Increasing Cancer Clinical Trials Participation of Patients from Racial and Ethnic Minority Populations in the Community

Randall A. Oyer, MD, FACCC

Executive Director of Cancer Services, Lancaster General Health

NORTH CAROLINA Oncology Association

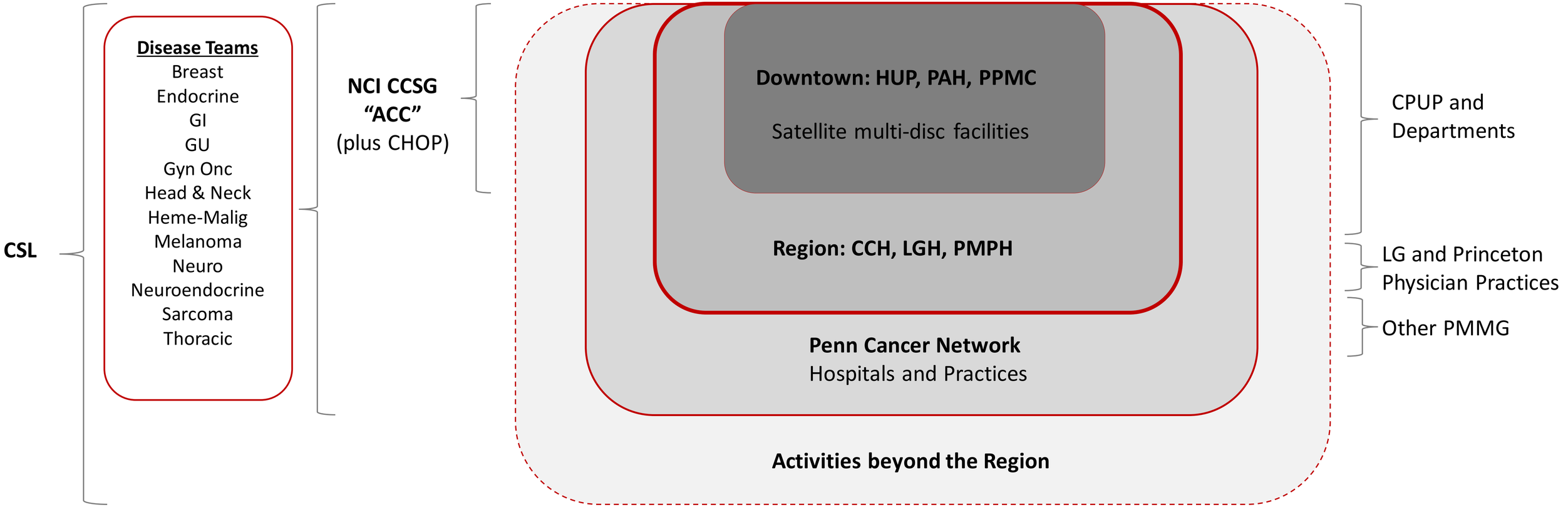
NORTH CAROLINA
Oncology Association

Penn Medicine Cancer Service Line

- Integrated Network: 6 hospitals, 18 cancer care locations, virtual care, cancer care at home
  - Annual Statistics: **42,000 new patient visits***, **350,000 visits***, 17,000 surgeries, 205,000 infusions, & 145,000 radiation treatments
  - Over 2,500 patient encounters per day
- 12 Disease specific, multidisciplinary leadership teams
  - Disease specific subspecialists in Surgical Oncology, Medical Oncology, Radiation Oncology, Diagnostic & Interventional Radiology, and Pathology
  - 20 Disease specific Tumor Boards
- NCI-Designated Comprehensive Cancer Center
- National Comprehensive Cancer Network Member
  - $158 Million in research funding
  - 1,260 annual publications
  - Over 7,000 patients accrued to clinical trials
  - 20 FDA approved Cancer Treatments and Therapies in the past 5 years

NORTH CAROLINA Oncology Association

Cancer Service Line Structure



Association of Community Cancer Centers

- Joined ACCC in 2006
- Clinical Affairs Committee 2014-2017
- Governmental Affairs Committee 2017-23
- Treasurer 2017-2020
- President 2020-21
- Chair ACORI 2021-present

ACORI Overview

ACCC Community Oncology Research Institute

Mission: To close the gap in cancer research through optimal community oncology partnerships.
Vision: To achieve its mission, ACORI will focus on three primary domains:

Equity: ACORI will lead advocacy and education related to equitable patient representation in oncology clinical trials.

