Meeting Report

Eighth Canadian Cancer Treatment Hackathon

March 19, 2025

Toronto, CANADA

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Executive Summary

The Eighth Canadian Cancer Treatment Hackathon, held on March 19, 2025, convened diverse healthcare stakeholders to explore the potential of outcomes-based agreements (OBAs) to improve access to cancer drugs in Canada. Despite major therapeutic advances, Canadian patients face lengthy delays, averaging 598 days, in accessing publicly reimbursed cancer treatments.[1] OBAs offer a promising mechanism to reduce this delay by tying reimbursement to real-world outcomes, thereby balancing early access while addressing clinical and financial uncertainties.

The event, organized by Colorectal Cancer Canada with support from pharmaceutical sponsors, included pre-panel presentations, breakout group discussions, and a plenary session. The breakout discussions were segmented by stakeholder type – industry, HTA agencies, public payers, and patient groups, to examine the success factors required to make OBAs effective in the Canadian context. Participants explored barriers, infrastructure needs, and outcome measurement strategies from their respective viewpoints. Key themes included the need for a national OBA framework, integration of real-world evidence (RWE), and incorporation of patient values in agreement design. The session used a hypothetical drug case (NetFelix) to assess OBA feasibility and stimulate discussion.

Major Findings:

- Pre-panel discussions highlighted international best practices (e.g., the UK's Cancer Drugs Fund) and identified Canada's lack of a formal OBA pathway as a barrier to implementation. Simplicity, data quality, and stakeholder trust were emphasized as core success factors.
- Industry participants stressed the need for clear criteria, pan-Canadian data infrastructure, and early engagement with HTA bodies. OBAs should prioritize timely access and patient-centered outcomes, using SMART metrics.
- Public payers emphasized operational feasibility, recommending simple, scalable models using existing data systems. They called for shared governance and greater integration of OBAs within HTA and reimbursement processes.
- HTA bodies advocated for a structured framework that includes early candidate identification, methodological flexibility, and standardized RWE expectations. HTA's role should evolve from evidence evaluator to system enabler.

- Patient groups urged that OBAs reflect meaningful outcomes such as quality of life and caregiver impact. They emphasized the need for transparency, access to genetic testing, and structured patient engagement.

Recommendations:

1. Develop a national OBA framework led by Canada's Drug Agency (CDA), with clear roles, eligibility criteria, and process guidelines.
2. Invest in digital infrastructure and standardized, real-world data systems to support OBA implementation.
3. Pilot OBAs using small-scale, stakeholder-aligned initiatives to build trust and test feasibility.
4. Engage patients and clinicians early to ensure agreements reflect real-world needs and values.
5. Promote integration with existing initiatives such as Time-Limited Recommendations (TLRs) and pCPA Temporary Access Process (pTAP) where appropriate.

Hackathon 8 reaffirmed the growing consensus that OBAs can support timely, evidence-informed access to cancer drugs in Canada, but only with clear policy direction, stakeholder collaboration, and sustained infrastructure investment.

1.0 Introduction

1.1 Background

Cancer remains a leading health challenge in Canada, with approximately two in five Canadians expected to be diagnosed in their lifetime and one in four expected to die from the disease. Although innovative and often targeted therapies have the potential to significantly improve survival and quality of life, Canadian patients face some of the longest delays in the developed world in accessing new treatments. On average, it takes 598 days, nearly double the wait time of most other OECD countries, for patients in Canada to gain public reimbursement access to newly approved medicines.[1] Public drug plans reimburse only 20% of new medicines launched globally, highlighting a critical lag in uptake and access within the current system.[2]

Several factors contribute to this delay. Canada's drug approval and reimbursement system is multi-layered and jurisdictionally fragmented, involving complex reviews and negotiations across federal and provincial bodies. Health Technology Assessment (HTA) agencies are integral to this process, providing structured evaluations of clinical efficacy, cost-effectiveness, and broader social and policy implications of new drugs. However, the standard HTA approach often struggles to evaluate precision oncology treatments, which are frequently supported by limited or emerging data and target small, genetically defined patient populations.

In this context, outcomes-based agreements (OBAs) have emerged as a promising policy and financing tool to bridge the evidence gap and improve access. OBAs are contractual arrangements between payers and manufacturers, in which reimbursement is linked to the real-world performance of a therapy.[3] These agreements allow risk to be shared between parties and facilitate earlier patient access while generating real-world evidence (RWE) to reduce clinical uncertainty. Internationally, countries like England, France, Germany, Italy, and Australia have incorporated OBAs into their early-access frameworks, but Canada has yet to establish a formal, transparent system for implementing OBAs at scale.[4]

Purpose of Hackathon 8

Against this backdrop, Hackathon 8, part of the ongoing Canadian Cancer Treatment Hackathon Series led by Colorectal Cancer Canada (CCC). The central aim of this session was to explore

how OBAs can be leveraged to accelerate timely access to cancer therapies in Canada, particularly in the face of clinical and economic uncertainties surrounding emerging treatments.

Building on the outcomes of the first seven hackathons, Hackathon 8 brought together key stakeholders to explore how OBAs could enhance timely access to cancer treatments in Canada, focused on generating insights and practical recommendations that could inform the design, adoption, and implementation of OBAs within Canada's regulatory and reimbursement landscape. The session focused on identifying the key success factors required to make OBAs effective in the Canadian context from the perspectives of multiple stakeholders: industry, HTA agencies, public payers, and patient groups. Participants collaboratively examined:

- System-level enablers and barriers for OBA implementation
- International best practices in structuring and executing OBAs
- Infrastructure and governance considerations for real-world evidence (RWE) collection
- Strategies for incorporating patient values and preferences into meaningful outcome selection

Hackathon 8 was a three-hour virtual session moderated by Bill Dempster (CEO, 3Sixty Public Affairs) with opening and closing remarks by Barry Stein (President & CEO, Colorectal Cancer Canada). Approximately 25 participants joined the session, including representatives from pharmaceutical companies, patient advocacy organizations, government agencies, clinicians, policy experts, and HTA professionals. *The detailed agenda for Hackathon #8 is provided in* ***Appendix 1****.*

The session was structured around:

- **Three pre-recorded panel discussions** shared prior to the event
- **A live plenary session** to introduce the agenda, review prior hackathon outcomes, and set the stage for the day's objectives
- **Breakout group discussions** segmented by stakeholder type (industry, HTA, patients, public payers) to explore focused questions.
- **Plenary report-outs** where each group presented key findings and proposed solutions
- **Post-hackathon activities**, including participant surveys and the development of a comprehensive report summarizing insights and recommendations

Scenario Case Study: NetFelix

To anchor discussions and simulate a real-world decision-making context, participants were presented with a hypothetical therapeutic scenario involving NetFelix, a novel monoclonal antibody for the treatment of advanced fallopian tube cancer—a rare and aggressive malignancy affecting less than 1% of gynecological cancers (**see Appendix 3** for full scenario details). The therapy is targeted at women aged 45 to 70 who carry a BRCA mutation or have a strong family history of gynecologic cancers. NetFelix has demonstrated a progression-free survival (PFS) advantage in Phase 2 trials (18 months vs. 12 months with standard chemotherapy), but lacks overall survival (OS) data and has limited long-term quality of life (QoL) data. Phase 3 trials are ongoing. The treatment is administered intravenously and may offer reduced toxicity compared to existing chemotherapy regimens.

Participants were asked to assess whether NetFelix is suitable for an OBA using a suitability framework developed by the Institute of Health Economics (IHE), which includes four evaluation pillars:

- Strategic Alignment
- Challenges
- Feasibility
- Value Potential

This scenario was designed not only to stimulate critical thinking about the mechanics of OBA implementation but also to provoke broader reflection on how Canada's health system can evolve to accommodate innovation in oncology drug access.

