Invigorating the Biopharmaceutical Sector's Contribution to Canada's Health Research and Innovation Ecosystem

Report of Research Canada's Expert Advisory Panel

23 April 2021

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Introduction

Background

The biopharmaceutical sector plays an important role in Canada's health research and innovation ecosystem—partnering with academic research organizations, health systems and health charities to sponsor clinical trials essential to bringing innovative medicines to patients, support the commercialization of discoveries arising from Canada's research centres, fund research chairs and scholarships to develop Canada's scientific talent pool, and contribute to health system modernization.

Stakeholders have expressed concern that Canada's approach to biopharmaceutical policy, regulation and adoption, including proposed amendments to Canada's Patented Medicines Regulations, may erode the viability of the Canadian pharmaceutical market and weaken industry partnerships essential to the competitiveness, resilience and vitality of our health research and innovation ecosystem.

Research Canada, with the support of Shift Health, has led an independent study focused on understanding the role that industry plays in Canadian health research and innovation and the potential impact that decreased industry involvement may have on the ecosystem at large.

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Expert Advisory Panel

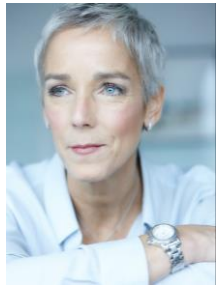
Research Canada assembled an Expert Advisory Panel of leaders across Canada's health research and innovation ecosystem—with representation from academic and research institutions, healthcare providers, not-for-profit organizations, and the investment community.

Dr. Rose Goldstein

Professor of Medicine and Former Vice-Principal of Research and Innovation, McGill University

Chair, Research Canada

Expert Advisory Panel Chair



Dr. Elizabeth Douville

Co-Founder and Managing Partner, AmorChem

Chair, Genome Canada

Dr. Pierre-Gerlier Forest

Director, School of Public Policy, University of Calgary

Dr. Scott Halperin

Director, Canadian Center for Vaccinology

Jacques Hendlisz

Executive President, CATALIS Québec

Sue Mack-Klinger

Program Head, Pharmacy Technician Program, Saskatchewan Polytechnic

Gordon McCauley

President and CEO, adMare BioInnovations

Dr. Catharine Whiteside

Former Dean of Medicine and Vice Provost, Relations with Health Care Institutions, University of Toronto

Dr. Bradly Wouters

Executive VP Science and Research, UHN

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High-level Approach

For this study, we:

- Gathered perspectives from Expert Advisory Panel members on the impact of the biopharmaceutical sector on Canada's health research and innovation ecosystem through one-on-one interviews;
- Substantiated insights gathered through discussions with Expert Advisory Panel members with evidence from the literature; and
- Developed and validated an overarching thesis, key messages and supporting evidence points through a series of four group discussions with the Expert Advisory Panel.

Output

The following report presents a synthesis of the key themes emerging from the Expert Advisory Panel's discussions, including supporting evidence of relevance uncovered through secondary research.

The aim of this report is to highlight critical considerations for ongoing discussions with stakeholders and decision-makers on approaches to optimizing industry's contribution to the Canadian health research and innovation ecosystem for the benefit of the health and wealth of the people of Canada.

Executive Summary

There is a gap in our understanding of the role of the biopharmaceutical industry in Canada's health research and innovation ecosystem and the implications for policy, investment and partnership.

Proposed amendments to Canada's Patented Medicines Regulations have triggered questions and varying degrees of concern across the health research and innovation ecosystem—but limited consensus. To address this gap and advance dialogue, Research Canada convened an Expert Advisory Panel to lead an **independent study focused on exploring the current, desired and potentially threatened role of industry within our health research and innovation ecosystem**. Key steps included:

- Gathering perspectives from Expert Advisory Panel members through one-on-one interviews;
- Substantiating Expert Advisory Panel insights with published evidence; and
- Developing and validating this report through four group sessions with the Expert Advisory Panel.

Expert Advisory Panel	
Dr. Rose Goldstein (Chair)	Professor of Medicine and Former Vice-Principal of Research and Innovation, McGill University; Chair, Research Canada
Dr. Elizabeth Douville	Co-Founder and Managing Partner, AmorChem Chair, Genome Canada
Dr. Pierre-Gerlier Forest	Director, School of Public Policy, University of Calgary
Dr. Scott Halperin	Director, Canadian Center for Vaccinology
Jacques Hendlisz	Executive President, CATALIS Québec
Sue Mack-Klinger	Program Head, Pharmacy Technician Program, Saskatchewan Polytechnic
Gordon McCauley	President and CEO, adMare BioInnovations
Dr. Catharine Whiteside	Former Dean of Medicine and Vice Provost, Relations with Health Care Institutions, University of Toronto
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If Canada is to realize the full health, social and economic potential of our health research and innovation ecosystem, we need a balanced approach to policy that supports an active and engaged biopharmaceutical sector.

Impactful health research and innovation happens in a multi-stakeholder ecosystem.

An integrated network of diverse stakeholders and partners is the engine of a functional health research and innovation ecosystem that translates ideas into impact and fortifies Canada's health and economic security.

The biopharmaceutical industry is integral to Canada's health research and innovation ecosystem.

The biopharmaceutical sector's unique and irreplaceable role in propelling science and technology, developing Canada's scientific talent pool, strengthening capacity for product development and transforming health and healthcare has been undermined by weaknesses in the partnership between the industry and Canada's health research and innovation ecosystem.

Our ecosystem needs to be a globally competitive environment for biopharmaceutical partnerships.

Our approach to biopharmaceutical policy, regulation and adoption must reflect a more holistic view of how our ecosystem functions to invigorate our relationship with the sector, ensure that we are helping to shape the agenda and elevate our global competitiveness.

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At a time when the importance of health research and innovation has never been more apparent, we must seize the moment to strengthen the trans-sectoral partnerships that can unlock Canada's potential, strengthen health security and drive economic growth.

Research Canada's Expert Advisory Panel is calling for change, not a return to the status quo. As the pandemic has laid bare, we need a renewed approach to cultivating an ambitious, futureproofed policy and investment environment that supports our ecosystem as a whole and positions Canada for sustainability, growth and leadership. We need an environment that:

- Appreciates and enables the critical role of the biopharmaceutical sector in advancing research and innovation in collaboration with academia, care providers, governments, not-for-profit organizations, patients and the public.
- Enlarges Canada's share of global biopharmaceutical sector investment in infrastructure, research and training programs, start-ups, technologies and jobs.
- Expands and diversifies opportunities for training and employing, attracting and retaining high-quality professionals.
- Accelerates the translation, commercialization and adoption of home-grown innovations that improve the lives of people in Canada and across the world.
- Fulfills the potential of our investments in science and talent by ensuring that health research and innovation are integral to and enabled by our healthcare system.

