CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pCODR Nomination/Application Information Package

- Oncologist pERC Member
- Clinical and Economic Guidance Panel Members

Date Updated: May 2, 2016

Contents

Nomination/Application Fact Sheet

Deciding whether or not to let your name stand as a nominee for a role with the **pan-Canadian Oncology Drug Review (pCODR)** is an important decision. The following information may help.

Which positions are being recruited?
pCODR is primarily recruiting one (1) Oncologist to participate as a member of the pCODR Expert Review Committee (pERC).

as well as both Clinical and Economic Guidance Panel members on an ongoing basis.

Who is needed for the pCODR Expert Review Committee?
pCODR is currently recruiting one (1) Oncologist. pERC's role is to assess the clinical evidence (from the Clinical Guidance Panel) and economic evidence (from the Economic Guidance Panel) of new cancer drugs, and to use this information to make recommendations to the provinces and territories to guide their drug funding decisions.

Who is needed for the Clinical Guidance Panel?
pCODR continuously recruits oncologists to sit on the 11 panels which are structured around specific tumour types. The tumour-based panels are: breast, endocrine, gastrointestinal, genitourinary, head and neck, leukemia, lymphoma and myeloma, lung, melanoma, neuro-oncology, sarcoma.

Who is needed for the Economic Guidance Panels?
pCODR continuously recruits economists with knowledge of pharmacoeconomics. These panels are established as each cancer drug is submitted. Their role is to assess the economic evidence provided by the submitter.

When is the term expected to start and finish?
The term is expected to start by mid-September 2016 and continue for a period of two to three years.

What are the time requirements?
Generally, members of pERC spend up to two days per month, including participating in monthly pERC meetings. While the time required will depend somewhat on the drug under review, members of the Clinical and Economic Review panels spend on average 5 – 15 hours per month on their work.

Is travel required?
pERC meetings are held in Toronto while the Clinical and Economic Guidance Panels conduct their work online and via conference calls (with occasional in-person meetings as required).

How long are membership terms and is it possible to extend?
Appointments to pERC and the Guidance Panels are for a period of two to three years, with the possibility to extend an appointment for a second term of two to three years.

What is the remuneration?
All members are paid $1,000 per day, pro-rated to an hourly rate based on 7.25 hours per day.

What is the deadline for applications?
Nominations for pERC will be accepted until 5:00 p.m. EDT on **June 6, 2016**.
Nominations for Clinical and Economic Guidance Panel members are accepted on an ongoing basis.

For more information, please consult the pCODR Nomination Package or email info@pcodr.ca.

