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Clinical Trial Equity: Achieving Representation and Improving Outcomes for All

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Learning Objectives

- Describe barriers to including patients from underrepresented demographics in clinical trials, treatments and therapies.
- Outline successful strategies to improve equitable patient representation in clinical trials and emerging therapies.

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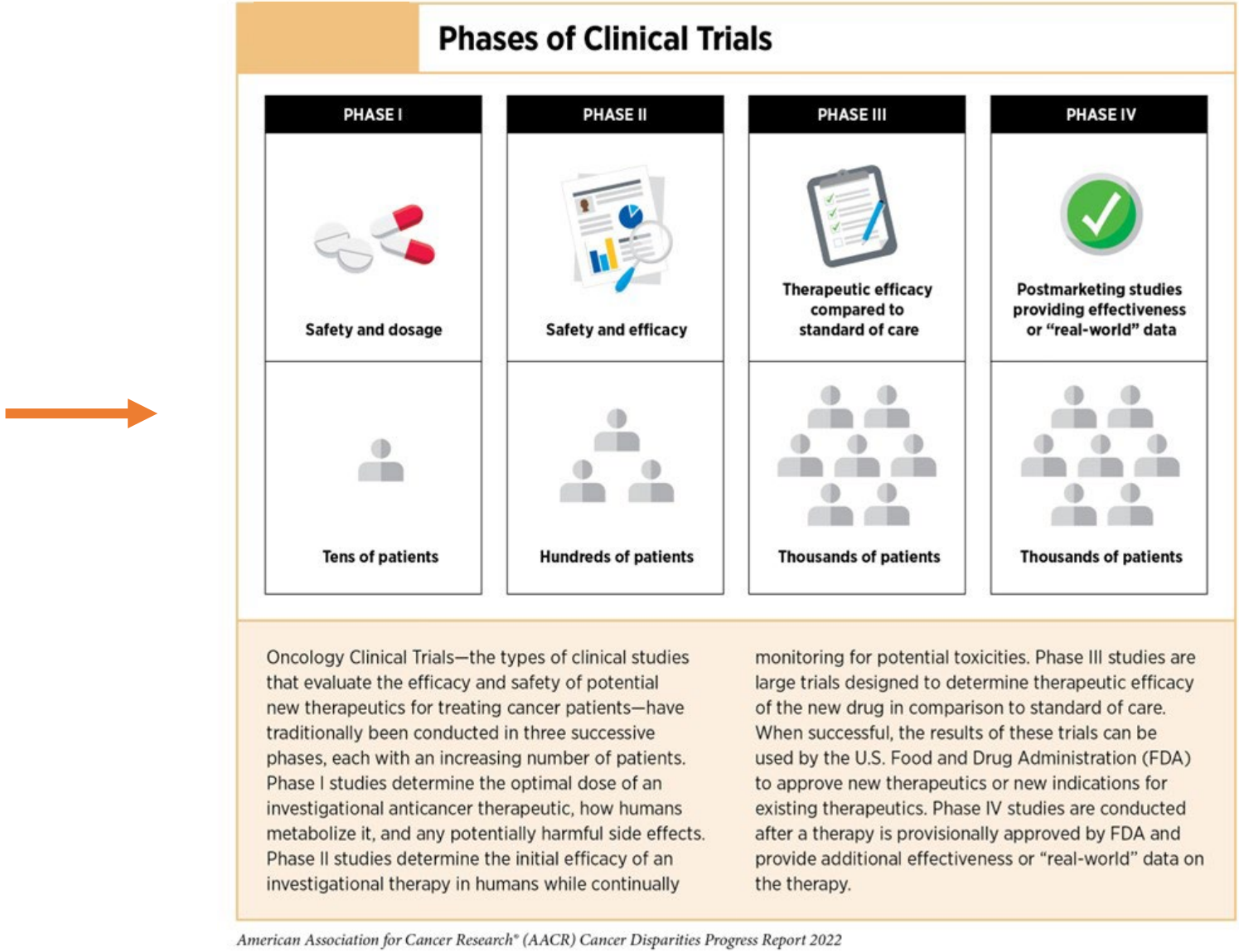
Types of Clinical Studies

- Prevention trials
- Screening/diagnostic trials
- Treatment trials
- Quality of life trials
- Observation studies
- Correlation Studies



American Association for Cancer Research® (AACR) Cancer Disparities Progress Report 2022

