

**Canada's Biomanufacturing  
and Life Sciences Strategy**



Government  
of Canada

Gouvernement  
du Canada

**Canada**

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# Message from the ministers

As the Minister of Innovation, Science and Industry and the Minister of Health, we are pleased to present Canada's Biomanufacturing and Life Sciences Strategy. Canada has a long and impressive history of achievement in health and life sciences innovation. Many know about the Canadian discovery of insulin one hundred years ago and that Canadian scientists were also instrumental in developing the polio and Ebola vaccines, as well as the first blood thinner. Therefore it came as no surprise that when the COVID-19 pandemic hit, Canadian companies, scientists and innovators stepped up to the challenge.

However, due to a decades long decline in Canada's domestic biopharmaceutical industry, Canada was left without the large-scale and flexible biomanufacturing capacity needed to quickly produce a COVID-19 vaccine when the pandemic hit. This is why the federal government is working tirelessly to rebuild Canada's domestic biomanufacturing sector by focusing on both quick strategic actions and a long-term vision. Throughout the pandemic, the Government of Canada's focus has been on protecting Canadians and doing everything possible to help them get through this safely. Today, Canada has one of the most diverse vaccine portfolios in the world, and we are leading globally in vaccination rates against COVID-19.

But we did not get here over night, and we have much more work to do to ensure Canadians remain protected against future health threats. We know we have to rebuild our biomanufacturing sector, and support the innovative and world-leading scientists who are finding made-in-Canada solutions to global challenges. The government of Canada has already invested over \$1.2 billion to re-build Canada's vaccine, therapeutics and biomanufacturing capacity right here at home. This will not only increase our resiliency but also drive economic growth and create good high-skilled jobs.

Canada's strategy is already yielding results, as we have successfully supported investments that will add capacity across a range of vaccine platforms



and production processes – like RNA vaccine development and production, protein-based vaccines, viral vector manufacturing capacity, and new fill and finish capabilities. In the first days of the pandemic, the Government of Canada announced support for Quebec-based Medicigo, a Canadian company that recently announced phase-3 clinical trials for its innovative plant-based COVID-19 vaccine. The federal government also supported improved pandemic preparedness in our public assets; providing \$126 million to the National Research Council of Canada to build the now-completed Biologics Manufacturing Centre in Montréal. This is where leading vaccine company Novavax has chosen to produce its COVID-19 vaccine, right here in Canada. The Government of Canada also partnered with the University of Saskatchewan’s Vaccine and Infectious Disease Organization, providing \$105.2 million to support its vaccine and biomanufacturing capacity.

With these investments and others, the Canadian ecosystem is being rebuilt, brick by brick. But there is more work to do. That’s why Budget 2021 doubled down on progress made, to provide \$2.2 billion towards implementing the Biomanufacturing and Life Sciences Strategy that the Government of Canada is pleased to present to you today.

Overall, this will help us grow a strong and competitive domestic life sciences sector, and ensure Canada’s readiness for future pandemics or other health emergencies. We are proud to note that this is truly a pan-Canadian strategy: The Government of Canada has invested more than a billion dollars in dozens of biomanufacturing, vaccine and therapeutics projects from Vancouver to Halifax.

The Government of Canada will continue to take action, based on the best available science, to fight

**As we look to a post pandemic future for Canada, it is important to continue establishing Canada’s competitive position on the global stage. That’s why the Government of Canada has developed a comprehensive strategy to re-build a strong and resilient domestic biomanufacturing and life sciences sector. The strategy has been developed in consultation with industry and scientific experts, academia and the public, and informed by the COVID-19 Vaccine Task Force and the COVID-19 Therapeutics Task Force. The Strategy is made up of five pillars:**

**1 Strong and Coordinated Governance:** Enabling rapid decision-making, informed by experts; and, to ensure our investments achieve maximum impact.

**2 Laying a Solid Foundation by Strengthening Research Systems and the Talent Pipeline:** From post-secondary institutions, research hospitals and Canadian scientists, we are supporting the foundational inputs necessary to have a healthy life sciences ecosystem. After all, there is no point having a state-of-the-art factory if we don’t have the people and talent to run it.

**3 Growing Businesses by Doubling Down on Existing and Emerging Areas of Strength:** We will continue to support Made-in-Canada solutions through the Strategic Innovation Fund to rebuild the sector. We have a strong pipeline of projects across the country that will create thousands of good jobs for Canadians while closing key gaps in our biomanufacturing supply chain.

**4 Building Public Capacity:** Taking advantage of the new capacity coming online at Canada’s National Research Council, including its new Biologics Manufacturing Centre. With this new facility built ahead of schedule, we will be able to produce vaccines for whatever the future may hold.

**5 Enabling Innovation by Ensuring World Class Regulation:** Lastly, this will make Canada a more attractive destination for leading life sciences firms to establish and grow. Overall, this will help us grow a strong and competitive domestic life sciences sector, and ensure Canada’s readiness for future pandemics or other health emergencies.

