Model Diversity Action Plan

Introduction

This document was developed to align with the FDA draft guidance on Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies[1] (here termed the "Diversity Action Plan" or DAP). It includes a DAP draft template and an appendix that is an adaptation from the MRCT Center's Recruitment Strategy Document[2] to assist in creating an effective DAP strategy and implementation plan.

This document is intended to ensure that all stakeholders, including sponsors, CROs, institutions, sites, investigators, and study staff are prepared to consider diverse and representative participation in a clinical trial program. This document will be updated upon the release of the final FDA guidance document.

By necessity, the FDA draft DAP does not give sufficient weight to the multiple strategies that will contribute to diverse participant participation. For instance, long-term, sustainable partnerships with communities and community organizations (e.g., community providers, faith-based institutions, employer groups, patient advocacy organizations, and others) help institutions, sponsors, sites, and study teams build trust and enhance access to clinical trials. Investment in clinical research infrastructure should be coupled with investment in education, innovation, and training of a diverse workforce. We provide resources elsewhere for those considerations.[3]

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[1] US Food and Drug Administration. *Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.* Accessed online, June 2024. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies.

[2] MRCT Center, available at: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/8/2021/03/13-Recruitment-Strategy-Document.pdf (Accessed December, 2023). Note that additional suggestions and tools are provided in the Recruitment Strategy Document. Please consult that resource for further helpful resources.

[3] See MRCT Center Diversity, Inclusion, and Equity in Clinical Research. Available at: https://mrctcenter.org/diversity-in-clinical-research/.

It is important for any sponsor, CRO, or other organization to ensure that strategies to increase inclusion and diverse representation in clinical research are integrated and communicated throughout the organization, centralized in review and oversight, and able to leverage experience to improve future work.

Developing a comprehensive Diversity Action Plan (DAP) is integral to fostering inclusivity and equity in clinical trials. This entails providing a fair and equitable opportunity not only for participation in research but also to derive benefits from the research, acknowledging that these benefits may take various forms. This draft template outlines key considerations for sponsors to establish enrollment goals, focusing on race/ethnicity, age, and sex/gender of participants[4] early in the clinical development process. The Plan is designed to enhance the understanding of any potential differential safety or effectiveness associated with different populations in the context of drug development. There is an emphasis on the collection of pharmacokinetic (PK), pharmacodynamic (PD), and pharmacogenomic data from these populations, facilitating analyses that inform drug exposure and response.

This document builds on the FDA's draft guidance to offer a broader global perspective. Sponsors are encouraged to specify the intended regions and countries participating in the trial and document proposed approaches to tackle barriers to diverse, inclusive, and equitable recruitment in countries beyond the US, although this information may not necessarily be required for FDA submission.

This draft DAP template was initially developed to align closely with the first iteration of the FDA's guidance on the DAP. As the FDA guidance evolved, its second iteration focused on articulating clear enrollment goals, the rationale behind these goals, and the study team's proposed measures to meet those goals to the forefront of the document and is more abbreviated in the operational description than in the first iteration. We, therefore, attempted to format this draft DAP template in a way that aligns with the flow of the most recent (second) iteration of the draft FDA guidance by including brief sections in the main body on setting enrollment goals, defining the rationale for enrollment goals, and stating the measures that will be enacted to meet enrollment goals. However, we then included an extensive Appendix that retains the format of the first FDA draft guidance and provides more

[4] This is not to discount the importance of other dimensions of diversity such as co-morbidities, geography, disability, and social determinants of health including nutrition, socioeconomic status, and housing security.
The same principles discussed in this document apply to other types of diversity. Less is known about the epidemiology of diseases across these dimensions at this time; these data should be collected and analyzed.

detailed process information to complement the sections in the main body of the draft DAP template. For example, the Appendix begins with an epidemiological overview to assess the prevalence of the disease or condition and the patient profile, then moves into scoping the medical product development program (and previous clinical studies), before beginning to set enrollment goals. This can serve as a valuable resource, enabling stakeholders to craft detailed and strategic diversity programs that are aligned with regulatory expectations.

