Terms of Reference for the Vaccine Surveillance Reference Group

#### 1. Preamble

Following meetings convened by the President of Public Health Agency of Canada (PHAC) on 16 November and 8 December 2020, approval by Health Canada of the first vaccine for COVID-19 on 9 December 2020, and plans for immediate vaccine distribution, it was agreed there was an urgent need to establish a Vaccine Surveillance Reference Group (VSRG).

The VSRG, with leadership by the National Advisory Committee on Immunization (NACI) and the Canadian Immunization Research Network (CIRN), was created by PHAC to coordinate the identification of data gaps and generation of these data to inform public health decision-making.

The VSRG receives administrative support from the COVID-19 Immunity Task Force (CITF), an entity housed at McGill University that is funded by and that is working in collaboration with PHAC to sponsor projects that measure the scope of novel coronavirus infection and immunity in Canada and provide information needed to manage the COVID-19 pandemic. The CITF is generating this vital information through strategic investments in rapid and reliable research drawing on experts from academic, public health and clinical settings across Canada and working closely with provincial and territorial public health officials.

#### 2. Mandate

Reporting to the President of PHAC, the VSRG will advance support for accelerated and effective implementation of vaccine surveillance plans across Canada in coordination with existing federal, provincial, territorial institutions and with attention to all priority groups including Indigenous persons, to monitor the safety and effectiveness of COVID-19 vaccines.

## 3. Key Responsibilities

The VSRG will:

• Curate a list of priority issues and questions related to COVID-19 vaccine safety and effectiveness emerging from <u>questions tabled by the NACI on November 13, 2020</u>.

- Inventory existing institutional resources and networks that have the capacity and mandate to monitor vaccine safety and effectiveness and support them to increase the scope and scale of their activities required to monitor more comprehensively and quickly the roll-out of COVID-19 vaccines.
- Mandate two working groups: i) VSRG Working Group on Vaccine Safety; and ii) VSRG Working Group on Vaccine Effectiveness. These working groups will comprise technical leads from key institutions/networks engaged in vaccine safety/effectiveness, respectively (TOR and membership information provided below).
- Assist the working groups to develop plans to address critical vaccine safety/effectiveness issues/questions that are fit-for-purpose i.e., appropriately comprehensive, accurate, timely, and at scale. The working groups will agree on a division of labor to avoid unnecessary duplication. The working group plans will be presented to the VSRG for feedback with an expectation that discrete vaccines safety and effectiveness proposals will be forthcoming from the working groups.
- Review proposals for vaccine safety/effectiveness emerging from the working groups and forward these to the CITF Executive Committee for approval for financing from PHAC.

VSRG Working Group on Vaccine Safety and Vaccine Effectiveness will:

- Work with the key questions identified by the National Advisory Committee on Immunization (NACI) related to vaccine surveillance covering both safety (AEFIs) and vaccine effectiveness.
- Identify standards related to study design, measures, tests, etc., drawing from national and international sources that are important in ensuring good quality vaccine surveillance.
- Draw on the inventory of existing vaccine surveillance efforts in Canada to identify how well they address key questions.
  - For questions that have established vaccine surveillance partners that are ready to go, or those that are already moving, working groups will work with their leaders to identify opportunities for improving their quality and coverage that can be translated into proposals for further support.
  - For questions that are not currently being addressed by existing vaccine surveillance partners, working groups will identify

pragmatic strategies, e.g., retrofitting existing studies through focussed funding calls, for generating vaccine surveillance proposals that would have sufficient scale and scope to address the question(s) in close collaboration with provincial and territorial health authorities.

## 4. Scope of Decision-Making Authority of the VSRG

The VSRG will oversee reviews of proposals for vaccine safety/effectiveness studies emerging from the two working groups, or from funding calls, and make recommendations for support of proposals to the CITF Executive Committee (EC). The CITF EC will function as an arm's-length audit/finance committee to ensure that due diligence has been done both scientifically and from a value-formoney perspective. The CITF EC will then recommend studies for approval by PHAC for financing.

