



Bringing Equity to Cancer Clinical Trials: Aligning Institutional and Community Partnerships and Priorities

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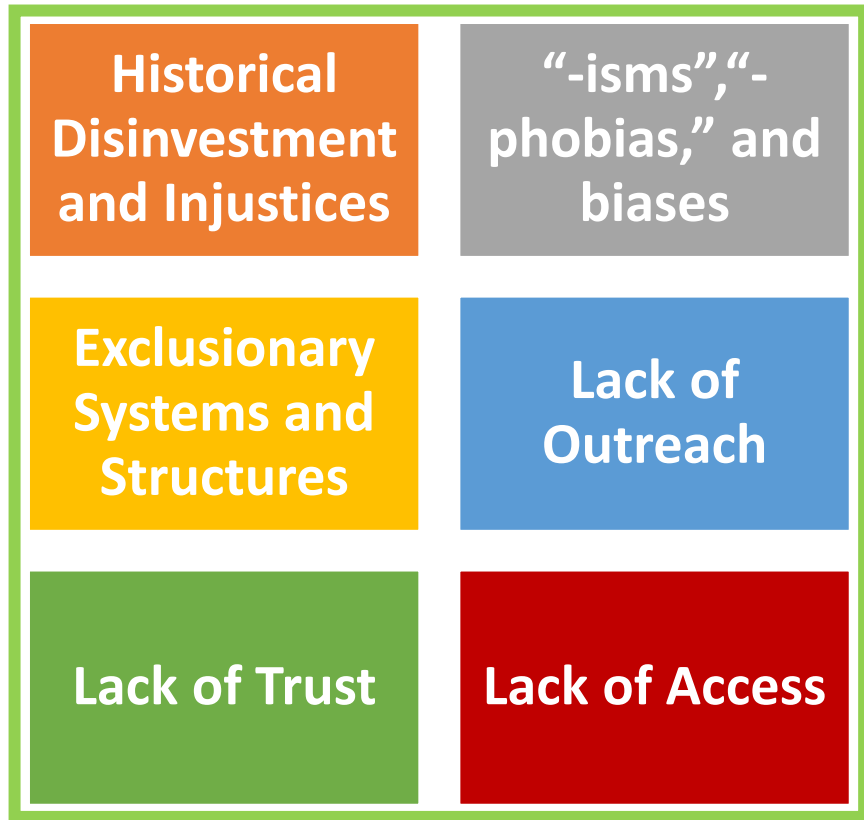
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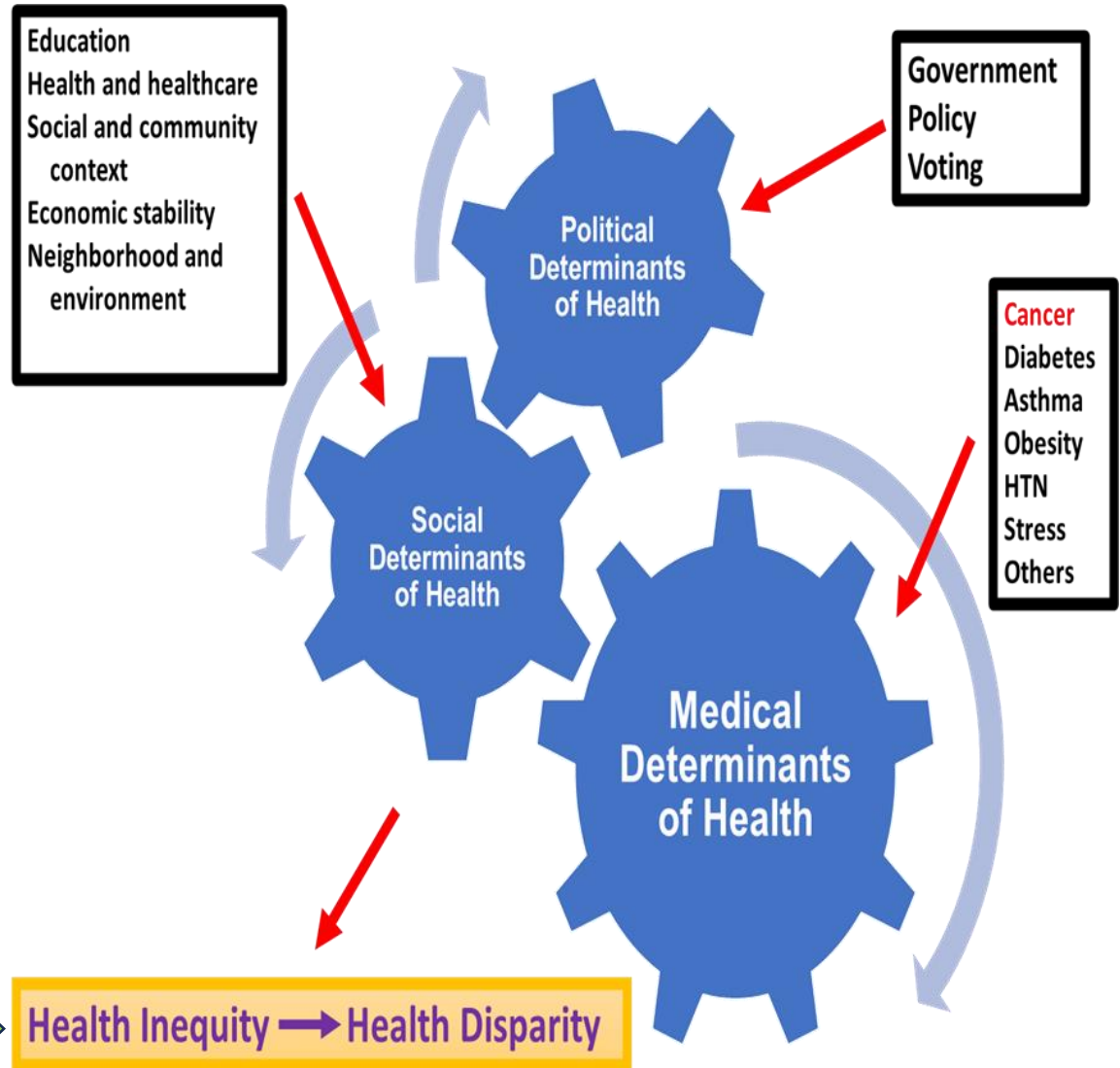
Learning Objectives

