# Guide to Providing Clinician Input and Feedback with the pCODR Program

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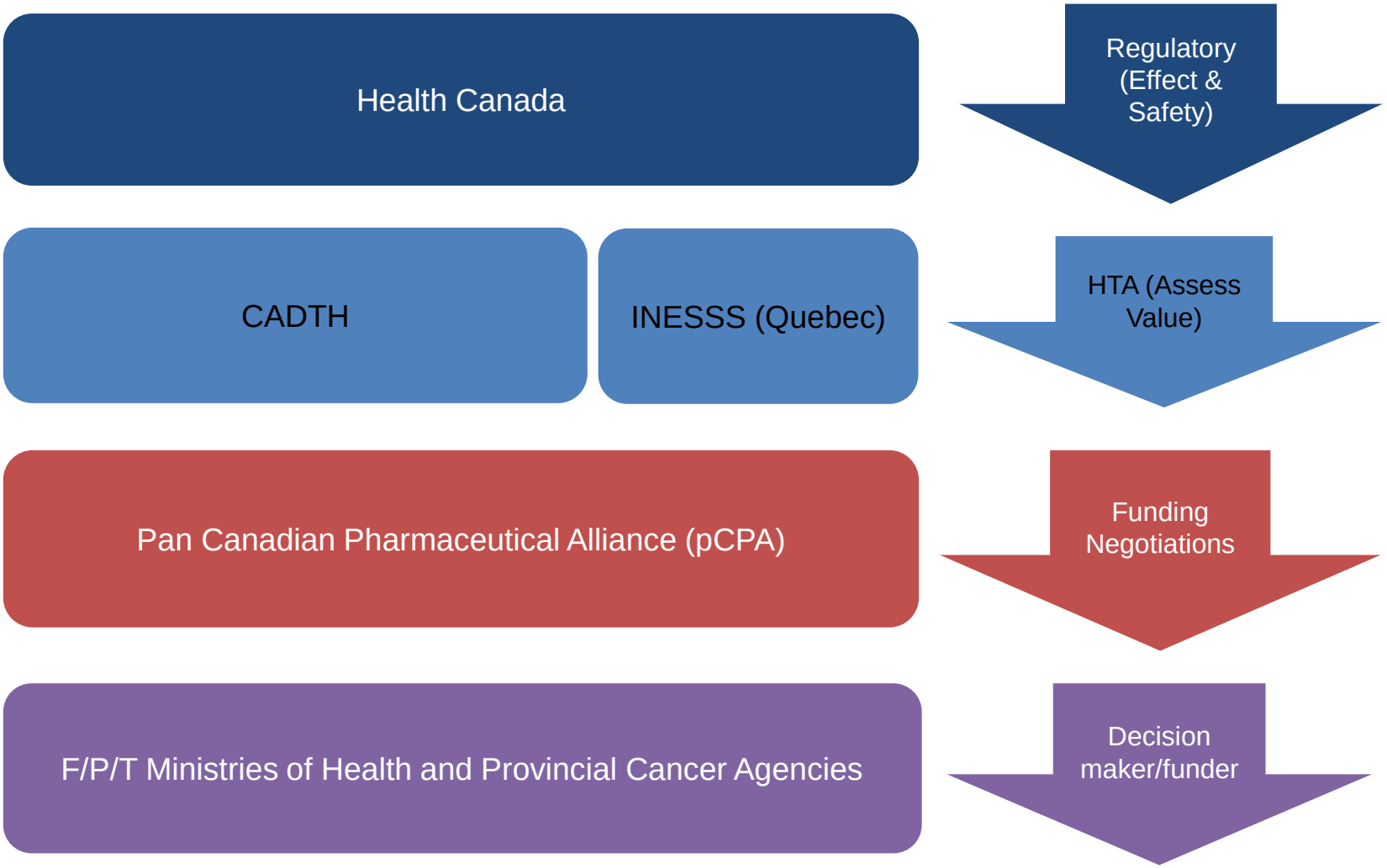
# Overview of Drug Review in Canada






CADTH – Canadian Agency for Drugs and Technologies in Health
INESSS – Institut national d'excellence en santé et en services sociaux