- Advocate for diversity, equity, and inclusion with trial sponsors and regulatory agencies.
- Develop education and resources that promote strategies and solutions that will achieve equity in clinical research.
- Investigate and mitigate persistent areas or influencers of disparities in trial participation.

Capacity Building: ACORI will build capacity and competency among community oncology sites to be research-ready.

- Develop education and resources that democratize knowledge, skills, and infrastructure for equitable clinical research.
- Facilitate mentorship opportunities between established and developing research sites.
- Convene community oncology research stakeholders for peer-to-peer learning, educational sessions, and networking.

Research Diffusion: ACORI will serve as the go-to resource for sponsors (academic and industry) seeking to expand their community oncology site portfolio.

- Foster relationships with trial sponsors and other research groups to align on ACORI mission.
- Vet research or trial opportunities brought to ACORI by sponsors and facilitate implementation at qualified community oncology research sites.
- Maintain a clearinghouse of open research and trial opportunities, as well as research results and findings.

NORTH CAROLINA Oncology Association

ACORI

Expanding Access to Clinical Trials Survey Objectives

1) To gain a better understanding of how cancer programs engage in cancer clinical research
2) To gather insights into common barriers and solutions related to clinical trial implementation and patient recruitment
3) To better understand the needs of programs that do not currently offer clinical trials
4) To identify tools and resources to support cancer programs

Survey Methods

- Developed in collaboration with representatives from City of Hope and reviewed by the project advisory committee
- Target audience:

a) At least 25% African American and Hispanic residents
b) ACCC members who were highly engaged with ACORI/clinical trials
c) All ASCO-ACCC pilot sites

- Targeted emails were sent from ACCC staff to specific contacts at each site
- The survey was open from June 20, 2022 through October 5, 2022

Survey Respondents (N = 58)

- 38% directors or administrators, 22% research managers or supervisors, and 16% physicians, among others
- 62% practice in urban settings
- 45% have an annual patient volume between 1,001-5,000
- 31% community and 33% comprehensive community cancer programs
- 21% were NCI-designated cancer centers
- 45% reported not being affiliated with an academic research institution

Survey Results

90% Currently Conduct Cancer Clinical Research

- 98% reported conducting cancer treatment clinical trials, 71% cancer prevention or screening trials, and 67% conducting cancer supportive care trials
- Phase 3 and phase 2 trials were the most common (90% and 88%, respectively)
- 38% had between 1-10 industry-sponsored trials accruing and 31% had 31 or more open
- Affiliation with a research network was common. Only 13% reported no affiliation
- Respondents were split on whether they had sufficient staffing for research activities: 43% agreed or strongly agreed that they did while 45% disagreed or strongly disagreed
- 52% of respondents reported enrolling between 100-1,000 patients on trials annually

Survey Results

Best Practices for Promoting Participant Diversity Varied

- Logistical supports and culturally appropriate and language accessible materials were the most widely applied practices, though not universal.

- The biggest opportunity for improvement across the respondent sites was in setting and monitoring progress toward diversity goals for trials, followed by offering appointments outside of normal business hours to increase patient access.

Survey Results

Sites Currently Conducting Research Experience Common Challenges

- The most common challenges included limited staff to absorb research activities (52%), difficulty recruiting patients (52%), available trials not matching patient population (48%), and limited clinician time (38%).

- Some reported limited clinician interest in trials (29%) , difficulty working with payers to cover trial costs (27%), limited staff with research training (27%), and competition with other cancer programs locally (23%).

Survey Results

4 of 6 Not Currently Conducting Research Want to in Future, but Report Challenges

- **Organizational-level most common barriers**: limited infrastructure (67%), lack of information about available research opportunities (50%), lack of support from management (50%), limited operating finances to open and run trials (50%)

- **Care team-level most common barriers**: limited staff with research training/skills (67%), limited funding to hire research staff (67%), limited staff to absorb research activities (50%), limited clinical investigator experience securing research grants (50%)

- **Patient-level most common barriers**: available trials do not match patient population (33%), difficulty with patient retention (33%), difficulty with payors covering trial costs (33%), lack of logistical supports to enable patient participation (33%)

Survey Results
Opportunities for ACCC/ACORI

- The two most common resources desired: communication about clinical research opportunities (74%) and connections to clinical trial sponsors (64%).