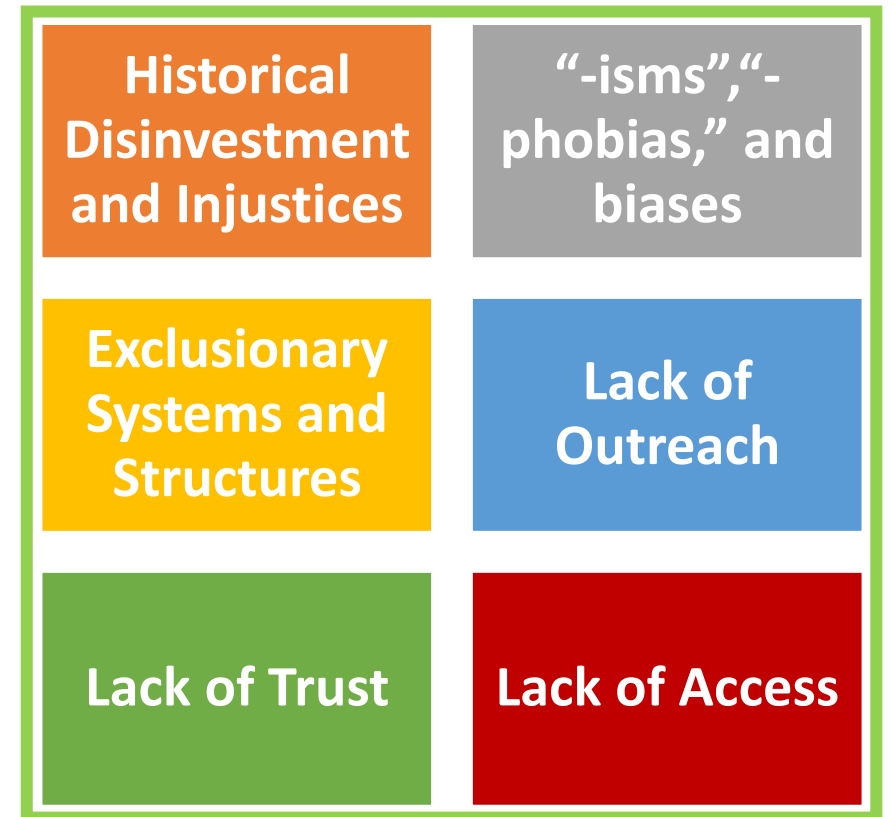
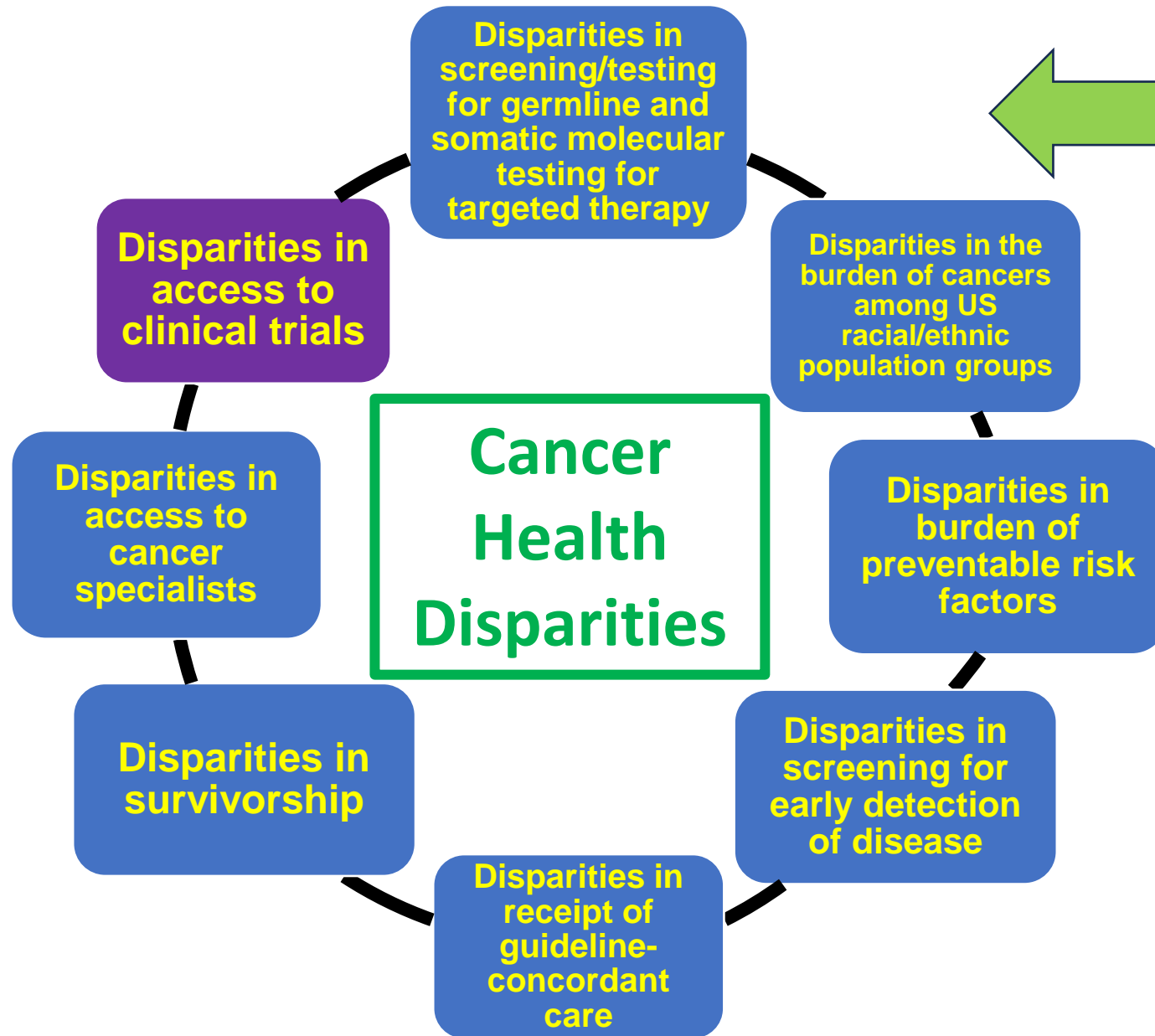
- Describe barriers to including patients from underrepresented demographics in clinical trials, treatments and therapies
- Outline successful strategies to improve equitable patient representation in clinical trials and emerging therapies that involve community engagement

