

# • ACT Canada: Annual All Networks Virtual Meeting

• October 28, 2025 | 12:00 – 1:30PM (ET)

**1. Introduction** – *Clara Bohm (co-chair)*

**2. Land Acknowledgement** – *Karthik Tennankore (co-chair)*

**3. ACT Updates** – *PJ Devereaux*

- *ACT Conference Summary*

- *ACT 2.0*

**4. ACT Initiatives Updates** – *Alexander Lim*

- *Single National REB*

- *Governing Participating Site Agreement for Tri-Council Funder Studies: Interventional and Regulated*

**5. Research Networks Updates** – *Clara Bohm*

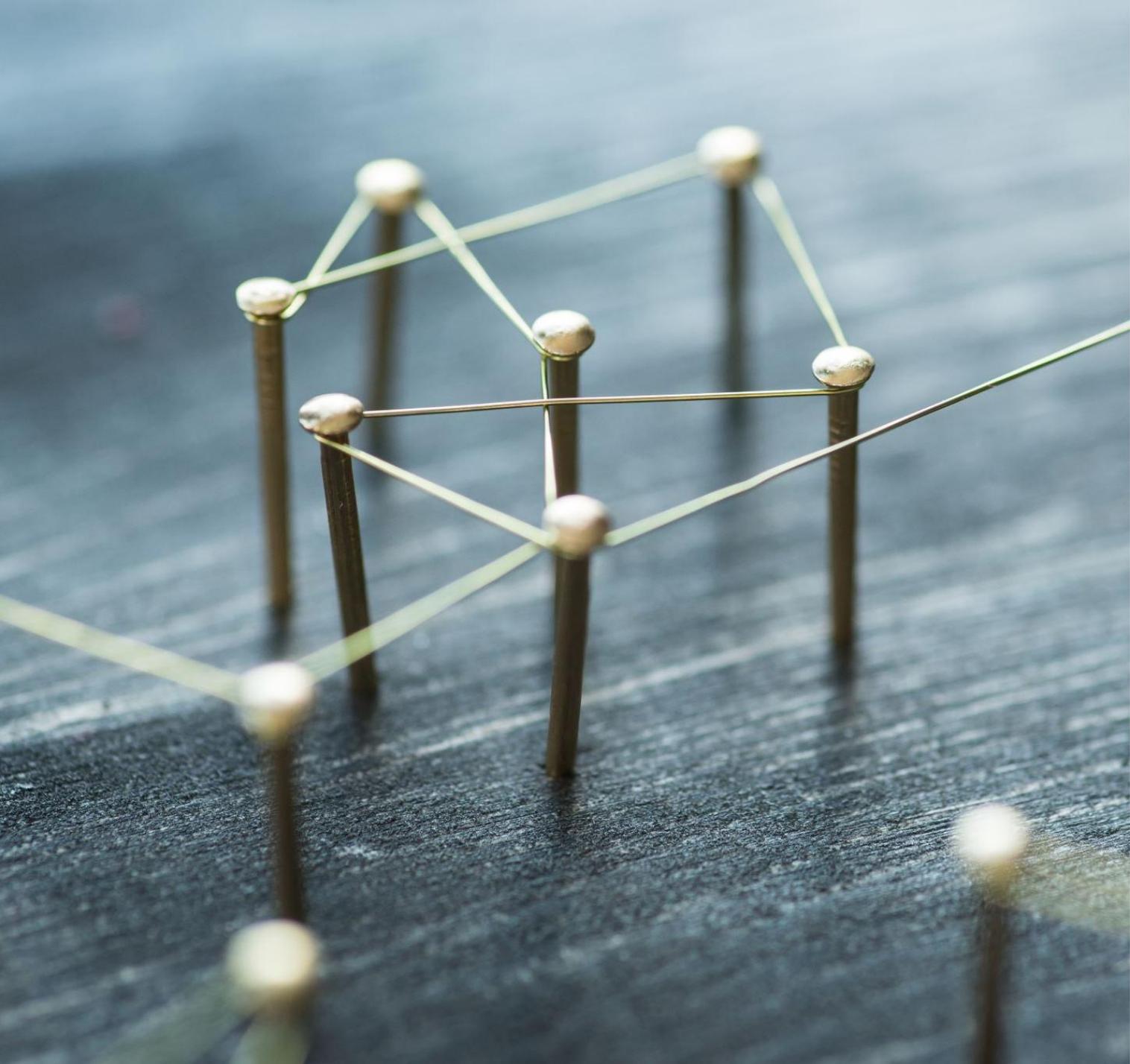
**6. Portfolio Hospitals** – *Aviva Blacher*

**7. General Discussion**

**8. Closing Remarks** – *Karthik Tennankore*



# Land Acknowledgement



# Discussion & Questions

# Update on Accelerating Clinical Trials (ACT) Consortium

P.J. Devereaux, MD, PhD

ACT Operations Committee Co-Chair

# Since the last All Networks Meeting...

*(June 2024)*

- Single national REB review and approvals process with strict timelines (CanReview) has launched
- ACT contracts working group has implemented the Governing Participating Site Agreement for Tri-Council Funded Studies: Interventional and Regulated (gPSA Regulated)
- CTU group has selected RAN Bio Links as the preferred eTMF vendor
- Ongoing engagement and advocacy with provincial/federal stakeholders on future funding for ACT 2.0

