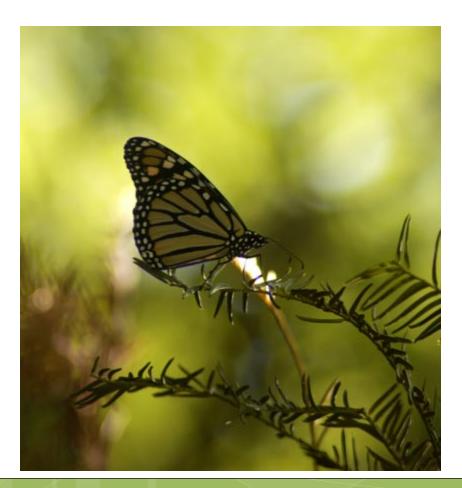
OF WOMEN, MINORITIES & CHILDREN IN CLINICAL TRIALS

JUDITH S KAUR, M.D. MAYO - ROCHESTER

Financial Disclosure

I have no conflicts to disclose



Alliance Inclusion Enrollment Report for Treatment Studies Report Period = 2/1/2013 - 1/31/2014

Total Enrollment: 7696

Part A. Total Enrollment Report: Number of Subjects Enrolled to Date by Ethnicity and Race

							Percentage
					Percentage	Percentage	(Excluding
					Unknown or	Unknown or	Unknown or
			Unknown or		Not Reported	Not Reported	Not Reported
Ethnic Category	Females	Males	Not Reported	Total	Gender	Ethicity	Ethnicity)
Hispanic or Latino	234	106	1	341	0.01%		4.69%
Not Hispanic or Latino	4748	2076	108	6932	1.40%		95.31%
Not reported: Patient refused or data not available	26	18	114	158	1.48%	2.05%	
Unkown: Patient is unsure of their ethnicity	181	74	10	265	0.13%	3.44%	
Totals:	5189	2274	233	7696	3.03%	5.50%	
Totals - excluding Unknown or Not reported:	4982	2182	109	7273		·	100.00%

Part B. Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

							Percentage
					Percentage	Percentage	Excluding
					Unknown or	Hispanic	Hispanic
			Unknown or		Not Reported	Unknown or	Unknown or
Race	Females	Males	Not Reported	Total	Gender	Not Reported	Not Reported
American Indian or Alaska Native	5	1	0	6	0.00%		2.20%
Asian	4	0	0	4	0.00%		1.47%
Native Hawaiian or Other Pacific Islander	1	1	0	2	0.00%		0.73%
Black or African American	4	3	0	7	0.00%		2.56%
White	162	91	1	254	0.29%		93.04%
Not reported: patient refused or not available	2	2	0	4	0.00%	1.17%	
More than one race	0	0	0	0	0.00%		0.00%
Unknown: Patient unsure	56	8	0	64	0.00%	18,77%	
Totals:	234	106	1	341	0.29%	19.94%	
Totals - excluding Unknown or Not reported:	176	96	1	273			100.00%

1	1	I	ı		Unknown or	HISDANIC	Hispanic
			Unknown or		Not Reported		•
Race	Females	Males	Not Reported	Total	Gender	Not Reported	Not Reported
American Indian or Alaska Native	5	1	0	6	0.00%		2.20%
Asian	4	0	0	4	0.00%		1.47%
Native Hawaiian or Other Pacific Islander	1	1	0	2	0.00%		0.73%
Black or African American	4	3	0	7	0.00%		2.56%
White	162	91	1	254	0.29%		93.04%
Not reported: patient refused or not available	2	2	0	4	0.00%	1.17%	
More than one race	0	0	0	0	0.00%		0.00%
Unknown: Patient unsure	56	8	0	64	0.00%	18.77%	
Totals:	234	106	1	341	0.29%	19.94%	
Totals - excluding Unknown or Not reported:	176	96	1	273		·	100.00%

Report date: 02/02/2014 Bugzilla - 10890

Who determines these categories??



