



Collaborating to build a Canada-wide research ethics review system that benefits all Canadians.

CTO Clinical Trials Conference November 5, 2025

### Now more than ever, Canada cannot be left behind.

Rigorous research ethics review is critical to safeguard participants. Canada's top-quality REBs are fit for the task. But right now, Canada-wide reviews are onerous, duplicative and can present a barrier to access.

# Canada needs a more competitive, resilient clinical trials ecosystem.

The global trials landscape is increasingly volatile. Other countries are moving forward with single reviews (Australia, Brazil, Denmark, Spain, UK, US). Canada must not fall behind.

# Clinical researchers and sponsors need clinical trials that are more predictable.

Multiple reviews create inconsistency, duplication, delays, and management burden. As a country, we must be more efficient or trials will go elsewhere.

## Canadians need equitable access to trial opportunities across Canada.

When trials come to Canada, Canadians should have equitable access to participate, regardless of where they live. When trials go elsewhere, patients miss out on critical opportunities.

### Efficient Review. Competitive Trials. Healthier Futures.

Our Vision:
A Canada-wide
ethics review
system that
benefits all
Canadians



Through collaboration, we aim to:

- Improve efficiencies and study start-up times
- Increase Canada's competitiveness in attracting global clinical trials
- Expand clinical trials to underserved, rural and remote locations
- Improve equitable access to trial participation
- Build a community of practice across REBs in Canada

CanReview is Canada's first system of this kind. Roadblocks are inevitable. Moving forward is critical.

### The CanReview Advantage:

#### **Speed**

- Canada-wide review in 28 business days\*
- Add sites in just 7 business days\*
- Faster trial activation across Canada

#### **Predictability**

- Guaranteed timelines
- Centralized coordination & support

#### **Consistency & Quality**

- High-quality and regulatory compliant reviews from CanReview Validated REBs
- Single auditable system with time-stamped records
- Standardized forms and templates
- Standardized fees across Canada
- Bilingual (French & English) system & reviews

#### Transparency

- Real-time visibility into review status, timelines and metrics
- Clear oversight and organization of the trial across all participating sites

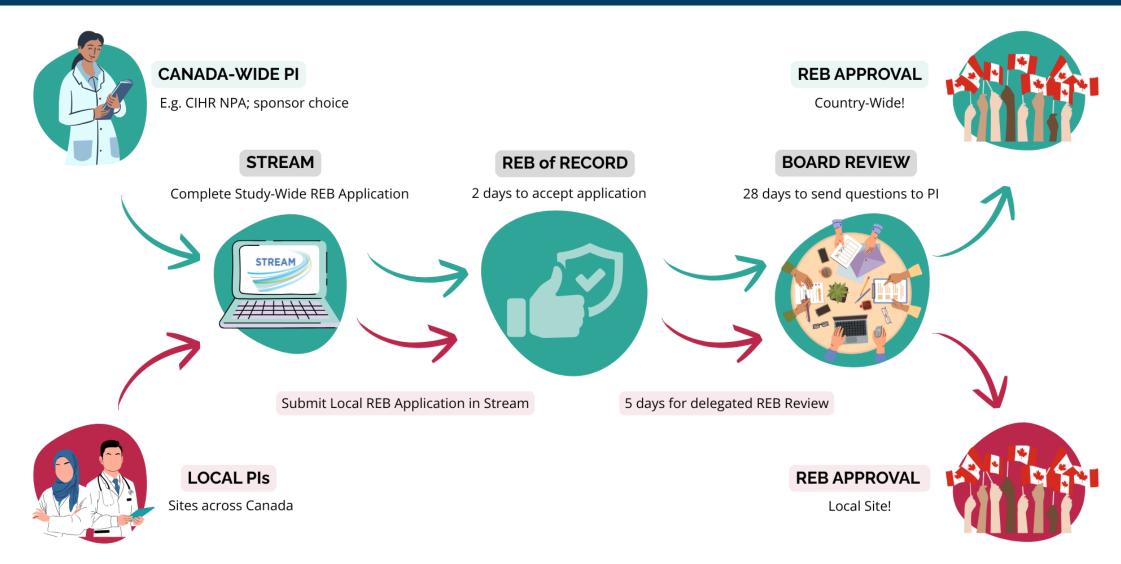
#### **Efficiency**

- One submission, one review process, one platform to manage study documents
- No duplication of reviews, less administrative waste



\*For Investigator-Initiated studies, 28-day timeline assumes an REB's typical 2-week deadline prior to Full Board Meeting and an application being submitted just prior to the deadline. Timelines exclude revisions, if required. Supports available to facilitate timelines.

