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Study Rescue

How to get your Clinical Trial Back on Track

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Introduction

It will probably come as no surprise for anyone to learn that most clinical trials do not proceed as planned since more than 90% of them fail to meet their original timeline.[1] The reason a study falls behind schedule or even fails entirely may involve issues involving the site start-up process, patient enrollment/retention barriers, protocol compliance and complexity, data quality and integrity, resourcing issues, and overall staff qualifications and expertise. Eighty (80%) of the clinical trials conducted in the United States in 2009 were delayed by at least a month due to slow enrollment.[2] Nowadays, up to 80% of clinical trials miss their patient enrollment targets, and 18% of clinical research sites fail to enroll any patient whatsoever.[3]

A delay of one day in product launch not only postpones the public's access to life-changing therapy but also costs the drug developer between $600,000 - $8 million in revenue.[4] Each study encounters unique challenges, and therefore there is no one-size-fits-all solution to study rescue. In this white paper, Vantage BioTrials would like to share our approach to effectively rescue failing studies from disastrous consequences.

Step 1: Building a Rescue Team

In this case, size matters. Having a small rescue team facilitates effective and streamlined communications while quickly putting in place and executing Action Plans to get a study back on track towards a successful conclusion. We suggest that a Rescue Team comprises a Rescue Lead (a senior project manager) and only a few Assistants (perhaps one Clinical Trial Assistant and one Clinical Research Associate) with proper experience and qualifications.

Step 2: Implementing Effective Tools

The following are examples of tools we have found useful for developing strategies and Action Plans for study rescues. We suggest you utilize an appropriate combination of these tools throughout the study rescue process.

A) Direct Site Interviews and Focused Surveys

You may gather information from the site personnel using relevant and focused questions. Contact through the phone is preferred over email as phone interview offers a better way to establish a personal connection with the site.

Direct Site Interviews may include questions such as:

- What do you think is the main reason that your patients are declining to participate?
- Could you describe how you pre-screen patients?
- Are you having any difficulties interacting with the Central Lab?

Focused Surveys (a.k.a. "Needs Assessment" Surveys), on the other hand, probes into the site personnel's wish list items that would make the trial a success within their environment. The survey may include a question such as:

- What are your current needs that you believe we can help support?

Direct Site Interviews and Focused Surveys help the Rescue Team identify critical issues in the site's practice as well as areas for improvement. Make sure your questions are objective and supportive, instead of accusatory, in nature.

B) SWOT Analysis

SWOT analysis is a strategic planning tool that provides a quick overview of internal (i.e., existing factors) and external (i.e., potential elements not currently affecting or within the scope of the research project) factors relevant to your achievement of project goals. Identify the Strengths, Weaknesses, Opportunities and Threats of the clinical trial conduct before developing your strategies for study rescue.

SWOT Overview	
STRENGTHS (INTERNAL FACTORS CONTRIBUTING POSITIVELY TO THE OBJECTIVES)	Strengths are the factors that may contribute to the success of the clinical trial. Identify these factors to unleash their full potential. • What are the potential benefits of this trial? (e.g., improving health care) • What are the benefits of this study for the participants and sites? (e.g., access to new treatment) • What useful tools are in place? (e.g., advertisement of the study) • What resources are available? (e.g., Medical Advisor)
WEAKNESSES (INTERNAL FACTORS CONTRIBUTING NEGATIVELY TO THE OBJECTIVES)	Weaknesses represent the GAP responsible for the lack of trial success. Identify these factors to develop strategies to resolve them or mitigate risks. • What are the potential obstacles to trial success? (e.g., protocol complexity) • What are causing delays? (e.g., lack of communication) • What should be improved? (e.g., resources not being used efficiently)
OPPORTUNITIES (EXTERNAL FACTORS THAT COULD POTENTIALLY HAVE A POSITIVE IMPACT ON THE ACHIEVEMENT OF THE OBJECTIVE).	Opportunities are new elements that may boost the chances of trial success. Identify these factors to optimize the Strengths and overcome the Weaknesses. • What element can be modified? (e.g., protocol amendment) • What tools can be developed? (e.g., communication platform) • What strategies can be put in place? (e.g., a new process at the site) • What resources can be brought in? (e.g., staff & technology) • What training can be done? (e.g., protocol training)
THREATS (EXTERNAL FACTORS THAT POSSIBLY COULD HAVE A NEGATIVE IMPACT ON THE STUDY)	Threats are emerging or potential future challenges that may sabotage the clinical trial. Identify and monitor these factors to prevent or mitigate their impact on the study. • Trends (e.g., lack of interest & changes in medical care) • Competing studies • Financial difficulties • Staffing issues (e.g., staff turnover) • Lack of time & resources dedicated to research

