Meeting Report

Sixth Canadian Cancer Treatment Hackathon

August 13, 2024

Virtual

Table of Contents

Thank-you to our Sponsors

AbbVie

AstraZeneca

Astellas

BMS

GSK

Janssen

Merck

Novartis

Takeda

Executive Summary

The Sixth Canadian Cancer Treatment Hackathon convened key stakeholders, including healthcare professionals, industry experts, policymakers, and patient advocates, to tackle the persistent barriers to timely access to cancer treatments in Canada. The focus of this Hackathon was the intricate and protracted drug negotiation process, particularly under the pan-Canadian Pharmaceutical Alliance (pCPA). With Canada trailing behind other OECD countries in providing swift access to new cancer therapies, this collaborative effort aimed to propose actionable solutions to expedite patient access to life-saving treatments.

Key Challenges and Context

Canada's multi-tiered drug approval system, which includes regulatory reviews by Health Canada, health technology assessments (HTAs) by agencies such as CADTH (Canadian Agency for Drugs and Technologies in Health) and INESSS, followed by pCPA-led price negotiations, significantly delays the availability of innovative cancer therapies. Despite advancements in targeted treatments, Canada lags in providing prompt access, ranking 19th out of 20 OECD nations with an average delay of 732 days for new medicines. These delays, coupled with a lack of transparency and limited accountability, hinder patient access to essential cancer therapies, highlighting the need for systemic improvements, particularly in pCPA processes.

Preparation and Collaboration

Hackathon 6 built upon previous iterations of this collaborative event, focusing on critical evaluations of the price negotiation process and emphasizing earlier and more meaningful patient involvement. Participants explored global best practices, discussed inefficiencies in the current system, and brainstormed solutions to streamline negotiations and reduce delays. Two pre-recorded webinars featuring experts like Dr. David Stewart, Dr. Nigel Rawson, and Steve Williamson provided insight into the Canadian and UK drug pricing models, setting the stage for deeper discussions during the Hackathon.

Breakout Sessions

The Hackathon's discussions were organized into three key breakout sessions, each addressing distinct aspects of the drug pricing and access process:

Group 1: Negotiation Process and Timelines – Focused on the inefficiencies and delays in pCPA negotiations and explored ways to integrate patient input earlier in the process.

Group 2: Enhancing Transparency and Efficiency – Examined the opaque nature of pCPA operations and proposed solutions to increase transparency, especially around how patient needs are factored into decision-making.

Group 3: Global Best Practices and Operational Improvements – Explored successful international models for drug access, particularly in the UK and France, and considered how Canada could adopt similar strategies to accelerate treatment availability.

Emerging Themes

Several key themes emerged from the discussions, leading to a set of actionable recommendations:

- **Patient-Centered Approaches**: Across all groups, the importance of incorporating patient perspectives early in the negotiation process was emphasized. Participants proposed formalizing patient involvement before negotiations, ensuring that real-world patient needs are considered alongside clinical and economic evaluations.
- **Inefficiencies in the pCPA Process**: Participants highlighted the lengthy and inconsistent timelines in the pCPA price negotiations, citing capacity constraints and procedural delays. Solutions such as early pipeline meetings between pCPA, manufacturers, and patient groups were proposed to expedite the negotiation process, particularly for high-priority cancer therapies.
- **Transparency and Accountability**: A major concern was the opaque nature of pCPA decision-making. The “black box” approach, where stakeholders have limited visibility into negotiations, hampers trust and efficiency. Participants recommended the implementation of performance metrics and regular reporting to hold pCPA accountable for meeting timelines and to improve the transparency of its processes.
- **International Best Practices**: Lessons from the UK’s managed access agreements and the French model of early reimbursement for promising therapies were highlighted as potential solutions for Canada. The concept of conditional approvals, already in place in several countries, was particularly appealing for providing early access to cancer drugs while real-world data is collected.
- **Flexibility in Value Assessments**: The reliance on traditional cost-effectiveness metrics, such as Quality-Adjusted Life Years (QALYs), was critiqued for its limitations in capturing the full value of cancer treatments, particularly those that improve quality of life. A more flexible, patient-centered approach to value assessment, incorporating real-world outcomes, was advocated.

Actionable Insights and Recommendations

Hackathon participants identified several actionable solutions to improve the drug negotiation process and patient access to treatments in Canada:

- **Formalize Patient Involvement**: Patient groups should be engaged before formal negotiations begin, and their perspectives should be integrated throughout the evaluation process.
- **Streamline Negotiation Timelines**: Initiatives such as early engagement meetings and fast-tracking simpler cases could free up resources and expedite negotiations for more complex cancer therapies.
- **Improve Transparency**: The pCPA should adopt performance metrics and provide regular reporting on its progress, ensuring that all stakeholders, including patients, have access to clear and timely information.
- **Leverage Conditional Approvals**: Implementing conditional approvals, allowing earlier access to life-saving therapies while gathering additional real-world data, could significantly improve patient outcomes.
- **Adopt Global Best Practices**: Canada should consider adopting international models like the UK's managed access agreements to streamline the approval and reimbursement process for innovative cancer treatments.

