

**Written Submission for the Pre-Budget Consultations in
Advance of the 2021 Budget**

Submitted by Hoffmann-La Roche Ltd.

Summary of Recommendations

Recommendation #1

That the federal government revive the Health & Biosciences Economic Strategy in cooperation with life science organizations, the pharmaceutical industry and patients. This will bring stakeholders across Canada together to grow the health and biosciences sector through innovation and collaboration.

Recommendation #2

That the federal government leverage the portion of the Safe Restart Agreement dedicated to data management to empower the Canadian Data Governance Standardization Collaborative to partner with provinces, territories, and healthcare system stakeholders to invest in the adoption of common standards for collecting and formatting health data and the development of frameworks for health data governance, privacy, and security. This will ensure that Canada is building a learning health system to enable optimal decision making.

Recommendation #3

That the federal government invest \$20 million over two years in the development of frameworks for using real-world data and real-world evidence in regulatory decision-making, funding decision-making, and ongoing formulary maintenance. When incidence is low and unmet medical need is high, real-world data and evidence may be an essential element of a comprehensive evidence package and can accelerate patient access to transformative health solutions.

Recommendation #4

That the federal government redirects funds currently dedicated to government funding programs and private equity investments allocated to emerging health innovations and entrepreneurship programs across the country to a new co-developed public-private Health Innovation Fund (HIF). The HIF will bridge the current gap between health innovators and their customers, thereby aiding the adoption of innovation in clinical practice.

Recommendation #5

That the federal government prioritizes and targets direct investments in federal, provincial and territorial (FPT) public health and laboratory infrastructure to provide increased diagnostic readiness in anticipation of potential future COVID-19 waves and/or other pandemics. This will ensure a consistent, coordinated and collaborative approach at a national level to mitigate risks as the economic restart is undertaken.

Background: Roche Canada

Roche Canada is a subsidiary of Swiss-based life sciences company F. Hoffmann-La Roche, which is a forward-looking and highly innovative company with a longstanding commitment to investing in Canada. As one of the largest innovative global biopharmaceutical companies and the leading oncology company operating in Canada, Roche is a proud contributor to Canadian research and development, and is committed to advancing science and improving health outcomes for Canadians.

With the Roche Pharmaceuticals division headquartered in Mississauga, Ontario and both Roche Diagnostics and Roche Diabetes Care in Laval, Quebec, we employ over 1,200 people across Canada, positioning us as a key contributor to Canada's life sciences ecosystem.

Roche Canada has directly contributed over \$1 billion to Canada's GDP over the past 5 years. In 2019, our total expenditure on research and development alone totaled approximately \$284 million in Canada, including over \$57 million in clinical research, with approximately 174 Roche-sponsored clinical trials currently underway in Canada.

Roche Canada is committed to an effective and sustainable healthcare system that delivers healthcare innovations to all Canadians. Creating an environment that ensures the development and adoption of innovation ensures the optimal health of Canadians as well as the strength of the life sciences sector, which is critical to relaunching the economy in the wake of COVID-19.

In this submission, Roche Canada has made five recommendations that will drive the development of:

- An evidence-based regulatory and policy environment built on a learning health system that allows the healthcare system to harness data and digital technologies and grow the economy,
- A sustainable healthcare system that increases access to innovative medicines for patients across the country, helping to keep Canadians healthy and in the workforce as long as possible, and
- A thriving life sciences sector that drives innovation and economic growth in Canada.

The implementation of these recommendations can be a key component of Canada's post-pandemic health system and economic recovery.

Recommendations: Background and Rationale

Recommendation #1

That the federal government revive the Health & Biosciences Economic Strategy in cooperation with life science organizations, the pharmaceutical industry and patients. This will bring stakeholders across Canada together to grow the health and biosciences sector through innovation and collaboration.

Roche supported the ambitious objectives of the Government of Canada's Health and Bioscience Economic Strategy Table (HBEST) report released in 2019, which includes the following targets for 2025:

- Double health and biosciences exports to \$26 billion.
- Double the number of health and bioscience firms to 1800.
- Double the number of health and bioscience high-growth firms to 80.

However, there has not been significant movement to realize these ambitions. The recent announcement of the Industry Strategy Council is a good start but we encourage the Government - with input from industry, patients and other sector stakeholders - to revitalize the HBEST work to identify specific and measurable next steps.

As we endeavour to double the size of the health and biosciences sector and become a top-three global hub by 2025, we need a coordinated yet flexible approach that leverages the work already underway in many provinces. The pharmaceutical industry, and companies like Roche, are the foundation of any national life sciences sector.

It is also important to acknowledge the need to rethink some of the recommendations in the context of pandemic planning and building our capacity for the next potential crisis.

Recommendation #2

That the federal government leverage the portion of the Safe Restart Agreement dedicated to data management to empower the Canadian Data Governance Standardization Collaborative to partner with provinces, territories, and healthcare system stakeholders to invest in the adoption of common standards for collecting and formatting health data and the development of frameworks for health data governance, privacy, and security. This will ensure that Canada is building a learning health system to enable optimal decision making.