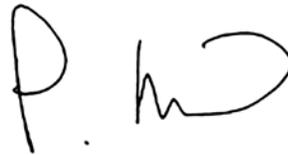
the COVID-19 pandemic and to be prepared for future health emergencies, while growing the sector and creating high quality research and manufacturing jobs for Canadians. The Health and Biosciences Economic Strategy Table will also continue to examine a strategic approach to further grow Canada's vibrant life sciences sector

Today marks an important step for Canada to build back better, stronger and healthier. This Biomanufacturing and Life Science Strategy will guide us to a future in which Canadian innovation leads. And it will enhance Canada's historic reputation as a beacon of life sciences innovation around the world.

Thank you,



**Francois-Philippe Champagne,**  
**Minister of Innovation, Science and Industry**



**Patty Hajdu,**  
**Minister of Health**





## Introduction

As we continue to battle the COVID-19 pandemic, never has the importance of a resilient and innovative biomanufacturing and life sciences sector been more evident. At a time when we are looking toward economic recovery and regrowth in the shadow of a transformational health emergency, opportunities to invest in and strengthen Canada's life sciences sector are front of mind.

Canada has an impressive history of achievement in this area. Most Canadians know about the discovery of insulin – a key Canadian innovation that has improved the lives of countless diabetics around the world. In fact, 2021 marks the 100th anniversary of that discovery. But many don't know that Canadian scientists were instrumental in discoveries related to the polio and Ebola vaccines. Or that it was in a Canadian lab that a compound was developed to stunt HIV's vicious rate of replication – a discovery which has saved millions of lives. These are just a few examples of the life saving work that can be done when the country has a strong, made-in-Canada life sciences and biomanufacturing sector.

The Biomanufacturing and Life Sciences Strategy aims to build resilience within this critical sector in Canada. The pandemic has been an extraordinarily painful time for Canadians. Many people lost loved ones, or saw their businesses and careers impacted through far-reaching economic and financial impacts. But there is light at the end of the tunnel. Today, Canada has a golden opportunity to build back better, stronger and healthier. But the Strategy is about so much more than this pandemic. The Strategy will guide us to a future in which Canadian innovation leads in preventing, treating and curing all kinds of illness and disease. It will help grow and enhance Canada's reputation as a beacon of life science innovation around the world.

## Lessons Learned from the COVID-19 Pandemic

The COVID-19 pandemic highlighted not only the importance of domestic capacity to develop and produce vaccines and therapeutics, but also significant breakthroughs in health science and technology. As a result, the pandemic has ushered in a new era of health innovation and renewed prioritization for preparedness, with countries re-evaluating the importance of domestic capabilities as a means of ensuring resiliency in the face of future health emergencies.

The current pandemic is not over, and researchers forecast that the frequency of pandemics involving novel pathogens may increase over time. The past months have shown that pandemics can bring severe health, economic and societal impacts. Although the long-term trajectory of COVID-19 is unknown, including the potential for it to become endemic, Canada and other countries must confront a profound shift in the global life sciences ecosystem. Decisions about ongoing vaccine supply must be considered in the context of increased and ongoing global demand for vaccines and therapeutics, recognizing that many countries have yet to reach the peak of their COVID-19 vaccination campaigns. As evidenced by Canada's experience with H1N1, the ability to ensure priority access to a domestically produced, filled and finished pandemic vaccine is critical to mitigating the risks of a global health emergency.



## Consultations on a Biomanufacturing and Life Sciences Strategy for Canada

In February and March 2021, Innovation, Science and Economic Development Canada, in collaboration with Health Canada and the Public Health Agency of Canada, and with the assistance of the COVID 19 Vaccine Task Force, engaged expert stakeholders in a series of virtual roundtables as well as by soliciting written submissions on the long-term elements of a robust domestic biomanufacturing sector. A detailed consultation paper entitled, Considering the Creation of New Biomanufacturing Capacity for Canada, laid out a series of considerations and key questions.

### Consultation key findings include emphasis on:

- Expanding the mandate of the initiative to cover the full biomanufacturing and life sciences ecosystem;
- Building flexibility to support a diverse portfolio of technologies;
- Enhancing connectivity across stakeholders, namely academic and research institutions, industry, and government, including government biomanufacturing assets;

- Ensuring sustainability of the sector outside of public health emergencies;
- Bolstering the number of highly qualified personnel to work in the sector;
- Aligning policies and regulations to support the goals of the initiative;
- Supporting research, sustaining the ecosystem by creating mechanisms for partnerships, and leveraging new capacity for commercial activities;
- Investing in strategic supply chain capabilities to differentiate Canada;
- Leveraging Canadian research and existing expertise and forming public-private partnerships; and
- Ensuring sufficient globally-relevant domestic capacity, such that Canada has the means to participate in strategic international partnerships and alliances.

The information gathered during this consultation process was taken into consideration and used to help develop and inform the life sciences and biomanufacturing Strategy. The Health and Biosciences Economic Strategy Table (HBEST) will also continue to examine a strategic approach to further grow Canada's vibrant life sciences sector.

