

Clinical Trial Diversity Planning for Sponsors: What to Know About FDA's Recent Draft Guidance



On April 13, 2022, the U.S. Food and Drug Administration (“FDA”) issued a [draft guidance](#) providing specific recommendations to the industry on how to improve diversity in clinical trials. The FDA’s focus on increasing racial and ethnic diversity in clinical trials is not new, with the agency issuing several guidances since 2016 on this topic.^{[1](#)} However, the recent draft guidance sets out new expectations for sponsors conducting clinical trials intended to support marketing authorization of drugs, biologics, and medical devices.

Read the [client alert](#) by FDA Senior Associate [Elizabeth Mulkey](#) and Partner [Alexander Varond](#).