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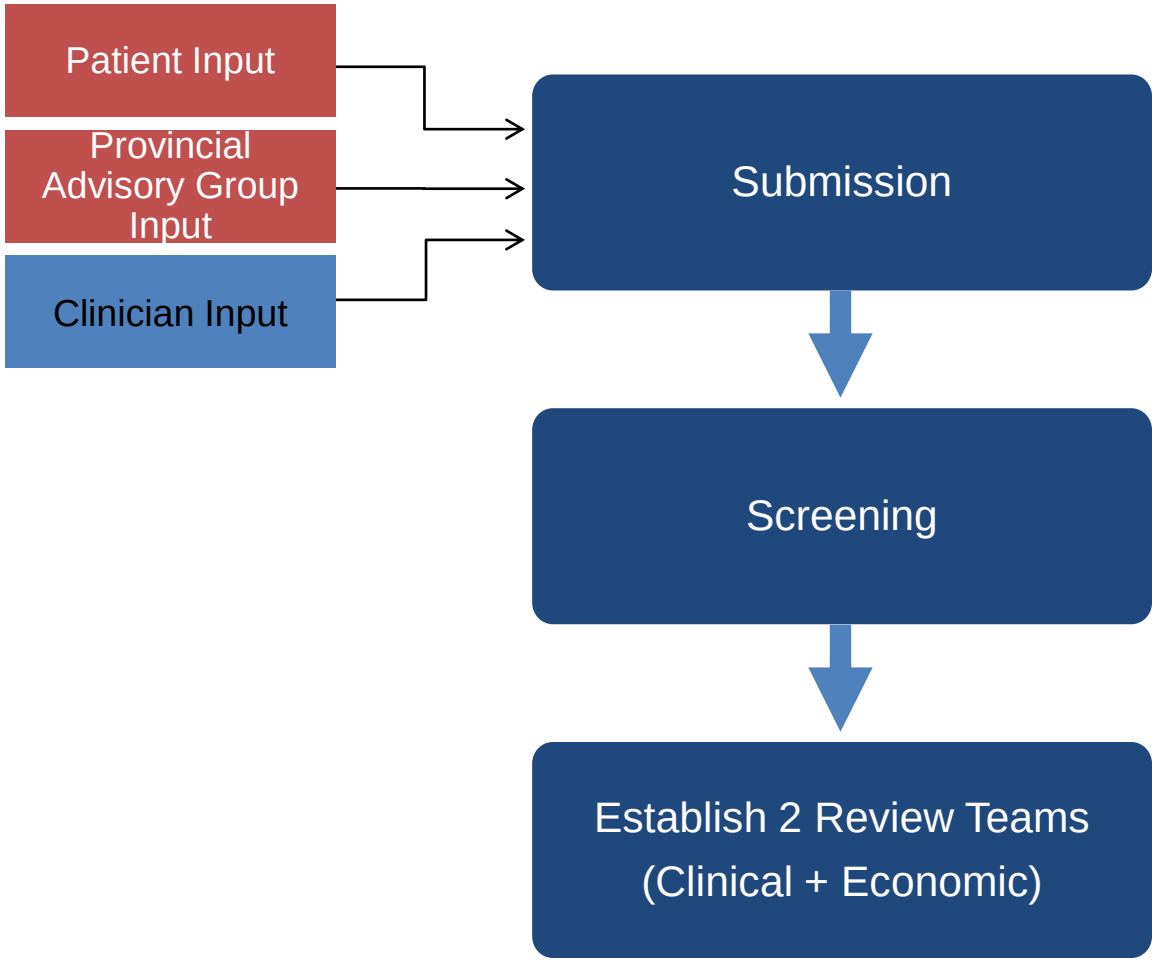
# The pCODR process is well defined

