

NIA Report of FY2022 - 2024 Inclusion Data

I. Background/Overview

NIA, one of the 27 Institutes and Centers of NIH, leads the federal government in conducting and supporting research on aging and the health and well-being of older people. The Institute seeks to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life.

In 1974, Congress granted authority to form NIA to provide leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. Subsequent amendments to this legislation designated NIA as the primary Federal agency on Alzheimer's disease research.

NIA's mission is to support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging; to foster the development of research and clinician scientists in aging; to provide research resources for research on aging; and to disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.

NIA pursues this mission by funding extramural research and training at universities and medical centers across the United States and around the world; maintaining an active communications and outreach program; and conducting a vibrant intramural research program at NIA laboratories in Baltimore and Bethesda, Maryland.

Strategic Directions.

Aging Well in the 21st Century: [Strategic Directions for Research on Aging](#) has NIA's "road map" for progress in aging research and outlines our goals and vision. It provides a point of reference for setting priorities and a framework for systematically analyzing the Institute's scientific portfolio and assessing progress.

NIA sponsors research on aging through extramural and intramural programs. The extramural program funds research and training at universities, hospitals, medical centers, and other public and private organizations nationwide. The intramural program conducts basic and clinical research in Baltimore, MD, and on the NIH campus in Bethesda, MD.

II. Strategies for Ensuring Compliance

The National Institute on Aging (NIA) as a component of the National Institutes of Health is mandated by the U.S. Congress under the NIH Revitalization Act of 1993, Public Law 103-43, Section 492B(2)(f), to report on the inclusion of women and minorities in clinical research studies. This act requires that each clinical research trial be designed and carried out in a manner sufficient to provide for valid analysis of variables that may affect women or minority groups. As interventions or therapies may affect women and /or men or members of minority groups and their subpopulations differently, it is, therefore, recognized that scientific evidence can be very important in leading to a change in health policy or standard of care. The NIA, consequently, pursues scientific evidence for these purposes and complies with NIH guidelines and other requirements of this law. This report provides a comparison of FY2022 through FY2024, inclusion of both sexes and all racial and ethnic minority groups in clinical studies at NIA.

A. Peer Review

The Scientific Review Branch (SRB) at the National Institute on Aging (NIA) is responsible for the initial peer review of specific research grant applications assigned to NIA. These include contract proposals, applications for Research Centers, Program Projects, scientific meetings, training and career development, and applications responding to Notice of Funding Opportunity announcements (NOFOs) published by NIA.

External peer reviewers selected from the grant community participate in the reviews, and an overall impact/priority score is given to grant applications. Scores range from 10 (best) to 90 (worst). We produce an official document (Summary Statement) for each reviewed application. Scores and Summary Statements are used by Program Division Staff and NIA Council in making final funding decisions.

Most investigator-initiated research projects (R01), exploratory/developmental research grants (R21), and small research projects (R03), submitted in response to parent announcements (PA, PAR, PAS) are reviewed at the Center for Scientific Review, NIH.

Reviewers on NIH peer review panels are given specific [guidance](#) on reviewing inclusion on the basis of sex, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex, 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.

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 officials consider the guidance provided by reviewers and request modifications to inclusion plans needed prior to award. 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 the requirement for 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, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, and race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by 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. NIA Training Approaches

Institute Program Officials/Program Directors and Scientific Review Officers attended the 2024 NIH Inclusion Training. Staff may access the archived training on the [Monitoring Inclusion in Clinical Research | Staff Training](#).

Guidance is available and training on the Human Subjects System (HSS) for DEA Program Officers, Principal Investigators and Assistants. Training is located on the [Office of Extramural Research \(OER\)](#) website and are available to everyone to view.

E. NIA Clinical Research Operations and Management

NIA relies on the NIA Clinical Research Operations and Management System (CROMS) to help the Institute ensure compliance with the inclusion policy. CROMS is an informatics IT tool that provides NIA staff and grantees near real-time tracking, reporting, and management of clinical research enrollment data, study documents, and activities. CROMS was developed to ensure the tracking of inclusion data on a study-by-study basis such that NIA can easily identify those studies that are enrolling as anticipated and those that are not meeting their inclusion goals. For the former, the NIA has a [new policy](#) recently released where NIA requires the submission of a Corrective Action Plan (CAP) for clinical trials whose timeline milestones and participant enrollment indicate that the clinical trial is delayed, and the rate of enrollment is less than

60% of its expected benchmark. The NIA is currently working to expand the request of a CAP to address trials not meeting their specific inclusion goals and expects to complete this expansion in 2025.

III. Analysis and Interpretation of Data

The total Inclusion Data Records (IER) for NIH-Defined Extramural and Intramural Clinical Research were 2,795 for FY2022, 2,749 for FY2023, and 2,627 for FY2024 (Table 2-1). The total number of IERs between FY2022 and FY2023 is comparable, whereas the total number of IERs between FY2023 and FY2024 shows a slightly decreasing trend. Table 3-1-B provides the total enrollment numbers for all NIH-Defined Extramural Clinical Research conducted between FY2022 and FY2024. Sex distribution among participants remains consistent for all NIH-Defined Extramural Clinical Research during this period. The remaining passage will exclude the 86,410,077 clinical research enrollees (all US site enrollees) from the Facebook App Message study on COVID-19 for FY2022 to accurately reflect the enrollment data and to prevent the misrepresentation of data trends due to the large enrollment number. The enrollment data for all Extramural Research Protocols for FY2022 was 1,185,142*, for FY2023 was 640,398, and for FY2024 was 1,186,922.

Table 3-3 presents the total enrollment number for NIH-defined Phase III Trials conducted between FY2022 and FY2024. In FY2022, there were 550,468* enrollees, followed by 54,837 enrollees in FY2023, and 159,927 enrollees in FY2024. There was a significant decrease in total enrollment for Phase III Trials from FY2022 to FY2023, but an increase in FY2024 relative to FY2023. Similarly, considering the Phase III Trials that are based only in US sites (Table 3-4-B), FY 2022 had 550,468* enrollees; FY2023 had 54,504 enrollees; and FY2024 had 159,637 enrollees. Trends for US site enrollment of Extramural Phase III Trials between FY2022-2024 are consistent with those that consider both US sites and non-US sites. When considering the US site enrollment of NIH-defined Phase III Trials by racial and ethnic minority, Table 4-2-2-D shows the number and percentage of minority enrollees. There is an increase in minority enrollees from FY2023 - FY2024. For a detailed analysis of US site enrollment by sex, race, and ethnicity in NIH-defined Extramural Phase III Clinical Research, please refer to Table 5-3-3-C. The total enrollment for Phase III Clinical Research is much lower for FY2023 relative to both FY2022* and FY2024, even after excluding the clinical research enrollees on Facebook App Message on COVID-19 in FY2022 (Table 5-3-3-C).