### CanReview: How it works



### **CanReview Status Report**

#### Thanks to you, tremendous progress in only 11 months!

- ✓ Stream system is live for pan-Canadian studies and fully operational in French and English
- ✓ Tactical Team outputs complete:
  - ✓ REB validation pathways; Fee structure; Timelines; Informed consent forms; Public reporting metrics
- ✓ National consultation on CanReview Agreement complete
  - 91 institutions across 9 provinces downloaded for review
  - 26 institutions across 7 provinces submitted input
  - Input under review; near completion
- √ 100+ organizations fueling momentum as CanReview Partners





Only industry-sponsored or industry-supported studies are charged ethics review fees. Invoices are sent directly to the sponsors listed in the ethics application forms

A fee schedule can be found here.

### **Challenges Facing CanReview**

#### **Provincial Legislative or Government Policy**

- Quebec: Ministerial directives primarily;
   Quebec Civil Code in prescribed
   circumstances; insurance
- Alberta: Legislated Research ethics review limited to prescribed REBs located in Alberta

#### **Solutions**

- Facilitated mechanisms to support use of CanReview
- Can legislation change?
- Suggestions welcome!

### Using Stream (external, institutionally independent system)

- Many institutions (hospitals/universities) have their own research ethics review systems
- May be imbedded in or connected to broader institutional systems, or other institutions

#### **Solutions**

- Enter external REB approval in institutional systems
- Transfer data from Stream to institutions via APIs
- Program institutional systems to bypass data requirements related to ethics review only
- Institutional officials have full access/viewing to REB applications & approval documents
- Suggestions welcome!

### The Big Question: What is New?

#### NEW!

- Pan-Canadian & purpose-built single research ethics review platform (Stream)
- Strict timelines, including timelines for investigators, that are reasonable and fair
  - <u>Timelines, not shortcuts!</u> Leveraging existing review frameworks
- Multiple validation pathways for REB participation that are accessible and compliant
  - Accredited via Human Research Accreditation Canada *qualified 2 boards in Canada*
  - via the CTO REB Qualification Program qualified 20+ boards in Canada/50+ reviews
  - Qualified via the CHEER REB Assessment Program has qualified 2 boards in Canada
- **Distinct, Canada-wide** fee structure (industry-funded studies); consent forms; agreements
- Dedicated supports for research teams in both official languages
- Bilingual system available in French and English



### The Big Question: What is Not New?

#### SAME!

- Reviews conducted by an REB external to an institution
  - Lots of precedent across Canada and internationally
  - Support for this approach in Canadian ethics policy
  - Canada has excellent, high-quality REBs that can and do review on behalf of multiple sites
- Patient support for efficiency and bringing more trials to Canada
  - Canadian health charities and patient organizations were the first to endorse CanReview, with 20+ becoming CanReview Partners in the first week
  - Taking leading roles in CanReview governance and voicing support

"Some of us count on clinical trials to keep us alive – and we don't have time for bureaucracy."



### The Big Question: What <u>Can</u> be New?

#### STRONGER TOGETHER!

- Cross-Canada community of practice for REBs
  - REB Working Group, mentoring, harmonization
- High-quality submissions
  - Investigator Working Group, mentoring, navigator support, education and training
- More clinical trials opportunities
  - Easily and quickly expand trials to underserved locations across Canada
- Canadian leadership on the global stage
  - Canada recognized as the leading jurisdiction for high-quality, timely, predictable research ethics review with a single entry point



