Confidential

How Canada is Modernizing Clinical Trials Regulations to Compete Globally

CTO Clinical Trials Conference
November 4, 2026
Toronto, ON

Health Canada Santé Canada

Canada

A prosperous, inclusive, innovative Canadian economy

Canada's National Security Strategy

- Canada’s security is supported by building strategic capabilities in critical sectors, and the life sciences sector is critical to both health and economic security

"Safeguarding supplies of essential medicines and biologics by strengthening biomanufacturing capacity, modernizing regulation, and securing critical health supply chains"

Pharmaceutical and Life Sciences Sector Task Force

- Canada’s strengths position it as an important contributor to global innovation and a promising environment for new therapies and technologies

“Decisive action, supported by sustained collaboration, will be required to strengthen outcomes for people in Canada and position Canada for greater resilience and growth in the global life sciences landscape”

New clinical trial regulations

Finalizing Regulations

Health Canada is finalizing new clinical trial regulations

System Objectives

Calibrated to risk, built on global cooperation, promoting strong industry and improving stakeholder experience

Standalone Framework

Will replace Division 5 of Part C of the *Food and Drug Regulations*

Provide Greater Regulatory Flexibility

Designed to optimize agility and operational efficiency across the sector

- **Risk-based approach**
- **Reduce red tape**

Overview of regulatory flexibilities

FROM (CURRENT STATE)		TO (MODERNIZED FRAMEWORK)
One-size-fits-all oversight	→	**Proportional, risk-based oversight**
Regulatory authority over the sale of drugs for use in a trial	→	**Regulatory authority over the conduct of the trial**
Mandatory clinical trial notifications for low-risk changes	→	**Elimination of some low-risk notifications**
No ability to use Terms and Conditions (T&Cs)	→	**Flexibility to use Terms and Conditions**
Requirement for written informed consent	→	**Requirement for documented informed consent**
Inflexible labelling requirements for clinical trial drugs	→	**Reduced labelling requirements for marketed products**
Requirement for notification to HC for each REB approval of a site	→	**Regulatory modifications to reduce burden for sponsors when new sites are approved by REBs with mutual recognition agreements**

Stakeholder feedback on the draft regulations

Broad support for the regulations in general across the stakeholder community

A Few Areas of Concern

- The creation of a list of national REBs
- Proposed ability for Health Canada to extend review timeline from 30 to 60 days

More Details Requested

- Terms and Conditions (T&Cs)
- Issuance of authorization process

All feedback is being carefully considered as Health Canada finalizes the regulations and associated guidance documents

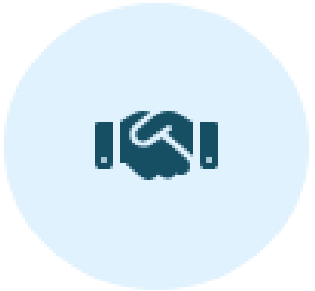
Next steps for clinical trials regulations



Canada Gazette, Part II, in June 2027, followed by a one-year coming-into-force period



Updated guidance documents published at the same time as new regulations



Currently exploring further opportunities to introduce greater regulatory flexibility in a phased approach



Commitment to encouraging innovation and greater access to clinical trials, while continuing to ensure participant safety

Interim policy for clinical trials modernization

Published by Health Canada on **September 14, 2026**, advancing regulatory flexibilities prior to the coming-into-force of the new regulations.