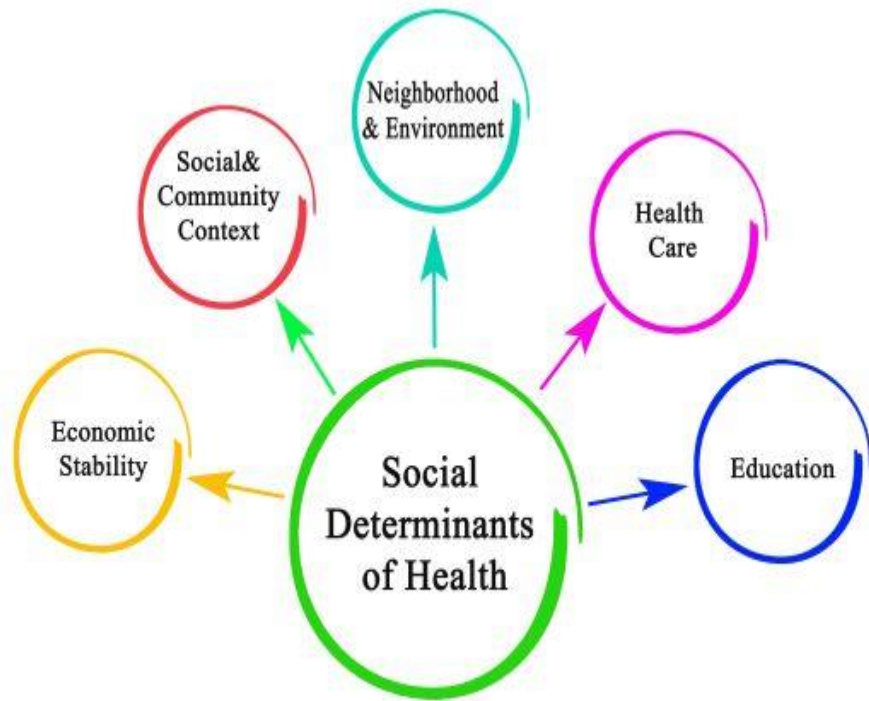




Health Inequity → Health Disparity





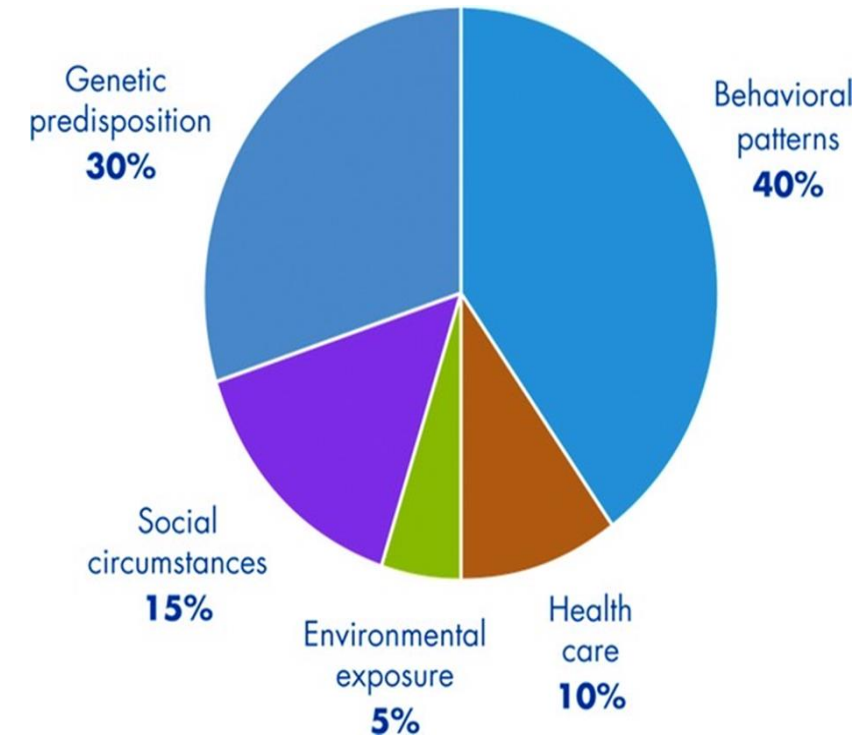


The circumstances in which people are born, grow up, live, work, pray, age and the systems put in place to deal with illness. They are shaped by the distribution of money, power, climate change, racism, and politics - CDC

Five Social Needs Prioritized by CMS

- Food insecurity
- Housing insecurity
- Utility needs
- Transportation needs
- Experience with interpersonal violence

Drivers of Health



HGHI, 2015

U.S. Racial and Ethnic Population Groups*

When federal agencies collect data that include race and ethnicity[§], the agencies follow the Office of Management and Budget (OMB) Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting (5). The basic racial and ethnic OMB categories[†] are:



American Indian or Alaska Native

A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Asian

A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Black or African American

A person having origins in any of the Black racial groups of Africa and the African Diaspora.