1.2 Pre-recorded Panels

*A complete list of panelists and their affiliations is available in **Appendix 2**.*

Pre-Panel Discussion 1:

Title: Innovative Pathways: Exploring OBAs in Canada
Panel Format: Pre-recorded session for Hackathon 8
Moderator: Bill Dempster, President, 3Sixty Public Affairs
Panelists:

- Allison Wills, Partner, 20Sense
- Dr. Rebeccah Marsh, Director, Health Technology Innovation Platform (HTIP), Institute of Health Economics

Objective:

This pre-panel discussion served to introduce the concept, purpose, and implementation challenges of OBAs in the Canadian healthcare landscape. It aimed to prepare participants for Hackathon 8 by offering foundational insights into the policy, operational, and ethical considerations of OBAs, especially in oncology. The discussion focused on definitions, international comparisons, decision-making frameworks, and the evolving role of patients in OBA design.

Key Themes and Insights:

1. Understanding OBAs and Related Frameworks

- Definition and Purpose of OBAs: OBAs are market access agreements in which reimbursement is tied to the clinical performance of a drug in the real world. Unlike traditional product listing agreements (PLAs), OBAs incorporate data collection to assess outcomes. Their central purpose is timely patient access, not solely financial savings or evidence generation.
- Distinction from Related Concepts: OBAs are a subset of broader managed entry agreements (MEAs) or managed access agreements (MAAs).
    - OBAs = Outcomes-based (performance-based) financial models.
    - MAAs/MEAs = Umbrella terms for agreements used internationally to address uncertainty while enabling patient access.
- Canada vs. Global Pathways: Canada lacks formal managed access frameworks that pair HTA decisions with listing pathways. In contrast, countries like the UK implement structured frameworks that enable earlier listing through mechanisms such as the Cancer Drugs Fund.

2. Current OBA Landscape in Canada

- Limited Uptake and Transparency: Although OBAs are used in Canada, they remain limited (estimated 10–20 simple OBAs). They are often embedded as confidential elements within broader PLAs and are not consistently tracked or made visible.
- Examples of Existing Elements: The pan-Canadian Pharmaceutical Alliance (pCPA) has acknowledged the use of OBA-like elements in some contracts (e.g., discontinuation rebates, patient caps, free trials), but these do not constitute formal OBAs.

- Examples from Other Jurisdictions: An illustrative Australian OBA tied payment to whether a lung cancer drug met OS benchmarks. Patients received immediate access while data was gathered, and payers and manufacturers agreed in advance on rebate triggers.

3. Key Success Factors for Implementing OBAs

- Appropriate Use Cases: OBAs should only be pursued when a traditional PLA is not viable, i.e., when uncertainty is significant and data is immature. Misuse or overuse risks undermining their feasibility.
- Criteria for Success:
    - Use of measurable and meaningful outcomes (e.g., OS in oncology).
    - Interim reporting and forecasting milestones to manage expectations.
    - Shared governance and stakeholder trust in data sources.
    - Clearly defined objectives—timely access should remain primary.
- IHE OBA Playbook and Canvas: Rebecca Marsh introduced a playbook under development by the Institute of Health Economics. It provides a decision-support tool (the "OBA Canvas") to assess OBA suitability and structure, encouraging:
    - Clarification of objectives.
    - Alignment on prioritized interests across stakeholders.
    - Simplification of complex decisions using shared frameworks.

4. Barriers to OBA Adoption in Canada

- Lack of a National Pathway: Canada lacks a formal pathway integrating HTA, payer negotiations, and implementation for OBAs. This creates uncertainty regarding:
    - Roles and responsibilities of CDA, pCPA, payers, and manufacturers.
    - Mechanisms to exit an OBA if outcomes are not met.
- Payer Hesitancy and Administrative Burden: There is concern among payers that introducing a formal OBA pathway might open floodgates and overwhelm limited system capacity. Lack of readiness and clarity can delay negotiations.
- Equity Across Jurisdictions: OBAs risk exacerbating access inequities unless frameworks address interprovincial disparities. The current system lacks coordination for pan-Canadian data collection and implementation.

5. Role of Patients and Patient Organizations

- Defining Meaningful Outcomes: Patients must be involved in identifying which outcomes matter to them.

- Engagement Beyond Advocacy: Patient organizations can:
    - Support the development of patient registries.
    - Participate in governance structures.
    - Serve as partners in data collection design.
- Transparency and Communication: UK frameworks offer public-facing portals that notify patients when a managed access agreement is in place. This model promotes transparency without disclosing confidential deal terms.

6. Next Steps for Expanding OBAs in Canada

- Building a Formalized Pathway: Stakeholders called for a structured, transparent framework akin to the UK's managed access process. Without this, OBAs in Canada will remain ad hoc and inconsistent.
- Stakeholder Alignment and Pilot Projects: Panelists advocated for small-scale experimental implementations to build confidence, test assumptions, and learn from real-world challenges.
- Political and Policy Will: Broader health system cooperation is needed. Interprovincial coordination and political commitment could accelerate OBA adoption, as has been the case with initiatives like Project Orbis and TLR.

Conclusion:

Pre-panel participants emphasized that the core purpose of OBAs is to facilitate timely access to innovative therapies, especially in oncology. While various OBA elements already exist in Canada, the absence of a clear, coordinated pathway remains the primary barrier to broader implementation. With growing international experience, rising pressure for early access, and tools like the IHE playbook, Canada is positioned to scale its OBA efforts. However, progress will depend on stakeholder alignment, regulatory clarity, infrastructure for real-world evidence, and authentic integration of patient perspectives.

Pre-Panel 2 Summary

Title: Improving Access to Cancer Drugs in the UK: The Role of Managed Access Agreements (MAAs)

Panel Format: Pre-recorded session for Hackathon 8

Moderator: Bill Dempster, President, 3Sixty Public Affairs

Panelists:

- **Dr. David Thomson**, Associate Director, Commercial Liaison Team, NICE

- **Daniel Stevens**, Senior RWD Scientific Operations Manager, Bionical Emas

Objective:

This pre-panel discussion explored how MAAS and RWE are used in the UK to improve patient access to cancer medicines. It aimed to inform Canadian stakeholders by highlighting practical examples, infrastructure, and policy principles from the UK experience. The discussion emphasized transferable lessons to support the design and implementation of OBAs in Canada, with attention to system readiness, stakeholder roles, and data governance.

Key Themes and Insights:

1. Understanding Managed Access Agreements in the UK

- MAAs in the UK include two core components:
    - **Data Collection Agreement (DCA):** Specifies data sources, duration, analytic plans, and publication processes.
    - **Commercial Access Agreement (CAA):** Includes drug pricing during access, an exit strategy if the drug is not recommended, and a commitment to control overspending.
- Two funds support MAAs in the UK:
    - **Cancer Drugs Fund (CDF):** Established nationally in 2016.
    - **Innovative Medicines Fund (IMF):** Launched in 2022 for non-cancer indications.
- A key principle is that patients already receiving therapy during the MAA period should continue, regardless of NICE's final recommendation, unless clinically inappropriate.

2. Criteria for Selecting MAA Candidates

- NICE uses four criteria to determine suitability for MAAs:
    1. Is there enough evidence for routine funding?
    2. Is there plausible potential for cost-effectiveness at the current price?
    3. Can the key uncertainties be addressed through additional data?
    4. Can data be collected in under five years without undue burden?
- Example: **Dostarlimab** for endometrial cancer met MAA criteria and entered the Cancer Drugs Fund. Real-world evidence collection was later removed because clinical trial data (OS) was deemed more decisive.

3. Real-World Data (RWD) Infrastructure

- The UK leverages:

    - **SACT (Systemic Anti-Cancer Therapy dataset):** Collects data automatically via e-prescribing systems across the NHS.
    - **National Institute for Health Research (NIHR):** Supports data sharing, patient engagement, and rapid contracting through research delivery networks.
- **Danny Stevens** emphasized that many logistical barriers to real-world data collection (e.g., contracts, ethics approval, feasibility assessments) have been reduced through centralized systems and pre-approved templates.
- NICE's **RWE Framework** offers standards for data quality, governance, and analysis. It helps clarify expectations for sponsors early on.

4. Patient-Reported Outcomes and Realities

- Patient-reported outcomes (PROs) are challenging to collect through national systems like SACT.
- There is an increasing demand to include patients early in study design. NIHR helps coordinate such efforts.
- While PROs are not routinely used in reimbursement decisions, their integration is expected to grow with decentralized trials and digital collection methods.

