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InnomarLive 2023 summary:

Emerging trends in the oncology ecosystem

Turning today's challenges into opportunities for patient care and access

On February 16, 2023, InnomarConsulting™ implemented the 11th annual InnomarLive Speaker Series, entitled "Emerging trends in the oncology ecosystem: Turning today's challenges into opportunities for patient care and access." The full day, in person event included presentations and panel discussions from key Canadian thought leaders from Health Canada, CADTH, INESSS, pCPA, a private payer, the pharma industry, an oncologist, and a patient advocate.

Over the course of the day, participants heard about the collaborative efforts launched by various stakeholders to address the increasing volume of new oncology treatments, the challenges this brings to payers in the evaluation of new therapies and the importance of RWE in their evaluations.

The audience heard compelling discussions from the oncologist's perspective in delivering quality care in a resource-constrained environment, and from the patient's perspective in seeking diagnosis, treatment, care, and support. The series of topics were rounded out with the promise of new cell and gene therapies, the need for drug plan sustainability and the important role played by Patient Support Programs (PSPs) in enhancing the oncology patient's journey.

Part One

Health Canada: Regulatory approaches to oncology reviews in a rapidly changing landscape

Melissa Hunt, Director, Bureau of Metabolism, Oncology and Reproductive Sciences, Pharmaceutical Drugs Directorate, Health Canada

Melissa described the Health Canada (HC) structure for oncology product reviews within the Pharmaceutical Drugs Directorate (PDD) and the Biologic and Radiopharmaceutical Drugs Directorate (BRDD). Oncology has been an area of innovation within Health Canada where approximately 77% of products with an NOC/c are in oncology and over the last 3 years, 41-54% of New Active Substance (NAS) submissions were part of an expedited pathway, many of these in oncology. Health Canada has implemented several strategies to address the increasing number of oncology therapies, including: Conditional Market Authorization, Priority Review, HTA alignment and the expanding use of RWE. Broader collaborative initiatives like ACCESS and ORBIS have enabled an increased number of approved NDSs and SNDSs by the PDD and BRDD. HC participates in Innovative Medicines Initiative's SISAQOL-IMI: Setting International Standards of PROs and QoL Endpoints in Cancer Clinical Trials, providing Canadian regulatory expertise on investigating the feasibility of developing recommendations for non-RCTs, and international recommendations for the terminology and definitions of clinical meaningful change in cancer trials.

CADTH: Update on oncology HTA

Brent Fraser, Vice President, Pharmaceutical Reviews, CADTH

Brent spoke about the oncology HTA submission volumes received by CADTH, their collaborative work and future opportunities. In 2023, 41% (41/100) of Total Completed and In Progress Reimbursement reviews were in Oncology. CADTH has overall ~60 ongoing, active reviews at any time in 2023. With international collaborations across similar HTA organizations (PBAC, NICE, SMC, Wales), they can build on the success of regulator collaborative initiatives (Project ORBIS and Access Consortium) as well as learn from other HTAs like NICE's proportionate approach. Looking forward, CADTH is developing RWE guidance (presented later) to support inclusion of data in submissions, implementing time limited recommendations and incorporating the GRADE (Grading Recommendations, Assessment, Development, and Evaluation) approach to drug reviews. CADTH completed the transition of Systematic Reviews to the manufacturers, and they expect improvements over time as manufacturers get used to this.

INESSS: The Quebec HTA perspective

Sylvie Bouchard, Director, Drug Evaluation and Technologies for Reimbursement Directorate, INESSS

Sylvie provided an update on Quebec's Strategic Plan for the Life Sciences Strategy (updated May 2022) and Policy for Rare Diseases (published June 6, 2022). Communication activities and implementation of methodological work by INESSS will make it possible to assess the relevance of innovation and specify the information to collect to demonstrate the clinical, societal, and economic value of Quebec innovations in medical technology.

To accelerate access to innovative medicines, INESSS encourages manufacturers to adhere to Health Canada's aligned review process. INESSS supports the competitiveness of listings by supporting efforts by the MSSS to reduce registration delays and their contribution to the management of increased LOI negotiations, employing new methods.

