Meeting Report

First Canadian Cancer Treatment Hackathon

November 14, 2022 - Virtual Meeting

Executive Summary

Colorectal Cancer Canada (CCC) held a Hackathon™ on November 14, 2022.

Over 25 participants, from patient groups, industry, government, and government agencies, shared their views on the question "*How do we optimize the current system and develop specific and actionable, time-saving opportunities at each of the following levels:"*

- Regulatory (Health Canada and Patented Medicine Prices Review Board [PMPRB])
- Comparative evaluation (Health technology assessment [HTA])
- Negotiation (pan-Canadian Pharmaceutical Alliance [pCPA]) & funding decisions (cancer agencies and provincial payers)

In total, over 50 opportunities were identified during brainstorming sessions, which were merged and prioritized for each level. The highlights of the Hackathon™ are summarized below.

Level	Top Opportunities
Regulatory (Health Canada and PMPRB	1. Global solution to review the same data at the same time to cut down on regulatory reviews; Project Orbis expanded (Canada, US, Asia, Europe) 2. Starting thinking of this as ONE process - not in silos. Re-engineer the process. -> Realign industry access process with others (Canadian Agency for Drugs & Technologies in Health [CADTH]; payors; etc.) 3. 'Rolling reviews' for regulatory - a key covid learning! 4. When do we start the timeline(s)? Could it start earlier, e.g., global launch? Analyze factors that go into launch decisions (list price, net prices in jurisdictions) 5. Increased certainty regarding the PMPRB pricing to ensure Canada remains a priority launch country for new cancer medicines
Comparative Evaluation (HTA)	1. International sharing of HTA reviews to expedite process in Canada (Project Orbis) - built in collaboration from the get go 2. Reduce certain elements of the HTA reviews not appropriate for small patient populations 3. Build out data development, stewardship and accreditation capacity to enhance the use of real-world evidence (RWE) in innovative reimbursement agreements that would provide early funding for cancer medicines conditional on ongoing evidence development 4. Shorter review for drugs with multiple indications - simplify some of the requirements
Negotiation (pCPA) & Funding Decisions	1. Negotiate at same time as HTA review (this is already happening, but formalize that opportunity) 2. Requirement for jurisdictions / pCPA to pick up a file for negotiation within a set timeframe (may be related to resources); for example, within 1 month of a positive HTA recommendation 3. Begin work earlier - triaging opportunities e.g. Initiation & file uptake, letter of interest (LOI) intake 4. Resources - more people to support the flow through 5. Develop a broader system / framework that would help avoid having to negotiate certain medicines or new indications

Results from this first Hackathon™ will serve as a base to develop the objective(s) for a second meeting, to help bring cancer medicines to Canadian patients faster.

Table of Contents

1.0 Introduction

On September 14, 2022, Colorectal Cancer Canada (CCC) held its first *Canadian Cancer Treatment Hackathon* with the aim **to explore ways to compress the time at each step of the review process for new cancer medicine approval in Canada to achieve an overall reduction in review process time of 50%.** Canadians with public drug coverage continue to have restricted or delayed access to new therapies due to the multi-layered sequential review processes, which informs public drug plans' decisions on whether to provide access and reimbursement to new medicines.[1]

Barry Stein, President & CEO of CCC, welcomed the participants and invited the group to openly share their views to elevate the review process, gathering the perspective from patient groups, industry, government, and government agencies, for the benefit of all Canadian cancer patients (Appendix A – Participants).

For this first Hackathon™, the objective was to compile and prioritize the participants' views to optimize the current system and develop specific and actionable, time-saving opportunities, at three levels:

1. Regulatory (Health Canada and Patented Medicine Prices Review Board [PMPRB])
2. Comparative evaluation (Health technology assessment [HTA])
3. Negotiation (pan-Canadian Pharmaceutical Alliance [pCPA]) & funding decisions (cancer agencies and provincial payers)

Participants brainstormed in breakout sessions, then potential opportunities were discussed, and prioritized, in a plenary session (Appendix B – Hackathon Agenda). To optimise the outcomes of the meeting, the participants received pre-read material, and the Hackathon™ was conducted using an electronic meeting system (EMS) (Appendix C – Links to Pre-Reads and Appendix D – Electronic Meeting System).

1.1 Background

It is estimated that two in five Canadians will receive a diagnosis of cancer in their lifetime and that one infour Canadians will die of cancer.[2] New and often precision medicines are helping patients with early andadvanced stages of cancer have an improved overall survival and quality of life.