## 5. Appointment and Terms

The VSRG is led by Co-Chairs who are recognized experts in vaccine surveillance in Canada. The VSRG will be in place at least until March 31, 2022. VSRG members commit to participate through this period. They may request to the VSRG Co-Chairs to be released from their responsibilities and they may be invited by the VSRG Co-Chairs to renew their membership should the VSRG and CITF extend beyond March 31, 2022.

## 6. Membership

Members will be chosen based on a mix of expertise, their willingness to devote the extra time involved, and attention to the Canadian mosaic. Members are expected to approach issues with a strategic lens, weighing the CITFs public interest duties and fiscal responsibilities, and paying due attention to any and all conflicts of interest, not least their own. They are expected to be creative problem solvers, be prepared to respectfully challenge assumptions, be strategic thinkers, demonstrate fiscal responsibility, and commit to the highest integrity. Members are expected to have the desire and capacity to represent the best interests of Canadians as a whole.

Members of the VSRG and ad hoc guests and/or observers with specialized expertise may be invited to participate at the discretion of the VSRG Co-Chairs.

See Annex A to see the list of current VSRG and VSRG Working Group members.

## 7. Meetings

The VSRG will meet on a regular basis. Meeting dates will be scheduled in advance to ensure that all members are aware of upcoming meetings within a reasonable timeframe. Additional meetings may be held as needed, at the discretion of the VSRG Co-Chairs.

Meetings will normally be held online via videoconferencing platforms such as Zoom and members may attend by connecting via Internet or calling in.

## 8. Quorum

A simple majority of the VSRG members constitutes quorum for meetings.

#### 9. Conflict of Interest

All VSRG members will comply with the <u>CITF Conflict of Interest Guidelines</u> posted on the CITF website.

The CITF and VSRG work with a modified version of the Tri-Agency definition of a Conflict of Interest (COI). A COI should be interpreted broadly to include any circumstances that could reasonably be perceived as giving rise to COI situations and can be actual, potential, or perceived in nature.

VSRG members must proactively complete the CITF COI disclosure form that will be publicly available on the CITF website. They must disclose any relevant external interests and influences to the VSRG Co-Chairs when a meeting is in session. VSRG members should seek the advice of the Executive Committee Co-

Chairs or the Executive Director of the CITF Secretariat if they are in doubt about their own COI.

## 10. Voting Procedure

VSRG decisions will be made by consensus with notation of any recusals from discussion and decision made by VSRG members. If consensus is not forthcoming within a reasonable timeframe, the meeting Chair may proceed with a vote on the question. For the vote to be valid, a majority of voting members must cast a vote. Each voting member has one (1) vote. In the case of a tied vote, the meeting Chair shall be entitled to a second or deciding vote.

## 11. Documentation of Meetings and Decisions

A written record of the decisions arising and any recusals at each VSRG meeting will be duly documented in official meeting notes, which will be circulated to the members at the following meeting for approval.

The VSRG will be supported by the CITF Secretariat in terms of facilitating all logistics related to convening meetings, preparing agendas and notes for the record, as well as any other necessary communications.

The CITF Secretariat will also support the convening of meetings, meeting agendas, and notes for the record of the two working groups on vaccine safety and vaccine effectiveness.

#### 12. Remuneration

All members of the VSRG serve without remuneration for their time. Should the VSRG or its members be required to travel to attend meetings then reasonable expenses related to travel and accommodation will be reimbursed by the CITF Secretariat, as per PHAC guidelines.

# 13. Terms of Reference Review History

The draft Terms of Reference for the VSRG were reviewed and revised at the first meeting of the VSRG on January 5, 2021 and adopted as final at its meeting on March 8, 2021.

# Annex A: Vaccine Surveillance Reference Group and Working Group Membership Lists (As of February 19, 2021)

#### Vaccine Surveillance Reference Group Members:

Scott Halperin (Co-Chair), Professor, Division of Infectious Diseases, IWK Health Centre, Dalhousie University; Principal Investigator, Canadian Immunization Research Network.