Standards for the Classification of Federal Data on Race and Ethnicity

Federal Register, August 28, 1995

AGENCY: Executive Office of the President, Office of Management and Budget (OMB), Office of Information and Regulatory Affairs

ACTION: Interim Notice of Review and Possible Revision of OMB's Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting: Summary and Analysis of Public Comments and Brief Discussion of Research Agenda

Summary: In 1977, OMB issued the Race and Ethnic Standards for Federal Statistics and Administrative Reporting that are set forth in Statistical Policy Directive No. 15. The standards in this Directive have been used for almost two decades throughout the Federal government for recordkeeping, collection, and presentation of data on race and Hispanic origin. The standards have been used in two decennial censuses and in surveys of the population, data collections necessary for meeting statutory requirements associated with civil rights monitoring and enforcement, and in other administrative program reporting.

SPECIAL ARTICLE -

Annual Report to the Nation on the Status of Cancer (1973 Through 1998), Featuring Cancers With Recent Increasing Trends

Holly L. Howe, Phyllis A. Wingo, Michael J. Thun, Lynn A. G. Ries, Harry M. Rose

Background: Ti

Cancer Institute

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SPECIAL ARTICLE

Annual Report to the Nation on the Status of Cancer, 1975–2000, Featuring the Uses of Surveillance Data for Cancer Prevention and Control

Hannah K. Weir, Michael J. Thun, Benjamin F. Hankey, Lynn A. G. Ries, Holly L. Howe, Phyllis A. Wingo, Ahmedin Jemal, Elizabeth Ward, Robert N. Anderson, Brenda K. Edwards

Background: The American Cancer Society, the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the North American Association of Central Cancer Registries (NAACCR) collaborate annually to update cancer rates and trends in the United States. This report updates statistics on lung, female breast, prostate, and colorectal cancers and highlights the uses of selected surveillunce data to assist development of state-based cancer control plans. Methods: Age-adjusted incidence rates from 1996 through 2000 are from state and metropolitan area cancer registries that mot NAACCR criteria for highest quality. Death rates are based on underlying cause-of-death data. Long-term trends and rates for major rudal and ethnic populations are based on NCI and CDC data. Incidence trends from 1975 through 2000 were adjusted for reporting delays, State-specific screening and risk factor survey data are from the CDC and other federal and private organizations. Results: Cancer incidence rates for all cancer sites combined increased from the mid-1970s through 1992 and then decreased from 1992 through 1995. Observed incidence rates for all cancers combined were essentially stable from 1995 through 2000, whereas the delay-adjusted trend showed an increase that had borderline statistical significance (P = .05). Increases in the incidence rules of breast cancer in women and prostate cancer in men offset a longterm decrease in lung cancer in men. Death rates for all cancer sites combined decreased beginning in 1994 and stabilized from 1998 through 2000, resulting in part from recent revisions in cause-of-death codes. Death rates among men continued to decline throughout the 1990s, whereas trends in death rules among women were essentially un-changed from 1998 through 2000. Analysis of state data for the leading cuncers revealed mixed progress in achieving mitional objectives for improving cancer screening, risk factor reduction, and decreases in mortality. Conclusions: Overall cancer incidence and death rates began to stabilize in the mid- to late 1990s. The recent increase in the delayadjusted trend will require monitoring with additional years of data. Further reduction in the burden of cancer is nostible but will require the continuation of strong federal, state, local, and private purtnerships to increase dissemination of evidence-based cancer control programs to all segments of the population. [J Natl Cancer Inst 2003;95:1276-1299]

The American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute

1276 SPECIAL ARTICLE

Journal of the National Cancer Institute, Vol. 95, No. 17, September 3, 2003

(NCI), and the North An Registries (NAACCR) co to the nation on the curre-In 1998, the initial report in cancer death rates sin tuted in the 1930s (1). Sub and provided updates (2-3 cancer trends associated sulting from the aging as These demographic trend communities that must de tion and control plans the residents.

