Meeting Report

Fourth Canadian Cancer Treatment Hackathon

November 13, 2023

Toronto, Canada

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Executive Summary

Speeding Up Public Access to New and Effective Medicines in Canada

The Fourth Canadian Cancer Treatment Hackathon, held on November 13th, 2023, convened stakeholders to collaboratively address challenges in accessing innovative medicines in Canada. The event aimed to build upon insights from the previous Hackathons, exploring international collaborations and innovative practices to reshape the Canadian drug access landscape.

Key Challenges and Context:

Persistent challenges in accessing new therapies in Canada are attributed to the complex review and reimbursement procedures. The Fourth Hackathon focused on examining the implications of current and upcoming health technology assessments (HTA) advancements, proposing tangible solutions to expedite the availability of new medicines.

Although Health Canada (HC) has granted regulatory approvals for new medications in Canada, challenges arise at various stages of the drug review and reimbursement process, particularly during the HTA conducted by agencies such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and l'Institut national d'excellence en santé et en services sociaux (INESSS); and the negotiation phase, overseen by the Pan-Canadian Pharmaceutical Alliance (pCPA), along with provincial funding determinations, contribute to the existing gap in accessing new and effective cancer medications in a timely manner.

Preparation and Collaboration:

In anticipation of the fourth Hackathon, participants engaged in preparatory sessions, exploring international collaborations and advancements in various other HTA initiatives. Pre-recorded panels provided valuable insights into Canada's HTA landscape, global best practices, and international collaborations, setting the stage for informed discussions during the hackathon.

Breakout Sessions:

Participants were divided into three groups, and each group had the opportunity to address all key themes during the breakout sessions. The breakout sessions aimed to generate actionable ideas and solutions, emphasizing possible tangible initiatives to ameliorate the timeline for access to new and effective drugs in Canada.

Theme 1: Challenges in Canada's Current Process for Reviewing and Reimbursing New Medicines

Group 1 concentrated on transitioning from conceptual to actionable ideas, addressing key gaps and

barriers in the current process. Key findings included:

- **Proactive Measures:**
  - Initiating processes without waiting for a Letter of Intent.
  - Undertaking work at pCPA during HTA reviews.
- **Provincial Engagement:**
  - Increasing provincial engagement earlier in the review process.
  - Committing to specific timelines for drug listings.
- **Broader Societal Perspective:**
  - Incorporating a broader societal perspective in value assessments.
- **Collaborative Planning:**
  - Building project plans through multi-stakeholder dialogues.
  - Increased use of the parallel review process/timelines/alignment
- **Stakeholder Integration:**
  - Integrating private payers into negotiation processes.
  - Proposing advance clearance for subsequent indications on an approved drug.

Additional Proposals:

- Allocating more resources for the pCPA.
- Pre-negotiating for future indications.
- Transparency in payer motivations.
- Enhanced patient engagement in the deliberative HTA process.

Theme 2: Best Practices from Other Jurisdictions

The discussion covered critical areas, drawing inspiration from international best practices:

- **Learning from the UK:**
  - Prioritizing the Innovative Medicines Fund linked to societal benefits.
- **Shared Risk-Taking:**
  - Advocating for shared risk-taking among key stakeholders.
- **Market Authorization Negotiations:**
  - Negotiating drug prices at the market authorization stage.

Additional Strategies:

- Streamlining reviews and processes.
- Including private payers in the HTA process.
- Transparent pricing evaluations.
- Focusing on utilization of Real-World Evidence (RWE) methods to collect Real World Data to allow for conditional access.

- Rethinking the economic model at CADTH.
- Collaborating earlier on with the pCPA.

Theme 3: International Collaborations

Group 3 focused on learning from international collaborations:

- **Project Orbis in HTA:**
  - Advocating for the implementation of Project Orbis (currently undertaken at the regulatory level by Health Canada) in HTA processes.
- **Single HTA Organization:**
  - Discussing the concept of a single HTA organization CADTH/INESSS combined
- **Standardized Frameworks:**
  - Emphasizing the need for standardized international frameworks.
- **Clinical Collaboration:**
  - Fostering clinical collaboration on a provincial level.
- **Data Sharing:**
  - Exploring the sharing of RWE and Real-World Data (RWD).
  - Proposing a consolidated pool of data.
- **Patient Engagement:**
  - Emphasizing greater patient group engagement in international collaborations.

Highest Priority Ideas:

In the pursuit of accelerating public access to new and effective medicines, the following ideas emerged as the highest priorities through a voting process:

- Learning from the UK's Innovative Medicines Fund.
- Initiating processes for listings without waiting for a Letter of Intent.
- Engaging provinces earlier in the review process and committing to a timeline for drug listing.
- Embracing shared risk-sharing agreements among stakeholders.

Conclusion

These ideas collectively underscore additional strategic and collaborative approaches toward expediting public access to new and effective medicines in the Canadian healthcare landscape. This Hackathon identified challenges and facilitated the generation of impactful solutions that have the potential to expedite drug evaluation and access in Canada. The momentum generated from this collaborative endeavor provides a foundation for continued dialogue, innovation, and transformation in the Canadian healthcare drug approval lifecycle.

1.0 Introduction

In Canada, individuals relying on public drug coverage grapple with persistent challenges in accessing new therapies due to intricate and sequential review procedures. These processes wield significant influence over decisions made by public drug plans regarding access and reimbursement for innovative medicines. The existing drug evaluation and reimbursement framework was identified as contributing to restrictions and delays in the timely access to new and effective treatments and has prompted a critical examination of its impact on healthcare outcomes and patient well-being.

As the healthcare landscape evolves, the need to streamline pathways for integrating new and promising medicines into the public system becomes increasingly evident. Recognizing the significance of these challenges, the Canadian Cancer Treatment Hackathons provide a platform for stakeholders to collaboratively delve into access-to-medicine issues. Persistent disparities in access times and reimbursement underscore the urgency of reevaluating the existing framework. Building upon insights gained from the three previous Hackathons, the focus remains on developing innovative solutions that foster efficiency and equity in making cutting-edge treatments accessible to Canadian patients.

