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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Richard Hodes, M.D.
Director
National Institute on Aging
February, 2022
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

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

*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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total IERs</th>
<th>IERs Without Enrollment</th>
<th>IERs With Enrollment</th>
<th>US Site IERs</th>
<th>Non-US Site IERs</th>
<th>Female Only IERs</th>
<th>Male Only IERs</th>
<th>IERs Excluding Male only and Female only*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>56</td>
<td>36</td>
<td>20</td>
<td>19</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>2020</td>
<td>120</td>
<td>87</td>
<td>33</td>
<td>32</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>2021</td>
<td>164</td>
<td>118</td>
<td>46</td>
<td>45</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>42</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>IERs Requiring Race Ethnicity Valid Analysis</th>
<th>% IERs Requiring Race Ethnicity Valid Analysis</th>
<th>IERs Requiring Sex Gender Valid Analysis</th>
<th>% IERs Requiring Sex Gender Valid Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>56</td>
<td>55</td>
<td>55</td>
<td>98.2</td>
</tr>
<tr>
<td>2020</td>
<td>120</td>
<td>119</td>
<td>119</td>
<td>99.2</td>
</tr>
<tr>
<td>2021</td>
<td>164</td>
<td>164</td>
<td>164</td>
<td>100.0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>1,992,621</td>
<td>748,244</td>
<td>37.6</td>
<td>1,239,388</td>
<td>62.2</td>
<td>5,139</td>
<td>0.3</td>
<td>63,165</td>
<td>3.2</td>
<td>720,014</td>
<td>36.1</td>
<td>685,079</td>
<td>34.4</td>
<td>519,224</td>
</tr>
<tr>
<td>2020</td>
<td>766,993</td>
<td>470,922</td>
<td>61.4</td>
<td>292,925</td>
<td>38.2</td>
<td>3,146</td>
<td>0.4</td>
<td>62,004</td>
<td>8.2</td>
<td>4,748</td>
<td>0.6</td>
<td>408,018</td>
<td>53.2</td>
<td>288,177</td>
</tr>
<tr>
<td>2021</td>
<td>876,489</td>
<td>547,628</td>
<td>62.8</td>
<td>322,723</td>
<td>38.8</td>
<td>6,138</td>
<td>0.7</td>
<td>75,137</td>
<td>8.6</td>
<td>16,140</td>
<td>2.1</td>
<td>472,491</td>
<td>53.8</td>
<td>304,583</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>1,978,892</td>
<td>741,893</td>
<td>37.5</td>
<td>1,231,861</td>
<td>62.3</td>
<td>5,138</td>
<td>0.3</td>
<td>63,165</td>
<td>3.2</td>
<td>719,903</td>
<td>36.4</td>
<td>678,728</td>
<td>34.3</td>
<td>511,958</td>
</tr>
<tr>
<td>2020</td>
<td>753,529</td>
<td>464,703</td>
<td>61.7</td>
<td>285,681</td>
<td>37.9</td>
<td>3,145</td>
<td>0.4</td>
<td>62,004</td>
<td>8.3</td>
<td>4,637</td>
<td>0.6</td>
<td>401,799</td>
<td>53.3</td>
<td>281,044</td>
</tr>
<tr>
<td>2021</td>
<td>863,636</td>
<td>541,669</td>
<td>62.7</td>
<td>315,829</td>
<td>36.6</td>
<td>6,138</td>
<td>0.7</td>
<td>75,137</td>
<td>8.7</td>
<td>16,029</td>
<td>2.1</td>
<td>466,532</td>
<td>54.8</td>
<td>297,800</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>13,729</td>
<td>6,351</td>
<td>46.3</td>
<td>7,377</td>
<td>53.7</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>111</td>
<td>0.8</td>
<td>6,351</td>
<td>46.3</td>
<td>7,266</td>
</tr>
<tr>
<td>2020</td>
<td>13,464</td>
<td>6,219</td>
<td>46.2</td>
<td>7,244</td>
<td>53.8</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>111</td>
