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Debra Haltrecht
Acting Executive Director
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Policy, Planning and International Affairs Directorate
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Health Canada
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sent via email: lrm.consultations-mlr@hc-sc.gc.ca

Re: Clinical Trials Regulations (the Regulations) published for consultation in Canada Gazette, Part I.

Dear Ms. Haltrecht,

On behalf of the member companies of BIOTECanada, I am writing regarding Health Canada's proposed Clinical Trials Regulations (the Regulations) published for consultation in Canada Gazette, Part I. BIOTECanada commends Health Canada's Clinical Trials Modernization initiative as a meaningful step toward updating Canada's clinical trial framework. The proposed framework contains many provisions that demonstrate a genuine commitment to building a modern, risk-based regulatory system, and we appreciate the significant effort and thoughtful consultation that have gone into its development. With significant international competition for clinical research investment, it is essential that the final Regulations reinforce rather than inadvertently weaken Canada's competitive position.

Canada's health and biosciences economic strategy table recommended that a high-performing regulatory system should be predictable, efficient, consistent and transparent, so as not to present barriers to business investment, innovation and ultimately, economic growth and improved patient outcomes. BIOTECanada looks forward to working collaboratively with Health Canada to ensure this framework effectively establishes a strong clinical trials ecosystem.

BIOTECanada is the national biotechnology industry association representing over 200 companies nationwide. To ensure Canada remains globally competitive, clinical trial modernization must promote the long-term growth of Canada's life sciences sector as part of Canada's Biomanufacturing and Life Sciences Strategy and Defence

Strategy thereby maintaining health sovereignty as a nation. It is imperative the clinical trial guidelines and regulations align with global standards and support the efficient development of novel biotechnologies, streamline the process and reduce regulatory Red Tape. The country is globally recognized for the quality and expertise of its clinical research and its ability to conduct clinical research in complex therapeutic areas with a diverse population. Many other jurisdictions recognize the value of a strong life sciences clinical trials ecosystem, and Canada must continue to modernize to remain globally competitive.

Clinical trials are foundational to our members' ability to bring innovative medicines to Canadian patients. The regulatory environment governing clinical trial conduct directly determines whether Canada is included in global development programs and, therefore whether Canadians have timely access to the innovations our members develop.

Health Canada's modernization initiative builds on the progress clinical trials have made over time. We are encouraged by several positive developments in the proposed framework, including the introduction of expanded investigator definitions to include additional healthcare providers, single authorization for master protocols, and new provisions enabling electronic consent and remote trial site participation. These represent meaningful advancements that align with ongoing technological progress and modern practices.

However, BIOTECanada has significant concerns regarding provisions that would, in practice, move Canada further from, rather than closer to, international standards and remain globally competitive. If left unaddressed, their combined effect could undermine the significant health and economic gains that positive elements of this framework are poised to deliver.

Clinical trials are often global endeavors with multiple international sites, where Canada is among the leading jurisdictions. The clinical trial regulatory modernization and associated guidance in Canada requires international consultation of global company offices to collect important feedback on how best to ensure Canada remains competitive in attracting clinical trials.

BIOTECanada strongly urges Health Canada to address the following priority areas for the final Regulations:

- **Protect Canada's Competitive Clinical Trial Review Timeline.** The proposed authority to extend clinical trial application (CTA) reviews from 30 to 60 days, based on broadly defined criteria, risks undermining both Canada's

competitiveness and the predictability required by global Sponsors. While Health Canada indicated during the stakeholder webinar that extended timelines would only apply to a small number of particularly complex trials and would not represent the "normal" review pathway, the Regulatory Impact Analysis Statement (RIAS) indicates that approximately 20% to 30% of CTAs would be subject to a 60-day review timeline. This proportion is significantly higher than the industry expectations and is unacceptable. From an operation and planning perspective, the unpredictability it creates for review timeline will jeopardize the allocation of many global clinical trials to Canadian sites. Applying a 60-day review timeline to nearly one-third of applications would effectively normalize longer startup timelines in Canada, placing the country at parity with or behind jurisdictions such as Europe, Australia and the United States rather than preserving its current competitive advantage. When combined with the ability to impose Terms and Conditions at any time—often with short response timelines—these measures introduce material uncertainty into trial planning and execution, increasing the risk that Canadian sites will be excluded from global development programs.

