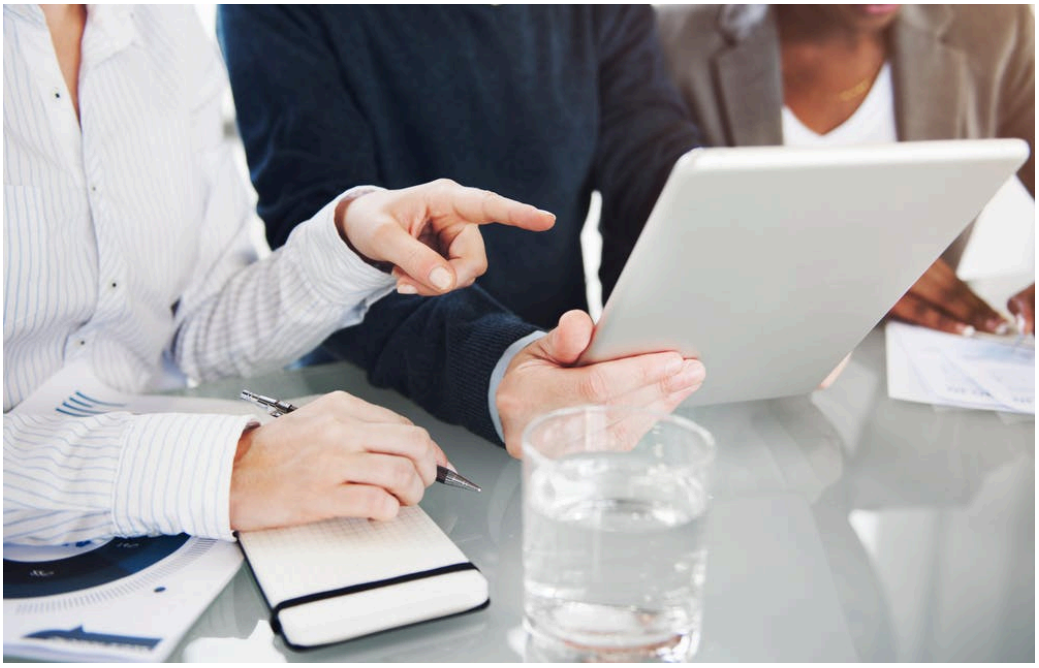
THE CANCER DRUG FUNDING SUSTAINABILITY INITIATIVE



30 April 2019

A Review of Program Development and Implementation – 2016 to 2019

The Cancer Drug Funding Sustainability Initiative

A REVIEW OF PROGRAM DEVELOPMENT AND IMPLEMENTATION – 2016 TO 2019

A MESSAGE FROM THE CHAIR

Canada is home to one of the best cancer systems in the world. However, provincial health systems are facing significant challenges due to increasing numbers of Canadians with cancer and the increasing cost of cancer treatment. The pressure on drug budgets is not sustainable.

A number of years ago, CAPCA's Board of Directors recognized that to build a more sustainable approach to drug funding, CAPCA should lead a coordinated effort across jurisdictions to strengthen how provinces evaluate, purchase and implement drugs in Canada. Working with partners, CAPCA launched the Cancer Drug Funding Sustainability Initiative early in 2016. Three years later we are pleased to report positive progress.

This has been primarily achieved through the creation and implementation of the Cancer Drug Implementation Advisory Committee (CDIAC). The CDIAC has proven to be an effective mechanism for provinces to increase consistency in funding decisions and inform pan-Canadian price negotiations. Our work has demonstrated that assessing scientific evidence for clinical benefit for patients and cost effectiveness is simply not enough. It is necessary to differentiate the clinical value of new cancer drugs against existing therapies and look at how new drugs fit into existing funding pathways. It has also demonstrated how critical it is to have these discussions at a pan-Canadian table, which includes all provincial cancer agencies and programs, as well as CADTH and pCPA.

Perhaps our biggest impact has been supporting greater harmonization of oncology drug coverage across Canada and helping provinces optimize their processes to get the best drugs to cancer patients in a timely way.

With this demonstrated success, a few key functions of our work are ready for transition to a more permanent home with CADTH. We are proud of the progress we have made over the last three years and look forward to our continued involvement in the area of drug funding sustainability. This report is intended to recap work to date, including results of the 2018 evaluation, and provide an overview of CAPCA's role moving forward as it relates to drug funding sustainability.

CAPCA and its Board of Directors have the unique capacity to bring the provinces together to focus on common challenges within the cancer system. Our impact in such a short period reinforces the impact of our collective focus.

Regards,

Michael Sherar
Chair, CAPCA Board of Directors

1. Overview

In 2016 CAPCA and its partners launched the Cancer Drug Funding Sustainability Initiative to strengthen cancer drug evaluation, funding and implementation across Canada. The objectives were to ensure that Canadian patients continue to have access to innovative and effective cancer treatments while supporting jurisdictions in achieving maximum value for money invested.

CAPCA launched this work in response to the growing challenges facing provincial health systems. The number of Canadians with cancer is growing and many of them require treatment for longer periods of time. The cost of cancer treatments – in particular drug costs – are rising rapidly, and the number of new treatments becoming available continues to grow.

The pressure on drug budgets is not sustainable and without a change in approach, Canadians may not have access to innovative cancer drugs in the future. There will also be fewer resources for other areas of cancer care, healthcare in general and society overall.

In the three years since CAPCA launched the Cancer Drug Funding Sustainability Initiative, significant progress has been made. This has been primarily achieved through the creation and implementation of the Cancer Drug Implementation Advisory Committee (CDIAC), which has proven to be an effective mechanism for provinces to increase consistency in funding decisions and inform pan-Canadian price negotiations.

Other positive outcomes of CAPCA's work include:

- Greater information sharing across the country and consistency in messaging through the establishment of the Cancer Drug Funding Communications Working Group.
- Contributions to a national understanding of affordability and budget impact and sustaining a focus on the role of real-world evidence in informing cancer drug funding and use.

To ensure viability and sustainability, key components of CDIAC will transition to CADTH in 2019. CAPCA will continue to remain involved and focused on issues relating to cancer drug funding sustainability through its work with CADTH and other partners.