Beginning in 2019, uncertainties surrounding new regulations to change the way the Patented Medicine Prices Review Board assesses drug prices led to delays in planned launches of new medicines inCanada, according to a survey of industry conducted by Life Sciences Ontario (LSO).[3]

As in many other countries, the processes of reviewing drugs for public reimbursement are complex; however, Canada's system is more complicated with several levels and jurisdictions regulating, reviewing, negotiating and funding medicines (Figure 1).[4] Unfortunately, Canada ranks third worst when it comes to public reimbursement of drugs. Health Canada approval time averages approximately 248 days after the firstglobal approval. It then takes 199 more days for the drug to be launched in Canada, with access onlythrough out-of-pocket payment or through private insurance only. Most importantly, it then averages 559 more days (1.5 years) for the drug's public reimbursement in Canada, which is giving access to most Canadians.[5] Therefore, Canadians who rely on public health payers to access medicines must wait significantly longer

compared to individuals in other countries around the world,[6] and Canadians who rely on private insurance plans.[1]

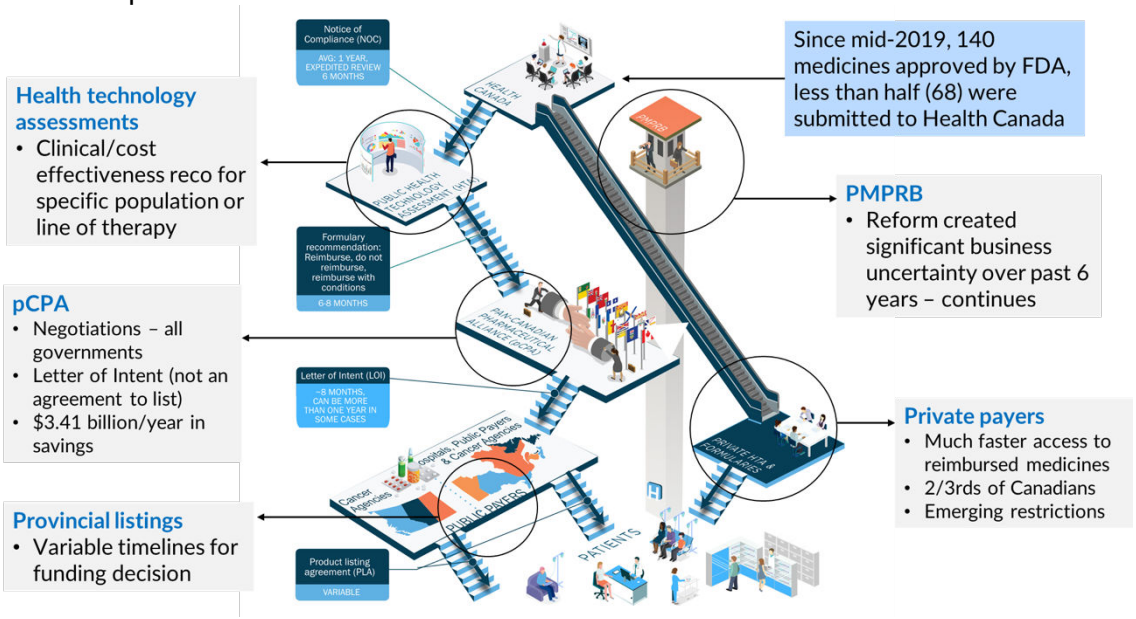

Figure 1. Pathway for new medicines in Canada

In recent years, there has been an increase in global regulatory alignment through Project Orbis with the Food and Drug Administration (FDA) and other regulatory agencies. These collaborations are welcomed because they are designed to improve efficiency and timely access for patients.[7] Similar collaborations can be explored amongst Canadian HTA agencies to seek similar efficiencies to enable performance standards to define maximum reasonable timeframes from Health Canada approvals to provincial reimbursement listings.

The world only required one year to develop COVID-19 vaccines, but it takes 12 years on average to bring effective cancer drugs from discovery to approval and even longer to reimbursement.[5] A study showed that there was an average 80,000 years of life lost for every year of delay in drug approval.[8] Therefore, the regulatory framework must innovate to find strategies to safely speed access as the number of potential life-years lost during the drug regulatory and funding process in Canada is substantial.

2.0 Regulatory Opportunities (Health Canada and PMPRB)

2.1 Brainstorm Session

The brainstorm session on regulatory aspects of the review process led to 13 time-saving potential opportunities, summarized in Table 1.

During the discussion, similar ideas shared by the participants were merged from the initial 19 opportunities generated in the 2 breakout sessions. These opportunities will be the starting point to continue elevating the review process on the regulatory level.

Table 1. Summary of Regulatory Opportunities to Optimize the Current Review Process