Canada's pharmaceutical pricing regime is critically important, but it is only one consideration in a complex network of policies impacting the vitality of our ecosystem—underscoring the need for an integrated, pan-sector strategy to maximize the contribution of health research and innovation to Canada's health security and economic prosperity.

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Invigorating the Biopharmaceutical Sector's Contribution to Canada's Health Research and Innovation Ecosystem

Realizing the full health, social and economic potential of Canada's health research and innovation ecosystem—our academic institutions, research hospitals, networks, incubators, start-ups, investors, health charities and patient groups—and ensuring a more prepared, resilient and sustainable ecosystem in the future requires a balanced approach to policy that supports a strong, active and engaged biopharmaceutical sector.

1. Impactful health research and innovation happens in a multi-stakeholder ecosystem.

1.1. A sustainable, resilient and vibrant health research and innovation ecosystem is essential to Canada's health and economic security.

Jurisdictions around the globe have made substantial investments in health research and innovation that have delivered enormous dividends.

$5.6[1] billion

(1988 – 2003)

HUMAN GENOME PROJECT

The U.S. Government has made a sustained investment in institutions, companies and laboratories to map the genes within the human genome from a physical and functional standpoint. All told, from 1998 to 2010, the investment in the Human Genome Project has generated:

- **$796B total economic impact[1] including $141 in impact for every $1 invested**
- **3.8M job-years of employment**
- **$244B[1] total personal income**

£15[2] billion

(1970-2009)

CANCER RESEARCH UK

wellcome trust

Public and charitable funding organizations supporting cancer-related research in the UK, such as Cancer Research UK and The Wellcome Trust, **have engaged in multi-sectoral collaborations and partnerships** to bring significant health and economic benefits. Key impacts from 1991 to 2009 include:

- **A ~40% annual return on investment in perpetuity**
- **5.9M quality adjusted life years**
- **£124B NMB[3]**

1 Converted to 2010 values
2 Converted to 2012 values
3 Net monetary benefit- health benefit measured in quality adjusted life years valued in monetary terms minus the cost of delivering that benefit

Making the economic case for investing in health systems
Economic Impact of the Human Genome Project
A vision for health and biomedical research from the Scientific Panel for Health
Estimating the returns to UK publicly funded cancer-related research in terms of the net value of improved health outcomes

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Appreciating the critical link between health and economic security, the Canadian government has made Canada's health research and innovation ecosystem a strategic growth priority.

$4B

Commitment by the Canadian government (in 2018) over a 5-year period to advance Canada's research ecosystem in order to drive economic growth, stimulate innovation and produce a highly-skilled workforce.

$518M

Investment by the Canadian government (in 2021) to support research and science in order to build a resilient and sustainable Canada—supporting 100+ research projects and nearly 1,000 researchers across the country.

2x

Target for growth of Canada's health and biosciences sector (as set by Canada's Economic Strategy Tables) to become a destination for investment and talent and to create a more resilient Canada, including:

- Doubling health and biosciences exports to $26B by 2025
- Doubling the number of health and biosciences firms to 1,800 by 2025
- Doubling the number of high-growth firms to 80 by 2025

"Canada needs to unlock the full potential of its innovations and accelerate the pace of commercialization to ensure a sustainable, globally competitive health ecosystem with a robust innovation economy and improved health outcomes."

Karimah Es Sabar
Chair, Health and Biosciences Economic Strategy Table

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Health, Healthcare and Nation-Building
New investments to support research and science across Canada
Report from Canada's Economic Strategy Tables: Health and Biosciences

1.2. An integrated network of diverse stakeholders and partners is the engine of a functional health research and innovation ecosystem that translates ideas into impact.

Each stakeholder brings unique and essential resources to the health research and innovation ecosystem—playing pivotal roles and benefitting from an integrated approach to research and innovation.

Bring:
- Critical expertise, facilities for biomedical research
- Strong training environment
- Interdisciplinary research partnerships

Gain:
- Access to expertise, infrastructure, funding to advance ideas into impact
- Training opportunities for students
- Access to trans-sectoral partners

Bring:
- Scientific, public health, policy expertise
- Research incentives, subsidies, credits
- Population data to inform research
- Funding support for research and innovation activities

Gain:
- Access to new innovations to reduce health burden
- Economic growth/development through new investments, jobs

Bring:
- Connections to patients, healthcare providers
- Critical infrastructure to conduct clinical trials
- Expertise in clinical research

Gain:
- Ability to engage with innovators, pharmaceutical companies to test and validate innovations
- Early access to and uptake of innovative health solutions

Bring:
- Voice representing public/patient needs and engagement
- Health research funding
- Access to thought leaders
- Education, engagement

Gain:
- Access to and collaboration with research and innovation leaders
- Insights into research activities
- Enhanced coordination and communication among stakeholders

Bring:
- Patient/public voice/perspective on health, research and innovation needs
- Access to health data, participants for clinical trials/research

Gain:
- Involvement in health research and innovation efforts that benefit patients
- Visibility into and involvement in clinical trials/research
- Knowledge, experience in research and innovation

Bring:
- Commercialization expertise
- Access to strategic partnerships (national/global)
- Ability to invest across development stages
- Market perspective to shape development

Gain:
- Early view into research activities, innovative solutions
- Access to thought leaders
- Receptor for solutions

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Many examples exist demonstrating the value and impact of integrated, multi-stakeholder partnerships in addressing research priorities and translating findings into patient care.

Canada's Strategy for Patient-Oriented Research (SPOR) is focused on coalescing multi-stakeholder partnerships—with patients and families at the heart of these partnerships—critical to translating knowledge into patient and health system impact.

Diabetes Action Canada

One of seven SPOR Networks, Diabetes Action Canada researchers have developed a digital registry to improve awareness, accessibility and recruitment into clinical trials, and have created a national diabetes repository to better analyze patient information to support improved health outcomes.

91 patient partners

108 researchers

29 funding partners

"Patients should be at the centre of all research and they should have a seat at the table when decisions are being made about what research projects have access to their data—even when that data is anonymous… Patient partners have the ability to sit with researchers and discuss the value of the work."

Diabetes Action Canada

SPOR Networks
Diabetes Action Canada

Multi-stakeholder partnerships are increasingly essential to successful translation and commercialization of discoveries and the realization of patient impact and health and economic potential.

CCRM Commercializing Living Therapies

The Centre for Commercialization of Regenerative Medicine (CCRM) provides extensive development, commercialization and business support to remove key bottlenecks and help move therapies from concept to market; CCRM has co-founded, incubated or helped launch 11 companies.

Aspect biosystems

One such company, Aspect biosystems, has leveraged its pioneering bioprinting platform to form its own collaborations with Merck, GSK, McGill University and the Canadian Cancer Society to develop immuno-oncology therapeutics and discover novel therapeutic target in a deal with $2.2M.

