

The National Eye Institute (NEI) Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021

Background/Overview

Mission Statement of the NEI: As part of the Federal Government's National Institutes of Health (NIH), the National Eye Institute (NEI) was established to protect and prolong the vision of the American people. The National Eye Institute's mission is to eliminate vision loss and improve quality of life through vision research. To achieve this mission, NEI provides leadership to:

- Drive innovative research to understand the eye and visual system, prevent and treat vision diseases, and expand opportunities for people who are blind or require vision rehabilitation
- Foster collaboration in vision research and clinical care to develop new ideas and share knowledge across other fields
- Recruit, inspire, and train a talented and diverse new generation of individuals to expand and strengthen the vision workforce
- Educate health care providers, scientists, policymakers, and the public about advances in vision research and their impact on health and quality of life

Description of the NEI Portfolio: The NEI supports a significant number of clinical research projects on potentially blinding eye diseases and other visual disorders. Examples include diabetic retinopathy, amblyopia, age-related macular degeneration, glaucoma, retinopathy of prematurity, corneal stromal keratitis, uveitis, retinitis pigmentosa, Leber's congenital amaurosis and myopia (nearsightedness).

NEI Strategies for Ensuring Compliance

The Director, Division of Extramural Scientific Programs (DESP), NEI, is the official with responsibility for ensuring compliance. To educate the vision research community, inclusion policies are highlighted on the NEI extramural research website. The policy is also explicitly detailed in all NEI Funding Opportunity Announcements, Requests for Applications, and Requests for Proposals.

Peer Review: The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing 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.

Program Monitoring and Grants Management Oversight: Prior to an award, 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 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.

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.

NEI Training Approaches: NEI staff are required to participate in the NIH Training on Gender, Race and Ethnicity. The Director, DESP, routinely distributes policy updates to all staff. NEI staff members participate in several trans-NIH committees regularly involved with compliance and policy issues. All NEI-funded Phase III clinical trials are supported through the cooperative agreement mechanism. NEI Clinical Program Directors collaborate with the study team to ensure that all protocols are designed with appropriate inclusion goals before funding. Most Phase III trials are multicenter, which permits broader sampling of minority subpopulations. NEI staff monitor enrollment in all Phase III trials routinely and document inclusion in the grant file. NEI staff work collaboratively with study biostatisticians to ensure that appropriate valid analyses of differences in intervention effect are performed.

Analysis and Interpretation of Data: The National Advisory Eye Council (NAEC) reviewed NEI-specific inclusion data for FY2019-21 at their February 11, 2022, meeting. Data for all clinical research, NIH-defined Phase III clinical trials, extramural and intramural research was reviewed. The appended tables and graphs show enrollment data for fiscal years (FY) 2019-2021. Table 2-1 includes Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research. Approximately 94 percent of NEI studies include both females and males. The NEI has few female-only or male-only studies and most of these are studies that include samples derived from existing data sources. Tables 5-1-1-C and 5-2-2-C include Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity and Enrollment for Phase III studies respectively. These tables include data from large international studies in Nepal and in Ethiopia resulting in the appearance of a very large percentage of “Asian American” and “Black/African American” participants. It also included one large, crowd-sourcing study where data was collected on-line and demographic characteristics were not obtained. Additional data was presented to Council excluding these studies - see appended graphs (Figure 1-6). NAEC noted that women represented approximately 52 percent of enrolled participants for all clinical research and 48 percent in Phase III clinical trials. The NEI data shows good representation of racial and ethnic inclusion. Approximately 30 percent of the NEI data were from minority participants. NEI data appropriately reflect the make-up of the U.S. population.

Women study participants were well represented in NEI-sponsored Phase III clinical trials. Inclusion of minority groups in Phase III clinical trials was commensurate with United States population averages. Inclusion of Hispanic participants in Phase III clinical trials was commensurate with United States population averages as well. The NEI currently supports 32 Phase III clinical trials. All NEI-funded Phase III clinical trials are designed with enrollment targets for gender, race, and ethnicity which result in sufficient power for valid subgroup analyses as required by policy. Inclusion data broken out by Research, Condition, and Disease Categorization (RCDC) can be found at: <https://report.nih.gov/RISR/>.

