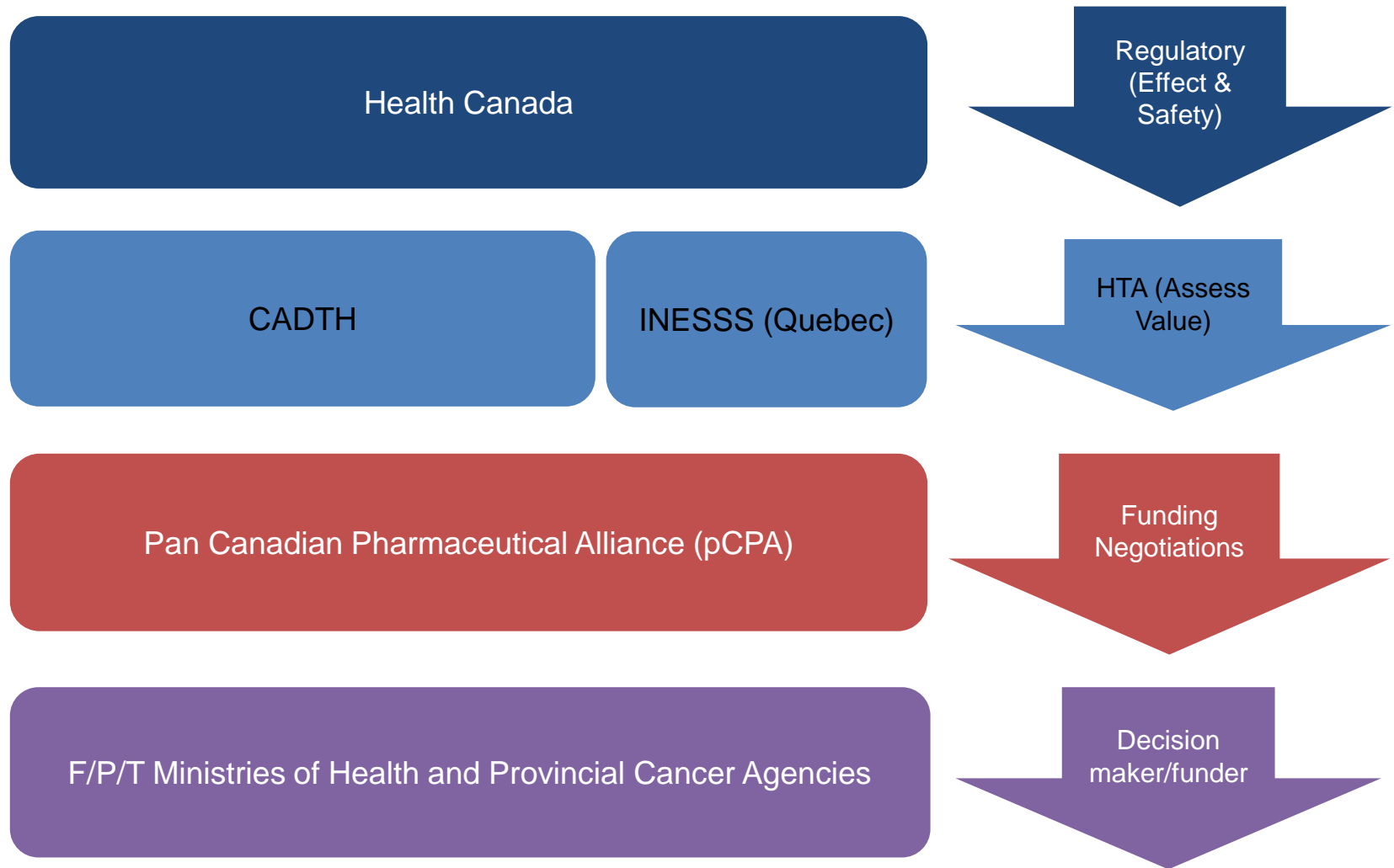
