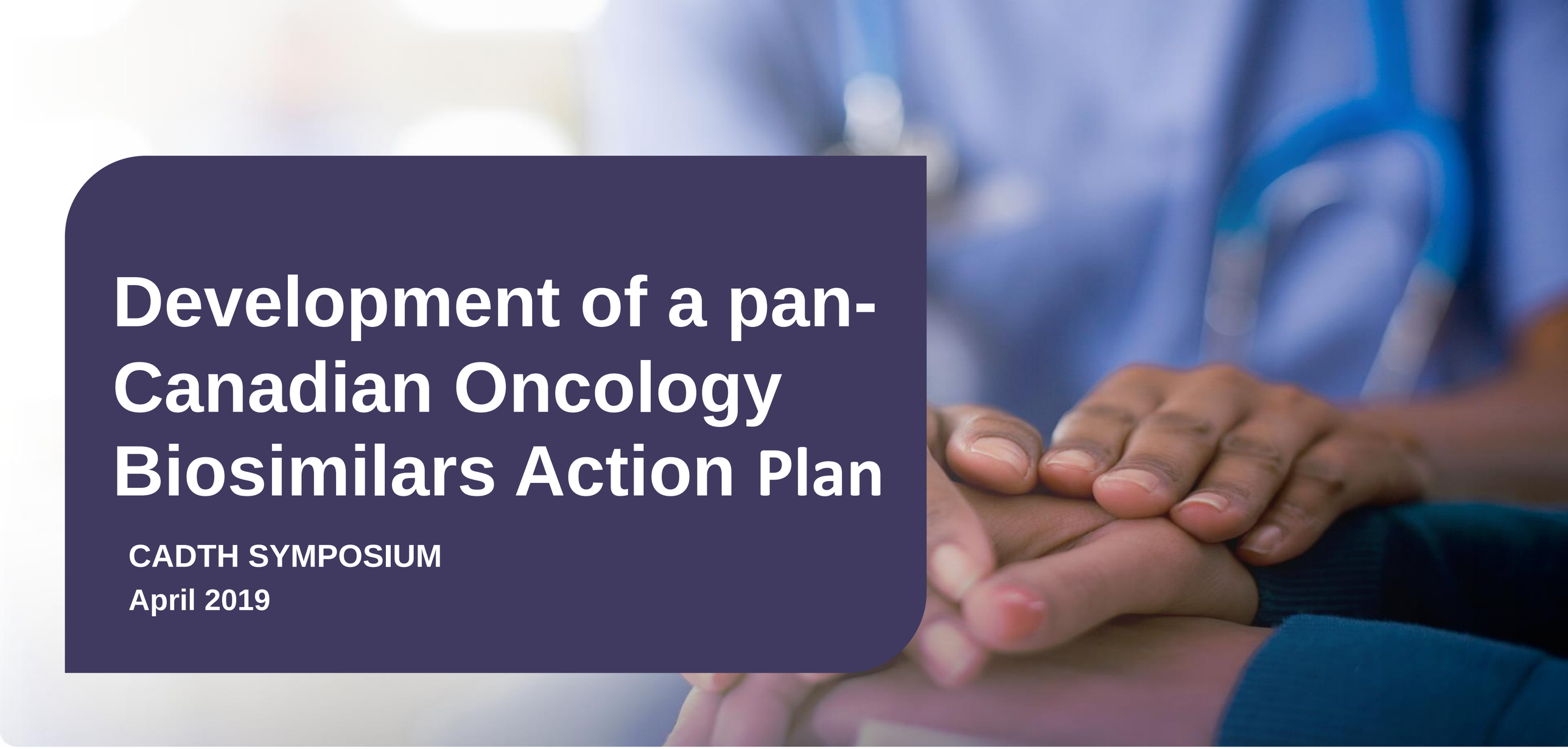

Development of a pan-Canadian Oncology Biosimilars Action Plan

CADTH SYMPOSIUM

April 2019

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Ontario Cancer Care Ontario

Disclosure

I have no actual or potential conflict of interest in relation to this topic or presentation.

