



MEMO

DATE: February 12, 2015
TO: Deputy Director, NIH Office of Extramural Research
FROM: Director, DEA and Executive Secretary, NCAB
SUBJECT: National Cancer Institute Report of FY 2013-14 Inclusion Data

This report includes FY 2013 and FY 2014 Extramural, NIH-defined Phase III, and Intramural clinical research data.

I. Background/Overview

As required by the NIH Revitalization Act of 1993 (PL 103-43), on 12 February 2015 the National Cancer Advisory Board (NCAB) reviewed procedures carried out by the National Cancer Institute to ensure compliance with the NIH guidelines on inclusion of women and minorities as subjects in clinical research studies and the NIH requirements for tracking and reporting enrollment to clinical research studies by ethnicity, race and sex/gender.

• **National Cancer Institute Enrollment Portfolio**

The inclusion data includes epidemiological, population-based interventions and therapeutic trials according to the NIH definition of clinical research and supported by the following NCI Divisions and Centers:

- Division of Cancer Biology (DCB)
- Division of Cancer Control and Population Sciences (DCCPS)
- Division of Cancer Prevention (DCP)
- Division of Cancer Treatment and Diagnosis (DCTD)
- OD, Center to Reduce Cancer Health Disparities (CRCHD)
- OD, Office of Cancer Centers (OCC)
- OD, Office of HIV and AIDS Malignancy (OHAM)
- OD, Small Business Innovation Research Development Center (SBIRDC)

II. Strategies for Ensuring Compliance

The policies and procedures employed by NCI staff to collect, implement, and disseminate information on compliance were reviewed with the Board. Data was presented to the NCAB indicating the overall aggregate accrual to all clinical research as defined by the NIH Office of Extramural Research, as well as subsets of specific types of trials such as observational vs. prevention vs. therapeutic treatment trials. The NCAB was also presented in closed session with summary data on 18 cases in 2013 and 26 cases in 2014 where accrual concerns were coded by initial review groups, and the subsequent outcomes of corrective actions taken to remove such bars to award.

It was emphasized that it is the responsibility of the staff within individual NCI program divisions to work with grantees to assure that the original accrual projections are actually attained as the study progresses, and that data indicating significant differences based on gender, race or ethnicities must be noted in analyses and reports of study outcomes.

- **Peer Review**

Peer reviewers receive instruction on policies and evaluate inclusion plans. Where concerns are noted, bars to award are put in place. NCI staff work with applicants to ensure appropriate revisions are made. Applications with bars are identified in a closed NCAB session, and a subsequent resolution is reported.

- **NCI Training Approaches**

The NCI Accrual Working Group has continued to develop training documents for the NCI staff on inclusion monitoring and tracking. For example, the NIH transitioned the inclusion monitoring from the Population Tracking System to the Inclusion Management System (IMS) in October 2014. Key individuals from each NIH IC were giving training on the new system and policies to ensure consistency across ICs regarding oversight and management of inclusion data in clinical research and clinical trials. NCI's key individuals, in turn, developed documents to train NCI staff on these new changes via classroom hands-on training and webinar training. This training is available to all Program Directors, Program Analysts, and other Program Staff involved or interested in inclusion monitoring.

- **Additional NCI-specific items used to ensure compliance with the inclusion policy**

The designated locus for assuring the data entry and quality of extramural reports is in the NCI Division of Extramural Activities (DEA). Dr. Rajasri Roy serves as Lead NCI Representative to the NIH Inclusion Operating Procedures Workgroup. Dr. Roy and Ms. Clarissa Douglas of the Research Analysis Evaluation Branch organize and coordinate the NCI Accrual Working Group with members from the

extramural program divisions of the NCI (listed at the end). Meetings are held monthly from September to December to resolve reporting issues, reconcile data discrepancies, coordinate training, and communicate policy issues between the NCI Accrual Working Group and the NIH Inclusion Operating Procedures Workgroup.