5. Commercial Considerations and Risks

- MAAs are not always attractive to industry due to:
    - Risk of reimbursement rejection at exit
    - Obligation to cover treatment costs for existing patients' post-exit
    - Evolving comparators, new market entrants, or changing methods during the 3–5 year access period
- Prices can be renegotiated at MAA exit—either increased or decreased based on updated cost-effectiveness assessments.
- MAAs in the UK rarely use **outcomes-based payment models** (i.e., conditional on performance). Instead, fixed pricing during access with renegotiation is standard.

6. Lessons for Canada

- Canada must:
    - Define core principles and exit strategies early to avoid stakeholder conflict.
    - Determine how burden-sharing for RWE will work across payers, providers, and sponsors.

- Align data infrastructure to avoid excess burden — learning from SACT and e-prescribing integration.
- Ensure decisions reflect patient values and address the growing role of surrogate endpoints in early-stage cancer therapies.

Conclusion:

The UK's experience with Managed Access Agreements (MAAs) offers valuable lessons for structuring real-world evidence collection and access frameworks in Canada. While MAAs in the UK prioritize data transparency, early stakeholder alignment, and centralized infrastructure, panelists noted that success ultimately hinges on trust, clarity, and shared responsibility. As Canada explores broader implementation of OBAs, adapting these principles, while accounting for jurisdictional complexity and domestic policy constraints, can help ensure sustainable access to high-cost cancer therapies. Key enablers will include robust national data systems, early definition of MAA terms and exit strategies, and greater inclusion of patient voices in determining meaningful outcomes.

Pre-Panel 3: Discussion Summary

Title: Global Perspectives on OBAs and Real-World Evidence (RWE)

Moderator: Barry Stein (Colorectal Cancer Canada)

Panelists:

- Jonathan Pearson-Stuttard, Partner and Head of Health Analytics, Lane Clark & Peacock (UK)
- Sania Chouman, Global Access Innovation Head, Takeda Pharmaceuticals

Objective:

This pre-panel discussion examined how outcomes-based agreements (OBAs) and real-world evidence (RWE) are utilized globally to improve patient access to cancer drugs. It aimed to explore current international practices and highlight opportunities to adapt similar approaches within the Canadian context. The discussion focused on implementation processes, challenges, and the potential for improving timely and equitable access to cancer treatments in Canada.

Key Themes and Insights:

1. Types and Purpose of Value-Based Agreements

- Panelists differentiated between financial-based agreements (e.g., budget cap, price-volume) and OBAs (e.g., pay-for-performance).
- OBAs are best suited when uncertainty exists in clinical performance or financial impact, particularly for cancer drugs entering the market with limited or phase II trial data.
- Managed Entry or Access Agreements were noted as time-limited, allowing for early access while data collection is ongoing.

2. Design Considerations for OBAs

- Simplicity and stakeholder alignment were emphasized as critical to successful OBA design.
- Key decisions include defining the measurable outcome, the timeline for evaluation (e.g., 8 weeks post-treatment), and linking payment to those outcomes.
- In Spain, tumor size at 8 weeks was used as a measurable outcome for reimbursement decisions, showing a practical example of a simple, clinical outcome-based model.

3. Challenges in Implementing OBAs

- Major barriers include:
    - Lack of infrastructure and national registries in many jurisdictions.

    - Inconsistent availability of key data like progression-free survival (PFS) and patient-reported outcomes (PROs).
    - Limited trust between payers and manufacturers often leads to reluctance in adopting OBAs.
- Patient-reported outcomes are still not widely used for payment decisions due to concerns about subjectivity and bias.

4. Real-World Data (RWD) Infrastructure and Responsibility

- RWD collection remains fragmented. In most cases:
    - Physicians input data into registries.
    - National/regional health systems own and control access.
    - Manufacturers may fund third-party audits but do not directly access patient-level data.
- In Spain and Italy, registries play a strong role in supporting OBAs.
- There is growing interest in incorporating digital tools and wearables for data collection to reduce hospital burden and increase objectivity.

5. Role of Patients and Patient Support Programs

- Current OBAs rarely incorporate direct patient feedback into outcome selection or payment models.
- Patient support programs are increasingly viewed as useful for post-marketing surveillance but not yet integrated into reimbursement frameworks.
- Future success in OBAs depends on early and meaningful involvement of patients, physicians, and payers in defining relevant and objective outcomes.

6. Recommendations for Canada

- Start with small pilots to build trust and refine operational frameworks.
- Invest in digital infrastructure and standardized data collection methods.
- Engage all stakeholders early—especially patients—to ensure relevance and transparency.
- Avoid overly rigid capitated models that may disincentivize innovation.

7. Long-Term Vision

- Panelists supported shifting from one-time access agreements to ongoing outcome-based reimbursement as a norm.
- OBAs were positioned as enablers of sustainable, value-based healthcare systems if trust, data quality, and stakeholder alignment are addressed.

Conclusion:

The panel underscored that while OBAs have the potential to drive sustainable access to innovative cancer therapies, their success is contingent on simplicity in design, shared accountability, and investment in real-world data infrastructure. Panelists emphasized the importance of starting with small-scale pilots, focusing on clear, objective outcomes, and fostering early alignment among patients, providers, payers, and manufacturers. Global examples from Spain, Italy, and the UK revealed that meaningful implementation requires flexible frameworks, robust data systems, and trust-based governance. For Canada, advancing OBAs will require targeted investments in digital infrastructure, stakeholder engagement, and practical outcome measures that reflect clinical relevance and patient value.

2.0 Key discussions from the four breakout groups

Group 1 Discussion: Industry Perspective

Objective

Using the NetFelix case scenario, the industry group examined the critical success factors required to implement OBAs in Canada. The discussion addressed conditions for OBA success, regulatory and policy barriers, challenges in real-world evidence (RWE) collection, global best practices, and expectations from stakeholders.

1. **Conditions for a Successful OBA for NetFelix**

From an industry standpoint, a successful OBA for NetFelix must prioritize timely and equitable patient access. Agreements should support faster access to novel treatments across all provinces, not just pilot implementations in a few jurisdictions. The OBA process itself must not become a barrier that delays listing; it should be a tool for resolving true uncertainty, not a workaround for delayed financial negotiations. Several interrelated factors were identified:

- **Outcome Relevance and Measurability**: Outcomes used to define success in the agreement must be both meaningful to patients and measurable in practice. This includes patient-centered outcomes like symptom control, functional status, and progression-free survival (PFS), provided they are aligned with HTA and payer expectations. The use of SMART criteria (Specific, Measurable, Achievable, Relevant, Time-bound) was emphasized.
- **Defining the Uncertainty**: A fundamental step before initiating an OBA is clarifying what uncertainty the agreement seeks to resolve. If uncertainty can be addressed financially (e.g., through discounts), the preference would be for swift negotiation. However, when clinical uncertainty is central, OBAs should be used strategically to generate confirmatory evidence.
- **Data Collection Feasibility and Cost:** The burden, duration, and cost of collecting data must be explicitly considered. OBAs must outline who collects the data, who pays for it, and how it is supported, whether through internal systems, public registries, or third-party platforms. Data collection should be streamlined and, where possible, use existing infrastructures.
- **Pan-Canadian Reach with Regional Flexibility**: While national access is critical, there is room for regional variation in data collection strategies. Industry stakeholders are open to flexible, scalable models provided the broader goal of national equity in access is preserved.
- **Infrastructure Investment and Global Integration:** Canada currently lacks the digital infrastructure to support OBAs at scale. The discussion highlighted the need for enhanced interoperability of health records, integration of real-time data, and alignment with global data

platforms, particularly critical in rare diseases, where pooling data internationally may improve confidence.

- **Trust and Collaboration:** A recurring theme was the need to rebuild trust across the ecosystem. Success will depend on credible data, shared governance, and transparent collaboration between regulators, payers, sponsors, clinicians, and patients. Without consensus on what data is "good enough," OBAs risk failure.