## Goals and Objectives of a Revitalized Life Sciences and Biomanufacturing Strategy

The objectives in advancing this Strategy are multifold: Canada requires a well-coordinated plan to ensure readiness for future pandemics and other health threats, which includes domestic vaccine and therapeutic development and production capabilities across priority and next-generation platforms; and, Canada stands to benefit from a plan to advance other important health and economic outcomes associated with the biomanufacturing and life sciences sector. These objectives will be supported by upstream federal enabling measures, such as support for clinical trials, training and skills development for the life sciences labor market, modern regulations and commercialization of Canadian innovations.

This Strategy is a leading part of an overall pandemic preparedness effort being developed across departments. This includes changes to how Canada produces, procures and manages a range of critical materials in times of need, including personal protective equipment and medical devices, such as testing kits.

### Pandemic preparedness will be critical moving forward

Triggered by the COVID-19 pandemic, the vaccine-development landscape has shifted dramatically with a marked reliance on newer platform technologies, such as synthetic mRNA and virus-like particles. These flexible and adaptable platforms have proven adept at rapidly developing vaccines, eliciting quick onset of immunity, and scaling up production to respond to disease outbreaks.

The ongoing risk of a future pandemic, or of the potential for co-circulating pathogens, underscores the importance of developing domestic production capacity for multiple, flexible vaccine platforms that can be quickly adapted and scaled up for pandemic production at population scale. Of course, increased production capacity must meet long-term economic objectives to entrench Canada as a major contributor in the global marketplace by focusing on areas of strength, global demand, and competitive advantage, while creating good quality jobs for Canadians.

Investment in foundational research and research infrastructure will accelerate the development of products and processes that will be translated into new IP. The Strategy provides significant support for start-ups and small businesses to help them develop new patented products, for example, by improving access to clinical trial material and laboratory facilities, streamlining regulations, and providing incubation services through adMare. Canada's Strategic Innovation Fund will also support IP generation through direct assistance to companies and by expanding biomanufacturing capacity in Canada, reducing the likelihood that domestic drug-developers will need to find manufacturing partners abroad.

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**\$126M investment for the National Research Council of Canada (Montreal, QC) to build a new Biologics Manufacturing Centre at its Royalmount site in Montréal. The new centre will produce large-quantity, end-to-end production of vaccines—approx 2M doses per month. Construction was completed June 2021 ([August 31, 2020](#)).**



## Canada's Five-Pillar Biomanufacturing and Life Sciences Strategy

Canada's Biomanufacturing and Life Science Strategy will improve Canada's long-term pandemic resilience and promote growth in the domestic life-sciences sector. This Strategy will guide investments supported through funds allocated in Budget 2021 for the revitalization of Canada's biomanufacturing and life science sector.

Informed by expert recommendations, the ambitious five-pillar Strategy proposes a coordinated approach to grow Canada's capacity to rapidly develop and produce vaccines, with strengthened capabilities across the value chain, in order to improve pandemic readiness and sector growth. The five priorities areas are as follows: **(1) Strong and Coordinated Governance; (2) Laying a Solid Foundation by Strengthening Research Systems and the Talent Pipeline; (3) Growing Businesses by Doubling Down on Existing and Emerging Areas of Strength; (4) Building Public Capacity; and (5) Enabling Innovation by Ensuring World Class Regulation.**

Action across the five pillars will be supported by existing resources and Budget 2021 investments, including support of \$2.2 billion outlined in Budget 2021 towards growing a vibrant domestic life sciences sector, securing pandemic preparedness, and creating good high-skilled jobs for Canadians.

### 1. STRONG AND COORDINATED GOVERNANCE

Recent experience and international best practice underscores the need for coordinated priority-setting and decision-making. A dedicated and coordinated governance structure will enable aligned priority-setting, linked through strategic planning, decision-making, performance monitoring, and risk management, and will be directly shaped by internal and external experts from academia, industry, and public health. It will provide integrated leadership that spans multiple departments and agencies to take timely, strategic decisions, and to bring to bear resources across the suite of initiatives in order to ensure maximum strategic outcomes and impact of investments, including those made from Budget 2021 funds.

The central objective of this governance structure will be to ensure that investments are strategic, targeted

and, in critical areas like the research, infrastructure, industrial capacity building, and clinical trials funding, are driven towards the core mandate and mission of the Strategy.

With this in mind, the governance arrangement will advance the following:

Integrated decision-making and priority-setting to support Canada's pandemic preparedness and response efforts, with the ability to strategically and rapidly deploy resources and programs to detect, prevent and respond to adverse health scenarios through research, skills, and industrial development;

- the Strategy collectively aims to address the ecosystem's gaps and structural issues to make it more robust, agile, and timely so that Canada has the core competencies and capabilities to support a strong ecosystem that can pivot rapidly and effectively to pandemic planning and response;
- Canadian life sciences industry and scientific and research capacity that is well-positioned to rapidly understand and respond to health threats and to help Canada contribute in the greatest possible way to international and multilateral efforts to respond to outbreaks or global crises;

- A pipeline of skilled research and talent to support the Strategy's objectives, with mechanisms to align research excellence and ground-up science with strategic priorities as they arise;
- Common objectives and shared priority setting, alongside coordination between pandemic preparedness and industrial development and monitoring, and across federal, provincial and territorial governments with mechanisms for ongoing tracking of progress and results, and regular opportunities for re-calibration; and
  - Priorities and decisions informed by expert advice.