Hispanic or Latino[#]

A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

Native Hawaiian or Other Pacific Islander

A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White

A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

* We recognize that the categories described here refer to heterogeneous groups of people and are only relevant based on their use within official registries, health systems, and the decennial census.

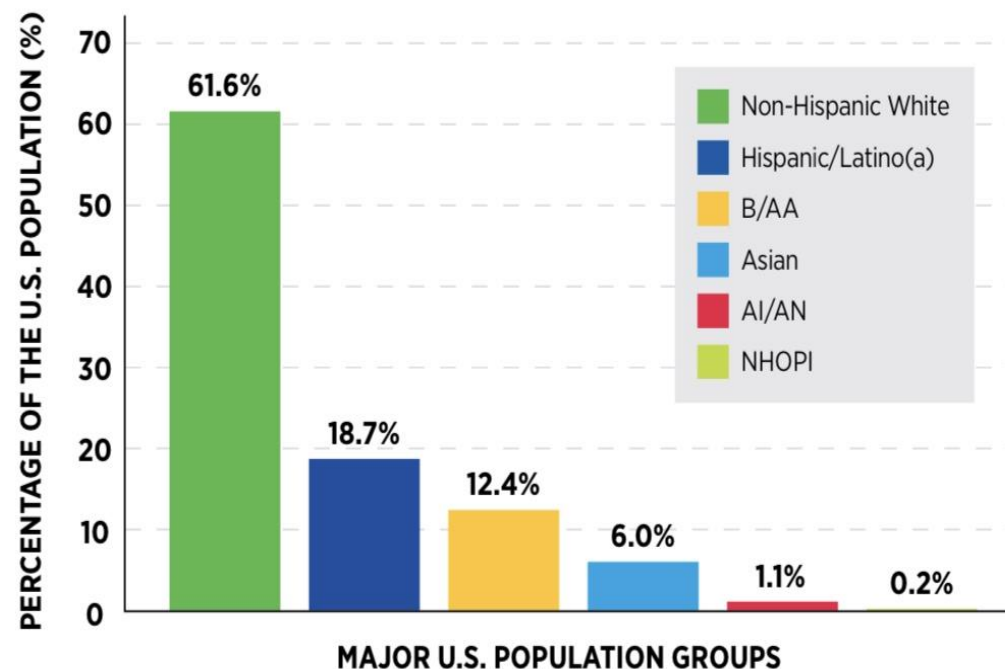
§ Data collected on race and ethnicity rely on individuals self-reporting this information. Therefore, the data may be influenced by sociopolitical constructs and may not fully reflect the individual's genetic ancestry.

† Throughout this report, we use these terms and/or categories without preference or prejudice.

Sometimes described in gender-neutral terms, Latinx or Latine.

FIGURE 1

Percent Representation of Racial and Ethnic Minorities in the U.S. Population

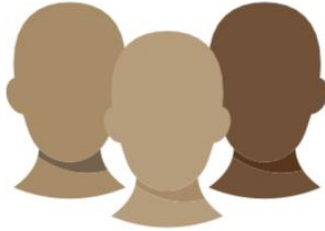


The major population groups are shown as percent of the U.S. population based on the U.S. Census 2020. Numbers represent percent of the U.S. population: non-Hispanic White, 61.6; Hispanic or Latino^a, 18.7; Black or African American (B/AA)^b, 12.4; Asian^b, 6.0; American Indian or Alaska Native (AI/AN)^b, 1.1; and Native Hawaiian or Other Pacific Islander (NHOPI)^b, 0.2.

^a Hispanic people may be of any race, so are also included in applicable race categories.

^b Includes persons reporting only one race.

**Individuals belonging to
different ancestry, race, or ethnicity**



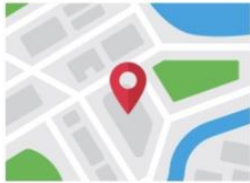
**Individuals of low
socioeconomic status**



**Individuals who lack or have
limited health insurance coverage**



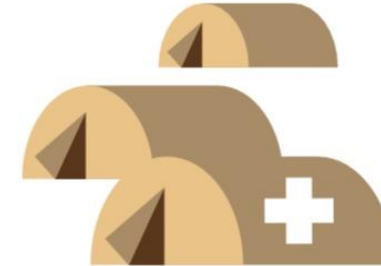
**Residents in certain U.S.
geographic locations, such as
rural areas, or territories, such
as Puerto Rico and Guam**



