Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

Integrating EDIIA into Cancer Clinical Trials

New Investigator Clinical Trial Course

August 21, 2024

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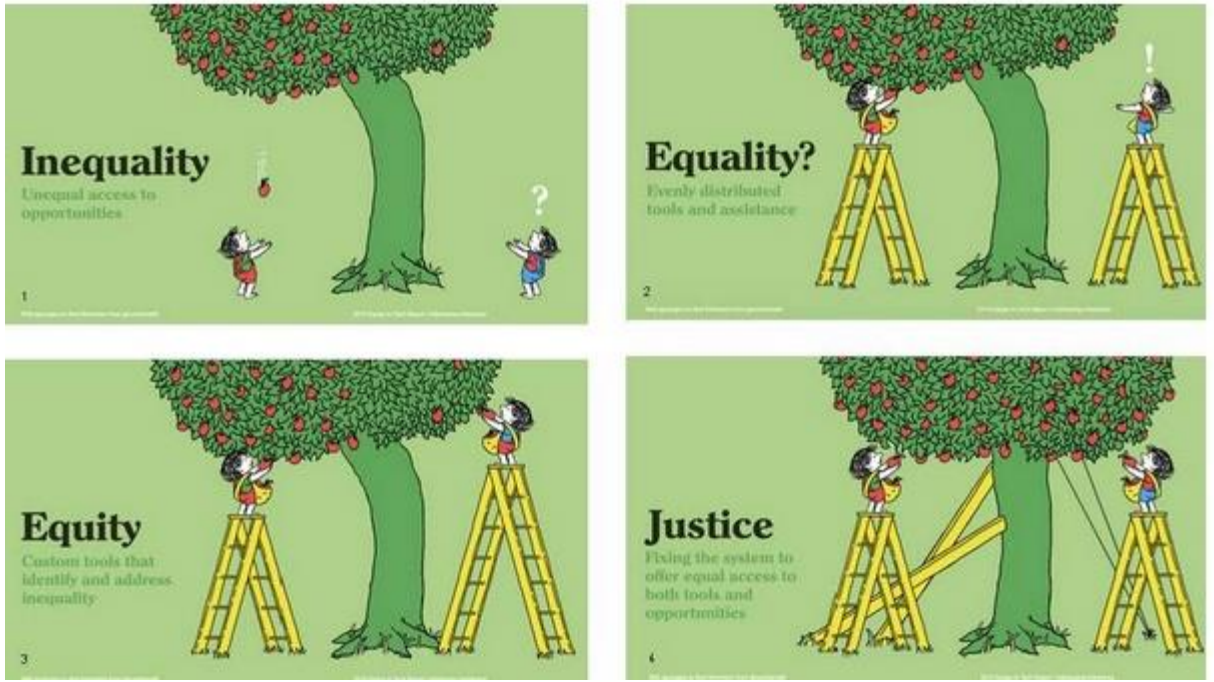
Learning Objectives

