April 19, 2026

Input into Health Canada's Consultation on Modernizing the Framework for Clinical Trials

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations working to advance **timely, equitable, and consistent access** for Canadians to **safe, effective** medicines that improve patient outcomes. Our mission includes improving pathways to timely access to medically necessary medicines, strengthening patient safety, and supporting secure drug supply. These goals align directly with a modern clinical trials system that enables participation and access to innovation.

Executive summary

Health Canada's proposal to establish clinical trials regulations and associated guidance is an important opportunity to:

1. **Improve participation** in trials by reducing unnecessary burdens, enabling decentralized and innovative trial designs, and supporting multi-site studies through streamlined ethics review; and
2. **Accelerate earlier access** to innovative therapies in Canada by making Canada a more attractive and feasible location for global trials, while maintaining strong protections for participants.

Best Medicines Coalition supports Health Canada's objective to regulate clinical trials through a risk-based lifecycle approach with system-level tools intended to improve equitable access to and efficiency of clinical trials. However, **BMC urges Health Canada to ensure that implementation details** are designed to **remove barriers for patients**, not inadvertently add new ones. This is especially true of decentralized elements, national ethics review, and sponsor obligations.

The modernized framework should result in patients getting earlier, faster access to more trials for innovative medicines in Canada, **including those with conditions that are difficult to treat**, with **more diverse and equitable participation**. Furthermore, transparency in reporting on the number and nature of trials held in Canada, both sponsored and unsponsored, is required.

Participation and early access

Health Canada notes that the existing framework's limitations, such as onerous and duplicative ethics reviews, can make certain trials less likely to come to Canada, thereby limiting Canadians' access. The Best Medicines Coalition appreciates Health Canada's candidness on this issue. **For many Canadians**, especially those living with serious, rare, or difficult-to-treat diseases, **clinical trials** are not only a way to advance science; they may **represent the only feasible pathway to access to cutting-edge therapies before market authorization or public reimbursement**, which can take months or years to achieve.

Health Canada can improve patient experience and access through modern clinical trials framework by:

- Supporting **decentralized elements** to reduce travel burden and widen access beyond major academic centres;
- Enabling **innovative trial designs** (e.g., master protocols, platform/adaptive trials), which can be particularly relevant in rare diseases and precision medicine;
- Defining the lifecycle and associated oversight to encompass all stages: pre-clinical, clinical trial design, trial recruitment, trial authorization, post-market surveillance, and patient access.
- Ensuring terms and conditions include **patient-inclusive trial design** that seeks to **improve diversity and access, reduce patient burden in participating in trials** (e.g. decentralization), with **ethical consent and plain language communication**, and **transparency of interim results**, particularly where safety is concerned.
- Increasing **predictability and efficiency through clearer lifecycle oversight tools**, including the ability to apply **terms and conditions** and tailor requirements **proportionate to risk**.

Patient participation

Decentralized and hybrid trials can materially expand access if implemented with patient-centered guardrails

Health Canada's decentralized clinical trials (DCT) work recognizes that decentralized elements can **reduce travel burden**, make trials **more accessible and diverse**, and connect providers in remote areas to pan-Canadian research efforts. This is significant because accessible and diverse trials are more likely to generate results that reflect the real-world use of treatments.

BMC strongly supports embedding decentralized flexibility into the modernized framework. For example, **financial concerns may prevent clinical trial participation**. Therefore, travel, time off work, caregiving responsibilities, disability, and out-of-pocket costs are among the most common reasons patients decline or withdraw from trials.

The Best Medicines Coalition recommends that Health Canada:

- **Makes "participant burden" an explicit design consideration** in guidance and templates (e.g., requiring sponsors to describe how protocol design minimizes travel/time burden). While participant burden may vary according to population and treatment in trials, trial design should generally consider travel distance, time off work and/or school, childcare, lack of IT infrastructure, language, gender and other important burdens patients may face.
- **Ensures that remote activities are treated as legitimate components of a trial site** under the new definition (main site plus remote locations under investigator oversight), and that this results in clear and transparent understanding of what is required to participate in trials for patients.
- Provides practical guidance on **technology access and support** (devices, connectivity, training, accessible formats) so that DCTs do not unintentionally exclude seniors, people with disabilities, rural/remote communities, or lower-income participants.

Inclusion and representation: Demographics Action Plans should be feasible, measurable, and patient-informed

Health Canada's draft proposed regulations for sex and gender-based analysis (SGGB+) and Demographics Action Plans (DAPs) are positive steps toward more inclusive trial design. The proposed regulations emphasize that representation across sex, gender, and intersecting demographic factors improves generalizability and is an ethical responsibility; DAP submission is voluntary but "strongly encouraged."

The Best Medicines Coalition recommends that DAP submissions be mandatory and encourages Health Canada to:

- Provide **standardized, plain-language DAP tools** (checklists, examples by disease area, small sponsor templates), so the expectation is achievable for non-commercial and smaller sponsors.
- Encourage sponsors to incorporate **patient organization input** into recruitment strategies, retention supports, protocol development, design of consent materials and culturally appropriate materials, particularly for underrepresented communities.
- **Promote transparent reporting of enrollment progress against DAP commitments**, including the number and nature of trials available,
- Exercise **flexibility for rare diseases** where population sizes are small and geographic dispersion is significant.

