

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

NATIONAL INSTITUTE ON AGING

FY2019 - 2021 INCLUSION REPORT
(Inclusion of Women and Minorities)

National Advisory Council on Aging Meeting

2022 TRIENNIAL ADVISORY COUNCIL REPORTS
CERTIFYING COMPLIANCE WITH THE
NIH POLICY ON INCLUSION GUIDELINES

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NIA Report of FY2019 - 2021 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 FY2019 through FY2021, inclusion of both genders 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 funding opportunity announcements (FOAs) 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/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, 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/gender, 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/gender 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, gender, 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 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](#).

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 has recently developed a new informatics system-based tool to help the Institute ensure compliance with the inclusion policy. NIA's Clinical Research Operations and Management System (CROMS) is a new tool that provides NIA staff and grantees 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 latter, we can then work directly with grantees to implement a corrective action plan and course-corrections to improve inclusion enrollment. This new system is currently integrating grants that support AD/ADRD clinical trials and will be fully operational by mid-2022.

III. Analysis and Interpretation of Data

NIA's Aggregate Extramural Enrollment Data, Analysis, and Interpretation: The Enrollment Data for all Extramural Research Protocols for FY2019 was 1,978,892, for FY2020 was 753,529 and for FY2021 was 863,636. These numbers are shown in (Table 3-1-B). These extramural inclusion enrollment numbers were included in 1,570 Inclusion Data Records for FY2019, 1,975 Inclusion Data Records for FY2020 and 2,395 Inclusion Data Records for FY2021 (Table 2-1) showing an increasing trend of inclusion enrollment records. Phase III Enrollment Data (Table 3-4-A) increased significantly in FY2021 compared to FY2019 and FY2020. Minority Enrollment: NIA had an increase in the percentage of the Minority enrollees from FY2019 to FY2021 (Table 4-1-2-D). For detailed prospective enrollment by race, please see Tables 5-1-1-C through 5-3-3-C. Prospective enrollment numbers were within acceptable US population trends. The Phase III trials prospective minority enrollee's percentage showed an increasing trend from FY2019 to FY2021. Nevertheless, the detailed data on Phase III Trials for All of US sites alone shows higher numbers for White US population than US population trends.

Research, Condition, and Disease Categorization (RCDC) Report

The NIH Report website is used by NIH to inform the public of how tax dollars are being spent on biomedical research within the 27 institutes and centers. Included are reports from Research Condition Disease Categorization (RCDC). RCDC is a NIH-wide, computer-driven text-mining process that reports spending in more than 300 categories of diseases, conditions, or research areas. The next RCDC Triennial Inclusion Report will cover FY2019-2021 and include IC and NIH totals and median proportions for each of the 300+ categories. This report anticipated update will post to the website in March 2022. The website for the RCDC report can be found here: <https://report.nih.gov/RISR/#>.

NIA HSS Enrollment Tables

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 2019 and 2021

Fiscal Year	Total IERS	IERS Without	IERS With	US Site IERS	Non-US Site	Female Only	IERS Excluding	
		Enrollment	Enrollment		IERS	IERS	Male Only IERS	Male only and Female only*
2019	1,570	648	922	903	19	45	31	846
2020	1,975	1,054	921	895	26	52	25	844
2021	2,395	1,348	1,047	1,016	31	83	28	936

*Inclusion Data Records (IERS) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

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 2019 and 2021

Fiscal Year	Total IERS	IERS Without	IERS With	US Site IERS	Non-US Site	Female Only	IERS Excluding	
		Enrollment	Enrollment		IERS	IERS	Male Only IERS	Male only and Female only*
2019	56	36	20	19	1	1	0	19
2020	120	87	33	32	1	2	1	30
2021	164	118	46	45	1	3	1	42

*Inclusion Data Records (IERS) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

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 2019 and 2021

Fiscal Year	Total IERS	IERS Requiring	% IERS	IERS Requiring	% IERS
		Race Ethnicity Valid Analysis	Requiring Race Ethnicity Valid Analysis	Sex Gender Valid Analysis	Requiring Sex Gender Valid Analysis
2019	56	55	98.2	55	98.2
2020	120	119	99.2	119	99.2
2021	164	164	100.0	164	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/Gender