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



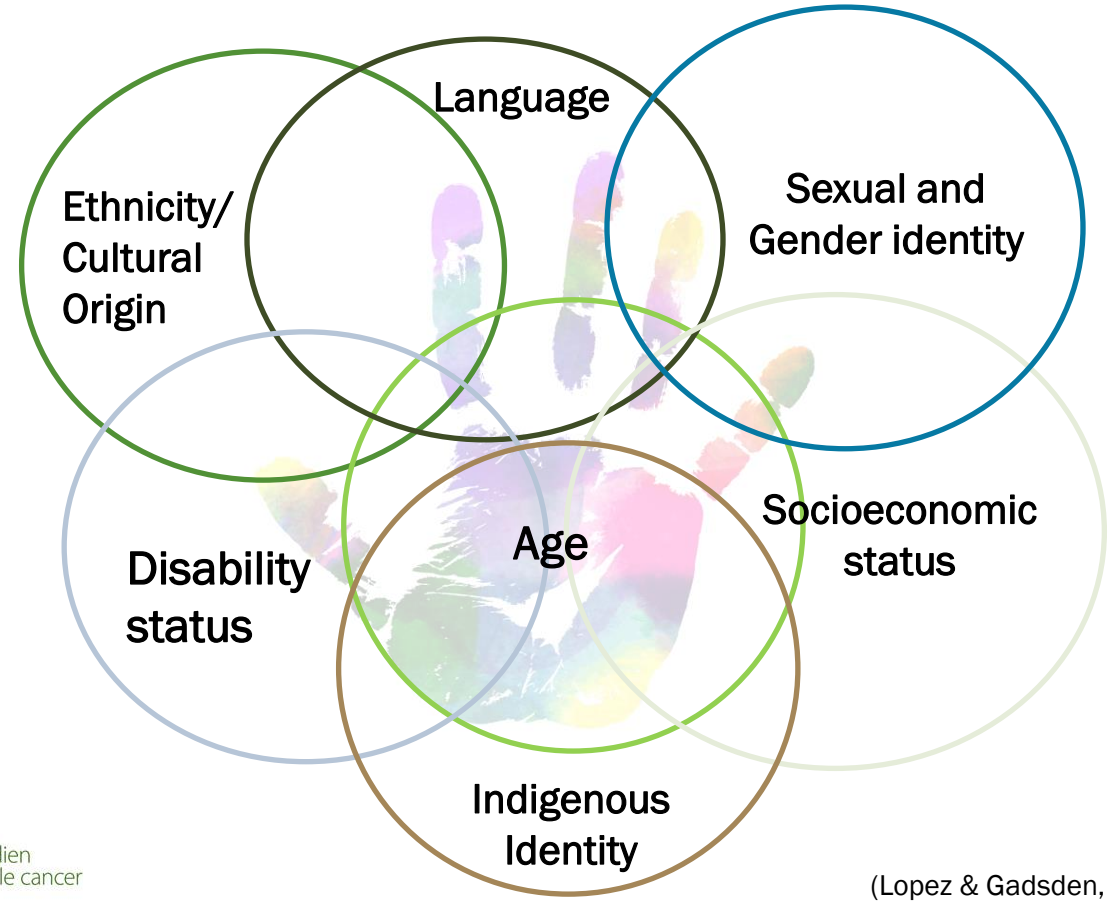
Tony Ruth (2019)

Populations Underrepresented in Clinical Trials

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

(Acuña-Villaorduña et al., 2023; Guerra et al., 2022; Shapiro et al., 2024)

Intersectionality & Dimensions of Diversity



(Lopez & Gadsden, 2017; Goodson et al., 2022)

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

(Guerra et al., 2022; ASCO, 2023; Versavel et al., 2023; FDA, 2024)

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)

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(Acuña-Villaorduña et al., 2023; Guerra et al., 2022; Shapiro et al., 2024)

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

(Acuña-Villaorduña et al., 2023; Guerra et al., 2022; Shapiro et al., 2024)

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

→<u>Defined by those receiving care</u>

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 possesses?
- 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

(Maar et al., 2019; Webb et al., 2023; Mainous et al. 2023)

Strategies to Advance Equity in Cancer Clinical Trials

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

(Guerra et al., 2022)

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?

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(Garrick et al., 2022; Oyer et al., 2022; Guerra et al., 2022)

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?**

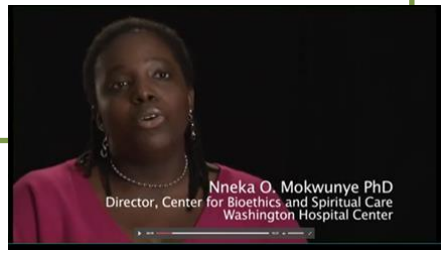
(Guerra et al., 2022; Oyer et al., 2022; Goodson et al 2022; Versavel et al., 2023)

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)



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

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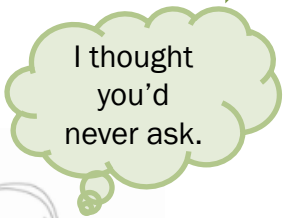
Investigators & Site Staff

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?



