CAN-IDEA Toolkit Launch

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4th ACT Conference
Cape Breton
September 26, 2025

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Table of Contents

Methods /
Development of the IDEA Toolkit

The IDEA Toolkit was developed through a multi-phase, evidence-informed process designed to identify challenges to inclusivity in Canadian clinical trials and generate practical strategies for improvement.

1

Identifying Barriers and Facilitators for Inclusive Trials

We conducted focus groups and stakeholder consultations with patients, community representatives, researchers, and health system partners to explore barriers such as underrepresentation, mistrust, and accessibility challenges, as well as facilitators that promote participation.

Scoping Review of Existing Toolkits

We systematically reviewed existing national and international toolkits addressing equity, diversity, and inclusion in clinical trials. This step helped us identify best practices, gaps, and lessons learned from prior initiatives to inform the structure and content of the IDEA Toolkit.

2

3

Reviewing Participant Diversity in Canadian Clinical Trials

We analyzed available data on participant demographics within Canadian clinical trials to understand current patterns of representation. This provided a Canadian-specific context for tailoring recommendations to ensure the toolkit's applicability and relevance.

Together, these phases ensured the IDEA Toolkit was developed using both empirical evidence and stakeholder insights, making it a practical and contextually grounded resource for embedding inclusivity, diversity, equity, and accessibility in clinical trials.

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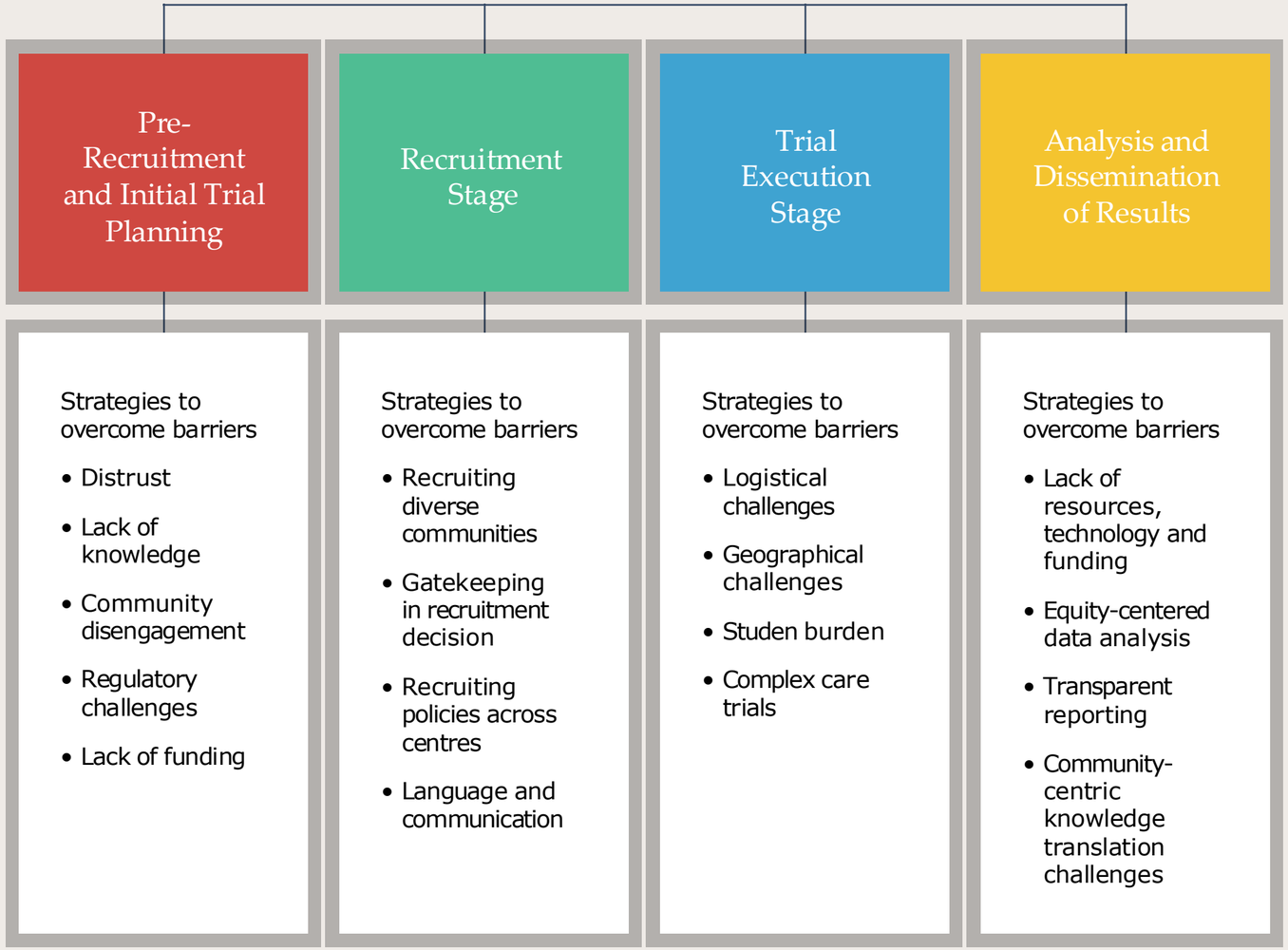
IDEA Toolkit