Healthcare system stakeholders know that Canada has significant opportunities to generate greater value from health data and information to (1) support evidence-based decision making, (2) support research on population health and system performance, and (3) improve health outcomes for Canadians, while maintaining their privacy. This value generation will also be critical to achieving the federal government's goal of doubling the size of Canada's health and biosciences sector by 2025.

A strong data ecosystem is also a key success factor in the response to COVID-19; the pandemic has exposed significant limitations in the ability to collect, access, integrate, share and analyze high-quality data efficiently and rapidly to inform optimal decision making. It has also magnified concerns that data cannot be shared easily to gain insights between jurisdictions as each province uses different data collection methodologies, standards and policies.

Common and agreed upon standards for collecting and formatting health data and frameworks for health data governance, privacy, and security are foundational components for a modern digital health strategy, as outlined by HBEST. Government investment in a common data infrastructure has the ability to expedite, accelerate and optimize decision making in healthcare.

Recommendation #3

That the federal government invest \$20 million over 2 years in the development of frameworks for using real-world data and real-world evidence in regulatory decision-making, funding decision-making, and ongoing formulary maintenance. When incidence is low and unmet medical need is high, real-world data and evidence may be an essential element of a comprehensive evidence package and can accelerate patient access to transformative health solutions.

Canada can advance personalized healthcare and improve health outcomes for Canadians through the use of data from the real world in decision-making. Real-world data (RWD) is data routinely collected in electronic medical records, product and disease registries, and even personal fitness trackers. Insights from RWD, which are known as real-world evidence (RWE), can paint a more robust picture of an individual or population's health journey over time than clinical trial data alone, as RWD/E is taken from the real world where external variables exist.

RWD is a significantly untapped resource for health innovation, and should become a part of the Health Technology Assessment reimbursement process for medicines: this would allow for the reconsideration of reimbursement decisions over time when relevant new evidence become available.

While there is currently work being done to incorporate RWD/E across the drug and biotechnology lifecycle, there are no shared standards for RWD/E across Canada. Establishing these standards would allow decision-makers to have more robust data to inform decisions, advance personalized healthcare, and improve resource allocation; it can also help promote growth in the life sciences sector.

Recommendation #4

That the federal government redirects funds currently dedicated to government funding programs and private equity investments allocated to emerging health innovations and entrepreneurship programs across the country to a new co-

developed public-private Health Innovation Fund (HIF). The HIF will bridge the current gap between health innovators and their customers, thereby aiding the adoption of innovation in clinical practice.

In Canada, \$2.3 billion dollars (through government funding programs and private equity investments) have been allocated to emerging innovations and entrepreneurship programs across the country. However, technologies showing promising results in the pilot phase still suffer from an inability to scale and achieve widespread adoption in clinical practice. Thus, it has been challenging to realize the economic and social returns of these investments, and the growth of Canadian start-ups has been stunted.

To address these challenges, Roche Canada proposes a new model to develop a fertile ground for open innovation within the Canadian healthcare systems. The principal components of this fertile ground include:

1. A collaborative development environment where emerging innovators are partnered with their primary customer base (e.g. pharmaceutical companies, health system stakeholders, etc.) to co-develop solutions that directly impact the challenges of patients and the healthcare system.
2. Rapid adoption of new health innovations into the Canadian healthcare systems and an open path to international markets.
3. A fully sustainable investment source that continues to grow as a result of the successes of each emerging innovator.

At the heart of this model is an investment fund we call the Health Innovation Fund. Investments are made into emerging innovators from this fund and the return on these investments are used to fund both future investments as well as the healthcare system in order to adopt the new health technologies being developed for use in clinical practice. This virtuous cycle is ensured through a supportive ecosystem that focuses not only on the start-up phase but also on the scale-out phase.

Recommendation #5

That the federal government prioritizes and targets direct investments in federal, provincial and territorial (FPT) public health and laboratory infrastructure to provide increased diagnostic readiness in anticipation of potential future COVID-19 waves and/or other pandemics. This will ensure a consistent, coordinated and collaborative approach at a national level to mitigate risks as the economic restart is undertaken.

Laboratories have been considered the “silent champion” of healthcare, influencing over 60% of clinical decisions, while accounting for only about 2-4% of total healthcare spending. Relative to other disciplines, healthcare systems globally and in Canada have underinvested in laboratory infrastructure despite high “value for money”. In this space, reasonable investments yield large returns for healthcare systems and for patients while helping shift the focus from cure to prevention.

The COVID-19 pandemic has illustrated the core need and importance of robust laboratory infrastructure. Recognizing that the value of diagnostics lies in “knowing”, Canada needs to continue to invest and commit to building testing infrastructure and capacity, which will contribute detection and diagnostic information that will support confident and effective back-to-work and economic restart plans.

The efforts should also go beyond direct COVID-19 related investments and towards enabling technologies or solutions that are allowing health systems to adapt to the necessity of finding new ways of working e.g. increased “point-of-care” testing which allows for tests to be performed “closer to home”. By making these investments, Canada would reap the benefits far beyond current pandemic response, as the value of laboratory testing highlighted through the crisis should be leveraged at scale across health and disease states.