Importance of Participating in Clinical Trials

Clinical trials yield advances in treatment

Participation in clinical trials is correlated with improvements in survival*

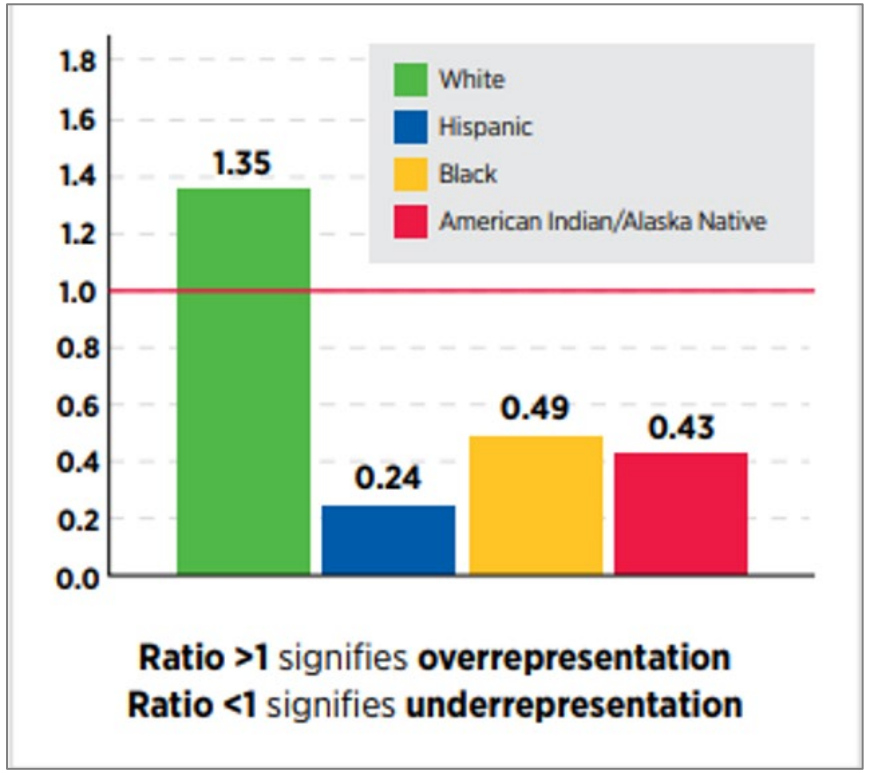
When Adults are Offered

- **8**% – Enrolled.
- **15**% – Did not enroll.
- **56**% – Trial unavailable at site
- **21**% – Not eligible

20% of pediatric and adolescent patients with cancer participate in CTs.

AACR 2023 Annual Cancer Progress Report; *Pediatric Blood Cancer. 2018; 65(8): e27074

Representation by race and ethnicity in 93 Precision Oncology Trials (n=5,867)



Inclusion by race and ethnicity in phase I pharma clinical trials for anticancer agents

Racial/ethnic groups	% of participants	US Population
White	84.2	76,5
Black	7.3	13.4
Asian	3.4	5.9
NH/PI	0.1	0.2
Amer Ind/AN	0.1	1.3
Hispanic	2.8	18.3

AACR 2022 Cancer Disparities Report

Trials by Biopharma with adequate representation in the respective racial/ethnic group

Trials, %	Race/ethnicity
90%	NH White
24%	Asian
16%	Black
8%	NH/PI
7%	Hispanic

Race/ethnicity of participants in trials of chemotherapeutic agents approved by FDA 2009-2019

NH White	70.0%
Black	2.5%
Hispanic	2.3%

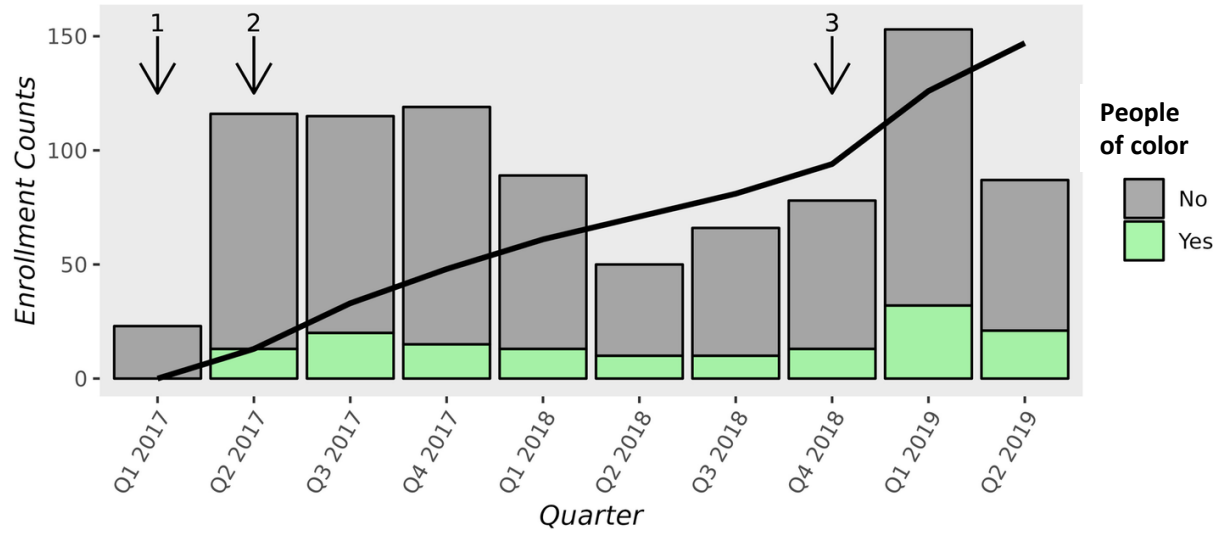
“When offered to participate” in Clinical Trials*