**Members of the sexual and
gender minority communities**



**Certain immigrants, refugees,
or asylum seekers**



Individuals with disabilities



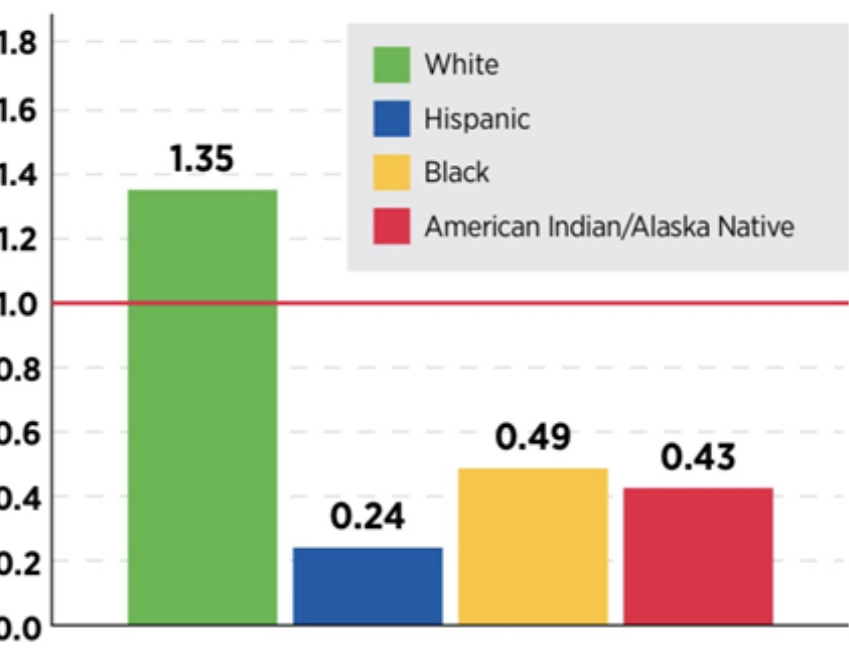
Adolescents and young adults



Elderly



In a recent **analysis of 93 precision oncology clinical trials** with 5,867 participants, **representation of racial and ethnic minorities** was calculated using the **ratio of the actual number of enrolled cases to the expected number of cases** based on their corresponding U.S. population (495).



Ratio >1 signifies **overrepresentation**
Ratio <1 signifies **underrepresentation**

A recent **analysis of phase I clinical trials** for anticancer agents developed by biopharmaceutical companies, showed **extremely low participation of patients from racial and ethnic minorities** compared to their proportion in the U.S. population (501).

RACE/ ETHNICITY	PERCENTAGE OF PATIENTS	PERCENTAGE OF U.S. POPULATION
White	84.2	76.5
Black	7.3	13.4
Asian	3.4	5.9
Native Hawaiian or Other Pacific Islander	0.1	0.2
American Indian or Alaska Native	0.1	1.3
Hispanic	2.8	18.3

Cancer health disparities are an enormous public health challenge in the United States. Examples of these disparities include:

- Compared to the **White** population:

80% higher	AI/AN population has 80 percent higher incidence rate of kidney cancer
HIGHER incidence	Asian population has higher incidence of cancers caused by infectious agents
More than DOUBLE	Black population has more than double the mortality rate of multiple myeloma
More than DOUBLE	Hispanic population has more than double the mortality rate of liver cancer
3X mortality	NHOPI population has nearly 3 times the mortality rate of stomach cancer .

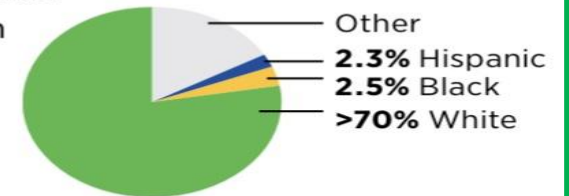
- Individuals **living under persistent poverty** have 43.2 percent higher mortality rate of stomach cancer.
- 77 percent of tumor samples** in *The Cancer Genome Atlas* are **from White populations**.



- Compared to cisgender individuals, individuals **transitioning from female to male** are 58 percent **less likely** to adhere to **cervical cancer screening**.

- Between 2009 and 2019, **FDA approved 81 oral anticancer chemotherapeutics**, based on data from 142 clinical trials. **Only 52 percent of these trials reported on race/ethnicity.**

CLINICAL TRIAL PARTICIPANTS



- Two thirds of rural cancer survivors** from the Appalachian region **report financial distress**.
- Liver cancer patients living in rural communities** at the time of diagnosis are 12 percent **less likely to receive treatment** and have nearly 10 percent **higher mortality** compared to patients living in urban communities.
- Individuals **living in rural areas** have 17 percent **higher death rate** from all cancers combined.
- Elderly Native Hawaiian or Other Pacific Islander patients** are **less likely** to be able to **pay medical bills** associated with cancer treatments and **more likely to delay or forgo medical care** compared to non-Hispanic White patients.



Consequences of Homogenous Patient Populations

- Lack of representation compromises the generalizability of clinical research findings.
- Lack of research costs hundreds of billions of dollars
- Lack of representation hinders innovation and new discoveries
- Lack of representation may lead to lack of access to effective medical interventions
- Lack of representation compounds health disparities in already underrepresented populations in clinical research



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]

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,
cost**

**Workforce/research
staff diversity**

**Lack of community
engagement**

**Lots of
descriptive
studies with few
comparative
studies among
different
strategies, lack of
trust**

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.



