National Institute of Diabetes and Digestive and Kidney Diseases

Triennial Report on the Inclusion of Women and Minorities in Clinical Research FY 2022 – FY 2024

I. Overview and Background

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

To guide his leadership of NIDDK's mission focused activities, Griffin P. Rodgers, M.D., M.A.C.P., Director, NIDDK, established several overarching principles, which have become known colloquially as "core values" (see https://www.niddk.nih.gov/about-niddk/meet-director/mission-vision). Among the five principles set out in the Director's vision statement is "*Support Pivotal Clinical Studies and Trials*." An indication that NIDDK has maintained focus on this principle is NIDDK's prioritization and continued high level of support of clinical research (see Figures 9A and 9B on NIDDK's "Funding Trends and Support of Guiding Principles" webpage https://www.niddk.nih.gov/research-funding/funded-grants-grant-history/funding-trends-support-core-values).

While funding prioritization is one indication of "support", another indication is appropriate attention to the scientific requirements and the statutory and policy obligations to ensure the appropriate inclusion of women and minorities in NIH supported clinical research.

History

In 1986, NIH established a policy for the inclusion of women in clinical research. This policy stemmed largely from a report of the Public Health Service Task Force on Women's Health in 1985. The policy was initially published in the NIH Guide to Grants and Contracts in 1987, and then, later that year the policy was revised to include language encouraging the inclusion of minorities in clinical studies as well.

To ensure that NIH rigorously implement and enforce the inclusion policy, Congress included in The NIH Revitalization Act of 1993 (Public Law 103-43) a section entitled *Women and Minorities as Subjects in Clinical Research.* In 1994, NIH revised its policies to harmonize with the statutory language.

The revisions essentially reinforced NIH's existing policies, but included four additional requirements:

- That NIH ensure that women and minorities and their subpopulations be included in all clinical research;
- That women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to follow for valid analyses of differences in intervention effect;
- That cost is not allowed as an acceptable reason for excluding these groups; and,
- That NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies.

The 21st Century Cures Act of 2016 amended the NIH required reporting on the inclusion of women and minorities in clinical research from biennial reporting to triennial reporting. This report is the third such Triennial Inclusion Report.

Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the Inclusion of individuals Across the Lifespan Policy, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on and after January 25, 2019, and contract solicitations and intramural studies initiated after this date.

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 the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among women, and racial and ethnic groups. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central factors: importance. rigor and feasibility, and expertise and resources. Inclusion criteria and coding and plans for valid design and analysis of Phase III clinical trials, previously evaluated under Additional Review Criteria, will be integrated within Factor 2 (Rigor and Feasibility). This change will help to emphasize the importance of these criteria in evaluating scientific merit.

Extramural Research Awards: Bars-to-Funding and Resolutions

In cases where the study section determines that a study is not in compliance or the applicant has not addressed the requirements in the application, a code is placed in the IMPAC II system that bars funding. In order for the application to be funded, the bar must be lifted and documentation of the grounds for lifting the bar must be included in the official grant file.

Responsibility for review and approval of finalized human subjects' research protocols resides with the Institutional Review Board (IRB) of record. NIH must receive certification of IRB approval before NIH funds can be used for human subject research. If certification of IRB approval cannot be provided prior to award, NIDDK may make restricted awards to allow the non-human subject research to go forward while human subjects concerns are addressed by the IRB. In general, once IRB approval is received, the Grants Management Specialist will request review by the Program Official before funding for human subjects research can be made.

NIDDK Scientific Review Procedures for Inclusion

Scientific Review Officers (SRO) read all applications and proposals and note if clinical research is being proposed and if the application is in compliance with NIH policy on the Inclusion of Women and Minorities.

SROs send "*NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications*" to scientists/clinicians that serve as peer reviewers on Scientific Review Panels to ensure they are up to date on all human subject policy issues when evaluating applications.

The study section evaluates each application during the initial review to determine if it is in compliance with the Inclusion Policy. The evaluation results are noted on the summary statement. In addition, reviewers are instructed to include compliance with the inclusion policy as a factor when assigning a priority score to an application.

Using specific codes, SROs document in the IMPAC II system any concerns regarding inclusion of women and minorities. Codes are also used to indicate and track studies that are Phase III clinical trials. If the study proposed is a clinical trial, then the type of trial (i.e., Phase I, Phase II or Phase III) is noted in the summary statement.

