Updates

ACT-Inclusivity, Diversity, Equity and Accessibility (IDEA) Working group

Co-Chairs: Drs. Louise Pilote and Marie-Annick Clavel

Committee Members

Postdoctoral Fellow: Dr. Syamala Buragadda

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Outline

IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

Phase 1-Identifying Barriers and Facilitators
Phase 2- Scoping Review of Existing Toolkits
Phase 3- Reviewing Participant Diversity in Canadian Clinical Trials

Resources- key components of the toolkit

ACT-IDEA Working Group Members

- **Eva Friedman (ACT staff)**

- Stuart Nicholls
- Diego Herrera
- Leanne Casaubon
- Julia Chehaiber
- David Collister
- Patricia Gongal
- Sarina Isenberg
- Alexandra King
- Patricia Li
- Heather Lochnan
- Manon Picard
- Courtney Pollock
- Amity Quinn
- Shannon Ruyzcki
- Shelley Zieroth

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

ACT-IDEA Working Group Objectives

Contribute to the democratization of clinical trials by

Understand Representation

Identify Barriers and Facilitators

Provide Guidance Tool kit

Gather Metrics

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Supporting Canadian Trialists

Toolkit for Conducting Inclusive Clinical Trials

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Inclusive Clinical Trials

More comprehensive data

Better health outcomes for marginalized communities

Effective healthcare interventions

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Outline

Overview of IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

- Phase 1-Identifying Barriers and Facilitators
- Phase 2- Scoping Review of Existing Toolkits
- Phase 3- Reviewing Participant Diversity in Canadian Clinical Trials

Resources- key components of the toolkit

Outline

Overview of IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

Phase 1-Identifying Barriers and Facilitators

Resources- key components of the toolkit

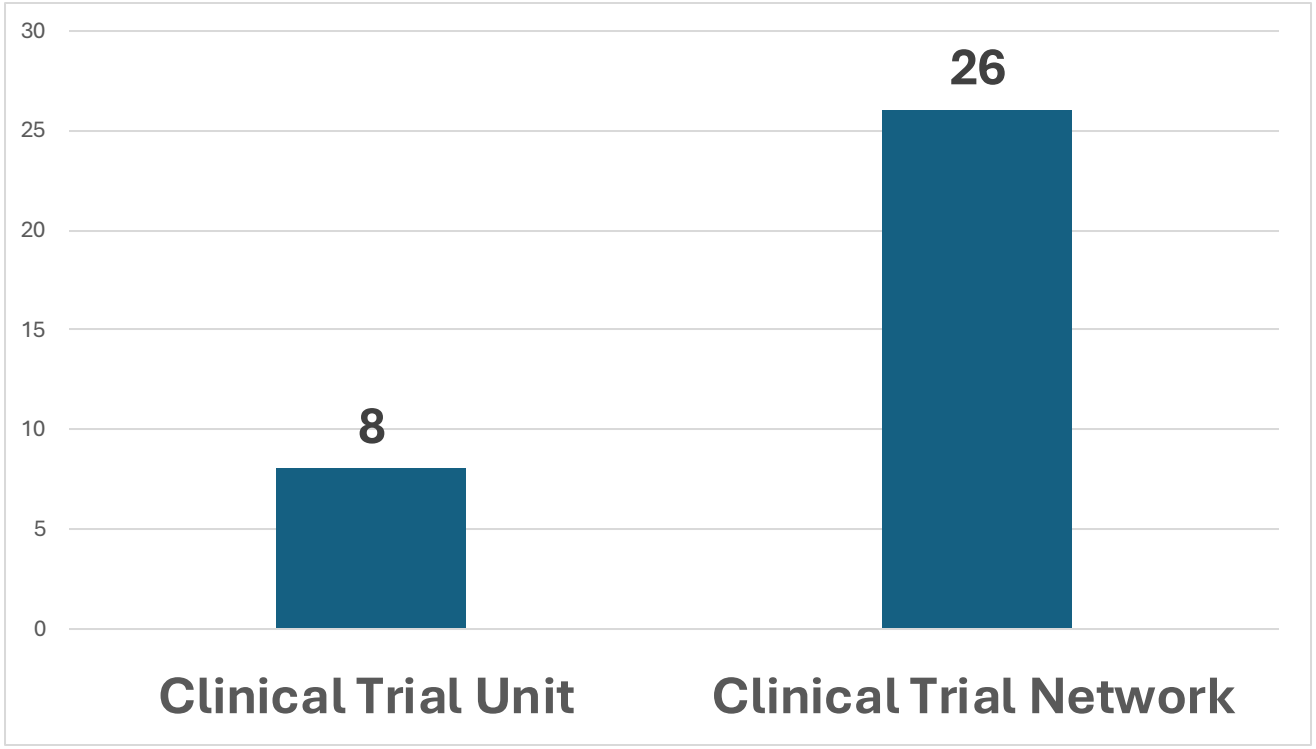
Phase 1
Identifying Barriers
Facilitators for inclusive trials

