pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

Transparency & Collaboration: The Pan-Canadian Oncology Drug Review

Applied Research in Cancer Control Conference

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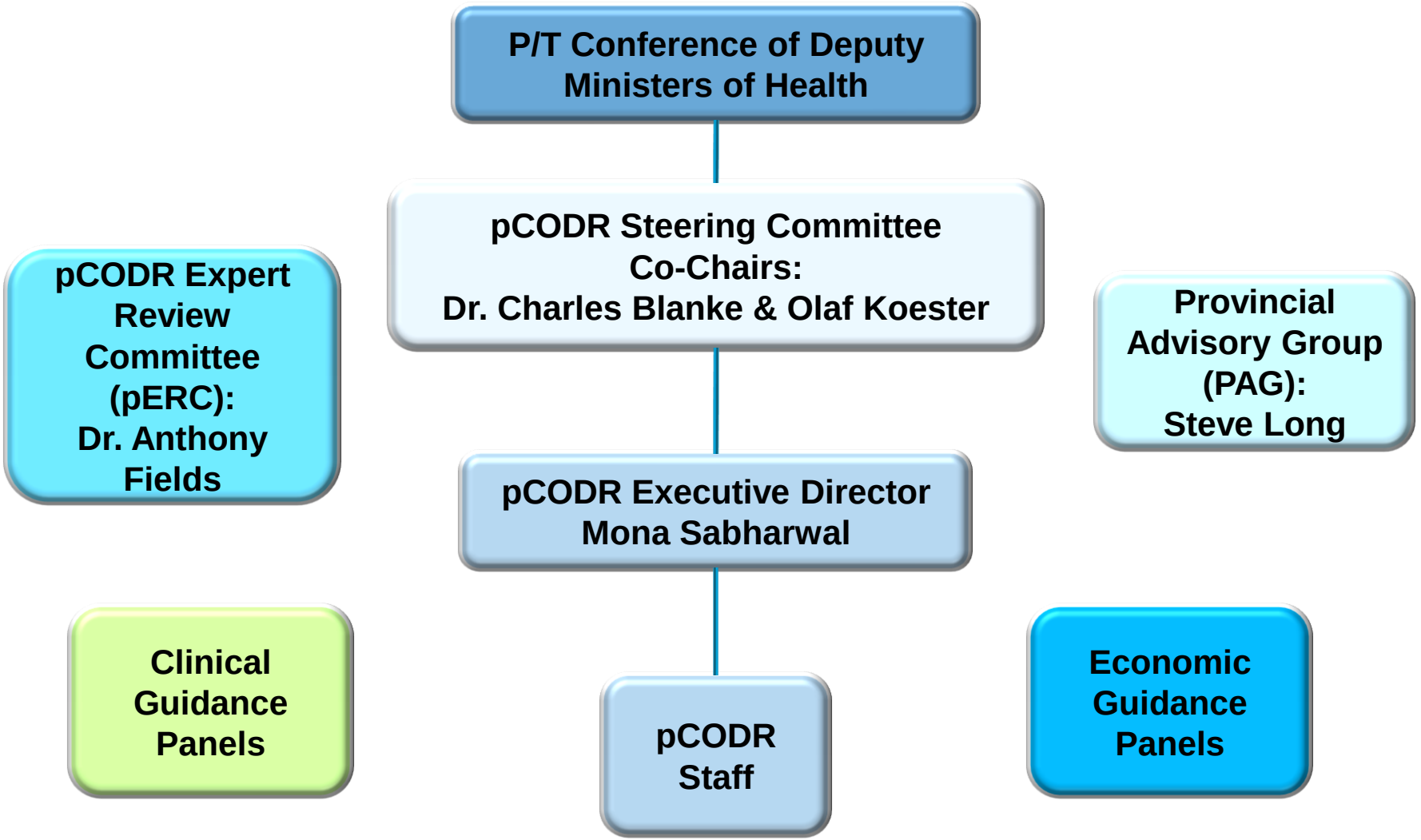
About pCODR