AMORCHEM

AmorChem is an early-stage venture fund supporting the translational research necessary to bridge the innovation gap between academic research and viable companies; AmorChem has invested $80M in >30 research academic programs and accelerated the creation of several biotech companies.

SEMA Roche

SemaThera, a company spun out from research conducted at the University of Montreal and Maisonneuve-Rosemont Hospital, has recently signed a multi-year research collaboration and licensing agreement with Roche to develop its promising new class of biologicals.

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CCRM
Aspect Biosystems Partnerships
AmorChem
SemaThera

1.3. COVID-19 has reinforced the criticality of strong intersectoral relationships in driving research and innovation that benefit the people of Canada—and made it impossible to ignore the impact of weakened partnerships on our health security and economic resilience.

Collaborations across the health research and innovation ecosystem have been the cornerstone of our global response to COVID-19.

There are many examples of trans-sectoral, interdisciplinary partnerships that have shaped our response to COVID-19 by collecting patient data, enabling rapid diagnosis and surveillance, and accelerating R&D and clinical innovation.

TransCelerate, **a collaboration of 21 global biopharmaceutical companies**, is leveraging its cloud-based platform to share deidentified, anonymized preclinical and clinical data from COVID-19 studies and will continue collaborating on developing industry-wide data standards and coordinating with global regulatory agencies on how to use real-world data to inform regulatory decisions.

The Gates Foundation, Wellcome Trust, Mastercard and 15 biopharmaceutical companies joined forces to launch the Access to COVID-19 Tools Accelerator to accelerate the development and ensure equitable allocation of therapeutics and vaccines to low- and middle-income countries; the first doses were delivered within 12 weeks of introduction in high-income countries and the program is on track to deliver 2B doses in 2021.

Trans-sectoral partnerships have driven rapid vaccine development and scale-up, including **biopharma and biotech** (e.g. Pfizer and BioNTech); **biotech and government** (e.g. Moderna & NIH); and **biopharma and academia** (e.g. AstraZeneca and the University of Oxford).

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TransCelerate
Bill & Melinda Gates Foundation, Wellcome, and Mastercard Launch Initiative to Speed Development and Access to Therapies for COVID-19
ACT Strategy 2021
Pfizer and BioNTech to co-develop potential COVID-19 vaccine
AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine
Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine
Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries

Canada has been able to navigate the threat of COVID-19 and mitigate its impact through a willingness—and imperative—to establish new trans-sectoral collaborations.

CanCOGeN

Launched in April 2020, the Canadian COVID Genomics Network (CanCOGeN) is an example of a pan-Canadian consortium established to better understand the disease, inform decision-making and build national capacity to address future pandemics, and contribute expertise and genomic surveillance to the global response.

Partners

Led by Genome Canada, CanCOGeN is a coordinated effort that includes federal, provincial and regional public health authorities, academia, industry, hospitals, research institutes and large-scale sequencing centers.

Impact

Through CanCOGen's activities, Canada has been able to **identify and track transmission trends** (including for variants of concern), **detect new clusters of cases**, **discover evolving virus characteristics** that might impact the disease, and **capture data to support current and post-vaccination surveillance**. To date, CanCOGen has sequenced >25K viral and >600 patient genomes, and is currently sequencing 5% of positive cases, ahead of other countries such as the US (which sequences only 0.3% of viral genomes).

> *"**A multi-pronged coordinated national approach** to harnessing robust genomic solutions and convening partners across sectors and borders **will ultimately lead to better patient outcomes."***

Dr. Rob Annan
President and CEO,
Genome Canada

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Genome Canada leads $40 million genomics initiative to address COVID-19 pandemic CanCOGeN

Indeed, the federal government has recognized the importance of bringing together multi-sectoral, interdisciplinary partnerships to stimulate research and innovation and achieve health outcomes for the people of Canada.

The National Research Council of Canada's COVID-19 Response Challenge Program has driven the formation of diverse teams—from government, universities and Canadian business—to develop and accelerate solutions in rapid detection and diagnostics, therapeutics, vaccine development and digital health.

Six collaborative projects were funded to address specific COVID-19 gaps and challenges, including:

- Facilitating clinical adoption of contactless sensors for COVID-19 patients;
- Developing guidelines and functionalities for the design of virtual care software for vulnerable populations;
- Developing and validating mobile application modules to attenuate mental health symptoms related to the pandemic;
- Developing latex agglutination tests for rapid, instrument-free COVID-19 diagnostics in saliva;
- Developing reagent combinations for the visual detection of SARS-CoV-2; and
- Developing a molecular assay for instrument-less SARS-CoV-2 rapid diagnostic from saliva.

National Research Council Pandemic Response Challenge program
Government of Canada announces funding for research and development to address COVID-19 gaps and challenges

Notwithstanding the impact of these collaborative efforts, COVID-19 has also underscored interdependencies across our health research and innovation ecosystem that, when disrupted, leave institutions vulnerable.

The impact that the early days of COVID-19 had on clinical research and clinical trial activity and, importantly, implications across multiple stakeholders within the health research and innovation ecosystem, is a salient example of the criticality of partnership and strong integration to drive research and innovation.

When clinical trial activity was temporarily suspended due to the COVID-19 pandemic, it was estimated that the loss in revenue (primarily from industry funding) for 24 of Canada's research institutes would be $500M in the first 6 months.

In order to enhance Canada's capacity in research and development and address shortfalls, the Government of Canada provided $275M in additional emergency funding for Canada's research hospitals.

UHN
Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

- $6M in lost revenue per month from halted industry-sponsored clinical trials.
- Revenue loss directly impacted 650 highly-educated people.

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All non-COVID19 research and clinical trials at hospitals suspended or cancelled due to funding crunch
With clinical trials halted, funding drop, UHN fears layoffs among researchers working on COVID-19
Prime Minister outlines Canada's COVID-19 response

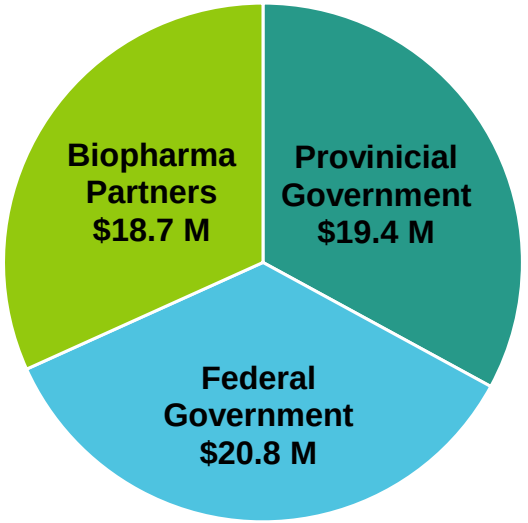
2. The biopharmaceutical industry is integral to Canada's health research and innovation ecosystem.

2.1. The biopharmaceutical sector plays a unique and irreplaceable role in a functional health research and innovation ecosystem—propelling science and technology, developing Canada's scientific talent pool, strengthening capacity for product development and transforming healthcare.

