ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Improving Access and Inclusion in Clinical Trials: Strategic Initiatives and Collaborations

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ASCO Strategic Plan

MISSION

Conquering cancer through research, education, and promotion of the highest quality, equitable patient care.

VISION

A world where cancer is prevented or cured, and every survivor is healthy.

CORE VALUES

Evidence | Care | Impact

5-year outcome: ASCO will achieve equity in access to high quality cancer care and research, healthy oncology work environments, and information to drive improved patient outcomes.

5-year goals

ACCESS

Remove barriers to high quality, equitable care and patient-centered research

PROFESSION

Drive healthy clinical and research work environments that lead to fulfillment for oncology professionals

KNOWLEDGE

Be the trusted source for timely and impactful continuous learning

Equity, Diversity and Inclusion

Global Impact

FLAGSHIP PROGRAMS

- Clinical Research
- Conquer Cancer Grants
- Meetings
- Publications
- Advocacy
- Practice Support
- Professional Development

ASCO Efforts to Improve Clinical Trials Access and Inclusion

- Partnerships to understand and address barriers
- Consensus-driven solutions
- Research and policy statements

Ongoing Clinical Trials Access and Inclusion Activities

- Research Site Self-Assessment for EDI Readiness
- Evaluating Screening and Enrollment Data
- Elevating Patient Partnerships and Engagement
- Decentralizing Clinical Trials
- Mapping Clinical Trial Sites
- Engaging Stakeholders

Key Partners

- Patient research advocates
- Sites (community-based and academic)
- Investigators and research administrators
- Multi-stakeholder task forces
- FDA
- NCI
- Industry and CROs
- Other subject matter experts (individuals and organizations)

Strategies to Improve Racial and Ethnic Equity, Diversity, and Inclusion in Clinical Trials

Research Statement

Site Assessment

Implicit Bias Training

Improving Racial and Ethnic Diversity in Cancer Clinical Trials

An ASCO-ACCC Research Statement

Details specific actions to engage all research stakeholders to address the lack of racial and ethnic diversity in cancer clinical trials and ensure every individual with cancer has an opportunity to participate in a clinical trial.

The recommendations cover:

- Access to Clinical Trials
- Equity-Focused Design
- Partnerships
- Education and Training
- Investment in Equity, Diversity, and Inclusion
- Sharing Data and Strategies

Oyer RA, Hurley P, Boehmer L, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. JCO **40**, 2163-2171(2022).DOI:10.1200/JCO.22.00754

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ACCC Association of Community Cancer Centers

Research Site Resources for Improving Equity, Diversity, and Inclusion (EDI)

Research Site Self-Assessment

ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment

Enables research sites and networks to conduct an internal review of policies, programs, and procedures to identify opportunities to improve EDI in clinical research across various levels of the organization and along the clinical trial enrollment continuum.

- Gain insights to improve programs, policies, procedures, and participation
- Identify evidence-based strategies to assess and mitigate barriers and disparities
- Hold focused and constructive EDI discussions with leadership and staff
- Demonstrate a commitment to EDI in clinical trials

Implicit Bias Training Program

Just ASK™ Increasing Diversity in Cancer Clinical Research: An ACCC-ASCO Training Program

Enables clinicians and staff to assess and mitigate biases regarding who is screened for and offered clinical trials.

- Curriculum-based training program
- Five interactive modules can be completed independently in about 60-90 minutes
- Companion guide facilitates team discussions about after completing training

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ACCC
Association of Community Cancer Centers

Screening and Enrollment Study

Research sites lack data about patients who are screened for clinical trials, by race and ethnicity.