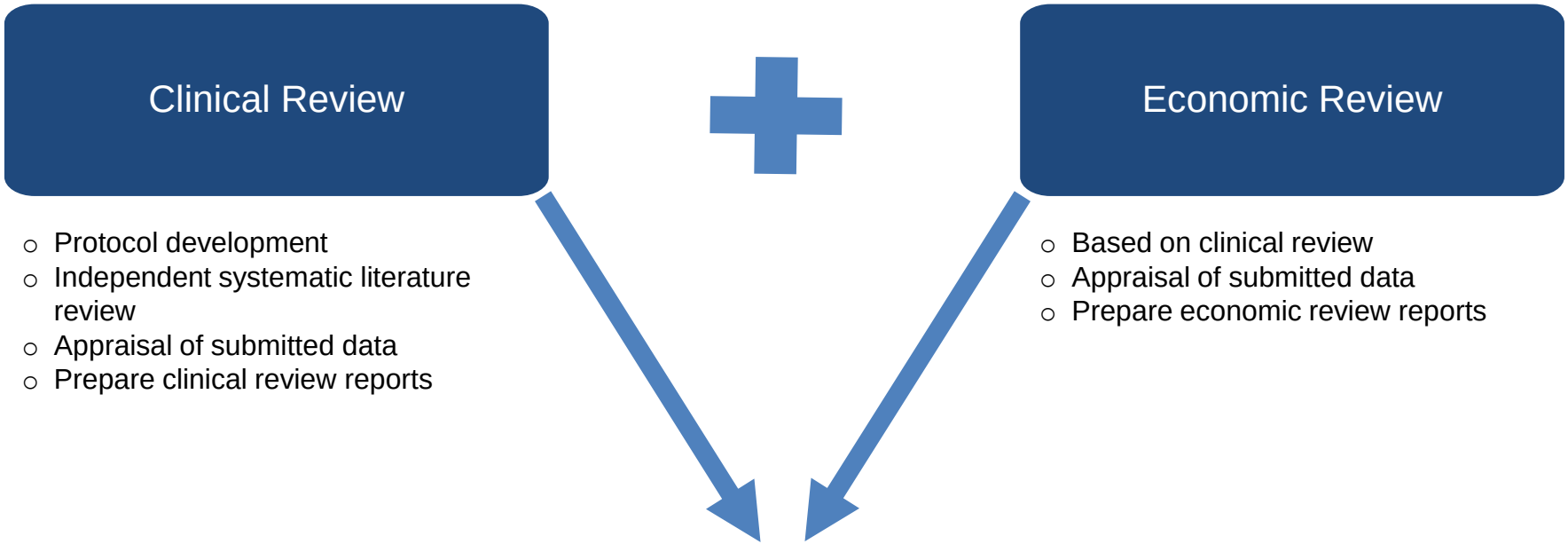



Screen for All requirements included

Based on:

- Expertise
- Qualifications
- Conflict of interest

# The pCODR process is well defined




- Protocol development
- Independent systematic literature review
- Appraisal of submitted data
- Prepare clinical review reports

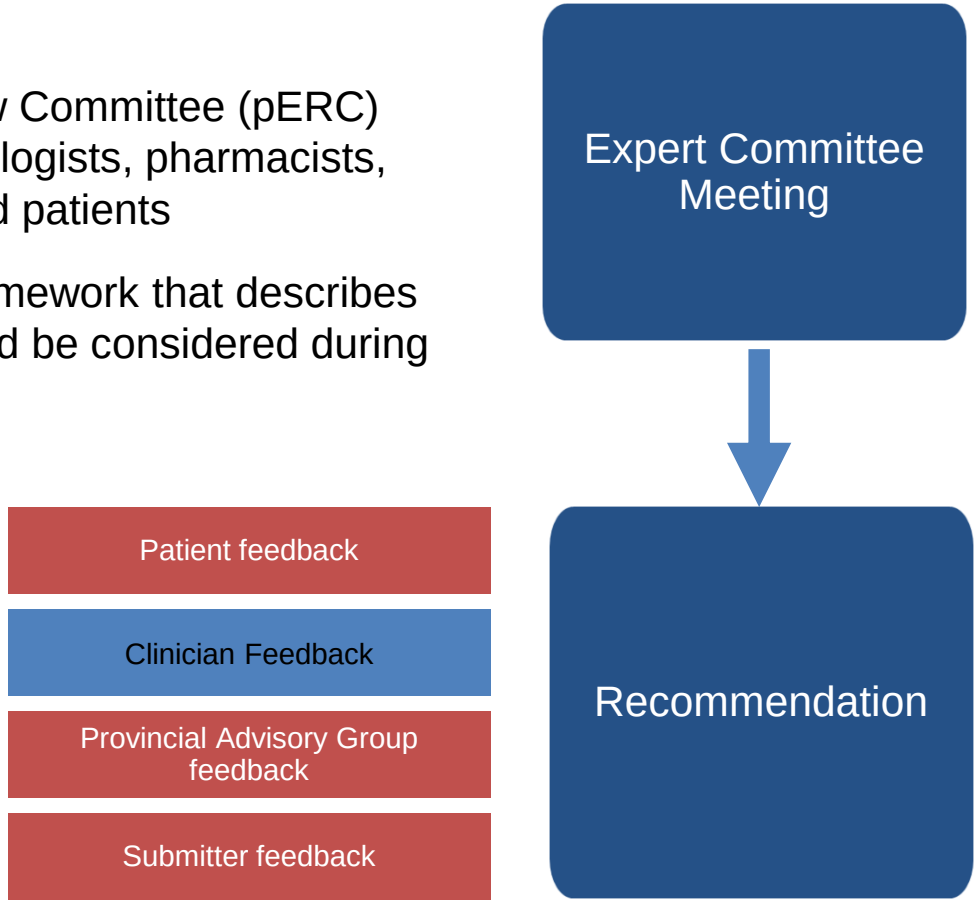
- Based on clinical review
- Appraisal of submitted data
- Prepare economic review reports