This phase involved collaborating with CTU/CTN to gather insights to understand what makes it challenging for trialists to achieve inclusion

- Surveys
- Focus groups

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

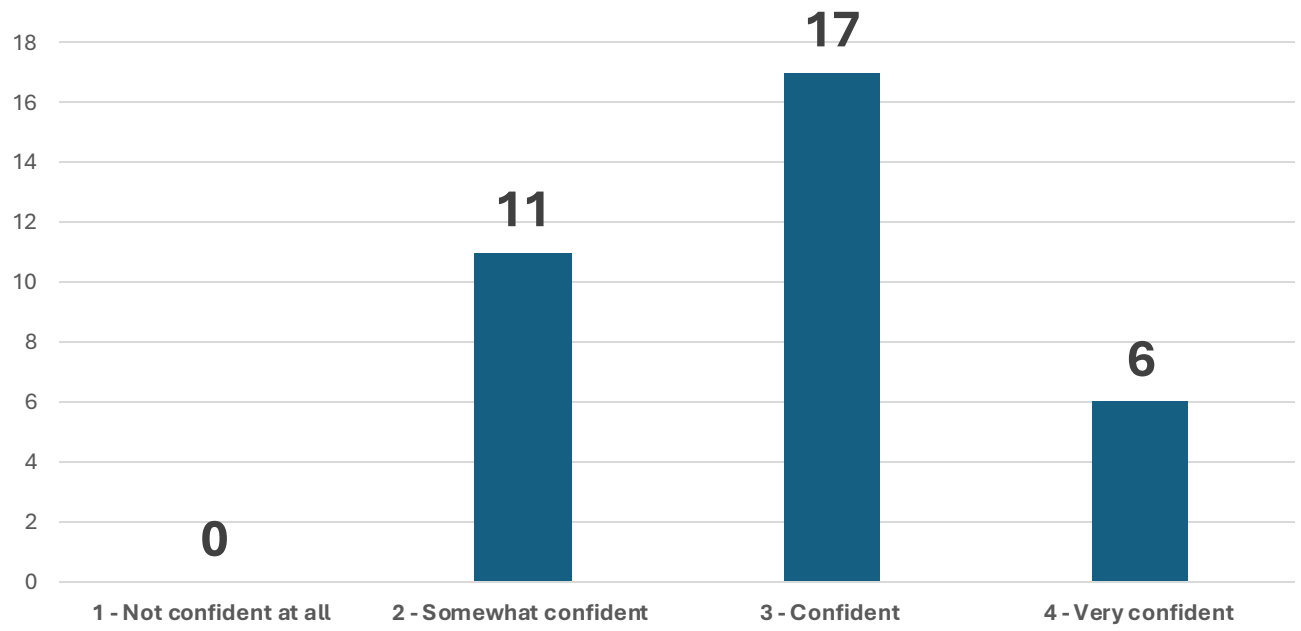
Survey Response from 28 CTNs and 11 CTUs



