Foreword on Moving Forward

The language and terms used throughout this course reflect contemporary best practice and guidance. To ensure continuous alignment with current best practice, terminology will be reviewed and updated as guidelines evolve. For example, when color is used regarding race, capital letters are used (e.g., Black, White, Brown), as recommended by the National Association of Black Journalists

Advancing Health Equity Across the Spectrum

Open Enrollment: Rewriting the Rules of Access in Clinical Trials

This program is supported by an educational grant provided by Johnson & Johnson.

In support of improving patient care, CME Outfitters LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

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Through an agreement between the Accreditation Council for Continuing Medical Education and the Royal College of Physicians and Surgeons of Canada, medical practitioners participating in the Royal College MOC Program may record completion of accredited activities registered under the ACCME's "CME in Support of MOC" program in Section 3 of the Royal College's MOC Program.

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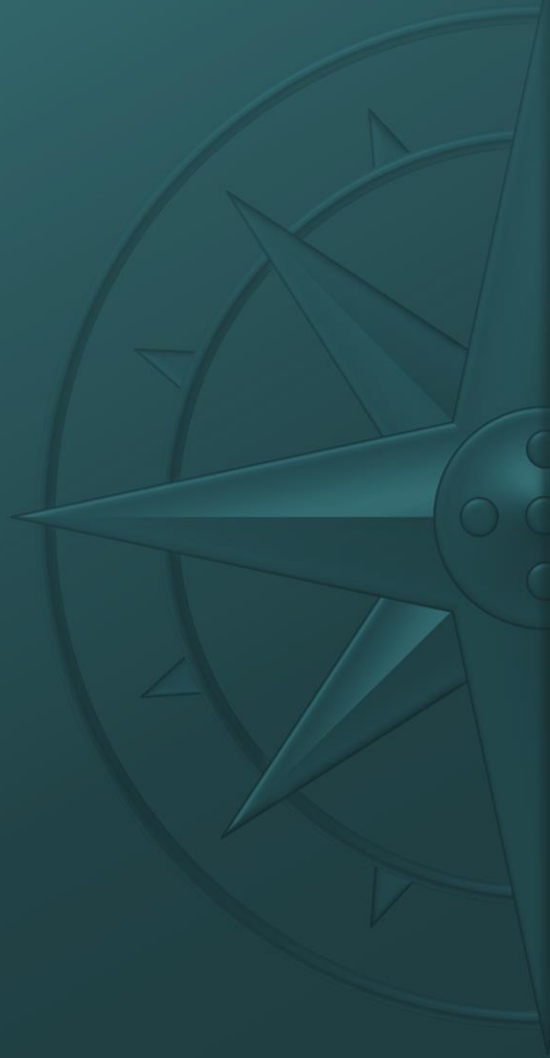
This activity may include discussions of products or devices that are not currently labeled for use by the U.S. Food and Drug Administration (FDA).

The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any uses not approved by the FDA) of products or devices.

To Ask a Question

To submit a question, please go to the *Ask Question* tab at the bottom of the screen.



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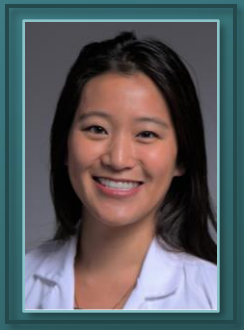

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Monica E. Peek, MD, MPH, MSc, reports no financial relationships to disclose.

Lea Ann Chen, MD, reports the following financial relationships:

Advisory Board—Lilly and Pfizer Inc.

Speakers Bureau—Pfizer Inc.

Priscilla Pemu, MD, MS, FACP, reports the following financial relationships:

Grants—Janssen Pharmaceuticals, Inc. (Principal Investigator on this investigator-initiated award. The award is made to Morehouse School of Medicine)

Research Support—Merck & Co., Inc.; Novartis Pharmaceuticals Corporation; and Sanofi (Principal Investigator – all contracts are with Morehouse School of Medicine)

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- Keshia Pitt, PhD (Planning Committee)
- Felicia Oyedepo, MD (Planning Committee)
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All identified conflicts of interest have been mitigated.

CME OUTFITTERS

LEARNING OBJECTIVE 1

Assess socioeconomic, geographic, and systemic factors that contribute to disparities in clinical trial access, particularly in underserved or community-based settings.