- **58**% of **Black** patients & **55**% of **White** patients participate
- Main reasons for not participating:
  - Treatment choice or lack of interest.
- Limited health care facilities in some communities
  - Most patients with cancer are treated at community clinics/hospitals
  - Participation rates are lower in community clinics/hospitals (16% vs. 7%)
- Lack of trust in medical research and institutions
- Dependent-care responsibilities
- Costs and time related to participating in CTs

AACR 2023 Annual Cancer Progress Report, J Natl Cancer Inst. 2021;113(3):244-257)

Access as a Barrier

- Evaluated trial of shared decision-making about anticoagulation to prevent strokes in atrial fibrillation
- **Participating sites:**
  - Mayo Clinic (1)
  - Park Nicollet (urban/suburban community) (**2**),
  - Hennepin Healthcare (1 inner city safety-net) (**2**)
  - **UAB, Univ. of Mississippi (3)**
- **Participants:**
  - 2247 evaluated; 1325 were eligible but did not enroll
  - 15% of Black vs. 11% of White patients did not enroll
- **Tactics that promoted enrollment of Black persons:**
  - Practices with higher volume of Black patients contributed the most
  - Specific efforts to reach Black patients had lower yield



Sivly A et al. BMC Health Serv Res. 2022:1032; PMID: 35962351

Trial Participant Perspectives

My Experience as a Trial Participant

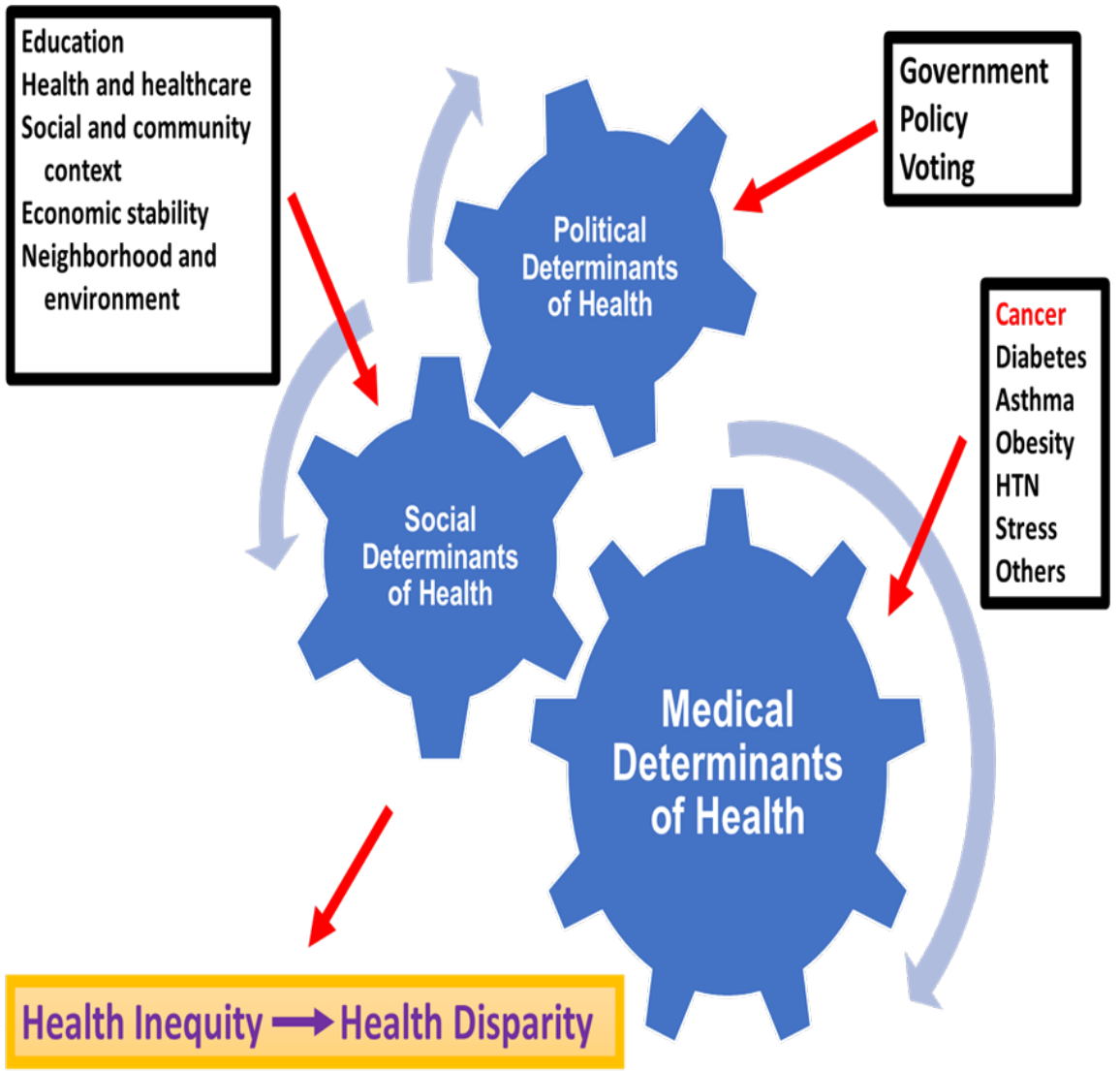
- Unease in trial communication (high levels of distrust)
- Diversity was an afterthought
- Community engagement was an afterthought
- The facility was difficult to reach
- Consent was lengthy
- Follow-up process was difficult to navigate