The recommendations from the Sixth Canadian Cancer Treatment Hackathon represent a collective vision for a more transparent, patient-centered, and efficient drug access system in Canada. By addressing these core challenges, the country can significantly reduce delays and ensure that cancer patients receive timely access to new, potentially life-saving therapies.

1.0 Introduction

1.1 Background

In Canada, accessing new and innovative cancer treatments remains a significant challenge for patients due to the intricate and prolonged processes involved in drug evaluation, price negotiation, and provincial reimbursement. The multi-level system, which encompasses regulatory reviews by Health Canada, health technology assessments (HTA) by agencies such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS), followed by price negotiations led by the pan-Canadian Pharmaceutical Alliance (pCPA), creates substantial delays in making life-saving therapies available to those in need. With cancer affecting two in five Canadians over their lifetime and one in four dying from the disease, the importance of timely access to cutting-edge treatments cannot be overstated.

Despite advancements in targeted therapies that improve survival and quality of life for cancer patients, Canada lags behind many of its international counterparts in providing swift access to these innovations. The country ranks 19th out of 20 OECD nations in terms of the time it takes to make new medicines available to patients, with an average delay of 732 days—more than double the waiting period in several comparable countries. Furthermore, Canadian public drug plans reimburse only 20% of the new medicines available globally, underscoring the urgent need for systemic improvements in the approval and reimbursement processes, particularly through the pCPA.

The Canadian Cancer Treatment Hackathons provide a collaborative platform for key stakeholders to ideate and propose solutions to expedite access to new cancer medicines. Previous hackathons focused on optimizing existing frameworks, learning from international best practices, and exploring novel approaches to decision-making. Hackathon 6 builds on these discussions, turning its attention to a critical evaluation of the price negotiation process and the role of the pCPA. This session emphasizes how patient values and perspectives can be integrated earlier and more effectively in the negotiation process to ensure faster, more equitable access to essential cancer therapies.

As Hackathon 6 builds on the momentum of the first five hackathons, participants will focus on evaluating and streamlining Canada’s drug negotiation processes, including earlier engagement

of patient groups, improving transparency in how decisions are made, and enhancing efficiency in negotiations. By tackling these barriers head-on, the goal of Hackathon 6 is to develop actionable solutions that address the root causes of delays and improve the overall system for getting new cancer drugs to Canadian patients in a timely and efficient manner.

1.2 Pre-recorded Panel

Panel Video 1: Canadian Cancer Treatment Hackathon: Price Negotiation Process for Cancer Drugs

The Canadian Cancer Treatment Hackathon webinar featured two prominent experts, Dr. David Stewart, a medical oncologist, and Dr. Nigel Rawson, a pharmaco-epidemiologist, who provided an in-depth exploration of the Canadian price negotiation process for cancer drugs. The discussion aimed to identify bottlenecks in the system and propose ways to improve patient access to cancer medications. The event was moderated by Bill Dempster.

Current Structure of the Price Negotiation Process

In Canada, new cancer therapies undergo a multi-stage process before they become accessible to patients. After Health Canada approves a drug for efficacy and safety, the Canadian Agency for Drugs and Technologies in Health (CADTH) evaluates it from both a clinical and economic perspective. The resulting recommendation, which compares the drug to existing treatments, is passed to the pan-Canadian Pharmaceutical Alliance (pCPA), which negotiates with manufacturers on behalf of Canadian public drug plans. The negotiation process typically leads to a confidential price discount and reimbursement terms, captured in a Letter of Intent (LOI). However, the process is complex and has faced increasing criticism due to long delays.

Key Issues and Challenges

1. **Lengthy Timelines:** Both Dr. Stewart and Dr. Rawson emphasized that timelines are excessively long at multiple stages. CADTH's standard timeline of 180 days for completing health technology assessments (HTA) is often exceeded, with fewer than 40% of drugs meeting this target. The average time to decision-making at the pCPA level is similarly lengthy, often extending well beyond the 60-day target. In some instances, decisions took over 250 days. Dr. Rawson highlighted that despite progress in 2014, performance has declined significantly in recent years, even before the pandemic. These delays have dire

consequences for cancer patients, who cannot afford to wait months or years for treatment.