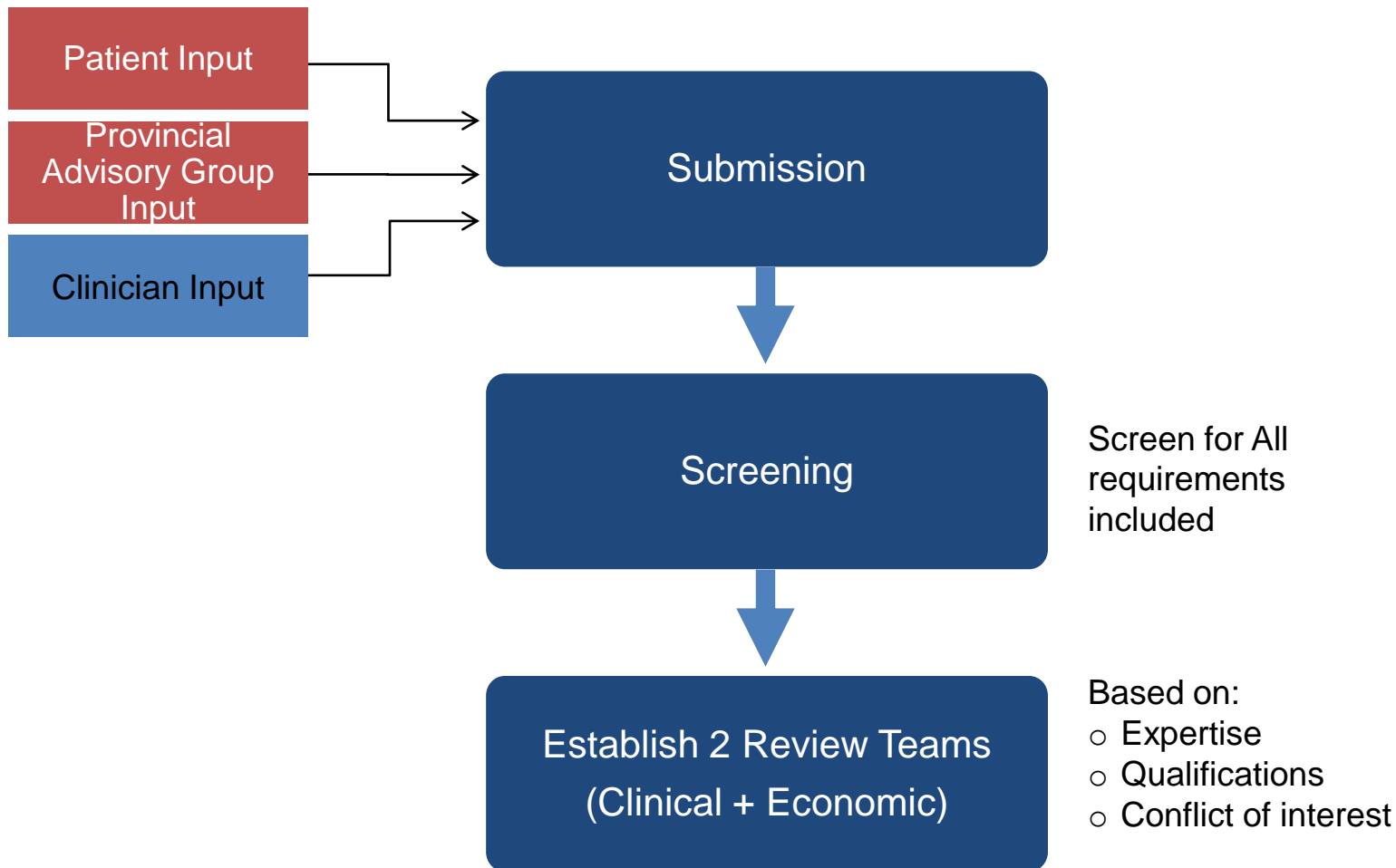


