

CASE STUDY:

CLINICAL TRIAL RESCUE: LEADERSHIP APPROACH TO PROPEL CLINICAL DEVELOPMENT

SITUATION

A rare disease biotechnology company's gene therapy clinical trial was put on hold, and the company found itself with a poor performing Clinical Trial Leader. Rudderless, and without a clear clinical operations strategy, they needed an experienced leader to navigate the headwinds and move the trial forward to meet their milestones. Missing their milestones had serious consequences. The company approached Halloran because of its experience in rare diseases, gene therapy, and clinical trial leadership.

CHALLENGE

In the critical juncture of being merely two months away from their inaugural site activation and first-in-patient milestone, the company faced a daunting challenge – their clinical operations strategy was teetering on inefficiency, jeopardizing the realization of their pivotal objectives. The urgency of the situation, coupled with constrained clinical resources, demanded immediate intervention.

Recognizing the gravity of the situation, the company decisively sought out expertise – a catalyst capable of orchestrating a swift and comprehensive turnaround. This seasoned professional was tasked with a multifaceted mission: to promptly assess the existing gaps and challenges within the clinical operations framework and, more crucially, to engineer and implement pragmatic solutions that would propel the trial's development forward.

SOLUTION

The selected expert at Halloran Consulting Group not only had to navigate the complexities of the existing operational landscape but also seamlessly transition into a pivotal role for the trial's success. Their strategic acumen and swift decision-making were reactive measures and proactive steps toward safeguarding the company's overarching goals.

Using a six-step plan demonstrated their capacity to showcase a determination to meet immediate objectives and fortify the foundation for a successful and sustainable clinical trial journey.

- Clinical Development and Operations Gap Assessment
 - Held interviews with key stakeholders to assess gaps in strategy and operations
- Bottleneck Review
 - Reviewed unfinished project deliverables and created a better path to completion
- Priority Establishment
 - Based on interviews, developed priorities to improve development and operations
- Vendor Management and Oversight Plan Improvement
 - Assessed issues and inefficiencies to implement solutions for the client and vendors
 - Established proper oversight responsibilities and cleared obstacles
- Workstream Management
 - Established workstreams to organize teams to meet deliverables and develop ownership
- Communication and Process Improvement
 - Created better communication workflow across the entire company's development ecosystem

RESULTS

The company's clinical hold was lifted, and they were able to meet their first-in-patient goal. With Halloran's expertise serving as their interim Clinical Trial Leader, their clinical strategy and operations improved to propel their development forward without any further delay.

The company hired a full-time replacement supported by Halloran's transition plan. Without Halloran's part-time support, the company's gene therapy trial would have been delayed.

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ABOUT HALLORAN

Halloran is a life science consulting firm that provides strategic regulatory, quality, clinical, and organizational support to industry leaders and startup visionaries in the pharmaceutical, biotechnology, and medical device sectors. Our consultants are subject matter experts who deliver a tailored approach to each engagement, successfully propelling our clients to their next inflection point. We connect clients with our trusted industry partners to drive operational excellence and innovation throughout their organizations. Our aim is to support our clients, and the patients they serve.

CLINICAL TRIAL LEADERSHIP AND OPERATIONS

Halloran's clinical program experts assume clinical program leadership and clinical project management roles within your organization to help you drive your team's success from strategic planning to implementation. Halloran's interim program leadership and project management leaders offer you a competitive advantage because of our insights and learnings from our vast client portfolio. When it comes to staffing your clinical team, resources need to expand and be as fluid as possible during times of intense financial fluctuations. Hiring full-time employees, with overhead costs, can be an expensive proposition.

Using Halloran's deep bench, our experts meet you where you are and provide the necessary clinical guidance and leadership your team may need in the short term. Our experts are backed by the resources of an entire Halloran bench who can provide essential insights.

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