Clinical / economic review reports includes:

- Provincial advisory group input
- Patient input
- Clinician Input

# 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



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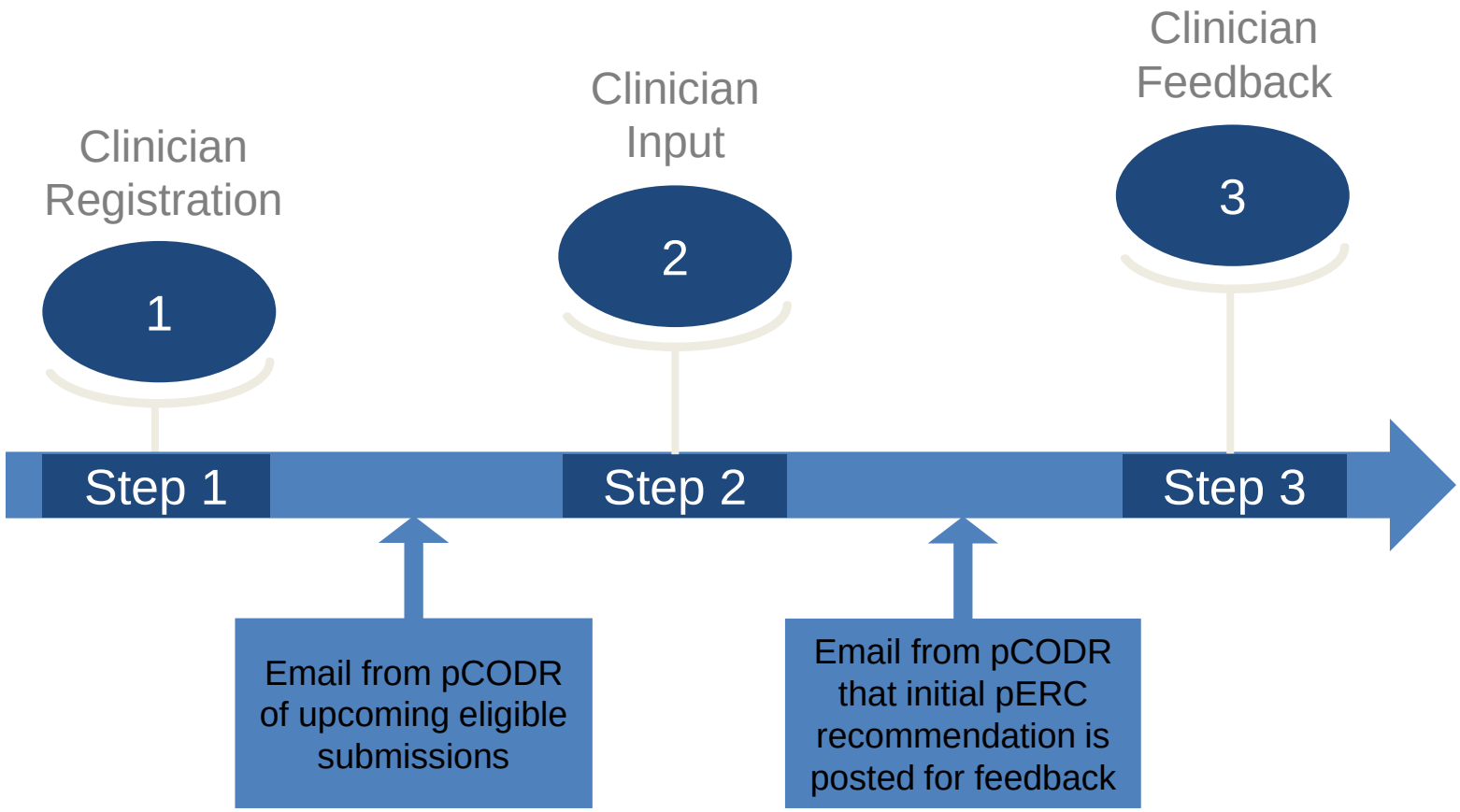
# Clinician input to pCODR

