# National Cancer Institute (NCI)

# Triennial Report

# Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

## I. Background and Overview

The NIH is mandated by the Public Health Service Act §. 492B, 42 U.S.C. §. 289a-2 to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal of this law is to ensure that research findings can be generalizable to the entire population.

As required by the NIH Revitalization Act of 1993 (PL 103-43) and amended by the 21st Century Cures Act, the advisory board or council of each Institute must prepare a triennial report describing the manner in which the Institute has complied with the NIH guidelines on inclusion of women and minorities as subjects in clinical research studies and the NIH requirements for tracking and reporting enrollment to clinical research studies by ethnicity, race, and sex. This triennial report provides information on inclusion of participants in National Cancer Institute (NCI) clinical research from FY2022–2024.

### A. NCI Mission Statement

NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

### B. NCI Portfolio for Inclusion Reporting

NCI's inclusion data include information from grant and contract NCI-funded studies that meet the NIH definition for clinical research. The NIH definition of clinical research includes research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2) Epidemiological and behavioral studies.
3) Outcomes research and health services research.

## II. Strategies for Ensuring Compliance

### A. Peer Review

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex, race, and ethnicity when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed study population and acceptability of the plan for inclusion by sex, race, and ethnicity with respect to the inclusion policies. For NIH-defined Phase III clinical trials, reviewers also assess plans to

conduct valid analyses of intervention effects among sex, racial, and ethnic groups. The priority score for an application reflects if an inclusion plan is unacceptable and staff document the finding in the minutes of the review session.

The National Cancer Advisory Board performs the second level of review and makes recommendations for funding to the NCI Director considering applications' overall impact score, percentile ranking, summary statement, and potential contribution to NCI's research priorities. If the initial reviewers found the proposed inclusion plans in an application were not acceptable, then program staff will notify the principal investigators, who must address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until the applicant has provided an acceptable resolution.

Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central factors: 1) Importance, 2) Rigor and Feasibility, and 3) Expertise and Resources. Before this, reviewers evaluated inclusion as part of the Additional Review Criteria. Now, reviewers will evaluate inclusion as part of Factor 2: Rigor and Feasibility.

### B. Program Monitoring and Grants Management Oversight

Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor requirements for plans and reporting of sex and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

### C. Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent. These plans are considered during the scientific review process. With the annual scientific review and IRB review renewal, the investigator documents the number, sex, race, and ethnicity of the participants accrued during the past year; any issues with accrual are addressed and plan to increase recruitment reviewed by both the Institute and the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

### D. Training

NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. Staff may access the training on the NIH staff intranet.

## III. Analysis and Interpretation of Data

### A. Data and Key Limitations

The appended tables show enrollment data for fiscal years (FY) 2022 through 2024. It is important to note that the inclusion data are cumulative and do not provide a precise snapshot of the number of NCI trials.

- **Inclusion Data Records (IERs) do not represent a count of total studies or trials.** Multiple IERs may be submitted for a single study. For studies taking place in the US and internationally, a separate IER must be submitted for domestic enrollment and international enrollment.
- **The inclusion data do not represent the enrollment for a single year.** The data represent cumulative reports submitted by grantees, contractors, and intramural researchers that cover the entire span of their project, rather than a single year.
- **Grants that are recompeted in a fiscal year are not included in the data for that year.** Type 2 grant applications provide only planned data, not actual data enrollment data for that year, so their records and enrollment are not included in the recompetition fiscal year.

Given the limitations, NIH recommends viewing this report as a broad overview of the general inclusion trends. The report is not a precise count of the total number of supported studies or enrolled participants.

### B. Number of Inclusion Data Records

Table 2-1 (Appendix A) provides the numbers of inclusion data records (IERs) for NIH-defined clinical research conducted in both extramural and intramural settings between FY2022 and FY2024. The total number of IERs increased slightly from 4,055 in FY2022 to 4,148 in FY2023 and 4,226 in FY2024. Many of these IERs were records for studies that had not yet started enrollment. The number of IERs with enrollment was 2,627 in FY2022, 2,773 in FY2023, and 2,903 in FY2024.

### C. Enrollments by Sex, Race, and Ethnicity

Table 5-1-1-C (Appendix B) provides the number and proportion of all enrollments by sex and cross-tabulated by race and ethnicity. Total enrollment can be calculated from Table 5-1-1C. Total reported enrollment decreased from 2,429,782 in FY2022 to 2,290,871 in FY2023 and 1,798,697 in FY2024. This decline largely reflects the start and stop of a few large studies. For instance, a very large intramural cohort study of more than 500,000 participants completed in FY2023 and thus was not reported in FY2024. The median enrollment to IERs with enrollment was steady at 39 in FY2022 and FY2023 and 40 in FY2024.