- Assesses cancer drugs and makes recommendations to provinces and territories to guide their drug funding decisions
- Designed to bring consistency and clarity to assessment of cancer drugs by looking at clinical evidence, cost-effectiveness and patient perspectives
- pCODR's partners:
  - provinces and territories (with the exception of Quebec)
  - provincial cancer agencies
  - Canadian Partnership Against Cancer (CPAC)
  - Canadian Agency for Drugs and Technologies in Health (CADTH)
- Committed to transparency and the need to be accountable to patients and public, and responsive to industry

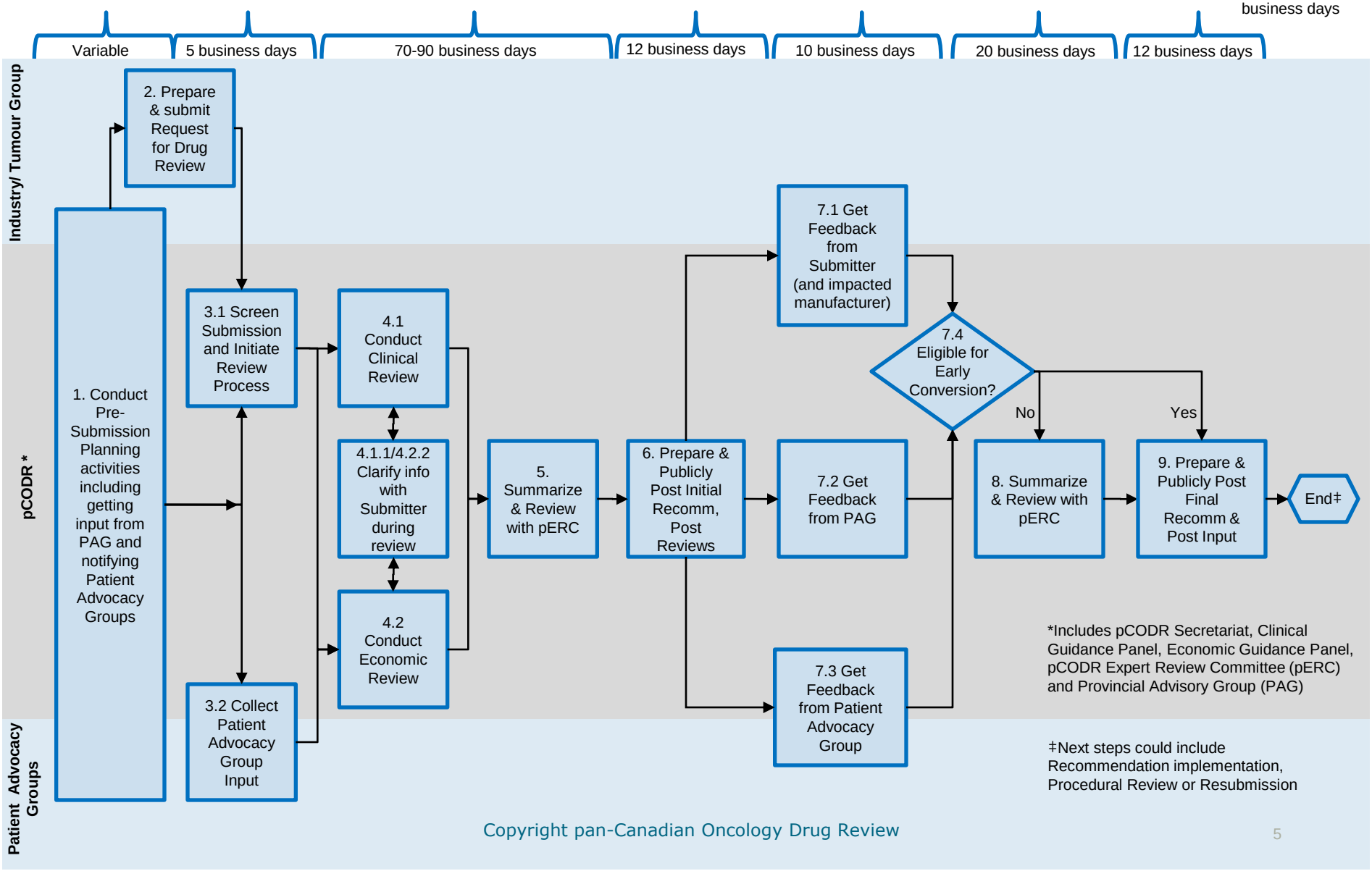
pCODR Guiding Principles - Overview

- Accountable governance
- Collaborative and representative
- Efficient and effective
- Continuous evaluation
- Health system focused
- Evidence-based
- Committed to excellence
- Ethical