- 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?



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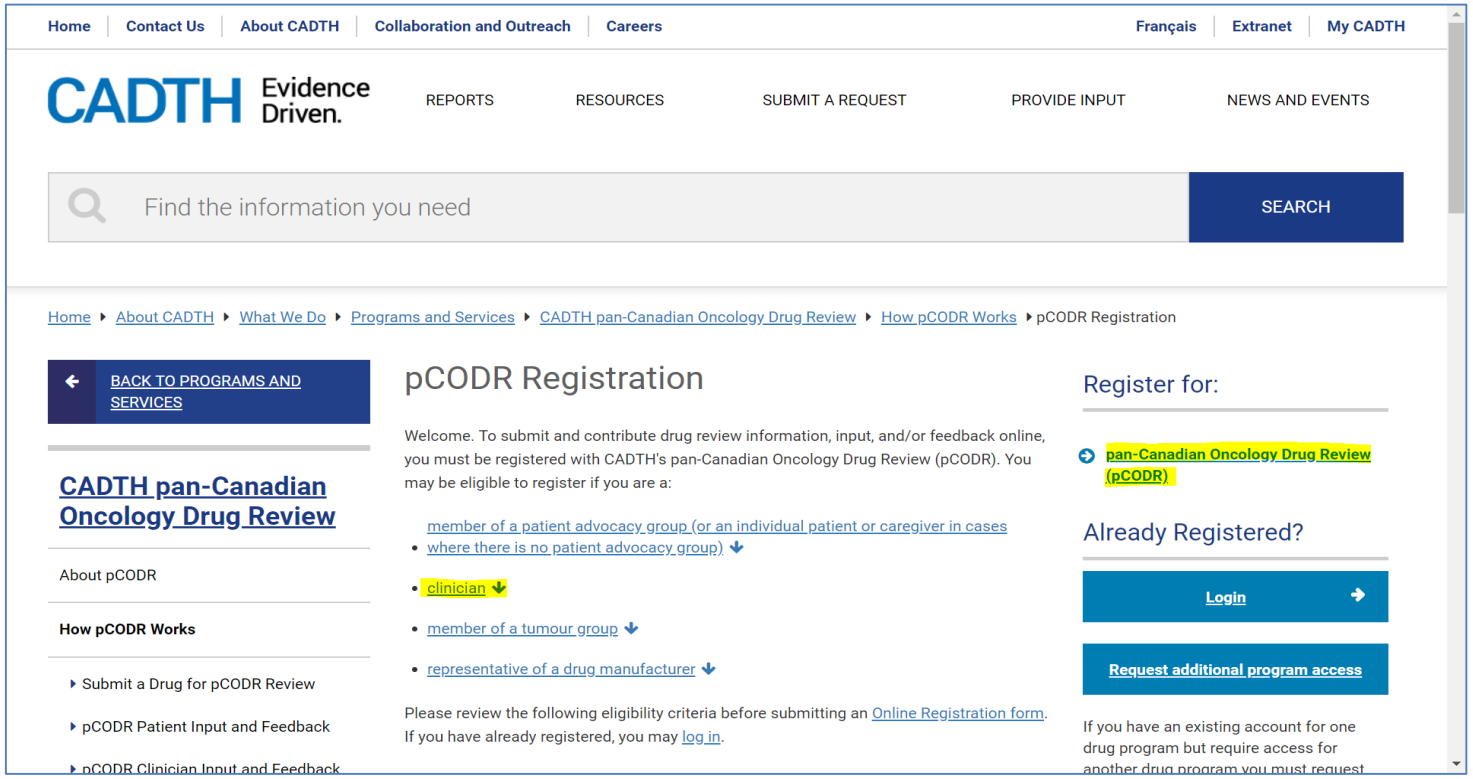
# Step 1: Clinician Registration

- 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?