Canada's success in addressing the COVID-19 pandemic has been driven by relying on a deep bench of experts providing hands-on expertise and industry experience. This level of expertise and expert engagement will certainly continue to be at the heart of this strategy and activities moving forward.

Ultimately, a strong coordinated structure for biomanufacturing and life sciences will enable rapid decision-making informed by experts to maximize benefit to Canadians. This will mean more made in Canada vaccines, therapeutics and other life saving medicines.

## COVID-19 VACCINE TASK FORCE

**The COVID-19 Vaccine Task Force (VTF) is an external advisory body comprised of volunteers who are experts in fields such as immunology, vaccinology, vaccine development, biomanufacturing and commercialization. The COVID-19 Task Force was created to ensure that Canadians had access to a safe and effective vaccine against COVID-19 as quickly as possible, whether domestic or international. Since its inception, the VTF has provided advice in three core areas: 1) domestic vaccine candidates; 2) international vaccine candidates; and 3) biomanufacturing proposals (from both domestic and international firms).**

**In order to complete its work in the third area, a Joint Biomanufacturing Sub-committee (JBS) was stood up in June 2020. The JBS was comprised of members from the Vaccine Task Force and the Therapeutics Task Force. It was tasked with providing advice to the Government of Canada in three areas: 1) biomanufacturing projects proposed to the Government under the Strategic Innovation Fund; 2) an overall strategy to increase Canada's biomanufacturing capacity; and 3) other priority areas, including efforts to attract international vaccine candidates to manufacture some of their vaccines in Canada.**

**The graphic on the right highlights some of the achievements of the VTF and JBS to date:**



## VACCINE TASKFORCE/JOINT BIOMANUFACTURING ADVICE AND ACTION TO DATE (July 22, 2021)

77 VTF and JBS meetings

41 Advice letters to Ministers

232 \* Interviews with media from Aug. 5, 2020 to May 3, 2021

### MANDATE

### ADVICE TO MINISTERS

### GOVERNMENT ACTION TO DATE



#### DOMESTIC VACCINES

- Assessed SIF Vaccine proposals – **recommended 3 for SIF funding** (VBI, PNI and Medicago)
- Recommended vaccine proposals **to NRC for funding consideration**

- The Government of Canada announced an agreement with Medicago.
- SIF or IRAP funding announced for VBI, Medicago (including APA), PNI, Biodextris, IMV, Symvivo, Entos, Glycovax and Providence Therapeutics



#### INTERNATIONAL VACCINES

- Recommended the government pursue a **portfolio of international vaccine candidates**
- Supported **procurement negotiations** with considerations to ensure the safety and efficacy needs of Canadians are met
- Engaging in **science diplomacy** with global experts and members of other international Task Forces (UK, Australia, Singapore, NZ)

- Announcement of 6 agreements (Moderna, Pfizer/BioNtech, J&J/Janssen, Novavax, Sanofi/GSK, AstraZeneca)
- Government a partner in global solidarity efforts with COVAX and recommendations on exercising options
- Canadian procurement strategy informed by scientific and technical advice of Task Force



#### BIO-MANUFACTURING

- Assessed SIF Biomanufacturing proposals and recommended several.
- Recommended a series of **critical short-term investments** in domestic biomanufacturing for therapeutics and vaccines to respond to COVID-19
- Recommended measures to strengthen Canada's biomanufacturing industry for therapeutics and vaccines into the future

- Announcement of investments for Medicago, NRC Royalmount, PNI, Novocel, KABS and Resilience Biotechnologies Inc.
- Government purchased select critical material e.g., syringes, alcohol swabs and other supplies, fill and finish capacity, etc.
- Work currently being undertaken to bolster domestic biomanufacturing capacity

\*As of February 01, 2021



## **2. LAYING A SOLID FOUNDATION BY STRENGTHENING RESEARCH SYSTEMS AND THE TALENT PIPELINE**

Canada's leading post-secondary institutions and affiliated research hospitals anchor much of the country's bio-innovation ecosystem. For Canada to establish a resilient and robust domestic biomanufacturing sector, it must invest both upstream and downstream in its innovation supply chain. Canada's leading post-secondary institutions and their affiliated research hospitals anchor much of the bio-innovation ecosystem. Important upstream components are centred in post-secondary institutions, including laboratories, research and talent. To ensure that investments in new commercial biomanufacturing capacity are sustainable, they must be accompanied by expanded research and innovation capacity at Canada's universities and in the life-science ecosystems they support.

Academic researchers and institutions can support talent development, contribute to the pipeline of new technologies and support the translation of academic research into applications and commercial products. It is these institutions that produce the trained graduates needed by industry to run state-of-art laboratory and biomanufacturing facilities and to spin-off innovative start-up companies. The discoveries in academic laboratories become the advanced products

commercialized by companies that have the expertise and business sophistication to navigate the regulatory process and capacity for scale distribution.

