

# Barriers to Diversity In Clinical Trials

## BARRIERS AFFECTING ENROLLMENT

- **Unconscious Bias**
  - Staff training to identify and correct bias tendencies
- **Mistrust/Historical Discrimination**
  - Community- Ambassadors (community laypeople) to increase trial awareness
  - Workforce-training to better communicate CT opportunities (videos, education level, cultural specifics),
  - Increase diversity in workforce
- **Location- clinical trials not available where their care is given**
  - Creating research collaborations with researchers, community based organizations and community cancer centers to bring trials to community centers
  - Infrastructure built for information sharing (both ways)
- **Inclusion/Exclusion Criteria**
  - Minimum enrollment requirements
  - Broaden eligibility criteria
  - Intentional enrollment of underrepresented populations
- **Cultural Competence**-Understanding and respect of the diversity of a population (Language, communication styles, beliefs, attitudes, behaviors)
  - Increase diversity in workforce - staff that shares cultural characteristics with the patients

# Barriers to Diversity In Clinical Trials

- **Language**
  - Consent language difficult to understand
  - Trial materials not offered in the native language
  - Translating consent forms can be costly and not covered by research budgets
  - Provide translated materials and even better to have access to in person/phone translation assistance
- **Financial Challenges** -(Cost of Participating in a clinical trial)
  - Medical costs **ACCESS**
    - Cover Routine care costs if denied by insurance OR
    - Clinical Trial Coverage Act (everyone should support this:
      - Introduced by Jackie Speier (SB37); now Anna Eshoo
  - Non-Medical Costs (Out of pocket costs)
    - Cost of Transportation
    - Cost of dependent and/or childcare
    - Lodging/meals
    - Standardize reimbursement for out-of-pocket costs, assist arranging
      - travel and parking
      - days off work
      - dependent care
- **Logistical Challenges (Indirect costs for patients)**
  - **Time commitment and dependent care**
    - Can be offset by telemedicine for routine visits, shipping oral study medications to patients, using local clinics and imaging for certain activities.(Implemented during COVID)

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# I-SPY ACCESS

**A**chieving  
**C**ancer  
**C**linical Trial  
**E**quity through  
**S**ocioeconomically diverse  
**S**ites

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## Sites Supporting Under-Represented Populations

- Hospitals associated with HBCUs
- Sites treating primarily Black, Hispanic/Spanish speaking, Asian and Native American patients
- Safety net hospitals/County hospitals
- Community Cancer Centers
- Rural Cancer centers



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# Understanding the Unique Facilitators and Barriers that Influence Clinical Trial Enrollment

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MHA Candidate at UCLA

# Project Background

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**Problem:** Increased difficulty enrolling diverse ethnic groups into clinical trials within the breast oncology clinic at Los Angeles General



**Project:** Understand the unique facilitators and barriers that influence patient enrollment at the LAG breast clinic



**Ideal setting:** LA County is the most populous and diverse county in the U.S.

# Methods

## REDCap Database

Record ID	Demographics	Income	Birthplace	Current Age	Current Address	Employment Status	Education	English Proficiency	Race Ethnicity	Health Insurance Coverage	Health Literacy	Clinical Trials	Clinical Trial Reassessment	Federal Poverty Level	Health Score
3															
4															
5															
6															
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## Survey Example

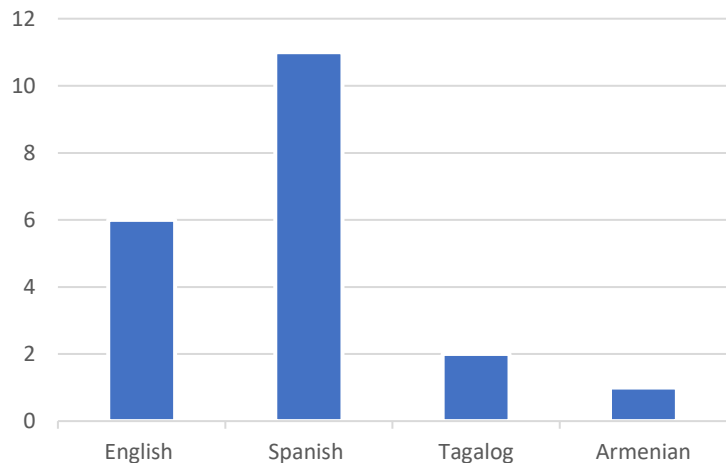
Awareness and Understanding	
How familiar are you with clinical trials for breast cancer?	<input type="radio"/> Very familiar <input type="radio"/> somewhat <input type="radio"/> Neutral <input type="radio"/> Not very <input type="radio"/> Not at all
How well do you understand the purpose and procedures in clinical trials?	<input type="radio"/> Very well <input type="radio"/> Well <input type="radio"/> Neutral <input type="radio"/> Not well <input type="radio"/> Not at all
Interest and Willingness	
How interested are you in participating in a breast cancer clinical trial?	<input type="radio"/> Very interested <input type="radio"/> Interested <input type="radio"/> Neutral <input type="radio"/> Not very interested <input type="radio"/> Not interested at all
Would you consider participating in a breast cancer clinical trial if recommended by your healthcare provider?	<input type="radio"/> Definitely Yes <input type="radio"/> Probably Yes <input type="radio"/> Not sure <input type="radio"/> Probably No <input type="radio"/> Definitely No
Motivations	
What motivates you to consider participating in a breast cancer clinical trial?	<input type="radio"/> Access to new treatments <input type="radio"/> Contribute to scientific research <input type="radio"/> Close monitoring and care <input type="radio"/> Support for future patients <input type="radio"/> Recommended by healthcare providers <input type="radio"/> Other
Concerns and Barriers	
What concerns do you have about participating in a breast cancer clinical trial? (Select all that apply)	<input type="checkbox"/> Potential side effects <input type="checkbox"/> Time commitment <input type="checkbox"/> Travel and Logistics <input type="checkbox"/> Uncertainty of effectiveness <input type="checkbox"/> Impact on quality of life <input type="checkbox"/> Costs and insurance coverage <input type="checkbox"/> Other (please specify)
How likely are concerns about side effects to affect your decisions to participate in a clinical trial?	<input type="radio"/> Very likely <input type="radio"/> Likely <input type="radio"/> Neutral <input type="radio"/> Unlikely



