pan-Canadian Oncology Drug Review
Clinical Guidance Report Template

[Insert Report Name and Number]

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RECORD OF UPDATES

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INQUIRIES

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1 GUIDANCE IN BRIEF

1.1 Background

[Insert Text Here]

1.2 Key Results and Interpretation

1.2.1 Systematic Review Evidence

[Insert Text Here]

Efficacy

Harms

1.2.2 Additional Evidence

[Insert Text Here]

Patient Advocacy Group Input

Provincial Advisory Group Input

Other

1.2.3 Interpretation and Guidance

[Insert Text Here]

1.3 Conclusions

[Insert Text Here]

2 CLINICAL GUIDANCE

This Clinical Guidance Report was prepared to assist the pCODR Expert Review Committee (pERC) in making recommendations to guide funding decisions made by the provincial and territorial Ministries of Health and provincial cancer agencies regarding [drug name and indication]. The Clinical Guidance Report is one source of information that is considered in the *pERC Deliberative Framework*. The *pERC Deliberative Framework* is available on the pCODR website,www.pcodr.ca.

This Clinical Guidance is based on: a systematic review of the literature regarding [drug name and indication] conducted by the [Tumour Group] Clinical Guidance Panel (CGP) and the pCODR Methods Team; input from patient advocacy groups; input from the Provincial Advisory Group; and supplemental issues relevant to the implementation of a funding decision.

The systematic review and supplemental issues are fully reported in Sections 6 and 7. Background Clinical Information provided by the CGP, a summary of submitted Patient Advocacy Group Input on [drug name and condition] and a summary of submitted Provincial Advisory Group Input on [drug name and indication] are provided in Sections 3, 4 and 5 respectively.

2.1 Context for the Clinical Guidance

2.1.1 Introduction

[Insert Text Here]

2.1.2 Objectives and Scope of pCODR Review

[Insert Text Here]

2.1.3 Highlights of Evidence in the Systematic Review

[Insert Text and Relevant Summary Tables Here]

2.1.4 Comparison with Other Literature

[Insert Text Here]

2.1.5 Summary of Supplemental Questions

[Insert Text Here]

2.1.6 Other Considerations

[Insert Text Here]

Patient Advocacy Group Input

PAG Input

Other

2.2 Interpretation and Guidance

[Insert Text Here]

Efficacy Interpretation

Harms Interpretation

2.3 Conclusions

[Insert Text Here]

3 BACKGROUND CLINICAL INFORMATION

This section was prepared by the pCODR [Tumour Group] Clinical Guidance Panel. It is not based on a systematic review of the relevant literature.

3.1 Description of the Condition

[Insert Text Here]

3.2 Accepted Clinical Practice

[Insert Text Here]

3.3 Evidence-Based Considerations for a Funding Population

[Insert Text Here]

3.4 Other Patient Populations in Whom the Drug May Be Used

[Insert Text Here]

4 SUMMARY OF PATIENT ADVOCACY GROUP INPUT

The following patient advocacy group(s) provided input on [drug name and indication] and their input is summarized below: [patient advocacy group 1, patient advocacy group 2, etc.].

4.1 Condition and Current Therapy Information

4.1.1 Experiences Patients have with [Cancer Type]

[Insert Text Here]

4.1.2 Patients' Experiences with Current Therapy for [Cancer Type]

[Insert Text Here]

4.1.3 Impact of [Cancer Type] and Current Therapy on Caregivers

[Insert Text Here]

4.2 Information about the Drug Being Reviewed

4.2.1 Patient Expectations for and Experiences To Date with [Drug Name]

[Insert Text Here]

4.3 Additional Information

[Insert Text Here]

5 SUMMARY OF PROVINCIAL ADVISORY GROUP (PAG) INPUT

The following issues were identified by the Provincial Advisory Group as factors that could affect the feasibility of implementing a funding recommendation for [drug and indication]. The Provincial Advisory Group includes representatives from provincial cancer agencies and provincial and territorial Ministries of Health participating in pCODR. The complete list of PAG members is available on the pCODR website (www.pcodr.ca).

