MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Integrating Considerations for Diversity, Equity and Inclusion (DEI) into a Recruitment Strategy Document

Purpose

Recruitment strategy documents are integral to recruitment and are intended to ensure that all stakeholders, including sponsors, CROs, institutions, sites, and investigators are adequately prepared to enroll participants into the trial. These prospective plans provide an opportunity to create the expectation of diverse recruitment in a trial.

This template document has been modified to integrate diversity, equity, and inclusion (DEI) considerations for those who prepare the RSD (e.g., sponsors, CROs, PIs and/or research teams), as well as those who may review the RSD (e.g., sponors, sites, IRBs) to assess if a study or site's recruitment strategy plan is appropriate. This resource is meant to aid stakeholders to incorporate robust DEI initiatives into their recruitment strategies and it closely aligns with the FDA's draft guidance, 'Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials.'[1]

Please note, creating 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. Investment in clinical research infrastructure in the community is important and should be coupled with investment in education, innovation, and training of a diverse workforce.

[1] Food and Drug Administration. Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials. Accessed online, June 2022. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

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Sponsor Logo

CRO Logo

Recruitment Strategy Document

Study Title

Protocol #

NCT #

Study Logo

[This Recruitment Strategy Document is a template and 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)

Document Approval Signatures

Owner/Author _____

[Name] [Date]

[Sr.] Clinical Project Manager

Approved by: _____

[Name] [Date]

Global Clinical Operations Lead

Approved by: _____

[Name] [Date]

Project Manager, CRO

Version History

Revision	Date	Author(s)	Description

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ABBREVIATIONS	
CPM	Clinical Project Manager
CRA	Clinical Research Associate
CRO	Clinical Research Organization
CST	Clinical Sub-Team
EPT	Early-Stage Product Team
FAQs	Frequently Asked Questions
FPI	First Patient In
FPO	First Patient Out
FPS	First Patient Screened
GCOL	Global Clinical Operations Lead
GMA	Global Medical Affairs
HCP	Healthcare Professional
IRB	Institutional Review Board
KOL	Key Opinion Leader
LPI	Last Patient In
LPO	Last Patient Out
LPS	Last Patient Screened
LPT	Late-Stage Product Team
MSL	Medical Science Liaison
NCT	National Clinical Trial (identifier number assigned by ClinicalTrials.gov when a study is registered)
PAG	Patient Advocacy Group
PR&R	Patient Recruitment and Retention Team
PST	Product Strategy Team
RSM	Remote Site Monitor
SSE	Study Site Engagement Team

RECRUITMENT PLAN OBJECTIVE

[Summarize the objective of this recruitment and retention plan. Include reference to if/how diverse and/or underrepresented populations are considered and the protocol's plan to identify sites to meet the intended recruitment and enrollment goal. Include relevant information or inquiry on the safety and efficacy of the research treatment or intervention and the population of interest. When there are no data that indicate that race and/or ethnicity or other demographic or non-demographic variables will impact safety or effectiveness, it is nonetheless appropriate that enrollment reflects the epidemiology of the disease.]

STUDY QUESTION

[Briefly describe the study question and intended population. Include reference to diversity and what the study question means for diverse populations or subgroup considerations.]

Does the study question (or protocol) provide a description of the intended population? The intended population should be supported by information regarding demographic (e.g., age, sex, gender, race, ethnicity, ancestry, etc.) and non-demographic factors (e.g., dynamic variables that may change, including gender identity, social determinants of health, comorbidities, current medications, etc.), distribution of the disease in the general population, the epidemiology of disease, and/or those for whom the intervention is intended.

STUDY CHALLENGES

[Outline the study challenges from a recruitment perspective, and then consider challenges related to retention . Consider anticipated barriers to recruitment and retention,in particular, those related to the recruitment of diverse and/or underrepresented populations.]

Have community and patient insights been incorporated into anticipated barriers? Do the challenges include anticipated barriers to recruitment related to diverse and/or underrepresented populations? For example, consider:

* Lack of awareness and access to clinical research or a particular study.
* Need for translation of participant-facing materials, including recruitment information
* Inaccessible sites and study materials for people with certain physical, auditory, cognitive, and visual disabilities
* Burdensome study design and research procedures.
* Logistical barriers, such as transportation, child-care, accessibility, etc.
* Concerns around payment and compensation for time.
* Inclusion of community and patient insights into anticipated barriers.

STUDY OPPORTUNITIES

[Outline the potential opportunities/benefits of the study and proactive approaches to address barriers from a recruitment perspective.]

Does the description provide opportunities or approaches to address and/or alleviate each of the anticipated barriers? If feasible to the study, are flexible accomodations listed that aim to ease access to a clinical trial/research study for those who may have time or logistical challenges? Including the possibility of virtual visits, after-hour/weekend hours, and/or using local labs or home visits may reduce recruitment and retention barriers.