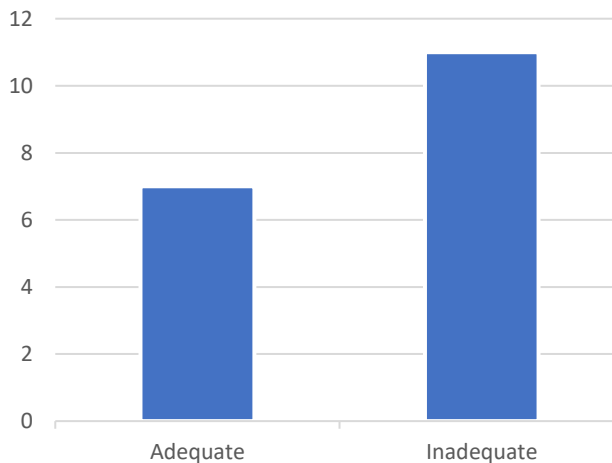
# Preliminary Result

## Pre-Intervention

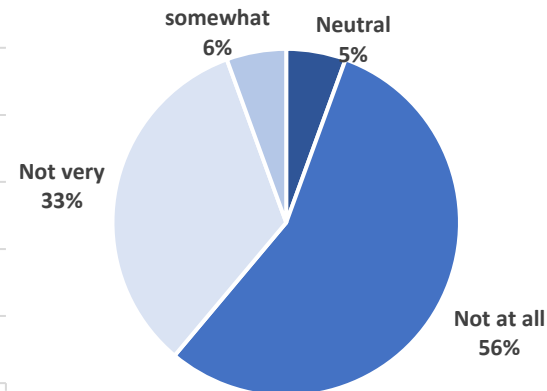
Primary Language



Health Literacy

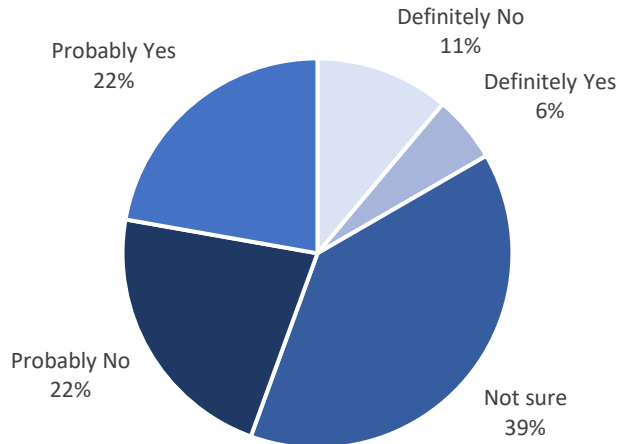


Clinical Trial Awareness & Understanding



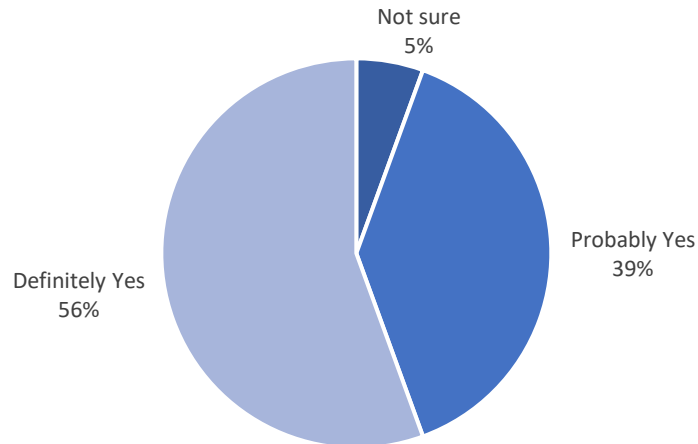
# Preliminary Results

**Participation if Recommended by  
Healthcare Provider**



Post Intervention

**Participation if Recommended by  
Healthcare Provider**



# Future Goals

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- Integrate additional surveys
- Continue data collection
- Resource allocation
- Provide recommendations