Total n=34

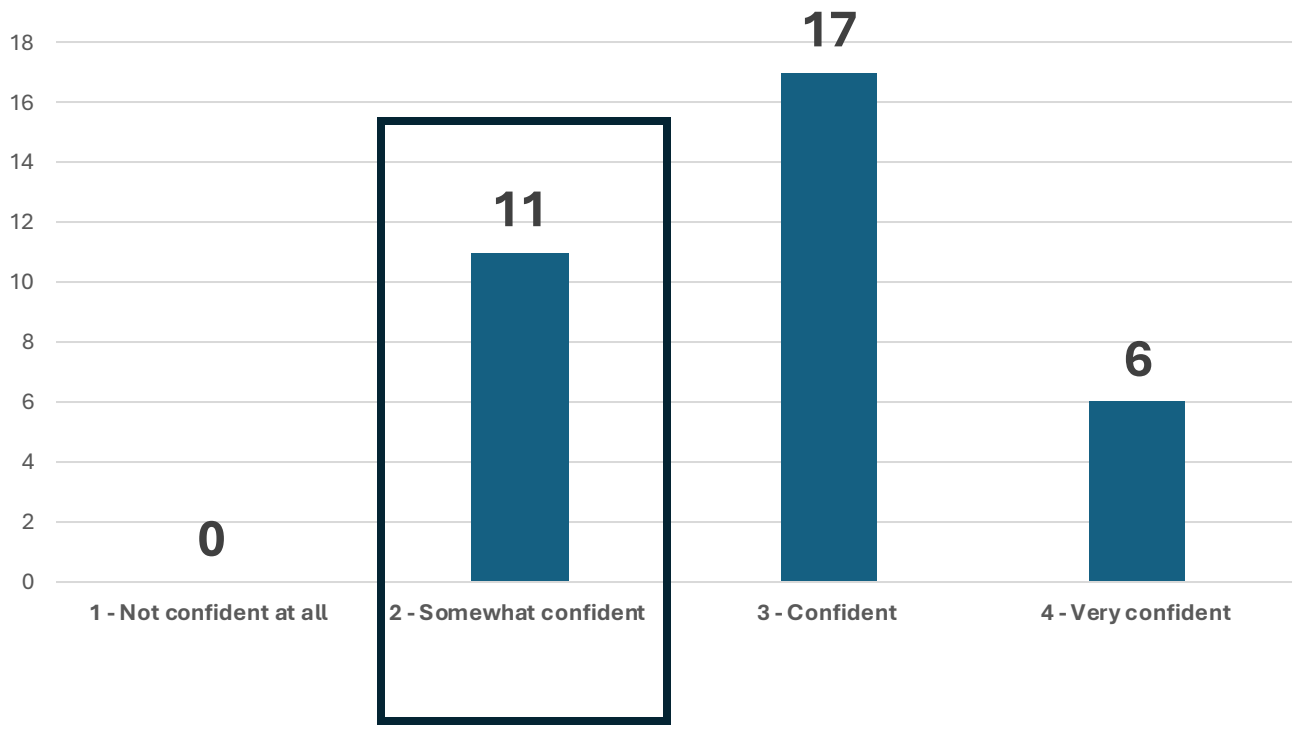
ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Confident in navigating and championing IDEA principles



ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

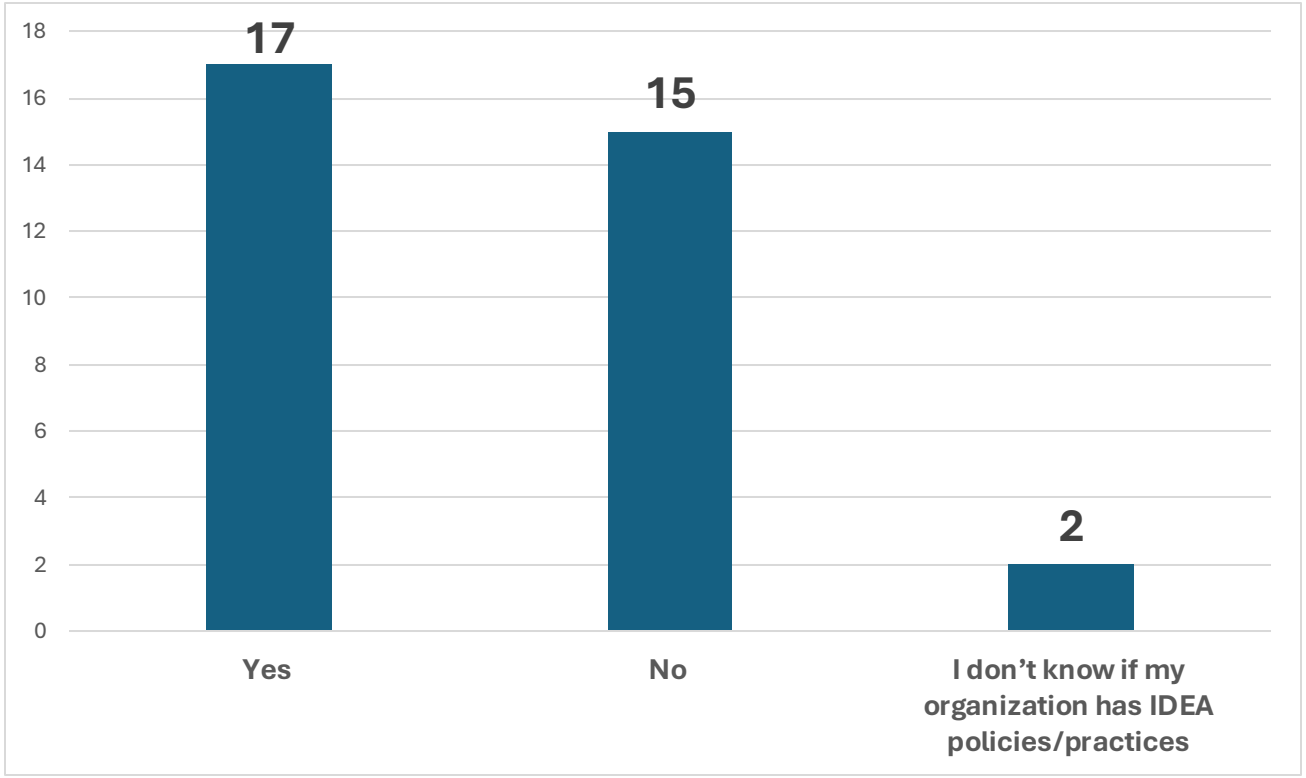
Confident in navigating and championing IDEA principles



n=11 (32.3 %) – somewhat confident

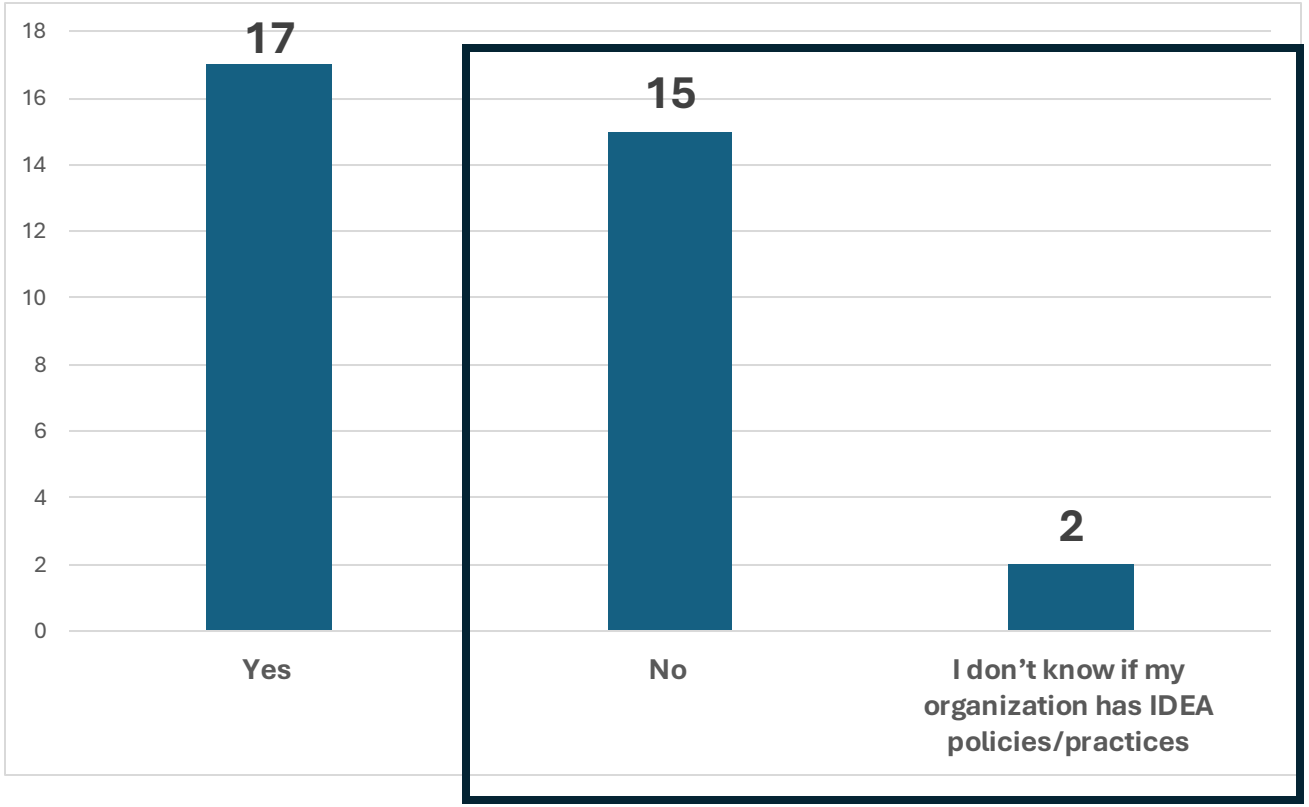
ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Number of responders have established IDEA policies/practices



ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

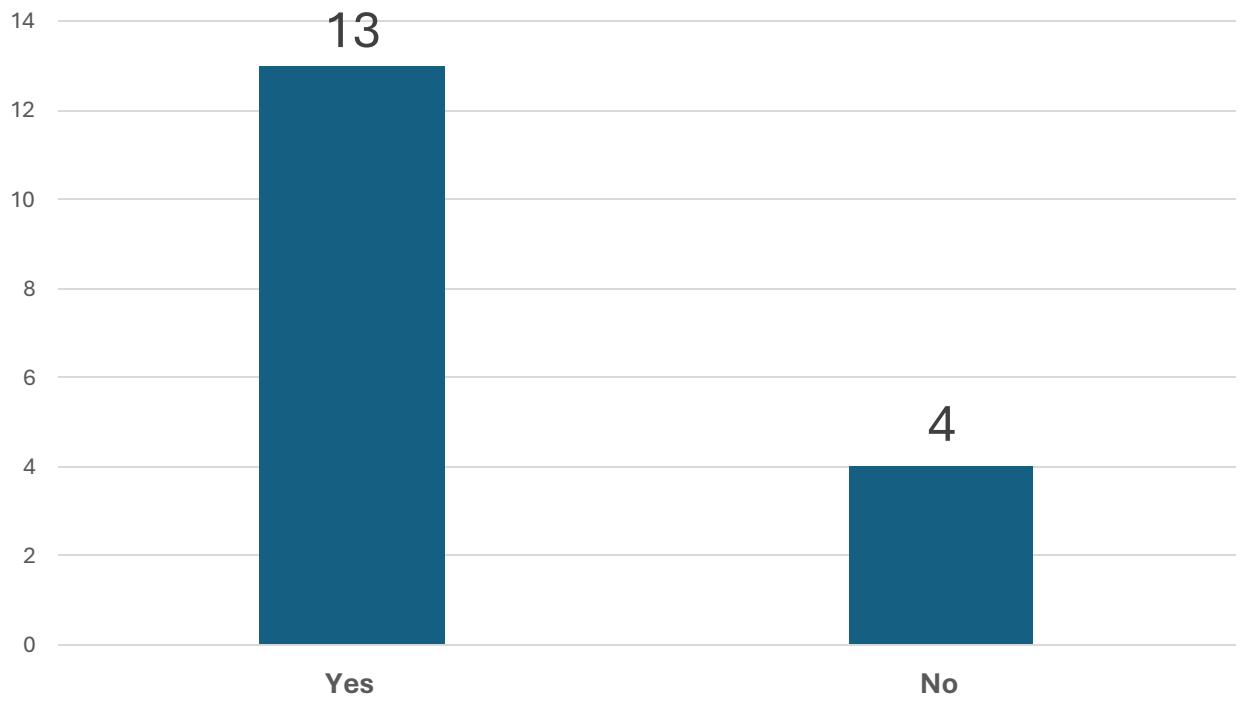
Number of responders have established IDEA policies/practices



n=17 (50% have no IDEA policies)