Age data based on inclusion records showed a good distribution across the lifespan – see appended Age Data Based on Inclusion Data Records (IERs) Table 1 and 2. NEI studies include infants who have retinopathy of prematurity, young children with a variety of vision disorders including amblyopia, strabismus and myopia, and older participants with diseases such as diabetic retinopathy, macular degeneration, glaucoma and cataracts.

The NAEC noted that the NEI data show good representation of women and minority populations in NEI clinical research studies. The NEI supports a large portfolio of clinical research. The NAEC reviewed the inclusion data and concluded that the NEI has complied with the NIH Policy on Inclusion of Women & Minorities in Clinical Research. Overall, inclusion of minority groups in NEI clinical research was commensurate with United States population averages.

Additional Information: The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to

individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this triennial report provides information on inclusion of participants in NIH clinical research from FY 2019 – 2021. Section IV of the [Report of the Advisory Committee on Research on Women’s Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2019 and 2020.

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2019 and FY2021

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	391	123	268	253	15	4	14	250
2020	473	185	288	268	20	8	9	271
2021	478	190	288	267	21	10	4	274

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

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		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		% Hispanic Latino		% Unknown Not Reported		% Unknown Not Reported	
		Minority	Minority	t	% Total	Native	Native	Asian	% Asian	American	American	Islander	Islander	White	% White	One Race	Race	Reported	Reported	Hispanic	% Not Hispanic	Latino	% Hispanic	Latino	Reported	% Not Reported	Latino	% Hispanic	Reported
2019	Female	25,032	47.6	52,604	53.8	174	0.3	2,301	4.4	19,324	36.7	111	0.2	25,064	47.6	560	1.1	5,070	9.6	44,467	84.5	2,867	5.5	5,270	10.0				
2019	Male	20,665	47.8	43,232	44.2	156	0.4	2,252	5.2	15,278	35.3	84	0.2	21,010	48.6	467	1.1	3,985	9.2	36,926	85.4	2,691	6.2	3,615	8.4				
2019	Unknown	1,223	64.8	1,886	1.9	1	0.1	1,112	59.0	30	1.6	0	0.0	108	5.7	8	0.4	627	33.2	1,283	68.0	74	3.9	529	28.0				
2020	Female	53,686	71.1	75,554	53.1	201	0.3	27,528	36.4	22,667	30.0	128	0.2	22,644	30.0	626	0.8	1,760	2.3	70,750	93.6	2,893	3.8	1,911	2.5				
2020	Male	47,613	72.3	65,899	46.3	188	0.3	25,785	39.1	18,826	28.6	103	0.2	18,839	28.6	581	0.9	1,577	2.4	62,667	95.1	2,472	3.8	760	1.2				
2020	Unknown	281	35.8	784	0.6	3	0.4	52	6.6	17	2.2	0	0.0	198	25.3	4	0.5	510	65.1	111	14.2	210	26.8	463	59.1				
2021	Female	79,755	82.2	97,049	52.3	164	0.2	51,445	53.0	25,421	26.2	55	0.1	15,282	15.7	558	0.6	4,124	4.2	91,201	94.0	2,549	2.6	3,299	3.4				
2021	Male	71,223	81.0	87,941	47.4	174	0.2	48,925	55.6	19,654	22.3	57	0.1	13,953	15.9	503	0.6	4,675	5.3	81,893	93.1	2,230	2.5	3,818	4.3				
2021	Unknown	86	13.1	659	0.4	0	0.0	54	8.2	3	0.5	0	0.0	52	7.9	3	0.5	547	83.0	92	14.0	27	4.1	540	81.9				