They published the Policy for Rare Diseases on June 6, 2022. However, the Action Plan detailing its deployment measures, as well as funding, are not yet available. Topics covered by the policy include: training for HCPs, access to preconception screening and prenatal diagnostics, genomic medicine, telehealth and tele pharmacy, pharmaceutical access, an enhanced food program, Quebec registry, research, and accelerating therapeutic innovations.

Since 2020, the increased number of oncology treatments and HTA reviews, as well as other challenges, have created a backlog within INESSS. Their goals in 2023 are to get back in line with CADTH, to allow Quebec to join the pCPA negotiations and rollback the backlog to zero. They have implemented the necessary actions to achieve these goals.

Precision Medicine has been an evolving area in oncology. INESSS's goal is to implement Companion Diagnostic Tests evaluation processes and inform the MSSS in a timely fashion that a medical biology analysis is associated with drugs evaluated. INESSS describes how to ensure Quebec cancer patients receive timely access to innovative technologies in two important published documents.[1,2] Approaches to conditional implementation for innovative technologies include: coverage with evidence development and performance-linked reimbursement to manage the use of technology to control its cost-effectiveness in real-world conditions. It is important that INESSS receives the Ministry's commitment and openness to receiving these kinds of recommendations.

1. https://www.inesss.qc.ca/publications/repertoire-des-publications/publication/implantation-conditionnelle-des-technologies-innovantes.html

2. https://www.inesss.qc.ca/fileadmin/doc/INESSS/DocuMetho/Bulletins_veille/Bulletin_1_VF.pdf

pCPA: Update on oncology drug negotiations

Daniel Sperber, Senior Economist, pan-Canadian Pharmaceutical Alliance (pCPA)

Daniel gave an overview of the pCPA's role in the Canadian drug review process and its transition to a stand-alone organization, as well as other changes anchored by the new pCPA Strategic Plan that they released in April 2022. Since then, a process has been underway to identify and incorporate a new organizational structure and put other resources in place.

In oncology, pCPA participants differ across payer and organizations across Canada (MOH drug plans, Cancer agencies, Health Authorities) and there is an extensive overlap between CADTH Provincial Advisory Group (PAG) and pCPA negotiation participants, giving a higher level of clinical familiarity with new drug submissions prior to pCPA negotiations.

In the CAR-T space, pCPA conducts CAR-T negotiations on an ongoing basis with unique payers and decision makers for CAR-T drugs. Although oncology negotiation activities during COVID-19 were impacted, they now exceed pre-pandemic levels, with overall file timelines and LOI rates similar to the pre-pandemic period.

Advice given to manufacturers included: 1) building internal acceptance of HTA clinical recommendations and criteria, 2) being ready to negotiate when an engagement letter is received, 3) preparing to offer cost effective/cost saving pricing, and 4) be mindful about proposals involving patient level tracking.

Private Payers: Assessing the value of oncology drugs

Daria O'Reilly, Lead Health Economist, Pharmacy Consulting Health Benefits and Payment Solutions, TELUS Health

Private payers consider an enhanced evaluation of budgets, populations, costs, values and philosophical beliefs. At TELUS Health, cancer treatments are in the top 10 (ranked #7) of drug classes by eligible amount, with 4.2% eligible costs from only 1.6% of claimants.

With many cancer subtypes defined as rare diseases, and over one-third of DRDs are oncology, there are evidence gaps in clinical trial data, productivity, disability, and difficulty in determining cost-effectiveness. Yet, it is imperative to reduce uncertainties and mitigate risk, given the lack of evidence available.

Payers/HTAs need to find ways to evolve their decision-making processes. One approach is to consider generating evidence from RWD. Potential sources of RWD include: EMR, registries, insurer databases, PSPs, preferred pharmacy networks, and other technologies, like mobile and wearable devices.

Potential uses of RWE includes initial drug review and post-listing evaluation, ongoing formulary management, adherence, market share (to assess financial risk) and outcomes-based agreements (OBAs).

In summary, it has been challenging to balance innovation with rising prices, under great uncertainty. Insurers are becoming more sophisticated in health technology assessments, and although public and private payers serve different populations, collaboration is necessary to find RWD and generate RWE for listing decision-making and OBAs.

