Canadian
Cancer Clinical
Trials Network

Equity, Diversity, and Inclusion (EDI) Framework for Clinical Trials

A Framework to support sites, clinical research staff, sponsors, and funders for accessing information and resources focusing on improving and sustaining equitable and inclusive best practices for underrepresented populations in clinical trials.

Executive Summary

The EDI Framework and Toolkit is designed to support research sites, clinical research staff, sponsors, and funders in improving aspects of Equity, Diversity, and Inclusion (EDI) in relation to clinical trials conduct and to facilitate implementation of recommended best practices benefitting trial participants and the clinical research community.

The Framework includes best practice recommendations aimed at removing barriers for underrepresented participant groups in clinical trials which include, but are not limited to, Indigenous Peoples (First Nations, Inuit, and Métis), racialized individuals, older adults (70+), Adolescents and Young adults (AYA), immigrants/newcomers, remote and rural individuals, persons with disabilities, women and gender minorities, and members of the sexual and gender diverse community. Other sets of recommendations focus on improving trial design, processes, research professional team diversity and training. Additional guidance on engaging Indigenous communities in research can be found in the **Improving Access to Clinical Trials for Indigenous People Guide**.

Users are encouraged to utilize this Framework and consider the activities and opportunities they can pursue to advance EDI in clinical trials and within their own research teams.

These icons are used to indicate key groups that would implement and support these recommendations in the clinical trial ecosystem.


Research Site and Staff


Funders


Sponsors


Government Institutions

The Toolkit is intended for use by members of these groups making up Canada's clinical trial ecosystem to easily identify available resources, templates, and guidelines that can facilitate the implementation of EDI best practices.

Improving Trial Participation

Fostering Trust and Improving Communication

Recommendations

	Use Patient Navigators and Indigenous (First Nations, Inuit, Métis peoples) Navigators to support trial participants.
	Establish communication channels or surveys to collect feedback and concerns from participants and non-participants to inform improvements to clinical trial conduct
	Establish a community advisory board to provide guidance on cultural safety, trauma informed care and care for sexual and gender diverse communities.
 	Consider different health literacy levels when communicating with participants and creating trial materials. Employ inclusive language, refrain from using technical jargon and stigmatizing language.
	Through participants' preferred communication methods (e.g. video calls, in-person meetings), engage participants in thorough discussions to encourage questions and address concerns.
	Enable participants to include a trusted support person in trial discussions.
	Enable participants to integrate traditional and cultural practices while participating in a trial (e.g., traditional medicine, dedicated space within the trial facility, etc.)
	Engage directly with members and leaders from underrepresented groups with the goal of cultivating trusted relationships that can inform trial recruitment strategies.
	Diversify trial staff team. Encourage clinical research professionals to engage with patients using cultural humility.
	Ensure shared spaces (e.g., waiting rooms, examinations rooms, etc.) are safe and welcoming environments to foster diverse and inclusive culture of care.
 	After study completion, share clinical trial results with participants.

Improving Trial Awareness

Recommendations

	Establish measures to provide reminders of trial match notifications to Investigators.
	Improve communication/referral pathways with local healthcare providers who serve underserved populations.
	Exchange knowledge and lessons learned between sites and collaborate on similar objectives for improving trial awareness (e.g., sharing resources).
	Use clinical trial matching programs in a culturally safe manner to match patients with suitable clinical trials based on their diagnosis and molecular profile. Consider alternate methods to share and provide access to these databases for patients less comfortable with technology or with limited accessibility.
	Translate available trial materials to languages/formats more suitable for diverse participants. Be aware of language complexities.
	Include funds for translating trial documents within trial budget
	Co-develop trial resources with underrepresented groups to ensure materials are inclusive and use relevant images and topics for target populations.
	Share trial materials with general trial information in community centres and common public spaces in addition to clinical settings.
	Incorporate a community-driven outreach by enlisting trial participants from underrepresented communities to share their trial experience within their communities.
	Organize knowledge-sharing events within targeted communities, where community members educate trial staff about barriers and research/trial staff inform community members about trials and address concerns.

Improving Trial Access

Recommendations

	Establish trial sites in diverse locations (rural and community sites). Modify compliance policies to align with this initiative.
	Establish partnerships between providers from large academic health care systems with community providers. Build strong rapport that will improve local enrollment for rural and diverse patients.
	Implement decentralized trial procedures (e.g., e-consent, remote data collection, assessments, use of local laboratory, etc.) and decrease frequency of study visits.
	Provide resources and funding to support and coordinate complex trials at all sites.
	Engage participants in discussions regarding accommodations and support they may need prior to visits.
	Incorporate funds for costs associated with participation such as transportation, lodging and childcare, within trial budget.