Guide to Providing Clinician Input and Feedback with the pCODR Program

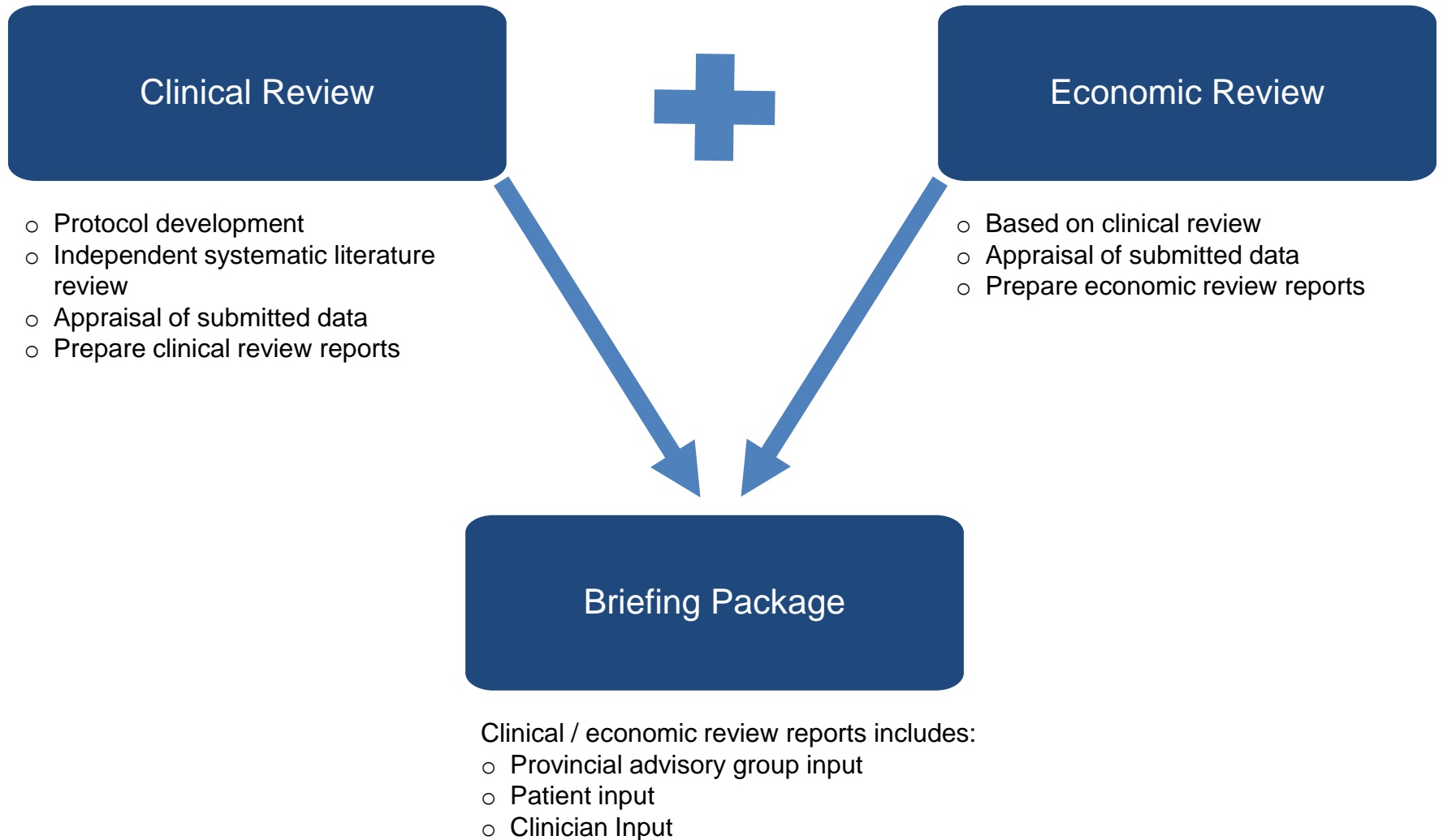
Overview of Drug Review in Canada



The pCODR process is well defined

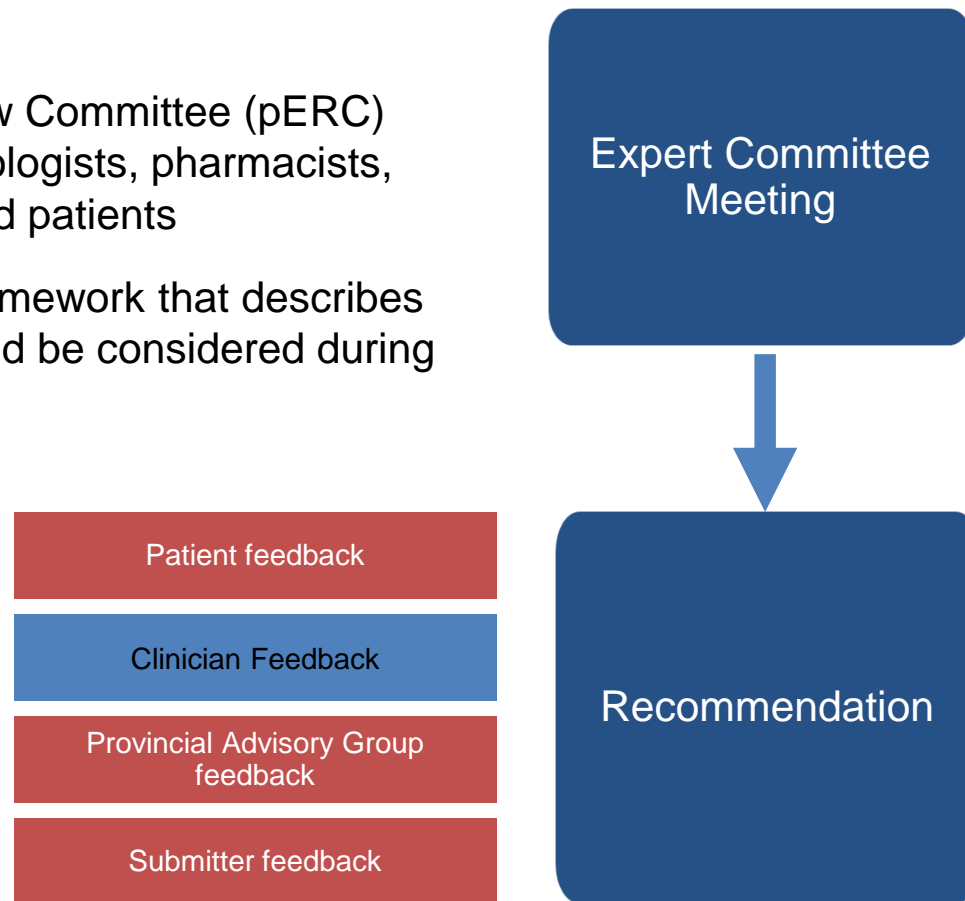


The pCODR process is well defined