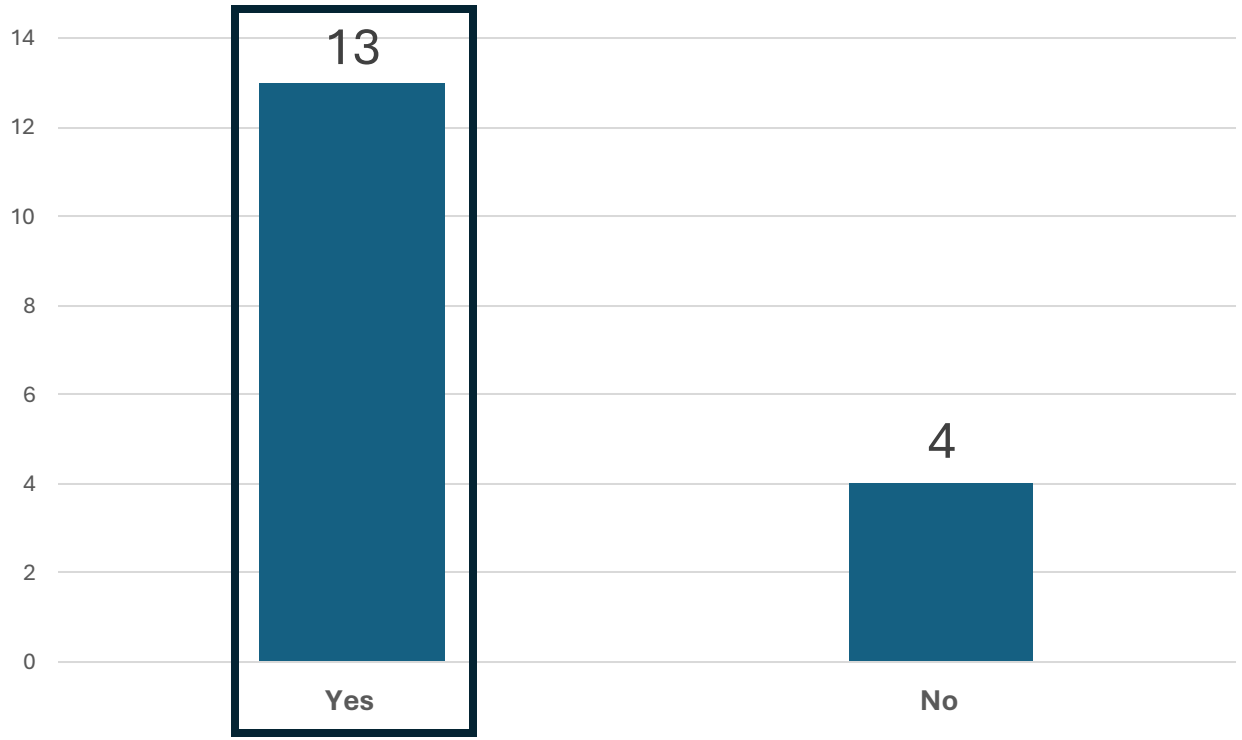
ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Interested in receiving assistance to establish IDEA policies



Accelerating Clinical Trials
Accélérer les Essais Cliniques

Interested in receiving assistance to establish IDEA policies



n=13 (77%) needs assistance

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Perception about Barriers to conducting inclusive clinical trials

- Lack of transport - 66%
- Lack of Childcare - 66%
- Lack of time and Geography - 100%
- Language and communication - 87%

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Perception about Facilitators to conducting inclusive clinical trials

- Community partnerships - 100%
- Adapting personalized approach -87%
- Cultural sensitive approaches - 87%
- Multilingual team members - 67%

Focus groups on IDEA in Clinical Trials

- 2 In-person at ACT-Quebec symposium

  (French and English)

- 1 Virtual

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Join Our Focus Group Discussion on Inclusivity, Diversity, Equity, Accessibility (IDEA) in Clinical Trials

We invite you to participate in an engaging focus group to discuss the barriers and facilitators, key challenges and strategies to improve inclusive clinical trials and assess the stakeholders' perception of developing an IDEA toolkit tailored to Canadian clinical trials.

Topics of Discussion:

- Understanding barriers and facilitators to inclusive clinical trials.
- Strategies for Improving IDEA in clinical trials.
- Perception of IDEA Toolkit Development

Mode of participation: *(choose one)*

- Virtual:
  - Date and time to be decided
- In-Person - Quebec City
  - October 8th, 2024 (Afternoon)
  - October 11th, 2024 (Morning)

Why Participate?