- Other helpful resources endorsed by respondents: training on grant writing skills and administrative support to build a research program (24%), a one-on-one consultative or mentoring service from other ACCC members successfully leading in cancer research (24%), and a community of practice or similar model for capacity building (22%).

- A suggested policy opportunity for ACCC to consider spearheading relates to state-level legislation requiring insurance providers to cover costs related to clinical trial participation to enable equitable participation.

Challenges in Providing Trials

- Time in the office visit
- Physician administrative time
- Trained staff
- Cost of infrastructure and staff
- Complexity of legal and regulatory compliance
- Burden of record keeping and data collection
- Required patient and family education
- Health insurance coverage
- Additional burden for patients

Benefits of Cancer Treatment Trials

- Treatment improvements come from treatment trials
- Ability to provide tomorrow's treatments today for your patients
- Marker of high quality oncology care
- Level one NCCN guideline recommendation
- Engage forward thinking teams
- Opportunities to inform trial design and treatments

The Clinical Trials Gap

- Despite the importance of clinical trials, overall participation levels remain low (2%-8% of adults with cancer), although most people who participate in cancer clinical trials report favorable views of their experience.

- Recent analyses of cancer therapeutic trials found that only 4%-6% of trial participants are Black and 3%-6% are Hispanic, despite representing 15% and 13% of people with cancer, respectively.

Unger JM, Vaidya R, Hershman DL, et al: Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. J Natl Cancer Inst 111:245-255, 2019

13 Studies (9 in academic and 4 in community settings) with 8,883 patients

Trial unavailability
55.6% (95% confidence interval [CI] = 43.7% to 67.3%)

Ineligibility for available trials
21.5% (95% CI = 10.9% to 34.6%)

Declined enrollment for a trial for which eligible
14.8% (95% CI = 9.0% to 21.7%)

Trial enrollment
Academic (15.9% [95% CI = 13.8% to 18.2%])
Community (7.0% [95% CI = 5.1% to 9.15])

Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury, ME. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. J Natl Cancer Inst. 2019 Mar 1; 111(3): 245-255. doi: 10.1093/jnci/djy221. PMID: 30856727; PMCID: PMC6410951.

Special Populations Traditionally Underserved and Under Represented on Treatment Trials

- Geriatric
- Minority
- Rural
- Uninsured & underinsured
- High health related social needs

ASCO-ACCC Initiative Goals

- Ensure cancer treatment trials better reflect the diversity of cancer populations, across communities.
- Collaborate to gain insights and generate ideas.
- Develop and test practical strategies and solutions to increase diversity of participation in cancer treatment trials, in all communities, with emphasis on patients from racial and ethnic populations historically underrepresented in clinical trials.

Key Milestones

- **Developed and Tested Site Self-Assessment and Implicit Bias Training Program**
  - 75 sites participated in pilot project to test the feasibility and utility
  - 4 manuscripts of findings have been published, 1 poster presented
  - A manuscript from the ASCO-ACCC Patient Partners Advisory Group is in preparation

- **Released ASCO-ACCC Research Statement** – published May 2022
  - Recommendations for research community to improve racial and ethnic EDI in cancer clinical trials (Oyer et al, JCO, 2022)

- **Released Resources for Research Sites** (free online access)
  - List of evidence-based strategies for sites – released May 2022
  - Implicit Bias Training Program (JustASK!) – released July 2022
  - Site Self-Assessment – released July 2022