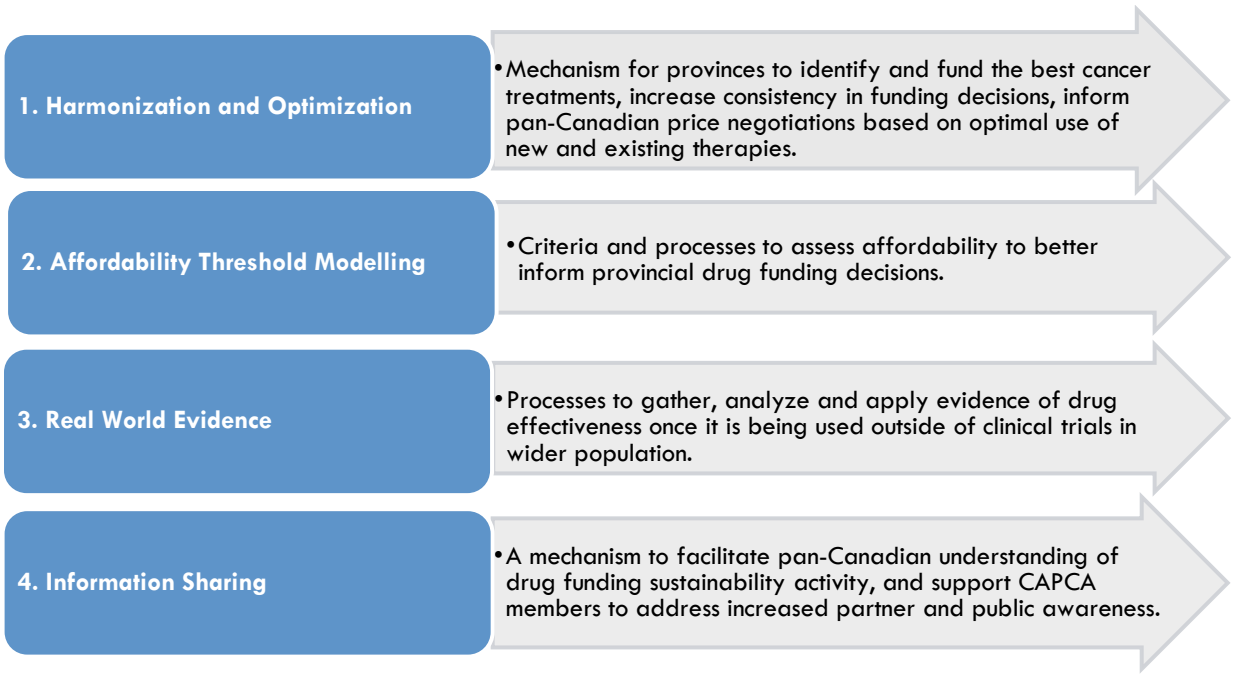
2. Development of the Cancer Drug Funding Sustainability Initiative

In 2015 the Cancer Quality Council of Ontario (CQCO) completed a Programmatic Review in which international, pan-Canadian, provincial and local experts, and patients were invited to help shape and comment on recommendations to address the sustainability of provincial drug funding programs.

The CAPCA Board of Directors took CQCO's recommendations forward and agreed to develop a process for prioritizing new cancer drugs and engaging with stakeholders about the prioritization approach. This was captured in a consensus statement presented by CAPCA to provincial ministries and departments of health in December 2015. All provinces indicated support to move forward.

Work got underway in 2016 to develop a common approach and strengthen pan-Canadian collective capacity for evaluating the affordability of new cancer drugs and real-world evidence. A key goal was to work with existing processes for drug evaluation and price negotiation established by CADTH/pCODR and INESSS in Quebec, and pCPA.

The following streams of work were identified and developed:



Partner organizations involved in the work:

- **CAPCA:** An association of provincially designated cancer programs, CAPCA provides a forum for leaders of Canada's cancer care system to address issues affecting cancer care delivery in Canada. The Board is made up of the most senior leaders responsible for cancer care in each province and the CEO of the Canadian Partnership Against Cancer.
- **Canadian Agency for Drugs and Technologies in Health /pan-Canadian Oncology Drug Review (CADTH/pCODR):** Housed within CADTH, pCODR is an evidence-based, cancer drug review process designed to bring consistency and clarity to the assessment of cancer drugs. It reviews clinical evidence, cost-effectiveness, and clinician and patient perspectives to make recommendations to Canada's provinces and territories (except Quebec) to guide their drug funding decisions.
- **Canadian Partnership Against Cancer (CPAC):** An independent organization funded by the federal government to accelerate action on cancer control for all Canadians.
- **Institut national d'excellence en santé et services sociaux (INESSS):** An organization that promotes clinical excellence and the efficient use of resources in the health and social services sector for the province of Quebec. It assesses clinical advantages and costs of technologies, medications and interventions used in health care and social services and provides recommendations to the minister of health concerning adoption, use and funding, and development of clinical practice guidelines to ensure optimal use.
- **The pan-Canadian Pharmaceutical Alliance (pCPA):** All provinces and territories and federally funded drug plans participate in pCPA. The goal is to work together to achieve greater value for brand name and generic drugs for publicly funded drug programs.

3. Implementation and Impact

Cancer Drug Implementation Advisory Committee

The Cancer Drug Implementation Advisory Committee (CDIAC) was created in April 2016 to provide a mechanism for provinces to discuss and share information about how new drugs will be integrated into current treatment plans, and by creating funding algorithms to help provinces identify and deliver the best cancer treatment. While the primary goal was to lead to greater consistency in drug funding decisions, it also was intended to inform pan-Canadian price negotiations and enhance information available to CADTH (INESSS in Quebec) and pCPA.

The group brought together experts who were already working on the evaluation and assessment of new cancer drugs at the provincial level including pharmacy leads, medical oncologists and an ethicist. Following input through a stakeholder consultation process in 2017, a patient, a family and a public representative all joined the CDIAC.

Between April 2016 and April 2019 CDIAC met on average monthly. While every drug that received a recommendation by pCODR to reimburse or reimburse with clinical criteria or conditions could be considered eligible for discussion by CDIAC, the primary focus was on drugs for which implementation issues may be considered a factor in funding and sustainability decisions.

Recommendations were submitted by CDIAC to the CAPCA Board of Directors. Once reviewed and endorsed, CAPCA shared the recommendations as advice to provincial ministries, and as needed to pCPA for their consideration.

As of April 2019, the CDIAC has submitted recommendations to the CAPCA Board for:

1. Acute lymphoblastic leukemia
2. Breast cancer
3. Castration-resistant prostate cancer
4. Classical Hodgkin's lymphoma
5. Chronic lymphocytic leukemia
6. Hepatocellular carcinoma
7. Hodgkin's lymphoma
8. Metastatic breast cancer
9. Metastatic melanoma
10. Metastatic Merkel cell carcinoma
11. Metastatic pancreatic cancer
12. Metastatic renal cell carcinoma
13. Metastatic urothelial cancer
14. Multiple myeloma
15. neuroblastoma
16. Non-small cell lung cancer
17. Ovarian cancer
18. Soft tissue sarcoma
19. Squamous cell carcinoma of head and neck

The CDIAC membership as of April 2019 can be found in Appendix A. Information about the transition of key functions of CDIAC to CADTH is described in the Looking Ahead section.