CME OUTFITTERS

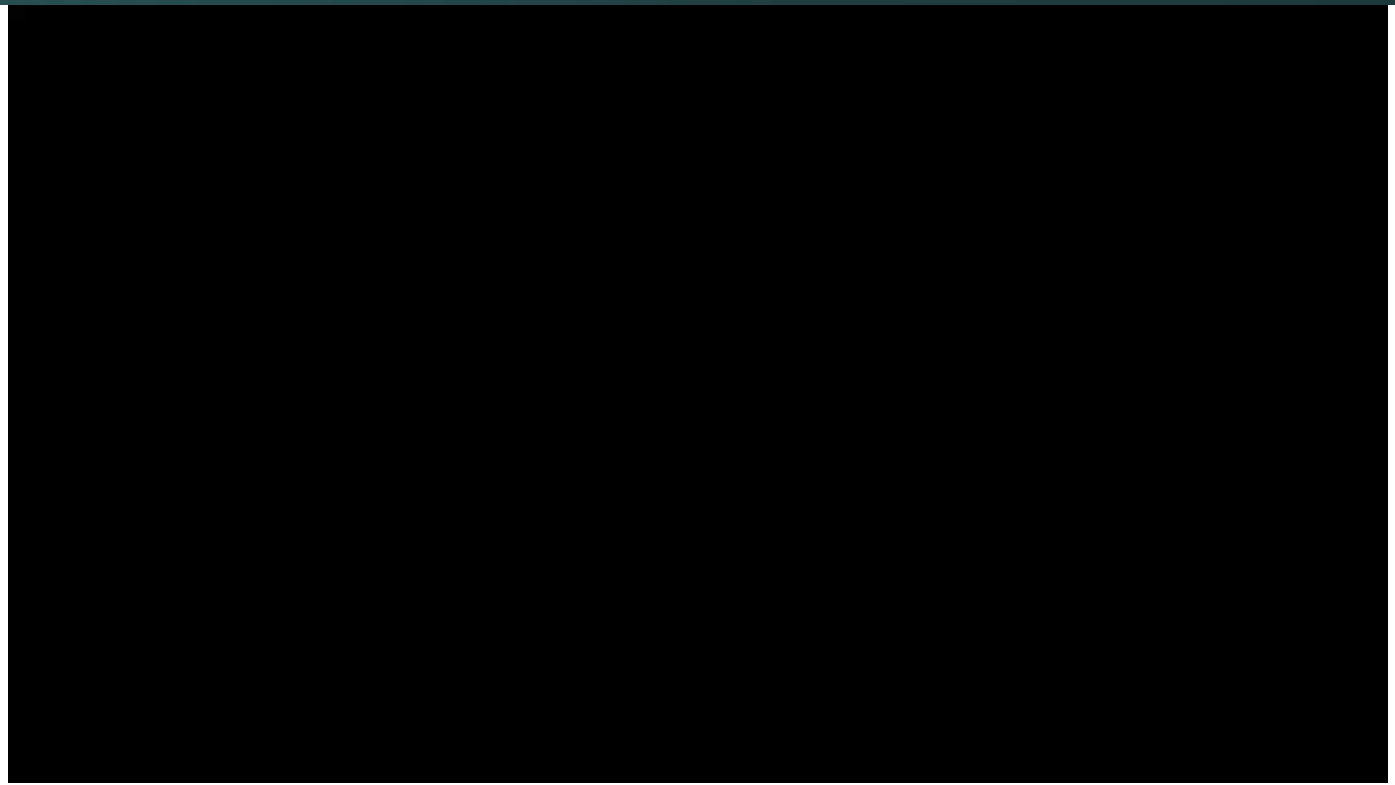
LEARNING OBJECTIVE 2

Identify interprofessional strategies, including use of culturally responsive communication, patient navigators, and advocacy partnerships, to engage underrepresented patients in clinical trial discussions and enrollment.