Public-private partnerships involving the biopharmaceutical sector have created effective mechanisms for enabling, enhancing and sustaining basic and applied biomedical research across Canada.

One of 4 Business-Led Networks of Centers of Excellence (BL-NCE) across Canada, CQDM leverages funding from the governments of Québec and Canada as well as industry partners (AstraZeneca, Merck, Pfizer & others) to enable drug discovery.

Funders



Research Partners

- **165** academic labs
- **31** pharmaceutical companies
- **31** small- and medium-sized enterprises (SMEs)

Outputs[1]

- **131** potential therapies
- **127** scholarly publications
- **6** start-ups
- **38** patents

1 From 2008 to 2018
Impact of CDQM on the Life Science Ecosystem

The biopharmaceutical industry's partnerships with academic health sciences centres are diverse, multifaceted and mutually beneficial to partners and patients.

One of Canada's leading academic health sciences centres, UHN has forged many partnerships with biopharmaceutical companies to share knowledge, resources and expertise in order to drive innovation and drug discovery and enhance clinical services—all with the goal of amplifying patient care and outcomes.

Pfizer

UHN

UHN's 5-year research collaboration with Pfizer's Centers for Therapeutic Innovation (CTI) brings together Pfizer's drug discovery expertise with UHN's leading cancer research programs—enabling UHN to leverage the Pfizer CTI team's discovery program, extensive libraries, and scientific expertise (through a hands-on working relationship) to rapidly identify a lead candidate for future clinical testing.

This industry partnership will accelerate an academia-generated target towards a novel therapeutic, reducing time to patient impact and leveraging both academic and industry expertise to potentially generate a new class of drugs.

BlueRock Therapeutics

BAYER

UHN's 4-year partnership with BlueRock Therapeutics drives innovation and collaboration in stem cell therapy for heart disease—bringing significant investment to UHN, critical scientific resources to BlueRock (e.g. assay testing, animal facilities), and ultimately groundbreaking stem cell discoveries to patients.

This academia-industry partnership is prime example of a bidirectional relationship that is bringing innovative stem cell therapies to patients and having a positive economic impact through local investment and job creation.

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TDC is pleased to announce collaboration with Pfizer on cancer immunotherapy
UHN Internal Research Commercialization Report

As home-grown Canadian biopharmaceutical companies launch and scale, forming collaborative partnerships with biopharmaceutical partners enhances their success.

Overview

- Headquartered in Vancouver, British Columbia, Zymeworks is a clinical-stage, biopharmaceutical company dedicated to the discovery, development, and commercialization of next-generation multifunctional biotherapeutics.

Support

- Zymeworks has leveraged its innovative therapeutic platforms to form **strategic partnerships with >10 global biopharmaceutical companies**, an endeavor that has significantly raised its profile.

Impact

- In May 2017, Zymeworks held an IPO on the Toronto Stock Exchange, raising $59 million— the largest Canadian biotech IPO in more than a decade.

Zymeworks
Zymeworks IPO bears good tidings for Canadian biotechnology

The biopharmaceutical sector is vital to building capacity and developing talent in Canada by employing highly-skilled personnel, training the next generation of life sciences leaders and strengthening the pipeline of graduate students.

SANOFI PASTEUR

Building on its $100M investment in a vaccine R&D facility in 2011, **Sanofi Pasteur is investing $500M (including $70M in federal and provincial government support)** to establish an advanced vaccine manufacturing facility in Toronto to support pediatric and booster capacity, resulting in **up to 1,250 new jobs**.

adMare Academy
EXECUTIVE INSTITUTE
Supported by Pfizer

Leveraging a **$1M contribution from Pfizer**, adMare launched the Executive Institute Program to develop, nurture and support Canada's pool of life sciences leaders, with a concomitant focus on addressing recognized gender gaps and other inequalities in scientific and business leadership positions.

Mitacs

THE UNIVERSITY OF BRITISH COLUMBIA

Boehringer Ingelheim

With matching funding from MITACS and **industry partners ($1.3M over six years)**, Canada's first graduate training program in blockchain and distributed ledger technology was launched in 2019—**providing 156 interns (18 Masters and 8 PhD per year)** with skills training and international experience in financial technology.

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Sanofi's Vaccine Manufacturing Facility, Toronto, Ontario, Canada
Sanofi to invest $500M in Toronto vaccine facility
CDRD/adMare Academy's Executive Institute
UBC launches Canada's first graduate blockchain training path
UBC launches Canada's first graduate blockchain training path with support from Mitacs
UBC Launches Canada's Frist Graduate Blockchain Training Path

Investments made by biopharmaceutical companies in start-ups and promising technologies emerging from Canadian institutions are fueling the research and innovation pipeline and enabling the development of home-grown innovations.

JLABS
PART OF Johnson & Johnson INNOVATION

By creating a unique open innovation environment, JLABS is an example of an incubator that helps bring entrepreneurs and innovators together to optimize R&D activities, share resources and connect with investment partners to build early-stage companies in biopharmaceuticals, medical devices, and consumer and digital health.

JLABS @ Toronto

- One of only 12 J&J supported incubators around the world.
- Helped grow 70+ Canadian companies and facilitated connections with >150 investors across North America to invest in resident companies.

The potential of JLABS in growing successful companies has been demonstrated across its portfolio of incubators; the full impact of the JLAB model across the globe (as of 2018) includes:

- **$11.6B** In funding for companies through financing and strategic relationships
- **25%** Of companies are conducting clinical trials
- **113** Deals between J&J and JLABS companies
- **26%** Of companies have a commercial product

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Impact Report 2018
Johnson & Johnson Innovation opens JLABS @ Toronto
Johnson & Johnson Innovation Announces 40+ Resident Companies now at JLABS @ Toronto
Toronto QuickFire Winner Avoids the Burn

The biopharmaceutical industry plays a key role in spearheading efforts to convene stakeholders and advance initiatives that accelerate system transformation to improve health outcomes for the people of Canada.

The Canadian Personalized Healthcare Innovation Network (CPHIN) is one example of a trans-sectoral, industry-led initiative aiming to transformation our health system and prepare for a data-enabled future.

CPHIN | UNIVERSITY OF WATERLOO | Roche | AMGEN | janssen

Overview

- CPHIN convenes healthcare stakeholders and orchestrates initiatives that accelerate system transformation to enable personalized healthcare in Canada.

Support

- Spearheaded by Roche and in collaboration with the University of Waterloo, CPHIN has secured commitments from dozens of diverse organizations from across Canada's healthcare research and innovation ecosystem.

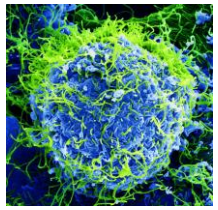
Impact

- CPHIN's "Kick Start Programs" focus on using aggregated, de-identified data to turn personalized healthcare research into applied technologies, processes, and programs.