# Since the last All Networks Meeting...

*(June 2024)*

- Publication and impact of several trials funded by ACT: 5 NEJM, 2 Lancet
- Contributed to international efforts
  - Promotion of WHO guidance for best practices for clinical trials
  - Application to the WHO's Global Clinical Trials Forum
- Held 2 funding opportunities
  - RFA 6 – Canadian Biotech
  - Knowledge Mobilization RFA
- Initiation of Indigenous demonstration projects

# RFA 5 – To bring high-impact RCTs to Canada

- RFA announced August 30, 2024
- Call to encourage new collaborations between Canadian researchers and international, high-impact RCTs
- Submission deadline September 30, 2024
- 19 applications from 12 networks

# RFA 5 – To bring high-impact RCTs to Canada

- Targeted peer review process
  - Each application was reviewed and scores by 5 independent reviewers with clinical trial experience
- Total \$2 million in funding available
  - 10 applications x \$200,000 CAD each
- Successful applications announced November 22, 2024
  - Includes collaborations across 5 countries - Australia, Finland, Germany, United Kingdom, United States

PI names	Country	RFA 5 Funded International RCT Brought to Canada
Dr. Reshma Amin, Dr. David Berlowitz	Australia	The 3TLA Study: A Randomized Controlled Trial of Polysomnographic Titration of Non-invasive Ventilation in Amyotrophic Lateral Sclerosis
Dr. Georg Schmölder, Dr. Calum Roberts	Australia	SURFSUP: SURFactant Administration by SUPraglottic Airway
Dr. David Collister, Dr. Meg Jardine	Australia	BEAT-Calci: Better Evidence And Translation for Calciphylaxis
Dr. Philippe Violette, Dr. Arnav Agarwal, Dr. Kari Tikkinen	Finland	ARTS: Avoiding Risks of Thrombosis and bleeding in Surgery
Dr. Jason Andrade, Dr. Paulus Kirchhof	Germany	EASThigh: Early atrial fibrillation ablation for stroke prevention in patients with high comorbidity burden
Dr. Ratika Parkash, Dr. Pier Lambiase	United Kingdom	CRAAFT-HF: Cryoballoon/Radiofrequency Ablation of Atrial Fibrillation versus Medical Treatment for Heart Failure
Dr. François Lamontagne, Dr. Neill Adhikari, Dr. Donald Arnold, Dr. Peter Watkinson	United Kingdom	Threshold for Platelets (T4P): a prospective randomised trial to define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure
Dr. Derek Dillane, Dr. Mark Neuman	United States	MAC-HF: My Anesthesia Choice: Implementing An Evidence-based Approach To Increase Shared Decision-making In Anesthesia Care For Patients Undergoing Hip Fracture Surgery
Dr. Laura Marie Drudi, Dr. Manesh R Patel	United States	IMPROVE-AD: IMPROving Outcomes in Vascular disease – Aortic Dissection
Dr. Maral Ouzounian, Dr. David Wood, Dr. Philippe Pibarot, Dr. Raj Makkar	United States	BELIEVERS: Imaging Substudy of Bicuspid aortic valve replacement: Evaluation of transcatheter Versus surgical-PILOT Trial

# RFA 6 – Canadian Biotech Trials II

- RFA announced November 5, 2024
- Call to fund trials evaluating biotechnologies from Canadian-controlled private corporations (CCPCs) in partnership with Canadian clinical trialists from ACT Networks
- Submission deadline January 5, 2025
- 31 applications from 19 networks

# RFA 6 – Canadian Biotech Trials II

- Targeted peer review process
  - Each application reviewed and scored by 9 independent reviewers
    - 4 biotechnology reviewers to assess technology potential
    - 5 clinical trialist reviewers to assess trial and budget
- Total \$2 million in funding available
  - 5 applications x \$400,000 each
- Successful applicants announced February 19, 2025

PI name(s)	Biotech	RFA 6 Funded RCT
Dr. Sean Dukelow Dr. Janice Eng Dr. Mark Bayley	VIBRAINT Inc.	ANIMATOR: brAin controlled robotic arM rehabilitation fOr stRoke
Dr. Sonny Dhanani Dr. Andrew Seely	TMS (Therapeutic Monitoring Systems)	Donation Advisor: Improving deceased organ donation and transplantation: a multicenter feasibility implementation randomized controlled trial of the Donation Advisor tool
Dr. Scott Halperin Dr. Brian Ward Dr. Joanne Langley	InventVac	HiaVaccinePhase2: A phase 2 randomized controlled trial of a Haemophilus influenzae type a vaccine in healthy Indigenous and non-Indigenous adults
Dr. Yasbanoo Moayedi Dr. Vivek Rao Dr. Phyllis Billia	Traferox Technologies	PROTECT PGD: Prospective Reduction Of Transplant complications through EnhanCed Preservation Therapy to prevent Primary Graft Dysfunction Pilot Randomized Trial
Dr. James Downar	Filament Health, Psilo Scientific Ltd.	PSYCHED-PAL: Psilocybin microdose for psychological distress in patients with advanced illness: A phase 3 double-blind, placebo-controlled, parallel-arm clinical trial