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

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		% Hispanic Latino		% Unknown Not Reported		% Unknown Not Reported	
		Minority	Minority	t	% Total	Native	Native	Asian	% Asian	American	American	Islander	Islander	White	% White	One Race	Race	Reported	Reported	Hispanic	% Not Hispanic	Latino	% Hispanic	Latino	Reported	% Not Reported	Latino	% Hispanic	Reported
2019	Female	15,809	99.4	15,900	55.4	2	0.0	1	0.0	15,798	99.4	1	0.0	90	0.6	1	0.0	7	0.0	15,892	99.9	6	0.0	2	0.0				
2019	Male	12,749	99.5	12,816	44.6	0	0.0	3	0.0	12,739	99.4	0	0.0	66	0.5	1	0.0	7	0.1	12,809	99.9	7	0.1	0	0.0				
2019	Unknown	0	0.0	2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	2	100.0				
2020	Female	44,309	97.9	45,268	52.2	10	0.0	24,895	55.0	19,077	42.1	9	0.0	1,159	2.6	53	0.1	65	0.1	44,957	99.3	296	0.7	15	0.0				
2020	Male	40,284	97.4	41,378	47.8	9	0.0	23,719	57.3	16,178	39.1	6	0.0	1,330	3.2	45	0.1	91	0.2	41,006	99.1	355	0.9	17	0.0				
2020	Unknown	3	100.0	3	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0				
2021	Female	70,328	98.6	71,296	51.9	11	0.0	49,387	69.3	20,597	28.9	9	0.0	1,171	1.6	55	0.1	66	0.1	70,977	99.6	302	0.4	17	0.0				
2021	Male	65,052	98.3	66,146	48.1	10	0.0	47,154	71.3	17,507	26.5	6	0.0	1,334	2.0	46	0.1	89	0.1	65,770	99.4	359	0.5	17	0.0				
2021	Unknown	2	28.6	7	0.0	0	0.0	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	5	71.4	2	28.6	0	0.0	5	71.4				