Please note that in the Appendix of this document (page 6), we expand upon the FDA's second iteration of the draft guidance, to operationalize planning from a global perspective.[5] The US FDA guidance speaks to the populations in the US, but medicinal products are evaluated with the intention of making the products available globally. The FDA DAP draft guidance acknowledges this tension: should the enrollment goals reflect the patient population in the US or globally? In essence, what does "intended use population" mean? The guidance does not resolve this question, and here we focus on the US but acknowledge the global impact—and the ultimate intention of the research to provide data that are useful internationally. We therefore encourage sponsors to specify the intended regions and countries participating in the trial and document proposed approaches to tackle barriers to diverse, inclusive, and equitable recruitment in countries beyond the US— whether or not this information is included in the submission to the FDA.

It is important to consider a phased approach in the development of the DAP, progressing from a US-centric strategy to a global one that acknowledges the unique needs, priorities, and populations of each country.5 Recognizing that a uniform approach may prove insufficient, it becomes imperative to formulate strategies tailored to the specific requirements of local studies. This involves a focus on diversity priorities, equity, and the reduction of barriers. The alignment with the ethical principles outlined in The MRCT Center's *Global Diversity Equity and Inclusion Roadmap* - is proposed to ensure a more nuanced and inclusive global approach. This draft DAP template is designed to be a global, dynamic, and evolving document, maintaining relevance amid the ever-changing landscape of clinical trials.

[5] Wright K, DeCormier Plosky W, Ahmed HR, White SA, Bierer BE. First, do no harm: a global perspective on diversity and inclusion in clinical trials. Nature Reviews Drug Discovery. 2024 May 8. 23, 481-482 (2024). doi: https://doi.org/10.1038/d41573-024-00078-4.

Definitions and Demographics

Race is a social construct and not a biological biomarker. Indeed, the concept of "race" has been used in the US but is not globally understood or a term of differentiation. Until 2024, the Office of Management and Budget (OMB) in the US defined five categorical races[6] and ethnicity as either "not Hispanic or Latino" or "Hispanic or Latino," creating artificial distinctions that were challenging to apply. In 2024, OMB finalized a new policy that eliminated these two separate categories (i.e., race and ethnicity) and instead instructs US reporting of ethnicity in a more permissive (and single ethnicity category) way.[7] The US OMB categorizations may still not reflect international complexity and, unfortunately, to date the FDA DAP draft guidance does not incorporate the revised OMB guidance. We have, however, in this document used the updated approach mandated by OMB as we believe that these designations more accurately reflect current expectations.

[6] American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White.

[7] The new OMB 2024 categories are using one combined question for race and ethnicity and encouraging respondents to select as many options as apply to how they identify. There was an addition of Middle Eastern or North African as a new minimum category. The new set of minimum race and/or ethnicity categories are: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Middle Eastern or North African, Native Hawaiian or Pacific Islander, and White.

[This is intended to serve as a guide. All sections should be revised, as necessary, to reflect the specific objectives and challenges of a given protocol)

Sponsor Logo	Other Logos

Clinical Trial Representation /Diversity Action Plan

Medical Product Name

IND #(s)

Protocol #(s)

NCT #(s)

Study Title

Study ID

DAP Version #
Date

Version History

Revision	Date	Author(s)	Description

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A. Enrollment Goals

To design a clinical trial effectively, the planned enrollment goals for participant populations should be articulated and justified. This justification should be rooted in the epidemiology of the disease or condition for whom the intervention is intended, and, to the extent possible, the epidemiology should consider what is known for the United States population and globally. In the absence of data about the epidemiology of the disease or condition, the demographics of the general population in the region should become the default plan.

The rationale for any eligibility criteria that might lead to the exclusion of underrepresented populations must be explicitly justified. This includes ethical, medical, and scientific bases, supported by empirical data when available. For instance, certain health conditions or genetic predispositions may necessitate exclusion to ensure participant safety or maintain the integrity of study outcomes. The ethical justification could involve considerations of participant vulnerability or potential harm from investigational interventions.

a. If applicable, describe how eligibility criteria will be adapted and amended over the course of the trial, consistent with the evolving demonstration of safety, to result in a study population that accurately reflects the population affected by the disease or condition.

b. If adaptive eligibility criteria are not anticipated, explain why not, and how the information will be collected and analyzed after the trial concludes.

