



NCCIH Report of FY19-21 Inclusion Data

I. Background/Overview

The mission of NCCIH is to define, through rigorous scientific investigation, the fundamental science, usefulness, and safety of complementary and integrative health practices and their roles in improving health and health care. The Center has worked to advance the position that evidence-based complementary therapies should be integrated with and not used as an alternative to conventional medicine. The new strategic plan for Fiscal Years 2021 – 2025 expands the definition of integrative health to include whole person health, to encourage improvements in health in multiple interconnected domains: biological, behavioral, social, and environmental. Research of interventions supported by the NCCIH clinical portfolio is comprised primarily of natural product-based and mind/body-based interventions. Much of our research is focused on pain management using these interventions. Generation of an evidence base for such interventions is crucial for informing decision-making by the public, by health care professionals, and by health policymakers regarding the use and integration of complementary and integrative health approaches. Therefore, the primary goals and objectives of the NCCIH clinical portfolio are to advance the science and practice of symptom management and develop effective, practical, and personalized strategies for promoting health and well-being.

- ❖ In support of its research goals and objectives, the NCCIH supports an extensive portfolio of interventional clinical trials and observational studies varying in size and complexity. As NCCIH-supported work is focusing on generating a knowledge base for many natural product and mind/body interventions, the portfolio includes primarily early-phase clinical

research in these areas. Clinical research efforts are therefore focused on formal intervention development, pilot, and feasibility testing, as well as some associated mechanistic studies. In view of the goals and objectives of the NCCIH research program, larger multi-center clinical trials of these interventions are not a current focus, although the progress in developing a deeper evidence base is underway and will ultimately inform plans for larger trials of interventions that demonstrate promise in early-phase testing. In view of the focus on early-phase testing and intervention development, maximizing enrollment diversity may not be feasible or warranted in some early small studies. Most of the work in this area is progression from early-phase to larger trials of efficacy or effectiveness. Therefore, the need for maximizing enrollment should always be balanced by the expanding diversity to address concerns of generalizability of research results. NCCIH is highlighting the value of increasing diversity in the clinical portfolio. One of our approaches included a NCCIH Hot Topic Webinar: [Engaging Diverse Communities in Complementary and Integrative Health](#).

II. Strategies for Ensuring Compliance

A. Peer Review Process

The implementation of the NIH inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific [guidance](#) on reviewing inclusion on the basis of sex/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. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding. An award is not issued until an acceptable resolution is received.

B. Program Monitoring and Grants Management Oversight

Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate.

Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor 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 the 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 minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural Institutional Review Boards (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, race, and ethnicity of those who were accrued over 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.

III. NCCIH Training Approaches

Institute Program Officials/Program Directors and Scientific Review Officers attended the September 2, 2020, training "NIH Inclusion Across the Lifespan II" training". Staff may access the archived training on the NIH staff intranet. Additional virtual training opportunities are available at the following link: [eRA Training - Human Subjects System \(HSS\) | eRA \(nih.gov\)](#)

IV Analysis and Interpretation of Inclusion Data

A. FY19-21 Data

See attached tables in Appendix 1. The appended tables (Appendix 1) show enrollment data for fiscal years (FY) 2019 through 2021.

Table 2.1 shows Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported between FY 2019- FY 2021. In FY 19, the NCCIH Extramural Program had 180 Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research with 102 clinical studies in enrollment status, among which 15 studies only enrolled women. In FY 2020, the NCCIH Extramural Program had 220 Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research, with 113 clinical studies in enrollment status, among which 10 studies only enrolled women. In FY 2021, the NCCIH Extramural Program had 226 Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research, with 123 clinical studies in enrollment status, among which 13 studies only enrolled women. There were two Phase III studies enrolling participants in 2019 and ten Phase III studies enrolling participants in 2020 and 2021.

***Note that “clinical studies” has been defined broadly, to include interventional clinical trials, as well as non-interventional clinical research, epidemiologic studies, behavioral studies, and observational studies.**

Table 3-1-A shows total enrollment for all NIH-defined Clinical Research by Sex categories for funding years (FY) 2019-2021. In FY 2019, NCCIH-funded clinical research enrolled 9,343 participants; 58% female, 38% male and 4% listed as unknown. In FY 2020, NCCIH-funded clinical research enrolled 15,850 participants; 50% female, 49% male and 2% listed as unknown. NCCIH-funded clinical research enrolled 49,100 participants; 52% female, 47% male and 1% listed as unknown.

