



# Open Drug Discovery of Anti-Virals Critical for Canada's Pandemic Strategy

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Canada needs a proactive innovation strategy to address current COVID-19 needs and to anticipate future pandemics. Canada and governments around the world made a tactical error in failing to build public capacity to develop novel anti-virals, preferring instead to hand off drug discovery and development to the private sector. In contrast, open science can support mission-oriented research and development (R&D), as well as commercialization. Open science shares skills and resources across sectors; avoids duplication; and provides the basis for rapid and effective validation due to full transparency. It is a strategy that can adjust quickly to reflect changing incentives and priorities, because it does not rely on any one actor or sector. While eschewing patents, it can ensure high quality drugs, low pricing and access through existing regulatory mechanisms. Open science practices and partnerships decrease transaction costs, increase diversity of actors, reduce overall costs, open new, higher-risk/higher-impact approaches to research and provide entrepreneurs freedom to operate and freedom to innovate. We argue that it is time to re-open science, not only in its now restricted arena of fundamental research, but throughout clinical translation. Our model and attendant recommendations map onto a strategy to accelerate discovery of novel broad-spectrum anti-viral drugs and clinical trials of those drugs, from first-in-human safety-focused trials to late stage trials for efficacy. The goal is to ensure low-cost and rapid access, globally, and to ensure that Canadians do not pay a premium for drugs developed from Canadian science.

### **Recommendations**

1. In addition to the Public Health Agency of Canada (PHAC) and financial support to individuals and firms, Canada ought to build a third pillar to its pandemic responsiveness: a flexible, open and stable non-profit, virtual drug discovery entity that coordinates and invests in a pipeline for the proactive development of anti-viral drugs (and possibly vaccines) for viruses with pandemic potential.
2. The independent, non-profit should be provided with long-term, stable funding to insulate it from day-to-day politics. The non-profit will inevitably invest in anti-virals and other interventions that fail, as failure is part of innovation. Tolerance for failure requires an arms-length entity (Kenney and Patton, 2009).
3. The non-profit and Canada's pandemic innovation preparedness ought to be embedded in an international, open, effort to coordinate R&D of new products, such as the international environments in which the SGC and DNDi operate. The broader the collaborative network, the more efficient the discovery efforts will be. By participating in R&D international efforts, Canada increases its ability to access and to afford interventions developed elsewhere.

4. To establish an equilibrium between open and proprietary R&D for drug discovery, funding councils and other funding bodies ought to establish specific open science calls, with significant funding, for those research projects that agree, upfront, to the following: 1) open and free availability to all data on an ongoing basis during the research endeavour; 2) publication in a journal complying with FAIR principles; 3) no patenting on any research results, even if achieved through collaboration with outside partners. Such funding should include support for data standardization, entry, etc.
5. Governments, granting councils and philanthropies ought to establish funding to collect data on and analyse open science partnerships both in Canada and internationally to assess their impact, costs and barriers to use. This will require data infrastructure, such as Canada's New Digital Research Infrastructure Organization, which should provide data storage and collection for open data, develop and maintain open data storage standards and requirements, establish rules and norms around data use (including privacy and security), and provide financial support for data entry.
6. All government or quasi-government grants or contracts supporting pandemic-related research ought to impose requirement of no patenting of research results and rapid dissemination of data and results in accordance with FAIR principles.
7. Philanthropies ought to prioritize pandemic-related research projects that are open and eschew patents.
8. Canada ought to take a leadership role in advancing open science partnerships that comply with best practices recommended by international governmental bodies, such as the World Intellectual Property Office (WIPO), the World Health Organization (WHO), and the Organization for Economic Co-operation and Development (OECD).
9. Canada ought to lead the world in open science policymaking, for example, by supporting Health Canada (and/or other regulators) to implement regulatory mechanisms that encourage open science drug development. Regulations might extend data protection periods for authorized products where the sponsor has made its preclinical and clinical trial data openly accessible to the research community, has not filed restrictive patents, and has agreed to make its product broadly accessible at affordable pricing.