Enrollment goals must be disaggregated by:

- Race and Ethnicity (per OMB 2024 direction)[8]
- Sex[9]
- Age group

[8] The Federal Register: The Daily Journal of The United States Government (2024). Available at: https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and (Accessed: 20 August 2024).

[9] Note gender is not included as a differentiating category in the FDA DAP draft guidance. We have therefore excluded it here, although we believe that issues of sexual orientation and gender identity should be included going forward.

[Sample recruitment planning table]

PLANNED	Female at Birth	Male at Birth	Unknown/Not Reported
Race and/or Ethnicity Categories			
American Indian or Alaska Native For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.			
Asian For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.			
Black or African American For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.			
Hispanic or Latino For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.			
Middle Eastern or North African For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.			
White For example, English, German, Irish, Italian, Polish, Scottish, etc.			

Please note that this table is an example, and the categories can be modified as appropriate. It is derived from the current updated OMB categories and can be changed as appropriate. If you are conducting Sexual Orientation and Gender Identity (SOGI) research, there are additional considerations. What is meant by 'sex' in this document is biological sex at birth, but other categories may need to be included if intersex individuals' part of the participant population of interest.

Note: the OMB guidance provides detailed instructions as to how to solicit this information from participants. Please see: https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and.

B. Rationale For Enrollment Goals

Diversity Action Plans should include a clear rationale for the enrollment goals of a study. To meet this statutory requirement, sponsors must provide sufficient information and analysis to justify how these goals were established. This includes comprehensive details on the disease or condition under study, encompassing its natural history, associated risk factors, and other pertinent factors.

In scenarios where multiple clinical studies are conducted to support a single marketing submission, and enrollment goals are specified across these studies, sponsors must clarify how each individual study contributes towards achieving the overall stated enrollment goals.

There is a hierarchy of enrollment goals. Studies should strive for enrollment that reflects:

1. The subgroup of the disease or condition as defined by genetics, biomarkers, or other factors that are known to subset the disease or condition by diagnosis, prognosis, severity, or treatment plan.
2. If no subgroup differentiators are known, then the demographics of the disease or condition itself should be used.
3. If the epidemiology of the disease or condition is not known, then the demographics of the general population should be used as the enrollment goal.

Other considerations may apply. The choice and extenuating considerations (e.g., ultra-rare disease) should be clearly described.

It is important to consider the enrollment goals on a global scale and their interconnectedness with FDA considerations in the Diversity Action Plan. How is global enrollment and recruitment used to satisfy US demographic expectations?

For drugs and biologics:

- The DAP submission should include data and information delineating the potential differences in the safety and effectiveness of the investigational drug among the clinically relevant populations. This encompasses variances in pharmacokinetics (PK) and pharmacodynamics (PD) that could influence treatment outcomes.

- Data regarding genetic differences in PK, PD, safety, or effectiveness (e.g., genetic variations, which may vary based on ancestry, that may impact drug metabolism or susceptibility to adverse reactions).
- The relevance of other population-level or individual characteristics, such as socioeconomic status, geographic location, or comorbidities, should be assessed based on data that suggest an impact on clinical outcomes.
- If an international trial is planned, the inclusion of a list of potential country sites and participants with a planned activation schedule is necessary. This involves carefully selecting regions, countries, and specific sites through feasibility assessments during study planning. The percentage of participants from the US and from each international region or country should be estimated, detailing demographics and other relevant subpopulation characteristics relevant to disease epidemiology, product safety, and efficacy assessments. The list the intended countries where sites will participate should be included, explaining their selection based on disease epidemiology and population characteristics. Each country's plan should be outlined to optimize participant representation and data collection efficacy, adapting as the study progresses. The inclusion of International enrollment will impact the final set of data reflecting the demographics of the population.