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021

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
2019	1,992,621	748,244	37.6	1,239,238	62.2	5,139	0.3	63,165	3.2	720,014	36.1	685,079	34.4	519,224	26.1
2020	766,993	470,922	61.4	292,925	38.2	3,146	0.4	62,904	8.2	4,748	0.6	408,018	53.2	288,177	37.6
2021	876,489	547,628	62.5	322,723	36.8	6,138	0.7	75,137	8.6	18,140	2.1	472,491	53.9	304,583	34.8

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-B. Total Enrollment for All NIH-Defined Extramural Clinical Research Between Fiscal Years 2019 and 2021

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
2019	1,978,892	741,893	37.5	1,231,861	62.3	5,138	0.3	63,165	3.2	719,903	36.4	678,728	34.3	511,958	25.9
2020	753,529	464,703	61.7	285,681	37.9	3,145	0.4	62,904	8.3	4,637	0.6	401,799	53.3	281,044	37.3
2021	863,636	541,669	62.7	315,829	36.6	6,138	0.7	75,137	8.7	18,029	2.1	466,532	54.0	297,800	34.5

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 2019 and 2021

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
2019	13,729	6,351	46.3	7,377	53.7	1	0.0	0	0.0	111	0.8	6,351	46.3	7,266	52.9
2020	13,464	6,219	46.2	7,244	53.8	1	0.0	0	0.0	111	0.8	6,219	46.2	7,133	53.0
2021	12,853	5,959	46.4	6,894	53.6	0	0.0	0	0.0	111	0.9	5,959	46.4	6,783	52.8

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
2019	1,786,854	633,386	35.4	1,148,597	64.3	4,871	0.3	63,165	3.5	720,014	40.3	570,221	31.9	428,583	24.0
2020	436,346	286,543	65.7	146,674	33.6	3,129	0.7	62,884	14.4	4,748	1.1	223,659	51.3	141,926	32.5
2021	834,301	523,578	62.8	304,606	36.5	6,117	0.7	75,084	9.0	18,140	2.2	448,494	53.8	286,466	34.3

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
2019	1,773,125	627,035	35.4	1,141,220	64.4	4,870	0.3	63,165	3.6	719,903	40.6	563,870	31.8	421,317	23.8
2020	422,882	280,324	66.3	139,430	33.0	3,128	0.7	62,884	14.9	4,637	1.1	217,440	51.4	134,793	31.9
2021	821,448	517,619	63.0	297,712	36.2	6,117	0.7	75,084	9.1	18,029	2.2	442,535	53.9	279,683	34.0

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
2019	13,729	6,351	46.3	7,377	53.7	1	0.0	0	0.0	111	0.8	6,351	46.3	7,266	52.9
2020	13,464	6,219	46.2	7,244	53.8	1	0.0	0	0.0	111	0.8	6,219	46.2	7,133	53.0
2021	12,853	5,959	46.4	6,894	53.6	0	0.0	0	0.0	111	0.9	5,959	46.4	6,783	52.8

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 2019 and 2021

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
2019	5,360	3,106	57.9	2,231	41.6	23	0.4	3	0.1	0	0.0	3,103	57.9	2,231	41.6
2020	7,796	4,703	60.3	3,032	38.9	61	0.8	20	0.3	30	0.4	4,683	60.1	3,002	38.5
2021	211,173	121,355	57.5	89,728	42.5	90	0.0	25	0.0	2,893	1.4	121,330	57.5	86,835	41.1

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

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
2019	5,355	3,104	58.0	2,228	41.6	23	0.4	3	0.1	0	0.0	3,101	57.9	2,228	41.6
2020	7,795	4,702	60.3	3,032	38.9	61	0.8	19	0.2	30	0.4	4,683	60.1	3,002	38.5
2021	211,168	121,351	57.5	89,727	42.5	90	0.0	25	0.0	2,893	1.4	121,326	57.5	86,834	41.1

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
2019	5,355	3,104	58.0	2,228	41.6	23	0.4	3	0.1	0	0.0	3,101	57.9	2,228	41.6
2020	7,795	4,702	60.3	3,032	38.9	61	0.8	19	0.2	30	0.4	4,683	60.1	3,002	38.5
2021	211,168	121,351	57.5	89,727	42.5	90	0.0	25	0.0	2,893	1.4	121,326	57.5	86,834	41.1

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
2019	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	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 Minority Enrollment