Patient and Patient Advocate perspectives*

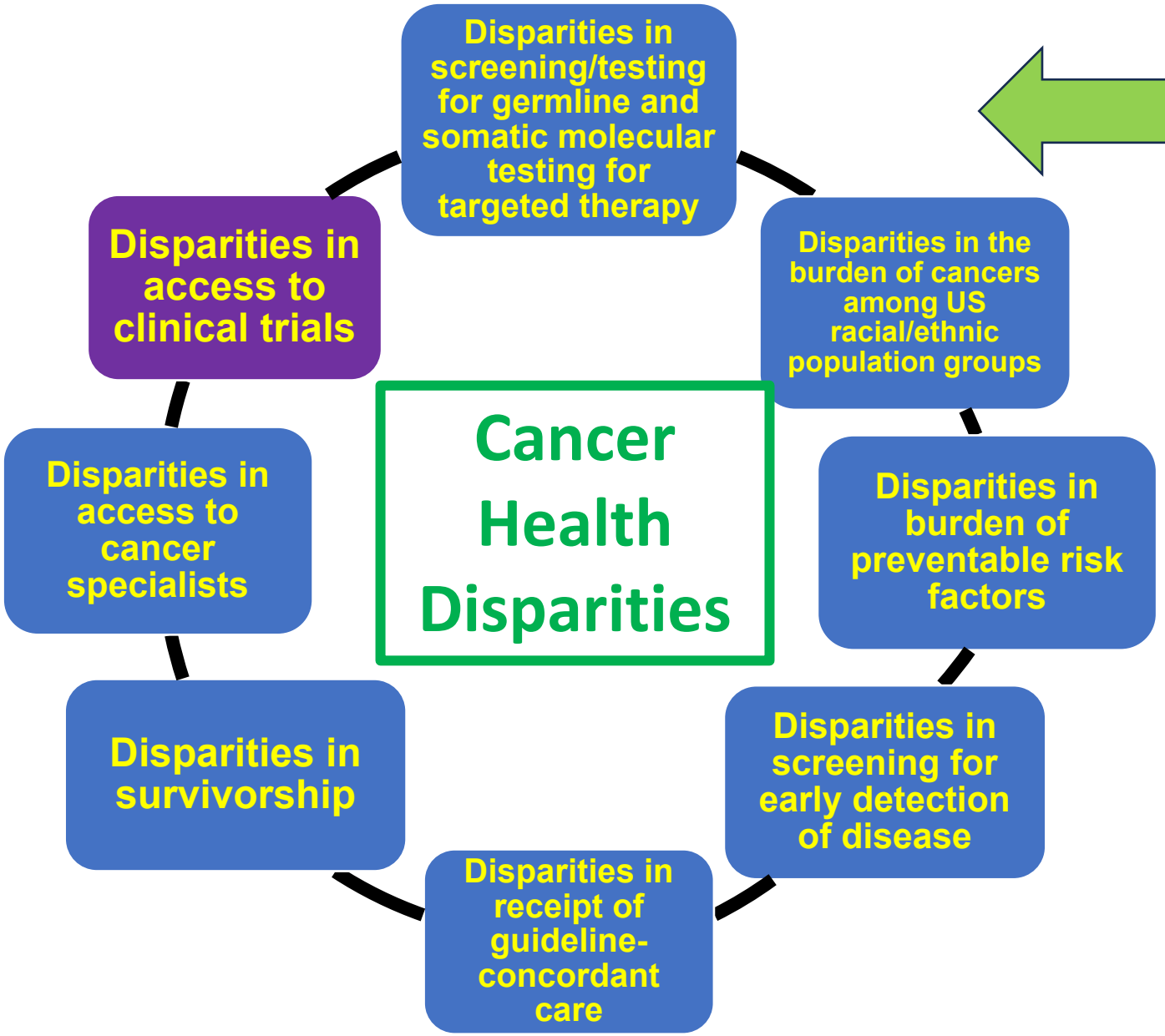
- **A systems issue**:
  - "Low enrollment is not their fault, it's our fault…
  - …we have to fix the system so people can get more involved in it."
- Lack of insurance
- Lack of support system
- Complex informed consent process
  - Not using plain language
  - Patients need to make "decisions that fit their lives…"
  - [make] "…clinical trials a normal part of the decision-making process."
- Lack of patient awareness
  - People may not pay attention to clinical trial until they have a condition.
- Help navigating treatment and clinical trial options.
- Regulatory barriers to data sharing (HIPAA).