STUDY PLANS

[Outline the original study assumptions and milestone goals.]

Number of Patients Screened:	**[# Screened]**
Number of Patients Randomized:	[# of Randomizations]
Estimated Screen Failure Rate:	[Screen Failure %]
Planned Randomization Rate:	[# Rand / # Sites / Enrollment Period Months]
Estimated Drop-out Rate:	[Drop-out Rate]
Planned Complete:	[Estimated number of completers]
First Patient in (FPI):	[Date]
Last Patient in (LPI):	[Date]
Number of Sites:	[# Sites]
Number of Countries:	[# Countries]

PARTICIPANT/PATIENT PROFILE

PARTICIPANT/PATIENT DISEASE PROFILE

[Outline the patient profile including disease prevalence, demographics, symptoms, burden of disease, diagnosis pathway, treating physician's treatment options, etc. Consider these with relation to the study question.]

Does the study provide a thorough profile of 'demographic variables' inclusive of, but not limited to race, ethnicity, sex, and age? Are 'non-demographic variables' included, such as gender identity, social determinants of health, co-morbidities, medications, etc?

PARTICIPANT/PATIENT JOURNEY

[Include a patient pathway visual or flow of where, how, when, and by whom (in relation to possible enrollment) a patient is diagnosed and/or treated. Identify potential times, locations, and opportunities for study awareness.

Seeking consultation from potential participants, community advisory boards, or patient advisory groups can help indicate where recruitment information should be posted and whether the journey as mapped is burdensome for potential participants, especially with respect to diverse and/or underrepresented populations.

CHALLENGES OF PARTICIPATING FROM A PARTICIPANT/PATIENT PERSPECTIVE

[Include a bulleted list of potential study-specific challenges and risks. Detail anticipated challenges, e.g., how study requirements, hours, locations, travel costs may impact recruitment of specific demographic and other groups. Include how this information was ascertained.]

Were patients, potential participants, and/or community representatives consulted to help answer these questions?

POTENTIAL OPPORTUNITIES OF PARTICIPATING FROM A PARTICIPANT/PATIENT PERSPECTIVE

[Include a bulleted list of potential study-specific opportunities and benefits.]

Have the potential benefits listed considered the needs of underserved populations?

Were patients, potential participants, and/or community representatives consulted to help design the study question or identify potential benefits?

STUDY RESPONSIBILITIES

[List the collaborators and vendors involved with site identification, engagement, training, recruitment, and retention. Additionally may outline the roles of the CRO / CRAs with overall and site-based recruitment responsibilities and the communication plan among vendors.]

Do any of the collaborators and vendors have particular experience or expertise in recruitment and retention of diverse populations?

Vendors/Collaborators	Roles/Responsibilities	Site	Competencies

COMPETITIVE LANDSCAPE

[Outline/summarize the current and known forthcoming competing studies, how they may impact your study recruitment, and how you are leveraging internal groups or other resources to keep up to date on potentially competitive trials.]

Trial Phase	Sponsor	Intervention(s)	Indication (Study Question)	Target Accrual	Trial Locations (Country/Site)	

STUDY FEASIBILITY SUMMARY

[Outline who conducted study feasibility and when it was completed. List the key learnings and how they may have been considered in protocol design and/or site selection, considering partnerships with community organizations and/or patient / advocacy input. Additionally, list the projected randomization rate and how this rate was established / validated.]

Does the study feasibility description provide information on how diverse site selection, feasibility assessments, and input from community organizations were conducted?

COUNTRY SELECTION

[Outline how and why the countries were chosen, and what additional representation they provide.]

Including different countries in research can result in wider demographic representation. Does the plan explain how/what additional representation will be provided by the countries selected? Do these countries add additional representation?

SELECTED COUNTRIES AND PLANNED PROJECTIONS

[Include country targeted sites and patients, along with site activation schedule]

Country	Randomzation 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)

BACKUP COUNTRIES

[Include a list of any backup countries in the event additional countries are required.]

COUNTRIES NOT SELECTED

[Include a list of any specific countries that were not selected or cannot participate in this study and the reasons why.]

SITE PROFILE

SITE CAPACITY PROFILE

[Outline the site profile of each site, including patient capacity, staffing/resourcing, translation services, specialty type (if any), experience, specific expertise, special needs/equipment, etc.

Detail the site's demonstrated capacity for recruitment of the intended population by demographic (e.g., age, sex, gender, race, ethnicity, etc.) and non-demographic factors (e.g., geographic location, gender identity, social determinants of health, co-morbidities, medications, etc.]