# Knowledge Mobilization (KM) Awards

- Announced February 10, 2025
- Knowledge Mobilization projects for high-impact RCTs
  - RCT must be completed by August 31, 2025
  - KM project must be completed by December 12, 2025
  - Up to \$10,000 available per project (\$50,000 total)
  - Evaluated by 3 reviewers: 2 trialists with KM expertise, 1 patient partner
- Submission deadline March 24, 2025
- Awardees announced May 5, 2025

# Knowledge Mobilization (KM) Awards

Study Title	PI
Your Answers When Needing Sleep in New Brunswick (YAWNS NB)	Dr. David Gardner, Dr. Andrea Murphy
Prevention of persistent pain with Lidocaine infusions in breast cancer surgery	Dr. James Khan
Walk 'N Watch Study	Dr. Janice Eng
Emergency Department Ondansetron Dispensing to Optimize Outcomes Through Knowledge Mobilization and Implementation	Dr. Stephen Freedman, Dr. Terry Klassen, Dr. Megan Bale-Nick
Virtual Rehabilitation for Long COVID: Knowledge Mobilization for Greater Impact	Dr. Tania Janaudis-Ferreira

# Annual ACT Conference Highlights

*Cape Breton, September 2025*

- Exploring alternative consent models
- Promoting investment in Canadian biotech
- Promoting WHO global action plan for clinical trials
- Removing barriers to the inclusion of populations traditionally excluded from clinical trials

# 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

# ACT-2.0 Actions to date...

- Created ACT-2.0 Renewal Committee
- Pitched proposal to Ministry of Health and Innovation, Science and Economic Development Canada (ISED)
- Discussed proposal with CIHR leadership
- Overall have received substantial support for what ACT has achieved and proposal for ACT-2.0
- Reached out to industry partners to request support
- No firm funding commitment as of yet
- We will continue to advocate for funding

# Reflections

- RCTs provide **health opportunities** for Canadians and have **positive impacts** on our economy
- ACT-1.0 has been successful
- There is a need for ACT-2 .0
  - to solidify the implementation of several ACT-1.0 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

# Gratitude for...

- ACT networks and CTUs
- Portfolio Hospitals
- Co-chairs and committee and working group members who have worked diligently towards ACT goals
- RFA reviewers
- Partners (CIHR, pharma, device companies, Bayer, IMC, Canadian biotech, Health Canada, patients)
- Central ACT support team

# Update on ACT/AEC Initiatives

Alexander Lim

ACT Consortium Manager

# Agenda

- CanReview – single national REB review and approvals process
- Contracts – gDSSA, sub-site template agreement, gPSA
- Training Opportunities

# Pan-Canadian, Distributive, Single REB Approval Process with Strict Timelines for Multi-Centre RCTs

- **Open** competition, objective selection process
- **CanReview** (<https://canreview.ca/>) selected
  - Leadership team consisting of experts from 10 Provinces and Territories
- Will utilize **digital platforms** for ethics approval which have already been audited and approved by both Health Canada and FDA

# CanReview

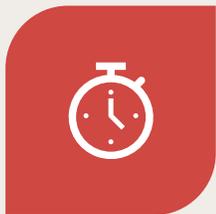
- Canada-wide review in 28 business days
- Add sites in 7 business days
- Guaranteed timelines and centralized support
- One submission, one review process, one platform to manage study documents
- Bilingual (French & English)

# CanReview Timeline

- Consultation window has ended in October
- Sign up institutions (starting Nov 2025); institutions signing on can:
  - Recruit participants to CanReview studies
  - Serve as a REB Host Institution (if validated)

To learn more or arrange a CanReview presentation for your network, please visit [www.canreview.ca](http://www.canreview.ca) or email [eva.friedman@canreview.ca](mailto:eva.friedman@canreview.ca)

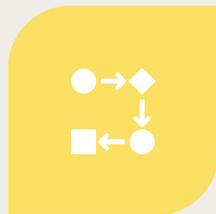
# Contracts Working Group Objectives



ACCELERATE THE CONDUCT AND EFFICIENCY OF CLINICAL TRIALS IN CANADA



STRENGTHEN COORDINATION AMONG CANADIAN CLINICAL TRIALS, FOSTERING COLLABORATION AND HARMONIZATION AMONG TRIAL UNITS, NETWORKS, AND STAKEHOLDERS.



REDUCE CYCLE TIMES IN THE NEGOTIATION AND EXECUTION OF AGREEMENTS.



DEVELOP MASTER CLINICAL TRIAL AGREEMENT(S) AND TEMPLATES.



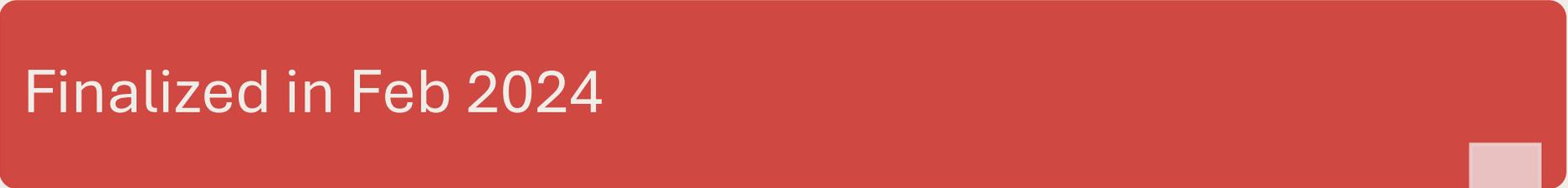
CREATE ADDITIONAL TOOLS, TEMPLATES, AND RESOURCES TO STREAMLINE CLINICAL TRIAL CONTRACTS IN CANADA.



