



# Integrating EDIIA into Cancer Clinical Trials

New Investigator Clinical Trial Course

August 21, 2024

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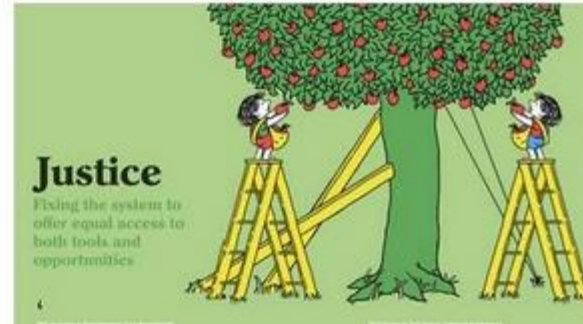
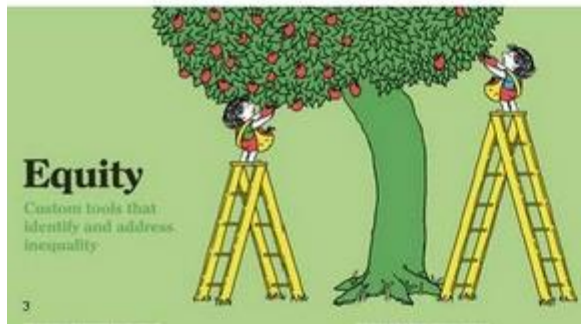
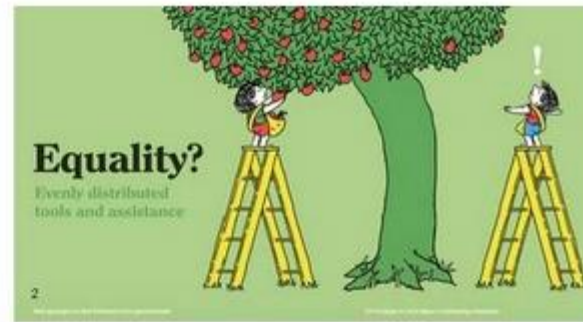


# Learning Objectives

1. Review the importance of embedding EDIIA into cancer clinical trials
2. Discuss strategies for integrating EDIIA into clinical trials from trial design to return dissemination

