
Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

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1 **Diversity Plans to Improve Enrollment of Participants from**
2 **Underrepresented Racial and Ethnic Populations in Clinical Trials**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
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14 **I. INTRODUCTION**
15

16 The purpose of this guidance is to provide recommendations to sponsors developing medical
17 products² on the approach for developing a Race and Ethnicity Diversity Plan (henceforth
18 referred to as the “Plan”) to enroll representative numbers of participants from underrepresented
19 racial and ethnic populations in the United States, such as Black or African American,
20 Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific
21 Islanders, and other persons of color, in clinical trials.³ Individuals from these populations are
22 frequently underrepresented in biomedical research despite having a disproportionate disease
23 burden for certain diseases relative to their proportional representation in the general population.
24 Adequate representation of these populations in clinical trials and studies supporting regulatory
25 submissions helps ensure that the data generated in the development program reflect the racial
26 and ethnic diversity of the population expected to use the medical product if approved, and may

¹ This guidance has been prepared by the Oncology Center of Excellence (OCE) in collaboration with the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Office of Minority Health and Health Equity (OMHHE) at the Food and Drug Administration.

² For the purposes of this guidance, medical product is used to refer to human drugs (including human biological products that are regulated as drugs) and medical devices.

³ FDA follows the Office of Management and Budget’s definitions of race and ethnicity. See Office of Management and Budget (OMB) Directive No. 15 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (October 30, 1997), available at <https://www.whitehouse.gov/wp-content/uploads/2017/11/Revisions-to-the-Standards-for-the-Classification-of-Federal-Data-on-Race-and-Ethnicity-October30-1997.pdf>. Consistent with OMB Policy Directive 15, the categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. Ethnicity is comprised of two categories: Hispanic/Latino or not Hispanic/Latino. Race is comprised of five minimum categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. In certain situations, as recommended in OMB Policy Directive 15, more detailed race and ethnicity information may be desired. OMB standards do not designate underrepresented populations, thus FDA’s recommendations regarding race and ethnicity data in clinical trials provide additional guidance, see the guidance for industry *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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27 potentially identify effects on safety or efficacy outcomes that may be associated with, or occur
28 more frequently within these populations.

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30 As discussed below, this guidance focuses specifically on racial and ethnic demographic
31 characteristics of study populations, recognizing the broader issues regarding health disparities
32 and differential access to health care in certain racial and ethnic populations, many of whom are
33 part of underserved communities. However, FDA advises sponsors to seek diversity in clinical
34 trial enrollment beyond populations defined by race and ethnicity, including other
35 underrepresented populations defined by demographics such as sex, gender identity⁴, age,
36 socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity. FDA
37 encourages sponsors to also submit plans that help ensure the adequate participation of relevant
38 and underrepresented populations and analyses of data collected from clinically relevant
39 subpopulations.⁵

40
41 This guidance expands on FDA’s guidance, *Collection of Race and Ethnicity Data in Clinical*
42 *Trials* (October 2016), which outlines how to collect and present race and ethnicity data in
43 submissions to the FDA and recommends that sponsors develop and submit a plan to address
44 inclusion of clinically relevant populations, for discussion to the Agency. Given the importance
45 of increasing enrollment from historically underrepresented racial and ethnic populations, FDA
46 is publishing this guidance to provide detail on what sponsors should include in a Race and
47 Ethnicity Diversity Plan. As described in further detail below, FDA recommends that a Plan to
48 enroll representative numbers of participants from historically underrepresented racial and ethnic
49 populations be submitted to the investigational new drug (IND) application, for a drug, including
50 biological products regulated as drugs, or the investigational device exemption (IDE)
51 application, for a device. This Plan should be discussed with the FDA as soon as practicable
52 during medical product development. For drugs, this should occur no later than when a sponsor is
53 seeking feedback regarding the applicable pivotal trial(s) for the drug (often during the End of
54 Phase 2 (EOP2) meeting). The current guidance provides general considerations for the content
55 and format of the Plan. This guidance is not intended to address all issues related to the clinical
56 development of medical products such as the design of studies, trial endpoints, or the data
57 package necessary to support a marketing application; sponsors should refer to the appropriate
58 FDA guidance documents for FDA recommendations on these matters.

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60 The contents of this document do not have the force and effect of law and are not meant to bind
61 the public in any way, unless specifically incorporated into a contract. This document is

⁴ See *National Strategy on Gender Equity and Equality*. <https://www.whitehouse.gov/wp-content/uploads/2021/10/National-Strategy-on-Gender-Equity-and-Equality.pdf>.