- Contribute to creating a more inclusive clinical trial process.
- Share your experiences and insights.
- Collaborate with other stakeholders and experts.
- Influence the development of a valuable IDEA toolkit.

How to RSVP:

Please confirm your participation to the ACT IDEA Committee Research Coordinator, Eva Friedman (Eva.Friedman@phri.ca), by July 10th, 2024

Outline

Overview of IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

Phase 2- Scoping Review of Existing Toolkits

Resources- key components of the toolkit

Phase 2
Scoping Review of Existing Toolkits

Many international resources and toolkits exist

to guide clinical trial inclusivity
but not fully address the Canadian context

Objective:

To review the existing toolkits to see what strategies have been effective globally and identify gaps that need to be filled for Canadian trials

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Title and abstract screening

TEAM PROGRESS

4521	DONE	58	CONFLICTS
0	ONE VOTE	0	NO VOTES

Team settings

Outline

Overview of IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

Phase 3- Reviewing Participant Diversity in Canadian Clinical Trials

Resources- key components of the toolkit

Phase 3
Reviewing Participant Diversity in Canadian Clinical Trials

Critical to assess the current state of diversity in Canadian clinical trials

- What populations are underrepresented?
- What is the distribution of participants by sex/gender, race/ethnicity, socioeconomic background, region and other factors?

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

A Meta-Epidemiologic Study of

Canadian Randomized Clinical Trials

Shannon M. Ruzycki , Kirstie C. Lithgow, Claire Song, Sarah Taylor, Abinaya Subramanian, Miriam Li MD, Stephanie Happ, Mark Shea MD, Debby Oladimeji, P.J. Devereaux, Wayne Clark, Dean Fergusson, Justin Ezekowitz, Michael Walsh, Sarina R. Isenberg , Patricia Li, Sangeeta Mehta, Stuart G. Nicholls PhD, Courtney Pollock, Louise Pilote, Amity Quinn, **David Collister**

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

STUDY DESIGN

- Meta-epidemiologic study of phase 2 and 3 RCTs of adults
- (Canada only) registered in ClinicalTrials.gov
- Over 10 years from January 1, 2010-December 31, 2020 with published results
- Data abstraction for participant diversity and eligibility criteria (PROGRESS-PLUS)

RESULTS

118 RCTs with 17387 participants mostly from large cities from Ontario, Quebec, British Columbia and Alberta

89% reported sex,
10.2% reported gender, no RCT reported both sex and gender
66.3% females/women, no gender diverse participants

Race/ethnicity reported in 23.7% participants without standardized nomenclature
72.0% White, 2.7% Black, 6.3% Asian, 0.2% Indigenous, rest others

Eligibility criteria related to PROGRESS-PLUS factors rare
except for cognition (n=42), substance use (n=25), pregnancy (n=29), breastfeeding (n=16) and elderly (n=26)

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

OBSERVATIONS

Incomplete reporting of study participant diversity

Underrepresentation of gender minorities, persons of colour and Indigenous persons

Additional research is needed to understand the barriers and facilitators

Outline

Overview of IDEA Committee

Inclusive clinical trials

Phased Approach to Develop Resources for Inclusive Clinical Trials

- Phase 1-Identifying Barriers and Facilitators
- Phase 2- Literature Review of Existing Toolkits
- Phase 3- Reviewing Participant Diversity in Canadian Clinical Trials

Resources- key components of the toolkit

Creation of ACT-IDEA Toolkit

- Use data from surveys, focus groups and review to design a toolkit unique diversity of Canada's population

- Provide Canadian trialists with actionable insights and strategies to target underrepresented groups

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Key components of IDEA toolkit

- ***Recruitment Strategies***
  Practical tools to help trialists reach underrepresented populations

- ***Community Engagement Templates***
  Ready-to-use materials to improve outreach and collaboration with community organizations and healthcare providers

- ***Informed Consent Resources***
  Simplified, culturally appropriate informed consent forms and procedures for diverse groups

- ***Data Collection and Analysis***
  Strategies for gathering and analyzing data in ways that respect diversity and accurately represent participant demographics

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

Conclusions

ACT-IDEA aims to ensure all Canadians who are eligible to participate in clinical trials have the opportunity to participate

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Thank you!