Does the description outline the specific sites capacity, particularly as it relates to DEI considerations and study objectives? For example, does the site capacity profile description include bilingual speakers for consent? Does the site capacity profile report the site's history of recruitment and retention, with specific attention to the intended population for this study? This site selection logic model is an additional resource to consider for site selection.

SITE POPULATION PROFILE

[Outline the local population profile and the site population profile; use the site's completed feasibility assessment data to inform the site population profile. Compare to geophysical data for the location, if available.]

What level of detail does the site population profile include? Are demographic and non-demographic profiles of the site population able to be shared? Are the variables of the intended study population included in the reported profile?

PATIENT RECRUITMENT STRATEGIES AND TOOLS

RECRUITMENT AND RETENTION STRATEGY

[Provide a high level overview of primary and secondary patient recruitment and retention strategies. What specific approaches and techniques will be used to access and engage intended populations?]

RECRUITMENT AND RETENTION MATERIALS

[Outline site, HCP, and patient materials to be developed and a brief description of how each material is to be used.]

Were materials reviewed for health literacy principles? Were materials reviewed for accessibility? Are materials created with inclusive and gender neutral language? Will materials be translated?

Was user-testing accomplished with representative populations?

Material	Brief Description	User-tested?	By Whom

DIRECT TO PATIENT/PARTICIPANT OUTREACH

[Outline what targeted patient outreach tactics or strategies will be used: in-clinic recruitment, patient navigators or ambassadors, website, mobile app, search engine marketing, display advertising, email outreach, trial listings, TV, radio, print, etc. What specific approaches and techniques (i.e., EHR mining) are employed to provide access to and engagement of intended populations?]

Do the targeted outreach approaches include techniques for reaching underrepresented and underserved populations (i.e., translations, outreach location listing, social media outlets, etc.)?

REFERRING PHYSICIAN OUTREACH

[Outline healthcare provider outreach, continued communication strategy, sources of data, implementation, and follow up plan. Have the diversity goals been emphasized with study clinicians?]

Will healthcare providers receive regular communications and followup?

Does the outreach strategy include physicians and health care sites that serve underrepresented and underserved populations?

PATIENT ADVOCACY OUTREACH

[Outline opportunities to work with relevant advocacy groups.]

Group Name	Group Contact	Outreach Goals

HEALTH CARE PROFESSIONAL SOCIETY OUTREACH

[Outline opportunities to work with professional societies and execution plan.]

Have professional societies, including those that specifically include diverse or underrepresented populations, been approached? Including diverse representatives that understand and empathsize with the potential participant population can be helpful.

INTERNAL AWARENESS

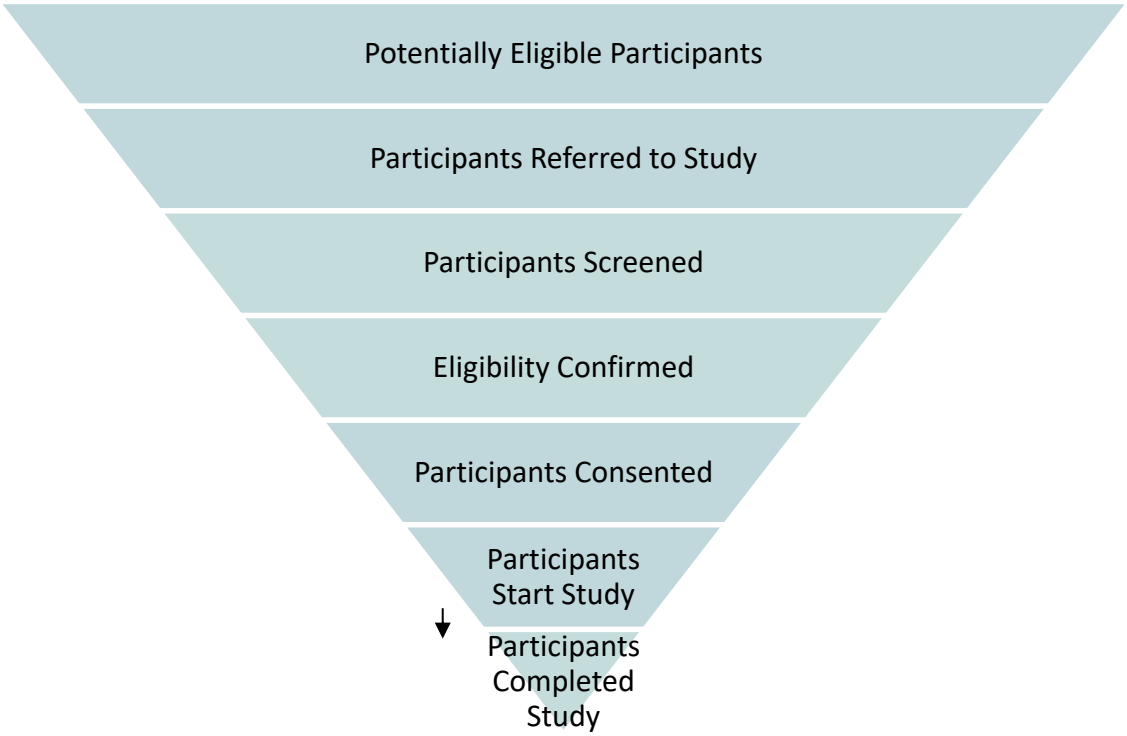
[Outline opportunities to raise awareness within the organization.]