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



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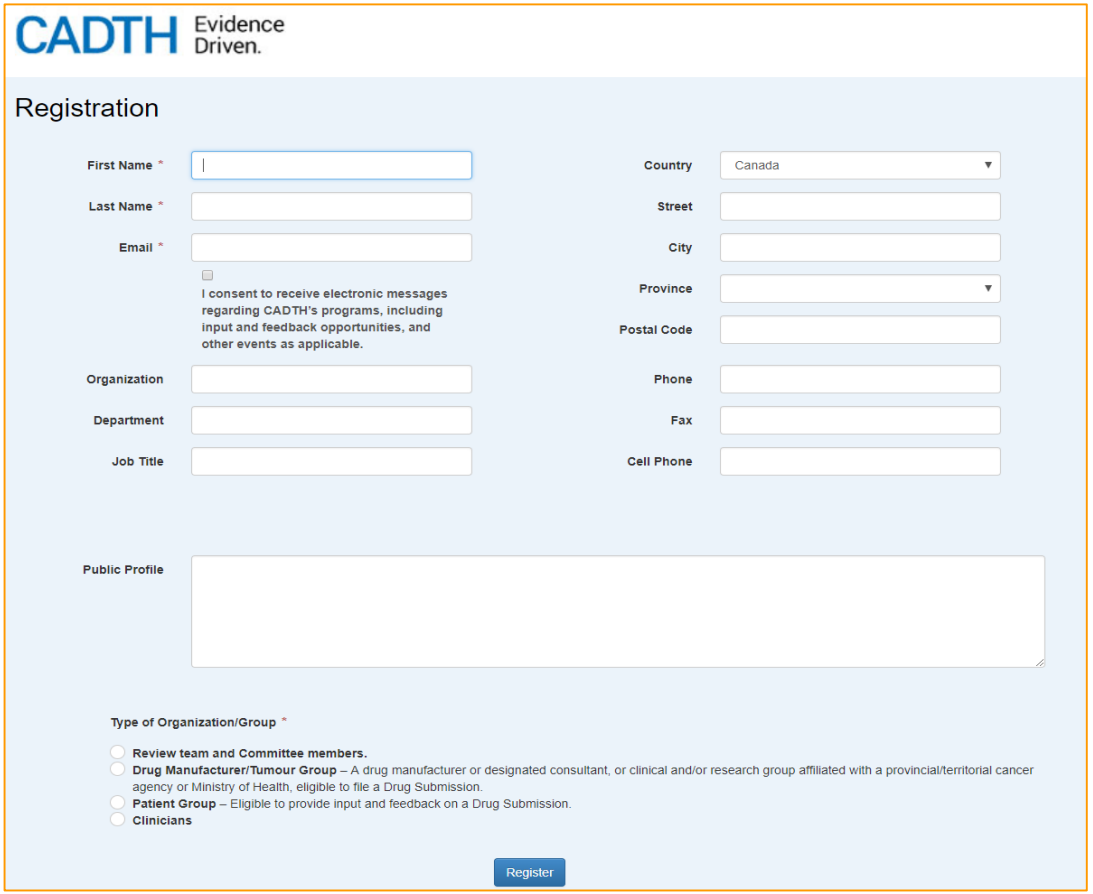
# Step 1: Clinician Registration

- What does the registration process look like?




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?

