DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
3rd VIRTUAL NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
February 12, 2015

Virtual
Building 31C, Conference Room 10
National Institutes of Health
Bethesda, Maryland

NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
February 12, 2015

The National Cancer Advisory Board (NCAB) convened for its 3rd virtual regular meeting on 12 February 2015. NCAB members attended virtually, and NCI staff attended in Conference Room 10, C Wing, Building 31, National Institutes of Health (NIH), Bethesda, MD. The meeting was open to the public on Thursday, 12 February 2015, from 9:00 a.m. to 9:50 a.m., and closed to the public from 9:50 a.m. to 10:30 a.m. The NCAB Chair, Dr. Tyler E. Jacks, Director, Koch Institute for Integrative Cancer Research, David H. Koch Professor of Biology, Massachusetts Institute of Technology, presided during both the open and closed sessions.

NCAB Members

Dr. Tyler E. Jacks (Chair)
Dr. David C. Christiani
Dr. Marcia R. Cruz-Correa
Dr. Kevin J. Cullen
Dr. Judy E. Garber
Dr. Elizabeth M. Jaffee
Dr. Beth Y. Karlan
Dr. Olufunmilayo I. Olopade (absent)
Dr. Mack Roach, III
Dr. Jonathan M. Samet
Dr. Charles L. Sawyers (absent)
Dr. William R. Sellers (absent)

Alternate *Ex Officio* NCAB Members

Dr. Michael A. Babich, CPSC (absent)
Dr. Vincent J. Cogliano, EPA (absent)
Dr. Michael Kelley, VA (absent)
Dr. Aubrey Miller, NIEHS (absent)
Dr. Richard Pazdur, FDA (absent)
Dr. Craig D. Shriver, DoD (absent)
Dr. Michael Stebbins, OSTP (absent)
Dr. Marie Sweeney, NIOSH (absent)
Dr. Lawrence Tabak, NIH (absent)
Dr. Richard Thomas, DOL (absent)
Dr. Sharlene Weatherwax, DOE (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Harold Varmus, Director, National Cancer Institute
Dr. Jeff Abrams, Co-Director, Division of Cancer Treatment and Diagnosis
Dr. Lynn Austin, Executive Officer, Deputy Director for Management
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
Dr. James Doroshow, Deputy Director for Clinical and Translational Research
Dr. Daniela S. Gerhard, Director, Office of Cancer Genomics
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Peter Greenwald, Associate Director for Prevention
Dr. Ed Harlow, Special Assistant for Science Planning
Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research
Dr. Warren Kibbe, Director, NCI Center for Bioinformatics and Information Technology
Dr. Barry Kramer, Director, Division of Cancer Prevention
Dr. Douglas R. Lowy, Deputy Director, National Cancer Institute
Dr. Alan Rabson, Deputy Director, National Cancer Institute
Dr. Dinah Singer, Director, Division of Cancer Biology
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis Staudt, Director, Center for Cancer Genomics
Dr. Joseph Tomaszewski, Co-Director, Division of Cancer Treatment and Diagnosis
Dr. Ted Trimble, Director, Center for Global Health
Mr. Michael Weingarten, Director, Small Business Innovation Research
Dr. Linda Weiss, Director, Office of Cancer Centers
Dr. Jonathan Wiest, Director, Center for Cancer Training
Dr. Robert Wiltrout, Director, Center for Cancer Research
Ms. Joy Wiszneauckas, Executive Secretary, Office of the Director
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy

Liaison Representatives

Ms. Carolyn Aldige, Cancer Research and Prevention Foundation
Dr. Carolyn Best, American Urological Association
Ms. Paula Bowen, Kidney Cancer Association
Dr. Susan Braun, National Cancer Institute, Director's Consumer Liaison Group
Mr. William Bro, Kidney Cancer Association
Dr. Carol Brown, Society of Gynecologic Oncologists
Mr. Matthew Farber, Association of Community Cancer Centers
Dr. Margaret Foti, American Association for Cancer Research
Dr. Francis Giardiello, American Gastroenterological Association
Dr. Mary Gullatte, Oncology Nursing Society
Ms. Shandi E. Hill, American Society of Therapeutic Radiology and Oncology
Ms. Ruth Hoffman, Candlelighters Childhood Cancer Foundation
Dr. Gerald F. Joseph, Jr., American College of Obstetricians and Gynecologists
Ms. Rebecca A. Kirch, American Cancer Society
Dr. Steven Klein, National Science Foundation
Ms. Laura Levit, American Society of Clinical Oncology
Dr. W. Marston Linehan, Society of Urologic Oncology
Ms. Margo Michaels, Education Network to Advance Cancer Clinical Trials
Dr. Patricia Mullan, American Association for Cancer Education
Ms. Christy Schmidt, American Cancer Society

