



ON INCREASING MINORITY PARTICIPATION IN CLINICAL RESEARCH

Summary of a December 2007 White Paper from The Endocrine Society

Health-care inequalities that disproportionately affect racial and ethnic minority groups have been recognized for many decades. Congruently, the under-representation of ethnic and racial minority groups in clinical research has been, and continues to be, a major component of health-care deficiencies in the United States. The under-representation of minorities occurs in all types of clinical research and all therapeutic areas, including those diseases that predominantly affect ethnic and racial minorities. Regrettably, little progress has been made toward including minorities in clinical research, and the key parties involved in planning and conducting clinical trials (investigators, sponsors, and regulators) have not yet made this a top priority.

The primary goal of the recommendations outlined by The Endocrine Society in the white paper on increasing minority participation in clinical research is to ensure that sufficient data are available to identify any race- or ethnicity-specific differences in response to therapeutics or in the reliability of bio-markers used to develop treatment strategies. In order for this goal to be realized, diverse subpopulations must be included in clinical trials.

While the combined efforts of Congress, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) have been quite successful in reversing the shortage of data that support therapeutic options for women, the problem of obtaining statistically powered data across race, ethnicity, and socioeconomic groups has yet to be broadly addressed.

Many studies have tried to determine the reasons that minorities are under-represented in clinical studies, and there appear to be multiple barriers to participation. These findings indicate:

- Lack of access to clinical trials, rather than unwillingness to participate, seems to be the primary barrier to minority participation.
- Some minorities may have greater distrust of the medical system.
- Minorities are more likely to encounter cultural, religious, and language barriers.
- Minorities are more likely to encounter social and economic barriers such as the need for transportation or child-care, or loss of wages.
- Minority patients often choose physicians of their own background, but minority investigators are very poorly represented in clinical trials in the United States today. Physicians with access to minority patients can be an important source of racial and ethnic minority trial volunteers.
- The inclusion of racial and ethnic minorities as clinical trial participants adds complexity and cost to the study.
- There is no clear-cut regulatory mandate for inclusion.



THE ENDOCRINE SOCIETY'S RECOMMENDATIONS FOR INCREASING MINORITY PARTICIPATION IN CLINICAL RESEARCH

Recommendations for All Stakeholders

- We recommend that there be a Consensus Conference with representatives from all stakeholder groups—including but not limited to NIH, FDA, pharmaceutical companies/contract research organizations (CROs), academic institutions, health-management organizations, community health networks, and community leaders—to address critical issues that prevent adequate inclusion of minorities in clinical research.

Recommendations for Congress

- Establish an Office of Minority Health within the Office of the FDA Commissioner.
- Require that clinical trials include women and minorities for all FDA approvals, similar to legislation passed in 1993 requiring the inclusion of these groups in NIH-funded trials.
- Provide incentives such as tax incentives or patent extensions for companies that adhere to FDA guidance on inclusion of minorities in clinical trials.

Recommendations for FDA

- Consider immediate adoption of NIH guidelines as outlined in the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research.
- Require rather than recommend adherence to guidelines. This requirement should be phased in over a period of time sufficient for CROs and pharmaceutical companies to build and access the resources needed to comply.
- Analyze data on minority participation comparing participation rates for Phases I through IV clinical trials including past studies to the extent possible and future studies based on parameters determined at the Consensus Conference.

Recommendations for NIH and Academic Institutions

- Adopt and utilize mechanisms such as the Small Business Innovation Research program to encourage entrepreneurs to establish CROs and/or limited liability corporations (LLCs) dedicated to recruiting diverse physicians and study populations.
- Establish and maintain the infrastructure required for minority practitioners to participate in research studies. Specifically, it is important to have a registry of community practices (including minority practices) from which investigators and trial sponsors could easily and efficiently recruit physicians and volunteers.
- Establish mentorship programs between academic institutions and community-based practices that are interested and willing to perform clinical research or to refer their patients to clinical trials.
- Create and fund Community Research Advisory Boards at appropriate sites. These boards would be mandated to promote community-based participatory research by: 1) facilitating communication between investigators and patients, 2) providing communication and feedback among the various stakeholders, 3) providing community oversight, and 4) allowing the community and its leaders to become proactive process participants.
- Increase the pipeline by developing programs at medical schools aimed at increasing enrollment and matriculation of diverse medical students.
- Offer training at medical schools in Good Clinical Research Practice and Cultural Competencies to all trainees and staff members who may directly or peripherally engage in clinical research.