The pCODR process is well defined

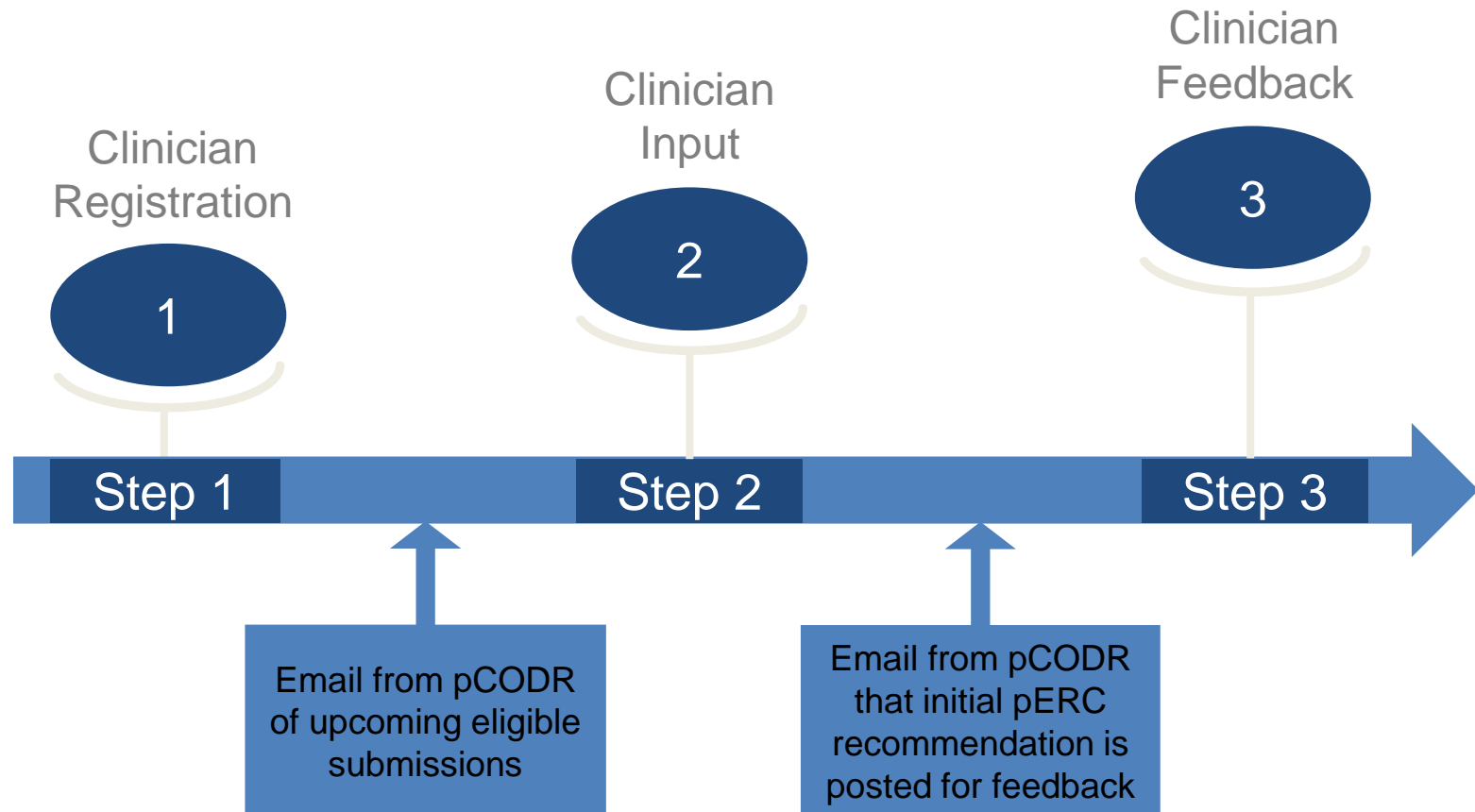
- pCODR Expert Review Committee (pERC) members include oncologists, pharmacists, health economists, and patients
- Follow a deliberate framework that describes all elements that should be considered during a review