III. Analysis of Data

1. Total Enrollment for NCI All Clinical Research (Extramural and Intramural Combined) by Sex/Gender, FY 2013 - FY 2014

		Cancer		
	Sex/Gender	Total Enrolled	Percent	Incidence*
2013 2,620 Studies	Female	4,827,206	57.08%	48.3%
	Male	3,595,727	42.52%	51.7%
	Unknown	33,511	0.40%	
	Total	8,456,444	100%	100%
		Cancer		
	Sex/Gender	Total Enrolled	Percent	Incidence*
2014 2,425 Studies	Female	5,152,206	69.28%	48.3%
	Male	2,022,289	27.19%	51.7%
	Unknown	262,821	3.53%	
	Total	7,437,316	100.00%	100.0%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

2. Total Enrollment for NCI All Clinical Research (Extramural and Intramural Combined) by Race/Ethnicity, FY 2013 - FY 2014

Race/Ethnicity	FY 2013 – 2,620 Studies		FY 2014 – 2,425 Studies		US Cancer Incidence**
	2013 Count	2013 Percent	2014 Count	2014 Percent	
White	4,949,173	58.53%	4,280,498	57.55%	81.4%
Asian	773,321	9.14%	534,015	7.18%	6.1%
Black or African American	730,000	8.63%	779,572	10.48%	10.4%
Hispanic or Latino*	(502,487)	(5.94%)	(408,073)	(6.27%)	(9.5%)
More Than One Race	51,733	0.61%	56,221	0.76%	
American Indian/ Alaska Native	25,119	0.30%	22,684	0.31%	0.4%
Hawaiian/Pacific Islander	23,217	0.27%	25,154	0.34%	
Unknown/Not Reported	1,903,881	22.51%	1,739,172	23.38%	
Total	8,456,444	100%	7,437,316	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

3. Total Extramural Enrollment for NIH-defined Phase III Clinical Trials by Sex/Gender, FY 2013 - FY 2014

	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
2013 222 Studies	Female	72,270	56.92%	48.3%
	Male	54,649	43.04%	51.7%
	Unknown	47	0.04%	
	Total	126,966	100%	100%
	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
2014 181 Studies	Female	63,366	57.5%	48.3%
	Male	46,771	42.44%	51.7%
	Unknown	69	0.06%	
	Total	110,206	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

4. Total Extramural Enrollment for NIH-defined Phase III Clinical Trials by Race/Ethnicity, FY 2013 - FY 2014

Race/Ethnicity	FY 2013 –222 Studies		FY 2014 – 181 Studies		US Cancer Incidence**
	2013 Count	2013 Percent	2014 Count	2014 Percent	
White	95,637	75.32%	80,578	73.12%	81.4%
Black or African American	16,033	12.63%	14,194	12.88%	10.4%
Asian	9,738	7.67%	9,730	8.83%	6.1%
Hispanic or Latino*	(7,408)	(5.83%)	(7,491)	(6.8%)	(9.5%)
Unknown/Not Reported	3,970	3.13%	4,255	3.86%	
More Than One Race	778	0.61%	709	0.64%	
American Indian/Alaska Native	554	0.44%	503	0.46%	0.4%
Hawaiian/Pacific Islander	256	0.20%	237	0.22%	
Total	126,966	100.00%	110,206	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

5. Total Enrollment for NCI Extramural Research by Sex/Gender, FY 2013 - FY 2014

NCI Enrollment for FY 2013 and 2014 Extramural Research Studies by Sex/Gender				
	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
2013 2,033 Studies	Female	2,677,294	56.34%	48.3%
	Male	2,067,444	43.51%	51.7%
	Unknown	7,156	0.15%	
	Total	4,751,894	100%	100%
	Sex/Gender	Enrolled**	Percent	US Cancer Incidence*
2014 1,837 Studies	Female	3,017,336	68.60%	48.3%
	Male	1,151,814	26.19%	51.7%
	Unknown	229,040	5.21%	
	Total	4,398,190	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