The experiences and lessons learned from past discussions laid the groundwork for refining strategies and forging ahead in the quest for an improved system. As stakeholders convened for the fourth Canadian Cancer Treatment Hackathon on November 13th, 2023, the collective effort aimed to build upon the momentum generated to delve deeper into actionable initiatives that have the potential to reshape the landscape of drug access in Canada.

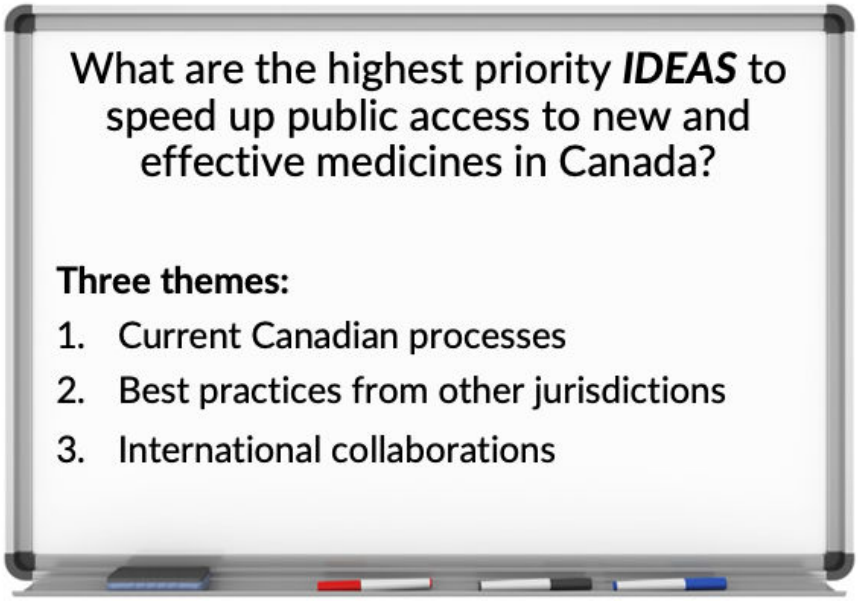
The preceding hackathons set the stage for ideation within existing structures and an exploration of international best practices. The third Hackathon in particular provided a platform for participants to conceptualize a new decision-making framework for patient access to new medicines in Canada. As the conversation evolved, the fourth Hackathon aspired to elevate the discourse.

In anticipation of the event, participants were provided with pre-recorded panels featuring leading experts. This format allowed participants the opportunity to view these panels before the in-person session. Panel #1 delved into global and emerging best practices, while Panel #2 focused on Health Technology Assessment (HTA) international collaborations and global best practices. These panels aimed to explore international collaborations and their implications for access to new medicines in Canada, providing insights into current and upcoming advancements in the HTA initiatives.

Figure 1. Hackathon 4 Key Themes

Hackathon 4

Speed up public access to new and effective medicines in Canada



Participants brainstormed in breakout sessions and shared their ideas in a plenary session (Appendix A – Fourth Hackathon Agenda).

Overall, Hackathon 4 aimed to address:

- The implications of current and upcoming HTA advancements.
- Tangible solutions to expedite the availability of new medicines, addressing Canada's current challenges.

1.1 Background

Over time, a persistent challenge in Canada has been the limited availability of medications. Despite approval in the EU, the US, and Canada over a five-year period, many drugs encounter obstacles in securing reimbursement in Canada. Only nine out of 83 drugs approved by all three regulators between 2016 and 2020 were funded in a provincial formulary by the end of 2021, highlighting a substantial gap in timely medicine delivery, with delays attributed not only to Health Canada's review but also to subsequent HTA, price negotiation and provincial listing steps.[1] Notably, Canada ranks 19th out of the 20 OECD countries in the time it takes for patients to access new medicines following approval, with an average of 732 days. This stark contrast is exemplified when compared to countries like the UK, where patients typically gain access in 264 days[1].

Concerns also centered around the Patented Medicine Prices Review Board (PMPRB) and its role in reviewing list prices and potentially investigating excessive pricing. Recent consultations by the PMPRB indicate an awareness of its broader ecosystem, considering factors such as the

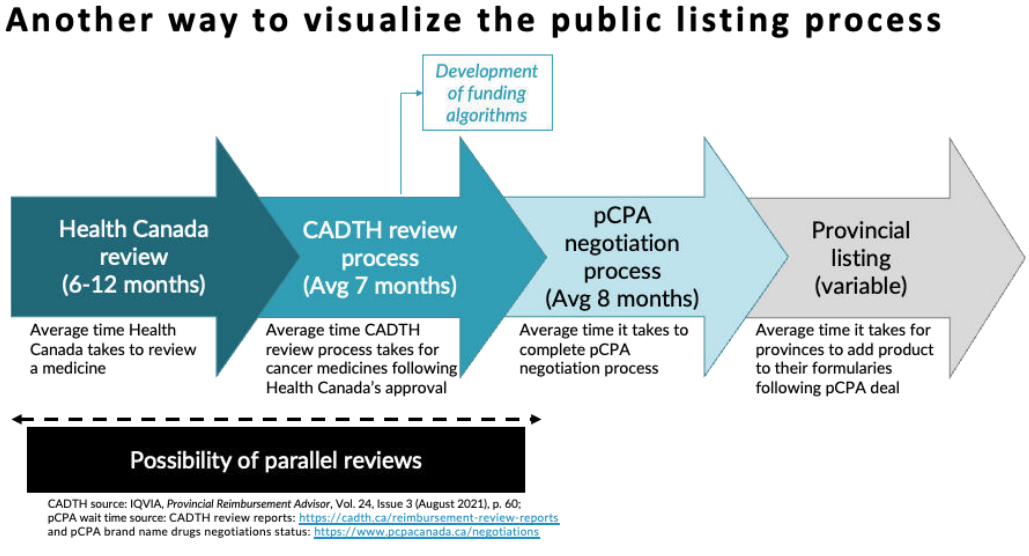
Canadian Agency for Drugs and Technologies in Health (CADTH), the pan-Canadian Pharmaceutical Alliance (pCPA), and provincial funding decisions. Post-Health Canada review, Health Technology Assessments (HTA) for clinical benefit, economic evaluation, patient-based values and adoption feasibility follow, leading to negotiations by the pan-Canadian Pharmaceutical Alliance (pCPA). The drug negotiation process is led by the Office of the pCPA where one province leads the negotiation process on behalf of the others, and once negotiations are complete, a letter of Intent (LOI) is entered into and the provinces may list the drug on their formularies at the negotiated price. Going forward, the Office of the pCPA will build out its own negotiation experience and begin to represent the jurisdictional payers.

