Real-World Evidence Steering Committee Terms of Reference

1.0 Mandate

The Real-World Evidence (RWE) Steering Committee is a collaborative initiative responsible for supporting the development of a pan-Canadian strategic framework (infrastructure and process) for the use of RWE in regulatory and reimbursement decision-making for drug products by publicly funded programs in Canada.

2.0 Roles and Responsibilities

The roles and responsibilities of the RWE Steering Committee are to:

- guide and support the development of a strategic framework for the optimal integration of RWE into regulatory and health technology assessment (HTA) programs and health care decision-making
- provide guidance on the development of learning projects about RWE for health care decision-making
- provide guidance on the development of collaborative processes between Health Canada and other organizations involved in health care decision-making that facilitate the optimal integration of RWE
- provide oversight to the RWE Steering Committee working groups (described in the Meetings section).

3.0 Authority

The RWE Steering Committee shall report to the CADTH President and CEO.

4.0 Membership

The member organizations, comprised of pan-Canadian organizations, patient and industry associations, the federal government, and L'Institut national d'excellence en santé et en services sociaux (INESSS), shall appoint representatives to the RWE Steering Committee. The member organizations are:

- CADTH
- Health Canada
- Pan-Canadian Pharmaceutical Alliance (pCPA)
- INESSS
- Canadian Organization of Rare Disorders
- Innovative Medicines Canada – Biotech
- Canadian Institute for Health Information (CIHI)

- Statistics Canada
- Canadian Institutes of Health Research (CIHR)
- Health Data Research Network

A CADTH representative shall chair, and Health Canada shall vice-chair, the RWE Steering Committee.

4.1 Appointment Process

Member organizations may appoint a designated representative.

5.0 Working Groups

The RWE Steering Committee may establish working groups on specific topics. Approval by a majority of RWE Steering Committee members is required to establish a working group.

Working groups will report to the RWE Steering Committee through the working group chair(s) or co-chairs.

A brief statement of any work to be undertaken by a working group must be developed and approved by the RWE Steering Committee. The statement of work should include:

- a purpose statement specifying the task and the rationale for the task
- a list of recommended working group members (task group members are selected based on technical expertise and their ability to make significant and constructive contributions to the topic under review; working group members will come from both inside and outside the RWE Steering Committee membership)
- clear deliverables
- a completion date for the deliverable(s).

The working group co-chairs will be appointed by CADTH and will provide regular reports on progress at each RWE Steering Committee meeting and provide a final report no later than the first meeting after the specified completion date.

RWE working groups and their membership shall be approved by the RWE Steering Committee.

Each working group must have a patient representative.

Initially, the committee will assign members to the following 3 working groups: RWE Guidance Working Group, RWE Oncology Working Group, and RWE Common Drug Working Group.

5.1 RWE Guidance Working Group

The mandate of the RWE Guidance Working Group is to provide advice and support on the selection, adaptation, or development of guidance and tools for the use of RWE for regulatory approval and HTA processes and the planning and execution of learning projects.

5.2 RWE Oncology Working Group

The mandate of the RWE Oncology Working Group is to provide advice and support on the optimal use of RWE for health care decision-making concerning oncology therapeutics in Canada and the planning and execution of learning projects.

5.3 RWE Non-Oncology Working Group

The mandate of the RWE Non-Oncology Working Group is to provide advice and support on the optimal use of RWE for health care decision-making concerning non-oncology therapeutics in Canada and the planning and execution of learning projects.

6.0 Meetings

The RWE Steering Committee shall meet a minimum of 4 times a year. The RWE Steering Committee will normally meet by videoconference.

RWE working groups shall establish their own meeting schedules, as required.

6.1 Attendance

Members of the RWE Steering Committee and the working groups shall make their best effort to attend all respective meetings.

However, an RWE Steering Committee member who is unable to attend a meeting in person may send the designated alternate from their organization to participate in the meeting.

6.2 Quorum

A minimum of two-thirds (≥ 66%) of members of the RWE Steering Committee or the RWE working groups shall constitute quorum.

6.3 Agenda

Meeting agendas will be prepared by CADTH in consultation with members of the RWE Steering Committee or RWE working group chairs or co-chairs.

6.4 Decision-Making

Decisions of the RWE Steering Committee and of the working groups shall ordinarily be decided by a consensus of the members present at the meeting. Should consensus not be reached, the chair shall refer the question to be decided by a majority vote of all RWE Steering Committee members.

6.5 Meeting Records

CADTH staff keep a record of meetings of the RWE Steering Committee and RWE working groups. A copy of the action list from each agenda item will be provided to each respective member.

A written summary of the RWE Steering Committee meetings will be publicly posted on the CADTH website within 60 days of the meeting.

6.6 Attendees

In addition to its member organizations and observers invited in accordance with section 6.7, only the following persons shall be entitled to attend RWE Steering Committee meetings:

- Specialist experts (as subsequently noted)
- CADTH Staff
- Health Canada Staff

Specialist experts may be invited to attend committee meetings to provide their expertise, as required. Specialist experts are thought leaders and may be drawn from a variety of fields relating to the life cycle of pharmaceutical products through their clinical activities, HTAs, academic or commercial research, and/or experience in health policy, health care administration, or other health-related work. Specialist experts include patients, health care providers, academics, ethicists, payers, or health policy decision-makers. The number of specialist experts will be determined based on the project.

6.7 Observers

If a member is absent, a designated observer from the same organization shall be entitled to receive notice of meetings and meeting materials, and attend meetings of the RWE Steering Committee, but shall not have the right to vote at these meetings.

Additional representatives from member organizations may observe meetings at the invitation of the Chair.

The RWE Steering Committee shall have the right to exclude observers from any meeting held in camera, either in whole or in part.

7.0 Code of Conduct

All members of the committee shall comply with the CADTH code of conduct.

8.0 Conflict of Interest

All members of the committee shall comply with the CADTH conflict of interest policy. Conflicts of interest shall be declared at the start of each meeting.

9.0 Secretariat Support

Secretariat support for the RWE Steering Committee and its working groups shall be provided by CADTH staff.

10.0 Amendment to Terms of Reference

These terms of reference may be amended at any time, at the discretion of the CADTH President and CEO.