B. Program Monitoring and Grants Management Oversight

Prior to award, Program Officials 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 monitor requirements for plans and reporting of sex and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure 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.

For multi-center clinical trials managed through a cooperative agreement or research contract, there is typically a steering committee on which the responsible NIDDK program staff member serves. This committee monitors recruitment to make sure the ongoing study is on target with the initial study design approved through peer review. The committee will take corrective actions to ensure recruitment stays on target by employing appropriate enrollment strategies. These studies have, in addition, an outside advisory Data and Safety Monitoring Board (DSMB) that also monitors recruitment. The proceedings of the DSMB meetings are reported to the Institutional Review Boards (IRB) at all participating sites.

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 those who were 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 (ORWH).

D. NIDDK Training Approaches

NIDDK Program Officials and Scientific Review Officers attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. Staff may access the archived training on the NIH staff intranet.

A section on inclusion guidelines is part of orientation training for all newly hired review and program staff members. In addition, the "NIDDK Extramural Program: Standard Operating Procedures (SOPs)," which are available on NIDDK's internal SharePoint site, include specific guidance to staff regarding inclusion. Some of the SOPs most focused on inclusion include:

- **SOP #8** - Preparing for Review Meetings At NIDDK: Administrative Review by the Scientific Review Officer
- **SOP #19** - Recording the Results of Review Meetings: Preparing and Releasing Summary Statements
- **SOP #27** - Staff Review of Applications Prior to Award: Resolving Concerns About the Inclusion of Women, Members of Minority Groups, and Children

NIDDK has a regularly updated section of its public website devoted to policies associated with conducting clinical trials that includes specific policies and implementation procedures for inclusion of women and minorities in clinical research (see https://www.niddk.nih.gov/research-funding/human-subjects-research/policies-clinical-researchers).

The NIDDK Division of Extramural Activities (DEA) recurrently schedules inclusion refresher training (includes review, program and grants management staff) to ensure that staff members are familiar with the materials and to address any questions that may arise. This refresher training was last presented at the Clinical Study Working Group meeting on April 13, 2022 by the NIDDK Inclusion Monitoring Officer, Mr. TJ Smith. Additionally, regular updates on inclusion policy are presented at the monthly Extramural Program (EP) Staff Meeting throughout the year.

E. Additional NIDDK Actions to Ensure Compliance with the Inclusion Policy

The NIDDK Division of Extramural Activities (DEA) conducts an annual review of ongoing efforts associated with inclusion policy compliance and provides data to the NIH Office of Research on Women's Health. The DEA Director oversees the process and provides leadership to all NIDDK Extramural Divisions. Within DEA, the Office of Research Evaluation and Operations (OREO) manages most inclusion monitoring and reporting activities, including the coordination of the triennial inclusion report. Each NIDDK Extramural Division has a designated inclusion program analyst or clinical trial specialist for data quality assurance and tracking at the division level. All NIDDK Program Officials are responsible for monitoring the clinical studies within their respective programs. The NIDDK Inclusion Policy Officer within OREO works closely with the division inclusion analysts to monitor reporting progress and reports any problems to the OREO director.

III. Analysis and Interpretation of Data

In June 2018, NIH transitioned from the previous Inclusion Management System (IMS) to the Human Subject System (HSS). In HSS, the Principal Investigator (PI) directly uploads their inclusion data, which is then reviewed and approved by the Program Official.

Starting with fiscal year 2022 (FY22) inclusion data, the National Institutes of Health (NIH) Office of Extramural Research in the Office of the Director requires that Institute/Center (IC) Director's review and approve the previous year's inclusion data after the IC's Advisory Council has the opportunity to review and concur. This analysis and interpretation provide a summarized overview of the FY22 to FY24 inclusion data for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Director's review and approval.

Annual data checks and certifications are part of new NIH standard operating procedures to ensure the inclusion data are as accurate as possible. Note that in cases where the total percentages are not 100%, this can occur as multiple selections are allowed in some categories.

NIDDK staff members have continued their efforts to ensure that persons of all sexes and all ethnic and racial backgrounds are included in studies involving human subjects (see data in Appendix, Tables 1-12).