This report updates da (lung, fermile breast, prost more than half of the car population. This report als surveillance data to plan. vention and control progra

SUBJECTS AND METHO

Cancer Cases and Deat

Information on newly States is based on data co ing in the NCI's Surveill (SEER1) Program or the Registries (NPCR) (6.8). American Association of 6

Affiliations of eathers: H. K. tion and Control, National Con-

Promotion. Centers for Discus-Thus, A. Jones, E. Ward, Epidemiology and Surveillance Research I American Cancer Society, Atlanta, B. F. Hankey, L. A. G. Ries, B. K. Division of Cancer Control and Population Sciences, National Cancer National Institutes of Health, Betherda, MD, H. L. Howe, North Art sociation of Central Cancer Registries, Springfield, II.; R. N. Anderso of Vital Statetics, National Center for Health Statetics, Centers Control and Prevention, Hygityville, MD.

Convergentieres in: Hannah K. Weir, PhD, Division of Cancer Prev Control, National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention, MS E-53, 4770 Buford Blvs.

Atlanta, GA 30341 (s-mail: hbw4@odc.gov). See "Notes" following 'References."

DOL 10.1093/jacktig040 Journal of the National Concer Institute, Vol. 95, No. 17, @ Oxford University Press 2000, all rights reserved.

Annual Report to the Nation on the Status of Cancer, 1975-2001. with a Special Feature Regarding

Survival

Ahmedin Jemal, oxw Limin X. Clegg, PAD²

Elizabeth Ward, PAD.

Patricia H. Jamison,

Holly L. Howe, n.p.4

Brenda K. Edwards.

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SPECIAL ARTICLE -

Annual Report to the Nation on the Status of Cancer, 1975-2002, Featuring Population-Based Trends in Lyne A. G. Ries, Ma² Xiaocheng Wu, w.o., w

Cancer Treatment

Brenda K. Edwards, Martin L. Brown, Phyllis A. Wingo, m.o. Elizabeth Ward, Lynn A. G. Ries, Deb Ahmedin Jemal, Xiao Cheng Wu, Caro Joan Warren, Robert N. Anderson, Lin Robert N. Anderson.

most common cancers in the five major raci

tions in the United States for 1992–2002 and feat

Epidemiology and Surveilla Background: The American Cancer Society terr for Direase Control and Prevention (CD) ² Distriction of Courses Control Cancer Institute (NCD, and the North Ame of Central Cancer Registries (NAACCR) co School of Public Health, Lo. ally to provide information on cancer rate: a How Olean, Louiston. United States. This year's report updates sta

based trends in cancer treatment. Methods Health Fremoton, Center to CDC, and the NAACCR provided inform carer, and the CDC provided information or District of Wint Statistics. Reported incidence and death rate: were age Prevention, Byzánniko, Mary 2000 U.S. standard population, annual per rates for fixed intervals was estimated by li-MCKGROUND, The Area and annual percent change in trends was estipoint regression analysis. Population-based and Prevention (CDC), were derived from the Surveillance, Epiden ican Association of Cer Results (SEER) Program registries, SEER-1 databases, and NCI Patterns of Care/Quality provide updated inform This year's report featur Results: Among men, the incidence rates for combined were stable from 1995 through 2002 **HETHODS**, Information the incidence rates increased by 0.346 anni and NAACCR and infor through 2002. Death rates in men and we from the CDC. The noth decreased by 1.1% annually from 1993 thre cancer sites combined and also for many of death rates by regressi mon cancers. Among women, lung cancer created from 1995 through 2002, but lung o time and across racial/ RESULTS, facidence rate rates stabilized from 1998 through 2002, Alti 2001, but riabilized from cancer treatment studies suggest that much The incidence rates for cancer treatment for selected cancers is consists based guidelines, they also point to get significant for delay ad economic, and age-related disparities in ca increasing for many de Conclusions: Cancer death rates for all canc Death rates decreased for and for many common cancers have declin time at the dissemination of guideline-base many of the top 15 ca the community has increased, although this survival rates improv thared equally across all racial and ethnic p