The timing aspects of drug approval processes in Canada were discussed. Health Canada's review timeline ranges from six to twelve months, with potential acceleration to three months through global collaboration in Project Orbis. Canada's active participation in over 50 Project Orbis reviews has expedited marketing authorizations, particularly for cancer drugs.

The CADTH review process takes six to seven months, consistently meeting timelines. Health Canada's review process aligns with these timelines, ensuring accuracy, especially in the context of cancer drugs. As part of the aligned review process with Health Canada, CADTH and INESSS began accepting pre-NOC submissions up to 180 calendar days prior to the anticipated date of market authorization.

There is also the possibility of developing a provisional funding algorithm during the CADTH review, emphasizing its significance in determining the place of a therapy in cancer treatment, and potentially affecting the use of other therapies in that specific line of treatment.

Figure 2. Visualization of the Listing Process

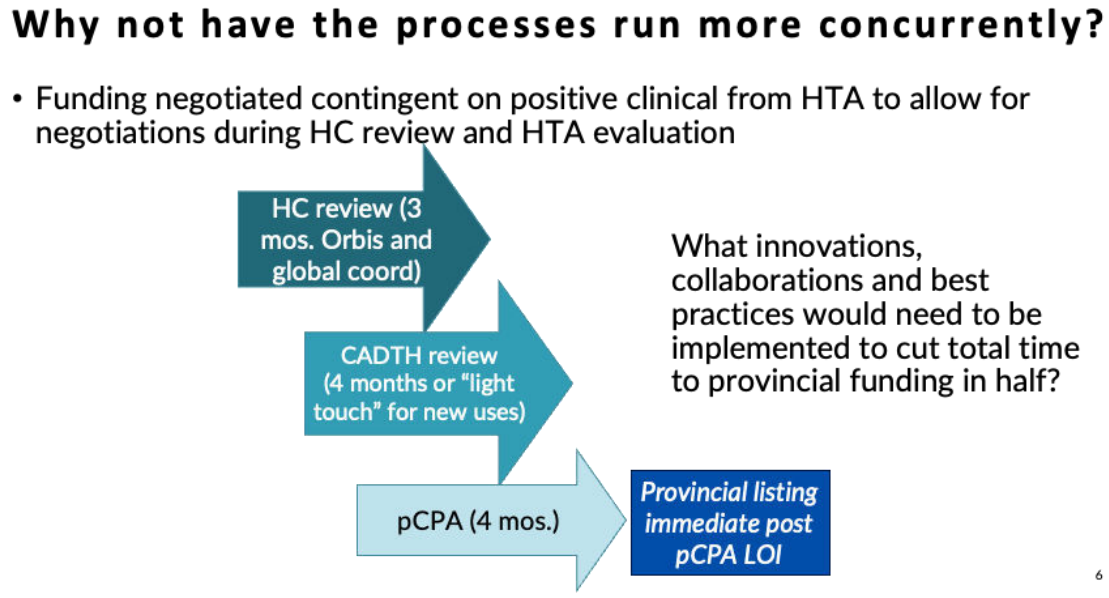


The provincial advisory group (PAG) and pCPA play a crucial role in accounting for funding algorithms for currently funded drugs. When a new indication or drug undergoes the CADTH review process, the baton is handed over to pCPA, with an average negotiation period of eight months, though it can extend further. IQVIA data indicates variable negotiation times, with a significant issue being the time to initiate negotiations after a positive recommendation from CADTH or the Institut national d'excellence en santé et en services sociaux (INESSS), taking up to six months. Time to complete negotiations once initiated – which leads to either a Letter of Intent to fund with jurisdictions or "no agreement" – is also variable.

Provincial listings vary in speed, with some occurring within three months and others taking considerably longer or not happening at all. pCPA issues a letter of intent (LOI), not a commitment to list within a specific timeframe. The decision often depends on provincial budgeting considerations or the need for additional HTAs or reviews.

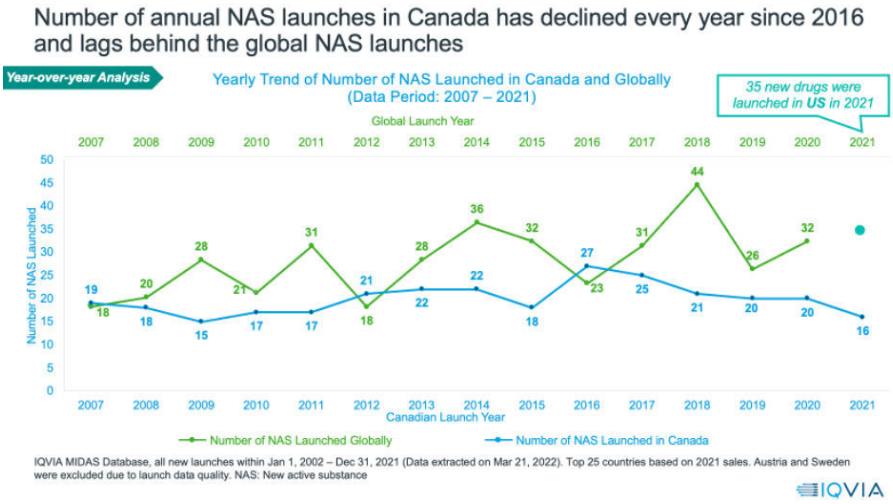
For cancer drugs, timelines differ significantly, emphasizing the need for targeted solutions. The discussions during the hackathons aimed to address these challenges, with innovations such as Time-Limited Reimbursement (TLR) and the pCPA temporary access process (pTAP) [2–4]. Hackathon challenge outcomes aimed to reduce timelines by an average of 50%, with a focus on optimizing the HTA review process prior to Health Canada NOC to further accelerate timelines. One proposed idea noted was the possibility of pCPA negotiations being done in parallel to CADTH/INESSS recommendations and being contingent on a positive recommendation from CADTH and/or INESSS .