Delivering on Canada's promise of value-based access to drugs for rare diseases

Durhane Wong-Rieger, President and CEO, CORD

Durhane presented what they have been working on at CORD over the past three years, during which time they have involved key stakeholders, including Health Canada. CORD will present their activities more fulsomely with workshops at their conference on March 28th and 29th in Ottawa.

Current timelines from NOC to listing are too long. On average, it takes a total of 18.9 months from NOC to pCPA agreement (best case scenario). Only three out of five DRDs approved by the FDA/EMA are submitted to Canada. Of those, 7/10 approved DRDs receive a recommendation for reimbursement in public drug plans, yet only 25% of eligible patients receive treatment, up to 5 years later. The longer we wait, the more we harm patients.

Some oncology drugs, although expedited, can take longer as they get hung up every step of the way due to data uncertainty, high prices, negotiations, and other challenges. At the end of the day, 30% will receive a 'Do Not List'. So, we are having a tough time getting innovative technologies into Canada, and when we do, we have a tough time getting them to patients.

CORD's proposed strategy involves three pillars: 1) Centers of Expertise for precise diagnoses, testing and treatment algorithms that make sense, 2) Managed Drug Access Plans, even with high levels of uncertainty 3) Research to support development of new drugs and on-going assessments in real-life. We can maximize the return on the $1B drug strategy investment by providing the right drug to the right patient at the right time for the right price. Alternative pathways are also being proposed, looking at RWE-based decision options/managed access pathways that are already in place in the big 5 EU countries.

Commercializing new oncology treatments: The manufacturer's perspective

Carlene Todd, Vice President, Access, Hoffmann-La Roche Limited

Carlene presented the challenges and opportunities from a manufacturer's perspective in commercializing new oncology treatments. Approval to access to health technologies in Canada requires many sequential steps, with each step introducing opportunities for delay that have been increasing over the past 10 years.

In 2020, the time from HC approval to its first provincial formulary listing (all drugs) was 21 months, which has almost doubled since the 2013-2015 period (11.5 months). Although Canada is one country, it feels more like thirteen countries, with each province having its own infrastructure and complexities. Upon first provincial listing, the time to 80% formulary listings for oncology drugs was significantly less than for non-oncology drugs (172 days vs 436 days).

Precision oncology is rapidly evolving, with up to 46 key biomarkers and ~84 targeted therapies expected in the US by 2025, increasing the opportunities to ensure the right care is delivered for the right patient at the right time. Canada is well positioned in creating a stronger, more resilient healthcare system, which starts with a recognition of industry's value to Canada and a commitment to building a long-lasting partnership between all healthcare system stakeholders. The private sector brings unique capabilities to the ecosystem, including expertise in innovative therapies, biomanufacturing and information technology in key areas of 1) health data and RWE, 2) partnerships and collaboration and 3) the value of innovation. Initiatives like PREDiCT (Personal Response Determinants in Cancer Therapy) at the BC Cancer Agency, deliver an RWE generation framework for innovative health technologies, providing learnings with sustainable, scalable data and testing infrastructure, enabling more timely personalized cancer care with less waste in the system.

For the value of innovation to be realized in cancer care, current processes, regulations, and approaches will have to change with 1) a broad concept of value applied across the entire access continuum, 2) early diagnosis and the right targeted therapy to reduce waste in the system, 3) Alternate formulations that help relieve hospital capacity issues and 4) Outcomes Based Agreements (OBAs) to address uncertainty.

Looking ahead, RWE informs streamlined reimbursement and funding pathways to enable timely access. We need to collaborate to solve the complexity of our healthcare challenges, and to capture and recognize holistic value propositions.

Part Two

Panel discussion summary: "How can we turn these challenges inopportunities which will benefit patient care and access?"

Panelists:
Brent Fraser, Vice President, Pharmaceutical Reviews, CADTH,

Daria O'Reilly, Lead Health Economist, Pharmacy Consulting Health Benefits and Payment Solutions, TELUS Health

Carlene Todd, Vice President, Access, Hoffmann-La Roche Limited

Gerald Batist, Director, Dept. of Oncology, Sir Mortimer B. Davis-Jewish General Hospital; Director, McGill University Centre for Translational Research in Cancer; Professor, Department of Oncology, McGill University

Facilitator:
Grant Perry, Senior Director, InnomarConsulting

How can HTA systems (payers, evaluators and industry) evolve together so that Canadian patients may benefit from scientific breakthroughs?