Canada's scientists need research support, high-performance tools and innovative research spaces and laboratories to bring their ideas from discovery through development and commercialization. In many cases, their work requires specialized equipment in appropriate bio-containment facilities to ensure that infectious-disease research is conducted under safe conditions. Supporting surveillance, diagnostics, pre-clinical and clinical trials infrastructure, with flexible research infrastructure capacity, is critical to underpin Canada's biomanufacturing and life sciences ecosystem.

However, it is vitally important the investments in research and research infrastructure flowing from Budget 2021 be made with a clear view to advance and support Canada's more focused biomanufacturing and pandemic priorities. This means that the new research funding needs to be focused in areas of critical importance to pandemic readiness, for example, and to build up needed research competencies. Research infrastructure investments similarly need to be made to close existing gaps and to complement private-sector assets. These investments will be purpose-driven with the goal of advancing pandemic readiness.

To advance the Strategy, Budget 2021 announced significant investments in bio-innovation research, including:

1. \$500 million over four years, starting in 2021-22, for the **Canada Foundation for Innovation (CFI) for a new Bio-Science Research Infrastructure Fund**, to support the bio-science infrastructure needs of post-secondary institutions and research hospitals;
2. \$250 million over four years, starting in 2021-22, for the federal research granting councils to create a **new, Tri-Agency Biomedical Research Fund**;
3. \$45 million over three years, starting in 2022-23, to **Stem Cell Network (SCN) to support stem cell and regenerative medicine research**; and,
4. \$92 million over four years, starting in 2021-22, to **adMare BioInnovations (adMare) to support company creation, scale up, and training activities** in the life sciences sector.

A complementary talent and skills approach will also be developed to build up all components of the talent pipeline across the research to commercialization continuum. Building on sector-specific investments and leveraging other federally funded broad-based skills investments, this approach will coordinate efforts to ensure the complementary interventions meet the skills needs of the biomanufacturing and life

science sector, while also creating good highly skilled jobs for Canadians.

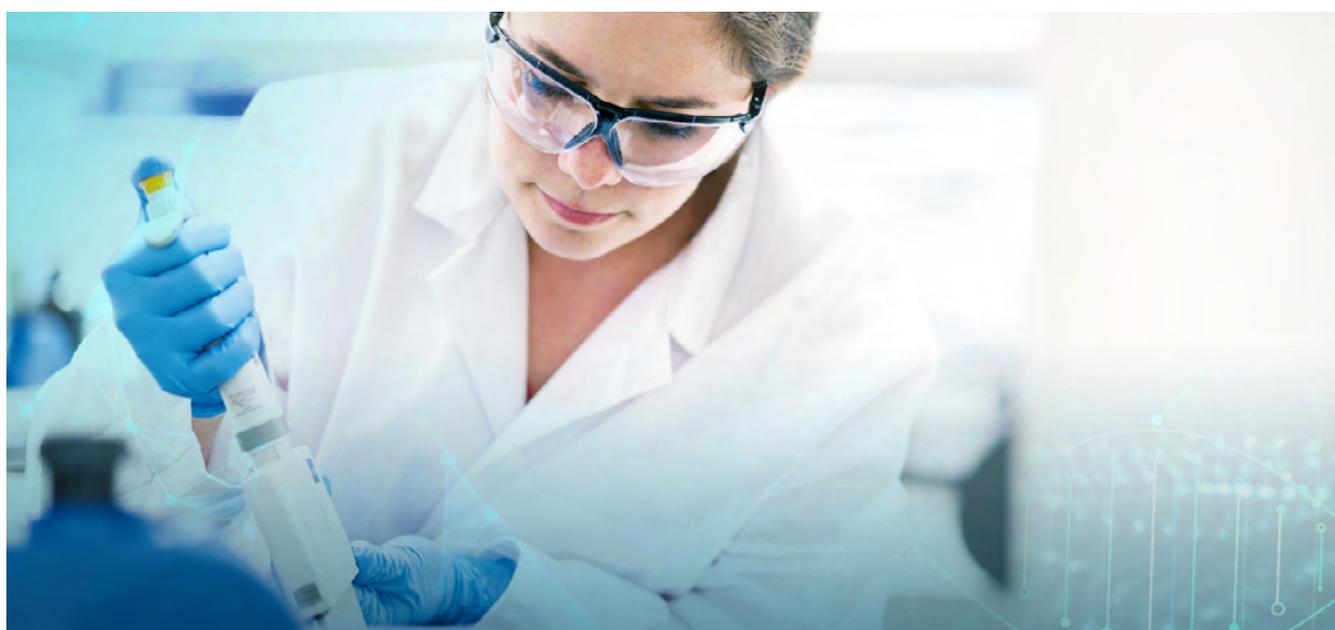
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**\$47M through Western Economic Diversification Canada, to the University of Saskatchewan's Vaccine and Infectious Disease Organization (VIDO) to accelerate development of its COVID-19 vaccine candidate and enhance its vaccine manufacturing facilities to the good manufacturing practices standards.**

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### **3. GROWING BUSINESSES BY DOUBLING DOWN ON EXISTING AND EMERGING AREAS OF STRENGTH**

New investments to address the remaining critical gaps in domestic capabilities and build on existing and emerging areas of strength in biomanufacturing and life sciences will ensure a leading sector that is able to capitalize on opportunities for economic growth and job creation, as well as contribute to greater domestic pandemic readiness. New investments and actions will build upon Canada's foundational research strengths in genomics, drug delivery, artificial intelligence and high-tech manufacturing to take drug development and biomanufacturing in Canada to the next level.