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

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2019	1,786,854	360,355	20.2
2020	436,346	131,255	30.1
2021	834,301	303,781	36.4

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

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2019	5,355	742	13.9
2020	7,795	1,895	24.3
2021	211,168	152,977	72.4

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

Section 5: Enrollment by Race

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

Fiscal Year	No. Inclusion Data				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
	Total Enrollment	Data Records	Minority Enrollment	% Minority Enrollment														
2019	1,992,621	1,570	404,576	20.3	3,714	0.2	47,004	2.4	207,923	10.4	1,664	0.1	1,449,891	72.8	25,728	1.3	256,697	12.9
2020	766,993	1,975	179,704	23.4	8,229	1.1	30,696	4.0	78,658	10.3	1,248	0.2	596,706	77.8	27,850	3.6	23,606	3.1
2021	876,489	2,395	342,127	39.0	2,823	0.3	55,492	6.3	90,998	10.4	2,542	0.3	666,888	76.1	11,644	1.3	46,102	5.3

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	No. Inclusion Data				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
	Total Enrollment	Data Records	Minority Enrollment	% Minority Enrollment														
2019	1,978,892	1,550	400,586	20.2	3,580	0.2	46,752	2.4	204,569	10.3	1,661	0.1	1,441,628	72.9	25,578	1.3	255,124	12.9
2020	753,529	1,957	175,223	23.3	8,089	1.1	30,450	4.0	74,923	9.9	1,133	0.2	589,202	78.2	27,694	3.7	22,038	2.9
2021	863,636	2,376	337,559	39.1	2,680	0.3	55,236	6.4	87,194	10.1	2,427	0.3	660,072	76.4	11,483	1.3	44,544	5.2

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

Fiscal Year	No. Inclusion Data				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
	Total Enrollment	Data Records	Minority Enrollment	% Minority Enrollment														
2019	13,729	20	3,990	29.1	134	1.0	252	1.8	3,354	24.4	3	0.0	8,263	60.2	150	1.1	1,573	11.5
2020	13,464	18	4,481	33.3	140	1.0	246	1.8	3,735	27.7	115	0.9	7,504	55.7	156	1.2	1,568	11.6
2021	12,853	19	4,568	35.5	143	1.1	256	2.0	3,804	29.6	115	0.9	6,816	53.0	161	1.3	1,558	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

Fiscal Year	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	1,786,854	1,515	360,355	20.2	3,714	0.2	31,757	1.8	207,822	11.6	1,592	0.1	1,277,756	71.5	7,624	0.4	256,589	14.4
2020	436,346	1,891	131,255	30.1	1,762	0.4	10,789	2.5	78,589	18.0	1,248	0.3	310,788	71.2	9,580	2.2	23,590	5.4
2021	834,301	2,300	303,781	36.4	2,823	0.3	29,361	3.5	82,513	9.9	2,521	0.3	660,085	79.1	11,623	1.4	45,375	5.4

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

Fiscal Year	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	1,773,125	1,495	356,365	20.1	3,580	0.2	31,505	1.8	204,468	11.5	1,589	0.1	1,269,493	71.6	7,474	0.4	255,016	14.4
2020	422,882	1,873	126,774	30.0	1,622	0.4	10,543	2.5	74,854	17.7	1,133	0.3	303,284	71.7	9,424	2.2	22,022	5.2
2021	821,448	2,281	299,213	36.4	2,680	0.3	29,105	3.5	78,709	9.6	2,406	0.3	653,269	79.5	11,462	1.4	43,817	5.3

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

Fiscal Year	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	13,729	20	3,990	29.1	134	1.0	252	1.8	3,354	24.4	3	0.0	8,263	60.2	150	1.1	1,573	11.5
2020	13,464	18	4,481	33.3	140	1.0	246	1.8	3,735	27.7	115	0.9	7,504	55.7	156	1.2	1,568	11.6
2021	12,853	19	4,568	35.5	143	1.1	256	2.0	3,804	29.6	115	0.9	6,816	53.0	161	1.3	1,558	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
2019	5,360	56	742	13.8	9	0.2	112	2.1	409	7.6	7	0.1	4,637	86.5	25	0.5	161	3.0
2020	7,796	120	1,895	24.3	8	0.1	167	2.1	1,104	14.2	12	0.2	5,507	70.6	56	0.7	942	12.1
2021	211,173	164	152,982	72.4	375	0.2	2,365	1.1	18,381	8.7	589	0.3	185,964	88.1	146	0.1	3,353	1.6