Ms. Susan Silver, National Coalition for Cancer Survivorship
Ms. Barbara Duffy Stewart, Association of American Cancer Institutes
Dr. Johannes Vieweg, American Urological Association
Ms. Pamela Wilcox, American College of Radiology
COL (Ret.) James E. Williams, Jr., Intercultural Cancer Council

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THURSDAY, 12 FEBRUARY 2015

THURSDAY, FEBRUARY 12, 2015

I. CALL TO ORDER AND OPENING REMARKS—DR. TYLER E. JACKS

Dr. Tyler E. Jacks called to order the 3rd virtual NCAB meeting. Dr. Jacks welcomed members of the Board, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Jacks reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to approve the NCAB meeting dates for 2016 was approved unanimously.

Motion. A motion to accept the minutes of the December 2, 2014, Joint Boards meeting was approved unanimously.

II. FUTURE BOARD MEETING DATES—DR. TYLER E. JACKS

Dr. Jacks called Board members' attention to the future meeting dates listed on the agenda.

III. NCI DIRECTOR'S REPORT—DR. HAROLD E. VARMUS

Dr. Harold E. Varmus, Director, NCI, welcomed members and expressed congratulations to Dr. Jacks on his reappointment as NCAB Chair. Dr. Varmus said that the fiscal year (FY) 2015 appropriations increased by one-half of a percent over the FY 2014 level. The FY 2016 President's Budget (PB) proposes a 2.3-percent increase for the NIH overall, which would restore the NIH budget to the FY 2012 level. Members were told that the PB includes $200 million (M) for the new Precision Medicine Initiative (PMI), of which approximately $130 M would fund a proposed Cohort Study to enroll 1 million members. The nature of the Cohort Study is under discussion, and will be overseen by an external committee under the leadership of Dr. Richard Lifton. He said that the proposed PMI budget designates $70 M for oncology work in precision medicine and will encompass expanded efforts in genomics activities; a pediatric Molecular Analysis for Therapy Choice (MATCH) trial and other trials focused on certain common cancers; improved understanding of cancer biology, such as through support for preclinical models, to better match drug therapies to cancers; and accelerated development of tools to assist with the processing and use of large amounts of genomic and clinical data. Members were told that that the House Appropriations Subcommittee will meet on March 3 regarding FY 2016 appropriations.

Dr. Varmus stated that the NCI-designated Cancer Centers Directors met on February 10 and discussed ways to share Cancer Centers' core facilities, the use of supplementary funding to support global health, and budget reallocation. He noted the upcoming retirement of Dr. Linda Weiss, Director, Office of Cancer Centers, and expressed thanks for her years of service.

Questions and Answers

In response to a query by Dr. Jacks regarding the PMI plans for preclinical model designs for new platforms for drug testing, Dr. Varmus said that efforts will build on existing initiatives to develop patient-derived xenografts (PDXs) and grants for studies of organoids and induced cancer stem cell cultures. The implementation of the ideas is under discussion and involves input from the White House, Office of Science and Technology Policy (OSTP), and the U.S. Food and Drug Administration (FDA), with topics of interest including therapeutic combinations to address drug resistance, and diagnostic testing regulations to support the development of genetic platforms. He noted the need for appropriations to be made for the PMI to commence and remarked on the bipartisan support for precision medicine.