2. Regulatory and Policy Barriers

Participants noted several policy-related challenges that could hinder broader OBA adoption in Canada:

- **Limited Clarity on Eligible Product Types:** There remains ambiguity about what types of therapies HTA bodies and public payers consider suitable for OBAs. Establishing clearer criteria would help set the sector up for success.
- **Administrative Complexity and Capacity Constraints**: OBAs are resource-intensive and often require longer timelines for negotiation and setup. There is limited bandwidth within current HTA and payer institutions to manage these agreements effectively, especially without additional resourcing.
- **Lack of Visibility into Existing Agreements:** The confidential nature of existing OBAs in Canada restricts shared learning. Greater transparency, such as access to templates or anonymized summaries of past agreements, could promote better understanding and adoption.
- **Payer Preferences and Endpoint Misalignment:** There is uncertainty over whether payers will accept surrogate endpoints such as PFS or require overall survival (OS) data. This misalignment between what is important to patients and what is valued by HTAs or payers needs resolution.
- **Delays in Early Access Pathways:** While tools like Time-Limited Recommendations (TLRs) and pTAP exist, it is not always clear how OBAs interact with these pathways. There is a need for guidance on whether OBAs can remove or replace such regulatory conditions.

3. Challenges in Collecting Long-Term RWE and Industry's Role

RWE is critical to the long-term success of OBAs, but Canadian infrastructure faces significant gaps:

- **Fragmented Systems and Lack of Real-Time Data:** Canada does not yet have a unified system for real-time health data. Existing assets like CIHI and Infoway provide limited coverage or are not agile enough to support OBAs.
- **Interjurisdictional Data Gaps:** Provinces vary widely in EMR adoption, making it difficult to establish consistent national datasets. Harmonizing data standards and consent models will be essential for scaling OBAs across Canada.
- **Emerging Data Innovations:** Participants discussed technologies such as:
  - Pentavere and other AI-driven platforms for real-world data extraction.
  - ADaM (Advanced Data Modeling) systems that generate synthetic datasets to simulate clinical trial outcomes based on real-world parameters.
- **Surrogate Outcomes and PROMs**: The acceptability of surrogate endpoints like PFS remains in question. There is a need to define how patient-reported outcomes and experiences (PROs/PROMs) can be incorporated meaningfully into OBA frameworks.
- **Patient Involvement in Data Generation:** Patient consent and participation are critical in data collection, especially when patient support programs (PSPs) are involved. OBAs must ensure that the outcomes being measured are both informed by and validated by patient input.

4. Global Best Practices for OBA Design

Several international models were referenced as potential benchmarks:

- **UK Subscription Model:** Offers a national-level RWE registry funded through a subscription approach. This structure supports data access and transparency while reducing the administrative burden on individual manufacturers.
- **Spain's Valtermed System:** Provides real-time data collection at the national level and is seen as a model of efficient, trusted data governance.
- **Trust-Based Payment Models:** In some jurisdictions, manufacturers are reimbursed upfront, and rebates are applied later if real-world outcomes are not achieved. This contrasts with the more risk-averse Canadian approach, where upfront trust in data systems remains limited.

These models highlight the value of national coordination, streamlined data access, and cross-stakeholder trust—conditions that must be cultivated for OBAs to succeed in Canada's more decentralized environment.

5. What Industry Needs from Stakeholders

To implement a viable OBA for NetFelix and other emerging therapies, industry stakeholders require:

- **Early, Transparent Engagement with HTA and Payers:** Proactive conversations during early phases of regulatory review are necessary to align expectations and timelines.
- **Clear Criteria for OBA Eligibility:** A framework outlining the types of clinical uncertainty or product categories appropriate for OBAs would promote clarity and consistency.
- **Defined Roles and Responsibilities in Data Governance:** OBAs must specify who is responsible for collecting, managing, and analyzing data, be it payers, manufacturers, third-party data stewards, or a centralized agency.
- **National Infrastructure for RWE:** There is a strong need for a pan-Canadian approach to data systems that includes integration of electronic health records, standardized PROMs, and linkage across jurisdictions.
- **Inclusion of Patient Voices**: Agreement design must incorporate patient-informed outcomes to ensure relevance and engagement throughout the data collection process.

Conclusion

The industry group's discussion underscored that while OBAs present a valuable opportunity to accelerate access to innovative cancer treatments like NetFelix, their success in the Canadian context depends on foundational system improvements and stakeholder alignment. A well-executed OBA must balance timely access with practical and patient-centered outcome measurement, supported by a reliable and interoperable real-world data infrastructure. To move from concept to implementation, Canada must establish clear eligibility criteria, enhance data governance, and foster trust among manufacturers, payers, HTA bodies, and patients. Without these conditions in place, OBAs risk becoming administratively burdensome and ineffective. However, with early collaboration, international learning, and national coordination, OBAs could become a strategic pathway to enable equitable and evidence-informed access to new cancer therapies.

Group 2 Discussion: Public Payer Perspective

Objective

The public payer group explored the feasibility and key success factors for implementing \OBAs in the Canadian context using the NetFelix scenario. The discussion reflected the unique responsibilities of public payers, who must balance healthcare sustainability, equitable access, and evidence-based decision-making. OBAs were recognized as a potential tool to manage clinical and financial uncertainty while enabling timely access to promising therapies, but only if designed to reflect the operational realities of provincial and territorial healthcare systems.

1. Conditions for a Successful OBA for NetFelix

Public payers identified five primary conditions necessary for the successful implementation of OBAs:

- **Implementation Simplicity and System Readiness**: There was a strong emphasis on ensuring that OBAs are not overly complex or resource-intensive. Canada is not currently resourced or structured to implement OBAs at scale. Agreements must therefore leverage existing infrastructure, such as data collection processes already embedded in clinical care, and avoid placing additional strain on administrative systems. Without simplification, OBAs risk delaying access rather than facilitating it.
- **Reliable and Efficient Data Collection**: Data must be collected consistently and credibly to assess therapeutic outcomes without excessive administrative burden. In the case of NetFelix, the ongoing phase 3 clinical trial provides a natural data collection pathway—e.g., regular scans every 3–4 months—reducing the need for new infrastructure. However, for broader application, mechanisms must be created that allow population-level data aggregation, are scalable, and align with real-world clinical practice timelines.
- **Trust in Data and Stakeholders**: Trust was seen as a cross-cutting issue, particularly concerning the reliability and independence of data collected by manufacturers. For OBAs to be viable, payers must have confidence in both the source and stewardship of real-world evidence (RWE). Transparent roles and governance structures are required to ensure that all parties—including payers, industry, clinicians, and patients—are aligned on how outcomes are defined, measured, and used.
- **Stakeholder Engagement and Early Collaboration**: Payers emphasized that discussions about OBAs should be initiated **early in the review process**, ideally at the point of HTA evaluation. Current processes often leave OBA discussions until after a

clinical “no,” creating missed opportunities for negotiation and delaying access. Embedding OBA considerations into existing HTA pathways, with leadership from Canada’s Drug Agency (CDA), would facilitate proactive and structured engagement across stakeholders.

- **Defined Timeframes and Outcome Thresholds**: Agreements must include a clear data collection period—three years was suggested as a reasonable timeframe to observe meaningful outcomes such as progression-free survival (PFS). Success criteria must also be predefined; for instance, if a patient fails to meet the PFS threshold, the payer may only be obligated to reimburse up to the cost of standard chemotherapy.

2. Regulatory and Policy Barriers

Several systemic barriers to OBA adoption were identified:

- **Limited Integration with Existing Pathways**: Current reimbursement structures, such as Time-Limited Recommendations (TLRs) and the pan-Canadian Pharmaceutical Alliance (pCPA), do not consistently accommodate OBAs. Clinical “no” decisions from CDA may end the conversation prematurely, even when a product may be viable under an OBA framework.
- **Fragmented Provincial Systems**: While larger provinces may have the administrative capacity to engage in OBAs, smaller jurisdictions often rely on standardized pCPA letters of intent (LOIs) and lack the infrastructure for individualized agreements. This creates inequities in access and implementation feasibility.
- **Unclear Product Eligibility for OBAs**: There is no formal framework outlining what types of therapies are suitable for OBAs, leading to inconsistency in uptake. Greater clarity on therapeutic areas, uncertainty profiles, or endpoints that justify an OBA would support more targeted implementation.
- **Regulatory Disconnects**: Additional hurdles such as the Patented Medicine Prices Review Board (PMPRB) and NOC/c (Notice of Compliance with Conditions) processes can create misalignment between regulatory approvals and reimbursement potential, particularly if further evidence is required post-market.