*Data presented excludes the 86,410,077 clinical research enrollees on Facebook App Message study on COVID-19 in FY2022.

NIA HSS Enrollment Tables

Age Data Based on Inclusion Data Records (IERs)

Table 1. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

Table 2. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

Metrics Based on Inclusion Data Records (IERs)

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

Total Inclusion Data Records (IERs): All NIH-Defined Phase III Trials

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

Total Inclusion Data Records (IERs): All NIH Phase III Clinical Trials

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

Metrics Based on Aggregate Enrollment: Sex

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and 2024

Table 3-1-B. Total Enrollment for All NIH-Defined Extramural Clinical Research Between Fiscal Years 2022 and 2024

Table 3-1-C. Total Enrollment for All NIH-Defined Intramural Clinical Research Between Fiscal Years 2022 and 2024

Table 3-2-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Clinical Research

Table 3-2-B. US Site Enrollment for All NIH-Defined Extramural Clinical Research

Table 3-2-C. US Site Enrollment for All NIH-Defined Intramural Clinical Research

Total Enrollment: All NIH-Defined Phase III Trials

Table 3-3. Total Enrollment for All NIH-Defined Phase III Trials Reporting Between Fiscal Years 2022 and 2024

US Site Phase III Trials Enrollment

Table 3-4-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Phase III Trials

Table 3-4-B. US Site Enrollment for All NIH-Defined Extramural Phase III Trials

Table 3-4-C. US Site Enrollment for All NIH-Defined Intramural Phase III Trials

US Site Racial and Ethnic Minority Enrollment

Table 4-1-2-D. Total US Site Enrollment of NIH-Defined Clinical Research

Table 4-2-2-D. US Site Enrollment of NIH-Defined Phase III Trials

Enrollment by Race

Table 4-1-1-C. Total Enrollment of All NIH-Defined Clinical Research

Table 4-1-1-D. Total Enrollment of NIH-Defined Extramural Clinical Research

Table 4-1-1-E. Total Enrollment of NIH-Defined Intramural Clinical Research

US Site Enrollment by Race

Table 4-1-2-B. Total US Site Enrollment of NIH-Defined Clinical Research

Table 4-1-3-B. US Site Enrollment of NIH-Defined Extramural Clinical Research

Table 4-1-4-B. US Site Enrollment of NIH-Defined Intramural Clinical Research

Total Phase III Trials Enrollment by Race

Table 4-2-1-C. Total Enrollment of All NIH-Defined Phase III Trials

US Site Phase III Trials Enrollment by Race

Table 4-2-2-B. Total US Site Enrollment of NIH-Defined Phase III Trials

Table 4-2-3-B. US Site Enrollment of NIH-Defined Extramural Phase III Trials

Table 4-2-4-B. US Site Enrollment of NIH-Defined Intramural Phase III Trials

Enrollment by Ethnicity

Table 4-1-1-D1. Total Enrollment of All NIH-Defined Clinical Research

Table 4-1-1-E1. Total Enrollment of All NIH-Defined Extramural Clinical Research

Table 4-1-1-F. Total Enrollment of All NIH-Defined Intramural Clinical Research

Enrollment of Hispanic or Latino Participants by Race

Table 4-1-1-G. Enrollment of Hispanic or Latino Participants in NIH-Defined Clinical Research

Table 4-1-1-H. Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Clinical Research

Table 4-1-1-I. Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Clinical Research

US Site Enrollment by Ethnicity

Table 4-1-2-C. Total US Site Enrollment of NIH-Defined Clinical Research

Table 4-1-3-C. US Site Enrollment of NIH-Defined Extramural Clinical Research

Table 4-1-4-C. US Site Enrollment of NIH-Defined Intramural Clinical Research

US site Enrollment of Hispanic or Latino Participants by Race

Table 4-1-2-D1. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Clinical Research

Table 4-1-3-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Clinical Research

Table 4-1-4-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Clinical Research

Total Phase III Trials Enrollment by Ethnicity

Table 4-2-1-D. Total Enrollment of All NIH-Defined Phase III Trials

Total Phase III Trial Enrollment of Hispanic or Latino Participants by Race

Table 4-2-1-E. Enrollment of Hispanic or Latino Participants in NIH-Defined Phase III Trials

US Site Phase III Enrollment by Ethnicity

Table 4-2-2-C. Total US Site Enrollment of NIH-Defined Phase III Trials

Table 4-2-3-C. US Site Enrollment of NIH-Defined Extramural Phase III Trials

Table 4-2-4-C. US Site Enrollment of NIH-Defined Intramural Phase III Trials

US Site Phase III Enrollment of Hispanic or Latino Participants by Race

Table 4-2-2-D1. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Phase III Trials

Table 4-2-3-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Phase III

Table 4-2-4-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Phase III Trials

Total Enrollment: All NIH-Defined Clinical Research

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

US Site Enrollment: All NIH-Defined Clinical Research

Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex by Race and Ethnicity

Table 5-1-3-C. US Site Enrollment for NIH-Defined Extramural Clinical Research, Sex by Race and Ethnicity Table 5-1-4-C.

US Site Enrollment for NIH-Defined Intramural Clinical Research, Sex by Race and Ethnicity

All Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Table 5-2-3-C. ALL Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex by Race and Ethnicity Table 5-2-4-

C. All Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex by Race and Ethnicity

US Site Enrollment: All NIH-Defined Clinical Research

Table 5-3-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Table 5-3-3-C. US Site Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex by Race and Ethnicity Table 5-3-4-C.

US Site Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Age Data Based on Inclusion Data Records (IERs)

Table 1. 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	186	148,330	138,978	3,411	290,905
	0.1%	51.0%	47.8%	1.2%	100%
2023	848	228,628	229,776	16,036	475,288
	0.2%	48.1%	48.3%	3.4%	100%
2024	1,949	472,794	533,710	17,881	1,026,334
	0.2%	46.1%	52.0%	1.7%	100%

Table 2. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024.