2.2. The environment we have created for global biopharmaceutical companies operating in Canada reflects broader industrial, commercial and structural barriers to building and scaling homegrown companies with global aspirations.

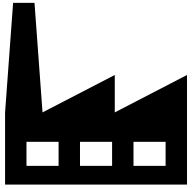
Gaps in domestic infrastructure and capabilities have impacted—and will continue to impede—the scale-up, commercialization and industrialization of Canadian innovations.

Commercialization



The development of a homegrown Ebola vaccine stalled when Canadian inventors struggled to gain the support of industry and government in Canada—selling the rights to a US biotech firm which, in turn, sold the rights to Merck for $50M. Merck is credited with bringing the vaccine to market.

Biomanufacturing



Years of unaddressed decline in Canada's biomanufacturing base has constrained our ability to manufacture made-in-Canada COVID-19 vaccines for clinical testing, as well as approved global vaccines.

"…we have raised the issue of Canada's unpreparedness for pandemic diseases for quite a while… You need to have manufacturing capacity. You need to have the ability to quickly respond."

Dr. Volker Gerdts
Director
VIDO-InterVac

Ineffective private-sector partner, federal funding cuts hampered Canada's efforts to develop Ebola vaccine: study
Made-in-Canada COVID-19 vaccine effort slowed by manufacturing delay
Why Canada can't make its own COVID-19 vaccine — and how to 'fix' the problem before the next pandemic

The growth, sustainability and success of Canadian biotech companies and innovations are predicated upon the presence of critical receptors of innovation and the willingness of these partners to invest.

- A 2018 survey of Canadian biotechnology companies reported that **57% of Canadian biotech companies** feel that **access to capital is the number one issue** facing their industry today.

- Historical analyses have shown that **Canadian high-growth technology companies were acquired for 3x less than those founded in the US**, indicating that they were sold prior to scaling into larger, global businesses, purportedly due to a lack of late-stage financing required to fuel growth.

[Canada's Scientific Research & Experimental Development Tax Incentives Program] cuts off R&D support at the exact instant when Canadian firms are demonstrating the greatest growth potential by going public or attracting foreign direct investment. It also removes a highly effective lever for retaining R&D activities in Canada once a Canadian [company] becomes publicly traded or controlled by foreign investors and further accentuates gravitational forces to move head offices and R&D activities outside of Canada.

Canada's Economic Strategy Tables
Health and Biosciences

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Deloitte: Biotechnology Industry Data Survey 2018
MaRS: Borderless Investments

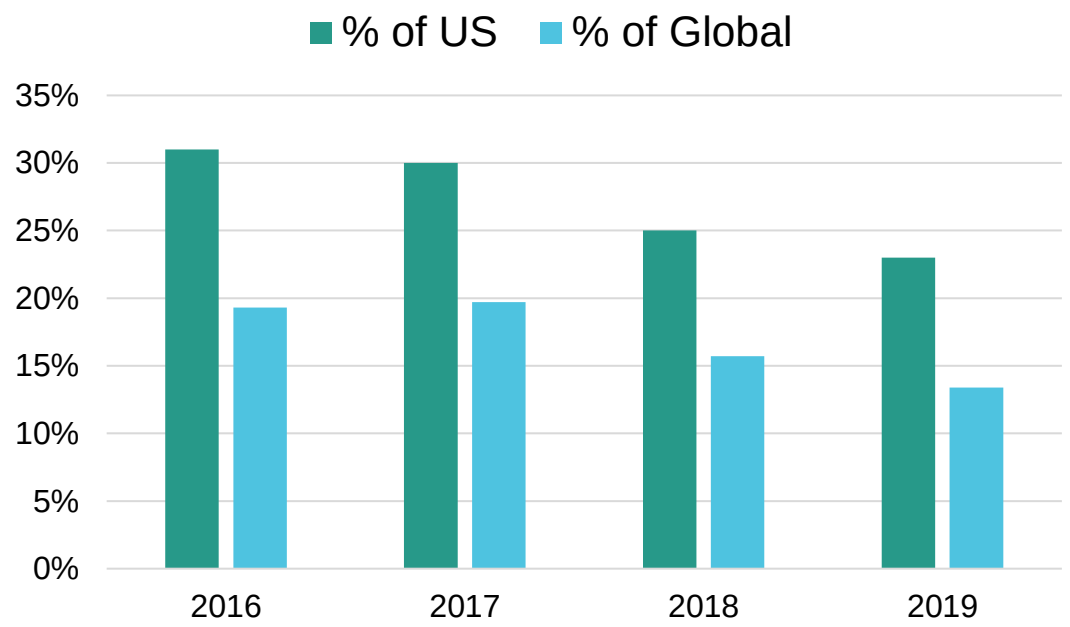
2.3. Weaknesses in the partnership between the biopharmaceutical industry and Canada's health research and innovation ecosystem are diminishing our global competitiveness and our ability to deliver innovations that improve health outcomes.

Over the past several years, industry-sponsored clinical trial activity in Canada has decreased more rapidly than in other jurisdictions, potentially impacting early patient access to innovative medicines.

Snapshot from 2016

- Industry-sponsored clinical trials were estimated to **offset $2.1B in costs to the health system** (including **$1.8B in drug costs** alone)
- **More than 20,000 patients participated in clinical trials** in over 2,000 facilities across Canada

Percentage of new industry-funded clinical trials launched in Canada



2016 → **2019**

Overall:

