, and future investment in Canada. Most importantly, it would increase the likelihood that Canadians will be among the first patients to benefit from therapies and technologies developed with Canadian expertise and public funding, creating a more direct link between taxpayer investment, economic growth, and improved health outcomes.

A prioritized pathway will succeed only if Health Canada has sufficient specialized expertise and review capacity to engage early and consistently with innovators. Advanced therapies raise complex questions about manufacturing, quality systems, small patient populations, individualized products and long-term evidence. Predictable access to specialized regulatory advice can prevent costly development errors, shorten time to market and make Canada a more attractive jurisdiction for trials and investment.

Build the Concierge Health Canada Already Envisioned

A concierge was part of Health Canada's original ATP implementation concept. In its 2019 consultation, Health Canada recognized that innovators would need guidance to navigate the new framework and proposed a specialized concierge service. That concept should now be implemented as a free, accessible, and human single window, particularly for academic teams and emerging Canadian companies that lack the regulatory resources of large industry.

The Concierge Should Deliver Three Things

ONE FRONT DOOR	A free single point of entry with a named human contact for Canadian academic innovators, emerging biotechs and other sponsors.
EARLY EXPERT GUIDANCE	Early access to the right Health Canada expertise to identify the appropriate route, available flexibilities and key evidence needs.
CONNECTION ACROSS THE SYSTEM	Navigation to relevant market-access, clinical and government supports, with added help for innovators whose internal regulatory capacity is limited.

The concierge should be a regulatory *navigation* service, not a substitute regulator or funding program. Its purpose should be simple: make the system easier to navigate, bring the right expertise to the table earlier and help promising Canadian innovations find the most appropriate path to patients and the market.

The Budget 2026 Decision

Canada does not need another strategy that starts from zero. It needs to activate the assets taxpayers have already paid for and turn Canadian science into a Canadian economic and health advantage. We have world-class research, talent and biomanufacturing capacity; a legislated Advanced Therapeutic Products framework; and the foundation for a specialized regulatory concierge service. **Budget 2026 should put these tools to work by implementing Made-in-Canada prioritization and pairing regulatory agility with a national life sciences industrial strategy supported by ATIAP.**

In practical terms: use the pathway, open the front door, and put Canadian science first. Doing so will help Canadian innovations move faster, attract capital on better terms, create more clinical activity, manufacturing demand, and skilled jobs, and give Canadians earlier access to therapies developed here.

The choice is clear: Canada can continue investing in research only to see too much of the resulting intellectual property, companies, and economic value leave the country, or it can use Budget 2026 to ensure that Canadian public investment yields lasting benefits for Canadians.

About the Stem Cell Network

The Stem Cell Network (SCN) is a mission-driven not-for-profit organization that unites researchers, clinicians, industry leaders, and health champions dedicated to transforming lives through regenerative medicine. As Canada's only national organization focused on this field, SCN is uniquely positioned to drive progress in the fight against disease and strengthen Canada's economy through company creation and the development of future leaders.

SCN brings together and invests in a pan-Canadian community of researchers, clinicians, trainees, patient partners, health-system leaders, and biotechnology companies. Through strategic research funding, talent development, commercialization support, and national coordination, SCN helps translate Canadian research into new therapies, companies, highly skilled jobs, and improved health outcomes.

Since its inception, SCN has invested over \$162 million in Canadian regenerative medicine research, leveraging an additional \$176 million from partners. This funding has positioned Canada as a global leader in regenerative medicine, fostering world-class expertise, spinning out innovative biotech companies, and pioneering life-changing clinical trials.