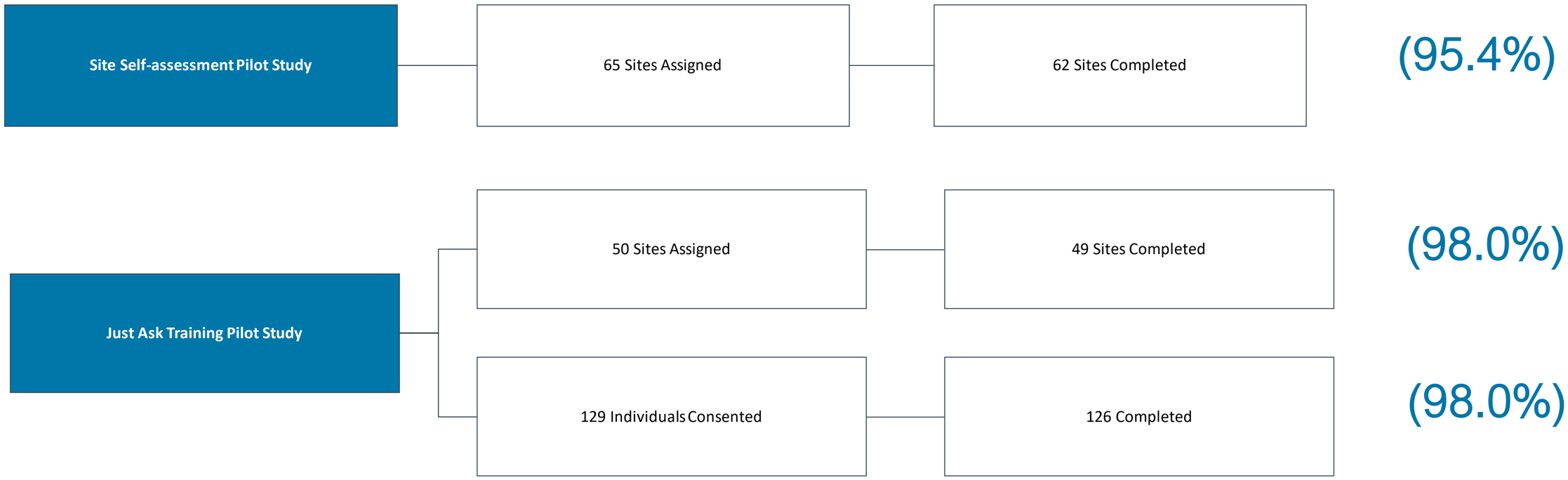
Key Collaborators

- ASCO-ACCC Steering Group
- ASCO-ACCC Patient Partners Advisory Group
- Working Groups
    i. Site Self-Assessment Tool
    ii. Implicit Bias Training
- Participating Pilot Project Research Sites!
- ASCO and ACCC Staff
- Other experts and published works

Important Role of Patient Partners Advisory Group

- ASCO and ACCC Steering Group formed a Patient Partners Advisory Group (PPAG) to provide patient insights during the collaboration.
- Purpose was to guide the development of resources and provided important feedback during critical milestones, including:
  - Insights during resource development and beta-testing
  - Interpretation of pilot project findings
  - Informed (and co-authored) recommendations for research community
  - Ensured end products reflect patient experience
- Provided a forum for patient research advocates to discuss and share
  - Key barriers for people from underrepresented racial and ethnic groups
  - Best strategies to improve equity and diversity in clinical trial access and participation
  - Effectives strategies to address biases

Pilot Project Completion Rates



All 75 enrolled sites participated in either the Tool Pilot Study or Training Pilot Study

NORTH CAROLINA Oncology Association

Overview of ASCO-ACCC Resources for Research Sites

NORTH CAROLINA Oncology Association

Increasing Racial and Ethnic Diversity in Cancer Clinical Trials:

An ASCO and Association of Community Cancer Centers (ACCC) Joint Research Statement

Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, Benson A, Bernick LA, Byatt L, Charlot M, Crews J, DeLeon K, Fashoyin-Aje L, Garrett-Mayer E, Gralow JR, Green S, Guerra CE, Hamroun L, Hardy CM, Hempstead B, Jeames S, Mann M, Matin K, McCaskill-Stevens W, Merrill J, Nowakowski GS, Patel MI, Pressman A, Ramirez AG, Segura J, Segarra-Vasquez B, Hanley Williams J, Williams JE, Winkfield KM, Yang ES, Zwicker V, Pierce LJ. 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.* 2022. DOI: 10.1200/JCO.22.00754.

Scan QR code to access statement:

NORTH CAROLINA Oncology Association

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

Learn more and access resources via:
www.asco.org/asco-accc

Scan QR code to access statement:

NORTH CAROLINA Oncology Association

ASCO-ACCC Recommendations

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.

Scan QR code to access statement:

NORTH CAROLINA Oncology Association

Research Site Self-Assessment

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

Enables research sites to identify opportunities to improve equity, diversity, and inclusion in clinical research while doing an internal review of their programs, policies, procedures.