Global	US	Canada
2% ↓	9% ↓	32% ↓

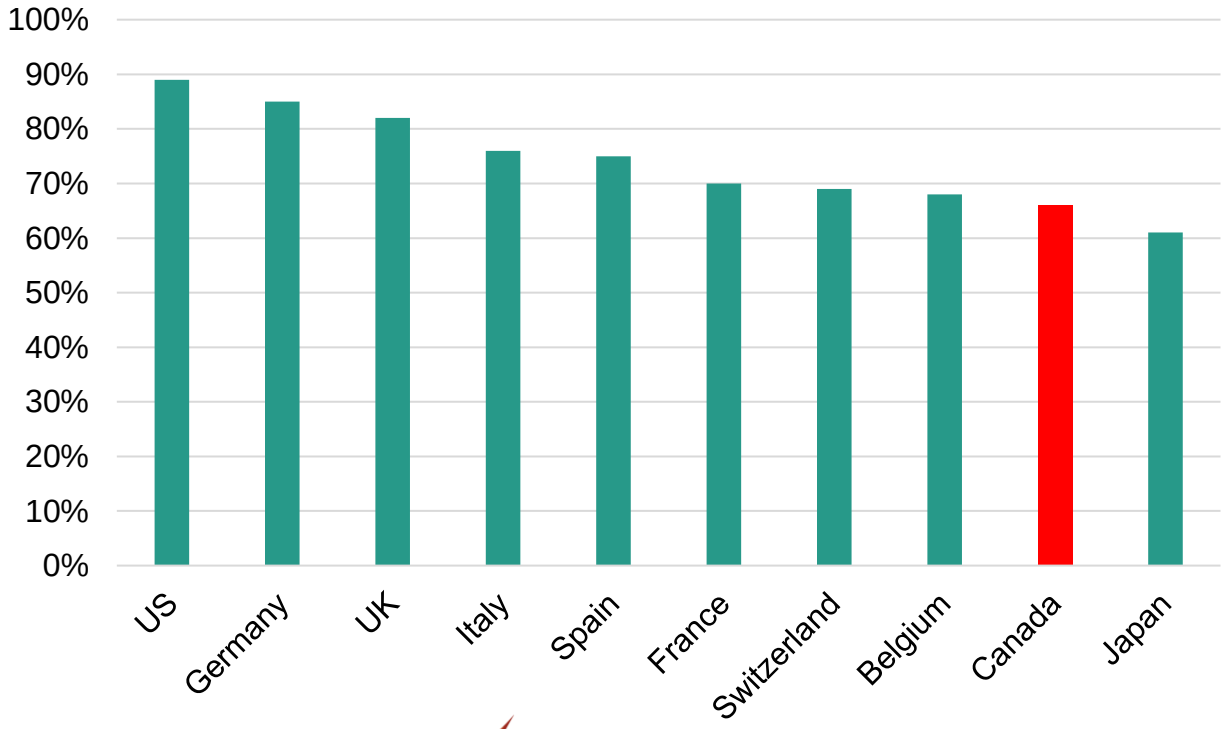
Pub Med: The Costs of Industry-Sponsored Drug Trials in Canada (2020). https://doi.org/10.1007/s41669-019-0161-0
Clinicaltrials.gov

Strong partnerships with the biopharmaceutical sector are critical in ensuring access to innovative medicines, which have decreased in Canada in recent years compared to other jurisdictions.

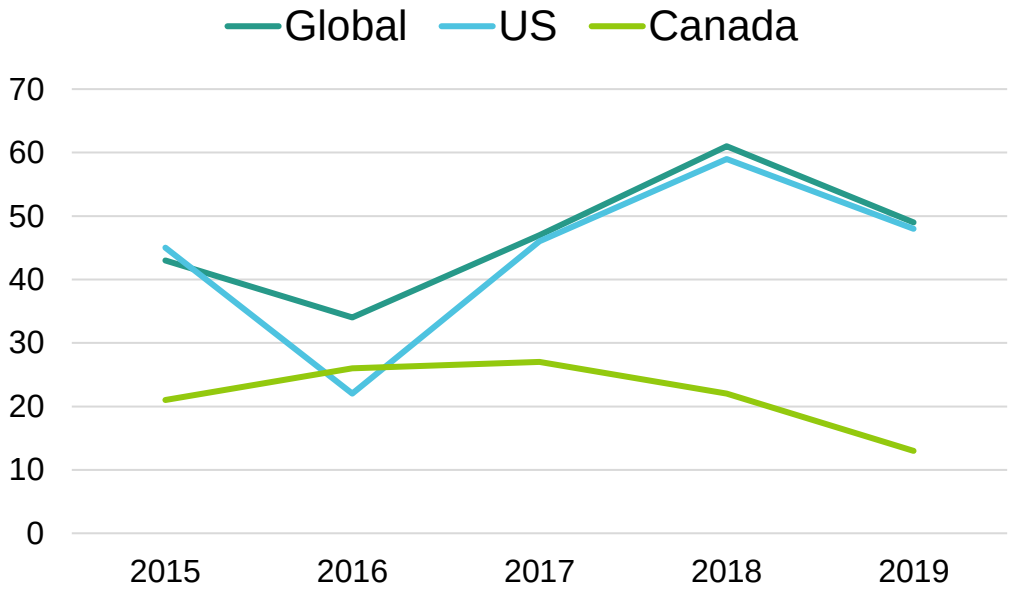
Canadian patients have not been able to access 176 new drugs in the last 20 years; recently, the people of Canada have been receiving less than half of new medicines launched globally.

Proportion of New Active Substances Launched by Country

(2000-2019, n=516)



Number of New Active Substances Launched



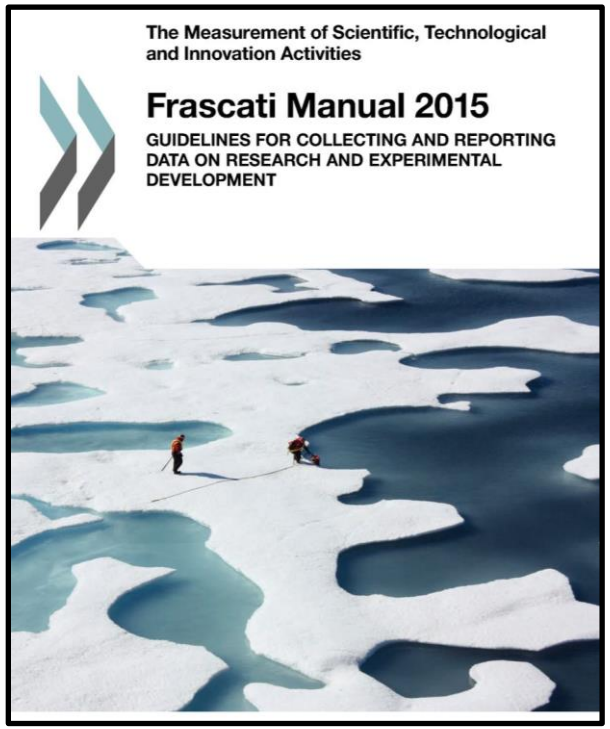
New Medicine Launches: Canada in a Global Context
New Drug Launches Worldwide Dipped In 2019

3. Our ecosystem needs to be a globally competitive environment for biopharmaceutical partnerships.

3.1. Our approach to biopharmaceutical policy, regulation and adoption must reflect a more holistic view of how our ecosystem functions, appreciating the inextricable role the sector plays in the broader health research and innovation environment.

Recognizing the ever-evolving landscape of biopharmaceutical R&D, other jurisdictions have taken a modern—and broader—approach to recognizing and measuring biopharmaceutical R&D.

Canada has not modernized the definition of biopharmaceutical scientific research and experimental development since 1987, making it not only out of date, but also inconsistent with the definition used by peer nations in the Organization for Economic Co-operation and Development (OECD).



Most recently updated in 2015, the Frascati Manual is not only a standard for R&D data collection defined by the OECD member countries, as a result of initiatives by the OECD, UNESCO, the European Union and various regional organizations. **While it has become a standard for R&D measurement worldwide, it is not being referenced by Canada.**

"…[The Frascati] manual pays specific attention to the relentless process of R&D globalization and the increasing variety of arrangements by which R&D is funded and performed within and across sectoral boundaries."

