



Improving EDI in Clinical Trials

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Improving Equity, Diversity and Inclusion in Clinical Trials

Clinical trial participants need to reflect the diverse people living with cancer

Better generalizability and validity of trial results



Equitable access to trials offering innovative therapies and improved surveillance

All communities can benefit from scientific advances – trial results can help improve treatment efficacy and outcomes





Addressing EDI Challenges in Clinical Trials – Our Approach







Environmental Scan

Framework and Toolkit Development

Knowledge Mobilization





Representative Stakeholder Working Group

- Provided expertise and strategic advice as PWLE, research knowledge leads
- Identified practical, best practice resources
- Assessed feasibility and priority-setting for implementing recommendations



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EDI Framework and Resource Toolkit

Themes

- Improving Trial Participation Fostering Trust and Improving Communication
- Improving Trial Awareness
- Improving Trial Access
- **Developing Inclusive Trial Design**
- Education and Training for Clinical Research Staff
- Increasing Diversity of Clinical Research Teams and Inclusive Hiring Practices
- Collection of Trial Participant Data Race, Ethnicity, Demographic Data

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.





hiring procedures are considered.





Framework Recommendations – Shared Responsibilities

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.



e.g.,: CRAFT DCT model









Equity, Diversity and Inclusion (EDI) Toolkit

Trial Awareness



Includes templates, research materials, practical strategies and case examples of interventions to improve awareness of clinical trials for underrepresented populations.

Trial Access & Participation



Includes resources, initiatives, remote access programs and culturally sensitive interventions to improve access and participation of clinical trials.

Trial Design



Includes protocol checklists and considerations during trial development to ensure unique considerations of all patient populations are considered.

Increasing Diversity of Clinical Research Teams & Inclusive Hiring Practices



Includes practical strategies tailored to support organization in diversifying their workforce, fostering an inclusive workplace culture, and ensuring equitable hiring procedures are considered.

Guidelines, Education & Training



Includes educational modules, courses and guidelines on engaging underrepresented members in research. Aimed to support clinical trial staff deliver culturally competent care, address health disparities, and mitigate unconscious bias.

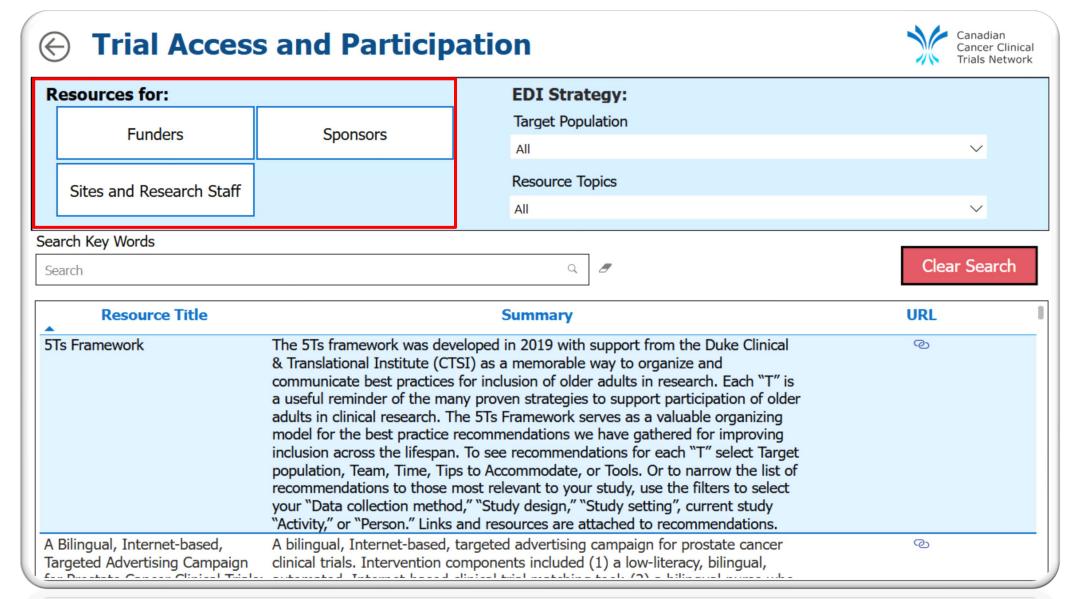
Collection of Race, Ethnicity & Social Demographic Data



Includes resources covering standards, guidelines, and practical strategies for collecting data on race, ethnicity, and socioeconomic status.