**An additional 10.5 million secondary analysis data from DCCPS are not included in the overall reported totals.

6. Total Enrollment for NCI Extramural Research by Race/Ethnicity, FY 2013 - FY 2014

Race/Ethnicity	FY 2013 – 2,033 Studies		FY 2014 – 1,837 Studies		US Cancer Incidence**
	2013 Count	2013 Percent	2014 Count***	2014 Percent	
White	3,240,056	68.18%	2,950,325	67.08%	81.4%
Asian	562,949	11.85%	567,709	12.91%	6.1%
Black or African American	480,777	10.12%	435,433	9.90%	10.4%
Hispanic or Latino*	(380,587)	(8.0%)	(314,478)	(7.15%)	(9.5%)
Unknown/Not Reported	380,562	8.01%	350,291	7.96%	
More Than One Race	49,410	1.04%	54,120	1.23%	
Hawaiian/Pacific Islander	20,413	0.43%	22,330	0.51%	
American Indian/ Alaska Native	17,727	0.37%	17,982	0.41%	0.4%
Total	4,751,894	100.00%	4,398,190	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

***An additional 10.5 million secondary analysis data from DCCPS are not included in the overall reported totals.

7. Total Enrollment for NCI Intramural Research Studies by Sex/Gender, FY 2013 - FY 2014

	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
2013 587 Studies	Female	2,149,912	58.03%	48.3%
	Male	1,528,283	41.25%	51.7%
	Unknown	26,355	0.71%	
	Total	3,704,550	100%	100%
	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
2014 588 Studies	Female	2,134,870	70.25%	48.3%
	Male	870,475	28.64%	51.7%
	Unknown	33,781	1.11%	
	Total	3,039,126	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

8. Total Enrollment for NCI Intramural Research Studies by Race/Ethnicity, FY 2013 - FY 2014

Race/Ethnicity	FY 2013 – 587 Studies		FY 2014 – 588 Studies		US Cancer Incidence**
	2013 Count	2013 Percent	2014 Count	2014 Percent	
White	1,709,117	46.1%	1,330,173	43.8%	81.4%
Black or African American	249,223	6.7%	98,582	3.2%	10.4%
Asian	210,372	5.7%	211,863	7.0%	6.1%
Hispanic or Latino*	(121,900)	(3.3%)	(93,595)	(3.1%)	(9.5%)
American Indian/ Alaska Native	7,392	0.2%	4,702	0.2%	0.4%
Hawaiian/Pacific Islander	2,804	0.1%	2,824	0.1%	
More Than One Race	2,323	0.1%	2,101	0.1%	
Unknown/Not Reported	1,523,319	41.1%	1,388,881	45.7%	
Total	3,704,550	100%	3,039,126	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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National Cancer Advisory Board

Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2015

NIH Policy on Inclusion of Women and Minorities in Clinical Research

Why does NIH have this policy?

- Mandated by Congress in 1993, Public Law 103-43.
- Ethical principle of justice and importance of balancing research burdens and benefits.

Public Law PL 103-43

- Women and minorities must be included in all clinical research studies.
- Women and minorities must be included in Phase III clinical trials, and the trial must be designed to permit valid analysis.
 - For the purpose of this policy, Valid Analysis means an unbiased assessment that does not require high statistical power and should be conducted for both large and small studies.

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Public Law PL 103-43

- Cost is not allowed as an acceptable reason for exclusion.
- NIH supports outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies.

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NIH Revitalization Act of 1993

“The Advisory Council of each National Institute shall prepare biennial reports describing the manner in which the institute has complied with this section.”

- Reported in odd-numbered years.

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NIH Report Approach

A summary report is prepared centrally by the NIH Office of Extramural Research and includes a statement that the NCAB reviews.

- NCI procedures for implementation of the NIH policy for inclusion of women and minorities in clinical studies.
- The results of that implementation.
- NCI compliance.