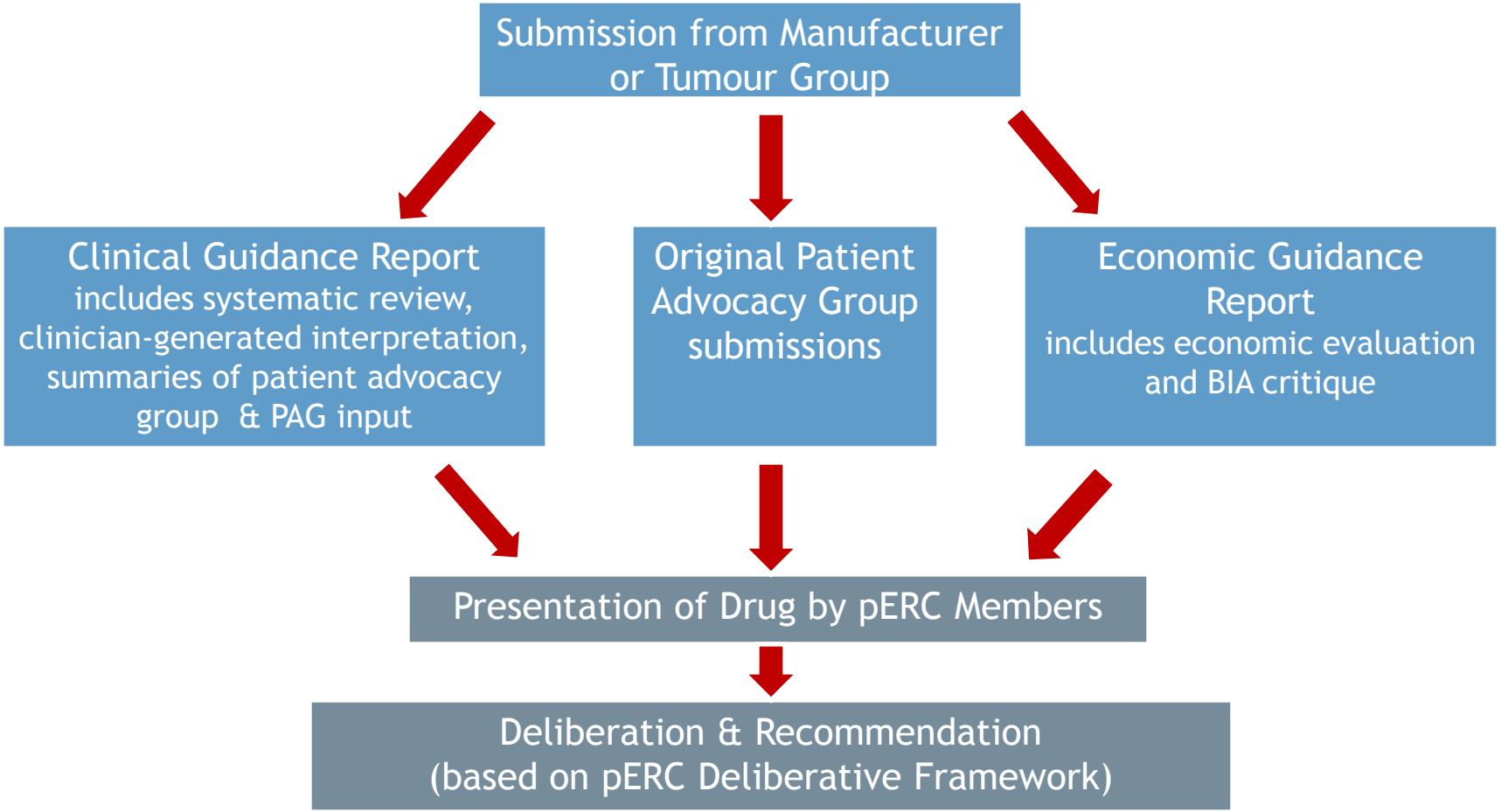
pCODR Structures



pCODR Review Process



Inputs into pERC Recommendations



pERC Deliberative Framework

- Developed collaboratively by pCODR Clinical and Process working group and pCODR Steering Committee
- Outlines elements to be considered during pERC deliberations
- Reinforces that no single element over-rides another, rather it is sum of all elements that pERC must use
- Can be applied to all oncology drugs and situations, including rare cancers or end of life drug treatments
- Reinforces there is no threshold that must be met for any single element in the review
- It is the individual drug, disease and context that determine pERC's information needs for each element of the framework

Role of Panels and pERC

- pERC deliberates on the drug and makes a funding recommendation taking into consideration:
  - Overall Clinical Benefit
  - Cost Effectiveness
  - Alignment with Patient Values
  - Feasibility of Adoption into Health Systems
- The Clinical Guidance Panel makes conclusions on the net overall clinical benefit of the drug for consideration by pERC
- The Economic Guidance Panel evaluates the submitted economic model and develops their own best estimates of cost-effectiveness for consideration by pERC. The panel also advises on considerations regarding budget impact analysis.

Collaborative Effort in Developing Clinical Guidance Reports

Participation in pCODR Reviews	Role
Methodologists	• Develop systematic review protocol • Conduct systematic review • Provide critical appraisal of evidence
Clinical Guidance Panel/Oncologists	• Provide evidence-based summary of clinical practice context • Develop systematic review protocol • Interpret systematic review results • Write guidance • Provide a conclusion on overall clinical benefit
Patient Advocacy Groups	• Provide input to pCODR which is incorporated into review protocol, e.g. side effects with existing therapy, inform adverse event outcomes