All NIDDK Clinical Research (Intramural and Extramural)

* **IMPORTANT NOTE:** In FY23, there was a coding error introduced by an awardee conducting an NIDDK Phase III Clinical Trial (see explanation associated with the PATHWEIGH study under the "NIDDK Phase III Clinical Trials (Intramural and Extramural)"). The error resulted in the inclusion of the study's enrollment. As a result, this error contributes to overreporting and impacts the full inclusion dataset for FY23. This issue was not identified until after the FY23 inclusion data were frozen, and NIDDK was not able to amend the data record. FY23 data are included in the summary below for transparency and consistency with the published data tables but should be considered in the context of the known coding/reporting/data issue for FY23.

The total number of Inclusion Enrollment Records (IERs) with enrollment (some IERs are registered by studies but have not yet started recruiting) was 1,076 in FY22 compared to *1,094 in FY23** and 1,240 in FY24 (Appendix Table 1).

The total enrollment in NIDDK clinical research was 391,107 in FY22, *399,621 in FY23*,* and 414,145 in FY24. FY24 total enrollment was 6% greater than total enrollment in FY22 (Appendix Table 5).

- The percentage of females enrolled within a given year in FY22-FY24 was higher than the percentage of males enrolled (Appendix Table 5). The breakdown for female and male enrollment was:
    - 46.7% female, 41.8% male, and 11.5% Unknown/Not Reported in FY22.
    - *49.5% female, 37.4% male, and 13.1% Unknown/Not Reported in FY23.**
    - 44.9% female, 44.5% male, and 10.6% Unknown/Not Reported in FY24.
- The percentage of persons enrolled in NIDDK Clinical Research who identified themselves belonging to one or more racial minority group(s) was 37.9% in FY22, *35.7% in FY23**, and 31.8% in FY24 (Appendix Table 6). Yearly reported enrollment of persons who identified as:
    - American Indian/Alaska Native (AIAN) was approximately 6%.**

      ****Note:** NIDDK's Phoenix Epidemiology and Clinical Research Branch within NIDDK's Intramural Research Program has a long-standing focus on AIAN populations, (see section IV. Additional Information below).

    - Asian was 3.5% in FY22, *4.0% in FY23*,* and 5.7% in FY24.
    - Black/African American was 14.7.3% in FY22, *11.3% in FY23*,* and 10.6% in FY24.
    - Native Hawaiian Pacific Islander was 0.8% in FY22, *0.7% in FY23*,* and 0.8% in FY24.
    - White was 54.0% in FY22, *55.6% in FY23*,* and 60.0% in FY24.
    - More Than One Race was 2.4% in FY22, *2.7% in FY23*,* and 2.1% in FY24.
    - Unknown/Not Reported was 18.6% in FY22, *19.7% in FY23*,* and 17.6% in FY24.
- The general decrease in racial minority enrollment in FY22-24 stems from a decrease in NIDDK's largest racial minority group, Black/African-American females and males (Appendix Table 3).
    - The percentages of Black/African-American females enrolled in NIDDK clinical research was 17.1% in FY22, *13.8% in FY23**, and 14.6% in FY24.
    - The percentages of Black/African-American males enrolled in NIDDK clinical research was 16.0% in FY22, *11.8% in FY23**, and 9.0% in FY24.
- Regarding ethnicity, for all three FYs, more than 70% of enrollees identified as "Not Hispanic/Latino" (Appendix Table 7).
    - The percentages of enrollees identifying as Hispanic/Latino was 12.3% in FY22, *12.7% in FY23*,* and 10.9% in FY24.
    - The percentages of enrollees whose ethnicity is Unknown/Not Reported was 14.2% in FY22, *15.5% in FY23*,* and 14.0% in FY24.

- The age distribution of persons enrolled in NIDDK clinical research in FY22-FY24 (Appendix Table 8):
    - Children (<18 years) was 29.2% in FY22, *23.1% in FY23*,* and 11.8% in FY24.
    - Adults (18 - 64 years) was 51.1% in FY22, *53.7% in FY23*,* and 64.9% in FY24.
    - Older Adults (65+ years) was 18.1% in FY22, *16.2 in FY23*,* and to 20.9% in FY24.
    - Unknown/Not Reported was1.6% in FY22, *7.0% in FY23*,* and 2.4% in FY24.