Introduction and Purpose/Overview

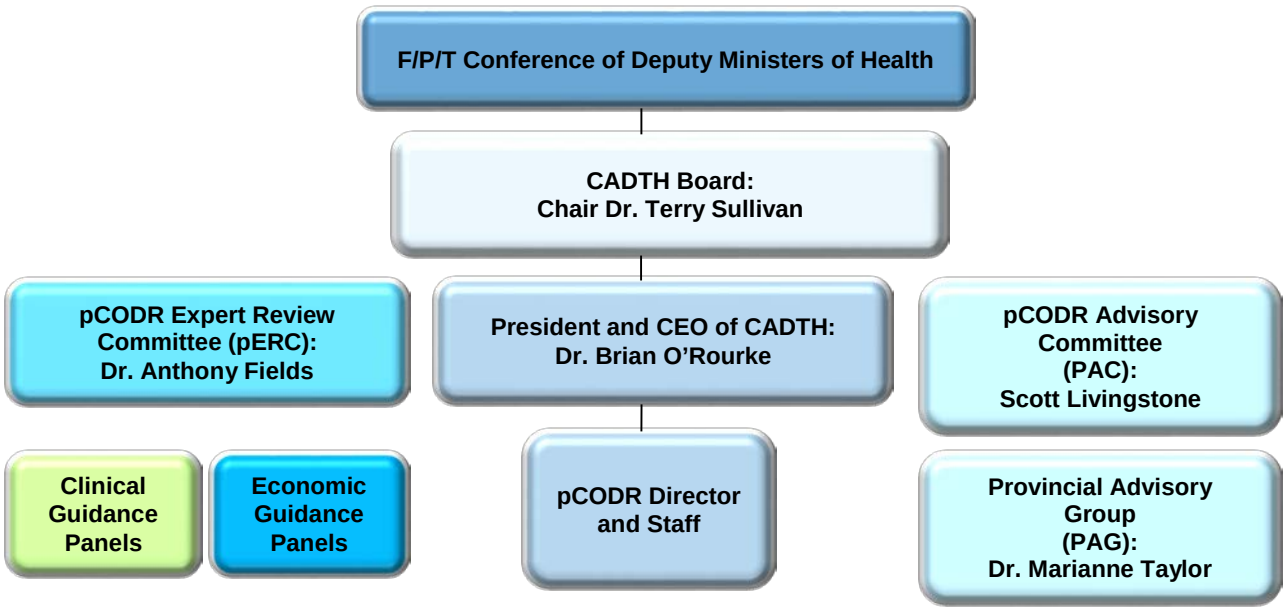
The purpose of this document is to provide a brief overview of the pCODR and to outline the criteria and process to become a member of the pCODR Expert Review Committee (pERC) or a member of the clinical or economic guidance panels. Involvement in the pCODR process is an exciting and high-profile opportunity to influence cancer care delivered to Canadians.

The pan-Canadian Oncology Drug Review (pCODR) is an evidence-based, cancer drug review process. The pCODR process is designed to bring consistency and clarity to the assessment of cancer drugs by reviewing clinical evidence, cost-effectiveness, and patient perspectives, and using this information to make recommendations to Canada's provinces and territories (except Quebec) in guiding their drug funding decisions.

Under the pCODR process, detailed assessments are conducted by a pan-Canadian expert review committee, with opportunities for input by patients, the pharmaceutical industry, clinician-based tumour groups, and the provincial advisory group.

In April 2014, pCODR was transferred to the Canadian Agency for Drugs and Technologies in Health (CADTH) to consolidate policy direction across Canada's drug review programs and to strengthen the pCODR governance structure in order to ensure its long-term viability and sustainability.

Governance Structures



F/P/T Conference of Deputy Ministers of Health

Deputy Ministers of Health for participating federal, provincial, and territorial governments have overall accountability for and provide direction to the CADTH Board.

CADTH Board

CADTH's 13-member Board of Directors is composed of an independent chair; a regional distribution of jurisdictional federal, provincial, and territorial representatives; and a number of non-jurisdictional representatives from health authorities, academia, and the general public. Directors are elected by the Members of the Corporation who are the Deputy Ministers of Health for participating federal, provincial, and territorial governments.

The Board has overall responsibility for administering the affairs of the Corporation and providing the strategic direction to guide CADTH's success as the Canadian "go to" provider of evidence and advice on the use of drugs and other health technologies.

President and CEO of CADTH

The role of the President and CEO of CADTH is to ensure that CADTH upholds its mandate to provide timely, relevant, evidence-based information and support to health care decision-makers, while following the strategic direction set by its various jurisdictional stakeholders.

pCODR Advisory Committee (PAC)

The PAC provides strategic advice for pCODR's ongoing development and management and provides advice on cancer-specific issues, to ensure the pCODR meets the needs of the Provincial/Territorial (P/T) governments, cancer agencies and federal programs. The PAC is comprised of six senior level P/T Ministry of Health representatives (as per the funding blocks; one from British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and one from Atlantic Canada), four senior level cancer agency representatives (one from British Columbia, one from the Prairie Provinces, one from Ontario, and one from Atlantic Canada), and one senior level representative from the federal programs.

pCODR Expert Review Committee (pERC)

The role of the pERC is to assess the clinical evidence and cost effectiveness of new cancer drugs, and to use this information to make recommendations to the provinces, territories and federal programs to guide their drug funding decisions.