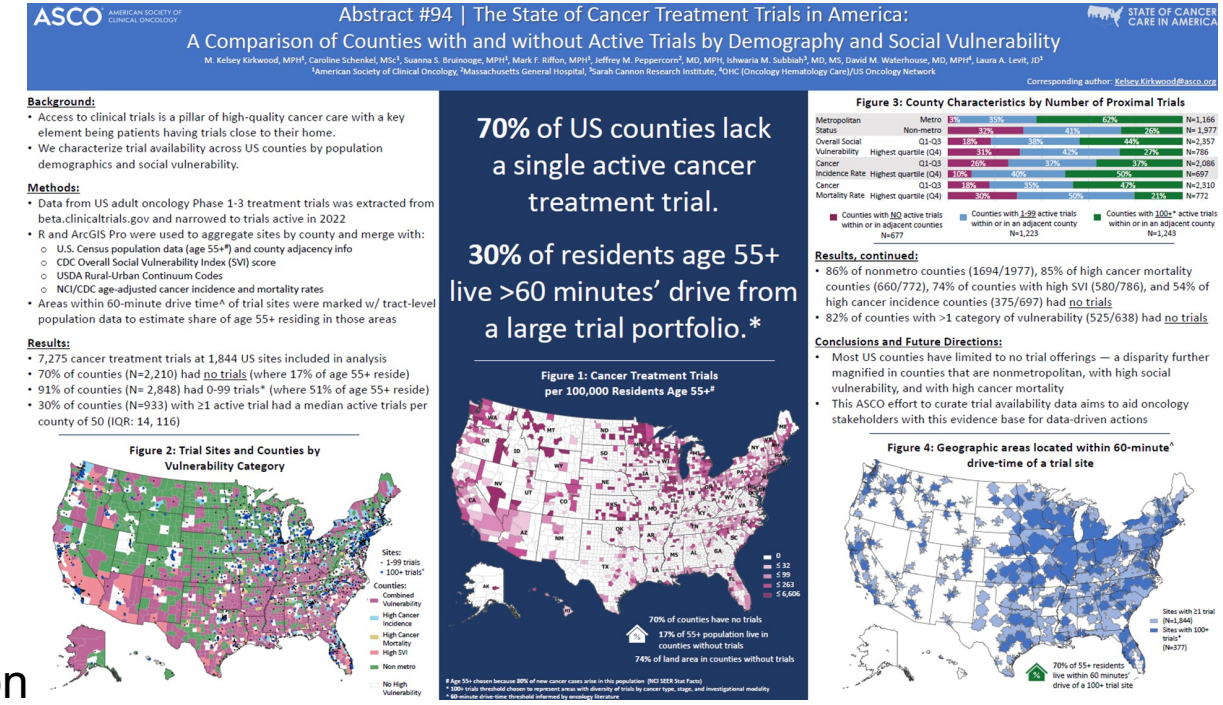
- Semi-structured interviews conducted with research sites
  - Identifying challenges and potential solutions for collecting screening and enrollment data, by race/ethnicity
- Next step: Disseminate takeaways and effective strategies for research sites

Broadening Eligibility Criteria

- ASCO and Friends of Cancer Research Collaboration
  - FDA, NCI, industry, investigator and patient partners
- Called for streamlined, scientifically-justified eligibility criteria
- Published recommendations for expanded eligibility criteria in 2017 and 2021
  - https://society.asco.org/research-data/clinical-trials/clinical-trial-eligibility-criteria
- Subsequent FDA guidance documents and NCI protocol template changes

Geographic Access to Cancer Treatment Trials

- Geographic analysis
  - Identify disparities and opportunities for targeted improvements in access to trials
  - US-based phase 1 to 3 cancer treatment trials registered on ClinicalTrials.gov
- Deliverables
  - 2023 ASCO Quality Symposium poster and abstract: doi.org/10.1200/OP.2023.19.11_suppl.94
  - March 2024 manuscript and infographic submission to *JCO Oncology Practice* (under review)



Patient-Focused and Decentralized Clinical Trials

Clinical trials available anywhere, anytime, to everyone.

Objectives

Address challenges with conducting clinical trials in settings where patient and healthcare provider **access to trials** and research **infrastructure** are limited.

Flexibility

Options

Access

FDA Form 1572 Fields of Concern

Section	Description	1572 Guidance May 2010
Field 3	Name and address of any medical school, hospital, or other **research facility** where the clinical investigation(s) will be conducted	Is intended to identify facilities where study activities will be conducted, and clinical data will be generated or collected.
Field 4	Name and address of any clinical **laboratory facilities** to be used in the study	Is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study.
Field 6	Names of **sub-investigators**	Is intended to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data.

Call-to-Action

Enabling patients to participate in clinical trials where they live.

Harvey, Miller, Hurley et al. A call-to-action to advance patient-focused and decentralized clinical trials. Cancer, Volume: 130, Issue: 8, Pages: 1193-1203, First published: 09 January 2024, DOI: 10.1002/cncr.35145

ASCO Clinical Trials Access and Inclusion Task Force

Objectives

- Expand ASCO's research and policy activities on access and inclusion in clinical trials
- Partner with diverse stakeholders: patient research advocates, investigators, research staff, trial sponsors (industry and US federal), health regulators, other research organizations

Key Deliverables

- Gap analysis
- Engage diverse stakeholders to gain insights and develop consensus
- Inform ASCO's activities to help broaden clinical trial engagement, access, and inclusion

Discussion