Clinical Rationale and Context for Inclusive Research

Why Trust and Invitation Matter

A Patient Navigator's Perspective



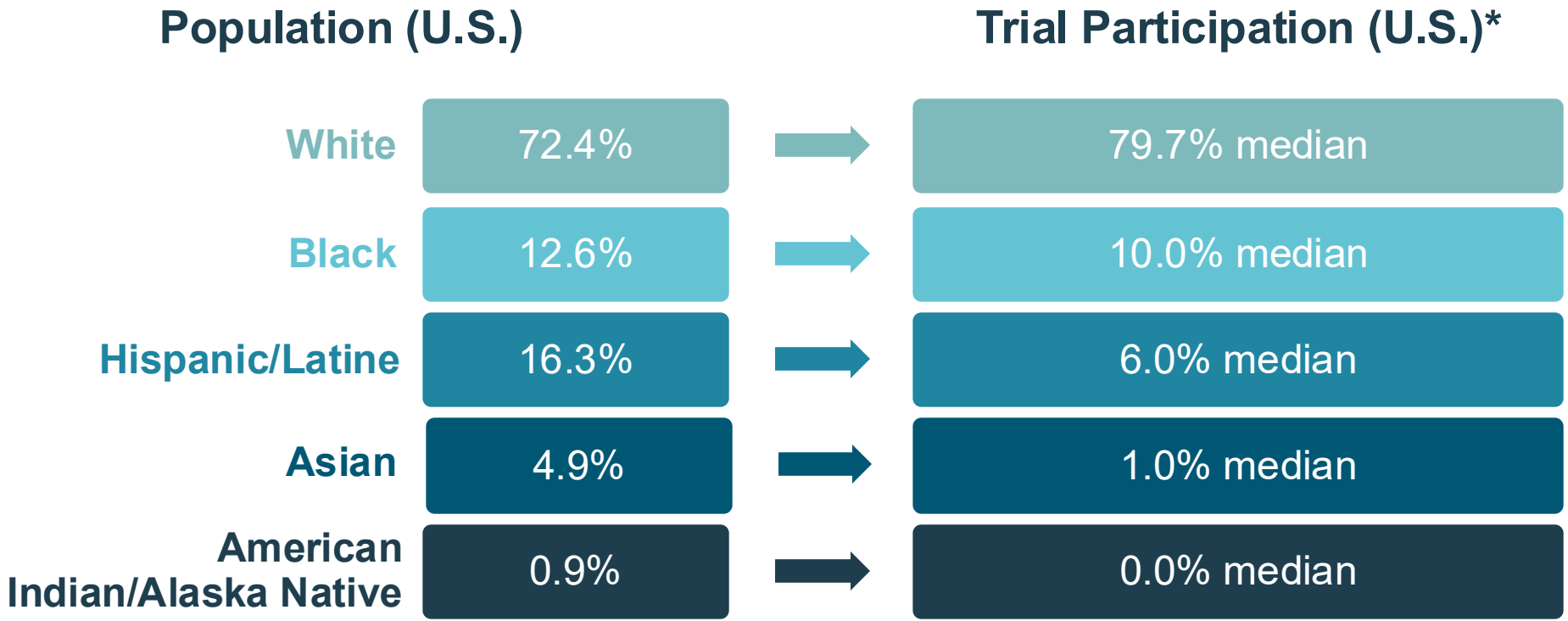
Audience Response

How often do you discuss clinical trial opportunities with patients from underserved communities?

A. Regularly: I actively look for opportunities
B. Sometimes: when obvious trials are available
C. Rarely: only when patients ask
D. Never: I don't feel equipped to discuss them

Bring The Full Picture Into Focus

Overall Medians Mask Specialty-Level Gaps; Many Trials Don't Report Race and Ethnicity, Biasing Medians



*Medians across U.S. trials registered 2000–2020; reporting often missing.

United States Census Bureau – 2010 Census. https://data.census.gov/cedsci/. Turner BE. *Lancet Reg Health Am.* 2022;11:100252.

Zoomed In: Who Is Missing From Trials?

Burden vs Enrollment Snapshots and Nonreporting Rates

Oncology	Black and Hispanic patients underrepresented in FDA-registration trials versus U.S. cancer burden. Black = 22% and Hispanic = 44% of expected participation. Underrepresentation (RQ = trial share ÷ US incidence): Black 0.42; Hispanic 0.60; White 0.98; Asian 1.04; AIAN 0.00; NH/PI 0.00. Values < 1.0 = underrepresented.
Cardiovascular	Underserved racial and ethnic groups persistently underrepresented across cardiology trials; representation lags burden. For example, in FDA-approval CV drug trials: Black participation overall 2.9%; PPR 0.29.
Diabetes/CVOTs	Hispanic/Latine, non-Hispanic Black, and Southeast Asian participants underrepresented in major CV outcome trials (DPP-4, GLP-1, SGLT2); reporting often incomplete.

CV = cardiovascular; CVOT = cardiovascular outcome trials; RQ = representation quotients; AIAN = American Indian/Alaska Native; NH = Native Hawaiian; PI = Pacific Islander; PPR = participation-to-prevalence ratio; DPP-4 = dipeptidyl peptidase-4; GLP-1 = glucagon-like peptide-1; SGLT2 = sodium-glucose cotransporter 2.

Turner BE. *Lancet Reg Health Am*. 2022;11:100252. Unger JM. *JAMA Netw Open*. 2023;6(7):e2322436. Taparra K, et al. *JAMA Health Forum*. 2024;5(6):e241388. Di Muro FM, et al. *JAMA Cardiol*. 2025;10(9):954-960. Vilcant V, et al. *Heart Lung Circ*. 2022;31(9):1263-1268. Sinclair MR, et al. *Front Public Health*. 2024;12:1412874.

MythBuster #1: Underserved Patients Aren't Interested in Clinical Trials

Patients Will Say Yes If Asked

- **Reality:** When asked, many say yes! In a U.S. cancer center survey, only 32% had ever been asked; 84% of those asked enrolled.
- **Black patients**: In an HIV care cohort, 67% were willing to join future trials and 86% said yes when invited; "not being asked" was a major barrier.
- **Hispanic/Latine patients**: A recent multi-site study shows 74-76% willing to participate, < 10% report being asked.
- **National context**: Only 9% of U.S. adults report receiving a trial invitation; offer rates drive participation.
- **Meta-analysis across 35 studies**: When offered a cancer trial, ~55% enroll, with participation of Black patients similar to that of White patients.

HIV = human immunodeficiency virus.

Moreland K, et al. *Curr Oncol*. 2024;31(9):5367-5373. Garber M, et al. *J Gen Intern Med*. 2007;22(1):17-42. Occa A, et al. *Prev Med Rep*. 2022;26:101742. Unger JM, et al. *J Natl Cancer Inst*. 2021;113(3):244-257.