- Gain insights to improve programs, policies, procedures, and mitigate disparities
- Identify evidence-based strategies and resources
- Create and/or maintain a culture of continuous quality improvement

Learn more via: www.asco.org/asco-accc

Site Self-Assessment Pilot Study Findings

Guerra C, Pressman A, Hurley P, Garrett-Mayer E, Bruinooge SS, Howson A, Kaltenbaugh M, Williams JH, Boehmer L, Bernick LA, Byatt L, Charlot M, Crews J, Fashoyin-Aje L, McCaskill-Stevens W, Merrill J, Nowakowski G, Patel MI, Ramirez A, Zwicker V, Oyer RA, Pierce LJ. Increasing Racial and Ethnic Equity, Diversity, and Inclusion in Cancer Treatment Trials: Evaluation of an ASCO-Association of Community Cancer Centers Site Self-Assessment, JCO Oncology Practice. (e-pub ahead of print)

Key Findings
Site Self-Assessment Pilot Study

- 62/65 sites completed the study (95% response rate)
- 81% were satisfied with the assessment
- 82% identified opportunities for improvement
- 63% identified specific strategies for improvement
- 74% thought the assessment had potential to help their site increase EDI
- 82% reported increased awareness about performance
- 63% identified specific strategies (63%) to increase EDI
- 65% of sites were able to provide data on the number of patients that consented
- **Only two sites were able to provide all requested trial screening, offering, and enrollment data by race and ethnicity**
  - In the Site Self-Assessment that was released, we removed that component
    - ASCO and ACCC will partner with sites to better understand their processes and the feasibility of collecting screening, offering, and enrollment data in systematic and automated ways.

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 enables research and care teams to address implicit bias
- Five interactive modules can be completed independently in about 60-90 minutes
- A companion facilitators' guide is available to help sites continue the conversation with the larger research team after taking the training

Learn more via: www.asco.org/asco-accc

NORTH CAROLINA Oncology Association

Implicit Bias Training Pilot Study Findings

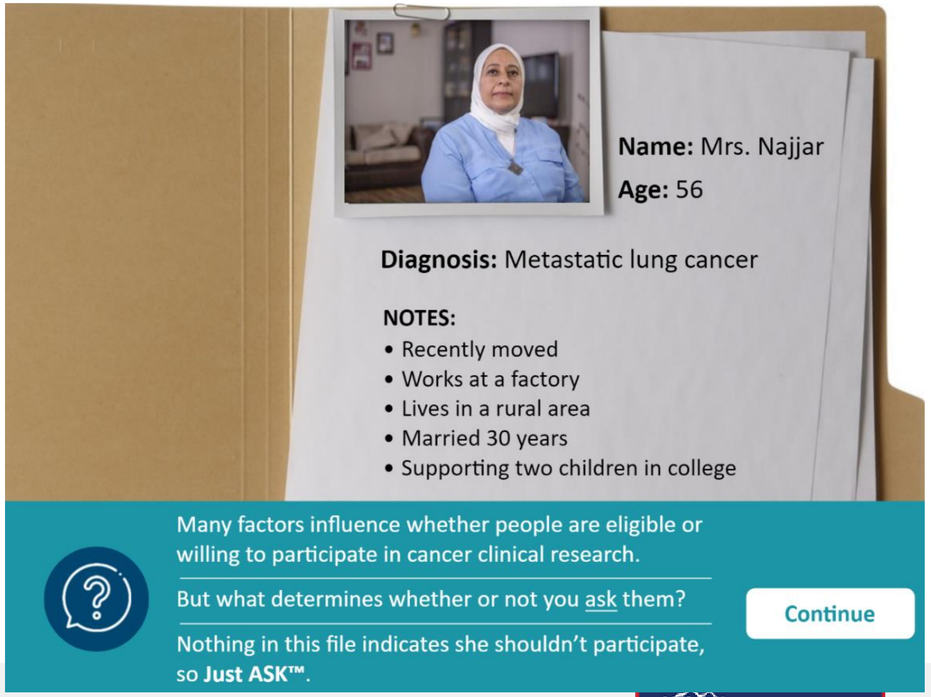
Barrett NJ, Boehmer L, Schrag J, Benson III AB, Green S, Hamroun-Yazid L, Howson A, Matin K, Oyer RA, Pierce LJ, Jeames SE, Winkfield K, Yang ES, Zwicker V, Bruinooge SS, Hurley P, Williams JH, Guerra CE. An Assessment of the Feasibility and Utility of an ACCC-ASCO Implicit Bias Training Program to Enhance Racial and Ethnic Diversity in Cancer Clinical Trials. JCO Oncology Practice. (e-pub ahead of print)