C. Measures To Meet Enrollment Goals

The Diversity Action Plan (DAP) must outline how the sponsor intends to monitor the designated enrollment goals.

- It should detail strategies for both recruiting and retaining participants, emphasizing diversity, and ensuring that the enrolled study population is representative.
- The DAP should also include a plan for monitoring enrollment progress throughout the clinical study to ensure that the specified goals are being met.

Appendix

This appendix is based on MRCT Center's Recruitment Strategy Document and structured according to the earlier FDA guidance on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials. The italicized sections below reflect the language in earlier FDA guidance. This appendix is intended to provide further details and procedures in order to create an effective "Diversity Action Plan" strategy that can guide the DAP submission process. This Appendix can be considered a worksheet to determine the appropriate enrollment goal(s) and a workplan for implementing measures to achieve the stated goal.

1. Overview of the Disease/Condition

Provide a comprehensive depiction of the disease or condition under investigation, intending to provide (1) information on demographic factors (e.g., race/ ethnicity, geography [region/country, rural/urban location], age, sex, gender identity, sexual orientation, disability status, socioeconomic status, pregnancy and lactation status, comorbidities, other) that are related to differences in risk factors, disease burden, or outcomes, (2) provide an overview of the disease/condition in each of the identified population(s) and (3) outline the incidence and mortality rates in each group. This section is intended to describe the real-world patient population, by subgroup, and by country for the disease or condition being studied, and not specifically for the investigational product or product development program. Cover the following key components:

I. Disease/Condition Incidence & Prevalence

- **Incidence, prevalence, and/or character of the disease or condition:** Give an overview of the disease's occurrence, encompassing its incidence (frequency of new cases per unit time), prevalence (total cases), and/or character (e.g., severity, temporal differences in progression, etc.) across (a) the overall population, (b) distinct racial and ethnic minority subgroups, and (c) other subgroups with relevant disparities as known.
    - For overall population: describe data sources used to collect information on incidence and prevalence of the disease or condition:

        - In the US
        - In other regions or countries, by region or country, if relevant
    - For distinct racial and ethnic minority populations: describe data sources used to collect information on incidence, prevalence, and character of the disease or condition, and completeness of those data. Include a brief description of data gaps. Include information based on data from the US and from other regions and countries.
    - For other subgroups (e.g., sex/gender/sexual orientation, geography, disability, veteran status, etc.): describe data sources used to collect information on incidence, prevalence, and character of the disease or condition, and completeness of those data. Include information based on data from the US and from other regions and countries (as relevant and available).
    - Summarize data to provide an assessment of the current understanding of subpopulation differences in the disease or condition in the US and outside the US.
- **Differences in Pathophysiology:** Using disparities by subgroup identified above, provide an in-depth discussion of differences in the disease's underlying biological mechanisms, and correlative and/or causative factors, across different subpopulations, if known.
- **Differences in Prevention, Screening, or Diagnostic Approaches:** Present an account of the differences in methodologies employed for diagnosing the disease, encompassing the range of tests, evaluations, and tools used for identification, as well as differences in screening or prevention strategies by subpopulation and/or geography, if known.
- **Differences in Treatment Strategies:** Offer insights into differences in the existing strategies used for treating the disease, by subpopulation and/or geography, if known.

II. Participant/Patient Disease Profile

- Outline the patient profile/study population, including disease prevalence, references to the demographics including but not limited to race, ethnicity, geography [region/country, rural/urban location], age, sex, gender identity, sexual orientation, disability status, socioeconomic status, pregnancy and lactation status, comorbidities, other, as relevant). Consider these in relation to the study question.

2. Scope of Medical Product Development Program

This section describes the medical product development program, prior and planned trials that will support the planned marketing submission(s). Include subpopulations (e.g., race, ethnicity, geography [region/country, rural/urban location], age, sex, gender identity, sexual orientation, disability status, socioeconomic status, pregnancy and lactation status, comorbidities, other, as relevant) and mention of the planned Pediatric Investigations Plan if available.

