

CASE STUDY:

CLINICAL TRIAL LEADERSHIP: ENHANCING EFFICIENCIES AND REDUCING RISK

SITUATION

A small biotech developing an innovative therapy needed to retain a clinical trial leader as they were launching their trial at multiple sites. The company experienced two cycles of leadership turnover, resulting in lagging strategy and operations. They needed to immediately hire an expert to drive progress forward, while they mindfully sought their full-time replacement.

CHALLENGE

To advance their goals the client needed to stabilize operations, establish processes, align roles and responsibilities, improve culture, foster trust, provide mentorship, and enable employees to focus on their workstreams. They needed to do this all simultaneously to drive efficiency and reduce the real risk of study startup delay.

SOLUTION

Up against a tight timeline, minimal resources, and numerous inefficiencies, the client chose Halloran because of our deep expertise, and ability to jump right into the midst of operations and quickly get up to speed. They needed to slow down and focus on finding the right replacement while knowing an expert could stabilize and enhance their clinical operations and infrastructure.

Halloran's step-by-step approach:

- Conducted interviews and set agendas with departing executives and key players to:
 - Gather essential information to further clinical trial strategy
 - Assess current state to provide future state recommendations
 - o Identify opportunities to streamline, optimize, and drive efficiencies with vendors
 - o Identify gaps in processes and redefine Contract Research Organization (CRO) management approach
- Established priorities
 - Realigned the team's meeting cadence, enabling employees more time to accomplish essential clinical trial tasks
 - Created clear avenues of internal communication to foster team trust through active listening, asking critical questions, leading with vulnerability, aligning on essential team conduct, and showing up with a commitment to success mindset
 - Redefined and clarified roles and responsibilities, solving the frustration of team members and clinical trial sites alike
 - o Drove forward initiatives that lagged because of turnover
- Revamped and identified gaps in critical processes
 - Refined CRO responsibilities, management, and processes, enabling proper sponsor oversight to enhance the sponsor-vendor relationship
 - Provided mentorship to team members new to the industry or new to their roles, while building and refining leadership and management approaches
 - Reviewed all vendor management plans, identifying gaps and realigning responsibilities to assure team efficiency and eliminate redundancies

RESULTS

Within the first month, the client shared that - on several different levels - they had already noticed a positive impact. As the six-month engagement ended, the client's operations improved, and noted enhanced, streamlined processes, and observed better internal and external relationships with sites and vendors. Halloran enabled them to focus on finding the right replacement while having confidence the ongoing trial would continue to reach critical milestones. As the client brought in their permanent hire, Halloran collaborated to assure a manageable and seamless transition; by the time the engagement ended, all projects were either completed or handed off to the new hire in an achievable fashion.

"We got more done in these new meetings than in the past due to Halloran's efficient processes and prioritization. It allowed us to 'take a breath' as we searched for our permanent replacement – all the while, knowing that things were continuing to drive forward." - Client feedback

THE CLIENT'S STREAMLINED OPERATIONAL INFRASTRUCTURE AND CLEAR PRIORITIZATION **ENABLED EFFICIENT INTERNAL COMMUNICATION AND VARIOUS OVERSIGHT** EFFICIENCIES, ALLOWING MANAGEMENT TO FOCUS ON FINDING THE RIGHT FULL-TIME CLINICAL LEADER REPLACEMENT WITHOUT RUSH OR RISK TO THEIR CLINICAL TRIAL.

ABOUT HALLORAN

Halloran experts offer deep expertise in science and advanced knowledge of the development and commercialization lifecycle, leading clients through their most challenging business goals to achieve their greatest chance of success. Whether it is leading new company formation with a fully integrated development team at the ready, enabling investments with robust diligence or market assessments, or providing accelerated, durable development strategies for enhanced company value creation, Halloran is your development partner.

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.

Want to learn more? Click here to read "Navigating Clinical Trial Leadership Turnover: Halloran's Five-Step Process"

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