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

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	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	5,355	55	742	13.9	9	0.2	112	2.1	409	7.6	7	0.1	4,632	86.5	25	0.5	161	3.0
2020	7,795	118	1,895	24.3	8	0.1	167	2.1	1,104	14.2	12	0.2	5,507	70.6	56	0.7	941	12.1
2021	211,168	161	152,977	72.4	375	0.2	2,365	1.1	18,381	8.7	589	0.3	185,962	88.1	146	0.1	3,350	1.6

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

Fiscal Year	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	5,355	55	742	13.9	9	0.2	112	2.1	409	7.6	7	0.1	4,632	86.5	25	0.5	161	3.0
2020	7,795	118	1,895	24.3	8	0.1	167	2.1	1,104	14.2	12	0.2	5,507	70.6	56	0.7	941	12.1
2021	211,168	161	152,977	72.4	375	0.2	2,365	1.1	18,381	8.7	589	0.3	185,962	88.1	146	0.1	3,350	1.6

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

Fiscal Year	No. Inclusion			% 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
	Total Enrollment	Data Records	Minority Enrollment															
2019	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
2020	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
2021	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-D. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	1,602,333	80.4	141,726	7.1	248,562	12.5
2020	643,604	83.9	57,492	7.5	65,897	8.6
2021	628,291	71.7	191,265	21.8	56,933	6.5

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 All NIH-Defined Extramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	1,589,610	80.3	141,513	7.2	247,769	12.5
2020	631,145	83.8	57,275	7.6	65,109	8.6
2021	616,449	71.4	191,042	22.1	56,145	6.5

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
2019	12,723	92.7	213	1.6	793	5.8
2020	12,459	92.5	217	1.6	788	5.9
2021	11,842	92.1	223	1.7	788	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 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
2019	1,425,333	79.8	112,960	6.3	248,561	13.9
2020	338,038	77.5	35,505	8.1	62,803	14.4
2021	589,819	70.7	187,556	22.5	56,926	6.8

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
2019	1,412,610	79.7	112,747	6.4	247,768	14.0
2020	325,579	77.0	35,288	8.3	62,015	14.7
2021	577,977	70.4	187,333	22.8	56,138	6.8

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
2019	12,723	92.7	213	1.6	793	5.8
2020	12,459	92.5	217	1.6	788	5.9
2021	11,842	92.1	223	1.7	788	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.

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
2019	4,490	83.8	193	3.6	677	12.6
2020	6,383	81.9	613	7.9	800	10.3
2021	66,625	31.5	137,045	64.9	7,503	3.6

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

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
2019	4,485	83.8	193	3.6	677	12.6
2020	6,383	81.9	613	7.9	799	10.3
2021	66,625	31.6	137,040	64.9	7,503	3.6

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
2019	4,485	83.8	193	3.6	677	12.6
2020	6,383	81.9	613	7.9	799	10.3
2021	66,625	31.6	137,040	64.9	7,503	3.6