Provincial Advisory Group (PAG)

The PAG provides advice primarily with an operational focus and also from time to time, on strategic and policy direction, to ensure recommendations are useful to drug funding decision makers. The PAG consists of appointed representatives from each of the provincial Ministries of Health, provincial cancer care agencies, and federal programs participating in the pCODR.

Clinical Guidance Panels

The pCODR Clinical Guidance Panels consist of oncologists from across Canada and are structured around specific tumour types. There are 11 tumour-based panels. Each of the Clinical Guidance Panels will contribute to the pCODR process by working with the Methods Leads to generate a high quality systematic review. In addition, each Clinical Guidance Panel will generate a clinical guidance document. Although the clinical guidance document will follow a general template, it will be the responsibility of the Clinical Guidance Panels to determine the breadth and depth of the information included in the guidance document based on the submission under consideration. These elements of the clinical review will be used by the pERC in making its recommendations.

Economic Guidance Panels

The pCODR Economic Guidance Panels will be established on a per-cancer drug submission basis to generate pCODR economic review deliverables. The mandate of the Economic Guidance Panels is to assess the economic evidence provided by the submitter for each cancer drug submission filed with the pCODR. The economic assessment report will be used by the pERC in making its recommendations.

pCODR Director & Staff

The Director is responsible for the leadership, development, and delivery of the pCODR. The pCODR staff is responsible for the administrative duties associated with the pCODR process.

Nomination/Application Process Summary

Provincial and territorial Ministries of Health, provincial cancer agencies, federal programs and professional associations are being asked to forward this nomination package to potential candidates. Nominations may be submitted on the candidate's behalf, or candidates may submit an application. Candidates will be screened based on qualifications according to the selection criteria. Candidates who are selected for the pERC or roster for one of the panels will be contacted by pCODR staff.

Steps for Nominations:

1. Review roles & responsibilities
2. Review selection criteria
3. Identify potential candidates and send them the information they need to apply or after obtaining consent, submit a cover letter with CV and references on the candidate's behalf by the deadline

Steps for Application:

1. Review roles & responsibilities
2. Decide to apply
3. Submit cover letter with CV and references by the deadline

Application Checklist:

1. Cover letter
2. CV
3. References (at least 2 – reference letters are preferred)
4. If you are submitting a cover letter with CV and references on the candidates behalf, your name, full affiliation information and nominator's signature should be included

	Oncologist pERC Member	Clinical Guidance Panels	Economic Guidance Panels
Call for nominations	May 2, 2016	Ongoing	Ongoing
Nomination/application deadline	June 6, 2016	Ongoing	Ongoing
Selection complete	July 31, 2016	Ongoing	Ongoing
Observe meeting	Sept. 15, 2016	Ongoing	Ongoing
Orientation complete	October 1, 2016	Ongoing	Ongoing
Participate in first meeting	October 20, 2016	Ongoing	Ongoing
Remuneration	$1,000 per day, pro-rated to an hourly rate based on 7.25 hours/day	$1,000 per day, pro-rated to an hourly rate based on 7.25 hours/day	$1,000 per day, pro-rated to an hourly rate based on 7.25/day
Time Commitment	Up to 2 days per month, including participating in up to 12 pERC meetings per year	Variable depending on the drugs under review. Involvement in each submission estimated to take on average 5-10 hours per month, for 3-5 months	Variable depending on the drugs under review. Involvement in each submission estimated to take on average 10-15 hours per month, for 3-5 months