Trial Access and Participation			Canadian Cancer Clinical Trials Network
Resources for:		EDI Strategy:	
Funders	Sponsors	Target Population All	^
Sites and Research Staff		 ☐ AYA Populations ☐ Black Community ☐ Indigenous Populations (First Nations, Inuits, Métis) 	
Search Key Words Search		 ☐ Multiple Racial/Ethnic Populations ☐ New Immigrants/Newcomers ☐ Non-Native English speakers 	arch
Resource Title		S Older Adults	1
5Ts Framework	The 5Ts framework was developed in 2019 with support from the Duke Clinical & Translational Institute (CTSI) as a memorable way to organize and communicate best practices for inclusion of older adults in research. Each "T" is a useful reminder of the many proven strategies to support participation of older adults in clinical research. The 5Ts Framework serves as a valuable organizing model for the best practice recommendations we have gathered for improving inclusion across the lifespan. To see recommendations for each "T" select Target population, Team, Time, Tips to Accommodate, or Tools. Or to narrow the list of recommendations to those most relevant to your study, use the filters to select your "Data collection method," "Study design," "Study setting", current study "Activity," or "Person." Links and resources are attached to recommendations.		
A Bilingual, Internet-based, Targeted Advertising Campaign	A bilingual, Internet-based, targeted advertising campaign for prostate cancer clinical trials. Intervention components included (1) a low-literacy, bilingual,		





← Trial Access and Participation				
Resources for:		EDI Strategy:		
Funders	Sponsors	Target Population All		
Sites and Research Staff		Resource Topics All		
Search Key Words Search		Best Practices for Inclusion of Older Adults Culturally Sensitive Interventions Decentralized Clinical Trial Framework and Models - Remote access for clinical		
Resource Title		Financial Reimbursement for Trial Participants Improve Access for Adolescents to New Anti-Cancer Drugs		
5Ts Framework	The 5Ts framework was deve & Translational Institute (CTS communicate best practices			
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Canadian Remote Access Framework for clinical Trials

CRAFT is a uniquely Canadian hybrid decentralized clinical trial (DCT) framework based on the Australasian Tele-Trials Model (ATM):

- TRIAL CLUSTER concept agile & scalable
 - ❖ a single "site" entity, overseen by a Primary Site
- RISK-BASED organization on a TRIAL BASIS
- Explicit delegation of role accountabilities determined by:
 - a. Satellite suitability research capacity, experience
 - b. Trial/activity complexity
- Sites' involvement in multiple clusters expands CT portfolio activity & patient access



Sabesan S. et al. Australiasian Tele-Trial Model, 2016





Putting Best Practices to Practice



CRAFT Implementation - Proof of Concept (PoC)

- Demonstrate model implementation through PoC sites
- Evaluate qual./quant measures of success, primary site/satellite experiences, CRAFT Toolkit

Primary Site	Satellites
Health Sciences North: (Sudbury, ON)	Sault Area Hospital (Sault Ste. Marie)
QI: Lacey Pitre	Timmins District Hospital (Timmins)
BC Cancer: (Prince George, BC) QI: Robert Olson	Mills Memorial Hospital (Terrace) Kootenay Boundary Regional Hospital (Trail)
Eastern Health Sciences Centre: (St. John's, NL)	Central Newfoundland Regional Health Centre (Grand Falls – Windsor)
QI: John Thoms	Western Memorial Regional Hospital (Corner Brook)

EDI Demonstration Projects

- Support EDI activities and initiatives across the pan-Canadian Cancer Centre Network
- Provide funding to drive meaningful changes in trial conduct and patient access
- Evaluation and assessment of impacts

Coming Soon!





Patient Partner Perspectives

"Beyond addressing the WHY of EDI... the focus must be on WHAT we are doing next."

- Michelle Audoin, 3CTN Patient Partner, EDI Working Group Member





The biggest impact on me and my family was the relief from indirect costs of travel to St. John's and concerns about hazards – weather, moose – often encountered during the long drive...with the satellite clinic, that stress is lifted.

Making trial involvement more enticing for patients from a greater portion of the province can benefit cancer research.

It's great news all around.

- Satellite Site Patient, NL





Key Takeaways From My Experience

- We can offer world-class cancer care and still have unmet needs
- We can listen to patients and still be dismissive
- We can have intent to do good, but still do harm
- Patient-centered care is essential
- Community connections are key

Food for Thought

- How as an organization, team, individual, do we show we value diversity and equity?
- How are we challenging the status-quo to ensure our trials and practices are barrier-free and inclusive?
- How do we move beyond mission statements and symbolic posturing towards everyday actions?
- Are the needs of some communities still being addressed as parentheses or footnotes?
- Be the person that asks questions and acts



Thank You!

For more information on the EDI Framework and Toolkit and CRAFT, please email info@3ctn.ca

www.3CTN.ca







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