Drug Funding Sustainability Communications Working Group

The DFS Communications Working Group was established as a mechanism to facilitate pan-Canadian understanding of drug funding sustainability activity, and to help prepare CAPCA members for increased partner and community awareness of related work and recommendations. The group provided communications input and guidance to the development of materials and communications planning and served as a liaison and central point of contact for related discussions. Their input was provided in an advisory capacity to the CAPCA Board of Directors.

Membership was comprised of communications representatives from cancer agencies / health ministries, CADTH and CPAC. A patient liaison provided input to key messages directly to CAPCA staff however did not sit formally on the group.

DFS Communications Working Group members as of April 2019 can be found in Appendix A. General key messages about the DFS work can be found in Appendix B.

Affordability Threshold Working Group

The Affordability Threshold Working Group (ATWG) was established in November 2016 to recommend an approach to address both the affordability and budget impact of new cancer drugs, and a process to expedite

access to therapies that have the greatest potential patient benefit. The working group included experts in health economics, health technology, provincial pharmacy and medical oncology, analysis and modeling, and ethics. CADTH/pCODR and the pCPA were also represented to ensure the work was appropriately embedded within the broader oncology drug approval pipeline.

The ATWG's work culminated in a brief submitted to the CAPCA Board in July 2017 that detailed the following:

- *Affordability Threshold Model* – A province's ability to cover additional costs of new oncology drugs can be prospectively defined at the beginning of each funding cycle, then allocated to the set of new therapies expected to receive Health Canada approval and a pCODR positive (or positive conditional) recommendation. Dividing the net funding envelope by the expected number of new therapies can provide an estimate of the maximum additional cost that can be incurred and facilitate more accurate short and mid-term budget forecasting and planning.

- *Budget Impact Analysis Model (BIA)* – Standardizing the methods, reporting and user-interface of BIA tools that reflect current best practice for cost-effectiveness analysis and value assessment will allow funders to make more consistent and better-informed decisions regarding the affordability of new oncology drugs. Consistency across resource-use models for budget impact and cost effectiveness, improved analysis of manufacturer data on incidence, prevalence and uptake, and standardized BIA reporting tools will improve the accuracy of budget impact assessments and allow payers to make better informed decisions.

- *Prioritization* – Augmenting the existing effectiveness and budget impact assessment through the introduction of a weighted "additional value" profile that supports a therapy's elevation up a prioritization list would help expedite access to therapies that have the greatest potential patient benefit.

While the initial intent was to incorporate budget impact, affordability and prioritization into the work of CDIAC, the CAPCA Board modified its approach to adopting the recommendations for two reasons:

- Concurrent discussions by CAPCA and CADTH regarding the potential shift of key CDIAC functions were expected to provide greater opportunity to embed affordability into the already robust pCODR process.

- The Government of Canada's announcement in 2017 of a refresh of the *Patented Medicines Regulations* and the Patented Medicine Prices Review Board (PMPRB) guidelines would bring greater consistency to manufacturer-submitted budget impact assessments (BIA) and had the potential to shift such considerations upstream, and potentially introduce efficiencies within the oncology drug approval pipeline.

ATWG recommendations have helped inform the transition of elements of CDIAC to CADTH and CAPCA continues to work with PMPRB to integrate a robust BIA tool into their guideline refresh. The theoretical nature of the ATWG's recommended prioritization assessment "additional value" profile was felt to be too immature to implement as part of the Cancer Drug Funding Sustainability Initiative and may be considered as a future priority. The ATWG wrapped up in July 2017. Its membership can be found in Appendix A.

Real World Evidence

Improving the ability to collect, analyze and apply real world evidence (RWE) in decision making can support reassessment and renegotiation of funded cancer drugs and was highlighted as a priority for CAPCA's Drug Funding Sustainability Initiative. In a supportive role CAPCA contributes to two projects led by CPAC:

- *Pan-Canadian Data Standard* - The development of a common data standard for cancer drugs in partnership with the Canadian Institute for Health Information (CIHI) yielded a CIHI-published minimum data standard in April 2018 based on CPAC's engagement of a broad group of Canadian experts, clinicians and provincial registry representatives.
- *The Application of Real World Evidence* – In 2017, a proof of concept study examining the real world evidence of an established drug was undertaken in collaboration with British Columbia, Saskatchewan and Ontario. The project set to determine the feasibility of assessing RWE compared with pre-implementation projections and other standard-of-care treatment options. The study was designed to assess four outcomes including 1) budget impact analysis and treatment utilization 2) effectiveness 3) safety and 4) cost-effectiveness.

The CPAC case study helped inform work of the Canadian Real-world Evidence for Value of Cancer Drugs (CanREValue) project funded by CIHR. The objective is to develop a framework for the generation and use of RWE for cancer drugs to enable health technology reassessment for recommendation-makers and the reassessment of funding decisions and criteria or renegotiations. CAPCA and other key partners have been involved in this work, which is expected to culminate in a set of recommendations in 2020 and will continue to find opportunities to connect RWE efforts across Canada to reduce fragmentation. Ministries will determine what process changes need to be implemented in order to be able to consider RWE once collected and available.

Deliberative Public Engagement

Although not formally part of the Cancer Drug Funding Sustainability Initiative, a project worth noting is CPAC's Deliberative Public Engagement.

In 2016 CPAC hosted events in communities across Canada to engage Canadians about their priorities for making cancer drug funding fair and sustainable. This work built on a deliberative public engagement program delivered by the Canadian Centre for Applied Research in Cancer Control (ARCC) in British Columbia in 2014.

CPAC's work was the first pan-Canadian approach to engage Canadians to understand their concerns and perspectives on:

- How health system resources should be allocated for cancer drug funding.
- How to approach making difficult decisions when using public health care funds in a way that is fair to all Canadians and is sustainable over time.

CPAC focused on cancer drug funding because cancer treatment costs have increased at a faster rate than in other areas of healthcare, and system leaders rank increasing treatment costs as a leading concern for the sustainability of the cancer system.

Participants from the six deliberative public engagement events identified recommendations that can be grouped into six themes:

- Cancer drug funding decision-making processes should be adequately supported through a range of inputs and evidence.
- Cancer drug spending must be justified using clear and consistent principles.
- Processes for re-reviewing data and making disinvestments should be developed and should be based on clear and consistent principles.
- Ensuring fairness and equity are important principles when considering the funding of cancer drugs.
- Decision-making processes, decisions and their rationales should be transparent and made available to the public.
- There should be a pan-Canadian approach to cancer drug funding decisions.