2. **Increased Volume of New Cancer Drugs:** Dr. Stewart pointed out that the number of available cancer therapies has risen dramatically in recent years, putting additional strain on an already slow system. However, he emphasized that the increase in cancer drugs was predictable, and health agencies should have prepared for this influx by allocating resources accordingly. Delays in drug approval and negotiation are particularly concerning in cancers like metastatic non-small cell lung cancer, where each week without treatment increases mortality by 4%.
3. **Challenges in Assessing Drug Value:** The metrics used to assess cancer drugs, particularly in clinical trials, were criticized as inadequate. Dr. Stewart explained that relying heavily on metrics like overall survival or progression-free survival in randomized trials does not always reflect a drug's true value. Differences in patient populations, crossovers in treatment arms, and the use of hazard ratios can obscure the effectiveness of new treatments. He argued that drug evaluation should also consider quality of life, response rates, and real-world impact. Dr. Rawson further emphasized that cost-effectiveness calculations often lead to unrealistic price-cut recommendations, such as 70-90% discounts, which undermine the true value of cancer therapies.
4. **Need for Speed:** Both panelists agreed that speed is critical in cancer care, where delays can lead to preventable deaths and diminished quality of life. Dr. Stewart strongly advocated for reducing the current timelines. He noted that most cancer patients need access to new treatments within days or weeks, not months or years. Despite this urgency, the system remains bogged down in bureaucratic inefficiencies. Stewart also mentioned that CADTH and pCPA could make use of existing data to accelerate the review and negotiation processes, particularly for drugs with novel mechanisms of action. Conditional approvals were proposed as one way to speed up access while still collecting additional data.
5. **Lack of Accountability and Transparency:** Dr. Rawson criticized the lack of accountability and transparency within both CADTH and pCPA. He pointed out that while CADTH and pCPA have established timelines, they rarely meet them and do not provide adequate explanations or strategies for improvement. Although pCPA recently implemented a dashboard to report on timelines, the lack of meaningful insights into why delays persist remains a major concern. Furthermore, Rawson highlighted that pCPA negotiations are conducted in a highly confidential manner, making it difficult for external

stakeholders to understand the rationale behind decision-making or verify claims of cost savings.

Recommendations for Improvement

1. **Improved Timelines and Flexibility:** Dr. Stewart called for a radical overhaul of the current system, reducing decision-making times from months to days. He suggested that CADTH and pCPA should have all necessary data at hand before negotiations begin, allowing them to expedite the process. Additionally, he recommended that new drugs, especially those with no alternative treatments, should be prioritized. Flexibility in negotiations, including the use of conditional approvals, could further help patients gain faster access to potentially life-saving therapies.
2. **Integration of Patient-Centric Metrics:** The panel emphasized that the current system often neglects the real-world impact of drugs on patients. Metrics like overall survival or incremental cost-effectiveness ratios (ICERs) fail to capture patient outcomes such as symptom relief, quality of life, or ability to remain out of the hospital. Both panelists argued for integrating more patient-centric metrics into the assessment and negotiation process. They proposed that patient feedback should play a larger role in determining the value of a drug, rather than relying solely on traditional clinical trial outcomes.
3. **Greater Accountability and Transparency:** Dr. Rawson called for both CADTH and pCPA to be more accountable to patients, clinicians, and stakeholders. He advocated for regular reporting on progress and delays, as well as clear explanations for why targets are missed. Public disclosure of how patient values are considered during negotiations would also increase trust in the system. He highlighted the importance of pCPA moving beyond confidential negotiations and providing concrete evidence of cost savings.
4. **Learning from International Models:** The webinar also explored international examples, particularly from the U.S. and Europe, where patients often receive faster access to new therapies. In the U.S., access to FDA-approved drugs is almost immediate, while some European countries use conditional approvals to provide early access to treatments pending further data collection. Both panelists argued that Canada should adopt similar practices to accelerate the approval and reimbursement process.

Conclusion

The Canadian Cancer Treatment Hackathon highlighted the critical need to improve the price negotiation process for cancer drugs in Canada. The panelists emphasized the importance of

faster timelines, greater transparency, and the integration of patient-centric metrics in drug evaluations. The current system's inefficiencies, long timelines, and limited accountability pose serious risks to cancer patients who need timely access to life-saving treatments. Moving forward, adopting international best practices, including conditional approvals and greater flexibility in negotiations, could significantly improve patient outcomes in Canada.

Panel video 2: UK Reimbursement and Price Negotiation Process for Cancer Drugs

In this second pre-hackathon webinar, Steve Williamson, an oncology pharmacist and associate director at the National Institute for Health and Care Excellence (NICE), provided an in-depth overview of the UK's system for evaluating and reimbursing cancer drugs. The discussion centered around the Health Technology Assessment (HTA) process, managed access agreements, and the involvement of patient voices in these critical stages of drug approval and reimbursement.

Overview of the UK Health Technology Assessment (HTA) Process

Steve Williamson started by explaining that NICE is responsible for the assessment of new cancer treatments in the UK. The evaluation process is supported by economic models submitted by drug manufacturers, which are reviewed by independent academic units known as evidence assessment groups. The assessments consider clinical and cost-effectiveness data, particularly focusing on Incremental Cost-Effectiveness Ratios (ICERs) and Quality-Adjusted Life Years (QALYs). NICE committees use these data to make recommendations, taking into account the strength of clinical trial data and the specific circumstances of the UK healthcare system.

Three primary outcomes are possible in the NICE evaluation process:

1. **Positive Recommendation (Yes):** This occurs when the treatment demonstrates strong clinical benefits at an acceptable price and meets the QALY threshold, which typically ranges between £20,000 and £30,000 per QALY.
2. **Managed Access (Maybe):** This decision is applied when the evidence is still early or uncertain, allowing the drug to enter a period of managed access through the Cancer Drugs Fund. This enables real-world data collection for two to five years before a final decision is made.
3. **Negative Recommendation (No):** NICE will not recommend the treatment if it does not meet the clinical or cost-effectiveness thresholds.