What This Means For Care Today

Drug Metabolism

Drug efficacy

Varies across populations. Underrepresentation limits generalizability and different groups can respond differently to therapies.

Adverse Reactions

Adverse events differ by race and ethnicity. For example, ACE-inhibitor angioedema risk is several-fold higher in Black patients than in White patients.

Treatment Response

Dosing requirements may vary.

Up to 40% difference in efficacy.

Dosing Requirements

Treatment guidelines are often based on limited populations, which compromises applicability to the whole U.S. population.

Why This Matters In Your Practice:

- Evidence-based medicine requires evidence from diverse populations, as safety and effectiveness can vary by age, sex, race, and ethnicity.

ACE = angiotensin-converting enzyme.

National Academies of Sciences, Engineering, and Medicine. *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. 2022. https://www.ncbi.nlm.nih.gov/books/NBK584403/. Kubo K, et al. *Pharmacogenomics J*. 2017;17(6):494-500. Ohara M, et al. *Clin Pharmacokinet*. 2019;58(8):1077-1089. Reichman ME, et al. *Pharmacoepidemiol Drug Saf*. 2017;26(10):1190-1196.

Trust Requires Transparency: Historical Context

Building Trust in Your Practice:

1. **Acknowledge** historical context when appropriate
2. **Explain** modern protections and oversight
3. **Demonstrate** transparency in your approach
4. **Follow through** on commitments to patients

Centers for Disease Control and Prevention [CDC]. 2024. https://www.cdc.gov/tuskegee/about/timeline.html. KFF. https://www.kff.org/racial-equity-and-health-policy/how-history-has-shaped-racial-and-ethnic-health-disparities-a-timeline-of-policies-and-events/. Lerner BH. *N Engl J Med*. 2007;356(18):1806-1807. Nong P, et al. *JAMA Netw Open*. 2020;3(12):e2029650. Haywood C Jr, et al. *J Gen Intern Med*. 2014;29(12):1657-1662.

Barriers in Community-Based Practice

System-Level Barriers:

- Information accessibility
- Language access (limited interpreter services; lack of translated handouts)
- Limited research infrastructure
- Time constraints in clinical workflow
- Lack of research coordinator support
- Distance to academic medical centers
- Insurance and transportation issues
- ID/documentation needed for screening/consent
- Billing rules excluding uninsured
- Site policy on stipends, alternative IDs, proxy addresses

Provider-Level Barriers:

- Unfamiliarity with available trials
- Discomfort discussing research
- Assumptions about patient interest
- Lack of training in research communication

Patient-Level Barriers:

- Language preferences not met (when system access is not provided)
- Work schedule inflexibility
- Childcare responsibilities
- Fear of being "experimented on"
- Privacy/immigration concerns
- Prior negative system interactions

ID = identification.

Ebrahimi H, et al. *JAMA Netw Open*. 2024;7(4):e248739. Minasian LM, et al. *JCO Oncol Pract*. 2020;16(3):125-127. Unger JM, et al. *CA Cancer J Clin*. 2025;75(4):341-361. Mackay CB, et al. *Cancer*. 2017;123(15):2893-2900. Williams CP, et al. *Cancer Med*. 2024;13(8):e7185. Castillo BS, et al. *Curr Oncol*. 2024;31(6):3017-3029. Jorge S, et al. *J Natl Compr Canc Netw*. 2023;21(1):27-32.e2. Bodicoat DH, et al. *Trials*. 2021;22(1):880. Zgierska AE, et al. *J Clin Transl Sci*. 2024;8(1):e38.

Practical Methods to Communicate, Navigate, and Enroll

Audience Response

What is your biggest barrier to discussing clinical trials?

A. I do not know what trials are available
B. Not enough time in appointments
C. Lack of research coordinator support
D. Worry patients will not understand
E. Concern about patient safety
F. Other