Opportunities	
1	Do we need a PMPRB? It was established before we had all of the other processes in place. Is it still relevant?
2	When do we start the timeline(s)? Could it start earlier, e.g., global launch? Analyzing the factors that go into launch decisions (list price and net prices in jurisdictions).
3	Global solution to review the same data at the same time to cut down on regulatory reviews; Project Orbis expanded (Canada, US, Asia, Europe).
4	Increased certainty regarding the PMPRB pricing to ensure Canada remains a priority launch country for new cancer medicines, given the current inability of innovators to identify what a compliant price will be under the proposed guidelines under consultation (there are situations where it's not possible to launch new medicines in Canada).
5	Drug sponsors develop a plan for how they will collect post-marketing data; ensure capacity expanded for non-traditional endpoints; think beyond randomized controlled trials (RCTs) - especially when the numbers / patient population is small; attitudinal shift; consider Health Canada's role in the data infrastructure; standardize what Health Canada accepts as real-world evidence/real-world data (RWE/RWD); better coordination between regulatory, HTA and payers regarding RWE. - Start to think about conditional approval subject to the collection of RWD (Project REACH)
6	How can we get payors to embrace RWD? How do we bring payors into the process?
7	The Canadian Agency for Drugs & Technologies in Health (CADTH) must also work together with payors.
8	Starting thinking of this as ONE process - not in silos. Re-engineer the process. -> Realign industry access process with others (CADTH; payors etc.). - How can we improve co-ordination across the system? (reduce duplication and inefficiencies). Co-ordination from a system wide versus functional perspective. - Have to look at the end result - not just each step of the process.
9	Project Orbis application outside of the regulatory process.
10	Standards - mutual recognition from other Regulatory authorities, as in the European environment.
11	'Rolling reviews' for regulatory - a key COVID-19 learning!
12	Resources to make ORBIS works effectively - is Health Canada able to handle flow of reviews coming in?
13	Buy-in for reasonable process that works and is not left to the discretion of different sub committees, etc.

- ***Additional/complementary discussion points:***

    - A need for targeted negotiation was discussed, e.g., line extensions versus novel with unmet needs.
    - Particularly with new precision medicine, conditional approvals should be developed, which would be subject to the collection of RWD.
    - As identified in the opportunities, the "silo" aspect was stressed as something that needs to be changed in order to shorten the review process; these silos should be broken down at every review stage. This would include having mutual recognition between jurisdictions.
        - For instance, the pricing guidelines are not just about getting the lowest price, but also a way to increase investment in sciences and to make sure that patients get access to the most effective medication.

2.2 Voting Results

On these 13 opportunities (Table 1), the participants voted, identifying the opportunity that was the most impactful at saving time for the review process at the regulatory level. The voting results are summarized in Figure 2 and Appendix E – Voting Results.

Twenty-four participants voted for a total of 114 selections. The opportunities voted the highest for their potential impacts were:

- **75.0%** (18/24): "Global solution to review the same data at the same time to cut down on regulatory reviews; Project Orbis expanded (Canada, US, Asia, Europe)"
- **62.5%** (15/24): "Starting thinking of this as ONE process - not in silos. Re-engineer the process. -> Realign industry access process with others (CADTH; payors etc.)"
- **54.2%** (13/24): "'rolling reviews' for regulatory - a key covid learning!"
- **54.2%** (13/24): "When do we start the timeline(s)? Could it start earlier, e.g., global launch? Analyzing the factors that go into launch decisions (list price and net prices in jurisdictions)".

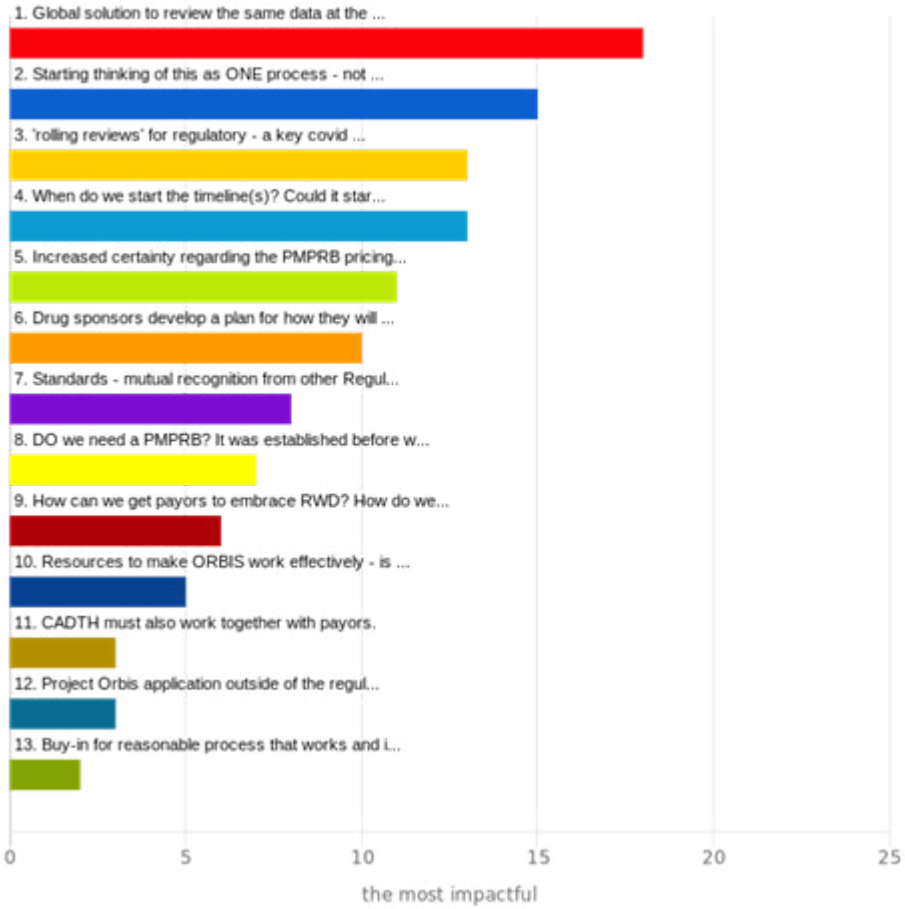

Figure 2. Voting Results on Regulatory Time-saving Opportunities

3.0 Comparative Evaluation (HTA)

3.1 Brainstorm Session

The brainstorm session on the comparative evaluation level led to the following 12 merged opportunities with regards to time-saving opportunities (Table 2). Additional/complementary discussion points are provided below.

