Improving Population Health Outcomes through Enhanced Clinical Data Capture and Standardization

Donna Sattler - Independent
Brian Harris - AstraZeneca

Meet the Speakers

Donna Sattler

Title: Clinical Data Strategy Leader
Organization: Open for Hire!

Visionary leader with 20+ years driving clinical data standards, programming, and strategic innovation. Expert in enhancing efficiency and quality between cross functional teams, with a strong commitment to advancing health equity by increasing inclusion of underrepresented populations in clinical trials through transformative data strategies and best practices.

Brian Harris

Title: Standards Developer Senior Director
Organization: AstraZeneca

Over 25 years of industry experience working as a biostatistician and, most recently, as a standards developer for data collection, cleaning, analysis, and reporting. Over 12 years of volunteer experience on the CDISC ADaM team supporting ADaM conformance, questionnaire supplements, and recent updates to the implementation guide. Served as ADaM team lead in 2022 & 2023.

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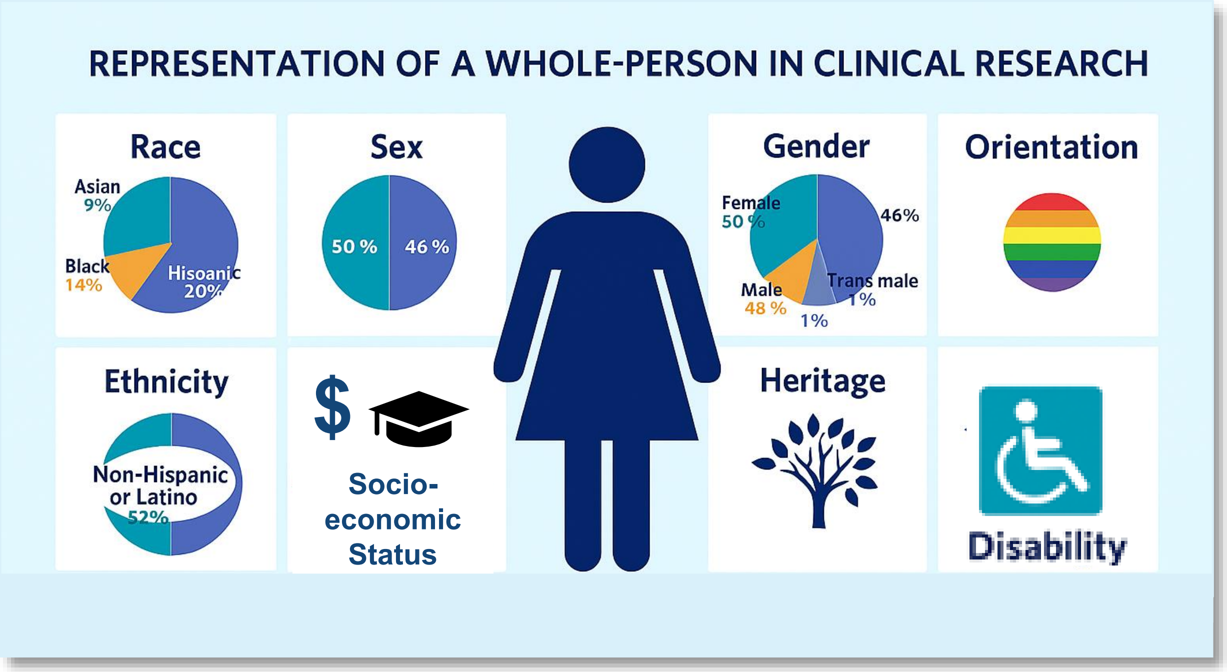
Health Equity = Everyone has a fair opportunity to live a long and healthy life.

