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 (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

	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
- 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

	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)).
- 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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References

1. Ahmed, S., Shahid, R.K., & Episkenew, J.A. (2015). Disparity in Cancer Prevention and Screening in Aboriginal Populations: Recommendations for Action. *Current Oncology, 22(6), 417-426.* https://doi.org/10.3747/co.22.2599

2. Bell, J.AH., Kelly, M.T., Gelmon, K., Chi, K., Ho, A., Rodney, P., & Balneaves, L.G. (2020). Gatekeeping in cancer clinical trials in Canada: The ethics of recruiting the "ideal" patient. *Cancer Medicine, 9(12),4107-13.* https://doi.org/10.1002/cam4.3031.

3. Brown, R. F., Bylund, C. L., Li, Y., Edgerson, S., & Butow, P. (2012). Testing the utility of a cancer clinical trial specific Question Prompt List (QPL-CT) during oncology consultations. *Patient education and counseling*, 88(2), 311–317. https://doi.org/10.1016/j.pec.2012.02.009

4. Canadian Institute for Health Information. (2022) *Guidance on the Use of Standards for Race-Based and Indigenous Identity Data Collection and Health Reporting in Canada.* Ottawa, ON. https://www.cihi.ca/sites/default/files/document/guidance-and-standards-for-race-based-and-indigenous-identity-data-en.pdf

5. Cancer Care Ontario. (2019). *First Nations, Inuit, Métis and Urban Indigenous Cancer Strategy 2019–2023. https://www.cancercareontario.ca/sites/ccocancercare/files/assets/PCC_4114_FNIMuI_ExecSummary.pdf*

6. Center for Information and Study on Clinical Research Participation (CISCRP). (2022). *Considerations for LGBTQ+ Inclusion in Clinical Research.* https://www.ciscrp.org/wp-content/uploads/2022/09/Industry-Report-Aug-2022.-Considerations-for-LGBTQ-Community-Inclusion-in-Clinical-Research.pdf

7. De Rojas, T., Neven, A., Terada, M., García-Abós, M., Moreno, L., Gaspar, N., & Péron, J. (2019). Access to Clinical Trials for Adolescents and Young Adults With Cancer: A Meta-Research Analysis. *JNCI cancer spectrum*, *3(4)*. https://doi.org/10.1093/jncics/pkz057

8. Dickmann, L. J., & Schutzman, J. L. (2018). Racial and Ethnic Composition of Cancer Clinical Drug Trials: How Diverse Are We? *The Oncologist*, *23(2), 243–246.* https://doi.org/10.1634/theoncologist.2017-0237

9. El-Deiry, W.S & Giaccone, G. (2021). Challenges in Diversity, Equity, and Inclusion in Research and Clinical Oncology. *Front Oncology, 24(11), 642112.* doi: 10.3389/fonc.2021.642112

10. Ezeife, D. A., Padmore, G., Vaska, M., & Truong, T. H. (2022). Ensuring equitable access to cancer care for Black patients in Canada. *CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne, 194(41), E1416–E1419.* https://doi.org/10.1503/cmaj.212076

11. Fienkeng, M., Croker, A., Recinos-Vasquez, Z., & Carter, M. (2022). Enhancing diversity in clinical trial populations: An agency-industry perspective. *Regulatory Focus*. https://www.raps.org/news-and-articles/news-articles/2022/12/enhancing-diversity-in-clinical-trial-populations

12. Forcina, V., Vakeesan, B., Paulo, C., Mitchell, L., Bell, J. A., Tam, S., Wang, K., Gupta, A. A., & Lewin, J. (2018). Perceptions and attitudes toward clinical trials in adolescent and young adults with cancer: a systematic review. *Adolescent health, medicine and therapeutics*, *9, 87–94.* https://doi.org/10.2147/AHMT.S163121

13. Gaba, P., Bhatt, D.L. (2020). The COVID-19 pandemic: a catalyst to improve clinical trials. *Nat Rev Cardiol, 17, 673–675*. https://doi.org/10.1038/s41569-020-00439-7

14. Government of Canada. (2022). *Government of Canada Gender-based Analysis Plus (GBA Plus).* https://www.canada.ca/en/women-gender-equality/gender-based-analysis-plus/take-course.html

15. Hussain-Gambles, M., Leese,B., Atkin, K., Brown, J., Mason, S., & Tovey, P. (2004). Involving South Asian patients in clinical trials. Health Technology Assessment, 8(42). https://njl-admin.nihr.ac.uk/document/download/2004837

16. IOM suggests ways to share clinical trial data. (2015). *Canadian Medical Association Journal*, *187*(3). https://doi.org/10.1503/cmaj.109-4980