Fiscal Year	0 - 28 Days	29-364 Days	<1 year, values other than 0-28 or 29-364 days *	<1 year, Total **	1-5 Years	6-12 Years	13-15 Years	16-17 Years	18-21 Years	22-25 Years	26-34 Years	35-44 Years	45-54 Years	55-64 Years	65-69 Years	70-74 Years	75-79 Years	80-84 Years	85-89 Years	90+ Years	Unknown or Not Reported	Total
2022	2	2	6	10	1	10	4	161	4,062	4,271	12,700	19,571	39,229	68,497	41,338	33,915	34,718	17,407	7,610	3,990	3,411	290,905
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	1.4%	1.5%	4.4%	6.7%	13.5%	23.5%	14.2%	11.7%	11.9%	6.0%	2.6%	1.4%	1.2%	100%
2023	211	9	3	223	2	14	44	565	10,480	9,299	23,819	35,992	52,683	96,355	69,373	63,972	46,583	26,583	14,139	9,126	16,036	475,288
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	2.2%	2.0%	5.0%	7.6%	11.1%	20.3%	14.6%	13.5%	9.8%	5.6%	3.0%	1.9%	3.4%	100%
2024	212	9	6	227	23	66	33	1,600	34,462	20,974	41,896	74,390	110,476	190,596	157,567	145,568	112,295	65,974	33,694	18,612	17,881	1,026,334
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	3.4%	2.0%	4.1%	7.2%	10.8%	18.6%	15.4%	14.2%	10.9%	6.4%	3.3%	1.8%	1.7%	100%

* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.
**Includes all ages equivalent to less than one year, including all those reported in days, weeks, months and years.

Section 2: Metrics Based on Inclusion Data Records (IERs)

Table 2-1. 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	2,795	1,476	1,319	1,286	33	118	37	1,164
2023	2,749	1,406	1,343	1,279	64	116	33	1,194
2024	2,627	1,227	1,400	1,350	50	109	25	1,266

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

Total Inclusion Data Records (IERs): All NIH-Defined Phase III Trials

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials 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	219	132	87	84	3	4	5	78
2023	194	105	89	85	4	0	1	88
2024	186	80	106	103	3	2	1	103

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

Total Inclusion Data Records (IERs): All NIH Phase III Clinical Trials

Table 2-3. 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	219	218	99.5	218	99.5
2023	194	193	99.5	193	99.5
2024	186	186	100.0	186	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.

Section 3: Metrics Based on Aggregate Enrollment: Sex

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and 2024

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	87,608,076	44,745,234	51.1	42,838,089	48.9	24,753	0.0	65,341	0.1	3,502	0.0	44,679,893	51.0	42,834,587	48.9
2023	653,811	393,489	60.2	245,652	37.6	14,670	2.2	5,349	0.8	1,364	0.2	388,140	59.4	244,288	37.4
2024	1,199,576	808,470	67.4	373,299	31.1	17,807	1.5	73,287	6.1	1,685	0.1	735,183	61.3	371,614	31.0

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 3-1-B. Total Enrollment for All NIH-Defined Extramural Clinical Research Between Fiscal Years 2022 and 2024

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	87,595,219	44,738,926	51.1	42,831,540	48.9	24,753	0.0	65,341	0.1	3,391	0.0	44,673,585	51.0	42,828,149	48.9
2023	640,398	387,096	60.4	238,632	37.3	14,670	2.3	5,349	0.8	1,253	0.2	381,747	59.6	237,379	37.1
2024	1,186,922	802,366	67.6	366,759	30.9	17,797	1.5	73,287	6.2	1,574	0.1	729,079	61.4	365,185	30.8

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 3-1-C. Total Enrollment for All NIH-Defined Intramural Clinical Research Between Fiscal Years 2022 and 2024

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	12,857	6,308	49.1	6,549	50.9	0	0.0	0	0.0	111	0.9	6,308	49.1	6,438	50.1
2023	13,413	6,393	47.7	7,020	52.3	0	0.0	0	0.0	111	0.8	6,393	47.7	6,909	51.5
2024	12,654	6,104	48.2	6,540	51.7	10	0.1	0	0.0	111	0.9	6,104	48.2	6,429	50.8

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 3-2-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Clinical Research

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	87,537,971	44,706,425	51.1	42,806,813	48.9	24,733	0.0	65,339	0.1	3,502	0.0	44,641,086	51.0	42,803,311	48.9
2023	546,871	336,355	61.5	195,968	35.8	14,548	2.7	5,336	1.0	1,362	0.2	331,019	60.5	194,606	35.6
2024	1,124,644	767,075	68.2	339,984	30.2	17,585	1.6	73,281	6.5	1,683	0.1	693,794	61.7	338,301	30.1

Table 3-2-B. US Site Enrollment for All NIH-Defined Extramural Clinical Research

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	87,525,114	44,700,117	51.1	42,800,264	48.9	24,733	0.0	65,339	0.1	3,391	0.0	44,634,778	51.0	42,796,873	48.9
2023	533,458	329,962	61.9	188,948	35.4	14,548	2.7	5,336	1.0	1,251	0.2	324,626	60.9	187,697	35.2
2024	1,111,990	760,971	68.4	333,444	30.0	17,575	1.6	73,281	6.6	1,572	0.1	687,690	61.8	331,872	29.8

Table 3-2-C. US Site Enrollment for All NIH-Defined Intramural Clinical Research

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	12,857	6,308	49.1	6,549	50.9	0	0.0	0	0.0	111	0.9	6,308	49.1	6,438	50.1
2023	13,413	6,393	47.7	7,020	52.3	0	0.0	0	0.0	111	0.8	6,393	47.7	6,909	51.5
2024	12,654	6,104	48.2	6,540	51.7	10	0.1	0	0.0	111	0.9	6,104	48.2	6,429	50.8

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

Total Enrollment: All NIH-Defined Phase III Trials

Table 3-3. Total Enrollment for All NIH-Defined Phase III Trials Reporting Between Fiscal Years 2022 and 2024

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	86,960,545	44,322,926	51.0	42,620,674	49.0	16,945	0.0	65	0.0	2,902	0.0	44,322,861	51.0	42,617,772	49.0
2023	54,837	31,933	58.2	22,172	40.4	732	1.3	0	0.0	1	0.0	31,933	58.2	22,171	40.4
2024	159,927	101,787	63.6	56,688	35.4	1,452	0.9	17,835	11.2	1	0.0	83,952	52.5	56,687	35.4

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

US Site Phase III Trials Enrollment

Table 3-4-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Phase III Trials

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	86,960,401	44,322,841	51.0	42,620,615	49.0	16,945	0.0	65	0.0	2,902	0.0	44,322,776	51.0	42,617,713	49.0
2023	54,504	31,753	58.3	22,019	40.4	732	1.3	0	0.0	1	0.0	31,753	58.3	22,018	40.4
2024	159,637	101,638	63.7	56,547	35.4	1,452	0.9	17,835	11.2	1	0.0	83,803	52.5	56,546	35.4

