

## Case Study: Fast-Tracking Your Product Development With An Integrated Development Plan



### Situation:

A startup microbiome platform company developing novel therapeutics against ABR (Antibiotic Resistant Bacteria) for C. Diff (Clostridium Difficile) infections needed a clear roadmap for their Proof-of-Concept (PoC) clinical study to generate confidence in their platform with investors and enable fundraising.

A PoC requires a clear and fast approach to the development plan because of the competitive landscape. Underestimating timelines and costs to run a PoC can have significant consequences for the product developer.

### Challenge:

The startup company did not have the proper staff to support its development plan and regulatory strategy. Considering their internal gaps, the company approached Halloran Consulting Group (Halloran) because they needed an expert who could develop a fast pathway to show PoC and feel confident their strategic choices would not compromise their development speed.

### Solution:

The company chose Halloran because of Halloran's Strategy & Program Leadership and Regulatory team integration. Halloran offered a holistic view of the company's development and regulatory roadmap – an Integrated Development Plan – to provide the strategic plan for the fastest way to show PoC.

Halloran provided the following recommendation in six weeks:

#### **Customized Integrated Development Plan:**

- Geography selection: Selected O-US and recommended Phase 1 clinical trials in Australia due to its unique regulatory landscape
- Incorporated FDA recommendations from recently issued guidance for C. Diff clinical development considerations
- Regulatory pathway: Confirmed three years to PoC supported with yearly regulatory objectives Assessed special designation targets, and recommended orphan designation
- Pre-IND Plan: Timeline supported with meeting goals, clinical data, and study read-out plan, and recommended FDA communications
- To support the Pre-IND timeline, mapped out non-clinical studies to provide meaningful safety data to the FDA
- The patient population is defined to enable fast recruitment

## Result:

The company had a strategic and clearly defined Integrated Development Plan enabling them to move forward with speed and accuracy and communicate clearly with investors about what it will take – time and money – to move their product through development.

Their Integrated Development Plan took the guesswork and obstacles out of their development roadmap so they could move with speed to remain competitive.

THE COMPANY'S INTEGRATED DEVELOPMENT PLAN ENABLED THEM TO MOVE FORWARD WITH SPEED AND ACCURACY AND COMMUNICATE WITH INVESTORS ABOUT WHAT IS REQUIRED TO MOVE THEIR PRODUCT THROUGH DEVELOPMENT.

## 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.

## Integrated Development Plan

An Integrated Development Plan (IDP) is a tool to streamline development strategy, highlight efficient development pathways, and to optimize the speed and efficiency of asset development. Halloran uses an integrated, cross-functional lens to provide benchmarking, assumptions, risk analysis, and resource planning with coordinated timelines and budgets for clients' programs. The plan is broken out by key activities and functional areas across clinical development, regulatory, chemistry, manufacturing, and controls (CMC), and non-clinical development. Throughout the creation of the IDP, Halloran is their clients' trusted partner to accelerate progress and is fully prepared to lead the implementation of the plan.

Ready to get to work?  
Contact us



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