

Recruitment Contingency Action Plan*

Audience: Sponsors/CROs, sites/investigators/study teams

Purpose: To provide an operational approach to contingency planning for issues or “leaks” in recruitment of any given subpopulation. The Recruitment Contingency Action Plan offers schematics that leverage two potential “intervention points” where monitoring or oversight can occur within a clinical trial and proactive planning should be considered:

- 1) Intervention point 1: between sponsor/CRO and site; and
- 2) Intervention point 2: between the site, investigators and study teams

The schematics below provide samples for actions that can be taken by sponsors and sites when a recruitment issue or “leak” emerges for a particular subgroup. The Recruitment Contingency Action Plan is intended to guide the process in determining *context specific* contingency plans detailed within the Recruitment Strategy Document (RSD).

Considerations for use

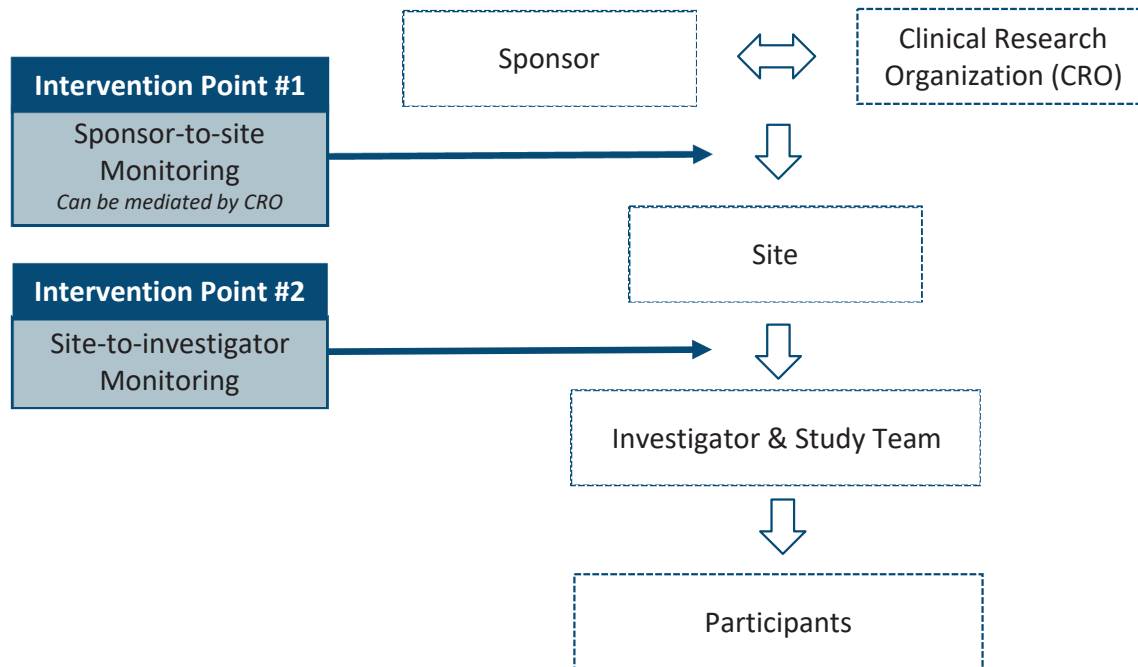
Adaptability – the schematics offer an example of an emergent issue in subpopulation-specific enrollment. However, the approach detailed is highly adaptable to whatever recruitment issues or “leaks” emerge within a particular clinical trial.

Monitoring systems – the schematics assume two intervention points within existing monitoring “intervention points” as detailed above. These “intervention points” might look different depending on the stakeholders involved, or in large, complex or multi-regional clinical trials.

*Adapted from: Harper, B. Clinical Research Recruitment & Retention Tactics. Clinical Performance Partners, Inc. 2017.

Multi-Tiered Monitoring in Clinical Trials

Intervention points for monitoring enrollment of specific populations



- Sponsors, CROs and sites can consider the following intervention points to monitor the recruitment and enrollment processes, evaluate how to enhance the pre-screening and screening processes and/or also minimize patient inconveniences, patient appointment “no-shows” or lost to follow-ups as well as consider additional areas to help support the patient education process.

Intervention Point #1:

Example of Recruitment Contingency Action Plan between Sponsor / CRO and Site

Issue	Action required by Site	Action required by Sponsor/CRO	Action plan status updates
<p>Proportion of enrolled participants of a particular demographic is below target, indicating site may not achieve demographic enrollment goal</p>	<p>Site to further define reasons for low enrollment achievement and implement strategic programming for this demographic</p>	<p>Sponsor/CRO to support action chosen by site, provide strategic guidance, share resources for targeted programming, and to provide additional budget (as available) for targeted programming</p>	<ol style="list-style-type: none"> 1. Site met with community organization 2. Additional funding received by site from sponsor/CRO 3. Targeted programming implemented by site staff 4. Continuously track enrollment figures for demographic subgroups
<p>Example: proportion of Black participants is lower than expected at the time of monitoring. This indicates that the site might not achieve its demographic enrollment goal for Black participants</p>	<p>Example: site staff to set up meetings with predetermined black community organizations to implement targeted pamphlet distribution for Black participant recruitment</p>	<p>Example: sponsor/CRO to provide predetermined demographic underperformance budget for targeted programming</p>	

Intervention point #2:
Example of Recruitment Contingency Action Plan between **Site and CRA**

Issue	Action required by CRA	Action required by Site	Action plan status updates
<p>Participants with similar demographic(s) miss appointment</p>	<p>Determine why these participants missed appointment and inform site</p>	<p>Site staff to incorporate additional retention methods to address subgroups' low rates of retention or missed visits</p>	<ol style="list-style-type: none"> 1. Site received additional recruitment supports from sponsor/CRO 2. Site has no more "no-shows" of target demographic(s) since reminder program
<p>Example: 3 young Latino participants missed their appointment</p>	<p>Example: contact participant and/or their families by phone/text/email to understand reason for missed appointment</p>	<p>Example: site staff to send appointment card/email reminder one week in advance of appointment, and text message reminder day before to young Latino participants</p>	