CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review Checkpoint Meeting Template

February 2018

RECORD OF UPDATES

Update	Version	Reported on pCODR Website
Original	July 2011	July 21, 2011
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INQUIRIES

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1 Purpose

The purpose of the pCODR Checkpoint Meeting with the Submitter is: (1) to directly clarify information in the Submission and any Additional Information being provided with members of the pCODR Review Team and (2) to discuss the management of Non-Disclosable Information included in the Submission. The Checkpoint Meeting is not for the purposes of confirming information that the pCODR Review Team will include in the report or to solicit the pCODR Review Team's interpretation of the Submission.

The pCODR Checkpoint Meeting with the Submitter will be conducted as outlined in the *pCODR Procedures*, which is available on the pCODR section of the CADTH website, www.cadth.ca/pcodr. Information and details provided in this document, the pCODR Checkpoint Meeting Template, give additional guidance around the conduct of the Checkpoint Meeting with the Submitter and any required follow-up actions resulting from the Checkpoint Meeting.

If procedures relating to the Checkpoint Meeting are not followed as outlined here in the *pCODR Checkpoint Meeting Template* or as outlined in the *pCODR Procedures*, the review of the Submission may be delayed or suspended.

2 Definitions

The capitalized terms in this document are as defined in the *pCODR Procedures*, which are available on the pCODR section of the CADTH website, www.cadth.ca/pcodr.

All references to the number of days in this document are in Business Days, as defined in the *pCODR Procedures*, unless otherwise specified.

3 General Format of the Checkpoint Meeting

The Checkpoint Meeting will occur in two parts and the conduct of each part of the meeting differs. Part one of the Checkpoint Meeting will be to clarify information in the Submission and any Additional Information being provided. Part two of the Checkpoint Meeting will be to discuss the management of Non-Disclosable Information included in the Submission. Part one and part two of the Checkpoint Meeting will be scheduled consecutively with a short break in between.

If the Submitter is not the manufacturer of the drug under review and the manufacturer has contributed substantive clinical or economic information to the review, the manufacturer may be invited to attend the Checkpoint Meeting with the Submitter.

Submitter and manufacturer attendees are required to attend the Checkpoint Meeting with pCODR in-person.

The Checkpoint Meeting will occur, in part, as a teleconference or in a webinar format to maintain the anonymity of the Submission-specific Review Team members. (Note: pCODR will disclose a general list of individuals involved in pCODR reviews but does not divulge Submission specific Review Teams as outlined in section B3.1.10 of the *pCODR Procedures*.) The anonymity of the Review Team is preserved by pCODR in order to protect pCODR participants from undue influence, to maintain the integrity of assessments without fear of reprisal and to limit the potential for harassment and intimidation of Review Team members in their professional capacity. The Submitter must not attempt to identify members of the Review Team during the interactive meeting.

Both part one and part two of the meeting will be recorded by pCODR and a record of the meeting will be retained on file at pCODR.

There is a maximum of four Submitter attendees for each part of the Checkpoint Meeting. Submitter attendees may differ for part one and part two of the meeting. No legal representation is permitted at the Checkpoint Meeting. A list of all attendees must be provided to the pCODR program at least 5 business days in advance of the meeting, otherwise the meeting may be cancelled. If a Checkpoint Meeting is not held by the target date, pCODR cannot guarantee the review will be completed within the posted timelines and/or the review may be temporarily suspended.

4 Clarification of Information – Part One of the Checkpoint Meeting

The procedures outlined below relate to part one of the Checkpoint Meeting.

- At part one of the Checkpoint Meeting, the Submitter will have an opportunity to provide, directly to the pCODR Review Team, responses to the clarifying questions and the request for Additional Information, which were sent to the Submitter ten (10) Business Days in advance.
- An electronic version of the Submitter responses to the clarifying questions and requests for Additional Information must be provided to pCODR at least **one (1) business day** in advance of the scheduled Checkpoint Meeting so that these can be provided to the pCODR Review Team prior to the interactive meeting.
- The duration of part one of the Checkpoint Meeting will be a maximum of one hour. Submitters will be provided with approximately 30 minutes to present responses to the submitted questions. The remainder of the meeting will allow for further clarifications based on the submitted questions and presented responses.
- Submitters should limit questions for the Review Team to topics raised in the list of submitted questions. Questions outside the scope of the Checkpoint Meeting will not be addressed at the meeting.
- Submitter attendees should include individuals with clinical and economic content expertise who will be able to provide adequate clarification on the content of the Submission to the pCODR Review Team.
- Attendees from pCODR can include CADTH staff, Clinical Guidance Panel members, Economic Guidance Panel members and individuals with methodological expertise who are assigned to the Review Team.
- Anonymous communication during the meeting between the pCODR Review Team and the Submitter will be facilitated by the pCODR program.