⁵ Adequate participation and analyses of data collected from clinically relevant subpopulations may provide important information pertaining to medical product safety and effectiveness for product labeling. Additional patient characteristics such as age, sex, gender, geographic location (e.g., rural), emotional, physical, sensory, and cognitive capabilities can often be important variables when evaluating medical product safety and efficacy. While these additional characteristics are not addressed in this guidance, FDA encourages sponsors to consider broadening their diversity plans to include all clinically relevant populations as appropriate. FDA guidance on *Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs* encourages the inclusion of persons with disabilities in clinical trials including during the study design phase. For example, FDA guidance recommends that sponsors consider the recruitment challenges that may occur because of the planned visit schedule and difficulties with accessibility. FDA also has guidance on inclusion of older adults in clinical trials.

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62 intended only to provide clarity to the public regarding existing requirements under the law.
63 FDA guidance documents, including this guidance, should be viewed only as recommendations,
64 unless specific regulatory or statutory requirements are cited. The use of the word *should* in
65 FDA guidance means that something is suggested or recommended, but not required.

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68 **II. BACKGROUND**

69

70 Clinical trials are used to characterize the safety and effectiveness of medical products intended
71 for the prevention, treatment, or diagnosis of many diseases, including those that are serious and
72 life-threatening. Across many therapeutic areas, participation in clinical trials may be an
73 important component of a participant’s clinical care.

74

75 FDA regulations require IND holders to include in their annual reports, among other things, the
76 total number of subjects initially planned for inclusion in a clinical study and the number entered
77 into the study to date, tabulated by age group, race, and gender.⁶ In addition, a new drug
78 application (NDA) must present effectiveness and safety data by gender, age, and race and must
79 identify any modifications of dose or dose interval needed for a specific subgroup.⁷

80

81 Medical product development programs should consider the clinical and demographic factors
82 that impact the generalizability of study results with respect to the patient population that will
83 use the medical product once it is approved. Diverse populations as defined by race and
84 ethnicity are relevant to the evaluation of medical products and there have been some observed
85 correlations between self-reported race, ancestry, genetic variations or ethnicity, and response.⁸

86

87 FDA has issued several sets of recommendations to improve clinical trial diversity.^{9,10} These
88 recommendations address a range of topics, including: the collection and analysis of racial and
89 ethnic data; measures that enhance diversity in clinical trials; and the broadening of eligibility
90 criteria when scientifically appropriate to improve clinical trial participation. Stakeholders have
91 also recommended that sponsors develop a plan that outlines the operational measures that will
92 be implemented to ensure diverse clinical trial participation to improve the generation of
93 evidence regarding safety and effectiveness across the entire population.¹¹ Such measures could
94 include but are not limited to offering financial reimbursement for expenses incurred by

⁶ See 21 CFR 312.33(a)(2).

⁷ See 21 CFR 314.50(d)(5)(v and vi).

⁸ Burchard EG et al., The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice. *N Engl J Med* 2003; 348(12):1170-1175.

⁹ See FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials available at <https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-907-inclusion-demographic-subgroups-clinical-trials>. See also FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data available at <https://www.fda.gov/media/89307/download>.

¹⁰ See the following three guidances for industry: *Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs* (November 2020); *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016); and *Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies* (September 2017).

¹¹ See Cancer Disparities Progress Report 2020: Achieving the bold vision of health equity for racial and ethnic minorities and other underserved populations. American Association for Cancer Research; ©2020. Available at <https://cancerprogressreport.aacr.org/disparities/>.

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95 participation in a clinical trial or study (e.g., travel or lodging)¹², providing language access to
96 participants with limited English language proficiency, and partnering with community-based
97 organizations to provide support to study or trial participants. FDA guidance documents define a
98 diverse population, when applicable, to be inclusive of all populations as defined by
99 demographic factors such as race, ethnicity, sex, gender identity, age, pregnancy status, lactation
100 status¹³, and by the presence of certain clinical characteristics such as multiple comorbidities.
101 Some individuals from these groups have often been underrepresented in medical product
102 development and FDA considers their representation in clinical trials and studies to be a priority.
103 FDA has, for some of these populations, already published specific guidance (e.g., enrollment of
104 women, including pregnant and lactating women, and older adults).^{14,15} However, FDA is
105 focusing this guidance on diversity plans to improve enrollment of participants from
106 underrepresented racial and ethnic populations because the lack of representation of these
107 populations in clinical research reflects, in part, a broader issue regarding differential access to
108 health care¹⁶, including access to centers that conduct clinical research programs for new
109 therapies and awareness of clinical trials conducted there. In addition, mistrust of the clinical
110 research system may stem from historical events that adversely impacted racial and ethnic
111 minorities, such as the unethical Tuskegee experiments.¹⁷ Clinical trials designed to include
112 pediatric participants should also take into account adequate representation of children from
113 racial and ethnic minority backgrounds.¹⁸

