



**Canada's Drug Agency**  
**L'Agence des médicaments du Canada**  
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

# Developing a Consensus-based Assessment Framework for Genetic and Genomic Biomarkers in Cancer Care

May 15, 2025



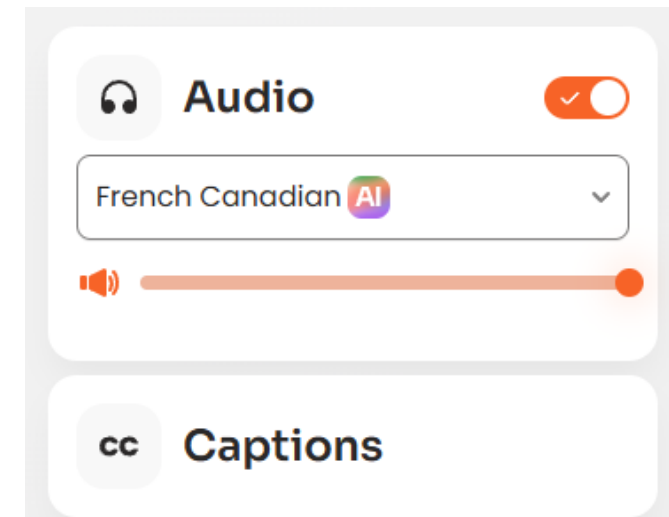
# Simultaneous Interpretation and Live Captioning



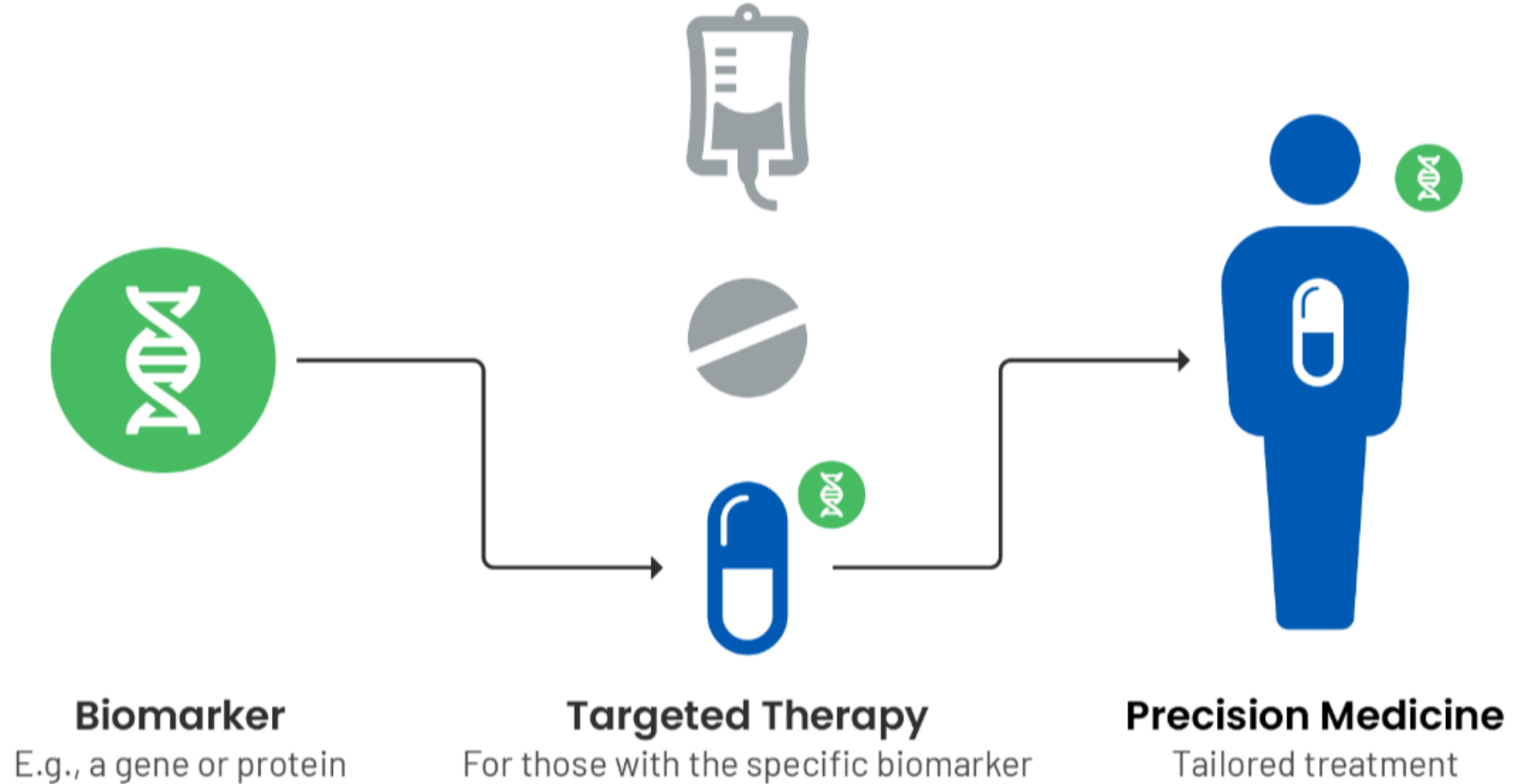
Simultaneous interpretation and live captioning are available in both official languages for today's webinar.