RECRUIT AND ONBOARD ADOPTEES

# Governing Data and Sample Sharing Agreement (gDSSA)

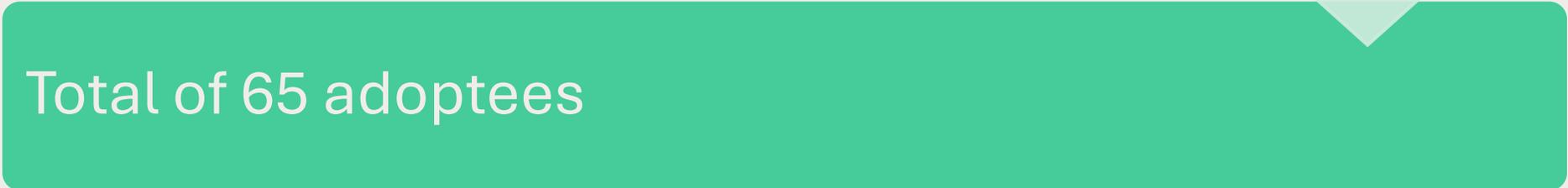
Finalized in Feb 2024



Execution copy circulated Feb 2024 which included 29 parties



Total of 65 adoptees



# Governing Participating Site Agreement for Tri-Council Funded Studies: Interventional and Regulated

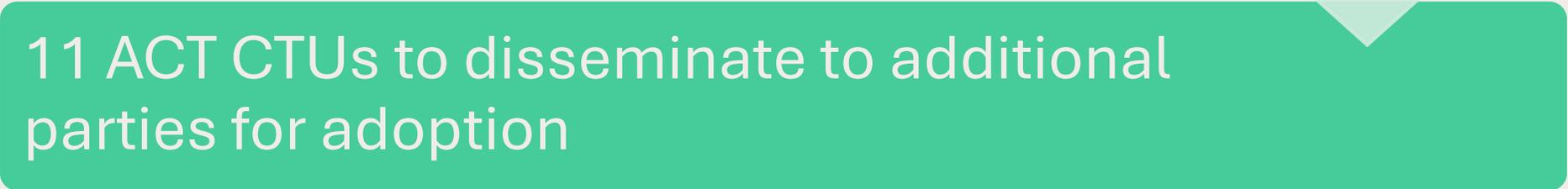
Finalized on July 12, 2025



Execution copy circulated August 2025  
included 28 parties



11 ACT CTUs to disseminate to additional  
parties for adoption



# Current Signatories & Adoptees

The Research Institute of the McGill University Health Centre	Dalhousie University
Kingston Health Sciences Centre Research Institute/Kingston Health Sciences Centre	The University of British Columbia
MICYRN	Provincial Health Services Authority (on behalf of BC Cancer)
CHU de Québec-Université Laval	Provincial Health Services Authority (on behalf of BC Children's Hospital and BC Women's Hospital & Health Centre)
The Hospital for Sick Children (Sick Kids)	Providence Health Care Society
Holland Bloorview Kids Rehabilitation Hospital	Vancouver Coastal Health Authority
IWK Health	University of Alberta
Shared Health	University of Manitoba
Hamilton Health Sciences Corporation	McMaster University
Research St. Joseph's - Hamilton o/a The Research Institute of St. Joe's Hamilton	Fraser Health Authority
Bruyère Health Research Institute	Vancouver Island Health Authority
London Health Sciences Centre Research Inc. dba. London Health Sciences Centre Research Institute (LHSCRI)	Unity Health Toronto
Lawson Research Institute (Lawson)	University Health Network
Ottawa Hospital Research Institute	The University of Western Ontario
	Sinai Health System
	Queen's University at Kingston

