BRINGING STAKEHOLDERS TOGETHER FOR THE EVOLUTION OF CANCER CLINICAL TRIALS IN THE ERA OF PRECISION MEDICINE

real world evidence | precision medicine | patient and patient group engagement

Conference Overview

CANCER COLORECTAL CANADA

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Main Objectives:

- **Increase efficiency of the drug development pathway and timely access to cancer therapies for patients, promoting patient-centered care in the era of precision medicine**
- **Promote collaboration between patient groups, health agencies, and stakeholders such as pharmaceutical and tech companies**
- **Support effective patient group participation in clinical trial design and implementation, encouraging their input and active participation**
- **Encourage the collection and use of real world data (RWD) and real world evidence (RWE) to generate more generalizable data to reflect the true effects of therapies in everyday clinical practice (the "real world", compared to the highly controlled environment of clinical trials)**

Key questions:

- **How can the Charter help to inform an organization's patient engagement model?**
- **How can the way an organization operates be better influenced by patient engagement?**

(Opening presentation by Anne-Marie Myers)

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Speakers: Judy Needham and Stephen Sundquist

Take away message:

Patient engagement in cancer research is two fold: patients as participants, and patients as partners, with the focus today leaning increasingly towards the latter. The future of cancer research should be involving patient partners throughout all phases of research, from determining how the research question can be delivered to collecting more patient-oriented evidence – evidence that measures things that a patient would care about such as symptoms, quality of life, costs, morbidity and mortality, length of stay.

Speaker: Stephen Lemery
International Regulatory Collaboration

Take away message:

Project Orbis is an example of an international collaboration in drug development. Benefits include reducing costs of development, fostering similar standards of care globally, as well as faster clinical trial processes, especially for rare diseases or mutations. It is a framework for parallel submission and review of oncology products among participating international partners (so far, Project Orbis is a collaboration between the US, Canada, Australia, Singapore and Switzerland).

Speaker: Murray Aitkin
Advancing RWE use in support of Precision Medicines

Take away message:

The migration towards precision medicine has created greater demand for evidence from small and more diverse subgroups of patients. Today, there are increasing options available to meet these demands for high quality data, with a greater number of data sources (ex. digital health records and patient-reported evidence) and more sophisticated data technologies to integrate RWD and RWE to better inform drug development decisions.

Speaker: Michael Seewald
Using RWE to inform value-based agreements

Take away message:

RWE can be used to better understand real world treatment patterns to confirm the value of patients' access to drug therapies. Encouraging strong stakeholder collaboration can help to improve patient outcomes and deliver better value to the healthcare system.

Speaker: Melissa Hunt
Health Canada's experience with Project ORBIS

Take away message:

The goal of Health Canada is to improve access to prescriptions medications by expanding collaboration with health partners to facilitate more timely access to drugs and devices. Through international collaborations such as Project Orbis, there is increased global alignment and the expediting of the availability of critical drugs to patients when they need them. Furthermore, international collaborations enable better sharing of information and resources, a reduction of duplicated submissions to sponsors, and faster review times without compromising high international standards.

Speaker: Margaret McCusker
Real World Evidence and Precision Medicine

Take away message:

Complexity of oncology treatment necessitates new and better sources of high quality evidence including RWE. It is estimated that only 8% of US adult patients with cancer enrol in clinical trials, leaving a large, unmet need among patients who are not enrolled. It is essential to understand the benefits and harms of drugs in everyday practice in real world populations. The Flatiron Network of community and academic practices aims to build an evolving database of RWD and RWE to help advance health care delivery and increase both the extent and rate of drug access for specific patient populations.

Speaker: Mackenzie Wildman
Novel approaches to precision medicine: Data collection in the wild

Take away message:

Patients and their outcomes have historically been characterized using limited, visible-to-the-system data, such as those collected in clinical trials. “Invisible data” or RWD, includes those that are collected passively and continuously in everyday life, collected directly from individuals that are universal but remain largely inaccessible to healthcare systems. Patient generated health data (ex. data collected using wearable devices) provides new ways of measuring health to better diagnose, predict and treat disease.

Speaker: Lillian Siu
Rethinking Clinical Trials in the Era of Precision Cancer Care

Take away message:
As oncology continually evolves towards increasingly tailored approaches to treatment, it is important that clinical trials reflect the diversity of patients and their needs (“smart” clinical trials). Rare diseases make it very hard to conduct large randomized clinical trials, stressing the importance of RWD/RWE to investigate patient access and treatment effectiveness. Clinical trial navigators are a critical feature of a precision medicine approach, helping to best coordinate care among patients and their local oncologists.

Speaker: Kam Kafi
Artificial intelligence: turning data into knowledge

Take away message:
Artificial intelligence (AI) has the potential to increase our human capacity in accelerating operations and informing healthcare procedures by saving time, cost and effort. AI together with the increasing adoption of virtual health approaches, including telemonitoring to improve patient adherence to therapies, can be integrated to produce better digital analytics including RWD collected via patient reported outcomes or wearables. Improved databases and computer systems can be used to make better predictions or decisions about a specific health-related task, with minimal cost and human effort.

Speaker: James Creeden
Impacting patients with innovative data products

Take away message:
While the gold standard of clinical data remains that which is collected from randomized controlled trials, this
data is not largely generalizable and does not represent the majority of cancer patients' experiences. RWD carries less scientific strength and validity, it is able to include larger sample sizes, longer follow-up, better side effect profiles in real world settings, and more realistic expectations of how a drug will affect specific patients. Organizations such as Foundation Medicine or Flatiron Health aim to provide harmonized and curated molecular and clinical data (Clinico-Genomics Database), combining the genomics of patients with their clinical therapeutic regimen to increase the efficiency of healthcare delivery, better treatment access and disease prediction capacity.

Speaker: Aaron Leibtag
Pentavere AI technology

Take away message:
AI can help to change economics and possibilities, to benefit patients and support regulatory decisions. It can
enable evidence and insight at very large scales that might not have been possible previously due to human constraints. With the advent of precision oncology, there is a large unmet need for studies dedicated to rare diseases and tumour types – something that would demand incredible amounts of time in order to gather sufficient results through traditional pathways. AI can help to drive down the currently unsustainable costs of bringing drugs to patients, opening doors to diverse stakeholders united to drive solutions.

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Speaker: Christopher McCabe
Research oriented market access

Drug programs face increasing budgetary pressures and strong evidence helps to support investment and disinvestment decisions. Cost-effectiveness analyses help to inform these decisions, but available evidence often leaves decision makers highly uncertain and further evidence is often expensive to generate. The Institute of Health Economics proposes a research-oriented market access (ROMA) protocol to assess the value of generating RWE within a life cycle health technology assessment framework, which builds upon existing health technology assessment methods for the assessment of the value of new technologies.

Final takeaway message:

The era of precision medicine in oncology is uncovering the large, unmet need for a greater diversity of high-quality data that more accurately reflects the real world experience of patients, especially those with rare mutations and diseases. Positioning patients at the centre of cancer care means involving them as partners in cancer research and throughout the clinical trial continuum. Novel technologies for real world data collection used in tandem with innovative stakeholder collaborations could help to improve the overall efficiency of healthcare delivery, increase patient access to necessary medications and advance disease prediction capacity.

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