Figure 3. Optimizing Pathways: Acceleration of Provincial Funding



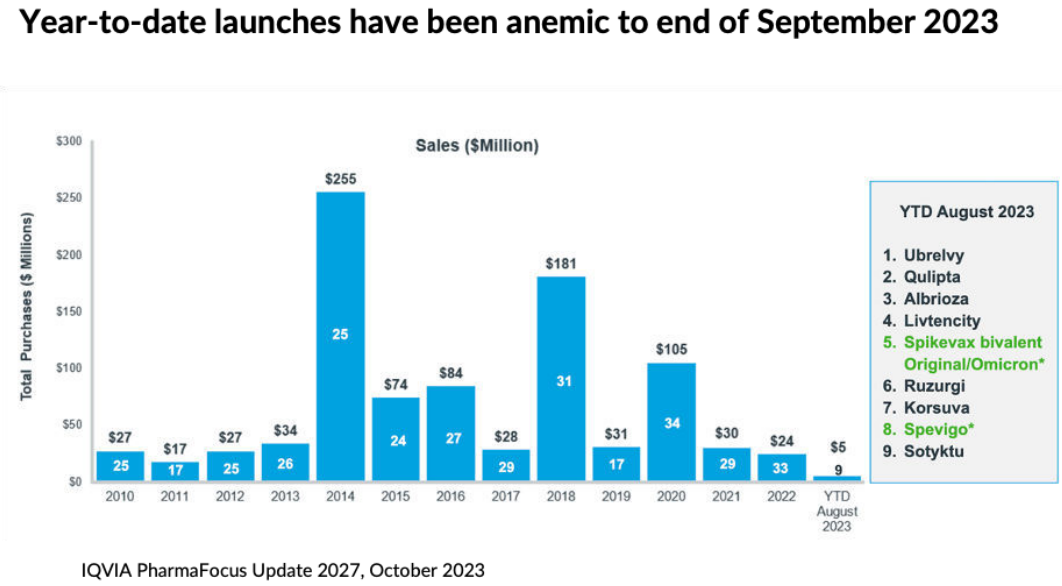
There has been a significant decline in drug launches in Canada in recent years. The following figure (developed in collaboration with IQVIA and Life Sciences Ontario shows the annual trend of new active substances launched in Canada compared to the US and globally. The data shows a significant decline in Canada's launches, averaging around half of those that could have been expected based on earlier trends.

Figure 4. Number of annual NAS launches in Canada



Year-to-date launches up to August 2023 have also been notably low, with only nine, highlighting a decline compared to previous years.

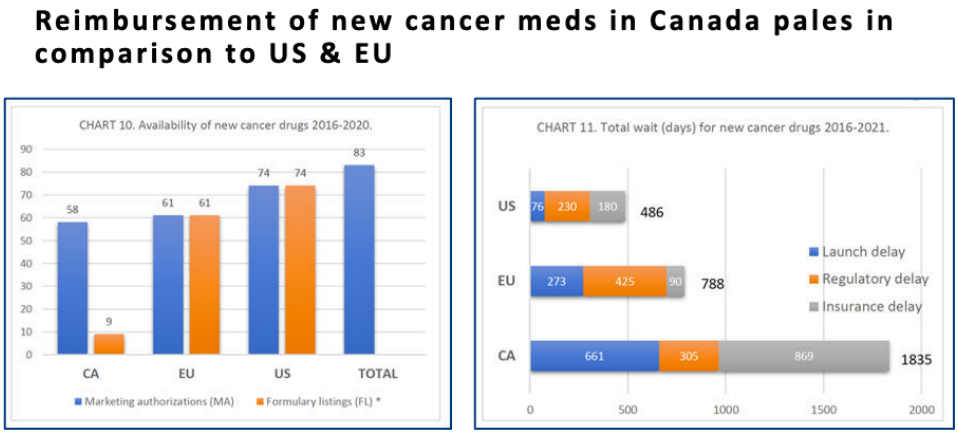
Figure 5: Year-to-Date Launches



A Study led by Bret Skinner at CHPI,[2] examined 83 medicines approved in Canada, the EU,

and the US between 2016 and 2020, and revealed that the US had access to 74 out of 83, all funded by the end of 2021. In contrast, Canada, with 58 approved, only had nine on a formulary by the end of 2021. This reflects how Canada can enhance its attractiveness for regular drug launches, considering disparities in timelines compared to the EU and the US. Delays are categorized into three sections: launch delay (developer-dependent), with Canada averaging 661 days; regulatory delay (comparable to the US and EU at 305 days for Health Canada review); and insurance delay impacting funded public access, signifying a significant lag in Canada, especially for cancer drugs.

Figure 6: Reimbursement of New Cancer Medications in Canada



Source: Skinner, Brett J (2023). New cancer drugs in Canada 2012 to 2021: an economic analysis of cost, benefit, availability, and public insurance coverage. Canadian Health Policy, Apr. 2023. https://doi.org/10.54194/IYUA1228.

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During the first Hackathon, the emphasis was on optimizing the existing system and identifying opportunities for time savings. Notably, participants strongly advocated for a global solution, promoting simultaneous international reviews to expedite regulatory processes.

The second Hackathon took a virtual tour across England, Wales, France, Germany, Italy, and Australia, showcasing unique practices observed in each jurisdiction. England and Wales stood out for their early access drug funds, managed entry agreements, and commitment to becoming a global leader in adopting new treatments and technologies. The discussions explored the benefits of managed access systems and transparent pricing, drawing inspiration from diverse global practices.

The third Hackathon was a creative session and provided participants the opportunity to assume the role of a new “Super Minister” of Health, Finance, and Economic Development and delving into five crucial themes: payer integration and consistency, process and decision-making, HTA and value-based decisions, patient-centric approaches, and transparency and accountability. Noteworthy ideas included contemplating a subscription system for patient registries, exploring negotiations contingent on positive clinical outcomes, and devising innovative agreement models for

managed access.