Table 3-4-B. US Site Enrollment for All NIH-Defined Extramural Phase III Trials

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	86,960,401	44,322,841	51.0	42,620,615	49.0	16,945	0.0	65	0.0	2,902	0.0	44,322,776	51.0	42,617,713	49.0
2023	54,504	31,753	58.3	22,019	40.4	732	1.3	0	0.0	1	0.0	31,753	58.3	22,018	40.4
2024	159,637	101,638	63.7	56,547	35.4	1,452	0.9	17,835	11.2	1	0.0	83,803	52.5	56,546	35.4

Table 3-4-C. US Site Enrollment for All NIH-Defined Intramural Phase III Trials

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	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	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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

Section 4: US Site Racial and Ethnic Minority Enrollment

Table 4-1-2-D. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Total Enrollees	Racial and Ethnic Minority Enrollees	% Racial and Ethnic Minority Enrollees
2022	87,537,971	25,574,727	29.2
2023	546,871	147,320	26.9
2024	1,124,644	291,043	25.9

Table 4-2-2-D. US Site Enrollment of NIH-Defined Phase III Trials

Fiscal Year	Total Enrollees	Racial and Ethnic Minority Enrollees	% Racial and Ethnic Minority Enrollees
2022	86,960,401	25,424,181	29.2
2023	54,504	19,460	35.7
2024	159,637	78,419	49.1

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded. Racial and Ethnic minority enrollment includes participants of any race category except White and Unknown, and Hispanic participants irrespective of race category.

Section 5: Enrollment by Race

Table 4-1-1-C. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	87,608,076	2,795	25,642,574	29.3	1,081,049	1.2	2,221,689	2.5	15,493,322	17.7	103,710	0.1	66,542,141	76.0	2,098,574	2.4	67,591	0.1
2023	653,811	2,749	245,850	37.6	6,409	1.0	90,402	13.8	78,131	12.0	2,024	0.3	394,875	60.4	20,530	3.1	61,440	9.4
2024	1,199,576	2,627	359,606	30.0	10,659	0.9	105,768	8.8	133,946	11.2	4,035	0.3	713,058	59.4	24,528	2.0	207,582	17.3

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 4-1-1-D. Total Enrollment of NIH-Defined Extramural Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	87,595,219	2,774	25,638,116	29.3	1,080,893	1.2	2,221,431	2.5	15,490,036	17.7	103,706	0.1	66,534,847	76.0	2,098,393	2.4	65,913	0.1
2023	640,398	2,727	241,015	37.6	6,266	1.0	89,278	13.9	74,820	11.7	2,021	0.3	387,764	60.6	20,368	3.2	59,881	9.4
2024	1,186,922	2,605	355,566	30.0	10,505	0.9	105,493	8.9	130,605	11.0	4,032	0.3	705,876	59.5	24,364	2.1	206,047	17.4

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 4-1-1-E. Total Enrollment of NIH-Defined Intramural Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	12,857	21	4,458	34.7	156	1.2	258	2.0	3,286	25.6	4	0.0	7,294	56.7	181	1.4	1,678	13.1
2023	13,413	22	4,835	36.0	143	1.1	1,124	8.4	3,311	24.7	3	0.0	7,111	53.0	162	1.2	1,559	11.6
2024	12,654	22	4,040	31.9	154	1.2	275	2.2	3,341	26.4	3	0.0	7,182	56.8	164	1.3	1,535	12.1

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

US Site Enrollment by Race

Table 4-1-2-B. Total US Site Enrollment of NIH-Defined Clinical Research

		No.			American	%			Black	%	Native	%				%	Unknown	%
Fiscal Year	Total Enrollment	Inclusion Data Records	Minority Enrollment	% Minority Enrollment	Indian Alaska Native	American Indian Alaska Native	Asian	% Asian	African American	Black African American	Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Not Reported	Unknown Not Reported
2022	87,537,971	2,704	25,574,727	29.2	1,081,045	1.2	2,188,642	2.5	15,477,267	17.7	103,695	0.1	66,539,680	76.0	2,080,204	2.4	67,438	0.1
2023	546,871	2,610	147,320	26.9	4,540	0.8	17,488	3.2	61,959	11.3	1,618	0.3	386,358	70.6	15,152	2.8	59,756	10.9
2024	1,124,644	2,515	291,043	25.9	8,738	0.8	68,813	6.1	108,388	9.6	3,632	0.3	708,180	63.0	23,610	2.1	203,283	18.1

Table 4-1-3-B. US Site Enrollment of NIH-Defined Extramural Clinical Research

		No.			American	%			Black	%	Native	%				%	Unknown	%
Fiscal Year	Total Enrollment	Inclusion Data Records	Minority Enrollment	% Minority Enrollment	Indian Alaska Native	American Indian Alaska Native	Asian	% Asian	African American	Black African American	Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Not Reported	Unknown Not Reported
2022	87,525,114	2,683	25,570,269	29.2	1,080,889	1.2	2,188,384	2.5	15,473,981	17.7	103,691	0.1	66,532,386	76.0	2,080,023	2.4	65,760	0.1
2023	533,458	2,588	142,485	26.7	4,397	0.8	16,364	3.1	58,648	11.0	1,615	0.3	379,247	71.1	14,990	2.8	58,197	10.9
2024	1,111,990	2,493	287,003	25.8	8,584	0.8	68,538	6.2	105,047	9.4	3,629	0.3	700,998	63.0	23,446	2.1	201,748	18.1

Table 4-1-4-B. US Site Enrollment of NIH-Defined Intramural Clinical Research

		No.			American	%			Black	%	Native	%				%	Unknown	%
Fiscal Year	Total Enrollment	Inclusion Data Records	Minority Enrollment	% Minority Enrollment	Indian Alaska Native	American Indian Alaska Native	Asian	% Asian	African American	Black African American	Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Not Reported	Unknown Not Reported
2022	12,857	21	4,458	34.7	156	1.2	258	2.0	3,286	25.6	4	0.0	7,294	56.7	181	1.4	1,678	13.1
2023	13,413	22	4,835	36.0	143	1.1	1,124	8.4	3,311	24.7	3	0.0	7,111	53.0	162	1.2	1,559	11.6
2024	12,654	22	4,040	31.9	154	1.2	275	2.2	3,341	26.4	3	0.0	7,182	56.8	164	1.3	1,535	12.1

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

Total Phase III Trials Enrollment by Race
Table 4-2-1-C. Total Enrollment of All NIH-Defined Phase III Trials