Clinician input to pCODR

- Since February 2016 pCODR allows clinicians to provide input and feedback and participate in the pCODR process.
 - pCODR updated the clinician input process in 2018 expanding the process to include oncology physicians, pharmacists and nurses.
- This initiative allows for broader clinician participation in providing and enhancing value-added information in the discussion of drug funding decisions in Canada.

How does a clinician provide input & feedback?

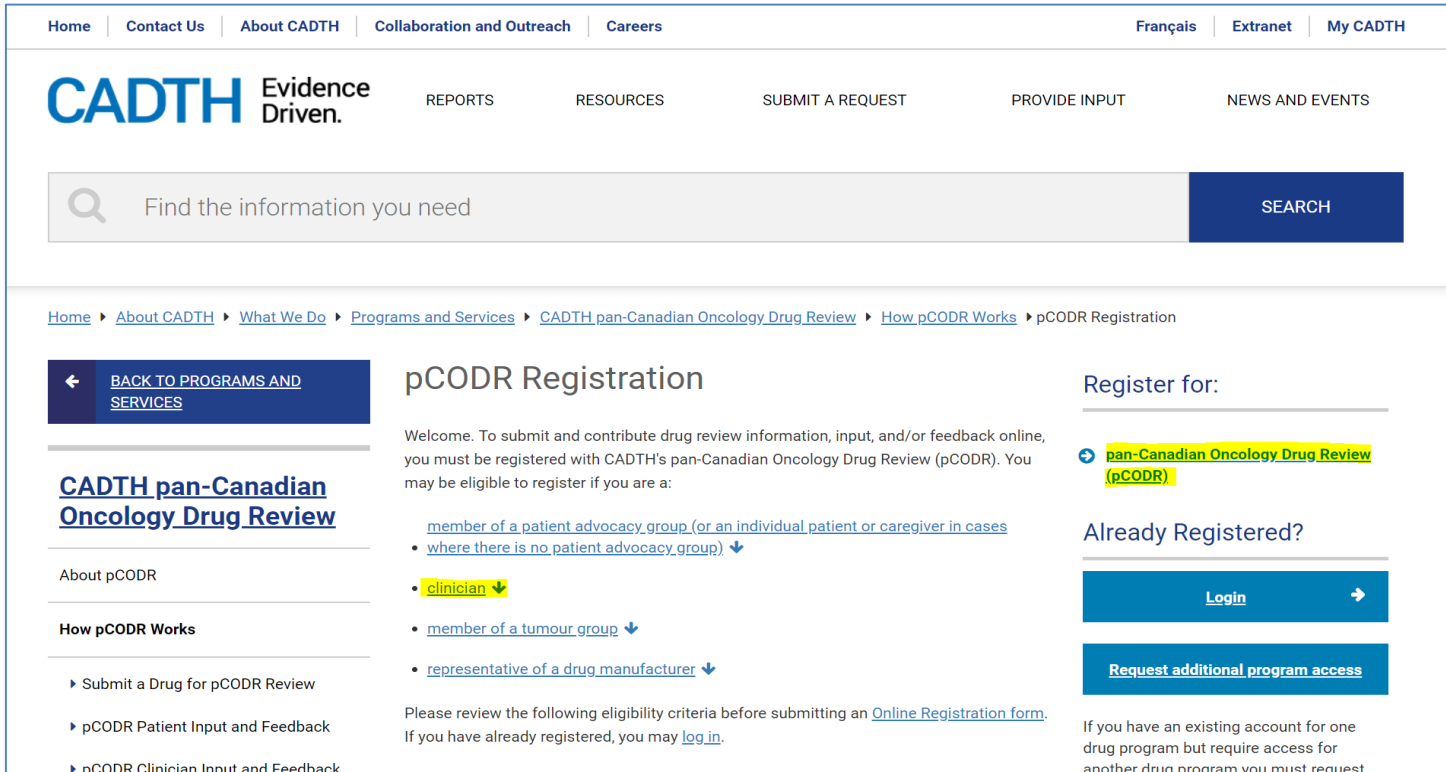


Step 1: Clinician Registration

- An eligible registrant must meet both requirements:
 - is an actively practising oncologist (or a physician who treats cancer patients), oncology pharmacist, or oncology nurse
 - submits a declaration of conflict of interest
- Note: The input from an oncology pharmacist and oncology nurse must be part of a joint submission with a registered oncologist or physician who treats cancer patients.
 - Clinicians can register through:
 - www.cadth.ca/pcodr/registration

Step 1: Clinician Registration

- What does the registration process look like?