Make The Conversation Easy To Understand

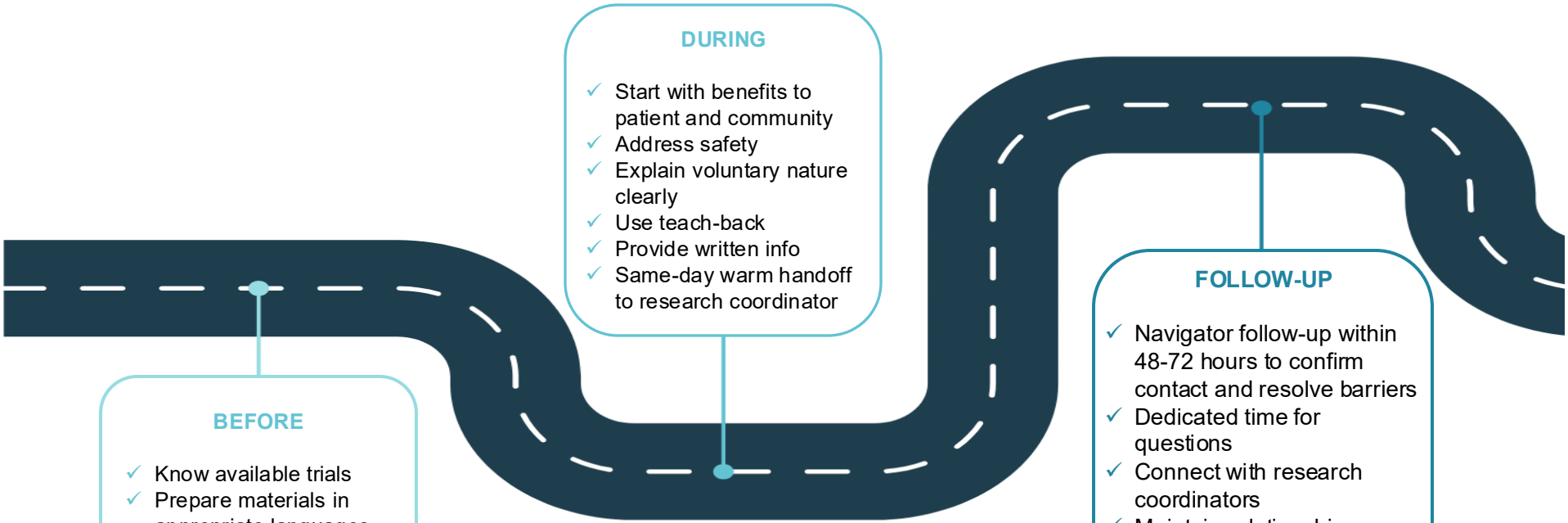
System-Focused Solutions:

- ☐ **Plain language** explanations
- ☐ **Visual aids** and written materials in multiple languages
- ☐ **Teach-back** methods to confirm understanding
- ☐ **Cultural brokers** and patient navigators
- ☐ **Multiple touchpoints** for information processing
- ☐ **Messaging transcreation** that adapts content for culture, language, and beliefs (not just reading level)

> **Health literacy** is not an individual characteristic that absolves care providers... it's a characteristic of the system within which you're delivering care.
>
> **- Dr. Priscilla Pemu**

Agency for Healthcare Research and Quality [AHRQ]. 2025. https://www.ahrq.gov/health-literacy/improve/precautions/index.html. Griffey RT, et al. *J Commun Healthc*. 2015;8(1):10-21. Ha Dinh TT, et al. *JBI Database System Rev Implement Rep*. 2016;14(1):210-247. Fouad MN, et al. *J Oncol Pract*. 2016;12(6):556-563.

Your Conversational Roadmap



BEFORE

- ✓ Know available trials
- ✓ Prepare materials in appropriate languages
- ✓ Consider patient context

DURING

- ✓ Start with benefits to patient and community
- ✓ Address safety
- ✓ Explain voluntary nature clearly
- ✓ Use teach-back
- ✓ Provide written info
- ✓ Same-day warm handoff to research coordinator

FOLLOW-UP

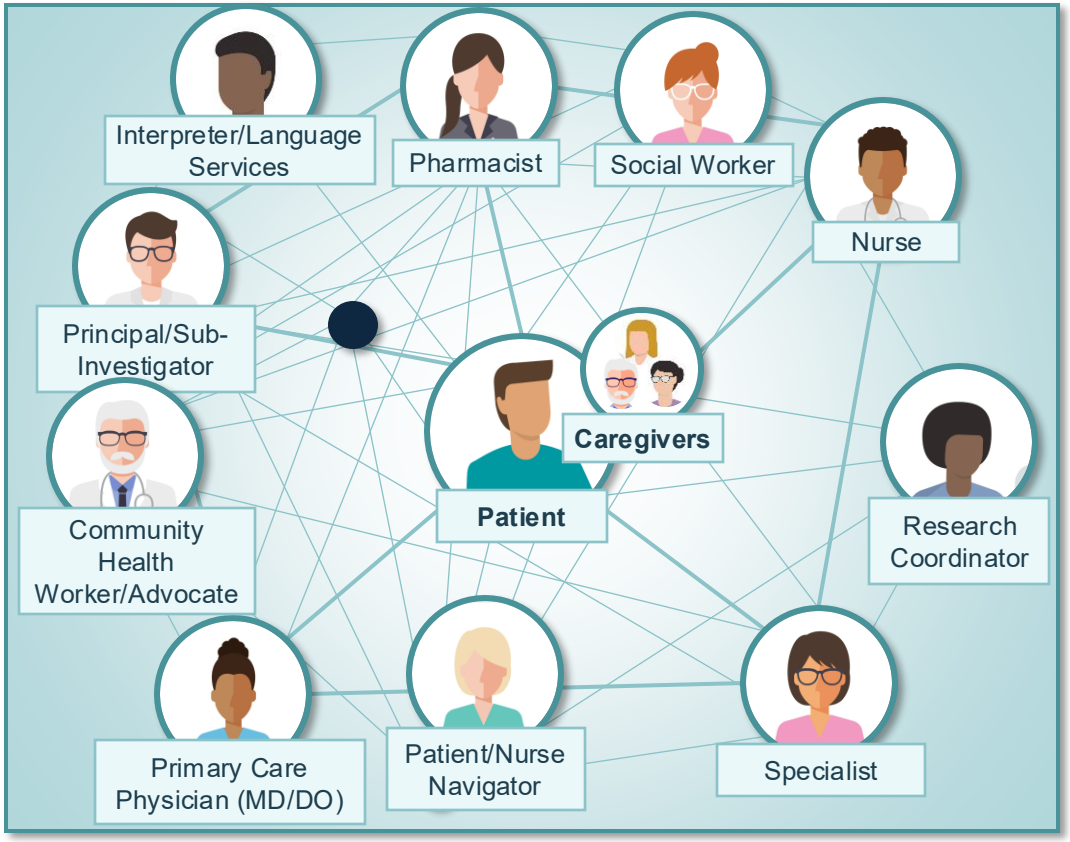
- ✓ Navigator follow-up within 48-72 hours to confirm contact and resolve barriers
- ✓ Dedicated time for questions
- ✓ Connect with research coordinators
- ✓ Maintain relationship regardless of participation decision

