

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	.3
Improving Trial Participation	.4
Improving Trial Awareness	.6
Improving Trial Access	.7
Developing Inclusive Trial Design	.8
Research Staff Education and Training1	0
Increasing Diversity of Clinical Research Teams1	1
Collection of Trial Participant Data 1	2
Acknowledgements 1	4
References 1	5

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.



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 (e.g., 2SLGBTQIA+ Navigators, Indigenous Navigators, etc.) to support trial participants from underrepresented communities.
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, gendered 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.
 Create an environment that visibly supports and includes sexual and gender diverse participants: Wearing rainbow lanyards or pins and displaying safe space stickers Ensure gender-neutral washroom facilities are available



- Offer materials with 2SLGBTQIA+ representation and gender-inclusive language
- Adopt inclusive communication practices (e.g., share pronouns and ask participants their pronouns)



After study completion, share clinical trial results with participants.



Improving Trial Awareness

Recommendations





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
- Ensure that language related to pregnancy and contraception is inclusive and does not inadvertently exclude 2SLGBTQIA+ participants.

Use gender-neutral terms and gender-neutral pronouns in study protocols and documents, such as 'participant' and 'they/theirs' to increase accessibility and inclusivity in studies.

Ensure sex and gender are not conflated in study protocols and documents, understanding that sex refers to biological attributes while gender refers to the socially constructed roles, behaviors, expressions, and identities of individuals.



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. Incorporate funds for their collaborative support.



Consult with Indigenous communities and community organizations from other underrepresented groups 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 ongoing, high-quality 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)
- Unethical treatment of marginalized communities within medicine and research
- Medical mistrust among marginalized communities
- Health disparities and minority stress



Regularly review resources and training programs to identify educational gaps and to ensure content is up to date.



Collaborate with community and advocacy groups of underrepresented populations to tailor training session content to target population.

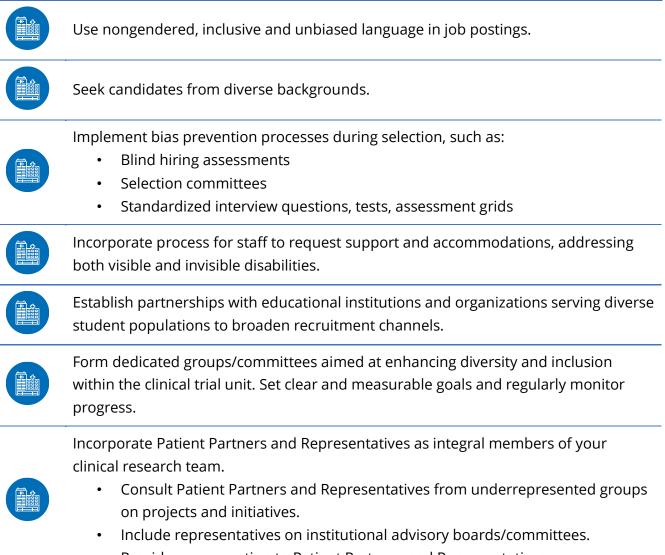




Increasing Diversity of Clinical Research

Teams

Recommendations



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)).
- Ensure that demographic information is self-reported by study participants.
- Avoid using "other" as an option, instead allow participants to self-identify utilizing free text options.
- Introduce option for "select all that apply" rather than limiting respondents to a single choice.

Include Sexual Orientation and Gender Identity (SOGI) data in trial forms (e.g., intake forms, data clarification forms, etc.) in line with current guidance to respect participants, improve study generalizability, and ensure beneficence:

- Include questions and answer options that capture sex assigned at birth, sexual orientation, current gender identity, the inclusion of Two-Spirit, and intersex characteristics.
- Incorporate optional organ inventory questions along with any surgical procedures to help inform clinical care and research data.

Consider use of data collection tools that respect participants privacy when completing SOGI questions (e.g., via ePROs / eCOA platform on a mobile device).



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. Ensure necessary safeguards are in place to protect patient identity and privacy.







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:

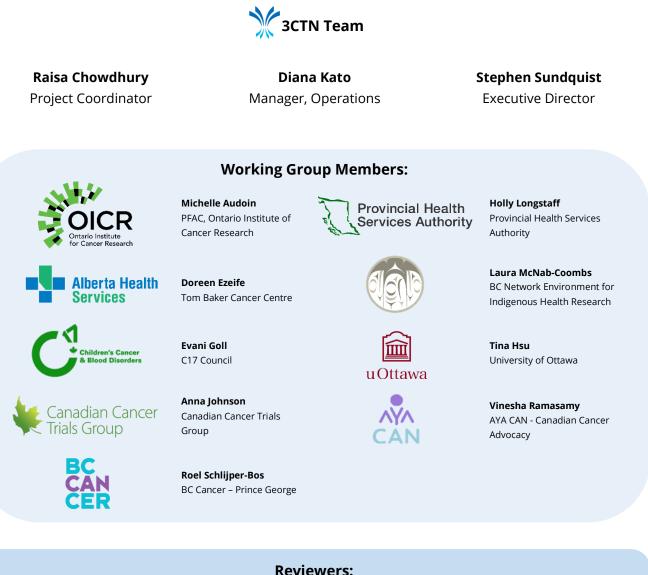
- Screening outcomes
- Participation, reasons for not qualifying or participating
- Retention rates

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



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Kim Meeking Queering Cancer



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