Enrollment by sex was steady over time. Excluding studies that solely enrolled male or female participants, the proportion of participants who were female was 48.4% in FY2022, 48.6% in FY2023, and 51.7% in FY2024.In the NIH inclusion data, minority participants are defined as participants with a non-White race and/or participants who are Hispanic or Latino. The proportion of minority participants was 25.8% in FY2022, 28.3% in FY2023, and 38.6% in FY2024. However, the closure of the large intramural cohort study contributed significantly to the changes in overall race and ethnicity in FY2024. More than 90% of the more than 500,000 participants in that study were White and fewer than 2% were Hispanic or Latino. The closure of the large intramural study also contributed to changes in enrollment of participants from specific racial groups.

### D. NIH-Defined Phase III Trial Data

There are special considerations for NIH-defined phase III clinical trials. The following definition is used for NIH-defined phase III trials:

> An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide

evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Table 2-2 (Appendix C) provides the numbers of inclusion data records (IERs) for NIH-defined phase III trials performed in both extramural and intramural settings between FY2022 and FY2024. The number of IERs with enrollment was 261 in FY2022, 271 in FY2023, and 312 in FY2024.

NIH-defined phase III clinical trials are required to report a "valid analysis" of group differences for each primary outcome measure by sex, race, and ethnicity. This requirement is waived for trials that are designed to study participants from only a single group. Table 2-3 (Appendix D) shows the proportion of all IERs, with and without enrollment, that require a valid analysis by sex and by race/ethnicity. Fewer IERs require valid analysis by sex because NCI supports a significant number of NIH-defined phase III trials in disease areas such as breast cancer, prostate cancer, and gynecologic cancers that plan to enroll participants from a single sex.

Table 5-2-2-C (Appendix E) provides the number and proportion of NIH-defined phase III trial enrollment by sex and cross-tabulated by race and ethnicity. Total cumulative enrollment in the phase III trials was 293,479 in FY2022, 259,223 in FY2023, and 308,313 in FY2024. There were large numbers of enrollments to a breast cancer screening study that recently closed; this study made up between 20 and 25% of total phase III trial enrollments each year. This breast cancer screening study only enrolled female participants, which contributed to high proportions of female participants overall: 70.3% in FY2022, 80.3% in FY2023, and 81.1% in FY2024. Similarly, the proportion of minority participants in phase III trials increased between FY2022 and FY2024; this is largely attributable to significant international enrollment in the breast cancer screening study.

## E. Inclusion Enrollment Data by Research Condition and Disease Categorization (RCDC) Category

NIH publishes inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category annually at this link: https://report.nih.gov/RISR/.

## IV. Appendices

**Note:** The data presented in these appendices show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

**Appendix A**. Table 2-1. Total Inclusion Data Records (IERs) for Extramural and Intramural NIH-Defined Clinical Research Studies Reported Between Fiscal Years 2022 and 2024.

**Appendix B.** Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research Studies, Sex by Race and Ethnicity.

**Appendix C.** Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Clinical Trials Reported Between Fiscal Years 2022 and 2024.

**Appendix D.** Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2022 and 2024.

**Appendix E.** Table 5-2-2-C. Enrollment for Extramural and Intramural NIH-Defined Phase III Clinical Trials, Sex by Race and Ethnicity.

**Appendix A. Table 2-1. Total Inclusion Data Records (IERs) for Extramural and Intramural NIH-Defined Clinical Research Studies Reported Between Fiscal Years 2022 and 2024.**

**Metrics Based on Inclusion Data Records (IERs) for NIH-Defined Clinical Research Studies**

| Fiscal Year | Total IERs | IERs Without Enrollment | IERs With Enrollment | Among IERs With Enrollment: US Site IERs | Among IERs With Enrollment: Non-US Site IERs | Among IERs With Enrollment: Female Only IERs | Among IERs With Enrollment: Male Only IERs | Among IERs With Enrollment: IERs Excluding Male-only and Female-only* |
|---|---|---|---|---|---|---|---|---|
| 2022 | 4,055 | 1,428 | 2,627 | 2,436 | 191 | 382 | 234 | 2,011 |
| 2023 | 4,148 | 1,375 | 2,773 | 2,531 | 242 | 433 | 240 | 2,100 |
| 2024 | 4,226 | 1,323 | 2,903 | 2,634 | 269 | 434 | 223 | 2,246 |

* The numbers in this column include IERs that report the following:

- Participants of male sex and participants of female sex,
- Participants of male sex, participants of female sex, and participants whose sex was unknown,
- Participants of unknown sex only,
- Participants of male sex and participants whose sex was unknown, and
- Participants of female sex and participants whose sex was unknown.

