

Case Study: Moving To a Clinical Development To BLA Through Strategy Planning



Situation:

There are many circumstances that make or break the success of a product moving from research to development.

Considering all the potential roadblocks, a small biotechnology company focused on immuno-oncology approached Halloran Consulting Group (Halloran) requesting a Development Program Manager to assist in their first Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA).

Challenge:

The company recently lost its Development Program Manager, cycled through multiple Vice Presidents of Regulatory Affairs, and very few team members held BLA experience. Considering their personnel gaps, the company was poorly aligned, lacked proper planning, had insufficient executive support, requirements, and expectations were unclear, lacked resources, and their choice of technology did not enable them to achieve their internal goals.

Solution:

Halloran engaged the company by addressing their infrastructure challenges preventing them from meeting submission goals. Halloran stepped in as the Development Program Manager and pivoted in the following ways:

POOR ALIGNMENT

Challenge: Strategies were not clearly documented or shared

Fix: Held a BLA kick-off meeting to gain goal alignment

IMPROPER PLANNING

Challenge: Timelines, critical pathway, budget estimates, and risk identification were not documented

Fix: Created a plan addressing all essential components

INSUFFICIENT EXECUTIVE SUPPORT

Challenge: Unclear priorities due to a sizeable portfolio

Fix: Established BLA priority with the executive team and removed barriers

UNCLEAR EXPECTATIONS

Challenge: Unclear strategy, roles and responsibilities, and timelines

Fix: Clear strategy established, communication plan created, roles and responsibilities defined, and timelines verified and monitored

LACK OF RESOURCES

Challenge: Missing resources resulted in poor quality control

Fix: Identified resource gaps to prevent future constraints

CHOICE OF TECHNOLOGY

Challenge: Multiple systems were used, resulting in duplicate work

Fix: Established systems for particular use cases, removing inefficiencies

Result:

The company's efficient and organized infrastructure propelled them to successfully file their BLA with the FDA. This model became the gold standard for future development candidates in their portfolio.

Preventing The Fear of Failure In Drug Development

1	POOR ALIGNMENT	Issue: Strategies are not clearly documented or shared Fix: Holding a kick-off meeting so everyone is aligned
2	BAD PLANNING	Issue: Timelines were not verified, critical path unknown, lack of a risk log and response plan Fix: Verify timelines, identify critical path, create risk log and response plan
3	LACK OF EXECUTIVE SUPPORT	Issue: Every program was a priority Fix: Meet with Executive Team early to ensure support and remove barriers
4	UNCLEAR EXPECTATIONS	Issue: Unclear strategies, roles & responsibilities, and timelines Fix: Clarify strategy, define assignments, and create timelines
5	LACK OF RESOURCES	Issue: Missing resources or resource turnover Fix: Identify missing resources early and develop back up plans for turnover or OOO
6	CHOICE OF TECHNOLOGY	Issue: Multiple systems for document management and timeline tracking Fix: Choose one system for document review and one system for timeline tracking

Program Management at Halloran

Halloran's Program Managers define the strategy within their clients' cross-functional teams and lead the development program through execution. Halloran's interim Program Managers offer their clients a competitive advantage through their integrated insights and learnings from the development of similar types of products in the industry.

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.

Ready to get to work?
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