The Role of Managed Access and Cancer Drugs Fund (CDF)

Managed access is a critical part of the UK's approach to early-stage cancer drugs, especially when full data are not yet available. Williamson explained that the Cancer Drugs Fund (CDF), established in 2013 and revamped in 2016, plays a key role in providing early access to promising

treatments while additional data is gathered. This allows drugs with incomplete evidence to be made available to patients while their long-term efficacy and safety are further evaluated.

The CDF is particularly useful for cancer drugs that show promise but lack comprehensive Phase III trial data. The fund offers interim reimbursement during the data collection period, ensuring that patients do not have to wait for years to access potentially life-saving treatments.

Involvement of Patients in the NICE Process

Patients play an essential role in the NICE evaluation process, especially during the HTA phase. Williamson emphasized the importance of patient representatives, who provide context about living with the disease and the potential impact of new treatments. Their input helps NICE committees understand not only the clinical benefits of a drug but also its real-world implications for quality of life and daily functioning.

Although patients do not participate directly in price negotiations between the NHS and pharmaceutical companies, their voices significantly influence how uncertainty in clinical data is weighed. The patient perspective is often crucial in shaping the committee's decision-making process when assessing whether a treatment's benefits justify its costs.

Price Negotiation and Commercial Framework

Once NICE committees issue a recommendation, the NHS enters into price negotiations with drug manufacturers. The primary mechanism for price setting is the Patient Access Scheme (PaaS), which often involves confidential discounts. Williamson highlighted that while NICE sets a baseline for what constitutes a cost-effective price, the NHS negotiates the final price, working closely with manufacturers. Commercial negotiations are generally confidential, and while they do not directly involve patients, patient input influences the context in which these negotiations occur.

NICE operates independently of the NHS, ensuring that the clinical and economic assessments are unbiased. Once NICE has set the framework for pricing, the NHS negotiates the terms, sometimes engaging in complex arrangements for drugs with multiple indications or those undergoing managed access.

Learning from the UK's Model

The UK's system, particularly the integration of managed access through the CDF, offers valuable insights for Canada, where delays in drug access have been a persistent issue. The structured HTA process and managed access agreements ensure that patients receive earlier access to cancer drugs while additional data are collected, addressing the challenge of incomplete evidence.

Canada's health system, with its multi-jurisdictional payer structure, faces unique challenges compared to the centralized NHS in the UK. However, the concept of managed access could be adapted to the Canadian context, potentially improving the speed at which new cancer treatments are made available to patients.

Conclusion

Steve Williamson's presentation on the UK's reimbursement process provided a comprehensive overview of how NICE evaluates cancer drugs and how the NHS negotiates prices with pharmaceutical companies. The emphasis on patient involvement, managed access through the Cancer Drugs Fund, and a transparent HTA process highlights key areas where the UK has successfully accelerated access to new treatments while ensuring cost-effectiveness. Canada could benefit from considering similar approaches to improve patient access to new cancer therapies, particularly through the use of managed access and early data collection.

2.0 Key discussions from the 3 groups that participated in the Hackathon 6

Group 1 Discussion: Negotiation Process and Timelines

Improving the Phases of pCPA Price Negotiation

The group explored ways to improve different phases within the pCPA price negotiation process, focusing on ensuring timely access to cancer medicines in Canada. The integration of the patient voice was a recurring theme, with discussions emphasizing its inclusion at earlier stages. One significant recommendation was scheduling a specific pre-submission meeting between pCPA, CADTH, innovators, and patient groups. These meetings would allow for patient considerations to be integrated early into the negotiation process. There were suggestions to move this even earlier, to pipeline discussions, ensuring all stakeholders were involved before formal submissions.

The group acknowledged inconsistencies in timelines, noting that while some oncology negotiations were completed quickly (within three months), other cases, particularly CAR T-cell therapies, faced delays due to their complexity. Additionally, delays were also noted in the listing phase post-LOI, which, in some cases, took as long as the negotiation phase itself. Capacity issues at pCPA, specifically related to available negotiators, were highlighted as a factor contributing to these delays.

Key Focus Phases

Discussions centered around which phases of the negotiation process should be prioritized. The initiation and negotiation phases were identified as critical areas where delays were most prevalent. The backlog in oncology negotiations was largely attributed to capacity constraints, though there was acknowledgment that some improvements were made last year when no delays occurred in oncology.

The group also discussed the initiation phase benefiting from earlier stakeholder engagement, such as pipeline meetings between pCPA, manufacturers, and patient representatives. These meetings, taking place even before submission, would allow for better understanding and potentially facilitate earlier negotiations.

Challenges Hindering pCPA's Adherence to Brand Process Guidelines (BPG)

The group delved into the challenges preventing the pCPA from meeting its BPG timelines, citing capacity issues as the primary factor. The limited number of negotiators hinders pCPA's ability to pick up files, and the group proposed **prioritization** of files as a potential solution. Simpler cases with straightforward pricing could be fast-tracked, allowing more resources to be allocated to complex cases.

Complex cases often face delays due to the time it takes to establish an acceptable pricing mandate, with the time needed to secure budget approvals from various jurisdictions' health ministers being another contributing factor.