Carlene Todd: We need to involve the voices of patients as well as the voices of all stakeholders.

Look at the entire continuum, not just one point in time. Think about evidence more broadly, from all over the world. Innovative licensing pathways and HTA collaborations across countries are necessary.

With the HTA challenges of assessing long-term impact, what is the mandate and how are you managing that?

Brent Fraser: There are tools available that manufacturers do not take advantage of (e.g. scientific advice). We have no concerns about receiving data beyond Canada, but it should still be relevant to the Canadian population. Data should be robust and answer the clear question, which may not always be straightforward, but there are opportunities to assess how we evaluate new treatments moving forward. Also, recognize it is difficult for us to commit to a certain path if we do not have the support from the jurisdictions.

Dr. Batist, beyond the clinic, you engage in a lot of the ancillary pieces discussed today. You are in a unique position to have a voice in this.

Gerald Batist: Yes, and it helps me appreciate all the constraints everyone has. We are working in a system that is not easily modified. On the other hand, approval and access to drugs must start moving faster for cancer patients. It really has to move at the speed of cancer, not at the speed of regulatory bodies. We used to take inspiration that this was possible, in terms of listening to the patient's voice earlier on, from the start-up activists in the AIDS community in the 80's and they were able to push FDA regulations in challenging and creative ways.

We only have to look back at the past years, another disruptor that showed that regulations can be modified so that drugs can be studied, approved, and accessed very rapidly. My focus is on innovation and urgency. There are many more people going to die of cancer than those who died of COVID in the past 3 years. All the elements are there, but we need major restructuring, which everyone understands - we just need to figure out how to proceed.

Daria, your customers play a different, yet integral role. Any thoughts from your perspective?

Daria O'Reilly: There was a question about using CADTH (public payer HTA) material. I would hope that our clients will start to get skills in being able to interpret HTAs that they receive. I hope that HTAs would consider private payers' perspective as well.

Audience Question: We have the necessary processes now to offer innovative treatments to patients (although it needs improvements) but when it comes to diagnostics, we do not have the same rigor and each province tends to take it on their own, because of that, the inequity in access is quite diverse. Will there be more of a framework for this?

Brent Fraser: We had a round table around genetic testing and companion diagnostics (in December) to get a sense of what is required to move a recommendation for funding. The devices team within CADTH is looking at that more closely. We want to put a process in place such that when a technology comes forward that requires some sort of testing, we can try to merge the two. INESSS does this much better than we do. It does come up in our cancer reviews, but often the provincial bodies say it is great we have this technology, but we don't have the funding for the diagnostics. Considering that our primary customers are drug plans, it is an issue for us. We don't know often where to set recommendations to make people aware that there may be a gap within their industries. In addition, they do not have the connections due to the decentralization of some of the services.

Gerald Batist: When companion diagnostics make their way into the clinics, they struggle. Meanwhile, clinicians and scientists have produced better diagnostics called laboratory-derived diagnostics, but they haven't been fully adjudicated where they fit in. Another way of doing it is doing a fulsome molecular diagnostic on every patient. This would be a simple bioinformatics exercise to look for a specific variant, amplification, etc., but this is only going to get more complicated. We need a comprehensive plan and should be done proactively. This should be a major push for all of us together.

Daria, with the number of private plans in the thousands, how does the companion diagnostic piece fit into your world?

Daria O'Reilly: Private payers do not pay for diagnostic tests. It's part of the public space, so it delays things further. It gets more complicated with sharing information and confidentiality. Unfortunately, there's several reasons why access gets delayed.

Gerald Batist: This is an opportunity to redefine cancer as a collection of uncommon and rare sub-groups looking at specific molecular profiles. We need to start thinking in those terms.

Carlene Todd: I wonder if there are learnings from the CAR-T space that we can apply to precision oncology?

Companion Diagnostics – no one owns it – has this been discussed during your round table discussions?