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
2019	0	0.0	0	0.0	0	0.0
2020	0	0.0	0	0.0	0	0.0
2021	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/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	Total		% American Indian Alaska Native		% Asian		% Black African American		% Native Hawaiian Pacific Islander		% White		% More Than One Race		% Unknown Not Reported		% Not Hispanic/Latino		% Unknown Not Reported			
				Enrollment	% Total	Native	Native	Asian	% Asian	American	American	Islander	Islander	White	% White	One Race	Than One	Reported	Reported	Hispanic	% Not Hispanic/Latino	Hispanic/Latino	% Hispanic/Latino	Not Reported	Unknown Not Reported
2019	Female	195,816	26.2	748,244	37.6	2,138	0.3	25,660	3.4	95,350	12.7	960	0.1	547,243	73.1	15,200	2.0	61,693	8.2	602,187	80.5	70,195	9.4	75,862	10.1
2019	Male	208,533	16.8	1,239,238	62.2	1,521	0.1	21,322	1.7	112,520	9.1	702	0.1	902,052	72.8	10,493	0.8	190,628	15.4	997,947	80.5	71,446	5.8	169,845	13.7
2019	Unknown	227	4.4	5,139	0.3	55	1.1	22	0.4	53	1.0	2	0.0	596	11.6	35	0.7	4,376	85.2	2,199	42.8	85	1.7	2,855	55.6
2020	Female	117,162	24.9	470,922	61.4	4,371	0.9	16,669	3.5	53,066	11.3	723	0.2	365,576	77.6	16,817	3.6	13,700	2.9	390,832	83.0	40,168	8.5	39,922	8.5
2020	Male	62,336	21.3	292,925	38.2	3,850	1.3	13,996	4.8	25,524	8.7	505	0.2	230,312	78.6	11,004	3.8	7,734	2.6	252,439	86.2	17,248	5.9	23,238	7.9
2020	Unknown	206	6.5	3,146	0.4	8	0.3	31	1.0	68	2.2	20	0.6	818	26.0	29	0.9	2,172	69.0	333	10.6	76	2.4	2,737	87.0
2021	Female	213,992	39.1	547,628	62.5	1,840	0.3	31,576	5.8	59,609	10.9	1,389	0.3	419,233	76.6	7,564	1.4	26,417	4.8	394,315	72.0	119,488	21.8	33,825	6.2
2021	Male	127,422	39.5	322,723	36.8	978	0.3	23,525	7.3	31,235	9.7	1,138	0.4	247,348	76.6	4,054	1.3	14,445	4.5	232,844	72.1	71,620	22.2	18,259	5.7
2021	Unknown	713	11.6	6,138	0.7	5	0.1	391	6.4	154	2.5	15	0.2	307	5.0	26	0.4	5,240	85.4	1,132	18.4	157	2.6	4,849	79.0

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

Fiscal Year	Sex Gender	Minority		%														%					
		Minority	% Minority	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	171,416	27.1	2,138	0.3	17,854	2.8	95,311	15.0	925	0.1	450,894	71.2	4,625	0.7	61,639	9.7	503,833	79.5	53,691	8.5	75,862	12.0
2019	Male	188,720	16.4	1,521	0.1	13,883	1.2	112,458	9.8	665	0.1	826,531	72.0	2,964	0.3	190,575	16.6	919,562	80.1	59,190	5.2	169,845	14.8
2019	Unknown	219	4.5	55	1.1	20	0.4	53	1.1	2	0.0	331	6.8	35	0.7	4,375	89.8	1,938	39.8	79	1.6	2,854	58.6
2020	Female	90,036	31.4	1,141	0.4	5,894	2.1	53,020	18.5	723	0.3	205,762	71.8	6,314	2.2	13,689	4.8	221,101	77.2	27,107	9.5	38,335	13.4
2020	Male	41,029	28.0	613	0.4	4,880	3.3	25,501	17.4	505	0.3	104,208	71.0	3,237	2.2	7,730	5.3	116,620	79.5	8,322	5.7	21,732	14.8
2020	Unknown	190	6.1	8	0.3	15	0.5	68	2.2	20	0.6	818	26.1	29	0.9	2,171	69.4	317	10.1	76	2.4	2,736	87.4
2021	Female	192,193	36.7	1,840	0.4	17,196	3.3	54,798	10.5	1,378	0.3	414,884	79.2	7,549	1.4	25,933	5.0	372,863	71.2	116,895	22.3	33,820	6.5
2021	Male	110,895	36.4	978	0.3	11,794	3.9	27,561	9.0	1,128	0.4	244,894	80.4	4,048	1.3	14,203	4.7	215,844	70.9	70,504	23.1	18,258	6.0
2021	Unknown	693	11.3	5	0.1	371	6.1	154	2.5	15	0.2	307	5.0	26	0.4	5,239	85.6	1,112	18.2	157	2.6	4,848	79.3