Findings were shared with the provincial cancer agencies and programs, and with CAPCA, and discussed by CDIAC to help guide their own decision-making. This and information about CPAC's involvement in RWE is described in Appendix E.

4. Stakeholder Involvement

The Cancer Drug Funding Sustainability Initiative presented a significant potential change to current processes. Success was reliant on input and collaboration with key stakeholders, and the continued engagement of experts, many of whom already participate in pCODR and pCPA. CAPCA also developed a process to also engage with a broader group of stakeholders including patient groups, pharmaceutical industry, oncologists.

The first of a phase of formal consultations began in early January 2017 with introductory webinars with patient group and pharmaceutical industry representatives, followed by roundtable discussions from February to April 2017, and an online survey in March and April 2017. More than 200 people participated. (See Appendix D for a list of participants).

A separate parallel consultation process was held with cancer physician specialists. Initial information was distributed in December 2016, followed by a webinar in February 2017 and a roundtable discussion in April 2017 in Toronto and one in June in Calgary. More than 90 clinicians participated in the webinar and/or a roundtable. Input was also received through other channels. Details about the stakeholder consultation process is captured in a summary document (see Appendix D).

A more recent point of stakeholder engagement took place in November 2018 to share information about the likely transition of key functions from CAPCA to CADTH. Information was shared with key stakeholders at a CADTH Drug Portfolio Information Session as an early alert, followed by a formal consultation launched on February 28, 2019. Further details were shared at a webinar in March 2019 along with a request for input from stakeholders to help guide CADTH's work.

Other avenues for stakeholder engagement included ongoing responses to patient group inquiries and participation in webinars hosted by the Canadian Cancer Survivor Network in 2017 and 2018.

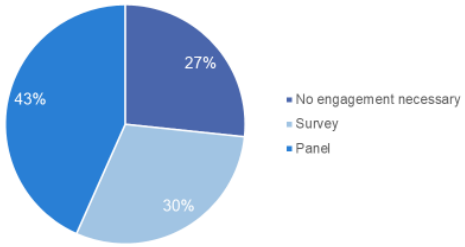
A patient, family and public representatives were also directly involved in CDIAC.

5. Evaluation

CAPCA undertook an evaluation of CDIAC process in 2018 to better understand the impact of the Cancer Drug Funding Sustainability Initiative on overall cancer drug funding and assessment in Canada. A combination of key informant interviews and quantitative analysis helped the CAPCA Board understand:

- CDIAC effectiveness in engaging the "right" people.
- Whether its operations and processes were leading to useful, implementable recommendations.
- The overall effectiveness and impact of the recommendations.

Clinician engagement was part of the CDIAC process for 22 of the 30 drugs where CDIAC identified implementation issues:



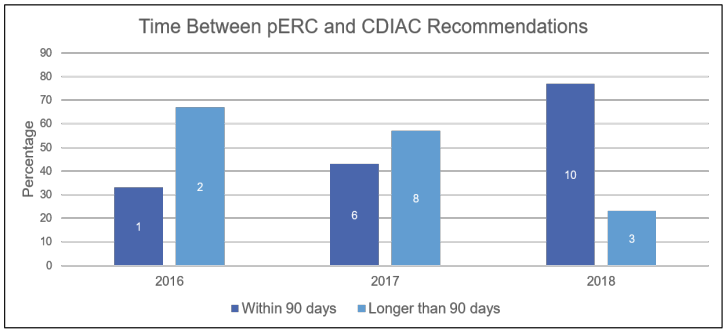
The evaluation results were presented to the CAPCA Board and stakeholders in May 2018. It demonstrated CAPCA / CDIAC is having a positive impact and is helping to enhance clinician input into how new drugs are implemented and supports consistency in provincial oncology drug listing. Importantly it was doing so without unnecessarily delaying patient access to these new therapies.

The evaluation of CDIAC generated a number of recommendations, including the need to:

1. Sustain CAPCA's work with CADTH and pCPA to track and analyze the impact of the duration of the review process from initial HTA to signed letter of intent, and the degree of provincial alignment in listing agreement consistency on patient access and drug funding sustainability.
2. Continue to engage clinicians and pharmacists in discussions regarding drug funding sustainability.
3. Optimize the role of individuals who sit on multiple cancer committees to support efficiencies within cancer programs.
4. Create opportunities to respond to system needs rather than allowing drug evaluation to be driven solely by industry submissions.
5. Support increased transparency in the oncology drug approval pipeline.

Although the evaluation was developed and conducted before it was confirmed that key CDIAC functions would move to CADTH, learnings from the evaluation of how CDIAC has contributed to overall drug funding assessment in Canada has helped CAPCA and CADTH develop a vision to integrate elements of the work into pCODR. A proposal describing changes to the pCODR process was endorsed by the CAPCA Board in January 2019, and will be implemented in July 2019, following a period of public consultation.

The Speed of CDIAC's Recommendations Is Increasing



NOTE: "2018" represents the period from January-July

6. Looking Ahead

CAPCA recognized at program inception that aspects of the work would eventually need to be housed in a pan-Canadian organization with the appropriate resources, infrastructure and system linkages. Given its broader role in drug assessment and evaluation, CADTH was the obvious recipient.

Since 2018, CAPCA and CADTH have been working together to explore options to embed key functions of CDIAC into CADTH's pCODR review process. Transition will begin in summer 2019. The goals will be to:

- Support enhanced harmonization of cancer drug funding decisions across Canada.
- Introduce greater transparency and stakeholder engagement to the cancer drug review process (i.e., stakeholder input into the development of funding algorithms).
- Streamline and reduce duplication of administrative processes.
- Enhance feasibility of adoption by embedding sustainability considerations into recommendations.

After the transition, CDIAC will disband. CAPCA will continue to focus on the overall question of system sustainability and will be involved in the following:

- **With CADTH**: Ongoing CAPCA Board input on representatives participating in the pCODR work, the addition of a non-voting CAPCA representative on pCODR's Provincial Advisory Group (PAG) and through formal endorsement of provisional algorithm recommendations and provisional algorithms.
- **Involvement with RWE**: Continued role as a knowledge user and through participation on the working groups to ensure CAPCA member interests are represented and outcomes are feasible to implement.
- **Hosting DFS Communications Working Group**: Ongoing engagement of the Communications Working Group to support consistent messaging relating to drug funding sustainability and other key initiatives, and to capitalize on perceived value of the committee by members.
- **A focus on affordability**: Continued support for the integration of an affordability and budget impact model into the modernization of the PMBRB guidelines.

