

Sponsor Logo

CRO Logo

Recruitment Strategy Document

Study Title

Protocol #

NCT #

Study Logo

[This Recruitment Strategy Document is a template is intended to serve as a guide and all sections should be revised, as necessary, to reflect the specific objectives and challenges of a given protocol]

Document Approval Signatures

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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)
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 diversity and plan to identify sites to meet diversity goals.]

STUDY QUESTION

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

STUDY CHALLENGES

[Outline the study challenges from a recruitment perspective. Consider anticipated barriers to recruitment and retention, including those related to the recruitment of diverse populations.]

STUDY OPPORTUNITIES

[Outline the study opportunities from a recruitment perspective.]

STUDY ASSUMPTIONS

[Outline the original study assumptions and milestone goals.]

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

PATIENT PROFILE

PATIENT DISEASE PROFILE

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

PATIENT JOURNEY

[Include a patient pathway visual or flow of how a patient gets diagnosed, treated and opportunities for study awareness.]

CHALLENGES OF PARTICIPATING FROM A PATIENT PERSPECTIVE

[Include a bulleted list of potential study-specific challenges and risks. Detail all anticipated challenges, e.g., how will study requirements, hours, locations, travel costs impact recruitment of specific demographic.]

OPPORTUNITIES OF PARTICIPATING FROM A PATIENT PERSPECTIVE

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

STUDY RESPONSIBILITIES

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

COMPETITIVE LANDSCAPE

[Outline/summarize the current and forthcoming competing studies, how they may impact your study recruitment, and how you are leveraging internal groups to keep up to date on competition.]

Trial Phase	Sponsor	Primary Drugs	Target Accrual	Trial Locations	Timeline

STUDY FEASIBILITY SUMMARY

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

COUNTRY SELECTION

[Outline how and why the countries were selected.]

SELECTED COUNTRIES AND PLANNED PROJECTIONS

[Include country targeted sites and patients, along with site activation schedule provided by CRO.]

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)
Global	50	15	0.230	15%	55.0%	40%	4-Apr-20	0	30	90	8-Jun-20

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

CURRENT SITE CAPACITY PROFILE

[Outline what the current site profile is including patient capacity, staffing/resourcing, specialty type (if any), experience, special needs/equipment, etc. Detail site capacity for recruitment of targeted demographics: age, sex, gender, race, ethnicity, etc.]

CURRENT 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.]

PATIENT RECRUITMENT STRATEGIES AND TOOLS

RECRUITMENT AND RETENTION STRATEGY

[Provide a high-level overview of primary and secondary patient recruitment and retention strategies. Include anticipated return on investment and recruitment funnel as appropriate. What specific approaches and techniques will be used to access and engage target populations / demographics?]

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.]

Material	Brief Description

DIRECT TO PATIENT 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 target populations / demographics?]

REFERRING PHYSICIAN OUTREACH

[Outline HCP outreach strategy, source of data, implementation and follow up plan. Have the diversity goals been emphasized with study clinicians?]

PATIENT ADVOCACY OUTREACH

[Outline opportunities to work with relevant advocacy groups.]

Group Name	Group Contact

HEALTH CARE PROFESSIONAL SOCIETY OUTREACH

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

INTERNAL AWARENESS

[Outline opportunities to raise awareness internally.]

PUBLICATIONS

[Outline opportunities to work with and produce publications.]

RECRUITMENT PROJECTIONS AND FUNNEL

[Insert recruitment funnels and projected total number of enrollments provided by recruitment vendor. Outline how enrollment will be measured, tracked (what specifically will be monitored), and expected timelines.]

[Detail site specific target numbers by subpopulation - age, sex, race, ethnicity etc.]

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.]

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.]

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.]

SITE BOOSTER VISITS

[Outline site booster visit strategy including when, who, how, and intent of booster visits to be conducted. This includes visits by sponsor staff (study manager, MD, RSSL, MSL, etc.)]

RECRUITMENT WEBINARS AND SITE COMMUNICATION

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

SITE-SPECIFIC ESCALATION PLAN

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

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 and meetings among recruitment partners involved in supporting the study.]