Whereas, Females have historically been underrepresented in biomedical research, including in oncology clinical trials; and

Whereas, Previous studies have found that females comprised only 34.7-38.6% of participants in cancer prevention and treatment trials from 1990-2010, a proportion far less than the actual incidence of cancers among females; and

Whereas, More recent literature relating to this topic documents that females remain underrepresented, especially as compared to the magnitude and proportion of their disease burden in surgical and other invasive oncology trials, and anal canal, bladder, bone/joint, esophageal, head/neck, kidney, stomach, and thyroid cancer trials; and

Whereas, The resulting generalizability of cancer clinical trial findings remains hindered by the persistent failure to proportionally enroll female participants relative to their disease burden, a factor which continues to limit women’s access to novel therapeutics and potentially improved survival through trial participation; and

Whereas, Current research also shows that industry-funded oncology clinical trials had greater odds of proportional female representation than U.S. government and academic-funded oncology trials, suggesting success of the Food and Drug Administration (FDA) exploratory committees investigating female participation (for nearly all industry-funded trials) over simple mandates for female participation as put forth by the National Institutes of Health (NIH) (for most government and academic-funded trials not overseen by the FDA); and

Whereas, Existing AMA policy encourages increased outreach and education only for minority and female physicians to promote minority and female patient recruitment in clinical trials, despite this being an issue that impacts all physicians and their patients; therefore, be it

RESOLVED, That our AMA amend H-460.911, Increasing Minority Participation in Clinical Research, by addition and deletion to read as follows:

Increasing Minority and Female Participation in Clinical Research H-460.911

1. Our AMA advocates that:
   a. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.
b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and
c. Resources be provided to community level agencies that work with those minorities and females who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Blacks/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.

2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities and females in clinical trials:
a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs;
b. Increased outreach to female all physicians to encourage recruitment of minority and female patients in clinical trials;
c. Continued minority physician education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety, and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate female and minority subject recruitment and methods for increasing trial accessibility for patients such as community partnerships, optimized patient-centered locations for accessing trials, and the ready availability of transportation to and from trial locations and child care services;
d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and
e. Fiscal support for minority and female recruitment efforts and increasing trial accessibility through optimized patient-centered locations for accessing trials, the ready availability of transportation to and from trial locations, child care services, and transportation, child care, reimbursements, and location.

Fiscal Note: Minimal

References:


Relevant AMA Policy:

H-460.911 Increasing Minority Participation in Clinical Research
1. Our AMA advocates that:
   a. The Food and Drug Administration (FDA) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.
   b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and
   c. Resources be provided to community level agencies that work with those minorities who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.
2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities in clinical trials:
   a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs;
   b. Increased outreach to female physicians to encourage recruitment of female patients in clinical trials;
   c. Continued minority physician education on clinical trials, subject recruitment, subject safety, and possible expense reimbursements;
   d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and
   e. Fiscal support for minority recruitment efforts and increasing trial accessibility through transportation, child care, reimbursements, and location.
3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.
Citation: BOT Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18

H-460.965 Viability of Clinical Research Coverages and Reimbursement
Our AMA believes that:
(1) legislation and regulatory reform should be pursued to mandate third party payer coverage of patient care costs (including co-pays/co-insurance/deductibles) of nationally approved (e.g., NIH, VA, ADAMHA, FDA), scientifically based research protocols or those scientifically based protocols approved by nationally recognized peer review mechanisms;
(2) third party payers should formally integrate the concept of risk/benefit analysis and the criterion of availability of effective alternative therapies into their decision making processes;
(3) third party payers should be particularly sensitive to the difficulty and complexity of treatment decisions regarding the seriously ill and provide flexible, informed and expeditious case management when indicated;
(4) its efforts to identify and evaluate promising new technologies and potentially obsolete technologies should be enhanced;
(5) its current efforts to identify unproven or fraudulent technologies should be enhanced;
(6) sponsors (e.g., NIH, pharmaceutical firms) of clinical research should finance fully the incremental costs added by research activities (e.g., data collection, investigators' salaries, data analysis) associated with the clinical trial. Investigators should help to identify such incremental costs of research;
(7) supports monitoring present studies and demonstration projects, particularly as they relate to the magnitude (if any) of the differential costs of patient care associated with clinical trials and with general practice;
(8) results of all trials should be communicated as soon as possible to the practicing medical community maintaining the peer reviewed process of publication in recognized medical journals as the preferred means of evaluation and communication of research results;
(9) funding of biomedical research by the federal government should reflect the present opportunities and the proven benefits of such research to the health and economic well being of the American people;
(10) the practicing medical community, the clinical research community, patient advocacy groups and third party payers should continue their ongoing dialogue regarding issues in payment for technologies that benefit seriously ill patients and evaluative efforts that will enhance the effectiveness and efficiency of our nation's health care system; and
(11) legislation and regulatory reform should be supported that establish program integrity/fraud and abuse safe harbors that permit sponsors to cover co-pays/coinsurance/ deductibles, otherwise not covered clinical care, and non-clinical ancillary costs in the context of nationally approved clinical trials.