5.1 Factors Related to Comparators

[Insert Text Here]

5.2 Factors Related to Patient Population

[Insert Text Here]

5.3 Factors Related to Accessibility

[Insert Text Here]

5.4 Factors Related to Dosing

[Insert Text Here]

5.5 Factors Related to Implementation Costs

[Insert Text Here]

5.6 Other Factors

[Insert Text Here]

6 SYSTEMATIC REVIEW

6.1 Objectives

[Insert Text Here]

6.2 Methods

6.2.1 Review Protocol and Study Selection Criteria

The systematic review protocol was developed jointly by the Clinical Guidance Panel and the pCODR Methods Team. Studies were chosen for inclusion in the review based on the criteria in the table below. Outcomes considered most relevant to patients, based on input from patient advocacy groups are those in bold.

Table 1. Selection Criteria

Clinical Trial Design	Patient Population	Intervention	Appropriate Comparators	Outcomes
[Abbreviations]				

6.2.2 Literature Search Methods

[Insert Text Here]

6.2.3 Study Selection

[Insert Text Here]

6.2.4 Quality Assessment

[Insert Text Here]

6.2.5 Data Analysis

[Insert Text Here]

6.2.6 Writing of the Review Report

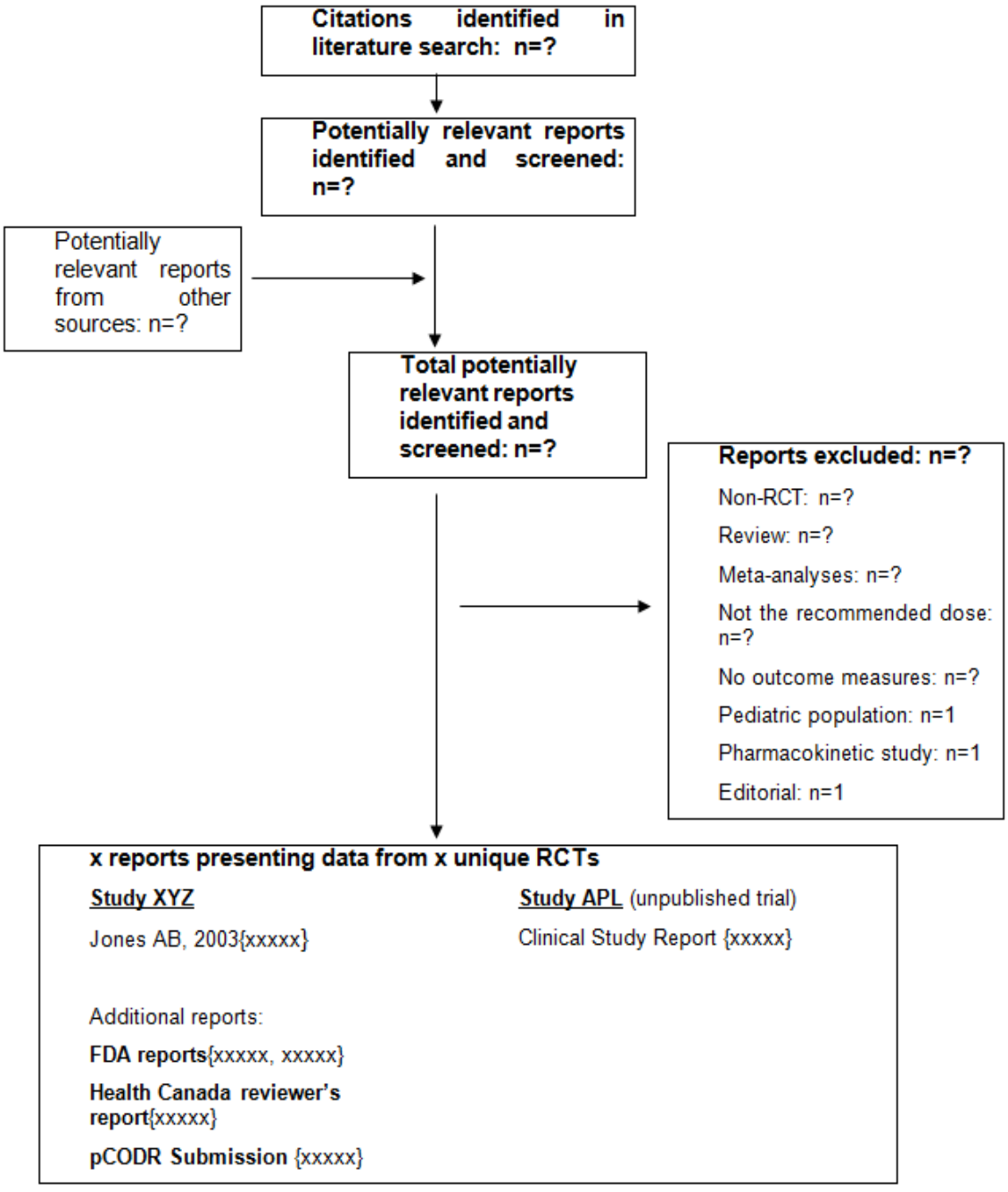
This report was written by the Methods Team, the Clinical Guidance Panel and the pCODR Secretariat:

- The Methods Team wrote a systematic review of the evidence and summaries of evidence for supplemental issues.
- The pCODR Clinical Guidance Panel wrote a summary of background clinical information, the interpretation of the systematic review and wrote guidance and conclusions for the report.
- The pCODR Secretariat wrote summaries of the input provided by patient advocacy groups and by the Provincial Advisory Group (PAG).

6.3 Results

6.3.1 Literature Search Results

Sample QUOROM Flow Diagram for Inclusion and Exclusion of studies



Note: Additional data related to studies XYZ, ZXC, APL were also obtained through requests to the Submitter by pCODR {xxxxx, xxxxx, xxxxx}

6.3.2 Summary of Included Studies

[Insert Text Here]

6.3.2.1 Detailed Trial Characteristics

a) Trials

[Insert Text Here]

b) Populations

[Insert Text Here]

c) Interventions

[Insert Text Here]

d) Patient Disposition

[Insert Text Here]

e) Limitations/Sources of Bias

[Insert Text and Summary Tables Here]

6.3.2.2 Detailed Outcome Data and Summary of Outcomes

a) Efficacy Outcomes

[Insert Text and Summary Tables Here]

b) Harms Outcomes

[Insert Text and Summary Tables Here]

6.4 Ongoing Trials

[Insert Text Here]

7 SUPPLEMENTAL QUESTIONS

The following supplemental issues were identified as relevant to the pCODR review of [drug name and indication]:

Topics considered in this section are provided as supporting information. The information has not been systematically reviewed.

7.1 [Issue 1]

7.1.1 Objective

[Insert Text Here]

7.1.2 Findings

[Insert Text Here]

7.1.3 Summary

[Insert Text Here]

7.2 [Issue 2]

7.2.1 Objective

[Insert Text Here]

7.2.2 Findings

[Insert Text Here]

7.2.3 Summary

[Insert Text Here]

8 ABOUT THIS DOCUMENT

This Clinical Guidance Report was prepared by the pCODR [Tumour Group] Clinical Guidance Panel and supported by the pCODR Methods Team. This document is intended to advise the pCODR Expert Review Committee (pERC) regarding the clinical evidence available on [drug name and indication]. Issues regarding resource implications are beyond the scope of this report and are addressed by the relevant pCODR Economic Guidance Report. Details of the pCODR review process can be found on the pCODR website (www.pcodr.ca).

The [Tumour Group] Clinical Guidance Panel is comprised of [type and number of clinicians] .The panel members were selected by the pCODR secretariat, as outlined in the pCODR Nomination/Application Information Package, which is available on the pCODR website (www.pcodr.ca). Final selection of the Clinical Guidance Panels was made by the pERC Chair in consultation with the pCODR Executive Director. The Panel and the pCODR Methods Team are editorially independent of the provincial and territorial Ministries of Health and the provincial cancer agencies.

APPENDIX A: LITERATURE SEARCH STRATEGY

[Insert Text here]

REFERENCES