Overview

- Biologics & Biosimilars – An Overview
- Pan-Canadian Pharmaceutical Alliance (pCPA) – Role and Mandate
- Pan-Canadian Biosimilars Strategy
- Pan-Canadian Oncology Biosimilars Initiative
  - Summit Overview
  - Action Plan
- Current Status of Work

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Biologics & Biosimilars – An Overview

- Biologic medications (biologics) are complex protein molecules created inside a living cell.
- In Canada, patents for some biologics are expiring and highly similar copies, known as biosimilars, are being developed.
- A biosimilar that is approved by Health Canada (HC) is not necessarily identical to its reference biologic, but based on guidelines and approval standards for the pharmacokinetics, pharmacodynamics, safety and clinical efficacy of biologics[1,2,3] the two are highly similar.
- Biosimilars are unlike generic medications which are exact copies of small molecule branded medications. Biosimilars and biologics can only be highly similar due to their complex nature.

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[1]Health Canada, 2016
[2]Health Canada, 2017
[3]ICH Expert Working Group, 2004

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Pan-Canadian Pharmaceutical Alliance (pCPA) – Role and Mandate

- The pan-Canadian Pharmaceutical Alliance is a member organization of jurisdictions who conduct joint provincial/ territorial/federal negotiations for drugs in Canada to achieve greater value for publicly funded drug programs.

- The pCPA's mandate is to enhance patient access to clinically relevant and cost-effective drug treatment options.

pCPA's pan-Canadian Biosimilar Strategy

- The pCPA is implementing a pan-Canadian biosimilar strategy with the goal of ensuring appropriate and cost-effective use of biologics (including biosimilars) across the country. This strategy applies to all biosimilars, non-oncology and oncology.
- The strategy's objectives are to:
  - Encourage a harmonized approach to policies and review processes for biologics across all key stakeholders in Canada.
  - Achieve the reduction of costs and to maximize access to effective treatments for Canadians.
  - Increase awareness and confidence in the use of biosimilars through clinical evidence, education, and support for prescribers and patients.
  - Promote appropriate uptake of biosimilars to enhance patient care and support drug plan sustainability.
  - Facilitate post-market evaluation and monitoring of biologics in support of optimal use.

Pan-Canadian Oncology Biosimilars Initiative

- Cancer Care Ontario (CCO) and the pCPA have partnered to develop and implement a pan-Canadian oncology-specific biosimilars strategy.

- The development of a cancer-specific strategy provides an opportunity to drive the acceptance and use of oncology biosimilars while considering the different environments in which cancer is treated with biologics. Three new pCPA-funded positions have been created at CCO to support this pan-Canadian initiative, through March 2020.

- One of the first deliverables was a consultation and engagement event with patients, patient advocacy organizations, clinicians, agencies, and other stakeholders.
  - The Oncology Biosimilars Summit was held on November 16, 2018, in Toronto.

Pan-Canadian Oncology Biosimilars Summit (Summit)

- A total of 75 participants from across 9 provinces were present at the summit.
  - Industry and consultants were excluded. pCPA consulted directly with these groups following the summit.

- Agenda and materials were planned with the support of a small Advisory Committee made up of payers, clinicians, patient advocacy organization representatives, pCPA and CCO.

- The summit was open, collaborative, consultative, and action-oriented.

Summit Objectives

- Discuss the challenges and opportunities of implementing oncology biosimilars in Canada.
- Garner lessons learned from other countries and therapeutic areas.
- Obtain feedback from participants on the initiative's strategic objectives for the development of a pan-Canadian Oncology Biosimilars Action Plan.
- Discuss the roles of clinicians and patient advocacy organizations for oncology biosimilars implementation and uptake.

Pan-Canadian Oncology Biosimilars Initiative Vision & Goals

Vision

Stakeholders across Canada have implemented an oncology biosimilars strategy that improves outcomes for patients, is evidence-informed, ensures appropriate quality and safety measures are in place, and facilitates access to innovative cancer treatments.

Pan-Canadian Oncology Biosimilars Initiative Vision & Goals

Goals

Stakeholder Engagement	Quality & Safety	Evidence-informed Policy Approach	Sustainability & Value for Money
Collaborate with stakeholders so they participate in the development of a pan-Canadian oncology biosimilars Strategy.	Ensure that oncology biosimilars are safely implemented and that clinical and patient considerations are taken into account.	Engage pan-Canadian partners to discuss pricing, implementation and usage strategies that are informed by best practices.	Improve system sustainability and performance by facilitating the uptake of oncology biosimilars and ensuring stakeholders are benefiting from the transition.