Pembrolizumab (Keytruda) NSQ-NSCLC - Registered Clinician Input Template

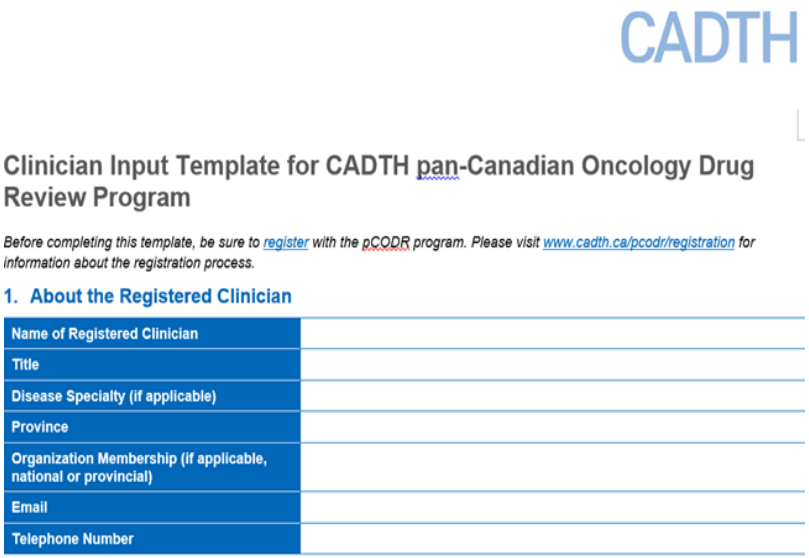
| | |
|---|---|
| Project Number | pCODR 10153 |
| Brand Name | Keytruda |
| Generic Name | Pembrolizumab |
| Tumour Type | Lung |
| Indication | Non-Squamous NSCLC |
| Funding Request | In combination with pemetrexed and platinum chemotherapy, for the treatment of metastatic non-squamous NSCLC, in adults 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 |



https://cadth.ca/keytruda-non-squamous-nsclc-details

# 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

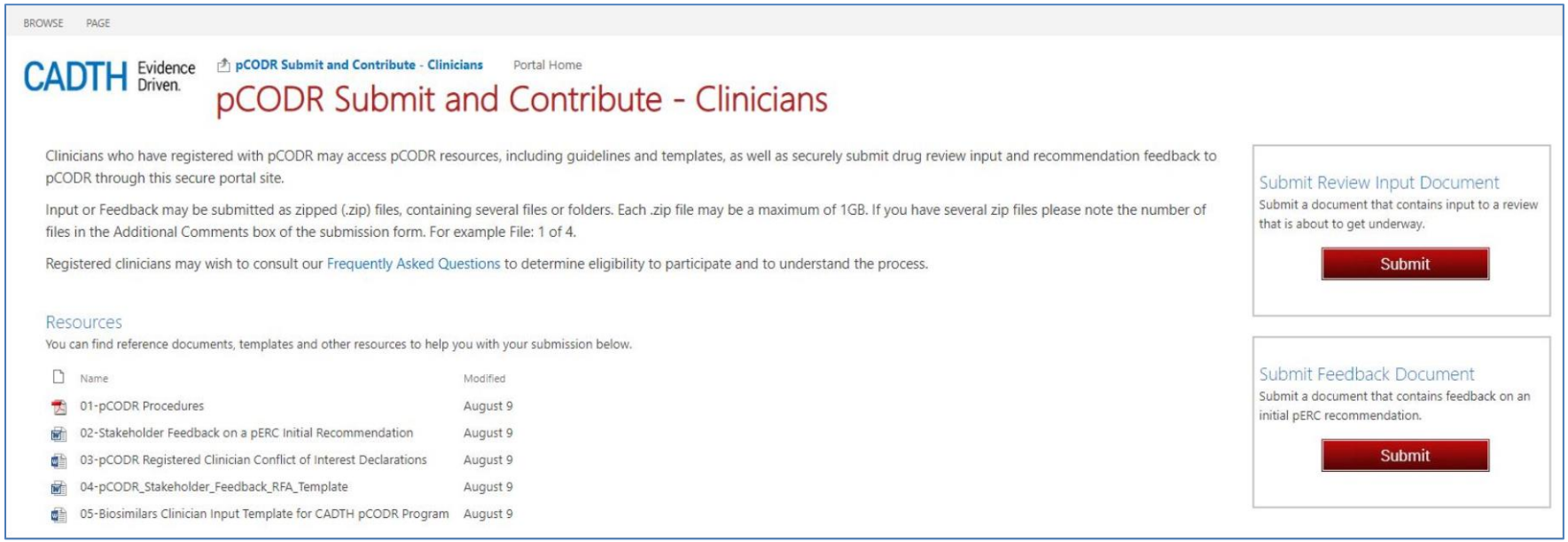
*Before completing this template, be sure to register with the pCODR program. Please visit www.cadth.ca/pcodr/registration for information about the registration process.*

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?