# Next steps...

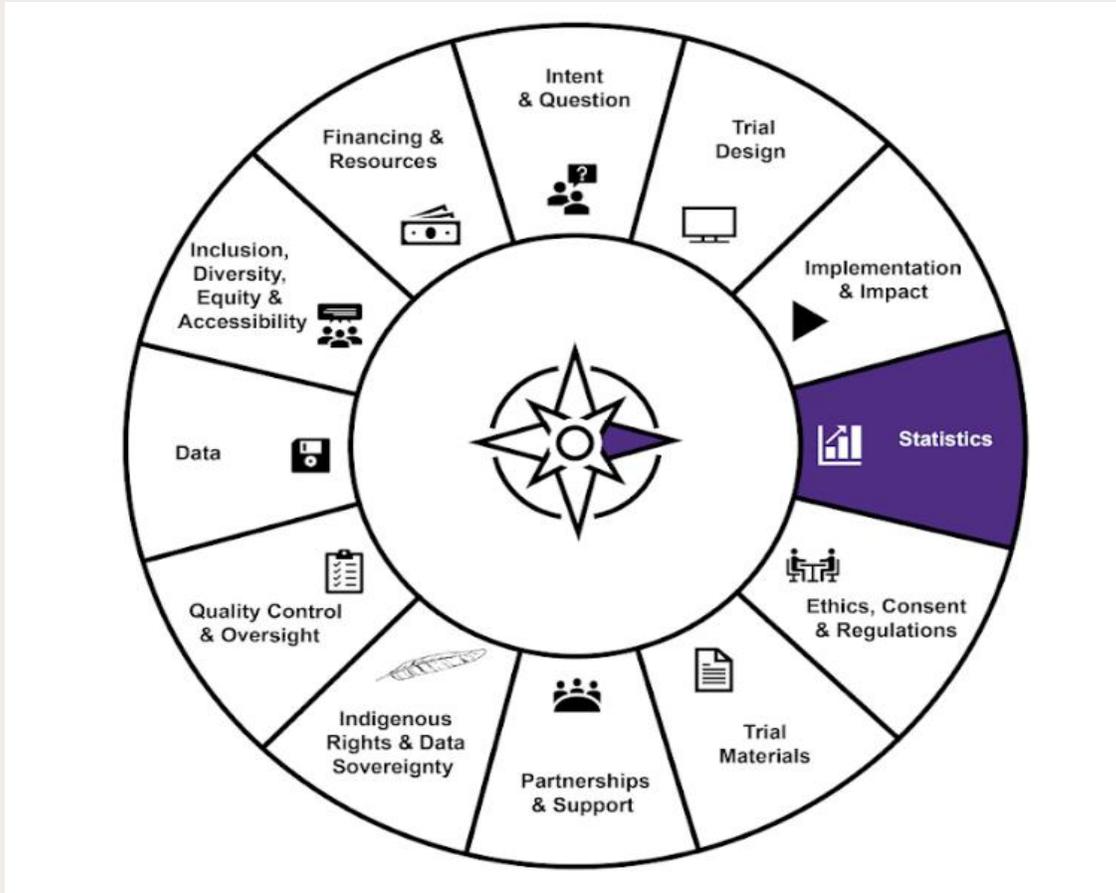
- Finalizing and rolling out the Governing Participation Site Agreement for the Tri-Council Funded and Unregulated Studies

For inquiries, email Contracts Working Group Co-Chairs  
[jencox@ohri.ca](mailto:jencox@ohri.ca) and [breanne.stewart@micyrn.ca](mailto:breanne.stewart@micyrn.ca)

# Training Opportunities

- Health Data Research Network Canada (HDRN)
  - Vision: data across Canada drive improvements in health and health equity
  - Mission: bring together people and organizations across Canada for transformative and world-leading health data use
  - Funded by CIHR
  - Provide educational material and training modules every week
    - Available to all

# Curriculum Wheel



For further information, visit:  
[www.hdrn.ca](http://www.hdrn.ca)

# Our CTTTP Partners



# Research Networks Committee Update

Dr. Clara Bohm

Dr. Karthik Tennankore

Co-Chairs ACT Research Networks Committee

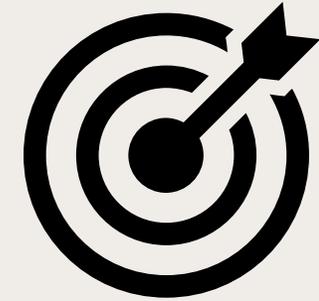
# Over the last 15 months...



- Research Networks Committee met with all ACT Networks
  - 28 existing ACT Networks
  - 6 New Networks
- During these meetings we discussed:
  - Yearly survey submissions
  - Network participation in ACT initiatives (RFAs, RFA reviews, meetings, committees, portfolio hospital collaboration, etc.)
  - Contractual obligations (structured governance, SOPs, etc.)
  - Research Networks Committee evaluation