# Equity, Diversity, Inclusivity, Indigenization & Accessibility (EDIIA)

**Goal:** Address structural & clinical barriers and create equitable and inclusive access to trials

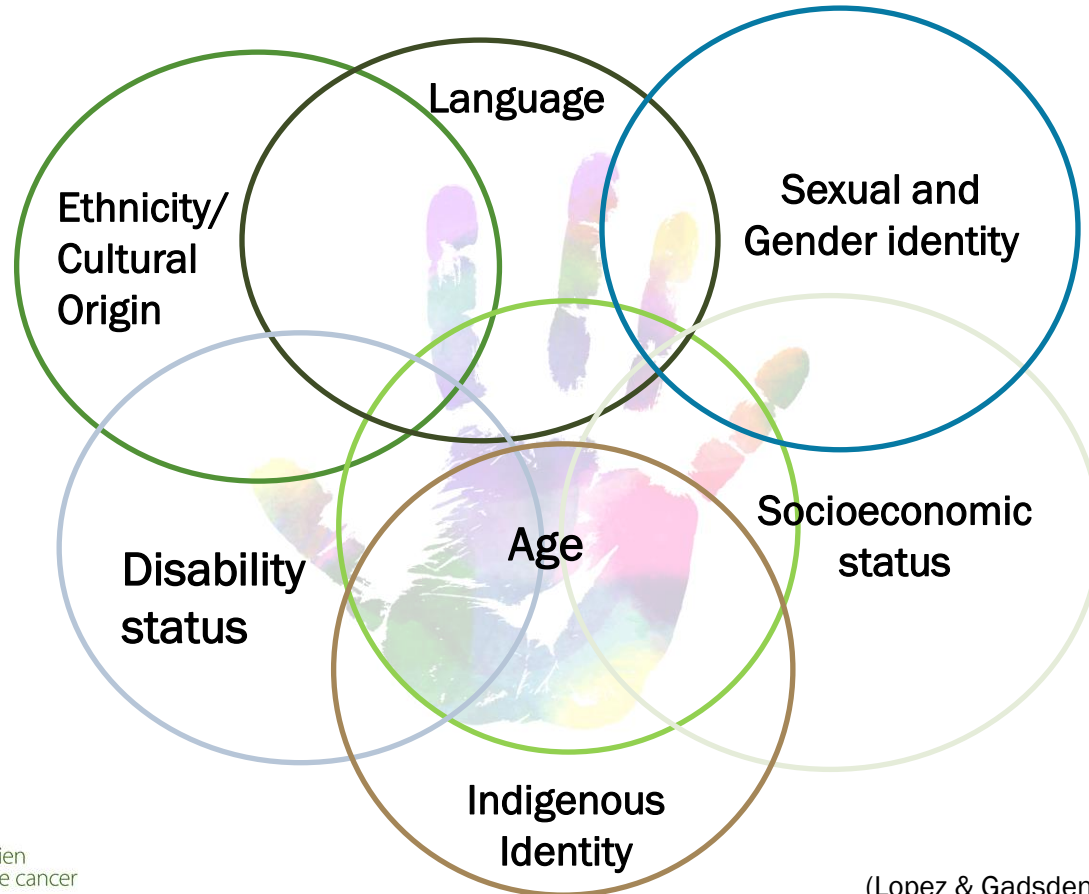


Tony Ruth (2019)

# Populations Underrepresented in Clinical Trials

- First Nations, Inuit, and Métis peoples
- Racialized persons
- Persons with disabilities
- Women
- Members of the 2SLGBTIA+ community
- Individuals at both ends of the age spectrum
- Immigrants/refugees
- Individuals whose primary language is not English or French
- Rural and remote populations

# Intersectionality & Dimensions of Diversity



# The case for embedding EDIIA in clinical trials

- All individuals should have the opportunity for early access to potentially effective treatments
- Lack of representation & accessibility of trials can compound low accrual
- Trial should include populations affected by the disease & those who will use the intervention being studied

## Efforts to improve representativeness in clinical trials support:

- More equitable access to treatments & interventions
- Generalizability of results for the intended patient populations
- The safe and effective use of the treatments & interventions
- Health equity
- Possible analyses for variation

# Barriers to Clinical Trials

## Clinical barriers

- Trial complexity
- Eligibility criteria
- Lack of flexibility
- Copy/pasting from previous protocols
- Lab values for certain ethnicities



## Structural barriers

- Conflicting budget priorities
- Limited human resource to support trials
- Geography ('clinical trial deserts')
- Availability (infrastructure)



# Barriers to Accessing Clinical Trials

## Patient level barriers

- Language
- Geographic location
- No primary care provider
- Socioeconomic status
- Medical system distrust
- Eligibility criteria
- Cancer type
- Clinical trial type

## Physician level barriers

- Unconscious biases
- Competing time priority
- Patient assumptions
- Limited incorporation of cultural safety in approach



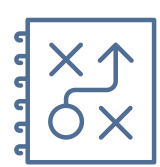
**Cultural Safety:** occurs when healthcare professionals practice self-reflection and awareness to communicate with a patient in that patient's social, political, linguistic, economic, and spiritual realm and delivers care free from racism and discrimination

→ Defined by those receiving care

**What does cultural safety look like when offering clinical trials to Indigenous peoples?**

**Consider:**

- How might historical legacies and colonial narratives in Canada affect how Indigenous peoples access healthcare, cancer care, and think about clinical trials? How can this inform the care I provide?
- What assumptions am I making about this patient? What biases do I possess?
- Recognize the power imbalances & institutional racism
- Avoid cultural stereotyping
- Two-way dialogue, validating questions, communication & taking the time (know who to talk to or where to refer patient)
- Respectfully ask about self-identification