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# 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**

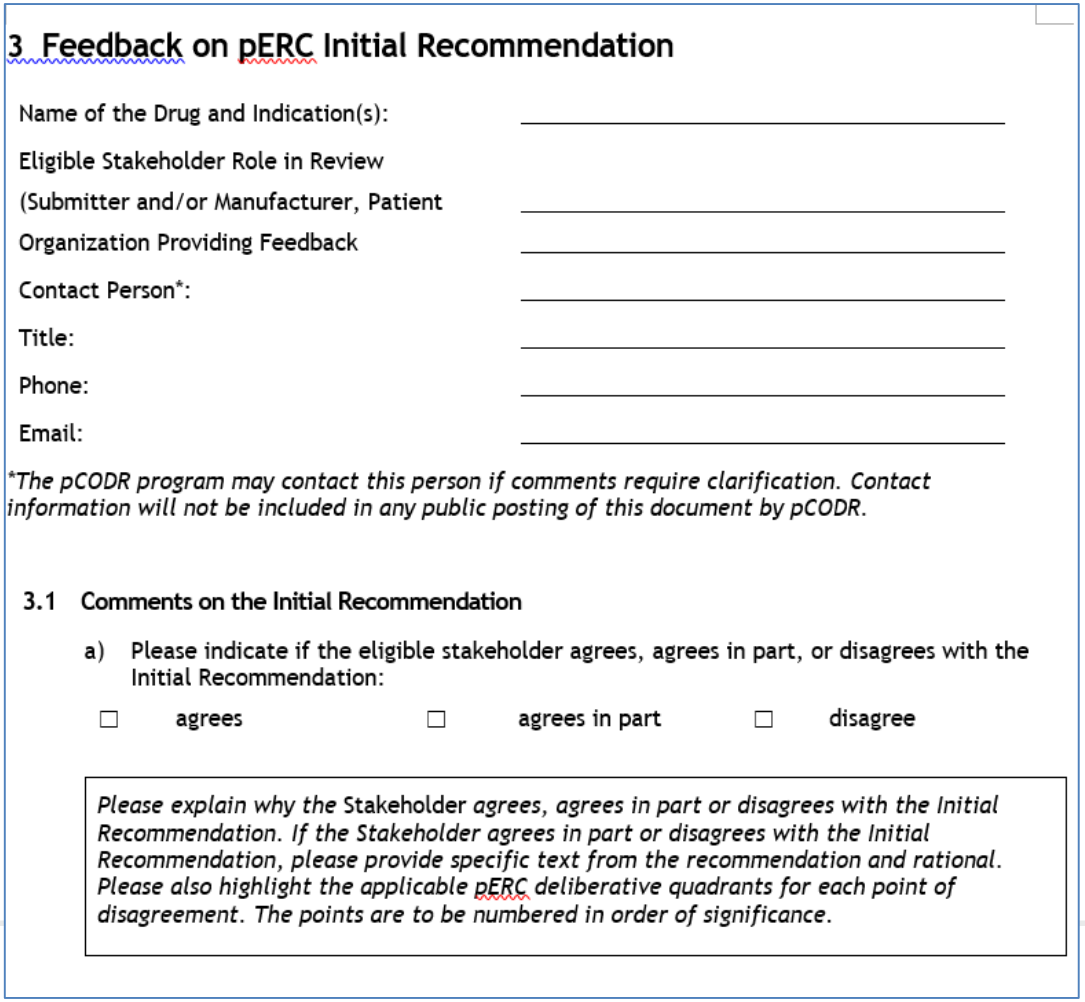
**The Committee deliberated on input from two clinician groups. pERC agreed with the clinicians' input that this indication and funding will affect only a very small number of patients and that there is currently no standard of care in relapsed or refractory patients with cHL. Two of the key benefits 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 naive, 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 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.

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