Diversity in Clinical Studies

- To account for the diverse lived experiences and exposures of various populations, clinical studies need to be inclusive of populations to whom the results of the studies will apply
- Inclusion of women was the first issue with many studies only including men
- Inclusion of women and racial and ethnic minorities as defined by the Census were required to be collected and reported
- Reporting of Age at enrollment with inclusion of all ages required
- US or Foreign birthplace
Inclusion of Women and Racial and Ethnic Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies.
- Any exclusions must be based on compelling rationale.
- Sex/gender and race/ethnicity analyses required for NIH-defined Phase 3 clinical trials.
Current Status of Inclusive Participation in Clinical Research in FY 2022

- 51.5% of participants are female
- 13% African American, 12.1% Latino, 3.4% Asian, 1% AI/AN, and 0.3% Native Hawaiian/Pacific Islander
- 30% minoritized populations
- 12.2% unknown — mostly due to EHR studies
  - Phase 3 Trials — only 8.2% are unknown
- Inclusion across the lifespan with emphasis for persons >80 yr. and children <2 yr.
- System to track inclusion by categories of disease
Inclusion in NIH Clinical Research FY 2016-2021

- Females
- Racial and Ethnic Minorities (U.S. Only)
Populations with Health Disparities

• Racial and ethnic minority populations in census
• Less privileged socio-economic status
• Underserved rural residents
• Sexual and gender minorities
• Social disadvantage that results in part from being subject to discrimination or racism, and being underserved in health care
• A health outcome that is worse in these populations compared to a reference population group defines a health disparity
Relative risk of All-Cause Mortality by US Annual Household Income Level

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Relative Risk</th>
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<tbody>
<tr>
<td>&lt; $25,000</td>
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<tr>
<td>&gt; $115,000</td>
<td>1.00</td>
</tr>
</tbody>
</table>

US Annual Household Income (Converted to 2013 US Dollars)

Implied Dementia Prevalence Rate vs Age

- Black, less than high school
- White, less than high school
- Black, high school
- Black, more than high school
- White, high school
- White, more than high school

Farina, M et al. (2020). J Gerontol B. 75(7):e105-e112
Age Adjusted Overdose Deaths by Race/Ethnicity and Income Inequality
25 States and DC, 2019-2020; MMWR 2022; 71:29: 940-947
Best Practices for Inclusive Participation in Clinical Studies

- Recruitment of participants with plan for target sample size to start
- Tailor recruitment strategies
- Community-engaged approach built on mutual trust — CEAL model
- Be intentional in achieving targets by population group
- Diverse investigator team
- Accountability in publication
Inclusive Participation in NIH-Funded Research: Looking Forward

• Mutually exclusive categories by race and ethnicity
• Decrease unknowns to <5% – EHR challenge
• Achieve demographic and meaningful representation
• Support a community-engaged platform to promote participation
• **Require standardized measure of SES**
• Accountability of investigators plans and annual reports
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