OECD

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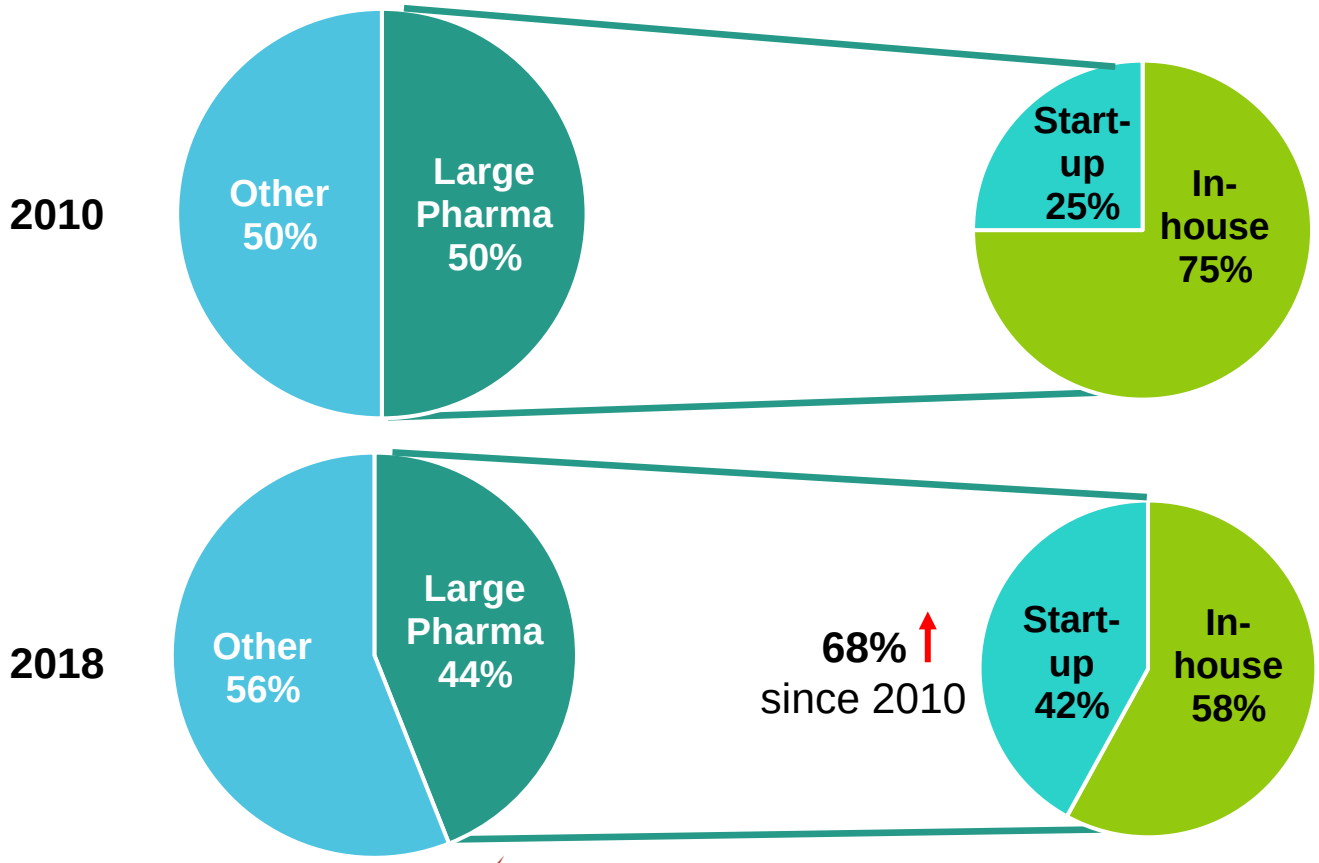
PMPRB: Patentee's Guide to Reporting
Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development

3.2. Profound shifts in the nature of biopharmaceutical innovation are transforming the model and amplifying the imperative of industry partnership. Canada must take an active, strategic approach to invigorating our relationship with the sector to ensure that we are helping to shape the agenda and elevating our global competitiveness.

The globalization of pharmaceutical innovation and shift to extramural R&D underscores the importance of leveraging Canada's scientific advantages to satisfy pharma's need for partnerships.

Breakdown of Drugs Launched by Stakeholder

Origin of new drugs launched by Large Pharma[1]



77% and 89% of Pfizer's and J&J's portfolios (in 2017), respectively, were discovered and developed by "third parties", many of whom are academic research centers.

1 Defined as biopharmaceutical companies with >$10B in revenue
Start-up defined as emerging biopharma with <$200M R&D spend
IQVIA: The Changing Landscape of Research and Development
STAT News

The very nature of biomedical innovation has also changed, promising great benefits for patient subgroups while emphasizing the need for novel approaches to biopharmaceutical partnership.

Shift to Personalized Healthcare

- **Cell, gene and nucleotide therapies** make up less than 10% of the total late-stage R&D pipeline but **have more than doubled in number over the past three years**; this number reached 269 by the end of 2018, up from 120 in 2015.
- There has been a **shift from broad spectrum drugs to tailored treatments**, with non-specific cytotoxic agents in the pipeline falling from 16.8% to 7.3% (2008-2018).
- **60% of cancer therapeutics launched in 2018 used predictive biomarkers** to identify and stratify specific patient sub-populations for precision medicines.

Implications for Partnership

- Opportunity (and need) for interdisciplinary partnerships (e.g. genomics, computer sciences).
- Opportunity (and need) for multi-sector, multi-stakeholder partnerships, including with patients and the public.
- Greater accountability and transparency, particularly with patients and the public, given the use of data to drive R&D and patient care.

IQVIA: The Changing Landscape of Research and Development
IQVIA: Global Oncology Trends 2019

3.3. Strengthening our partnership with the biopharmaceutical industry will ensure that patients have access to innovative medicines and receive the best possible care—a healthcare right and expectation of all the people of Canada.

Global jurisdictions have worked with the biopharmaceutical sector to support a balanced approach to research and innovation that ensures access to innovative medicines while controlling costs.

To strike a balance between supporting innovation in the pharmaceutical industry, helping individuals quickly receive cost-effective medicines and controlling expenditures on drug costs, the UK launched the voluntary scheme for branded medicines pricing and access (VPAS) with policies designed to incentivize innovation and promote R&D. While too early to assess all outcomes, highlights from the VPAS approach include:

New therapeutics will be fast tracked to approval, quickly adopted into practice, and exempt from qualifying as taxable sales for 36 months; smaller companies have an extended exemption window.

Proactively promote uptake of new therapeutics through tailored implementation campaigns for drugs that offer exceptional value and significant health gain (early outcomes have shown that new medicines are prescribed 77% more often compared to the 12 months prior to launch).