- 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)

(Bell et al., 2020; Abbott et al., 2021; Andraski et al., 2021)

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

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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.

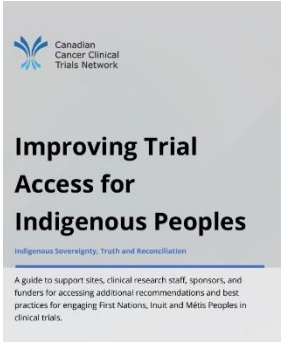
INVEST IN EDI

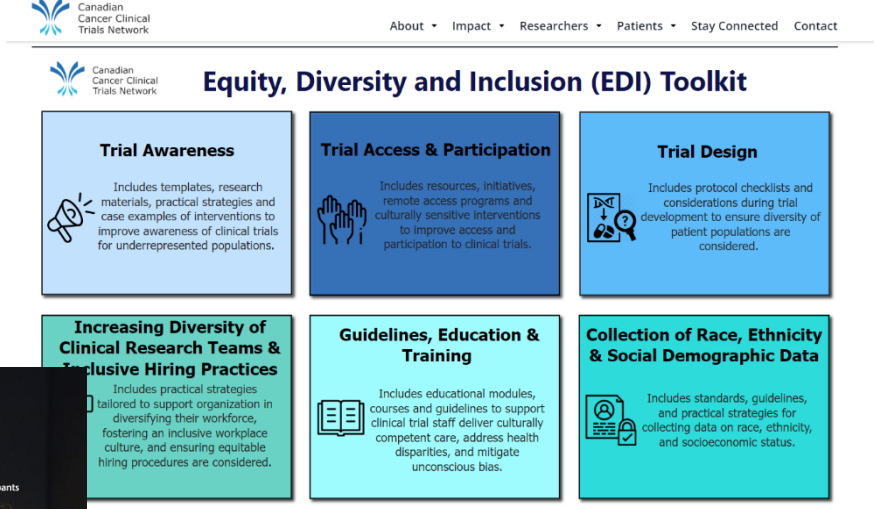
Research stakeholders should invest in programs and policies that increase EDI in clinical trials and in the research workforce.

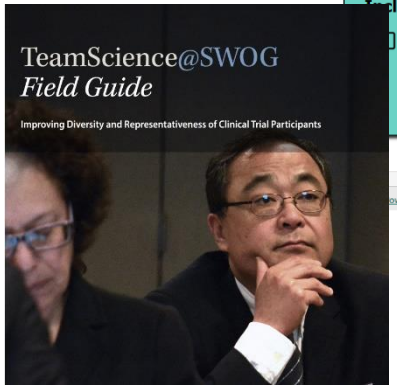
SHARING DATA & STRATEGIES

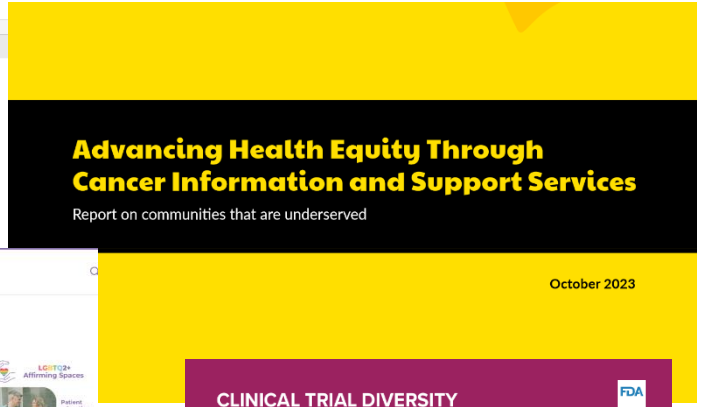
Research stakeholders should collect and publish aggregate data on racial and ethnic diversity of trial participants when reporting the results of trials, programs, and interventions used to increase EDI.