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*, 2023

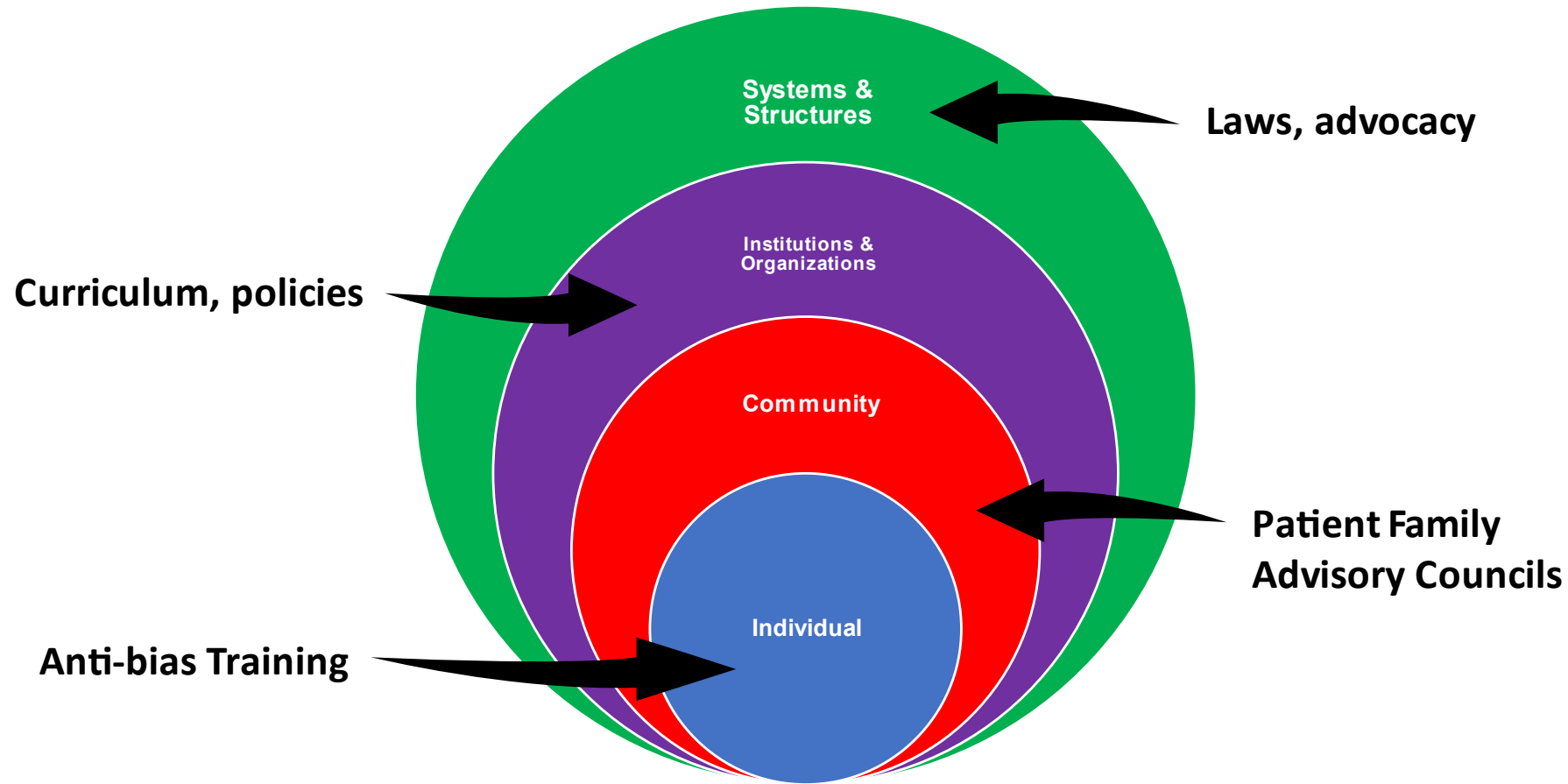
Barriers and Obstacles

- **Trial enrollment**
- **Trial design**
- **Sponsor-related**
- **Patient-related**
- **Clinician-related**

Summary of Action Items and Mitigation Strategies

- **Placed-based**
- **System-level**

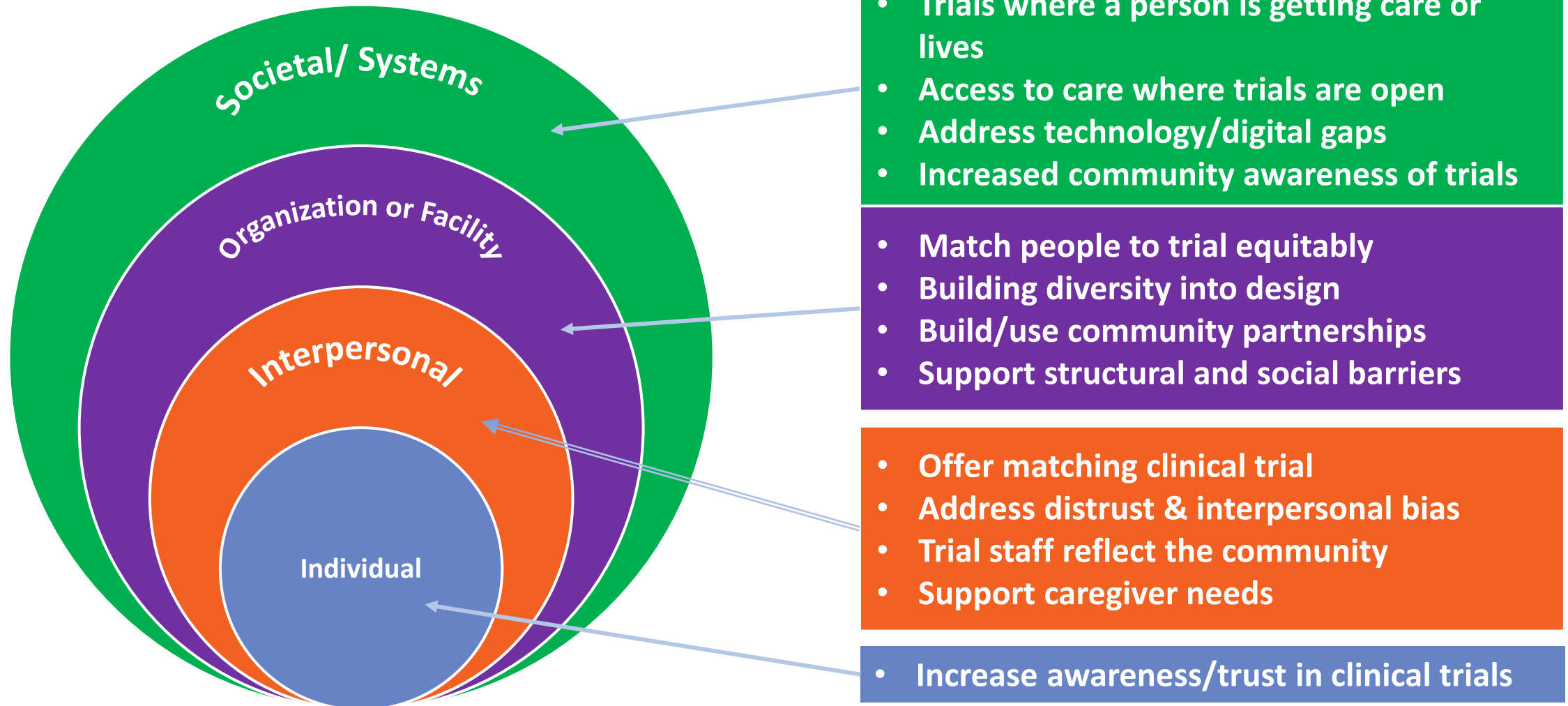
Micro-Macro Paradigm to Address Diversity in Clinical Trial Enrollment