Caroline Quach Thanh (Co-Chair), Professor, Microbiology and Immunology, CHU Ste-Justine, Université de Montréal; Chair, National Advisory Committee on Immunization.

Evan Adams (Ex-Officio), Deputy Chief Medical Officer of Public Health, Indigenous Services Canada.

Shelley Deeks, Surveillance Medical Officer of Health, Nova Scotia Public Health; Vice-Chair, National Advisory Committee on Immunization.

Kim Elmslie (Ex-Officio), Assistant Deputy Minister, Health Promotion and Chronic Disease Prevention Branch, Public Health Agency of Canada.

Timothy Evans, Professor, Inaugural Director and Associate Dean of the School of Population and Global Health (SPGH) in the Faculty of Medicine and Associate Vice-Principal (Global Policy and Innovation), McGill University; Executive Director, Covid-19 Immunity TaskForce.

Catherine Hankins, Professor of Public and Population Health, Faculty of Medicine, McGill University; Co-Chair, Covid-19 Immunity Task Force.

Mel Krajden, Professor Pathology and Laboratory Medicine, University of British Columbia; Medical Director of the British Columbia Centre for Disease Control Public Health Laboratory.

Jeff Kwong (Ex-Officio; Chair, VSRG Working Group on Vaccine Effectiveness), Professor, Dalla Lana School of Public Health, University of Toronto; Senior Scientist, ICES; Scientist, Public Health Ontario.

David Naylor, Professor of Medicine and President Emeritus, University of Toronto; Co-Chair, Covid-19 Immunity Task Force.

Kelly Robinson (Ex-Officio), Director General, Health Canada.

Karina Top (Ex-Officio; Chair, VSRG Working Group on Vaccine Safety)

Associate Professor, Division of Infectious Diseases, Dalhousie University; Co-Investigator, Canadian National Vaccine Safety Network.

#### Vaccine Surveillance Reference Group, Effectiveness Working Group Members:

Jeff Kwong (Chair), Professor, Dalla Lana School of Public Health, University of Toronto; Senior Scientist, ICES; Scientist, Public Health Ontario.

Shelly Bolotin, Scientist, Public Health Ontario.

Nicholas Brousseau Associate clinical professor, Institut national de santé publique du Québec, Associate Researcher, CHU de Québec - Université de Laval.

Shelly McNeil, Clinical Research Scholar, Dalhousie University; Chief, Division of Infectious Diseases, Nova Scotia Health Authority.

Gina Ogilvie, Professor, School of Population and Public Health, University of British Columbia; Assistant Director, Women's Health Research Institute; Senior Public Health Scientist, British Columbia Centre for Disease Control.

Manish Sadarangani, Director, Vaccine Evaluation Center, British Columbia Children's Hospital Research Institute and Assistant Professor, Division of Infectious Diseases, Department of Pediatrics, University of British Columbia.

Danuta Skowronski, Clinical Professor, School of Population & Public Health, University of British Columbia; Clinical Professor and physician epidemiologist, British Columbia Centre for Disease Control; Principal Investigator, Canadian Sentinel Practitioner Surveillance Network.

#### Vaccine Surveillance Reference Group, Safety Working Group Members:

Karina Top (Chair), Associate Professor, Division of Infectious Diseases, Dalhousie University; Co- Investigator, Canadian National Vaccine Safety Network.

Julie Bettinger, Associate Professor, Division of Infectious Diseases, Vaccine Evaluation Center, Department of Pediatrics, University of British Columbia.

Deshayne Fell, Associate Professor, School of Epidemiology and Public Health, University of Ottawa, Children's Hospital of Eastern Ontario Research Institute.

James Kellner, Professor and Head, Department of Pediatrics, University of Calgary; Chair, Alberta Advisory Committee on Immunization.

Monika Naus, Professor, School of Population and Public Health, University of British Columbia; Medical Director, Communicable Diseases & Immunization Service, British Columbia Centre for Disease Control.

Sarah Wilson, Medical Epidemiologist Communicable Diseases, Emergency Preparedness and Response, Public Health Ontario.