*Ms. Deborah Collyar, PAIR (Patient Advocates in Research) [IOM. Barriers to Patient Recruitment and Physician Participation. 2009]

- Historical Disinvestment and Injustices
- "-isms","-phobias," and biases
- Exclusionary Systems and Structures
- Lack of Outreach
- Lack of Trust
- Lack of Access



Hines, J Med Assoc Atlanta, 92 (2) March, 2021



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Research on Community-Engaged Recruitment Strategies

Approach	Recruitment approaches	Recruitment findings
Inform	• Outreach to promote study	Allows members of population of focus to: • Learned about the study • Established relationships with the study team
Consult	• Community Advisory Board (CAB) • CAB enable access to potential participants	• Changed recruitment plan • Centered community voice • Connected with stakeholders
Involve	• CAB directly participates in recruitment	• Engaged trusted community members • Incorporated contextual factors

Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-Engaged Approaches for Minority Recruitment Into Clinical Research: A Scoping Review of the Literature. MCP. 2021;96(3):733-743.

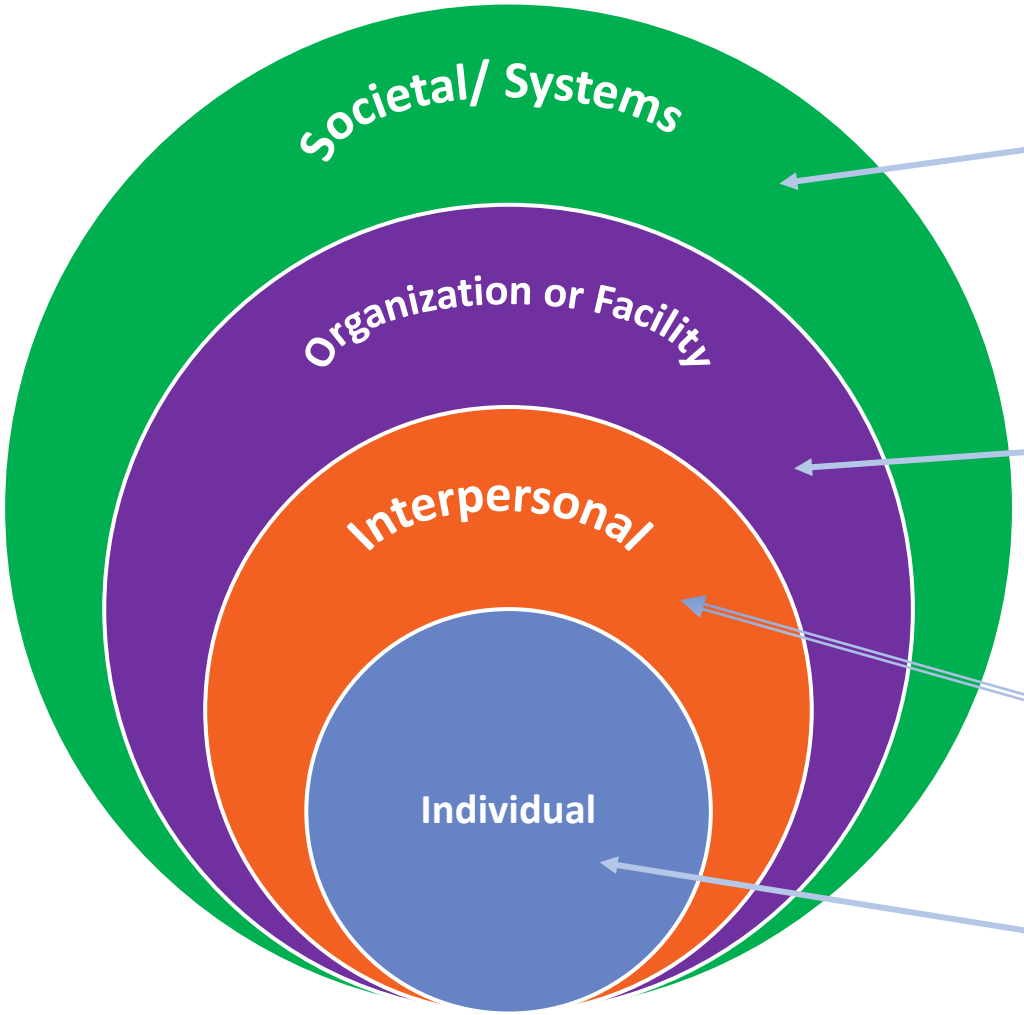
Research on Community-Engaged Recruitment Strategies