The screenshot shows the CADTH Evidence Driven website. The top navigation bar includes links for Home, Contact Us, About CADTH, Collaboration and Outreach, and Careers. The main header features the CADTH logo and a search bar. The breadcrumb trail indicates the path: Home > About CADTH > What We Do > Programs and Services > CADTH pan-Canadian Oncology Drug Review > How pCODR Works > pCODR Registration.

Left Sidebar:

- [BACK TO PROGRAMS AND SERVICES](#)
- CADTH pan-Canadian Oncology Drug Review**
- About pCODR
- How pCODR Works**
 - Submit a Drug for pCODR Review
 - pCODR Patient Input and Feedback
 - pCODR Clinician Input and Feedback

Main Content Area:

pCODR Registration

Welcome. To submit and contribute drug review information, input, and/or feedback online, you must be registered with CADTH's pan-Canadian Oncology Drug Review (pCODR). You may be eligible to register if you are a:

- [member of a patient advocacy group \(or an individual patient or caregiver in cases where there is no patient advocacy group\)](#) ↓
- clinician** ↓
- [member of a tumour group](#) ↓
- [representative of a drug manufacturer](#) ↓

Please review the following eligibility criteria before submitting an [Online Registration form](#). If you have already registered, you may [log in](#).

Right Sidebar:

Register for:

- [pan-Canadian Oncology Drug Review \(pCODR\)](#)

Already Registered?

[Login](#)

[Request additional program access](#)

If you have an existing account for one drug program but require access for another drug program you must request

<https://www.cadth.ca/pcodr/registration> (Accessed March 21 2018)

Step 1: Clinician Registration

- What does the registration process look like?

The screenshot shows the CADTH Evidence Driven Registration form. The form is titled "Registration" and includes the CADTH logo and tagline "Evidence Driven." The form is divided into two main sections: "Registration" and "Public Profile".

Registration Section:

- First Name ***: Text input field.
- Last Name ***: Text input field.
- Email ***: Text input field.
- Country**: Dropdown menu with "Canada" selected.
- Street**: Text input field.
- City**: Text input field.
- Province**: Dropdown menu.
- Postal Code**: Text input field.
- Phone**: Text input field.
- Fax**: Text input field.
- Cell Phone**: Text input field.
- Organization**: Text input field.
- Department**: Text input field.
- Job Title**: Text input field.
- Consent**: A checkbox with the text "I consent to receive electronic messages regarding CADTH's programs, including input and feedback opportunities, and other events as applicable."

Public Profile Section:

- Public Profile**: A large text area for a public profile.

Type of Organization/Group *

- ☐ Review team and Committee members.
- ☐ Drug Manufacturer/Tumour Group – A drug manufacturer or designated consultant, or clinical and/or research group affiliated with a provincial/territorial cancer agency or Ministry of Health, eligible to file a Drug Submission.
- ☐ Patient Group – Eligible to provide input and feedback on a Drug Submission.
- ☐ Clinicians

Register: A blue button at the bottom right of the form.

<https://drugreviewsadmin.cadth.ca/Landing/register/register.aspx?token=pCODR> (Accessed March 21 2018)

Step 1: Clinician Registration

- Within two business days of submitting your registration request, you will receive an email from CADTH with instructions on the final steps for completing your registration
- Complete the final steps outlined in the email. You will create a username and password, which will then allow you to log in to CADTH's secure Collaborative Workspaces page
 - Access to the Collaborative Workspaces page will allow clinicians to upload completed input documents

Step 2: Clinician Input

- Registered clinicians will receive notifications via email of all upcoming reviews at pCODR one month prior to manufacturers submissions.
- The email notification will have information pertaining to the drug and indication under review, the link to the clinician input template, and the deadline date for, submitting.
- A notification will also be issued once a manufacturer submission is received. Only submit your input after you receive notification that a submission has been received by pCODR.

Step 2: Clinician Input

- What does the pCODR Review Status look like?