Enrollment in NIDDK clinical research in the FY22-FY24 timeframe generally aims to reflect the age, sex, race, and Hispanic origin characteristics of the United States as reported by the United States Census Bureau (see www.census.gov). There are some areas where alignment appears imperfect. In this context, Unknown/Not Reported enrollment data within NIDDK clinical research studies can complicate interpretation. The specific focus of studies that constitute the NIDDK clinical research portfolio within snapshots of time is another factor that also needs to be considered. Each year new studies begin and previously supported studies end. The dynamics of proposed studies that do well in peer review (and hence are more likely to be supported) and the research focus of those studies in any one FY can impact enrollment data overall and result in considerable within group changes. For example, the general decrease in female enrollment in FY24 is likely impacted by decreased enrollment in NIDDK female-only clinical research that was supported by the NIDDK extramural research program during a snapshot in time: there were 9,703 enrolled in female-only studies in FY22 and 8,000 in FY24; a decrease of 1,073 (18% decrease) (Appendix Table 5). At the same time, enrollment in male-only clinical research supported by the NIDDK extramural research program increased substantially at a coincident snapshot in time: there were 2,055 enrollees in male-only research in FY22, but this was followed by an increase to 52,470 enrolled in male-only research in FY24; an increase of 50,415 (2,453% increase) (Appendix Table 5).

NIDDK Phase III Clinical Trials (Intramural and Extramural)

*** IMPORTANT NOTE:** As indicated in the section above, the apparent large spike in enrollment reported for FY23 is largely attributable to a reporting error associated with an extramural disease prevention-focused grant, which accounted for 89% of the total NIDDK Phase III Clinical Trial participant enrollment in FY23 (PATHWEIGH: Pragmatic Weight Management in Primary Care, R18DK127003). This issue is likely to have created some cross-cutting distortions in the data set for FY23. FY23 data are included in the summary below for transparency and consistency with the published data tables but should be considered in the context of the known coding/reporting/data issue for FY23.

The total reported enrollment in NIDDK Phase III clinical trials was 10,824 in FY22, *was reported as 61,355 in FY23**, and then decreased from FY22 levels to 8,609 in FY24 (Appendix Table 9).

- The percentage of females and males enrolled in NIDDK Phase III clinical trials shifted from a slightly higher percentage of males in FY22 to a higher percentage of females in FY24 (Appendix Table 9). The breakdown for female and male enrollment was:
    - 48.4% female and 51.5% male in FY22.
    - *59.7% female and 40.3% male in FY23.**
    - 56.1% female and 43.8% male in FY24.

- The percentage of persons enrolled in NIDDK Phase III clinical trials identified themselves belonging to one or more racial minority group(s) was 41.2% in FY22, *23.6% in FY23**, and 37.5% in FY24 (Appendix Table 10). Yearly reported enrollment of persons who identified as:
    - AIAN was 7.2% in FY22, *1.5% in FY23*,* and 6.3% in FY24.**
    - Asian was 3.0% in FY22, *1.8% in FY23**, and 2.5% in FY24.
    - Black/African American was 16.3% in FY22, *6.1% in FY23*,* and 19.4% in FY24.
    - Native Hawaiian Pacific Islander was 0.4% in FY22, *0.2% in FY23*,* and 0.4% in FY24.
    - White was 66.7% in FY22, *79.8% in FY23*,* and 65.9% in FY24.
    - More Than One Race was 4.1% in FY22, *3.1% in FY23**, and 1.7% in FY24.
    - Unknown/Not Reported was 2.3% in FY22, *7.4% in FY23**, and 3.8% in FY24.

- The general decrease in racial minority enrollment in Phase III clinical trials stems from a decrease in More Than One Race females and males (Appendix Table 4).
    - The percentages of More Than One Race females enrolled in NIDDK clinical research was 4.4% in FY22, *3.5% in FY23**, and 2.1% in FY24.
    - The percentages of More Than One Race males enrolled in NIDDK clinical research was 3.8% in FY22, *2.6% in FY23**, and 1.2% in FY24.

- Despite this general decrease in racial minority enrollment in Phase III clinical trials, NIDDK's largest racial minority group, Black/African-American females and males, experienced little to no decline in enrollment from FY22-24. As a result, their proportional makeup in FY24 increased (Appendix Table 4).
    - The percentages of Black/African-American females enrolled in NIDDK clinical research was 18.0% in FY22, *6.9% in FY23**, and 19.6% in FY24.
    - The percentages of Black/African-American males enrolled in NIDDK clinical research was 14.6% in FY22, *4.9% in FY23**, and 19.3% in FY24.