**Appendix B. Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research Studies, Sex by Race and Ethnicity.**

**Total Enrollment: NIH-Defined Clinical Research Studies**

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total by Sex | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 437,212 | 30.7 | 1,425,527 | 58.7 | 1,155,823 | 81.1 | 159,063 | 11.2 | 110,641 | 7.8 |
| 2022 | Male | 186,263 | 19.6 | 949,826 | 39.1 | 837,548 | 88.2 | 56,016 | 5.9 | 56,262 | 5.9 |
| 2022 | Unknown | 2,691 | 4.9 | 54,429 | 2.2 | 4,360 | 8.0 | 910 | 1.7 | 49,159 | 90.3 |
| 2023 | Female | 454,830 | 33.3 | 1,366,740 | 59.7 | 1,134,062 | 83.0 | 165,911 | 12.1 | 66,767 | 4.9 |
| 2023 | Male | 190,632 | 21.5 | 887,366 | 38.7 | 805,777 | 90.8 | 44,006 | 5.0 | 37,583 | 4.2 |
| 2023 | Unknown | 2,816 | 7.7 | 36,765 | 1.6 | 4,311 | 11.7 | 780 | 2.1 | 31,674 | 86.2 |
| 2024 | Female | 461,473 | 42.2 | 1,092,625 | 60.7 | 808,587 | 74.0 | 211,254 | 19.3 | 72,784 | 6.7 |
| 2024 | Male | 231,953 | 34.4 | 674,979 | 37.5 | 512,872 | 76.0 | 92,508 | 13.7 | 69,599 | 10.3 |
| 2024 | Unknown | 1,292 | 4.2 | 31,093 | 1.7 | 1,875 | 6.0 | 536 | 1.7 | 28,682 | 92.2 |

*(cont)*

| Fiscal Year | Sex | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 9,426 | 0.7 | 87,112 | 6.1 | 170,274 | 11.9 | 2,323 | 0.2 | 981,961 | 68.9 | 19,213 | 1.3 | 155,218 | 10.9 |
| 2022 | Male | 5,019 | 0.5 | 62,954 | 6.6 | 59,959 | 6.3 | 1,617 | 0.2 | 752,939 | 79.3 | 5,661 | 0.6 | 61,677 | 6.5 |
| 2022 | Unknown | 49 | 0.1 | 123 | 0.2 | 1,548 | 2.8 | 10 | 0.0 | 3,107 | 5.7 | 232 | 0.4 | 49,360 | 90.7 |
| 2023 | Female | 7,847 | 0.6 | 100,707 | 7.4 | 166,191 | 12.2 | 10,133 | 0.7 | 928,796 | 68.0 | 16,780 | 1.2 | 136,286 | 10.0 |
| 2023 | Male | 4,313 | 0.5 | 77,768 | 8.8 | 55,987 | 6.3 | 7,277 | 0.8 | 693,913 | 78.2 | 6,005 | 0.7 | 42,103 | 4.7 |
| 2023 | Unknown | 39 | 0.1 | 98 | 0.3 | 1,853 | 5.0 | 18 | 0.0 | 2,758 | 7.5 | 181 | 0.5 | 31,818 | 86.5 |
| 2024 | Female | 9,521 | 0.9 | 72,681 | 6.7 | 161,684 | 14.8 | 2,260 | 0.2 | 670,212 | 61.3 | 19,970 | 1.8 | 156,297 | 14.3 |
| 2024 | Male | 4,074 | 0.6 | 67,120 | 9.9 | 62,804 | 9.3 | 1,702 | 0.3 | 464,704 | 68.8 | 11,540 | 1.7 | 63,035 | 9.3 |
| 2024 | Unknown | 38 | 0.1 | 83 | 0.3 | 565 | 1.8 | 8 | 0.0 | 1,358 | 4.4 | 149 | 0.5 | 28,892 | 92.9 |

**Appendix C. Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Clinical Trials Reported Between Fiscal Years 2022 and 2024.**

**Metrics Based on Inclusion Data Records (IERs) for NIH-Defined Phase III Clinical Trials**

| Fiscal Year | Total IERs | IERs Without Enrollment | IERs With Enrollment | Among IERs With Enrollment: US Site IERs | Among IERs With Enrollment: Non-US Site IERs | Among IERs With Enrollment: Female Only IERs | Among IERs With Enrollment: Male Only IERs | Among IERs With Enrollment: IERs Excluding Male-only and Female-only* |
|---|---|---|---|---|---|---|---|---|
| 2022 | 319 | 58 | 261 | 200 | 61 | 57 | 20 | 184 |
| 2023 | 348 | 77 | 271 | 203 | 68 | 58 | 19 | 194 |
| 2024 | 384 | 72 | 312 | 235 | 77 | 70 | 25 | 217 |

* The numbers in this column include IERs that report the following:

- Participants of male sex and participants of female sex,
- Participants of male sex, participants of female sex, and participants whose sex was unknown,
- Participants of unknown sex only,
- Participants of male sex and participants whose sex was unknown, and
- Participants of female sex and participants whose sex was unknown.