Beyond competitiveness, normalizing a 60-day review pathway would have a disproportionate impact on innovation and patient access to clinical trials in Canada. The criteria used to define a "complex" clinical trial—such as novel trial designs, master protocols, innovative technologies, advanced manufacturing processes, and trials involving vulnerable populations—are precisely the hallmarks of cutting-edge and next-generation research. As innovation increasingly drives clinical development, a growing proportion of trials will meet this definition, meaning that well over one-third of trials could reasonably be classified as complex over time. This creates a structural disincentive for sponsors to place innovative trials in Canada, as extended and unpredictable regulatory timelines complicate global study sequencing and startup decisions. The result would be reduced participation of Canadian sites in first-in-human and early-phase studies, delayed access for Canadian patients to potentially life-saving therapies, and a diminished role for Canada in global drug development programs. In an already highly competitive and time-sensitive global clinical research environment, embedding longer review timelines for innovative trials risks further constraining Canada's ability to attract and retain high-value clinical research investment.

To maintain regulatory certainty, predictability, and Canada's attractiveness for innovative clinical research, BIOTECanada strongly encourages Health Canada to retain the current 30-day review timeline in the final Regulations.

- **Concerns with Expanded Terms and Conditions Authority.** The proposed authority for Health Canada to impose, amend, or add Terms and Conditions at any point during the lifecycle of a clinical trial—often with limited notice and

short response timelines—introduces significant regulatory uncertainty for sponsors that is unprecedented among major regulatory jurisdictions. The absence of clearly defined triggers, procedural safeguards, or meaningful opportunities for dialogue prior to the imposition of T&Cs creates operational risk, particularly for global trials governed by fixed protocols and timelines. This level of discretion, when combined with extended and unpredictable review timelines, undermines confidence in Canada's regulatory environment and complicates trial planning, resourcing, and execution. Without greater clarity, transparency, and predictability around the use of T&Cs, sponsors may be deterred from selecting Canadian sites, limiting patient access to innovative clinical research.

- **Strengthen Global Alignment for Innovative Clinical Trial Designs.** Decentralized and innovative trial designs represent the new global standard for clinical research, yet elements of the proposed framework would make Canada more restrictive than peer jurisdictions by introducing unique national requirements that exceed international standards (ICH E6) and create compounding disadvantages—particularly for the very types of trials Health Canada states it wants to enable. These include:
- Bringing CROs, SMOs and other service providers within the regulatory scope, with a definition that fails to distinguish between GCP-critical services and ancillary functions. The proposed requirement making sponsors responsible for documented oversight, control, and compliance of all delegated activities is substantially more restrictive than ICH E6, which treats vendor oversight as a quality-by-design expectation. Neither the FDA nor the EMA regulates vendors directly in this manner. The definition should be narrowed to apply only to those providing GCP-related services within Canada.
- Broad discretionary use of Terms and Conditions that exceed international norms. FDA clinical holds require specific statutory criteria and provide defined due process. The absence of clear limits or appeal mechanisms introduces unpredictability, which is more restrictive than peer regulatory systems.
- Mandating SGBA+ and an action plan as part of the CTA package exceeds international standards, where most peer jurisdictions encourage diversity plans primarily through policy guidance. By embedding SGBA+ into regulatory authorization, HC transforms a policy objective into a potential approval barrier.
- The final Regulations must promote decentralized trials as the default, strengthening patient access, research competitiveness, and Canada's ability to attract global investment.

Patient access to innovative therapies depends entirely on Canada being a viable and competitive clinical trial destination. The concerns outlined above are not theoretical; they reflect the operational realities that global sponsors evaluate when making trial allocation decisions. Every provision that introduces unpredictability, diverges from international standards, or adds administrative complexity without a clear safety benefit risks undermining the significant gains the positive elements of this framework are designed to deliver, resulting in fewer trials conducted in Canada and fewer Canadians benefiting from access to innovative medicines. With the right refinements, Canada has a clear opportunity to establish itself as a strong global leader in clinical research, and BIOTECanada looks forward to working collaboratively with Health Canada to realize this potential for the benefit of patients, researchers, and the broader life sciences ecosystem.

The attached document provides BIOTECanada's detailed input on behalf of the diverse biotechnology ecosystem.

Sincerely,

Wendy Zatylny
President and CEO
BIOTECanada