Brent Fraser: It does come up in the discussion, but it usually happens too late in the process. It would be helpful to have it upfront as we go through the reviews. A lot of the issues that come up, like interprovincial billing, we cannot do anything to resolve those issues. It is a government issue that needs to be taken back and dealt with under their processes. But we can bring more people to the table and engage our clinical experts. We do an ethics review (not all) but for these more complicated ones where things like access, remote versus urban, centers of excellence, genetic testing all get raised and taken to a

separate table and then have a discussion with the drug plans to understand what the implications may be related to funding. None of us want to go through this process, issue a recommendation and have it fall flat because of issues around implementation. Our committee struggles with a lot of those issues, so we are trying to figure out ways to have those conversations upfront. And it's not because people aren't there to talk about the issue, but whether it is within their mandate to start looking at how to access a specific type of genetic test, interprovincial billing, as patients need to go to other centers to get access to therapy. Discussions just get harder and harder.

Dr. Batist: Another element that needs more discussion is the concept of value-based care. We get caught up in the cost of the drug rather than the cost of the treatment and all its elements. We need to take this approach to the ground. E.g., An example would be a mechanism whereby a clinician can submit their case for access (medicaments d'exception). We are just analyzing the data that comes from that and it is quite striking that we can predict and show patient benefit. We can also predict whether INESSS will approve that drug within 6 months based on the data available to us at that time.

OBAs and their challenges within the provinces, the jurisdictions, generating data, who owns it, etc., it's a BIG question.

Daria O'Reilly: RWE is not new. We have been talking about it for at least 20 years and there are a lot of challenges, but I think it's time we started somewhere. I know CADTH's initiative is to start looking at RWE. We need to find out where the data is, partner with academics on sound methodologies to generate evidence. I'm motivated by the fact that we are talking about opportunities and a plan moving forward as opposed to just talking about the challenges all the time.

Brent Fraser: One of the key things is we have to understand what the right outcome is and that is where we all get hung up as there are different perspectives on what the outcome should be within an agreement. Some of the experiences talking with NICE and their Cancer Fund and the Innovative Life Sciences review – it feels like (based on anecdotal information) they are not getting as much success as they are hoping to achieve with these agreements mainly because the data coming doesn't support the outcome that is intended to be measured. There is a lot to learn. We do not advocate one way or the other. That's really within the provincial jurisdiction to determine if that is something they can move forward with. CADTH is certainly there to help. If they need guidance around RWE, available data sources, we have our own perspective on which outcomes are important. However, patients are going to have a different perspective and we see that in the patient submission when we have our reviews, there can sometimes be a disconnect. We can work to see where the data sources are. There is a wealth of information out there and it's about making the right connections.

Gerald Batist: I think it does come down to data and finding a solution to standardize operations. It should be a big push across the country, whether pan-Canadian or provincial. There are multiple databases that are not connected and should be. We need a data infrastructure that is strong enough to support this before we can even ask the regulators to follow down this path.

Carlene Todd: I agree with everything that was said. But the point here is starting early, and we need to bring the right people together at the right time. It would be helpful to bring together CADTH, pCPA, and provinces to identify the right outcomes and data sources.

End of panel discussion

Part Three

Caring for Canadian oncology patients – the physician's perspective

Dr. Gerald Batist, Director, Dept. of Oncology, Sir Mortimer B. Davis-Jewish General Hospital; Director, McGill University Centre for Translational Research in Cancer; Professor, Department of Oncology, McGill University

Following the lively interactive panel discussion, Dr. Gerald Batist took to the stage to deliver insights on the physician's perspective on delivering quality care to oncology patients. Covid-19 has certainly been a disruptor in the treatment approach for cancer patients. While many challenges arose during the pandemic, what we face today may be more alarming wherein there are larger numbers of patients presenting with more advanced disease than before, thwarted by a shortage of healthcare professionals – what Dr. Batist referred to as the "post-covid cancer tsunami." However, today's technological advances and innovations are bringing real promise in managing cancer care with precision medicine. More effective and targeted treatments can lower overall treatment costs by optimizing patient-treatment matching, thereby avoiding predictably ineffective, toxic, and costly treatments while improving overall clinical outcomes. In just the past few years, there has been a surge of New Active Substance approvals in oncology, most of which are targeted therapies. In oncology, innovative approaches like Exactis Innovation and the Oncology Interactive Navigator can improve personalized treatments and successful person-centered care.