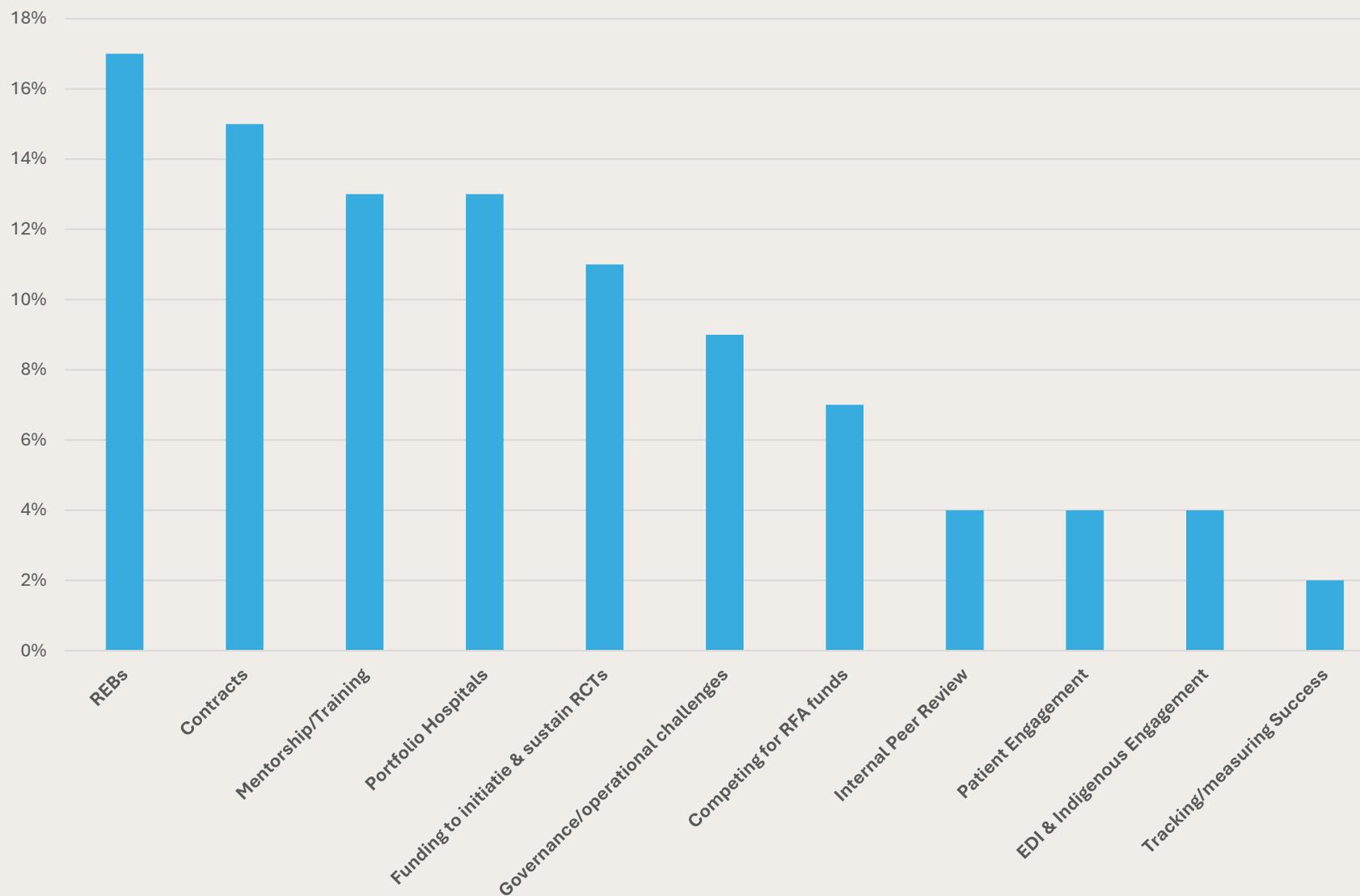


# Notable Successes

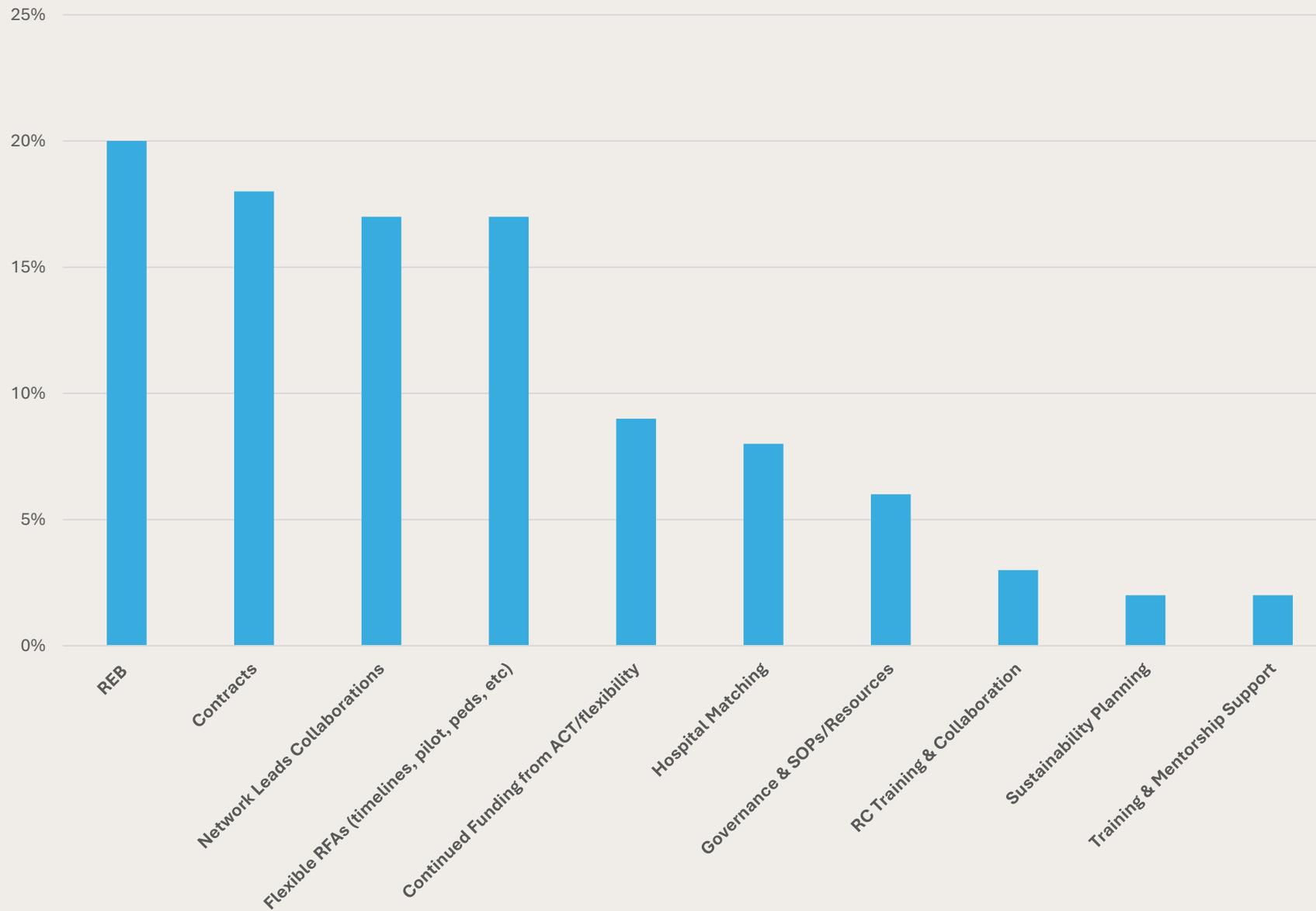


- Development of mentorship opportunities
  - Canadian Nephrology Trials Network
  - Pan-Canadian Palliative Care Research Collaborative
  - Canadian Platform for Trials in Non-Invasive Brain Stimulation
- Expansion into pediatrics
  - Infectious Disease SNAP trial
- Submission of large infrastructure grants
  - Pan-Canadian Palliative Care Research Collaborative
- Major CIHR-funded projects
  - Canadian Research Network for Adult Congenital Heart Disease Interventions

# Challenges Identified by Research Network



# How ACT Could Further Support Research Networks



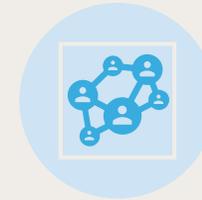
# Support Provided by Networks Committee



Governance documents and SOPs



Individualized guidance around proposed areas of development



Connected with networks, committees, and working groups to leverage specific network opportunities



Promoted additional meeting funding support of \$2800/year



Shared training opportunities



Present network highlights in monthly ACT newsletter

# Planned Future Support

- Network Leads meeting
  - Cross-network learning and collaboration
- Research Network Coordinator meeting
  - Potential training component
- Exploration of trial tracking platform and portfolio hospital matching
- Implement central platform for network resources
- Follow up with networks that may need additional support
- Summary reports & funding extensions



Q&A

Thank you



# Portfolio Hospital Updates

Aviva Blacher

*Third All Networks Virtual Meeting*

*October 28, 2025*

# 20 Portfolio Hospital Sites Across Canada

Funding for research coordinator to support clinical trial activities (1.0 FTE x 3 years)