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	86,960,545	219	25,424,222	29.2	1,077,428	1.2	2,173,203	2.5	15,409,540	17.7	102,779	0.1	66,098,768	76.0	2,066,557	2.4	32,270	0.0
2023	54,837	194	19,506	35.6	283	0.5	2,754	5.0	9,383	17.1	100	0.2	35,339	64.4	3,154	5.8	3,824	7.0
2024	159,927	186	78,453	49.1	658	0.4	44,250	27.7	23,896	14.9	397	0.2	80,694	50.5	1,412	0.9	8,620	5.4

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

US Site Phase III Trials Enrollment by Race
Table 4-2-2-B. Total US Site Enrollment of NIH-Defined Phase III Trials

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	86,960,401	213	25,424,181	29.2	1,077,424	1.2	2,173,203	2.5	15,409,537	17.7	102,779	0.1	66,098,672	76.0	2,066,545	2.4	32,241	0.0
2023	54,504	186	19,460	35.7	281	0.5	2,753	5.1	9,381	17.2	97	0.2	35,080	64.4	3,147	5.8	3,765	6.9
2024	159,637	177	78,419	49.1	657	0.4	44,250	27.7	23,893	15.0	397	0.2	80,464	50.4	1,407	0.9	8,569	5.4

Table 4-2-3-B. US Site Enrollment of NIH-Defined Extramural Phase III Trials

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	86,960,401	213	25,424,181	29.2	1,077,424	1.2	2,173,203	2.5	15,409,537	17.7	102,779	0.1	66,098,672	76.0	2,066,545	2.4	32,241	0.0
2023	54,504	186	19,460	35.7	281	0.5	2,753	5.1	9,381	17.2	97	0.2	35,080	64.4	3,147	5.8	3,765	6.9
2024	159,637	177	78,419	49.1	657	0.4	44,250	27.7	23,893	15.0	397	0.2	80,464	50.4	1,407	0.9	8,569	5.4

Table 4-2-4-B. US Site Enrollment of NIH-Defined Intramural Phase III Trials

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	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	0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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

Section 6: Enrollment by Ethnicity

Table 4-1-1-D1. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	82,002,100	93.6	5,519,910	6.3	86,066	0.1
2023	537,904	82.3	63,319	9.7	52,588	8.0
2024	950,093	79.2	98,772	8.2	150,711	12.6

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 4-1-1-E1. Total Enrollment of All NIH-Defined Extramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,990,796	93.6	5,519,143	6.3	85,280	0.1
2023	525,504	82.1	63,094	9.9	51,800	8.1
2024	938,451	79.1	98,538	8.3	149,933	12.6

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 4-1-1-F. Total Enrollment of All NIH-Defined Intramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	11,304	87.9	767	6.0	786	6.1
2023	12,400	92.4	225	1.7	788	5.9
2024	11,642	92.0	234	1.8	778	6.1

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

Section 6: Enrollment of Hispanic or Latino Participants by Race

Table 4-1-1-G. Enrollment of Hispanic or Latino Participants in NIH-Defined Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,519,910	207,616	3.8	47,239	0.9	357,173	6.5	4,618,589	83.7	27,966	0.5	235,686	4.3	25,641	0.5
2023	63,319	1,353	2.1	318	0.5	2,202	3.5	25,622	40.5	206	0.3	10,886	17.2	22,732	35.9
2024	98,772	2,079	2.1	1,653	1.7	3,468	3.5	43,551	44.1	352	0.4	10,550	10.7	37,119	37.6

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 4-1-1-H. Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,519,143	207,526	3.8	47,236	0.9	357,146	6.5	4,618,203	83.7	27,965	0.5	235,613	4.3	25,454	0.5
2023	63,094	1,276	2.0	318	0.5	2,200	3.5	25,597	40.6	206	0.3	10,832	17.2	22,665	35.9
2024	98,538	2,002	2.0	1,653	1.7	3,466	3.5	43,525	44.2	352	0.4	10,498	10.7	37,042	37.6

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 4-1-1-I. Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	767	90	11.7	3	0.4	27	3.5	386	50.3	1	0.1	73	9.5	187	24.4
2023	225	77	34.2	0	0.0	2	0.9	25	11.1	0	0.0	54	24.0	67	29.8
2024	234	77	32.9	0	0.0	2	0.9	26	11.1	0	0.0	52	22.2	77	32.9

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

US Site Enrollment by Ethnicity

Table 4-1-2-C. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,950,754	93.6	5,501,203	6.3	86,014	0.1
2023	438,329	80.2	56,113	10.3	52,429	9.6
2024	881,511	78.4	94,774	8.4	148,359	13.2

Table 4-1-3-C. US Site Enrollment of NIH-Defined Extramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,939,450	93.6	5,500,436	6.3	85,228	0.1
2023	425,929	79.8	55,888	10.5	51,641	9.7
2024	869,869	78.2	94,540	8.5	147,581	13.3

Table 4-1-4-C. US Site Enrollment of NIH-Defined Intramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	11,304	87.9	767	6.0	786	6.1
2023	12,400	92.4	225	1.7	788	5.9
2024	11,642	92.0	234	1.8	778	6.1

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

US site Enrollment of Hispanic or Latino Participants by Race
Table 4-1-2-D1. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,501,203	207,614	3.8	47,239	0.9	357,171	6.5	4,618,328	84.0	27,966	0.5	217,339	4.0	25,546	0.5
2023	56,113	1,344	2.4	311	0.6	2,080	3.7	25,202	44.9	204	0.4	5,611	10.0	21,361	38.1
2024	94,774	2,019	2.1	1,634	1.7	3,272	3.5	42,687	45.0	352	0.4	9,635	10.2	35,175	37.1

Table 4-1-3-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,500,436	207,524	3.8	47,236	0.9	357,144	6.5	4,617,942	84.0	27,965	0.5	217,266	3.9	25,359	0.5
2023	55,888	1,267	2.3	311	0.6	2,078	3.7	25,177	45.0	204	0.4	5,557	9.9	21,294	38.1
2024	94,540	1,942	2.1	1,634	1.7	3,270	3.5	42,661	45.1	352	0.4	9,583	10.1	35,098	37.1

Table 4-1-4-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Clinical Research

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	767	90	11.7	3	0.4	27	3.5	386	50.3	1	0.1	73	9.5	187	24.4
2023	225	77	34.2	0	0.0	2	0.9	25	11.1	0	0.0	54	24.0	67	29.8
2024	234	77	32.9	0	0.0	2	0.9	26	11.1	0	0.0	52	22.2	77	32.9

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

Total Phase III Trials Enrollment by Ethnicity

Table 4-2-1-D. Total Enrollment of All NIH-Defined Phase III Trials

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,469,304	93.7	5,444,695	6.3	46,546	0.1
2023	44,682	81.5	5,736	10.5	4,419	8.1
2024	145,391	90.9	10,912	6.8	3,624	2.3