Gaining access to diagnosis, treatment, and care – the patient's perspective

Claire Edmonds, Registered Psychotherapist, affiliated with Wellspring

In her own compelling patient narrative, entitled 'Blind Sided', Claire portrayed the deep anguish, thoughts, feelings, and determination she experienced dealing with ocular melanoma as she walked us through her journey of challenges and successes as a cancer patient, and an allied health care professional.

In her research, Claire has looked at a lot of Kaplan-Meier Curves assessing survival of patients or groups, trying to understand good prognostic indicators. Now, she sees these curves with the data points as people, people trying hard to survive, trying hard to live…some of them will make it, some of them won't. And so, in your work, when you look at these datapoints, know that each datapoint is a patient, and that each patient has a story, and there are possibilities for skillful interactions and possibilities for unskillful interactions.

With this 'tsunami' of patients entering hospitals and cancer care, there has been tremendous stress on hospitals, staff, and psycho-social services. To relieve this stress, hospitals are looking to download the psycho-social needs onto community cancer centers, such as Wellspring and other resources.

Wellspring is a cancer support organization that provides a variety of programs and services to people affected by cancer, including patients, survivors, and caregivers. Patient expression through medical narratives (such as Claire's 'Blind Sided' narrative) is one of Wellspring's support offerings. They offer emotional, psychological, and practical support, such as counseling, educational workshops, and fitness classes.

The role of the oncology Drug Access Navigator

Shirley Chen, Medication Reimbursement Specialist, Princess Margaret Cancer Centre

Drug Access Navigators (DANs) are patient advocates who are subject matter experts on medication coverage, eligibility criteria and resources, helping patients explore and understand their drug coverage and funding, and facilitating medication access in a timely manner. Challenges faced by DANs include navigating through a complex medication coverage system; access and funding gaps for new medicines which are not listed; long turnaround times; high out of pocket costs for patients; the nuances around PPNs (Preferred Provider Networks); private clinics that present safety concerns; treatment delays and inconveniences.

In addition, DANs have a heavy workload, with limited resources. They need to keep up with emerging changes in the complex funding landscape, as well as to frequently deliver bad news to patients. Although pharmaceutical companies may provide financial support, in many cases, patients are still out of pocket for healthcare expenses. Patient Support Programs offer helpful general access solutions by providing generous financial support, compassionate and bridging support, nursing care, home injection and other home care services. It would be helpful if industry would engage the DANs in the early planning stages of programs, as they can offer valuable insights.

Hope and challenges for cell and gene therapies, turning today's challenges into opportunities for patient care and access

Dale Hanna, Director, Cell and Gene Therapy Solutions, AmerisourceBergen

Cell and Gene Therapy Solutions is a new and unique group within the AmerisourceBergen organization. They sit at the enterprise level looking globally across all business units to understand the needs of all stakeholders. This enables them to help solve the hurdles they face related to the complexities of cell and gene therapies.

Dale highlighted three hopeful promises from the patient's perspective: 1) Scientific innovations are leading to greater health outcomes for the sickest patients; 2) inclusion of patient and caregiver voices is coming to the forefront of development and commercialization efforts; 3) Biopharma is pushing the health industry into the 21st century across many different workstreams and perspectives.

There are many challenges within "the reality of the cell and gene complexity experience." From a manufacturer's perspective, the key challenges are that in an increasingly competitive and complex environment, unlocking commercial success requires speed to market. They face a war on talent, complexity of process, and miscues during clinical operations for commercial handoff. To successfully scale up volume, an integrated strategy involving service providers is essential. Providers also face challenges when it comes to securing access to treatments for their patients, and not to mention the funding and reimbursement struggles from a financial perspective.

RWE continues to be significant, as it holds the promise of representing real-world practice and behaviors of patients throughout their treatment experience. A patient-driven outcome that is aligned with their daily lives should be included. Patient support services are often in place to address unmet needs beyond the clinical setting. Designing services around the patient and caregiver to address pre- and post - treatment needs will improve both health and commercial outcomes.

Get ahead of many unknowns and design flexibility in your access pathways when coming to market. You can never partner early enough with industry, regulators, patients, caregivers, and providers to ensure your product has optimal reach and success.