Table 2. Summary of Comparative Evaluation (HTA) Opportunities to Optimize the Current Review Process

	Opportunities
1	Build out data development, stewardship, and accreditation capacity to enhance the use of RWE in innovative reimbursement agreements that would provide early funding for cancer medicines conditional on ongoing evidence development.
2	Mandatory requirements for information sharing - improve the flow of submission related material (CADTH, Health Canada, *Institut national d'excellence en santé et services sociaux* [INESSS]) - access to information will accelerate the review.
3	Shorter review for drugs with multiple indications - simplify some of the requirements.
4	International sharing of HTA reviews to expedite process in Canada (Project ORBIS) - built in

	Opportunities
	collaboration from the get go.
5	Managed Entry Agreements - innovative agreements once approved by Health Canada; they can be available to patients right away (similar to the German system)
6	Pre-submission meeting to align on common elements of the file. - More transparency to identify information gaps and be addressed early on
7	Phase 2 submission - framework to help get approval on Phase 2 data (early approval for set period of time pending validation of data at a later date).
8	Recognize the need for managing economic challenges (oncology medicine budgets, caps, etc.); need for framework that works for all parties to get ahead of the risk mitigation challenges in a systematic/holistic way (this is what allows National Institute for Health and Care Excellence [NICE] in the United Kingdom to implement managed access agreements)
9	Reduce certain elements of the HTA reviews that are not appropriate for small patient populations (e.g., when quality-adjusted life years [QALYs] are not appropriate / additive to the review); could make Canada a more attractive country for launching / commercializing new medicines (e.g., small patient populations with high response rates) - Focus efforts of the expert review committees on the clinical evaluation elements (economics can be dealt with by the payers)
10	Open/public deliberation meetings, heightened opportunities for dialogue between sponsor and agency
11	Eliminate/manage/address silo issues including full ecosystem (industry, patient groups, etc.)
12	Seek conditional listings - conditional listings be made by CADTH

- ***Additional/complementary discussion points:***
    - As identified in a previous session at one of the *CCC Clinical Trial Conferences*, there is a need for more transparency from industry in identifying gaps, allowing gaps to be addressed faster .
    - Creating a more elaborate structure is not a way to shore up timeline.

3.2 Voting Results

The voting results on these 12 opportunities on comparative evaluation (Table 2) are presented in Figure 3 and Appendix E – Voting Results.

Twenty-three participants voted for a total of 122 selections. The opportunities voted the highest for their potential impacts were:

- **62.5%** (15/24): “International sharing of HTA reviews to expedite process in Canada (Project ORBIS) – built in collaboration from the get go”
- **62.5%** (15/24): “Reduce certain elements of the HTA reviews that are not appropriate for small patient populations (e.g., when QALYs are not appropriate / additive to the review); could make Canada a more attractive country for launching / commercializing new medicines (e.g., small patient populations with high response rates)”
- **58.3%** (14/24): “Build out data development, stewardship and accreditation capacity to enhance the use of real-world evidence (RWE) in innovative reimbursement agreements

that would provide early funding for cancer medicines conditional on ongoing evidence development"

- **50.0%** (12/24): "Shorter review for drugs with multiple indications - simplify some of the requirements"