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

Total Phase III Trial Enrollment of Hispanic or Latino Participants by Race
Table 4-2-1-E. Enrollment of Hispanic or Latino Participants in NIH-Defined Phase III Trials

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,444,695	206,431	3.8	46,854	0.9	355,333	6.5	4,585,238	84.2	27,754	0.5	213,608	3.9	9,477	0.2
2023	5,736	51	0.9	16	0.3	320	5.6	1,662	29.0	35	0.6	1,482	25.8	2,170	37.8
2024	10,912	149	1.4	1,167	10.7	631	5.8	4,409	40.4	59	0.5	1,066	9.8	3,431	31.4

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

US Site Phase III Enrollment by Ethnicity

Table 4-2-2-C. Total US Site Enrollment of NIH-Defined Phase III Trials

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,469,205	93.7	5,444,657	6.3	46,539	0.1
2023	44,428	81.5	5,694	10.4	4,382	8.0
2024	145,161	90.9	10,882	6.8	3,594	2.3

Table 4-2-3-C. US Site Enrollment of NIH-Defined Extramural Phase III Trials

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	81,469,205	93.7	5,444,657	6.3	46,539	0.1
2023	44,428	81.5	5,694	10.4	4,382	8.0
2024	145,161	90.9	10,882	6.8	3,594	2.3

Table 4-2-4-C. US Site Enrollment of NIH-Defined Intramural Phase III Trials

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	0	0.0	0	0.0	0	0.0
2023	0	0.0	0	0.0	0	0.0
2024	0	0.0	0	0.0	0	0.0

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

US Site Phase III Enrollment of Hispanic or Latino Participants by Race
Table 4-2-2-D1. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Phase III Trials

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,444,657	206,429	3.8	46,854	0.9	355,331	6.5	4,585,237	84.2	27,754	0.5	213,596	3.9	9,456	0.2
2023	5,694	49	0.9	16	0.3	320	5.6	1,659	29.1	33	0.6	1,475	25.9	2,142	37.6
2024	10,882	148	1.4	1,167	10.7	630	5.8	4,407	40.5	59	0.5	1,063	9.8	3,408	31.3

Table 4-2-3-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Extramural Phase III Trials

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	5,444,657	206,429	3.8	46,854	0.9	355,331	6.5	4,585,237	84.2	27,754	0.5	213,596	3.9	9,456	0.2
2023	5,694	49	0.9	16	0.3	320	5.6	1,659	29.1	33	0.6	1,475	25.9	2,142	37.6
2024	10,882	148	1.4	1,167	10.7	630	5.8	4,407	40.5	59	0.5	1,063	9.8	3,408	31.3

Table 4-2-4-D. US Site Enrollment of Hispanic or Latino Participants in NIH-Defined Intramural Phase III Trials

Fiscal Year	Hispanic Latino	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	White	% White	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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

Total Enrollment: All NIH-Defined Clinical Research

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

Fiscal Year	Sex																								
		Minority	% Minority	Total Enrollment	% Total	American Alaska Native	American 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	13,215,116	29.5	44,745,234	51.1	539,884	1.2	1,149,054	2.6	8,171,727	18.3	50,097	0.1	33,744,922	75.4	1,061,294	2.4	28,256	0.1	42,033,764	93.9	2,670,147	6.0	41,323	0.1
2022	Male	12,426,761	29.0	42,838,089	48.9	541,125	1.3	1,072,520	2.5	7,321,400	17.1	53,599	0.1	32,796,480	76.6	1,037,139	2.4	15,826	0.0	39,966,980	93.3	2,849,389	6.7	21,720	0.1
2022	Unknown	697	2.8	24,753	0.0	40	0.2	115	0.5	195	0.8	14	0.1	739	3.0	141	0.6	23,509	95.0	1,356	5.5	374	1.5	23,023	93.0
2023	Female	148,447	37.7	393,489	60.2	3,763	1.0	48,732	12.4	49,690	12.6	1,218	0.3	246,275	62.6	12,489	3.2	31,322	8.0	327,705	83.3	41,386	10.5	24,398	6.2
2023	Male	96,019	39.1	245,652	37.6	2,447	1.0	41,581	16.9	27,859	11.3	760	0.3	145,533	59.2	7,831	3.2	19,641	8.0	206,454	84.0	21,457	8.7	17,741	7.2
2023	Unknown	1,384	9.4	14,670	2.2	199	1.4	89	0.6	582	4.0	46	0.3	3,067	20.9	210	1.4	10,477	71.4	3,745	25.5	476	3.2	10,449	71.2
2024	Female	232,103	28.7	808,470	67.4	6,805	0.8	59,852	7.4	89,885	11.1	2,489	0.3	479,517	59.3	16,850	2.1	153,072	18.9	626,944	77.5	68,578	8.5	112,948	14.0
2024	Male	125,583	33.6	373,299	31.1	3,625	1.0	45,731	12.3	43,362	11.6	1,506	0.4	229,871	61.6	7,412	2.0	41,792	11.2	318,078	85.2	29,594	7.9	25,627	6.9
2024	Unknown	1,920	10.8	17,807	1.5	229	1.3	185	1.0	699	3.9	40	0.2	3,670	20.6	266	1.5	12,718	71.4	5,071	28.5	600	3.4	12,136	68.2

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

US Site Enrollment: All NIH-Defined Clinical Research
Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	13,177,559	29.5	539,882	1.2	1,131,329	2.5	8,162,690	18.3	50,092	0.1	33,743,538	75.5	1,050,732	2.4	28,162	0.1	42,005,758	94.0	2,659,371	5.9	41,296	0.1
2022	Male	12,396,491	29.0	541,123	1.3	1,057,218	2.5	7,314,382	17.1	53,589	0.1	32,795,403	76.6	1,029,331	2.4	15,767	0.0	39,943,660	93.3	2,841,458	6.6	21,695	0.1
2022	Unknown	677	2.7	40	0.2	95	0.4	195	0.8	14	0.1	739	3.0	141	0.6	23,509	95.1	1,336	5.4	374	1.5	23,023	93.1
2023	Female	95,776	28.5	2,863	0.9	10,105	3.0	40,583	12.1	983	0.3	241,728	71.9	9,780	2.9	30,313	9.0	274,394	81.6	37,586	11.2	24,375	7.2
2023	Male	50,163	25.6	1,478	0.8	7,294	3.7	20,794	10.6	589	0.3	141,563	72.2	5,162	2.6	19,088	9.7	160,191	81.7	18,054	9.2	17,723	9.0
2023	Unknown	1,381	9.5	199	1.4	89	0.6	582	4.0	46	0.3	3,067	21.1	210	1.4	10,355	71.2	3,744	25.7	473	3.3	10,331	71.0
2024	Female	193,985	25.3	5,874	0.8	40,487	5.3	74,550	9.7	2,254	0.3	476,867	62.2	16,335	2.1	150,708	19.6	589,028	76.8	66,174	8.6	111,873	14.6
2024	Male	95,141	28.0	2,635	0.8	28,141	8.3	33,139	9.7	1,338	0.4	227,643	67.0	7,009	2.1	40,079	11.8	287,413	84.5	28,003	8.2	24,568	7.2
2024	Unknown	1,917	10.9	229	1.3	185	1.1	699	4.0	40	0.2	3,670	20.9	266	1.5	12,496	71.1	5,070	28.8	597	3.4	11,918	67.8

