HealthCare*CAN*'s Submission for Health Canada (Consultation on the Modernization of Canada's Clinical Trials Framework)

HealthCare*CAN* welcomes Health Canada's efforts to modernize Canada's clinical trial framework and appreciates the opportunity to provide input. HealthCare*CAN* is the national voice of Canada's hospitals, health authorities, health research institutes and healthcare organizations. HealthCare*CAN* members are central to the delivery of clinical trials in Canada. They are where trials are activated, patients are identified and enrolled, investigational products are administered, and ethics, safety, pharmacy, data, and operational oversight are managed. For that reason, HealthCare*CAN* members are directly affected by whether the proposed framework enables efficient trial delivery or introduces additional complexity at the site level.

Key Issues Raised by HealthCareCAN Members for Consideration

HealthCare*CAN* members recognize the importance of modernizing Canada's clinical trial framework. At the same time, members remain concerned that the proposed regulations may not sufficiently reduce regulatory burden and, in some areas, may introduce additional uncertainty. HealthCare*CAN* supports the central recommendations advanced by RareKids-CAN/SickKids, particularly the need to reduce net burden, improve predictability, preserve clearer risk-proportionate pathways for lower-risk studies, and address ongoing fragmentation across product types.

Members emphasized that these pressures are felt most acutely at the point of trial delivery. Hospitals, research institutes, clinicians, and trial teams must absorb the operational, legal, pharmacy, diagnostic, data, and workforce demands associated with running clinical trials, often within already stretched care environments. Members also noted that the proposal does not sufficiently reflect the realities of academically driven and institutionally delivered trials, including studies designed to answer important questions for patients and health systems outside commercial market authorization pathways.

Members further noted that where lower-risk studies are not treated proportionately, this can create additional burden not only for institutions and clinicians, but also for patients, including more complex processes, added visits, and delays in access. These pressures also have clear equity implications, as institutions with fewer resources may be less able to absorb added burden, meaning access to clinical trials can increasingly depend on geography and local capacity. In a country where many trials depend on broad multi-site participation, the final framework should reduce unnecessary burden and support more equitable participation across institutions and regions.

Recent discussion with industry partners, including Innovative Medicines Canada, reinforced the importance of a framework that supports clinical trial activity in Canada, strengthens patient access, and improves Canada's competitiveness as a destination for clinical research. They emphasized the need for a more efficient and predictable end-to-end pathway from clinical trial application submission to site activation and patient enrolment, noting that delays across this continuum can affect trial feasibility and influence sponsor decisions on where to place trials. While the proposed framework introduces new tools and flexibilities, it does not yet provide sufficient clarity that these measures will reduce burden or improve predictability in practice. Extended review timelines, broad discretionary authorities, and

continued fragmentation across product types risk adding uncertainty rather than enabling more efficient trial delivery. Members also emphasized that modernization should be reflected in faster trial start-up, more timely patient enrolment, and a more workable delivery pathway across sites.

Key Regulatory Changes Needed

The proposed changes fall far short of what is required to meaningfully modernize Canada's clinical trials regulatory framework and risk adding regulatory burden at a time when government has committed to cut red tape. The recommendations advanced by RareKids-CAN/SickKids are reinforced by HealthCare*CAN* member and industry feedback, and HealthCare*CAN* urges Health Canada to strengthen the proposed regulations in the following key areas.

1. Review Timelines: HealthCare*CAN* members support maintaining the 30-day clinical trial application review timeline as the standard. The proposed ability to extend timelines to 60 days introduces uncertainty and risks delay, particularly without clearly defined and transparent criteria. Members noted that delays at the regulatory stage affect site activation, clinician workflows, patient enrolment, and overall trial feasibility across both pediatric and broader trial contexts.

2. *Terms and Conditions:* Members identified a lack of clarity regarding the use of Terms and Conditions. Without clearer guidance, these authorities may introduce additional uncertainty and operational burden for the institutions responsible for implementing trials. For HealthCare*CAN* members, predictability is essential to planning, resourcing, and supporting clinicians and research teams. Greater clarity, including clearer enabling use cases, would help ensure Terms and Conditions function as a tool for proportionate oversight rather than an added source of operational complexity.

3. *Risk-Proportionate Pathways:* HealthCare*CAN* members emphasized the importance of preserving clear and workable pathways for lower-risk and treatment-oriented studies, including pragmatic and academically led trials involving authorized products with established safety profiles. Members noted that the absence of a clear pathway for these studies poses challenges, particularly where important clinical questions are being pursued outside commercial drug development pathways. Without a clear risk-proportionate approach, institutions may face unnecessary regulatory complexity that adds burden for clinicians, trial teams, and patients without corresponding benefit to patient safety. Health Canada should clearly state whether and how the Investigational Status Assessment (ISA) pathway, or an equivalent successor mechanism, will operate under the new framework.

4. *Harmonization:* Members also noted that the exclusion of medical devices and natural health products from the proposed framework is a missed opportunity. Increasingly, trials involve integrated designs across product types, and maintaining separate pathways creates duplication and administrative complexity for the institutions delivering trials. Members further emphasized the importance of reducing fragmentation more broadly across jurisdictions and processes, as

more coordinated pan-Canadian approaches to trial start-up and delivery would improve efficiency, support multisite participation, and strengthen competitiveness. HealthCare*CAN* encourages Health Canada to consider a second phase of modernization that advances harmonization across drugs, devices, and natural health products.