CTTI Recommendations:
Efficient and Effective Clinical Trial Recruitment Planning
Executive Summary

Clinical trial sponsors and investigators continue to face difficulties meeting recruitment goals, and the challenges appear to be increasing. Many explanations have been offered for why trials fail to recruit adequate numbers of participants. Little has been done to systematically examine recruitment obstacles, or share practices for overcoming them. **Actionable solutions are needed** since, without them, the promise of many trials will remain unfulfilled. It is time to move recruitment planning upstream and parallel to the clinical trial design process to ensure trial feasibility given the anticipated scientific, environmental, financial, time, and resource constraints.

Overall, recruitment must involve a critical level of thought that is more inclusive of **all** who might have influence on, or be influenced by, the development and implementation of a clinical trial. Additionally, the development of protocol elements must be done with attention paid to upstream activities that may have a downstream impact on recruitment.

This document should be used as a tool to guide a new approach to strategic recruitment planning (see Figure 1). CTTI offers these recommendations to enhance recruitment through thoughtful improvement of trial design, protocol development, trial feasibility, site selection, recruitment and communication planning, and performance monitoring in cooperation with all relevant stakeholders. Together with periodic stakeholder input, these recommendations for efficient and effective clinical trial recruitment planning will help optimize enrollment efficiency.

The following recommendations are intended to dovetail with both the Recommendations and Tools for Effective Engagement with Patient Groups Around Clinical Trials (PGCT) and Quality by Design Principles, Recommendations, and Toolkit (QbD). When combined with the above recommendations and tools, trial designers can develop high-quality, efficient clinical trials that speed the delivery of new therapies to patients and improve public health.

Section I: Recommendations for Trial Design and Protocol Development

Rigorous attention to minimizing recruitment challenges at the trial design and protocol development stages is essential if the necessary culture shift is to be achieved—one that holistically integrates recruitment planning into study design and development. Study planners should spend the extra time necessary to engage with stakeholders and obtain their input upfront[1] to ensure a trial will not be delayed by protocol amendments needed to remove barriers hampering efficient enrollment (e.g., broadening the eligibility criteria).

In addition, mentorship and training for investigators (junior and senior), trial designers, statisticians, and other stakeholders is crucial to the successful implementation of a holistic approach toward strategic recruitment planning that will ultimately enhance the quality and efficiency of clinical trials.

[1] For a helpful decision-making aid to use when engaging with stakeholders in study design & development, please see Tool #1 (Decision Tree).

When considering the design and development of feasible clinical trials, trial designers and planners should:

1. Identify and engage all stakeholders[2] as equal partners in the process
2. Ensure the relevance of the scientific question to stakeholders
3. Limit protocol complexity to reduce the burden of participation[3]
4. Develop realistic eligibility criteria
5. Optimize data collection to only what's necessary to maintain patient safety and answer the scientific question

Section II: Recommendations for Trial Feasibility and Site Selection

These recommendations encourage proactively considering trial feasibility and site selection issues early in study development as a crucial part of recruitment planning. Many of these points can, and will, affect recruitment and retention. Hence, a thoughtful approach before study activation will alleviate downstream recruitment and retention challenges, further ensuring trial viability.

To ensure trial feasibility and appropriate site selection, trial designers and planners should:

1. Conduct an evidence-based trial feasibility analysis
2. Establish realistic metrics and milestones
3. Develop an adequate budget and resources
4. Ensure appropriate site selection
5. Engage in suitable site performance monitoring

Section III: Recommendations for Recruitment Communication Planning

To optimize recruitment communication planning, trial planners should:

1. Identify ALL stakeholders and partners
2. Identify participant locations based on where participants may seek treatment and relevant information
3. Develop and test tailored messages
4. Develop creative material and select appropriate channels for delivery
5. Develop a realistic communication budget
6. Monitor and evaluate both the recruitment process and performance with meaningful metrics[4]

To the steps above, consider including an additional step when appropriate:

7. Embedding recruitment intervention studies into clinical trials and share the results (good and bad) to contribute to the development of best practices

- *These recommendations are based on results from CTTI's Recruitment Project.*
- *CTTI's Executive Committee approved the recommendations.*
- *Released in May 2016*

[2] For tools and resources that can help you identify and engage with stakeholders, please see Tool #2 (Stakeholder Identification and Analysis Tool).
[3] When considering whether to include Patient Reported Outcomes (PROs) in your study, please see Tool #4.
[4] When considering how to monitor recruitment process and performance, see Tool #3.

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Figure 1. Framework for Strategic Recruitment Planning