- For FY22-24, 80% or more of enrollees of NIDDK Clinical Trials identified as "Not Hispanic/Latino" (Appendix Table 11).
    - The percentages of enrollees identifying as Hispanic/Latino was 13.6% in FY22, *12.8% in FY23**, and 9.0% in FY24.
    - The percentages of enrollees whose ethnicity is Unknown/Not Reported was 5.8% in FY22, *1.3% in FY23*,* and 7.2% in FY24.

In accordance with the NOT-OD-18-014 amendment to the "*NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*," all grant recipients conducting applicable NIH-defined Phase III clinical trials must ensure results of valid analyses by sex, race, and/or ethnicity are submitted to Clinicaltrials.gov. The total number of NIDDK Phase III trials requiring valid analyses by both sex and race and ethnicity was 44 (98%) in FY22; 32 (94%) in FY23; and 46 (100%) in FY24 (Appendix Table 2).

Inclusion enrollment data summarized by this report can be further explored using the Research Condition and Disease Categorization (RCDC) module through this link: https://report.nih.gov/RISR/.

NIDDK staff will continue to encourage participation of all minority groups in clinical research, to maintain diversity and scientific integrity of the Institute's funded clinical research. In addition, the NIDDK will continue to seek out and fund clinical research in areas of high relevance to either a specific sex or racial group.

NIDDK has established additional procedures to identify and resolve inclusion data submission errors well before inclusion data are frozen. In FY23, NIDDK hired a new Inclusion Policy Officer, who coordinates with each NIDDK division's inclusion point of contact in reconciling inclusion data discrepancies throughout the year and before annual inclusion data are frozen. As training, support, and monitoring continue and as investigators and NIH staff become more familiar with the HSS system, we expect data quality to increase. NIDDK will continue to provide training and support for staff and closely monitor inclusion data for any issues.

IV. Additional Information

All NIDDK Clinical Research (Intramural)

As NIDDK is committed to having diverse representation in our clinical research, having American Indian and Alaska Native (AIAN) participants enrolled in Intramural Research Program (IRP) studies is important because of the high incidences of diabetes in these populations. NIDDK's Phoenix Epidemiology and Clinical Research Branch, part of the IRP, conducts clinical trials on obesity and diabetes leveraging the large AIAN patient population in the area. The goal of this research is to identify the causes of obesity and type 2 diabetes in humans for the purposes of improved prevention and treatment. The total number of American Indian and Alaska Native (AIAN) participants in the IRP was 21,740 (47.8%) in FY22; 21,765 (47.5%) in FY23; and 21,725 (46.1%) in FY24 (Appendix Table 12). Over 92% of the intramural AIAN participants are enrolled in one of three epidemiological studies (*Prospective Studies of Diabetes Mellitus and its Complications in the Gila River Indian Community, Z01DK900002/ ZIADK069028; Family Investigation of Nephropathy and Diabetes (F.I.N.D.), ZIADK069094; Molecular and Clinical Profile of Diabetes Mellitus and its Complications, ZIADK075071*).

V. APPENDIX

Table 1: Metrics Based on Inclusion Data Records (IERs)

Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2022	1,735	659	1,076	1,031	45	99	37	940
2023	1,753	659	1,094	1,052	42	102	34	958
2024	1,908	668	1,240	1,195	45	111	41	1,088

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex, and combination of unknown and any sex(es).

Table 2: Valid Analysis by Sex and Race/Ethnicity

Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2022 and 2024

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	45	44	97.8	44	97.8
2023	34	32	94.1	32	94.1
2024	46	46	100.0	46	100.0

Current methodology to monitor valid analysis began in 2019 and differs from what was used in 2018 (N/A in 2018). 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.