Attainability of Current pCPA Timelines

There was a debate about whether current pCPA timelines are realistic, given that only 11% of drugs met the BPG in Q1 of 2024 and 24% in Q2 of 2024. While some oncology drugs were negotiated quickly, the group pointed out that capacity constraints remained a significant issue. To address these delays, the group proposed early engagement between manufacturers, patient representatives, and pCPA negotiators.

Pre-scheduled meetings between pCPA, manufacturers, and patient groups during the negotiation phase were suggested as a way to keep negotiations on track. This idea received positive feedback, with some participants suggesting these pipeline meetings could occur even earlier, potentially during the CDA phase.

Measures to Achieve pCPA Performance Standards

To help pCPA meet its performance standards, the group proposed several measures:

1. **Pipeline Meetings and Early Engagement**: Formalizing pipeline meetings to involve multiple stakeholders, including patient advocacy groups, clinicians, and CADTH, earlier in the process. These meetings could occur even before submission, allowing for broader discussions around expectations and the product pipeline.
2. **Resource Allocation and Streaming**: The idea of streamlining negotiations by allocating more resources to complex files was discussed. Simpler cases, where pricing is

straightforward, could be fast-tracked, freeing up resources for more complex negotiations.

3. **Pre-LOI Engagement**: Encouraging interactions between patient groups, manufacturers, and pCPA negotiators during the initiation phase (before the LOI) to streamline the process. This engagement would provide clarity on expectations and address concerns early in negotiations.
4. **Financial Consequences**: There was brief discussion around whether financial consequences should be introduced for the pCPA if it fails to meet its BPG timelines. However, the group did not reach a consensus on this idea.

Concerns were raised about resource limitations faced by patient organizations, emphasizing the need for clarity around the commitments expected from patient advocacy groups. It was noted that involving patient organizations in too many meetings could lead to their role becoming more symbolic than substantive. The group agreed that patient involvement must be well-defined and meaningful.

CDA Performance Metrics and Accountability

The group discussed whether CADTH should create performance metrics around its 180-day target for issuing draft recommendations. While CADTH generally meets this target, participants questioned whether it was the most pressing issue. There was a suggestion that a more important consideration is whether early negotiation could begin once a draft recommendation is available.

There was strong support for the idea of early negotiation upon receiving a draft recommendation. This approach could help speed up the process, as it would enable manufacturers and pCPA to begin negotiations before the final recommendation is issued. Parallel reviews, where negotiations take place while clinical reviews are ongoing, were also discussed as a potential method for accelerating the process.

Redesigning the Price Negotiation Process for Efficiency and Timeliness

To improve efficiency and timeliness in the price negotiation process, the group proposed several redesigns:

1. **Expand Early Negotiation Opportunities**: The group recommended expanding opportunities for early negotiations based on draft recommendations from CADTH. This

approach, already applied in some cases, should be more broadly adopted to reduce overall timelines.

2. **Post-LOI Implementation**: Concerns were raised about the uneven implementation of negotiated agreements across provinces, suggesting that formal discussions about readiness for implementation should occur during the LOI phase to ensure quick patient access once negotiations are completed.
3. **Equity Considerations**: It was emphasized that the CADTH patient input template should be updated to include questions on equity, ensuring that treatments contribute to or do not exacerbate disparities. Additionally, there is a need for more transparency regarding how quickly drugs are listed across provinces post-negotiation.

Discussion After Group 1 Presentation

During the discussion following the group's presentation, additional insights were shared on how to bring the patient perspective to the forefront. A suggestion was made to require all negotiators to read an impact statement at the start of each negotiation session, ensuring that patient input and real-life implications are considered before moving into discussions of price and cost-effectiveness.

Participants emphasized the need for earlier and more robust patient input during the HTA phase to influence negotiation mandates. It was proposed that everyone involved in the negotiation process should have access to patient input documents from the HTA process to integrate these perspectives effectively.

The group also discussed whether CADTH's 180-day performance metric for draft recommendations was meaningful, given that negotiations often do not start until the final recommendation is issued. It was suggested that revising these metrics and beginning negotiations earlier could improve the process.

The importance of setting more ambitious timelines for the entire process was emphasized, with the suggestion that multi-stakeholder discussions incorporating patient value earlier in the process could enhance the efficiency of negotiations.

Conclusion and Final Suggestions

In conclusion, the group offered several suggestions for improving the pCPA negotiation process:

1. **Implementation Readiness at LOI Stage**: Discussing provinces' readiness to implement agreements at the LOI stage to ensure quick patient access once negotiations are completed.
2. **Expanding Early Negotiations**: Moving negotiations forward as soon as a draft recommendation is available, especially for cases with a high likelihood of a positive final recommendation.
3. **Patient Input and Equity**: Updating the CADTH patient input template to include questions on equity and ensuring that patient input is integrated into negotiations at multiple stages.