Table 4.1.2.D reports total minority enrollment and Table 4.1.2.C reports Hispanic Latino / Non-Hispanic Latino. In FY 19, NCCIH-funded studies involving 25% minority enrollment, 6% Hispanic Latino enrollment, and 83% non-Hispanic enrollment. In FY 20, NCCIH-funded studies involving 26% minority enrollment, 8% Hispanic Latino enrollment, and 80% non-Hispanic enrollment. In FY 21, NCCIH-funded studies involving 27% minority enrollment, 6% Hispanic Latino enrollment, and 88% non-Hispanic enrollment.

Table 3-3 shows all enrollment for all NIH-Defined Phase III Clinical Research by sex. In FY 19, there were 268 participants enrolled in NCCIH-funded Phase III clinical research, 26% female and 74% male. In FY 20 there were 1476 subjects enrolled in NCCIH-funded Phase III clinical trials, 32% female, 68% male enrollment. In FY 21 there were NCCIH-funded Phase III clinical trial with 1169 participants enrolled including 32% female and 68% male.

Table 4-2-1-B has enrollment by minority status and Table 4-2-1-D has enrollment by Ethnicity for NCCIH Phase III Clinical Trials. In FY 2019 there were 42% minority, 28% Hispanic Latino, and 71% Non-Hispanic participants enrolled. In FY 2020 there were 32% minority, 14% Hispanic, and 81% non-Hispanic participants enrolled. In FY 2021 there were 46% minority, 19% Hispanic Latino, and 76% non-Hispanic participants enrolled.

NIH policies requires valid analysis by gender for Phase III Clinical Trials. TABLE 4-2-2-B has the enrollment percentages by Race for Phase III Clinical Studies. For Phase III Clinical trials, in 2019, participants were 1% American Indian / Alaska Native, 2% Asian, 10% Black/ African American, 3% Native Hawaiian / Pacific Islander, 4% more than one Race, and 81% White. In 2020, participants were 1% American Indian / Alaska Native, 4% Asian, 11% Black/ African American, 1% Native Hawaiian / Pacific Islander, 4% more than one Race, and 74% White. In 2021, participants were 1% American Indian / Alaska Native, 5% Asian, 20% Black/ African American, 1% Native Hawaiian / Pacific Islander, 4% more than one Race, and 66% White.

Table 3-1-C and Table 4-1-1-E has enrollment in the NCCIH intramural program by sex and minority status. There were 334 participants enrolled in 2019 with 64% minorities, 56% female, and 44% male participants. There were 1407 participants enrolled in 2020 with 33% minorities, 45% female, and 55% males. There were 2102 participants enrolled in 2021 with 38% minorities, 45% females, and 51% males. There were no Phase III clinical trials enrolling in the intramural program for this reporting period.

B. Discussion of FY19-FY21 Inclusion Data

In summary, NCCIH has continued to increase the number of participants in clinical research studies during the three-year reporting period. A small proportion of these studies are being done as Phase III clinical trials. We noted a decrease in the number of participants in these Phase III studies between FY 2020 and FY 2021 (from 1476 to 1169 participants). This decrease may be due to the COVID19 pandemic which was seen nationally by March 2020 (the latter six months of FY 2021 reporting year). NCCIH funded researchers in the extramural community informed NCCIH of many studies halting and redesigning studies from in-person to remote interventions when possible, shifting clinicians from research to clinical work, or halting studies until the investigators and / or the IRBs of record determined the studies could be safely restarted.

NCCIH continues to do well in the recruitment of women in clinical studies with the proportion close to 50% overall in the portfolio. Efforts to increase the proportion of women in Phase III clinical studies are identified and implemented, such as expanding into evening hours or weekends as well as providing transportation to study clinic for visits. We have found these efforts can be applied beyond female recruitment, based on discussions with study Data and Safety Monitoring Boards, and find these approaches also enhance recruitment of men.

