

Statement on Health Canada's pilot to reduce regulatory barriers to paediatric standard of care clinical trials

22 October 2026

On October 14, 2026, Health Canada announced a pilot program to reduce barriers for select academic-led paediatric standard of care clinical trials. The announcement is the result of months of collaborative work led by [RareKids-CAN](#) and the [SickKids Child Health Policy Accelerator](#), with contributions from academic paediatric clinical trialists across Canada.

Challenges associated with paediatric epidemiology, limited funding, and deficiencies in drug labelling have left many routine therapies for children with critical gaps in evidence to guide everyday care. Evidence generation is further hindered by paediatric-specific regulatory barriers that require studies examining drugs with longstanding safety and efficacy data, such as ibuprofen and oxygen, to comply the same clinical trial regulations as new molecules or gene-based therapies.

To enhance access to high-quality, evidence-based care for children, RareKids-CAN and the Child Health Policy Accelerator have been advocating for **a full regulatory exemption pathway for low-risk paediatric clinical trials involving drugs routinely used in clinical practice. We welcome Health Canada's pilot as a first step towards this objective.**

Beginning 30 October 2026, academics holding appointments in departments of paediatrics at Canadian faculties of medicine may apply to Health Canada's Paediatric Standard of Care Clinical Trials Pilot designed to reduce administrative requirements for eligible studies. Once accepted into the pilot, studies will be exempt from the requirement to submit a Clinical Trial Application (CTA), obtain a "no objection letter", and file CTA amendments and notifications. Participating studies must continue to comply with good clinical practices (GCP) and be approved by an institutional Research Ethics Board (REB).

The pilot is limited to studies involving pharmaceuticals sourced from the Canadian market used in accordance with standard of care practices described in institutional, local, national or international guidelines. Drugs must also meet at least once of the following criteria: be approved in Canada for the investigational indication for adults; have been approved and available on the Canadian market for at least 10 years; or be approved by the European Medicines Agency (EMA) or US Food and Drugs Administration (FDA) for the same use in the target paediatric population.

We applaud Health Canada for taking this important first step towards addressing administrative barriers to paediatric clinical trials. We will continue to work collaboratively towards a complete regulatory exemption for all academic-led, low-risk paediatric clinical trials, aligned with leading international regulators and the Government of Canada's red-tape reduction initiative. In the interim, we look forward to supporting the pilot's implementation and evaluation.

Further information on barriers to paediatric clinical trials and international models for risk-proportionate regulation is available in our [PRACTICE white paper](#).

About RareKids-CAN and the SickKids Child Health Policy Accelerator

RareKids-CAN is a diverse coalition of researchers, patient and family partners, research networks and patient organizations across 16 paediatric research institutions in Canada. It aims to develop and accelerate high-quality paediatric rare disease clinical trials and enable access to innovative treatments in Canada for children and their families.

The SickKids Child Health Policy Accelerator is Canada's first hospital-based applied child and youth health and social policy initiative. It aims to close the gap between what we know is effective in optimizing the well-being of children and youth, and what we do to attend to the needs of young people in the federal public policy space.

For further information, please contact the SickKids Child Health Policy Accelerator team at childhealth.policyaccelerator@sickkids.ca.