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

Fiscal Year	Sex Gender	Minority		%														%					
		Minority	% Minority	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	169,368	27.0	2,079	0.3	17,725	2.8	93,579	14.9	922	0.1	447,013	71.3	4,549	0.7	61,168	9.8	497,892	79.4	53,592	8.5	75,551	12.0
2019	Male	186,779	16.4	1,447	0.1	13,760	1.2	110,836	9.7	665	0.1	822,149	72.0	2,890	0.3	189,473	16.6	912,781	80.0	59,076	5.2	169,363	14.8
2019	Unknown	218	4.5	54	1.1	20	0.4	53	1.1	2	0.0	331	6.8	35	0.7	4,375	89.8	1,937	39.8	79	1.6	2,854	58.6
2020	Female	87,952	31.4	1,080	0.4	5,771	2.1	51,284	18.3	683	0.2	202,050	72.1	6,236	2.2	13,220	4.7	215,290	76.8	27,008	9.6	38,026	13.6
2020	Male	38,633	27.7	535	0.4	4,757	3.4	23,502	16.9	430	0.3	100,416	72.0	3,159	2.3	6,631	4.8	109,973	78.9	8,204	5.9	21,253	15.2
2020	Unknown	189	6.0	7	0.2	15	0.5	68	2.2	20	0.6	818	26.2	29	0.9	2,171	69.4	316	10.1	76	2.4	2,736	87.5
2021	Female	190,068	36.7	1,777	0.3	17,065	3.3	53,032	10.2	1,338	0.3	411,472	79.5	7,469	1.4	25,466	4.9	367,314	71.0	116,794	22.6	33,511	6.5
2021	Male	108,452	36.4	898	0.3	11,669	3.9	25,523	8.6	1,053	0.4	241,490	81.1	3,967	1.3	13,112	4.4	209,551	70.4	70,382	23.6	17,779	6.0
2021	Unknown	693	11.3	5	0.1	371	6.1	154	2.5	15	0.2	307	5.0	26	0.4	5,239	85.6	1,112	18.2	157	2.6	4,848	79.3

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

Fiscal Year	Sex Gender	Minority		%														%					
		Minority	% Minority	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	2,048	32.2	59	0.9	129	2.0	1,732	27.3	3	0.0	3,881	61.1	76	1.2	471	7.4	5,941	93.5	99	1.6	311	4.9
2019	Male	1,941	26.3	74	1.0	123	1.7	1,622	22.0	0	0.0	4,382	59.4	74	1.0	1,102	14.9	6,781	91.9	114	1.5	482	6.5
2019	Unknown	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
2020	Female	2,084	33.5	61	1.0	123	2.0	1,736	27.9	40	0.6	3,712	59.7	78	1.3	469	7.5	5,811	93.4	99	1.6	309	5.0
2020	Male	2,396	33.1	78	1.1	123	1.7	1,999	27.6	75	1.0	3,792	52.3	78	1.1	1,099	15.2	6,647	91.8	118	1.6	479	6.6
2020	Unknown	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
2021	Female	2,125	35.7	63	1.1	131	2.2	1,766	29.6	40	0.7	3,412	57.3	80	1.3	467	7.8	5,549	93.1	101	1.7	309	5.2
2021	Male	2,443	35.4	80	1.2	125	1.8	2,038	29.6	75	1.1	3,404	49.4	81	1.2	1,091	15.8	6,293	91.3	122	1.8	479	6.9
2021	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

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/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority		Total Enrollment		% American Indian Alaska Native		% American Indian Alaska Native		% Black African American		% Black African American		% Native Hawaiian Pacific Islander		% Native Hawaiian Pacific Islander		% More Than One Race		% Unknown Not Reported		% Unknown Not Reported		% Not Hispanic		% Not Hispanic		% Unknown Not Reported		% Unknown Not Reported																					
		% Minority	% Total	Enrollment	% Total	Native	% Total	Native	% Total	American	% Total	American	% Total	White	% Total	One Race	% Total	Not Reported	% Total	Not Reported	% Total	Hispanic	% Total	Hispanic	% Total	Not Reported	% Total	Not Reported	% Total	Not Reported																					
2019	Female	490	15.8	3,106	57.9	6	0.2	63	2.0	282	9.1	4	0.1	2,663	85.7	10	0.3	78	2.5	2,603	83.8	127	4.1	376	12.1	2019	Male	252	11.3	2,231	41.6	3	0.1	49	2.2	127	5.7	3	0.1	1,971	88.3	15	0.7	63	2.8	1,884	84.4	66	3.0	281	12.6
2019	Unknown	0	0.0	23	0.4	0	0.0	0	0.0	0	0.0	0	0.0	3	13.0	0	0.0	20	87.0	3	13.0	0	0.0	20	87.0	2020	Female	1,340	28.5	4,703	60.3	4	0.1	101	2.1	811	17.2	8	0.2	3,126	66.5	32	0.7	621	13.2	3,783	80.4	427	9.1	493	10.5
2020	Male	537	17.7	3,032	38.9	4	0.1	65	2.1	287	9.5	4	0.1	2,376	78.4	24	0.8	272	9.0	2,588	85.4	175	5.8	269	8.9	2020	Unknown	18	29.5	61	0.8	0	0.0	1	1.6	6	9.8	0	0.0	5	8.2	0	0.0	49	80.3	12	19.7	11	18.0	38	62.3
2021	Female	89,379	73.7	121,355	57.5	224	0.2	1,388	1.1	10,566	8.7	340	0.3	106,903	88.1	95	0.1	1,839	1.5	38,843	32.0	80,226	66.1	2,286	1.9	2021	Male	63,572	70.8	89,728	42.5	150	0.2	970	1.1	7,811	8.7	249	0.3	79,047	88.1	51	0.1	1,450	1.6	27,760	30.9	56,799	63.3	5,169	5.8
2021	Unknown	31	34.4	90	0.0	1	1.1	7	7.8	4	4.4	0	0.0	14	15.6	0	0.0	64	71.1	22	24.4	20	22.2	48	53.3																										

