Ontario Health
Cancer Care Ontario

pCPA pan-Canadian Pharmaceutical Alliance

APP Alliance pancanadienne pharmaceutique

pan-Canadian Biosimilars Initiative Evaluation Framework

A Toolkit

October 2021

Introduction

This supplementary document to "pan-Canadian Biosimilars Initiative Evaluation Framework – Summary Report" provides a toolkit to support the measurement and monitoring of biosimilar implementations.

The Biosimilars Evaluation Toolkit is a set of indicators (and supporting questions, to be used to address the qualitative experiential indicators) that would allow for a comprehensive evaluation of biosimilar implementation activities, focusing on the stakeholder engagement process, funding policies, local implementation effects, and educational resources.

As indicated in the Data Collection column, some data may be available in administrative datasets (administrative), some data would need to be collected independently by organizations (e.g., Ministries of Health, provincial cancer agencies) (organizational), and other data would need to be collected via qualitative methods such as informational interviews, focus groups or surveys (qualitative).

Biosimilars Evaluation Toolkit

List of Indicators

Stakeholder Engagement

Stakeholder engagement

Indicator	Data Collection
Number and names of groups engaged	Organizational
How and when stakeholders were engaged	Qualitative
How stakeholder input was used	Qualitative
Stakeholder perceptions of their contributions	Qualitative

Funding Policies and Implementation Strategies

Communication of funding policies

Indicator	Data Collection
Number and type of internal and external roles involved in the development of funding policies within a jurisdiction	Organizational
Intended recipients of communicated funding policies	Organizational
Resources, evidence, reports, and stakeholder feedback used to develop funding policies	Qualitative
Changes made to the funding policy after initial funding policy released	Qualitative

Utilization of biosimilars

Indicator	Data Collection
Biosimilar utilization by drug	Administrative

Utilization of related drugs

Indicator	Data Collection
Use of concomitant drug products after a switch to a biosimilar, compared to historical cohorts	Administrative
Discontinuation rates of a biosimilar, compared to historical cohorts on the reference biologic	Administrative
Patients who switched to a new therapeutic class instead of switching to a biosimilar	Administrative
Patients switching back to the reference biologic after switching to the biosimilar	Administrative

Exceptional processes

Indicator	Data Collection
Number of jurisdictions that have an exception policy or process	Organizational Administrative
Number of exception requests received	Organizational Administrative
Approval rate of exception requests	Organizational Administrative

Cost savings

Indicator	Data Collection
Cost savings within a defined time period post implementation	Administrative

Market distribution

Indicator	Data Collection
Market distribution of brands for a drug	Administrative

Administrative impact of negotiation and contracting

Indicator	Data Collection
Number of amendments to Letters of Intent or Product Listing Agreements	Organizational
Timing of jurisdictional funding of new biosimilar drugs after Health Canada approval or price negotiation	Organizational
Number of amendments to Letters of Intent or Product Listing Agreements	Organizational

Change in utilization of health care resources

Indicator	Data Collection
Number of out-patient physician visits compared to historical cohorts	Administrative
Number of hospitalizations compared to historical cohorts	Administrative
Number of Emergency Department visits compared to historical cohorts	Administrative
Number of out-patient physician visits compared to historical cohorts	Administrative

Patient experience

Indicator	Data Collection
Change in travel distance to treatment site after switching to a biosimilar	Qualitative
Change in patient out-of-pocket expenses after switching to a biosimilar	Qualitative

Technology / Systems

Indicator	Data Collection
Changes that were made to existing systems to support data collection with respect to biosimilars	Qualitative

Local Implementation

Front-line staff impacts

Indicator	Data Collection
Activities used to implement biosimilars on the front lines of care (e.g., IT system upgrades, education delivery, revisions to policies and procedures)	Qualitative
Resources required for implementation of biosimilars (e.g., time, money, human resources)	Qualitative
Changes in physician time for each patient switched to a biosimilar	Qualitative
Changes in nursing time for each patient switched to a biosimilar	Qualitative
Changes in pharmacist time for each patient switched to a biosimilar	Qualitative
Changes in administrative time for each patient switched to a biosimilar	Qualitative
Types of resources in place to support new biosimilar implementations	Qualitative