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115 Swift development and approval of medical products is a highly desirable goal for the public,
116 sponsors, and the FDA. There has been increasing reliance on relatively small studies,
117 intermediate endpoints, and innovative study designs to expedite development and approval of

¹² FDA does not consider reimbursement for reasonable travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. Similarly, consideration may be given to paying participants in exchange for their participation in research. FDA recognizes, however, that payment for participation may raise difficult questions that should be addressed by the Institutional Review Board (IRB), such as how much money participants should receive, and for what participants should receive payment, such as their time, inconvenience, discomfort, or some other consideration. See Information Sheet “Payment and Reimbursement to Research Subjects” (January 2018) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

¹³ See the draft guidance for industry *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials* (April 2018)). When final, this guidance will represent the FDA’s current thinking on this topic. See also the guidance for industry *Evaluation of Sex-Specific Data in Medical Device Clinical Studies* (August 2014).

¹⁴ See the guidance for industry *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* (July 1993). See the following two draft guidances for industry: *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials* (April 2018) and *Clinical Lactation Studies: Considerations for Study Design Guidance for Industry* (May 2019). When final, these guidances will represent the FDA’s current thinking on these topics.

¹⁵ See the following guidances for industry: *Guideline for the Study of Drugs Likely to be Used in the Elderly* (November 1989) and *E7 Studies in Support of Special Populations: Geriatrics Questions and Answers* (February 2012).

¹⁶ Cooper Lisa A., Health Inequity and Racism Affect Patients and Health Care Workers Alike Vol. 2 No. 3 March 2021 NEJM Catalyst Innovations in Care Delivery, 2021;03. doi:10.1056/CAT.21.0033.

¹⁷ Shariff et al., More than Tuskegee: Understanding Mistrust about Research Participation J Health Care Poor Underserved. 2010 August; 21(3): 879–897. doi:10.1353/hpu.0.0323.

¹⁸ For further considerations regarding the inclusion of pediatric participants in clinical investigations, see the guidances for industry *E11 Clinical Investigation of Medicinal Products in the Pediatric Population* (December 2000) and *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans* (July 2020).

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118 medical products, notably for rare diseases and for serious and life-threatening conditions.
119 Specific approaches are needed to both obtain data in diverse populations and facilitate efficient
120 medical product development and approval. This underscores the importance of prospectively
121 defining the approach to generating data for a broader and more diverse population early in the
122 development program. Consistent implementation of actions to improve racial and ethnic
123 diversity in clinical trials and studies can support early access to medical discoveries and
124 innovations, improve the generalizability of results across all patient populations, improve our
125 understanding of the disease and/or medical product under study, and inform the safe and
126 effective use of the medical product for all patients who are expected to use the medical product
127 if approved.

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130 III. WHEN A RACE AND ETHNICITY DIVERSITY PLAN IS RECOMMENDED

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132 FDA recommends a Plan be submitted for medical products for which an IND submission is
133 required and/or for which clinical studies are intended to support a marketing submission under
134 section 351(a) of the Public Health Service Act for a standalone Biologics License Application
135 (BLA), or under 505(b)(1) or 505(b)(2)¹⁹ of the Federal Food, Drug, and Cosmetic Act (the
136 FD&C Act) for an NDA. A Plan is also recommended for medical products for which an IDE is
137 required and/or for which clinical studies are intended to support a device marketing submission,
138 whether a premarket notification (510(k))²⁰, premarket approval (PMA) application²¹, a De Novo
139 classification request²², or a humanitarian device exemption (HDE) application.²³ FDA will
140 evaluate the Race and Ethnicity Diversity Plan as an important part of the sponsor's development
141 program.