### Cross-Canada Collaboration: Leadership Team

### Represents 9 provinces and 1 territory, and includes Indigenous and patient and caregiver perspectives

- Barbara Mason, Ethics Director, Newfoundland Health Research Ethics Authority
- Eileen Denovan-Wright / John Sapp, Associate Dean Research, Faculty of Medicine, Dalhousie University
- Catherine Connors, Director, Research Ethics, Dalhousie University
- Jacquelyn Legere, Director, Human Research Protection Program, Horizon Health Network
- Denis Prud'homme, President and Vice-Chancellor, Université de Moncton
- Richard Carpentier, Associate Professor, Faculty of Medicine, Sherbrooke University
- **Erika Basile,** Director, Research Ethics and Compliance, Western University
- Lam Pho, Chief Information Officer, Canadian Cancer Trials Group
- Jacqueline Senych, Doctoral nurse, Indigenous perspective and diversity advocate; Co-Chair, Canadian Research Ethics Board Standing Operating Procedures, N2

- Kim McGrail, Professor, UBC; Principal Investigator, Canadian Health Data Platform
- **Anurag Singh**, Director, Northern Centre for Clinical Research; Assistant Professor, UBC; Assistant Professor, University of Northern BC
- Alexandra Hook, Chair, Research Ethics Committee and College Librarian, Aurora College
- Sunila Kalkar, Manager, Research Ethics & Regional Programs, Aurora College
- Donna Lillie, Caregiver perspective, CTO College of Lived Experience
- Murray Walz, Participant perspective, CTO College of Lived Experience
- Justin Ezekowitz, Professor, Faculty of Medicine & Dentistry, University of Alberta
- Susan Jelinski, Director, Human Research Ethics, University of Saskatchewan
- Alison Orth, Portfolio Director, Research Programs, Michael Smith Health Research BC
- Elizabeth Lylyk, Director, RITHIM, Research Manitoba





### **Cross-Canada Collaboration: External Advisory Committee**

### Represents 5 provinces, cross-cutting Canada-wide sectors and regulators, and includes international perspectives from the U.K., the U.S., Australia and WHO

Dr. Alice Aiken, Professor, School of Physiotherapy, Dalhousie University

**Andrew Casey**, Vice President, Government Relations & Policy, Apotex

**Anne McKenzie,** Manager, Community Engagement, Telethon Kids Institute (Australia)

**Dr. Bettina Hamelin, President & CEO, Innovative Medicines Canada** 

**Dr. Fei Fei Liu,** Professor, Departments of Radiation Oncology, Medical Biophysics, and Otolaryngology, University of Toronto

**Dr. Guy Rouleau,** Chair of the Department of Neurology and Neurosurgery, McGill University

**Dr. PJ Devereaux**, Senior Scientist, Deputy Director, PHRI

**Thomas Smith,** Research Ethics Committee member (HRA), Expert Patient (NIHCE), Health Research Authority & the National Institute for Health and Care Excellence (UK)

Wendy Zatylny, President & CEO, BIOTECanada

**Dr. Janet Dancey,** Director, Canadian Cancer Trials Group

Dr. Justin Ezekowitz, Professor, Faculty of Medicine & Dentistry, University of Alberta

Matt Westmore, Chief Executive, Health Research Authority (UK)

**Dr. Megan Bettle,** Executive Director, Clinical Trials, Canadian Institutes of Health Research / Government of Canada

**Megan Singleton**, Associate Dean, Human Research Protections and Director of the Human Research Protections Program, Johns Hopkins University School of Medicine

Nicole Dekort, President & CEO, Medtech Canada

**Dr. Robert McMaster,** Co-Chair, HealthCare CAN, and University of British Columbia (UBC)

David Lee, Senior Policy Advisor, Health Canada

(Observer) Dr. Vasee Moorthy, Infectious Diseases Physician, Immunologist and Product Developer, Office of the Chief Scientist, World Health Organization (WHO)





### Cross-Canada Collaboration: Tactical Teams

Following an open call for volunteers, 150+ people from across Canada participated on Tactical Teams to make key decisions and develop CanReview resources.

CanReview's five Tactical Teams included members from REBs, institutions, sponsors and patients, representing 9 provinces and 1 territory.