> in medical informatics and electronic medi facilitate monitoring of the translation of b Inversal of the National Canner Institute, Vol. 97, 1

from population-based cancer registries, a

linkage with administrative databases, are

tource for monitoring the quality of cancer t

this cancer surveillance system, along with n

Annual Report to the Nation on the Status of Cancer, 1975–2003, Featuring Cancer Among U.S. Hispanic/ Latino Populations

Holly L. Howa, rso1 Xiaochana Wu, we, ww^{1,2} Lynn A. G. Rice, us Vilma Cokkinides, no Farugue Ahmed, rec^a Ahmedin Jemal, eve.ree* Barry Miller, rud Molanio Williams, rue^{1,0} Elizabeth Ward, rw⁴ Phyllis A. Wingo, and Amelio Ramirez, ever Bronda K. Edwards, me²

- Hoth American Association of Central Genor Registres, Springfield, Blinds.
- School of Public Health, Louistone State University Health Science Centre, New Orleans, Louistone.
- Division of Carcer Control and Population Sciences, Hattonal Concer Institute, Define ou, Maryland.
- ⁶ Epidemid opyrand Surveillance Research Department, American Cancer Society, Atlanta, Georgia.
- Division of Carcer Prevention and Control, Hatland Center for Chaptic Disease Presention and Health Promotor, Centers for Disease Control and Preventor, Atlanta, Georgia.
- Teass Department of State Health Services, Austin, Teass.
- Dan L. Duncan Concer Center, Baylor College of Medicine, Houston, Tesse.

BACKGROUND. The American Cancer So dety. Genters for Disease Control and Frevention, National Cancer Institute, and North American Association of Central Cancer Registries collaborate annually to provide U.S. cancer information, this year featuring the first comprehensive compilation of cancer information for U.S.

METHODS. Cancer incidence was obtained from 90% of the Hispanic/Latino and 82% of the U.S. populations. Cancer deaths were obtained for the entire U.S. population. Canoer acreening, risk factor, incidence, and mortality data were compiled for Latino and non-Latino adults and children (incidence only). Long-term (1975-2000) and fixed-interval (1995-2000) trends and comparative analyses by disease stage urbanicity and area poverty were evaluated.

RESULTS. The long-term trend in overall cancer death rates, declining since the early 1990s, continued through 2003 for all races and both acces combined. However, female lung cancer incidence rates increased from 1975 to 2003, decelerating

HISTORICAL ISSUES

PRIOR TO 1985 WOMEN EXCLUDED DUE TO CONCERN ABOUT RISKS TO CHILDBEARING

CARDIAC AND HYPERTENSION DRUGS EXCLUDED ALL WOMEN INITIALLY

NOW TRIALS MUST STATE WHY WOMEN WOULD NOT BE INCLUDED

ETHNICITY:

ONLY TWO RECOGNIZED

WHAT ARE THEY?