Approach	Recruitment approaches	Recruitment findings
Collaborate	• Partner with people who work with the population of focus; • Partners may take lead on recruitment; • Co-plan with partners on recruitment	• Fostered trust • Partners served “face” of the research • **Partnerships often preceded funding**
Co-lead	• Established partnership principles • Community partners lead recruitment • Developed long-term CBPR infrastructure • Leverage community assets	• Partners/participants become advocates • **Partnerships that extend beyond studies** • Recruitment guided by communities • **Partnership often precedes project conception**

Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-Engaged Approaches for Minority Recruitment Into Clinical Research: A Scoping Review of the Literature. MCP. 2021;96(3):733-743.

Enrollment and Retention in Clinical Trials

Barriers, promoters, and Solutions



- Trials where a person is getting care or lives
- Access to care where trials are open
- Address technology/digital gaps
- Increased community awareness of trials

- Match people to trial equitably
- Building diversity into design
- Build/use community partnerships
- Support structural and social barriers

- Offer matching clinical trial
- Address distrust & interpersonal bias
- Trial staff reflect the community
- Support caregiver needs

- Increase awareness/trust in clinical trials

Lessons from COVID-19 to Streamline Cancer Clinical Trials

The guidance issued by FDA and NCI during 2020 to minimize the adverse effects of the pandemic on the conduct of cancer clinical trials offers valuable lessons that can be implemented to streamline future oncology clinical trials, increase participation from diverse groups, and accelerate the pace of progress against cancer. These lessons include:

Consenting remotely, using electronic means, to participate in a clinical trial.
Currently, in-person consent is required to participate in a cancer clinical trial.

Allowing the use of any laboratory and imaging centers that meet the specifications required for participation in a clinical trial.
Currently, individuals are required to use a clinical trial-specified laboratory or imaging center.

Permitting telehealth approaches for routine clinical assessments, such as safety of the experimental treatment.
Currently, individuals are required to visit clinics in person for these evaluations.

Increasing the engagement of community-based network sites in conducting a clinical trial.
Currently, experimental therapeutics are only available at the institutes where clinical trials are being conducted.

Allowing home delivery of investigational oral drugs directly to patients and concomitant medication reporting via digital tools.
Currently, an in-person visit is required to receive experimental drugs.

Making clinical trials more accessible to rural areas and underserved populations.
Currently, underserved populations have limited access to clinical trials for a variety of reasons.

American Association for Cancer Research® (AACR) Cancer Disparities Progress Report 2022

Regulatory approaches to improve diversity

- FY23 Federal appropriations omnibus allows FDA to require companies to:
  - Develop a **Diversity Action Plan**
  - Document outcome*

- Decentralized CTs gained increased awareness during COVID-19
  - Remote consenting
  - Use local laboratory and imaging facilities
  - Telehealth visits for monitoring
  - **Saves** cost; **increases** patient enrollment and achieves **faster** completion

- FDA-NCI Collaborations to Promote Innovative Clinical Research**
  - Pursue new trial designs
  - Improve access to historically underserved communities

*https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-09399.pdf ; ** https://www.cancer.gov/research/infrastructure/clinical-trials/ctiu

Reasons for Lack of Diversity

"When Offered," 58% of Black patients and 55% of White patients participate in CTs.*

Diversity considered in hindsight

- Did not prospectively integrate diversity strategies

Systemic and structural barriers

- No access to care where trial are open
- Design, informed consent process, location of facility preclude enrollment

No plans to address social/ cultural barriers and historical injustices

- Language, education, health literacy, digital literacy; transportation
- Competing family/caregiving and work needs
- Workforce/research staff diversity

Lack of community engagement

- Lots of descriptive studies with few comparative studies among different strategies.

J Natl Cancer Inst. 2021;113(3):244-257)

Lessons Learned

Community-Engaged Strategies for Recruitment

Engagement Activity	Best Practices	Benefits to Community
Increase access to trustworthy information	Share information on the purpose of research Share research results with the community Remain engaged after the research	Gain knowledge about the condition from trustworthy sources
Build trust in research	Acknowledge past research injustices, if relevant Demonstrate how a clinical trial can be just, ethical, & safe Be transparent about the research process Engage communities to identify high-priority research and in planning the research.	Learn about the value of science and how they can be protected and respected.
Strengthen access to resources	During a trial, provide needed resources to community. Make successful treatments available to volunteers.	Community gains access to diagnostic, therapeutic, preventive resources.
Build community capacity	Include community members on the research team. Hire from the community Develop young people in science and health care.	Build community capacity, develop future scientific partners, and build trust.