Group 2 Discussion: Enhancing the Transparency and Efficiency of the pCPA Process

Transparency and Patient-Centric Focus in the pCPA Process

The group began by discussing concerns surrounding the CDA (Canadian Drug Agency) process, particularly the perception that it tends to prioritize economic evaluations over innovation and patient input. This issue extends into the pCPA (pan-Canadian Pharmaceutical Alliance) negotiation process, where it was perceived that some products were selected primarily for their potential for quick savings rather than their value to patients. The group felt that there needed to be a shift in focus to ensure that patient needs and values were more deeply embedded in the process from Health Canada all the way through to the provincial drug plan listings.

A central issue raised was the lack of transparency in the process. The negotiation queue is often referred to as a "black box," where both companies and patient groups have limited insight into how decisions are made and what factors are prioritized. The group suggested a more holistic approach that brings together the economic, patient-centric, and clinical perspectives to improve decision-making across all stages of the product lifecycle.

Addressing Uncertainty in Recommendations

The group explored ways to improve how patient groups and clinician groups can engage before formal negotiations. The idea of addressing uncertainty in the recommendations before negotiations begin was discussed. A level-setting conversation, sometimes referred to as an "empty chair for the patient," was proposed to ensure that patient needs are always prioritized

during negotiations. Triage systems were also considered, with the goal of accelerating negotiations for products with a clear patient benefit, aligning with the concept of a forced triage to bring patient perspectives earlier into the process.

Negotiation Timelines and Resource Allocation

One of the group's primary concerns was the timelines of the negotiation process, particularly from a patient group perspective, where time delays mean prolonged access issues for patients. It was recognized that the work involved in preparing an HTA submission is considerable and requires early notice to ensure that patient groups have the time and resources needed to contribute effectively.

The group underscored the importance of prioritizing breakthrough products that could have a tangible impact on patient outcomes. However, there was also a recognition of the value in products that may appear similar to existing therapies but offer unique advantages, particularly in environments where drug shortages are a concern.

The group referenced insights from the Steve Williamson video, which discussed the importance of flexibility from companies during negotiations. The video emphasized that having earlier engagement could allow for greater adaptability and readiness on all sides, ensuring that timelines remain on track.

Incorporating Patient Values into the Process

The discussion touched on patient values, emphasizing the need for more transparency in how these values are considered during negotiations. There was a strong consensus that patient groups should be involved earlier in the process, particularly before negotiations begin, to allow them to contribute meaningfully. This could involve earlier notice about the data from clinical trials so that patient organizations can form their positions in time for the HTA (Health Technology Assessment) and negotiation processes.

The importance of evaluating a product's unmet need was discussed, with a focus on drugs that offer new mechanisms of action. These drugs, which provide solutions for patients who have exhausted all other treatment options, were seen as having the highest priority for faster access. However, it was acknowledged that drugs with similar mechanisms of action or that work in

combination therapies should be considered lower in priority compared to those with novel mechanisms.

Cost Considerations in Price Negotiations

Another area of discussion focused on the cost of drug development and how it impacts price negotiations. The group highlighted the significant difference in cost between drugs approved based on Phase I or Phase II data compared to those that undergo large Phase III trials. It was suggested that drugs approved earlier in the development process should have a lower cost due to the reduced expense of conducting Phase III trials.

The need for realistic pricing was emphasized, with participants advocating for binding arbitration in cases where negotiations stall. There was also discussion around whether the ICER (Incremental Cost-Effectiveness Ratio) calculations should be adjusted to reflect unmet needs more accurately.

The Steve Williamson video also contributed to this discussion, highlighting how in the UK, negotiators apply flexibility and ensure that price considerations fit into a larger cost-effectiveness framework, which could serve as a model for Canada.

Provincial Implementation Challenges

A significant concern raised during the discussion was the time lag between reaching a Letter of Intent (LOI) and the actual provincial listing of a drug. The group felt that there needed to be earlier discussions with provinces about their capacity to implement drug listings to reduce these delays. The idea of funding becoming available immediately after a positive CDA recommendation was also explored, with the understanding that adjustments could be made afterward if necessary.

Improving the Assessment of Value

The group extensively discussed the challenge of assessing value in negotiations. QALYs (Quality-Adjusted Life Years) were seen as a highly imprecise metric, with many participants questioning their continued use as the gold standard. The group agreed that multiple factors need to be considered when determining the value of a drug, including its impact on quality of life, potential for lower toxicity through dosage adjustments, and its real-world effectiveness. There

was concern that relying too heavily on QALY calculations might result in misleading conclusions about the value of new drugs.

Furthermore, participants emphasized the importance of factoring in patient preferences and values into the decision-making process. It was suggested that patient preference studies could help quantify the weight that should be assigned to patient values during negotiations, though it was acknowledged that HTA agencies globally are still grappling with how to integrate this effectively.