3. Mechanisms for Data Collection and Burden Minimization

Payers recognized that RWE is essential for OBAs but acknowledged multiple challenges in its collection and application:

- **Leveraging Existing Structures**: One suggestion was to adapt existing provincial processes, such as public drug plan Exceptional Access Programs (EAPs) or prior

authorization systems. These already involve some level of outcome documentation, although currently manual and unstandardized. While these systems are not optimized for analytics, they offer a starting point that could be built upon or digitized for small patient populations.

- **Clarifying Roles and Responsibilities**: Manufacturers are expected to lead data collection efforts, but shared governance is essential. Questions remain about whether payers will accept data they did not collect or whether they should participate more actively in data validation and funding.
- **Standardization and Equity Across Jurisdictions**: To avoid disparities, provinces must work toward aligned expectations for data submission and analysis. National coordination through CDA or pCPA was suggested as a way to ensure consistent standards and avoid fragmented or duplicative efforts.
- **Patient Involvement**: Although discussed less directly, the group recognized the importance of integrating patient-reported outcomes (PROs) and aligning endpoints with patient experience. The success of OBAs depends on ensuring that the outcomes tracked are meaningful to patients and can be feasibly captured.

4. Equitable Access Across Jurisdictions

Provincial variability in data infrastructure, personnel, and funding capacity presents a major challenge to equitable OBA implementation. Without centralized guidance or support, smaller provinces may be left out of national-level agreements or unable to meet the administrative requirements. Participants suggested that pCPA could play a coordinating role to streamline engagement and ensure that all jurisdictions, regardless of size, have a seat at the table.

5. Risk-Sharing and Financial Protection Models

From a payer perspective, OBAs must strike a balance between protecting public funds and enabling early access to innovation:

- **Flexible, Shared Risk Models**: Rather than expecting payers to fund initial access entirely or bear administrative costs, OBAs could be designed with built-in adjustment mechanisms. For example, if NetFelix meets performance targets over three years, a portion of the manufacturer's cost could be recouped retroactively. This would allow risk-sharing without requiring upfront payer investment.
- **Linking Price to Outcome**: Agreements must allow for tiered pricing based on clinical results. Products that do not meet predefined thresholds—such as a minimum PFS benefit—could be reimbursed at the level of standard care alternatives, reducing financial exposure.

6. What Payers Need from Stakeholders

To support successful OBA implementation, public payers highlighted several key requirements from other stakeholders:

- **From HTA Bodies**: More flexible guidance that enables conditional recommendations—rather than strict "no" decisions—when uncertainty exists. HTA should also outline conditions under which an OBA might be appropriate, making recommendations more actionable across jurisdictions.
- **From Manufacturers**: Clear, early proposals outlining how uncertainty can be resolved, how data will be collected, and what outcomes will be measured. Proposals should reflect the realities of provincial systems and avoid adding undue burden.
- **From Coordinating Bodies (CDA, pCPA)**: Leadership in convening multi-stakeholder discussions, facilitating alignment on outcomes and timelines, and standardizing OBA frameworks across Canada. This would ideally include the development of templates, pathways, and data-sharing agreements.

Conclusion

Public payers acknowledged that OBAs can serve as a pragmatic solution to balance clinical uncertainty with timely patient access. However, for OBAs to succeed in Canada, agreements must be simple, aligned with existing systems, and supported by trusted, population-level data. Early engagement, cross-jurisdictional coordination, and flexible, outcome-linked financial models are essential. Without dedicated infrastructure, shared governance, and clearly defined roles, OBAs risk creating further inequities and administrative burden. Yet, with thoughtful implementation, OBAs offer a path forward that aligns healthcare sustainability with innovation and patient-centered care.

Group 3 Discussion: HTA Body Perspective

Objective

The HTA group explored the role of health technology assessment bodies in enabling OBAs in Canada, using the NetFelix scenario as a conceptual guide. Participants reflected on the functions that HTA bodies could and should assume within the broader lifecycle of OBAs, from early identification of candidate products to supporting negotiation, evidence generation, and system-wide learning. The conversation emphasized that while HTA organizations have traditionally focused on evaluating high-certainty clinical data, the OBA model demands greater flexibility, role clarity, and strategic collaboration across stakeholders.

1. Conditions for a Successful OBA for NetFelix

Participants emphasized that HTA bodies must actively participate in shaping the OBA ecosystem, not only as evidence assessors but as system enablers. To that end, several conditions were identified as critical for successful OBA design and execution:

- **Defined Framework and Process Pathway**: HTA bodies should provide a structured framework that clearly outlines when and how OBAs should be considered, including:
    - Early candidate identification for therapies likely to face clinical uncertainty.
    - Defined procedures and criteria for evaluating whether an OBA is appropriate.
    - A process package that could be passed to the pCPA or relevant negotiation body, ensuring continuity between evidence review and price negotiation.
- **Early Feasibility and Value of Information (VOI) Assessments**: Before initiating an OBA, HTA bodies should conduct feasibility studies to determine if available real-world evidence (RWE) sources can adequately resolve the key uncertainties. This could include a VOI analysis to assess the value of additional data and whether it would justify delay or conditional reimbursement.
- **Trusted RWE Standards and Flexibility**: The success of OBAs depends on ensuring that RWE is methodologically sound and acceptable for decision-making. HTA bodies must clearly define what constitutes “trusted data,” potentially through a standardized checklist for registries and real-world data sources. However, flexibility is key: local, regional, or international data should all be considered acceptable if they meet scientific standards. There should be no rigid requirement for national datasets.
- **Clarity on Success Metrics**: OBAs should be evaluated based on pre-specified measures of success, such as clinical effectiveness, patient-reported outcomes, and

financial sustainability. HTA bodies have a role in ensuring that these metrics are realistic, measurable, and aligned with the uncertainties identified in the original submission.

2. Regulatory and Policy Barriers

The group identified several regulatory and procedural limitations that hinder the implementation of OBAs from an HTA perspective:

- **Rigid Evidence Standards**: There is a prevailing expectation within HTA bodies for gold-standard randomized controlled trial (RCT) data. In the context of OBAs, this standard may be unrealistic. Participants emphasized the need for HTA processes to adapt to the **evidence that exists**, not just the evidence that would be ideal. This includes accepting well-structured observational or international data when local RWE is limited.
- **Lack of Funding Flexibility**: In the current environment, HTA recommendations do not always translate into feasible funding mechanisms. A dedicated fund or pool of resources, potentially coordinated at the federal level, was proposed as a means to support OBAs, particularly where there is no guarantee that provinces will allocate a budget to support access under conditions of uncertainty.
- **Role Ambiguity in Negotiation**: While HTA bodies do not directly participate in price negotiations, there is a need for greater integration between HTA recommendations and pCPA processes. The group suggested that HTA bodies should play a facilitating role in enabling OBAs, through early identification of candidate products and guidance on evidence acceptability, without directly engaging in pricing discussions.

3. Real-World Evidence Collection and Minimizing Burden

HTA bodies were viewed as critical actors in setting the methodological standards for RWE used in OBAs. The group identified several mechanisms to strengthen RWE collection:

- **Adaptable Data Collection Models**: Rather than insisting on a centralized national RWE hub, the group emphasized flexibility. For some therapies, particularly those targeting rare diseases, regional or international datasets may be sufficient. HTA guidance should enable the use of the most relevant and scientifically valid data, regardless of origin.
- **RWE Standards and Checklist**: A standardized checklist or set of methodological requirements could support consistent data evaluation across jurisdictions and therapeutic areas. This would provide clarity to manufacturers and payers on what is expected for RWE to be deemed reliable.