Adkins-Jackson PB, …Doubeni CA, … Trial Participation and Vaccine Hesitancy Working Groups. Inclusionary Trials: A Review of Lessons Not Learned. Epidemiol Rev. 2022;44(1):78-86

Key Takeaways

Barriers and Obstacles

- Trial enrollment
- Trial design
- Sponsor-related
- Patient-related
- Research team-related

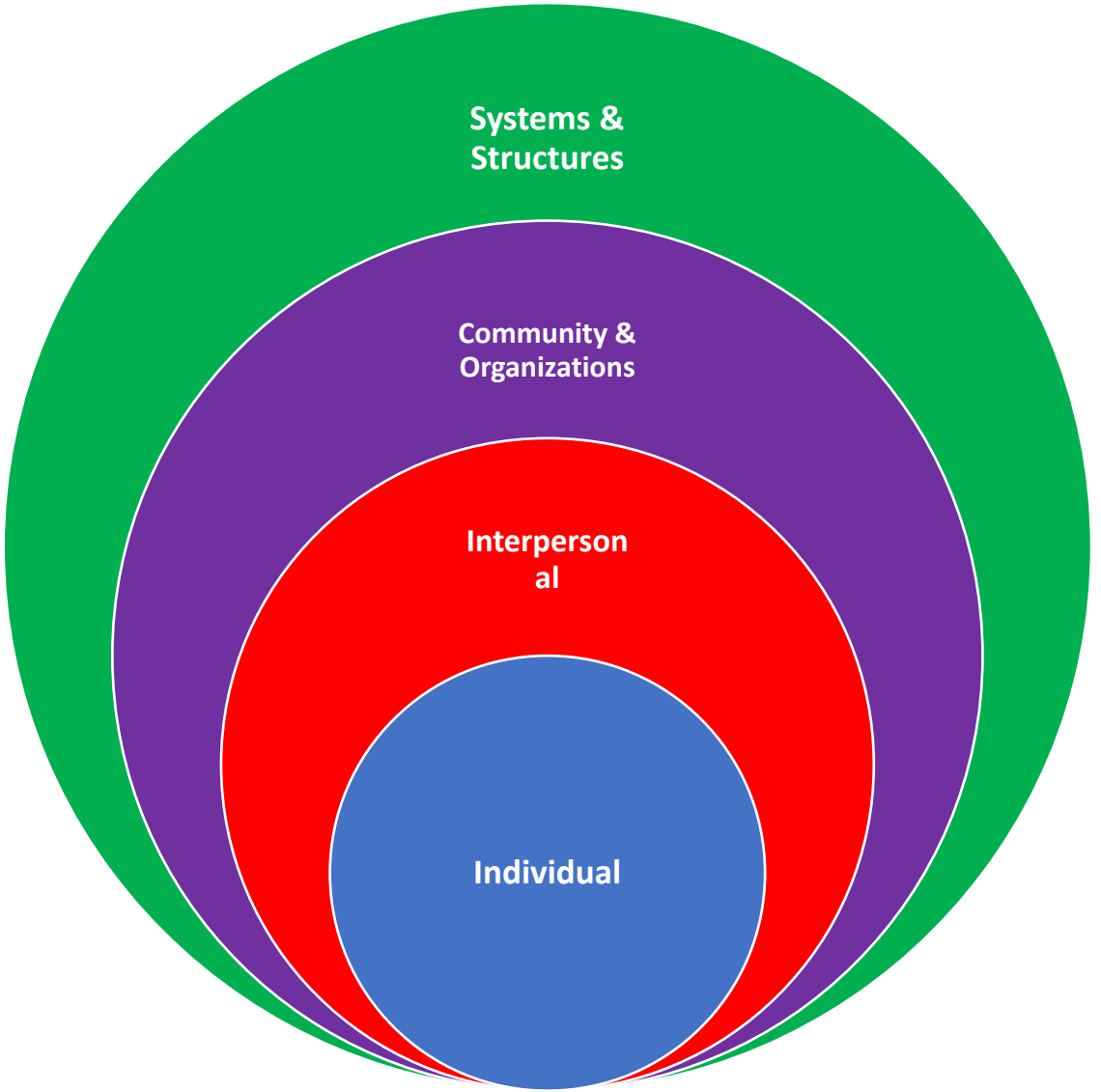
Summary of Action Items and Mitigation Strategies