Conclusion and Final Suggestions

The discussion concluded with several recommendations for improving the pCPA process:

1. **Increased Transparency**: There is a need for greater transparency in the CDA and pCPA processes, particularly regarding how patient values and unmet needs are factored into negotiations.
2. **Early Engagement of Patient Groups**: Ensuring that patient groups receive early access to trial data and are involved in discussions before negotiations begin will help them provide more **meaningful input**.
3. **Triage System for Negotiations**: A forced triage system that prioritizes breakthrough therapies with significant patient benefits should be implemented to expedite negotiations for these products.
4. **Re-evaluating QALYs**: The group called for a reassessment of the QALY framework, advocating for a more nuanced approach to evaluating drug value that incorporates patient experiences and real-world effectiveness.
5. **Binding Arbitration**: Binding arbitration could be used to resolve stalled negotiations, ensuring that patients are not left waiting for access to new therapies.
6. **Provincial Listing Challenges**: Addressing the delays between LOI and provincial listings by engaging provinces earlier in the process could help ensure quicker access to new treatments for patients.

Group 3 Discussion: Global Best Practices and Operational Improvements for pCPA

Exploring Best Practices from International Models

The group began by examining best practices from other countries, such as **France** and its approach to early payment and reimbursement. In France, if a product demonstrates therapeutic improvement, it gets funded immediately, and if it fails to do so, funding ceases. This was contrasted with the now-defunct Human Drug Advisory Panel in Canada, which previously helped determine the level of therapeutic improvement and prioritized certain products for early funding. There was agreement that Canada could potentially reinstate or adapt a similar process to expedite access to priority products.

In addition, the UK's model was mentioned, which integrates health technology assessment (HTA) and negotiation teams more closely. In the UK, negotiations are structured within a cost-effectiveness framework, with an emphasis on ratification by NICE (National Institute for Health and Care Excellence), ensuring that cost-effectiveness thresholds are met.

Insights from the Steve Williamson video also reinforced the importance of integrating flexibility into negotiation processes, as seen in the UK, where negotiations are tightly aligned with cost-effectiveness assessments, allowing for faster access to therapies.

The Challenges of Comparative International Models

While international comparisons can provide insights, the group expressed caution, particularly in referencing countries like New Zealand, where budget capping significantly limits drug access. Participants noted that despite some appealing aspects of New Zealand's system, it ultimately led to widespread dissatisfaction and significant limitations in cancer drug access. This example highlighted the risks of adopting models from countries where healthcare systems face different challenges and constraints.

Encouraging Greater Engagement with Life Sciences

Life sciences were identified as a potential driver for influencing HTA processes and negotiations, as seen in the UK and Quebec. In Quebec, life sciences investment plays a crucial role in influencing drug negotiations and fostering faster patient access. The group discussed whether

Canada could better leverage its life sciences investments to enhance patient access and improve negotiation efficiency.

Patient Involvement in Negotiations: Lessons from Global Systems

There was consensus that patient groups should have a more formalized role in negotiations. While patients are invited to provide input, their voices are often not directly heard at negotiation tables. The group noted that although Canada has a framework for patient involvement in policy-level discussions, a similar mechanism is missing from the pCPA negotiation process.

One idea raised was to provide patients with training and resources to help them better articulate their needs and understand the negotiation process. This would allow patients to contribute more meaningfully to policy and decision-making discussions. There was also interest in seeing pCPA leadership expand its board membership to include patient advocates, as seen in the UK and other jurisdictions.

Incorporating Patient Values in Decision-Making

The group discussed efforts in Europe and Canada to integrate patient values into HTA processes. Workshops and discrete choice experiments are being conducted by HTA agencies to better understand patient preferences. However, a significant challenge remains in determining how much weight to give to patient input, especially when balancing it with clinical benefits and cost-effectiveness.

The group agreed that although work is ongoing in this area, Canada lags behind in applying patient values to negotiation outcomes. One potential solution was requiring pCPA to report on how patient values are applied in its decision-making framework, fostering greater accountability and transparency.

Improving Transparency and Accountability in pCPA

Several participants raised concerns about the lack of transparency in the pCPA's decision-making process. The German system was cited as an example where real-world data (RWD) is collected and reassessed to guide future negotiations. Participants suggested that Canada adopt a similar approach to collect evidence on how medicines work in the real world, allowing for more informed negotiations based on actual patient outcomes.

Another suggestion was to develop performance standards for pCPA, similar to global benchmarks. These standards would hold the pCPA accountable for meeting timelines, making decisions more transparent, and improving operational efficiency. There was also discussion about requiring pCPA to publicly report on its progress and explain how it applies principles of patient-centric decision-making.

The Steve Williamson video highlighted that greater transparency in the UK system has led to more effective negotiations and improved patient access. The group discussed how Canada could adopt a similar model to enhance transparency and accountability within pCPA.

Conditional Approvals and Real-World Data (RWD)

The group explored the idea of conditional approvals, which allow for immediate patient access while collecting additional real-world data. This model is already being used in precision oncology and rare disease settings, where early access can significantly impact patient outcomes. Participants suggested expanding this model to other therapeutic areas, using real-world data to inform future negotiations and pricing decisions.

The collection of RWD was seen as an essential tool for ensuring timely access while still allowing the system to make informed decisions about a drug's long-term value and effectiveness. This would allow the negotiation process to begin earlier and provide patients with potentially life-saving treatments before all clinical trials are completed.