Generous R&D tax credits that encourage risk-taking by providing relief on costs across all stages of drug development; tax relief payments will also be processed and paid within rapid timeframes to assist firms seeking to accelerate growth.

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The UK's new five-year pricing agreement
Update on the PPRS: What's Changed?
The 2019 Voluntary Scheme for Branded Medicines Pricing and Access
Research and Development tax relief for small and medium-sized enterprises

Approaches to strengthening partnerships with the biopharmaceutical sector vary across jurisdictions, but ultimately aim to creating a more integrated, more productive health research and innovation ecosystem.

SWITZERLAND INNOVATION

Switzerland has **strengthened relationships between ecosystem stakeholders** to facilitate collaboration, networking, and commercialization; in 2019 alone, biotech industry employment grew by 10% and 62 companies were founded in the Basel area.

Many EU and OECD nations use health data and outcomes to **price medications based on their performance and utilization, minimizing uncertainty for all stakeholders;** several drug makers provide refunds to governments if their Hepatitis C treatments are not curative.

iisa Industry Innovation and Science Australia

Australia is listening to advice from industry experts and implemented the Entrepreneurs' Programme **to help businesses and researchers commercialize and grow**; on average, participants have created >4 new jobs each, and exporters have increased their export revenue by >$500K.

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Switzerland Innovation Parks | Biotech Employment | Basel Area
Canada in the Topsy Turvy World of Pharmaceuticals
Performance-based managed entry agreements for new medicines in OECD countries and EU member states
Pharmaceutical managed entry agreements | UK outcomes based pricing| PWC: Outcomes based pricing
PubMed: Dealing with uncertainty and high prices of new medicines. doi: 10.1016/j.socscimed.2014.11.003
Industry Innovation and Science Australia | Entrepreneur's Programme

Finding an appropriate balance across the many levers that control our ability to deliver innovative, life-saving medicines to the people of Canada will be vital to our health and economic security.

While one of many levers in strengthening our health research and innovation ecosystem and partnership with the biopharmaceutical industry, drug pricing is an important driver of ensuring access to innovative medicines.

- A meta-analysis of peer-reviewed studies conducted between 1995 and 2020 found that **policies that reduced drug prices** resulted in a **decrease in biopharmaceutical investment in R&D** and **lower access to innovative medicines for the people of Canada.**
  - 10/16 studies show a significant negative link between drug price and pharmaceutical R&D spending.
  - 21/27 studies show a significant negative link between drug price and access to new drugs.
- In December 2020, a report noted that:
  - **72%** of the people of Canada indicated that new medicines should be made available as soon as possible even if it means Canada has to pay a higher price.
  - **52%** of the people of Canada do not support making medicines more affordable if that means some treatments are delayed or not available in Canada.

Evidence that regulating pharmaceutical prices negatively affects R&D and access to new medicines.
A Perspective on Medicine Pricing in Canada

4. Our ecosystem will succeed only if we plan and act as an integrated community of partners.

The health research and innovation ecosystem is at a crossroads.

At a time when the importance of our health research and innovation ecosystem is more apparent than ever, we must seize the moment to modernize and strengthen trans-sectoral, transdisciplinary partnerships that can unlock Canada's potential to realize health security and economic resilience.

- Partnerships are essential to the success and impact of the health research and innovation ecosystem, and we need to ensure that interdependent health, science and economic policies and investments are coherent and strengthen, sustain and expand collaborations among stakeholders.
- While Canada has a strong foundation for partnership—and many examples of success—we need to ensure that our policy and investment environment makes trans-sectoral partnership the expectation, not the exception.
- We enjoy an historic opportunity to turn our global leadership in science and healthcare into a globally leading health research and innovation ecosystem that maximizes social, economic and health impact. It is essential that we capitalize on this moment to secure Canada's health and economic future.

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We have an opportunity to chart a new path and invigorate a new spirit of partnership.

We are calling for change, not a return to the status quo. As the pandemic has laid bare, we need a renewed approach to cultivating an ambitious, futureproofed policy and investment environment that supports our ecosystem as a whole and positions Canada for sustainability, growth and leadership. We need an environment that:

- Appreciates and enables the critical role of the biopharmaceutical sector in advancing research and innovation in collaboration with academia, care providers, governments, not-for-profit organizations, patients and the public;
- Enlarges Canada's share of global biopharmaceutical sector investment in infrastructure, research and training programs, start-ups, technologies and jobs;
- Expands and diversifies opportunities for training and employing, attracting and retaining high-quality personnel;
- Accelerates the translation, commercialization and adoption of home-grown innovations that improve the lives of people in Canada and across the world; and
- Fulfills the potential of our investments in science and talent by ensuring that health research and innovation are integral to and enabled by our healthcare system.

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We look forward to working with the Government of Canada to develop an accountable, sustainable and impactful action plan.

Canada's pharmaceutical pricing regime is critically important, but it is only one consideration in a complex network of policies impacting the vitality of our ecosystem—underscoring the need for an integrated, pan-sector strategy to maximize the contribution of health research and innovation to Canada's health security and economic prosperity. Research Canada welcomes the opportunity to work with key stakeholders across the country to co-create a national approach to fortifying our ecosystem, potentially including:

- Developing a national **health research and innovation vision and strategy** that sets an ambitious agenda for our ecosystem and provides a framework for the supports, policies, investments, incentives and programs that will be needed to strengthen partnerships and deliver maximum health and socioeconomic impact.
- Creating and applying an **integrated scorecard** to evaluate the performance of and ensure accountability within the health research and innovation ecosystem and report to the people of Canada on health, social and economic outcomes.
- Establishing a mechanism to engage expert opinion on the performance and the potential of the ecosystem, potentially through a permanent, trans-sectoral **Advisory Council on Health Research and Innovation** responsible for providing balanced, evidence-based advice to the federal government and policymakers.

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We thank all members of the Expert Advisory Panel for volunteering their sharp insights, critical review and valuable time.

We feel fortunate to work with leaders who are so passionate about and resolutely committed to advancing Canada's health research and innovation ecosystem.

Disclosures

- Neither Research Canada nor any member of the Expert Advisory Panel was remunerated for participation in this study.
- Dr. Scott Halperin has received research grants and contracts from most major global vaccine manufacturers, as well as SMEs and start-ups to undertake vaccine clinical trials. He also served on *ad hoc* scientific advisory panels for multiple vaccine manufacturers.
- Ms. Sue Mack-Klinger is a practicing community pharmacist for Wal-Mart Canada, Inc.
- Shift Health has contracts with clients across the health research and innovation ecosystem, including the biopharmaceutical industry. Shift Health's research, advisory and project management support for this study was partially funded by Boehringer Ingelheim Canada.
- Research Canada and the Expert Advisory Panel exercised independent control over study design, data analysis and report development. A final version of the report was shared with Boehringer-Ingelheim Canada only upon unanimous endorsement by the Expert Advisory Panel.

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