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144 IV. TIMELINES AND PROCESS FOR SUBMITTING RACE AND ETHNICITY **145 DIVERSITY PLANS**

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147 Sponsors may discuss their strategy to enroll a diverse study population at any time throughout
148 the medical product's development.²⁴

149 A. For drugs, sponsors should submit the Plan to the relevant IND application as soon as
150 practicable during drug development but no later than when a sponsor is seeking
151 feedback regarding the applicable pivotal trial(s) for the drug (often at the EOP2
152 meeting). The Plan can be submitted to the IND as part of a milestone meeting package,

¹⁹ To the extent that the submission will include clinical studies that are sponsored by the applicant.

²⁰ See 21 CFR 807

²¹ See 21 CFR 814.20

²² See section 513(f)(2) of the FD&C Act

²³ See 21 CFR 814.104

²⁴ The plan should emphasize the enrollment of participants from underrepresented racial and ethnic populations early and throughout medical product development to ensure the availability of sufficient data about the safety and effectiveness of the product in diverse populations. In the event that recruitment goals are not met despite best efforts, sponsors should discuss with FDA a plan to collect this data in the post-marketing setting.

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- 153 or on its own. Sponsors should request FDA feedback on the Plan by including specific
154 questions in a formal milestone meeting request and Meeting Package.²⁵
- 155 B. For devices, sponsors should submit their Plan as part of the investigational plan included
156 in the IDE application. To discuss a proposed enrollment strategy before submitting the
157 Plan to the IDE or for clinical studies not conducted under an IDE, a sponsor should
158 follow the Q-submission process for obtaining feedback or requesting a meeting with
159 FDA.
- 160 C. For IND, IDE, or Q submissions containing a Plan, sponsors should alert the FDA by
161 marking the submission with “**RACE AND ETHNICITY DIVERSITY PLAN**” in
162 large, bolded type in the cover letter. FDA may request that sponsors provide periodic
163 updates to specific components of the Plan throughout medical product development.
- 164 D. Sponsors should include the Plan in the marketing application for the medical product as
165 well as a description of the successes and challenges in implementing it.

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V. CONTENT OF THE RACE AND ETHNICITY DIVERSITY PLAN (THE PLAN)

- 171 • Sponsors should define enrollment goals for underrepresented racial and ethnic
172 participants as early as practicable in clinical development for a given indication. These
173 enrollment goals should be based in part on the pre-specified protocol objectives of the
174 investigation. While in many cases race- and/or ethnicity- defined populations may be
175 genetically heterogenous such that analyses to characterize differential effects due to
176 pharmacogenomic variability may be difficult to discern, the Plan should begin with an
177 assessment of any data that may indicate the potential for a medical product to have
178 differential safety or effectiveness associated with race or ethnicity. For drug
179 development, as applicable to the particular drug, the collection of sufficient
180 pharmacokinetic (PK), pharmacodynamic (PD), and pharmacogenomic data from a
181 diverse population is strongly encouraged to inform analyses of drug exposure and
182 response.²⁶ For devices, data on the relevant factors for device performance (e.g.,
183 phenotypic, anatomical, or biological) should be collected to inform any differential
184 effects across a diverse population. For example, variations in skin pigmentation exist
185 across diverse populations and it is known that skin pigmentation can affect the
186 performance of certain devices. For studies of such devices (e.g., pulse oximeters), skin
187 pigmentation data in a diverse population would be a relevant attribute to collect to
188 inform the assessment of any differential effects.

²⁵ See draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (December 2017). When final, this guidance will represent the FDA’s current thinking on this topic.

²⁶ See guidance for industry *Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications* (May 2003) and draft guidance for industry *Population Pharmacokinetics* (July 2019). When final, this guidance will represent the FDA’s current thinking on this topic.

