Goals for Today

• Understand NIH policies regarding inclusion of women, racial and ethnic minorities, and individuals across the lifespan in NIH-funded clinical research

• Review status of Government Accountability Office (GAO) recommendations related to inclusion of women and minorities

• Review FY 2019-FY 2020 data on the inclusion of women and minorities in NIH-funded clinical research

• Learn about NIH resources related to the inclusion of women, members of racial and ethnic minority groups, and individuals across the lifespan in NIH-funded research
Timeline of NIH Inclusion Policies

1986
• NIH establishes policy encouraging researchers to include women in studies

1993
• PL103-43 requires inclusion of women and minorities in NIH clinical research

1998
• NIH issues policy requiring inclusion of children in NIH clinical research

2016
• 21st Century Cures Act includes new requirements for inclusion and reporting of participants based on sex/gender, race, ethnicity and age

2017
• NIH requires NIH-defined Phase 3 trials report results of sex/gender, race and ethnicity analyses in Clinicaltrials.gov

2019
• Inclusion Across the Lifespan policy becomes effective. First NIH RCDC Inclusion Statistics Report released.
Inclusion of Women and Minorities in NIH Research

• NIH policy requires:

• Women and minorities be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion

• NIH-defined phase III clinical trials be designed to permit analysis by sex/gender, race and ethnicity and report results of analyses in Clinicaltrials.gov

  • Applicable* NIH-defined Phase III clinical trials must report results by sex/gender and/or race/ethnicity in Clinicaltrials.gov within 1 year of primary completion date

• NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations
Inclusion Across the Lifespan

• Effective for applications submitted for due dates on or after January 25, 2019 (and for contract solicitations issued and intramural studies initiated after that date).
  o See NOT-OD-18-116

• Requires individuals of all ages be included in NIH human subjects research unless there are scientific or ethical reasons not to do so

• Requires submission of individual-level data on participant age at enrollment in progress reports
October 2015

NATIONAL INSTITUTES OF HEALTH

Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research
GAO Recommendations

1. Make IC-level enrollment data readily available through public means **CLOSED**

2. Examine approaches for aggregating more detailed enrollment data at the disease and condition level **CLOSED**

3. Ensure that program officers have a means of recording their monitoring of awardees plans for and progress in conducting analysis of potential sex differences **CLOSED**

4. On a regular basis, systematically collect and analyze summary data regarding awardees’ plans for analysis of potential sex differences **CLOSED**

5. Report on this summary data and analysis in its regular report to Congress on the inclusion of women in research **OPEN**
Summary of FY 2019 and FY 2020 NIH Clinical Research Inclusion Records

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Inclusion Records</th>
<th>Inclusion Records with Enrollment</th>
<th>US Site Inclusion Records</th>
<th>Non-US Site Inclusion Records</th>
<th>Female Only Inclusion Records</th>
<th>Male Only Inclusion Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>20,976</td>
<td>14,225</td>
<td>12,819</td>
<td>1,406</td>
<td>1,542</td>
<td>738</td>
</tr>
<tr>
<td>2020</td>
<td>23,856</td>
<td>14,260</td>
<td>12,759</td>
<td>1,501</td>
<td>1,545</td>
<td>659</td>
</tr>
</tbody>
</table>

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Inclusion Records</th>
<th>Inclusion Records with Enrollment</th>
<th>US Site Inclusion Records</th>
<th>Non-US Site Inclusion Records</th>
<th>Female Only Inclusion Records</th>
<th>Male Only Inclusion Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>664</td>
<td>404</td>
<td>335</td>
<td>69</td>
<td>41</td>
<td>12</td>
</tr>
<tr>
<td>2020</td>
<td>907</td>
<td>489</td>
<td>373</td>
<td>116</td>
<td>84</td>
<td>32</td>
</tr>
</tbody>
</table>
NIH-defined Phase 3 Sex/Gender, Race, and Ethnicity Analysis Requirements

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2020

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total IERs</th>
<th>IERs Requiring Race/Ethnicity Valid Analysis</th>
<th>% IERs Requiring Race/Ethnicity Valid Analysis</th>
<th>IERs Requiring Sex/Gender Valid Analysis</th>
<th>% IERs Requiring Sex/Gender Valid Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>664</td>
<td>622</td>
<td>93.7</td>
<td>625</td>
<td>94.1</td>
</tr>
<tr>
<td>2020</td>
<td>907</td>
<td>853</td>
<td>94.0</td>
<td>800</td>
<td>88.2</td>
</tr>
</tbody>
</table>

Plans for valid analysis methodologies specified in the project application are reported for all Inclusion Enrollment Records (IERs), including IERs that have no reported actual enrollment at the time of reporting.
All Clinical Research Enrollment by Sex/Gender