7. In Summary

CAPCA's focus on cancer drug funding sustainability has proven to help address an urgent gap in how new and existing oncology drugs are evaluated and funded in Canada.

CAPCA and CDIAC's work demonstrated that assessing scientific evidence for clinical benefit for patients and cost effectiveness is not enough. It is necessary to differentiate the clinical value of new cancer drugs against existing therapies and look at how new drugs fit into existing funding pathways.

As a forum for pan-Canadian discussions on implementation issues, CDIAC directly supports greater clarity on drug comparators and funded treatment pathways. Perhaps its biggest impact has been in supporting greater harmonization of oncology drug coverage across Canada and helping provinces optimize their processes to get the best drugs to cancer patients in a timely way. Integrating the collection and assessment of RWE developed through the CanREValue project will add further value to these efforts.

The work of both CDIAC and the DFS Communications Working Group is supporting CAPCA member's ability to share consistent information about the Cancer Drug Funding Sustainability Initiative. Their work directly and

indirectly supports individual system needs and funding plans, and helps members, their staff and patients better understand clinical implications of reimbursement decisions.

The groundwork laid through CAPCA's Affordability Threshold Working Group has contributed to increased understanding of how affordability and budget impact assessment modelling can be integrated into Canada's oncology drug approval process and the positive impact the introduction of "additional value" models may have on oncology drug budgets.

CAPCA and its Board of Directors have the unique capacity to bring the provinces together to focus on common challenges within the cancer system. The Cancer Drug Funding Sustainability Initiative evolved through a common goal of improving the sustainability of oncology drug funding within provinces and with its partners, the impact CAPCA has made in just three years is significant. As key aspects of CDIAC's work transitions to CADTH, CAPCA and the Board will continue to facilitate provincial involvement to ensure long-term impact is sustained.

APPENDIX A

Membership Lists

CDIAC (as of March 2019)

Organization	Member Name
BC Cancer	Malcolm Moore (Chair), Chief Executive Officer Helen Anderson, Medical Oncologist Lynne Nakashima, Provincial Pharmacy Director
Yukon Hospital Corporation	Prev Naidoo, Pharmacy and Chemotherapy Services Manager
Alberta Health Services	Carole Chambers, Director of Pharmacy, Cancer Services
Health Quality Council of Alberta (HQCA)	Eric Wasylenko, Palliative Care Physician and Clinical Ethicist
Saskatchewan Cancer Agency	Darryl Boehm, Provincial Manager of Oncology Pharmacy Services
CancerCare Manitoba	Marc Geirnaert, Director, Provincial Oncology Drug Program Piotr Czaykowski, Chief Medical Officer
Cancer Care Ontario	Lyndee Yeung, Clinical Program Manager, Provincial Drug Reimbursement Programs
INESSS	Patrick Dufort (ovserver), coordonnateur scientifique en pharmacoéconomie Marie Hotte (observer), Coordonnatrice scientifique Direction du médicament
Le ministère de la santé et des services sociaux, Quebec	Louise Paquet (observer), Agent de recherche et de planification
New Brunswick Cancer Network	Erica Craig, Provincial Pharmacy Director
Nova Scotia Health Authority	Christine Smith, Communications Manager, Nova Scotia Cancer Care Program Joanne Houlihan, Pharmacist
PEI Cancer Treatment Centre	Philip Champion, Medical Director Beth Bradley, Pharmacist Clinical Coordinator
Eastern Health Authority, Newfoundland	Rick Abbott, Regional Pharmacy Manager, Systemic Therapy
pCPA	Sang Mi Lee (observer), Senior Pharmacist

The committee also includes a patient, a family and a public representative to provide input that reflects patient, family and public values and perspectives. The names of those individuals are not made public.

DFS Communications Working Group (as of March 2019)

Organization	Member
BC Cancer	Pamela Gole, Communications Director
Cancer Control Alberta – Alberta Health Services	Haydon Dewes, Director, Provincial Programs Communications Kristin Whitworth, Senior Communications Advisor, Provincial Programs
Saskatchewan Cancer Agency	Lisa Adam, Communications Director
Cancer Care Manitoba	Anita Gadhok, Strategy and Policy Officer
Cancer Care Ontario	Paula Knight (Chair), VP, People, Strategy and Communications Marko Perovic, Director, Corporate Communications
Ministère de la santé et des services sociaux	Louise Paquet, Agent de recherche et de planification
New Brunswick	N/A
Nova Scotia Health Authority	Christine Smith, Communications Manager, Nova Scotia Cancer Care Program
Newfoundland & Labrador	N/A
PEI	N/A
CAPCA	Erika Brown, Interim Executive Director Sarah Hicks, Communications Liaison
CADTH	Randy Allen, Director Marketing & Communications
CPAC	Kari Kerr, Director Communications & Outreach

AFFORDABILITY Threshold Working Group (July 2017)

Expertise	Members
Economist	Doug Coyle, University of Ottawa
	Chris McCabe, University of Alberta
	Jeffrey Hoch, University of California, Davis
Health Technology Assessment	Chris Cameron, Cornerstone Research Group Ottawa
	Don Husereau, Universities of Ottawa and Austria
	Dan Ollendorf, Institute for Clinical and Economic Review, US
	Janet Martin, Western University, Ontario
Economic and Pharmaceutical Policy / Modelling	Jason Sutherland, Cancer Care Ontario
	Jaclyn Beca, University of Toronto, Canadian Centre for Applied Research in Cancer Control (ARCC)
	Mike Doyle, Eastern Health and Memorial University, Newfoundland
Clinical Oncology	Dr. Rajat Kumar, CancerCare Manitoba
	Dr. Gary Pansegrau, BC Cancer Agency
Provincial Oncology Pharmacy Lead	Scott Gavura, Cancer Care Ontario
	Lynne Nakashima, BC Cancer Agency
Ethicist	Scott Berry, Sunnybrook Cancer Centre
CADTH/pCODR representatives	Brent Fraser and Alex Chambers
pCPA representative (Executive and Staff)	Sang Mi Lee, Senior Pharmacist pCPA
CAPCA's Chief Operating Officer Round Table (COORT) representative	Garth Matheson

APPENDIX B

General Key Messages

These key messages were developed and used to support communication with stakeholders and media about the drug funding sustainability work. These are current as of March 2019.