- ✓ System Timelines & Transparency
- ✓ REB Validation Process Tactical Team
- ✓ Agreements Tactical Team
- ✓ Single Informed Consent Form Tactical Team
- ✓ Industry Fees Tactical Team



### Cross-Canada Collaboration: Partners Fueling Momentum

100+





#### **Health Charities & Patient Organizations**

- Advocacy for Canadian Childhood Oncology Research Network
- Breakthrough T1D Canada
- Canadian Arthritis Patient Alliance
- Canadian Cancer Survivor Network
- Canadian Council of the Blind
- Canadian Lung Association
- Canadian PKU and Allied Disorders
- Canadian Skin Patient Alliance
- Colorectal Cancer Canada
- Colorectal Cancer Resource & Action Network
- Cystic Fibrosis Canada
- Fibromyalgia Association Canada
- Heal Canada
- Migraine Canada
- Ovarian Cancer Canada
- Pancreatic Cancer Canada
- Peer Medical Foundation
- Queering Cancer
- ReThink Breast Cancer
- Save Your Skin Foundation
- The Heather Cutler Foundation

#### **Research Ecosystem Partners**

- ACT-AEC
- BioTalent
- Canadian Institutes of Health Research (CIHR)
- Clinical Trials BC
- Clinical Trials Ontario
- Health Data Research Network Canada
- ICES
- Ontario SPOR SUPPORT Unit (OSSU)
- Research Manitoba
- Unité de soutien SSA Québec
- VITAL

#### Institutions

- Bruyère Health Research Institute
- Cape Breton University
- Centre for Addiction and Mental Health (CAMH)
- Hamilton Health Sciences
- Horizon Health Network
- Kingston Health Sciences Centre (KHSC)
- Kingston Health Sciences Research Institute
- Lakeridge Health
- Lawson Research Institute
- London Health Sciences Centre Research Institute
- McGill University Health Centre
- McMaster University
- Montreal Behavioural Medicine Centre
- Oak Valley Health
- Ottawa Hospital Research Institute
- Population Health Research Institute
- Queen's University
- SickKids
- Shared Health Manitoba
- Sunnybrook Health Sciences Centre
- Sunnybrook Research Institute
- The Research Institute of St. Joe's Hamilton
- The Royal
- Unity Health Toronto
- University Health Network
- University of Manitoba
- University of Ottawa Heart Institute
- University of Saskatchewan
- University of Waterloo
- Western University
- William Osler Health System

#### **Industry & Suppliers**

- Bayer
- Care Access Research Canada
- GSK
- Innovative Medicines Canada
- Roche Canada
- RAN BIOLINKS

#### Research Networks

- BioCanRx
- Canadian Association of Interventional Cardiology CT Network
- Canadian Critical Care Trials Group
- Canadian Donation and Transplantation Research Program
- Canadian Emergency Department Research Network
- Canadian Heart Function Alliance
- Canadian Home Mechanical Ventilation Research Network
- Canadian Immunization Research Network
- Canadian Medical Cannabis Clinical Trials Network
- Canadian Medication Appropriateness and Deprescribing Network
- Canadian Nephrology Trials Network
- Canadian Paediatric Inpatient Research Network
- Canadian Research Network for Adult Congenital Heart Disease Interventions
- Canadian Stroke Consortium
- Canadian Stroke Prevention Intervention Network (CSPIN)
- CANet
- CanSPARK LTC
- CanStroke Recovery Trials
- CANUCS
- Chronic Pain Network
- Diabetes Clinical Trials Network (DCTN)
- Digital Health and Discovery Platform
- GEMINI
- IMAGINE Network
- Infectious Disease Network
- INFORM Rare Network
- Life Saving Therapies Networks
- Marathon of Hope Cancer Centres Network
- Network for Obesity Trials
- Orthopaedic Trauma Surgery Research Network
- Pan-Canadian Palliative Care Research Collaborative (PCPCRC)
- Pan-Canadian Trial Network in Valvular Heart Disease
- Perioperative Care Network
- PregTrial
- Terry Fox Research Institute
- The Network of Networks (N2)

### Forward Momentum

#### CanReview is a collaboration. Let's row together!

This is Canada's first attempt at a much-needed solution to improve research ethics review and strengthen Canadian clinical research.

We are calling on everyone to make it the best it can be.

#### **GET INVOLVED:**

- Serve as an REB Host Institution
- Become a Participating Site/REB
- Become a CanReview Partner
- Advocate for change
- Let's meet and talk











# CanReview

## Thank you

Contact us:

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