Document the intended patient population(s) for the product. Explain differences in the plan compared to the real-world patient population affected by the disease or condition. Include an overview of the study design, study population, eligibility criteria, endpoints, and the expected geographic locations of the studies. Discuss how the study will address inclusion of underrepresented racial and ethnic populations and other relevant subpopulations. As applicable, summarize any differences in clinical pharmacology studies (PK/PD data, pharmacogenomics) associated with subpopulations (e.g., race, ethnicity, sex, age, ability, co-morbidity) and/or other relevant information.

I. Product Development Program

- Outline the overall product development plan and planned product indication.
- Describe prior pre-clinical and clinical studies that specifically address whether there are product differences by subpopulation. Provide evidence of, or the lack of, product differences by subpopulation. Include a summary of prior pharmacokinetic/pharmacodynamic (PK/PD) and pharmacogenomic studies in different subpopulations that have been performed that provide evidence of similarity or differences in safety or efficacy across those subpopulations.

- If prior studies are inadequate, describe how the product development program will develop evidence of product differences or lack thereof in the current or planned future studies. Note that if the biology (e.g., genetics) or course (e.g., prognosis, treatment options, co-morbidity etc.) differs by subpopulation, then the product will need to be tested in these different subpopulations even if the PK/PD and pharmacogenomic studies show no differences.
- Describe how this current study fits into the overall product development plan. Describe any concurrent studies that overlap and/or may provide insights into this study and the proposed DAP.
- Summarize planned future studies that will support the marketing application, including geographic locations of the studies, and how these future clinical trials or studies will contribute to the safety and efficacy of the investigational product in different subpopulations and to an understanding of subpopulation differences, if any.

II. Summary of Clinical Studies Included in this Diversity Action Plan

- Briefly outline the overall study questions, design, eligibility criteria, and planned outcomes and endpoints.
- Describe how the study question reflects the needs of diverse populations or subgroups and the input of patients and/or local communities within the different countries in which the study is being conducted (if applicable).
- Describe how healthcare provider, patient, participant and/or community input was sought, collected, and included in the design of the study, selection of outcomes and endpoints, and population-specific insights (e.g., recruitment approaches, review of participant-facing materials).
    - Include a description of the demographic representation of the individuals and groups from whom that input was sought.
- When applicable, describe the detailed operational measures that will be implemented to enroll and retain underrepresented populations in the planned study(ies) and the planned use of data to characterize the safety, efficacy, and optimal dosage in these participants. when applicable. Include whether sub-

studies are planned with any subpopulation to assess potential product differences (e.g., PK/PD studies of an understudied subpopulation).

- Summarize the plan to assess subpopulation variance of recruitment, screen failure, enrollment, retention, adverse events and serious adverse events, and efficacy.

* Please note that certain aspects may be centrally managed, such as randomization, outcomes and endpoints, while others will require country and site-specific attention, like recruitment approaches and reviews of participant-facing materials

3. Goals for Enrollment in the Clinical Study

In this section, provide justification for the planned enrollment goals of participants from racial and ethnic subpopulations, and other subpopulations, as relevant to the real-world patient population affected by the disease or condition. Here, describe the goals for enrollment of subpopulations, based on the epidemiology of the disease or condition and/or based on identified subpopulation differences. These goals are most effectively established when incorporated into the development program with early engagement with FDA. This ensures alignment between sponsors and FDA on these "goals," emphasizing that they are not intended as mere minimum quotas.

Include plans for adaptation of the trial or enrichment of certain subpopulations that may be needed to identify potentially important differences.

I. Study Plans

- Describe and justify the planned enrollment goals of the intended participant populations, including under-represented populations, based on epidemiology of the disease or condition in the U.S. and other countries.
- Justify any eligibility criteria that result in exclusion of underrepresented populations. Include the ethical, clinical, or scientific basis for such criteria, and upon what data the criteria were based.
    - If applicable, describe how eligibility criteria will be adapted and amended over the course of the trial, consistent with demonstration of safety, to

result in a study population that accurately reflects the population affected by the condition.

- If adaptive eligibility criteria are not anticipated, explain why not, and how the information will be collected and analyzed after the trial concludes.