Canadian Toolkit for Inclusivity, Diversity, Equity, and Accessibility in Trials

The toolkit is designed as a modular and user-friendly resource, allowing researchers to implement IDEA principles at every phase of a clinical trial. It combines practical tools, case studies, and evaluation metrics to ensure that inclusivity, diversity, equity, and accessibility are not just theoretical goals but measurable outcomes.



Pre-Recruitment and Initial Trial Planning

Laying the groundwork for inclusivity begins with deliberate planning and engagement.

A. Identified Barriers

1. Distrust
   Historical mistrust of clinical research among marginalized communities

2. Lack of knowledge
   Limited awareness of clinical trials among potential participants and even healthcare providers

3. Limited community engagement
   Underrepresentation of diverse voices in trial design and planning

4. Regulatory complexity
   Variations across provinces/institutions create operational challenges

5. Insufficient funding
   Lack of financial support for trials focusing on diversity and inclusivity

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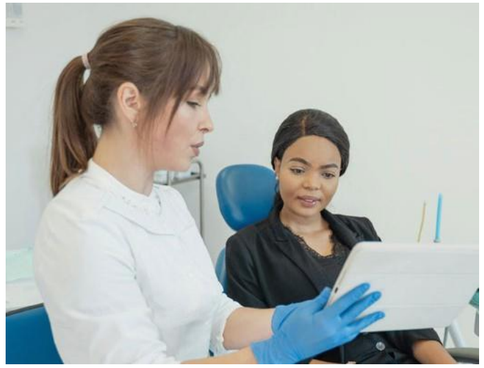
B. Resources & Guidance Documents

1. Addressing Distrust –>
   Guidance on Building Trust Through Stakeholder Engagement

   Community Engagement
   - Establish a Community Advisory Board
   - Use a checklist for engaging community partners
   - Host Town Halls and Listening Sessions

   Participant-Facing Materials
   - Lay-friendly informed consent templates
   - "Myths vs. Facts" handout on clinical trials
   - Multilingual patient information sheets

   Investigator & Site Training Resources
   - Cultural competency & implicit bias training
   - Informed Recruitment Checklist (see checklist on the right).



Why trust matters

Distrust is a significant barrier to inclusive participation. Practical frameworks help trialists foster trust through transparent communication and meaningful engagement.

Informed Recruitment Checklist

- ☐ Use clear, non-technical language.
- ☐ Provide a safe/private discussion space.
- ☐ Allow participants to bring a trusted support person.
- ☐ Offer multiple communication/participation methods.
- ☐ Allow ample decision-making time.
- ☐ Ensure culturally competent communication.
- ☐ Partner with trusted community leaders.
- ☐ Acknowledge historical harms openly.
- ☐ Train staff in trauma-informed care & implicit bias.
- ☐ Allow opt-out of sensitive questions.
- ☐ Provide fair compensation and support services.
- ☐ Share study results with participants.

Recruitment Stage

This stage ensures outreach strategies target diverse populations and reduce barriers to participation.

A. Identified Barriers

1. Diverse community recruitment challenges
   Difficulty reaching and engaging underrepresented groups

2. Recruitment challenges
   General difficulty in enrolling participants

3. Gatekeeping in recruitment decisions
   Clinicians as gatekeepers which limit participant access

4. Recruitment policies across centers
   Inconsistent policies create barriers to recruitment

5. Language and communication barriers
   Limited availability of materials in multiple languages.

B. Resources & Guidance Documents

1. Diverse community recruitment challenges –> *Strategies for inclusive recruitment*
2. Recruitment Challenges –> *Evidence-based recruitment approaches*
3. Gatekeeping in Recruitment Decision –> *Training for healthcare professionals on ethical recruitment*
4. Recruitment policies across centers –> *Standardized recruitment policy framework*
5. Language and communication barriers –> *Multilingual recruitment materials*

Trial Execution Stage

Ensuring inclusivity and accessibility during the study is vital for participant retention and data integrity.