# Strategies to Advance Equity in Cancer Clinical Trials

Domain	Factor	Approaches	Relevance to Equity
<b>Structural</b>	Availability of trials	Trial site self-assessments <sup>38,39</sup> ; trial site checklists and toolkits <sup>40,41</sup>	Promotes a diverse trial portfolio; evaluates health equity measures
	Trial recruitment	Screening and accrual logs <sup>15,42–44</sup> ; minority recruitment plans <sup>44,45</sup> ; trial site self-assessments <sup>38,39</sup> ; trial site checklists and toolkits <sup>40,41</sup>	Ensures that trial adequately represents community demographics
<b>Clinical</b>	Patient ineligibility	Reformed eligibility guidelines <sup>21–26</sup>	Reduces unnecessary exclusion, especially for patients with baseline comorbid conditions
<b>Physician</b>	Trial screening and referral	Implicit bias training <sup>46</sup> ; trial matching <sup>47,48</sup>	Minimizes bias in trial referral for eligible patients; improves cultural competency of workforce
<b>Patient</b>	Understanding of trial	Community-based or tailored outreach <sup>46,48–51</sup> ; informed-consent models <sup>52</sup> ; language interpreters; patient navigators <sup>53,46,54–59</sup>	Addresses health care mistrust; improves understanding of trial benefits; provides decision-making support
	Financial burden related to trial participation and accessibility	Financial and social needs-assistance programs <sup>53,46</sup>	Assists with out-of-pocket trial-related expenses; addresses trial barriers related to social determinants of health (e.g., transportation)



# Developing Research Questions

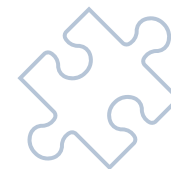
How can we develop research objectives & trials with an EDIIA lens?



- Look for patient advocacy groups to partner with
  - Allow community input
- Bring together community expertise with clinical expertise to develop RQs
- Apply for grant funding for workshop to co-develop research priorities
- Embed research questions in trial that are a priority of an overrepresented population
- Look at research team: whose interests are represented?



# Designing a Trial

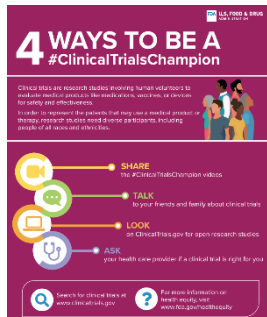


How can we keep EDIIA in mind when designing a trial?  
(example: eligibility criteria, complexity, where to open trial)



- **Create a diversity action plan**
  - Patient population (where to open?)
  - Recruitment strategy
  - Partnerships
- **Broadening eligibility criteria**
- **Flexibility to enable participation (ex: telehealth, decentralized trials)**
- **Can we conduct any sub-studies of EDIIA interventions or initiatives?**

# Accruing Participants



How can we reach the intended patient population?  
(and in particular, underrepresented populations)

What strategies/tools are you familiar with?



- Electronic companion for consent (Kraft & Doerr, 2018)
- Language & literacy level & inclusive (Kraft & Doerr, 2018)
- Involve community members in development of materials & distribution of materials (EAZ171)
- Culturally targets videos (Bander et al., 2012; EAZ171)
- Community education & outreach events (EA115/TMIST)
- Patient advocacy groups (EAZ171)



Groupe canadien  
des essais sur le cancer

(Kraft & Doerr, 2018; Boyd et al., 2021; Ezeife et al., 2022)

# Investigators & Site Staff

How can we improve investigator/site staff factors to increase enrollment of underrepresented populations on trials?

How can investigators/site staff tailor discussions about trials?



I thought you'd never ask.

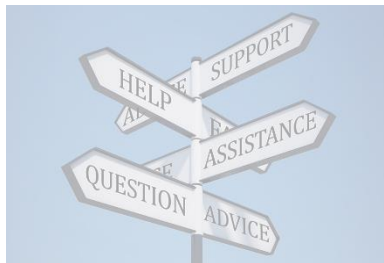
- Address biases that lead to patients not being asked to participate
  - Perception of a patient's personal suitability for a trial:

*Ideally, a married couple is always a good thing because a spouse is normally there for support. That's not to say single people shouldn't go on trials. Well-supported single people – and even if they don't have families but have a very supportive friend network...Where I tend to be a bit more worried is the person who lives on their own, doesn't seem to have a lot of friends, may have a lot of pets.* (Bell et al., 2020)

- Trial & Research Diversity Action Plans, partner with local communities/advocacy groups (monitor progress)



# Resources & Limitations



What are resources we need & limitations we may face that we need to consider when embedding EDIIA in trials?