4. Specific Plan of Action to Enroll and Retain Diverse Participants

In this section, the region, country and site, selection process are specified, including how the feasibility assessment is conducted to optimize the likelihood of success in recruitment, enrollment, and retention of the intended populations. The methods to identify, assess, and validate sites with access to and experience with the intended study populations are described.

In addition, the recruitment and retention strategies are detailed, including special tactics, services, modifications, and accommodations that will be provided, as well as other methods to reduce participant burden and optimize recruitment and retention. Patient, patient advocacy and community engagement plans, and outreach to local and community healthcare providers, as outlined above, are discussed.

I. Selected Countries and Planned Projections

- Include a list of potential country sites and participants with the planned activation schedule as available.
- Describe the criteria and process for selecting these regions, countries, and sites in study planning and the feasibility assessment performed.
- Provide the percentage of total participants who will be enrolled from the US and from each region and/or country outside the US. For each country, describe the percentages of participants by demographic variable.
    - Consider whether over-enrollment of certain subpopulations is necessary to gather important data on safety or efficacy for those subpopulations.
    - Describe how and how frequently (1) enrollment, and enrollment by subpopulation and (2) retention, and retention by subpopulation will be monitored over the course of the study.

- Explain how under-enrollment or differential retention of any defined subpopulation will be identified, communicated, and mitigated as the study progresses.
- List the intended countries (and sites if known) that will participate in the clinical trial/program:
  - Country 1
  - Country 2
  - Country 3…
- Describe how and why the countries were chosen and the demographics of the population represented based on the epidemiology of the disease.

- For each country, provide the intended country plan to the extent possible, and complete the table as the study progresses. This can vary from country to country.

Country	Randomization Target (N)	Total Number of Sites	Monthly Randomization Rate per Site (P/S/M)	Over Enrollment Allowance (%)	Screen failure ratio (% screen fail)	Sites Actively Screening (%)	Target First Site Initiated (Date)	# of days until 25% Sites Active	# of days until 50% Sites Active	# of days until 90% Sites Active	First Patient Screened (FPI) (Date)

II. Site Capacity Profile

- Describe criteria for site selection to maximize potential to enroll intended subpopulations.
    - Use a data-driven approach to identify sites that can effectively enroll diverse populations, including both those with a history of successful enrollment and those with potential future enrollment. Specify the data sources and planned analyses.
    - Describe any geographical mapping that has been performed to optimize the likelihood of site recruitment of the intended subpopulations relevant to the disease or condition.
        - If known, include data on satellite sites or partner organizations (e.g., community health centers) that may be relevant to recruitment and retention.
- Describe any flexibilities in planned study conduct. These may include options to ease access to a clinical trial/research study for those who may have time or logistical challenges (e.g., the possibility of virtual visits, after-hour/weekend hours, use of local labs or home visits). Describe whether there are risks to the data (e.g., comparability, integrity) introduced by the different flexibilities planned, and how these potential risks will be mitigated. Describe accommodations to enable people with disabilities access to research are essential and are required by law in the US.
    - Include information on other measures that have been or will be introduced to reduce participant burden (e.g., provision of reimbursement, compensation, transportation, food, childcare, eldercare).
    - Describe how the number or frequency of procedures has been minimized to reduce burden, and whether the site(s) align and agree.
- Describe permissible remote or decentralized elements (e.g., local imaging facilities and laboratories, remote or in-home visits, telehealth, electronic data capture, electronic patient reported outcomes, etc.) that further reduce participant burden, whether participants will be able to choose whether to use those decentralized elements, and whether sites are able to implement these changes.

  - Ensure that selected sites have processes and procedures in place to implement the planned study modifications, accommodations, and flexibilities.
  - Describe whether there are concerns with data comparability and integrity or source documentation.