Questions may be e-mailed to info@pcodr.ca

pERC Members

Roles and Responsibilities

- to establish, maintain, and apply standards and methodologies to evaluate the therapeutic value and cost effectiveness of cancer drug products for active disease management;
- to consider submissions made by manufacturers, and/or tumour groups, and all related clinical reviews and economic reviews prepared and submitted in accordance with the pCODR's standards;
- to evaluate submissions and pCODR Advisory Committee (PAC) or Provincial Advisory Group (PAG) requests for advice in terms of therapeutic advantages and disadvantages, cost-effectiveness, and patient perspective on impact of the cancer drug product under review, compared to accepted or existing therapies;
- to recommend, after consideration of a submission, to the provincial/territorial Ministries of Health and provincial cancer agencies, those new cancer drug products for active disease management, which should be considered for funding and advise the provincial/territorial Ministries of Health and provincial cancer agencies, of the conditions under which such products may be funded;
- to provide reasons for every recommendation made to the provincial/territorial Ministries of Health and provincial cancer agencies, for public dissemination;
- to provide advice and, if appropriate, a change to a previously issued recommendation, in response to every request for advice by the PAC or PAG;

Qualifications for all pERC members, including Chair

- currently not employed by any pharmaceutical or related companies;
- able and willing to comply with Conflict of Interest and Confidentiality requirements of the pCODR;
- availability/commitment of time to participate fully in the pERC;
- knowledge of, experience with, and understanding of, issues related to cancer and its management (diagnosis, treatment and care);

- knowledge and understanding of pCODR's mandate and the mandate of the committee, including their role in the broader cancer system as well as the healthcare system;
- willingness to work within the defined processes and parameters for reviewing cancer agents, including evidence-based medicine, cost-effectiveness and patient values;
- experience in committee and/or community work;
- ability to communicate effectively;
- ability to acquire the information and adopt the skills needed to successfully negotiate important issues; strong listening skills;
- ability to act with integrity and independence of specific interests;
- ability to relate to and respect a diverse range of values and beliefs;
- ability to gain respect and credibility within a diverse range of stakeholders and the wider public;
- ability to work constructively as a member of a team

Additional qualifications for professional members of pERC

- a professional degree from a recognized institution in at least one of the following disciplines: medicine, pharmacy, pharmacology or health economics;
- be in active practice and/or research in either the community, hospital and/or academic setting;
- should have an understanding of the use and delivery of oncology drugs within the Canadian context.

On appointment

Remuneration

- pERC members receive $1000 per day, which is pro-rated on a hourly basis, using 7.25 hours/day

- Any reasonable travel costs for pERC or other pCODR meetings, in accordance with the CADTH Travel Policy.

Time commitment

- Up to 2 days per month. pERC members are required to travel for up to once-monthly pERC meetings, which are expected to last a full day in duration.

- Once monthly pERC meetings are held in Toronto, Ontario.

Term of appointment

- The appointment is for a period of 2 to 3 years.

- The appointment can be renewable at the end of the appointment period, subject to satisfactory evaluation. There should be no expectation of automatic reappointment.

- The successful candidates will be required to subscribe to the pCODR Code of Conduct.

- Candidates should note the requirement to declare any potential conflict of interest that might arise in the course of pCODR business.

How to apply/How to Nominate?

To apply for this position or nominate an individual you must submit a cover letter outlining how you/the nominee meets the criteria and include your/the nominee's CV and references and return this by **June 6, 2016.**

Please send your application/nomination to: info@pcodr.ca

Once we receive your application/nomination

Candidates will be screened and selected based on qualifications. You will be contacted by pCODR staff if you are selected for the committee.