Figure 1

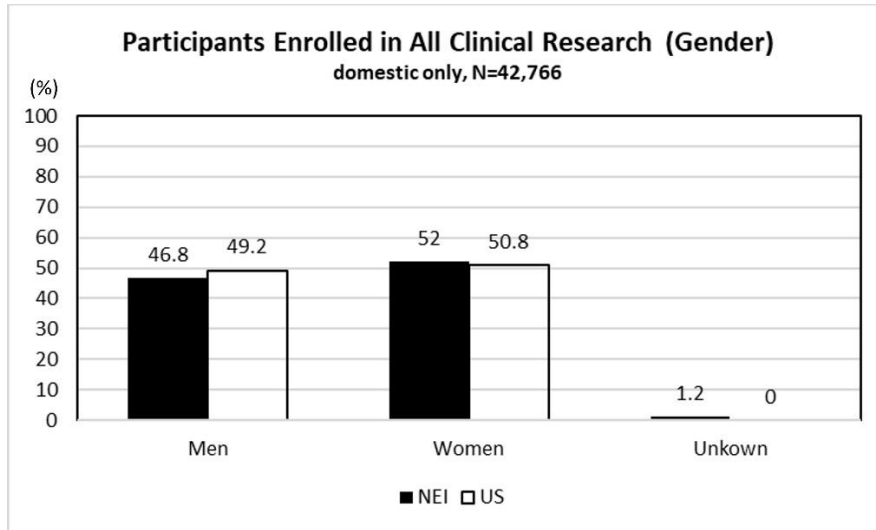


Figure 2

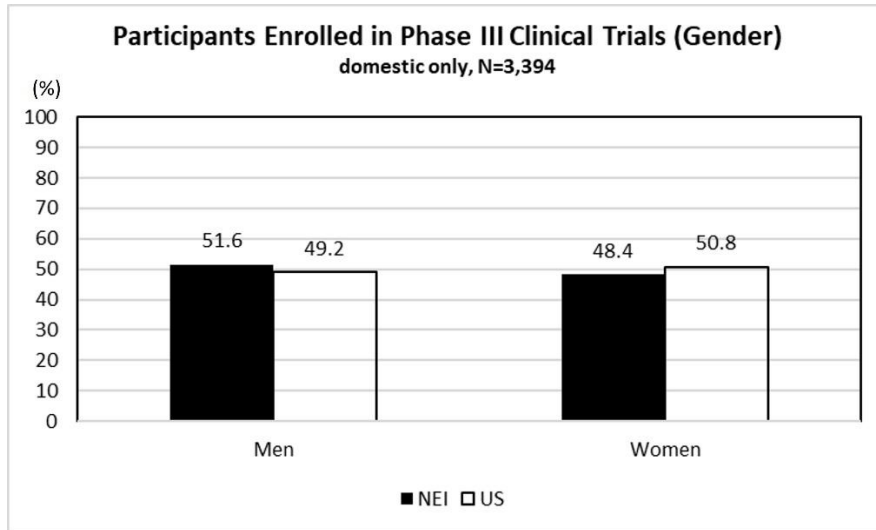


Figure 3

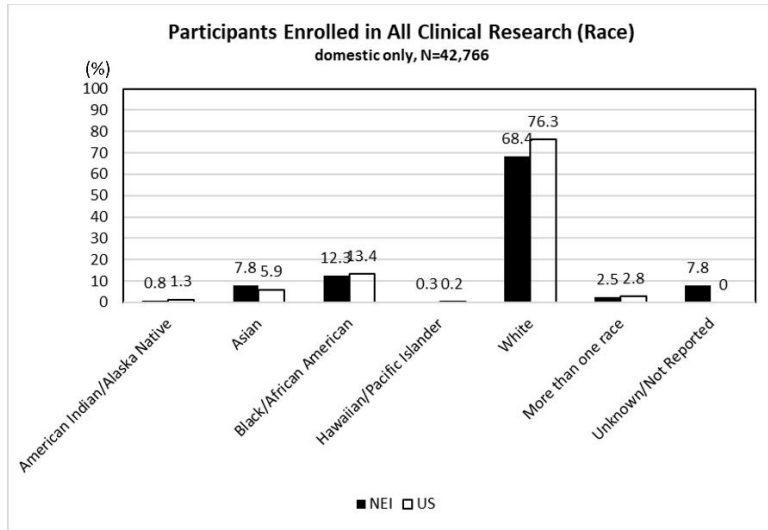


Figure 4

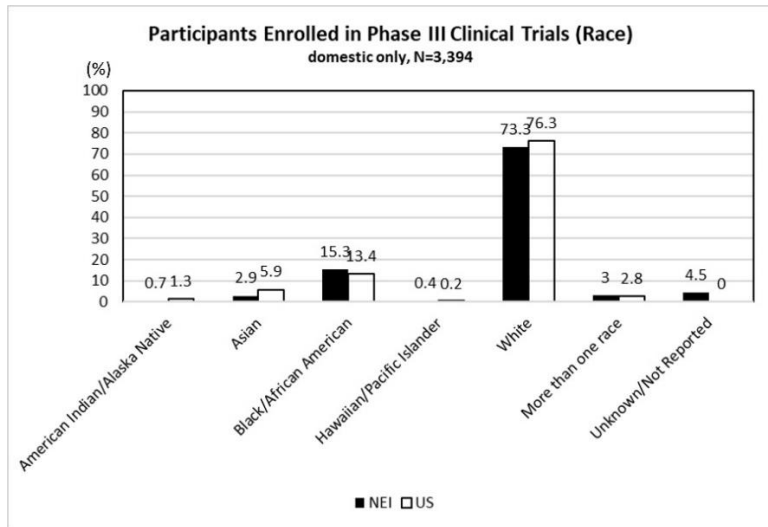


Figure 5

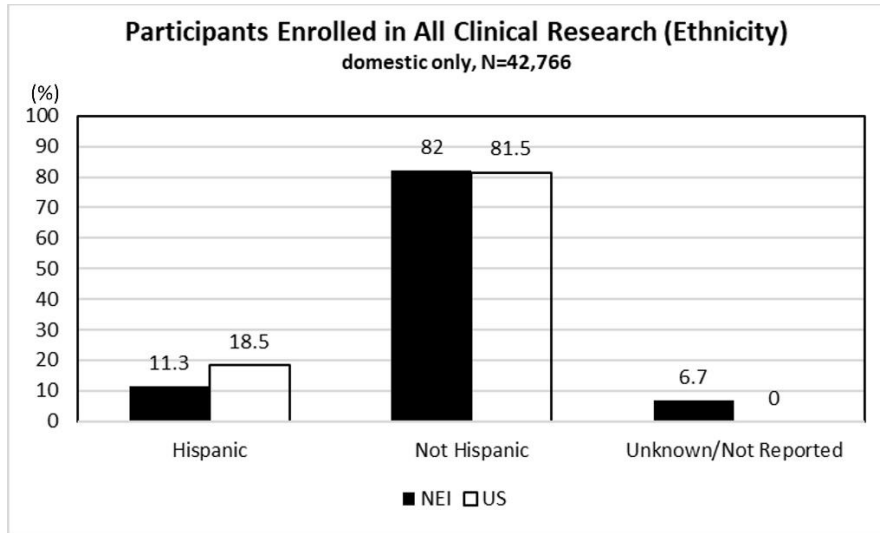
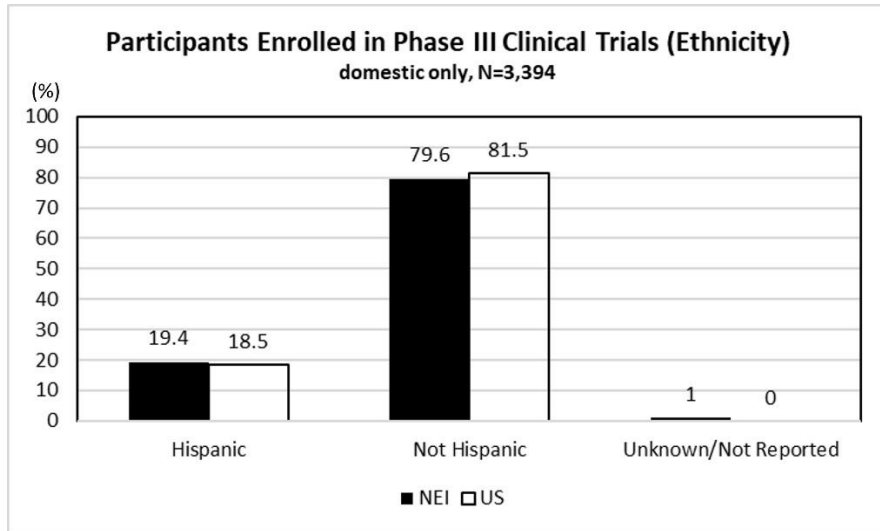


Figure 6



Age Data Based on Inclusion Data Records (IERS)

Table 1. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2021	15,400 37.6%	21,928 53.6%	2,995 7.3%	591 1.4%	40,914 100%

Table 2. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021

Fiscal Year	0-28 Days	29-364 Days	<1 year, values other than 0-28 or 29-364 days *	<1 year, Total **	1-5 Years	6-12 Years	13-15 Years	16-17 Years	18-21 Years	22-25 Years	26-34 Years	35-44 Years	45-54 Years	55-64 Years	65-69 Years	70-74 Years	75-79 Years	80-84 Years	85-89 Years	90+ Years	Unknown or Not Reported	Total
2021	72 0.2%	466 1.1%	54 0.1%	592 1.4%	3,725 9.1%	6,681 16.3%	2,706 6.6%	1,696 4.1%	3,296 8.1%	3,454 8.4%	6,031 14.7%	3,990 9.8%	2,878 7.0%	2,279 5.6%	979 2.4%	860 2.1%	584 1.4%	346 0.8%	145 0.4%	81 0.2%	591 1.4%	40,914 100%

* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.

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