- **Defined Roles and Responsibilities**: While HTA bodies are not responsible for collecting data directly, they can specify who should collect it, what type of data is needed, and how it will be assessed. This upstream guidance is essential for ensuring that OBAs are structured around achievable and meaningful evidence targets.
- **Patient Involvement in Outcome Design**: While not a central theme in the HTA group discussion, alignment with patient-centered outcomes was acknowledged as important. HTA frameworks should encourage the inclusion of patient-reported outcomes (PROs) where appropriate and feasible.

4. Monitoring and Adaptation of OBAs

HTA bodies do not see themselves as responsible for monitoring individual OBAs, but rather for monitoring the overall OBA framework and adapting it over time. Their responsibilities in this domain may include:

- Updating methodological standards based on evolving evidence types.
- Tracking which types of products and conditions have successfully moved through OBAs.
- Reviewing systemic challenges and feeding those insights into future HTA guidance.

Participants also recommended the development of a public-facing transparency portal, similar to models in the UK, where stakeholders can view summaries of OBA agreements, outcomes, and decision processes. This would promote stakeholder trust and accountability across the OBA lifecycle.

5. Risk-Sharing Models and Stakeholder Alignment

From an HTA perspective, OBAs must be framed as shared-risk mechanisms in which all parties understand their roles in balancing innovation, access, and sustainability. The role of HTA bodies in this context includes:

- Encouraging upstream alignment on outcome measures and data sources.
- Supporting payment models that link reimbursement to RWE-confirmed value.
- Recommending structures that allow payers to pay only for value received, while allowing manufacturers to demonstrate therapeutic benefit in the real world.

While HTA bodies are not responsible for the financial design of these agreements, they can inform acceptable models by clarifying how clinical uncertainty can be addressed and what evidence would change a “no” into a “yes.”

6. What HTA Bodies Need from Other Stakeholders

To effectively support OBA implementation, HTA bodies require:

- **From Manufacturers**: Early identification of uncertainty, clear RWE plans, and flexibility in outcome definition. Submissions should proactively consider what evidence can realistically be generated to resolve outstanding questions.
- **From Payers**: Budget flexibility and willingness to act on conditional recommendations. A dedicated fund or budget envelope for OBA-eligible products may help HTA bodies issue more confident recommendations under uncertainty.
- **From Coordinating Bodies (e.g., CDA, pCPA)**: Support for integrated planning across regulatory, HTA, and reimbursement stages. Clear roles, early alignment meetings, and consistent templates would streamline the OBA process across jurisdictions.

Conclusion

HTA bodies have a central role to play in enabling the effective use of OBAs in Canada, not as passive evaluators, but as strategic enablers of innovation and evidence-informed access. By providing structured frameworks, transparent guidance, and methodological flexibility, HTA organizations can help translate promising but uncertain therapies like NetFelix into access pathways grounded in measurable real-world value. However, this will require cultural shifts within HTA bodies, greater inter-agency collaboration, and coordinated investment in flexible data infrastructure. When supported with clear roles, realistic expectations, and shared resources, OBAs can become a viable and equitable solution for addressing uncertainty while advancing access to high-value care.

Group 4 Discussion: Patient and Patient Advocacy Group Perspective

Objective

The patient and patient advocacy group discussion focused on ensuring that the design and implementation of OBAs meaningfully reflect patient priorities, improve timely access to therapy, and consider lived experiences beyond clinical endpoints. Using the NetFelix case scenario, participants explored how patients can influence OBA development, how their voices should be represented in outcome selection and decision-making, and how patient groups can play a supporting role in RWE collection and broader system coordination.

1. Conditions for a Successful OBA for NetFelix

Patients emphasized that the primary condition for a successful OBA is that it must deliver early and equitable access to therapy. Any agreement structure that delays or restricts access risks failing the core population it intends to serve. Additionally, patients expressed the need for OBAs to be centered on meaningful, patient-defined outcomes, which often extend beyond traditional clinical endpoints like survival.

Key conditions identified included:

- **Patient-Centered Outcomes**: The OBA should incorporate outcomes that matter to patients, such as the ability to meet life milestones, maintain independence, or continue caregiving roles. Patients may prioritize outcomes like symptom management, daily functioning, and emotional well-being over survival duration alone.
- **Caregiver Impact**: The impact of disease and treatment on caregivers should also be considered. OBAs should aim to capture caregiver burden as part of the broader health outcomes assessed, especially in conditions like advanced cancers.
- **Clear and Fair Access Criteria**: Patients must be informed and able to understand the criteria for accessing NetFelix, including genetic eligibility, treatment line (e.g., third-line therapy), and clinical trial availability.
- **Strong Clinician and System Buy-In**: Implementation success depends on clinician participation and system-level support. Clinicians are vital not only in prescribing therapies but in advising, collecting patient-reported data, and helping patients navigate access pathways.
- **Defined Scope of Data Collection**: OBAs must define what percentage of the patient population will contribute data, what constitutes sufficient data to evaluate success, and

how long data will be collected. The collection strategy must be practical, transparent, and ethically sound.

2. Influence of Patient Preferences in Outcome Selection

Participants emphasized that patient values and lived experiences should inform which outcomes are used to assess OBA success. Patient groups can play a critical role in this process by:

- Surveying patients to identify preferred outcomes and surrogate endpoints that reflect their treatment priorities.
- Supporting the adaptation of patient-reported outcome (PRO) questionnaires to capture dimensions beyond survival and disease progression.
- Advocating for inclusion of qualitative outcomes such as mental health status, quality of life, and treatment tolerability.

There was also acknowledgement that tensions can arise between objective clinical outcomes, which are traditionally prioritized by payers and HTA bodies, and subjective outcomes valued by patients. These differences must be negotiated through multi-stakeholder consultation to ensure OBAs remain relevant and grounded in real-world experience.

3. Regulatory and Policy Barriers

Several barriers that could limit patient access or delay the implementation of OBAs were identified:

- **Variability in Access to Genetic Testing**: For therapies like NetFelix, which may be restricted to BRCA-positive individuals or those with a strong family history, access to genetic testing is essential. However, significant disparities exist across provinces in both availability and public funding of such testing. This inconsistency may hinder timely access and equitable implementation of the OBA.
- **Ethics Approvals and Data Registries**: Collecting patient data through disease registries or observational studies may require ethics approval, the timelines and requirements for which vary by jurisdiction. These processes can be slow, complex, and regionally inconsistent.
- **Lack of Early Coordination Among Stakeholders**: OBAs are often implemented too late in the drug access process. Without early engagement between Health Canada, Canada's Drug Agency (CDA), pan-Canadian Pharmaceutical Alliance (pCPA), and provincial payers, OBA implementation may be delayed or fragmented. Pipeline meetings and early alignment conversations are critical.

- **Organizational Buy-In**: All stakeholders—regulators, HTA bodies, payers, manufacturers, clinicians, and patient groups—must be aligned from the outset. Without shared commitment and clear communication, OBAs risk failure in execution.

4. The Role of Patient Advocacy Groups in Shaping OBAs

Patient groups are well-positioned to support OBA design and implementation in multiple ways:

- **Defining Meaningful Outcomes**: Rather than collecting data themselves, patient organizations can work with manufacturers and payers to determine which outcomes matter most. This insight is essential to ensure the OBA is designed around relevant goals.
- **Supporting Awareness and Navigation**: Patient groups can serve as navigators, helping patients understand access pathways, clinical trial opportunities, and inclusion criteria for therapies like NetFelix. They can also advocate for equitable access to genetic testing and companion diagnostics.
- **Facilitating Patient Input in OBA Suitability**: Patients should be engaged early in the process to assess whether a proposed OBA structure aligns with their needs. This includes identifying if certain agreements might delay treatment or fail to capture meaningful measures of success.
- **Ensuring Transparency**: Patients need visibility into how an OBA may impact their access, what data is being collected, and how it will be used. Clear and accessible communication from HTA bodies and payers is essential to build trust.