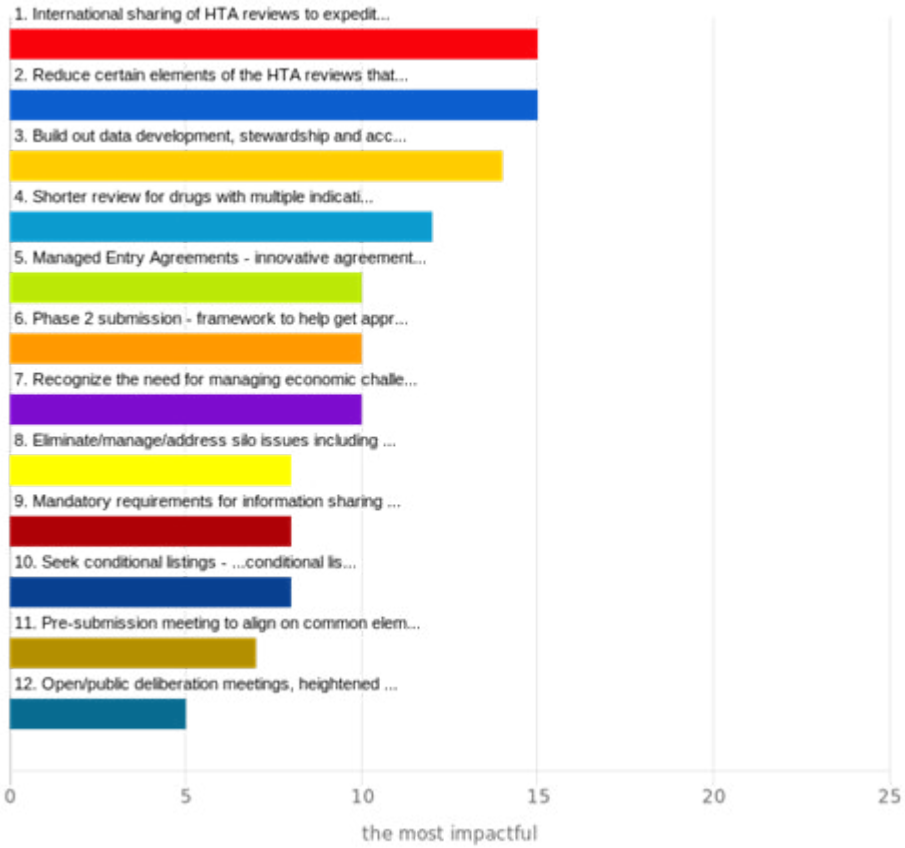

Figure 3. Voting Results on Comparative Evaluation Time-saving Opportunities

4.0 Negotiation and Funding Decisions

4.1 Brainstorm Session

The participants developed 15 opportunities with regards to improving the current system at the negotiation and funding decisions level, summarized in Table 3.

Table 3. Summary of Negotiation and Funding Decisions Opportunities to Optimize the Current Review Process

	Opportunities
1	Begin work earlier - triaging opportunities, e.g., Initiation and file uptake and letter of intent intake
2	After letter of intent (LOI) - how to improve time to list
3	Triaging process for not novel processes - Separate out a line extension process versus "novel or net new" - "Me too" products go through a targeted process

	Opportunities
4	More engagement between manufacturer and pCPA
5	Resources - more people to support the flow through
6	RWE could help address uncertainty to bridge clinical trial gap - include payers at other steps of the review process (HTA for example)
7	Transparency in metrics to help clarify - give people a better sense of expected time
8	Transparency in negotiated prices - we don't know what negotiated prices are for comparators (if CADTH had access to these, it would make their reports more realistic)
9	Resources - beyond more people, perhaps more technical expertise; resources at the jurisdictional level
10	HTA can start informing commercial side earlier in the process - issues that pop up during HTA review, this can be flagged for the commercial side earlier so that they can address this. This part of the process is very sequential!
11	High price reductions may be counter productive
12	Requirement for jurisdictions / pCPA to pick up a file for negotiation within a set timeframe (may be related to resources); for example, within 1 month of a positive HTA recommendation
13	Develop a broader system / framework that would help avoid having to negotiate certain medicines or new indications
14	Negotiate at same time as HTA review (this is already happening, but formalize that opportunity)
15	Lower prices?

- ***Additional comments:***
    - Emphasis on having binding arbitration was discussed, resolving issues within a fixed period of time, while patient support programs continue regardless of the process.

4.2 Voting Results

Participants voted on these 15 opportunities (Table 3), and the voting results appear in Figure 4 and Appendix E – Voting Results.

Twenty-four participants voted for a total of 143 selections. The opportunities voted the highest for their potential impacts were:

- **70.8%** (18/24): Negotiate at same time as HTA review (this is already happening, but formalize that opportunity)
- **62.5% (**15/24): Requirement for jurisdictions / pCPA to pick up a file for negotiation within a set timeframe (may be related to resources); for example, within 1 month of a positive HTA recommendation
- **54.2%** (13/24): Begin work earlier - triaging opportunities e.g. Initiation and file uptake and letter of intent intake
- **54.2%** (13/24): Resources - more people to support the flow through