Table 5-1-3-C. US Site Enrollment for NIH-Defined Extramural Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	13,175,155	29.5	539,810	1.2	1,131,197	2.5	8,160,980	18.3	50,089	0.1	33,739,794	75.5	1,050,636	2.4	27,611	0.1	42,000,250	94.0	2,658,880	5.9	40,987	0.1
2022	Male	12,394,437	29.0	541,039	1.3	1,057,092	2.5	7,312,806	17.1	53,588	0.1	32,791,853	76.6	1,029,246	2.4	14,640	0.0	39,937,864	93.3	2,841,182	6.6	21,218	0.0
2022	Unknown	677	2.7	40	0.2	95	0.4	195	0.8	14	0.1	739	3.0	141	0.6	23,509	95.1	1,336	5.4	374	1.5	23,023	93.1
2023	Female	93,390	28.3	2,799	0.8	9,634	2.9	38,863	11.8	980	0.3	238,141	72.2	9,699	2.9	29,846	9.0	268,415	81.3	37,482	11.4	24,065	7.3
2023	Male	47,714	25.3	1,399	0.7	6,641	3.5	19,203	10.2	589	0.3	138,039	73.1	5,081	2.7	17,996	9.5	153,770	81.4	17,933	9.5	17,245	9.1
2023	Unknown	1,381	9.5	199	1.4	89	0.6	582	4.0	46	0.3	3,067	21.1	210	1.4	10,355	71.2	3,744	25.7	473	3.3	10,331	71.0
2024	Female	191,917	25.2	5,806	0.8	40,350	5.3	72,817	9.6	2,251	0.3	473,249	62.2	16,255	2.1	150,243	19.7	583,337	76.7	66,072	8.7	111,562	14.7
2024	Male	93,179	27.9	2,549	0.8	28,003	8.4	31,531	9.5	1,338	0.4	224,079	67.2	6,925	2.1	39,019	11.7	281,462	84.4	27,881	8.4	24,101	7.2
2024	Unknown	1,907	10.9	229	1.3	185	1.1	699	4.0	40	0.2	3,670	20.9	266	1.5	12,486	71.0	5,070	28.8	587	3.3	11,918	67.8

Table 5-1-4-C. US Site Enrollment for NIH-Defined Intramural Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	2,404	38.1	72	1.1	132	2.1	1,710	27.1	3	0.0	3,744	59.4	96	1.5	551	8.7	5,508	87.3	491	7.8	309	4.9
2022	Male	2,054	31.4	84	1.3	126	1.9	1,576	24.1	1	0.0	3,550	54.2	85	1.3	1,127	17.2	5,796	88.5	276	4.2	477	7.3
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	2,386	37.3	64	1.0	471	7.4	1,720	26.9	3	0.0	3,587	56.1	81	1.3	467	7.3	5,979	93.5	104	1.6	310	4.8
2023	Male	2,449	34.9	79	1.1	653	9.3	1,591	22.7	0	0.0	3,524	50.2	81	1.2	1,092	15.6	6,421	91.5	121	1.7	478	6.8
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	2,068	33.9	68	1.1	137	2.2	1,733	28.4	3	0.0	3,618	59.3	80	1.3	465	7.6	5,691	93.2	102	1.7	311	5.1
2024	Male	1,962	30.0	86	1.3	138	2.1	1,608	24.6	0	0.0	3,564	54.5	84	1.3	1,060	16.2	5,951	91.0	122	1.9	467	7.1
2024	Unknown	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	10	100.0	0	0.0	10	100.0	0	0.0

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

All Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			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	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported						
		Minority	% Minority	Enrollment	% Total															Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	13,072,985	29.5	44,322,926	51.0	537,422	1.2	1,121,811	2.5	8,116,062	18.3	49,526	0.1	33,447,007	75.5	1,041,517	2.3	9,581	0.0	41,688,343	94.1	2,618,491	5.9	16,092	0.0
2022	Male	12,351,213	29.0	42,620,674	49.0	540,005	1.3	1,051,392	2.5	7,293,474	17.1	53,251	0.1	32,651,711	76.6	1,025,032	2.4	5,809	0.0	39,780,869	93.3	2,826,193	6.6	13,612	0.0
2022	Unknown	24	0.1	16,945	0.0	1	0.0	0	0.0	4	0.0	2	0.0	50	0.3	8	0.0	16,880	99.6	92	0.5	11	0.1	16,842	99.4
2023	Female	11,711	36.7	31,933	58.2	164	0.5	1,371	4.3	5,743	18.0	69	0.2	20,587	64.5	1,816	5.7	2,183	6.8	26,188	82.0	3,773	11.8	1,972	6.2
2023	Male	7,648	34.5	22,172	40.4	116	0.5	1,365	6.2	3,547	16.0	26	0.1	14,444	65.1	1,329	6.0	1,345	6.1	18,049	81.4	1,940	8.7	2,183	9.8
2023	Unknown	147	20.1	732	1.3	3	0.4	18	2.5	93	12.7	5	0.7	308	42.1	9	1.2	296	40.4	445	60.8	23	3.1	264	36.1
2024	Female	49,597	48.7	101,787	63.6	420	0.4	25,547	25.1	17,217	16.9	243	0.2	51,820	50.9	958	0.9	5,582	5.5	92,241	90.6	7,198	7.1	2,348	2.3
2024	Male	28,420	50.1	56,688	35.4	228	0.4	18,613	32.8	6,414	11.3	146	0.3	28,310	49.9	447	0.8	2,530	4.5	52,213	92.1	3,646	6.4	829	1.5
2024	Unknown	436	30.0	1,452	0.9	10	0.7	90	6.2	265	18.3	8	0.6	564	38.8	7	0.5	508	35.0	937	64.5	68	4.7	447	30.8