5. Real-World Evidence Collection and the Role of Patients

While the primary responsibility for RWE collection may fall to manufacturers and healthcare systems, patients and patient organizations can contribute to defining and contextualizing the data collected. Suggested mechanisms included:

- **Patient-Reported Outcome (PRO) Tools**: Tools should be co-developed or adapted with patient input to ensure they reflect real-world experiences. These may include validated surveys, symptom diaries, and mobile apps that allow for digital reporting.
- **Use of Patient Support Programs (PSPs)**: These can be leveraged to gather data in a structured, ethical, and scalable manner, especially when aligned with system-level data collection efforts.
- **Collaboration with Clinicians**: Clinicians are essential allies in encouraging patients to contribute to data collection efforts, interpreting the relevance of outcomes, and supporting continuity of care across treatment settings.

6. What Patients and Patient Groups Need from Other Stakeholders

To ensure their contributions are meaningful and the OBA process results in better access and outcomes, patients require the following from key stakeholders:

- **From HTA Bodies**: Transparent processes, opportunities for structured feedback, and implementation guidance that incorporates patient-defined outcomes and values.
- **From Manufacturers**: Early engagement and collaboration on outcome identification, clear communication of access criteria, and support for patient education.
- **From Payers**: Commitment to using patient-centered outcomes in determining reimbursement conditions and flexibility in how success is defined, particularly for outcomes not traditionally captured in clinical trials.
- **From Coordinating Bodies (e.g., CDA, pCPA)**: Inclusive pipeline meetings, streamlined consultation processes, and public communication that enables patients to understand how and why access decisions are made under OBAs.

Conclusion

Patients and patient advocacy groups are essential to ensuring that OBAs are designed around what truly matters—improving quality of life, enabling timely access to innovation, and respecting lived experiences across the care continuum. Their role is not merely to react to system decisions, but to shape them proactively. As OBAs continue to evolve in the Canadian context, patient voices must not only be included but prioritized in the development of outcomes, access frameworks, and evaluation mechanisms. When grounded in trust, transparency, and collaboration, OBAs can become powerful tools for aligning innovation with what patients value most.

3.0 Conclusion - Plenary Reflections

Following the breakout discussions, the plenary session reinforced several key themes while highlighting areas for collective progress. While each stakeholder group brought forward distinct priorities, a central message emerged: the absence of a structured, nationally endorsed pathway for OBAs remains the most significant barrier to their broader adoption in Canada. *A summary of stakeholder-specific insights and key takeaways is presented in* ***Appendix 4****.*

Participants agreed that many of the individual components of successful OBAs, trusted RWE frameworks, stakeholder engagement models, and international best practices have been

explored in prior initiatives. However, implementation remains fragmented due to unclear roles, inconsistent policy integration, and a lack of institutional leadership to champion a national framework.

The plenary emphasized three forward-looking imperatives:

- **Establishing a National OBA Pathway:** There is a need for a pragmatic, consensus-driven roadmap, potentially led by Canada's Drug Agency (CDA), to define when, where, and how OBAs should be pursued. Such a framework would clarify expectations, standardize roles and responsibilities, and support faster decision-making aligned with system capacity.
- **Prioritization and Role Clarity:** OBAs are often burdened by attempting to address multiple objectives simultaneously (e.g., performance-based pricing, uncertainty resolution, real-world validation). Participants recommended narrowing the scope of each OBA based on the specific context and aligning stakeholder expectations accordingly.
- **Leadership and Policy Mandate:** In contrast to other jurisdictions where political or policy directives have enabled more streamlined implementation (e.g., the UK), Canadian progress has been hindered by institutional hesitancy. Several participants called for a clearer mandate, whether through federal coordination, pCPA integration, or expansion of tools like Time-Limited Recommendations (TLRs), to shift OBAs from pilot-stage to routine practice.

Additional reflections included the need for consistent patient engagement, stronger public-private data infrastructure, and clear criteria for evaluating success. While some noted recent progress through the rare disease drug strategy and bilateral provincial agreements, participants reiterated that meaningful adoption of OBAs will require collective leadership, resource investment, and cross-jurisdictional trust.

In closing, the plenary discussion underscored that while the concept of OBAs is now well understood, Canada must evolve from discussion to action. A fit-for-purpose national framework, rooted in shared goals, system readiness, and real-world feasibility, was identified as the critical next step in advancing timely, equitable access to innovative therapies.

4.0 Post-Event Survey Report

Overview

A post-event survey was distributed to participants to gather feedback on their roles, perspectives on OBA implementation pathways, alignment with existing frameworks such as Time-Limited Recommendations (TLRs), and ideas for future hackathons. A total of 8 participants completed the survey, representing a cross-section of the healthcare ecosystem, including industry leaders, HTA experts, consultants, and patient group representatives.

1. Participant Roles

- 62.5% of respondents identified as industry leaders
- Other respondents identified as patient group representatives, consultants, and HTA leaders.
- Notably, no respondents self-identified as clinicians, government officials, or policymakers, underscoring a potential engagement gap for future sessions.

2. Pathway Development for OBAs

Participants were unanimous in identifying the absence of a structured OBA pathway in Canada as a critical barrier to progress. Their recommendations for first steps included:

- Governance Alignment: Coordination between manufacturers, HTA bodies, and the pan-Canadian Pharmaceutical Alliance (pCPA) was highlighted as essential.
- Clear Ownership and Process Clarity: Several respondents emphasized the need to consolidate oversight—such as housing pCPA within CDA—as recommended by the Hoskins National Pharmacare Report.
- Identification of Eligible Products: Early identification of products or indications suitable for OBAs would allow for proactive planning.
- Framework Adoption: Some advocated for adapting or socializing existing models (e.g., HTIP/IHE frameworks, BIOTECanada guidance) to accelerate implementation.
- These insights are summarized in Table 1, which highlights key themes and their implications for OBA implementation.

3. Integration with Existing Pathways (TLRs)

Survey responses revealed mixed views on whether OBAs should be integrated with or developed independently from Time-Limited Recommendations (TLRs):

- 62.5% believed that TLRs should be expanded before OBA pathways are developed.
- However, qualitative responses revealed that this is not a binary choice. Many respondents argued that parallel development is possible and that TLRs could serve as a testing ground for OBAs in cases with aligned eligibility (e.g., planned Phase III trials).
- Others noted that OBAs and TLRs serve distinct purposes, with OBAs being better suited to situations involving real-world evidence generation or where Phase III data is unavailable or unfeasible (e.g., rare diseases).

4. Recommendations for Future Hackathon Topics

Participants offered diverse ideas for future Hackathon themes, suggesting both conceptual and technical areas of exploration:

- Ideating a Pathway for Implementing OBAs in Canada (top choice; 50%)
- The Use of Artificial Intelligence to Support HTA Decisions
- Investigating the Negotiation Process after LOI
- Leveraging Synthetic Data for Real-World Evidence
- Examining System Barriers Using the I2U Readiness Tool
- Other suggestions included emulating Project Orbis models to streamline HTA processes through international collaboration.

5. Preferred Timing for Hackathon 9

- September emerged as the most preferred month (50%)
- July and August received fewer votes, suggesting that early fall may be ideal for maximizing attendance.

6. Additional Feedback

Respondents offered both appreciation and suggestions to improve future events:

- Stakeholder Representation: A repeated theme was the need for stronger HTA and payer participation in future Hackathons.
- Planning and Engagement: One respondent suggested using tools like Doodle polls to better coordinate participation.
- Event Design Praise: Participants appreciated the small group format, balanced facilitation, and the diversity of perspectives present in discussions.

Table 1. Key Themes and Implications

Theme	Implication
Governance and Alignment	Consolidated ownership (e.g., CDA-pCPA integration) needed to reduce fragmentation.
Early Product Identification	Define criteria for OBA-suitable products to guide negotiation pathways.
Parallel Pathway Development	TLRs and OBAs can co-evolve; frameworks must be tailored to unique challenges.
Trust and Transparency	Participants consistently called for clearer roles, public guidance, and shared expectations.
Future Focus Areas	Pathway design, synthetic data, AI in HTA, and negotiation mechanics were prioritized.