Ministries of Health and Cancer Agencies	• Provide input to pCODR which is incorporated into review protocol, e.g. most relevant and utilized comparators
Economic Guidance Panel /Economists	• Provide input on systematic review protocol, e.g. comparators and outcomes to consider based on those included in economic model
pERC	• Respond to questions from pCODR on scope and development of review, on an as-needed basis

Collaborative Effort in Developing Economic Guidance Reports

Participation in pCODR Reviews	Role
Economic Guidance Panel /Economists	• Assesses economic model and budget impact analysis provided in submission • Provide alternate estimates of overall cost-effectiveness • Provide guidance on budget impact considerations
Patient Advocacy Groups	• Provide input to pCODR which is incorporated into economic review protocol, e.g. patient-relevant outcomes, MCID
Ministries of Health and Cancer Agencies	• Provide input to pCODR which is incorporated into review protocol, e.g. drug wastage
Clinical Guidance Panel/Oncologists	• Provide clinical input to EGP which is relevant to economic review, e.g. comparators, health outcome measures, clinical assumptions
Methodologists	•Work with EGP on systematic review protocol, e.g. comparators and outcomes to consider based on those included in economic model
pERC	• Respond to questions from pCODR on scope and development of review, on an as-needed basis

pCODR's Approach to Transparency

- pCODR has committed itself to transparency and the need to be accountable to patients and the public, and responsive to industry
- pCODR considers it essential that the evidence upon which pERC recommendations are based be publicly available
- pCODR posts review related documents publicly:
  - Initial pERC recommendation with key messages, a summary of pERC deliberations and relevant background information
  - Full clinical guidance report
  - Summary of economic guidance report
  - Final pERC recommendation with key messages, a summary of pERC deliberations and relevant background information
  - All feedback submitted on an initial recommendation