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NCI Coordination Division of Extramural Activities

Implements Inclusion Policy at NCI

- Institute-wide coordination and communication
- Accrual Working Group –Division Reps
- Information, Training, Problem Solving

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NCI Procedures for Implementation of NIH Policy

POLICY DISSEMINATION

- ESAs work with applicants to disseminate requirements (*NIH Guide and NCI and NIH Websites*).
- NCI extramural staff are kept up-to-date via trans-NIH education programs and desktop distribution of policies and procedures.

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NCI Procedures for Implementation of NIH Policy

PRE-AWARD ACTIVITIES

- Peer reviewers receive instruction on policies and evaluate inclusion plans.
- Where concerns are noted, bars to award are put in place. NCI staff work with applicants to ensure appropriate revisions are made.
- Applications with bars are identified in a closed NCAB session, and a subsequent resolution is reported.

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NCI Procedures for Implementation of NIH Policy

POST-AWARD MONITORING

- Awardees report cumulative accrual annually.
- Progress of studies and cumulative accruals are reviewed by Program Directors.
- Target and enrollment numbers are entered into the NIH Population Tracking application.
- Staff provide oversight, advice, and assistance and work with awardees to disseminate findings and encourage new studies.

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NCI Procedures for Implementation of NIH Policy

AGGREGATE REPORTING

- NIH requires a format that aggregates all clinical trials whether treatment, behavioral, or epidemiologic observation.
 - Individual clinical trials vary considerably.
 - Large population-based screening trials dominate aggregate data.

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Instructions in PHS 398

Inclusion of women and minorities sections **must** include:

- Subject selection criteria and rationale.
- Rationale for any exclusions.
- Enrollment dates (start and end).
- Outreach plans for recruitment.
- Proposed composition using tables.

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Accrual to NCI Clinical Trials

- Data include epidemiological, population-based interventions and therapeutic trials according to the NIH definition of clinical research.
- Subset analyses by race, ethnicity, and sex/gender are required of all Phase III clinical trials with initial funding after 1995.
- Current reporting cycle covers data reported in FY2013 and 2014, which represents subjects enrolled in FY2012 and 2013.

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Requirements for NIH-Defined Phase III Clinical Trials

Definition: Broadly based prospective Phase III clinical investigation,

- usually involving several hundred or more human subjects,
- for the purpose of evaluating an experimental intervention or comparing two or more existing treatments.
- Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

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US Incidence for All Cancers 2007-2011

	White	Black	Asian/ PI	American Indian	Total (All Races/ Sexes)	Hispanic **
Incidence Rate per 100,000*	468.9	480.8	306.7	319.3	460.4	353.2
Number of Incidence Cases	1,628,476	208,379	121,493	7,934	2,001,481	190,832
Estimated Percent of Total*	81.4%	10.4%	6.1%	0.4%	100%	9.5%

*US Cancer Percent estimated from SEER Number of Incidence Cases for 2007-2011.

**Hispanic incidence included in other categories.

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NCI Enrollment for FY 2013 and 2014 Extramural Research Studies by Sex/Gender

2013 2,033 Studies	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
	Female	2,677,294	56.34%	48.3%
	Male	2,067,444	43.51%	51.7%
	Unknown	7,156	0.15%	
	Total	4,751,894	100%	100%
2014 1837 Studies	Sex/Gender	Enrolled	Percent	US Cancer Incidence*
	Female	3,017,336	68.6%	48.3%
	Male	1,151,814	26.2%	51.7%
	Unknown	229,040	5.2%	
	Total	4,398,190	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011

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NCI Sex/Gender Enrollments FY 2013 and 2014 excluding All Male and All Female Studies

2013 -1424 Studies	Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
	Female	1,435,030	57.8%	48.3%
	Male	1,041,138	41.9%	51.7%
	Other/Unknown	7,156	0.3%	
	Total	2,483,324	100%	100%
2014 -1318 Studies	Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
	Female	1,431,549	56.0%	48.3%
	Male	881,103	35.0%	51.7%
	Other/Unknown	229,040	9.0%	
	Total	2,541,692	100%	100%

Subset of studies reported for 2013 and 2014; Studies include both Males and Females.