C) GAP Analysis

GAP analysis involves the comparison of current performance with desired performance. GAP refers to the space between the actual situation and the expected one. This tool helps to identify the priority issues that require immediate attention. The level of priority is determined by the extent your intervention may bridge the GAP and improve the performance. Whenever new information is available, promptly analyze the data and update your GAP Report.

GAP Analysis - *Example*					
Issue	Priority	Actual Situation	Expected Situation	GAP	Action
Patient enrollment is behind schedule	High	Some sites do not show activity	Sites actively enroll new trial participants	Patient recruitment is slower than expected due to the unsatisfactory performance of some sites	To develop tools and new process for the sites to help patient recruitment

D) Root Cause Analysis

Root cause analysis is a problem-solving tool for identifying the highest-level cause (i.e., the root cause) of a problem among causal factors. Perform a systematic review to identify the underlying causes of significant issues. Only after identifying the root cause can you develop the most effective interventions for your study rescue.

Step 3: Implementing the Action Plan

It is paramount to identify Key Performance Indicators (KPIs), define the acceptable range of KPI measurements and establish an effective way to monitor the performance metrics before starting a clinical trial. You should review all the KPI parameters, and continue monitoring trial/site performance closely to develop and revise your Action Plans throughout the study rescue process.

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The tools we introduced to you here can not only help you analyze the problems in your clinical trial but also reveal areas of focus for your Action Plans. Organize the proposed interventions in the Action Plan into groups and prioritize them according to potential impact, i.e., their effectiveness on the significant issues you are addressing. Communicate your ideas effectively across relevant stakeholders of the study, and hold bi-weekly or monthly Strategy Sessions with your Sponsor's study team to discuss evolving strategies.

Last but not least, performing on-site "support visits" is often indispensable for successful study rescue. The purpose of on-site support visits is to provide support to clinical research sites, rather than to perform monitoring activities. Tailor your focus to the site's needs, and have discussions revolve around critical issues such as protocol, recruitment strategies, workflows and study resources.

In-person interactions may help motivate site personnel, and these visits provide the Rescue Team an opportunity to understand the operational structure of a site. Include in your visit report the key points discussed as well as your recommendations specific to each site. Send a follow-up email with detailed action plans, and let the site personnel know you remain available to assist the site through on-site visits or teleconferences.

Study rescue is often challenging, and different studies require different approaches to addressing their unique situations. Use the tools we provided effectively for your study rescue projects. For example, you can gather as much information as possible to have an idea of fundamental problems and issues at the beginning of the study rescue. Start with a high-level overview of the study (e.g., SWOT analysis), and then proceed to analyze the issues that are failing the trial (e.g., GAP analysis & root cause analysis). Next, develop and implement interventions (Action Plan), and provide the sites with sufficient support (e.g., on-site support visits).

Continue making good use of appropriate tools, and adapt your strategies to new situations or new challenges throughout the study rescue. Finally, always engage all stakeholders, and maintain a positive atmosphere of collaboration.

Vantage BioTrials has successfully rescued many studies entrusted by our clients. If you have a study that is missing key deadlines or milestones, contact us to learn more about how we can help you get your study back on track.

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About Vantage BioTrials

Vantage BioTrials is a leading Canadian Contract Research Organization (CRO) that uses innovative clinical trial management strategies for the life science industry with a focus on patient safety & advancing new therapies to market. We offer pharmaceutical, biotech & medical device companies a complete and integrated set of full service clinical trial management solutions.

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