- Placed-based
- System-level

Inclusion, Diversity, Equity, and Access (IDEA) in Gynecologic Cancer Clinical Trials: A Joint Statement from GOG Foundation and Society of Gynecologic Oncology (SGO). Bhavana Pothuri; Stephanie Blank; Tashanna Myers; Jeffrey Hines; Leslie Randall; Roisin O'Cearbhaill; Brian Slomovitz; Ramez Eskander; Angeles Alvarez Secord; Robert Coleman; Joan Walker; Bradley Monk; Katherine Moore; David O'Malley; Larry Copeland; Thomas Herzog; *Gynecol Oncol*, 174, 278-287, 2023

Key Takeaways

Macro-Micro Paradigm to Address Diversity in Clinical Trial Enrollment



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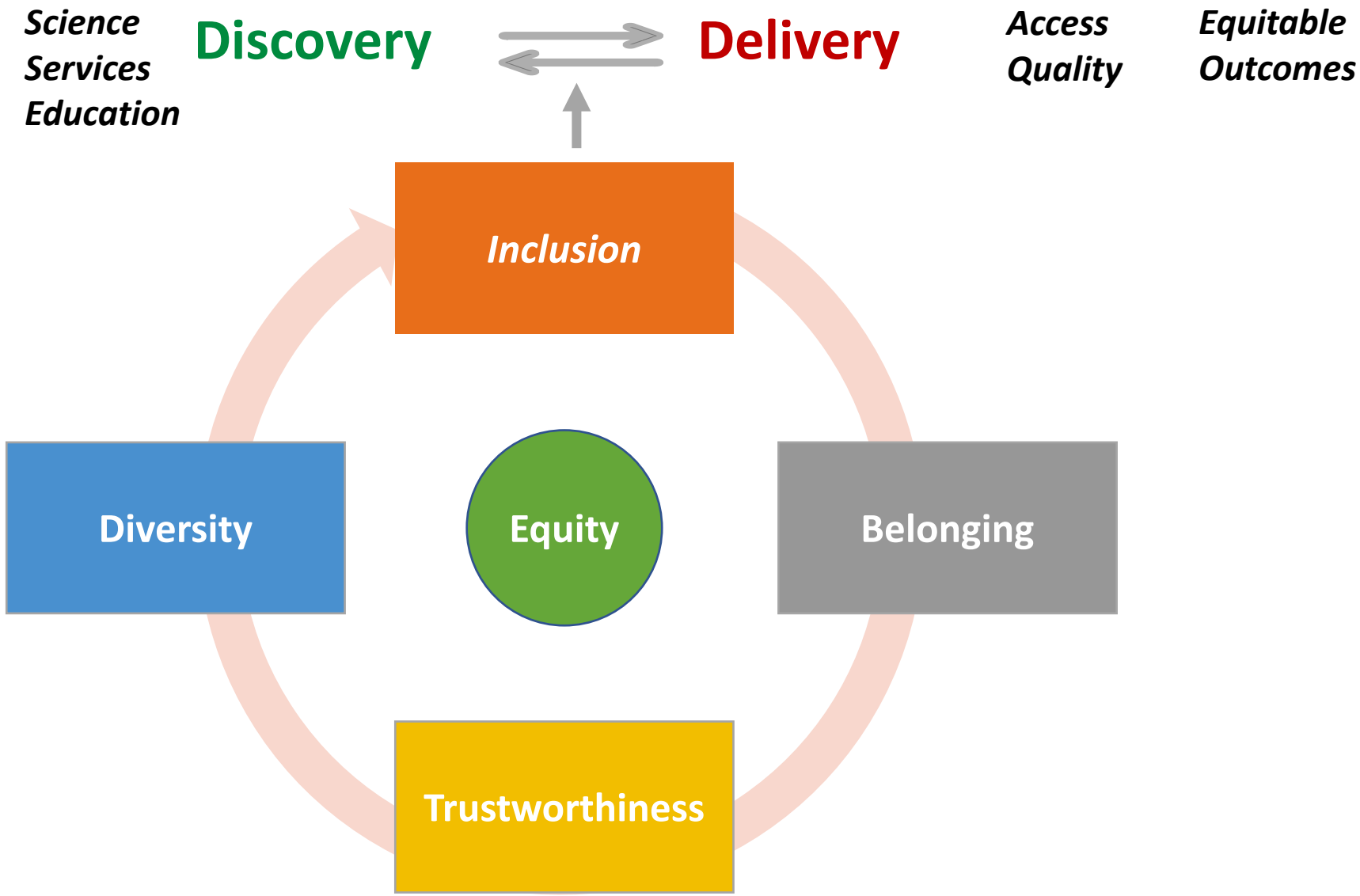
Key Takeaways

Guiding Equitable Implementation



Key Takeaways

Inclusion

Equity

Essential Elements of Transformation

- Inclusive policies
- Inclusive workplace
- Inclusive language
- Inclusive research
- Inclusive care

Framework

Commit (Intention)

Understand, Prioritize

Act

Evaluate

Questions?

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