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What's New in GCP?
FDA Looks To Improve Clinical Trial Diversity in 2016

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"Increasing diversity in clinical trials is a priority for FDA," Robert Califf, nominee for FDA Commissioner, said in an FDA Voice blog posted Jan. 27. Califf, who is FDA's Deputy Commissioner for Medical Products and Tobacco, said the agency is planning a number of projects in 2016 "to push for greater inclusion, including more minority participation" in clinical trials.

Califf noted the FDA's Office of Minority Health developed several tools to support clinical trial participation, including a collaboration with the National Library of Medicine to help consumers and patients find clinical trials and educational materials on trials, as well as a multimedia campaign highlighting the importance of clinical trial participation. "These materials are designed to urge those underrepresented in clinical trials to find out more information and consider enrolling," Califf said.

The FDA Office of Women's Health launched the Diverse Women in Clinical Trials initiative in collaboration with the National Institute of Health's Office of Research on Women's Health. "This multipronged effort will raise awareness and share best practices about clinical research design, recruitment and subpopulation analyses," Califf said.

FDA "biostatisticians, trial design experts, and quantitative scientists will continue to work with the research community to develop methods to refine our approach to the conduct and analysis of trials to provide the best estimates of treatment effects for diverse populations," he said, and the agency "will continue its commitment to include patient advocacy groups to engage patients in clinical trial design, feedback and evaluation from a patient's perspective. By engaging patients early in the trial design process, feasibility and participation may be improved."

Califf added the FDA Office of External Affairs will publish a consumer update describing what it is like to participate in a clinical trial and encouraging the public to enroll in trials.

He noted the projects are part of FDA's response to Section 907 of the Food and Drug Administration Safety and Innovation Act of 2012. "This provision directed FDA to conduct an inventory of how well various population groups were being represented in clinical trials of FDA-regulated medical products and whether these data were publicly reported. Once that was done, FDA was directed to develop an action plan, which we published in August 2014. "We've been diligently working toward implementation and sustainability ever since."

Califf added a public meeting Feb. 29 "will continue the dialogue with important stakeholders to continue this momentum. We want to make 2016 the year of more diversity in clinical trials, but we can't do it alone."

In addition, Barbara Buch, associate director for medicine in FDA's Center for Biologics Evaluation and Research, provided an update on the agency's progress in three priority areas outlined in the action plan.

Quality

The FDA updated and/or finalized relevant guidance on demographic subgroup data. Two examples are: Integrated Summary of Effectiveness Guidance and Evaluation of Sex-Specific Data in Medical Device Clinical Studies.

The Office of Minority Health developed a plan that supports specific research projects and leads to better understanding of medical product clinical outcomes in racial/ethnic demographic subgroups.

The Centers for Devices and Radiological Health, Drug Evaluation and Research, and Biologics Evaluation and Research modified their clinical review templates.

CDER developed a review process that encourages reviewers to watch for inappropriate clinical trial exclusion and inclusion criteria. Accompanying training emphasizes the need to include broad population diversity in clinical trials.

CDRH and CBER modified statistical reviewer templates to include analysis of demographic subgroup information.

CBER and CDER incorporated discussions on diverse inclusion and subgroup participation and analysis into pre-application submission meetings with industry.

The agency updated its MedWatch forms to standardize collection of demographic information on possible adverse events that occur after medical products are broadly available on the U.S. market.

The Office of Women's Health (OWH) posted a Research Roadmap and strategic plan for women's health research. The office also funded research projects on methods to improve data quality in demographic subgroups and the examination of sex-specific outcomes with cardiac resynchronization therapy.

Participation

OWH collaborated with NIH on the "Meet the Faces of Clinical Research: Beyond Inclusion" workshop, which featured clinical trial participants and researchers discussing the importance of diversity in clinical trials.

The FDA made demographic information from clinical trials more easily available to consumers through its online Drug Trials Snapshots.

The Office of Minority Health and the Institute of Medicine convened a public meeting to discuss minority health disparities and clinically meaningful differences.

The FDA and the Johns Hopkins University co-sponsored a clinical trials workshop on assessing safety and efficacy for a diverse population.

Transparency

The FDA established a Language Access Plan Working Group to implement communication strategies sensitive to the needs of under-represented subpopulations, focusing on language access and health literacy.

CBER launched a transparency pilot program to make demographic information available to physicians and the public for original Biologics License Applications.

CDRH modified templates for some documents that are posted to the FDA website upon approval of certain medical devices to ensure that demographic information is consistently included.

Other Recent Developments in the Guide to Good Clinical Practice

FDA Examines French Phase 1 Study

Public Citizen Asks VA To Investigate Trial Conduct

ICMJE Wants Deidentified Patient Data Sharing