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- The Plan should describe the planned assessment of race and ethnicity in addition to other covariates with known potential to affect the safety and effectiveness of the medical product. In particular, for drugs, covariates with known potential to affect PK and PD should be assessed in order to facilitate exposure-response analyses and to inform safe and effective dosing regimens across the intended patient population, as applicable. For devices, device performance may be impacted by factors associated with race (e.g., the ability of a device to detect skin cancer based on skin pigmentation).
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- When there are data that indicate that the medical product may perform differentially across the population based on factors associated with race or ethnicity, the Plan should specify the study design features that will support analyses that will inform the safety and effectiveness of the medical product in the relevant racial and ethnic populations. In some cases, increased (i.e., greater than proportional) enrollment of certain populations may be needed to elucidate potential important differences. When there are no data that indicate that race or ethnicity will impact safety or effectiveness, it is nonetheless appropriate that enrollment reflects the epidemiology of the disease. FDA recognizes that enrollment based on epidemiology alone may not be sufficient to detect any differences in safety and effectiveness or make such inferences; however, consistent representative enrollment may provide opportunities for pooling data to evaluate outcomes by race and ethnicity.
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- The Plan should outline the sponsor’s plan to collect data to explore the potential for differences in safety and/or effectiveness associated with race and ethnicity throughout the entire development life-cycle of the medical product and not just during the pivotal trial(s) or studies.
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- In certain situations, it may be challenging to set an enrollment goal based on the epidemiology of the disease due to limited data to characterize the incidence and/or prevalence of the disease across diverse racial/ethnic populations (e.g., diseases that are defined by the presence of a rare molecular aberration). FDA encourages sponsors to leverage various data sources (e.g., published literature and real-world data) to set enrollment goals; if this is not feasible, it may be appropriate to set the enrollment goal based on demographics in the overall population with the disease or condition.
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- The Plan should include the clinical pediatric studies that are planned for inclusion as part of the pediatric development of the medical product.
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- The table below outlines the recommended elements of the Plan. Note that the examples provided in the table are intended to illustrate the type of information that should be included in the Plan and are not meant to be an exhaustive list of the measures that may be undertaken to improve diversity in clinical trials or studies.

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Category	Recommended Scope
1. Overview of the disease/condition	A. Describe available data on the pathophysiology of the disease or condition in underrepresented racial and ethnic populations. As appropriate, describe

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Category	Recommended Scope
	<p>any differential application or use of currently available prevention, screening or diagnostic strategies and treatments, across racial and ethnic populations.</p> <p>B. Discuss the current understanding of and available evidence supporting any similarities and/or differences in the disease or condition under study that are associated with the underrepresented racial and ethnic populations in the United States.</p>
2. Scope of medical product development program	<p>Briefly describe the planned trials or studies that will support the medical product’s safety, effectiveness and, if a drug, dosage in a future marketing submission. Outline the following:</p> <p>A. Study design, study population (including study eligibility criteria), endpoints and, the expected geographic locations of the trials or studies and how these aspects of the trial or study may specifically address inclusion of underrepresented racial and ethnic populations.</p> <p>B. As applicable, summarize any differential findings from clinical pharmacology studies (PK /PD data, pharmacogenomics) that may be associated with certain racial and ethnic populations and/or other relevant information.</p>
3. Goals for enrollment of underrepresented racial and ethnic participants	<p>Define and provide justification for the planned enrollment of participants from underrepresented racial and ethnic populations.</p> <p>A. Specify underrepresented racial and ethnic populations based on assessment in Category #1.</p> <p>B. Specify goals for enrollment of underrepresented racial and ethnic participants (e.g., based on the epidemiology of the disease and/or based on <i>a priori</i> information that may impact outcomes across racial and ethnic groups; and where appropriate, leverage pooled data sources or use demographic data in general population). In some cases, increased (i.e., greater than proportional) enrollment of certain populations may be needed to elucidate potential important differences.</p>

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Category	Recommended Scope
<p>4. Specific plan of action to enroll and retain diverse participants</p>	<p>A. Describe in detail the operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants in the planned trial(s) or studies, and the planned use of data to characterize safety, efficacy, and optimal dosage in these participants, when applicable.</p> <p>B. Describe specific trial enrollment and retention strategies, including but not limited to:</p> <ul style="list-style-type: none"> i. site location and access (e.g., language assistance for persons with limited English proficiency, reasonable modifications for persons with disabilities, and other issues such as transportation); ii. sustained community engagement (e.g., community advisory boards and navigators, community health workers, patient advocacy groups, local healthcare providers, etc.); iii. reducing burdens due to trial/study design/conduct (e.g., number/frequency of study-related procedures, use of local laboratory/imaging, telehealth); <p>C. Describe metrics to ensure that diverse participant enrollment goals are achieved and specify actions to be implemented during the conduct of the trial(s) or studies if planned enrollment goals are not met.</p>
<p>5. Status of meeting enrollment goals (as applicable)</p>	<p>A. As the diversity plan is updated (when applicable), discuss the status of meeting enrollment goals. If the sponsor is not able to achieve enrollment goals despite best efforts, discuss a plan and justification for collecting data in the post-marketing setting.</p>