IV. BIENNIAL INCLUSION REPORT—DR. JEFF ABRAMS

Dr. Jeff Abrams, Co-Director, Division of Cancer Treatment and Diagnosis (DCTD), explained that the NIH policy on the inclusion of women and minorities in all clinical research studies, particularly Phase III clinical trials, was mandated by Congress in 1993 (P.L. 103-43), in espousal of the ethical principle of justice and of the importance of balancing research burdens and benefits. Dr. Abrams stated that the policy requires that women and minorities be included in all clinical research studies, including Phase III clinical trials, and that cost is not allowed as an acceptable reason for exclusion. The NIH Revitalization Act of 1993 requires the preparation of biennial reports that describe the NIH Institutes and Centers' (IC) compliance with this requirement. He described the process for preparing the biennial report and the role of the DEA in implementing the policy.

Dr. Abrams described the NCI's implementation procedures. During the pre-award phase of the grant application process, peer reviewers receive instructions and evaluate inclusion plans for all applications. 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. During the post-award phase, awardees report cumulative accrual annually, with Program Directors reviewing progress of studies and cumulative accruals. This information is entered into the NIH Population Tracking application. Staff provide oversight, advice, and assistance and work with awardees to disseminate findings and encourage new studies. Inclusion of women and minorities sections must include subject selection criteria and rationale, rationale for any exclusions, enrollment dates (start and end), and outreach plans for recruitment. The NCI is required to aggregate these data whether the clinical trial is a treatment or behavioral trial or an epidemiological observation trial, as well as subset analyses by race, ethnicity, and sex/gender for all Phase III clinical trials with initial funding after 1995. The current report cycle covers data reported in FY 2013–2014, which represents subjects enrolled in FY 2012–2013.

Members were informed about overall reporting data, including data specifically for cancer treatment trials. NCI enrollment by gender during 2013–2014 showed an aggregate of more than 4 million per year, which is dominated by large observational cohorts. Based on U.S. cancer incidence, a higher percentage of women is enrolled than men, a trend that also is seen when gender-specific studies are excluded. Enrollment data by racial composition compared to the U.S. cancer incidence show highest minority accrual of the Asian and African American populations, with a little underrepresentation of the Hispanic population. The NCI intramural research studies enrolled approximately 3.7 million cases in 2013 and 3 million cases in 2014, including close to 1.5 million cases of unknown race/ethnicity from ongoing studies. Enrollment data for Cancer Therapy Evaluation Program (CTEP) treatment trials show a drop in accrual by race in 2014, with a cancer incidence rate that matches the U.S. population. For the Division of Cancer Prevention (DCP), trial data indicate relative balance by gender but a slight under-representation of Hispanics and Asian Americans during 2013–2014. The Division of Cancer Control and Population Sciences (DCCPS) accrual to large epidemiologic studies, including social networks and the spread of cancer care practices studies, totaled nearly 13 million patients enrolled in 2014, with both genders represented, as well as reasonable proportions of African Americans, Hispanics, and Asians.

Questions and Answers

Dr. Cullen [For consistency with other minutes, SCG should include his full name, title and affiliation]asked about the constitution of CTEP treatment trials. Dr. Abrams confirmed that the CTEP trials reported are interventional trials and not correlative studies.

Dr. Roach re[For consistency with other minutes, SCG should include his full name, title and affiliation quested information about trends in the inclusion of women and minorities in NCI's clinical research to indicate improvements or issues during the past 2 years. Dr. Abrams stated that although some fluctuation occurs between years, accrual percentages have remained mostly the same during the past 6 years.

Motion. A motion to accept the report of the Biennial Review of Inclusion of Women and Minorities in Clinical Research was approved unanimously.

V. ANNUAL DELEGATIONS OF AUTHORITY—DR. PAULETTE S. GRAY

Dr. Gray r[For consistency with other minutes, SCG should include her full name, title and affiliation equested concurrence by the NCAB on two Delegations of Authority to the Director of the NCI. She described the delegations and the provisions in the Statement of Understanding. Delegation A allows the Director to obtain the services of not more than 151 special experts or consultants who have scientific or professional qualifications. Dr. Gray also said that Delegation B specifies that the NCAB delegates to the NCI Director can appoint advisory committees composed of private citizens and officials of Federal, state, and local governments to advise the Director with respect to his functions.