Collectively, these hackathons underscore the significance of collaborative, data-driven approaches to enhance the efficiency of the Canadian healthcare system. The discussions center around integrating best practices from international jurisdictions, exploring inventive funding and negotiation models, and prioritizing patient-centric and transparent decision-making processes.

1.2 Pre-recorded Panels:

The pre-recorded panels with HTA experts and representatives (Appendix 2) of other HTA systems set the stage for the Fourth Hackathon session, offering participants valuable insights into crucial topics. During the first panel session, the focus was on exploring the current HTA landscape in Canada as well as new initiatives such as time-limited reimbursement (TLR) and the use of Real-World Evidence (RWE). This comprehensive exploration aimed to provide a nuanced understanding of the challenges and innovations within Canada's HTA framework. This provided participants with an opportunity to gain a robust foundation to engage in informed discussions during the subsequent in-person Hackathon session. Additionally, the second-panel session emphasized international collaborations and global best practices, shedding light on their implications for the review and reimbursement of new medicines, ultimately influencing access to innovative treatments. The pre-recorded panel sessions were distributed in advance of the meeting to ensure participants were well-prepared for the in-person session and ready to contribute meaningfully to the collaborative discourse.

Panel Session #1 – Exploring Global and Emerging Best Practices:

The examination of Canada's current HTA landscape revealed multifaceted challenges and ongoing initiatives. Central to the discourse was the consideration of the proposed time-limited reimbursement procedure at the CADTH and INESSS level and the development of managed access agreements at the pCPA level.

The imperfections of the UK's Cancer Drugs Fund were acknowledged, yet its role in providing patients early access to medicines was emphasized, prompting contemplation on potential adaptations for the Canadian context.

Addressing the inherent uncertainties in HTA decision-making, particularly concerning drugs where there is only phase II data and small patient populations and characteristics, allows for the integration of Real-World Data (RWD) as a pivotal solution. Databases, notably in the UK, were highlighted for their potential to collect real-world data from cancer patients undergoing treatments. Real World Evidence (RWE) is gaining prominence as a valuable tool for evaluating patient outcomes and reevaluating medicines, with specific attention given to its role within the Cancer

Drugs Fund framework.

In the pursuit of enhanced access and reimbursement strategies, insights from global practices were deemed essential. A notable emphasis was placed on the necessity for Canada to learn from international models and foster more efficient collaboration. Bureaucratic hurdles, especially prolonged timelines misaligned with the urgent needs of patients, were discussed and the participants urged a more collaborative and streamlined approach to regulatory and HTA policies.

A comparative analysis of the Canadian and UK models underscored the advantages of a centralized system, allowing manufacturers to engage with HTA organizations at an earlier stage. Silo-busting, breaking down organizational barriers, was presented as an important opportunity to expedite processes, fostering collaboration and concurrent actions. However, concerns about the reluctance to embrace managed entry agreements in Canada were expressed, citing apprehensions about drugs being withdrawn when appropriate and hesitancy to make medicines available due to potential risks.

The discussion extended to insights from the representative of the UK system, spotlighting successful elements in their HTA approach. NICE's forward-thinking vision statement, characterized by a proportionate approach, sandboxing for new methods, and frameworks on equity and relevance, was highlighted. Factors influencing the evolution of this vision, such as leadership changes, Brexit, and the recognition of the value of life sciences investment, were also explored.

The role of RWE in supporting access to new medicines took center stage, with a focus on its growing importance in evaluating treatment effectiveness. Challenges in utilizing RWE, especially in rare diseases, were acknowledged, along with the pragmatic use of single-arm trials. The UK's pragmatic approach and the publication of a RWE framework by NICE were recognized as positive steps in this direction.

Willingness-to-pay thresholds in the UK and Canada were scrutinized, with a call for a more patient-focused approach that incorporates broader elements of “value”. Real-world data was highlighted as crucial in quantifying the impact of diseases and demonstrating the societal and economic benefits of treatments.

The session concluded with reflections on the need for a more pragmatic approach, involving payers at an early stage and transcending academic frameworks. International collaboration emerged as a recurring theme, emphasizing shared learning and potential synergies between countries. The hope for a more global approach to HTA, streamlining processes, and submitting joint evidence packages was expressed, providing valuable insights into the considerations for future improvements in the HTA landscape.

Panel Session #2 – HTA International Collaborations and Global Best Practices:

The discussion delved into the evolving landscape of HTA, specifically focusing on international collaborations and emerging best practices for reviewing and reimbursing new medicines. Experts explored innovative approaches and trends within the HTA processes, offering a global perspective on the matter. There was significant emphasis on adopting an innovative mindset to incorporate different types of evidence into HTA, to enhance the understanding of a drug's impact. The potential benefits of utilizing RWE, particularly from robust registries, were highlighted, although challenges around standardization and methodology were acknowledged.

The conversation also touched on the German approach to market access, emphasizing the unique process of reimbursement preceding assessment. Fast-tracking of pharmaceuticals in Germany, particularly through the Federal Joint Committee, was examined, shedding light on the country's distinctive method.

International collaborations, such as those involving Canada's HTA agencies, were discussed as mechanisms for sharing insights and avoiding duplication of efforts. Challenges in aligning methodologies and overcoming logistical hurdles were acknowledged, signaling the need for ongoing refinement and synchronization.

A key topic of interest was the upcoming changes in European Union regulations. The European Union (EU) wide health technology assessment also known as the Joint Clinical Assessment (JCA) goes into effect in January 2025 for oncology medicines and advanced therapy medicinal products (ATMP). It aims to harmonize processes and evidence requirements, establish predictability, avoid duplication of dossier development for manufacturers, and accelerate patient access across its member states through a single clinical assessment occurring in parallel with the European Medicines Agency (EMA) marketing authorization process. This discussion offered insights into the potential harmonization of methodologies and timelines across EU member states, providing a preview of a standardized approach to HTA. Critically, pricing and reimbursement decision-making will remain the responsibility of individual member states. While there may be advantages the risk is that it becomes an additional administrative layer (EUnetHTA)[5,6].