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# Components of Precision Medicine



\* Promises may only be realized with timely and equitable access to biomarker testing

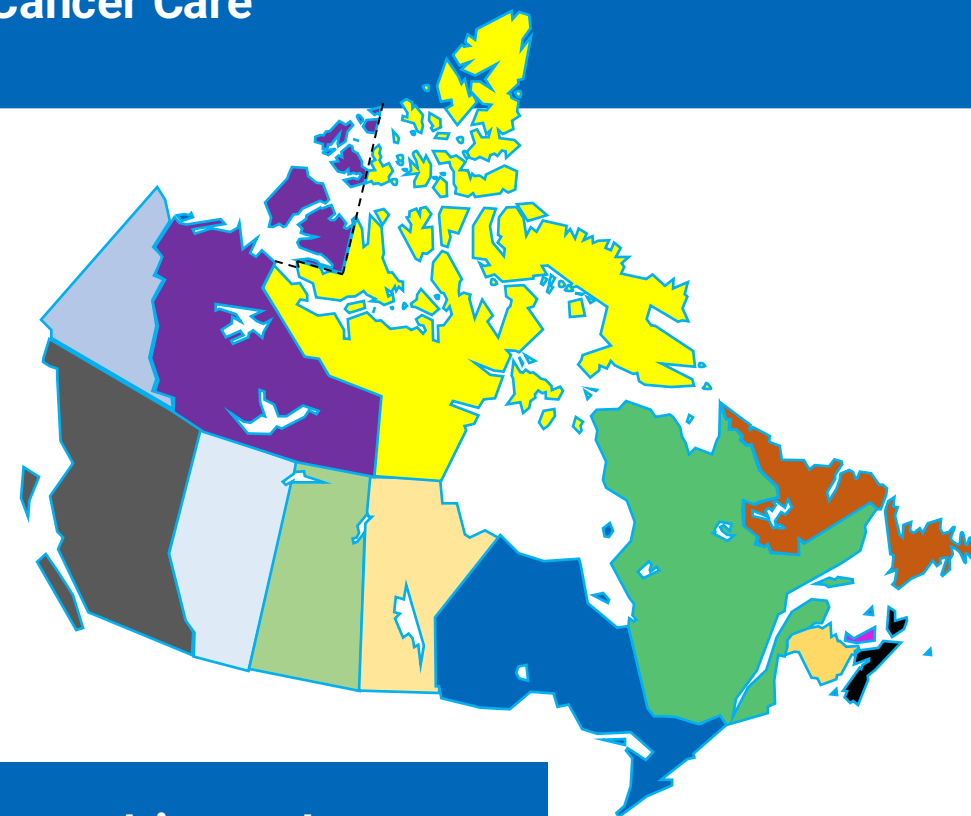
# Biomarker Review Processes in Canada



## Environmental Scan

Genetic and Genomic Biomarker Testing Assessment Frameworks, Processes, and Inventories in Cancer Care  
March 2025

- **Inconsistencies, lack of coordination and duplication of effort** within and across jurisdictions
  - 13 different jurisdictions = 13 (or more) different processes
- Different assessment processes for biomarkers for drug eligibility, and other biomarker testing purposes
- **Inequities in timely access** to biomarker testing and subsequent treatments



**Desire for a coordinated pan Canadian approach for cancer biomarker assessment**

# Cancer Biomarker Assessment Framework: Advisory Panel (time-limited)

## Objectives



**Develop a consensus-based framework** for assessing genetic and genomic biomarkers to inform adoption or funding decisions in cancer care.