Initial Thoughts

[Donna's slido | Present mode]

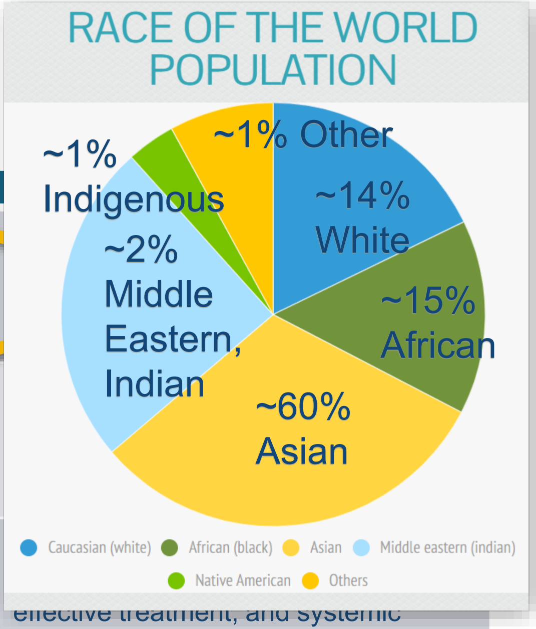
Social Determinants of Health



[Real-World Case: Systemic Exclusion of Transgender Women in Clinical Trials]()

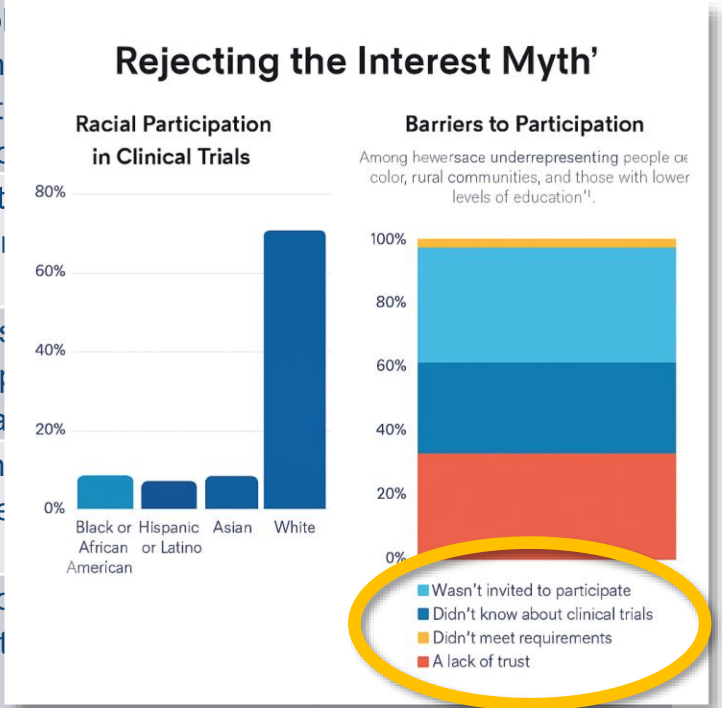
The Equity Gap examples

Study / Source	Key Findings	
FDA Global Participation Analysis (2020)	Of 297,000 global trial participants: 76% were white, 11% Asian, 7% Black. Yet 60% of the global population is Asian and 16% African.	
Inovalon Real-World Outcomes Study	Black patients with advanced Parkinson's disease were 3× less likely to receive device-aided therapy than white patients.	
Breast Cancer Mortality Study	Black women have a 41% higher breast cancer mortality rate than white women and the lowest 5-year survival rate.	effective treatment, and systemic bias.
Wellcome Trust Survey (UK)	White British individuals were 64% more likely to participate in health research than ethnic minorities.	Skewed data can misinform public health policies and clinical guidelines, excluding vulnerable populations.
COVID-19 Trials	Ethnic minorities were underrepresented in COVID-19 vaccine and treatment trials despite bearing a higher disease burden.	Undermines trust and limits understanding of vaccine efficacy and safety across diverse groups.



Disproportion Clinical Trial Myths

✕ Myth	☐ Implications
Collecting race data is enough to ensure equity.	Oversimpl gender, in can lead t interventic
Diverse recruitment happens naturally if trials are open to all.	Ignores st access, ai outreach,
Standardizing data means treating all populations the same.	Risks eras data interp reflect rea
Minority participation is low because of lack of interest.	Blames in issues like language
Equity is achieved once diversity metrics are met.	Focuses c True equit access to decision-making.