<td>0.8</td>
<td>6,219</td>
<td>46.2</td>
<td>7,133</td>
</tr>
<tr>
<td>2021</td>
<td>12,853</td>
<td>5,959</td>
<td>46.4</td>
<td>6,894</td>
<td>53.6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>111</td>
<td>0.8</td>
<td>5,959</td>
<td>46.8</td>
<td>6,783</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>Females, Excluding Female only</th>
<th>% Females, Excluding Female only</th>
<th>Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>1,786,854</td>
<td>633,386</td>
<td>35.4</td>
<td>1,148,597</td>
<td>64.3</td>
<td>4,871</td>
<td>0.3</td>
<td>63,165</td>
<td>3.5</td>
<td>720,014</td>
<td>40.3</td>
<td>570,221</td>
<td>31.9</td>
<td>428,583</td>
<td>24.0</td>
</tr>
<tr>
<td>2020</td>
<td>436,346</td>
<td>286,543</td>
<td>65.7</td>
<td>146,674</td>
<td>33.6</td>
<td>3,129</td>
<td>0.7</td>
<td>62,884</td>
<td>14.4</td>
<td>4,748</td>
<td>1.1</td>
<td>223,659</td>
<td>51.3</td>
<td>141,926</td>
<td>32.5</td>
</tr>
<tr>
<td>2021</td>
<td>834,301</td>
<td>523,578</td>
<td>62.8</td>
<td>304,606</td>
<td>38.6</td>
<td>6,117</td>
<td>0.7</td>
<td>75,084</td>
<td>9.0</td>
<td>18,140</td>
<td>2.2</td>
<td>448,494</td>
<td>53.8</td>
<td>236,466</td>
<td>34.3</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>Females, Excluding Female only</th>
<th>% Females, Excluding Female only</th>
<th>Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>1,773,125</td>
<td>627,035</td>
<td>35.4</td>
<td>1,141,220</td>
<td>64.4</td>
<td>4,870</td>
<td>0.3</td>
<td>63,165</td>
<td>3.6</td>
<td>719,903</td>
<td>40.6</td>
<td>563,870</td>
<td>31.8</td>
<td>421,317</td>
<td>23.8</td>
</tr>
<tr>
<td>2020</td>
<td>422,882</td>
<td>280,324</td>
<td>66.3</td>
<td>139,430</td>
<td>33.0</td>
<td>3,128</td>
<td>0.7</td>
<td>62,884</td>
<td>14.9</td>
<td>4,637</td>
<td>1.1</td>
<td>217,440</td>
<td>51.4</td>
<td>134,793</td>
<td>31.9</td>
</tr>
<tr>
<td>2021</td>
<td>821,448</td>
<td>517,619</td>
<td>63.0</td>
<td>297,712</td>
<td>36.2</td>
<td>6,117</td>
<td>0.7</td>
<td>75,084</td>
<td>9.1</td>
<td>18,029</td>
<td>2.2</td>
<td>442,535</td>
<td>53.9</td>
<td>279,683</td>
<td>34.0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>Females, Excluding Female only</th>
<th>% Females, Excluding Female only</th>
<th>Males, Excluding Male only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>13,739</td>
<td>6,351</td>
<td>46.3</td>
<td>7,377</td>
<td>53.7</td>
<td>1</td>
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</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
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<td>3,104</td>
<td>58.0</td>
<td>2,228</td>
<td>41.6</td>
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<td>1.4</td>
<td>121,326</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>Total Females</th>
<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>5,355</td>
<td>3,104</td>
<td>58.0</td>
<td>2,228</td>
<td>41.6</td>
<td>23</td>
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<td>4,702</td>
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<td>3,032</td>
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<tr>
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<td>2,893</td>
<td>1.4</td>
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### Table 3-4-C. US Site Enrollment for All NIH-Defined Intramural Phase III Trials