RACIAL CATEGORIES: WHITE, BLACK, ASIAN, AIAN, PI, MULTIPLE

MINORITIES

2 ETHNIC CATEGORIES
5 RACIAL CATEGORIES; NEWLY ADDED MULTIPLE

SELF IDENTIFICATION

LOW NUMBERS IN CLINICAL TRIALS MAKE SUBSET ANALYSIS DIFFICULT

GENERALIZABILITY IN DOUBT FROM MAJOR TRIALS EXCLUSION FELT TO BE DETRIMENT TO MANY POPULATIONS

CHILDREN

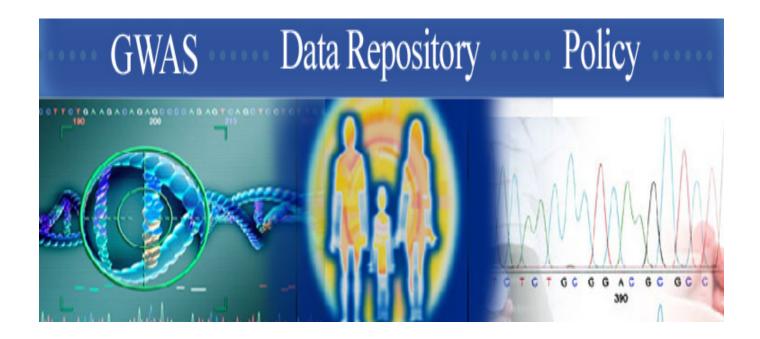
MOST DRUGS WERE NEVER TESTED ON CHILDREN

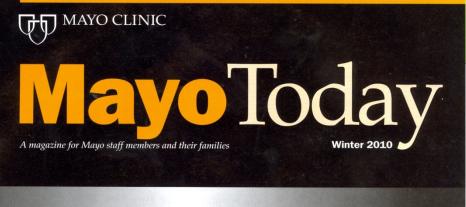
IRONICALLY MORE PEDIATRIC DRUGS ARE AVAILABLE NOW TO ADULTS (SARCOMAS)

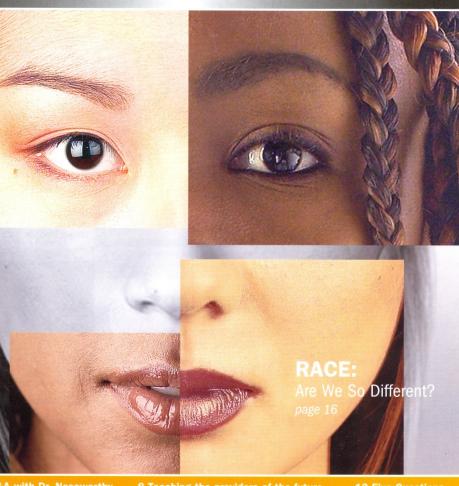
TRIALS MUST STATE WHY CHILDREN ARE EXCLUDED WITH BIOLOGIC SCIENTIFIC EVIDENCE



Data Sharing







RACE & ETHNICITY

NOT SCIENTIFIC SOCIAL **CONSTRUCTS CORRELATE WITH** RISK FACTORS AND ACCESS

New Cancer-Gene Test Seeks To Match Drugs to Patients

BY RON WINSLOW

A new test that analyzes tumors for more than 200 genes is attracting interest among drug companies and researchers, reflecting how genetic information is transforming drug development and treatment for cancer.

Foundation Medicine Inc., which developed the test, plans to disclose Thursday that Novartis SA will use it to analyze tumors in most patients in earlystage clinical trials of the drug maker's experimental cancer agents. The intent is to direct patients to studies of drugs they are likely to benefit from and to

University Medical Center, Nashville, Tenn. "You want to get the most comprehensive information to help make a decision to move a drug forward."

In addition, some 20 academic centers, including Vanderbilt and a total 172 doctors, including 20% from outside the U.S., have sent in tissue for testing from individual patients, according to Michael J. Pellini, Foundation's president and chief executive officer.

Historically, it can take about \$1 billion and up to a decade or more of research on thousands of patients to get new cancer drugs to market. A big part of

a gene called ALK.

Pfizer had a drug in development that targeted an anomaly in this gene, and the compan used the test to quickly sele patients likely to benefit. The led to U.S. Food and Drug ministration approval of drug, Xalkori, in just four y based on studies involving tal of 255 patients.

But growing information genetics and cancer sugg identifying a single g enough. Researchers h fied a dozen differe anomalies that drive for instance-and m don't respond to the Tecting patients for



"We think it has something to do with your genome."

Your thoughts ...

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