Example of More Inclusive Research

Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA)

Established by the NIH to form a community-based network to involve a demographically, geographically, and socio-economically diverse population in HIV clinical research.

Race & Ethnicity: Evolving Guidance

Before 24 March 2024:

OMB standards for race & ethnicity
(Policy Directive 15)

2 Categories for Ethnicity*

- Hispanic or Latino
- Not Hispanic or Latino

5 Minimum* Categories for Race

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

As of 24 March 2024:

OMB standards for race & ethnicity
(Policy Directive 15)

6 Minimum* Categories for Race

- Asian
- Black or African American
- Hispanic or Latino
- Middle Eastern or North African
- Native Hawaiian or Pacific Islander
- White

Also to be captured: American Indian or Alaska Native

For more information, see ***FDA guidance****:* *The Collection of Race & Ethnicity in Clinical Trials (2016)*, ***and*** *Collection of Race and Ethnicity Data (draft, Jan 2024)* which defines minimum standards for collecting and presenting data on race & ethnicity.

*In some situations, more detailed race and ethnicity information may be required, but these should map back to the 2 designations for ethnicity and 5 designations for race (see p.11 of 2016 FDA guidance)
In 2024, OMB standards were updated, and the FDA will be updating their guidance in due course, however until that point, these categories should be followed.

AZ’s Journey of Rethinking Race & Ethnicity Collection

1. US-centric categories

- Limits ability to measure representation regarding race & ethnicity outside US
- Restricts ability to adequately monitor & address disparities

2. Looked for Authoritative References outside US

Explored country-specific or region-specific data collection based on census categories

- **Pro:** Standardized & familiar categories
- **Con:** Complex execution

3. Expansion Approach

Determine best approach was to have one global CRF with expanded categories mapped by to OMB categories

4. Gap Analysis

Identified countries from historical AZ trials (across all TAs) with high rates of “null” or “free text” entries by participants, pinpointing populations under-represented by existing categories

5. Diversity/Need Weighting

Prioritized additional categories basis on current and future-planned clinical research footprint

6. Iterative Refinement

Drafted the initial AZ standard list and compared to established standards (OMB, international, hybrid crosswalks); refined subcategories to maximize inclusivity, alignment, and global applicability) and eCRF technical implementation considerations

7. Consultation

Intensive, broad, and comprehensive cross-functional consultation

Health Equity is a Core Ethical Principle

The most recent version of the guideline on Good Clinical Practice, ICH E6(R3), includes requirements that study participants are not unnecessarily excluded and that the participant selection process should be representative of the population groups the investigational product is intended to benefit

- **Focus on quality:** There should be "quality by design" throughout the clinical trial process, including early-stage planning that accounts for diversity issues.
- **Flexibility in trial design:** There should be more flexibility in trial design, technology, and data sources, enabling innovative approaches to reduce burdens on underrepresented populations

Key Takeaway

[Donna's slido | Present mode]

Key Takeaway

Diversity in clinical trials ensures that study results are applicable to all populations affected by the condition.

- Including diverse populations in clinical trials helps ensure that the results are generalizable and relevant to all groups impacted by the condition. This enhances the scientific validity and equity of medical research, reducing disparities in treatment outcomes.
- Equity is achievable, but only if we design for it intentionally and standardize meaningfully.

Call to Action

Let's commit to designing inclusively, standardizing meaningfully, and collaborating boldly. Together, we can transform research.

Scan to Volunteer with CDISC

Create intentional & diverse patient registration strategies:

- Include decisive stakeholders
- Start with study protocol
- Be conscience of the ways that data collection & analysis can be burdensome to patients & sites.
- Be more flexible in trial design and reduce the barriers for participation.
- Join our CDISC working group(s) as a volunteer

Thank You!