Priority Areas Addressed in the Strategic Objectives

- Stakeholder Engagement
- Clinical Operations
- Education
- Reimbursement
- Clinical Guidance
- Reinvestment
- Evaluation

Summit Key Learnings

Stakeholder Engagement

- Ongoing stakeholder engagement is critical for successful biosimilars implementation and uptake.

Education & Information Sharing

- Comprehensive education is needed for patients and clinicians.
- Education will help clinicians discuss biosimilars with patients.
- Patient-clinician conversations are especially important for the understanding and acceptance of biosimilars.

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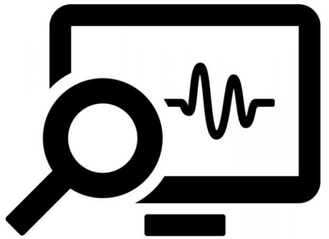
Summit Key Learnings

Clinical Operations

- Implementation issues for biosimilars are to be addressed at the hospital level.
- Appropriate systems must be in place to maintain pharmacovigilance.

Reinvestment

- Savings should be reinvested in the cancer system, especially in the cancer drug budget, to help fund new and innovative therapies.



Monitoring

- A system should be in place to track and monitor adverse events accurately.
- Real-world data should assess utilization, safety and effectiveness of oncology biosimilars.

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Pan-Canadian Oncology Biosimilars Action Plan Overview

Pre-Launch

1. Horizon Scanning [2018, ongoing]

- Watch the market for new biosimilars to ensure sufficient time to complete pre-implementation steps
- Invite biosimilar manufacturers to share expected product launch dates
- Bevacizumab and trastuzumab are expected to enter the market in Q3 of FY2019/20

2. Stakeholder Engagement [Jan 2019, ongoing]

- Engage stakeholders within the following priority areas as described by the strategic objectives:
    - Education
    - Clinical Operations
    - Clinical Guidance
    - Reimbursement
    - Evaluation
    - Reinvestment

Existing committees will be leveraged to obtain advice and guidance as it relates to some of these priority areas.

For Education and Clinical Operations, two working groups have been formed.

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Disclaimer: Timelines identified are target dates

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Oncology Biosimilars Action Plan Overview

Pre-Launch

3. Education Working Group [Feb 2019, ongoing]

- Provide input, share advice, and vet biosimilar educational resources that will be developed specifically for clinicians and patients.
- Resources will be designed to meet the needs of clinicians and patients and address educational gaps.
- Major deliverables: Standardized educational materials made available in various modalities (print, online, peer-to-peer education)

4. Clinical Operations Working Group [Feb-Aug 2019]

- Evaluate service impact and anticipated challenges of implementing biosimilars.
- Support the transitioning of cancer systems to the routine use of biosimilars
- Major deliverables: Provide guidance for developing a system-wide change management plan that mitigates risk and promotes consistency across jurisdictions; discuss solutions to ensure that the brand of the administered biologic can be traced to the individual patient; and champion the work at the local level.

Pan-Canadian Oncology Biosimilars Action Plan Overview

Pre-Launch

5. Clinical Guidance [Jan-Mar 2019]

- Engage existing expert committees to discuss and advise on initiating, switching & extrapolation
- Nuances between jurisdictions exist, however consistent policies and approaches will be sought

6. Reimbursement [April-July 2019]

- Reimbursement policies – depend on decisions on clinical issues (initiating, switching etc.), market share, pricing and pharmacy system readiness.

Launch

7. Biosimilars Implementation [currently anticipated for Q3, 2019]

- The exact date of a biosimilar being publicly funded will depend on multiple variables including pricing, reimbursement decisions, product availability, clinical decisions and clinical-operation readiness.