- Describe what community engagement efforts, if any, will be utilized to support sites in engaging the communities of the intended patient population

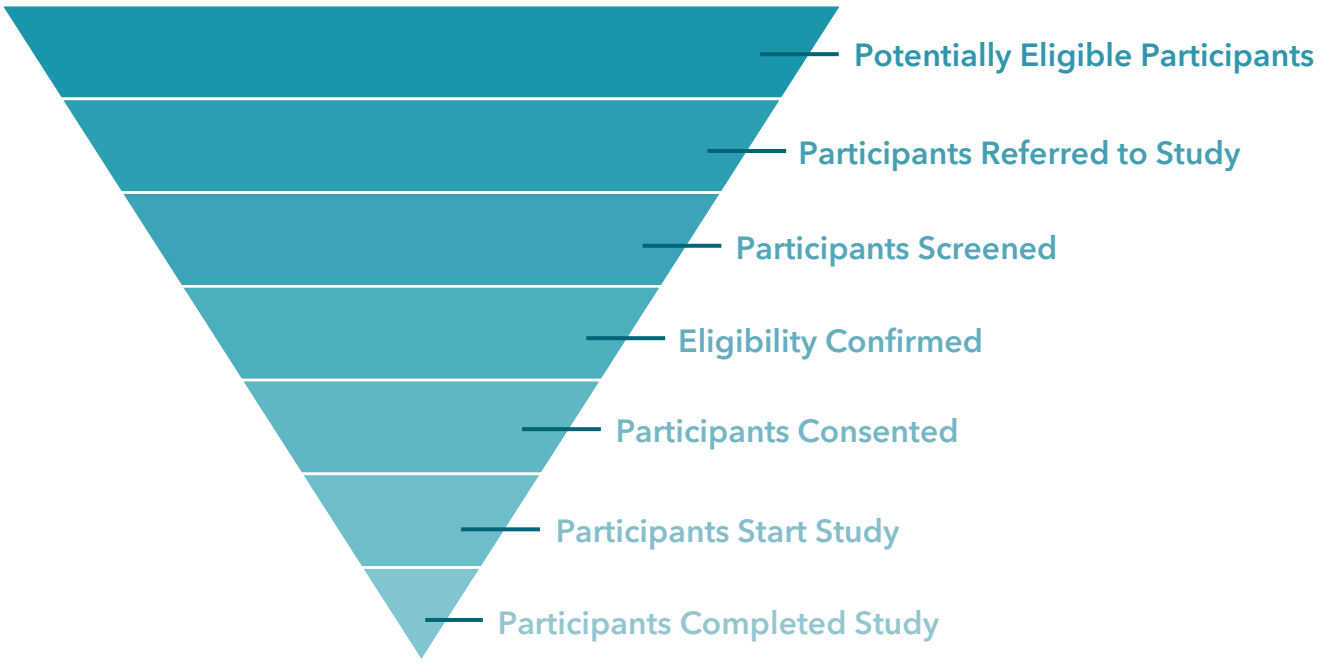
III. Recruitment and Retention Strategies

- Describe community engagement activities and partnerships that will enable education, awareness, and access amongst intended populations, including advisory boards, advocacy organizations, community healthcare workers, and providers.
- Provide a high-level overview of primary and secondary participant recruitment and retention strategies. What specific approaches and techniques will be used to access and engage intended populations?
- Describe healthcare provider materials, outreach, and plans for dissemination.
- Describe patient/participant recruitment materials that are or will be developed and how they are going to be used.
  - Describe any patient, participant, or community review of those materials.
  - Explain whether and when the patient/participant recruitment materials will be translated and into which languages, and whether modifications to the materials have been or will be made for inclusion of people with disabilities.
  - Describe the process for dissemination to the intended populations to optimize relevant patient populations who will have access to the materials.
  - Describe efforts to simplify referral and intake processes, including the provision of patient navigators and/or linguistically and culturally appropriate interpreters.

- Include specific activities planned that address barriers to participation for any of the intended study populations.
    - Identify sustained community engagement efforts and community partnerships by sponsor and/or site.
    - Describe planned patient, patient advocacy, and community engagement activities that may increase access, referrals, and recruitment of relevant subpopulations.
    - Include outreach to community healthcare providers, referral networks, and others, and whether contract vendors will be used.
        - Identify method of outreach (e.g., email, webinars, in-person, or virtual meetings).
    - Describe how principal and site investigators and their study teams have been engaged and trained to fulfill the goals of broad and diverse participant recruitment.
    - Describe any specialized technology that will be used.