Table 3: Total Enrollment: All NIH-Defined Clinical Research – NIDDK

NIDDK Total Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2022	Female	80,221	44.0	182,515	46.7	12,532	6.9	7,195	3.9	31,279	17.1	1,580	0.9
2022	Male	67,002	41.0	163,449	41.8	10,857	6.6	6,298	3.9	26,101	16.0	1,502	0.9
2022	Unknown	886	2.0	45,143	11.5	4	0.0	78	0.2	187	0.4	0	0.0
2023	Female	81,472	41.2	197,805	49.5	12,913	6.5	8,324	4.2	27,343	13.8	1,669	0.8
2023	Male	60,522	40.5	149,329	37.4	10,920	7.3	7,740	5.2	17,663	11.8	1,316	0.9
2023	Unknown	778	1.5	52,487	13.1	15	0.0	15	0.0	165	0.3	2	0.0
2024	Female	77,355	41.6	186,068	44.9	12,790	6.9	7,213	3.9	27,209	14.6	1,769	1.0
2024	Male	53,644	29.1	184,098	44.5	10,862	5.9	6,035	3.3	16,585	9.0	1,392	0.8
2024	Unknown	494	1.1	43,979	10.6	12	0.0	34	0.1	190	0.4	3	0.0

Fiscal Year	Sex	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	108,494	59.4	4,988	2.7	16,447	9.0	149,819	82.1	26,240	14.4	6,456	3.5
2022	Male	102,289	62.6	4,482	2.7	11,920	7.3	137,085	83.9	21,184	13.0	5,180	3.2
2022	Unknown	574	1.3	105	0.2	44,195	97.9	705	1.6	522	1.2	43,916	97.3
2023	Female	124,972	63.2	6,225	3.1	16,359	8.3	162,244	82.0	28,954	14.6	6,607	3.3
2023	Male	96,653	64.7	4,304	2.9	10,733	7.2	124,052	83.1	21,117	14.1	4,160	2.8
2023	Unknown	738	1.4	104	0.2	51,448	98.0	745	1.4	501	1.0	51,241	97.6
2024	Female	115,151	61.9	5,414	2.9	16,522	8.9	150,759	81.0	26,828	14.4	8,481	4.6
2024	Male	132,760	72.1	3,112	1.7	13,352	7.3	159,336	86.5	17,992	9.8	6,770	3.7
2024	Unknown	694	1.6	129	0.3	42,917	97.6	979	2.2	155	0.4	42,845	97.4

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 4: Total Enrollment: All NIH-Defined Phase III Trials - NIDDK

NIDDK Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2022	Female	2,385	45.5	5,244	48.4	538	10.3	97	1.8	946	18.0	15	0.3
2022	Male	2,074	37.2	5,575	51.5	237	4.3	232	4.2	814	14.6	31	0.6
2022	Unknown	1	20.0	5	0.0	1	20.0	0	0.0	0	0.0	0	0.0
2023	Female	9,229	25.2	36,624	59.7	634	1.7	566	1.5	2,528	6.9	87	0.2
2023	Male	5,224	21.1	24,729	40.3	271	1.1	547	2.2	1,202	4.9	64	0.3
2023	Unknown	1	50.0	2	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	1,821	37.7	4,827	56.1	364	7.5	70	1.5	947	19.6	16	0.3
2024	Male	1,410	37.4	3,768	43.8	176	4.7	147	3.9	727	19.3	18	0.5
2024	Unknown	1	7.1	14	0.2	0	0.0	0	0.0	0	0.0	0	0.0

Fiscal Year	Sex	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	3,284	62.6	231	4.4	133	2.5	4,196	80.0	753	14.4	295	5.6
2022	Male	3,937	70.6	214	3.8	110	2.0	4,527	81.2	714	12.8	334	6.0
2022	Unknown	0	0.0	0	0.0	4	80.0	1	20.0	0	0.0	4	80.0
2023	Female	28,737	78.5	1,275	3.5	2,797	7.6	31,208	85.2	4,955	13.5	461	1.3
2023	Male	20,245	81.9	636	2.6	1,764	7.1	21,476	86.8	2,916	11.8	337	1.4
2023	Unknown	1	50.0	1	50.0	0	0.0	2	100.0	0	0.0	0	0.0
2024	Female	3,154	65.3	99	2.1	177	3.7	4,107	85.1	421	8.7	299	6.2
2024	Male	2,515	66.7	47	1.2	138	3.7	3,104	82.4	351	9.3	313	8.3
2024	Unknown	2	14.3	1	7.1	11	78.6	3	21.4	0	0.0	11	78.6