1. A cancer diagnosis and treatment can be extremely difficult for cancer patients and their families. Cancer programs and ministries of health across Canada are committed to providing the best cancer treatment options while ensuring patient safety and effectiveness of cancer drugs.
    - **Support message**: 1 in 2 Canadians will develop cancer in their lifetime and 1 in 4 will die from cancer. In 2017 it was estimated over 200,000 new cancers would be diagnosed and over 80,000 will die.[1] It is projected that the number of cancers diagnosed in 2030 will be almost 80% greater than the number diagnosed in 2005.[2]
2. The numbers of Canadians with cancer are growing and many require increasingly complex treatment for longer periods of time. Costs of cancer treatment – in particular drug costs – are rising, and the number of new expensive drugs is also mounting.
    - **Support message**: The impact on cancer drug budgets is already sobering. In the last five years cancer drug budgets have increased between 43% and 82% in British Columbia, Alberta, and Ontario. In Ontario, this translates to an increase of $50 million per year.
    - **Support message**: Continued pressure on drug budgets is not sustainable and there is a real possibility that this will limit access to innovative cancer drugs, place an even greater financial burden on the cancer system, patients and their families, and mean fewer resources for other areas of cancer care.
    - **Support message:** Spending limited resources on less effective cancer treatments means that there may not be funds for future treatments that show greater benefit. It may also result in lost opportunities to invest in other areas of cancer care (e.g. palliative and supportive care) and/or provincial needs (other areas of health, social services, schools etc.)
    - **Support message**: Canada is not alone. Countries around the world are facing similar challenges.
3. The goal of the Cancer Drug Funding Sustainability Initiative is to ensure Canadian patients continue to have access to new and effective cancer treatments and that our cancer system is achieving maximum value for money invested. This work was launched in 2016 by the Canadian Association of Provincial Cancer Agencies (CAPCA) and its partners because the sustainability and strength of our cancer system are at risk.
    - **Support message**: It is critical to strengthen how new and existing drugs are evaluated and funded. Assessing scientific evidence for clinical benefit for patients and cost effective is not enough, it is critical to differentiate the clinical value of new cancer drugs against existing therapies, and how new drugs fit into existing treatment pathways. We also need to improve the availability of evidence and information about the effectiveness of new drugs in the general population (real world evidence).
    - **Support message:** It is critical to assess affordability in addition to cost effectiveness to ensure that funding a single drug will not distort a province's ability to pay for other important treatments and services. The question of affordability is linked to a number of factors – size of the potential number of people who may need the drug, duration of treatment, impact on the use of other health resources, and how quickly clinicians and patients start using the drug.
    - **Support message:** CAPCA and partners are working with existing processes for drug evaluation and price negotiation established by the Canadian Agency for Drugs and Technologies in Health

[1] Canadian Cancer Society n Canadian Cancer Statistics: A 2018 special report
[2] Canadian Cancer Society's Advisory Committee on Cancer Statistics. Canadian Cancer Statistics 2015. Toronto: Canadian Cancer Society; 2015.

/pan-Canadian Oncology Drug Review (CADTH/pCODR), the Institut national d'excellence en santé et services sociaux (INESSS) in Quebec, and the pan-Canadian Pharmaceutical Alliance (pCPA).

- **Support message:** CAPCA is an association of provincially designated cancer programs that provides a forum for the leaders of Canada's cancer care system to address issues that affect delivery of cancer care in Canada. The CAPCA Board of Directors includes a senior staff person from every provincial cancer program.

4. CAPCA's Cancer Drug Implementation Advisory Committee (CDIAC) is a key mechanism in the Cancer Drug Funding Sustainability Initiative. Their role is to provide advice to the CAPCA Board of Directors, ideally prior to the initiation of pan Canadian Pharmaceutical Alliance (pCPA) negotiations, about how new drugs can be integrated into existing treatment pathways. The CAPCA Board reviews CDIAC's recommendations and if endorsed the recommendations are then provided as advice to provincial Ministries of Health and as needed to the pCPA.

   Support message: A 4-month consultation process (January to April 2017) shared information and sought input from patient groups, the pharmaceutical industry and patients. In response to input about the need for greater transparency with regards to CDIAC and the need for a patient and public representative at the CDIAC table, new information has been added to the CAPCA website about CDIAC membership and process, and a patient and public representative have joined the CDIAC. Work continues in the area of real world evidence, which confirms if what is seen in clinical trials is what will be the case when the drug is launched and made available to a larger population.

   Support message: To identify potential patient and family representative to bring this critical perspective to CDIAC discussions, CAPCA worked through existing processes with provincial patient and family advisory council (PFAC) staff leads. A public representative was identified through support from Asking Canadians – the group that identified participants for CPAC's deliberative public engagement program. A number of potential candidates were identified and interviewed, then selected by the CAPCA Board of Directors.

   Support message: As part of CAPCA's Drug Funding Sustainability Initiative, a group of experts developed a set of recommendations for an affordability threshold tool; a budget impact tool; and an approach to prioritization. Patented Medicine Prices Review Board (PMBRB) is providing support in tool development.

5. A review of CAPCA's work and the role of CDIAC in this process demonstrates it is having a positive impact, is helping to enhance clinician input into how new drugs are implemented and supports consistency in provincial oncology drug listing. Importantly it is do so without unnecessarily delaying patient access to these new therapies.

6. Many of the features of Canada's drug review and approval system are among the best and most innovative in the world, however more can be done to make it more efficient, support timely access to new therapies and build better linkages. To support these efforts, CAPCA and CADTH are discussing how key components of the CDIAC's work could be transitioned from CAPCA to CADTH.

7. Our shared responsibility is to ensure a sustainable, high quality cancer system that provides timely access to the most effective cancer drugs. We will continue to share information and engage with key stakeholders as the work progresses.

APPENDIX C

2017 Final Report - pan-Canadian Cancer Drug Funding Sustainability Initiative Stakeholder Consultation

June 6, 2017

Dear Colleague,

On behalf of the Canadian Association of Provincial Cancer Agencies Board of Directors, thank you for participating in the cancer drug funding sustainability initiative consultation process. Your input and feedback will help ensure that Canadians continue to have access to evidence-based, innovative cancer medicines.

As we review and consider how best to move forward, we want to share a summary of the themes that emerged from the consultation process and outline our immediate next steps.

THE CONSULTATION

The Canadian Association of Provincial Cancer Agencies (CAPCA) with input from its partners – the Canadian Partnership Against Cancer (CPAC), CADTH, and the pan-Canadian Pharmaceutical Alliance (pCPA) – launched an intensive stakeholder consultation process in January 2017 as our approach to addressing drug funding sustainability was being developed and refined.