IV. Recruitment and Retention Projections

- Detail both study-specific target numbers by subpopulation – age, sex, race, ethnicity, etc. Recognize that not every site needs to enroll a target number of diverse or underrepresented patients, but the overall study should.
- Review enrollment data on a monthly basis to track progress towards targets. Conduct a comprehensive analysis quarterly and evaluate progress at major milestones to ensure targets are met. Adjust recruitment strategies as needed based on ongoing data and provide regular updates to involved parties on progress.



[Sample recruitment planning table]

PLANNED	Female at Birth	Male at Birth	Unknown/Not Reported
Race and/or Ethnicity Categories			
American Indian or Alaska Native For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.			
Asian For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.			
Black or African American For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.			
Hispanic or Latino For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.			
Middle Eastern or North African For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.			
White For example, English, German, Irish, Italian, Polish, Scottish, etc.			

Please note that this table is an example, and the categories can be modified as appropriate. It is derived from the current updated OMB categories and can be changed as appropriate. If you are conducting Sexual Orientation and Gender Identity (SOGI) research, there are additional considerations. What is meant by 'sex' in this document is biological sex at birth, but other categories may need to be included if intersex individuals' part of the participant population of interest.

5. Status of Meeting Enrollment Goals

In this section, how recruitment and retention will be monitored, and suggested action steps for mitigation if recruitment or retention are under target, are explained. Risk and contingency management plans are considered.

I. Recruitment Monitoring and Mitigation Plan

- Detail how and how often tracking, review, and analyses of recruitment and enrollment numbers will be ascertained.
    - Plan for who will collect the data and the frequency of data transfer.
    - Include age, sex/gender, race/ethnicity, disability, and other categories as relevant.
    - Include specific oversight of site performance against site-specific recruitment commitments.
    - Periodically collect information from sites on persistent recruitment barriers, unforeseen challenges, and, equally, successful strategies.
    - Provide suggested mitigation strategies if recruitment and enrollment are under target compared to anticipated plans.
- Provide information on how each site, country, and region will be monitored and by whom. Include information on whether there are dedicated sponsor or sponsor designees assigned to the region, country, or site for support.

II. Retention Monitoring and Mitigation Plan

- Describe how and how often tracking, review, and analyses of enrolled participants and study follow-up will be performed.
    - Plan for who will collect the data and the frequency of data transfer.
    - Include age, sex/gender, disability, and other categories as relevant.
    - Include specific oversight of site performance against site-specific retention commitments.

- Periodically, collect information from sites on persistent retention barriers, unforeseen challenges, and, equally, successful strategies.
- Provide methods that will be used to monitor retention (i.e., patient navigators or ambassadors; frequency and style of follow-up reminders) and provide suggested action steps for mitigation if retention is under target.
    - Consider schedule of escalating interventions if site-specific recruitment does not improve with implementation of mitigating strategies.
- Include information on whether and how often rates of screen failure, enrollment, drop-out, and lost-to-follow up will be performed on subpopulations.

III. Risk and Contingency Management

- Outline the risks associated with this study in terms of recruitment timelines and milestones, and list the contingency strategies, triggers, and the action plan, annotating any differences in:
    - US sites, investigators, and study staff
    - Other regions and countries
- Outline data-driven methods for monitoring and for mitigation if the projected balance of enrolled subpopulations is skewed. Mitigations strategies may include:
    - Closing or pausing enrollment by site and/or by subpopulation
    - Dynamic adjustments of site subpopulation commitments
    - Addition of new sites

IV. Data Analysis

Here, a plan and justification for collecting data in the post-marketing setting if enrollment goals are not met should be outlined. Learnings from the process should be retained and adjustments made to future diversity action plans.

- Outline what would trigger a post-approval study for further collection of subpopulation data (post-approval requirements and/or post-approval commitments studies).
- Describe whether and how real-world data will be collected to enhance understanding of product effects in diverse patient populations.
- Perform post hoc analysis of performance on diversity metric and memorialize lessons learned.