To this end, Budget 2021 includes a significant commitment to continuing to grow the life sciences sector. This includes **\$1 billion on a cash basis over seven years, starting in 2021-22, of support through the Strategic Innovation Fund (SIF), which will be targeted toward promising domestic life sciences and biomanufacturing firms.** The Strategy's next phase of industrial investment and action will include investments flowing from this SIF funding, as well as an investment in VIDO, which were provided in Budget 2021. In parallel, the **Venture Capital Catalyst Initiative also received \$50 million** to invest in the sector. Canada's next phase investment strategy in the sector will focus on **three initial priority areas:**

**1)** Address **remaining biomanufacturing gaps** highlighted by the pandemic – for example, continuing to establish capabilities across novel vaccine technology areas, based on capacity requirement modeling to meet future pandemic requirements and grow the sector.

As Canada considers next steps to strengthen the domestic biomanufacturing sector as a critical component to improving future pandemic readiness, investment decisions will be driven by a series of guiding principles, including:

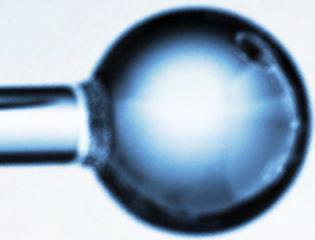
- ensuring capabilities across strategic and varied vaccine platforms, fill-finish capacity and emerging technology areas;
- establishing a minimum capacity threshold across each priority platform that will be sufficient to support mobilization to quickly vaccinate the Canadian population in pandemics, while also being attractive from a manufacturing partnership perspective;
- ensuring project commercial viability and a business plan for sustainable growth; and
- prioritizing flexible platforms that are able to quickly pivot to help meet Canada's pandemic requirements.



**2)** Build strength in **emerging technology areas** with high potential to solve current and future health challenges – focus on precision medicines, including cell and gene therapies, RNA, and viral vectors, and monoclonal antibodies. Leverage strengths, such as artificial intelligence (AI), to drive health innovation.

The platforms identified are important because they hold potential treatments for cancers and rare diseases through more accurate targeting of diseases. This reiterates the need for investments in the facilities, supply chains and talent so Canada stays at the forefront of medical technology.





**3)** Augment supply chains in areas of strategic importance – assure a level of national security and reduce Canada’s reliance on foreign imports, improve the ability to attract new investments, advance technology innovation and build strategic alliances with international trade partners.

Canada’s natural resources and industrial manufacturing base are assets to establish a unique advantage and secure domestic supply. To grow Canada’s capabilities in these areas and build more robust supply chains, a four-point framework will be applied:

- **lead innovation and clean growth through investments** in R&D and technology development to advance technology innovation, climate objectives and economic sustainability;
- **attract new investment to support growth and firm development** to enable firms, technologies and infrastructure to scale up capabilities and capacity;
- **establish targets and actions to realize national security** to reduce Canada’s reliance on foreign imports at times of health crises and build a resilient life sciences sector to spur growth; and
- **build strategic alliances and diversify international trade partners** to address critical gaps, achieve economic sustainability and enhance opportunities for innovation across the supply chain.



#### 4. BUILDING PUBLIC CAPACITY

While strategic investments have been made to support the growth of innovative Canadian life sciences companies, the Government has also worked to expand key public assets to support pandemic preparedness. The Government will continue to advance the work to operationalize the National Research Council of Canada’s (NRC) Biologics Manufacturing Center (BMC) which will serve as a foundational element for a proposed broader system of federal capabilities and assets to respond to future pandemics or other health priorities, supporting Canada’s national biomanufacturing security and sovereignty. The NRC’s Human Health Therapeutics (HHT) research centre and Clinical Trial Manufacturing Facility (CTMF) will also play an integral role in this broader system, supporting activities across the biopharmaceutical development process.

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**Up to \$199.16M to [Resilience Biotechnologies Inc. \(RBI\)](#) (Mississauga, ON) to increase its manufacturing and fill-finish capacity for vaccines and therapeutics, including novel technology like mRNA.**

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On the biopharmaceutical development continuum, the NRC’s HHT research centre is a key linchpin between the core discovery and R&D work at universities, and later stage commercialization and industrial application. Investment in innovation at this facility will complement broader efforts to build up Canada’s pandemic readiness by supporting advancement of vaccine and therapeutics candidates along the continuum from research through to production. A specific focus of HHT competence is in the production platforms for cell-based therapies, including those used for protein sub-unit and virus-like particle vaccines, which are likely to remain among key technology platforms going forward.