Project Number	pCODR 10153
Brand Name	Keytruda
Generic Name	Pembrolizumab
Tumour Type	Lung
Indication	Non-Squamous NSCLC
Funding Request	In combination with pemetrexed and platinum chemotherapy, for the treatment of metastatic non-squamous NSCLC, in adults with no EGFR or ALK genomic tumor aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC.
Review Status	Pending
Pre Noc Submission	Yes
NOC Date	
Manufacturer	Merck Canada
Submitter	Merck Canada
Submission Date (Target Date)	September 14, 2018
Submission Type	New Indication
Prioritization Requested	
Stakeholder Input Deadline	September 28, 2018

 [Pembrolizumab \(Keytruda\) NSQ-NSCLC - Registered Clinician Input Template](#)

Step 2: Clinician Input

- The registered clinician must use the drug specific template.
- Key questions for clinician input include:
 - current treatments for indication under review
 - eligible patient population
 - relevance to clinical practice
 - Sequencing and priority or treatments
 - companion diagnostic testing
- There may be other questions from public funders related to implementation. These questions are specific to the drug and indication under review.

CADTH

Clinician Input Template for CADTH pan-Canadian Oncology Drug Review Program

Before completing this template, be sure to [register](#) with the pCODR program. Please visit www.cadth.ca/pcodr/registration for information about the registration process.

1. About the Registered Clinician

Name of Registered Clinician	
Title	
Disease Specialty (if applicable)	
Province	
Organization Membership (if applicable, national or provincial)	
Email	
Telephone Number	

Step 2: Clinician Input

- What does the input submission process look like?

BROWSE PAGE

CADTH Evidence Driven. **pCODR Submit and Contribute - Clinicians** Portal Home

pCODR Submit and Contribute - Clinicians

Clinicians who have registered with pCODR may access pCODR resources, including guidelines and templates, as well as securely submit drug review input and recommendation feedback to pCODR through this secure portal site.

Input or Feedback may be submitted as zipped (.zip) files, containing several files or folders. Each .zip file may be a maximum of 1GB. If you have several zip files please note the number of files in the Additional Comments box of the submission form. For example File: 1 of 4.

Registered clinicians may wish to consult our [Frequently Asked Questions](#) to determine eligibility to participate and to understand the process.

Resources

You can find reference documents, templates and other resources to help you with your submission below.

Name	Modified
01-pCODR Procedures	August 9
02-Stakeholder Feedback on a pERC Initial Recommendation	August 9
03-pCODR Registered Clinician Conflict of Interest Declarations	August 9
04-pCODR_Stakeholder_Feedback_RFA_Template	August 9
05-Biosimilars Clinician Input Template for CADTH pCODR Program	August 9

Submit Review Input Document

Submit a document that contains input to a review that is about to get underway.

Submit

Submit Feedback Document

Submit a document that contains feedback on an initial pERC recommendation.

Submit

Step 2: Clinician Input

- How is the Clinician Input Used?

Registered Clinician Input

Two clinician inputs were provided: One joint submission from four clinicians submitted on behalf of the Hematology Drug Advisory Committee at Cancer Care Ontario and one group input from six oncologists across five provinces: British Columbia, Manitoba, Newfoundland, Ontario and Quebec.

Overall the oncologists providing input agreed that this indication and funding will only affect a very small number of patients and that there is currently no standard of care in relapsed/refractory patients with Hodgkin Lymphoma (cHL). Two of the key benefits identified by both clinician groups was the encouraging response rate and good safety profile of pembrolizumab. An unmet need was identified by both groups. Pembrolizumab would be used in patients with refractory/relapsed HL past autologous stem cell transplant (auto-SCT) and brentuximab vedotin (BV) and patients who are ineligible for transplant and have no access to BV. In patients who are eligible for allogeneic stem cell transplant (allo-SCT), pembrolizumab may replace conventional chemotherapy to provide a bridge to transplant. In patients who have chemo-refractory HL, but who are BV-naïve, PD1 inhibitors may replace BV in patients who would not be able to tolerate BV (e.g. baseline neutropenia or neuropathy). The clinicians also noted that PDL1 testing would not be required.

Registered clinician input: Need for effective treatment for small population

The Committee deliberated on input from two clinician groups. pERC agreed with the clinicians' input that this indication and funding will affect only a very small number of patients and that there is currently no standard of care in relapsed or refractory patients with cHL. Two of the key benefits identified by both clinician groups was the encouraging response rate and good safety profile of pembrolizumab. An unmet need was identified by both groups. Pembrolizumab could be used in patients with refractory or relapsed cHL post ASCT and BV or patients who are ineligible for transplant and have no access to BV. In patients who are eligible for allogeneic stem cell transplant, pembrolizumab may replace conventional chemotherapy to provide a bridge to transplant. In patients who have chemo-refractory cHL but who are BV naïve, PD-1 inhibitors may replace BV in patients who would not be able to tolerate BV (e.g., baseline neutropenia or neuropathy). The clinicians also noted that PDL-1 testing would not be required.