**Appendix D. Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2022 and 2024.^**

**Metrics Based on Inclusion Data Records (IERs) for NIH-Defined Phase III Clinical Trials Supported by Extramural Grants**

| Fiscal Year | Total IERs | IERs Requiring Race Ethnicity Valid Analysis | % IERs Requiring Race Ethnicity Valid Analysis | IERs Requiring Sex Valid Analysis | % IERs Requiring Sex Valid Analysis |
|---|---|---|---|---|---|
| 2022 | 319 | 317 | 99.4 | 261 | 81.8 |
| 2023 | 348 | 346 | 99.4 | 274 | 78.7 |
| 2024 | 384 | 377 | 98.2 | 291 | 75.8 |

^ Plans for valid analysis methodologies specified in the project application are reported for all IERs, including IERs that have no reported actual enrollment at the time of reporting.

**Appendix E. Table 5-2-2-C. Enrollment for Extramural and Intramural NIH-Defined Phase III Clinical Trials, Sex by Race and Ethnicity.**

**Total Enrollment: NIH-Defined Phase III Clinical Trials**

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total by Sex | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 74,047 | 35.9 | 206,440 | 70.3 | 150,267 | 72.8 | 46,269 | 22.4 | 9,904 | 4.8 |
| 2022 | Male | 12,369 | 18.5 | 66,839 | 22.8 | 56,878 | 85.1 | 3,811 | 5.7 | 6,150 | 9.2 |
| 2022 | Unknown | 38 | 0.2 | 20,200 | 6.9 | 149 | 0.7 | 4 | 0.0 | 20,047 | 99.2 |
| 2023 | Female | 82,120 | 39.4 | 208,230 | 80.3 | 145,608 | 69.9 | 52,094 | 25.0 | 10,528 | 5.1 |
| 2023 | Male | 13,475 | 31.0 | 43,399 | 16.7 | 35,008 | 80.7 | 4,971 | 11.5 | 3,420 | 7.9 |
| 2023 | Unknown | 69 | 0.9 | 7,594 | 2.9 | 144 | 1.9 | 13 | 0.2 | 7,437 | 97.9 |
| 2024 | Female | 105,235 | 42.1 | 249,980 | 81.1 | 177,295 | 70.9 | 62,517 | 25.0 | 10,168 | 4.1 |
| 2024 | Male | 18,819 | 32.5 | 57,940 | 18.8 | 50,858 | 87.8 | 4,702 | 8.1 | 2,380 | 4.1 |
| 2024 | Unknown | 72 | 18.3 | 393 | 0.1 | 131 | 33.3 | 33 | 8.4 | 229 | 58.3 |

*(cont)*

| Fiscal Year | Sex | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 808 | 0.4 | 5,000 | 2.4 | 19,681 | 9.5 | 358 | 0.2 | 158,178 | 76.6 | 3,084 | 1.5 | 19,331 | 9.4 |
| 2022 | Male | 346 | 0.5 | 1,315 | 2.0 | 6,433 | 9.6 | 166 | 0.2 | 51,127 | 76.5 | 615 | 0.9 | 6,837 | 10.2 |
| 2022 | Unknown | 0 | 0.0 | 7 | 0.0 | 22 | 0.1 | 1 | 0.0 | 121 | 0.6 | 4 | 0.0 | 20,045 | 99.2 |
| 2023 | Female | 1,085 | 0.5 | 6,973 | 3.3 | 20,293 | 9.7 | 397 | 0.2 | 163,109 | 78.3 | 3,267 | 1.6 | 13,106 | 6.3 |
| 2023 | Male | 345 | 0.8 | 1,676 | 3.9 | 6,130 | 14.1 | 123 | 0.3 | 29,777 | 68.6 | 718 | 1.7 | 4,630 | 10.7 |
| 2023 | Unknown | 2 | 0.0 | 6 | 0.1 | 44 | 0.6 | 2 | 0.0 | 95 | 1.3 | 5 | 0.1 | 7,440 | 98.0 |
| 2024 | Female | 3,893 | 1.6 | 9,429 | 3.8 | 28,953 | 11.6 | 464 | 0.2 | 189,625 | 75.9 | 4,039 | 1.6 | 13,577 | 5.4 |
| 2024 | Male | 501 | 0.9 | 3,731 | 6.4 | 9,602 | 16.6 | 155 | 0.3 | 39,161 | 67.6 | 572 | 1.0 | 4,218 | 7.3 |
| 2024 | Unknown | 3 | 0.8 | 4 | 1.0 | 26 | 6.6 | 0 | 0.0 | 104 | 26.5 | 13 | 3.3 | 243 | 61.8 |