**FY 2019**
- 3.1% Unknown/Not Reported
- 52.1% Male
- 44.8% Female

**FY 2020**
- 4.5% Unknown/Not Reported
- 55.1% Male
- 40.4% Female
NIH-Defined Phase 3 Enrollment by Sex/Gender

FY 2019
- 36.2% Male
- 61.4% Female
- 2.4% Unknown/Not Reported

FY 2020
- 36.6% Male
- 61.8% Female
- 1.6% Unknown/Not Reported
All Clinical Research Enrollment by Race

FY 2019
- % Unknown Not Reported: 2.1%
- % White: 57.1%
- % Native Hawaiian Pacific Islander: 0.2%
- % Black African American: 18.0%
- % Asian: 9.6%
- % American Indian Alaska Native: 2.5%

FY 2020
- % Unknown Not Reported: 2.6%
- % White: 55.3%
- % Native Hawaiian Pacific Islander: 0.2%
- % Black African American: 19.6%
- % Asian: 7.1%
- % American Indian Alaska Native: 0.9%
NIH-Defined Phase 3 Enrollment by Race

- % Unknown Not Reported
- % More Than One Race
- % White
- % Native Hawaiian Pacific Islander
- % Black African American
- % Asian
- % American Indian Alaska Native

FY 2019:
- 8.0% White
- 1.1% Black
- 54.2% Asian
- 0.1% American Indian Alaska Native
- 0.8% Native Hawaiian Pacific Islander
- 0.6% Unknown Not Reported

FY 2020:
- 7.5% White
- 3.4% Black
- 38.4% Asian
- 0.2% American Indian Alaska Native
- 0.6% Native Hawaiian Pacific Islander
- 0.8% Unknown Not Reported
U.S. Only NIH-Defined Phase 3 Enrollment by Race

FY 2019
- % White: 73.2%
- % Black: 18.1%
- % Native Hawaiian Pacific Islander: 0.2%
- % Black African American: 1.1%
- % Asian: 2.4%
- % American Indian Alaska Native: 1.1%
- % Unknown Not Reported: 1.4%

FY 2020
- % White: 62.8%
- % Black: 19.3%
- % Native Hawaiian Pacific Islander: 0.3%
- % Black African American: 1.1%
- % Asian: 3.2%
- % Unknown Not Reported: 7.7%
- % More Than One Race: 5.6%
All Clinical Research Enrollment by Ethnicity

FY 2019

- % Not Hispanic: 78.6%
- % Hispanic or Latino: 10.9%
- % Unknown/Not Reported: 10.5%

FY 2020

- % Not Hispanic: 77.1%
- % Hispanic or Latino: 11.0%
- % Unknown/Not Reported: 11.9%
U.S. Only Clinical Research Enrollment by Ethnicity

FY 2019
- % Not Hispanic: 79.5%
- % Hispanic or Latino: 9.0%
- % Unknown/Not Reported: 11.5%

FY 2020
- % Not Hispanic: 75.7%
- % Hispanic or Latino: 10.9%
- % Unknown/Not Reported: 13.4%

Legend:
- % Not Hispanic
- % Hispanic or Latino
- % Unknown/Not Reported
NIH-Defined Phase III Enrollment by Ethnicity

FY 2019

86.3%

3.9%

9.9%

FY 2020

81.6%

3.9%

14.5%

Legend:
- % Not Hispanic
- % Hispanic or Latino
- % Unknown/Not Reported
U.S. Only NIH-Defined Phase III Enrollment by Ethnicity

FY 2019
- 88.4% % Not Hispanic
- 2.9% % Hispanic or Latino
- 8.7% % Unknown/Not Reported

FY 2020
- 78.6% % Not Hispanic
- 4.1% % Hispanic or Latino
- 17.3% % Unknown/Not Reported
NIH Inclusion Statistics Report

Available at https://report.nih.gov/risr/#/
Training

*Entering Inclusion Data Using the Participant Level Data Template*
February 26, 2020

https://youtu.be/lHYrdIPfKVo

*Including Diverse Populations in NIH-funded Clinical Research*
October 30, 2020

https://youtu.be/fYoNnlf1o
Resources

• NIH Office of Extramural Research Inclusion of Women and Minorities Website

• NIH Office of Extramural Research Inclusion Across the Lifespan Website
  • https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

• Inclusion RePORT page
  • https://report.nih.gov/research/inclusion-women-and-minorities-clinical-research#

• Human Subjects System (HSS) Training Page
  • https://era.nih.gov/help-tutorials/era-training-hss.htm