- **Additional funding** (Are there grant opportunities that may help?)
- **Relationship building required** (on research team & with communities)
- **Healthcare structural barriers**
- **Available Personnel** (ex: Indigenous Cancer patient navigators)
- **Trial phase & type**



**Sponsors**



**Trial Committees**



Every stakeholder has a responsibility to commit to making trials more accessible and representative of patient populations

**Investigators & Site Staff**

**Patient Representative  
& Advocacy Groups**





# ASCO recommendations to increase racial & ethnic diversity in cancer clinical trials



## IMPROVE ACCESS

Every person with cancer should have the opportunity to participate in clinical trials, as an integral component of high-quality cancer care.



## EQUITY FOCUSED DESIGN

Trials should be designed with a focus on reducing barriers and enhancing EDI and work with sites to conduct clinical trials in ways that increase participation of underrepresented populations.



## PARTNERSHIPS

Clinical trial sponsors, researchers, and sites should form long-standing partnerships with patients, patient advocacy groups, and community leaders and groups.



## EDUCATION & TRAINING

Those designing or conducting trials should complete recurring education, training, and evaluation to demonstrate and maintain cross-cultural competencies, mitigation of bias, effective communication, and a commitment to achieving EDI in clinical trials.



## INVEST IN EDI

Research stakeholders should invest in programs and policies that increase EDI in clinical trials and in the research workforce.



## SHARING DATA & STRATEGIES

Research stakeholders should collect and publish aggregate data on racial and ethnic diversity of trial participants when reporting the results of trials, programs, and interventions used to increase EDI.

## Improving Trial Access for Indigenous Peoples

Indigenous Sovereignty, Truth and Reconciliation

A guide to support sites, clinical research staff, sponsors, and funders for accessing additional recommendations and best practices for engaging First Nations, Inuit and Métis Peoples in clinical trials.

## TeamScience@SWOG Field Guide

Improving Diversity and Representativeness of Clinical Trial Participants



Information Stories Education Blog

### Our mission:

To transform cancer care for the sexual and gender diverse (SGD) community by improving research, resources, and support for patients, families, caregivers, and healthcare professionals.

### What we do:

- Collate and share resources and information through our database, blogs and social media
- Source and provide education for healthcare professionals to support affirming care
- Curate stories and first person accounts from SGD

## 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 to clinical trials.

### Trial Design



Includes protocol checklists and considerations during trial development to ensure diversity of 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 to support clinical trial staff deliver culturally competent care, address health disparities, and mitigate unconscious bias.

### Collection of Race, Ethnicity & Social Demographic Data



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

## Advancing Health Equity Through Cancer Information and Support Services

Report on communities that are underserved

October 2023

## CLINICAL TRIAL DIVERSITY



### Fact Sheet

Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness. These studies may also show which medical products or therapies work best for people with certain illnesses or for certain groups of people. Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity.

Office of Minority Health and Health Equity

## EQUITY BY DESIGN IN CLINICAL RESEARCH: A SIX-PART COURSE

OVERVIEW FACULTY ACCREDITATION REGISTER/TAKE COURSE

Instructions for Equity by Design in Clinical Research: A Six-Part Course.pdf

Welcome to **EQUITY BY DESIGN IN CLINICAL RESEARCH: A SIX-PART COURSE**, a training course to advance diversity, equity, and inclusion (DEI) of underrepresented populations in clinical trials and is applicable to clinical research across all health areas. Ethical and regulatory considerations are included, and practical guidance for commitment, communication, partnership, and conduct is emphasized.