pCODR's Approach to Disclosure of Information

- pCODR recognizes and respects that information owners retain right to make final decision in relation to release of information into public domain
- pCODR reserves right to determine how non-disclosable information is used in pERC deliberations, if at all
- Submitters should keep to a minimum the types and volume of information they consider to be non-disclosable
- Submitters are accountable for self-identifying that information which they consider to be non-disclosable

pCODR's Approach to Disclosure of Information

- A formal process step allows submitter and pCODR to dialogue in-person, then 10-day dispute resolution period to have clear up-front understanding of use of non-disclosable information
- Under exceptional circumstances, information that owner has decided not be allowed into public domain could be accepted for inclusion in pERC deliberations under agreement of confidentiality through redaction e.g., journal has publication embargo
- Redaction of information would be time-limited, to allow owner primary determination of release into public domain

Early observations on the process

- Checkpoint Meeting very well received by pCODR Review Team – opportunity for clarification and dialogue valued
- Guidance Panels approach, with mix of clinical and technical expertise, brings depth of perspectives
- Transparency requires thoughtfulness, for manufacturers and reviewers alike
- Provincial Advisory Group connected to the process, as seen by input and feedback being provided for upcoming submissions
- pCODR Expert Review Committee demonstrating commitment and open-mindedness

Thank you and Questions?

Appendix A: pCODR Structure Descriptions and Membership

pCODR Structures Description (1)

P/T Conference of Deputy Ministers of Health
Deputy Ministers of Health from participating provincial and territorial governments have overall accountability for and provide direction to the pCODR Steering Committee.

pCODR Steering Committee
Reporting to the Conference of P/T Deputy Ministers, the role of the pCODR Steering Committee is to oversee the development and implementation of the pCODR, provide strategic direction to the collaborative, including the Executive Director. The pCODR Steering Committee is comprised of six senior level P/T representatives, four senior level cancer agency representatives, one CADTH representative (observer), and one CPAC representative (observer).

pCODR Expert Review Committee (pERC)
The role of the pERC is to assess the clinical evidence and cost effectiveness of new cancer drugs, and to use this information to make recommendations to the provinces and territories to guide their drug funding decisions.

Provincial Advisory Group (PAG)
The PAG provides primarily operational, as well as some strategic advice, to ensure recommendations are useful to drug funding decision makers. The PAG consists of appointed representatives from each of the provincial Ministries of Health and provincial cancer care agencies participating in the pCODR.

pCODR Structures Description (2)

Clinical Guidance Panels
The pCODR Clinical Guidance Panels consist of oncologists from across Canada and will be structured around specific tumour types. Initially, there will be 11 tumour-based panels. Each of the Clinical Guidance Panels will contribute to the pCODR process by working with either the Program in Evidence-Based Care (PEBC) or the Canadian Agency for Drugs and Technologies in Health (CADTH) to generate a high quality systematic review. In addition, each Clinical Guidance Panel will generate a clinical guidance document. Although the clinical guidance document will follow a general template, it will be the responsibility of the Clinical Guidance Panels to determine the breadth and depth of the information included in the guidance document based on the submission under consideration. These elements of the clinical review will be used by the pERC in making its recommendations.

Economic Guidance Panels
The pCODR Economic Guidance Panels will be established on a per-cancer drug submission basis to generate pCODR economic review deliverables. The mandate of the Economic Guidance Panels is to assess the economic evidence provided by the submitter for each cancer drug submission filed with the pCODR. The economic assessment report will be used by the pERC in making its recommendations.

pCODR Executive Director & Staff
The Executive Director is responsible for the leadership, development, and delivery of the pCODR. The pCODR staff is responsible for the administrative duties associated with the pCODR process.

pCODR Steering Committee Participants

Co-Chairs

- Dr. Charles Blanke, Co-Chair, pCODR Steering Committee, Vice-President, Systemic Therapy, British Columbia Cancer Agency
- Olaf Koester, Co-Chair, pCODR Steering Committee, Director, Drug Management Policy Unit, Manitoba Health

