

Strategic IND Support for a Small Biotech: Derisking the Pathway to Phase 1



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CASE STUDY



Situation

A small startup biotechnology company nominated their development candidate, enabling the transition from research to clinical development. The company's leadership was driving towards the next value inflection point to secure additional funding, seeking regulatory expertise to navigate Investigational New Drug (IND) readiness to begin their Phase 1 clinical trial.

CHALLENGE

The majority of discovery-phase biotech staff have limited (or no) experience engaging with the FDA, preparing for an IND, and navigating clinical development, but it's more important than ever as they move from research to development. This company sought Halloran's support for regulatory strategy, project management, medical writing, and clinical strategy and planning, serving as their interim regulatory and clinical experts.

SOLUTION

Halloran employed the following regulatory and clinical strategies and tactics to advance their drug development program to reach their next value inflection point to procure additional funding.

GAP ANALYSIS

Pre-IND INTERACTION

IND APPLICATION

CLINICAL STUDY

IND MAINTENANCE

Conducted a Gap Analysis

- Reviewed nonclinical and CMC (Chemistry, Manufacturing, and Controls) materials against FDA guidance to identify regulatory gaps and de-risk FDA interactions
- Reviewed the current clinical landscape to help create a clinical synopsis or protocol design to initiate a Phase 1 clinical study acceptable to the Agency with minimal changes
- Provided regulatory recommendations to enable a successful Pre-IND interaction with the FDA by providing guidance on the meeting package contents including developing questions and outline for the Sponsor supporting data and rationale

Pre-IND Readiness

- Conducted high-level orientation on regulatory strategy, timelines, and submission requirements so the team is aligned with the path forward
- Advised the team on potential questions to ask the FDA and author a meeting package with CMC, nonclinical, and clinical components to optimize the outcome
- Served as regulatory FDA point of contact on the company's behalf, translating FDA comments into a digestible format, seeking clarification when needed
- Authored the clinical synopsis/protocol draft for the Phase 1 study and developed rationale for the design to optimize top-line results and accelerate enrollment
- Deployed project management techniques to develop achievable timelines and manage communications with the team
- Prepared novice cross-functional teams on meeting etiquette, potential questions, preliminary comment responses, and rehearsals prior to FDA meeting



IND Preparation

- Commenced a kick-off meeting to align on the regulatory, CMC, nonclinical, and clinical strategy post Pre-IND feedback
- Authored and reviewed regulatory, CMC, nonclinical and clinical documents to ensure compliance with FDA guidance
- Published and formatted FDA compliant documents to advance through the Electronic Submission Gateway without error
- Implemented an integrated development plan outlining all cross-functional activities for the critical path forward
- Deployed an IND content tracker, assignments matrix, and document review timelines along with a communication plan to keep stakeholders accountable
- Served as the Regulatory FDA point of contact on the company's behalf to address potential information requests during the 30-day review period

■ Regulatory Strategies that De-Risk Programs

Regulatory strategies are vital for de-risking programs. This involves positioning pre-IND questions with precise, supportive data to achieve desired outcomes. Acting as the regulatory point of contact facilitates effective communication between the FDA and the company. Additionally, creating and submitting IND applications with clear messaging and high-quality content minimizes feedback and helps prevent clinical holds supported by appropriate source data.

■ Clinical Strategies that Optimize Study Success

Clinical strategies focus on evaluating the landscape to design studies that are achievable, enrollable, and cost-effective while gathering valuable human data. Advising on accelerated study startup techniques ensures the first patient is enrolled quickly. Serving as the clinical point of contact streamlines study startup, enrollment, data reporting, and closeout processes.

■ Program Management Strategies for Operational Excellence

Program management strategies enhance operational excellence through an Integrated Development Plan that aligns stakeholders and clearly defines goals and dependencies. By creating timelines and accountability processes, risks are mitigated, and decisions are documented. Serving as the program-level point of contact integrates all development activities into a cohesive plan.

IND Maintenance

- Ensured processes and mechanisms were in place to manage submissions related to protocol amendments, clinical reports, final nonclinical reports, and CMC stability updates.
- Managed process for development safety update report/annual report to highlight clinical development progress.

RESULTS

Halloran's regulatory strategy and operations, project and program management, medical writing, and clinical development expertise enabled our client to successfully submit an IND to the FDA, accelerating their path to a Phase 1 clinical trial, and securing the necessary funding to propel their development forward.

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From Product Development to Market & Patient Access, from Regulatory Affairs and Safety & Vigilance to Consulting & Digital, our global experts join forces to shape the future of PLG's client offering across multiple domains, including Biopharma industries, Consumer Healthcare, and Medical Devices. With a goal of continuously improving the value delivered to people and customers, PLG is committed to long-term partnership, innovation, flexibility, and cost efficiency.