

CANADIAN PARTNERSHIP  
AGAINST CANCER



PARTENARIAT CANADIEN  
CONTRE LE CANCER

## Building Elements of a Framework for High-Quality Molecular Cancer Biomarker Testing in Canada



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# Presentation Objectives

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## Why?

Overview of the Partnership

Case for Change: Need for Comprehensive Pan-Canadian Standards for Quality of Routine Biomarker Testing

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## How?

Findings from Literature Review

## What?

Explore Elements of a National Framework

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## Next Steps

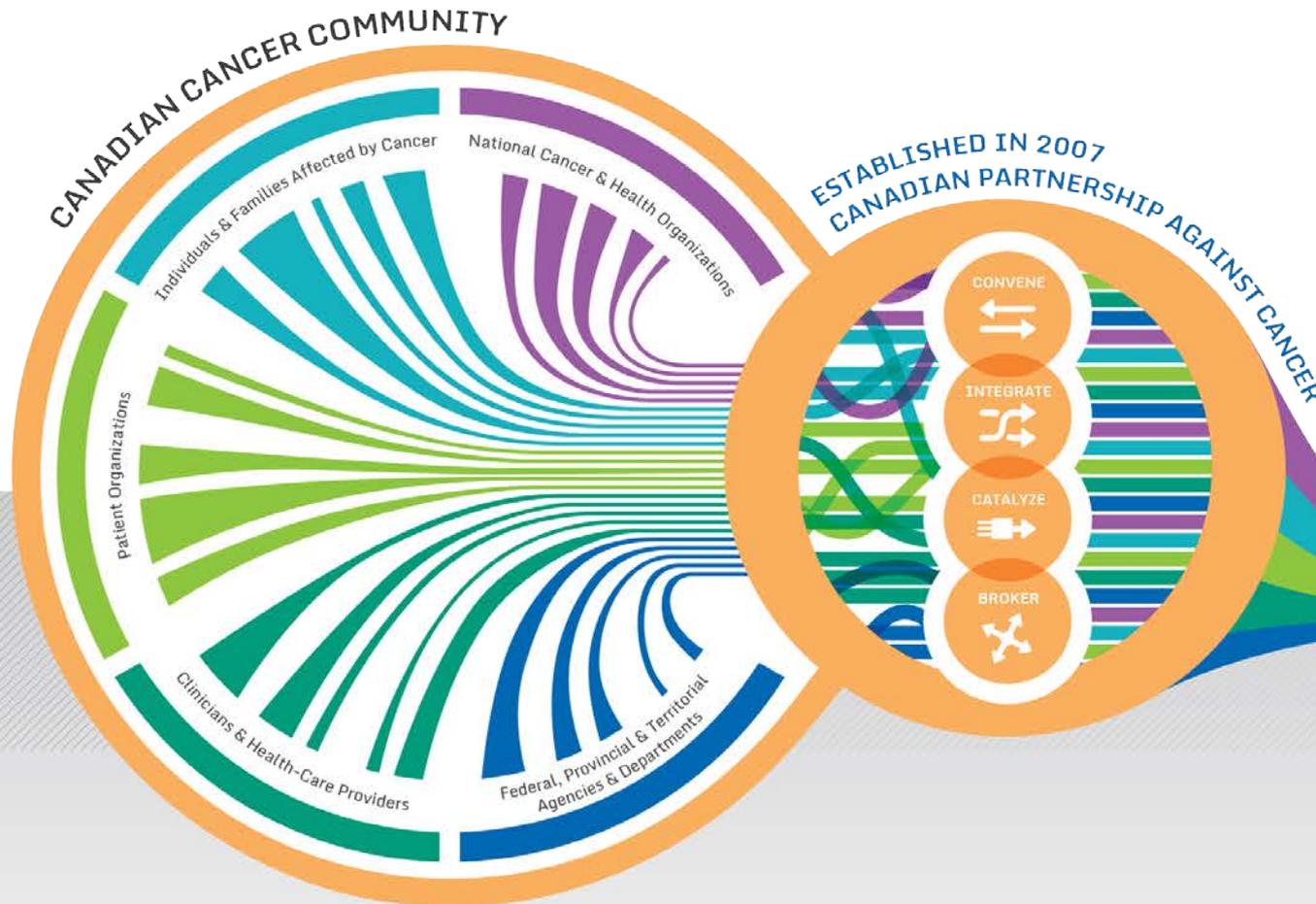
Recommendations on National Framework

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Convene a Stakeholder Group to Review Recommendations

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# Canadian Partnership Against Cancer



# Case for Change

Some standards in use in Canada for certain biomarkers but standards are needed for all current and emerging diagnostic, prognostic and predictive biomarkers



Varying regulatory requirements and fragmented legal frameworks governing genetic lab services between the federal and provincial jurisdictions



Need for comprehensive pan-Canadian standards for the quality of routine biomarker testing

# CADTH Foundational Document

The Partnership recently commissioned the Canadian Agency for Drugs and Technologies (CADTH) to conduct an environmental scan and literature review that addresses the following questions:

1. What are the quality assurance and accreditation requirements for cancer biomarker testing in each Canadian jurisdiction?
2. What is the association between the quality of laboratory test results for cancer biomarkers and the laboratory experience and volume of testing?