To date, hundreds of stakeholders from across Canada have participated through one or more of the following channels:

- Two webinars in January and February 2017 that attracted more than 200 representatives from patient advocacy groups and the pharmaceutical industry, and 70 clinical leaders.
- Four in-person roundtables starting in February in Vancouver, Toronto in March and two in Ottawa in April with more than 70 representatives from patient advocacy groups and the pharmaceutical industry. While the format for each was similar, the level of discussion deepened at each subsequent event.
- Two in-person roundtables for clinical leaders, one in Toronto in April and a second in Calgary in early June, after which more than 80 clinical leaders from across Canada will have participated.
- An online survey that generated 16 distinct submissions and more than 75 pages of content, with consistent feedback about: opportunities to address the collection and analysis of real world evidence; reducing funding inconsistencies across provinces and between intravenous and oral forms of chemotherapy; and ensuring continued access to evidence-based, clinically effective innovative cancer drugs.

WHAT WE HEARD

Across these feedback channels, a number of common themes emerged:

1. Efforts to ensure continued timely access to innovative, evidence-based cancer treatment for Canadians is vital. If CAPCA continues to lead this work, it should focus on preserving access to cancer treatment and avoid language that might suggest a singular focus on cost-containment.
2. Stakeholders expect meaningful, ongoing opportunities for their voices to be heard, which builds on the approach CADTH has embedded into pCODR. From a patient advocacy perspective, there was consensus that the patient voice is essential and should be represented on the Cancer Drug Implementation Advisory Committee (CDIAC).
3. CAPCA's creation of CDIAC was news to many and obtaining information about the committee was deemed difficult. There was strong support for CAPCA to be transparent about CDIAC's role in the drug funding sustainability initiative and its relationship to other aspects of the existing system.

4. Many of the features of Canada's drug review and approval system are among the best and most innovative in the world, but the process is already complex, so every effort should be made to improve efficiency and reduce, or ideally eliminate, duplication of effort. Consultation participants wonder if there is an opportunity to consolidate efforts by folding some of the work that CAPCA is leading into another national or pan-Canadian entity to improve overall timeliness of the review process.
5. Over time, the current approach of funding pilot projects and assessing the applicability of real-world evidence should be enhanced and expanded. Consultation participants voiced a commitment to this goal, and many offered similar opinions about the disconnected way in which real-world evidence is being addressed currently and the lack of a central coordinated effort.
6. Everyone is concerned about workload, especially clinical and patient advocacy group leaders engaged in drug review and approval processes. Many patient advocacy groups commented on the amount of time required to gather meaningful patient information, and many clinicians said that they were feeling pressure as patient numbers increase, treatments become more complex and more targeted, and the number of tables at which their opinion is being sought grows. Maximizing opportunities to seek and use patient and clinical input through pCODR or CAPCA's drug funding sustainability work was strongly supported.

OUR NEXT STEPS

We reviewed every submission and received regular updates throughout the consultation process from CAPCA staff. Additionally, we were able to meet with participants at the Vancouver, Toronto, and Ottawa roundtables.

The views of everyone who participated have been considered and discussed by the CAPCA Board—whose members lead provincial cancer programs—and we have begun discussions with Assistant Deputy Ministers—who manage provincial drug budgets.

As a result of these discussions, CAPCA will be moving forward with five immediate next steps:

1. Evaluate the impact of our work through the development and assessment of key performance indicators. Our commitment is to ensure that this step does not slow drug funding decisions.
2. Actively explore how to identify appropriate patient and public representatives to join CDIAC to ensure that patient and public voices are represented.
3. Make public the CDIAC membership, mandate, and current process for providing drug funding recommendations to provincial Ministries of Health.
4. Continue to explore with publicly funded organizations how to enhance and expand approaches to collecting, analyzing and using real-world evidence in discussions about provincial reimbursement and the price of cancer drugs, and explore the experiences of other jurisdictions through discussions with international entities and the pharmaceutical industry.
5. Seek the perspectives of stakeholders about the possible transition some or all of the work currently being led by CAPCA to another, more appropriate pan-Canadian or national entity.

Your input and our discussions over these last few months demonstrate that we share a commitment to ensuring that Canada's cancer system continues to be among the best in the world and that Canadians continue to have access to innovative, evidence-based cancer drugs. With your ongoing support, we will be able to achieve both while addressing the challenges posed by the rising cost of cancer treatment and the challenges that lie ahead.

On behalf of the CAPCA Board of Directors, I would like to thank you again for your input. We look forward to working together on our drug funding sustainability initiative.

Sincerely,

Michael Sherar
Chair, CAPCA Board of Directors

APPENDIX D:

Patient group and industry stakeholder consultation participants

These organizations participated in a roundtable, webinar or provided written submissions.

	Patient Groups		Pharmaceutical / Industry
1.	Best Medicines Coalition		Abbvie
2.	Bladder Cancer Canada		Amgen
3.	Canadian Breast Cancer Foundation		Andor Technology
4.	Canadian Breast Cancer Network		AstraZeneca
5.	Canadian Cancer Action Network		Astrellas
6.	Canadian Cancer Society		Bayer
7.	Canadian Cancer Survivor Network		BioCanRx
8.	Canadian Organization for Rare Disorders		BioteCANADA
9.	CanCertainty Coalition		Boehringer Ingelheim
10.	CLL Patient Advocacy Group		Bristol-Myers Squibb
11.	Cancer Advocacy Coalition of Canada		Celgene
12.	Chronic Myelogenous Leukemia Society of Canada		Eisai
13.	Colon Cancer Canada		Eli Lilly
14.	Colorectal Cancer Association of Canada		Hoffman-La Roche
15.	Craig's Cause Pancreatic Cancer Society		Innovative Medicines Canada
16.	Crohn's and Colitis Canada		Ipsen
17.	Kidney Cancer Canada		Janssen
18.	Leukemia & Lymphoma Society of Canada		Lundbeck
19.	Life Saving Therapies		Merck
20.	Lung Cancer Canada		Novartis Pharmaceuticals Canada
21.	Lymphoma Canada		Roche Pharma
22.	Melanoma Network of Canada		Sanofi
23.	Metastatic Breast Cancer Advocacy Canada		Sanofi Genzyme
24.	Ovarian Cancer Canada		Servier Canada
25.	Myeloma Canada		Shire
26.	Pancreatic Cancer Canada		Sun Life
27.	Patient Access Solutions Inc.		Sunovion Pharmaceuticals Canada
28.	Patient Voices Network		Takeda Canada, Inc.
29.	Patients as Partners		
30.	Prostate Cancer Canada		
31.	PEI Metastatic Breast Cancer Survivors		
32.	Rethink Breast Cancer		
33.	Save Your Skin Foundation		
34.	Shine Through the Rain Foundation		
35.	The Caregiver Network		
36.	The Friends of Gilda's Society NS		
37.	Wellspring Calgary		

Other participating organizations included: partner organizations, Health Canada, Sunlife and consulting firms. Invitations were sent to a broader list with no response or participation. A separate consultation was held for clinicians. A least 90 clinicians participated in a webinar and/or a roundtable.