Conclusion

Survey responses reflect a strong endorsement of OBAs as a viable solution for improving access to novel cancer therapies in Canada, but only if supported by structural reforms, stakeholder alignment, and methodological clarity. There is momentum to build upon insights from the Hackathon and translate them into actionable guidance, particularly through further ideation and system-level discussions at Hackathon 9. A strategic focus on pathway creation, data infrastructure, and multi-stakeholder engagement will be essential to move OBAs from theoretical promise to practical implementation. Future Hackathons should also prioritize enhanced payer and HTA participation, as well as continued collaboration across sectors.

Appendix 1: Hackathon #8 Agenda

Time Agenda item Lead	Time Agenda item Lead	Time Agenda item Lead
1:10 – 1:25 pm	Opening remarks Barry Stein	Barry Stein
1:25 – 1:50 pm	• Roundtable introductions • Review agenda and highlight purpose and intended outcome. • Review outcomes from previous Hackathons • Review OBA scenario and stakeholder roles	Bill Dempster
1:50 – 2:00 pm	Review format and breakout group assignments	Bill Dempster
2:00 – 2:50 pm	Breakout groups	All
2:50 – 3:30 pm	Presentations to the plenary (10 mins. per group)	All
3:30 – 3:40 pm	**Closing remarks and next steps**	Barry Stein
4:00 pm	Session adjourns	N/A

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

Panel Discussion #1: Canadian Cancer Treatment Hackathon: Exploring Outcome-Based Agreements (OBAs) in Canada

- Allison Wills – Partner at 20Sense - Specialty Pharmaceutical Consultant and Industry Commentator
- Rebeccah Marsh – Director, Health Technology Innovation Platform (HTIP)

Panel Discussion #2: Cancer Cancer Treatment Hackathon: Improving Access to Cancer Drugs in the UK - The Role of MAAs

- Danny Stevens – Senior RWD Scientific Operations Manager, Bionical Emas
- David Thomson – Associate Director, Commercial Liaison Team, National Institute for Health and Care Excellence (NICE)

Panel Discussion #3: Canadian Cancer Treatment Hackathon: OBAs and RWE for Accelerating Patient Access to Cancer Drugs

- Jonathan Pearson-Stuttard – Partner & Head of Health Analytics – Lane Clark & Peacock (LCP) (UK) Head of Health Analytics at LCP
- Sania Chouman - Global Access Innovation Head at Takeda Pharmaceuticals and part of the advisory committee for the new MSc program at University College London (UCL)

Appendix 3: Outcomes Based Agreement Scenario - NetFelix (a novel treatment for Fallopian Tube Cancer)

Condition overview	Fallopian tube cancer is a rare and aggressive malignancy that originates in the fallopian tubes, often presenting with symptoms similar to ovarian cancer. It accounts for less than 1% of all gynecologic cancers. Due to its rarity and vague early symptoms, the cancer is usually diagnosed at an advanced stage. Prognosis depends on the stage at diagnosis, with earlier stages offering better outcomes. If diagnosed at an early stage, the survival rate is approximately 90%, but the survival rate drops significantly once it has spread to other parts of the body.
Population	The targeted population for this agreement includes adult women, primarily those aged 45–70, as this age group is most commonly diagnosed with fallopian tube cancer. The agreement also focuses on women who are at high genetic risk for ovarian and fallopian tube cancers (e.g., BRCA gene mutation carriers) or those with a family history of gynecological cancers.
Symptoms	The onset of fallopian tube cancer can go undetected, with symptoms often appearing vague or being mistaken for other conditions. Common symptoms include: • Abdominal pain or discomfort • Bloating or swelling of the abdomen • Unexplained weight loss • Abnormal vaginal bleeding or discharge • Pain during intercourse • Changes in bowel or urinary habits

	These symptoms may overlap with other gynecological disorders, making early diagnosis difficult. Many patients are diagnosed at an advanced stage when the cancer has spread to the peritoneum or other organs.
Treatment	The treatment being evaluated in this outcomes-based agreement is a new targeted therapy that aims to improve progression-free survival in patients diagnosed with advanced fallopian tube cancer, , for which there are limited treatment options. This therapy utilizes a novel monoclonal antibody that targets specific cancer cell markers associated with fallopian tube cancer and inhibits tumor growth and metastasis. The therapy would be administered intravenously and is being evaluated in clinical trials for its effectiveness in both early and late-stage cancers. The outcomes of the agreement will be based on: 1. progression-free survival rates, 2. overall survival, and 3. quality of life measures as reported by patients and healthcare providers
Preliminary findings	Early-phase clinical trials have shown promising results, with the targeted therapy significantly improving progression-free survival in a cohort of patients with advanced-stage fallopian tube cancer. In a phase II trial, patients receiving the therapy had a median progression-free survival of 18 months compared to 12 months for patients receiving standard chemotherapy. Furthermore, adverse events were consistent with those seen in other monoclonal antibody therapies, including mild infusion reactions and temporary gastrointestinal symptoms. Additionally, a subset of patients showed a partial response to the treatment, with tumor shrinkage observed in imaging scans. Quality of life assessments

	indicated a reduction in cancer-related symptoms and an improvement in overall physical functioning, though further data is needed for definitive conclusions. Larger phase III trials are ongoing, with results expected to further inform the therapy's efficacy and long-term safety profile.

Appendix 4: Stakeholder Reflections on OBA Design and Implementation

Industry	• Timeliness and fast access • Feasibility and efficiency • Global alignment • Patient outcomes that are measurable/reasonable (SMART, address uncertainty under review) • Data collection isn't given the same priority in Canada • Trust • Need for infrastructure/capacity – we don't even have this
Payers	• Implementation challenges: Is Canada positioned to implement and scale?; how do we make this as simple as possible, building on infrastructure in place? How decisions are pulled through across all jurisdictions. • Trust, particularly regarding data and data collection and reliability; re: collection, how is it funded and tracked? With Phase III trials underway, that solves for data collection piece (it's forthcoming). How to use each province's EAP (in Ontario) process (already collecting the data); private payer prior auth data; could potentially address the trust issue (could be customized to a drug or therapeutic area). Could also be a barrier – e.g., smaller provinces don't have infrastructure or personnel. • Stakeholder engagement and collaboration (e.g., when do you start this process? Point of HTA, with CDA leading the conversations; including OBAs in the pathway for review and funding process vs. always for industry to propose?); if you get down with HTA clinical "no", could an OBA be proposed to bring it back on track? When there are challenges with simple discounts, have that conversation much earlier.
HTA	• HTA has a role in OBAs; we should provide a role and pathway to clarify process/roles and candidate identification; a package to pass on to the pCPA as appropriate; need to be involved in some way in the negotiations for OBAs • Flexibility in evidence acceptance • Separate fund to support OBAs and/or reimbursement • Policy steering committee (as in the UK to oversee)

	• RWE standards • Feasibility study (value of information analysis) to inform the decision on go/no-go for OBA • Clarity (e.g., through checklist) for elements presence of trusted data • Not needed to require national approach (don't have to have barriers "have to have national solution"; but could have one) • Drug fund or funding capacity (gives HTA some comfort that if they recommend an OBA, there will be funding to facilitate it) • Transparency for all stakeholders (UK example) using a website for each drug for all stakeholders – provide clarity and gameplan
Patients	• Patient outcomes beyond survivability; asking patients what their specific milestones are important (e.g., PFS, QoL but maybe others) • Caregiver perspectives (what impact does the treatment have on those around the patient?) • Early and quick access to the drug • Strong clinician participation and buy-in (e.g., disease registries; although there are some challenges for ethical approval) • Defining what level of data is sufficient • Patient roles (e.g., help define what data SHOULD be collected via OBA via surveys and analyzing patient prefs, etc.) • Equity in access to diagnostics (CDx and genetic testing) recognizing discrepancies x-provs; relevant to NetFelix • Planning / coordination across all parties, early engagement, and desire from the payers to list the med and usefulness of OBA; organizational buy-in from all parties • Patients are aware of inclusion/exclusion criteria; patients are advisors throughout this process
Other points	Expectation for industry to fund all the infrastructure vs. other players also contributing. What should be considered as the data required to reduce uncertainty required for reimbursement? Depends on what the uncertainty is…

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