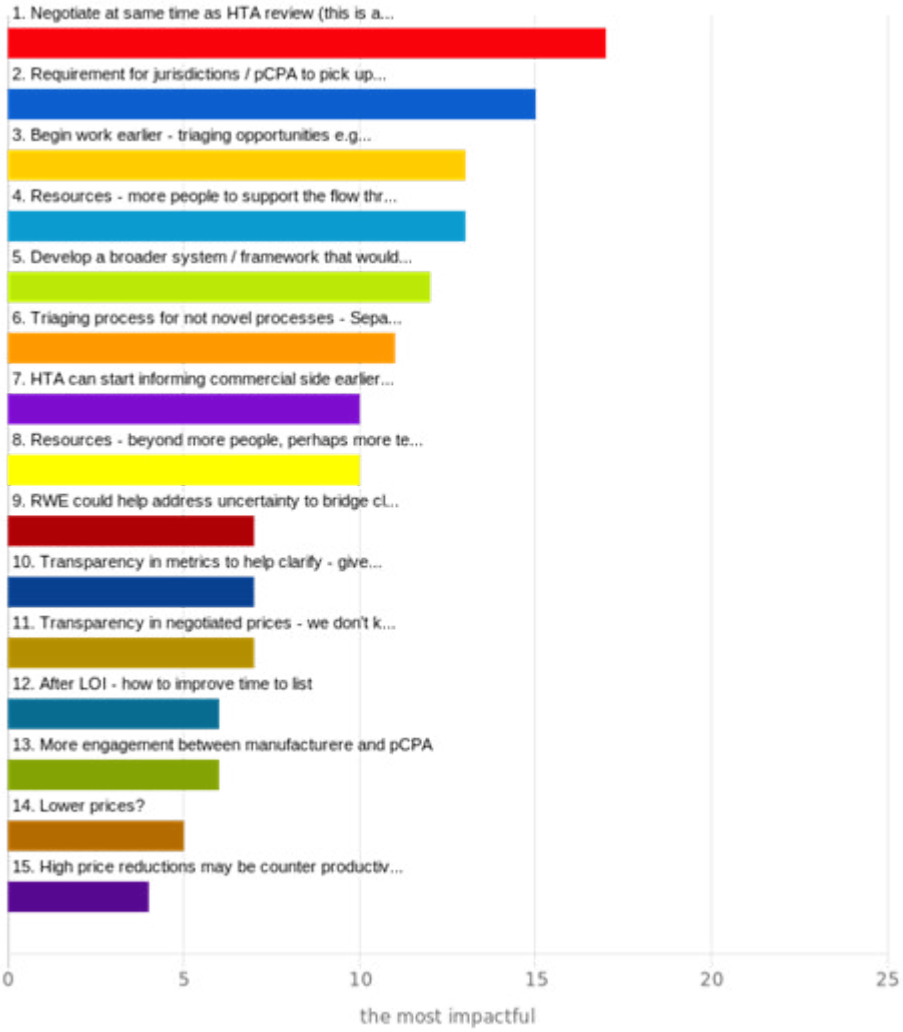

Figure 4. Voting Results on Negotiation and Funding Decisions Time-saving Opportunities

5.0 Additional Discussion Points

5.1 Other Opportunities

Aside from the pre-identified levels presented above, additional opportunities were identified to help shorten the review process, from providing education to re-thinking the initiation process (Table 4).

Table 4. Additional Opportunities to Optimize the Current Review Process

	Opportunities
1	Educate patients and clinicians about what happens before they can get access to cancer therapies, so they understand how it works and where to advocate for access.
2	Tough: Negotiation period itself; it needs to be shortened.
3	Initiation - we do not have a first come first served basis
4	Starting thinking of this as ONE process - not in silos. Re-engineer the process. -> Realign industry access process with others (CADTH; payors, etc.)

Opportunities
- Have to look at the end result - not just each step of the process. - How can we improve co-ordination across the system? (reduce duplication and inefficiencies). Co-ordination from a system wide versus functional perspective.

- ***Additional/complementary discussion points:***
    - Importantly, to be kept in mind throughout this process is the patient, who should be benefiting from some of these opportunities, as soon as possible.
    - The goal is to know how to make Canada the best place for patients, and also the best place to do research and launch new medications.
    - The central idea of these opportunities was to decrease the time within each of the stages of review.
        - For the next Hackathon™, the focus will be on reimagining the system from a broader level.
        - Heterogeneity across provinces will have to be part of the discussion. Ideally, one big umbrella across the country should be put in place, so that when a drug is approved, every province and everybody in every province has access at the same time.

5.2 Hackathon™ Final Comments

On the topic of building awareness, the participants were asked "how do we collaborate to help secure these process changes and reduce delays?" For instance, by " Surveying Ministers and Deputy Ministers on their estimate of a reasonable performance standard to time from Health Canada submission to funding decisions?"

Other suggestions and advice shared by participants were summarized as:

1. *"The TNP is a beautiful example of the "devil being in the details" of how it is administered. We have had some very bitter experiences with how it has played out. n=2 or so :)*
2. *Focus on TIME lines*
3. *PMPRB elimination indirectly improves timelines in that it makes industry more likely to launch promptly in Canada, rather than wait and see (IMHO)*
4. *Look in the mirror and compare with other Economic Co-operation and Development (OECD) countries dynamically -- justify discrepancies*
5. *The CIRCS document shared with us in the pre read said we are 2nd fastest from regulatory to HTA rec. So this tells me that a focus on negotiation and more TNP is a way to really shorten.*
6. *Gov't funding needed for conditional approval with data collection agreements for innovative medicines (similar to CDF)*
7. *identify payor needs for RWE to address uncertainty with clinical trial data (indication for funding differs from clinical trial) - outcomes based agreements?*
8. *Justify provincial discrepancies and INESSS/CADTH disagreements*
9. *National pharmacare system devoted to cancer care*
10. *We should see 100% uptake of parallel review opportunities if that speed is a goal...but perhaps companies are not ready to submit at/prior to market auth, might need more mature evidence to support reimbursement decisions*
11. *Recruit input from clinician experts like CCO used to."*