# Methodology

1. What are the quality assurance and accreditation requirements for cancer biomarker testing in each Canadian jurisdiction?
    - Surveys were sent to key informants from cancer agencies and health care agencies across Canada to identify the QA and accreditation requirements for cancer biomarker testing
  2. What is the association between the quality of laboratory test results for cancer biomarkers and the laboratory experience and volume of testing?
    - Literature search was conducted to identify association between the quality of lab test results and the experience or volume of the labs
- Of the survey responses received, all have QA requirements for cancer biomarker testing

# Provincial Participation



# CADTH Findings

- Authors identified many methods for Quality Assurance (QA) for cancer biomarker testing across jurisdictions including:
  - Internal Quality Assurance (IQA)
  - Participation in External Quality Assessment (EQA)
  - Equipment management
  - Standard operating procedures
  - Lab accreditation through external accreditation agencies
  - Best practices-sharing amongst labs
- Analysis of literature found experience of lab personnel an important aspect of QA
  - Continuous education and participation in EQA programs were identified as ways to ensure personnel proficiencies

# External Quality Assessment (EQA)

- EQA programs promote standardization of lab practices
- There is currently:
  - No requirement to demonstrate that accredited labs in Canada produce similar results when testing the same specimen
  - No national regulatory agency that mandates participation in EQA programs in Canada
- Only two provinces mandate participation in EQA programs for molecular testing: BC and ON
- Most provinces generally require labs to participate in specialized external quality control programs of their choice, such as the Clinical Laboratory Improvement Amendments (CLIA) standards offered by the College of American Pathologists

# Does your province have a TECHNICAL lab accreditation programme, and if yes what organization operates it?

Prov.	YES	Program; Organization who operates programme
<b>BC</b>	X	Diagnostic Accreditation Program (DAP); College of Physicians and Surgeons of British Columbia
<b>AB</b>	X	Diagnostic Laboratory Testing Accreditation; College of Physicians and Surgeons of Alberta
<b>SK</b>	X	Laboratory Quality Assurance Program; College of Physicians and Surgeons of Saskatchewan
<b>MB</b>	X	Lab Accreditation Program (LAP), College of American Pathologists (CAP) ; College of Physician and Surgeons of Manitoba
<b>ON</b>	X	Ontario Laboratory Accreditation (OLA) Quality Management Program – Laboratory Services (QMPLS); Ontario Medical Association (OMA)
<b>QC</b>	X	Programme d'assurance-qualité externe; Laboratoire de Santé Publique, Ministry of Health
<b>NB</b>	X	Ontario Laboratory Accreditation (OLA); IQMH – This is true by the Fall end 2013 *OLA and Accreditation Canada are looking to collaborate starting 2014
<b>NS</b>	X	Laboratory and Blood Services Qmentum Program; Accreditation Canada
<b>PE</b>	X	Laboratory and Blood Services Qmentum Program; Accreditation Canada
<b>NL</b>	X	Ontario Laboratory Accreditation (OLA); Institute for Quality Management in Healthcare (IQMH)/QMPLS

# Jurisdictional Scan

- In **Canada**, there is Western Canada Diagnostics Working Group that is focused on quality, protocols and accreditation-related lab issues and intended to promote multi-jurisdictional collaboration
- **Australian** diagnostic labs are subject to federally enforce QA standards, adapted from Organization for Economic Co-operation and Development (OECD) QA Guidelines
- The **United Kingdom** National EQA Service is voluntary and educational
- In both **Australia** and **UK**, EQA schemes have close links with the professions, ensuring that their services are determined by clinical need

# Other Findings: Slide-based tests

- Globally, there are several proficiency testing programs covering slide-based tests including cIQc which has key focus on improving quality of clinical biomarker testing
- The cIQc is in a unique position to facilitate a pan-Canadian approach to ensure high-quality testing for cancer biomarkers by immunohistochemistry
- *Opportunity Area → While EQA could be provided at the national level, the enforcement arm of the QA cycle occurs at the provincial level and participation in EQA schemes is voluntary in most provinces (with BC's DAP being a notable exception)*

# Liquid-phase molecular tests

- UK-based European Molecular Genetics Quality Network (EMQN) provides 28 disease specific, 2 molecular pathology, and 3 technique specific EQA schemes for molecular genetic testing
- *Opportunity Area → Leading Canadian labs participate in EMQN schemes on a voluntary basis*

# Next Steps

## 1. Discussion Paper (October 2016)

*Commission a discussion paper to explore the elements of a framework for high-quality molecular cancer biomarker testing in Canada.*

*Review models of labs QA and lab accreditation in Canadian jurisdictions and internationally*

## 2. Stakeholder Meeting (TBD)

*Convene a stakeholder group to review the recommendations and inform development of pan-Canadian framework*

# Thank you