17. Lauren M. Hamel, Louis A. Penner, Terrance L. Albrecht, Elisabeth Heath, Clement K. Gwede, and Susan Eggly. (2016). Barriers to Clinical Trial Enrollment in Racial and Ethnic Minority Patients with Cancer. *Cancer Control, 23(4), 327-337.* doi.org/10.1177/107327481602300

18. LaVallie, D. L., Wolf, F. M., Jacobsen, C., & Buchwald, D. (2008). Barriers to Cancer Clinical Trial Participation among Native Elders. *Ethnicity & Disease*, *18*(2), 210–217. https://www.jstor.org/stable/48667335

19. Letendre, A., Garvey, G., King, A., King, M., Crowshoe, R., Bill, L., Caron, N. R., & Elias, B. (2020). Creating a Canadian Indigenous Research Network Against Cancer to Address Indigenous Cancer Disparities. *JCO global oncology, 6, 92–98.* https://doi.org/10.1200/JGO.19.00049

20. Loree, J.M, Anand, S, Dasari A, et al. (2019). Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. *JAMA Oncology, 5(10): e191870*. https://doi:10.1001/jamaoncol.2019.1870

21. Mainous, A.G., Kelliher, A., & Warne, D. (2023). Recruiting Indigenous Patients Into Clinical Trials: A Circle of Trust*. The Annals of Family Medicine*, 21(1), 54-56. https://doi.org/10.1370/afm.2901

22. Mittal, N., Saha, A., Avutu, V. *et al.* (2022). Shared barriers and facilitators to enrollment of adolescents and young adults on cancer clinical trials. *Scientific Reports, 12, 3875*. https://doi.org/10.1038/s41598-022-07703-5

23. National Academies of Science, Engineering, and Medicine (NASEM). (2022). *Measuring Sex, Gender Identity, and Sexual Orientation*. https://dpcpsi.nih.gov/sgmro/measurement-and-data/2022-NASEM-report

24. Ontario Health. (2023). *First Nations, Inuit, Métis and Urban Indigenous Health Framework. https://www.ontariohealth.ca/sites/ontariohealth/files/FNIMUI-HealthFrameworkReport.pdf*

25. Oyer, R. A., Hurley, P., Boehmer, L., Bruinooge, S. S., Levit, K., Barrett, N., et al. (2022). Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *40(19), 2163–2171.* https://doi.org/10.1200/JCO.22.00754

26. Pratt-Chapman, M. L., Tredway, K., Wheldon, C., Streed. C. G, Scout, NFN., Ose, J., and Jackman, S. S. (2024). Strategies for Advancing Sexual Orientation and Gender Identity Data Collection in Cancer Research. *JCO Oncol Pract 20, 883-888*. https://doi.org/10.1200/OP.23.00629

27. Sedrak, M. S., Freedman, R. A., Cohen, H. J., Muss, H. B., Jatoi, A., Klepin, H. D., et al. (2021). Older adult participation in cancer clinical trials: A systematic review of barriers and interventions. *CA: a cancer journal for clinicians*, *71(1), 78–92.* https://doi.org/10.3322/caac.21638

28. Siembida, E. J., Loomans-Kropp, H. A., Tami-Maury, I., Freyer, D. R., Sung, L., Crosswell, H. E., Pollock, B. H., & Roth, M. E. (2021). Barriers and Facilitators to Adolescent and Young Adult Cancer Trial Enrollment: NCORP Site Perspectives. *JNCI cancer spectrum*, *5*(3), pkab027. https://doi.org/10.1093/jncics/pkab027

29. The First Nations Information Governance Centre. (2014). *Ownership, Control, Access and Possession (OCAP™); The Path to First Nations Information Governance*. Ottawa, ON. https://fnigc.ca/wp-content/uploads/2020/09/5776c4ee9387f966e6771aa93a04f389_ocap_path_to_fn_information_governance_en_final.pdf

30. The MCRT Center of Brigham and Women's Hospital and Harvard. (n.d.). *LGBTQIA+ Inclusion by Design in Clinical Research Toolkit*. LGBTQIA+ Inclusion. https://mrctcenter.org/lgbtqia-inclusion/

31. Williams, J.S., Walker, R.J., & Egede, L.E. (2016). Achieving Equity in an Evolving Healthcare System: Opportunities and Challenges. *Am J Med Sci, 351, 33–43.* 10.1016/j.amjms.2015.10.012

32. Yee, K. W., Pater, J. L., Pho, L., Zee, B., & Siu, L. L. (2003). Enrollment of older patients in cancer treatment trials in Canada: why is age a barrier? *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *21*(8), 1618–1623. https://doi.org/10.1200/JCO.2003.12.044