Implicit Bias Training Program

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

- Don’t assume; “Just Ask” patients
  - What they think
  - How they feel
  - What they need
  - What is important for them
  - Are they interested in participating in a trial
  - What challenges they have related to participating in research
  - What is possible for them
- Open ended questions
- Respect for autonomy

Learn more via: www.asco.org/asco-accc



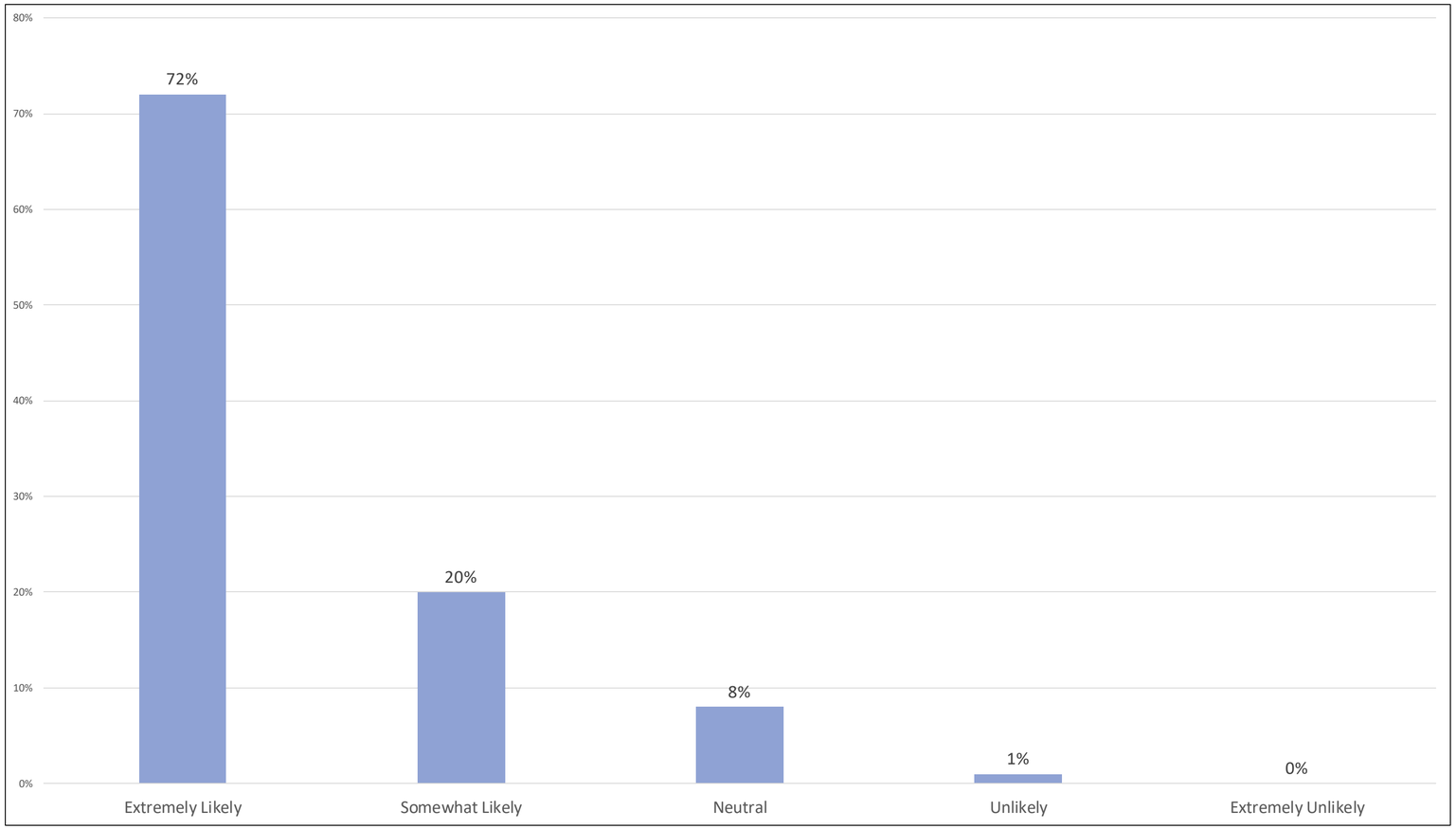
NORTH CAROLINA Oncology Association

Key Takeaways

- Preliminary analysis suggests the training has high utility and is feasible
- Participants experienced increased knowledge in key areas
- High satisfaction rates

NORTH CAROLINA Oncology Association

“How likely are you to implement this course, once publicly available, at your practice or research site?”