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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NCI Extramural Research Studies by Race/Ethnicity FY 2013 – 2,033 Studies FY 2014 – 1,837 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	3,240,056	68.18%	2,950,325	67.08%	81.4%
Asian	562,949	11.85%	567,709	12.91%	6.1%
Black or African American	480,777	10.12%	435,433	9.90%	10.4%
Hispanic or Latino*	(380,587)	(8.01%)	(314,478)	(7.15%)	(9.5%)
Unknown/Not Reported	380,562	8.0%	350,291	7.96%	
More Than One Race	49,410	1.04%	54,120	1.23%	
Native Hawaiian/ Pacific Islander	20,413	0.43%	22,330	0.51%	
American Indian/ Alaska Native	17,727	0.37%	17,982	0.41%	0.4%
Total	4,751,894	100%	4,398,190	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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**FY 2013 and 2014 NCI Enrollment
Extramural Phase III Research Studies (Only)
by Sex/Gender**

	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2013 222 Trials	Female	72,270	56.92%	48.3%
	Male	54,649	43.04%	51.7%
	Unknown	47	0.04%	
	Total	126,966	100%	100%
	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2014 181 Trials	Female	63,366	57.5%	48.3%
	Male	46,771	42.44%	51.7%
	Unknown	69	0.06%	
	Total	110,206	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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NCI Extramural Phase III Research Studies (Only)
FY 2013 – 222 Studies FY 2014 – 181 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	95,637	75.32%	80,578	73.12%	81.4%
Black or African American	16,033	12.63%	14,194	12.88%	10.4%
Asian	9,738	7.67%	9,730	8.83%	6.1%
Hispanic or Latino*	(7,408)	(5.83%)	(7,491)	(6.8%)	(9.5%)
Unknown/Not Reported	3,970	3.13%	4,255	3.86%	
More Than One Race	778	0.61%	709	0.64%	
Amer. Indian/Alaska Native	554	0.44%	503	0.46%	0.4%
Hawaiian/Pacific Islander	256	0.2%	237	0.22%	
Total	126,966	100%	110,206	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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NCI Intramural Research Studies

FY 2013– 587 Studies

FY 2014 – 588 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	1,709,117	46.1%	1,330,173	43.8%	81.4%
Black or African American	249,223	6.7%	98,582	3.2%	10.4%
Asian	210,372	5.7%	211,863	7.0%	6.1%
Hispanic or Latino*	(121,900)	(3.3%)	(93,595)	(3.1%)	(9.5%)
American Indian/ Alaska Native	7,392	0.2%	4,702	0.2%	0.4%
Hawaiian/Pacific Islander	2,804	0.1%	2,824	0.1%	
More Than One Race	2,323	0.1%	2,101	0.1%	
Unknown/Not Reported	1,523,319	41.1%	1,388,881	45.7%	
Total	3,704,550	100%	3,039,126	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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CTEP Treatment Trials Enrollment

FY 2013 – 466 Studies

FY 2014 – 392 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	19,717	82.02%	16,074	81.01%	81.4%
Hispanic or Latino*	(2,232)	(9.28%)	(1,794)	(9.04%)	(9.5%)
Black or African American	2,021	8.41%	1,688	8.51%	10.4%
Unknown/ Not Reported	1,099	4.57%	979	4.93%	
Asian	941	3.91%	909	4.58%	6.1%
American Indian/ Alaska Native	123	0.51%	107	0.54%	0.4%
Native Hawaiian/ Pacific Islander	85	0.35%	55	0.28%	
More Than One Race	53	0.22%	29	0.15%	
Total	24,039	100%	19,841	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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CTEP Treatment Trials Enrollment by Gender

		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2013	466 Studies	Female	14,479	60.23%	48.3%
		Male	9,539	39.68%	51.7%
		Unknown	21	0.09%	
		Total	24,039	100%	100%
		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2014	392 Studies	Female	11,102	55.95%	48.3%
		Male	8,731	44.00%	51.7%
		Unknown	8	0.04%	
		Total	19,841	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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CTEP Treatment Trials Enrollment by Gender (excluding Gender Specific Trials)