5 Review of Non-Disclosable Information - Part Two of the Checkpoint Meeting

The procedures outlined below relate to part two of the Checkpoint Meeting.

- At part two of the Checkpoint Meeting, the pCODR program and the Submitter will discuss the management of Non-Disclosable Information included in the Submission.
- The duration of part two of the Checkpoint Meeting will be a maximum of one and a half hours. At the meeting, pCODR and the Submitter will go through the submitted Summary of Non-Disclosable Information tables and any submitted structured summaries of economic and

clinical information, focusing on relevant information that may be included in the pCODR Clinical Guidance Report and the pCODR Economic Guidance Report.

- If new Non-Disclosable Information is provided in part one of the meeting, an Addendum to the Summary Table of Non-Disclosable Information an electronic version must be provided by the Submitter at least **one (1) business day** in advance of the scheduled Checkpoint Meeting. No additional meeting materials are required.
- Submitter attendees should include at least one senior representative with the authority to make decisions regarding disclosure of information.
- Attendees from pCODR will include only CADTH staff.

6 Checkpoint Meeting Decisions

The pCODR program will write a *Record of Decisions* for the Checkpoint Meeting. Decisions will include both those related to Additional Information and clarification of the Submission as well as the review of Non-Disclosable Information in the Submission. Both pending decisions and decisions agreed upon at the Checkpoint Meeting will be documented.

The *Record of Decisions* will be provided to the Submitter and/or Manufacturer within two (2) business days of the Checkpoint Meeting via secure electronic transmission. An email notification will be sent to the Submission contact with a unique, time-limited and user-specific link to the Record of Decisions. The Submission contact is the individual identified as the contact by the Submitter when the Submission was filed with pCODR.

Decisions made at the meeting will not be open for further negotiation and discussion following the Checkpoint Meeting.

Upon receipt of the Record of Decisions, the Submitter will have five (5) Business Days to submit proposed resolutions to items noted as pending decisions. The Submitter should provide the resolution to pCODR through the secure Collaborative Workspaces.

The pCODR program will have five (5) Business Days to review the proposed resolutions. If agreement cannot be reached, pCODR will not use the information in the Clinical Guidance Report or the Economic Guidance Report provided to the pCODR Expert Review Committee (pERC).

An *Addendum to the Record of Decisions* will be written by pCODR and provided to the Submitter via secure electronic transmission, within five (5) Business Days of receiving the proposed resolutions from the Submitter. The *Addendum* will outline pCODR's final decisions on the management of Non-Disclosable Information in the review. An email notification will be sent to the Submission contact with a unique, time-limited and user-specific link to the *Addendum to the Record of Decisions*.

pCODR may share the *Record of Decisions* and *Addendum to the Record of Decisions* with Authorized Recipients, as defined in the *pCODR Disclosure of Information Guidelines*.

7 Verification of Handling Non-Disclosable Information Following the Checkpoint Meeting

Three (3) days prior to the posting of the pERC initial recommendation and the pCODR guidance reports, the Submitter will be provided with the opportunity to verify that Non-Disclosable Information was handled in the manner agreed upon at the Checkpoint Meeting, and as documented in the *Record of Decisions* and the *Addendum* to the Record of Decisions.

The Clinical Guidance Report and Economic Guidance Report to be publicly posted will be made available to the Submitter via secure electronic transmission. An email notification will be sent to the Submission contact with a unique, time-limited and user-specific link to the Clinical Guidance Report and Economic Guidance Report.

If during the review of the report, the Submitter and/or Manufacturer of the drug under review identify any discrepancies or errors, they should be submitted in writing to pCODR within the three (3) Business Day period through the secure Collaborative Workspaces. pCODR will consider the proposed discrepancies and errors and make revisions or additional redactions to the Clinical Guidance Report, the Economic Guidance Report and the pERC Initial Recommendation as deemed necessary by the pCODR program and prior to public posting of these documents. Discrepancies and errors should be documented in a table using the format provided below:

Verification of Non-Disclosable Information in Guidance Reports			
Discrepancies or Errors in Handling Non-Disclosable Information			
Report Location (EGR or CGR, page number)	Statement	Agreed upon handling of Non-Disclosable Information as per Checkpoint Meeting *Record of Decisions* & *Addendum*	Proposed Handling of Information
Gross Factual Errors			
Report Location (EGR or CGR, page number)	Statement	Correct Information and Location in Submission	Proposed Handling of Information

CGR: Clinical Guidance Report; EGR: Economic Guidance Report