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

Fiscal Year	Sex Gender	Minority		Total Enrollment		% American Indian Alaska Native		% American Indian Alaska Native		% Black African American		% Black African American		% Native Hawaiian Pacific Islander		% Native Hawaiian Pacific Islander		% More Than One Race		% Unknown Not Reported		% Unknown Not Reported		% Not Hispanic		% Not Hispanic		% Unknown Not Reported		% Unknown Not Reported																					
		% Minority	% Total	Enrollment	% Total	Native	% Total	Native	% Total	American	% Total	American	% Total	White	% Total	One Race	% Total	Not Reported	% Total	Not Reported	% Total	Hispanic	% Total	Hispanic	% Total	Not Reported	% Total	Not Reported	% Total	Not Reported																					
2019	Female	490	15.8	3,106	57.9	6	0.2	63	2.0	282	9.1	4	0.1	2,663	85.7	10	0.3	78	2.5	2,603	83.8	127	4.1	376	12.1	2019	Male	252	11.3	2,231	41.6	3	0.1	49	2.2	127	5.7	3	0.1	1,971	88.3	15	0.7	63	2.8	1,884	84.4	66	3.0	281	12.6
2019	Unknown	0	0.0	23	0.4	0	0.0	0	0.0	0	0.0	0	0.0	3	13.0	0	0.0	20	87.0	3	13.0	0	0.0	20	87.0	2020	Female	1,340	28.5	4,703	60.3	4	0.1	101	2.1	811	17.2	8	0.2	3,126	66.5	32	0.7	621	13.2	3,783	80.4	427	9.1	493	10.5
2020	Male	537	17.7	3,032	38.9	4	0.1	65	2.1	287	9.5	4	0.1	2,376	78.4	24	0.8	272	9.0	2,588	85.4	175	5.8	269	8.9	2020	Unknown	18	29.5	61	0.8	0	0.0	1	1.6	6	9.8	0	0.0	5	8.2	0	0.0	49	80.3	12	19.7	11	18.0	38	62.3
2021	Female	89,379	73.7	121,355	57.5	224	0.2	1,388	1.1	10,566	8.7	340	0.3	106,903	88.1	95	0.1	1,839	1.5	38,843	32.0	80,226	66.1	2,286	1.9	2021	Male	63,572	70.8	89,728	42.5	150	0.2	970	1.1	7,811	8.7	249	0.3	79,047	88.1	51	0.1	1,450	1.6	27,760	30.9	56,799	63.3	5,169	5.8
2021	Unknown	31	34.4	90	0.0	1	1.1	7	7.8	4	4.4	0	0.0	14	15.6	0	0.0	64	71.1	22	24.4	20	22.2	48	53.3																										