NCCIH and NIH continue to support increased participation of minorities in NCCIH-funded research. There are many approaches NCCIH, and NIH are utilizing to enhance recruitment of minority subjects. We highlight several NCCIH presentations to the research community which include the NCCIH Hot Topic Webinar: Engaging Diverse Communities in Complementary and Integrative Health (recording online) <https://bit.ly/EngagingDiverseCommunities>, a two-hour webinar on April 27, 2021. The meeting was recorded and is available on the NCCIH website. NCCIH hosted, along with the NIH Collaboratory Coordinating Center, a series of presentations as part of a workshop aimed to enhance recruitment and participation of minorities in pragmatic clinical trials research. These talks were recorded and are available on the Rethinking Clinical Trials website available at: <https://rethinkingclinicaltrials.org/news/tag/diversity-workshop/> The NIH Unite Initiative is also working to address the importance of enhancing minority recruitment, as well as a variety of other topics to enhance minority participation in research at a wide variety of levels. More information on the NIH UNITE Initiative: <https://www.nih.gov/ending-structural-racism>

This information was provided to the NCCIH Council on January 21, 2022, during the Open Session of the Council. Dr. Partap Khalsa, as the Executive Secretary, chairs this meeting. Meeting recording:

[Advisory Council Meeting 79th Meeting | NCCIH \(nih.gov\)](#)

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IV. Additional information

The RCDC Website <https://report.nih.gov/RISR/> displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

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Appendix 1

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 Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	180	77	103	102	1	15	1	87
2020	220	105	115	113	2	10	2	103
2021	226	101	125	123	2	13	1	111

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

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 Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	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	1,376	25.4	5,427	58.1	16	0.3	312	5.7	588	10.8	14	0.3	4,032	74.3	178	3.3	287	5.3	4,835	89.1	346	6.4	246	4.5
2019	Male	916	25.6	3,576	38.3	9	0.3	220	6.2	413	11.5	16	0.4	2,662	74.4	79	2.2	177	4.9	3,186	89.1	229	6.4	161	4.5
2019	Unknown	2	0.6	340	3.6	0	0.0	1	0.3	0	0.0	0	0.0	6	1.8	0	0.0	333	97.9	9	2.6	1	0.3	330	97.1
2020	Female	2,038	26.0	7,841	49.5	66	0.8	370	4.7	753	9.6	12	0.2	6,091	77.7	291	3.7	258	3.3	6,686	85.3	623	7.9	532	6.8
2020	Male	2,046	26.7	7,661	48.3	44	0.6	394	5.1	774	10.1	15	0.2	5,961	77.8	253	3.3	220	2.9	6,408	83.6	644	8.4	609	7.9
2020	Unknown	7	2.0	348	2.2	0	0.0	1	0.3	3	0.9	0	0.0	13	3.7	2	0.6	329	94.5	22	6.3	3	0.9	323	92.8
2021	Female	7,162	28.3	25,332	51.6	233	0.9	756	3.0	4,475	17.7	80	0.3	18,866	74.5	388	1.5	534	2.1	23,184	91.5	1,463	5.8	685	2.7
2021	Male	5,931	25.4	23,326	47.5	233	1.0	844	3.6	3,074	13.2	47	0.2	18,307	78.5	331	1.4	490	2.1	20,943	89.8	1,608	6.9	775	3.3
2021	Unknown	56	12.7	442	0.9	4	0.9	12	2.7	10	2.3	8	1.8	29	6.6	16	3.6	363	82.1	54	12.2	20	4.5	368	83.3

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	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	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	31	44.9	69	25.7	1	1.4	0	0.0	11	15.9	3	4.3	51	73.9	3	4.3	0	0.0	51	73.9	17	24.6	1	1.4
2019	Male	80	40.2	199	74.3	1	0.5	4	2.0	15	7.5	4	2.0	167	83.9	8	4.0	0	0.0	140	70.4	59	29.6	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	151	31.9	474	32.1	6	1.3	18	3.8	61	12.9	6	1.3	339	71.5	19	4.0	25	5.3	397	83.8	53	11.2	24	5.1
2020	Male	314	31.5	996	67.5	4	0.4	49	4.9	91	9.1	7	0.7	750	75.3	37	3.7	58	5.8	788	79.1	150	15.1	58	5.8
2020	Unknown	0	0.0	6	0.4	0	0.0	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0
2021	Female	165	45.1	366	31.3	6	1.6	9	2.5	76	20.8	8	2.2	237	64.8	11	3.0	19	5.2	278	76.0	66	18.0	22	6.0
2021	Male	356	44.6	799	68.3	3	0.4	45	5.6	136	17.0	8	1.0	543	68.0	32	4.0	32	4.0	606	75.8	152	19.0	41	5.1
2021	Unknown	2	50.0	4	0.3	0	0.0	0	0.0	1	25.0	0	0.0	1	25.0	1	25.0	1	25.0	0	0.0	0	0.0	4	100.0

