

Update on ACT-2 proposal

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ACT-2.0 goals

- 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
 - provides platform that would allow CIHR to require single review process for CIHR funded trials, consistent with government goal of avoid duplication of approvals
- Sustain and expand portfolio funding embedding study personnel in community hospitals across Canada creating
 - greater democratization of access to trials for more Canadians and
 - facilitating pandemic preparedness

ACT-2.0 goals

- Seek additional **3 years of funding** to solidify system changes
 - Ensure successful implementation of master clinical trial contracts
 - improve clinical trial timelines and bring more trials to Canada
 - Continue to help grow Canadian biotech through granting opportunities for trials evaluating Canadian biotech
 - help keep Canadian biotechnology Canadian and grow Canadian economy
- Ensure implementation of WHO regulatory guidance for conduct of clinical trials
 - enhance efficiency of trials

ACT-2.0 goals

- New **Initiatives**
 - Creating change to ensure study personnel can **inform** all eligible patients about trials relevant to their health
 - Create network **contact process** to facilitate rapid determination of interested sites for pharma and investigator-initiated trials
 - Create **concierge service** to help direct investigators and companies regarding Canadian processes and services for conducting trials (e.g., regulatory, ethics, CTUs, networks)
 - Create more equitable system to ensure women of **childbearing potential** or **pregnant/lactating** women are not automatically excluded from trials
- Request additional \$40 million in funding for next 3 years

Activities to date

- Renewal committee
- Pitched proposal to Ministry of Health and ISED
- Discussed with CIHR leadership
- Overall substantial support for what ACT has achieved and proposal for ACT-2
- Reaching out to industry partners to request support
- No firm funding commitment as of yet
- We will continue to advocate for funding

Conclusions

- RCTs provide **health opportunities** for Canadians and have **positive impacts** on our economy
- ACT-1 has been successful
- There is a need for ACT-2
 - to solidify the implementation of several ACT-1 initiatives and
 - create further system change to make Canada the most efficient country in the world for doing trials
 - so investigators and companies will bring their trials to Canada
 - we will create more health opportunities for Canadians and
 - we will grow the economy in the process