INCLUSION OF WOMEN, MINORITIES & CHILDREN IN CLINICAL TRIALS

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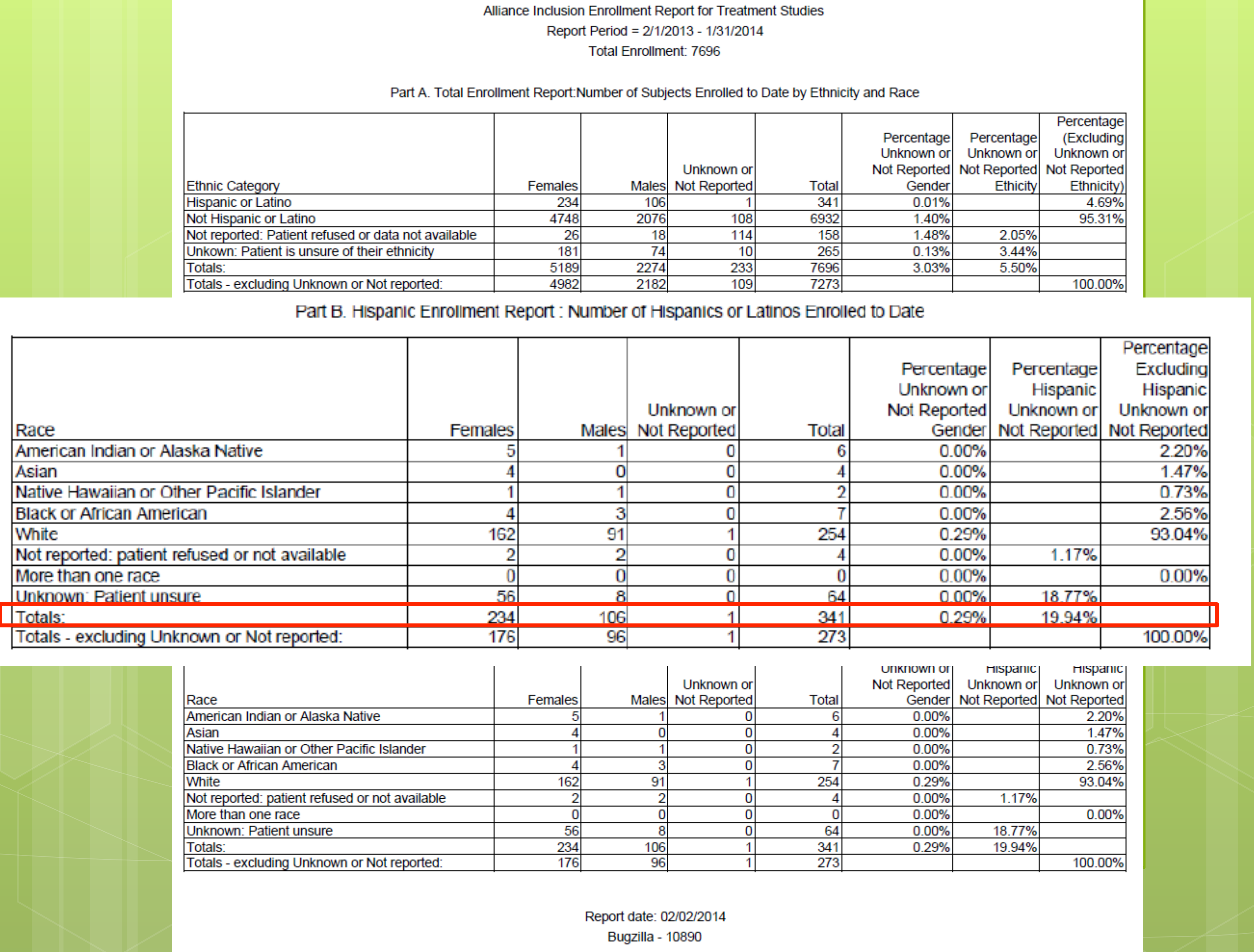
Financial Disclosure

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

Ethnic Category	Females	Males	Unknown or Not Reported	Total	Percentage Unknown or Not Reported Gender	Percentage Unknown or Not Reported Ethicity	Percentage (Excluding Unknown or Not Reported 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

Race	Females	Males	Unknown or Not Reported	Total	Percentage Unknown or Not Reported Gender	Percentage Hispanic Unknown or Not Reported	Percentage Excluding Hispanic Unknown or 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%

Race	Females	Males	Unknown or Not Reported	Total	Unknown or Not Reported Gender	Hispanic Unknown or Not Reported	Hispanic Unknown or 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,

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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 surveillance 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 met NAACCR criteria for highest quality. Death rates are based on underlying cause-of-death data. Long-term trends and rates for major racial 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 rates of breast cancer in women and prostate cancer in men offset a long-term 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 rates among women were essentially unchanged from 1998 through 2000. Analysis of state data for the leading cancers revealed mixed progress in achieving national 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 delay-adjusted trend will require monitoring with additional years of data. Further reduction in the burden of cancer is possible but will require the continuation of strong federal, state, local, and private partnerships 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

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

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SPECIAL ARTICLE

Annual Report to the Nation on the Status of Cancer, 1975–2002, Featuring Population-Based Trends in Cancer Treatment

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

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BACKGROUND. The American Cancer Society, Centers for Disease Control and Prevention, 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. Latinos.

