Frequently Asked Questions: New Pilot Initiative to Increase Opportunities for Clinician Input and Feedback in CADTH pan-Canadian Oncology Drug Review Process

1. When will the new pilot initiative to increase opportunity for clinician input and feedback under the pCODR process come into effect?

This initiative will allow for expanded clinician participation in the pCODR process, providing value-added information on local issues and insight into areas of unmet need. This input will be incorporated into the pCODR process in a formal and meaningful way. This pilot initiative will be in effect for new pending pCODR submissions announced in **February 2016** and onward.

2. How will CADTH evaluate the pilot initiative?

CADTH intends to evaluate this pilot initiative after 25 cancer drug submissions with clinician input have been received, or sooner as may be appropriate, and will consult with stakeholders on any significant changes to the pCODR process.

3. Is registration required for a clinician to make a submission to the pCODR program?

Yes. Similar to other eligible pCODR review participants (e.g., patient advocacy groups, individual patients and caregivers), clinicians are required to register in order to submit their input. Clinicians are encouraged to visit the CADTH website at https://www.cadth.ca/pcodr/registration to learn more about the registration process and to register in well in advance to ensure their eligibility to provide input and feedback on a pCODR submission, and to receive notification of upcoming submissions.

4. What are the eligibility criteria for a clinician to register with the pCODR program?

Clinicians must meet *all* of the following key criteria to be eligible to register with the pCODR program:

- you are an actively practising physician
- you are a member of a provincial cancer agency or similar body or a national cancer organization *and*
- you submit a declaration of conflict of interest.

5. Why do I need to submit a declaration of conflict of interest and what are the requirements?

The principles of transparency and disclosure are essential to ensure the highest ethical standards and to maintain the integrity of the research undertaken by and/or sponsored by the pCODR program at CADTH. By disclosing to CADTH any and all relevant personal, occupational, and financial connections or interests, participants in pCODR activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of pCODR processes.

There are two steps to the conflict of interest declaration:

Step 1: Registration
All clinicians who register with pCODR will be required to indicate if they have been employed or engaged by a pharmaceutical manufacturer or a government or government agency within the past two years.

Step 2: Providing input and/or feedback on a pCODR submission
As part of the clinician input process, **clinicians will be required to complete the pCODR Conflict of Interest Declarations Form** and to declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. This form requests details regarding the nature of financial support provided to the clinician (e.g., payments, grants, holdings) and the estimated monetary value of these supports over the past two years. Details of the nature of supports received will be posted on the CADTH website; however, monetary values will not be disclosed.

Conflict of interest declaration is requested for transparency — it does not negate or preclude the use of clinician input.

6. How do I submit clinician input to pCODR?

The pilot process for registered clinicians to submit their input is similar to the requirements set for other eligible participants (e.g., patient advocacy groups, individual patients and caregivers).

The registered clinician must use the *pCODR Registered Clinician Input on a Drug Review* template.

In completing the input template, the registered clinician is required to:

- identify himself or herself
- indicate if the clinician has experience with the drug under review
- where applicable, indicate if it is a joint clinician submission, and list the names of the other registered clinicians, their titles, and their specialties
  and
- complete the pCODR Conflict of Interest Declarations Form, and confirm if any assistance was received in preparing the submission.

Registered clinicians should complete those sections of the template where they have substantive comments and should not feel obligated to complete every section, if particular sections do not apply. Please note that comments may be attributed to a specific individual clinician and that registered clinicians who submit input will be identified as contributors to the specific input. CADTH's pCODR program maintains the discretion to remove any information that may be out of scope of the review.

7. Will joint input and feedback from registered clinicians be accepted?

Yes, CADTH strongly encourages collaboration among registered clinicians, and their input and feedback for a specific drug or indication can be submitted jointly. When providing input, the lead registered clinician must indicate in the *pCODR Registered Clinician Input on a Drug Review* template if the input is a joint clinician submission, and must list the names of the other registered clinicians, their titles, and their specialties. All registered clinicians must submit a declaration of conflict of interests, as is required by all review participants.

8. What are the timelines for a registered clinician to make an input submission?

Similar to other eligible participants' input timelines, the specific deadline for registered clinician input is posted on the details page of each drug submission of the CADTH website. Registered clinicians will have

10 business days after pCODR receives a drug submission to submit their input. However, pCODR will strive to notify registered clinicians when confirmation of a pending drug review is received from a potential submitter (about one month in advance), so that registered clinicians have as much notice as possible about a pending cancer drug review.

Registered clinicians must submit their input by the posted deadline date (within 10 business days of pCODR receiving the submission) in order for pCODR to make use of the information to develop the review plan (i.e., protocol) — a critical step that takes place early in the review. Any input from registered clinicians submitted after the posted deadline date will not be accepted.

9. Is a registered clinician eligible to provide feedback on a pCODR Expert Review Committee (pERC) Initial Recommendation?

Yes; however, **only those registered clinicians who provided input early in the process** for use in the preparation of the guidance reports will be eligible to provide feedback on the pERC Initial Recommendation for pERC reconsideration purposes. Registered clinicians must use the *pCODR Registered Clinician Feedback on a pERC Initial Recommendation* template. Any feedback from registered clinicians made after the posted deadline date will not be accepted. This is similar in approach to other eligible participants.

10. Who should I contact if I have any questions about this new pilot initiative and/or the process?

You are encouraged to contact pCODR directly to obtain further guidance. Please contact us at info@pcodr.ca.