Step 3: Clinician Feedback

- Clinicians will receive emails when initial recommendations are posted.
 - Only clinicians who provided input at the beginning of the process may provide feedback on the initial recommendation
 - Clinician feedback will be considered when making the Final Recommendation
- The registered clinician must use the “Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation” template accessed at:
- <https://cadth.ca/pcodr/guidelines-procedures-and-templates>
- This template consists of one part:
 - Section 3: Feedback on pERC Initial Recommendation

Step 3: Clinician Feedback

- What does the clinician feedback form look like?

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s): _____

Eligible Stakeholder Role in Review
(Submitter and/or Manufacturer, Patient) _____

Organization Providing Feedback _____

Contact Person*: _____

Title: _____

Phone: _____

Email: _____

**The pCODR program may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR.*

3.1 Comments on the Initial Recommendation

a) Please indicate if the eligible stakeholder agrees, agrees in part, or disagrees with the Initial Recommendation:

☐ agrees ☐ agrees in part ☐ disagree

Please explain why the Stakeholder agrees, agrees in part or disagrees with the Initial Recommendation. If the Stakeholder agrees in part or disagrees with the Initial Recommendation, please provide specific text from the recommendation and rational. Please also highlight the applicable pERC deliberative quadrants for each point of disagreement. The points are to be numbered in order of significance.

Step 3: Clinician Feedback

- How clinician feedback is deliberated?

According to registered clinician input, patients in whom TKIs fail have a very short life expectancy (approximately three months based on prior studies) and no other viable treatment options. Clinician input indicates that venetoclax is the only agent with documented efficacy in this population. Registered clinician input indicated that the key benefits of venetoclax were its high response rates and durable responses in a patient population with no other effective treatment options. Response rates with venetoclax were also indicated to be considerably higher when compared with treatment with alternate TKI after failure of a first TKI. During the deliberation on the Initial Recommendation pERC acknowledged that the evidence (M14-032 trial) suggests that there is promising antitumour activity with venetoclax; however, the magnitude of effect was uncertain given the lack of comparative data on long-term outcomes important to patients, such as OS and PFS. Upon reconsideration of the pERC Initial Recommendation, pERC considered the clarification from registered clinicians and feedback from registered clinicians, two patient advocacy group and the manufacturer on the interpretation of the available evidence. Based on this feedback and substantive deliberation, pERC agreed that in a setting where there is poor prognosis and no effective treatment options, the magnitude of PFS and OS rates observed at one year are meaningful. These results were also longer than what is seen with historical outcomes. pERC also agreed that ORR from the M14-032 trial was high in this population and that complete remission, although occurring in a small proportion of patients, is not typically anticipated in this disease setting. pERC therefore agreed that the observed results in the M14-032 trial demonstrate meaningful outcomes for patients.

Best Practice Suggestions

- This is your opportunity to provide valuable information about the need for and use of new cancer drug therapies, based on your clinical experience.
- Register with pCODR (one-time, online registration):
- <https://drugreviewsadmin.cadth.ca/Landing/register/register.aspx?token=pCODR>
- Use the appropriate forms to complete the submission. All submissions that are posted as a pending review will have a **drug- and indication-specific template for clinicians** to provide their input. The template will be located on the CADTH Web page (<https://www.cadth.ca/pcodr/find-a-review>) for the corresponding drug and indication.
- Provide input that is relevant to your practice and patients:
 - How important you feel it is to have this treatment reimbursed
 - Factors that would influence its ease of administration
 - How well the drug is tolerated (not always captured in QoL measures)
 - Side effects management
 - Whether there is equipoise that would allow an RCT to occur
 - Consider implementation issues (e.g., sequencing, CDx, etc.)

Best Practice Suggestions

- Reach out to a patient advocacy group (e.g. Lung Cancer Canada, Lymphoma Canada, Myeloma Canada) to help facilitate a group clinician submission.
 - Patient groups can guide you through the process, contact additional physicians who have experience with the drug/indication under review, and collate all documents for submission by the lead clinician.
 - Each participating physician must complete a COI form, to be submitted by the lead physician.
- If you agree or don't agree with pERC's initial recommendation, you have an opportunity to provide feedback, but ONLY if you participate in the initial submission.
- Feedback must be submitted using pCODR's Stakeholder Feedback Form:
<https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/StakeholderFeedbackonInitialRec.docx>

Thank you to all who contributed to this resource. It is made possible through a joint collaboration by CADTH (pCODR program), Innovative Medicines Canada (Joint Oncology Project Team) and Lymphoma Canada.