Appendices

Appendix A – Participants

Group A		***Group B***		***Group C***	
Bob Bick	CanCertainty	Brent Fraser	VP, Pharmaceutical Reviews, CADTH	Barry Stein	President & CEO, Colorectal Cancer Canada
Alexandra Chambers	Novartis	Tara Cowling	Founder, MEDLIOR	Don Husereau	Adjunct Professor of Medicine, University of Ottawa
Brett Hogan	Roche	Angela Behboodi	Director, Government Affairs and Advocacy, Amgen	Michael Dietrich	IMC
Sang Mi Lee	Morse Consulting	Stephane Barakat	Abbvie	Ben Peacock	Director Value and Access, Amgen
Scott Gavura	Ontario Health	Henry Conter	Roche	Madison DeLong	Policy Analyst, Health Canada
Dr. Ron Burkes	Princess Margaret Cancer Center	Ross Wallace	Santis Health	Jaclyn Beca	Morse Consulting
		Dr. Sandeep Sehdev	Ottawa Hospital Cancer Centre	Nathalie Ross	Medical Writing

Appendix B – Hackathon Agenda

4:30 pm	**Introduction** - Roundtable introductions - Context and review of current processes - Setting the target (50% reduction in time to access)	Bill Dempster, 3Sixty Public Affairs
4:50 pm	**Breakout Groups** - How do we optimize the current system and develop specific and actionable, time-saving opportunities at each of the following levels? 1. Regulatory (Health Canada and PMPRB) 2. Comparative evaluation (HTA) 3. Negotiation (pCPA) & funding decisions (cancer agencies and provincial payers)	Erik Lockhart, Queen's Executive Decision Centre
5:30 pm	**Plenary** - How can we prioritize, innovate, and accelerate within and across each step of the review process (i.e., feasibility and impact assessment)?	Erik Lockhart, Queen's Executive Decision Centre
6:00 pm	**Awareness Building** - How do we collaborate to help secure those process changes and reduce delays?	Erik Lockhart, Queen's Executive Decision Centre
6:25 pm	**Summary and Next Steps**	Bill Dempster, 3Sixty Public Affairs
6:30 pm	**Session Adjourns**	

Appendix C – Links to Pre-Reads

1. The Pathway for New Cancer Drug Access in Canada: https://www.mdpi.com/1718-7729/29/2/41
2. Review of HTA outcomes and timelines in Australia, Canada and Europe 2017-2021: https://cirsci.org/download/cirs-rd-briefing-86-review-of-hta-outcomes-and-timelines-in-australia-canada-and-europe-2017-2021/
3. Procedures for CADTH Reimbursement Reviews, September 2022: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf

Appendix D – Electronic Meeting System

The planning session was conducted using an electronic meeting system (EMS), an innovative facilitation process developed from research at the Smith School of Business at Queen's. The Queen's EMS, called "the Decision Centre", combines expert facilitation with a state of the art group decision support system to enable groups to rapidly accelerate idea generation and consensus building. This facility consists of a network of laptops accessing software designed to support idea generation, idea consolidation, idea evaluation and planning. The tool supports, but does not replace, verbal interaction; typically 25% of interaction takes place on the computers. Feedback from groups who have used the Executive Decision Centre process includes: meeting times can be cut in half; participation goes way up; better idea generation and alternative evaluation; a more structured process; and automatic documentation of deliberations.

Over 1500 organizations around North America use the Centre for meetings such as: strategic planning, visioning, annual planning, focus groups, team building, budgeting, program review, project planning, risk assessment, job profiling, 360 degree feedback, alternative evaluation, new product development and a variety of other meeting types. This approach can be employed in both face to face and virtual environments.

In the session, participants were asked, for example, "what are the critical issues that we need to address in the near future?" Participants typed in ideas on the laptops all of which appeared on a public screen at the front of the room (or, if in virtual mode, on everyone's screens). These ideas were then discussed and categorized into common themes. The group was then asked "if we could only address five of these in the next year, which ones are most critical?" Individuals selected his/her top 5 and the overall results were then displayed to the group and further discussed.

For more information on this process, please contact:
Erik Lockhart
Erik.Lockhart@queensu.ca
ph# 613 533-6681

Appendix E – Voting Results

Level 1: Regulatory (Health Canada and PMPRB)

