

**Position Statements for the Implementation of Oncology Biosimilars from the
pan-Canadian Clinical Operations Working Group
Frequently Asked Questions**

1. What is the pan-Canadian Oncology Biosimilars Initiative?
 - The pan-Canadian Oncology Biosimilars Initiative (pCOBI) aims to ensure that the implementation and use of therapeutic oncology biosimilars are appropriate and cost-effective across Canada. It is a joint initiative supported by the pan-Canadian Pharmaceutical Alliance and managed by Cancer Care Ontario on behalf of all provincial, territorial and federal drug plans. This initiative is part of the pan-Canadian Pharmaceutical Alliance's biosimilars strategy.
2. What is the pan-Canadian Clinical Operations Working Group (COWG)? What was its purpose?
 - The COWG is a pan-Canadian working group that was convened as part of the pCOBI to address the impact of biosimilars implementation on clinical operations. This was achieved through the development of a Position Statement.
3. Who participated on the COWG? How were they selected?
 - The COWG is primarily comprised of oncology pharmacists, but also has representation from oncology prescribers and nursing.
 - Members of the COWG were nominated by the pan-Canadian Oncology Drug Review (pCODR) Provincial Advisory Group.
4. Who was consulted in drafting the Position Statement?
 - All recommendations outlined in the Position Statement were borne from consultations between the pCOBI team and the COWG.
5. What is the objective of the Position Statement?
 - The objective of the Position Statement is to assist hospitals and cancer centres across Canada prepare for the implementation of oncology biosimilars.
6. How did the group reach consensus on the recommendations outlined in the Position Statement?
 - The COWG reached consensus on each position statement through facilitated discussions. Scenario analysis was used as a method to problem-solve operational challenges: the COWG considered different clinical scenarios for each operational step, took these scenarios to their respective jurisdictions, and gathered further input as part of the consensus building process. Additionally, COWG members invited specific colleagues (e.g., nursing) to share their expertise on operations relevant to their clinical practice. This was to ensure that the healthcare providers who may be impacted by the recommendations were involved in the development of the recommendations.

7. Who is the intended audience of this Position Statement? Is it relevant to my practice?
- The recommendations outlined in this Position Statement are intended for oncology pharmacists, prescribers and nurses. It is likely that that these recommendations will impact your clinical practice as they discuss the entire clinical operations process flow, from drug procurement to drug administration. Additionally, some recommendations may directly impact policies at your institution and/or in your jurisdiction. Therefore, the COWG encourages you to be familiar with your institutions'/jurisdictions' policies as they relate to biosimilars.
8. Are the recommendations outlined in the Position Statement mandatory?
- The COWG recommends the position statements in this document as best practices for oncology biosimilars implementation across Canada and encourages their uptake as they are relevant to safe and effective practices of care. The COWG recognizes that jurisdictions and institutions differ in their policies and procedures. As such, some jurisdictions and/or institutions may have additional requirements that must be satisfied, and therefore may not align entirely with these recommendations. The recommendations in this document are for guidance purposes only and are not mandatory.
9. I am leading the oncology biosimilars implementation in my jurisdiction/institution. How much time do I have to implement the recommendations outlined in the Position Statement?
- The implementation timing of oncology biosimilars will depend upon funding/reimbursement policies of each province. It is advised that the recommendations in the Position Statement be implemented before oncology biosimilars are publicly funded in your jurisdiction as they are relevant to safe and effective practices of care.
10. How will the COWG know whether the recommendations were implemented successfully? Will the COWG revisit these recommendations after the first oncology biosimilar is implemented?
- Following the implementation of the first oncology biosimilar, the COWG will reconvene to discuss feedback received from their jurisdictions as to whether institutions were able to successfully implement the recommendations outlined in the Position Statement, how to move forward with additional biosimilars coming to market, and whether the Position Statement needs to be updated. The COWG intends to reconvene in November 2019.
11. Is there opportunity to provide feedback on the recommendations outlined in the Position Statement? How can I provide feedback?
- Yes, feedback on these recommendations can be provided to InfoPDRP@cancercare.on.ca; a member from the pCOBI team will be monitoring this email address. Additionally, please reach out to your COWG representative, through appropriate channels, so that they are able to share all feedback when the COWG reconvenes.