Members

- Tijana Fazlagic, Director of Formulary Management, Pharmaceutical Services, British Columbia Health Services
- Steve Long, Executive Director, Pharmaceutical Funding and Guidance Branch, Alberta Health and Wellness
- Kevin Wilson, Executive Director, Drug Plan & Extended Benefits Branch, Saskatchewan Ministry of Health
- Scott Livingstone, CEO, Saskatchewan Cancer Agency
- Brent Fraser, Director, Ontario Public Drug Programs, Ontario Ministry of Health and Longterm Care
- Dr. Carol Sawka, Vice-President, Clinical Programs and Quality Initiatives, Chair of the Clinical Council for Cancer Care Ontario
- Judy McPhee, A. Director, Pharmaceutical Services, Nova Scotia Department of Health
- Dr. Kara Laing, Clinical Chief, Eastern Health Cancer Care Program

National Observers

- Aslam Bhatti, Chief Financial and Administrative Officer, CPAC
- Chander Sehgal, Director, Common Drug Review and Rapid Response, CADTH

Provincial Advisory Group Participants

Chair

- Steve Long, Executive Director, Pharmaceutical Funding and Guidance Branch, Alberta Health and Wellness

Members

- Jillian Hardy, Pharmacist, Formulary Management, Pharmaceutical Services, British Columbia Health Services
- Dr. George Browman, Medical Oncologist, BC Cancer Agency
- Fred Rumpel, Senior Manager, Pharmaceutical Funding and Guidance Branch, Alberta Health and Wellness
- Carole Chambers, Director, Cancer Services, Tom Baker Cancer Clinic Pharmacy
- Anne Champagne, Senior Pharmaceutical Policy Analyst, Drug Plan & Extended Benefits Branch, Saskatchewan Ministry of Health
- Kathy Gesy, Provincial Leader, Oncology Pharmacy Services, Saskatchewan Cancer Agency
- Kathy McDonald, Pharmaceutical Consultant, Provincial Drug Programs, Manitoba Health
- Venetia Bourrier, Director of Provincial Oncology Drug Program, CancerCare Manitoba
- Christine Seager, Acting Senior Manager, Drug Benefits Management, Ontario Public Drug Programs, Ontario Ministry of Health and LongTerm Care
- Scott Gavura, Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario (Vice-Chair)
- Lisa Zwicker, Manager, Insured Pharmaceutical Programs, Nova Scotia Department of Health and Wellness
- Dr. Mark Dorreen, Chief, Division of Medical Oncology at Dalhousie University and Medical Lead, Provincial Medical Oncology Program
- Brenda Wild, Clinical Pharmacist, Department of Health and Community Services, Pharmaceutical Services Division, Newfoundland and Labrador
- Leanne Jardine, Executive Director, Pharmaceutical Services, New Brunswick Department of Health (alternate – Andrea Walsh)
- Diane Strong, Provincial Director of Pharmacy, New Brunswick Cancer Network
- Roy Cairns, Pharmacy Consultant, Health System Planning & Development, PEI Department of Health and Wellness
- Dr. Philip Champion, FRCPC, Prince Edward Island Cancer Treatment Center

pERC Membership

Chair

- Dr. Anthony Fields, Oncologist

Vice-Chair

- Dr. Maureen Trudeau, Oncologist

Members

- Dr. Chaim Bell, Economist
- Dr. Scott Berry, Oncologist
- Bryson Brown, Patient Representative
- Mario de Lemos, Pharmacist
- Dr. Sunil Desai, Oncologist
- Mike Doyle, Economist
- Dr. Bill Evans, Oncologist
- Dr. Alan Grill, Family Physician
- Dr. Paul Hoskins, Oncologist
- Danica Lister, Pharmacist
- Carole McMahon, Patient Alternate
- Jo Nanson, Patient Representative
- Dr. Peter Venner, Oncologist
- Dr. Tallal Younis, Oncologist

Appendix B: Oncology Drug Funding in Canada

Provincial Drug Plans

- Administered by Ministries of Health
- Each develops and maintains its own formulary (lists of drugs covered by plan)
- Different from plan to plan
  - ~ 55 - 60% commonality of drug listings across jurisdictions
  - ~ 90% of reimbursement within a set of core drugs
- Each formulary will include elements to manage drug utilization:
  - Benefits, criteria and conditions, prior authorization
- Tendency to add to list but not review old listings