# Thank You

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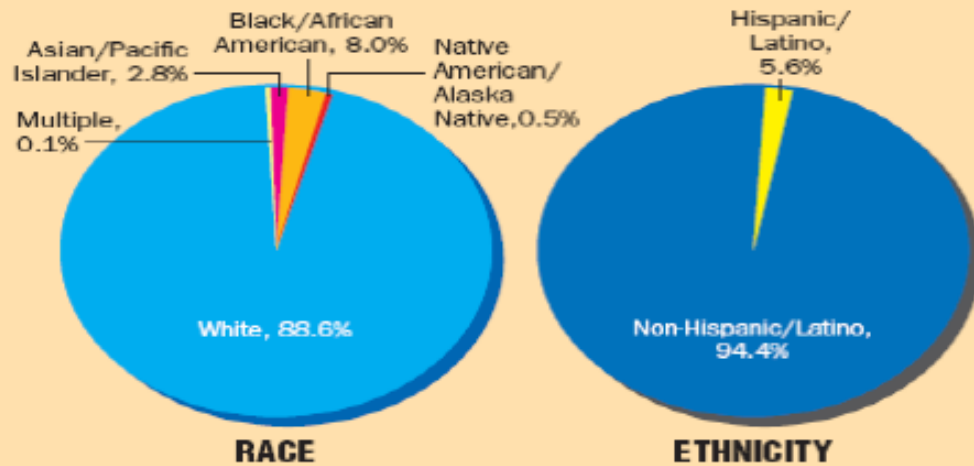
# Financial Barriers and Insurance Coverage in Clinical Trials

MODERATOR: KIM RHOADS

**UCSF** Helen Diller Family  
Comprehensive  
Cancer Center



**Enrollment by Race and Ethnicity**  
**National Cancer Institute, Publicly Funded Cancer Clinical Trials**  
**(Phase I-III Treatment Studies)**  
January 1, 2003 – June 30, 2005



Source: Baseline Study of Patient Accrual Onto Publicly Sponsored Trials," Coalition of Cancer Cooperative Groups for the Global Access Project, National Patient Advocate Foundation, April 2006.

Racial/ethnic diversity is historically low in cancer clinical trials nationally





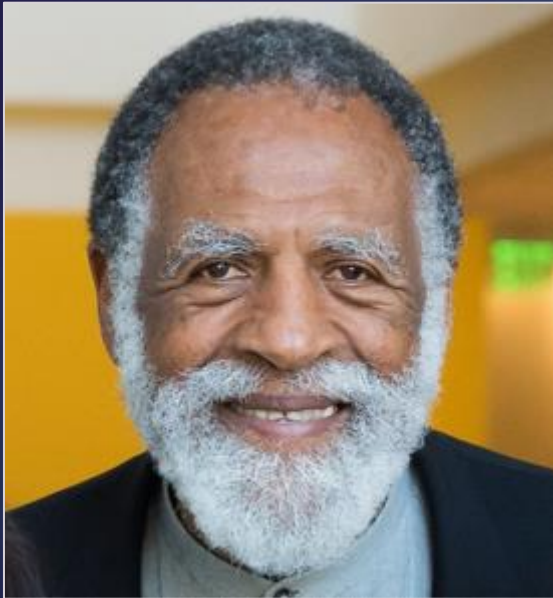
# Addressing low representation in clinical trials requires transformational change

## Methods

- Meta analysis
- N=13 trials included
- N=8800 US patients

Magnitude of structural, clinical & physician and patient barriers to participation (Unger, et al. JNCI 2019)





“After all is said and done, a lot more is said than done”

--ARNOLD PERKINS, FOUNDING MEMBER, AND RECENT PAST CHAIR,  
HDFCCC COMMUNITY ADVISORY BOARD (2005-2023)







# Editorial: Who should fund much needed change?

Stakeholder	Incentive	Description of work	
Patients	Better outcomes	Transportation, clinical companionship, childcare	
Non-Profit Orgs	Addressing inequity	Community engagement & navigation & training, Transportation, clinical advocacy, childcare, addressing financial toxicity, food and housing needs	
Cancer Centers & Clinics	Better science/results	Cultural Competence training and...??	
Pharma	Reputation & Future Sales	Funding trials; smaller funding support for community engagement and navigation	