Clinical Guidance Panel Members

Roles and Responsibilities

- provide input and advice on a "as requested basis", to the Methods Leads, as the generators of the systematic reviews, and on the direction from pERC or pCODR staff. The Methods Leads will generate systematic reviews. The Clinical Guidance Panel, through it's lead, will provide input as required in the preparation of the systematic reviews of new cancer agents or those with new indications, which will be submitted to the pERC as part of the deliberative process in making a recommendation regarding funding for these drugs by the Canadian health care system. The clinical input includes but is not limited to providing guidance on key search variables, identification of issues related to management of the specific tumour type, identification of new approaches or literature related to the management of the tumour type, reviewing the systematic review, etc;

- through the Clinical Guidance Panel Lead, the panel will generate a Clinical Guidance document, which will be submitted to the pERC to be used as part of the deliberative process to make final funding recommendations. The expert clinical input includes but is not limited current issues in the management of the specific tumour type, new approaches or literature related to the management of the specific tumour type, place of therapy discussion, issues around targeted molecular testing, other factors impacting clinical applications of drug treatment for a specific tumour type, etc;

- communicate and consult with other experts as required regarding clinical issues raised in the preparation of the systematic review or clinical guidance documents.

Qualifications

- A Fellow of the Royal College of Physicians and Surgeons of Canada in a specialty or subspecialty discipline (medical oncology, hematology-oncology, radiation oncology; or a surgeon/gynecologist with subspecialty training in an oncology discipline, if there is no Royal College exam for that discipline).

- A minimum of 5 years in oncology practice (e.g. the provincial; College register as an oncologist).

- A recognized expert in the specific tumour site (e.g. breast, colorectal, etc.) as evidenced by a Provincial Cancer Agency, a National or International cancer organization or similar body.

- Must have experience in guideline development (provincially, nationally or internationally) and experience in systematic review and/or a track record of leadership. Participation in clinical trials and peer-reviewed publications in the specific tumour site is highly desirable.

- Must have a willingness to be a part of a collaborative team in the development of timely, high quality guidance documents.

- Candidates may be currently employed or in practice at an academic setting, government setting or hospital or community practice.

On appointment

Remuneration

- Clinical Guidance panel members will receive $1000 per day, to be pro-rated on an hourly basis, using 7.25 hours/day. Travel is unlikely to be required for Clinical Guidance Panel members.

Time commitment

- Variable, depending on the drug submissions under consideration. Involvement with each submission estimated to take on average 5-10 hours per month, for 3-5 months.

Term of appointment

- The term of appointment for all Panel members shall be 2 to 3 years. The term may be renewed at the discretion of the pCODR Executive Director, in consultation with pERC.

- The successful candidates will be required to subscribe to the pCODR Code of Conduct.

- Candidates should note the requirement to declare any potential conflict of interest that might arise in the course of pCODR business.

How to Nominate?

To nominate an individual you must submit a cover letter outlining how the nominee meets the criteria, with the nominee's CV and references. Nominations/applications are being accepted on an ongoing basis.

Please send your nomination to: info@pcodr.ca

Once we receive your application/nomination

Candidates will be screened and selected based on qualifications. Candidates selected for the roster of clinical experts will be contacted by pCODR staff.

Economic Guidance Panel Members

Roles and Responsibilities

- assess the economic evidence presented by a submitter for a cancer drug submission to pCODR on direction from pCODR staff;
- to communicate as required with Clinical Guidance Panels, Methods Leads, or Provincial Advisory Group (through the pCODR staff) to ensure that the relevant clinical and utilization information (e.g., clinical outcomes, comparators, etc) are used in the submitted economic evaluation;
- to prepare a guidance report for use by the pERC in making its recommendations. This report will include but is not limited to: qualitative and quantitative assessments of the submitted economic evidence, specific suggestions to improve the quality or applicability of the submitted economic evidence, specific suggestions for national collaboration to improve the quality of economic evidence that can be used to further support decision making.

Qualifications

- Advanced degree (e.g. Masters) in health economics, clinical epidemiology, or equivalent work experience;
- academic affiliation or public agency economics unit;
- experience with applied Health Technology Assessment;
- good written and oral communication skills;
- willingness to work as part of a collaborative team in the development of time-sensitive, high-quality guidance documents.