When complete, the NRC CTMF will produce small-batch clinical trial material from cell-based biologics production, including platforms such as viral vector, protein subunit, virus-like particles, and other recombinant proteins. It will be an R&D and product development bridge in the domestic production of vaccine and other biologics material for first-in-human clinical trials, as well as a technology transfer hub to complete verification runs and optimize GMP manufacturing processes prior to producing material at larger scale.

Further to a mandate provided in the Fall 2020 Economic Statement, ISED continues to conduct the market due diligence required for the Government to consider additional strategic investments that build upon the aforementioned NRC standing capacity and further Canada's readiness to:

- respond to pandemics and other infectious-disease threats;
- increase domestic vaccine and therapeutics manufacturing capabilities in an emergency;
- advance and promote the biotech workforce by providing workforce development programs;
- provide integrated training facilities for business, research, and production specialists; and
- provide laboratory space and equipment, including AI-based infrastructure; and preclinical and clinical trial assets, including small to large-batch manufacturing capacity.

## 5. ENABLING INNOVATION BY ENSURING WORLD CLASS REGULATION

To take full advantage of new investments through the Strategy, Canada must continue to ensure it has a best-in-class regulatory system, world-class expertise, and infrastructure for clinical trials through sustained improvements of Canada's regulatory system and the creation of a new Clinical Trial Fund (CTF). These enabling elements are fundamental supports that form the backbone of health innovations, which will attract the best companies and researchers to set up and do their work here in Canada.

### ENHANCING CANADA'S REGULATORY SYSTEM FOR HEALTH PRODUCTS

Health Canada's regulatory system responded rapidly to the COVID-19 pandemic to review and authorize critical medical devices, personal protective equipment, diagnostic tests, vaccines, and therapeutics. The department put in place emergency temporary legislative, regulatory, and policy measures to facilitate clinical trials and ensure product access in time of crisis, engaged with international regulatory partners to ensure alignment, and exercised exceptional collaboration and communication with companies interested in importing and manufacturing products to support Canada's COVID-19 response. These efforts supported all companies developing COVID-19 products, whether based in Canada or globally.

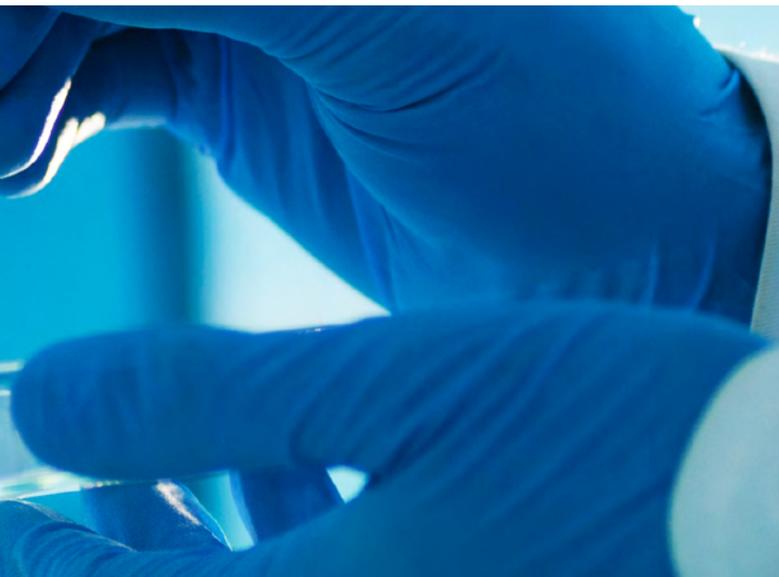
The emergency measures put in place aim to make the



regulatory system more agile, so that it can mobilize quickly to allow access to health products needed to diagnose, treat and slow the spread of the virus without compromising safety, efficacy and quality.

Specifically, the regulatory response focused on: actively collaborating with domestic and international stakeholders and partners; establishing emergency regulatory pathways and measures to prioritize and expedite the processes for regulatory review and establishment licensing; setting up dedicated teams of multi-disciplinary experts to conduct rolling reviews for vaccines and drugs, where multiple teams work simultaneously and in real time to review information from manufacturers as it comes; enhanced post-market surveillance of safety and effectiveness; and, strengthened communications and transparency activities.

As Health Canada moves forward beyond its pandemic response, it is taking the lessons learned from these emergency measures and applying them to its [Regulatory Innovation Agenda \(RIA\)](#). Through this agenda, Health Canada is advancing an ambitious plan to make its regulations and market access more agile and responsive to innovation, building directly on the Government's regulatory review of the health and biosciences sector and the recommendations of the [Health and Biosciences Economic Strategy Table \(HBEST\)](#).