Inclusion, Diversity, Equity, and Access (IDEA) in Gynecologic Cancer Clinical Trials: A Joint Statement from GOG Foundation and SGO, Pothuri B, Blank SV, Myers TK, Hines JF, Randall LM, O’Cearbhaill RE, Slomovitz BM, Eskander RN, Alvarez Secord A, Coleman RL, Walker JL, Monk BJ, Moore KN, O’Malley DM, Copeland LJ, Herzog TJ; Gynecol Oncol, 2023

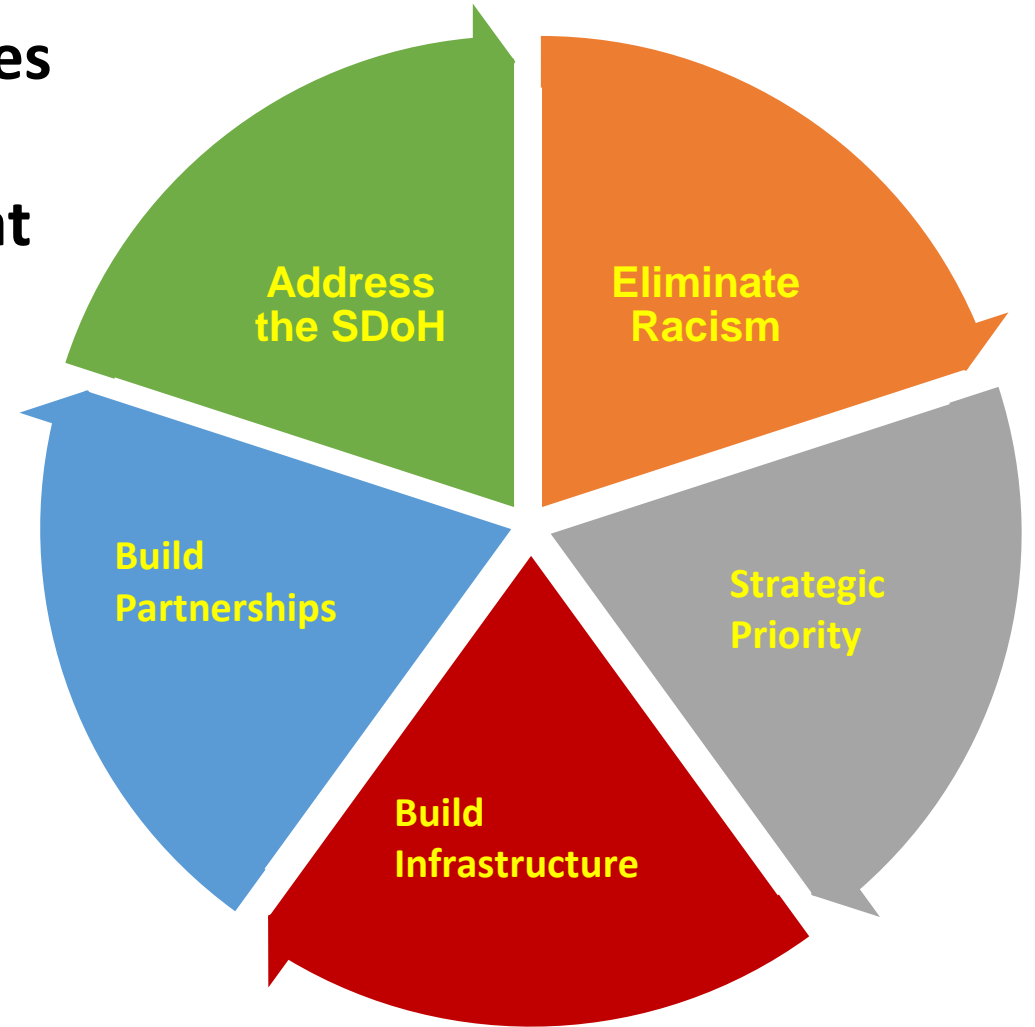
Enrollment and Retention in Clinical Trials