Pan-Canadian Oncology Biosimilars Action Plan Overview

Post-Launch

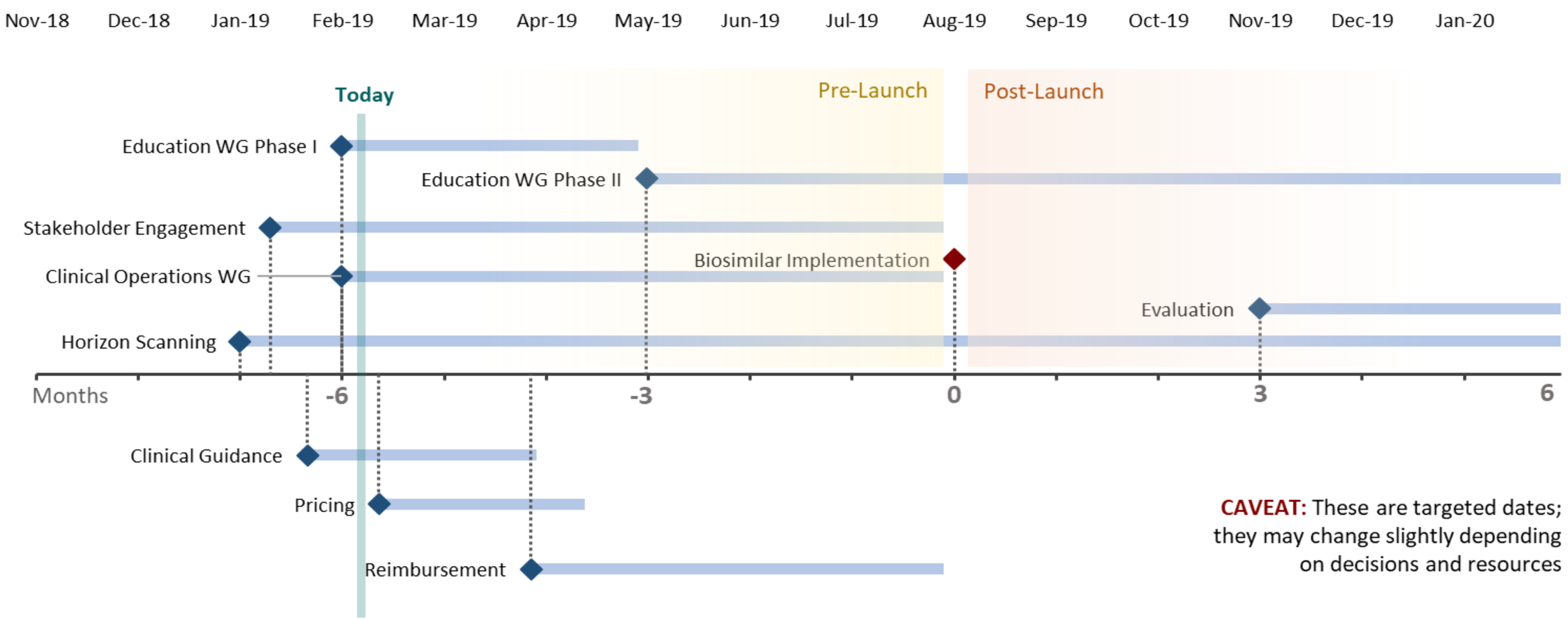
8. Evaluation

- Rate of uptake, utilization and budget impact will be assessed periodically
- The scope of RWE work can be scaled-up depending on the availability of resources

9. Reinvestment

- The reinvestment of cost savings from the use of biosimilars is at the discretion of each jurisdiction and they will ultimately decide how funds are used to optimize health outcomes. However, stakeholders consulted to date have strongly supported reinvestment in the cancer system as a priority.

Pan-Canadian Oncology Biosimilars Action Plan Overview



CAVEAT: These are targeted dates; they may change slightly depending on decisions and resources

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Current Status of Oncology Biosimilars Work

Deliverable	Status
Horizon Scanning	Ongoing
Stakeholder Engagement	Ongoing
Publication of Summit Proceedings Report and Action Plan	Complete
Education Working Group	• WG formed • Meetings underway • Educational materials are being developed
Clinical Operations Working Group	• WG formed • Meetings underway • Implementation standards document being developed
Clinical Guidance	Cross-jurisdictional discussions are ongoing
Reimbursement	Cross-jurisdictional discussions are ongoing
Evaluation	A plan will be developed to track utilization and uptake of biosimilars within Ontario

Additional Information

The pan-Canadian Oncology Biosimilars Initiative Webpage

The pan-Canadian Oncology Biosimilars Initiative has launched a webpage which currently hosts the November 2018 Summit Proceedings Report and Action Plan.

https://www.cancercareontario.ca/en/programs/provincial-drug-reimbursement/oncology-biosimilars-initiative

Questions?

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