**Identify best practices** and existing gaps across jurisdictions in Canada.



**Provide actionable implementation considerations** to facilitate implementation of the framework within jurisdictions.



**Engage contributing parties** across jurisdictions to build consensus.

2025

Sep

Framework  
ready for  
implementation  
in jurisdictions

# Cancer Biomarker Assessment Framework Advisory Panel



## Panel Chair

Maureen Trudeau

## Panel Membership

Representation across various roles within the health system, geographic location, race, sex and gender.

Diversity in perspectives

- medical oncology, molecular pathology, patients' perspectives and lived experience, health economics, health services research, ethics, implementation, decision-making and payers for both biomarker testing and drugs.

9 jurisdictions (not PEI, no territories)



# Scope



## PURPOSE OF THE BIOMARKER

- Drug eligibility assessment
- Diagnostic
- Prognostic
- Recurrence detection
- Monitoring and treatment response



## TYPE OF DECISION

In scope

- New biomarker not currently tested
- Continue/discontinue funding of a biomarker
- Approved for one indication, used in another

Out of scope

- Location of testing



## ASSESSMENT CRITERIA

In scope

- Criteria to support decision-making on adoption or funding

Out of scope

- Test platform or assay
- Non-cancer



## IMPLEMENTATION

In scope

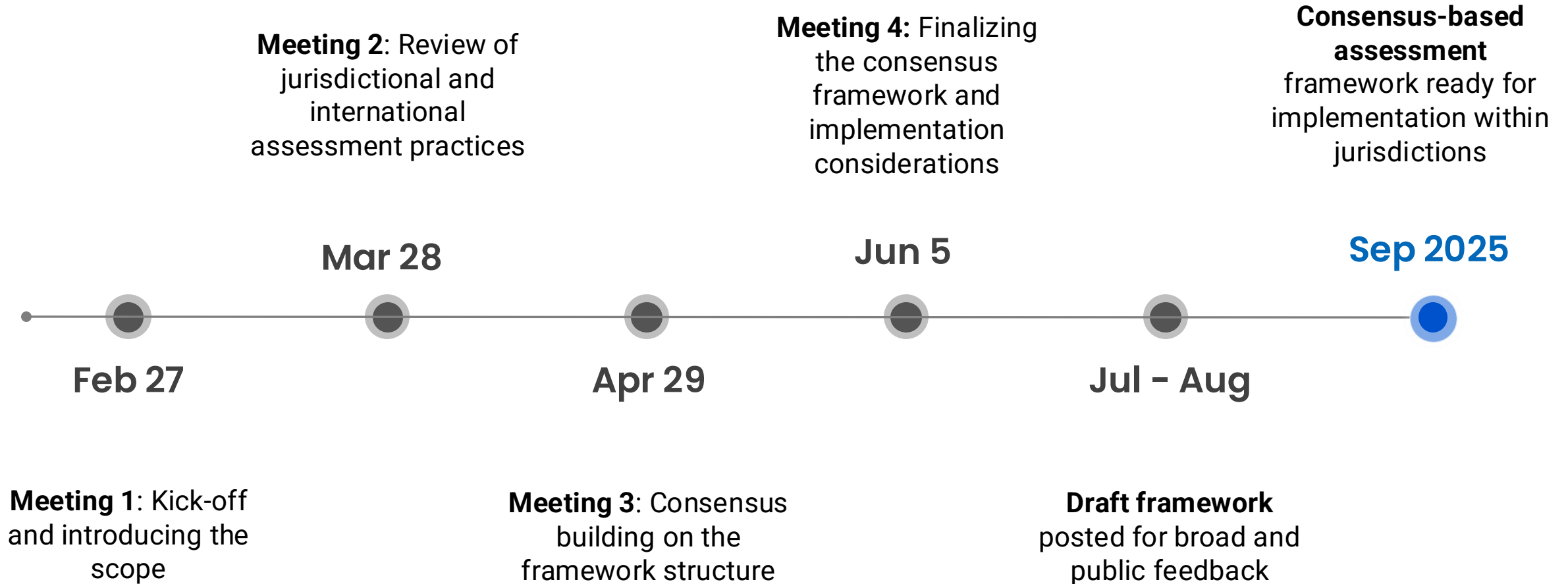
- Implementation considerations or recommendations

Out of scope

- Implementation of rules or requirements



# Advisory Panel Workplan and Timeline





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# Discussion and Q&A



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