Real-world evidence: Moving from engagement to implementation

Brent Fraser, on behalf of Nicole Mittman, Vice-President, Scientific Evidence, Methodologies, and Resources

Brent provided an update on the Real-World Evidence Guidance initiative and its next steps. Stakeholder consultations for the guidance were completed on January 6, 2023. Based on the HTAi's Global Policy Forum after 3 rounds, key principles that surfaced were Transparency, Impartiality, and Inclusivity, with Transparency being at the top of all three rounds.

The goal is to develop, in collaboration with Health Canada, a guidance document for reporting RWE as a supplement to submissions. This will improve reporting standards, the quality of submitted data and better inform decision making. Fifty-four different stakeholders provided comments, constructing some general themes and learnings. CADTH and Health Canada will respond to the comments by organizing the themes, providing a response to the comments and then determine whether the Guidance Document will be updated. The RWE Guidance Document will be launched at the CADTH Symposium on May 16th to 18th, 2023.

It is particularly important to look at the evidence, and the quality of the evidence. RWE will not lead to automatic approvals but will help fill the gaps of uncertainty. It is necessary to determine what are the appropriate outcomes that need to be measured before we can discuss Outcomes Based Agreements (OBAs). Pharmaceutical manufacturers can prepare by consulting with CADTH and the right stakeholders, patient groups, to understand what the right outcomes are, to ensure the best data comes forward.

Role of Patient Support Programs (PSPs) in enhancing the oncology patient's journey

Sandra Anderson, SVP International Commercialization, AmerisourceBergen

PSPs for oncology are different from specialty medications, as oncology patients' needs are different. Quality of life and personal support for these patients, and caregivers, are paramount. As new cancer therapies and new treatment paradigms surge, there is a further shift in the oncology patient journey and payer mindset.

The oncology PSP is one component of an individual's treatment journey. It requires simplified and compassionate enrollment, reimbursement and financial support, quality administration coordination, caring support, education, and proper adherence to the program. Partnerships with advocacy groups for peer-to-peer live, and virtual, mix of support for oncology patients can provide a seamless patient experience. Patient support programs are designed to meet the emotional, social, practical, and restorative needs of cancer patients, with access to bilingual peer support from volunteers that assists patients/caregivers with the tools to help manage their disease and reduce burdens, allowing them to focus on their health and well-being.

Data collected through PSPs can provide reliable and credible data sources for generating real world evidence which can play a significant role in evaluating new oncology medicines.

Key learnings and takeaways

Key messages from this exchange of information by regulatory, HTAs, payers, HCPs, manufacturers, and patient stakeholders focused on how HTA systems (payers, evaluators, HCPs, and industry) can evolve together so that Canadian patients may benefit from scientific breakthroughs. Involving the voices of patients and all stakeholders earlier in the process is necessary in bringing these innovative technologies into Canada and making them accessible. This must be done at the 'speed of cancer'. Applying learnings from regulatory collaborative initiatives such as ORBIS and ACCESS in the HTA system can help achieve improvements. While the expanding use of RWE to monitor patient outcomes may be useful to overcome the challenges of assessing the long-term impact of innovative technologies, data must be robust and of high-quality. RWE can also offer solutions for OBAs. The importance of addressing the issue of companion diagnostics was discussed, particularly in the context of cancer care. The need for a comprehensive plan and proactive approach to this issue was emphasized, as well as the importance of redefining cancer as a collection of uncommon and rare sub-groups looking at specific molecular profiles. Drug Access Navigators (DANs) help patients navigate through the complex medication coverage system and can provide valuable insights during the early development phase of access programs. In addition, Patient Support Programs offer general access solutions by providing financial support, nursing care, home injection and other home care services. Finally, there is an urgent call for more collaboration among stakeholders and more engagement with clinical experts to address the challenges facing the HTA system.

Conclusion

At the InnomarLive 2023 Conference, distinguished experts from regulatory bodies, health technology assessment organizations, payers, healthcare providers, manufacturers, and patient advocates convened to address pertinent issues within the current oncology landscape in Canada. The speakers acknowledged that all stakeholders encounter comparable difficulties in keeping pace with the rapid proliferation of innovative technologies. Thus, it is crucial for them to collaborate and devise comprehensive strategies to meet the growing demand for efficient and prompt patient access to innovative treatments and technologies.