AHRQ. 2025. https://www.ahrq.gov/health-literacy/improve/precautions/toolkit.html. Gilligan T, et al. *J Oncol Pract*. 2018;14(1):42-46.

Five Steps – One Flow

Janitz AE, et al. *N Engl J Med*. 2025;393(10):940-942.

One Team, Clear Roles for Trial Access



The Role of Patient Navigators

What Patient Navigators Provide:

- **Cultural competency** and language skills
- **Community trust** and relationships
- **Practical support** (scheduling, transportation)
- **Education** and advocacy
- **Bridge** between patients and research teams
- **Close loop** on eligibility within 48 hours

Implementation in Your Practice:

- **Partner** with community health workers
- **Train** existing staff in navigation skills
- **Connect** with local patient advocacy groups

Documented gains with navigation include increased underserved population participation (9% → 16%) and ~2x higher trial retention.

Uveges MK, et al. *Contemp Clin Trials Commun*. 2018;12:98-102. Fouad MN, et al. *J Oncol Pract*. 2016;12(6):556-563. Sae-Hau M, et al. *JCO Oncol Pract*. 2021;17(12):e1866-e1878. Akingbade E, et al. *J Clin Oncol*. 2024;42(Suppl 16):11093.

Addressing Common Patient Concerns

"Are you experimenting on me?"

- Explain rigorous safety monitoring
- Describe phases of clinical research
- Emphasize voluntary participation
- Share oversight mechanisms
- Clarify what trials do **not** do

"Will I get worse care if I'm in a study?"

- Clarify enhanced monitoring in trials
- Explain standard of care protections
- Discuss right to withdraw anytime

"What if the treatment doesn't work?"

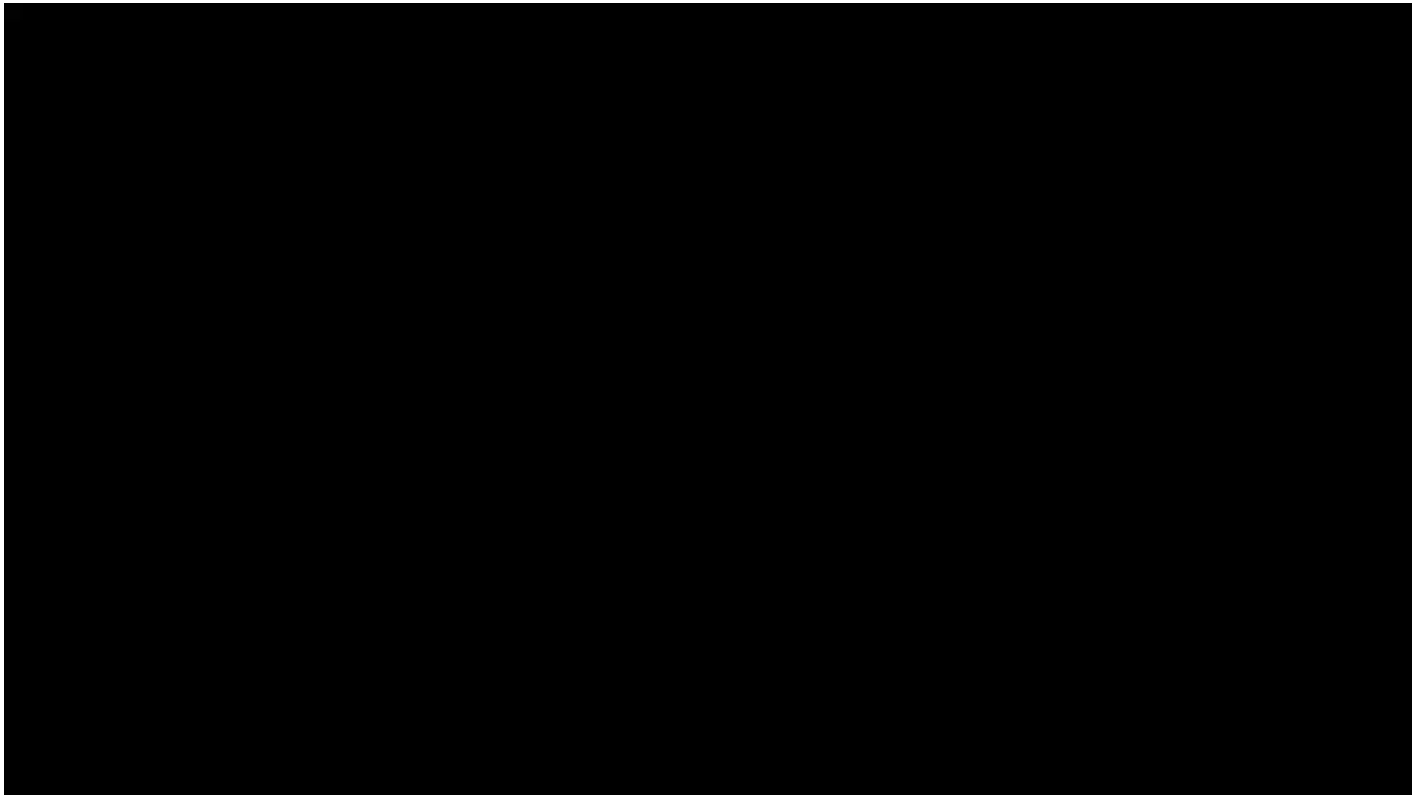
- Acknowledge uncertainty inherent in research
- Discuss alternative treatment options
- Explain how trial results benefit future patients