## Health and Biosciences Economic Strategy Table (HBEST)

**Canada ranks fourth in global health and biosciences hubs, according to measures identified by the U.K. BioIndustry Association. That puts Canada behind the U.S., U.K. and Germany. To double the sector and break into the top three, we'll need strategic action to strengthen every facet of the sector. The 2018 report from the Health and Biosciences Economic Strategy Table (HBEST) called for Canada to become a destination for investment and talent, growing our health and biosciences firms to support a more sustainable health system while advancing Canada's prosperity. Since the publication of this report, the Government of Canada has introduced a range of measures towards this goal. Budget 2019 provided funding to Health Canada and Justice Canada over five years for policy and regulatory development related to HBEST objectives of making Canada's health and biosciences sector a globally competitive hub of innovation through more agile and streamlined regulatory approaches that support access to products needed by Canadians.**

**The Biomanufacturing Strategy is an important step towards achieving the HBEST vision of a vibrant ecosystem that will unleash the full potential of the sector.**

**The HBEST perspective was also an integral part of the work of the Industry Strategy Council, established in June 2020 to assess the scope and depth of COVID-19's impact on industries and to understand specific sectoral pressures. Moving forward, HBEST will build on the Council's insights on the current state of key sectors and potential recommendations for the future.**



## **BUILDING A BEST-IN CLASS CLINICAL TRIALS INFRASTRUCTURE**

Canada has many competitive advantages when it comes to conducting clinical trials. The country is globally recognized for the quality and expertise of its research clinicians and its ability to conduct clinical research in complex therapeutic areas with a diverse population.

To support research teams and infrastructure across the country to conduct clinical trials that will test new vaccines and therapies, treatments, and interventions to prevent, detect, treat or manage various diseases or medical conditions, Budget 2021 provided \$250 million, over three years, to Canadian Institute of Health Research (CIHR) to establish a new Clinical Trial Fund (CTF). As part of a suite of complementary investments along the bio-innovation pipeline, the funding will contribute to addressing the current gap between discovery and life-saving vaccines and therapeutics in Canada by moving innovations in health from discovery to application, thereby improving the health of Canadians.

Through the CTF, CIHR will support a mix of research investments in people (highly-qualified personnel), projects (funding for specific trials to be conducted), and platforms (clinical trial coordination networks). This fund will support research and researchers across the country to conduct the full spectrum of clinical trials that will develop and test new drugs, treatments, and public health and health system interventions to prevent, detect, treat or manage various diseases or medical conditions. This investment will ultimately strengthen research capacity in Canada and accelerate the development of new scientifically proven treatments and vaccines, leading to improved health outcomes for Canadians. The CTF will bridge a critical gap related to clinical

trials by ensuring that the next generation of researchers, including clinician scientists, are trained and then supported in order to better position them within the greater biomanufacturing ecosystem. Guided by a robust national and international consultative process to develop a long-term pan-Canadian Clinical Research strategy, CIHR will work in parallel to develop and implement three complementary components/programs to carry out the proposed initiative through investments in projects, people, and platforms:

- 1. Clinical Trials funding opportunity to support the full spectrum of clinical trials research**, including dedicated support for domestic and multi-jurisdictional trials with international linkages;
- 2. Training and mentorship program** to develop highly qualified personnel in trials research who can direct the conception, design and implementation of controlled trials, using a broad range of supports (including but not limited to health research training platforms, etc.); and
- 3. A clinical trials network** to provide coordination and collaboration infrastructure for clinical trials activities across the country, building on existing initiatives supported by CIHR.

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**Up to \$18.2M in [Precision NanoSystems \(Vancouver, BC\)](#) to help advance a COVID-19 vaccine candidate through preclinical studies and clinical trials and an additional \$25.1M to support a \$50.2M project to expand Canada's capabilities in the production of ribonucleic acid (RNA) vaccines and future genetic medicines.**

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## Looking to the Future

To ensure Canada is well-positioned to respond to future health emergencies and to promote the long-term growth of Canada's life sciences sector, it is imperative for the Government to support the development of novel and disruptive health technologies through clinical development to commercialization and manufacturing through a long-term Strategy. Efforts to enhance pandemic preparedness and biosecurity require an ecosystem approach, including considerations beyond human health, such as animal vaccines, given the close interplay between human population health and zoonotic diseases.

The Strategy presented above would effectively align consideration of investments across clinical trials, research and research infrastructure, skills initiatives, and support for biomanufacturing and life science firms, followed by harmonized tracking and reporting on results. Central to this work is the coordinated governance function described as part of the Strategy, which will drive shared priorities and ensure alignment across investments.

We believe that this strategy, consisting of five pillars, will significantly strengthen Canada's biomanufacturing and life sciences sector, improve economic growth and ensure pandemic readiness for generations to come.

Together, the Strategy's five pillars will achieve meaningful results for Canadians. It will do that by ensuring collaboration between the private sector and the government, laying the foundation for a strengthened talent pipeline, growing Canada's biomanufacturing and life sciences sector to create more good paying jobs, building out public assets such as the National Research Council's Biomanufacturing Centre and leveraging it for success, and ensuring best in class regulation and a world class clinical trials system to make sure that Canada is a strong and competitive place for life science and biomanufacturing companies to do business for years to come.