Provincial Cancer Agencies

- Eight of ten Canadian provinces have formally structured provincial cancer agencies or separate divisions within their ministry, which are responsible for a provincial system of cancer control
- Varying responsibilities for drug funding
- Apply knowledge and best practices to a spectrum of activities, including prevention, screening, diagnosis, treatment, rehabilitation/support and palliative care
- Varying levels of basic research, translational research, clinical research and population-based epidemiologic research
- Many of the provinces have cancer acts that clearly define responsibilities

Who is Responsible for Cancer Drug Funding?

	Hospital	Cancer Agencies	Provincial or Territorial Drug Plan
BC		X	
AB		X	X
SK		X	
MB		X	X
ON	X	X	X
NB	X		X
PEI	X		X
NS	X		X
NL	X		X

Appendix B: Funding Recommendations

Funding Recommendations

- pERC recommendations will help guide funding decisions; final funding decisions remain responsibility of each participating jurisdiction
- Funding recommendations are not static - they are context specific, such as:
  - Evidence available at that point in time
  - Existing programs and policies – who is covered, what is/is not covered
  - Basket of currently available and/or funded treatment options
  - Current pricing arrangements
- Almost all cancer drug funding bodies (ministry or agency) in Canada already identify specific patient populations or context for use (e.g., protocols) within their funding criteria for cancer drugs

Categories for pERC Recommendations

- Developed collaboratively between pCODR Steering Committee and Provincial Advisory Group, to get both strategic and implementation viewpoints
- For pERC recommendations to be most useful to end-users, a thoughtful balance of competing objectives is being pursued:
  - Flexibility, respecting autonomy of funding body and need to address local issues
  - Directionality (positive/negative/equivocal) and priority, to leverage best advice possible at a point in time

Three Categories of pERC Recommendations

Recommend

- A drug with a clear clinical benefit and economic benefit

Consider with Conditions

- Provides context and describes conditions under which a specific jurisdiction may or may not want to fund the drug
- These conditions would relate to issues that directly change the efficacy or cost-effectiveness of the drug
- Factors or conditions to consider could include utilization patterns, funding of comparators, availability/accessibility of other options

Do Not Recommend

- No reason to recommend identified during pERC deliberations

Detailed Description of Each Element of the pERC Deliberative Framework (1)

Criteria	Sub-Criteria	Sub-Criteria Definitions
Overall Clinical Benefit	Effectiveness (systematic review in the Clinical Guidance Report)	The potential health impact of the drug compared to the other drug and non-drug alternatives, measured in terms of relevant patient outcomes such as mortality, morbidity, quality of life. Magnitude, direction and uncertainty of effect should be considered.
	Safety (systematic review in the Clinical Guidance Report)	Frequency and severity of adverse effects associate with the new drug compared to other drug and non-drug alternatives.
	Burden of Illness (Clinical Guidance Report, patient advocacy group input)	Incidence, prevalence or other measure of disease burden on the population.
	Need (Clinical Guidance Report, patient advocacy group input)	Availability of an effective alternative to the drug technology.

Detailed Description of Each Element of the pERC Deliberative Framework (2)

Criteria	Sub-Criteria	Sub-Criteria Definitions
Alignment with Patient Values	Patient Values (patient advocacy group input)	Patient based values which bear on the appropriate use and impact of the drug.
Cost effectiveness	Economic Evaluations (Economic Guidance Report and pharmaco-economic model review)	A measure of the net cost or efficiency of the drug and companion technology compared to other drug and non-drug alternatives. The uncertainty of results should be considered.
Feasibility of Adoption into Health Systems	Economic Feasibility (evaluation of budget impact assessment in Economic Guidance Report)	The net budget impact of the new drug on other drug and health system spending, including companion testing technology.
	Organizational Feasibility (Provincial Advisory Group input)	The ease with which the new drug can be adopted, with an assessment of health system enablers and barriers to implementation, inclusive of all elements: operational, capital, human resources, legislative and regulatory requirements