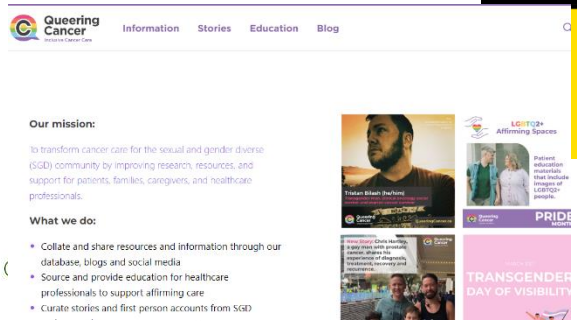
(ASCO, 2023)

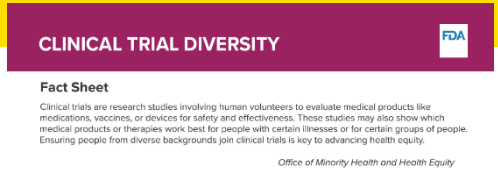


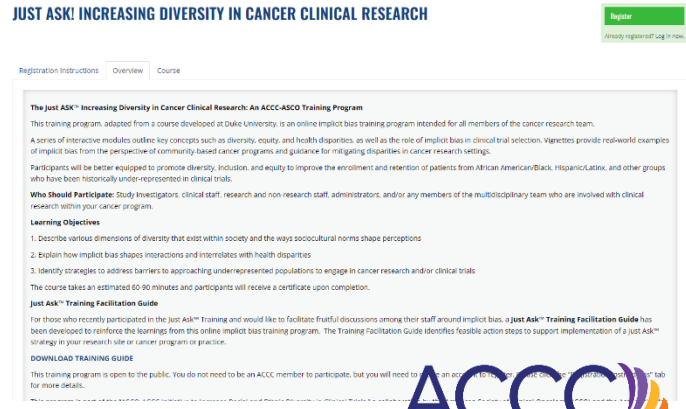












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CCTG EDIIA Action Plan

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	**Presentations on Trials of Focus** **HN13:** *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)*	**Ian Poon**
	PR25: *A Phase III Trial Investigating Platinum and Taxane Chemotherapy in Metastatic Castration Resistant Prostate Cancer Patients with Alterations in DNA Damage Response Genes*	**Michael Kolinsky**
11:35 am	**Strategies for Improving Equity and Access in Clinical Trials** *The Black Community*	**Doreen Ezeife**
	Older Adults	**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**	

Canadian Cancer Society / Société canadienne du cancer

CCTG is a CCS national program.

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

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

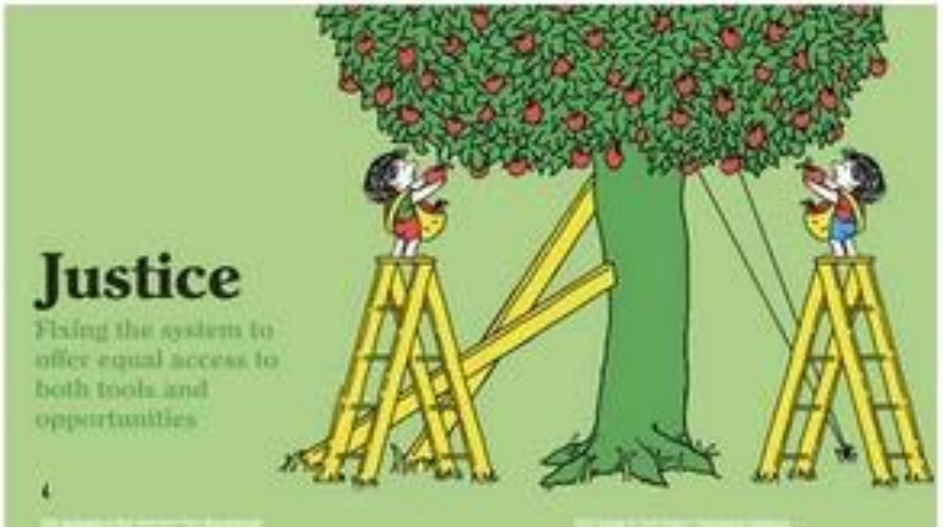
- Reimbursement policy

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)

(Acuña-Villaorduña et al., 2023; Guerra et al., 2022)



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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