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<th>Total Enrollment</th>
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<th>% Females</th>
<th>Total Males</th>
<th>% Males</th>
<th>Total Unknown</th>
<th>% Unknown</th>
<th>Enrollment in Female only</th>
<th>% Female only</th>
<th>Enrollment in Male only</th>
<th>% Male only</th>
<th>% Females, Excluding Female only</th>
<th>% Males, Excluding Male only</th>
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</thead>
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<td>0.0</td>
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<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
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<td>0</td>
<td>0.0</td>
<td>0</td>
<td>0.0</td>
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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

<table>
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<th>Fiscal Year</th>
<th>Total Enrollees</th>
<th>Minority Enrollees</th>
<th>% Minority Enrollees</th>
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<tbody>
<tr>
<td>2019</td>
<td>1,786,854</td>
<td>360,355</td>
<td>20.2</td>
</tr>
<tr>
<td>2020</td>
<td>436,346</td>
<td>131,255</td>
<td>30.1</td>
</tr>
<tr>
<td>2021</td>
<td>834,301</td>
<td>303,781</td>
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#### Table 4-2-2-D. US Site Enrollment of NIH-Defined Phase III Trials

<table>
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<td>211,168</td>
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The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.
## 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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>No. Inclusion Data Records</th>
<th>Minority Enrollment</th>
<th>% Minority Enrollment</th>
<th>American Indian Alaska Native</th>
<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>% More Than One Race</th>
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<th>Unknown Not Reported</th>
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<td>404,576</td>
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<td>3,714</td>
<td>0.2</td>
<td>47,004</td>
<td>2.4</td>
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<td>10.4</td>
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<td>0.1</td>
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<td>25,728</td>
<td>1.3</td>
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<td>1.3</td>
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</tr>
<tr>
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<td>252</td>
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<td>0.0</td>
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<td>1,573</td>
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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

#### 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

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

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>No. Inclusion Data Records</th>
<th>Minority Enrollment</th>
<th>% Minority Enrollment</th>
<th>American Indian Alaska Native</th>
<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>Unknown Not Reported</th>
<th>Unknown Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>1,786,854</td>
<td>1,515</td>
<td>360,355</td>
<td>20.2</td>
<td>3,714</td>
<td>0.2</td>
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<td>10,789</td>
<td>2.5</td>
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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 NIH-Defined Extramural Clinical Research

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

<table>
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<th>Fiscal Year</th>
<th>Total Enrollment</th>
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<th>Minority Enrollment</th>
<th>% Minority Enrollment</th>
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<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>Unknown Not Reported</th>
<th>Unknown Not Reported</th>
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</thead>
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### US Site Enrollment of NIH-Defined Intramural Clinical Research

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

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### Total Phase III Trials Enrollment by Race

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

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<th>Native Hawaiian Pacific Islander</th>
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<tbody>
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<td>9</td>
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<td>409</td>
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<td>86.5</td>
<td>25</td>
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<td>167</td>
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<td>1,104</td>
<td>14.2</td>
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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

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<th>Total Enrollment</th>
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<th>American Indian Alaska Native %</th>
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<th>Black African American %</th>
<th>Native Hawaiian Pacific Islander</th>
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<th>More Than One Race %</th>
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<tr>
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<td>118</td>
<td>1,895</td>
<td>24.3</td>
<td>8</td>
<td>0.1</td>
<td>167</td>
<td>2.1</td>
<td>1,104</td>
<td>14.2</td>
<td>12</td>
<td>0.2</td>
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<td>56</td>
</tr>
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<td>211,168</td>
<td>161</td>
<td>152,977</td>
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<td>0.2</td>
<td>2,365</td>
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<td>18,381</td>
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<td>185,962</td>
<td>88.1</td>
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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 4-2-3-B. US Site Enrollment of NIH-Defined Extramural Phase III Trials

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<th>Black African American %</th>
<th>Native Hawaiian Pacific Islander</th>
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<td>8</td>
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<td>167</td>
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<td>2,365</td>
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<td>8.7</td>
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### Table 4-2-4-B. US Site Enrollment of NIH-Defined Intramural Phase III Trials

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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