Table 5-2-3-C. ALL Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			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	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported						
		Minority	% Minority	Enrollment	% Total															Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	13,072,985	29.5	44,322,926	51.0	537,422	1.2	1,121,811	2.5	8,116,062	18.3	49,526	0.1	33,447,007	75.5	1,041,517	2.3	9,581	0.0	41,688,343	94.1	2,618,491	5.9	16,092	0.0
2022	Male	12,351,213	29.0	42,620,674	49.0	540,005	1.3	1,051,392	2.5	7,293,474	17.1	53,251	0.1	32,651,711	76.6	1,025,032	2.4	5,809	0.0	39,780,869	93.3	2,826,193	6.6	13,612	0.0
2022	Unknown	24	0.1	16,945	0.0	1	0.0	0	0.0	4	0.0	2	0.0	50	0.3	8	0.0	16,880	99.6	92	0.5	11	0.1	16,842	99.4
2023	Female	11,711	36.7	31,933	58.2	164	0.5	1,371	4.3	5,743	18.0	69	0.2	20,587	64.5	1,816	5.7	2,183	6.8	26,188	82.0	3,773	11.8	1,972	6.2
2023	Male	7,648	34.5	22,172	40.4	116	0.5	1,365	6.2	3,547	16.0	26	0.1	14,444	65.1	1,329	6.0	1,345	6.1	18,049	81.4	1,940	8.7	2,183	9.8
2023	Unknown	147	20.1	732	1.3	3	0.4	18	2.5	93	12.7	5	0.7	308	42.1	9	1.2	296	40.4	445	60.8	23	3.1	264	36.1
2024	Female	49,597	48.7	101,787	63.6	420	0.4	25,547	25.1	17,217	16.9	243	0.2	51,820	50.9	958	0.9	5,582	5.5	92,241	90.6	7,198	7.1	2,348	2.3
2024	Male	28,420	50.1	56,688	35.4	228	0.4	18,613	32.8	6,414	11.3	146	0.3	28,310	49.9	447	0.8	2,530	4.5	52,213	92.1	3,646	6.4	829	1.5
2024	Unknown	436	30.0	1,452	0.9	10	0.7	90	6.2	265	18.3	8	0.6	564	38.8	7	0.5	508	35.0	937	64.5	68	4.7	447	30.8

Table 5-2-4-C. All Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			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	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported						
		Minority	% Minority	Enrollment	% Total															Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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

US Site Enrollment: All NIH-Defined Clinical Research

Table 5-3-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	13,072,959	29.5	537,420	1.2	1,121,811	2.5	8,116,062	18.3	49,526	0.1	33,446,954	75.5	1,041,511	2.3	9,557	0.0	41,688,288	94.1	2,618,466	5.9	16,087	0.
2022	Male	12,351,198	29.0	540,003	1.3	1,051,392	2.5	7,293,471	17.1	53,251	0.1	32,651,668	76.6	1,025,026	2.4	5,804	0.0	39,780,825	93.3	2,826,180	6.6	13,610	0.
2022	Unknown	24	0.1	1	0.0	0	0.0	4	0.0	2	0.0	50	0.3	8	0.0	16,880	99.6	92	0.5	11	0.1	16,842	99.
2023	Female	11,680	36.8	162	0.5	1,370	4.3	5,743	18.1	69	0.2	20,452	64.4	1,813	5.7	2,144	6.8	26,059	82.1	3,743	11.8	1,951	6.1
2023	Male	7,633	34.7	116	0.5	1,365	6.2	3,545	16.1	23	0.1	14,320	65.0	1,325	6.0	1,325	6.0	17,924	81.4	1,928	8.8	2,167	9.8
2023	Unknown	147	20.1	3	0.4	18	2.5	93	12.7	5	0.7	308	42.1	9	1.2	296	40.4	445	60.8	23	3.1	264	36.
2024	Female	49,580	48.8	420	0.4	25,547	25.1	17,216	16.9	243	0.2	51,706	50.9	957	0.9	5,549	5.5	92,127	90.6	7,182	7.1	2,329	2.3
2024	Male	28,403	50.2	227	0.4	18,613	32.9	6,412	11.3	146	0.3	28,194	49.9	443	0.8	2,512	4.4	52,097	92.1	3,632	6.4	818	1.4
2024	Unknown	436	30.0	10	0.7	90	6.2	265	18.3	8	0.6	564	38.8	7	0.5	508	35.0	937	64.5	68	4.7	447	30.

Table 5-3-3-C. US Site Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	13,072,959	29.5	537,420	1.2	1,121,811	2.5	8,116,062	18.3	49,526	0.1	33,446,954	75.5	1,041,511	2.3	9,557	0.0	41,688,288	94.1	2,618,466	5.9	16,087	0.
2022	Male	12,351,198	29.0	540,003	1.3	1,051,392	2.5	7,293,471	17.1	53,251	0.1	32,651,668	76.6	1,025,026	2.4	5,804	0.0	39,780,825	93.3	2,826,180	6.6	13,610	0.
2022	Unknown	24	0.1	1	0.0	0	0.0	4	0.0	2	0.0	50	0.3	8	0.0	16,880	99.6	92	0.5	11	0.1	16,842	99.
2023	Female	11,680	36.8	162	0.5	1,370	4.3	5,743	18.1	69	0.2	20,452	64.4	1,813	5.7	2,144	6.8	26,059	82.1	3,743	11.8	1,951	6.1
2023	Male	7,633	34.7	116	0.5	1,365	6.2	3,545	16.1	23	0.1	14,320	65.0	1,325	6.0	1,325	6.0	17,924	81.4	1,928	8.8	2,167	9.8
2023	Unknown	147	20.1	3	0.4	18	2.5	93	12.7	5	0.7	308	42.1	9	1.2	296	40.4	445	60.8	23	3.1	264	36.
2024	Female	49,580	48.8	420	0.4	25,547	25.1	17,216	16.9	243	0.2	51,706	50.9	957	0.9	5,549	5.5	92,127	90.6	7,182	7.1	2,329	2.3
2024	Male	28,403	50.2	227	0.4	18,613	32.9	6,412	11.3	146	0.3	28,194	49.9	443	0.8	2,512	4.4	52,097	92.1	3,632	6.4	818	1.4
2024	Unknown	436	30.0	10	0.7	90	6.2	265	18.3	8	0.6	564	38.8	7	0.5	508	35.0	937	64.5	68	4.7	447	30.

Table 5-3-4-C. US Site Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex			American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
		Minority	% Minority																				
2022	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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