Barriers, promoters, and Solutions

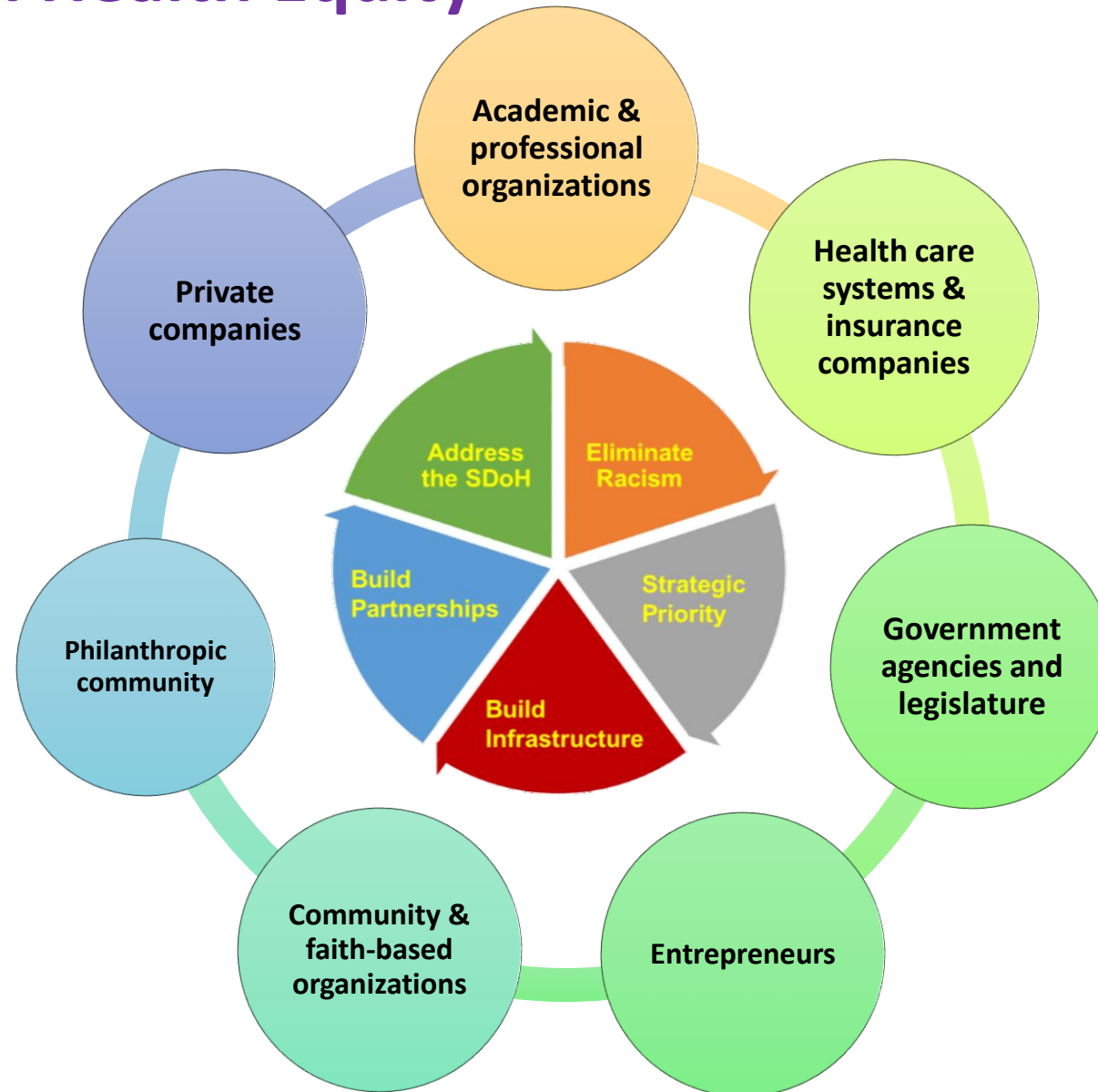


Designing a Framework and Strategy to Achieve Clinical Trial Diversity Through Health Equity

- Strengthen and advocate for the communities we serve
- Acknowledge racism as a public health threat
- Embrace institutional diversity and inclusion through training and process/terminal outcome metrics
- Address institutional culture and climate
- Use of disaggregated data
- Create equity metrics
- Workforce diversity development
- Address the structural drivers of disparity
- Lead with equity and drive accountability



Designing a Framework and Strategy to Achieve Clinical Trial Diversity Through Health Equity



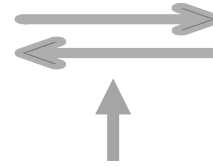
Key Takeaways

- Patient and family advisory councils (PFACs)
- Patient advocates
- Trusted, proximate, and participatory community partnerships
- Community influencers
- Disaggregated data
- Culturally aligned communication with cultural humility and language concordance
- Community health workers (CHWs)

Guiding Equitable Implementation

Science
Services
Education

Discovery



Delivery

Access
Quality

Equitable
Outcomes

Inclusion

Diversity

Equity

Belonging

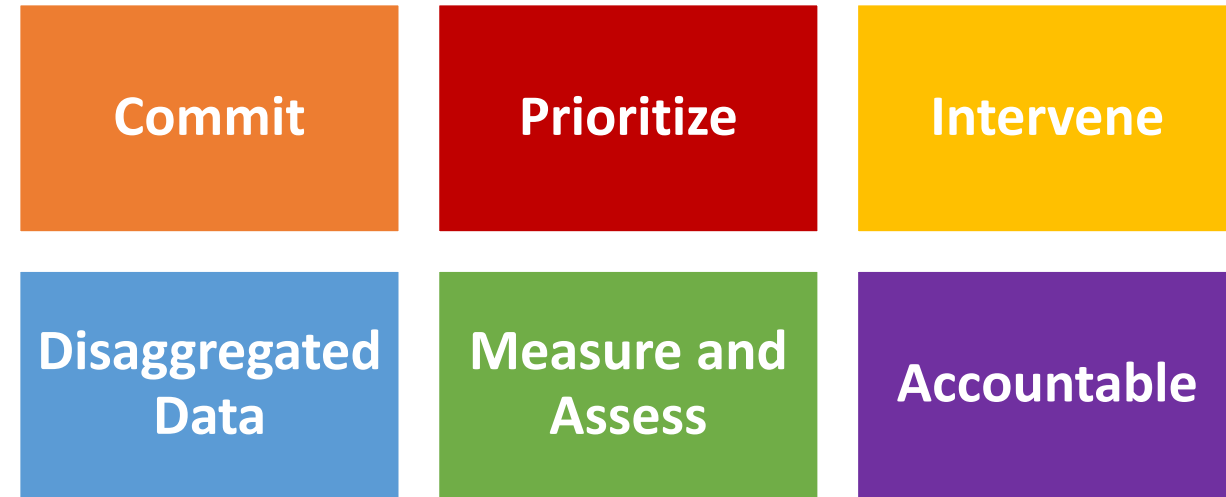
Trustworthiness



Anchoring the Drive Towards Transformation



Essential Components



Framework

Questions and Discussion