In addition to the above, the following would be considered desirable but not mandatory:

- experience in economic evaluations of cancer interventions (treatment, prevention or screening);
- experience in policy relevant research collaborations with government decision makers;
- have a clinical (medical or pharmacy) background.

On appointment

Remuneration

- Economic Guidance Panel members will receive $1000 per day, pro-rated on an hourly basis, using 7.25 hours/day. Travel is unlikely to be required for Economic Guidance Panel members.

Time commitment

- Variable, depending on the drug submissions under consideration. Involvement with each submission estimated to take on average up to 10-15 hours per month, for 3-5 months.

Term of appointment

- The term of appointment for all Panel members shall be 2 to 3 years. The term may be renewed at the discretion of the pCODR Executive Director, in consultation with pERC.

- The successful candidates will be required to subscribe to the pCODR Code of Conduct.

- Candidates should note the requirement to declare any potential conflict of interest that might arise in the course of pCODR business.

How to Nominate?

To nominate an individual you must submit a cover letter outlining how the nominee meets the criteria, with the nominee's CV and references**.** Nominations/applications are being accepted on an ongoing basis.

Please send your completed application to: info@pcodr.ca

Once we receive your application/nomination

Candidates will be screened and selected based on qualifications. Candidates selected for the roster of economic experts will be contacted by pCODR staff.

Appendix 1 – pCODR Overview

What is pCODR?

The role of the pan-Canadian Oncology Drug Review (pCODR) is to assess the clinical evidence and cost effectiveness of cancer drugs, and to use this information to make recommendations to the provinces and territories in guiding their drug funding decisions. The pCODR evolved into a permanent process from the interim Joint Oncology Drug Review (JODR), which itself demonstrated that a national collaborative platform for assessing new cancer drugs provides significant value to cancer care decision makers.

What is the value of pCODR?

The increasing use and introduction of new, complex cancer drugs require rigorous review of the clinical effectiveness and cost effectiveness of these therapies, to best inform public funding decisions. The pCODR process, with its detailed assessment of evidence conducted by an expert review committee, and opportunity for input by patients, the pharmaceutical industry and clinician-based tumour groups, reduces duplication of this effort by each individual province and territory and ensures reviews are done in a timely manner.

The expert oncology drug review committee called pERC consists of practicing cancer specialists (oncologists), a non-cancer physician (non-oncologist), pharmacologists, health economists, pharmacists and patient representatives. At least one of these committee members should also have expertise in health ethics.

Benefits of pCODR

The creation of pCODR brings consistency and clarity to the cancer drug review process, allowing for greater understanding by all stakeholders, while ensuring individual provinces and territories can make funding decisions informed by evidence that has been carefully evaluated by experts.

Ensuring that scarce health-care resources are used to fund the most effective cancer drugs is critical to supporting quality cancer care across Canada, which benefits all Canadians.

Appendix 2 – pCODR Guiding Principles

Governance
A review process with governance structures which are fair, objective, transparent and accountable to patients, payers and the public.

Health System Focus
Cancer treatment drugs are evaluated within a review process and decision making framework that are consistent with those used for drugs for other diseases.

Representation
A review process that is multidisciplinary, cross-jurisdictional and collaborative in nature with appropriate input from key stakeholders and linked to other key national initiatives.

Excellence
A review process that reflects an ongoing commitment to excellence through incorporation of best practices in a spirit of continuous quality improvement.

Evidence-based
A review process with capacity for rigorous and consistent evidence-based clinical and economic reviews to support evidence-based decision-making.

Ethical Framework
A review process that includes an ethical framework.

Efficient and Effective
A review process that is cost-efficient, effective and streamlined (i.e. reduced duplication) to support timely decision-making.

Evaluation
A review process with capacity for data capture and ongoing evaluation (decision monitoring/ performance measurement) to support continuous process improvements. In addition, capacity for health outcomes and economic impact analysis to support decision-making and planning.