

# Considerations for Accelerating Clinical Trials-2 (ACT-2)

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# Impressions on ACT

- A lot has been achieved in the first 1.75 years
- We do not believe initiatives like ACT should live on forever
- ACT will have achieved its goal if:
  - Permanent efficient systems are implemented, government implements sustained funding for RCTs and portfolio hospital program, Canadian biotech grows, and more big pharma and device company trials come to Canada
    - This ultimately benefits the Canadian public

# Question

- Are the roots of system changes we are implementing deep enough to ensure they will live on after the grant ends in September 2025?

# Laying the Groundwork for ACT-2

- Feb 2024: National and International Advisory Committee recommended that ACT:
  - Continue to implement system changes needed within the Canadian clinical trials ecosystem
  - Advocate for funding for ACT-2 to ensure system changes are permanent

# What an ACT-2 might look like

- Seek additional 3 years of funding to solidify system changes
  - ensure success of pan-Canadian, distributive, single REB review and approval process with strict timelines
  - sustain and expand portfolio funding embedding study personnel in community hospitals across Canada
  - ensure successful implementation of master clinical trial agreements
  - continue to help grow Canadian biotech through granting opportunities for trials evaluating Canadian biotech

# What an ACT-2 might look like

- New initiatives:
  - creating change to ensure study personnel can inform all eligible patients about trials relevant to their health
  - set up network contact process to facilitate rapid determination of interested sites for pharma and investigator-initiated trials
  - stakeholder process to inform waiver of consent

# Planning for ACT-2

- Need to make our case that ACT has been successful and is worth funding for an additional 3 years to solidify important system changes
- Work with partners to help make our case

# Survey Results: ACT's Impact to Date

- **Enhancing** research infrastructure, supporting salaries for research coordinators, and ensuring smaller hospitals can practice in clinical trials through the **Clinical Trials Units**
- **Building** and **strengthening** coordinated networks between ACT networks, clinical trials units, and hospitals, and improving collaborative research efforts
- **Standardizing** frameworks for ethics, data-sharing agreements, and a unified National Research Ethics Board (REB) for more streamlined approvals
- **Building research capacity** with “Boots on the Ground” efforts like funding on-site research staff to sustain clinical trial momentum and success, and building training platforms
- **Advocating** for a unified RCT framework and gathering thought leaders to address research barriers and clinical trial limitations



# Survey Results: Looking Forward to ACT-2

- Creating a more **unified and efficient clinical research environment**
- Continuing to fund research coordinators in community hospitals and underrepresented fields
- **Expanding trial networks** beyond major centers
- Establishing a **National Research Ethics Board**
- **Simplifying ethics and regulatory processes** and paperwork
- Continuing to support **Canadian Biotech**

# Survey Results: Looking Forward to ACT-2

- Supporting **early-career** researchers
- Securing more **funding** for **pilot trials**
- Building a **platform** for **sharing research tools** and best practices

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# Our Support for ACT Has 4 Elements



Conducting a **Policy and Funding Environmental Scan** to capture (I) the current state of federal health data and research funding; and (II) the policy and political drivers shaping its future state over the next 12-18 months.



Developing a **Sustainability & Impact Plan** that provides ACT-AEC with a set of core strategic priorities and the accompanying actions and tactics required to secure additional financial support from the Government of Canada.



Delivering a **Messaging and Materials Audit** to better highlight the ACT-AEC's value via a robust portfolio of briefing notes and infographics to slide decks and leave-behinds.



Serving as a **Government Relations Advisor and Counsel** as the organization begins to implement its Sustainability Plan and leverage its new collateral.

**1. Gathering Key Insights**

**2. Developing a Value Case**

**3. Communicating with Policymakers**

# Questions for Consideration

- Are there any additional focus areas we should consider for ACT-2?
- Do you have any ideas on how we can secure funding to sustain and expand these efforts?