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. Cancer screening, risk factor, incidence, and mortality data were compiled for Latino and non-Latino adults and children (incidence only). Long-term (1975–2003) and fixed-interval (1995–2003) 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 sexes 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 RACIAL

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

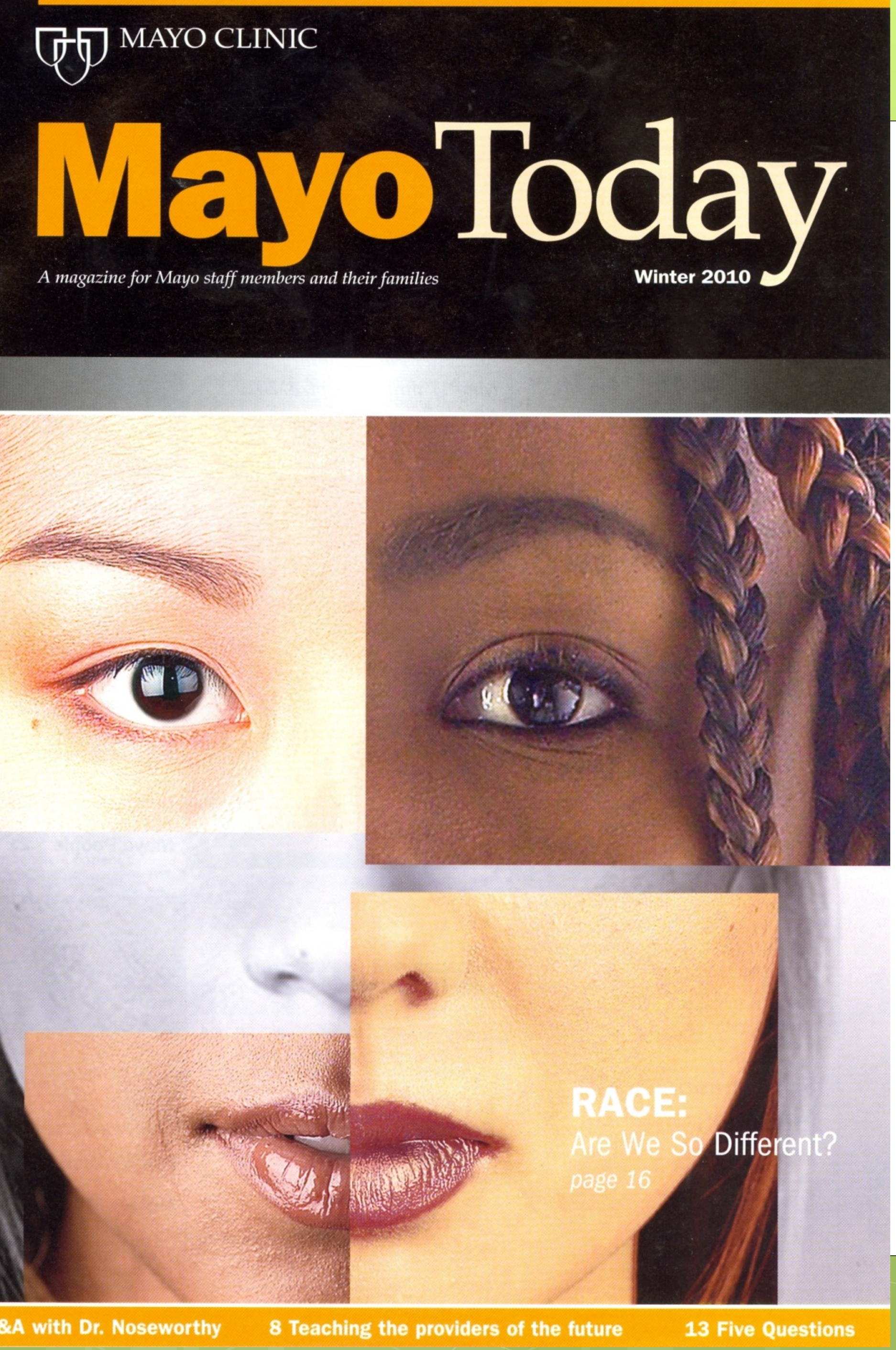
MOST DRUGS WERE NEVER TESTED ON CHILDREN

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

TRIALS MUST STATE WHY CHILDREN ARE EXCLUDED WITH BIOLOGIC SCIENTIFIC EVIDENCE


I ♥ DATA

Data Sharing



MAYO CLINIC

Mayo Today

A magazine for Mayo staff members and their families

Winter 2010

RACE:
Are We So Different?
page 16

&A with Dr. Noseworthy 8 Teaching the providers of the future 13 Five Questions

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 early-stage 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 anomal in this gene, and the compan used the test to quickly sele patients likely to benefit. T led to U.S. Food and Drug ministration approval of drug, Xalkori, in just four based on studies involvin tal of 255 patients.

But growing informatio genetics and cancer sugg identifying a single enough. Researchers h fied a dozen differe anomalies that drive for instance—and m don't respond to th Testing patients fo

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

Your thoughts …

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