Key Recommendations for pCPA Based on Group 3 Discussion:

1. **Adopt Best Practices from Global Models**: Leverage international examples like the French and UK systems to integrate HTA and negotiation more closely, prioritize therapeutic innovation, and expedite funding for high-priority products.
2. **Engage Patient Groups Earlier and More Meaningfully**: Formalize patient involvement at the negotiation level and provide training to help patients better articulate their needs. Expand pCPA leadership to include patient representatives.
3. **Transparency and Reporting**: Implement performance standards that hold pCPA accountable for meeting timelines and ensuring patient-centered decision-making. Require pCPA to report on how patient values are integrated into negotiations.
4. **Conditional Approvals with Real**-World-Data: Expand the use of conditional approvals to allow early patient access while collecting real-world data to guide future negotiations.

3.0 Conclusion

The Sixth Canadian Cancer Treatment Hackathon brought together key stakeholders, including industry experts, patient advocates, healthcare professionals, and policymakers, to critically examine the barriers to timely access to cancer treatments in Canada. Through a comprehensive exploration of the drug negotiation process, participants identified several systemic challenges, including protracted timelines, capacity limitations, and a lack of transparency in the decision-making process at various stages of the pan-Canadian Pharmaceutical Alliance (pCPA) framework. These delays directly affect patient outcomes, highlighting the urgency of reforming the price negotiation and reimbursement processes.

One of the most significant outcomes of the Hackathon was the consensus on the importance of integrating patient perspectives early and consistently throughout the drug evaluation process. Participants emphasized the need to involve patient advocacy groups before formal negotiations begin, ensuring that patient needs and real-world experiences are factored into decisions about drug pricing and accessibility. This shift toward a patient-centered approach marks a critical step toward more equitable access to cancer therapies, where patient outcomes and quality of life are given equal weight alongside economic considerations.

The discussions also underscored the potential for Canada to adopt global best practices, particularly from countries like the UK and France, where systems of managed access and conditional approvals have successfully accelerated patient access to innovative treatments. Participants explored how such models could be adapted to the Canadian context, especially in light of Canada's multi-jurisdictional healthcare system. The concept of conditional approvals, in particular, emerged as a promising solution for providing early access to life-saving cancer drugs while gathering additional real-world data to inform long-term pricing and reimbursement decisions.

Transparency and accountability within the pCPA process were recurrent themes throughout the Hackathon. The "black box" nature of the negotiation queue, where limited information is available to stakeholders, was identified as a significant impediment to trust and efficiency. To address this, participants recommended the implementation of performance metrics and reporting standards for the pCPA, ensuring that timelines are met and that decision-making processes are clear and

accessible to all stakeholders, including patients. These measures would not only improve the operational efficiency of the pCPA but also enhance public confidence in the fairness and effectiveness of the system.

In addition, the Hackathon brought attention to the need for flexibility in price negotiations, particularly for breakthrough cancer treatments that offer new mechanisms of action or address unmet medical needs. The current reliance on traditional cost-effectiveness metrics like Quality-Adjusted Life Years (QALYs) was critiqued for its limitations in capturing the full value of cancer therapies, especially those that provide significant improvements in quality of life or symptom management. Participants advocated for a more nuanced approach to value assessment, one that incorporates patient feedback and real-world outcomes in a meaningful way.

The group discussions also highlighted operational improvements that could streamline the negotiation process, such as earlier pipeline meetings between manufacturers, patient groups, and the pCPA, as well as the prioritization of simpler cases to free up resources for more complex negotiations. This approach would ensure that high-priority cancer drugs, particularly those with no existing alternatives, are expedited through the system, reducing the time patients must wait for access to new therapies.

Ultimately, the Sixth Hackathon served as a critical forum for developing actionable solutions aimed at improving the timeliness, transparency, and fairness of cancer drug access in Canada. The recommendations put forward—ranging from enhanced patient involvement to the adoption of conditional approvals and real-world data—represent a collective vision for a more efficient and equitable system. By addressing these core issues, Canada can better meet the needs of its cancer patients, ensuring that they receive timely access to the innovative treatments that have the potential to save and improve lives. The success of this Hackathon lies not only in the identification of these challenges but in the collaborative effort to propose practical, patient-centered solutions that can drive meaningful change in the Canadian healthcare landscape.

Appendix 1: Hackathon #6 Agenda

Time	Agenda item	Lead
10:05–10:15am	Opening remarks	Barry Stein
10:15 – 10:40am	• Review agenda and highlight purpose and intended outcome. • Roundtable introductions • Review outcomes from previous Hackathons	Bill Dempster
10:40 – 11:00am	Overview of key Hackathon results/recommendations	Bill Dempster
11:00 – 11:10am	Review format and breakout group assignments	Bill Dempster
11:10-11:20am	BREAK	All
11:20 – 12:10pm	Breakout groups	All
12:10 – 12:50pm	Presentations to the plenary (10-15 mins. per group)	All
12:50 – 1:00pm	Closing remarks and next steps	Barry Stein
1:00pm	Session adjourns	N/A

Appendix 2 – List of experts and representatives on the pre-recorded panel

Dr. David Stewart, a medical oncologist

Dr. Nigel Rawson, a pharmaco-epidemiologist

Steve Williamson, oncology pharmacist and associate director at the National Institute for Health and Care Excellence (NICE)