Multi-Site Trials

How to notify Health Canada about ethics approvals in multi-site trials, in line with coordinated ethics review models

Qualified Investigator

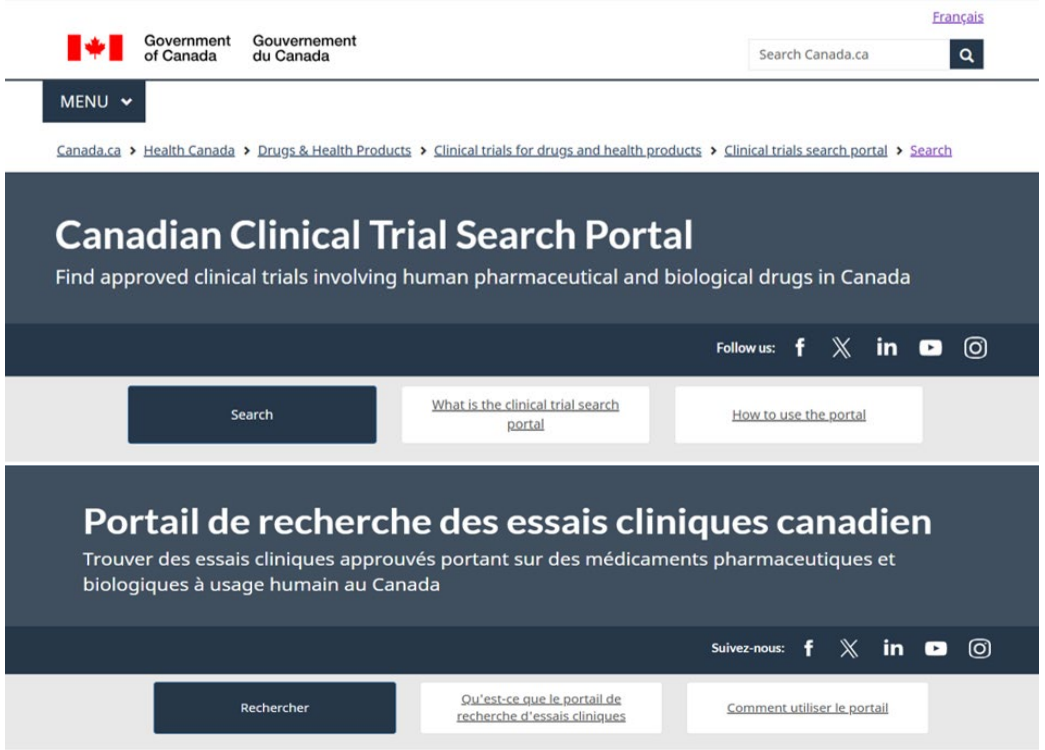
Qualification requirements now support competency-based approaches aligned with ICH E6

Informed Consent

Non-traditional "documented" informed consent approaches, including remote and electronic methods

Canadian Clinical Trial Search Portal

- Launched in **July 2026** to enhance transparency, accessibility, and navigation across the Canadian clinical research ecosystem.
- Provides comprehensive information in a user-friendly manner.
- Supports health care practitioners and patients in finding trials and accessing new treatments.
- Follows modern accessibility standards.
- **The Portal is not a clinical trial registry.**



SGBA Plus Demographics Action Plan



- Provides guidance on the submission of an SGBA+ Demographics Action Plan (DAP) alongside their clinical trial application (CTA)
- Supports inclusive clinical trial practices and consideration of demographic factors
- Not a regulatory requirement, but strongly encouraged
- **Final guidance to be published alongside the final regulations in June 2027**

Pediatric Standard of Care Clinical Trials Pilot

Launch Date

The Pilot was launched on October 14, 2026

Applications

The Pilot will accept applications on October 30, 2026

Core Objective

Intent: reduce the regulatory burden for select pediatric standard of care clinical trials, with the goal of providing medical professionals with better information to inform clinical decision making

Compliance & Requirements

Once accepted under the pilot, trialists will not be expected to file a CTA or associated amendments or notifications and would be expected to follow similar requirements to Phase IV trials

What’s next at Health Canada?

Task Force Recommendations

The Pharmaceutical and Life Sciences Sector Task Force made recommendations specific to clinical trials with the objective of:

- Enhancing the global competitiveness of Canada’s clinical trial infrastructure and networks
- Ensuring the preservation and growth of clinical trial activity across the country

Destination of Choice

Maintaining and improving Canada’s position as an attractive destination for research investment and clinical trials is an opportunity for us to advance our shared goals.