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FDA Issues Guidance on Increasing Diversity in Clinical Trials

Finalizing a document issued last year, on Nov. 9 the Food and Drug Administration issued "Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs," which FDA said "offers recommendations on how product sponsors can improve clinical trial diversity by accounting for logistical and other participant-related factors that could limit participation." Additionally, the final guidance "provides recommendations on broadening clinical trial eligibility criteria for clinical trials of investigational drugs intended to treat rare diseases and recommendations on improving enrollment and retention of participants with rare diseases. The guidance notes that sponsors should consider early engagement with patient advocacy groups and patients to elicit suggestions for designing trials that participants would be willing to enroll in and support," the agency said.

Changes that study sponsors could make include "reducing visit frequency, when appropriate, in addition to considering whether flexibility in visit windows is possible and whether electronic communications, such as phone, email, social media platforms, or other digital health technology tools can replace site visits and provide investigators with real-time data," according to FDA. The guidance also addresses ways of boosting trial inclusion of "pregnant women, racial and ethnic minorities, children, and older adults, and provides references to more specific guidances."

Link to FDA announcement