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

Fiscal Year	Sex Gender	Minority		Total Enrollment		% American Indian Alaska Native		% American Indian Alaska Native		% Black African American		% Black African American		% Native Hawaiian Pacific Islander		% Native Hawaiian Pacific Islander		% More Than One Race		% Unknown Not Reported		% Unknown Not Reported		% Not Hispanic		% Not Hispanic		% Unknown Not Reported		% Unknown Not Reported																			
		% Minority	% Total	Enrollment	% Total	Native	% Total	Native	% Total	American	% Total	American	% Total	White	% Total	One Race	% Total	Not Reported	% Total	Not Reported	% Total	Hispanic	% Total	Hispanic	% Total	Not Reported	% Total	Not Reported	% Total	Not Reported																			
2019	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	2019	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		
2019	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	2020	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
2020	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	2020	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
2021	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	2021	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
2021	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/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority % Minority		%														Unknown %					
				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	Not Hispanic	% Not Hispanic				
2019	Female	490	15.8	6	0.2	63	2.0	282	9.1	4	0.1	2,661	85.7	10	0.3	78	2.5	2,601	83.8	127	4.1	376	12.1
2019	Male	252	11.3	3	0.1	49	2.2	127	5.7	3	0.1	1,968	88.3	15	0.7	63	2.8	1,881	84.4	66	3.0	281	12.6
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	13.0	0	0.0	20	87.0	3	13.0	0	0.0	20	87.0
2020	Female	1,340	28.5	4	0.1	101	2.1	811	17.2	8	0.2	3,126	66.5	32	0.7	620	13.2	3,783	80.5	427	9.1	492	10.5
2020	Male	537	17.7	4	0.1	65	2.1	287	9.5	4	0.1	2,376	78.4	24	0.8	272	9.0	2,588	85.4	175	5.8	269	8.9
2020	Unknown	18	29.5	0	0.0	1	1.6	6	9.8	0	0.0	5	8.2	0	0.0	49	80.3	12	19.7	11	18.0	38	62.3
2021	Female	89,375	73.6	224	0.2	1,388	1.1	10,566	8.7	340	0.3	106,902	88.1	95	0.1	1,836	1.5	38,843	32.0	80,222	66.1	2,286	1.9
2021	Male	63,571	70.8	150	0.2	970	1.1	7,811	8.7	249	0.3	79,046	88.1	51	0.1	1,450	1.6	27,760	30.9	56,798	63.3	5,169	5.8
2021	Unknown	31	34.4	1	1.1	7	7.8	4	4.4	0	0.0	14	15.6	0	0.0	64	71.1	22	24.4	20	22.2	48	53.3

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

Fiscal Year	Sex Gender	Minority % Minority		%														Unknown %					
				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	Not Hispanic	% Not Hispanic				
2019	Female	490	15.8	6	0.2	63	2.0	282	9.1	4	0.1	2,661	85.7	10	0.3	78	2.5	2,601	83.8	127	4.1	376	12.1
2019	Male	252	11.3	3	0.1	49	2.2	127	5.7	3	0.1	1,968	88.3	15	0.7	63	2.8	1,881	84.4	66	3.0	281	12.6
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	13.0	0	0.0	20	87.0	3	13.0	0	0.0	20	87.0
2020	Female	1,340	28.5	4	0.1	101	2.1	811	17.2	8	0.2	3,126	66.5	32	0.7	620	13.2	3,783	80.5	427	9.1	492	10.5
2020	Male	537	17.7	4	0.1	65	2.1	287	9.5	4	0.1	2,376	78.4	24	0.8	272	9.0	2,588	85.4	175	5.8	269	8.9
2020	Unknown	18	29.5	0	0.0	1	1.6	6	9.8	0	0.0	5	8.2	0	0.0	49	80.3	12	19.7	11	18.0	38	62.3
2021	Female	89,375	73.6	224	0.2	1,388	1.1	10,566	8.7	340	0.3	106,902	88.1	95	0.1	1,836	1.5	38,843	32.0	80,222	66.1	2,286	1.9
2021	Male	63,571	70.8	150	0.2	970	1.1	7,811	8.7	249	0.3	79,046	88.1	51	0.1	1,450	1.6	27,760	30.9	56,798	63.3	5,169	5.8
2021	Unknown	31	34.4	1	1.1	7	7.8	4	4.4	0	0.0	14	15.6	0	0.0	64	71.1	22	24.4	20	22.2	48	53.3

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

Fiscal Year	Sex Gender	Minority % Minority		%														Unknown %					
				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	Not Hispanic	% Not Hispanic				
2019	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
2019	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
2019	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
2020	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
2020	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
2020	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
2021	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
2021	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
2021	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

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