This course is a six-part series. It was originally conducted as a live virtual course (titled Equity by Design in Clinical Research: Cancer Trials) and has been reformatted as an online course. All modules begin with a 45-minute recorded instructional session, followed by a 45-minute recorded discussion session with leaders in the field. Each module also contains: transcripts for each recorded session, a PDF of the instructional session slides, and a list of resources referenced in the lecture.

- Module 1: Commitment to DEI
- Module 2: Community Engagement and Representation
- Module 3: Study Planning and Communications
- Module 4: Study Conduct
- Module 5: Workforce Development
- Module 6: Accountability, Advocacy, and Justice

### COURSE SUMMARY

Course opens: 07/15/2022  
Course expires: 08/15/2025  
Cost: \$0.00



**MULTI-REGIONAL  
CLINICAL TRIALS**  
THE MRCT CENTER OF  
BRIGHAM AND WOMEN'S HOSPITAL  
AND HARVARD

## JUST ASK! INCREASING DIVERSITY IN CANCER CLINICAL RESEARCH

Register

Already registered? Log in now.

Registration Instructions Overview Course

### The Just Ask! Increasing Diversity in Cancer Clinical Research: An ACCC-ASCO Training Program

This training program, adopted from a course developed at Duke University, is an online implicit bias training program intended for all members of the cancer research team. A series of interactive modules outline key concepts such as diversity, equity, and health disparities, as well as the role of implicit bias in clinical trial selection. Participants provide real-world examples of implicit bias from the perspective of community-based cancer programs and guidance for mitigating disparities in cancer research settings. Participants will be better equipped to promote diversity, inclusion, and equity to improve the enrollment and retention of patients from African American/Black, Hispanic/Latino, and other groups who have been historically under-represented in clinical trials.

**Who Should Participate:** Study investigators, clinical staff, research and non-research staff, administrators, and/or any members of the multidisciplinary team who are involved with clinical research within your cancer program.

### Learning Objectives

- Describe various dimensions of diversity that exist within society and the ways sociocultural norms shape perceptions
- Explain how implicit bias shapes interactions and interrelates with health disparities
- Identify strategies to address barriers to approaching underrepresented populations to engage in cancer research and/or clinical trials

The course takes an estimated 60-90 minutes and participants will receive a certificate upon completion.

### Just Ask! Training Facilitation Guide

For those who recently participated in the Just Ask! Training and would like to facilitate fruitful discussions among their staff around implicit bias, a **Just Ask! Training Facilitation Guide** has been developed to reinforce the learnings from this online implicit bias training program. The Training Facilitation Guide identifies feasible action steps to support implementation of a Just Ask! strategy in your research site or cancer program or practice.

### DOWNLOAD TRAINING GUIDE

This training program is open to the public. You do not need to be an ACCC member to participate, but you will need to create an account and log in to access the training materials for more details.



ASSOCIATION OF CANCER CARE CENTERS™

**ASCO** AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY



# CCTG EDIIA Action Plan



## EDI Strategy & Policy

- Develop EDI policy
- Review policy with stakeholders & incorporate feedback
- Implement EDI policy through communication & training
- Create initial Action Plan



## Governance & Management

- Create EDI Working Group
- Finalize EDI Action Plan timeline & review annually
- Review and update TOR for governance and scientific committees



## OSC Facility Staff

- Incorporate equity into hiring and recruitment practices
- Promote and complete equity resources and training opportunities



## Research Community & Network Users

- Integrate EDI into scientific priorities and research activities
- Work towards understanding & addressing EDI barriers
- Conduct an EDI workshop for research community



## Research

- Review and update clinical trial generic protocol, informed consent form, data standards and dictionaries, policies, and SOPs
- Incorporate EDIIA considerations throughout research process