"Can I afford this?"

- Clarify what trial covers vs insurance
- Discuss potential cost savings
- Address time off work concerns
- Address options for uninsured/underinsured patients

Evans SR. *NEJM Evid*. 2022;1(1):EVIDctw2100005. de Melo-Martín I, et al. *J Med Ethics*. 2008;34(3):202-205. Christopher PP, et al. *PLoS One*. 2017;12(9):e0184224. McConnell T. *Journal of Law, Medicine & Ethics*. 2010;38(4):840-846. Huey RW, et al. *Oncologist*. 2021;26(7):588-596. Williams C, et al. *Mayo Clin Proc Innov Qual Outcomes*. 2023;7(6):524-533.

What Helps a Patient Say Yes?



MythBuster #2: Clinical Trials Are Too Complicated for Community Practice

Trials Serve The Community

Reality:

- Many trials designed for **community implementation**
- Research networks **support** community providers
- Telemedicine + tele-prescreen reduces travel burden; **e-consent** where permitted
- Eligibility check **≤ 48 hours**
- Simple protocols becoming **more common**

Examples of Community-Friendly Trials:

- **Pragmatic** clinical trials in real-world settings
- **Registry-based** randomized trials
- **Digital** health interventions
- **Prevention** studies

National Institutes of Health [NIH] Common Fund. 2023. https://commonfund.nih.gov/hcs-research-collaboratory. National Cancer Institute, Community Oncology Research Program [NCORP]. https://ncorp.cancer.gov/about/infographics/ncorp-relationship.html.

Strategies for Implementing Clinical Trials in Practice

1

Start Small:

1. Identify 1-2 therapeutic areas of interest
2. Connect with local research networks
3. Train one staff member as a research liaison
4. Track eligible patients systematically

2

Build Momentum:

1. Celebrate successes (enrollment and outcomes)
2. Share patient stories (with permission)
3. Expand to additional therapeutic areas
4. Mentor other practices

3

Measure Impact

1. Patient enrollment rates by demographics
2. Patient satisfaction with trial discussion
3. Provider confidence in research communication
4. Community engagement metrics

ARHQ. 2024. https://www.ahrq.gov/health-literacy/improve/precautions/tool1.html. National Cancer Institute. 2019. https://www.cancer.gov/research/infrastructure/clinical-trials/ncorp. ARHQ. 2024. https://www.ahrq.gov/health-literacy/improve/precautions/tool17.html.

Community Network = Reach

Community Engagement Strategies:

Health fairs with research information

Faith-based partnerships for education

School programs about medical research

Patient organizations and community advisory boards for research priorities

Local media coverage of research benefits

Provider Network Development:

Research practice networks for peer support

Peer mentoring programs

Continuing education on research topics

Quality improvement collaboratives

NIH, Community Engagement Alliance [CEAL]. https://ceal.nih.gov/impact/bringing-research-to-communities-through-partnerships. Gibbons GH, et al. *Am J Public Health.* 2024;114(S1):S7-S11. Stewart MK, et al. *J Clin Transl Sci.* 2019;3(5):218-226. Craig LS, et al. *Am J Public Health.* 2024;114(S1):S29-S32. Vance KG, et al. *J Clin Transl Sci.* 2025;9(1):e184. ARHQ. 2025. https://www.ahrq.gov/ncepcr/communities/pbrn/index.html.

Audience Response

After today's discussion, what is your next step?