The conversation also touched upon the role of real-world evidence in Germany, where laws mandate the collection of RWE data in specific cases. The challenges associated with this ongoing process, including reliance on quality registries and the exploration of new methodologies like target trial emulation, were acknowledged.

Patient engagement emerged as a critical component of the HTA process, with both Canada and Germany highlighting the involvement of patient representatives in decision-making. Examples were provided where patient input influenced coverage decisions, showcasing the importance of incorporating diverse perspectives.

Overall, the discussion underscored the dynamic nature of HTA processes, with a focus on

continual innovation, collaboration, and the integration of real-world evidence to enhance access to new medicines globally.

2.0 Key Discussions Generated from Hackathon 4 Breakout Sessions

Themes and Guiding Questions for Breakout Sessions:

Participants split into three groups, each focusing on a key theme. The breakout sessions aimed to generate actionable ideas and solutions, emphasizing tangible initiatives to reshape the Canadian drug access landscape.

Theme 1: Gaps / Barriers in Canada's Current Process for Reviewing and Reimbursing New Medicines

- What do you perceive as some of the biggest barriers or gaps in the current process that were identified in Hackathon 1 that you would like to prioritize?
- Are there additional barriers or gaps not captured in the output from Hackathon 1 that you would like to prioritize?

Supporting material: printouts of a one-page summary of key outcomes from Hackathon 1

Theme 2: Best Practices from Other Jurisdictions

- What are the key aspects from other jurisdictions that were discussed during Hackathon 2 that should be prioritized and implemented in Canada?
- Are there additional key elements that other jurisdictions are doing that that Canada should look to adopt?

Supporting material: printouts of a one-page summary of key outcomes from Hackathon 2; printout of comparison of HTA processes in Canada, France, UK, Germany, Australia, and Italy

Theme 3: International Collaborations

- How can international collaborations among HTA organizations (i.e., CADTH/INESSS, NICE, AIFA, HAS, etc.) improve access to RWE and ultimately improve access to new medicines?
- What other elements should international collaborations explore to improve access to new medicines (i.e., accepting patient input data and/ or clinical data from collaborating jurisdictions within Canada's HTA process)?

Supporting material: pre-recorded panel discussions on International Collaborations

Theme 1: Gaps / Barriers in Canada's Current Process for Reviewing and Reimbursing New

Medicines

Top Voted High Priority Idea: Jurisdictions should not wait for a Letter of Intent (LOI) before preparing their processes for listings (7 votes)

Group 1 addressed the need to transition from conceptual to concrete, actionable ideas. The focus was on making the suggestions more tangible and impactful. The key ideas from this group included a call to expedite the processes without waiting for a LOI. Provinces should not wait for a LOI before preparing processes for drug listings. pCPA should begin its work while the HTA review is still in process.

Participants emphasized the need for increased provincial engagement early in the review process, advocating for a commitment to specific timelines for drug listing.

Additionally, the idea of considering a broader societal perspective in the determination of "value" assessments was introduced, suggesting a more comprehensive evaluation framework. The concept of building a project plan through multi-stakeholder dialogue between all parties including Health Canada, CADTH, INESSS, and pCPA at the outset of the process underscored the participants' interest in collaborative planning.

The integration of private payers into the negotiation process also garnered some attention, reflecting a recognition of the importance of involving diverse stakeholders for a more inclusive and effective process. "Nexus-Type" advanced clearance emerged as another idea to facilitate early access for subsequent indications after successfully negotiating the first.

Additional Ideas (Not Voted):

Advocacy for more resources for the CADTH, INESSS, and pCPA, emerged as an additional idea to increase the pace of drug reviews. Participants also discussed the idea of pre-negotiating for future indications, emphasizing the potential for streamlining negotiations and reducing the time required for future agreements.

Transparency emerged as a recurrent theme, with suggestions ranging from more transparent communication of payer motivations to the need for the pCPA to communicate its prioritization criteria.

Another important aspect was the proposal to integrate live patient and patient group input, emphasizing the significance of incorporating lived experiences into the expert committee deliberative process. It was noted that the Formulary Management Expert Committee (FMEC) is piloting this at present.

Additionally, participants called for more funding for cancer medicines in general and suggested exploring the possibility of a separate fund within jurisdictions to ensure a comprehensive

approach to cancer treatments.

Table 1 (a). Key Ideas and Votes for Gaps/Barriers in Canada's Current Medicines Review and Reimbursement Process:

Sno	Key Ideas	Total Votes
1.	Jurisdictions should not wait for a Letter of Intent before preparing their processes for listings – there is work pCPA can undertake while the HTA review is in process.	7
2.	Get the provinces more engaged in the process earlier in the review process – commit to a timeline for listing	6
3.	Account for a broader societal perspective in "value" assessments	3
4.	Build a project plan in a multi-stakeholder dialogue at the outset of the process	2
5.	Look for ways to integrate private payers into the product negotiation process	1
6.	Nexus-type clearance to avoid unnecessary delays	1

Table 1 (b). Additional Ideas: Gaps/ Barriers in Canada's Current Medicines Review and Reimbursement Process:

Sno.	Ideas
1.	More resources for pCPA to support (particularly within jurisdictions)
2.	Dedicated resources in each plan to implement Provincial Listing Agreements (P LA's)
3.	Pre-negotiate for future negotiations in other indications
4.	More transparency about what motivates payers to act earlier
5.	pCPA should communicate its prioritization criteria
6.	Could sponsors incentivize payers by ensuring complete dossiers are submitted earlier and make better use of the parallel review process – require sponsors to engage with HTA in pre-submission meetings
7.	Integrate patient input with lived experience into the expert committee deliberative process
8.	Call for more cancer medicines funding and/or a separate fund

Theme 2: Best Practices from Other Jurisdictions

Top Voted High Priority Idea: Innovative Medicines Fund and Societal Benefits (9 Votes):

Participants highlighted several ideas that could inform and enhance Canada's approach to drug evaluation. One standout proposal involved learning from the UK's Innovative Medicines Fund, which is linked to societal benefits. Participants expressed a keen interest in understanding and applying the principles of this fund, showcasing a collective enthusiasm for adopting successful models from other healthcare systems.