		Sex/Gender	2013 Count	Percent of Total	US Cancer Incidence*
FY 2013	357 Studies	Male	8,051	56.06%	48.3%
		Female	6,299	43.79%	51.7%
		Unknown	21	0.15%	
		Total	14,371	100%	100%
		Sex/Gender	2014 Count	Percent of Total	US Cancer Incidence*
FY 2014	315 Studies	Male	7,147	58.69%	48.3%
		Female	5,024	41.26%	51.7%
		Unknown	6	0.05%	
		Total	12,177	100%	100%

Subset of studies reported for 2013 and 2014. Studies include both Males and Females.

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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DCP Trials Enrollment

2013 – 60 Studies

2014 – 60 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	7,755	84.1%	5,159	82.5%	81.4%
Black or African American	906	9.8%	574	9.2%	10.4%
Hispanic or Latino*	(662)	(7.2%)	(449)	(7.2%)	(9.5%)
Asian	263	2.9%	232	3.7%	6.1%
Unknown/ Not Reported	181	2.0%	209	3.3%	
American Indian/ Alaska Native	48	0.5%	48	0.8%	0.4%
Native Hawaiian/ Pacific Islander	22	0.2%	9	0.1%	
More Than One Race	42	0.5%	24	0.4%	
Total	9,217	100%	6,255	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

** US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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DCP Trials Enrollment by Gender

	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2013 60 Studies	Female	6,186	67.1%	48.3%
	Male	3,031	32.9%	51.7%
	Unknown	0	0%	
	Total	9,217	100%	100%
FY 2014 60 Studies	Female	4,689	75.0%	48.3%
	Male	1,566	25.0%	51.7%
	Unknown	0	0%	
	Total	6,255	100%	100%

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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DCP Trials Enrollment by Gender (excluding Gender Specific Trials)

	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2013 32 Studies	Female	2,518	74.0%	48.3%
	Male	886	26.0%	51.7%
	Unknown	0	0%	
	Total	3,404	100%	100%
	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2014 33 Studies	Female	1,560	53.9%	48.3%
	Male	1,336	46.1%	51.7%
	Unknown	0	0%	
	Total	2,896	100%	100%

Subset of studies reported for 2013 and 2014; Studies include both Males and Females.

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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DCCPS Epidemiology Studies by Gender

	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2013 369 Studies	Female	2,136,223	58.3%	48.3%
	Male	1,522,453	41.6%	51.7%
	Unknown	3,519	0.1%	
	Total	3,662,195	100%	100%
	Sex/Gender	Count**	Percent of Total	US Cancer Incidence*
FY 2014 354 Studies	Female	8,253,016	59.2%	48.3%
	Male	4,993,379	35.8%	51.7%
	Unknown	693,192	5.0%	
	Total	13,939,587	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

**SEER and Medicare pre-existing Data.

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DCCPS Epidemiology Studies

2013 – 369 Studies

2014 – 354 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count***	2014 Percent	US Cancer Incidence**
White	2,451,743	66.9%	10,512,922	75.4%	81.4%
Black or African American	372,180	10.2%	1,302,240	9.3%	10.4%
Hispanic or Latino*	231,889	(6.3%)	(913,117)	(6.6%)	(9.5%)
Asian	468,370	12.8%	905,952	6.5%	6.1%
Unknown/ Not Reported	326,912	8.9%	900,332	6.5%	
American Indian/ Alaska Native	13,471	0.4%	61,008	0.5%	0.4%
Native Hawaiian/ Pacific Islander	3,795	0.1%	63,854	0.5%	
More Than One Race	25,724	0.7%	193,279	1.4%	
Total	3,662,195	100%	13,939,587	100%	100%

*Hispanic or Latino counts are not exclusive and may be included in other categories.

** US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

***Observational Study with increased years reported.

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