# CCTG EDIIA Strategies

## Workshop- Integrating EDI into Clinical Trials: A Focus on PR25 & HN13

11:00 am	Welcome & Introduction to Workshop	Janet Dancey Anna Johnson
11:15 am	<b>Presentations on Trials of Focus</b> <b>HN13:</b> <i>Optimizing Head and Neck Tumour and Symptom Control in Patients Unable to Tolerate Curative Intent RT: A Phase III Trial Comparing Stereotactic Body Radiation Therapy (SBRT) to Standard Palliative Radiation Treatment (ON-TASC Study)</i>  <b>PR25:</b> <i>A Phase III Trial Investigating Platinum and Taxane Chemotherapy in Metastatic Castration Resistant Prostate Cancer Patients with Alterations in DNA Damage Response Genes</i>	Ian Poon  Michael Kolinsky
11:35 am	<b>Strategies for Improving Equity and Access in Clinical Trials</b> <i>The Black Community</i>  <i>Older Adults</i>	Doreen Ezeife  Tina Hsu
12:00 pm	LUNCH	
1:00 pm	Breakout Session One: Addressing Participant Level Equity Barriers	
2:35 pm	BREAK	
2:45 pm	Breakout Session Two: Incorporating EDI into Trial Design & Addressing Structural Barriers	
4:20 pm	Breakout Group Priority Setting	
4:45 pm	Summary, Conclusion, & Next Steps	Janet Dancey Anna Johnson
5:00 pm	ADJOURNED	

Determine actionable strategies to address participant level barriers, increase recruitment of underrepresented populations, and incorporate principles of EDI into HN13 & PR25



CCTG is a CCS national program.

# EDIIA initiatives for PR25 & HN13



## Research

**Tertiary objective:** To compare OS in participants by ethnic or cultural origin and determine if differences in OS (if any) are associated with social determinants of health

## Protocol

- Virtual visits, dose alternations, standard of care with local healthcare provider
- Develop diversity action plans

## Patient level

- Reimbursement policy

## Physician level

- Update trial training material for investigators and site staff
- Develop resources including videos, FAQ documents, and scripts on offering trials in a trauma informed & culturally safe manner



**Equity**

Were all individuals provided the support they needed to consider participation?

**Diversity**

Were attempts made to ensure the participant population is representative of the patient population?

**Inclusivity**

Were all populations invited to participate?

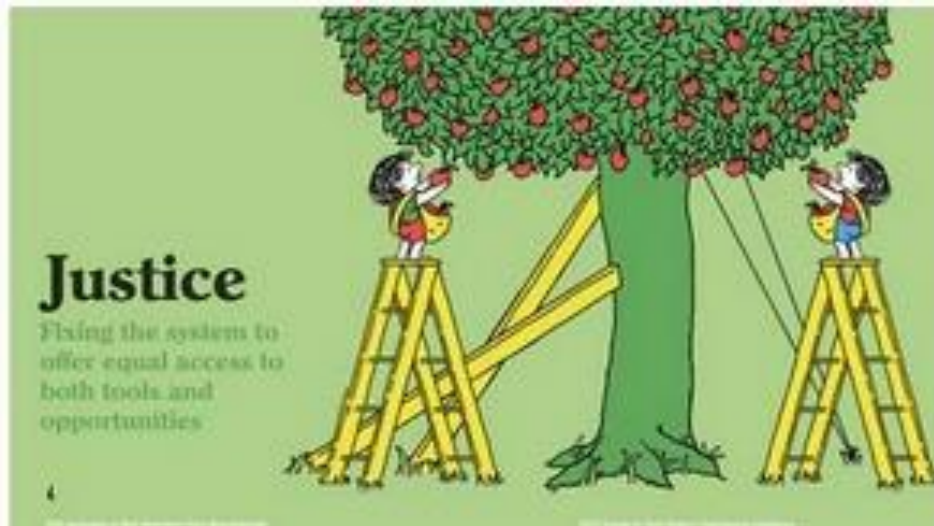
**Indigenization**

Were Indigenous communities consulted in the trial design? Are all trial elements trauma informed and do they consider cultural safety?

**Accessibility**

Were attempts made to make the trial more accessible to all interested potential participants? (ex: geographically, financially, language, age, disability)





Tony Ruth (2019)

Underlying structural barriers have been addressed with health equity in mind & all prospective participants have the opportunity to discuss participating in the trial and what they need to facilitate their participation.

What are structural barriers that you've seen?

What challenges do you face when looking for the opportunity to present a trial to a patient?

Thank you!

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