A. Identified Barriers

1. Logistical challenges
   Issues with transportation, scheduling, and accessibility

2. Geographical challenges
   Limited access for participants in rural or remote areas

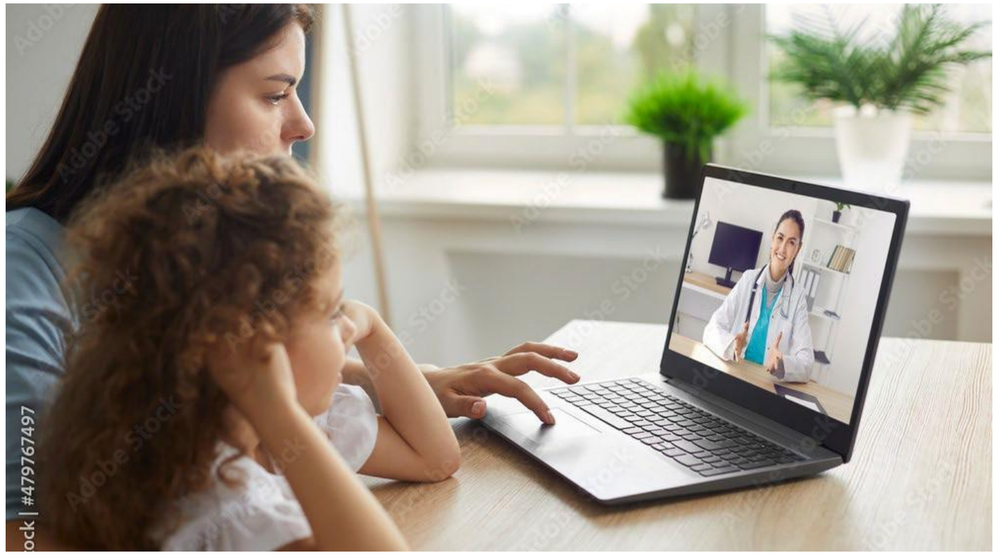
3. Study burden
   Time and resource demands on participants

4. Complex care trials
   Difficulty in executing trials involving patients with multiple conditions

5. Emotional impact
   Psychological strain on participants and caregivers

B. Resources & Guidance Documents

1. Logistical challenges –> *Practical solutions for transportation, scheduling, and accessibility*
2. Geographical challenges –> *Telehealth solutions and decentralized trial options*
3. Study burden –> *Flexible participation options to reduce burden*
4. Complex care trials –> *Guidance on conducting trials for patients with complex medical conditions*



Analysis and Dissemination of Results

This stage emphasizes equity in data interpretation and inclusive knowledge translation.

A. Identified Barriers

1. Lack of resources or technology
   Limited data collection and analysis tools access

2. Research funding
   Difficulty in securing long-term funding for diverse and inclusive trials

3. Equity-centered data analysis
   Challenges in analyzing diverse participant data

4. Transparent reporting framework
   Need for clear and unbiased reportings

5. Community-centric knowledge translation
   Difficulty in sharing results with communities in meaningful ways

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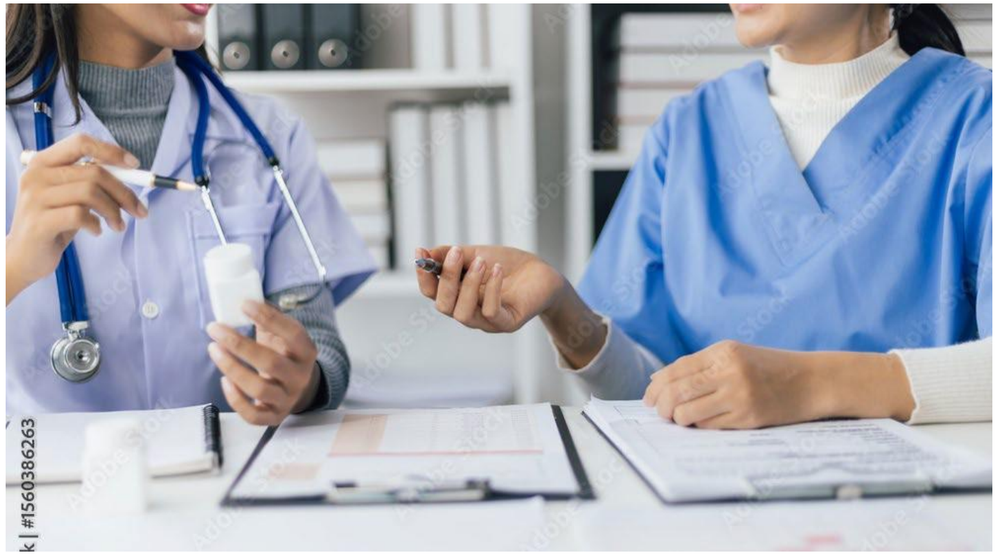
B. Resources & Guidance Documents

1. Lack of resources or technology –> *Strategies to integrate cost-effective technology*
2. Research funding –> *Advocacy resources for sustainable funding models*
3. Equity-centered data analysis –> *Best practices in analyzing diverse data sets*
4. Transparent reporting framework –> *Guidelines on ethical and inclusive reporting*
5. Community-Centric Knowledge Translation –> *Culturally tailored dissemination strategies*



Strategies Overview

Communication Engagement

Inclusive Recruitment

Analysis and Dissemination of Results

Overcoming Regulatory Challenges

Trial Execution

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