Table 5: Total Enrollment: All NIH-Defined Clinical Research - NIDDK

NIDDK Total Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only
2022	391,107	182,515	46.7	163,449	41.8	45,143	11.5	10,085	2.6
2023	399,621	197,805	49.5	149,329	37.4	52,487	13.1	12,153	3.0
2024	414,145	186,068	44.9	184,098	44.5	43,979	10.6	8,374	2.0

Fiscal Year	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	2,269	0.6	172,430	44.1	161,180	41.2
2023	875	0.2	185,652	46.5	148,454	37.1
2024	52,690	12.7	177,694	42.9	131,408	31.7

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 6: Total Enrollment: All NIH-Defined Clinical Research - NIDDK

NIDDK Total Enrollment for All NIH-Defined Clinical Research, Race

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2022	391,107	1,735	148,109	37.9	23,393	6.0	13,571	3.5
2023	399,621	1,753	142,772	35.7	23,848	6.0	16,079	4.0
2024	414,145	1,908	131,493	31.8	23,664	5.7	13,282	3.2

Fiscal Year	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	57,567	14.7	3,082	0.8	211,357	54.0	9,575	2.4	72,562	18.6
2023	45,171	11.3	2,987	0.7	222,363	55.6	10,633	2.7	78,540	19.7
2024	43,984	10.6	3,164	0.8	248,605	60.0	8,655	2.1	72,791	17.6

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 7: Total Enrollment: All NIH-Defined Clinical Research - NIDDK

NIDDK Total Enrollment for All NIH-Defined Clinical Research, Ethnicity

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	287,609	73.5	47,946	12.3	55,552	14.2
2023	287,041	71.8	50,572	12.7	62,008	15.5
2024	311,074	75.1	44,975	10.9	58,096	14.0

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 8: Age Data Based on Inclusion Data Records (IERs) - NIDDK

Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022-2024.

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2022	45,343 29.2%	79,442 51.1%	28,128 18.1%	2,503 1.6%	155,416 100%
2023	52,054 23.1%	121,099 53.7%	36,439 16.2%	15,783 7.0%	225,375 100%
2024	28,605 11.8%	157,451 64.9%	50,751 20.9%	5,912 2.4%	242,719 100%

Table 9: Total Enrollment: All NIH-Defined Phase III Trials - NIDDK

NIDDK Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only
2022	10,824	5,244	48.4	5,575	51.5	5	0.0	124	1.1
2023	61,355	36,624	59.7	24,729	40.3	2	0.0	123	0.2
2024	8,609	4,827	56.1	3,768	43.8	14	0.2	123	1.4

Fiscal Year	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	0	0.0	5,120	47.3	5,575	51.5
2023	1	0.0	36,501	59.5	24,728	40.3
2024	5	0.1	4,704	54.6	3,763	43.7

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 10: Total Enrollment: All NIH-Defined Phase III Trials - NIDDK

NIDDK Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Race

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2022	10,824	45	4,460	41.2	776	7.2	329	3.0
2023	61,355	34	14,454	23.6	905	1.5	1,113	1.8
2024	8,609	46	3,232	37.5	540	6.3	217	2.5

Fiscal Year	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	1,760	16.3	46	0.4	7,221	66.7	445	4.1	247	2.3
2023	3,730	6.1	151	0.2	48,983	79.8	1,912	3.1	4,561	7.4
2024	1,674	19.4	34	0.4	5,671	65.9	147	1.7	326	3.8

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 11: Total Enrollment: All NIH-Defined Phase III Trials - NIDDK

NIDDK Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Ethnicity

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	8,724	80.6	1,467	13.6	633	5.8
2023	52,686	85.9	7,871	12.8	798	1.3
2024	7,214	83.8	772	9.0	623	7.2

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 12: Total Enrollment: All NIH-Defined Intramural Clinical Research - NIDDK

NIDDK Total Enrollment for All NIH-Defined Intramural Clinical Research, Race

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2022	45,463	111	31,904	70.2	21,740	47.8	1,471	3.2
2023	45,839	106	31,902	69.6	21,765	47.5	1,448	3.2
2024	47,140	111	32,892	69.8	21,725	46.1	1,596	3.4

Fiscal Year	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	4,063	8.9	2,360	5.2	9,559	21.0	488	1.1	5,782	12.7
2023	3,979	8.7	2,359	5.1	10,199	22.2	529	1.2	5,560	12.1
2024	4,229	9.0	2,353	5.0	11,011	23.4	626	1.3	5,600	11.9

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.