APPENDIX E:

Canadian Partnership Against Cancer's Initiative on Oncology Drug Sustainability

CANADIAN PARTNERSHIP AGAINST CANCER | PARTENARIAT CANADIEN CONTRE LE CANCER

December 4, 2018

The Initiative on Oncology Drug Sustainability

BACKGROUND

One of the major contributors to the growing concern of delivering high quality cancer care is Canada is the cost associated with new systemic cancer therapies. Sustainability of drug funding in the Canadian cancer control system has been identified as a priority by the Canadian Association of Provincial Cancer Agencies (CAPCA). The Canadian Partnership Against Cancer (CPAC) is collaborating with CAPCA on various complementary initiatives to inform cancer drug decision making from a pan-Canadian perspective. Members of CAPCA and CPAC interact regularly at Partnership Council meetings to discuss the nature and frequency of collaboration, review progress on their respective initiatives and develop action plans as work progresses.

EFFORTS TO DATE AND CURRENT DEVELOPMENTS

CAPCA has work underway to develop and implement recommendations to prioritize how new and existing cancer drugs are evaluated, purchased and used. CAPCA has developed the Cancer Drug Implementation Advisory Committee (CDIAC) to implement a prioritization framework as part of the drug approval pipeline. A new committee, the Affordability Threshold Working Group, has been established to work with other areas of the system, operated and staffed by CAPCA, to recommend an affordability threshold on cancer drugs. At this time, the intent is that CAPCA will endorse the decisions of the committee and be the mechanism by which the provinces implement them.

CPAC is leading work in two areas that resulted from a previously conducted economic analysis that identified factors driving drug spending and the levers available to influence sustainability. These areas include:

1. development and application of real world evidence (RWE) as it relates to cancer drugs and
2. development of a framework of public values and priorities in cancer drug decision-making.

1. Application of Real World Evidence

CPAC is conducting two parallel streams of work to develop and apply real world evidence to drug decision-making including the development of pan-Canadian standards for oncology drug data and a proof of concept study to support application of RWE to decision-making.

Development of Pan-Canadian Data Standard

CPAC and the Canadian Institute for Health Information (CIHI) are coordinating efforts to develop pan-Canadian data standards for oncology drugs. In April 2018, CIHI published a minimum data standard based on CPAC's engagement of a broad group of Canadian experts, clinicians and provincial registries. Future work will include analysis of the feasibility of collecting data.

Case study for application of Real World Evidence

CPAC has funded a proof-of-concept study to examine the real world evidence of an established drug available for treatment of solid malignancies. Bevacizumab (Avastin) has been identified as the choice for the case study as it has been available for treatment of metastatic colorectal cancer (CRC) since 2005 and represents one of the highest drug expenditures (in cost and volume) in oncology across Canada. Because there are robust and mature data available for Avastin, there is a strong case to re-evaluate the status of Avastin in CRC treatment by applying RWE and based on findings, the possibility of negotiating price.

Led by Dr. Kelvin Chan, key experts in medical oncology and RWE from three provinces (Ontario, British Columbia, and Saskatchewan) have been engaged in this project which aims to examine real world outcomes of first-line Avastin for patients with metastatic colorectal cancer (mCRC) compared to a) pre-implementation projections and b) first-line chemotherapy irinotecan, capecitabine and oxaliplatin.

This study was designed to assess four outcomes including 1) budget impact analysis and treatment utilization, 2) effectiveness, 3) safety and 4) cost-effectiveness and all assessments were completed in 2018/19. An important finding is that British Columbia, Saskatchewan and Ontario have data elements to produce equivalent analytics for budget impact and treatment utilization. This proves the concept that it is possible to analyse budget impact assessment for the same drug across provinces and may pave the way for data-rich provinces to mobilize knowledge across Canada.

Dr. Chan is also leading the Canadian Real-world Evidence for Value of Cancer Drugs (CanREValue) project funded by a CIHR under the Partnerships for Health System Improvement (PSHI) for Cancer Control program. His objective is to develop a framework for the generation and use of RWE for cancer drugs to enable health technology reassessment for recommendation-makers and the reassessment of funding decisions, funding criteria or renegotiations for decision-makers/payers across Canada. PHSI is an integrated knowledge translation program and Dr. Chan has named CPAC and CAPCA in the grant as a knowledge user with the expectation that we will inform the research questions and disseminate results.

In the absence of a formal pan-Canadian mechanism to revisit health technology assessments, there may be a role for CPAC in convening an expert panel to make a recommendation to CAPCA's CDIAC on the use of bevacizumab. Looking beyond the current case study, any effort by CPAC to foster generation of RWE would need to be complemented by a formal process to re-examine drug approvals. Internationally, there is much interest in revisiting drug-funding decisions to ensure payers are obtaining optimal value.

2. Framework of Public Values and Priorities in Cancer Drug Decision-Making

In 2016 CPAC funded the Canadian Centre for Applied Research in Cancer Control (ARCC) and the McMaster Health Forum to engage Canadians about their priorities for making cancer drug funding fair and sustainable. A series of deliberative public engagement events were held in communities across Canada with people reflecting a diversity of life experiences and economic and social backgrounds.

A synthesis of six key messages that emerged from the six citizen panel deliberations and their resulting recommendations and a final (seventh) key message representing the perspective of the research team based on their observations and analyses of the deliberations as a whole were discussed at Partnership Council in May 2017. The seven key messages are provided in an appendix to this note. In August, CPAC shared highlights of the final report "Making Fair and Sustainable Decisions about Funding for Cancer Drugs in Canada" and supporting materials with CAPCA and asked CAPCA members to share these materials with Assistant Deputy Ministers (ADMs) responsible for pharmaceutical decisions within their provincial ministries of health. In early September, CPAC shared the report highlights with other pan-Canadian organizations and stakeholders involved in or with an interest

in cancer drug funding decision including patient groups, Health Canada, the pan-Canadian Pharmaceutical Alliance, and CADTH and pCODR's advisors and experts. As of September 5, 2017, the final report has been available on CanEngage.ca, a website set up to facilitate public engagement in health policy decisions in Canada and supported by ARCC, BC Cancer, Canadian Cancer Society and UBC.

Dr. Peacock and Dr. Mike Burgess (two of the deliberative engagement leads) are using a CIHR PHSI grant to develop a framework for sustained public involvement to better support priority setting processes in the context of cancer control. CAPCA and CPAC are named as knowledge users in the grant, along with CADTH, pCODR and the pan-Canadian Pharmaceutical Alliance.