Another key idea centered around risk-sharing agreements, emphasizing collaboration as a strategy for advancing public access to new medicines. The concept of negotiating drug prices at the market authorization stage, drawing inspiration from the German model, also garnered attention as a potential best practice. Additionally, the importance of evaluating clinical benefit first, adopting a rolling submission approach, and enhancing collaboration with the pCPA was underscored, drawing inspiration from the EU model. These ideas reflected participants' focus on societal benefits, collaboration, and efficiency in the drug evaluation and reimbursement process.

Additional Ideas (Not Voted):

Participants put forth several additional suggestions to enhance best practices. Recommendations included streamlining reviews, drawing inspiration from NICE practices, and focusing on reimbursement of biosimilar drugs. Collaboration between CADTH, INESSS, and Health Canada for expanded access to previously approved drugs was proposed, along with the inclusion of private payers in the HTA process. Suggestions also encompassed a focus on transparent pricing to better evaluate the value of new treatments, rethinking the economic model at CADTH, and collaboration with the pCPA. Participants emphasized the need for increasing the engagement with patient groups, drawing inspiration from Germany, and advocated for funding for patient groups from government sources to assist in their providing input to the HTA agencies. The importance of focusing on RWE, and transparency in committees' decision-making processes emerged as additional considerations together with risk sharing and managed entry agreements. These ideas collectively reflected participants' interest in adopting best practices from other jurisdictions to inform and enhance the Canadian drug evaluation and reimbursement landscape.

Table 2 (a). Major Key Ideas and Votes for Best Practices from Other Jurisdictions:

Sno	Key Ideas	Total votes
1.	Market authorization first, then focus on clinical efficacy	
	Drug prices are negotiated at the market price	2
	UK has an innovative medicines fund → linked to societal benefits.	9
2.	Risk sharing among key stakeholders	4
3.	Evaluation of clinical benefit first → rolling submissions	2
4.	Negotiation process for pCPA	1
5.	National Standards on quality and timing of HTA and out of pocket costs	1
6.	EU regulation on clinical benefit assessment and collaboration – 2025 target.	1

Table 2 (b). Additional Ideas: Best Practices from Other Jurisdictions

Sno.	Ideas
1.	Streamline reviews
2.	NICE utilizes this for everything.
3.	Reimbursement of biosimilar drugs
4.	Collaboration between CADTH and INESSS, Health Canada for expanded access to previously approved drugs
5.	Collaborative process that includes private payers in the HTA process
6.	Focus on transparent pricing to better evaluate the “value” of new treatments
7.	Rethink the economic model at CADTH and collaboration with pCPA
8.	Inclusion and better engagement with patient groups – Germany
9.	Funding for patient groups from government sources e.g. included in the cost for CADTH Scientific Advice Focus on diverse funding structure (50/50 of pharma + government)

	What country does patient group engagement "best"?
10.	Focus on RWE – UK and Italy
11.	Transparency of managed entry agreements – UK
12.	Transparency of committees on their discussions and decision-making process
13.	Early access prioritization – regulatory, industry, HTA,

Theme 3. International Collaborations

Top Voted High Priority Idea: Project Orbis in HTA (3 votes)

Participants engaged in discussions aimed at learning from global practices and extracting beneficial insights. One significant idea involved the implementation of Project Orbis in HTA processes. The concept of a single HTA organization, specifically mentioning the EUnetHTA[6], was introduced. Participants acknowledged the complexity and challenges associated with this vision, suggesting that it might not be the most practical starting point.

The conversation expanded to explore the sharing of RWE and RWD on an international scale, contemplating the development of standardized frameworks and processes. This concept resurfaced in other groups, emphasizing the challenge of implementing such standards across Canadian provinces. Addressing the need to diminish a siloed mentality, the group recognized the importance of collaboration but questioned the specific desire for such collaboration in Canada. An intriguing point surfaced regarding whether the discussion was confined to HTA or extended to the broader regulatory process. The group expressed interest in learning more about CADTH's international collaboration but emphasized the necessity for increased communication and dialogue in this space. Patient group engagement was highlighted as a crucial aspect, possibly a more fitting starting point to add value. Building on previous discussions, there was a proposal to create a consolidated pool of data, referencing Italy's centralized patient registries. However, concerns were raised about data management and trusted sources. The group expressed curiosity about the activities of international organizations and emphasized the need for more information and dialogue to enhance learning and collaboration.

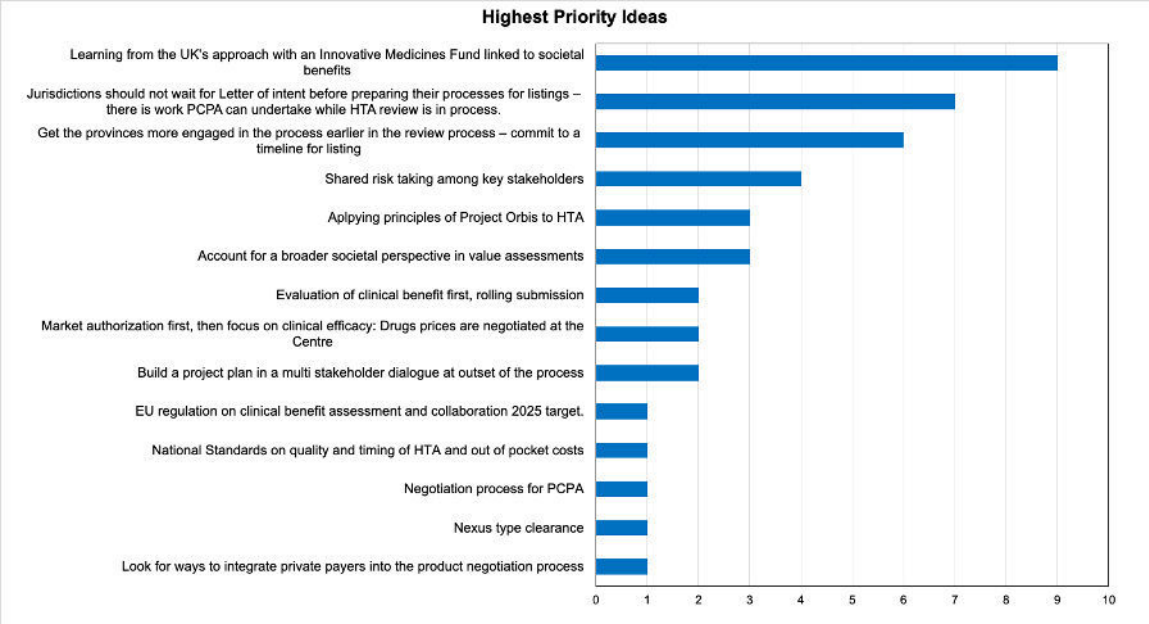
Table 3. Major Key Ideas and Votes for International Collaborations:

Sno	Key Ideas	Total votes
1.	Project Orbis in HTA	3
2.	One HTA Organization	0
3.	Acronyms and Education	0
4.	Standardized International Frameworks	0
5.	Diminishing Siloed Mentality	0
6.	Clinical Collaboration on a Provincial Level	0

3.0 Highest Priority Ideas to Accelerate Public Access to New and Effective Medicines in Canada:

In the pursuit of accelerating public access to new and effective medicines in Canada, a consensus emerged around the highest priority ideas, determined through a voting process. Topping the list with the most votes was the proposal to learn from the UK's Innovative Medicines Fund, which garnered a total of 9 votes. Participants expressed a keen interest in understanding and applying the principles of this fund, particularly its link to societal benefits, showcasing a collective enthusiasm for adopting successful models from other healthcare systems.

Closely following, with 7 votes, was the idea that jurisdictions should not wait for a Letter of Intent before initiating processes for listings. This suggests a shared belief in the significance of proactive measures and the need for parallel actions by jurisdictions during the HTA review. The emphasis on prompt action reflects a collective recognition of the importance of efficiency in the processes related to new medicine evaluations.



Gaining substantial support, the concept of getting provinces more engaged in the review process earlier and committing to a timeline for drug listing secured 6 votes. This idea underscores the value placed on collaborative efforts and timely commitments to facilitate the efficient listing of new medicines, showcasing a dedication to streamlining the review process.

Additionally, with 4 votes, the notion of risk-sharing agreements among key stakeholders emerged as a significant approach to advancing public access to new medicines. While not securing as many votes as the top two ideas, the substantial support for risk sharing highlights its importance as a strategy for fostering collaboration among stakeholders in the healthcare ecosystem. These

high-priority ideas collectively reflect a strategic and collaborative approach toward expediting public access to new and effective medicines in the Canadian healthcare landscape.

4.0 Conclusion:

In conclusion, the Fourth Canadian Cancer Treatment Hackathon served as a pivotal platform for stakeholders to collaboratively address the challenges impeding timely access to new and effective medicines in Canada to improve patient outcomes. The event built upon the momentum generated in previous hackathons, aiming to delve deeper into actionable initiatives that could reshape the landscape of drug access. The discussions, informed by pre-recorded panels explored critical themes and ideas. These encompassed gaps in the current process, best practices from other jurisdictions, and the potential for international collaborations including among HTA agencies.

Notably, the highest priority ideas, determined through participant voting, highlighted a collective recognition of the need to learn from the UK's Innovative Medicines Fund. This idea, securing the highest votes, reflects a strong interest in applying successful international models, particularly those linking drug approval to societal benefits. Following closely were proposals advocating for proactive jurisdictional actions during the HTA review and engagement of provinces in the review process, each securing substantial support. Furthermore, the discussions emphasized tangible strategies, such as building project plans, integrating private payers, and exploring innovative funding models. The emphasis on transparency, patient engagement, and risk sharing emerged as recurrent themes, underscoring the importance of a holistic and collaborative approach.

As the Canadian healthcare system evolves, the insights and recommendations generated during the hackathon sessions provide a foundation for refining strategies and policies. The collaborative spirit exhibited in these discussions reflects a shared commitment to expediting public access to new and effective medicines, ultimately contributing to improved healthcare outcomes for Canadians. The innovative ideas and solutions put forth during this event paved the way for continued dialogue, collaboration, and transformative changes in the Canadian drug access and reimbursement landscape.

Appendix 1– Fourth Hackathon Agenda

Time	Agenda item	Lead
8:30 – 9:30am	*Breakfast and Optional viewing of pre-recorded panels*	*Barry Stein*
9:30 – 9:35am	Opening remarks	Barry Stein
9:35 – 9:55am	Review agenda and highlight purpose and intended outcome Roundtable introductions - Review outcomes from previous Hackathons	Bill Dempster
9:55 – 10:15	Breakout Session 1. Gaps / Barriers in Canada's Current Process for Reviewing and Reimbursing New Medicines	All
10:15 – 10:25	Coffee break	All
10:25 – 10:45	Breakout Session 2. Best Practices from Other Jurisdictions	All
10:45 – 11:05	Breakout session 3. International Collaborations	All
11:05 – 11:35	Group presentations of prioritized ideas (10 mins. per group)	All
11:35 – 11:55	Voting on ideas and facilitated discussion of results	Bill Dempster
11:55 – 12:00	Closing remarks and next steps	Barry Stein

Appendix 2 – List of Panelists

Panel #1: HTA International collaborations and global best practices

- **Sudha Kutty** *CADTH's Executive Vice-President, Evidence, Products, and Services*
- **Dr. Matthias Perleth** *Head of the Department for Methodological Advice at the Federal Joint Committee (G-BA)*

Panel #2: Exploring Global and Emerging Best Practices

- **Dr. Nigel Rawson** *Senior Fellow, Macdonald-Laurier Institute and Fraser Institute, an Affiliated Scholar with the Canadian Health Policy Institute*
- **Tara Cowling** *Founder of Medlior Health Outcomes Research Ltd*
- **Dr. Sreeram (Ram) Ramagopalan** *Principal of Access Evidence, Consultancy LCP*

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