The Statement of Understanding with NCI Staff on Operating Principles in Extramural Grants also falls within the Delegations of Authority to the Director, NCI. NCAB operations are conducted in accordance with management and review procedures described in the NIH Manual Issuance 4513. Concurrence of the NCAB with recommendations of initial review groups will be required, except for the following: (1) Training grants and fellowships and other non-research grant applications are not subject to NCAB review and approval, and without other concerns may be awarded without presentation to the NCAB for concurrence, with the exception of Ruth L. Kirschstein National Research Service Awards. (2) Applications over the 50th percentile will not have summary statements presented to the NCAB unless the Institute is considering an award of such an application or other special consideration is required, requested, or required by NCI or NIH policy or for special consideration by an appointed member of the Board. (3) For applications assigned raw scores that are not percentiled, the cutoff will be a priority impact score of 50 for all mechanisms except R41, R42, R43, and R44 awards; for the latter, all scored applications will be included. Expedited Concurrence: (1) for R01 and R21 applications with percentiled or raw scores that fall within the NCI paylines for that mechanism, a process of expedited concurrence will be used; and (2) the Executive Secretary will alert Board members with responsibility for expedited concurrence when review outcomes for eligible applications are available on the Electronic Expedited Concurrence portion of the Electronic Council Book. Administrative Adjustments: (1) Permission is delegated to the Director, NCI, to allow staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards. (2) Administrative requests for increases in direct costs that are the result of marked expansion or significant change in the scientific content of a program after formal peer review will be referred to the Board for advice and recommendation. (3) Actions not requiring Board review or advice, such as change of institution, change of PI, phase-out of interim support, or additional support, need not be reported to the Board. (4) NCI staff may restore requested time and support that were deleted by the initial review group when justified by the PI in an appeal letter or when restoration is in the best interest of the NCI and the project is of high NCI programmatic relevance.

In an effort to continue responsible stewardship of public funds, the NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators. Applications from PIs who have $1 M or more in direct costs from active NIH Research Project Grants (RPGs) must be given additional consideration.

Motion. A motion to approve the NCI Annual Delegations of Authority was approved unanimously.

VII. CLOSED SESSION—DR. TYLER E. JACKS

"This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 552b(c)(6), Title 5 U.S. code and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2)."

Members were instructed to exit the room if they deemed that their participation in the deliberation of any matter before the Board would be a real conflict or that it would represent the appearance of a conflict. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect.

En bloc: The NCAB en bloc vote for concurrence with IRG recommendations was unanimous. During the closed session, a total of 2,563 NCI applications requesting direct cost support of $$778,867,825 were reviewed.

X. ADJOURNMENT— DR. TYLER E. JACKS

Dr. Jacks thanked all of the Board members, as well as all of the visitors and observers, for attending.

There being no further business, the 3rd virtual meeting of the NCAB was adjourned at 10:30 a.m. on Thursday, 12 February 2015.

_____ _____

Date Tyler E. Jacks, M.D., Chair

_____ _____

Date Paulette S. Gray, Ph.D., Executive Secretary

National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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

FY 2013
222 Trials

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	72,270	56.92%	48.3%
Male	54,649	43.04%	51.7%
Unknown	47	0.04%	
Total	126,966	100%	100%

FY 2014
181 Trials

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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.

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.

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.

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.

CTEP Treatment Trials Enrollment by Gender

FY 2013

466 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	14,479	60.23%	48.3%
Male	9,539	39.68%	51.7%
Unknown	21	0.09%	
Total	24,039	100%	100%

FY 2014

392 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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.

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

FY 2013

357 Studies

Sex/Gender	2013 Count	Percent of Total	US Cancer Incidence*
Male	8,051	56.06%	48.3%
Female	6,299	43.79%	51.7%
Unknown	21	0.15%	
Total	14,371	100%	100%

FY 2014

315 Studies

Sex/Gender	2014 Count	Percent of Total	US Cancer Incidence*
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.

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.

DCP Trials Enrollment by Gender

FY 2013

60 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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.

DCP Trials Enrollment by Gender
(excluding Gender Specific Trials)

FY 2013

32 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	2,518	74.0%	48.3%
Male	886	26.0%	51.7%
Unknown	0	0%	
Total	3,404	100%	100%

FY 2014

33 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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.

DCCPS Epidemiology Studies by Gender

FY 2013

369 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
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%

FY 2014

354 Studies

Sex/Gender	Count**	Percent of Total	US Cancer Incidence*
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.

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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