A. Research what clinical trials are available in my area
B. Talk to my practice about research opportunities
C. Attend training on clinical research communication
D. Partner with community organizations
E. All of the above

SMART Goals

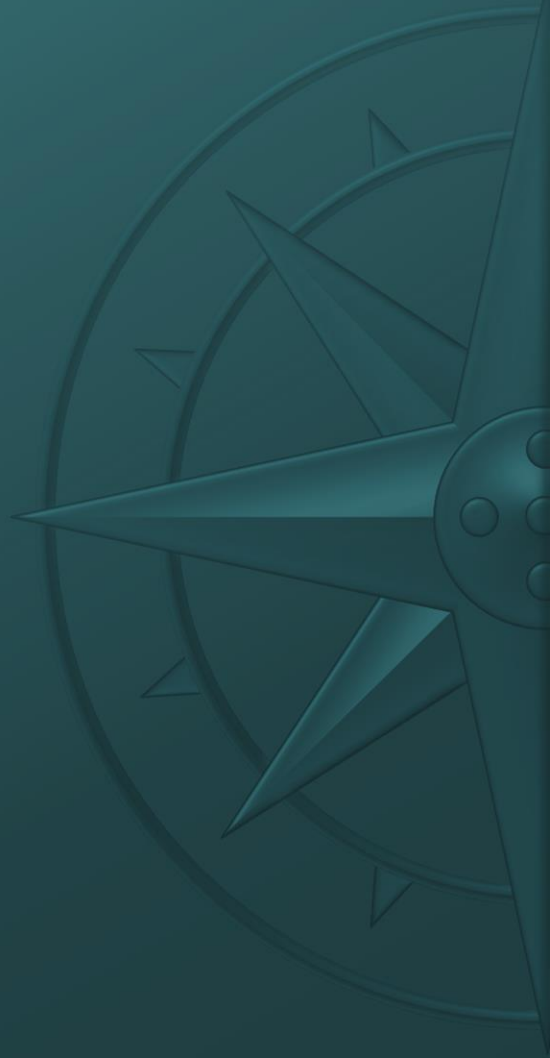
Specific, Measurable, Attainable, Relevant, Timely

Practice Playbook: Invite, Communicate, Navigate, Close Barriers:

- **Specific:** Use a standard invite and rights script (“voluntary, can stop anytime, care continues”), teach-back, and a brief barrier screen (transport, time off, childcare, language, privacy/immigration) at the first trial talk; provide handouts in at least 3 languages and offer interpreter/bilingual staff.
- **Measurable:** For every eligible visit, document: offer made, teach-back done, interpreter use/decline when applicable, same-day warm handoff, navigator follow-up within 2-3 days, and top barrier recorded and addressed.
- **Achievable:** Add an EHR “eligibility and offer/referral” prompt, a one-page rights/safety script, and transcreated handouts, one designated staff liaison, and a simple tracker for offers, language, barriers, and follow-ups.
- **Relevant:** I will operationalize equity by (1) asking every eligible patient, (2) using plain, transcreated, language-concordant communication with teach-back, and (3) closing top practical barriers (transport, time, childcare, cost) so underrepresented patients can make an informed yes or no.
- **Timely:** Launch within the next month; meet language and documentation standards soon after; make warm handoffs and timely follow-ups routine by end of the quarter; achieve equitable invitation rates by midyear; show clear progress toward enrollment parity by year’s end.

To Ask a Question

To submit a question, please go to the *Ask Question* tab at the bottom of the screen.



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Free resources and education
for health care professionals and patients

https://www.cmeoutfitters.com/practice/diversity-and-inclusion-hub/

CME OUTFITTERS

Other activities in this series include:

- Weight of Inequity – Addressing Social and Structural Barriers in Bariatric Surgery
- The Nursing Network: Bias, Barriers, and Breakthroughs in Care
- Optimizing Biomarker Usage in NSCLC
- Nursing Knowledge, Social Impact: Meeting the Needs of Underserved Patients

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- To receive CME/CE credit for this activity, participants must complete the post-test and evaluation online.
- Click on the *Request Credit* tab to complete the process and print your certificate.

Other Participants

Scan the QR code to create or log in to a *CME Outfitters learner account.* Complete the necessary requirements (e.g., pre-test, post-test, evaluation) and then claim your credit.*

*To receive credit, participants must register an account and apply for credit within 10 days of the live activity. For questions or technical difficulties, please contact info@cmeoutfitters.com.

Claim ABIM MOC Credit

3 Steps to Complete

1. Actively participate in the discussion today by **responding to questions** and/or **asking the faculty questions** *(MOC credit can be claimed even if a question goes unanswered or an incorrect response is entered)*
2. Complete the post-test and evaluation at the conclusion of the webcast
3. Enter your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so credit can be submitted to ABIM

ABIM CME MOC ACCREDITED

CME for MIPS Improvement Activity

How to Claim This Activity as a CME for MIPS Improvement Activity

- Actively participate today by responding to ARS questions and/or asking the faculty questions
- Complete the post-test and activity evaluation at the link provided
- Over the next 3 months, actively work to incorporate improvements from this presentation into your clinical practice
- In approximately 3 months, complete the follow-up survey from CME Outfitters

CME for MIPS IMPROVEMENT ACTIVITY

CMEO will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.