Association of American Cancer Institutes
Recommendations for Increasing Diversity in Cancer Clinical Trials

Below are recommendations to the U.S. Department of Health and Human Services (HHS) for increasing diversity in cancer clinical trials, compiled by the Association of American Cancer Institutes' (AACI) Clinical Research Innovation (CRI) Steering Committee.

1. Create a clinical research infrastructure at community research sites
    a. The federal government should provide dedicated funding to Federally Qualified Health Centers and Health Resources Services Administration or similar mechanisms. For example, the government could provide additional percentage incentives through Centers for Medicare and Medicaid Services payments to providers to develop clinical research infrastructures. The funding could be allocated on a sliding scale based on the percentage of patients offered participation in a clinical trial, as documented in electronic medical records, and number of interventional trials available.
    b. To accrue more patients, the U.S. Food and Drug Administration (FDA) should consider approving new drug applications for trials that are designed with less complexity that would encourage/improve enrollment. HHS should use funds allocated at their discretion to support long-term efforts of clinical research associates and community and patient navigators and urge Congress to designate additional funding in future budgets.
    c. HHS should consider partnerships with health care and cancer professional societies that provide institutional and professional accreditation and certification processes to promote quality standards and continuing education to address these priorities/policies. Examples of such organizations include, but are not limited to, the American Cancer Society, American College of Surgeons Commission on Cancer, Joint Commission on Accreditation of Healthcare Organizations, American Society of Clinical Oncology, National Cancer Institute (NCI) Office of the Cancer Centers, American Society of Hematology, Leukemia and Lymphoma Society, Association of Clinical Research Professionals, Society of Clinical Research Associates, Oncology Nursing Society, and the Hematology Oncology Pharmacy Association.
    d. HHS and the FDA should encourage oncology research protocols, and support innovative models of trial conduct that are not exclusive to academic cancer centers but include community partners and their research affiliates and networks.
    e. The FDA should define the minimum footprint required for researchers and sponsors to include in a clinical trial to achieve the trial's endpoints and ensure safe and efficacious research that achieves trial accrual goals. Trials can be completed without collecting unnecessary research data (e.g., grade one laboratory adverse events), and be designed to allow a reasonable timeframe for study procedures. This includes allowing researchers to move study events occurring on holidays or weekends to another day to accommodate patients while avoiding non-compliance.
    f. The NCI should be encouraged to report the demographics of participants enrolled year by year on the various NCI-defined trials (e.g., treatment, non-therapeutic intervention, non-intervention, pragmatic) as a function of each cancer center's catchment area and cancer cases seen at the center, which would serve as a key metric to track progress nationwide. However, recognizing that many other cancer-relevant catchment area activities take place and are important, this should be done in a way not to create a disincentive to serve larger areas.
2. Eliminate financial toxicity for patients

    a. HHS should work with industry sponsors to encourage clinical trials that do not include restrictive and burdensome out-of-pocket expenses for patients while on study or in follow-up.
        i. Sponsors should aim to diminish financial barriers to trial participation by covering participants expenses for necessities such as travel, gas, parking, lodging, and food. They should also consider up-front reimbursement to patients or use of pharmacy cards to cover medications required for supportive care and covering standard of care medications on clinical trials when the patient does not have a mechanism for coverage.
3. Improve patient and physician education
    a. Funding should be provided for grassroots campaigns related to clinical research education.
    b. A universal policy should be established for all health care institutions and their affiliated practice sites to screen patients for a clinical trial and document the reason patients were not enrolled in a trial. These data could improve future trials.
4. Encourage trial sponsors and the FDA to revise clinical trials enrollment criteria
    a. Sponsors should write patient-friendly trials that can be conducted in the community, allowing labs, radiology procedures, and physician follow-up visits to be performed closer to the patient's home at reasonable times or days for all patients.
    b. HHS should facilitate a discussion with relevant stakeholders to develop best practices that ensure physicians consider all patients for clinical trials.
5. Request more funding for clinical research from the National Institutes of Health
    a. Federal funding should be increased to support the NCI National Clinical Trials Network and cooperative group trials. Many of these trials are developed with the cancer community setting in mind, but grant funding provided to trial sites does not match the effort needed to work with these trials. Staff effort to conduct clinical research is often an unfunded mandate, not reimbursed by payers and sponsors and not based on relative value units. Staff tasks include obtaining regulatory approvals, collecting and entering research data into electronic case report forms, managing and resolving trial queries, reporting safety events, and seeking regulatory approvals.