PUBLICATIONS

[Outline opportunities to work with and produce publications with selected community members who can inform the study.]

RECRUITMENT PROJECTIONS AND FUNNEL

[Insert recruitment funnels and projected total number of enrollments. If a CRO or recruitment vendor is involved, they may provide those estimates. Outline how enrollment will be measured, tracked (what specifically will be monitored), and expected timelines.]



[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.]

[Sample recruitment planning table]

PLANNED	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Ethnicity Unknown / Not Reported			
Racial Categories	Female at birth	Male at birth	Unknown / Not Reported	Female at birth	Male at birth	Unknown / Not Reported	Female at birth	Male at birth	Unknown / Not Reported	**Total**
American Indian / Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
TOTAL										

Please note that this table is an example and the categories can be modified 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.

RECRUITMENT MONITORING AND MITIGATION PLAN

[Detail frequency of tracking and review of recruitment and enrollment numbers; provide suggested action steps for mitigation if recruitment and enrollment are under target compared to anticipated plans. Include age categories as relevant]

[Example recruitment tracking table]

Make sure the recruitment monitoring plan tracks diverse or underrepresented patients as outlined in the recruitment plan.

CUMULATIVE (Actual)	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Ethnicity Unknown / Not Reported			
Racial Categories	Female at birth	Male at birth	Unknown / Not Reported	Female at birth	Male at birth	Unknown / Not Reported	Female at birth	Male at birth	Unknown / Not Reported	**Total**
American Indian / Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
TOTAL										

RETENTION MONITORING AND MITIGATION PLAN

[Detail frequency of tracking and review of enrolled participants and study follow-up; provide details on strategies that will be used to monitor retention (i.e., patient navigators or ambassadors; frequency and style of follow-up reminders, etc.) and provide suggested action steps for mitigation if retention is under target.]

Does the plan include mechanisms to monitor retention of diverse and underrepresented participants? Are suggested action steps included if retention significantly differs from planned or from retention of other participants with different demographic characteristics?

Does the plan include specific mitigation measures to address under-enrollment of intended populations? Are the mitigation measures tailored to specific populations?

SITE ENGAGEMENT

[Outline strategy and plan on how to keep sites engaged throughout the enrollment period.]

SITE SPECIFIC RECRUITMENT PLANS

[Summarize the site specific recruitment plan findings and how the team intends to hold the sites to their enrollment goals.]

The site recruitment plan should reference the overall study recruitment plan. In the site specific recruitment plan, are the enrollment goals representative and inclusive of those affected by the study question?

SITE BOOSTER VISITS

[Outline site booster visit strategy including when, who, how, and intent of booster visits to be conducted. The booster visit strategy is inclusive of visits by sponsor staff]

Site booster visits are intended to bolster sites enrollment numbers. Booster visits can be conducted by the sponsor, CRO, or a recruitment consultant. Booster visits provide an opportunity to assess if the sites recruitment practices are inclusive, and to review and enhance the sites ability to enroll and retain a diverse population.

RECRUITMENT WEBINARS AND SITE COMMUNICATION

[Outline schedule and approach for study recruitment webinars, and any additional touch points around site communications.]

SITE-SPECIFIC ESCALATION PLAN

[Outline escalation plan for triggers and actions for sites.]

Does the site-specific plan provide ways in which sites will be held accountable for their enrollment commitments? 'Triggers' are red flags that signal problems with recruitment (e.g., an under enrollment of the intended patient population, or skewed representation of the enrolled participants).

Are escalation plans established if a site fails to enroll participants reflective of the intended population, as noted in the individual site plan?

RISK AND CONTINGENCY MANAGEMENT

[Outline the risks associated with this study in terms of recruitment timelines and milestones, and list out the contingency strategies, triggers, and the action plan addressing those risks.]

STUDY COMMUNICATION

[Outline communication strategy, community outreach strategy, user-testing strategy and meetings among recruitment partners involved in supporting the study.]

Are there other measures for recruitment, including the use and availability of patient navigators/ambassadors or other community engagement activities?