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 Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	7	5	2	1	1	0	0	2
2020	22	12	10	8	2	0	0	10
2021	19	9	10	8	2	0	0	10

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	9,343	5,427	58.1	3,576	38.3	340	3.6	349	3.7	22	0.2	5,078	54.4	3,554	38.0
2020	15,850	7,841	49.5	7,661	48.3	348	2.2	321	2.0	2	0.0	7,520	47.4	7,659	48.3
2021	49,100	25,332	51.6	23,326	47.5	442	0.9	383	0.8	1	0.0	24,949	50.8	23,325	47.5

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	344	194	56.4	150	43.6	0	0.0	0	0.0	0	0.0	194	56.4	150	43.6
2020	1,407	639	45.4	768	54.6	0	0.0	0	0.0	0	0.0	639	45.4	768	54.6
2021	2,102	955	45.4	1,081	51.4	66	3.1	0	0.0	0	0.0	955	45.4	1,081	51.4

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	268	69	25.7	199	74.3	0	0.0	0	0.0	0	0.0	69	25.7	199	74.3
2020	1,476	474	32.1	996	67.5	6	0.4	0	0.0	0	0.0	474	32.1	996	67.5
2021	1,169	366	31.3	799	68.3	4	0.3	0	0.0	0	0.0	366	31.3	799	68.3

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
2019	9,343	180	2,294	24.6	25	0.3	533	5.7	1,001	10.7	30	0.3	6,700	71.7	257	2.8	797	8.5
2020	15,850	220	4,091	25.8	110	0.7	765	4.8	1,530	9.7	27	0.2	12,065	76.1	546	3.4	807	5.1
2021	49,100	226	13,149	26.8	470	1.0	1,612	3.3	7,559	15.4	135	0.3	37,202	75.8	735	1.5	1,387	2.8

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
2019	344	7	221	64.2	1	0.3	51	14.8	126	36.6	1	0.3	136	39.5	11	3.2	18	5.2
2020	1,407	5	457	32.5	47	3.3	71	5.0	257	18.3	3	0.2	949	67.4	37	2.6	43	3.1
2021	2,102	6	790	37.6	55	2.6	140	6.7	349	16.6	49	2.3	1,377	65.5	70	3.3	62	2.9

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	8,025	85.9	576	6.2	737	7.9
2020	13,067	82.7	1,270	8.0	1,462	9.3
2021	44,132	90.0	3,091	6.3	1,826	3.7

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

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2019	9,338	2,294	24.6
2020	15,799	4,081	25.8
2021	49,049	13,139	26.8

Table 4-1-4-B. US Site 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
2019	344	7	221	64.2	1	0.3	51	14.8	126	36.6	1	0.3	136	39.5	11	3.2	18	5.2
2020	1,407	5	457	32.5	47	3.3	71	5.0	257	18.3	3	0.2	949	67.4	37	2.6	43	3.1
2021	2,102	6	790	37.6	55	2.6	140	6.7	349	16.6	49	2.3	1,377	65.5	70	3.3	62	2.9

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	268	7	111	41.4	2	0.7	4	1.5	26	9.7	7	2.6	218	81.3	11	4.1	0	0.0
2020	1,476	22	465	31.5	10	0.7	67	4.5	152	10.3	13	0.9	1,095	74.2	56	3.8	83	5.6
2021	1,169	19	523	44.7	9	0.8	54	4.6	213	18.2	16	1.4	781	66.8	44	3.8	52	4.4

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	191	71.3	76	28.4	1	0.4
2020	1,191	80.7	203	13.8	82	5.6
2021	884	75.6	218	18.6	67	5.7

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
2019	263	6	111	42.2	2	0.8	4	1.5	26	9.9	7	2.7	213	81.0	11	4.2	0	0.0
2020	1,425	20	455	31.9	10	0.7	63	4.4	152	10.7	11	0.8	1,054	74.0	52	3.6	83	5.8
2021	1,118	17	513	45.9	9	0.8	50	4.5	213	19.1	14	1.3	740	66.2	40	3.6	52	4.7

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	186	70.7	76	28.9	1	0.4
2020	1,142	80.1	203	14.2	80	5.6
2021	835	74.7	218	19.5	65	5.8