Criterion "the most impactful" sorted by sum 6 selections of 13 items. Ratings submitted: 24. Total selections 114. Abstentions permitted.		
Nr	**Item**	**#votes/24**
1	Global solution to review the same data at the same time to cut down on regulatory reviews; Project Orbis expanded (Canada, US, Asia, Europe)	18
2	Starting thinking of this as ONE process - not in silos. Re-engineer the process. -> Realign industry access process with others. (CADTH; payors etc.)	15
3	'rolling reviews' for regulatory - a key covid learning!	13
4	When do we start the timeline(s)? Could it start earlier, e.g., global launch? Analyzing the factors that go into launch decisions (list price and net prices in jurisdictions)	13
5	Increased certainty regarding the PMPRB pricing to ensure Canada remains a priority launch country for new cancer medicines, given the current inability of innovators to identify what a compliant price will be under the proposed guidelines under consultation (there are situations where it's not possible to launch new medicines in Canada).	11
6	Drug sponsors develop a plan for how they will collect post-marketing data; ensure capacity expanded for non-traditional endpoints; think beyond RCTs - especially when the numbers / patient population is small; attitudinal shift; consider Health Canada's role in the data infrastructure; standardize what HC accepts as RWE/RWD; better coordination between regulatory, HTA and payers regarding RWE	10
7	Standards - mutual recognition from other Regulatory authorities. as in the euro environment	8
8	DO we need a PMPRB? It was established before we had all of the other processes in place. Is it still relevant?	7
9	How can we get payors to embrace RWD? How do we bring payors into the process?	6
10	Resources to make ORBIS work effectively - is HC able to handle flow of reviews coming in	5
11	CADTH must also work together with payors.	3
12	Project Orbis application outside of the regulatory process.	3
13	Buy-in for reasonable process that works and is not left to the discretion of different sub committees, etc.	2

Level 2: Comparative evaluation (HTA)

Criterion "the most impactful" sorted by sum 6 selections of 12 items. Ratings submitted: 23. Total selections 122. Abstentions permitted.		
Nr	**Item**	**#votes/24**
1	International sharing of HTA reviews to expedite process in Canada (Project ORBIS) - built in collaboration from the get go	15
2	Reduce certain elements of the HTA reviews that are not appropriate for small patient populations (e.g., when QALYs are not appropriate / additive to the review); could make Canada a more attractive country for launching / commercializing new medicines (e.g., small patient populations with high response rates)	15
3	Build out data development, stewardship and accreditation capacity to enhance the use of real-world evidence (RWE) in innovative reimbursement agreements that would provide early funding for cancer medicines conditional on ongoing evidence development	14
4	Shorter review for drugs with multiple indications - simplify some of the requirements	12
5	Managed Entry Agreements - innovative agreements once approved by HC they can be available to patients right away (similar to German system)	10
6	Phase 2 submission - framework to help get approval on Phase 2 data (early approval for set period of time pending validation of data at a later date).	10
7	Recognize the need for managing economic challenges (oncology medicine budgets; caps; etc.); need for framework that work for all parties to get ahead of the risk mitigation challenges in a systematic/holistic way (this is what allows NICE in the UK to implement managed access agreements)	10
8	Eliminate/manage/address silo issues including full ecosystem (industry, patient groups etc.)	8
9	Mandatory requirements for information sharing - improve the flow of submission related material (CADTH, HC, INESSS) - access to information will accelerate the review	8
10	Seek conditional listings - ...conditional listings be made by CADTH	8
11	Pre-submission meeting to align on common elements of the file ...More transparency to identify information gaps and address early on	7
12	Open/public deliberation meetings, heightened opportunities for dialogue between sponsor and agency	5

Level 3: Negotiation (pCPA) & funding decisions (cancer agencies and provincial payers)

Criterion "the most impactful" sorted by sum 7 selections of 15 items. Ratings submitted: 24. Total selections 143. Abstentions permitted.		
Nr	**Item**	**#votes/24**
1	Negotiate at same time as HTA review (this is already happening, but formalize that opportunity)	17
2	Requirement for jurisdictions / pCPA to pick up a file for negotiation within a set timeframe (may be related to resources); for example, within 1 month of a positive HTA recommendation	15
3	Begin work earlier - triaging opportunities e.g. Initiation and file uptake and letter of intent intake	13
4	Resources - more people to support the flow through	13
5	Develop a broader system / framework that would help avoid having to negotiate certain medicines or new indications	12
6	Triaging process for not novel processes - Separate out a line extension process versus "novel or net new"	11
7	HTA can start informing commercial side earlier in the process - issues that pop up during HTA review, this can be flagged for the commercial side earlier so that they can address this. This part of the process is very sequential!	10
8	Resources - beyond more people, perhaps more technical expertise; resources at the jurisdictional level	10
9	RWE could help address uncertainty to bridge clinical trial gap - include payers at other steps of the review process (HTA for example)	7
10	Transparency in metrics to help clarify - give people a better sense of expected time	7
11	Transparency in negotiated prices - we don't know what negotiated prices are for comparators (if CADTH had access to these, it would make their reports more realistic)	7
12	After LOI - how to improve time to list	6
13	More engagement between manufacturer and pCPA	6
14	Lower prices?	5
15	High price reductions may be counter productive	4

[1] https://www.frontiersin.org/articles/10.3389/fphar.2019.00196/full
[2] Canadian Cancer Statistics Advisory Committee in collaboration with the Canadian Cancer Society, Statistics Canada and the Public Health Agency of Canada. Canadian Cancer Statistics 2021.
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[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6964142/#onco13086-bib-0001
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