Developing Inclusive Trial Design

Recommendations

	Review inclusion and exclusion criteria to assess potential biases against underrepresented populations and make necessary adjustments to promote inclusivity. Consider how trial design elements can ensure trial populations reflect patients observed in clinics. • Incorporate comprehensive age ranges • Refrain from using sex and gender exclusions
	Incorporate meaningful trial endpoints that are relevant and reflect the health priorities of underrepresented populations.
	Engage and consult underrepresented groups during trial development to ensure study eligibility, requirements and trial procedures are fair and inclusive.
	Consult with Indigenous communities to ensure appropriate cultural and ethical practices are followed.
	Incorporate flexible treatment schedules to accommodate participants' diverse lifestyles and availabilities.
	Shorten and simplify consent forms or create accompanying resources to simplify and explain consent process. Consent process should accommodate diverse participants and literacy levels.

Research Staff Education and Training

Recommendations

	Require all staff to undergo Equity, Diversity, and Inclusion (EDI) training. Incorporate training into the onboarding and orientation process for new staff members. Training should include but not limited to: • Implicit/Unconscious bias • Indigenous health, cultural safety, trauma informed care • Cultural Humility • Accessibility • Care for Sexual and Gender Diverse groups (e.g., 2SLGBTQIA+ health education, sex and gender bias, etc.) • Considerations for Adolescent and Young Adults (AYAs) • Considerations for geriatric patients • Considerations for racial and ethnic minorities in trials (e.g., Black, East Asian, South Asian, Hispanic groups)
	Regularly review resources and training programs to identify educational gaps and to ensure content is up to date.
	Collaborate with underrepresented groups to tailor training session content to target population.

Increasing Diversity of Clinical Research Teams

Recommendations

	Use nongendered, inclusive and unbiased language in job postings.
	Seek candidates from diverse backgrounds.
	Implement bias prevention processes during selection, such as: • Blind hiring assessments • Selection committees • Standardized interview questions, tests, assessment grids
	Incorporate process for staff to request support and accommodations, addressing both visible and invisible disabilities.
	Establish partnerships with educational institutions and organizations serving diverse student populations to broaden recruitment channels.
	Form dedicated groups/committees aimed at enhancing diversity and inclusion within the clinical trial unit. Set clear and measurable goals and regularly monitor progress.
	Incorporate Patient Partners and Representatives as integral members of your clinical research team. • Consult Patient Partners and Representatives from underrepresented groups on projects and initiatives. • Include representatives on institutional advisory boards/committees. • Provide remuneration to Patient Partners and Representatives.

Collection of Trial Participant Data

Race, Ethnicity and Social Demographic Data

Recommendations

Standardize collection of EDI data elements (race, ethnicity, social determinants of health)

- Consult with underrepresented populations and follow recommended data guidelines to ensure data collection is performed safely and appropriately. Understand barriers and concerns of data collection before implementation.
- Broaden data collection to include information about healthcare and social supports available for each patient.
- Consider other international organizations to standardize collection of patient characteristics (e.g., Alliance for Clinical Trials in Oncology or European Organization for Research and Treatment of Cancer (EORTC)).
- Allow option of race, ethnicity and gender to be self-identified by study participants.

Include Sexual Orientation and Gender Identity (SOGI) data in trial forms (e.g., intake forms, data clarification forms, etc.)

Engage in informative discussions to clarify purpose and relevance of collecting, analyzing and reporting race, ethnicity and demographic data and to address privacy and confidentiality concerns with participants.

Incorporate reimbursement for sites' collection of demographical data in the trial budget.

Regularly review the following performance measures for underrepresented populations to inform recruitment strategies:

- Screening outcomes
- Participation, reasons for not qualifying or participating
- Retention rates

Consider use of Clinical Trial Management Systems as an efficient resource for this activity.

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3CTN Team

Raisa Chowdhury
Project Coordinator

Diana Kato
Manager, Operations

Stephen Sundquist
Executive Director

Working Group Members:

Michelle Audoin
PFAC, Ontario Institute of Cancer Research

Holly Longstaff
Provincial Health Services Authority

Doreen Ezeife
Tom Baker Cancer Centre

Laura McNab-Coombs
BC Network Environment for Indigenous Health Research

Evani Goll
C17 Council

Tina Hsu
University of Ottawa

Anna Johnson
Canadian Cancer Trials Group

Vinesha Ramasamy
AYA CAN - Canadian Cancer Advocacy

Roel Schlijper-Bos
BC Cancer – Prince George

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