- **Cambridge Cardiac Care (CCC)**
  - Dr. Shekhar Pandey - Cambridge, ON
- **Cape Breton Regional Hospital (CBRH)**
  - Dr. Paul MacDonald - Sydney, NS
- **Centre Hospitalier Affilié Universitaire Régional (CHAUR) de Trois-Rivières**
  - Dr. Jean-François Naud - Trois-Rivières, QC
- **Dr. Georges-L.-Dumont University Hospital Centre (DGLDUHC)**
  - Dr. Rémi LeBlanc - Moncton, NB
- **East Kootenay Regional Hospital (EKRH)**
  - Dr. Denise Jaworsky - Cranbrook, BC
- **Grace Hospital**
  - Dr. Gloria Vazquez-Grande - Winnipeg, MB
- **Health Sciences North (HSN)**
  - Dr. Robert Ohle and Dr. Ravinder Jeet Singh - Sudbury, ON
- **Hôpital de la Cité-de-la-Santé (CISSSLAV)**
  - Dr. Marios Roussos and Dr. Marco Bergevin - Laval, QC
- **Hôtel-Dieu de Lévis (HDL)**
  - Dr. Patrick Archambault and Dr. Martin Crête - Lévis, QC
- **Humber River Health (HRH)**
  - Dr. Gihad Nesrallah - North York, ON
- **Kelowna General Hospital (KGH)**
  - Dr. Matthew Boyko and Dr. Aleksander Tkach - Kelowna, BC
- **Mackenzie Health**
  - Dr. Kimia Honarmand and Dr. Tess Fitzpatrick - Richmond Hill, ON
- **Medicine Hat Regional Hospital (MHRH)**
  - Dr. Alejandro Manosalva - Medicine Hat, AB
- **Nanaimo Regional General Hospital (NRGH)**
  - Dr. David Forrest - Nanaimo, BC
- **Niagara Health**
  - Dr. Jennifer Tsang - St. Catharines, ON
- **Oak Valley Health (OVH)**
  - Dr. Dipayan Chaudhuri, Dr. Paul Lee, and Dr. Anthony La Delfa - Markham, ON
- **Penticton Regional Hospital (PRH)**
  - Dr. Michelle Scheepers - Penticton, BC
- **Queen Elizabeth Hospital (QEH)**
  - Dr. Heather Williams - Charlottetown, PE
- **Regina General Hospital (RGH)**
  - Dr. Payam Dehghani - Regina, SK
- **Windsor Regional Hospital (WRH)**
  - Dr. Wassim Saad and Dr. Caroline Hamm, - Windsor, ON