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<th>% Unknown Not Reported</th>
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<td>141,726</td>
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<td>12.5</td>
</tr>
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<td>83.9</td>
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<td>65,897</td>
<td>8.6</td>
</tr>
<tr>
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<td>628,291</td>
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<td>21.8</td>
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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

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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

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<td>213</td>
<td>1.6</td>
<td>793</td>
<td>5.8</td>
</tr>
<tr>
<td>2020</td>
<td>12,459</td>
<td>92.5</td>
<td>217</td>
<td>1.6</td>
<td>788</td>
<td>5.9</td>
</tr>
<tr>
<td>2021</td>
<td>11,842</td>
<td>92.1</td>
<td>223</td>
<td>1.7</td>
<td>788</td>
<td>6.1</td>
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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

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

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<tr>
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#### Table 4-1-4-C. US Site Enrollment of NIH-Defined Intramural Clinical Research

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</thead>
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<td>2019</td>
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<td>92.7</td>
<td>213</td>
<td>1.6</td>
<td>793</td>
<td>5.8</td>
</tr>
<tr>
<td>2020</td>
<td>12,459</td>
<td>92.5</td>
<td>217</td>
<td>1.6</td>
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</tr>
<tr>
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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**

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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

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

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

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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

<table>
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<tr>
<th>Fiscal Year</th>
<th>Sex</th>
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<th>% Total</th>
<th>American Indian Alaska Native</th>
<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
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<th>Unknown Not Reported</th>
<th>Not Hispanic</th>
<th>% Not Hispanic</th>
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<th>% Hispanic Latino</th>
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<td>70,195</td>
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</table>

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Sex</th>
<th>Minority %</th>
<th>Total Enrollment % Total</th>
<th>American Indian Alaska Native %</th>
<th>Black African American %</th>
<th>Native Hawaiian Pacific Islander %</th>
<th>% White</th>
<th>More Than One Race</th>
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<th>Unknown Not Reported</th>
</tr>
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<tbody>
<tr>
<td>2021 Female</td>
<td>89,379</td>
<td>73.7</td>
<td>121,355</td>
<td>57.5</td>
<td>224</td>
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<td>1,388</td>
<td>1.1</td>
<td>10,566</td>
<td>8.7</td>
</tr>
<tr>
<td>2021 Male</td>
<td>63,572</td>
<td>70.8</td>
<td>89,728</td>
<td>42.5</td>
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<td>0.2</td>
<td>970</td>
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Table 5-2-3-C. ALL Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

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<th>Fiscal Year</th>
<th>Sex</th>
<th>Minority %</th>
<th>Total Enrollment % Total</th>
<th>American Indian Alaska Native %</th>
<th>Black African American %</th>
<th>Native Hawaiian Pacific Islander %</th>
<th>% White</th>
<th>More Than One Race</th>
<th>Unknown Not Reported</th>
<th>Unknown Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021 Female</td>
<td>89,379</td>
<td>73.7</td>
<td>121,355</td>
<td>57.5</td>
<td>224</td>
<td>0.2</td>
<td>1,388</td>
<td>1.1</td>
<td>10,566</td>
<td>8.7</td>
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<tr>
<td>2021 Male</td>
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<td>70.8</td>
<td>89,728</td>
<td>42.5</td>
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<td>970</td>
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<td>7,811</td>
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Table 5-2-4-C. ALL Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

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<th>Fiscal Year</th>
<th>Sex</th>
<th>Minority %</th>
<th>Total Enrollment % Total</th>
<th>American Indian Alaska Native %</th>
<th>Black African American %</th>
<th>Native Hawaiian Pacific Islander %</th>
<th>% White</th>
<th>More Than One Race</th>
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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 5-3-3-C. US Site Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

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<th>% Minority</th>
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<th>Black</th>
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<th>Pacific Islander</th>
<th>Native Hawaiian</th>
<th>Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>% More Than One Race</th>
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<th>Not Hispanic</th>
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<th>% Hispanic Latino</th>
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### Table 5-3-4-C. US Site Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

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<th>% More Than One Race</th>
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<th>Not Hispanic</th>
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<th>Latino</th>
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The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.