Changes made at the institutional level to implement biosimilars

Indicator	Data Collection
Work effort (i.e., FTE) for initial and subsequent biosimilar drug implementations by type of activity (e.g., clinician education, system upgrades, policy and procedure revisions, patient education, administrative requirements for switching a patient to a biosimilar)	Qualitative
Number of new and existing FTE resources dedicated to initial and subsequent biosimilar drug implementations	Qualitative
Timelines for initial and subsequent biosimilar drug implementation	Qualitative
Readiness of data collection systems to collect biosimilar data	Qualitative
The extent to which desired outcomes and/or targets were achieved	Qualitative
Enablers and barriers to institutional implementation	Qualitative
Gaps that were identified and supports that were needed during implementation	Qualitative

Education

Need and value of biosimilar education

Indicator	Data Collection
Types of individuals targeted for biosimilar education	Organizational
Clinician and patient groups not targeted or missed for biosimilar education	Qualitative
Percent of individuals who indicated increased knowledge after receiving education on biosimilars	Qualitative
Number of individuals who access the education materials	Organizational
Ways materials were incorporated into practice (e.g., protocols updated, links to materials on website, placement of printed materials in clinics, training requirements)	Qualitative

Additional Supporting Questions for Qualitative Indicators

Stakeholder Engagement

Sample Qualitative Questions	Additional Probing Questions
How were stakeholders engaged throughout the continuum of biosimilar implementation?	• Explore the time points at which stakeholders were engaged
Do stakeholders believe their contribution was valued, making them champions of the work?	• Were the methods, timeliness and frequency of engagement appropriate for the intended outcomes and the stakeholder groups engaged?
Are stakeholders interested in engaging in future discussions?	• Understand stakeholder preferences for continued engagement and why
Who was engaged in developing the funding policies, and to which stakeholder groups were these policies communicated?	• Explore the method(s) used in communicating funding policies to stakeholders. • Explore the method(s) used to engage with each stakeholder group. • Discuss the appropriateness of the methods of engagement and communication with each stakeholder group. • Discuss the appropriateness of the timing and frequency of engagement with each stakeholder group. • Discuss preferences for future engagement (e.g., earlier or later, frequency) with each stakeholder group.

Local Implementation

Sample Qualitative Questions	Additional Probing Questions
Which individuals and groups of people (i.e., roles/positions) were engaged in preparing for the implementation of biosimilars at your site? How were they engaged? What were their roles?	• Discuss the types of techniques used to implement biosimilars (i.e., technical upgrades, education, policies and procedures) • Explore the resources required for implementation of biosimilars (i.e., time, money, human resources)
What intended outcomes or targets were monitored at the institutional level?	• Explore the type of indicators, targets, or metrics collected at the institutional level • Identify what worked, what did not work and reasons why
Were the targets reached and after how long?	• Determine the extent to which desired outcomes and/or targets were achieved • Explore length of time to reach intended outcomes • Explore contextual information to understand met or unmet targets
What enablers or barriers impacted biosimilar implementation at the institutional level?	• Exploration of known enablers and barriers encountered in institutional implementation (e.g., stakeholders, existing IT systems, existing practices / operations, available staff) • Discuss any gaps that were identified during implementation
What changes were made at the institutional level to implement biosimilars?	• Explore how education was delivered to clinicians and to patients • Discuss any system upgrades, and/or revisions to policies and procedures • Explore changes in clinician (physician, nursing, pharmacist) and administrative time (in FTEs or number of extra visits) for each patient switched to a biosimilar
What supports are in place to ensure the ease of ongoing use of biosimilars?	• Explore any gaps identified, or additional supports needed • Discuss the types of resources in place to support new biosimilar implementations • Explore how supports for biosimilars are embedded into standard practice