# ACT-AEC Portfolio Hospitals

# Network Trials at ACT Portfolio Hospitals

Sites

**20**

Networks

**17**

Trials

**75**

Patients  
Screened\*

**6500+**

Patients  
Enrolled

**1600+**

*...thank you for all your hard work!*

# Feedback So Far

- From Research Networks

- *Specialties and services* available at sites
- Communication regarding staff availability and feasibility
- Acknowledgment that not all research areas are suited to this model

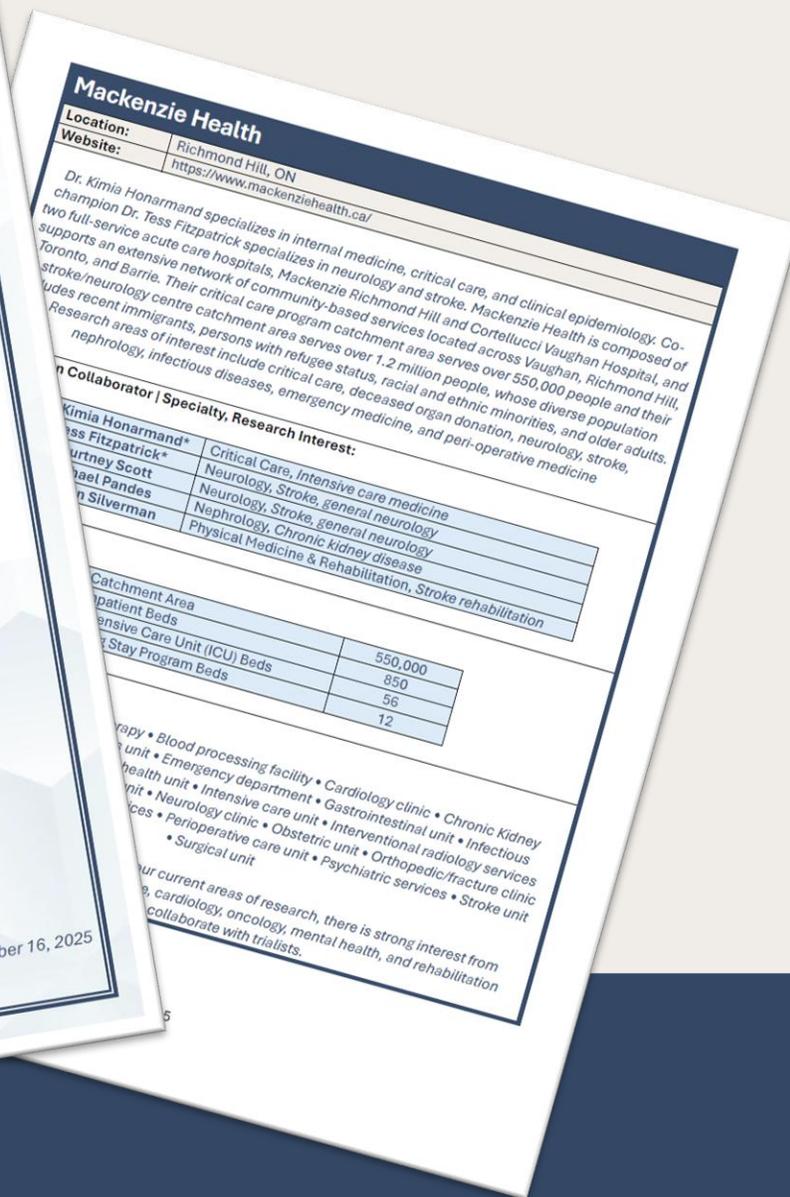
- From Portfolio Hospitals

- *Availability and timelines* for trials across networks
- Communication as new trials become available
- Requests for pragmatic trials, stage 3 trials, trials with lower staff burden, and trials focused on patient outcomes

# Trial Matching Resources



# Site Identification: Profiles and Videos



- Physician specialties and research interests
- Catchment area, Inpatient beds, ICU beds, IMCU beds
- Available units and services
- Hospital website
- **Videos upon request**

# Trial Identification: Notification and Repository

- ACT Trials Survey

- 5 mins survey for trials that want to recruit from portfolio hospitals
  - *e.g. anticipated recruitment start and end dates, provincial REB approvals, specialists/services required*
- Accessible to all trialists from **ACT Networks and CTUs**
- Selected sites receive summary of trial details

- ACT Trials Repository

- Central location for all trials looking to recruit from sites
- As availability changes, sites can refer to this collection

# Trial Identification: Notification and Repository

## ACT Trials Survey:

[redcap.link/ACTTrialsSurvey](https://redcap.link/ACTTrialsSurvey)

## ACT Trials Report:

[redcap.link/ACTTrialsReport](https://redcap.link/ACTTrialsReport)

*Please let us know if you would like  
your trial featured in a*

**Recruitment Newsletter**



# Other Planned Support

- **Portfolio Hospital Committee**
  - Dedicated support and direction
  - Final annual reporting
- **Metrics Tracking**
  - Clarity on trial enrolment and site activity
  - Information sharing across sites
- **Targeted Info Sessions**
  - Scientific Research and Experimental Development (SR&ED) tax credits and CIHR payments for physician-researchers
- **Lessons Learned**
  - Paper summarizing site and trialist experience



# Questions?

[aviva.blacher@phri.ca](mailto:aviva.blacher@phri.ca)

*Thank you!*