Streamlining ethics review can reduce delays for multi-site trials

Health Canada's consultation includes centralized research ethics board (REB) reviews and a **Canadian List of National Research Ethics Boards (REBs)** to help streamline approval for multi-site trials. The draft regulations state that when a sponsor obtains approval by a national REB on the list, they are not required to obtain separate REB approval for each site.

BMC agrees with the centralized research ethics board process proposed in the draft regulations. Sequential ethics processes can delay trial initiation and reduce Canada's competitiveness which can ultimately reduce patient access to trials.

The Best Medicines Coalition recommends that Health Canada:

- Ensures the national REB approach preserves **local context** (e.g., community engagement, Indigenous-specific considerations, local feasibility) while preventing duplicative reviews.
- Publishes **clear service standards and performance metrics** (time to review, reasons for delay, consistency measures) so patients and sponsors can see real-world improvements.

Earlier access to innovative medicines

More global trials in Canada

Health Canada's Regulatory Impact Analysis Statement notes that limitations in the current framework may make trials less likely to come to Canada, thereby limiting Canadians' access. Limitations include but are not limited to geographic and logistical barriers to participation, such as time off work or school, slow start ups and rigid participation requirements for rare populations. A modern, risk-based framework that aligns with those of trusted foreign regulators (e.g. those recognized for reliance orders) can increase Canada's attractiveness for global sponsors. This may be especially true for

complex, adaptive, and decentralized protocols. BMC advocates for an approach that bringing earlier access opportunities to Canadian patients.

Risk-based, lifecycle oversight can speed start-up while maintaining safety

The draft CTA regulations include features such as:

- A shift to regulating **trial conduct** across the lifecycle;
- A proportionate, **risk-based approach** and the ability to apply **terms and conditions** over the lifecycle; and,
- The ability to **accommodate complex trials and evolving innovations**, including decentralized and master protocol trials.

The Best Medicines Coalition supports these tools because they can **improve predictability and reduce unnecessary delays** of launching trials in Canada.

Implement "contingent authorization" to avoid unintended delays

The draft CTA guidance indicates Health Canada will issue an acknowledgment and a **"contingent authorization"** early in the process, which becomes full authorization after the review period elapses or once Health Canada issues a notice of no objection, but **contingent authorization does not authorize importation or other regulated activity while under review**.

If operational steps (e.g., drug importation, site activation, contracts, logistics) cannot be developed in parallel, the model could unintentionally extend start-up timelines which in turn can delay patient access and trial outcomes.

The Best Medicines Coalition recommendations for authorization operations:

- **Clarify, in guidance, what preparatory activities may proceed during the contingent period** (e.g., contracts, site training, pre-screening, scheduling) to avoid "dead time" that delays first-patient-in.
- Provide transparent criteria for **extended review timelines** (30 to 60 days) and how Health Canada will **mitigate delays for urgent/serious conditions**.
- **Establish patient-relevant performance indicators** (e.g., median time from submission to authorization, and from authorization to first participant dosed), published annually.

Oversight, accountability, and trust: protecting participants while enabling access

The Best Medicines Coalition recognizes and supports the intent to maintain strong participant protection while improving access to innovative therapies. The proposed framework expands clarity on roles and responsibilities, emphasizing that sponsors retain ultimate accountability for participant safety and data integrity, including when third-party service providers are involved.

The BMC recommends:

- **Clear, plain language patient-facing information about who is responsible for key aspects of trial conduct** (privacy, safety reporting, complaints), especially in decentralized models with multiple service providers., as well as **what each part of the trail entails**; and a **report of trial outcomes**.

- Guidance that ensures a **decentralized approach does not reduce the quality of informed consent or patient understanding; flexibility in consent processes should improve access while safeguarding comprehension and consent.**

Summary of recommendations

To ensure modernization translates into meaningful patient benefit, BMC urges Health Canada to:

1. **Operationalize patient-centered DCT guidance** with equity safeguards (technology access, accessible design, and support).
2. **Make national REB streamlining real and measurable by providing centralized REB processes**, reducing duplication without losing local context.
3. **Ensure the contingent authorization model does not delay trial start-up**, through clear guidance on parallel activities and predictable timelines.
4. **Embed inclusion best practices** through feasible SGBA+ DAP tools and patient-informed recruitment/retention strategies.
5. **Publish performance measures** that matter to patients (speed, access, and representation), reinforcing trust and continuous improvement

Conclusion

The Best Medicines Coalition supports Health Canada's modernization initiative and agrees that a modernized, risk-based, lifecycle framework can strengthen participant protection while improving access to new and innovative therapies in Canada. **With patient-centered implementation can deliver tangible benefits such as more trials in Canada, broader participation, and earlier access to treatments. This is especially true of decentralized trial elements, inclusive enrollment practices, and streamlined ethics reviews.**

The BMC appreciates the opportunity to provide input and would welcome ongoing engagement as the regulations and guidance are finalized, implemented and reviewed over time.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 33 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors composed of representatives of member organizations and elected annually.

Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Family Alliance on Severe Mental Illnesses
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medicines Access Coalition – BC
Migraine Canada
Millions Missing Canada
Mood Disorders Society of Canada
Ovarian Cancer Canada
Parkinson Canada
Platelet Disorder Support Association
Psoriasis Canada
Pulmonary Hypertension Association of Canada (PHA Canada)
the cancer collaborative