92% of participants reported they are extremely or somewhat likely to implement

NORTH CAROLINA Oncology Association

Improve Equity, Diversity, and Inclusion in Your Cancer Clinical Trials

READ

Research Statement on
Diversifying Clinical Trials

TAKE

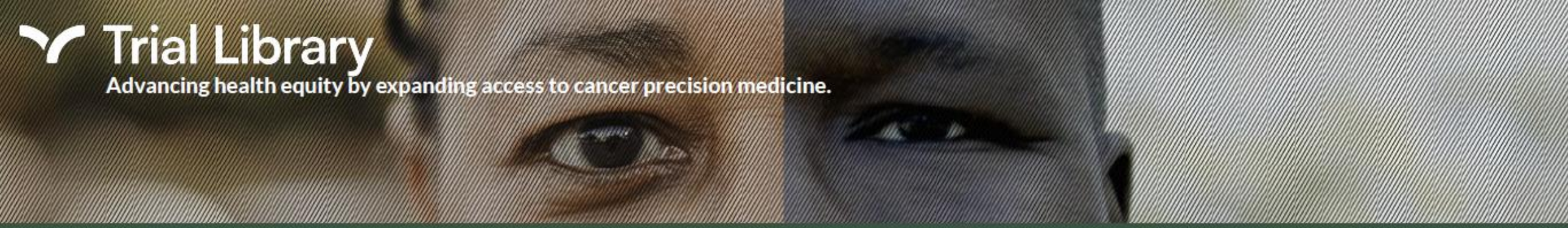
EDI Research Site
Self-Assessment

COMPLETE

Just ASK™
Implicit Bias Training Program

NORTH CAROLINA
Oncology Association

Other Resources



Trial Library

Advancing health equity by expanding access to cancer precision medicine.

Our provider-facing software is integrated with tech-enabled patient navigation to advance health equity in oncology clinical trials.

WHAT WE DO

1 **Apply an Evidence-Based Strategy**
Access a broader and more diverse patient participant pool

2 **Augment Visibility of Your Clinical Trials**
Promote visibility of clinical trial opportunity among community practices

3 **Enhance Capacity of Your Clinical Trial Sites**
De-centralize pre-screening to optimize efficiency at existing clinical trial sites

We partner with providers in physician-owned practices across the United States to grow a community-engaged network in collaboration with the Association of Community Cancer Centers (ACCC).

Trial Library partners with independent community practices within 100 miles of active clinical trial sites for decentralized pre-screening for clinical trials.

Trial Library works with study sponsors to convert trials in our community to sponsored trials.

HOW IT WORKS

Trial Library Web Application enables community providers to discover nearby trials where paid pre-screening opportunities exist and be alerted of new opportunities as they are added. Providers can search for trials, view trial details and contact the PI if they have questions. Providers can accept the opportunity to pre-screen through a registration process, provide updates about pre-screening activities, agree to discuss clinical trial opportunities with their patient.

Centralized, Tech-Enabled Ally Navigation Team supports completion of comprehensive clinical trial pre-screening evaluation and provides study site hand-off to research personnel at clinical trial site.

- Evaluate/address patient social determinants of health, provide counseling on access to resources
- Interpreter/translation services for multilingual capacity in 350+ languages
- Patient engagement software allows communication to/from navigators via SMS, telephone or video calls

Trial Library is a San Francisco-based public benefit company and UCSF spin-out. To learn more, visit us at www.triallibrary.com or contact us at info@triallibrary.com.

Clinical Pipe

Blue Button

NORTH CAROLINA
Oncology Association

Expanded Clinical Treatment Access Going Forward

Sponsor

- Decentralized trials
- Expanded eligibility criteria
- Support for trial expenses
- Linguistically and culturally appropriate education & consent materials

Program

- Trials networks across geography that makes sense
- Mentorship and shared resources
- Jointly identify priority trials that can answer most critical questionsLocal availability of trials that match local need

Patient and family level

- Community trust
- Preparatory community education

Thank you for this invitation and your attention!

NORTH CAROLINA
Oncology Association